5PSQ-155 ASSISTANCE PRESSURE IN ONCOHAEMATOLOGICAL DISPENSATION AREA DURING THE COVID PANDEMIC

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Background and importance During the pandemic caused by the SARS-CoV-2 virus, many pathologies have not been diagnosed and/or treated in hospitals because most of the material and human resources have been allocated to the diagnosis and treatment of COVID-19 as well as to preventing the spread of the virus. In the case of oncological and haematological patients, the first analyses show that a significant number of Spanish patients have had delays in starting their treatments and interruptions, according to the Spanish Society of Medical Oncology (SEOM).

Aim and objectives The objective was to analyse the evolution of the care activity provided to oncohaematological patients with hospital dispensation of oral chemotherapy in the pharmacy service of a Spanish hospital during the SARS-CoV-2 pandemic.

Material and methods A retrospective descriptive study was carried out. It included all patients who attended the oncohaematological dispensation area of the pharmacy service between March and June 2020. Results were compared with the same period in the previous year (2019).

Results The total number of dispensations during the 4 months of the study was 2182 patients in 2019 and 2155 in 2020, so the total reduction in the number of patients was not significant (1.24% lower). However, during April and May, coinciding with the critical point of the quarantine period, the largest differences occurred: 11.6% and 18.4%, respectively, with a total of 545/482 and 615/503 patients.

During April and May, initiation of treatments decreased by 33.33% and 39.47% compared with the same months in the previous year, and treatment continuations showed a reduction of 9.7% and 16.9%. These results confirm the data published by the SEOM regarding the delay in the initiation and discontinuation in certain patients. Delays in initial care and diagnosis are especially worrisome because of the consequences they can have on the evolution and prognosis of patients.

Conclusion and relevance The results showed a reduction of almost 40% in the initiation of treatments during the main months of quarantine in Spain. The delay in starting treatment highlights the risk. Telematic visits and the possibility of electronic drug prescription have partially controlled this attention deficit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-156 COMPLIANCE OF RECOMMENDATIONS FOR THE PREVENTION OF HEPATITIS B VIRUS REACTIVATION DURING DARATUMUMAB TREATMENT

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Background and importance The risk of reactivation due to hepatitis B virus (HBV), including fatal cases, in patients treated with daratumumab was reported in June 2019. Health authorities recommended HBV screening in patients before initiation of daratumumab and in patients already receiving treatment. Previous autologous stem cell (ASCT), concurrent and/or prior lines of immunosuppressive therapy (IT) and patients from HBV prevalent regions were established as risk factors for reactivation.

Aim and objectives To analyse the level of compliance with the recommendations for the prevention of HBV reactivation and the risk in our hospital.

Material and methods A retrospective observational study was carried out from January 2017 to September 2020 in a tertiary hospital. It included all patients treated with daratumumab. Medical records and serology tests were reviewed from the start of daratumumab treatment. Information was collected from Abucasis, Farmis and Gestlab. Variables collected were: sex, age, diagnosis, daratumumab start date, HBV reactivation risk factors, serology tests, vaccination and hepatitis B (HB) infection.

Results 20 patients were included with a median age of 70 ±17 years and 60% were men. The main diagnoses were multiple myeloma in 95% and amyloidosis in 5%. Regarding the prevalence of risk factors for HBV reactivation, 20% received previous ASCT, 90% were treated with IT and no patient had lived in a region of high HBV prevalence. 45% of patients started daratumumab treatment before the alert notification. 44% of the patients in this group had a HB serology test prior to the start of treatment. Of the remaining 55%, a serology test was done in one patient after the alert notification. All serology results for HB surface antigen (HBs-Ag) and HB core antibody (anti-HBc) were negative. No patient had HB before, during or after daratumumab treatment. 44% were vaccinated against HB. 55% started daratumumab treatment after the alert notification. Only 55% of patients in this group had a HB serology test prior to the start of treatment. Serology results for HBs-Ag and anti-HBc were negative except for one patient. Complementary tests were carried out resulting in HBV infection in the past. The patient started treatment with tenofovir 15 days before starting daratumumab as prophylactic treatment for HBV reactivation. 9% were vaccinated against HBV prior to daratumumab treatment. No case of HBV reactivation was detected.

Conclusion and relevance Only 65% of patients treated with daratumumab had at least one HBV serology test performed. More serology tests should be carried out to detect patients at risk for HBV reactivation. Any case of reactivation was detected in our hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-157 EXPENDITURE AND CONSUMPTION DESCRIPTIVE ANALYSIS: RITUXIMAB ORIGINATOR VERSUS BIOSIMILAR IN AN ITALIAN DISTRICT

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Background and importance The introduction of biological drugs changed the pharmaceutical market, improving patients' prognoses and quality of life. Intravenous MabThera, authorised in January 1998, is the originator of the monoclonal antibody rituximab. In Italy, the regulatory agency approved the first rituximab biosimilar, Truxima, in July 2014, and the second, Rixathon, in December 2017.

