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# Experience Outside of Clinical Trial with Everolimus

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## Introduction

Luminal metastatic breast cancer has undergone a major breakthrough thanks to the emergence of mTOR inhibitors to the progression of aromatase inhibitors as shown by studies such as BELLE-2 and BOLERO-2 (1,2). The aim of our study is to reflect the clinical characteristics of patients treated with ever olimus in our Hospital as well as the toxicity derived from them.

## Material and Methods

Retrospective study of 5 patients diagnosed in the University Hospital of Fuenlabrada in treatment with ever olimus outside clinical trials during last 2 years.

## Results

100% of the patients are <65 years old (1 premenopausal, on treatment with gnRH analogue), with an ECOG 0-1 in 100%. 40% started as a metastatic disease. Disease-free interval was greater than 2 years in 100% of the patients.20% present 3 or more metastatic locations, while the remaining 80% present between 1-2 locations. 100% have visceral involvement. The indication of everolimus in the 5 patients was as much in 1st line as in 2nd, 3rd, 4th and 5th line. The patient who received everolimus in the first line was due to progression to aromatase inhibitor during the adjuvant setting. Regarding the treatments previously received, 60% were treated with fulvestrant, while also 60% had previously received chemotherapy for metastatic disease. 80% were on exemestane in combination with everolimus, while 20% combined it with letrozole. The starting dose of everolimus was 10 mg in all patients. The median time on everolimus was 7.5 months (2-14), presenting in 60% (3/5) toxicity, being 2/3 in the first 15 days and 1/3 in the following 15-30 days. A patient continues with everolimus at present. The most frequently reported toxicity is as mucositis in 60% (2/3 grade 3, 1/3 degree 2) that requires dose delay in all of them and dose reduction to 5 mg in 2/3. The second most frequent toxicity was pneumonitis (2/5 = 40% grade 1 and 2 respectively). All patients received mouthwash with dexamethasone prior to the onset of everolimus. As a hematological toxicity, only grade 1 plaquetopenia stands out in 20%. The maximum response was in the form of stability in 3/5 (60%), no partial or complete reduction, while progression was in 2/5 (40%) at the first re-evaluation test [1,2].

Treatment regimens that received the progression were hormonal therapy (fulvestrant) in 20% while the remaining 60% were on chemotherapy with nab paclitaxel, capecitabine or the combination of gemcitabine + vinorelbine. One patient (20%) continues with everolimus as we presented previously.

## Conclusion

a. The median time on everolimus was 7.5 months, requiring dose reduction to 5 mg in 60% of patients.

b. The most frequently reported toxicity is as mucositis and pneumonitis.

c. The profile of patients who are being treated outside the clinical trial are patients <65 years with ECOG 0-1 and several metastatic localizations (visceral involvement).

d. Chemotherapy is the treatment most used when progression.

## References

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