patients with arrhythmias. There is room for improvement, and the clinical pharmacist could collaborate in optimisation, improving the final results, and avoiding complications and drug related adverse effects. Creating a drug dispensing protocol in addition to a comprehensive clinical evaluation for antiarrhythmic therapy, taking all the risk factors, drug interactions and each patient's particular needs into consideration, is essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of interest No conflict of interest

4CPS-231 REAL WORLD DATA OF MONOCLONAL ANTIBODIES FOR THE TREATMENT OF HYPERLIPIDAEMIA: ANALYSIS 3 YEARS AFTER INTRODUCTION IN CLINICAL PRACTICE

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Background and importance Hyperlipidaemia is the main risk factor for the early manifestations of atherosclerosis and related complications. In recent years, new monoclonal antibodies have become available in clinical practice (evolocumab and alirocumab), termed PCSK9 inhibitors (PCSK9i). Web based monitoring register was used to monitor the access to therapy.

Aim and objectives The objectives of the study were to determine the direct healthcare costs in the 3 year period 2017–2019, as well as the incidence of adverse events reported by clinicians related to PCSK9i therapy at the regional level.

Material and methods A retrospective study was conducted. Real data (prescription, dispensed units) were derived from informatics administrative databases. Expenditure incurred for the purchase of pharmacological therapies was instead calculated considering the ex factory price net of the SSN discounts. Adverse reactions (ADRs) were extrapolated from the National Pharmacovigilance Network (RNF) and evaluated using Naranjo's algorithm.

Results In 2017, the first year PCSK9i became available, 96 patients were treated (78.5% evolocumab; 21.5% alirocumab) for a total of 587 units dispensed, and expenses were 141 396.34€. In the period under study, there was a growing trend in units dispensed. In 2018, an increase of +429% was seen compared with 2017, probably due to the conclusion of some clinical trials. Evolocumab was preferred to alirocumab (delta 2018–2019=+163.70%). In particular, one of the five local health authorities appeared to have dispensed 46.81% of the total units. Only three ADRs occurred in regional patients. Patients (men:women=2:1), with a mean age of 64.33±15.27 years, had been in treatment for 45 days. 75% of ADRs were attributable to evolocumab. Naranjo's algorithm revealed that 25% of ADRs related to evolocumab were classified as possible and 75% as likely (distributed equally between the two active ingredients).

Conclusion and relevance Although the analysis showed an increase in the use of evolocumab, the incidence of use

remained too low compared with potential patients eligible for treatment (n=637).¹ The clinical pharmacist, because of his knowledge and skills, is able to take up the challenge that the new paradigm of real world data is posing and generating 'real data for real tests'.

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4CPS-232 USE OF DUPILUMAB IN THE TREATMENT OF ATOPIC DERMATITIS IN REAL CLINICAL PRACTICE

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Background and importance Atopic dermatitis (AD) is one of the most common cutaneous inflammatory diseases. Intense itching and rash can significantly compromise the patient's quality of life. Treatment of AD was based on topical/systemic non-specific anti-inflammatories drugs, immunosuppressants or phototherapy. In 2016, the Italian marketing authority (AIFA) approved dupilumab for severe AD treatment. This monoclonal antibody inhibits the signal transduction of interleukin 4 and interleukin 13, implicated in the inflammatory cascade of the pathology.

Aim and objectives The purpose of this work was to describe dupilumab's use in real clinical practice and to compare its effectiveness with the marketing authorisation trials.

Material and methods The efficacy and safety of dupilumab were evaluated over 52 weeks in a randomised, double blind, placebo controlled clinical trial (LIBERTY_AD_CHRONOS). Disease index for patients enrolled in our structure (January 2019 to June 2020) was recorded in an anonymous database built by matching administrative data and the AIFA monitoring register. The χ^2 test was used to show a statistically significant difference between the clinical trial and real life.

Results 166 patients were enrolled during the observed period: median age 43 years (range 25–58), 58% men. At baseline: EASI median value was 28 (range 25–32), NRS was 8 (range 8–9) and DLQI was 21 (range 15–25). After 52 weeks, 60 patients were reassessed. EASI median value was 4 (range 2–7.8), NRS was 2 (range 1–3) and DLQI was 3 (range 2–5). The average percentage reduction in EASI was –81.2% (SD 21.3%), NRS –69.9% (27.0%) and DLQI –15.9% (7.5%). A reduction of 75% in EASI value was recorded for 47 patients (78%).

Conclusion and relevance In our structure, 47 (78%) patients had at least a 75% reduction in EASI compared with 58 (65%) in the LIBERTY_AD_CHRONOS study. The average percentage reduction in EASI in our structure was –81.2 ±21.3 compared with –78.4±4.4 in the trial. Although the efficacy data seemed to be different, the χ^2 test showed that there was no statistically significant difference between the trial data and our data ($P>0.05$). Full compliance with the eligibility criteria, also guaranteed by AIFA's monitoring database, confirmed the efficacy of dupilumab in the real world setting with therapy outcomes similar to the marketing authorisation trial.

