5PSQ-088 ANTI SARS-COV-2 MONOCLONAL ANTIBODIES: FROM CLINICAL TRIAL TO REAL-WORLD EVIDENCE

[1]M Brachet Cota, [2]A Ucciero*, [3]L Lanzone, [4]M Massa, [5]S Bonetta, [6]D Brustia, [6]A Barco, [2]A Pisterna. [1]*Scuola di Specializzazione in Farmacia Ospedaliera Novara, Scienze del Farmaco – Novara, Novara, Italy*; [2]*AOU Maggiore della Carità di Novara, SC Farmacia, Novara, Italy*; [3]*ASL Biella, Soc Farmacia, Biella, Italy*; [4]*ASL Vercelli, SC Farmacia, Vercelli, Italy*; [5]*ASL VCO, SC Farmacia, Verbania, Italy*; [6]*AOU Maggiore della Carità di Novara, SCDU Malattie Infettive, Novara, Italy*

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Background and importance Monoclonal antibodies (mAbs) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were recently shown to be promising in preventing hospitalisation and death among patients with mild to moderate COVID-19 symptoms in randomised controlled trials. These medicines are subject to additional monitoring and, in our country, this occurs through the Italian Medicine Agency (AIFA). They have been authorised in subjects >12 years, positive for SARS-CoV-2, not hospitalised for COVID-19, not on oxygen therapy, with mild to moderate symptoms of recent onset at high risk of progression into severe disease. In the absence of solid safety and efficacy data, regulatory bodies recommend infusion in a hospital/protected setting. To our knowledge, limited data are available on real-life use of mAbs.

Aim and objectives The aim of the work was to evaluate the risk of a hospitalisation or death in patients using these medications and the occurrence of side effects.

Material and methods Clinical data of SARS-Cov-2 patients that initiated mAb infusions supplied by our SC Pharmacy, Eastern Piedmont Storage Hub Centres (serving over 1 million inhabitants), were retrospectively collected during the March–August 2021 period. The primary endpoint was a composite of COVID-19-related hospitalisation or death at day 28.

Results The population included 85 patients; median age 68 years (80% male); 18 positive due to nosocomial infection; main comorbidities were cardiovascular and onco-haematological diseases (33%–16%). The proportion of patients with COVID-19-related hospitalisation at 28 days was 16% (14 events). There were a total of 9 deaths. The mean time between mAb therapy and r*everse transcription-polymerase chain reaction* (RT-PCR) negative nasopharyngeal swab test was 19 days. AEs were observed in only 3 patients (hypotension, dyspnoea, chills, fever).

Conclusion and relevance Our results were consistent with recent results showing a reduced risk of hospitalisation or death in outpatients with mild-to-moderate COVID-19. Multidisciplinary dialogue between the pharmacist, virologist and general practitioner showed the need to define homogenous methodologies for collection of clinical data in the real-world context (ie, nasopharyngeal swab test execution data). Further real-world studies are needed to validate these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-090 USE OF MONOCLONAL ANTIBODIES AGAINST THE CALCITONIN GENE-RELATED PEPTIDE PATHWAY IN CHRONIC MIGRAINE IN CLINICAL PRACTICE

[1]MDP Briceño Casado*, [2]MD Gil-Sierra, [1]B De La Calle-Riaguas, [1]FJ Julia-Luna, [1]C Piqueras-Romero. [1]*Hospital Nuestra Señora del Prado, Hospital Pharmacy, Talavera de La Reina, Spain*; [2]*Hospital Universitario Puerto Real, Hospital Pharmacy, Cadiz, Spain*

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Background and importance Migraine is a neurological disorder with a high prevalence. Monoclonal antibodies against the calcitonin gene-related peptide pathway (CGRP-mAbs) are indicated for the prevention of chronic migraine (CM).

Aim and objectives The aim of this study was to assess effectiveness and safety of CGRP-mAbs in CM in clinical practice.

Material and methods Descriptive retrospective study was conducted in patients with CM receiving CGRP-mAbs between May 2018 and September 2021. Electronic clinical history and prescription software Farmatools were used to record data: gender, age, previous preventive treatment, CGRP-mAb prescribed, dosage, duration of therapy and monthly migraine days. Effectiveness was measured by the reduction in pain intensity (any subjective clinical improvement) and the reduction ≥50% of monthly migraine days from baseline. Failure to meet both criteria was considered as non-response. Effectiveness endpoints were measured at 3 and 9 months. Safety was evaluated according to adverse events (AE) and discontinuations of treatment.

Results Thirty-nine patients were included, 33 (85%) were women and 6 (15%) men. Mean age was 48 (23–74) years. Mean of prior preventive drugs was 6 (3–14), including: botulinum toxin A (n=39), topiramate (n=30), flunarizine (n=28), amitriptyline (n=27), zonisamide (n=26) and propranolol (n=24). Nineteen (49%) patients received galcanezumab 120 mg monthly (with 240 mg induction dose), 13 (33%) erenumab 70 mg monthly and 7 (18%) fremanezumab 225 mg monthly. Mean duration of therapy was 11 (4–22) months. Baseline monthly migraine days were ≥8 in all patients. At 3 months: 66% of patients presented both reduction in pain intensity and reduction ≥50% of monthly migraine days, 5% presented only reduction in pain intensity and 29% no response. At 9 months: 48% patients presented both reduction in pain intensity and reduction ≥50% of monthly migraine days, 10% presented only reduction in pain intensity and 42% no response. According to the safety profile, 8% patients presented injection site reactions as AE. No discontinuations of treatment were reported.

Conclusion and relevance CGRP-mAbs presented an adequate effectiveness in more than half of the patients at 3 months, although this effectiveness was slightly reduced at 9 months. CGRP-mAbs were well tolerated, with few AEs.

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