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# Feasibility and Delivery of Patient-Reported Outcomes in Clinical Practice Among Racially Diverse Bladder and Prostate Cancer Patients

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## Abstract

**Objective:** To assess the feasibility of enrollment and collecting PRO data as part of routine clinical urologic care for bladder and prostate cancer patients and examine overall patterns and racial variations in PRO use and symptom reports over time.

**Subjects/Patients and Methods:** We recruited 76 patients (n=29 Black and n=47 White) with prostate or bladder cancer at a single, comprehensive cancer center. The majority of prostate cancer patients had intermediate risk (57%) disease and underwent either radiation or prostatectomy. Over half (58%) of bladder cancer patients had muscle invasive disease and underwent cystectomy.

Patients were asked to complete PRO symptom surveys using their preferred mode [web- or phone-based interactive voice response (IVR)]. Symptom summary reports were shared with providers during visits. Surveys were completed at three time points and assessed urinary, sexual, gastrointestinal, anxiety/depression, and sleep symptoms. Feasibility of enrollment and survey completion were calculated, and linear mixed effects models estimated differences in outcomes by race and time.

**Results:** 63% of study participants completed all PRO measures at all three time points. Black patients were more likely to select IVR as their survey mode (40% vs 13%, $p<0.05$), and less likely to complete all surveys (55% vs 74%, $p=0.13$). Patients using IVR were also less likely to complete all surveys (41% vs 69%, $p=0.046$).

**Conclusion:** Reported preferences for survey mode and completion rates differ by race, which may influence survey completion rates and highlight potential obstacles for equitable implementation of PROs into clinical care.



### Keywords

patient-reported outcomes (PROs); racial disparities; bladder cancer; prostate cancer


## Introduction

Cancer treatments, including surgery, radiotherapy and chemotherapy, are often linked to acute and late side effects. Historically, these effects were assessed by physicians and scored using standardized scales such as the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE).[1] However, multiple studies have demonstrated that patient-reported outcome (PRO) measures more accurately capture patient symptoms than physician assessment, particularly when symptoms are severe.[2–4] Findings from these prior studies are consistent with evidence from a recent systematic review, which concluded that PRO data were essential for the evaluation of symptoms in cancer survivors.[2]

Incorporation of PRO data into routine clinical care can facilitate better detection and management of cancer- and treatment-related effects.[2,4] However, implementation strategies for incorporating PROs into clinical settings are poorly understood.[5] Further, given longstanding racial differences in symptom assessment and experiences (e.g., severity and frequency) among cancer patients[6–10] and limited evidence of effective strategies for mitigating such inequities, understanding Black-White racial differences in implementation

of PRO assessment in the clinical setting is important for advancing equity in symptom management.

Therefore, the goals of our study were to 1) assess the feasibility of enrollment and collecting PRO data as part of routine clinical care for follow-up of bladder and prostate cancer patients undergoing treatment for localized disease; and 2) examine racial variations in feasibility of PRO collection and in reported symptoms and function over time.

## Methods

### Design

Between May and September of 2017, we recruited 76 Black and White patients with prostate or bladder cancer from the University of North Carolina Genitourinary Oncology clinics (including Urology and Radiation Oncology). Patients were identified by treating providers, and identified as those receiving definitive treatment for localized bladder or prostate cancer. Given the objective to evaluate racial variations in feasibility of PRO collection, Black patients were oversampled. We collected PRO data most relevant to this patient population, including systems in the gastrointestinal, urinary, sexual function, anxiety/depression, and sleep domains. Patients completed these PRO surveys at three time points: 1) baseline (pre-treatment); 2) during treatment defined as radiation therapy or surgery (approximately 1 month after the start of treatment); and 3) after treatment (end of radiation therapy or 3 months after surgery, when possible two days before post-op appointment) (Figure 1). All data collection and participant tracking were completed using the UNC PRO Core system,[11] a survey system similar to REDCap or Qualtrics. Patient-Reported Outcomes Core (PRO Core) is a shared resource of the University of North Carolina's Lineberger Comprehensive Cancer Center. PRO Core provides scientific consultation to investigators during the grant writing and protocol development phases regarding the use of valid PRO instruments and specific approaches for data collection. The software platform provides state-of-the-art modalities and system features, including web-based and interactive voice response (IVR) surveys, computer adaptive testing (CAT), surveys administered in multiple languages, dyadic assessment (e.g., patient and caregiver), collection of data from activity trackers, real-time symptom reports and alerts for clinicians, longitudinal survey scheduling, automated reminders for participants and study staff, and survey compliance tracking. PRO Core supports single-site and multi-site studies, and the services are available to cancer center members as well as investigators from other institutions. For this study, the PRO Core system was configured to automatically generate study-specific surveys and customized PRO data reports. The surveys and reports were configured to be tailored to have different content based on whether the patient had prostate or bladder cancer, surgery or radiation, and was male or female.

