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National poster winner abstracts

NP-001 DEVELOPING THE ROLE OF PRIMARY CARE CLINICAL PHARMACIST

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Background Primary healthcare has a significant role in promoting the rational use of medicines. Finland's health and social services reform aims to strengthen primary healthcare services and prevent diseases with multi-professional teamwork. Pharmacists should be involved in the development of the medication management process in primary care.

Purpose The aim was to identify risk factors in the medication management process in primary care to target a clinical pharmacist's work tasks which could improve medication safety.

Material and Methods This study was conducted in public health centers in Espoo, Southern Finland. First, a medication safety audit tool for primary healthcare was developed based on the audit tool for hospitals. Second, medication safety audits were conducted at four public health centers. In the audits, the pharmacotherapy plan and the medication management process were observed, and the renewal process of electronic prescriptions was evaluated. Based on the audit results, a proposal was made on the key development areas of the medication management process and the role description of the clinical pharmacist.

Results The key development areas identified with the medication safety audits were 1) updating and implementing the unit-based pharmacotherapy plans, 2) standardizing the medication reconciliation protocol, 3) documenting and utilizing the patient's pharmacotherapy plan, 4) standardizing the protocol for reviewing and documenting drug allergies, and 5) a need for medication safety protections in emergency care services. Furthermore, the lack of up-to-date medicines information when renewing electronic prescriptions was identified, as most of the prescriptions are renewed outside physicians' appointments without direct contact with a patient. The suggested core task areas of the primary care clinical pharmacist at public health centers to improve medication safety were: 1) pharmacotherapy plan and quality control; 2) medication risk management; 3) development of the medication management process; and 4) other work tasks related to clinical pharmacy.

Conclusions With medication safety audits, it was possible to identify the medication safety risks in the medication management process and prioritize a clinical pharmacist's work tasks that improve medication safety. The identified development areas and medication safety work would suit the primary care clinical pharmacist's role.

Conflict of Interest No conflict of interest

NP-002 'CAPSULE PHARMA', AN INNOVATIVE DIGITAL TRAINING TOOL TO LEARN ABOUT IMPORTANT STERILE MEDICAL DEVICE (SMD) CONCEPTS

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10.1136/ejhpharm-2023-eahp.2

Background and Importance Staff knowledge of Sterile Medical Device is weakened by staff turnover, acute understaffing, constant changes in the SMD field, market changes, and numerous marketing shortages and discontinuations. However, the daily use of medical devices is a source of misuse if important concepts are unknown. Comments and questions from hospital staff reveal a need for training sessions. We had to innovate and build new communication tools for staff that be better trained.

Aim and Objectives The main objective of this work is to remind SMD staff of important notions to improve the quality and safety of SMD use by a video tool.

Materials and Methods We defined 50 technical or practical notions thanks to our interventions history about SMD. They have been classified into 5 themes: general information, bandages, digestive approach, parenteral approach, and miscellaneous. Their knowledge was evaluated among hospital staff with a web-based survey. A rate of knowledge (RK) was calculated for each notion and theme, considered known if the RK>70% or unknown if the RK<40%. The unknown themes will be the subject of a series of training videos produced with Adobe Première Pro®.

Results We obtained 266 answers to the survey. The average rate of knowledge of the 50 concepts was 47%. Only 11 concepts were well known, while 19 are unknown. For example, the interviewed staff did not know the meaning of the two stripes logo or what -ENFit connectivity is. The two topics with the lowest level of knowledge were general information (RK=37%) and the digestive approach (RK=36%). The first video of the 'Capsule Pharma' explains generalities in 4 minutes. It was sent online and the overall satisfaction score was 9,5/10.

Conclusion and Relevance This study shows how important continuous training is the key for hospital staff to better understand SMD. The format of short videos has been chosen for its attractiveness and its unlimited quick playback on different media. «Capsule Pharma» will become an innovative and institutional communication tool for SMD and other health products.

NP-003 PHARMACEUTICAL INFUSION SCHEDULES AS A TOOL TO IMPROVE FLUID RESTRICTION IN PICU PATIENTS

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10.1136/ejhpharm-2023-eahp.3

Background Children in intensive care unit (PICU) are at increased risk for fluid overload, which is associated with increased morbidity. Therefore, unnecessary fluid administration should be avoided. The volume needed for flushing infusion lines during IV drug administration is often not considered in the daily calculation of fluid intake.

Aim and Objectives The aim of our study was to reduce the daily flushing volume and thereby fluid overload in PICU patients.

Materials and Methods A prospective intervention study was conducted in our PICU (control period: Jan-July 2020; intervention period: Oct 2020- Aug 2021). Patients with ≥ 2 i.v. medications, >24h length of stay, and age 0-18 years were included. Primary outcome was the occurrence of fluid overload. The intervention was the preparation of patient-specific infusion schedules by a clinical pharmacist. The schedules

indicated the IV access through which IV medications, parenteral nutrition, and infusion solutions should be administered to avoid incompatibilities and whether flushing of the infusion line was required.

Results In both periods, 66 patients each were included in the evaluation. Flushing volume was reduced from a median of 0.68ml/kg/day (Q25/Q75 0.35/1.33) to 0.31ml/kg/day (Q25/Q75 0.05/0.74; $p < 0.001$). In the control period, the median fluid overload per patient was 2.3%, while 1.5% fluid overload occurred in the intervention period ($p < 0.001$). Also, fewer patient days with fluid overload of $\geq 10\%$ occurred during the intervention period. Fluid overload of $\geq 20\%$ were only observed in the control period.

Conclusion The use of pharmaceutical infusion schedules with recommendations for flushing infusion lines according to compatibility has reduced the flushing volume. This can avoid the administration of unnecessary IV fluids. Reducing fluid intake helps to reduce the occurrence of fluid overload in PICU patients.

NP-004

RETROSPECTIVE STUDY ON INDIVIDUALISED MEDICATION OF DEMENTIA PATIENTS RECEIVING CHRONIC HOSPITAL CARES

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10.1136/ejhp-harm-2023-eahp.4

Background and Importance Those elderly, dementia patients who receive treatments for their various chronic diseases belong to a high risk cohort. Their individualised medication should avoid treatment with multiple drugs and with active substances which pose a health risk for them. This may eliminate the adverse effects to which these patients are particularly susceptible.

Aim and Objectives The study evaluates the medical treatment of dementia patients receiving chronic and palliative cares simultaneously. We collected data of individualised medications from historic patient records in 2020–2021. The study was approved by the research ethics committees of the university and the hospital (IG/02176-000/2022)

Materials and Methods We examined the real-world data of drug treatment in dementia patients aged 65 or older who spent at least 5 days in the hospital. We analysed the anonymised, aggregate data. We used international databases compiled from meta-analyses and systematic reviews (Beers Criteria, START/STOPP, WHO, EMA and UCSF).

Results We analysed the drug treatment history of 108 patients (74 women and 34 men with the average age of 80.5 ± 9 year), who met the preliminary selection criteria. We classified the patients into the following cohorts: 1.9% direction diagnosis, 20.4% basis of the main diagnosis, 35.2% main diagnosis, 38.9% comorbidity and 3.7% disease underlying death. The distribution of dementia types were: 53.7% vascular, 1.9% related to other diseases and 44.4% unspecified. The average number of medicines taken per day per patient was 10.8 pieces. Multiple drug treatment occurred in 86.1% of patients. 10% of the patients received medicine to treat dementia (donepezil in 60% of the cases, memantine 40% of the cases). At least one required medication was not administered for 38.9% of dementia patients because of its adverse effect.

Conclusion and Relevance From this investigation we concluded that the active involvement of a clinical pharmacist and the internationally validated clinical database systems are essential. They enhance the clinical effectiveness of the medication by reducing multiple drug uses and by eliminating adverse drug reactions. Our real-world study is highly beneficial for the individualised medication of dementia patients receiving chronic hospital cares.

NP-005

SELF-ASSESSMENT ON THE IMPLEMENTATION OF RECOMMENDATIONS OF THE PERIOPERATIVE PROCESS: INFECTIOUS RISK MANAGEMENT IN SURGERY SETTING

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10.1136/ejhp-harm-2023-eahp.5

Background and Importance Surgical site infections (SSIs) are among the most common complication in surgery. They are associated with longer postoperative hospital stays, may necessitate additional surgical procedures, require long antimicrobial treatment leading to an increased antimicrobial resistance contributing to a costly healthcare. It's necessary to adopt a healthcare policy aimed at a more rational use of antimicrobials to limit antimicrobial resistance.

Our aim was to develop a self-assessment on the implementation of the recommendations, in order to identify key gaps and provide guidance and recommendations for improving IPC (infection prevention and control) practices.

Materials and Methods A multidisciplinary collaboration has involved infectious disease specialists, hospital pharmacists, microbiologists, intensivists, emergency surgeons, nurses. It was conducted a thorough self-assessment on the four following surgery areas: general surgery, emergency surgery, Orthopedic Surgery, Cardiosurgery Unit during July 2021 – March 2022.

A summary results of the recommendations core components self-assessment was provided by a scored checklist attributed to a specific level of recommendations implementation (score 0: not applicable; 1: no implementation; 2: $\leq 50\%$; 3: $> 50\%$; 4: 100% implementation).

The checklist report 13 macro-requisites to which a score is assigned; for each requirement was reported the number of improvement actions.

Results Following the assessment, 31 improvement actions were identified. The comparison versus total average of values shows 4 macro requirements under threshold: Screening per *S. Aureus*; Preoperative bathing; mechanical bowel preparation and the use of oral antibiotics and the maintenance of adequate circulating volume control/normovolemia.

This self-assessment reported 8 improvement actions in Emergency Surgeon: 10 in Orthopedic Surgery, 6 actions in General Surgery and 7 improvement actions in Cardio Surgery.

Furthermore, were highlighted important shortcomings such as antimicrobial prophylaxis for the prevention of SSI in colorectal surgery: scored 1,3 (NA); screening per *S. Aureus* in orthopedic surgery: score 1.

Conclusion The assessment allowed the identification of the priority areas intervention, in order to set innovative strategic actions to improve safety in the perioperative process.

In the future it will be possible to implement strategies with proven effectiveness and a global approach. The aim is

to overcome and refining guidelines by providing a comprehensive range of evidence-based recommendations for the prevention of SSIs.

NP-006 IMMUNOTHERAPY IN SECOND-LINE TREATMENT OF NON-SMALL CELL LUNG CANCER

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10.1136/ejhp-2023-eahp.6

Background and Importance The introduction of immunotherapy in the treatment of patients with non-small cell lung cancer (NSCLC), whose disease progressed after first-line treatment, was considered an important advance. Real-life use data for these drugs are essential to measure their real added value in the treatment of these patients.

Aim and Objectives Our aim was to study the effectiveness of Atezolizumab (ATZ), Nivolumab (NVL) and Pembrolizumab (PMB), in the second-line treatment of NSCLC, in real clinical practice and analyze it considering the efficacy described in published clinical trials.

Materials and Methods This is an observational retrospective study of patients diagnosed with locally advanced or metastatic NSCLC, treated in second-line or later until the end of August 2021, with one of the following drugs: ATZ; NVL or PMB. Effectiveness was evaluated in terms of Progression-Free Survival and Global Survival.

Results Thirty-two patients treated with ATZ, 46 with NVL and 17 with PMB were included. Of the treated patients, 59.4% for ATZ, 39.1% for NVL and 100% for PMB had positive expression of PDL1 (>1%). The median progression-free survival calculated was 5.6 months for ATZ; 8.4 months for NVL and 5.0 months for PMB. The median overall survival calculated was 16.3 months for ATZ, 15.7 months for NVL and 32.6 months for PMB.

Conclusions and Relevance The progression-free survival and overall survival obtained demonstrate that, when used in clinical practice, the drugs studied are effective, with results not lower than those demonstrated in clinical trials. Immunotherapy proves to be a relevant therapy in the second-line treatment of NSCLC.

REFERENCE

1. Lancet 2016 387(10027):1540–1550; Lancet 2017 389(10066):255–265; NEJM 2015;373(2):123–35; NEJM 2015; 373:1627–39

NP-007 RECOMMENDATIONS FOR ADMINISTRATION OF IMMUNOSUPPRESSANTS VIA ENTERAL FEEDING TUBE ACCORDING TO THEIR *IN-VITRO* ADMINISTRATION

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Background and Importance Immunosuppressants (IS) are used in the treatment and prevention of graft rejection after solid organ or tissue transplantation.¹ Their administration via an enteral feeding tube (EFT) is problematic regarding their narrow therapeutic index, cytotoxic, teratogenic potential, and occupational hazard. Incomplete absorption due to incorrect

administration via EFT may lead to graft rejection.² Appropriate drug forms of IS for administration via EFT are missing in our country.

Aim and Objectives Despite multiple published guidelines for the administration of medicines via EFT, available drug forms differ between countries. Our aim was to create local recommendations for the safe administration of IS via EFT reflecting the available medicines in our country, while preventing EFT occlusion and preserving optimal effect.

Materials and Methods A literature search was aimed to determine the site of absorption, incompatibilities, and measures to decrease the occupational hazard. The practical part consisted of dissolving tablets, capsules' content, and their administration via EFTs of diameters 10, 8, and 6 Fr. The administration of IS was realized by the adapted protocol by White et al., 2015.³ We evaluated the rate of disintegration of tablets and tube occlusion.

Results Only one brand of mycophenolate mofetil tablets and two brands of azathioprine tablets disintegrated in a syringe. All the other tablets need to be crushed. Two of the studied IS caused the occlusion of a 6 Fr EFT, no EFT of wider diameter was occluded. We summarize our recommendations in a table.

Conclusion and Relevance Crushing tablets or opening capsules is often the only possibility for IS administration via EFT. In these cases, using personal protective equipment is always needed. Ciclosporin, mycophenolate mofetil, and azathioprine can be administered relatively safely. Special attention is needed when an EFT of 6 Fr is used due to its easy occlusion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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1. Hartono et al., Cold Spring Harb Perspect Med., 2013.
2. Silva et al., J Clin Pharm Ther., 2020.
3. White et al., Handbook of drug administration via enteral feeding tubes, 2015.

NP-008 EMERGENCY DEPARTMENT REVISIT SCORE BASED ON PHARMACOTHERPAY

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10.1136/ejhp-2023-eahp.8

Background and Importance Drug-related problems (DRPs) are a common reason for visiting the emergency departments (ED). However, the information available on risk factors associated with new ED visits based on the patient's pharmacotherapy is limited.

Objective To develop a predictive model of the risk of revisiting the ED at 30 days based on patients' treatment at discharge.

Methods Retrospective cohort study involving adult patients who attended the ED in Catalonia (Period: 2019) with a triage level of 1–3. A 30-day return visit prediction model was created in a referral cohort (60%) using a logistic regression model, being validated in a validation sample (40%). Variables included in the multivariate analysis were assigned a score proportional to the regression coefficient. The sociodemographic variables considered in this study were age, sex and income level, multimorbidity burden based on the Adjusted

Morbidity Groups (GMA). Forty-four groups of drugs associated with DRPs were evaluated.

Results 851,649 patients were included [201,445 (23.6%) with >9 drugs prescribed at discharge], of whom 134,560 (15.8%) visited the ED after 30 days. The four variables evaluated (sex, age, GMA, and income level) and 34 ATC groups were associated with the risk of repeat ED consultation and were combined into a final score (DRP-Score). The drugs with the highest risk score were osmotic laxatives (RR:1.421(95% CI:1.264–1.596)), b-lactam antibiotics (1.333(1.123–1.583)), digoxin (1.282 (1.256–1.309)), heparins (1.150 (1.112–1.190)) and lithium (1,146 (1.000–1.315)) The model achieved an area under the receiver operating curve (AUC-ROC) values of 0.648 (95% CI: 0.646–0.650) in the reference cohort and 0.647 (0.644–0.649) in the validation group. Three risk categories were generated, with the following estimated risks of revisiting the ED at 30 days: low risk: 10.2%, intermediate risk: 18.3%, and high risk: 28.4%. The score was validated in a sample of 1437 patients who visited the ED for DRPs, maintaining its predictive capacity.

Conclusion and Relevance The DRP-score identifies patients at high risk of returning to the ED within 30 days based on pharmacotherapy, being a useful tool for prioritizing interventions from these units.

NP-009

ASSESSMENT OF MEDICATION DISCREPANCIES BY PHARMACIST-LED MEDICATION RECONCILIATION AT ADMISSION: A PROSPECTIVE STUDY IN TRAUMATOLOGY

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10.1136/ejhpharm-2023-eahp.9

Background and Importance Medication errors leading to preventable adverse drug events occur mainly during transitions of care (admission/discharge from a healthcare facility, hospital interdepartmental transfers). Data on drug reconciliation in surgical wards are scarce.

Aim and Objectives The purpose of this study was to assess the prevalence of medication discrepancies in patients admitted to an orthopaedic and trauma department during the medication reconciliation process performed by a pharmacist at admission, and to identify potential risk factors.

Materials and Methods This was a prospective single-center observational study conducted over a 15-week in 2021. Eligible patients were adults hospitalized in two units of an orthopaedic and trauma department of a tertiary university hospital in Switzerland, admitted for a duration of hospitalization > 48 hours, in the presence of a chronic pathology and/or a medication at risk and/or on the physician in charge of the patient's request. The Best Possible Medication History list was established for each patient and compared to the prescription on admission to identify medication discrepancies. These discrepancies were classified as intentional/unintentional on the basis of the medical record and, if necessary, a discussion with the physician. A multivariable analysis by logistic regression was performed to identify predictors of the 'presence of an unintentional medication discrepancy (UMD)'.

Results 120 patients were included in the study with a median age of 71 years [IQR 63.5 – 83.5]. 71.7% of patients were taking ≥ 5 medications before admission. The median pharmaceutical time required to perform the medication reconciliation activity was 36 minutes [IQR 29 – 45]. 60.8% of admitted patients had at least one UMD on admission with a median of 2 per patient [IQR 1 – 3]. Unintentional drug omission (67.3%) and dose modification (21.2%) were the most frequently encountered UMD. 88.5% of identified UMD were corrected. Polymedication (≥ 5 medications) was the only variable associated with 'presence of an UMD' at a level very close to the established statistical significance level of $p = 0.05$ [OR 2.24, p-value 0.065].

Conclusion and Relevance This study confirms the major interest of the medication reconciliation at admission in an orthopaedic and trauma department in an elderly and polymedicated population, exposed to high-risk medications and to a risky process.

NP-010

DEVELOPMENT OF A 2% LIDOCAINE GEL FOR LOCAL ANAESTHESIA OF THE EYE PRIOR TO INTRAVITREAL INJECTION

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Background and Importance Intravitreal injection is a very common eye surgery. The preparation of the injection is time-consuming and labour-intensive, because patients receive several ophthalmic drugs beforehand like locally disinfecting, pupil dilating and local anaesthetic eye drops. Additionally, eye drops containing oxybuprocaine must be applied 3 to 5 times at minute intervals for a sufficient anaesthetic effect.

Aim and Objectives To simplify the process, a local anaesthetic eye gel preparation was requested. The increased viscosity leads to a longer local exposure time on the eye. A single dose is therefore sufficient to achieve the required local anaesthetic effect. As far as we know, a corresponding product is not available on the German market, so an in-house product was developed.

Material and Methods The active ingredient lidocaine hydrochloride 2% (w/w) is dissolved in hot WFI with 0.48% (w/w) sodium chloride as an isotonic additive. 0.25% (w/w) sodium monohydrogen phosphate x 12 H₂O, leads to a pH value of 6 -7 in the finished gel. pH 7 must not be exceeded, to prevent precipitation of lidocaine base. Hydroxyethylcellulose 250 (Natrosol 250 G pharm®), a sterilizable gelling agent, is incorporated into the hot solution at a concentration of 2.5% (w/w). After cooling, WFI is added to the full batch weight, the batch is stirred vigorously and left to stand covered overnight. A homogeneous gel of suitable viscosity develops overnight. The following day, the gel is filled into Redipac® single-dose containers with subsequent autoclaving under standard conditions.

The identity and content of the preparation is checked by UV/VIS spectroscopy.

Results The preparation described achieves a sufficient local anaesthetic effect after single application, is free of preservatives and can be stored at room temperature.

Conclusion and Relevance The lidocaine gel in single-dose containers has significantly accelerated and simplified the preparation of intravitreal injections in the UKSH Eye Clinic.

Section 1: Introductory statements and governance

1ISG-001 ECONOMIC IMPACT GENERATED BY NATALIZUMAB OPTIMISATION

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Background and Importance In our hospital there are 568 patients with multiple sclerosis (MS) in active treatment. Administration of natalizumab is every 4 weeks, but the neurologists at our hospital have optimised the administration every 5 or 6 weeks.

Aim and Objectives Evaluate economic impact from natalizumab optimisation.

Material and Methods Retrospective observational economic study performed in a third-level hospital between January 2019 and June 2022. Demographic data (sex, age), clinical data (MS treatment, posology and quantity of cycles administered) and economic data (Laboratory Purchase Price (LPP) including VAT) collected from prescribing programme and economic management platform. Patients receiving natalizumab for at least 3 cycles were included.

According to posology, calculation of active treatment time and number of cycles saved. Comparison between theoretical economic import (associated to administration every 4 weeks) and real. Analysis of changes of treatment and costs associated.

Results From 568 patients with MS, 43 are receiving natalizumab in our study period. Only 37 received more than 3 cycles of natalizumab. These 37 patients include 24 women, with an average age of 41.2 years (23-65), 4 patients were receiving natalizumab every 6 weeks, and the others every 5 weeks. 111.5 weeks of active treatment time (20-198) averaged, with 21.7 cycles (4-36) associated, meaning 229 vials of natalizumab saved.

Natalizumab's costs according to LPP (€1302) in our study period come to €1.045.506,00. If natalizumab would have been administered every 4 weeks, its cost would come to €1.343.664,00. Savings amount to €298.158,00 globally, or to €85.188,00 annually. Of 37 patients, 4 needed to change treatment due to outbreaks. The new treatment was ocrelizumab, with a PPL of €4.666,64/vial. Total annual cost of patients' ocrelizumab amount to €74.666,24.

Conclusion and Relevance Natalizumab's optimisation with administration every 5 weeks has meant a total saving of €10.521,76, after having reinvested part of the savings in the new treatments with ocrelizumab, allowing our patients to access innovative therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

1ISG-002 MEDICATION WASTE IN AN ORTHOPAEDIC DEPARTMENT: EFFECT OF PATIENT'S OWN MEDICATION USE AND SELF-ADMINISTRATION DURING HOSPITALISATION AND THE VIEWS OF PATIENTS AND HOSPITAL STAFF

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Background and Importance Medication waste has detrimental effects on the environment and healthcare costs. Pharmacotherapeutic changes contribute to medication waste (e.g. substitution to hospitals' medication formulary). Patient's own medication (POM) where patients bring their own medicines for use during admission is known to positively affect medication waste. Self-administration of medication (SAM) can be combined with POM use and allows capable patients to manage their medication regimen throughout hospitalisation. It is not clear how the combination of POM use and SAM affects medication waste. Furthermore, both patients and hospital staff play a major role in medication management during hospitalisation. Their awareness hereof may affect medication waste, but their views on this are unknown.

Aim and Objectives To determine if POM use and SAM reduce the volume and monetary value of medication waste during hospitalisation. To determine the views of patients and hospital staff on medication waste.

Material and Methods A prospective pre-post intervention study was conducted, including all patients admitted to an orthopaedic ward between March and May 2022. In April 2022, POM use and SAM were implemented. Data on volume (in pieces) and monetary value (in euros (€)) of medication waste were collected. A 5-point Likert scale survey on medication waste was conducted among patients and hospital staff. Data were analysed using descriptive statistics.

Results The volume of wasted medicines decreased 44.3% from 477 to 331 pieces per 100 inpatient days after the implementation of POM use and SAM. The monetary value in hospital purchase price of wasted medicines decreased 151.8% from €283.80 to €112.70 per 100 inpatient days. 30 patients and 78 hospital staff members responded to the survey. The majority were aware of and interested in medication waste. Interestingly, 53% of patients did not feel that they contribute to medication waste as opposed to 19% of hospital staff. Both patients and hospital staff were positive towards POM use and SAM as means to reduce medication waste.

Conclusion and Relevance The implementation of POM use and SAM during hospitalisation seems to have the potential to reduce medication waste and concomitant costs at an orthopaedic ward. Patients and hospital staff seem positive towards this topic. Therefore, we recommend to further implement POM use and SAM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

11SG-012 COST-MINIMISATION ANALYSIS: PROPHYLACTIC TREATMENT OF HAEMOPHILIA TYPE A, WHAT TO CHOOSE BETWEEN FACTOR VIII, RECOMBINANT FACTORS VIII (MOROCTOCOG-ALFA AND OCTOCOG) AND EMICIZUMAB?

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Background and Importance Haemophilia type A is a hereditary bleeding disorder linked to a deficiency in FVIII, treated by intravenous administration of FVIII. Emicizumab represents an alternative to FVIII concentrates, without anti-FVIII inhibitor, administered in a single subcutaneous dose.¹

Aim and Objectives The aim is to evaluate the use of emicizumab compared to the three biosimilars used for prophylaxis in haemophilia type A, in order to ensure good care with a good quality of life.

Material and Methods The analysis of the cost of using emicizumab compared to the three biosimilars we have in the hospital, namely plasma and recombinant FVIII (Moroctocog-alfa and Octocog) by calculating the direct, indirect and intangible costs, to assess the advantages and consequences of emicizumab use.

Results According to the cost minimisation analysis, we found a total annual cost for FVIII €125,293.7, Octocog €252,183.7, Moroctocog-alfa €2,753,70.6 with a significant intangible cost because the frequent trip to the hospital makes the patient tired and increases the non-medical cost and the indirect cost, with the possibility in 30% of patients of developing anti-FVIII inhibitors and therefore the administration of high dose plasma FVIII of 6000-9000 IU three times a week with an annual cost of €366,565.8.

On the other hand, emicizumab is indicated even for patients with an anti-FVIII inhibitor whose annual cost is €233,402.9, with a gain of €136,484.23, in addition to a good quality of life. We deduce that plasma FVIII is useful for patients without an inhibitor and emicizumab should be reserved for haemophiliacs with an anti-FVIII inhibitor.

Conclusion and Relevance Our cost evaluation study is a tool for decision support and reduction of uncertainty between four drugs, which makes it possible to adapt purchases according to the needs expressed for an optimal allocation of resources following the evolution of health expenditure.

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Conflict of Interest No conflict of interest

Section 2: Selection, procurement and distribution

2SPD-001 USE AND COST EVOLUTION OF INFLIXIMAB AND ADALIMUMAB OVER 8 YEARS IN A TERTIARY HOSPITAL

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Background and Importance The ongoing rise in healthcare costs makes it necessary to establish containment strategies, in parallel with the commitment to improve access to the most effective and safest treatments. The introduction of biosimilar medicines is an opportunity for health systems (HS) and patients.

Aim and Objectives The aim of the study was to evaluate the use and cost evolution of infliximab and adalimumab in the gastrointestinal department of a tertiary hospital over the last eight years. In this period, biosimilar molecules of both drugs have been incorporated.

Material and Methods Data were collected based on consumed units of adalimumab and infliximab between January 2014 and December 2021. We grouped the different presentations of original brand and biosimilar molecules available and the cost associated at the time it was consumed.

Results Both, infliximab and adalimumab, consumption have gradually increased over the past eight years, from 1,774 to 2,765 units (+55.9%) and from 920 to 3,420 units per year (+271.7%), respectively.

Infliximab biosimilar was introduced in the centre in 2015 and was progressively rolled out in starts and switches, becoming the sole since 2021. This has led to a gradual reduction in costs, from €852,022 in 2014 to €497,235 in 2021 (-41.6%).

Adalimumab biosimilar was not introduced in the hospital until 2019. Consumption rose from 920 to 2,153 units per year (+134.0%) between 2014 and 2018, in tandem with cost: from €442,745 to €936,175 per year (+111.5%). Nevertheless, between 2018 and 2021, consumption increases from 2,153 to 3,420 (+58.9%) with an absolute cost reduction of €563,683 (-60.2%). Overall, adalimumab spending has decreased by 15.9% over the eight years despite the increase in consumption.

Conclusion and Relevance Innovation in biological therapies, as well as the increase in candidates to receive them, has grown significantly. It is associated with an increase in costs that may become unaffordable for public HS.

The introduction of two biosimilar molecules in our centre has led to significant savings, despite the increase in consumption.

The commercialisation of biosimilar molecules, alongside policies that allow their introduction in healthcare centres, promotes the system's sustainability, enables access to a greater number of patients, while allowing for the continued incorporation of innovative molecules.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-002 COST-SAVING IMPACT OF GENERICS: A LOCAL EXPERIENCE ON LENALIDOMIDE

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Background and Importance Boosting generics is an indispensable approach in conducting cost-saving management in healthcare systems. In fact, generics can provide similar effectiveness and safety to originators but with lower costs and can increase market competition.

Aim and Objectives The purpose of this work was to demonstrate the economic advantage of a generic lenalidomide in real practice, showing and comparing costs and consumption during the period 2021 to 2022.

Material and Methods To conduct this analysis, patients, type of prescription (originator or generic), number of patients treated, number of cycles, administered milligrams and purchase prices, during the period September 2021 to August 2022, were extrapolated from pharmacy software and matched.

Results Compared with period from September 2021 to February 2022, during March to August 2022, the number of treated patients remained similar (105 vs 104) and the number of cycles administered (388 vs 390).

Abstract 2SPD-002 Table 1

| | Number patients treated | Cycles received in total | Cost |
|-----------------------------|-------------------------|--------------------------|--------------|
| Generic lenalidomide 5 mg | 22 | 92 | € 26,371.92 |
| Original lenalidomide 5 mg | 23 | 96 | € 238,950.61 |
| Generic lenalidomide 10 mg | 47 | 211 | € 26,863.21 |
| Original lenalidomide 10 mg | 39 | 192 | € 599,542.24 |
| Generic lenalidomide 15 mg | 12 | 35 | € 49,506.20 |
| Original lenalidomide 15 mg | 19 | 53 | € 188,691.08 |
| Generic lenalidomide 20 mg | 5 | 10 | € 11,317.07 |
| Original lenalidomide 20 mg | 3 | 7 | € 27,478.14 |
| Generic lenalidomide 25 mg | 18 | 42 | € 33,061.60 |
| Original lenalidomide 25 mg | 21 | 40 | € 150,177.08 |

The total expenditure of generic lenalidomide has been € 147,120 and original lenalidomide € 1,204,839.15, therefore the total saving has been 87.80%.

Likelihood, the generic lenalidomide has been as well tolerated as original lenalidomide.

Conclusion and Relevance Currently, cost savings and rationalisation policy are playing an essential role in healthcare systems, and generics represent a great opportunity to reallocate available resources. This study demonstrated that enhancing a generic lenalidomide is a good strategy for the sustainability of care. Lenalidomide costs decreased while the number of patients remained similar. In summary, generics constitute an efficient strategy for the sustainability of national health services, allowing resource reallocation and access to care to a larger number of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. No conflict of interest

Conflict of Interest No conflict of interest

2SPD-003 ERRORS DETECTED IN THE TELEPHARMACY PROCEDURE

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Background and Importance After the rise of telemedicine with the COVID-19 pandemic, a telepharmacy consultation has been implemented in our hospital in the pharmacy outpatient area, sending medicines to community pharmacies within a population area of 600,000 inhabitants.

Aim and Objectives The purpose of this study is to analyse the medication errors (ME) that have occurred during a specific period of time, throughout the process of medication delivery. The aim is finding causes and possible improvements.

Material and Methods We carried out a retrospective descriptive study. The errors that occurred between January 2021 and August 2022 (20 months) in the telepharmacy process were analysed, taking into account everything from the preparation in the hospital pharmacy to the collection of the medication by the patient in the community pharmacy. The MEs were collected in a local database. We described date, personal data of the patient, codes assigned to the single shipping route and destination community pharmacy, type of error and step in which the ME was detected.

Results In the period studied, a total of 69 MEs were recorded. We break them down into the following types: 20 cases with a quantitative lack of medication (28.99%), 19 cases in which a different medication was sent (27.54%), 15 with another patient's medication (21.74%), 10 with medicine with wrong dose (14.49%), 2 cases in which the medicine was not sent (2.90%) and another 2 in which the medicine was sent badly packaged (2.90%), 1 case in which the one in which the misidentified medicine was sent (1.45%) and 1 case in which a larger quantity was sent (1.45%). 48 MEs were detected by the patient (69.56%), 15 were detected in the community pharmacy (21.74%), 4 were detected in the hospital pharmacy (5.80%) and 2 cases were detected during the transportation of the medication (2.90%). None of the errors detected had consequences for the patient to our knowledge.

Conclusion and Relevance Among the MEs detected, the most common were those related to a quantity defect or lack of a medication and those in which a different medication was sent. In general, they are errors that could be avoided by automating processes that are currently carried out manually.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-004 ECONOMIC EVALUATION AND BUDGET IMPACT FOR A REGIONAL HEALTH SERVICE ASSOCIATED WITH THE INCLUSION OF THE FLUOCINOLONE ACETONIDE INTRAVITREAL IMPLANT IN A REGIONAL PHARMACOTHERAPEUTIC GUIDELINE

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Background and Importance Due to the high cost of the implant of fluocinolone acetonide (FAc) 190 µg, it is especially important to realise an economic evaluation and budget impact analysis before inclusion in the pharmacotherapeutic guide of any health institution.

Aim and Objectives Realise an economic evaluation and a budget impact analysis to assess its inclusion in our regional pharmacotherapeutic guide, maintaining the financing conditions of our National Health System (NHS).

Material and Methods PubMed and reports from independent evaluators were consulted: National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) among others.

Results According to the product information, an implant releases FAc for a maximum of 36 months, and an additional implant can be placed after 12 months if vision decreases or retinal thickness increases. Pivotal studies and the IRISS observational study concluded in the need to use 1.3 implants/eye and 1.13 implants/eye affected during the first 3 years respectively, this last value being the one considered by the ERG (Evidence Review Group). Taking this last reference, the cost of treatment/affected eye at € 1558.84/eye/year or € 4676.53/eye/3 years.

To estimate the target population, we used the criteria of the SMC evaluation report in which they considered a total of 179 patients with pseudophakic chronic DME eligible for treatment in the first year, increasing to 186 in the fifth year. Unlike the SMC, our NHS restricts its funding to third-line, after anti-angiogenic agents and in patients with a suboptimal response to various intravitreal dexamethasone implants or pseudophakic patients.

Making a parallelism with the Scottish population, 33.5 patients/1st year–34.8 patients/5th year would be candidates to receive FAc in our region.

NICE and the ERG found that in clinical practice 35% of patients would require bilateral treatment. Thus 12 patients/year would need treatment in both eyes in our population. The economic impact in our region would range between € 5,3000.56/year if it were inserted in only one eye and € 71,706.64/year in both eyes.

Conclusion and Relevance The financing conditions of our NHS position the drug in the third-line, which in a certain way contains the budget impact.

Since SMC restricting the conditions of use more than our NHS, the budget impact could be underestimated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-005 NEW CLOSED SYSTEM TRANSFER DEVICE CONTAINS REAL DRUG VAPOURS FOR UP TO 28 DAYS

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Background and Importance Several Closed System Transfer Devices (CSTDs) are currently approved a 7-day usage period. Increasing pressure to reduce drug costs and data supporting stability of some drugs beyond 7 days create a demand for CSTDs that contain hazardous drug vapours for 28 days. A previous study proved that a model air-cleaning CSTD contains drug vapours for 7 days.

Aim and Objectives The aim was to test drug vapour containment of an air-cleaning CSTD under extreme conditions for 28 days.

Material and Methods Cyclophosphamide (CP) was chosen as the representative drug. A model CSTD (Chemfort™) Vial Adaptor (VA) was connected to each vial, and CP was reconstituted using the CSTD Syringe Adaptor. VAs at the end of their shelf life, representing extreme conditions, were tested both immediately following and 28 days after reconstitution, with and without intact Toxi-Guard® air-cleaning systems (an integral part of the Chemfort™ VA).

Each vial was transferred to a closed test chamber connected to a vapour trap. To increase drug vapourisation, the chamber was heated to 50°C and nitrogen gas was constantly introduced into the vials. Any vapours potentially released from the Chemfort™ VA were trapped and then extracted with solvent.

Quantification of CP was performed using a validated LC/MS/MS method.

Results No CP was detected for any of the VAs with intact Toxi-Guard® components, whether tested immediately or 28 days after reconstitution, even when heat and gas flow were employed to encourage the production of vapours and when the VA was at the end of its shelf life. The limit of detection of the method was estimated at 0.02 ng. Without an intact Toxi-Guard®, 110.3 ng of CP were released into the environment.

Conclusion and Relevance The model CSTD utilising Toxi-Guard® air-cleaning technology contained drug vapours after a 28-day usage period, even under extreme conditions. A recent study proved 28-day prevention of microbial ingress by the same CSTD. Taken together, the two studies support pharmacists' decision to use drugs for their full shelf life or to extend the beyond-use-date up to 28 days when using an appropriate CSTD, thus reducing cost and waste.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships:

Ofer Raz and Elana Slutsky Smith are employed by Simplivia Healthcare Ltd, the manufacturer of Chemfort™. Dekel Navarro and Daniel Epstein declare no conflict of interest relating to the material presented in the abstract. Funding for this project was provided by Simplivia Healthcare Ltd, the manufacturer of Chemfort™.

2SPD-006 ARE ALL BIOLOGIC AGENTS IN THE TREATMENT OF ANKYLOSING SPONDYLITIS EQUIVALENT ALTERNATIVES?

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Background and Importance Nine drugs are currently approved for the treatment of ankylosing spondylitis (AS) in adults: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, upadacitinib and tofacitinib. Tofacitinib was the last of them to receive its approval. However, there are no direct comparisons between them.

Aim and Objectives To establish whether the drugs approved for AS in adults can be considered equivalent therapeutic alternatives (ATE) in efficacy in AS.

Material and Methods A search of clinical trials of these drugs in adult patients with AS was conducted, phase II or III, double-blinded, controlled with another drug or placebo.

Other inclusion criteria were

- Endpoint: ASAS40 (a ≥40% improvement and an absolute improvement from baseline of the Assessment in SpondyloArthritis International Society).
- Follow-up time: 12-16 weeks.

For those drugs with more than one study, a previous meta-analysis was performed using Joaquin Primo calculator. An adjusted indirect comparison (IC) of the drugs used in AS versus tofacitinib was performed using the Bucher method, using Joaquin Primo calculator. Due to lack of data in the literature and considering that therapy failure can be recovered with second lines, half of the ASAS40 value obtained in meta-analysis was taken as delta value. ATE guide was followed in order to establish a positioning.

Results

Sixteen studies were included 4 adalimumab, 2 golimumab, 1 infliximab, 1 certolizumab, 2 etanercept, 1 upadacitinib, 2 tofacitinib, 1 secukinumab and 2 ixekizumab. The difference in ASAS40 of the drugs before versus tofacitinib expressed as RAR (IC 95%) was: Adalimumab [4 (-6,1; 14,1)], certolizumab [-7,3 (-25,1; 10,5)], etanercept [2 (-11,5; 15,5)], golimumab [-5 (-16,3; 6,3)], infliximab [8,43 (-4,8; 21,6)], ixekizumab [-9 (-20, 6; 2,6)], secukinumab [-2,7 (-18,3; 12,9)], upadacitinib [-1,9 (-17,8; 13,9)]. Adalimumab, etanercept and tofacitinib are considered ATE. Infliximab, upadacitinib, secukinumab, golimumab, certolizumab, ixekizumab and tofacitinib can also be considered ATE, being the probability of clinically relevant difference <50% (most of the 95% CI is in the equivalence range) and the failure does not involve serious/irreversible damage.

Conclusion and Relevance Tofacitinib and the rest of these drugs could be considered ATE. For a definitive statement, the criteria of safety and adequacy should be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-008 BUDGETARY IMPACT DUE TO THE REPLACEMENT OF ORIGINAL LENALIDOMIDE INTO GENERIC LENALIDOMIDE

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Background and Importance The use of generic drugs is one of the most effective tools to increase efficiency in the economic management of the health system. From March 2021 to February 2022, the acquisition of the original molecule of lenalidomide (Revlimid®) represented the main expense in the ABC of drug purchases. As of this date, a generic specialty was commercialised and the Pharmacy Service proposed a replacement between them, given that both share the same indications as in the technical datasheet.

Aim and Objectives Quantifying the economic impact in the expenses of chapter II of a general hospital, caused by the acquisition of generic lenalidomide instead of Revlimid® and its repercussion on the budget during 12 months.

Material and Methods Although only two months of evolution with the new generic molecule are available, we have extrapolated this data to one year so that we can calculate the economical differences when it comes to the budget.

Results From March 2021 to February 2022, the purchase of Revlimid® has meant a net amount of € 1,014,886.46, which represents 9.8% of the total expense in chapter II (€10,246,115.23) and positions it as first spend in the ranking of medicines purchased in this period of 12 months.

The amount derived from the purchase of generic lenalidomide corresponding to the studied period, comes up to € 1,601.27. That results in an estimate of € 9,607.62 for 12 months.

Assuming that the same number of patients and treatments with lenalidomide were stable throughout the period, as well as the expenditure on the rest of the ABC of drugs, the economic impact generated would mean a saving of approximately € 1,005,278.84, which would cause a significant decrease in the chapter II for our Hospital (-14.25%).

Conclusion and Relevance The economic impact caused by the introduction of generic lenalidomide in our Hospital will produce savings of more than one million euros.

Speeding up the authorisation processes for generic medicines, as well as other pricing policies, are essential manoeuvres to get a cohesive health system that guarantees equal access to medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-009 AVOIDED COSTS FROM THE INCLUSION OF BREAST CANCER PATIENTS IN CLINICAL TRIALS

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Background and Importance Breast cancer is one of the tumours with the highest incidence in Spain, and its pharmacological treatment generates a huge economic impact. Clinical trials are essential for evaluating the efficacy and safety of new therapies, and also provide a financial benefit to the public health system.

Aim and Objectives The aim of this research is to calculate the saving costs in drugs, derived from the participation of breast cancer patients in clinical trials (based on the drug free support provided by the sponsor of each study).

Material and Methods A retrospective analysis was made of all breast cancer clinical trials initiated in our hospital since January 2020, and all patients included in these trials were selected. The data collected were: trial phase, investigational drug, number of subjects enrolled and number of treatment cycles received. The Oncology Department was contacted to discuss the therapeutic alternative of choice and its theoretical duration if the patient had not participated in the clinical trial. The cost of each option was calculated using the acquisition price of the drug (laboratory sale price – discount + 4% VAT). Information was obtained from the database of the clinical trials unit.

Results Since 2020, 8 breast cancer clinical trials (2 phase II and 6 phase III), were initiated in our hospital. Were included 10 subjects, receiving a total of 106 treatment cycles. The investigational medical products studied were: trastuzumab and conjugates, pertuzumab, atezolizumab, olaparib, alpelisib and palbociclib. The overall cost saving was € 198.775,32. The trial with the highest cost impact offers a saving of € 8.269,48 per cycle of each enrolled patient. The drug with highest avoided cost was pemetrexed (€ 32.890,54).

Conclusion and Relevance Clinical trials in breast cancer patients, in addition to offering the possibility of access to

new therapeutic alternatives, represent a considerable economic saving and a significant reduction in pharmaceutical costs. It is important to improve patient recruitment in these types of studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-010

REVIEW OF THE ENVIRONMENTAL CRITERIA INTRODUCED IN THE TENDERING OF DRUGS, MEDICAL DEVICES AND NON-MEDICAL EQUIPMENT IN A HEALTH GROUP PROCUREMENT ORGANISATION

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Background and Importance Green public procurement is a process of contracting products, services, and works with the least possible damage to the environment during their life cycle. In order to improve knowledge on the application of environmental criteria in healthcare procurement, it is necessary to assess the current implementation situation.

Aim and Objectives To review the incorporation of environmental criteria in public procurement procedures for drugs, medical devices and non-medical equipment (paper, clothing, garbage bags, etc.) in a group procurement organisation.

Material and Methods A retrospective study was performed in which all the tenders carried out by the group procurement organisation from 2017 to the first quarter of 2022 were reviewed. All tenders that had included environmental criteria in the evaluation criteria were identified. In order to evaluate the impact of these criteria in the suppliers' bids, it was considered as positive if compliance with the environmental criteria was given in at least one of the products offered. Classification of the suppliers (drugs, medical devices, and non-medical equipment) was made on the basis of subject matter of the procurement.

Results A total of 117 tender files were reviewed, where 15 (12.8%) included environmental criteria in the technical specifications: 4 (26.6%) for drugs, 6 (40%) for medical devices and 5 (33.3%) for non-medical equipment. A total of 130 suppliers presented tender bids in the 15 tenders identified: 80 (61.5%) met one or more of the environmental criteria included in the specifications. Regarding the subject matter of the contract, 19 companies submitted bids to drug tender files, 55 to medical devices and 6 to non-medical equipment. During the period 2018-2021, the highest number of tenders with environmental criteria were those of medical devices. Overall, a growing trend with the incorporation of environmental criteria is observed over the years.

Conclusion and Relevance The introduction of environmental criteria in healthcare procurement is still low but with an increasing trend towards a higher percentage of the tendered contracts. The current sustainable procurement policies in Europe encourage for a wider introduction of social and environmental criteria in the procurement of drugs, medical devices and non-medical equipment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-013

INTERVENTIONAL CARDIOLOGY: ANALYSIS OF STERILE MEDICAL DEVICE'S CONSUMPTION AND ASSESSMENT OF DIFFERING PRACTICES

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Background and Importance Therapeutic angioplasty (TA) allows the dilatation of coronary stenosis. This minimally invasive procedure, often combined with diagnostic angiography, requires various costly medical devices (MD).

Aim and Objectives This study was conducted to highlight if there is a difference in interventional cardiology (IC) practices between physicians and estimate the associated costs.

Material and Methods First, data (characteristics of cardiac procedures (CP), number and type of MD (nMD)) were extracted from the cardiovascular information software (Cardi-report®) on a period of three months. Then, Excel® was used to calculate the average MD cost (AC) per procedure for each operator. Finally, data were explored in RStudio® using the Multiple-Regression, Clustering with K-means and Ward's method, in order to classify the similitudes and visualise the differences in practices.

Results Our sample of 74 CP includes 11 TA and 63 combined procedures. These, concerned 63 patients (average age 68 years), 26% of females and 76% of males among whom 10 had at least 2 CP. The AC estimated per procedure is € 1125 of which € 602 is not covered by additional payments (NCA) while € 523 is covered (CA). Five physicians A/B/C/D/E operate in IC with a respective percentage of activity of 5%/9%/12%/22%/51%.

Abstract 2SPD-013 Table 1

| Operator | A | B | C | D | E |
|----------|------|------|------|------|------|
| CA | 539€ | 821€ | 899€ | 474€ | 552€ |
| NCA | 327€ | 989€ | 675€ | 578€ | 407€ |

Multiple-Regression shows that cost of CP is explained at 89% by nMD and NCA cost as significant variables (adjusted $R^2=0.891$ with P-value $<5\%$ ($1.465e-12$) so null-hypothesis can be rejected). Clustering and Ward's dendrogram grouped procedures with common characteristics and showed that there were differences in practices among physicians. After excluding operators, A and E, clustering shows that operator C is singular in his practices (with a higher rate of complex procedures defined as longer than 90 minutes for combined procedures), while B and D have similarities in terms of choice of MD.

Conclusion and Relevance The hospital pharmacist, as MD expert plays a central role in managing consumption analysis. Expanding the sample to confirm the results would be more relevant. Thus, it would be interesting to explore the impact of communicating this work to physicians in order to homogenise their practices.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-014 COST STUDY: REUSABLE FLEXIBLE URETEROSCOPES VERSUS SINGLE-USE IN A HEALTHCARE FACILITY

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Background and Importance In our hospital, we use flexible ureteroscopes for lithiasis treatment, which is at high risk of material breakage. In the devices park, we have six adult devices (inadequate in view of the activity) and one paediatric (obsolete), which are often unavailable, for disinfection or repair.

Aim and Objectives To compensate for unavailability, we could use single-use devices. Our objective is to compare reusable versus single-use devices' costs, to determine if referencing single-use devices is relevant.

Material and Methods We set a working group, including urologists, pharmacists, biomedical engineers and health executive from disinfecting centre. We base the calculation of the cost on 300 uses per year. Reusable cost gather the purchase price, the amortisation expense for a 3 year product lifetime, disinfections cost (products, equipment, staff), maintenance contract and repair cost. Single-use cost is assimilated with the purchase price of 300 units. The manufacturer provides the console free of charge. Our study does not consider waste treatment cost.

Results For 300 uses, reusable ureteroscopes cost €133 360 yearly pre-tax (€445/unit): €27 813 for amortisation expense, €66 000 for maintenance contract, €20 594 for the repairs. Disinfection costs €12 900 yearly, in addition to €4 353 yearly for maintenance and €1700 for amortisation of equipment. If we only used single-use ureteroscopes, it would cost €184 500 yearly (€615/unit). The incremental cost would be €51 140 yearly.

Conclusion and Relevance Our results show that, in our case, single-use is more expensive, especially since we have a new disinfection facility for our reusable ureteroscopes. Moreover, the single-use ureteroscopes' picture quality is lower, which led the group to speak in favour of the park increase to eight units for usual use. In addition, it recommends punctual purchase of single-use in cases of unavailability or act at high risk of material breakage. Indications for paediatric use are rare, the group recommends purchasing a few single-use units and to write off the reusable ureteroscope.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-017 TELEPHARMACY AND HOME DELIVERY PROGRAMME FOR OUTPATIENTS THROUGH THE COMMUNITY PHARMACY

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Background and Importance The SARS-CoV-2 pandemic accelerated the implementation of alternative ways of remote pharmaceutical care and dispensation. Telepharmacy and home delivery programmes (THDP) allow hospital pharmacists (HP)

to provide remote pharmaceutical care for vulnerable populations (elderly, socioeconomic or mobility problems).

Aim and Objectives To describe the implementation of a THDP in a hospital through the community pharmacy (CP).

Material and Methods Observational retrospective study between 1 October 2021 and 30 September 2022. Patients that voluntarily requested to be part of the THDP were evaluated to meet the established criteria: >3 months of treatment, compliance with consultations, adherent, and proper understanding of the information on the THDP and signing an informed consent form. Due to the human and economic resources available, priority was given to older patients (>65 years), distance to the hospital centre, disability or dependency. Neither pathology nor medication were taken into consideration. CP requested the medication via web. Then, patients received follow-up phone calls by the HP after reviewing the electronic medical records. The medication was packaged individually with barcode labels and sent to the nearest CP through a pharmaceutical cooperative.

Results 8168 patients attended the outpatient unit, 444 (5.4%) were included in the THDP. Rheumatoid arthritis (17.8%) treatments were the most in-demand medication, followed by multiple sclerosis treatments (10.1%) and antiretroviral drugs (8.5%).

Abstract 2SPD-017 Table 1

| Treatment | Disease | Number of patients |
|--|---|--------------------|
| Antiviral drugs | HIV | 38 |
| Dermatologic and rheumatologic disorders | Ankylosing spondylitis | 36 |
| | Psoriasis and others | 17 |
| | Psoriatic arthritis | 34 |
| Digestive disorders | Rheumatoid arthritis | 79 |
| | Hepatitis B virus | 22 |
| Erythropoiesis-stimulating agents | Inflammatory bowel disease | 28 |
| | Anaemia in patients with cancer or chronic kidney disease | 30 |
| Neurological disorders | Multiple sclerosis | 45 |
| | Preventive treatment of migraine | 11 |
| Oral anticancer therapy | Solid tumours and haematologic malignancies | 10 |
| | Chronic pulmonary infection | 4 |
| Respiratory disorders | Idiopathic pulmonary fibrosis | 17 |
| | Pulmonary hypertension | 11 |
| | Severe asthma | 5 |
| | Systemic sclerosis | 7 |
| Others | Hypercholesterolemia | 19 |
| | Hyperparathyroidism | 11 |
| | Miscellany | 20 |

Eight incidents occurred: dosing error (25%), wrong drug (12.5%), wrong formulation (62.5%), that were resolved.

Conclusion and Relevance The implementation of THDP has been a new challenge for HP. It enables us to provide drugs to patients in their immediate environment without extra cost to the healthcare system. However, the evidence of the impact of these programmes is sparse.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-018 BEZLOTOXUMAB: STRATEGIES TO REDUCE ECONOMIC IMPACT

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Background and Importance *Clostridium difficile* is the most common cause of infectious diarrhoea in hospitalised patients and causes great morbidity due to the high percentage of recurrence. Bezlotoxumab was the first humanised monoclonal antibody against C.difficile toxin B approved for prevention of recurrent *Clostridium difficile* infection (CDI) in high-risk adults in conjunction with standard of care antibiotics. Bezlotoxumab vial power is 1,000 mg, is given as a one-time infusion in recommended dose of 10 mg/kg over 60 minutes. New guidelines on the management of CDI have been published in 2021: ACG and IDSA/SHEA, which recommend using bezlotoxumab in patients with a high risk of recurrence.

In order to reduce economic impact of the administration of bezlotoxumab, our centre promoted scheduling selected patients on the same day to use the rest of the vials.

Aim and Objectives To assess the economic impact of the appointment strategy in patients treated with bezlotoxumab.

Material and Methods A retrospective analysis of pharmaceutical expenditure of bezlotoxumab prescribed for CDI was conducted from June 2019 to August 2022. Data collected were number of patients treated with bezlotoxumab, weight, date of infusion, number of vials required. Data were collected from electronic prescribing program and economic software.

Results 45 adult patients were included in the study. They all received bezlotoxumab for CDI at high risk of recurrence, in single infusion of 10 mg/kg. 24 patients (53.3%) were cited to prevent vial waste. 21 patients (46.7%) required a complete vial: due to their weight, difficulties in making an appointment, or both. Of 24 patients, median weight was 50 kg (rank 34-66 kg).

In the period of our study, 35 vials of bezlotoxumab were used. Cost of bezlotoxumab vial is € 1,480. Estimated expenditure was: € 51,800 if patients were cited vs € 66,600 if not. The cost of treatment decreased by € 14,800 due to the administration appointment strategy.

Conclusion and Relevance Bezlotoxumab is an effective treatment in preventing CDI relapse in high risk recurrence patients, following guidelines. Administration appointment strategy in selected patients has proven to be efficient since more patients can be treated with the same budget.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): <https://pubmed.ncbi.nlm.nih.gov/34164674/>

ACG Clinical Guidelines Prevention, Diagnosis, and Treatment of *Clostridioides difficile* Infections: <https://pubmed.ncbi.nlm.nih.gov/34003176/>

Conflict of Interest No conflict of interest

2SPD-020 IMPACT OF COVID-19 TREATMENT OPTIONS ON HOSPITAL PHARMACY'S WORKLOAD: LESSONS LEARNED

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Background and Importance Treatment guidelines for COVID-19 have rapidly been evolving. Different drugs against COVID-19 have urgently emerged to control the pandemic, challenging hospital pharmacies to make these antiviral and immunomodulatory therapies timely available for admitted patients.

Aim and Objectives To analyse the prescribing patterns of COVID-19 drugs in our hospital and its impact on the pharmacy's workload.

Material and Methods We retrospectively analysed drug registration data from 1 January 2020 to 16 March 2022 of COVID-19 drugs (dexamethasone, remdesivir, baricitinib, casirivimab/imdevimab and sotrovimab) for hospitalised patients. Consumption data were expressed as number of patients and number of preparations. To determine pharmacy's workload, we measured the average time for drug ordering, preparation and dispensing. Hydroxychloroquine and baricitinib were excluded as these are commercially available oral drugs which are distributed according to standard procedures.

Results The volume of dispensed COVID-19 drugs fluctuated along with the hospitalisation waves of the COVID-19 epidemic. Oral dexamethasone was the most frequently prescribed drug throughout the whole period, which is consistent with the strong recommendation in the national guideline. Remdesivir, introduced in our practice since October 2020, was the second most prescribed drug despite low evidence. From October 2021 until December 2021, 41 infusions of remdesivir were administered, compared to 381 infusions from January 2022 until March 2022. Compared to dexamethasone and remdesivir, monoclonal antibodies (casirivimab/imdevimab and sotrovimab) were less commonly used: 48 prepared infusions between September 2021 and March 2022. Most drugs were given in combination. Remdesivir and monoclonal antibodies were manually ordered to fulfil urgent needs as the supply is managed nationwide by the government. Infusions were prepared at once due to limited stability. Ordering, preparing and dispensing required an average of 35 minutes per patient to complete.

Conclusion and Relevance The COVID-19 pandemic impacted pharmacy's workload. We could have made more timesaving decisions such as the use of commercially available methylprednisolone instead of dexamethasone and batching remdesivir preparations. Hospital pharmacists should be involved in developing national guidelines and take into account the impact on daily practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Sciensano, Interim clinical guidance for adults with confirmed COVID-19, July 2022, Version 29

Conflict of Interest No conflict of interest

Section 3: Production and compounding

3PC-001 PREPACKED BOXES FOR OUTPATIENT PARENTERAL ANTIBIOTIC THERAPY (OPAT) – A QUESTIONNAIRE SURVEY ON KNOWLEDGE, OPINION AND WISHES

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Background and Importance To support a simple and quality-assured outpatient parenteral antibiotic therapy (OPAT) workflow, the hospital pharmacy offers specially prepacked boxes for use in the patient's home after discharge. There are boxes for three different antibiotics; benzylpenicillin, cefuroxime and piperacillin/tazobactam, containing antibiotic powder, utensils and solvent for three days of treatment. Another box contains only utensils and solvent for three administrations.

Aim and Objectives The aim is to explore knowledge, opinion and wishes to the prepacked antibiotic and utensils boxes in attempt to fulfil the needs of the hospital wards.

Material and Methods In an electronic questionnaire with 17 questions, one nurse at each hospital ward was asked about their knowledge, opinion and wishes to the antibiotics and utensils boxes.

All hospitals wards in Central Denmark Region that discharge patients to OPAT received a questionnaire. The questionnaire was designed after interview with two nurses and pilot tested by two other nurses on different wards.

Results 39 wards of 53 (74%) responded to the questionnaire. The results confirmed that the boxes are valued in the OPAT workflow on the hospital wards. 87% knew about some of the antibiotics boxes, 59% knew about the utensils box. There was agreement (97%) that the uniformity that comes with the boxes, contributes to patients' safety in primary-care.

There was general satisfaction with the number of treatment days in the boxes. One third of respondents would have liked a supplementary box with one day of antibiotic treatment, enabling a more flexible solution and reduced drug waste. 25% would like boxes containing other antibiotics.

Several commented on the availability of the boxes on the wards, as a factor that sometimes prevents use.

Conclusion and Relevance The survey shows that the boxes are known and highly appreciated, but there is a need to increase knowledge about all the boxes and improve their availability.

Currently the existing prepacked boxes cover most cases of OPAT, but a supplement of a one-day treatment may provide a more flexible solution with less drug waste.

To evaluate the wishes for other antibiotics in prepacked boxes, more data about use of antibiotics for OPAT patients is needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-002 HAZARDOUS DRUG AND ANTIBIOTIC RESIDUE SURFACE CONTAMINATION – IS THERE A NEED TO REDUCE EXPOSURE?

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Background and Importance Exposure to Hazardous Drugs (HD) is a potential health risk. Multiple regulatory agencies have provided guidance involving enhanced cleaning procedures and the use of Closed System Transfer Devices (CSTDs) to minimise the risk of exposure. However, despite the potential for side effects involving the use of antibiotics (ABs), guidance has not been provided for facilities to reduce or minimise these risks.

Aim and Objectives The aim of this study was to identify the level of AB and HD surface contamination in a hospital pharmacy and eight wards to increase awareness for the need for enhanced controls involved in AB use.

Material and Methods Six HDs were analysed in four surface wipe samples from a pharmacy and two wards. Sampling was repeated four times (trials) over a period of eight months (288 endpoints). A CSTD was used for HD preparation during the entire study. Eight ABs were analysed in two surface wipe samples from six wards collected during the four trials (384 endpoints). Sampling was at the same timepoints as for HD sampling. A CSTD was not used in AB handling. Enhanced cleaning was implemented following the first trial. Samples were analysed with liquid chromatography tandem mass spectrometry.

Results HD surface contamination was detected in 6% of the samples collected during the four trials. Samples with high levels of contamination were not found. AB surface contamination was detected in 68% of the samples. 15% of the samples show high levels of contamination. Despite enhanced cleaning procedures, AB contamination was increased in the last trials compared to the initial trials.

Conclusion and Relevance The study illustrates that institutional guidance, involving the use of a CSTD and effective cleaning, has proven to be effective to minimise unintentional exposure of healthcare workers to HD surface contamination. On the contrary, guidance, controls and cleaning were not sufficient to reduce surface contamination with potential harmful ABs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

- Alert and action levels for surface contamination with HDs in The Netherlands (https://www.dokterhoe.nl/fileadmin/user_upload/documents/cytostatica/meetstrategie-werkinstructie.pdf)

Conflict of Interest Corporate sponsored research or other substantive relationships:

The study was financially supported by ICU Medical USA. Paul Sessink is receiving an honorarium from ICU Medical for this presentation.

3PC-004 ECONOMIC SAVINGS OF ERENUMAB REDOSING IN A THIRD-LEVEL HOSPITAL

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Background and Importance Erenumab is a new monoclonal antibody for the treatment of migraine that binds to the calcitonin gene-related peptide (CGRP) receptor to inhibit its function. Erenumab is a drug with a considerable economic impact on the hospital's annual budget.

Aim and Objectives To evaluate the budgetary impact of the redosification of the commercial dose of erenumab 140 mg into doses of 70 mg.

Material and Methods An observational, retrospective study was conducted in a tertiary care hospital with a clean room. All patients treated with erenumab between 1 January 2019 and 30 August 2022 were included. The variables collected were: sex, age, dose prepared per patient, number of redoses per patient, and number of syringes of erenumab used. To calculate the budgetary impact of erenumab, a pharmacoeconomic study was carried out in which the savings obtained by the redosification of 140 mg in doses of 70 mg were evaluated since both commercial presentations have the same price (PTR erenumab 70 mg and 140 mg = €200). The actual cost of the treatments with redosing and the theoretical cost without redosing were calculated, considering the number of doses and the duration of treatment in each patient. The information was obtained from the corporate prescription programme and patients' clinical records.

Results A total of 281 patients were treated with erenumab during the study period. The mean age was 46 years (range 17-75), 86.8% (n=244) women and 13.2% men (n=37). A total of 1,133 syringes of erenumab 70 mg (mean: 2; range 0-29) and 1,875 of 140 mg (mean 4; range 0-28) were consumed. The real annual cost of the treatments with redosing was €519,827; compared to a theoretical annual cost of €629,282 if the redosing had not been carried out. Therefore, the redosification of erenumab 140 mg into 70 mg has saved 547.28 syringes of erenumab 140 mg per year (€109,455). An estimated saving of €389.52 per patient was obtained by the redosification of erenumab 140 mg dose into 70 mg.

Conclusion and Relevance The results show that the repackaging of the 140 mg dose into 70 mg is a great economic saving practice and easy to implement in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-005

CLOSED SYSTEM TRANSFER DEVICE (CSTD) EXTENDS PRACTICAL IN-USE SHELF LIFE TO 28 DAYS AFTER FIRST PUNCTURE OF NON-PRESERVED SINGLE-USE-VIALS IN BOTH CONTROLLED AND UNCONTROLLED ENVIRONMENTS

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Background and Importance Closed system transfer devices (CSTD) were originally designed to protect operators from cytotoxic, mutagenic, and reprotoxic agents. There is increasing pressure to reduce cost burden by preserving drugs, especially in the field of oncology. One solution is drug vial optimisation, which can be accomplished by extending the

practical beyond use date of drug vials, through use of CSTDs.

Aim and Objectives This study aimed to test if the Chemfort™ CSTD can maintain microbiological integrity after 10 withdrawals from vials over a period of 28 days.

Material and Methods Tests were performed in both a controlled GMP Class A environment and an uncontrolled environment (350 vials in each environment). Environmental conditions were monitored by continuous air sampling. The rubber stoppers of all vials, containing tryptic soy broth (TSB) growth medium, were disinfected prior to mounting Chemfort™ Vial Adaptors (VAs) on the vials. The Chemfort™ Syringe Adaptor (SA) was attached to a 10 mL syringe and subsequently connected to the VA. The septa of both the VA and SA were disinfected prior to every connection. Ten 5 mL aliquots were withdrawn from each vial at 2-week intervals (days 0/3 syringes, 14/3 syringes, and 28/4 syringes), incubated for 7 days at 20–25°C and then 7 days at 30–35°C. After 28 days, the vial containing the remaining growth medium (50 mL) was also incubated for 7 days at 20–25°C and then 7 days at 30–35°C. Vials and syringes were inspected visually for signs of microbial growth during each incubation. Ten positive control containers were subjected to a growth promotion test.

Results No signs of microbial growth were observed in any of the 7,000 samples, nor in the growth medium remaining in the vials after transfers were performed in either an uncontrolled or controlled environment.

Conclusion and Relevance The data presented demonstrates the ability of the tested CSTD to maintain microbiological integrity and support the decision to extend the practical in-use shelf life of drug products for up to 28 days when used with Chemfort™ in either aseptic conditions or uncontrolled conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

3PC-006

CONTAINER CLOSURE INTEGRITY TESTING AND PROCESS VALIDATION OF CLOSED SYSTEM TRANSFER DEVICES FOR ASEPTIC RECONSTITUTION OF DRUG VIALS CONNECTED TO FLUID BAGS

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Background and Importance The closure integrity and process validation of closed system transfer devices (CSTD) should be assured before implementation in clinical settings. However, there are no gold standard methods for Container Closure Integrity Testing (CCIT) of CSTDs.

Aim and Objectives We aimed to investigate the closure integrity and validate the aseptic procedure of two types of CSTDs (Vial-Mate from Baxter, hereafter called CSTD A and Ecoflac Connect from B. Braun, hereafter called CSTD B) by using a combination of the dye ingress test and a media fill test.

Material and Methods The dye ingress test with methylene blue was used as CCIT for both CSTDs with ten samples of meropenem drug vials of three brands (n = 60). A media fill test was performed with both CSTDs (n = 300 per CSTD, 150 carried out in a safety cabinet and 150 under non-classified environmental conditions).

Results In all samples of both CSTDs methylene blue was absent after visual inspection and spectrophotometric analysis. The nutrient media of one sample with CSTD A, reconstituted in a safety cabinet, was contaminated whereas none of the CSTD B samples with reconstitution in a GMP grade A environment were contaminated. Under non-classified environmental conditions, one sample of CSTD A and two samples of CSTD B were contaminated.

Conclusion and Relevance In conclusion, both CSTDs connected to meropenem vials of three brands are in compliance with the closure integrity by using the dye ingress. The aseptic procedure of CSTB B was validated with the media fill test when reconstituted in a GMP grade A environment, but failed for CSTD A. The added value of CSTDs in a hospital (pharmacy) remains debatable without a clearly demonstrated closure integrity when bedside reconstitution is done. Hospital pharmacists are strongly advised to perform sufficient and adequate closure integrity tests with CSTDs before implementing them in clinical use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-008 SLOW ANAKINRA DESENSITISATION PROTOCOL DESIGN FOR DELAYED HYPERSENSIBILITY REACTION

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Background and Importance Anakinra, a recombinant human IL-1 receptor antagonist, is indicated in rheumatoid arthritis (RA) with a good safety profile, nonetheless its administration has been associated with a severe delayed injection-site reaction without a fully understood pathogenesis. To deal with that several desensitisation schemes have been published in the literature.

Aim and Objectives The aim is to describe the design of a slow desensitisation protocol (SDP) for subcutaneous (SC) anakinra for patients who have failed the rapid desensitisation scheme (RDP).

Material and Methods We introduce a 72 year-old patient diagnosed for RA and treated with SC anakinra after failing other treatment lines who presents severe injection-site reactions after 3 weeks of treatment. An attempt was made to desensitise quickly but it was not tolerated either. As there were no more lines of treatment available, it was decided, in collaboration with allergists, to design a SDP.

It was designed for 56 doses of increasing concentrations (until 100 mg dose). Lower dose was 0,1 mg and dose change was performed every 3-4 days. Solutions were elaborated in the Pharmacy Service. Starting from a mother solution (MS) of 100 mg anakinra in physiologic serum 0,9% (SF) to a final volume of 1mL (1:1 solution) two anakinra dilutions were

made: 1:10, 1:5. The MS was prepared from anakinra 100 mg/0,67 ml injection. The dilution 1:10 was made by taking 0,5 ml from the MS and SF until 10 ml (concentration 5 mg/ml). The dilution 1:5 was prepared by diluting 1 ml from 1:10 dilution until 5ml final volume with SF (concentration 1 mg/ml).

To prevent hypersensitivity reactions it was needed to add antihistamines during the SDP.

Results Although RDP was not well tolerated, the proposed scheme had satisfactory results. At first the lowest dose (0,1 mg) was not tolerated by the patient, so it was decided to add antihistamines during the process. If any dose could react, the dose change was done instead of 3 after 5-7 days. Actually, the patient has completed the doses until 50 mg without adverse reactions.

Conclusion and Relevance The SDP proposed by allergist in collaboration with hospital pharmacist has allowed the safe administration of anakinra, avoiding a loss of the last therapeutic line possible in a patient with RA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-009 CYCLOPHOSPHAMIDE SURFACE CONTAMINATION IN A ROBOTIC CHEMOTHERAPY COMPOUNDING PROCESS

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Background and Importance There is a wild consensus about the risks associated to the occupational exposure to hazardous drugs, but recent studies have shown that there is still surface contamination in pharmacies preparing antineoplastic drugs. The main reason for the implementation of robotic compounding systems is to improve safety; for the patient and for healthcare workers, avoiding repetitive strain injuries and hazardous drugs exposure.

Aim and Objectives The aim of this study was to evaluate cyclophosphamide exposure of pharmacy nurses during the robotic chemotherapy compounding process.

Material and Methods The sampling areas were selected after being identified as the highest risk of personal contamination in a risk assessment. Wipe samples were taken from vials, infusion bags, gloves, and different locations of the robotic system. Surface monitoring was performed using a semi-quantitative device based on thin layer immunochromatography. The sampling was performed at the end of the workday over several days before cleaning process to identify the highest potential degree of contamination to which healthcare workers could be exposed.

Results Cyclophosphamide compounding was performed during the study days and several months before. There was no cyclophosphamide spill in the three months prior to the study. External contamination was measured on 15 vials and 10 bags of cyclophosphamide and on 10 gloves and 5 robot areas after cyclophosphamide compounding during 5 non-consecutive days. There were not Cyclophosphamide contamination over the detection limit of 0.5ng/cm² in none of the samples

from the robot; vial, gloves and bags samples were also negative.

Conclusion and Relevance The robotic chemotherapy compounding enables cyclophosphamide preparation with low levels of personal exposure. Cyclophosphamide is a good standard for measuring hazardous drugs contamination because its preparation method, frequency of use and the availability of occupational exposure studies.

To our best knowledge, this is the first study in robotic hazardous drug contamination using a semi-quantitative method. Despite this technology does not allow precise quantification of the amount of HD present the use of semi-quantitative methods could facilitate its widespread determination due to a lower cost and immediacy of results, allowing the implementation of corrective measures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-010 FORMULATION OF TACROLIMUS SOLUTION FOR SUBLINGUAL USE

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Background and Importance Tacrolimus is an immunosuppressive agent used in solid organ transplantation (SOT) for prophylaxis of rejection. In our hospital SOT are performed including rare multivisceral transplantations (MTVx). There are clinical situations when oral tacrolimus can not be administered to the MTVx patient because of a non-functional bowel. In home care, patient could be treated with tacrolimus for sublingual use. There is no commercial product for sublingual administration available, so formulation has to be developed.

Tacrolimus is practically insoluble in water; however, suspension can be prepared using tacrolimus capsule powder content. This formulation is unstable with risk of sedimentation, therefore uniform dose can not be achieved. We used solubility of tacrolimus in ethanol and prepared the homogenous sublingual solution from substance.

Aim and Objectives To formulate solution of tacrolimus 10 mg/mL based on ethanol and glycerol. To describe the preparation, container, storage conditions and shelf-life of tacrolimus solution for sublingual use.

Material and Methods Tacrolimus belongs to hazardous drugs, H 361. Biological safe cabinet (BSC) is recommended for tacrolimus preparation.

Solution was prepared using the glass beaker and stick. Tacrolimus was dissolved in ethanol 96%, then glycerol 85% was slowly added. The citric acid was used to adjust pH 5-6, optimal for stability of tacrolimus. Orange flavour was added for higher palatability. The amber glass container with adapter for oral syringe was used.

Results Turbid and homogenous solution with orange scent and pH 6 was obtained. Concentration of tacrolimus was 10 mg/mL. Shelf-life of 30 days was given, stored in 15°C–25°C according to the USP <795>. Oral dosing syringe was used to apply the sublingual solution.

Conclusion and Relevance The formulation of tacrolimus was developed. Variety of concentrations of tacrolimus solution may be prepared. This allows us to prepare solution with

higher concentration with the same volume, if needed. Our MTVx patient had a good tolerance to this solution. He has taken this solution since November 2021 and has remained stable without rejection of transplanted stomach, liver and pancreas.

It is necessary to work fast, because of an air flow in BSC, the ethanol evaporates and the solution may precipitate. Clinical effectiveness might be investigated to confirm the utility of this formulation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-011 A VIRTUAL STERILISATION AREA: AN INTERACTIVE TRAINING TOOL

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Background and Importance The training of sterilisation technicians represents a major challenge to ensure the safety, security and limit the contamination of reusable medical devices.

Aim and Objectives The objective was to develop a tool to ensure basic and continuous training of sterilisation technicians, taking into account their professional backgrounds and skills.

The tool aims to contribute to the integration of newcomers and the standardisation of training, which currently is mainly done through mentoring.

Material and Methods A training booklet was developed, covering the different stages of the sterilisation process. It was used as a basis for the realisation of instructional videos, showing the entire sterilisation process.

The videos were then included in a virtual blueprint of the sterilisation area made with 3D mapping software.

Results The guide was written following the French Sterilisation Guidelines and the internal practices of the technicians. It was divided into 4 main parts, corresponding to the different steps of the sterilisation circuit, which are: individual outfitting of technicians, washing of the medical devices, assembly of the sterile boxes, and unloading systems for autoclaves.

These parts were illustrated by 4 videos, which were integrated into the different rooms of the 3D layout. A 3D layout was created with Kozikaza®, 3D mapping software, from the measured blueprint of the sterilisation area. It replicated the technicians' work environment as realistically as possible. To complete their virtual training, the agent decides either to follow the classic circuit or to choose one step specifically. Then, they click on the hyperlink in the virtual room which refers them to a video corresponding to the step of the circuit.

Conclusion and Relevance This interactive tool allows catering to different professional backgrounds, taking into account the technicians' preferences regarding training methods. It enables an improvement of the quality of the circuit, of sterilisation practices, and facilitates the training of sterilisation technicians. This training, systematically offered to employees upon their arrival and annually to the whole team, will be evaluated to identify their needs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-014 METAMORPHINE INSTEAD OF POLYSUBSTANCE USE?

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Background and Importance Opioid therapy is still not optimal. As PCA pumps with combinations of opioids and NSAR are produced in many hospital pharmacies to minimise the dose and the side effects of opioids, this polysubstance use is accompanied by incompatibility problems. Several admixtures with opioids and metamizole change their composition during administration time. In case of admixtures with morphine and metamizole, we could define and isolate the main reaction product ‘metamorphine’. Dependent on morphine concentration, storage temperature and storage time, PCA-pumps with admixtures of metamizole and morphine can contain 100% metamorphine instead of morphine.

Aim and Objectives As the stability problems did not result in a change of the prescribing routine, the pharmacology of this new substance was interesting, especially because the PCA pumps still had their analgesic potency and new adverse effects were never reported.

Material and Methods After permission of the Ethics Committee and informed consent, morphine and metamorphine were determined in serum samples of patients with regular morphine/metamizole PCA therapy.

Results Up to now, we have determined the morphine and metamorphine concentrations in serum of four patients treated with admixtures of morphine/metamizole. In three of them we could identify or quantify metamorphine beside morphine. In one patient’s serum we found 0,75 µg/mL metamorphine beside a morphine concentration of 0,16µg/mL. No loss of the analgesic effect and no change of adverse effects during PCA therapy of these patients was found.

Conclusion and Relevance Incompatibilities of polysubstance use in PCA pumps can also lead to other active substances than prescribed. Since patients do not notice a loss of the analgesic potency or change of side effects and the serum level of morphine decreased significantly, it is very likely that metamorphine has analgesic and/or spasmolytic potency and compared to morphine alone its effects to μ -, κ - and δ -opioid receptors may be different. The study is relevant to understand a successful, well-established therapy and leads possibly to a new optimised opioid therapy in future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-015 IN-USE STABILITY OF COMIRNATY AND SPIKEVAX CLINICAL SOLUTIONS: PFIZER-BIONTECH AND MODERNA COVID-19 VACCINES: A COMPARATIVE STUDY FROM A HOSPITAL PHARMACY PERSPECTIVE

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Background and Importance COVID-19 emerged as a novel infectious disease by late 2019, spreading very rapidly and being categorised as a pandemic by March 2020 by the WHO. Several vaccines have been authorised and administered worldwide, demonstrating efficacy and safety, being Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) the mostly administered globally. Although having demonstrated efficacy and safety, one of the major issues has been their stability, from which hardly any stability data is available in the public domain. Analysing the *in-use* stability of these novel vaccines is paramount for ensuring rationale use in hospitals.

Aim and Objectives This study is aimed at assessing and comparing the *in-use* stability of Comirnaty and Spikevax clinical solutions by characterising the particulate profile using Dynamic Light Scattering (DLS).

Material and Methods Expired and non-expired clinical solutions of the vaccines were subjected to different stress conditions: visible light and mechanical stresses. The Z average and the polydispersity index (PDI) of the vaccines clinical solutions were evaluated by DLS, using a Zetasizer Nano ZS-90 (Malvern, UK). For statistical analysis, a simple ANOVA followed by Dunnett’s post-hoc test, using GraphPad Prism 8 Software was used. Stressed samples were compared to control (non-stressed samples). Furthermore, differences were considered significant at a p-value < 0.05. The study was conducted in triplicate.

Results Comirnaty DLS parameters were mainly affected by mechanical agitation and vortex stresses. In this case, the Z-average and PDI increased significantly, even in the expired samples. On the other hand, the DLS parameters were maintained in Spikevax clinical samples regardless of the stress and the expiration date.

Conclusion and Relevance This study highlights the necessity of a careful preparation of these vaccines, given their demonstrated fragility upon gentle stress. However, Comirnaty has proven to be more fragile than Spikevax in their handling in real-use conditions. Previous literature commented on the stability of Comirnaty, having presented similar results. Nonetheless, no stability data were available on the *in-use* stability of Spikevax. Therefore, this data will be of interest to hospital pharmacists towards following vaccination campaigns.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-016 DOES A HOSPITAL COMPRESSOR SYSTEM CONTINUOUSLY DELIVER MEDICINAL AIR ACCORDING TO THE EUROPEAN PHARMACOPOEIA?

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Background and Importance Hospitals in Norway produce medicinal air for patient treatment. The medicinal air is produced by a compressor central and supplied by a pipeline system for patient treatment at the hospital. The quality of the medicinal air is controlled annually according to the European pharmacopoeia. The monograph for medicinal air in the European pharmacopoeia includes tests for O₂, CO, CO₂, SO₂, NO_x, oil and H₂O. Both ambient air composition and components in the compressor central have influence on the medicinal air quality. The time for periodic control may therefore affect the result. There are no publications presenting results from continuous monitoring of hospital produced medicinal air quality.

Aim and Objectives The aim of the study was to confirm that hospital produced medicinal air continuously is safe and in compliance with the European pharmacopoeia. Based on a risk assessment it was chosen to monitor O₂, CO and H₂O as indicators for air quality. Other test in the European pharmacopoeia was included in the periodic control.

Material and Methods The compressor central is situated in Oslo, about 500 metres from a main road. The components of the compressor central are compressor (*Atlas Copco ZR 75VSD*), pressure tank (*Maskinspecialisten, type B+F*), adsorption dryer (*Atlas Copco, BD185+*), carbon filter/hopcalite catalyst (*Atlas Copco, QDT HOC 185*) and filters (*Atlas Copco, PDP*). The air quality was monitored downstream the compressor central by detectors for O₂, CO and H₂O (Kimessa Monoline 504/404 and CS-instruments FA500). The period for monitoring was two weeks to include daily variations.

Results The results from the monitoring complies with the European pharmacopoeia at all times during the test period. Monitoring data: O₂20,4 – 21,4%, CO <5 ppm, and H₂O <67 ppm.

Conclusion and Relevance The monitoring data shows that a hospital compressor central is able to continuously deliver medicinal air according to the European pharmacopoeia, even with daily variations in the ambient air quality and compressor system. This is relevant information for pharmacist and technical staff when planning quality control strategies for a compressor central.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Technical staff at Oslo University Hospital

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3PC-017 IMPACT OF AGITATION ON PEMBROLIZUMAB (KEYTRUDA®) SAFETY AND EFFICACY: AGGREGATION AND FUNCTIONALITY

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Background and Importance Pembrolizumab (Keytruda®) is a human IgG4 monoclonal antibody (mAb) from the group of immunomodulators, which binds to programmed death receptor 1 (PD-1). Given its structural complexity, physical aggregation and chemical degradation can occur throughout its life, and even modest environmental stresses can cause extensive damage which may affect the safety and efficacy of the medicine.¹

Aim and Objectives To assess the impact of agitation on pembrolizumab (Keytruda®, 25 mg/mL) safety and efficacy through the study of aggregation and functionality when mishandling in real hospital conditions.

Material and Methods Pembrolizumab (Keytruda®, 25 mg/mL) fresh opened vials were used. Agitation stress was carried out in a mechanical laboratory shaker (300 rounds/min, 24h, 25°C) and gentle agitation was performed manually (1 min, 25°C). Aggregation was assessed by Dynamic Light Scattering (DLS) and Size-Exclusion Ultra-High-Performance Liquid Chromatography (SE/UHPLC-UV). Pembrolizumab functionality was evaluated by Enzyme-Linked Immunosorbent Assay (ELISA).

Results Pembrolizumab control sample (25 mg/mL) showed a single particulate population with hydrodynamic diameter (HD) of 9.5 ± 2.8 nm corresponding to pembrolizumab monomers. SE/UHPLC-UV chromatograms of the control sample revealed a main chromatographic peak assigned to pembrolizumab monomers and a small one assigned to native dimers. DLS and SE/UHPLC-UV showed that agitation stress did not promote increase in aggregation. However, pembrolizumab functionality was affected after applying agitation stress since ELISA revealed a significant loss of functionality. As a consequence, a gentle agitation of pembrolizumab was performed in order to investigate if this loss of functionality could also happen in less stressful conditions. As a result, ELISA also revealed a significant loss of functionality in gently agitated pembrolizumab.

Conclusion and Relevance The exposure to agitation stress did not induce aggregate formation in pembrolizumab. Nevertheless, both agitation stress and gentle agitation led to a loss of its functionality not related to agitation. Thus, we recommend preventing pembrolizumab from agitation when handling in hospitals.

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3PC-018 TIME TO AVAILABILITY OF INJECTABLE ANTICANCER DRUGS FOR OUTPATIENTS: REASSESSMENT IN A FRENCH COMPREHENSIVE CANCER CENTRE

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Background and Importance Excessive waiting time is one of the main causes of patient dissatisfaction in oncologic daily care unit (DCU). Lean management, dose banding, advanced prescription and automatised are usually used in our hospital to improve patient care pathway. In our adult DCU (>26 000 patients/years), patients have to wait for their treatment less than an hour.

Aim and Objectives The aim of this work is to reassess the time of availability in this DCU and to identify the factors influencing this time.

Material and Methods It is an ambispective monocentric study in which human factors (n=2), equipment factors (n=7), organisational factors (n=4), productivity factors (n=16) and time-related factors (n=6) were recorded randomly between September 2021 and April 2022 (i.e. 15 days studied). Data were also extracted from CHIMIO® software and from our institutional 'LEAN tool' for real-time monitoring of patients in oncologic DCU, in order to calculate time between the prescription of the day and the dispensation of the treatment.

Results The average number of patients and preparations manufactured per day were respectively 105 (+/-7) and 146 (+/-12); 52% of these preparations prepared the day before. The average number of preparations not prescribed in advance is 49 [18-62] (34%) for an average number of 31 patients [14-43] (30%). The average time to availability was 54 min (+/- 16) with a median of 60 min. On average, 12 [0-24] patients per day waited more than an hour after the prescription with a maximum waiting time of 360 min.

Four days (27%) were identified with an average dispensing time greater than 60 min. During these critical days, a percentage of anticipated preparations less than 50%, with a high number of prescriptions (>30 patients) and particularly before 9:45 a.m. or between 12:00 and 14:00 p.m. were observed. We noticed also a higher productivity ([174-214] preparations), the lack of coordination (2 of 4 days), or additional productions (analgesic syringe preparations).

Conclusion and Relevance Main impacting factors seem to be human factors and productivity. Time to availability became an essential quality indicator of our compounding anti-cancer unit. This study showed that our working procedures are efficient for a majority of patients, but not for all.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-022 FORMULATION AND QUALITY CONTROL OF A BISOPROLOL 0.5 MG/ML ORAL SOLUTION FOR PAEDIATRIC USE

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Background and Importance Bisoprolol is a beta blocker indicated for the treatment of heart failure in paediatric patients. There are no licensed bisoprolol containing paediatric dosage forms available in the EU. Pharmacy preparation of patient individually dosed bisoprolol capsules is common practice by using licensed bisoprolol tablets as starting material. However, the preparation and use of bisoprolol oral liquids are the gold

standard for paediatric patients because they allow body weight oriented dosing for different age groups. So far, there is no published information regarding the formulation, quality control, and stability of pharmacy-prepared bisoprolol oral solutions.

Aim and Objectives The aim of this project was to formulate a bisoprolol fumarate 0.5 mg/mL oral solution for paediatric use, establish suitable quality-control measures, and to perform stability tests.

Material and Methods Bisoprolol oral solution was formulated in analogy to propranolol hydrochloride oral solution described in Neues Rezeptur-Formularium 2015/1, Germany. Efficacy of antimicrobial preservation was tested regarding to Ph. Eur. 5.3.1 by an external lab. A stability indicating RP-HPLC method was established and validated based on the known method of Joshi et al.¹

Results 100 mL bisoprolol fumarate 0.5 mg/mL oral solution contain bisoprolol fumarate 0.05 g as active ingredient as well as potassium sorbate 0.15 g, anhydrous citric acid 0.07 g, sucrose 25 g, raspberry flavour 0.1 g, and purified water 84.33 g as excipients. Antimicrobial preservation regarding Ph. Eur. 5.3.1 was demonstrated. After a 6 months period the bisoprolol concentration amounted to 103% ± 1% of the initial concentration and the pH remained unchanged (4.6).

Conclusion and Relevance Sweetened and flavoured bisoprolol fumarate oral solution was successfully developed as pharmacy preparation suitable for preparation in stock. Adequate in-use preservation is given and stability is proven for at least 6 months. A second version of bisoprolol oral solution without sucrose and raspberry flavour is under development.

REFERENCE

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Conflict of Interest No conflict of interest.

3PC-023 PATCH TESTS WITH ETHAMBUTOL 10%, ISONIAZID 15% AND PYRAZINAMIDE 25%: A CASE REPORT

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Background and Importance A 55 year old male patient, developed a DRESS (drug rash with eosinophilia and systemic symptoms) reaction after starting first-line tuberculosis treatment with rifampicine, ethambutol, isoniazid and pyrazinamide. To assess the responsibility of a suspected drug in a DRESS reaction and posterior safe reintroduction of therapy, patch tests (PT) are the most useful tool. For the purpose, the Hospital Pharmacy was asked to develop magistral preparations of ethambutol, isoniazid and pyrazinamide. The PT were performed with each tuberculostatic drug diluted in 4 IQ Ultra Chambers, applied on the patient's skin at the back and kept in occlusion for 48 hours. The readings were performed at day 2 and day 3. Only erythema, infiltration, papules or vesicles were considered positive reactions.

Aim and Objectives Development and validation of magistral formulas for topical application to accomplish patch tests of

ethambutol 10% (w/w), isoniazid 15% (w/w) and pyrazinamide 25% (w/w).

Material and Methods

Scarce bibliographic information Review article published by the French Society of Dermatology, in which the concentrations of the active ingredient to be used in each PT are established.

Application of the general rules of Good Handling Practices, according to the Portuguese Galenic Formulary.

Results The pastes used in the PT were obtained by geometric dilution of pulverised ethambutol 400 mg, isoniazid 300 mg and pyrazinamide 500 mg tablets in white petrolatum.

After quality-control tests that includes colour, homogeneity and mass verification assays, the pastes were placed in a syringe for an easier application in the skin. It was given 30 days of stability at room temperature.

Conclusion and Relevance This preparation made possible to develop PT for the study of a delayed hypersensitivity reaction to tuberculostatic drugs, that was not available before in the market, allowing a safer reintroduction of the treatment.

Although the PTs were negative in this patient, it was possible to develop and validate three compounding formulas with an adequate safety profile and low cost. This accomplishment will be useful in further cases.

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2. Portuguese Galenic Formulary 2001

Conflict of Interest No conflict of interest

3PC-026 EFFECTIVENESS AND SAFETY OF INSULIN 1UI/ML EYE DROPS

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Background and Importance Epithelial corneal defects are damaged areas of the corneal epithelium as a consequence of injury. The existence of insulin and insulin-like growth factor receptors in cornea keratocytes and epithelial cells could explain the increment on the corneal epithelial healing rates. Clinical experience with insulin eye drops is limited and more evidence in both diabetic and non-diabetic patients is still needed.

Recently, the insulin eye drops formulation 1 IU/mL has been prepared in Pharmacy Hospital for patients with keratitis, dry eye and a persistent epithelial corneal defect (PECD).

Aim and Objectives The aim is to describe effectiveness and tolerance of insulin 1 IU/mL eye drops treatment for different refractory corneal diseases.

Material and Methods Retrospective observational study in a tertiary hospital. 21 patients were included, treated with insulin eye drops during the period between February 2022–September 2022. The variables collected were: demographics, indication, duration of treatment, clinical response and adverse effects. All data were obtained from the electronic medical history.

Results 21 patients were treated with insulin eye drops 1 UI/mL, six of them with diabetes mellitus and other 15 were non-diabetic. Administration frequency was 4 times in a day (QID). They presented different corneal diseases that were refractory to conventional treatment. The median age was 74 (43-89) years. A total of 52.4% were women. 38.1% were diagnosed with non-herpetic keratitis, 19% with herpetic keratitis, 23.8% with corneal erosion, and 19% with persistent epithelial corneal defect (PECD). The median duration of treatment was 6 months (2-9 months). 100% of patients responded to treatment and continued with insulin eye drops after epithelial healing. All patients presented epithelial healing in about 30-60 days, most of them referred improved of symptoms during first two weeks.

No significant adverse effects were reported. None hypersensitivity reaction were reported because of m-cresol presence in insulin eye drops.

Conclusion and Relevance The insulin eye drops formulation 1 IU/mL administered QID can be a quick, effective, and safe option for different corneal diseases refractory to the usual treatments in both diabetic and non-diabetic patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-028 FORMULATION OF AN ORAL PLATELET LYSATE GEL TO TREAT CHRONIC GRAFT VERSUS HOST DISEASE ASSOCIATED ORAL MUCOSITIS: EFFECTIVENESS IN A SERIES OF CASES

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10.1136/ejpharm-2023-eahp.45

Background and Importance Chronic graft versus host disease (cGVHD) associated oral mucositis is a complication after stem-cell transplantation. Corticosteroids are the standard treatment, but there is no consensus in case of refractory lesions. Platelet concentrates may be a safe treatment option.

Aim and Objectives Design a sterile oral formulation able to release platelet lysate (PL) on oral cavity, and evaluate its effectiveness in a series of cases.

Material and Methods PL gel 25% was compounded by mixing in aseptic conditions 1:1 carboxymethyl cellulose sodium base 5% previously autoclaved with PL also diluted 1:1 with sodium chloride 0.9%. PL gel was packaged in 3mL aliquots using oral syringes, which were stored in the freezer until their use. Galenic validation was performed.

Patients with cGVHD associated oral mucositis from November 2021 to August 2022 who accepted to initiate oral PL gel were monitored. Effectiveness was evaluated based on severity of the oral mucositis (NCI-CTCAE Grade 1-4). Patient satisfaction was self-assessed in a visual scale 0-10 according to the degree of pain/discomfort. Adherence was assumed based on the number of syringes dispensed.

Results PL gel obtained was slightly yellow, translucent, pH=6, with medium consistency that leads adequate bioadhesive characteristics. No changes of pH, colour, weight, or microbial growth were observed during galenic validations. A beyond-use date of 45 days at -20°C was given.

Six patients with moderate oral mucositis (grade 3) who failed to first-line topical steroids therapy started PL gel. Two

of six discontinued after one month because their lifestyle prevented them from preserving the gel properly. Four patients (three men, one woman) went on with the gel for an average of 5 months (range 3-9). Clinical evaluation showed an improvement of 1 degree in oral mucositis in three patients and 2 degrees in the patient with the longest treatment (9 months). The self-assessment scale showed an average decrease of pain/discomfort of 2 points. Estimated adherence in patients who received the treatment for more than one month was 80.8% (95% CI: 56.8-104.9).

Conclusion and Relevance The formulation of a gel based on sodium carboxymethyl cellulose was adequate to administer PL on the oral cavity. Four patients with cGVHD associated oral mucositis refractory to standard treatment were successfully treated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-029 MANAGEMENT OF A CHEMOTHERAPY PRODUCTION AFTER A CYBER-ATTACK IN A PUBLIC HOSPITAL

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Background and Importance In August 2022, our hospital was victim of a massive cyber-attack. Every software, network and connected items were unusable including CHIMIO® which manages production of chemotherapy from prescription to administration. Our Chemotherapy Production Unit (CPU) usually produces about 19,000 sterile preparations a year.

Aim and Objectives The objective was to pursue the production of chemotherapy respecting in maximum the usual production and quality process.

Material and Methods The first 3 days prescriptions were already validated and printed at the pharmacy, serving as: patient history, prescription and protocol model. A molecule data register was created on Excel® listing cytotoxic drugs data (stability, concentration...). First, Manufacturing Sheets (MS) were totally handwritten then an Excel® MS was developed, mimicking CHIMIO®. At first, a single model using copy-paste for labels was developed. Then, several models for bags, syringes or infusers were created, using formulas to automatically fill the labels, to secure and speed up the process. A scheduler traced all preparations by a unique number. Finally, a patient's history register was created with data needed for pharmaceutical validation. A second pharmacist double-checked every MS.

Results 437 preparations were made in degraded mode during 6 days (73/day). Only 5% of the production was outsourced in other hospitals. The first 5 MS were handwritten. Printing every MS with the first version of Excel® MS took about 3h/day. Then, improving Excel MS reduced edition and double-checking time to about 1h/day. Double-checking MS detected most of editing errors. During final checking of preparations, 3 errors (<1%) were detected. Two majors with wrong patient's name and dose (-47%) and one minor with wrong scheduler number. The recovery of CHIMIO® database was effective after 6 days. Transcription in CHIMIO® found only one undetected prescription error.

Conclusion and Relevance Development of a semi-automated Excel® tool and double control of MS has allowed us to

maintain a safe and almost normal production. Excel® tool tracing patients history permits to detect prescriptions errors (dose adjustment, intervals of administration, protocols respect). Regular backups and development of a degraded mode protocol will be undertaken soon.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-031 A DELPHI METHOD TO STANDARDISE THE PREPARATION OF AUTOLOGOUS SERUM EYE DROPS?

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Background and Importance Dry eye disease is a frequent cause of ophthalmology consultation (5%–34% of population worldwide). Severe forms, refractory to conventional treatments (artificial tears, topical corticosteroids, cyclosporine A, contact lenses, punctal occlusion, systemic diseases appropriate management), are responsible for a significant visual impairment and disability. Autologous serum eye drops (ASEDs) are then proven to be an interesting therapeutic alternative. First, in March 2019 we carried out a national inventory of ASED preparations practice that highlights: low supply (13 producer centres) and production heterogeneity.

Aim and Objectives

General objective to improve ASEDs quality, safety and supply in our country care institutions.

Specific objectives to define the consensual items, in order to establish a national standardised preparation protocol.

Material and Methods

Method for consensus reaching Delphi method. Four protocol parts aborbed: sampling, preparation, controls, conservation. Expert panel recruited by remobilising centres approached in 2019 (ASEDs producers, non-producers, or did not respond). Local steering group: pharmacy resident, head of compounding unit, pharmacy methodologist. Circuit: questionnaire construction, mailing with link access to Google Forms®, response analyses, consensus rate calculation (consensus when $\geq 80\%$), result synthesis, anonymous referral to experts. As many rounds as necessary to achieve consensus.

Results

Twelve answering experts After 4 rounds: out of 39 proposals initially submitted, 26 validated and 10, abandoned. In sampling: 15 items validated, 5 dropped. Preparation: 5 validated, 1 dropped. Control: 3 validated, 4 dropped. Conservation: 3 validated. Four rounds took 86 days.

Conclusion and Relevance A standardised protocol ASEDs preparation will be proposed. This could improve the supply of care across the country. Method strengths: Expert opinion solicited on the initial questionnaire; qualified experts on the topic; no geographical limitations; anonymity avoiding opinion leader influence; applicability criteria. Limitations: no ophthalmologists, biologists, patients in the panel; no participation of the largest eye drop producer (despite requests).

A clear definition of this eye drop status (pharmaceutical preparation or not) is also necessary.

Biochemical quality controls, abandoned, to be resubmitted (molecules supposed to support ASEDs efficacy). Supplementary round necessary to decide the fate of the last item (solution volume in each eye drop bottle).

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Acknowledgements to all colleagues participating to 2019 study or/and Delphi method.

Conflict of Interest No conflict of interest

3PC-035 GALENIC DEVELOPMENT OF A GENERIC SPECIALTY WITH CONVENTIONAL RELEASE BASED ON ACARBOSE

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Background and Importance In the case of the development of a generic drug, the approach is based almost exclusively on galenic and analytical developments. However, to facilitate formulation, it is still necessary to go through a pre-formulation stage. Therefore, a generic drug must meet the same quality, safety and efficacy requirements as the originator drug.

Aim and Objectives The objective of our work consists on a pre-formulation stage followed by a formulation stage in order to arrive at an optimal, stable and effective galenic formula and to develop a generic oral anti-diabetic drug based on acarbose 50 mg.

Material and Methods During the development of this generic specialty, a preliminary study of the raw materials was conducted (physico-chemical characteristics, rheological properties and compatibility study) in order to determine the quantitative formula and the manufacturing process. Then, 6 formulas were prepared in order to improve the flow time. The tablets obtained were tested for uniformity of mass, hardness, friability, disintegration time and dissolution in vitro. Subsequently, a comparative study of the dissolution profiles obtained with that of the reference drug was made by calculating the difference factor f_2 and similarity f_1 in order to determine the best formula.

Results The method for the determination of the active substance by HPLC has been validated. The raw material has been well studied and the choice of excipients and the method of manufacture have been justified. Formula F5 having a friability percentage equal to 0,16%, a disintegration time (5,9 min) and a dissolution profile similar to that of the reference specialty ($f_1 < 15\%$ and $f_2 > 50\%$) was selected. It was considered the closest to the princeps.

Conclusion and Relevance The generic specialty formulated presented an equivalence in terms of in vitro dissolution with the reference specialty. Thus, comparative studies in 3 different pH environments need to be completed to judge this in vitro equivalence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. No conflict of interest.

Conflict of Interest No conflict of interest

3PC-036 CENTRALISED AND PERSONALISED PREPARATION OF INTRAVENOUS KETAMINE FOR PATIENTS WITH RESISTANT DEPRESSION

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Background and Importance Depression is the third leading cause of disability in the world and about 1/3 of depressive disorders have resistance to successive treatments.

Intravenous infusion of off-label ketamine in subanaesthetic doses has favourable therapeutic responses in a relatively short evaluation time. Accumulated safety evidence is considered an added value in the therapeutic arsenal to treat this pathology.

Safety issues of the use of central anaesthetics without the support of anaesthesiology are a pivotal drive for implementing a clinical protocol that includes the pharmacy. The use of fixed dilutions and rhythms of administration as well as personalised centralised preparation in the pharmacy overcomes most concerns about the regular and safe use of this approach on resistant depression.

Aim and Objectives Evaluate the implemented circuit, characterisation of the population and analysis of the impact on the effectiveness and safety of ketamine in resistant depression.

Material and Methods A 19-month retrospective analysis was made on the use of ketamine in patients with resistant depression. The pharmaceutical services database and the Soarian Clinicals® programme were used to collect information and to consult the electronic clinical process of patients that used this therapeutic approach.

Results Indication for ketamine treatment, in addition to the absence of contraindications, means that the patient is not responsive to at least three antidepressants SNRIs and a tricyclic, a potentiation strategies and a score ≥ 9 in the *Patient Health Questionnaire-9 (PHQ-9)*.

The data collected correspond to the period between 01/2021 and 07/2022 and are summarised in table 1.

Abstract 3PC-036 Table 1

| | | |
|-------------------------------|---------|---------|
| Total of patients | | 9 |
| Sex F (%) | | 77.8 |
| Average age | | 45 |
| Total number of preparations | | 118 |
| Number of sessions (median) | | 12 |
| Average dose (mg/kg) | Total | 0.51 |
| | Initial | 0.27 |
| | Final | 0.66 |
| Average duration of treatment | | 58 days |

All cases reported psychopathological improvement recognised by themselves as well as by assistant psychiatrists.

Conclusion and Relevance Ketamine has shown to be a safe alternative provided that local strategies are created to ensure the implementation of criteria in patient selection, preparation, administration, and follow-up protocols. The acceptance and short-term recognition of the benefit of the treatment by patients and professionals allow for achieving the goal of clinical discharge.

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Conflict of Interest No conflict of interest

3PC-037 LIQUID CHROMATOGRAPHY MASS SPECTROMETRY ANALYSIS OF DOXORUBICIN AND EPIRUBICIN AFTER FREEZING

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Background and Importance The chemical-physical stability, reported among the technical characteristics of the drugs, indicates the parameters to be respected for the safety use of the preparations but often the conditions of storage of the drugs can undergo significant variations. The stability data reported by the manufacturers are often limited while in clinical practice it is necessary to extend the conditions of use and the validity times of the preparations. In reality, it may happen that drugs are transported, stored and used in temperature conditions other than those indicated by the manufacturer without, however, having sufficient data on safety and stability for use outside the certified conditions.

Aim and Objectives The objective of the analysis performed is to evaluate the chemical and physical stability of doxorubicin and epirubicin after being stored in the freezer.

Material and Methods The formulations of doxorubicin and epirubicin stored in the freezer for a period of time exceeding 48h were analysed. The drug solutions were thawed at room temperature and stored in the refrigerator until the time of the chemical-physical analysis. For analysis 10 microliters were subsequently diluted from each vial and injected into LC QTOF MS(n=4).

Results Data obtained from the analysis carried out with a mass chromatographic technique highlighted the chemical and physical stability of the drugs analysed. The measured concentration of doxorubicin for the overrange sample was 1.995 ± 0.005 mg/ml while for the external doxorubicin standard was 1.996 ± 0.008 mg/ml. Some trend was observed for epirubicin, 2.009 ± 0.007 mg/ml versus 2.005 ± 0.005 mg/ml for the overrange sample.

Conclusion and Relevance The analysis showed the chemical-physical stability of the compounds studied allowing their use even outside the storage conditions indicated in the technical data sheet. The results showed that there were no statistically significant differences in the concentration of over range doxorubicin and epirubicin samples even after accidental freezing. This consists in a reduction of drug waste in real conditions. An easy access to mass spectrometry analytical platform may allow the evaluation of drug stability, redefining the chemical-physical stability with certified data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

Section 4: Clinical pharmacy services

4CPS-002 EFFECTIVENESS AND SAFETY OF MONOCLONAL ANTIBODIES FOR MIGRAINE PREVENTION AFTER TWO AND A HALF YEARS OF CLINICAL EXPERIENCE

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Background and Importance Erenumab, galcanezumab and fremanezumab were approved in 2019 for migraine crisis prevention. Efficacy and safety were demonstrated in three-months lasting clinical trials. At present, long-term effectiveness and safety can be analysed.

Aim and Objectives To evaluate the effectiveness and safety of monoclonal antibodies (mAb) utilised in migraine after two-and-a-half years of clinical use.

Material and Methods Prospective, observational study conducted in a tertiary hospital (December 2019 to June 2022). Data were obtained from patients' medical records (approved by our Ethics Committee).

Effectiveness and tolerance are evaluated 3 months after initiation and if it is effective and well tolerated it is maintained up to 12 months. Response is defined as a decrease in headache and/or migraine days per month $\geq 50\%$ compared to baseline and/or a significant improvement in quality of life (measured by HIT-6 and MIDAS scales). If partial response (PR) (decrease $\leq 50\%$) or adverse effects (AE) another mAb can be employed with different mechanism of action. If lack of response (LR) (decrease $\leq 25\%$) treatment is suspended. If response is achieved during the last months, the mAb can be maintained for another year.

Results 253 patients initiated treatment with a mAb. 69% (n:175) completed 12 months of treatment with effectiveness (responders) and 31% (n:78) stopped at third-month evaluation (PR/LR patients and AE-suffering patients), 42 of which changed to a second mAb. Ending reasons were: PR/LR (n:52), PR/LR and AE (n:9), AE (n:8) and others not related to the treatment (n:9).

After completing 12 months, 140 patients stopped the treatment; 25 maintained it for another treatment course, some of which have already started a third course (median duration: 23 [17-37]), and 10 switched to a second mAb.

Regarding safety, 33% (n:83) of patients reported at least one AE during the treatment with the first and/or second mAb, being the reason for discontinuation in 7% (n:17) of patients (due to vertigo and constipation, mainly). Most frequent AE were vertigo/dizziness (17%, n:45), constipation (13%, n:33) and skin rashes after injection (4%, n:11).

Conclusion and Relevance Anti-CGRP mAb are effective and safe treatments that improve migraine suffering patients' quality of life. A significant percentage of patients completes the treatment course and only 7% of patients discontinues the mAb due to intolerance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-003 EXPERIENCES WITH A BEST POSSIBLE MEDICATION HISTORY (BPMH) CONDUCTED BY PHARMACY STUDENTS IN THE HOSPITAL SETTING: A SCOPING REVIEW

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Background and Importance Improvement of patient safety at transition of care points is a key strategic aim of the 3rd WHO Global Patient Safety Challenge.¹ Medication reconciliation on admission into hospital increases patient safety by reducing medication errors and adverse events and has been shown to reduce hospital readmissions.² Collection of an

accurate best possible medication history (BPMH) is the first step. This is often resource intensive. Final year pharmacy students are now being assigned to obtain BPMHs, as a cost-effective alternative.

Aim and Objectives The aim of this scoping review was to determine the experiences with a best possible medication history (BPMH) conducted by pharmacy students in the hospital setting.

Material and Methods A scoping review was conducted involving PubMed, PubPharm, LIVIVO and Web of Science (2010-2021) including original studies and systematic reviews and their reference lists. Only papers investigating pharmacy students BPMH compared to other healthcare professionals in hospital practice were included. Two independent reviewers screened titles, abstracts and full text articles and completed data extraction with discrepancies being verified by a third. Data charting was used to identify variables corresponding to the research question. Reporting was completed in accordance with PRISMA-ScR.

Results Out of 235 papers, 18 papers met the inclusion criteria. Australia (n=1); Canada (n=1) and the USA (n=16) included a total of 7293 patients. Pharmacy students use more information resources (77,6%; n=972) compared to pharmacy technicians (58,4%; n=743); identified more prescription/non-prescriptions drugs (n=10,2) compared to nurses (n=6,8) and medics (n=7,1); make fewer mistakes identifying allergies/intolerances (n=6) compared to nurses (n=27) and reduced the 30-day re-admission rate (0,6%).

Conclusion and Relevance Pharmacy students are able to effectively contribute to patient safety by carrying out very detailed best possible medication histories, offering an economical alternative to technicians, nurses, pharmacists and medical healthcare professionals. In addition to the benefits to the healthcare system this offers additional opportunities for education/interdisciplinary training between pharmacy and medical/nursing students.

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Conflict of Interest No conflict of interest

4CPS-004 TRENDS IN TREATMENTS DURING COVID-19 PANDEMIC IN A UNIVERSITY TERTIARY HOSPITAL

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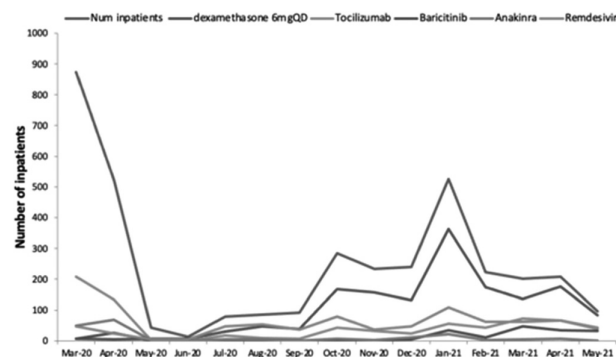
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Background and Importance Pharmacotherapeutic management of SARS-CoV-2 infection from the beginning of COVID-19 pandemic to now has evolved in accordance with research and clinical experience, improving treatments and thus clinical outcomes.

Aim and Objectives Our aim is to analyse the changes in the epidemiology and prevalence of use of the different treatments used against COVID-19 and its clinical outcomes throughout the pandemic (from March 2020 to May 2021) in a retrospective unicentre study. We present the data of a university tertiary hospital.

Material and Methods We identified all COVID-19 patients admitted to our hospital >48h through the electronic medical records (SAP Medication®). We evaluated demographic data (age and sex), clinical features (number of admissions/month in ICU or regular wards, mean length of stay and deaths including those <48h) as well as monthly drug consumption of remdesivir, hydroxychloroquine, lopinavir/ritonavir, beta-interferon, tocilizumab, baricitinib, anakinra, corticoids (dexamethasone 6 mg/day and >20 mg/day, methylprednisolone >40 mg/day, prednisone >30 mg/day, hydrocortisone>100 mg/day) and antibiotics.

Results A total of 4406 patients with SARS-CoV-2 infection were admitted of which 3723 met the inclusion criteria. The median age was 66 years, with higher percentage of men (59%). The number of patients admitted to ICU, semi critical care or a regular ward was, respectively 20%, 5,3% and 74,7%. The percentage of deaths after the large peak of mortality (15,2%) in March progressively decreased to 7,7% in the first trimester 2021. The median length of stay for ICU/semi critical care or regular care was 26,2 and 8,7 days. Trends in monthly use of the most frequent drugs are shown in the figure below. More than 80% of inpatients took lopinavir/ritonavir and hydroxychloroquine at the beginning, but consumption was drastically reduced after. The use of beta interferon was anecdotal after first months. The most used antimicrobials were ceftriaxone (45,5%) and azithromycin (34,9%), followed by levofloxacin (8,9%), amoxicillin/clavulanate (7,1%) and ceftaroline (6,0%).



Abstract 4CPS-004 Figure 1

Conclusion and Relevance The use of drugs during the pandemic of COVID-19 has shown a clear evolution over months towards more standardised treatments, with remdesivir as antiviral and dexamethasone, tocilizumab and baricitinib standing out as anti-inflammatory drugs in our centre. Homogenisation and standardisation of COVID-19 treatments have been managed as a reflection of the scientific evidence accumulated throughout the pandemic.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-005 **SUCCESSFUL TREATMENT OF OSTEOMYELITIS CAUSED BY DIFFICULT-TO-TREAT RESISTANT PSEUDOMONAS AERUGINOSA WITH CEFIDEROCOL AS MONOTHERAPY: A CASE REPORT**

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Background and Importance Cefiderocol is a new siderophore cephalosporin which effectively penetrates the outer cell membrane of gram-negative bacteria. Although several studies have demonstrated the efficacy of cefiderocol in the treatment of severe infections caused by multidrug-resistant gram-negative bacilli, current information on efficacy in osteoarticular infection is scarce.

Aim and Objectives We aimed to report a case of difficult-to-treat resistant *Pseudomonas aeruginosa* osteomyelitis successfully treated with cefiderocol for 6 weeks.

Material and Methods This is a 64-year-old diabetic male patient who developed a *P. aeruginosa* osteomyelitis secondary to a surgical wound infection following a supracondylar amputation. It was treated with multiple surgical debridement and several antibiotic series (ciprofloxacin, piperacillin/tazobactam and meropenem). Despite this, cultures from surgical site continued to grow *P. aeruginosa* which became multidrug-resistant, (only it was susceptible to colistin, aminoglycosides, ceftolozane/tazobactam and cefiderocol). Ceftolozane/tazobactam distribution was temporarily stopped at this time and amputation of the lower limb was believed to be the only option remaining.

The patient was treated with cefiderocol as a monotherapy for 6 weeks (June-August 2021) at a tertiary hospital, at a dose of 2 g every 8 hours administered in a 3-hour infusion. In addition, four surgical debridements were performed during this time.

Results After 3 weeks of therapy with cefiderocol, the wound swab cultures were negative. The patient remained afebrile during and at the end of the antibiotic therapy. No drug-related adverse effects or infusion reactions were reported. There was no leukopenia, leucocytosis, or worsening renal function. The inflammatory marker values decreased until they normalised and the magnetic resonance improved considerably after 6 weeks of treatment.

Two-control magnetic resonance and blood tests were performed, at week 15 and 45. They showed no evidence of persistent or recurrent infection and no elevations of acute phase reactants. Furthermore, the patient was febrile, asymptomatic and pain-free.

Conclusion and Relevance This case adds more experience to the scarce literature on the use of cefiderocol in *P. aeruginosa* osteomyelitis.

Its success in the treatment of osteomyelitis suggests that this drug penetrates well in bone tissue and could be a good therapeutic option, in conjunction with surgical debridement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-006 **COMPLETE CLINICAL RESPONSE IN METASTATIC BREAST CANCER AFTER FRONT-LINE TREATMENT WITH RIBOCICLIB/TAMOXIFEN**

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Background and Importance Endocrine therapy with ovarian suppression or ablation is the standard first-line treatment for perimenopausal or premenopausal women with hormone receptor (HR) positive, HER2-negative, advanced breast cancer; however, endocrine therapy resistance and disease progression occur in most cases. Ribociclib is a selective, small molecule inhibitor of cyclin dependent kinases (CDKs) 4 and 6 has showed that alongside endocrine therapy can improve progression-free survival and achieve higher proportions of overall responses than endocrine therapy alone in premenopausal women with HR-positive, HER2-negative, advanced breast cancer.

Aim and Objectives We present the case of a woman patient diagnosed with stage-IV HR+/HER2- breast cancer (Ki67-25%) who achieved complete response to first-line ribociclib treatment.

Material and Methods This was an observational retrospective study of the use of ribociclib in a 60-year-woman diagnosed with HR+/HER2- metastatic breast cancer. Data were obtained of the electronic medical records.

Results The premenopausal 54-aged patient was diagnosed with HR+/HER2- (Ki67-10%) localised infiltrating ductal carcinoma of left breast (1.5cm-size tumour) in July/2015. She underwent tumorectomy and received adjuvant radiotherapy and five-year tamoxifen 20 mg treatment. In March 2021, she suffered from loss of strength of left upper limb. CT-scan revealed a mass in the left axillary region between pectoral region and first rib and hypermetabolic bone lesions in the trochanter of the left femur, compatible with bone metastases. HR+/HER2- breast cancer was confirmed by tumour biopsy. Ki67 expression was 25%. In June/2021, this premenopausal 60-year woman was treated with 3-monthly 10.8 mg goserelin, daily 20 mg tamoxifen and ribociclib 600 mg once daily for 21 consecutive days followed by 7 days off treatment, resulting in a complete cycle of 28 days. In September 2021, she achieved complete metabolic response of the lesions described in the axilla and bone, without current foci of neoplastic disease. In June 2022, the last CT-scan revealed absence of neoplastic disease, therefore, she continues with the same treatment without dose modifications or delays. Side effects: treatment was well tolerated; she underwent grade I haematological toxicity.

Conclusion and Relevance This case report documents an exceptional tumour response of a fast growing, locally advanced, bone metastatic HR+/HER2- de novo breast cancer treated by ribociclib/tamoxifen/goserelin combination therapy. Treatment success is long lasting with few side effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-007 TARGETING PATIENTS WITH PNEUMONIA BY COVID-19 THAT COULD BE BENEFICIATED BY COLCHICINE

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Background and Importance Available data reported different results about the effect of colchicine in patients with COVID-19 pneumonia (CN) proving the need for more analysis. Currently, many of these patients are treated with high-cost new drugs with poor results.

Aim and Objectives To evaluate whether treatment with colchicine added to the standard therapy for CN was related to deaths reduction. Secondary objectives: to analyse differences in length of stay (LOS) and combination of drugs in treatment protocols with better results.

Material and Methods Multicentre, real-world, controlled, retrospective cohort study (March-June 2020). Inclusion criteria: hospitalised adult patients with CN. Admitted to critical care units were excluded. Experimental group: Patients treated with colchicine who met inclusion criteria (colchicine therapy group [CG]). Control group: those who met inclusion criteria and did not received colchicine (non-colchicine therapy group [NCG]). Patients were matched 1:1 by age (\pm 2years), sex, severity of the disease and comorbidity. To select controls, we chose the consecutively next admitted patient after one treated with colchicine. This allowed us to select control subjects at a close time and place to cases, that is, under similar circumstances in terms of patient care protocols.

Results 222 (111 treated with colchicine) patients were analysed. Median age 79 years [66–88] (81 years [66–87] in CG vs 79 years [66–88] in NCG, $p=0.978$). 52.3% men (54.1% CG vs 50.5% NCG; $p=0.591$). Primary endpoint of death occurred in 19 (17.1%) patients in the CG as compared with 32 (29.4%) in the NCG (OR: 0.497; 95% CI: 0.261–0.946; $p=0.031$). Hospital LOS was dichotomised by the median value (10 days), the use of colchicine was associated with a longer hospital LOS when comparing with the control group (OR=1.856; 95% CI:1.089–3.162; $p=0.022$). Proportion of deaths were higher in NCG than in CG in patients ≥ 70 years ($p=0.012$). With respect to sex and comorbidity, distribution of deaths showed no significant differences. Almost all patients received antimicrobials (91.9%) concomitantly, death rate: 19/50 (38%) CG vs.31/50 (62%) NCG; $p=0.023$), by antimicrobial: azithromycin (9/19) (47.4%) in CG vs.10/19 (52.6%) NCG; $p=0.517$; ceftriaxone 16/44 (36.4%) CG vs 28/44 (63.6%) NCG; $p=0.022$ and levofloxacin 4/12 (33.3%) CG vs 8/12 (66.7%) NCG; $p=0.232$.

Conclusion and Relevance Our study showed lower mortality in hospitalised patients who received colchicine to treat CN. This treatment was particularly beneficial for elderly treated with antibiotics concomitantly. Findings in our study support the need of more randomised clinical trials that could fully elucidate the type of patients who may potentially benefit from this low-cost drug.

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Conflict of Interest No conflict of interest

4CPS-008 DOES COMORBIDITY AFFECT ADHERENCE TO INHALERS IN SEVERE ASTHMA PATIENTS TREATED WITH BIOLOGICS?

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Background and Importance Comorbidities are often associated with severe asthma including those patients treated with biologics. That often contributes to poorly controlled asthma¹, which could be related to deficient adherence to inhalers.

Aim and Objectives To evaluate proportion of non-adherence to inhalers in patients with severe asthma (SA) treated with biologics according to their comorbidity and to compare two methods to assess non-adherence.

Material and Methods Cross-sectional retrospective observational study of patients with SA recruited from the SA unit of a tertiary hospital in Madrid from June to December 2020. We registered demographic data, comorbidities and concomitant therapy for asthma. Non-adherence was defined as pharmacy refill data (PRD) $<80\%$ to the primary inhaler² and/or Test of Adherence to Inhalers questionnaire (TAI) result $s<50$ ³. Concordance was assessed by determining the Cohen's kappa statistic. Primary variable: Proportion of patients classified as not having therapeutic adherence measured by both of the following methods: PRD $<80\%$ in the previous 6 months, and TAI questionnaire: a value <50 . Comorbidities considered: rhinoconjunctivitis, nasal polyposis, anxiety and depression, gastroesophageal reflux, bronchiectasis, aspirin-exacerbated respiratory disease (AERD) and allergic bronchopulmonary aspergillosis.

Results 53 patients were evaluated. Median age was 61 years (IQR 51.8–67) and 33 (61%) were women. 41(77%) had comorbidity: 25(61%), rhinoconjunctivitis, 16 (38%) nasal polyposis, 15 (36%) anxiety and depression, 7 (17%) gastroesophageal reflux, 6 (15%) bronchiectasis, 5 (12%) AERD and 1(2%) allergic bronchopulmonary aspergillosis. The highest non-adherence was detected in patients with rhinoconjunctivitis by the two methods: 50% and 55% according to TAI and PRD, respectively ($k=0.022$ 95% CI -0.256–0.3). Agreement of both methods was low in all comorbidities; nasal polyposis: 42% vs 23% ($k=-0.049$ 95% CI -0.421–0.519); anxiety and depression: 25% vs 32% ($k=0$ 95% CI -0.317–0.317); gastroesophageal reflux: 8% vs 10% ($k=0.364$ 95% CI -0.21–0.938) and AERD 17% vs 10% ($k=-0.154$ 95% CI-0.659–0.967).

Conclusion and Relevance Our results highlight a high prevalence of non-adherence to inhalers in patients with SA and other comorbidities treated with biologics. Therefore, hospital pharmacists should focus on this patient's adherence to inhalers, especially those with rhinoconjunctivitis, when providing pharmaceutical care to SA treated with biologics in practice.

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Conflict of Interest No conflict of interest

4CPS-009 ABSTRACT WITHDRAWN

4CPS-012 **PLATELET TO LYMPHOCYTE RATIO (PLR) AS
BIOLOGICAL MARKER OF INTEREST IN
IMMUNOTHERAPY**

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Background and Importance Inflammation plays a major role in the progression of neoplasms such as non-small-cell lung cancer (NSCLC), so it is vitally important to find biomarkers that are easily applicable and reproducible in routine clinical practice that allow us to classify patients according to their forecast.

4CPS-010 ABSTRACT WITHDRAWN

Aim and Objectives To analyse the inflammatory marker platelet/lymphocyte ratio (PLR) as a predictor of efficacy in immunotherapy treatments; to assess whether there is a relationship between PLR value and response to treatment.

Material and Methods Retrospective and observational study of patients diagnosed with NSCLC and treated with pembrolizumab in a tertiary hospital, from January 2018 to December 2021. We collected demographic variables (sex and age), ECOG, histology, presence of metastases, PD-L1 expression and previous treatments. Progression-free survival (PFS) and overall survival (OS) were calculated by the Kaplan-Meier method and log-rank as hypothesis testing.; PLR (absolute platelet count/absolute lymphocyte count) was calculated and PLR=200 was considered the cut-off point. Cox regression test was used to assess the influence of PLR on treatment efficacy.

Results Seventy-three patients treated with pembrolizumab (80.8% male, n=59) and median age 65 [83-37] years. Adenocarcinoma histology was 90% (n=66); 40 patients ECOG=0, 31 patients ECOG=1 and 2 patients ECOG=2; 26 patients PD-L1<50%, 19 patients PD-L1>50% and for 28 patients it was unknown; 12 patients CNS metastases and 22 patients had liver/bone metastases. Significant differences were obtained in the group of patients with liver/bone metastases in PFS with median of 6.3 (2.9-9.6) CI 95% vs 17.3 (11.4-23.2) CI 95% months (p=0.03), and in the group of patients with CNS metastases in OS with a median of 9.6 (1.2-17.9) CI 95% vs at 24.9 (18.6-31.2) 95% CI months (p=0.003). Median PFS was 15.6 [10.15-21.1] 95% CI for PLR <200 vs 9.97 [2.86-17.1] 95% CI months for PLR >200 (p=0.04); median OS was 26.25 [19.87-32.64] 95% CI for PLR <200 vs 11.31 [3.86-18.79] 95% CI months for PLR >200 (p=0.001). Cox regression test: HR=1.001 (p=0.017) for PFS and HR=1.002 (p=0.003) for OS.

Conclusion and Relevance PLR and the presence of metastases correlates with PFS and OS. PLR, with a cut-off point =200, appears useful as a prognostic biomarker for patients with NSCLC treated with pembrolizumab; higher PLR values, result in lower PFS and OS (HR>1 in PFS and OS).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-014 COMPARISON OF TWO PROTOCOLS FOR THE ADMINISTRATION OF LEUCOVORIN RESCUES AFTER HIGH DOSE METHOTREXATE INFUSION OF 24 HOURS

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Background and Importance Therapeutic drug monitoring (TDM) of methotrexate (MTX) in plasma is a standard procedure to early identify patients with delayed drug elimination and adjust leucovorin dose. Adequate leucovorin rescues (LR) should start within 42-48h of the beginning of high dose (HD)-24h-MTX infusion to avoid MTX toxicity but extending LR more than needed can reduce MTX antitumour effect. Before implementation of new PETHEMA-2019 protocol at our hospital, standard LR were prescribed and MTX plasma concentration was determined 48h after infusion completion. Following new protocol recommendations, pharmacists started TDM.

Aim and Objectives To assess whether the implementation of the new protocol allowed reducing the total leucovorin dose administered after HD-24h-MTX infusion. Secondary outcomes: compare the incidence of toxicity and the level of compliance of appropriate MTX sampling times and LR between both protocols

Material and Methods Retrospective observational study conducted at a university tertiary hospital. Adults treated with a HD-24h-MTX infusion as treatment for acute lymphoblastic leukaemia (ALL) and Burkitt lymphoma from May 2019 to June 2022 were included. Patients were stratified (1:1) according to the protocol followed. Data collected were: age, sex, haematology malignancy, MTX dose, LR and serum creatinine.

Results Fifty-eight HD-24h-MTX infusions were analysed corresponding to 20 patients for the new protocol (75% males; mean \pm SD age 49 \pm 15 years; 7 with lymphoma, 11 ALL-B, 2 ALL-T) and to 20 for the original (65% male; mean \pm SD age 49 \pm 16 years; 10 lymphoma; 7 ALL-B, 3 ALL-T). The median [interquartile range] leucovorin dose administered per cycle following the original protocol was an 87% higher than the dose administered with the new protocol (597 mg/m² [475,700] vs 75 mg/m² [45,180], p<0,001). Nephrotoxicity incidence (increase of 0,3 mg/dl from basal creatinine) was 21% in the original protocol vs 19% in the new one (p=0,84). Sample extractions for TDM were correctly drawn in 93% of the cases and LR were correctly administered in 76% of the cases when using the new protocol, in comparison with 97% and 55% when using the original protocol).

Conclusion and Relevance Implementation of the new protocol allows a significant reduction of the leucovorin dose by 87% without an increase in nephrotoxicity. Measures to increase adherence to the new protocol may be implemented hereafter.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-015 ROLE OF CLINICAL PHARMACIST IN THE OPTIMISATION OF NIRMATRELVIR/RITONAVIR PRESCRIPTION IN THE EMERGENCY DEPARTMENT

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Background and Importance Nirmatrelvir/ritonavir (Paxlovid[®]) has been recently authorised for treating coronavirus disease 2019 (COVID-19) in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe disease. Due to multiple drugs metabolised by CYP3A may have significant interactions with ritonavir, physicians and pharmacists should work together for the safe and effective use of paxlovid.

Aim and Objectives To describe the pharmacist interventions (PIs) in the emergency department (ED) regarding optimisation of paxlovid prescriptions in non-hospitalised COVID-19 patients.

Material and Methods An observational prospective study was conducted from 1 April 2022 to 31 August 2022 in a 1000-bed university hospital. Clinical variables were obtained using electronic medical records. We registered demographic data (sex, age), vaccination status and comorbidities, hospitalisation and prescription with other therapies (such as remdesivir and baricitinib) after paxlovid treatment, posology, potential drug

interactions and contraindications. PIs were classified into the following types: (1) dose adjustment, (2) contraindication, (3) potential interaction, (4) non-compliance with the indication. We also identified primary non-adherence to paxlovid.

Results We included 77 patients, 56% female, median age of 67 years (IQR 52-81). Most patients (87%) were fully vaccinated (including booster dose), 12% required subsequent hospitalisation for COVID-19, none of them died and only one patient required remdesivir as other therapies. In relation to comorbidities, 86% of patients had respiratory diseases, 33% hypertension, 30% cancer treated with chemotherapy, 21% autoimmune diseases, 17% renal disease, 16% diabetes mellitus, 9% liver disease. The percentage of patients with PIs was 70%. The total of PIs carried out was 87:(1) 31%, (2) 13%, (3) 33%, (4) 23%. Forty-six potential interactions were detected being the most frequent: statins (33%), antihypertensives (11%), anticoagulants (6%), immunosuppressants (6%), among other drugs, as well as, 14 contraindications, in which statins again stood out. Primary non-adherence was detected in 10% of patients. 100% of PI were accepted.

Conclusion and Relevance Hospital pharmacists are key in the optimisation of paxlovid prescriptions in the ED. This includes assessing for potential drug interactions, as well as contraindications, among other PIs. Due to the recent conditional marketing authorisation of paxlovid, it is important to encourage multidisciplinary work to reduce potential dosing errors and adverse reactions, increasing patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-016 PREDICTIVE PERFORMANCE OF GLOMERULAR FILTRATION RATE EQUATIONS BASED ON CYSTATIN C, CREATININE AND THEIR COMBINATION IN CRITICALLY ILL PATIENTS

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Background and Importance Twenty-four hour urine creatinine clearance (24h-CrCr) remains the gold-standard for estimating glomerular filtration rate (GFR) in critically ill patients; however, it has several drawbacks. Serum creatinine (SCr) is the most frequently used parameter to estimate GFR, however, Cystatin-C (CystC) may reflect GFR changes earlier than SCr.

Aim and Objectives To assess the performance of equations based on SCr, CystC, and their combination (SCr-CystC) for estimating GFR in critically ill patients in comparison to 24h-CrCr.

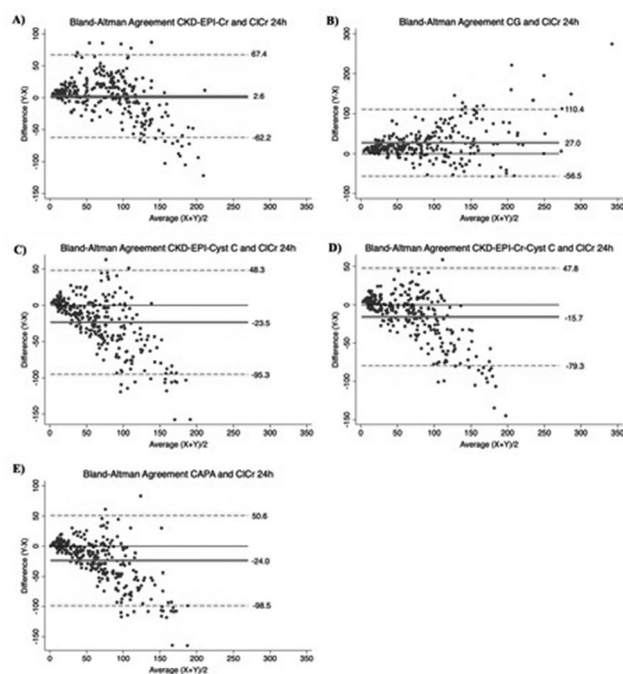
Material and Methods Retrospective, observational study in a tertiary-care hospital (May 2020 to July 2022). Patients with CystC, SCr and 24h-CrCr measurements within ± 2 days were included. Altered thyroid status and corticosteroids use for >5 days were recorded, as both can alter CystC values.

24h-CrCr was considered the reference method. GFR was estimated using SCr-based equations: CKD-EPI-Cr and Cockcroft-Gault (CG); CystC-based equations: CKD-EPI-CystC and CAPA; and Cr-CystC-based equations: CKD-EPI-Cr-CystC.

Bland-Altman plots were used to compare GFR estimations with 24h-CrCr. Pearson's correlation coefficients and concordance correlation coefficients (CCC) were calculated. Bias was assessed as (estimated GFR - 24h-CrCr); and precision as the SD of bias. Further analysis was performed with stratified data into 24h-CrCr <60 mL/min/1.73m², 60-130 mL/min/1.73m² and ≥ 130 mL/min/1.73m².

Results We included 275 measurements, corresponding to 186 patients. Mean (SD) SCr, CystC and 24h-CrCr were 1.3 (1.1) mg/dL, 1.8 (1.2) mg/L, and 77.0 (57.7) mL/min, respectively. The influence of altered thyroid status (N=22) and corticosteroids therapy (N=64) on CystC values was statistically significant (p:0.0138 and p<0.000, respectively); however, as box-plot were overlapped, we did not exclude them from the analysis.

Bland-Altman plots are shown in figure 1. In the overall population, CKD-EPI-Cr equation showed the lowest bias (2.6) and best precision (33.1). In patients with 24h-CrCr <60 mL/min/1.73m² (N=124), CystC-based equations showed the lowest bias (<3.0) and CKD-EPI-Cr-CystC was the most accurate (13.6). In the subgroup of $60 \leq 24h\text{-CrCr} < 130$ mL/min/1.73m² (N=100), CKD-EPI-Cr-CystC was the most precise (20.9). However, in patients with 24h-CrCr ≥ 130 mL/min/1.73m² (N=51), CystC-based equations underestimate GFR, while CG overestimates it (22.8). CKD-EPI-Cr-CystC obtained the highest Pearson's coefficient (0.742) and CKD-EPI-Cr the highest CCC (0.785).



Abstract 4CPS-016 Figure 1 Bland-Altman plots showing mean differences between estimated GFR and measured 24h-CrCr

Conclusion and Relevance Our study showed no evidence of superiority of any equation over others for all evaluated parameters. CystC-based equations were less biased in individuals with impaired renal function (GFR <60 mL/min/1.73m²), CKD-EPI-Cr-CystC performed properly in GFR from 60-130 mL/min/1.73m² and CG in patients >130 mL/min/1.73m².

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-018 EVOLUTION OF ANTIMICROBIAL USE IN COVID-19 PATIENTS

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Background and Importance Antimicrobial prescribing prevalence in COVID-19 patients is estimated to be around 75%, whereas bacterial coinfection prevalence is estimated to be less than 10%. This data shows the unnecessary use of antibiotics.

Aim and Objectives To compare the evolution of antimicrobial consumption in COVID-19 patients between the beginning of the pandemic and the third COVID-19 wave in our hospital.

Material and Methods Observational retrospective study conducted in a tertiary care hospital during March to June 2020 and May to August 2021 in COVID-19 Intensive Care Unit (CICU) and COVID-19 medical ward (CMW) patients. We extracted antimicrobial consumption data from the Pharmacy database (Silicon) and bed-days data from Admission Service.

