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

MT Albanese*, D Pinnavaia, E Bastonero, F Federico, L Omini, F Enrico. *Fondazione del piemonte per l'oncologia-i.r.c.c.s di candiolo, farmacia ospedaliera, candiolo, italy*

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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

G Miron Elorriaga*, A Igleasias Lambarri, A Martin Torrente, O Mora Atorrasagasti, M Palacios Filardo, O Ibarra Barrueta, L Torio Alvarez, Y Viseda Torrellas, I Palacios Zabalza, L Menendez Liendo, I Ibarrondo Larramendi. *Hospital Galdakao-Usansolo, Pharmacy, Galdakao, Spain*

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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%),