

# Radical Prostatectomy for the Treatment of Moderate to Severe Lower Urinary Tract Symptoms in Organ-Confined Prostate Cancer

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Authors' disclosures of potential conflict of interest are found at the end of this article.

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## Abstract

A diagnosis of prostate cancer in men who have moderate to severe lower urinary tract symptoms (LUTS) frequently results in a recommendation to undergo radical prostatectomy. The rationale for this recommendation is that removal of the prostate will treat the prostate cancer and eliminate or minimize urinary symptoms, thus improving the patient's quality of life. The aim of this review is to summarize the current literature on men with prostate cancer and moderate to severe LUTS who undergo radical prostatectomy. This review is specific to the postoperative treatment impact on symptoms. We conclude that LUTS is a complex symptoms issue that cannot be answered with a straightforward, single recommendation. Patients require extensive education on treatment outcome risks; advanced practitioners working with this patient population are ideal candidates to provide this intervention. Although postoperative outcomes provide significant hope for resolution or improvement in moderate to severe symptoms of preoperative LUTS, the postoperative risk for urinary incontinence exists.

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**I**n the United States, prostate cancer is the most commonly diagnosed solid tumor and the second leading cause of cancer death in men (Jemal, Siegel, Xu, & Ward, 2010). The dilemma for most men diagnosed with organ-confined, clinically localized prostate cancer is that several treatment options are associated with comparable 10-year survival rates (American Cancer Society, 2009). Although

treatment-specific survival rates may each exceed 90%, specific side effects for each treatment option may differ and adversely affect a patient's quality of life (QOL; American Cancer Society, 2009).

Multiple options often make decision-making for prostate cancer treatment complex. Accessible, practical, and objective information should be available to patients to provide direction regarding treatments that maxi-

mize the opportunity for a cancer-free outcome while minimizing treatment side effects. Advanced practitioners can be critical in providing this information to patients. Therefore, clinician recommendations and guidance about appropriate treatment options should include treatment-specific considerations of age, stage, and grade of cancer, in addition to treatment-specific outcomes such as risk of exacerbation of current urinary symptoms, risk of incontinence, and risk of erectile dysfunction. Additionally, patient-specific comorbidities, which may have an impact on posttreatment outcomes, must be considered.

## Background

Lower urinary tract symptoms (LUTS) is a term used to describe a variety of urinary symptoms (Pillay, Marshall, & Pinnock, 2000). In men, LUTS commonly include urinary storage or voiding disturbances with one or more of the following symptoms: urinary frequency, nocturia, urgency with incontinence, urgency without incontinence, hesitation or difficulty initiating the stream, a weak or diminished urinary stream, a sense of incomplete emptying of the bladder, and dysuria (Dorey, 2000a; Pillay, Marshall, & Pinnock, 2000). The prevalence of LUTS increases with age, with 25% to 30% of men age 50 and older reporting moderate to severe symptoms (Dorey, 2000a; Schwartz & Lepor, 1999). Likewise, the risk for prostate cancer increases with age; the lifetime risk is 1 in 6 men (American Cancer Society, 2009).

Men who have moderate to severe LUTS when diagnosed with prostate cancer frequently receive a primary recommendation to undergo radical prostatectomy (RP) (Slova & Lepor, 2007). The clinician's rationale for this approach is that removing the prostate not only removes the cancer but also eliminates or minimizes urinary symptoms and thus improves QOL. However, conflicting information currently exists in the literature for the impact of prostatectomy on LUTS. The purpose of this review is to summarize the current literature on men with moderate to severe LUTS who have undergone RP to treat prostate cancer, with a specific focus on the treatment impact on LUTS.

## Methods

A literature search was conducted to identify articles that specifically addressed the postopera-

tive effect of RP in patients with prostate cancer who had moderate to severe preoperative LUTS. The following databases were searched: Ovid MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), SCOPUS, and the Cochrane Library. The following search terms were used: "lower urinary tract symptoms" plus "prostate cancer" plus "prostatectomy." Because QOL is broadly defined as a reflection of each individual's perception, which may include various contextual issues (Campbell, 1976), it was not the focus of this review.

Quality-of-life issues were included as an outcome variable in this systematic review, but only when discussed within the context of the identified articles. As long-term data do not exist for all surgical approaches, no distinction was made among open RP, laparoscopic prostatectomy, and robot-assisted laparoscopic prostatectomy. Articles preceding 1995 that focused solely on prostatectomy outcomes were not included. This selection cutoff was made to eliminate the probable risk of including data not relevant to outcomes in contemporary practice.

