were retrospectively reviewed from February-2020 to February-2021.

The QC had been carried out with the RSP-method and the USP-method was then applied. For this, the theoretical weight of a capsule was calculated taking the average weight of 5 empty capsules (0.0493g) as reference and the weight of the batch content (13.8g=dexamethasone (4g) + excipient (9.8g)) calculated in the compounding design being the acceptance interval 0.169–0.206g.

Results The RSP-method requires a sample of 20 capsules and uses their average weight as a reference, while the USP-method requires a sample of 5% or 10 capsules (whichever is less) and uses the theoretical weight of a capsule as a reference. The RSP-method admits a deviation of ± 10% or ± 7.5% depending on the average weight; and no >2 capsules can deviate from the limits and none more than double. The USP-method accepts a limit of ± 10% respect to the theoretical weight, and no capsule must deviate.

Regarding the compounding method, the RSP allows elaboration by volumetric filling according to the Spanish-National-Formulary (excipients weight is not required). However, the USP-method requires knowing the theoretical capsule weight, which implies weighing the excipients.

Since February-2020 to February-2021, 8 batches of dexamethasone 40mg were elaborated. They were accepted with the RFE-method. After applying the USP-method, none were rejected.

Conclusion and Relevance The USP-method is safer than the RSP-method because for the same acceptance interval (± 10%) it does not admit any deviation. It also requires knowing the weight of all the excipients. Therefore, it is capable of detecting errors in the elaboration that the RFE-method would not detect (as long as the error is >10% and the capsules are homogeneous).

Currently, the USP-method has been incorporated in the HPD as a reference of hard capsules QC, since it provides greater safety in their preparation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-039 RAF-KINASI PATHWAY INHIBITORS IN TREATMENT OF METASTATIC MELANOMA: WHEN COMPLIANCE DOES NOT MATCH WITH TOLERANCE

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Background and Importance Background and importance: Melanoma is a malignant tumour that originates from melanocytes of the skin and mucous membranes or rarely from melanocytes located in extracutaneous sites. In 2020 in Europe, approximately 50.972 females and 55.397 males are diagnosed with melanoma, and 9.457 males and 7.031 females died because of it. 45–50% of melanomas have a mutation in the BRAF gene and the most frequent is V600E.Oncogenic mutations of BRAF lead to constitutive activation of the RAS/RAF/MEK/ERK pathway. Target therapies are the most appropriate to obtain an effective therapeutic action.

Aim and Objectives We analysed the 2 most prescribed oral associated therapies in our centre for the treatment of mutated BRAF metastatic melanoma with the aim of identifying which is the most tolerated and highlighting the types of toxicity that emerged from real life data bases.

Material and Methods The data were extrapolated from our prescription software and from the electronic medical records of the investigated patients.

Results In the period 2019–2022 we considered 36 patients treated with Dabrafenib 75 mg + Trametinib 2 mg or Encorafenib 75 mg + Binimetinib 15 mg, 50% treated with both therapies. 33 patients started the combination therapy of Dabrafenib + Trametinib and of these only 7 (20%) did not show any severe toxicity leading to discontinuation of treatment. The most frequent toxicity was pyrexia (40%), followed by skin toxicity (25%), gastrointestinal toxicity (12.5%), asthenia (8%). Patients who discontinued treatment for progression disease were 9 (28%). Owing to unacceptable toxicity, 14 patients (43%) switched to Encorafenib + Binimetinib: only 2 of these patients showed toxicity (G1-G3 asthenia, G2 nausea) upon discontinuing treatment. 3 patients of analysed population started therapy with Encorafenib + Binimetinib as first-line treatment, without toxicity to discontinue therapy.

Conclusion and Relevance These data point out that the first choice is a combination therapy Dabrafenib + Trametinib associated with better patient compliance, thanks to more easily manageable number of tablets to take daily. However, the toxicity appears to be higher. For this reason, the therapy with a lower compliance is actually the best tolerated and prolonged therapy with fewer suspensions, ensuring better continuity of care and therapeutic efficacy.

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Conflict of Interest No conflict of interest.

5PSQ-050 ANALYSIS OF THE USE OF USTEKINUMAB FOR CROHN DISEASE IN THE REAL CLINICAL PRACTICE

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Background and Importance Ustekinumab (UST) is an anti-IL-12/23 antibody which is used in Crohn disease. Although the dosage form is defined in its data sheet, in the clinical practice, intensifications and intravenous reinductions are performed when there is a loss or inadequate of response.

Aim and Objectives To describe and evaluate the different dosage regimens of UST performed in patients with Crohn disease by relating them to biomarkers of inflammation and clinical data.

Material and Methods Observational, retrospective and descriptive study included patients with Crohn disease who started with UST (January 2017-April 2022).

Data obtained from electronic medical records was: previous treatments, faecal calprotectin (Fcal) and C-reactive protein (CRP) levels, stools daily (SD) and abdominal pain (AP), and dosage regimen.