We standardised antimicrobial consumption to defined daily doses (DDD)/100 bed-days. The descriptive analysis was performed with SPSS. We conducted a normality, an independence and a correlation test.

Results An 8% decrease in global antimicrobial use was observed. However, we found a 30% decrease in CMW, and a 39% increase in CICU.

The antibiotic use in the two periods showed a significance correlation ($p < 0,001$).

Conclusion and Relevance

- There is a light decrease of antimicrobial prescriptions in all COVID-19 patients.
- There is an important decrease in antimicrobial use in CMW and a considerable increase in CICU.
- These results suggest the need for more antimicrobial stewardship programmes in CICU

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-019 QUALITY ASSESSMENT OF THE EVIDENCE UNDERPINNING PHARMACIST-LED ANTIMICROBIAL STEWARDSHIPS INTERVENTIONS

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Background and Importance Antimicrobial resistance (AMR) is a global problem threatening public health, security and economic development. Antimicrobial stewardship (AMS) programmes have been implemented worldwide as they have demonstrated clinical, economical and ecological benefits promoting the adequate use of antibiotics. Pharmacist-led antimicrobial stewardships (AMS) interventions are proposed as key strategies to optimise antibiotic use and reduce adverse events, including the selection of antimicrobial resistance. Systematic reviews are at the highest level of the evidence validity hierarchy and provide insight and support policy-makers in clinical practice and research.

Aim and Objectives To evaluate the quality of the systematic reviews measuring the impact of PHARMACIST-LED AMS interventions.

Material and Methods An umbrella review of the systematic reviews on AMS was conducted following the PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) guideline. Following prospective registration (Prospero CRD42022333928), two reviewers independently searched in PubMed, Scopus, Cochrane Library and Google Scholar, without language or time restrictions until June 2022. We included systematic reviews covering pharmacist-led AMS interventions. Two reviewers independently assessed methodological quality using a modified AMSTAR-2 tool and collated the main findings.

Results From 1004 citations, 20 reviews were eligible for inclusion summarising a total of 648 studies. The overall quality of 15 (75%) reviews was critically low. Four studies (20%) were of low quality and one study was of high quality (5%). The most loss-making domains involve providing a list of excluded studies, measuring the risk of bias (RoB) with an appropriate tool, to explicitly state that the review methods

Abstract 4CPS-018 Table 1

| | MARCH-JUNE 2020 | | | MAY-AUGUST 2021 | | | EVOLUTION 2020-2021 | | |
|---|-----------------|------|--------|-----------------|------|--------|---------------------|----------------|---------------|
| | CICU | CMW | GLOBAL | CICU | CMW | GLOBAL | CICU | CMW | GLOBAL |
| BED-DAYS | 573 | 2346 | 2919 | 493 | 2114 | 2607 | | | |
| Co-amoxiclav DDD/100BED-DAYS | 0,9 | 22 | 17,9 | 1,2 | 21,1 | 17,3 | +0,3 (33,3%) | -0,9 (-4%) | -0,6 (-3,4%) |
| 3 rd generation cephalosporins DDD/100BED-DAYS | 32,3 | 8,9 | 13,5 | 35,7 | 3,5 | 9,6 | +3,4 (10,5%) | -5,4 (-60%) | -3,9 (-28,9%) |
| Antipseudomonal antibiotics DDD/100BED-DAYS | 16,1 | 9,1 | 10,5 | 27,8 | 5,9 | 10 | +11,7 (72,7%) | -3,2 (-35,1%) | -0,5 (-4,%) |
| Quinolones DDD/100BED-DAYS | 2,3 | 3,6 | 3,4 | 10,8 | 1,4 | 3,2 | +8,5 (370%) | -2,2 (-61,1%) | -0,2 (-5,9%) |
| Anti-MRSA antibiotics DDD/100BED-DAYS | 23,4 | 3,4 | 7,3 | 18,6 | 2 | 5,1 | -4,8 (-20,5%) | -1,4 (-41,2%) | -2,2 (-30,1%) |
| Antifungal treatments DDD/100BED-DAYS | 4,4 | 1 | 1,6 | 22,9 | 0 | 4,4 | +18,5 (420%) | -4,4 (-100%) | +2,8 (175%) |
| Total antimicrobial consumption DDD/100BED-DAYS | 135,1 | 62,6 | 76,8 | 187,3 | 43,7 | 70,8 | +52,2 (38,6%) | -18,9 (-30,2%) | -6 (-7,8%) |

were previously established and taking RoB into account in the interpretation of results. The only high-quality study (5%) reported on the sources of funding for the studies included in the review and provided a list of excluded articles.

Conclusion and Relevance Systematic reviews provide the best level of evidence, but their quality must be assured. The overall quality of the systematic reviews measuring the impact of PHARMACIST-LED AMS interventions is low. There is a need for high level literature covering the participation and implication of pharmacists in AMS. The real impact of AMS is unknown to support policy makers and efficient designs in both clinical practice and research.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-021 EFFECTIVENESS, PERSISTENCE, AND ADHERENCE OF BARICITINIB IN RHEUMATOID ARTHRITIS: LONG-TERM REAL-WORLD EVIDENCE STUDY

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Background and Importance Baricitinib (BAR) is a Janus kinase inhibitor (JAKi) selective for isoenzymes 1 and 2. It is used in rheumatoid arthritis (RA) with an inadequate response to conventional synthetic disease-modifying drugs (csDMARD).

Aim and Objectives The objective was to evaluate the effectiveness, persistence, and adherence of BAR in RA in a real-world setting.

Material and Methods An ambispective observational study was designed in a third-level hospital. Patients with RA who started BAR between September 2017 and June 2021 were included and signed an informed consent. Patients participating in a clinical trial were excluded. Patients were followed up until December 2021. Effectiveness was evaluated by variation of the Disease Activity Score (28-joint count) using C-reactive protein (DAS28PCR); and by the percentage of patients achieving therapeutic target: low disease activity (LDA) (DAS28CRP \leq 3.2) or disease remission (DAS28CRP $<$ 2.6). Adherence was analysed using the 5 items Compliance-Questionnaire-Rheumatology (CQR5) applied to patients every 6 months, and the medication possession ratio (MPR). The study was approved by the Institutional Review Board of the hospital.

Results 61 patients were included, 51/61 (83.6%) were female. The mean age was 58.1 (15.4) and the mean disease duration was 13.9 (8.3) years. 47/61 (77.0%) and 43/61 (70.5%) patients presented anti-citrullinated protein antibodies and rheumatoid factor, respectively. 44/61 (72.1%) patients had prior exposure to biologic DMARDs. 10/61 (16.4%) patients were on BAR monotherapy. A significant decrease was observed in DAS28PCR from baseline to the end of treatment/follow-up (3.9 (0.9) vs 2.7 (1.3), a difference of 1.2, $p=0.000$). In addition, 6/61 (9.8%) and 37/61 (60.7%) patients achieved LDA or remission, respectively. 31/61 (50.8%) patients remained on treatment at the end of follow-up, with a median persistence of 31.3 (14.1-47.7) months. The mean MPR was 0.96 (0.08), and all but one patient were

adherent (MPR $>$ 0.8). According to the CQR5, all patients were 'good adherers'.

Conclusion and Relevance JAKi are the most recent alternative available for RA treatment. BAR demonstrated effectiveness in our study cohort, with a significant decrease in DAS28PCR, a high percentage of patients reaching the therapeutic target, and a persistence exceeding two years. Adherence to treatment was very high, almost 100%. More studies in real-world setting are needed to confirm these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-022 ADHERENCE TO EVOLOCUMAB AND ITS IMPACT ON LDL CHOLESTEROL REDUCTION

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Background and Importance According to the latest recommendations, the need to achieve lower cholesterol levels has become more important. Therefore, the use of protein convertase subtilisin/kexin type 9 (PCSK9) inhibitors has been increasing recently.

Aim and Objectives To establish patients' adherence to evolocumab therapy, a PCSK9 inhibitor, and to analyse the reduction of patients' LDL-C levels.

Material and Methods Descriptive retrospective observational study carried out between January and December 2021 in a third-level hospital. Patients with three or more dispensations of evolocumab were selected. The number of prefilled pens and the date when it was supplied were considered to calculate compliance. Demographics and clinical data (prescription and LDL-C values: pre-treatment, after 12 weeks, and at the end of the study) were compiled through the medical record.

Results 139 patients were included in the study, 79 males (57.25%) with a median age of 62.97 years (IQR 15.53). 73 patients (52.90%) were prescribed due to secondary prevention and the remainder due to familial hypercholesterolemia. All patients received 140 mg every 2 weeks.

Patients were divided into three groups (1, 2, and 3) according to their medication adherence ($\geq 90\%$, 75 – 89.99%, and $<75\%$ respectively). 90 patients (65.22%) were in group 1, 30 (21.74%) in group 2 and 18 (13.04%) in group 3.

After 12 weeks of treatment, a reduction of LDL-C levels by at least 50% was observed in 71 patients (78.79%) from group 1, 23 (76.67%) from group 2, and 11 (61.11%) from group 3. The reduction percentage medians were -69.18% (IQR 26.69), -68.64% (IQR 28.89), and -54.56% (IQR 44.69) respectively for each group. Results in group 1 and 2 are better than existing literature data (table 1). Group 3 obtained worse efficacy results.

Abstract 4CPS-022 Table 1

| Phase III clinical trial (N) | Reduction percentage (CI 95%) |
|------------------------------|-------------------------------|
| 20110114 MENDEL-2 (614) | -58 (-60, -55) |
| 20110115 LAPLACE-2 (1896) | -64 (-66, -62) |
| 20110117 RUTHERFORD2 (329) | -63 (-66, -59) |
| 20110116 GAUSS-2 (307) | -57 (-61, -54) |

Conclusion and Relevance Low adherence seems to decrease LDL-C reduction capacity, while moderate compliance seems to maintain it. Further research is required, nevertheless, these results would support the possibility of decreasing the frequency of administration, favouring the adherence to treatment and reducing costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-024 COMPARISON OF CHANGES IN CLINICAL VALUES OF INTENSIVE CARE PATIENTS AT VETERANS HOSPITAL ACCORDING TO VARIOUS FAT EMULSIONS FOR PARENTERAL NUTRITION

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10.1136/ejhp-2023-eahp.68

Background and Importance The purpose of this study was to compare the changes in the clinical values of fish oil and non-oil-based TPN in critically ill patients and to provide a clinical rationale for TPN administration.

Aim and Objectives Data were collected from critically ill patients who received TNA (Fish oil-based or non- Fish oil-based TNA, the latter consisting of olive-soybean oil-based TNA or soybean oil-based TNA) at Veterans Health Service medical centre from 1 June 2019 to 31 May 2021.

Material and Methods Albumin, hs CRP, AST, ALT, Total Bilirubin (TB), PT, INR, WBC, Hb, Hct, PLT, Lymphocyte (LYT) levels were analysed.

Results This study collected 224 subjects (172 fish oil-based TNA, 45 olive soybean oil-based TNA, and 7 soybean oil-based TNA). The mean changes in hs-CRP before and after TNA injection were -8.71, -47.48, and -33.33 in the order of fish oil, olive-soybean oil, and soybean oil. The albumin level changes were -0.26, +0.05, and -0.03, respectively. Other than that, there were no statistically significant changes.

In the olive-soybean oil group, the decrease in hs-CRP showed a tendency to increase as the number of prescription days increased. Only in the fish oil group, as the APACHE2 score increased, the TB ($p < 0.01$) and AST ($p < 0.01$) tended to increase, and the thrombocytopenia tended to increase ($p < 0.01$). In the olive soybean oil group ($p < 0.01$) and soybean oil group ($p = 0.037$), the increase in INR tended to increase as the BMI increased. In the fish oil group, ALT increased with age ($p = 0.014$).

Conclusion and Relevance As a result of the study, there was no significant difference in clinical values between the preparations containing fish oil and the preparations containing non-fish oil except for hs-CRP and albumin. Therefore, it is judged that considering the nutritional components and economic feasibility of TNA preparations when administering TNA will be helpful in improving the nutritional status of patients and reducing the economic burden.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-026 EFFECTIVENESS OF SODIUM ZIRCONIUM CYCLOSILICATE IN REDUCING POTASSIUM CONCENTRATIONS IN HOSPITALISED PATIENTS

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Background and Importance Hyperkalaemia is a common but hazardous complication in patients with chronic kidney disease (CKD). Recent studies showed that new resins are effective in reducing potassium serum levels but its effectiveness is usually tested according to standard recommendations of shock and maintenance doses. Are these recommendations followed in clinical practice? If not, is it equally effective?

Aim and Objectives To evaluate the use and effectiveness of sodium zirconium cyclosilicate (SZC) treatment in routine clinical practice.

Material and Methods Observational and retrospective study carried out in a tertiary level hospital that included patients admitted with hyperkalaemia who started treatment with sodium zirconium cyclosilicate since December 2021.

Drug's technical data recommends shock dose of 10g/8h for a maximum of 72h until normokalaemia and from there, maintenance regimen with the minimum dose that allows concentrations between 3.5-5mmol/L. Therapeutic Positioning Report recommends reserving its use for patients with failure or intolerance to exchange resins like calcium polystyrene sulfonate (CPS).

Results 32 patients with a median age of 83 years (IQR 14) were recruited, 17 men. Main underlying cause of hyperkalaemia was CKD, 78% of cases.

Only 12.5% of all patients received a shock regimen of 10g/8h, 37.5% received 10g/24h, 6.3% received 5g/8h and 43.8% did not receive shock dose.

Regarding maintenance regimen, most common dosage was 5g/24h in 59.4% of the patients, followed by 10g/24h in 9.4% and 5g/48h in 3.1%. Remaining 28.1% did not receive a maintenance. 44.4% were never treated with resins and 3.7% showed intolerance to them.

Mean potassium concentration before treatment was 5.9 ± 0.7 mmol/L. 46.9% of the patients reached target potassium levels (3.5-5mmol/L) at 48h of treatment, 15.6% were below 3.5mmol/L; and 37.5% continued with concentrations above 5 mmol/L, half of whom had received SZC as a single dose.

Conclusion and Relevance A significant percentage of patients did not reach the potassium concentration target after treatment with SZC, which could be related to the lack of shock dose. This agrees with available literature, which concludes that doses higher than 10g/day lead to a greater potassium depletion. Almost one third of patients had not previously received resins so the most efficient option was probably not used since, as cost-comparison studies claim, CPS has a slightly better cost-effectiveness compared to SZC.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-029 ECONOMIC IMPACT OF BIOLOGICAL TREATMENT OPTIMISATIONS IN RHEUMATOLOGICAL AND DERMATOLOGICAL DISEASES

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Background and Importance Appropriate optimisation of biological agents in immune-mediated inflammatory diseases can improve treatment efficiency by decreasing number of drug administrations.

Aim and Objectives To estimate economic impact of optimising the use of etanercept and adalimumab in patients with immune-mediated dermatological and rheumatological diseases.

Material and Methods A descriptive retrospective study was conducted between November 2021 and September 2022. Patients with psoriasis, spondyloarthritis, rheumatoid arthritis and psoriatic arthritis treated with etanercept or adalimumab therapies for at least 6 months uninterruptedly were screened. Therapy optimisations were quantified. Optimised therapies were defined as treatments with extended dosing regimens or treatment discontinuations due to adequate pathology control. These therapy optimisations were applied according to a multidisciplinary protocol of clinical decisions based on biochemical tests (including serum drug levels and presence of anti-drug antibodies), pharmaceutical interviews about patients' perception of their disease course and medical criteria. Data recorded: medical departments, drugs, biochemical tests, pharmaceutical interviews, serum drug levels and presence of anti-drug antibodies. Regarding economic impact, savings from biological therapy optimisations were estimated as the difference between costs of real doses used with optimised regimens and the hypothetical costs with doses used prior to treatment optimisations. The number of decreased drug administrations was estimated.

Results This study screened 256 patients: 182 of Internal Medicine Department and 74 of Dermatology. Distribution of drugs was: 171 patients received etanercept and 85 adalimumab. There were 258 biochemical test and 258 pharmaceutical interviews (2 patients required 2 biochemical tests and 2 pharmaceutical interviews). Serum drug levels were outside the optimal therapeutic ranges of drugs according to the literature in 71.6% of cases. Presence of anti-drug antibodies were found in 15 patients. Treatment optimisations were performed in 115 patients: 86 (74.8%) of Internal Medicine Department and 29 (25.2%) of Dermatology. Total economic savings associated with optimisation of biological therapies were € 68804.96, € 53169,58 saved in Internal Medicine Department and € 15635.38 saved in Dermatology. The average monthly savings for these treatment optimisations was € 6255/month. Number of drug administrations avoided was 777.

Conclusion and Relevance The optimisation of etanercept and adalimumab regimens in our patients with immune-mediated dermatological and rheumatological diseases provided high efficiency by decreasing the number of drug administrations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of Interest No conflict of interest

4CPS-030 IMPACT OF PHARMACEUTICAL PROPOSALS IN MULTIDISCIPLINARY PROGRAMME FOR CLINICAL DECISION-MAKING IN IMMUNE-MEDIATED INFLAMMATORY DISEASES

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Background and Importance Pharmaceutical proposals (PPs) in a multidisciplinary programme (MP) for immune-mediated inflammatory diseases could improve drug effectiveness and efficiency of clinical decision-making.

Aim and Objectives To evaluate the impact of PPs in a MP for the management of immune-mediated inflammatory dermatological and rheumatological diseases.

Material and Methods Patients with rheumatoid arthritis (RA), spondyloarthritis, psoriasis and psoriatic arthritis (PA) receiving etanercept or adalimumab for at least 6 months continuously were screened in MP during May 2021 to September 2022. Internists, dermatologists, pharmacologists and pharmacists composed the MP. Bibliographic search on optimal therapeutic ranges (OTRs) of drugs was developed and PP protocol based on biochemical and clinical criteria was designed. Biochemical tests on serum drug levels and anti-drug antibodies were provided by pharmacists. Pharmaceutical interviews (PIs) about disease evolution were conducted before PPs. PPs were treatment optimisation (TO) based on extended dosing regimens or treatment discontinuations, drug switching (DS) due to loss of effectiveness, or unchanged therapy (UT). Patients with accepted TO had telematic PIs after 1 and 3 months (answers: 'good course'/'mild disease'/'poor course'). Recorded data: drugs, multidisciplinary meetings, biochemical test and PIs, drugs levels and anti-drug antibodies, type of accepted PPs and telematic PI answers.

Results MP included 645 patients. Drugs distribution: 51.8% etanercept and 48.2% adalimumab. There were 25 multidisciplinary meetings. Up to study cut-off time, 408 biochemical tests and PIs were performed. Results of bibliographic search presented adalimumab OTRs of 5-8 µg/mL for RA and PA, 3.2-7 µg/mL for psoriasis and 4.6-12 µg/mL for spondyloarthritis. Etanercept OTRs: 2-3 µg/mL for RA and spondyloarthritis, and 2-7 µg/mL for PA and psoriasis. Serum drug levels were outside the OTR in 72.9% of patients. Anti-drug antibodies were found in 18 patients. PPs accepted were 305: 183 (60%) TO, 52 (17%) DS and 70 (23%) UT. Telematic PIs answers 1 month after TO were: 81.8% 'good course', 3.6% 'mild disease' and 14.6% 'poor course'. At 3 months were: 69.8% 'good course', 5.7% 'mild disease' and 24.5% 'poor course'.

Conclusion and Relevance Most of accepted PPs in our MP (DS and TO) can improve effectiveness and efficiency of treatments for immune-mediated inflammatory diseases in clinical decision-making. Almost three quarters of patients with TO presented good disease evolution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of Interest No conflict of interest

4CPS-031 THERAPEUTIC DRUG MONITORING OF CEFTAZIDIME/ AVIBACTAM ADMINISTERED BY CONTINUOUS INFUSION: PK/PD TARGET ACHIEVEMENT AND CLINICAL OUTCOMES

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Background and Importance Ceftazidime/avibactam (CAZ/AVI) is a novel betalactam antibiotic utilised for multi-drug resistant (MDR) gram-negative bacteria. Therapeutic drug monitoring (TDM) ensures that CAZ/AVI levels achieve the pharmacokinetic/pharmacodynamic (PK/PD) target. Continuous infusion (CI) has been used to optimise CAZ/AVI pharmacodynamics.

Aim and Objectives To analyse the correlation between PK/PD target attainment of CAZ/AVI administered by CI, clinical outcomes and toxicity.

Material and Methods Patients treated with CAZ/AVI administered by CI and undergoing TDM of the CAZ plasma concentrations were included. Definitions:

CAZ/AVI PK/PD target:

- time that CAZ free concentrations remain 4 times above the minimum inhibitory concentration (MIC) of the causative pathogen ($\%fT > 4 \times \text{MIC}$).
- Overexposure: $\%fT > 10 \times \text{MIC}$.
- Clinical cure: disappearance of all signs and symptoms related to the infection and no requirement for additional antibiotic treatment initiation (except as part of de-escalation strategy) for the disease to be investigated within 48h after completion of the study drug.
- Thirty-day all-cause mortality: death from any cause during the 30 days following the end of treatment.

When real MIC was not available, a MIC of 8 mg/L was assumed.

Results Thirty-one patients (28 males, median (range) age of 64 (37-78) years) infected with extensively drug-resistant *Pseudomonas aeruginosa* and extended-spectrum betalactamase-producing *Klebsiella pneumoniae* were included (26 directed treatments and 5 empirical).

Twenty-six (83.9%) achieved the PK/PD target, 15 of which presented overexposure. Only 4 (26.6%) overexposed patients presented adverse reactions (3 increased liver enzymes and 1 thrombocytopenia).

Twenty-one (67.7%) patients achieved clinical cure, 18 (85.7%) of which achieved the PK/PD target. There was a higher frequency of patients with $\%fT > 4 \times \text{MIC}$ that achieved clinical cure (18/26 (69.2%) in patients with clinical cure vs 2/5 (40%) with clinical failure, $p = 0.686$).

The 30-day all-cause mortality was 19.4% (6 patients). A lower mortality rate was observed in patients that did achieve $\%fT > 4 \times \text{MIC}$ (14.8%) in patients who survived vs 50% in those who died, $p = 0.096$.

Conclusion and Relevance CI seems a useful strategy to reach the PK/PD target of CAZ/AVI. Few patients with overexposure presented adverse events. There seems to be a correlation between PK/PD target attainment, clinical cure and 30-day all-

cause mortality but larger studies with bigger samples are needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-034 ANALYSIS OF THE EFFECTIVENESS OF SOTROVIMAB IN PATIENTS DIAGNOSED WITH COVID-19

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Background and Importance Sotrovimab is indicated in treatment of COVID19 in adults and adolescents who do not require supplemental oxygen and who are at increased risk of progressing to COVID-severe. The drug is administered according to prioritisation criteria published by the Spanish Agency of Medicines and Health Products (AEMPS)1.

Aim and Objectives To analyse the effectiveness of sotrovimab and to know the profile of patients.

Material and Methods Observational, retrospective and descriptive study in a tertiary level hospital. Patients who had received sotrovimab from January/2022-May/2022 were included. Variables: sex, age, mild-moderate/severe disease, vaccination-COVID, risk factors, hospitalisation/death at 29 day. Effectiveness was measured as rate of patients without progression to COVID-severe (defined as hospitalisation/death at 29 days). Variables were collected from digital medical records and in-hospital electronic prescribing.

Results Thirty-seven patients were included, mean age=61 years (21-82), 20 women (54.05%). Twenty-nine patients (78.38%) had mild-moderate COVID. 29 patients (78.38%) had received a complete vaccination regimen (3 doses), 6 patients (16.22%) two doses and 2 patients (5.41%) not vaccinated. Risk factors: 23 hypertension (62.16%), 13 diabetes (35.14%), 5 obesity (13.51%) and 4 asthma (10.81%). All patients were immunosuppressed. 17 patients (45.94%) with 2 risk factors, 9 with 3 risk factors (24.32%), 7 with 1 risk factor (18.91%) and 2 patients (5.40%) with 4 risk factors. According to the AEMPS prioritisation criteria, all belonged to the group of 'Immuno-compromised persons and high-risk conditions, regardless of vaccination status'. The high-risk conditions were: 23 patients (62.16%) had received solid organ transplantation with immunosuppressive treatment, 13 patients (35.14%) had received immunosuppressive treatment with antiCD20 in the previous 6 months (100% rituximab) and 1 patient (2.7%) was receiving active treatment with myelotoxic chemotherapy (inotuzumab) for acute lymphocytic leukaemia. 7 patients (18.9%) were hospitalised/dead at 29 days (3 exitus). All these patients had received rituximab. 30 patients (81.1%) did not progress to severe COVID. During the study period, 6 patients attended the emergency department, without admission.

Conclusion and Relevance Most patients presented good response and tolerance to treatment. This result was independent of previous treatments or risk factors. Previous treatment with anti-CD20 seems to show a tendency to progression to severe COVID. Long-term studies are needed to confirm results

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-037 INDIRECT COMPARISONS OF BIOLOGICAL TREATMENTS IN PSORIATIC ARTHRITIS

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Background and Importance Psoriatic arthritis (PA) is a complex inflammatory musculoskeletal and skin disease. Nowadays, there are several therapeutic options to treat this disease.

Aim and Objectives To conduct indirect comparisons (ICs) between abatacept, brodalumab, guselkumab, ixekizumab, risankizumab, secukinumab and ustekinumab using a common comparator in patients diagnosed with PA.

Material and Methods A review in PubMed and European Medicines Agency databases was performed. Inclusion criteria: phase III randomised clinical trials (RCTs) of treatments cited with a double-blind and placebo-controlled design, which included patients previously treated with anti-tumour necrosis factor agents. Exclusion criteria: RCT without a comparator common to alternatives considered and recruiting treatment-naive patients. American College of Rheumatology 50% improvement criteria (ACR50) at 24 weeks in RCTs were selected as endpoint to estimate absolute risk reduction (ARR) for each drug. We conducted adjusted ICs using Bucher method. The therapeutic alternative with the greatest magnitude of effect in RCTs was selected as reference therapy. The maximum difference without clinical relevance (Δ) was defined as $\pm 16\%$ according to previous published literature.

Results

Seven studies were included All treatments –except abatacept– showed benefit over placebo. Regarding ixekizumab 80 mg monthly (reference therapy), ARRs were: -4.2% [95% confidence interval (CI), -15.43 to 7.03] vs brodalumab 210 mg biweekly; -9.20% [95% CI, -22.53 to 4.13] vs guselkumab 100 mg every 8 weeks; -12.20% [95% CI, -32.37 to 7.97] vs secukinumab 300 mg monthly; -13.60% [95% CI, -25.25 to -1.95] vs risankizumab 150 mg every 12 weeks; -19.5% [95% CI, -32.30 to -6.70] vs ustekinumab 45 mg every 12 weeks; and -25.50% [95% CI -37.87 to -13.13] vs abatacept 125 mg weekly. Ixekizumab showed statistically significant benefit compared to risankizumab, ustekinumab and abatacept. Nevertheless, no statistical difference was found compared to brodalumab, guselkumab and secukinumab. Ixekizumab only demonstrated a clinically relevant benefit versus ustekinumab and abatacept.

Conclusion and Relevance Our ICs provide comparative efficacy data between current therapeutic alternatives for PA in terms of ACR50. No statistically significant benefit was observed between ixekizumab, brodalumab, guselkumab and secukinumab. Ixekizumab did not show relevant clinical superiority over brodalumab, guselkumab, secukinumab and

risankizumab. These results could promote price competition between these drugs and improve the efficiency of PA treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-038 CHALLENGES RELATED TO TRANSITIONING FROM HOSPITAL TO TEMPORARY CARE AT A SKILLED NURSING FACILITY

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Background and Importance With decreasing number of hospital beds, more patients are discharged from hospitals to temporary care at skilled nursing facilities requiring handling of more complex and frail citizens in a non-hospital setting.

Aim and Objectives We aimed to systematically map challenges related to the transition of patients from hospital to temporary care at a skilled nursing facility in relation to (i) medication management, (ii) responsibility of the medical treatment, and (iii) communication.

Material and Methods This descriptive study included medical or surgical patients admitted to hospital and discharged to temporary care at a skilled nursing facility from May-December 2022.

Results Preliminary results are available for 67 patients (52% women and mean age 77 years). A nurse from the skilled nursing facility used in average a ten minute phone call to coordinate with a nurse from the hospital before discharge. In 100% (n=67) of the patients the medication to the first day sent from the hospital was used, even if there in 30% (20 of 67) was problems due to missing update of the Shared Medication Record, changed strength, missing or unidentified medication, or other discrepancies. Only 58% (n=39) received all needed medication during the first day needed for further medication dispensing. The nurses made in average three (range 0-10) calls and sent three electronically correspondences per patient about medication within the first five days. In 36 of 60 (60%) patients did the discrepancy between the discharge notice from the nurses and the discharge letter, not result in any further action from the skilled nursing facility. However in 38% (n=9) of the 24 patient records that required extra action from the skilled nursing facility, the action could have been avoided if the nurses from the skilled nursing facility had had the discharge letter. Full results for an expected 200 patients will be available and presented at the EAHP conference.

Conclusion and Relevance We identified challenges related to, in particular, lack of needed medication and communication. A third of the actions related to medication management were considered avoidable with improved practices around communication.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-039 CLINICAL AND ECONOMIC IMPACT OF MULTI-SWITCHING FROM ORIGINAL ADALIMUMAB TO BIOSIMILARS

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Background and Importance As the access to biosimilars at competitive prices increases, it is necessary to evaluate multiple switches to provide data on their interchangeability. Recently, the European Medicines Agency (EMA) has notified that medicines approved as biosimilars in the EU may be prescribed interchangeably.

Aim and Objectives The objective is to assess the efficiency and safety of switching from innovator adalimumab (Humira®) to biosimilar adalimumab (Imraldi®) and successive to another biosimilar (Hyrimoz®) in a real-life setting.

Material and Methods Retrospective observational study conducted in a 200-bed hospital. We included all patients who had been treated with the innovator adalimumab between 1-September-2019 and 31-March-2022 and switched to two adalimumab biosimilars. Variables analysed: clinical prescribing service, disease, patients who discontinued treatment with biosimilar and reason. Clinical and economic data were obtained from electronic medical records and management programs.

Results The first switch from innovator adalimumab to the first biosimilar adalimumab included 114 patients: 47.4% prescribed by the rheumatology department, 28.0% by the digestive unit and 24.6% by dermatologists.

The most frequent disease was rheumatoid arthritis (26.3%), following by Crohn's disease (23.7%), psoriasis (17.5%) and psoriatic arthritis (13.2%).

The percentage of patients that discontinued the first biosimilar was 15.8%. While 61.1% of patients discontinued due to inefficacy, 38.9% had adverse effects. A total of 96 patients switched twice. The retention rate after the second switch was 96.9%. No major changes in disease activity were observed.

In the first switch (January 2019), the acquisition cost in our hospital of one unit of the original drug was € 431.10, while that of the biosimilar (Imraldi®) was € 176.80. In the second switch (August 2019) the price of Imraldi® was the same and for Hyrimoz® was € 158.0. If we consider the most frequent posology in our patients (a dosage every two weeks), the first switch resulted in annual savings of € 753,745.20 and the second switch resulted in € 46,949.76. The multi-switching of 96 patients resulted in a total saving of € 681,682.56.

Conclusion and Relevance The retention rate after multiple switches from innovator adalimumab to adalimumab biosimilars is high. Considering this multi-switching successful experience with biosimilars regarding safety and economic impact, interchangeability between biological medicinal products should be common in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-040 ELECTRONIC CLINICAL DECISION SUPPORT FOR PHARMACOTHERAPEUTIC INTERVENTIONS TO REDUCE ANTICHOLINERGIC BURDEN IN OLDER HOSPITALISED PATIENTS

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Background and Importance Patients' anticholinergic burden is the cumulative effect of taking one or more anticholinergic medications. It is associated with adverse outcomes such as falls, cognitive impairment, delirium and increased morbidity, especially in elderly. Previous studies demonstrated that hospitalisation may increase anticholinergic burden. Pharmacotherapeutic interventions supported by electronic clinical decision support (eCDS) may have the potential to prevent this.

Aim and Objectives The aim of this study was to investigate whether the anticholinergic burden, expressed as score on the Anticholinergic Burden Scale (ACB score), in older hospitalised patients could be reduced through performing eCDS-based interventions during hospitalisation.

Material and Methods Prospective intervention study in April and May 2022. Study population: patients ≥ 65 years with an ACB score ≥ 8 and a hospital stay of ≥ 3 days. An eCDS tool was used to detect patients that met inclusion criteria. Patients' anticholinergic medication was reviewed and intervened if possible. An intervention consisted of pharmacist-led advice to the patient's attending physician by phone. Primary outcome: number and proportion of patients whose anticholinergic burden was reduced by the interventions. Secondary outcomes: (i) acceptance rate of pharmacotherapeutic interventions by attending physicians and (ii) nature and frequency of anticholinergic side effects. Descriptive statistics were used to analyse the results.

Results 208 patients were included (44.7% female; mean age 75.7 (\pm 6.6) years). Anticholinergic medication of 43 patients was reviewed which led to 43 interventions for 23 patients (53.5%, mean 1.87 (\pm 0.81) interventions per patient): 7 suggestions for dose reduction (16.3%), 4 suggestions for alternative medication (9.3%) and 32 suggestions for discontinuation of medication (74.4%). 28 of the 43 interventions were directly accepted by the attending physician (acceptance rate 65.1%) leading to a total ACB score reduction of 41 points i.e. an average ACB score reduction of 1.46 points (\pm 0.79) per intervention. 33 of the 43 reviewed patients (76.7%) experienced one or more anticholinergic side effects. Constipation occurred most often (45.2%).

Conclusion and Relevance Anticholinergic burden was reduced through eCDS-based pharmacotherapeutic interventions in more than half of reviewed patients and acceptance by attending physicians was high, indicating a promising potential for this initiative in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-041 ASSESSMENT OF QUALITY OF LIFE IN PATIENTS UNDERGOING ANTIMIGRAINE TREATMENT

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Background and Importance Migraine affects 15% of the world's population so is necessary to carry out interventions to help improve the quality of life of patients.

Aim and Objectives Evaluation of quality of life in migraine patients treated with erenumab or galcanezumab before administration, three months after and one year later.

Material and Methods Retrospective study conducted in a hospital by EQ-5D-5L questionnaires before drug administration, three months and one year later. The following data were collected: sex, age, educational level and quality of life dimensions (mobility, self-care, activities of daily living, pain/discomfort and anxiety/depression). Patients completed the visual analogue scale (VAS), graduated from 0 (worst condition) to 10.

Results Of the 67 patients, 45 completed the questionnaire after three months. 16 patients discontinued treatment before one year, so the percentage of surveys received was 50%. Mean age 48.9 years (85.1% women). 37.3% had higher education and 43.3% primary or secondary education. The rest did not provide data.

-**Mobility dimension** 76.1% described mild symptoms and 2.98% severe. After three months: 55.22% and 2.8%. One year later, mild symptoms decreased (28.87%).

-Mild self-care symptoms were described by 91.1% and severe by 2.98%. Three months later: 52.23% mild symptoms. One year later: 37.31% and 0%.

-35.8% reported mild problems in performing daily activities and 22.38% showed severity. Three months later, 13.4% continued with severe problems. At one year, mild symptoms: 29.9%.

-**Pain/discomfort** severe symptoms were 68.6%, three months later 25.4% and one year later 4.5%. Mild symptoms did not improve.

-**Severe anxiety/depression** initially 26.9%. Three months later 13.4% and one year 6%. Mild symptoms decreased from 52.2% to 23.9% at one year.

On the VAS scale, a median of 5 was obtained at the beginning of treatment compared to 6.25 three months later and 7 one year later.

Conclusion and Relevance "Pain/discomfort" and "depression/anxiety" are the most affected dimensions.

After three months and after one year, "pain/discomfort" was the most improved and "activities of daily living" was not affected.

The VAS scale showed an increase in quality of life after three months by a median of 1.25 points and 2 points after one year.

This questionnaire helps us to assess the patients' perspective, although we do not yet have the total number of surveys.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-042 OFF-LABEL USE OF USTEKINUMAB IN NONBULLOUS CONGENITAL ICHTHYOSIFORM ERYTHRODERMA: A CASE REPORT

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Background and Importance Nonbullous congenital ichthyosiform erythroderma (NBCIE) is a rare disease that predominantly affects the skin, courses with palmoplantar keratoderma anhidrosis, and nail dystrophy. In severe cases, there is alopecia in certain areas.

Aim and Objectives The objective of this report is to describe the off-label use of ustekinumab in a patient with NBCIE, and to assess the safety of the treatment and tolerability profile.

Material and Methods We ran a descriptive study of 6 year old man with NBCIE diagnosed at the time of birth. The patient presented very itchy generalised NBCIE affecting patient's quality of life. Patient's skin was entirely affected with visible redness of approx 90% of body surface. Patient went through several treatments with no success: emollients emulsions, topical and oral corticosteroids and H1-antihistamines.

In February 2021, a new outbreak occurred that led the Dermatology department to request the off-label use of Ustekinumab.

The Pharmacy and Therapeutics Committee approved the treatment initiation based on the published efficacy studies. NBCIE patients have a dominant profile of TH17/IL-23 and it has previously been demonstrated the successful use of ustekinumab in patients affected by ichthyosis.

Efficacy was evaluated based on IASI scheme (Ichthyosis Area Severity Index).

Results The patient started treatment with ustekinumab in May 2021 with a dose of 1.2 mg/kg. Dosing was provided by the Hospital Pharmacy Department adjusted as per patient's weight. The first 2 months, the patient received monthly doses while hereafter the dosing was adjusted to a bi-monthly frequency.

At the 3rd month of treatment, the patient observed a mild improvement while presenting diffused erythema with scaling and rough skin in the folds, with an impact of 60% of body surface. At month 6, a fourth dose of 27,6 mg of ustekinumab weight-adjusted was provided. Thereafter, the patient observed a significant improvement that directly affected his quality of life, achieving a 60% reduction extension according to IASI and a 66% reduction erythema according to IASI and no side effects were reported.

Nevertheless Dermatology department request the off-label use of dupilumab.

Conclusion and Relevance Results demonstrate ustekinumab provides only partial response at month 6 of NBCIE treatment, with modest but significant improvement in the patient's quality of life with a good safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-043 DRUG-DRUG INTERACTIONS WITH NIRMATRELVIR/RITONAVIR FOR COVID-19 AND THE ROLE OF HOSPITAL PHARMACISTS

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Background and Importance Nirmatrelvir/ritonavir has recently been approved for treating COVID-19, but an elevated risk of drug-drug interactions (DDI) has been exposed.

Aim and Objectives The aim of this study was to evaluate DDI with nirmatrelvir/ritonavir and the role of hospital pharmacists.

Material and Methods Retrospective study in a tertiary hospital between May-September 2022. All patients that received nirmatrelvir/ritonavir were included.

Data collected demographic, age-adjusted Charlson comorbidity index, medical department, concomitant drugs. All DDI and pharmacy interventions were screened and categorised.

Continuous data expressed as median (IQR). U-Mann Whitney for continuous variables and Chi-square for qualitative data.

Results A total of 48 patients with 350 concomitant drugs were selected. Female 24(50%), age 69(24-95) years, CHARLSON 5(0-12).

DDI were detected in 26 (54.2%) patients and in 52 (14.9%) drugs. Seven (0-16) concomitant drugs per patient.

Statistical significant differences were found with ATC and DDI category ($p < 0.001$): cardiovascular system drugs had more X-category DDI (41.7%) and nervous system drugs had more C-category DDI (60.8%).

Haematology department had more patients presenting any DDI (23.1%, $p = 0.047$).

No DDI provoked any adverse event during treatment with nirmatrelvir/ritonavir.

Conclusion and Relevance A high risk for DDI with nirmatrelvir/ritonavir was found, although most of them were mild and none provoked any adverse event. Cardiovascular system drugs showed the most severe DDI.

Haematology patients and those receiving nervous system drugs had higher prevalence for DDI.

Almost half of pharmacy recommendations were to discontinue the drug presenting the DDI. None of the pharmaceutical interventions induced any adverse event derived from the modification of concomitant treatment during nirmatrelvir/ritonavir administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-044 EFFECTIVENESS AND SAFETY OF DIFFERENT INITIAL DOSES OF ARIPIPRAZOLE INTRAMUSCULAR DEPOT

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Background and Importance Aripiprazole intramuscular depot treatment is used for maintenance of schizophrenia in adult patients stabilised with oral aripiprazole. This drug can be started with single or double injection (400 or 800 mg). Real clinical data of these two regimens could be required to optimise treatments.

Aim and Objectives To describe efficacy and safety of two different doses for starting aripiprazole depot therapy.

Material and Methods Retrospective descriptive study with period between March 2019 and July 2021. Hospitalised patients who started treatment with aripiprazole depot were included. Outcomes were collected from medical records and electronic prescription programme: gender, age, diagnosis, start doses, oral aripiprazole concomitant treatment, concomitant antipsychotic therapy. Effectiveness endpoint was percentage of patients with requirement of hospitalisation for single and double injection groups with aripiprazole intramuscular depot treatment at 12 and 26 weeks. Safety was evaluated by the rate of adverse effects (AEs) and types in each scheme.

Results There were 77 patients (67.5% male and 32.5% female). Population presented a mean age of 40 (22-74) years. Distribution of diagnoses: 61% psychotic disorder, 23.4% paranoid schizophrenia, 13% bipolar disorder and 2.6% others. Single injection was used in 61% of patients and double injection in 39%. Population with single dose presented 58.6% of patients with concomitant oral aripiprazole and 78.2% with different concomitant antipsychotics. Patients with double dose had 73.3% of cases with concomitant oral aripiprazole and 76.6% with different concomitant antipsychotics. About effectiveness results at week 12, 29.8% of cases in single dose group required hospitalisation versus 20% of population in double dose group. At week 26, 42% of patients required hospitalisation in single dose group versus 26.7% in double dose group. In terms of safety, 27 cases refer adverse effects: 36% in single dose group and 32% with double dose. Most common AEs of single dose population: sedation (25%),

Abstract 4CPS-043 Table 1

| | |
|--|----------|
| DDI category, n(%) | 24(46.2) |
| C: monitor therapy | 16(30.8) |
| D: consider therapy modification | 12(23.1) |
| X: avoid concomitant use | |
| ATC of DDI, n (%) | 21(40.4) |
| N-nervous system | 13(25) |
| C-cardiovascular system | 5(9.6) |
| B-blood and blood forming organs | 4(7.7) |
| G-genito urinary system | 3(5.8) |
| H-systemic hormonal preparations | 2(3.8) |
| L-antineoplastic and immunomodulating agents | 2(3.8) |
| A-alimentary tract and metabolism | 1(1.9) |
| M-musculo-skeletal system | 1(1.9) |
| R-respiratory system | |
| Medical department with DDI, n(%) | 6(23.1) |
| Haematology | 4(15.4) |
| Oncology | 3(11.5) |
| Nephrology | 3(11.5) |
| Pneumology | 3(11.5) |
| Emergency room | |
| Pharmacy intervention on concomitant drugs, n(%) | 23(44.2) |
| Discontinuation | 15(28.8) |
| Adverse events monitoring | 7(13.5) |
| Dose reduction | 5(9.6) |
| Substitution | 2(3.8) |
| Efficacy monitoring | |

anxiety (18.8%), somnolence (18.8%) akathisia (12.5%) and others (24.9%). Most frequent AEs in double dose population: akathisia (33%), anxiety (22%), sedation (11%), somnolence (11%) and others (23%).

Conclusion and Relevance Start with double dose aripiprazole depot treatment showed lower percentages of re-hospitalisation than single-dose regimen for maintenance treatment of patients with schizophrenia. Similar AEs were observed for both regimens.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-046 A QUALITATIVE STUDY OF FEASIBILITY AND ACCEPTABILITY OF A PHARMACY PRIORITISATION TOOLKIT BY A FRAILTY FOCUSED MULTIDISCIPLINARY TEAM IN AN ACUTE HOSPITAL EMERGENCY DEPARTMENT

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Background and Importance The number of frail, older patients presenting to the emergency department (ED) is increasing. As frailty is highly linked to medication issues, a pharmacy prioritisation toolkit (PPT), completed by a frailty multidisciplinary team (MDT), is effective to identify patients who would benefit the most from the frailty pharmacist's medication review.

Aim and Objectives To investigate feasibility and acceptability of a five-question PPT by the MDT after four months of use.

Material and Methods An anonymised, mixed methods questionnaire (open/closed questions) was distributed to the MDT (consultant, registrar and clinical nurse in geriatrics, dietician, occupational, physio and speech & language therapists). The questions aimed at establishing barriers and facilitators to the PPT. The straightforwardness of the toolkit questions was ranked using a Likert scale. A focus group was held to expand on the results of the questionnaire and inform future work to enhance the toolkit use.

Results Of 8 questionnaires circulated, 7 were returned. Barriers identified, in order most mentioned theme to least:

- difficulty identifying high risk medications
- lack of full medical/medication history in ED
- difficulty interpreting handwritten notes
- time taken to complete the toolkit

Although time taken to complete the PPT was a barrier, 5 respondents reported an average of 4 minutes for completion, which was deemed acceptable when discussing at the focus group. The group agreed, that some barriers are not modifiable such lack of full medical/medication history in ED. The most common facilitator was recognition that the tool clearly identifies when a pharmacy review is needed. Further education, self-learning and practice of the tool, but also upskilling on high risk medications and falls related medications, were considered potential future facilitators. 'Regular use of more than 10 medications' was the most straightforward question to answer in the toolkit while the least was 'Reason for admission potentially related to medications or admitted with non-mechanical fall'.

Conclusion and Relevance The toolkit was generally accepted by the MDT, the concise completion time was considered adequate taking into account the high prevalence of

medication issues in frail patients. Based on the responses, further education to the frailty MDT is planned, with main focus on recognition of high risk medications and falls related medications.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-047 IMPACT OF CORTICOSTEROID ON THE EFFECTIVENESS OF IMMUNOTHERAPY

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Background and Importance Symptomatic management of cancer patients often involves the use of corticosteroids. Recently, an association has been found between baseline corticosteroid levels and the response rate to immunotherapy in non-small-cell lung cancer (NSCLC).

Aim and Objectives Analyse the impact of corticosteroid administration on the effectiveness of immunotherapy.

Material and Methods Retrospective and descriptive study including patients who initiated immunotherapy between 2014 and 2021 for the treatment of locally advanced or metastatic stage NSCLC. Patients without a response assessment were excluded.

The following variables were collected and analysed through the oncology patient management programme and the electronic medical record: age, sex, Eastern Cooperative Oncology Group (ECOG), histology, drug, duration of treatment.

According to their pharmacy dispensing record, patients were classified into two groups: those who had received corticosteroids at doses higher than 10 mg of prednisone or equivalent within two months (before or after) of immunotherapy initiation the start of immunotherapy and patients who did not receive corticosteroids in that period of time.

Effectiveness was assessed by comparing Progression Free Survival (PFS) between the two groups of patients.

Results The study included 144 patients (103 men) with a mean age of 66 years. 97% of patients had an ECOG \leq 1 at baseline. In terms of histology, 65% were adenocarcinomas, 33% were epidermoid and the remaining 2% were undifferentiated NSCLC. 47% of patients were treated with pembrolizumab, 51% with atezolizumab and the remaining, 26% with nivolumab.

The corticosteroids prescribed were prednisone (50%), dexamethasone (38%) and methylprednisolone (3%).

The group of patients who received corticosteroids had a PFS of 3,72 months (95% CI; 2,76-6), while the group of patients who did not receive corticosteroids had a PFS of 5,52 months (95% CI; 4,56-9). The differences found were statistically significant ($p=0,021$).

Conclusion and Relevance The use of corticosteroids at doses higher than 10 mg prednisone or equivalent within two months (before or after) of immunotherapy initiation has been shown to reduce PFS of patients with NSCLC.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-049 TELEPHARMACY AND NEW HEALTHCARE MODELS: CLOSER TO PATIENTS

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Background and Importance The WHO defines telemedicine as 'the provision of health services (where distance is a determining factor) by health professionals through the use of information and communication technologies (ICTs) for the exchange of information relevant to diagnosis, treatment, disease prevention, research and evaluation, and for the continuing education of health professionals, with the ultimate goal of improving the health of populations and communities'. Telepharmacy is part of the transformation process of our current healthcare system that allows us to provide pharmaceutical care to specific groups of patients, such as frail patients or those who have problems traveling to the hospital.

Aim and Objectives The aim of this study is to describe and analyse the implementation of a telepharmacy consultation in a second-level hospital.

Material and Methods The study was conducted from February 2021 to May 2022. Patients were selected as candidates to be included in the telepharmacy consultation for pharmacotherapeutic follow-up, to detect and resolve any medication-related problems, to analyse and improve patient adherence and to check that the follow-up by the medical specialist was effective.

Results A total of 262 patients were identified as candidates to participate in the project to send medication to their respective health centres due to difficulties in accessing our hospital; 247 patients (94%) were selected for regular appointments and interviews in the telepharmacy consultation every 3, 6 or 12 months. At the time of the consultation, 5.70% (n=15) of the patients could not be contacted. The average telepharmacy time was 12h/month with an average of 15 minutes per patient.

In 86 (32.8%) patients a medication-related problem (MRP) was detected: 23.2% occurrence of adverse effects, 22.4% dispensing errors, 9.6% prescription errors, 8.0% insufficiently treated health problems, 7.2% poor adherence to treatment, 4% incorrect administration of medication, 0.8% inadequate storage of medication, 24.8% other.

Conclusion and Relevance Telepharmacy involves improving adherence to treatment and its monitoring, detection of pharmacological interactions or side effects. Telepharmacy allows achieving internal optimisation of resource management and care burden and improves accessibility to health services for patients, by reducing trips to hospital, time and resource consumption. Telepharmacy guarantees a continuous, patient-centred care model.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-050 ANALYSIS OF REAL-LIFE USE OF IBRUTINIB AFTER RELAPSE TO CONVENTIONAL CHEMOTHERAPY IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA

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Background and Importance Ibrutinib has revolutionised the treatment of chronic lymphocytic leukaemia (CLL). Clinical trial data showed similar survival between patients randomised to ibrutinib or chemoimmunotherapy with crossover to ibrutinib at progression.

Aim and Objectives Outcome analysis of the real-life use of ibrutinib after relapse to conventional chemotherapy in patients with chronic lymphocytic leukaemia.

Material and Methods Observational retrospective study of patients treated with ibrutinib as second line from 2017 to the present at a tertiary level hospital. Clinical variables: sex, age, diagnosis date, comorbidities, Eastern Cooperative Oncology Group scale (ECOG), Binet Staging System, cytogenetics (mutation TP53, immunoglobulin heavy-chain variable region gene (IGHV), chromosome deletion (11, 13, 12 and 17), treatment, duration, response (complete, partial) and relapse, progression-free survival (PFS), adverse effects, dose modification or discontinuation. Data was obtained from electronic prescription with the application Prisma[®] and electronic health records with Diraya[®].

Results 31 patients were treated with ibrutinib (18 patients as second line and 13 as third). Median age 71 years (IQR 65-78), 51.6% male. Median age of diagnosis 2012 (IQR 2008-2014). 29.5% of patients had previous hypertension, 23.6% kidney disease, 17.3% diabetes mellitus, 11.8% cardiac diseases and 5.5% respiratory pathologies. 41% of patients had Binet Staging A, 28.4% B and 5.8% C. All patients had ECOG 0. TP53 mutated in 16 patients, 15 with unmutated IGHV, 24 with 11q negative and 18 with 13q and 17q negative. Treatments used as first line were chlorambucil (9), fludarabine, cyclophosphamide and rituximab (7), bendamustine and rituximab (5). 14 patients achieved complete response, 4 partial and 7 discontinued due to toxicity. PFS 19.17 months. As second line in patients without ibrutinib, the most frequent treatment was bendamustine with rituximab (50%). All except one started with 420 mg dose. Median duration of treatment was 32 months. 11 patients reduced dose due to toxicity (66.6% diarrhoea, 16.6% renal failure and skin toxicity), 7 suspended indefinitely due to cardiac toxicity and 4 temporarily due to cardiac and gastrointestinal toxicity. 4 patients died from causes other than the disease. No patient lost response to treatment.

Conclusion and Relevance Treatment with ibrutinib proved effectiveness as second or third line in CLL. However, adverse effects require dose adjustments and sometimes discontinuation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-051 IMPACT OF THE NEW ANTI-EPILEPTIC DRUG MONITORING PROGRAMME ON THE ACTIVITY OF THE PHARMACY AND NEUROLOGY DEPARTMENTS

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Background and Importance In 2016 therapeutic drug monitoring programme (TDMP) began for new anticonvulsant drugs

(NAD) for inpatients and outpatients at our hospital. Weekly multidisciplinary meetings were held to revise out-of-range trough drug levels (TDL) on epileptic outpatients, and to make early drug adjustment interventions (EDAI) before their scheduled clinical follow-up.

Aim and Objectives To evaluate the impact of NAD TDMP on the activity of the Pharmacy and Neurology departments.

Material and Methods

Inpatients Quantification of pharmacokinetic interventions (PI) and patients monitored between 2016-2021.

Outpatients Activity analysis between July 2017 and May 2019: TDL revision, patients monitored and number of EDAI made. TDL and EDAI percentage calculation for each drug.

Results

Inpatients Anticonvulsant drug PI were 56% of all PI (6.067 of 10.910) during the study period. PI of classic anticonvulsant drugs (CAD) decreased from 934 in 2016 to 348 in 2021 (63%). In 2021 the percentage of PI of NAD and CAD were 27% and 16% (602 and 348 out of 2.209) respectively. Levetiracetam and Lacosamide accounted for 63% (380) and 27% (163) of all monitored NAD. Regarding CAD monitoring Valproate was the most 86% (299) and Fenitoin the least 4% (15) monitored.

Outpatients 1.096 TDL out of 2.324 ordered were revised (47%) which belonged to 424 patients of a total of 877 monitored (48%). 273 TDL (25%) led to an EDAI, which affected 196 patients, that is 46% of revised patients and 22% of all monitored patients. Most EDAI supposed an increase or reduction of dosage, 51% and 34% (139 and 92 out of 273) respectively. Levetiracetam, Perampnel and Lacosamide were the most monitored NAD: 26% (286), 13% (145) and 10% (110) respectively, and the most EDAI-prone: 29% (79), 27% (73) and 11% (29) respectively.

Conclusion and Relevance Inclusion of outpatients to TDMP allowed early drug adjustment of almost half of the revised patients.

The creation of a multidisciplinary team that includes pharmacists and neurologists with a focus on active monitoring of NAD TDL might be significant to better care for epileptic outpatients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-052 LONG-TERM MONITORING OF UREA AS TREATMENT FOR HYPONATREMIA ASSOCIATED TO INADEQUATE SECRETION OF ANTIDIURETIC HORMONE (ISADH)

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Background and Importance Normal blood sodium levels (BSL) is between 136-145 mEq/L. ISADH courses with hyponatremia, plasmatic hypoosmolality, high urine osmolality, and high natriuresis. Available drugs are demeclocycline and lithium, both nephrotoxic, and vasopressin receptor inhibitors, such as tolvaptan, which are effective but highly costly.

Aim and Objectives To describe the experience of use of urea as an alternative for treatment of ISADH and results monitored one year after treatment.

Material and Methods Retrospective observational study in which patients treated with urea (powder for oral solution) were analysed along two years (January 2020-December 2021) and one year after treatment. Data collection of: age, sex, quantification of BSL (at admission, during urea therapy, 60 days after drug administration and one year after treatment), initial therapy, duration of urea treatment and need of tolvaptan use.

Results Total of patients was 11. Mean age was 82 years (71-94 years). 45% were women. Average duration of treatment was 15 days (3-60 days). Initial therapy was hypertonic saline solution, water restriction and/or loop diuretics or potassium sparing agents. Only one patient did not tolerate urea. Dosage was variable: in 54% was 15 g daily, 27% 15 g bid and 18% 30 g daily.

Patients were classified according to initial hyponatremia: 27% had mild hyponatremia (130-135 mEq/L), 45% moderate (125-129 mEq/L), and 27% severe (<125 mEq/L).

Results were

-Mild hyponatremia 66% recovered BSL, while 33% remained mildly hyponatraemic.

-Moderate hyponatraemia, 60% normalised BSL and 20% worsened to severe hyponatraemia. 20% did not analysed.

-Severe hyponatremia, 66% normalised BSL. 33% did not have analytical control.

45% of patients achieved BSL once treatment ended. 27% required treatment with tolvaptan 15 mg daily.

50% of patients with urea as monotherapy maintained BSL 60 days after finishing treatment and 81.8% kept normal BSL after one year of treatment. Just 9% is still in treatment.

Conclusion and Relevance Most clinical guidelines contemplate urea as an option for hyponatremia for ISADH, but it is not clear its preference respect other alternatives. Urea is shown to be a safe and moderately effective option, and also, more effective.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-053 KOUNIS SYNDROME SECONDARY TO METAMIZOLE: A CASE REPORT

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Background and Importance Kounis syndrome (KS) is an acute coronary syndrome (ACS) triggered by mast cell and platelet activation in the context of anaphylactic reactions. The diagnosis of KS requires a high index of suspicion and should be considered in patients presenting with ACS, plus other associated symptoms such as pruritus, rash, urticaria or angioedema, shortly after administration of a new drug or possible allergic stimulus.

Aim and Objectives To determine the contribution of pharmacist in allergic reactions.

Material and Methods A 75-year-old patient was admitted to a regional hospital for scheduled surgery for anterior rectus dehiscence. During surgery, coinciding with the administration of metamizole, he presented hypotension, tachycardia and decreased oxygen saturation, so the infusion of this drug was

immediately withdrawn. Despite administration of IV hydrocortisone, hypotension and desaturation persist. The patient began to fibrillate and went into cardiorespiratory arrest and cardiopulmonary resuscitation manoeuvres were started. The patient required the administration of adrenaline, amiodarone, noradrenaline, atropine and dobutamine.

Results He was transferred to our centre for intraoperative anaphylactic shock with troponins increasing from 41 ng/L to 3144 ng/L in the following determination and elevation of serum tryptase concentration to 15.4 µg/L, which supports the suspicion of anaphylaxis secondary to metamizole. Allergy Department performs diagnostic skin tests for latex and metamizole allergy. The skin tests were performed according to international guidelines and included 15-minute readings for immediate reactions. Pharmacy Department performed the preparation for skin tests solutions for metamizole, PRICK (400 mg/ml) and intra-dermo reaction (IDR1 4 mg/ml and IDR2 10 mg/ml) in the horizontal laminar flow cabinet. The IDR is only performed on the patient if the PRICK skin test is negative.

The skin test was negative for latex and positive in IDR 2 for metamizole. Pyrazolone allergy was confirmed and was probably the cause of Kounis syndrome.

Conclusion and Relevance Drug allergies can sometimes cause severe reactions such as anaphylactic reactions or Kounis syndrome. The prognosis of these reactions depends on a correct and immediate diagnosis and rapid treatment.

Electrocardiograms and different laboratory markers such as tryptase and troponins are available for diagnostic orientation. Suspected allergy should always be confirmed by allergy testing and the Pharmacy Department can ensure correct preparation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-054 USE OF INTRATHECAL LIPOSOMAL-AMPHOTERICIN B FOR CANDIDA MENINGITIS: A CASE REPORT

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Background and Importance Amphotericin B (AmB) is a standard treatment for opportunistic fungal pathogens such as cryptococcal meningitis. Its toxicity has been reduced by using lipid formulations of AmB (L-AmB), allowing the administration of higher doses. However, AmB shows slow and poor penetration to the cerebrospinal fluid (CSF) when administered by intravenous injection. To achieve higher concentration in CSF, intrathecal administration of L-AmB has been successfully used. Appearance of different *Candida* species in CSF are infrequent but critical. There are still significant knowledge gaps in pharmacodynamics and pharmacokinetics as the experience of central nervous system (CNS) *Candida* infections treated with L-AmB intrathecal literature is limited to one case report.

Aim and Objectives To describe the use of intrathecal L-AmB in *Candida* meningitis in one patient.

Material and Methods A 59-year-old woman with a history of obesity with metabolic syndrome was admitted to the Neurosurgery Service for bilateral cerebellar ischemic infarction needing decompressive craniectomy. During her evolution she presented as a complication CSF fistula requiring lumbar draining of CSF and subsequent urgent surgical intervention. CSF analysis revealed leukocytes 1398/mm³, 6.38 mg/dL of glucose and 315 mg/dL of protein. *C. albicans* and *Nakaseomyces glabrata* (previously named *C. glabrata*) were isolated in removed adipose flap and CSF, respectively. Intravenous and intrathecal antifungal therapy was required and so, the Pharmacy Service was asked to develop a L-AmB intrathecal injection.

Results Treatment with intravenous L-AmB (5 mg/kg/day) and oral flucytosine (25 mg/kg/6 hours) were initiated. After ten days, due to the inability of removing the lumbar drain and the persistence of CNS infection, L-AmB intrathecal was added (0.5 mg/day, dissolved in 3 mL of 5% dextrose). Given the good evolution, it was proposed to de-escalate to voriconazole, flucytosine and intrathecal L-AmB. Intrathecal L-AmB was discontinued at the 20th day of treatment when the CSF cell count, glucose and protein levels returned to normal levels and the last four CSF cultures kept sterile. L-AmB treatment was well tolerated, and no side effects were observed.

Conclusion and Relevance Despite the limitations in the interpretation of this case report, the administration of intrathecal L-AmB may constitute a less toxic therapeutic alternative to conventional AmB (deoxycholate) for *Candida* meningitis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. DOI: 10.1155/2015/340725.

Conflict of Interest No conflict of interest

4CPS-057 SEARCHING FOR A TREATMENT FOR PERIPHERAL TISSUE ISCHEMIA IN NEWBORNS: A CASE REPORT

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Background and Importance Peripheral tissue ischemia (PTI) is a complication of vascular catheterisation in newborns. Conservative measures are often insufficient. Topical nitroglycerin has been used off-label as salvage therapy. We were requested 2% topical nitroglycerin ointment (TNO) as a compounding formula for PTI in two pretermatures. Due to the shortage of raw material, an effective and safe alternative had to be sought out.

Aim and Objectives To identify an alternative for 2% TNO as therapy for PTI, and thus, to describe the effectiveness and security of applying 0,4% rectal nitroglycerin ointment (RNO) in the affected areas.

Material and Methods Prospective study between January-June 2022, of 2 newborns with PTI. Patient 1: female, 31+5; 2 days, 1500g, ecchymosis in 4 fingers. Patient 2: female, 24 +6; 5 days, 595g, marked necrosis in the pads of 5 fingers.

The manufacturing laboratory and other hospitals were contacted to find out the availability of the raw material. We also

consulted the Spanish Pharmacy Preparations and Compounding Group, and the Spanish Agency for Medicines and Medical Products (AEMPS) database for alternatives. We systematically searched MEDLINE, PubMed, Embase, Google Scholar. A close follow-up was carried out in coordination with paediatricians, and electronic prescription and computerised medical records were consulted daily, to evaluate effectiveness and security.

Results Due to the lack of raw material and alternatives in its preparation, other marketed pharmaceutical forms of nitroglycerin were evaluated (intravenous solution, transdermal patches, sublingual tablets, rectal ointment and sublingual spray). Application of 0.4% RNO in the affected areas was considered the most effective, safest, easy to dose, and quickest to acquire alternative.

Patient 1: ecchymosis completely disappeared in 48 hours of treatment. No adverse events, normal control of methaemoglobin. Good perfusion without vasoactives. **Patient 2:** 10 days to remit the marked necrosis. Well tolerated, initial slight drop in blood pressure, needing an increase of dopamine. Loss of the phalanges was avoided in both patients.

Conclusion and Relevance Commercialised 0.4% RNO in PTI was effective and safe in low birth weight premature newborns. However, it is necessary to be studied in more patients.

Pharmacist's role in the preparation, control and dispensing of medicines is essential, and its integration in the multidisciplinary team is crucial to ensure a quick response in emergency situations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-059 ABSTRACT WITHDRAWN

4CPS-060 EFFECTIVENESS AND ECONOMIC ANALYSIS OF WEIGHT-BASED VERSUS FIXED DOSING OF PEMBROLIZUMAB IN NON -MALL CELL LUNG CANCER

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Background and Importance Pembrolizumab is an anti-PDL-1 monoclonal antibody widely used in a variety of tumoural diseases. Initially used in a fixed-dose regime, trials showed that a weight-based dosing was more cost-effective and thus it was authorised by the Pharmacy Committee in our centre.

Aim and Objectives To compare the effectiveness of pembrolizumab, either as a fixed 200 mg dose or as a weight based 2 mg/kg dose every three weeks, in combination with pemetrexed and platinum, used in the first line setting as treatment of non-squamous non-small-cell lung cancer (NSCLC), with a CPS count <50%. In addition, to evaluate the economic impact of this dosing change.

Material and Methods Retrospective, observational, descriptive study of all patients treated with pembrolizumab, pemetrexed and platinum in non-squamous NSCLC between January 2018-August 2022. Collected variables: age, sex, weight, dosing, number of cycles, best response, progression-free survival (PFS), overall survival (OS). Actual cost was calculated

accounting for each patient, cycle and milligram of pembrolizumab administered.

Results Forty-six patients (38 men and 8 women), with a median of 65 years old (range 39-77) were included. 26 patients (57%) received a weight based, 2 mg/kg dose (WD group). The median body weight was 73 kg in both groups (range 49-105). Overall response rate (complete/partial response) was 60% in the WD and 50% in the FD group. PFS was 13.24 months (CI95% 10-16.5) on average in the WD group and 13.7 months (CI95% 8.1-19.1) in the FD group. OS was 18.15 months (CI95% 14.3-22) in the WD group and 18.16 (CI95% 12.6-23.6) in the FD group. No significant differences were found in the log-rank test.

Patients in the WD group received an average of 148 ± 27 mg of pembrolizumab for a median of 22 cycles; the FD group received 200 mg and a median of 41 cycles. Most patients (95%) received a lower dose than those in the FD group. On average, the total treatment cost per patient was reduced by 34% in the WD group. The estimated saved public expenditure was €420852 in this pathology.

Conclusion and Relevance Pembrolizumab weight-based dosing was as effective as the fixed dose regime and reduced costs in patients with NSCLC.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-061 APPLICATION OF PROPORTION OF DAY COVERED (PDC) TO EVALUATE ADHERENCE AND PERSISTENCE TO TREATMENT WITH FINGOLIMOD IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background and Importance Multiple sclerosis (MS) is a chronic, neurodegenerative disease of the central nervous system with an unpredictable and potentially disabling course. Although there is no definitive cure for MS, the disease-modifying drugs (DMDs) represent available strategies to improve the patient's quality of life treating relapses, modifying the disease course and managing symptoms. Therapeutic adherence is essential to obtain the efficacy of these treatments: poor adherence reduces its clinical effectiveness which can adversely impact disease progression, MS-related hospitalisation and mortality rates.

Aim and Objectives The aim of this study was to evaluate adherence and persistence to therapy with fingolimod, an oral DMD, in patients followed up by a MS reference centre.

Material and Methods With the aim to evaluate therapeutic adherence and persistence, a retrospective study has been conducted in collaboration with a neurology ward, by analysing the fingolimod prescriptions registered in a 12 months' period (June 2021 – May 2022). This study has involved 46 patients. Data were obtained by consulting an informatic program indicating for each patient: age, therapy start and eventual end date, switch from or to other drugs. Adherence was calculated as proportion of days covered (PDC) and classified in low

adherence (PDC<40%), partial adherence (PDC=40–79%) and adherence (PDC≥80%)¹.

Results The study findings showed PDC values >80% in 41 patients (89.1%), 40%< PDC <80% in 1 patient (2.2%) and PDC<40% in 4 patients (8.7%). Among the patients with low adherence, two of these suspended definitively the treatment with fingolimod, two suspended it temporarily due to bad compliance, while one was lost at follow up. Anyway, 41 patients showed persistence to fingolimod treatment over 365 days.

Conclusion and Relevance From the data obtained it is possible to assert that the oral therapy with fingolimod presents good adherence and compliance, very important factors to get clinical effectiveness of MS pharmacological treatment. This study showed also the important role of hospital pharmacist, together with the clinician, in monitoring medication adherence.

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Conflict of Interest No conflict of interest

4CPS-062 EVALUATION AND FOLLOW-UP OF PAEDIATRIC PATIENT WITH SHORT BOWEL SYNDROME ON TREATMENT WITH TEDUGLUTIDE: CASE REPORT

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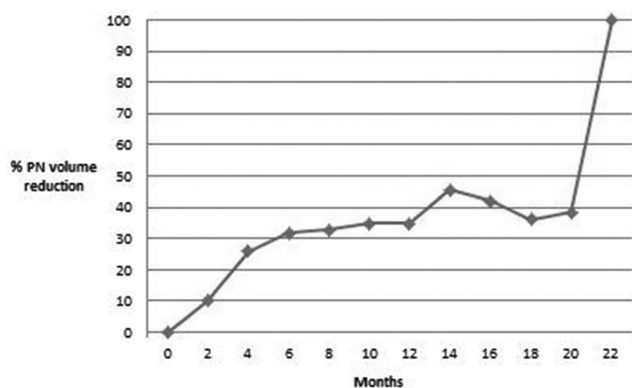
10.1136/ehpharm-2023-eahp.94

Background and Importance Short bowel syndrome (SBS) is an unusual disorder caused by resection of a part of the small bowel. Frequently these patients are dependent on total parenteral nutrition (TPN) because they suffer malnutrition. Long-term TPN is associated with complications such as infections and thrombosis. Teduglutide is a glucagon-like peptide (GLP-2) analogue that increases the proliferation of intestinal mucosal cells causing an increase in the absorption surface area and a reduction in the volume of TPN.

Aim and Objectives To evaluate the effectiveness of teduglutide in a PN-dependent paediatric patient with SBS.

Material and Methods A retrospective, observational and descriptive study of the only referenced case was designed to evaluate the effectiveness of treatment with Teduglutide. For this purpose, the reduction of the volume of TPN until its withdrawal was analysed. This withdrawal must be complete to establish the success of treatment with teduglutide. Data were extracted from the clinical database of the Andalusian Health System (Diraya).

Results The patient needed a TPN per day. The following figure shows the percentage of volume of TPN varied every two months from the start of treatment in our patient. The volume of TPN was 500 mL when the first dose of teduglutide (0.05 mg/kg/day) was administered. However, the volume decreased by 45.6% (272mL) after 14 months. Subsequently, volume increases of up to 8% (month 18) were detected due to admissions for diarrheal crises. Finally, PN was suspended due to multiple complications after 22 months.



Abstract 4CPS-062 Figure 1

Conclusion and Relevance In our case, the percentage of TPN volume reduction is higher compared to other studies collected in a recent meta-analysis.¹ Moreover, the TPN was totally withdrawn in less time than described in some studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-063 USING MACHINE LEARNING TO PREDICT PHARMACEUTICAL INTERVENTIONS IN A HOSPITAL SETTING

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Background and Importance The digitisation of hospital drug prescriptions has enabled the collection of a huge amount of data. Developing pharmaceutical decision support systems is facilitated thanks to artificial intelligence and the collected data.

Aim and Objectives Build a predictive algorithm that can detect prescriptions requiring pharmaceutical intervention (PI).

Material and Methods The algorithm was developed using machine learning techniques. Data collected during four years were extracted from patients' records from the prescription assistance software of a selected hospital. Various variables were used, including PIs generated by clinical pharmacists.

Results We used 1,961,176 drug prescriptions, including 312,591 PIs, to develop the matrix of the predictive algorithm in R. The model classifies each drug prescription according to the presence or the absence of a PI. The results after a

random forest statistical model are encouraging, yet perfectible, especially the sensibility.

A new approach of model construction is undergoing including a pharmaco-ontology gathering the characteristics of the drugs based on the summaries of product characteristics. This will allow the model to learn the context of the prescription leading to a PI and detect PIs with new data in a similar context. Such pharmaco-ontology exists regrouping only drug-drug interactions.¹

Conclusion and Relevance Pharmaceutical decision support systems usually predict PIs thanks to rules designed by pharmacists. Our model aims to detect these high-risk prescriptions thanks to machine learning and previous data validated by clinical pharmacists in their daily practice. The ontology will help associate a context to each PI previously detected and predict PIs on new data. Integrating this model into prescribing assistance software will make it easier for clinical pharmacists to detect PIs.

The predictive algorithm developed in our research project is not a substitute for pharmaceutical analysis of prescriptions. It is an expert system for the identification of risk situations that will be integrated into a team approach to clinical pharmacy practices.

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Conflict of Interest No conflict of interest

4CPS-066 BIOLOGICAL TREATMENTS USED TO TREAT HIDRADENITIS SUPPURATIVA IN A TERTIARY HOSPITAL

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Background and Importance Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease which causes painful inflamed lesions in the apocrine gland-bearing areas of the body, with high impact on patients' quality of life. Treatment is based on a combination of surgical and medical therapies, within biological agents play a key role. Adalimumab is currently the only biologic approved, what leads to use off-label biological treatments when adalimumab fails.

Aim and Objectives Our objective is to analyse the prescription of biological treatments, dosages used and adherence in a tertiary hospital to treat HS.

Material and Methods Medical charts of patients treated with biological drugs for HS where reviewed. Demographic features (sex, age, weight, height, smoking status), clinical stage (hurley score) and biological treatment used –including dosages, number of previous lines and adherence– were recorded.

Results Forty-one patients were included. Median age was 43 (IQR 30-52) and median body mass index was 27 (IQR 24-33). Nineteen out of 41 had a hurley score of 3 (H3) and 22 had a hurley score of 2 (H2). Twenty-seven patients were on adalimumab, including all patients H2 and 5 patients H3. Sixteen out of 27 were on 40 mg q.wk, and 11 were on 80 mg q.wk. The rest of H3 patients were on: infliximab 10 mg/kg (4), infliximab 7.5 mg/kg q.4.wk (1), subcutaneous infliximab

240 mg q.wk (2), brodalumab 210 mg q.wk (3), tocilizumab 8 mg/kg q.4.wk (1), guselkumab 100 mg q.4.wk (2), and ustekinumab 90 mg q.8.wk (1). Median previous lines in H3 patients were 1 (IQR 1-3), and five of H3 patients does not show a satisfactory improvement with current treatment. Only 3 patients showed an adherence <80% to treatment based on recorded dispensations.

Conclusion and Relevance Most patients with moderate to severe HS do not respond at approved dose of adalimumab, forcing to use higher doses or switching to other biological treatments, which are also used at higher doses than indicated in the Summary Product Characteristics. Unfortunately, these treatments are not always effective, and there is no consensus about how to manage it. It is necessary to keep a close follow up of these patients, looking for adverse events and lack of adherence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-067

A CROSS-SECTORAL PHARMACIST INTERVENTION FOR PATIENTS IN TRANSITION BETWEEN HOSPITAL AND GENERAL PRACTICE: A PILOT STUDY

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Background and Importance Drug-related problems (DRPs) in cross-sectoral transitions are often seen, primarily due to inconsistent information about patients' medicines at transfer.

Aim and Objectives To test a cross-sectoral pharmacist intervention for patients in healthcare transitions.

Material and Methods The study was performed in one hospital and four General Practices (GPs). The pharmacists had shared employment between the Hospital Pharmacy and the GPs.

Intervention

Transition GP to Hospital

Medication history, medication reconciliation, updating the Shared Medication Record (SMR).

Transition Hospital to GP

Medication review, overview of medication changes, follow-up telephone calls, communication with GP on DRPs.

The intervention was tested in one GP and evaluated descriptively.

Afterwards, the intervention was tested in four GPs with differing characteristics and evaluated qualitatively (semi-structured interviews).

Results Test in one GP:

Transition GP to Hospital (n=14)

The GP updated the SMR in 86% of patients. The medication history revealed discrepancies between SMR-prescriptions and actual medication intake in 64% of these patients; 91% of discrepancies were easily solved by correcting the SMR.

Transition Hospital to GP (n=30)

Hospital medication changes occurred in 79% of patients; 71% were communicated to the GP and 42% to homecare nurses.

Medication reviews revealed 55 DRPs in 67% of patients, mostly related to medication reconciliation, dose or interactions.

Follow-up telephone calls on 23 patients revealed DRPs in 30% of these.

Test in four GPs:

Seven interviews were performed – one per GP, three with the pharmacists involved (mean 71 minutes).

Clinical staff had positive attitudes towards the intervention and saw the advantages of a pharmacist with a shared employment. Economics were identified as a barrier for future implementation.

Pharmacists in smaller GP clinics had easier access to clinicians and felt a more integrated member of the team.

The larger clinics were more structured and used to interdisciplinary collaboration, allowing the pharmacist more freedom to work independently.

Conclusion and Relevance GPs had little focus on updating the SMR prior to admission. Medication changes and follow-up plans were not always communicated to the patient, GP or homecare at discharge.

Shared employment with unique access to health records in both sectors was the most important tool in identification and resolution of DRPs.

The intervention was transferable to other GPs and was considered acceptable and relevant by all.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-068

CONDUCTION OF AN AUDIT TO REDUCE THE ECONOMIC LOSS DUE TO UNUTILISED ONCOLOGICAL DRUG PREPARATIONS

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Background and Importance The costs related to unutilised oncological drugs preparations have the greatest impact on the expense of a hospital. In order to reduce wastes, it is possible to act on procedure that leads to failure to administer an already compounded oncological drug. This represents an economic loss for hospital.

Aim and Objectives The aim of the study is to identify the reasons that led to the failure to administer the compounded oncological drugs, in order to reduce errors and, wastes and economic loss.

Material and Methods The analysis was conducted between January-August 2022. Data were collected through an array including protocol, dosage, ward and reason for non-administration. It also included whether the drug had been reused (totally or partially) or thrown away and the economic loss. To conduct the analysis an audit was carried out between doctors, pharmacists and nurses aimed at identifying both the reasons that causes the economic loss and possible improvements.

Results Of 14.000 preparations, 92 were not administered; 27/92 were totally or partially reused, 65/92 were thrown away causing an economic loss of € 31.461,09. The reasons that led to the non-administration were mainly attributable to the unsuitable clinical condition of the patient at the time of administration (64%-59/92). In 19%(17/92) of cases the administration was not carried out due to errors in the prescribing phase (therapeutic indication inadequate to the protocol, absence of off label authorisation, etc.). In 12%(11/92) of cases, the cause was inadequate communication by the department (therapy confirmed in the absence of the patient). 5%(5/92) of cases were caused by interruption of administration due to adverse reactions during the infusion.

Conclusion and Relevance The results obtained have highlighted the interventions needed. It would be advisable for the confirmation of the therapy to take place on the same day as the specialist visit and clinical tests. In this way, waste related to the patient's non-presentation and/or the presence of clinical conditions incompatible with the administration would be avoided. It is also important that the validation of a protocol is carried out by at least two specialists (including an oncologist) in order to avoid inappropriate prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-070 THE CLINICAL PHARMACIST: AN ESSENTIAL ACTOR IN TIMES OF CRISIS

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10.1136/ejpharm-2023-eahp.99

Background and Importance During the health emergency period related to the emergence of the COVID-19 pandemic, clinical pharmacists have played a vital role in mitigating medication errors, especially prescription errors in hospitals.

Aim and Objectives The aim of this study was to carry out a descriptive analysis of the pharmaceutical interventions (PI) on the prescriptions of the patients of the COVID units of our establishment.

Material and Methods A prospective study was conducted on patients with positive COVID-19 status admitted to a hospital COVID unit over a period of four months. The pharmaceutical analysis prompted interventions to rectify medication-related errors.

Results The study included 108 patients. Prescription analysis led to 63 PIs. The sex ratio (M/F) was 0.5 in a favour of female predominance. Hypertension was the most common cardiovascular disease, affecting 34% of patients. Most drug-related problems were overdose accounting for 38% (16/63). The most common PI in 40% of cases was dosage adjustment (18/63). The main drug classes concerned were general anti-infective agents for systemic use 25% (16/63), followed by corticosteroids 23% (15/63) and hydroxychloroquine 19% (12/63) especially in the event of interaction with drugs that lengthen the QT interval.

Conclusion and Relevance The commitment of clinical pharmacy in such a pandemic is therefore important. Its presence has led to a reduction in the problems of drug prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. No conflict of interest.

Conflict of Interest No conflict of interest

4CPS-072 REAL-WORLD EXPERIENCE IN HAEMOPHILIA B PATIENTS AFTER SWITCHING TO FIX EXTENDED HALF-LIFE USING PHARMACOKINETIC POPULATION SOFTWARE AND MONOCOMPARTMENTAL MODEL

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10.1136/ejpharm-2023-eahp.100

Background and Importance New strategies have been developed for the prophylactic treatment of patients with haemophilia B (HB) such as extended half-life recombinant factor IX concentrates (rFIX EHL). These products have shown favourable pharmacokinetic properties, attaining a half-life 3- to 5-fold longer in rFIX EHL compared to standard FIX concentrates

Aim and Objectives Efficiency of a pharmacokinetic-based tailored prophylaxis-dosing schedule versus standard dosing (DS) is compared, in HB, treated with two rFIX-EHL.

Material and Methods Observational, analytical, prospective, multicentre study, involving HB patients, being treated with rFIX-EHL linked to albumin (rFIX-FP) or to fragment crystallisable (rFIX-Fc). Demographic and clinical data, and DS and dosing interval (DI) and actual FIX trough levels were recorded. Pharmacokinetic characterisation was performed following both a population (WAPPS-HEMO) and a linear one-compartment (OC) approach. For each approach and rFIX preparation, an estimation of the time to the target trough (5 IU FIX/dL) was made. Statistical analysis was performed by means of the Student-Fisher t-test.

Results Fifteen patients were included, nine being treated with rFIX-FP (mean age, 33 years; weight 60 kg), and six with rFIX-Fc (49 years, 86 kg). Mean DS was 3222 UI (SD, 1716) every 11,9 days (SD, 4,4) for rFIX-FP patients; and 4333 UI (SD, 606) every 14,0 days (SD, 0,0) for rFIX-Fc patients. The individual tailored DI, for a 0,05 UI/dL trough target was: applying OC; 13,6 days (SD, 5,1), -1,8 days (SD, 5,9) vs DS, representing 240 IU/day (SD, 136,1) for rFIX-FP (p=0,40), and 8,6 days (SD, 1,2), +5,4 days (SD, 1,2) vs DS, representing 508 IU/day (SD, 65,6), for rFIX-Fc, (p<0,001). Applying WAPPS-HEMO; it was 15,0 days (SD, 5,1), -3,1 days (SD, 5,3) vs DS, 217 IU/day (SD, 114,7), for rFIX-FP (p=0,12), and 10,2 days (SD, 2,5), +3,8 days (SD, 2,5) vs DS, 449,7 UI/day (SD, 129,1), for rFIX-Fc, (p=0,012).

Conclusion and Relevance Efficiency of rFIX-EHL treatment following a pharmacokinetic-based tailored prophylaxis-dosing schedule versus DS in HB patients, is significantly better. Depending on the commercial preparation, rFIX-FP or rFIX-Fc. Daily-adjusted dose, for a 5 IU FIX/dL trough target, ranges between 217-240 IU/day for rFIX-FP, or 449-508 IU/day for rFIX-Fc, according to the two pharmacokinetic approaches (OC and population based).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-073 ANALYSIS OF EFFECTIVENESS AND POSITIVE PREDICTIVE VALUE OF ANTIMICROBIAL STEWARDSHIP ALERTS USING A CLINICAL-DECISION SUPPORT SYSTEM

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Background and Importance Clinical-decision support systems (CDSS) are commonly used in clinical practice to generate antimicrobial stewardship (ASP)-alerts, which could help implement evidence-based recommendations.

Aim and Objectives To analyse use, effectiveness, and positive predictive value (PPV) of a bundle of ASP alerts generated by CDSS in a first-level hospital.

Material and Methods Observational, retrospective study. Inclusion criteria: ASP alerts generated between 1 November 2021 and 31 August 2022. The bundle of alerts included (1) >7 days of intravenous antimicrobial therapy (IAT), (2) transition from IAT to oral therapy, (3) antimicrobial dosage adjustment in renal impairment, (4) therapeutic antibiotic monitoring (TAM) and (5) duration of restricted antimicrobials (RA) (carbapenems, daptomycin, piperacillin/tazobactam, linezolid, tigecycline, ceftazidime/avibactam, echinocandins and voriconazole) >72 hours. Total number of generated alerts, number of patients with at least one alert during their hospital stay, type of alert and antimicrobial related that triggered the alert were recorded and analysed.

Effectiveness was calculated as a proportion between alerts requiring intervention and total number of alerts. PPV was calculated as a proportion between accepted interventions and total number of alerts. Both proportions were expressed as percentages (%).

Results A total of 2,546 alerts (on 927 patients) generated during the time of study. Most frequent antimicrobials that triggered the alerts were: 28.6% piperacillin/tazobactam (727/2,546), 13.6% meropenem (346/2,546), 7.5% linezolid (190/2,546), 6.7% levofloxacin (171/2,546) and 6.2% ceftriaxone (158/2,546). The type of ASP-alert generated was: >7 days of IAT (32.0%), duration of RA >72 hours (31.6%), antimicrobial dosage adjustment in renal impairment (19.2%), transition from IAT to oral therapy (13.2%) and TAM (4.0%).

The effectiveness was 14.5%, with a PPV of 9.6%. By type, effectiveness was 9.5% (type 1), 21.1% (type 2), 11.0% (type 3), 19.6% (type 4) and 18.1% (type 5). PPV for these alerts was 6.2% (type 1), 19.9% (type 2), 9.2% (type 3), 11.8% (type 4) and 8.7% (type 5).

Conclusion and Relevance The most frequently triggered ASP-alerts were duration of IAT and RA, and antimicrobial dosage adjustment in renal impairment. However, those alerts with a higher PPV were transitions from IAT to oral therapy and TAM. Further studies are needed to determine ASP-alerts with a higher effectiveness to optimise their use and to avoid alert fatigue.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-074 EFFICACY AND SAFETY OF SOTROVIMAB: RESULTS OF A RETROSPECTIVE OBSERVATIONAL STUDY IN A FRENCH HOSPITAL

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Background and Importance COVID-19 results in hospitalisation or death in older patients and those with underlying conditions. Sotrovimab is a monoclonal antibody that was designed to prevent progression of COVID-19 in high-risk patients early in the course of disease.

Aim and Objectives We aimed to assess the efficacy and safety of sotrovimab for adults infected with COVID-19 in a 400-bed French hospital.

Material and Methods This is a monocentric retrospective observational study conducted on 36 patients, which received sotrovimab from January to March 2022 in our hospital. Adult patients who had a positive result on rt-PCR or antigen SARS-CoV-2 testing and an onset of COVID-19 symptoms within the previous 5 days were eligible to treatment by sotrovimab. The patients were at high risk of progression because of older age (≥ 80 y) or diabetes, obesity, chronic kidney disease, congestive heart failure, chronic obstructive pulmonary disease, asthma and cancer. All the patients provided written informed consent.

Results Out of the 36 patients treated, mean age was 82.6 ± 9.5 y with 80% patients ≥ 75 y, BMI 25.3 ± 4.7 and sex ratio 0.3. Almost all of them were living in nursing homes (30 patients). 83% had ≥ 2 conditions considered to be risk factors for progression of COVID-19. The most common risk factors were: age ≥ 80 , congestive heart failure and cancer. 30 patients (83%) had received a complete schema of COVID-19 vaccine and 18 patients (50%) had already been infected with the SARS-CoV-2 virus. Among hospitalised patients, none who received sotrovimab was admitted to ICU. Among those living in nursing home, none was admitted to hospital. Most of the patients had few symptoms. 3 patients had disease progression leading to low flow oxygenation. 2 patients died the month following the infection, including 1 related to COVID-19. Among unvaccinated patients, 33% (2/6) had disease progression. 3 patients received corticosteroid, 5 anti-coagulant and 4 antibiotic therapy. Adverse event was reported for 1 patient (itchy skin reaction) but none had serious adverse event.

Conclusion and Relevance Sotrovimab reduces the risk of disease progression to hospitalisation or death among patients with mild-to-moderate COVID-19. This seems to be legit in our study, as does the safety, especially for elderly patients. Also, the effectiveness of this antibody against disease progression appears to be better for vaccinated patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-075 PERSISTENCE AND COST ANALYSIS OF SECUKINUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS AND PSORIASIS

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Background and Importance We know that the lack of persistence of the treatment affects its efficacy and can lead to an increase in the dose, which triggers an increase in risk and cost. Knowing the persistence of treatment with secukinumab in psoriatic arthritis (PsA), ankylosing spondylitis (AS) and psoriasis, could lead to new lines of research that compare the different therapeutic alternatives for these pathologies based on the cost per persistent treatment.

Aim and Objectives To determine the persistence of treatment with secukinumab and the cost of persistent treatment in its approved indications: PsA, AS and psoriasis.

Material and Methods Descriptive, retrospective observational study, which included adult patients with PsA, AS and psoriasis treated with secukinumab between November 2017 and August 2021. The demographic variables of age and sex were considered. The main variables were the persistence of secukinumab treatment and the annual cost per persistent treatment. Treatment persistence was analysed using the Kaplan-Meier test for each indication. The cost per persistent treatment was calculated based on the probability of persistence, which was estimated with the area under the curve for each of the three curves obtained in the Kaplan-Meier analysis. The secondary variables collected were diagnosis, duration and interruption of secukinumab treatment and previous lines of treatment.

Results We included 138 patients with a mean age of 52.2 ± 13.9 years, of whom 67 (48.6%) were women. The mean persistence of secukinumab treatment in PsA was 36.5 (95% CI 30.7-42.2) months, for AS it was 39.7 (95% CI 34.3-45.2) months and in psoriasis it was 40.4 (95% CI 35.1-45.7) months. A relationship between age, gender, indication, and line of treatment with secukinumab persistence could not be established. Median persistence was not reached for any of the three diagnoses. The annual cost per persistent treatment, calculated based on the probability of persistence, was €11,064 for PsA, €8,183 for AS, and €15,420 for psoriasis.

Conclusion and Relevance Mean secukinumab persistence was higher for psoriasis compared to PsA and AS ($p > 0.05$). The highest annual cost per persistent treatment was for psoriasis. More studies with real-life data and larger sample sizes are needed to establish the factors that play a key role in the persistence of secukinumab treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

Background and Importance Doravirine is a non-competitive, non-nucleoside reverse transcriptase inhibitor (RTI), used in combination regimens with other antiretrovirals for the treatment of HIV-1 without evidence of resistance to non-nucleoside inhibitors.

Aim and Objectives To describe the clinical-epidemiological characteristics and the clinical and analytical evolution of DORA associated with (ABC/3TC), (DTG) and (RPV).

Material and Methods To assess the efficacy of DORA, clinical response was analysed through follow-up consultations and serological tests, measuring viral load (VL), CD4-T lymphocytes, liver profile, and renal function. Follow-up was performed at 2, 4 and 6 months from the start of treatment.

Results We followed up 36 patients (31 men), with a mean age of 53.8 years (26-64), 20 were being treated with (ABC/3TC+DORA), 9 with (RPV+DORA) and 7(DTG+DORA). 77% were smokers and 7 of them diagnosed with alcohol habit. At the beginning, 94.4% had undetectable viral load ($VL < 50$ cop/ml), except for two that showed $VL > 10 \times 6$ cop/ml, probably due to non-compliance or abandonment of treatment. $VL < 50$ cop/ml were observed during the study, except for those previously mentioned that achieved a maximum reduction of 110 and 150 cop/ml. All were classified in stages A2 and A3, except two of them classified as B3. The most common side effects were diarrhoea, nausea and/or vomiting, and mild headaches. Two of them reported myalgia, although we suspect it was unrelated to DORA, as they were treated with atorvastatin 80 mg/24h for hypercholesterolemia. The patients with (RPV+DORA) came from (ABC/3TC+DORA), who were replaced by RPV due to hypercholesterolemia, liver disorders or intake of PPIs or NSAIDs. The mean CD4-T lymphocyte count was $720/\mu\text{L}$ (262-1169/ μL) and the mean creatinine was normal and between 0.9 and 1.1 mg/dl (laboratory range), except for two patients with 1.13 mg/dl and 1.29mg/dl.

Conclusion and Relevance Doravirine has been shown to be a safe and effective therapeutic alternative for HIV-1 infection, especially in patients with metabolic disorders or interactions with other drugs. The role of hospital pharmacists was to guarantee adherence to treatment and to document the most frequent side effects by reporting them to the Local HIV Commission.

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Thanks to Infectious disease Unit DORA: doravirine, RPV: rilpivirine, ABC/3TC: abacavir/lamivudine, DTG: dolutegravir, PPIs: proton-pump inhibitors, NSAIDs: non-steroidal anti-inflammatory drugs

Conflict of Interest No conflict of interest

4CPS-078 ASSESSMENT OF THE QUALITY OF A HOSPITAL'S CLINICAL TRIAL INITIATION VISIT

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Background and Importance The clinical trial (CT) initiation visit is the meeting designed to prepare the investigational site that will conduct the study. This procedure is performed with the site personnel who will assume study responsibilities. The

4CPS-077 CLINICAL-EPIDEMIOLOGICAL CHARACTERISTICS OF A COHORT OF PATIENTS TREATED WITH DORAVIRINE

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staff is divided into an investigator team and a pharmacy team.

Aim and Objectives Quality assessment at the initiation visits of a clinical trial.

Material and Methods Observational, prospective, single-centre, prospective study to evaluate the quality at the start of a CE in a tertiary level hospital. The study period was from June to August 2022. A 16-item survey was carried out, which includes the aspects to be taken into account in the performance of a CE. The questions collected were: investigator service, phase of the trial, knowledge of the presentation and stability of the drug, mode of preparation, administration and destruction of the experimental product. When the trial monitor (CRA) knew the question, a score=1 was assigned if he/she did not know=0. The tools used were: Excel® for data collection, Fundanet® for EECC registration and Google Teams® for meetings. The maximum score obtained was 20 and a poor start was considered with scores below 13.

Results Thirty CT onsets were analysed during the study period. The main clinical services under investigation were: oncology > dermatology > haematology. The phases of the trials to be initiated were: III (14), II (10), I/IB (6) and IV (0). The mean quality score obtained was 16.62. There were 4 clinical trials with a score between 10-13 and 2 trials with a score of less than 10. This led to a second review of the CE by the sponsor, which meant a delay in the start of the investigation.

Conclusion and Relevance Although most of the clinical trials met the quality criteria for initiation, there is a non-significant proportion with poor results. In those clinical trials that do not meet the minimums, a delay in initiation is necessary for the resolution of doubts on the part of the sponsor.

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Conflict of Interest No conflict of interest.

4CPS-082 MOST FREQUENT ERRORS IN THE INHALATION TECHNIQUE OF ASTHMATIC CHILDREN

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Background and Importance Asthma is a real public health problem. Inhalation therapy is the mainstay of the management of this chronic disease. one of the most important reasons for failed therapy is improper inhaler technique.

Aim and Objectives Demonstrate the most frequent errors in the technique of inhalation in asthmatic children treated in our establishment

Material and Methods A prospective observational study was conducted with asthmatic children admitted to our establishment over a period of 2 months. We have developed an evaluation grid for the inhalation technique. it was considered correct when all steps were performed correctly.

Results A total of 50 patients were included. The average age was 3.7 years. Inhalers observed were metered-dose inhalers. All patients declared having had a demonstration of the

inhalation technique mainly by their doctor. Among 50 participants, 30 (60%) performed the inhalation technique incorrectly. Errors were most common at the stage of slow, full, deep breathing as recommended by the guidelines (70%), followed by no spray agitation (15%).

Conclusion and Relevance Our results support poor inhaler technique in children that may have adverse consequences on therapeutic efficacy. The educational role of the clinical pharmacist is very important to improve the proper use of the inhalation technique and the management of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. No conflict of interest.

Conflict of Interest No conflict of interest.

4CPS-083 CREATININE AND CYSTATIN-BASED ESTIMATED RENAL FUNCTION IN VANCOMYCIN MONITORING

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Background and Importance Glomerular filtration rate (GFR) is usually estimated by using renal markers like creatinine (cr) or cystatin C (cysC), but results are not always overlapping.

Aim and Objectives Evaluate the effect of using Cockcroft-Gault (CGCr) and Chronic Kidney Disease-Epidemiology Collaboration (EPIcr, EPIcysC and EPIcr/cysC) equations in vancomycin monitoring.

Material and Methods Data from the last 5 years were collected retrospectively. All patients (n=34) who had simultaneously cr, cysC and observed vancomycin concentrations (Cobs) obtained within a range of 48h (n=47), were included. Pharmacokinetic Bayesian estimation was performed with PKS – Abbott®. For each pair GFRs/Cobs, the predicted concentration (Cp) and the daily dose required to obtain a maximum and minimum concentration of 25 and 15 µg/ml, respectively, were determined. The absolute error (E), E=Cobs-Cp=0, was used as an indicator of the adequacy of the equations used.

Results Estimated GFR showed statistically significant differences (mean ± standard deviation): CGCr=110.6 ± 76.5, EPIcr=97.5 ± 36.3, EPIcysC=42.8 ± 18.6 and EPIcr/cysC=64.3 ± 25.2 ml/min/1.73 m² (p<<0.05).

CGCr, EPIcr and EPIcr/cysC equations overestimated (E>0) renal function: E=1.50 ± 1.53 (95% confidence interval [CI]: 1.05 to 1.95), E=1.62 ± 1.35 (95% CI: 1.22 to 2.02) and E=0.47 ± 1.14 (95% CI: 0.14 to 0.81) µg/ml, respectively. Renal function was underestimated (E<0) with EPIcysC, E=-1.06 ± 1.54 (95% CI: -1.51 to -0.60) µg/ml.

The estimated differences in daily doses ranged from 100 to 1600 mg/70Kg/day, considering CGCr equation as reference.

Conclusion and Relevance The overestimation of GFR with equations dependent on cr, CGCr, EPIcr and, to a lesser extent, EPIcr/cysC, was marked in patients with abnormally low cr. Conversely, with EPIcysC equation, which depends on cysC, a biomarker independent of muscle mass, GFR was underestimated. This may be due to factors that increase cysC, without renal function impairment, such as hypertension, corticosteroid therapy and malignancy, all common in hospitalised patients, but poor data did not allow to explore this association.

The differences in the GFR estimates are clinically relevant on dosing adequacy, being suggestive that in the presence of abnormally low cr, equations with cysC are preferred.

Studies are needed to identify the variables responsible for the observed variability, in order to previously select the most appropriate equation for each case.

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Conflict of Interest No conflict of interest.

4CPS-084 EFFECTIVENESS ANALYSIS OF PEMBROLIZUMAB IN PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG CANCER WITH VERY HIGH VS HIGH PD-L1 EXPRESSION

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Background and Importance Pembrolizumab showed longer overall survival compared with chemotherapy in the first-line treatment of advanced non-small-cell lung cancer (aNSCLC)

Aim and Objectives To evaluate the effectiveness of pembrolizumab in highly expressing patients with aNSCLC, comparing patients with PD-L1 expression $\geq 90\%$ (very high) vs those with PD-L1 50-89% (high) in a tertiary hospital.

Material and Methods Observational, retrospective study. Inclusion criteria: patients with NSCLCa with pembrolizumab from August 2018 to August 2022. The clinical database of the Andalusian Health System (Diraya), its analytical module (Modulab) and the pharmaceutical validation program (Farmis-Oncofarm) were consulted. Variables collected: sex, age, ECOG (initial), smoking (current/past/non-smoker), percentage of PD-L1 expression and date of administration (first/last). Statistical analysis using the nonparametric Kaplan-Meier model with random censoring studying whether there is an increase in overall survival progression in very high versus high PD-L1 groups. A Cox regression model was included to analyse whether the rest of the variables studied affect overall survival.

Results 65 patients enrolled, 40 were included, 16 with very high PD-L1 and 24 with high PD-L1 expression (excluded 14 patients PD-L1<50% and 11 with 1 single administration of pembrolizumab). 73.17% patients were male with median age 43 years [80-37] and ECOG=1 [0-2]. 39.02% were current smokers, 53.65% were former smokers and 4.8% were non-smokers. Median overall survival in PD-L1 (high) patients was 16.46 months vs 21.57 months median overall survival in PD-L1(very high) patients. $P=0.92$ is obtained from the PD-L1(High) versus PD-L1(very high) survival curves. Current smoking is the only variable with $p=0.49$ that positively affects the probability of death with respect to those studied (age, sex, ECOG, past smoking/non-smoking, PDL).

Conclusion and Relevance Survival results in PD-L1 patients ($\geq 90\%$) compared to less expressors were positive but without statistically significant differences. It could be due to the small study sample. However, the median survival obtained is consistent with data from previous studies, it would be advisable to study this hypothesis in larger cohorts.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-088 CORRELATION BETWEEN IMMUNE-RELATED ADVERSE EVENTS AND EFFICACY IN NON-SMALL-CELL LUNG CANCER TREATED WITH NIVOLUMAB

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Background and Importance Nivolumab, an immune checkpoint inhibitor, has shown a relationship between immune-related adverse events (irAEs) and efficacy in different studies, although these are not very consistent.

Aim and Objectives The aim was to assess the association between irAEs and the efficacy of nivolumab in adults with locally advanced or metastatic non-small-cell lung cancer (mNSCLC) after prior chemotherapy.

Material and Methods Retrospective observational study including all patients with mNSCLC who received nivolumab 3mg/kg or flat dose of 240 mg every two weeks from August 2015 to June 2022 in a second-level hospital. Data collected were demographic (age, sex) and clinical (histology, smoking habit, performance status (ECOG), line of treatment, response to previous chemotherapy and irAEs).

Overall survival (OS) and progression-free survival (PFS) analysis was performed using Kaplan-Meier. The association between irAEs and OS were analysed by Cox Regression.

Results 67 patients (88% men) with a median age at the beginning of treatment of 67 years (IQR: 59-75) were included. Histology was squamous in 40% of patients. The smoking habit was: former smokers (53%), smokers (39%) and non-smokers (8%). 52% presented an ECOG 0-1. 73% of the patients received it as a second line treatment. Disease Control Rate (DCR) was 78%.

Median OS in the irAE patient group was 12.1 months (95% CI 7.9-16.3; $p<0.05$) vs 4.4 months (95% CI 1.9-7.0; $p<0.05$) in the non-irAE patient group; hazard ratio: 0.35, 95% CI 0.2-0.6; $p<0.05$. The median PFS was 8.7 months (95% CI 0-41.2; $p<0.05$) vs 3.3 months (95% CI 1.9-4.7; $p<0.05$), respectively.

Subgroup analysis of the association between irAEs and OS was:

Abstract 4CPS-088 Table 1

| irAEs type | N=28 irAEs (22 patients) | HR (95% CI) | p |
|------------------|--------------------------|----------------|-------|
| Pneumonitis | 10 | 0.62 (0.3-1.3) | 0.2 |
| Endocrine | 6 | 0.23 (0.1-0.7) | 0.014 |
| Gastrointestinal | 6 | 0.59 (0.2-1.6) | 0.3 |
| Skin | 6 | 0.2 (0.1-0.7) | 0.008 |

Conclusion and Relevance In this study our data suggest a relationship between irAEs and increased OS, specially endocrine and skin.

As our study was observational, other features as sex, ECOG or smoking habit that could bias results were not balanced between the study groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-089 CURRENT STATUS OF HEPATITIS C VIRUS INFECTION

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Background and Importance According to the 'Global health sector strategy on viral hepatitis 2016-2021' published by the World Health Organization (WHO), one of the objectives to be achieved before 2030 is to detect 90% of people infected by Hepatitis C virus (HCV) and provide treatment to 80% of them.

Aim and Objectives To describe and analyse the current situation of HCV-infected patients treated with direct-acting antivirals (DAAs) in a second-level hospital.

Material and Methods A retrospective observational study of all patients treated with DAAs in 2021 was conducted. Data collected from the electronic medical history and electronic prescription programme were: demographic data, date and setting of detection of HCV infection, coinfection with human immunodeficiency virus (HIV) and/or hepatitis B virus (HBV), viral load, degree of fibrosis, previous treatments for HCV, therapeutic option used, tolerance and effectiveness).

Results Thirty-seven patients (70% men) were included, with a median age of 56 years [interquartile range (IQR): 49-65]. The median time from diagnosis to start of treatment was 49 months (IQR: 2-145). Only 5 patients (13%) had been previously treated.

Diagnosis was made by the general practitioner (25 patients), a care centre for drug addicts (4 patients) and external consultations of different specialties (8 patients). Three patients were coinfecting with HIV. Regarding the degree of fibrosis, F0-F1: 19 patients, F2: 5 patients, F3-F4: 12 patients (6 with cirrhosis). The median viral load at the start of treatment was 3,870,000 IU/ml (IQR: 1,160,000-6,430,000).

The therapeutic options used included sofosbuvir/velpatasvir for 12 weeks (25 patients), sofosbuvir/velpatasvir for 24 weeks (1 patient with liver cirrhosis with previous decompensation, pretreated with peginterferon/ribavirin), glecaprevir/pibrentasvir for 8 weeks (9 patients), and ledipasvir/sofosbuvir 8 weeks (2 patients). There was no therapeutic failure requiring rescue with another DAA. No patient suffered adverse effects related to antiviral treatment.

Conclusion and Relevance Most of the patients were detected through the screening programs currently implemented in the different care settings of our health area, which may allow achieving the objectives of the WHO.

With these programs an early detection of the infection was achieved, which leads to less liver damage.

All our patients were treated according to the pharmacotherapeutic options officially recognised as more cost-effective.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-091 WHAT YOU NEED TO KNOW ABOUT BRUGADA SYNDROME IF YOU ARE A HOSPITAL PHARMACIST

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Background and Importance Brugada syndrome (BRS) is a rare inherited heart rhythm disorder characterised by ST-segment elevation and a potential risk of fatal arrhythmias. It is a disorder of transmembrane ion channels that predisposes to arrhythmias. Channelopathies are pure electrical diseases that are not associated with underlying structural heart disease, making early diagnosis difficult.

Aim and Objectives Review the literature related to contraindicated drugs in BRS; create an updated list to facilitate pharmaceutical validation in these patients and compare the list created with the known list of QT-modifying drugs.

Material and Methods A critical analysis of EMBASE and PUBMED studies was performed. The terms 'brugada syndrome' AND 'drugs' were used. Included studies met the following criteria: reviews, within the last 5 years and in humans only. The list of drugs described on the *brugadadrugs.org* website in 2017 was used as a preliminary basis. The medicines finally identified were classified into two groups, according to their level of risk. The group of contraindicated drugs (should not be used under any circumstances) and group of potentially dangerous drugs (with inconclusive data. Use should be evaluated on an individual basis). The list of QT-modifying drugs was obtained from the *crediblemeds.org* website and compared with the list of drugs identified for BRS.

Results Nine articles met the inclusion criteria. The medicines classified in both groups are shown in table.

Abstract 4CPS-091 Table 1

| Contraindicated drugs in BRS | Potentially hazardous drugs in BRS |
|------------------------------|------------------------------------|
| Ajmaline | Amiodarone |
| Alapinine | Atropine |
| Acetylcholine | Bupropion |
| Amitriptyline | Carbamazepine |
| Bupivacaine | Cybenzoline |
| Clomipramine | Cyamemazine |
| Desipramine | Clotiapine |
| Dopamine | Desflurane |
| Etacizine | Dexamethasone |
| Ergonovine | Diphenhydramine |
| Phenylephrine | Dimenhydrinate |
| Flecainide | Disopyramide |
| Levobupivacaine | Dobutamine |
| Lithium | Dosulepine |
| Loxapine | Doxepin |
| Methoxamine | Etomidate |
| Neostigmine | Phenytoin |
| Norepinephrine | Fluoxetine |
| Oxcarbazepine | Fluvoxamine |
| Pilsicainide | Glycopyrrolate |
| Pyridostigmine | Granisetron |
| Procaine | Imipramine |
| Procainamide | Indapamide |

| | |
|-----------------|--------------------------|
| Propafenone | Isoflurane |
| Propofol | Isoprotenerol |
| Ropivacaine | Ketamine |
| Trifluoperazine | Lamotrigine |
| | Lidocaine |
| | Maprotiline |
| | Metoclopramide |
| | Ondansetron |
| | Nitrous oxide |
| | Paroxetine |
| | Perphenazine |
| | Propranolol |
| | Sevoflurane |
| | Sugammadex |
| | Terfenadine/fexofenadine |
| | Thiopental |
| | Thioridazine |
| | Tramadol |
| | Verapamil |
| | Vernakalant |

The degree of agreement obtained with the list of QT-modifying drugs was 29.21%.

Conclusion and Relevance The low concordance with respect to the list of QT-modifying drugs makes it necessary to define a specific drug list for patients with RBS. This could improve the quality of treatment validation by the hospital pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-092 STATISTICAL RELATIONSHIP BETWEEN BIOMARKERS WITH PROGNOSTIC VALUE IN ANTI-PDL1 TREATMENTS IN CANCER PATIENTS

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Background and Importance The prognostic value of biomarkers such as neutrophil/lymphocyte ratio (NLR), derived neutrophil/lymphocyte ratio (dNLR) and platelet/lymphocyte ratio (PLR) is increasingly studied, showing their usefulness in patients with different anti-PDL1 treatments in the context of oncological pathologies.

Aim and Objectives To analyse whether there is a statistical relationship between these three parameters and to analyse the biomarkers and to analyse their effect on survival.

Material and Methods Observational and retrospective study in patients treated with pembrolizumab and diagnosed with non-small-cell lung cancer (NSCLC) in a tertiary level hospital. Demographic variables (sex and age) were collected, NLR as neutrophil/lymphocyte count, dNLR as neutrophil/leukocyte/neutrophil count and PLR as platelet/lymphocyte count were calculated. Progression-free survival (PFS) and overall survival (OS) were calculated using the Kaplan-Meier method and log-rank test as a hypothesis test. The cut-off points were NLR=5, dNLR=3 and PLR=200. Spearman's correlation test was used to check the correlation between the three

biomarkers (previously the non-normality of the samples was checked by Kolmogorov-Smirnov test).

Results A total of 74 patients treated with pembrolizumab were registered, 59 men (80,8%) and 14 women, with a median age of 65 [83-37] years. Median neutrophil count was 5.45 [6.1-1.5] $\times 10^9$ neut/L, lymphocyte count was 1.45 [3.9-0.2] $\times 10^9$ linf/L and platelet count was 174.7 [56.92-1345] $\times 10^9$ platelets/L. Table 1 shows the survival results obtained.

Abstract 4CPS-092 Table 1 Results of Kaplan-Meier survival method and log-rank test

| | Progression-free survival | | Overall survival | |
|----------------|---------------------------|--------------------|-----------------------|--------|
| | Median IC95% (months) | p LR-t | Median IC95% (months) | p LR-t |
| NLR<5 (n=41) | 16,1 (10,5-21,6) | 0,05 | 24,9 (18,5-31,3) | 0,01 |
| NLR>5 (n=29) | 12,5 (5,1-19,9) | 17,4 (9,1-25,6) | | |
| dNLR<3 (n=42) | 14,65 (9-20) | 0,09 | 23 (17,1-30,6) | 0,04 |
| dNLR>3 (n=26) | 11,5 (13,7-19,3) | 17,09 (8,2-25) | | |
| PLR<200 (n=42) | 15,6 (10,15-21,1) | 0,04 | 26,25 (19,87-32,64) | 0,001 |
| PLR>200 (n=26) | 9,97 (2,86-17,1) | 11,31 (3,86-18,79) | | |

Spearman's correlation test showed statistical significance in the relationship between the three biomarkers showing a strong association between them, Spearman's coefficients obtained are shown: NLR-dNLR 0.934 (p=0), NLR-PLR 0.697 (p=0) dNLR-PLR 0.616 (p=0).

Conclusion and Relevance For the three biomarkers there are significant differences in survival outcomes for the selected cut-off points, offering prognostic value for our patients. Spearman's test indicates that there is a correlation between the biomarkers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-093 POLYPHARMACY AND INAPPROPRIATE DRUGS IN PATIENTS WITH OROPHARYNGEAL DYSPHAGIA

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Background and Importance Oropharyngeal Dysphagia (OD) is a symptom where patients who present it usually have multiple nutritional, functional, morbidity and quality of life complications. It is associated with a higher incidence of aspiration pneumonia. OD can be caused by adverse effects of medications, such as dopamine antagonists (DA), central nervous system depressants (CNSD), anticholinergic drugs, which block the action of acetylcholine, among others.

Aim and Objectives To analyse the prevalence of polypharmacy (≥ 5 chronic drugs) and inappropriate drugs (anticholinergics and CNSD) in patients with OD. It was also

calculated anticholinergic risk (AR) using different anticholinergic scales (AS).

Material and Methods A retrospective observational study was carried out in a general tertiary hospital. Data from patients diagnosed with OD were collected from the otorhinolaryngology consultation of years 2019-2021. Demographical, clinical and pharmacotherapeutic data were obtained from the electronic medical record. AR was calculated using anticholinergic scales (AS) with the anticholinergic burden calculator (available at www.anticholinergicscales.es).

Results Sixty patients were recruited; 4 were low due to not having their medication prescription record. Of the 56 remaining patients, 28 (50%) were men. The average age was 73.2 years [14.5-90.3].

Forty-three (76.79%) patients were polymedicated. 461 drugs were analysed, finding 104 (22.56%) potential medications to cause OD. Of these, 91 (19.74%) were drugged with AR, 13 (2.82%) were CNSD and 7 (1.52%) were DA. When analysing the AS scale it was found: that 12 (21.42%) patients had a high-risk AR, 15 (26.78%) had medium risk load and 3 (5.36%) patients had low risk AR being mostly men (56.66%). The most repeated drug was tamsulosin (1.73%).

Conclusion and Relevance It is observed that there is a high percentage of patients with OD are polymedicated. The prevalence of AR is high. A good pharmacological review with AS must be carried out and try to make a description, to reduce the anticholinergic load and the number of drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-095 INFUSION AUDIT IN HAEMATOLOGY: IMPORTANCE OF EVALUATION AND OPTIMISATION OF PROFESSIONAL PRACTICES

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Background and Importance Intravenous administration is the source of numerous identified risks requiring periodic evaluation of professional practices. In February 2022, an observational audit in the haematology unit was carried out in order to optimise the infusion setups.

Aim and Objectives The objective of this audit is to evaluate the professional practices of the nursing team and thus to implement permanent corrective actions.

Material and Methods An evaluation grid based on the good infusion practices defined by the 'Observatoire du Médicament, des Dispositifs médicaux et de l'Innovation Thérapeutique' Centre was updated and validated by a multidisciplinary group.

In February 2022, two pharmacy interns observed 62 drugs administered by analysing the prescriptions of all hospitalised patients in the unit.

Results Regarding the infusion configuration, only 90% of the peripheral infusion line were closed using an adapted plug. No misuse was observed on the administration of parenteral nutrition.

Regarding flow rate problems, only one infusion configuration exhibits an infusion drip chamber filled beyond the maximum limit. Interestingly, during a flow-sensitive drug infusion

and contrary to guidelines, absence of non-return valve was observed in 9% of the infusion configuration.

A potential risk of drug incompatibility has also been identified with the current perfusion set-up.

Conclusion and Relevance The results of this audit appear to be very positive. The haematology unit, whose nursing team is aware of the risks associated with the administration of chemotherapy, is a unit accustomed to the availability of pharmacists.

This audit allowed us to observe some errors during infusion practice: inadequate programmed flow rate, absence of plugs and absence of non-return valve during flow-sensitive drugs infusion.

In order to improve infusion practice, a new standardised infusion set-up will be proposed to the unit including non-return valves. This set-up should make it possible to reduce the risks, particularly those related to flow rate and incompatibilities.

However, this change in practice will require support for the teams and a new audit to evaluate the impact of this work.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-096 EVOLUTION OF SELECTIVE IMMUNOMODULATE THERAPY IN SPECIAL SITUATIONS

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Background and Importance Biological therapy has supposed a great therapeutical progress on immunomodulated diseases. Nevertheless, some pathologies have no labelled indication. Therefore, medication access on special situations are essential and more frequent.

Aim and Objectives The objective of this study is to analyse the request on immunomodulate therapy in special situations among last years.

Material and Methods Retrospective study performed in a tertiary hospital between January 2017-December 2021. Off-label (OL) and compassionate use (CU) requests on selective immunomodulatory drugs received by the Pharmacy and Therapeutics committee were included (P&T).

Data collected: number, type and drugs requested, indication, clinical department, and approval by P&T. A temporal evolution on the number of requests, drugs and clinical departments was analysed. On those which showed an increase, an exhaustive analysis was performed.

Results A total of 95 requests were identified, 78 (82.1%) OL and 17 (17.9%) CU, representing a 17.3% (95/549) of all kind of requests to the P&T. Twenty-one drugs and 42 different indications were identified. Eighty-seven (91.6%) were approved; six were denied due to lack of evidence and two due a lack of funding by the national health system.

Main drugs requested ustekinumab (18 (18.9%)), dupilumab (15 (15.8%)), rituximab (14 (14.7%)), tofacitinib (9 (9.5%)), tocilizumab (7 (7.4%)), adalimumab (5 (5.3%)).

Requesting clinical departments dermatology (48 (50.8%)), digestology (20(21.1%)), rheumatology (18(18.9%)),

nephrology (5(5.2%)), internal medicine (2(2.1%)), pneumology (1(1.1%)), coronary unit (1(1.1%)).

An exponential increase was observed among OL and CU during the study period (requests/year: 8/2017, 12/2018, 14/2019, 21/2020, 40/2021; $y=5.2269e0.3778x$, $R^2=0.9559$).

The main growth was observed in dermatology ($y=1.99e0.4277x$, $R^2=0.768$) and digestology ($y=1.5x-0,5$, $R^2=0.9375$).

Indications requested by dermatology: atopic dermatitis (15 (31.3%)), hidradenitis suppurativa (8 (16.7%)) folliculitis decalvans (4 (8.3%)), others (21 (43.8%)).

Drugs requested by dermatology: dupilumab (15 (31.3%)), ustekinumab (5 (10.4%)), tofacitinib (4(8.3%)), mogamulizumab (4 (8.3%)), adalimumab (4 (8.3%)), secukinumab (3 (6.3%)), rituximab (3 (6.3%)), infliximab (2 (4.2%)) and others (8 (16.7%)).

Indications requested by digestology: ulcerative colitis (13 (65.0%)), Crohn's disease (4 (20.0%)), collagenous colitis (3 (15.0%)).

Drugs requested by dermatology: ustekinumab (13 (65.0%)), tofacitinib (4 (20.0%)), vedolizumab (2 (10.0%)), infliximab 1 (5.0%).

Conclusion and Relevance

- Dermatology performed half of requests, specially in atopic dermatitis and hidradenitis suppurativa, which have obtained more evidence on their treatment last years.
- The exponential increase on number of requests in special situations, specially off-label ones, reveals the need to increase the resources assigned to evaluation committees.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-099 NINTEDANIB AND PIRFENIDONE IN IDIOPATHIC PULMONARY FIBROSIS: COMPARATIVE EFFECTIVENESS AND SAFETY IN A THIRD-LEVEL HOSPITAL

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Background and Importance Idiopathic pulmonary fibrosis (IPF) is a chronic and progressive disease characterised by a bad prognosis. The only available pharmacological treatments are two antifibrotic drugs, pirfenidone and nintedanib, which slow down the development of the disease but have an unfavourable safety profile, with a high incidence of adverse effects.

Aim and Objectives To compare the effectiveness and safety of the two available antifibrotic drugs, nintedanib and pirfenidone, used as treatment of idiopathic pulmonary fibrosis.

Material and Methods Retrospective, observational and descriptive study of all the patients diagnosed with idiopathic pulmonary fibrosis treated with pirfenidone or nintedanib between January 2014 and February 2022. The collected variables were: age, sex, forced vital capacity (FVC), duration of treatment, adverse effects (AE) and grade, and survival. Patient confidentiality was preserved throughout the data gathering.

Results 41 patients, 30 of them men, were included. 24 treated with nintedanib and 17 with pirfenidone, both groups had a median age of 73 years old (range 54-89).

Average difference from basal FVC was +4,82% at 6 months, + 1,85% at 12m, +1,85% at 16m and -6,25% at 24m with nintedanib and +2,4% at 6m, -5,5% at 12m, -5,5% at 16m and -18,5% at 24m with pirfenidone.

Median duration of treatment was 26 months with nintedanib and 45 months with pirfenidone. Overall survival was 65 months (CI 95% 57.5-73.9) on average for nintedanib and 33 months (CI 95% 23.4-42.5) for pirfenidone (log-rank $p=0.009$).

Treatment was poorly tolerated, with a high incidence of AE (nintedanib: no AE: 21%, G1: 4%, G2: 42%, G3: 29%, G4: 4%; pirfenidone no AE: 53%, G1: 12%, G2: 29%, G3: 6%). Most frequent AE was gastrointestinal reactions in 17 (71%) with nintedanib and 6 (35%) with pirfenidone, followed by headache in 3 (13%) with nintedanib and 4 (24%) with pirfenidone, hepatic enzyme alteration in 5 (21%) with nintedanib, dermatological 4 (17%) nintedanib, renal toxicity in 2 (8%) with nintedanib, haematological 1 (4%) with nintedanib.

AE caused the discontinuation of treatment in 11 (46%) patients with nintedanib and in 4 (24%) with pirfenidone.

Conclusion and Relevance Nintedanib was significantly more effective in terms of overall survival, with a slower decrease in FVC, although presented worse tolerance than pirfenidone, as treatment of IPF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-100 VALIDITY, RELIABILITY AND USER-PRACTICABILITY OF A CLASSIFICATION TOOL FOR DRUG-RELATED PROBLEMS AND PHARMACIST INTERVENTIONS WITHIN AN UPPER AUSTRIAN HOSPITAL TRUST

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Background and Importance In order to fully capture the contribution of clinical pharmacists to pharmacotherapy, a standardised and validated classification tool for drug-related problems (DRP) and pharmacist interventions (PI) is essential for both research purposes and management tasks. Such an instrument is not yet available in Austria. Therefore, the documentation system, 'DokuTool', has been developed by an Upper Austria hospital trust following the expansion of its clinical pharmacy services.

Aim and Objectives This study aimed to assess the reliability, validity and user-practicability of the classification system, 'DokuTool', within an Upper Austrian hospital trust.

Material and Methods Two-phase quantitative methodology: 1) Twenty-nine clinical pharmacists classified 24 sample cases with 'DokuTool'. Inter-rater and test-retest reliability was determined using the kappa statistic. Validity was determined by correlating the individual ratings with a gold standard (majority vote of experts) using contingency coefficient. 2) User-practicability was assessed by an online survey using a 5-point Likert scale.

Results 'DokuTool' achieved moderate agreement in the inter-rater reliability test of the two main categories 'Type of DRP'

($k = 0.528$ [95% confidence interval (CI): 0.514 – 0.541]) and ‘Cause of DRP’ ($k = 0.594$ [95% CI: 0.587 – 0.601]). The category ‘Planned PI’ showed substantial agreement ($k = 0.638$ [95% CI: 0.629 – 0.647]). Test-retest reliability achieved an almost perfect agreement for all three main categories: ‘Type of DRP’ ($k = 0.825$ [95% CI: 0.734 – 0.915]), ‘Cause of DRP’ ($k = 0.896$ [95% CI: 0.825 – 0.967]) and ‘Planned PI’ ($k = 0.891$ [95% CI: 0.819 – 0.964]). The median rater-specific contingency coefficient was 0.84 [range: 0.75 – 0.89], 0.95 [0.94 – 0.96] and 0.93 [0.91 – 0.94]. ‘DokuTool’ was rated comprehensive (median: 2 [interquartile range: 1.75]), user-friendly (2 [1]) and practical (2 [1]). Time expenditure was considered adequate (3 [1]), but the completeness and clarity of the categories were rated negatively (3 [2]).

Conclusion and Relevance Moderate to substantial inter-rater reliability, almost perfect test-retest reliability, good criterion validity and acceptable user-practicability demonstrated that ‘DokuTool’ is a valid and reliable classification instrument of DRPs and PIs, that is well-suited for Austria.

However, the evaluation of usability led to suggestions for improvement for future versions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-101 CAUSALITY OF ADVERSE DRUG REACTIONS IN HIV-PATIENTS TREATED WITH BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE

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Background and Importance Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) has been positioned as a preference drug in the main guidelines in the treatment of HIV. BIC/FTC/TAF has demonstrated an excellent safety and efficacy profile in pivotal studies. In clinical practice few studies have been published concerning these two aspects.

Aim and Objectives To assess the causality of adverse drug reactions (ADRs) of HIV-patients treated with BIC/FTC/TAF.

Material and Methods Observational and retrospective study from May 2019 to March 2021 in a general hospital. The patients were classified into two cohorts based on whether they continued treatment or not after reporting ADRs. The variables analysed were: age, sex, prior and subsequent antiretroviral treatment (if applicable). All ADRs were classified according to the organ class system. The causality was evaluated with The Naranjo Algorithm. This is a method to assess whether there is a causal relationship between an identified untoward clinical event and a drug, using a simple questionnaire to assign probability scores. The total score are: definite (>9), probably (5-8), possible (1-4) and doubtful (0).

Results A total of 1,275 patients were collected, of which 185 patients (14.5%) with at least one ADR were evaluated. The first cohort consisted of 53 patients (4.1%) who changed their

treatment (25 men (48%) versus 27 women (52%), median age 56 [IQR 51 – 60]); while the second cohort consisted of 132 patients (10.4%) who maintained such antiretroviral treatment (107 men (80.5%) versus 25 women (18.8%), median age 45 [IQR 33 – 55]). In total 266 ADRs were detected: 216 probable, 46 possible and 4 improbable relationship. A 27.8% were headaches ADRs, 18.8% gastrointestinal effects (diarrhoea, abdominal pain, nausea), 16.2% sleep disorders (insomnia) and 37.2% others.

Conclusion and Relevance The frequency of ADRs of HIV-patients in treatment with BIC/FTC/TAF is low and most of people who suffer it can continue with their treatment. Most ADRs were consider as probably and the most common was the headaches, the gastrointestinal disorders and the insomnia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-103 PHARMACOKINETIC INTERACTION STUDY OF OSIMERTINIB AND DIGOXIN: A CASE REPORT

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Background and Importance Tyrosine kinase inhibitors (TKI) have meant a change of paradigm in the treatment of non-small-cell lung cancer (NSCLC) with driver mutations. Many TKI drugs interact with the drug-efflux pump P-glycoprotein (P-gp) involved in the absorption and/or transport of drugs and xenobiotics. P-gp inhibitors, as osimertinib, may increase the serum concentration of P-gp substrate. This is key in narrow therapeutic range drugs, like digoxin, as levels higher than 1.2 ng/ml are associated with increased risks of death. Although this interaction has been described in theory, this is the first case report in scientific journals.

Aim and Objectives To describe the potential drug-drug interaction between osimertinib and digoxin mediated by P-gp in a 77 year old woman with a history of permanent atrial fibrillation. The patient was diagnosed with eGFR mutant NSCLC stage IIB. Left lower lobectomy was performed. Subsequent tumour progression provoked osimertinib treatment and after that an increase of previously in range digoxin levels is recorded.

Material and Methods

Descriptive and retrospective case report Data were obtained from computerised medical records. Mediware software was used to make pharmacokinetics prediction and adjust dosage recommendation.

Results Osimertinib treatment started at doses of 80 mg/day in March 2022 and after two months it was interrupted because of diarrhoea and mucositis. Two weeks later the patient shows severe hypomagnesemia requiring hospitalisation. Laboratory results revealed serum digoxin level of 1.38 ng/ml, thus digoxin dose was reduced from 125 mcg/day to 100 mcg/day. At hospital discharge osimertinib treatment was restarted with half-dose reduction. The next digoxin levels went up to 1.9 ng/ml, so the Pharmacy Department recommended to reduce the digoxin dose to 75 mcg/day. Thereafter, digoxin levels

increased up to 1.31 ng/ml and 1.45 ng/ml, requiring dose reduction to 50 mcg/day.

Conclusion and Relevance In our case report, therapeutic drug monitoring of digoxin has allowed for the detection of increased levels of digoxin and higher risks of toxicity. It coincides with the start of osimertinib exposure, being the P-gp inhibition the most plausible factor for this finding.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-104 ANALYSIS OF INTERVENTIONS IN PHARMACEUTICAL VALIDATION IN A THIRD LEVEL HOSPITAL

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Background and Importance Pharmaceutical validation is necessary to achieve maximum clinical benefit. Thanks to clinical pharmaceutical interventions (CPI) many prescription errors, drug interactions and adverse reactions are prevented.

Aim and Objectives To analyse CPI carried in a 1040-bed hospital and to assess the acceptance rate of these interventions.

Material and Methods Observational and retrospective study of CPI performed between June and August 2022 in hospitalised patients. They were recorded in the pharmaceutical intervention module of PharmNet application of Millennium programme. The variables evaluated were: episode number, date, type of intervention, prescribing service, drug and indication. Interventions that led to a change in the prescription within 48 hours of the CPI were considered accepted.

Results A total of 324 interventions were analysed in 293 patients, which were 100% of those performed. More than half of the interventions were therapeutic duplications (36.4%; n=118) and dosing errors (25.9%; n=84) (overdose 62% and underdose 23%). They were followed in frequency by: incomplete medical orders (18.5%; n=60); drugs not indicated (6.8%; n=22); drug interactions (4.6%; n=15); inappropriate dosage form (4.6%; n=15) and adverse events (3%; n=10). The distribution of the number of interventions according to prescribing service was: cardiology (n=54); gastroenterology (n=44); pneumology (n=32); internal medicine (n=30); vascular medicine (n=29); neurology (n=23) and traumatology (n=28). The acceptance rate of the CPI was 80,3% (n=260) with the following service distribution: 90% internal medicine; 87.5% pneumology; 84% gastroenterology, 82.7% neurology and 79.3% cardiology. Drugs which caused most interventions were antibiotics (17%), anti-inflammatory drugs (11.4%), cardiovascular agents (11.1%) and antidepressants (9%).

Conclusion and Relevance The clinical pharmaceutical interventions proposed to the prescribing services were highly accepted. This shows the importance of pharmaceutical validation by the hospital pharmacist to better manage the quality and safety of pharmacological treatment prescribed to patients during their hospital stay.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-105 CEFIDEROCOL TREATMENT IN COVID-19 POSITIVE PATIENTS CO-INFECTED WITH PAN-RESISTANT PSEUDOMONAS AERUGINOSA

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Background and Importance Immunosuppression due to SARS-CoV2 infection (COVID19) has caused an increase in identification of multi-resistant organisms in Intensive Care Units (ICU), among which multi-resistant *Pseudomonas aeruginosa* rise about others. Cefiderocol is a costly new cephalosporin against extensively resistant Gram-negative bacteria.

Aim and Objectives The objective of this study is to describe the characteristics and clinical results of patients treated with cefiderocol, as well as the dosage of this treatment, in ICU inpatients with COVID19 pneumonia and co-infected with pan-resistant *Pseudomonas aeruginosa*.

Material and Methods Retrospective observational study carried out in a general hospital from September 2020 to December 2021. Inpatients at ICU diagnosed with COVID-19 pneumonia that were treated with cefiderocol due to *P. aeruginosa* infection were included. Collected data were: days admitted in ICU, days of treatment with cefiderocol, concomitant treatment, cefiderocol dosage and results of the treatment.

Results Three patients fulfilled the inclusion criteria among 70 patients admitted to ICU with COVID-19 in the study period (4.3%). All patients included were men and the median age was 66.6 ± 6.5 years old. They presented as comorbidities obesity, hypertension and diabetes mellitus. They were admitted during 87 ± 28.6 days, with detection of pan-resistant *P. aeruginosa* in the range of 32.5 ± 2.1 days after admission at ICU. All of these cultures were only sensitive to cefiderocol, being resistant to all other tested antibiotics. Due to that, all patients received cefiderocol during their stay and dose adjustment to their renal function or renal replacement therapy were applied. Every patient received a bolus of 2 grams in 30 minutes and the maintenance dose in at least 3 hours. The average of treatment days was 20.5 ± 4.5 days. In all cases, the isolated strains were sensitive to colistin, so cefiderocol was used in combination with it. The results of the treatment were disparate: one cure, one death, and one development of resistance to cefiderocol.

Conclusion and Relevance Cefiderocol use for multi-resistant bacteria treatment requires prior knowledge of its pharmacokinetics, taking into account the physiological factors of patients in its dosage. New treatments are not exempt from the development of resistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-107 EFFECT OF PATIENT BODY WEIGHT ON THE PHARMACOKINETIC BEHAVIOUR OF AMIKACIN

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Background and Importance Obesity is a disease that influences numerous physiological processes. Currently there is little pharmacokinetic data in obese patients and extrapolated data from patients with normal weight are often used. In order to optimise the dosage of drugs in obese patients, it is necessary to design specific population models in this group of patients.

Aim and Objectives To analyse the differences in the pharmacokinetic parameters of amikacin in hospitalised patients based on body mass index (BMI).

Material and Methods Retrospective observational study in which patients treated with amikacin between January and August 2022 were analysed. The variables collected were: age, weight, height, sex, serum creatinine, dosage regimen and amikacin level.

Patients were classified according to their BMI: less than 30 Kg/m² (non-obese) and greater than 30 Kg/m² (obese). The mean and standard deviation of the volume of distribution (Vd) and clearance (Cl) of the two groups were calculated using a pharmacokinetic programme (MwPharm) based on a single compartment model.

Statistical analysis was performed using Student's t-test for independent samples.

Based on the data collected, BMI and creatinine clearance (according to the Cockcroft-Gault equation) were calculated. Patients with a glomerular filtration rate of less than 30 mL/min were excluded.

Results 42 patients (52% women) with 156 levels of amikacin and a mean age of 69 ± 28 years were included. The distribution of patients according to BMI was: 59% normal weight and 41% obese.

The mean and standard deviation of Cl of obese patients and normal weight were 2.67 ± 1.41 L/h and 1.92 ± 1.04 L/h, respectively. P-value from t-test was 0.04 (p < 0.05) for Cl.

Vd data were 0.314 ± 0.068 L/Kg (obese) and 0.28 ± 0.034 L/h (normal weight). P-value was 0.648 (p>0.05) for Vd.

Conclusion and Relevance Statistically significant differences were found in Cl between both groups: in obese patients amikacin Cl was higher than in patients with normal weight.

No significant differences in Vd were found between the two study groups.

Future studies are needed to design population pharmacokinetic models of amikacin in obese patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-108 PATIENT AND PHYSICIANS'S SATISFACTION WITH CLINICAL PHARMACY SERVICES ON A HAEMATOLOGY WARD IN A LARGE TERTIARY CARE HOSPITAL

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Background and Importance Oral anticancer therapy is increasingly used for the treatment of hematologic malignancies. Despite its convenience, several challenges such as medication adherence may impact therapeutic effectiveness and outcome.

Therefore, a clinical pharmacy service was initiated on the haematology ward at our hospital .

Aim and Objectives To determine the satisfaction rate of the clinical pharmacy service in patients with haematological malignancies treated with oral anticancer therapy and in haematologists-in-training.

