

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) V.5.0. 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

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#### 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.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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#### 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

based on quality criteria from different societies when it is carried out in a generalised, standardised and regulated way.

**Aim and objectives** To describe the implementation of a computerised checklist for the validation of prescriptions of oncological chemotherapy (ChemO) according to recommendations and clinical practice guidelines; and to evaluate the results of its implementation in terms of safety interventions.

**Material and methods** The checklist was designed in database format. This included the BOPA and GEDEFO recommendations for validation by having a series of different coloured alerts when laboratory values were not within normal limits for administration of ChemO. From this database the variables number of validations, interventions, type, and acceptance or not by the oncologist were collected from 1 January to 30 June 2019. Demographic data of the patients (age and sex) were also collected. Frequencies and means were analysed for the variables studied.

**Results** The data of 3050 validated prescriptions were included, with the checklist corresponding to 1162 patients of whom 593 (51%) were women. Mean age of the patients was 59.3 years ( $\sigma=15.0$ ). A total of 293 interventions were performed (9.6% of prescriptions). The most common reasons for intervention were related to the diagnosis not reflected in the prescription (165 interventions (5.4%)), the periodicity of the chemotherapy scheme (46 (1.5%)) and the location of the patient within the hospital (63 (2.1%)). Seventeen (0.6%) interventions were related to the scheme, cytostatic, volume and prescribed serum. Regarding the severity of the intervention, 31 (1.0%) required consultation with the oncologist, 22 (70.1%) of which were accepted. Among the latter, the main reason for the consultation was related to laboratory parameters outside normal limits.

**Conclusion and relevance** The application of a checklist to the validation of the prescription served to improve patient safety as it standardised the process and marked the order for all the items reviewed. It was also useful for unifying the criteria among pharmacists and was helpful in the training of resident pharmacists.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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#### 5PSQ-043 IMPLEMENTATION OF A PREPARATION PROTOCOL FOR CHEMOTHERAPY ADMIXTURES OF HIGH ECONOMIC IMPACT

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**Background and importance** The administration of intravenous admixtures (IVMs) in the haemato-oncology day hospital is determined by the patient's health status. Poor health is a cause of non-administration of IVMs, causing medication and economic losses due to their low stability.

**Aim and objectives** To implement a protocol for the preparation of IVMs of antineoplastic drugs with high economic impact, low physical-chemical stability and/or high frequency of adverse effects; and to analyse the results obtained and to propose lines of improvement.

**Material and methods** The protocol consisted of review of the analytical data available early in the morning by the pharmacist and assessment of the physical condition of the patient by

the nursing staff before preparation. All data on IVMs of the drugs included in this protocol and their cost were collected as well as the total number of IVMs prepared over a period of 3 months. We calculated the percentage of unprepared IVMs overall and per drug, including the amount of IVMs unprepared and the savings that they represented with respect to the total number of controlled IVMs.

**Results** The number of drugs included in the protocol was 17. In the period evaluated, a total of 5426 IVMs of antineoplastics were programmed: 399 IVMs were included in the protocol. Of these, 58 (14.5%) IVMs were not prepared. Seven of the 17 drugs included in the protocol presented causes for not being administered and, therefore, were not prepared. Drugs not prepared: panitumumab and nab-paclitaxel (10.4%), eribulin (8.6%), nivolumab and aflibercept (5.2%), pemetrexed and liposomal doxorubicin (1.7%). Fluorouracil (13.7%), gemcitabine (6.9%), oxaliplatin and irinotecan (5.2%), carboplatin and denosumab (3.4%) were not prepared in association with these drugs. The most frequent reasons for non-preparation were haematological adverse effects (36 (62.0%)), digestive adverse effects (10 (17.2%)), surgical intervention (4 (6.8%)) and other (4 (6.8%)). The economic savings in unprepared mixtures was € 24 703.24 (7.1% of the total controlled mixtures included).

**Conclusion and relevance** The protocol was an important tool for cost savings in the preparation of antineoplastic IVMs. Of the drugs involved, only a limited number had reasons not to be prepared, so that the protocol could be updated with a smaller number of drugs while maintaining its objectives.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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#### 5PSQ-044 IMPACT OF DRUG INTERACTIONS IN HIGH DOSE METHOTREXATE ELIMINATION

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**Background and importance** High dose methotrexate (HDMTX) chemotherapy, defined as a dose  $>500$  mg/m<sup>2</sup>, is used to treat several oncological and haematological malignancies. Despite appropriate hydration, urine alkalisation and leucovorin rescue, nephrotoxicity remains a risk which can lead to significant morbidity and mortality. Different drugs have been associated with altered elimination (AE) of HDMTX due to delayed elimination or nephrotoxicity.

**Aim and objectives** To describe the incidence of AE and assess the impact of drug interactions in HDMTX induced AE.

**Material and methods** A bibliographic research in the Lexi-comp database was conducted to identify drug interactions with HDMTX. A retrospective study was carried out including all patients who received HDMTX between 2010 and 2019. Data collected were age, sex, methotrexate dosage, number of HDMTX cycles, creatinine level before and after HDMTX, serum levels of methotrexate and potentially interacting medications (PIM) prescribed 24 hours before HDMTX infusion and during methotrexate elimination. AE was defined as plasma concentration  $>1$  µmol/L at 48 hours and/or 0.1 µmol/L at 72 hours, or nephrotoxicity according to the Common Terminology Criteria for Adverse Events criteria V4.0.