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The association between race and treatment regret among men with recurrent prostate cancer

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Abstract

BACKGROUND—To examine the impact of race on treatment regret among men with recurrent prostate cancer after surgery or radiation.

METHODS—The prospective Comprehensive, Observational, Multicenter, Prostate Adenocarcinoma (COMPARE) registry was used to study a cohort of 484 men with biochemically recurrent prostate cancer after radical prostatectomy, external beam radiation or brachytherapy. Multivariable logistic regression was used to model the association between race and treatment regret and to determine whether there was an interaction between race and sexual problems after treatment with regards to treatment regret.

RESULTS—Black men ($N = 78$) were significantly more likely to have treatment regret when compared with non-black men ($N = 406$; 21.8% versus 12.6%) on univariable analysis (odds ratio (OR) 1.94; 95% confidence interval 1.05–3.56; $P = 0.03$). On multivariable analysis, black race trended towards but was no longer significantly associated with an increase in treatment regret (adjusted OR (AOR) 1.84 (0.95–3.58); $P = 0.071$). There was an interaction between race and sexual problems after treatment ($P_{\text{interaction}} = 0.02$) such that among those without sexual problems, black men had more treatment regret than non-black men (26.7% versus 8.4%: AOR 4.68 (1.73–12.63); $P = 0.002$), whereas among those with sexual problems, there was no difference in treatment regret between black and non-black men (18.8% versus 17.3%: AOR 1.04 (0.44–2.46); $P = 0.93$).

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

CONCLUSIONS—Among men with recurrent prostate cancer after surgery or radiation, black men were nearly twice as likely to experience treatment regret. Treating physicians should ensure that patients are fully apprised of the pros and cons of all treatment options to reduce the risk of subsequent regret.

INTRODUCTION

Prostate cancer represents the most commonly diagnosed noncutaneous malignancy in men and there will be ~ 238 590 new cases of prostate cancer and 29 480 deaths due to prostate cancer in the United States in 2014.¹ A majority of these men will present with clinically localized disease for which treatment with either radical prostatectomy or radiation remains the standard of care as established by the National Comprehensive Cancer Network.² However, treatment with either surgery or radiation can be associated with several risks and potential harms (including erectile dysfunction, incontinence, urinary obstruction, rectal irritation, and so on),³⁻⁵ and some men may eventually regret their treatment choice.

As most men treated for localized prostate cancer can expect to live beyond 15 years after diagnosis,⁶⁻⁸ the morbidities associated with treatment are often experienced over an extended period of time and treatment regret can have long-term negative consequences on a patient's quality of life and psychological well being.^{9,10} Previous studies have demonstrated that a large proportion of patients with prostate cancer experience some regret after treatment and this regret tends to increase over time.¹¹⁻¹⁴ It is important, therefore, to elicit the factors that may be associated with treatment regret in order to reduce its burden. As black men have poorer outcomes after prostate cancer diagnosis and report greater levels of mistrust of the health-care system compared with non-black men,^{1,15,16} it is particularly critical to understand the relationship between race and regret after treatment for prostate cancer.

We used the prospective Comprehensive, Observational, Multi-center, Prostate Adenocarcinoma (COMPARE) registry to examine the impact of race on treatment regret among men with recurrent prostate cancer after surgery or radiation. Furthermore, as sexual dysfunction after prostate cancer therapy is a major factor associated with treatment regret,^{9,17,18} and given the published qualitative data that have identified sexual function as a factor influencing prostate cancer screening and treatment behaviors among black men,¹⁹⁻²² we examined whether there was an interaction between the presence of patient-reported sexual problems and race with regard to treatment regret.