Results 45 patients were included, 68.8% women with a mean age of 49.2. Previous treatments: adalimumab (75.5%),

azathioprine (71%), infliximab (51%), vedolizumab (11%) and methotrexate (8.8%). 31% of the patients had received two anti-TNF[].

Initially, 46.6% of the patients presented AP, 31% >5 SD, Fcal 382 mg/kg(30–1919) and CRP 18.3 mg/dl(<1-92).

64.4% patients underwent dose escalation: to every 4 weeks (93.1%), 6 weeks (3.4%) and 8 weeks (3.4%). Prior to this intensification, 31% presented AP, 24.1% >5 SD, mean Fcal 401.2 (11–2625) and CRP 10.4(<1–40.3) .The mean time to first intensification was 426 (147–1157) days.

2 patients required a second intensification.

6 patients also underwent intravenous reinduction, who presented: 33% AP, 83.3% > 5 SD, Fcal 818 (45–1492) and CRP 18(5–23). The time from the first intensification to reinduction was 338(145-730) days. 3 patients required a second reinduction as they all presented >5 SD, Fcal 941(297–2032) and CRP 4.13.

Currently, 88.8% of patients continue with UST. Patients without intensification present Fcal 146.77 and CRP 3, while those with a shortened dosage interval present clinical remission with Fcal 175.56 and CRP 4.01. Those who had also undergone at least one reinduction presented clinical remission too with Fcal 382 and CRP 7.5.

Conclusion and Relevance UST was effective in the majority of our cohort of patients. More than half of the patients required shortening of dosage interval and a fifth part of these also required one or two intravenous reinductions to control the disease.

Conflict of Interest No conflict of interest

5PSQ-052 CHANGES IN POLYMEDICATED PATIENTS' PRESCRIPTIONS AFTER OUTPATIENT HOSPITAL CONSULTATIONS IN REAL LIFE SITUATIONS

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Background and Importance In public health system one of the main management issues is polypharmacy because of the increasing number of patients involved each year and its economic impact. On a daily basis, a high number of polymedicated patients come through the outpatient medical consultations in which, after a consultation with the doctor, it is unknown if any change in treatment is made, or drugs are stopped or added to their treatments.

Aim and Objectives The aim of this study is to analyse how polymedicated patients' prescriptions change after a medical consultation in a hospital which attends 450.000 inhabitants in the outpatient setting, under real-life situations linked to practice through the prescriber.

Material and Methods Observational prospective study of ten days duration performed in the field of hospital medical consultation with outpatient patients. We included all polymedicated patients (those with a consumption of ≥15 drugs/month) that come to a medical consultation in a second level hospital. Patients´ number of prescriptions were analysed before and after the medical consultation. We analysed if there was any change in the medication, and whether this change was an addition, discontinuation, or substitution of treatment.

Results From 25 October 2021 to 5 November 2021, 603 polymedicated patients (women: 65.2%; average age: 74.7 ± 10.8 years) attended the hospital's outpatient consultations of all medical specialties. In the 87% of the patients (n=522) no modification was made in their treatment by the prescriber after the consultation, and in the 13% remaining patients (n=78) the following treatment changes were made: 88 additions, 15 discontinuations and 7 substitutions of treatment.

Conclusion and Relevance More than 8 out of 10 polymedicated patients with more than 15 drugs/month who attend medical consultations do not suffer changes in their medication. In the rest of the patients, the vast majority of occasions medication is added to their treatment, and medication is rarely suspended. This study highlights the need to review and approach to handling unnecessary medication use and polypharmacy due to the increasing number of patients involved each year that may have a negative impact on patients and the healthcare system. Pharmacists could serve as advisors for the review of patients' unnecessary polypharmacy in the outpatient setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-061 NEW-ONSET MULTIPLE SCLEROSIS ASSOCIATED WITH ADALIMUMAB TREATMENT: ABOUT TWO CASE REPORTS

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Background and Importance Treatment with adalimumab offers an improvement in autoinmune diseases and it is considered well tolerated. Demyelination with adalimumab have been described in several case reports.

Aim and Objectives To describe two cases of Multiple sclerosis (MS) triggered by adalimumab treatment.

Material and Methods Descriptive and retrospective clinical cases that occurred in October 2021. Data were obtained by medical records. The causal relationship between adalimumab and MS was assessed using the Naranjo's algorithm.

Results Patient 1, 41-year-old, woman with psoriasis diagnosed 5 years ago in treatment with adalimumab for 2 years with no history of neurological disease.

She presented loss of strength, ataxia and paresthesias. She was treated with methylprednisolone for 5 days with functional improvement and adalimumab was stopped.

Magnetic resonance imaging (MRI) revealed intramedullary lesion of C2, showing two possible diagnosis: inflammatory myelitis as the first possibility or tumour origin. She presented systemic autoimmunity stigmas (positive antibodies antinuclear, oligoclonal bands (OCBs) positive in cerebrospinal fluid and serum and psoriasis).

Six months later, she had a new possible cervical outbreak. MRI showed the appearance of a parasagittal occipital corticosubcortical lesion confirming the diagnosis of MS according to McDonald's criteria (2017). She started treatment with dimethylfumate.