REAL-WORLD EFFECTIVENESS AND SAFETY OF EVOLOCUMAB AND ALIROCUMAB

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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.
- 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

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 disease¹

Type of PCSK9-I

- Evolocumab: 27
- Alirocumab: 11

Fat-lowering drug combination

- Statins: 7
- Ezetimibe: 6
- Both: 6
- Any: 18

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: -102.5mg/dL
- Treatment goal reached ¹: 19 patients (50%)
- Differences between evolocumab and aliocumab: (-58 % vs -50 %; p=0.334)

- 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).

Safety

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 first follow-up visit.
- PCSK9-I were well tolerated 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