MATERIALS AND METHODS

Patient selection

The prospective COMPARE registry was opened across 150 geographically diverse sites throughout the United States in February 2004 and enrolled 1120 men with biochemical recurrence after primary therapy for localized prostate cancer through March 2007.²³ Men of any age presenting with an increasing PSA after treatment of primary nonmetastatic prostate adenocarcinoma were eligible for this observational, prospective database, with the higher PSA level defined as follows: (1) an increase of 0.2 ng ml^{-1} on repeated testing after

radical prostatectomy or (2) 2 increases greater than the nadir, with a PSA value 50% greater than the nadir and a minimal PSA value 0.2 ng ml^{-1} greater than the post-radiation therapy nadir (a steering committee recommended modification of the Phoenix definition). Patients who received adjuvant or neoadjuvant androgen deprivation therapy (ADT) for 3 years were eligible but must have ceased ADT for 44 months before enrollment. Exclusion criteria included any ongoing treatment of prostate cancer and certain comorbidities. The full exclusion criteria have been detailed in previous reports.²³ To be included in the current study, patients must have received radical prostatectomy, external beam radiation therapy or brachytherapy without adjuvant ADT. Furthermore, patients must have had complete information on demographic characteristics of interest and regret status. Of the entire registry, 311 patients were excluded for receiving adjuvant ADT, 250 men were excluded for not having information on regret status and 75 patients were excluded for incomplete information on demographic characteristics of interest, leaving a total of 484 patients who met inclusion criteria and who constituted the study cohort.

Data collection

On enrollment into the study, data obtained from each patient included prostate cancer history, comorbidities, current physical examination parameters and pertinent laboratory data, and patient-reported common complaints. Each patient also completed the validated 'Prostate Health-Related Quality-of-Life Questionnaire' questionnaire including questions on demographics and the impact on quality of life during the previous 4 weeks of his urinary function, sexual function, bowel function and other medical problems.²⁴ Patients were scheduled for follow-up visits according to their physicians' standard of care at which time follow-up quality of life questionnaires as above were completed. Patients gave informed consent and data were made anonymous. Each participating site submitted registry documents to the central or local Institutional Review Board and obtained written approval before conducting any registry-related procedures. Investigators obtained informed consent from patients and provided them with a Health Insurance Portability and Accountability Act statement before enrollment.

Definition of regret, race, health literacy and functional problems Treatment regret was assessed based on a validated two-question questionnaire. Patients were considered to have treatment regret if they either answered 'definitely false' or 'mostly false' to the question 'If I had known everything I could have known, I would still have chosen the same treatment approach for prostate cancer,' or if they answered 'mostly true' or 'definitely true' to the question 'During the past 4 weeks, I felt I would be better off if I had chosen a different treatment approach for prostate cancer.'^{9,10} Race was determined at the time of the study as non-Hispanic white, black, non-black Hispanic, Asian and American-Indian. Health literacy was determined based on the Rapid Estimation of Literacy of Medicine (REALM-SF), a reliable and validated short form derived from the widely used and validated longer (66-word) REALM form.²⁵ English-speaking persons were asked to pronounce the following seven words aloud: 'Menopause, Exercise, Rectal, Behavior, Antibiotics, Jaundice and Anemia.' We collapsed health literacy findings into two mutually exclusive groups—ninth grade or higher health literacy (all seven words pronounced correctly) or less than ninth grade health literacy (less than seven words pronounced correctly). For each of sexual,

bowel and urinary domains, patients were asked ‘Overall, how big a problem has your function been for you during the last 4 weeks?’ with the five possible answers being ‘No problem,’ ‘Very small problem,’ ‘Small problem,’ ‘Moderate problem,’ ‘Very big problem.’ As more than 50% of the patients answered ‘No problem,’ we dichotomized functional issues for the purpose of modeling as ‘No problem’ versus ‘Any problem.’