Material and Methods Between January and May 2022, a survey was developed to assess patient and haematologists-in-training satisfaction and perceived value of healthcare services provided by clinical pharmacists at a tertiary care hospital. The survey was taken by a pharmacist not involved in daily clinical pharmacy practice. The survey contained questions addressing demographic, type of oral anticancer therapy and pharmacist-specific items. Responses were analysed using descriptive statistics. Satisfaction was assessed by 5 Likert-scale questions and either 8 or 4 open-ended questions for cancer patients and for haematologists in training, respectively. We aimed to have a satisfaction rate of at least 80%.

Results A total of 65 patients and 11 haematologists-in-training participated in the survey. All patients (100%) ranked the pharmacists' explanation about medication intake and side-effects as either very satisfying or satisfying . Counselling about drug interactions was the only criterion that did not result in the achievement of the predefined 80% satisfaction rate, with 27.6% of patients being very satisfied and 51.7% of patients being satisfied about this topic, respectively. Overall, the majority of patients (89.7%) indicated that pharmacist counselling and follow-up visits were of added value. All 11 included haematologists in training expressed high levels of satisfaction with the clinical pharmacist service.

Conclusion and Relevance High levels of satisfaction with the clinical pharmacist service was reported by both patients with a haematological malignancy and haematologists-in-training. This survey identified that counselling on drug interactions of oral cancer therapy might be improved. Further studies may include assessment of the association between patient satisfaction and compliance and treatment outcomes. Also the added value and cost effectiveness of the clinical pharmacist service needs to be investigated in future research.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-109 THERAPEUTIC DRUG MONITORING OF VANCOMYCIN IN ONCOLOGIC AND HAEMATOLOGIC PATIENTS: REAL-WORLD DATA

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Background and Importance Vancomycin clearance tends to be higher in patients with neutropenia¹; consequently, therapeutic drug monitoring (TDM) is highly recommended.²

Aim and Objectives To assess the achievement of a therapeutic pharmacokinetics/pharmacodynamics (PK/PD) target of vancomycin in oncologic and haematologic patients using trough-only TDM.

Material and Methods We conducted a retrospective and descriptive study that included oncological and haematological

patients admitted to a second-level hospital, starting treatment with vancomycin and dosing adjustment guided by TDM at the Pharmacy service.

Demographic variables, Cockcroft-Gault creatinine clearance (CrCl), initial dosage, dose adjustments, the first trough level, duration of treatment, and reason for withdrawal were collected. Renal impairment was defined as CrCl < 60 ml/min. Dosages of 15-20 mg/kg/dose and trough levels between 10 and 20 µg/ml were considered optimal for intermittent infusion schedules. TDM used the PKS[®] software.

Results Vancomycin trough levels were obtained in 49 patients; 12 were oncological, and 37 were haematological.

Dosage adjustment was necessary for 30 patients (61%), 25/30 due to subtherapeutic level (trough level <10 µg/ml) and 5/30 due to supratherapeutic level (through level >20 µg/ml with or without renal impairment).

The initial mean dosage was 13,7 ± 2,5 mg/kg/12h, except in three patients who started every 24 h due to renal impairment. After the dosage adjustment, the recommended mean dosage was 14 ± 3 mg/kg/8h in 18 patients and 13,6 ± 7,6 mg/kg/12h in 12 patients.

The mean duration of antibiotic treatment was 7 ± 4,2 days. The reasons for stopping the treatment were: clinical improvement (n=29), switch to a target treatment (n=10), clinical deterioration (n=9) and nephrotoxicity (n=1). Nine patients died.

Conclusion and Relevance More than half of the patients had subtherapeutic vancomycin levels and required antibiotic dose adjustment.

Most patients required shorter dosing intervals rather than increased doses to reduce the incidence of nephrotoxicity.

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Conflict of Interest No conflict of interest

4CPS-110 ASSOCIATION BETWEEN BASELINE CHARACTERISTICS AND FIRST-LINE CHEMOTHERAPY IN ADVANCED GASTRIC CANCER PATIENTS

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Background and Importance There is no standard first-line regimen for HER2-negative advanced gastroesophageal adenocarcinoma.

Aim and Objectives To study the variability in the choice of regimens according to tumour, patient baseline variables and prescribing physician.

Material and Methods Patients with HER2-negative advanced gastroesophageal adenocarcinoma diagnosed between 2008 and 2021 from a multicentre registry (34 centres) were included. Patients received chemotherapy based on platinum (cisplatin or oxaliplatin) and fluoropyrimidine (5-fluorouracil or capecitabine). Association between the following baseline variables: specialty of the prescribing oncologist, ECOG-PS (Eastern Cooperative Oncologic Group Performance Status), serum albumin, tumour location, Lauren classification and platinum and fluoropyrimidine regimens were evaluated and Chi 2 test was performed.

Results A total of 1334 patients were registered, 66.49% (n=893) were male. Seventy percent of our population was treated almost equally with FOLFOX6 (n=468) and XELOX (n= 466), followed by XP 19% (n=252), FP3w 7% (n=95) and in fewer percent with FUOX modified 3%(n=44), FP4w 1% (n=12) and FLO (n=6). Oxaliplatin was the most commonly used platinum (73%, p=971) while both fluoropyrimidines were administered in a similar proportion (capecitabine 54%). Patients were mainly treated by an oncologist specialising in gastric cancer (95%). General oncologist preferred oxaliplatin-based regimens (46% vs 6%) and specialist opted more for cisplatin and capecitabine associated regimens (p=0.031). Patients with worst performance status (ECOG=2) were treated to a greater extent than the overall population with schemes based on oxaliplatin and 5-fluorouracil 50% versus 38% of the general population. Those with ECOG=0 received more than expected schemes with cisplatin and capecitabine (21%, n=55). Patients with baseline hypoalbuminaemia (albumin < 35 g/dL) received intravenous fluoropyrimidine schedules with both oxaliplatin (47%, n=156) and cisplatin (9%, n=3) in a higher proportion than expected (p<0.000). According to Lauren's classification, there was a higher use of capecitabine versus 5-FU in intestinal tumours. This trend is reversed in diffuse tumours (p<0.000).

Conclusion and Relevance In this study we found an association between the platinum and fluoropyrimidine selected in patients with advanced gastric cancer and certain baseline variables. Future studies are needed to evaluate whether this choice has an impact on patient benefit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. This study is part of a doctoral thesis of the Doctoral Programme in Pharmacy of the University of Granada. Thanks for your support in this research.

Conflict of Interest No conflict of interest

4CPS-111 IMPORTANCE OF IMPLEMENTING A CLINICAL PHARMACOKINETIC UNIT IN HOSPITAL PHARMACY SERVICE

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Background and Importance Pharmacokinetic monitoring is a tool used in therapeutic optimisation to achieve the best clinical results and minimise the incidence of adverse effects.

It is particularly useful in drugs with a dose-dependent clinical response and toxicity relationship and with a narrow therapeutic margin. Computing software are used to integrate

patient data into population models through which pharmacists can establish the optimal dosage regimen.

Aim and Objectives To analyse the influence of pharmacokinetic reports on clinical decision.

Material and Methods A retrospective observational study was conducted from January to August 2022 in a general hospital. Patients with at least one plasma concentration of amikacin, amitriptyline, carbamazepine, digoxin, phenytoin, phenobarbital, gentamicin, lithium, theophylline, tobramycin, valproic acid, and vancomycin were included.

Collected data included gender, age, weight, height, serum creatinine, drug, dosage, plasma concentrations and concomitant medication.

A pharmacokinetic software was used. By Bayesian estimation, optimal dosage regimen was calculated. Based on these data, the pharmacist prepared the pharmacokinetic report and dosage recommendations for the physician.

Recommendations made by the pharmacist were recorded and classified according to following criteria: Underdosing, intoxication, no adjustment required, lack of adherence and interaction adjustment. The percentage of acceptance of the interventions was analysed.

Results 182 patients and 395 interventions were evaluated.

Clinical services that received more pharmacokinetic reports were internal medicine (48%) and psychiatry (19%). The most common monitored drugs were digoxin (24%), valproic acid (22%) and vancomycin (18%).

In 21% of the patients adjustments were made due to underdosing, 13% due to overdosing, 4% due to lack of adherence, and 2% due to drug-drug interactions. There was no need to adjust dosage in 40% of monitored patients. The remaining 20% were interventions related to errors in the extraction of the analytics.

71% of the recommendations addressed to physicians were accepted.

Conclusion and Relevance The most common dosage adjustment was due to underdosing so that the efficacy of the treatment was compromised. It should also be noted that there is a high percentage of errors in the analytic extraction procedure. Health professionals who perform the sample collection must be properly trained.

Clinical pharmacokinetics is a tool that allows us to optimise the patient's dosage regimen.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-115

DEVELOPMENT AND IMPLEMENTATION OF A REVIEW PROGRAMME ASSISTED BY THE PHARMACIST TO IMPROVE THE ADEQUACY OF TREATMENT IN POLYMEDICATED PATIENTS IN HOSPITAL OUTPATIENT SETTING

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Background and Importance A high number of polymedicated patients pass through outpatient consultations and prescribers often don't have the time or capacity to deal with their polypharmacy.

Aim and Objectives Development of a web tool for the review and analysis of polymedicated patients (>15 drugs/month) who attend outpatient consultations in order to improve the prescription of polymedicated patients and increase the presence of the pharmacist in outpatient consultations.

Material and Methods A web application named VIGÍA was developed (VIEwer of Potentially InAdequate Pharmacotherapeutic Groups). It can calculate adherence to treatment according to pharmacy dispensing record and detect inadequacies in pharmacotherapy: duplicities, prescribing cascades, drugs with low therapeutic value, drugs that prolong the QT-interval and drugs contributing to anticholinergic burden, giving a score named Potential Inadequacy Index (PII):

| Potential Inadequacy Index (PII) | |
|----------------------------------|------------|
| Duplicity | 1 point |
| Low therapeutic value | 1 point |
| Prescribing cascades | 0,5 points |
| QT interval prolongation | 0,5 points |
| Anticholinergic burden | 0,5 points |

VIGIA can filter patients by consultation date. Doctors have the reviews available online with the pharmacist recommendations, being able or not to modify the prescription at their choice.

PII before and after the study was calculated, comparing the means through Student's t-test for two means of the same population (two tails, significance at 5%).

Results After a study period of 120 days, we elaborated 486 review reports from rheumatology and digestive consultations, achieving to reduce the PII score from 1.58 to 1.46, and average number of medications went from 18 to 17.3. Student's t test for the PII value before and after the study period was significant ($p < 0.05$).

Abstract 4CPS-115 Table 1

| Inadequacies | Before pharmacist review | After pharmacist review |
|--|--------------------------|-------------------------|
| Duplicities | 0.84 | 0.75 |
| Prescribing cascades | 0.15 | 0.13 |
| Drugs with low therapeutic value | 0.31 | 0.28 |
| Drugs that prolong the QT interval | 0.33 | 0.33 |
| Drugs contributing to anticholinergic burden | 0.41 | 0.38 |
| PII | 1.58 | 1.46 ** ($p < 0.05$) |
| Average number of medications | 18 | 17.3 |

Conclusion and Relevance Review of polymedicated patients by the pharmacist seems to reduce inadequacies of their pharmacotherapy.

This PII score, made up of different situations considered to be at risk, can give an idea of the benefit of its reduction, not only in terms of patient safety but also economic, by reducing the average number of drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-116 **THE EFFICIENCY AND COST-EFFECTIVENESS OF HEALTHCARE AND NUTRITIONAL INTERVENTIONS IN THE MANAGEMENT OF POST-STROKE OROPHARYNGEAL DYSPHAGIA, RESULTS OF A SYSTEMATIC REVIEW**

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Background and Importance Post-stroke oropharyngeal dysphagia (PS-OD) causes significant high costs during hospitalisation that increase with the development of malnutrition and respiratory infections at long-term. This data suggests that the appropriate management of PS-OD including the use of early detection programmes, texture-modified diets, commercially thickened fluids, domiciliary enteral nutrition, and rehabilitation programmes including restorative treatments could lead to cost-effective reduction of clinical complications.¹

Aim and Objectives To assess literature on the efficiency and cost-effectiveness of available healthcare interventions on the management of PS-OD.

Material and Methods Systematic review following PRISMA recommendations. MEDLINE, Embase, NHS-EED and CEA-Registry were searched up to 30 June 2021 to include studies on PS-OD. Outcomes of interest were the efficiency and the cost-effectiveness of healthcare interventions on the management of PS-OD. Economic evaluation studies were included. Oesophageal dysphagia and non-stroke studies were excluded.

Results 235 studies were identified and 10 included. Svendsen-*et-al* found lower hospitalisation costs (HC) (USD12,556 CI95% 9,751-15,361) when PS-OD was assessed during the first 24 hours after admission. Liu-*et-al* did not find differences in HC when PS-OD was assessed with the water swallowing vs volume-viscosity swallowing test if the water test failed. Schwartz-*et-al* found a non-significant reduction on HC (Australian dollars18,053 vs 16,548, p=0.722) using a protocol to manage OD after thrombolysis. Wilson *et-al* showed video fluoroscopy as the most cost-effective screening method compared to bedside evaluation and a combination of both. Khiaochaoen *et-al* and Suksathien *et-al* showed cost-effective rehabilitation programmes that included OD management. Pelczarska *et-al* showed that the use of texture-modified diets using a gum-based thickener (Nutilis Clear®) was cost-effective (PLN21,387-20,977 per QALY), and Kotecki *et-al* that commercially thickened fluids use was more efficient than *in situ* preparation. Elia *et-al* showed domiciliary enteral nutrition cost-effective (£12,817 per QALY) and Beavan-*et-al* showed higher nutrient intake and low HC increase using looped-nasogastric tube (5,20 sterling for every 1% increase).

Conclusion and Relevance Healthcare interventions to manage PS-OD with a positive clinical effect tend to be cost-effective. Future studies assessing the cost-effectiveness of applying compensatory and/or restorative strategies among with reporting cost-savings by appropriate PS-OD early evaluation and management are ne

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Conflict of Interest No conflict of interest

4CPS-117 **USE OF ERYTHROMYCIN AS PROKINETIC IN CRITICALLY HOSPITALISED PATIENTS**

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Background and Importance Critically patients sometimes suffer from gastrointestinal disorders which are necessary to treat to improve clinical outcomes. Erythromycin is an antibiotic with prokinetic activity due to its agonist activity on motilin receptors, accelerating gastric emptying.

Aim and Objectives To evaluate the efficacy of intravenous erythromycin as a prokinetic in critically ill hospitalised patients.

Material and Methods Retrospective observational study in critically ill patients over a period of 12 months (04/2021-03/2022). Patient data were obtained using Farmasyt® and Orion Clinic® software: sex, age, weight, start and end date of treatment, dosage, clinical service, diagnosis, concomitant prokinetics (metoclopramide, dexamethenol) and clinical course. The efficacy of erythromycin use was assessed by the absence of symptoms such as abdominal distension, flatus and hydro aerial sounds or nausea.

Results 39 patients were studied, 64% were men and 36% women, with a mean age of 64 years and an average weight of 71 kilograms. 85% were in surgical intensive care unit, the rest in intensive care unit. All patients were prescribed erythromycin at doses of 250 milligrams every 8 hours, maintaining treatment for an average of 5 days. The diagnoses for which erythromycin was prescribed were: weak peristalsis in 13 patients, absent peristalsis in 18, intolerance to enteral nutrition in 6 patients, and upper gastrointestinal bleeding in 2. On the other hand, 39% of all patients had already been prescribed 10 mg of intravenous metoclopramide every 8 hours as a prokinetic prior to starting erythromycin, and this was maintained when treatment with the macrolide was initiated. In 41.5% of patients, metoclopramide was prescribed together with erythromycin. Erythromycin treatment was ending in 37 patients due to clinical improvement with resolution of abdominal distension, auscultation of peristalsis and presence of stool, in 1 patient due to tolerance to enteral nutrition and 1 patient died.

Conclusion and Relevance The use of erythromycin as a prokinetic in the population evaluated has been shown to be effective in improving intestinal motility. There was no difference between groups which were administered metoclopramide or not before or during the treatment with erythromycin. Given the variability observed, in terms of duration, concomitant prokinetics or indication, there is a need to establish a protocol for the use of erythromycin as a prokinetic.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-118 HEALTH OUTCOMES IN A COHORT OF HIV+ PATIENTS STRATIFIED USING THE KAISER PERMANENTE PYRAMID POPULATION-BASED RISK STRATIFICATION MODEL

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Background and Importance In recent years, hospital pharmacists have been approaching population-based risk stratification models for selected groups of patients. The implementation of these strategies as routine would facilitate the adequation of the pharmaceutical care to patient complexity.

Aim and Objectives To analyse the health outcomes of HIV+ patients on Antiretroviral Therapy (ART) in a comparative manner according to their classification in the Kaiser Permanente Pyramid (KPP).

Material and Methods Retrospective observational study including all HIV+ patients with active ART on 2022/01/03 followed up in the outpatient pharmacy of a tertiary hospital. The results extracted on 2022/01/03 from the clinical history were analysed according to the KPP risk stratification model. Data collected: sex, age, HIV Viral Load (VL), CD4+, polypharmacy (≥ 6 drugs, ART included), ART cost/patient/Undetectable VL (UVL; < 50 copies/mL), Emergency Department Attendances (EDA)/previous year, and stratum of KPP (General population: Promotion and Prevention (PP); Chronic patients: Self-management Support (SS); High-risk patients: Illness Management (IM); Patients with severe complications: Case Management (CM)).

Results 947 (68% men) with a median (IQR) age of 54 years [46-59] were included. 92% had UVL and 2% > 200 copies/mL. 5% had < 200 CD4+/ μ L, 23% 200-500 CD4+/ μ L and 72% > 500 CD4+/ μ L. 39% of patients had polypharmacy. EDA/previous year was: 0, 67% patients; 1-3, 29% patients; 4-8, 3.5%; > 8 , 0.5%.

Classification according to KPP: 3.5% unclassified, 3%PP, 45%SS, 33%IM and 15.5%CM. 4% of PP, 16%SS, 88%IM and 85%CM had polypharmacy.

91% of PP, 93%SS, 93%IM and 87%CM had UVL. No PP patients, 2%SS, 1% IM and 5% CM had CV > 200 copies/mL.

No PP patients, 3% SS, 4% IM and 10% CM had < 200 CD4+/ μ L. 82% of PP patients, 79% SS, 71% IM and 57% CM had > 500 CD4+/ μ L.

EDA/previous year was 0, 77% PP-75% SS-65% IM-38% CM; 1-3, 23% PP-23% SS-33% IM-44% CM; 4-8, No PP-1% SS-2% IM-16% CM; > 8 , No PP or SS-1% IM-2% CM.

The ART/patient/UVL cost was the same as the overall cost in PP and IM patients, 9% lower in SS and 22% higher in CM.

Conclusion and Relevance The study shows a worsening in HIV health outcomes and an increase in resource consumption as patient complexity enhances.

The KPP model allows us to identify patients at greater risk of sickness-related complications and with a potentially high consumption of resources, who may require an individualised and more specific pharmaceutical care in our setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-119 PNEUMONOLOGY-PHARMACY COLLABORATION IN THE PHARMACOTHERAPEUTIC OPTIMISATION OF MONOCLONAL ANTIBODIES IN PATIENTS WITH SEVERE UNCONTROLLED ASTHMA

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Background and Importance In chronic diseases, concern about safety and economic implications of treatment with biological drugs have raised, the need to adapt, by reducing doses, the treatment used once reached the individualised therapeutic goal for each patient.

Aim and Objectives Implementation of a pharmaceutical care consultation for patients with Severe Uncontrolled Asthma (SUA).

To establish a collaboration with the Pneumology Service for the referral of candidate patients for pharmacotherapeutic optimisation.

Material and Methods Pharmaceutical care consultations were scheduled for all SUA patients.

Candidates for optimisation were those treated with any monoclonal antibody for more than 1 year, had no exacerbations in the last 12 months, ACT score > 20 , FEV1 $> 80\%$, withdrawal of oral corticosteroids, had good adherence to treatment measured by the Test of Adherence to Inhalers and the pharmacy dispensing record.

If a patient met these requirements was referred to pneumologist with a treatment optimisation proposal (lengthening the interval between doses or reducing the dose). Pneumologists were able to accept the optimisation proposal or not. If there was worsening after dose optimisation, the initial prescription was returned.

Results During a 2-year period, from May 2020 to May 2022, 38 patients received Mepolizumab, 20 Benralizumab, 14 Reslizumab and 59 Omalizumab. 125 patients came to pharmacy consultation.

35 patients that met the criteria for optimising treatment and were proposed to pulmonologist, with acceptance of the proposal: 9 with mepolizumab every 5 weeks, 1 with benralizumab every 9 weeks, 5 with benralizumab every 5 weeks, and 20 with omalizumab at half initial dose.

In September 2022, 25 patients continue to be optimised, 10 patients have returned to the usual dose because they were not fully controlled with the optimised regimen, none of whom had asthma exacerbations.

Conclusion and Relevance Pharmacotherapy optimisation exposes patients with total control of asthma to less drug and less probability of developing adverse effects, while minimising costs in the health system.

Abstract 4CPS-119 Table 1

| Monoclonal antibody | N patients | N optimisation | % optimisation |
|---------------------|------------|----------------|----------------|
| Mepolizumab | 38 | 9 | 23,7% |
| Benralizumab | 20 | 1 | 5% |
| Reslizumab | 14 | 5 | 35,7% |
| Omalizumab | 59 | 20 | 33,9% |
| Total patients | 131 | 35 | 27% |

The collaboration pneumology-pharmacy allows the identification of patient candidates for optimisation, managing to optimise almost 1 out of every 3 patients in treatment with monoclonal antibodies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-120 ADVERSE EFFECTS OF ANTIRETROVIRALS: EXPERIENCE OF PATIENTS. «TALK ABOUT IT TO BETTER MANAGE IT»

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Background and Importance Antiretroviral (ARV) drugs are used in the treatment and prevention of HIV infection, they have improved the prognosis of the disease.¹

However, ARVs expose to many adverse effects, which can compromise the quality of life and vital prognosis.²

Aim and Objectives The aim of this study is to evaluate the frequency and intensity of the adverse effects of ARVs observed with PLHIV (people living with the human immunodeficiency virus) and the action to be taken in order to reduce these effects.

Material and Methods It is a prospective study conducted over a period of 3 months on 40 patients consulting for HIV in the infectious disease department.

Data collection was done using a questionnaire: a collection sheet with 2 sections:

- the frequency and intensity of adverse effects of ARVs
- what to do to reduce the adverse effects of their antiretroviral treatment.

The data collected was entered into a database (Excel 2007).

Results The sample is composed of 45% (n=18) women and 55% (n=22) men.

The main adverse effects of ARVs observed with PLHIV are dizziness with a frequency of (F=92%) and intensity (I=85%), diarrhoea (F=80%, I=75%), headache (F= 78%, I= 69%), sleep disorders and skin problems.

52.5% of patients are uninformed on how to reduce side effects.

40% stopped their treatment due to adverse effects, 50% chose the self-medication and others consulted specialist doctors because, for them, certain effects are not considered as warning signs.

Only 10% of patients feel that side effects are well managed, whereas a remarkable percentage of 77.5% are 'without opinion'.

Conclusion and Relevance Most PLHIV do not talk about their side effects to their doctor or pharmacist despite their high frequency and intensity. It is urgent to strengthen and improve information to patient on the management of adverse effects and especially to pass from information to therapeutic education.

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Conflict of Interest No conflict of interest

4CPS-121 ANALYSIS OF THE USE OF INTRAVENOUS IRON IN OUTPATIENTS

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Background and Importance For the last several years, there has been a growing tendency of administering ferric carboxymaltose in hospitals. This study has been carried out due to the fact that intravenous iron treatments require very specific occasions.

Aim and Objectives Evaluating the amount of ferric carboxymaltose administered to outpatients.

Material and Methods A retrospective, descriptive study. All patients administered with intravenous ferric carboxymaltose from January 2022 to June 2022 were included.

The following data was collected: demographic parameters (age and sex), clinics and blood test: administered dose, haemoglobin, iron profile, comorbidities that affect said profile (kidney failure, heart failure, immune-mediated disorders, oncological procedure, infection) and the concomitant use of oral iron.

The indication was assessed following the data sheet. Cases with discrepancies were revised by the haematology ward. It was checked whether a control blood test had been carried out within three months and whether iron overload had occurred.

Results 273 patients were included, 60% were women with an average age of 63,7 ± 19,03 years old. 26.4% of patients had normal values of haemoglobin. 79.9% of patients had their iron profile requested. 26.4% had an oral iron treatment and 12.1% had it prescribe it afterwards. In 29.7% of patients, the treatment's effectiveness was not proven since there was not a subsequent analysis within the next three months. An iron overload after the intravenous iron treatment was noticed in 2.2% of patients.

26% of treatments were not indicated: 8.3% due to the brief duration of the oral treatment, 56.3% due to the inexistence of a previous iron profile and 35.2% since an iron deficiency was not found.

Conclusion and Relevance This study concluded that a high percentage of patients received intravenous iron treatment when it was not indicated. The main reasons were the lack of an iron profile and the absence of a previous oral iron treatment. An intravenous iron usage protocol should be set in motion in the hospital to ensure its correct use and to carry out a subsequent study to analyse the results after its implementation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-123 CASE-CONTROL STUDY ON THE ASSOCIATION BETWEEN NOSOCOMIAL BLOODSTREAM INFECTIONS AND GLUCOCORTICOIDS, TOCILIZUMAB, SYSTEMIC ANTIBIOTICS, MECHANICAL VENTILATION AND LENGTH OF HOSPITAL STAY IN COVID-19 HOSPITALISED PATIENTS

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Background and Importance Hospitalised patients with COVID-19 are often exposed to immunosuppressive and anti-inflammatory drugs in addition to systemic antibiotic treatments. Nosocomial bloodstream infections (nBSI) have been associated with the need for mechanical ventilation or venous catheter insertion. However, there is current controversy regarding the influence of immunosuppressive, anti-inflammatory and antimicrobial drugs on nBSI occurrence.

Aim and Objectives Assess the association between glucocorticoids, tocilizumab, systemic antibiotics and nonpharmacologic health interventions and the occurrence of nBSI in hospitalised patients with COVID-19.

Material and Methods Case-control study including cases of nBSI episodes in adult inpatients with SARS-CoV-2 pneumonia over a one-year period and controls without nBSI. Sociodemographic and clinical data were collected during hospitalisation. Bivariable analysis was performed. Numerical variables were compared using the Student's t-test or the Mann-Whitney test and categorical variables using the χ^2 or Fisher's exact test. Variables with a p-value < 0.1 in bivariable analysis were included in a multivariable logistic regression model to assess the factors independently associated with nBSI occurrence (p-value < 0.05).

Results 50 cases with COVID-19 and 50 controls were included. Mean age was 63.0 ± 12.4 (66% men, 2.3 ± 2.1 mean Charlson index and comparable between groups). nBSI episodes showed significantly higher length of hospital stay (LOS) (OR 1.173, 95% CI: 1.144-1.257, $p < 0.001$), surgeries (OR 10.80, 95% CI: 1.310-88.5, $p = 0.008$), need for mechanical ventilation (OR 8.10, 95% CI: 3.31-19.8, $p < 0.001$) antibiotic and glucocorticoids therapy days (OR 1.166, 95% CI: 1.112-1.122, $p = 0.017$ and OR 3.20, 95% CI: 1.325-7.287, $p = 0.010$, respectively), and tocilizumab use (OR 9.33, 95% CI: 1.115-77.125, $p = 0.017$). Non-significant higher number of chronic renal failure cases were present among nBSI episodes ($p = 0.1$). Multivariate regression analyses showed mechanical ventilation (aOR 4.892, 95% CI: 1.206-19.845, $p = 0.026$) and LOS (aOR 1.231, 95% CI: 1.104-1.371, $p < 0.001$) as independent risk factors for nBSI when corrected for the presence of surgeries, central venous catheter, tocilizumab, chronic renal failure and the days of antibiotic and glucocorticoid treatment.

Conclusion and Relevance This study found nBSI independently associated with mechanical ventilation and LOS and did not find an association between nBSI and the pharmacological interventions assessed. However, given the bivariate association between these pharmacological interventions and nBSI, and previous inconclusive literature on the effects of these treatments on bacterial and fungal infections occurrence, further investigation with a larger sample is required.¹

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Conflict of Interest No conflict of interest

4CPS-125 PREEXPOSURE PROPHYLAXIS IN MEN AT HIGH RISK FOR HIV-1 INFECTION

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Background and Importance The Preexposure Prophylaxis (PrEP) for HIV infection with the drugs tenofovir and emtricitabine (FTC/TDF) is recommended by World Health Organization as part of HIV prevention to people at substantial risk HIV infection. Many countries have included it in their healthy police. However, there is a lack of information on its implementation in real practice.

Aim and Objectives To evaluate adherence, the effectiveness and safety to treatment for PrEP.

Material and Methods A retrospective and descriptive study of all adult patients who used FTC/TDF for PrEP from September 2020 to September 2022. Clinical data were obtained from digital clinical history and the prescription software Dominion®: sex, age, duration of treatment, high-risk for HIV and adherence to treatment.

The adherence to treatment was measured using the dispensing registry. Effectiveness was determined by relative reduction of HIV incidence; HIV testing was performed every three months during this study. In terms of safety, adverse events (AE) were recorded.

Results Forty patients, 100% men, were included, with an average aged of 35 (20-57) years. All patients were received (FTC/TDF), once daily. The average duration of treatment was 6 months (1-30), 8 patients received only two months. All patients were at high risk for HIV, defined as: sexual risk behaviour (ten or more sexual partners and any bacterial sexually transmitted infections (STIs) last year). 25% patients had discontinued therapy due to lack of adherence.

None of these patients were diagnosed HIV during study. 100% relative reduction of HIV incidence.

No treatment-associated adverse effects were observed, although 75% of patients had PrEP-associated bacterial STIs.

Conclusion and Relevance

- A quarter of patients were non-adherent to treatment, a possible alternative would be on-demand regimen in these cases.
- In terms of efficacy, a greater therapeutic result was observed, becoming a good tool prevention.
- PrEP used was associated high increased bacterial STIs, probably due to not using a condom.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-127 PHARMACOKINETIC MONITORING OF VANCOMYCIN, GENTAMICIN AND AMIKACIN IN PAEDIATRIC POPULATION

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Background and Importance The aim of pharmacokinetic monitoring is to improve clinical outcomes. A protocol was agreed between the paediatric and the pharmacy services to establish an initial dosage in this population to reach a therapeutic benefit.

Aim and Objectives To evaluate the initial dosage of these antibiotics by carrying out pharmacokinetic monitoring.

Material and Methods Retrospective observational study from May 2020 to May 2022, including patients treated with vancomycin, gentamicin, or amikacin from the paediatrics service aged <1 year. The following variables were collected at Orion Clinic®: data on age(postnatal, gestational), weight, and dosage. The pharmacokinetic results, creatinine, and pharmaceutical recommendation were collected from Gestlab®. The optimal trough intervals established in the protocol for vancomycin, gentamicin, and amikacin were 10-15 mcg/mL, 0.5-1.5 mcg/mL, 2-5 mcg/mL, and the dosage according to postnatal and gestational age were 10-12mg/kg/8h, 2.5-4mg/kg/24h, 15mg/kg/24-48h, respectively.

Results 231 patients were analysed, 50 treated with vancomycin, 169 with gentamicin and 12 with amikacin. The mean weight was 2.58kg, 2.52kg, and 1.79kg for vancomycin, gentamicin, and amikacin, respectively. Regarding gestational age (GA), in the vancomycin group 22 patients <29weeks, 23 between 30-36, and 5 >37 weeks. For gentamicin, the GA was <29 weeks in 25 patients and >29 weeks in 144. The GA in the amikacin group was <30 weeks in 7 patients, between 30-34 weeks in 4, and >35 weeks in 1 patient. For vancomycin, 58% of patients were treated for suspected sepsis, while gentamicin and amikacin were started empirically in 100% of cases. The initial dosing regimen was in line with the protocol in 86%, 94% and 67% patients for vancomycin, gentamicin and amikacin, respectively. After the first monitoring, 30% patients treated with vancomycin were within the target range, 63% in the case of gentamicin, and 33% for amikacin. A second monitoring was performed, after dosage individualisation, in 35, 19 and 6 patients, of vancomycin, gentamicin and amikacin, reaching the objective in 49%, 68% and 67%, respectively.

Conclusion and Relevance In most patients, the initial dosage of the three antibiotics was adjusted to the hospital protocol. A high number of patients treated with vancomycin required dose adjustment, in contrast with gentamicin and amikacin. The role of the pharmacist, together with pharmacokinetic monitoring, is appreciated to achieve optimal concentrations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-128 CLINICAL PRACTICE: ANTI-VEGF THERAPY FOR RESISTANT MACULAR OEDEMA

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Background and Importance Therapy approved for diabetic macular oedema (DME) are intravitreal ranibizumab (IR), intravitreal aflibercept (IA) and dexamethasone intravitreal (ID). Currently there is a gap of information on its use in unresponsive to previous treatment.

Aim and Objectives To evaluate clinical effectiveness and safety of aflibercept or ranibizumab (Anti-VEGF) therapy for resistant macular oedema.

Material and Methods An observational retrospective study of all patients with DME unresponsive to previous anti-VEGF therapy from September 2021 to September 2022. Clinical data were obtained from digital clinical history and the prescription software: sex, aged, pathology, previous therapy, type treatment, number injections during study, response and adverse events (AE).

Effectiveness was determined by complete or partial response. Complete response was defined as maintenance of visual acuity (VA) reduction of subretinal fluid and inflammatory activity. Secondly, partial response was considered if only one of these parameters was observed. In terms of safety, adverse events (AE) were recorded.

Results Thirty-four patients, 53% women (n=18), were included, with an average aged of 69 (35-90) years. The population was patients diagnosed with resistant macular oedema. Almost all patients received treatment with one-line anti-VEGF therapy (80% aflibercept, 20% ranibizumab), only one patient received treatment with two lines anti-VEGF (bevacizumab and ranibizumab). During the study, 261 injections of IR (median 9, range 3-12) were administered into 32 eyes corresponding to 27 patients and 35 injections of IA (median 5, 2-7) were administered into 9 eyes corresponding to 7 patients. 12% (n=4) for patients who received combined therapy with ID. Complete response was observed in 27% patients (n=9), partial response in 26% (n=8) and non-response 47% (n=17).

No treatment-associated adverse effects were observed.

Conclusion and Relevance

- The effectiveness was relatively low in unresponsive to previous treatment. Future controlled trials are needed to confirm the use of this type of treatments in unresponsive patients.
- The safety profile for use of the therapy showed it was tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-131 SOCIAL FUNCTION OF THE TELEPHARMACY: A SOCIOECONOMIC ANALYSIS

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Background and Importance remote medication delivery systems (telepharmacy) are increasingly used by hospitals nowadays. In our hospital an inclusion and interruption protocol is used, in order to ensure correct pharmaceutical care, safe and traceable distribution and dispensing of medications. Since its implementation, a progressive increase in the number of telepharmacy requests has been observed. Despite this, it is still unknown which kind of patients would benefit the most with this system.

Aim and Objectives to conduct a socioeconomic analysis of medication delivery requests to outpatients in a telepharmacy programme.

Material and Methods retrospective observational study from February 1 to May 31, 2022. We analysed whether the average income or the distance to the hospital in each locality of the patients influenced the number of telepharmacy requests by performing two dispersion maps of requests: a map of the province with the number of telepharmacy requests of each locality per total inhabitants and a second map of the province with the average per capita income of each locality.

Results 2,842 patients were included with 14,833 total requests. According to the map of requests frequency dispersion, there was no relationship between the volume of requests for telepharmacy and the distance to the hospital. Some of the most distant areas showed fewer applications, while areas close to the hospital, were among the locations with most applications per inhabitant. As shown in the map of average income per capita, we found a relationship between the number of requests from each locality and its average income. The eastern zone of the province, which highest incomes, had fewer applications per inhabitant, while more applications tended to be associated with the western zone, which has lower incomes. This relationship was not absolute in all localities, although there was a general trend. Exceptions were areas such as Bellavista and Sanlúcar de Gadiana, with high incomes but many applications.

Conclusion and Relevance telepharmacy performs a social function by facilitating access to medication for the population with fewer economic resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-132 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS REGARDING ADMISSION RECONCILIATION

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Background and Importance Medication reconciliation (MR) is a pharmaceutical activity that aims to resolve errors that occur in the continuation of chronic treatment at the transition

among different levels of Healthcare Systems and that increase patient morbidity and mortality.

Aim and Objectives To analyse the MR activity on admission by the Pharmacy Service of a second level hospital to determine its usefulness as a method for preventing medication errors.

Material and Methods Retrospective descriptive observational study (January 2022-July 2022) of the pharmaceutical interventions (PI) reviewed in relation to MR. The variables studied were: clinical service, pharmacotherapeutic group, type of error and acceptance. We used the programme of electronic medical record MambrinoXXI® for reviewing chronic treatments and the pharmaceutical validation programme Farnatools®.

Results In this period of time, 12,946 admissions were validated and 658 PI about MR were performed on a total of 516 patients. The clinical services with more PI were: Internal Medicine (N=287, 43.62%), General and Digestive Surgery (N=78, 11.85%), Digestive (N=57, 8.66%) and Neurology (N=40, 6.08%). The most frequent type of reconciliation error was: omission (N=523, 79.48%), followed by change of dosage regimen (N=114, 17.33%). The pharmacotherapeutic groups with most PI were: lipid-lowering agents (N=75, 11.40%), antihypertensives (N=69, 10.49%), antidepressants (N=66, 10.03%), urological drugs (N=53, 8.06%) and inhaled antiasthmatics (N=30, 4.56%). The acceptance rate was: 43.92% (N=289), 24.31% non-accepted (N=160) and 31.76% non-evaluable (N=209). Excluding non-evaluable results, the acceptance rate was 64.37%.

Conclusion and Relevance Although less than half of the PI were accepted, the role of the pharmacist in MR is useful. This activity could be optimised by the presence of the pharmacist both in the emergency department and on the hospitalisation unit, as well as by implementing actions such as patient interviews. The detection of the main clinical services and pharmacological groups requiring this type of intervention would make it possible to prioritise MR criteria and create protocols in order to improve the patient safety and reduce the proportion of non-evaluable results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-133 SAFETY AND EFFECTIVENESS OF GUSELKUMAB ON MODERATE TO SEVERE PLAQUE PSORIASIS

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Background and Importance Psoriasis is a chronic inflammatory disease associated with various comorbidities, which requires multidisciplinary treatment. In recent years, anti-IL-23 drugs have emerged as a new therapeutic option for plaque psoriasis.

Aim and Objectives To evaluate safety and effectiveness of guselkumab in moderate to severe plaque psoriasis.

Material and Methods Multicentric, observational and retrospective study of patients diagnosed with moderate to severe plaque psoriasis. Study period of data collection was June 2021-June 2022, active patients in treatment and patients starting treatment. The anthropometric data were age, sex,

and previous biological treatments. The effectiveness variables are affected body surface area (BSA) and psoriasis area severity index (PASI) AND 90% PASI clearance (PASI90) collected at baseline, and next visits with dermatologist. The main tools used: Diraya© for the clinical history, Modulab© for laboratory values and Excel© for anonymised data recording. The information was collected according to data minimisation policy, article 5.1 of data protection.

Results 49 patients (29 men) included with a mean age of 50.9 years. The main biologic pre-treatments were etanercept (31), adalimumab (11), secukinumab (9) and ustekinumab (9). Averaged pre-treatment BSA (13.6 ± 10.27 SD) and PASI (9.7 ± 6.68 SD). Next dermatologist's control at 5 months 43 patients averaged BSA (3.9 ± 9.27 SD) and PASI (2.9 ± 4.17 SD). PASI90 was reached by 48.8% of patients. There were four treatment discontinuities during this period (1 due to lack of adherence, 1 due to primary failure, 1 due to secondary failure and 1 due to toxicity). At 10 months 25 patients averaged BSA (1.8 ± 3.28 SD), PASI (1.8 ± 3.30 SD), and PASI90 was reached by 72%. 3 treatment discontinuities in this period (1 due to gestational desire and 2 due to secondary failure). At 18 months 15 patients averaged BSA (0.9 ± 1.55 SD) and PASI (0.5 ± 0.91 SD). PASI 90 was reached by 73%. Patients not counted had not gone to dermatology control yet when our analysis were made.

Safety: One patient had to stop treatment due to strong diarrhoeas after each dose.

Conclusion and Relevance According to the results obtained, it is possible to evaluate guselkumab as an effective and safe alternative in the treatment of moderate to severe psoriasis resistant to conventional treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-136 STANDARD FIRST DAY OF LIFE CENTRAL PARENTERAL NUTRITION, EXPERIENCE IN REAL CLINICAL PRACTICE

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Background and Importance Standard parenteral nutrition (PN) solutions should generally be used over individualised PN solutions in the majority of paediatric and newborn patients, including very-low-birth-weight premature infants,¹ starting as soon as possible and within 8h at the latest.² In 2021 our Paediatric and Pharmacy Departments designed a standard central PN (CPN) to have ready to use, in order to meet the nutritional needs of most newborn patients in their first day of life.

Aim and Objectives Evaluate the use of the standard first day of life CPN and describe clinical data of patients and the time frame for its start.

Material and Methods Observational, retrospective and longitudinal study conducted between March 2022 and September 2022 in a tertiary hospital. A database was designed to record all prepared CPN, their use and data of patients who received them.

Results 55 CPN were prepared and 32 (58.2%) were administered. 31 newborn required PN and 100% received the standard first day of life CPN, 18 (58.1%) patients were female, the mean gestational age was 28.5 weeks, the mean weight was 1138.2g and 12 (38.7%) were multiple pregnancies. The indication of PN was: 23 (74.2%) preterm infants born <32.0 weeks with birth weight <1500g, 4 (12.9%) preterm babies born >32.0 weeks with <1500g and 4 (12.9%) patients born <32.0 weeks with birth weight >1500g. The mean time to start CPN was 6:01h (range 1:13-22:54h), 26 (83.9%) babies initiated within 8h at the latest and 5 (16.1%) patients after 8h of life (3 due to a lack of central line, 1 lack of 2 ready to use CPN for twins and 1 delayed prescription). 30 patients (96.8%) started trophic feeding with breast milk (maternal or bank) within the first 24h of life.

Conclusion and Relevance Standard first day of life CPN ready to use has considerably reduced the time to start PN in newborn patients. However, CPN was initiated after 8h of life in 5 patients (mostly due to a lack of central line). Standard first day of life CPN met the nutritional requirements of all newborn requiring PN, not needing to produce individually tailored CPN in any case.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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- Neonatal parenteral nutrition. NICE guideline 2020

Conflict of Interest No conflict of interest

4CPS-137 EVALUATING THE POTENTIAL CLINICAL AND ECONOMIC IMPACT OF CHEMOTHERAPY PRESCRIBING BY PHARMACISTS AT A UNIVERSITY TEACHING HOSPITAL

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Background and Importance Chemotherapy prescribing errors represent a potentially serious risk of causing patient harm. Whilst pharmacist prescribing has a well-established role in many clinical settings worldwide and has been shown to be effective, there is a paucity of research on pharmacist prescribing chemotherapy.

Aim and Objectives Assess the potential clinical and economic impact of pharmacist prescribing versus medical prescribing of chemotherapy (including supportive medicines) at a university teaching hospital.

Quantify the error rate in pharmacist- and doctor-prescribed chemotherapy prescriptions.

Classify prescribing errors according to the Pharmaceutical Care Network Europe (PCNE) classification framework for drug-related problems (DRPs).

Assess the potential severity of prescribing errors made by the pharmacists and doctors using a validated tool and peer review panel.

Evaluate the time taken for the chemotherapy prescribing process by doctors and pharmacists and assign costs to these times. Estimate the cost of the provision of a pharmacist prescribing service in comparison to the doctor prescribing practice.

Material and Methods This was a comparative, prospective study that examined the same set of 155 prescriptions prepared by both doctors and pharmacists for the same set of patients. The potential severity and adverse drug event (ADE) probability associated with the prescribing errors was assessed using a validated tool and peer review panel. The cost avoidance associated with the provision of pharmacist prescribing was also determined.

Results In the comparative sample of 155 prescriptions, doctors made significantly more errors (105 in 40.6% of prescriptions) than pharmacists (23 in 14.8% of prescriptions); $p < 0.05$. None of the pharmacists' errors were classified as 'severe', whilst 16.7% of doctors' errors were 'severe' ($n=17$). Regarding cost avoidance, a potential yearly net cost benefit of € 1,254,347.72 and a cost-benefit ratio of € 41.82 was calculated for the provision of a pharmacist chemotherapy prescribing service.

Conclusion and Relevance This study has shown that having pharmacists prescribing – and better using their expert skillset – results in fewer chemotherapy prescribing errors. While this minimises healthcare professionals' workload as well as any potential delays for patients to receive chemotherapy, pharmacist prescribing most importantly improves patient safety, and therefore this is ultimately why this initiative should be considered for implementation in cancer care services on a much wider scale in future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-138 USE OF SODIUM ZIRCONIUM CYCLOSILICATE IN HYPERKALAEMIC EMERGENCIES

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Background and Importance Hyperkalaemia ($K > 5.5$ mEq/L) is an electrolyte alteration that can determine fatal clinical complications, the most serious being cardiovascular and muscular. Sodium zirconium cyclosilicate binds potassium throughout the gastrointestinal tract reducing serum potassium levels and increasing faecal excretion to resolve hyperkalaemia.

Aim and Objectives Analysis of the effectiveness of sodium zirconium cyclosilicate (SZC, Lokelma®) for the treatment of hyperkalaemia in patients treated in hospital emergency or in different hospitalisation units in the first 48 hours.

Material and Methods One-year retrospective and observational study was carried, including patients treated in hospital emergency or admitted with initial potassium levels ≥ 5.5 mEq/L who received SZC. The SZC regimen was 10 g every 8 h orally. Serum potassium concentrations were considered normal with values between 3.3-5.1 mEq/L. The variables collected were age, sex, diagnosis of heart failure, serum potassium concentrations (at 0, 24, and 48 hours after starting treatment with SZC), the reason for hyperkalaemia, glomerular filtration rate (GFR, estimated with CKD-EPI formula), concomitant drugs that could influence the hyperkalaemia.

Results 66 patients (63% men) with a median age of 79 years (41-97) were included. Heart failure was diagnosed in 27 patients (41.0%). The GFR was < 60 ml/min/1.73 m² in 61

patients (92.0%) and < 30 ml/min/1.73 m² in 41 (62.0%). The causes of hyperkalaemia were: chronic kidney disease (CKD) (47.0%, N=31), acute kidney disease (AKD) (39.4%, N=26), iatrogenic (7.6%, N=5) and other causes (6.0%, N=4). The drugs contributing to hyperkalaemia were angiotensin-receptor blockers (41.0%, N=27), aldosterone antagonists (28.8%, N=19), non-steroidal anti-inflammatory drug (24.2%, N=16), and angiotensin-converting enzyme inhibitors (16.7%, N=11).

Initial serum potassium concentration mean was 6.4 mEq/L (5.5-8.2), being > 7.5 mEq/L in 21 patients (32.0%). Mean reduction in potassium concentrations at 24 hours was 14.1% (N=22) and 22.5% (N=21) at 48 hours. 24 hours after starting treatment with SZC, potassium concentrations were normalised in 33.3% (N=22) of patients and in 31.8% (N=21) after 48 hours.

Conclusion and Relevance Hyperkalaemic emergencies are fundamentally associated with patients with AKD, CKD and in concomitant treatment with drugs inducing hyperkalaemia. SZC treatment is an alternative to be considered in patients with hyperkalaemic emergencies, contributing to the normalisation of serum potassium levels in first 24-48 hours after starting treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-139 THE PHARMACEUTICAL NEWSLETTER AS AN INFORMATION TOOL: USEFUL OR FUTILE?

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Background and Importance Since July 2007, pharmaceutical team writes a monthly pharmaceutical newsletter (PN) to hospital staff (HS). It contains information about drugs or medical devices (pharmaceutical news, reminders of appropriate use, etc.). It is currently sent to health managers and HS by e-mail and is accessible on the hospital web portal. However, since its implementation, no study has been carried out concerning the adherence of HS to this tool.

Aim and Objectives The aim is to assess the adherence of HS to the PN and to propose areas of improvement.

Material and Methods We developed two surveys in digital and paper format: one for the health managers and the other for the readers of the PN. The survey for the managers was first sent to them to find out how they circulated the PN to the staff in their units. Units for which managerial responses had not been collected were excluded. The survey was conducted in September 2022 by two pharmacy interns.

Results 16 health managers responded to the survey: 100% read the PN, 81% distributed it (85% posted it in the department and 15% by e-mail).

123 readers (including 40% of nurses, 20% of nursing assistants, 15% of doctors) from 20 departments responded to the survey. 68% of HS read the PN: 20% consulted it by e-mail, 30% read it on the hospital web portal, 34% read it displayed in the unit and 5% read it at the pharmacy. 75% find it useful, 83% are satisfied with its content, 83% with its presentation and 63% with the distribution channel. Finally, 48% of readers would like the PN to be displayed in their

units, 40% would like it to be sent by email and 15% would like a dedicated website.

Conclusion and Relevance The majority of HS support the PN, find it useful and appreciate its content and presentation. Part of the HS did not know the PN, which shows that the distribution method needed to be improved. We have therefore updated the mailing list. This survey has enabled us to highlight the satisfaction with the HN and improve its distribution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-141 PHARMACEUTICAL INTERVENTIONS IN A MEDICAL EMERGENCY DEPARTMENT: 6-MONTHS EXPERIENCE

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Background and Importance Medication errors are a major global public health problem that requires a very important approach and collaborative work between physicians, pharmacists and nurses. Pharmaceutical interventions (PI) are an effective way to fight drug iatrogeny.

Aim and Objectives The objective of the study was to analyse pharmaceutical interventions and their impact on patients hospitalised in a medical emergency department

Material and Methods This is a retrospective study conducted in a medical emergency department of the Ibn Sina Hospital in Rabat over a period of 6 months. Prescriptions were analysed and validated according to the methodology of the French Society of Clinical Pharmacy (SFPC). The relevance of the PIs was assessed by their acceptance rate by the prescribers and their clinical impact was evaluated according to the Hatoum scale.

Results A total of 158 Pharmaceutical interventions were recorded over six months. Of these, 98% were accepted by the prescriber. The sex ratio (male/female) was 1.35. The average age of our patients was 56.06 ± 15.81 years. 86 PIs (55%) concerned an antibiotic. The main prescription problems were overdose (29%). Our interventions concerned dosage adjustment (32.27%), optimisation of administration modalities (22.15%).

Conclusion and Relevance This study highlights the importance of the clinical pharmacist in the fight against drug iatrogeny.

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Conflict of Interest No conflict of interest

4CPS-142 EVALUATION OF PREMEDICATION USE IN ADVERSE DRUG REACTIONS OCCURRENCE IN PATIENTS WHO RECEIVED INFlixIMAB TO TREAT INFLAMMATORY BOWEL DISEASE

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Background and Importance Infliximab can cause infusion-related reactions like delayed hypersensitivity or anaphylactic shock. Using corticosteroids or antihistamines as premedication can reduce adverse drug reactions (ADRs) frequency.

Aim and Objectives To evaluate premedication impact on ADRs occurrence in patients with inflammatory bowel disease (IBD) who received infliximab.

Material and Methods Retrospective observational study in patients with IBD who received intravenous infliximab from January 2016 to December 2020. The variables collected were: demographic (age, sex), clinical (type of inflammatory bowel disease, Harvey index Bradshaw in Crohn's disease, Mayo index in ulcerative colitis), premedication used (type of drug and number of administrations), number of infliximab administrations and the ADRs characteristics. For the statistical analysis, mean, standard deviation and absolute risk were used.

Results 119 patients were included with an average age of 46 ± 17 years and 42% women. 42 patients had ulcerative colitis, 74 patients had Crohn's disease, and 3 patients had indeterminate colitis. In the base line study, patients with Crohn's disease had Harvey score mean of 7.1 ± 3.7 and patients with ulcerative colitis had partial Mayo score mean of 3.7 ± 2.3 . A total of 1909 infliximab infusions were administrated and premedication was used in 1185 administration in 80 patients. Premedication was administrated in 21.2% (n=17) during induction phase, in 32.5% (n=26) during maintenance phase, and in 46.3% (n=37) during both phases. Glucocorticoids were used as a premedication in 97.5% of cases.

25 ADRs were recorded in 21 patients. The patients (n=17) who received premedication had 21 ADRs and an absolute risk of 10.3% (CI95, 0.7%-19.8%). In the other group, the patients who did not receive premedication had 4 ADRs (n=4) and an absolute risk of 21.3% (CI95, 12.3%-30.2%). 44% of ADRs occurred in induction phase and 56% in maintenance phase. The main symptoms of ADRs registered were skin manifestations (n=16), cardiovascular (n=6) and respiratory symptoms (n=3).

Conclusion and Relevance No lower absolute ADR risk were observed in patients who received premedication compared to patients who did not receive premedication. More studies are needed in order to evaluate the impact of premedication on ADRs occurrence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-144 EXPERIENCE OF USING REMDESIVIR IN THE TREATMENT OF PATIENTS WITH SARS-COV2 INFECTION

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Background and Importance Remdesivir was the first antiviral authorised by the European Medicines Agency for the treatment of CoVID-19 disease.

Aim and Objectives The aim is to describe the effectiveness and safety of remdesivir in patients with SARS-CoV-2 infection in real clinical practice.

Material and Methods Observational, descriptive, retrospective study in a level-II hospital.

Hospitalised patients with SARS-CoV-2 infection and prescription of remdesivir from April21-March22 were included. Data were obtained from the Unidosis Farmatools® module and MambrinoXXI®.

Variables: sex, age, recommendations of remdesivir datasheet (time from symptom onset to administration ≤ 7 -days, dosing regimen, duration of treatment and glomerular filtration rate (GFR) (contraindicated if < 30 mL/min).

Effectiveness assessment: hospital stay, Intensive Care Unit (ICU) admission, clinical recovery inpatients with 5-day treatment.

Safety assessment: elevated transaminases (pre-and-post-remdesivir levels; contraindicated if ≥ 5 times upper limit of normal-LSN)

Results 59 patients were included, 64% male, median age 67 (30-101) years. 100% started within 7-days of symptomatology onset (median: 3-days) and complied with the recommended dosing regimen. In 93.2% the duration was 5-days, one patient remained on treatment for 7-days and 3 discontinued earlier due to clinical worsening. Mean GFR: 79 mL/min and 96.6% complied with the recommendation (GFR > 30 mL/min). The median hospital stay was 8-days (3-133). Twelve patients required admission to the ICU, two of whom died. Clinical recovery was achieved in 91.1% of patients who completed the 5-day regimen. During the hospital stay, 7 patients died with a median age of 85 years (59-95). Prior to administration, 22.2% patients showed transaminase levels above the LSN, including one patient with 5LSN. After administration, transaminases increased in 31.1%, including 5 patients with 5LSN, 2 of whom had initially normal values.

Conclusion and Relevance All patients received remdesivir as early as recommended and according to the conclusions of the pivotal clinical trial, where this subgroup was postulated to have the greatest clinical benefit. Although one third of patients had elevated transaminasemia, none required treatment discontinuation. However, other parameters would need to be collected to assess safety more comprehensively. Despite the limitations of the study, in our experience, remdesivir appears to have a good effectiveness and safety profile and may be a therapeutic alternative in the treatment of COVID-19 disease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-145 CONSENSUS VALIDATION OF A SCREENING TOOL FOR CARDIOVASCULAR PHARMACOTHERAPY IN GERIATRIC PATIENTS: THE RASP_CARDIO LIST

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Background and Importance Cardiovascular therapies have been identified as major culprits for adverse drug events. Their inappropriate (under)use puts geriatric patients at increased risk for avoidable harm. These therapies are used frequently, accounting for approximately half of all prescribed drugs in geriatric patients. Paradoxically, most studies on medication reviews in geriatric patients have not specifically targeted cardiovascular therapies. This might be owing to a lack of resources, training or explicit support to perform targeted medication reviews. Consequently, there is a clear need for an updated screening tool, specifically targeting cardiovascular therapies in geriatric patients.

Aim and Objectives We aimed to update and validate the cardiovascular segment of a previously developed screening tool, the RASP list. The updated RASP_CARDIO list was intended for use in geriatric patients by trained health care professionals.

Material and Methods A three-step study was conducted by a collaboration of the pharmacy, geriatric medicine and cardiology departments of a large, academic hospital. First, the cardiovascular segment of the RASP list (version 2014) was updated taking into account published research, other available screening tools and the input of end-users. Secondly, this draft was reviewed during three panel discussions with five expert cardiologists and three clinical pharmacists, all of whom had relevant expertise in geriatric pharmacotherapy. Thirdly, the content was validated using a modified Delphi Technique by a panel of European hospital pharmacists, cardiologists, geriatricians and an internal medicine physician. Consensus was achieved in case of $\geq 80\%$ agreement among experts. The final construct was compared to the cardiovascular segment of the STOPP/START criteria version 2.

Results Seventeen experts from four European countries participated in two validation rounds. Consensus was achieved for all statements of the RASP_CARDIO list. One new statement was added. The final construct comprised a list of 95 statements related to potentially inappropriate prescribing of cardiovascular agents. Approximately 90% (29/32) of the cardiovascular statements of the second version of the STOPP/START criteria were included in the RASP_CARDIO list and the RASP_CARDIO list had 66 additional statements.

Conclusion and Relevance The RASP_CARDIO list is an updated and validated explicit screening tool to optimise cardiovascular pharmacotherapy in geriatric patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-146 'REAL WORLD' EXPERIENCE OF ELEXACAFTOR/TEZACAFTOR/IVACAFTOR IN THE TREATMENT OF CYSTIC FIBROSIS: EFFECTIVENESS AND SAFETY EVALUATION

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Background and Importance Cystic fibrosis (CF) is a life-limiting recessive genetic disorder caused by pathogenic variants in the CFTR (cystic fibrosis transmembrane conductance regulator) gene, resulting in increased viscosity and difficult mucus clearance. Introduction of elexacaftor (ELX)/tezacaftor (TEZ)/ivacaftor (IVA) to clinical practice has brought a change in the clinical approach since they modulate CFTR.

Aim and Objectives To assess effectiveness and security of ELX/TEZ/IVA in patients on a tertiary hospital.

Material and Methods Observational, retrospective study carried out between March 2020 and September 2022, including all adult patients treated with ELX/TEZ/IVA+IVA in our hospital.

Variables included: age, sex, age of diagnose, pulmonary function: measured with % pFEV1 (median percent predicted forced expiratory volume in 1 second) and pulmonary exacerbations; treatment adjustment, adverse events and treatment suspension.

Data were collected from electronic medical records and pharmacy dispensing programs.

Results

Thirty-one patients were included: male 45% (n=14), median of 31 years old (rank 17-45), median age of diagnosis of 4 months (0-38). Before taking ELE/TEZ/IVA+IVA, 45% (n=14) patients received TEZ/IVA+IVA as CFTR modulator; 55% (n=17) did not receive any CFTR modulator. Median length of ELX/TEZ/IVA+IVA treatment at the moment of the analysis was 9.43 months (4.5-31.4).

% pFEV1 during treatment augmented in 83% patients (n=26), slightly decreased in 13% (n=3) and did not vary in 1 patient. Two patients (6.5%) presented pulmonary exacerbations that required antibiotic treatment but not hospital admission.

Two patients (6.5%) required ELX/TEZ/IVA+IVA adjustment: one due to interactions with potent CYP3A4 inhibitors and other because of hepatic insufficiency (Child-Pugh B). Nine (29%) patients presented an increase of transaminase and/or bilirubin in clinical analysis: one patient temporarily discontinued therapy and one suspended treatment definitely.

Conclusion and Relevance The introduction of ELEX/TEZ/IVA to CF treatment has been a hopeful advance that has shown in our population to have a good safety profile -which can be managed with regular check-ups- and with a good efficacy profile, achieving an increase of % pFEV1 in a short time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Conflict of Interest No conflict of interest

4CPS-147 REAL WORLD DATA (RWD) ANALYSIS ON USE OF IMMUNE CHECKPOINT INHIBITORS (ICI) FOR NON-SMALL-CELL LUNG CANCER (NSCLC)

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Background and Importance In Italy, monoclonal antibodies acting on programmed cell death protein (PD-1), nivolumab (N) and pembrolizumab (P), or on the PD-L1 ligand, atezolizumab or durvalumab, are authorised for the treatment of NSCLC. Registration RCTs may not give definitive answers regarding the optimal ICI's duration of treatment (DOT). There is evidence that treatment may be interrupted before progression, or before scheduled cycles are completed for different reasons and that potentially affects efficacy. Are the causes for patient discontinuation treatment (TDC) in RCTs and in the real world comparable?

Aim and Objectives Aim: evaluate the appropriateness of treatment choices by analysing DOT with ICI in a cohort of patients with NSCLC

Material and Methods For 27 months data were recorded on patients treated in I-line with P or combinations of P+pemetrexed+platinum chemotherapy (PPC), or in II-line with N. The percentage of PD-L1 expression (PD-L1el) was observed; median DOT was measured, and the data were stratified according to treatment discontinuation causes.

Results A total of 73 patients were treated, 62% men, 38% women, 29% smokers, 3% non-smokers, 40% ex-smokers, and 28% n.a. At the present date 5% of the 73 patients are undergoing treatment and 4% completed all cycles of therapy. Patients were treated with: 33% N, 49% P, and 18% PPC. The PD-L1el in the population treated was for: N 4% >50%, 63% <1%, 33% n.a. versus RTC 77% >5% and 33% >50% (3); for P: <5% 8% and >50% 92% versus RTC 100% >50% (4); for PPC: 67% <5% and 33% <50% versus RCT-data <=50% 63% and 32% >50%. Median DOT for P (8 vs 7.9 months), N (5 vs 2.8 months), and PPC (2 vs 9.8 months) in RWD and RCTs respectively. RWD TDC: 96% 7%(4% N, 3% P 17% C), progression 67%(79% N, 53% P and 67% PPC) toxicity 22%(13% N, 28% P and 17% PPC). From RCT data: death/progression (67%N, 47% P, 30.8% PC) and toxicity(3%N, 13.6% P, 13.8%PPC)

Conclusion and Relevance RCT and RWD data are conflicting. Median DOT for P and the N death/progression rate are comparable. The treatment choices made were appropriate, maximising treatment efficacy, while respecting the risk/benefit profile in a population different from that of the RCTs

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-149 PAIN MANAGEMENT IN MENTAL HEALTH

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Background and Importance In health institutions, pain management is an obligation from diagnosis to treatment. However, in mental health, it is difficult to treat it because psychiatric diseases may alter the perception of the pain and there are drug interactions (DI) between psychotropic drugs and analgesics.

Aim and Objectives The aim of the study is to find guidelines on pain management in psychiatry and review the current state of analgesic prescriptions in our psychiatric units.

Material and Methods A bibliographic search on pain management in psychiatry was carried out and an observational audit of analgesic prescriptions was done, at a given day, in the five psychiatric units of our establishment.

Data are expressed as average +/- standard deviation and results as percent.

Results The bibliographic search offers pain assessment scales in psychiatry even if they are not specific to this population. Nevertheless, there is not any consensus on the therapeutic pain management in mental health, neither at national nor international level.

The day of the audit, on 88 patients, 47 (53%) were treated with analgesics. These patients were 50 +/- 17 years old and the sex-ratio was 1.04.

Fifty prescription lines for analgesics were identified. The main molecules found were : paracetamol, prescribed alone on 42 prescriptions (90%), and tramadol, alone on 2 prescriptions (4%) or co-prescribed with paracetamol on 2 prescriptions (4%). One prescription (2%) included paracetamol/opium + ibuprofen.

Of all the painkillers, 90% were prescribed conditionally, including 79% 'if needed/pain'; 14% 'if Analog Visual Scale > 3, temperature > 38°C'; 7% 'if Analog Visual Scale > 3'.

A DI analysis has been performed between analgesics/psychotropics and a single prescription with an association not recommended (tramadol/paroxetine with risk of inefficiency of tramadol due to metabolic inhibition) was found. The absence of contraindication can be explained by the pharmaceutical analysis of the prescriptions.

Conclusion and Relevance Following this audit, a cross-referenced table of existing DI between analgesics/psychotropics was made and alternative treatment in case of DI was proposed. These works, and also reminders of the scales that can be used in psychiatry to assess pain and the possibilities of treatment according to the mental disorder, were presented to psychiatrists during a session to facilitate their pain management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-150 THE ROLE OF CLINICAL PHARMACIST IN EMERGENCY DEPARTMENT

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Background and Importance Pharmacist role in the emergency department (ED) has expanded over the last decades. However, there is limited published literature related to the interventions carried out in these units.

Aim and Objectives To perform a descriptive analysis of pharmaceutical interventions (PI) in ED, their acceptance rate, the main prescribing errors (PE) detected and the main Anatomical Therapeutic Chemical (ATC) groups involved.

Material and Methods A retrospective multicentric study was performed in the ED of a secondary and a tertiary hospital that serve about 685.000 total inhabitants with an overall of 228.550 emergency attendances per year. PI and PE were documented from Monday to Friday over a 4-hour period between June-September 2022. Dosage and frequency adjustment, formulary and drug modification, medication initiation and discontinuation, and pharmacokinetic monitoring were the PI included. PE were divided into three groups: lack of efficacy, potential safety problem or necessary/unnecessary treatment.

Results Out of 857 interventions registered, 40.4% were related to dosage adjustment; 32.0% medication initiation; 16.0% medication discontinuation; 5.6% drug modification; 3.5% pharmacokinetic monitoring; 1.5% frequency adjustment and 1.1% formulary interchange. Regarding PI, 71.9% were accepted, 21.9% were rejected and 6.2% were not evaluated because patients were discharged or dead. As for PE, 37.8% were related to necessary/unnecessary treatment, 32.6% potential safety problem and 29.6% to a lack of efficacy. The PE detected were reconciliation discrepancies (39.7%), underdose (21.4%), overdose (19.0%), duplicities (4.9%), contraindications (3.3%), adverse drug events (1.5%) and interactions (0.9%). The main ATC Groups involved were blood and blood forming organs (B) (21.7%), anti-infective for systemic use (J) (21.7%), cardiovascular system (C) (20.9%) and nervous system (N) (18.1%).

Conclusion and Relevance Dosage adjustments and drug therapy initiation were the most common documented interventions. More than half of PI were accepted. The most frequent PE were related to necessary/unnecessary treatment. The majority observed PE were reconciliation discrepancies. The main ATC groups involved were B, J and C. The great number of interventions and the high rate of acceptance seems to show that ED pharmacist, as a member of a multidisciplinary patient care team, is able to decrease the number of medicine errors and to improve the quality and safety of medical care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thank you all.

Conflict of Interest No conflict of interest

4CPS-151 ACETYLSALICYLIC ACID DESENSITISATION IN PATIENTS WITH CORONARY ARTERY SYNDROME: LITERATURE REVIEW, RETROSPECTIVE ANALYSIS AND PATIENT FOLLOW-UP PROCEDURE IN AN ITALIAN CARDIOLOGICAL CENTRE

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Background and Importance Desensitisation protocols for the treatment of hypersensitivity to acetylsalicylic acid (ASA)

consist in the administration of increasing doses of ASA at a set time in order to sensitise the patient to the active substance and initiate a chronic treatment. **Hypersensitivity** to the drug occurs in a wide range of the population, both in healthy subjects and patients with coronary heart disease. This condition may affect patient compliance to therapy and increase the risk of ischemic events especially in secondary prevention.

Aim and Objectives The aim of the work is obtaining a systematic review of the literature concerning the existing **desensitisation protocols**. The purpose is to conduct a descriptive analysis of the population and evaluate the effectiveness and safety of the protocol over the short and long term.

Material and Methods A retrospective analysis was conducted on a group of patients treated with **Rossini's protocol**,¹ an increasing oral administration of ASA to 100 mg in five and a half hours.

Results The literature's review has shown the Rossini's protocol has the greatest number of sample and the best efficacy and safety data. The retrospective analysis allowed the evaluation of the group composed of 30 patients aged > 18 years, admitted to the centre between January 2020 and April 2022, diagnosed with coronary artery syndrome. 83.33% reported a history of hypersensitivity to ASA, especially with skin manifestations (n=8). The most sensitive patients received pre-medication before undergoing the procedure; despite treatment, 20% developed mild adverse reactions. At discharge 73.33% of patients were treated with an antiplatelet therapy of which 77.27% with ASA. 50% of the patients underwent a follow-up, which took place on average after 6 months; upon re-evaluation 60% were on treatment with ASA.

Conclusion and Relevance The evidence suggests that the Rossini's protocol is effective for a wide spectrum of patients. The hospital pharmacist in agreement with the cardiologist will evaluate the possibility to implement a solution-based formulation to treat more fragile patients, who present history of allergy to ASA, dysphagia or requiring interventional procedures.

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Conflict of Interest No conflict of interest

4CPS-153 OFF-LABEL USE OF KETAMINE FOR RESISTANT DEPRESSION: ROLE OF THE HOSPITAL PHARMACIST

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Background and Importance An intravenous slow infusion of ketamine, glutamate receptor antagonist, has emerged as an effective, safe and rapidly acting antidepressant in different studies. Its efficacy is reported in treatment of resistant recurrent major depression and bipolar depression.

In our country, ketamine is not currently authorised for these indications therefore it is used off-label.

Aim and Objectives The purpose is to present the role of pharmacists monitoring ketamine's off-label prescriptive

appropriateness and give treatments data of 2021 and the first eight months of 2022 in our hospital.

Material and Methods The authors present their role in the authorisation process for off-label use, in compliance with current legislation, and monitoring data which are collected from specialists' assessments/re-evaluations. Psychiatrists collect the patient's informed consent, fill out the authorisation form and deliver it to pharmacists. Pharmacists assess whether exist the conditions under which the ketamine infusion is sustainable in terms of both appropriateness and costs. Once the treatment has been authorised, the collected data are entered in a database periodically updated with authorisation and dispensing information.

Results 37 patients were treated from 01/01/21 to 31/08/22, 17 in 2021 and 20 in 2022.

In 2021, 4 patients had already received 1+ treatments the previous year, whilst 13 patients received the induction dose. Of these patients, 10 switched to a standard maintenance dosage as rapid therapeutic benefit was observed; only 3 discontinued treatment or had a different dosage for clinical reasons.

Between 01/01/22 and 31/08/22, 12 patients received the induction dose while 8 had already received 1+ treatments the previous year; of the 12 patients, 10 switched to a standard dose as a rapid therapeutic benefit was observed whereas only 2 discontinued treatment.

Conclusion and Relevance An intravenous slow infusion of ketamine is safe and effective in the symptoms' stabilisation.

The role of the pharmacy will be to continue monitoring and improve a database to be used to propose ketamine's administration in depression for inclusion in the list of medicines supplied by the National Health Service to be used for a therapeutic indication other than the authorised ones.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-155 CREATION AND VALIDATION OF A MEDICATION REVIEW SUPPORT TOOL FOR POTASSIUM CHLORIDE INJECTION (KCL-INJ) PRESCRIPTIONS

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Background and Importance KCl-inj is a risky drug, its administration error is a Never Events. Limiting its use to justified situations contributes to its security. Medication Review (MR) contributes to this limitation. Despite awareness campaigns, non-compliant prescriptions persist. During the MR, the Pharmaceutical Intervention (PI) includes a Prescription Proposal (PP): for KCl-inj the clinical context has a strong impact and complicates the MR.

Aim and Objectives Creation and validation of a support tool for the MR of KCl-inj prescriptions allowing taking into account the entire clinical context of the patient.

Material and Methods Bibliographic research associated with brainstorming on the various clinical and biological criteria of the patient and their consequences allowed setting up of a flowchart.

For validation: experimentation of the tool in a prescriptions prospective study (for each prescription the problem related to

therapeutics, the proposed PP and its acceptance are collated in an Excel file); then discussion and validation of the results in Medicines and Sterile Medical Devices Commission (MSMDC), in particular for the not accepted PIs.

Results The flowchart criteria are kalemia, oral intake, KCl-inj concentration, KCl-inj in prevention during high-dose hypokalemic treatments, initiation of treatment. Each of the situations identified is linked to a PI or the absence of PI. 6 axes of PP have been identified including oral co-prescription, switch by electrolyte solution, and adaptation of the volume of solvent.

The study over one month gives 172 lines with a MR according to our tool. 85 prescriptions were compliant. 87 PI formulated including 6 without PP. The PI acceptance rate is 43.2%, with a maximum of 52% for the oral relay and a minimum of 0% for adaptation of the volume of solvent or electrolyte solution switch. At the end of the MSMDC, our tool is validated after an agreement on the importance of promoting the use of electrolyte solution.

Conclusion and Relevance The acceptance rate and the conclusions of the MSMDC allow us to validate the flowchart. Its use improves the relevance of PIs, their acceptance and reduces the use of KCl-inj. To facilitate the use of the tool, an Excel file that identifies the PPs according to the criteria is being developed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-157 COMPARISON OF THE EFFECTIVENESS BETWEEN INTERLEUKIN-23 INHIBITORS FOR TREATMENT OF PSORIASIS IN A THIRD LEVEL HOSPITAL

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Background and Importance Interleukin-23 (IL-23) is a cytokine involved in inflammatory and immune responses in psoriasis. Novel therapies such as tildrakizumab, guselkumab, and risankizumab inhibit the IL-23-receptor interaction.

Aim and Objectives To compare the effectiveness between IL-23 inhibitors in patients with psoriasis in a third level hospital.

Material and Methods An observational, retrospective, descriptive study was conducted in patients with psoriasis treated with tildrakizumab, guselkumab or risankizumab between August-20 and August-22. Demographic, clinical, and treatment specific variables were collected. Effectiveness was determined through the comparison of psoriasis area severity index (PASI) prior starting IL-23 inhibitor and after the first visit (between weeks 4 and 16 after start).

Results The study included 58 patients [62.1% men, median age 51 (23-83) years] out of whom 8 (13.8%) had psoriatic arthritis comorbidity, 11 (18.9%) were treated with tildrakizumab, 20 (34.4%) with guselkumab and 27 (46.5%) with risankizumab. Median of treatment line was 3 (2-5) with tildrakizumab and guselkumab, and 2 (1-12) with risankizumab. Adalimumab was the most common previous therapy (54.5%, n=6 for tildrakizumab; 40.0%, n=8 for guselkumab; 38.5%, n=10 for risankizumab) and the median time of treatment with previous drug was 58.4 (9.8-665.0), 64.5 (1.5-921.0) and 46.6 (0.0-299.0) weeks, respectively. Reasons for

switching to IL-23 inhibitors were treatment failure (100.0%, n=11 for tildrakizumab; 85.0%, n=17 for guselkumab; 84.6%, n=22 for risankizumab), adverse events (15.0%, n=3 for guselkumab; 11.5%, n=3 for risankizumab) or drug interaction (3.8%, n=1 for risankizumab). Median time of treatment with IL-23 inhibitor was 41.9 (16.9-68.0), 44.1 (9.2-168.0) and 26.3 (14.9-96.1) weeks for tildrakizumab, guselkumab and risankizumab, respectively. Median PASI before switching to IL-23 inhibitor treatments vs after first visit were 7.7 (3.3-10.8) vs 1.4 (0.0-5.2) for tildrakizumab, 8.9 (1.0-29.1) vs 0.9 (0.0-6.8) for guselkumab and 7.8 (2.8-21.8) vs 1.2 (0.0-10.4) for risankizumab. 7 patients (35.0%) and 10 patients (37.0%) in treatment with guselkumab and risankizumab respectively achieved PASI 0, while only 3 patients (27.3%) in treatment with tildrakizumab did.

Conclusion and Relevance The duration of the previous treatment was prolonged. Treatment failure was the main reason to initiate an IL-23 inhibitor treatment. Data suggest that guselkumab and risankizumab could be more effective treatments between 4 and 16 weeks compared to tildrakizumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-158 IMPROVEMENT IN PATIENT CARE BY PHARMACIST PHONE CALL AFTER STARTING TREATMENT

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Background and Importance Outpatient Pharmacy Unit (OPU) is the last place that patient goes within the hospital circuit. Usually, patient arrives overloaded with information and worried about his new disease, not being able to assimilate all the information that is offered to him about the new treatment that he has to start.

Aim and Objectives To develop a communication project between patients and OPU professionals to help patients understand, remember and improve adherence to treatment prescribed, detect possible medication-related problems (MRP) and increase the degree of satisfaction with the care received at the OPU.

Material and Methods Project started in April 2019, in the OPU of a regional hospital. Three profiles of patients were included; Profile 1: patients who, after a recent diagnosis, may have a greater psychological impact; Profile 2: those who start treatment with devices that require specific manipulation and Profile 3: those who, due to their special conditions (language, age...) are considered to need reinforcement of the information received in the first visit to the Pharmacy (FVP). When the patient comes to the OPU for the first time, he is offered all the information necessary to start his treatment and is included in a follow-up programme, doing a phone call 3 to 5 days after begin the new medication. On the second visit to the OPU, a satisfaction survey is given.

Results Data collected between April 2019-December 2021. Patients included: 142. Calls made to 100% of patients, 118 patients (83.1%) answered the call. 52.1% of the patients were classified as Profile 1; 37.3% Profile 2, and 10.6% Profile 3. 49 patients (34.5%) reported adverse effects, of which 41 (85.4%) evolved favorably and 8 (14.6%) changed

treatment due to poor tolerance. Regarding the satisfaction survey, 92.4% of the patients reported call was useful to them 95.8% were satisfied or very satisfied with care received at the FVP and at the phone call.

Conclusion and Relevance Phone call after starting treatment reinforces the information given in OPU during the FVP and allows early intervention in detection and resolution of MRP. A high percentage of patients consider the project useful, showing a high degree of satisfaction with the care received.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-160 REAL-WORLD PERSISTENCE WITH DOLUTEGRAVIR/LAMIVUDINE VERSUS BICTEGRAVIR/EMTRICITABINA/TENOFOVIR ALAFENAMIDE AMONG HUMAN IMMUNODEFICIENCY VIRUS PATIENTS

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Background and Importance Persistency can provide information on the comparative effectiveness, durability and tolerability in real-world patient populations.

Little is known about comparative persistence of dolutegravir/lamivudine (DTG/3TC) and bictegravir/emtricitabine/tenofovir-alafenamide (BIC/FTC/TAF), two preferred antiretroviral treatments in our country.

Aim and Objectives To compare persistence between two preferred antiretroviral therapies and analyse reasons for discontinuation.

Material and Methods We conducted a retrospective, non-interventional, longitudinal study. All HIV patients over 18 years treated with DTG/3TC or BIC/FTC/TAF in our centre were included.

Persistence was defined as the duration of time from initiation to discontinuation of therapy (last dispensing or end of the study in March 2022). Persistence was also calculated as a dichotomous variable at the conclusion of the first year of therapy. Permissible gap (days between two prescription fills exceeding the allowable refill period) was 90 days.

Covariates collected from medical record were: age, gender, viral load (VL), CD4 count, number of previous antiretroviral medications, Charlson comorbidity index and Medication Possession Ratio (MPR).

Persistence after first year was compared using the χ^2 test. Kaplan-Meier survival analysis was performed and differences were evaluated using the log-rank test. Adjusted risk of discontinuation was assessed with Cox Proportional Hazard models. Significance level was 0.05.

Results Three hundred and sixty-two patients were included, 79.2% were male. 5.2% were naive. Age (mean \pm SD) was 47 \pm 12 years. 91.2% had VL < 200 copies and 10.1% CD4 < 200/ml. Number of previous treatments was 3.5 \pm 2.6. MPR was 95.4 \pm 11.1 Charlson comorbidity index was 1 \pm 1.66. 49.2% were treated with BIC/FTC/TAF.

97.8% vs 89.7% of patients were persistent after the first for DTG/3TC and BIC/FTC/TAF respectively [OR = 5.1 (CI95% 1.7-15.6); p = 0.002].

Overall, mean persistence duration was 1.189 days (CI 95% 1.163-1.215). Persistence with DTG/3TC was 1.231 days (CI 95% 1.206-1.255) and persistence with BIC/FTC/TAF was 980 days (CI 95% 944-1.016); p = 0.001. However Cox-model adjusted HR was 2.5 (IC95% 0.5-12; p = 0.26).

The main reasons for discontinuation for BIC/FTC/TAF were tolerability/toxicity (n = 9) and death (n = 3). Only two patients withdrew DTG/3TC, due to toxicity (n = 1) and death (n = 1).

Conclusion and Relevance In our study, more patients on DTG/3TC were persistent after the first year compared to BIC/FTC/TAF. However, there were no differences in overall persistence in covariate-adjusted analysis. Main reason for BIC/FTC/TAF discontinuation was tolerability/toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-162 TRIPLE WHAMMY DRUG-DRUG INTERACTION: CLINICAL RELEVANCE AND RESULTS OF PHARMACEUTICAL INTERVENTION

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Background and Importance Acute kidney injury (AKI) is a highly prevalent condition among inpatients, usually attributed to pharmacological causes. One of the most clinically relevant drug-drug interactions (DDI) in this context is the triple whammy interaction (TWI), caused by the addition of three potential nephrotoxic groups of drugs: Non-steroidal anti-inflammatory drugs (NSAIDs), diuretics and ACE inhibitors/angiotensin receptor blockers (ARB).

Aim and Objectives To evaluate clinical significance of the TWI, as well as the role of pharmaceutical intervention (PI) in preventing possible adverse events due to this DDI.

Material and Methods Observational retrospective study that included patients who were prescribed the TWI over a period of 4 years (2018 to 2022). Data were collected using computerised medical records, nurse administration registry and PI data base. ICU patients were excluded from this study. Recommendation of monitoring serum creatinine and potassium, as well as discontinuing the triple therapy was carried out in all patients. Incidence of AKI was calculated according to AKIN criteria. Impact of PI was estimated based on average number of days patients received the combination and amount of time until complete resolution of AKI.

Results 34 patients were included and stratified according to their risk factors for developing AKI. 87.5% patients were considered at high risk. The first cause of admission was surgery in 62% of cases. Mean basal SCr was 0.99 (CI 95% 0.82-1.15). Acceptance of PI rate was estimated in 65.62%. Incidence of AKI was 29.4% (10/34), 8 of which were classified as AKIN 1. Mean duration of the triple therapy was 6.81 days (CI 95% = 3.47-10.15) in non-accepted PI group vs 3.17 days (CI 95% = 2.23-4.11) in the accepted PI group. AKI was detected more frequently in accepted PI patients (7/10). However, these patients recovered normal renal function faster than patients with no approved PI: 10 days (CI 95% = 5.41-14.58) vs 14.33 days (CI 95% = 8.52 - 20.14), respectively.

Conclusion and Relevance The TWI can participate in acute kidney injury, particularly in high risk patients. Clinical pharmacists play an important role detecting patients at increased risk of AKI, preventing adverse events due to TW interaction, monitoring AKI biomarkers and recommending deprescription of possible nephrotoxic drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-163 CYTOCHROME P450 2C19 GENOTYPING FOR PERSONALISATION OF PROTON PUMP INHIBITOR THERAPY

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Background and Importance Proton pump inhibitors (PPIs) are hepatically metabolised primarily by the cytochrome P 450 2C19 enzyme. PPIs are generally considered effective, however CYP2C19 genetic polymorphisms may result in patients not responding appropriately to treatment. CYP2C19 genotyping and interpretation of results may be a contribution by pharmacists towards personalisation of PPI therapy.

Aim and Objectives The aim was to determine the prevalence of CYP2C19 genetic polymorphisms in a cohort of patients showing PPI therapy resistance.

Material and Methods Patients diagnosed with gastro-oesophageal reflux disease or peptic ulcer disease and with documented PPI therapy resistance were identified using ambulatory reflux monitoring and endoscopy databases. An EDTA blood sample was collected from each patient, followed by genomic DNA extraction with the QIAcube (Qiagen). CYP2C19 genotyping was performed with real-time polymerase chain reaction on the GeneAmp PCR System 9700 thermal cycler and reverse hybridisation using the TwinCubator with the PGX-CYP2C19 StripAssay® (Vienna-Lab). Genotypes (phenotypes) were classified as: *1*1 (normal metabolisers, NMs), *1*17 (rapid metabolisers, RMs), *1*2 or *2*17 (intermediate metabolisers, IMs), or *2*2 (poor metabolisers, PMs). The 2021 Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline was used for genotype-based dosing recommendations, which suggests that NMs may be at increased risk of therapeutic failure compared to IMs/PMs, RMs are at increased risk of therapeutic failure, while IMs/PMs have increased chance of efficacy but risk potential toxicity.

Results Thirty-eight patients were recruited; all Caucasian; 20 female, mode 50-59 years (n=11). Most patients (n=17) experienced reflux hypersensitivity, followed by persistent oesophagitis despite PPI treatment (n=10). PPI therapy included esomeprazole (n=20), omeprazole (n=16) or lansoprazole (n=2). The majority of patients (n=20) were genotyped as *1*1 (NM), followed by *1*/17 (n=7, RM), *2*17 (n=6, IM), *1*2 (n=4, IM) and *2*/2 (n=1, PM).

Conclusion and Relevance The majority of patients in this study may be (53% NMs) or are (18% RMs) at risk of therapeutic failure, and the guideline recommends considering a

dose increase and monitoring for efficacy in these patients. In patients at risk of side-effects (29% IMs, PMs), the guideline suggests reduction in dose and continued monitoring for efficacy. Pharmacist-led CYP2C19 pharmacogenetic testing can be used a tool to guide dosing and monitoring in patients taking PPIs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-164 ADEQUACY REVIEW IN THE USE OF DAPAGLIFLOZIN FOR THE TREATMENT OF HEART FAILURE

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Background and Importance Protocol for use of dapagliflozin was approved for the adult treatment of symptomatic chronic heart failure with reduced left ventricular ejection fraction (LVEF) in patients uncontrolled with first-line therapies, angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) with beta blockers, and second-line therapies, aldosterone antagonists.

Aim and Objectives To evaluate the use of dapagliflozin in the treatment of heart failure in hospitalised patients, assessing the degree of prescription compliance with the protocol agreed upon by the Pharmacy and Therapeutics Committee.

Material and Methods Retrospective observational study between December 2021 and April 2022 of hospitalised patients who started treatment with dapagliflozin. The study variables were: sex, age, reason for admission, presence of heart failure with LVEF <40%, concomitant treatment with ACEI, ARB, beta blockers, aldosterone antagonists, positive inotropics, sacubitril/valsartan or diuretics, and presence of diabetes with or without antidiabetic treatment. Clinical data were obtained from the Orion-Clinic® electronic medical record program.

Results In the period evaluated, 61 patients initiated dapagliflozin 10 mg per day, 42 men (69%), with a median age of 76 years (IQR 84-66). A total of 46 patients (75%) presented heart failure on admission and the rest were admitted for other cardiac pathology. Only 38 patients (62%) had an LVEF registry, of which 22 patients (36%) had an LVEF < 40% with a median LVEF of 32% (IQR 35-25). Forty-four patients (72%) were diabetic and 6 patients (17%) were treated with dapagliflozin in combination with metformin. For the study of concomitant treatments: 22 patients (36%) were prescribed ACEI/ ARB, 38 patients (62%) beta blockers, 8 patients (13%) positive inotropics, 21 patients (34%) aldosterone antagonist diuretics, 41 patients (67%) loop/thiazide diuretics and 9 patients (14.8%) sacubitril/valsartan. To highlight, 11 patients (18%) were being treated with the combination ACEI/ARA-II +beta blockers+aldosterone antagonist. Finally, only 35 patients (57%) continued with dapagliflozin as discharge treatment.

Conclusion and Relevance The degree of adequacy of dapagliflozin prescription to the approved protocol for use was high but an appreciable percentage of patients do not adhere to the inclusion criteria, indicating that the protocol

recommendations should be revised to ensure effective use of dapagliflozin. Only half of the patients who initiated treatment continued after discharge.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-166 IMPLEMENTATION OF A LINEZOLID PHARMACOKINETIC MONITORING PROGRAMME

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Background and Importance Linezolid is an antibiotic that presents high inter- and intra-individual variability and therefore may compromise its clinical efficacy or increase the risk of associated toxicity.

Aim and Objectives To establish a programme for monitoring linezolid plasma levels that will allow us to proactively identify patients who can benefit most from its use and to evaluate its results in our centre.

Material and Methods A literature review was performed to define the criteria that allowed us to identify patients who were candidates for pharmacokinetic monitoring of linezolid.

We established the determination of plasma concentrations before the administration of the 5th dose and then periodically every 3-4 days until the end of treatment. The efficacy and safety criterion was to maintain the trough plasma concentration (C_{min}) in the therapeutic range (between 2 and 8 mg/L).

Results The criteria selected for the identification of patients who were candidates to be part of the monitoring programme were: critical patients, transplanted patients, severe burns or cystic fibrosis, obese patients (BMI > 30), kidney failure (creatinine clearance < 30 ml/min) and liver failure (Child Pugh C), renal replacement therapies, prolonged treatments (> 3 weeks) and treatment with Glycoprotein-P inducers.

From January to April 2022, a total of 20 patients that met at least one of the aforementioned criteria were included in the programme. All patients started treatment in critical care units and the chosen route of administration was intravenous. Eighty-five percent of the patients were men, the median age was 69 years and the mean duration of treatment was 11.6 days.

A total of 50 samples were analysed (2.5 samples per patient). The mean C_{min} was 5.3 mg/L. Thirty samples (60%) were out of therapeutic range.

Fifty pharmacokinetic reports were performed. In 60% of the cases, modifications of the dosing regimen were made: 17 were dose increases and 13 were dose decreases.

Conclusion and Relevance Incorporating this programme into clinical practice allows us to proactively identify the patients who could benefit most from linezolid monitoring.

The results demonstrate the high variability of linezolid plasma levels and the usefulness of dosing recommendations issued by the Pharmacy service to ensure that the C_{min} remains within the therapeutic range.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-167 CURRENT TRENDS IN THE USE OF CHECK-POINT INHIBITORS FOR NON-SMALL-CELL LUNG CANCER

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Background and Importance Over the last years, immunotherapy has changed the treatment paradigm of non-small-cell lung cancer (NSCLC). The number of patients treated with immune check-point inhibitors (ICI): atezolizumab, durvalumab, pembrolizumab and nivolumab has dramatically increased.

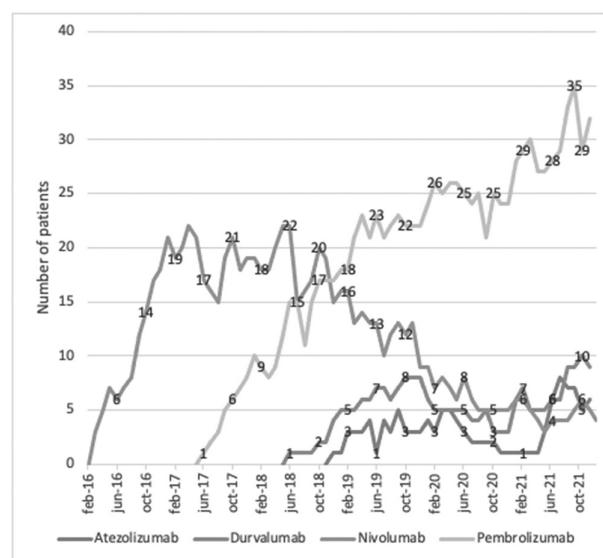
Aim and Objectives To evaluate the current trends in the use of ICI for NSCLC in a third level hospital.

Material and Methods A retrospective observational study was conducted, including patients with NSCLC who had received treatment between 2016 and 2021 with chemotherapy or ICI (atezolizumab, durvalumab, nivolumab or pembrolizumab). The data collected was drug, date and number of administrations, days between each administration and clinical response.

Results During the study period, there were 606 patients being treated for NSCLC, and 254 of them received ICI (41.91%).

Conclusion and Relevance The total number of patients treated with ICI for NSCLC has increased constantly during this period of time (49.15% increase between 2016 and 2021). Moreover, immunotherapy entail the treatment of nearly half of the NSCLC patients.

During the time period studied, the use of nivolumab has decreased, favouring pembrolizumab, probably because of the rise of its new approved indications. Secondly, the number of patients who have received atezolizumab and durvalumab has kept comparable.



Abstract 4CPS-167 Figure 1

Abstract 4CPS-167 Table 1 Number of patients, administrations and days between each administration of ICI

| | Atezolizumab | Durvalumab | Nivolumab | Pembrolizumab |
|--|--------------|------------|------------|---------------|
| Number of patients (%) | 26 (10.24) | 24 (9.45) | 85 (33.46) | 120 (47.24) |
| Median number of administrations (IQR) | 4 (3-8) | 13 (5-24) | 7 (3-22) | 6 (3-13) |
| Mean days between administrations (SD) | 24 (7.43) | 18 (7.67) | 22 (31.38) | 25 (15.99) |

We can see a significant decrease on the number of patients treated with an ICI between May 2020 and August 2020, possibly influenced by the decrease in the number of patients diagnosed with NSCLC during the COVID-19 pandemic.

The mean days between each ICI administration was slightly above the approved posology, possibly due to delays because of adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-168 RESULTS OF THE USE OF GALCANEZUMAB IN ROUTINE CLINICAL PRACTICE

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Background and Importance Migraine is a highly disabling neurovascular disorder characterised by a severe headache and trigeminovascular system activation, involving the release of calcitonin-gene related peptide (CGRP). Galcanezumab is a humanised monoclonal antibody blocking the CGRP.

Aim and Objectives

Analyze:

- The effectiveness of galcanezumab in the prophylaxis of chronic migraine
- Response to other anti-CGRP monoclonal antibodies after galcanezumab failure

Material and Methods Observational-retrospective study from January 2020 to September 2022. Patients in whom at least one year had passed since the start of galcanezumab treatment were included.

Variables analysed: demographics, baseline migraine days/month (MDM), three months later, objective response rate (ORR) >50%, duration, reason for suspension, and action. The headache impact test (HIT-6) was performed at baseline vs after three months of treatment. This score presents a range between 36 and 78 (<49= little or no impact, 50-55= certain impact, 56-59= important impact, >60= very severe impact).

Quantitative variables were expressed as median (interquartile range).

Results 56 patients were included.

| | |
|-----------------------|-----------------|
| Age | 50(43-58) years |
| Gender (woman) | 77% |
| Galcanezumab duration | 6(6-9) months |
| MDM month 0 | 15(14-17) |
| MDM month 3 | 5(3-6) |
| ORR>50% | 84% |
| HIT6 month 0 | 72(68-76) |
| HIT6 month 3 | 49(48-57) |

- 9%(5) of the patients continue with active treatment, 100% maintain effectiveness, median MDM: 3(2-6).
- 91% (51) discontinued treatment:

| Reason for suspension | 67% Neurologist's decision | 29%lack of effectiveness | 4% Toxicity |
|-----------------------|----------------------------|---------------------------|-------------------------------|
| | (34) | (15) | (2) |
| Medical action | Reset Galcanezumab | No required reset* | Change to Erenumab |
| | | | Change to Fremanezumab |
| N°Patients | 19 | 15 | 7 |
| MDM month 0 | 15(12-16) | | 15(15-20) |
| MDM month 3 | 4(3-5) | | 15(12-17) 15(7-20) |
| ORR >50% | 89% | 25% | 43% |
| HIT-6 month 0 | 73(68-76) | | 73(68-78) 66(59-70) |
| HIT-6 month 3 | 57(50-68) | | 72(64-78) 57(55-67) |

*Median months without treatment after suspension: 7(5-11).

Conclusion and Relevance A high percentage of patients presented a good response to galcanezumab, with an improvement in the HIT-6 score.

A large number of patients who received temporary prophylaxis with galcanezumab did not require another visit to the neurologist. Most of the patients who required reintroduction of galcanezumab reached an ORR>50%.

Less than half of the patients who restarted therapy with a different anti-CGRP after galcanezumab failure, achieved an ORR>50%.

All patients who continued with galcanezumab from the start, maintained effectiveness of the treatment

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-171 METHADONE DRUG-DRUG INTERACTIONS POTENTIALLY RELATED TO CARDIOVASCULAR EVENTS IN CLINICAL PRACTICE

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Background and Importance Methadone continues to be the drug of choice in managing opioid withdrawal. However, it is known that its use is related to QT prolongation, torsades de pointes and even sudden cardiac death. The interaction with other drugs could worsen this effect.

Aim and Objectives To quantify the prevalence of methadone drug-drug interactions with risk of QT interval prolongation and the incidence of cardiovascular events during admission.

Material and Methods We conducted a retrospective, descriptive study that included all patients receiving methadone in a tertiary hospital between January 2021 and September 2022.

The variables collected were: age, sex, opioid abuse, treatment with methadone prior to admission, methadone dose, cardiovascular history, number of drugs prescribed -in addition to methadone- likely to prolong QT during admission, and development of cardiovascular complications. Interactions were consulted in Lexicomp

Results A total of 109 patients were collected, the median age of 56 (interquartile range (IQR) 50-60), and 74.3% were male. 82.6% of patients had a history of substance abuse recorded in the electronic medical record, with previous opioid use explicit in 61.5% and were on methadone treatment. Remaining percentage were on methadone for: respiratory weaning (9.3%), analgesia (3.5%) and new managing opioid withdrawal (4.6%). The median methadone dose was 50 mg (IQR 35-80 mg). A total of 9.2% had a history of cardiovascular disease prior to admission.

Patients received a mean of 1.8 QT-prolonging drugs in addition to methadone during admission. In this cohort, 93.6% of patients received any QT-prolonging drug, 48.6% and 21.1% two or three QT-prolonging drugs, respectively. The most frequently prescribed QT-prolonging drugs were quetiapine (24.8%), mirtazapine (19.3%) and ondansetron (12.9%). During admission, 11.0% of patients suffered a cardiovascular event with arrhythmias being the most frequent event (54.6%). A higher proportion of patients with previous cardiovascular history suffered a new cardiovascular event (19.3% vs 7.2%).

Conclusion and Relevance Our results show a high prevalence of patients using methadone concomitant with other drugs likely to prolong QT during admission.

A more significant proportion of patients with a previous history of cardiovascular events suffered a new event during hospitalisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-172 BROADALUMAB'S EFFECTIVENESS ON MODERATE TO SEVERE PLAQUE PSORIASIS IN REAL PRACTISE

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Background and Importance Plaque psoriasis is a chronic pathology with an important impact on patients' quality of life and emotional health. Brodalumab was the last anti-interleukin17 (IL-17) arriving to patients.

Aim and Objectives To evaluate brodalumab effectiveness in real practise

Material and Methods Multicentric, retrospective and observational study performed to evaluate brodalumab in patients with moderate – severe plaque psoriasis between June 2021 and June 2022. Data extracted from clinical records application and prescribing programme, demographic data (age, sex), and clinical (previous biologic treatment lines, body surface area (BSA) and psoriasis area severity index (PASI) before treatment and in each dermatologic control). Effectiveness was measured comparing AMAGINE clinical trials PASI75 results (efficacy calculated with weighted average).

Results 41 patients with brodalumab as active treatment, 1 was excluded due to lack of follow up and other due to late start of treatment. 39 patients included, 52.4 years averaged, 66.7% were men. Other lines of treatments approved for moderate-to-severe plaque psoriasis were used as first line in 19 patients, as 2nd line in 5, as 3rd line in 3 and as 4th line in 5 patients.

Average BSA and PASI at baseline were 14.32 and 11.55 respectively. After a median of 23 weeks, our patients reached PASI75 in 56%, PASI90 in 51% and PASI100 in 49% of cases. No patient stopped treatment.

After 40 weeks, 3 patients had changed their treatment and 4 had not reached the next visit to Dermatology. PASI90 and PASI100 kept in 9 of 23 patients (39%), as PASI75 still was kept by 11 patients (48%).

After one year of treatment, only 15 patients were active with treatment, and PASI90 and PASI100 were kept by 5 patients of 10 with recorded data.

According to clinical trials, brodalumab achieves a PASI75 in 85% of patients at 12th week and kept a PASI75 in 68% of patients at 52nd week.

Limitations: several patients did not have recorded in their clinical history BSA and PASI after 12th week visit.

Conclusion and Relevance Our findings show that brodalumab is less effective in real practice but it can be considered as a potent antipsoriatic agent in clinical practise. Further and longer studies should be made.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-173 EVALUATION OF INCLUSION CRITERIA OF OUTPATIENTS INCLUDED AT HOSPITAL MEDICATION DISPENSING PROGRAMME THROUGH COMMUNITY PHARMACIES

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Background and Importance During the context of the COVID-19 pandemic, in order to avoid the possible transmission of SARS-COV2, some hospitals developed an outpatient hospital medication dispensing programme through delivery to community pharmacies. To access the programme, outpatients had to meet all the criteria established by Health Authorities: adherence to treatment, live more than 30 km from the hospital and present some vulnerability condition (age >65 years, reduced mobility or respiratory pathology). This programme has been maintained over time due to the excellent acceptance by patients.

Aim and Objectives To evaluate the compliance of our hospital with the inclusion criteria and analyse possible deviations, assessing whether it is necessary to modify them based on the current health context.

Material and Methods Cross-sectional observational study in which all active outpatients in the programme between July and September 2022 were included.

The following variables were collected: demographic, distance between home and hospital, vulnerability conditions and adherence to treatment.

Results 95 patients were evaluated, 94 (98.9%) of them were adherent to chronic treatment, 81 (85.3%) lived more than 30 km from the hospital. Regarding the vulnerability conditions: 68 (71.6%) were older than 65 years and 14 (14.7%) had a vulnerability condition other than age over 65 years.

Of all the evaluated patients, 75 (78.9%) met all the inclusion criteria. 20 (21.1%) patients were in the programme, but did not meet some criteria: 6 (30.0%) patients lived less than 30 km away, 8 (40.0%) did not have a vulnerable condition and 6 (30.0%) did not meet more than one inclusion criteria.

Conclusion and Relevance The medication dispensing programme through community pharmacies offers an option for vulnerable patients and/or those with difficulty going to the hospital to collect their chronic medication, thus facilitating therapeutic compliance of treatment.

Although a high percentage of patients met the established criteria, deviations were detected. That make us consider the need to modify these criteria in order to access in the programme according to current needs of outpatients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-175 SEPSIS CODE: IMPROVING OUTCOMES FOR PATIENTS WITH SEPSIS

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Background and Importance Sepsis is a common and potentially life-threatening condition triggered by an infection.

Code Sepsis (CS) includes standardised Surviving-Sepsis-Campaign management bundles meant to guide early recognition and prompt goal-directed therapy, in order to improve clinical outcomes.

Multidisciplinary CS-team daily evaluates all patients with 'CS-alert' in order to guarantee compliance with sepsis bundles and promoting appropriate antimicrobial-use.

Aim and Objectives To assess the impact of CS implementation on clinical outcomes and antibiotic therapy.

Material and Methods Experimental study from November-2020 to September-2022. All patients with confirmed sepsis/septic shock were included.

Mean outcome: overall and trend of in-hospital mortality rate (MR).

Secondary variables:

- Median length of hospital-stay (LOS) and Intensive Care Unit stay (ICU-LOS).

- Severity criteria: ICU-admission (%).
- Mean length of antibiotic therapy (LAT): overall, antipseudomonal-carbapenems and antibiotics against resistant-gram-positive bacteria (daptomycin, vancomycin and linezolid).

Variables were analysed by trimesters. Median and interquartile range (IQR) were used to describe all the quantitative variables. Lineal-regression was performed for trend analysis.

All statistical analyses were assessed with SPSS®V25.0. Significance level was 0.05.

Results A total of 422 CS alert was activated in 402 patients. Median age=79 years (RIQ 16), 61.1% males.

Admission ward=12.8% surgical, 81.5% medical and 5,7% ICU.

Global MR was 20.6% with a significantly downward trend (slope=-2.2; CI95% -3.4 to -1.0). The overall MR was reduced in 53.8% (38.9% vs 20.9%).

Median LOS was 8days (RIQ 12) and showed a negative trend (slope=-0.4; CI95% -0.7 to 1.02). The median ICU-LOS stay was 6days (RIQ 8.7) with a 9.0% of ICU-admissions, which also decreased during the study (slope=-0.2; CI95% -0.6 to 0.2).

The overall LAT was 9.3days, with trend toward shorter courses (slope=-3.2; CI95% -0.9 to 0.2). Mean duration of antipseudomonal-carbapenems was 4.2days (slope=-2.2; CI95% -0.5 to 0.1), whereas anti-gram-positive was 5.4days (slope=-0.1; CI95% -0.8 to 0.6).

Conclusion and Relevance The CS implementation was associated with a decrease mortality, with an overall reduce by up to 50%. The downward trend in LOS and ICU-admissions suggests that an early recognition of sepsis and optimised-treatment are crucial in preventing complications.

Daily patient surveillance and follow-up by a multidisciplinary team promoting antimicrobial de-escalation/discontinuation was associated with shorter courses of antibiotics without worsening clinical outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-176 EVALUATION OF NIRMATRELVIR/RITONAVIR USE AND EFFECTIVENESS

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Background and Importance Nirmatrelvir/ritonavir (PAXLOVID) is a recently approved drug to prevent progression in high-risk COVID-19-infected patients.

Aim and Objectives To evaluate prescribing and dispensing of PAXLOVID and the proportion of patients with hospitalisation or death from any cause at 28 day.

Material and Methods Descriptive, retrospective, observational study carried out between May and August 2022 in a second-level hospital. All patients with PAXLOVID prescription were selected. Sources of information were: electronic medical records and the prescription programme. The Variables analysed were: sex, age, risk factors, indications, interactions,

dispensation (yes/no) and final treatment received. Risk factors were evaluated with our country's drug regulatory agency (DRA) recommendations to assess the indication. Efficacy was assessed by the proportion of patients admitted to hospital and 28-day mortality.

Results PAXLOVID was prescribed to 34 patients, 14 (41.2%) were women. The median age was 76.3 years old [RIQ 25.4]. Main indications for PAXLOVID were: to be undergoing treatment with myelotoxic chemotherapy (32.3%), corticosteroids or other immunosuppressants (29.4%); being over 80 years of age and presenting specific Risk factors (14.7%) and primary immunodeficiency (5.8%). 21 patients (61.8%) had some relevant interaction with their usual medication. The most frequent interactions were with statins (23.5%), analgesics (20.6%), oral anticoagulants (12%), antiarrhythmics (8.8%), antiplatelet drugs (5.8%), antidepressants (5.8%) and antiarrhoeals (5.8%).

After Validation by the Pharmacy Service, 11 patients (32.4%) did not receive PAXLOVID, 5 because they did not meet DRA criteria, 2 because their glomerular filtration rate was less than 30 ml/min and 4 because they had incompatible interactions. 4 patients finally received 3 days-remdesivir.

Among patients who received PAXLOVID, 82.26% received full doses, with 4 patients (11.76%) requiring adjustment for renal impairment. 3 patients (13%) were hospitalised in the first month, none died.

Conclusion and Relevance The main indications for which PAXLOVID was prescribed were patients undergoing chemotherapy and/or immunosuppressive treatments. Interactions with PAXLOVID were frequent and in some cases limited treatment. Validation by Pharmacy Service prevented a considerable number of patients from receiving PAXLOVID when it was no-indicated or when they had insurmountable interactions, also allowed patients to receive the dose adjusted for renal impairment. PAXLOVID was effective in avoiding hospital admission and mortality in the majority of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-177 OPTIMISATION OF THE THERAPEUTIC MANAGEMENT OF PATIENTS ON ECMO IN THE PAEDIATRIC INTENSIVE CARE UNIT

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Background and Importance Extracorporeal Membrane Oxygenation (ECMO) is a last-resort rescue technique that allows the replacement of circulatory and/or respiratory functions. The pharmacokinetic modifications generated by this circulatory assistance require the adaptation of the dosage of certain drugs

Aim and Objectives The objective was to compare the drug prescription of patients under ECMO with data available in the literature to propose appropriate dosages

Material and Methods Our 6-month prospective observational monocentric study focuses on patients in the paediatric intensive care unit receiving ECMO. Clinico-biological data were collected from the computerised patient record and by our daily presence in the department. We noted

the type and indication of ECMO, complications and adequacy of dosages compared to the literature for relevance

Results 14 patients under ECMO were included: mean age 18 months [0 to 168 months], sex ratio=1. Renal function was impaired in 8 patients (57%). The average duration of ECMO was 15 days [3-24 days]. 6 patients were weaned, 4 of whom were still hospitalised on the ward (43%) and 8 patients died (57%). 13 patients (93%) were on veno-arterial ECMO, following acute respiratory distress syndrome (8 cases or 61%), refractory cardiac arrest (3 cases 23%), cardiogenic shock (8%) or septic shock (8%). 1 patient (7%) was on veno-venous ECMO following an acute respiratory distress syndrome (ARDS). 11 patients (79%) developed complications related to ECMO (9 haemorrhages, 8 hemolysis, 6 oxygenation difficulties, 5 PAO, 4 stroke). Concerning the drug management of these patients, we counted 16 overdoses and 2 underdoses not justified either by the literature or by therapeutic drug monitoring (TDM) i.e. 18 nonconformities out of 73 lines analysed (Vancomycin, Gentamicin, Fluconazole, Caspofungin, Voriconazole, Ganciclovir, Heparin, Morphine, Sufentanil, Midazolam, Cisatracurium, Hydrocortisone Hemisuccinate, Methadone)

Conclusion and Relevance The populations studied in the literature remain different from ours, making it difficult to discuss our clinical results. However, following the non-conformities of dosage noted, we propose a table of dosage adaptation under ECMO synthesising the literature for the studied molecules which is systematically accompanied by instructions to make a TDM

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-180 VANCOMYCIN: CONCORDANCE OF DOSAGE ADJUSTMENT ACCORDING TO MINIMUM PLASMA CONCENTRATION AND AREA UNDER THE CURVE/ MINIMUM INHIBITORY CONCENTRATION

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Background and Importance The pharmacokinetic/pharmacodynamic (PK/PD) target for vancomycin has recently been defined as an area under the curve (AUC) over 24 hours/minimum inhibitory concentration (MIC) of 400-600.

Aim and Objectives To evaluate the degree of concordance of recommendations after dose adjustment of vancomycin according to minimum plasma concentration (C_{min}) and AUC/MIC ratio.

Material and Methods Retrospective study in adult patients who were treated with vancomycin administered by intermittent perfusion and monitored by the Pharmacy Service at a general hospital during the month of August 2022.

Variables collected: sex, age, weight, height, glomerular filtration rate (according to Cockcroft-Gault), total daily dose and recommendation issued based on the determination of C_{min} and AUC/MIC.

Appropriate C_{min} were considered 15-20µg/mL in complicated infection (endocarditis, nosocomial pneumonia,

meningitis, osteomyelitis/osteoarticular infection and wound infection/abscess) and 10-15µg/mL in all other infections. For the calculation of AUC/MIC, MIC=1µg/mL was assumed. Interpretation of plasma level and individualised vancomycin adjustment was performed using MediWare Pharm++[®] software using a bicompartamental model and a single vancomycin level (C_{min}).

Results Vancomycin treatment was initiated and monitored in 42 patients (52.4% female; 72.3 ± 12.3). Anthropometric parameters (weight: 81.8 ± 17.9kg; height: 163.8 ± 7.9cm; glomerular filtration rate: 61.5 ± 27.0ml/min/1.73m²); total daily dose: 1,878.5mg ± 524.8mg. The recommendation issued was concordant via C_{min} and AUC/MIC in 35.7%. In the case of discordance, overexposure was observed in 66.6% of cases.

Conclusion and Relevance Approximately 2 out of 3 recommendations were discordant according to the method used, with a high number of overexposures observed in the case of recommendations based on C_{min}. Therefore, despite the small sample size, the implementation of vancomycin therapeutic monitoring according to AUC is considered necessary for the optimisation of therapeutic management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-181 FOLLOW-UP OF EXPOSED NEWBORNS TO HIV IN PREGNANCY IN A TERTIARY HOSPITAL

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Background and Importance The rate of new HIV diagnoses due to vertical transmission (VT) in Spain is very low and the new cases are related to failures in the implementation of prevention measures.

Aim and Objectives The aims of study are to identify and quantify risk factors (RF) for VT in the prenatal, intrapartum and postnatal periods and to evaluate the adequacy of antiretroviral (ART) prophylaxis, the appearance of adverse events and follow-up during the first year of life.

Material and Methods A descriptive, retrospective and observational study was designed which included all the children who were followed up in the hospital during the 2010-2020 period. The main RFs that could contribute to VT were defined in the three periods and demographic and clinical variables of mothers and children were collected. The follow-up was recorded during the first year.

Results A total of 30 children, of 22 HIV + mothers, were included. They were young women, mostly from immigrant communities and without toxic habits. 17% of the pregnant women were diagnosed during the pregnancy controls and of the remaining, 20% did not take ART treatment at the beginning of pregnancy. At the time of birth, 34.5% had detectable viral loads (CV). Regarding children, 57% were born by cesarean section and 13% were premature. The RF detected correspond mainly to the prenatal period (62.5%), followed by the intrapartum (26.8%) and the postnatal period. The most frequent RFs were detectable CVs followed by premature rupture of membranes. All the children received prophylaxis that was well tolerated, observing

discrepancies regarding the regimen received. All children could be analytically confirmed the absence of VT, in some cases after 18 months.

Conclusion and Relevance None of the newborns became infected with HIV. Although the majority of mothers carried out controls during pregnancy, the absence of ART before/during pregnancy stands out, together with detectable CVs as the main RF detected. Information campaigns are necessary for the prevention of VT viewing during pregnancy, as well as, training for professionals and constant updating of protocols to guarantee the correct management of children exposed to HIV.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-182 EXPERIENCE OF DISCONTINUATION TYROSINE KINASE INHIBITORS THERAPY IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA IN CLINICAL PRACTICE

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Background and Importance The treatment of chronic myeloid leukaemia (CML) with tyrosine kinase inhibitors (TKI) results in optimal cytogenetic and molecular responses, improving life expectancy. Nevertheless as a lifelong pharmacological treatment, can lead to adverse events (AEs) that can substantially impact the quality of life, adherence and therefore the success of treatment. Nowadays, discontinuing treatment in patients who achieved a sustained deep molecular response (DMR) is the main goal in CML therapy, in order to achieve a Treatment-Free Remission (TFR), leading to lower occurrence of drug-related AEs, cost reduction and feeling of cure.

Aim and Objectives To describe the clinical experience of discontinuing the therapy with TKI in patients diagnosed with CML.

Material and Methods Retrospective, descriptive, single centre (350-bed university hospital) study of patients with Philadelphia chromosome (Ph) positive CML in chronic phase, treated with TKI till august 2022. Criteria for discontinuing the treatment: ≥5 years with TKI treatment and DMR achieved (molecular response (MR) ≥4.0 during ≥36 months). Outcomes were collected from medical records: gender, age, TKI treatment, follow-up time, candidates to discontinuation, time elapsed to reach MR, time between treatment start and discontinuation, TFR duration, percentage of patients who lost response and were reintroduced to therapy, time to lost of response, withdrawal symptoms and disease progression.

Results There were 48 patients, 70,83% male. Population presented a mean age of 61 (25-81) years. All received first-line imatinib, except one patient who received dasatinib. Follow-up time median was 60 months (3-243). 25% were candidates to discontinuation, median time to reach MR was 15 months (3-50). Time between treatment start and discontinuation showed a median of 9 years (3-16). TFR median was 10 months (3-108). Percentage of patients who lost response and were reintroduced to therapy was 25%. Median time to lost of response was three months since discontinuation. Just

one patient shows a withdrawal symptom (severe anemic) and none of them shows a progression to advanced disease stages.

Conclusion and Relevance High percentage of candidates were safely discontinued and currently remain untreated. Reduction of toxicities associated with TKI therapy could drive to a clinical benefit for CML patients, improving living conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-183 EFFECTIVENESS AND SAFETY OF NIRMATRELVIR/RITONAVIR IN REAL LIFE SETTING

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Background and Importance On March 28th 2022, nirmatrelvir/ritonavir was marketed in Spain. The Spanish Agency for Medicines and Medical Devices (AEMPS) established criteria to prioritise its administration in patients at high risk of progression to severe COVID. Data regarding the effectiveness and safety of nirmatrelvir in preventing severe coronavirus disease outcomes are limited.

Aim and Objectives To assess the effectiveness and safety of nirmatrelvir/ritonavir in patients at high risk for severe COVID-19.

Material and Methods Prospective descriptive study from April to August 2022 of patients treated with nirmatrelvir/ritonavir. Sociodemographic variables, vaccination status, hospital admission, high risk factors for progression and concomitant treatment were recorded. Readmissions were recorded within 30 days of the end of antiviral treatment.

Results 53 patients were included with a mean age of 64 years, 51% women and 49% men. 57% were vaccinated with 3 doses, 17% with 2 doses, 9% with 4 doses, 6% with 1 dose and 11% were not vaccinated. 34% (18/53) were hospitalised at the time of initiation of treatment.

The most prevalent high-risk criteria were: 24% active treatment with myelotoxic chemotherapy, 21% treatment in the previous 6 months with anti-CD20 drugs, 14% over 80 years vaccinated with some risk factor for progression, 7% patients with onco-haematological treatment and 7% in treatment in the previous 3 months with inhibitors of the protein-kinase. 3 treatments were performed off-label for persistent covid.

The mean number of days from the onset of symptoms to the start of treatment was 1.6 days. 23% of patients required dose adjustment due to renal impairment.

53% required adjustment of chronic treatment for interactions, mainly with metemazole, statins, fentanyl and diazepam.

2 patients received remdesivir and sotrovimab, 2 remdesivir and another two sotrovimab.

4 (7%) patients were readmitted within 30 days after the end of treatment with nirmatrelvir ritonavir, 1 of them with persistent covid. One patient stopped treatment for hives.

Conclusion and Relevance Nirmatrelvir ritonavir has been shown to be a safe and effective drug in high-risk patients of progression to severe covid.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-184 WHAT IS THE ADDITIONAL VALUE OF PHARMACEUTICAL INTERVENTIONS ON [123I]-METAIODOBENZYLGUANIDINE SCINTIGRAPHY?

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Background and Importance [¹²³I]-metaiodobenzylguanidine (mIBG) scintigraphy is a tool to assess cardiac sympathetic innervation. It is used to discriminate parkinsonian syndromes. However, many drugs are known to interfere with this radiopharmaceutical that can lead to false results¹

Aim and Objectives The aim of this study was to try to assess the impact of stopping interfering drugs with [¹²³I]-mIBG in a retrospective study before the recent introduction of pharmaceutical interventions in a nuclear medicine department.

Material and Methods A retrospective study from 01/01/2010 to 31/03/2022 was conducted to find out if a drug interaction could explain diagnostic mismatches between a [¹²³I]-Ioflupane and [¹²³I]-mIBG scintigraphies, focusing on the neurological indication i.e. the differential diagnosis of Parkinson's disease. On the nuclear medicine software, a search of all the patients who had both a [¹²³I]-Ioflupane and a [¹²³I]mIBG scan 2010 and June 2022 was performed. Each patient's chart is analysed and the diagnosis is collected.

Results 81 patients underwent [¹²³I]-mIBG imaging for the differential diagnosis of neurodegenerative disease and among them 42 had non-contributory [¹²³I]-Ioflupane imaging (51.9%). A divergent diagnosis between [¹²³I]-mIBG and [¹²³I]-Ioflupane was found in 31% of cases, representing 13 patients. A drug interaction could explain this medical interpretation mismatch in 2 patients (15.4%). Concerning the latter, drugs involved were calcium channel blockers. No abnormality of the sympathetic innervation was found whereas the [¹²³I]-Ioflupane scintigraphy found an abnormality of the dopaminergic transmission. These results may complement existing data suggesting that calcium channel blockers interfered in cardiac [¹²³I]-mIBG imaging through increased sympathetic activity².

Conclusion and Relevance There is a great medical interest in continuing pharmaceutical interventions because drug interactions can lead to non-contributory or inconclusive examinations. In addition, setting up a clinical trial by re-examining these two patients but temporarily stopping the drugs potentially involved could be very interesting. Indeed, this work demonstrates the complexity of assessing the impact of pharmaceutical interventions. Moreover, this process should be evaluated for other categories of radiopharmaceuticals.

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Conflict of Interest No conflict of interest

4CPS-185 ABSTRACT WITHDRAWN

Background and Importance Cilgavimab/tixagevimab are two recombinant human IgG1 \square monoclonal antibodies indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents ≥ 12 years old weighing ≥ 40 kg. In Spain, potential candidates are people with high degree of immunosuppression (due to pathology or treatment), who do not respond adequately to vaccination (anti-anati-S antibodies < 260 BAU/ml).

Aim and Objectives To analyse the effectiveness and safety of cilgavimab/tixagevimab in a tertiary care hospital.

Material and Methods Descriptive, observational, retrospective study. Patients who received cilgavimab/tixagevimab from May-2022 to August-2022 were included. Variables collected: age, sex, risk condition and COVID-19 infection. The risk conditions, according to criteria of the Spanish Agency of Medicines and Health Products were: 1) haematopoietic progenitor transplant recipient or CART-T, in immunosuppressive treatment or with graft-versus-host disease; 2) solid organ transplant recipients; 3) primary combined and B-cell immunodeficiencies with absence of response to vaccination-COVID-19; 4) immunosuppressive treatment with biologic immunomodulators (anti-CD20, abatacept, belimumab or mycophenolate, mainly); 5) solid organ cancer under treatment with cytotoxic chemotherapy or treatments that carry a high risk of severe COVID-19 progression; 6) people at very-high-risk of severe COVID-19 who are contraindicated for COVID-19-vaccination. The primary endpoint was COVID-19-infection after cilgavimab/tixagevimab administration. Safety was analysed by incidence of adverse reactions.

Results 43 patients were included. 23 men (53.5%), median age=64 years old (27-77). 36 patients (83.7%) were in risk group 4 (26 patients treated with rituximab, 6 patients with ocrelizumab, 1 patient with adalimumab and 1 patient with interferon beta-1A) and 7 patients were in risk group 2 (all kidney transplant). 4 patients (9.3%) had COVID-19 infection after treatment with cilgavimab/tixagevimab (3 were in group 4 and 1 was in group 2). The median number of days to COVID-19-infection occurrence in these patients was 25 days. 1 patient had adverse reactions after treatment (tachycardia, general malaise, hematoma, headache, nausea and diffuse abdominal pain).

Conclusion and Relevance The treatment was effective in the majority of patients in our hospital. This supports the use of the drug as prophylaxis to prevent COVID-19 in people who do not respond sufficiently to vaccination. The treatment was well tolerated, presenting low incidence of adverse reactions. Longer term studies should be performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-187 PATIENTS WHO ARE CANDIDATES FOR TREATMENT WITH MONOCLONAL ANTIBODIES FOR PRE-EXPOSURE PROPHYLAXIS OF COVID-19

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Background and Importance Cilgavimab/tixagevimab are recombinant human IgG1 \square monoclonal antibodies, which are indicated for COVID-19 pre-exposure prophylaxis in adults and adolescents ≥ 12 years of age weighing ≥ 40 kg.

4CPS-186 EFFECTIVENESS AND SAFETY OF CILGAVIMAB/TIXAGEVIMAB IN PRE-EXPOSURE PROPHYLAXIS OF COVID-19

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Aim and Objectives To assess patients who are potential candidates for treatment with cilgavimab/tixagevimab in a tertiary care hospital and to describe the search strategy.

Material and Methods In Spain, potential candidates for treatment with cilgavimab/tixagevimab are people with a high degree of immunosuppression (due to pathology or treatment) who do not respond adequately to vaccination. The Spanish Agency of Medicines and Health Products establishes the conditions for patients who are candidates for treatment with cilgavimab/tixagevimab¹. A search for patients was carried out, prioritising the following criteria: haematological patients on treatment with rituximab during the last 9 months, patients with solid organ transplant, patients with multiple sclerosis on treatment with ocrelizumab/rituximab, and patients with recent infection by COVID-19 who belong to any risk group. All of them underwent serology, including in the study those with negative serology (anti-anati-S antibodies < 260 BAU/ml). Those patients were scheduled for cilgavimab/tixagevimab administration.

Results 112 patients (38 = haematological patients on rituximab treatment, 50 = multiple sclerosis patients on rituximab/ocrelizumab treatment and 24 = kidney transplantation) were enrolled. 72 patients were included, 38 women (52.8%), median age 59.5 years old (27-77). The cause of exclusion was positive serology in all cases. 64 patients (88.9%) were on treatment with biologic immunomodulators (35 haematologic patients treated with rituximab <9 months, 27 patients with multiple sclerosis on treatment with rituximab/ocrelizumab/interferon beta-1A and 1 patient on treatment with adalimumab) and the rest were kidney transplant patients. Cilgavimab/tixagevimab was administered to 62 patients (86.1%), 7 patients with unknown reasons, 2 patients had COVID-19 infection and 1 patient had to be excluded for deep vein thrombosis due to the development of symptoms at the time of the appointment.

Conclusion and Relevance More than half of the patients enrolled did not have an adequate response to COVID-19 vaccination. The search strategy was a good tool for administering pre-exposure prophylaxis of COVID-19 to these more vulnerable patients. Further studies are needed to evaluate the effectiveness of the treatment.

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Conflict of Interest No conflict of interest

4CPS-188 QUALITY OF LIFE IN PATIENTS ON GALCANEZUMAB LONG-TERM TREATMENT

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Background and Importance Galcanezumab is a drug indicated for migraine prophylaxis. People with migraine experience significant functional and quality of life (QoL) impairment. Migraine-Specific Quality-of-Life Questionnaire (MSQ) version

2.1 was developed to address physical and emotional limitations.

Aim and Objectives To assess changes in long term QoL in patients treated with Galcanezumab.

Material and Methods Descriptive study of patients who received Galcanezumab (February 2020 to August 2022). QoL data were collected from patients at weeks 0, 4, 12 and 48 and from the electronic clinical history: sex, age, type of migraine, number of monthly migraine headache days (MHD) prior to treatment and duration of treatment. To assess effectiveness was used MSQv2.1(14-item questionnaire that measures QoL impacts in 3 domains: Role Function-Restrictive (RFR), measures limitations in social and work activities; Role Function-Preventive (RFP), measure the impact through prevention of these activities; and Emotional-Function (EF), assess the emotional impact. Higher scores indicate better QoL). The main variable was the rate of responders according to RFR defined as patients whose average change from baseline was ≥ 25 over week 48. Secondary outcomes were responders according RFR over week 4 and 12, and mean changes from baseline in RFR, RFP, EF and MSQ-total at weeks 4, 12 and 48.

Results 34 patients were included, 33 woman, mean age 45 years (29-69). Type of migraine: 70,5% chronic migraine and 29,5% high frequency episodic migraine. Mean monthly MHD prior to treatment were 18 days (8-30) and mean duration of treatment of 15 (3-27) months. 8 patients did not reach 48 weeks, treatment was discontinued for ineffectiveness. Main outcome: the rate of responders was 38,2% at week 48. Secondary outcomes: 34,2% and 45,7% responders at week 4 and 12 respectively. The table shows average change from baseline score in MSQ-domains and MSQ-total:

| | WEEK 4 | WEEK 12 | WEEK 48 |
|-----------|--------|---------|---------|
| MSQ-RFR | 22,90 | 26,30 | 13,11 |
| MSQ-RFP | 24,41 | 27,35 | 11,32 |
| MSQ-EF | 22,54 | 27,25 | 17,25 |
| MSQ-total | 23,27 | 26,80 | 11,84 |

Conclusion and Relevance In this study, long-term galcanezumab treatment had a moderate effectiveness in improving the RFR-domain of QoL. The number of responders decreased over time. All domains improved from baseline over the weeks studied. However, at week 48, quality of life worsened compared to weeks 4 and 12.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-189 ANALYSIS OF MEDICATION PERSISTENCE IN MIGRAINE PATIENTS TREATED WITH ANTI-CGRP MONOCLONAL ANTIBODIES

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Background and Importance Monoclonal antibodies targeting the calcitonin gene-related peptide (anti-CGRP) are recently available for migraine treatment. Real-world data on the utilisation of these drugs in clinical practice is scarce, but this information could help hospital pharmacists afford a better selection of the available drugs.

Aim and Objectives The study aimed to explore differences in medication persistence in patients with migraine treated with erenumab, a human monoclonal antibody that binds to the receptor for CGRP, or fremanezumab and galcanezumab, humanised monoclonal antibodies that bind CGRP.

Material and Methods RPT is a drug registry of patients with migraine initiating biologic treatment in public university hospitals in Catalonia. For this study, we retrieved from the registry data of patients initiating treatment after 01/02/2020 with erenumab, fremanezumab or galcanezumab. The primary outcomes assessed were: gender, age, discontinuation rate, time to discontinuation, and the causes of it. We also collected data to measure the treatment response, such as migraine days per month and the validated quality of life scales (Migraine Disability Assessment Scale and Headache Impact Test-6).

Retrieved data was dissociated before any analysis. Chi-square was used to compare proportions and t-Student for continuous variables.

Results Data from 131 patients was retrieved: 55/131 were treated with erenumab and 76/131 with galcanezumab/fremanezumab. 85% of patients were women, with a median age of 51. Medication persistence three months after initiating treatment was 36/55 with erenumab and 57/76 with fremanezumab/galcanezumab. There were no significant differences between the two mechanisms of action.

The mean time to discontinuation in patients treated with erenumab was 8,9 months and in patients treated with fremanezumab or galcanezumab, 6,8 months, without significant differences.

2/19 and 3/19 patients discontinued treatment due to toxicity with erenumab and fremanezumab/galcanezumab, respectively.

30/131 patients' treatment were switched to a different mechanism of action. A three-month follow-up after the treatment change revealed significant improvement in 15/30 patients.

Conclusion and Relevance Medication persistence in migraine treatment with anti-CGRP monoclonal antibodies seems similar for both mechanisms of action.

More extensive studies are needed to clarify the difference in response to different anti-CGRP monoclonal antibodies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-190 ANALYSIS OF IBRUTINIB DOSE REDUCTION IN PATIENTS DIAGNOSED WITH CHRONIC LYMPHOCYTIC LEUKAEMIA: ARE WE DOING IT RIGHT?

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Background and Importance The usual oral dosage of ibrutinib in chronic lymphatic leukaemia (CLL) is 420 mg every 24h.

However, comorbidities, adverse effects and drug interactions require a dose reduction (DR), and the efficacy of treatment may be compromised.

Aim and Objectives To analyse the reasons of ibrutinib dose reduction and its consequences on disease progression/death.

Material and Methods Retrospective observational study that includes patients (n=60) diagnosed with CLL treated with ibrutinib between 09/16/2020-09/16/2022 and not involved in a clinical trial. The demographic characteristics of patients were the following: 43 males (72%), mean age 72.9 years (53-89).

Data collection include DR requirements, DR reasons, treatment suspensions, disease progression and death with their respective date recording.

The percentage of patients requiring DR and the reason thereof were calculated. Percentage of disease progression and death also. In addition, median treatment durations were calculated in months and expressed in percentages; overall median duration (OMD) and after DR requirement (DRMD).

The data was obtained from the electronic medical record (Osabide Global) and the electronic prescription program (Onkobide).

Results 35% of patients (n=21) required DR during the study period. The main reasons for DR were toxicity 76,1% (n=16), pharmacological interactions 9,5% (n=2), efficacy 4,8% (n=1), aging 4,8% (n=1) and patient decision 4,8% (n=1). 10% of DR patients (n=2) suffered CCL progression and 29% (n=6) died. 5% (n=2) of patients non-requiring DR suffered CCL progression and 13% (n=5) died. The OMD of the treatment was 17 months (0-73) and the DRMD was 12 months (0-70).

Conclusion and Relevance The ibrutinib DR does not influence the disease progression or mortality, although the sample size is not enough for a formal statistical analysis. Toxicity was identified as the most common reason for DR. The OMD and DAMD data presented in this work are lower than those commonly published in the literature (1) due to the technical limitations on the software systems.

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Conflict of Interest No conflict of interest

4CPS-191 IMPACT OF THE COVID-19 PANDEMIC ON THE ADHERENCE OF HIV PATIENTS

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Background and Importance In 2020 Spain was involved in the SARS-CoV-2 pandemic. This situation entailed in the dispensing of drugs from pharmacy services to patients' homes. This way of reaching the patient facilitated the access to anti-retroviral treatment (ART) in this difficult situation. However, due to the social stigmas, certain patients did not consent to access this dispensing system.

Aim and Objectives The objective is to study how adherence to antiretroviral treatment was affected in HIV-positive patients during the months of the first alarm state in Spain (March 14 to June 21 2020); because during those period ART was home dispensation.

Material and Methods Observational retrospective study, included patients HIV-positive who received ART during the first alarm state in Spain during COVID-19 pandemic and in the same period of 2019.

Collected data were: sex, age and variables related to pharmacological treatment (ART in the selected periods, number of dispensations made, galenic units dispensed).

To measure adherence, an indirect method was used, comparing the dispensations made in the hospital pharmacy of the hospital of León during the studied period and the same dates of the previous year.

$\% \text{ adherence} = [\text{dispensed galenic units/planned galenic units}] \times 100$

Results We analyse 444 patients with a median age of 54 years (45-59) being 77.93% (n=346) men.

During the study period 83 patients (18.69%) changed their ART. 38.55% (n=32) carried out a simplification of ART in 2020 (from a treatment based on several pharmaceutical forms to a treatment based on a single one).

The mean adherence in the periods studied in 2019 and 2020 was 91.89% (CI 90.44-92.90) and 90.25% (CI 87.61-92.90), respectively. In 2019, 67.12% (n=298) of patients had adherence greater than 95%, compared to 86.71% (n=385) in 2020.

For 38 patients there are no medication dispensations during the 2020 period. Of the majority (n=27) the reason for the absence is unknown; 6 were not disposed of from the hospital of León for spending the confinement outside the city; 4 have died and 1 did not accept home dispensation.

Conclusion and Relevance The implementation of home dispensing could have positively influenced adherence in HIV-positive patients. It is necessary to evaluate in the future that the implementation of new telepharmacy programmes can have a positive influence on adherence.

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Conflict of Interest No conflict of interest

4CPS-192 ANALYSIS OF ADHERENCE AND ASSOCIATED RISK FACTORS IN MULTIPLE SCLEROSIS PATIENTS UNDER DISEASE-MODIFYING THERAPY

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Background and Importance Multiple sclerosis (MS) is one of the most frequent causes of disability among young people. Understanding patients' adherence to treatments is of great importance to assess the effectiveness and safety of the prescribed treatments.

Aim and Objectives To analyse the adherence of patients with MS that were prescribed with disease-modifying treatment (DMT) and to identify risk factors.

Material and Methods A retrospective observational study was conducted including MS outpatients under active DMT in 2021. Variables collected: gender, age, drug type (subcutaneous interferon beta 1b, intramuscular interferon beta 1a, subcutaneous interferon beta 1a, teriflunomide, dimethyl fumarate, fingolimod), route of administration (oral vs parenteral), polypharmacy (> 5 drugs/day), adverse effects (AEs), type of MS (relapsing remitting MS -RRMS-, secondary progressive MS -SPMS-, primary progressive MS -PPMS-), time course, Expanded Disability Status Scale (EDSS) score at onset of DMT, number of previous flares and hospitalisations, and comorbidities.