Aim and objectives The objective was to analyse and compare MabThera and its biosimilars in our region in the period 2017–2019 in terms of regional consumption, costs and adverse drug reactions (ADRs).

Material and methods Regional consumption and costs data for rituximab between January and September 2017, 2018 and 2019 were collected and analysed, using Microsoft. ADR reports were extracted from the Adverse Drug Reactions National Report (ADRsNR) and stratified by gravity, gender of the patient and diagnosis.

Results In 2017, the number of intravenous MabThera dispensed packs was 10 017, with a progressive reduction over the years (552 in 2019). Truxima decreased from 2274 delivered packs in 2018 to 117 in 2019; Rixathon increased from 3491 in 2018 to 9259 in 2019. Intravenous distributed pack numbers of MabThera decreased from 2017 to 2019 and was about –94.49%. Regarding costs, MabThera expenditure in 2017 was about 9 902 232.64€, in 2018 it was 3 590 428.00€ and in 2019 it was 613 502.88€. Truxima costs were 2 027 695.38€ in 2018 and 91 438.67€ in 2019. Rixathon expenditure was 2 066 974.79€ in 2018 and 5 473 728.71€ in 2019. A reduction of 93.80% was registered for MabThera expenditure from 2017 to 2019. From January 2002 to March 2020, ADRsNR rituximab ADRs were 2865: 10.23% MabThera, 19.02% Truxima and 10.66% Rixathon. 50.3% of patients were men and 49.7% women. ADR gravity was 2.2% deaths, 39.1% serious and 57.8% not serious. Diagnoses principally concerned itch 7.9%, dyspnoea 7%, neutropenia 7.3% and pyrexia 7%.

Conclusion and relevance ADRsNR biosimilar data are still limited: greater collaboration between health professionals is needed to structure a system of more robust and adequate pharmacovigilance, to overcome the information gap relating to the security of the originator and biosimilar. Nonetheless, biosimilar drugs are a valid therapeutic alternative for patients, and a good way to reduce expenditure and to optimise available resources, ensuring good pharmaceutical governance. Biosimilar switch involves a multidisciplinary team composed by prescribers and pharmacists. Pharmacovigilance is important to discover and characterise ADRs in the post-marketing phase.

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5PSQ-158 OFF-LABEL USE OF PEMBROLIZUMAB IN PD-L1 POSITIVE METASTATIC ANAPLASTIC THYROID CARCINOMA: A CASE REPORT

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Background and importance Anaplastic thyroid carcinoma (ATC) is a rare aggressive carcinoma representing 1–2% of all thyroid carcinomas. For patients with metastatic ATC, systemic

chemotherapy with taxanes, platinum compounds or adriamycin is recommended. Several studies have shown that BRAF mutated tumours have higher expression of programmed death ligand 1 (PD-L1) (82%) compared with BRAF wild-type tumours (13%). For patients with metastatic ATC, systemic chemotherapy with taxanes, platinum compounds or adriamycin is recommended.

Aim and objectives To describe the clinical case of a 38-year-old man with BRAF negative and PD-L1 positive metastatic ATC, treated with pembrolizumab. This drug is not indicated for ATC treatment but its off-label use in combination with lenvatinib is justified by one study¹ and a few case reports.^{2 3}

Material and methods At the end of 2019, the patient presented with paraesthesia and slight swelling in the mandibular, and in March 2020 a progressive increase in the volume of the lesion was observed. From March to April 2020, evaluations were carried and multifocal infiltrations in the mandible, thyroid, liver, lungs, bones, bone marrow and vena cava inferior were observed. Blood tests (thyroglobulin value was 6468 ng/mL) and thyroid biopsy were performed and the results confirmed the diagnosis of metastatic ATC. Because of the spread of the metastases and the speed of development of carcinoma, radiotherapy and surgery were not indicated. Therefore, the patient was treated with paclitaxel 80 mg/m² once a week combined with lenvatinib 14 mg/day. Metastatic progression was observed by CT after 20 days. Treatment with pembrolizumab 200 mg every 3 weeks combined with lenvatinib 14 mg/day was started.

Results After 3 months from the start of pembrolizumab and after 14 weeks from the start of lenvatinib, a reduction in thyroglobulin was detected (4906 ng/mL) and the results of vertebral MR and mandibular CT showed a reduction in metastases. Currently, the treatment is ongoing (six doses administered) and is well tolerated.

Conclusion and relevance Pembrolizumab combined with lenvatinib seemed to be effective in treating metastatic ATC and could become a therapeutic choice for patients presenting with PD-L1 expression.

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5PSQ-159 PALBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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Background and importance Loss of cell cycle regulation due to pathway alterations in cyclin D-CDK4/6-Rb is common in breast cancer. Palbociclib is a CDK4/6 inhibitor, indicated in metastatic breast cancer (mBC).

Aim and objectives The aim of this study was to analyse the safety profile of patients with mBC positive hormone receptors receiving treatment with palbociclib.

Material and methods A retrospective descriptive study was conducted in patients with mBC receiving treatment with palbociclib from July 2019 to July 2020. Electronic prescription