

Treatment Decisional Regret Among Men With Prostate Cancer: Racial Differences and Influential Factors in the North Carolina Health Access and Prostate Cancer Treatment Project (HCaP-NC)

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BACKGROUND: It has been demonstrated that treatment decisional regret affects quality of life in patients with prostate cancer (CaP); however, there are limited studies that identify factors associated with treatment decisional regret, particularly within a racially diverse patient population that has extended follow-up. **METHODS:** Logistic regression analysis was used to determine associations between decisional regret and potential predictors in a population-based cohort of 348 African American men and 446 Caucasian American men approximately 3 years after CaP diagnosis. **RESULTS:** Of 794 research participants, 12% experienced treatment decisional regret. Decisional regret was associated with androgen-deprivation therapy (odds ratio [OR], 2.1; 95% confidence interval [CI], 1.1-4.0), recent urinary bother (OR, 3.4; 95% CI, 1.6-7.3), satisfaction with understanding potential treatment side effects (very unsatisfied: OR, 13.3; 95% CI, 5.5-32.2; somewhat unsatisfied: OR, 5.0; 95% CI, 2.3-11.2; neutral: OR, 3.8; 95% CI, 1.9-7.6), and CaP treatment effect on the spousal relationship (very affected: OR, 3.9; 95% CI, 2.0-7.6; somewhat affected: OR, 3.1; 95% CI, 1.4-7.3; neutral: OR, 2.4; 95% CI, 1.9-7.6). Younger African Americans were more likely to experience regret than older African Americans (OR, 3.0; 95% CI, 1.1-8.1), and older African Americans were less likely to experience regret than older Caucasian Americans (OR, 0.2; 95% CI, 0.1-0.7). **CONCLUSIONS:** Treatment decisional regret remains an important issue in CaP survivors beyond initial treatment. Potential interventions should involve younger African Americans and patient spouses. Increased regret may reflect the unexpected influence of treatment side effects on the patient's everyday life; helping the patient relate potential side effects to his individual situation could improve patient satisfaction. *Cancer* 2015;121:2029-35. © 2015 American Cancer Society.

KEYWORDS: African Americans, emotions, health status disparities, prostatic neoplasms, quality of life, spouses.

INTRODUCTION

Prostate cancer (CaP) is the most commonly diagnosed cancer among men in the United States, resulting in an estimated 27% (233,000) of all new cancers diagnosed in men.¹ African Americans (AAs) have a 70% higher incidence rate and more than twice the death rate of Caucasian Americans (CAs).¹ Quality of life (QOL) is an important outcome after CaP diagnosis and treatment given the relatively high survival rates for patients with CaP (94% survive 15 years beyond diagnosis).¹ Previous studies have demonstrated that CaP treatment decisional regret is an influential factor in a patient's QOL,²⁻⁶ but the factors that contribute to decisional regret in patients with different racial and sociocultural backgrounds remain understudied.

Decisional regret can be defined as the cognitively based, negative emotion experienced when an individual realizes or imagines that the current situation would have been better had they acted differently.⁷ Decisional regret specific to CaP treatment involves the patient's feeling that he would have been better off had he chosen a different treatment.⁸ The racial

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disparity observed in multiple other dimensions of CaP survivorship warranted study of racial differences in CaP treatment decisional regret to identify factors specific to CaP characteristics, sociodemographics, and the health care experience that may be associated with regret. Previous studies have identified greater CaP treatment decisional regret among nonwhites and AAs compared with CAs; however, those studies were limited by small sample sizes and restricted disease stage or treatment groups.⁹⁻¹¹ In addition, related literature has often involved surveys of patients shortly after diagnosis and may be less applicable to long-term CaP survivors.

The objective of the current study was to examine long-term treatment decisional regret and identify predictors of decisional regret within a large, racially diverse population of CaP survivors who had extended follow-up. The identification of influential factors could reveal avenues of intervention to prevent or reduce decisional regret and, thus, lead to an improvement in QOL after CaP treatment.

