(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.

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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