Statistical analysis

Responses to initial questionnaires at study entry were used for all analyses. Fisher’s exact test was used to perform univariate analyses to determine whether race (black versus non-black), health literacy (health literate versus not), sexual problems (yes versus no), urinary problems (yes versus no), bowel problems (yes versus no), age (continuous), cardiovascular comorbidity (yes versus no, as previously reported),²⁶ living situation (lives with partners versus not), educational status (graduated high school versus not) or treatment type (radiation versus surgery) was associated with treatment regret. Fisher’s exact test was also used to compare baseline clinical and demographic characteristics between non-black and black patients. Multivariable logistic regression was used to determine whether race was associated with treatment regret after adjusting for the previously listed sociodemographic factors, time since initial treatment, health literacy, treatment type and patient-reported complications after treatment (bowel, urinary and sexual). Furthermore, a multivariable logistic regression model was used to explore whether there was an interaction between race and the presence of patient-reported sexual problems with regards to treatment regret. Adjusted odds ratios (AORs) and 95% confidence intervals (CIs) were reported for each covariate and a P-value of ≤ 0.05 was used to determine statistical significance. SAS version 9.3 (SAS Institute, Cary, NC, USA) was used for all calculations.

RESULTS

Patient baseline characteristics

Baseline patient clinical and demographic characteristics are displayed in Table 1. The median time from initial therapy to the administration of the questionnaires was 5.9 years (interquartile range: 2.5 years—9.7 years). A total of 484 men who received radical prostatectomy, external beam radiation therapy or brachytherapy with complete information on race, health literacy, educational status, age, living situation, sexual problems after treatment, urinary problems after treatment, bowel problems after treatment and comorbidity constituted the study cohort. Notably, of the 484 patients, 78 (16.1%) were black versus 406 non-black (83.9%); furthermore, 314 (64.9%) received radical prostatectomy, 107 (22.1%) were treated with external beam radiation therapy and 63 (13.0%) underwent brachytherapy. Table 1 also demonstrates baseline clinical and demographic characteristics by race (non-black versus black).

Impact of race on treatment regret

Among the 484 men included in this study, 68 (14.0%) had treatment regret. Black men were significantly more likely to have treatment regret when compared with non-black men (21.8% versus 12.6%) on univariable analysis (OR 1.94; 95% CI 1.05–3.56; $P = 0.03$; Table 2). Univariable analysis also revealed that men who experienced sexual or bowel problems

after treatment were more likely to have treatment regret compared with those who did not (OR 1.80; 95% CI 1.06–3.04; $P=0.03$ and OR 1.70; 95% CI 1.01–2.85; $P=0.04$, respectively; Table 2). On multivariable analysis, after adjusting for race, health literacy, sexual problems, urinary problems, bowel problems, age, cardiovascular comorbidity, living situation, educational status and treatment type, the black race was associated with a near-significant increase in treatment regret (AOR 1.84 (0.95–3.58); $P=0.071$). However, the presence of sexual problems after treatment (AOR 1.35; 95% CI 0.75–2.43; $P=0.31$) was no longer significantly associated with treatment regret on multivariable analysis (Table 2).

Influence of sexual problems after treatment on racial trends in treatment regret

On multivariable analysis, after adjusting for the aforementioned covariates, there was a significant interaction between race and sexual problems after treatment for prostate cancer ($P_{\text{interaction}}=0.02$) such that among those without sexual problems after treatment, black compared with non-black men were more likely to regret receiving treatment (26.7% versus 8.4%: AOR 4.68; 95% CI 1.73–12.63; $P=0.002$), whereas among those with sexual problems after treatment, there was no difference in treatment regret between black and non-black men (18.8% versus 17.3%: AOR 1.04; 95% CI 0.44–2.46; $P=0.93$; Table 3).

DISCUSSION

Treatment regret after definitive therapy for prostate cancer can occur and have detrimental effects on quality of life and psychological well being. Using a large multicenter prospective registry, we found that among 484 men with biochemically recurrent prostate cancer after surgery or radiation, 14% of men experienced treatment regret. Black men accounted for 16.1% of the study cohort and were alarmingly nearly twice as likely to have treatment regret when compared with non-black men ($P=0.03$). After adjusting for sociodemographic factors, health literacy, treatment type and patient-reported complications after treatment, on multivariable analysis, black men were 84% more likely to experience treatment regret relative to non-black men, although this association only trended toward significance ($P=0.071$).

