REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all the collaborators.
No conflict of interest.

5PSQ-025 PULMONARY ARTERIAL HYPERTENSION DRUGS: EPIDEMIOLOGICAL ANALYSIS CONCERNING AN ITALIAN DISTRICT

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Background In recent years, numerous patients with pulmonary arterial hypertension (PAH) were treated in this district and the therapy approach changed radically, with a lot of different drugs provided from the hospital pharmacy. In fact, the number of available drugs increased, and also the therapy strategies have evolved, for example with associations of two or three drugs.

Purpose The aim of this study was an epidemiological and prescription analysis of the period from 2004 to 2017 to highlight average age, gender prevalence, survival and age at the first dispensation. Furthermore, this study analysed the prescription trend from 2012 to 2017.

Material and methods Data were obtained from the constant updating of dispensed drugs in this hospital pharmacy. At this point, they were processed by software such as Microsoft Access and Excel, to obtain epidemiological and prescriptive informations from 2004 to 2017. Furthermore, the prescription frequency of combination therapies from 2012 to 2017 was analysed, using the same computer programs.

Results Patients' average age was 55 years (comparable with the literature data) and the gender prevalence was higher in females (66%). There were six patients in 2004, rising to 57 in 2017. 39.6% died with an average survival of 2.8 years and the average age at the first dispensation was 56 years' old. The prescriptive trend saw a progressive redistribution of consumption, with a prescriptions' increase of innovative medicines. Drugs association is a growing strategy and the collected data are aligned with the reference guidelines (in 2017, 43 patients were treated with monotherapy and 14 with two-three drug therapy).

Conclusion Recent pharmacology and studies, and improved early diagnosis, showed an increase in patient numbers, average age and survival. In the case of monotherapy failure, polytherapy, which is constantly increasing, is a good strategy that gives more efficacy with comparable side effects.

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No conflict of interest.

5PSQ-026 IMPACT OF A SAFETY ALERT WITH VALSARTAN IN A HEALTH MANAGEMENT AREA

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Background Valsartan is an angiotensin II receptor antagonists (ARAI), used to treat high blood pressure and heart failure. In July 2018, a safety alert about the presence in certain

drugs with valsartan of an impurity (N-nitrosodimethylamine (NDMA)), potentially cancer-causing, was released by all health agencies. In our country, the local agency informed about all brands contaminated, encouraging patients affected to change it for another one in their pharmacies.

Purpose To describe the impact of a safety alert in the consumption of valsartan.

Material and methods A retrospective observational study of all patients in treatment with valsartan was conducted. First, after the safety alert, we obtained a list of patients in treatment with valsartan, selecting those with the impure drug. Second, in October we reviewed if those patients continued with valsartan or changed to another ARAII.

The variables were age, sex, drug before and after the alert, time between the alert and the measure taken, if one was made (change of ARAII, suspension of treatment, maintained the same ARAII but changed to an original brand or another generic).

Results Two-hundred and twenty-six patients were included (131 females), with an average age of 72.32 years (44–96). From all patients, 73 (32%) did not go to the doctor and when they had to pick up the next box was when the pharmacist gave them a non-contaminated drug. The rest of the 153 patients (68%) visited the doctor after the safety alert. In these patients: 105 changed to losartan, three to telmisartan and three to candesartan; 37 changed the label of valsartan (35 to an original brand and two to generic); and six suspended the ARAII drug. The average time between the alert and the doctor's visit was 12.7 days.

Conclusion Many physicians preferred to change medications than to continue with valsartan, so we will have to check if this trend remains in time and the consumption of valsartan is reduced. In addition, 32% of patients did not go to the doctor and did not change the drug until it had finished, without being aware of the safety alert, so the method of communicating health alerts to patients will have to be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-027 EFFECTIVENESS AND SAFETY OF TOLVAPTAN AND UREA FOR THE TREATMENT OF SEVERE SYMPTOMATIC HYPONATRAEMIA: A CASE SERIES

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Background Tolvaptan and, recently, urea were both indicated for the treatment of hyponatraemia secondary to the Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH) in our country. The FDA also contemplated its use in patients with heart failure (HF). Regarding safety of these drugs, patients with very low baseline natraemia may be at risk for too-rapid correction of serum sodium (>12 mEq/L/24 hours).

Purpose To analyse the effectiveness and safety of tolvaptan and urea, and its use in relation to the diagnosis of hyponatraemia.

Material and methods Retrospective observational study of all cases of severe symptomatic hyponatraemia diagnosed during

2016 in a tertiary care hospital and patients who started treatment with oral urea or tolvaptan during hospitalisation. Variables collected: etiology of hyponatraemia, analytical parameters, dose and duration of treatment.

Results Seven patients treated with tolvaptan: four diagnosed with HF and three with SIADH. Dose ranged from 15 mg/day to 30 mg/day. Median duration: 7 days (2–28). Baseline and final mean natraemia: 119.8 mEq/L and 133 mEq/L respectively. Two patients with SIADH and one with HF had eunatraemia. Three patients were exitus. Six patients were treated with urea, five diagnosed with SIADH and one with adrenal insufficiency. Urea dose ranged from 15 g/day to 30 g/day. Median duration of treatment: 15 days (7–147), three patients continued at home. Baseline and final mean natraemia were 123.4 mEq/L and 133 mEq/L respectively. Three patients with SIADH achieved eunatraemia, two patients were exitus. Only three urea patients had all necessary data for a diagnosis of SIADH. The mean increase in natraemia at 24 hour was 4.57 mEq/L (0–8) in the urea group; 9.9 mEq/L (–3 to 21) in the tolvaptan group (>12 mEq/L in the three cases of SIADH and one case of HF). Deaths were due to complications related to their advanced disease.

Conclusion Off-label use of tolvaptan in HF has not been shown to be effective. Regarding hyponatraemia in SIADH, tolvaptan has shown to be moderately effective, but the correction was too rapid. This result can be related to an incorrect diagnosis of SIADH and/or a too low baseline natraemia. Urea proved to be an alternative of moderate efficacy but safer, allowing its ambulatory use. Therefore, the pharmacy service proposed to establish in our hospital a protocol for the management of severe hyponatraemia to improve the efficacy and safety of tolvaptan and urea.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-028 THE GOVERNANCE OF PCSK9-INHIBITORS FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA: APPROPRIATENESS ANALYSIS

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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 of the PCSK9-inhibitors prescribing centres and for the prescriptive appropriateness.

Purpose Our goal was to monitor the use of the PCSK9-inhibitors to assess the reliability of the forecasts made by the RWG and the appropriateness.

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.

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No conflict of interest.

5PSQ-029 EFFECTIVENESS AND SAFETY OF EVOLOCUMAB IN REAL CLINICAL PRACTICE

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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 hypolipemiant.

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.