Relief of Urinary Symptom Burden after Primary Prostate Cancer Treatment


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Purpose: Harms of prostate cancer treatment on urinary health related quality of life have been thoroughly studied. In this study we evaluated not only the harms but also the potential benefits of prostate cancer treatment in relieving the pretreatment urinary symptom burden.

Materials and Methods: In American (1,021) and Spanish (539) multicenter prospective cohorts of men with localized prostate cancer we evaluated the effects of radical prostatectomy, external radiotherapy or brachytherapy in relieving pretreatment urinary symptoms and in inducing urinary symptoms de novo, measured by changes in urinary medication use and patient reported urinary bother.

Results: Urinary symptom burden improved in 23% and worsened in 28% of subjects after prostate cancer treatment in the American cohort. Urinary

**Abbreviations and Acronyms**
- AUA-SI = American Urological Association Symptom Index
- BMI = body mass index
- BT = brachytherapy
- EPIC-26 = Expanded Prostate Cancer Index Composite short form
- HRQOL = health related quality of life
- LUTS = lower urinary tract symptoms
- PROST-QA = Prostate Cancer Outcomes and Satisfaction with Treatment Quality Assessment
- RP = radical prostatectomy
- XRT = external radiotherapy

Editor’s Note: This article is the *** of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages *** and ***.
medication use rates before treatment and 2 years after treatment were 15% and 6% with radical prostatectomy, 22% and 26% with external radiotherapy, and 19% and 46% with brachytherapy, respectively. Pretreatment urinary medication use (OR 1.4, 95% CI 1.0–2.0, p = 0.04) and pretreatment moderate lower urinary tract symptoms (OR 2.8, 95% CI 2.2–3.6) predicted prostate cancer treatment associated relief of baseline urinary symptom burden. Subjects with pretreatment lower urinary tract symptoms who underwent radical prostatectomy experienced the greatest relief of pretreatment symptoms (OR 4.3, 95% CI 3.0–6.1), despite the development of deleterious de novo urinary incontinence in some men. The magnitude of pretreatment urinary symptom burden and beneficial effect of cancer treatment on those symptoms were verified in the Spanish cohort.

**Conclusions:** Men with pretreatment lower urinary tract symptoms may experience benefit rather than harm in overall urinary outcome from primary prostate cancer treatment. Practitioners should consider the full spectrum of urinary symptom burden evident before prostate cancer treatment in treatment decisions.

**Key Words:** prostatic neoplasms, quality of life, outcome assessment (health care), surveys and questionnaires, patient-centered care

DEFINITIVE treatment of localized prostate cancer often occurs in an age distribution of men in whom preexisting LUTS from benign prostatic hyperplasia or the local effects of prostate cancer are already a significant health problem. However, most analyses do not account for baseline urinary health related quality of life, and focus purely on the negative effects of treatment, failing to consider the full spectrum of potential posttreatment changes in urinary symptom burden, including the possibility of symptom relief.

While several prospective multicenter studies have investigated the effects of prostate cancer treatment on urinary HRQOL, few have examined urinary medication use and/or operative interventions, and most have focused on urinary incontinence as the primary outcome. The relative degree to which patients are bothered by urinary incontinence and LUTS is unclear. Outcomes are often reported as changes in mean HRQOL scores across treatment groups, which favors a one size fits all approach that obscures the diversity of individual changes within treatment groups, ie who is getting worse, staying the same or getting better. Achievement of patient centered care and individualized adjustment of urinary outcome expectations requires an understanding of how patient pre-treatment HRQOL and other factors may influence the potential for symptom worsening or symptom relief after treatment.

We previously described a multicenter, prospective study evaluating HRQOL outcomes after RP, XRT and BT. To better understand which patients experience a worsened, unchanged or improved urinary symptom burden after prostate cancer treatment, as well as the relative impact of urinary incontinence and LUTS, we reevaluated this cohort after all participants had completed at least 2 years of followup, and described urinary medication use, operative interventions and changes in overall urinary symptom burden. We used ordinal logistic regression to identify significant predictors of urinary outcome changes after prostate cancer treatment.

**METHODS**

**Study Subjects**

The PROST-QA cohort consists of 1,201 men with previously untreated stage T1 to T2 prostate cancer. They were enrolled from 2003 to 2006 at 9 university affiliated hospitals into an institutional review board approved protocol after providing written informed consent. We analyzed the 1,021 cohort participants who had complete 2-year urinary HRQOL followup, including 522 treated with RP, 239 who received XRT and 260 treated with BT.

