suspicions, 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
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SECURITY PROFILE OF IBRUTINIB AS MONOTHERAPY IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA: EXPERIENCE IN A TERTIARY HOSPITAL

C Fernandez Cuerva1, OC Ortiz de La Cruz, M Ortíz, MI Muñoz Castillo. 1Hospital Regional Universitario De Málaga, Servicio De Farmacia, Málaga, Spain; 2Hospital Regional Universitario De Málaga, Servicio De Hematología, Málaga, Spain

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 first-line 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), periferal 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.

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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 (SD=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.

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

I. Méndez Acosta*, P. Tardaguilla Molina, A. Yuste Gutiérrez, P. De Juan García Torres, M. Blanco Crespo, M. Lavandeira Pérez, AM Horta Hernández. Guadalajara University Hospital, Pharmacy Department, Guadalajara, Spain

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**Background and importance** High dose methotrexate (HDMTX) chemotherapy, defined as a dose >500 mg/m², 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.