These results importantly demonstrate higher rates of treatment regret among the black community compared with the general population. This association may reflect the downstream impact of racial disparities in prostate cancer outcomes, treatment patterns and mistrust in health care on patient perceptions of the efficacy, benefits and harms of the treatment and care that they received. Black men with prostate cancer have poorer access to care, are more likely to experience delays from diagnosis to treatment, receive differential treatment and have poorer cancer-specific outcomes.^{1,27-29} These disparities in addition to the historical mistreatment of black men and women are potential drivers of mistrust of the health-care system, different expectations regarding medical outcomes and higher rates of refusal of cancer-directed therapies among the black community.^{15,16,30} Thus, in the setting of historical mistreatment, knowledge of poorer outcomes in one's community, and potentially higher baseline levels of mistrust in the health-care system, it may be the case that black men are more likely to regret prostate cancer therapy especially in the setting of negative outcomes and biochemical recurrence may have been enough to drive the observed

racial differences in treatment regret in our study. Of note, the black men in this study were significantly younger and less educated than non-black men, two factors that could have contributed to higher regret among black men. Specifically, even though age and education were not significantly associated with treatment regret on multivariable analysis, younger men have longer to live with any side effects, may notice a bigger loss of quality of life and, if less educated, may not have had the same level of pretreatment understanding about potential side effects—all situations that could lead to regret and that should be examined in future larger studies.

The results of our study are congruent with the limited historical literature that has examined the association between race and decisional regret after prostate cancer treatment. Specifically, prior studies have demonstrated that non-white or black men with prostate cancer are more likely to experience treatment regret.^{17,31,32} However, two of those studies focused on regret after prostatectomy only,^{17,32} and the other study examined regret among a relatively homogeneous population of low-income underserved men in California. Our study uniquely contributes to the small growing body of literature on treatment regret by race in that it demonstrates treatment regret across multiple modalities and also in a diverse national cohort that is representative of the US population. Furthermore, this study places racial trends in treatment regret in a unique context by examining this association in a cohort of men with recurrent disease who may be less satisfied with their treatment decisions and more likely to experience regret.^{9,33} Our results, in addition to data from the historical literature, reinforce the notion that providers should ensure that patients are fully aware and educated of the potential benefits and harms of all treatment options to reduce the risk of consequent decisional regret. Decision-making tools in addition to educational tools, nomograms and risk calculators have been proposed as potential aids that can prepare patients for potential benefits, harms and risks of treatment and that can lead to minimal treatment regret.^{34,35}

Another interesting and novel finding in this study was the significant interaction between race and sexual problems after treatment for prostate cancer ($P_{\text{interaction}} = 0.02$) such that racial differences in treatment regret were modified by the presence of patient-reported sexual problems after treatment. Notably, among men without sexual problems after prostate therapy, black men were nearly five times as likely to experience regret relative to non-black men, whereas among those with sexual problems, black men only had a 1.5% absolute increased risk of treatment regret and there was no difference in treatment regret between black and non-black men on multivariable analysis (AOR 1.04; $P = 0.93$). This suggests that in the presence of sexual dysfunction, differences in treatment regret by race are mitigated. Although some historical qualitative data have suggested that sexual function is a major concern of black men when considering prostate cancer screening and treatments,¹⁹⁻²² other qualitative studies have shown that the most prevalent prostate cancer fears among all men are sexual problems and death, regardless of race or socioeconomic status.³⁶ Rather than finding that black men who experience dysfunction are more regretful than white men, our results seem to support the latter notion that sexual dysfunction is a ubiquitous concern following prostate cancer treatment among all men regardless of race and in the presence of sexual issues after treatment, there are no detectable differences in the rate of regret across

racers. Still, this interaction and the underlying reasons for this effect must be studied further in larger studies.