At enrollment, patients completed baseline surveys in a private clinic room on a tablet, which included the baseline PRO surveys as well as demographic questions such as age, sex, education, income, and county of residence. Patients had the option of completing subsequent surveys from home via the PRO Core web-interface or automated phone survey via the PRO Core interactive voice response (IVR) system. Patients who did not feel comfortable completing questionnaires online were provided an option to complete a paper

survey. However, no patient requested this option. Summarized reports of the patient's PRO symptom scores and comparisons to prior time points were made available to patients and providers on paper prior to the clinical encounter (or mailed to the patient and hand-delivered to the provider) if the assessment was not associated with a clinical encounter (Figure 2). Clinical cancer characteristics were obtained through chart abstraction.

## PRO Measures

Several validated PRO measures were administered prior to, during, and 3 months following completion of oncologic treatment including: the Patient-Reported Outcomes Measurement Information System® (PROMIS®) Sleep Disturbance, Fatigue, Anxiety, Depression, Constipation (for surgical patients), Diarrhea (for radiation patients), Sexual Function and Satisfaction profile v.1.0; and Expanded Prostate Cancer Index Composite (EPIC) urinary domain or bladder cancer index urinary domain for prostate and bladder cancer patients, respectively.

All PROMIS measures were scored on the PROMIS T-score metric and can be interpreted relative to a US general population mean of 50 and standard deviation of 10. Higher scores for symptoms indicate worse symptom burden for Sleep Disturbance, Fatigue, Depression, Anxiety, GI Disturbance; and better symptom burden for Sexual Activity and Satisfaction.[12]

The EPIC urinary domain consists of 7 questions that address urinary habits such as leakage, hematuria, dysuria, urinary control, use of pads/diapers, and the bother associated with these symptoms.[13] Response items for each EPIC item were reported using a Likert scale, and domain scores were transformed to a 0–100 scale based upon scoring instructions, with higher score indicating better function.[13]

The Bladder Cancer Index (BCI) Urinary Domain consists of 9 questions and was developed from the EPIC questionnaire and adjusted for patients with bladder cancer.[14] Questions address emptying of bladder (or ostomy), leakage during daytime, leakage during sleep, and the bother associated with these symptoms. Similar to the EPIC questionnaire, domain scores were calculated by standardizing each Likert scale item to a 0 to 100 scale and determining the mean of the standardized items that comprise that domain, with higher scores indicating better health-related quality of life.

## Statistical Analysis

We defined feasibility of enrollment a priori as at least 40% of eligible patients who were approached about the study agreeing to enroll. Feasibility enrollment was based upon historic rates of prospective PRO study intervention enrollment at our institution. Based upon prior feasibility studies for questionnaire completion,[15,16] we defined feasibility of PRO questionnaire completion as at least 70% of study participants completing the PRO questionnaires at any distinct assessment time point. Linear mixed effects models were fit to estimate differences in feasibility by race, modality, cancer type and time. Localized cancer was defined as clinical or pathologic stage T2 or less; and locally advanced as T3 or greater. P-values <0.05 were defined as statistically significant. Analyses were performed using SAS v.9.4 (Cary, NC). This study was approved by the University of North Carolina at Chapel

Hill Institutional Review Board, and all patients provided informed consent for their participation.