Citations were included if they were published in English and from a peer-reviewed journal. All citations identified in the search were reviewed for relevancy to the identified topic of LUTS, prostate cancer and prostatectomy. A review of secondary sources of information was also conducted and related references from the identified articles were included.

## LUTS in Patients With Prostate Cancer

Patients with moderate to severe preoperative LUTS are frequently recommended for RP to treat clinically localized prostate cancer. This recommendation is based in part on findings from a key study by Schwartz and Lepor (1999), which indicated that RP significantly improved irritative voiding symptoms and QOL in their patient population. This prospective longitudinal study compared the seven common symptoms routinely assessed by the American Urological Association Symptom Index (AUA-SI). Symptoms assessed included bladder emptying, urinary frequency, intermittency of stream, urinary urgency, stream caliber, straining, and nocturia. Assessments were obtained preoperatively and then repeated 12 months after RP. A paired Student's t-test was per-

formed on each symptom score, and all domains except nocturia showed a statistically significant improvement from baseline in the 46 patients with preoperative moderate to severe LUTS ( $p < .05$ ). An additional question was posed to evaluate the patient's global QOL assessment based on urinary function. The response to this question showed a statistically significant postoperative improvement despite a reported 10% incidence of clinically significant stress incontinence.

### EVIDENCE-BASED MANAGEMENT

Several studies provide evidence-based support that RP might be the appropriate recommendation for patients with moderate to severe LUTS at the time prostate cancer is diagnosed. Baptista-Miranda et al. (2007) studied 1,546 patients over 50 years old with known LUTS who had completed a survey to assess the impact of LUTS on QOL. Nocturia and incomplete bladder emptying were the strongest predictors for a significantly negative impact on QOL.

Robertson et al. (2007) also assessed the correlation between LUTS and QOL. The results of this large epidemiologic study showed that approximately 20% of men over 40 years old had some or all of the symptoms that encompass LUTS, and that percentage increased with age. Increased severity of LUTS was associated with a significant decrease in both mental and physical health QOL components, and this decrease was noted across varied cultural settings. QOL was assessed using the Short Form Health Survey (SF-12), and LUTS was assessed using the International Prostate Symptom Score (IPSS), a survey instrument used interchangeably with AUA-SI (the questions are the same). Of note was the correlation on the health component score that moderate LUTS affects QOL much like hypertension, diabetes, or cancer. Although uncommon (3.5%), the relative effect on QOL of LUTS graded as severe was similar to that of heart attack or stroke.

These studies provide insight into the current management of patients with significant LUTS and prostate cancer. Penson and Litwin (2003) described how localized prostate cancer alone can also be a source of LUTS. They found that the focus on QOL was often only within the context of postoperative side effects such as impotence and incontinence and that few studies have examined the impact on the expectant management

of localized prostate cancer.

In a study conducted by Jonler, Nielsen, and Wolf (1998), a self-administered survey was mailed to patients who had undergone surveillance as a treatment option for prostate cancer. Of the 52 men who completed Health-Related Quality of Life (HRQOL) surveys during a 39-month period of follow-up, 31% (16/52) required a transurethral resection of the prostate (TURP) for either LUTS or acute urinary retention. In the same population, 21% described problematic incontinence requiring the use of a pad, and 31% reported that a urethral stricture developed after the prostate cancer was diagnosed.

Of interest, however, the relationship between altered urinary function and perceived bother is also highly individualized. A study by Fowler et al. (1995) described survey results of 222 men who reported dripping urine incontinence that required the use of either pads or a penile clamp. In that group, 44% (98/222) described the use of pads or a penile clamp as either a very small or small problem, whereas 53% (118/222) described it as a moderate to big problem. The remaining 3% (6/222) described it as no problem at all.

Slova and Lepor (2007) postulated that since LUTS progress in men as they age and since the risk of developing LUTS increases over an individual's lifetime, RP may actually offer the long-term benefit of preventing the development of LUTS in men who are asymptomatic at the time of RP. These investigators examined a cohort of 453 men who underwent RP and completed the AUA-SI at baseline, 12, and 48 months after surgery. Of the 453 men who completed the study, 36% (163/453) presented with moderate to severe LUTS. This population was noted to have a significant improvement in LUTS at 48 months after surgery ( $p < .001$ ). Among the remaining 64% (290/453), those men without any or minimal clinically significant symptoms at baseline showed no increase in AUA-SI scores at 48 months, which provided further evidence that RP may prevent progression of LUTS in the aging male with prostate cancer.

