enterocolitis and acute renal failure. The next day, hemicolectomy had to be performed for signs of intestinal ischaemia. Finally, the patient was discharged after multiple infectious complications and 56 days of hospital stay.

The Naranjo algorithm established as 'probable' (score 6) the relationship between docetaxel and neutropenic enterocolitis. The Spanish Pharmacovigilance System was notified.

Conclusion and relevance In this case, docetaxel was probably responsible for neutropenic enterocolitis. In order to know the real incidence of adverse events listed as rare, it is essential that healthcare professionals officially report suspected adverse reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-038 SAFETY OF CYCLIN DEPENDENT KINASE INHIBITORS IN THE TREATMENT OF BREAST CANCER WITH POSITIVE HORMONAL RECEPTORS AND NEGATIVE HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2

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Background and importance Cyclin dependent kinase (CDK) inhibitors are an innovative therapeutic target for the treatment of locally advanced or metastatic breast cancer with positive hormonal receptors (HR) and negative human epidermal growth factor receptor 2 (HER2). Some adverse reactions have been reported than can decrease a patient's functional status or even lead to suspension of this line of therapy.

Aim and objectives To analyse the frequency of the main drug adverse reactions described for the different CDK inhibitors used for the treatment of patients with locally advanced or metastatic breast cancer in a third level hospital.

Material and methods A retrospective observational study was performed in patients who had started treatment with a CDK inhibitor between 1 June 2018 and 30 September 2019. Demographic and clinical features were obtained from the electronic patient clinical history (DIRAYA) and the electronic prescription programme (PRISMA) and recorded in an Excel worksheet. Adverse reactions recorded were diarrhoea, digestive disturbances, mucositis, asthenia, neutropenia, leucopenia, anaemia, thrombopenia, nausea and vomiting, anorexia and elevated transaminase blood levels.

Results Forty-two patients were found (41 women): 18 received palbociclib, 15 received ribociclib and 9 received abemaciclib. Average age was 56.8 ± 10.0 years. Average length of treatment was 135.4 ± 92.5 days, with an average number of cycles of 3.8 ± 3.4 . In 19% of patients, treatment was discontinued due to death (50%), progression (25%) or toxicity (25%).

The most frequent drug adverse reactions were neutropenia (52.4% of patients), asthenia (40.5%) and anaemia (26.2%), followed by thrombopenia (19%), nausea and vomiting (19%), diarrhoea (16.7%) and elevated transaminase levels (9.5%). In some cases, digestive disturbances (4.8%), mucositis (4.8%), anorexia (2.3%) and leucopenia (2.3%) were reported. Between the different drugs, diarrhoea and asthenia were the most prevalent adverse reactions in patients receiving

abemaciclib (55.6% in each), and neutropenia in those receiving palbociclib (66.7%) and ribociclib (53.3%).

Conclusion and relevance According to our results, the main adverse reactions should have been expected, in accordance with the drug data sheets. Knowledge of possible RAM allows us to improve patient safety. Nevertheless, it is necessary to expand the study to have more information on the frequency of these reactions during long term treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-039 PANCREATITIS INDUCED BY IMMUNOTHERAPY? TWO CASE REPORTS

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Background and importance Immunotherapy stimulates the body's natural defences to fight tumour cells. In the literature, it is considered a safe drug. However, one of the adverse reactions described in the data sheet as uncommon is autoimmune pancreatitis.

Aim and objectives To describe two cases of pancreatitis related to immunotherapy.

Material and methods This was a descriptive retrospective clinical study. Data were obtained from the clinical records. A literature search was conducted on the adverse effects of immunotherapy. The causality of the adverse reaction was established using the algorithm of Karch–Lasagna modified by Naranjo.

Results A 67-year-old man was diagnosed with non-small cell lung cancer and received palliative treatment with nivolumab, 37 cycles. After 18 months of treatment, the patient complained of abdominal pain the days following the infusion. Analytical tests were performed showing an increase in amylase and lipase. Gastroscopy was performed, confirming the diagnosis of pancreatitis. The patient remained asymptomatic, so no specific treatment was initiated, but nivolumab was discontinued. A few weeks later, the patient arrived at the hospital complaining of abdominal pain, nausea and vomiting. The analysis showed a higher increase in both enzymes. The diagnosis of immunomediated pancreatitis was confirmed by gastroscopy. Enolic and lithiasic origin were ruled out, due to the absence of previous episodes. Corticotherapy was initiated, obtaining clinical and analytical improvement.

A 58-year-old woman was diagnosed with poorly differentiated carcinoma of probable pulmonary origin and received palliative treatment with pembrolizumab, 25 cycles. She went to the emergency room for abdominal pain and vomiting. A CAT scan was performed where radiological findings compatible with pancreatitis were found. High dose steroid therapy and antibiotherapy treatment was initiated. She was left with fluid therapy and days after she began a pancreatic diet. The patient progressed favourably. After applying the Karch–Lasagna–Naranjo algorithm, we established a probable causal relationship between immunotherapy and pancreatitis.