## Results

The study sample included 76 patients (n=29 Black and n=47 White), 87% of whom were men and 64% who had prostate cancer (Table 1). Overall, 99% (80 of 81) of all eligible patients who were approached about the study agreed to enroll while an additional 5% (4 of 81) dropped out after enrolling. Prostate cancer patients had a median PSA of 8.1. Most patients had intermediate risk (57%) and clinically localized (<pT3) (92%) disease. Half of patients underwent radiation with the other half undergoing prostatectomy. Among bladder cancer patients, 58% had muscle invasive disease with 63% undergoing cystectomy and 33% receiving intravesical therapy. Nearly one quarter of patients had node positive disease following cystectomy.

A survey was administered at each of 3 time points (time point 1= baseline; time point 2 = 1st follow-up; time point 3 = 2nd follow-up). The administered survey included multiple (n=7) PRO measures. With regard to feasibility of completion, 67% of study participants completed at least one PRO measure at all three time points, and 63% of participants completed all 7 PRO measures at each time point (Figure 3). Black patients were less likely to complete at least one PRO measure at all three time points (55% vs 74%, p=0.13), as well as all surveys at each time point (52% vs 70%, p=0.14). Patients using IVR were also less likely to complete at least one PRO measure at all three time points (53% vs 71%, p=0.24), and particularly all surveys at each time point (41% vs 69%, p=0.046).

Survey completion varied by time point. At time point 1, 100% and 99% completed at least 1 PRO measure and all 7 PRO measures at baseline, respectively. At time point 2, 75% completed at least 1 PRO measure, with 72% completing all 7 PRO measures. At time point 3, 79% completed at least 1 PRO measure, with 76% completing all 7 PRO measures. Black patients were slightly less likely to complete surveys at follow up, with a significant difference noted at the time point 3, with 65% of Black patients completing at least one survey compared to 87% of White patients (p=0.04). Patients with bladder cancer were less likely to complete their surveys at time point 2 (p<0.01) but there were no significant differences across race. Finally, patients who chose IVR as their preferred survey mode were less likely to complete surveys, particularly at Time Point 3 with 59% of patients using IVR completing all surveys compared to 81% of those using the web (p=0.10).

## Discussion

Our study demonstrated the feasibility of incorporating PRO assessment into clinical care for both Black and White patients undergoing prostate and bladder cancer treatment and identified racial variations in preference for mode of data collection and survey completion rates. Given longstanding racial differences in symptom assessment and symptom experiences (e.g., severity, frequency) among cancer patients[6–10] and limited evidence of effective strategies for mitigating such inequities, this study is an important first step in

understanding how to effectively and equitably implement PRO assessment into the clinical cancer setting.

PRO assessment has been associated with improved outcomes. The link between PROs and survival was first suggested in 2011 in which patient and provider symptom reporting in 14 EORTC trials were predictive of survival, particularly for models that incorporated symptoms of fatigue, vomiting, nausea and constipation.[17] In a recent landmark study, oncology patients were randomized to usual care or PRO reporting, and patients in the PRO group demonstrated a 5-month improvement in overall survival.[18] Given the strong evidence supporting use of PROs in the clinical setting, attention has recently shifted to optimizing implementation of PRO assessments in clinical workflows. With >70% of questionnaires completed at each time point, our study findings suggest that electronic PROs are feasible among bladder and prostate cancer patients overall. These findings align with prior studies assessing feasibility of PRO collection in other disease sites such as stem cell transplantation. Among 390 enrolled patients, 74% completed PRO surveys, and PRO survey completion was associated with transplant outcomes.[19] Evidence from the orthopedic surgery literature has indicated even higher completion rates, with one study reporting electronic PRO completion rates of 93–95% following knee surgery.[20]

