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 first-line and second-line 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.

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 first-line 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).

No conflict of interest.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

RIBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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Background and importance Relevant AE that occurred during the study period were hypothyroidism, pneumonitis, hepatitis, nephritis and colitis. Their prevalence was higher than expected.

Conclusion and relevance Comparing AE frequency obtained with those in routine clinical practice than expected.

No conflict of interest.

ANALYSIS OF DRUG INTERACTIONS BETWEEN ORAL ANTI NEOPLASTIC AGENTS AND CONCURRENT MEDICATIONS


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 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 involved in more PDIs were: enzalutamide (PDI=231, PDI/patient=2.8), thalidomide (PDI=91, PDI/patient=2.7), cyproterone (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 OAs presented at least one PDI with concurrent medicine. 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 OAs.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

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. 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 PDIs 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 PDIs, 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
No conflict of interest.