### URINARY FUNCTION

Postprostatectomy urinary incontinence is also a consideration, as reported by Namiki et al. (2006). These investigators examined a cohort study of 225 patients who had undergone RP to

treat prostate cancer. Of the study population, 113 (50%) of the patients were classified as having moderate to severe preoperative LUTS based on an IPSS  $\geq 8$ . This group of 113 patients showed a statistically significant improvement in mean symptom score, from 13.3 to 8.2 ( $p < .001$ ) at 24 months after surgery. The University of California, Los Angeles, Prostate Cancer Index (UCLA PCI) scores were also obtained to assess urinary leakage and overall continence. Patient scores calculated using this instrument were lower than baseline at 24 months ( $p < .001$ ), although incremental improvement was noted at 6, 12, 18, and 24 months postoperatively when continence assessment was based on pad requirement. In addition, the results of the UCLA PCI indicated that patients would likely have difficulty returning to baseline urinary continence after RP. However, when the IPSS QOL question was scored, significant improvements compared with baseline were noted ( $p < .01$ ). The authors concluded that the positive effects of RP on LUTS outweighed the negative effects of stress urinary incontinence, as approximately 90% of the study cohort did not require pads for their level of urinary incontinence.

Hollenbeck et al. (2002) surveyed both urinary incontinence and obstructive irritative symptoms in men who underwent RP and compared those findings to an age-matched control group to evaluate patient self-reported urinary impairment and satisfaction. The UCLA PCI urinary function subscale was included to capture urinary symptoms in addition to those reflected in the AUA-SI for irritative voiding symptoms postprostatectomy. In this study, findings indicated that men followed for 34 months post-RP had moderate to severe symptoms of LUTS (33% vs. 35%,  $p = .7$ ) at the same rate as age-matched controls. In contrast to the previously noted findings of Schwartz and Lepor (1999), Hollenbeck et al. hypothesized that their findings may have been a result of the prolonged follow-up, which allowed time for the long-term effects of RP to be expressed, or a result of the study being underpowered and unable to detect a significant difference in symptoms.

### LUTS Assessment Instruments

A variety of instruments are in use to assess urinary function in men and should be considered when reviewing the literature. Table 1 summa-

rizes characteristics of the studies, which examined LUTS and QOL in men after prostate cancer treatment. The list of surveys used is varied, and each survey characterized LUTS based solely on patient report.

The Wallenburg Symposium conducted and reported by Altwein et al. (1997) attempted to identify and standardize the reporting of complications from the various forms of treatment for prostate cancer, in addition to assessing their subsequent effect on QOL. The development of a cancer-specific QOL questionnaire was deemed necessary to answer prostate-specific questions. Assessments for worry regarding prognosis, level or presence of bone or pelvic pain, LUTS, urinary incontinence, urinary diversion, bowel function, sexual function, endocrine effects, and satisfaction with medical care were recommended. In addition, this group concluded that any trial to assess prostate cancer treatment that did not include a prostate-specific, validated QOL assessment questionnaire could not be considered a sufficient trial.

In fact, several instruments have been developed and introduced for use in men with prostate cancer, including assessments classified as HRQOL (health-related quality of life). The UCLA PCI, the Functional Assessment of Cancer Therapy-Prostate (FACT-P), and the Expanded Prostate Cancer Index Composite (EPIC) are population-specific, validated questionnaires that were introduced in 1995.

The AUA-SI and IPSS were both introduced in 1992. Although each is a questionnaire routinely used to evaluate lower urinary tract voiding patterns, the absence of questions concerning urinary incontinence should be considered a weakness of these tools, given the postoperative symptom profile of patients who have undergone RP (Hara et al., 2003). Hara et al. recommended use of the International Continence Society, Male-Short Form (ICS male SF) and proposed that the assessment tool be used to more extensively evaluate postoperative status, as it includes a supplemental domain for urinary incontinence.

