

# REAL WORLD EFFECTIVENESS OF PALBOCICLIB AND RIBOCICLIB IN WOMEN WITH METASTATIC BREAST CANCER.

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## Background and importance

Palbociclib and ribociclib are **novel oral agents** in Hormone-Receptor-positive (HR+) and Human-Epidermal-GrowthFactor2-negative (HER2-) metastatic breast cancer (MBC). As these drugs have recently been released, it is necessary to provide insight into the **real-world use**.

## Aim and objectives

Provide data on effectiveness in patients treated with palbociclib and ribociclib in clinical practice.

## Materials and methods

- ✓ Observational, descriptive and retrospective study conducted in a tertiary hospital. All HR+/HER2- MBC patients who initiated treatment with palbociclib or ribociclib from March 2018 to March 2019 were included. Patients were followed-up until March 2020.
- ✓ Patients demographics, clinical characteristics and treatment patterns were obtained from electronic medical record and the pharmacy database Farmatools®.
- ✓ The primary effectiveness variable was progression-free survival (PFS). Overall survival (OS), survival probabilities at 12 and 18 months were also estimated. OS was estimated with Kaplan-Meier and PFS with a competitive risk study, using the software R (v2013).

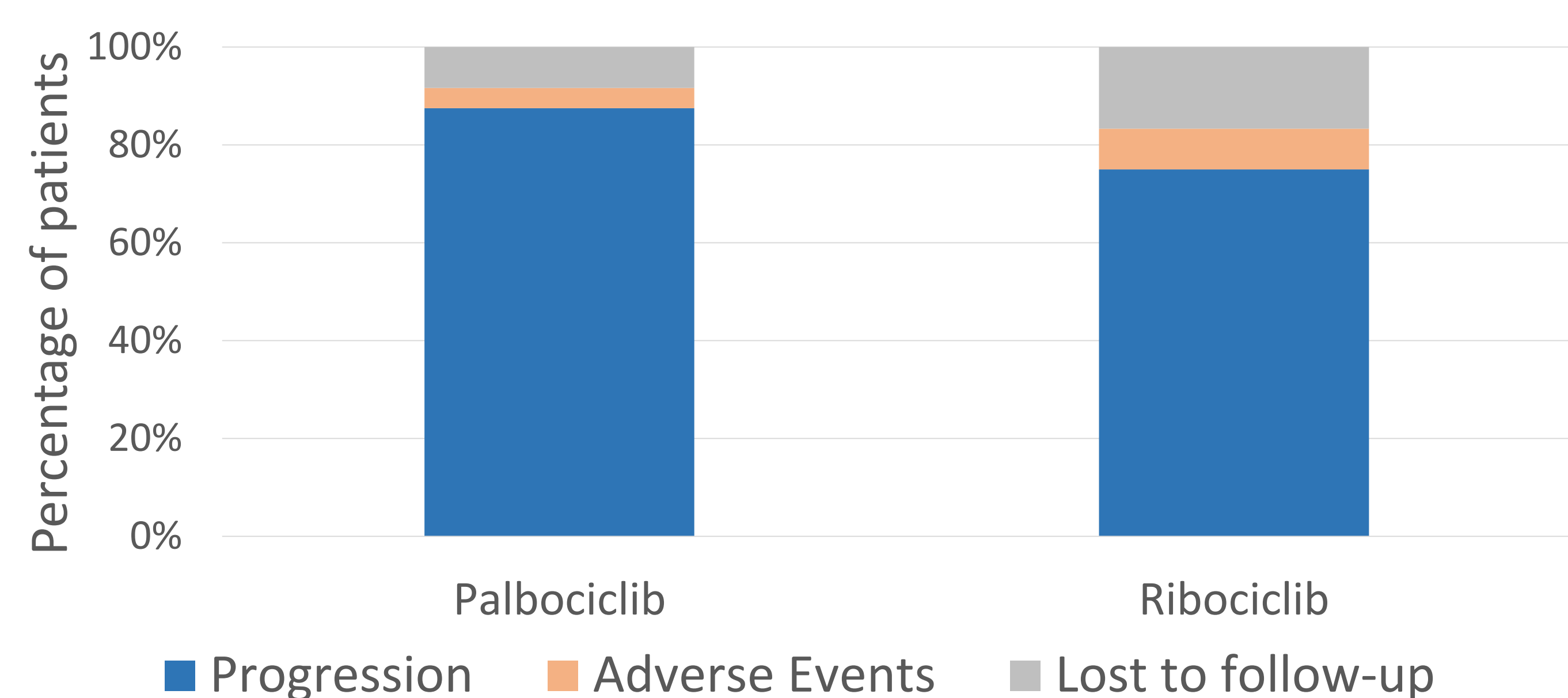
## Results N= 61 patients

Table 1. Characteristics of the Patients at Baseline.

	Palbociclib (N= 33)	Ribociclib (N= 28)
Median age (range) years	60.5 (40-86)	56.0 (43-86)
<b>ECOG Performance Status</b>		
0-1	31	27
≥2	2	1
<b>Number of metastasis</b>		
<2 sites of metastasis	18	16
≥2 sites of metastasis	15	12
<b>Line of treatment</b>		
First line	6	19
Second line	27	9

Treatment was discontinued in 24 patients with palbociclib and 12 patients with ribociclib. **Disease progression was the most common reason of discontinuation**

FIGURE 1. REASONS OF TREATMENT DISCONTINUATION.



Median follow-up (months): palbociclib 12,2; ribociclib 15,2.

	Palbociclib	Ribociclib
Median PFS	12,7 months (95% CI, 7.5 to not estimable)	Not reached
12-months PFS rate	51,5% (95%CI:34 -69)	78,6% (95%CI:63-94,1)
18-months PFS rate	37,7% (95%CI:20,1-55,4)	68,9% (95%CI:49,9-88)
<b>Line of treatment</b>		
Nº of deaths (os results not mature)	8 patients	4 patients
12-months OS rate	87,7% (Standard Error(SE):6,8%)	95,8% (SE:4,1%)
18-months OS rate	61,6% (SE:12,2%)	87,1% (SE:7%)

## Conclusions and relevance

1. Our findings in the **real-world setting** confirm clinical benefit for women with HR+/HER2- MBC.
2. Palbociclib and ribociclib **outcomes are comparable to those reached in the phase-III trials**, PALOMA-3 and MONALEESA-2, due to the profile of the patients treated with both drugs.
3. As palbociclib and ribociclib were used in different settings, **outcomes cannot be compared**.