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Real-world ARASENS triplet therapy in high-volume mHSPC: a single-centre cohort

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1 BACKGROUND / OBJECTIVE

To describe feasibility, safety and early outcomes of androgen-deprivation therapy (ADT), darolutamide and docetaxel in patients with de novo high-volume/high-risk metastatic hormone-sensitive prostate cancer (mHSPC) treated at a single Spanish centre.

2 METHODS

- Retrospective single-centre cohort.
- ARASENS-like triplet (ADT + darolutamide + docetaxel), March 2024–March 2026.
- Primary endpoint: feasibility — 6 docetaxel cycles completed; darolutamide continued when appropriate.
- Secondary: PSA response, clinical improvement, grade ≥3 AEs, hospitalisation, CRPC progression, status at follow-up.

3 PATIENT CHARACTERISTICS

n = 16 patients

Median age	**66.5 years (range 50–75)**
ECOG PS 0/1/2	**5 / 9 / 2**
De novo high-volume/high-risk disease	**100%**
Visceral metastases	**6 patients (37.5%)**
Symptomatic at baseline	**14 (87.5%)**
Required opioids at baseline	**8 (50.0%)**
Cardiovascular comorbidity	**13 (81.3%)**
Median follow-up	**12.0 months (IQR 7.5–19.8)**

4 TREATMENT FEASIBILITY AND ACTIVITY

- 15/16 patients (93.8%) completed 6 docetaxel cycles
- 1 patient remained on treatment after 5 cycles
- Docetaxel delay or dose modification: 10 patients (62.5%)
- Darolutamide interrupted/discontinued: 7 patients (43.8%)
- Main reason for darolutamide interruption/discontinuation: progression (n = 6); 1 cardiovascular event

Early clinical improvement: **15/15 evaluable patients**

PSA50 response: **100%**

PSA90 response: **100%**

PSA <0.2 ng/mL: **8 patients (50.0%)**

5 SAFETY AND OUTCOMES

Grade ≥3 adverse events	Serious adverse events / treatment-related hospitalisation	Acute cardiovascular event	Progressed to CRPC at last follow-up	Deaths at last follow-up	Remained on darolutamide
4 (25.0%)	**3 (18.8%)**	**1 (6.3%)**	**7 (43.8%)**	**3 (18.8%)**	**8 (50.0%)**

6 CONCLUSIONS

In this real-world, comorbid cohort, ARASENS-like triplet therapy was feasible, with high docetaxel completion and deep PSA responses. However, dose modifications were frequent and early progression occurred in a clinically relevant subset, supporting close haematological and cardiovascular monitoring and longer follow-up.