

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 hypolipaeamic 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% hypertransaminasaemia 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 the 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-022 PCSK9 INHIBITORS: EVALUATION OF EFFECTIVENESS IN OUR CENTRE IN RELATION TO THE OFFICIAL CLINICAL ENDPOINTS

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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 reevaluation. 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. Medium 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 ($\Delta=91.35\pm36.96$, $\rho<0.000$) 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 ($\Delta=112.06\pm38.90$, $\rho<0.000$), 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.

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

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

Aim and objectives To assess the long term efficacy, safety and adherence to alirocumab after 96 weeks of treatment in a cohort of patients with dyslipidaemia.

Material and methods This was a retrospective observational study performed in a university tertiary hospital. All patients starting alirocumab before September 2017 in our institution and treated for at least 96 weeks were included.

Demographic, clinical and alirocumab data were collected. Treatment efficacy was calculated as per cent reduction in low density lipoprotein cholesterol (LDL-c) from baseline to 96 weeks after treatment initiation. Adverse effects were collected and classified according to the common terminology criteria