and evolocumab were approved for primary hypercholesterolaemia (heterozygous family (HHHe) 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 PSCK9I 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**

R Claramunt García*, CL Muñoz Cid, A Sánchez Ruiz, AM López, E Pérez Cano, Y Jimenez López, J Jerez Rojas. Hospital Universitario de Jaén, Pharmacy, Jaén, Spain

10.1136/ejhpharm-2020-eahpconf.121

**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.
Aim and objectives To evaluate the effectiveness of alirocumab and evolocumab in reducing low density lipoprotein cholesterol (LDL-c) and RCE in patients with poorly controlled hyperlipidaemia.

Material and methods This was an observational and retrospective study which included every patient treated with alirocumab and evolocumab between March 2016 and September 2019. Demographics and clinical variables were collected from the electronic medical records: sex, age, drug, dose, frequency of administration, previous hypolipidaemic treatment, causes of suspension and analytical parameters at the start of treatment, and after 12 weeks and 24 weeks (total cholesterol (TC), LDL-c, high density lipoprotein (HDL)-cholesterol and triglycerides). To assess RCE, the Framingham scale was used, and if patients were diabetic or smokers was also recorded. To assess effectiveness, we calculated the percentage reduction (PR) of TC, LDL-c and RCE. Adverse effects (AE) were recorded to assess safety.

Results Forty-six patients were included (76% men, average age 60.8 (SD 11.1) years: 24 were treated with alirocumab and 22 with evolocumab. Median duration of treatment was 27.2 months (0.2–43.8). At drug initiation, 71.7% of patients were on high dose statins and 76.1% were on ezetimibe as an adjuvant. Six patients discontinued treatment: 4 for toxicity, 1 for associated pathology and 1 due to loss of follow up.

The mean baseline values for TC, LDL-c, HDL-cholesterol and triglycerides were, respectively: 237.6 (SD 79.5), 149.7 (SD 54.7), 52.3 (SD 13.9) and 166.2 (SD 111.5).

After 12 weeks of treatment, the PR in TC, LDL-c and RCE were 31.1%, 49.3% and 34.1%, and at 24 weeks, 29.9%, 43.7% and 32.8%, respectively. Eight patients recorded AE: 37.5% headache, 25% arthralgias, 25% flu-like syndrome, 12.5% hypertransaminasemia and 12.5% syncope.

Conclusion and relevance PCSK9 inhibitors are an effective and safe therapeutic tool in the control of LDL-c and cardiovascular risk. In our patients, a more pronounced reduction in parameters was observed in the first 12 weeks and was maintained afterwards. In addition, the results obtained were similar to those of clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-023 LONG TERM EFFICACY, SAFETY AND ADHERENCE TO ALIROCUMAB IN PATIENTS WITH DYSLIPIDAEMIA FROM A TERTIARY HOSPITAL COHORT

Aim and objectives Alirocumab is a monoclonal antibody approved for the treatment of hypercholesterolaemia but long term clinical data are still limited.

Background and importance Cardiovascular diseases are the main cause of mortality in developed countries. One of the main cardiovascular risk factors is high levels of low density lipoprotein cholesterol (LDL-c). However, for those categories of patients with severe hypercholesterolaemia, or patients who are intolerant to statins, there are limited therapeutic options. Currently, evolocumab and alirocumab, cholesterol lowering monoclonal antibodies, are used. Clinical studies show that their use, in addition to statins, is associated with a reduction in LDL-c of up to 50–60% compared with basal levels.

Aim and objectives The aim of the study was to review the use of PCSK9 inhibitors in our centre evaluating effectiveness in relation to official clinical endpoints.

Material and methods A retrospective cohort study was conducted in patients who began using proprotein convertase subtilisin-kexin type 9 (PCSK9) inhibitors between August 2017 and September 2019. The data were retrieved from the web based register of the Italian Medicines Agency, patient electronic medical records and the internal dispensation programme. All patients being treated with evolocumab and alirocumab were analysed from the first prescription to the first revaluation. The main variables collected were: gender, age, indication, LDL value before and after the first evaluation of treatment, and high density lipoprotein (HDL) and triglycerides values before and after the first evaluation. The collected data were analysed and evaluated through the SPSS programme.

Results A total of 52 patients were analysed, 29 patients treated with evolocumab and 23 patients with alirocumab, of whom 62.00% were women. Mean age was 60.30±14.20 years and 50.00% had a family type disease, 15.00% a non-family type and 35.00% mixed dyslipidaemia. For patients treated with evolocumab, the mean LDL value before treatment was 189.90±57.62, HDL 51.63±19.79 and triglycerides 186.16±86.76. After treatment, the LDL value was 98.54±48.49 (Δ=91.35±36.96, p<0.000) a decrease of 51.89%. For patients treated with alirocumab, the median LDL value before treatment was 196.06±45.38, HDL 48.50±12.94 and triglycerides 164.28±71.19. After treatment, LDL was 84.00±39.53 (Δ=112.06±38.90, p<0.000), a decrease of 51.13%.

Conclusion and relevance The data confirm the results of clinical studies: treatment with evolocumab and alirocumab achieve the primary endpoint of lowering LDL. A statistically significant reduction in HDL and triglycerides was not observed.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.