Poster #84

Real-World Analyses of Mortality Risk After Androgen Deprivation Therapy Initiation in Black vs White Prostate Cancer Patients

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BACKGROUND

- Two studies found significantly longer overall survival in Black vs White patients with metastatic castration-resistant prostate cancer (PCa): a 2019 meta-analysis of 9 phase III trials[1] and a 2020 registry study[2]
- Our real-world data study compared all-cause mortality risk for Black vs White PCa patients

OBJECTIVE

Compared to the prior studies, our study encompasses a broader scope and is not exclusive to men with castration-resistant PCa

METHODS

- Data were collected from the Decision Resources Group Real World Evidence repository, which links medical and prescription claims, and US Electronic Healthcare Records
- The analysis set included PCa patients who received ≥1 androgen deprivation therapy (ADT) injection between 1991-2020
- Cox regression was used to compare all-cause mortality rates between White and Black patients
- Multivariable regression model accounted for the following variables: baseline metastasis, BMI (<18.5 vs ≥18.5 kg/m^2), oncology vs urology setting, antagonist vs agonist, personal major adverse cardiovascular event (MACE) history, tobacco history, baseline PSA (>4 vs ≤4 ng/mL), race (White vs Black), statin use, increasing age per year, ethnicity (non-Hispanic vs Hispanic), increasing ADT exposure/yr, diabetes, hypertension, & family MACE history

RESULTS

- 44,439 patients were included for the all patient analyses. 34,762 patients were included in the Black vs White analyses: 5,817 and 28,945 were Black and White, respectively **(Table 1)**
- Overall, mortality risk was 2.6% and 17% at 1 and 4 years after ADT initiation, respectively **(Figure 1)**
- Mortality risk after ADT initiation was 1.6% and 2.6% at 1 year and 11.7% and 18.1% at 4 years for Black and White patients, respectively **(Figure 2)**

RESULTS (CONT.)

- Both unadjusted (HR=1.66, 95% CI 1.53-1.80, p<0.001) and adjusted (HR=1.24, 95% CI 1.01-1.52, p=0.04) mortality risks were higher for White vs Black patients **(Figure 2)**
- Mortality risk was higher for White vs Black patients (HR=1.67, 95% CI 1.51-1.84, p<0.001) and patients with BMI <18.5 vs BMI ≥18.5 (kg/m^2) (HR=2.91, 95% CI 2.23-3.80, p<0.001) **(Table 2)**

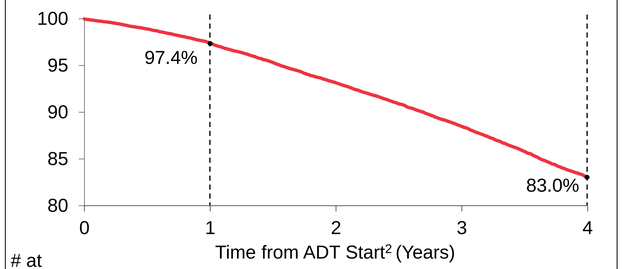
Table 1. DRG Demographics Table – All Patients[1], White, and Black

Categories		All Patients[1] N = 44,439	White N = 28,945	Black N = 5,817
Age	Mean (SD)	73.8 (8.3)	74.3 (8.0)	71.2 (8.6)
	Median (25-75%)	75.0 (68-81)	75.0 (69-81)	71.0 (65-78)
Race	White, %	65.1	100.0	0.0
	Black, %	13.1	0.0	100.0
	Asian, %	1.3	0.0	0.0
	Other, %	2.3	0.0	0.0
	Unknown, %	18.2	0.0	0.0
Personal History	MACE, %	5.5	5.9	4.5

1 Includes all patients regardless of race

Figure 1. KM of Mortality[1] Since ADT Start[2]: All Patients (n=44,439)

