Background and importance
Serious medication errors can be made during unexpected hospital admittance through the emergency ward. In particular, anticoagulants portray a great risk for patients when proper medication reconciliation is absent. We started using pharmacy practitioners (PPs) to improve this process on the emergency ward. We report here the results of two case series with respect to accuracy in the medication reconciliation on the emergency room (ER) ward.

Aim and objectives
To investigate if appropriate embedding of PPs in the process of medication reconciliation during unexpected admittance to the hospital could lead to fewer medication errors downstream in other hospital wards.

Material and methods
A PP was embedded in the ER ward team during office hours (08:00 to 17:00) to perform the medication reconciliation of unexpectedly admitted patients instead of ER physicians.

The two case series of admitted patients were chosen in a post-propter design. As a zero measurement, a case series of patients administered TCZ between October 2020 and February 2021 in a tertiary hospital. Criteria for TCZ use were PAFI <300 and meeting two of the following three criteria: C-reactive protein (CRP) >150 mg/L, D-dimer >1500 mg/mL and ferritin >2000 ng/mL, and not having contraindications for its use.

Each patient received a single dose of 400 mg if weight <75 kg and 600 mg if weight >75 kg.

Demographic data, comorbidities and days from symptom onset to TCZ administration were collected. Follow-up of analytical data (CRP, D-dimer and ferritin pre- and post- (15 days) TCZ administration). Clinical evolution was evaluated by mortality rate at 28 days.

Statistical analysis: Stata/MP v16.0. Student’s t-test was used for comparison of quantitative variables.

Results
39 patients were included, 25 (64.1%) were male, median age 74 (IQR 61–80) years. 61.5% had hypertension, 33.3% obesity, 41% diabetes mellitus, 17.9% chronic kidney disease, 12.8% heart disease. The median time from symptom onset to TCZ administration was 10 (IQR 7–15) days.

The medians prior to and at 15 days of TCZ administration were, respectively: 152.5 mg/L (IQR 89–220.8) and 1.7 mg/L (IQR 0.65–4.2) CRP (p<0.001); 2300 ng/mL (IQR 11 959–4889) and 1124 ng/mL (IQR 567–1439) D-dimer (p=0.1726); 1242 ng/mL (IQR 647–2705) and 851 ng/mL (IQR 268–1384) ferritin (p=0.1294). Mortality at 28 days was 64.1%.

Conclusion and relevance
Our sample size is smaller than that of the RECOVERY study; however, the days of symptoms until TCZ administration (10 vs 9) and the median CRP prior to TCZ (143 vs 152.5 mg/L) in both studies are very similar. Our mortality is much higher (64.1% vs 29%). We found a statistically significant difference between our pre- and post-CRP data.

With this result, the in-hospital protocol was modified and new criteria for TCZ administration in COVID patients became oxygen saturation <92% or PAFI >300 and CRP >75 mg/L, with no contraindications for use.
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

USE OF GALCANEZUMAB IN PATIENTS WITH MIGRAINE IN A TERTIARY HOSPITAL: HEALTH RESULTS

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10.1136/ejhpharm-2022-eahp.386

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±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 CM 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 efficacy (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 CM 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. Thi si s, 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

RITUXIMAB PHARMACOKINETICS CHARACTERISATION IN PLASMA AND URINE IN A PATIENT WITH NEPHROTIC SYNDROME

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10.1136/ejhpharm-2022-eahp.387

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 being studied in cases of nephrotic syndrome (NS) (Fogueri 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, dislipemia and obesity (81 kg) diagnosed with membranous nephropathy in September 2020. Usual medication included magnesium, amloidpine and ezetimibe.

Material and methods In October 2020 the patient suffered severe NS (proteinuria:16 g/24 hours, hypoalbuminaemia: 2.1g/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 monocompartimental model and nonlinear regression (Winnolin). RTX maximum concentration (Cmax), distribution volume (Vd), clearance (Cl) and half-life (t1/2) were determined.

Results RTX plasma concentration: 0 µg/mL at day 1 (d1) (pre-dose), 26.38 µg/mL at d 7, 7.93µg/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: Cmax=92.0 µg/mL, Vd=135.1 mL/kg, Cl=1.075 mL/kg/hour, t 1/2= 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 Vd was increased which may be due to NS-related oedema; Cmax was lower, Cl was increased and t1/2 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
Conflict of interest No conflict of interest