

## Objectives

To describe the effectiveness and safety of palbociclib combination therapy for metastatic breast cancer in clinical practice.

## Methods

Retrospective and observational study from December 2015 until April 2018 in a tertiary hospital. Collected data included: age, ECOG performance status, number of cycles received, duration and prior lines of treatment.

**Effectiveness** endpoint was progression-free survival (PFS) according to RECIST version 1.1.

**Adverse events** related to treatment with palbociclib and registered in the patient's medical records were included in the study. Toxicity was evaluated as defined by the NCI-CTCAE, version 4.0.

## Results

	n (%)
<b>Patients</b>	
Female	29 (100%)
<b>Age (mean)</b>	57 (38-71)
<b>ECOG</b>	
0	23 (79.3%)
1	4 (13.8%)
2	2 (6.9%)
<b>Phenotype</b>	
Luminal A	5 (17.2%)
Luminal B	24 (82.8%)
<b>Menopausal stage</b>	
Peri	5 (17.2%)
Post	24 (82.8%)
<b>Concomitant HT</b>	
Fulvestrant	17 (58.6%)
Aromatase inhibitor	12 (41.4%)
<b>Naive</b>	
Yes	6 (20.7%)
No	23 (79.3%)
<b>N° of prior lines (mean)</b>	1 (0-10)
<b>Initial dose</b>	
125 mg	29 (100%)
<b>Dose reductions</b>	
Yes	14 (48.3%)
No	15 (51.7%)
<b>Suspension cause</b>	
Progression	9 (31.0%)
Toxicity	1 (3.5%)
<b>N° cycles (mean)</b>	9 (1-21)
<b>Median treatment duration (95% CI) (months)</b>	6.3 (0.1-19.2)
<b>Median PFS (95% CI) (months)</b>	7.7 (0.1-19.2)

Adverse Events	Frequency n (%)	Grade		
		1	2	≥3
<b>General</b>	10 (34.5%)			
Asthenia, fatigue		4	1	2
Headache		3		
<b>Gastrointestinal</b>	8 (27.6%)			
Nausea		4	2	
Constipation		2		
<b>Hematological</b>	16 (55.2%)			
Neutropenia			4	12
<b>Skin and mucous membranes</b>	9 (31.0%)			
Alopecia			2	
Mucositis			4	
Dermatitis			1	2
<b>Infections</b>	4 (13.8%)			
Urinary tract infection				2
Tonsillitis				1
Sepsis				1

## Discussion

Significant difference in PFS was observed compared to published clinical trials PALOMA-2 (PFS 24.8 months) and PALOMA-3 (PFS 11.2 months). Otherwise, palbociclib showed a similar safety profile.

## Conclusions

Further studies are needed to establish effectiveness of palbociclib in clinical practice as 19/29 patients are still receiving treatment.

