4CPS-048 IMPROVING SAFETY IN THE USE OF MONOCLONAL ANTIBODIES IN PATIENTS WITH MIGRAINE: AN INTERDISCIPLINARY STUDY

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Background and importance Erenumab and galcanezumab are two subcutaneously administered monoclonal antibodies (MAs) indicated for migraine prophylaxis in adults.

These MAs are newly marketed drugs. The integration of the hospital pharmacist (HP) in interdisciplinary teams (IT) has been shown to reduce the complications of these treatments. In addition, it improves monitoring of health outcomes, reduces unnecessary medication, treatment costs and minimises hospital admissions.

Aim and objectives To analyse the outcomes after the creation of an MA dispensing circuit and an IT composed of neurologists, nutritionists and HPs. This team focused on the treatment of migraine and the early detection, treatment and prevention of adverse reactions (AR).

Material and methods Retrospective observational study conducted from January 2020 to September 2021. Patients diagnosed with chronic or episodic migraine under treatment with MA were included.

These treatments are exclusively prescribed by the neurologist and are dispensed in the outpatient consultation services by an HP. The HP conducted the clinical interview, recorded effectiveness data, AR and other clinical data of interest, and generated the corresponding report in the patient's medical record. In addition, the HP provided pharmaceutical advice and all necessary information to the patient. The nutritionist prepared the nutritional recommendations for the treatment and prevention of constipation.

Results During the study period 77 patients (85.7% female) were attended, with a median age of 51 (22–79) years.

The occurrence of constipation was detected in 30 patients (38.96%), substantially higher than that described in the pivotal trials (PT) of reference: erenumab 70 mg: 1.3%; 140 mg: 3.2%. Galcanezumab 120 mg: 1%; 240 mg: 1.5% and in the erenumab therapeutic positioning report (TPR): 3.3%.

The occurrence of hypertension was also detected in 7 patients (9.09%), not described in the PT or TPR.

All AR were reported. Oral and written information was provided to the patient.

Conclusion and relevance The creation of the IT brings value in the quality of healthcare and fosters cooperation between physician, nutritionist and HP. Furthermore, it favours early detection, prevention and treatment of AR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-049 MANAGEMENT OF PAN-RESISTANT *STENOTROPHOMONAS MALTOPHILIA*

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Background and importance The detection and dissemination of pan-resistant bacteria in hospitals is relatively frequent. It is necessary to know new therapeutic alternatives available to eradicate them.

Aim and objectives The aim of this study was to evaluate the effectiveness and safety of cefiderocol in the management of pan-resistant *Stenotrophomonas maltophilia* (SM) isolated in a retroperitoneal collection.

Material and methods Description of a clinical case. The microbiological cure, defined as the eradication of SM in the material extracted from the abdominal abscess, was established as the effectiveness criteria and the non-presentation of adverse effects (AE) as the safety criteria.

Results A 72-year-old man with a history of acute lithiasic pancreatitis, chronic liver disease, and cholecystectomy was readmitted to the intensive care unit due to sepsis caused by acute lithiasic pancreatitis. During admission, the patient received several antibiotics: piperacillin/tazobactam, meropenen and linezolid. Day +30, he presented an episode of septic shock whose focus was a retroperitoneal collection in the pararenal space. It was drained percutaneously and SM resistant to cotrimoxazole (drug of choice) and sensitive to levofloxacin was isolated. He was treated for 20 days with levofloxacin 500 mg/12 hours and meropenem 2 g/8 hours. Day +60, he presented a second episode of septic shock (leukocytes: 40.57×10^3/μL, neutrophils: 38.58×10^3/μL, C-reactive protein (CRP): 274.5 mg/L). In the extracted material, SM resistant to all marketed antibiotics was isolated. The compassionate use of cefiderocol was requested and approved. SM was sensitive to cefiderocol. He was treated with cefiderocol 2 g/8 hours in monotherapy for 21 days. Day +3 of the start of treatment, a surgical drainage was performed to control the focus. SM was not isolated in the extracted material. Day +7 of treatment, once the focus was controlled, the patient remained afebrile, improving clinically and analytically (leukocytes: 8.8×10^3/μL, neutrophils: 7.13×10^3/μL and CRP: 71.3 mg/L). SM was not re-isolated during the 113-day admission. He was admitted on day +250 for collagenitis and day +377 for septic shock, not isolating SM. He did not present any AE related to cefiderocol.

Conclusion and relevance New therapeutic alternatives must be available for pan-resistant bacteria. Cefiderocol in monotherapy was effective and safe in the treatment of pan-resistant SM.

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4CPS-051 PHARMACOKINETICS ALTERATIONS IN TWO CRITICALLY ILL PATIENTS ON EXTRACORPOREAL MEMBRANE OXYGENATION RECEIVING ISAVUCONAZOL

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Background and importance Extracorporeal membrane oxygenation (ECMO) can modify drug pharmacokinetics and pharmacodynamics. We report two cases of critically ill patients on ECMO receiving isavuconazol.

