EFFECTIVENESS AND SAFETY OF MONOCLONAL ANTIBODIES AGAINST PROPROTEIN CONVERTASE SUBTILISIN/KEXIN 9 (PCSK9 INHIBITORS) FOR THE TREATMENT OF HYPERCHOLESTEROLAEMIA

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1. Background:

Alirocumab and Evolocumab (PCSK9-Inhibitors), are new drugs incorporated to the therapeutic arsenal for the treatment of hypercholesterolemia and having shown effectiveness and safety in the performed clinical trials.

2. Purpose:

To assess effectiveness and safety of PCSK9-Inhibitors, to evaluate if both drug are same effective and to evaluate if there is any efficacy difference when using them as monotherapy agents or plus other lipid-lowering therapies (OLLT).

3. Setting and Metods:

Observational, retrospective and analytical study of patients in treatment with PCSK9-Inhibitors between Feb2016- Aug2017

Variables →

- ✓ **Demographic**: Sex, age
- ✓ **Clinical:** diagnosis, prescribed PCSK9-Inhibitors, OLLT, adverse events (AE)
- ✓ **Analytical:** LDL-Cholesterol (LDL-C) and transaminases at week 0,24 and 48

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*Effectiveness was defined as the percent change in LDL-C from baseline to week 24 or 48. Safety was assessed by analysing AE and transaminases increase during treatment. Effectiveness difference between groups were analyzed (Alirocumab Vs Evolocumab and PCSK9-Inhibitors Vs PCSK9-Inhibitors plus OLLT) using t-test with SPSS®v23.

4. Results:

Study population:

№ Patients :	39 patients
Sex:	Men: 62% Women: 38 %
Mean age:	56 years (34-78)
Diagnosis:	• Primary hypercholesterolemia 77% (97% heterozygous, 3% homozygous) • Mixed dyslipidemia 33%
Mean basal LDL-C:	165.13±45.37 mg/dl
PCSK9-Inhibitors prescribed:	Evolocumab 59% Alirocumab 41%
Patients with PCSK9-inhibitors in monotherapy:	6 patients (15,38%)
Patients with PCSK9-inhibitors plus OLLT	33 patients (84,61%)

Effectiveness:

The percent change in LDL-C from baseline to week 24 were -41% and to week 48 were -61%.

Effectiveness difference between groups:

The percent change in LDL-C from baseline to week 24 in **Evolocumab group** were -50% and -46% in **Alirocumab group** (P=0.736)

The percent change in LDL-C in the **monotherapy group** were -36% and -51% in the group **plus OLLT** (P=0.283).

Safety:

No EA were reported, however, 5% of patients present elevation of transaminases at 12 weeks. There were no cases of patients requiring suspension or interruption of the treatment.

5. Conclusions:

Our study have shown a reduction in LDL-C that is comparable with shown in clinical trials, with a greater tendency for reduction in Evolocumab group and in patients with OLLT combined, probably associated with the synergistic effect of both drugs. We must continue to study whether this is related to a reduction in morbidity and mortality.

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