From a nursing perspective, Dorey (2000a, 2000b) published a series evaluating the impact of nursing on patients with LUTS and recommended the development of a detailed, classified data system for evaluating male incontinence. Dorey (2000b) concluded that an additional subjective assessment of the patient's current

descriptive assessment of urinary bother should also be conducted. Robinson, Avi-Itzhak, and McCorkle (2007) and Robinson, Bradway, Nuamah, Pickett, and McCorkle (2008) subsequently developed two prostate-specific questionnaires: the Male Urogenital Distress Inventory (MUDI) and the Male Urinary Symptom Impact Questionnaire (MUSIQ). These instruments provide detailed measurement of LUTS and their effect on HRQOL; the validation and utilization of these two instruments is ongoing as of this writing.

### LUTS and Incontinence Outcomes After Radical Prostatectomy

The reported statistics of post-RP incontinence range from 2.5% to 87% (Appell, 2007) and vary widely because of differences in the definition of urinary incontinence, the previously noted multiple methods for assessing incontinence, the method for selecting patients for surgery, and the surgeon's expertise (Lepor, Kaci, & Xue, 2004). In an early intervention study for incontinence, Filocamo et al. (2005) reported that 93.3% (278/298) of postprostatectomy patients achieved continence after 1 year.

In contrast, based on the ICS-male SF assessment, Kao et al. (2000) found that the incidence requiring some level of pad protection after RP was 33% by self-report. In the same study by Kao et al., 47.4% patients reported dripping or leaking urine when the bladder was full before getting to the bathroom. It should be noted, however, that even with RP morbidity common and QOL affected, 77.5% patients in the study by Kao et al. reported they would elect to have RP again. Also notable was the finding that 2 to 3 years after RP, patients were less likely to be willing to undergo the same treatment than were patients who were more than 5 years post-RP (odds ratio = 0.48).

As in prior reports, Hara et al. (2003) confirmed that QOL related to difficulty with urination, when impaired prior to surgery, was significantly improved as a surgical outcome ( $p < .05$ ). However, the same study reported that 6 months after the surgery, QOL was significantly disturbed due to urinary incontinence ( $p < .05$ ), but HRQOL was not altered. These seemingly contradictory data provide additional evidence that a detailed assessment of LUTS is needed to more completely quantify postoperative symptoms.

### PROST-QA STUDY

The Prostate Cancer Outcomes and Satisfaction with Treatment Quality Assessment (PROST-QA) study by Sanda et al. (2008) highlighted the complexity associated with characterizing the outcomes of QOL and satisfaction in patients treated for prostate cancer. Sanda et al. observed that although authors propose satisfaction with outcome as the ultimate arbitrator, when patients rate overall satisfaction from the perspective of being cancer-free, it is difficult to obtain critical characterization of treatment-specific outcome satisfaction.

Surveys used in the PROST-QA study include the Expanded Prostate Cancer Index Composite (EPIC-26) and the Service Satisfaction Scale for Cancer Care (SCA). A total of 1,201 patients and 625 partners were evaluated at baseline and then 2, 6, 12, and 24 months after treatment by radical prostatectomy, external-beam radiation therapy, or brachytherapy was completed. Partners took the adapted versions of the same instruments (SCA-P and EPIC Partner) at the same time intervals as the patient. HRQOL was evaluated in treatment groups over time, with the evaluations consisting of rating the degree of urinary incontinence, urinary irritation or obstruction, urinary function, sexual function, bowel or rectal function, and vitality or hormonal function.

Among the 603 patients in the prostatectomy treatment group, the 30% complaining of dysuria, weak stream, and frequency in the preoperative assessment decreased to 14% when surveyed 24 months after surgery. However, in the prostatectomy incontinence group, a baseline 20% complained of symptoms that consisted of either leaking more than one time per day, frequent dribbling, any pad use, any leaking problem, or any overall urinary problem; 24 months after surgery, that percentage had increased to 54%. The greatest increase was seen in the "any pad use" category, which increased from 1% at baseline to 20% at 24 months after treatment.

