The Governance of PCSK9-inhibitors for the Effectiveness and Safety of Evolocumab in A214

Purpose The goal was to monitor the use of the PCSK9-inhibitors prescribing centres and for the prescriptive appropriateness.

Background Recently the European Medicines Agency approved Alirocumab and Evolocumab, two monoclonal antibodies against PCSK9 (PCSK9-inhibitors), 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 hypercholesterolaemia or intolerance to statins.

In 2017, the Regional Working Group (RWG), using the GRADE method, drafted the guidelines for the identification criteria. The establishment of the RWG to define the care path for patients with high cardiovascular risk was essential for the epidemiological evaluation and monitoring of PCSK9-inhibitors therapies. This allows us to analyse 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.

Material and methods The guidelines for appropriateness have been drawn up using the GRADE method.

The data on therapeutic adherence have been extrapolated from the Health.db, appropriateness analysis tool adopted in our region since 2013.

The pharmaco-utilisation data for the period January 2017 to June 2018 were obtained from the IQVIA database.

Results The pharmaceutical use data showed that about 8.6% of the regional population was treated with statins.

The epidemiological evaluation using Health.db showed that the patients with high adherence to combined statin + Ezetimibe treatment were 0.2%; of these, 0.03% did not reach the therapeutic target. It is expected that only 185 patients (0.01%) present distance from the therapeutic target of more than 30% and, therefore, eligible for treatment with PCSK9-inhibitors.

Also, the pharmaco-utilisation data (real data) demonstrated that the number of patients suitable for treatment with PCSK9-inhibitors in the period July 2017 to June 2018 was 190, almost equal to that provided by the epidemiological analysis performed by Health.db according to the GRADE method.

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

Conclusion The establishment of the RWG to define the care path for patients with high cardiovascular risk was essential for the epidemiological evaluation and monitoring of PCSK9-inhibitors therapies. This allows us to analyse 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.

References and/or acknowledgements

No conflict of interest.

5PSQ-029 Effectiveness and Safety of Evolocumab in Real Clinical Practice


Background Monoclonal antibody PCSK9-inhibitor, evolocumab, is a new drug for the treatment of patients with uncontrolled familial hypercholesterolaemia (FH), uncontrolled stable atherosclerotic cardiovascular disease (ASCVD), mixed dyslipidaemia, or in patients who cannot tolerate or cannot be given statins. Evolocumab is used in monotherapy or in combination with statins or another hypolipemic.

Clinical trials (CT) showed that evolocumab obtained LDL-C reductions of 64% when combined with statins and of 58% in monotherapy, at week 12. No significant adverse events were detected.

In our hospital, pharmacists validate every prescription of evolocumab according to the regional autonomous authorisation criteria.
Purpose To compare the efficacy and safety of evolocumab in the clinical practice with the CT.

Material and methods Retrospective observational study (May 2017 to September 2018) of all evolocumab prescriptions. Demographic, clinical, analytical and treatment variables were collected at baseline and after the first follow-up visit. Efficacy was measured, by the percentage of LDL-C reduction at week 12, using laboratory analysis and medical records. Safety was obtained from medical and pharmaceutical records.

Results Thirty patients (63% male) with a mean age of 62.2 (52–78) were considered for treatment. One of them was not treated because he did not comply with the authorisation criteria (LDL >100 mg/dl). Diagnosis was ASCVD (15/29), statins intolerance (10/29) and FH (4/29). Evolocumab was prescribed in combination with statins in 13 patients, in five with another hypolipemiant and in 11 in monotherapy. The percentage change in LDL-C from baseline in the combination with statins group, was a reduction of 67% ((+7.2%) to (−79.1%)) at week 12 (7–20). In the monotherapy group, it was of 68% ((+24.5%) to (−92.2%)) at week 9 (7–12). Treatment adherence was >96% in all patients. Regarding safety, 20% of patients had an adverse event: itching (2/29), fatigue (1/29), myalgia (1/29), abdominal pain (1/29), diarrhoea (1/29) and glucose alterations (1/29).

Conclusion In clinical practice, the reduction in LDL-C in the future. It would be interesting to evaluate if these reductions are maintained in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

A TWO-YEAR RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS WITH FLUOROQUINOLONE AND QUINOLONE ANTIBIOTICS

Background On 9 February 2017, the Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review of disabling and potentially long-lasting side effects reported with systemic and inhaled quinolone and fluoroquinolone antibiotics at the request of the German medicines authority, following reports of long-lasting side effects in the national safety database and the published literature.

Purpose To review the adverse drug reactions (ADRs) of systemic and inhaled fluoroquinolone and quinolone antibiotics that involved peripheral and central nervous system, tendons, muscles and joints reported from our Pharmacovigilance Department (PVD).

Material and methods Retrospective analysis of ADRs reported in our PVD involving ciprofloxacin, fluomequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin, rufloxacin, cinoxacin, nalidixic acid and pipemidic given systemically (by mouth or injection). The period considered was September 2016 to September 2018.

Results Twenty-two ADRs were reported in our PVD involving fluoroquinolone and quinolone antibiotics in the period considered and that affected peripheral or central nervous system, tendons, muscles and joints. The mean patient age was 67.3 years (range: 17–92 years). 63.7% of the ADRs reported were serious, of which 22.7% caused hospitalisation and 4.5% caused persistent/severe disability. 81.8% of the ADRs were reported by a healthcare professional (physician, pharmacist or other) and 18.2% by patients or a non-healthcare professional.

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A215