To date, there had been limited evidence on the feasibility of implementing PROs in routine clinical care for racially diverse patient groups. In our study, we found that Black patients were less likely than White patients to complete PRO surveys over time. One facet of equitable implementation may involve racial differences in preferences for data collection (i.e., web vs. IVR) In our study, we compared IVR to web-based reporting and found that Black patients were more likely to select IVR (38% Black vs. 13% White) and less likely to complete surveys, particularly at time point 3 (65% Black vs. 87% White). When investigating modality alone, IVR participants (regardless of race) were less likely to complete surveys, particularly at time point 3 (65% IVR vs. 83% Web-based), although this difference was not statistically significant. Different response rates by modality may be due to literacy barriers, internet access challenges, and/or usability issues, in which respondents lack the ability to repeat response options or change responses. The implications are that we may lose symptom data for subsets of the population who may prefer IVR due to socioeconomic factors. Thus, we may miss opportunities to intervene on problematic symptoms if relying on IVR as the sole mechanism to communicate symptom problems. Furthermore, IVR may be useful but may require optimization to achieve adequate completion rates. Additionally, the length of the questionnaire may have been more onerous or burdensome on the IVR than on the web interface, as the time it takes to listen to the question and response options is longer than the time it takes to read the question and response options for most respondents.

Our findings provide evidence that supplements prior evaluations of acceptability of various data collection modes.[21] A different study tested administration of the PRO-CTCAE in three modes: web-enabled touchscreen tablet computer, IVR, and paper.[21] Among 112 participants across seven US sites, 92% completed questionnaires by all three modes but did note that IVR required more time. The proportion of participants that reported “no problems” was higher for tablet (86%) and paper-based (98%) reporting but lower for IVR

(72%). Likely, preference for PRO modality depends on the patient population and their comfort with technology, and must be taken into account when considering the collection of PROs across broad and diverse populations.

This study provides important and novel information regarding racial differences in the collection of PROs in cancer care; however, it has several limitations. First, our study included a small sample size which may limit our ability to detect small but clinically significant differences in outcomes over time. Second, our study was conducted at a single site, which may limit generalizability. Finally, our study is limited to Black and White bladder and prostate cancer patients, and therefore results may not generalize to other racial/ethnic groups (e.g., Latinos) or disease sites. Nevertheless, our study is the first to report racial differences in preferences for PRO administration modes and feasibility following bladder and prostate cancer treatment. Given that thorough and accurate assessment of symptoms facilitate timely symptom management yet longstanding racial differences in symptom burden exist, accounting for racial differences in PRO use and preferences is critical to advancing equity and optimizing cancer care outcomes. Future studies should investigate drivers for differences in symptom experience as well as investigate potential racial disparities in how symptoms are gathered and managed by the care team.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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## HIGHLIGHTS

- Preferences for survey mode delivery differ by race, with Black patients more likely to select interactive voice response compared to White patients
- Patients who select interactive voice response for questionnaire completion were less likely to complete surveys when compared to those using web-based surveys
- Bladder cancer patients were less likely to complete electronic patient-reported outcomes when compared to prostate cancer patients

