28TH EAHP CONGRESS 2024
BORDEAUX

N. 5PSQ-058
C10- LIPID MODIFYING AGENTS

EFFICACY EVALUATION OF ANTI-PCSK9 DRUGS FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA OR MIXED DYSLIPIDAEMIA

L. SILVA (1), G. BABAGLIONI (1), E. FESTA (1), D. PAGANOTTI (1), T.E. TESTA (1)
1) ASST Spedali Civili of Brescia, Hospital Pharmacy, Italy

Keywords

Proprotein Convertase Subtilisin/Kexin type 9; Primary hypercholesterolaemia; Mixed dyslipidaemia; Evolocumab; Alirocumab.

Background and importance

The anti-PCSK9 monoclonal antibodies alirocumab and evolocumab were authorised in 2015 for the treatment of primary hypercholesterolaemia (heterozygous HeFH or non-family noFH) or mixed dyslipidaemia (MD).
They have been studied in statin-intolerant patients, in combination with a statin or as monotherapy and have been shown to reduce LDL cholesterol by 50-70% overall (1).

Material and methods

The C-LDL and C-HDL values at the beginning and at the end of treatment were compared as therapy efficacy indicators. In addition, comorbidities and concomitant therapies were analysed. The data reported refer to the overall average duration of treatment for each patient.

• • •

Conclusion and relevance

Anti-PCSK9 are effective in reducing C-LDL levels: a 40% reduction was reported for alirocumab 75 mg over an average of 35,5 months of treatment (2-62,3), 41% for alirocumab 150 mg over 35,2 months (10,8-64,9) and 42,5% for evolocumab over 34,7 months (8-73,9).
These values are lower than those of the registrative clinical studies although they refer to shorter treatment periods (2-3 months).
These data suggest that in addition to efficacy, it is important to monitor patients' adherence and tolerability: in the former case, 76% of patients changed therapy after an average of 35,5 months and in the latter case, 13.5% discontinued therapy due to the occurrence of adverse reactions after an average of 17,7 months.

Aim and objectives

The analysis aims to evaluate, by checking AIFA monitoring registers, the efficacy of alirocumab and evolocumab and the therapeutic adherence in patients who completed the treatment for primary hypercholesterolaemia or mixed dyslipidaemia.

Results

Of the 37 patients (mean age 63 years, 36-81), 28 received alirocumab and 9 evolocumab.
The average duration of treatment was 34,7 months (4,6-73,9) and 76% had at least two comorbidities. Also, 83,8% of patients were taking ezetimibe, 19% rosuvastatin and 13,5% atorvastatin. 57% of the sample was eligible for noFH, 32% for MD and 11% for HeFH.
The mean C-LDL reduction from baseline after therapy with alirocumab was 39,9% while with evolocumab it was 42,8%. An average C-HDL increase of 13% occurred in both therapies.

References

1. **Joel Schmitz, Ioanna Gouni-Berthold. Anti-PCSK9 Antibodies: A New Era in the Treatment of Dyslipidemia. Curr Pharm Des. 2017;23(10):1484-1494.**