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 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 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. The most frequent adverse events (AEs) reported in pivotal studies were neutropenia, leucopenia, anaemia, stomatititis, 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 The available literature was reviewed

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

No conflict of interest.