REAL-WORLD EFFECTIVENESS OF EVOLOCUMAB AND ALIROCUMAB AT 12 MONTHS OF TREATMENT

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Background

Alirocumab and Evolocumab are proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9-I) that have been authorized by the Autonomous Health Service under the following conditions:

- 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 and follow-up at 12 months of treatment

- Inclusion criteria: patients treated with PCSK9-I during the study period.
- Variables collected: demographic, clinical, analytical and treatment.
- Evaluation of efficacy: the percentage of reduction of LDL-C. (Cut-off date June 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

- analyze effectiveness of PCSK9-I in patients treated at a tertiary care hospital

Results

- Demographic

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

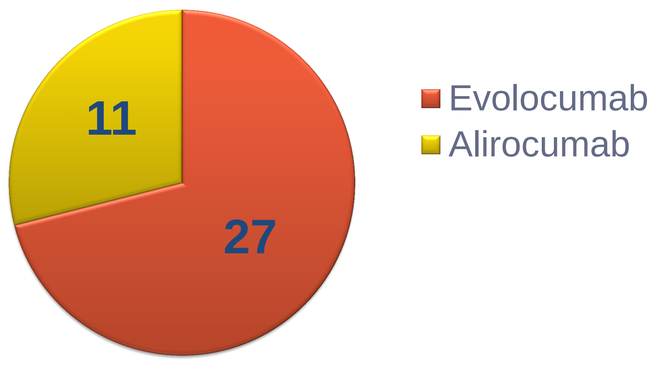
- Clinical

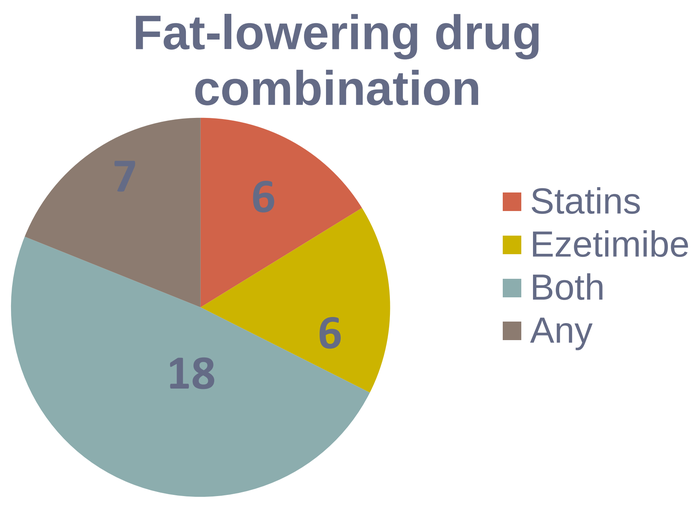
Indications

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 14 and 24 patients respectively, according to the European Guidelines on cardiovascular disease[1]

- Treatment





- Efficacy

After 12 months (mean of 53 weeks[42+76])*	
Mean LDL baseline	180.5±49.4mg/dl
Mean LDL after 12 months	84.6 ± 43.8mg/dl
Mean percentage change	-50.8 ± 34.8%
Absolute change	-102,5 mg/dl
Treatment goal reached [1]	15 patients (60%)
Diferences between evolocumab and alirocumab	(-55,2% versus -40,8%, p = 0,408)

*data were collected from 25 (65.8%) patients, in 11 cases (28.9%) the blood test was not done and 2 (5.3%) discontinued treatment due to patient decision

- 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 60% of patients achieved the recommended goal after one year of treatment.
- 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.

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