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 frontline 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 letrozimine hormone releasing hormone agonists. Management of severe adverse drug reactions (ADRs) may require temporary dose interruptions, dose reductions or permanent 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 frontline 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, pruritis 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.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.