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EFECTIVIDAD DE KETOCONAZOL EN PACIENTES CON CANCER DE PROSTATA METASTASICO RESISTENTE A LA CASTRACION NO CANDIDATOS A QUIMIOTERAPIA

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Background

Ketoconazole (KT) has been extensively used in chemo-naive patients (mCRPC) with metastatic castration-resistant prostate cancer due to the absence of therapeutic alternatives.

Objective

To determine the effectiveness of KT in chemo-naive patients with mCRPC.

Materials and Methods

- **Retrospective observational study**
- **Inclusion criteria:** chemo-naive patients on therapy with ketoconazole during ≥ 3 months for mCPRPC between 06/2010-06/2014 in a tertiary hospital.
- **Exclusion criteria:** < 3 months on therapy, patients with insufficient information in their medical records.

Variables

- Age
- Baselline PSA
- % PSA decrease from baseline to nadir
- PSA-RR*$^{\gamma}$ at week 12
- bPFS**$^{\beta}$

*PSA response rate. **biochemical progression-free survival
$^{\gamma}$Defined as a ≥50% PSA decline from baseline maintained for ≥3 weeks efinida en base a las recomendaciones del Prostate Cancer Clinical Trials Working Group (PCWG2).
$^{\beta}$Defined as the time between ketoconazole initiation and PSA (or radiologic) progression according to PCWG2 criteria.

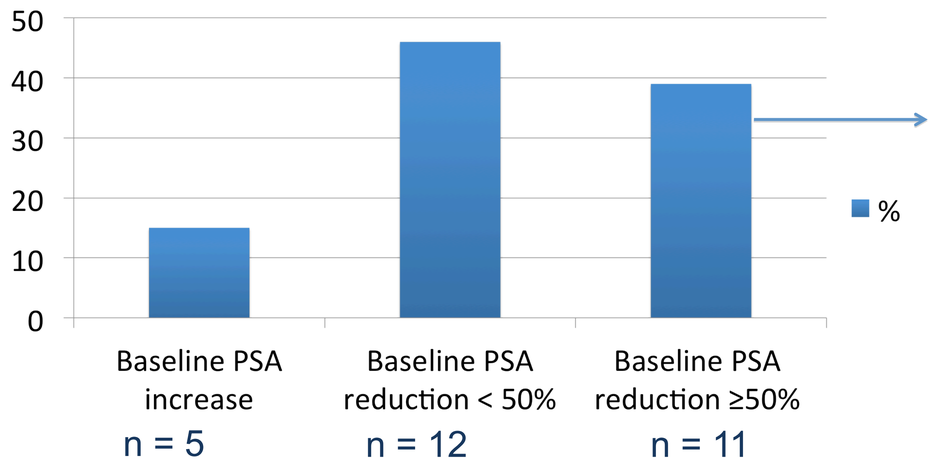
- **Statistical analysis:** Means ± standard deviation or the median and the 25th-75th percentiles summarize results. Kaplan-Meier analysis was performed to determine the bPFS. Data analysis was performed using IBM SPSS Version 20.0.

Results

Twenty-eight patients (76±11 years) were included. The median baseline PSA was 29[14-89] ng/ml.

PSA change aftter starting KT

The % PSA decrease from baseline to nadir was 54%±29.



The mean time to achieve this reduction was 13±15 weeks.

PSA-RR at week 12 was 31% (9 patients).

Median bPFS

Patients with a baseline PSA declined after starting KT (n=23): 87[IC95%: 35-139] weeks.
Patients with a ≥ 50% PSA decline at 12 weeks: median bPFS not reached at the time of data analysis.

Conclusions

- Approximately one third of patients treated with KT experienced rapid PSA declines close to those observed with abiraterone (37-42%).
- The PSA-RR, the significant bPFS, its low cost and the possibility of starting abiraterone after KT highlight KT as an alternative in chemo-naïve patients with mCRPC.