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% thrombocytopaenia 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 thrombocytopaenia 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 thrombocytopaenia 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.

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Oncology and pharmacy departments.

No conflict of interest.

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

¹MA Perez Quiros*, ²M Cortés-Sansa, ¹A Planas-Giner, ¹MS Aldirra-Taha, ¹R Rodríguez-Mauriz, ¹N Almendros-Abad, ¹L Borrás-Trias, ¹C Seguí-Solanes, ¹N Rudi-Sola. ¹Granollers General Hospital, Pharmacy, Granollers Barcelona, Spain; ²Granollers General Hospital, Hematology, Granollers Barcelona, Spain

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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 administrated 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.

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Haematology department.

No conflict of interest.

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

¹A Pinilla Rello*, ¹H Navarro Aznarez, ¹A Magallón Martínez, ¹B Abad Bañuelos, ¹O Pereira Blanco, ¹A Casajus Navasal, ¹MR Abad Sazatornil, ²A Herrero Ibañez. ¹Universitary Miguel Servet Hospital, Hospital Pharmacy, Zaragoza, Spain; ²Universitary Miguel Servet Hospital, Oncology Service, Zaragoza, Spain

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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

treatment was temporarily suspended due to decreased haemoglobin and three (37.5%) had adverse effects (nausea, vomiting, stomach pain) without interruption of treatment.

Niraparib: four (36.4%) patients started with 300 mg and seven (63.6%) 200 mg. Five (45.5%) patients needed dose reduction, two with initial dose 300 mg and three 200 mg: three of them continued (one of 300 mg and two of 200 mg initial dose). In five (45.5%) patients, treatment was discontinued, two (40%) due to adverse effects (neutropaenia, thrombocytopenia and increased creatinine respectively) and three due to progression (60%), in addition temporarily suspending it due to neutropaenia. Six continued (three with 200 mg and three with 100 mg) and three of them had to temporarily interrupt it due to thrombocytopenia.

Conclusion In both treatments, the haematological adverse effects are more severe, frequent and worse tolerated in the case of Niraparib than Olaparib. In addition, greater discontinuity of treatment is observed in patients with Niraparib.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-058 MEASURING ADHERENCE TO EUROPEAN SOCIETY OF CARDIOLOGY GUIDELINES FOR PATIENTS TREATED WITH TRASTUZUMAB

R Rainone*, O Gleizes, S Foucher, A Rieutord. *Antoine-Béclère Hospital AP-HP, Pharmacy, Clamart, France*

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Background There are two types of breast cancer: *in situ* or invasive. Among invasive, 15% over-express a particular receptor called Human Epidermal growth factor Receptor 2 (HER2). Trastuzumab specifically targets this oncoreceptor. Nevertheless, this molecule has a partially reversible cardiotoxicity in 4.6% to 34% of patients. Monitoring of cardiotoxicity should be implemented according to the European Society of Cardiology (ESC).

Purpose The aim of the study was to assess the adherence to cardiac toxicity monitoring recommended by the ESC in patients treated with trastuzumab.

Material and methods Patients treated with at least two injections of trastuzumab (intravenously or subcutaneously) between 1 January and 1 July 2018, were included. Clinical data were assessed retrospectively from the hospital software patient's record. Data collected included the demographics characteristics at the start of the treatment, the administration data and the potential risk factors for cardiotoxicity. Parameters used to monitor the occurrence of cardiotoxicity and its management were also assessed and compared to the ESC guidelines and the trastuzumab summary of product characteristics.

Results Among 20 females included, 15 (75%) were followed up according to the recommendations. One (5%) was presenting a discrepancy in the imaging follow-up of left ventricular ejection fraction (LVEF), three (15%) did not have a close follow-up of the LVEF compared to the recommendations and one (5%) had a break in treatment of six cycles before restarting because of the decrease in LVEF. Six of the 20 patients (30%) had a LVEF decrease which required closer monitoring. Among these, three cases of cardiotoxicity with clinical signs were observed. A case of irreversible cardiotoxicity despite beta blocker (BB) management, a reversible case but requiring a temporary interruption of six cycles and

treated with BB and angiotensin converting enzyme inhibitor and finally a totally reversible case treated with BB. All three patients received pre-treatment with anthracycline (epirubicin) and had hypertension since initiation of trastuzumab.

Conclusion Seventy-five per cent of patients treated were followed up in accordance with the recommendation. The appearance of cardiotoxicity seems to be favoured by some previous events as mentioned in the literature. Nevertheless, since the number of patients included is small, a larger study should support these results.

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No conflict of interest.

5PSQ-059 CYCLIN DEPENDENT KINASES 4/6 INHIBITORS: NEW OPTIONS IN HR+ HER2- BREAST CANCER

¹J Ramos Rodríguez*, ²S Hernández Rojas, ³I González Perera, ⁴MM Viña Romero, ¹GJ Nazco Casariego, ²FJ Merino Alonso, ¹S García Gil, ¹B Del Rosario García, ¹L Cantarelli, ¹F Gutiérrez Nicolás. ¹Hospital Universitario de Canarias, Pharmacy, Santa Cruz De Tenerife, Spain; ²Hospital Universitario Nuestra Señora de la Candelaria, Pharmacy, Santa Cruz De Tenerife, Spain

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Background The HR +HER2 subtype is the most common molecular profile in women with breast cancer and the appearance of this new group of drugs has drastically changed the prognosis of this group of patients.

Purpose To describe the safety profile of Palbociclib and Ribociclib in two third-level hospitals.

Material and methods A multicentre, retrospective, 39 month study (May 2015 to August 2018), in which we analysed all patients treated with Palbociclib or Ribociclib. The following variables were collected: age of treatment onset, metastatic disease treatment line, adverse effects, suspension and/or dose reduction. Toxicities were classified according to the Common Terminology Criteria for Adverse Events (CTCAEv5.01) (January 2018).

Results Data were collected from 26 patients, 69.2% of which (18) were treated with Palbociclib, and 30.8% (eight) with Ribociclib. Drugs were used in the first-line in 38.5% of the cases (10) and in the second-line in 61.5% (16).

The adverse reactions described for both drugs were the following: 76.9% patients (20) suffered neutropaenia, of which 7.7% were grade 1 (two), 34.6% grade 2 (nine), 42.3% grade 3 (11) and 7.7% grade 4 (two); seven joint pain (26.9%); eight asthaenia (30.7%); four nausea (15.3%); three dizziness (11.5%); four patients experienced anaemia (15.4%), grade 1 in 3 cases (11.5%) and grade 3 in the remaining case (3.8%); three headache (11.5%); three dyspnea (11.5%); two papulo-pustular rash (7.7%), two abdominal pain (7.7%), two vomiting (7.7%); two respiratory infection (7.7%); two hot