inappropriate use and healthcare costs. In addition, audit and educational feedback might strengthen the results.

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No conflict of interest.

4CPS-017 EFFICACY AND SAFETY OF TOLVAPTAN IN THE TREATMENT OF POLYCYSTIC KIDNEY DISEASE

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Background and importance Tolvaptan is the first authorised drug for the treatment of autosomal dominant polycystic kidney disease (PQRAD).

Aim and objectives To analyse the efficacy and safety of tolvaptan in the treatment of PQRAD compared with the results of the TEMPO study.

Material and methods This was a descriptive, observational and retrospective study of patients treated with tolvaptan (August 2017–April 2019). Variables studied were: age, sex, arterial hypertension, total renal volume (VRT), creatinine, serum potassium and sodium, transaminases and glomerular filtration rate (GFR). Adverse reactions were recorded. For collection of data, the electronic medical history was used. Statistical analysis was performed with the Stata14 programme.

Results We included 23 patients (8 women, 5 men), median age 46 years (31–63) years. All had VRT >1000 mL (median 1920 mL (1230–3154)). At the beginning of treatment, GFR was 49.7 mL/min/1.73 m² (25.6–102.31): 3 patients had stage 1 chronic kidney disease, 2 patients had stage 2, 10 patients stage 3A, 6 patients stage 3B and 2 patients stage 4. All patients suffered progressive deterioration of renal function during treatment: 5.25 mL/min/1.73m² (–3.61–18.29) and 8.28 mL/min/1.73 m² (–1.87–15.59) at 3 and 6 months, respectively, and 8.49 mL/min/1.73 m² (4.21–14.06) at the end of the treatment year. Tolvaptan was suspended in three patients due to impaired renal function (GFR <20 mL/min/1.73 m²); all other patients were still receiving treatment at the end of the study (five with dose reduction to 60/30 mg). All patients reported polyuria and polydipsia and no patient suffered clinically relevant alterations in serum sodium or potassium. Relative to liver function, three patients suffered specific alterations in AST, ALT and GGT above normal values (57, 76 and 63 IU/L, respectively).

Conclusion and relevance Our results, compared with the TEMPO study, showed a higher rate of renal function deterioration, measured as a decrease in GFR rate after 1 year of treatment (8.49 vs 2.7 mL/min/1.73 m²), probably in relation to the worst baseline condition of the patients included in our study. Therefore, it is essential to identify the population susceptible to receiving this drug, prioritising those patients with GFR >45 mL/min/1.73 m² and with a high risk of rapid progression.

REFERENCES AND/OR ACKNOWLEDGEMENTS

TEMPO clinical trial.

No conflict of interest.

4CPS-018 EFFICACY OF UREA IN THE TREATMENT OF HYPONATRAEMIA IN SYNDROME OF INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION

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Background and importance The consequence of the syndrome of inappropriate antidiuretic hormone secretion (SIADH) is a hypotonic hyponatraemia. Urea is a well tolerated therapeutic option indicated to correct sodium levels, acting as an osmotic diuretic, eliminating a large amount of water in urine accompanied by an increase in plasma sodium concentration.

Aim and objectives To evaluate the efficacy of urea in controlling hyponatraemia due to SIADH in a third level hospital.

Material and methods This was a quasi-experimental study. Patients with hyponatraemia treated with urea in 2019 were included.

The main variable of our study was serum sodium level before treatment with urea at 24 hours, 48 hours, 14 days and 60 days. Age and sex were included as secondary variables.

There were no extreme outliers and the data were normally distributed for each measured time, as assessed by box plot and the Shapiro–Wilk test ($p > 0.05$), respectively. A one-way repeated measures ANOVA was conducted to determine whether there was a statistically significant difference in sodium concentration before and after treatment with urea. The analyses were performed using the SPSS/PC statistical programme (V.24.0 for Windows, SPSS Inc, Chicago, Illinois, USA).

Results Thirty-three patients were treated with urea for 9 months. Of these, 67% were men and mean age was 77 ± 13 years. Serum sodium levels before treatment and at 24 hours, 48 hours, 14 days and 60 days were 125 ± 4 , 127 ± 5 , 129 ± 5 , 134 ± 4 and 134 ± 4 mg/dL respectively. Time did not elicit statistically significant changes in sodium levels before and after treatment with urea ($F = 4.1$, $p = 0.074$).

Conclusion and relevance In the study, there were no significant differences in plasma sodium values before and after urea treatment, so we did not demonstrate the efficacy of urea. The main drawback in the study was the small population analysed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-019 ALIROCUMAB AND EVOLOCUMAB: EFFECTIVENESS AFTER 3 YEARS OF FOLLOW-UP IN A REAL WORLD SETTING

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Background and importance Hypercholesterolaemia leads to a higher risk of atherosclerosis and cardiovascular events. Familial hypercholesterolaemia is more resistant to usual treatments. In 2015, the PCSK9 inhibitors (PCSK9I) alirocumab

and evolocumab were approved for primary hypercholesterolaemia (heterozygous family (HFHe) and non-familial (HNF)) and mixed dyslipidaemia (DM). Due to their recent approval and high cost, it is crucial to evaluate their real world results.

Aim and objectives To analyse the long term effectiveness of PCSK9I over 3 years, approved by the pharmacy service (PS).

