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

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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.

Methods: We retrospectively reviewed patients treated with an ARASENS-like triplet between March 2024 and March 2026. The primary endpoint was treatment feasibility, defined by completion of six docetaxel cycles and continuation of darolutamide when clinically appropriate. Secondary endpoints included PSA response, early clinical improvement, grade ≥3 adverse events, treatment-related hospitalisation, progression to castration-resistant prostate cancer (CRPC) and status at last follow-up. Descriptive statistics were used.

Results: Sixteen patients were included. Median age was 66.5 years (range 50–75) and baseline ECOG PS was 0/1/2 in 5/9/2 patients, respectively. All had de novo high-volume/high-risk disease; 6 patients (37.5%) had visceral metastases, 14 (87.5%) were symptomatic and 8 (50.0%) required opioids at baseline. Cardiovascular comorbidity was present in 13 patients (81.3%). Median follow-up was 12.0 months (IQR 7.5–19.8). Fifteen patients (93.8%) completed six docetaxel cycles; one remained on treatment after five cycles. Docetaxel delay or dose modification was required in 10 patients (62.5%). Darolutamide was interrupted or discontinued in 7 patients (43.8%), mainly due to progression (n=6) and one cardiovascular event. Early clinical improvement occurred in all evaluable patients (15/15). PSA50 and PSA90 responses were achieved in all patients, while 8 (50.0%) reached PSA <0.2 ng/mL. Grade ≥3 events occurred in 4 patients (25.0%); serious adverse events and treatment-related hospitalisation occurred in 3 (18.8%). One patient (6.3%) developed an acute cardiovascular event. At last follow-up, 7 patients (43.8%) had progressed to CRPC, 3 (18.8%) had died and 8 (50.0%) remained on darolutamide.

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.