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Pathological and Biochemical Outcomes among African-American and Caucasian Men with Low Risk Prostate Cancer in the SEARCH Database: Implications for Active Surveillance Candidacy

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Abstract

Purpose—Racial disparities in the incidence and risk profile of prostate cancer at diagnosis among African-American men are well reported. However, it remains unclear whether African-American race is independently associated with adverse outcomes in men with clinical low risk disease.

Materials and Methods—We retrospectively analyzed the records of 895 men in the SEARCH (Shared Equal Access Regional Cancer Hospital) database in whom clinical low risk prostate cancer was treated with radical prostatectomy. Associations of African-American and Caucasian race with pathological biochemical recurrence outcomes were examined using chi-square, logistic regression, log rank and Cox proportional hazards analyses.

Results—We identified 355 African-American and 540 Caucasian men with low risk tumors in the SEARCH cohort who were followed a median of 6.3 years. Following adjustment for relevant covariates African-American race was not significantly associated with pathological upgrading (OR 1.33, $p = 0.12$), major upgrading (OR 0.58, $p = 0.10$), up-staging (OR 1.09, $p = 0.73$) or positive surgical margins (OR 1.04, $p = 0.81$). Five-year recurrence-free survival rates were 73.4% in African-American men and 78.4% in Caucasian men (log rank $p = 0.18$). In a Cox proportional

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hazards analysis model African-American race was not significantly associated with biochemical recurrence (HR 1.11, $p = 0.52$).

Conclusions—In a cohort of patients at clinical low risk who were treated with prostatectomy in an equal access health system with a high representation of African-American men we observed no significant differences in the rates of pathological upgrading, up-staging or biochemical recurrence. These data support continued use of active surveillance in African-American men. Upgrading and up-staging remain concerning possibilities for all men regardless of race.

Keywords

prostatic neoplasms; African Americans; watchful waiting; neoplasm staging; neoplasm grading

The suitability of active surveillance for AA men with otherwise clinically favorable PCa at presentation has been questioned on the presumption of more aggressive disease. This assertion has been difficult to validate, given the marked underrepresentation of AA men in the landmark cohorts that have established the viability of surveillance in the low risk state.^{1,2} Indeed, AA men bear a comparatively greater PCa burden relative to that of other major American demographic groups, including increased PCa rates, higher proportions of high grade and advanced stage disease at presentation, and a greater risk of cancer specific mortality.^{3–5} However, it is unclear whether these disparities persist following adjustment for disease characteristics, therapeutic selection, socioeconomic status and access to care because conflicting studies addressing this issue exist.^{6,7}

Most studies that directly addressed outcomes in AA patients during active surveillance indicate higher rates of disease reclassification and treatment compared with Caucasian men, although they are limited by the smaller sample sizes and the relative underrepresentation of AA patients in these cohorts.^{8–11} In the absence of larger studies the concordance between clinical grade and stage with pathological parameters at radical prostatectomy has been offered as a proxy for evaluating candidacy for active surveillance in men with low risk disease. Several studies with disproportionately low participation rates of AA men relative to the American population have shown contrasting results. Single institution and cross-sectional data from NCDB (National Cancer Data Base) have shown higher rates of upgrading and up-staging while others, including a multi-institutional study from CaPSURETM, showed no significant differences by race.^{12–15}

In this context we evaluate rates of pathological upgrading, up-staging and recurrence-free survival among a racially diverse cohort of men at clinically low risk undergoing surgical treatment for PCa in the United States Veterans Affairs system, an equal access health system with a high representation of AA men.

MATERIALS AND METHODS

Under institutional review board supervision data on men who underwent radical prostatectomy between 1989 and 2011 at 6 United States Department of Veterans Affairs medical centers, including West Los Angeles, San Diego and Palo Alto, California; Durham and Asheville, North Carolina; and Augusta, Georgia, were combined into the SEARCH

database. Data collected in SEARCH included sociodemographic parameters, clinical tumor characteristics, surgical pathology, followup PSA and disease recurrence. Details regarding SEARCH methodology have been reported previously.^{16,17}