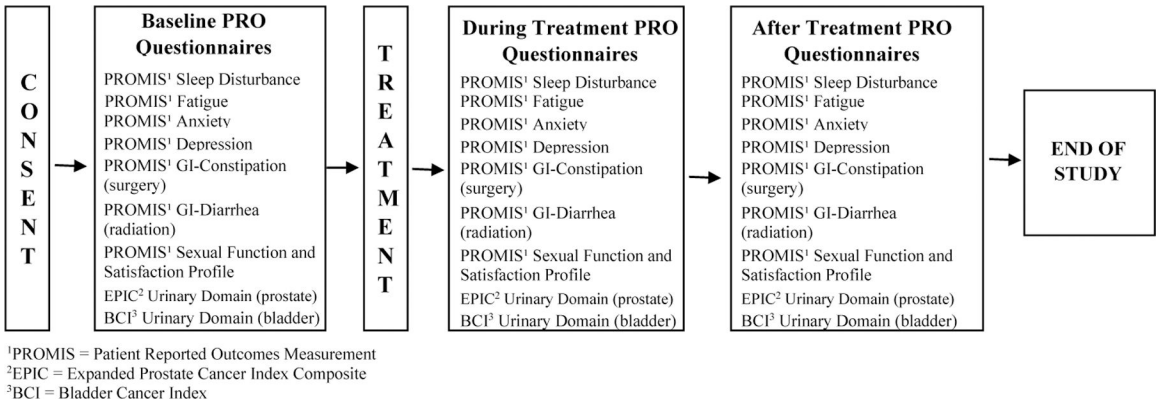


**Figure 1:**

Study Design

[1]PROMIS = Patient-Reported Outcomes Measurement Information System

[2]EPIC = Expanded Prostate Cancer Index Composite

[3]BCI = Bladder Cancer Index

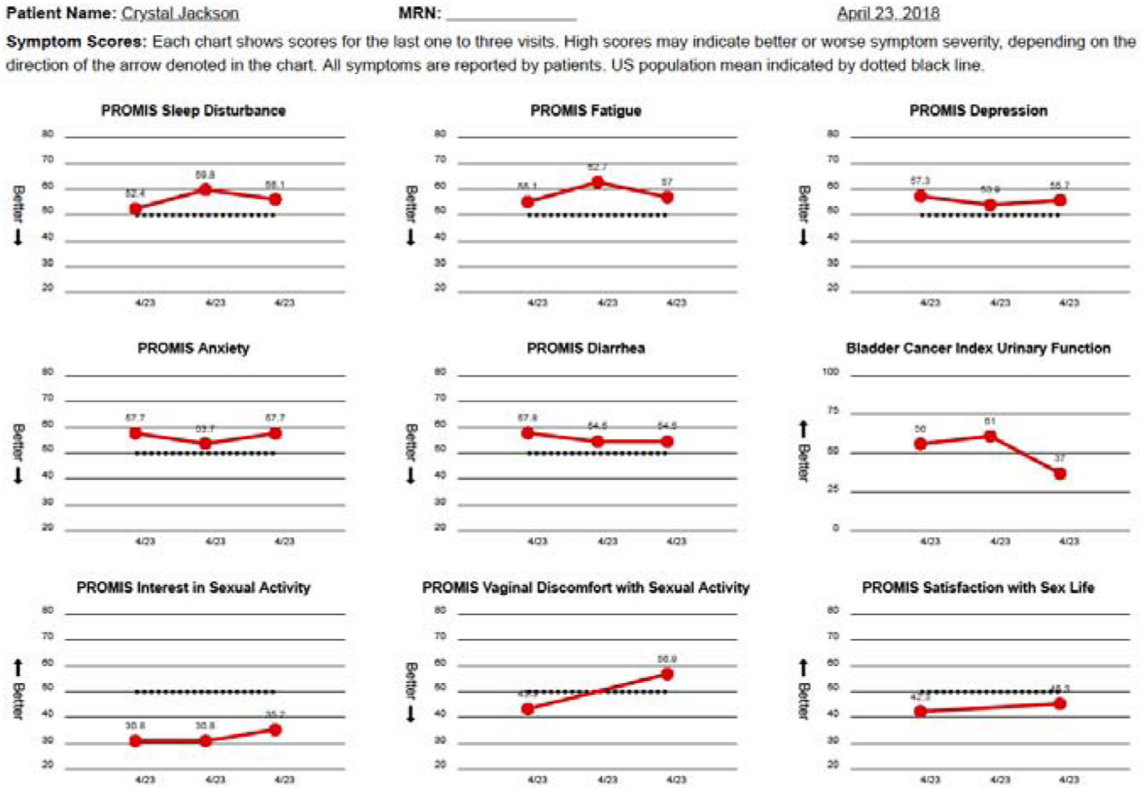


**Figure 2:**

Example of Patient- and Provider-Facing PRO Symptom Summary Report*

*Name and data are not from an actual patient

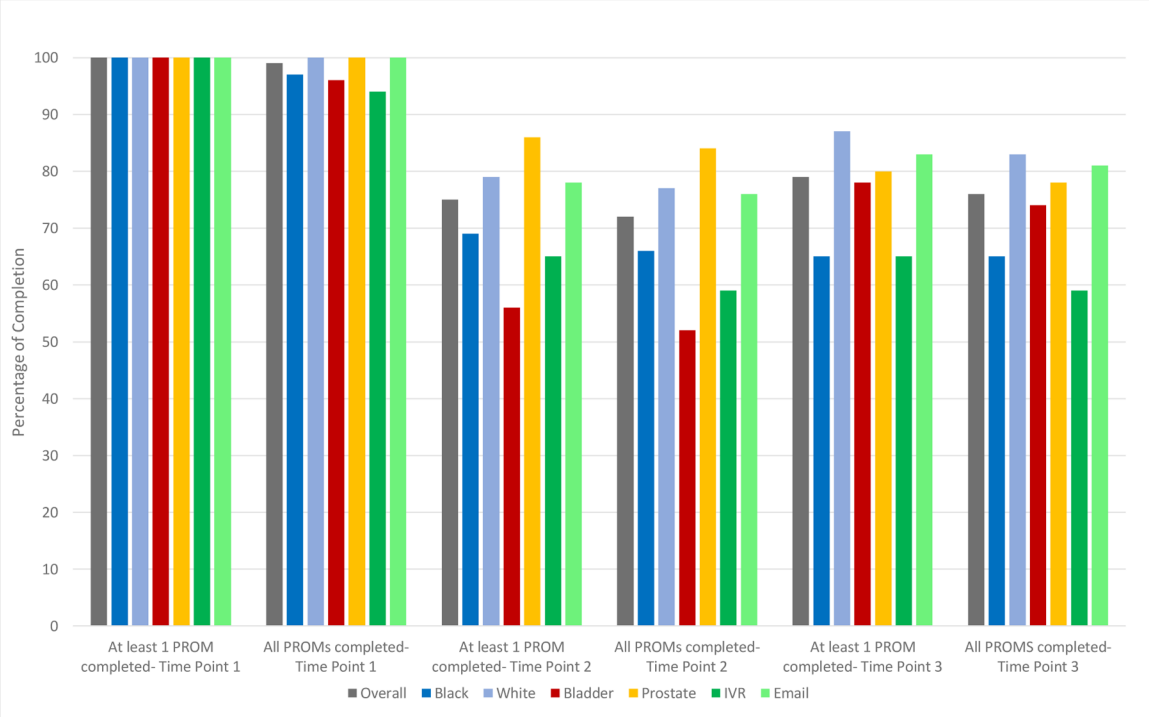


**Figure 3:**

Completion Feasibility for PRO Measures

*PROM = patient-reported outcome measure

**Table 1:**

Characteristics of Enrolled Patients by Race

| | | Overall (n=76) | Black (n=29) | White (n=47) | p-value |
|---|---|---|---|---|---|
| Median Age | | 66 (IQR 59–71) | 61 (IQR 56–71) | 68 (IQR 63–72) | 0.09 |
| Gender | Male | 66 (87%) | 24 (83%) | 42 (89%) | 0.49 |
| | Female | 10 (13%) | 5 (17%) | 5 (11%) | |
| Cancer Type | Prostate | 49 (64%) | 20 (69%) | 29 (62%) | 0.62 |
| | Bladder | 27 (36%) | 9 (31%) | 18 (38%) | |
| Education Status | High school or less | 19 (25%) | 10 (34%) | 9 (19%) | 0.23 |
| | Some college/vocational/ tech school | 22 (29%) | 9 (31%) | 13 (28%) | |
| | College | 19 (25%) | 7 (24%) | 12 (26%) | |
| | Graduate School | 16 (21%) | 3 (10%) | 13 (28%) | |
| Marital Status† | Married, living with partner | 58 (76%) | 18 (62%) | 40 (85%) | 0.03 |