Conversely, the 11% at baseline who were categorized as having overall urinary problems in the prostatectomy group decreased to 7% at 24 months after surgery (Sanda et al., 2008). Significance levels for these comparisons were not provided. Additionally, in the prostatectomy group, factors associated with significant changes in after-treatment QOL scores were negative

**Table 1. Studies Examining LUTS and QOL in Men With Prostate Cancer**

Lead author	Purpose/research question	Research design	Sample characteristics	Instrument
Sanda (2009)	Identify determinants of HRQOL after initial treatment and effect of determinants on treatment outcome satisfaction in patients and partners	Prospective, observational, survey	N = 1,201 patients and 625 partners, who completed surveys before and after RP, XRT, or brachytherapy	For patients: EPIC-26 and SCA; for partners: SCA-P and EPIC-Partners
Couper (2009)	Assess psychological impact of treatments for localized prostate cancer	Prospective, observational study	N = 211 patients recruited prior to PCA treatment at multiple sites; 193 completed questionnaires prior to treatment; 172 completed questionnaires at 12 mo posttreatment	SF-36, BSI-53; HRQOL assessed
Matsukawa (2009)	Assess LRP vs. RP impact on continence	Retrospective analysis	N = 63 LRP patients compared with 58 RP patients	
Robertson (2007)	Investigate impact of LUTS on QOL across cultures and potential for confounding effects of comorbidities and demographics	Population-based epidemiologic study	2 population-based studies from 5 countries of either stratified random samples of men (N = 4,800) or recruited men (N = 1,686)	SF-12, IPSS
Slova (2007)	Evaluate long-term effect on LUTS with RP as treatment for prostate cancer	Longitudinal cohort survey	N = 453 of 587 men undergoing RP	AUA-SI
Namiki (2006)	Survey on lower urinary tract function and QOL after RP	Posttreatment survey	N = 225 men post-RP	UCLA PCI, IPSS, and IPSS QOL
Ponholzer (2006)	Assess LUTS, UI, ED, and QOL in patients post-RP or XRT	Retrospective survey with matched-pair analysis	N = 364 after RP and N = 82 after XRT treated at 1 of 19 Austrian institutions; followed and completed surveys 4.5 yr after treatment	Bristol LUTS, IIEF-5, SF-36

*Note.* AS = active surveillance; ASA = American Society of Anesthesiologists; AUA-SI = American Urological Association Symptom Index; ED = erectile dysfunction; EORTC = European Organisation for Research and Treatment of Cancer; EPIC = Expanded Prostate Cancer Index Composite; GHI = General Health Index; HRQOL = health-related quality of life; ICED = Index of Coexistent Disease; ICS = International Continence Society; IIEF = International Index of Erectile Function;

Variable assessed	Results	Study limitations or advantages	Summary statements for practice
Patients electing definitive treatment for prostate cancer at 2, 6, 12, and 24 mo after treatment; partners completed modules at same time intervals	After RP, UI was observed; urinary irritation and obstruction improved, particularly in patients with large prostates Adjuvant hormones associated with decreased QOL among radiation patients Brachytherapy patients had long-lasting urinary irritation, bowel, and sexual symptoms	<i>Limitations:</i> Multiple high-volume centers participated; extensive variation in providers Follow-up at 2 yr is relatively short	Each prostate cancer treatment option is associated with specific side-effect profile and changes in QOL domain
Organ-confined PCA; surveys completed prior to and 12 mo following treatment	RP, XRT, and AS groups scored same HRQOL 12 mo after treatment	<i>Limitations:</i> No controls for physician treatment recommendation prior to study enrollment	Hormone therapy associated with decreased HRQOL and vitality compared with RP, XRT, or AS
Assessed continence; compared urodynamic change 2-3 days prior to and 3-9 mo after surgery	Continence rates after LRP: 82%, after RP: 78% Lower bladder compliance and a higher incidence of detrusor overactivity seen in incontinent patients and open prostatectomy group	<i>Limitations:</i> Follow-up period had significant range that could affect results Preoperative urodynamic results not available for RP patients	No difference between LRP and RP in postoperative urethral function LRP might be associated with less postoperative impairment to bladder function Continence rates after LRP: 82%, after RP: 78%
Survey assessed associations between QOL, IPSS, comorbidities, and lifestyle factors	Increasingly severe LUTS associated with lower QOL Moderate LUTS impact on QOL is similar to having diabetes, hypertension, or cancer Severe LUTS has an impact on QOL similar to that of a heart attack or stroke	<i>Limitations:</i> Combination of random and recruited patients	LUTS has independent effect on QOL more pronounced than on potentially more severe comorbidities LUTS may affect mental component of QOL more than comorbidities
Completed survey before, 12 mo after, and 48 mo after surgery	Clinical and statistically significant short- and long-term improvement in AUA scores of total, storage, and voiding symptom scores in men with moderate to severe preoperative baseline LUTS	<i>Limitations:</i> No data on use of $\alpha$ -blockers, 5 $\alpha$ -reductase inhibitors or anticholinergics; could alter preoperative and postoperative AUA scores	Recommendation for RP as prostate cancer treatment in men with moderate to severe LUTS prior to surgery
Completed surveys 3, 6, 12, 18, and 24 mo after RRP	Overall mean total scores on IPSS and and IPSS QOL improved Preoperatively vs. postoperatively, nocturia was not statistically significant for improvement UCLA PCI scores for urinary function did not recover to baseline at 24 mo	<i>Limitations:</i> Objective data such as prostate volume and preoperative urodynamic measurements not obtained	Important to assess LUTS and UI after RP RP has a significantly beneficial effect on LUTS Urinary continence after RP and age can affect recovery of voiding function
Patients who had undergone either RP or XRT assessed for LUTS, UI, ED, and QOL	UI was reported at 41.3% after RP and 18.8% after XRT ( $p = .001$ ) Urgency was more common after XRT than after RP but was not statistically significant	<i>Limitations:</i> Small number in XRT study arm, multiple facilities (19 centers, 28 practices) drawing conclusions; difficult to interpret from outcomes	The incidence for LUTS, UI, and ED was substantially higher than was reported in outcomes from physician-directed studies or centers of excellence