Aim and objectives Primary aim: to assess the correlation between the dose of isavuconazol administered and its plasma drug concentrations (IsaPlasmConc). Secondary aim: to analyse differences in IsaPlasm at different points in the ECMO circuit to study drug sequestration.
Material and methods Prospective study in critically ill patients treated with intravenous isavuconazol and receiving ECMO in the intensive care unit (ICU) from August to October 2021. Isavuconazol area under the curve (AUCisa) was calculated using the trapezoidal method. Blood samples were drawn from an arterial catheter and from ECMO circuit pre- and post-oxygenator at 0 (predose) and 1 hour (end of infusion), and from an arterial catheter at 2, 4, 6 and 12 hours after isavuconazol infusion.

A therapeutic goal of IsaPlasmConc 2.5–10 µg/mL was established. The analytical method used was high-pressure liquid chromatography. Differences greater than 10% on ECMO sites were considered as possible drug sequestration.
Results Both patients received a loading dose of isavuconazole 200 mg/8 hours over 48 hours. No relevant drug interactions were identified.

Patient 1: male, 61 years, 65 kg. Pulmonary aspergillosis treated with isavuconazole 200 mg/24 hours intravenously (IV). On day 4, IsaPlasmConc (arterial, pre-oxygenator and post-oxygenator) were: C0h: 1.39, 1.36 and 1.34, respectively; C1h: 2.83, 2.64 and 3.02; C2h: 2.28; C4h: 1.6; C6h: 1.61; C12h: 1.06 µg/mL. AUCisa was 36.8 µg/hour/mL. It was considered infra-therapeutic, so the isavuconazol dosage was increased to 200 mg/12 hours. On day 10, IsaPlasmConc were: C0h: 2.16, 2.17 and 2.09; C1h: 3.17, 2.99 and 2.96; C2h: 3.10; C4h: 2.67; C6h: 2.41; C12h: 2.24. AUCisa was 144.3µg/hour/mL. The patient achieved negative cultures and clinical improvement.

Patient 2: male, 65 years, 84 kg. Pulmonary aspergillosis treated with isavuconazole 200 mg/12 hours IV. On day 4, IsaPlasmConc (arterial, pre-oxygenator and post-oxygenatore) were: C0h: 2.00, 1.95 and 1.86, respectively, C1h: 3.01, 3.34 and 3.21; C2h: 3.00; C4h: 2.44; C6h: 2.34; C12h: 3.09. AUCisa was 125.2 µg/hour/mL. The patient died due to external causes.
Conclusion and relevance In our patients there was not a significant sequestration of isavuconazole in the ECMO circuit. However, patients required higher isavuconazole doses to achieve IsaPlasmConc therapeutic goals. Therapeutic drug monitoring during ECMO is appropriate to assure therapeutic efficacy and security.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

4CPS-053 GALCANEZUMAB IN PROPHYLAXIS OF REFRACTORY HIGH-FREQUENCY EPISODIC MIGRAINE IN CLINICAL PRACTICE

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Background and importance High-frecuency episodic migraine (HFEM) represents an important health problem due to its high prevalence and to the loss of quality of life. The therapeutic approach is based on prophylactic and symptomatic treatment.

Galcanezumab has been authorised by the European Medicines Agency (EMA) for the prophylaxis of migraine in adults with at least 4 days of migraine per month (MDM).
Aim and objectives To study the effectiveness and safety of galcanezumab in the prophylaxis of HFEM in real-life clinical practice.
Material and methods Observational, retrospective study of patients with HFEM who initiated treatment with galcanezumab between June 2020 and June 2021. Demographic data, number of prophylactic treatments received, date of diagnosis, mean MDM, and HIT-6 scale score at baseline and 3 months after treatment initiation were collected from the electronic medical record.
Results In the study period, 48 patients (81%, 39 women) with HFEM started treatment with galcanezumab. The median age was 47 (24–68) years. The time since diagnosis was 71 months. 52% had received more than five prophylactic drugs. Topiramate was used in 90% (43) of the patients, and was contraindicated in the remainder; it was discontinued in 56% (27) of the cases due to lack of response and in 33% (16) due to poor tolerance. Other treatments used were: amitriptyline (79%, 38); off-label botulinum toxin (77%, 37), flunarizine (75%, 36), propranolol (46%, 22), metoprolol (33%, 16) or valproic acid (38%, 18).

Three-month follow-up was carried out in 94% (25) of the patients. The median MDM at baseline was 10.5; and after treatment, 4; implying a median reduction in MDM of 58%. The median HIT-6 score at baseline was 68 (56–79). Variation in HIT-6 could not be assessed due to lack of data.

The median treatment duration at cut-off was 8 (3–15) months. Treatment was discontinued in 6 cases due to lack of response (3), adverse effects (2) or the patient's decision (1). Adverse effects were reported in 23% (11) of the patients, the most frequent being dizziness and instability (4) and constipation (2).
Conclusion and relevance Galcanezumab appears to be an effective treatment in patients with multidrug-refractory HFEM. Further studies are needed to assess these results in the long term. Galcanezumab has an acceptable safety profile, with the incidence of dizziness and constipation being higher than described in clinical trials, but rarely leading to treatment discontinuation.

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4CPS-054 ANALYSIS OF REAL-WORLD DATA FOR ERENUMAB UTILISATION AND PATIENT-RELATED OUTCOMES

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Background and importance Erenumab was approved for migraine prophylaxis shortly before the COVID-19 pandemic. After 18 months, there was enough data to conduct several studies.
Aim and objectives Evaluate effectiveness and safety of erenumab using real-world data and compare the results with clinical trials.