MATERIALS AND METHODS

Study Population

The current analysis draws from the North Carolina Health Access and Prostate Cancer Treatment Project (HCaP-NC), a multidisciplinary, prospective follow-up study of 348 AA and 446 CA CaP research participants. The HCaP-NC cohort was recruited from the North Carolina-Louisiana Prostate Cancer Project (PCaP), a population-based study of racial differences in CaP aggressiveness. PCaP methods have been described elsewhere.¹² Briefly, PCaP provided an extensive evaluation of health care system interactions and of patient-level and tumor-level factors at diagnosis (baseline) among 2236 research participants from North Carolina and Louisiana who had newly diagnosed CaP and were identified using rapid case ascertainment. HCaP-NC involved comprehensive follow-up of the North Carolina research participants annually for 3 years and extending to an average of 5 years after diagnosis using questionnaires and detailed abstraction of medical records. For the current analysis, we used baseline data from the PCaP project and the first year of follow-up data from HCaP-NC study for North Carolina men participating in both PCaP and HCaP-NC. The University of North Carolina at Chapel Hill Institutional Review Board provided approval and oversight, and all research participants provided informed consent.

Outcome Variable

The primary outcome variable was decisional regret, which we measured using the regret scale described by

Clark et al and validated in CaP survivors with a Cronbach α value of .89.² The 2 questions that were administered during follow-up concerned whether the research participant would have been better off with a different treatment (definitely false, somewhat false, neither true nor false, somewhat true, definitely true) and the amount of time spent wishing he could change his mind about the treatment (none of the time, rarely, neither a little nor a lot of the time, some of the time, all of the time). Decisional regret was derived by dichotomizing the regret scale, as previously reported,² which allowed us to generate odds ratios. A research participant was considered to be experiencing regret if he definitely or somewhat agreed that he would have been better off choosing a different treatment or if he spent all or some of the time wishing he could change his mind about the treatment chosen.

Covariates of Interest

Covariates of interest included variables in 3 categories: CaP-specific factors, sociodemographics, and the research participant's experience with CaP health care.

CaP-specific factors

CaP aggressiveness was derived according to the 2004 National Comprehensive Cancer Network CaP guidelines risk groups,¹³ which were in effect at the time of the first possible diagnosis date (July 1, 2004). Risk for recurrence was determined according to clinical Gleason grade, disease stage, and prostate-specific antigen level at diagnosis.¹³ Research participants were categorized into 6 risk groups (low, intermediate, high, very high, lymph node involvement, metastatic disease) based on previously described methods.¹⁴ Additional categorical variables included CaP treatment chosen (prostatectomy, radiation, androgen-deprivation therapy, active surveillance, brachytherapy, other) and the degree to which CaP treatment affected the research participant's relationship with his spouse (on a 5-point scale ranging from 1 ["not at all affected"] to 5 ["affected a lot"]), both of which were derived from questionnaire data. The categorical variables urinary bother ("how big of a problem urinary dysfunction has been over the past 4 weeks") and sexual bother ("how big of a problem sexual dysfunction has been over the past 4 weeks") were used to examine current or persistent self-reported symptoms at follow-up. These variables were graded on a 5-point scale ranging from 1 ("no problem at all") to 5 ("a big problem"). Dichotomous questionnaire variables included urinary dysfunction since diagnosis (yes, no), sexual dysfunction since diagnosis

(yes, no), and symptomatic versus asymptomatic at diagnosis (yes, no).

Sociodemographics

The level of educational attainment (less than high school graduate, high school graduate, some college, college graduate, graduate-level training) and health insurance status (all, part, or none of the time) were treated as categorical variables. Income was calculated as household income before taxes divided by the number of individuals supported by that income. Dichotomous variables included age at diagnosis (<65 years, ≥65 years), race (AA, CA), and current employment status as affected by CaP (unable to work or retired because of CaP or its treatment vs status unaffected by CaP). Age was dichotomized at age 65 years to allow for comparisons between older and younger men. All variables were derived from self-reported follow-up questionnaire data.

