

INFLUENCE OF PALBOCICLIB TOXICITY IN THE REAL WORLD CLINICAL PRACTICE



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Background and importance

Palbociclib was approved by the EMA for the treatment of hormone receptor **(HR)-positive**, human epidermal growth factor receptor 2 **(HER2)-negative** locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant.

Aim and objectives

- To study adverse events (AEs) and their impact on dosing and cycle delays in patients treated with palbociclib.
- To characterize the safety of palbociclib in real world.

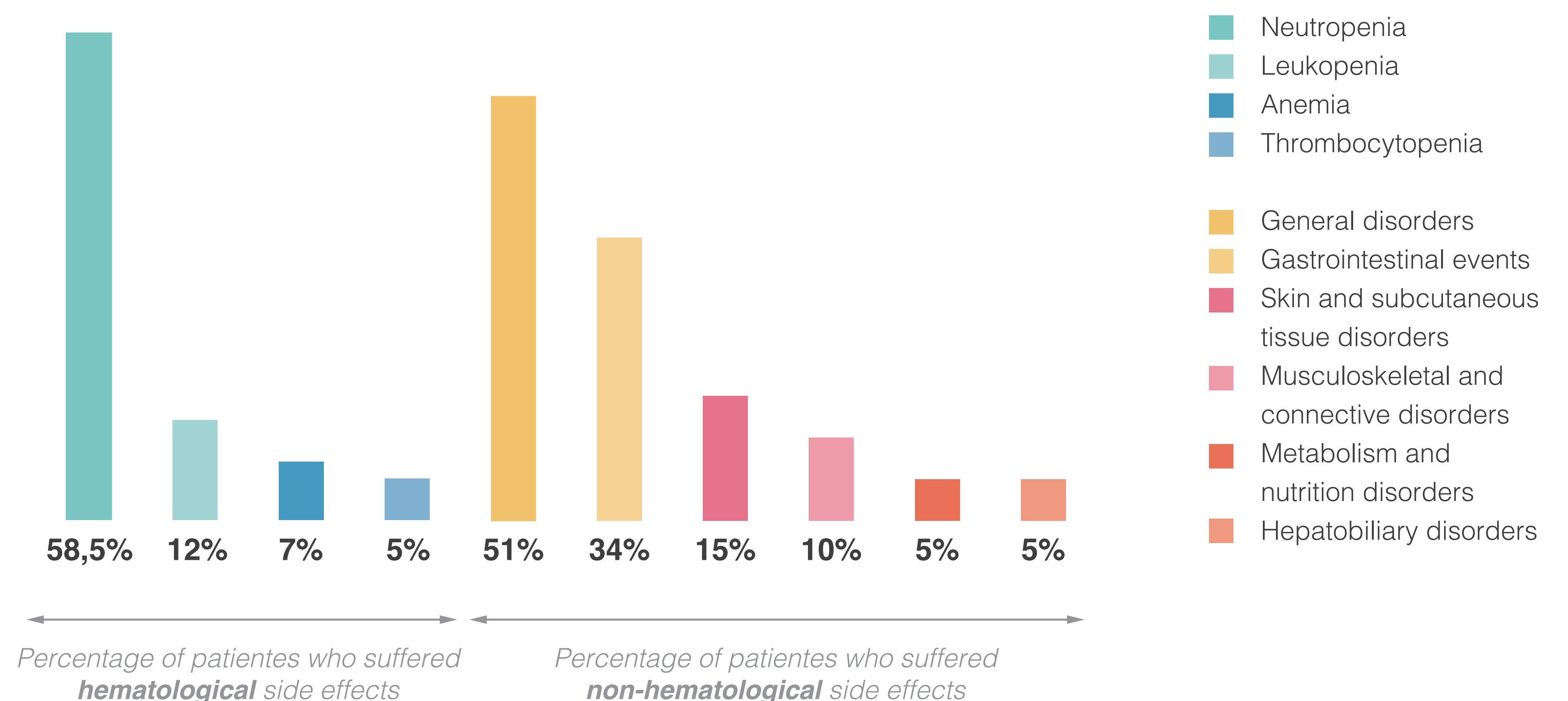
Material and methods

- Retrospective and observational study (March 2018 - July 2019).
- Patients' demographics, clinical and treatment related data and AEs were analysed.
- Toxicity was classified by CTCAE (Common Terminology Criteria for Adverse Events).

Results

Sample: 41 women
Mean age: 59 (37-78)
Mean number of cycles received: 8,5 (1-18)

→ **37 patients (90%) presented AEs.**



→ **17 patients (41%) required dose reduction due to treatment-related AEs.**

In 13 cases (32%) the cause of the modification was neutropenia.

- **Others:** anemia, fatigue, cholelithiasis, pruritus.
- **Second dose reduction:** 5 patients, and the reasons were the same (neutropenia, fatigue).
- **Mean interval between reductions:** 5 cycles (3-10). Currently all continue treatment with palbociclib.

→ **27 patients (67,5%) required cycle delays as a result of AEs.**

- **Main causes:** neutropenia (50%), anemia (5%) and fatigue (5%).
- **Others:** leukopenia, thrombocytopenia, diarrhea, pruritus and non-treatment reasons.

→ **10 patients (24%) discontinued treatment.**

- 9 due to disease progression.
- 1 due to hypertransaminemia produced after the first cycle.

Conclusion and relevance

· Thanks to the proper management of toxicities the majority of patients do not need to discontinue treatment and palbociclib may be an option in these patients. However, some patients presented AEs which led to delays in the cycles and dose modifications.