| | Widowed, divorced, separated, never married | 18 (24%) | 11 (38%) | 7 (15%) | |
| Current Employment Status† | Full- or part-time employment | 27 (36%) | 6 (22%) | 21 (45%) | 0.04 |
| | Medical leave or unemployed | 5 (7%) | 4 (15%) | 1 (2%) | |
| | Retired | 42 (57%) | 17 (63%) | 25 (53%) | |
| Health Insurance† | Medicaid | 9 (12%) | 7 (25%) | 2 (4%) | 0.03 |
| | Medicare or Tricare | 30 (41%) | 13 (46%) | 17 (38%) | |
| | Medicare w/ supplemental | 14 (19%) | 3 (11%) | 11 (24%) | |
| | Private health insurance | 20 (27%) | 5 (18%) | 15 (33%) | |
| Patient-Preferred Delivery Method at Baseline† | IVR | 17 (22%) | 11 (38%) | 6 (13%) | 0.02 |
| | Web | 59 (78%) | 18 (62%) | 41 (87%) | |
| | | | | | |
| **Prostate Cancer Specific Characteristics** | | | | | |
| | | **Overall (n=49), 100%** | **Black (n=20)** | **White (n=29)** | |
| Median PSA at diagnosis | | 8.1 (IQR 5.1–13.4) | 7.8 (IQR 4.7–14.1) | 8.2 (IQR 5.7–13.4) | |
| Gleason Score from Biopsy | 6 | 4 (8%) | 0 (0%) | 4 (14%) | |
| | 7 | 24 (49%) | 7 (35%) | 17 (59%) | |
| | 8 | 6 (12%) | 2 (10%) | 4 (14%) | |
| | 9 | 12 (24%) | 8 (40%) | 4 (14%) | |
| | 10 | 3 (6%) | 3 (15%) | 0 (0%) | |
| Clinical Stage* | T1 | 39 (80%) | 16 (80%) | 23 (79%) | |
| | T2 | 6 (12%) | 0 (0%) | 6 (21%) | |
| | T3 | 4 (8%) | 4 (20%) | 0 (0%) | |
| Pathologic Stage | T2 | 12 (48%) | 3 (30%) | 9 (60%) | |
| | T3 | 13 (52%) | 7 (70%) | 6 (40%) | |