CaP health care experience

Categorical variables included the research participant's satisfaction with understanding of available treatment options (assessed by the degree he agreed or disagreed with the statement that he "had all the information needed to make a treatment decision") and satisfaction with his understanding of potential treatment side effects (assessed by the degree to which he agreed or disagreed with the statement that "the doctors told me the whole story about side effects"). Responses were measured on a 5-point scale ranging from 1 ("very unsatisfied") to 5 ("very satisfied"). The patient-health care provider interaction was measured using the interpersonal treatment scale described by Safran et al, which included questions aimed at determining the research participant's satisfaction with his health care provider's patience, friendliness, concern, and respect for them.¹⁵ Patient-health care provider communication was assessed using a scale reported by Safran et al and included questions pertaining to the research participant's feelings toward the thoroughness of his health care provider's questions and attention from his health care provider as well as his health care provider's explanations, instructions for seeking further care, and advice making decisions.¹⁵ All variables were derived from self-reported follow-up questionnaire data.

Analytic Method

Using logistic regression, variables that were significantly associated with decisional regret in the univariable analysis ($P < .05$) were identified and considered in the multivariable model. Two-way product term interactions between

variables that were significant in the univariable analysis were assessed for contribution in the multivariable analysis. Predictors (including two-way interactions) that were not closely related to decisional regret ($P > .05$) were dropped from the multivariate model using backwards, step-wise elimination to create the final model. All analyses were performed using SAS software (version 9.2; SAS Institute, Inc., Cary, NC).

RESULTS

Descriptive Analysis

The population in this analysis (Table 1) consisted of 44% AAs and 56% CAs, and 62% were aged <65 years at the time of diagnosis. The average time from treatment to follow-up was 2.8 years (median, 2.8 years; range, 0.9-5.7 years; interquartile range, 1.9 years). Educational attainment levels were widespread, and the average annual pre-tax household individual income was \$26,000. Almost all research participants had insurance coverage for the entire period between diagnosis and the first follow-up interview. Approximately 16% of research participants had a high risk or a very high risk for recurrence, lymph node involvement, or metastatic CaP, 46% had intermediate risk for recurrence, and 36% were considered low risk for recurrence. The most common first course of treatment chosen was radical prostatectomy (62.1%). Of 794 research participants, 12% were experiencing treatment decisional regret at the time of this follow-up study. Approximately 12% of AAs and 13% of CAs experienced regret, and about 13% of younger men and 11% of older men experienced regret. Of those experiencing regret, 36% were younger AAs, 32% were younger CAs, 27% were older CAs, and 6% were older AAs (Table 2).

Logistic Regression Analysis

Variables that were significant in univariable analyses and, thus, were considered in the multivariable analysis included sexual bother in the past 4 weeks, patient-health care provider interaction, patient-health care provider communication, satisfaction with understanding of available treatment options, time from diagnosis to follow-up questionnaire, androgen-deprivation therapy, satisfaction with understanding of potential treatment side effects, urinary bother in the past 4 weeks, the degree to which CaP treatment affected the spousal relationship, age, and race. Variables that were not significant in univariable analyses and were subsequently excluded from the multivariate model included National Comprehensive Cancer Network risk for CaP recurrence, prostatectomy, radiation, active surveillance, brachytherapy, other treatment

TABLE 1. Characterization of the North Carolina Health Access and Prostate Cancer Treatment Project Cohort

Variable	No. of Patients (%)
Age, y	
<65	491 (61.8)
≥65	303 (38.2)
Race	
African American	348 (43.8)
Caucasian American	446 (56.2)
Educational attainment	
<High school graduate	109 (13.7)
High school graduate	193 (24.3)
Some college	184 (23.2)
College graduate	149 (18.8)
Graduate-level training	158 (19.9)
Missing	1 (0.1)
Health insurance status from diagnosis to present	
All of the time	736 (92.7)
None of the time	15 (1.9)
Part of the time	37 (4.7)
I don't know	4 (0.5)
Missing	2 (0.3)
Household income, ^a \$	26,141.20/23,750.00
NCCN risk for CaP recurrence	
Low	288 (35.8)
Intermediate	369 (45.9)
High	99 (12.3)
Very high	6 (0.8)
Lymph node involvement/metastatic disease	20 (2.5)
Missing	22 (2.7)
CaP treatment chosen	
Prostatectomy	493 (62.1)
Radiation	139 (17.5)
Androgen-deprivation therapy	115 (14.5)
Brachytherapy	49 (6.2)
Watchful waiting	37 (4.7)
Other	52 (6.6)
CaP treatment decisional regret	
Yes	98 (12.2)
No	696 (86.6)
Missing	10 (1.2)