Adherence was calculated through the Medication Possession Ratio (MPR) using pharmacy dispensation record database. Good adherence was considered $\text{MPR} \geq 80\%$. A statistical analysis was performed with IBM SPSS Statistics v21.0.

Results A total of 214 patients were included [(62.1% female), mean age 43.9 (SD 9.7) years].

The most prescribed drug was teriflunomide (26.6%), followed by dimethyl fumarate (20.6%), subcutaneous interferon beta 1b (14.5%), glatiramer acetate (12.6%), fingolimod (12.1%), intramuscular interferon beta 1a (7.0%), and subcutaneous interferon beta 1a (6.5%). The most frequent route of administration was oral (59.3%) vs parenteral (40.7%). 38.3% of patients were polymedicated and 53.7% suffered AEs.

95.3% of patients had RRMS and 4.7% had SPMS. Median time with MS was 11 (0.2 - 45) years and median EDSS was 1.5 (0 - 8). Previous flare-ups were 51.4%, hospitalisations 39.3% and comorbidities 79.4%.

Good adherence ($\text{MPR} \geq 80$) was determined for 89.7% of the patients. Median MPR was 100 (19 - 100).

Adherence was influenced by route of administration ($p=0.024$) and comorbidities ($p=0.014$) with statistically significant differences. A statistically significant difference was not observed for the any other variable.

Conclusion and Relevance Adherence was satisfactory in most patients. Determining modifying factors of adherence is important to identify patients at risk of non-adherence who shall receive personalised pharmaceutical care and optimised treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-193 SUITABILITY OF THE DUAL ANTIPLATELET THERAPY TO THE GUIDELINES OF EUROPEAN SOCIETY OF CARDIOLOGY IN ACUTE CORONARY SYNDROME

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Background and Importance The dual antiplatelet therapy (DAPT) consisting of acetylsalicylic acid plus one P2Y12 platelet receptor inhibitor represents the first line to treat patients with diagnosis of acute coronary syndrome (ACS).

Aim and Objectives To review the DAPT prescribed to patients with ACS admitted in a third level hospital and to assess their

adequacy grade to the European guidelines of cardiology (ESC).

Material and Methods Observational and retrospective study done between January-June 2022 where data for patients with ACS diagnosis: unstable angina(UA) or myocardial acute infarction with and without ST elevation (STEMI, NSTEMI) have been collected. Studied variables were demographic and clinical information (diagnostic, treatment, cardiovascular risk factors(CVRF)). For each patient ischemic and haemorrhagic risk have been calculated (using GRACE and CRUSADE score). Patients with 3 or more of the CVRF described have been considered fragile patients. ESC guidelines established the appropriate DAPT for each patient according to the ACS's type and patient's ischemic-haemorrhagic risk. Adequacy was assessed in terms of compliance or non-compliance with these recommendations.

Data were exported from medical history thanks to SAP® informatics' tool and Silicon® electronic prescription program. Statistic analysis was made by Stata.v.15.0®. Qualitative variables were expressed in percentages and absolute frequencies. Quantitative ones like average ± standard deviation.

Results A total of 95 patients were diagnosed with ACS 74,74% (71) of which were men with an average age of 64,38 ± 12,77 years, the 7,37% (7) with UA, 44,21% (42) NSTEMI and 48,42% (46) STEMI. All were under treatment with DAPT and moreover the 21,05% (20) were anticoagulated after percutaneous coronary intervention. The 51,58% (49) were low, 33,68% (32) medium and 14,74% (14) high ischemic risky patients. Regarding the bleeding risk the 53,86% (51) were low, 23,16% (22) medium and 23,16% (22) high.

The 37,89% (36) of the prescribed treatments weren't complying with the recommended DAPT in ESC guidelines according to ACS's type and patient's risk factors. By diagnosis, in 42,85% (3/7) of UA patients, 42,85% (18/42) of NSTEMI and 30,43% (14/46) of STEMI the prescriptions did not conform to guidelines.

Conclusion and Relevance Percentage of non-adequacy of prescribed DAPT to recent published ESC guidelines is considerable, leading to disparity of criteria with guidelines and between professionals and possible treatment's inequity between patients. Future studies could explore the importance of pharmacist integration and validation to avoid reported discrepancies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-194

BASELINE AUDIT OF POTENTIAL TO OPTIMISE THERAPY THROUGH USE OF SGLT2I IN A COHORT OF PATIENT ADMITTED WITH AN ACUTE MYOCARDIAL INFARCTION

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Background and Importance There are around 100,000 hospital admissions each year in the UK due to acute myocardial infarctions (AMI). Co-morbidities in those with ischaemic heart disease are common and include heart failure, diabetes and chronic kidney disease (CKD), the interplay between these conditions being recently termed cardiometabolic syndrome.

Recent updates in UK NICE guidance support the use of SGLT2i for those with type II diabetes (T2DM) and cardiovascular (CV) risk, for treatment in those with heart failure with reduced ejection fraction and most recently for CKD.

Aim and Objectives Assess patients at a large London based cardiovascular centre, being previously discharged with a diagnosis of AMI to identify the opportunity to optimise therapy through prescribing SGLT2i.

Material and Methods Retrospective analysis of patients admitted with an AMI between January and October 2021 at a large London based cardiovascular centre to compare the optimisation of SGLT2i at discharge (DC) and at 12 months in those with cardiometabolic risk factors (i.e T2DM, HF and CKD).

Results 450 patients with AMI were followed during 1 year, average aged of 57.3 years old with 84% male, T2DM (25.7%), HF (23.5%), CKD (10%), 43% smokers and 3% with AF.

At discharge, SGLT2i were prescribed in 4.6% of all AMI patients. In patients with T2DM, HF and CKD, the respective rates of SGLT2i at discharge were 18%, 3.7% and 2.2%.

At 12 months post-discharge, T2DM increased to 28% (11 newly diagnosed), 23.5% of patients with HF and 16% with CKD (26 patients newly diagnosed). SGLT2i were prescribed in 10.4% of patients with respective rates of 30%, 16% and 11.1%.

Conclusion and Relevance This data supports an opportunity to improve SGLT2i prescribing in our post-MI cohort with additional cardiometabolic risk factors. There was a small increase in prescribing noted after 12 months but recent updates in UK policy would support a wider adoption of SGLT2i use, in particular noting the high rates of T2DM and HF seen in the post-AMI group. Strategies to facilitate optimisation include protocolisation of initiation, communication for 1ry care physicians to start shortly after discharge and consideration of earlier initiation prior to discharge in those with cardiometabolic risk factors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-195

E-LUNGING: EVALUATION OF AN E-LEARNING PROGRAM INTENDED FOR HEALTHCARE PROFESSIONALS REGARDING THE MEDICATION OF LUNG TRANSPLANT PATIENTS

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Background and Importance Our institution is specialised in lung transplantation (LT). The drugs associated with this procedure are numerous and of complex management. However, the long-term success of LT is directly linked to patient adherence. In our institution, nursing staff turnover is frequent, and the replacement staff is not always specialised in LT. This observation led to the development, in collaboration with the medical and nursing teams, of an online training program (e-learning) for health care staff, intending to reinforce the appropriate use of transplant drugs and better respond to patients' queries.

Aim and Objectives To evaluate the impact of our training on the acquisition of knowledge by nursing and pharmaceutical staff.

Material and Methods The content and format of the e-learning were decided during multidisciplinary meetings, and the training was created using specific software (Articulate Storyline®). It is divided into 5 parts and contains an assessment questionnaire to be completed before and after the training. The e-learning was distributed to the nursing staff of the thoracic surgery and intensive care units, as well as to the pharmaceutical staff of our hospital group. The rate of correct answers obtained before and after the training was collected and compared.

Results 34 people completed the training. The average rate of correct answers obtained before and after completing the training increased significantly, from 75% to 86% ($p < 0.001$). The most represented professional categories were pharmacy students (15/34), pharmacy residents (7/34), and nurses (7/34).

100% of people said they were 'satisfied' or 'very satisfied' with the training and 97% would recommend it.

Conclusion and Relevance The increase in the rate of correct answers before and after the training shows that the nursing and pharmaceutical staff has acquired knowledge. A main limitation of the project was the difficulty for nurses to find dedicated time to complete the training. The impact on daily practices in our institution still remains to be evaluated. The distribution of the training to community pharmacies that treat lung transplant patients could prove valuable to strengthen our community relations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-196 POTENTIALLY INAPPROPRIATE MEDICATIONS AND POTENTIALLY PRESCRIBING OMISSIONS IN OLDER PEOPLE LIVING WITH HIV

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Background and Importance Due to a higher burden of non-HIV comorbidities and the use of multiple medicines in comparison to non-infected population, older people living with HIV (PLWH) are more likely to be at risk of drug-related problems, including potentially inappropriate medications (PIMs) and potentially omitted prescriptions (PPOs).

Aim and Objectives To determine the prevalence of PIMs and PPOs in older PLWH. To identify the main groups of medications involved in PIMs and PPOs according to the STOPP-START criteria.

Material and Methods A cross-sectional, observational, multi-centre study was conducted. Older PLWH (aged 65 or older) who were on active antiretroviral treatment at four different hospitals between 1 September 2021 and 31 December 2021 were included. Demographic and clinical-pharmacotherapeutic data were obtained from electronic medical records. A

comprehensive medication review was conducted by a hospital pharmacist. PIMs and PPOs were identified using the STOPP-START criteria.

Results One hundred patients were included, 83% male, mean age 73.1 years (SD 6), mean VACS index 40.8 (SD 11), 96% were multipathological (mean number of non-HIV comorbidities 4.3, SD 2). Mean number of chronic drugs per patient (excluding antiretroviral treatment), 8.5 (SD 3.4), 92% presented polypharmacy. For the patients included, a total of 124 PIMs and 119 PPOs were identified. The global prevalence of PIMs and PPOs was 75%. The prevalence of PIMs and PPOs separately was 53% and 68% respectively. Seventeen different STOPP criteria were identified. The most frequent STOPP criteria were A1 (drug without evidence-based clinical indication, $n=51$, 41.1%), D5 (benzodiazepines for 4 or more weeks, $n=20$, 16.1%) and K1-K4 (benzodiazepines and Z-drug prescriptions, $n=20$, 16.1%). Twenty different START criteria were identified. The most frequent START criteria were I1-I2 (influenza and pneumococcal vaccine, $n=56$, 47%), E4 (bone antiresorptive or anabolic therapy in osteoporosis, $n=10$, 8.4%) and G8 (5-alpha reductase inhibitor with symptomatic prostatism, $n=8$, 6.7%).

Conclusion and Relevance Three quarters of the patients included in our cohort of older PLWH present PIMs or PPOs. The main group of drugs involved in PIMs and PPOs are benzodiazepines and vaccines. Medication review is essential to optimise pharmacotherapy and prevent drug related problems in this population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

STOPP-START criteria (O'Mahony *et al.*, 2015). PMID 25324330

Conflict of Interest No conflict of interest

4CPS-198 ANALYSIS OF ANTIPSYCHOTIC DRUGS USE AT A SPANISH TERTIARY HOSPITAL

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Background and Importance The effectiveness of second generation antipsychotics (SGA) has been shown to be equivalent to the first-generation antipsychotics (FGA), with different side effect profiles.

Aim and Objectives The aim of this study was to determine the patterns of antipsychotics prescription and related costs at a university hospital.

Material and Methods One year retrospective observational study at a Spanish university general hospital. Identification of outpatients under treatment with antipsychotics during 2021, which had been prescribed at hospital. FGA and SGA data consumption was obtained from Microstrategy® database. Comparative analysis in relation to the European patterns of prescription and cost analysis were performed. Main outcome measures: percentage of patients with SGA, FGA and long-acting antipsychotics (LAI) and costs per patient.

Results A total of 16,967 patients under treatment with antipsychotics during 2021 were identified: 9.01% FGA and 90.9% SGA. The most frequent FGA were: oral haloperidol (44.4%), oral clotiapine (26.6%) and oral levomepromazine (17.9%). Among the SGA, the most used were: oral

quetiapine (37.3%), oral olanzapine (20.2%), oral aripiprazole (15.7%) and oral risperidone (11.4%). Regarding the total prescriptions, the percentage of use of LAI was 6.66% (3.43% and 6.98% among FGA and SGA, respectively). The 95.31% total LAI prescriptions were SGA. The use of LAI at hospital was found to be lower than in other European countries (15% according to Arango C. et al 2019). However, the proportion of second generation LAI was higher than the European average (34%). The mean cost per patient was higher for SGA than for FGA (353.5€ vs 27.0€). Likewise, in comparison to conventional injectable antipsychotics, costs per patient were higher for LAI: 155.1€ vs 15.8€ for FGA and 2887.5€ vs 72€ for SGA, respectively.

Conclusion and Relevance In comparison with other European countries, a predominance of the use of second generation LAI has been detected. However, the use of LAI is lower. Cost-effectiveness studies regarding the use of SGA versus FGA and conventional versus LAI antipsychotics are needed in order to optimise the benefits to the patient and minimise the economic burden for the health system.

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Conflict of Interest No conflict of interest

4CPS-199 PHARMACO-ECONOMIC IMPACT OF DRUG INTOXICATIONS IN CHILDREN

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Background and Importance Drug Intoxications in children, by its social-economic implications, represent a major problem of Public Health. They constitute the main cause of emergency admissions and also one of the principal causes of death in children and adolescents.

Aim and Objectives The aim of this study is to evaluate the pharmaco-economic impact of drug intoxications registered in the paediatric emergency department.

Material and Methods This is a study spread over a period of 12 months from January 1, to December 31, 2021, in the paediatric emergency department. It is based on the analysis of costs to manage all drug intoxications recorded in children for one day of hospitalisation which include the cost of: drugs and antidotes administered, laboratory and radiological analysis, hospitalisation fees.

The reference of the identify costs is given by the billing department of our hospital.

Results During this period 69 cases of drug intoxications were admitted. According to ATCCS classification, the class N (Nervous System) was the most common class involved in drug intoxications (50%) followed by Musculo-Skeletal System (15%) then Genito-Urinary System and Sex Hormones (11%), Respiratory System (8%) and 16% for other classes. To manage these drug intoxications, a symptomatic treatment and antidotes administration is registered in 32.5% of cases (500 €), in 35.5% of cases laboratory and radiology analysis were done (1400 €). The distribution of the costs for one

day of hospitalisation related to each intervention and for all recorded drug intoxications is summarised in the table below:

| | Drugs and antidotes administered per day | Laboratory analysis | Radiological examinations | Hospitalisation fees per day | Total costs per day |
|-------|--|---------------------|---------------------------|------------------------------|---------------------|
| Costs | 500 € | 800 € | 600 € | 1100 € | 3000 € |

On average, intoxicated children stay in the hospital for at least 48 hours under medical supervision, the total cost of treatment for drug intoxication becomes 6000 € and it can increase depending on the severity of intoxication.

Conclusion and Relevance In our study we have included only the drug intoxications and we have found that their management represents a considerable pharmaco-economic impact also the research has allowed us to conclude that half of the drugs used by children belong to the class of the nervous system which constitutes a significant danger.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-200 SUSTAINING A PHARMACEUTICAL DECISION SUPPORT SYSTEM BY DETERMINING THE CLINICAL RISK'S LEVEL OF DETECTED DRUG-RELATED PROBLEMS

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Background and Importance Pharmaceutical decision support system (PDSS) is a positive triangulation between patients' data, modelled situations standing for drug-related problems and a reasoning software sending alerts. So the pharmaceutical interventions better prevent adverse drug events and better reduce healthcare costs. But to be optimal the PDSS has also to link the modelled situations to a clinical well-defined risk. As consequences each pharmaceutical intervention's impact will be documented and the PDSS's interest in patients' safety sustained.

Aim and Objectives To present the results of an e-Delphi study during which health professional experts evaluate the clinical risk's level of 52 modelled situations standing for drug-related problems or adverse drug events.

Material and Methods Twenty experts across 4 francophone countries were involved because of their clinical skills. Based on their experience, physicians (5) or pharmacists (15) scored the likelihood of occurrence of clinical consequences and its severity for each of the 52 modelled patients' situations using a five-point Likert scale. These situations were chosen among a panel of 199 one, according to their high frequency in the health facilities. The degree of consensus between participants was defined as the proportion that gave a risk score in the same category as the median. Consensus was obtained if the score was 75% or more. Then the 2 median scores -occurrence and severity-

were combined to produce the risk level for each situation. Only 2 Delphi rounds were necessary.

Results After the first round a consensus was reached for 8 situations. Experts agreed on the level of risk associated with 48 out of 52 modelled situations. A high or extreme consensus risk level is determined for 45 modelled situations. These situations represent a variety of drug-related problems. Overdosing was the most frequent situation [12 (22%)]. Cardiovascular, Psychiatric and Endocrinological drug classes are the most common involved in respectively [25 (45%)], [7 (13%)] and [5 (9%)] situations.

Conclusion and Relevance The symbolic artificial intelligence to detect drug-related problems in patients' medications will be much more shared if pharmaceutical algorithms including the clinical risk are defined through consensus.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-201 PHARMACEUTICAL CARE TO OPTIMISE TREATMENT FOR ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN A PRISON

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Background and Importance Lung disease prevalence in the prison population is higher than in the general population of the same age. Pharmaceutical care detects and reduces drug-related problems by helping in therapy optimisation and improving treatment adherence.

Aim and Objectives 1/ To improve the bronchodilator treatment of patients with asthma or chronic obstructive pulmonary disease (COPD) in prison.

2/ To identify patients with low adherence in order to check the patient's inhalation technique and ensure proper administration.

Material and Methods Observational, descriptive and retrospective study of patients with asthma and/or COPD diagnosis in August 2022. Demographic data (age, sex), clinical data (body mass index, smoking habit, presence of exacerbations) and type of treatment were collected. Adherence was calculated through dispensing records (packages collected/packages prescribed) between August 2021 and August 2022. Adherent patient was defined if they had 100-80% of dispensations, non-adherent if they had <80%, and poorly controlled due to bronchodilator treatment abuse if they had >100%.

Results 46 (6.7%) patients under bronchodilator treatment were identified out of 686 prisoners. 10 patients were excluded because they were not chronic treatment. The 36 selected patients had a mean age of 40 ± 9 years and 8.3% were women. 28 patients had asthma diagnosis, 6 COPD diagnosis and 2 had mixed pattern. 33 patients were smokers and 24 were overweight or obese.

Bronchodilator treatment could be optimised in 16/36 (44.4%) of patients: 10 patients with asthma (5 without inhaled short-acting bronchodilator (SABA) and 5 used inhaled corticosteroids), and 6 patients with COPD (3 used SABA as maintenance treatment and 3 used inhaled corticosteroids

without exacerbations over the last year). 28/36 patients required pharmaceutical care to improve patient's inhalation technique (23 non-adherent and 5 treatment overuse).

Conclusion and Relevance Pharmacists play a key role to optimise complex therapies. This study shows us that almost half of bronchodilator treatments in prison can be optimised, and more than three quarters of the population have poor adherence. A specific pharmaceutical care programme in prison should be carried out to identify drug-related problems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-202 THE USEFULNESS OF A PHARMACY RESIDENT STAGE IN THE CRITICAL CARE UNIT

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Background and Importance The presence of pharmacists as members of the multi-professional critical care team is increasingly accepted and welcome. However, the impact of this presence is not always easy to measure since the offered service portfolio varies widely from hospital to hospital.

Aim and Objectives This study measures the intervention impact of the rotation of a pharmacy resident in the critical care unit of a hospital after assessing the unit's complexity level.

Material and Methods Critical care complexity was measured as the mean Medication Regimen Complexity-ICU (MRC-ICU) throughout the study period and compared to previous studies.¹

Pharmacist interventions in the critical care unit over 7 weeks were prospectively recorded.

There were three types of interventions: clinical (affecting the pharmacotherapy of an admitted patient), informative (regarding general information of medicines), and logistical (regarding the critical unit organisation and medicines distribution).

Interventions were also classified by the addressee (medical, nursery staff, or both) and by intensity (low, medium, or high), measured as previously described.²

Acceptance of the interventions was also recorded.

Interventions regarding parenteral nutrition and therapeutic drug monitoring were excluded from this study since they were already standard care in our hospital.**Results**

The mean MRC-ICU score was 10.46 (standard deviation 5.4).

Among the 108 interventions recorded, for 83 patients, 75 (70%) were clinical, 22 (20%) informative and 11 (10%) logistical. In 85 cases (79%), the addressee of the intervention was the medical staff, 18 (17%) the nurses, and 5 (4%) both. Regarding the intensity, 11/108 (10%) were classified as low, 37/108 (35%) medium and 58 (55%) as high. The acceptance of interventions was high: 106/108 (98%).

Conclusion and Relevance Critical care complexity in this study was above average compared to previous studies.¹

A clinical pharmacist, even a trainee pharmacy resident, can improve critical healthcare and clinical decision-making by the critical care team.

A high intervention acceptance rate shows how valuable the rest of the professionals in the intensive care team consider the clinical pharmacist.

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2. *Crit Care Med* 2022 Sep 1;50(9):1318–1328. doi: 10.1097/CCM.0000000000005585. Supplemental Digital Content – Table 3. (<http://links.lww.com/CCM/H141>).

Conflict of Interest No conflict of interest

4CPS-204 NATIONAL SURVEY ON CLONIDINE PRESCRIBING PRACTICES IN COMPLEX TRAUMA IN CHILD PSYCHIATRY

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Background and Importance The management of complex trauma in children and adolescents is difficult because of his multidimensional nature. Research into this area is particularly challenging and very few clinical studies are available. Clonidine is used off-label in our country for this indication.

Aim and Objectives The aim of this work is to study the prescribing practices of clonidine in children and adolescents with complex trauma : the pre-therapeutic assessment, the targeted symptoms, the galenic formulation and the tolerance.

Material and Methods National distribution of a questionnaire via the mailing of the Psychiatry Information Communication network and the Federative Association of Psychiatric Students of our country to find out about the practices of prescribing clonidine in other health establishments. Questionnaire validated upstream by the referent child psychiatrist then extraction of the answers and descriptive analysis of the data collected.

Results 88 responses were obtained, 58% from psychiatrists and 38% from residents in psychiatry with at least one response per region. The analysis shows the use of Clonidine, especially in tablet form, as a last resort and very often in combination medication. Among the 25 people who answered the entire questionnaire, good tolerance was observed in 84% of cases, the remaining 12% reported episodes of hypotension or headaches. A pre-therapeutic assessment with electrocardiogram, blood pressure and pulse are carried out in 72% of cases and clinical efficacy is observed in 76% of cases, in particular on nightmares, insomnia and anxiety.

Conclusion and Relevance Preliminary data seem to indicate that clonidine could have a positive clinical impact on certain symptoms of complex trauma. A multicentre, double-blind clinical study, Clonidine versus placebo, on a larger sample and taking into account the environmental context of the child, could make it possible to confirm or not this hypothesis.

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children's hospital: the case of clonidine for post-traumatic stress. *Gen Hosp Psychiatry.* déc 2002;24(6):422–9.

Conflict of Interest No conflict of interest

4CPS-206 EVALUATION OF IRON CARBOXYMALTOSÉ VS IRON SUCROSE ADMINISTRATION FOR THE CONTROL OF ANAEMIA IN HOSPITALISED PATIENTS

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Background and Importance Iron carboxymaltose (ICM) and iron sucrose (IS) are two types of intravenous iron used for the treatment of iron-deficiency anaemia. Differences between the dosing regimen and hospital length have led many centres to perform cost-effectiveness studies with variable results.

Aim and Objectives To compare the effectiveness and cost of intravenous ICM vs IS for the control of anaemia in hospitalised patients.

Material and Methods Retrospective cohort study in anaemic patients (Hb≤12g/dL) who received ICM (500-1,000mg, single-dose) or IS (≥3 X 100mg) between April 2021 and April 2022 was performed. Demographic variables (age, gender), total dose administered, Hb pre and post-treatment (>6 days), patients with increased Hb≥1g/dl, previous treatment with oral iron, hospital admission length and direct cost were collected.

Cohorts were matched for baseline characteristics (age, gender and hospital service) and initial Hb values. Selected variables were compiled from the electronic medical history and prescription and compared using student's t test with SPSS v.22.0.

Results A total of 98 patients (63.3% women) were included: 49 received ICM and 40 IS. Mean age was 75.5 ± 13.8 and 75.9 ± 13.6 years for the ICM and IS groups respectively. In the ICM cohort, patients received a mean dose of 867.35 ± 223.0mg and 36.7% had previously received oral iron. Patients in the IS cohort received a mean dose of 438.8 ± 199.8mg and 22.4% had previously received oral iron.

The mean previous Hb was: 9.5 ± 1.4g/dl in the ICM group and 9.4 ± 1.3g/dl in the IS group. In the ICM group, 38.7% patients showed an increase Hb≥1g/dl, while 24.5% did so in the IS group. Statistically significant variations in Hb levels were observed in both groups (+0.71g/dl in ICM vs +0.31g/dl in IS; p<0.05). However, the analysis showed no significant differences between both cohorts (p=0.06).

Hospital duration length mean was shorter in the IS group (15.3 ± 21.9 vs 19.9 ± 22,9 days) without significant differences between cohorts (p=0.307). A mean cost of 144.2 ± 37.1€/patient and 5.0 ± 2.3€/patient was estimated for the ICM and IS groups respectively.

Conclusion and Relevance ICM and IS administration produced an improvement of Hb levels in both cohorts without showing a significant difference in the hospital admission length. ICM treatment entailed an increase of direct costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-208 TELEPHARMACY INTERVENTIONS IN PATIENTS WITH CHRONIC DISEASES

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Background and Importance The emergence of information and communication technologies has enabled the development of telepharmacy programmes (TPP) as a complementary tool to personal care, through which pharmaceutical care can be provided without the need to visit the hospital. TPP began in December 2019 with delivery of medication to primary healthcare centres previous pharmaceutical care by telephone from the hospital pharmacy.

Aim and Objectives Describing the pharmaceutical interventions (PI) of patients included in a TPP

Material and Methods Prospective, descriptive study, from december 2019-september 2022. Pharmacotherapy follow-up consisted of structured telephone interviews scheduled every 3 months. Inclusion criteria: duration of treatment greater than 3 months, stable chronic disease, adherence greater than 90%, good tolerance to medication and/or mobility or dependency problems. Exclusion criteria: onco-haematological treatment, and patients with cognitive problems, or technological barriers to telephone pharmacotherapeutic follow up.

PI were classified as: drug-drug interactions (DDI), clinical monitoring (CM), adverse drug reactions (ADR) and/or lack of efficacy (LOF). In addition, the results of each PI were recorded as: temporary/permanent discontinuation (TPD), change of treatment (ChOT), change of dosing regimen (ChDR) or continuation of treatment (COT). The degree of acceptance of the Pi was calculated.

Results A total of 4.497 telephone interviews were conducted with 410 patients included in the TPP. Fifty-seven percent of treatments were biologics, 27% antiretrovirals, 6% multiple sclerosis/amyotrophic lateral sclerosis treatment, 3% lipid-lowering drugs, 3% somatropins, 2% pulmonary antihypertensives and 2% other drugs.

88 Pi were registered, 58% of which were accepted by the prescribing physician.

| N | ADR (27) (30,7%) | CM (27) (30,7%) | LOF (19) (21,6%) | DDI (15) (17%) | TOTAL |
|------|------------------------|--------------------|---------------------|----------------------|---------------|
| TPD | 6 (22,2%) | 6 (22,2%) | 2 (10,5%) | 0 | 14 (15,9%) |
| ChOT | 7 (25,9%) | 1 (3,7%) | 9 (47,4%) | 1 (6,7%) | 18 (20,5%) |
| ChDR | 2 (7,4%) | 1 (3,7%) | 2 (10,5%) | 14 (93,3%) | 19 (21,6%) |
| COT | 12 (44,4%) | 19 (70,4%) | 6 (31,6%) | 0 | 37 (42%) |

Conclusion and Relevance Pharmacotherapeutic monitoring of patients included in the TPP mainly allowed for the detection of ADRs and ensured adequate clinical supervision of in-patient medication.

The outcome of the interventions was mostly COT followed by modification of the prescribed regimen.

The pharmacist's activity in a TPP can contribute to a better use of medicines, as well as prevent and solve medication-related problems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-209 EXPERIENCE OF THE NOCEBO EFFECT IN PATIENTS WITH SWITCH TO BIOSIMILARS IN RHEUMATOID ARTHRITIS

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Background and Importance The nocebo effect is described as the worsening of associated symptoms or an increase in adverse effects due to a negative attitude towards a particular drug or pharmacological therapy, in this case biosimilar treatment. Lack of patient knowledge and discrepancies in the information provided are the main causes of negative expectations with biosimilars and their exchange with the original drug.

Aim and Objectives Study of the nocebo effect in patients with spondyloarthritis and psoriatic arthritis after switching from the original drug to the biosimilar of adalimumab in a tertiary hospital.

Material and Methods Retrospective and observational study from January 2020 to October 2021. Clinical information was obtained from the electronic medical record. The following clinical and demographic variables were recorded: age, sex, medication, type of adverse reaction, adherence, and follow-up after the change.

Results During the study period, 66 switches were made from Humira® (original drug) to Hyrimoz® (biosimilar), with 72% biosimilar use in this clinical context. In 4% (3 patients) of the switches, a clinical worsening was observed at 6 months, the mean age was 46 years, male. Adherence to treatment (Hyrimoz) was over 90%. The most frequent symptoms were: skin symptoms with pruritus, axial clinical worsening, morning arthralgias. In all cases, and after discussion with the prescribing physician, it was decided to switch to the original brand. After returning to the reference brand, the patients presented an improvement of the symptomatology associated with the change to the biosimilar drug.

Conclusion and Relevance The nocebo effect is an uncommon effect, but it causes an increase in pharmaceutical expenditure, as well as in medical visits and complementary tests. Due to the small sample size, clinical worsening cannot be associated with the nocebo effect in this study. Therefore, further research on this topic is required. It may also lead to the administration of new drugs to counteract the symptoms caused by the nocebo effect. Better education of both healthcare professionals and patients on the knowledge of biosimilars can help reduce the likelihood of triggering a nocebo effect.

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Conflict of Interest No conflict of interest

4CPS-210 EFFECT OF MONOCLONAL ANTIBODIES TO PREVENT PROGRESSION TO SEVERE COVID-19 DISEASE: REAL-LIFE DATA OF A UNIVERSITY HOSPITAL

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Background and Importance Since February 2021, our National Medicines Agency has temporarily authorised for emergency use the monoclonal antibodies to treat COVID-19 disease.

Furthermore, first authorised and most used ones in our Hospital were bamlanivimab-etesevimab monoclonal antibody combination, casirivimab-imdevimab combination and sotrovimab.

Monoclonal antibody therapy for Coronavirus disease 2019 (COVID-19) is recommended in mild to moderate disease patients who are at risk of progressing to severe disease, with at least one risk factor, including age over 65.

Aim and Objectives Aim of the study is to evaluate the effect of monoclonal antibody therapy for COVID-19 to prevent disease's progression, hospital admissions and deaths.

Material and Methods Data related to treated patients from 29/03/2021 to 02/05/2022 were collected from our National Medicines Agency database. These data were: sex, age, outcomes of the treatment and antibody administered.

Results 336 patients were treated in our Hospital from 29/03/2021 to 02/05/2022.

Patients treated with bamlanivimab-etesevimab (700 mg + 1400 mg) combination were 117: 48 females (F); 69 males (M); 64 patients aged over 65. These patients were treated with this combination from 29/03/2021 to 29/12/2021. The outcomes were: 112 healings, 3 hospitalisations or emergency department visits, 1 death, 1 not available.

Patients treated with casirivimab-imdevimab combination (1200 mg + 1200 mg) were 121: 59 F and 62 M ; 72 patients aged over 65. These patients were treated with this combination from 16/07/2021 to 31/12/2021. The outcomes were: 110 healings, 9 hospital discharges (2 patients, treated with high dosage (4000 mg + 4000 mg), were hospitalised for COVID-19 while 7 were hospitalised for other reasons), 2 hospitalisations or emergency department visits.

Patients treated with sotrovimab (500 mg) were 98: 42 F and 56 M ; 38 aged over 65. These patients were treated with this antibody from 29 December 2021 to 2 May 2022. The outcomes were: 96 healings, 1 hospital discharge (hospitalised for other reasons) and 1 not available.

Conclusion and Relevance The administration of monoclonal antibodies in patients with COVID-19, with comorbidities, who are at risk of severe disease's progression reported a reduced risk of hospitalisation or death (only 5 hospitalisations or emergency department visits and 1 death on 336 treated patients).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-212 SPECIALIST PHARMACIST-LED MULTIDISCIPLINARY CARE PATHWAY FOR OPTIMISING LIPID THERAPY – SIX MONTHS INTERIM ANALYSIS

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Background and Importance Cardiovascular disease (CVD) is a leading cause of mortality worldwide and accounts for approximately 27% of all deaths in United Kingdom. The relationship of hypercholesterolemia to CVD is well established and understood in terms of atherogenesis. Reduction of atherogenic lipoproteins, in particular, low-density lipoprotein with lipid modification treatments has been shown to reduce the risk of CVD events and mortality.

Aim and Objectives Design, test and develop an integrated care pathway that utilises specialist cardiovascular pharmacists working with primary care teams. This involves optimising secondary prevention with lipid modification therapy in people with established CVD across 42 General Practitioner practices over one-year pilot programme .

Material and Methods Specialist cardiovascular pharmacists were commissioned to work with primary care clinicians to identify, review and optimise secondary prevention in high-risk patients not receiving lipid modification therapy.

Eligible patients' clinical notes were reviewed to confirm CVD diagnosis, history of treatment, blood test results and CVD risk factors. Complex cases were reviewed by a virtual lipid specialist multidisciplinary team to agree a treatment plan. Patients were contacted for a virtual consultation to discuss and initiate tailored lipid modification therapy.

Results A preliminary review of practices CVD list showed 20% (2200/11233) of patients had a CVD diagnosis and were not receiving lipid modification therapy. A six-month interim analysis of 1100 out of the 2200 clinical reviews conducted by specialist pharmacists, identified that 60% (660/1100) were eligible for statin therapy with only 4% (44/1100) of patients having a true statin intolerance.

The remaining 36% (396/1100) were not for lipid modification therapy. Of these patients: 6% (66/1100) declined treatment, 9% (96/1100) were palliative or the risk of treatment outweighed the benefits, 8% (90/1100) had non-atherosclerotic CVD, 9% (100/1100) had incorrect CVD diagnosis and the remaining 4% (44/1100) were no longer part of the practice list.

Conclusion and Relevance An integrated care pathway using specialist cardiovascular pharmacists supporting a multidisciplinary workforce within primary care has shown a significant improvement in lipid modification therapy prescribing to reduce the risk of myocardial infarction (MI) and stroke. Extrapolating these results nationally would avert 17,000 MIs and 5,000 strokes over a 5-year period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-213 CHARACTERISTICS OF MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN VERSUS KAWASAKI ON CLINICAL ASPECTS, SPECIFICITIES AND TREATMENT

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Background and Importance Since the Coronavirus (COVID-19) pandemic, there has been a high number of children hospitalised in the paediatric intensive care unit (PICU) for Paediatric Multisystemic Inflammatory Syndrome (MIS-C) resembling Kawasaki Disease (KD)

Aim and Objectives The objectives of this study were to describe the clinic and the therapeutics that we used in PIMS, compared to those of KD. To describe the impact of the treatments used and discuss the clinical evolution of our patients

Material and Methods This is a retrospective observational study in the paediatric intensive care unit, over a 9-month period from April to December 2020. The clinical, biological and medication data was collected via the computerised patient record, our presence in the department and thanks to the prescription software for PIMS patients and compared to the KD data of the scientific literature

Results We included 12 children, median age 8 years [2 -16 years] and sex ratio = 2, diagnosed with MIS-C. Negative PCR tests on admission and presence of anti-SRAS-CoV-2 antibodies in all patients. All presented fever, with a mean duration of 5 days. 5 patients presented 2 clinical criteria characteristic of KD insufficient to diagnose complete KD. Gastrointestinal symptoms (10 patients), rarely seen in KD. All had inflammatory and cardiac markers higher than those in KD. Cardiac damage was observed in 10 patients: 50% had persistent systemic hypotension and 5 had ECG abnormalities. Drug therapy was to reduce inflammation. 9 patients received intravenous immunoglobulin (IVIG), 5 patients received a 2nd dose of IVIG and 2 a 3rd dose. Corticosteroid therapy for 4 days was administered to 10 patients and 9 required anti-inflammatory treatment with acetylsalicylic acid. These treatments, combined with vasopressor or diuretic and anticoagulant support, were necessary. There were no deaths in our cohort, the average time of management in the department was 6 days [2-13 days].

Conclusion and Relevance Our patients described a clinical picture suggesting KD, with a broader symptomatology and severity, much more marked inflammatory and cardiac markers, a shorter fever, a lower platelet count, more frequent gastrointestinal involvement, the median age of our cohort was higher. The therapeutic strategy: IGIV and corticosteroid therapy appeared to be effective in our study

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-215 DESCRIPTION OF THE PRE-EXPOSURE PROPHYLAXIS COVERAGE AGAINST THE HUMAN IMMUNODEFICIENCY VIRUS

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Background and Importance Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection aims to prevent HIV transmission in people at risk of acquiring the infection, consisting of daily tenofovir disoproxil fumarate with emtricitabine (TDF/FTC).

Aim and Objectives The aim of the study is to describe PrEP coverage and patients' baseline characteristics taking PrEP.

Material and Methods Retrospective, descriptive study. Patients that started with PrEP from October 2020 to April 2022 were included. Patients who took PrEP less than 6 months were excluded. Demographic variables (age and sex), indication criteria, sexually transmitted infections (STIs) (before and during), creatinine values, seroconversion to HIV and withdrawal reasons were collected. For the statistical analysis, the mean, standard deviation (SD) and *t-student* test were used.

Results 52 patients received PrEP during the study period. 10 patients were excluded. Of the patients included (n=42), 97.4% (n=41) were men with a mean age \pm SD of 35.8 \pm 8.4 years.

The indications for treatment were: 97.6% had more than 10 different sexual partners in the last year; 90.2% had anal sex without a condom in the last year; 29.3% had drug use related to having sex without a condom in the last year; 14.6% had received post-exposure prophylaxis on several occasions in the last year and 36.6% had at least one bacterial STI in the last year.

66.7% (n=28) of the patients had one or more previous STIs. The most frequent STI was *Treponema pallidum* (n=21) followed by *Neisseria gonorrhoeae* (n=12). While patients were taking PrEP, 40.5% (n=17) of them presented STIs: 19.0% (n=8) had *chlamydia trachomatis*; 14.3% (n=6) had *Neisseria gonorrhoeae* and 9.5% (n=4) had *Mycoplasma genitalium*. Baseline mean \pm SD creatinine was 0.86 \pm 0.11 mg/dl and at the end of the study was 0.90 \pm 0.11 mg/dl (p=0.024). 26.8% (n=11) of the patients discontinued PrEP (n=5 due to stable couple; n=2 by their own decision; n=2 due to lack of follow-up; n=1 due to change of centre and n= 1 due to proteinuria). There was no seroconversion to HIV in any patients.

Conclusion and Relevance The majority of PrEP patients are young men with risky sexual practices. During the use of PrEP, STIs were frequent. There was no seroconversion to HIV during the study period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-217 THE USE OF CYSTIC FIBROSIS CONDUCTANCE REGULATOR MODULATORS IN PATIENTS WITH RARE MUTATION

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Background and Importance Cystic Fibrosis (CF) is a monogenic and multi-organ disease. This condition is related to mutations in Cystic Fibrosis Transmembrane Regulator (CFTR), the gene encoding the epithelial ion channel that normally transports chloride and bicarbonate. Therapeutic

strategies deeply changed when Ivacaftor (2015) and the combination therapy Ivacaftor/Tezacaftor/Elxacaftor (ETI) (2021) were marketed. At this moment ETI therapy is licensed to treat CF's patients >6 years with at least one F508del mutation, the most common one; however, patients with rarer CFTR's mutations don't have access to this therapy.

Aim and Objectives With this work we would like to report the use of the combination therapy Ivacaftor-ETI in two young patients with rare CFTR's mutations: the N1303K/2183AA>G and the W1282X/N1303K.

Material and Methods Starting from the off-label authorisations from January-2015 to June-2022 by our Hospital Committee (composed with a Clinician, a Pharmacologist and a Hospital Pharmacist) in accord to Law 94/98, we identified patients that required off-label CFTR modulators' combination therapy due to their CFTR's rare mutations and in vitro response to ETI therapy. For these we analysed: age at the beginning of the therapy, gender, type of mutation, clinical manifestations, period of therapy, Adverse Drug Reactions (ADRs) notified.

Results Only in 2022 two patients were authorised to use off-label CFTR modulators' combination therapy due to their rare CFTR's mutations. The first patient (P1) was a female, 20 years, W1282X/N1303K mutations; her clinical history showed meconium ileus, serious pneumopathy and she often required antibiotic therapy due to her lungs infections. The second patient (P2) was a female, 19 years, N1303K/2183AA>G mutations; her clinical history showed pancreatic and lungs insufficiency, BMI<14, infections induced by multi-drug resistant Pseudomonas and Mycobacterium Abscessus, D hypovitaminosis. At first, Hospital Committee authorised 3 cycles of therapy for P1 and 4 cycles (28 days for each cycle) for P2; both of them were authorised to prolonge their therapy due to clinical evident efficacy. No significant ADRs related to treatment were notified.

Conclusion and Relevance CFTR modulators are small molecules that directly impact and achieve the function of CFTR channel. They give long-term improvements in clinical outcomes and we hope more research on their efficacy in patients with rarer CFTR's mutations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-218 TNF GENE POLYMORPHISMS PREDICTORS OF RESPONSE TO ANTI-TNF DRUGS IN PATIENTS DIAGNOSED WITH MODERATE-SEVERE PSORIASIS

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Background and Importance Psoriasis is a chronic inflammatory skin disease. Biological treatments against tumour necrosis factor (anti-TNF) are effective in treating this disease, however, not all patients respond to this treatment, and it can cause serious side effects. Biomarkers involved in the TNF cytokine may be implicated in the response to the anti-TNF drug.

Aim and Objectives To determine the utility of Single Nucleotide Polymorphisms of HLA-B and TNF-238, TNF857, TNF-308, TNF-1031, TNFRSF1B as prognostic and predictive markers in patients diagnosed with moderate-severe psoriasis treated with adalimumab, etanercept or infliximab. As well as, to evaluate the efficacy of anti-TNF treatment in the induction phase.

Material and Methods A prospective cohort study was performed. Data and DNA were obtained from saliva samples of 103 patients residing in the province of Granada with moderate and severe psoriasis who had been treated with anti-TNF. The genotypes were determined by Taqman PCR Real Time.

Results Patients' mean age was 54.19 ± 13.65 years; 54 male (54/103); 100 had plaque psoriasis (100/103), 90 located in trunk and extremities, and 89 on scalp and face, 42 with psoriatic arthritis (42/103), 33 smokers (33/103), 36 drinkers (36/103), 62 had psoriasis family history (62/103). These 103 patients have been treated with 135 anti-TNF (adalimumab, ADA=80; etanercept, ETN=39; infliximab, INF=16). Also 20 received oral administration of the concomitant methotrexate (20/135).

In reference to efficacy, 74 patients had a response to anti-TNF (74/135), and 61 do not show the expected response in the induction phase (61/135). Concerning PASI75 values, 55 patients treated with ADA achieved PASI75 at 3-6 months (55/80), 12 patients treated with ETN (12/39), and 7 patients treated with INF (7/16).

Furthermore, patients carrying TNFRSF1B-rs1061622-G allele an association with ADA response at 3 months (p=0.0026) and patients carrying TNFα-1031-rs1799964-T an association with ETN response at 6 months (p=0.0047), also patients carrying TNFα-238-rs361525-G treated with INF have a response at 6 months (p=0.045).

Conclusion and Relevance In conclusion, response to anti-TNF drugs was associated with different single nucleotide allelic polymorphisms of the TNF gene. Nonetheless, further studies with large cohorts of patients have to be performed to confirm these data in order to apply for this personalised medicine in routine clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-219 AGAMENON-SEOM MODEL FOR THE PREDICTION OF SURVIVAL IN PATIENTS WITH HER2-POSITIVE ADVANCED OESOPHAGOGASTRIC ADENOCARCINOMA RECEIVING TRASTUZUMAB-BASED FIRST-LINE TREATMENT

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Background and Importance Trastuzumab associated with chemotherapy (platinum and fluoropyrimidine) is the standard first-line treatment in HER2-positive advanced oesophagogastric adenocarcinoma (AGA); however, its benefits are heterogeneous.

Aim and Objectives To develop and validate a predictive model for overall survival (OS) and progression-free survival (PFS) in patients with AGA treated with trastuzumab.

Material and Methods Patients from the Spanish Society of Medical Oncology (SEOM)-AGAMENON registry with HER2-positive AGA treated in first-line with chemotherapy and trastuzumab between 2008 and 2021 were selected for this study. An accelerated time-to-event model was developed to predict survival and represented as a nomogram and an online calculator. The nomogram was externally validated in an independent series from The Christie NHS Foundation Trust hospital in Manchester, England.

Results 737 patients were recruited (AGAMENON-SEOM, n=654; Manchester, n=83). In the referral cohort the median PFS and OS were 7.76 (95% CI, 7.13-8.25) and 14.0 months (95% CI, 13.0-14.9), respectively. Patients received a median of six cycles of platinum, eight cycles of fluoropyrimidine and trastuzumab for a median of 7.6 months (95% CI, 7.10-8.30).

In the validation cohort, the median PFS and OS were 8.1 (95% CI, 7.1-11.3) and 12.8 months (95% CI, 10.3-20.4), respectively. Patients received chemotherapy for a median of five cycles and trastuzumab for a median of 6.3 months.

Six covariates were significantly associated with OS and were used to construct the nomogram: neutrophil-lymphocyte ratio (time ratio (TR):0.73; 95% CI: 0.63-0.83), ECOG status (TR:0.59; 95% CI 0.48-0.73), Lauren histologic subtype (TR:0.73; 95% CI 0.57-0.94), HER2 expression (TR:0.85; 95% CI 0.73-1), histologic grade (TR:0.87; 95% CI 0.72-1.07), and tumour burden (TR:1.69; 95% CI 1.34-2.13). The AGAMENON-HER2 model demonstrated adequate calibration and fair discriminatory ability with a c-index for PFS and OS of 0.606 (95% CI 0.58-0.64) and 0.623 (95% CI 0.59-0.66), respectively. In the Manchester validation cohort, the model is well calibrated, with a c-index of 0.65 and 0.68 for PFS and OS, respectively.

Conclusion and Relevance HER2-positive AGA patients receiving trastuzumab and chemotherapy can be stratified according to their estimated survival endpoints using the AGAMENON-HER2 prognostic tool. This nomogram could be a valuable tool for making treatment decisions in daily clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-222 HAPLOIDENTICAL HAEMATOPOIETIC CELL TRANSPLANTATION IN PATIENTS AGED > 55 YEARS WITH ACUTE MYELOID LEUKAEMIA

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Background and Importance In the elderly patients with AML, both the development of reduced-intensity conditioning (RIC) regimens and the use of haploidentical donors have improved their accessibility to allo-HCT.

Aim and Objectives To analyse the clinical characteristics and results of haploidentical family donor allo-HCT, performed in

our hospital during the years 2014 to 2021, in patients with AML >55 years.

Material and Methods

Retrospective observational study. Data collected: age, sex, HCT status, time from diagnosis to transplant, ECOG Performance Status, comorbidity indexes (HCT-CI, EBMTs, DRindex), haematopoietic progenitor source (HPS), CMV-mismatch, conditioning regimen, graft-versus-host disease (GVHD) prophylaxis, and post-HCT complications. Overall survival (OS) and progression free survival (PFS) were analysed using Kaplan-Meier.

Results Thirty patients were included. Median (range): 64 (56-71) years, 57% women. 70.3% in first complete remission. Median (range) time from diagnosis was 6.5 (3.47-52.37) months. 74% ECOG 0. 33% DR index high and very high 15% patients. The EBMTs >4 in 26% and the HCT-CI ≥ 3 in 56% patients. HPS was peripheral blood in 52% and bone marrow in 48%. 56% CMV-mismatch (donor -/ patient +). All patients received a RIC regimen and post-HCT cyclophosphamide and 89% tacrolimus as the only immunosuppressant.

Major non-haematological toxicities included mucositis, gastrointestinal and liver toxicity in 26%, 19% and 7% of patients, respectively. 19% patients developed haemorrhagic cystitis, one patient underwent thrombotic microangiopathy, 41% developed acute GVHD and 37% patients presented chronic GVHD cmv infection occurred in 78% of patients.

Median (range) follow-up was 21.55 (1.67-89.80) months, OS at 1 year was 65% (95% CI, 46-83%), at 2 years 56% (95% CI, 36-75%). PFS at 1 year was 61% (95% CI, 42-80%), at 2 years 48% (95% CI, 28-68%). 48% are still alive and all in complete remission.

Conclusion and Relevance The small sample prevents numerous affirmations from being emphatically extracted, but the results obtained, which are very comparable to the published experiences, support the use of this type of donor in this patient population. Currently, we should not delay transplantation in elderly patients with AML trying to find an HLA-identical donor. If the experience of the Centre is extensive, performing a transplant from a haploidentical donor should be considered in the algorithm of the Allo-HSCT procedure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-223 BOTULINUM TOXIN TYPE A: THE NON-INVASIVE SUCCESS FOR OVERACTIVE BLADDERS

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Background and Importance Intradetrusor injections of botulinum toxin type A (TBA) have significantly changed the management of overactive bladder (OAB), allowing the acquisition of urinary continence and control of renal risks. This technique makes it possible to avoid bladder replacement surgery by

enterocystoplasty. HAV incurs direct and indirect costs to society.

Aim and Objectives Our study has two main objectives: to evaluate the improvement of the handicap of patients with urinary incontinence by bladder hyperactivity, after injection of botulinum toxin A then to evaluate the cost effectiveness ratio.

Material and Methods A retrospective observational study of 74 patients, who received education on self-catheterisation and treated with TBA at the Urology Department of between January 2018 and August 2022. A model was developed to estimate costs by comparing the cost of TBA versus a standard protocol (involving behaviour al therapy, incontinence pads, anti-cholinergic treatment and, catheters) excluding loss of productivity. A quality of life questionnaire was also administered to patients at the follow-up visits.

Results Profiles of TBA use: Primo-injection in 83.78%. For the indication, AVH without leakage in 32.43%, urinary incontinence by AVH in 35.14%, multiple sclerosis in 13, 51% and spinal cord injury in 18.92%. The injections were performed in the operating room. A median paramedical time of 30min to prepare the patient and the product. Injection conducted endoscopically lasted a median of 8min with a median hospital stay of 2 days. Clinical improvement in 81% with a median duration of efficacy of 98 days. For adverse events: hypo or a contractile bladder requiring self-catheterisation (n=81%), generalised fatigue (n=40%) and muscle weakness (n=35%). Calculated costs: The cost of an injection is 7000MAD (price produced with the hospital package). The cost of standard treatment without self-catheterisation is 2340MAD (for anti-cholinergic treatment associated with behavioural therapy). If use of catheters the cost of the injection is 8340MAD. If urinary retention occurs, the cost is 13000MAD. Our study shows that the hospital cost is higher than the standard treatment without self-catheterisation and less expensive if catheterisation was previously used, but with a significant improvement in the quality of life according to the questionnaire results.

Conclusion and Relevance For our centre, since 2014, TBA represents a new therapeutic option in second-line treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-225

HEALTH IMPACT OF TREATMENT FOR INFLAMMATORY BOWEL DISEASE WITH BIOLOGICAL AGENTS FROM THE PATIENT'S PERSPECTIVE: A CROSS-SECTIONAL STUDY USING PATIENT REPORTED OUTCOME MEASURES (PROMS)

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Background and Importance The clinical manifestations of inflammatory bowel disease (IBD) compromise patient's daily life. In this regard, the use of Patient Reported Outcome Measures (PROMs) to determine health status, quality of life and treatment effectiveness from the patient's perspective can add significant value in clinical practice.

Aim and Objectives Assess disease impact in patients affected with IBDs using PROMs.

Material and Methods Cross-sectional study including outpatients treated with biological agents for ulcerative colitis (UC) and Crohn's disease (CD) ≥ 18 years. Socio-demographic and clinical characteristics were collected from clinical records: age, gender, type of IBD, diagnosis year, biological treatment, starting date of biological treatment, previous biological treatment, concomitant immunosuppressive treatment, previous surgeries due to IBD and smoking habits. We used 2 questionnaires to evaluate PROMs: IBD-Control (IBD-Control-8 sub-score plus visual analog scale (VAS), that range from 0-16 and 0-100, respectively, higher scores representing better disease control) and IBD-Disk (that ranges from 0-100, higher score representing higher IBD daily-life burden).

Results 42 patients with CD and 21 with UC were included (mean age 44.25 ± 14.67 , 54% men). 44 patients were treated with infliximab (69.84%), 9 with ustekinumab (14.29%), 7 with vedolizumab (11.11%), 2 with golimumab (3.17%) and 1 with adalimumab (1.59%). 22 (34.92%) were previously treated with biological agents. 4 were diagnosed during the last 18 months while others were diagnosed before. 44 patients (69.84%) took oral immunosuppressant. 60 were treated >6 months with their current biological agent, the other 3 cases for 3-5 months.

Mean IBD-Control-8 score was 12.41 ± 3.87 . Mean VAS score was 87.19 ± 18.17 . Mean IBD-Disk score was 33.22 ± 25.95 (69.84% of patients being below 50 points). 4 out of 63 cases had worse overall measurements (IBD-Control-8 score ≤ 7 , VAS score ≤ 60 and IBD-Disk score ≥ 63). 3 were women with CD and smoking habits (2 current smokers and 1 ex-smoker). 3 of them were treated with infliximab and 1 with vedolizumab (3 requiring concomitant immunosuppressants). 2 required previous surgery.

Conclusion and Relevance This study adds novel literature on health status of these patients using PROMs. Measurements were generally favorable but 4 patients out of 63 had worse overall measurements. Literature on this topic is scarce. PROMs are useful tools that could be incorporated in pharmaceutical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-227

REAL WORLD EVIDENCE OF THE USE OF DEFIBROTIDE FOR PROPHYLAXIS OF VENO-OCCCLUSIVE DISEASE AFTER POST-HAEMATOPOIETIC STEM-CELL TRANSPLANTATION IN CHILDREN

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Background and Importance Hepatic veno-occlusive disease (VOD) is a life-threatening condition caused by the obstruction of liver sinusoids.

Since 2014, in Italy the standard of care for the management of VOD is represented by defibrotide. Recent evidence suggested that defibrotide could help preventing the onset of hepatic VOD when allogeneic haematopoietic stem cell

transplantation is needed. On June 2022, however, a 'direct health professional communication' issued by the European Medicines Agency (EMA) invoked not to use defibrotide anymore for VOD prophylaxis due to lack of effectiveness.

Aim and Objectives The aim of this work is to explore the difference in the incidence of VODs at 30 days in 2 groups of children, with and without prophylaxis therapy with defibrotide before undergoing haematopoietic stem cell transplantation.

Material and Methods A single-centre, retrospective study was conducted at a University Hospital. All data were collected from electronic health records. These data were cross-checked with data from an integrated analytics application (Qlikview®, QlikTech International AB, King of Prussia, USA).

All paediatric patients (age <18 years) undergoing haematopoietic stem cell transplantation for onco-haematological diseases and considered at high-risk for developing VOD were enrolled. We observed an initial group, called the 'intervention' group, consisting of patients who had received the drug, compared with a 'historical' control group of patients with similar baseline characteristics but who did not have access to defibrotide.

Results Between 2020 and 2022, data were collected from 27 patients. The baseline characteristics of the two groups were similar regarding age (9 years old for both groups), gender and onco-haematological disease, all showing no statistically significant differences. In terms of outcome, we witnessed only one episode of VOD, in the treatment group (1 of 11 patients, 9%), at 30 days after transplantation. No episodes were documented in the controls.

Conclusion and Relevance According to the recent statement made by EMA, our data – although not definitive – show that proportion of VOD in children undergoing blood stem transplantation in patients who received a prophylaxis treatment with defibrotide was comparable with the one in children where no prophylaxis strategy has been adopted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-228 HIGH DOSE PHENOBARBITAL COMA IN PAEDIATRIC REFRACTORY STATUS EPILEPTICUS

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Background and Importance Status epilepticus (SE) is associated with high morbimortality. Early treatment has been demonstrated to decrease the risk of death and sequelae. When first-line drugs cannot solve SE, therapeutic coma should be initiated with midazolam (most used), propofol, thiobarbital or phenobarbital (better therapeutic profile with low evidence, especially in paediatrics) are used for this practice.

Aim and Objectives Describing high-dose phenobarbital (HD-PHB) used in therapeutic coma in paediatric refractory SE and their side effects. Exposing the pharmacokinetic monitoring to achieve barbiturate coma (BC).

Material and Methods Observational retrospective study of a third-level paediatric hospital conducted between 2012-2022. 51 paediatric intensive care unit (PICU)'s patients who received intravenous phenobarbital treatment were included, 6 of them underwent BC. Variables collected were age, weight,

number of previous antiepileptic treatments, loading and maintenance doses of phenobarbital, phenobarbital plasmatic levels during coma, BC days until resolution of SE, exitus and adverse effects of HD-PHB. All data were obtained from the clinical history programme.

Results 51 patients were included, of them 6 (median 9 years [0.2-14.5] and 20.2kg) were treated with HD-PHB to achieve BC due to the presence of seizures refractory to propofol or midazolam: 5 had a previous history of epilepsy, treated with a median of 3 antiepileptics at home. The resolution was evaluated by encephalogram. The initial phenobarbital doses used to achieve BC were 60mg/kg/day [50-125]. Reported phenobarbital plasma levels achieved in the BC phase were 943µmol/L [743-1883]. Patients were in coma for a median of 4.5 days [1-6] and in all of them a suppression burst was observed in the encephalogram. Glasgow Scale before coma was 9[7-13] and during coma was 3[2-5]. After resolution of the status, tapering regimen was carried out until phenobarbital plasma levels were below 350µmol/L and a maintenance dose (10mg/kg/12h [2-20]) was continued. The adverse effects reported were haematological in 5 patients (decrease in haemoglobin and haematocrit levels) and hepatic in 2 patients (elevation of transaminases levels). One patient died before 6 months post-coma.

Conclusion and Relevance HD-PHB seems to be an effective therapeutic procedure in paediatric refractory SE. Pharmacokinetics is important to ensure the maintenance of coma and avoid toxicity. More pharmacokinetic studies are needed to establish a population model and clear protocols for BC management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-229 THE ADDED VALUE OF A NATIONAL ELECTRONIC HEALTH RECORD FOR THE BEST POSSIBLE MEDICATION HISTORY OBTAINED BY A CLINICAL PHARMACIST

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Background and Importance Obtaining the Best Possible Medication History (BPMH) is an essential step in the medication reconciliation process, that should ideally be based on the most appropriate sources of information, such as patient health records, to which access is often limited. Implementation of a National Electronic Health Record (NEHR) system aims at streamlining this process by converging relevant data into a singular database.

Aim and Objectives This research aimed to assess the added value of NEHR to BPMH. In addition, the quality of NEHR-based BPMH was compared to the former physician/nurse-led Standard of Care (SoC), in order to explore the added value of clinical pharmacy services in obtaining BPMHs.

Material and Methods The study took place between 05.2022-08.2022 in the general surgery department of a county hospital, enrolling patients over 18 years of age, admitted from their homes, with at least one regularly taken prescribed medication and without major communication difficulties. Medication reconciliation was initiated by clinical pharmacists, based

on the documentation available at the point-of-care ('Hospital list'), which in turn got validated via NEHR data ('NEHR list'), with the final step being a patient interview, formulating the final medication list ('BPMH list'). Primary outcome metrics were the frequency and types of medication discrepancies derived from the comparison of the aforementioned lists, including the former SoC.

Results The study included 100 patients (52% female, average age=62 years). 231 discrepancies were found between the NEHR list and the Hospital list (median=2; IQR=4), 64% of the patients being affected. The most common discrepancy was drug omission (65%) and incorrect daily dose (26%). There was an inconsistency between the BPMH list and the SoC in 90% of the patients (median=3; IQR=3), the most common errors being drug omission (41%) and incorrect daily dose (31%).

Conclusion and Relevance Based on these results, the NEHR can contribute to the compilation of a more prudent BPMH due to its more comprehensive data content. This methodology may, in turn, facilitate the prevention of multiple medication-related errors. These outcomes also underline the legitimacy of pharmacists' access to such national systems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-230

ALLOGENEIC HAEMATOPOIETIC CELL TRANSPLANTATION IN PATIENTS AGED <60 YEARS WITH ACUTE MYELOID LEUKEMIA

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Background and Importance Allogeneic haematopoietic cell transplantation (allo-HCT) is a potentially curative therapeutic modality for acute myeloid leukaemia (AML), but it still carries high morbidity and mortality; there are limited data regarding outcomes, so it is important to research its results, and the factors that influence them.

Aim and Objectives To assess the survival of allo-HCT in AML patients age <60 years, describe its characteristics, and identify factors that are related to the best outcomes.

Material and Methods

Retrospective observational study. We included all patients with AML, aged <60 years, who underwent allo-HCT performed at our centre between 2016-2019.

We analysed their age, sex, cytogenetic risk group, disease status at the time of transplantation, Karnofsky performance status (KPS) score, comorbidity indexes (HCT-CI and EBMT-score), donor type, source, conditioning regimens, graft-versus-host disease (GVHD) prophylaxis, retransplantation, donor age, donor sex, CMV-mismatch, ABO-mismatch, development of GVHD, related hospitalisations, progression, and death.

Overall survival (OS) and progression-free survival (PFS) were analysed using Kaplan-Meier and Log-Rank test.

Results

Thirty-seven patients were included. Mean age was 44.81 ± 12.26 [18-59] years. 64.9% were women. 51.4% intermediate-risk and 43.2% high-risk. 70.3% in first complete remission (CR). 91.9% patients had a KPS score over 90% at the time of transplantation. 54.1% HCT-CI between 0-2, 81.1% EBMT score ≤4. 64.8% related donor (43.2% HLA-identical and

21.6% haploidentical), 35.1% unrelated donor (21.6% HLA-identical, 10.8% HLA 9/10, and 2.7% HLA 8/10). 70.3% allogeneic peripheral blood stem cell transplantation. 64.9% reduced-intensity conditioning. 16.2% retransplantation. Most donors were men >30 years. 37.8% received post-transplantation treatment with cyclophosphamide, tacrolimus, and mycophenolate mofetil. 18.9% CMV-mismatch (patient pos/ donor neg), 56.8% ABO-compatible, 54.1% development chronic GVHD and 40.5% acute GVHD. 43.2% did not require related hospitalisation.

PFS at 12 months was 72% (95% CI, 55-84%), and 51% (95% CI, 34-66%) at 24 months. OS at 12 months was 78% (95% CI, 61-89%) and 62% (95% CI, 45-76%) at 24 months. Median PFS and OS were not reached. The median follow-up for PFS was 33 months [1-69] and 34 months [1-69] for OS.

PFS was significantly higher in patients in 1st CR, EBMT-score ≤4, and lower-risk.

Conclusion and Relevance Patients undergoing allo-HCT show encouraging survival, although more extended follow-up is required to define more accurately their prognosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-232

COMPARATIVE EFFICACY OF RISANKIZUMAB AND GUSELKUMAB IN MODERATE TO SEVERE PLAQUE PSORIASIS

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Background and Importance Anti-interleukin 23 drugs were approved in the last 5 years. The absence of comparison between alternatives such as risankizumab (RIS) or guselkumab (GUS) needs to be fulfilled.

Aim and Objectives To evaluate the effectiveness through indirect comparisons of risankizumab and guselkumab in plaque psoriasis.

Material and Methods Multicentric, retrospective and observational study. Comparison made with plaque psoriasis patients with active treatment with risankizumab or guselkumab from June 2021 and June 2022. Demographic (sex, age) and clinical (body surface area (BSA), psoriasis area severity index (PASI) at baseline and in subsequent dermatology controls, PASI clearance (PASI100)) data collected. Comparison made through PASI100 and BSA and PASI reduction.

Results 59 patients treated with RIS, 64% men, 52,4 ± 15,3 SD years old averaged, and BSA and PASI of 11,4 ± 8,2 SD and 8,7 ± 4,2 SD respectively at baseline. 49 patients treated with GUS, 59,2% men, 50,9 ± 12,1 SD years old averaged, and BSA and PASI of 10,25 ± 10,27 SD and 8 ± 6,69 SD respectively at baseline.

RIS achieved at mean 21,6 ± 15,7 SD weeks a BSA and PASI of 2,24 ± 6 SD and 1,81 ± 3,7 SD respectively, with PASI100 reached by 46% of patients. GUS achieved at mean 22,9 ± 13,1 SD weeks a BSA and PASI of 3,87 ± 9,28 SD and 2,89 ± 4,26 SD respectively, with PASI100 reached by 45%.

At 39,5 ± 10,8 SD weeks, RIS obtained BSA 0,66 ± 1,27 SD and PASI 0,64 ± 1,01 SD, with PASI100 in 64% of

patients, while GUS obtained BSA $1,82 \pm 3,28$ SD and PASI $1,89 \pm 3,3$ SD, with PASI100 in 50% of patients in $44,6 \pm 17,5$ SD weeks.

After $63,6 \pm 14,5$ SD weeks, RIS achieved BSA $0,68 \pm 0,94$ SD and PASI $0,9 \pm 1,14$ SD, and PASI100 maintained by 57% patients. GUS achieved BSA $0,95 \pm 1,55$ SD and PASI $0,53 \pm 0,92$ SD, and PASI100 maintained by 67% patients.

Conclusion and Relevance RIS and GUS are effective alternatives for plaque psoriasis treatment, although it seems that after a year, the activity of RIS starts to decrease. Further studies should be performed to determine this hypothesis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-233 PD-L1 EXPRESSION AND HISTOLOGICAL TYPE AS PREDICTORS OF RESPONSE IN METASTATIC NON-SMALL-CELL LUNG CANCER (NSCLC) PATIENTS TREATED WITH PEMBROLIZUMAB IN FIRST-LINE

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Background and Importance In patients with NSCLC and programmed death ligand-1 (PD-L1) expression $\geq 50\%$, pembrolizumab as first-line treatment has shown an increase in survival over platinum-based chemotherapy. To date, it is not known whether higher PD-L1 expression is associated with longer survival.

Aim and Objectives The aim of this study is to evaluate the impact of PD-L1 expression levels on progression free survival (PFS) and overall survival (OS), in patients receiving first-line pembrolizumab treatment for NSCLC and its association to histologic type.

Material and Methods A retrospective analysis of patients with metastatic NSCLC and PD-L1 expression level of $\geq 50\%$, who were treated with pembrolizumab monotherapy as first-line therapy in our centre from January 2020 to January 2022 was carried out. The difference in response between the histologic type of NSCLC (adenocarcinoma and non-adenocarcinoma), and efficacy of pembrolizumab by level of PD-L1 expression was studied. ROC curve was used to evaluate the optimal PD-L1 cut-off point to identify a greater possibility of response. Event-time distributions were estimated using Kaplan–Meier methodology. Log-rank tests were used to test for differences in event-time distributions. All p-values are 2-sided and CIs are at the 95% level, with significance predefined to be at the 0.05 level.

Results 49 patients were included in the study. 36 patients (73.5%) had adenocarcinoma histology, 10 (20.4%) epidermoid, and 3 (6.1%) other. A cut-off of 80% for PD-L1 expression was established. 40 (81.6%) had PD-L1 expression $< 80\%$ and 9 (18.4%) $\geq 80\%$. Median PFS was 14.7 months (95% CI: 7.0-15.1) in patients with PD-L1 $< 80\%$ and 25.8 months (95% CI: not reached) in patients with PD-L1 $\geq 80\%$ ($p=0.017$). No differences were found in OS. Patients with adenocarcinoma and PD-L1 expression $\geq 80\%$ obtained better results in terms of PFS: 19.3 months (95% CI: not reached, $p=0.031$).

Conclusion and Relevance Statistically significant differences in PFS but not OS were found in patients with NSCLC and PD-L1 $\geq 80\%$ expression. Adenocarcinoma with PD-L1 $\geq 80\%$ seem to benefit the most from pembrolizumab treatment than other NSCLC histologies. These findings could have implications for treatment selection based in NSCLC histology. Future research is needed.

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Conflict of Interest No conflict of interest

4CPS-236 LOSS TO FOLLOW-UP FACTORS OF PEOPLE LIVING WITH HIV

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Background and Importance Loss of adherence to antiretroviral treatment (ART) is one of the leading causes of virological failure in people living with HIV (PLWHIV). Lack of adherence is associated with a loss of follow-up by the health system, particularly in the Pharmacy Department.

Aim and Objectives To identify factors in PLWHIV which cause their follow-up to fail by the Pharmacy Department.

Material and Methods Case-control study conducted in a tertiary hospital which attends 3,000 PLWHIV. Patients who had run out of medication for more than one month, according to pharmacy registrations between September 2020 and September 2021, were identified and named after cases if the reason to not come to the Pharmacy were not justified (death, hospital transfer, inclusion in a clinical trial, etc.). We conducted a case-control study (1:4), and cases were matched according to age (5 years) and date of the last dispensation.

Statistical analysis was performed using the STATA 17.0 program (StataCorp LLC). All models were performed univariately, and a $p < 0.05$ was considered significant.

Variables studied were: gender, age, region of birth, studies, stable housing, route of HIV transmission, CD4 nadir, years after diagnostic, type of ART, years on ART, stage, adverse effects to ART, number of lines of treatment, pharmacy registrations of adherence, alcohol use, drug use, and psychiatric problems. Data were obtained from the clinical database

Results Sixty-one cases were identified and matched with 244 controls. Statistical differences were found in gender, where cis-man have an OR=4.5 (CI95% 1.0–19.6, $p=0.047$) and trans-man have an OR=23.9 (CI 95% 2.9–195.8, $p=0.003$) in comparison with women, and region where Latin-American have an OR=2.7 (CI 95% 1.3–5.6, $p=0.008$). Patients who fail to adhere to treatment according to the records in Pharmacy have an OR=0.04 (CI 95% 0.01–0.11, $p=0.000$) and patients who are alcoholics or drug abusers, have an OR=3.24 (CI 95% 1.30–8.04, $p=0.011$) and an OR=2.01 (CI 95% 1.03-3.93, $p=0.039$), respectively.

Conclusion and Relevance Clinicians should pay special attention to cis or trans-men, Latin Americans, historic bad

adherence registrations by pharmacists and alcoholic or drug abusers who are more prone to losing follow-up in their treatments. This enhances the importance of multidisciplinary team approach to these patients. Clinical, pharmacist and nurse interventions and information registration are crucial to identify these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-237 HYPERKALAEMIA AND RISK FACTORS: SCREENING AND ASSESSMENT IN HOSPITAL PATIENTS

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Background and Importance Hyperkalaemia is a frequent electrolyte alteration (EA) in hospital patients (HP). Thus, close monitoring of plasma potassium levels (PKL) and appropriately management is necessary. High levels of potassium may lead to heart and muscle disorders.

Aim and Objectives Main objectives are to evaluate and monitor hyperkalaemia in HP, to study risk factors and potentially implicated drugs (PIDs) and to analyse the degree of acceptance (DA) of the pharmaceutical interventions on PKL normalisation.

Material and Methods Observational, descriptive and prospective study from October 2021 to January 2022.

Patients with hyperkalaemia ($K^{+} > 5.3 \text{ mEq/L}$) in the first 24 hours were evaluated with the assistance of an EA locator included in the health record system.

PKL were classified as minor ($5.3\text{-}5.9 \text{ mEq/L}$), moderate ($6\text{-}6.5 \text{ mEq/L}$) or severe ($>6.5 \text{ mEq/L}$).

Age, sex, basal PKL and measured PKL four days after, prescribed PIDs, comorbidities such as kidney impairment (KI), previous therapeutic approach or dietary potassium restrictions (DKR) were collected.

Depending on the PKL and the patient characteristics, different recommendations were made: discontinuation of potassium-containing serums; PKL monitoring and DKR consideration in minor hyperkalaemia cases; ion-exchange resin (IER) evaluation when patients with moderate-severe hyperkalaemia tolerated oral intake. If there were any prescribed PIDs, pharmacists recommended an alternative.

PKL were evaluated after interventions and DA was determined.

Results We analysed 87 patients. 64,4% were men and the average age was 77. The most accepted recommendations were: discontinuation of potassium-containing serums (DA 100%), PKL monitoring and DKR (DA 64.2%) and IER prescription (DA 46.15%). The proposed alternatives to PIDs had not a high DA. The PIDs prescribed were heparin 58.6%, renin-angiotensin system inhibitors 39%, anti-inflammatory drugs 27.9% and K-sparing diuretics 3.4%. 66.7% of the patients were treated with more than one PID, 41% of them had KI.

We made an intervention in 40,2% of the cases. The DA was 65,7% with a 60.8% of PKL normalisation versus a 25% of recovery in those patients with non-accepted intervention.

Conclusion and Relevance Hyperkalaemia is more frequent in men and patients with KI. There is an association between PID co-prescription and hyperkalaemia episodes.

The development of pharmaceutical validation support tools such as EA locators provides the screening and monitoring of disorders that might trigger health consequences.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-240 FINGOLIMOD: ANALYSIS OF USE AND SAFETY IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background and Importance Fingolimod is used when the disease remains active despite treatment with at least one other disease-modifying therapy, or is severe and getting worse rapidly. It had the benefit of being taken by mouth while most other drugs are given by injection.

Aim and Objectives To analyse the use of fingolimod treatment and analyse the causes of fingolimod's treatment discontinuation.

Material and Methods Retrospective descriptive study was performed in an area reference hospital. All patients treated with fingolimod from its inclusion in the hospital's pharmacotherapeutic guide in August 2012 to the present were included. Data collected: age, sex, previous treatment received, reason for prescription, date of start and end of treatment, the reason for suspension and clinical data (basal, final or current EDSS). We used Excel to analyse the data.

Results A total of 61 patients were included, one person was excluded for receiving only one dose, 39(65%) were women, with a media age of 42 ± 11 years. All patients were their heart activity closely monitored after the first dose. 7(10%) of patients used fingolimod as first line, whose prescription reason was: four for rapid and aggressive evolution and three due to positive JC antibody. 53(90%) of patients had used other disease-modifying therapies before, 23(43.4%) glatiramer acetate, 14(26.4) interferon beta-1a, 4(6.5%) dimethyl fumarate, 4(6.5%) teriflunomide, 1(1.8%) interferón beta-1b and 7(13.2%) started fingolimod after failure to natalizumab. Median EDSS was 1 in naïve patients and 1.5 in pretreated patients.

Median time to discontinuation was 42.3[49.8] months. 32 patients (53.3%) discontinued treatment for different reasons. Side effects was the main cause 17(53.1%), followed by inefficacy 10(31.2%), for both reasons 2(6.2%) and 2(6.2%) unknow. Lymphopenia represented the most prevalent of the adverse events (47.3%), followed by cefalea(21%), liver enzyme levels(21%) and other like arterial hypertension, atrioventricular block and infections. Median EDSS increased one point both in those who discontinued treatment due to inefficacy and adverse effects.

Conclusion and Relevance Therapeutic success is not assured, as it is a drug with a high prevalence of adverse effects, which makes it necessary to withdraw treatment. Is essential

detecting the symptoms and signs of toxicity for avoid unwanted effects, it is possible by frequent visits to the hospital pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-241 FINAL VALIDITY OF A TOOL FOR RATING SIGNIFICANCE OF PHARMACISTS' CLINICAL CONTRIBUTIONS IN HOSPITAL

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Background and Importance To date there is no gold standard for rating clinical significance of pharmacy contributions to care.

IMPACCTS (InstruMENT for PhArMacy Clinical Contributions To care Significance) is based on the Hatoum scale¹ and consists of five ordered categories or levels, each underpinned by descriptive statements (total of 45 statements).

A robust process to ensure simplicity and clarity of the instrument has been previously reported.²

Aim and Objectives **Aim:** To complete the validation of IMPACCTS.

Objectives were to:

- demonstrate comprehensiveness of IMPACCTS
- quantify interrater reliability of IMPACCTS

Material and Methods This study was completed February 2022. The study did not require ethics approval.

To assess comprehensiveness, 20 senior pharmacists with prior experience of using IMPACCTS were paired to review 45 scenarios (450 different scenarios in total) and asked to find a corresponding statement, or failing that, a suitable significance level.

For interrater reliability, all 20 pharmacists were given the same 15 detailed scenarios to rate clinical significance. Intraclass correlation statistics (two-way, random effects, absolute agreement, individual) were calculated using Stata v14.

All data were collected via a web survey platform.

Results Comprehensiveness – for all scenarios, at least one person found a statement. For 441/450 (98%) scenarios, both respondents in a pair found a corresponding statement. Out of the nine scenarios where one person from the pair did not find a statement, a level could be assigned for eight of these. Therefore, a statement and/or level could be assigned for 449/450 (99.8%) of the scenarios by all respondent pairs.

Intraclass correlation was 0.71 (95% CI = 0.55, 0.86) which demonstrates moderate to good pharmacist interrater agreement.

Conclusion and Relevance This study demonstrates excellent comprehensiveness and moderate to good interrater reliability of IMPACCTS. These data support readiness of the tool for use in research and practice to assess clinical severity of pharmacy contributions in hospital.

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Conflict of Interest No conflict of interest.

4CPS-242 ISAVUCONAZOLE TREATMENT IN TWO PAEDIATRIC PATIENTS DURING EXTRACORPOREAL MEMBRANE OXYGENATION SUPPORT: THE ROLE OF THERAPEUTIC DRUG MONITORING

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Background and Importance Extracorporeal membrane oxygenation (ECMO) may lead to pharmacokinetic alterations of antimicrobials. Isavuconazole is not approved in paediatric patients (PedP) (off-label use) and data on paediatric ECMO are non-existent.

Aim and Objectives To describe two case reports using therapeutic drug monitoring (TDM) to optimise isavuconazole dosage in PedP during ECMO.

Material and Methods Prospective study in critically ill PedP treated with intravenous isavuconazole receiving ECMO (January 2021 to August 2022). Biodemographic, clinical and pharmacokinetic data were collected. Initial proposed dose of isavuconazole base was 5.4 mg/kg (first 48h q8h, followed by q24h; maximum 200 mg/dose). Isavuconazole trough serum concentration (IsaCmin) of 2.5-5 µg/mL was considered as therapeutic range (internal protocol). Continuous variables were expressed as median (range).

Results 1) A 2-year-old boy (11.5kg, 90cm) lung transplant recipient (pulmonary capillary hemangiomatosis) diagnosed with tracheobronchitis caused by *Aspergillus flavus* (9 months after transplant). Isavuconazole was started at a proposed dose and IsaCmin remained in therapeutic range: 5.1(2.5-5.5) µg/mL. Secondary prophylaxis with isavuconazole was maintained (same dose), requiring ECMO due to severe acute respiratory failure (multifactorial). During ECMO (165 days), it was necessary to increase the dose to 16.5 (8.7-19.1) mg/kg/24h to achieve target concentration of median IsaCmin 2.82 (1.3-6.5) µg/mL (24 blood samples). No new fungal infections were observed but sadly the patient died due to intracranial haemorrhage.

2) A 11-year-old girl (70kg, 158cm) admitted for influenza A infection and necrotising pneumonia (*Staphylococcus aureus*), requiring ECMO. Invasive fungal infection was probable (EORTC criteria; positive galactomannan and tracheal aspirate for *Aspergillus niger*) and isavuconazole was started: loading dose of 300mg/6h (suspected interaction with pentobarbital during first 48h) and TDM-guided maintenance therapy. During ECMO (30 days) median maintenance dose was 900mg (12.9mg/kg)/24h (varied widely ranging from 200mg/12h to 250mg/4h) and median IsaCmin remained in the therapeutic range: 4.0 (1.1-8.4) µg/mL (9 blood samples). After ECMO decannulation, isavuconazole dose was reduced to 200mg/12-24h and median IsaCmin remained in range: 3.9 (2.8-11.4)

µg/mL. She continues isavuconazole maintenance treatment with a partial response.

Conclusion and Relevance

- PedP on ECMO may require higher doses of isavuconazole to achieve therapeutic concentrations, suggesting that TDM may be clinically useful.
- Further studies in critically ill PedP, especially those on ECMO, are necessary to confirm the optimal isavuconazole dosage.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-243 DELAYED HIV TREATMENT AND FACTORS ASSOCIATED

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Background and Importance Clinical practice guidelines (EACS, DHHS, Gesida) recommend starting antiretroviral therapy (ART) as soon as possible after HIV diagnosis, irrespective of CD4 cell count (CD4c). Postponing ART start until complementary assessments depends on the setting, medical indications and risk of loss from care.

Aim and Objectives To analyse delay in treatment initiation over the past ten years and to understand factors associated with delayed ART initiation.

Material and Methods Retrospective observational study in patients diagnosed with HIV infection in an integrated health area from January-2012 to June-2022. Variables collected: age, sex, route of infection, healthcare setting of diagnosis, time from diagnosis to ART initiation (delay time), ART, AIDS stage, baseline VL and CD4c.

Data were collected from electronic medical records and outpatient dispensation program. Statistical analysis was performed using Student's t-test and linear regression method (dependent variable: delay time) by SPSS[®] v.15.0.

Results 108 patients were included, median age was 34 years (IQR 29.2-42.7) and 76.9% were men. 41.7% were diagnosed in primary care and 58.4% in the hospital setting. 38.9% were in AIDS stage at diagnosis. The predominant route of infection was men who have sex with men (MSM) 50.9%.

ART was initiated with nucleoside reverse-transcriptase inhibitors (NRTI) combined with integrase-strand-transfer inhibitors (INSTI) 66.7%, non-nucleoside reverse-transcriptase inhibitors (NNRTI) 13% and boosted protease inhibitors (PI/b) 20.4%.

The median baseline logVL was 4.63 (4.13-5.14) and CD4c was 325 (95-500).

The median delay was 21 days (IQR 9-55). Factors associated with delay: baseline CD4c (for every 100 CD4 increase the delay time was extended by 2.29 days (95% CI 0.56 to 4.02; $p=0.01$); baseline logVL (-3.25 days 95% CI 1.57-8.08; $p=0.18$); AIDS at diagnosis (-5.40 days; 95% CI 3.30-14.10; $p=0.2$); use of INSTI or PI/b compared to NNRTI (-31.28 days; 95% CI 7.85-54.71; $p=0.016$). For each year of evolution, the time to ART initiation was reduced by 3.05 days (95% CI 1.59-4.50; $p<0.001$). Comparing 2012-2018 vs 2019-

2022, the delay was reduced by 20 days (95% CI 13.66 to 27.26; $p<0,001$).

Conclusion and Relevance The delay to ART initiation has been significantly reduced in recent years. Factors related to the decrease in delay are lower CD4c, starting treatment with INSTI or PI/b vs NNRTI and being within 2019-2022 vs 2012-2018.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-246 TREATMENT AND NURSING CARE OF MUCORMYCOSIS IN PAEDIATRICS: A CASE REPORT

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Background and Importance Mucormycosis is a serious fungal infection that causes fast invasion, especially in immunocompromised people.

Rhino-orbital cerebral involvement manifests with oedema, sinusitis, periorbital cellulitis and others.

Treatment often requires combined endovenous and topical therapy, and depending on the involvement, surgery.

Aim and Objectives Explaining the therapeutic approach and evolution of a very severe lesion with deep necrosis in the right nostril, with rapid progression and infected by *Acinetobacter Baumannii* extremely multidrug-resistant (ABXDR), *Aspergillus niger* and *Rhizopus arizus*.

Material and Methods A 13-year-old patient (45kg) with Atypical Haemolytic Uremic Syndrome, admitted in another centre where she started treatment with eculizumab and receive corticotherapy, was transferred to our centre due to clinical worsening.

Presented a rapidly progression lesion with deep necrosis in the right nostril.

Wound culture isolated *Acinetobacter Baumannii* extremely multidrug-resistant (ABXDR) and *Aspergillus Niger*. Subsequently, *Rhizopus arizus* was isolated in the biopsy and a diagnosis of rhino-orbital mucormycosis was made. Furthermore, ABXDR is isolated in conjunctival swab and tracheal aspirate.

Systemic treatment was started with isavuconazole (loading dose: 200mg/8h for 2 days and maintenance with 200mg/24h, plasmatic levels 3.85µg/mL), liposomal amphotericin-B (225 mg/24h), meropenem 2g/8h given as a 4-hour extended infusion and nebulised colistin 2MUI every 8 h.

Locally, the wound was first surgically debrided in two steps and targeted therapy was initiated. Due to the lack of commercially available formulations, sterile gels of amphotericin B deoxycholate 0.15% and colistin 0.5% were prepared by the pharmacy service; both were prepared on a water-soluble basis. They were applied every 4 hours alternately.

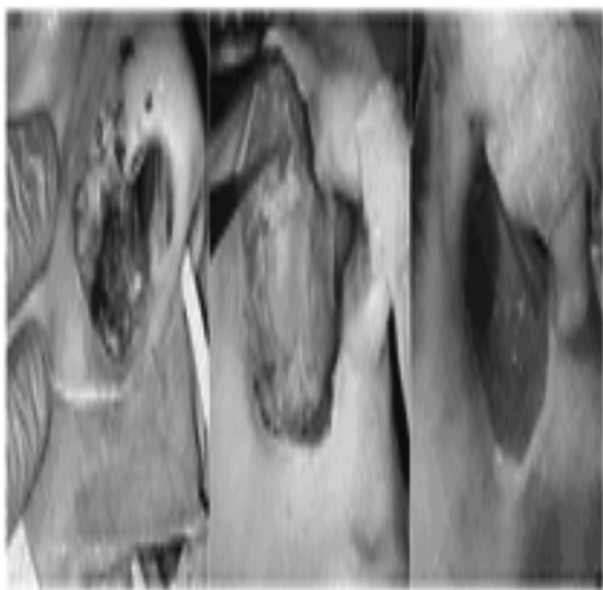
During admission, topical dressings with sodium hypochlorite fomentation (MicrodacynR) plus bacteriostatic gel-based mesh (Cutimed SorbactR) were performed every 24h.

A pharmacy-prepared colistin 0.2%/6h ophthalmic gel was applied to the eyes.

Throughout the hospitalisation, the wound was closely monitored performing smears to detect the microbial growth.

Results Clinical Outcomes were a rapid wound reduction with 80% granulation and negative microbial cultures after 28 days

of continuous treatment. After a month, the patient was discharged from the unit.



Abstract 4CPS-246 Figure 1

Conclusion and Relevance Rhino-orbital mucormycosis is a very serious condition that requires specific targeted treatment and the nursing care, surgery and pharmacy involvement as a team is essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-247 INITIATIVES TO IMPROVE THE MANAGEMENT OF PATIENTS WITH HEREDITARY ANGIOEDEMA BY HOSPITAL PHARMACY

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Background and Importance Hereditary angioedema (HAE) is a rare, hereditary disease with a negative impact on the quality of life of patients. The increase in the knowledge of HAE and the appearance of new treatments in recent years have contributed to modifying the course of this disease. In this scenario, hospital pharmacists have acquired a more significant role.

Aim and Objectives Identify and promote initiatives to improve the management of patients with HAE by Hospital Pharmacy and evaluate the importance of care coordination for a multidisciplinary approach to patients with HAE.

Material and Methods Initiatives to improve the care of patients with HAE were identified, evaluated and prioritised by a multidisciplinary panel of experts (a group of hospital pharmacists, one allergist and one nurse/HAE patient). The initiatives were grouped into seven key areas of activity: evaluation and selection of medicines; dispensation and

telepharmacy; pharmacokinetic monitoring and telemedicine; care coordination; patient health education; research, education and training. Subsequently, the initiatives were prioritised based on their impact on improving patient care and on the feasibility of their implementation (scale of 1-5).

Results Twenty-eight initiatives were identified and grouped in seven work areas. After the prioritisation of the initiatives, the experts identified five priority initiatives for Hospital Pharmacy:

- Evaluation and selection of medicines:
 - Incorporate the patient's perspective and opinion in HAE treatment decision-making processes using PROs (Patient Reported Outcomes) and PREMs (Patient Reported Experience Measures).
 - Participate in multidisciplinary meetings for the evaluation and selection of drugs for HAE.
- Care coordination:
 - Develop a guideline of recommendations for the coordination of the healthcare professionals responsible for the management of patients with HAE.
- Patient health education:
 - Promote the use of telepharmacy tools for patient education and information as a complement to face-to-face care.

Conclusion and Relevance Five priority initiatives are proposed for the management of patients with HAE, highlighting the importance of care coordination to improve the multidisciplinary approach of these patients. From this study, specific actions have been identified that could improve the approach to patients with HEA by hospital pharmacists. Thus, these professionals will be able to promote potentially implementable initiatives that could have a real impact on patients' lives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-249 RELATIONSHIP BETWEEN RENAL FUNCTION AND ERTAPENEM PLASMA CONCENTRATION IN ADULT PATIENTS

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Background and Importance Ertapenem is a parenteral β -lactam antibiotic with predominantly renal excretion. It presents a time-dependent bactericidal activity and usual dose is 1g every 24h, but in patients with estimated glomerular filtration rate (eGFR) <30ml/min is recommended 0.5g every 24h.

Aim and Objectives Our aim is to evaluate the relationship between renal function (eGFR) and ertapenem plasma trough concentration (Cert).

Material and Methods Retrospective cohort study conducted at a tertiary university hospital from October 2019 to February 2021. Adult patients treated with ertapenem for at least 72 hours and who had a Cert determination were included. Bio-demographic, analytical and treatment-related data were collected. Continuous variables were expressed as mean \pm standard deviation (SD) and categorical variables as

percentages (cases). High-performance liquid chromatography-ultraviolet (HPLC-UV) was used to measure Cert.

Cert was measured after at least two doses of ertapenem (>48h) and before the next dose administration (trough). Renal function was measured as eGFR according to CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration).

Pearson correlation coefficient (R) was calculated to study the correlation between eGFR (independent variable) and Cert (dependent variable). To determine the statistical significance of R, the analysis of variance (ANOVA) was performed and p value was obtained (IBM SPSS Statistics V21.0).

Results 102 patients with Cert determination were included, 53% male sex, with 73.0 ± 12.2 years old. Mean eGFR was 57.5 ± 27.86 mL/min/1,73 m². Cert was measured 6.4 ± 4.04 days after starting ertapenem and the mean duration of treatment was 15.5 ± 11.4 days.

R valor was -0.436 ($R^2=0.190$) which explains an inverse linear correlation between eGFR and Cert with statistical significance ($p=0.001$). Influence of other covariates (albumin, platelets, ertapenem dose, sampling time) on the relationship between Cert and eGFR was studied, with no significant impact observed.

Mean Cert for the different eGFR ranges were summarised in the table:

| eGFR category (mL/min/1,73 m ²) | Cert (mcg/mL) |
|---|-----------------|
| eGFR >90 (n=24) | 7.3 ± 12.1 |
| eGFR 60-90 (n=24) | 14.1 ± 10.1 |
| eGFR 30-60 (n=29) | 19.4 ± 19.5 |
| eGFR <30 (n=25) | 29.7 ± 28.0 |
| Total (n=102) | 17.8 ± 20.3 |

Conclusion and Relevance

- Decrease in eGFR is correlated with an increased in Cert, with a possible overexposure in patients with renal dysfunction.
- A dose adjustment could be considered in patients with compromised renal function, even if the eGFR >30 mL/min/1,73 m².

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-251 HEREDITARY ANGIOEDEMA: IMPACT OF THE BURDEN OF DISEASE IN SPAIN

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Background and Importance Hereditary angioedema (HAE) is a rare disease with a negative impact on patients' quality of life. Understanding the patient pathway would contribute to reducing the burden of the disease.

Aim and Objectives Understand the patient with HAE pathway by identifying and assessing the elements that comprise the burden of the disease of patients.

Material and Methods Descriptive study based on a bibliographic review and the expertise of a multidisciplinary panel of 18 professionals with knowledge and experience in HAE (Allergology, Immunology, Medical Emergency, Hospital Pharmacy, Nursing and Patient Associations). The patient pathway was elaborated by identifying the elements that comprise the burden of the disease. Those elements were evaluated from the patient's and the healthcare system's perspectives.

Results A patient with HAE suffers an average of 5.8 attacks per year, although there is great variability among patients. It has been estimated that 35% of patients take long-term prophylaxis (LTP).

The estimated average cost of a patient with HAE is € 47,825/year, including pharmacological costs, admissions, medical appointments and procedures and indirect costs (transport and loss of productivity). Pharmacological treatment of LTP represents 79% of the total costs; however, it decreases the number of attacks by 76%, and therefore reducing the burden of disease.

In terms of lost productivity, it is estimated that a patient with HAE losses 2.5 days of work per year, although this varies depending on the treatment and situation. The loss of productivity associated with the loss of educational and professional opportunities and the emotional impact of HAE are important components of the burden of the disease.

The prescription of LTP in patients with a high number of attacks and the implementation of telepharmacy/telemedicine programs improves the quality of life, reduces visits to health care facilities and decreases sick leaves. The possibility of having the medication available at home for self-administration is an important benefit for patients and the healthcare system.

Conclusion and Relevance HAE has a high impact on patients and the healthcare system. Identifying the key elements at each stage of the patient pathway is essential to improve their quality of life while ensuring the sustainability of the healthcare system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-254 DAPAGLIFOZIN PRESCRIPTION PRACTICE IN PATIENTS WITH CHRONIC HEART FAILURE

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Background and Importance Dapagliflozin is a sodium-glucose cotransporter 2 (SGLT2) inhibitor authorised by the Spanish Medication and Healthcare Products Agency for chronic symptomatic heart failure (HF) with reduced left ventricular ejection fraction (LVEF). In the pivotal study DAPA-HF, the risk of cardiovascular death or worsening of the HF was reduced with dapagliflozin compared with placebo.

Aim and Objectives The objective of the study was to evaluate the use of dapagliflozin in a level four university hospital for HF indication according to the DAPA-HF study inclusion

criteria, emergency room visits, and hospital readmissions due to HF decompensation, or death from any cause.

Material and Methods This was a retrospective study January-July 2021 that included HF patients with at least one dose of dapagliflozin. The variables recorded were: gender, age, LVEF, N-terminal B-type natriuretic peptide (NT-proBNP), standard treatment, HF classification according to the New York Heart Association (NYHA), readmissions/emergency room visits for HF, and death. The follow-up period lasted 14 months.

We evaluated whether the prescription of dapagliflozin met the inclusion criteria of the DAPA-HF study which were: LVEF $\leq 40\%$, NT-proBNP ≥ 600 pg/mL, NYHA class II-IV and standard therapy (angiotensin-converting-enzyme inhibitors, angiotensin II receptor blockers or sacubitril/valsartan, plus beta blockers and mineralocorticoid antagonists).

Results We had 51 patients (20% female) with an average age of 71 (49-88). Prescriber adherence to all of the criteria was achieved in 30/51 patients (59%). Adherence for each criterion was: LVEF $\leq 40\%$ in 46 patients (90%), NT-proBNP ≥ 600 pg/mL in 44 (86%), NYHA II-IV in 38 (74.5%) and adequate treatment with standard therapy in 45 (88%) patients.

Seventy-six percent (39/51) of patients continued with dapagliflozin at 14 months. During the follow-up period 10/51 visited an emergency room and 10/51 were readmitted for HF decompensation. The cause of death of three of the four patients who died was cardiovascular.

Conclusion and Relevance More than half of the prescriptions for dapagliflozin met the criteria for inclusion in the study. The percentage of HF decompensation or death from cardiovascular causes was greater in our cohort than in the clinical trial sample.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-255 ANTIPARKINSONIAN MEDICATION RECONCILIATION: HOW PREVENTING MEDICATION ERRORS PROMOTES THERAPEUTIC QUALITY AND SAFETY

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Background and Importance Pharmacotherapy is the primary treatment for Parkinson Disease (PD). The administration of PD medication needs to be carried out at a particular time to avoid missing doses or inaccurate dosage schemes that may result in motor and non-motor consequences. One-third of all patients with PD visit an emergency department or hospital each year, yet about 70% of neurologists report that PD patients do not get their medication properly when hospitalised. Besides, 1 in 3 patients with PD is prescribed contraindicated drugs during hospitalisation and serious complications, mostly neuropsychiatric, occur in more than half of these patients.

Aim and Objectives To design and implement a medication reconciliation protocol led by clinical pharmacists that allowed to identify, characterise and, eventually, prevent antiparkinsonian medication errors to promote therapeutic quality and safety in daily practice.

Material and Methods This was an interventional, single-centre, one-year, prospective study analysing the impact of developing an antiparkinsonian medication reconciliation programme. All the patients who were hospitalised and had, at least, one active prescription containing an antiparkinsonian drug at hospital admission were included. The medication reconciliation was performed by following a three-phased check: inpatient electronic prescription validation after assessing the outpatient medication schedule, review of the latest clinical report emitted by the Neurology Department, and pharmacist-driven interview of the patient and/or caregiver to confirm the information regarding medication gathered.

Results 171 admission episodes from 132 patients were registered between February 1, 2021, and January 31, 2022. Of 224 prescription lines involving antiparkinsonian drugs, 179 contained, at least, one medication error (59.8%). Commission errors (91.62%) were more frequent than omitted drugs (8.38%). The most common medication errors were related to timing (41.90%), frequency (21.23%), and dosing (19.55%). The implementation of the medication reconciliation programme prevented the erroneous administration of 2716 antiparkinsonian doses, 60% of the total number of doses prescribed during this period. Interestingly, a significant relationship between the number of medication errors and having levodopa prescribed was evidenced ($p < 0.05$). A contraindicated drug was prescribed in almost one-third of the episodes (29.82%).

Conclusion and Relevance Clinical pharmacists' implementation of an antiparkinsonian medication reconciliation programme sharply reduced medication errors, and contraindicated drugs prescription, thus improving therapeutics and drug safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-257 PREOPERATIVE INTRAVENOUS IRON TO TREAT ANAEMIA BEFORE MAJOR ORTHOPEDIC SURGERY

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Background and Importance Preoperative anaemia, is a risk factor for poor outcome in patients undergoing surgery. Sufficient data exist to support intravenous iron as efficacious and safe if surgery is planned for $< 2-3$ weeks after the diagnosis of iron deficiency. Treatment of preoperative iron deficiency anaemia should be implemented as early as possible before the scheduled surgical procedure, most major surgery is elective.

Aim and Objectives The purpose of this study is to review the clinical effectiveness of IVI administered preoperatively for iron deficient in adult patients undergoing elective orthopedic surgery

Material and Methods Retrospective Observational study conducted between January 2021 and December 2021

Eligible participants, identified in preoperative hospital visit were older than 18 years of age and had haemoglobin less than 13 g/dL for men and 12 g/dL for women.

Preoperative assessment visit scheduled 1-2 weeks before surgery, able to receive infusion at least 7 days before the planned operation date.

Intervention: Intravenous iron was administered as a single 500-1000 mg dose of ferric carboxymaltose (FCM)

Endpoints included: demographic characteristics, clinical effectiveness (hemoglobin level before surgery >13 g/dL), time span between first FCM administration and surgery, safety (rate of adverse events).

Limitations: no evidence with respect to outcomes such as quality of life, post-operative complications, morbidity and mortality were identified.

Results We recruited 165 adults patients (86,6% female and 13,3% male). The median age was 71,1 years. The type of orthopedic surgery was: hip 66 (40%), knee 77 (46,7%) and spine 18 (10,9%). Treatment with intravenous iron were administered en 79 patients (48%) between 7-15 days before surgery.

Intravenous iron was administrated as a single 500 mg dose in 44 patients (26,6%) and a single 1000 mg in 121 pacientes (73,3%)

The day of the surgery, 7,27% of the patients reached haemoglobin concentration levels ≥ 13 g/dL

Patients were monitored for adverse events or signs of hypersensitivity during and for at least 30 min after treatment and no severe adverse events related to FMC occurred

Conclusion and Relevance The primary results of our study show no evidence of clinical benefit in giving intravenous iron preoperatively to patients undergoing major surgery

The study suggests that current protocol on preoperative iron therapy should be revised to improve the results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-259 MANAGEMENT OF VORICONAZOLE-INDUCED LIVER TOXICITY IN A PAEDIATRIC PATIENT

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Background and Importance Invasive fungal infections are an important cause of morbidity and mortality in immunocompromised patients. Voriconazole has variable pharmacokinetics and children usually require higher doses to have voriconazole concentrations within the therapeutic range (TR) and due to variability, close monitoring of plasma concentrations (Cp_{vor}) is recommended.

Aim and Objectives To describe pharmacokinetic/pharmacokinetic (PK/PD) management, efficacy and safety of voriconazole-induced liver toxicity in a paediatric patient.

Material and Methods PK/PD management was performed by clinical pharmacists and the goal was to have plasma Cp_{vor} within the TR (1.5-5.5 mg/L). Voriconazole has variable pharmacokinetics linked to age, cytochrome CYP2C19, hepatic dysfunction and drug interactions. Efficacy is defined as analytical, clinical and radiographic improvement and safety as the absence of adverse reactions. Cp_{vor} were measured by a validated high-performance liquid chromatography method.

Results An 8-year-old paediatric patient undergoing active chemotherapy for acute myeloid leukemia. During the 2nd consolidation (probable invasive aspergillosis) and after the 3rd (proven invasive aspergillosis) the patient was

hospitalised and treated with voriconazole, reaching the therapeutic target with voriconazol 20mg/kg/12h oral/IV. In both admissions, separated by 8 months, the patient suffered hepatic toxicity (increased transaminases). On both occasions the following plan was developed: 1) close monitoring of Cp_{vor} and 2) close monitoring of liver function. During the first hospitalisation (Cp_{vor}=1.23mg/L; ALT=90U/L; AST=58U/L; GGT=430U/L) it was recommended to maintain the dose of 20mg/kg/12h oral and monitor liver function. At 10 days Cp_{vor}=3.52mg/L and transaminases decreased. During the 2nd hospitalisation (Cp_{vor}=9.7mg/L; ALT=35U/L; AST=72U/L; GGT=569U/L) it was recommended to decrease the dose from 20mg/kg/12h IV to 15mg/kg/12h IV and monitor liver function. At 10 days Cp_{vor}=1.58mg/L and transaminases decreased. The patient was treated with oral and IV voriconazole, oral bioavailability was estimated to vary between 70-100%. Treatment with voriconazole was effective, the patient presented clinical, analytical and radiographic improvement.

Conclusion and Relevance Voriconazole was effective in the treatment of probable and proven aspergillosis. Although voriconazole-induced liver toxicity is not dose-dependent, on the second admission the patient had Cp_{vor} above the TR. The patient presented voriconazole-induced hepatotoxicity, which was resolved with PK/PD management on both occasions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-261 ANALYSIS OF DRUG INTERACTIONS BETWEEN ORAL ONCOLOGICAL TREATMENT OF PROSTATE CANCER AND CHRONIC MEDICATION

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Background and Importance Potential interactions are detected with new oral treatments for prostate cancer. Interactions with these drugs need to be reviewed in elderly people are fragile, polypathological and polymedicated

Aim and Objectives To detect and analyse the interactions between the selective inhibitor of the enzyme 17 α -hydroxylase (abiraterone) and the androgen receptor inhibitors (apalutamide and enzalutamide) with the chronic medication of patients who come to the outpatient clinic.

Material and Methods Observational and transversal study carried out in the Outpatient Unit(UPE) for two months (July-August 2022) in an area reference hospital.

The pharmacist conducted a clinical interview with all patients receiving treatment with abiraterone, apalutamide, and enzalutamide who came to pick up their medication at the outpatient clinic. In necessary cases, we rely on the computerised electronic prescription. In addition, age, disease classification and treatment start date were collected.

The data collected was analysed using the Lexicomp database, which classifies interactions into 5 categories according to the recommendation: Category A and B (No follow-up necessary), C(Monitor the patient), D(Consider modification of therapy) and X. (Avoid combination). The interactions of

categories C, D and X have been considered. The degree of rigor and the reliability rating were also collected.

Results A total of 69 men were interviewed. The mean age was 77 years, all older than 60 years. 31 patients were receiving treatment with apalutamide, 26 with abiraterone and 12 with enzalutamide. The patients had a mean of 12.6 ± 15.1 months of treatment. 88.5% took 5 or more medications.

A total of 709 lines of treatment were analysed, finding that 66.6% of the patients presented an interaction in their treatments, 1.9 interactions per patient.

According to the severity of the interactions, 76.2% (91) were C, 10.1% (12) D and 12.7% (15) category X. 63.5% of the interactions were with apalutamide, 26.2% with enzalutamide and 10.1% with abiraterone. 4 pharmacological groups are responsible for category D interactions and 1 is responsible for category X interactions (proton pump inhibitors).

Conclusion and Relevance

- The study has allowed us to detect a high number of interactions, although the proportion of patients with clinically relevant interactions is low.
- The pharmacist plays a very important role in the prevention, detection and monitoring of interactions in this group of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-262 A NOVEL ARTIFICIAL INTELLIGENCE-BASED TOOL TO ASSESS ANTICHOLINERGIC BURDEN: A SURVEY

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Background and Importance Many medications possess anticholinergic activity. Their use is associated with a number of serious adverse effects including cognitive effects. The cumulative anticholinergic effect of medications as assessed by tools such as the anticholinergic burden scale (AchB) can identify people particularly at risk of anticholinergic side-effects. Currently, more than 20 tools are available for clinicians to use, but there is no consensus on the most appropriate tool.

Aim and Objectives To assess the overall need for an assessment tool as well as the usability of a newly created tool, the International Anticholinergic Cognitive Burden Tool (IACT), to assess anticholinergic burden of medications.

Material and Methods A newly created online tool, International Anticholinergic Cognitive Burden Tool (IACT), based on natural language processing and chemical structure analysis, was developed and made available for clinicians to test its functions. We carried out a survey (between 8 February to 31 March, 2021) to assess the overall need for an assessment tool as well as the usability of the IACT.

Results A total of 110 responses were received from different countries and practitioners' groups. The majority of the participants (86.11%) stated they would use a tool for AchB assessment if available and when they were asked to rate the IACT against other tools, amongst 34 responders, 20.59% rated it better and 8.82% rated it significantly better, 44.12% rated it neither better, nor worse, 14.71% rated it worse and 11.76% somewhat worse.

Conclusion and Relevance There is a need for an anticholinergic burden calculator to assess the anticholinergicity of medications. Tools such as the IACT potentially could meet this demand due its ability to assign scores to current and new medications appearing on the market based both on their chemical structure and reported adverse pharmacological effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-263 THE PHARMACIST'S ROLE IN OPTIMISING SURGICAL ANTIBACTERIAL PROPHYLAXIS (SAP)

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Background and Importance Surgical antibiotic prophylaxis in orthopaedic joint arthroplasties is common reason for unnecessary, excessive and irresponsible use of antibiotics.

Aim and Objectives The purpose of this study was to analyse whether the continuous presence of clinical pharmacist on the ward may improve SAP guidelines adherence and clinical outcomes.

Material and Methods The study was conducted at an Orthopaedics Department of a tertiary care medical centre. Overall guideline adherence (agent, dose, frequency, duration), clinical outcomes (length of stay-LOS, number of surgical site infections-SSIs), antibiotic exposure and direct antibiotic costs were compared between pre-intervention (retrospective observational) and intervention (prospective) periods. The clinical pharmacist's interventions consisted of proactively controlling antibiotic prophylaxis every day on an individual level to ensure compliance with SAP (agent selection, dosage, and duration) guidelines, attending surgical ward visits, participating in antibiotic related decisions, and providing continuous counselling service. SAP guideline adherence, antibiotic exposure, and costs in the two periods were compared using Chi-square, Fisher exact, and Mann-Whitney tests.

Results Significant improvement in overall SAP guideline adherence (by 56.2%, from 2% to 58.2%, $p < 0.001$) was observed. Significant reduction in SAP duration (by 42.9%, 4.1 ± 2.1 vs 2.1 ± 1.9 days, $p < 0.001$), in SAP antibiotic exposure (by 41%, from 6.1 ± 0.05 to 3.6 ± 4.3 DDD/patient, $p < 0.001$), and average prophylactic antibiotic cost (by 54.8%, 9278.8 ± 6094.3 vs 3598.2 ± 3354.6 HUF/patient)

were observed. Moreover, prolonged prophylaxis has no benefit on clinical outcomes (LOS: decreased by 37.2%, 11.2 ± 7 to 7.62 ± 3 days, $p < 0.001$; confirmed SSIs: decreased by 1.8%, from 3% to 1.2%, $p = 0.21$).

Conclusion and Relevance Continuous presence of the clinical pharmacist is crucial in optimising antibiotic use. Pharmacist's intervention led to a significant improvement in SAP guideline adherence, that entailed also the significant reduction of antibiotic exposure, length of stay, and costs. Additional research, focusing on empirical and targeted antibiotic therapy and implementation of optimising antibiotic use, is needed.

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Conflict of Interest No conflict of interest

Section 5: Patient safety and quality assurance

5PSQ-002 PHARMACIST IN SECURING DRUG CIRCUIT: FROM PRESCRIPTION TO ADMINISTRATION (ANALYSIS AND ACTIONS)

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Background and Importance In a multidisciplinary hospital with 426 beds, roles of hospital pharmacist are varied and drug circuit presents many risks of medication error. According to the WHO, the roles of pharmacists are 'the Seven star Pharmacist': care giver, decision maker, communicator, leader, manager, lifelong learner and teacher.

Aim and Objectives Objective of this study is to measure effectiveness of actions taken by pharmacists to reduce medication errors: from prescription to administration.

Material and Methods Between 2019 and 2022, a compilation of audits have been made. Various stages of drug circuit were audited using previously validated audit grids. Each audit have been made during 15 days for all new prescriptions. A statistical analysis of proportion comparing the error rate before and after the implementation of improvement actions was carried out. Prescription of all injectable drugs has been formalised, new doctors arriving at the hospital are made aware. Concerning medication reconciliation: in the event of a discrepancy observed, doctor is systematically informed, a pharmacy student has been assigned to the surgery unit. Errors not detected during pharmaceutical validation were presented to all pharmacists. Measures to reduce risk of task interruption were implemented during dispensing (dedicated emergency telephone line, redefining tasks). Concerning administration of medication: training workshop days for nurses have been created by pharmacists.

Results Results showed a statistically significant improvement in certain criteria (statistical analysis of proportion : comparing error rate before and after actions ; $\alpha = 5\%$) : medication reconciliation rate increased from 64% in 2019 to 73% in 2021 (64% VS 73%); errors not detected during

pharmaceutical validation (2% VS 1%); dispensing error (3% VS 2%); lack of knowledge of the establishment's drug administration procedure (58% in 2019 VS 33% in 2022). On the other hand, certain criteria have deteriorated: prescription compliant in 70% in 2019 and 65% in 2022.

Conclusion and Relevance This study has made it possible to objectify that actions of pharmacists have been beneficial in management of patients. However, we find that actions taken to improve prescription of drugs have not been effective. It would be interesting to set up continuous training for doctors on the use of the prescription software in our establishment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-003 PERFORMANCE OF A COLD MAINTENANCE DEVICE DURING THE IMPLEMENTATION OF A PNEUMATIC CIRCUIT

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Background and Importance Few information are available about the performance of cold maintenance device.

Within the framework of the implementation of a pneumatic system in a new university hospital, the feasibility of sending different types of medicines, including cold products with a pneumatic system was studied.

Aim and Objectives The objective of this study is to evaluate the compliance of a cold maintenance device within a pneumatic.

Material and Methods The study was led in a French University Hospital with 1495 beds and more than 80 care units between May and September 2022. The analysis was made with kits provided for the cartridges dedicated to cold transport and with qualified electronic temperature recorders Log-tags[®] (C.M.I France, Neung-sur-Beuvon). Different conditions were tested, one condition per test, reproduced at least 3 times: kits placed at room temperature, in the fridge (2/8°C) or in the freezer, presence or not of a secondary packaging, eutectic plate or putting the kit in the cartridge. The supplier had certified on his commercial leaflet a duration of 50 min between 2 and 8°C under the following conditions: 500 ml infusion bag stored at 5°C, with thermal recorder inside the bag, placed in the kit then in the cartridge.

Results All the results of the 9 different tests (one condition per test, reproduced at least 3 times) do not meet the 50 min data indicated by the supplier. The method applied by the supplier shows a mean duration between 2 and 8°C of 4.20 min [4;5] Using the same starting conditions: freezing the kit, gave an average of 8.20 min [7;9], using a secondary packaging, the average was 6.40 min [6;7], outside the cartridge, the average was 4.40 min [4;6], and adding an eutectic plate, the average was 29.24 min [11;60] but with a temperature below 0°C. The average for all tests is 8.46 min.

Conclusion and Relevance This study showed that the supplier's device and data did not comply the good practices concerning management of health products subject to cold chain and the patient safety.

Various studies have been undertaken at the level of the Hospital pharmacy and the cold supplier to improve the supplied isothermal enclosure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-004 EPLUSA RELATED SLEEPINESS: A CASE REPORT

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Background and Importance Eplusa is a two-drug combination administered as a single daily pill containing Velpatasvir and Sofosbuvir used to treat de Hepatitis C. The treatment duration is 12 weeks and the cure rates are from 97% to 100% in those patients without cirrhosis or with compensated cirrhosis.

Based on data obtained from phase 3 clinical studies, the percentage of patients experiencing any serious adverse event was 3.2%. The most common adverse reactions observed are headache and fatigue.

Pharmacovigilance collects information, and analyses and notifies case of suspected adverse drug reactions (ADRs) to prevent them occurring in the future

Aim and Objectives To describe a case of sleepiness in a patient treated with Eplusa and establish its possible association.

Material and Methods We describe a case of an 72-year-old woman diagnosed with hepatitis C with compensated cirrhosis and treated with Eplusa. In May 2022, before starting the treatment with Eplusa, her home medication was checked at the Pharmacy Department, which include atorvastatin, enalapril and omeprazole; pointing out to separate the intake of omeprazole and Eplusa 4 hours and proving there no were any drug interactions. After 16 days receiving the treatment with Eplusa, she was referred to the emergency department presenting sleepiness and general deterioration. As a result, she was diagnosed with common cold and treated with amoxicilin. It also coincided with constipation, which spontaneously resolved within two days. Finally Eplusa treatment was stopped.

Results 4 days after, she reported improvement in sleepiness after discontinuation of treatment, although the iatrogenic origin cannot be guaranteed since it has also coincided with catarrhal symptoms and constipation, both situations in resolution. Naranjo's algorithms establish the causality relationship as possible (score of 2). The Spanish pharmacovigilance centre was notified.

Conclusion and Relevance The European Medicines Agency's technical sheet for Eplusa does not describe sleepiness as an ADR. Patient could confuse fatigue with sleepiness in dealing with subjective symptoms. The RPC reported this case as the only Eplusa ADR notified in our country. The reporting of ADRs in hospitals is very important because innovative new drugs are usually used, severe ADRs are most likely to be seen in hospitals and it can be detected early helping others how to act.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-005 ANALYSIS OF ANTI-ANGIOGENESIS-RELATED ADVERSE EVENTS ASSOCIATED WITH VASCULAR ENDOTHELIAL GROWTH FACTOR RECEPTOR-TYROSINE KINASE INHIBITORS (VEGFR-TKIS) IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA

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Background and Importance Oral vascular endothelial growth factor receptor – tyrosine kinase inhibitors (VEGFR-TKIs) are standard treatments for metastatic renal cell carcinoma. The VEGF pathway plays an important role in the physiological function and homeostasis of the cardiovascular and kidney systems, resulting in anti-angiogenesis-related adverse events (AEs). Limited studies have evaluated anti-angiogenesis-related AEs involving VEGFR-TKIs using real-world data, which may provide important evidence for drug choice and monitoring in the treatment of metastatic renal cell carcinoma.

Aim and Objectives This study aimed to investigate the incidence and patterns of anti-angiogenesis-related AEs associated with the use of VEGFR-TKIs in patients with a metastatic renal cell carcinoma using real-world data.

Material and Methods This cross-sectional study included patients with a diagnosis of metastatic renal cell carcinoma who received axitinib, cabozantinib, pazopanib, sorafenib, and sunitinib at the third level hospital in South Korea between January 2007 and December 2019. Anti-angiogenesis-related AEs were rated 'possible' or higher on the WHO-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale. The severity of AEs was graded using the CTCAE v.5.0. To compare the incidence of AEs associated with different VEGFR-TKIs, we divided the enrolled patients into those who had not previously received a VEGFR-TKI (VEGFR-TKI-naïve) and those who had previously received a VEGFR-TKI (VEGFR-TKI-experienced).

Results A total of 988 patients were included (75% men, median 61 years). 644 patients were VEGFR-TKI-naïve and 314 patients were VEGFR-TKI-experienced. Anti-angiogenesis-related AEs of any grade occurred in 65.1% of VEGFR-TKI-naïve patients and 54.8% of VEGFR-TKI-experienced patients. In addition, severe AEs occurred in 34.6% of VEGFR-TKI-naïve patients and 36.0% of VEGFR-TKI-experienced patients. Regardless of treatment history, the most common AE was hypertension, with a 48.6% of VEGFR-TKI-naïve and 35.0% of VEGFR-TKI-experienced. For VEGFR-TKI-experienced patients, the overall rate of anti-angiogenesis-related AEs for sorafenib (24.3%) was lower than that for other VEGFR-TKIs ($p < 0.05$). Female gender (adjusted hazard ratio [aHR] 1.23, 95% confidence interval [CI] 1.02-1.48) and high blood pressure (aHR 1.47, 95% CI 1.23-1.76) were risk factors for VEGFR-TKI-associated AEs.

Conclusion and Relevance More than half of patients with renal cell carcinoma receiving VEGFR-TKI experienced anti-angiogenesis-related AEs. Any grade of AEs occurred more frequently in VEGFR-TKI-naïve patients, while severe AEs occurred more frequently in VEGFR-TKI-experienced patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-006 **IMPACT OF PUIZZLE, A PLAYFUL EDUCATIONAL TOOL ON HIGH-ALERT MEDICATIONS ON HEALTHCARE PROFESSIONALS' KNOWLEDGE: A 7-MONTHS ANALYSIS**

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Background and Importance High-alert medications (HAMs) can lead to serious adverse events when errors occur during the drug management. To raise awareness among healthcare professionals (HCPs), our hospital pharmacy has developed a fun educational tool in puzzle form: PUIzzle (PUI is the French acronym for internal use pharmacy).

Aim and Objectives To evaluate PUIzzle's impact on HCPs' knowledge on HAMs, as well as participants' satisfaction.

Material and Methods Our monocentric study took place in a 300-bed hospital in Paris region (France) between January and August 2022. No ethical approval for the study was requested as participation was voluntary and anonymous. PUIzzle consists of 12 pieces containing general information on HAMs and a description of their management, monitoring and antidotes. A question-card is associated with each puzzle piece. To assess their knowledge, participants completed a pre- and post-training questionnaire consisting of five multiple-choice questions, with a total score ranging from 0 to 5. They also completed a satisfaction questionnaire consisting of four items rated from 1 'dissatisfied' to 4 'very satisfied'.

Results A total of 147 participants were trained during 39 sessions: 92 nurses, 17 pharmacy technicians, 17 paramedical students, 12 caregivers, 7 healthcare students, 1 pharmacist and 1 physician. Session median duration was 60 minutes [min=55 ; max=110]. The average knowledge scores before and after training (AFT) were respectively 1.1/5 and 3.1/5 (+40%). Before training, 54 (37%) HCPs had a score of 0, versus 4 (3%) AFT, 43 (29%) a score of 1, versus 20 (14%) AFT, 34 (23%) a score of 2, versus 21 (14%) AFT, 13 (9%) a score of 3 versus 42 (29%) AFT, 3 (2%) a score of 4, versus 35 (24%) AFT. Twenty-five HCPs (17%) achieved the highest score of 5, only AFT. A significant improvement ($p < 0.001$) with an average increase of +2 points ($\sigma = 0.104$) was observed. Regarding satisfaction of the training, participants attributed an average score of 3.8/4 ($\sigma = 0.096$).

Conclusion and Relevance PUIzzle is a fun educational tool that significantly improves HCPs' knowledge on HAMs. Suitable to all HCPs, this training will gradually be extended to more physicians. Therefore, PUIzzle will be part of a continuing education programme on drug-induced adverse events implemented at our institution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-007 **IMPACT OF PUIZZLE, A PLAYFUL EDUCATIONAL TOOL ON HIGH-ALERT MEDICATIONS ON HEALTHCARE PROFESSIONALS' KNOWLEDGE: WHAT'S NEW AND WHAT'S LEFT?**

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Background and Importance High-alert medications (HAMs) have higher risks of causing harm to patients. To prevent this, our hospital pharmacy trained 147 healthcare professionals (HCPs) on this topic using a fun educational tool in puzzle form: PUIzzle (PUI is the French acronym for internal use pharmacy), which has significantly improved short-term knowledge on HAMs. However, its impact on long-term knowledge retention is not known.¹

Aim and Objectives To evaluate PUIzzle's impact on HCPs' knowledge retention and its contribution to professional practices.

Material and Methods Our monocentric study took place in a 300-bed hospital in Paris region (France) between January and August 2022. No ethical approval for the study was requested. HCPs' knowledge was assessed with a self-questionnaire administered 3 weeks after the training (3WAT). The first part focused on professional practices. The second part was identical to the pre- and post-training knowledge questionnaire, to compare the scores of the pre-training (PrT), post-training (PoT) and 3WAT questionnaires. The third part had five other questions on HAMs.

Results Of the 141 eligible HCPs, 60 completed the 3WAT (31 nurses, 13 pharmacy technicians, 5 paramedical students, 4 caregivers, 6 healthcare students and 1 pharmacist) in a mean time of 3.6 months ($\sigma = 1.37$), 48 were lost to follow-up and 33 did not respond. Fifty-two (87%) HCPs could situate one of the two HAMs' location list, and 44 (75%) could identify HAMs on the prescription software. Most changes in practice were observed at the prescribing level ($n = 31$; 52%). HCPs declared being more attentive to HAMs' labelling. The mean score of PrT, PoT and 3WAT second part were respectively 1.1/5 ($\sigma = 0.04$), 3.1/5 ($\sigma = 0.14$) and 2.5/5 ($\sigma = 0.33$). A significant improvement between PrT and 3WAT ($p < 0.03$) and a non-statistical decrease between PoT and 3WAT ($p < 0.17$) were observed. The 3WAT's third part mean score was identical to the second one ($\sigma = 0.27$).

Conclusion and Relevance PUIzzle's impact is positive on HCPs' practices and overall knowledge retention on HAMs. Therefore, our hospital will organise regular training sessions, and this training will be transposed into continuing professional education.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-008 A DIGITAL ASSISTANT TO SUPPORT PATIENTS IN PREPARING MEDICATION RECONCILIATION: PATIENT EXPERIENCES

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Background and Importance Medication reconciliation has become standard care to obtain a complete overview of the current medication of a patient. However, it is time-consuming and labour-intensive. Studies have shown promising results for online medication reconciliation preparation done by patients. Nonetheless, there is a need for enhanced patient support to make this process as simple and effective as possible.

Aim and Objectives To ascertain the experiences of patients using a digital assistant for pre-visit online medication reconciliation.

Material and Methods This study followed a qualitative, descriptive design. In May 2022, rheumatology and neurology outpatients were approached face-to-face by a rheumatologist/neurologist during their visit, if considered capable to participate. They received an information letter explaining the study. Participation was voluntary. After written consent, patients were instructed to use a digital assistant for verifying and complementing their home medication online, after which semi-structured individual interviews were conducted, audio recorded with the participant's permission. Interview data were anonymised and evaluated using inductive thematic analysis according to the method of Braun and Clarke. A waiver was obtained from the regional Medical Ethics Review Committee.

Results Eleven patients were included. The study population comprised 2 men and 9 women with a median age of 64.0 years (interquartile range [IQR] 50.0-70.0). The main themes identified amongst patient experiences were related to usability, method of input, layout, safety, communication, perception and necessity. Advantages patients mentioned were place and time independence, efficiency and increased awareness of their medication use. Limited information technology (IT) skills among elderly was the most frequently mentioned barrier for using the digital assistant. Suggestions for improvement were related to usability of the digital assistant (e.g. larger font style and ascertain that texts fit the device), layout (e.g. provide overview of given answers) and safety (e.g. integrate digital assistant in online hospital environment and explicitly state that patient data are saved in a secure environment), amongst others. The majority of the patients preferred the digital assistant over a medication reconciliation conversation with a pharmacy technician.

Conclusion and Relevance Overall experiences of patients using a digital assistant for medication reconciliation were positive, demonstrating there is potential for the use of a digital assistant in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-010 DIGOXIN ADJUSTMENT: COMPARATIVE ANALYSIS OF THREE PHARMACOKINETIC SOFTWARE

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Background and Importance Digoxin is a drug with a narrow therapeutic index (0.8-1.2 ng/mL). Therapeutic drug monitoring is an important tool to improve therapeutic safety and efficacy, especially in elderly patients.

Aim and Objectives To estimate the accuracy and precision of three pharmacokinetic software to analyse serum digoxin concentrations (SDC).

Material and Methods Retrospective observational study in elderly patients admitted to a tertiary hospital and treated with digoxin in 2020. We excluded patients over 80 years-old. Variables recorded: sex, age, body mass index (BMI), SDC, creatinine clearance evaluated by the Cockcroft-Gault equation (CrCl), and concomitant treatment: proton pump inhibitors (PPIs) and non-steroidal anti-inflammatory drugs (NSAIDs).

SDC were estimated with three pharmacokinetic software: Mediware, PKS and NONMEM.

Accuracy and precision were assessed using Sheiner and Beal's prediction error theory. Accuracy with the mean prediction error (MPE) and precision with the mean absolute prediction error (MPAE) and the square root of the root mean square prediction error (RMSE).

Two subgroups were analysed: renal impairment patients (CrCl<60mL/min) and patients with two or more SDC.

Results 53 patients with 130 SDC, 31 women (58.5%), median age 75.5 years-old (66.5-80.7). 64% on concomitant treatment with PPIs and 41.5% with NSAIDs.

Accuracy: MPE 0.002, -0.011, -0.081, for Mediware, PKS and NONMEM respectively.

Precision: MPAE 0.193, 0.201, 0.243; RMSE 0.331, 0.345, 0.328 for Mediware, PKS and NONMEM.

Renal impairment: 32 patients with 64 levels.

Accuracy: MPE -0.052, -0.028, -0.106 for Mediware, PKS and NONMEM.

Precision: MPAE 0.192, 0.246, 0.275; RMSE 0.330, 0.416, 0.363 for Mediware, PKS and NONMEM.

≥2 levels: 36 patients

Accuracy: MPE 0.003, -0.010, -0.080 for Mediware, PKS and NONMEM.

Precision: MPAE 0.205, 0.211, 0.235; RMSE 0.347, 0.360, 0.312 for Mediware, PKS and NONMEM.

Conclusion and Relevance The three software showed similar accuracy and precision for analysing SDC.

Mediware is the best tool for daily clinical practice in terms of ease of use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-011 PHARMACOKINETIC EVALUATION OF DRUGS WITH A NARROW THERAPEUTIC RANGE AND THEIR INFLUENCE ON CLINICAL DECISION

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Background and Importance There is a need to carefully prescribe drugs with a narrow therapeutic range and pharmacokinetic reports on their serum concentrations are the necessary tool for this commitment.

Aim and Objectives Evaluate the impact of pharmacokinetic reports on clinical decision.

Material and Methods A prospective analysis was conducted in a secondary care hospital between March and August 2020 including adult patients with at least one serum concentration of valproic acid, amikacin, carbamazepine, cyclosporine, digoxin, phenytoin, phenobarbital, lithium, gentamicin, theophylline, vancomycin and voriconazole.

Dialyzed and non-admitted patients were excluded. Data was obtained from medical records and pharmacokinetic software. The variables collected were: age, sex, prescribed drug, clinical department, pharmacokinetic report and medical decision.

Results 166 patients with 613 pharmaceutical interventions were recorded. Ninety-five (57.2%) were women with a mean age of 73 years (28-100), mean weight 66 kg (40.5-139.2) and mean serum creatinine 1 mg/dL (0.3-12.5).

The number of pharmacokinetic reports were digoxin: 265 (43.2%); vancomycin: 139 (22.7%); valproic acid: 79 (12.9%); lithium: 69 (11.3%); amikacin: 17 (2.8%); carbamazepine: 10 (1.6%); theophylline: 9 (1.5%); phenytoin: 8 (1.3%); gentamicin: 8 (1.3%); cyclosporine: 4 (0.7%); phenobarbital: 3 (0.5%); voriconazole: 2 (0.3%).

Pharmacokinetic reports according to the prescribing clinical department: internal medicine: 223 (36.4%), psychiatry: 100 (16.3%); and cardiology: 71 (11.6%) were the main ones.

The physician's acceptance of the pharmacokinetic reports according to the drug were digoxin: 112 (37.6%); vancomycin: 74 (24.8%); valproic acid: 43 (14.4%); lithium: 38 (12.8%); amikacin: 13 (4.4%); phenytoin: 4 (1.3%); theophylline: 4 (1.3%); gentamicin: 3 (1.0%); carbamazepine: 2 (0.7%); cyclosporine: 2 (0.7%); phenobarbital: 2 (0.7%); voriconazole: 1 (0.3%).

Acceptance of pharmaceutical recommendations by major clinical services were internal medicine: 110 (36.9%); psychiatry: 54 (18.1%); and geriatrics: 32 (10.7%).

Accepted recommendations were dose maintenance: 202 (75.4%); dose suspension: 26 (72.2%); dose reduction: 41 (68.3%); dose increase: 26 (66.7%).

The pharmacokinetic reports accepted 295 (73.2%). 8% were not accepted due to patient discharge or death.

Conclusion and Relevance A pharmacokinetic area supports clinicians in order to establish the safest and most effective dosing regimens.

A high percentage of pharmacokinetic reports were accepted, however, it is necessary to increase this percentage by talking to physicians and remarking the importance of this activity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-012 CASE REPORT: INHALED GRANULOCYTE-MACROPHAGE COLONY-STIMULATING FACTOR FOR MILD-TO-MODERATE AUTOIMMUNE PULMONARY ALVEOLAR PROTEINOSIS – 24 MONTHS OF FOLLOW-UP

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Background and Importance Autoimmune pulmonary alveolar proteinosis (aPAP) is a disease caused by IgG antibodies against granulocyte-macrophage colony-stimulating factor (GM-CSF). The treatment of choice is bronchoalveolar lavage (BAL).

Aim and Objectives To present aPAP evolution during 24 months of treatment with inhaled GM-CSF.

Material and Methods A 37-year-old male diagnosed with aPAP in April 2014 has required 3 BAL (October 2014, February 2016 and March 2019). In the last BAL, he developed major complications that required admission to the intensive care unit. In October 2019, he presented a new worsening, so off-label treatment with sargamostim (250µg inhaled every 12 hours for 7 days every other week) was chosen.

The pharmacy service prepared a favorable report on off-label treatment and requested drug from regulatory agency. In the pharmaceutical care consultation, the administration technique, stability, dosage regimen, storage (2-8°C) were explained and doubts were resolved.

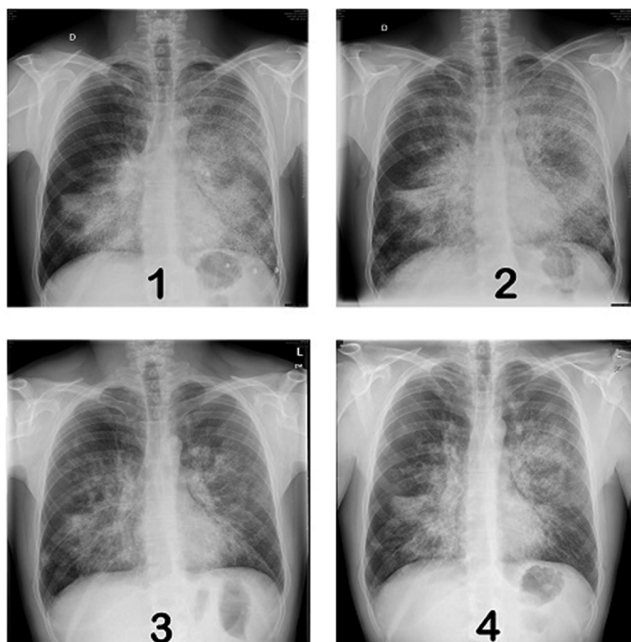
Results The clinical and functional evolution of the ventilatory parameters and the six-minute walk test are shown in the table 1.

Abstract 5PSQ-012 Table 1

| | 7 months after third BAL | 3 months treatment | 6 months treatment | 18 months treatment | 24 months treatment |
|--|--------------------------|--------------------|--------------------|---------------------|---------------------|
| Pulmonary function test | | | | | |
| Forced expiratory volume in one second (FEV1) ml (%) | 2630(63) | 2690(72) | 3080(75) | 2900(71) | 3030(75) |
| Transfer factor of the lung for carbon monoxide, corrected (cTLCO) (%) | 37 | 53 | 52 | 74 | 68 |
| Transfer coefficient of the lung for carbon monoxide, corrected (cKCO) (%) | 59 | 69 | 64 | 85 | 74 |
| Six-minute walk test | | | | | |
| Theoretical distance (m) | | 614.52 | 435.71 | 627.06 | 619.17 |

| | | | | |
|---|-----|-----|-----|-----|
| Heart rate minute 6 (beats per minute) | 136 | 108 | 108 | 105 |
| Oxygen saturation minute 6 (%) | 89 | 89 | 93 | 91 |

The figure 1 shows the radiological evolution (chest X-ray) from the situation before third BAL (1), further worsening after 7 months after third BAL (2), improvement after 3 months of treatment with inhaled GM-CSF (3) and stability after 18 months of treatment (4).



Abstract 5PSQ-012 Figure 1

After 24 months of treatment, the patient has not presented any adverse events and maintains an excellent response with significant improvement in gas exchange, which has allowed home oxygen therapy to be withdrawn.

Conclusion and Relevance In conclusion, our case supports that inhaled GM-CSF has been safe and effective in the treatment of aPAP and represents a therapeutic option after resistance or contraindication to BAL.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-013 PALBOCICLIB IN METASTATIC BREAST CANCER TREATMENT: NEUTROPENIA MANAGEMENT IN CLINICAL PRACTICE

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Background and Importance Palbociclib is a selective cyclin-dependent kinase 4/6 (CDK4/6) inhibitor approved for the treatment of hormone receptor-positive, human epidermal

growth factor receptor 2-negative (HR+/HER2-) locally advanced or metastatic breast cancer (LA/MBC). Neutropenia is the most common adverse event. In contrast to neutropenia induced by chemotherapy agents, neutropenia resulting from CDK4/6 inhibitors is reversible and dose reductions and modifications are recommended.

Aim and Objectives The aim of this study was to evaluate the neutropenia due to palbociclib and to analyse how modifications in treatments are made in clinical practice.