Our results must be viewed within the limitations of the study. First, although we were able to demonstrate racial trends in treatment regret, we were unable to determine whether patients specifically regretted the particular modality (surgery versus radiation) they chose to receive or, if they regretted more generally, regretted receiving any form of treatment for their prostate cancer at all. Second, the study only included patients who experienced recurrence and, therefore, the factors that drive regret for men that experience recurrence may be different than for men that do not. Nevertheless, this places our study in a unique and meaningful context to examine racial differences in treatment regret. Third, this study is retrospective and cross-sectional in nature, and therefore is hypothesis-generating; future prospective studies are needed to confirm our results. Fourth, there is potential for selection bias, given the exclusion of patients with missing data. Fifth, given the small sample size, there is limited power to detect differences in our multivariable analyses and this study should therefore serve as a hypothesis-generating study to guide future studies with larger sample sizes. Lastly, we do not have information on time to recurrence or disease progression, both of which could have contributed to observed differences in treatment regret.

In summary, our study found that among men with recurrent prostate cancer after surgery or radiation, black men were more likely to experience treatment regret. Furthermore, we found that racial differences in treatment regret may be mitigated by the presence of sexual problems after treatment. Treating physicians should ensure that patients are fully apprised of the pros and cons of all treatment options in a culturally competent and relevant manner in order to reduce the risk of subsequent regret.

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Table 1

Baseline clinical and demographic characteristics overall ($N = 484$) and by race (non-black ($N = 406$) versus black ($N = 78$))

<i>Characteristic, N (%)^a</i>	<i>Overall (N = 484)</i>	<i>Non-black (N = 406)</i>	<i>Black (N = 78)</i>	<i>P^b</i>
<i>Age group (years)</i>				<i>0.002</i>
60	106 (21.9)	76 (18.7)	30 (38.5)	
61–70	238 (49.2)	209 (51.5)	29 (37.2)	
71–80	132 (27.3)	113 (27.8)	19 (24.3)	
>80	8 (1.6)	8 (2)	0 (0)	
<i>Education</i>				<i>0.0079</i>
Completed high school	434 (89.7)	371 (91.4)	63 (80.8)	
Did not complete high school	50 (10.3)	35 (8.6)	15 (19.2)	
<i>Living situation</i>				<i>0.26</i>
Lives with partner	400 (82.6)	339 (83.5)	61 (78.2)	
Lives alone	84 (17.4)	67 (16.5)	17 (21.8)	
<i>PSA (ng mL⁻¹)</i>				<i>0.61</i>
4	63 (13.0)	56 (13.8)	7 (9.0)	
>4–10	250 (51.7)	207 (51.0)	43 (55.1)	
>10–20	95 (19.6)	82 (20.2)	13 (16.7)	
>20	29 (6.0)	23 (5.7)	6 (7.7)	
Unknown	47 (9.7)	38 (9.4)	9 (11.5)	
<i>Initial Gleason score</i>				<i>0.79</i>
6	247 (51.0)	204 (50.3)	43 (55.1)	
7	121 (25.0)	101 (24.9)	20 (25.6)	
8–10	36 (7.4)	31 (7.6)	5 (6.4)	
Unknown	80 (16.5)	70 (17.2)	10 (12.8)	
<i>Initial clinical T stage</i>				<i>0.18</i>
T1	190 (39.3)	155 (38.2)	35 (44.9)	
T2	221 (45.7)	193 (47.5)	28 (35.9)	
T3	32 (6.6)	24 (5.9)	8 (10.3)	
T4	0 (0)	0 (0)	0 (0)	
Unknown	41 (8.5)	34 (8.4)	7 (9.0)	
<i>Comorbidity</i>				<i>0.72</i>
Cardiovascular	132 (27.3)	113 (27.8)	19 (24.4)	
Noncardiovascular	219 (45.3)	184 (45.3)	35 (44.9)	
None	133 (27.5)	109 (26.9)	24 (30.8)	
<i>Initial treatment</i>				<i>0.88</i>
Radical prostatectomy	314 (64.9)	265 (65.3)	49 (62.8)	
External beam radiation therapy	107 (22.1)	89 (21.9)	18 (23.1)	
Brachytherapy	63 (13.0)	52 (12.8)	11 (14.1)	

<i>Characteristic, N (%)^a</i>	<i>Overall (N = 484)</i>	<i>Non-black (N = 406)</i>	<i>Black (N = 78)</i>	<i>P^b</i>
<i>Race</i>				
White	371 (76.7)			
Black	78 (16.1)			
Hispanic	20 (4.1)			
Asian	13 (2.7)			
American-Indian	2 (0.4)			

^aPercentages may not add to 100 because of rounding.