Abbreviations: CaP, prostate cancer; NCCN, National Comprehensive Cancer Center.

^a Calculated as household income before taxes divided by the number of individuals supported by this income; Shown as mean/median.

chosen, urinary dysfunction since diagnosis, sexual dysfunction since diagnosis, symptomatic versus asymptomatic at diagnosis, educational attainment, health insurance status, income, employment status, and satisfaction with understanding of available treatment options.

The final multivariable regression model included androgen-deprivation therapy, satisfaction with understanding of potential treatment side effects, urinary bother in the past 4 weeks, the degree to which CaP treatment affected the spousal relationship, age, race, and an age*race interaction term (Table 3). The age*race interaction term was the only interaction term that remained significant. This term allowed for comparisons to be made both

within race groups, comparing younger men of the same race with older men of the same race, and between race groups, comparing AA men of similar age with CA men of similar age. A sensitivity analysis was conducted examining the effect of dichotomizing age for the age*race interaction term, and no significant changes in variables for inclusion or point estimates in the final multivariable model were noted (data not shown).

On the basis of the final multivariable model, men who reported receiving androgen-deprivation therapy had approximately twice the odds of regret compared with men who did not receive androgen-deprivation therapy. Men who felt that urinary bother was a big problem in the past 4 weeks had 3 times the odds of regret as those who did not believe it was a problem. Men who reported being very unsatisfied with their understanding of the potential side effects of treatment had 13 times the odds of regret compared with men who were very satisfied with their understanding. Similarly, men who were somewhat unsatisfied with their understanding had 5 times the odds of regret, and men who felt neutral on the subject had almost 4 times the odds of regret. Men who felt that their relationship with their spouse had been somewhat affected or very affected by CaP treatment had 3 and 4 times the odds of regret, respectively, compared with men who reported that their relationship was unaffected. Younger AAs (aged <65 years) demonstrated a significant tripling of the odds of decisional regret compared with older AAs, and older AAs (aged ≥65 years) had significantly less regret than CAs. Younger AAs were less likely to experience decisional regret compared with CAs of similar age, and younger CAs were less likely to experience regret than older CAs, although these estimates were not significant in the model (Table 3).

DISCUSSION

The percentages of research participants reporting regret in this study population were similar to those previously reported.^{2,6,9,10,16,17} Many of the previous studies of decisional regret included surveys of patients shortly after diagnosis (for example, a mean of 10 months),⁴ whereas the patients studied herein, on average, were 3 years post-diagnosis. Findings from this study suggest that decisional regret is present and persistent well beyond initial diagnosis and treatment, and decisional regret has the potential for long-term adverse effects on the QOL of patients with CaP.

To our knowledge, this is the first study with sufficient power to examine racial differences in CaP treatment decisional regret. Two previous studies have

TABLE 2. Prostate Cancer Treatment Decisional Regret Within and Between Race

	No. of Patients (%)					
Age Group	Regret	No Regret	Missing	Total	Chi-Square Statistic	P
Within race						
AA						
<65 y	35 (13.9)	215 (85.3)	2 (0.8)	252 (100)	4.203	.04 ^a
≥65 y	6 (5.9)	92 (90.2)	4 (3.9)	102 (100)		
CA						
<65 y	31 (12.9)	210 (87.1)	0 (0)	241 (100)	0.003	.95
≥65 y	26 (12.4)	179 (85.7)	4 (1.9)	209 (100)		
Between race						
<65 y						
AA	35 (13.9)	215 (85.3)	2 (0.8)	252 (100)	0.136	.71
CA	31 (12.9)	210 (87.1)	0 (0)	241 (100)		
≥65 y						
AA	6 (5.9)	92 (90.2)	4 (3.9)	102 (100)	3.02	.08
CA	26 (12.4)	179 (85.7)	4 (1.9)	209 (100)		
Total	98	696	10	804		

Abbreviations: AA, African American; CA, Caucasian American.

