SAFETY PROFILE OF ENZALUTAMIDE IN PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER: REAL LIFE DATA

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Background and Importance

Enzalutamide is a key treatment for **castration-resistant prostate cancer** (CRPC), but its real-world safety profile requires further evaluation. Evaluating its **adverse effects** in clinical practice helps optimize patient management.

Aim and Objectives

To describe the safety profile of enzalutamide in metastatic castration-resistant prostate cancer (mCRPC) patients..

Materials and Methods

Retrospective observational study of **mCRPC patients** in enzalutamide

JANUARY 2015 → DECEMBER 2023

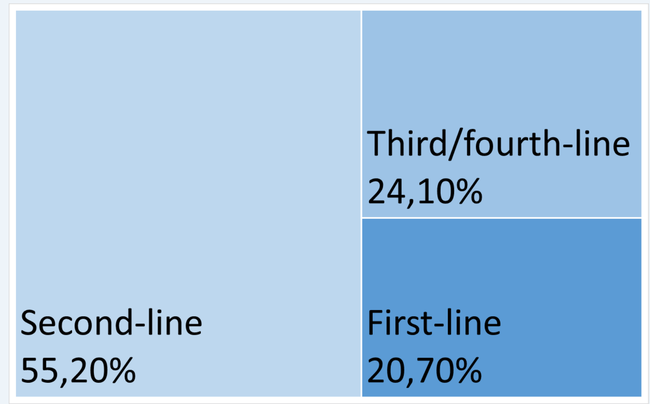
VARIABLES COLLECTED

- Age
- ECOG status
- PSA at the start of treatment
- Gleason score
- Metastasis location
- Treatment line
- Reason for discontinuation

Adverse reactions (ARs) and toxicity grades were classified by **CTCAE v5** and **grouped by system** according to MedDRA

Results

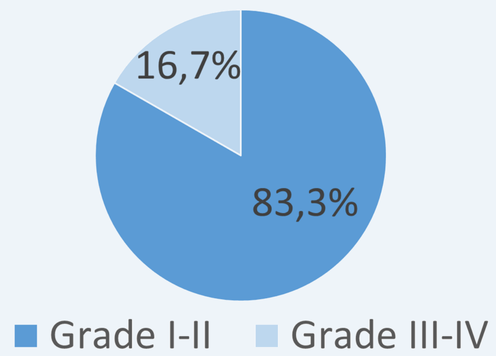
29 ♂ receiving 240 mg/day
Median age 76,9 years (IQR 67,5–84,9)
82,8% ECOG 0-1 vs 13,8% ECOG ≥ 2
Median baseline PSA 32,7 ng/mL (IQR 7,1–90,6)
Gleason ≤ 6 10,3%, =7 17,2%, ≥ 8 65,6%
Metastasis locations: 55,2% lymph nodes, 37,9% bones and 6,9% bones+visceral



DISCONTINUATION → 23 patient (79,3%) discontinued due to: progression (16, 69,6%); **toxicity** (5, 21,7%); general health deterioration unrelated to enzalutamide (2, 8,7%)

Persistent grade II nausea
Grade III seizures
Grade III hypersensibility reactions
Grade III focal seizures
Grade IV asthenia

25 (86,2%) patients experienced **ARs**



GRADE I-II		GRADE III-IV
3 cases hematologic and lymphatic system disorders (anemia) 2 cases nervous system disorders (headache, behavioral changes) 4 cases vascular disorders (hot flashes) 2 cases ocular disorders (visual acuity loss) 6 cases gastrointestinal disorders (nausea, constipation, anorexia, diarrhea)	2 cases renal and urinary disorders (fluid retention) 2 cases respiratory disorders (dyspnea) 4 cases skin disorders (cutaneous reactions) 2 cases musculoskeletal disorders (tremor, muscle pain) 9 cases general disorders (asthenia)	2 cases of asthenia 1 case of fluid retention 1 hypersensitivity reaction 1 case of anorexia 1 case of tremor 1 seizure 1 case of hypertension 1 case of focal seizures

Conclusion and Relevance

1. Enzalutamide was generally well tolerated, with most ARs being Grade I-II. Toxicity-related discontinuation was higher than in clinical trials but lower than in some real-world studies.
2. Visual acuity loss and tremor, not listed in the official drug label. Both events have been reported to FEDRA and EudraVigilance pharmacovigilance systems.

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