

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

No conflict of interest.

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 asthenia.

**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. Dasatinib 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.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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