^a Indicates statistical significance, with $P < .05$.

identified greater CaP treatment decisional regret among nonwhites and AAs compared with CAs; however, those studies were limited by small sample sizes and restricted treatment groups.^{9,10} Another racially diverse study indicated that age, rather than race, was significantly associated with treatment regret, but that study was restricted to those who had experienced biochemical recurrence.¹¹ Our study identified an interaction between the age and race variables, such that younger AAs were more likely to experience regret, whereas older AAs were less likely. Interventions focused on decreasing treatment decisional regret would benefit by directing efforts to this higher risk subpopulation.

Men who believed that they were not told “the whole story about side effects” by their health care providers had significant treatment decisional regret regardless of side effects experienced, age, or race. The belief that patients were uninformed about the possible side effects of treatment has been suggested as an explanation for increased decisional regret in other studies.^{2,4} In the current analysis, however, understanding of side effects was not modified by the side effects experienced, the patient’s overall understanding of available treatment options, or the patient’s satisfaction with patient-health care provider interaction and health care provider communication in general. Thus, it is possible that increased regret is associated particularly with how unexpected treatment side effects affected the patient’s life, such as urinary bother or effects on his spouse, rather than feeling uninformed about treatment options. This may be especially true for

men receiving androgen-deprivation therapy, with its wide range of side effects, which may be even more distressing¹⁸ and reportedly are associated with worse QOL.¹⁹ Oncologists may have limited opportunity to establish a strong relationship with a patient in the narrow timeframe of diagnosis and treatment discussions, which can make tailoring information to the patient’s needs more difficult.⁴ In addition to this, when first confronted with a CaP diagnosis, men may be less psychologically able to absorb the wealth of treatment information provided and may need this information presented again at a later time or in a variety of ways.¹⁸ The inclusion of nurse navigators may assist in developing this relationship across the continuum of care, specifically in understanding how a treatment’s side effects might impact an individual patient, and could provide multiple opportunities for presentation of information and discussion.

Some studies have reported an association between regret and treatment-related urinary dysfunction,^{4-6,20} whereas others have not.^{9,21} The inconsistency of these findings may have resulted from the inability in previous studies to address patients’ expectations of post-treatment side effects rather than the presence or absence of side effects, which were more accurately captured using a validated survey. The longevity of HCaP-NC allowed for the assessment of current side effects in relation to regret, manifested as urinary bother in the past 4 weeks. This variable was significantly associated with regret, whereas urinary dysfunction since diagnosis was not. An article by Diefenbach and Mohamed reported similar associations,

TABLE 3. Factors Influencing Prostate Cancer Treatment Decisional Regret: Multivariable Regression Model

Variable	No. of Patients (%)	OR [95% CI]
Hormone therapy		
Yes	115 (14.5)	2.1 [1.1-4.0] ^a
No	679 (85.5)	Ref
Urinary bother in the past 4 wk		
Big problem	57 (7.2)	3.4 [1.6-7.3] ^a
Somewhat of a problem	83 (10.5)	1.9 [0.9-4.1]
Neutral	104 (13.1)	2.1 [1.0-4.4]
Not much of a problem	203 (25.6)	0.9 [0.4-1.8]
No problem	347 (43.7)	Ref
Satisfaction with understanding of potential treatment side effects		
Very unsatisfied	37 (4.7)	13.3 [5.5-32.2] ^a
Somewhat unsatisfied	49 (6.17)	5.0 [2.3-11.2] ^a
Neutral	99 (12.47)	3.8 [1.9-7.6] ^a
Somewhat satisfied	224 (28.21)	1.3 [0.7-2.5]
Very satisfied	378 (47.61)	Ref
Missing	7 (0.9)	
Spousal relationship		
Very affected	97 (12.2)	3.9 [2.0-7.6] ^a
Somewhat affected	63 (7.9)	3.1 [1.4-7.3] ^a
Neutral	97 (12.2)	2.4 [1.1-5.1] ^a
Somewhat unaffected	158 (19.9)	1.6 [0.8-3.4]
Not affected	367 (46.2)	Ref
Missing	12 (1.5)	
Race*age		
Within race		
AA		
<65 y	250 (31.5)	3.0 [1.1-8.1] ^a
≥65 y	98 (12.3)	Ref
CA		
<65 y	241 (30.4)	0.8 [0.4-1.6]
≥65 y	205 (25.8)	Ref
Between race		
<65 y		
AA	250 (31.5)	0.9 [0.5-1.7]
CA	241 (30.4)	Ref
≥65 y		
AA	98 (12.3)	0.2 [0.1-0.7] ^a
CA	205 (25.8)	Ref

