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

No conflict of interest.