

In subsequent studies we will test whether this update helps to improve mortality outcomes.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

**Conflict of interest** No conflict of interest

#### 4CPS-050 USE OF GALCANEZUMAB IN PATIENTS WITH MIGRAINE IN A TERTIARY HOSPITAL: HEALTH RESULTS

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**Background and importance** Galcanezumab, a humanised monoclonal antibody that binds calcitonin gene-related peptide, has demonstrated a significant reduction in monthly migraine headache days.

**Aim and objectives** To perform a first preliminary evaluation 3 months after using galcanezumab in patients with migraine.

To compare the health results with the ones in the pivotal clinical trials REGAIN and EVOLVE.

**Material and methods** A retrospective, descriptive study was conducted. Data were collected from patients with migraine who had started treatment with galcanezumab from February 2020 to July 2021.

The data collected were: sex, age, type of migraine (episodic (EM) or chronic migraine (CM)), number of previously used preventive drugs, presence of analgesia abuse, dosage, date of start and end of treatment, reason for end of treatment, number of monthly migraine headache days (MHD) prior to treatment, and number of MHD after 3 months. All the information was obtained from the electronic medical record.

**Results** 59 patients with a diagnosis of EM or CR were analysed (81.4% women), with a mean age of  $53.8 \pm 12.2$  years. 76.3% had CM (45) and only 14 patients suffered from EM. Patients had tried a mean of 4.2 preventive drugs. At least 44.1% of patients presented analgesia abuse.

All patients received the same posology: 120 mg monthly (with a 240 mg loading dose) of galcanezumab.

17 patients stopped treatment, the main reasons were: inefficacy (70.6%), stability (17.6%), no adherence (5.9%) and toxicity (5.9%). 6 patients were excluded from the study on account of them not having received the re-evaluation after 3 months of treatment. The mean of MHD in patients with EM was 11.6 before treatment and 5.2 after (-6.5 MHD). The mean of MHD in patients with CM was 16.5 before treatment and 8.2 after (-8.3 MHD). So, 69.2% and 57.5% of patients with EM and CM, respectively, reduced the number of MHD by at least half.

**Conclusion and relevance** For patients with EM, the results were better than in the pivotal clinical trial EVOLVE (-4.7 vs -6.5 MHD). The same was the case for patients with CM, the results are better than in REGAIN (-4.8 vs -8.3 MHD). Galcanezumab seems to present a better effect than expected in clinical trials. This is, however, a first preliminary evaluation, and a follow-up would be necessary to see the long-term effect.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

**Conflict of interest** No conflict of interest

#### 4CPS-062 RITUXIMAB PHARMACOKINETICS CHARACTERISATION IN PLASMA AND URINE IN A PATIENT WITH NEPHROTIC SYNDROME

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**Background and importance** Rituximab (RTX) is a monoclonal antibody used to treat various conditions including glomerular diseases (GD) as an off-label indication. There is high variability in RTX pharmacokinetics (PK) and it has scarcely been studied in cases of nephrotic syndrome (NS) (Foguero *et al*, 2019). We report the PK analysis of RTX in a case of GD and measure RTX excretion in urine.

**Aim and objectives** We present a 72-year-old male with hypertension, dyslipemia and obesity (81 kg) diagnosed with membranous nephropathy in September 2020. Usual medication included magnesium, amlodipine and ezetimibe.

**Material and methods** In October 2020 the patient suffered severe NS (proteinuria: 16 g/24 hours, hypoalbuminaemia: 2.1 g/mL, hypercholesterolaemia: 406 mg/dL) and RTX was prescribed, according to available knowledge at the time: 1 g days 1 and 15.

Routine blood and 24-hour urine samples were collected. RTX was measured in serum with an ELISA kit: Lisa-Tracker-Rituximab (Theradiag). The quantitative determination of RTX in urine was performed using in-house standards and urine samples diluted to 1/100 in Phosphate-Tween Buffer.

RTX's PK analysis was done using a monocompartmental model and nonlinear regression (Winnolin). RTX maximum concentration (C<sub>max</sub>), distribution volume (V<sub>d</sub>), clearance (Cl) and half-life (t<sub>1/2</sub>) were determined.

**Results** RTX plasma concentration: 0 µg/mL at day 1 (d1) (pre-dose), 26.38 µg/mL at d 7. 7.93 µg/mL at d15 (pre-dose), 64.99 µg/mL at d15 (post-dose) and 3.72 µg/dL at d28.

RTX urine concentration: 0.18 µg/mL at d1 (pre-dose), 2.12 µg/mL at d7 and 0.18 µg/mL at d15.

PK analysis: C<sub>max</sub>=92.0 µg/mL, V<sub>d</sub>=135.1 mL/kg, Cl=1.075 mL/kg/hour, t<sub>1/2</sub>= 88.91 hours=3.7 day.

By d7 there were 93.2 mg of RTX in the body and 17.8 mg were eliminated that day. Considering a 1500 ml/24 hour urine production, 3.18 mg of RTX were excreted at d7, 3.4% of RTX in plasma was excreted by urine every 24 hours and urine excretion justified 17.9% of RTX elimination.

Tacrolimus was initiated in December 2020 due to persistent NS.

Ten months after RTX administration the patient remains in complete remission (proteinuria: 0.5 g/24 hours, serum albumin: 3.8 g/ml, serum cholesterol: 237 mg/dL).

**Conclusion and relevance** The patient's RTX V<sub>d</sub> was increased which may be due to NS-related oedema; C<sub>max</sub> was lower, Cl was increased and t<sub>1/2</sub> was notably shorter than reported values, which can be justified by RTX elimination in urine. RTX PKs are altered in cases of NS, leading to a reduced exposure. RTX may be aberrantly eliminated in urine in cases of NS and its concentration can be measured with ELISA.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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