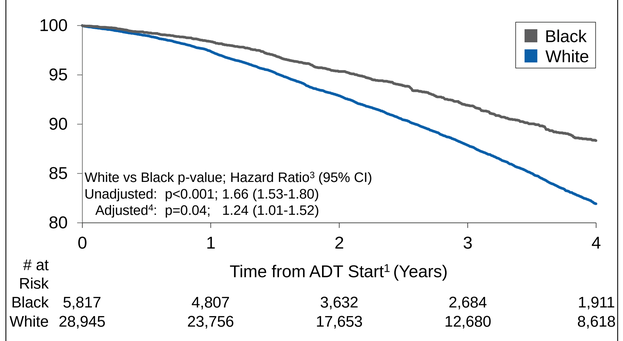
Event-Free (Survival) Probability



1 Mortality from all causes
2 Date of earliest LHRH injection recorded for patient

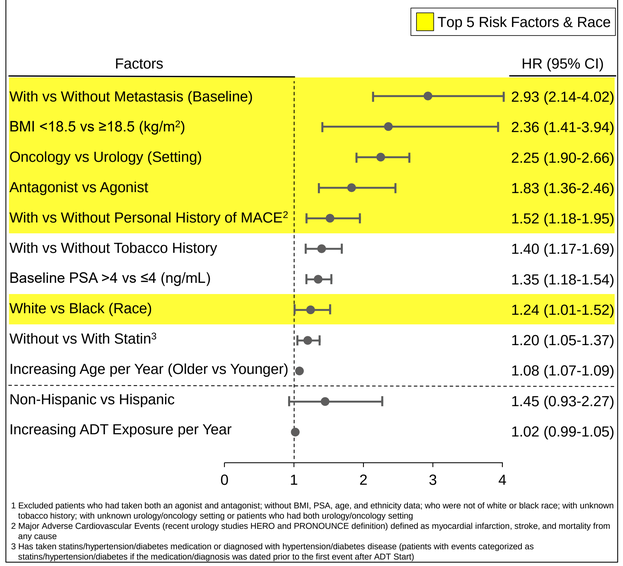
Figure 2. KM for Mortality 4-Years Since ADT Start[1] by Race (n=34,762[2])

Event-Free (Survival) Probability



1 Date of earliest LHRH injection recorded for patient
2 Excluded patients with no race data
3 Hazard ratio is calculated with cox regression analysis of all time data (~10 years)
4 Multivariate cox regression; factors considered include oncology vs urology setting, with vs without baseline metastasis, personal MACE history, BMI (<18.5 vs ≥18.5 kg/m^2), antagonist vs agonist, race (white vs black), baseline PSA (>4 vs ≤4 ng/mL), without vs with statin, increasing age per year, ethnicity (non-hispanic vs hispanic), family MACE history, history of hypertension, history of tobacco use, history of diabetes, and increasing ADT exposure per year (univariate significant factors only)

Figure 3. Hazard Ratio (95% CI) and P-Value of All-Cause Mortality for Factors in Multivariate Analysis (N=6,882[1])



1 Excluded patients who had taken both an agonist and antagonist; without BMI, PSA, age, and ethnicity data; who were not of white or black race; with unknown tobacco history; with unknown urology/oncology setting or patients who had both urology/oncology setting
2 Major Adverse Cardiovascular Events (recent urology studies HERO and PRONOUNCE definition) defined as myocardial infarction, stroke, and mortality from any cause
3 Has taken statins/hypertension/diabetes medication or diagnosed with hypertension/diabetes disease (patients with events categorized as statins/hypertension/diabetes if the medication/diagnosis was dated prior to the first event after ADT Start)

Table 2. Hazard Ratio (95% CI) and P-Value of All-Cause Mortality for Factors in Univariate and Bivariate Analysis

Factors	Univariate			Bivariate (N=28,231[1,2])	
	N	HR (95% CI)	P-Value	HR (95% CI)	P-Value
BMI <18.5 vs ≥18.5 (kg/m^2)	35,918[1]	2.56 (2.03-3.24)	<0.001	2.91 (2.23-3.80)	<0.001
White vs Black (Race)	34,762[2]	1.66 (1.53-1.80)	<0.001	1.67 (1.51-1.84)	<0.001

1 Excluded patients without BMI
2 Excluded patients who were not of white or black race

CONCLUSIONS

- All-cause mortality incidence was higher in White vs Black patients
- BMI and race are largely independent and do not account for the other factor's increased mortality risk
- Adding to the body of evidence, our research also reveals that Black race is associated with a protective effect on survival for all-cause mortality in men undergoing ADT

IMPLICATIONS

- Potential hypotheses for higher mortality in White vs Black patients include survival bias to MACE (i.e., Black patients may have died from PCa before having MACE) and survival bias to be diagnosed with PCa (i.e., Black patients may have higher rate of CV death and kidney failure prior to PCa diagnosis)
- The large size (~45,000 patients from a database with >300 million patients), long follow-up (10 years for some patients), recent clinical experience (99% from 2010-2020), and diversity of the dataset give weight to the results being an accurate representation of current clinical experience
- Future studies should confirm our findings that White PCa patients have higher mortality risk and investigate the above hypotheses

References:
1 Halabi S. et al., *J Clin Oncol*. 2019.
2 Sartor O. et al., *Prostate Cancer Prostatic Dis*. 2020.

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