Material and Methods We conducted a descriptive, observational and retrospective study (April 2016-July 2022) of patients treated with Palbociclib in a third level hospital. The data were obtained from the electronic medical records of the patients and the Farmatools Management programme. The parameters analysed were: demographic information, menopausal status, prior lines of therapy to palbociclib, frequency and grades of neutropenia, time from first dose to first episode onset, doses reductions, cycles delays, use of human granulocyte colony stimulating factor (G-CSF), changes to other CDK4/6 inhibitor and discontinuation treatment. Data were processed by Microsoft Excel software

Results 50 women with HR+/HER2- MBC were treated with palbociclib. Median age was 62 years. 92%(46/50) was post-menopausal. 80%(40/50) received prior therapy to palbociclib and 58%(23/40) was in the context of MBC. 54%(27/50) received Palbociclib as first-line treatment. Starting dose were: 82%(41/50) 125 mg; 12%(6/50) 100 mg; 6%(3/50) 75 mg.

The frequency of neutropenia (all-grade) was 74%(37/50); 27%(10/37) was grade 1-2; 73%(27/37) was grade 3-4. Time from first dose to first episode onset (cycles) was reported in: 8,1%(3/37) first-cycle; 56,7%(21/37) second-cycle; 13,5%(5/37) three-cycle; 21,6%(8/37) ≥ fourth-cycle. Neutropenia led to dose reduction in 54%(20/37) of patients; 32%(12/37) required a dose reduction; 21,6%(8/37) required two doses reductions. Cycles delays occurred in 78%(29/37) of patients. 19%(7/37) was treated with G-CSF as supportive therapy. 5,4%(2/37) needed to change to another CDK4/6 inhibitor. 10,8%(4/37) discontinued treatment.

Conclusion and Relevance The frequency of neutropenia in our population was similar to clinical trials.¹ In clinical practice this toxicity can be managed with dose reduction and cycles delays without lead to discontinuation treatment (only four patients) as it is described in guidelines.²

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Conflict of Interest No conflict of interest

5PSQ-014 IMPACT OF HISTAMINE-2 ANTAGONIST SHORTAGE ON THE INCIDENCE OF HYPERSENSITIVITY REACTIONS TO PACLITAXEL – TOWARDS CRISIS MANAGEMENT AND A PREMEDICATION RECONSIDERATION IN FRANCE (PACLIREACT STUDY)

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Background and Importance At the beginning of October 2019, an international shortage of ranitidine forced us to adjust paclitaxel-based chemotherapy premedication regimens. After several modifications, we implemented an anti-allergic premedication protocol based on Dexchlorpheniramine as histamine-1 antagonist (H1A), Methylprednisolone as corticosteroid (Double dose at first injection) and withdrawal of histamine-2 antagonists (H2A).

Aim and Objectives This study aimed to determine the efficacy of this modified regimen and assess the hypersensitivity reactions (HSRs) associated with it.

Material and Methods We conducted a single-centre observational retrospective study of paclitaxel administrations (n=831 patients). All incidents characterised as drug allergies in the prescribing software were exhaustively recorded over a two-year period from January 2019 to December 2020 (before and after ranitidine shortage, including the period with oral Famotidine as a transitional alternative). To model the risk of allergy at each injection according to the type of injection and possible confounding factors, a mixed logistic regression model was implemented to account for repeated administration per patient.

Results Among the 7146 paclitaxel administrations, there were a total of 27 HSRs occurring in 24 patients, among whom three patients had two consecutive events. No protective effect was observed for H2A premedication regimens, neither when comparing the two types of H2A (famotidine or ranitidine) separately ($p = 0.94$) nor when comparing injections with H2A premedication versus injections without H2A (OR: 1.12, 95% CI, 0.36-3.50, $p = 0.84$). However, the risk of HSRs was significantly lower for paclitaxel injections with corticosteroids than for those without corticosteroids (OR: 0.08, 95% CI: 0.008-0.78, $p = 0.03$). In addition, the risk of HSR was significantly higher for the first, second, or third paclitaxel injections than for the subsequent injections (OR: 10.1, 95% CI: 3.23-31.4, $p < 0.001$).

Conclusion and Relevance We did not find evidence of an increased risk of HSR due to the absence of H2A in the premedication protocols of Paclitaxel. Our findings support the choice of a premedication protocol without H2A, despite what is historically stated in Paclitaxel monographs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-016 HUMAN FACTORS ROLE IN MEDICATION ERRORS: DILUTING INTRAVENOUS MEDICATIONS AT HOSPITAL WARDS – A STUDY BASED ON INCIDENT REPORTS

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Background and Importance Humans make mistakes, inadvertently when making poor decisions, being distracted or when not perceiving risk whilst managing medications. Health professionals do not make mistakes on purpose, yet medication errors remain the most common type of medical errors. A human factors approach can be applied to address the causation of medication errors from a

process point of view while addressing our error-prone human nature. Intravenous medications are complex to prepare and administer. Specific tasks, such as diluting intravenous medications are at a higher risk of medication errors.

Aim and Objectives This study aims to address human factors in medication calculation errors involving dilution of intravenous medications.

Material and Methods From the medication errors reported in 2016 and 2017 to the Norwegian Incident Reporting System, we specifically scrutinised medication calculation errors that required dilution during medication preparation, dispensing and administration. We included real events that had reached the patients, and which contained sufficient incident description to allow for causal analysis. From the incident descriptions, we conducted a content analysis of human factors.

Results In total, 14 incidents met the inclusion criteria and involved the dilution of morphine, oxycodone, adrenalin, and noradrenalin. Several human factors exposed the intravenous preparation process to risks. For example, performing tasks with cognitive loads, such as dilution, followed by bedside dose calculation whilst providing patient care. Some dilution errors were caused by not knowing the exact concentration after dilution, which resulted in one infant receiving 7 mg of morphine instead of 0.7 mg. Administering from a syringe that contains more than the prescribed dose was found as a high-risk practice. Most dilution errors led to overdosages and resulted in patient harm.

Conclusion and Relevance This study discusses how cognitive processing is related to medication errors. Addressing human factors that contributed to medication errors should involve systemic measures which take in account how humans think and process information to avoid patient harm from dilution errors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-019 ANALYSIS OF THE USE OF IDARUCIZUMAB IN A TERTIARY HOSPITAL

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Background and Importance The evaluation of anticoagulation reversal practices of direct-acting oral anticoagulants allows their optimisation by improving their safety and efficiency.

Aim and Objectives To review the use of idarucizumab in the reversal of the effect of dabigatran and to evaluate its effectiveness in the normalisation of coagulation parameters and clinical evolution of the patient.

Material and Methods Descriptive, observational, retrospective study of all patients who received idarucizumab in the period from December 2015 to June 2022, inclusive, in a tertiary hospital. Data were collected from the electronic medical record. Variables assessed were: demographics (age, sex); coagulation parameters [activated partial thromboplastin time (aPTT)]; indication and dose of dabigatran; reason for

prescription and dose of idarucizumab; response to treatment (normalisation of aPTT and clinical evolution).

Results Fifty-four patients prescribed idarucizumab were identified. One patient was excluded because active treatment was declined (n=53). Median age was 82 years (RIQ: 75-88.5), 58.5% male and 41.5% female. The indication for dabigatran was stroke prevention and systemic embolism due to non-valvular atrial fibrillation in 52 patients and stroke in 1 patient. The doses of dabigatran reported in the medical records were: 150 mg/12 h in 16 patients, 110 mg/12 in 34 patients and 75 mg/12 in 1 patient (no data in 2 patients). Thirty-six patients received idarucizumab for major bleeding, 12 for urgent surgery, 3 for urgent invasive procedure and 2 for supratherapeutic levels of dabigatran. In all cases the indication was established by the haematology department. Median aPTT before antidote administration was 46.95 seconds (RIQ: 35.2-52.5) (n=52); 1 patient had supratherapeutic levels of dabigatran, showing incoagulable. Median aPTT after idarucizumab administration was 27.4 seconds (RIQ: 25-29.8) (no post-administration aPTT values in 6 patients). The dose of idarucizumab was 5 g in all cases. Four patients died. In 49 patients treatment was effective with no episodes of rebleeding or thromboembolism.

Conclusion and Relevance Idarucizumab was mostly used in major bleeding. Treatment was effective in 92% of the study population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-020 ANALYSIS OF A PHARMACEUTICAL INTERVENTION IN POLYMEDICATED PATIENTS TO INCREASE THE SAFETY AND ADEQUACY OF THEIR TREATMENT

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Background and Importance Polymedication has potential health risks for patients such as interactions and increased risk of adverse effects that can be fatal.

Aim and Objectives The aim of this study was to analyse a pharmaceutical intervention carried out by a group of pharmacists in patients taking 15 or more drugs concomitantly to improve the safety and adequacy of their prescriptions.

Material and Methods Pre-post study that included patients of any age, with 15 or more drug prescriptions, prescribed by a general practitioners (GPs) in the electronic prescription system, from January to December 2021. The intervention was performed by 9 pharmacists in 35 primary health-care centres (PHCC) and 673 GPs. They provide health care to 677,782 inhabitants. First, a general session was held in each PHCC, presenting the objectives and informative material. Subsequently, individual meetings were scheduled with each physician, in which the pharmacists provided the prescribers with lists of polymedicated patients (PP) and various local documents, STOPP/START, Beers criteria and clinical practice guidelines to help review treatments. Each prescribed drug was evaluated based on its necessity, effectiveness, appropriateness and safety. In addition, the pharmacists also issued review reports on patients with particularly complex pathologies. The reviews performed were recorded by the GPs in the digital health record. These records and lists of PP were

extracted thanks to a local software application and analysed in Excel.

Results Pharmacists provided 39 group training sessions and 387 individual meetings to the GPs. A total of 1468 patients met the criteria for PP. Mean age 73.58 years+11.14(58% women). Prescriptions of 91.7% of PP were reviewed at least once in 2021. A total of 4,848 reviews were performed.

In 14.41% of the cases, a new treatment was started. In 14.73% of the revisions, it was necessary to change the dosage or the prescribed treatment regimen. In 27.81% of the cases, the GPs cancelled a drug from the patient's prescriptions. In 54.68% of the reviews, no change in treatment was made

Conclusion and Relevance The intervention had a high level of acceptance.

Despite the high percentage of patients reviewed, it is striking the high number of patients in whom, no change in their treatment was made, which raises the question of whether the reviews were correct.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-021 AUTOMATION MEETS TRACEABILITY TO OPTIMISE DRUGS AND MEDICAL DEVICES LOGISTICS GUARANTEEING PATIENT SAFETY AND HOSPITAL STAFF WELL-BEING

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Background and Importance Hospital San Raffaele was seeking a solution to improve the medication management process and logistics, spanning from central pharmacy to the patient's bedside, in order to avoid shortage, improve staff well-being and patient safety by ensuring the five rights of medication administration (patient, drug, dose, time and route).

Aim and Objectives The Covid emergency, the shortage of personnel and the need to control healthcare spending, are key drivers in seeking innovative solutions to improve the efficiency in drugs and medical devices logistics.

The new system includes a new generation of automated carts and cabinets: before each round, the software predicts the overall need for drugs/medical devices.

The drugs are automatically loaded into the carts without any human intervention.

During the round, once the patient is identified, the automated cart retrieves the drug(s) to be administered and places them directly on the countertop.

The system tracks all the operations: which drug was administered, at what time and by whom.

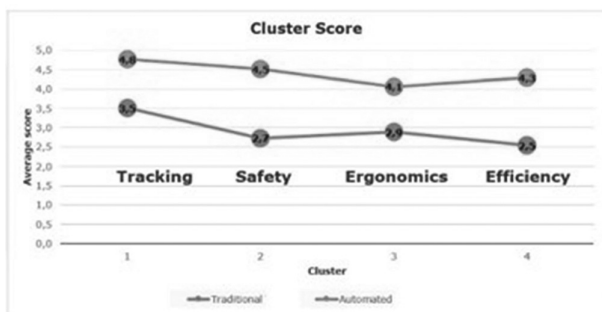
The new system enables end-to-end traceability ensuring the complete visibility to the hospital pharmacists/staff on drug flows from the central pharmacy up to medicines' administration and bringing many benefits such as: logistics optimisation and inventory accuracy by avoiding waste and shortage, while guaranteeing precise recalls/withdrawals and having a real-time visibility on the entire hospital stocks. **Material and Methods**

The study compared the new AUTOMATED solution versus the TRADITIONAL one by measuring different metrics and KPI.

A panel of nurses was selected to conduct the test with different profiles (age, experience, and confidence with IT applications). Each nurse was asked to carry on some cycles of the therapy dispensing and to express evaluations, in a ranking from 1 to 5, on several parameters related to:

- Tracking of all operations
- Patient Safety
- Ergonomics
- Efficiency

Results



Abstract 5PSQ-021 Figure 1

Conclusion and Relevance The results show that the automatic system is prevailing over all target metrics, with particularly a high gap on safety and efficiency, thanks to the reduction of non-value-added activities such as manual drugs replenishment of the stocks within cabinets and carts, enabling what really matters: the Patient Care.

This provides to the healthcare systems a new disruptive platform that makes the work of hospital staff easier, more efficient, reliable thus ensuring patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-022 ANALYSIS OF HEALTHCARE VISITS TO EMERGENCY SERVICES FROM PATIENTS WITH PAINFUL VASCULAR ULCERS TREATED WITH TOPICAL SEVOFLURANE

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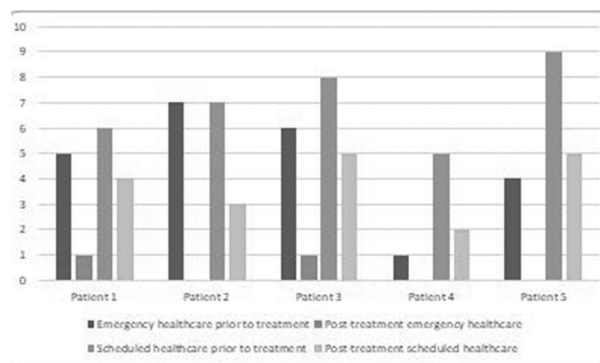
Background and Importance Patients with chronic vascular ulcers (VUs) suffer pain that is frequently managed with systemic analgesics such as opioids, exposing the patient to the secondary effects of these drugs. Therefore, there is a decrease in the patient's quality of life and an increase in emergency healthcare. Recently, sevoflurane has been shown to have a rapid analgesic effect when applied topically on VUs, providing a new therapeutic alternative in pain management.

Aim and Objectives To evaluate the analgesic effectiveness of topical sevoflurane in poorly controlled VUs using a comparative analysis of emergency and scheduled health care before and after the beginning of treatment.

Material and Methods A retrospective study was designed to quantify urgent and scheduled care visits in the 12 months

prior to the beginning of treatment and in the 6 months after treatment of 5 patients (3 women and 2 men). Data were collected from the clinical database of the Andalusian Health System (Diraya). All patients had a high degree of comorbidity and VUs with uncontrolled pain.

Results The following figure shows the number of times that patients go to health services for uncontrolled pain associated with vascular ulcers. There is a decrease in emergency care visits in all the patients studied after the start of treatment. It should be pointed out that patients 2, 4 and 5 did not have to go to the health emergency services.



Abstract 5PSQ-022 Figure 1

Conclusion and Relevance This study seems to show a decrease in emergency healthcare after applying topical sevoflurane due to its role as an analgesic in patients refractory to conventional therapies. Obviously, relevant clinical trials are required to adequately establish the role of topical sevoflurane in the pain management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-023 SEVERE PHOTOTOXICITY REACTION ASSOCIATED WITH VANDETANIB: A CASE REPORT

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Background and Importance Vandetanib is a tyrosine kinase inhibitor used for the treatment of metastatic medullary thyroid cancer (MMTC). This drug has been associated with phototoxicity, but rarely severe.

Aim and Objectives To report a case of severe phototoxicity reaction associated with vandetanib.

Material and Methods The clinical management of a case with rare phototoxicity adverse reaction was described. Electronic medical records were used to collect patient data: baseline clinical context, adverse events, treatment, and clinical evolution. Naranjo algorithm was used by hospital pharmacist to establish the causality of phototoxicity.

Results An 82-year-old man newly diagnosed with MMTC started treatment with vandetanib. After 12 days, he

presented slight rash in dorsal region. The patient received one radiotherapy session. Seventeen days after starting vandetanib, he visited Emergency department for generalised erythema (on face, neck, upper and lower limbs), flushing and pruritus, related to brief sun exposure. The patient was treated with single dose intramuscular methylprednisolone and oral dexchlorpheniramine. Vandetanib and radiotherapy were discontinued. Five days later, the patient presented severe deterioration, progression of erythema and intense oedema in hands, feet and face. Deflazacort was prescribed. After diagnosis by Dermatology department of acute phototoxic eruption, treatment was started with prednisone 45 mg/day for 7 days with progressive decrease, emollients and topical methylprednisolone. Between days 26-40, gradual improvement of oedema and erythema was observed without appearance of new toxicity. Prednisone dose was reduced. Progressively, desquamation and scabs were observed on both hands, with improvement of leg and foot ulcers. Poor pain control required tapentadol 25 mg/12 hours. On day 62, there was a worsening with increased erythema since oral prednisone was reduced. Treatment with *Polypodium leucotomos*, vitamin D, C and E was initiated. On day 68, there was a significant improvement with no itchiness. Three months after symptom onset, itching and erythema had almost disappeared. Remaining hyperpigmentation of the skin was observed. Naranjo's algorithm determined a probable relationship (score 5) and reintroduction of vandetanib was discouraged.

Conclusion and Relevance Hospital pharmacist determined a probable relationship between vandetanib and severe phototoxicity reaction in a patient with MMTC. The role of hospital pharmacists is essential in pharmacovigilance and in informing patients about possible adverse events of drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-024 HAZARD VULNERABILITY ANALYSIS (HVA): EVALUATION OF RISK IN EXPERIMENTAL ONCOLOGICAL DRUGS COMPOUNDING

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Background and Importance Various clinical trials, especially in oncology and haematology, involve chemotherapeutic drugs compounding. These preparations require standard working procedures for which hospital pharmacist is responsible. Oncological drugs used in clinical trials are characterised by: low therapeutic index; unknown toxicity; dosage to be personalised on patient; assignment of number kit/placebo to specific patient; associations with other drugs not known in consolidated clinical practice. All these elements can contribute to the occurrence of potential errors.

Aim and Objectives The aim of this study is to use Hazard Vulnerability Analysis in order to classify, into high, medium, low risk, experimental protocols that provide for chemotherapeutic drugs compounding and which are currently active our hospital. For protocols classified as high risk, standard procedures will be outlined to minimise risks.

Material and Methods In order to determine the percentage risk(R%), is calculated: probability(P) that an error will occur, by calculating the number of preparation-phases; magnitude (MA) by calculating carcinogenicity, storage time of preparation and chemical incompatibility between drugs and medical devices; mitigation(MI) by calculating drug dosage, chemical-physical preparation stability, possible use of safety-devices. By applying the formula $R\%=(P/3)*[(MA+MI)/18]*100$, protocols are defined low-risk if $R\%<30\%$, moderate-risk if $30\%\leq R\%\leq 60\%$, High-risk if $R\%>60\%$.

Results Among 35 active clinical-trials analysed, 18 require chemotherapeutic drugs compounding. For 33%(6/18) of protocols the probability is low; 50%(9/18) is moderate; 17%(3/18) is high. For 44%(8/18) of protocols the magnitude is low; 50%(9/18) is moderate; 6%(1/18) is high. Finally, for 6%(1/18) of protocols the mitigation is low; 88%(16/18) is moderate; 6%(1/18) is high. By applying the formula to calculate percentage risk it was found that 5/18 protocols are low risk, 10/18 moderate risk, 3/18 high risk.

Conclusion and Relevance HVA provides a systematic approach to analysing hazards that may affect hospital service. Clinical protocols classified as 'high risk' have been monitored, and standard procedures have been outlined to minimise the risks (e.g. procedures for managing vial accidental breaking, cold chain control for prepared drugs, use of software to calculate drug dosage based on body surface). These procedures are aimed at all personnel involved in preparation phase, including the hospital pharmacist. Hospital pharmacist is coordinates whole process, deals with risk management and ensures personnel/patients safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-025 IMPACT AND EVALUATION OF PHARMACOKINETIC MONITORING IN PRIMARY CARE

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Background and Importance Monitoring of narrow-margin drugs in primary care is important to optimise the efficacy and safety of treatment.

Aim and Objectives To analyse the impact of the activity and repercussions of monitoring plasma levels of antiepileptics, lithium and digoxin in primary care patients carried out by the Pharmacokinetics Area-Hospital Pharmacy Service (PA-HPS).

Material and Methods Two-month retrospective observational study of the pharmacokinetic reports of all patients who required monitoring of their plasma levels. The circuit starts with a request from the primary care physician asking for the determination of the plasma level, the blood sample is analysed by the laboratory and the PA-HPS interprets all the data from the clinical history, finally producing a pharmacokinetic report integrated in the clinical history together with the analytical.

The variables recorded from the analyses and clinical history were: age, sex, renal clearance, liver enzymes (GOT, GPT

and gamma), monitored drug and plasma level, pharmacokinetic reports and their degree of acceptance.

Results A total of 202 pharmacokinetic reports were performed targeting 191 ambulatory patients. The mean age of the total was 42.33 ± 16.46 years (range: 6-106) and 51% were female. Only 5 patients had established renal insufficiency with renal clearance < 60 ml/min and 3 patients with hepatic insufficiency (liver enzymes greater than 3 times the upper limit of normal).

The pharmacokinetic reports produced were valproic (43.56%), lithium (37.62%), carbamazepine (8.91%), digoxin (5.94%), phenytoin (2.47%) and phenobarbital (1.48%). Of the patients, 82.68% had plasma levels in therapeutic range, 14.85% were subtherapeutic and 2.47% were supratherapeutic. We highlight a degree of intervention in 17.32% of the pharmacokinetic reports made, and 10.93% of these reports required a change in the dosing regimen or dosing interval together with a new monitoring. The degree of acceptance by the physician was 67%.

Conclusion and Relevance It is important to perform an adequate follow-up of patients with active treatment of drugs with a narrow therapeutic margin for a constant optimisation of the treatment

The data reflect the importance of the hospital pharmacist as part of the multidisciplinary team and the need for direct communication with the primary care physician.

The high degree of acceptance of pharmacokinetic reports shows that the circuit is well received.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-026 MEDICATION-RELATED OSTEONECROSIS OF THE JAWS AND CDK4/6 INHIBITORS

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Background and Importance Medication-related osteonecrosis of the jaw (MRONJ) is a relatively uncommon but serious complication of osteoclast inhibitors therapy with intravenous bisphosphonates and denosumab. Dose, schedule, and duration of inhibition are associated with MRONJ risk. Marcianò et al.¹ launched an alert about a possible association between MRONJ and cyclin-dependent kinase (CDK)4/6 inhibitors in breast cancer patients with osteoclast inhibitors therapy.

Aim and Objectives Evaluate the use of CDK4/6 inhibitors as a risk factor for MRONJ in our cohort of patients with metastatic cancer and denosumab.

Material and Methods

Retrospective observational study. All patients with denosumab (January 2011 to February 2022) were included. Cases of MRONJ found were described. Relationship between CDK4/6 inhibitors and MRONJ was analysed with a Chi-square analysis.

Results 363 patients with denosumab were included. 21 cases of MRONJ were detected: 62.5% women, 57.1% (12/21) with breast cancer, 19% (4/21) prostate cancer, and 9.5% (2/21) lung cancer. 42.9% with extraosseous metastases. Median treatment duration for denosumab was 19 months (1-52). 7

with CDK4/6 inhibitors (3 palbociclib, 2 abemaciclib and 2 ribociclib). Median treatment duration with CDK4/6 inhibitors was 27 months (10-35). The mean time from the start of denosumab to the appearance of the event was 23 months (16-29).

Incidence of this complication in patients treated with denosumab but without CDK4/6 inhibitors was 5.24% (14/267) and 7.29% (7/96) in patients with denosumab and a CDK4/6 inhibitor. Although the group with CDK4/6 inhibitors had a higher incidence of MRONJ cases, the difference was not significant (0.461).

Conclusion and Relevance The incidence of MRONJ in our cohort of patients with metastatic cancer and denosumab was higher in the group of patients with CDK4/6 inhibitors. However, this difference was not significant. Our data are somewhat higher than those reported in the literature according to which the risk of MRONJ with denosumab is 1.1% during the first year, 3.7% the second year and 4.6% per year thereafter. Studies with more patients would be necessary to confirm the relationship between the use of CDK4/6 inhibitors and MRONJ.

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Conflict of Interest No conflict of interest.

5PSQ-027 APPROPRIATENESS OF PRESCRIPTION OF TRICYCLIC ANTIDEPRESSANTS ACCORDING TO STOPP CRITERIA: SYSTEMATIC REVIEW OF THE CRITERIA REFERRED TO THE USE OF TRICYCLIC ANTIDEPRESSIVES IN DEMENTIA

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Background and Importance The STOPP-START criteria are a useful tool to detect potentially inappropriate prescriptions (PPIs). For tricyclic antidepressants (TCAs), there are 6 STOPP criteria.

Aim and Objectives To analyse the adequacy according to the STOPP criteria of the prescription of TCAs in patients older than 64 years and to systematically review the literature related to the use of TCAs in patients with dementia, analysing the suitability of the STOPP criteria.

Material and Methods Descriptive cross-sectional study that included all patients over 65 years of age receiving TCAs. The systematic review was conducted following the PRISMA Declaration.

Results 63 patients (50 women) with a median age of 70 years (65-88) were reviewed. In 21 patients (33.3%), the prescription of TCAs according to the STOPP criteria was not appropriate (9 patients received concomitant treatment with opiates, 4 patients dementia medication, 3 had prescribed calcium antagonists, another 3 medication for benign prostatic hyperplasia and, finally, 2 for constipation). No significant differences were found in the relationship between the number of prescribed drugs and the adequacy of the TCAs prescription ($p = 0.74$). In the systematic review,

7articles were included. One study showed that in clinical practice, TCAs dispensations were maintained after the diagnosis of dementia. Two studies concluded that TCAs are the antidepressants least associated with the onset of dementia. In another study, the long-term use of TCAs was associated with a decrease in the incidence of dementia. A review by the Cochrane Group stated that the evidence on the safety of antidepressants in patients with dementia is of moderate quality, with little data from the antidepressant subgroups. The last two articles associated the use of antidepressants with dementia without differentiating the antidepressant groups.

Conclusion and Relevance Based on the data from our population, the high inappropriateness of TCAs prescription according to the STOPP criteria suggests that this is a field with ample room for improvement. PPIs could be reduced if STOPP criteria were computerised in electronic prescription programs. Since the results of the review are not consistent, we believe that the STOPP criteria regarding the use of TCAs in patients with dementia should be more flexible, assessing the benefit-risk of treatment on an individual basis and closely monitoring adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-029 PERCEIVED EXPERIENCE OF PATIENTS WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) AFTER IMPLEMENTING A TELEPHARMACY PROGRAMME

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Background and Importance Telepharmacy promotes continuous and quality health care based on the use of new technologies.

Useful in patients with chronic diseases that require a pharmacovigilance programme, such as HIV patients.

Aim and Objectives To determine if a telepharmacy model, improves the perceived HIV patient experience compared to a traditional (face-to-face) model of health care.

Material and Methods Prospective observational interventional study (January to August 2022). Included 35 HIV patients with antiretroviral treatment (ART) of legal age under follow-up by the pharmacist, with access to technologies to receive telepharmacy assistance and who gave their consent.

The study was divided into 2 stages: T-4 pre-implementation of telepharmacy (January to April 2022), T+4 post-telepharmacy (May to August 2022).

Patients were recruited during the T-4 period in the pharmaceutical care office, where they were given the questionnaire: Instrument for the Evaluation of Chronic Patient eXperience (IEXPAC), a 15-item questionnaire with 11 global questions and 4 conditional questions, which makes it possible to assess the patient's perceived experience of health care.

The SPSS® program and Wilcoxon test assessed whether there are differences in the IEXPAC (global and conditional) in the same population before and after implementing a telepharmacy programme.

Other stratification data were: sex, age, time since diagnosis and number of tablets per day.

Results 35 patients were included (100% male), median age 53 years (31-72), 97.6% took one tablet daily, median disease evolution 17 years (0.5-33).

4 telematic consultations were carried out with each patient.

Global IEXPAC: 27 patients had a better experience, 8 remained the same. **Conditional IEXPAC:** 30 patients had a better experience and 5 remained the same. The Wilcoxon test compared the results of IEXPAC before and after implementing a telepharmacy programme ($p < 0.01$).

Conclusion and Relevance The implementation of telepharmacy programmes improves the experience perceived by HIV patients of pharmaceutical care.

Telepharmacy could be a useful tool for the control and pharmacotherapeutic follow-up of HIV patients and other pathologies, avoiding unnecessary trips by vulnerable patients who have difficulty in going to the hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-030 SAFETY AND SECURITY OF CICLOSPORIN EYE DROPS IN PATIENTS WITH XEROPHTHALMIA

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Background and Importance Ciclosporin 1 mg/ml eye drops is indicated for the use of xerophthalmia in patients with severe keratitis unresponsive to artificial tears. Ocular dryness is a refractory symptom of many systemic pathologies. It is difficult to manage clinically and therapeutic options are limited.

Aim and Objectives To review the tolerance of patients to cyclosporine 1 mg/ml eye drops, as well as the rate of associated eye infections and the feeling of improvement evaluated by the patient himself.

Material and Methods Retrospective study carried out in a 350-bed general hospital. Patients who had started treatment with cyclosporine 1mg/ml eye drops from 2018 to 2022 and who had been diagnosed with keratoconjunctivitis sicca (KS), Sjögren's syndrome (SS), Graves-Basedow syndrome (GBS) with xerophthalmia were studied. Data collected: sex, median age [range], pathology, positive Schirmer test (< 5 mm), associated eye infections during treatment, treatment of these infections, discontinuation of cyclosporine due to infections, tolerance to treatment, discontinuation due to poor tolerance and clinical improvement perceived by the patient. Data obtained from the digital medical record, the assisted electronic prescription program (Dominion®) and the clinical interview with the patient in the pharmacy consultation

Results 37 patients. 25 women (67.57%). Median age 46[4-75]. Patients with SS 14 (37.84%), KS 19 (51.5%), GBS 4 (10.81%). All (100%) of them with positive Schirmer test (< 5 mm). Associated eye infections during treatment 11 (29.73%), need for antibiotic treatment 9 (24.32%). Patients who left the treatment for any circumstance 20 (54.05%), due to poor tolerance 14 (37.84%). Patients that perceived clinical improvement 21 (56.77%).

Conclusion and Relevance Xerophthalmia is a hard to control symptom in systemic pathologies. Treatment with cyclosporine eye drops is an alternative for those patients. Some do not

tolerate the drug correctly and it is necessary to resort to other treatment strategies. Associated infections could be a risk factor for discontinuing cyclosporine eye drops, but each patient must be evaluated individually and closely monitored for possible complications that may arise from treatment. The response to ciclosporin treatment improved patient's life quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-032 PHARMACIST INTEGRATION IN THE MULTIDISCIPLINARY EMERGENCY TEAM

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Background and Importance Hospital pharmacists' activity is turning towards the direct care on clinical units. In Emergency Department (ED), medication errors (ME) may occur due to multiple factors: lack of coordination between services or pressure in medical care. Numerous studies, highlight the benefit of pharmacist intervention in the multidisciplinary health team.

Aim and Objectives The aim of this study was to analyse pharmaceutical interventions (PIs) carried out in ED, studied the ATC group of drugs involved and evaluate medical acceptance.

Material and Methods This two month (April-May 2022) prospective study was carried out in the Half-Stay Unit (HSU) of the ED in a second level hospital.

Inclusion criteria: age ≥ 65 years and polypharmacy (≥ 5 drugs in chronic treatment).

Variables collected: demographic, PIs, cause of PIs, medical acceptance and ATC group of drugs involved.

Daily list of patients was obtained through the electronic prescription program and PIs were notified on-site or using this program.

PIs were classified according to the system of the Consensus of Granada modified in drug discontinuation (unnecessary/duplicity/contraindication/interaction), drug change (contraindication/interaction), change of dose, frequency or schedule, initiation of treatment (usual treatment not prescribed/need additional treatment), monitoring (determination of plasma drug levels and follow-up) and prescription errors.

PIs were considered accepted when doctor modified treatment in medical order or discharge report.

Results Final analyses included 52 patients. Median age was 82 years (IQR: 68-88), 58% men. During the study period, 120 PIs were performed and the 77% were accepted.

46% of PIs corresponded to initiation of treatment (usual treatment not prescribed), 15% to discontinuation (unnecessary drug), 15% to change in dosage, frequency or schedule, 14% to prescription errors and 10% others.

ATC groups most frequently involved were C group (cardiovascular system) (35%) B group (blood and blood forming organs) (25%) and N group (nervous system) (20%).

Conclusion and Relevance Most of PIs corresponded to initiation of usual non-prescribed treatment followed by discontinuation of unnecessary drugs.

Medical acceptance was high. Highlight PIs carried out around group C (lipid-lowering and antihypertensive drugs).

Multidisciplinary team helps improve pharmacotherapeutic profile and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-033 ANTIVIRAL TREATMENT DISCONTINUATION IN PATIENTS WITH HEPATITIS B

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Background and Importance Studies suggest the safest strategy of treatment discontinuation with nucleos(t)ide analogues (NAs) against hepatitis B virus (HBV), is proposed after loss surface antigen (HBsAg). Evidence supports the possibility of discontinuing NAs in the following situations:

- Patients with positive e antigen (HBeAg) without cirrhosis: after negativisation of HBV-DNA and HBeAg seroconversion, confirmed in 2 determinations separated by 3-6 months and after NAs at least 12 months.
- Patients with negative HBeAg, without advanced fibrosis early in treatment: after negativisation of HBV-DNA for at least 3 years and HBsAg clearance (qHBsAg) ≤ 1000 IU/mL.

Aim and Objectives The objective was to characterise the population in treatment with NAs and analyse patients who met requirements for treatment discontinuation

Material and Methods Cross-sectional, descriptive, retrospective study of patients under active treatment with NAs between August 2020-August 2021.

Variables collected: demographic, NAs used, treatment duration and clinical (positive or negative HBeAg, HBeAg seroconversion, HBV-DNA, qHBsAg, degree of hepatic fibrosis, HBsAg loss, virological relapse (RV) (HBV-DNA > 2000 IU/ml after treatment discontinuation).

Results We included 50 patients (70% men). Median age was 56 years (IQR: 48-66) and median of treatment duration was 66 months (IQR: 27-108). 62% were treated with tenofovir disoproxil fumarate and 38% with entecavir.

8% of patients had positive HBeAg without seroconversion and without negative HBV-DNA. 92% had negative HBeAg with seroconversion and negative DNA-HBV.

32% of patients had qHBsAg ≤ 1000 IU/ml, 28% ≥ 1000 IU/ml and 40% not determined. 30% of patients had advanced fibrosis.

In 12% of patients with positive HBsAg, treatment discontinuation could be considered. All of them had HBeAg negative, fibrosis F0-F1 at the beginning of treatment, negative HBV-DNA maintained at least 3 years and qHBsAg ≤ 1000 IU/ml.

HBsAg loss occurred in 6% of patients who had not discontinued treatment and 16% of patients had to restart treatment for RV.

Conclusion and Relevance

- Study population includes patients who meet criteria for treatment discontinuation.
- Treatment discontinuation requires close follow-up to detect RV.
- In patients with HBsAg loss, treatment was not discontinued due to advanced fibrosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-034 **FIXED VS WEIGHT-BASED DOSING OF PEMBROLIZUMAB FOR PATIENTS UNDER 80 KG, BASED ON OBSERVED ADRS IN ONE CANCER SETTING**

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Background and Importance Monoclonal antibodies are usually dosed by the kilogramme of the patient's weight, due to perceived contribution of body size in pharmacokinetic variability. Lately, especially during the COVID pandemic, a lot of monoclonal antibodies, including pembrolizumab, were switched to fixed dosing. Pembrolizumab was initially dosed at 2 mg/kg, fixed dosing includes 200 mg every three weeks or 400 mg every six weeks (Freshwater, 2017). The fixed dosing is more convenient, eliminates the waste, might improve patient's compliance and reduces dosing errors. However, for the patients that weight less than 80 kg, fixed dose is associated with almost maximum exposure, which is also associated with greater occurrence of toxicity (CADTH, 2020).

Aim and Objectives The aim of this retrospective study was to determine whether it is better to use fixed or weight-based dosing of pembrolizumab for patients under 80 kg in order to avoid serious ADRs.

Material and Methods We observed ADRs that occurred with 391 patients receiving pembrolizumab in 2021, regardless the diagnosis. We collected the data, by reviewing patients' documentation. The patients were distributed across oncology indications, including NSCLC, melanoma, breast cancer, urothelial carcinoma, cervical cancer, Hodgkin's lymphoma, head and neck squamous cell carcinoma, oesophageal cancer and renal cell carcinoma.

Results The patients were split into two subgroups, under and over 80 kg in weight (group 1 and 2). For 29 patients, data about weight was not available. 198 patients were in group 1, whereas in group 2 there were 164 patients. The ADRs occurred in 69 patients (34,8%) from group 1 and 46 patients from group 2 (26%). The most common ADRs occurred were skin toxicities, hypothyreosis, muscle and joint pain, diarrhoea and fatigue. There were no significant differences in the occurred ADRs between group 1 and 2.

Conclusion and Relevance The results indicated that for patients under 80 kg, weight-based dose would not only be better in terms of less toxicity, but it would also be more cost effective. The adaptation of fixed dosing regimens would lead to the estimated 26% of additional cost (e.g. 50 kg patient

would receive 100 mg dose, which means half price of the fixed dose) (Monirul et al, 2020).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-036 **MEDICATION ERRORS RELATED TO HIGH-ALERT MEDICATIONS IN A TERTIARY CARE PAEDIATRIC HOSPITAL – AN ANALYSIS OF REGISTER-BASED DATA**

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Background and Importance Paediatric patients are prone to adverse drug events, including medication errors (MEs). Although high-alert medications are often associated with serious MEs (1), fewer studies have focused on describing these errors within paediatric populations (2–3).

Aim and Objectives The aim of this study was to investigate the prevalence and characteristics of self-reported MEs related to high-alert medications in a paediatric university hospital setting.

Material and Methods This was a cross-sectional study of self-reported MEs (n=2,404) in a tertiary care paediatric hospital during 2018–2020; 743 (31%) of the MEs involved high-alert medications (3). A quantitative descriptive analysis (frequencies and percentages) was performed using Microsoft Excel[®]. The prevalence of different high-alert medications, Anatomical Therapeutic Chemical (ATC) groups, drug formulations and administration routes appearing in the study sample were defined. Finally, the most severe MEs were identified and summarised.

Results Among the studied sample of ME reports (n=743), 71 different high-alert medications were identified. The most common ATC subgroups were blood substitutes and perfusion solutions (B05; n=345, 40%) antineoplastic agents (L01; n=139, 16%), and analgesics (N02; n=98, 11%). The most common medications comprised parenteral nutrition (n=130, 15%), hypertonic sodium chloride (n=93, 11%), potassium chloride concentrate (n=66, 8%), morphine (n=47, 5%), and heparin (n=43, 5%). Most high-alert medications were administered intravenously (n=636, 73%). Moreover, IV preparations were administered via off-label routes (n=52, 6%), such as oral, inhalation and intranasal routes. Most serious MEs (n=16, 2%) were associated with analgesics (N02) (n=8), antineoplastic agents (L01) (n=3), and antithrombotic agents (B01) (n=3).

Conclusion and Relevance According to the present and previous studies, MEs on concentrated electrolytes and parenteral nutrition represent a central risk to paediatric medication safety (1–2). While severe MEs in these groups remained low in this study, a high proportion of severe MEs associated with analgesics and antineoplastic agents represented a key finding. Preventive risk management actions should be targeted on these high-alert medications as well as to secure safety in intravenous administration and off-label drug use in paediatric patients.

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Conflict of Interest No conflict of interest.

5PSQ-037 ABSTRACT WITHDRAWN

5PSQ-038 **DRUG RELATED VISITS TO THE EMERGENCY DEPARTMENT IN NURSING HOME PATIENTS**

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Background and Importance Drug related problems (DRPs) are one of the main causes requiring assistance to the Emergency Department (ED) in frailty people. Many of these patients live in nursing homes (NH). Identifying the differential characteristics of patients and DRPs that cause consultation in this subgroup, can help to improve the pharmaceutical care programs implemented in our environment in NH.

Aim and Objectives To identify drugs that are associated with DRPs that causes consultation of ED in patients coming from NH and compare the drugs involved, and the characteristics and comorbidities of these patients with non-NH patients.

Material and Methods Retrospective, descriptive observational study was conducted between February 21-May 2022 in the ED of a university hospital. We included adult patients who attended ED for DRPs.

The following variables were collected and compared between NH patients and no NH patients: age, sex, chronic pathologies at admission, number of drugs prescribed in the electronic prescription, drug involved in the DRPs and diagnosis related to the DRPs.

Qualitative variables have been compared between the NH patients vs no NH patients using the Chi-Square test and quantitative variables using the independent data t-test.

Results 1029 patients were included. 98 of them (9.53%) were referred from NH nh patients were older (84,6 (8.9) years old vs 77,1 (15.7) P<0.001*), mostly women [64 (65.3%) vs 511 (54.8%) P=0,046*], with a higher percentage of cognitive impairment [59 (60.2%) vs 189 (20.0%) P<0.001*], severe functional dependence [68 (69.3) vs 216 (23.2) P<0.001*] and severe polypharmacy (>=10 home medications) [53 (54.0%) vs 276 (29.6%) P<0.001] than the rest of the patients who consulted the ED for DRPs. DRPs related to the ATC group C (cardiovascular system) were more prevalent in NH patients [21 (21.4%) vs 310 (33.2%) P=0.017*] as well as diagnostics gastrointestinal motility disorders [23 (23.4%) vs 129 (13.8%) P=0.011*] and confusional syndromes [5 (5.1%) vs 17 (1.8) P=0.031*]

Conclusion and Relevance NH patients that consult ED for DRPs were older, mostly women with a high degree of socio-functional, cognitive dependence and extreme polypharmacy than no NH patients. DRP related with C ATC group and diagnosis of confusional syndrome and gastrointestinal motility disorders are also more prevalent.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-040 ANALYSIS OF THE IMPACT OF THE COVID-19 PANDEMIC ON PSYCHOTROPIC DRUG USE

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Background and Importance The COVID-19 disease, declared a pandemic in March 2020, radically changed people's way of life. The health risk, the measures of the state of alarm and its impact at social and economic level have exposed the population to a threat to their psychological well-being.

Aim and Objectives To analyse the relationship between COVID-19 and changes in the trend of psychotropic drug consumption.

Material and Methods Descriptive drug utilisation study which included 665,222 inhabitants. This population is distributed in an urban (UA) (275,990 inhabitants) and rural, peri-urban (RA) (389,232 inhabitants) area. The study period was January 2018 to December 2021. Data were obtained from the database of dispensed and billed prescriptions. The unit used was the Defined Daily Dose (DDD) and the main variable was the DDD per 1000 inhabitants and day (DHD). The therapeutic groups studied were benzodiazepines (N05BA, N05CA, N05CF) and antidepressants (N06AB, N06AX), according to the Anatomical Therapeutic Chemical Classification System (ATC). Mann-Whitney test was used for statistical analysis.

Results The group of drugs with the greatest increase in consumption was benzodiazepines, followed by antidepressants, the latter being higher in the 2nd and 4th quarter of 2020, coinciding with the first and second wave and higher in rural areas. In antipsychotic dispensations, a slight increase was only observed in the metropolitan area ($p < 0,05$). During the year 2021, the rates of benzodiazepines were decreasing, ending the year at values similar to pre-pandemic rates. In contrast, the increase in antidepressant use was sustained during 2021.

-DHD 2nd Quarter:

BENZODIAZEPINES

UA: 2018:86.71;2019: 83.58; 2020:86.16; 2021:81.71

RA:2018:88.97;2019: 88.95; 2020:97.63; 2021:87.85

ANTIDEPRESSANTS

UA:2018:38,79; 2019:39,73;2020:40,16;2021 41,38

RA:2018:44.76; 2019:45.58;2020:48.49;2021:47.85

-DHD 4th Quarter

BENZODIAZEPINES

UA: 2018: 84.67; 2019: 83.15; 2020: 87.60; 2021: 82.00

RA: 2018: 88.42; 2019: 89.97; 2020: 97.38; 2021: 87.84

ANTIDEPRESSANTS

UA: 2018: 38.73; 2019: 39.72; 2020: 40.99; 2021: 43.14

RA: 2018: 45.12; 2019: 46.24; 2020: 48.91; 2021: 49.19

It was only statistically significant the increase in the consumption of antidepressants ($P=0.019$) in the periods 2020-2021vs 2018-2019.

Conclusion and Relevance The uncertainty in the first months of the pandemic, bereavement, isolation and the effects of the economic crisis may have favoured an increase in the consumption of antidepressants and benzodiazepines. It would be necessary to reorient clinical practice strategies, promoting the appropriate and safe use of these drugs in the primary and hospital care setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-041 STERILE INTRAOCULAR INFLAMMATION AFTER INTRAVITREAL AFLIBERCEPT

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Background and Importance Sterile intraocular inflammation (SII) is a known complication of therapeutic intravitreal injections, particularly with all anti-vascular endothelial growth factor drugs. These events usually occur sporadically but there has been an increase in the number of reported cases due to aflibercept¹.

Aim and Objectives To analyse the appearance of SII in patients with intravitreal aflibercept.

Material and Methods Descriptive observational study of patients with SII after intravitreal aflibercept reported from August to November 2021. Data collected: sex, age, eye, pathology, pre-treatment, doses and batch of aflibercept, time to presentation and description of symptoms, best-corrected visual acuity (BCVA) prior to last dose, after the onset of symptoms and at six months of follow-up. Patients treated bilaterally were counted as two treatments.

Results SII was observed in 14 of the 110 patients treated (12.7%); 57% women; mean age: 78.9 ± 8.3 years.

17 eyes were treated: right 28.6%, left 50.0%, bilateral 21.4%.

Pathology: neovascular age-related macular degeneration 85.8%, diabetic macular oedema 7.1%, branch retinal vein occlusion 7.1%.

Patients previously received ranibizumab, bevacizumab and an average of 11 doses of aflibercept. All doses were from batch KT09625.

Mean time to presentation symptoms was 22 days, which included myodeopsis, precipitation in the vitreous with crystals of aspect of 'starry sky', vitreous inflammation and decrease of the BCVA. No patient presented infectious endophthalmitis and one required vitrectomy. Mean BCVA prior to last dose and after the onset of symptoms was 0.57 ± 0.42 logMAR and 0.56 ± 0.27 logMAR, respectively, and to the six months was 0.66 ± 0.39 logMAR.

All adverse effects were reported to the Spanish Pharmacovigilance System, manufacturer laboratory of aflibercept and Drug Inspection and Control Department of the Spanish Agency for Medicines and Medical Devices.

Conclusion and Relevance

- SII is associated with intravitreal antiangiogenic drugs, especially with aflibercept.¹ However, the sudden onset of symptoms alerted the Ophthalmology Department.
- It was initially suspected to be related to the batch of aflibercept, but the results are inconclusive.
- The clinic was important, without showing a sharp decrease in BCVA.
- Long-term monitoring of these patients is necessary to assess the resolution of the inflammation.
- Multidisciplinary pharmacovigilance coordination is crucial for the detection of known or unexpected adverse effects.

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Conflict of Interest No conflict of interest.

5PSQ-042 PREVALENCE OF MEDICATION PRESCRIPTION WITH A POTENTIAL NEGATIVE EFFECT ON SWALLOWING IN OUTPATIENTS WITH COGNITIVE IMPAIRMENT AND A DIAGNOSIS OF DYSPHAGIA

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Background and Importance Dysphagia is a highly prevalent syndrome in the elderly population, and especially in those with cognitive impairment. In addition to age-related factors and comorbidities, drugs with a potential negative effect on swallowing function have been identified, many of which are commonly used in pathologies that are also prevalent in the elderly. Knowing and raising awareness about the dimension of this problem can help increase the safety of pharmacological treatment in these patients.

Aim and Objectives To determine the prevalence of medication prescription with a potential negative effect on swallowing in elderly outpatients with cognitive impairment and diagnosis of dysphagia.

Material and Methods Observational, descriptive and cross-sectional study in which we analysed the pharmacological treatment of patients with cognitive impairment and a diagnosis of dysphagia attending the nutrition hospital pharmacy clinic of a tertiary hospital. We recorded sociodemographic, prescribed medications, potential effect on swallowing function and its mechanism data. Medications with a potential effect on swallowing were selected from the existing literature and the information contained in summaries of products characteristics.

Results We analysed 594 prescriptions corresponding to 68 patients whose mean age was 85,5. We identified 170 drugs belonging to 12 therapeutic groups. 66 patients (97%) had been prescribed some medication with a potential negative effect on swallowing function, and the mean number of these medications prescribed per patient was 3.6. 246 prescriptions (41,6%) corresponded to medications with negative potential on the swallowing function, mainly due to their sedative effect (n=118, 48%), followed by production of xerostomia (n=44, 18%), neuromuscular action (n=33, 13.4%), direct irritants (n=18, 7.3%), and unknown mechanisms (n= 4%). 23 prescriptions (9,3%) shared different mechanisms.

Conclusion and Relevance We observed a high prevalence of drug prescriptions with a potential negative effect on swallowing in this subgroup of patients. These results highlight the importance of re-evaluating the clinical need for these medical prescriptions in patients with dysphagia. Hospital pharmacy has an important role in detecting these medical prescriptions and promoting the search for alternatives to ensure the best benefit-risk ratio. The need to extend the study to other subpopulations of patients with dysphagia should be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-044 REAL-LIFE SAFETY AND SATISFACTION OF CFTR PROTEIN MODULATORS IN CYSTIC FIBROSIS

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Background and Importance The new transmembrane conductance regulator (CFTR) modulator drugs (ivacaftor/tezacaftor/elexacaftor) are bringing about a major change in the treatment and quality of life of cystic fibrosis (CF) patients. There is a need to collect information on patient perception of benefit and safety.

Aim and Objectives To assess the satisfaction and adverse effect (AE) profile reported by patients on ivacaftor/tezacaftor/elexacaftor treatment.

Material and Methods Observational, prospective, single-centre study from March to June 2022. CF patients with at least one p.Phe508del mutation in treatment with CFTR modulators. Variables: sociodemographic (age and sex) and biochemical (GOT-ASAT, GPT-ALAT, bilirubin and CPK) collected from patients' medical records. Treatment Satisfaction Questionnaire for Medication (TSQM 1.4) with 14 items in four scales assessing efficacy, side effects, convenience and overall satisfaction from the patient's own perspective, the higher the score, the higher the satisfaction. Adverse Effects Questionnaire (ad hoc), Patient Informed Consent.

Results Out of 58 patients on treatment, 43 answered the questionnaires, 17 (40%) female, median age 30 (26-37). For TSQM the median score for each item was 21 (20-21) over 21; 19 (16-20) over 21; 21 (18-21) over 21 and 17 (16-17) over 17 respectively. Regarding AEs: 39.47% reported increased appetite, 31.58% rash, 23.68% headache, 13.16% runny nose, increased blood pressure, diarrhoea and itchy skin, 10.53% abdominal pain or discomfort, common cold and itchy or stinging eyes and ≤ 2% flatulence, memory loss, yellowing of skin and eyes, muscle pain, fluid retention, insomnia, acne, nausea and vomiting. One patient presented with severe rash requiring discontinuation of treatment. Three months after starting treatment, only three patients had GPT-ASAT >3 LSN and only one patient >5 LSN, one patient had increased CPK >5 LSN and no patient had bilirubin >2 LSN.

Conclusion and Relevance Although a high percentage of patients have experienced AEs, CFTR modulators are widely accepted drugs with a favourable AE profile. The most frequent AEs reported by patients were increased appetite, rash and headache. The AEs described by patients are described in the data sheet. More real-life studies are needed to confirm our study and to provide further evidence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-045 IMPACT OF PHARMACEUTICAL INTERVENTIONS IN CRITICAL PATIENTS

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Background and Importance The high healthcare burden in the Intensive Care Unit (ICU) due to the SARS-CoV2 Coronavirus pandemic has created a work environment that increased medication errors. It is known that pharmaceutical interventions reduced medication errors.

Aim and Objectives The objective of this study is to know the impact of pharmaceutical intervention in critically ill patients.

Material and Methods Retrospective observational study carried out in a general hospital. All the pharmaceutical interventions performed in the Intensive Care Unit (ICU) between the months of October 2020 and April 2021 were analysed. It was registered in a database: Positive diagnosis of COVID-19 (SARS-CoV2 coronavirus disease), number of interventions, type of intervention and acceptance of the intervention.

Results A total of 51 interventions were obtained in 169 patients admitted during the 7 months of the study (0.3 interventions / patient). 42.6% of the patients had a diagnosis of COVID-19. 17% of the patients admitted to the ICU had at least one intervention, of which 38% had more than 1 (mean 1.76 interventions per intervened patient). The most frequent reasons for intervention were dose modification due to inappropriate dose (35.3%) and inappropriate choice of presentation due to the route of administration (21.5%). 84% of the interventions were carried out in COVID-19 patients, with the mean number of interventions performed in these patients higher than in non-COVID-19 patients (1.87 vs 1.33). 92% of the interventions conducted by the pharmacist were accepted.

Conclusion and Relevance Pharmaceutical validation in the Intensive Care Unit (ICU) is essential to optimise the treatment of critical patients, increasing safety and efficacy of medications they receive and reducing medication errors. Patients diagnosed with COVID-19 are especially likely to benefit from pharmaceutical interventions, which are highly accepted by physicians.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-046 FMEA (FAILURE MODE AND EFFECT ANALYSIS) APPLICATION TO PARENTERAL NUTRITION BAGS MANUFACTURING PROCESS: ROLE OF HOSPITAL PHARMACIST

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Background and Importance Correct identification of unexpected/unwanted processes variability allows us studying solutions for increasing any system reliability. FMEA (Failure Mode and Effect Analysis) is an inductive method that provides a 'bottom up' approach; starting from activities process

analysis, it reaches identification of possible inconveniences (failure mode) and effects on an entire system.

Aim and Objectives Our purpose was detecting the most critical phases of Parenteral Nutrition bags (PNB) compounding process through an audit consisting of hospital pharmacists, doctors, nutritionists and nurses.

Material and Methods FMEA was applied to PNB compounding process in a hospital with 639 beds. The process was divided into four phases (prescription, formulation, compounding, quality-control). By making an estimate of severity, probability and detectability, we have defined appropriate actions to be taken for eliminating potential problems' occurrence. The product between previously identified values (on scale from 1 to 10) provides Risk Priority Index (IPR), an overall criticality measure.

Results The highest IPR value (384) was found in formulation phase where bag's osmolarity was higher than venous access type chosen. An IPR=168 was found in prescriptive phase concerning patient incorrect selection from software (homonymy cases), followed by data incompleteness, relating to microelements addition (with an IPR=150). An IPR=140 was found during Siframix machine setting up regarding microelements' housings exchange (danger due to Potassium replacement with microelement required in greater quantities). Finally, IPR=144 was found, during compounding phase, due to confusion about 'look alike sound alike' constituents (inframin/siframin replacement); this allowed PNB compounding with a qualitative-quantitative composition different from that requested.

Conclusion and Relevance Joint audit proposed solutions for each phase. For prescriptive one, it would be desirable to take advantage of a software that gives access to medical records in order to check that bag suited patient's needs. During formulation phase, it is necessary that a hospital pharmacist (HP) performs a double check between worksheet drafting and label, verifying correspondence, completeness and overlapping with data indicated in prescription. HPs have to control prescription feasibility and that volume is suitable for access provided for patient. For set-up phase, a double check should be carried out to make sure that each housing contains corresponding nutrient; in addition, at least two technicians should be present to carry out the operations in duplicate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-047 PRECAUTIONARY CANCELLATION: TOOL TO IMPROVE PATIENT SAFETY

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Background and Importance Precautionary cancellation is a new tool for primary care and hospital pharmacist that allows them to cancel prescriptions and avoid dispensing medicines at pharmacies.

Aim and Objectives Analyse the precautionary annulments made in a hospital and quantify the degree of acceptance of the doctor.

Material and Methods Prospective study lasting five months in a country hospital. All patients outpatients with onco-

haematological prescriptions and home treatment were included. The precautionary annulments were codified as safety: interaction between drug (INT): category X (avoid combination) and category D (modify therapy), unnecessary medication (UM), overdose (OD) and therapeutic duplicity (TDUP). The variables collected were: age, sex, prescribing service, type of precautionary annulments and degree of acceptance of the doctor. Sources used: digital clinical history Diraya, corporate dispensing module, Uptodate interactions and electronic prescription program Farmis Oncofarm v4.0.11.164.

Results We analysed 35 precautionary annulments. Population of mean age 52 years (range 46-87). 71% were women. The prescribing services were Oncology (97.14%) and Hematology (2.86%). The precautionary annulments were of safety: INT 80% (category X 85.72% and category D 14.28%), UM 14.28%, OD 2.86% and DUPL 2.86%. The degree of acceptance of the doctor was 88.57% and modified the treatment 11.43%.

Conclusion and Relevance The results of the series studied show a high degree of acceptance by the doctor of the precautionary cancellations made by the hospital pharmacist. It is a useful safety tool, emphasising serious interactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

5PSQ-048 WHAT DO ONCOLOGISTS AND PHARMACISTS THINK AND WANT FROM A CAHMS-DRUG INTERACTION CHECKER? A BROADSCALE SURVEY TO ASSESS EXPECTATIONS

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Background and Importance The use of complementary and alternative herbal medicines (CAHMs) is widespread and popular among cancer patients for different reasons. Unfortunately, CAHMs can interfere with anticancer treatments leading to both toxicity or decreased efficacy with therapeutic failure. The availability of a tool for the management of potential CAHM-drug interactions (CAHMDI) could provide health care professionals (HCP) with scientific evidence-based information. It may facilitate open communication about potential adverse effects without neglecting patient's beliefs and preferences. Such a tool does not yet exist in our hospital.

Aim and Objectives The aim of this survey was to assess future user's expectations of a practical tool to manage CAHMDI.

Material and Methods Two e-surveys, carried out in Google Forms, were sent to 1) health care providers (HCPs) of all oncological disciplines in our hospital and research departments and 2) all hospital pharmacists of UHL.

Results The survey was completed by 37 HCP and 27 hospital pharmacists (HP). The results clearly demonstrated an interest

in a CAHMDI, as confirmed by 94.6% and 100.0% of the HCP and HP, respectively. All respondents indicated a preference for a website rather than a tool integrated in the clinical decision support system (51.0% HCP and 46.4% HP, respectively). In their current daily practice, the most commonly consulted resources for checking CAHMDI by HCP were consulting a clinical pharmacist (33.9%) and Lexicomp Drug Interactions® (21.4%). HP mentioned Stockley's Herbal Drug Interactions® (21.3%) and Lexicomp Drug Interactions® (21.3%). Key requirements for the development of a tool were management options, potential clinical consequences, severity level, mechanism and level of evidence.

Conclusion and Relevance Developing a user-friendly CAHMDI checker would be helpful for HCP and HP. Alerting about HDI could enhance prescribers' knowledge and awareness about this topic and enable them to inform patients about the potential adverse effects of these easily accessible CAHMs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-049 ASSESSMENT AND OPTIMISATION OF THE MANAGEMENT OF HIGH-RISK MEDICINES IN A GENERAL HOSPITAL

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Background and Importance High Risk Medicines (HRMs) are medicines with an increased risk of significant harm to the patient if they are misused.

Regarding the storage of HRMs, our hospital guidelines are based on the reference system of our accreditation organisation.

Compliance with guidelines is essential to ensure the quality of care.

Aim and Objectives

- To determine the rate of adverse drug events related to HRMs.
- To evaluate the impact of the introduction of low-concentration electrolytes (KCl) on the consumption of concentrated electrolytes (KCl).
- To test the impact of pharmaceutical interventions on four quality indicators linked to HRMs storage in care units.

Material and Methods

- Among all the adverse drug events encoded during the year 2021, we identified those related to HRMs.
- A consumption analysis of injectable Potassium Chloride (KCl) concentrated and low-concentrated solutions was performed during the years 2018-2022.
- Audits targeting HRMs was conducted in 6 care units over a period of 3 weeks in December 2021. These audits focused on the following items : storage, quantity, labelling and expiry date of each HRM stored in care unit. During each audit, a pharmaceutical intervention took place as follows : tidying, relabelling, withdrawal of expired HRMs, feedback of audit, education and awareness. The impact of the pharmaceutical interventions was further evaluated. For comparison between the groups (pre-test and intervention groups), data were analysed using Chi Square test for all HRMs.

- The LEAN Methodology was used to draft our action plan to improve HRMs practices.

Results

- We identified that 14% of adverse drug events were related to HRMs.
- Our consumption analysis indicated that the introduction of low-concentrated KCl solutions in care units was not followed by the expected decrease in the prescriptions of injectable KCl concentrated solutions.
- A total of 171 HRMs were audited in care units. The impact of the pharmaceutical interventions performed during these quality audits was evaluated, which allowed to demonstrate a statistically significant improvement ($p < 0,05$) in terms of storage and expiry of HRMs.

Conclusion and Relevance This work highlights the importance of the hospital pharmacist as a key contributor in the continuous quality improvement approach to optimise the management of HRMs in a hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

<https://www.eahp.eu/24-5PSQ-161>

Conflict of Interest No conflict of interest.

5PSQ-051 PARKINSONISM INDUCED BY TAKING TRAZODONE AS A HYPNOTIC: A CASE REPORT

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Background and Importance Sleep disturbance is very prevalent in critically ill patients. Treatment approaches to improve sleep have focused on both non-pharmacologic and pharmacologic strategies. Trazodone is an atypical antidepressant used with highly frequency as hypnotic.

The main side effects described for trazodone are self-injurious thoughts, anaemia, seizures, paraesthesia, confusion or dyspnoea. It can inhibit dopaminergic neurotransmission in the midbrain and as result, cause extrapyramidal effects.

Aim and Objectives To describe a case of parkinsonism induced by taking trazodone as hypnotic in a patient admitted in a Critical Care Unit (CCU).

Material and Methods A 57-year old man with no relevant medical history was admitted to CCU in May 2021 with pneumonia caused by COVID-19 disease. The patient suffered from insomnia. The physician prescribed trazodone starting with a dose of 50 mg and then 100 mg.

Results That afternoon, after taking trazodone, the nurse described slight tremor intensified with movement in upper extremities. The physician on duty was notified but he did not find any explanation. Next day, the official physician checked the medication with the critical care pharmacist.

The syndrome was not explained by analytics or other tests. The pharmacist checked all patient's medications searching information in different databases: the official labels and the clinical trials, PubMed® and UpToDate®. In addition, she checked possible interactions in Lexicomp® database but she did not find nothing. Trazodone was the unique drug associated with the syndrome.

The physician and the pharmacist agreed to discontinue the medication to check if the syndrome disappeared.

The following days, the patient continued with tremble on movement. The pattern of the movement was similar each day. It started at afternoons and disappear during nights. The intensity of the movement was reduced each day. The syndrome disappeared completely one week later.

Based on causality assessment of adverse drug reactions by Naranjo et al., we classify this event as probable/likely. The pharmacist notified this adverse effect to pharmacovigilance.

Conclusion and Relevance Trazodone is considered safe and used frequently in our medical system, so the knowledge of effects like that is important. Nevertheless, the parkinsonism induced was reverse and disappear one week later once the treatment was stopped.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-053 DESIGN OF A PRIORISATION SYSTEM BY COMPLEXITY OF THE REVIEW IN POLYMEDICATED PATIENTS: POTENTIAL INADEQUACY INDEX

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Background and Importance In our health area, which serves 450,000 patients, we have >2,000 polymedicated patients (PP) with >15 drugs/month. For an efficient approach to these PP it is necessary to establish some prioritisation criteria for their review.

Aim and Objectives To design an index of prioritisation to review PP based on the inadequacy of their polypharmacy, named Potential Inadequacy Index (PII).

Stratify all PP (>15 drugs/month) according to the score of the PII through an automated analysis of their prescriptions.

Material and Methods PII is made up of different situations that can occur in the pharmacological treatment of PP: duplicities, prescribing cascades, drugs with low therapeutic value, drugs that prolong the QT-interval and drugs contributing to anticholinergic burden were chosen as components of the PII, giving them a score in case of appearance:

| Potential Inadequacy Index (PII) | |
|----------------------------------|------------|
| Duplicity | 1 point |
| Low therapeutic value | 1 point |
| Prescribing cascades | 0,5 points |
| QT interval prolongation | 0,5 points |
| Anticholinergic burden | 0,5 points |

All PP were stratified according to the PII score, review's complexity degree of the polymedicated patient and estimated time for review are shown:

| Review's complexity | | |
|----------------------|-----------------|-------------------------|
| Degree of complexity | PII punctuation | Estimated revision time |
| Very low complexity | < 1 | 10 min |
| Low complexity | 1 to < 2 | 15 min |
| Moderate complexity | 2 to < 4 | 30 min |
| High complexity | 4 to < 8 | 90 min |
| Very high complexity | ≥ 8 | 160 min |

Results 2,258 PP were included, with a mean number of medications per patient of 16.78 (95% CI 14.65-18.79), and the mean PII score was 2.01 (95% CI 1.96-2.06). Patients' distribution by review's complexity is shown in the following table:

| Complexity group | Potential Inadequacy Index | N patients | % patients | % Acum |
|----------------------|----------------------------|------------|------------|--------|
| Very low complexity | <1 | 388 | 17 | 17 |
| Low complexity | 1 to <2 | 729 | 32 | 50 |
| Moderate complexity | 2 to <4 | 880 | 39 | 89 |
| High complexity | 4 to <8 | 228 | 10 | 99 |
| Very high complexity | ≥8 | 22 | 18 | 100 |
| All | 0 a 17,5 | 2247 | 100 | 100 |

Conclusion and Relevance The automated analysis of the prescriptions of polymedicated patients, in search of potential criteria of inadequacy, can facilitate prioritisation in the review of patients.

The PII can help guide the identification of those patients with the greatest care needs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-054 ASSESMENT OF OCCUPATIONAL PRACTICES: ANALYSIS OF THE PRESCRIPTIONS OF TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

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Background and Importance Transcatheter implantation of an aortic bioprosthesis (TAVI) allows the replacement of the aortic valve by a prosthesis without open surgery. Like any medical device, the implantation of these prostheses must comply with the CE mark. As the funding of TAVIs is under specific criteria, those must also be respected.

Aim and Objectives To carry out an overview of the compliance of the TAVI prescriptions with the funding criteria (FC). **Material and Methods** 33 patients were randomly selected from the 300 TAVIs implanted in 2021. Valve models, implantation routes, and patient data were extracted from the internal traceability software (GILDAS) at the university hospital and from computerised medical records (DxCare). These data were analysed with a grid developed from the FC.

Results Among the 33 patients selected, 15 were men et 18 were women, ranging in age from 68 to 94 years, with an

average age of 80.1 years. 84.8% (n=28) of the valves were placed transfemorally, 6.1% (n=2) transapically and 9.1% (n=3) transcarotidly. 28 patients had symptomatic severe aortic stenosis (ASN), 1 patient had asymptomatic ASN, and 4 patients had cardiac decompensation on ASN. Contraindications to surgery were documented in the patient record in 84.8% (n=28) of cases. The Society of Thoracic Surgeons (STS) database score was specified in 42.4% (n=14) of the cases and the Euroscore was not specified for any patient. Multidisciplinary consultations were carried out in 100% of cases, as well as pre- and post-TAVI assessments. A total of 24 non-compliances (NC) were observed, including 16 patients with 1 NC and 4 patients with 2 NC. The funding criteria were not respected in 27.3% (n=9) of cases.

Conclusion and Relevance Although most of the patient files stipulate comorbidities consistent with the placement of a TAVI, there is still a lack of formalisation of the indications: the STS score is mentioned in only 42.4% of the cases, even though it is part of the FC. A report was presented to the recruiting physicians and the importance of transcribing the STS score in the patient file was explained.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-055 SAFETY TESTING ASSESSMENT FOR THE ADHERENCE OF DOSE REDUCTION IN ONCOLOGY TREATMENT FOLLOWING CLINICAL GUIDELINES RECOMMENDATIONS IN PATIENTS PRIOR RECEIVING FLUOROPYRIMIDINES (5-FLUOROURACIL, CAPECITABINE AND TEGAFUR)

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Background and Importance Fluoropyrimidines in solid tumours are metabolised by dihydropyrimidine dehydrogenase (DPD) enzyme, encoded by DPYD gene. Up to 3-6% of the population have a DPYD variant, which, without appropriate dose reduction, will lead to severe toxicity/death[i].

Since 2020 the regulatory agencies in Europe and the UK recommend all patients to be tested for DPD deficiency before initiation to minimise the risk of these reactions[ii],[iii].

Five London cancer providing trusts (CPT) assured testing was being performed[iv].

The North Thames Genomic Medicines Service Alliance (NTGMSA) is one of the seven in the UK working on a national project to ensure equitable implementation of DPYD pharmacogenomic testing.

Aim and Objectives To establish that all CPT within NTGMSA are safely implementing DPYD testing.

Material and Methods Five questions analysed from national survey:

Who is involved in checking the result of the DPYD genetic test?;

Who makes dose adjustments?;

Protocol?;

Is chemotherapy prescribed prior the test report?;

Is chemotherapy delayed when results are pending?

Results Within NTGMSA all 14 CPT responded. Everyone provides DPYD testing for all cancer indications which include fluoropyrimidine treatment. Multiple healthcare professionals

check and action the test results, following dose reductions, following guidance. Chemotherapy is prescribed prior receiving the genetic report in 10 CPT. 6 hospitals would delay administration when result is missing.

Conclusion and Relevance There is a rich multidisciplinary involvement in checking the results of the test, including making the correct dose adjustments. The use of DPYD tests to prevent chemotherapy toxicity follows a safe and robust pathway within our region.

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Conflict of Interest No conflict of interest

5PSQ-056 HETEROGENEITY OF DEXMEDETOMIDINE TREATMENT EFFECT ON MORTALITY ACCORDING TO AGE

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Background and Importance Dexmedetomidine is an alpha-2 agonist with sedative effects. It is used for the sedation of patients in the Intensive Care Unit (ICU) and sedation of surgical procedures. In June-2022, the Spanish Agency for Medicines and Medical Devices (AEMPS) published a safety letter reporting an increased risk of mortality in patients ≤ 65 years of age compared to standard sedative agents¹.

Aim and Objectives To analyse the use of dexmedetomidine in our hospital and to compare the heterogeneity of the effect on mortality according to age in real life.

Material and Methods Observational, descriptive and retrospective study. Patients treated with dexmedetomidine or propofol during the year 2021 were included. Variables collected: age, sex, number of days on treatment with dexmedetomidine/propofol, admission diagnosis to the ICU, surgical intervention during ICU stay and 90-day mortality from any cause. Variables were collected through the digital medical record and the hospital's electronic prescription program. Data were analysed using Excel.

Results 403 patients were included (169=dexmedetomidine vs 234=propofol). 75.7% were men (125=dexmedetomidine vs 180=propofol). Baseline patient characteristics are shown in the following table. There were 74 deaths at 90-days in the control group vs 31 deaths at 90-days in the dexmedetomidine group, odds ratio (OR)=0,49 [95% CI: 0,30 – 0,78]. In the >65 years group there were 35 vs 13 deaths at 90 days (propofol vs dexmedetomidine, respectively), OR=0,39 [95% CI: 0,18 – 0,86]. Deaths at 90 days in the group aged ≤ 65 years were 39 vs 18 (propofol vs dexmedetomidine, respectively), OR=0,55 [95% CI: 0,30 – 1,02].

| | All patients (403 patients) | Dexmedetomidine ≤ 65 years (120 patients) | Propofol ≤ 65 years (180 patients) | Dexmedetomidine > 65 years (49 patients) | Propofol > 65 years (73 patients) |
|---------------------------|--------------------------------|---|--|---|--|
| Age (years) | 39 (23,8 years) | 32 (26,7 years) | 32 (17,8 years) | 70 (66,78 years) | 71 (66,85 years) |
| Male gender n (%) | 305 (75,7%) | 90 (75,0%) | 125 | 35 | 35 |
| Type of admission n (%) | | | | | |
| Non-operative | 308 (76,4%) | 96 (80,0%) | 114 (70,8%) | 47 (95,9%) | 52 (71,2%) |
| Elective surgery | 33 (8,2%) | 15 (12,5%) | 11 (6,8%) | 2 (4,1%) | 7 (9,8%) |
| Emergency surgery | 62 (15,4%) | 9 (7,5%) | 55 (30,4%) | 0 (0,0%) | 12 (16,4%) |
| Admission diagnosis n (%) | | | | | |
| Sepsis | 10 (2,5%) | 5 (4,2%) | 3 (1,9%) | 1 (2,0%) | 1 (1,4%) |
| Respiratory | 216 (53,6%) | 72 (60,8%) | 75 (46,8%) | 11 (22,2%) | 15 (20,9%) |
| Cardiovascular | 28 (6,9%) | 9 (7,5%) | 6 (3,3%) | 6 (12,2%) | 7 (9,8%) |
| Neurology | 33 (8,2%) | 13 (10,8%) | 20 (11,1%) | 3 (6,1%) | 3 (4,1%) |
| Neurological | 35 (8,6%) | 4 (3,3%) | 34 (21,1%) | 2 (4,1%) | 15 (20,9%) |
| Other | 38 (9,4%) | 10 (8,3%) | 14 (8,3%) | 2 (4,1%) | 10 (13,7%) |

Abstract 5PSQ-056 Figure 1

Conclusion and Relevance The data obtained do not reproduce those obtained in the study on which the alert received was based. This may be due to limitations of our study. Even so, the use of dexmedetomidine in young patients should be carried out with caution. The pharmacy service has communicated the alert to the hospital services.

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- 1 <https://sinaem.aemps.es/CartasFarmacovigilanciaDoc/2022/DHPC-dexmedetomidine.pdf>

Conflict of Interest No conflict of interest

5PSQ-057 EFFICACY AND SAFETY OF ADALIMUMAB IN THE TREATMENT OF INFLAMMATORY FACIAL GRANULOMA SECONDARY TO SILICONE

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Background and Importance The administration of silicone as a filler material is associated with the development of inflammatory granuloma due to an increase in the proinflammatory cytokine tumour necrosis factor (TNF- α). Based on the pathophysiology of granulomas, anti-TNF- α drugs are postulated as possible therapeutic alternative for patients not responding to initial treatments.

Aim and Objectives To describe the efficacy and safety of the use of adalimumab in patients diagnosed with inflammatory facial granuloma due to filler material (silicone).

Material and Methods A 3-month retrospective descriptive observational study of a patient under treatment with adalimumab for inflammatory facial granuloma due to silicone.

Study variables included number and size of granulomas and adverse events (AE) occurrences associated with adalimumab.

Results 62-year-old woman follow-up by dermatology department due to inflammation compatible with silicone showed three lesions, one on the glabella and two on the cheeks. She received as first line treatment systemic corticosteroids (partial control of the process), methotrexate (no clinical response and even worsening after 3 weeks), doxycycline (no clinical response after 6 weeks) and finally hydroxychloroquine in association with doxycycline (no clinical response). She starts adalimumab 40 mg/2weeks.

- Response: After 6 doses of adalimumab were administered (12 weeks of treatment) combined with doxycycline 100mg/24h and hydroxychloroquine 400 mg/24h. Since treatment started patient experienced a decrease in the

number of lesions and a reduction in the size of the masses: from three initial lesions only lesion at the glabella level remains visible and palpable. After objective clinical improvement it was decided to withdraw doxycycline and infiltration of dexamethasone at the persistent lesion. Treatment with adalimumab together with hydroxychloroquine was maintained.

The patient did not report any AE associated with the use of adalimumab.

Conclusion and Relevance The use of adalimumab in this patient showed objective clinical benefits over previously used alternative treatments by achieving a significant reduction in the number and size of lesions in a reduced treatment time without experiencing AE. Together with the evidence collected previously the use of TNF- α inhibitors

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-059 REAL-WORLD CLINICAL DATA OF PALBOCICLIB AND RIBOCICLIB IN BREAST CANCER PATIENT

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Background and Importance Cyclin-dependent kinase (CDK) 4/6 inhibitors, block the transition from the G1 to S phase of the cell cycle by interfering with Rb phosphorylation and E2F release, showing potent antitumour activity and manageable toxicity in HR+/HER2–breast cancer patients.

Aim and Objectives The main objective of this work is to compare Real world data (RWD) between palbociclib and ribociclib in order to investigate the continuity in treatment and the frequency of hematologic adverse events (AEs) before and after CDK inhibitors dose reduction (DR).

Material and Methods A cohort of 128 pts has been analysed from medical and pharmacy records, of these 101 treated with palbociclib and 27 with ribociclib. Patients (PTS) has been observed from 2019 to 2021 and the results were compared with those of pivot trials. The DR was defined as reducing palbociclib dose from 125 mg to 100 mg or 75 mg ($\geq 20\%$ DR), while in ribociclib from 600mg to 400mg or 200mg. In both cases, DR is effective in the management of AE

Results RWD shows that time to first DR is similar in both cases: 11 and 10 months respectively for palbociclib and ribociclib. If a second DR is necessary, it occurs by the 16,5 months for palbociclib and 16.6 for ribociclib. Of 101 pts treated with palbociclib, 50 (49.5%) discontinued for progression disease (PD) and one of them for metastatic melanoma. 6/27 of pts (22.22%) in the ribociclib setting stopped for PD. In both cases, neutropenia is the prior AE to dose reduction as shown in real life and clinical trials. Its frequency decreases during the first cycle following the dose reduction, with a reduction in the severity. Other AEs observed were: hematologic disorder, hepatic cytolysis, drug intolerance, anaemia, leukocytosis, febrile neutropenia and fever.

Conclusion and Relevance As shown by the pivot trials, both the treatments are equal in terms of toxicity and duration. The proportion of pts with PD appears to be superior in the Palbociclib setting, even though need a deeper study with a good

statistical model to confirm results. For clinician using ribociclib is much more comfortable than palbociclib, due to the possibility of DM without interrupting treatment

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-060 GLUTEN IN MEDICINES. A PRESCRIPTION HELPING TOOL

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Background and Importance The use of excipients containing gluten in medicines can be a problem for celiac patients, especially for those with chronic pathologies. Based on this, current Spanish legislation requires pharmaceutical laboratories to declare excipients containing gluten and those that may contain gluten.

Aim and Objectives To evaluate the presence of unsafe excipients for celiac patients in medicines and the quality of the information regarding gluten content for patients and prescribers; as well as to create an application that facilitates prescription by professionals.

Material and Methods A database in a table format was created to determine the percentage of pharmaceutical presentations with excipients that may contain gluten. Data collected was: active ingredients, therapeutic group, type of excipient, and marketing status. This data was obtained from the prescription Nomenclator tables (source: Agencia Española del Medicamento y Productos Sanitarios). With this database, an application was created to find out which presentations may contain these excipients and what alternatives are available on the market.

Results 41319 presentations were recorded, of which 19957 were commercialised. The database revealed that 8% of the presentations commercialised included excipients that may contain gluten. Of these, 93.05% corresponded to carboxymethyl starch and sodium carboxymethyl starch, of which it is difficult to know the source of the starch and its possible gluten content. Moreover, 1.836% contained wheat starch, which can have variable amount of gluten. The information found in the data sheets was variable and, in some cases, insufficient to acknowledge the real risk.

With this data, an application has been created in which it is possible to search by active ingredient or therapeutic group, providing specialties that contain excipients with gluten or its derivatives, as well as therapeutic alternatives suitable for celiac patients. In addition, this application warns of the presence of lactose.

Conclusion and Relevance Carboxymethyl starch and sodium carboxymethyl starch are the most used excipients that may contain gluten and there is a great difficulty in finding reliable information about their origin. This situation makes prescription difficult and shows the need for tools that allow quick and easy access to data, guiding towards a safer prescription for celiac patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-062 REVIEW AND DEPRESCRIPTION OF MEDICATION IN POLYMEDICATED PATIENTS WITH PSYCHOACTIVE DRUGS

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Background and Importance Approximately 38% of European population has a mental health disorder that requires chronic and complex treatment, which have a high risk of long-term toxicity. Moreover, in the therapeutic groups used, it is advisable to carry out a progressive decrease in the dose until the drug is withdrawn.

Aim and Objectives To evaluate a medication review and deprescription programme in patients who have prescribed three or more drugs for pathologies under mental health follow-up.

Material and Methods Descriptive and prospective study, carried out with three cohorts in each of which patients had to have three or more concomitant prescriptions of: antidepressants (A), neuroleptics (B) and benzodiazepines (C); followed by the mental health unit of a tertiary hospital.

Pharmacy service obtained the lists in May 2022 through Information Processing Module to know the consume through electronic prescription, and posted on a corporate application, so that each doctor could access the individualised review during the current year. Four months later, a section was made to study the degree of strategy's implementation.

Demographic data (age; sex) and review's percentages were collected, analysing deprescription (one/two drugs), treatment maintenance (by reason of severity/prescription on demand/de-escalation phase/other reasons), dose changes and new drug's prescription (substitution/addition).

Results Study population obtained of 338 patients (mean age: 51 years; men: 55.3%): 34 (10.1%) (A), 81 (53.5%) (B) and 123 (36.4%) (C). The results obtained: 53.9% reviewed [(A): 44.1%; (B): 58%; (C): 50.4%], 34% pending review [(A): 26.5%; (B): 31.5%; (C): 39.9%] and 12.1% excluded (review not applicable). Some drugs was deprescribed in 17.6% [(A): 20%; (B): 17.1%; (C): 17.7%]: 14.8% (one) and 2.8% (two). Same prescriptions' number was maintained in 82.4% [(A): 80%; (B): 82.9%; (C): 82.3%]: 75.3% severity, 15.3% scheduled demand, 8.7% de-escalation and 0.7% other. Dose changes were reported in 12.1% [(A): 6.7%; (B): 15.2%; (C): 8.1%]: all of them decreased. Finally, 1.7% of new prescriptions were obtained [(A): 6.7%; (B): 1%; (C): 1.6%]: all of substitution. In no case was the prescriptions number increased.

Conclusion and Relevance This tool provided has allowed prescribers to access and review the population susceptible to deprescription. The degree of acceptance has been good. In the majority of patients the prescriptions were maintained, but in 1/5 the patient's medication deprescription was performed. The study should be extended until the review of the entire selected population.

Periodic reviews can make a high impact on these patients' health as well as a positive economic impact. Furthermore, it would be useful to create our own drug review/deprescription algorithms and to implement this strategy in other units.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-063 A CROSS-SECTIONAL STUDY ON THE POTENTIALLY INAPPROPRIATE PRESCRIBED AND CONTRAINDICATED HIGH-RISK MEDICATION IN HOSPITALISED CHRONIC COMPLEX PATIENTS

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Background and Importance Increased life expectancy has supposed a higher presence of comorbidities leading to polypharmacy rising the prevalence of potentially inappropriate prescriptions (PIPs) and high-risk medication (HRM) burden. PIPs can be a cause of harm or no longer provide health benefits which is why pharmacists-led interventions aimed at detecting and reducing it have emerged during recent years.

Aim and Objectives Assess the prevalence of PIPs, HRM and contraindicated medications in chronic complex patients (CCP) to whom pharmacist-led in-hospital reconciliation have been performed and to determine de HRM burden consequence of PIPs.

Material and Methods Cross-sectional study on hospitalised CCP between March and April 2022. Pharmacist-led medication reconciliation, PIPs identification (using the List of Evidence-based Deprescribing for Chronic Patients (LESS-CHRON) criteria) and contraindicated (using the Spanish datasheet) and HRM (using the High-Alert Medications in Chronic Patients Institute for Safe Medication Practices (ISMP) list) identification was performed.

Demographic data together with Pfeiffer and Barthel index were collected from patients' medical records. Chi-square test was utilised to determine differences in the proportion of PIPs between HRM and non-HRM.

Results 60 patients were included, (43.3% women, mean age was 76.8 ± 9.8 years). Pfeiffer index was 0-2 (normal cognitive level) in 35 (58.3%) and Barthel index was 60-99 (low dependence level in 26 (43.4%) of patients. Mean number of prescribed medications was 12.8 ± 4.7 . At least one PIP was detected in 100% of patients (mean number of 4.7 ± 4.1 PIPs). In 11 patients (18.3%) the detected HMR also was PIPs. Mostly involved drugs were benzodiazepines (72.7% of cases), spironolactone (9.1%), vildagliptine (9.1%) and quetiapine (9.1%). In 13 cases (21.7%) HRM was also contraindicated (23% oral anticoagulants, 23% digoxine and 15% eplerenone). There were non-significant differences in the proportion of PIPs between HRM and non-HRM (3.9% vs 3%, $p \geq 0.05$).

Conclusion and Relevance Considering these findings, a high prevalence of PIPs was found through pharmacist-led assessment in hospitalised CCP according to LESS-CHRON criteria.

Moreover from HRM assessed by IRMP, a high number of PIPs and contraindicated medication were identified, of which benzodiazepines and anticoagulants were the most detected according to the literature and the results obtained.

This fact highlights the need for pharmacists-led treatment-assessment and optimisation programs in this population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-064 **CONCOMITANT TREATMENT WITH ATEZOLIZUMAB AND ENZALUTAMIDE FOR METASTATIC NON-SMALL-CELL LUNG CANCER AND METASTATIC PROSTATE CANCER: A CASE REPORT**

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Background and Importance Only one phase III trial of enzalutamide with or without atezolizumab in men with metastatic prostate cancer who progressed on abiraterone has been reported in the literature. No cases have been reported in clinical practice with experience in the management of patients with lung and prostate cancer under concomitant treatment with atezolizumab and enzalutamide.

Aim and Objectives To describe the efficacy, safety and adherence of concomitant treatment with enzalutamide for metastatic castration-resistant prostate cancer and atezolizumab for metastatic lung adenocarcinoma in a patient case.

Material and Methods This was a descriptive, retrospective clinical case. The data (diagnostic tests, therapy and clinical course) were obtained by review of electronic medical records. Adherence was evaluate using medication possession ratio (MPR).

Results A 72-year-old male patient with stage IV non-small-cell lung cancer, negative eGFR, ALK and PD-L1, diagnosed in January 2019, received a first line standard chemotherapy. In September 2019, there was evidence of tumour progression and treatment with atezolizumab was started. In December 2019, patient was diagnosis of prostate adenocarcinoma with possible ganglionic involvement, surgery was performed and anti-androgen treatment was started. The patient continues maintenance treatment with atezolizumab and in December 2021, bone metastases of prostate origin were detected. Enzalutamide treatment is proposed for prostate cancer and maintenance atezolizumab for lung cancer. No cases have been reported in the literature, but there is one phase III trial, Imbassador250, which at least reports concomitant administration of the two drugs for prostate cancer. Given the favourable safety data from the study, and the efficacy data reported for both treatments for their corresponding indications, enzalutamide is initiated while treatment with atezolizumab is maintained. No toxicity from the treatments has been reported. The patient has maintained both treatments to the present day, maintaining clinical response for both tumours. The patient has shown 100% adherence to oral and intravenous treatment.

Conclusion and Relevance This is the first case report with evidence of efficacy of concomitant treatment with atezolizumab for lung cancer and enzalutamide for prostate cancer, with no additional toxicity. It is important to report these cases in real clinical practice because these conditions will not be present in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-065 **BE A HUMAN, NOT A CASE REPORT: HOSPITAL PHARMACISTS MAKE THE DIFFERENCE**

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Background and Importance The hospital pharmacy of our Health Institute is eligible to carry out phase 1 study till 2017. In July 2021 a multidisciplinary team, which includes pharmacists, approve the choice to enlist a 61 year old man of 70 kg affected by colon cancer fourth stage, inoperable, with failure of all drug therapies and without therapeutic treatment.

Aim and Objectives The aim of our work was to create a personalised pharmacological therapy in order to improve patient's life expectancy, minimising side effects.

Material and Methods Evaluation and creation of a custom pharmacological protocol, with continuous monitoring patient's vital parameters, before, during and after drug administration. The calculated dose was 5mg/kg. Pharmacists were involved also in monitoring of adverse drug reactions scheduling periodical patient interview and participating in the review of therapy with clinicians. Specifically 24 h from the first injecton; 7 and 15 days after drug administration.

Results Reduction in the volume of morphological lesions after a month from first infusion, observed by computed tomography, according to response evaluation criteria in solid tumours (RECIST 1.1): supraclavicular lesion on the left (cm 1.6 vs cm 2.7); paratracheal formation (cm 1.6 vs 1.4); formation of the aorta-pulmonary window (cm 1.6 vs 1.8); decreased hepatic formation (cm 4.6 vs cm 5.1). After nine months from first administration, we observed that reduction of morphological volume lesions remains constant. No adverse reactions were presented in the whole observational period. in addition, the patient interviewed reports less fatigue and increased mobility.

Conclusion and Relevance Phase 1 study (eudract 2017-002615-33) involves the use of LNA- i-miR-221, a new molecule synthesised to inhibit mir-221, which may be responsible for cellular dysfunction attributable to increased proliferation and inhibition of apoptosis, which has always been allmarkers of cancer. Single drug vial contains 35 mg. The For calculated dose was 350 mg, reconstituted with 20 ml NaCl, infused in total volume of 100 ml for 30 minutes. Therapy personalisation and interdisciplinary collaboration proved to be a success in ensuring help and limiting adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-066 ADEQUACY TO PROTOCOL OF USE OF TOCILIZUMAB FOR MANAGEMENT OF COVID-19 DISEASE

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Background and Importance The severe affectation by the COVID-19 virus is caused by an inflammatory response triggered in the individual. The use of immunosuppressive agents such as tocilizumab may be effective due to cytokine storm blockade. Since it is about off-label use, experts recommend developing management protocols from hospitals.

Aim and Objectives To determine the efficacy of tocilizumab in severe COVID-19 disease and the adequacy to a protocol of use.

Material and Methods A retrospective, observational and descriptive study over a 12-month period was conducted. All COVID-19 patients who received tocilizumab were included.

For the protocol development, following criteria were included: 1) Interstitial pneumonia with respiratory insufficiency and high-flow oxygen; 2) Absence of response to 3 boluses of corticosteroids; 3) Interleukin-6 > 40 UI/L. In the absence of interleukin-6, patients had to meet at least 3 criteria: C-reactive protein (CRP) > 10 mg/dl; D-Dimer > 1 µg/ml; Ferritine > 1000 ng/ml; cytopenia of at least 1 series. To evaluate response, CRP was monitored.

Collected data were age, gender, administration date, vaccination against COVID-19, administered dose, CRP, exitus.

Data were collected from an electronic prescription programme Farmatools® and the computerised medical history, MambrinoXXI®.

Results A total of 32 patients were analysed, of which 90.6% adhered to the protocol for use. Of those who were not adhered 9.4% due to severity of sudden illness.

The mean value of the initial CRP was 5.96 mg/dl reducing to 1.14 mg/dl after the tocilizumab administration. In 81.3% of patients there was a reduction.

Referring to dose based on weight, 60% of the patients received the 600 mg dose, the remaining 40% receive the dose of 400 mg.

Of the total of patients, 43.75% had not been vaccinated against COVID-19, 37.5% of patients treated the final result was exitus, all of them vaccinated.

Conclusion and Relevance A high percentage of patients meet the protocol criteria. The reason why Patients accomplished the protocol was a rapid evolution of the disease.

A high percentage of treated patients were not vaccinated. In general, the vaccine protects from severe disease.

The role of the hospital pharmacist is important in the development of protocols, especially in these cases of off-label uses for a correct treatment approach avoiding indiscriminate use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-067 TRACKING THE OVERALL IN USE AND STRESS STABILITY OF ROMIPLISTIM (N-PLATE®) BY THE EVALUATION OF A SELECTED SET OF CRITICAL QUALITY ATTRIBUTES

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Background and Importance Romiplostim (N-Plate®) is a Fc-fusion protein in which a TPO agonist peptide is associated with the Fc domain of a human antibody. It contains of two identical subunits each consisting of an Fc domain of human immunoglobulin IgG1 linked to a peptide containing two human TPO receptor binding domains. This drug is indicated in the treatment of immune thrombocytopenic purpura (ITP). As proteinaceous based-medicine, romiplostim is indicated to have low stability, thus the studies on the effects of possible in-use mishandling and in stress conditions are welcomed to get knowledge upon its stability and degradation.

Aim and Objectives To evaluate the impact of in use mishandling and forced degradation on romiplostim chemical structure by evaluation of several Critical Quality Attributes (CQAs).

Material and Methods Vials of romiplostim (N-plate, 0.5 mg/mL) were reconstituted as it is indicated by the manufacturer and submitted to several stress stimuli: exposition at 80 °C (2h), smooth shaking (12h), room light and temperature (excursion aprox. 20-24 °C) exposition (24h), accelerated light exposition (24h) and 1 freeze/thaw cycle. The CQAs evaluated were: (A) primary structure, by peptide mapping-RP/UHPLC-(Orbitrap)MS/MS; (B) tertiary structure by Intrinsic tryptophan fluorescence spectroscopy; (C) aggregation by SE-HPLC/DAD; and functional activity (as the capacity to bind to its therapeutic target) by ELISA.

Results Changes in the primary and tertiary structure and the formation of aggregates were detected after romiplostim samples were submitted to high temperature and to room conditions. These changes detected were accompanied by a loss of functionality. Similar effects were caused when stressed by accelerated light exposition. The smooth shake and freeze/thaw cycle stimuli did not affect the CQAs studied.

Conclusion and Relevance This study proves that romiplostim must be reconstituted and administrated avoiding long-time light exposure and elevated temperatures as they can induce the activation of several degradation pathways which cause loss of functionality and aggregation, and thus, losing the original safety, quality and efficacy of the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-068 **DIARRHEA OCCURRENCE ANALYSIS IN IDIOPATHIC PULMONARY FIBROSIS PATIENTS**

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Background and Importance Nintedanib and pirfenidone are the only drugs indicated for the treatment of c (IPF). Both drugs have diarrhoea in 62.4% and 18.8%, respectively, described in the Summary of Product Characteristics (SmPC) as a frequent adverse effect (AE).

In case of diarrhoea, it is recommended to reduce the dose or stop treatment.

Aim and Objectives To analyse the frequency of appearance of diarrhoea of the treatment with pirfenidone and nintedanib described in SmPC with that of the patients in the study and to describe the action carried out.

Material and Methods Retrospective observational study between January 2017 and August 2022 in which IPF patients treated with nintedanib or pirfenidone were included.

The following variables were collected: age, sex, drug, duration of treatment, withdrawal reason, existence of diarrhoea and severity according to medical evaluation and, if necessary, the corrective action taken (dose reduction, treatment discontinuation or control of the AE with another drug).

For statistical analysis, mean, median and standard deviation (SD) were performed. The odds ratio (OR) was calculated with the data obtained and those described in the SmPC of each medication.

Results Thirty patients were included with a mean \pm SD age of 72 ± 8 years, of which 23.3% (7) were women. 80.0% (24) received treatment with nintedanib (duration range: 37 and 1953 days), and 20.0% (6) were treated with pirfenidone (duration range: 124 and 1073 days).

Of the patients treated with pirfenidone, 83.0% (5) discontinued treatment (none due to EA). 17% (1) had mild diarrhoea that was controlled with loperamide.

66.7% (16) of nintedanib patients presented diarrhoea (7 severe, 7 moderate, and 2 mild). Of these, 37.5% (6) were treated with loperamide maintaining the dose, 18.7% (3) discontinued treatment, and 43.8% (7) underwent a dose reduction. This adjustment allowed treatment to continue in 71.4% (5/7) of the patients. The OR of diarrhoea in study patients, compared to described in SmPC, with nintedanib was 1.21 CI95 (0.51-2.86) and with pirfenidone was 0.86 CI95 (0.10-7.47).

Conclusion and Relevance The appearance of diarrhoea in both drugs is very frequent. No statistically significant differences were observed in the frequency of onset of diarrhoea in patients at our hospital compared to those described in the SmPC.

In most cases diarrhoea was controlled by dose reduction or loperamide administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-070 **PHARMACEUTICAL CARE IN AN ONCO-HAEMATOLOGICAL CLINICAL TRIALS UNIT**

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Background and Importance The pharmacist's role in the health care for patients participating in clinical trials (CTs) goes beyond telling them how to take the medication at the start of treatment. CT protocols are very complex and compliance with all their requirements is essential.

Patients always have available a pharmacy direct phone and email in order to make it easier to solve any queries they may have about drug-drug interactions, side effects or dietary and daily living recommendations.

Aim and Objectives To evaluate all pharmaceutical care queries addressed to the pharmacist team in a CTs unit.

Material and Methods Retrospective study carried out in a tertiary university hospital over a 7-months period (January – July 2022). All the consultations were evaluated and classified according to the phase of the CT in which the patient was included, sex, pathology, person who asked (patient, oncologist, etc.), communication media and reason of consulting.

Results A total of 596 queries were received, mostly about patients included in phase I trials (58,6%). The number of consultations increased steadily from January (37) to July (115).

According to sex and pathology, 559 queries could be evaluated. More than half were about women (58,9%). Most frequent consultations were about patients with breast (17,4%), lung (14,1%) and genitourinary (13,8%) cancer.

Of the fully evaluable queries (494), 40,7% were done by patients, followed by study coordinators (32,8%) and physicians (25,9%). Most of the consultations (57,7%) were received by email. Related to the topic, almost all of the queries were related to interactions with concomitant therapies (92,5%), followed by instructions on how to take the drug (3,8%).

Conclusion and Relevance Pharmacists receive a huge number of consultations about drug-drug interactions. Both patients and healthcare professionals need to have a quick way to have their consultations solved.

Continuous pharmaceutical attention is vital to ensure the efficacy, safety and controlled use of the investigational drug and to facilitate compliance with CT protocols.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-071 ANALYSIS OF MEDICATION PROVIDED BY PATIENTS

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Background and Importance Many patients bring medication with them during their admission to hospital, which is a source of error.

Aim and Objectives Analyse the prescription of medicines provided by the patient and evaluate their correct use.

Material and Methods Cross-sectional descriptive study of patients admitted to a second level hospital on 11-11-2021 which had treatments prescribed as 'medication provided by the patient' (MPP). The sources of information used were: the electronic medical record and the prescription programme. The variables collected were: age, sex, prescribing service, whether or not the medication was provided, patient knowledge of the dosage of the medication provided, number of total active ingredients prescribed per patient, and medications provided, number of therapeutic duplications in the complete treatment.

Results A total of 96 patients had a prescription for a MPP, representing 28.92% of the patients admitted to the hospital at that time. Of this total, after excluding those who could not be interviewed due to their clinical situation (Intensive Care, Resuscitation, Psychiatry, Emergency, Home Hospitalisation Unit and isolated patients), 42 patients were analysed, with a median age of 74.5 years [RIQ 70-80.75], 59.52% being male. The main prescribing service was internal medicine (59.52%) followed by surgery (16.67%) and traumatology (16.67%). Of the total number of patients with prescribed MPP, 85.71% actually provided it and 97.22% were aware of its dosage. The median number of active ingredients prescribed per patient was 13 [RIQ 11-17], with the median number of MAPs being 2 [RIQ 1-2.75]. Therapeutic duplication was found between the medication provided and that of the admission in 2 patients.

Conclusion and Relevance A considerable percentage of patients admitted to the hospital provide medication, with the majority of patients belonging to the Internal Medicine Department. After the interview, it was observed that most of them controlled their medication; however, a significant percentage, despite having medication prescribed as provided, did not have it during their admission. For this reason, we consider that the patient should not provide medication as far as possible, in order to try to prevent medication errors during the hospital stay and to adjust his treatment to the hospital pharmacotherapeutic guide.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-073 IS THERE A SAFETY DIFFERENCE? JANUS KINASE INHIBITORS IN REAL CLINICAL PRACTICE

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Background and Importance Tofacitinib, baricitinib, upadacitinib and filgotinib are Janus kinase inhibitors (JAKs) indicated in rheumatoid arthritis (RA). The EMA notified that in patients with RA who were ≥ 50 years with at least one cardiovascular risk factor had an increased risk of major adverse cardiovascular events (MACE), and malignancies with use of tofacitinib relative to TNF-alpha inhibitor: https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-xeljanz-tofacitinib-increased-risk-major-adverse_en.pdf

Although it is being evaluated, it is still unknown if this risk is shared by other JAKs.

Aim and Objectives To describe and compare the safety of tofacitinib, baricitinib, upadacitinib and filgotinib in patients with RA in a real-world-setting.

Secondary objective to analyse if there is a relationship between MACE and malignancies with a patient profile with a higher risk of developing them as established in the alert.

Material and Methods Retrospective/prospective observational study of RA patients under treatment with tofacitinib, baricitinib, upadacitinib and filgotinib until September 2022.

Safety was determined based on the adverse events (AEs) reported.

Variables sex, age at start, time-of-treatment, reason for discontinuation, risk factor's MACE, risk factors for malignancies, and AEs.

Statistical analysis a description of characteristics and events that occurred in the cohort was carried out. Associations were later explored.

Results 124 patients (80.6% women) were enrolled. Mean age: 55.8 (SD11.8) years.

Treatments received tofacitinib (n=60), upadacitinib (n=49), baricitinib (n=21) and filgotinib (n=14), because 19 patients (15.3%) were treated with more than one JAK sequentially.

Median of treatment; tofacitinib: 399 (171-884) days, baricitinib: 308 (210-632), upadacitinib: 287 (130-477) and 93 (60-171) for filgotinib.

We identified 110 patient treatments with an increased risk of MACE or malignancies.

AEs were reported in 39 (31,5%) treatments (21, 9, 7, and 2 cases with tofacitinib, upadacitinib, baricitinib and filgotinib) being the most common herpes zoster. Only 2 patients suffered a MACE in the total cohort (both with tofacitinib).

There were 79 end-of-treatment because of inefficacy (n=46), AE (n=22), both (n=7) or for being considered a risk patient (n=4).

No association could be established between risk patient and the development of adverse events, neither minor or major.

Conclusion and Relevance Therefore, it is still unknown if the exchange strategy between them is adequate to reduce the risk. Limitation: a larger sample size and longer follow-up time are required to detect major AEs and their association with patients at risk.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-074 INTERACTIONS DETECTED WITH THE USE OF NIRMATRELVIR/RITONAVIR IN A TERTIARY HOSPITAL

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Background and Importance The incorporation of nirmatrelvir/ritonavir into the therapeutic arsenal for the treatment of SARS-CoV2 infection has made it necessary for Pharmacy departments to activate circuits and tools that allow us to adequately review the potential multiple interactions that ritonavir can produce.

Aim and Objectives To describe the interactions detected since the beginning of the use of nirmatrelvir/ritonavir in a tertiary hospital.

Material and Methods All patients who received nirmatrelvir/ritonavir from April to the end of August 2022 were included. The patient's usual treatment was consulted in the electronic prescription system of the region of Madrid, as well as an interview with the patient, and the medical history was consulted when deemed necessary. For the detection of interactions, the 'COVID-19 Drug Interactions' platform of the University of Liverpool was used and Farmaweb, an application of the Madrid Health Service, was used to validate the dispensing of medication. If there are any interacciones the pharmacist notifies the prescribing physician, as well as the necessary adjustments, these treatment modifications are also explained to the patient when the medication is given to them. An Excel table was used to record whether the patient had any interaction and, if there were any, the drugs were recorded.

Results During the study period, these drugs were dispensed to a total of 81 patients, and interactions with the patient's usual medication were detected in 61.73% (50 patients). 18 patients had one interaction, 21 patients had 2 interactions, 6 patients had 3, 4 patients had 4 and one patient had 5 potential interactions. The most commonly detected interaction was with atorvastatin (19) followed by metamizole (11), simvastatin (7), amlodipine (6) and tramadol (4).

Conclusion and Relevance The percentage of patients with interactions is very high, and it is very important to review the usual treatment as well as an interview with the patient to identify whether the patient is taking other unregistered medication that could interact.

This has highlighted the importance of interdisciplinary collaboration between the medical team (mainly in the emergency department, where most of these drugs have been prescribed) and the pharmacy team to ensure the correct use of this drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-075 PROPOSAL FOR THE ADJUSTMENT AND OPTIMISATION OF THE MEDICATION PROVIDED BY THE PATIENT

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Background and Importance Many patients bring medication with them during their admission to hospital, which is a source of error

Aim and Objectives To adapt the Pharmacotherapeutic Guide (PTG) to home treatment and patient conformity to therapeutic exchange during admission.

Material and Methods Cross-sectional descriptive study of patients admitted to a second level hospital on 11-11-2021 with treatments prescribed as Medication Provided by the patient (MPP). The sources of information used were: the electronic medical record and the prescription programme. The variables collected were: age, sex, therapeutic group of the PPM according to the ATC classification, inclusion status in the PTG and/or in the therapeutic exchange protocol, and patient agreement with the exchange for another available.

Results A total of 96 patients had a prescription for MPP, representing 28.92% of the patients admitted. 42 were analysed after excluding those who could not be interviewed due to their clinical situation, with a median age of 74.5 years (IQR70-80.75), 59.52% being male. Of the MPPs, the most frequent therapeutic group was C (38.82%) followed by N (20%) and R (15.29%) among others. Analysing group C, the most frequent subgroup was: agents acting on the Renin-Angiotensin System(RAS) (33.33%), lipid-modifying agents (21.21%). 47.06% of the MAPs were included in the PT. Among those not included in the guidelines, 84.78% were included in the therapeutic exchange protocol while 15.22% were not, which were recommended to be maintained during admission. 80.56% of the patients showed compliance with the change for another medication available in the hospital

Conclusion and Relevance A striking percentage of patients admitted to the hospital bring medication, the most frequent therapeutic group and subgroup were those related to the cardiovascular system and the RAS, respectively. A high percentage of the MPP were found in the PTG, and could have been dispensed by the Pharmacy Service. Those medicines not available in the hospital were included in the therapeutic exchange protocol; For non-interchangeable drugs, was recommended to maintain during admission. Most patients would have no objection to their medication being exchanged during admission. We consider that the best approach would be to avoid the supply of medication by patients, with all medication being dispensed by the Pharmacy Service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-076 PATIENTS' SATISFACTION AFTER CHANGING FROM 150MG TO 300MG SECUKINUMAB PEN PRESENTATION

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Background and Importance Secukinumab is an anti-interleukin-17 drug used for psoriasis, psoriatic arthritis or spondyloarthritis. Recently, our hospital changed from 150mg to 300mg secukinumab pen presentation in order to simplify treatment and facilitate administration. However, as patients often have other expectations, desires and priorities evaluating the degree of satisfaction allows us to identify deficiencies and causes of dissatisfaction.

Aim and Objectives To determine patients' satisfaction after changing from 150mg to 300mg secukinumab pen presentation.

Material and Methods Retrospective study carried out in a regional hospital. Patients on treatment with secukinumab 2x150mg/month who changed presentation to 300mg/month

during November-December 2021 were included. Patients who hadn't taken both presentations for at least 4 months and patients impossible to locate were excluded. Those who gave their verbal consent underwent a telephone survey. Variables collected: sex, age, drug indication, treatment duration, self-administration, pain measured with VAS(Visual Analogue Scale) with both presentations, presence of administration site reactions with both presentations, satisfaction with pen change measured from 0 to 10 (0 minimum-10 maximum), 300mg pen discontinuation and reason. Qualitative variables were expressed as frequency and percentage and quantitative ones as mean and standard deviation. Statistical analysis was performed with Excel (v.12.0).

Results Total number of patients with 300mg pen presentation:33. Included: 24 (72.2%). Women:9(42.9%). Age:49 (13.9). Patients with psoriasis:19(79.2%), psoriatic arthritis 4 (16.7%) and spondyloarthritis 1(4.2%). Treatment duration (months) 38.7(22.6). Patients who self-administered medication: 23(95.8%). VAS with 150mg presentation 1.8(1.2) and with 300mg presentation 2.2(1.9). Regarding the 150mg presentation, 2(8.3%) patients reported having bruises at the injection site and regarding the 300mg presentation, 3(12.5%) reported having suffered swelling that reverted spontaneously. Two(8.3%) had to discontinue the 300mg presentation due to severe pain during administration. Regarding change satisfaction, 1(4.1%) referred to the change as indifferent, 2(8.3%) as not satisfactory and 21(87.5%) as satisfactory, with the average satisfaction being 8.0(2.2).

Conclusion and Relevance

- Changing from 150mg to 300mg secukinumab pen presentation was considered satisfactory for 87.5% of patients.
- Two patients suffered greater pain during administration, leading to a return to the previous presentation.
- It would be advisable to carry out additional follow-up in order to detect possible reactions at the administration site or greater pain after the change of presentation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-078 ANALYSIS OF CASIRIVIMAB AND IMDEVIMAB USE IN OUTPATIENTS WITH COVID-19

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Background and Importance At height of COVID-19 pandemic surge of delta variant, monoclonal antibodies became a vital treatment option for SARS-COV-2 positive outpatients at high risk of severe disease progression. Casirivimab and imdevimab (C/I) were used under EMA emergency use authorisation (EUA) and there was paucity of real-world data on safety and effectiveness.

Aim and Objectives The study aimed to describe drug safety, self-reported symptom burden and vaccination status in SARS-COV-2 positive outpatients within 90 days post-C/I infusion.

Material and Methods Prospective multicentric survey of SARS-CoV-2 positive outpatients with mild symptoms at high-risk of severe COVID-19 progression (defined criteria under EUA authorisation for C/I ambulatory administration) was conducted from September 2021 till January 2022 in three teaching hospitals. The data collected using electronic medical records comprised: patient details, vaccination status, date of SARS-COV-2 positive test, indication, adverse drug reaction to infusion, hospitalisation. Structured telephone questionnaire with symptom scoring adapted from BLAZE-1 trial was used on D (day) 0, D+7, D+29 and D+90 post- C/I infusion. Data were analysed using MS Excel. Ethics committee approval was obtained.

Results Within studied period 404 out of 471 patients were included (median age 66 years; 57.4% females). Excluded patients included prophylactic C/I, not consented or dropped out. 396 patients had the first COVID-19 episode. The most frequent indications included age over 65 years (55.5%), hypertension (56.8%), diabetes mellitus II (19.4%). C/I infusion was administered with a mean of 2.3 days (range 0–11 days) since virus positivity. 62.4% patients had complete vaccination (2 or 3 doses Comirnaty, 1 dose Janssen vaccine) prior C/I infusion. Adverse events were reported by 11.6% of patients, most commonly chills, fever, diarrhea. Subjective worsening of symptoms after C/I infusion was reported by 3.4% subjects by D+7. 11.6% patients observed no difference in symptom score between D0 and D+7. Altogether 85%; 92% and 93.6% patients reported improvement in symptom burden score by D+7, D+29 and D+90 respectively.

Conclusion and Relevance We describe real-life outpatient utilisation of C/I in terms of patient characteristics, self-reported symptom burden and adverse events. Therapeutic value of C/I timely administration is evident in high-risk patients with completed vaccination.

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Conflict of Interest No conflict of interest

5PSQ-079 FONDAPARINUX IN AN INFANT WITH SUSPECTED HEPARIN-INDUCED THROMBOCYTOPENIA. A CASE REPORT

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Background and Importance A 3-month-old infant (3kg) was admitted in the paediatric intensive care unit for extracorporeal membrane oxygenation (ECMO) after a pulmonary lobectomy.

Anticoagulant treatment was performed with unfractionated heparin (UFH).

During treatment with UFH, the patient had a sustained decrease in platelet count (>50% of basal) and inferior cava deep venous thrombosis (DVT). Once ECMO was finished, anticoagulant treatment was modified to enoxaparin.

Due to persistent thrombocytopenia and DVT, heparin-induced thrombocytopenia was suspected. Anticoagulant was replaced to fondaparinux, whose recommended dose in paediatrics is 0.1mg/kg/day.

Aim and Objectives To show the need to redose fondaparinux in paediatrics, as registered presentations don't allow fractionation: they are single-dose pre-filled syringes based on two concentrations: 5mg/ml and 12.5mg/ml.

To verify the stability of the preparation through the study of the pharmacotherapeutic effect, indirectly measured by plasma levels of anti-Xa factor (antiXa).

Material and Methods Subcutaneous fondaparinux was started at a dose of 0.3mg/day (0.06mL). To facilitate administration, the preparation was initially diluted 1mg/mL in normal saline under sterile conditions. The dose was packaged in 1ml dead space free syringe with a purged needle. According to the datasheet, the preparation is stable for 24h at room temperature.

AntiXa was monitored 3 hours after administrations. The dose was adjusted according to Table1 until the target level (0.5mg/l) was reached.

Subsequently, as the dose increase allowed, the undiluted dose (0.4mg/0.08ml) was fractionated from commercial presentation. Stability of 7 days in the refrigerator was defined according to the risk matrix (low risk) of the Good Pharmaceutical Practices for the preparation of sterile drugs.

Results The dose was adjusted according to antiXa (Table2). The monitoring of antiX, necessary for the clinical follow-up, allowed us to obtain indirect data on the stability of the fractionated drug, maintaining correct levels throughout treatment, as shown in graph.

After fondaparinux initiation, the platelet count increased to normal values. Anticoagulation therapy was discontinued after three months, upon confirmation of DVT resolution.

We verify stability of the fractionated dose with the therapeutic effect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-083

FOUR YEARS OF A PHARMACEUTICAL CARE PROGRAMME IN PATIENTS UNDERGOING CARDIAC SURGERY

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Background and Importance The preoperative setting is an area with high risk for medication errors with potentially severe consequences. Pharmaceutical care programmes(PCP) can help to achieve an adequate preoperative pharmacological management, to ensure patients reach surgery in optimal pharmacological conditions. Adequate coordination with other specialists such as surgeons and anaesthetists is paramount to guarantee patient safety.

Aim and Objectives To evaluate the impact of a PCP in patients undergoing cardiac surgery in preventing medication errors after 4 years of implementation.

Material and Methods Retrospective, observational, descriptive study. Time of study: July 2018-July 2022. All patients scheduled for cardiac surgery were interviewed by a clinical pharmacist 24-72h before the surgery. Interviews were conducted by phone. During the interview, patients' complete medication list, including over the counter medicines and herbal products, was collected and instructions for adequate preoperative medication management according to current guidelines and anaesthetist instructions were reinforced.

Avoided medication errors were categorised according to Overhage-classification and their severity was analysed according to NCC-MERP.

Savings were calculated by multiplying the probability of adverse event occurrence with the error(NCC-MERP \geq F:high risk of admission or prolonged hospital stay) by avoided cost (6.745€ according to Ministry of Health, Consumer and Social Welfare).

Results During the time of study, 1020 pharmacist preoperative interviews were performed. Mean age was 66.8(sd:12.6) years and 65.8% of the interviewed patients were males.

41.8% of patients were taking at least one drug that needed to be discontinued before surgery. The most frequent were angiotensin-converting enzyme inhibitors, angiotensin-II receptors blockers and diuretics(23.6%), anticoagulants and antiplatelet treatment(22.2%) and hypoglycaemic treatment (11.4%). 43.5% of patients needed heparin bridge therapy.

A total of 807 pharmacy interventions were conducted with 94.2% of acceptance rate: 533 requirements to discontinue drugs before surgery(70.1%), 81 dose error(10.7%), 49 drug omission(6.4%), 32 associated with duration, frequency or indication(4.2%).

673 serious errors were avoided, 236(31.1%) of these errors could have resulted in permanent harm(G/H), 277 (36.4%) in temporary harm(E/F) and 160(21.1%) monitoring patients to confirm no harm(D).

Potential medication errors avoided an estimated cost of 992.130€.

Abstract 5PSQ-079 Table 1

TABLE I. Dose Adjustment of Fondaparinux

| Level (mg/L) | Dose adjustment |
|--------------|-----------------------------|
| <0.3 | Increase dose by 0,03 mg/kg |
| 0.3 - 0.5 | Increase dose by 0,01 mg/kg |
| 0.5 - 1 | No change |
| 1 - 1.2 | Decrease dose by 0,01 mg/kg |
| > 1.2 | Decrease dose by 0,03 mg/kg |

TABLE II. Dose Adjustment of Fondaparinux in our Patient

| Day* | Dose (mg) | Fxa (U/mL)** | Dose adjustment |
|---------|-----------|--------------|-----------------|
| 1 - 2 | 0,3 | 0,38 | ↑ 0.01 mg/kg |
| 3 - 4 | 0,35 | 0,32 | ↑ 0.01 mg/kg |
| 5 - 8 | 0,38 | 0,44 | ↑ 0.01 mg/kg |
| 9 - 40 | 0,4 | 0,5 | No change |
| 41 | 0,4 | 0,4 | ↑ 0.01 mg/kg |
| 42 - 78 | 0,5 | 0,54 | No change |

*Day of treatment with Fondaparinux

**Plasmatic levels 3h post-administration of Fondaparinux

Conclusion and Relevance Individualised dosing of fondaparinux by dilution or fractionation has allowed DVT treatment, using a commercial presentation unsuitable for paediatric s.

Conclusion and Relevance A PCP in patients undergoing cardiac surgery was successfully implemented, ensuring a correct preoperative drug management, with 0.8 severe medication errors avoided per patient that was interviewed and potential savings of 992.130€.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-084 ASSESSING QUALITY OF LIFE OF PATIENTS WITH SEVERE ASTHMA MEASURED BY PATIENT REPORTED OUTCOMES

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Background and Importance Severe asthma, which affects approximately 5-10% of people with asthma, is a heterogeneous, chronic and complex disease. It usually has a negative physical, mental, emotional and social impact.

Aim and Objectives To analyse quality of life of patients with severe asthma currently treated with biological drugs using Patient Reported Outcomes Measures (PROM).

To identify the domains and specific questions most frequently altered, by using mini-AQLQ.

Material and Methods A descriptive cross-sectional study between April-May 2022 in a tertiary hospital was carried out. Adult patients with severe asthma on active treatment with a biological drug for at least one year who provided informed consent were included.

Electronic medical records were reviewed to obtain:

- Age, sex
- Number of asthma-associated comorbidities
- FEV1 and FEV/FVC

A telephone interview was also conducted to record the PROMs:

- Mini-AQLQ (maximum score: 7)
- EQ5D-5L (maximum score:1) (with Visual analogue scale, score 0-100 (VAS))

Results Fifty-five patients who met the inclusion criteria were identified. 38 who agreed to participate were located. Median age was 65 years (56-71.5) and 60.5% (23) were female. Median number of asthma-related comorbidities was 2.5 (1-4). FEV1 and FEV/CVF were 76.3% (SD=3.2) and 69% (SD=1.3) respectively.

The mean score for the EQ5D-5L was 0.924 (0.818-1), while the median VAS was 70 (60-85).

The average score for the mini-AQLQ was 6.1. By domains, environmental had the worst mean (5 (4.3-6.3)), followed by limitation of activities (6.1 (5.5-6.7)), symptoms (6.2 (5.8-7)) and emotional (7 (5.3-7)).

Three (0.8%) patients did not have any disturbances in the responses, but a 81.6% (31) had altered limitation of activities, 79.3% (29) environmental, 73.7% (28) symptoms and 55.3% (21) emotional.

Specifically, the question that most frequently receive a score below 7 was 'did you feel that tobacco smoke bothered you or did you have to avoid a place because of tobacco smoke?' in 76.3% (29) patients.

Conclusion and Relevance The quality of life of patients with severe asthma treated with biological drugs is good, according to specific asthma questionnaires used as PROM, although few patients do not have any altered sphere.

The most altered sphere was environmental. Tobacco is considered a major threat.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-086 ANALYSIS OF POTENCIALLY INAPPROPRIATE PRESCRIPTION IN A NURSING HOME

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Background and Importance Potentially inappropriate medication prescription can increase the risk of adverse drug reactions (ADRs). Therefore, multiple tools have been developed to detect inappropriate prescriptions. STOPP (Screening Tool of Older Person's Prescriptions)/START (Screening Tool to Alert to Right Treatment) criteria is one of them.

Aim and Objectives To analyse inappropriate prescriptions (IP) or the need of potential prescriptions in polymedicated institutionalised patients in order to improve patients safety.

Material and Methods A descriptive, transversal study was performed in September 2022. We included all polymedicated residents (>6 drugs) of a nursing home attached to a Pharmacy Department. Data collect were age, sex, number of medications/resident and drugs prescribed. STOPP/START criteria v.2. was applied to detect inappropriate prescriptions or the need of potential treatment. Data were collected from electronic prescription programme ATHOS-Prisma and computerised medical record Diraya.

Results A total of 50 patients were included, 66% men. The median age was 73 years (range: 69-83). Average drugs prescribed by residents was 10 (6-21).

Seventy-two percent of the residents (36) presented at least one STOPP criteria. Total IPs were 142, with an average of 5 IPs per resident (0-7). Most prevalent were treatment duration longer than defined (72%), prolonged use (> 4 weeks) of benzodiazepines (72%), drugs that adversely affect fallers (most related to benzodiazepines) (72%) and prescription of two drugs within the same class (22%).

Regarding START criteria, 23 residents (42%) presented any prescription initiation criteria. The total potential prescribing omission were 26, with an average of 1 per resident (0-2). The most common were: use of laxatives in patients with opioid treatments (47,8%) and vitamin D supplements in older patients (34,8%).

Conclusion and Relevance STOPP criteria was the most frequently found. The majority related with inappropriate duration or duplicity of benzodiazepin treatment.

For START criteria, the indication of laxatives for patients receiving opioids on a regular basis was the most frequent potential prescribing omission.

The use of STOPP/START criteria could improve patients safety, which are able to detect the inappropriate prescription

of some drugs in addition to the omission of potential indicated medication.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-087 EVALUATION OF THE EFFECTIVENESS OF LAMIVUDINE IN THE PROPHYLAXIS OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS WITH HAEMATOLOGICAL DISEASES

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Background and Importance The use of lamivudine as prophylactic treatment in patients with past hepatitis B virus (HBV) infection and on treatment with drugs considered at high risk of reactivation has been associated with a higher likelihood of reactivation compared to the use of other antivirals.

Aim and Objectives To evaluate the effectiveness of lamivudine in the prophylaxis of HBV reactivation in patients with haematological disease, undergoing immunosuppressive or chemotherapy treatment and presenting positive serology for HBV.

Material and Methods Observational and retrospective study including all haematological patients over 18 years of age who started HBV prophylaxis between January 2018 and December 2020 in a tertiary hospital. Follow-up was performed from the start of treatment until December 2021 to observe whether HBV reactivation occurred.

Electronic medical records were reviewed and the following variables were collected: demographic data (age and sex), haematological diagnosis, immunosuppressive or chemotherapy treatment received, analytical data (HBsAg, HBeAg, HBcAb, HBsAb, HBV DNA, transaminases) and HBV prophylactic treatment.

Results In the study period, 65 patients started HBV prophylaxis, of which 3 patients were excluded due to false positive. Sixty-two patients (33 women) were reviewed, with a median age (range) of 70 years (20-91). Diagnoses were lymphomas (26 patients), monoclonal gammopathies (13), chronic lymphoproliferative syndromes (7), autoimmune diseases (6), acute leukemias (5), chronic myeloproliferative syndromes (4) and bone marrow aplasia (1).

Out of the 62 patients, 60 patients were HBsAg negative and anti-HBc positive at the initial serological control. All of which received lamivudine prophylaxis. The other 2 patients had chronic HBV infection at the start of prophylaxis, with positive HBsAg, positive anti-HBe and undetectable HBV DNA. One of them started prophylaxis with tenofovir, and the other received lamivudine as prophylaxis.

Of the patients who started lamivudine prophylaxis, 60.7% were being treated with drugs considered at high risk of reactivation (rituximab, doxorubicin or idarubicin).

No patient had either clinical reactivation or detectable HBV viral load during the study period. Fourteen patients died during follow-up due to non-HBV causes.

Conclusion and Relevance In our patients, 60.7% of whom received high-risk drugs, no reactivation event occurred. Lamivudine has proven to be effective in the prophylaxis of HBV reactivation in our study population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-091 TRIFECTA™ BIOPROSTHESES : EVALUATION OF THE SAFETY BASED ON THE STUDY OF DEGENERATIONS ACCORDING TO THE VARC-3 CLASSIFICATION

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Background and Importance In 2021, cardiologists reported to the medical-devices-vigilance sector serious incidents in four patients with a first-generation Trifecta™ bioprosthesis that resulted in three aortic valve replacement (AVR) and one death. The question of degeneration of their bioprosthesis arose.

Aim and Objectives The aim was to evaluate the intrinsic imputability of Trifecta™ for dysfunction in patients implanted and to reassess their referencing in our centre.

Material and Methods A retrospective, single-centre and observational study of computerised patient records (CPR) was conducted between 02/04/2011, date of our centre's first implantation, and 12/31/2016 to have 5 years of follow-up per patient.

Trifecta™ valves and data related to the implantation were extracted from the traceability software. The collection of echographic and clinical follow-up data was based on the CPR with an extended follow-up period until 03/31/2022.

Dysfunctions were classified according to the VARC-3 classification criteria : structural valve deterioration (SVD), non-structural valve dysfunction (NSVD), thrombosis and endocarditis.

The study was approved by our local research department. **Results** A total of 382 bioprostheses was implanted in 378 patients, mean age 73.0 years and 60.7% male. Data were missing for 253 bioprostheses and 15 patients died perioperatively. Among the 114 bioprostheses with conclusive data, 50 functioned properly (mean follow-up time of 6.6 years) and 64 presented dysfunctions : 34 SVD, 10 NSVD (8 paravalvular regurgitation, 2 prosthesis-patient mismatches) and 20 endocarditis. AVR occurred for 20 patients following SVD and for 11 patients following endocarditis (4 of whom had a second Trifecta™) within a mean time of 6.7 years and 3.4 years, respectively.

Conclusion and Relevance The classification of failures according to VARC-3 allowed us to confirm the intrinsic imputability of the Trifecta™ bioprostheses regarding to the number of SVD-type dysfunctions. Although this study has limitations, it shows the understatement of medical-devices-vigilance cases by the medical staff. The 64 files with dysfunctions will be transmitted to the national health authority. The patients will be reviewed to complete the data and perform an echographic follow-up. According to the manufacturer, degenerations could be related to the expansion system that was improved in the second-generation Trifecta™ marketed in 2016. Since this study, the Trifecta™ has been removed from the hospital formulary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-093 PHARMACEUTICAL INTERVENTION AFTER INAPPROPRIATE PRESCRIPTION OF ZOLPIDEM

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Background and Importance Zolpidem is a benzodiazepine-like hypnotic that acts on GABA-omega receptors in the central nervous system. It is indicated for the short-term treatment of insomnia in adults.

In 2014, an informative note was published by The Spanish Medicines and Medical Devices Agency (AEMPS) recommending a dose of 5mg/day in elderly patients (over 65 years old), instead of 10mg (usual dose), in order to reduce the number of cases of alterations in attention and concentration capacity, including parasomnias.

Aim and Objectives Evaluate the impact of hospital pharmaceutical intervention (PI) on the prescription of zolpidem after the publication of the AEMPS informative note.

Material and Methods Multicentre and prospective intervention study which includes all patients admitted to treatment with zolpidem. The study interval was from September 2021 to September 2022. The variables collected were the following: age, sex, dosage and prescription of zolpidem as home treatment. Clinical records (Diraya[®]) and the electronic prescription program (Prisma[®]) were reviewed. The IF consisted of sending an informative note to the doctor responsible for the patients who did not comply with the AEMPS recommendation. **Results** A total of 62 patients were included (mean age: 72 ± 15 years; sex: 37 men). PI was performed in 59.7% (37/62) because the prescription was not adjusted to the AEMPS alert. Regarding the 37 patients with inappropriate prescription, the dose was reduced to 5mg/day in 37.8% (14/37) of the cases. The dose of the rest of patients, 62.2% (23/37), was not change, of which 87% (20/23) had the origin of the prescription at the primary care level.

Conclusion and Relevance The acceptance of the PI was performed in a low number of cases due to the fact that the origin of zolpidem prescriptions is primary care. This creates the need to establish channels of communication between the primary care physician and the hospital pharmacist to report possible errors detected in their prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-094 TOXICITY IN PATIENTS TREATED WITH VENETOCLAX. A SAFETY STUDY IN REAL-WORLD PRACTICE

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Background and Importance Venetoclax acts as an inhibitor of the anti-apoptotic protein Bcl-2, which is increased in Chronic Lymphocytic Leukemia (CLL) and Acute Myeloid Leukemia (AML). It is described on its label the frequent occurrence of haematological toxicity, among other adverse events (AE).

Aim and Objectives 1) To evaluate the haematological toxicity of venetoclax during dose escalation and; 2) To describe AE associated with venetoclax during treatment.

Material and Methods Multicentre, observational, retrospective study in patients who initiated venetoclax until 01/06/2022 with a treatment period ≥ 3 months. Variables collected: sex, age, diagnosis, treatment schedule, hemoglobin, neutrophil and platelet levels at baseline and after dose escalation and; AE developed during treatment appearance as well as its gravity according to Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

Hematologic toxicity during escalation was analysed using Student's t-test (SPSS Statistics 25.0).

Results 41 patients initiated venetoclax, of whom 33 maintained treatment ≥ 3 months (63.6% male, mean 68.7 ± 9.7 years). Diagnosis (CLL: 20, AML: 10, myelodysplastic syndrome: 3), treatment schedule [monotherapy: 2; bitherapy (rituximab: 16, azacitidine: 13, decitabine: 1, obinutuzumab: 1)]. 5 patients required dose adjustment due to concomitant use of azoles (posaconazole: 2, voriconazole: 2, fluconazole: 1).

Mean hemoglobin at baseline and after dose escalation (10.6 ± 1.9 vs 10.8 ± 2.1g/dL; p=0.282), mean neutrophils at baseline and after dose escalation (1,667.6 ± 1,064.9 vs 1,237.3 ± 1,011.5/μL; p=0.001), mean platelets at baseline and after dose escalation (120,060.0 ± 77,662.3 vs 116,121 ± 77,012.0/mm³; p=0.697). AE developed during treatment: anaemia (G2:3, G3:4), neutropenia (G1:1, G2:6; G3:6, G4:4), thrombocytopenia (G2:1, G3:4), asthenia (G1:2, G3:1), bradycardia (G2:1), diarrhoea (G1:1), fever (G1:1), hypertransaminemia (G2:1), mucositis (G1:1), pneumonia (G2:2, G3:3), tumour lysis syndrome (G3:2). During treatment, 15 patients required discontinuation of treatment (restarts: 7) and 5 required dose reduction.

Conclusion and Relevance During dose escalation, the main haematological toxicity of venetoclax was neutropenia. This adverse effect also occurred more frequently during maintenance treatment. We consider it relevant to carry out serial haematological controls in patients treated with venetoclax.

Limitations of the study: retrospective study with a small sample size; therefore, it is considered necessary to perform more studies to confirm the results presented.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. 27 November 2017.

Conflict of Interest No conflict of interest

5PSQ-095 CARDIAC CONDUCTION DISORDERS ASSOCIATED WITH THE USE OF TRICYCLIC ANTIDEPRESSANTS IN THE ELDERLY

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Background and Importance Tricyclic antidepressants (TCAs) block sodium channels in the heart, which can prolong the QT interval and cause arrhythmias. Patients over 64 years of age are at increased risk of these side effects.

Aim and Objectives To conduct a systematic review of the cardiac effects of TCAs in patients older than 64 years. As a secondary objective, the frequency of TCAs prescriptions in patients older than 64 years with cardiac conduction disorders (CCD) was analysed, reviewing concomitant treatments.

Material and Methods A systematic review of the published scientific literature was conducted following PRISMA Declaration. In addition, a descriptive cross-sectional study was carried out, including all patients over 64 years of age receiving TCAs treatment. An anonymised database containing the variables age, sex, and prescribed medications was used.

Results After the search, 5 articles were included in the qualitative synthesis. A study concludes that TCAs cause CCD, but without clinical compromise. The second shows an association between the use of TCAs and sudden death in patients with previous heart disease (HD). Another study concludes that normal doses of TCAs in patients with severe HD are equivalent to toxic doses in patients without HD. The fourth shows no correlation between serum sodium levels, electrocardiogram changes, and severity of TCAs toxicity. The latest study shows that prolonged exposure to TCAs is also related to the occurrence of coronary disease events in patients without known HD. The prescriptions of 63 patients receiving TCAs with a median age of 70 (65-88) years were reviewed. No patient had prescribed treatments for CCD, however, 49,2% of patients had prescribed ³¹ drug that prolongs the QT interval.

Conclusion and Relevance The literature reviewed reveals CCD caused by TCAs. In the data sheet of TCAs, their use is contraindicated in patients with previous HD. In our sample, the prescription of TCAs is appropriate; however, we recommend that in patients over 64 years of age without CCD, electrocardiograms be performed before starting treatment with TCAs and periodically. In addition, after verifying the high frequency of prescription of drugs that prolong the QT interval, we believe that it is essential to review the concomitant medication, looking for therapeutic alternatives for these drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-096 A PROSPECTIVE OBSERVATIONAL STUDY OF MEDICATION PRESCRIBING ERRORS IN AN EMERGENCY DEPARTMENT

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Background and Importance Prescribing errors (PE) are an important cause of medication-related adverse events in the Emergency Departments (ED) but limited data are available in ED with *electronic* prescribing and *administration* (ePA) systems. Knowing the frequency and types of PE can help healthcare professionals to prevent and reduce the risk of them occurring.

Aim and Objectives To determine the rate of PE in the ED, to classify incident types and to identify critical points where measures should be implemented to improve patient safety.

Material and Methods Prospective, observational and cross-sectional study in an ED with ePA system during 6 working days (May-June 2021). The inclusion criteria were patients stayed more than 8 hours in the ED and all patients awaiting hospitalisation. Prescriptions were analysed by a multidisciplinary team made up of two pharmacists, an emergency physician and the person in charge of the hospital's medication errors committee. PE were reported to the hospital's patient safety-related incident notification system.

Results Of the 65 prescriptions revised during the study period, PE were reported in 84 cases and 15 situations with the capacity to cause errors were detected. The average age of patients was 67 ± (SD=17,9) years and each prescription had an average of 8.4 medications. The rate of PE was 1.52 errors per patient, being higher in less severe patients than monitored patients (1.09 vs 2.0 PE per patient, respectively). The most common types of EP were omission of the usual medication (60.7%), wrong dose (15.5%), wrong frequency (7.1%) and drug is not indicated (7.1%). No adverse reactions related to EP were detected. According to the Spanish consensus about *Medication Reconciliation in Emergency Units*, 47.1% of omissions of usual medication were drugs that should be reconciled during the first 4 hours in the ED. The results of the study and the importance of medication reconciliation are highlighted in a session in the ED.

Conclusion and Relevance The PE rate in the ED was 1.52 per patient and the main type was omission of the usual medication. A cross sectional study will be made in the future and compared to the current one to establish the impact of the implemented measures on the PE rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-097 HEALTH ALERT OF TOFACITINIB AND PHARMACEUTICAL INTERVENTION

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Background and Importance Tofacitinib is a selective inhibitor of the janus kinase family indicated for the treatment of various rheumatological pathologies such as rheumatoid arthritis (RA) and psoriatic arthritis (PsA) and used, off label, in pathologies such as alopecia areata (AA).