Conclusion and relevance Immunotherapy has demonstrated efficacy and a good safety profile in clinical trials but possible adverse effects due to its use can be observed, with little evidence described in the literature. In the event of any

suspicion, it is important to notify the official organisations and to establish a possible causal relationship by means of an approved test.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-040 SECURITY PROFILE OF IBRUTINIB AS MONOTHERAPY IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA: EXPERIENCE IN A TERTIARY HOSPITAL

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Background and importance Ibrutinib is a tyrosine kinase inhibitor indicated for the treatment of chronic lymphocytic leukaemia (CLL) among other pathologies.

Aim and objectives To assess the frequency and severity of adverse events (AEs) in CLL patients treated with ibrutinib.

Material and methods This was an observational, retrospective, descriptive study including all patients aged >18 years old diagnosed with LLC treated with ibrutinib 420 mg/24 hours in our hospital. The study period was July 2015–September 2019. Variables collected were sex, age, diagnosis and cytogenetics, previous treatment lines, duration of treatment, AEs, dose adjustment, temporal discontinuations and definitive suspensions. AEs were classified following the National Institute Cancer (NCI): Common Terminology Criteria for Adverse Events (CTCAE) V5.0. Data were collected from the electronic clinical history, electronic prescribing software and drug therapy follow-up.

Results Thirty-one patients were included (9 women and 22 men) with an average age of 72 years (range 48–90). Poor prognostic cytogenetics was presented in 71% of patients: 45.16% had del (17p), 12.90% had del (11q) and 12.90% had both. Ibrutinib was prescribed as firstline treatment in 10 patients and as rescue treatment in 21 patients that had a median of 1 previous line (range 1–5).

Median length of treatment was 12.7 months (range 2–42.3). Nine patients suspended ibrutinib permanently: progression (n=5), death (n=2), grade 3/4 AEs (n=1, haemorrhagic) and alogenic transplant (n=1). In addition, six patients discontinued ibrutinib because of grade 3/4 neutropenia (n=3), respiratory infections (n=2) and bleeding grade 3/4 (n=1). Twenty-two patients were continuing ibrutinib treatment when the study was closed.

AEs grade 1/2 included musculoskeletal AEs (muscle cramps (n=3), arthralgia (n=4), musculoskeletal pain (n=3)), haematologic AEs (neutropenia (n=1), thrombocytopenia (n=1)), gastrointestinal AEs (diarrhoea (n=1)) and infections (urinary (n=1), periferic oedema (n=1)). One patient was diagnosed with atrial fibrillation and another with hypertension that required treatment.

Conclusion and relevance In our patients, ibrutinib had an adequate safety profile, highlighting haemorrhage as the most serious AE. Periodic follow-up of patients is necessary to assess adverse reactions and the need for temporary suspension in patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-041 CONSUMPTION OF HERBAL MEDICINE IN PATIENTS ON ORAL ANTICANCER DRUGS: STILL A LONG WAY TO GO

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Background and importance There are few data on the use of herbal medicines and the potential risks of herbal drug interactions (HDI) with oral anticancer drugs (OACD), even though their consumption is increasing.

Aim and objectives The aim of this study was to collect data on consumption of medicinal plants by patients on OACD and to assess the potential HDI and their knowledge among patients and physicians.

Material and methods This was an observational study conducted within a hospital outpatient pharmacy for 6 weeks. Patient interviews were carried out using a questionnaire on the following themes: phytotherapy products consumed, point of purchase, consumption objectives and awareness of health professionals. Potential HDI were evaluated using the MSKCC and Hedrine databases. A targeted questionnaire was sent to haematologists and physicians to assess their knowledge and needs.

Results Among the 59 included patients receiving OACD, 17% (n=10) were using phytotherapy. Of these 10 patients, 4 were taking herbal medicine as a complement to their anticancer treatment and the other 6 for another purpose (well being, cough, cold). The majority (70%) consumed on a regular basis on average of 2.4 different products. Four (40%) had informed a professional of their consumption. The products were mainly purchased in organic product shops (40%) and in pharmacies (20%), on the advice of a member of the family and friends (50%) or a health professional (40%). Five interactions were found. These were HDI at risk of hyperkalaemia, increased risk of bleeding and toxicity of OACD by reduced metabolism. Among the 21 physicians who answered the survey, a difference in practice between general practitioners and haematologists was highlighted. All doctors were seeking training in complementary medicine.

Conclusion and relevance The consumption of herbal medicines in patients treated with OACD is not negligible. Patients appear to be poorly or not informed about HDI, as well as doctors. The pharmacist has a major role to play in this context. Distribution of a recommendation guide could reduce the risk of HDI.

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No conflict of interest.

5PSQ-042 EVALUATION OF AN INFORMATION CHECKLIST FOR VALIDATION OF ANTINEOPLASTIC PRESCRIPTIONS

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Background and importance The pharmaceutical validation of oncological prescriptions means improvement in patient safety