(10%). The median dose received was 7. If the number of doses was calculated according to diagnosis, RC patients received 11 doses, 9 for MC, 4 for LC and 4 for HNC. During the study period, 84.2% of LC patients, 60% of HNC, 20% of MC and 50% of RC died.

Regarding AE, very common (>10%) ones were an increase in lactate dehydrogenase (25%), hypothyroidism (14.6%), eruption (10.4%) and increases in gamma-glutamyl transferase and glutamic-oxaloacetic transaminase (10.4%). The remaining AE were classified as common according its frequency (1–10%): pneumonitis (6.3%), nephritis (4.2%), hepatitis (4.2%), increase in alkaline phosphatase (6.3%), diarrhoea (2.1%), colitis (2.1%), liver failure (2.1%) and arthritis (2.1%). Comparing AE frequency obtained with those reported on the DS, we found that the prevalence of hypothyroidism, colitis, hepatitis, nephritis and arthritis was higher in routine clinical practice than expected.

We found that 77% of patients interrupted nivolumab due to progression of disease (78.4%), AE (16.2%) or ending treatment (5.4%).

Conclusion and relevance Relevant AE that occurred during the study period were hypothyroidism, pneumonitis, hepatitis, nephritis and colitis. Their prevalence was higher than expected and they caused interruption of treatment. The increased prevalence of AE in routine clinical practice highlights the need for strict monitoring of analytical parameters to detect AE as early as possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-047 RIBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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Background and importance Treatment goals for advanced or metastatic breast cancer include not only delaying the progression of disease and extending survival, but also maintaining or improving quality of life for the patient. CDK4/6 inhibitors, such as ribociclib, in combination with hormonal therapy, is a new standard firstline and secondline treatment for women with advanced or metastatic hormone receptor positive (HR+/HER2-) breast cancer. The starting dose is 600 mg/day for 3 weeks followed by 1 week off, combined with hormonal therapy, aromatase inhibitor and/or luteinising hormone releasing hormone agonists. Management of severe adverse drug reactions (ADRs) may require temporary dose interruptions, dose reductions or discontinuations of treatment.

Aim and objectives To assess the safety of ribociclib and analyse the ADRs and severe toxicity that cause dose reductions, dose interruptions and permanent discontinuations.

Material and methods A retrospective observational study was conducted in a tertiary hospital. We analysed the safety of ribociclib by reviewing medical and pharmaceutical records of all patients treated with ribociclib from January 2018 until September 2019. Collected data were age, ECOG, cancer stage, metastatic location, treatment line and dose reduction/interruption. ADRs were collected for the safety profile assessment.

Results Forty-two patients were included, median age 58 years (range 40–72). ECOG at the beginning of the treatment was 0 in 67% (28) of patients, 1 in 31% (13) and 2 in 2% (1). A total of 98% of patients were in stage IV disease and the main metastatic location was bone (76%). Ribociclib combined with hormonal therapy was prescribed as firstline treatment in 79% (33) of patients. One of two patients suffered first dose reduction (400 mg/day) by adverse events due to ribociclib and one of 10 suffered second dose reduction (200 mg/day). The most common ADR grade 3 (severe) was neutropenia (n=11), followed by skin and subcutaneous tissue disorders such as rash, pruritus and erythema (n=5), and gastrointestinal disorders (n=3) that caused delays and dose reduction. There were no permanent discontinuations due to toxicity.

Conclusion and relevance In spite of the manageable safety profile of ribociclib by dose modifications and delays in cycles, it was necessary for close monitoring of side effects and toxicity due to interpatient variability, to find the optimal dose for each patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-048 ANALYSIS OF DRUG INTERACTIONS BETWEEN ORAL ANTINEOPLASTIC AGENTS AND CONCURRENT MEDICATIONS

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Background and importance The development and commercialisation of oral antineoplastic agents (OAAs) to treat cancer has increased significantly in recent years. Drug interactions are the most frequent drug related problems with regard to these drugs.

Aim and objectives To analyse the potential drug interactions (PDIs) of OAAs with concurrent medication.

Material and methods A cross sectional observational study was carried out in outpatients who started treatment with OAAs between December 2015 and May 2019. PDIs were analysed using the Lexicomp and the database About Herbs of the Memorial Sloan Kettering Cancer Centre. PDIs were classified according to severity (major, moderate, minor), risk (X, D, C) and reliability (excellent, good, fair, poor) ratings and mechanism (pharmacokinetics and pharmacodynamics).

Results A total of 881 patients were included (56.2% men) with a median (range) age of 67.8 years (22.5–94.4). The most frequent types of tumours were prostate cancer (16.8%), multiple myeloma (13.6%), hepatocellular carcinoma (13.3%), breast cancer (11.5%), renal carcinoma (n=90; 10.2%) and non-small cell lung cancer (9.9%). Thirty-seven different OAAs were assessed. A total of 860 PDIs were identified. The targeted OAAs involved in more PDIs were: enzalutamide (PDI=231, PDI/patient=2.8), thalidomide (PDI=91, PDI/patient=2.7), everolimus (PDI=77, PDI/patient=1.0), imatinib (PDI=75, PDI/patient=1.8) and sorafenib (PDI=68, PDI/patient=0.6). The most frequent severity and risk ratings were major (55.3%) and C (42.8%), respectively. In total, 61.7% of

the PDIs had a pharmacokinetic mechanism. The most frequent enzymatic systems involved in those interactions were: CYP3A4 (71.8%), CYP2C19 (10.8%), CYP2D6 (7.6%) and CYP1A2 (2.8%). The type of PDIs with higher severity and risk ratings were decrease in OAA absorption (80.0% major severity and 41.3% X risk) and induction of concurrent medication metabolism (87.1% major severity and 29.0% X risk) ($p<0.001$). The induction of concurrent medication metabolism was the PDI with the higher reliability (73.3% good reliability) ($p<0.001$).

