EFFICACY AND SAFETY OF DAROLUTAMIDE IN THE ROUTINE CLINICAL PRACTICE CONDITIONS

4CPS-223

L02- ENDOCRINE THERAPY

L. DOMINGUEZ SENIN[1], T. BLANCO-ESPESO[1], B. APARICIO-CASTELLANO[2], J. ESQUIVEL NEGRÍN[3], I. CORRIENTE GORDÓN[1], E. PARADELA GARCÍA[1].
[1]HOSPITAL JUAN RAMÓN JIMÉNEZ, HOSPITAL PHARMACY, HUELVA, SPAIN
[2]HOSPITAL UNIVERSITARIO REINA SOFIA, HOSPITAL PHARMACY, CORDOBA, SPAIN
[3] HOSPITAL UNIVERSITARIO NUESTRA SEÑORA DE CANDELARIA, HOSPITAL PHARMACY, SANTA CRUZ DE TENERIFE, SPAIN

BACKGROUND AND IMPORTANCE

Apalutamide, enzalutamide and darolutamide are oral treatments. They have been approved in combination with androgen deprivation therapy. The therapeutic efficacy and safety of darolutamide were established in two multicenter, randomized, placebo-controlled phase III studies in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) (ARAMIS) and metastatic hormone-sensitiveprostate cancer (mHSPC) (ARASENS). Darolutamide was commercialized in 2020.

AIM AND OBJECTIVES

To evaluate the therapeutic efficacy and safety of darolutamide in patients with mHSPC and nmCRPC in the routine clinical practice conditions.

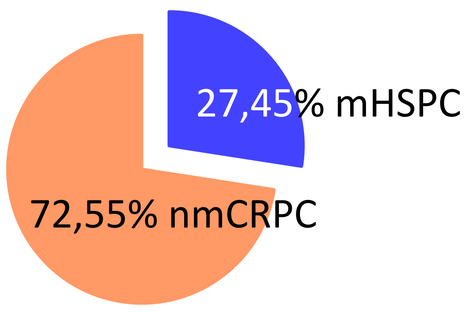
METHODS AND MATERIALS

Retrospective observational multicenter study. All patients with darolutamida and with at least 3 months of clinical follow-up in 3 public hospitals in Spain (Huelva, Córdoba and Santa Cruz de Tenerife) were included. Data on age, diagnosis, disease volume (high/low), median PSA before darolutamide, median time from diagnosis to initiation of darolutamide, PSA decline after 3 and 12 months of darolutamide, patients continuing on treatment at 12 months, and reason for treatment discontinuation (toxicity or death/progression) were collected from digital medical records. A comprehensive descriptive statistical analysis was performed.

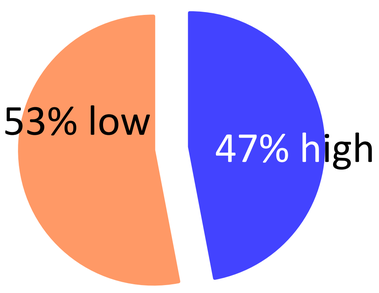
RESULTS

51 patients
Median age: 77 years (IQR=71-84)

INDICATIONS

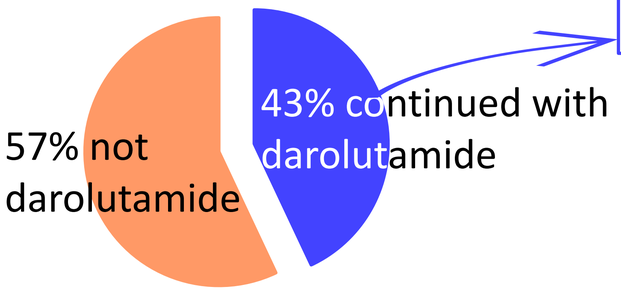


DISEASE VOLUME



After 3 months of treatment with darolutamide the reduction in baseline PSA was > 90% in 54,9% and > 50% in 82,4%.

After 12 months

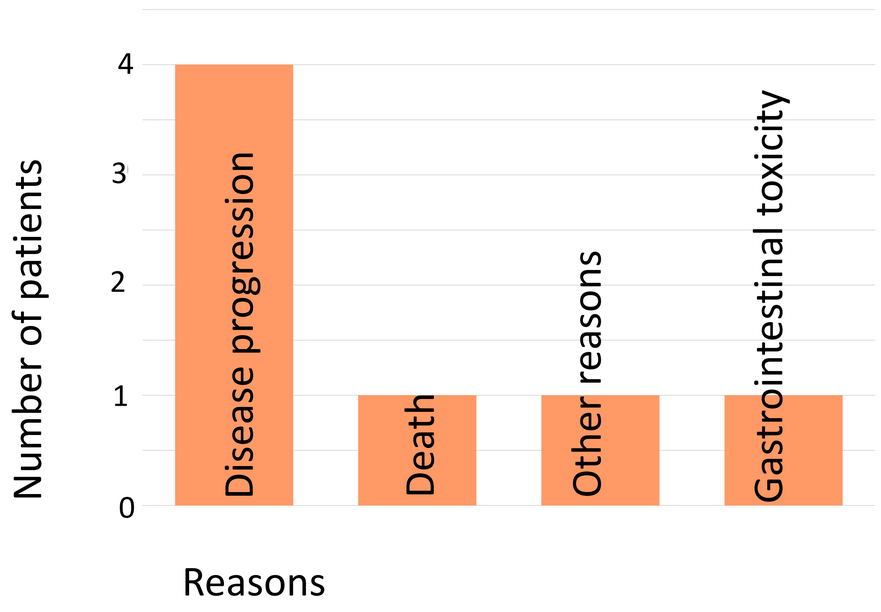


> 90% reduction in baseline PSA in 15 patients.

The median pre-treatment PSA was 4,2 (IQR= 1,5-13,3) ng/ml.

The median time from diagnosis was 3,45 (IQR= 1,5-31,6) months.

DISCONTINUED TREATMENT



CONCLUSIONS AND RELEVANCE

Darolutamide shows high efficacy, reduction of PSA >90% after 3 and 12 months of treatment, with an acceptable toxicity profile in routine clinical practice conditions. The inclusion of patients with and without metastases reinforces its therapeutic versatility and the possibility of integrating the drug into different stages of management.
This study provides real data from three Spanish public hospitals, providing local evidence on the efficacy and safety of darolutamide.