The primary study objective was to examine the effect of AA vs Caucasian race in the development of any adverse pathological characteristics in men with clinical low risk PCa treated with prostatectomy. We identified patients at low risk, defined as Gleason pattern 3 + 3 or less on diagnostic biopsy, PSA 10 ng/ml or less and clinical stage T2a or less. Men of other races, including missing or undefined responses, were excluded from analysis since Asian, Latino or Pacific Islander status represented a small proportion of the cohort (46 patients). Clinical and demographic characteristics were compared across AA and Caucasian strata using frequency tables; the Kruskal-Wallis, Wilcoxon and Mann-Whitney rank sum tests; the chi-square test; and the t-test as appropriate. We further described postoperative risk status using the CAPRA-S postoperative score based on pretreatment PSA and pathological characteristics.¹⁸

We examined several definitions of adverse pathology findings, including any Gleason upgrade (3 + 4 or greater), major Gleason upgrade (4 + 3 or greater), upstaging (pT3a or greater, or N1) or positive surgical margins. These end points were selected based on an association with adverse longitudinal oncologic outcomes. They are often regarded as surrogates, although intermediate ones, for active surveillance candidacy.

We constructed multivariable logistic regression models to examine the impact of race adjusted for other relevant clinical and pathological characteristics, including age, PSA, clinical stage (T2 vs T1), percent of cores positive for cancer, treatment year, body mass index in kg/m² and treatment center. Covariates included in the analysis of positive margin status included prostate weight and surgical technique (open retropubic, perineal, laparoscopic or robot-assisted). We tested for interaction terms between covariates that may have modified the response variables in the multivariable logistic regression models. Two-sided $p < 0.05$ was regarded as significant. All statistical analysis was performed using STATA®, version 13.

Subanalyses were done using more restrictive definitions of active surveillance candidacy, including JHU and UCSF criteria.^{19,20} JHU criteria included Gleason grade 3 + 3 or less, PSA density 0.15 ng/ml/ml or less, clinical stage T1c or less, 2 or fewer cores positive and no single core involvement of cancer 50% or greater.¹⁹ UCSF criteria included Gleason 3 + 3 or less, clinical stage T2c or less, 33% or fewer cores positive and no single core involvement of cancer 50% or greater.²⁰ PSA density was calculated using pathological specimen weight for the 853 men (95.3%) without available volume calculations at biopsy. This was performed because we previously found a strong correlation between preoperative ultrasound measured volume and pathological prostate weight in SEARCH.²¹ Core specific data, including the maximum percent of tissue involved with tumor, were lacking for individual treatment centers (as low as 25.3%) and yet were relatively complete for other centers (highest 92.3%). Complete clinical and pathological data allowing for the calculation of strict active surveillance definitions were available on 532 men (59.4%) for JHU criteria and on 544 (60.8%) for UCSF criteria.

Recurrence was defined as a single postoperative PSA value greater than 0.2 ng/ml, 2 values of 0.2 ng/ml each (BCR) or the receipt of any salvage PCa therapy administered for increased PSA. Time to recurrence was compared between the AA and Caucasian groups using Kaplan-Meier plots and the log rank test. We examined the role of AA vs Caucasian race using the Cox proportional hazards method adjusted for significant clinical and pathological characteristics, including age, pathological Gleason score, preoperative PSA, margin status, presence or absence of seminal vesicle invasion, extracapsular extension, treatment year, treatment center and body mass index. Patients who received adjuvant radiation for undetectable postoperative PSA were censored at that time as not having recurrence.

RESULTS

Clinical and Demographic Characteristics

We identified 895 men with clinical low risk tumors who were treated with surgery, including 355 AA (39.7%) and 540 Caucasian men (60.3%) in a cohort of 3,492 patients. Among all patients median PSA was 5.2 ng/ml (IQR 4.2–6.9) and mean age was 61.0 years. Compared with Caucasian men AA men were younger at diagnosis (mean age 59.5 vs 62.0 years, $p < 0.01$) and had significantly higher PSA (median 5.5 vs 5.1 ng/ml, $p < 0.01$) and PSA density (median 0.134 vs 0.126 ng/ml/ml, $p = 0.02$). A higher proportion of AA than Caucasian men had clinical stage T1c disease at diagnosis (78.3% vs 69.3%, $p < 0.01$). A total of 344 men met strict UCSF active surveillance criteria, as did 204 by JHU criteria, representing 63% and 38% of patients, respectively, with clinical data sufficient for calculation. Table 1 lists complete clinical and demographic characteristics.