**Treatment**

RP was performed with open retropubic (335) or laparoscopic/robotic (187) techniques. Overall 92% of patients underwent unilateral or bilateral nerve sparing surgery. Of the men who underwent XRT 84% had intensity modulated radiation therapy (the remainder had conformal beam) and 31% received neoadjuvant hormonal therapy. BT was performed transperineally with permanent low dose rate isotopes (typically I-125). Adjuvant/salvage hormonal therapy rates within 2 years were low (less than 5%).

**Outcome Measures**

Patient reported outcomes were collected prospectively by a third party telephone survey facility before treatment through 2 years after treatment. We measured urinary incontinence using the EPIC-26, and we measured LUTS using the EPIC-26 and the AUA-SI. We measured subject global urinary symptom burden with the EPIC-26 overall urinary bother question, “Overall, how much of a problem has your urinary function been for you?” measured on a 5-point Likert scale (no problem to big problem).
Case report forms collected data on urinary medication use before and after treatment as well as the incidence of operative interventions. Operative interventions were categorized as 1) urinary reconstruction, eg artificial urinary sphincter, male urinary sling, urethropasty; 2) hospitalization for urinary complication; 3) endoscopic/minimally invasive intervention with intent to repair/diagnose a urinary complication; 4) any urinary catheterization and 5) diagnostic cystoscopy. An adjudication panel comprised of a non-treating urologist and radiation oncologist blinded to treatment type determined operative category. The principal investigator resolved lack of consensus. Subjects with multiple interventions in the same category were counted once and those with interventions in different categories were counted once per category. We classified urinary medications as alpha blockers, 5-alpha reductase inhibitors and anticholinergics. Pretreatment medications excluded the prophylactic initiation of alpha blockers immediately before BT.

Statistical Considerations
We used longitudinal logistic regression with generalized estimating equations to compare the use of urinary medications among groups over time, and logistic regression to compare the incidence of urinary interventions among groups.

In each treatment group we examined how each individual subject’s overall symptom burden changed from before treatment to 2 years after treatment. To capture the magnitude and direction of change we categorized this bother change into a 5-item ordinal scale of −2—major worsening, −1—minor worsening, 0—no change, 1—minor improvement and 2—major improvement, where minor indicates a 1-point change and major refers to a 2-point or greater change. We used ordinal logistic regression to identify factors that predicted a higher ordinal score across all levels of urinary bother change (ie a more favorable or less unfavorable change in urinary symptom burden). Several covariates were considered, including age, race, cohabitation, education level, comorbidities, BMI, D’Amico risk group,17 prostate size, pretreatment use of urinary medications, pretreatment LUTS and pretreatment incontinence. We used backward elimination to identify the variables retained in the multivariable model with an inclusion threshold of p < 0.10. We tested for interaction between treatment group and the strongest outcome predictor.

External Validation
The Multicentric Spanish Group of Clinically Localized Prostate Cancer,10 known as the Spanish cohort, served as an external validation cohort. Of the 614 subjects who completed the 2-year follow-up and met the Spanish cohort original inclusion and exclusion criteria, 539 had the equivalent demographic and HRQOL information from before treatment to 2 years after treatment that was examined in the PROST-QA analysis. Several covariates including medication use were not available for comparison. To determine whether the factors predictive of urinary outcome change would replicate in an independent cohort, we performed ordinal logistic regression as previously described.

RESULTS
We describe treatment group characteristics in table 1 as well as previously described detailed trends in urinary HRQOL from before treatment to 2 years after treatment.12 Pretreatment incontinence was rare (table 2). Pretreatment moderate to severe LUTS were common throughout the cohort

