

**Purpose** To describe the safety profile of palbociclib in clinical practice.

**Material and methods** The study included patients treated by at least two cycles with palbociclib, from November 2017 to July 2018, in a university hospital that covers almost 4 00 000 inhabitants. Data was extracted from the clinical history and the following variables were recorded in Microsoft Excel: age; absolute neutrophil count, haemoglobin and platelets at the start of treatment, at the fifteenth day of treatment (first nadir) and before each cycle; other toxicities; degree of toxicities; dose reduction; and date and reason (toxicity/progression) of finishing the treatment.

**Results** Twenty patients were included, all females, with a median age of 61 years. Haematological toxicities observed were neutropaenia in all the patients, 35% anaemia, 25% thrombocytopenia and 5% lymphopaenia, of any degree. Grade 3 neutropaenia was detected in 65% of patients and none of grade 4. Ninety per cent of patients presented neutropaenia of any degree at first nadir (39% grade 3). Grade 3–4 anaemia or thrombocytopenia were not detected, but one patient suffered grade 3 lymphopaenia. Other toxicities: asthaenia (35%), rash (15%), stomatitis (10%), ocular alterations (10%) and anorexia, nasal dryness, diarrhoea or alopecia in 5% of patients. The dose was modified due to toxicity in 55% of patients: 20% of them required a second dose reduction. Any patient finished treatment due to toxicity.

**Conclusion** The frequency of neutropaenia in our sample was higher than reported in the prescribing information but similar in terms of anaemia and thrombocytopenia frequency. More than half of the patients required dosage reduction, a greater proportion than observed in the randomised clinical trials. The main reason for dose reduction was neutropaenia so palbociclib and neutropaenia were closely related.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Oncology and pharmacy departments.  
No conflict of interest.

#### 5PSQ-056 SAFETY BETWEEN THE USE OF COMMERCIAL AND GENERIC IMATINIB: IS THE EXCIPIENT RELEVANT?

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**Background** Imatinib (IM) is a tyrosin kinase inhibitor approved to treat chronic myeloid leukaemia (CML) and other diseases. This drug can be administered in commercial and generic formulations. Not all generic formulations are exactly designed as the commercial drug because the excipient is not always the same. In our hospital, we changed imatinib from commercial to generic in June 2016.

**Purpose** The aim of our study was to analyse if there were significant differences in terms of safety between the use of commercial and generic formulations of imatinib from June 2016 to September 2018 in our hospital, and to compare tolerance changes when the excipient was changed.

**Material and methods** We performed a retrospective, observational and descriptive study to evaluate patients treated with commercial imatinib (CI) and generic imatinib (GI) in a second-level hospital. With this purpose we analysed the next

variables: demographic data, diagnosis, changes between commercial and generic treatment, adverse events (AEs) with both presentations and dose.

**Results** We included 24 CML patients (58.3% males); average age 67.5±9.13 years. Of all the patients who were on treatment with IM, 66.7% switched from CI to GI, 25% started with GI, 4.16% did not switch and remained with CI and 4.16% changed to nilotinib. Of the 22 patients treated with GI, 45.5% stopped therapy and restarted CI and 4.5% changed to bosutinib because of serious AEs. In 63.6% of the patients treated with GI, significant AEs were found in 50% (haematological, cutaneous, gastrointestinal, ocular, muscular, systemic, respiratory side effects). Patients treated with CI experienced AE in 81% (>Grade III–IV in 5.9%). Significant differences between both presentations were found with the excipients: GI contained hydroxypropylmethylcellulose and CI had microcrystalline cellulose.

**Conclusion** Patients treated with GI experienced more serious AEs than with CI. This difference could be explained because of the difference in excipients between both presentations. In conclusion, we think that inclusion of new generic drugs in hospital guidelines should include a comparison of excipients' profile before their admission, in order to evaluate tolerance.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Haematology department.  
No conflict of interest.

#### 5PSQ-057 OLAPARIB AND NIRAPARIB SAFETY PROFILE IN THE CLINICAL PRACTICE OF A TERTIARY-LEVEL HOSPITAL

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**Background** Olaparib and Niraparib are oral antineoplastics used for the maintenance treatment of high-grade ovarian cancer, relapsed, complete or partial response to platinum-based chemotherapy. Olaparib is indicated for patients with BRCA +mutation and marketed in our country: Niraparib is independent of the mutation and it is used in compassionate use.

**Purpose** Comparing the safety profile of Niraparib and Olaparib, in the everyday clinical practice of a tertiary hospital.

**Material and methods** Descriptive, transversal, retrospective research of all patients treated with Niraparib or Olaparib until September 2018. Data: clinical and pharmacological history (Farmatools). Variables: age, date of beginning, end and/or reintroduction of treatment, reason for suspension, initial dose, dose reduction, current dose, days of treatment and adverse effects. Analysis: SPSS Statistics.

**Results** Eight patients with Olaparib and 11 with Niraparib, with an average age of 65 (50–86) and 61 (48–73) respectively. The median of treatment with Olaparib was 455 (25–1264) and with Niraparib 35 (2–91).

Olaparib: seven (87.5%) patients started with 400 mg and one (12.5%) with 200 mg. Three (50%) needed dose reduction and all had started with 400 mg. In two patients the treatment was suspended due to death and progression respectively. Six (75%) continued in treatment (three with 400 mg, two 200 mg and one 100 mg). In one (16.7%) of them the