REAL-WORLD EFFECTIVENESS AND SAFETY OF EVOLOCUMAB AND ALIROCUMAB

P. Rovira Torres[1], A. Jimenez Portilla[2], M. Ortiz Gonzalez[1], M.M. Santandreu Estelrich[1], A. Gomez Lobon[1], O. Delgado Sanchez[1], J.R. Urgeles Planella[2].

[1]Hospital Universitario Son Espases, Pharmacy, Palma de Mallorca, Spain.
[2]Hospital Universitario Son Espases, Endocrinology , Palma de Mallorca, Spain.

Background

In our Community, Alirocumab and Evolocumab, first-in-class proprotein convertase subtilisin–kexin type 9 inhibitors (PCSK9-I), have been authorized by the Public Health System for the treatment of patients with :

- uncontrolled familial hypercholesterolaemia (FH) with LDL-C>130mg/dL
- uncontrolled stable atherosclerotic cardiovascular disease (ASCVD) with LDL-C >130mg/dL or
- unstable ASCVD with LDL-C>100mg/dL

in combination with a statin and ezetimibe at maximum tolerated doses and in patients who cannot tolerate or cannot be given statins with LDL-C>100mg/dl.

Material and methods

Retrospective study from April 2016 to June 2017

- Inclusion criteria: patients treated with PCSK9-I during the study period.
- Variables collected: demographic, clinical, analytical and treatment.
- Evaluation of efficacy: mean percent change in LDL-C level from baseline to first follow-up visit. (Cut-off date 04 October 2017).
- Statistical analysis: IBM® SPSS Statistics® v22.0. The variables are presented by means and percentages. Chi-square test was used for comparison among groups. The results were analyzed according to the intention-to-treat principle.

Purpose

- Describe the efficacy and safety of PCSK9-I at a tertiary care hospital.

Results

- Demographic

38 patients with PCSK9-I (20 females)
Median age: 56 years (range 35-80)

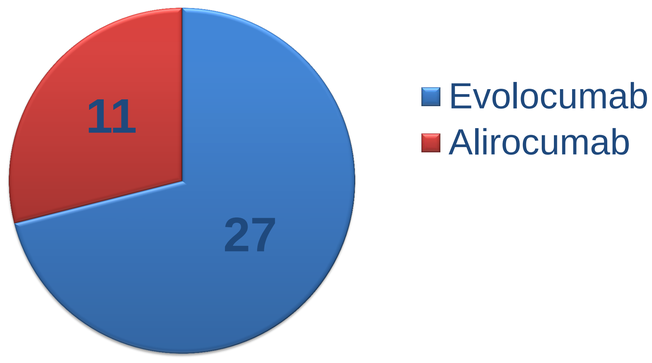
- Clinical

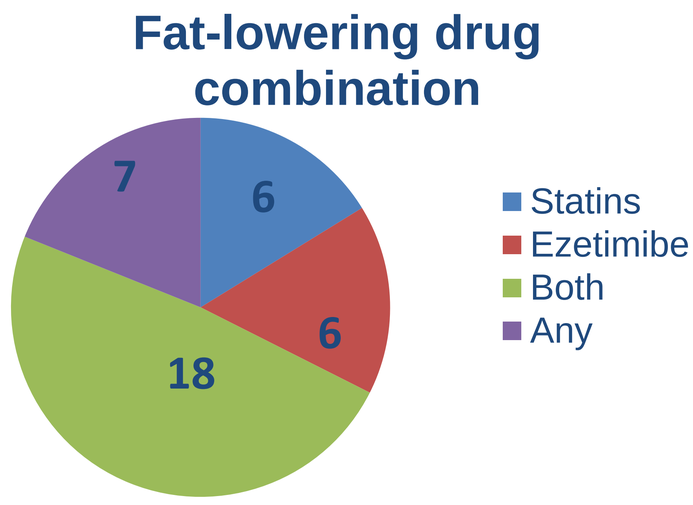
Indications

19 patients with ASCVD | **15** patients with FH | **4** patients with ASCVD and FH

Mean baseline LDL-C level was **180.5 ± 49.4mg/dL (range 91 to 321mg/dL)**.
15 were statin intolerant and **7** ezetimibe intolerant.
The recommended goal for LDL-C was 100mg/dL and 70mg/dL for 30 and 24 patients respectively, according to the European Guidelines on cardiovascular disease[1]

- Treatment





- Efficacy

After first follow-up visit (mean of 14,0±8,3 weeks)	
Mean LDL baseline	180.5±49.4mg/dl
Mean LDL after first follow-up visit	79.4±38.8mg/dl
Mean percentage change	-56 %
Absolute change	-102,5 mg/dl
Treatment goal reached [1]	19 patients (50%)
Diferences between evolocumab and alirocumab	(-58 % vs -50 %; p=0,334)

- Safety
  - One patient had poor compliance due to adverse events (hair loss and nail fungus), although it is not described in the EPAR (European Public Assessment Report).

Conclusion

- LDL-C reductions obtained with PCSK9-I in clinical practice are similar than those described in clinical trials (50-70%)[2,3] although only 50% obtained the recommended goal in the fist follow-up visit.
- PCSK9-I were well tolerate without discontinuations due to side effects.
- These new drugs bring a treatment opportunity to patients that are intolerant or non-responders to the currently available therapies.

References

- [1] 2016 European Guidelines on cardiovascular disease prevention in clinical practice
- [2] European Medicines Agency (EMA). Repatha®. European Public Assessment Report (EPAR). EMA/CHMP/222019/2015.
- [3] European Medicines Agency (EMA). Praluent®. European Public Assessment Report (EPAR). EMA/CHMP/392430/2015.