Abstract ID#: 116851 A Systematic Literature Review of Randomized Controlled Trials Reporting Efficacy and Safety of Treatments in Patients with Advanced Prostate Cancer in Asian Countries Dedeepya Gutta, Ritu Shah, Manpreet Singh Kalsey, Raju Gautam, Mahendra Kumar Rai

Figure 2: Forest plots for Hazard ratio of a Progression-free survival & b. Overall survival

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Background

Several therapies are available for the treatment of advanced/metastatic prostate cancer (PC). However, the systematic assessment of evidence pertaining to the use of these therapies in Asian patients is lacking.

Objectives

The study aimed to conduct a systematic literature review (SLR) to evaluate the efficacy and safety of treatments available in advanced PC patients in Asian countries.

Methodology

A comprehensive SLR was performed in the PubMed database to identify relevant randomized controlled trials (RCTs) published in English from 2016 to 2021 as full papers. Additional citations were taken from gray literature. Outcomes of interest were progression-free survival (PFS), overall survival (OS), and safety.

Figure 1: PRISMA diagram for study selection



- Of the 1,277 publication records identified from the database, seven different RCTs were included (Fig. 1). Patients in these RCTs were enrolled from China, East Asia, Japan, Malaysia, Russia, South Korea, Taiwan, and Thailand
- All RCTs were placebo controlled. Included RCTs had patients with non-metastatic castration-resistant PC (nmCRPC; n=2), metastatic castration-sensitive PC (mCSPC; n=3), and mCRPC (n=2). The sample size in RCTs ranged from 51 to 313 and the total number of patients included is 824.
- In nmCRPC patients, darolutamide plus ADT provided a significant benefit in PFS with a hazard ratio (HR) of 0.13 (95% CI: 0.05-0.33), whereas apalutamide plus ADT provides a better survival, compared with placebo.
- In mCSPC patients, abiraterone acetate (AA) plus prednisone conferred benefits for both OS and PFS with HR of 0.61 (95% CI: 0.27-1.42) and 0.32 (95% CI: 0.167-0.620), respectively.
- In mCRPC patients, enzalutamide provided benefits in OS and PFS with HR of 0.63 (95% CI: 0.36-1.10) and 0.33 (95% CI: 0.19-0.56), respectively. (Fig. 2)
- Overall incidence rate of adverse events (AE) was above 60%; however, the incidence of grade >=3 was low. No new safety signals were observed in Asian patients. (Table 1)

<i>Fig. 2a</i> Study name	Disease status	Intervention	Haza	rd Ratio of Pro	gression	-free Surv	vival	Hazard ratio [95% CI]	Study name	Disease status	N	Treatment	t Safety data		
	0000	Development of a ADT			1			0.42 (0.05, 0.22)	ARAMIS	nmCRPC	62	Darolutamide + ADT	32	85 Any SAE	
ARAIVIIS	nmCRPC	Apolutamide + ADT						0.13 [0.05, 0.33]	ARAMIS	nmCRPC	33	Placebo + ADT	9 64	Any TEAE	
TITAN	mCSPC	Apalutamide +ADT	TITAN					0.35 [0.17, 1.73]	CDADTAN	nmCPDC	24	Analutamida I ADT	24		
ARCHES	mCSPC	ENZ + ADT	ARCHES					0.39 [0.13, 1.18]	SPARTAN	IIIICAPC	54	Apalutamide + ADT	24	94	
ATITUDE	mCSPC	AA + prednisone	LATITUDE		1.			0.32 [0.17, 0.62]	SPARTAN	nmCRPC	21	Placebo + ADT		86	
re 2017	mCRPC	AA + Prednisone	Ye 2017					0.42 [0.27, 0.65]	TITAN	mCSPC	28	Apalutamide +ADT	18	96	
PREVAIL	mCRPC	ENZ	PREVAIL	H -				0.33 [0.19, 0.56]	TITAN	mCSPC	23	Placebo + ADT	26	100	
			0	0.5	1	1.5	2	2.5	ARCHES	mCSPC	36	ENZ + ADT	31	89	
Fig. 2b									ARCHES	mCSPC	56	Placebo + ADT	16	91	
Study name	Disease status	Intervention		Hazard Rati	o of Ove	rall Surviv	val	Hazard ratio [95% CI]	LATITUDE	mCSPC	35	AA + prednisone		97	
ARAMIS	nmCRPC	Darolutamide + AD	T ARAMIS	⊢ ● 				0.72 [0.12, 4.31]	LATITUDE	mCSPC	35	Placebo		97	
SPARTAN	nmCRPC	Apalutamide + AD1	SPARTAN					0.36 [0.03, 4.03]	Ye 2017	mCRPC	157	AA + Prednisone	4 66		
TITAN	mCSPC	Apalutamide +ADT	TITAN	⊢●		-		0.84 [0.21, 3.36]	Ye 2017	mCRPC	156	Placebo + Prednisone	7 73		
ARCHES	mCSPC	ENZ + ADT	ARCHES	· • •				0.92 [0.15, 5.52]	PREVAIL	mCRPC	73	ENZ	32	95	
LATITUDE	mCSPC	AA + prednisone	LATITUDE	I				0.61 [0.27, 1.42]	PREVAIL	mCRPC	75	Placebo	13	83	
PREVAIL	mCRPC	ENZ	PREVAIL	H H				0.63 [0.36, 1.10]					بــــــــــــــــــــــــــــــــــــ	100	
				0 1	2 3	4	5	6					Percent of patients with AE	100	

AA, Abiraterone Acetate; ADT, androgen deprivation therapy; ADT, androgen-deprivation therapy; ENZ, Enzalutamide; NR/NYR, Not reported/Not yet reached; NE, Not estimable; nmCRPC, Non-metastatic castration-resistant prostate cancer; mCSPC, Metastatic castration-sensitive prostate cancer; mCRPC, Metastatic castration-resistant prostate cancer; TEAE, Treatment emergent adverse events; SAE, Serious adverse events

Conclusion

Among all the treatments, androgen receptor inhibitors showed significant benefit in OS and PFS in patients with mCRPC and nmCRPC, whereas abiraterone acetate plus prednisone showed better efficacy in mCSPC patients. This SLR provides evidence that could help physicians to make better treatment decisions in the management of PC.

Conflict of Interest

Results

Gutta D, Shah R, Kalsey MS, Gautam R, Rai MK are employees of EVERSANA India.

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Table 1: Safety results of seven RCTs

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