^b*P* comparing baseline characteristics of non-black to black men.

Table 2Univariable and multivariable logistic regression for treatment regret ($N = 484$)

<i>Characteristic</i>	<i>Univariable analysis</i>		<i>^aMultivariable analysis</i>	
	<i>OR (95% CI)</i>	<i>P</i>	<i>Adjusted OR (95% CI)</i>	<i>P</i>
<i>Race</i>				
Non-black	1.0 (ref)		1.0 (ref)	
Black	1.94 (1.05–3.56)	0.03	1.84 (0.95–3.58)	0.071
Age (per year increase)	0.97 (0.94–1.00)	0.08	0.96 (0.93–1.00)	0.07
Time since initial treatment (per year increase)	0.99 (0.93–1.04)	0.60	0.98 (0.93–1.04)	0.60
<i>Treatment received</i>				
Radiation therapy	1.0 (ref)		1.0 (ref)	
Radical prostatectomy	0.80 (0.47–1.35)	0.39	0.74 (0.41–1.33)	0.31
<i>Cardiovascular comorbidity</i>				
No	1.0 (ref)		1.0 (ref)	
Yes	1.04 (0.59–1.84)	0.89	1.04 (0.58–1.87)	0.89
<i>Sexual problems after treatment</i>				
No	1.0 (ref)		1.0 (ref)	
Yes	1.80 (1.0–3.04)	0.03	1.35 (0.75–2.43)	0.31
<i>Urinary problems after treatment</i>				
No	1.0 (ref)		1.0 (ref)	
Yes	1.63 (0.98–2.73)	0.06	1.43 (0.82–2.51)	0.21
<i>Bowel problems after treatment</i>				
No	1.0 (ref)		1.0 (ref)	
Yes	1.70 (1.01–2.85)	0.04	1.63 (0.92–2.88)	0.10
<i>Lives with partner</i>				
No	1.0 (ref)		1.0 (ref)	
Yes	1.26 (0.61–2.57)	0.53	1.21 (0.57–2.57)	0.63
<i>Graduated high school</i>				
No	1.0 (ref)		1.0 (ref)	
Yes	1.22 (0.50–2.99)	0.66	1.07 (0.41–2.77)	0.89
<i>Health literate</i>				
No	1.0 (ref)		1.0 (ref)	
Yes	1.22 (0.66–2.26)	0.52	1.30 (0.68–2.49)	0.43

Abbreviations: CI, confidence interval; OR, odds ratio.

^a All variables in the multivariable analysis are provided in the table.

Table 3

Assessment of effect modification between race (black versus non-black) and sexual problems after treatment (yes versus no) for the outcome of treatment regret ($N = 484$)

<i>Characteristic</i>	<i>^a Multivariable analysis</i>	
	<i>Adjusted OR (95% CI)</i>	<i>P</i>
<i>No sexual problems after treatment</i>		<i>0.002</i>
Non-black	Ref (1.0)	
Black	4.68 (1.73–12.63)	
<i>Presence of sexual problems after treatment</i>		<i>0.93</i>
Non-black	Ref (1.0)	
Black	1.04 (0.44–2.46)	

Abbreviations: CI, confidence interval; OR, odds ratio.

^a Multivariable analysis for the interaction model was adjusted for race, age, time since initial treatment, treatment type, cardiovascular comorbidity, bowel problems after treatment, urinary problems after treatment, sexual problems after treatment, living situation, educational status and health literacy.