Pathological Findings

At radical prostatectomy Gleason score was concordant with biopsy (3 + 3) in 523 men (58.4%). A higher proportion of AA men experienced any upgrade from diagnostic biopsy (3 + 4 or greater) compared with Caucasian men (46.8% vs 38.2%, $p = 0.01$). However, unadjusted rates of major upgrading (4 + 3 or greater) were significantly higher in Caucasian than in AA patients (11.9% vs 7.3%, $p = 0.03$). Positive surgical margins were found in 41.5% of AA men compared with 35.2% of Caucasians ($p = 0.06$). No significant differences were observed between AA and Caucasian men in pathological up-staging, seminal vesicle invasion or extracapsular extension. One Caucasian patient had positive lymph nodes at surgery while node status was not assessed in 58% of patients. Postoperative CAPRA-S scores were similar in the 2 groups. Table 1 lists complete pathological outcomes.

On multivariable logistic regression analysis adjusted for clinical and pathological characteristics AA race was not significantly associated with pathological upgrading to 3 + 4 or greater (OR 1.33 95% CI 0.92–1.93, $p = 0.12$), major upgrading (OR 0.58, 95% CI 0.31–1.10, $p = 0.10$), up-staging (OR 1.09, 95% CI 0.65–1.83, $p = 0.73$) or positive surgical margins (OR 1.04, 95% CI 0.73–1.49, $p = 0.81$, supplementary table 1, <http://jurology.com/>). On separate subset analyses of men who met JHU and UCSF strict active surveillance criteria ($p = 0.50$ and 0.75 , respectively) AA status was not significantly associated with pathological upgrading to 3 + 4 or greater. Moreover, there was no

significant association between AA or Caucasian race with major pathological upgrading, up-staging or surgical margin status in these subsets (supplementary table 2, <http://jurology.com/>).

Recurrence-Free Survival

Among patients who did not experience BCR median followup was 6.3 years (IQR 3.8–8.9). Median followup was shorter in AA than in Caucasian patients (5.7 years, IQR 3.2–8.6 vs 6.6, IQR 4.2–9.2, $p = 0.03$). A total of 209 men experienced BCR, including 89 AA (22.3%) and 120 Caucasian men (25.2%) ($p = 0.32$). Five-year freedom from BCR rates were 73.4% and 78.4% for AA and Caucasian men, respectively (log rank $p = 0.18$, see figure). After adjustment for clinical and pathological characteristics AA race was not significantly associated with time to BCR (HR 1.11, 95% CI 0.81–1.50, $p = 0.52$, table 2). On multivariable Cox proportional hazards analysis there was no association between race and time to BCR upon further restricting analysis to men meeting JHU ($p = 0.95$) or UCSF ($p = 0.56$) active surveillance criteria.

DISCUSSION

Whether AA men are at greater risk for adverse outcomes during surveillance for clinically low risk PCa is a matter of significant clinical importance. Because AA men endure a higher burden of PCa in relation to Caucasian men, exclusion from active surveillance would expose a considerable proportion of AA men to treatment and, therefore, it warrants closer scrutiny.⁶ Currently, discordance exists in the literature with some studies indicating higher risks of pathological up-staging and biochemical recurrence in AA men while others show equivalence when adjusting for relevant factors. However, the unifying limitations in these studies are the disproportionately low participation rates of AA patients, and the unmeasured influences of socioeconomic status and access to care.^{1,12,14}

We evaluated the role of AA vs Caucasian race in a large, diverse cohort of men at clinically low risk receiving treatment at 6 United States Veterans Affairs medical centers. We observed no significant association between AA race and pathological upgrading, up-staging, positive margin status or biochemical recurrence after treatment.

Prior studies of the incidence of pathological upgrading and up-staging in AA men have yielded conflicting results. Sundi et al described 1,801 men at very low risk who were treated with prostatectomy at The Johns Hopkins Medical Institutions.¹² Of these men 256 (14%) who were AA were significantly more likely to experience adverse pathological findings even given highly restrictive criteria for low risk disease.¹² Higher rates of upgrading and up-staging in The Johns Hopkins Medical Institutions cohort have been attributed in part to a higher incidence of anterior tumors in AA men, which resulted in clinical under staging.²² In contrast, Jalloh et al evaluated similar end points in 273 AA (6.5%) and 3,771 Caucasian men (89.1%) derived from UCSF and the CaPSURE registry, a national disease registry drawing from 43 sites, in which no difference was observed in the rate of upgrading or up-staging by race.¹⁴

