

PALBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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FJ SALMERON-NAVAS, E RIOS-SANCHEZ, M DOMINGUEZ-CANTERO, EM BARREIRO-FERNANDEZ.

Hospital Universitario Puerto Real

BACKGROUND AND IMPORTANCE

Loss of cell cycle regulation due to pathway alterations Cyclin D-CDK4/6-Rb is common in breast cancer. Palbociclib is a CDK4/6 inhibitor, indicated in metastatic breast cancer (mBC).

AIM AND OBJECTIVES

Safety profile

Patients with mBC positive hormone receptors in treatment with Palbociclib.

MATERIALS AND METHODS

- **Retrospective descriptive** study, from 01/07/2019 until 21/07/2020.
- Patients with **mBC** on treatment with **Palbociclib**.
- Variables recorded:

- Sex
- Age
- Menopause status
- Performance status (PS)
- Cancer stage
- Presence of visceral metastatic disease
- Number of cycles received
- Therapeutic scheme

• **Safety** →

- Number of adverse events (AE)
- Severity of AEs was graded on the basis of the "Common Terminology Criteria for Adverse Events" version 5.0.
- Number of patients and reason for delays and dose reduction

Nº Patients	Variable recorded	Results
44 patients	Sex	100% women
	Age	60 (47-81) years-old
	Menopause Status	71% postmenopausal
	Performance status (PS)	PS≤1 → 29 patients
	Cancer stage	metastatic disease → 100%
	Presence of visceral metastatic disease	76% patients
	Therapeutic scheme	Palbociclib 125mg every 3 weeks
	Number of cycles received	7 (1-17) cycles

RESULTS

Nº AEs (Nº patients)	Adverse Event Reports	Results
105 AEs (31)	HEMATOLOGIC	54
	METABOLIC	23
	DIGESTIVE	10
	ASTHENIA	7
	INFECTIONS	2
	OTHERS CAUSES	9

	Grade-1	Grade-2	Grade-3
EAs	Anemia, Anorexia Asthenia, Diarrhea, Dysgeusia, Increased Levels of GGT/AST/ALT/LDH, Mucositis, Nausea, Neutropenia, Itching, Palmar-Plantar Erythrodysesthesia Syndrome, Thrombopenia, Urticaria and Vomiting	Anemia, Anorexia, Asthenia, Headaches, GGT Increased, Infections, Mucositis, Nausea, Neutropenia and Vomiting	Asthenia, Neutropenia and GGT Increased
%	59%	30%	12%

- **Delayed:** 13 patients → Reason: Neutropenia (85%)
- **Reduced doses:** 6% of patients → Reason: Neutropenia and Mucositis.

CONCLUSION AND RELEVANCE

1. There was a high incidence of adverse reactions, the most frequent being grade 1.
2. The most common AE were hematologic, with neutropenia being the highest degree.
3. Our studies suggest a high percentage of delays and dose reduction.