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# **Experience Outside of Clinical Trial with Cyclin Inhibitors**



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#### Introduction

Luminal metastatic breast cancer has experienced a great advance thanks to the emergence of cyclin inhibitors, being a new line of treatment very well tolerated and that manages to prolong the overall survival in> 24 months based on the studies PALOMA-2, PALOMA-3 AND MONALEESA [1-3]. The aim of our study is to reflect the clinical characteristics of patients treated with cyclin inhibitor in the last months since its approval as well as the tolerance and toxicity profile.

#### **Material and Methods**

Retrospective study of 8 patients diagnosed in the University Hospital of Fuenlabrada in treatment with cyclin inhibitor in the last 4 months.

#### Results

50% of patients are <65 years old (3 premenopausal, on treatment with gnRH analog in 2/3 and 1/3 oophorectomy), with an ECOG 0-1 in 100%. 75% have expression of both estrogen and progesterone receptors, with 25% presenting only estrogenpositive receptors. 75% (6/8) was initially diagnosed as a locally advanced tumor and only 25% started as a metastatic disease. The disease-free interval was less than 2 years in 50% (4/8) of the patients. 25% present 3 or more metastatic locations, while the remaining 75% present between 1-2 locations. 25% have exclusive bone disease while 37.5% have visceral involvement. All patients except those with bone involvement have measurable disease. Regarding the treatments received, 25% had received fulvestrant and only one of them (12.5%) received chemotherapy for metastatic disease. 62.5% receive cyclins as the first line of metastatic disease while 25% receive it in the 5th line and the remaining 12.5% in the 3rd line. 50% receivec in combination with cyclins, while 37.5% combine it with letrozole, 12.5% with exemestane. 75% receive palbociclib while the other 25% ribociclib.

All patients currently continue to have cyclin inhibitors, except one (12.5%) that progresses to the pleural level at 3 months and is being treated with paclitaxel. The most frequently reported toxicity is in the form of neutropenia (grade 2 in 37.5%) that occurs in the first or second cycle and needs a delay of 1 week of treatment. Only in 1/8 (12.5%) dose adjustment to 100 mg daily of palbociclib is needed. No patient presented hepatic or cardiac toxicity

#### **Conclusions**

- a) The treatment with cyclin inhibitors is safe and with a manageable profile of side effects.
- b) The profile of patients being treated outside the clinical trial is both pre and postmenopausal (50%> 65 years, ECOG 0-1 and with several metastatic locations.
- c) The most frequent toxicity is in the form of grade 2 neutropenia that after a dose delay of one week is recovered and usually does not need dose reduction [1-3].

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