We noted higher unadjusted rates of positive surgical margins in AA men. However, on multivariable analysis incorporating relevant clinical and pathological features at diagnosis this relationship was not statistically significant. These findings are supportive of those reported by Witte et al in 260 AA men compared with 347 Caucasian men.²³ In that study race was not an independent predictor of margin status. Other groups, including Jalloh et al,¹⁴ detected persistent differences in margin status associated with race even when adjusted for relevant clinical factors, including prostate size, year of treatment, nerve sparing technique and surgical approach. Notably, high rates of positive margins were observed in AA and Caucasian patients relative to that in many published open and robotic series. Although consistent with prior analyses in the SEARCH database, these findings highlight technical and patient related factors that may contribute to higher rates of positive margins.^{24,25} Variations in pelvic anatomy between AA and Caucasian men, including steeper symphysis pubis angles and more narrow mid pelvic areas in AA men, have been described that may impart a greater technical challenge, particularly during apical dissection.^{26,27}

Prior studies of disparities in recurrence-free survival outcomes among risk stratified AA men have demonstrated inconsistent results with several studies indicating an independent association of race and recurrence.^{1,28} In this updated study restricted to men at low risk we did not detect significant differences in the rate of clinical recurrence among AA men. Our findings are in agreement with an earlier SEARCH analysis of pathological outcomes in men who were candidates for active surveillance, including 140 AA patients, comprising 42.5% of the cohort.²⁹ In that series AA race was not significantly associated with time to BCR at a median 43-month followup.

The current results in a restricted cohort of men at clinically low risk are also consistent with prior publications from the broader SEARCH experience that have shown a small but consistently increased risk of recurrence in AA men on multivariable analysis that did reach thresholds for statistical significance.^{17,30} Greater statistical power may be required to definitively address this question in a longitudinally followed surgical cohort. However, if present, such an effect would likely be small.

There are limitations to this analysis that require discussion. Improvements in biopsy with routine use of extended sextant sampling may not be well reflected in participants in earlier study years. This factor may exaggerate a discordance between biopsy and prostatectomy. To account for this we adjusted for year of surgery in our analyses. In addition, we observed an almost 1-year difference in followup between AA and Caucasian participants, which introduces the possibility of followup bias in our analysis of recurrence-free survival. To address this we used time to event analysis, which accounts for differential followup. In addition, pathological specimens were not reviewed centrally, a limitation that may affect the relationship between biopsy and surgical pathological assignment.

Lastly, a subset of SEARCH participants lacked complete clinical and demographic information, particularly for early study year participants. Such limitations also impacted the description of biopsy characteristics, including the percent of cores involved with tumor and

the greatest single core tumor volume at treatment sites. These variables prevented the description of JHU or UCSF strict criteria in approximately 40% of the study population.

We studied the role of AA vs Caucasian race on immediate pathological and distant biochemical outcomes in a cohort of men at clinically low risk who were treated with prostatectomy. AA men were diagnosed at younger ages and with higher PSA. However, when controlling for relevant disease characteristics, AA race was not independently associated with pathological upgrading, up-staging, positive surgical margins or clinical recurrence. These findings may directly impact the treatment of AA men who have newly diagnosed PCa with low risk features by demonstrating parity in surgical outcomes, which may offer a valuable surrogate inclusion criterion for active surveillance candidacy.

Ultimately, greater racial diversity in a longitudinal surveillance cohort is required to explicitly study outcomes with time in AA patients with favorable disease. However, our results support the validity of clinical risk stratification in AA men with localized PCa.

CONCLUSIONS

In a diverse, multicenter, multiethnic cohort of men at clinically low risk in an equal access medical system African-American race was not associated with pathological upgrading, up-staging, positive surgical margins or clinical recurrence. Active surveillance in African-American men with clinically favorable risk prostate cancer should not be withheld based on higher risks of adverse pathological features at prostatectomy.

