Spain. Being consider as low evidence drugs the rest of them. Finally, compliance with the funding criteria set by the Health Ministry to start monoclonal antibody treatment was determined: having 8 or more days of migraine/month and having failed at least three prophylactic treatments for at least 3 months, one of them being botulinum toxin in the case of chronic migraine.

Results A total of 38 patients (79% women) started treatment with antimigraine biologics. The average number of prophylactic treatments was 3.9 and only one patient did not receive the minus 3. 10.5% reported some type of intolerance with any of the treatments. The duration of treatment reached at least 3 months in 78% of the patients and exceeded 6 months in 48%. 43% of the drugs used in prophylaxis had an indication. In the 57% of patients that received drugs without indication, the following were used: pregabalin (5), valproic acid (4), diazepam (2), candesartan (1), levetirazetam (1), citalopram (1), zonisamide (1), tizanidine (1) and Lisinopril (1). 14 patients (37%) did not meet the funding criteria: 8 for not having reached 3 months of treatment, 3 for presenting less than 8 MMD and 2 for presenting chronic migraine and not having received botulinum toxin A.

Conclusion and relevance More than half of the patients (57%) received drugs without indication for migraine prophylaxis and more than a third (37%) did not meet the funding criteria for these biological drugs. The work of the hospital pharmacist could improve the adequacy of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-142 EFFECTIVENESS AND SAFETY OF ATEZOLIZUMAB IN METASTATIC UROTHELIAL CARCINOMA

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Background and importance Few options exist for patients with metastatic urothelial carcinoma (MUC). Atezolizumab, an anti-PD-L1 immune checkpoint inhibitor, has been shown to reduce tumour size in patients who have been treated with platinum chemotherapy or who are not eligible for such treatment in MUC.

Aim and objectives To evaluate the effectiveness and safety of atezolizumab in MUC in real clinical practice, comparing the results with the pivotal clinical trial IMvigor211.

Material and methods This was a retrospective observational study including all patients with MUC treated with atezolizumab, between January 2018 and October 2021. Variables included were age, sex, smoking status, Eastern Cooperative Oncology Group (ECOG), line of treatment, cycles received, duration and causes of treatment discontinuation (progression, toxicity, death). Effectiveness was assessed by the Kaplan–Meier method (SPSS v25.0) in terms of progression-free survival (PFS) and overall survival (OS). Adverse effects (AE) were collected and classified according to the *Common Terminology Criteria for Adverse Events* (CTCAE) scale v5.0.

Results 33 patients (87.9% men) were included. Median age was 67 (53–85) years. 24.2% were smokers and 66.7% former smokers. All patients had ECOG ≤1 at the begining of treatment. Treatment line of atezolizumab: 12.1% firstline, 72.7% secondline, 12.1% thirdline and 3% fourthline. 87.9% received at least one previous platinum-based line. Median of cycles received and duration of treatment were 5 (1–21) and 4 months, respectively. 81.8% of the patients discontinued therapy: 21.2% due to death and 60.6% due to progression. Median PFS and OS were 5 months (95% CI 3.9 to 6.1) and 15 months (95% CI 1.7 to 28.3), respectively. In IMvigor211, median PFS and OS were 2.1 and 8.6 months, respectively. 39.4% of patients had AE only grade 1–2. The most comon AE were pruritus (n=6), asthenia (n=3), oedema (n=3), constipation (n=2) and neuropathy (n=2). In IMvigor211, 95% had AE (55.8% ≥ grade 3) and the most common of any grade were fatigue, pruritus and asthenia.

Conclusion and relevance The effectiveness results observed in real clinical practice appear to be superior to those obtained in the pivotal study, although our sample size and design are limited. The safety profile appears to be better than IMvigor211 with a similar toxicity profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-145 EFFECTIVENESS AND SAFETY OF BARICITINIB AND TOFACITINIB IN RHEUMATOID ARTHRITIS IN CLINICAL PRACTICE

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Background and importance Baricitinib and tofacitinib are Janus kinase inhibitors indicated in rheumatoid arthritis (RA) with a demostrated effectiveness and safety in various clinical trials.

Aim and objectives To evaluate the effectiveness and safety of baricitinib and tofacitinib in patients diagnosed with RA in clinical practice.

Material and methods Retrospective descriptive study that included patients with RA treated with baricitinib or tofacitinib between September 2018 and September 2021. The data were obtained from the review of clinical and analytical histories in Diraya. The variables collected were: age, sex, previous treatment, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and follow-up time. To evaluate the effectiveness, the decrease in the value of the inflammatory parameters (ESR and CRP), the reduction in the number of painful joints, the remission of the disease, the dose reduction and the treatment changes were taken into account. Safety was determined based on the adverse reactions (ARs) described.