IPSS = International Prostate Symptom Score; LRP = laparoscopic radical prostatectomy; LUTS = lower urinary tract symptoms; MHI = Mental Health Index; PCA = patient-controlled analgesia; QOL = quality of life; RP = radical prostatectomy; RRP = radical retropubic prostatectomy; SCA = Service Satisfaction Scale for Cancer Care; SF = Short-Form Health Survey; UCLA PCI = University of California, Los Angeles, Prostate Cancer Index; UI = urinary incontinence; XRT = external-beam radiation therapy.

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**Table 1. Studies Examining LUTS and QOL in Men With Prostate Cancer (cont.)**

Lead author	Purpose/research question	Research design	Sample characteristics	Instrument
Hara (2003)	Compare QOL after LRP to open RP	Prospective, observational survey	N = 52 patients post-LRP compared with 54 post-RP	EORTC Prostate Cancer QOL Survey, IIEF, and ICS Male SF
Hollenbeck (2002)	Evaluate LUTS for patient perception of urinary impairment and satisfaction	Case-matched controls survey	N = 228 post-RP compared with age-matched, zip code-matched random sample of 228 men without PCA	UCLA PCI, and AUA-SI
Stanford (2000)	Measure changes in urinary and sexual function after RP	Prospective, longitudinal cohort	N = 1,291 black, white, or Hispanic, 39 to 79 yr, post-RRP within 6 mo of clinically localized disease diagnosis	Investigator-developed survey
Kao (2000)	Assess incidence of postprostatectomy UI, ED, bladder neck contracture ± urethral stricture, QOL, and willingness to repeat treatment	Survey post-RP, 1962–1997 (85.7% post-RP after 1990)	N = 1,069 patients who completed surveys based on Fowler questionnaire of N = 1,396 eligible patients post-RP	Investigator-developed survey
Schwartz (1999)	Evaluate long-term effect on LUTS and QOL with RP as treatment for prostate cancer	Prospective longitudinal	N = 104 patients preoperatively and 12 mo after RP	AUA-SI, QOL, and continence question
Talcott (1998)	Assess treatment complications in early prostate cancer	Prospective, longitudinal cohort survey	N = 279	American College of Surgeons Patterns of Care Study Instruments and ICED Changes in sexual and urinary function
Jonler (1998)	Evaluate LUTS and QOL in patients with PCA on AS	Observational study by response to mailed, self-administered questionnaire	N = 52 of 71 consecutive patients on AS	ASA Index, Fowler questionnaire, MHI, GHI

*Note.* AS = active surveillance; ASA = American Society of Anesthesiologists; AUA-SI = American Urological Association Symptom Index; ED = erectile dysfunction; EORTC = European Organisation for Research and Treatment of Cancer; EPIC = Expanded Prostate Cancer Index Composite; GHI = General Health Index; HRQOL = health-related quality of life; ICED = Index of Coexistent Disease; ICS = International Continence Society; IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; LRP = laparoscopic radical prostatectomy;



