consultation (63.0%), prescriptions with inadequate validity until the subsequent consultation (21.0%), prescription errors (8.6%), patient non-attendance at the preceding consultation (4.9%), absence of a patient consultation within the last year (1.2%), and rescheduling of the previous consultation (1.2%).

Within our sampled cohort, the median consultation waiting time amounted to 36 minutes, with an extreme delay reaching up to 3 hours.

Conclusion and Relevance As evidenced by this investigation, the absence of an active prescription at the dispensation juncture exerts an adverse influence on the day-to-day operations of the Hospital Outpatient Pharmacy. It is our assertion that enhanced training and more robust communication with the implicated clinical services could prove invaluable in proactively addressing this predicament.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-119 REVIEW OF REAL-WORLD MANAGEMENT OF NATALIZUMAB TREATMENT IN MULTIPLE SCLEROSIS: A DOUBLE-EDGED WEAPON

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Background and Importance We know that natalizumab is an effective treatment in patients with relapsing-remitting multiple sclerosis with high activity. More doubts arise regarding its safety which will lead to having to closely monitor the patient.

Aim and Objectives To evaluate the safety of treatment with natalizumab for relapsing-remitting multiple sclerosis (RRMS), specifically John Cunningham virus (JCV) infection that can cause Progressive Multifocal Leukoencephalopathy (PML). Also evaluate effectiveness by counting outbreaks during treatment and time in treatment.

Material and Methods Retrospective observational study since the approval of the drug. All patients with RRMS under treatment with natalizumab were included and the variables sex, age, previous and subsequent treatments, positive JCV serology at any time, duration of treatment, relapses and number of them, and reason for discontinuing treatment were collected. Data was extracted from FarmaTools® software database and the electronic medical.

Results A total of 75 patients were analysed, 47 (63%) of them women. Mean age at the time of initiation of treatment of 41 years (28–69), median number of previous lines of 1 (0–5), being used as first line in 15 patients (20%), second line in 42 patients (56%). The patients analysed were on treatment for an average of 2.6 years, the reasons for suspension being: Positive JCV serology 39 (52%), adverse effects 11 (15%), outbreaks six (8%), progressive worsening five (7%), unknown cause three (4%) and 2 (3%) discontinued due to pregnancy. Nine (12%) are still receiving treatment. Sixteen patients (21%) had an outbreak during the time on treatment.

Conclusion and Relevance A large proportion of the patients analysed manage to reach the 2-year treatment period, after which the risk of JCV infection increases. At that point, the majority of patients discontinue treatment. The drug is well tolerated, with little suspension of treatment due to adverse effects, and is usually chronic fatigue (also associated with the disease). Effective drug, with only 16 patients having an outbreak during treatment. With these data, we can conclude that in our patients it has been an effective treatment, used once the patient has high activity to stop it. Regarding safety, JCV would be the main drawback, requiring close monitoring for possible infection.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-120 PEMBROLIZUMAB IMMUNE-MEDIATED TOXICITY

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Background and Importance Checkpoint inhibitors (ICI) are increasingly used in various cancers. While they offer clinical benefits, they also introduce drug management challenges due to their adverse effects (AE). A notable concern is the potential for severe immune-mediated toxicities, which can pose significant risks to patients. The presented case is unique as it underscores the severe repercussions of immune-mediated toxicity from pembrolizumab.

Aim and Objectives This reports a case of a 70s male with clear cell renal cell carcinoma (ccRCC) who developed severe immune-mediated toxicity following treatment with pembrolizumab. The patient had a history of some comorbidities. The initial presentation was incidental detection of ccRCC post-trauma. His subsequent treatment, adverse reactions, and outcomes form the crux of this case.

Material and Methods The patient was in his 70s, caucasian male, 1.64 m, 58 kg, non-smoker, and non-alcoholic. His medical history included type 2 diabetes, hypertension, nephrolithiasis, benign prostatic hyperplasia, pacemaker implant due to bradycardia. Daily medication: metformin, amlodipine, perindopril/indapamide, acetylsalicylic acid, dutasteride, afluzosin, lactulose, sodium picosulfate. First line treatment with intravenous pembrolizumab 400 mg (6/6 weeks) and axitinib 5 mg twice daily.

Results Days after the first cycle of treatment, the patient presented to the emergency service (ES) with swallowing difficulties, imbalance, and muscle pain. A probable diagnosis of G3 polymyositis with suspected pembrolizumab-induced myopathy was made. Despite suspending the oncology treatment and initiating high-dose corticosteroid therapy, the patient's condition deteriorated. He developed myocarditis leading to severe global dysfunction of left ventricular systolic function. Subsequent treatments including human immunoglobulin and abatacept were unsuccessful, and the patient unfortunately succumbed to cardiorespiratory arrest two weeks later.

