

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

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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

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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

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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.

Results Seventy-four patients, 64% men, mean age 58.6 years. All of them were high/very high CDV risk (stable or unstable coronary artery disease, ischaemic stroke, transient ischaemic attack or peripheral arterial disease). Eighty per cent presented baseline LDL-C levels higher than 150 mg/dL. Forty (54%) patients reached the targeted range for LDL-C. Thirty-four (46%) patients reached LDL-C levels >70. All of them started with 75 mg every 14 days. Only nine patients (27%) have increased the dose of praluent to 150 mg/14 days in the week 12.

Conclusion Dosage adjustments according to LDL-C levels should be followed closely to achieve better outcomes. The dose should be increased to 150 mg every 2 weeks at week 12 if LDL-C is greater or equal to 70 mg/dL at week 8. An adequate organisation and coordination between the different implicated medical services would be desirable, as the dates for monitoring LDL-C and the optimal monitoring interval are already established.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Alirocumab: EPAR – Summary for the public. EMA
No conflict of interest.

4CPS-032 SKIN PROTECTION AND PREVENTION OF CUTANEOUS MYCOSIS

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Background Skin protectors Dexeryl (D) and Bepanthen (B) contain petroleum derivatives (PD) such as petroleum jelly and paraffin. These substances may favour cutaneous mycosis by triggering an epidermidis pH imbalance and development of fungal infection.¹ This observation led our department to limit the use of D and B in favour of calcium hydroxyde liners (L) and care oil (O). In 2016, we initiated a change in practice by providing recommendations, analysis and follow-up of cutaneous topical prescriptions.

Purpose The purpose of this study was to determine if there is a correlation between the prescription of PD and the consumption of a topical antifungal, Econazole (E).

Material and methods Four-year retrospective analysis of consumption in a geriatrics ward:

- Skin protector with PD: D, B.
- Natural skin protector with: L, O.
- Topical antifungal: E.

Comparison of consumption over two periods (period 1: 2014–2015; period 2: 2016–2017) with the Mann–Whitney log rank test.

Results Average of mensual consumption, expressed in tubes (T):

- Period 1: B=117.5T (56; 177), D=52.4T (36; 103), E=79.4T (44; 121), L=2.5T (0; 24), O=171.5T (0; 337).
- Period 2: B=4.8T (0; 18), D=0.3T (0; 3), E=47.2T (22; 128), L=139.3T (59; 220), O=242T (153; 338).

The consumption of B, D, E and L were significantly different between these two periods ($p < 0.001$)

Conclusion A change in routine practice led to decreased consumption of B and D in favour of L. This correlated with a

significantly decreased c consumption of E. These results are in agreement with those of a case control study that shows that the use of PD promoted an increase in the incidence of systemic candidiasis.¹ From now on, B use is limited only to diaper dermatitis resistant to natural skin protectors in order to limit the risk of epidermitis deterioration. A prospective clinical follow-up is ongoing, with physicians from our department, to complete the data.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-033 THE USE OF ORAL APREMILAST FOR THE TREATMENT OF PLAQUE PSORIASIS

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Background The current treatment for psoriasis depends on the severity of the disease, in mild disease topical therapies alone, and with increasing disease severity in combination with phototherapy and/or traditional systemic therapy (methotrexate, cyclosporine, acitretin) or biologics agents.

Apremilast is a selective inhibitor of phosphodiesterase 4, able to down-regulate the inflammatory associated with psoriasis. An oral option for treating chronic moderate/severe plaque psoriasis (PP) in adults whose disease has not responded to other therapies or are contraindicated/not tolerated.

Purpose To report the hospital cases of moderate/severe PP treated with apremilast, describing patients' profile and analysing the efficacy and safety of apremilast.

Material and methods A retrospective case series. We reviewed the clinical history of the patients with moderate/severe PP treated with apremilast until August 2018.

To assess the severity of the disease: Psoriasis Area and Severity Index (PASI) or % of body surface area (BSA). Moderate disease: PASI ≥ 10 or 5%–10% of BSA; severe disease: PASI >20 or BSA >10%. Adequate response to treatment: 90%, 75% or 50% reduction (improvement) from baseline in PASI score (PASI90, PASI75 or PASI50) at 16 weeks.

We investigated previous treatments from the beginning of the disease, analysed the efficacy of apremilast collecting the PASI or BSA scores at the beginning, after 16 and 32 weeks, and collected the adverse events during the treatment.

Results Eighteen patients, 83% men, mean age 52 (± 12) years. Three patients suffered PP and psoriatic arthritis. Previous treatment: 83% (15) topical therapies and 17% (three) phototherapy. Sixty-seven per cent (12) had received prior systemic therapy with conventional agents and 17% (three) biologic agents. At the start of apremilast: five patients suffered severe disease, nine moderate disease and one without data. Three patients were unmeasurable because of the recent start of apremilast. Sixty per cent (nine) of patients achieved PASI75/PASI90 from baseline at week 16, thirty-three per cent (five) PASI50% and 7% (one) without improvement. Maintenance improvement at week 32 (21% without data): 64%. During treatment six gastrointestinal adverse events, one atrial fibrillation and two cholesterol increased.