

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 (AUC_{isa}) 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. AUC_{isa} 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. AUC_{isa} was 144.3 µg/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-oxygenator) 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. AUC_{isa} 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

L Macía-Rivas*, L Velasco-Roces, CL Fernandez-Laguna, C Álvarez-Asteinza, M Maray, S Fernández Lastras, DLFV Irene, L Oyague López, M Eiroa Osorio, A Lozano Blázquez. *Hospital Universitario Central de Asturias, Hospital Pharmacy, Oviedo, Spain*

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Background and importance High-frequency 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.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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

M Rodríguez Goicoechea*, B Sanchez Rodríguez, E Elvira Ladrón de Guevara, I Alférez García, F Verdejo Reche. *Hospital Universitario Torrecárdenas, Pharmacy, Almería, Spain*

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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.

Material and methods A retrospective, observational study was performed in a second-level hospital. Evaluation of patients with migraine being treated with erenumab for at least 6 months. Data extraction from clinical histories and prescription software. Patient-related outcomes filled in their clinical history by the neurologist and pharmacist.

Results 55 patients recruited to commence treatment with erenumab between January 2020 and April 2021. 48 patients included (7 patients excluded due to lack of follow-up). 44 women, average age 49.7 years, and 21 days per month with migraine (MMD).

26 patients reached a reduction of MMD of $\geq 50\%$, and 10 of $\geq 75\%$ (54.2% and 20.8%, respectively) after a follow-up of between 3 and 9 months. Of the 22 patients that did not reach at least 50% reduction in MMD, 7 patients tried a dosage increase, with 5 of them achieving an average 61% reduction in MMD. All patients mentioned having softer migraine pain.

Regarding safety, only 11 patients experienced adverse reactions, mostly constipation. Three patients needed to cease treatment.

Conclusion and relevance Erenumab has established a new treatment in migraine prophylaxis that works even better than in the clinical trials. According to clinical trials results, erenumab can reduce MMD by 50% in about 40% of patients regardless of the dosage, and by 75% in about 18.9% of patients. In our findings, erenumab achieved a 50% reduction in 54.2% of patients, and a 75% reduction in 20.8% of patients, achieving better results in real life than in the clinical trials.

Our study has as a limitation the follow-up being carried out by physicians and not by pharmacists, which could improve patient-related outcomes and experiences as hospital pharmacists dispense medication every 2 months in our hospital. The hospital pharmacist's role can be useful for evaluating treatments results described by patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-055 SUCCESSFUL SOFOSBUVIR/VELPATASVIR TREATMENT IN A HEPATITIS C PATIENT RECEIVING CHRONIC ANTIEPILEPTIC THERAPY: A CASE REPORT

M Rodríguez-Reyes*, JM Sotoca, D Soy-Muner. *Hospital Clínic, Pharmacy Department, Barcelona, Spain*

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Background and importance Co-administration of direct-acting antivirals (DAA) with strong cytochrome P-450 (CYP)-inducing drugs, such as some antiepileptic medications, is contraindicated because it can result in loss of efficacy and virological failure.

The majority of interactions between DAA and the concomitant medication are manageable since the interacting drug can temporarily be stopped or substituted. However, there is usually some reluctance to modify chronic antiepileptic therapy in patients with well-controlled seizures.

This case report contributes to the limited literature regarding co-administration of sofosbuvir/velpatasvir and antiepileptic drugs since there are only two reported cases.¹

Aim and objectives The objective was to assess the efficacy of sofosbuvir/velpatasvir for 12 weeks in a patient taking

the strong CYP-inducing drugs carbamazepine and phenobarbital.

Material and methods Descriptive and retrospective clinical case. Data were obtained by review of electronic medical records.

Results A 54-year-old woman was diagnosed with chronic hepatitis C infection. Ultrasound transient elastography showed F3 stage liver fibrosis and she was naïve to hepatitis C antiviral agents. The patient was receiving treatment with carbamazepine, clonazepam, phenobarbital, topiramate, folic acid and omeprazole.

The use of the pangenotypic antivirals glecaprevir/pibrentasvir and sofosbuvir/velpatasvir was contraindicated with carbamazepine and phenobarbital. Elbasvir/grazoprevir was also contraindicated.

It was recommended not to stop or change the patient's anticonvulsant drugs, so it was decided to commence treatment with sofosbuvir/velpatasvir for 12 weeks with viral load measurement at 4 weeks, 12 weeks and 24 weeks post-treatment initiation. Treatment success was defined as an undetectable hepatitis C virus RNA level 24 weeks post-treatment initiation, that is, 12 weeks after completion of therapy (sustained virologic response, SVR12).

Concomitant use of omeprazole can reduce sofosbuvir and velpatasvir concentrations, so omeprazole was administered 4 hours after the antiviral drug.

Treatment adherence to sofosbuvir/velpatasvir was correct according to the dispensing records. No adverse effects were reported during antiviral therapy, and the patient has remained seizure-free.

Viral load was undetectable at every point of measurement and SVR12 was achieved.

Conclusion and relevance Sofosbuvir/velpatasvir administered for 12 weeks in a patient receiving treatment with carbamazepine and phenobarbital achieved SVR12 despite the enzyme-inducing effect of these antiepileptic drugs on the hepatitis C antiviral concentrations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-057 DISCONTINUATION OF PROTON PUMP INHIBITORS DURING HOSPITALISATION: A RANDOMISED CONTROLLED TRIAL

¹JL Nielsen*, ²CA Sørensen, ³M Stawowy, ¹DK Bonnerup. ¹Hospital Pharmacy, Central Denmark Region, Clinical Pharmacy, Randers Regional Hospital, Randers, Denmark; ²Hospital Pharmacy, Central Denmark Region, Research and Development and Clinical Pharmacy, Aarhus, Denmark; ³Randers Regional Hospital, Central Denmark Region, Medical Department, Randers, Denmark

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Background and importance Many patients take proton pump inhibitors (PPIs) even though the drugs are no longer needed.¹

² We know that there are side effects to long-term PPI treatment.³ No previous studies have examined whether it is possible to reduce or discontinue treatment during hospitalisation and continue it successfully after discharge.

Aim and objectives The aim of the study was to investigate if PPIs can be discontinued or reduced through counselling by pharmacy staff during hospitalisation.