A descriptive analysis of treatment patterns and clinical outcomes in patients with metastatic Castration Sensitive Prostate Cancer (mCSPC) who initiated apalutamide or darolutamide in U.S. Community Urology Practices

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Background and methods

Retrospective descriptive analysis of treatment patterns and outcomes in patients with mCSPC treated with apalutamide or darolutamide

OBJECTIVE

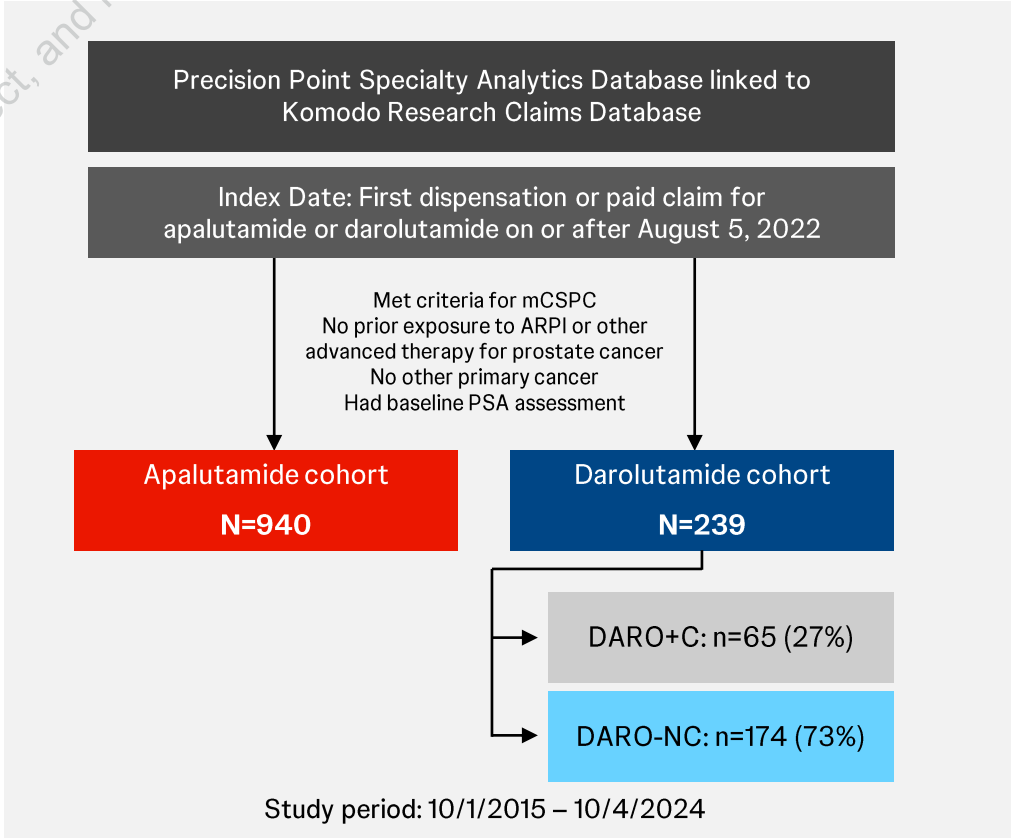
- To evaluate treatment patterns and outcomes among patients with mCSPC who initiated apalutamide or darolutamide (with or without concurrent chemotherapy)

BACKGROUND

- Apalutamide has been extensively evaluated in real-world practice, particularly on outcomes of early, deep PSA reduction (PSA90) and overall survival[1,2]
- Limited real-world evidence has been produced on darolutamide in combination with or without chemotherapy for the treatment of mCSPC

METHODS

- **Study design:** Retrospective, descriptive analysis of patients with mCSPC who initiated apalutamide or darolutamide
- **Data sources:** Linked clinical data from EMR (Precision Point Specialty Analytics) and healthcare claims databases (Komodo Research Claims Database)
- **Patient selection:** Patients with mCSPC and ≥12 months of pre-index claims and clinical activity
- **Patient stratification:** Patients initiating darolutamide were stratified by receipt (DARO+C) or absence (DARO-NC) of concurrent chemotherapy (i.e., receipt of chemotherapy within 6 weeks before or after the index date)
- **Statistical analyses:** Patients were followed from index date until the end of insurance or clinical activity, death, or end of data availability (October 4, 2024). Unweighted Kaplan-Meier analyses were used to assess time to PSA90 (90% reduction in PSA from baseline), and progression to CR



ARPI, androgen-receptor pathway inhibitor; C, chemotherapy; CR, castration resistance; DARO, darolutamide; EMR, electronic medical record; mCSPC, metastatic castration-sensitive prostate cancer; NC, no chemotherapy; PSA, prostate-specific antigen; PSA90, 90% reduction in PSA.

1. Bilen MA, et al. Poster presented at: 2024 European Congress of Oncology Pharmacy (ECOP); October 2–4, 2024; Lisbon, Portugal. 2. Lowentritt B, et al. Poster presented at: 2024 European Congress of Oncology Pharmacy (ECOP); October 2–4, 2024; Lisbon, Portugal.

Results: Baseline characteristics

Patient population

Across cohorts, the majority were White, had Medicare, and used concurrent ADT*

Select baseline characteristics

	APA n=940	DARO+C n=65	DARO-NC n=174
Median follow-up, months	9.9	11.6	9.0
Age in years, mean (SD)	74.1 (8.3)	67.9 (7.3)	72.4 (9.2)
Medicare insured, %	79.8	58.5	78.7
Quan-CCI score [excluding PC diagnosis], mean (SD)	5.1 (3.2)	6.5 (2.3)	5.4 (3.2)
Most recent Gleason score, %			
≤6	5.9	9.2	4.6
7	28.2	20.0	24.1
8	16.3	10.8	16.7
9	20.9	33.8	23.6
10	2.0	1.5	1.1
Unknown	26.8	24.6	29.9

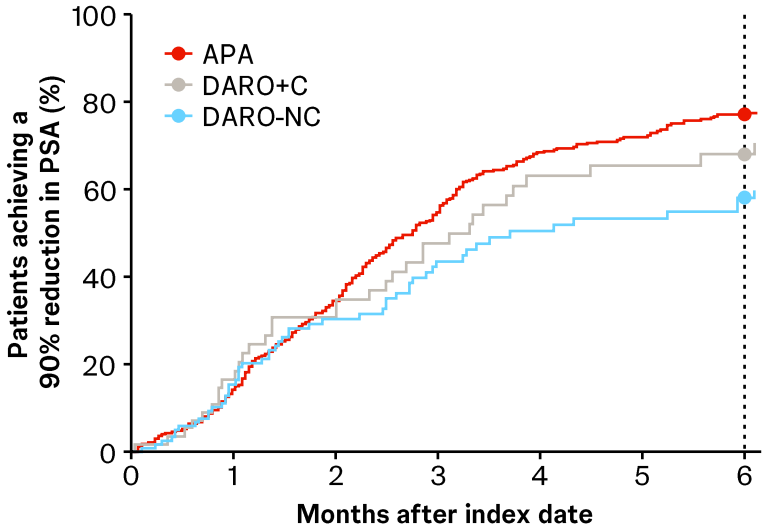
	APA n=940	DARO+C n=65	DARO-NC n=174
***De novo* mCSPC before ARPI, %**	30.7	55.4	39.7
Metastasis type, %			
Bone	64.9	52.3	62.1
Nodal	56.0	87.7	73.0
Visceral	5.2	13.8	12.1
Multiple sites	25.7	52.3	43.7
Concurrent use of ADT*, %	88.6	98.5	92.5
PSA levels in ng/mL, mean (SD)	21.9 (105.9)	94.0 (239.3)	60.5 (358.5)

*Concurrent ADT use is defined as use of ADT within 6 months before or after the index date.
ADT, androgen deprivation therapy; APA, apalutamide; ARPI, androgen-receptor pathway inhibitor; C, chemotherapy; CCI, Charlson Comorbidity Index; DARO, darolutamide; mCSPC, metastatic castration-sensitive prostate cancer; NC, no chemotherapy; PC, prostate cancer; PSA, prostate-specific antigen; PSA90, 90% reduction in PSA; SD, standard deviation.

Results: PSA90 and castration resistance

Proportion achieving PSA90*

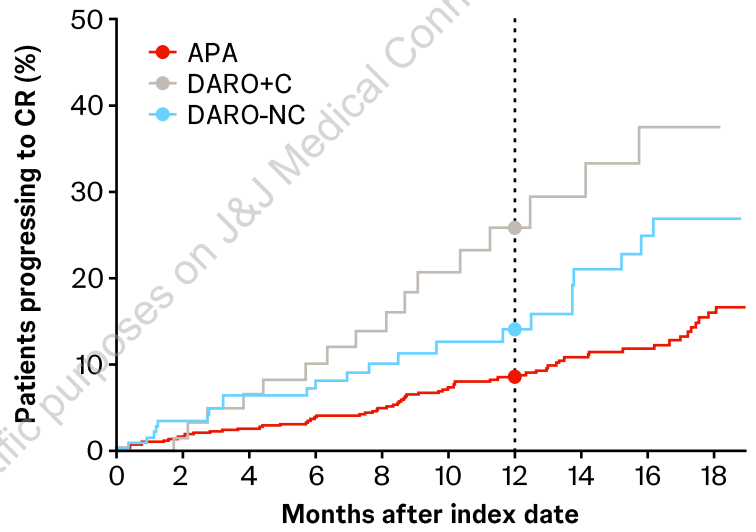
Among patients with baseline PSA >0.2ng/ml, **the proportions of patients achieving a PSA90** by 6 months were **77.1% (APA)**, **68.0% (DARO+C)**, and **58.2% (DARO-NC)**



PSA90*	6 months (95% CI)
APA	77.1% (72.2–81.0)
DARO+C	68.0% (51.2–79.1)
DARO-NC	58.2% (45.8–67.7)

Proportion progressing to CR†

By 1-year post-index, **the proportion of patients progressing to CR** was **8.6% (APA)**, **26.0% (DARO+C)**, and **14.2% (DARO-NC)**



Progression to CR†	12 months (95% CI)
APA	8.6% (6.3–10.8)
DARO+C	26.0% (12.4–37.5)
DARO-NC	14.2% (7.3–20.6)

*Among patients with baseline PSA >0.2ng/ml. Patients were censored at index ARPI treatment discontinuation (treatment gap >90 days), switching to the other index ARPI treatment, add-on of or switching to another advanced therapy for prostate cancer, progression to castration resistance, or initiation of chemotherapy (APA and DARO-NC cohorts only). †Patients were censored at switching to the other index ARPI treatment, or initiation of chemotherapy (APA and DARO-NC cohorts only).

APA, apalutamide; ARPI, androgen-receptor pathway inhibitor; C, chemotherapy; CI, confidence interval; CR, castration resistance; DARO, darolutamide; EMR, electronic medical record; mCSPC, metastatic castration-sensitive prostate cancer; NC, no chemotherapy; PSA, prostate-specific antigen; PSA90, 90% reduction in PSA from baseline.

LIMITATIONS

- No statistical comparisons and no adjustments for differences in patient baseline criteria were made

KEY TAKEAWAY

- In patients with mCSPC, concurrent chemotherapy use with darolutamide was observed in less than one-third of patients treated with darolutamide
- Descriptive differences in early PSA reduction and progression to castration resistance were observed in the apalutamide vs darolutamide (with or without chemotherapy) cohorts

CONCLUSION

- The rapid, deep 90% reduction in PSA observed with apalutamide was consistent with previous studies
- Further causal analyses are warranted to better assess differences in treatment effect