The Spanish Medicines and Medical Devices Agency (AEMPS) released in July 2021 a safety alert stating that patients over 65 years of age, smokers or ex-smokers and with cardiovascular risk factors or with a predisposition to the development of neoplasms, should not receive treatment with tofacitinib unless no other available therapeutic alternative can be used, based in the results from the ORAL Surveillance clinical trial. Health policy in Andalucía establishes the need to follow-up on the application of the safety notes issued by the AEMPS regarding prescriptions of drugs.

Aim and Objectives Evaluate the pharmaceutical intervention on the review of tofacitinib prescriptions to ensure their adaptation to the criteria established by the AEMPS, according to the Andalusian regional regulations.

Material and Methods Retrospective review of tofacitinib prescription in a tertiary hospital. All patients on treatment with

tofocitinib from July 2021 to February 2022 were included. Variables collected were age, sex, risk factors included in the health alert and continuation or discontinuation of treatment.

Results A total of 71 patients receiving tofacitinib treatment were included (mean age: 41 ± 16; sex: 74.6% women). The treatment was discontinued in 25.4% (18/71) of the patients due to inefficacy, adverse reactions or presenting at least one risk factor. However, 74.6% (53/71) of the patients continued treatment, with 43.4% (23/53) having at least one risk factor. Results were shown to the Pharmacy Commission, where the pharmacist developed a protocol regarding tofacitinib safety issues.

Conclusion and Relevance This is the first experience in our hospital regarding the global monitoring of safety notes released by the AEMPS, endorsed by autonomic regulation. Despite the presence of risk factors, tofacitinib was not withdrawn nor justified in a high percentage of patients. This finding underlines the relevance of systematic patients follow-up and the need to develop protocols agreed by the pharmacists and involved physicians.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-099 ADEQUACY OF SOTROVIMAB PRESCRIPTION IN SARS-COV-2 INFECTION IN A UNIVERSITY HOSPITAL

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Background and Importance The Spanish Medicines and Health Products Agency (AEMPS) has developed criteria to adapt the prescription of sotrovimab¹, due to the pandemic situation and the limited drug stock.

Aim and Objectives To describe the patients' population on treatment with sotrovimab and to assess the adequacy of this prescription according to the criteria established by the AEMPS.

Material and Methods Retrospective observational study analysing all sotrovimab prescriptions in patients with SARS-CoV-2 infection from 01/25/2022 to 08/31/2022.

Demographic variables and data required by the AEMPS for sotrovimab prescription were collected: Omicron variant infection, SARS-CoV-2 vaccination status, serology [anti-S antibody <260 BAU (binding antibody units)/mL]. Also, patients had to belong to one of the following groups:

- Group 1: Immunocompromised, regardless of vaccination status.
- Group 2: >80 years unvaccinated.
- Group 3: >65 years (regardless of vaccination status) and ≥1 risk factor for progression.

Prescriptions for sotrovimab were collected and analysed to determine whether they met the criteria and whether they were accepted. Data collected from electronic medical records and processed using Excel2019[®].

Results Fifty patients were included, 62% male; median age 69 years (IQR=60-76). 100% had the Omicron variant. Vaccination status: 84% complete, 6% incomplete and 10% unvaccinated. Serology: 96% (<260 BAU/mL) and 4% (>260 BAU/ml). 92% belonged to group 1 (39% solid organ transplantation, 29% active myelotoxic chemotherapy, 13% non-cytotoxic

onco-haematological treatments with neutropenia/lymphopenia, 13% treatment with biological immunomodulators, 2% Down's syndrome, 2% haematopoietic stem cell transplantation or CAR-T, 2% HIV infection (with ≤200 cells/mL). Two per cent belonged to group 2. The remaining patients (6%) did not belong to any group. Ten per cent of the applications did not meet the criteria: four of them were not accepted (patients did not belong to any risk group); one was accepted, although it was a well-controlled HIV.

Conclusion and Relevance The main profile of patients treated with sotrovimab is men with solid organ transplantation, vaccinated and with negative immunity to SARS-CoV-2. Although the appropriateness of the prescription is high, it is necessary to continue protocolising the use of this drug to ensure its rational use.

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Conflict of Interest No conflict of interest

5PSQ-100 UTILITY OF SOCIAL MEDIA AS A SOURCE OF PAEDIATRIC DRUG SAFETY, A SYSTEMATIC REVIEW

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Background and Importance Paediatric population are predisposed to have more adverse drug reactions (ADR) and other drug related problems (DRP). Social media (SM) could be an innocuous source of pharmacovigilance.

Aim and Objectives Assess ADR and DRP evidence reported in SM.

Material and Methods A systematic review according PRISMA recommendations was conducted in MEDLINE, Embase and LILACS. Articles in English, Spanish and Catalan languages from inception up to September 2021 were reviewed using search terms related to paediatric age, SM and DRP. In the screening phase, articles not mentioning paediatrics and SM were excluded including grey literature. In the eligibility phase, articles related to non-pharmacological treatments/substances, surveys, recruitment protocols, sociological studies, professional use of SM and technological implementation were excluded. Articles including information about commonly used drugs in paediatrics were evaluated. Demographic variables, SM platforms, medicines and type of information (ADR, DRP or experiences and opinions (EO)) were analysed.

Results 6079 articles were assessed and 28 (0,4%) met the inclusion criteria. 16 (57%) studies were qualitative, 6 (21%) quantitative and qualitative and quantitative 6 (21%). When mentioned, most articles analysed data from parents/caregivers (10;36%) and adolescents (2;7%). Gender of SM users was not systematically reported but females were reported in 7 (25%) articles in a range in of 22-77%, in an article 245 females compared to 74 males and one referred that posts were

mostly from mothers of young children. Most articles included data from forums (13;46%), Twitter (5;18%) and Facebook (6;21%). 17 (61%) reported information about vaccines, 3 (11%) asthma medications and 8 (28%) other medicines. 8 articles (28%) reported an ADR including tremor, auto-injector wounds and vaccine ADR. Only in one article the severity was reported. EO were reported in 25 (89%) studies and 10 (36%) articles mentioned a DRP. Studies reported lack of adherence (4;14%), difficulties (3;11%) or doubts (2;7%) about drug administration of asthma inhalers (2;7%), epinephrine auto-injector (1;4%), antibiotics (1;4%), oral drugs (1;4%), ophthalmic drugs (1;4%) and topical drugs (1;4%).

Conclusion and Relevance Articles evaluating pharmacological drugs in paediatrics focused mostly on EO and scarce data about ADR and DRP were mentioned in SM. Consequently, more studies are required to take advantage from SM as a potential tool in paediatric pharmacovigilance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-101 ANALYSIS OF HIP PROSTHESES OVER A YEAR

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Background and Importance One of the most common orthopedic operations is the prosthetic replacement of the hip joint. To judge the choice of a prosthesis, we often lack factual data.

Aim and Objectives Our objective is to assess whether the recommendations of the High Health Security are respected and to analyse their average costs to optimise pharmaceutical validation by creating a prescription sheet for orthopedic implants.

Material and Methods Census of the various interventions was carried out during the year 2019 by type of act: Total Hip Prostheses (THP); Intermediate Prosthesis (IHP); Repeats (REP); Rebuilds (REB).

Analysis of the different friction couples (head/insert): Ceramic/polyethylene (C/PE); Metal/PE (M/PE); Ceramic/Ceramic (C/C).

The software used for data collection is ACCESS and for statistical analysis is SPSS.

Results 140 hip interventions in 2019 including: 34 HIP; 88 THP; 16 REP; 2 REB. Ages according to the type of operations carried out: 25.71% (≤ 50 years); 12.85% (50-70 years); 61.44% (≥ 70); with the distribution according to the type of prosthesis: THP (mean age 75 years); IHP (82 years); REP (47 years). Clinical indications were coxarthrosis 39.23% (THP); Femur fracture 14.28% (HIP, THP); Osteonecrosis 7.14% (THP); Rheumatoid arthritis 10.71% (IHP); Dislocation 17.81% (REP). Friction couples used were C/PE 3.57%; M/M 13.71%; C/C 82.72% distributed according to CLAS rating: competition (100% C/C), activity (78.7% C/C), leisure (80.8% M/PE), sedentary (100% M/PE). Breakdown of the average cost according to the allocated budget was 62.85% THP, 24.28% HIP, 8.57% REP, 1.42% REB.

Conclusion and Relevance The study showed that the most frequent interventions are IHP and THP, IHP are placed in very elderly patients in whom osteosynthesis is not possible, the C/C couple is reserved for people under the age of

50, with a level of activity and a life expectancy. Finally, we noticed that the most costly intervention is THP. Results are in accordance with the recommendations of the HAS. This study allowed us to create a prescription sheet from the analysis of these data indicating: identification of the patient specifying age and activity; clinical indication and type of prosthesis and friction. This procedure optimises the pharmaceutical validation by directing the clinician towards the right medical and pharmacoeconomic choice of the prosthesis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-102 SAFETY EVALUATION OF MIDLINE CATHETERS USED FOR ANTIBIOTIC THERAPY

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Background and Importance In patients with difficult intravenous access or those who require short-term intravenous drug administration, midline catheters (MLC) can be a safe alternative to peripherally inserted central catheters (PICCs).

Aim and Objectives The objective of this study is to describe outcomes in patients who had a midline placed for the indication of antibiotic therapy.

Material and Methods This cohort study analysed data from hospital registry including patients who had a midline placement for intravenous antibiotic therapy. Patient demographics and clinical data (diagnoses, comorbidities, medications, laboratory values, antibiotic use and duration of infusion therapy), and device variable (placement arm and vein of insertion, catheter gauge, and number of catheter lumens) were abstracted directly from medical records. Data were analysed from June 2021 to September 2022.

Results Sixty-nine patients with MLC were included for analysis, 68% were male and mean age was 70 years (range 28–96). The most common diagnoses were bloodstream infection (46.4%), respiratory tract infections (17.4%) and urinary tract infections (14.5%). The most prescribed antimicrobials were piperacillin-tazobactam (52.2%), ertapenem (19%) and meropenem (11.6%).

In total 69 MLC were placed, totaling 952 catheter-days, with an average midline dwell-time of 14 days (range = 2–43 days; median = 12 days). Total complications were 31.9%, including four (5.8%) ‘leak’, fourteen (20.3%) catheter obstructions, two (2.9%) phlebitis and one (1.45%) thrombosis. In addition, one patient presented a grade I infiltrations (INS Infiltration Scale). There were no confirmed or suspected bloodstream infection.

Conclusion and Relevance In this study, the MLC complication rate was 31.9%. The complications were mostly mechanical (81.8%) and did not require the suspension of the antibiotic therapy or the withdrawal of the catheter.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-103 PARENTAL UNMET NEEDS ON PAEDIATRIC DRUGS EXPRESSED IN FORUMS

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Background and Importance Social Media (SM) could be a source of unmet needs of parents about drug use in paediatrics. Knowing subjective information (SI) can lead to improve pharmaceutical care.

Aim and Objectives Analyse content of posts from parent forums (PF).

Material and Methods Observational, ambispective study on PF related to primary care medicines in paediatrics. PF were selected if included child-health sections in Catalan, Spanish or English and permission was obtained. Data mining software was developed using ontologies from Spanish Agency of Medicines and Medical Devices and Medical Dictionary for Regulatory Activities. Posts were excluded if written by professionals, referred to non-pharmacological treatments, adults, pregnancy, hospital drugs, non-original entries or duplicates. SI was classified into positive, negative or doubts according tone and adjectives expressed.

Results 3572 posts from two PF were downloaded, 821 (26%) analysed. Excluded entries (94;11%): non-pharmacological treatments (42;5%), hospital drugs (12;1%), adults (12;1%), non-original entries (9;1%), pregnancy (2;0,02%) or duplicates (2;0,02%). 444 (72%) users mentioned SI in 591 posts (1,3 SI/post). Notifier were mainly parents (177;40%) and caregivers (233;52%). SI posts contained neutral (223;38%), doubts (259;44%), negative (63;10%), positive (47;8%) SI. Posts referred to 453 children, infants (28 days-23 months) (156;26%) and children (3-11 years) (107;18%) and not classified (190;56%). Reported drugs: antibiotics (214;36%), respiratory (99;17%) and nervous system (78;13%) medications, other (200, 34%). Routes: oral (330;56%), parenteral (123;21%), other (138, 23%). Topics reported were:

| | Positive (47) | Negative (63) | Doubts (256) |
|---------------------------------------|---------------|---------------|--------------|
| Attitudes (32;5%) | | | |
| Future medicine | 2(4%) | 20(32%) | 0(0%) |
| Current medicine | 5(11%) | 5(8%) | 0(0%) |
| Drug information (270;46%) | | | |
| Pharmacokinetics | 0(0%) | 1(2%) | 7(3%) |
| Posology | 0(0%) | 0(0%) | 16(6%) |
| Avoided/delayed/discontinued medicine | 0(0%) | 3(5%) | 23(9%) |
| Peer Advice | 0(0%) | 0(0%) | 97(39%) |
| Vaccination schedule | 0(0%) | 0(0%) | 34(13%) |
| Alternative therapies | 0(0%) | 9(14%) | 20(8%) |
| Route of administration | 3(6%) | 1(2%) | 8(3%) |
| Reconstitution | 0(0%) | 0(0%) | 21(1%) |
| Conservation | 0(0%) | 0(0%) | 10(0%) |
| Adverse Events | 0(0%) | 9(14%) | 15(6%) |
| Contraindications | 0(0%) | 0(0%) | 1(0%) |
| Interactions | 0(0%) | 0(0%) | 1(0%) |

| | | | |
|------------------------------|---------|---------|--------|
| Effectiveness | 37(79%) | 10(16%) | 12(5%) |
| Accessibility (24;4%) | | | |
| Vaccines | 0(0%) | 0(0%) | 7(3%) |
| Other | 0(0%) | 5(8%) | 12(5%) |

Conclusion and Relevance Doubts, negative attitudes towards a future medicine and positive opinions about drug effectiveness were the most SI expressed by PF users. Pharmacists can have a main role providing more information and knowledge to parents about drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-106 SAFETY PERCEIVED BY PROFESSIONALS AFTER THE INNOVATION OF THE MEDICATION USE CIRCUIT IN A NEONATAL INTENSIVE CARE UNIT

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Background and Importance Recently, a redesign has been taking place in circuit of prescription, dispensing, preparation and administration of medications in Neonatal Intensive Care Unit (NICU). These changes are aimed at improving the safety of the medication use process.

Aim and Objectives To evaluate the safety related to the use of medications perceived by professionals after the implementation of improvement measures in the circuit.

Material and Methods A questionnaire was developed for nursing staff to assess the perceived safety in: prescription by assisted electronic prescription (AEP), dispensing through an automated medication dispensing system integrated with AEP, and drug administration through smart pumps. Secondly, a questionnaire was developed for medical staff to assess the perceived safety of EAP and pharmaceutical validation. In both, questions were included about measures to be implemented to improve circuit safety.

The questionnaires consist of 17 (nursing staff) and 14 (medical staff) questions with an average completion time of 2 minutes. Both were designed in GoogleForms® to give maximum diffusion.

Results Response rate was of 60% (42 people filled out the questionnaire, 26 from nursing staff and 16 of medical staff). Regarding AEP, nursing staff agreed that it provides greater safety than manual prescription, although 7.7% (n=2) considered that the information is not always clear and complete. Regarding medical personnel, 88% consider that the AEP provides greater security.

Regarding pharmaceutical validation, 100% of medical staff believe that it is an improvement in the quality of care and that it provides security to the process.

Regarding dispensing, 96% consider that medicines are more easily found with respect to the plant medicine cabinet system and 85% consider that the integration with AEP allows unequivocally obtaining the prescribed medication.

In the administration, 85% of nursing staff consider that smart medication infusion pumps prevent exceeding therapeutic doses.

Finally, in terms of areas for improvement, the majority of nursing staff considers that the measures should focus on preparation (57.7%) and the medical staff considers that they should focus on administration (75%). Administration by barcode is the measure most voted for both groups to work on in coming years.

Conclusion and Relevance The perception of safety by NICU staff of measures implemented is high. There are still areas for improvement such as preparation or administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-107 SAFETY ASSESSMENT OF ERENUMAB AND GALCANEZUMAB IN CLINICAL PRACTICE

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Background and Importance Erenumab and galcanezumab are two monoclonal antibodies (mAbs) administered subcutaneously indicated for migraine prophylaxis in adults. As these are newly approved drugs, it is important to know their safety profile.

Aim and Objectives To analyse the adverse effects (AE) of these mAbs in real life in a tertiary hospital.

Material and Methods Observational, retrospective, 30-month study (March 2020 – September 2022). The study included all patients diagnosed with chronic migraine (CM) or episodic migraine (EM) and who received treatment with galcanezumab or erenumab respectively.

The following variables were collected sex, age, type of migraine, duration of treatment and AE.

Data were collected through the outpatient module of the Farmatools® software and the electronic health record, Mambrino XXI®.

Results Ninety-five patients (92% female, 8% male) with a median age of 50 years (18-73) were included. Of these, 72% had CM and 28% had EM. 45% and 55% of patients received erenumab and galcanezumab respectively.

48 patients (44% erenumab, 56% galcanezumab) experienced some type of AE during treatment, considered mild-moderate in severity. Four patients (75% erenumab, 25% galcanezumab) had to discontinue treatment due to poor tolerability despite prophylactic treatment. 17 (41% erenumab, 59% galcanezumab) had injection site reaction or pain, 27 (48% erenumab, 52% galcanezumab) constipation and 4 (25% erenumab, 75% galcanezumab) nausea and vomiting. AEs were more frequent among patients with CM (65%) vs EM (35%).

Comparing the data obtained with those described in other clinical trials, it was observed that the proportion of AEs was very different from that reported in the trials. In addition, there were no cases of nasopharyngitis or respiratory tract infection described as common in the trials. No cardiovascular AEs were observed.

Conclusion and Relevance Based on the results of our study, it was observed that galcanezumab and erenumab AEs were categorised as mild-moderate. The incidence of AEs was higher for the group of patients receiving galcanezumab. In addition, a small number of patients discontinued treatment due to AEs. It is essential to know the safety profile of newly

approved drugs in clinical practice so as to compare them with those described in clinical trials and to see possible differences between them that contribute to generate new evidence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-108 COMPUTERISED PHYSICIAN ORDER ENTRY WITH CLINICAL DECISION SUPPORT IN PREVENTING WRONG DOSE ERRORS IN PAEDIATRIC MEDICATION ORDERS: A SYSTEMATIC REVIEW

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Background and Importance Prescribing is a specific high-risk task within the paediatric medication-use process, which is why defenses are needed to prevent or stop errors. Such system-centric barriers include electronic health record (EHR) systems with computerised physician order entry (CPOE). Clinical decision support (CDS) tools can be integrated into the CPOE systems to assist safe prescribing.

Aim and Objectives The objective of this systematic review was to examine the effects of CPOE systems with CDS functions on preventing wrong dose errors in paediatric medication orders.

Material and Methods This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 criteria and Synthesis Without Meta-analysis (SWiM) items. The study protocol was registered in PROSPERO. The literature search was conducted in MEDLINE Ovid, Scopus, Web of Science and EMB Reviews in January 2022. Study selection and data extraction were carried out by two independent reviewers. After this, the quality of evidence of the included studies were assessed. Finally, vote counting method was used to evaluate the effectiveness of CPOE-CDS systems to reduce wrong dose errors.

Results A total of 18 studies published in 2007–2021 met the inclusion criteria. The most common CDS tools appearing in the studies were dose range check (n=14/18), dose calculator (n=8/18) and dosing frequency check (n=8/18). In nine studies, a specific alert function was added to the CDS tool, whereas alerts were recorded in 15 studies. A statistically significant reduction in wrong dose errors was found in eight studies. None of the studies reported an overall increase of wrong dose errors.

Conclusion and Relevance CPOE-CDS systems have a great potential to promote paediatric medication safety. System customisation for paediatric populations, implementing CDS alerts, and the use of dose range check seem to be most useful interventions to reduce wrong dose errors. However, CPOE-CDS systems cannot prevent all wrong dose errors as human errors continue to occur. Implementation of new technology can also pose new medication safety risks, such as alert fatigue. Therefore, further studies and systematic development activities are needed to optimise the safe use of CPOE-CDS systems in paediatric care settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-109 RANSOMWARE ATTACK ON A CYTOTOXIC PREPARATION UNIT (CPU): WHAT NOW?

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Background and Importance The informatisation of processes has increased the susceptibility of the healthcare sector to computer attacks through ransomware. These can manifest by the impossibility of accessing the internet, and computer systems, with consequent interruption of electronic prescription, registration in patient diary, consultation of previous clinical data, request for means diagnostic tools, among others. Pharmaceutical Services are particularly vulnerable to these attacks.

Aim and Objectives The aim of this work was to systematise the strategies adopted during the cyberattack, minimising the error and allowing the work to be carry out at the CPU, with the elaboration of a guideline to be adopted in a future cyberattack.

Material and Methods Retrospective study between April 26 and May 10, 2022.

Results CPU was restructured in order to guarantee its functionality. Through the information on paper from the production maps of April 2022, chemotherapy protocols, charts with reconstitution/dilution of used drugs, literature and coordination of information with the nursing and medical team, it was possible prevent the collapse of the unit. It was performed a daily survey of patients marked in agenda, and respective information about the cycle.

In the first 15 days of attack, 28.8% (n=132) of scheduled patients (n=458) were unchecked due to lack of access to complementary means of diagnosis and history of chemotherapy protocols. The preparation of cytotoxics was possible through the elaboration of manual labels (n=615), using the validation of paper prescriptions. In the first week (April 26 to 29) 41.9% (n=67) of the patients (n=160) were unchecked and in the second week (May 2 to 6) 25% (n=54) of patients (n=216). In the initial days of cyberattack no new patients were scheduled.

Conclusion and Relevance Faced with the reality of a computer attack, the CPU priority was to ensure a safety preparation of chemotherapy. On the other hand, this attack showed that it is crucial to have mechanisms of replacement of information such as the chemotherapy prescriptions file. Anticipating future cyberattacks, a guideline has been developed to ensure circuit safety in case of computer failure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Not applicable.

Conflict of Interest No conflict of interest

5PSQ-111 MEDICATION ERRORS, THEIR PERCEPTION, ANALYSIS, AND PROPOSAL OF SOLUTIONS IN A PUBLIC HOSPITAL

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Background and Importance A medication error is a mistake in the use of a medicine that can result in harm to the patient. Medication errors can increase hospitalisation costs and prolong hospital stays. Whereas the medication errors are preventable, it is important to identify the most vulnerable steps.

Aim and Objectives The aim of our work was to analyse the perception of medication errors by healthcare professionals in our hospital concerning parenteral medicines. Subsequently to find the role of hospital pharmacists in the process of eliminating medication errors. Furthermore, to identify the medicines in which a medication error can occur most often.

Material and Methods Retrospective, observational study in a public hospital from August 2021 to December 2021. The study was conducted using questionnaires administered by hospital pharmacists filled by healthcare professionals (doctors and nurses). The questions focused on medication errors, their causes, and their future solutions. Several questions were focused on specific drugs regarding the preparation and administration of specific parenteral drugs.

Results 47 doctors and 72 nurses from the different departments participated in the survey. 72% doctors and 46% nurses encountered medication errors. Increased workload (87% doctors, 79% nurses) and negligence (61% doctors, 47% nurses) were identified as the most common causes. The most frequently observed medication errors of parenteral drugs occurred during the process of prescription (75% doctors, 54% nurses) and administration (68% doctors, 50% nurses). While doctors most often consulted their colleagues (78%) or look for the literature (55%), nurses consulted doctors (81%) when solving issues concerning parenteral drugs preparation and administration. On the other hand, up to 49% of doctors also approached the hospital pharmacist, in the case of nurses it was only 22%. More than 87% of doctors and 76% of nurses would welcome lectures and training from pharmacists focused on the correct administration and prescription of parenteral drugs.

Conclusion and Relevance Our results confirm the literature data, which say that the most common medication errors occur during prescribing and administering drugs. Hospital pharmacists with their knowledge can significantly contribute to the elimination of medication errors and increase the safety of hospitalised patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-113 REAL-LIFE EFFECTIVENESS, SAFETY AND ADHERENCE OF DUPILUMAB IN PATIENTS WITH ATOPIC DERMATITIS

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Background and Importance Dupilumab, an anti-IL-4/13, is a monoclonal antibody approved for the treatment of moderate-to-severe atopic dermatitis (AD). So far, few studies have evaluated dupilumab effectiveness and safety in real clinical practice.

Aim and Objectives To evaluate the effectiveness, safety and treatment adherence of dupilumab in patients with AD in clinical practice.

Material and Methods We conducted a retrospective study carried out in a tertiary hospital. We included all AD patients treated with dupilumab with a minimum follow-up of 52 weeks.

We collected the following data from electronic medical records: age, gender, previous treatments, eczema area and severity index (EASI) and dermatology life quality index (DLQI) at baseline and at 52 weeks of follow-up, adverse effects and treatment adherence (calculated by medication possession ratio [MPR]).

Effectiveness was determined by the change in the EASI and DLQI values at 52 weeks compared to baseline. Safety endpoints were the number and type of adverse effects (AE) during the follow-up period.

Results In total, 61 patients were included in the study. The mean age (\pm SD) was 40 (\pm 18) years. Thirty-five patients (57%) were men.

As previous topical treatments, 100% of patients had received corticosteroids; whereas 49%, tacrolimus. Besides, 70% had undergone phototherapy. Regarding systemic treatment, 79% had received corticosteroids; 70%, cyclosporine; 25%, mycophenolate mofetil; 25%, azathioprine; and 28%, methotrexate.

Mean (\pm SD) EASI and DLQI baseline values were 33 ± 11 and 19 ± 5 , respectively. At 52 weeks follow-up, these indexes were 2 ± 3 and 4 ± 5 , respectively. The reduction in EASI and DLQI was statistically significant ($p < 0.001$). During this period, AE were reported in 22 patients (36%): conjunctivitis (20%), arthralgia (5%), herpes virus infection (5%) and paradoxical psoriasis (3%) were the most common ones. Three treatments were discontinued due to ineffectiveness, 4 due to AE and 2 because of clinical remission.

The mean MPR (\pm SD) was $100 \pm 14\%$, which demonstrates good rates of therapeutic adherence. No patient presented a MPR $< 75\%$, so we could not determine the impact of this variable on treatment effectiveness.

Conclusion and Relevance Our study shows that dupilumab is an effective and safe drug for moderate-to-severe DA. Our cohort experienced a statistically significant improvement in EASI and DLQI at 52 weeks of treatment. Additionally, therapeutic adherence was very high.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-115 DEPREScribing LONG-TERM TREATMENTS WITH BIPHOSPHONATES: PHARMACEUTICAL INTERVENTION BRINGS VALUE

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Background and Importance Bisphosphonate treatment lasting more than 5 years (BP5y) in patients without previous fractures and/or low risk of fracture does not confer additional benefits. The antiresorptive effect is maintained for a time after drug discontinuation and the side-effects risk is minimised. The increased risk of rare and long-term side-effect associated with the prolonged use of bisphosphonates has been reason of

safety notes issued by the Spanish Agency for Medicines and Health Products and other regulatory agencies. So, a re-evaluation of the treatment is necessary considering the benefits and risks for the patient individually, especially after 5 years of use.

Aim and Objectives The aim of the present study was to identify patients in treatment with BP5y and to evaluate the acceptance of pharmaceutical intervention (PI) over deprescribing in primary prevention.

Material and Methods By means of the primary care data exploitation platform (Digitalis®) and after reviewing the electronic prescription, patients on treatment with BP5y were identified until December-2021. Patients > 85 -years-old were selected due to their increased frailty, comorbidities and polypharmacy. The physicians were informed via the informative sheets of the primary care information system (Turriano®) about the susceptible condition to deprescribing after more than 5 years of continuous treatment in primary prevention. Seven months later, acceptance degree of PI was assessed.

Results At the start of the study, 186 patients were identified in treatment with BP5y, 51 of whom were > 85 years-old. Finally, PI was performed on 43 patients belonging to the selected health centres. Seven months later, bisphosphonate withdrawal was observed in 10 patients, with a prescribing doctors acceptance rate of 23% (10/43). Currently, 33 patients continue with such treatment either out of necessity or due to lack of knowledge of PI. Only one of the 8 patients without PI (12.5%) had bisphosphonate discontinuation.

Conclusion and Relevance The monitoring, analysis of treatments with BP5y and the corresponding PI have promoted the deprescription in almost a quarter of the cases, creating the need to extend the study to the rest of the patients. The importance of the pharmacist in the review of treatments is highlighted, as well as the interdisciplinary collaboration with physicians to achieve a safe use of the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-116 PERSISTENCE OF INHIBITORS OF INTERLEUKIN-23 (ANTI-IL-23) FOR THE TREATMENT OF MODERATE-TO-SEVERE PSORIASIS (MSPS) IN THE ROUTINE CLINICAL PRACTICE CONDITIONS

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Background and Importance Anti-IL-23 have emerged as safe and effective options for the treatment of msPs.

Aim and Objectives We aimed to evaluate the persistence of anti-IL-23 (guselkumab and risankizumab) in patients with msPs. Secondly, these patients' clinical outcomes and health-related quality of life (HRQL) and the safety profile were also assessed.

Material and Methods Retrospective observational study from January 2019 to September 2022. Patients with msPs receiving anti-IL-23 were included. Demographic (sex, age) and clinical data (previous biological treatments, therapy duration and baseline Psoriasis Area and Severity Index (PASI)) were collected from the digital medical record. Non-persistence was defined as treatment discontinuation or a treatment gap > 90

days. The cumulative probability of treatment persistence was analysed by Kaplan-Meier method. Secondary endpoint: PASI90 response at 1 year, change in HRQL through dermatology life quality index (DLQI) at 1 year, and safety profile.

Results 44 patients were included (26 women), 30 received guselkumab and 14 risankizumab. Mean age was 53.5 years. 93.2% received biologic therapies before, and 86.3% conventional systemic treatment. At data cut-off time, 73.3% and 92.8% patients remained on guselkumab and risankizumab respectively. The main cause of discontinuation was primary failure. In 13.3% of guselkumab patients, dose interval was extended >8weeks and in 7.1% of risankizumab patients was extended >12 weeks. The cumulative probability of guselkumab treatment persistence was 79.7% at 1 year and for risankizumab 92.6%. The median PASI score was 8 and 9 at guselkumab and risankizumab treatment initiation respectively. 50% of guselkumab patients and 64.3% of risankizumab patients achieved PASI90 improvement at 1 year. 44.8% of guselkumab and 71.4% of risankizumab patients achieved a minimal clinically significant difference (>4-point reduction) in DLQI score at 1 year. One patient experienced one adverse reaction (ARs) related to guselkumab: headache and two risankizumab patients experienced increase in transaminases.

Conclusion and Relevance Our cohort shows a moderate persistence rate and PASI improvement at 1 year with guselkumab and a moderate benefit in improving HRQL. High persistence rate and moderate PASI improvement was reached with Risankizumab and a substantial improvement in HQRL. No important adverse reactions were found, without treatment withdrawals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-118 PATIENTS' EXPERIENCE WITH SUBCUTANEOUS INJECTION SELF-ADMINISTRATION AND THE ROLE OF VIRTUAL REALITY

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Background and Importance The number of patients treating themselves via the subcutaneous (SC) administration route has widely increased in recent years. Although self-medication can reduce waiting times and save money, is a public health concern that it may carry some potential risks associated with inappropriate management. Getting the correct method of administration is essential to ensure the drug's effectiveness and minimise the risk of complications.

We propose to take advantage of the benefits that new technology, such as virtual reality (VR), could provide for patients' performance.

Aim and Objectives This investigation aimed to explore patients' perceptions of their experiences with SC injection self-administration and their willingness to implement VR to improve their learning process of the method of administration.

Material and Methods An observational and transversal study was performed. The adults who attended for subcutaneous medicine dispensing were included. A yes/no survey was conducted regarding to medication first self-administration

knowledge, handling skills, administration errors, risk perception, clarity of information received and whether a VR environment would help their learning.

Results

Forty-five patients were included Mean \pm SD age was 51 \pm 12 years. Most of the patients interviewed were in treatment with drugs for immune-mediated inflammatory disorders. The first administration was done by a health professional in 53.3% of the cases, 44.4% were done by themselves and 2.2% were done by a family member. Although 95.6% of the participants considered that the information given by the pharmacist was clear enough, 15.6% of them discarded the injections due to handling failures and 66.7% reported injection site reactions. Finally, 75.6% of participants believed that VR may help to learn the administration process.

Conclusion and Relevance Although the information and training provided by the pharmacist were clear enough, some patients do not feel confident with their first self-administration having to discard the medication due to some handling failures.

The VR represents a potential alternative for promoting a safe environment to improve the knowledge, skills and attitudes in SC injection self-administration through reproducing environments close to the real one.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-119 A NEW PHARMACEUTICAL CARE PROGRAMME FOR COVID-19 PATIENTS TREATED WITH PAXLOVID®: IMPLEMENTATION AND SAFETY OUTCOMES REPORTED

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Background and Importance The COVID-19 pandemic has highlighted the important role that hospital pharmacists play in improving pharmacotherapy outcomes. Paxlovid® (Nirmatrelvir/ritonavir) was recently granted an Emergency Use Authorisation for the treatment of mild to moderate COVID-19. However, the use of Paxlovid® with certain other drugs in high-risk patients may result in potentially significant drug-drug interactions (DDI) and adverse drug events (ADE).

Aim and Objectives To assess the impact of a comprehensive pharmaceutical care program (CPCP) focusing on the prevention of DDI and ADE, initiated in a hospital pharmacy for patients with mild to moderate COVID-19 treated with Paxlovid®.

Material and Methods Design: Quasi-experimental study performed between 1 May and 31 July 2022. Pharmacists were responsible for proposing COVID-19 local guidelines to physicians, monitoring adherence to guidelines, managing DDI and ADE, providing patient education, and evaluating health outcomes. A telephone consultation was carried out 10 days after the end of Paxlovid® treatment.

Potential DDI were detected according to Lexi-Comp® and Liverpool COVID-19 databases. Paxlovid-related ADE reported were graded according to Common Terminology Criteria for Adverse Events, version 4.

Results 140 patients (60.7% outpatients) initiated Paxlovid[®] and were enrolled in the CPCP. Adherence to local guidelines for the use of Paxlovid[®] was 100%.

Overall, 232 DDI were detected in 111 (79.3%) patients, 142 (61.2%) of which required specific management (34.5% discontinuation of the concomitant drug and 65.5% dose adjustment).

Pharmacists made 267 interventions that led to the prevention of 177 ADE (1.3/patient), 96 (54.2%) of which were grade G-H (NCC MERP classification).

At day 10, 96 ADEs were reported in 42 patients (26.1% of which were grade ≥ 3), being dysgeusia and diarrhoea the most common. Premature discontinuation of Paxlovid[®] due to ADEs was necessary in 4 (2.8%) patients.

Conclusion and Relevance The implementation of a CPCP developed by hospital pharmacists for patients treated with Paxlovid[®] was an effective approach for monitoring adherence to guidelines, managing DDI, providing patient education, and evaluating safety outcomes. Paxlovid[®] showed an acceptable safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-120 ANALYSIS OF THE PHARMACEUTICAL INTERVENTIONS PERFORMED ON ONCO-HAEMATOLOGICAL PATIENTS THROUGH AN ONCO-HAEMATOLOGY PHARMACY CONSULTATION

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Background and Importance In the area of onco-haematology, medication errors are of great importance because oral antineoplastic drugs have a narrow therapeutic margin, complex dosing regimens, possible interactions with other drugs and foods, and low supervision of their self-administration by healthcare professionals, increasing the risk of medication errors.

Aim and Objectives To analyse the pharmaceutical interventions performed on onco-haematology patients seen in an Onco-haematology Pharmacy consultation.

Material and Methods Prospective observational study of onco-haematology patients in a tertiary hospital for a period of one year. To identify the type of intervention performed, a database was created using an Excel[®] spreadsheet to record and categorise it. Once identified, it was entered as an episode in the patient's clinical history in the Diraya Clínica[®] programme so that the clinician could consult it in the patient's evolution. Finally, errors, interactions and adverse reactions avoided by performing these interventions were recorded.

Results A total of 35 onco-haematology patients underwent pharmaceutical interventions. 55% men and 45% women. The median age was 64 years. The patients belonged to two clinical services, 40.8% to Haematology and 59.2% to Oncology. The onco-haematological pathologies where most interventions were performed were: Prostate Cancer (30%), Colon Cancer (25%), Chronic Lymphatic Leukaemia (16%), Multiple Myeloma (10%), Ovarian Cancer (7%), Brain Tumours (5%), Lung Cancer (4%), Breast Cancer (3%). 45% of the pharmaceutical interventions performed were incorrect doses of antineoplastic

drugs, 25% relevant drug interactions, 18% omission of the drug, 10% incorrect frequency of administration and 2% detected adverse reactions. The most frequent dose errors were poor adjustment for renal function (40%), failure to write the dose in the patient's clinical course (30%), failure to adjust for liver failure (20%), poor adjustment for body surface area (10%). 100% of the errors were detected in the pharmaceutical validation process during the dispensing of oral cytostatics. 100% of the pharmaceutical interventions were entered in the patient's clinical history as a clinical report. 97% were accepted and prevented 97% of medication errors in patients.

Conclusion and Relevance Pharmaceutical interventions have proven to be an effective tool to contribute to the achievement of the patient's therapeutic goals.

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1. *J Oncol Pract* 2011;7(1): 7–12.

Conflict of Interest No conflict of interest.

5PSQ-122 COVID-19 VACCINE VIGILANCE: COMPARATIVE STUDY BETWEEN HOSPITAL, REGIONAL AND NATIONAL DATA

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Background and Importance Following AIFA's authorisation of first mRNA vaccine on 27/12/2020, COVID-19 vaccination campaign started in Italy together with vaccine vigilance in order to individuate expected and unexpected Adverse-Events-Following-Immunisation (AEFIs) and the benefit/risk balance.

Aim and Objectives The aim of this work is comparing reports of vaccine vigilance in our Hospital from December 2020 to June 2022 to national and regional data.

Material and Methods Starting from data of the National System of Pharmacovigilance (RNFV), we analysed reports by age, sex, severity of reaction, reporter and System-Organ-Class (SOC) involved (Meddra classification system). Finally, we compared results with twelfth vaccine surveillance report published on June 2022 by the Italian Agency of Drugs (AIFA) and to 2021 annual regional report.

Results In the period our Hospital administered about 111000 doses (99%Comirnaty, 0.3%Vaxzevria, 0.6%Spikexvax). 176 reports were collected: 69(39%) concerned Covid vaccination (reporting-rate RR0,06%). 52(75,4%) of Covid-reports were not severe and 17(24,6%) were severe; among those severe, 2 cases of ineffective vaccination (Comirnaty), 1 case of heart attack (Spikexvax), 1 case of adrenal hematoma (Vaxzevria) and 1 episode of deep vein thrombosis (Comirnaty). 59 (85,5%) involved women and 10(14,5%) men. 65 (94,4%) involved Comirnaty (23% severe, and further 9% of severe reaction are given by association with other drugs, RR0,06%), 2 (2,9%) Spikexvax (50% severe, RR0,6%), 2 (2,9%) Vaxzevria, (50% severe, RR0,3%). 216 AEFIs were collected; 83 (38%) general diseases and conditions related to site of injection (13 fever, 9 asthenia); 37 (17%) nervous system diseases (26 headache); 30 (14%) generalised muscular pains (8 myalgia). Little

percentage involved also vision, skin and respiratory system. 49% of reports were from doctors, 30% from pharmacists, 15% from other health worker and last 6% patients. 35 (51%) AEFIs were from first dose, 32 (46%) from second and 2 (3%) from third. Almost all reports involved age range 18-64. **Conclusion and Relevance** Results on Comirnaty are in line with AIFA's and regional ones; Spikevax and Vaxzevria show altered percentage because of little number of reports. Reporting rates are comparable. Most of reports concerned not severe reactions, mainly related to site of injection. It is important to underline the essential role of vaccine vigilance to identify red flags for public health in order to contain main severe reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-125 BRIDGING ANTICOAGULATION IN PATIENTS WITH ATRIAL FIBRILLATION AFTER A TRANSURETHRAL RESECTION: PATIENT MANAGEMENT IS DONE APPROPRIATELY?

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Background and Importance The management of anticoagulation in patients undergoing surgical procedures like transurethral resection (TUR) is challenging. A balance between reducing thromboembolism risk and preventing excessive bleeding must be reached. This risk is aggravated in patients treated with anticoagulants.

Aim and Objectives The aim of the study was to assess the adequacy bridging anticoagulation after TUR in patients treated with direct-acting oral anticoagulants (DOACs) or Vitamin K antagonists (VKAs) to prevent stroke in atrial fibrillation (AF).

Material and Methods Retrospective observational study carried out in an area reference hospital serving a population of 200,000 inhabitants, from January 2021 to June 2022. Patients who underwent TUR with diagnosis of AF were included. Data were obtained from Minimum Basic Data Set (CMBD). We reviewed whether patients were anticoagulated, the type of anticoagulant drug prescribed (VKA, DOAC) and the prescribed drug (acenocoumarol, warfarin, dabigatran, rivaroxaban, apixaban, edoxaban). We verified whether the reintroduction of anticoagulant treatment after TUR was appropriate to hospital protocol and the rate of subsequent readmissions due to bleeding.

Because of the moderate bleeding risk of TUR, the protocol for reintroducing anticoagulant medication after TUR in the case of patients treated with VKAs consists of administering bempiparin or enoxaparin at anticoagulant doses 24 hours after TUR together with the usual dose of acenocoumarol or warfarin. In the case of patients treated with DOAC, the protocol consists of reintroducing their medication at the usual dose 24 hours after TUR.

Results The mean age of the 37 included patients was 81 ± 6 years. 94.6% were male. 89.19% of the patients were anticoagulated (60% AVK, 40% DOAC).

The protocol for reintroducing anticoagulant treatment was not followed in 100% of anticoagulated patients. The drug

prescribed in these cases after TUR was bempiparin at a prophylactic dose of 3500 IU every 24 hours.

59.5% of patients were attended at Emergency Department (ED) after TUR with haematuria diagnostic.

Conclusion and Relevance Although anticoagulation was not reintroduced as the protocol established, more than 50% of patients were readmitted in the ED for haematuria. Therefore, our study confirms that appropriate interruption of anticoagulation in the perioperative period is a delicate balancing act between complications of bleeding and thrombosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-127 PHARMACOLOGICAL RISK FACTORS FOR DRUG-DRUG INTERACTIONS IN PEOPLE LIVING WITH HIV: A SYSTEMATIC REVIEW

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Background and Importance Improved survival of people living with HIV (PLWH) increases comorbidities burden leading to polypharmacy and drug-drug interactions (DDIs). DDIs suppose a higher concern in PLWH due to antiretroviral therapy (ART). Presence so risk factors (RF) for developing DDIs are of interest to detect cases needing for pharmaceutical assessment.

Aim and Objectives Assess literature on the pharmacological RF for developing DDIs in PLWH.

Material and Methods Following the PRISMA recommendations, a search combining terms associated with 'ART', 'DDIs' and 'RF' was conducted in MEDLINE database for relevant English- and Spanish-language articles from 2006 through January 2022. Longitudinal and cross-sectional studies were included. Articles not mentioning data on DDIs between ART and non-ART were excluded in a first screening phase. In a subsequent selection phase, articles were excluded if they did not contain information on RF for DDIs. The outcome of interest was the pharmacological RF for DDIs (or grouped by severity) between ART and non-ART in PLWH ≥ 18 years. Data was synthesised narratively.

Results 349 articles were identified and 10 included (4 longitudinal and 6 cross-sectional). Kunitomo-*et-al*, found an association between the occurrence of potential DDIs and number of comedications (OR=1.52[1.16-1.99]), similar correlation was reported by Okoli-*et-al* (OR=1.3[1.2-1.3]), Pontelo-*et-al* (OR=1.13[1.11-1.15]) and Bastida-*et-al* (OR=1.18[1.14-1.22]). El Moussaoui-*et-al* found that the number of comedications independently associated with orange- (OR=1.8[1.6-2.0]) and red-flag (OR=1.4[1.3-1.6]) DDIs. Related to comedication, Kunitomo-*et-al* found polypharmacy as a severe RF for DDIs (OR=11.69[3.01-45.40]), this also reported by López-Centeno-*et-al* for red- (OR=2.65[1.98-3.54]) and orange-flag (OR=2.17[1.90-2.47]) DDIs. Halloran-*et-al* reported that ART-regimens containing protease inhibitors (PIs) were more likely to have DDIs compared with those containing non-nucleoside reverse transcriptase inhibitors (NNRTI)- and integrase inhibitors (II). This increased risk of IP-regimens was also notified by Chen-*et-al* (OR=2.54[1.25-5.16]) and Bastida-*et-al* (OR=1.18[1.14-1.22]), instead Fernández Cañabate-*et-al* found it in PI-regimens (OR=8.82[4.07-19.14]) as also NNRTI-

regimens (OR=2.65[1.25–5.16]). Moreover, El Moussaoui *et-al* found PIs as an independent RF for red-(OR=7.9[3.2-19.5]) and orange-flag (OR=7.5[4.5-12.5]) DDIs while NNRTI (OR=2.4[1.5-4.0]) and the II (OR=1.6[1.0-2.6]) only it were for orange-flag. This risk of PIs of were more involved in red-flag/contraindicated was also reported by López-Centeno *et-al* and Holtzman *et-al*.

Conclusion and Relevance This is the first systematic review summarising literature in this field and is helpful to stratify patients at need for specialised management to reduce DDIs and polypharmacy burden.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-129 SWITCHING BETWEEN ANTI-CALCITONIN GENE RELATED PEPTIDE MONOCLONAL ANTIBODIES IN MIGRAINE

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Background and Importance Monoclonal antibodies (mAb) against calcitonin gene related peptide (anti-CGRP) and its receptor (anti-CGRP-receptor) are effective in the prophylaxis of migraine. However, studies to determine effectiveness and safety on switching between them in non-responders are scarce.

Aim and Objectives To evaluate the real-world clinical effectiveness and safety of mAb switch in migraine patients.

Material and Methods Retrospective cohort study of adult patients who switched between mAb in a tertiary hospital from December 2019 until September 2022. Sociodemographic and clinical data were recorded. Outcome measures: the reduction of Headache Impact Test (HIT-6) scale punctuation and the reduction of monthly migraine days.

Results We analysed 147 patients treated with anti-CGRP or anti-CGRP-receptor. Among these, 20 patients (13.6%) switched between mAb and had at least one follow-up visit after switching. 16 patients (80%) suffered from chronic migraine (CM) with a baseline median days of migraine a month of 15 [13-24], median Regicor scale of 2% [1-3%] and median HIT-6 of 67 [62.5-72.3]. 19 (95%) were female.

Out of these 20 patients, 15 (75%) started with Erenumab and 5 (25%) with Galcanezumab. First mAb switching was performed after a median of 7.4 months treatment [5.9-11.8] (12 from Erenumab to Galcanezumab; 3 from Erenumab to Fremanezumab; 2 from Galcanezumab to Erenumab and 3 from Galcanezumab to Fremanezumab). 5 patients required a second switch, and one received a third mAb. Reasons for first switching: 12 (60%) non-response, 7 (35%) loss of response and 1 (5%) adverse event. 1 patient (5%) discontinued mAb treating during the study period due to lack of effectiveness.

Median reduction in HIT-6 after first and second switching was -2 [-11.5-0], and -3.5 [-11.8-0], respectively. Median reduction of monthly migraine days after first, and second switching was -4.15 [-7-0] and -4.8 [-6.5 to -0.6], respectively.

Constipation (38.7%) and itchiness (3.2%) were the most frequent adverse events during the study period.

Conclusion and Relevance Our findings in 20 treatment-resistant patients indicated that switching between CGRP mAbs could be beneficial to some non-responders to a initial mAb.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-132 PHARMACOGENETIC-GUIDED TREATMENT IN PATIENTS WITH DYHYDROPIRIMIDINE DEHYDROGENASE DEFICIENCY

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Background and Importance Certain polymorphisms in *DPYD* gene are associated with partial or complete deficiency of dihydropyrimidine dehydrogenase (DPD) enzyme and are linked to a greater risk of severe toxicities after fluoropyrimidines-based treatment. In 2020, the European Medicines Agency recommended that patients should be tested for the deficiency of DPD prior to treatment with fluorouracil, capecitabine or tegafur.

Aim and Objectives To assess the prevalence of *DPYD* variants linked to DPD deficiency in cancer patients who are candidates to treatment with fluoropyrimidines and to evaluate the safety of pharmacogenetic guided treatment in patients with DPD deficiency.

Material and Methods Prospective, observational study at a third level hospital. Cancer patients who underwent genotyping test for DPD deficiency between 1 November 2021 and 15 September 2022 were included. Demographic and clinical data were collected from electronic medical records. The polymorphisms studied were rs3918290, rs55886062, rs67376798 and rs75017182. DNA was obtained from peripheral blood samples and a pharmacogenetic analysis was performed using a real-time polymerase chain reaction technique. Patients were classified as normal, intermediate, and poor metabolisers according to the result of the test. Severe toxicities (grade 3-4 CTCAE 5.0) in intermediate and poor metabolisers were screened during the first two cycles of treatment.

Results A total of 345 patients were included, 52.6% male, mean age 68.3 years (SD 11.7). The most frequent diagnoses were colon cancer (43.8%), rectal cancer (18.9%), pancreatic cancer (9.8%), breast cancer (8.0%) and gastric cancer (7.1%).

Overall, 14 patients were classified as intermediate metabolisers: 8 patients were heterozygous for rs75017182, 3 patients were heterozygous for rs67376798, 2 patients were heterozygous for rs3918290 and one patient was homozygous for rs75017182.

Eleven of the intermediate metabolisers were treated with fluoropyrimidine-based chemotherapy (three patients did not start treatment) with an initial 50% dose reduction and further adjustment based on initial tolerance to treatment. During follow up, these patients underwent treatment without suffering any grade 3-4 adverse event. No further dose reductions or treatment delays were required in this group of patients.

Conclusion and Relevance Overall, 4.1% of the patients of our cohort had partial DPD deficiency. Treatment individualisation

based on *DPYD* genotyping can help to avoid severe adverse events in patients treated with fluoropyrimidines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-133 PHARMACISTS – GENERAL PRACTITIONERS (GPs) COLLABORATION TO IDENTIFY DRUG-RELATED PROBLEMS (DRPs) IN PATIENTS IN POLYTHErapy

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Background and Importance Medication reconciliation and medication review are indispensable instruments in the prevention of clinical risk. In clinical practice, such methods are not always used. This exposes the patient, in treatment transitions, to DRPs, including Adverse Drug Reactions (ADRs), which could cause his rehospitalisation. How many clinical symptoms are related to disease or hidden ADRs? The Clinical pharmacist, through remote monitoring provides, can support to the GP by a periodic analysis of the therapy taken by the individual patient.

Aim and Objectives The objective of the study was to outline a pharmaceutical care and drug monitoring methodology based on Pharmacist-GP collaboration to identify DRPs that could generate predisposing clinical conditions that can be identified as signs of hidden ADRs.

Material and Methods From April to September 2022, we established a teamwork between Pharmacists and GPs in a Local Health Authority, selecting patients >65 years of age receiving >4 drugs. Patient-related drug prescriptions on the health card were analysed, excluding herbal products, homeopathic products, and supplements. Treatment duplications, ATC therapy switches and drug interactions were examined, simultaneously verifying dosing schedules. Appointments have been set up with GPs to complement the information. Final reports were prepared for individual patient to be delivered to the GP on the clinical alerts to be monitored.

Results N.24/1304(1,84) GPs were involved, n. 149 patients were identified (average 72 years) and n. 1348 drugs and dosing schedules were analysed. Duplications identified: 13/1348 (0,96). Unmotivated drug switches 23/72(31,94), drug alerts for interactions: n.2357. Ex. fluoroquinolone-quetiapine, statin-clopidogrel, ASA-omega-3. We identified n. 10 hidden ADRs, subsequently registered on the Pharmacovigilance National Network.

Conclusion and Relevance The identification of hidden ADRs in polytreated patients avoided the inclusion of a new drug to treat the clinical symptom not related to a new disease. The next goal is to integrate the patient into the path, a valuable source of information currently unavailable, thus implementing territorial health care through narrative pharmacovigilance that will allow a complete picture of the individual patient. The aim is to an enhanced care model with the top the patient between GP and pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-134 UNIT DOSE IN A CYBERATTACK SCENARIO

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Background and Importance At dawn on the 26th of April 2022, our hospital suffered a cyberattack. All hospital's computer systems and applications were inaccessible, and the network and most workstations inoperable. The only few computers that remained operational were standalone, that is, not connected to a network. The institutional email was only available on mobile phones. At that time, we were considered a paper-free hospital, totally computerised, with electronic patient records and online prescription totally implemented, and pharmaceutical procedures highly dependent on technology and automation so, it was particularly challenging to continue to provide pharmaceutical care in this scenario.

Aim and Objectives Description of procedures implemented in a scenario of cyberattack by the pharmacy department and establishment of preventive measures for the future.

Material and Methods This study is a description of a case.

Results Due to lack of access to clinical and pharmacotherapeutic profile of patients, it was necessary to reverse the prescription for paper support, in inpatient wards. The Kardex System remained operational, having been disconnected from the network in a timely manner, allowing the reconstitution of the history treatment of patients through the previous day therapeutic map files. Microsoft Excel files were created for all patients admitted to services with unit dose distribution, using laptops stand-alone. The communication with the nursing team was made daily, by telephone, with conference of all the patients. The Excel files with the transcription of the prescriptions, per patient, were manually coded by service, patient and drug, and, at the end of the day, transformed into the appropriate format to be correctly read by Kardex system, transferred to it by pen-drive, allowing the Unit Dose preparation. Contact was strengthened with the medical and nursing staff to avoid duplication of drugs or inadequate posology errors. Paper file folders were created by service for all prescriptions made, and updated daily. All Excel files were posteriorly accounted for regularisation of consumption.

Conclusion and Relevance In this cyberattack context, it was evident the difficulty in reversing the prescriptions for paper support, especially by young doctors. It will be necessary to implement validated procedures with periodic measures, including training in contingency protocols and cloud backup information maintenance.

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Conflict of Interest No conflict of interest

5PSQ-135 HAS AN ANTIMICROBIAL STEWARDSHIP PROGRAMME HAD AN IMPACT ON THE ANTIBIOTIC CONSUMPTION?

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Background and Importance The increasing use of antimicrobials and the global surge of antimicrobial resistance is a major public health concern.

Antimicrobial Stewardship Programmes (AMSP) are an important security strategy in hospitals because their implementation promotes an optimal use of antimicrobials, improving patient outcomes while decreasing the risk of adverse events as well as antimicrobial resistance.

Aim and Objectives To evaluate if an AMSP had an impact in the overall consumption of antibiotics, measured as number of defined daily doses per 100 stays (DDD/100 s), in an acute care hospital during the first year of implementation.

Material and Methods AMSP started in Araba University Hospital in October 2020.

The AMSP was conducted 3 days per week by a hospital pharmacist and an infectious disease specialist with the possibility of consulting a microbiologist by telephone.

An Antimicrobial Stewardship Programme Support System (AMSPSS) was used to alert of antibiotic prescriptions that need a revision. These alerts were previously designed by the AMSP team.

Antibiotic recommendations were made in the health electronic record or by telephone to the patient responsible doctor. They were registered in the AMSPSS as well.

We retrospectively analysed interventions and measured the global antibiotic consumption as DDD/100s using the pharmacy dispensation registers from January to December 2021.

Results 1206 alerts of the ASPSS were reviewed by the AMSP team and 434 of them (36%) generated prescription recommendations (one or more).

A total of 820 antibiotic recommendations were performed with a global acceptance of 78,3%.

A reduction of 10,6 DDD/100 s was found in 2021 compared to 2020 (58,42 DDD/100 s vs 69,02 DDD/100 s).

Conclusion and Relevance After the implantation of the AMSP, there was a decrease in the antibiotic use in 2021. Although other factors may have also contributed to this reduction, we confirm that a daily AMSP is a useful tool to optimise antimicrobial consumption.

It is necessary to continue with the implementation of the AMSP to guarantee the proper use of antimicrobials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of Interest No conflict of interest

5PSQ-136 ANALYSIS OF ANTIRETROVIRAL THERAPY POTENCY IN HIV- NAÏVE PATIENTS

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Background and Importance Clinical practice guidelines recommend initiation of antiretroviral therapy (ART) as soon as possible after diagnosis of HIV infection with a combination of nucleoside reverse transcriptase inhibitors (NRTI) with integrase inhibitors (INSTI), non-nucleoside NNRTI or protease inhibitors pharmacologically boosted (PI/b).

Aim and Objectives Compare the potency of different combinations of NRTI with NNRTIs, INSTIs or PI/bs.

Material and Methods Retrospective observational study of naive patients diagnosed between January-2012 and June-2022. Variables analysed were age, sex, route of infection, ART, AIDS, viral load (VL) and time to reach undetectable VL (<50 copies/ml).

Data were collected from the electronic medical records (Mambrino XXI[®]) and outpatient dispensing software DPE Farmatools[®].

Statistical analysis was performed using a linear regression method (dependent variable: potency of the combination characterised as the reduction in VL corrected for the time (months) in which undetectable VL is achieved and an analysis of variance (ANOVA) using SPSS[®] v.15.

Results Ninety-six people were diagnosed with HIV infection. Median age: 34 years (RIC 30-43), 78% male. AIDS stage was present in 34%. The most common route of transmission was men sex men (MSM) 53%.

Initiation of ART NRTI combined with INSTI was 73%, NNRTI 7% and IP/b 20%. The mean log VL baseline was 4.63 (SD: 0.93).

The mean VL reduction per month of treatment in patients treated with NRTI + INSTI was 2.45 copies/ml/month, NRTI + PI/b was 1.72 copies/ml/month and NRTI + NNRTI was 1.63 copies/ml/month. The significance of the analysis of variances of the means obtained was 0.112.

Conclusion and Relevance INSTIs potency was higher than the other TAR combinations, although the differences were not significant.

Study heterogeneity in the follow-up times between diagnosis and the date of VL analysis as well as the number of patients treated with NNRTIs, and PI/bs was lower than the INSTIs group may explain the non-significant results.

It would be interesting to extend the sample with a multi-centre study to validate the results obtained.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-137 ANALYSIS OF THE DPYD GENE MUTATIONS IN CANCER PATIENTS WHO ARE CANDIDATES FOR TREATMENT WITH FLUOROPYRIMIDINES

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Background and Importance Dihydropyrimidine dehydrogenase (DPD) encoded by the DPYD gene, is the rate-limiting enzyme of fluoropyrimidines catabolism.

Among around 450 missense DPYD single-nucleotide polymorphisms, only approximately twenty of them acquire a functional significance. Four of these variants are considered to be of clinical relevance for recognised effects on the protein, their identified higher risk of severe toxicity, and for their population frequency.

Aim and Objectives To analyse DPYD gene mutations in all patients who are candidates for receiving a fluoropyrimidine-based regimens and their influence on the individualisation of cancer treatment.

Material and Methods Retrospective observational study from July/2020-July/2022. All patients who underwent a genotyping test for DYPD were included. Demographic variables were recorded. The loss-of-function variants in the DPYD gene were analysed: c.1905+1G>A that identifies the DPYD*2A haplotype, and c.1679T>G that identifies the DPYD*13 haplotype. It also studies the variants of reduced function: c.1129-5923C>G that identifies the HapB3 haplotype and c.2846A>T. The frequency of each of these variants were determined, and the recommendations of treatment individualisation were collected.

Results We analysed 638 requests for DPYD gene determination, mean age was 62.65 ± 12.58 years, and 52.98% were men. Thirty-two (5,0%) had some mutation in the DPYD gene. Four (0,6%) patients were heterozygous for the loss-of-function variant c.1905 + 1G> A and one (0,16%) patient was heterozygous for the variant c.1679T>G. Twenty-three (3,6%) patients were heterozygous for the decreased function variant c.1129-5923C>G, and four (0,6%) patients were heterozygous for the reduced function variant c.2846A>T.

All of them were intermediate metabolisers, who if they started treatment with fluoropyrimidines, they should start treatment with a dose reduced to approximately 50% and then escalate the dose in later cycles if no toxicity was observed.

The recommendation of individualisation of treatment was: sixteen patients started treatment at 50% of the dose, in seven patients the chemotherapy regimen were changed, in seven patients adjuvant therapy were dismissed, one patient was not treated, and one patient received radiotherapy alone.

Conclusion and Relevance The determination of DPYD polymorphisms prior to the start of treatment with fluoropyrimidines, allows to identify DPD-deficient patients, and avoid may experience serious side effects when treated with fluoropyrimidines; and thus clinicians' decisions are influenced by the results of DYPD genotyping.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-138 CHEMOTHERAPY ERRORS DETECTED DURING PHARMACEUTICAL VALIDATION

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Background and Importance Chemotherapy errors represent a potentially serious risk of patient harm because of the narrow therapeutic window of antineoplastic and their high toxicity. Pharmaceutical validation aims to optimise chemotherapy treatment in order to obtain the best results for patients' health and to minimise potential prescription errors.

Aim and Objectives To describe the chemotherapy prescription errors of intravenous cytostatic detected during the pharmaceutical validation and the interventions made to avoid potential harm to the patient, helping prevent mistakes.

Material and Methods Observational, descriptive, retrospective study of chemotherapy prescribing errors detected by pharmaceutical validation that resulted in a prescription change in intravenous chemotherapy.

They were recorded between November 2020 to September 2021 and the programme used for prescribing and recording was OncoFarm.

The errors were classified into 10 groups: 1) Upper/lower dose <10%, 2) Upper dose >10%, 3) lower dose >10%, 4) Inappropriate cycle frequency, 5) Relevant interaction or adverse effect, 6) Dose adjustment or delay administration (renal and hepatic impairment, haematologic toxicity), 7) Incorrect protocol, 8) Missing drug, 9) Excess drug, 10) Others.

Results During the study period, 180 chemotherapy errors were detected among 53.243 doses of intravenous chemotherapy prepared in a hospital pharmacy for 2.944 patients (63% from oncology service, 32% haematology service, 3% urology service; 2% others). These errors detected through pharmaceutical prescription review induced changes in chemotherapy prescriptions: 88 in haematology prescriptions, 83 in oncology prescriptions, 6 in urology prescriptions and 3 in onco-haematology prescriptions.

Classification 6 Upper/lower dose <10%, 60 upper dose >10%, 7 lower dose >10%, 17 inappropriate cycle frequency, 4 relevant interaction or adverse effect, 14 dose adjustment or delay administration (renal and hepatic impairment, haematologic toxicity), 20 incorrect protocol, 12 missing drug, 18 excess drug, 22 others

The most common errors were attributed to error prescription of upper dose >10%, in 36% were carboplatin dose mistakes; and also errors in prescribing and protocol frequency.

Conclusion and Relevance Despite the number of detected chemotherapy errors does not represent a large volume in the total number of patients treated in almost two years, they led to a probable reduction in adverse drug events, toxicities and patients overdose. This gives us an idea of the benefit and the importance of pharmaceutical validation in chemotherapy treatment optimisation and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-139 USING A TEXT-MINING APPROACH TO IDENTIFY THE CONTEXT VARIABLES LANGUAGE BARRIER, LIVING ALONE, COGNITIVE FRAILTY AND NON-ADHERENCE FROM ELECTRONIC HEALTH RECORDS (EHR)

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Background and Importance Electronic Health Records (EHRs) contain free text fields such as clinical notes. These text fields frequently contain valuable information about the context of patients. Nevertheless, this information is often unused as text fields are time-consuming to read. The context variables language barrier, living alone, cognitive frailty and non-adherence are associated with unplanned hospital readmissions. Previous studies have not explored whether text-mining could help to identify these variables from free text.

Aim and Objectives The primary aim of this study was to identify the four context variables language barrier, living alone, cognitive frailty, and non-adherence from the EHRs using text-mining.

Material and Methods The study population was from a database of $n = 1,120$ unplanned hospital readmissions (30-days) at OLVG hospital. A manual standard was created by extracting information from clinical notes and categorising each patient for each variable (in duplo). For the simple terms language barrier and living alone, a rule-based algorithm was used, see figure 1. For the more complex terms cognitive frailty and non-adherence, a Named Entity Recognition (NER) algorithm was used, see figure 2. Each algorithm was validated against the manual standard until a high percentage agreement was achieved for a maximum of five iterations. The primary outcome was the percentage agreement and kappa value between the manual standard and the algorithm. Descriptive data analysis were used.

Results The rule-based algorithm for language barrier had a percentage agreement of 96.8% and a Kappa of 0.90. For living alone the percentage agreement was 76.8% and the Kappa 0.53. The NER model for cognitive frailty had a percentage agreement of 95.1% and Kappa of 0.83, and for non-adherence the agreement was 91.9% and Kappa 0.37. Generally, the models overestimated the number of patients with a context variable (e.g. a family member with a language barrier rather than the patient himself).

Conclusion and Relevance In this study, text-mining was able to identify context variables from EHRs, with a good kappa for the variable language barrier and cognitive frailty. Future studies should explore how overestimation in text-mining could be reduced. Text-mining could help healthcare professionals to anticipate on patient context in the future to optimise care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-140 FREQUENCY OF BLEEDING EVENTS REQUIRING HOSPITALISATION IN PATIENTS UNDERGOING HOME TREATMENT WITH DIRECT-ACTING ORAL ANTICOAGULANTS (DOACS)

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Background and Importance DOACs were developed to minimise the drawbacks of oral vitamin K antagonists (VKAs). The goal of the new drugs was to keep or improve the efficacy as well as the safety in the bleeding monitoring. Pivotal clinical trials showed a favourable benefit/risk ratio. However, these studies had methodological limitations.

Aim and Objectives To determine the frequency of bleeding events that require hospital admission in patients receiving DOAC treatment, analysing the characteristics of the patients and classifying the bleeding events according to the type of DOAC and the site of bleeding.

Material and Methods Retrospective observational study that includes all patients treated with DOACs who required hospital admission due to a bleeding event (ICD-10-CM: T45.51). The study was performed between January 2016 and March 2022. The variables collected were: sex, age, DOAC and type of haemorrhage responsible for hospital admission. Data were collected from computerised medical records and they were analysed with the statistical program SPSS®.

Results 53 hospital admissions were included. The mean age was 79.3 ± 7.1 years. 37 (69.8%) episodes corresponded to men. If bleeding event was associated with the type of DOAC, it was found: 20 (37.7%) episodes for dabigatran, 17 (32.1%) for apixaban, 8 (15.1%) for rivaroxaban and 8 (15.1%) for edoxaban. Regarding type of haemorrhage, 23 (43.4%) episodes were related to lower gastrointestinal bleeding (LGIB), 11 (20.8%) to haematuria, 9 (17%) to upper gastrointestinal bleeding (UGIB) and 7 (13.2%) to intracranial haemorrhage (ICH).

The most prevalent DOAC in each haemorrhage was studied. Dabigatran was the most frequent with 10 (43.5%) events in LGIB and with 5 (71.4%) cases in ICH. However, apixaban was the most frequent with 4 (44.4%) episodes in UGIB and with 4 (36.4%) cases of haematuria.

Regarding type of bleeding by sex, LGIB (OR=1.68; CI =0.74-3.83) and ICH (OR=2.19; CI =0.98-4.90) were more frequent in women, while haematuria (OR=1.41; CI =1.06-1.90) and UGIB (OR=1.35; CI = 0.99-1.85) were more common in men.

By age range, percentages of UGIB, haematuria and ICH cases were higher in patients aged 80 years or older, being 55.6%, 54.5% and 57.1% respectively. LGIB occurred in patients younger than 80 years (56,5%).

Conclusion and Relevance Patients who required hospitalisation were elderly, having a higher risk of suffering different haemorrhages when were over 80 years old. Statistically significant differences between haematuria and men were observed. Gastrointestinal haemorrhages and haematurias were the most

frequent diagnosis. Dabigatran was the cause for most of the hospital admissions, being mainly involved in LGIB and ICH, followed by apixaban, related with UGIB and haematuria.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-141 FALLS IN ELDERLY PATIENTS AND CHRONIC CONSUMPTION OF ANXIOLYTIC BENZODIAZEPINES

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Background and Importance Falls in the elderly have a multifactorial component, among these factors, one of the main causes is chronic consumption of benzodiazepines (BZD).

Aim and Objectives To describe the prevalence of chronic consumption of anxiolytic BZD in elderly people who have suffered falls within hospital admission schemes.

Material and Methods Cross-sectional descriptive and observational study in a health area. We identified through the Minimum Basic Data Set (CMBD) patients older than 64 years with hospital admission with code W19.XXXA (Unspecified acute fall, initial contact) according to the International Classification of Diseases version 10, between 2017 and 2021. Variables collected: date of birth, sex, comorbidities and Van Walraven Comorbidity Index.

Chronic consumption (more than 4 weeks) of anxiolytic BZD (ATC-WHO code N05BA) recorded in the prescription billing system was analysed in these patients. Patients who had picked up BZD at the community pharmacy during the fall episode were the ones selected.

Data were analysed using Stata/BE v17 statistical software.

Results 1585 patients (63.8% female) with acute fall code hospital admission between 2017 and 2021 were identified. Median age at admission was 82.6 [IQR 11.5]. And median of Van Walraven Comorbidity Index was 5.0 [IQR 11.0], mainly: hypertension (49.0%), arrhythmias (29.5%) and diabetes (22.4%). Patients that had more than one fall episode represented 6.5% of total, with a median of 7.0 [IQR 7.4] days of hospitalisation. Chronic anxiolytic BZD use during the fall episode was observed in 23.3% (77.3% female) of patients. The most frequently used anxiolytic BZD were lorazepam (48.6%), bromazepam (29.4%) and diazepam (14.3%), the first two being of short/intermediate half-life and diazepam of long half-life.

Conclusion and Relevance Almost a quarter of the study population with unspecified acute falls were chronic anxiolytic BZD users, mainly with a short/intermediate half-life. Because BZD use in the elderly is a causative factor in falls, it is necessary to adjust treatment, recommending de-prescription or gradual dose reduction where possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-143 THE ROLE OF THE PHARMACIST IN INCREASING HEALTH VIGILANCE AMONG HEALTH PROFESSIONALS: ANGIOEDEMA FOLLOWING THE ADMINISTRATION OF RITUXIMAB

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Background and Importance Angioedema is a rapid swelling of the skin and mucous membranes in the head and neck area and should be treated as an emergency.¹ Rituximab is a chimeric monoclonal antibody used in chemotherapy against the CD20 surface molecule.²

Aim and Objectives This work is aimed to evaluate the efficacy and the safety of rituximab administration by determining the causality of suspected angioedema in patients receiving chemotherapy.

Material and Methods We are reporting two cases of angioedema on Rituximab :

- A 66 years old man with DLBCL who received four courses of RCHOP (Rituximab, Cyclophosphamide, Doxorubicin and Vincristine). On the fifth course and 15 minutes after starting administration of rituximab, he developed angioedema, after that, he received hydrocortisone and adrenaline and was quickly transferred to the intensive care unit, 12 hours later, he was pronounced dead
- A 52 years old woman with a history of pulmonary tuberculosis treated 18 years ago, treated for marginal zone lymphoma with RCHOP protocol, she presented an angioedema two hours after the start of the rituximab infusion during the 2nd course of the protocol. The patient received hydrocortisone and adrenaline and she recovered well.

The cause/effect assessment was carried out according to the French method after a thorough investigation.³

Results For both cases, the results showed that rituximab was incriminated with an intrinsic imputability score of I5 and an extrinsic imputability score of B4, caused by administration of a high rate of rituximab (200mg/h) at the start of the infusion.

To avoid this type of adverse event, the hospital pharmacist adjusted the rituximab infusion, starting with infusion rate of 50mg/h for 30 minutes and then increasing by 50mg/h every 30 minutes to reach a maximum of 400mg/h.

Conclusion and Relevance This observation illustrates the role of the hospital pharmacist in making nurses and doctors aware of the risks of administering drugs that can cause angioedema, in particular rituximab, to prevent the risk of incidence and improve vital prognosis.

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Conflict of Interest No conflict of interest

5PSQ-144 **ELECTRONIC PATIENT REPORTED OUTCOME (PROM) MEASUREMENT USING PRO-CTCAE[®] QUESTIONNAIRE TO IMPROVE QUALITY OF LIFE ASSESSMENT AND HEALTHCARE RESOURCES MANAGEMENT IN PATIENTS WITH LYMPHOMA RECEIVING INTRAVENOUS CHEMOTHERAPY**

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Background and Importance PROMS begin to make a place in the world of clinical care, for this reason, it was implemented in our hospital.

Aim and Objectives The primary objective was to compare the adverse events (AEs) profile reported in the electronic medical record (EMR) and those reported by patients through a validated questionnaire (PRO-CTCAE[®]). Secondary, were to analyse the impact in the reduction of visits to Emergency Room (ER).

Material and Methods Patients with diagnosis of non-Hodgkin's lymphoma in the need of IV therapy between January 2019 and December 2021 were included. 'E-Res Salud' was launched in January 2020. Patients included in 2019 were the control arm. PRO-CTCAE[®] was electronically sent through the app after 1st, 3rd, and 6th month of therapy. Those symptoms of low intensity were to receive recommendations automatically through the app. Those symptoms of high intensity were to receive a teleconsultation call by the nurse. A Sankey diagram was built to depict flows of severity of symptoms. Two-sided test and p-values <0.05 were considered statistically significant.

Results Among the 201 patients included in the study, 76 patients (37.8%) reported outcomes in the ePROM program. Most frequently AEs reported in the EMR were haematological (73%), gastrointestinal (62%) and psychological (38%). In contrast, the most frequently patient-reported adverse events were cutaneous (47%), gastrointestinal (44%) and oral (26%), according to PRO-CTCAE[®] categories (p<0.01).

After the first course of chemotherapy, 46% of patients reported symptoms of high frequency, intensity or impact in their QoL. At third month the proportion was significantly higher (67% vs 46%; p<0.05). Differences were also statistically significant between first and sixth month (p<0.01).

Those who were adherent to the program had fewer number of visits to ER (19.2% vs 55.2%; p<0.01) and required fewer unscheduled hospital admissions (15.8% vs 37.6%; p<0.01). When analysing outcomes of patients who were called by a nurse reduced the proportion of patients who visited the ER vs those who did not report any or low intensity symptoms (18.8% vs 53.8%; p<0.01). Survival among patients visiting ER was significantly shorter than among those who did not (hazard ratio, 2.26; 95% [CI], 1.11 to 4.63; p=0.025).

Conclusion and Relevance Better understanding of patient-reported symptoms could aid pharmacist to develop an individualised treatment dose adjustment and reduction of ER visits should be a key target for haematologists as it may impact in survival.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-145 **A PATIENT SATISFACTION SURVEY ON UNIT DOSE DRUG DISTRIBUTION IN HOSPITAL**

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Background and Importance Since the beginning of the COVID-19 pandemic drug distribution in the Hospital St. John of God, Linz, has been switched to automated unit dose packaging. We intended to create evidence for patients' satisfaction with pharmacy delivered blister sachets, as literature on this topic is limited and our service is so far unique in Austrian hospitals.

Aim and Objectives We performed a patient satisfaction survey to investigate the status quo as well as potential needs for improvement and to provide the basic data for further analyses.

Material and Methods Patients were interviewed inhouse with an internally developed questionnaire. Its mixed design – 12 multiple-choice questions and fields for comments – enabled quantitative and qualitative findings.

Patients not familiar with the blister medication (e.g. no oral drugs) or not (mentally) fit enough were excluded. Within a period of two weeks hospital pharmacists carried out 38 face-to-face interviews.

Results Patient satisfaction with the blisters was high; Transparency in administered drug therapy was considered important. Patients not or rather not satisfied stated difficulties in handling the blisters (20%). Poor physical conditions, vision deficiency and higher age correlated with utilisation problems and lower satisfaction. One in 10 patients had not been capable of opening the blister sachets and taking the medication without assistance. Two-thirds found unit dose drug distribution preferable or equal to traditional pill dispensers. Some patients commented on the environmental effects of the plastic sachets.

Responding to the reported difficulties we placed infographics in the patient rooms illustrating the labelling and handling of the unit dose sachets. The staff on the wards were trained to give further information to patients and assistance in opening and emptying the blisters.

Conclusion and Relevance Studies on the effects of unit dose supply usually focus on cost-effectiveness, medication safety and nursing staff time and satisfaction. Our results add information on the patient perspective and were important for quality improvement: This pilot study not only allowed for immediately implemented actions (graphic depictions for patients and staff training) but is also a guidance for the design of a larger study (patient selection, interview technique, reliable and valid questions) to obtain sufficient statistical power and quantifiable and actionable data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

Section 6: Education and research

6ER-001 THE USE OF GAMIFICATION TO EVALUATE PUBLIC UNDERSTANDING OF ADVERSE DRUG REACTIONS

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Background and Importance The public was far less aware of adverse drug reactions than the efficacy of drugs. Everyone needed to take care of their own medication safety.

Aim and Objectives To develop an interactive game to evaluate public understanding of adverse drug reactions.

Material and Methods We designed an interactive game through the use of 'Wordwall' online template: 'Quiz' for 'Adverse drug reactions'. The correct answer of each question could be shown automatically at the end of the game. The outcomes were collected during July 2022 and evaluated with t-test by SPSS (Statistical Product and Service Solutions) 23.0.

Results 46 people were included in the game and the total correct rate was $81.74 \pm 18.29\%$. The lack of knowledge about adverse drug reactions was found, for example, 26.08% people thought that adverse drug reactions must occur when taking medicine. Besides, 41.30% people thought that the medication must be discontinued if any adverse drug reaction occur. 17.39% people agreed that adding on other drugs may increase the incidence of adverse drug reactions. Finally, 6.52% people did not know they could feed back to prescribing physicians and pharmacists to mark the adverse drug reaction in medical records.

Conclusion and Relevance 'Wordwall' was an easy-to-play and user-friendly game. Our results indicated that gamification was well accepted among people and helped pharmacists understand what people really think about adverse drug reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-004 EFFECTIVENESS AND SAFETY OF COVID-19 VACCINATION IN PATIENTS WITH IMMUNE-MEDIATED DISEASES ON BIOLOGICAL THERAPY

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Background and Importance The effectiveness and safety of COVID-19 vaccines has been demonstrated in the pivotal trials that have led to their approval. However, there is no specific information available regarding COVID-19 vaccination in patients with immune-mediated diseases (IMD).

Aim and Objectives Evaluate the effectiveness and safety of COVID-19 vaccines in patients with IMD who are being treated with biological drugs (BD).

Material and Methods Prospective descriptive observational study of patients with IMD treated with BD who have received at list one dose of any of the COVID-19 vaccines commercialised.

Variables collected: age, sex, IMD, BD, post-vaccination COVID-19 infection, adverse reactions observed after vaccination.

Demographic and clinical data were obtained from the medical records.

To assess effectiveness, we checked the number of patients who became infected with SARS-CoV-2 after vaccination and whether the infection was asymptomatic, with mild symptoms or required hospital admission.

To assess safety, a standardised interview of adverse reactions observed in the first seven days after COVID-19 vaccination was conducted during routine pharmacy practice.

This study was approved by the Ethics Committee of Research with Medicines under code: 2021/435.

Results 106 patients (52.8% female) were included, with a median age of 53 years (21-76). The most frequent IMD were: rheumatoid arthritis (33%), psoriatic arthritis (15%), psoriasis (15%) and Crohn's disease (11.3%). The most commonly used BDs were: adalimumab (33.9%), etanercept (25.5%), abatacept (7.5%), ixekizumab (6.6%), secukinumab (6.6%), golimumab (5.7%) and ustekinumab (4.7%).

Twenty-two patients (20.75%) were infected after receiving doses of COVID-19 vaccines: 2 after the first dose, 6 after the second dose and 14 after the third dose. Infected patients had mild symptoms (77.3%) or were asymptomatic (22.7%). No patient required hospital admission.

The most common adverse reactions were: pain at the injection site (79.2%), fatigue (48%), malaise (42.4%), myalgia (35.8%), headache (33%), arthralgia (25.5%), fever (21.7%), pruritus (11.3%), nausea or vomiting (9.4%), and lymphadenopathy (9.4%).

Conclusion and Relevance 79.25% of the patients studied were not infected with SARS-CoV-2 after vaccination. Most of the infected patients had mild symptoms and none of them required hospital admission.

Adverse reactions were similar to those described in the general population, the most frequent being pain at the injection site, fatigue and malaise.

COVID-19 vaccines were effective and safe in patients with IMD treated with BD included in the study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-005 EFFECTS OF ADHERENCE TO THE MEDITERRANEAN DIET IN PATIENTS WITH AUTOIMMUNE DISEASES

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Background and Importance Adherence to a healthy dietary pattern has been shown to be inversely associated with metabolic syndrome. Low adherence to the Mediterranean diet is directly associated with a worse profile of plasmatic inflammation markers. Some studies have shown that this diet may reduce the risk of autoimmune diseases.

Aim and Objectives To evaluate adherence to the Mediterranean diet in patients with autoimmune diseases as well as their quality of life.

Material and Methods Retrospective, descriptive study of the adherence to the Mediterranean diet in patients with autoimmune diseases during January to March 2021. Variables collected: demographic (sex, age), diagnosis, body mass index (BMI), biological therapy, lifestyle, cholesterol, triglycerides, glucose, ferritin, calprotectin and C-reactive protein levels.

Adherence was measured by the PREDIMED questionnaire. Quality of life was determined by: Visual Analog Scale for Pain (VAS), Checklist Individual Strength (CIS) and The Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F). Information sources: electronic prescription and computerised medical record. Statistical analysis with R[®] software.

Results 66 patients were included (50% women), median age 48 (IQR 38-56). Median BMI 26.3 (IQR 26-39.1). Most frequent diseases: rheumatoid arthritis (18), Crohn's disease (10), ankylosing spondylitis (8) and multiple sclerosis (7). 42% of patients had no previous comorbidity, 28% had arterial hypertension, 13.6% hypercholesterolemia and 6% depression. The median diagnosis year of the disease was 2012 (IQR 2002-2016). 37.8% of patients have had two lines of treatment, 24.2% three lines, 4.5% four lines. The most frequent drugs were anti-TNF therapy (19 adalimumab, 4 certolizumab, 4 etanercept), tocilizumab (5) secukinumab (4) and tofacitinib (4). Median scale VAS was 4 (IQR 1-6), CIS 83 (IQR 76-91) and FACIT-F 16 (11-24). Median of the PREDIMED questionnaire was 7 (low dietary adherence). No statistically significant differences were found between adherence to the Mediterranean diet and scores on quality of life questionnaires. Statistically significant differences were found with calprotectin levels and glomerular sedimentation volume. 78.7% of patients are not aware of foods with potential anti-inflammatory properties and 87.8% would like to receive dietary recommendations from healthcare professionals.

Conclusion and Relevance Although more studies are needed to link diet to autoimmune diseases, it is true that an appropriate diet reduces the risk of multiple pathologies. Patients demand information and as health professionals we must give it to them and reinforce adherence to good dietary patterns such as the Mediterranean diet.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-008 CORRELATES OF ONE-YEAR MORTALITY AMONG PATIENTS LIVING WITH HIV ACCORDING TO THE STRATIFICATION LEVEL OF THE PHARMACEUTICAL CARE MODEL

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Background and Importance The success of highly active anti-retroviral (ARV) therapy has allowed people living with HIV (PLWH) to have a near-normal life expectancy. However, the increase in life expectancy has generated a new set of challenges in these patients, who often experience age-related comorbidities and, with it, polypharmacy with the negative consequences that this entails.

Aim and Objectives To analyse the effect that the level of stratification has on mortality results at one year and develop a predictive model in PLWH on active ARV

Material and Methods A single-centre, cross-sectional study that included PLWH on active ARV who attended Pharmaceutical Care outpatient between 1 January and 15 March 2021 and were followed up for a period of 1 year. Demographic, clinical, pharmacotherapeutic variables were collected and pharmaceutical care, level of stratification (according to

HIV patient model published by SEFH). A survival analysis was performed to assess how the level of stratification predicted mortality at one year. The survival rate was estimated using Kaplan-Meier and differences between levels were evaluated using a log-rank test. After verifying the proportional hazard assumption, a Cox regression was run to estimate hazard ratios (HR). To evaluate the discriminatory power of the model, the calculation of the area under the ROC curve (AUC-ROC) was carried out. The analysis was carried out using the SPSS v.28.0 software.

Results A total of 428 PLWH were included. More than 90% of the patients had adequate immunovirological control. The distribution of patients according stratification model was: level 3 (83%), followed by 12% and 5% for level 2 and 1, respectively. At the end of follow-up, 5 patients died. The results of log-rank analysis showed significant differences regarding level of stratification for mortality at one year ($p=0.02$). Cox regression identified level of stratification as a risk factor for mortality, where patients stratified as level 1 had a 99.7% higher risk (HR: 0.003; 95% CI: 0.001-0.027). The AUC-ROC was 0.98 (95% CI: 0.96-1.00).

Conclusion and Relevance Patients classified as level 1 in pharmaceutical care stratification model have a higher risk of mortality at one year. The predictive model developed highlights the importance of this concept and the need for both individualised pharmaceutical care and comprehensive monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-009 COMPARATIVE EFFICACY OF ABEMACICLIB AND PALBOCICLIB AS ADJUVANT TREATMENT IN PATIENTS WITH EARLY BREAST CANCER

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Background and Importance Abemaciclib in combination with endocrine therapy (ET) has recently been authorised for adjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2) negative and luminal early breast cancer (EBC) at high risk of recurrence.

Aim and Objectives To assess the comparative efficacy between abemaciclib and palbociclib in HER2-negative, high risk of recurrence and luminal EBC patients and to establish whether these drugs can be considered equivalent therapeutic alternatives (ETA), through an adjusted indirect treatment comparison (ITC).

Material and Methods A bibliographic search was conducted to identify phase III clinical trials with abemaciclib or palbociclib as adjuvant treatment in a similar EBC population (luminal type, HER2-negative and high risk of recurrence), duration and endpoints. The primary endpoint was invasive disease-free survival (IDFS) and ET was used as a common comparator. Similar clinical trials, consistent results and efficacy demonstration against the common comparator (ET) were required for the adjusted ITC.

Results Two trials were included, one of each drug. Both of them were phase III trials, randomised, in patients with HER2-negative, high risk and luminal EBC. Differences were found in the trial design (abemaciclib open-label vs palbociclib

double-blind), number of patients included (abemaciclib N=5637 vs palbociclib N=1250), treatment duration (abemaciclib two years vs palbociclib one year) and percentage of patients pretreated with taxane, anthracycline or both (abemaciclib 37% vs palbociclib 99%). Clinical trials were not similar due to these differences.

Abemaciclib was effective in HER2-negative, high risk and luminal EBC. However, palbociclib was not. IDFS abemaciclib group was statistically significant (HR=0.70; 95% CI: 0.59-0.82; $p < 0.0001$) with a median follow-up of 27 months (90% patients completed treatment). In contrast, IDFS palbociclib group was not statistically significant (HR=0.93; 95% CI: 0.74-1.17; $p = 0.525$) with a median follow-up of 43 months (92% patients completed treatment).

Regarding consist results, 2-year IDFS rate was different too: abemaciclib 93% vs palpociclib 88%. In short, relevant methodological limitations were detected so adjusted ITC was not possible.

Conclusion and Relevance Abemaciclib and palbociclib cannot be considered ETA in HER2-negative, high risk and luminal EBC, although abemaciclib demonstrated efficacy as adjuvant treatment in these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-010 EVOLUTION OF ONCO-HAEMATOLOGICAL CLINICAL TRIALS FROM 2016 TO 2021: EXPERIENCE FROM A TERTIARY HOSPITAL

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Background and Importance Previous work has described changes in the trends in onco-haematological clinical trials in recent years, describing an increase in the use of surrogate endpoints, changes in their funding or a greater number of non-randomised trials (1, 2).

Aim and Objectives To describe and compare the characteristics of onco-haematological clinical trials opened in a tertiary hospital in 2016 and 2021.

Material and Methods All interventional clinical trials initiated in our hospital in 2016 and 2021 were included. The following variables were collected: title, funding, tumour site, blinding, control, randomisation and primary endpoint. Data were compared using the Pearson χ^2 . Results were deemed statistically significant at $p < 0.05$. Statistical analysis was performed using STATA (StataCorp, Texas, USA).

Results We found 89 interventional clinical trials started in 2016 and 71 studies in 2021. The majority were in the Medical Oncology service (93.6% and 83.1%). Breast cancer accounted for the largest number of trials initiated (22.5% and 19.7%). In both study periods, most clinical trials were industry-sponsored, with an increase over time (82.0% vs 94.4%; $p = 0.019$). More than half of the studies initiated were controlled (58.4% vs 54.9%; $p > 0.05$), randomised (59.6% vs 66.2%; $p > 0.05$) and open-label (78.7% vs 67.6%; $p > 0.05$), with no statistically significant differences between 2016 and 2021. An increase in the number of phase 3 clinical trials was observed (37.0 vs 54.9%; $p = 0.017$), with a predominance of open-label design (54.6% vs 51.3%; $p > 0.05$)

and the use of surrogate endpoints as primary outcomes (54.5 vs 69.2%; $p > 0.05$). No trial had quality of life as a primary endpoint

Conclusion and Relevance Most phase 3 clinical trials used an open-label design and surrogate endpoints as primary outcomes.

Although this is a single-centre analysis, some trends observed by other authors, such as a higher number of industry-sponsored studies, were observed.

None of the 160 clinical trials initiated had quality of life as a primary endpoint.

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Conflict of Interest No conflict of interest.

6ER-011 EFFICACY OF THERAPIES IN NON-SMALL-CELL LUNG CANCER WITH EGFR EXON 20 INSERTION MUTATIONS: A SYSTEMATIC REVIEW

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Background and Importance Patients with non-small-cell lung cancer (NSCLC) and epidermal growth factor receptor (EGFR) exon 20 insertion mutations have poor prognosis and few therapeutic alternatives.

Aim and Objectives To develop a systematic review of platinum pre-treated NSCLC harbouring eGFR exon 20 insertions to assess efficacy of treatments and scientific quality of studies.

Material and Methods Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines was applied in bibliographic review. Search was conducted in PubMed® database up to 15 September 2022. Filter 'clinical trial' on types of articles was applied to the following review strategy: (exon 20 insertion) AND (Therapy/broad[filter]). Inclusion criteria: Randomised clinical trials (RCTs) evaluating treatments in patients diagnosed with advanced or metastatic NSCLC harbouring EGFR exon 20 insertions who had previously received platinum-based chemotherapy. Efficacy endpoints considered were objective response rate (ORR), progression-free survival (PFS) and overall survival (OS). Data recorded: publication date, study design, comparator arm, therapies, sample size, treatment line, efficacy data.

Results Forty search results were found in review. Twelve RCTs were included. Publication dates of studies were between April 2015 and July 2022. Design of studies: 9 (75%) phase II RCT (one was basket trial) and 3 (25%) phase I/II. None of them presented a comparator arm. Therapies assessed: poziotinib, osimertinib (high and low doses), pertuzumab-trastuzumab combination, mobocertinib, amivantamab, erlotinib-onalespib combination, luminespib, ado-trastuzumab emtansine and dacomitinib. Sample size of RCTs ranged from 10 to 114 patients. Both untreated and platinum-pretreated patients were recruited in 4 (25%) RCTs and the rest

comprised exclusively platinum-pretreated population. Ado-trastuzumab emtansine showed the best numerical results according to ORR (54.5%), but the worst PFS (2.8 months; 95% CI 1.4-4.4) and OS (8.1 months; 95% CI 3.5-13.2) of all therapeutic alternatives. The highest numerical efficacy results were achieved by amivantamab [PFS = 8.3 months (95% CI 6.5-10.9); OS = 22.8 months (95% CI 14.6 to not reached)] and mobocertinib [PFS = 7.3 months (95% CI 5.5-9.2); OS = 24.0 months (95% CI, 14.6-28.8)].

Conclusion and Relevance Results of amivantamab and mobocertinib suggested a higher numerical efficacy for clinically relevant endpoints in platinum pre-treated NSCLC harbouring EGFR exon 20 insertions. However, comparative RCTs with larger sample sizes are necessary to obtain reliable data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-017 STRUCTURED OBJECTIVE CLINICAL EVALUATION FOR PHARMACY STUDENTS ON INTERNSHIPS AT THE HOSPITAL

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Background and Importance Structured assessment for final year students is a teaching tool based on the Miller's Pyramid that has been implemented in Spain for many years. To carry out this evaluation system for students doing internships in the hospital's Pharmacy Service is very innovative.

Aim and Objectives To describe the process of designing a structured evaluation for students who are doing their internship in the hospital Pharmacy Service. The purpose of the objective assessment is to verify that the students can demonstrate what they have learned during their hospital practice. To do this, different clinical skills and technical skills will be evaluated, simulating real situations related to the work of the Pharmacy Service.

Material and Methods Six tests have been established: pharmaceutical care for outpatients, validation of medical prescriptions, stock management, reconciliation of medication on admission, preparation of a master formula and oncology pharmacy. All tests are related to daily assistance activities of the hospital pharmacy. In each test, the student has a limited time to perform the task that is indicated. The qualification method is totally objective, through a previously defined checklist. A schedule has been scheduled for everything to be ready in January 2023.

Results The objective clinical evaluation has been structured in 6 tests, in which a total of 24 students may be examined. The presence of 6 evaluators and 3 actors will be necessary. The cost of each test will be minimal because most of the materials are donations from pharmaceutical laboratories and other companies. The qualification is immediate, and the duration of the test will be about 3 hours. The checklist of each test will be reviewed by two evaluators, and must include items on clinical, technical and interprofessional communication skills.

Conclusion and Relevance The clinical evaluation system for internship students in the pharmacy service is expected to be very useful for pharmacists in the Pharmacy Service. Thanks to this exam they will have objective information about their teaching role with these students, thus detecting points for improvement. In addition, the student learns about clinical reasoning, decision-making, problem solving, and interpersonal relationship skills.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-019 THE STUDENT PHARMACIST EXPERIENCE OF ENHANCED CLINICAL PLACEMENTS

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Background and Importance The role of a pharmacist is ever-expanding with an increasing need for the provision of enhanced health services. In response to the General Pharmaceutical Council's recent announcement for 'prescribing ready' pharmacy graduates by 2025, Health Education England has, this year, broadened the clinical tariff for education providers to include pharmacy giving an opportunity to enhance the clinical placements offered to pharmacy students in the UK.

Aim and Objectives The aim of this project was to assess the overall experience students had on an Enhanced Clinical Placements over a variety of clinical settings.

Material and Methods The placement was patient-facing (5-days) under the primary supervision of a prescriber, with a pre-placement induction (15 hours of blended learning) consisting of simulated clinical activities, and a post-placement conference (1 day). During the placement, students had the opportunity to develop an extended range of clinical skills and observe and discuss the prescribing decisions made by their prescribing supervisor which are currently outside the scope of the pharmacy degree.

Two focus groups (n=10 and n=9) were held with students at the post-placement conference. Students were asked about their induction and placement experience. Focus groups were transcribed and analysed using Thematic Analysis.

Results Four main themes emerged from the data, which were named Variety, Consolidation of prior learning, Professional identity, and Logistics. Students expressed an appreciation for the ECP in providing them with additional clinical experience over a wider variety of settings than they had seen before. There was a recognition that the ECP helped to consolidate learning they had gained on the taught courses and that it heightened their professional identity but students also raised some areas for improvement in terms of the general logistics of the placement.

Conclusion and Relevance This was a useful exercise to provide students with a range of experiences, helping them to promote an understanding of their professional value and role within a multi-disciplinary team. Future implementation needs to consider the level of standardisation between placements

and the importance of having clear expectations for students and providers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-020 PRESCRIPTION AND USE OF LIPOSOMAL AMPHOTERICIN B DURING THE COVID-19 PANDEMIC

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Background and Importance The impact of COVID-19 and its influence in the management of hospitalised patients has been indisputable. Many publications present combinations of different antimicrobials to treat the patients infections, and the liposomal amphotericin b (AmB-L) is an example of one of the most prescribed.

Aim and Objectives To compare the prescription and indication of AmB-L in a tertiary hospital before and during the COVID-19 pandemic.

Material and Methods Observational, retrospective, descriptive study of patients prescribed AmB-L from March-2020 to March-2021, and the comparison to the year before the pandemic.

Results 58 patients analysed: 40 (69%) men, median age 71 years (IQR 54.5-75.2), and 18 (31%) women, median age 63.5 years (IQR 49.5-71.25). The months in which more patients received AmB-L were: July 2020 (6/56), December 2020 (7/56) and February 2021(12/56).

-39 (69.6%) CRITICAL patients. Out of these: 22 with a covid diagnosis, 14 non-covid and 3 onco-haematological. 26/39 patients received AmB-L as a targeted treatment for *Candida Glabrata* and *Albicans*(16/26), *Aspergillus Fumigatus* (6/26) and *Mucor* (4/26). As a concomitant therapy, anidulafungin and isavuconazole were the preferent ones. The most prescribed dose of AmB-L was 400 mg (5 mg/kg) with a median of 7 days of treatment (IQR 4-17.5). 86.4% out of the total experienced death.

-17 (30.4%) NON-CRITICAL patients: 0 covid patients, 6 (35.3%) non-covid and 11 (64.7%) onco-haematological patients. 10 (58.8%) patients received AmB-L as empirical treatment for febrile neutropenia, with posaconazole and itraconazole as the most commonly used antifungals. The most prescribed dose was 200 mg (3.3 mg/kg) for a median of 9 days (IQR 6-16).

In the previous year (March 2019 to February 2020) we observed: 17 patients received treatment with AmB-L, 53% (9/17) onco-haematological, 12 men with a median of 53 years (IQR: 38.2-59.1). Most prescribed dose: 180 mg (3mg/kg).

Conclusion and Relevance The data observed in this period reflects how the prescription of AmB-L tripled compared to the previous year. It targets a completely different profile: unstable patients, with invasive lung disease, risk factors in critical care units, treated with high doses of AmB-L. The fact of being an antifungal with a high cost/day per patient, the way of monitoring the situation of this type of patient is a crucial strategy to guarantee efficiency and optimise pharmaceutical spending.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-021 RETROSPECTIVE OF DRUG INNOVATION DURING THE SARS-COV2 PANDEMIC: DEVELOPMENT OF A GAME-BASED TRAINING

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Background and Importance Hospital pharmacies have contributed to the research and development of remedies against coronavirus disease 2019 (COVID-19), by managing many drugs, off-label, in clinical trial, or in early access program. Within the framework of continuing education of pharmacy technicians, a retrospective of this drug innovation process, with a short and playful format, was proposed.

Aim and Objectives To develop and evaluate a game-based training, for the pharmacy technicians, in order to understand the drug innovation process, during the SARS-Cov2 pandemic.

Material and Methods Regardless of their status, 32 medications, used against COVID-19, in our hospital, from March 2020 to May 2022, were identified. For each medicine, a playing card was created with on the front: International Non-Proprietary Name (INN) and princeps, and on the back: INN, princeps, drug status, pharmacological class and family, date of first dispensing. 2 teams of 3 players competed to align the playing cards in chronological order, then the trainer debriefed the game. A presentation support of the training was done, detailing the pedagogical objectives, the rules of the game and the theoretical knowledge. A self-assessment and a feedback form were created.

Results 2 one-hour (30 minutes of play, 30 minutes of debriefing) sessions were conducted. 34 health care professionals, from 14 hospitals, participated in training. 94% of participants completed questionnaires. At the end of the session, 100% improved their knowledge, 84% could chronologically locate the drugs used against COVID-19 (against 16% at the beginning of the session) and 97% could explain the stages of drug innovation during the pandemic (against 3% at the beginning of the session). Regarding the feedback form, 100% appreciated the content and 97% the rhythm of the game. The overall satisfaction rate was 97% (good or very good).

Conclusion and Relevance This gamification of training was very much appreciated. The format combines conviviality and cooperation, while providing serious content. The experience could be replicated, during continuing education, with other themes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-022 CLINICAL IMPACT OF THE USE OF GLUCOCORTICOIDS FOR THE TREATMENT OF COVID-19 IN INTERMEDIATE RESPIRATORY CARE UNITS

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Background and Importance During the pandemic, patients admitted to intermediate respiratory care units (IRCU) received non-invasive respiratory support and pharmacological treatment, mainly glucocorticoids (GC). Dexamethasone is the only one that has shown reducing mortality; however, there are no comparative efficacy studies between the different GC.

Aim and Objectives To determine the possible influence of the type and dose of GC on the patients' evolution with SARS-CoV-2 pneumonia admitted to the IRCU during the first and second wave of the pandemic.

Material and Methods Descriptive, observational and retrospective study of patients with SARS-CoV-2 infection admitted to the IRCU in a tertiary care hospital since March until December 2020. Demographic variables, comorbidities, GC therapy received and final resolution (improvement, transfer to ICU, or death) were analysed. The data were obtained from the clinical history and the electronic prescription.

Results 135 patients (62.5% men) were included with a mean age of 67.00 (SD:13.16) years. 69.31% of them had overweight and 29.41% respiratory pathologies.

89.63% of the patients admitted to the IRCU received treatment with GC, within them, 89 received treatment with a single GC, 27 received the combination of two and only 3 patients received three GC. 64 GC-treated patients improved, receiving a mean prednisone equivalent dose of 65.43 (SD:88.77) mg daily for a mean of 13.40 (SD:7.02) days.

The 19 patients transferred to the ICU received a mean dose of 89.18 (SD:71.81) mg daily for 6,00 (SD: 5.19) days. The 38 patients who died in IRCU treated with GC received a mean dose of 114.18 (SD: 90.39) mg daily for a mean of 8.92 (SD: 6.17) days.

The most used GC or combinations were: dexamethasone (76 patients), dexamethasone and prednisone (13 patients), methylprednisolone (11 patients), dexamethasone and methylprednisolone (8 patients), and methylprednisolone and prednisone (5 patients). 100% of patients treated with dexamethasone and prednisone improved, followed by dexamethasone and methylprednisolone (62.5%) and methylprednisolone and prednisone (60%). 27.27% of the patients treated with methylprednisolone alone improved, with 63.64% dying.

Conclusion and Relevance Most of the patients admitted to the IRCU with coronavirus received GC and the results suggest some improvement in those who received lower doses of GC for longer periods.

The GC combination was associated with a higher rate of improvement, especially with dexamethasone and prednisone. Treatment with methylprednisolone alone had the highest death rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-024

COMPARISON OF REDUCTIONS IN MONTHLY MIGRAINE DAYS BETWEEN NEW SMALL MOLECULE CGRP RECEPTOR ANTAGONISTS (GEPANTS) AND MONOCLONAL ANTIBODIES TARGETING CGRP/CGRP RECEPTOR

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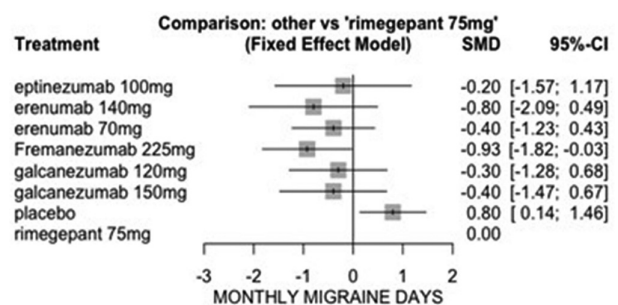
Background and Importance Migraine is characterised by repeated headache attacks lasting hours or days and usually accompanied by other associated symptoms. According to the International Headache Society, it can be classified into

migraine with aura, without aura and chronic migraine. A target pathway to treat or prevent migraine is the calcitonin gene-related peptide. Available treatments in our country that act interfering that pathway are erenumab, fremanezumab, galcanezumab, iptenezumab and rimegepant.

Aim and Objectives To analyse whether the different therapeutic options are equivalent alternatives through an adjusted indirect comparison.

Material and Methods The therapies included were found after a systematic search performed in PubMed. The analysis included randomised, double-blind, phase 2 and 3, controlled trials, prophylaxis therapies and number of migraine days reduced measurement after 12 weeks of treatment. The analysis was performed using the R[®] software to estimate Bayesian statistics, with rimegepant taken as a reference for the comparison. A delta value of 1 day, as provided by the regulatory agencies FDA and EMA, was used to determine the margin (maximum acceptable difference as a non-inferiority criteria) and the average number of migraine days reduced. To establish the therapeutic positioning, the National Equivalent Therapeutic Alternatives Positioning Guide criteria were applied.

Results As shown in Figure 1, the difference in the mean number of migraine days reduced per month versus placebo was favourable in all cases. Each treatment reduced migraine by between one to two days per month, showing statistically significant differences. The most outstanding being fremanezumab (-1,73 [-2.33;-1.12]). Based on the results obtained, a subsequent analysis was carried out comparing fremanezumab with the other alternatives. In this case, erenumab 140 mg showed the most similar efficacy result (0.13 [-1.14; 1.39]). Nevertheless, it did not show a statistically significant difference against any treatment, exclusively against placebo. No differences were found in terms of safety.



Abstract 6ER-024 Figure 1 Forest-plot of the decrease in average number of migraine days per month. Comparator: rimegepant 75mg/48h. SMD: standard mean difference. 95% CI: 95% confidence interval

Conclusion and Relevance No statistically significant differences were found between rimegepant and monoclonal antibodies against the CGRP/CGRP receptor except for fremanezumab. Fremanezumab presented a statistically significant more pronounced response in the decrease of migraine days per month at 12 weeks of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-025 EFFECTIVENESS AND SAFETY OF 20% AUTOLOGOUS SERUM EYE DROPS IN PATIENTS WITH CORNEAL SURFACE PATHOLOGIES

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Background and Importance Autologous serum eye drops (SAED), a pharmaceutical formulation prepared from patient's blood, are used in corneal surface pathologies. Since alternative therapies are limited, its prescription has increased in recent years.

Aim and Objectives Analyse effectiveness and safety of SAED in patients diagnosed with corneal surface pathologies.

Material and Methods Observational, retrospective study in a secondary hospital between January 2019 and March 2022 including patients treated with 20% SAED.

Variables: demographic data, diagnose, concomitant diseases, duration of treatment, ocular affectation (left eye (LE), right eye (RE), both eyes (BE)), subjective clinical improvement (SCI), adverse effects (AE), concomitant treatments, visual acuity (VA) at months 0, 3 and 6 of treatment.

Effectiveness was evaluated by SCI and VA, measured on a decimal scale, at three and six months of treatment. Safety was evaluated by AE documented in medical records.

Results Thirty-five patients (77% women) were included with mean age 61 years (20-96). Principals diagnoses were: dry eye syndrome (n=15), superficial punctate keratitis (n=10) and Sjögren's syndrome (n=9). Forty-eight percent of patients presented concomitant diseases, highlighting fibromyalgia in six of them.

Mean treatment length was 500 ± 348 days. Ten patients (28%) discontinued treatment during the study. The reasons were: reaction to 20% SAED (n=4), remission (n=4), death not associated with the treatment (n=1) and change of hospital (n=1).

Twenty-nine patients (82%) had affectation in BE. SCI was observed in 82% of patients at months three and six. Principals AE were: conjunctival hyperaemia (n=4), blepharitis (n=2), stinging (n=1) and tears with excess mucus (n=1). Artificial tears (51%) and corticosteroids eye drops (11%) were the main concomitant treatments.

VA data was available in 14 patients (40%). Mean VA in RE was 0.80 ± 0.29 , 0.80 ± 0.31 and 0.82 ± 0.25 at months 0,3 and 6 respectively. Mean VA in LE was 0.85 ± 0.25 , 0.83 ± 0.23 and 0.87 ± 0.15 respectively.

Conclusion and Relevance According to SCI and VA's progressive improvement over the months and a low incidence of AE, 20% SAED are an effective and safe treatment for corneal surface pathologies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-026 SPECTRUM OF HEART FAILURE IN 16 SUB-SAHARAN AFRICAN COUNTRIES: TREATMENTS AND IN-HOSPITAL OUTCOME

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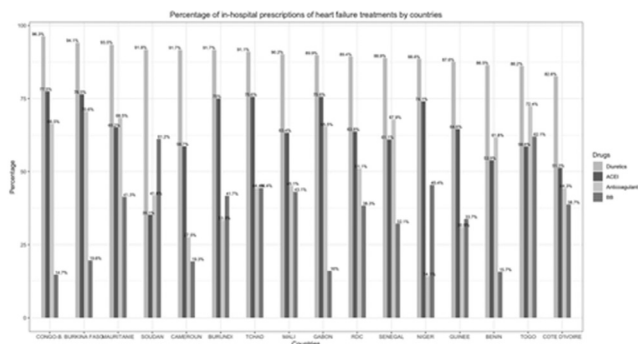
10.1136/ejhp-2023-eahp.349

Background and Importance Heart failure (HF) is the most common primary diagnosis for patients admitted to hospital with heart disease in sub-Saharan Africa (SSA). However, little is known about the management of HF in hospitalisation in SSA.

Aim and Objectives To describe in hospital drugs strategies to manage HF in 36 cardiovascular (CV) departments.

Material and Methods We conducted a transversal and longitudinal study in CV departments of 36 hospital (public and private) in 16 SSA countries. The February study is an ongoing observatory included all inpatients in February from each year since 2016. Data including socio-demographic and clinical characteristics, CV risk factors, causes of admission, medication and length of stay were collected during hospitalisation by physicians. Patient wealth index was assessed by physicians as low, middle and high according to patient capacity to afford hospitalisation. All analyses were performed with random effect on countries and through scripts developed in the R software 4.0.3.

Results Overall, 2084 patients were admitted for HF in the February study. HF representing 47.9% of all patients included. The mean age was 57 ± 17.4 years and 53.8% were men. Proportions of patients admitted for HF varied across countries from 21.4% in Burundi to 66% in Congo ($p < 0.01$). Average length of stay in hospitals was 11 days and mortality rate was 13%. Among HF patients, 74% of patients had CV risk factors and hypertension was reported in 55.8% of patients. During hospitalisation, 88.8% of patients were treated with diuretics followed by angiotensin-converting enzyme inhibitors (ACEI) (61.8%), anticoagulant (47.8%) and beta blockers (BB) (34.6%) (figure). Monotherapy were used in 14%, combination of two drugs, three drugs and four drugs strategies were used in 35%, 33% 12% respectively. Diuretics were mostly prescribed in patient with low wealth index whereas ACEI, BB and anticoagulant in high wealth index ($p < 0.05$).



Abstract 6ER-026 Figure 1

Conclusion and Relevance HF treatment access varied significantly across countries and according to patient wealth index.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-027 ASSESSMENT OF ATTITUDES AND PERCEIVED SKILFULNESS OF PHARMACY STUDENTS IN CARING FOR UNDERSERVED POPULATIONS

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Background and Importance Studies indicate that gaps in knowledge about underserved patient care issues may be associated with the level of comfort and attitudes of pharmacy students caring for underserved patients.

Aim and Objectives The objective of this study was to assess the attitudes, perceived knowledge, and skills of pharmacy students to deliver care to underserved populations.

Material and Methods 385 pharmacy students were eligible to participate in the study. Students completed a modified version of the Health Professionals' Attitudes Toward the Homeless Inventory administered between December 2020 and January 2021. Each participant was asked to rate their level of agreement with 8 statements concerning attitudes toward the underserved and 8 statements regarding perceived skilfulness in caring for the underserved in providing medication reconciliation services and patient counselling on a scale from 1 to 5.

Results The response rate was 22% (n=85). Most students felt comfortable providing medication therapy management (78%), medication reconciliation (79%), and patient counselling (78%) services. 88% felt they knew how to communicate with patients from different cultural backgrounds. The average perceived skilfulness in completing medication reconciliation activities varied longitudinally across class years (P1, 3.4 ± 1.08 ; P2, 4.27 ± 1.01 ; P3, 4.8 ± 1.01 ; P4, 5.0 ± 0.89). The average perceived skilfulness in addressing patients from different cultural backgrounds was highest for students in the P1 years (4.09 ± 1.12) and lowest for students in the P2 class year (3.91 ± 1.21).

Conclusion and Relevance The attitudes and comfort levels of students toward underserved populations did not differ significantly between class years. The perceived skilfulness increased longitudinally between first and fourth-year students in the areas of conducting medication reconciliation activities, counselling and assessing medication understanding in underserved patients. Students in the P1 class year perceived skilfulness in caring for the underserved was higher than students in the P4 class year.

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Conflict of Interest No conflict of interest.

6ER-029 EYE DROPS OF INTERFERON ALPHA-2B TO TREAT OCULAR PATHOLOGIES

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Background and Importance Interferon alpha-2b is an option of treatment in malignant ocular pathologies such as ocular squamous surface neoplasia (OSSN) but its use is less extended to benign diseases like pterygium. In our country we had available Intron® to made eye drops until 2021 June, but its production was discontinued and another drug (Bioferon®) with few data of safety in ocular administration was imported.

Aim and Objectives To evaluate the efficacy and safety of two different drugs (Intron® and Bioferon®) in the treatment of ophthalmic pathologies.

Material and Methods All patients who underwent treatment with eye drops of interferon alpha-2b in our hospital from April of 2009 until August of 2022 were selected. We registered age, type of pathology, time of treatment, adverse events, recurrences and response (partial, complete or surgery immediately after or before treatment).

A literature search was done to make the eye drops from Bioferon® and finally we used water for injection to reconstitute the vial and balanced saline solution to complete 10 mL of volume (concentration of 10 mg/mL).

Results Thirty-six patients received 38 treatments (two patients had both eyes affected). By type of pathology, 24 were pterygium, 8 OSSN, 2 papilloma, 1 epidermoid carcinoma and 1 clear cell carcinoma. From the total of patients with pterygium, 54% received surgery, 21% had partial response and 25% had no response; four patients with malignant pathology (OSSN and carcinomas) had complete response, 2 had partial responses and 4 were operated. All patients with papilloma underwent surgery.

On groups of malignant pathology and papilloma 1 patient had recurrence at each one. Evaluation of recurrences in pterygium group was hard due to lack of follow up after

surgery, but with the data available 70% of them had no recurrences.

Only one of all patients had an adverse event (ocular irritation).

Two patients received Bioferon[®], both with OSSN. One had complete response and the other partial response with no adverse effects.

Conclusion and Relevance We can conclude that eye drops of interferón alfa-2b are safe and effective to treat malignant pathologies and the formulation with the new drug Bioferon seems to maintain safety and efficacy, but we need more patients to confirm it.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-031 KNOWLEDGE ABOUT HUMAN IMMUNODEFICIENCY VIRUS (HIV) TRANSMISSION IN PEOPLE LIVING WITH HIV IN ANTIRETROVIRAL THERAPY

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Background and Importance Human Immunodeficiency Virus (HIV) infection is nowadays chronic due to antiretroviral therapy (ART).

Knowledge about HIV transmission (KHIVT) empowers people living with HIV (PLWHIV) to engage in ART.

Aim and Objectives To describe KHIVT among PLWHIV on ART and to identify factors associated with lower access to this information.

Material and Methods Multicentre (5 centres), observational, prospective and cross-sectional study. We included adult PLWHIV on ART with >3 months since diagnosis.

KHIVT was evaluated using an *ad hoc* questionnaire of 20 statements, to be replied 'true' or 'false'. Results are the percentages of correct answers, considering as optimal knowledge results $\geq 80\%$.

Factors collected were sexual orientation, gender identity, racialisation, religion, social support, educational level, relationship and economic status, social visibility, drug use, and involvement in sex work.

Associations between quantitative and qualitative variables were analysed with Student's T test or Mann-Whitney U test based on normality tests. Spearman correlation coefficient (r) was used between quantitative variables.

P-values <5% were considered statistically significant.

Results We enrolled 169 participants, aged 20-81 years old ($\bar{x}=46.6 \pm 12.2$); 147 men, 19 women, and 3 non-binary people.

KHIVT obtained an average result of $87.2 \pm 10.4\%$. 77.52% of participants had optimal knowledge.

Three of the four statements with the worst results were that related to HIV untransmissibility in PLWHIV with undetectable viral load (U=U).

| STATEMENT | PARTICIPANTS THAT ANSWERED CORRECTLY (%) |
|---|--|
| ART could allow unprotected sex without risk of transmission (TRUE) | 38.46% |
| There is no risk of transmission when the viral load is undetectable (TRUE) | 64.50% |
| HIV can be transmitted through infected bodily fluids (TRUE) | 72.78% |
| Children of HIV+ pregnant persons will always be HIV+ (FALSE) | 75.15% |

Women achieved worse results than men ($\Delta\bar{x}=8.16$ | CI95%:3.3-13.0 | $p=0.001$).

Heterosexual men achieved worse results than homosexual men ($\Delta\bar{x}=6.1$ | CI95%:2.7-9.5 | $p=0.001$). There were no significant differences between bisexual men and other men.

PLWHIV with no/only primary education obtained worse results ($\Delta\bar{x}=7.5$ | CI95%:3.2-11.8 | $p=0.000$).

PLWHIV with an income <1,000€/month (gross) obtained worse results ($\Delta\bar{x}=3.7$ | CI95%:0.5-6.8 | $p=0.015$).

Age was inversely correlated with KHIVT ($r=-0.367$ | $p=0.000$).

Conclusion and Relevance About a quarter of PLWHIV have sub-optimal KHIVT. Furthermore, the premise U=U is not yet sufficiently widespread.

Women, heterosexual men, older people, people with low education level and those with a limited economical income have greater difficulty accessing this information.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-032 HOW CAN DUTCH UNIVERSITY HOSPITALS CONTRIBUTE TO AFFORDABLE MEDICINES AND COST CONTAINMENT OF TOTAL HOSPITAL DRUG EXPENDITURE: A DELPHI STUDY

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Background and Importance Increasing expenditure on pharmaceuticals is of growing concern to the affordability of health-care systems across Europe. As stated in the European Commission (EC)'s Pharmaceutical Strategy for Europe all stakeholders should be involved in tackling this problem. The EC has indicated that solutions along the entire drug life cycle (DLC) should be considered as it offers a more comprehensive and integrated view to address this topic. Being a stakeholder, university hospitals (UH) are engaged in multiple phases of the DLC, consisting of (pre-)clinical research, market authorisation, pricing and reimbursement, manufacturing, procurement, prescribing, dispensing and monitoring real-world effectiveness.

Aim and Objectives We aimed to explore which activities UHs perform or should perform to contribute to cost containment of medicines.

Material and Methods We used a Delphi technique and assembled an expert panel of 31 pharmaceutical experts of Dutch UHs (i.e., doctors, researchers, hospital pharmacists, directors), health insurers and governmental authorities. In the first round, we explored activities UHs currently perform or should perform throughout the DLC and what barriers or dilemmas they encounter. In the second round, we asked our panel on a 5-point Likert point scale to (dis)agree with all mentioned activities and barriers. The third round was used to reach consensus on activities and barriers which were (dis)agreed upon less than 50%.

Results The panel agreed that, considering (pre-)clinical research, UHs should increase involvement in drug repurposing and monitoring of real-world effectiveness of medicines. Furthermore, while prescribing medicines is reserved for medical specialists UHs should raise more awareness on cost-effective prescribing by doctors via more active involvement of hospital pharmacists, adjustment of national prescribing guidelines and extending pharmacotherapy education. Finally, cost containment could be enhanced by reducing spillage, e. g., efficient dosing. Controversy among the panel remained on the notion of UHs building more knowledge on regulatory affairs for marketing authorisation and increasing their effort on self-manufacturing of medicines. Agreed upon barriers restricting UHs to expand their activities were insufficient financial resources and legal and entrepreneurial expertise.

Conclusion and Relevance UHs should increase their efforts to reduce costs of medicines throughout the whole DLC, but especially on activities regarding drug repurposing, avoidance of spillage and cost-effective prescribing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-033 PEMBROLIZUMAB AND ATEZOLIZUMAB AS POSSIBLE EQUIVALENT FIRST-LINE THERAPEUTIC ALTERNATIVES IN PD-L1-EXPRESSING TRIPLE-NEGATIVE BREAST CANCER

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Background and Importance Recent studies have established the influence of the immune system on disease progression in triple negative breast cancer (TNBC) patients.

Aim and Objectives To determine if pembrolizumab and atezolizumab can be considered equivalent first-line therapeutic alternatives (ATE) by using a common comparator, for patients with locally recurrent unresectable or metastatic unresectable TNBC in adults whose tumours express PD-L1 and who have not received prior chemotherapy.

Material and Methods A bibliographic search was conducted to select phase III randomised clinical trials of first-line treatments for TNBC. The indirect comparison was performed with the Bucher method. The variable selected to determine clinical equivalence was progression-free survival (PFS), due to the lack of maturity with respect to the overall survival variable. The maximum acceptable difference as a clinical non-

inferiority standard Delta (D), and its inverse were set at 0.65 and 1.54, respectively. They were established by ESMO-Magnitude of Clinical Benefit Scale.

To establish the positioning, we applied the criteria of the guide on therapeutic alternatives.

Results According to the clinical studies reviewed, a potential therapeutic equivalent to pembrolizumab, atezolizumab combined with nab-paclitaxel (IMpassion 130) was identified for the treatment of TNBC whose tumours overexpress PD-L1 \geq 1% and who have not received prior chemotherapy for their metastatic disease. Although in our case (KEYNOTE-355), the PD-L1 \geq 10 subgroup was considered the reference subgroup for the study, we have data from the PDL1 \geq 1 subgroup in patients treated with pembrolizumab in combination with chemotherapy that allow us to make the comparison.

After applying the Bucher method, a HR=0.85 (95% CI 0.63 to 1.16) was obtained for pembrolizumab + chemotherapy versus atezolizumab + nab-paclitaxel. Considering the standard delta established, this is a probable clinical equivalence. We have to resort in this case to Shakespeare's calculator which states that there is a 4.25% probability that the value is below 0.65. Since this is a probability of less than 17%, we can conclude that these are equivalent therapeutic alternatives.

Conclusion and Relevance Pembrolizumab and atezolizumab could be considered ATE, however, recent studies such as the Impassion 131 bring a great deal of uncertainty to this determination.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-034 USE OF CLOSED SYSTEM TRANSFER DEVICES WITH INVESTIGATIONAL DRUG PRODUCTS

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Background and Importance Investigational drug products (IDP) should be treated as hazardous drugs (HD) as it is not frequent to have hazard studies available or the information about safety is usually insufficient. This is a handicap for pharmacists, who must guarantee the safety of professionals during the handling, preparation and administration of IDP as well as drug quality.

Recommendations by NIOSH and USP include the use of closed system transfer devices (CSTDs) in the healthcare setting to reduce occupational exposure to HD.

Frequently there is a lack of information about the potential impact of using CSTDs on product quality. This may be a challenge, especially when they are used with IDP, monoclonal antibodies (mAb) and drug-conjugated mAb.

Aim and Objectives To review the scientific evidence related to the use of CSTDs when compounding and administering IDPs, in order to determine the main challenges related to its use and to establish the use criteria in daily practice.

Material and Methods A comprehensive search in PubMed database was performed. The search strategy was based on a combination of the following terms: closed system transfer devices, drug development and biologic products (meSH

term). We included studies evaluating CSTD, safe handling and drug quality.

Results We included 7 articles (one systematic review, four reviews and two prospective studies) that showed the following critical issues:

- There is a wide variety of components in CSTDs that can potentially cause incompatibility issues, physical and chemical instabilities as well as drug loss and poor quality product due to adsorption onto CSTD materials.
- CSTDs are associated with higher incidence of insoluble fine particles related to silicone oil droplets. MAb are known to form aggregates when CSTDs are used that could be potentially detrimental to patient safety.
- CSTDs holdup volume range from 0,04 to 1 mL which has an impact on deliverable drug dose which is especially worrying in low volume-dose IDP.

Conclusion and Relevance Frequently, there is insufficient information to exclude safety concerns for IDP leading to broad use of CSTDs according to guidelines.

There is an urgent need to increase knowledge about the hazard of new therapies and to assess CSTDs impact on product quality, clinical trial outcome and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

Late breaking abstracts

1ISG-003 PROTOCOL FOR THE OPTIMISATION OF PHARMACEUTICAL VALIDATION IN HOSPITALISED PATIENTS

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Background and Importance Pharmacist validation of hospitalised patients' medication is a fundamental task that spends much of the hospital pharmacist's time.

Aim and Objectives To establish a protocol for optimisation of pharmaceutical validation through the analysis of the validation timetable of prescribing physicians.

Material and Methods A validation statistics report was carried out for the prescribing medical staff for the last 6 months (March 2022 to September 2022). In this, the total validations were divided into the 24 hours of the day, calculating the percent corresponding to each of the hours. With the results obtained, an analysis was made of the hours with the most validations per day. With this, the pharmacist validation was adapted to those hours in such a way that most prescriptions were reviewed shortly after being validated by the doctor, and the rest of time were left for other assistance tasks of the pharmacist.

Results The hours with the highest medical validation were 10 a.m. (15.98%) and 11 a.m. (13.52%), while the night hours (0 a.m. to 7 a.m.) had the least validation (0.06–1.03%). Therefore, the pharmaceutical validation schedules were adapted to the following:

- 8 am: to review the treatments validated by the physician between 3 p.m. and 8 a.m. (hours in which the Pharmacy Service is closed), and which correspond to 27.48% of daily medical validations.
- 11 am: to review the treatments accumulated in the hours with the highest medical validation. They correspond to 36.71% of daily medical validations.
- 2 pm: to finish reviewing pending treatments before sending the medication to the patients (which is at 3 p.m.). They correspond to 35.81% of daily medical validations.

Conclusion and Relevance Optimising the timetable of pharmaceutical validation allows the pharmacist to use the rest of the time in other care tasks, which has a positive impact on patients, while still being able to resolve any discrepancies found in the validation at the right time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

1ISG-009 A FRAMEWORK FACILITATING ACCESS TO MEDICINES IN THE EUROPEAN UNION

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Background and Importance In the European Union (EU), access to medicines is established as a fundamental right, enforceable through the judicial system. However, equity to access has become increasingly challenging, with Member States adopting different healthcare models seeking to attain cost-containment quality of care and improved patient outcomes. As a result, patients experience disparate levels of access to medicines. Ensuring enhanced, timely and equitable access is acknowledged as an important goal. This study sought to identify access enablers which may be embedded in the wider health system domain and flexibly adopted by EU Member States.

Aim and Objectives To identify and evaluate factors which impact medicines' access and propose a methodology enabling sound decision-making strategies optimising timely patient access to effective medication.

Material and Methods The study consisted of four phases. Phase 1 addressed pharmacists and healthcare professionals, intended to obtain their feedback on access to medicines through unstructured open-ended questionnaires. In phase 2, structured interviews were held with pharmaceutical policy-makers and experts. Phase 3 consisted of a questionnaire to pharmaceutical regulators and prescribers. In Phase 4, a focus group discussion was organised with policymakers and regulators to collate qualitative and quantitative data and propose the factors impacting medicines access and obtain consensus on the developed access framework.

Results The developed access framework consists of four dimensions that highlight indicators supporting strategies to optimise timely patient access to medication. The domains and the respective indicators are: 1) Uptake (reimbursement, affordability, sustainability); 2) Utilisation (shortages, rational use through protocols, educational material); 3) Audit

(utilisation studies, prescribing databases and patient registers); and 4) Re-evaluation (re-appraisal, actioning of audit results).

Conclusion and Relevance The developed access framework can be implemented across different healthcare ecosystems and in different EU countries to identify strategies and actions that improve timely patient access to good quality, safe and effective medicines. A structured generic framework that provides a common decision-making platform, but which may be flexibly adopted by the Member States offers an opportunity to strengthen the effectiveness and resilience of European health systems and provide improved patient care. Access to effective medication is a multi-faceted issue which, unless appropriately understood and managed, has the potential for grave repercussions to public health.

Conflict of Interest No conflict of interest

11SG-010 PHARMACY STAFF SATISFACTION AND OPINION OF NEW WEBSITE APPLICATION FOR OUTPATIENT CARE

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Background and Importance Up until March 2022, medical prescription orders and next appointments were printed on paper for pharmaceutical validation and medication dispensation. A new website was developed to optimise this process.

Aim and Objectives Assess the level of improvement and satisfaction of professionals with the new outpatient website application.

Material and Methods A seven question Likert-type survey was conducted in September 2022 among pharmacy technicians and pharmacists who had worked with and without the new website. There were five questions assessing patient waiting time, time spent on pharmaceutical validation and dispensation, communication between pharmacists and technicians, safety, and information accessibility about patients and their treatment. There were two remaining questions assessing global satisfaction before and after the web. To assess improvement and satisfaction, answers were scored from one (totally disagree) to five (totally agree). All questionnaires were anonymous. The mean score was calculated with Microsoft Excel® (v.2019) for each of the questions. The results obtained were analysed for each of the professional categories.

Results A total of 14 pharmacy technicians and 17 pharmacists were included. According to technicians, 40% (6) believe that patient waiting time has been reduced (mean: 3), 27% (4) believe that validation and dispensing times have been reduced (mean: 3), and 20% (3) believe that technician-pharmacist communication has improved (mean: 3). 80% (12) answered that safety has improved (mean: 4) and 47% (7%) responded that accessibility to information regarding patients and their treatment has improved (mean: 3). 76% (13) of pharmacists responded that patient waiting time has been reduced (mean: 4), 82% (14) thought that the time spent on validation and dispensation has been reduced and that technician-pharmacist communication has improved (mean: 4). 88% (15) believe that safety has improved (mean: 4) and 100% (17) of

pharmacists believe that accessibility to information regarding patients and their treatment has improved (mean: 5). The global average satisfaction without the website was 3 points, with the website was 4 points for technicians and 5 points for pharmacists.

Conclusion and Relevance Staff opinions differ according to their professional category: for pharmacists, the new web has reduced working time and has improved communication, safety and accessibility to treatment. For technicians, it has only improved safety. However, the overall staff satisfaction with the website is higher.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

11SG-011 MANAGEMENT OF UNADMINISTERED THERAPIES: IMPACT OF PHARMACIST-DOCTOR COLLABORATION TO OPTIMISE THE PROCESS OF PREPARING CANCER THERAPIES

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Background and Importance At our Antiplastic Drugs Unit (ADU), pharmacy staff fulfil requests from three hospitals. From October 2021 to March 2022, oncological preparations were frequently returned unused. In some cases, the preparations could be reused, but many others were disposed of. In order to reduce waste and improve efficiency, the costs were quantified in terms of economic value as dedicated time and sharing results with prescribers.

Aim and Objectives This work evaluated how pharmacist-doctor collaboration could reduce waste and optimise the process of setting up oncological therapies

Material and Methods An Excel file recorded the returns, quantified the cost of the therapies disposed of and the therapies recovered before and after the collaboration with prescribers, with whom it was agreed to give double confirmation before setting up therapies that are costly and/or have short chemical-physical stability.

Results Between 1 October 2021 and 31 March 2022, out of 13,008 therapies set up, 210 (1.6%) were returned, for an economic value of €96,192. Of these, 141 (67.14%) were reassigned to other patients and thus €58,926 were recovered, but 69 of them (32.86%) were disposed of, thus wasting €37,266. The time dedicated by the ADU staff was 28 hours (8 minutes for each preparation). After implementing a collaboration with clinicians (April to May 2022) only 43 therapies were returned, on average 21.5 per month for an economic value of €18,661. Of these, 33 (76.7%) were reused, recovering €12,989 and 10 of them (23.25%) were disposed of, wasting €5,672.

Conclusion and Relevance Hospital pharmacists tracked cancelled therapies and communicated these findings to prescribing physicians. By implementing corrective measures, this collaboration proved successful in optimising the use of resources and for further improvement of traceability, a special return form will be made.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-007 USE OF DRUGS IN SPECIAL SITUATIONS

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Background and Importance The use of medications in special situations is a common practice worldwide, even though it is a field with very few published studies at present. A lot of effort is spent daily in hospital pharmacy services to process requests for these medications. Knowing which medical specialties and which drugs are most commonly used in such situations can be a good policy to know what economic weight these drugs have over the total.

Aim and Objectives Analyse the drugs used in special conditions in the hospital in 2021. The specific objectives were to describe the use and budgetary impact of foreign drugs and drugs authorised under conditions other than those established in the technical data sheet. In addition, another objective was the description of the use of compassionate medicines.

Material and Methods Electronic search on the AEMPS website for drug use under special conditions.

Search for the cost of each of the foreign drugs purchased.

Data mining of individualised requests for treatment with indications not included in the prescribing information drug.

Calculation of the cost per patient of those drugs used under conditions other than those authorised in prescribing information drug.

Results 173 patients were treated with foreign drugs (55 active ingredients in 71 indications).

The foreign drugs requested the most in 2021 were thyrotropin alfa, alpha tocopheryl acetate and defibrotide. The majority corresponded to oncology and haematology requests. Total expenditure was € 1,346,000.

There were 259 compassionate drug applications processed (35 active ingredients in 38 indications). Remdesivir was the most widely used compassionate drug.

Off-label drugs were validated and dispensed for 2,033 patients (108 active ingredients in 193 indications) with an expenditure of € 6,308,000 in 2021.

88.2% of the off-label drug requests were made under protocols authorised by the Pharmacy Commission.

The most frequent individualised off-label drug requests were for ustekinumab and pembrolizumab, and the active ingredients with the greatest economic impact were ustekinumab and atezolizumab/bevacizumab, accounting for 25.9% of total expenditure.

Conclusion and Relevance There is a need to continue with the protocolisation of special uses to improve their knowledge and facilitate their availability. The information systems should be completed to speed up the use of data and to include requests for drugs pending funding.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-011 COMPARATIVE EFFICACY OF EPTINEZUMAB, GALCANEZUMAB, FREMANEZUMAB AND ERENUMAB IN THE PREVENTIVE TREATMENT OF CHRONIC MIGRAINE

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Background and Importance Several monoclonal antibodies for preventive treatment of chronic migraine have been approved in recent years. However, there are no studies that directly compare these treatments.

Aim and Objectives To establish, through an indirect comparison (IC) against placebo, whether eptinezumab (Ep), galcanezumab (Ga), fremanezumab (Fre) and erenumab (Ere) could be considered equivalent alternatives in efficacy for the preventive treatment of chronic migraine.

Material and Methods A PubMed search was performed for pivotal clinical trials (CTs) of eptinezumab (300 mg/12 weeks), galcanezumab (240 mg/4 weeks), fremanezumab (675 mg/12 weeks) and erenumab (140 mg/4 weeks) for the preventive treatment of chronic migraine. The variable for comparison was the percentage of patients with $\geq 75\%$ response (% of patients with a 75% reduction in migraine days per month) at week 12 after the start of treatment. With the results of $\geq 75\%$ response, relative risk (RR) compared to placebo was calculated. Finally, with these values, an IC of these drugs was performed using the Bucher method (ITC calculator, Indirect Treatment Comparisons, of the Canadian Agency for Health Technology Assessment). The results were analysed, seeing if there were statistically significant differences between these four drugs.

