

THE GOVERNANCE OF PCSK9 INHIBITORS FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLEMIA: APPROPRIATENESS ANALYSIS.

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Background

Recently European Medicines Agency approved Alirocumab and Evolocumab, two monoclonal antibodies against PCSK9 (anti-PCSK9), a key-protein in LDL-receptor degradation. These drugs, as monotherapy or in combination with other lipid-lowering agents, represent an important therapeutic strategy in patients with high cardiovascular risk with severe familial hypercholesterolemia or intolerant to Statins.

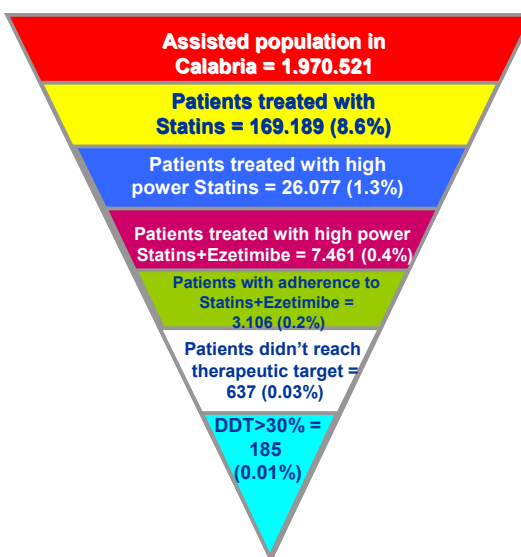
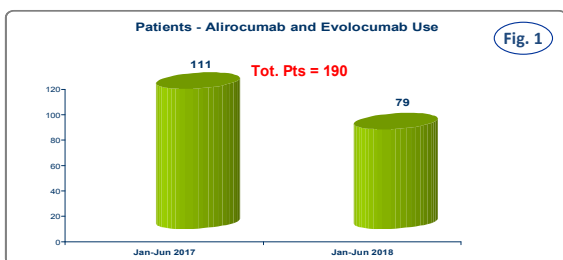
In 2017, the Regional Working Group (RWG), using the GRADE method, drafted the guidelines for the identification of the anti-PCSK9 prescribing centres and for the prescriptive appropriateness.

Purpose

Our goal is to monitor the use of the anti-PCSK9 to assess the reliability of the forecasts made by the RWG and the appropriateness.

Material and methods

The guidelines for appropriateness have been drawn up using the GRADE method. The pharmacoutilization and therapeutic adherence data have been extrapolated from the Health.db, appropriateness analysis tool adopted in our region since 2013. The consumption data for the period January 2017-June 2018 were obtained from the IQVIA database.

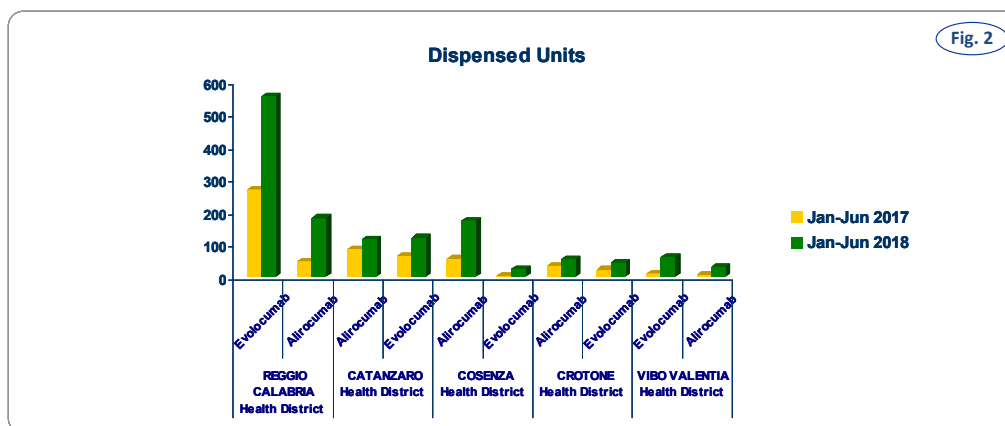


Results

Pharmaceutical use data showed that about 8.6% of the regional population is treated with Statins.

Epidemiological analysis using Health.db showed that the patients with adherence to combined Statin+Ezetimibe treatment are 0.2%; of these, 0.03% didn't reach the therapeutic target. It is expected that only 185 patients (0.01%) present distance from the therapeutic target of more than 30% (DDT>30%) and, therefore, eligible for treatment with anti-PCSK9. Also from the consumption data (real data) we observed that the number of patients suitable for treatment with anti-PCSK9 in the period July2017-June 2018 was 190 patients, almost equal to that provided by the epidemiological analysis performed by the method GRADE and Health.db. (Fig. 1).

The use of anti-PCSK9 at regional level increased significantly in the first half of 2018 compared to 2017 ($\Delta_{units}=+128\%$), probably due to the effectiveness and continuity of the treatments (Fig. 2).



Conclusions

The establishment of the RWG for the definition of the care path for patients with high cardiovascular risk was essential for the epidemiological evaluation and monitoring of anti-PCSK9 therapies. This allows to analyze the cases of suspension of therapy and the eventual occurrence of adverse events. We plan to evaluate the long-term efficacy of these treatments by observing the lowering of LDL-Cholesterol.