| | | Overall (n=76) | Black (n=29) | White (n=47) | p-value |
|---|---|---|---|---|---|
| Treatment modality | -Radiation w/ADT | 17 (35%) | 9 (45%) | 8 (28%) | |
| | -Radiation Only | 7 (14%) | 1 (5%) | 6 (21%) | |
| | -Prostatectomy Only | 24 (49%) | 9 (45%) | 15 (52%) | |
| | -Prostatectomy w/ ADT | 1 (2%) | 1 (5%) | 0 (0%) | |
| | | | | | |
| **Bladder Cancer Specific Characteristics** | | | | | |
| | | **Overall (n=), %** | **Black (n=), %** | **White (n=), %** | |
| Clinical Stage* | T1 | 11 (42%) | 2 (25%) | 9 (50%) | |
| | T2 | 13 (50%) | 5 (63%) | 8 (44%) | |
| | T3 | 2 (8%) | 1 (12%) | 1 (6%) | |
| Pathologic T Stage | T0 | 5 (29%) | 2 (40%) | 3 (25%) | |
| | Tis | 1 (6%) | 0 (0%) | 1 (8%) | |
| | T1 | 1 (6%) | 0 (0%) | 1 (8%) | |
| | T2 | 4 (24%) | 2 (40%) | 2 (17%) | |
| | T3 | 3 (18%) | 0 (0%) | 3 (25%) | |
| | T4 | 3 (18%) | 1 (20%) | 2 (17%) | |
| Pathologic N Stage | N0 | 13 (76%) | 3 (60%) | 10 (83%) | |
| | N1 | 1 (6%) | 0 (0%) | 1 (8%) | |
| | N2 | 3 (18%) | 2 (40%) | 1 (8%) | |
| Treatment modality | Intravesical therapy | 9 (33%) | 4 (44%) | 5 (28%) | |
| | TURBT | 10 (37%) | 4 (44%) | 6 (33%) | |
| | Radiation | 2 (7%) | 0 (0%) | 2 (11%) | |
| | Chemotherapy | 10 (37%) | 3 (33%) | 7 (39%) | |
| | Cystectomy | 17 (63%) | 5 (56%) | 12 (67%) | |

† $p<0.05$

* No patients had cN+ or metastatic disease