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 hypolipaemic 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 subtilsin-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 evolucumab 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 (Δ=91.35±36.96, ρ<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, ρ<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

for adverse events (CTCAE) V.4.0 grades. Mean adherence at 96 weeks was calculated by the medication possession ratio based on pharmacy refill records.

Results Thirty-three patients started alirocumab treatment in 2017 and 31 (93.9%) were still on treatment after 96 weeks. Two patients (6.1%) discontinued therapy: one due to an active malignancy and one due to loss of follow-up.

Patient characteristics were 58.1% men with a median (IQR) age of 65 (11) years. Alirocumab dose was 75 mg/2 weeks in 87.1% of patients and 150 mg/2 weeks in 12.9%. Secondary prevention was 83.9% and there was a high cardiovascular risk in 80.6%. Type of hypercholesterolaemia was heterozygous familial in 29.0% of patients, polygenic in 67.7% and combined familial hyperlipidaemia in 3.2%. Statin intolerance was found in 38.7% of patients. Comorbidities included diabetes mellitus 19.4%, hypertension 54.8% and smoking 3.2%.

Median (range) adherence was 100% (81.7–100%) (only 2 patients (6.5%) with adherence <90%). Median (IQR) reduction in LDL-c reduction was 59.5 (22.6)%. Only one patient did not have a reduction in LDL from baseline (adherence 82%). A high cardiovascular risk was the only patient factor associated with 100% adherence (p=0.034). Mild adverse effects were present in 19.3% of patients (27.3% constipation, 18.2% flu-like syndrome, 18.2% pruritus and other (dizziness, palpitations, headache, dysgeusia) 9.1% each). All adverse effects (100%) were classified as CTCAE grade 1.

Conclusion and relevance More than 90% of patients starting alirocumab persisted with treatment for 96 weeks after initiation. Alirocumab showed good long term efficacy with a median reduction in LDL of >50%. It was also well tolerated because all reported adverse events were mild and did not lead to any treatment discontinuation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-024 EFFECTIVENESS OF ANTI-INTERLEUKIN-17 DRUGS IN PSORIASIS IN CLINICAL PRACTICE

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Background and importance Anti-interleukin-17 (IL-17) drugs are a new option for treating patients with psoriasis which have demonstrated high efficacy in clinical trials.

Aim and objectives To analyse the effectiveness of anti-IL-17 drugs for psoriasis in clinical practice.

Material and methods A cross sectional study was conducted in two regional hospitals with a total of 196 biologic treatments (BT) for psoriasis. Inclusion criteria were patients in active treatment for at least 12 weeks with an anti-IL-17 drug (secukinumab or ixekizumab) for psoriasis until October 2019. Data collected included patient characteristics, type of psoriasis, previous and actual treatment, effectiveness measured by the psoriasis area severity index (PASI) and the impact on quality of life measured by the dermatology life quality index (DLQI). Statistical analysis was carried out with SPSS Statistics V.22. Results are presented as mean (SD) for quantitative data and percentages for qualitative data.

Abstract 4CPS-024 Table 1

	Previous	Post	P value
PASI	12.5 (5.7)	0.9 (1.3)	<0.001
DLQI	10.0 (7.4)	0.6 (1.1)	<0.001

Results Thirty patients were included in the study (15.3% of the total BT for psoriasis in both hospitals), 16 (53.3%) of whom were men, and mean age was 50.2 (13.6) years.

Distribution by types of psoriasis: 30 (100.0%) plaque, 7 (23.3%) nail, 6 (20.0%) palmoplantar, 6 (20.0%) scalp and 2 (6.6%) inverse psoriasis. Thirteen (43.3%) patients had more than one type.

Distribution by treatment: 23 (76.7%) secukinumab and 7 (23.3%) ixekizumab. Twenty-three (76.7%) patients had received at least one systemic agent, which was usually methotrexate (69.6%), followed by acitretin (26.1%) and ciclosporin (4.4%). Moreover, for 13 (43.3%) patients, the anti-IL-17 drug was the first BT, while in 17 (56.7%) there had been another BT previously. Two (6.7%) patients had previously received an anti-IL-17 drug, which in both cases was secukinumab. Effectiveness is shown in table 1.

Twenty-two (73.3%) patients achieved a PASI of 90 (almost complete clearance of psoriatic lesions) and 24 (80.0%) had a DLQI ≤1 (no impact on quality of life) within 12 weeks of treatment. No significant differences in previous and actual PASI and DLQI were found between secukinumab and ixekizumab.

Conclusion and relevance

- More than half of the patients had more than only plaque psoriasis.
- Most patients had been treated previously with one systemic treatment.
- Anti–IL–17 drugs were effective in clinical practice.
- There were no differences between secukinumab and ixekizumab in terms of effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-025 DUPILUMAB IN THE TREATMENT OF MODERATE TO SEVERE ATOPIC DERMATITIS: CASE REPORTS

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Background and importance Dupilumab is authorised in the European Union for the treatment of moderate to severe atopic dermatitis (AD) in adult patients who are candidates for systemic treatment. It is a non-funded drug in Spain, so patients can only access this treatment through medication management under special circumstances according to the Spanish Agency for Medicines and Health Products (AEMPS).

Aim and objectives To analyse the criteria for use, effectiveness and economic impact of dupilumab in the treatment of moderate to severe AD.