ACONTECEU NO EAU 2024

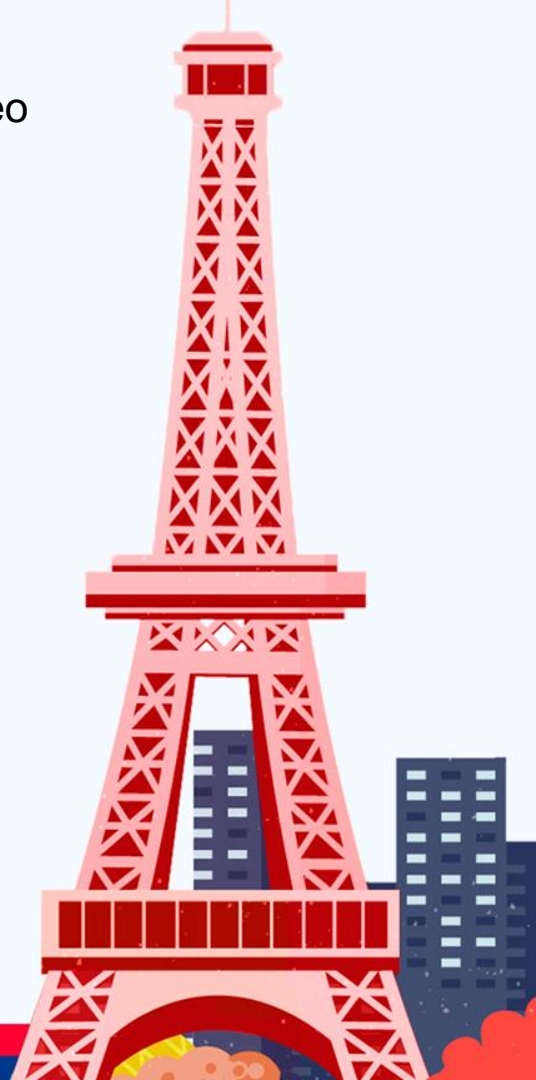
Apresentado por: Alexandre Pompeo

SOCIEDADE BRASILEIRA DE UROLOGIA

São Paulo

Apoio: Janssen Oncology

PHARMACEUTICAL COMPANIES OF Johnson&Johnson



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Survival Outcomes of APA as a Starting treatment: Impact in real-world patients with mCSPC (OASIS)

Benjamin L. Maughan[1], Yanfang Liu[2], Suneel Mundle[3], Mehregan Nematian-Samani[4], Xiayi Wang[5], Shawn Du[6], Lawrence Karsh[7] (larrykarsh@gmail.com)

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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 started treatment with any ARSI, docetaxel (DTX), or ADT alone were included. Treatment groups were defined hierarchically with priority given to patients who started treatment with APA+ADT, ENZ+ADT, AAP+ADT, DTX+ADT, and ADT alone.
- Patients were followed up for at least 6 months, death, loss to follow-up, or March 31, 2023 for overall survival (OS), time to castration resistance (TTCR), time to ≥50% decline (PSA50) and ≥90% decline (PSA90) in PSA from baseline, and time to undetectable PSA (≤0.2 ng/mL).
- Kaplan–Meier method was used to estimate OS, PSA reduction, and castration resistance rates.
- Adjusted hazard ratios (aHR) of risk of death was estimated using Inverse Probability of Treatment Weighted (IPTW) multivariate Cox proportional hazard models adjusted for age, comorbidities, BMI, and baseline PSA.

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Resultados

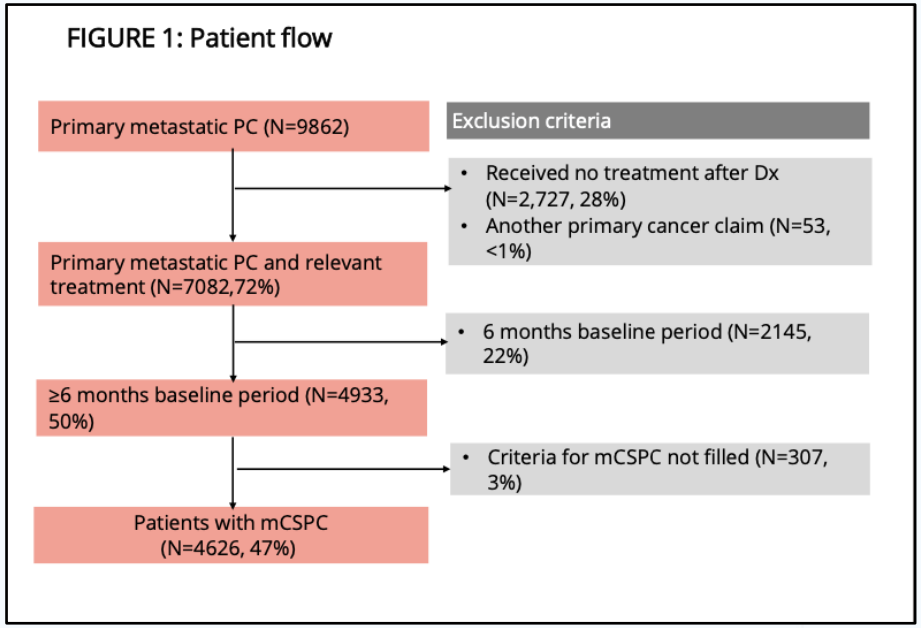

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Table 1. Baseline clinical features of patients with mCSPC