Material and methods This was an observational retrospective study conducted at a third level hospital from January 2016 to March 2019. All PCSK9I were evaluated by the PS according to the criteria of the Regional Pharmacotherapeutic Commission. Patients approved who initiated the treatment were included.

Biodemographic, clinical and pharmacotherapy data was collected from the medical records. Parameters were evaluated at treatment initiation and after 6 months. Clinical response, defined as a reduction in low density lipoprotein (LDL) >30%, was analysed by indication.

Results PS accepted 93 of 123 patient requests. Only 72 patients (median age 58 years (37–84), 56% men) were included due to lack of data. Cardiovascular risk factors were: hypertension (47.2%), family history of ischaemic heart disease (40.3%), smoking (38.3%), obesity (15.3%), diabetes (12.5%) and ischaemic heart disease (58.3%).

Initial LDL values (mg/dL) were 100–129 (23.6%), 130–159 (34.8%), 160–190 (20.8%), and >190 (20.8%). Frequency of additional lipid lowering drugs were: atorvastatin (40.3%), rosuvastatin (27.8%), fluvastatin (2.8%), pitavastatin (2.8%), statin free (26.4%) and ezetimibe (72.2%). During the study, 41.7% of patients showed statin intolerance and 88.9% reached their maximum tolerated dose.

After initiating PCSK9I, 83.3% of patients maintained the same dose of statin, 8.3% reduced the dose, 6.9% stopped taking the medication, 4.3% switched to another statin and 1.4% increased the dose. LDL plasma concentration decreased by more than 50% in 52.1% of patients, by 30–50% in 31.2% of patient and by <30% in 16.7% of patients. The clinical response in primary HFHe prevention was alirocumab 16.7% versus evolocumab 50%, and in secondary HFHe, alirocumab 68.8% versus evolocumab 83.3%. The clinical response in primary HNF prevention was alirocumab 60% (no evolocumab patient) and in HNF/DM secondary prevention, alirocumab 50% versus evolocumab 100%.

Conclusion and relevance We found that 16.7% of our population did not achieve a clinical response; PS may play a relevant role, suggesting treatment cessation in these patients. Evolocumab could be especially effective in HFHe; more studies are needed to confirm this finding.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-020 USE, EFFICACY AND ADHERENCE TO TREATMENT WITH PCSK9 INHIBITORS IN REAL CLINICAL PRACTICE

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Background and importance In recent years innovative therapies have been developed for the treatment of hypercholesterolaemia that allow an effective decrease in low density lipoprotein (LDL)-cholesterol (LDL-c). These are alirocumab and evolocumab, anti-proprotein convertase subtilisin-kexin

type 9 (PCSK9) monoclonal antibodies. The Pharmacy and Therapeutics Commission of our hospital has accepted the following indications: familial hypercholesterolaemia (HF) with LDL-c >100 mg/dL with maximum tolerated dose of statins, cardiovascular disease (CVD) established with LDL-c >100 mg/dL with maximum tolerated dose of statins and statin intolerant with LDL-c >100 mg/dL.

Aim and objectives To study the correct use of PCSK9 inhibitors in real clinical practice in a third level hospital. To evaluate efficacy and adherence to treatment.

Material and methods This was an observational, analytical and retrospective study of patients treated with anti-PCSK9 who attended the pharmacy service for a consultation. On 30 September 2019, a cross section was performed and the data collected were: sex, prescribed anti-PCSK9, dosage, theoretical and real dispensed units, indication and analytical data at 0 and 12 weeks (total cholesterol, LDL-c, high density lipoprotein cholesterol and triglycerides).

Results A total of 82 patients (53 men, 29 women) were studied: 57(69.5%) patients received evolocumab and 25 (30.5%) alirocumab. The distribution by diagnoses were: 17.1% HF, 46.3% CVD, 13.3% statin intolerance and 15.8% other.

After 12 weeks, the mean reduction in LDL-c was 54.3%, reaching the LDL-c target <100 mg/dL in 89.0% of cases. However, 4.9% of patients experienced an increase in LDL-c levels. Adherence to treatment was calculated by an indirect method from the record of dispensations (medication possession rate (MPR)=real/theoretical dispensed units×100). A patient with MPR >80% was considered adherent. Only 8.5% of patients were below the established limit, and were non-adherent.

Conclusion and relevance PCSK9 inhibitors are effective in decreasing LDL-c levels (<100 mg/dL). The reduction obtained in our study was similar to that obtained in pivotal studies. The prevalent diagnosis was uncontrolled CVD with maximum doses of statins. Only in 15.8% of cases was the PCSK9 inhibitor not indicated (initial LDL-c <100 mg/dL). Adherence to treatment was high but it could have been overestimated because it was assumed that the patient administered the dispensed medication. More long term studies are needed to corroborate the data. In real clinical practice, it would be interesting to assess if this reduction in LDL-c is associated with a decrease in cardiovascular events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-021 ALIROCUMAB AND EVOLOCUMAB: RESULTS IN CLINICAL PRACTICE

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Background and importance Hypercholesterolaemia is a well established risk factor for developing coronary heart disease and increasing the risk of cardiovascular events (RCE). Alirocumab and evolocumab, proprotein convertase subtilisin-kexin type 9 (PCSK9) inhibitors, can complement the management of patients who do not achieve target cholesterol levels with standard treatment or are intolerant to it.