Results Four CTs were found, one with each drug, all of them compared to placebo as a common comparator. All the studies presented a similar methodology. However, CT of erenumab was a phase 2 CT, while the others were phase 3. Moreover, in the erenumab CT the sample size (667 patients) was smaller than in the other CTs (between 1072 and 1130 patients). These limitations for IC were eventually accepted. After applying the Bucher method, the following results were obtained:

OR (Ep 300 mg vs Gal 240 mg) 0,89 [IC 95% 0,48–1,65]; $p=0,70$

OR (Ep 300 mg vs Fre 675 mg) 0,95 [IC 95% 0,56–1,61]; $p=0,85$

OR (Ep 300 mg vs Ere 140 mg) 1,21 [IC 95% 0,69–2,13]; $p=0,50$

OR (Fre 675 mg vs Gal 240 mg) 0,93 [IC 95% 0,46–1,89]; $p=0,85$

OR (Ere 140 mg vs Gal 240 mg) 0,73 [IC 95% 0,35–1,52]; $p=0,40$

OR (Fre 675 mg vs Ere 140 mg) 1,28 [IC 95% 0,66–2,46]; $p=0,47$

Conclusion and Relevance According to the results obtained, given that no statistically significant differences have been established between the different drugs in terms of efficacy, the choice of one or the other should be based on safety and efficiency criteria. Nevertheless, it would be of special interest

to have a direct comparison of these drugs to confirm the equivalence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-012 COMPARATIVE EFFICACY OF ABROCITINIB, BARICITINIB AND UPADACITINIB IN MONOTHERAPY FOR THE TREATMENT OF ATOPIC DERMATITIS

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Background and Importance Several oral drugs for atopic dermatitis have been approved in recent years. However, there are no studies that directly compare these treatments.

Aim and Objectives To establish, through an indirect comparison (IC) against placebo, whether abrocitinib, baricitinib and upadacitinib can be considered equivalent alternatives in efficacy for the treatment of atopic dermatitis, when used as monotherapy.

Material and Methods A PubMed search was performed for pivotal clinical trials (CTs) of abrocitinib (200 mg/24h), baricitinib (4 mg/24h), and upadacitinib (30 mg/24h) for atopic dermatitis, as monotherapy. The main variable for comparison was the results of the EASI75 (Eczema Area and Severity Index) at week 16 after the start of treatment. With the results of the EASI75 (%), the relative risk (RR) compared to placebo was calculated. Finally, with these values, an IC of these drugs was performed using the Bucher method (ITC calculator, Indirect Treatment Comparisons, of the Canadian Agency for Health Technology Assessment). The results were analysed, seeing if there were statistically significant differences between these three drugs.

Results Five CTs were found, one with abrocitinib, two with baricitinib (CTB1, CTB2) and upadacitinib (CTU1, CTU2), all of them compared to placebo as a common comparator. All the studies presented a similar methodology. However, in the CT of abrocitinib, patients under 18 years of age were not included, while in upadacitinib (13.5%) and baricitinib (22%) they were. Moreover, in the abrocitinib CT the EASI75 is measured at 12 weeks while in the others at 16 weeks. These limitations for IC were eventually accepted. After applying the Bucher method, the following results were obtained:

OR (abrocitinib 200 mg vs baricitinib 4 mg) 0,53 [IC 95% 0,24–1,18]; p=0,12 (in CTB1) and 0,65 [IC 95% 0,27–1,54]; p=0,32 (in CTB2),

OR (abrocitinib 200 mg vs upadacitinib 30 mg) 0,92 [IC 95% 0,46–1,82]; p=0,81 (in CTU1) and 1,04 [IC 95% 0,52–2,08]; p=0,92 (in CTU2),

OR (baricitinib 4 mg CTB1 vs upadacitinib 30 mg) 1,73 [IC 95% 0,98–3,07]; p=0,06 (in CTU1) and 1,95 [IC 95% 1,08–3,52]; p=0,03 (in CTU2),

OR (baricitinib 4 mg CTB2 vs upadacitinib 30 mg) 1,42 [IC 95% 0,73–2,73]; p=0,30 (in CTU1) and 1,6 [IC 95% 0,81–3,13]; p=0,17 (in CTU2).

Conclusion and Relevance According to the results obtained, it could be that Upadacitinib 30 mg presented greater efficacy

than Baricitinib 4 mg as it is the only IC that has given a statistically significant difference. However, due to the aforementioned limitations, these results should be taken with caution and safety and efficiency criteria should also be taken into account.

Conflict of Interest No conflict of interest

2SPD-019 EXPLORING ECONOMIC AND QUALITATIVE ASPECTS OF DRUG USE IN A PENITENTIARY INSTITUTE

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Background and Importance Penitentiary institute contain a population of prisoners or interned who, from the moment they enter the prison, they bring with them their personal experience of discomfort that results in the concentration in a single environment of physical, mental and behavioural diseases. The direct consequence is the use of a large number of drugs. The activities of the hospital pharmacy include the distribution of drugs to the penitentiary institute.

Aim and Objectives The objective of the study was to analyse the use of drugs in the prison population strongly influenced by the contingent situation and which has a high demand for health needs.

Material and Methods A study was conducted to examine data of drugs required from the penitentiary institute in terms of quantity expressed in dosage units and costs from the data consumption of hospital medicines in the three-year period 2019–2021.

Results The total cost of medicine consumption in the penitentiary institution considered is €103522.9 in 2019, €81.484.31 in 2020, down by 21.2% compared to the previous year and €86.525.72 in 2021 ($\Delta\%$ 21–20 = +5.8). Analysing the first level of Anatomical Therapeutic Chemical (ATC) classification system, the highest consumption value is related to drugs for the nervous system (N), followed by those active on alimentary tract and metabolism (A) and cardiovascular drugs (C). By analysing costs, the highest value is observed for the category of drugs for the nervous system, 68% in 2019–2020 of the total cost and 61% in 2021. Drugs active on alimentary tract and metabolism represent the 7% in 2019–2020 and 11% in 2021 respectively. The therapeutic category with the highest consumption are psycholeptics, antiepileptics and drugs for disorders related to acid secretion. Among the substances with the greatest cost are clonazepam and aripiprazole in 2019–2020, while in 2021 is promazine. Valproic acid and quetiapine are the most used substances in the three-year period.

Conclusion and Relevance The data described the use of drugs in a penitentiary institute emphasised the high pharmacological burden consequence of many pathologies in this population. In fact, psychotropic drugs are the most commonly used substances. This data is related to the presence of neuro-psychiatric disorders in prisoners.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-012 IMPACT AND SATISFACTION IN DRUG ADDICTS' ATTENTION CENTRES AFTER INCREASING THE STABILITY OF METHADONE ORAL SOLUTION

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Background and Importance We studied the physicochemical and microbiological stability of two methadone oral solutions 10 mg/mL. We demonstrated they were stable at $5 \pm 3^\circ\text{C}$, $25 \pm 2^\circ\text{C}$, and $40 \pm 2^\circ\text{C}$ for 91 days so that we increased the beyond-use-date (BUD) from 30 to 91 days.

Aim and Objectives Describe and analyse the impact after increasing the methadone solution BUD as well as the overall satisfaction in the-Methadone-Maintenance-Programme (MMP) Drug-Addicts-Attention-Centres (CAID) in our city, in which methadone compounding, distribution and dispensing is centralised in our Hospital-Pharmacy-Department.

Material and Methods One year after this implementation, a survey (8 questions) was designed with 6 possible Likert-scale answers (value 0 = 'no-improvement' and 5 = 'very-significant-improvement') asking if the BUD increase had allowed improvements in:

1. Day-to-day organisation.
2. Vacation organisation.
3. Human Resources (HR) distribution.
4. Dosing/dispensing methadone time reduction.
5. Other benefits not included in the survey.
6. Patient visits to the centre reduction (yes/no).
7. Other benefits in dispensing (yes/no).
8. Overall satisfaction (value 1 = 'not-at-all-satisfied' and 5 = 'very-satisfied').

The first 7 questions also included a free field to justify their score.

Results The response rate was 90% (18/20). Globally, the BUD increase has led an improvement in 61.1% CAID, highlighting better organisation, management and forecasting/internal planning (orders, shifts, vacations, doctor-nurse activities), as well as the possibility of dispensing more doses. During vacation/festive periods, 66.7% have noticed an improvement (being important/very-important in 38.9%), allowing better planning and dosing in advance. Regarding the HR distribution, the new BUD has not meant an improvement, or it has been of little importance in 94.6%. The reduction of dosing/dispensing time, has obtained a significant/very-significant improvement in 16.6%. In 22.2% CAID, it has allowed to reduce the number of visits to the centre. 27.8% found other important benefits for patients: adequacy of dispensing to their needs (travel, quarantine, vacations). 11.1% CAID indicated other benefits not included in the survey, highlighting the peace of mind due to the scientific certainty of the new BUD, as well as the possibility of ordering more methadone solution. The overall satisfaction was high: 55.6% very-satisfied/fairly-satisfied and the rest indifferent.

Conclusion and Relevance The increased stability of methadone oral solution has meant a high satisfaction degree in the

MMP's CAID, highlighting an improvement in the daily organisation and in festive periods; in relation to better planning/forecasting of shifts and internal activities; as well as a greater doses dispensing to patients whose clinical situation allowed it, reducing the number of visits to the centre.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-013 FORMULATION AND ELABORATION OF INTRATHECAL TRASTUZUMAB FOR THE TREATMENT OF A MENINGEAL CARCINOMATOSIS

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Background and Importance There is limited evidence on the preparation of intrathecal (IT) trastuzumab.

Aim and Objectives To define a formulation of IT trastuzumab (in combination with hydrocortisone and methotrexate), for a woman with metastatic breast cancer, HER2+, with meningeal carcinomatosis and brain metastases.

Material and Methods A bibliographic search was carried out in several sources (Google Scholar, PubMed, Uptodate) to find case reports (keywords Trastuzumab + Intrathecal/Intrathecal). Only the articles that described the methodology of preparation (at least the reconstitution) were selected. Based on the available evidence, the formulation of IT trastuzumab was defined.

Results Only 4 articles were identified (5 cases). The periodicity of the maintenance doses was always 7 days. Attending at the product used in the reconstitution, 2 articles specified 'diluent without preservatives'. 2 articles described the fully process: the vial of trastuzumab 150 mg is reconstituted with 7.2 ml of sterile water and were elaborated IT doses from 20 mg to 100 mg. 1 article specified that the patient received IT methotrexate 12 mg followed by IT trastuzumab and in the other article IT trastuzumab was administered first, followed by IT methotrexate 15 mg, and finally IT hydrocortisone 24 mg.

Based on the available evidence we reconstituted 1 vial of 150 mg (from a biosimilar presentation that contained the same excipients as the first authorised brand of trastuzumab) with 7.2 ml of sterile water for injections. A 25 mg (1.2 mL) dose was refilled into a polypropylene immediate-use syringe.

The patient also needed IT methotrexate and IT hydrocortisone (both prepared in separate polypropylene syringes) and the administration sequence was: methotrexate 12 mg/ 4.8ml (obtained from methotrexate 50 mg/2ml diluted with 0.9% sodium chloride), hydrocortisone 20 mg/ 0.2 ml (obtained from hydrocortisone 100 mg reconstituted with 0.9% sodium chloride) followed by trastuzumab 25 mg/1.2 ml.

Although the patient died after receiving 2 doses (separated by 7 days), did not present any complications due to the administration (no headache, nausea or vomiting).

Conclusion and Relevance Due to the limited information about the elaboration of IT trastuzumab, is important to have available new evidence. Our formulation also use a biosimilar

presentation of trastuzumab, which was safe and well tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-019 INDIGO CARMINE SOLUTION AND ADRENALINE IN SUBMUCOSAL CHROMOENDOSCOPY

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Background and Importance Chromoendoscopy involves the injection of dye into the submucosal layer of the intestine wall that enhances the injected area and facilitates the delimitation and marking of areas that are susceptible to endoscopic treatment. The classic technique consists of adding indigo carmine (IC) to the injected solution, colouring the resulting bulge, and ensuring that the injected layer is the submucosa, which reduces the risk of perforation and the feasibility of endoscopic resection. The inclusion of adrenaline in the solution, with a concentration 10 times lower than for haemostatic purposes, reduces the potential risk of haemorrhage and highlights the well-vascularised epithelia. There is no commercialised or standardised preparation for performing this technique.

Aim and Objectives Description and galenic validation of a solution of IC and adrenaline in colloid plasma for use in chromoendoscopy. Establishing the period of validity according to the Guide to Good Preparation Practices (GPP).

Material and Methods The developed formula was made of adrenaline 1 mg, IC 32 mg (4 mL of IC 0.8%) and q.s. ad 100 mL protein-based colloid derived from gelatine. The preparation added to a sterile 100 mL polyolefin bag.

The risk of the final preparation was determined according to the GPP matrix and galenic validation was carried out by evaluating the following parameters: physical stability due to colour change by qualitative assessment on a black and white background by two observers; chemical stability with pH determination by potentiometry; microbiological stability (trypticase soy agar culture). Determinations were made at 0, 15, 30 and 45 days post-preparation.

Results There was no colour change in any sample except at t45, where a marked change in colouration was observed. Regarding the pH, the following results were obtained: t0: 6.65 ± 0.02 ; t15: 6.83 ± 0.02 ; t30: 6.57 ± 0.03 ; t45: 6.70 ± 0.02 . There was no microbiological growth in any sample. A medium risk level and a validity period of 14 days between 2–8°C were established according to the GPP.

Conclusion and Relevance The IC solution is physically, chemically and microbiologically stable for 14 days at 2–8°C. The final concentration of IC used and the association with adrenaline allow, in the opinion of the endoscopists, the adequate differentiation of the areas susceptible to endoscopic resection.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-020 CLOBETASOL PETROLATUM OINTMENT 0.015% FOR THE TREATMENT OF CUTANEOUS GRAFT-VERSUS-HOST DISEASE IN PAEDIATRIC PATIENTS: A CASE REPORT

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Background and Importance Chronic graft-versus-host disease (cGVHD) is an important late complication after allogeneic haematopoietic stem cell transplant (HSCT). The skin is usually the first and most affected organ involved in cGVHD and topical steroids are one of the most commonly used drugs for this affection.¹

Aim and Objectives A 3-year-old boy was diagnosed with acute myeloid leukaemia in 2019 and, after HSCT, manifested cutaneous cGVHD. The hospital pharmacy service was asked to develop a paediatric magistral formula of topical ointment based on clobetasol 0.015% in petrolatum.

Material and Methods A scientific literature search was conducted. Galenic development and validation of the formula were described in the monograph 'Semi-solid preparations for cutaneous application' of the Official Pharmacopoeia of the Italian Republic.

A topical magistral formula of clobetasol ointment 0.015% in petrolatum was developed, to be administered once daily on lesions. The efficacy of the formulation was evaluated by the physician. Skin therapy also included a moisturising lotion and almond oil.

Results The development was based on a case series of oral cGVHD in which a hydrophilic gel formulation was used successfully. Clobetasol has been shown to have higher potency and the highest level of evidence.

In contrast to the hydrophilic gel, the 0.015% clobetasol ointment preparation was formulated on petrolatum to allow for superior skin permanence, starting with low concentrations of clobetasol as the patient aged. Petrolatum forms an occlusive, hydrophobic layer on the skin, physically blocking transepidermal water loss and creating increased skin hydration for more than 4 hours.

A shelf life of 30 days has been established, based on the critical skin injury in this paediatric patient. Odour, colour and phase separation remained stable during the month.

The patient well tolerated the treatment, and the doctor confirmed, after four months of treatment, the improvement of the skin lesion. The paediatric patient, after the described improvement, discontinued the clobetasol ointment.

Conclusion and Relevance Clobetasol ointment 0.015% is a good therapeutic solution in paediatric patient with cGVHD, especially for its pharmaceutical formulation.

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Conflict of Interest No conflict of interest

3PC-021 AMPHOTERICIN AND COLISTIN GELS FOR NECROTISING WOUNDS: GALENIC AND MICROBIOLOGICAL VALIDATION

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Background and Importance In the intensive care unit, wound infections are complications with highly associated morbimortality, especially in immunocompromised patients. In some circumstances, a combination of endovenous and topical therapies may be required. Due to the lack of adequate commercial presentations, a compounded topical treatment could be a solution to manage a specific infection.

Aim and Objectives Developing a sterile topical gel of Amphotericin B-deoxycholate (Amfob-dc) and colistin to treat severe necrotic wound caused by *Aspergillus fumigatus*, *Acinetobacter baumannii* and *Rhizopus arizus refractory* to surgical debridement in a critical patient. Galenic and microbiological validation.

Material and Methods Bibliographic research was done first and based on the information compiled, it was decided to use sterile water-soluble gel (Varihesive Hydrogel®) as an excipient base. Varihesive Hydrogel is used on the debridement of necrotic wounds. When used with Amfob-dc 0,15% and colistin 0,5% in sterile conditions, both refrigerated, remained 7-days stable based on the risk matrix (low risk) of Good Pharmacy Practices. For galenic and microbiological validation, 3 samples of both gels were stored in refrigerator and in room temperature protected from light. Organoleptic characteristics (colour and fluidity), pH and weight were controlled and validated at days 0,7,14,21 and 28 of preparation. Microbiological validation was performed at day 28. Efficacy of treatment was studied with wound reduction and granulation one month after the initiation of the treatment, which was applied 3 tid.

Results Particle-free, homogeneous and viscous gels were obtained. The Amfob-dc gel exhibited yellow colour and the colistin-based gel gray-translucent. No microbial growth was observed between days 0 to 28. Organoleptic characteristics remained constant throughout the period, however, once stored at cold temperatures they exhibited more viscosity. There were no differences in pH levels or weight variation of >10% (table 1).

Clinical Outcomes were excellent one month after the initiation resulting in an 80% reduction and granulation of the wounds and negative microbiological cultures.

Conclusion and Relevance These formulations are simple and give accurate results as a targeted therapy for necrotising infected wounds. The individualised topical preparations allow to solve problems of unavailability of adequate commercial forms. According to our validation, the galenic stability of the product seemed to be extended. However, further stability and quantitative studies should be conducted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-027 STABILITY OF TACROLIMUS ORAL SUSPENSION IN DISPOSABLE POLYPROPYLENE SYRINGE

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Background and Importance Within the post-operative period following a solid organ transplantation, multidisciplinary teams prioritise tacrolimus administration *per os* to minimise the neurotoxicity associated with its use via continuous intravenous infusion. Despite being classified as a hazardous drug, there is no tacrolimus liquid dosage form commercially available ready for direct administration by oral route.

Aim and Objectives To validate physical, chemical and microbiological stability of an affordable extemporaneous tacrolimus oral solution/suspension in single-dose disposable polypropylene syringe.

Material and Methods A search on chemical compatibility between tacrolimus and polypropylene was accomplished. The formulation developed for study case was split in three samples stored at 20–25°C and three others at 2–8°C, ensuring every assay was performed in triplicate.

Stability parameters were tested every 7 days for a 28-day period. The analysis included organoleptic properties, sedimentation time, homogeneity, pH, redispersibility, crystal growth and weight variation. In order to identify and quantify any potential colony-forming unit (CFU), cultures with blood agar were read after 24 and 48 hours from incubation at 37°C, whereas Sabouraud agar cultures were read after 24, 48, 72 and 96 h.

Results Chemical stability of tacrolimus 1 mg/mL suspension formulated with 1:1 Ora Plus® and Ora Sweet® in polypropylene syringe was reported.

For the present study, tacrolimus 1 mg/mL suspension based on a 2:1 blend of simple syrup and carboxymethylcellulose 1.5% aqueous gel was developed since its composition is simple and saves € 8,51/100 mL.

Physical and chemical parameters remained constant during all the study period regardless of storage temperature: The formulation was homogeneous, sheer with yellowish hue and sweet. No crystal growth or sediment were observed. Median weight variation was 0.96% for the fraction stored at 20–25°C (0.38%–1.65%) and 0.75% for the stored at 2–8°C (0.58%–1.08%). Average pH values were 5.70 (5.60–5.76) and 5.72 (5.70–5.76) respectively.

Abstract 3PC-021 Table 1

| Amfob-dc | | | | | |
|--------------|-----|-----|-----|-----|-----|
| pH (Day) | 0 | 7 | 14 | 21 | 28 |
| RT | 7 | 7 | 7 | 7 | 7 |
| Refrigerator | 7 | 6.5 | 7 | 7 | 7 |
| Weight (Day) | 0 | 7 | 14 | 21 | 28 |
| RT | 7.5 | 7.6 | 7.1 | 7.0 | 7.0 |
| Refrigerator | 8.9 | 8.9 | 9.0 | 8.9 | 8.8 |
| Colistin | | | | | |
| pH (Day) | 0 | 7 | 14 | 21 | 28 |
| RT | 7 | 7 | 6 | 6 | 7 |
| Refrigerator | 7 | 7 | 6 | 6 | 6 |
| Weight (Day) | 0 | 7 | 14 | 21 | 28 |
| RT | 9.1 | 9.1 | 9.0 | 8.7 | 9.1 |
| Refrigerator | 9.2 | 9.2 | 9.2 | 9.2 | 9.2 |

One *Staphylococcus hominis* CFU was detected on day 14 in one sample stored at 2–8°C. No subsequent microbial growth was found, therefore it was considered contamination.

Conclusion and Relevance Tacrolimus 1 mg/mL oral suspension in simple syrup and carboxymethylcellulose 1.5% in a 2:1 ratio is stable when conditioned in polypropylene syringe for 28 days and stored at room or refrigerator temperature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-030

EVALUATION OF EXCIPIENTS USED IN PAEDIATRIC COMPOUNDED FORMULATIONS PRESCRIBED IN A NEONATAL INTENSIVE CARE UNIT

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Background and Importance The absence of marketed medicines adjusted to the pathophysiological profile of the neonate often implies the preparation of personalised compounded medicines. To meet therapeutic needs and improve medicines' stability, several vehicles have been developed and studied for different drugs. The choice of excipients is a critical point in paediatric compounded formulations (PCF), as there are limits inherent to the target population.

Aim and Objectives Evaluation of exposure to PCF excipients, according to individualised medical prescriptions to patients admitted to a Neonatal Intensive Care Unit (NICU) between September 2019 and August 2020, considering the recommended limits. Search for related adverse events (AEs) when limits are exceeded. Propose solutions for the non-conformities detected.

Material and Methods Definition of excipients to be evaluated, search of the respective recommended limits and AE reported.

Ranking PCF containing at least one of the selected excipients and calculation of its concentration in the formulation.

Analysis of prescriptions, calculation of excipient/patient daily intake and evaluation according to age recommendations.

In cases where the limits were exceeded, search the patient's medical record for AE that may be related to exposure to the excipient.

Results Evaluated excipients: benzyl alcohol, benzoic acid/sodium benzoate, ethanol, propylene glycol (PG), propylparaben (PP), polysorbate 80 and sorbitol.

Considering the 10 selected PCF, present in 86 prescriptions corresponding to 172 exposures, only 2 of the evaluated excipients were found: PP and PG. In 52 exposures there was ingestion above recommended limits, 50 of which were of PG in neonates with less than 28 days of age. 5 records of AE described in bibliography with a causal link were found in the medical files.

Conclusion and Relevance In cases of formulations where exceeded excipient limits were detected, an alternative with a different composition or concentration should be investigated. As 50 out of 52 non-compliances were with PG, used as a solvent in the paraben concentrate, this formulation will be tested using water instead of PG. It was not possible to retrospectively confirm a causal assessment related to the AE

found as these are common clinical conditions in these patients. Individualisation of medication through compounding is the right direction as it best suits the patient's profile. However, the choice of excipients is crucial for patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-032

USE OF ORAL KETAMINE FORMULATION IN PATIENTS WITH CHRONIC REFRACTORY PAIN

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Background and Importance Chronic pain lasts more than three months and includes primary and neuropathic pain. Ketamine provides analgesia and amnesia at a subanaesthetic dose, therefore proposing its use as chronic pain treatment when it is refractory to the standard based on tricyclic antidepressants (TCAs), gabapentinoids, and opioids.

Aim and Objectives To analyse the use of an oral formulation of ketamine prepared and dispensed by hospital pharmacy at a third-level hospital in chronic refractory pain (CRP) treatment.

Material and Methods Observational retrospective study including a cohort of patients with CRP treated with an oral 10 mg/ml ketamine solution at a third-level hospital between January 2021 to December 2021. All of them signed informed consent. A tolerance test with intravenous ketamine was performed on every patient before initiating treatment. Data were collected from clinical history and pharmacy programs. For statistical analysis, continuous variables were categorised according to median (range) or percentage values.

Results 30 patients were included (67% men, median age 48.5 years (18–73)). Chronic pain type was neuropathic in all cases, cancer-associated (37%), trauma-caused neuronal damage (33%), demyelinating (17%), and 14% to other causes. Patients received oral ketamine during a median of 20 months (1–58) and daily dosage varied from 40 mg to 150 mg, the most frequent being 60 mg/d (40%), 90 mg/d (27%) and 120 mg/d (23%). 80% were in adjuvant treatment with opioids; of them, 88% took major opioids. 40% had reached the therapeutic limit by being treated with opioids, TCAs and gabapentinoids without any differences in pain origin. 43% had not included TCAs in treatment.

Treatment was discontinued in 5 patients (17%); 4 due to adverse effects (dizziness, cognitive alterations, tachycardia, hypertension), and 1 due to death unrelated to treatment.

Conclusion and Relevance This study shows oral ketamine analgesic use in neuropathic CRP treatment at 40–150 mg/d; the most frequent 60 mg/d and 90 mg/d. Inferior to those referred to in the literature (up to 400 mg/d). Good tolerance and an acceptable safety profile were observed (17% discontinued) without serious adverse events. As to adjuvant treatment, 80% received opioids and 40% the combination of opioids, gabapentinoid, and TCAs. More studies are needed to evaluate the long-term effectiveness and safety of oral ketamine treatment and to position it in CRP management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-034 USE OF A MIXTURE OF BLEOMYCIN, LIDOCAINE AND EPINEPHRINE IN THE TREATMENT OF KELOID SCARS: ON THE SUBJECT OF A CASE

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Background and Importance Keloid scars represent an abnormality in wound repair in predisposed individuals. They are distinguished by an excessive synthesis of connective tissue. The treatment is difficult, recent studies have shown that the mixture of bleomycin, lidocaine and epinephrine (BLE) can be useful in the treatment of these lesions. The addition of lidocaine has an anaesthetic effect and also improves the cytotoxicity of bleomycin. Epinephrine has a vasopressor effect that prevents the passage of bleomycin and lidocaine into the blood.

Aim and Objectives To evaluate the efficacy and safety of the administration of the BLE mixture, by superficial puncture in a patient with keloid scars. Describe the preparation of the mixture in the Pharmacy Service.

Material and Methods Retrospective observational study of a patient to whom the BLE mixture was applied to keloid scars. The variables collected were: sex, age, size and location of the lesions, previous and concomitant treatments and data related to treatment with the BLE mixture (concentration, dose, frequency of administration, duration of treatment, effectiveness and safety). The clinical response to treatment was described with the following scale: complete crushing, very significant crushing, significant crushing. The patient's clinical history and the preparation protocol for the BLE mixture were reviewed.

Results A 14-year-old patient presented with keloid scars in the right cervical, scapular, and left thigh areas. He previously received intralesional punctures of corticosteroids, botulinum toxin and treatment with topical mometasone. The concentration of the BLE mixture was: bleomycin (0.75 g/l), lidocaine (3.5 g/l) and epinephrine (3.5 mg/l). 0.5 to 2 ml was administered in each puncture, monthly, making a total of 4 punctures. The clinical response was described as very significant crushing, with more inactive and whitish scars being observed. No adverse effect was observed.

The mixture was prepared in a vertical laminar flow hood. For this, a vial of bleomycin 15 mg/5 ml, 7 ml lidocaine hydrochloride 1% and 7 ml of diluted adrenaline 0.01 mg/ml were loaded into a 20 ml syringe. It was made up to 20 ml with 0.9% physiological serum.

Conclusion and Relevance The use of the BLE mixture was effective and safe in the treatment of the patient's keloid scars.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-001 EMICIZUMAB IN ACQUIRED HAEMOPHILIA TYPE A: A CASE REPORT

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Background and Importance Acquired haemophilia A is a coagulation disorder in which antibodies against factor VIII are produced, interfering with its activity and leading to potentially severe bleeding. Among numerous causes, cancer is a prevailing one. First-line haemostatic treatment until inhibitor eradication consists of bypass agents, including recombinant factor VII activated (rFVIIa) or activated prothrombin complex concentrates (aPCC).

Aim and Objectives We present the case of a 70-year-old male patient diagnosed with metastatic prostate cancer who went to the emergency department of a tertiary referral hospital due to an acute-onset extensive hematoma on the right thigh, with neither personal nor family history of haemophilia.

Material and Methods The patient was diagnosed with paraneoplastic acquired haemophilia. Therefore, immunosuppressive (methylprednisolone + cyclophosphamide) and haemostatic treatment (rFVIIa at 5 mg every 8h) was initiated.

9 days in, off-label use of emicizumab was requested, intended to guarantee a haemostatic level that would allow outpatient management. Emicizumab was administered subcutaneously at 3 mg/kg weekly over 4 weeks and then fortnightly over 16 weeks between January 13th and May 25th, 2022.

Haemostatic was monitored daily during hospitalisation and weekly after discharge through determination of inhibitor activity (Bethesda Units, UB) and FVIII activity (bovine based Chromogenic Factor VIII assay, UI) in blood samples.

Results The patient was successfully treated until the resolution of bleeding and normalised FVIII levels. Over the treatment with emicizumab as the only haemostatic agent (107 days), 8 subcutaneous injections were administered (cost: € 51,255.2).

Having used rFVIIa (5 mg every 12 h) would have entailed 214 intravenous infusions, with a direct cost of € 618,301.64. Thus, emicizumab treatment meant direct cost saving of € 567,046.44.

Moreover, contributing factors to overheads as prolonged hospital stay, expenditure on consumables or staffing should be taken into account. Also risk of vascular access complications and quality of life must be considered.

Conclusion and Relevance Emicizumab has been a safe and cost-effective alternative to rFVIIa in haemorrhage prophylaxis, reducing direct costs by more than 10 times and allowed outpatient management.

Self-administration at home represents a major improvement in acquired haemophilia A quality of life.

Hospital pharmacy and haematology must collaborate to achieve a rational use of resources and an improvement in quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-011 CLINICAL AND ECONOMIC IMPACT OF PHARMACIST ANTIMICROBIAL INTERVENTIONS IN A SMALL HOSPITAL

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Background and Importance Several studies have indicated that pharmacists can play a key role in promoting the optimal use of antimicrobials and monitoring the prescriptions.

Aim and Objectives To assess the potential clinical and economic impact of pharmacist interventions (PIs) to improve antibiotic prescribing practices for hospital inpatients.

Material and Methods Prospective study in a public hospital (<200 beds) from 1 January 2019 to 31 December 2020. All inpatients who received at least 24 hours of antimicrobial therapy were included. Any discharged patient who was readmitted was considered as a new patient. The pharmacist performed and recorded PIs in the electronic prescribing, focused on highly restricted drugs and prescriptions for >10 days. When necessary, the pharmacist interacted directly with the prescriber in person or by phone. To assess the potential impact of PIs, we utilised the CLEO tool.¹

Results A total of 847 antimicrobial PIs were proposed (in 696 patients), being 88% accepted (table 1). Regarding the clinical impact of PIs, the number of avoids or fatality PIs was 30 (4%). Almost half were graded as major (42%). PIs classified as moderate were 38%, minor or null significance were 17%. No adverse events were noted after implementing a PI in any patient. In relation to economic impact, 79% mean in a decrease in cost, 3% no change and 18% an increase in cost. The total saving in the study period was € 164953.

Abstract 4CPS-011 Table 1

| Pharmacist interventions (n = 847) | n (%) | Acceptance (%) |
|--|---------|----------------|
| Discontinuation due to excessive duration | 198(24) | 172(87) |
| Therapy de-escalation | 130(15) | 105(81) |
| Dose adjustment or interval modification | 128(15) | 128(100) |
| Deleting an antibiotic of the complete treatment due to use of redundant antimicrobial therapy | 103(12) | 97(94) |
| Switching from intravenous to oral administration | 93(11) | 75(81) |
| Changing the empirical therapy because of inappropriateness | 85(10) | 72(85) |
| Therapeutic escalation | 58(7) | 55(95) |
| Discontinuation due to a lack of indication to proceed | 44(5) | 37(84) |
| Others | 8(1) | 7(88) |

Conclusion and Relevance PIs carried out to improve the use of antimicrobials positively impact on clinical and economic outcomes, with a high acceptance by physicians.

REFERENCE

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Conflict of Interest No conflict of interest

4CPS-013 TREOSULFAN-BASED CONDITIONING REGIMEN FOR ALLOGENEIC HAEMATOPOIETIC STEM CELL TRANSPLANTATION IN CHILDREN WITH SICKLE CELL DISEASE: EFFICACY AND SAFETY

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Background and Importance Allogeneic haematopoietic stem cell transplantation (allo-HCT) is the only curative therapy in patients with sickle cell disease (SCD). Conditioning regimens traditionally were busulfan based. Treosulfan shows advantages such as intense immunosuppressive activity, low extra-medullary toxicity and linear pharmacokinetics that decreases variability.

Aim and Objectives To evaluate safety and potential complications associated to allo-HCT after treosulfan-based conditioning regimen in children with SCD.

Material and Methods Retrospective, observational, unicentric study. Inclusion criteria comprised paediatric patients diagnosed with SCD who had undergone allo-HCT at a tertiary hospital between April 2015 and September 2022. Conditioning regimen included thiotepea, treosulfan, fludarabine and anti-thymocyte globulin. Variables: gender, age, age of diagnosis, age of allo-HCT, type of HCT, graft versus host disease (GvHD) prophylaxis, seizure prophylaxis, veno-occlusive disease (VOD) prophylaxis, cumulative incidence of GvHD, non-haematological toxicity (potentially associated to conditioning regimen) during the first 30 days after HCT, graft failure, peripheral blood chimerism data collected and death related to HCT. Disease-free survival and overall survival after HCT were also measured.

Results 31 patients were included in the study (17 female, 14 male). Median age of diagnostics was 2 months (2–120) and median age of allo-HCT was 64 months (25–154). Median time between diagnostic and HCT was 4 years (1.9–12.5). Transplantation was the first for all children except for one (graft failure after a previous allo-TPH). All donors were human leucocyte antigen (HLA)-matched siblings. Double-therapy immunosuppression was used in GvHD prophylaxis (21/31 cyclosporine with mycophenolate mofetil and 10/31 tacrolimus with mycophenolate mofetil). All received levetiracetam and ursodeoxycholic acid for seizure and VOD prophylaxis, respectively. 11/31 developed cutaneous GvHD (10 grade I-II and 1 grade III-IV) and 2/31 grade I-II hepatic GvHD. 4/31 developed grade I-II mucositis and 4/31 grade III-IV mucositis. 3/31 cases of mild diarrhoea, 5/31 neurological toxicities (seizures and encephalopathy) and 1/31 case of hepatomegaly (not associated to VOD) were registered. All resolved adequately. 25/31 children showed complete chimerism in peripheral blood at the end of follow-up. Immunosuppression was enhanced in case of mixed chimerism. There were no graft failures. All children are alive and remain disease-free after median follow-up of 47 months (12–78).

Conclusion and Relevance Treosulfan-based conditioning shows clinically manageable toxicity profile and low morbidity and mortality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-017 REAL-WORLD EVIDENCE ON RHEUMATOID ARTHRITIS TREATMENT PERSISTENCE: JANUS KINASE INHIBITORS VERSUS BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS

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Background and Importance The therapeutic armamentarium for rheumatoid arthritis (RA) has been remodelled over the last decades with the advent of biologic disease-modifying antirheumatic drugs (bDMARDs) and the emergence of Janus Kinase inhibitors (JAKi). So far, real-world data comparing the persistence of these different treatment approaches are scarce.

Aim and Objectives This study aims to compare treatment persistence between JAKi and bDMARDs in a real-world setting of RA patients.

Material and Methods A retrospective study (January 2017 to September 2022), including all RA patients from a tertiary hospital under treatment with JAKi, tumour necrosis factor inhibitor (TNFi), interleukin (IL) 6 inhibitor (IL6i), cluster of differentiation (CD) 80/86 inhibitor (CD80/86i), or CD20 inhibitor (CD20i). Demographic, clinical, and pharmacological data were collected from hospital claim records. Persistence was examined through Kaplan-Meier survival analysis. Median survival times were compared statistically using log-rank test and Cox model. Statistical analyses and graphic representations were performed utilising STATA15[®] software.

Results We included 582 cases: 166 (28.5%) JAKi treatments, 180 (30.9%) TNFi treatments, 124 (21.3%) IL6i treatments, 64 (11.0%) CD80/86i treatments, and 48 (8.3%) CD20i treatments, corresponding to 293 RA patients (86% women, 63 ± 14 years old).

The median JAKi treatment persistence was 428 [95 CI% = 262–609] days, which did not differ significantly with regard to the median treatment persistence of: TNFi (HR=1.19 [95 CI%=0.91–1.56]; p=0.215), IL6i (HR=1.06 [95 CI%=0.79–1.43]; p=0.695), CD80/86i (HR=1.40 [95 CI%=0.99–1.98]; p=0.054), and CD20i (HR=0.77 [95 CI%=0.50–1.18]; p=0.227). Median treatment persistences are presented in table 1.

Kaplan-Meier curves represent the estimated survival functions (figure 1).

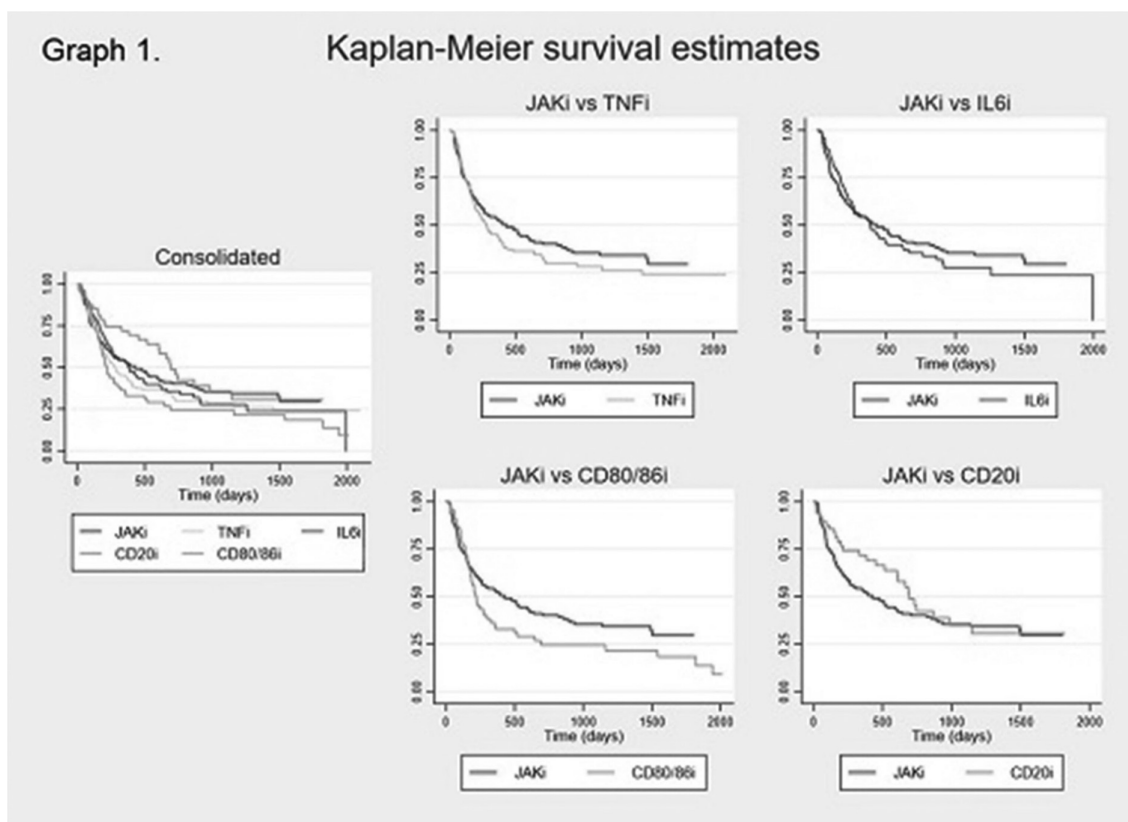
Abstract 4CPS-017 Table 1 JAKi and bDMARDs treatment persistences

| Drug (n=582) | Median persistence, days [95CI%] | HR [95CI%]; p-value |
|-----------------|----------------------------------|---------------------------|
| JAKi (n=166) | 428 [262–609] | - |
| TNFi (n=180) | 281 [210–378] | 1.19 [0.91–1.56]; p=0.215 |
| IL6i (n=124) | 381 [263–504] | 1.06 [0.79–1.43]; p=0.695 |
| CD80/86i (n=64) | 221 [177–321] | 1.40 [0.99–1.98]; p=0.054 |
| CD20i (n=48) | 692 [516–1,146] | 0.77 [0.50–1.18]; p=0.227 |

Conclusion and Relevance Based on the results from our RA real-world cohort, JAKi treatment persistence is in line with TNFi and other bDMARDs treatment persistences. Further research is needed to confirm our findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest



Abstract 4CPS-017 Figure 1

4CPS-020 TREATMENT PERSISTENCE AND DISCONTINUATION REASONS OF JANUS KINASE INHIBITORS IN A REAL-WORLD SETTING OF RHEUMATOID ARTHRITIS PATIENTS

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Background and Importance Janus Kinase inhibitors (JAKi) are the most innovative drug class for Rheumatoid Arthritis (RA). To date, limited real-world data are available about treatment persistence and discontinuation reasons of tofacitinib and baricitinib.

Aim and Objectives This study aims to evaluate treatment persistence and discontinuation reasons of tofacitinib and baricitinib in a real-world setting of RA patients.

Material and Methods A retrospective study (2017/01–2022/09), including all RA patients from a tertiary hospital under treatment with tofacitinib or baricitinib. Persistence was examined through Kaplan-Meier survival analysis and drug retention rates. Survival times were compared statistically using Log-rank test and Cox model. Discontinuation reasons were classified into ineffectiveness, adverse events (AE), and others. Data were collected from hospital claim records. Statistical analyses were performed utilising DATAtab[®] software.

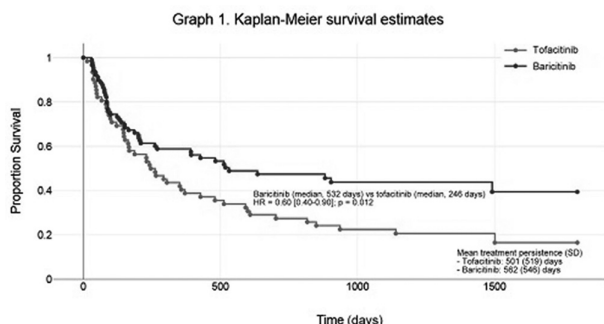
Results We included 152 cases from 117 RA patients (86% women, 63 ± 13 years old) under treatment with tofacitinib (n=62; 40.8%) and baricitinib (n=90; 59.2%).

Median treatment persistence for baricitinib was significantly greater than for tofacitinib (Graph1; HR=0.60 [95CI% =0.40–0.90]; *p*=0.012), with no significant differences between mean treatment persistences (Graph1; *p*=0.494).

After 12 months of treatment, tofacitinib showed lower drug retention (n=25; 40.3%) compared to baricitinib (n=54; 60.0%).

For this study, a high percentage of tofacitinib patients (80.6%) had to discontinue the treatment because of ineffectiveness (46.0%), AE (52.0%), or others (2.0%). The discontinuation reasons (percentages) in baricitinib patients who had to withdraw the treatment (52.2%) were: ineffectiveness (48.8%), AE (48.8%), and others (2.4%).

Conclusion and Relevance Our study concludes that tofacitinib showed lower median treatment persistence, lower drug retentions, and higher proportion of AE compared to baricitinib.



Abstract 4CPS-020 Figure 1 Kaplan-Meier survival estimates

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-023 TOPICAL RAPAMYCIN IN RARE TUBEROUS SCLEROSIS DISEASE: LIPOSOMAL FORMULATION STABILITY

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Background and Importance Different formulations of topical rapamycin have been tested for facial angiofibromas in tuberous sclerosis, most using an ointment as a vehicle.

Aim and Objectives To develop a liposomal formulation and to determine the validity period according to chemical, physical and microbiological stability in rare tuberous sclerosis disease.

Material and Methods A liposomal formulation of rapamycin 0,4% was prepared in biological safety cabinet.

Packing and Conservation 20g bottle protected of ambient light and stored in a cold room at 5°C ± 3°C.

Composition rapamycin 0,4%, transcuto-P 10%, liposomal solution 25%, cholesterol 0,1%, isopropile miristrate 10%, propylene glycol 10%, carbopol 2%, NaOH 10% q.s. pH 7,5, API q.s. 20g.

1. **Chemical stability:** An analytical method based on liquid-liquid extraction of rapamycin with apolar solvents and analysis by high-performance liquid chromatography with ultraviolet/visible detection was developed and validated. The percentage of remaining sirolimus content (%CR) was determined by triplicate at t=0, 2, 14, 21, 28, 42, 56, 70 and 84 days. T₉₀ was established when % CR was ≤90%.

2. **Physical stability:** pH, uniformity, extensibility, absence of crystals and absence of phase separations were evaluated on a transparent surface according to 3 levels: level 1, the least favourable and level 3, the most favourable, at t=0 days. Further, mean particle size, zeta potential and encapsulation efficiency (EE%) was determined by triplicate at t=0 days. Mean particle size and zeta potential was determined using particle size analyser which uses laser diffraction method. EE % were determined via ultra-filtration, using Amicon[®] ultra-centrifugal filters.

3. **Microbiological stability:** Culture samples in blood-agar media of each formulation were incubated at 37°C by duplicate at t=28,56, and 84 days.

Results Liposomal formulation were chemically, physically and microbiologically stable after 84 days. Mean particle size and zeta potential of prepared liposomes determined a good quality result of the analysis with a polydispersity index value <0.2, indicating a homogenous dispersion. EE% turned out to be very favourable for the liposomal formulation, with a high load of rapamycin per liposome formed (89%).

Conclusion and Relevance This study describes a new liposomal formulation to improve the previously treatment for facial angiofibromas in tuberous sclerosis. It also provides favourable stability data for liposomes. However, more dermokinetic and clinical studies are needed to confirm that liposomes are most appropriate to ensure effectiveness, safety and high patient satisfaction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-033 EVALUATION OF THE EFFECTIVENESS OF REINDUCTION OR INTENSIFICATION WITH USTEKINUMAB IN INFLAMMATORY BOWEL DISEASE

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Background and Importance In the context of loss of efficacy in patients treated with subcutaneous maintenance of ustekinumab (UST) for inflammatory bowel disease, Crohn's disease (CD) and ulcerative colitis (UC), one of the strategies implemented has been re-induction or intensification.

Aim and Objectives To evaluate the effectiveness of re-induction or intensification with UST.

Material and Methods Retrospective observational study conducted in a tertiary hospital including patients treated with UST on subcutaneous maintenance every 8 weeks and who received a re-induction/intensification regimen between September 2019 and September 2022.

The following variables were collected sex, age, pathology, previous biological treatments (anti-TNF α [infliximab, adalimumab, certolizumab] or anti- α 4 β 7 integrin [vedolizumab]), re-induction/intensification, analytical data (haemoglobin, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), faecal calprotectin) and clinical data (abdominal pain and daily stools).

The follow-up period was 6 weeks.

Results A total of 30 patients were included, with a median age of 40 years (17–73). Men represented 57%. A total of 77% were diagnosed with CD and 35% were diagnosed with UC. All patients with CD had been previously treated with one (13%) or more (87%) anti-TNF α drugs and 35% had received vedolizumab. All patients with UC also received treatment with one (29%) or two (71%) anti-TNF α drugs and 57% had received vedolizumab.

Out of 23 patients with CD, 11 received a re-induction and 12 intensified the regimen. Out of 7 patients with UC, 2 received a re-induction, 2 intensified the regimen and 3 received both. The re-induction consisted of an intravenous administration according to weight, except in 3 cases in which a fixed dose of 130 mg was administered. The intensification consisted of shortening the administration to every 4–6 weeks.

The percentages of patients who showed improvements in analytical measurements after the chosen strategy was administered are shown below.

Conclusion and Relevance Re-induction/intensification with UST is an effective option in the treatment of inflammatory bowel disease, in line with published clinical trials. The analytical data were better with re-induction. 77% of patients remain on the treatment.

Abstract 4CPS-033 Table 1

| | Re-induction | Intensification | Both |
|---------------------|--------------|-----------------|------|
| Haemoglobin | 60% | 50% | 0% |
| ESR | 65% | 63% | 100% |
| CRP | 80% | 71% | 100% |
| faecal calprotectin | 93% | 86% | 100% |
| abdominal pain | 70% | 78% | 100% |
| Daily stools | 0% | 100% | 0% |

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest

Conflict of Interest No conflict of interest

4CPS-035 ASSOCIATION OF DIHYDROPYRIMIDINE DEHYDROGENASE DEFICIENCY WITH CAPECITABINE TOLERANCE

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Background and Importance Dihydropyrimidine dehydrogenase (DPD) is the first of the enzymes in the fluoropyrimidine metabolic pathway. Recently, the Spanish Agency of Medicine and Health Products reported an informative note warning that patients with partial or total deficiency in DPD activity cannot adequately degrade fluoropyrimidines, increasing the risk of serious toxicity. DPD genotyping is recommended as standard practice for predicting the occurrence and severity of capecitabine toxicity.

Aim and Objectives To assess the rate of deficiency of the metabolising enzyme DPD in patients treated with capecitabine and to describe the associated toxicity.

Material and Methods A retrospective observational study was conducted during 2022 in a regional hospital. Age, gender, Eastern Cooperative Oncology Group (ECOG) and diagnosis were collected from the electronic clinical history. To determine the variants of DPD, a pharmacogenomics analysis was performed using a real-time polymerase chain reaction technique. The polymorphisms studied were rs3918290, rs55886062, rs67376798 and rs56038477. Regarding the management of patients, the doses reduction, adverse events (AE), and withdrawal treatments were recorded.

Results Thirty-six patients were included with median age 70.9 (50–88) years. ECOG 0–1 was observed in 94% of cases. Capecitabine was used for the following diagnoses: colorectal cancer (n=22, 61%), gastric cancer (n=9, 25%) and breast cancer (n=5, 14%). DPD genotyping was performed on 25 patients (69%). A mutated allele heterozygote was detected in 3 (8.3%) patients: rs56038477 (n=2, 5.5%) and rs67376798 (n=1, 2.8%). A 50% dose reduction was prescribed initially according to pharmacogenetics recommendations in DPD deficiency and this dose was maintained throughout the entire treatment. In patients without mutation a dose reduction was required in 8 (32%). All patients with DPD mutation and 20 (80%) without DPD mutation presented AE. The most common AE in this population were weakness (n=18, 50%), diarrhoea (n=17, 47.2%), gastrointestinal such as nausea (n=10, 27.8%), dactylitis (n=8, 22.2%), mucositis (n=8, 22.2%), paraesthesia (n=8, 22.2%), hyperpigmentation (n=6, 16.7%) and constipation (n=4, 11.1%). Six (16.7%) discontinuations of capecitabine due to AE were reported.

Conclusion and Relevance It is important to know the DPD polymorphism to correctly adjust the capecitabine dose. A considerable percentage of patients without DPD mutation report AE. Determination of variants of DPD can help avoid serious or fatal EA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-036 **SUCCESSFUL TREATMENT OF POST-SURGICAL MENINGITIS CAUSED BY BACILLUS CEREUS: A CASE REPORT**

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Background and Importance *Bacillus cereus* is a spore-forming, gram-positive bacterium that is ubiquitous in the environment. It is frequently dismissed as contaminants, however, in the proper setting these organisms have the potential to be virulent. Clinical infections caused by *B. cereus* fall into six broad groups: local infections of wounds, burns, bacteraemia, CNS infections, respiratory infections, endocarditis and food poisoning. Despite aggressive treatment with broad-spectrum antibiotics and using them appropriately, the mortality is high.

Aim and Objectives To describe a case of *Bacillus cereus* central nervous system infection associated with post-surgical meningitis and a patient successfully treated with antibiotics.

Material and Methods Descriptive and retrospective clinical case. Data were obtained by review of electronic medical records.

Results A 72-year-old woman underwent a decompressive laminectomy due to lumbar spinal stenosis. Past medical history included hypertension and dyslipidaemia. She was discharged without complications. One week later, the patient was brought to the emergency room for altered consciousness, dysarthria, hemiplegia and fever. Her vital signs included a blood pressure of 109/82 mmHg, heart rate 125 beats/min, SpO₂ 92%, and Glasgow Coma Scale score of 7/15. C-reactive protein (CRP) level was 95 mg/l (reference <5 mg/l). Polymerase chain reaction (PCR) testing for SARS-CoV-2 was negative. Blood culture was negative. After a lumbar puncture, *Bacillus cereus* was isolated. The isolate was found resistant to β -lactam antibiotics (including penicillin, ampicillin and cephalosporin) and trimethoprim/sulfamethoxazole, and showed susceptibility to macrolides, vancomycin, clindamycin, carbapenems and quinolones. Triple antibiotherapy with meropenem, vancomycin and linezolid was initiated. After a few days of clinical stability, absence of fever and negative microbiological cultures, the triple antibiotic therapy was withdrawn and vancomycin and meropenem were continued. With adequate control of the source of infection and after a good evolution of the surgical wound, antibiotic therapy was switched to the oral route with linezolid. The patient was discharged with no evidence of sequelae from the meningeal infection, normal neurologic examination and CRP levels within the normal range.

Conclusion and Relevance This case highlights the clinical challenge to diagnose *B. cereus* and the importance of the delay between the detection of *B. cereus* and the establishment of an effective, targeted antibiotic therapy, especially in immunocompromised patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-045 **ECOLOGICAL AND CLINICAL IMPACT OF AN ANTIMICROBIAL STEWARDSHIP PROGRAMME ON THE INCIDENCE OF CARBAPENEM RESISTANT KLEBSIELLA PNEUMONIAE**

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Background and Importance Carbapenem-resistant Enterobacteriaceae are a critical public health threat, and carbapenem use contributes to their spread. In 2012, an outbreak of carbapenemase KPC-producing *Klebsiella pneumoniae* (KPC-Kp) was reported in a tertiary-care hospital, causing a high mortality rate. To combat this problem, an antimicrobial stewardship programme (ASP) was implemented in 2014, which achieved a substantial reduction in carbapenem consumption and the incidence density (ID) of KPC-kp isolates two years after starting the programme.

Aim and Objectives To assess whether this reduction in KPC-kp isolates was indeed associated with a decrease in KPC-kp infections and associated mortality.

Material and Methods A quasi-experimental study was conducted in a tertiary-care hospital one year before (January 2013-January 2014) and two years after (February 2014-February 2016) the implementation of an ASP aimed at hospitalised adult patients treated with carbapenems. We assessed monthly ID of KPC-kp infections and 30-day crude death rate associated per 1000 occupied-bed days. The clinical category was classified according to the EUCAST breakpoints. Joinpoint regression analysis was used to model trends over time and identify the estimated location of any significant change in the slope of a trend line (Joinpoint Regression Program, version 4.9.1.0). A two-sided p-value of <0.05 was considered significant. Infection control indicator trends remained steady during study period.

Results A substantial reduction in KPC-kp infections was observed during post-intervention period, with a monthly change in slope of -2.9% (95% CI, -4.5 -1.3, p=0.01). The crude death rate of KPC-kp infections also showed a significant reduction after the intervention, with a monthly change in slope of -5.1% (95% CI, -8.5 -1.7, p=0.005).

Conclusion and Relevance Although most ASPs have reduced antibiotic consumption, recent systematic reviews have found no strong evidence of clinical and ecological impact of these interventions due to the small number of studies evaluating this relationship, as well as a large heterogeneity in study designs. Indeed, most ASPs have only shown the absence of deleterious effects of this reduction on mortality rates. This work provided new evidence, showing that the implementation of this ASP contributed to decreasing KPC-kp infections and the associated mortality, which was very high in our centre, probably due to the lower incidence of these infections associated with reduced use of carbapenems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-048 ANALYSIS OF PAXLOVID® FOR THE TREATMENT OF COVID-19 IN ARAGÓN, SPAIN

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Background and Importance Paxlovid® is indicated for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19. The Spanish Drug Agency published prioritisation criteria for its access. Paxlovid® has significant drug interactions, mainly due to ritonavir. Hospital pharmacists must validate the prescription, carrying out a thorough review of the patient's medical history to check its suitability, as well as the concomitant medication to avoid interactions.

Aim and Objectives Analyse the use of Paxlovid® in Huesca and Sector-1 of Zaragoza (Aragon, Spain) in early months post-authorisation.

Material and Methods All Paxlovid's prescriptions from April to September 2022 were reviewed. The following variables were collected: gender, age, vaccination schedule, prioritised high-risk criteria and renal function. All concomitant medication was reviewed for drug interactions using a protocol created by Coordination Unit for the Rational Drug Use of Aragon. The observations made to the prescribing physician by the hospital pharmacist were recorded.

Results 40 requests were received. 5 were prescription errors. 29 (82.9%) were accepted and 6 (17.1%) rejected. Median age (years, interquartile-range q1-q3) was 52.2 (45.6–65.3), 57.1% were male. Vaccination status was complete primary vaccination with booster-dose (62.8%) followed by complete vaccination (25.7%) and incomplete vaccination (11.5%). As high-risk criteria prioritised, 91.4% belonged to group composed by immunocompromised persons. 91.4% had renal function >60ml/min. Only in 3 cases (8.6%) the prescribing physician indicated the patient had potential drug interactions.

All patients had concomitant medication, median of 8 drugs (4–10). 60% had any potential interaction, with serious drug interactions in 42.9% of them. Drugs with potential serious interactions were statins (5/11); benzodiazepines (2/11) and antithrombotic agents (2/11).

44.8% prescriptions were accepted with recommendations to modify or temporary stop some of the patient's usual treatment. 80% of the rejected cases were due to serious drug interactions.

Conclusion and Relevance In the use of Paxlovid®, the role of hospital pharmacists was crucial, as drug interactions were detected in 60% of patients and were serious in 42.9% of them, leading to recommendations for adjustments in patients' drug therapy in almost half of the cases, with potentially serious drug interactions being the main reason to not dispense Paxlovid®.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-055 EFFECTIVENESS AND SAFETY OF RIBOCICLIB IN THE FIRST LINE OF LUMINAL METASTATIC BREAST CANCER

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Background and Importance Ribociclib is a cyclin-dependent kinase inhibitor used in the first line of luminal metastatic breast cancer (MBC).

Aim and Objectives To assess the effectiveness and safety of ribociclib in first-line treatment of hormone receptor positive and human epidermal growth factor receptor 2 (HER2) negative MBC.

Comparison with the results of the MONALEESA-2 trial.

Material and Methods Observational, retrospective study, carried out in a second level hospital between July 2017 and March 2022. All patients diagnosed with MBC treated with ribociclib in combination with hormonal therapy from diagnosis of the first metastasis to tumour progression were included.

The effectiveness variable measured was the median progression-free survival (mPFS).

The safety variables measured were adverse reactions (AR) presented and percentage of patients who required dose reduction due to adverse reactions.

Variables such as gender, age and location of metastases were also recorded.

The data was obtained from the Electronic Medical Record and the Pharmacy dispensing programme.

For analysis of mPFS, the Kaplan-Meier test was used using the statistical program SPSS® and results were compared with the results of MONALEESA-2 study.

Safety was assessed according to CTCAE criteria.

Results 34 patients were included, 100% were women with a median age of 58 years (31–73).

Locations of metastases found were bone, lung, mediastinum, liver, pleura, skin, brain, and peritoneum. 58.82% (20/34) of patients had 2 or more metastatic locations and 41.17% (14/34) had a single metastasis, this being bone location in 64.28% (9/34) of patients.

The median follow-up was 13.9 months (2.73–29.5), 41.17% (14/34) of patients progressed to treatment with ribociclib and mPFS was not reached.

In MONALEESA-2 study, median follow-up was 26.4 months and mPFS was 25.3 months.

The adverse reactions presented mainly were neutropenia in 52.94% (18/34) and asthenia in 26.47% (9/34). In MONALEESA-2 study, both were adverse reactions reported with a frequency > 20%.

55.88% (19/34) of patients required dose reduction due to adverse effects of ribociclib. In MONALEESA-2 study, dose reduction was required in 50.6% (10/19) of patients.

Conclusion and Relevance A longer follow-up time is necessary for our patients to be able to compare the effectiveness in terms of PFS with the MONALEESA-2 study. Regarding the safety of ribociclib, the data reflected are similar to those presented in the MONALEESA-2 study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-058 SYMBALOO AS DIGITAL TOOL FOR HAEMOPHILIA

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Background and Importance In rare diseases such as haemophilia, the access to rigorous information is essential.

Aim and Objectives To describe the virtual desktop developed by our pharmacy service for haemophilia patients. It includes shortcuts to selected resources. The aim is to facilitate quick, free and easy access to information about the disease and its treatment.

Material and Methods The tool selected to create the virtual desktop was Symbaloo® (symbaloo.com), which brings together in one place the selected links to useful and rigorous websites. It has been organised in colour-coded sections according to the type of information offered in each block. The name of the virtual desktop is 'Haemophilia for patients'.

Results The desktop has a total of 43 web links organised in 16 blocks belonging to 8 sections:

1. Introduction to haemophilia.
2. Regional, national and international haemophilia associations and a list of national treatment centres.
3. Children's blocks.
4. Advice on sports and lifestyle habits in haemophiliacs.
5. Document for the haemophiliac traveler.
6. Treatments: patient leaflets, self-infusions and individualised treatment.
7. Information sheets from our pharmacy service.

This is a dynamic desktop that is updated with news and improvements to adapt it to the patient's needs. The link to access our virtual desktop is: <https://bit.ly/HEMOPHILIA>.

A web prescription sheet was also designed with a QR code to be scanned with the patient's cell phone to facilitate the access, including instructions for using the desktop and the pharmacist's contact information.

Conclusion and Relevance Symbaloo is a potentially useful digital platform for providing quality information and useful web resources to haemophilia patients. Healthcare professionals can, and should, provide our patients with useful digital content that allows them to learn about the management of their disease. Through these online tools, patients' digital health literacy can be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-064 EFFECTIVENESS OF RIBOCICLIB AND ABEMACICLIB AS FIRST LINE TREATMENT FOR METASTATIC BREAST CANCER IN POST-MENOPAUSAL WOMEN

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Background and Importance Ribociclib and abemaciclib are cyclin-dependent kinase 4/6 inhibitors (CDK4/6-i) used as treatment for patients with negative epidermal growth factor receptor 2 (HER2-) and positive hormone receptor (HR+) metastatic breast cancer (MBC). MONALEESA-2 and MONARCH-3 trials evaluated the efficacy of these drugs as first line treatment in post-menopausal women.

Aim and Objectives To assess effectiveness of ribociclib and abemaciclib in HER2- and HR+ MBC in clinical practice, comparing results with reference bibliography.

Material and Methods Descriptive retrospective study included post-menopausal women with HER2- and HR+ MBC receiving CDK4/6-i as first line of treatment between August-2017 and September-2022. Data were recorded from electronic clinical history and prescription program Prisma®: gender, age, ECOG, CDK4/6-i and combined endocrine therapy, dosage and treatment duration. Effectiveness was assessed by progression free survival (PFS), overall survival (OS) and PFS rate at 12 months, using Kaplan-Meier statistical analysis with SPSS V.21.0. Results were compared with those described in pivotal clinical trials.

Results A total of 63 women were included. Mean age was 63 (range 50–84) years. At baseline, ECOG=0/1 was observed in 93.7% cases and ECOG=2/3 in 6.3%. Abemaciclib was used in 50.8% patients and 49.2% ribociclib. CDK4/6-i were combined with letrozole in 58.7% patients and fulvestrant in 41.3%. Dose reduction occurred in 48.4% patients with ribociclib and 34.4% with abemaciclib. For ribociclib, median treatment duration was 16 (2–54) months and 11 (2–32) months for abemaciclib. Estimated PFS median for ribociclib was 28.0 (95% Confidence Interval: 6.6–49.3) months and was not reached for abemaciclib. Ribociclib and abemaciclib estimated OS median were not reached at data cut-off. PFS rate at 12 months was 67.3% (95% CI: 58.8–75.8) for ribociclib, and 60.7% (95% CI: 51.4–70.0) for abemaciclib. For ribociclib, MONALEESA-2 trial presented a PFS median of 25.3 months, OS median of 63.9 months and 12-month PFS rate of 72.8%. For abemaciclib, MONARCH-3 showed a PFS median of 28.2 months, OS median was not reached and 12-month PFS rate was not described.

Conclusion and Relevance Real-life effectiveness results confirmed a substantial benefit of ribociclib and abemaciclib. These data appeared to be slightly superior than those described in the literature. Larger sample size and longer follow-up time are necessary to extract more conclusive information.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-069 EXPERIENCE OF ONCO-HAEMATOLOGY PATIENTS IN OUTPATIENT THERAPY WITH COMPREHENSIVE MEDICATION MANAGEMENT IN THE CONTEXT OF A COVID 19 PANDEMIC

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Background and Importance The opening of a pharmaceutical care service for onco-haematology patients (OHP) in the midst of the health care crisis caused by the COVID19 pandemic, made it possible to maintain the healthcare activity, avoid the collapse and provide the opportunity to implement Comprehensive Medication Management (CMM).

Aim and Objectives To investigate the pharmacotherapeutic experience of OHP in outpatient therapy with CMM services; to know important aspects perceived for the identification of barriers/facilitators that determine the quality of the service and proposals for improvement.

Material and Methods Descriptive observational design with a qualitative approach, using informal and semi-structured in-depth interviews (participant observation and peer review) during January-June 2021. ATLAS.ti software was used for content analysis. Oncohaematology patients in outpatient therapy with any medication-related problem and who received CMM services were interviewed. Those who, due to cognitive limitation, could not be interviewed or who did not have a caregiver/family member available were excluded.

Results 19 interviews were conducted: 57.89% patients and 42.10% caregivers; 57.89% were women. All patients were very satisfied with the care received, the vast majority preferred to be attended by a pharmacist, and valued telepharmacy as an alternative or complementary option. The vision of the pharmacy professional as an expert in medicines improves. They suggest improvement related to location, waiting times and greater accessibility of the pharmacist. After the researchers' reflective process, were identified as barriers: care pressure, limited time/resources, lack of interlevel coordination, and facilitators: prioritisation of interventions, integration of pharmacist in the multidisciplinary team, trust in the pharmacist and the new model of care. Improvement strategies: provision of human/material resources with release of pharmacist's time to provide the CMM, extension of hours, information management with the development of personal learning environment and use of programs for recording/integration of information and interventions.

Conclusion and Relevance Delving into patients' experiences can be key to improving the quality of care. In our case, the implementation of the CMM service in OHP has been a challenge and an opportunity in the current context of the COVID-19 pandemic. The pharmacy adapted to the needs and implemented a new model of care with excellent acceptance by users.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-079

COMPARATIVE ANALYSIS OF THE EFFECTIVENESS OF CEFTAZIDIME-AVIBACTAM ADMINISTERED BY INTERMITTENT INFUSION VERSUS CONTINUOUS INFUSION

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Background and Importance The method of administration indicated in the data sheet of ceftazidime-avibactam (CAV) is by intermittent infusion (INTINF) over 120 minutes. However, continuous infusion (CONTINF) is an off-label

recommendation in beta-lactam antibiotics in order to achieve the pharmacokinetics/pharmacodynamics efficacy objectives.

Aim and Objectives To compare the effectiveness of the administration of CAV by INTINF (2 g every 8 hours in adults or 50 mg/kg/8 hours in the paediatric population) versus CONTINF (6g in 24 hours).

Material and Methods An observational retrospective study including patients treated with CAV until April 2022 was conducted. Variables collected were: sex, age, empirical/directed therapy, isolated microorganism, treatment duration, previous/concomitant antibiotic, infection site, admission to intensive care unit (ICU), culture negativisation, clinical resolution and exitus.

Results 92 patients were included, 67 in the INTINF group and 25 in the CONTINF cohort (70.1% and 72.0% men, respectively). Median age was 47 (1–86) years (INTINF) and 51 (1–84) years (CONTINF).

Treatment was directed in 92.5% (INTINF) and 96.0% (CONTINF), and the main microorganisms isolated were, respectively: multidrug-resistant *Pseudomonas aeruginosa* (75.8% vs 76.0%), *Klebsiella pneumoniae* (8.1% vs 12.0%), *Burkholderia cenocepacia* (4.8% vs 4.0%), and others (13.3% vs 8.0%). The median duration of CAV treatment was 11 (1–58) months (CONTINF) and 10 (1–29) months (CONTINF). 79.1% (INTINF) and 80% (CONTINF) received previous antibiotic therapy, and 77.6% (INTINF) and 80% (CONTINF) of the patients received concomitant antibiotics. The infection site was: respiratory (70.0% vs 64.0%), skin and soft parts (9.0% vs 0%), bacteraemia (7.5% vs 5.0%), abdominal (6.0% vs 4.0%), and others (7.5% vs 8.0%). 50.7% (INTINF) and 80.8% (CONTINF) of the patients were admitted to the ICU.

Negativisation of the cultures was 34.3% in the INTINF cohort and 32.0% in the CONTINF group. The resolution of the infectious process in INTINF and CONTINF patients was 56.7% vs 48.0%, and exitus was 20.8% vs 40.0%, respectively.

Conclusion and Relevance In this study, the administration of CAV by INTINF showed greater effectiveness than CONTINF. Therefore, it seems essential to carry out new studies that corroborate the effectiveness of CAV administered by CONTINF.

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Conflict of Interest No conflict of interest.

4CPS-080

OPTIMISATION OF ANTIRETROVIRAL THERAPY: RESULTS AFTER SIMPLIFICATION TO BITHERAPY WITH DOLUTEGRAVIR/LAMIVUDINE OR DOLUTEGRAVIR/RILPIVIRINE

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Background and Importance Simplification of antiretroviral therapy with dolutegravir/lamivudine (DTG/3TC) or dolutegravir/rilpivirine (DTG/RPV) improves the safety profile and cost-effectiveness of treatment in patients with human immunodeficiency virus (HIV).

Aim and Objectives To evaluate the efficiency of simplification to bithery with DTG/3TC or with DTG/RPV in patients with HIV.

Material and Methods Observational, retrospective study, carried out in a second-level hospital from July 2019 to March 2022. All patients diagnosed with HIV who simplified antiretroviral treatment to bithery with DTG/3TC or DTG/RPV were included.

The main variables studied were the percentage of patients with undetectable viral load (viral load <50 copies/mL) measured in the first analytical determination performed after treatment simplification and the economic impact of this simplification.

Other variables recorded were age, sex, viral load prior to treatment simplification, and type of bithery received.

The data was obtained from the electronic medical record and the pharmacy dispensing program.

Statistical data analysis was performed using descriptive frequency analysis.

For the analysis of the economic impact, the difference between the annual consumption of each patient in treatment with triple therapy and with bithery was calculated.

Results 415 patients receiving antiretroviral treatment were in follow-up in our centre. Treatment simplification was performed on 154 patients (37.10%). 76.62% (118/154) were men. The median age was 45 years (22–87). Before the change in treatment, 98.7% (152/154) of patients had undetectable viral load. 96.1% (148/154) of patients had a new viral load determination after treatment simplification. This determination was made with a median follow-up of 5.33 months (1.5–12.76). Of these, 100% (148/148) of patients maintained undetectable viral load.

In 94.81% (146/154) of patients, treatment was simplified to DTG/3TC and in 5.19% (8/154) to DTG/RPV.

The economic impact of the simplification of treatment to bithery for 154 patients implies a saving of € 198,842.62/year (€ 179,352.64/year with simplification to DTG/3TC of 146 patients and € 19,489.98/year with simplification to DTG/RPV of eight patients).

Conclusion and Relevance The simplification of antiretroviral treatment to bithery with DTG/3TC or DTG/RPV has proven to be a good treatment option in terms of efficiency: patients maintain undetectable viral load after simplification of therapy and this change translates into considerable savings. However, long-term clinical results need to be verified.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-081 EVALUATION OF EFFECTIVENESS, SAFETY AND ADHERENCE OF PRE-EXPOSURE PROPHYLAXIS AGAINST HIV

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Background and Importance Pre-exposure prophylaxis against HIV infection (PrEP) consists of the prescription of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) in people risk of acquiring the infection. PrEP is part of the package of measures of health agencies aimed at preventing HIV.

Aim and Objectives The objective of this study is to evaluate the effectiveness and safety of treatment with TDF/FTC for HIV pre-exposure prophylaxis, as well as therapeutic adherence in a third-level hospital.

Material and Methods Retrospective, observational study including patients who received for a minimum of 4 months, Prep with TDF/FTC (March 2020-May 2022).The data have been obtained through the patient's clinical history and outpatient dispensing module. The variables collected were: age, sex, duration of treatment, reason for suspension, number of partners in the last year, sexually transmitted infections (STIs) before and during treatment, use of chemsex, administration schedule, adverse drug reactions, serum creatinine, prior administration of post-exposure prophylaxis (PEP) and HIV serology during treatment. Safety was assessed by reporting adverse reactions during the study and renal function before and after starting treatment. The effectiveness was evaluated according to the results of HIV serologies.

Results 63 patients were included, all of them HIV-negative men, mean age of 36.7 years. All patients met criteria for initiation PrEP.15.9% of the included patients had been treated at least once with PEP,63.5% had had more than 10 partners in the last year, 63.5% did not use chemsex, 17.5% occasionally and the rest regularly. 79.4% of the patients had contracted STIs before starting treatment and 55.6% after. The most common STIs were syphilis, gonorrhoea, ureaplasma urealyticum and chlamydia. Only 7 patients did not have any STIs before or during treatment. 95.2% opted for the daily administration and only 3 patients the alternative regimen. Regarding safety, 10 patients reported any adverse reaction, the majority were digestive: diarrhoea and nausea,1 patient with increased transaminases and 1 patient with increased creatinine serum. Only 8 patients suspended treatment, 3 of them due to adverse reactions. Concerning adherence, the 90,5% were considered adherent to treatment.

Conclusion and Relevance All patients remained negative for HIV 1–2 serology during the study. Only 3 patients discontinued treatment due to adverse reactions and only 1 had worsening renal function. Adherence to treatment was good. It is necessary to insist on the recommendation of condom use in this patient population to prevent other STIs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-085 PHARMACEUTICAL INTERVENTIONS IN A NEONATOLOGY UNIT

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Background and Importance In neonates, frequent changes in dosing intervals and drug dosage can increase the risk of medication discrepancies and adverse drug events. The role of pharmacists is essential to avoid these medication errors in this sensitive population.

Aim and Objectives To analyse the pharmaceutical interventions carried out in hospitalised patients in the Neonatology Unit of a tertiary care hospital and to evaluate their degree of acceptance.

Material and Methods A descriptive prospective study of the pharmaceutical interventions (PI) performed in hospitalised neonates between 1 July and 15 September 2022 was conducted. The following variables were collected from the electronic medical record and prescription program: total number of admitted neonates, number of patients for whom a PI was issued, main pathologies associated with PI, number and type of PI carried out, and degree of acceptance of the recommendations.

Results 166 patients were admitted to the Neonatology Unit. Of the total number of patients, 45 PI were performed on 35 of them (21.1%).

The main pathologies related to PI were: respiratory (51.1%), infectious (26.7%), endocrine (17,8%) and cardiovascular (4.4%).

Of all the interventions carried out (n=45), the pharmacist recommended: dose adjustments (42.9%, n=15), changing the route or rate of administration (24.4%, n=11), pharmacokinetic drug monitoring (vancomycin) (13.3%, n=6), adapting the dose to the pharmaceutical presentation (11%, n=5), adding another medication to the prescription (6.6% n=3) or suspending a medication (6.6%, n=3), exchanging of a drug for a therapeutic equivalent (2.2%, n=1), and changing a medication to a more effective one (2.2%, n=1).

The degree of acceptance of the interventions by neonatologists was 86.6%.

Conclusion and Relevance Most of the PI were related to dose modifications, changes in the route or rate of administration, as well as the optimisation of antibiotic treatment through pharmacokinetic monitoring. The degree of acceptance of the interventions was very high, which reinforces the integration of the hospital pharmacist in a multidisciplinary team.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-086 COMPARISON OF A TRADITIONAL ELISA TECHNIQUE VERSUS A POINT-OF-CARE TECHNIQUE IN THE DETERMINATION OF ADALIMUMAB LEVELS IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Background and Importance ELISA is the most commonly used technique to determine adalimumab (ADL) levels in patients with inflammatory bowel disease (IBD), as it is simple and inexpensive. Its disadvantage is that it requires a specialised laboratory and several tens of samples have to be accumulated to make the cost of each determination more efficient, with the consequent delay in obtaining the results. Rapid tests make it possible to obtain levels in a very short time (15 minutes) and to act immediately to optimise biological therapy.

Aim and Objectives The aim of this study is to compare the reference technique for quantifying ADL levels using ELISA with quantification using a rapid test, the point of care (POC) test.

Material and Methods ADL levels of 56 IBD patients were tested by both methods. Samples were obtained prior to ADL infusion. Promonitor®ADLv2 kits from Progenika Biopharma were used for the enzyme-linked immunoassay (ELISA). For the rapid assay (POC), the Quantum Blue® Adalimumab Lateral Flow Immunochromatography technique (BÜHLMANN Laboratories) was used.

Quantitative comparison of both techniques was assessed with Bland-Altman plots, Student's t-test and regression line to test for agreement between the two techniques. A p-value of <0.05 was considered statistically significant. The 95% limits of agreement were calculated using the mean ± 1.96*SD. Correlation was assessed using Pearson's correlation coefficient (r). Statistical analyses were performed with the R®v4.1.2 package.

Results The median ADL concentration was 12.4 µg/mL (range 0.3–24.4 µg/mL) using the ELISA test and 13.8 µg/mL (range 1–35 µg/mL) using the POC test (Quantum Blue®). The Pearson correlation for both was high (r=0.87, p<0.001) and the regression line y=1.06x+1.90, whose slope of 1.06 indicates good agreement between the two techniques. The mean difference between ELISA and POC test was -2.76 µg/mL (95%CI, -11.70–6.18) (<0.05). The Bland-Altman plot indicates that at concentrations above approximately 15 µg/mL, the rapid test (POC) overestimates the ADL concentration values compared to the ELISA technique.

Conclusion and Relevance The Quantum Blue® Adalimumab POC rapid test shows high correlation and concordance and minimal acceptable differences compared to the reference ELISA tests, making it reliable and allowing results to be obtained within minutes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-087 PERSISTENCE IN THE METHADONE MAINTENANCE PROGRAMME AND ITS RELATIONSHIP WITH THE MEDICATION REGIMEN COMPLEXITY INDEX IN OPIOID DEPENDENT PATIENTS

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Background and Importance It has been shown that the Medication-Regimen-Complexity-Index (MRCI) is a useful and reliable tool for calculating the complexity of the pharmacotherapeutic regimen (CPR). Furthermore, high MRCI is associated with lower adherence. However, MRCI in opioid-dependent patients (ODP) has not been studied.

Aim and Objectives Calculate the methadone-maintenance-programme (MMP) persistence and the MRCI score in a ODP cohort. Second, to analyse its relationship and association with other variables.

Material and Methods An observational study including adults with a confirmed diagnosis of opiate-dependence according to the DSM-5 in a MMP centre was carried out from November 2021 to April-2022.

To define MMP-persistence, a group was created with the researchers who defined five weighted items according to the importance agreed.

The variables collected were sex, age, social/work situation, comorbidities, substances consumption, methadone treatment (doses, frequency, duration, number of dropouts/interruptions since the MMP onset). MRCI score and MMP-persistence were calculated. They were collected and managed using REDCap. Statistical analysis was carried out using SPSS® Statistics (v.27).

The study was approved by the Ethics Committee.

Results 84 patients signed the informed consent. 79.8% were male (median age:51(46–56)). 25.4% had a job and 14.9% was homeless. 57.0% had any comorbidity. 62.5% had infectious disease and almost 40% mental health disorder.

Substances consumption was tobacco (81.4%), benzodiazepines (74.0%), cocaine (65.0%), alcohol (42.4%), heroin (33.9%) and cannabis (28.3%). 2.9% were intravenous-drug-users (IVDU). Median methadone dose was 60mg (40–80). 63.1% received maintenance doses. 38.1% received methadone for >10 years. None of the patients abandoned MMP at any time.

The median MRCI score was 13.5 (8.5–21.8) (maximum:40.5).

Regarding MMP-persistence, a patient was considered persistent with a score $\geq 90\%$ according to our definition. We found 77.4% persistent patients.

No association was found between MRCI and MMP-persistence ($p=0.74$). However, the following variables had relationship: age ($p=0.04$), comorbidity (0.002) and patients receiving maintenance doses ($p=0.024$).

Regarding MRCI, we found association with age ($p=0.04$), homeless ($p=0.002$), comorbidity ($p=0.0$), HBV ($p=0.003$), mental health disorder ($p=0.006$), active heroin consumption ($p=0.03$) and IVDU($p=0.03$).

Conclusion and Relevance A new MMP-persistence definition has been created. We identified age, comorbidities, and receiving methadone maintenance doses as successful predictors for MMP-persistence.

MRCI does not seem to be a useful tool to determine the MMP-persistence, probably because there are multiple factors that influence in addition to the CPR. It is necessary to continue searching for more precise selection and stratification tools for ODP to improve their persistence. However, it should not be an obstacle to implementing measures to optimise their pharmacotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-094

ANALYSIS OF INTERVENTIONS ON ANTIBIOTIC PRESCRIPTIONS BY THE ANTIMICROBIAL STEWARDSHIP PROGRAMS AT THE EMERGENCY DEPARTMENT

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Background and Importance Antibiotics are some of the most prescribed drugs at the Emergency Department (ED) and it is usually inappropriate. An educational intervention by the antimicrobial stewardship programme (ASP) could be effective to improve the use of antibiotics.

Aim and Objectives To compare and analyse the interventions carried out on empirical antibiotic prescription (EAP) in two periods at ED by the multidisciplinary ASP(MASP). To compare defined daily doses per 100 discharges (DDD/100D) of meropenem in both periods.

Material and Methods Quasi-experimental study was conducted to compare the interventions performed by the MASP (formed by infectious disease doctors, clinical pharmacists and microbiologists) at ED of a tertiary hospital during June-2019(first period, FP) and March-2021(second period, SP). Unique recommendations on the adequacy of EAP were made for each patient and antibiotic dose optimisation. Collected data included patient demographics, diagnosis, prescription and its adequacy, recommendations made and grade of acceptance. Meropenem consumption of hospitalised patients during the intervention period and following month was obtained through the drug record programme in order to calculate the DDD/100D.

A database was created in Excel and analysed with SPSSv17.0 statistical software.

Results 145 patients were included: 58.6% men, mean age 71.2 years (SD:17.4). 42 on FP group (FPG) and 103 on SP group (SPG).

Abstract 4CPS-094 Table 1

| Type of Infection | Number Patients(%) |
|-------------------|--------------------|
| Urinary tract | 53(36.6%) |
| Respiratory tract | 33(22.8%) |
| Intra-abdominal | 25(17.2%) |
| Other | 34(23.5%) |

Over all the prescriptions, 58.6%(80/145) were appropriate, 50%(21/42) in FPG and 57.3%(59/103) in SPG. When inadequate prescription:

Abstract 4CPS-094 Table 2

| Type | Recommendation FPG | Recommendation SPG |
|-------------------|--------------------|--------------------|
| Increase spectrum | 23.8% | 14.6% |
| Decrease spectrum | 7.1% | 11.7% |
| Discontinue | 19.0% | 16.5% |

Global acceptance was 95.9% (139/145), being 95.9% (40/42) in FPG and 96.1% (99/103) in SPG.

The most prescribed antibiotic was ceftriaxone (49/145), followed by amoxicillin/clavulanate (26/145) and piperacillin/tazobactam (25/145).

The EAP of meropenem was 26.2% (11/42) in FPG and 6.8% (7/103) in SPG with statistically significant differences ($p<0.002$).

DDD/100D of meropenem was 27.9 in FPG and 22.9 in SPG.

Conclusion and Relevance An improvement in EAP has been observed. Although the acceptance rate in both periods was very high, the results show that more work needs to be done on training of prescribers.

Having established the MASP at EM has led to significant decrease of empirical meropenem use. This may have contributed to reduce DDD/100D of it in our hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-097 COMPARATIVE EFFECTIVENESS OF RISANKIZUMAB AND SECUKINUMAB IN MODERATE TO SERIOUS PSORIASIS

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Background and Importance In 2015, secukinumab emerged as the first anti-IL17 in psoriasis, characterised by a rapid onset of action. In 2017, the development of drugs with a new, different target of action, anti-IL23, began. The wide range of drugs and mechanisms of action makes the choice of treatment for patients with moderate to severe psoriasis increasingly complex.

Aim and Objectives Evaluation of effectiveness through indirect comparisons between risankizumab (anti-IL23) and secukinumab (anti-IL17).

Material and Methods Multicentre, observational, retrospective study to indirectly compare patients on risankizumab (RIS) and secukinumab (SEC) between June 2021 and June 2022. The anthropometric data were age, sex and previous biological treatments. comparative effectiveness was measured by the medians of the following variables: body surface area affected (BAS) scale, psoriasis area severity index (PASI), physician global assessment (PGA) at baseline, 12, 24 and 48 weeks after treatment. Safety was assessed with adverse event (EA) and the DLQI quality questionnaire were recorded. The main tools used: SAP[®] for the clinical history, Modulab[®] for laboratory values and Excel[®] for anonymised data recording. The information was collected according to data minimisation policy, article 5.1 of data protection.

Results A total of 111 patients were selected (60 risankizumab/50 secukinumab). The median age was 51.1 (risankizumab) and 39.8 (secukinumab). Of the patients, 63.3% were male. The main biologic treatments previously used were: Etanercept (31) > Adalimumab (23). Regarding efficacy: at baseline median BSA 11.9 vs 11.4 and PASI 8.3 vs 8.6 (SEC vs RIS), at 12 weeks BSA 1.6 vs 2.3 and PASI 1.5 vs 1.8 (SEC vs RIS), at 24 weeks BSA 1.5 vs 0.7 PASI 0.6 vs 0.7 (SEC vs RIS), and at 48 weeks BSA 1.63 vs 0.7 and PASI 0.5 vs 0.9. The main adverse events were headache and mild injection site reaction for both drugs.

Conclusion and Relevance Based on data from comparative studies, there is no significant difference between the effectiveness of risankizumab and secukinumab. More studies are needed to define the gold-standard drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Risankizumab data sheet.

Secukinumab data sheet

Conflict of Interest No conflict of interest

4CPS-098 NIRMATRELVIR-RITONAVIR EFFECTIVENESS ANALYSIS AND INTERACTION PROFILE ANALYSIS

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Background and Importance New drugs have been investigated with the aim of preventing serious pathology in high-risk patients with COVID. As a result, nirmatrelvir-ritonavir emerged, approved by the European Medicines Agency in December 2021 thanks to the pivotal EPIC-HR clinical trial.

Aim and Objectives To analyse the effectiveness and pharmacological interaction profile of nirmatrelvir-ritonavir in patients diagnosed with SARS-Cov2.

Material and Methods Retrospective study in which patients diagnosed with mild-moderate SARS-Cov2 for whom treatment with nirmatrelvir-ritonavir was requested from the approval of the drug until 08/31/2022 were preselected. Patients who received treatment were included. The primary effectiveness endpoint was hospital admission or death from any cause through day 28. As a secondary variable, the profile of pharmacological interactions between nirmatrelvir-ritonavir and the patients' medication and its management. Selection of patients, demographic and clinical data were obtained from the electronic medical record. Descriptive statistical analysis was performed using Excel[®] 16.48.

Results We preselected 86 patients, 37 (43.02%) did not receive treatment. The reasons for non-indication were: patients not considered high risk 30/37 (81.08%), receiving oxygen therapy 4/37 (10.82%), >6 days of symptoms, unmanageable interactions and received remdesivir, 1/37 (2.70%) each one. Obtaining a final sample of 49 patients. Mean age was 67.5 years (SD=16) and 25 (51.02%) of them were men. Indication's reasons were: high-risk immunocompromised patients 32/49 (65.31%), vaccinated >6 months ago over 80 years with risk factor 14/49 (28.57%), unvaccinated over 80 years 2/49 (4.08%), unvaccinated over 65 years with a risk factor 1/49 (2.04%). Of these, 10/49 (20.41%) required adjustment to renal function. An event (hospital-admission or death) during the 28 days after the start of treatment was registered in 16/49 (32.65%) patients. Of these 14 (28.57%) events were hospital-admission and 2 (4.08%) deaths. We detected 77 interactions in 39/49 (79.59%) patients [2.14 interactions/patient; SD=1.42], that required: to monitor 55/77 (71.43%), suspend treatment and reintroduce it 3 days after 20/77 (25.98%) and reduce dose 2/77 (2.59%). Main therapeutic groups with interactions: statins 14/77 (18.17%), metamisazole 9/77 (11.68%), calcium channel blockers 8/77 (10.38%), antidepressants 5/77 (6.49%), opioids 4/77 (5.19%), direct oral anticoagulants 4/77 (5.19%), and tamulosin 4/77 (5.19%).

Conclusion and Relevance It seems that real-life results of nirmatrelvir-ritonavir are inferior to those obtained in the pivotal RCT, due to higher number of hospital admissions. Most patients presented interactions, which could be managed in a simple way through temporary suspension and monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-102 DRUG RELATED PROBLEMS SECONDARY TO HEPARIN TREATMENT IN PATIENTS DISCHARGED FROM THE EMERGENCY DEPARTMENT

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Background and Importance It is a common practice to discharge patients from the emergency department (ED) with low-molecular-weight-heparin (LMWH). But there is limited knowledge of the risk factors associated with drug related problems secondary to heparin treatment in patients discharged from ED.

Aim and Objectives To assess drug related problems secondary to heparin treatment in patients discharged from ED including bleeding and thromboembolic episodes.

Material and Methods Retrospective observational study. Adults patients discharged from ED with LMWH were included (February to April 2022). Study variables included comorbidities of the patient, number of drugs at discharge, drugs that may be related to bleeding episodes, length of treatment, and 30-day ED revisits. The association between 30 days ED revisits, comorbidities and patient treatment was evaluated using Ji-square or Fisher's test.

Results Over the duration of the study 90 patients were included (mean age=73.1 years (SD 16.2); females 32 (49.2%). Reason for anticoagulation with LMWH included atrial fibrillation (32;35.6%), prophylaxis (7;7.8%) and thromboembolism (51;56.67%). Duration of treatment with heparin was less than 7 days (17;18.9%), 7 to 30 days (37;41.2%) and more than 30 days (36;40%). Of the 90 patients, 3 came back due to haemorrhage and 2 due to thromboembolism.

A greater tendency to return to the ED once discharged at 30 days was observed in patients over 80 years old (10.5% vs 1.9%; $p=0.158$) and in patients >10 drugs (10% vs 2%; $p=0.167$).

Conclusion and Relevance About a 5% of patients who were discharged with heparin from ED returned after 30 days due problems as bleeding or thromboembolism, more frequently in patients over 80 years old and polypharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-106 BEDSIDE CHECK OF MEDICATION APPROPRIATENESS (BED-CMA) AS A RISK-BASED TOOL FOR BEDSIDE CLINICAL PHARMACY SERVICES: A PROOF-OF-CONCEPT STUDY AT THE TRAUMA SURGERY WARD

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Background and Importance Implementation of bedside clinical pharmacy services prevents medication errors and associated adverse events but is not possible in many European countries on a hospital-wide and/or on full-time basis due to limited

resources. Clinical rules using structural information in the electronic health record can help bedside pharmacists to prioritise their work on the ward by identifying potential high-risk situations. Hence, a risk-based clinical pharmacy service was developed and implemented at the trauma ward, as a proof of concept.

Aim and Objectives To evaluate the impact of a risk-based clinical pharmacy service on potential inappropriate prescriptions (PIPs) at the trauma ward.

Material and Methods The impact on the proportion of residual PIPs per day, i.e. the number of PIPs that persisted up to 24h after pharmacist intervention divided by the number of PIPs at T0, was evaluated using an interrupted time series analysis. The pre-intervention cohort received usual pharmacy services, i.e. 0.3 FTE availability of a junior bedside clinical pharmacist. In the post-intervention period, the pharmacist could rely on 16 clinical rules, targeting antimicrobial, anticoagulant and analgesic therapy. The pre-intervention period was compared to two post-intervention scenarios to investigate possible requirements for the intervention: (scenario A) clinical rule alerts reviewed by a junior clinical pharmacist on a 0.3 FTE basis; and (scenario B) clinical rule alerts reviewed daily for approximately 1h by a clinical pharmacist with one year of clinical pharmacy experience.

Results Pre-intervention, a median proportion of 67% residual PIPs per day was observed. Scenario A showed an immediate relative reduction of 42% ($p=0.15$) and scenario B a significant immediate relative reduction of 77% ($p=0.03$) in residual PIPs per day. In scenario A, recommendations were provided by the pharmacist for 19% (44/232) of clinical rule alerts, of which 69% was accepted by the trauma surgeon within 24h. In scenario B, recommendations were given for 56% (167/299) of clinical rule alerts, of which 84% was accepted.

Conclusion and Relevance The use of clinical rules is an effective approach to organise bedside clinical pharmacy services and improves the efficiency of the clinical pharmacist at the trauma ward. Pharmacist's experience and daily follow-up of the clinical rule alerts are two requirements to be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-112 SURVEY OF DIETARY SUPPLEMENT USE AND VACCINATION STATUS AMONG RHEUMATOID ARTHRITIS PATIENTS DURING THE COVID-19 PANDEMIC

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Background and Importance In recent years not just the novel therapeutic approaches, but the Coronavirus pandemic has also affected the therapy management of patients with rheumatoid arthritis. Beside these changes, the immunisation against COVID-19 has also been an issue and raised several questions from clinicians to patients.

Aim and Objectives Therefore, our aim was to find out the possible changes that patients were experiencing and the potential factors influencing their therapy.

Material and Methods Data was collected through structured personal interviews with a 33-item questionnaire licensed by

the Regional Research Ethics Committee of the University of Pécs and review of the medical records from January until September in 2022. We used the data available in the ambulatory medical records and the itemised reporting interface of the National Health Insurance Fund. Drug interactions were analysed using UpToDate Lexicomp database.

Results 35 female patients (average age: 63.53 years \pm 13.82) and 23 male patients (average age: 53.54 \pm 12.96) received biological or targeted therapy for an average of 7.17 years (\pm 4.12), while the average patient activity index DAS28 was 3.15 (\pm 1.17) and BASDAI was 5.29 (\pm 5.52). 87.93% (51/58) of the patients have used non-medication health products, mainly vitamin C or D. 34.48% of the patients were confirmed with coronavirus infection during the pandemic, while the vaccination rate was 87.89%. 83.45% of the patients received at least one mRNA vaccine. In our patient group, the influenza vaccination rate was 36.21%, while only 5.21% of the patients had been vaccinated against Pneumococcus in six months previous to our survey. The total number of serious (category X and D) interactions were 216, in 135 cases a vaccine and in 58 cases a monoclonal antibody or targeted therapy was included as interacting pair.

Conclusion and Relevance Despite the growing number of new therapeutic approaches and vaccines, the screening methods for analysing potential drug interaction are lacking behind and the Summary of Product Characteristics are not suitable for comprehensive evaluations. The inclusion of these therapies and the optimisation in vaccination status in the medication review process and the understanding of immunological mechanism potentially influencing the therapy of patients is warranted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-114 DEVELOPMENT AND PROSPECTIVE VALIDATION OF A PREDICTION MODEL TO IDENTIFY CLINICALLY RELEVANT MEDICATION DISCREPANCIES AT THE EMERGENCY DEPARTMENT

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Background and Importance Medication discrepancies occur in a majority of hospital admissions to the emergency department (ED) and are a major source of avoidable harm. Obtaining an accurate medication history is essential to identify drug-related problems early on. However, the medication reconciliation process is prone to many errors and is furthermore labour-intensive. As a result, many patients simply do not receive a complete medication reconciliation, mostly owing to limited resources. We hence need an approach which enables us to identify those patients at the ED who are at increased risk for clinically relevant discrepancies.

Aim and Objectives To develop and prospectively validate a prediction model to identify patients who are at risk for at

least one clinically relevant medication discrepancy at the time of ED presentation.

Material and Methods A prospective study was carried out at the ED. Medication histories were obtained and clinically relevant discrepancies were identified, using an internally validated scoring tool. Two distinct datasets were created. A first dataset (n=824) was used to build and internally validate a prediction model. We used multivariable logistic regression with backward stepwise selection to select the final model. A second dataset (n= 350) was used to prospectively validate the prediction model. The predictive performance of this model was assessed by measuring calibration, discrimination and classification.

Results The final model contained nine predictors that can easily be obtained upon ED admission, including age, origin before admission (home/nursing home) and number of drugs. Prospective validation showed excellent calibration with a slope of 1.09 and an intercept of 0.18. Discrimination was moderate with a c-index of 0.66. Using a probability threshold of 0.4, the sensitivity, specificity, positive predictive value, negative predictive value and alert rate was 41%, 81%, 56%, 70% and 27%, respectively.

Conclusion and Relevance The presence of at least one clinically relevant medication discrepancy can be predicted by our model with moderate performance. Using our prediction model is more efficient than performing medication reconciliation at random and can guide the rational use of limited resources at the ED. Depending on the available resources, different probability thresholds can be applied to increase either the specificity or the sensitivity of the prediction model.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-122 CLINICAL FOLLOW-UP IN PATIENTS WITH MIGRAINE AFTER DISCONTINUATION OF PROPHYLACTIC BIOLOGICAL TREATMENT: A REAL-WORLD EXPERIENCE

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Background and Importance Monoclonal antibodies targeting the calcitonin gene-related peptide (CGRP) pathway are recommended by European Headache Federation for migraine prevention. They are considerate effective and safe in the long-term.

In individuals with episodic or chronic migraine (EM, CM) the duration of preventive treatment is not defined. Some experts recommend a pause after 12–18 months of continuous treatment. Restarting the treatment is suggested when migraine worsen after treatment withdrawal.

Aim and Objectives To evaluate the course of migraine after anti-CGRP treatment withdrawal and the prevalence of restart treatment in our population.

Material and Methods Descriptive, retrospective and observational study of patients treated with erenumab, galcanezumab and fremanezumab from January 2020 to September 2022

who required restarting anti-CGRP therapy after 12 months of treatment.

Electronic medical history was used to record following variables: demographic data (sex, age) and clinical data (migraine type, months without anti-CGRP, biological drug, monthly migraine days (MMD), Headache Impact Test-6 score (HIT-6)) at two visits: before the initial biological treatment (baseline); before resumption of biological treatment.

The Shapiro-Wilk normality test and the Student's t-test were used for statistical analysis. Results with p-values <0.05 were considered significant.

Results 44 patients were included (13 erenumab, 25 galcanezumab, 6 fremanezumab). 84% (37/44) were women and average age was 49 years [26–77]. 52% (23/44) were CM and 48% (21/44) high frequency EM (≥ 8 MMD). All patients completed 12 months of anti-CGRP treatment due a good response ($\geq 50\%$ MMD reduction).

55% (24/44) patients restarted treatment due to clinical worsening. Months without treatment were $6,3 \pm 3,0$.

17% (4/24) patients restarted treatment with a different initial anti-CGRP by medical decision (tolerance or improvement of response).

Baseline data were $14,0 \pm 4,6$ average MMD and $68,3 \pm 3,7$ on the HIT-6 score and when restarting biological treatment were $12 \pm 3,0$ and $67,7 \pm 6,1$, respectively.

The reduction the MMD at the time of restarting treatment compared to baseline is statistically significant ($p < 0,01$), while the HIT-6 score not ($p > 0,05$).

Conclusion and Relevance Restart of treatment is not required in all patients. Follow-up of them is necessary to assess the long-term benefit after treatment discontinuation. Despite treatment is restarted, a reduction in MMD compared to baseline is observed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. <https://doi.org/10.1186/s10194-022-01431-x>

Conflict of Interest No conflict of interest

4CPS-124 EFFECTIVENESS AND SAFETY OF ERENUMAB IN A SECOND-LEVEL HOSPITAL

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Background and Importance Migraine is a highly disabling disease, especially in patients with high frequency episodic migraine and chronic migraine. Migraine management is limited due to side effects and a lack of effectiveness of current available prophylactic therapies. Erenumab is a monoclonal antibody approved with a specific mechanism of action in the prevention of migraine, blocking the activity of calcitonin-gene-related peptide (CGRP), a potent vasodilator which plays a role in pain signalling activities.

Aim and Objectives To quantify patients who achieve clinical benefit with erenumab (50% reduction in monthly migraine days) and describe of erenumab safety profile in a second-level hospital.

Material and Methods Observational and retrospective study that includes all patients treated with at least three doses of erenumab in our hospital. As a limitation, it is decided to start treatment only in patients with > 8 monthly migraine

days and with previous failure to at least three prophylactic drugs. The following data were collected: sex, age, previous monthly migraines days, previous non-effective prophylactic treatments, current migraines days, dose of erenumab and related adverse effects.

Results 34 patients were selected, 82.4% of whom were women and the average age was 44.5 years ($s=13.1$). 26.5% of patients (9 patients) had 15 or more monthly migraine days before treatment with erenumab. The average number of prophylactic treatments was 4.6 ($s=1.7$), and the most frequently used were amitriptyline (20.9% of patients), topiramate (19.6%), flunarizine (18.3%) and zonisamide (10.5%). 73.5% of patients (25 patients) achieved clinical benefit, 47.1% of them with the minimum dose of 70 mg. The remaining 9 patients of the sample abandoned treatment, 8 due to non-effectiveness and 1 due to lack of adherence. 40% of patients who achieved clinical benefit (10 patients) are just now in a phase of interruption due to a maintenance of effectiveness. Side effects: 5 patients suffered constipation, 1 paraesthesia and 1 itch at the injection site.

Conclusion and Relevance Although the patient sample offered is small, erenumab appears to be an effective and safe option for selected patients with high-frequency migraines who have exhausted traditional alternatives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-129 REAL-LIFE EFFECTIVENESS AND SAFETY OF NIRAPARIB AND OLAPARIB IN HIGH-GRADE OVARIAN CANCER

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Background and Importance Poly (ADP-ribose) polymerase (iPARP) enzyme inhibitors, have recently revolutionised high-grade epithelial ovarian cancer treatment. These new drugs have a new efficacy and safety profile. Currently, there are three iPARP approved: olaparib, niraparib and rucaparib.

Aim and Objectives Review effectiveness and safety of olaparib and niraparib (iPARP), according to standard clinical practice, in patients with high-grade epithelial ovarian cancer.

Material and Methods Retrospective observational study, in a tertiary care hospital, included patients with high-grade epithelial ovarian cancer who started treatment with olaparib or niraparib between May 2019 and December 2020. We collected demographic, patient clinical data, tumour-specific and treatment variables. Data were extracted from electronic medical records. Efficacy variables used: overall survival (OS) and progression-free survival (PFS). Survival analysis was performed using the Kaplan-Meier method. Safety variables used were adverse events (AEs), temporary discontinuations, dose reductions and/or discontinuations due to toxicity.

Results Thirty-four patients were included, 44.1% on olaparib and 55.9% on niraparib. The median age was 59 years (IQR 53 – 68). All of them present a baseline ECOG between 0

and 1. All patients who received olaparib had mutated BRCA, while those who received niraparib had BRCA wildtype. Median follow-up was 15.6 (IQR 9.8–29.5) months.

Eighty-five point three per cent of our patients received maintenance treatment with an iPARP after relapse. Median PFS and OS were not reached in the olaparib group. Median PFS with niraparib was 11.30 (95% CI = 2.65–19.95) months and median OS was 36.01 (95% CI = 13.37–58.64) months.

On olaparib group, 93.3% of patients experienced an AE. Of these, 20% required temporary discontinuation and 20% required dose reduction due to toxicity. All niraparib-treated patients reported AEs, 57.9% required temporary discontinuation and 52.6% required dose reduction. Grade ≥ 3 AEs occurred in 33.3% patients on olaparib group and 63.1% with niraparib. No patient discontinued treatment due to toxicity.

Conclusion and Relevance Olaparib and niraparib achieve relevant results in patient survival. The differences respect to pivotal trials could be explained by a greater knowledge on the use of these drugs, which allows a better selection of the patients to be treated. In terms of safety, most patients experience some AEs during treatment, which are reversible and controllable with dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-130 EVALUATION OF TIXAGEVIMAB-CILGAVIMAB IN PRE-EXPOSURE PROPHYLAXIS OF COVID-19

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Background and Importance In the context of pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older (> 40 kg), tixagevimab-cilgavimab is currently included in clinical guidelines. The recommended dose is administered as two separate sequential intramuscular injections (150 mg of tixagevimab and 150 mg of cilgavimab), preferably in the gluteal muscles. Due to their recent authorisation, effectiveness and security of this treatment is not well known.

Aim and Objectives The aim of this study was to analyse the effectiveness and security of tixagevimab-cilgavimab in patients with COVID-19 risk after a complete vaccination regimen, collated with the data from PROVENT clinical trial.

Material and Methods Retrospective observational study in a cohort of COVID-19 risk patients. Electronic medical record and prescription application were used to collect the following data: sex, age, comorbidities, anticoagulation, and titles of anti-Spike antibodies, and COVID-19 infections after administration.

Results The study includes 41 patients (52.5% women, median age 64.5 years (SD 13.5)), who were candidates to prophylaxis because of their comorbidities: anti-CD20 active treatment (21), solid organ transplantation (renal (10) and pulmonary (14)), chronic kidney disease (2), immunosuppression (1), cytotoxic chemotherapy (1) or haematopoietic Stem Cell transplant (1). After the last vaccination, 97.5% of the patients had low antibodies (< 260 BAU/mL), which

demonstrates an inadequate response to active immunisation. These comorbidities and clinical conditions were similar in PROVENT.

In PROVENT, the duration of protection is estimated to be at least 6 months (0.2% COVID-19 positive cases after administration prior to day 183). In our study population, 3 patients were COVID-19 positive (7.5%) prior to day 90 after administration without severe or critical symptomatic illness.

As with any other intramuscular injections, should be given with caution to patients with thrombocytopenia or coagulation disorders; 5 patients were on anticoagulation therapy and no bleeding events were recorded. Therefore, non-hypersensitivity reactions have been observed.

Conclusion and Relevance Effectiveness and security of the pre-exposure prophylaxis with tixagevimab-cilgavimab was adequate in most of the patients treated, and similar to the data of the clinical trials. Even so, pre-exposure prophylaxis is not a substitute for vaccination. Nevertheless, further studies were necessary to establish the effective and security profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-135 MELANOMA ADJUVANT THERAPY: FROM TRIALS TO CLINICAL PRACTICE

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Background and Importance Clinical trials show that recurrence-free survival (RFS) is significantly improved in melanoma patients treated adjuvantly with immune checkpoint inhibition (ICI) and targeted therapy (TT). The Stage of disease is an important factor in risk assessment of RFS and also influences the clinician's decision. The adjuvant therapy in melanoma BRAF V600 mutated involves two treatment strategies: anti-PD-1 (nivolumab or pembrolizumab) and BRAF- MEK inhibitors (dabrafenib and trametinib).

Aim and Objectives Real World Data were collected from 01/08/2019 to 31/03/2021 in an Italian Oncological Hospital, in order to observe the time of RFS and toxicities.

Material and Methods 168 patients were included (11 stage IIIa, 19 IIIB, 64 IIIC, 12 IIID, 5-V), of which 65 were women and 103 men (median age: 56). In particular, 76 patients received nivolumab (6 patients V600E mutated, 2 mut-NRAS, 3 mut-V600K), 28 pembrolizumab (1 pts mut-V600k and pK6001E, 1 pts mut-V600E) while 64 received TT.

Results Among the 64 pts treated with TT, 9 of them discontinued therapy, of which 5 for toxicity and 4 for progression disease (PD). In the nivolumab setting, 9 patients discontinued therapy, 6 because of toxicity (1 undifferentiated arthritis) and 3 for PD. In the pembrolizumab setting only 1 patient discontinued for toxicity and 1 for PD. In 33 pts with recurrence, the median time from start of adjuvant treatment to 1st recurrence was 18 months in TT (10), 14 months in nivolumab cohort (19), 8 months in pembrolizumab cohort (4). IIIC was the stage of disease that manifested the greatest risk of recurrence both among the cohort of patients treated with TT and in ICI. However, the number of patients going into PD was greater among those treated with ICI. Duration of therapy was the highest in pts treated with Nivolumab.

Conclusion and Relevance Based on our findings, TT and ICI therapies are comparable to pivotal studies in terms of duration, safety, and reasons for treatment discontinuation. In patient mut-BRAF, TT seems to show a better RFS when compared to ICI. However this could be due to the different stages of disease; stage IV (visceral involvement) is eligible only for ICI therapy and this can lead to a worse prognosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-143 CORE BINDING FACTOR ACUTE MYELOID LEUKAEMIA FOLLOWING IMMUNE CHECKPOINT INHIBITION FOR SOLID TUMOURS: TWO CASE REPORTS AND LITERATURE STATE OF THE ART

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Background and Importance Immune checkpoint inhibition (ICI) can induce responses in patients with advanced malignancies. Although a well-established downside of ICI is its diverse spectrum of immune-related adverse events, the incidence of second primary malignancies associated with ICI is still a matter of debate.

Aim and Objectives We present two consecutive patients treated in our Hospital in 2022 who developed clinically acute myeloid leukaemia (AML) during or after ICI treatment for solid tumours.

Patient 1 is a man with a previous history of metastatic lung adenocarcinoma treated with pembrolizumab, which was stopped due to complete response (CR) 5 months before diagnosis of AML in April 2022. Patient 2 is a woman, with a previous history of ductal breast cancer treated with adjuvant chemoradiotherapy; she also developed a metastatic V600E BRAF-mutated melanoma, treated with BRAF/MEK inhibitors. Finally after two months of pembrolizumab, she developed AML in April 2022.

Material and Methods In both Patients 1 and 2, peripheral blood (PB) and bone marrow blood testing confirmed Core Binding Factor (CBF) AML, according to the presence of (inv16) (p13;q22) in 80% and 70% of blasts in the PB, respectively.

According to ESMO AML Guidelines, therapy with gemtuzumab ozogamycin associated standard chemotherapy was recommended for both patients.

Results Patient 1 achieved a CR after induction and consolidation therapy; patient 2 performed cytarabine-based consolidation therapy due to leukaemia-aberrant immunophenotype. Both patients are alive at current follow-up (4 months after diagnosis).

Conclusion and Relevance A case of AML after 3 cycles of pembrolizumab for the treatment of non-small-cell lung cancer and 5 cases of myeloid neoplasia after treatment with ICIs were recently reported.

Hyperprogression of subclinical myeloid malignancies could be a potential explanation since a myeloid clone with acquired driver mutation(s) could obtain an extra proliferation advantage from functional myeloid PD-1 knockout after ICI. Abberant PD-1 expression was observed in 8–26% of CD34+ blasts in myelodysplastic syndromes, chronic myelomonocytic leukaemia, and AML. Moreover chemotherapy and BRAF inhibitor

exposure, together with short exposure to pembrolizumab in Patient 2, suggest a major role of previous therapies in the development of AML.

The correlation between ICI and myeloid neoplasias is still uncertain.

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Conflict of Interest No conflict of interest

4CPS-152 PERSISTENT CYTOPENIA AFTER CAR-T CELLS: TREATMENT WITH ELTROMBOPAG: A CASE REPORT

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Background and Importance Impaired haematopoietic recovery is observed in about 30–50% of patients treated with anti-CD19 CAR-T cells, with prolonged cytopenia appearing as an unmet need for optimal treatment. Generally, treatment consists in the use of erythropoietin and G-CSF (Granulocyte Colony Stimulating Factor). Thrombopoietin receptor agonists (TPOa) can be an option too, on the basis of their consolidated use in refractory poor graft function, following allogeneic stem cell transplantation and aplastic anaemia.

Aim and Objectives We present a 72 year old patient who received commercial tisagenlecleucel treatment for a diffuse large B-cell lymphoma (DLBCL) in July 2021. Complete molecular response at one month from infusion was obtained but persistent cytopenia was developed, requiring transfusional support.

Material and Methods At 28 days from CAR-T infusion, the patient showed pancytopenia, which persisted in the following months and required transfusions of both platelets and erythrocytes. No clinical response to erythropoietin nor G-CSF was obtained. In March 2022, bone marrow examination allowed to exclude the myelodysplastic syndrome diagnosis and showed relative myeloid hyperplasia and altered distribution of megakaryocytes. In June 2022, the patient was receiving monthly transfusion of erythrocytes and fortnightly transfusion of platelet, despite supportive care. Complete molecular response of lymphoma was confirmed. Treatment with eltrombopag was started at 50 mg/day.

Results Haematologic recovery was progressively obtained, achieving independence from transfusion as 40 days since starting the eltrombopag therapy; treatment with erythropoietin was stopped at 60 days and the G-CSF administration frequency was progressively reduced to 1 G-CSF dose per week. Eltrombopag dose was maintained at 50 mg/day, with no side effects.

Conclusion and Relevance The mechanism for late-onset cytopenia following CAR-T cells is still not clear, but it could be related to the sustained role of cytokines secreted by CAR-T cells during their expansion phase and during the following persistence phase. A series of 6 patients treated with eltrombopag and one patient treated with romiplostim are reported, with positive results in terms of haematological recovery. Although, further data on the role of TPOa in post-CAR-T

bone marrow toxicity are needed as a few reports are available.

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Conflict of Interest No conflict of interest

4CPS-156 ANALYSIS OF EFFECTIVENESS AND COSTS OF DRUG THERAPY PRESCRIBED IN SPECIAL SITUATIONS IN OUR HOSPITAL

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Background and Importance A marketing authorisation is a general rule in the legal framework of medicines. However, EU legislation does not regulate how drugs are ultimately used in medical practice.

The Royal Decree 86/2015 regulates the Pharmacy and Therapeutics Committee of the Balearic Islands. This P&T-Committee is an advisory panel of experts, composed by pharmacists and physicians, which elaborate technical reports to allow or deny drugs prescribed in special situations: off-label drugs(OLDs), compassionate drugs(CDs) and drugs not included in the hospital's pharmacotherapeutic guide(HPG).

Aim and Objectives To analyse the clinical response achieved by the treatments approved by P&T-Committee and their associated costs.

Material and Methods Prospective study of the drugs requested to the P&T-Committee between January/20-December/21.

A Microsoft-Access® database was created for collecting the variables: type of treatment (OLD,CD or not included in the HPG), level of evidence, clinical response, adverse effects and costs. Clinical response was defined as success or failure based on the therapeutic objective established by the physician at the time of the request. The cost was calculated based on the duration of the treatment until the objective was achieved or until treatment was discontinued.

The data were obtained from patients' electronic medical records(HP-HCIS®).

Results In total, 182 requests were approved: 30.8% successes, 29.7% failures, 6.6% interrupted because of adverse effects, 8.7% not initiated and in 24.2% insufficient time had passed for them to make a valid assessment of the real effectiveness.

Almost half of the treatments(44,5%) were considered to have a high level of evidence. In reference to the type of treatment: 57.5% were OLDs, 35.5% were drugs not included in the HPG and 7% were CDs. Oncology and Haematology submitted more than 50% of the requests.

The overall estimated cost of the 182 authorised treatments was 3.672.751,93€. The average cost per request was 20.179,93€. The medical services that have a greatest impact on the cost were Oncology(35.307,22€/treatment) and Haematology(20.686,16€/treatment).

Conclusion and Relevance The percentage of treatments analysed that achieved their therapeutic goal was very similar to those that didn't, probably because of the high level of heterogeneity of the treatments analysed. However, we can't ignore the high economic impact of these drugs and we need to define therapy follow-up plans.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-159 ESTIMATING RENAL FUNCTION FOR DRUG DOSING: CORRELATION BETWEEN CKD-EPI AND COCKCROFT-GAULT IN AN ELDERLY POPULATION

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Background and Importance Estimates of glomerular filtration rate (eGFR) should provide accurate measure of an individual's kidney function. This is even more important in old people since there is age-related physiological change in the kidney, which could lead to reduced GFR. The overestimation of GFR may lead to drug toxicity and the underestimation may lead to sub-therapeutic drug levels.

Use of multiple equations to evaluate renal function can lead to differences and corresponding drug dosing regimens. The Cockcroft-Gault (CG) equation, despite inaccurate in the elderly, remains the most widely used equation for determining the creatinine clearance (CrCl). On the other hand, estimation of GFR using the CKD-EPI has gained increasing acceptance. This formula is used to classify chronic kidney disease.

Aim and Objectives To determine the correlation between estimated CrCl by CG with eGFR by CKD-EPI. Additionally, we have compared the differences among dose adjustments recommendations and evaluated the patient's profile in the most discrepant results.

Material and Methods The study included hospitalised patients in the Medicine ward aged 70 and above with prescriptions of enoxaparin, meropenem, amoxicillin + clavulanate and piperacilin + tazobactam. Demographic data and serum creatinine (SrCr) were collected. CrCl was calculated using CG equation and eGFR by CKD-EPI 2021 equation.

Results

| Population characteristics | |
|--|------|
| Number of patients | 32 |
| Men | 12 |
| Women | 20 |
| Mean age (years) | 85,6 |
| Mean serum creatinine (mg/dL) | 1,71 |
| Number of enoxaparin prescriptions | 26 |
| Number of meropenem prescriptions | 8 |
| Number of amoxicillin + clavulanate prescriptions | 3 |
| Number of piperacilin and tazobactam prescriptions | 2 |

| Characteristics of patients with different drug dose recommendation | | | | | | |
|---|--------------|-------------|-------------|------------------|--------------------------------------|---------------------------|
| Age | SrCr (mg/dL) | Weight (kg) | Height (cm) | CrCl CG (ml/min) | GFR CKD (ml/min/1.73m ²) | Prescription |
| 92 | 1,24 | 50 | 155 | 22,85 | 40,83 | Enoxaparin +Meropenem |
| 94 | 1,33 | 53 | 150 | 21,64 | 37,07 | Amoxicillin + clavulanate |
| 81 | 1,6 | 65 | 160 | 28,3 | 32,2 | Enoxaparin |
| 91 | 2,24 | 80 | 170 | 24,31 | 27 | Meropenem |

Abstract 4CPS-159 Figure 1

Conclusion and Relevance In only four patients did difference in the estimation of renal function using the two equations, leading to different drug dosing recommendation. One patient had both enoxaparin and meropenem prescribed, all others only one drug. It seems that it is safe to use the CKD-EPI equation to drug dosing, with caution in patients with extreme weight and age characteristics. Future studies should

extend to a greater number of patients and include other drugs with adjustment to renal function. In order to validate the estimated renal function and understand which formula is closest to reality, it would be important to determine the measured GFR. Controversy remains as to whether adoption of eGFR for drug dosing is appropriate given that dosing recommendations for many available drugs are based on CG estimates of kidney function. Using the same kidney function estimate for management of kidney disease, drug development and dosing would harmonise all clinical areas.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-161 NEGATIVE PRESSURE WOUND THERAPY IMPORTANCE IN WOUND CARE

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Background and Importance Negative pressure wound therapy (NPWT) consists in the use of a system that applies negative pressure to the surface of a wound, accelerating the wound healing process.

The mechanism of action is complex including the reduction in substances that inhibit healing, decrease of oedema, elimination of exudate, stimulation of granulation tissue formation, physical stimulation of mitosis and wound contraction.

This therapy is indicated in various types of wounds such as: open abdomen, diabetic foot ulcers, pressure ulcers, after debridement or even as a prophylactic way to prevent surgical site infection.

The reduction in healing time with fewer dressing changes compared to conventional therapy is the great advantage. The main disadvantage is the associated cost, which mandates for rational use. In our hospital this is assured by handing on to the doctor responsible for the team of wounds the decision whether or not to apply the NPWT. Also, the technical opinion of the pharmacist of the team is essential to achieve the approval from the executive board. The application of the NPWT requires the work from the multidisciplinary team which includes nurses with specific training, essential for best practice.

Aim and Objectives To evaluate the use of NPWT in our hospital.

Material and Methods Analysis of the medical justification formularies submitted to the executive board to use of NPWT between January 2021 and August 2022.

Results Between January 2021 and August 2022, we had 47 patients under treatment with NPWT, both inpatients and outpatients. The main indication was surgical dehiscence and post-operative care (48.9%). Treatment of pressure ulcers comes as second (23.4%) followed by treatment of diabetic foot ulcers and complications (19.1%). Duration of treatment varies from 3 to 6 weeks in most patients but can be extended as far as 28 or even 48 weeks.

Conclusion and Relevance NPWT has increasingly been an option for the treatment of complex wounds in which

treatment would take longer or even be less effective with conventional therapies. It is essential to maintain the assessment of the profile of patients who undergo this therapy in order to ensure the best use of it. The multidisciplinary team of wound prevention and management delivers better results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-165 ADAPTATION OF MARKETED PARENTERAL NUTRITION TO THE NEEDS OF A HOSPITAL

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Background and Importance More and more hospitals are using commercially available parenteral nutrition for their patients, and there is an increasing supply to try to cover energy, protein and electrolyte needs.

Aim and Objectives To analyse the adequacy of commercially available parenteral nutrition to the energy and protein needs of our patients.

Material and Methods Retrospective observational study of patients receiving parenteral nutrition support from January to September 2022.

Demographic characteristics (sex, age), anthropometric data (weight, height, body mass index), energy and protein requirements, type of commercialised nutrition were collected

Energy requirements were adequate if the calories administered met at least 75% of the total requirements.

Protein requirements were considered optimal if they had a normo or hyperproteic diet and were determined not to be optimal if they were hypoproteic or excessive.

Four levels of protein intake were determined: low protein, less than 1g protein/kg, normal protein, between 1–1.2 gr/kg, high protein between 1.3 and 1.7, and excessive if it was higher than 1.7.

Results A total of 71 nutritional supports were performed corresponding to 68 patients, 36 women (50.7%), with a mean age of 70.9 years (SD=15.7 years).

The mean anthropometry was 66.6 kg (SD=18.96 kg), 165.4 cm (SD=17.6 cm) and a mean body mass index of 24 (SD=6.6).

The mean energy requirements were 1353 Kcals (SD=223Kcals) for basal energy expenditure and 1761 Kcals (SD=223Kcals) for total energy expenditure with a mean stress factor of 30%.

The mean duration of nutritional support was 8.9 days (SD=8.13 days).

The 53.42% of the patients (n=38) met the energy requirements, of the remaining 46.58% (n=33), 8 were on peripheral parenteral nutrition and 5 on supplementary parenteral nutrition.

In 21 of the 33 patients, the speed had to be adapted because they did not meet the energy requirements with the available nutrition.

The 46.48% (n=33) didn't meet the protein requirements, 19 due to low protein intake and 14 due to excessive protein intake, 53.52% (n=38) did meet the protein requirements,

with 23 patients presenting a hyperproteinic intake and 15 patients with a normal protein intake.

Conclusion and Relevance It would be necessary to have a wider variety of commercially available nutritional products in order to meet both the caloric and protein needs of our patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-169 PHYSICOCHEMICAL CHARACTERISATION OF ORAL LIQUID FORMS AND REVIEW OF THE LITERATURE FOR SAFE AND EFFECTIVE ADMINISTRATION BY ENTERAL FEEDING TUBES

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Background and Importance Although the choice of oral liquid forms facilitates administration in patients with enteral feeding tubes, it can cause adverse effects such as diarrhoea, vomiting or additional gastrointestinal intolerance associated with an osmolality >500 mOsm/L, pH <3.5 and high sorbitol content of these preparations.

Aim and Objectives The objective of the study is to obtain updated data on physicochemical and gastrointestinal absorption properties from the main drugs marketed as oral liquid forms in order to establish practical instructions to increase the safety and efficacy of their administration by transpyloric tube.

Material and Methods 45 formulations were analysed for which the pH, osmolality and density were experimentally determined in triplicate. In addition, the sorbitol content was reviewed from the descriptions of the technical data sheet. The pH was measured with a pH meter (Crison-2006, Hach-Lange-Spain, S.L.U., Spain). Osmolarity was determined using the Micro-Osmometer-Fiske Model 210 apparatus (John-Morris-Scientific Pty Ltd., Australia). The osmolality data provided (mOsm/kg), is multiplied by the density of the solution (g/ml) to obtain the osmolality (mOsm/L). The density data was obtained with two Nahita densimeters with ranges of 1000–1200 mg/ml and 1200–1400 mg/ml.

Results According to the literature, only 23,3% of the drugs presented a similar bioavailability when administered by transpyloric tubes in comparison to oral administration. Of the formulations analysed, only 7% complies with optimal physicochemical properties for transpyloric administration. The causes detected that discouraged a transpyloric administration were that 17,5% had extreme pH values, 92,5% had high osmolarities and 10% contained a high sorbitol content.

Conclusion and Relevance In most of the active ingredients studied, the gastrointestinal absorption of the drug is not sufficiently characterised, which generates uncertainty in its bioavailability when administered by transpyloric tube. Most formulations have a high osmolality, so prior dilution is

necessary. The pH values of some of them can be an added factor for the development of digestive intolerances.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-174 EFFECTIVITY AND SAFETY OF CYCLIN-DEPENDENT KINASE INHIBITORS IN METASTATIC BREAST CANCER PATIENTS

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Background and Importance Breast cancer is among the most frequent cancers worldwide. Standard of care for locally advanced or metastatic luminal breast cancer is a cyclin-dependent kinase inhibitor (CKI) (abemaciclib, palbociclib, ribociclib) plus endocrine therapy. All three have shown efficacy and safety in clinical trials, but real-life effectivity and safety data is required.

Aim and Objectives - To determine real-life progression-free survival (PFS) amongst patients treated with abemaciclib, palbociclib and ribociclib.

- To describe their safety profile.

Material and Methods Unicentric, observational and retrospective study, including patients from 11/2017 to 12/2021. No exclusion criteria. Variables obtained: age, gender, treatment start and end dates, reason for treatment termination, adverse events (AE) and severity evaluated by CTCAE criteria.

Descriptive statistical analysis percentages for qualitative results and mean, standard deviation (SD) and ranks for quantitative ones. PFS estimated with Kaplan-Meier method, statistical significance being $p < 0,05$.

Results Patients included: 103, 102(99%) women. Characteristics displayed at table 1:

| | Patients (number) | Age (years, mean \pm SD) | Ongoing patients at study end (%) | PFS, median, months (95% CI) |
|-------------|-------------------|----------------------------|-----------------------------------|------------------------------|
| Abemaciclib | 20 | 55.2 \pm 11.8 (30–76) | 20 | 6.5(6–7.04) |
| Palbociclib | 61 | 60.7 \pm 13.9 (33–86) | 24.6 | 10(3–15) |
| Ribociclib | 22 | 51.9 \pm 12.4 (33–80) | 36.4 | 11.8(8.5–15.2) |
| Total | 103 | 57.8 | 26.2 | 9.8(7.3–12.3) |

At study end, 50.5% had suffered disease progression, while 13.6% had discontinued due to toxicity, 4.9% to death, 1% to personal choice and 3.9% to other reasons; 26.2% still ongoing. Median PFS was 9.8 months (table 1), without statistically significant differences among the three drugs (ribociclib-abemaciclib: $p=0,055$; abemaciclib-palbociclib: $p=0,12$; ribociclib-palbociclib: $p=0,296$). Ribociclib presented the longest PFS and abemaciclib the shortest one.

Safety results are shown in table 2:

| | Most frequent AE, any grade(%) | AE grade >=3(%) | Discontinuation due to toxicity(%) | Mean ± SD of AE per patient |
|-------------|--|-----------------|------------------------------------|-----------------------------|
| Abemaciclib | Diarrhoea(75%) Fatigue(55%) Neutropenia(45%) | 35 | 25 | 4.2 ± 2.4 (0–9) |
| Palbociclib | Neutropenia(80.3%) Fatigue(72.1%) Arthralgia/myalgia (24.6%) | 62.3 | 9.8 | 4.1 ± 2.2 (0–9) |
| Ribociclib | Neutropenia(81.8%) Fatigue(54.4%) Arthralgia/myalgia (31.8%) | 63.6 | 13.6 | 3.8 ± 1.6 (1–6) |

Conclusion and Relevance No statistically significant differences were found among abemaciclib, palbociclib and ribociclib PFS. While PFS is lower than reported in clinical trials, safety profile is similar, being neutropenia, fatigue and diarrhoea the most common AE. Study limitations include the reduced sample size and its retrospective and unicentric character.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-178 DURABILITY OF TREATMENT AND REASONS FOR DISCONTINUATION OF DIMETHYL FUMARATE AND TERIFLUNOMIDE IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background and Importance Dimethyl fumarate (DMF) and teriflunomide (TRF) are oral immunomodulatory drugs used in the treatment of relapsing-remitting multiple sclerosis (RRMS) since 2015.

Aim and Objectives To determine the durability of treatment and to analyse the reasons for discontinuation of DMF and TRF in patients with RRMS.

Material and Methods An observational, retrospective and longitudinal study was conducted. All patients with RRMS treated with DMF and TRF from 2015 to September 2022 were included. The variables analysed were sex, age, initial Expanded Disability Status Scale (EDSS) score, previous treatments, treatment starting date and treatment discontinuation date, reasons for discontinuation and adverse reactions that led to treatment discontinuation. Treatment discontinuation free-survival was calculated using a Kaplan-Meier method and survival curves were compared using log-rank test. Statistical significance was set at $p < 0.05$.

Results 97 patients were included, 66 treated with DMF (median age 43.6 ± 10.5 years, women 57.6%, 2 ± 1.4 EDSS at baseline) and 31 treated with TRF (median age 49.1 ± 8.9 years, women 58.1%, 1.5 ± 1.6 EDSS at baseline). Treatment was discontinued by 41 patients (62.1%) in the DMF group and 22 patients (70.9%) in the TRF group

($p = 0.27$). Median of treatment discontinuation free-survival in DMF group was 24.2 months (IC95% 0 – 62.2) and 17.5 months (IC95% 0 – 44.1) in TRF group ($p = 0.29$). Reasons for treatment discontinuation were due to disease progression (43.9% in DMF vs 63.9% in TRF, $p = 0.13$), adverse reaction (53.7% in DMF group vs 31.8% in TRF group, $p = 0.09$), loss to follow-up (2.4% in DMF group) and patient's decision (4.5% in TRF group). Adverse reactions leading to discontinuation of treatment in the DMF group were lymphopenia (36.6%), gastrointestinal intolerance (9.7%), diarrhoea (2.4%), generalised severe pruritus (2.4%) and hypotension (2.4%). Adverse reactions that led to treatment discontinuation in the TRF group were diarrhoea (13.6%), elevated transaminases (9.1%), allergy (4.5%) and alopecia (4.5%).

Conclusion and Relevance In this study, no statistically significant differences were found in the durability of DMF and TRF treatments in patients with RRMS.

Patients with DMF tend to discontinue more due to adverse reactions and patients with TRF more due to disease progression.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Conflict of Interest No conflict of interest

4CPS-179 REVERSAL OF ANTICOAGULATION IN ORTHOGERIATRIC PATIENTS WITH HIP FRACTURE REQUIRING EARLY SURGICAL INTERVENTION

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Background and Importance Hip fractures are excruciating for the elderly. Reducing hospital stays can improve health results, and entail important savings for healthcare centres.

Aim and Objectives To estimate the hypothetical cost of anti-coagulation reversal and the potential hospital stay reduction by early surgery.

Material and Methods Retrospective, observational study among orthogeriatric patients candidates for hip fracture surgery between January 1/2020-December 31/2021. Variables: number of patients, admission/surgery timespan, anticoagulant, reversal drugs and costs, pretreatment INR, potential days and admission costs saved. Calculation of reversal strategy:

Vitamin K antagonists: prothrombin complex concentrate, 4-factor, unactivated (4F-PCC):

- Pretreatment INR<1,4: no reversal; 1,4 to <4: 25IU/kg, maximum: 2,500IU; 4–6: 35IU/kg, maximum: 3,500IU; >6: 50IU/kg, maximum: 5,000IU. All patients would require simultaneous vitamin K administration (1 injectable solution/patient, intravenous dose = 1–10mg, based on INR).

Factor Xa inhibitors direct oral anticoagulants: 4F-PCC:

- Intravenous fixed-dose: 2000IU.
- Dabigatran: idarucizumab:
- 5g (two separate 2.5g doses).

Reversal strategy costs in Spain: 4F-PCC Laboratory Sale Price (LSP) 500 UI/20mL: 214,9€, vitamin K LSP 10mg/1mL: 1,1 €, Idarucizumab LSP 2.5g/50 mL: 1500€. Cost calculated by rounding to the number of vials (for example, 4F-PCC 1600IU=4 vials). Currently, daily hospital stay cost in a surgical unit =258,8€/day.

Results 691 patients included, 148 (21,0%) anticoagulated. 25 (4,0%) excluded because of no surgery, so the final analysis included 666 patients, 141 anticoagulated. 63 (44,7%) were anticoagulated with acenocoumarol, 40 (28,4%) apixaban, 29 (20,6%) rivaroxaban, 12 (8,5%) dabigatran, 8 (5,7%) edoxaban and 1 (0,7%) with warfarin. Early surgical goal in orthogeriatric patients in Spain (proximal femur fracture in patients >65 years) is intervention in <48 hours since admission. It was only achieved in 12,8% of anticoagulated patients in 2020 and 2021 (18). Meantime between admission and surgery = 4 ± 6 days. Days between admission and surgery = 574 for all anticoagulated patients in total. Estimated total cost of anticoagulant reversal = 134.683,5€ (955,2€/patient). Assuming this strategy is used and surgery is performed in the first 24 hours, hypothetical hospitalisation cost could decrease, saving 574 admission days and 148.537,3€.

Conclusion and Relevance Early hip fracture surgery within 48 hours from admission reduces complications in elderly patients. Anticoagulation reversal strategies in anticoagulated patients have a significant economic impact but would allow to reduce hospital stay with potential savings in healthcare costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-197 CONCOMITANT USE OF PROTON PUMP INHIBITORS AND PALBOCICLIB: ¿IS THERE A REAL IMPACT ON RESPONSE?

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Background and Importance The concomitant use of palbociclib with proton pump inhibitors (PPIs) has recently been associated with a reduction in PFS (progression-free survival). However, the results of the study are questionable for methodological reasons.

Aim and Objectives To determine whether concomitant use of palbociclib with PPIs in our cohort of patients with metastatic breast cancer is associated with clinical response.

Material and Methods Retrospective observational study including all patients who started treatment with palbociclib between December 2016- November 2021. Demographic and clinical data were obtained from the electronic clinical records. Patients were categorised whether they were taking concomitant PPIs or not. Primary endpoints included both PFS and OS (overall survival).

PFS and OS were analysed through Kaplan-Meier survival curves using the log-rank test to check differences between curves. The Cox regression model was used to identify independent risk factors for PFS and OS.

Results A total of 87 patients were included. Demographic and clinical characteristics are shown in table 1.