Variable assessed	Results	Study limitations or advantages	Summary statements for practice
Patients completed surveys prior to and 6 mo after treatment	Sexual function and UI significantly disturbed by surgery ( $p < .05$ ) but voiding dysfunction was significantly improved after surgery ( $p < .05$ ) in both groups	Limitations: Small comparison group, short-term patient follow-up	General HRQOL not affected by either treatment approach; patients after open or robotic approach without significant differences in QOL 6 mo after surgery
Both groups completed surveys; regression models constructed to evaluate symptom effect on impairment and satisfaction	Control group reported greater continence ( $p < .0001$ ) and less impairment ( $p < .0001$ ) than did RP group Obstructive symptoms associated with impairment in both groups UI associated with impairment in RP group > than in control group ( $p < .01$ ) Greater obstructive, irritative, and incontinence symptoms associated with lower satisfaction	Limitations: No baseline data; assumption that RP group had baseline moderate to severe LUTS may be incorrect	Urinary incontinence was more common in RP group; differences in obstructive symptoms not seen
Sexual and urinary function surveyed at baseline, 6, 12, and 24 mo after surgery	Sexual and urinary outcomes varied by age; overall, 8.4% incontinence with highest rate postoperatively in the 75-79 yr old group	Limitations: Possible recall bias, self-selected population, survey not validated	Significant effect on ED, some decline in urinary function more common with increased age
Urinary symptoms survey completed 6 mo posttreatment; 77% return rate, evaluated by third party for results	Patient-reported incidence of any degree of UI: 65.6%; 33% requiring protection Persistent urethral stricture uncommon (2.8%) 77.5% of patients would elect same treatment	Limitations: Survey not validated; possible recall bias based on length of time from surgery; did not survey pretreatment continence	Self-reported willingness to undergo same treatment procedure, even with significant side effects
Evaluated LUTS and QOL by survey and direct question preoperatively and 12 mo after RRP	Statistically significant improvements in AUA-SI responses, except for nocturia, after RP in men with moderate to severe preoperative LUTS 10% of men reported clinically relevant stress incontinence 98% were satisfied with treatment decision	Limitations: Questions administered to capture level of continence and satisfaction with treatment decision not validated prior to study	Recommendation for RP as prostate cancer treatment in men with moderate to severe LUTS prior to surgery
Reported changes in sexual and urinary function pretreatment and 3 and 12 mo after treatment	Bowel and bladder irritation are more common after XRT; incontinence is occasional Greater sexual dysfunction and UI occurs after RP	Advantages: Single-center outcome study Third-party (objective) data collection	Postsurgical complication rates of ED and UI higher than those previously reported
Surveys regarding QOL and medical intervention related to LUTS when on AS	High frequency of incontinence and LUTS without active PCA treatment	Limitations: Self-selected population of patients based on completion of questionnaire	Patients content with AS from a general QOL perspective High frequency of incontinence and LUTS without PCA

LUTS = lower urinary tract symptoms; MHI = Mental Health Index; PCA = patient-controlled analgesia; QOL = quality of life; RP = radical prostatectomy; RRP = radical retropubic prostatectomy; SCA = Service Satisfaction Scale for Cancer Care; SF = Short-Form Health Survey; UCLA PCI = University of California, Los Angeles, Prostate Cancer Index; UI = urinary incontinence; XRT = external-beam radiation therapy.

for urinary incontinence when compared with age ( $p = .005$ ) and black race ( $p = .03$ ) and were positive when urinary irritation or obstruction correlated with prostate size ( $p = .005$ ).

The Sanda et al. PROST-QA study also assessed the association between changes in QOL scores and satisfaction regarding treatment outcomes, for both patients and their partners. The bivariate analyses in patients revealed a significant association between satisfaction with outcome and improvements in each of five QOL domains, including urinary incontinence ( $p < .001$ ) and urinary obstruction or irritation ( $p = .02$ ).

## Discussion

When patients are diagnosed with organ-confined prostate cancer, those with moderate to severe LUTS often receive a recommendation for RP. The expectation that elimination of baseline LUTS will improve QOL is evidence-based for a large percentage of patients. Evidence also exists for preventing the development of LUTS with RP, given that the risk of irritative or obstructive voiding symptoms increases with age in men.

In an outpatient setting, a urologist most commonly assesses urinary bother with baseline surveys (AUA-SI or IPSS). Based on these scores, patients may be characterized as experiencing mild, moderate, or severe LUTS. Incontinence, as a voiding symptom, is not routinely reported or assessed as a preoperative concern. However, incontinence is a potentially significant side effect in the post-RP population of patients. This side effect is not well characterized in the literature, as there is significant variation in both the severity and subsequent impact on QOL.