Abbreviations: AA, African Americans; CA, Caucasian Americans; CI, confidence interval; OR, odds ratio; Ref, referent category.

^a Indicates statistical significance, with $P < .05$.

indicating that the patient's perception of dysfunction or bother may play a greater role than objective dysfunction.⁵ Another potential explanation is that patients currently experiencing these symptoms so far removed from treatment may believe that this impairment is no longer temporary but will be a lifelong struggle.⁹

The health care provider can play an important role in minimizing decisional regret, particularly in portraying how potential treatment side effects like urinary dysfunction could impact the patient's life. Health care provider interaction should not be limited to the patient, however, but also should involve the patient's spouse. Previous studies have demonstrated that the spousal relationship is

affected by CaP diagnosis and treatment,⁸ and that *the greatest negative impact* falls on this relationship.²² The current analysis indicates that CaP patients experience more regret when CaP treatment affects the spousal relationship regardless of age, race, or sexual bother. The association between a CaP patient's relationship with his spouse and decisional regret has not been well characterized to date. Focus groups have identified issues distinct from sexual impact, such as decreased intimacy, affection, and independence,⁸ but further study is needed.

This study has some potential limitations. A widely accepted measurement of CaP treatment decisional regret has not been established, making it difficult to compare results across studies. More consistent use of a validated scale, such as the regret scale² used in this study, should be considered in future studies. Decisional regret was associated with the impact of treatment on the patient's relationship with his spouse, but not with sexual bother; although we were unable to elucidate specific areas of the spousal relationship to target for intervention, it is clear that decisional regret extends beyond the sexual dimension. In light of the limited research on this topic, specific factors that influence the spousal relationship after prostate cancer diagnosis deserve further exploration, especially within a racially diverse sample such as the HCaP-NC. Most of the data used in this study were obtained from questionnaires, and although general limitations in self-reported information exist, the authors view this as a strength given the psychosocial measurements derived. Other strengths include increased length of follow-up, racial and socioeconomic diversity, the large sample size, and the population-based study design.

Given the relatively high survival rates of patients with CaP and the influence of CaP treatment decisional regret on a patient's QOL after CaP diagnosis,⁸ the factors related to treatment decisional regret identified in this study should be considered carefully as a patient with CaP makes his treatment decision. Targeting educational efforts regarding the potential side effects of CaP treatments is especially important for minimizing decisional regret. Health care providers have the unique opportunity to influence treatment decisional regret, both in the initial stages of diagnosis and when providing follow-up care, by remaining aware of this issue and intervening with treatment to reduce side effects and supportive referrals, such as counseling, when appropriate. As this analysis has demonstrated, decisional regret remains a major concern for some CaP patients years after initial diagnosis and treatment, and the general practitioner, as well as the oncologist, can play a powerful role. The presence of decisional

regret beyond the initial diagnosis and treatment phase necessitates increased attention to explore and reduce the potential long-term effects of decisional regret on patients' QOL through research and services that enhance psychosocial support and patient education for CaP patients and their spouses.

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CONFLICT OF INTEREST DISCLOSURES

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