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# KETOCONAZOLE AND PERFORMANCE STATUS AS PREDICTIVE FACTORS OF RESPONSE TO ABIRATERONE IN METASTATIC PROSTATE CANCER IN REAL-LIFE CONDITIONS

Tovar-Pozo M, Escudero-Vilaplana V, Ribed A, Ortega-Navarro C, Herranz Alonso A, Sanjurjo Sáez M.

Servicio de Farmacia. Hospital General Universitario Gregorio Marañón. Instituto de Investigación Sanitaria Gregorio Marañón (IISGM). Madrid, España

## OBJECTIVES

Abiraterone is an oral antiandrogen therapy approved in September 2011 by the European Medicines Agency (EMA) for metastatic castration resistant prostate cancer (mCRPC) in men whose disease had progressed on a docetaxel-based chemotherapy, and was included in our Hospital's formulary in 2012.

**OBJECTIVE:** To assess the effectiveness of abiraterone in patients with mCRPC in our hospital in real-life conditions and to analyze previous ketoconazole therapy and patient performance status as prognosis factors of response to the treatment with abiraterone.

## METHODS

**Design:** retrospective observational study (January 2012-October 2014)

- **Inclusion criteria:** patients that had started treatment with abiraterone for mCRPC after chemotherapy
- **Exclusion criteria:** clinical trial patients



### VARIABLES

**Demographic:** date of birth  
**Clinical:** ECOG, progression date  
**Pharmacotherapeutic:** dosing, treatment duration, previous treatments for the mCRPC

### EFFECTIVENESS : Progression free survival (PFS)

- Median PFS (Kaplan-Meier plots)
- Subgroup analyses by:
  - previous ketoconazole therapy
  - performance status

## RESULTS

Table 1. Baseline population characteristics

BASELINE POPULATION (n=36)		
Mean age [range]	78 [65 - 87]	
ECOG PS n (%)	ECOG ≤1	30 (83.3)
	ECOG >1	6 (16.7)
Previous Ketoconazole therapy n (%)	13 (36.1)	
Median duration of treatment with abiraterona [range]	7.1 [3.0 -23.7]	

**EFFECTIVENESS VARIABLE :**  
Median PFS 7.5 months  
(CI 95% 5.14 – 9.85)



Table 2. Subgroup analyses of posible predictive response factors

	Patients without Previous Ketoconazole		Patients with Previous Ketoconazole		p
	PFS	(CI 95%)	PFS	(CI 95%)	
<b>KETOCONAZOL AS PREVIOUS THERAPY</b>	9.5	(5.7 – 11.4)	6.9	(4.3 – 9.8)	n.s.
	Patients with ECOG≤1		Patients with ECOG>1		p
	PFS	(CI 95%)	PFS	(CI 95%)	
<b>PERFORMANCE STATUS</b>	7.5	(5.4 – 9.5)	6.3	(2.5 – 10.1)	n.s.

## CONCLUSIONS

The effectiveness of abiraterone in the treatment of mCRPC under real-life conditions is consistent with the clinical trials. Patients without previous ketoconazole treatment and a good performance status had better progression free survival outcomes, although there was no result statistically significant.