Results 32 patients with a median age of 55 years were evaluated. 21 received treatment with baricitinib (15 women) and 11 with tofacitinib (10 women). The median treatment time was 18 months. The median of previous treatments in patients with baricitinib was 2 biologics and for patients with tofacitinib of 1 biological. In 13 patients with baricitinib and in 4 with tofacitinib there was a reduction in inflammatory parameters. Baricitinib decreased the number of painful joints in 15 patients and tofacitinib in 11. There was remission in 15 patients treated with baricitinib (of which 5 reduced doses) and in 10 with tofacitinib. 6 ARs related to the use of baricitinib (2 weight gains, 1 neutropenia, 1 herpes zoster, 1

interstitial pneumonia and 1 anxiety attack that forced a change in treatment) and 5 with the use of tofacitinib (1 herpes zoster, 1 dry lip, 1 tinnitus, 1 oedema and 1 dyslipidaemia). Of the 21 patients with baricitinib, 4 changed treatment due to ineffectiveness (2 to tofacitinib and 2 to biologics), and of the 11 treated with tofacitinib 2 switched to biologics and 1 suspended treatment due to cardiovascular risk.

Conclusion and relevance In our clinical experience, baricitinib and tofacitinib are shown to be effective in the treatment of RA, with a good safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Abstract 4CPS-146 Table 2 Validation parameters according to FDA guidance

Analyte	Rt (min)	Equation	R^2	Within-day mean (µg/mL) (%VC)			Between-day mean (µg/mL) (%VC)		
				Low	Medium	High	Low	Medium	High
Voriconazole	3.7	y= 0.2363x-0.0083	0.9992	1.56 (3.6)	3.47 (1.3)	6.57 (0.6)	1.56 (4)	3.43 (1.5)	6.51 (0.6)
Isavuconazole	5.8	y= 0.6587x+0.0326	0.0999	1.38 (0.5)	4.82 (0.1)	9.19 (0.1)	1.43 (1.2)	5.14 (0.2)	9.12 (0.6)
Posaconazole	4.1	y= 0.6485+0.0008	0.9989	0.51 (0.8)	1.04 (1.27)	1.39 (0.8)	0.47 (1.23)	0.91 (2.3)	1.29 (1.24)

4CPS-146 DEVELOPMENT AND VALIDATION OF A RAPID HIGH-PERFORMANCE LIQUID CROMATOGRAPHY METHOD (HPLC) FOR THE DETERMINATION OF TRIAZOLES IN HUMAN PLASMA

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Background and importance The incidence of invasive fungal infections has increased significantly. Triazoles are the antifungals of choice for pulmonary aspergillosis, but they have a high intra- and interindividual variability in pharmacokinetics and are associated with a large number of interactions, thus requiring analytical techniques that allow therapeutic drug monitoring to ensure the effectiveness and safety of these drugs.

Aim and objectives The aim of this study was the development and validation of a high-performance liquid chromatography (HPLC) method for measuring voriconazole, isavuconazole and posaconazole in human plasma using tioconazole as an internal standard.

Material and methods The system consisted of an Agilent 1260 Infinity chromatograph with an ultraviolet diode array detector (UV-DAD). The column used was a Kinetex F5 4.6 ×150 mm, 5 µm (Phenomenex, USA). The method was validated according to the Food and Drug Administration (FDA) bioanalytical method validation guidance. The analysis run time for all drugs was 7.5 min. The chromatographic conditions are shown in Table 1. To process the samples were taken 100 µL of internal standard, 200 µL of plasma and 300 µL of acetonitrile. Then, they were homogenised for 30 s and centrifuged at 15 000 g for 5 min.

Results The results are shown in Table 2.

Conclusion and relevance A method has been validated for the determination of triazoles by HPLC in human plasma that will allow therapeutic drug monitoring to be performed in target patients.

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Conflict of interest No conflict of interest

4CPS-147 EXPERIENCE OF USE OF BIOLOGICAL ANTIMIGRAINE TREATMENTS IN CLINICAL PRACTICE

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Background and importance The comparative efficacy and safety of antimigraine monoclonal antibodies (mAb) is not known in clinical practice.

Aim and objectives Describe the clinical experience of using mAb in migraine management.

Material and methods Retrospective descriptive research of patients with migraine treated with erenumab, fremanezumab or galcanezumab between October 2019 and September 2021. All patients had 8 days of migraine monthly and 3 failures to prophylactic treatments, one of these being botulinum toxins. In all cases, the administration was monthly with a dose of 70 or 140 mg for erenumab, 225 mg for fremanezumab and 120 mg for galcanezumab (after a single dose of 240 mg the first month). Efficacy was evaluated at 12 weeks and considered: reduction of monthly headache days, reduction to 50% of the number of attacks, decrease in the consumption of symptomatic medication, and discontinuation.

Abstract 4CPS-146 Table 1 Chromatographic conditions of methods

Analyte	Mobile phase	λ (nm)	Calibration range (mg/mL)	Flow (mL/min)	Temperature (°C)	Injection volume (mL)
Voriconazole	60% Buffer ($KH_2PO_4$0.05 M pH=3.5)/40% acetonitrile	254	1–7	1	25	40
Isavuconazole	50% Buffer ($KH_2PO_4$0.05 M pH=3.5)/50% acetonitrile	260	0.5–10	1	25	50
Posaconazole	50% Buffer ($KH_2PO_4$0.05 M pH=3.5)/50% acetonitrile	260	0.3–1.5	1	25	50