4CPS-029 CLINICAL EXPERIENCE OF NEW LIPID-LOWERING THERAPIES: EVOLOCUMAB AND ALIROCUMAB

MP Monforte Gasque*, I Varela Martínez, CA Moncín Torres. *Hospital Royo Villanova, Pharmacy, Zaragoza, Spain*

10.1136/ehpharm-2019-eahpconf.178

Background Evolocumab and alirocumab, protein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, are indicated for the treatment of familial hypercholesterolaemia and atherosclerotic cardiovascular disease.

Purpose The objectives of the study were to evaluate the profile of medication use, effectiveness and safety of the treatment.

Material and methods Retrospective observational study of patients treated with evolocumab or alirocumab from September 2016 to the present.

The collected variables were: sex, age, statins tolerance, lipid profile, lipid-lowering therapies coadjuvant, duration and reason for treatment. Effectiveness was evaluated as low-density lipoprotein-cholesterol (LDL-C) reduction. The safety profile has been determined according to the adverse reactions.

Results Twenty patients were included, 12 male; follow-up (median, range): 60 (19–109) weeks; age: 55 (33–74) years. Two patients were excluded because follow-up was less than 4 weeks. The therapeutic indications were: familial hypercholesterolaemia 61% (n=11) and atherosclerotic cardiovascular disease 39% (n=7). All of them had been previously treated with statins until resistance (maximum dose) or intolerance was developed. The treatment received was: evolocumab (72%) and alirocumab (28%). The average of basal LDL-C and post-treatment was 164 mg/dL (108–369) and 78 mg/dL (39–153), respectively. Patients treated with evolocumab decreased LDL-C levels by 67% and patients treated with alirocumab decreased LDL-C levels by 29%. Fifty-five per cent of the patients received PCSK9 inhibitor treatment combined with statin and ezetimibe. Currently, all patients continue with the treatment.

Conclusion Clinical criteria for treatment initiation should be considered individually. The results of the study evidence the effectiveness of both treatments, being superior in the group treated with evolocumab. The treatment's safety profile is very favourable. Studies with a larger sample size are required to obtain representative data and determine the optimal duration of the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-030 ANALYSIS OF ADAPTATION TO A PROTOCOL OF USE OF THE PCSK9 INHIBITORS

D Yáñez Fera, P Selvi Sabater, A Pelaez Bejarano, O Montero Pérez*, MD Santos Rubio. *Hospital Juan Ramon Jimenez, Pharmacy, Huelva, Spain*

10.1136/ehpharm-2019-eahpconf.179

Background The aim of the Hospital Medicine and Therapeutics Committees (HMTTC) is to promote the rational use of drugs through therapeutic improvement in terms of effectiveness, safety and cost.

Purpose To analyse the degree of adaptation to a protocol established by the HMTTC on the use of the PCSK9 inhibitors (Evolocumab and Alirocumab).

Material and methods A retrospective observational study including patients who received Evolocumab and Alirocumab since the approval of the protocol (December 2016) until August 2018. It was established to adjust the diagnosis to the four indications under the National Health System coverage, providing also clinical and analytical data of the patient (previous lipid-lowering treatment, intolerance of statins and previous levels of low-density lipoprotein cholesterol (LDL-C)). Furthermore, we proposed to re-evaluate the result 1 month after starting treatment and suspend it if LDL-C >70 mg/dl or had not reduced >40% regarding the baseline value. The variables collected were: sex, age, diagnosis, type of PCSK9 inhibitor, previous LDL-C levels, previous cardiovascular event (CVD) (yes/no), previous treatment (yes/no) and discontinuations (yes/no). Data were obtained from electronic prescription software (APD-Prisma) and medical records.

Results Twenty-six patients were treated, mean (SD) age 55 (21) years and 58% men: 77% of them received Alirocumab. Median (SD) previous LDL-C levels were 155.6 mg/dL (47, 6): 77% had suffered some previous CVD. One hundred per cent had been previously treated with lipid-lowering drugs. Discontinuation occurred at some time in 15% of patients. The main diagnosis was (73%) established atherosclerotic cardiovascular disease with the maximum tolerated dose of a statin and LDL-C level greater than 100 mg/dL. In no case, there was a re-evaluation on the next month. Fifty per cent reached levels <70 mg/dl but at 3 months with a median (SD) of 72 mg/dl (62, 9).

Conclusion The degree of adaptation to our protocol was irregular. While the adjustment to indications was fairly good, the follow-up based on clinical and analytical data could be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest

4CPS-031 THE PRIMARY EFFICACY ENDPOINT FOR ALIROCUMAB, REDUCTIONS IN LOW-DENSITY LIPOPROTEIN CHOLESTEROL

J Polo García*, J Preciado Goldaracena, N Larrea Goñi, R de la Riva Bohigas, JA Illodo Becerra, A Rodríguez Esquiroz, M Coma Punset, P Aldave Cobos, B Larrayoz Sola, M Sarobe Carricas. *Complejo Hospitalario de Navarra, Farmacia, Pamplona, Spain*

10.1136/ehpharm-2019-eahpconf.180

Background Cholesterol levels in many patients with familial hypercholesterolaemia (HeFH) or dyslipidaemia are poorly controlled despite dietary changes and maximally tolerated statin therapy. Alirocumab, a monoclonal antibody that targets a specific protein, PCSK9, provides another option for patients who have not been able to lower their low-density lipoprotein cholesterol (LDL-C).

Purpose To analyse the use and outcomes of alirocumab treatment in patients with HeFH, or dyslipidaemia with high/very high cardiovascular (CDV) risk, as an adjunct to diet in a tertiary-level hospital.

Material and methods Retrospective, observational study of patients who started alirocumab treatment from September 2016 to September 2018. Variables: sex, age, diagnosis, dose modification, and serum levels of LDL-C. Inadequate control was defined as LDL-C greater than or equal to 70 mg/dL after 12 week of treatment.