To further confuse the risk vs. benefit consideration, patients with postoperative incontinence appear to agree that if given the option to undergo surgery again, they would overwhelmingly choose it as their treatment. Filcarno et al. (2005) observed that when post-RP outcome statistics for QOL were evaluated, RP was the most frequent cause of iatrogenic incontinence in men, with the surgical impact on QOL directly proportional to the duration and intensity or severity of the reported incontinence.

The data that Schwartz and Lepor (1999) obtained from their patient population—and from which many of these treatment recommendations were made—should also be examined for poten-

tial bias. The patients in that study, who rated both urinary function and satisfaction with the surgery outcome in relation to QOL, were queried in a face-to-face session with a nurse. This data-gathering approach risks confounding results, because direct questioning by a representative of the provider may decrease the patient's candor.

In a similar study, Talcott et al. (1998) made the observation that physician reports of lower complication rates may well be attributed to patients minimizing treatment complications and their physicians, in turn, subconsciously dismissing the symptom report. In addition, the likelihood that a patient would be unwilling to report dissatisfaction with a positive outcome from a cancer-free perspective should also be considered.

A variety of instruments have been used to characterize and quantify symptoms that affect QOL in this population. Moreover, variability of patient reporting may result from self-selection issues: whether a bias is introduced by the outcome of the patient who agrees to participate, the manner in which the data are collected, whether the patient population understands the information that is being compiled, the manner in which the questions are framed, and whether the patient is actually surveyed on questions that apply to his outcomes. Additionally, there is the reliance on patient self-reports to capture and quantify the impact of symptoms. Thus, the use of multiple survey instruments and the selection of patients who complete the surveys are variables that can potentially bias the overall assessment and comparison of outcomes specific to the population.

A primary concern in the assessment of men who experience LUTS is the lack of randomized clinical trials, which provide comparative outcomes. Along with the subjectivity of the survey instruments, unwillingness of the patients to consider randomization into a treatment group is a consistent obstacle in prostate cancer treatment outcomes research. The data obtained from studies are routinely observational after patient decisions have been made.

## Implications for Advanced Practice

Based on the current literature, when an advanced practitioner (AP) provides patient education, an identifiable obstacle is the difficulty in providing patients with a clear picture of the treat-

ment risks and projected outcomes. The outcomes data are varied and dependent on the surveys used, the population of patients varies greatly, and therefore generalizations cannot be made routinely. In the newly diagnosed prostate cancer patient population, an essential component of the AP role is familiarity with current outcomes literature and an ability to offer assistance to the patient in weighing and sorting through treatment options.

Consideration of the primary concerns the patient identifies must also be an area for discussion, as the AP often serves as the patient advocate in ways not possible for the specialist advising the patient. The urologist, radiation oncologist, or medical oncologist has an inherent bias for an area of expertise; in the patient education role, the AP provides the patient with assistance in understanding treatment options from an unbiased perspective. It is critical that the APs caring for these patients be familiar with the specific literature regarding newly diagnosed prostate cancer and the complex symptoms this population may experience.

## Conclusions

Patients frequently receive a recommendation to undergo RP when moderate to severe baseline LUTS exist at the time of prostate cancer diagnosis. The basis for this recommendation is that patients should experience a decrease in LUTS after RP. However, this is a complex issue that cannot be answered with a straightforward, single recommendation. The issues for consideration include the actual incidence and cost in side-effect outcomes that patients may experience in an effort to resolve baseline LUTS. Randomized controlled trial data are not available to provide solid guidance for treatment outcomes. Patients should therefore be educated about the risk of urinary incontinence—another form of LUTS—as part of any treatment discussion.

Future recommendations include the need for a large-center prospective, multitreatment comparison of outcomes for all standard treatment populations using validated survey instruments that measure all domains for LUTS and QOL. Additionally, an assessment of patient symptoms and outcomes by an objective clinician may reveal more information than would a survey conducted by the actual treatment providers. Finally, patients must have the opportunity

to receive education about all possible treatment risks, because although postoperative outcomes of RP provide significant hope for resolution or improvement in moderate to severe symptoms of preoperative LUTS, the postoperative risk for urinary incontinence does exist.

## DISCLOSURES

The authors have no conflicts of interest to disclose.

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