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Abbreviations and Acronyms

AA	African-American
BCR	biochemical recurrence
CAPRA-S	Cancer of the Prostate Risk Assessment
JHU	Johns Hopkins University
PCa	prostate cancer
PSA	prostate specific antigen
UCSF	University of California-San Francisco

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Figure 1.
Biochemical recurrence-free survival by AA (blue curve) vs Caucasian (green curve) race

Table 1

Characteristics at diagnosis and pathological characteristics of 895 men treated with radical prostatectomy for low clinical risk Gleason 3 + 3 PCa between 1990 and 2011

	Caucasian	African-American	p Value
No. pts	540	355	—
Mean ± SD age at diagnosis	62.0 ± 5.8	59.5 ± 6.7	<0.01
Median ng/ml PSA at diagnosis (IQR)	5.1 (4.0–6.6)	5.5 (4.5–7.2)	<0.01
Median ng/ml/gm PSA density (IQR)	0.126 (0.088–0.177)	0.134 (0.096–0.192)	0.02
Mean ± SD biopsy cores (SD):			
No. sampled	9.1 ± 3.0	9.3 ± 3.1	0.40
No. pos	2.5 ± 1.8	2.5 ± 1.7	0.75
% Pos	0.30 ± 0.21	0.28 ± 0.19	0.28
Median ml prostate vol (IQR)*	33 (26–44)	33 (25–44)	0.99
No. clinical stage (%):			<0.01
T1c	374 (69.3)	278 (78.3)	
T2a	166 (30.7)	77 (27.2)	
No. treatment yr (%):			0.03
1990–1996	59 (10.9)	38 (10.7)	
1997–2003	248 (45.9)	133 (37.5)	
2004–2011	233 (43.2)	184 (51.8)	
No. surgical approach (%):			0.001
Open retropubic	367 (69.0)	275 (77.5)	
Perineal	143 (26.9)	54 (15.2)	
Laparoscopic	14 (2.6)	11 (3.1)	
Robotic	8 (1.5)	13 (3.7)	
Unknown	8 (1.5)	2 (0.6)	
No. pathological Gleason grade (%):			<0.01
3 + 3	334 (61.9)	189 (53.2)	
3 + 4	142 (26.3)	140 (39.4)	
4 + 3	39 (7.2)	14 (3.9)	
4 + 4 or Greater	25 (4.6)	12 (3.4)	

	Caucasian	African-American	p Value
No. pathological T stage (%):			0.46
T2	455 (87.0)	306 (86.9)	
T3	58 (11.1)	35 (9.9)	
T4	10 (1.9)	11 (3.1)	
No. lymph node status (%):			0.55
pN1	1 (0.2)	0	
pN0	217 (40.5)	153 (43.1)	
pNx	317 (59.3)	202 (56.9)	
No. pos surgical margin (%):	179 (35.2)	144 (41.5)	0.06
No. extracapsular extension (%):	50 (9.3)	33 (9.3)	0.99
No. seminal vesicle invasion (%):	12 (2.2)	12 (3.4)	0.29
No. Gleason upgrade (%):			
Any 3 + 4 or greater	206 (38.2)	166 (46.8)	0.01
Major 4 + 3 or greater	64 (11.9)	26 (7.3)	0.03
Mean $\pm$ SD pathological wt (gm)	41.9 $\pm$ 18.1	42.8 $\pm$ 19.8	0.49
No. pathological up-stage (%): [†]	68 (13.0)	46 (13.1)	0.98
No. any upgrade or up-stage (%):	233 (43.2)	182 (51.3)	0.02
No. CAPRA-S group (%):			0.16
0–2	387 (71.7)	234 (65.9)	
3–5	142 (26.3)	110 (31.0)	
6–10	11 (2.0)	11 (3.1)	

* Diagnostic transrectal ultrasound volume unavailable in 479 patients.

[†] pT3 or greater, or N1.

Table 2

Cox proportional hazards analysis modeling recurrence-free survival in 895 men treated with radical prostatectomy

Independent Variable	HR (95% CI)	p Value
Race (AA vs Caucasian)	1.105 (0.814–1.501)	0.521
Age at diagnosis	0.998 (0.975–1.021)	0.865
Pathological Gleason score: *		
3 + 3 (referent)	1.357 (0.975–1.889)	0.071
3 + 4	1.459 (0.787–2.704)	0.230
4 + 3	2.022 (1.071–3.817)	0.030
PSA at diagnosis	1.107 (1.029–1.191)	0.006
Margin status	2.134 (1.563–2.913)	0.000
Seminal vesicle invasion	1.854 (0.900–3.821)	0.094
Extracapsular extension	1.096 (0.702–1.711)	0.687
Treatment yr	0.980 (0.945–1.017)	0.286
Body mass index (kg/m ² /5 units)	1.107 (0.953–1.286)	0.183

* No patient had pathological Gleason score 4 + 4 or greater.