Conclusion and relevance Half of the patients treated with targeted OAAs presented at least one PDI with concurrent medicines. More than half of PDIs had high risk and severity ratings, and their main mechanism was pharmacokinetic. Therefore, PDIs have an important impact on the management of patients treated with OAAs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-049 PALBOCICLIB IN METASTATIC BREAST CANCER TREATMENT: REAL LIFE TOXICITY AND FREQUENCY OF DOSE REDUCTION OR PERMANENT DISCONTINUATION

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Background and importance Palbociclib is an oral selective inhibitor of the cyclin dependent kinases CDK4 and CDK6 labelled for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer. The most frequent adverse events (AEs) reported in pivotal studies were neutropenia, leucopenia, anaemia, stomatitis, nausea, diarrhoea, alopecia, infections and fatigue. Among these, the most common grade 3 or grade 4 AEs were neutropenia, fatigue and infections. In the pivotal studies, 34% of patients required a decrease in their palbociclib dose and 4% of patients required permanent discontinuation. Currently, real life toxicity data on palbociclib are still scarce.

Aim and objectives The aim of this study was to assess the real world tolerability of palbociclib and to compare our results with the safety outcomes of the pivotal studies.

Material and methods We collected real life toxicity data by analysing computerised health records, internal databases and pharmacovigilance reports, and subsequently we compared the incidence of toxicity, dose modifications and permanent discontinuations due to AEs with data reported in the pivotal studies.

Results In an oncological hospital, 199 patients were treated with palbociclib, 149 in association with fulvestrant and 50 with letrozole. Palbociclib dose reduction occurred in 77/199 (38%) patients due to AEs, 14/199 (7%) requiring second level of dose reduction. In total, 67/77 (87%) patients had dose reductions due to haematological toxicity, mainly neutropenia, 15 of whom had other haematological toxicities. Overall, 10/199 (5%) patients had permanent discontinuation for any toxicity, 7 due to non-haematological toxicity, mainly hepatic toxicity, epigastralgia and astenia.

Conclusion and relevance The incidence of haematologic and non-haematological reactions, dose reductions and treatment interruption due to toxicity in real world clinical practice were comparable with the results obtained in the pivotal studies. Haematological toxicity, particularly neutropenia, was the first cause of dose reduction, while non-haematological toxicity was found to be the first cause of definitive treatment interruption.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-050 SUCCESSFUL DESENSITISATION IN A PATIENT WITH DASATINIB HYPERSENSITIVITY

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Background and importance A 65-year-old woman with Philadelphia chromosome positive acute lymphoblastic leukaemia was treated with dasatinib 140 mg daily. After the first dose, the patient experienced anaphylactic shock presenting poor general condition, nausea, rash, diarrhoea, severe hypotension, anuria and angioedema. Dasanitib treatment was discontinued and corticosteroid and fluid therapy were initiated. The allergy was not confirmed by skin testing as the reaction was very recent and it was considered essential to start a dasatinib desensitisation protocol immediately.

Aim and objectives To report the successful oral desensitisation protocol for dasatinib.

Material and methods The available literature was reviewed and the following oral desensitisation protocol was designed to reach the therapeutic daily dose of 140 mg. Day 1: a tablet of dasatinib 20 mg was crushed, dissolved and diluted in water to prepare six solutions: 20 ng/mL (A), 200 ng/mL (B), 2 µg/mL (C), 20 µg/mL (D), 200 µg/mL (E) and 2 mg/mL (F). It was administered as nine increasing dasatinib doses at 30 min intervals: 1 mL of solutions A–E followed by 1 mL, 2 mL, 3 mL and 4 mL of solution F. In the following days: from tablets, consecutively each day, one of these increasing doses was given 20 mg, 40 mg, 70 mg, 90 mg, 110 mg and 140 mg.

Results When the patient took the 90 mg dose she experienced pruritic malar oedema, neck erythema and abdominal hives. She was administered antihistamines and corticosteroids. The protocol was restarted after 48 hours at the 70 mg dose, with premedication. Some hours later, the patient experienced rash in the upper left limb and facial oedema. The next day the scheme was begun at 40 mg. It was followed by 70 mg, 90 mg (divided into two daily doses of 70 mg and 20 mg), 110 mg (divided into 70 mg and 40 mg) and reached 140 mg (70 mg twice a day). It has been well tolerated for 7 weeks.

Conclusion and relevance This was a successful dasatinib desensitisation protocol. The use of a desensitisation protocol enables patients with hypersensitivity reactions to the drug to be treated safely with the most convenient therapy.

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No conflict of interest.