Table 1. Pretreatment patient and disease characteristics in the PROST-QA cohort

<table>
<thead>
<tr>
<th></th>
<th>RP</th>
<th>XRT</th>
<th>BT</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age at enrollment (IQR)*</td>
<td>60 (56–65)</td>
<td>69 (63–74)</td>
<td>66 (61–71)</td>
<td>63 (58–68)</td>
</tr>
<tr>
<td>No. race (%)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>25 (5)</td>
<td>34 (14)</td>
<td>28 (11)</td>
<td>87 (9)</td>
</tr>
<tr>
<td>Other</td>
<td>497 (95)</td>
<td>205 (86)</td>
<td>232 (89)</td>
<td>534 (91)</td>
</tr>
<tr>
<td>Median kg/m² BMI (IQR)</td>
<td>27 (25–30)</td>
<td>28 (25–31)</td>
<td>28 (25–31)</td>
<td>28 (25–31)</td>
</tr>
<tr>
<td>No. cohabitation (%)*</td>
<td>456 (87)</td>
<td>187 (78)</td>
<td>207 (80)</td>
<td>850 (83)</td>
</tr>
<tr>
<td>No. comorbidities (%)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-1</td>
<td>402 (77)</td>
<td>144 (60)</td>
<td>172 (66)</td>
<td>718 (70)</td>
</tr>
<tr>
<td>2</td>
<td>82 (16)</td>
<td>58 (24)</td>
<td>59 (23)</td>
<td>199 (19)</td>
</tr>
<tr>
<td>3+</td>
<td>38 (7)</td>
<td>37 (15)</td>
<td>29 (11)</td>
<td>104 (10)</td>
</tr>
<tr>
<td>Median ml prostate vol (IQR)*</td>
<td>40 (30–52)</td>
<td>42 (30–59)</td>
<td>36 (29–47)</td>
<td>39 (30–53)</td>
</tr>
<tr>
<td>Median ng/ml PSA (IQR)*</td>
<td>5.5 (4.2–7.5)</td>
<td>6.3 (4.3–9.7)</td>
<td>5.2 (4.2–6.8)</td>
<td>5.5 (4.2–7.8)</td>
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<tr>
<td>No. clinical T stage (%)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cT1</td>
<td>374 (72)</td>
<td>164 (69)</td>
<td>214 (82)</td>
<td>752 (74)</td>
</tr>
<tr>
<td>cT2</td>
<td>148 (28)</td>
<td>75 (31)</td>
<td>46 (18)</td>
<td>239 (26)</td>
</tr>
<tr>
<td>No. Gleason score on initial biopsy (%)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 or Less</td>
<td>316 (61)</td>
<td>105 (44)</td>
<td>199 (77)</td>
<td>602 (61)</td>
</tr>
<tr>
<td>7</td>
<td>181 (35)</td>
<td>100 (42)</td>
<td>60 (23)</td>
<td>341 (33)</td>
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<tr>
<td>8–10</td>
<td>25 (5)</td>
<td>34 (14)</td>
<td>1 (0)</td>
<td>60 (6)</td>
</tr>
<tr>
<td>No. D’Amico risk group (%)17,*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>275 (53)</td>
<td>84 (35)</td>
<td>184 (71)</td>
<td>543 (53)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>205 (38)</td>
<td>106 (44)</td>
<td>72 (29)</td>
<td>383 (38)</td>
</tr>
<tr>
<td>High</td>
<td>42 (8)</td>
<td>49 (21)</td>
<td>4 (2)</td>
<td>95 (9)</td>
</tr>
</tbody>
</table>

* Treatment groups differed in distributions of age, race, marital/living status, number of comorbidities, prostate volume, PSA, clinical stage, Gleason score and D’Amico risk group (each p < 0.01).12
Subjects treated with RP had a clinically significant decrease (worsening) in mean EPIC-26 incontinence score (−14 ± 24 points, p < 0.001)\textsuperscript{18} and a clinically significant increase in mean EPIC-26 irritation/obstruction score (improved LUTS) 2 years after treatment (5 ± 15, p < 0.001). Subjects who received BT had clinically significant worsening of mean incontinence (−6 ± 19 points, p < 0.001) and irritation/obstruction (−6 ± 18, p < 0.001) scores from before to 2 years after treatment.

**Urinary Medication Use and Operative Intervention**

The pretreatment rate of urinary medication use differed among the groups (p = 0.03) and was lowest in those treated with RP. The proportion of subjects treated with RP requiring urinary medications decreased significantly from before (15%) to after treatment (6%). Of the 76 men in the RP group taking a pretreatment urinary medication 84% were able to discontinue the medication and 28% started a new medication, most commonly an anticholinergic (supplementary table 1, http://jurology.com/).

Urinary medication use was unchanged after XRT (26% vs 22% before treatment). After brachytherapy urinary medication use increased significantly (46% vs 19% before treatment, p < 0.001), with 43% of patients taking alpha blockers at 2 years compared to 14% before treatment. Overall 75 (36%) subjects in the BT group who were not taking urinary medications before BT started and remained on a new urinary medication at 2 years after BT (supplementary table 1, http://jurology.com/).

The rate of operative interventions for post-treatment urinary complications was not statistically significantly different among the treatment groups (p = 0.20, table 2). Most urinary reconstructive procedures were performed in the RP group. The BT group had the highest proportion of men undergoing unplanned urethral catheterization and diagnostic cystoscopy.