	APA+ADT N=165	ENZ+ADT N=643	AAP+ADT N=1064	DTX+ADT N=293	ADT alone N=543
Age, median (Q1, Q3)	74 (66, 80)	75 (68, 82)	73 (67, 81)	68 (63, 74)	74 (67, 82)
CCI, mean (SD)	0.57 (0.98)	0.69 (1.29)	0.71 (1.27)	0.66 (1.08)	0.77 (1.41)
Site of metastases, n (%)					
Bone	88 (84.6)	406 (84.8)	644 (84.6)	176 (76.9)	314 (80.1)
Visceral	11 (10.6)	32 (6.7)	62 (8.1)	23 (10.0)	36 (9.2)
Nodal	5 (4.8)	41 (8.6)	55 (7.2)	30 (13.1)	42 (10.7)
Unknown	61 (37.0)	164 (25.5)	303 (28.5)	64 (21.8)	151 (27.8)
Baseline PSA*, median (Q1, Q3) (ng/mL)	9.3 (1.7, 46.5)	14.5 (3.3, 66.8)	13.4 (2.5, 67.8)	26.9 (3.9, 128.0)	5.1 (0.5, 33.9)
Baseline Testosterone, Median (Q1, Q3) (ng/dL)	17.9 (10.0, 140.8)	15.0 (8.0, 32.0)	19.9 (8.0, 217.7)	19.9 (7.2, 272.0)	14.2 (7.0, 46.5)
Comorbidities, n (%)					
Cerebrovascular disease	6 (3.6)	25 (3.9)	45 (4.2)	8 (2.7)	36 (4.8)
COPD	7 (4.2)	31 (4.8)	78 (7.3)	19 (6.5)	38 (7.0)
Congestive heart failure	11 (6.7)	40 (6.2)	91 (8.6)	13 (4.4)	40 (7.4)
Diabetes	23 (13.9)	72 (11.2)	105 (9.9)	42 (14.3)	68 (12.5)
Peripheral vascular disease	7 (4.2)	32 (5.0)	64 (6.0)	22 (7.5)	38 (7.0)
Renal disease	8 (4.8)	52 (8.1)	74 (7.0)	18 (6.1)	51 (9.4)
Duration of the treatments (month), median (Q1, Q3)	11.5 (7.2, 20.4)	11.1 (4.9, 20.9)	13.3 (6.3, 23.0)	7.4 (4.0, 14.4)	10.1 (3.8, 19.2)

AAP, abiraterone acetate plus prednisone; ADT, androgen deprivation therapy; APA, apalutamide; CCI, Charlson Comorbidity Index; COPD, chronic obstructive pulmonary disease; DTX, docetaxel; ENZ, enzalutamide; SD, standard deviation; Q1, Q3, first and third quartiles.

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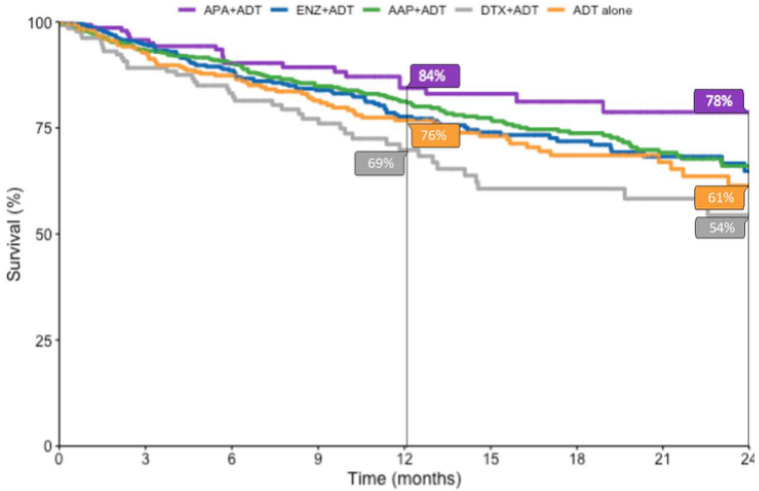
FIGURE 2: Overall survival using the Kaplan–Meier method

OS ($p<0.01$) was significantly longer in patients starting with APA+ADT compared with ADT alone.



