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 monotherapy group was slightly higher than in CT. The adding of statins did not affect the efficacy in our patients, they were similar in both groups. Safety was comparable to CT. It would be interesting to evaluate if these reductions are maintained in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-030

DO WE KNOW WHICH ANTIBIOTICS SHOULD BE AVOIDED IN OUR PATIENTS? ANTIBIOTIC ALLERGY SURVEY AMONG HOSPITALISED PATIENTS

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Background It is known from allergy databases that antibacterials belong to the common sensitising drugs. However, antibacterials are frequently administered in the hospital setting both for prophylactic and for therapeutic purposes. Considering drug allergy is an important drug safety issue, but inadequate allergy labelling can negatively affect drug choice.

Purpose To assess the prevalence and characteristics of antibiotic allergy and to differentiate cases where the allergic nature of drug reaction can be excluded/or has weak grounding.

Material and methods A structured interview guide was used for the face-to-face anonymous interviews with hospitalised adult inpatients.

Results During the 19 study days, among the 1522 hospitalised patients 114 mentioned allergy to systemic antibiotics (7.5%). Most of the patients were allergic to one active agent, (100 patients), while 14 patients were polysensitised (allergic to two or more antibacterials). In the majority of cases (81 cases) penicillin products caused the drug reaction, and second, sulfonamides (18 cases) were mentioned. In 24 cases, the patient did not have any information on signs/symptoms of the drug reaction and in 14 cases drug allergy can be

excluded (e.g. diarrhoea as the only reaction). Most often drug reactions occurred in the hospital setting (30 cases), if not, in 12 cases hospital admission was necessary due to severity. Antibacterials most often resulted in cutaneous reactions (71 cases). Skin reaction/pruritus was the only sign in 48 cases and in 15 cases this reaction happened in childhood. Severe cutaneous drug reaction – EEM and SJ syndrome occurred in seven cases. Unintended drug re-exposure occurred in eight cases, resulting in reactions similar to the earlier ones (in two cases with severe life-threatening anaphylaxis). Only 12 patients (10.5%) had an allergy ‘passport’.

Conclusion Antibiotic allergy was prevalent among the interviewed inpatients. In some of these reactions allergic nature can be excluded by the anamnesis, while other cases had weak evidence due to the complete lack of the anamnesis/childhood occurrence of skin reactions. Only very few patients had an allergy passport. Hospital pharmacists can exclude untrue allergic reactions during the reconciliation process and can help in the proper documentation of drug allergy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-031

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

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Background On 9 February 2017, the Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review¹ 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, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin, rifloxacin, 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.