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SAFETY PROFILE OF APALUTAMIDE FOR THE TREATMENT OF PROSTATE CANCER IN CLINICAL PRACTICE

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Background and importance

Apalutamida is a second-generation androgen receptor inhibitor used for the treatment of prostate cancer (PC). Its safety was demonstrated in the phase 3 studies (ARN-509-003 and 56021927PCR3002).

Aim and objectives

Study of safety of apalutamide in a third level hospital

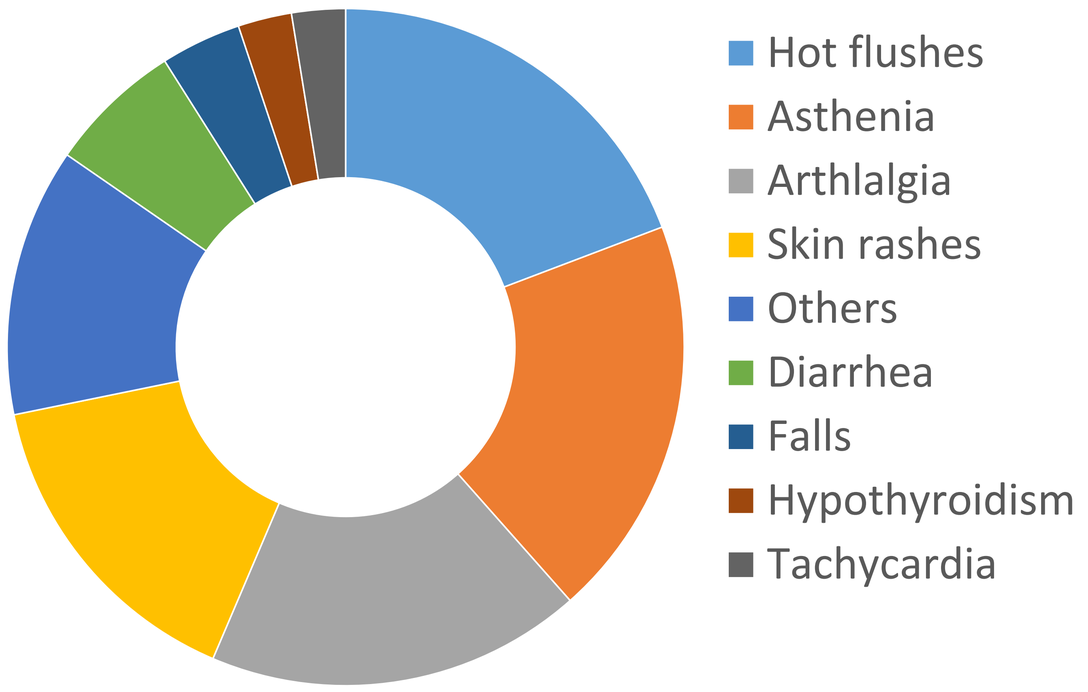
Material and methods

- ✓ Observational, retrospective, descriptive study
- ✓ January 2022 - December 2023
- ✓ The data was obtained from the electronic medical record and the pharmacotherapeutic record elaborated in the onco-haematological pharmaceutical care consultation.

- Age/Sex
- Quality of life (ECOG "Eastern cooperative oncology Group" scale)
- Baseline PSA (prostate-specific antigen)
- Metastasis type
- Adverse effects (AEs)
- Duration/discontinuation/suspension of treatment
- Reasons for discontinuation

Results

Median age 73 (IQR 69-82)
88% mHSPC (M1a 23%, M1b 47%, M1c 30%), 12% nmCRPC
Baseline ECOG 0-1 in 97%, ECOG 2 in 3%
Baseline median PSA 2.88 ng/mL (IQR 14.75-0.63)
Safety record: 94.1% reported any AEs



Discontinuation reasons:
- ✓ 29% lack of efficacy
- ✓ 20% safety reasons (60% falls, 28% tachycardia)

Median of treatment duration: 4.6 months (IQR 10.5-2)

Conclusion and relevance

Results showed a safety profile of apalutamide in accordance with the data obtained in the literature. Most patients reported treatment-related AEs. A high percentage of patients discontinued treatment for safety reasons, mostly related to falls or tachycardia.