**Changes in Overall Urinary Symptom Burden**

We examined how subjects’ global perception of urinary symptom burden (overall urinary bother)
changed from before treatment to 2 years after treatment (supplementary tables 2–5, http://jurology.com/). Of the entire cohort 23% reported improvement and 28% reported worsening of urinary problems. The RP and XRT treatment groups each had approximately equal proportions of subjects perceiving urinary improvement and worsening (28% and 27% for RP; 25% and 24% for XRT, respectively). The proportion of the RP group with moderate to severe urinary bother decreased from 11% to 7% after treatment (p = 0.01), despite worse overall incontinence. This proportion was unchanged in the XRT group and significantly increased in the BT group (8% before BT vs 14% after BT, p = 0.005), with subjects who were more likely to have worsened urinary problems 2 years after treatment (37% worsened, 12% improved).

We then performed multivariable ordinal logistic regression to identify pretreatment factors predictive of favorable pretreatment to posttreatment change in overall urinary symptom burden over a 5-point ordinal scale from major worsening to major improvement (table 3). For all treatment groups the most powerful positive predictor of favorable (or less unfavorable) change in urinary bother was the presence of moderate to severe (AUA-SI 8 or greater) pretreatment LUTS (OR 2.8, 95% CI 2.2–3.6, p <0.001). Pretreatment urinary medication use was also a significant positive predictor (OR 1.4, 95% CI 1.0–2.0, p = 0.04). Baseline incontinence was not significant (p = 0.4). There was significant effect modification between the most powerful outcome predictor (baseline LUTS) and treatment group (p = 0.003, table 3). This was especially pronounced in subjects treated with RP, for whom having pretreatment LUTS conferred a greater than 4 times higher odds of urinary symptom relief from before to after treatment (OR 4.3, 95% CI 3.0–6.1, p <0.001). This interaction between treatment group and pretreatment LUTS is illustrated in the figure. Of the subjects in the RP group with pretreatment LUTS 52% reported improvement in urinary bother after treatment and 21% reported worsening. Of the 52 (10%) subjects treated with RP with pretreatment LUTS and urinary medication use 76% reported improvement (48% major, 28% minor) after RP (supplementary table 6, http://jurology.com/). More patients in the BT group with preexisting LUTS had symptom worsening vs improvement after treatment (31% and 26%, respectively).

We found similar results on analysis of a separate, previously described Spanish cohort (supplementary table 7, http://jurology.com/). On ordinal logistic regression pretreatment LUTS was the most significant predictor of favorable change in overall urinary bother (OR 1.7, p = 0.01), and there was significant interaction between this effect and treatment group (p = 0.01). The effect of pretreatment LUTS on favorable urinary bother change was again most prominent with RP (OR 4.15, p <0.001), but nonsignificant for XRT and BT (OR 0.85 and 1.66, respectively, p >0.05).

### Relative Impact of Urinary Incontinence and Irritation/Obstruction

We then investigated the relative effects of incontinence and irritation/obstruction on overall urinary bother by further evaluating those in the RP group who reported pretreatment moderate to severe LUTS (table 4). Most subjects whose urinary incontinence after RP was mild (0 to 1 pads per day) preferred their posttreatment urinary state to their pretreatment state (63% of patients reported improvement, 10% reported symptom worsening), while severe incontinence (3+ pads per day) negated any relief gained from improvement in LUTS. Overall urinary bother for all subjects was more closely correlated with urinary irritation/obstruction score (Spearman correlation 0.70) than urinary incontinence score (Spearman correlation 0.55).

### DISCUSSION

The deleterious effects of prostate cancer treatment on urinary function have been studied extensively.5,19–22 Our study highlights the prevalence and importance of burdensome pretreatment urinary problems in men with prostate cancer, and further examines how treatment induced changes affect patients' urinary quality of life, an inherently subjective concept that incorporates patients' individual perceptions of problems and the efforts required to mitigate them.
LUTS were a substantial pretreatment problem in this cohort. Overall 37% of the men had AUA-SI scores that indicated moderate to severe symptoms and 17% were on pretreatment urinary medications. These rates are comparable to those in men of a similar age without prostate cancer in population based cohorts, and are less than those of men on observation for early stage prostate cancer, of whom 49% reported moderate to severe symptoms. To our knowledge, this is the first multicenter prospective study to report the pretreatment and posttreatment rate of urinary medication use. Urinary medications may not only influence urinary HRQOL domain scores, but themselves constitute an often unmeasured quality of life and cost burden, as medications being taken 2 years after treatment are likely needed on a lifelong basis. Our findings suggest that those studies that report urinary problems after BT occurring primarily in the acute setting may fail to account for the increase in alpha blocker use from before treatment (14%) to after treatment (43%), and likely underestimate the long-term effects of treatment.

