

Initial experience with the use of PCSK9-inhibitors in the real-world clinical practice

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Background

New lipid lowering therapies with excellent results on LDL cholesterol (LDL-C) levels came to market at more than 5 times the cost of the most effective statin regimen.

We need strategies to put these treatments into practice and ensure their cost-effectiveness.

Purpose

Here we review our initial clinical experience with the use of PCSK9 inhibitors, after the the regional autonomic pharmacy and therapeutic committee published the authorization criteria for its use, in December 2016.

Materials and methods

Descriptive study of PCSK9 inhibitor utilization in a secondary level hospital, from Dec 2016 to Sept 2017.

Data source: electronic medical records, prescription program and authorization request files

Variables: demographics, prescription data and the authorization process, treatment effectiveness and tolerance

Results

Twenty-five requests for authorization of PCSK9 inhibitors were received.

Median age: 64 (43-77). 37% women.

Prescriber: cardiology 12, internal medicine 13.

Diagnosis:

- familial hypercholesterolemia
- ASCVD, LDL-C goal not reached

Statin intolerance was claimed in 68%.

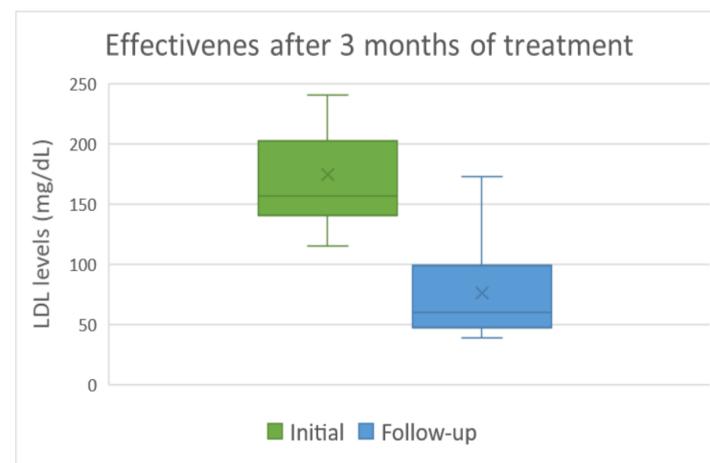
Authorization process

40% of treatments initially denied due to lack of documentation supporting:

- adequate trial of statin therapy (n=6)
- adherence to statin therapy (n=2)
- statin intolerance (n=1)
- another medical issues to be resolved first (n=1)

Two request reassessed and approved after additional documentation was provided.

Seventeen treatments were finally authorized, 13 have been initiated:



32,9% - 74,2% LDL level decrease

- 100% adherence
- No medication related problems observed

Pharmacist intervened on three occasions, reminding the prescriber about the need for a follow up.

Conclusions

- Our small series confirms effectiveness and good tolerance of treatment with PCSK9 inhibitors.
- Given the high cost of these treatments, patient selection and their routine follow-up are crucial.
- The pharmacist is in an ideal position to ensure compliance with follow-up recommendations and to assess the adherence, effectiveness and safety of these new treatments