Abstract 4CPS-197 Table 1 Patients' characteristics

| | Total patients (n=87) |
|--|-----------------------|
| Age in years, mean \pm SD | 63.4 \pm 12.8 |
| Female, N(%) | 85 (97.7%) |
| Body mass index (BMI) in kg/m ² , mean \pm SD | 26.6 \pm 5.6 |
| Baseline ECOG PS 0-1, N(%) | 80 (87.0%) |
| Line of therapy, N(%) | |
| 1 | 63 (72.4%) |
| 2 | 17 (19.5%) |
| ≥ 3 | 7 (8.1%) |
| Concomitant drug, N(%) | |
| Fulvestrant | 33 (37.9%) |
| Aromatase inhibitor | 54 (62.1%) |
| Concomitant PPI, N(%) | 32 (36.8%) |

Fifty-two patients (59.8%) discontinued treatment and 39 (44.8%) required ≥ 1 dose reduction. Median PFS and OS were 19.9 ± 13.6 and 26.0 ± 14.3 months, respectively.

In univariate analysis, concomitant treatment with fulvestrant and ≥ 3 treatment line, were significantly associated with PFS (HR 1.83; 95% CI(1.05-3.20) $p=0.032$ and HR 8.88; 95% CI(3.32-23.8) $p<0.001$, respectively). Treatment lines 2 and 3, were significantly associated with OS (HR 2.68; 95% CI(1.13-6.34) $p=0.025$ and HR 14.6; 95% CI(4.87-43.6) $p<0.001$, respectively).

Patients with PPIs were not associated with a significantly prolonged median PFS (log-rank $p=0.560$) nor OS (log-rank $p=0.058$).

Conclusion and Relevance Contrary as described in the literature, patients in our cohort under concomitant treatment with PPIs showed no negative impact on PFS nor OS.

However, studies with larger numbers of patients, multivariate analysis and longer follow-up are needed to confirm these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-203 ANTIBIOTIC STEWARDSHIP PROGRAMME INTERVENTIONS IN A THIRD LEVEL HOSPITAL IN SPAIN: A ONE-YEAR REVIEW

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Background and Importance Antibiotic stewardship programme (ASP) consists of a multidisciplinary group involving infectious diseases physicians, microbiologists and pharmacists. ASP improves clinical outcomes, patient safety and help to combat antibiotic resistance. In our hospital, ASP includes daily review of antifungal and broad-spectrum antibiotic prescriptions (AP) in order to optimise the management among hospitalised patients.

Aim and Objectives To assess the appropriateness of antifungal and broad-spectrum AP and the acceptance of interventions made to optimise the antimicrobial management during one year.

Material and Methods Retrospective and observational study of interventions made as a part of the ASP in a multidisciplinary meeting from May 2021 to May 2022. Antifungal (casposfungina, anidulafungin, liposomal amphotericin and triazoles), last treatment choice and broad-spectrum antibiotics prescribed for 2 days were analysed (attending specially to meropenem, ceftazidime-avibactam and ceftolozane-tazobactam). We examined the indication of the AP, if it was an empirical, prophylactic or targeted treatment and the appropriateness. It was considered as inappropriate if an intervention of ASP was needed. Then we made a recommendation according to dosage optimisation, duration of treatment, antibiotic de-escalation and escalation, and necessity for supplementary tests. Finally, interventions acceptance was checked.

Results We analysed 1552 AP. 120, 7.7% were stopped before analysing their appropriateness. Meropenem was the antimicrobial most commonly reviewed (906; 58.4%), followed by casposfungina (74; 4.8%), linezolid (65; 4.2%) and daptomycin (59; 4.8%). Indications for AP were: intraabdominal infections (565; 39.4%), lower respiratory tract infections (269; 18.8%), urinary tract infections (161; 11.2%), bacteremias (83; 5.8%), skin and soft tissue infections (75; 5.2%), febrile neutropenias (66; 4.6%), and less frequently endocarditis and osteoarticular or central nervous system infections.

AP reviewed were: empirical (1020; 71.2%), targeted (377; 26.3%) and prophylactics (36; 2.5%).

Overall, 413, 28.8% of AP were judged inappropriate, 1019, 71.1% appropriate. Regarding unsuitable prescriptions, ASP recommended to: de-escalate (53%), suspend (25.4%), optimise the dose (9.2%), request supplementary test (4.3%) and change the antibiotic (2.4%).

Regarding acceptance of inappropriate AP, 300 (72.6%) interventions were accepted.

Conclusion and Relevance It's essential to stress the importance in optimising the use of antibiotics with other strategies such as infection control, guidelines development and other activities promoted by an ASP to prevent the spread and emergence of antibiotic resistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-205 PHARMACIST'S INTERVENTION IN THE THERAPEUTIC MANAGEMENT OF PATIENTS WITH HEART FAILURE – AN OPPORTUNITY FOR IMPROVEMENT

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Background and Importance Patients with Heart Failure (HF) have high morbidity and mortality, which implies the use of a vast number of drugs. This polymedication is associated with a great potential for drug interactions and lack of adherence to treatment by patients. The balance between the ability to adequately medicate each patient and therapeutic

simplification is a challenge for healthcare professionals. Literature suggests that interdisciplinary approach has significant gains in terms of adherence to therapy and quality of life in patients with HF.

Aim and Objectives To characterise pharmacist's interventions in patients with HF followed in a pharmacist consultation at a central hospital.

Material and Methods Descriptive, observational, retrospective study, which includes patients referred by the physician for pharmaceutical consultation, between May 2021 and August 2022.

Results It were performed 176 pharmaceutical consultations regarding 110 HF patients, 62 males (56%), mean age of 77 ± 11 years. Therapeutic reconciliation and medication review were carried out and an updated pharmacotherapeutic guide was given to these patients as well as education and literacy about the use of medicines. We identified 145 drug interactions of category X or D. Of those, 44 mandatory dose adjustment due to renal function alteration; 27 medications needed administration schedule adjustment; 18 dosage adequacy; 13 discrepancies and 3 required liver function adjustment. In this context, 225 pharmaceutical interventions were performed, 89 were accepted by the physician. Of the remaining, 90 corresponded to suggestions for additional monitoring and 17 were directed to physicians from different specialties who follow these patients for concomitant pathologies.

Conclusion and Relevance This data confirms that hospital pharmacists, working collaboratively with the multidisciplinary health team, have a fundamental role in comprehensive medication management as well as in identifying unmet-needs, thus, opportunities for therapy improvement in patients with HF. Pharmaceutical consultation stands as a great opportunity for promoting drug safety and medicines use optimisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-214 REAL-LIFE RESULTS ON THE USE OF TRASTUZUMAB EMTANSINE IN HER2-POSITIVE METASTATIC BREAST CANCER

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Background and Importance Trastuzumab emtansine (T-DM1) as a single agent is approved for patients with HER2-positive locally advanced or metastatic breast cancer (MBC) previously treated with a taxane and trastuzumab.

Aim and Objectives To estimate the Overall Survival (OS) and the Progression-Free Survival (PFS) in patients with HER2-positive MBC treated with T-DM1. The results will be compared with those obtained with the pivotal trials.

Material and Methods Retrospective study which included all patients receiving T-DM1 for the treatment of HER2-positive MBC between 2016 and 2022 in a tertiary hospital.

The variables studied were sex, age, ECOG stage, treatment duration, reason for discontinuation and percentage of dead patients at the end of the study.

Data were collected through the electronic clinical record and the onco-haematological prescription program. Statistical analysis was performed with SPSS v.22.0. The Kaplan-Meier method was used to calculate OS and PFS.

Results A total of 30 patients were analysed (100% women). The median age was 58 (range, 48 to 66) years. The 66,7% of patients (N=20) had ECOG 0–1 and the 33,3% (N=10) had ECOG 2.

The median number of cycles received were 8 (range, 3 to 16) and the median treatment duration was 6 (range, 3 to 12) months.

The reasons for the treatment discontinuation were: 53,3% progression (N=16), 6,7% toxicity (N=2) and 10% death (N=3).

At the end of the study, the 30% of patients (N=9) continued with the treatment and the 48,3% (N=14) had died.

The median OS obtained was 16,80 months (95% CI 7,64 to 25,96) and the median PFS was 10,27 months (95% CI 5,34 to 15,35).

In the study TDM4450g/BO21976, the median of PFS and OS were 9,4 and 30,9 months, respectively. In the pivotal trial TDM4370g/BO21977, the median PFS was 14,2 months and the OS could not be estimated.

Conclusion and Relevance The median PFS in patients with HER2-positive MBC treated with T-DM1 reported in our study was similar than the pivotal trials. However, the median OS was substantially lower than the study TDM4450g. This difference could be mainly due to the sample size. Moreover, patients included in the previous study had a better functional status (100% ECOG 0–1) than our patients at the start of the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-220 COMPARATIVE ANALYSIS OF SKIN TOXICITY ON PATIENTS WITH METASTATIC COLON CANCER TREATED WITH EPIDERMAL GROWTH RECEPTOR BLOCKING DRUGS

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Background and Importance Treatment with chimeric recombinant IgG1 (cetuximab) and human IgG2 (panitumumab) epidermal growth factor receptor (anti-eGFR) blocking antibodies, is associated with skin and subcutaneous tissue disorders in most patients.

This may result in the discontinuation of treatment in patients with stage IV colon cancer.

Aim and Objectives To evaluate skin toxicity and analyse tolerance to both anti-eGFR drugs.

Material and Methods An observational, retrospective, and descriptive study of patients treated with panitumumab or cetuximab in monotherapy or associated with chemotherapy between June 2020 – June 2022 was conducted in a tertiary hospital.

Safety was evaluated according to Cancer National Institute-Common Terminology Criteria for Adverse Events version 5.0(CNI-CTCAE-v5.0). The data collected were: sex, age, weight, location and grade of metastasis, Eastern Cooperative Oncology Group (ECOG), cycle and grade of the first episode of toxicity, and tolerance. The information was obtained from the Oncofarm[®] program and the Diraya[®] digital medical record. Data analysis was performed using the PASWStatistic18 statistical package.

Results Forty-two patients were evaluated, 21 treated with panitumumab and 21 cetuximab. 35/42 (80%) developed skin toxicity. Skin toxicity was more frequent in the panitumumab group than in the cetuximab group: 18 patients (87.5%) vs 17 (81%). The first skin reactions occurred in cycle 1, in 88.9% with panitumumab and in 64.7% with cetuximab. Grade 1 toxicity was observed in 21 patients (60%), mainly acne, being more frequent in the cetuximab group than panitumumab: 12 patients (70.6%) vs 9 (50%). However, 50% of the panitumumab group developed severe toxicities (grade 2–3), mainly xerosis and acneiform rash. No grade 4 toxicities were reported. Cetuximab was well tolerated in 70.6% of patients while panitumumab produce poor tolerance in 68%, causing treatment discontinuation due to severe skin toxicity in 11%. Adherence to preventive treatment measures (hydration, sun protection, topical formulations and/or antibiotic therapy) allowed the continuity of treatment, with disease progression being the cause of suspension in 47.6% (20 patients).

Conclusion and Relevance In this study, panitumumab has shown more aggressive toxicity than cetuximab. Good practice in preventive toxicity treatment is necessary for continuity of anti-eGFR therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-221 ASSESSMENT OF CLINICAL BENEFIT OF CANCER TREATMENTS ACCORDING TO THE EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY SCALE

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Background and Importance The European Society for Medical Oncology – Magnitude of Clinical Benefit Scale (ESMO-MCBS) is a tool designed to evaluate the clinical benefit of cancer treatments and can facilitate decision-making.

Aim and Objectives To analyse which of the cancer treatments started providing a substantial magnitude of clinical benefit according to the ESMO-MCBS. Know the prevalence of patients who have started some low benefit treatment. Assess whether the ESMO-MCBS could be a good indicator of the prescription's quality.

Material and Methods Retrospective observational study that included all cancer treatments that were started in a tertiary care hospital from 03/01/22 to 06/30/22. The variables were collected: patient, treatment(s) prescribed, indication and ESMO-MCBS rating. The ESMO-MCBS score is considered in two different therapeutic settings: potentially curative treatments (A, B and C) and non-curative treatments (1 to 5). Substantial magnitude of clinical benefit was graded as A, B, 5

and 4. The variables calculated were: % of treatments with scores of greater clinical benefit and % of patients with at least one treatment of low benefit.

Results A total of 245 starts of treatment were reviewed, of which only 75 (31%) had an ESMO-MCBS rating. In 63% of the cases (n=47), treatments considered to be of relevant clinical benefit were started. Of these, 3 (6%) were treatments with curative intent (all level A) and 44 (94%) with palliative intent (level 4–5). Of those rated at level 4–5, pembrolizumab (n=14; 32%) in non-small-cell lung cancer and nivolumab (n=4; 9%) in head-neck cancer were predominant. 37% (n=28) of the patients started some low benefit treatment (level 1–3), being the most frequent atezolizumab (n=5; 18%) in small-cell lung cancer and nab-paclitaxel (n=5; 18%) in pancreatic adenocarcinoma.

Conclusion and Relevance More treatments with substantial benefit are started than those with less clinical benefit. All treatments with curative intent were level A. The non-curative setting presents a greater number of treatments with doubtful benefit. For most of the treatments classified as low benefit, there is no better therapeutic alternative, so we cannot assume that it is an indicator of poor prescription. Furthermore, we cannot classify most treatments because many of them do not have an ESMO-MCBS classification assigned.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-224 IMPACT OF AUGMENTED RENAL CLEARANCE ON ANTIMICROBIAL DOSING IN SEVERELY BURNED PATIENTS

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Background and Importance Augmented renal clearance (ARC) is a phenomenon characterised by increased renal filtration with mean creatinine clearance (CrCl) of more than 130 mL/minute, commonly observed in critically ill patients. Neurologic injury, trauma and burns are other factors consistently identified as at risk of ARC. Subtherapeutic drug concentrations and antibacterial exposure in ARC patients are the main reasons for clinical treatment failure, especially when it comes to antibiotics that undergo renal elimination.

Aim and Objectives The aim of this observational study was to describe the prevalence of ARC in a cohort of severely burned patients and the potential impact on the dosage of antibiotic treatment.

Material and Methods Retrospective observational study that includes critically ill burned patients admitted to the burn unit between January/2020 and November/2021 in a tertiary hospital. Patients were classified as having ARC if an included sample taken during their length of stay had a creatinine clearance ≥ 130 mL/min. This value was obtained through the Cockcroft-Gault equation. Data was collected

from the clinical history. Continuous variables are expressed as medians (range) and categorical variables as cases (percentage).

Results Forty-eight patients were included, 17(35.5%) females, with a median age of 45(16–85) years. Forty (87.5%) had third degree burns, burned body surface area was 22% (5–85) and Abbreviated Burn Severity Index (ABSI) was 8 (3–13). The main cause of admission was due to flame in 45 (93.4%) and there was smoke inhalation in 26 (54.1%). Length of stay was 32 (2–208) days and overall mortality 14.6% (n=7).

Median serum creatinine was 0.65 [0.3–2.1] mg/dL and CrCl was 152 [44.8–256.3] ml/min. 60.4% (n=29) had ARC, 29.2%(n=14) had normal filtration and 10.4% (n=5) were in acute renal failure.

In patients with ARC, 24 (82.8%) received antibiotic therapy and were all treated with beta lactams during their stay. Other hydrophilic antibiotics were aminoglycosides (29.2%), daptomycin (20,8%), linezolid (16,7%), and teicoplanin (20,8%).

Conclusion and Relevance Our findings provide further evidence that severely burned patients, as observed with other subsets of critically ill patients, frequently exhibit ARC. Almost two-thirds of our patients presented ARC and the majority of them were being treated with antibiotic therapy that could potentially be underdosed. Pharmacists can play an important role in identifying these patients and optimising the dosage taking this phenomenon into account.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-226 CONTINUOUS INFUSION OF VANCOMICYN: WHO ARE THE PATIENT CANDIDATES AND HOW SAFE IT IS?

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Background and Importance Data about the efficacy and toxicity of vancomycin used by continuous infusion (CI) compared to intermittent infusion (II) are still controversial.

Aim and Objectives To compare the profile of patients treated with II or CI of vancomycin and the frequency of nephrotoxicity within a therapeutic drug monitoring (TDM) programme. **Material and Methods** Retrospective pharmacokinetic (PK) study in adult patients treated with II/CI of vancomycin and undergoing TDM in a university hospital during 2022.

Data collected demographics, clinical (serum creatinine (Cr) and estimated glomerular filtration rate (CKD-EPI) (eGFR) at baseline and end of treatment) and pharmacokinetic data (PK).

TDM samples: before dose (C_{min,ss}) and 1h after the end of the intravenous infusion (C_{max,ss}) (II) or at any time (C_{ss}) (CI). Mean area under the curve in plasma (AUC_{24h}) was estimated by a Bayesian software.

Results Patients included: 128: 62.7(14.6) years, 88(68.8%) males, 61 (47.7%) directed treatments. Most frequent pathogens: 22 (17.2%) *S. epidermidis*, 14 (10.9%) *E. faecium* and 7 (5.5%) MRSA.

Abstract 4CPS-226 Table 1 Comparative data between patients with continuous and intermittent infusion

| | Intermittent (N = 72) | Continuous (N = 56) | p |
|--|-----------------------|---------------------|-------------|
| Sex (male) | 48(66.7%) | 40(71.4%) | 0.56 |
| Age (years) | 63.6(14.2) | 61.4(15.1) | 0.39 |
| Weight (kg) | 78.9(19.2) | 80.1(21.3) | 0.74 |
| DOT (days) | 9.4(6.5) | 9.6(11.1) | 0.87 |
| Critically ill | 26(36.1%) | 33(58.9%) | 0.01 |
| Septic shock | 1(1.4%) | 6(10.7%) | 0.04 |
| Chronic kidney failure | 6(8.3%) | 1(1.8%) | 0.14 |
| Augmented renal clearance | 6(8.3%) | 6(10.7%) | 0.65 |
| Dose (mg/kg/day) | 28.8(10.1) | 26.1(9.4) | 0.12 |
| Baseline Cr (mg/dL) | 0.8(0.5) | 0.7(0.3) | 0.15 |
| Final Cr (mg/dL) | 0.9(0.8) | 0.6(0.3) | 0.01 |
| Baseline GFR (mL/min/1,73 m ²) | 88.2(28.9) | 96.6(28.4) | 0.12 |
| Final GFR (mL/min/1,73 m ²) | 88.8(35.9) | 104.2(27.3) | 0.01 |
| AUC _{24h} (L/mg*h) | 509.5(138.1) | 464.7(162.0) | 0.1 |
| AKI (KDIGO) | 14(19.4%) | 5(8.9%) | 0.01 |
| Number of nephrotoxic drugs | 1.5(1.0) | 1.4(1.1) | 0.55 |
| In-hospital mortality | 2(2.8%) | 9(16.1%) | 0.01 |

Conclusion and Relevance

- The use of continuous infusion of vancomycin was more frequent among ICU patients, with septic shock and lower baseline serum creatinine.
- The CI group had better renal function at the end of vancomycin treatment and seem to have a lower nephrotoxicity rate.
- Patients treated with CI had a higher severity status (they were more frequently severy-ill and sepsis), what probably could explain the higher in-hospital mortality rate observed. However, more data are needed to study the efficacy and safety of this strategy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-234

DEVELOPMENT AND VALIDATION OF A RAPID HIGH PERFORMANCE CHROMATOGRAPHY METHOD (HPLC) FOR THE DETERMINATION OF LINEZOLID IN HUMAN PLASMA

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Background and Importance Linezolid is an oxazolidinone antibiotic with time-dependent activity and moderate post-antibiotic effect used as a treatment against multidrug-resistant gram-positive pathogens. Recent guidelines recommend therapeutic drug monitoring (TDM) of linezolid in critically ill patients, who often manifest great inter- and intra-individual pharmacokinetic variability. The latter is the reason why in this kind of patients conventional dosing may not achieve optimal efficacy and safety concentrations (2–7 mcg/mL).

Aim and Objectives The aim of this study was the development and validation of a high-performance liquid chromatography (HPLC) method for measuring linezolid in human plasma using tedizolid as an internal standard (IS).

Material and Methods The chromatographic system consisted of an Agilent® 1260 Infinity with an ultraviolet diode array detector (UV-DAD). The column used was a BDS HYPER-SIL C18 4.6X250 mm, 5 µm (Thermo Scientific®, USA). The method was developed under isocratic conditions and the analysis run time was 8 minutes. The method was validated according to the Food and Drug Administration (FDA) bioanalytical method validation guidance. Chromatographic conditions and calibration methods are shown in table 1. Plasma drug extraction was performed by adding 100 µL of IS (tedizolid 25 µg/mL) into a test tube, followed by 250 µL of plasma (QC or samples) and 500 µL of acetonitrile/methanol (50/50, v/v). The tube was vortexed for 1 min and then centrifuged at 15000 rpm for 5 min. After centrifugation, 300 µL of the supernatant was injected into the HPLC.

Results

Abstract 4CPS-234 Table 2 Validation parameters according FDA guidance

| Analyte | Rt (min) | Equation | R ² | Within-day mean (µg/mL) (%CV) | | | Between-day mean (µg/mL) (%CV) | | |
|-----------|----------|-------------------|----------------|-------------------------------|------------------|-----------------|--------------------------------|------------------|-----------------|
| | | | | Low (3 µg/mL) | Medium (7 µg/mL) | High (10 µg/mL) | Low (3 µg/mL) | Medium (7 µg/mL) | High (10 µg/mL) |
| Linezolid | 4,3 | y= 0.2451x-0.0179 | 0.9995 | -3.39 (1.57) | -3.25 (0.56) | 1.46 (6.89) | -6,18 (2,21) | -5,45 (1,97) | -2,78 (7,54) |

Conclusion and Relevance A method has been validated for the determination of linezolid by HPLC in human plasma. This will allow in future to improve therapeutic outcomes in critically ill adult patients, limiting the risk of dose-related adverse effects and avoiding suboptimal concentrations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

Abstract 4CPS-234 Table 1 Chromatographics conditions and calibration methods

| Analyte | Mobile Phase | λ nm | Calib ^{*****} on range | Flow (mL/min) | Temperature (°C) | Injection volume (µL) |
|-----------|--|------|---|---------------|------------------|-----------------------|
| Linezolid | 75% BUFFER (KH ₂ PO ₄ 20 nM Ph=3.5)/25% acetonitrile | 260 | - 6 calibration levels: range 1–14 µg/mL -n=5 replicates/calibration levels - Blank (no analyte, no IS) - Zero calibrator (blank + IS) | 1.5 | 25°C | 50 |

4CPS-235 IMPACT OF TELEPHARMACY ON BIOLOGIC THERAPIES ADHERENCE AND CLINICAL OUTCOMES IN PATIENTS WITH PSORIASIS

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Background and Importance Biologic therapies (BT) used in psoriasis are hospital restricted dispensation medications. Lately, telepharmacy procedures, including non-face-to-face dispensation had become more common.

Aim and Objectives To analyse if a telepharmacy programme (dispensation through community pharmacies (DTCP) and follow-up pharmacist-teleconsultations) can improve adherence and clinical outcomes in a cohort of patients with psoriasis receiving BT.

Material and Methods Patients with psoriasis on stable BT were offered to enter a telepharmacy programme in February 2020 in the Pharmacy Outpatients Area of a tertiary hospital. The programme consisted in DTCP accompanied with follow-up pharmacist teleconsultations.

Patients included in the study must had been in stable treatment for at least one year before entering this programme ('previous period', February 2019-February 2020) and stay for 6 months ('later period').

Adherence (Medication Possession Ratio) and clinical variables (Body Surface Area (BSA) and Psoriasis Area and Severity Index (PASI)) were assessed during both periods. In the 'later period' adherence to BT dispensed through community pharmacies was confirmed with patients by pharmacist teleconsultations.

Differences between adherence and clinical outcomes were evaluated in both periods as well as variables associated with an improvement in adherence. Quantitative data expressed as frequency and qualitative data as median (IQR).

Results Of 221 patients, 99(44,8%) accepted to enter the programme. Of them, 45 (45,5%) were excluded: change of treatment 32 (14,5%), BT for less than 1 year 12 (5,4%) and loss of follow-up 7(3,2%).

Baseline characteristics of the 54 included patients: 31 (59,6%) male, age 53 (44–63) years, 32 (61.5%) BT-naïve. 5,7 (2,9–10,1) years on BT.

BT: adalimumab 15 (28,8%), secukinumab 12 (23,1%), ixekizumab 10 (19,2%), others 17 (31,5%).

Adherence was 92,3% (IQR:78,0%-97,9%) in the previous period and 95% (IC95%:88,3%-100%) in the later period with a significant increase (p=0,003).

The median increase in adherence was 4% (IQR2%-15,7%) in 29 (55,8%) patients. Increase in adherence was greater in female patients (53,3% vs 22,7%, p=0,044). No significant differences observed when comparing PASI values, % patients with PASI<2 and BSA between both periods.

Conclusion and Relevance Telepharmacy programs (dispensation through community pharmacies with teleconsultations) may improve adherence to biologic therapies in patients with psoriasis.

We need to evaluate a larger number of patients and for a long period to analyse whether this increase in adherence is associated with better outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-238 PROFILE OF ELDERLY PATIENTS AT HIGH FALL RISK AND POLYPHARMACY IN THE EMERGENCY DEPARTMENT

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Background and Importance Polypharmacy and falls are associated with increased morbidity and mortality, most of which are preventable.¹

Aim and Objectives To identify the association between grade of polypharmacy and falls, and to obtain an index that allows rapid selection of patients who consult for falls in Emergency Department(ED) and who could benefit from a medication review with the pharmacist to prevent new falls.

Material and Methods Retrospective observational study in which patients ≥75 years admitted to the ED codified as 'fall' in the period between 01/01/2022 and 31/07/2022 were selected. Patients without a confirmed fall were excluded. Analyzed characteristics:sex,age,previous falls,median number of drugs prescribed(polypharmacy[≥5 drugs];extreme polypharmacy[≥10 drugs]).Medication information was extracted from the first ED medical note.The main variable was the risk of falls regarding patient pharmacotherapy(FPc),calculated by obtaining a sum where each drug in the following groups contributed one point:tranquilisers-sedatives, diuretics, hypotensives, antiparkinsonians, antidepressants, opioids, neuroleptics, and first-generation antihistamines drugs. A value≥2 was classified as high fall risk(Downton-Scale).The secondary variables were the association between sex,age,previous falls, polypharmacy and high-FPc. Data were obtained from the electronic-medical records. Statistical methods employed were Chi-square-test, Cramer's-V, and odds ratio(OR).IBM-SPSSv.26.

Results A total of 118 patients were selected.No patients were excluded.The 76.3%(90/118) were female, mean age 83.72 years(SD=6.12) and 48.3%(57/118) had previous falls. The median number of drugs prescribed was 9(IQR=6–11). The 84.7%(100/118) of patients had polypharmacy and 41.5%(49/118) had extreme-polypharmacy.Median FPc was 3 (IQR=2–4) and 83.1%(98/118) were classified as high risk. Association between high-FPc and collected variables:No association with age or sex (p=0.6;p=0.9 respectively).Association with previous falls(p=0.028), polypharmacy(p<0.001) and extreme-polypharmacy(p=0.002) with insignificant intensity(Cramer's-V=0.15), moderate intensity(Cramer's-V=0.562) and low intensity(Cramer's-V=0.289), respectively.The OR for high fall risk was 23 times higher for polypharmacy patients, and 8 times higher in extreme-polypharmacy patients.

Conclusion and Relevance There is an association between polypharmacy and falls. Most patients had polypharmacy and were also classified as high fall risk with our index tool. There seem to be no major differences between having 5 or 10 drugs. Patients with a history of falls seem to have a higher probability of having a new fall.Our pharmacological stratification tool seems to associate positively high fall risk with polypharmacy.

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Conflict of Interest No conflict of interest

4CPS-239 POPULATION PHARMACOKINETICS OF ISAVUCONAZOLE BASED ON PHARMACOGENETICS IN IMMUNOSUPPRESSED PATIENTS

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Background and Importance Isavuconazole has a safety profile and favorable pharmacokinetic characteristics. However, studies in real-life practice have found unexpected drug levels in different groups of patients.

Aim and Objectives To develop a population pharmacokinetic model (PopPK) that describes the behaviour of isavuconazole in prophylaxis and treatment of invasive fungal infections (IFI) and to evaluate possible factors affecting dosage.

Material and Methods A prospective, multidisciplinary study including immunosuppressed patients treated with oral and intravenous isavuconazole as prophylaxis or treatment for IFI was carried out from June 2020 to January 2022. Variables considered were: demographic, clinical, biochemical and genetic (polymorphisms, presence of inductors, inhibitors and the degree of saturation -DG- of drug-metabolising enzymes of CYP3A4, CYP3A5 and CYP2B6). DG was tested using SuperCYPsPred.

Blood samples were collected predose Isavuconazole was analysed using ultra performance liquid chromatography coupled with ultraviolet detection.

Non-linear mixed effects modelling using first-order conditional estimation with interaction (FOCEI) was used to develop the PopPK model using NONMEM v7.4. Data visualisation and statistical analyses were carried out in R v.3.4.

Results A total of 31 patients (10 females) from the haematology (19) and intensive care (12) services were included in the study. The median (interquartile range) age was 58 (17) years and total body weight was 77 (17) kg. The percentage of patients who presented non-wild type genotypic was 20% for CYP3A4. 99 samples were determined and the mean concentration (standard deviation) was 1.80 (0.95) µg/mL.

Isavuconazole PK was best described by a single-compartment model with first order absorption and elimination. Isavuconazole absorption rate was fixed at 22.6 1/h as previously reported by Cojutti et al. 2021. The apparent volume of distribution was 147 L and the apparent clearance (CL/F) was described by the following equation:

$$CL/F(L/h) = 3.54 * (ALB/2.9)^{-0.7} * (BS/1.9)^{1.9} * (1 + 0.8)^{3A4ind}$$

where serum albumin (ALB) is expressed in g/dL; body surface (BS) in m² and 3A4ind indicates the presence of inductor drugs for CYP3A4.

The interindividual variability for CL/F was 40% and the residual variability was 30% (additive) and 0,05 µg/mL (proportional).

Conclusion and Relevance The developed PopPK model adequately characterises the kinetic behaviour of isavuconazole and includes the ALB, BS and the presence of inductors of CYP3A4 parameters that affect its clearance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-244 ANALYSIS AND COMPARISON OF OLANZAPINE ADMINISTRATION IN SMOKING AND NON-SMOKING PATIENTS

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Background and Importance Olanzapine is an atypical antipsychotic that is metabolised by the cytochrome P-450 (CYP1A2 isoenzyme). This isoenzyme is induced by tobacco smoke, resulting in reduced plasma concentrations of olanzapine when both are administered concomitantly.

Aim and Objectives The aim is to analyse and compare the daily dose of olanzapine and its plasma concentration in smoking and non-smoking patients.

Material and Methods Retrospective observational study of patients on chronic treatment with olanzapine, whose levels were monitored in the clinical pharmacokinetics area of the Pharmacy Service of a regional hospital between 01/01/2021 and 08/06/2021. The daily doses administered, age, sex and results of plasma monitoring were consulted by accessing their clinical records. Therapeutic range of olanzapine considered: 20–80 mcg/mL. To evaluate the effect of CYP1A2 isoenzyme induction, the mean concentrations obtained were compared with those that should theoretically be present in the group of smokers according to the linear dose-concentration pharmacokinetic behaviour of olanzapine in non-smokers.

Results Sixty-two patients were monitored, five were excluded (four for undetectable levels and one for a self-harm attempt), so that the analysis finally included 57 patients in total: 17 smokers (29.8%) and 40 non-smokers (70.2%). 21 women (36.8%): 9 smokers and 12 non-smokers; 36 men (63.2%): 8 smokers and 28 non-smokers. Median age: 44 years (IQR=31.5–54.5).

Abstract 4CPS-244 Table 1

| | Women smokers | Women non-smokers | Men smokers | Men non-smokers |
|-------------------------------------|--------------------------|---------------------------|--------------------------|--------------------------|
| Mean daily dose of olanzapine (mg) | 15.3 (95% CI =10.6–20.0) | 14.8 (95% CI =11.0–18.6) | 22.5 (95% CI =18.0–27.0) | 18.4 (95% CI =13.8–23.0) |
| Mean plasma concentrations (mcg/mL) | 52.5 (95% CI =38.1–66.9) | 80.8 (95% CI =46.8–114.8) | 49.8 (95% CI =29.0–70.6) | 50.1 (95% CI =37.0–63.2) |

For the mean olanzapine dose observed in women and men smokers, the mean theoretical concentration would have been 83.5 mcg/mL in women and 61.3 mcg/mL in men. This is 37.1% and 18.8% higher than the results obtained, respectively.

Conclusion and Relevance In the smokers group, the mean prescribed dose was 3.3% higher in women and 18.2% higher in men, and the mean plasma concentration was 35% lower in women and 0.6% lower in men, compared to the non-smokers group.

Differences were observed between smokers and non-smokers that would correspond to the tobacco-inducible effect,

although studies with larger numbers of patients are needed to establish the tobacco-olanzapine interaction as clinically relevant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-245 PREVENTION OF REFEEDING SYNDROME IN PATIENTS ON PARENTERAL NUTRITION: A REVIEW OF APPROPRIATENESS

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Background and Importance Refeeding syndrome (RFS) is a metabolic disorder that can be triggered after nutritional replacement. This condition can be life-threatening, so early identification and prevention is important.

Aim and Objectives Describe a system of screening and nutritional support in patients at risk of RFS. Assess the degree of adequacy of initial parenteral nutrition (TPN) to published NICE guidelines.

Material and Methods Retrospective observational study including patients from January 2020 to September 2022 identified with RFS risk, according to NICE guidelines criteria, at the beginning of TPN.

Variables collected were: age, sex, weight, height, service, low/no intake in 5–10 days prior to starting TPN, type of RFS risk (high or extreme), kilocalories (Kcal) of TPN at baseline and at reaching total requirements, time to establishment of total kcal on TPN and development of RFS (decrease in serum levels of potassium, phosphate, magnesium in the first 72 hours).

Results 33 patients were included. The mean age was 59,6 years (SD: 15,5). 54,5% were men. The mean BMI was 20,2 (SD: 4,0). 33,3% were surgery patients; 27,3% onco-haematology; 24,2% digestive; 9,1% critical care; 6,1% others. 75,8% of the patients had low/no intake prior to the introduction of TPN. A total of 90,9% were at high risk of developing RFS. The mean kcal/kg of TPN at the start was 20,4 (SD: 3,7). In 63,6% of patients total kcals were instituted within 2 days, and in 36,4% within 3 days. 3 patients developed RFS, all at high risk, 2 of them being onco-haematological.

Conclusion and Relevance Most patients who developed RFS were onco-haematologic, a group at risk for RFS, and had little/no intake prior to the initiation of TPN.

In line with the recommendations established by NICE guidelines, the kcal/kg provided by TPN at baseline are higher than recommended (20.4 vs 10 kcal/kg). In addition, the total kcal were reached between 2–3 days, the recommendations being between 4–7 days. Only 9.1% of the patients developed RFS, so that future studies could consider a less restrictive caloric start in TPN than that proposed in the aforementioned guidelines.

The role of the pharmacist, together with the rest of the multidisciplinary team, has allowed early detection and prevention of developing RFS in 90.9% of the patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-248 THERAPEUTIC DRUG MONITORING OF LINEZOLID IN SOFT-TISSUE AND OSTEOARTICULAR INFECTIONS: A RETROSPECTIVE ANALYSIS

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Background and Importance Both prospective and retrospective trials and case reports suggest that therapeutic drug monitoring (TDM) of linezolid may be useful, especially in situations when there's a potential alteration of its pharmacokinetics or an increased risk of adverse events (AE); obesity, renal failure, drug interactions or prolonged treatments.

Aim and Objectives To assess effectiveness and safety of linezolid in SOI regarding linezolid serum concentrations (LSC) and analyse the influence of glomerular filtration rate (GFR) and body mass index (BMI) in LSC.

Material and Methods Observational retrospective study including patients with SOI treated with linezolid between January/2019 and December/2021.

Demographic, prescription and clinical data were collected from hospital's medical records. Creatinine clearance was estimated by the Cockcroft-Gault formula.

Quantification of linezolid was performed by HPLC-UV. Therapeutic target trough concentrations were settled at 2–8 mg/L.

We studied the relationship among GFR and BMI with LSC using a multivariate regression analysis with IBM SPSS® Statistics program

Results Forty-two patients (mean age 58.7 ± 16.1, 69.1% male) were included. All patients received linezolid 600mg q12h orally as initial dose. The median duration of treatment was 34.2 ± 17.4 days. No relevant drug interactions were observed.

Twenty-two patients (52.4%) had LSC outside therapeutic range (TR): 10(45.5%) above and 12(54.5%) below TR. In only 3(18.7%) patients with suprathreshold LSC posology was modified. All infections (including ones in patients with LSC below TR) were resolved.

AE occurred in 16(38.1%) patients, 7(43.8%) over TR. Eight of them (50%) discontinued treatment due to AE (50% diarrhea, 62.5% glossitis, 25% thrombocytopenia, 12.5% anaemia).

Seven (16.6%) patients had GFR<60 ml/min, of which 4 (57.1%) were over TR. Seventeen (40%) patients had a BMI>30, of which 5(29.4%) had linezolid determinations outside the TR: 3(60%) below TR. It was not found a significant correlation between BMI and LSC (p=0.34), whereas a significant inverse correlation was found between GFR and LSC (p=0.01).

Conclusion and Relevance A great proportion of patients were outside the TR, and the variable that seems to affect the most is GFR (p=0.01), so TDM would be specially recommended in patients with a lower GFR to decrease AE, which occur frequently with high LSC. Effectiveness was demonstrated in all patients including the ones with LSC below TR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-250 EXPERIENCE OF TECOVIRIMAT AND CIDOFOVIR USE IN A PATIENT WITH MONKEYPOX: A CASE REPORT

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Background and Importance Current treatment for Monkeypox's disease (MPXV) is mainly symptomatic. However, in immunocompromised patients, hospitalisation and treatment with antiviral drugs may be necessary. With the recent outbreak of MPXV, new strategies have been proposed.

Aim and Objectives The aim of the study was to describe our clinical experience with tecovirimat and cidofovir in the treatment of MPXV in a patient whose CD4+ lymphocyte level is less than 50 cells/ml.

Material and Methods The effectiveness of tecovirimat-cidofovir was assessed by the evolution of the rash from macule to crusts that dry up and fall off.

Results The patient was a 35-year-old man diagnosed with MPXV who presented skin lesions in the perineal area, extremities, face, trunk and back and severe proctitis. At admission, the patient was diagnosed with HIV (severely immunosuppressed with CD4+ lymphocyte levels of <40 cells/ml), so he was started on antiretroviral treatment (BIC/TAF/TDF). Sexually transmitted infection screening detected Chlamydia trachomatis infection, which was treated with doxycycline. In the context of MPXV proctitis, it was decided to apply for tecovirimat, the antiviral treatment of choice. The dosage for tecovirimat is weight-based, 600 mg was administered every 12 hours for 14 days (30/08/22–12/09/22). Regarding effectiveness, no new lesions were observed and those already present were regressing, except in the perianal area, where the lesions continued to progress. Therefore, it was decided to administer intravenous cidofovir 5 mg/kg twice weekly (09/09/22, 16/09/22). To avoid toxicity, oral probenecid was administered concomitantly: 2 g 3 hours before and 1 g 2 and 8 hours after completing the perfusion, in addition to 0.9% saline solution 1000 ml 1 h before. After the treatment, there was a progression of lesions in the right inguinal region, palpating left inguinal adenopathy and intense involvement of the testicle, groin and perineal area.

Conclusion and Relevance In contrast to previous cases of patients whose CD4+ lymphocyte levels were above 500 cells/ml, the treatment with tecovirimat and cidofovir in this patient did not achieve a satisfactory response due to the continuous appearance of new lesions. The severe immunosuppression could probably explain the aggressive development of the disease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-252 OPTIMISATION OF ERTAPENEM POSOLOGY IN A CRITICALLY ILL PATIENT BY THERAPEUTIC DRUG MONITORING: A CASE REPORT

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Background and Importance Therapeutic drug monitoring (TDM) of ertapenem is recommended in critically ill patients (CIP) to address their variability in exposure because of its time-dependent, highly protein bound and hydrophilic characteristics.

Aim and Objectives To describe efficacy and safety in a CIP after optimising the posology of ertapenem.

Material and Methods A case report in a CIP treated with ertapenem is described. Data were collected from electronic medical records and ertapenem concentrations were measured by high-performance liquid chromatography.

Results A 35-year-old man with a body mass index (BMI) of 32.6kg/m² with a surgical wound culture positive for AmpC-producing *Klebsiella pneumoniae* was started ertapenem 1g q24h (minimum inhibitory concentration (MIC) of 0.38 for *Klebsiella*). Three days after initiation, ertapenem plasma concentrations were determined. In that moment, his creatinine value was 0.21mg/dL with a glomerular filtration rate (GFR) of 700ml/min by the Cockcroft-Gault formula, and his albumin value was 2.9mg/dL. Ertapenem serum concentrations were 1.65mcg/ml (total drug); 0.16mcg/ml of unbound fraction (fu), considering a protein binding of 90%. Fu should be above the MIC, ideally 4 times the MIC (≥ 1.52 mcg/ml), and fever persisted, so in agreement with the medical team the dosage was optimise to 0.5g q12h considering its time-dependent pharmacokinetics. Two days after posology optimisation, the patient became afebrile, and 6 days after being with the new regimen, blood concentrations were remeasured resulting in 6.97mcg/mL, and a fu of 0.69 mcg/mL, which is 1.8 times the MIC. Despite not having reached fu of 4 times the MIC, given that the patient remained afebrile after dose optimisation and as a precaution for not reaching toxic concentrations due to an increase in the total daily dose, the 0.5g q12h dosage was maintained for another week, when the infection was solved and the antibiotic discontinued.

No adverse effects related to ertapenem were reported.

Conclusion and Relevance The optimisation of ertapenem posology, changing the frequency without increasing the total daily dose, allowed increasing ertapenem concentrations and improved the clinical outcome of a CIP with augmented renal clearance, low albumin and high BMI, characteristics that may lower ertapenem concentrations, without decreasing the safety of the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-256 ENHANCING THE SAFETY OF INJECTABLE CYTOTOXIC CHEMOTHERAPY AT A TERTIARY CARE HOSPITAL: A RETROSPECTIVE ANALYSIS OF PHARMACISTS' INTERVENTIONS IN CHEMOTHERAPY PREPARATION SERVICES

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Background and Importance Cytotoxic chemotherapeutic agents are classified as high alert medications according health accreditation standards. Detection and resolving of drug related problems (DRP) in chemotherapy prescriptions was associated with overall positive clinical and economic impact in international studies.

Aim and Objectives to describe the economic and clinical impact of interventions performed by pharmacists in the chemotherapy preparation unit at Sultan Qaboos University Hospital (SQUH).

Material and Methods This was a retrospective analysis of pharmacists' interventions on injectable chemotherapy orders between January and December 2021. At SQUH, chemotherapy including biologicals/targeted therapies are centrally prepared within the pharmacy. SQUH is a tertiary care multi-speciality hospital in Oman. Chemotherapy prescriptions were routinely verified by trained pharmacists against set treatment protocols and in accordance to patients' clinical and laboratory parameters prior to preparation/mixing. Consequently, a proportion of prescriptions was withheld on the day and differed to another subject to patients' conditions. The direct cost reduction of unprepared doses was calculated.

The remaining prescriptions were screened for any DRP prior to mixing/preparation and PI were then documented on a specific form that was incorporated into the electronic patient record. Each intervention was then graded according to predefined criteria as death, major, moderate and minor according to the associated potential harm prevented.

Results A total of 9,515 orders were received in chemotherapy preparation unit including 18,408 individual injectable medications prescriptions, for 1,096 patients during 2021. A total of 4,440 interventions were performed on the individual medication prescriptions representing 24.1% of total orders. Prior to mixing, 4,069 orders (22.1% of total) were differed and the estimated potential direct cost reduction from the unprepared doses was around 1,000,000 OMR (2,000,000 €). A total of 303 PI were documented and 96% of them were accepted by the prescriber. The most common type of PI was dose adjustment (37.0%) followed by omission (17.2%) and wrong cycle (13.3%). PI prevented death in 1.6% while it prevented a major harm in 3.8%, moderate in 41.0%, minor in 3.0% and improved a suboptimal standard of care in 33.1% of cases.

Conclusion and Relevance Chemotherapy order verification and pharmacists' interventions have minimised potential harm associated with cytotoxic chemotherapy regimens and resulted in considerable cost saving.

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Conflict of Interest No conflict of interest

4CPS-260 PERSISTENCE, SAFETY AND ASSOCIATED LYMPHOPENIA OF DIMETHYL FUMARATE IN RELAPSING REMITTING MULTIPLE SCLEROSIS, REAL WORLD DATA

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Background and Importance Dimethyl fumarate(DMF) is a hospital dispensing drug indicated for the treatment of relapsing remitting multiple sclerosis(RRMS). Lymphopenia is a frequent adverse event(AE), eventhough it is not an extensive discontinuation cause.

Aim and Objectives To analyse the persistence of dimethyl fumarate and reason of discontinuations. To describe the toxicity of the treatment, focusing on lymphopenia.

Material and Methods Observational, retrospective study of RRMS patients who started treatment with DMF between August-15 and October-2020. They were followed up from the start until August-2022, follow-up of lymphopenia was 22 months. Variables collected: sex, age, previous treatments, date and reason for discontinuation, type of dose-escalation(our standard is 0-0-120mgx7 days, 120-0-120x7,120-0-240x7,240-0-240 onwards), AE and quarterly(± 2 month) lymphocyte levels (classified according to Common Terminology Criteria for AE). Statistics analysed with SPSSv.20.

Results 94 patients were analysed, 68.1%(64/94) female; mean age at baseline is 40.3 years (SD=10.1). Mean EDSS (n=82) 2(0-6,5). No difference in discontinuation according to sex(p=0.385), age (p=0.761) or EDSS (p=0.828). 79.8% (75/94) patients were previously treated with disease modifying therapies. 48.8% (44/94) patients discontinued treatment: AE-47.7% (21/44) (lymphopenia-13.6% (6/44), disease progression-31.8% (14/44), patient's choice-18.2%(8/44), pregnancy planning-11.4% (5/44). 7.4% (7/94) follow-up losses.

Median persistence was 61.6 months (IC95%: 36.9-86.2). Persistence at 6 months was 93.6%, 88.3% at 1 year, 76.4% at 2 years and 56.3% at 5 years. There were 10.6% (10/94) restarts and 13.8% (13/94) patients required slower than our standard dose-escalation.

52.7% (39/74) pretreated patients discontinued vs. 25.0% (5/20) naïve (p=0.028). No difference in persistence (p=0.178).

85.1%(80/94) patients experienced any EA: gastrointestinal-62.5%/50/80), vascular (flushing, heat, hypersensitivity, reddening) -52.2 (42/80), pruritus-28.8% (23/80), other EA-48.8% (44/94).

36.2% (34/94) patients developed lymphopenia; grade (G) 1-34.3%, G2-60.0%, G3-5.7%. At follow-up ending, 14 patients continued lymphopenic: 7.1% (1/14) since beginning, 28.6% (4/14) since 3th month; 28.6% (4/14) since 6th; 7.1% (1/14) since 9th, same since 12th and 15th; 14.3% (2/14) since 18th.

Conclusion and Relevance In our hospital, the largest number of DMF discontinuations are due to intolerance; gastrointestinal toxicities mostly observed. Despite the higher discontinuation in no-naïve, persistence isn't different.

Lymphopenia appears in similar percentage to observed in clinical trials. As described in these, real-life data on lymphocyte levels may decrease during the first year of treatment, but stabilise after a few months, recovering normal levels most of patients

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-001 **EFFICACY AND SAFETY OF THE COMBINATION OF ISATUXIMAB, CARFILZOMIB AND DEXAMETHASONE IN PATIENTS WITH MULTIPLE MYELOMA: A CASE REPORT**

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Background and Importance Multiple myeloma is a neoplastic proliferation of plasma cells in the bone marrow. Isatuximab is a new IgG1 kappa monoclonal antibody directed against CD38, which has been approved by the EMA and FDA in combination with carfilzomib and dexamethasone (Isa-Kd) in patients with multiple myeloma who have received at least one prior line of therapy.

Aim and Objectives The aim of this study is to describe the efficacy and safety of the Isa-Kd combination in a patient with multiple myeloma refractory to previous lines.

Material and Methods Retrospective clinical case in which we followed the patient during treatment with Isa-Kd. Data were obtained from the electronic medical record.

Results We describe a 55-year-old male, weight 69 kg and height 173 cm. He was diagnosed with multiple myeloma in September 2017 and ever since has received 4 lines of treatment, not being a candidate for autologous haematopoietic progenitor transplantation due to psychiatric illness.

In July 2021 it was decided to start with Isa-Kd and since he has received 4 cycles of 28 days, following the IKEMA study scheme; during the first cycle, isatuximab was administered at 10 mg/kg on days 1, 8, 15 and 22, and from the second cycle onwards every 15 days. Carfilzomib was administered the first cycle at 20 mg/m² on days 1 and 2, at 56 mg/m² on days 8, 9, 15 and 16, and from the second cycle onwards at 56 mg/m² on days 1, 2, 8, 9, 15 and 16.

No adverse reactions were observed during infusion, such as hypertension, anaphylaxis or nausea. After Isa-Kd administration, the patient presented asthenia, but it did not prevent him from performing his usual tasks. During the 4 treatment cycles we did not detect a reduction in the erythrocyte count, nor any hospital admission for pneumonia.

After 4 months of treatment, Isa-Kd treatment was discontinued due to disease progression.

Conclusion and Relevance Isa-Kd administration achieved a progression-free survival of 4 months, much lower than the 19,5 months reached in the IKEMA study.¹ Nevertheless, Isa-Kd infusion in our patient has been shown to be safe in the treatment of refractory multiple myeloma.

REFERENCE

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Conflict of interest No conflict of interest

Conflict of Interest No conflict of interest

5PSQ-009 **EFFECTIVENESS AND SAFETY OF MONOCLONAL ANTIBODY SWITCHING IN MIGRAINE PATIENTS**

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Background and Importance Monoclonal antibodies targeting the calcitonin gene-related peptide (CGRP-mAbs) are used in the prophylaxis of migraine. The therapeutic target is not exactly the same as Erenumab targets the CGRP receptor, whereas Galcanezumab and Fremanezumab target circulating CGRP. However, their relative effects in patients with prior migraine treatment failure remains uncertain.

Aim and Objectives To describe the use, effectiveness and safety of CGRP-mAbs switching in patients with migraine.

Material and Methods Retrospective observational study between 1-September-2019 and 30-September-2022 in a third-level hospital. Data collected: sex, age, comorbidities, CGRP-mAbs prescribed, treatment duration, causes of suspension, adverse reactions (AR), Headache Impact Test (HIT) and Migraine Disability Assessment (MIDAS) scores, average number of migraine days per month (NMDM) and days with triptans at baseline, prior and concomitant preventive drugs. Data were obtained from electronic medical records and patients interviews. The study had been approved by the Ethics Committee. Informed consent was obtained from all participants.

Results Of 167 patients on treatment with CGRP-mAbs, 17.4% (89.7% women, median age: 45.1(37.4–53.8) years) switched to another mAb: Erenumab (38%), Galcanezumab (31%), Fremanezumab (31%). While 75.9% of patients discontinued due to ineffectiveness, 24.1% had AR. Most of them (77.4%) had chronic migraine, 22.6% high-frequency episodic migraine. The main comorbidities were anxious-depressive syndrome (19.3%) and fibromyalgia (12.9%). The average NMDM was 15 ± 7.7 days and 31.0% patients used triptans ≥7 days/month. All patients had >3 prior treatments: beta blockers (87.1%), calcium antagonists (100%), antidepressants (93.5%), antiepileptics (100%) and botulinum toxin (79.3%). Concomitant preventive drugs was used 75.8% of patients, concomitant botulinum toxin in 13.8%. Median treatment duration of the second line: 5(3.3–7) months.

Fifteen patients (51.7%) switched to a third line: Erenumab (6.6%), Galcanezumab (60.0%), Fremanezumab (33.4%). Median treatment duration: 4 (1.7–4) months. The retention rate after the second switch was 93.3%. No AR were observed.

Conclusion and Relevance Some migraine patients who did not respond to a first drug responded initially to the switch, however half of them need to switch to a third mAb. Although non-responders to treatment may profit from a switch of antibody class, more studies are needed to describe which patients will respond to CGRP-mAb switching. Considering the low number of AR, treatment with CGRP-mAbs can be considered safe.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-015 **PERSISTENCE OF TREATMENT WITH JAK INHIBITORS IN RHEUMATOID ARTHRITIS IN PATIENTS ALREADY TREATED WITH THEM**

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Background and Importance Different JAK inhibitors (JAKi) are recently marketed at Spain for the treatment of

rheumatoid arthritis (RA). However, there is little data about their persistence when a previous JAKi has been used on RA treatment, which could influence pharmacotherapy with these drugs.

Aim and Objectives To analyse the persistence to treatment with a second JAKi treatment in RA patients which have previously been treated with a first JAKi.

Material and Methods Observational, retrospective study including all patients with RA treated with more than one JAKi until August 31, 2022. Demographic variables, median disease duration, median time on treatment (mToT) of JAKis including causes of end of treatment (loss of effectiveness or adverse reaction). Persistence was measured through mToT.

Results 18 patients (16 women), median age of 48 years [interquartile range (IQR):40–55] were included. Median time from diagnosis 9.4 years (IQR:6.3–11.8). Concomitant treatment: methotrexate (n=7) or leflunomide (n=2). Before first JAKi treatment, 12 patients were treated previously with at least a biologic disease-modifying antirheumatic drug (bDMARD). 4 patients were treated with at least a bDMARD after finishing first JAKi, rest of patient switched directly to another second JAKi.

Total mToT with the first JAKi: 12.1 months (IQR:3.3–31.3). Causes of end of treatment: loss of effectiveness (n=11; mToT: 15.7 months, IQR:11.9–35.3) and adverse effects (n=6; mToT: 2.5 months, IQR:1.4–4.7); a patient changed JAKi treatment due to cardiovascular risk.

Among patients who finished first JAKi due to loss of effectiveness (n=11), mToT with second JAKi was 9.6 months (IQR:4.1–14.2; 6/11 continue treatment; 1/11 loss of follow-up). Considering only patients who finished both first and second JAKi due to loss of effectiveness (n=4), mToT was 12.5 months (IQR: 8.0–17.7) vs 6.6 (IQR:3.1–16.1) respectively.

33% of patients (2/6) who finished first JAKi treatment because of adverse effects did not tolerate neither the second JAKi (mToT: 2.5 months, IQR:1.4–14.0; 3/6 continue treatment).

Conclusion and Relevance Persistence is higher with first JAKi when treatment with both first and second JAKi finished due to loss of efficacy, however data is still immature. Patients who do not tolerate treatment with a first JAKi seems to have a higher chance of not tolerating a second JAKi.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-017 IMMUNE-MEDIATED ADVERSE EFFECTS OF CHIMERIC ANTIGEN RECEPTOR T CELLS (CAR-T) THERAPY IN REAL LIFE POPULATION: WE CONTINUE TO LEARN

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Background and Importance Treatment with CD19-targeted chimeric antigen receptor T-cells (CAR-T) is transforming the therapeutic landscape of some B-cell malignancies, achieving high rates of responses. However, they have a new toxicity profile identified in the clinical trials, related to T-cell hyperactivation, namely cytokine release syndrome (CRS) and

Immune effector cell-Associated Neurotoxicity Syndrome (ICANS). Hospital Pharmacists should continue generating knowledge about these adverse effects (AEs) in real-life population.

Aim and Objectives Describing the toxicity profile of CAR-T cells therapies in a cohort of real-life patients and looking for possible risk factors related to current and previous treatments.

Material and Methods All patients infused with anti-CD19 CAR-T therapies in our centre between 01/01/2019 and 21/07/2022, out of clinical trials, were retrospectively analysed. We collected different descriptive variables of the patient, their pathology, CRS and ICANS type AEs, and treatments against them. For the statistics, proportion comparison tests and multivariate logistic regression were performed.

Results 88 patients were included (mean age 54.5 years, 44.3% women), 92.0% treated for B lymphomas and 8.0% for acute lymphoblastic leukemias. 56.8% received axicabtagene ciloleucel and 43.2% tisagenlecleucel, with 2.46 (1–6) previous lines received on average. About AEs, 79 (89.8%) patients suffered CRS (38.0% of them grades 2 to 4) and 31 (35.2%) ICANS (58.1% grades 2 to 4). The proportion of CRS was significantly higher (diff=55.5%, p>0.001), but, on the other hand, when the AE had occurred, the probability of it being grade 2–4 was significantly higher for ICANS than for CRS (diff=20.1%, p<0.05).

Concerning treatments employed, 77.1% of patients received tocilizumab, 61.4% corticosteroids (18.2% bolus doses), 27.3% siltuximab, and 19.2% anakinra. 53 (60.2%) patients required 2 or more treatments. Performing logistic regression, we found no significant risk factors for CRS, while having received tocilizumab, using axicabtagene ciloleucel, and suffering previous CRS grades 2–4 were associated with increased risk of ICANS (OR=6.72, 4.46, and 4.45 respectively, p<0.05).

Conclusion and Relevance Our real-life study supported the conclusions of other authors. After infusing a CAR-T, it was more likely to suffer CRS than ICANS, but, if it occurred, ICANS was more likely to be more severe. Suffering ICANS seems to be associated with previous tocilizumab use, axicabtagene ciloleucel, and previous moderate-severe CRS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-018 PRESCRIBING ERRORS IN CHILDREN: WHAT IS THE IMPACT OF A COMPUTERISED PHYSICIAN ORDER ENTRY?

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Background and Importance Prescribing errors represent a safety risk for hospitalised patients, especially in paediatric s.¹ Computerised physician order entry (CPOE) might reduce prescribing errors, although its effect has not yet been thoroughly studied on paediatric general wards.

Aim and Objectives This study investigated the impact of a CPOE on prescribing errors in children on general wards at a University Children's Hospital.

Material and Methods We performed medication reviews on 1000 patients from 0 – 18 years on paediatric general wards before and after the implementation of a CPOE. The CPOE included limited clinical decision support (CDS) such as a drug-drug interaction check and checks for duplicates. Prescribing errors, their type according to the PCNE classification, their severity (adapted NCC MERP index) as well as the interrater reliability (Cohen's Kappa) were analysed.

Results CPOE significantly reduced the rate of errors from 25 errors/100 prescriptions (95% CI: 23 – 27) to 16 errors/100 prescriptions (95% CI 14 – 18). Particularly the prescribing quality was improved by reducing PCNE error 5.2 (e.g. lacking drug form or maximum possible number of doses for reserve medication). Medication reconciliation problems (PCNE error 8), such as drugs prescribed on paper as well as electronically, were significantly increased after introduction of the CPOE. The most common paediatric prescribing errors, the dosing errors (PCNE errors 3), were not statistically significantly altered after introduction of the CPOE. Overall severity of errors was reduced. Interrater reliability showed moderate agreement ($K = 0.48$).

Conclusion and Relevance The CPOE increases patient safety by reducing the rate and severity of prescribing errors. The reason for the observed increase in medication reconciliation problems might be the hybrid-system with remaining paper-prescriptions for special medication. The lacking effect on dosing errors might be explained by the fact that a web application CDS covering dosing recommendations (PEDeDose) was already in use before implementation of the CPOE. Further investigations should focus on eliminating hybrid systems, interventions on how to increase the usability of the CPOE, and full integration of CDS tools into the CPOE.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest Corporate sponsored research or other substantive relationships:

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5PSQ-031 ANALYSIS OF THE USE OF ISAVUCONAZOLE IN CRITICALLY ILL PATIENTS WHEN THE USE OF VORICONAZOLE IS INDICATED

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Background and Importance Isavuconazole and voriconazole are antifungals that have shown similar clinical efficacy in the treatment of invasive aspergillosis. Isavuconazole has certain advantages such as a lower interaction profile and can be used in patients with renal insufficiency; however, its similar efficacy limits its use in situations where voriconazole is contraindicated.

Aim and Objectives The aim of this study is to describe the proportion of isavuconazole prescriptions in which the use of voriconazole would not be contraindicated.

Material and Methods Descriptive, observational and retrospective study in which all patients over 18 years of age who

received isavuconazole in 2021 in a hospital were included. Exclusion criteria were: age less than 18 years, pregnancy or duration of treatment less than 24 hours.

The use of intravenous voriconazole is contraindicated in patients with moderate to severe renal insufficiency (ClCr <50mL/min), in severe hepatic insufficiency (Child-Pugh C) and in combination with CYP450 substrates.

The main variable under study was the proportion of isavuconazole prescriptions in which the use of voriconazole would not be contraindicated.

The following variables were also collected: sex, age, number of days of treatment and mycological culture results.

Patients treated with isavuconazole were obtained from a database of the pharmacy service, sociodemographic and clinical variables from the OrionClinic computer program.

A descriptive statistical analysis was performed using measures of central tendency such as mean and median, through the SPSS v.23[®] program.

Results 37 patients treated with isavuconazole were included. Four patients were excluded. The median age was 63 years (24–82) and 68% were male.

Voriconazole was not contraindicated in 65% of the isavuconazole prescriptions. Thirty-five percent of the patients had renal insufficiency. The mean number of days of treatment was 6 ± 4.9 days.

A mycological culture was performed in 89% of the patients, with 78% of the results being negative.

Conclusion and Relevance A high percentage of patients treated with isavuconazole in our critical care unit did not meet the conditions for which it was included in the pharmacotherapeutic guide of the hospital. These results suggest the need for a specific PROA in critical patients or the multidisciplinary elaboration of a protocol for the use of antifungals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-035 MASS UNIFORMITY OF HARD CAPSULES: ROYAL SPANISH PHARMACOPOEIA VS UNITED STATES PHARMACOPOEIA

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Background and Importance Quality control (QC) is an important part of the quality assurance of the elaborating process in a Hospital-Pharmacy-Department (HPD). The mass uniformity is the most commonly procedure used for QC of hard-capsules.

Aim and Objectives Analyse comparatively the Royal-Spanish-Pharmacopoeia (RSP) hard-capsule mass uniformity method versus the United-States-Pharmacopoeia (USP).

Material and Methods The following parameters of each method were analysed: sample, average reference weight, percentage and acceptance requirements. Also, the elaborating process necessary to apply each method.

Finally, the elaboration of a batch of 100 hard-capsules of dexamethasone 40mg according to the HPD Standard-Operating-Procedure was taken as a reference. Then the elaborations

were retrospectively reviewed from February-2020 to February-2021.

The QC had been carried out with the RSP-method and the USP-method was then applied. For this, the theoretical weight of a capsule was calculated taking the average weight of 5 empty capsules (0.0493g) as reference and the weight of the batch content (13.8g=dexamethasone (4g) + excipient (9.8g)) calculated in the compounding design being the acceptance interval 0.169–0.206g.

Results The RSP-method requires a sample of 20 capsules and uses their average weight as a reference, while the USP-method requires a sample of 5% or 10 capsules (whichever is less) and uses the theoretical weight of a capsule as a reference. The RSP-method admits a deviation of $\pm 10\%$ or $\pm 7.5\%$ depending on the average weight; and no >2 capsules can deviate from the limits and none more than double. The USP-method accepts a limit of $\pm 10\%$ respect to the theoretical weight, and no capsule must deviate.

Regarding the compounding method, the RSP allows elaboration by volumetric filling according to the Spanish-National-Formulary (excipients weight is not required). However, the USP-method requires knowing the theoretical capsule weight, which implies weighing the excipients.

Since February-2020 to February-2021, 8 batches of dexamethasone 40mg were elaborated. They were accepted with the RFE-method. After applying the USP-method, none were rejected.

Conclusion and Relevance The USP-method is safer than the RSP-method because for the same acceptance interval ($\pm 10\%$) it does not admit any deviation. It also requires knowing the weight of all the excipients. Therefore, it is capable of detecting errors in the elaboration that the RFE-method would not detect (as long as the error is >10% and the capsules are homogeneous).

Currently, the USP-method has been incorporated in the HPD as a reference of hard capsules QC, since it provides greater safety in their preparation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-039 RAF-KINASI PATHWAY INHIBITORS IN TREATMENT OF METASTATIC MELANOMA: WHEN COMPLIANCE DOES NOT MATCH WITH TOLERANCE

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Background and Importance Background and importance: Melanoma is a malignant tumour that originates from melanocytes of the skin and mucous membranes or rarely from melanocytes located in extracutaneous sites. In 2020 in Europe, approximately 50.972 females and 55.397 males are diagnosed with melanoma, and 9.457 males and 7.031 females died because of it. 45–50% of melanomas have a mutation in the BRAF gene and the most frequent is V600E. Oncogenic mutations of BRAF lead to constitutive activation of the RAS/RAF/MEK/ERK pathway. Target therapies are the most appropriate to obtain an effective therapeutic action.

Aim and Objectives We analysed the 2 most prescribed oral associated therapies in our centre for the treatment of

mutated BRAF metastatic melanoma with the aim of identifying which is the most tolerated and highlighting the types of toxicity that emerged from real life data bases.

Material and Methods The data were extrapolated from our prescription software and from the electronic medical records of the investigated patients.

Results In the period 2019–2022 we considered 36 patients treated with Dabrafenib 75 mg + Trametinib 2 mg or Encorafenib 75 mg + Binimetinib 15 mg, 50% treated with both therapies. 33 patients started the combination therapy of Dabrafenib + Trametinib and of these only 7 (20%) did not show any severe toxicity leading to discontinuation of treatment. The most frequent toxicity was pyrexia (40%), followed by skin toxicity (25%), gastrointestinal toxicity (12.5%), asthenia (8%). Patients who discontinued treatment for progression disease were 9 (28%). Owing to unacceptable toxicity, 14 patients (43%) switched to Encorafenib + Binimetinib: only 2 of these patients showed toxicity (G1-G3 asthenia, G2 nausea) upon discontinuing treatment. 3 patients of analysed population started therapy with Encorafenib + Binimetinib as first-line treatment, without toxicity to discontinue therapy.

Conclusion and Relevance These data point out that the first choice is a combination therapy Dabrafenib + Trametinib associated with better patient compliance, thanks to more easily manageable number of tablets to take daily. However, the toxicity appears to be higher. For this reason, the therapy with a lower compliance is actually the best tolerated and prolonged therapy with fewer suspensions, ensuring better continuity of care and therapeutic efficacy.

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Conflict of Interest No conflict of interest.

5PSQ-050 ANALYSIS OF THE USE OF USTEKINUMAB FOR CROHN DISEASE IN THE REAL CLINICAL PRACTICE

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Background and Importance Ustekinumab (UST) is an anti-IL-12/23 antibody which is used in Crohn disease. Although the dosage form is defined in its data sheet, in the clinical practice, intensifications and intravenous reinductions are performed when there is a loss or inadequate of response.

Aim and Objectives To describe and evaluate the different dosage regimens of UST performed in patients with Crohn disease by relating them to biomarkers of inflammation and clinical data.

Material and Methods Observational, retrospective and descriptive study included patients with Crohn disease who started with UST (January 2017-April 2022).

Data obtained from electronic medical records was: previous treatments, faecal calprotectin (Fcal) and C-reactive protein (CRP) levels, stools daily (SD) and abdominal pain (AP), and dosage regimen.

Results 45 patients were included, 68.8% women with a mean age of 49.2. Previous treatments: adalimumab (75.5%),

azathioprine (71%), infliximab (51%), vedolizumab (11%) and methotrexate (8.8%). 31% of the patients had received two anti-TNF[\square].

Initially, 46.6% of the patients presented AP, 31% >5 SD, Fcal 382 mg/kg(30–1919) and CRP 18.3 mg/dl(<1–92).

64.4% patients underwent dose escalation: to every 4 weeks (93.1%), 6 weeks (3.4%) and 8 weeks (3.4%). Prior to this intensification, 31% presented AP, 24.1% >5 SD, mean Fcal 401.2 (11–2625) and CRP 10.4(<1–40.3). The mean time to first intensification was 426 (147–1157) days.

2 patients required a second intensification.

6 patients also underwent intravenous reinduction, who presented: 33% AP, 83.3% > 5 SD, Fcal 818 (45–1492) and CRP 18(5–23). The time from the first intensification to reinduction was 338(145–730) days. 3 patients required a second reinduction as they all presented >5 SD, Fcal 941(297–2032) and CRP 4.13.

Currently, 88.8% of patients continue with UST. Patients without intensification present Fcal 146.77 and CRP 3, while those with a shortened dosage interval present clinical remission with Fcal 175.56 and CRP 4.01. Those who had also undergone at least one reinduction presented clinical remission too with Fcal 382 and CRP 7.5.

Conclusion and Relevance UST was effective in the majority of our cohort of patients. More than half of the patients required shortening of dosage interval and a fifth part of these also required one or two intravenous reinductions to control the disease.

Conflict of Interest No conflict of interest

5PSQ-052 CHANGES IN POLYMEDICATED PATIENTS' PRESCRIPTIONS AFTER OUTPATIENT HOSPITAL CONSULTATIONS IN REAL LIFE SITUATIONS

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Background and Importance In public health system one of the main management issues is polypharmacy because of the increasing number of patients involved each year and its economic impact. On a daily basis, a high number of polymedicated patients come through the outpatient medical consultations in which, after a consultation with the doctor, it is unknown if any change in treatment is made, or drugs are stopped or added to their treatments.

Aim and Objectives The aim of this study is to analyse how polymedicated patients' prescriptions change after a medical consultation in a hospital which attends 450.000 inhabitants in the outpatient setting, under real-life situations linked to practice through the prescriber.

Material and Methods Observational prospective study of ten days duration performed in the field of hospital medical consultation with outpatient patients. We included all polymedicated patients (those with a consumption of ≥ 15 drugs/month) that come to a medical consultation in a second level hospital. Patients' number of prescriptions were analysed before and after the medical consultation. We analysed if there was any change in the medication, and whether this change was an addition, discontinuation, or substitution of treatment.

Results From 25 October 2021 to 5 November 2021, 603 polymedicated patients (women: 65.2%; average age: 74.7 \pm 10.8 years) attended the hospital's outpatient consultations of all medical specialties. In the 87% of the patients (n=522) no modification was made in their treatment by the prescriber after the consultation, and in the 13% remaining patients (n=78) the following treatment changes were made: 88 additions, 15 discontinuations and 7 substitutions of treatment.

Conclusion and Relevance More than 8 out of 10 polymedicated patients with more than 15 drugs/month who attend medical consultations do not suffer changes in their medication. In the rest of the patients, the vast majority of occasions medication is added to their treatment, and medication is rarely suspended. This study highlights the need to review and approach to handling unnecessary medication use and polypharmacy due to the increasing number of patients involved each year that may have a negative impact on patients and the healthcare system. Pharmacists could serve as advisors for the review of patients' unnecessary polypharmacy in the outpatient setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-061 NEW-ONSET MULTIPLE SCLEROSIS ASSOCIATED WITH ADALIMUMAB TREATMENT: ABOUT TWO CASE REPORTS

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Background and Importance Treatment with adalimumab offers an improvement in autoimmune diseases and it is considered well tolerated. Demyelination with adalimumab have been described in several case reports.

Aim and Objectives To describe two cases of Multiple sclerosis (MS) triggered by adalimumab treatment.

Material and Methods Descriptive and retrospective clinical cases that occurred in October 2021. Data were obtained by medical records. The causal relationship between adalimumab and MS was assessed using the Naranjo's algorithm.

Results Patient 1, 41-year-old, woman with psoriasis diagnosed 5 years ago in treatment with adalimumab for 2 years with no history of neurological disease.

She presented loss of strength, ataxia and paresthesias. She was treated with methylprednisolone for 5 days with functional improvement and adalimumab was stopped.

Magnetic resonance imaging (MRI) revealed intramedullary lesion of C2, showing two possible diagnosis: inflammatory myelitis as the first possibility or tumour origin. She presented systemic autoimmunity stigmas (positive antibodies antinuclear, oligoclonal bands (OCBs) positive in cerebrospinal fluid and serum and psoriasis).

Six months later, she had a new possible cervical outbreak. MRI showed the appearance of a parasagittal occipital cortico-subcortical lesion confirming the diagnosis of MS according to McDonald's criteria (2017). She started treatment with dimethylfumarate.

Patient 2, 43-year-old, woman with ankylosing spondylitis HLA-B27+ in treatment with adalimumab 5 months ago and no history of demyelinating diseases.

She presented ataxia and hemihypoesthesia She was treated with methylprednisolone for 5 days with functional improvement stopping adalimumab treatment.

In the MRI, multiple lesions with dissemination criteria in space (1 periventricular, 1 infratentorial), and in time (only one of them with gadolinium uptake, currently apparently asymptomatic), the patient met McDonald's criteria (2017) for MS with OCBs negative and she started treatment with ocrelizumab.

Naranjo's algorithm determined as adverse drug reactions probable in patient 1 and possible in patient 2.

Conclusion and Relevance A potential link between adalimumab and MS was related in these cases. Although this relationship have been associated in rare cases, adalimumab should be avoided in patients with history of demyelinating disorders. Patients should be informed of possible symptoms at the start of therapy and treatment should be discontinued if they develop them.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-072 ANALYSIS OF THE DURATION AND COMPLICATIONS ASSOCIATED WITH PERIPHERAL PARENTERAL NUTRITION: A COHORT STUDY

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Background and Importance Peripheral parenteral nutrition (PPN) is a widely-used and complex intravenous formulation with certain singularities. According to the European and the American Societies of Parenteral and Enteral Nutrition (ESPEN and ASPEN), an appropriate duration of PPN (7–10 days) is related to a lower number of complications such as catheter infections or metabolic imbalances.

Aim and Objectives To assess whether a longer duration of PPNs is related to an increase in associated complications.

Material and Methods A retrospective observational cohort study was conducted in adult patients hospitalised in the Digestive Service who received PPN between 1 January 2021 and 15 September 2022. The following variables were collected: demographic data (sex and age), underlying disease, duration of PPN administration reason for discontinuation and PPN-associated complications. Data were obtained from digital medical records and parenteral nutrition software (KABISOFT).

Results A total of 35 patients (34.29% female) with a mean age of 56.06 years \pm 18.44 were included. The mean number of days with PNN was 4.43 \pm 2.70, and only 1 patient received PNN for more than 10 days. The patients recruited had the following underlying diseases: intestinal inflammation (28.57%), dysphagia (25.71%), pancreatitis (20%), intestinal perforation (8.57%), achalasia (8.57%), intestinal obstruction (5.71%), and others (2.86%). The main reasons for a

discontinuation of PNN were a change to central line PN (65.71%) and the onset of oral tolerance (34.29%). Of the total number of patients (n=35), the following PNN-associated complications were recorded: phlebitis (n=14, 40%), affecting up to 60% of users with PNN for more than 5 days, and extravasation, which was reported in 9 patients (28.57%).

Conclusion and Relevance Most patients in our cohort received PNN for the duration recommended by international guidelines. In addition, a higher incidence of phlebitis was observed in those patients who continued PNN for more than 5 days.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-080 IDENTIFICATION OF PHARMACOLOGICAL INTERACTIONS BETWEEN IVACAFTOR/TEZACAFTOR/ELEXACAFTOR AND DIETARY SUPPLEMENTS/HERBS IN PATIENTS WITH CYSTIC FIBROSIS IN AN OUTPATIENT PHARMACEUTICAL CARE UNIT

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Background and Importance CFTR (cystic fibrosis transmembrane conductance regulator) modulators have meant a significant change in clinical course of cystic fibrosis (CF) patients.

Ivacaftor/tezacaftor/elexacaftor (IVA/TEZ/ELX) are metabolised by cytochrome CYP3A4/5; and tezacaftor and elexacaftor are P-glycoprotein substrates. For this reason, it is essential to review possible drug interactions (DIs) between IVA/TEZ/ELX with drugs, dietary supplements or herbs.

In Spain, dietary supplements and/or herbs use in complex chronic patients was 60–85% in 2021.

Aim and Objectives Identification and evaluation of possible DIs between IVA/TEZ/ELX and dietary supplements and/or herbs in CF adult patients.

Material and Methods Prospective interventional study conducted in an Outpatient Pharmaceutical Care Unit (OPCU) from December 2021-March 2022 that included CF adult patients who started IVA/TEZ/ELX.

Following OPCU protocol, a first structured pharmaceutical care (PC) visit was conducted at the start of IVA/TEZ/ELX to inform about dosage, administration, DIs, precautions, and adverse reactions.

Biodemographic data, *F508del* mutation, previous CFTR modulators and concomitant dietary supplements and/or herbs were collected.

Results 104 patients (53 women, median age 28.3(21.9–36.7) years) were included; 65 patients (62.5%) were heterozygous for *F508del* mutation. One patient was in previous treatment with ivacaftor, 48 patients with ivacaftor/tezacaftor and 13 patients in clinical trial or managed access programs with IVA/TEZ/ELX.

We identified 14 patients (9 women) with median age 35.1 (22.1–40.0) years who took dietary supplements and/or herbs at the start of IVA/TEZ/ELX, 13.5% of all patients.

Possible CYP3A4/5 DIs (*Silybum marianum*, *Curcuma longa*, *Hypericum perforatum*, *Bacopa Monnieri*, *Ginkgo*

biloba, *Citrus aurantium* and *Vaccinium*) were identified in five patients. Due to the possible DIs, pharmaceutical recommendation was the withdrawal of the supplements or herbs, which were suspended in all cases. In one patient, possible P-glycoprotein DI was detected (*Boswellia serrata*), but removal was not considered necessary.

Conclusion and Relevance Dietary supplements and/or herbs use in our population was lower than in other complex chronic patients. However, identification of possible DIs led to the withdrawal of the supplements and/or herbs in approximately one third of the patients.

DIs with IVA/TEZ/ELX can have great clinical relevance and impact on health outcomes. Therefore, the review of concomitant treatments in the PC visit is essential to guarantee the effectiveness and safety of IVA/TEZ/ELX.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-085 MEDICATION ADMINISTRATION IN PATIENTS WITH DYSPHAGIA: SEARCHING FOR THE BEST PHARMACEUTICAL FORM

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Background and Importance Dysphagia is usually associated to age and different conditions (neurodegenerative diseases such as Parkinson and amyotrophic lateral sclerosis (ALS), muscular dystrophy or respiratory diseases). Medication handling is very common and may affect to bioavailability, efficacy and toxicity profile of drugs, leading to administration errors.

Aim and Objectives To evaluate medication administration in patients with dysphagia by matching them to the best pharmaceutical form with recommendations on correct manipulation, after the request of reconciliation by the physician and the development of a pharmaceutical report. We also evaluated the recommendations acceptance.

Material and Methods Observational, retrospective study performed from January 2019 to August 2022. Collected data were: disease, number of drugs, suggested alternative suitable for dysphagia, drugs that cannot be handled due to their pharmaceutical form or because of being hazardous drugs, and most common active ingredients. Patients' clinical data were collected from our EHR.

Results We included 72 patients, median age was 73 (IQR 66–84), 51% women. Among them, 46% were inpatients and 54% outpatients. Most prevalent diseases were: ALS 29 patients (40%) and stroke 17 patients (24%). The median of drugs for which manipulation was evaluated was 8 (6–10) per patient. A dysphagia reconciliation report was performed in 52 (72%) patients, a median of 3 (1–4) alternatives to a more appropriate dosage form were proposed. Fifty drugs were found to be prescribed and should not be manipulated as hazardous drugs, soft capsules, extended-release or gastro-resistant tablets.

We analysed the drugs of 52/72 patients. Among the 379 active ingredients prescribed, most frequent therapeutic drug was group N (nervous system) 38,8%, group C (cardiovascular system) 20,1% and group A (alimentary tract and metabolism)

19,3%. The most prescribed active ingredients were paracetamol (26 patients), omeprazole (16), riluzole (11), and sertraline (11).

The suggested alternatives were mainly oral solutions (57%) and orodispersible dosage forms (36%).

Medical acceptance of recommendations about therapeutic alternatives adapted to swallowing disorders was 100%.

Conclusion and Relevance Dysphagia is a prevalent condition not only in elderly patients.

Medication reconciliation in patients with swallowing disorders is essential to ensure treatment efficacy.

Elaboration of pharmaceutical reports with treatment alternatives is very useful in hospital setting and during transitions of care.

Acceptance has been very positive by both physicians and patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-088 EXPLORING THE NEED FOR A CHECK OF COMPOUNDING APPROPRIATENESS SERVICE: EVALUATION OF SPONTANEOUS CHECKS BEFORE COMPOUNDING AT A LARGE TERTIARY CARE HOSPITAL

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Background and Importance Medication errors (MEs) occur in 5% of drug administrations in inpatients. Avoiding MEs is key to improve patient safety. Our centre implemented the Check of Medication Appropriateness (CMA), a back-office validation service, which significantly reduces potentially inappropriate prescriptions (PIPs). However, prescriptions for compounded medicines are lacking in this validation system.

Aim and Objectives The aim of this study was to evaluate which checks are currently performed in a spontaneous and implicit way for prescriptions of compounded medicines. These checks identify possibilities for future development of an explicit and standardised service called the 'Check of Compounding Appropriateness' (CCA).

Material and Methods An anonymous e-questionnaire was implemented at the compounding unit of our centre. Pharmacists and pharmacy technicians were asked to complete the e-questionnaire for every prescription of compounded medicines for which they performed implicit and spontaneous checks.

Results Data saturation was obtained after two months yielding registrations for 315 prescriptions, accounting for 30% of total compounded prescriptions. Top category formulations included capsules (n = 240) and ointments & creams (n = 26), accounting for 84%. Eighty-nine percent (n = 281) of the prescriptions were ordered electronically instead of paper prescriptions. In total 1002 (clinical) checks were performed for the 315 prescriptions leading to the identification of 120 PIPs (38.1%). Ninety-four PIPs accounted for a logistic problem, mainly substitution (n = 58) or double order (n = 11);

25 were clinical PIPs, mainly incorrect dosing (n = 15); one PIP contained both a clinical and logistic problem. In 67.5% of PIPs, colleagues were contacted. In prescriptions with PIPs, the final action included cancellation of the preparation because of substitution to a commercially available drug/stock preparation (50.0%), cancellation of the preparation due to other reasons than substitution (23.3%), compounding of an adapted prescription (13.3%) and compounding of the original prescription (13.3%).

Conclusion and Relevance PIPs also occur in prescriptions for compounded medicines. At our centre, these PIPs mainly include logistic and dosing problems. Next to the set-up of back-office CCA, this survey revealed that prescribing support, such as a substitution or dosing module, should be implemented to increase the efficiency at the compounding unit and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-092 PHARMACOVIGILANCE OF BIOLOGICAL THERAPIES FROM THE OUTPATIENT DEPARTMENT

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Background and Importance Pharmacovigilance has an essential role in monitoring outpatient treatments. As healthcare professionals we have the responsibility to report suspected adverse drug reactions (ADRs), so these data can be analysed by pharmacovigilance centres to determine the causality of possible unknown risks or changes in the severity and frequency of those already known.

In the last decade, the rise of biological therapies as standard treatment in a huge array of pathologies in outpatient practices has led us to focus our project on them.

Aim and Objectives Analyse suspected ADRs reported to the National Pharmacovigilance System of the Agency of Medicines and Health Products (AMHPS), from the outpatient department in a central Hospital Pharmacy.

Material and Methods Single-centre observational retrospective study of suspected adverse reactions reported over a three-month period [July 2022 – September 2022]. The following data were collected: age, sex, treatment, indication, date of initiation, ADRs type and duration. Results were compared with the AMHPS National database, which is updated every 3 months.

Results In these months, we reported seven suspected ADRs. Most of them were reported in women (85,8%), with a mean age of 49,6 years (32–64). The biological therapies suspected of triggering ADRs were adalimumab, sarilumab, etanercept, abatacept, erenumab and galcanezumab. The adverse reactions reported were mostly related to the presence of infections (42,8%), followed by muscle disorders (28,6%), nausea (14,3%) and neutropenia (14,3%). Among the biological therapies used, the one associated with the highest number of notifications was sarilumab (28,6%) and the most frequent indication was rheumatoid arthritis (57,14%).

Conclusion and Relevance Comparing the results with the AMHPS database, in our population we observe a greater number of notifications for sarilumab, being the one with

the fewest national notifications, probably related to its recent authorisation and not being used in first-line treatments. On the other hand, in the overall number of national ADRs notifications, infections are not the most frequent ADR, being in the first place musculoskeletal and gastrointestinal disorders.

It is important to be aware of the role of pharmacists and all healthcare professionals in contributing to the detection of ADRs. Collecting this data and taking a global view of it by healthcare institutions allows to improve safety in outpatient treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-098 SAFETY AND PERSISTENCE OF ANTI-FIBROTIC DRUGS IN INTERSTITIAL LUNG DISEASES

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Background and Importance Interstitial lung diseases (ILD) is a group of rare diseases with bad prognosis, being Idiopathic pulmonary fibrosis (IPF) the most frequent of them. They can be treated with antifibrotic drugs: nintedanib or pirfenidone. However, these drugs have a high rate of adverse effects, which has a significant impact on treatment persistence.

Aim and Objectives To analyse the safety of pirfenidone and nintedanib in patients with ILD as well as treatment's persistence, in a third-level hospital.

Material and Methods Retrospective observational study of patients with ILD treated with antifibrotic drugs from January 2016 to August 2022. Variables: sex, age, drug, duration of antifibrotic treatment, associated drug, switch to another antifibrotic drug, side effects, discontinuations, deaths. Information was collected from the hospital's information systems.

Results 66 patients, 67% men, mean age 67 (47–86).

44 patients with nintedanib: 23 IPF, 14 progressive pulmonary fibrosis (PPF), 2 ILD associated with systemic sclerosis, 4 fibroemphysema and 1 ILD not classified. 5 of them were treated with an associated immunosuppressive drug: mycophenolate mofetil. 12 patients needed a dose reduction due to gastrointestinal effects: 100% diarrhea, 80% nausea. 1 patient needed temporary discontinuation due to increased transaminases, which were finally stabilised, being able to return to a higher dose. 2 patients needed discontinuation of treatment due to bleeding: 1 patient was on antiplatelet therapy and the other had a background of epistaxis. These two patients switched to pirfenidone.

22 patients with pirfenidone: all of them IPF. 2 patients needed dose reduction due to diarrhoea and 2 needed treatment discontinuation due to severe sunburns. These patients switched to nintedanib.

Persistence until progression 18 months with nintedanib and 24 months with pirfenidone. 8 patients died during treatment, 4 of them because of COVID-19 infection.

Conclusion and Relevance Thanks to a close follow-up in patients with ILD, it is possible to modify the dose and to achieve greater tolerance to treatments. The pandemic affected negatively during the year 2020, not only because of the impossibility of receiving medical appointments, but also due

to the acceleration of their death. The rapid establishment of anti-fibrotic treatment and the adequate control of adverse effects are the key for this type of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-104 ERRORS IN ACENOCOUMAROL RECONCILIATION IN PATIENTS ADMITTED FROM THE EMERGENCY DEPARTMENT

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Background and Importance Acenocoumarol is an anticoagulant derived from coumarin, which acts as a vitamin K antagonist. Its dosing regimen is adjusted according to the desired international normalised ratio (INR). Given its great inter and intraindividual variability, very disparate dosing is required, and the narrow therapeutic margin makes it a drug that is very susceptible to adverse drug events.

Aim and Objectives The aim of this study is to detect errors in the reconciliation of treatment with acenocoumarol in patients admitted to the emergency department.

Material and Methods Descriptive, observational, retrospective study, which included all patients over 18 years of age, treated with acenocoumarol, admitted to the hospital in April 2022. The primary endpoint was the incidence of acenocoumarol prescribing errors in the emergency department. The weekly dose prescribed in hospital and the weekly outpatient dose were compared. The following variables were also obtained: sex, age, medical observations on acenocoumarol prescription, pharmacy treatment reconciliation report, and whether the regimen was adjusted during hospitalisation. A descriptive statistical analysis was performed using measures of central tendency such as median and mean, using the SPSS v.23® program.

Results 31 patients treated with acenocoumarol were included who were admitted to the emergency department in April 2022. Sixty-one percent were men and the median age was 80 ± 12 years (RIQ, 72–85). Prescribing errors were found in 58% (18) of patients, with a higher than expected dose in 19%. Of these patients, the prescriber recorded a note in 61% of patients and the pharmacy service requested treatment reconciliation in 56%. Among the 18 patients with prescribing errors, the regimen was corrected before hospitalisation in 6%, while in 56% the regimen was not adjusted during admission. In 1 patient an overdose with acenocoumarol was observed, causing a serious adverse effect that required treatment.

Conclusion and Relevance In our study we observed a high percentage of prescription errors with acenocoumarol during hospital admission. This shows the need for treatment reconciliation in the emergency department. The erroneous regimen is maintained during hospital stay in 56% of patients, which can lead to serious medication errors. We conclude that the variable dosing of acenocoumarol requires greater attention on the part of health staff when reconciling treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-105 DEVELOPMENT OF HYPOMAGNESEMIA IN CRITICAL PATIENTS TREATED WITH ISAVUCONAZOLE

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Background and Importance Isavuconazole is an antifungal drug belonging to the triazole group. It is indicated in invasive aspergillosis and mucormycosis in patients for whom amphotericin B is not appropriate. A rare adverse effect of this drug is hypomagnesemia (from $\geq 1/1,000$ to $1/100$ cases per patient according to the technical data sheet), which can trigger other electrolyte disturbances such as hypocalcemia or hypokalemia.

Aim and Objectives The aim of this study is to observe the occurrence of hypomagnesemia in a cohort of patients treated with isavuconazole.

Material and Methods Descriptive, observational, retrospective, single-centre, retrospective study, in which all patients over 18 years of age, who were treated with isavuconazole throughout the year 2021, were included. Exclusion criteria were: age less than 18 years, pregnancy or treatment duration less than 24 hours. The main variable under study was the incidence of hypomagnesemia. The variables collected were: sex, age, plasma magnesium concentration before starting treatment with isavuconazole and at the end of treatment, number of days of treatment, need for intravenous magnesium sulfate rescue and concomitant treatment with proton pump inhibitors. A descriptive statistical analysis was performed using measures of central tendency with SPSS v.23®.

Results 37 patients treated with isavuconazole were included. Four patients were excluded. The median age was 63 years (Min-Max, 24–82) and 68% were men. The mean number of days of isavuconazole treatment was 6 ± 4.9 days. Plasma magnesium concentration was measured in 18 (49%) of the patients, of whom 12 were being treated with proton pump inhibitors. The mean plasma concentration before starting treatment was 0.88 ± 0.18 mmol/L, while the mean at the end of treatment was 0.79 ± 0.14 mmol/L. Hypomagnesemia was detected in 17% of patient safter treatment and 11% required rescue with intravenous magnesium sulfate.

Conclusion and Relevance In this observational study of patients treated with isavuconazole, we observed that the occurrence of hypomagnesemia is more frequent than described in the drug technical data sheet. Since hypomagnesemia is a known adverse reaction to the administration of this antifungal drug, and that it can cause other electrolyte alterations, it may be advisable to monitor plasma magnesium levels more closely during the duration of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-112 RELATIONSHIP BETWEEN EFFECTIVENESS AND IMMUNE-MEDIATED TOXICITY OF IMMUNE CHECKPOINT INHIBITORS IN ADVANCED NON-SMALL-CELL LUNG CANCER

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Background and Importance According to some data, there is evidence suggesting correlation between immune-related adverse events (irAEs) and favorable clinical outcomes in several tumour types during the treatment with immune checkpoint inhibitors.

Aim and Objectives To assess the presence of irAEs and if it is associated with clinical benefit in patients diagnosed with non-small-cell lung cancer who are treated with immune checkpoint inhibitors.

Material and Methods Observational and retrospective study including patients with NSCLC treated with pembrolizumab, atezolizumab or nivolumab in first or second-line therapy (March 2018- August 2022). To assess treatment effectiveness, the overall survival (OS) and progression-free survival (PFS) were evaluated with Kaplan-Meier method. The survival curves were compared based on the presence of irAEs or not. The severity of irAEs were graded based on National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

Results 133 patients were evaluated: 74% men, mean age of 66.84 ± 9.06 , 58% adenocarcinoma, PD-L1 >50% 46% and 82.7% ECOG 1.

54.8% received pembrolizumab, 30.8% atezolizumab and 14.3% nivolumab.

The mean duration of treatment was 8.4 ± 10.4 months.

194 irAEs were recorded. 61.6% of the patients experienced almost one irAEs of any grade. Incidence of toxicity was more likely with pembrolizumab (59,8%). Severity of the irAEs were mild (grade 1) in most cases (78.3%), followed by moderate (grade 2) 15.4%, severe (grade 3) 5.6% and life-threatening (grade 4) 0.5%.

The most common irAE were gastrointestinal (36%), followed by cutaneous(22%), musculoskeletal (11%), haematological (9.3%) and endocrine (6.7%).

In 5.3% of patients the treatment had to be permanently retired due to toxicity, while 14,3% the treatment was temporarily discontinued until the irAE resolution. However, 2.2% needed a hospital admission until irAEs was released.

The median PFS was 8.2 months in patients who have an irAE and 2.2 months in those without it ($p < 0.05$). The median OS was 10.9 months in patients who have an irAE and 3 months in those without it ($p < 0.05$).

Conclusion and Relevance In our cohort of patients, more than a half underwent at least one irAE, being pembrolizumab the drug that has produced most irAEs. The presence of irAE was significantly associated with improved PFS and OS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-114 PERSISTENCE AND LEVEL OF CLEARANCE IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS TREATED WITH GUSELKUMAB

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Background and Importance Recent publications indicate that there are currently certain unmet needs shown by patients, highlighting the rapid onset of action and the persistence of the drug related to the increase in quality of life and the decrease in the stigma of the pathology. The appearance of new therapeutic targets presents us with a hopeful future in the treatment of psoriasis. In this context, it is of interest to know the persistence of guselkumab, the first anti-IL 23 marketed in 2017.

Aim and Objectives To evaluate the persistence and complete skin clearance of guselkumab in all patients with moderate-severe psoriasis in our hospital.

Material and Methods Retrospective descriptive study conducted from the first prescription of guselkumab, May 2019, to September 2022. The electronic clinical record and the Farmatools application were used to record the following variables: age, sex, previous biological treatments, duration of therapy, posology and Psoriasis Area and Severity Index (PASI). The guselkumab regimen was 100 mg subcutaneously at weeks 0 and 4, followed by a maintenance dose of 100 mg every 8 weeks, in some patients the dose interval is longer in maintenance adjusted for drug response.

Results Forty-four patients were included (52% men), aged 54 ± 13 years. 50% of the patients were treated with a previous line, 39% with 2 or more lines, and 11% were naive for monoclonal antibody (mAbs). Two patients discontinued during induction due to primary failure and one due to adverse reaction. There were 2 losses to follow-up. The overall mean persistence was 758 (± 312 days).

Currently 32 patients continue in treatment with guselkumab, 61% presented PASI 0 in the last clinical evaluation. 34% have an optimised schedule: 22% every 10–12 weeks, 9% every 16 weeks, and one patient takes it every 24 weeks.

Conclusion and Relevance High levels of persistence and level of clearance of guselkumab in our clinical practice, which 90% of patients have been previously treated with mAbs, are in line with the 5 year results presented by Reich K. et al.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-117 EVALUATION OF CARDIOTOXICITY BY OSIMERTINIB IN CLINICAL PRACTICE

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Background and Importance Osimertinib is a tyrosine kinase inhibitor (TKI) indicated for the treatment of epidermal growth factor receptor mutated non-small-cell lung cancer (NSCLC). Despite a better safety profile than other TKIs for the same indication, osimertinib could produce some potentially fatal cardiotoxicity. However, the available evidence on cardiotoxicity in clinical practice is very limited.

Aim and Objectives To analyse the incidence of cardiotoxicity associated with osimertinib in the real clinical practice.

Material and Methods We conducted an observational cross-sectional study in a third-level hospital in Spain. We included all adult patients diagnosed with NSCLC treated with osimertinib between February 2018 and May 2021. We collected socio-demographic data and treatment characteristics, as well as cardiological history, all events of cardiac toxicity during treatment and other comorbidities. Descriptive statistical analysis was performed.

Results 33 patients were included, with a median age of 72.5 (interquartile range [IQR]= 62.2–81.0) years, and 63.6% were women. The indication for osimertinib was metastatic lung adenocarcinoma (32 patients, 96.7%) and epidermoid non-small-cell lung cancer (1 patient, 0.3%). It was used as the first-line of treatment in 39.4% of the patients and as the second-line or successive in 60.6% of them.

At the start of treatment, 57.6% of the patients had cardiovascular comorbidities. The most frequent comorbidities were arterial hypertension (48.5%), dyslipidemia (36.4%), and diabetes mellitus (12.1%), and one patient was diagnosed with congestive heart failure.

The median time on osimertinib treatment was 11.0 (IQR= 4.6–17) months. Of the 33 patients, 21.2% of patients had previous cardiac examinations before starting osimertinib treatment. During the treatment, 4 (12.1%) patients developed cardiac adverse reactions: 2 (6.1%) suffered a decrease in the Left Ventricular Ejection Fraction (LVEF), 1 (3.0%) experienced atypical chest pain, and 1 (3.0%) developed an increase in the D-dimer and hyperfibrinogenemia. One of the patients with LVEF decreased required hospitalisation and invasive management. The rest of the cardiotoxicities were managed with dose reduction and conservative measures.

Conclusion and Relevance More than 10% of osimertinib-treated patients had cardiotoxicity. Of these, 25% required hospitalisation. Oncologists should always assess cardiac function at the start of osimertinib and during the follow-up.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-121 CYTOKINE RELEASE SYNDROME RELATED TO THE TREATMENT WITH TECLISTAMAB: A CASE REPORT

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Background and Importance Teclistamab is a bispecific antibody (BsAb) targeting the CD3 receptor complex on T cells and BCMA on B cells. This treatment is the process of approval for patients with relapsed or refractory multiple myeloma (RRMM). It is only available in some countries through an Expanded-Access Program. The posology consists of two set up-doses of 60 and 300 µg/Kg separated 2–4 days, and treatment doses of 1500 µg/Kg administered weekly. Hospitalisation is required for at least 48 hours from the start of administration of the two set-up doses and the first treatment dose.

It has been observed that the administration of BsAb such as Teclistamab might cause the cytokine release syndrome (CRS). CRS is a potentially life-threatening, systemic inflammatory response.

Given the BsAb market is growing rapidly, it is important to train the healthcare professionals to good handling these adverse reactions.

Aim and Objectives To describe the CRS produced by Teclistamab in one patient with RRMM and the management of this adverse reaction.

Material and Methods A case report identified in a tertiary hospital in 2022. Clinical data were collected through the electronic medical record.

Results A 76-year-old man with hypertension history and diagnosed with RRMM, was admitted to hospital to be treated with Teclistamab. Just 24 hours after the first set-up dose, the patient experienced CRS-related symptoms such as chills and a hypertensive crisis (300/140 mmHg). He was treated with a dose of Tocilizumab 600 mg, corticosteroids, antipyretics and oral antihypertensives, without clinical improvement. The patient was transferred to the Intensive Care Unit (ICU) for the management of his hypertension. At the ICU, he received two more doses of Tocilizumab 600 mg every 8 hours. The hypertension was controlled with oral antihypertensive drugs and the patient was discharged from the ICU the following day.

The subsequent doses of Teclistamab were well tolerated and the patient did not experience any other adverse reaction.

Conclusion and Relevance Although CRS is predictable in patients who receive BsAb and it is well controlled with Tocilizumab, it is important to monitor the patients within the 24–48 hours after the first administration of Teclistamab. This monitoring is particularly crucial for those patients with history of arterial pressure alterations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-126 EFFECTIVENESS AND SAFETY OF OMALIZUMAB, MEPOLIZUMAB AND BENRALIZUMAB IN PATIENTS WITH SEVERE UNCONTROLLED ASTHMA

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Background and Importance Despite following adequate treatment, a high percentage of patients with asthma is not controlled; therefore, alternative treatments that are effective and safe are necessary, especially in patients with severe uncontrolled asthma. Among the new treatments for asthma,

biological therapy with monoclonal antibodies against selective targets may be a suitable option.

Aim and Objectives To assess the effectiveness and safety in routine clinical practice of omalizumab, mepolizumab and benralizumab in patients with severe uncontrolled asthma.

Material and Methods Retrospective observational study in a regional hospital undergoing patients diagnosed with severe asthma treated with omalizumab, mepolizumab and benralizumab. Effectiveness was assessed based on oral corticosteroid dose reduction, exacerbations and improvement in lung capacity. Safety was demonstrated based on adverse effects onset. Data was obtained from clinical history program and drug dispensing program.

Results 30 patients (53% women) with a median age of 56 years (range: 16–78) have received biological drugs in our hospital to treat severe uncontrolled asthma. 9 patients were treated only with omalizumab, 5 with Mepolizumab, 2 with benralizumab; 7 patients sequentially omalizumab→mepolizumab, 5 cases omalizumab→benralizumab and 2 with the three drugs sequentially.

52% of patients on omalizumab, 71% of patients on mepolizumab, and 78% on benralizumab experienced a decrease in oral corticosteroid dose. Regarding exacerbations: 65% omalizumab, 85% mepolizumab and 78% benralizumab reduced the number of exacerbations. Improvement in lung capacity as a function of Forced Expiratory Volume in 1 second (FEV1) was observed in 74% of patients on omalizumab, 79% on mepolizumab, and 89% on benralizumab. Adverse reactions occurred in 5 cases treated with omalizumab: arthralgia (2), headache, tiredness, cough; 2 cases with benralizumab: skin rash, nasal congestion; and one case of hypertension with the administration of mepolizumab.

Conclusion and Relevance Treatment with omalizumab, mepolizumab and benralizumab in severe asthma is effective in most patients under normal clinical practice conditions. The frequency of adverse effects is low, being mild in most cases, so they can be considered safe drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-128 THROMBOPROPHYLAXIS IN THE EMERGENCY DEPARTMENT. ADEQUACY OF THE PRESCRIPTION

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Background and Importance In Europe, the VITAE study estimates an annual incidence of venous thromboembolic disease (VTD) of 243/100,000 inhabitants.

About 25% of VTD cases are related to hospital admissions and 50–75% of VTD cases occur in non-surgical hospitalised patients. PRETEMED is a validated thrombotic risk (TR) scale for clinical prediction that have been designed to be used in daily clinical practice. As well, it is recommended to assess the bleeding risk (BR) with another validated scale called IMPROVE scale before starting thromboprophylaxis (TP).

Aim and Objectives Determine the (TR/BR) and analyse whether the prescription of thromboprophylaxis in patients from the Emergency Department who are going to be admitted to the hospital ward is adequate.

Material and Methods Prospective observational cohort study, carried out in a 2nd level hospital during a period of 10 days. Adult patients in the ED awaiting admission to the hospital ward were included.

Patients with therapeutic effort limitation, COVID-19 patients, those who had been transfused in the last 48 hours, bleeding patients or those with underlying pathology that require anticoagulation were excluded. Using the PRETEMED/IMPROVE scales, the TR/BR was determined, as well as the indication of thromboprophylaxis.

Results 62 patients. 31 women (50%). The median age [range] was 71 [18–93] years. 31 patients with TP regimen, no interventions had to be performed, they had an adequate indication with PRETEMED > 4 and IMPROVE < 7. 31 patients without TP regimen; 7 (23%) of them had indication for TP and they went into the operating room with PRETEMED > 4 and IMPROVE < 7. 7 (11.3%) of the patients required pharmaceutical intervention to adequate their TP, all of them by default.

Conclusion and Relevance The prescription of TP in adults who visit the ED could be considered adequate in a high percentage, however it can be optimised according to the PRETEMED and IMPROVE guidelines. It is essential to recommend on the use of scales that assess TR/BR for the correct decision-making in the prescription of TP. The limitation of the study was the small sample size.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-130 OFF-LABEL USE OF CIDOFOVIR INTRALESIONAL INJECTIONS IN EXTENSIVE ANOGENITAL CONDYLOMATOSIS: A CASE REPORT

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Background and Importance Genital warts caused by human papillomavirus (HPV) in condylomatosis often show a variable response to recommended therapies, especially in immunocompromised patients. New alternatives to improve their approach are needed.

Aim and Objectives To describe the effectiveness, safety, and preparation of cidofovir intralesional injections (ILI) for the treatment of HPV condylomatosis in an immunocompromised patient.

Material and Methods We describe the case of a 33-year-old woman with a giant perianal condylomata accuminata (affecting the clitoris, labia majora and minora, vagina, anal canal and both nae). She was initially immunocompromised due to a renal transplant (no renal graft at the starting of cidofovir) and a late-detected common variable immunodeficiency. Condylomatosis precipitated several episodes of bacterial cellulitis. The patient had been previously treated with liquid nitrogen, podophyllotoxin, imiquimod 5%, sinecatechins and 5-fluorouracil, obtaining no response.

Off label treatment with monthly cidofovir ILIs for cytoreductive purposes was proposed and approved. Response to cidofovir ILIs was assessed by reduction in both the number and size of anogenital warts.

Results Cidofovir ILIs were prepared by diluting a vial of cidofovir 375 mg in 60 ml of 0.9% sodium chloride, obtaining a final concentration of 6.25 mg/ml. Of these 60 ml, 5 syringes of 12 ml were loaded (75 mg of cidofovir in each one), which have a stability of 5 months refrigerated (2–8°C), according previous studies.

Intralesional cidofovir treatment started in February 2022. After three drug administrations, a significant improvement in lesions was described by a reduction in both their volume and extension. A bad odor of superficial exudate was also reported, which was solved with first polymyxin and later fusidic acid, both administered topically, twice a day. The patient presented good tolerance to injections, only requiring local anesthesia with lidocaine for pain.

Conclusion and Relevance This is the first case of use of this formulation of cidofovir ILIs in a patient with anogenital condylomatosis and immune deficiency. Previously, it was used in other manifestations of HPV infection. The formulation also proved to be stable, well-tolerated, and easy to prepare. Therefore, this therapy may be considered a reasonable option for the treatment of HVP condylomatosis when other treatments seem ineffective.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-131 LETERMOVIR, GANCICLOVIR AND IMMUNOGLOBULINS COMBINATION TREATMENT IN AN IMMUNOCOMPROMISED PATIENT WITH CYTOMEGALOVIRUS INFECTION: A CASE REPORT

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Background and Importance Cytomegalovirus (CMV) is one of the most common pathogens in immunocompromised patients. Patients who develop severe CMV infection should be treated with antiviral agents until symptoms are resolved

and plasma CMV load is controlled. Management of these patients is sometimes difficult due to resistance or ineffectiveness.

Aim and Objectives To describe the response to combined treatment with letermovir, ganciclovir and anti-CMV immunoglobulins (Ig) for CMV infection in an immunocompromised patient refractory to monotherapy treatments.

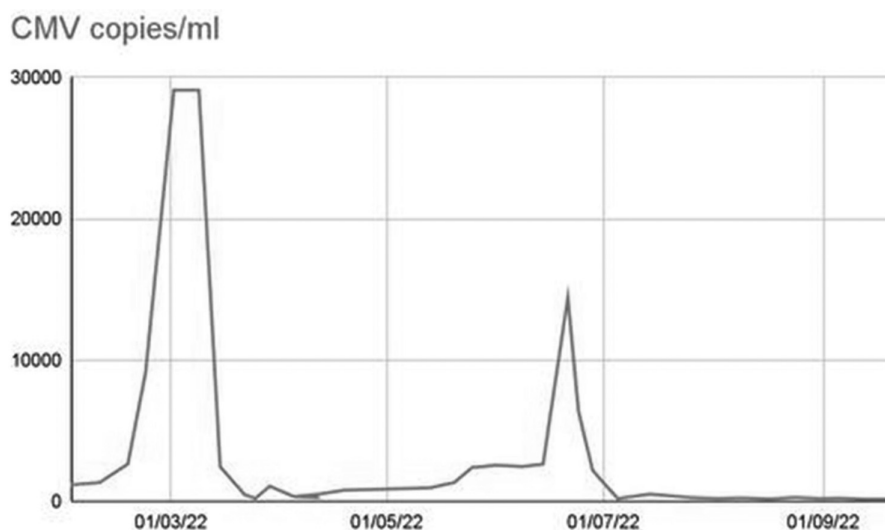
Material and Methods We describe the case of a 72-year-old male diagnosed with Good's syndrome (thymoma-associated immunodeficiency), who developed enterocolitis and systemic infection by CMV. Initially, treatment with IV ganciclovir produced clinical and virological response, but later relapse occurred and resistance to ganciclovir was detected. IV Foscarnet was initiated, obtaining response. After switching to oral letermovir (secondary prophylaxis) having low plasma CMV levels, the patient showed virological failure and foscarnet therapy was reinitiated. After a transient response, foscarnet proved to be insufficient (alone or in combination with ganciclovir) to stop a progressive rise in CMV plasma levels. To control CMV and facilitate intravenous to oral switch, combined treatment with oral letermovir and IV ganciclovir was proposed, added to anti-CMV Ig that the patient was already receiving monthly since the onset of CMV infection.

Effectiveness of this triple therapy was assessed by reduction of CMV plasma load.

Results When absence of letermovir resistance was confirmed, combined off-label use of letermovir, ganciclovir and anti-CMV Ig was approved. The authorisation was based on the absence of therapeutic alternatives and the support of several cases reflecting the good results of this triple therapy.

Despite an initial peak in CMV viral load, triple therapy exhibited a good virological response (CMV <1000 copies/ml) and tolerance. No renal or bone marrow toxicity was detected. IV Ganciclovir was later replaced by valganciclovir for home treatment, maintaining low levels of CMV <300 copies/ml.

Conclusion and Relevance This is the first case of letermovir-ganciclovir-antiCMV Ig combined therapy in a patient with acquired immune deficiency. Previously, it was used in a small cohort of transplant patients. Therefore, this triple therapy should be considered as a possible therapeutic



Abstract 5PSQ-131 Figure 1

alternative for refractory CMV infection, even if resistant to ganciclovir.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-142 EVALUATION OF ADEQUACY, ADHERENCE AND SAFETY OF HUMAN IMMUNODEFICIENCY VIRUS POST-EXPOSURE TREATMENT

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Background and Importance Preventing human immunodeficiency virus(HIV) transmission is a major public health challenge. Consideration is given to the role of post-exposure treatment(PEP) of HIV prevention strategies.

Aim and Objectives To describe the adequacy, adherence and safety of PEP.

Material and Methods A retrospective observational study conducted in a tertiary hospital: patients older than 16 years old treated with PEP who consulted to emergency department(ED) January 2021-july 2022. Sex, age, risk and type exposure, adequacy of PEP based in clinical guidelines (<72 hours to start PPE, combination:EMTRICITABINE/TENOFOVIR/RALTEGRAVIR), previous PEP, HIV-status source, basal/monthly serology, dispensing-shift, suitable patient for pre-exposure treatment(PrEP), adherence, completeness and safety of PEP were collected as variables. Statistical analysis was performed using Stata MPv17.0.

Results 70 patients(67.14% men; median age 24.44, Interquartile range[IQR:21.69–35.91]) visited de ED 77 times to get PEP: 5/70(7.14%) presented twice and 1/70(1.43%) three times. 13/70(18.57%) were suitable to start PrEP and 1/13 had already started PrEP.

67/77(87.01%) of dispensing treatment were carried out in our centre and 70/77(90.90%) were the standard combinations. Exposure risk were: 36/77(46.75%) low, 32/77(41.56%) minimum, 7/77(9.09%[CU1]) high and 2/77(2.60%) unknown. Of all, only 3/77(3.89%)PEP were not adequate according clinical guidelines. All patients were provided by pharmaceutical care and a large proportions of all PEP visits 46/77 (59.74%) were between 10pm-8am.

75/77(97.40%) of exposure were non-occupational: 54/75 (72%) sexual exposure, 18/75(24.00%) suspected sexual aggression and 3/75(4.00%) accidental puncture. Most of HIV-status of the source were unknown(63/77;81.82%), followed by positive status(12/77;15.58%) and negative status (2/77;2.60%). HIV serologies at the baseline were negatives(72/77) or unknown(4/77) except 1 who had positive status. In the monthly serology, most of the patients had a negative result(55/76) or unknown due to loss of follow-up(LFU)(21/76).

After finishing PEP, 60/77(77.92%) patients had adherence, 8/77(10.39%) had no-adherence and 12/77(15.58%) unknown because of LFU.

21/77(27.27%) PEP were not finished due to LFU(15/21;71.43%), medical decision (5/21;23.81%) or treatment intolerance(1/21;4.76%).

Side effects(SE) were reported in 24/77(31.17%):(4;16.66%) patients reported moderate SE[CU2].

Abstract 5PSQ-142 Table 1

| SE | % |
|------------------------|-------|
| GASTROINTESTINAL | 65.62 |
| CENTRAL NERVOUS SYSTEM | 19.35 |
| PSIQUIATRIC | 6.45 |
| GENERAL DISORDERS | 6.45 |

Conclusion and Relevance In summary, PEP decision-making was adequate in the majority of visits. It should be noted the large number of patients who are LFU[CU1] . Therefore, work should be done to avoid such losses.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-002 WHAT'S ANOTHER PEER? EXPLORING THE USE OF NEAR PEER TEACHING OF MEDICATION HISTORY TAKING IN PHARMACY UNDERGRADUATES IN THE UK

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Background and Importance Ten Cate and Durning (2007)¹ propose that a fundamental goal of higher education is to achieve 'progressive independence of the learner'. They argue that when fostering independent thought and decision-making, learning may also incorporate elements of teaching and mentorship. One way to achieve this is to facilitate the teaching of others or the concept of 'peer' or 'near peer' teaching (NPT). Final year pharmacy students were introduced to the concept of NPT via a workshop and then taught second year pharmacy students completing medication histories on placement.

Aim and Objectives To explore final year undergraduate pharmacy students' experiences of near peer teaching as part of their hospital experiential learning programme.

Material and Methods This qualitative study involved the use of a focus group in February 2022, with eight final year students who had taken part in NPT on placement in December 2021. A topic guide directed the discussion of the focus group which was digitally recorded. The data was transcribed verbatim, and the transcript analysed using Thematic Analysis.²

Results Four main themes were identified from the analysis. The theme of 'relationships' had subthemes of 'trust', 'role modelling' and 'being valued'. The theme of 'emotions' had subthemes distinguishing negative and positive feelings as a result of feedback. The theme of 'curriculum and organisational culture' had subthemes of 'timing' and format of feedback' and 'feedback literacy'. Finally, the theme 'views of peer teaching' had the subthemes of 'power' and 'two-way learning'.

Conclusion and Relevance Final year pharmacy students demonstrated an appreciation for the teaching activity, stating it had improved their confidence and enhanced their professional identity. They indicated that their second year peers benefitted from the activity as they learnt to take accurate medication histories. As the UK Pharmacy degree will be updated in line with new standards this year, it is imperative that students

have the opportunity to meaningfully engage in NPT to foster independence.

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Conflict of Interest No conflict of interest.

6ER-003

THE CLIMATE EMERGENCY, HOW CAN PHARMACY MAKE A DIFFERENCE?

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Background and Importance Climate change is acknowledged as 'the most significant health threat that modern society has ever faced'(1). Medicines alone are responsible for 25% of the NHS's carbon emissions. One aspect that needs to be explored is what is currently being taught in this area at undergraduate level.

Aim and Objectives To identify any current sustainable healthcare teaching included within pharmacy degrees in the UK. To establish whether respondents felt it was important for sustainability to be included within pharmacy degree programmes.

Material and Methods Two questionnaires, one for academics in the schools of pharmacy, and one for undergraduate pharmacy students, were compiled on Microsoft Forms. The staff questionnaire was sent to the Heads of School in all UK schools of pharmacy for completion by the most suitable staff member. The Head of School was asked to forward the student questionnaire link to their final year pharmacy students. Data was analysed using Excel and Chi squared. Ethical approval was gained from Queens University Belfast.

Results The staff questionnaire response rate was 28.6% (8/28). The student response rate for Northern Ireland institutions was 30.2% (42/139), an estimated response rate of 4.7% (14/300) was gained from respondents studying in Scotland. No responses were received from pharmacy students studying at Welsh or English universities. The majority of respondents (students: 98.2% staff: 87.5%) thought sustainability teaching was important. When students were asked if their Pharmacy degree had prepared them to apply sustainability in the pharmacy profession all respondents (100%) replied 'No' or 'Don't know'. All staff respondents replied 'No' to the same question. All student respondents stated that less than 5 hours teaching in sustainability had been delivered in their degree to date.

Conclusion and Relevance Sustainable healthcare teaching within UK pharmacy degree programmes is limited. There is a disconnect between student respondents 'lived experience' of sustainable topics in the MPharm and staff knowledge of the intended curriculum. There is a need for this content to be included in future Pharmacy degrees.

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Conflict of Interest No conflict of interest.

6ER-006

CURRENT PERFORMANCE OF HOSPITAL PHARMACY SPECIALISTS TRAINED AT A TERTIARY HOSPITAL IN SPAIN

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Background and Importance Professional success may be an indicator of quality of specialised training. Pharmacy services should analyse the employment of their residents.

Aim and Objectives To describe and analyse a cohort of specialists trained at a tertiary hospital as quality control of the teaching performance.

Material and Methods Names, gender, residency start dates, and current job position of all residents trained in our tertiary hospital from 1979 to the present were recorded. The current jobs were classified as: deceased, retired, never worked, community pharmacy, public administration, primary care pharmacy, hospital pharmacy, currently in the training period, or other. For hospital pharmacy jobs, it was tabulated whether it was in a public or private one and the Spanish province where it is located (or a foreign country).

Results In 43 years (1979–2022), 80 professionals (54 women, 67.5%) have started their residency in our department. The distribution by five years of the proportion of women is presented in table 1.

Abstract 6ER-006 Table 1

| | 1979–1983 | 1984–1988 | 1989–1992 | 1993–1998 | 1999–2003 | 2004–2008 | 2009–2013 | 2014–2018 | 2019–2022 |
|---------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Males | 2 | 6 | 5 | 1 | 0 | 3 | 3 | 2 | 4 |
| Women | 4 | 4 | 5 | 5 | 8 | 7 | 9 | 8 | 4 |
| Proportion of women | 4/6 | 4/10 | 5/10 | 5/6 | 8/8 | 7/10 | 9/12 | 8/10 | 4/8 |

Nowadays, 61, 8, and 2 specialists are active, retired and have passed away, respectively. 8 residents are being trained.

Among the 61 active specialists, 5 work in administration, 4 in primary care, 3 in community pharmacy, 1 in another specialty, 1 is unemployed and 47 work in a hospital pharmacy (5 in private hospitals).

Among the 61 active specialists, 12 have been heads of pharmacy services.

Among the 47 specialists working in hospitals, 20 do so in our hospital, 16 in other Andalusian hospitals, and 11 in other communities.

Conclusion and Relevance Our hospital has contributed to the Hospital Pharmacy speciality by training eighty specialists. Mostly women working overwhelmingly in public hospitals. The development of the hospital pharmacy profession in Spain and specifically in our centre has allowed many specialists to work in the same hospital they were trained.

The fact that several of our colleagues have been heads of a pharmacy department may indicate a special motivation imparted towards managerial skills.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-012 TREATMENT DECISIONS ACCORDING TO 1-YEAR RISK MORTALITY IN PULMONARY ARTERIAL HYPERTENSION PATIENTS: A MULTICENTRE RETROSPECTIVE STUDY

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Background and Importance The 2015 and 2022 ESC/ERS Guidelines for pulmonary hypertension treatment provide algorithms for decision-making based on patients' 1-year mortality risk, with strong recommendations to intensify treatment in patients with intermediate-high risk.

Aim and Objectives To assess whether treatment decisions in pulmonary arterial hypertension [PAH] patients are currently being made according to the treatment algorithms provided by the ESC/ERS Guidelines.

Material and Methods A retrospective, descriptive, cross-sectional (March 2022) study was carried out in 2 tertiary hospitals, including alive adult PAH patients who initiated a PAH-specific therapy after 2016 and whose medical charts provided enough data to estimate the risk of 1-year mortality with the simplified four-strata risk-assessment tool.

Medical charts were consulted in order to collect several variables: demographic data, PAH subclassification according to aetiology, PH-specific drug initiated, World Health Organization functional class [WHO-FC], 6-minute walking distance [6MWD], and N-terminal pro-brain natriuretic peptide [NT-proBNP].

1-year mortality risk and the appropriateness of PH-specific therapies prescribed were assessed according to PAH treatment algorithms provided by the 2015 and 2022 ESC/ERS Guidelines.

Results 37 patients complied with inclusion criteria, 54.1% women aged 50 (28–84).

Patients' HAP subsets: 14, 6, 2, 2, and 1 were associated with adult congenital heart disease, portal hypertension, connective tissue disease, drugs and toxins, and human immunodeficiency virus infection, respectively. 6 patients were classified as idiopathic HAP.

52 changes in pulmonary-specific therapy were carried out in the studied period. At treatment initiation patients:

- WHO-FC: I, II, III, and IV in 2, 21, 26, and 3 cases, respectively.
- 6MWD: 425 (146–760) metres
- NT-proBNP: 369 (12–7200) ng/L
- Risk: 17 low, 20 intermediate-low, 14 intermediate-high, and 1 high.

36/52 treatment initiations were adequate according to clinical guideline algorithms; most discrepancies were due to:

- Initiation of selexipag (n=9) or riociguat (n=3) in patients with risk other than intermediate-low.

Conclusion and Relevance In this cohort of PAH patients whose 1-year mortality risk could be estimated, treatment decisions were generally made according to treatment guidelines.

Patients' preferences could explain most discrepancies, as they may prioritise avoiding treatments that require parenteral administration, such as epoprostenol and treprostinil and rather try oral alternatives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-013 1 YEAR-MORTALITY RISK ASSESSMENT IN PULMONARY ARTERIAL HYPERTENSION PATIENTS: A MULTICENTRE RETROSPECTIVE STUDY

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Background and Importance The 2015 and 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary arterial hypertension [PAH] recommend treatment decisions based on an estimation of the patient's 1-year mortality risk. Furthermore, the 2022 guideline provides a simplified four-strata risk-assessment tool for this estimation

Aim and Objectives To assess whether patients' mortality risk is estimated and registered in clinical charts to guide treatment decisions in a cohort of PAH patients.

To assess whether it is possible to measure patients' risk with the simplified tool using medical chart data.

Material and Methods A cross-sectional, retrospective, descriptive (March 2022) study was carried out in 2 tertiary hospitals, including alive adult PAH patients who initiated a PAH-specific therapy after 2016.

We collected variables from medical charts: demographic data, PAH subsets, PH-specific drug initiated, year of the initiation, and physician's explicit assertions of the patient risk.

We calculated the simplified four-strata risk-assessment tool with the following variables: World Health Organization functional class [WHO-FC], 6-minute walking distance [6MWD], and N-terminal pro-brain natriuretic peptide [NT-proBNP]. Data are presented as percentages and medians (range).

Results Overall, 102 patients complied with inclusion criteria, 64.7% women aged 56 (18–99). Patients' HAP subsets were 35%, 29%, 9%, 3%, and 2% associated with adult congenital heart disease, connective tissue disease, portal hypertension, human immunodeficiency virus infection, drugs and toxins, respectively. 22% were classified as idiopathic HAP.

Overall, 145 changes in pulmonary-specific therapy were observed. Physicians registered the patient's risk in clinical charts in only 13.8% (20/145) of treatment initiations.

Using the simplified tool, we were able to estimate the patient's risk in 35.9% (52/145) treatment initiations: 17 low, 20 intermediate-low, 14 intermediate-high, and one high risk. We were unable to calculate the risk due to missing: 6MWD, NT-proBNP, and WHO-FC in 46% (67/145), 39% (56/145), and 27% (39/145) of cases.

Conclusion and Relevance In this multicentre study, it was rare for physicians to explicitly claim patients' mortality risk.

Even when trying to assess patients' risk with the simplified tool, it was impossible to estimate it for most patients. Therefore, this process is missing critical clinical variables, even if

the mortality risk is being assessed but not registered in clinical charts.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-014 EFFECTIVENESS AND SAFETY OF THE ADMINISTRATION OF MURPHY'S ENEMA FOR THE TREATMENT OF REFRACTORY CONSTIPATION IN A TERTIARY HOSPITAL

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Background and Importance Constipation is a common complication during hospitalisation due to the presence of risk factors such as bed rest, diseases causing reduced bowel motility or administration of medications (opioids, anticholinergic drugs...). The standard therapy is laxative drugs. Murphy's enema (ME) is used for the treatment of constipation and faecal impaction when patients do not respond to laxatives. It consists of administering an evacuating solution (milk 300 mL, liquid vaseline 100 mL, oxygenated water 200 mL and saline solution 500 mL) through a rectal probe during 6 hours (53 drops/min), leading to a softening of the stool and osmotic evacuation. Although this is a common clinical practice in our hospital, we have not found any published study evaluating its effectiveness and safety.

Aim and Objectives To assess the effectiveness and safety of ME for the treatment of constipation and faecal impaction.

Material and Methods We performed a descriptive, retrospective study of effectiveness and safety of the administration of ME in patients with admitted in a tertiary hospital. We included patients who received ME from June-2020 to August-2022. We registered data of comorbidities, defecation achievement and adverse events related to the administration. Data were obtained from the electronic prescription program and the electronic health records.

Results We included 33 patients, 18 women and 15 men, with a mean age of 76 years. Two patients were readmitted, therefore a total of 37 ME were administered. The most frequent comorbidities were hypertension (40,5%), chronic constipation (33,3%), diabetes mellitus II (21,2%), heart failure (18,1%), atrial fibrillation (18,1%), dyslipidemia (12,1%), cognitive impairment (12,1%) and kidney failure (12,1%). The indication of ME was constipation (67,5%), faecal impaction (27,2%) and paralytic ileum (5,4%). ME was effective in the 64,8% of cases, with defecation achievement after administration. ME was overall well tolerated; one case of hypotension, one of nausea and one of abdominal pain were registered.

Conclusion and Relevance ME constitutes a safe and effective alternative for patients with constipation and faecal impaction not responding to the usual therapies. Furthermore, there is no published evidence regarding this practice, so this study may constitute a starting point for the development of further studies with larger sample sizes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-015 AZACITIDINE IN THE TREATMENT OF JUVENILE MYELOMONOCYTIC LEUKAEMIA: AN UP-TO-DATE PHARMACY PROTOCOL

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Background and Importance Juvenile Myelomonocytic Leukemia (JMML) is a paediatric haematological malignancy with a poor prognosis. In August 2019 in our paediatric hospital, we have a case of JMML. A protocol pharmacy related to medicinal product indication, preparation, and flow chart instructions was made based on the information given by the patient's doctor, marketing authorisation, and internet research. In Europe, azacitidine is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with specific diagnostic criteria. The reconstituted solution should be injected subcutaneously. For this reason, diagnosis and route of administration, this request was an off-label use. Azacitidine is cytotoxic and is prepared in a centralised production unit, under the pharmacist's responsibility. In 2022 we intended to research the current state of the art.

Aim and Objectives A systematic review of azacitidine in the treatment of JMML, in a recent period of time and, based on the results, update the pharmacy protocol of our hospital.

Material and Methods To perform this work, we used the following databases: PubMed and Embase, limited to publication years from 01 January 2020 to 09 September 2022. Key words included: azacitidine AND Juvenile Myelomonocytic Leukemia. An Excel table was made with the results.

Results Data synthesis: We found 57 articles. Among them, 27 were excluded by the title and 10 by the summary. Among the 20 analysed manuscripts, 6 were repeated and 8 were excluded after reading the full text. Thus, 6 articles were selected for this review.

Conclusion and Relevance A significant change occurred in May 2022. Food and Drug Administration (FDA) approved azacitidine monotherapy as a suitable option for children with newly diagnosed JMML based on the results of the AZA-JMML-001 trial. Although long-term safety and efficacy remain to be fully elucidated in this population, the data demonstrate that azacitidine provides valuable clinical benefit to JMML patients prior to HSCT. In Europe, it has not yet been approved for this clinical situation.

It is important to share treatments for rare diseases. Pharmacists are medication experts and play a critical role in this. Accordingly, we review a pharmacy protocol and update azacitidine new findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-018 OFF-LABEL USE OF USTEKINUMAB IN REFRACTORY EPIDERMOLYTIC ICHTHYOSIS: A CASE REPORT

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Background and Importance Epidermolytic ichthyosis (EI) is a skin genetic disorder that predominantly affects joints and friction areas with a limited number of therapeutic options (topical and systemic treatments). In some severe EI subtypes, the off-label use of ustekinumab is based on marked elevation of cytokines in the Th17/IL-23 pathway, similar to inflammatory diseases like psoriasis.

Aim and Objectives To evaluate the efficacy and security of ustekinumab in an 8-year-old female patient with severe EI with KRT1 mutation, refractory to topical treatment and oral retinoids.

Material and Methods Firstly, she underwent keratolytics and emollients with scarce clinical response. Due to the absence of effectiveness of these topical therapies, she received oral retinoids (acitretin) up to maximum tolerated dose, but some erythematous lesions and hyperkeratosis rapidly appeared on her skin. For this reason, the treatment had to be discontinued several times. In April 2022, Dermatology Service requested the off-label use of ustekinumab with a dosage of 0.75 mg/kg at weeks 0, 4, 8 and 12, and then administered each 12 weeks to the Pharmacy therapeutics committee.

Afterwards, an extensive review was carried out by Pharmacy Service. A report was made with a positive assessment for approval of treatment. This decision was supported by some case reports showing clinical results of ustekinumab in some EI subtypes and the lack of available alternative therapies in this case.

Results At the beginning of treatment with ustekinumab, extensive scaly erythematous lesions with circinate margins were observed, affecting the facial area, trunk and extremities, accompanied by diffuse palmoplantar keratoderma.

After three months of the first administration of ustekinumab, the patient was examined by a dermatologist. An excellent clinical response was observed with resolution of the facial lesions and almost complete on the trunk, with hyperkeratotic lesions persisting in folds, without underlying erythema. Moreover, no adverse events related to ustekinumab were registered.

Conclusion and Relevance Ustekinumab is suggested to be an alternative therapy in some severe EI subtypes refractory to topical and systemic treatments. In spite of being safe and effective in this patient, longer studies are needed to consider ustekinumab in the therapeutic management of EI.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-028 ASSESSMENT OF SYMPTOMS AND SIGNS SEVERITY IN PSORIASIS PATIENTS

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Background and Importance Psoriasis is a chronic inflammatory skin disease in which moderate to severe forms can be treated with monoclonal antibodies (mAbs). Assessment of disease improvement is usually made by the Psoriasis Area Severity Index (PASI) and Body Surface Area (BSA). However, sometimes patients' feelings do not correlate with these scores.

Aim and Objectives To describe the symptoms and signs in patients with moderate-to-severe psoriasis by using Psoriasis Symptoms and Signs Diary (PSSD).

Material and Methods Prospective observational study conducted between 1-February-2022 and 30-September-2022 in a university hospital. Patients treated at least 3 months with mAbs were included. Data collected: age, sex, diagnostic, mAbs prescribed, previous treatments, PASI and BSA scores. PSSD was used to measure patient-reported outcome (PRO). It assesses the severity of psoriasis symptoms (itching, tightness, burning, pain) and signs (bleeding, cracking, dryness, scaling, shedding, redness) using a 0–10 numerical rating scale. Summary scores were derived using a scale of 0–100. Patients with a PSSD score ≥ 20 were referred to the dermatology service to assess the mAb switching. Data were obtained from electronic medical records and patients' interviews.

Results Thirty-eight patients completed the PSSD (50% women) with a median age 51.3 (37.8–61.4) years, 84.2% with psoriasis and 15.8% also with psoriatic arthritis (PA) as comorbidity. mAbs prescribed: adalimumab (44.7%), ustekinumab (13.1%), guselkumab (10.5%), tildrakizumab (10.5%), risankizumab (7.9%), secukinumab (5.3%), brodalumab (5.3%), ixekizumab (2.7%). Twenty-four patients (63.2%) received mAbs as the first line, 21.0% as the second-line and 13.1% as the third or more lines. Eight patients had PASI > 2 . The PSSD average score was: itching 1.9 ± 2.9 , dryness 3.5 ± 2.8 , cracking 1.2 ± 2.4 , tightness 1.4 ± 2.2 , scaling 1.2 ± 2.2 , shedding 2 ± 2.9 , redness 2.3 ± 2.7 , bleeding 0.5 ± 1.5 , burning $1.2 \pm .2$, pain 0.5 ± 1.6 . Dryness was the highest rated and bleeding the lowest score. Twelve patients (31.6%) had a PSSD score of ≥ 20 and the main treatment was adalimumab (41.6%). Three patients switched the mAb. Only in five patients the PASI and BSA scores were correlated with PSSD.

Conclusion and Relevance PSSD is a reliable and valid PRO instrument for assessing psoriasis-associated symptoms and signs in patients treated with mAbs in clinical practice. This score, together with PASI and BSA, could be used to guide mAbs switching.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-030 USING A PHARMACIST-LED ASTHMA SERVICE TO ASSESS THE CONCORDANCE BETWEEN PATIENT-REPORTED ICS ADHERENCE AND OBJECTIVE E-MONITORING OF ICS THERAPY

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Background and Importance The prevalence of asthma and scale of sub-optimal inhaled corticosteroid (ICS) use, demands efficient detection of non-adherence. The easy to administer Test of Adherence to Inhalers¹ (TAI) questionnaire asks patients to rate their agreement with 10-items, and the subsequent score classifies adherence as good, intermediate or poor. A more objective, though expensive tool, is the electronic monitor (eMonitor) that when attached to the inhaler, records the date/time of each actuation. If the person receives $> 75\%$ of doses, this is good adherence. The biomarker Fractionated expired Nitric Oxide (FeNO) decreases following sustained ICS use. Thus, if eMonitor ICS adherence is good and there is a significant decrease in FeNO ($> 42\%$ from baseline), pre-

eMonitor adherence is unlikely. This is a positive FeNO suppression test² (FST). If there is no significant change in FeNO, this is a negative FST.

Aim and Objectives This study aimed to assess if the TAI could accurately detect non-adherence to an ICS in a cohort of people with difficult-to-control asthma.

Material and Methods Patients attending a hospital pharmacist asthma clinic completed the TAI, had FeNO measured and received an eMonitor. Follow-up was 6 weeks later.

Results Data for 88 patients were included, of whom 76 (86%) had good ICS adherence according to the eMonitor. 35 people had a positive FST; 12 (34%) had a TAI adherence that was designated good, 19/35 (54%) intermediate and 4 (11%) poor. In the negative FST group, 15/41 (37%) had a TAI adherence classification of good, 21 (51%) intermediate and 5 (12%) poor.

Conclusion and Relevance In this cohort, a third of patients with eMonitoring/biomarker evidence to suggest *suboptimal*

ICS adherence (positive FST) completed a TAI that *over-estimated* ICS use. Conversely, in the FST negative patients (likely to have been adherent prior to eMonitor initiation), almost two-thirds of patients identified themselves on TAI as having suboptimal adherence. This suggests that the TAI may not accurately predict adherence or potentially, that using the eMonitor in itself encourages better adherence in the short-term.

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