Rapid and deep prostate-specific antigen (PSA) response to apalutamide plus ADT correlates with improved survival in metastatic castration-sensitive prostate cancer (mCSPC) in real world practice in the US (OASIS Project)

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KEY TAKEAWAY

- Rapid and deep PSA responses with use of APA+ADT as a starting therapy for mCSPC was associated with significantly improved survival in real world practice.

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CONCLUSIONS

- To our knowledge, these real-world data are the first to confirm the favorable prognosis of PSA responses observed in prior prospective studies
- The speed and depth of the PSA response to treatment positively impacts survival in patients with mCSPC.
- The faster and deeper the response, the better the survival rate.

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INTRODUCTION

- Apalutamide (APA) in combination with androgen-deprivation therapy (ADT) is an effective life-prolonging treatment option for mCSPC. APA+ADT has been shown to induce early and deep PSA responses.[1]
- Early and deep reductions in PSA are response indicators in metastatic castration-resistant PC that have been associated with improved clinical outcomes after initiation androgen receptor signaling inhibitors (ARSIs).[2]
- We evaluated correlations between PSA and long-term clinical outcome in adults with mCSPC in real-world practice treated with upfront APA+ADT in real-world practice.

References:
1. Chowdhury et al. Deep, rapid, and durable prostate-specific antigen decline with apalutamide plus androgen deprivation therapy is associated with longer survival and improved clinical outcomes in TITAN patients with metastatic castration-sensitive prostate cancer. Ann Oncol. 2023;34(5):477-485.
2. Facchini et al. Very early PSA Response to abiraterone in mCRPC patients: A novel prognostic factor predicting overall survival. Front Pharmacol. 2016; 18;7:123

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METHODS

- This was a retrospective observational cohort study using ConcertAI.
- ConcertAI integrates data from electronic health records for >4 million patients from medical oncology clinics across the US. ConcertAI Patient 360 captures staging, PSA values, and castration resistance status.
- All patients ≥18 years with a diagnosis of mCSPC from 01 Jan 2018 until 30 Sept 2022 who initiated treatment with APA+ADT were included. Patients were followed up for at least 6 months, death, loss to follow-up, or March 31, 2023 for overall survival (OS).
- Correlations between time to 50% and 90% declines in PSA (PSA50 and PSA90), and time to undetectable PSA (≤0.2 ng/mL) and 24-month OS were evaluated. Adjusted Hazard ratios (aHRs) were estimated using multivariate Cox proportional hazard models adjusted for age, comorbidities, BMI, baseline PSA.

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RESULTS

- 183 patients with mCSPC who initiated APA+ADT treatment and had monthly PSA testing were included in the analysis;
- Mean age 73 years (SD 8); median baseline PSA 4.8 ng/mL (Q1-Q3 0.8, 20.7); mean duration of follow up 18 months (SD 10).
- A majority of patients (n=124, 68%) achieved a PSA reduction of at least 50% by 3 months after treatment initiation and 37% reached undetectable PSA.
- The median (range) time to undetectable PSA was 2.1 (1.1, 3.0) months in the ≤3-month group and 4.7 (3.0, 24.6) months in the >3-month group.

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Table 1: Baseline clinical features of patients with mCSPC treated with APA+ADT by post-treatment PSA level

	All patients N=183	Reached undetectable PSA		
		Within ≤3 months N=67	After 3 months N=49	Not reached N=67
Age, median (Q1, Q3)	73 (66, 9)	71 (64, 78)	75 (69, 79)	75 (66.5, 80)
CCI score, n (%)				
0-1	160 (57.4)	61 (79.0)	41 (83.7)	58 (86.6)
≥2	23 (12.6)	6 (9.0)	8 (16.3)	9 (13.4)
Baseline PSA ng/mL, median (Q1, Q3)	4.8 (0.8, 20.7)	0.7 (0.1, 2.3)	13.2 (2.5, 35.8)	10.4 (3.6, 36.2)
BMI, kg/m2, median (Q1, Q3)	27.6 (24.0, 31.2)	29.4 (24.8, 31.6)	28.2 (23.4, 29.5)	26.5 (24.5, 31.8)
Person-years of follow-up, mean (SD)	18 (10)	18 (11)	22 (10)	15 (8)

Undetectable PSA = ≤0.2 ng/mL).
BMI, body mass index; CCI, Charlson comorbidity index; SD, standard deviation; Q1, Q3, inter-quartile range.

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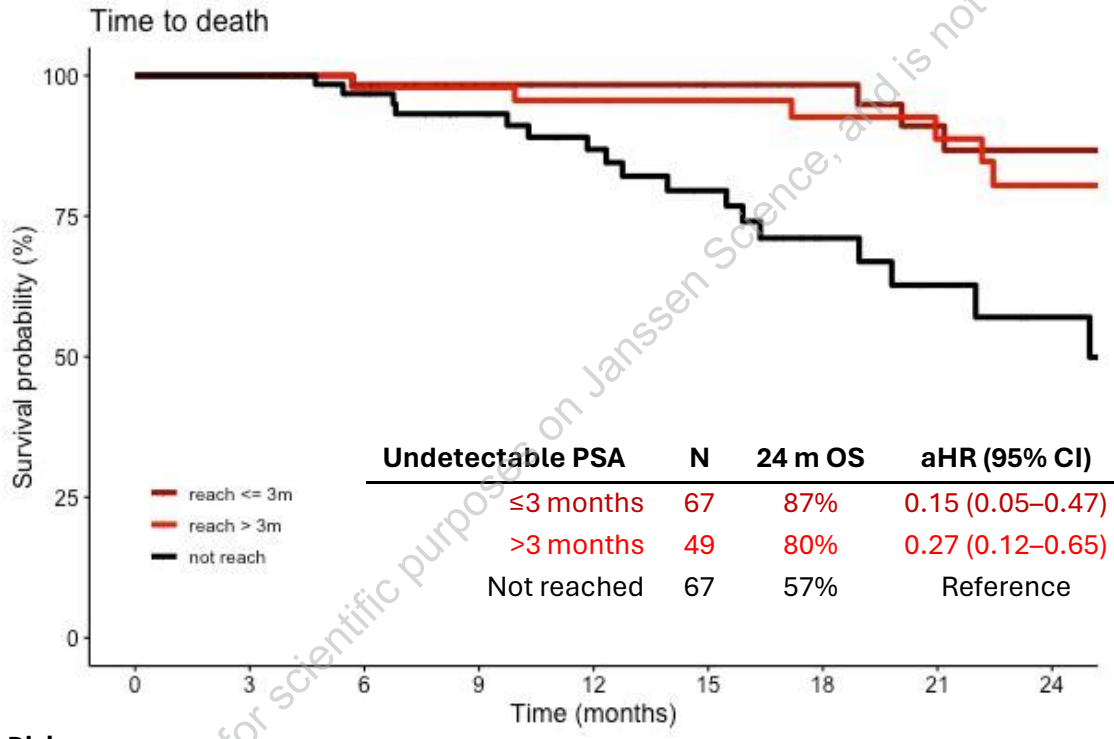
RESULTS

FIGURE 1: Overall survival by time to undetectable PSA (≤0.2 ng/ml)

- Overall survival was significantly longer in patients who achieved undetectable PSA within 3 months after initiating treatment with APA+ADT, compared to patients who did not achieve undetectable PSA (p<0.001).



Undetectable PSA	N	24 m OS	aHR (95% CI)	P-value
≤3 months	67	87%	0.15 (0.05–0.47)	<0.001
>3 months	49	80%	0.27 (0.12–0.65)	<0.01
Not reached	67	57%	Reference	

N at Risk									
≤ 3m	67	67	59	50	43	37	30	23	18
> 3m	49	49	47	45	40	35	30	24	16
not reach	67	67	59	49	41	31	17	12	8

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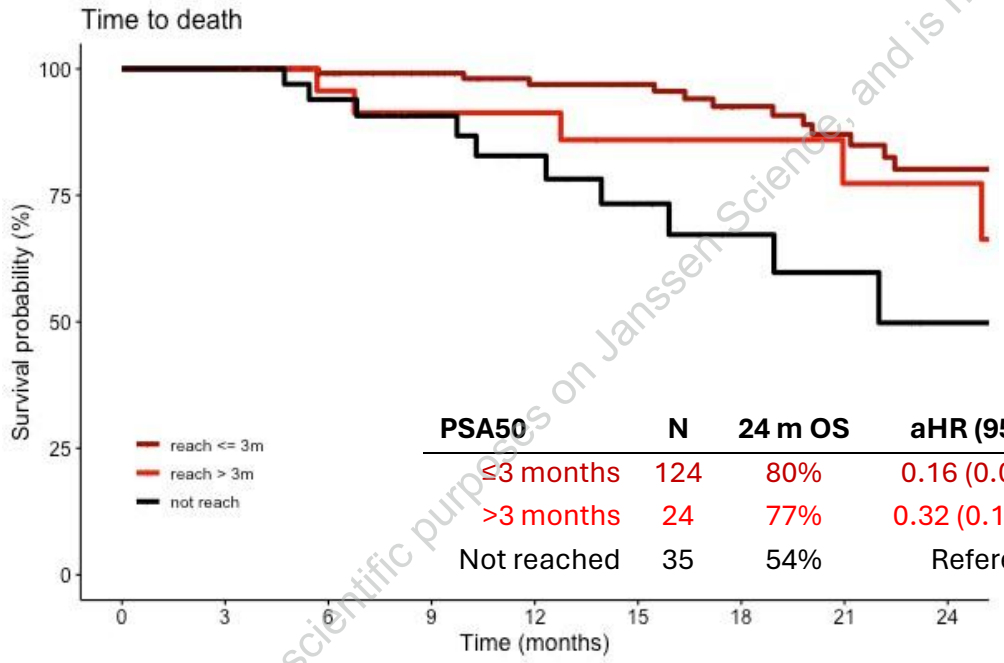
FIGURE 2: Overall survival by time to PSA50 response

- Overall survival was significantly longer in patients who achieved PSA50 within 3 months after initiating treatment with APA+ADT, compared to patients who did not reach PSA50 (p<0.0001).



PSA50	N	24 m OS	aHR (95% CI)	P-value
≤3 months	124	80%	0.16 (0.06–0.4)	<0.0001
>3 months	24	77%	0.32 (0.11–0.97)	<0.05
Not reached	35	54%	Reference	

N at Risk									
≤ 3m	124	124	110	99	86	73	53	41	31
> 3m	24	24	23	19	18	14	13	9	7
not reach	35	35	32	26	20	16	11	9	4

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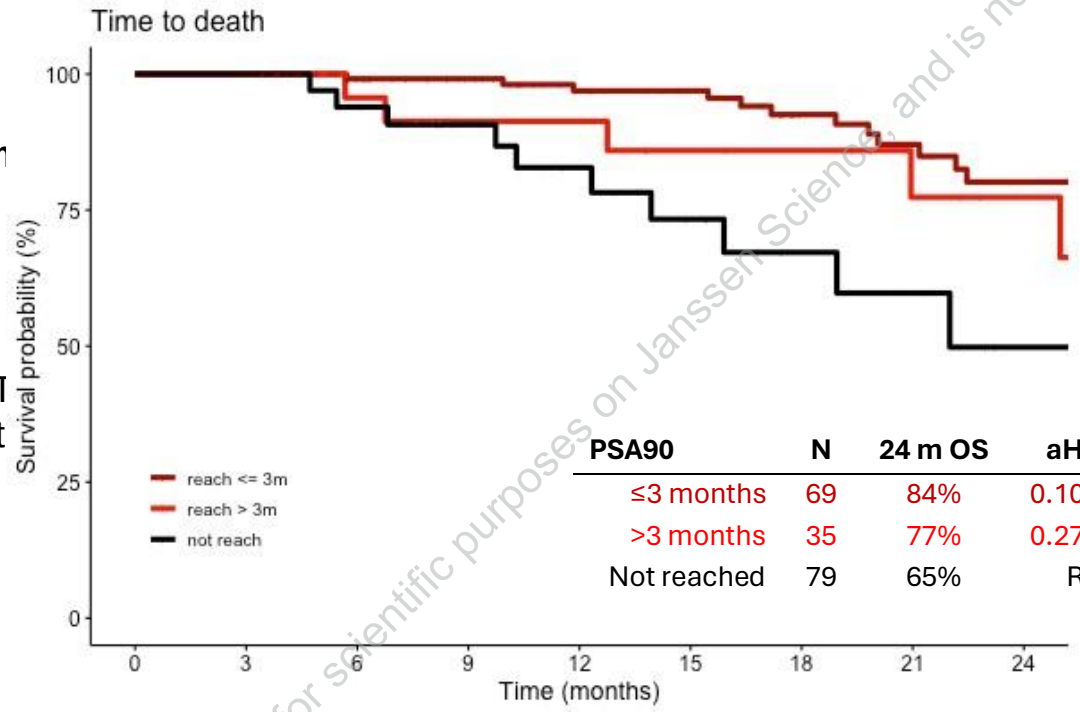
FIGURE 3: Overall survival by tim to PSA90 response

- Overall survival was significantly longer in patients who achieved PSA90 within 3 months after initiating treatment with APA+ADT compared to patients who did not reach PSA90 (p<0.0001).



PSA90	N	24 m OS	aHR (95% CI)	P-value
≤3 months	69	84%	0.10 (0.04–0.30)	<0.0001
>3 months	35	77%	0.27 (0.10–0.70)	<0.01
Not reached	79	65%	Reference	

N at Risk

≤ 3m	69	69	65	58	51	43	30	22	16
> 3m	35	35	33	30	27	23	20	16	11
not reach	79	79	67	56	46	37	27	21	15

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TABLE 2: 24-month survival by PSA response

PSA response	Within ≤3 months	After 3 months
Undetectable PSA	87%	80%
PSA90	84%	77%
PSA50	80%	77%

Survival is increased when PSA responses are faster (within 3 months);

Survival is increased when PSA responses are deeper (undetectable vs PSA50).

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DISCLOSURES:

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Yanfang Liu, Suneel Mundle, and Xiayi Wang are employees of Johnson & Johnson LLC. Yanfang Liu and Suneel Mundle hold stock/shares in Johnson & Johnson LLC.

Lawrence Karsh owns stock in Swan Valley Medical, has received honoraria from Astellas, Astra-Zeneca, Abbvie, Bayer, Dendreon, Janssen, Merck, Myovant, Pfizer, and Sanofi, has received financial compensation as a paid consultant/advisor to Astellas, Astra-Zeneca, Abbvie, Bayer, Bristol Myers Squibb, Bayer, Ferring, Dendreon, Janssen, Merck, Myovant, Pfizer, and Sanofi, and has received financial compensation to participate in speakers bureaus for Astellas, Astra-Zeneca, Bayer, Dendreon, Janssen, Merck, Myovant, and Pfizer.

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