

# REAL-WORLD SAFETY AND TOLERABILITY OF PALBOCICLIB AS FIRST-LINE THERAPY IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CANCER

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## BACKGROUND AND IMPORTANCE

Palbociclib is a selective cyclin-dependent kinase inhibitor approved for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (LA/MBC) in combination with an aromatase inhibitor as first line treatment. Real-world data regarding its safety and tolerability when prescribed as first line treatment is still scarce.

## AIM AND OBJECTIVES

To determine the long term safety profile of palbociclib when prescribed as first line treatment for HR-positive, HER2-negative LA/MBC.

## MATERIAL AND METHODS

An observational, retrospective, descriptive study was performed at a tertiary hospital

### Inclusion criteria

All patients who started palbociclib as first-line treatment for HR-positive, HER2-negative LA/MBC between January 2018 and August 2019.

### Variables

Frequency of adverse events (AE), graded according to CTCAE V5.0 criteria.

Frequency and causes of dose delays, reductions or permanent treatment discontinuations due to AE.

Clinical and analytical data were obtained from electronic clinical records, and treatment data from the dispensing electronic program.

External reference data were used from PALOMA-2 trial to compare the real-world data.

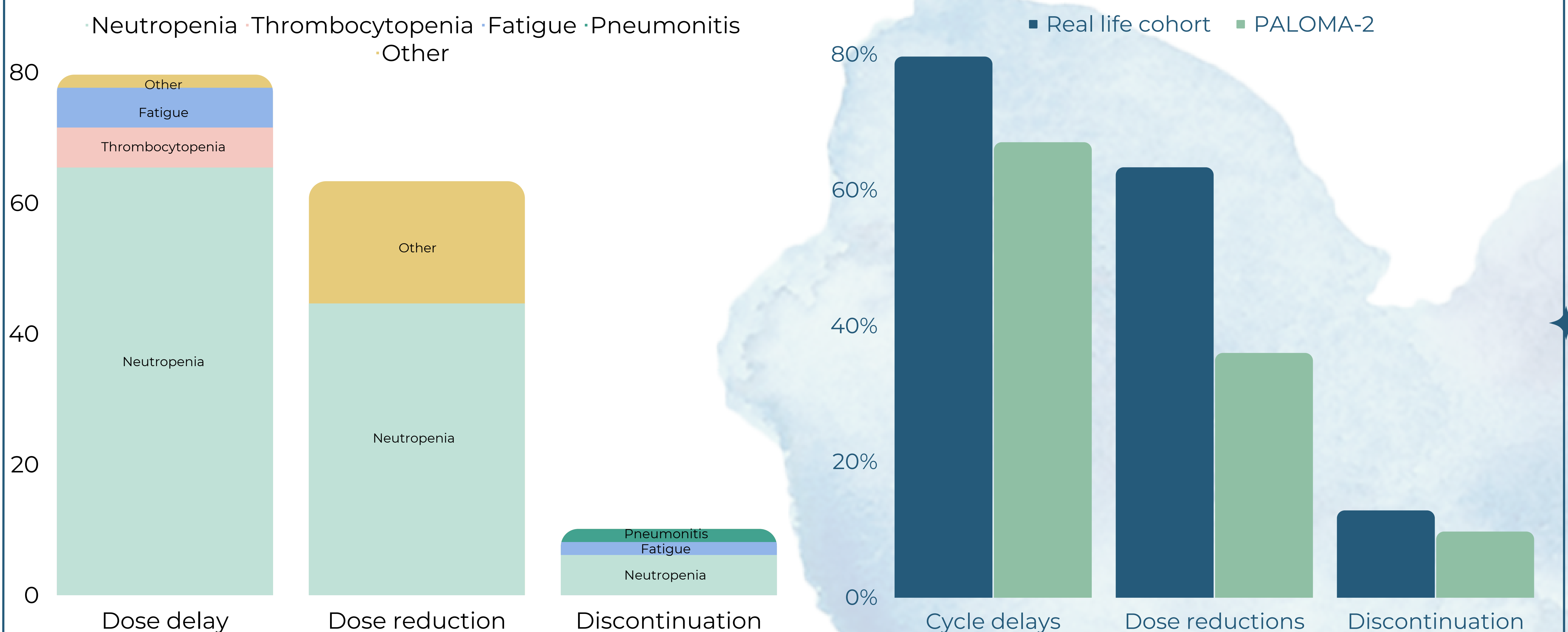
## RESULTS

A total of 49 women were studied with a median follow-up of 33 (range 1-44) months.

All patients had an AE of any grade and 39 (79.6%) presented grade 3 or 4 AE.

The most frequent grade 3 or 4 AE were neutropenia (69.4%), leukopenia (34.7%) and thrombocytopenia (6.1%).

Two (4.3%) deaths occurred due to pneumonitis and progressive multifocal leukoencephalopathy.



## CONCLUSIONS AND RELEVANCE

The real clinical practice toxicity profile of palbociclib as first line treatment for HR-positive, HER2-negative LA/MBC is similar from the previously reported in PALOMA-2, although more treatment modifications were necessary.