N at Risk	0	3m	6m	9m	12m	15m	18m	21m	24m
APA+ADT	144	132	107	85	63	51	37	23	12
ENZ+ADT	394	342	283	225	169	120	93	56	35
AAP+ADT	555	490	429	351	270	206	153	102	70
DTX+ADT	131	113	93	69	50	39	32	20	12
ADT alone	308	252	198	150	113	86	65	41	27

AAP, abiraterone acetate plus prednisone
ADT, androgen deprivation therapy
APA, apalutamide
DTX, docetaxel
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FIGURE 3: Time to castration resistance using the Kaplan–Meier method

Time to castration resistance (p<0.001) was significantly longer in patients starting with APA+ADT compared with ADT alone.

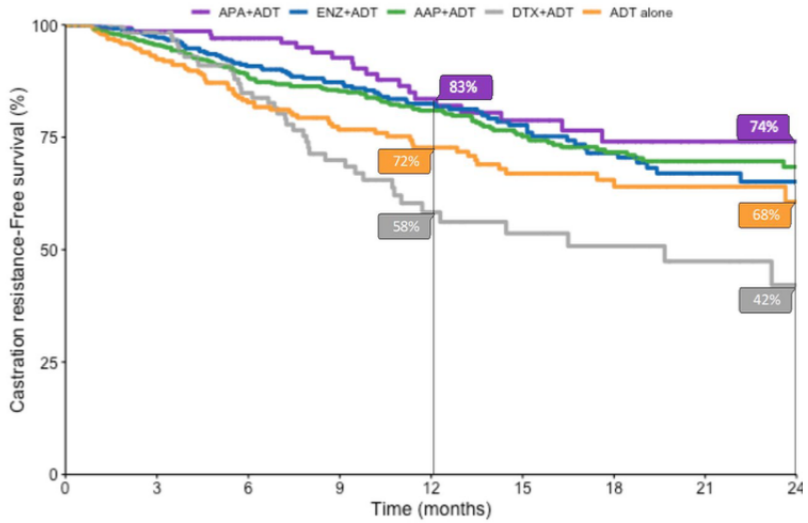

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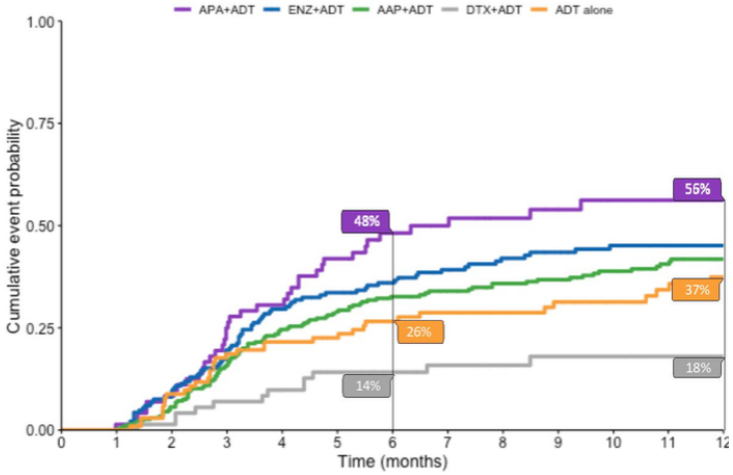
FIGURE 4: Time to undetectable PSA (≤0.2 ng/ml) using the Kaplan–Meier method

In patients with regular PSA assessment, a higher % starting with APA+ADT achieved undetectable PSA (p<0.0001) at 3 months compared with ADT alone.



N at risk	0	1m	2m	3m	4m	5m	6m	7m	8m	9m	10m	11m	12m
APA+ADT	72	71	66	54	49	40	31	27	23	21	17	17	15
ENZ+ADT	185	185	170	145	124	114	102	91	80	74	63	60	53
AAP+ADT	266	266	251	222	196	179	156	146	136	129	115	99	87
DTX+ADT	72	72	71	66	62	57	53	48	42	38	37	34	29
ADT alone	102	102	93	83	80	77	69	63	58	52	48	44	38

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Table 2. Multivariate Cox regression (IPTW method) of risk of death in patients with mCSPC by starting treatment

Comparison between Treatments	aHR	95%CI	P-value
APA+ADT vs ENZ+ADT	0.5	(0.28, 0.92)	< 0.05
APA+ADT vs AAP+ADT	0.51	(0.29, 0.9)	< 0.05
APA+ADT vs DTX+ADT	0.52	(0.16, 0.75)	< 0.01
APA+ADT vs ADT Alone	0.38	(0.21, 0.7)	< 0.01

Starting treatment with APA+ADT was associated with a statistically significantly lower risk of death compared with ENZ+ADT or AAP+ADT:

- 50% reduction in risk of death in comparison with ENZ+ADT ($p<0.05$)
- 49% compared with AAP+ADT ($p<0.05$).

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CONCLUSIONS

- 15% of patients were not treated with intensified therapies, despite their increased effectiveness as life prolonging therapies.
- Use of APA+ADT as starting treatment for mCSPC demonstrated significantly better clinical outcomes than other ARSIs or ADT alone in real-world clinical practice in the US.