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4CPS-233 HOME MANAGEMENT OF ACUTE MULTIPLE SCLEROSIS OUTBREAK: ADAPTATION TO CORONAVIRUS PANDEMIC

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Background and importance An outbreak of multiple sclerosis (MS) is defined as symptoms and neurological signs typical of demyelinating disease, with a duration of at least 24 hours. It appears in all forms of MS, contributing to short and long term disability. The main treatments for outbreaks are high dose steroids given intravenously or orally for 3–5 days. In our clinical practice, we used oral prednisone 1400 mg for 5 days prepared in a hospital pharmacy to avoid staff attendance at health centres.

Aim and objectives To evaluate oral prednisone effectiveness as a treatment for acute MS outbreaks.

Material and methods This was a retrospective multidisciplinary study, from March to June 2020 (4 months), during the limited mobility period due to the coronavirus pandemic (SARS-CoV-2). The results of 31 patients were analysed. The following data were collected: sex, age, type of MS, expanded disability status scale (EDSS), treatment at the time of the outbreak, symptoms and evolution. The programmes used were: patient medical history (DIRAYA), outpatient dispensing (DOMINION) and MRI (CARESTREAM). Specialist role was: the neurologist made the clinical evaluation, the pharmacist prepared the prednisone capsules from original tablets and its dispensation, and the nurse provided patient education.

Results 31 patients (25 women) with a mean age of 44.85 ±13 years were assessed. Every patient had a diagnosis of recurrent relapsing MS. Treatments were: interferon beta (20), dimethyl fumarate (10) and cladribine (1). The mean EDSS was 3. The main symptoms were: paraesthesias, muscle weakness and urinary incontinence. The EDSS progressed positively: 83.78% of patients evolved favourably, a subjective decrease in paraesthesia and weakness was observed and MRI showed less inflammation signs. Another aspect was the comfort of the patient in carrying out this treatment at home rather than attending hospital.

Conclusion and relevance The results suggested that 1400 mg of oral prednisone administration for 5 days could be considered a safe, effective and comfortable alternative treatment for acute outbreaks of MS. Multidisciplinary care is essential to obtain better clinical results.

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4CPS-234 GLUCOCORTICOID INDUCED HYPERGLYCAEMIA IN NON-DIABETIC PATIENTS IN AN EMERGENCY DEPARTMENT

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Background and importance Glucocorticoid induced hyperglycaemia (GIH) is a common and underdiagnosed condition in the hospital emergency department (ED) that leads to increased hospital stay and a worsening prognosis.

Aim and objectives To determine the cumulative incidence of the development of GIH in non-diabetic patients treated with systemic glucocorticoids (SG) in the ED, and to study the associated risk factors. Secondary objectives were to determine the mean time to develop GIH, as well as compliance with the general recommendations of scientific societies for its therapeutic management.

Material and methods This was a prospective descriptive study. Non-diabetic patients who started SG in the ED were included. Data were collected over 3 months: age, obesity, family history of diabetes, type of glucocorticoid and accumulated dose, equivalence to hydrocortisone, and received prior to GIH or within 72 hours if the event did not occur. Hyperglycaemia was defined as preprandial and postprandial capillary glucose ≥140 and ≥180 mg/dL, respectively. Recommendations were defined as periodic monitoring of capillary blood glucose for 72 hours or less if the patient was discharged. In the case of patients who initially were not monitored for glucose, this was indicated by the pharmacist. Patients without glycaemia data were excluded.

The χ^2 test or Fisher's exact test was applied for categorical variables and the Mann-Whitney U test for quantitative variables. Time from SG initiation to GIH was measured using the Kaplan-Meier test. SPSS V15.0 programme was used to analyse the data.

Results A total of 32 patients (53.13% men) were included, with a mean age of 72±17.6 years, 28.12% were obese patients and 96.87% had no family history of diabetes. Most patients (90.7%) were treated with intermediate acting glucocorticoids and mean accumulated dose of hydrocortisone received was 468.13±276 mg. GIH cumulative incidence was 53.12% in 72 hours. No risk factor showed a statistically significant difference related to the development of GIH. Mean time to develop GIH was 46.15 hours (95% CI 36.1 to 56.1). Older patients had a higher risk of developing GIH than younger patients (HR=1.05; 95% CI 1 to 1.1; p=0.047). Regarding compliance and recommendations, only 21.87% of patients were initially monitored for glucose.

Conclusion and relevance Data obtained showed a high GIH cumulative incidence (53.12%) and no risk factor was associated with GIH, probably because of the size of the sample. However, the risk of developing early GIH increased with age. The low rate of compliance with the recommendations confirms the importance of implementing an easily applicable protocol that minimises this situation, especially in older patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest