reductions were not associated with an increased risk of progression. Bone metastasis is very common in metastatic or locally advanced breast cancer. Since the authorisation for firstline use (PALOMA-2) it has become a standard of treatment for metastatic or locally advanced breast cancer.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-164 REAL SAFETY OF DARATUMUMAB IN MYELOMA MULTIPLE

MC Sánchez Argañiz*, M Valera Rubio, N Martínez Casanova, B Cancela Díez. *Hospital Virgen De La Victoria, Hospital Pharmacy, Málaga, Spain*

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Background and importance The overall survival of patients with multiple myeloma (MM) has changed dramatically in the last decade. Immunotherapy has emerged as a promising treatment, such as daratumumab. This human monoclonal IgG kappa antibody that targets CD38 is used in monotherapy or in combination, and has demonstrated durable responses. But good clinical management of toxicities is needed to reach the goal of therapy.

Aim and objectives To assess the safety of daratumumab in monotherapy and in combination with other agents used in our institution, and to review the clinical management of toxicities.

Material and methods A retrospective observational study was conducted in a second level hospital. We reviewed the medical records of all patients diagnosed with MM who received at least one cycle of daratumumab as monotherapy or as combination therapy in our hospital until August 2020. Collected data were: sex, age, cytogenetic risk, prior line of therapy, prior autologous stem cell transplantation (ASCT), daratumumab monotherapy or combination therapy, adverse drug reactions (ADRs), grade and clinical management (supportive treatments, temporary interruptions and permanent discontinuations).

Results 33 patients received at least one cycle of daratumumab and were included (26% men). Median age was 64 (42–77) years, 26% (8) had high cytogenetic risk abnormalities, median number of prior lines of therapy was 2 (0–6) and 74% (23) of patients received daratumumab in combination therapy. Average number of cycles received was 8 (1–38). 39% (13) of patients had infusion reactions (IRs) but the majority (92%) occurred during the first infusion and were grades 1–2. We registered 22 haematological severe ADRs (grades 3–4) and the most common was thrombocytopenia (60%), followed by neutropenia (22%), all requiring supportive treatment, and in 32% temporary interruption of treatment was necessary. 28 non-haematological severe ADRs (grades 3–4) were registered, 50% were severe infections, most of them respiratory that required temporary interruption to therapy, and 10 (71%) needed hospital admission. Almost one in three patients experienced permanent discontinuation of daratumumab related to toxicity (90% receiving combination therapy).

Conclusion and relevance Most adverse reactions related to daratumumab therapy were clinically manageable, but the incidence of severe haematological toxicity and severe respiratory infections makes close monitoring of side effects necessary,

along with practical management strategies to reach the maximal benefit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-165 INCIDENCE AND MANAGEMENT OF ETOPOSIDE HYPERSENSITIVITY IN PAEDIATRIC PATIENTS

N Báez Gutiérrez, H Rodríguez Ramallo*, C Alvarez Del Vayo Benito, B Fernández Rubio. *Virgen Del Rocío University Hospital, Pharmacy, Seville, Spain*

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Background and importance Etoposide is widely used in paediatric chemotherapy treatment, although hypersensitivity can be severe and treatment limiting. There are conflicting data in the literature regarding the incidence of etoposide hypersensitivity reactions in adults and children. Reported rates of hypersensitivity range from 2% to 51%.

Aim and objectives The aim of this study was to assess the incidence of etoposide hypersensitivity and to evaluate potential risk factors for hypersensitivity in paediatric patients in a third level hospital.

Material and methods A retrospective observational study was conducted in paediatric patients treated with etoposide from June 2013 to September 2020. Data collected were: demographics (age, sex), diagnosis, dose, infusion rate, infusion concentration, symptoms of hypersensitivity, CTCAE grade of hypersensitivity reaction and management of hypersensitivity reaction. Data were collected from the electronic medical records and pharmacy records.

Results 213 patients were treated with etoposide during the period of the study. Mean age was 6.75 (range 0.16–17) years and 58.68% were male. Indications for etoposide were lymphocytic acute leukaemia 20.18%; neuroblastoma 16.9%; Ewing's sarcoma 16.9%; Hodgkin's lymphoma 11.27%; myeloid acute leukaemia 8.9%; and other 25.82%. Doses administered ranged from 200 to 100 mg/m² and from 2.5 to 6 mg/kg. Median infusion rate was 55 (2–200) mg/hour. Median infusion concentration was 0.3 (0.2–0.5) mg/mL. Hypersensitivity reactions occurred in 23 (10.8%) patients; 3 and 20 cases were classified as grade I and grade II of the CTCAE, respectively. Symptoms of hypersensitivity were lip cyanosis (n=7), pruritus (n=7), flushing (n=7), nausea (n=5), cutaneous rash (n=5), cough (n=4), rhinoconjunctivitis (n=1), hypotension (n=1), shortness of breath (n=1), abdominal pain (n=1), facial paraesthesia (n=1), fever (n=1) and angioedema (n=1). All hypersensitivity reactions were successfully managed with medication (corticoids and antihistamines). Subsequent doses were administered with premedication and reduction of the infusion rate. We did not observe any statistically significant associations between the variables collected and the appearance of hypersensitivity reactions.

Conclusion and relevance The incidence of hypersensitivity reactions was moderate, affecting approximately 10% of patients. All hypersensitivity reactions were mild and were resolved by standard treatment. We were unable to establish if any of the variables collected were risk factors for hypersensitivity reactions, probably due to the small sample size derived from the rarity of the event. Other studies have observed a relationship between the rate of infusion and the concentration of etoposide.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-166 MANAGEMENT OF TOXICITIES RELATED TO CYCLIN DEPENDENT KINASE 4/6 INHIBITORS IN METASTATIC BREAST CANCER

MC Sánchez Argañiz*, M González Padilla, M Gómez Delgado, B Cancela Díez, I Moya Carmona. *Hospital Virgen De La Victoria, Hospital Pharmacy, Málaga, Spain*

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Background and importance Treatment goals for advanced or metastatic breast cancer include not only delaying progression of the disease and extending survival, but also maintaining or improving the quality of the patient's life. New targeted therapies, such as cyclin dependent kinase (CDK) 4/6 inhibitors, have improved patient outcomes with hormonal receptor positive, HER negative, metastatic breast cancer compared with conventional single agent endocrine therapy. They contribute to clinical benefit but at the same time they are the cause of complex and potentially severe adverse events that require good clinical management of toxicities.

Aim and objectives To assess the safety of CDK4/6 inhibitors, analysing the relevant adverse drug reactions (ADRs) and reviewing the clinical management of toxicities.

Material and methods A retrospective observational study was conducted in a second level hospital. We assessed the safety of three CDK4/6 inhibitors (ribociclib, palbociclib and abemaciclib), reviewing the medical and pharmaceutical records of all patients that attended the pharmacy department from January to March 2020. Collected data were: age, ECOG, cancer stage, metastatic location, type of CDK4/6 inhibitor in combination with endocrine therapy, ADRs, grade and clinical management (dose reductions, temporary interruptions and permanent discontinuations).

Results 58 patients were included, median age 55 years (75–39), and 67% (39) received ribociclib, 29% (17) received palbociclib and 4% (2) received abemaciclib. ECOG at the beginning was 0 in 55% (32) of patients, 1 in 28% (16) and 2 in 10% (6). 100% of patients had disease stage IV and the main metastatic location was bone (87%). Average number of cycles received was 15 (1–36). 38 (66%) patients had severe ADRs (grades 3–4), approximately 3 severe ADRs per patient. Neutropenia was the most common ADR grade 3/4 (85%) related to CDK4/6 inhibitors, and was highest with ribociclib compared with the other CDK4/6 inhibitors, followed by gastrointestinal disorders (5%). These severe ADRs required dose reductions in 15% (31), temporary interruptions in 37% (79) and permanent discontinuation of treatment in 4% (7). 19 patients also needed supportive treatments.

Conclusion and relevance In spite of the manageable safety profile of CDK4/6 inhibitors in clinical practice, the frequency of severe ADRs associated with these treatments makes consistent close monitoring of side effects and toxicity necessary due to inter-patient variability, along with practical management strategies to find the optimal therapy for each patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-167 ANALYSIS OF FIRSTLINE TREATMENT IN THE ELDERLY WITH METASTATIC COLORECTAL CANCER

A Magallon Martínez*, MJ Agustín Ferrández, A Pinilla Rello, L Cazorla Poderoso, M Pérez Moreno, A López Pérez, J Perales Pascual, MR Abad Sazatornil. *University Miguel Servet Hospital, Hospital Pharmacy, Zaragoza, Spain*

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Background and importance The increase in life expectancy, the higher incidence of cancer in elderly patients and the lack of clinical trials in these patients makes it necessary to carry out studies that allow us to know the effect and safety of the treatments.

Aim and objectives To analyse the effectiveness and safety of firstline treatment of metastatic colorectal cancer (CRCm) in the elderly treated in a third level hospital.

Material and methods This was an observational retrospective study including patients aged ≥ 75 years with CRCm, who received chemotherapy treatment in 2017. The main variables studied were type of treatment, clinical response, progression free survival (PFS), overall survival (OS), dose reductions and treatment delays due to adverse events.

Results 59 patients (71.2% men) with a median age of 76 years were enrolled, 27.1% were ≥ 80 years old. 41/59 patients presented with colon cancer, the left colon being the most frequent location. 26/59 metastases were hepatic, 11/59 pulmonary, 9/59 hepatic and pulmonary, and 13/59 in other locations. They were treated with nine different schemes: 50/59 in combination with two or more drugs and 9/59 as monotherapy with capecitabine. 36/59 patients were treated with target therapies. The median number of administered cycles was 10. The response was complete in 6/59 patients, partial in 29/59, stable disease in 17/59 and progression of disease in 7/59. Median PFS and OS were 12 and 30 months, respectively. We observed that patients with left colon tumours, no RAS mutation, tumours with a degree of differentiation 1 and 2 (well differentiated) and patients rescued by surgery had better OS ($p < 0.05$). 23/59 patients started treatment with doses lower than recommended in clinical practice guidelines. In terms of safety, 34/59 patients had at least one dose reduction, and 30/59 had one treatment delay. Adverse events with frequency $\geq 50\%$ were asthenia, peripheral neuropathy, diarrhoea and palmar-plantar erythrodysesthesia.

Conclusion and relevance Our patients presented with baseline clinical characteristics similar to the general adult population, with no tumour characteristics associated with advanced age. Effectiveness and safety were similar to those in clinical trials, although our patients had more dose reductions. Considering the heterogeneity of patients and in the absence of clinical trials in the elderly, real life studies can be very useful.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

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5PSQ-168 INTEREST AND IMPLEMENTATION OF RAPID DARATUMUMAB INFUSION DURING THE HEALTH CRISIS

¹C Sereni*, ¹L Maljean, ¹F Morey, ²S Dupire, ¹B Manguen. ¹Centre Hospitalier De Bourg-En-Bresse, Pharmacy, Bourg-En-Bresse, France; ²Centre Hospitalier De Bourg-En-Bresse, Oncology-Haematology Department, Bourg-En-Bresse, France

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