A Swedish randomized trial comparing RP to watchful waiting in a cross-sectional analysis found that a smaller proportion of men experienced posttreatment obstructive LUTS after RP than watchful waiting, but was limited by the lack of pretreatment urinary HRQOL assessment. Several other studies have suggested urinary obstruction relief after RP, but neither identified individual characteristics predisposing to favorable outcome nor assessed urinary medication use. Most studies report outcomes as changes in mean function scores, which can mask changes for individual subjects in treatment groups. Stratification by pretreatment function can help elucidate individual changes as suggested in a single center study.

We chose to further investigate changes in subjects’ global perceptions of urinary symptom burden by examining overall urinary bother, which encompasses urinary incontinence and

| Table 4. Effect of posttreatment urinary incontinence severity on ordinal change in overall urinary bother in patients treated with RP with moderate to severe pretreatment LUTS |
|---|---|---|---|---|---|
| No. of incontinence pads/day | −2 | −1 | 0 | 1 | 2 |
| No. (%) of total | 680 |
| 0 | 681 |
| 1 | 682 |
| 2 | 683 |
| 3+ | 684 |
irritation/obstruction. By analyzing this outcome in a novel, ordinal fashion, we captured the full spectrum of potential changes in urinary quality of life, including the direction (worsening vs improved) and degree (major vs minor) of HRQOL change. Our use of ordinal logistic regression allowed us to identify pretreatment LUTS as a factor that should not be ignored when counseling patients on what to expect in terms of urination after treatment.

Urinary incontinence was a sufficiently substantial problem after RP that more than 20% of subjects with pretreatment LUTS reported worse overall urinary problems after surgery despite the potential for LUTS relief. Previous urinary HRQOL studies examining urinary function and bother have suggested that subjects may find LUTS more bothersome than incontinence.\textsuperscript{20,29} Our data are consistent with this finding. Subjects treated with RP reported the lowest rate of posttreatment moderate to severe urinary problems, and those with pretreatment LUTS mostly found posttreatment incontinence less bothersome than pretreatment symptoms as long as the incontinence was mild.

This study has several limitations. As a nonrandomized study, selection bias makes comparisons among treatment groups challenging. However, such comparisons were not a goal of this analysis as we focused on outcome changes from before to after treatment in each group and aimed to identify subject characteristics that may predict a more favorable posttreatment outcome. While our results may be affected by floor/ceiling effects, we do not believe they explain the magnitude of interaction between pretreatment LUTS and treatment group, especially for RP. Overall urinary bother is a complex entity that may not only represent a global assessment of urinary status and function, but may also encompass more abstract notions such as perceived cancer cure, coping mechanisms and patient expectations. However, a patient’s experience and perception of urinary status may be the ultimate measure of urinary quality of life, an inherently subjective concept.

CONCLUSIONS

The preexisting urinary problems of patients heavily influence the wide spectrum of changes in urinary symptom burden seen after prostate cancer treatment. In a setting where adverse urinary consequences are common, the possibility of identifying those who may experience urinary symptom improvement should not be ignored. The impact of individualized assessment of pretreatment urinary symptoms and its potential effect on prostate cancer treatment decision making warrant further study.

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REFERENCES


EDITORIAL COMMENT

The findings of the PROST-QA Consortium are a welcome validation for those who continue to be enthusiastic regarding prostatectomy. As suggested by previous reports and long-standing urological dogma, men with significant pretreatment LUTS have improved voiding symptoms after
prostatectomy, as long as incontinence is mild. Meanwhile, men with significant LUTS who receive radiation (in particular, brachytherapy) fare worse after treatment.

One might expect androgen ablation to have an impact on LUTS. Nevertheless, in a multivariable model androgen ablation was not a significant factor for urinary bother. This may be due to a lack of granular data relating to the relative timing of the questionnaire and androgen ablation administration.

This study gives us a uniquely nuanced understanding of urinary symptomatology after primary treatment.1,2 Importantly these findings equip providers with guidance for patient selection. These data will need to be integrated into future quality adjusted life expectancy decision analyses to help objectify clinical decision making.3

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