Conclusion and Relevance This case report brings attention to the severe immune-mediated toxicity, emphasising the challenges in its management. While acute AE can often be managed with symptom-based approaches and high-dose corticosteroids,[1] this case demonstrates that these measures may sometimes be insufficient. Creating structured protocols and conducting in-depth research is imperative. Medical professionals should remain vigilant to such adverse effects. This case underlines the importance of risk assessment and continuous monitoring of patients on immunotherapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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This case has never been reported/published before.

Conflict of Interest No conflict of interest.

5PSQ-121 A REVIEW OF THE EXPOSURE TO POTENTIALLY HARMFUL EXCIPIENTS THROUGH ORAL LIQUID FORMS IN PAEDIATRIC INPATIENTS IN FRANCE

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Background and Importance Despite growing interests for the use of excipients with described toxicities (excipients of interest., EOI) in children and neonates, even today the lack of paediatric data makes it difficult to establish precise recommendations about quantitative levels of EOI in commercialised paediatric formulations.

Aim and Objectives The primary objective of this work is to identify the EOI present in oral liquid forms used in paediatric departments. The secondary endpoint is to quantify the EOI exposure for often-prescribed molecules (originator formulations and generic brands) used in recommended posology ranges, for different age categories.

Material and Methods A review of medications used in French hospitals has allowed establishing a list of oral liquid forms used for paediatrics and neonatology inpatients. The formulation of each medication has been examined using the summaries of product characteristics (SmPC). Ten of the most prescribed molecules have been selected concerning princeps and generics formulations for a total of 31 formulations. EOI exposure has been calculated and STEP Database and European Médicine Agency (EMA) recommendations were used to evaluate the exposure levels.

Results The analysis involved 219 formulations including 123 active molecules and 140 excipients. Sixteen excipients were present in above 10% of the formulations and nine of them are recognised as EOI (ethanol, propylene glycol, glycerol, sodium benzoate, methyl and propyl paraben, aspartame, sorbitol, saccharose). A total of 95% of all studied formulations involve at least one EOI. The amounts of EOI found in the 10 studied molecules outcome the recommended levels for 45% of the 31 formulations. A rate of 73% of the drugs with neonatalogy marketing authorisation include at least one excipient not recommended in this age category.

Conclusion and Relevance Pediatric and neonates inpatients are receiving a wide range of harmful excipients, among others through the administration of oral liquid forms. Although specific studies tend to enlarge the knowledge about specific use and toxicity of the excipients in paediatrics, too little remains, especially in preterm. When EOI cannot be avoided, quantitative information about their amount in drug formulations should be easily known to help physicians and pharmacist to select the most appropriate drugs and anticipate possible adverse effects or adapt drugs posology.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-122 SEQUENTIAL CHANGE OF DOSING INTERVAL OF PALIPERIDONE PALMITATE BASED ON PLASMA CONCENTRATION MONITORING

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Background and Importance Paliperidone is an antipsychotic used for the treatment of schizophrenia. To increase adherence to treatment and thus reduce the risk of relapse, it was formulated as an extended-release injectable. There are 3 types of formulations: monthly, quarterly and semi-annually. Monitoring of paliperidone plasma concentrations can help to optimise treatment, as patients who do not require dose adjustments may benefit from the longer therapeutic interval formulations (quarterly and semi-annual)

Aim and Objectives To analyse the relationship between the change of presentation of paliperidone palmitate and its pharmacokinetic monitoring

Material and Methods Retrospective observational study in which all patients whose plasma concentrations of paliperidone were determined from January to July 2023 were included. Patients on treatment with oral paliperidone were excluded.

The variables collected were sex, age, current plasma concentrations of paliperidone palmitate, type of paliperidone palmitate formulation used in current treatment, initiation of paliperidone palmitate, presence of previous controls of another type of paliperidone palmitate formulation, previous plasma concentrations of paliperidone palmitate.

Results Sixty-nine patients were included, 69.6% male with a median age of 50 years (20–72).

Of the patients, 42.0% had plasma paliperidone palmitate concentrations within the therapeutic range. Of the patients, 36.3% were on paliperidone palmitate monthly, 42.0% were on paliperidone palmitate quarterly, and 21.7% were on paliperidone palmitate semi-annually.

A change of paliperidone palmitate presentation had occurred in 87.0% of the patients. Of these, only 43.3% had pharmacokinetic monitoring prior to the change of presentation. Of these patients, 46.2% had plasma concentrations in range in the control with the previous presentation of paliperidone palmitate.

Conclusion and Relevance Although the pharmacokinetic determination of plasma concentrations of paliperidone palmitate allows individualising the treatment to each patient, the decision to switch from one formulation of injectable paliperidone palmitate to another with a different dosing interval was not based on the plasma concentrations of the drug in our population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.