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## Quantification of Long-term Stability and Specific Relief of Lower Urinary Tract Symptoms (LUTS) After Robot-assisted Radical Prostatectomy

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### Abstract

**OBJECTIVE**—To assist in preoperative counseling by assessing long-term changes in American Urological Association symptom scores (AUAss) and lower urinary tract symptom (LUTS)-related quality of life (QOL) in patients undergoing robot-assisted radical prostatectomy (RARP).

**MATERIALS AND METHODS**—RARP was performed on 666 men by one surgeon from 2002 to 2007 at a single institution. AUAss and QOL were queried preoperatively and at 3, 9, 15, 24–48, 60–84, and 96+ months postoperatively. LUTS subgroups were compared pre-/postsurgery using univariate and multivariate statistics.

**RESULTS**—The mean and median follow-up for all responders was 3.0 and 2.4 years. Pad-free continence at 12 months was 89%. A subset of 174 men reported preoperative and long-term responses; average follow-up was 5.8 years (range 4.0–10.3 years). AUAss for all men declined from baseline to 5 years by 3.7 (8.6 to 4.8) whereas QOL/Bother scores decreased by 0.5 (1.7 to 1.2) (all  $P < .05$ ). Men with baseline mild LUTS remained clinically unchanged with long-term AUAss. Individuals with moderate and severe preoperative LUTS had marked improvements in AUA and QOL scores (all  $P < .05$ ).

**CONCLUSION**—Men with mild LUTS have short-term increases in AUAss but most return to baseline and are stable at 5 years. Benefits were found for men with preoperative moderate and severe LUTS in that 63% had significant QOL improvements and 68% reduced their AUAss to mild LUTS, persisting years after RARP. This study suggests that certain patients with preoperative urinary symptoms and bother may experience improvements in LUTS and associated QOL after RARP.

As men age, a significant portion of the male population experiences a degradation of quality of life (QOL) due to lower urinary tract symptoms (LUTS).<sup>1–3</sup> Many of these lower

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### APPENDIX

Supplementary Data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.urology.2016.03.028>.

urinary tract signs and symptoms are secondary to benign prostatic hyperplasia.<sup>4-6</sup> Studies report incidences of clinically significant (moderate and severe) LUTS that correlate with increasing age.<sup>7-12</sup> The primary goal of radical prostatectomy (RP) is cancer control and patient survival. RP may additionally improve urinary symptoms in men with LUTS secondary to benign prostatic hyperplasia.<sup>13</sup>

The reported urinary outcomes after open RP are well documented and include long-term assessment<sup>14-16</sup>; however, results after robot-assisted RP (RARP) are short term and mixed. Choi et al<sup>17</sup> demonstrated that men with severe preoperative LUTS had a trend toward decreased urinary function using the Expanded Prostate Cancer Index Composite scale. Rogers et al<sup>18</sup> found a slight decrease of median baseline American Urological Association (AUA) scores from 8.0 to 5.0 at 26 months for men aged > 70. Wang et al<sup>19</sup> found a small decrease from 4.1 to 1.8 at 12 months for 100 consecutive RARP men, but a 4-fold decrease in AUA scores in moderate and severe LUTS for 17 men who markedly improved from a baseline of 14.1 to 2.9 at 12 months. Kim et al<sup>20</sup> presented 1-year results after RARP, showing that mean AUA scores doubled at 3 months in men with mild LUTS and remained slightly elevated at 1 year. For men with AUA < 8, the mean scores increasingly improved over the course of the first year, whereas Gordon et al<sup>21</sup> found that men with preoperative severe LUTS showed a significant improvement in AUA and QOL/Bother scores short and long term after RARP.

Our goal as surgeons in the preoperative period is to accurately counsel our patients regarding postoperative expectations; thus, we must question if RARP provides any long-term benefits or detriments with regard to urinary symptoms, and who is affected most. This report will address these key questions.

## MATERIALS AND METHODS

After Investigational Review Board approval (HS 1998-1984), 666 consecutive patients who underwent RARP from 2002 to 2007 by a single surgeon (T.A.) were prospectively monitored. All prostatectomies were performed via the 5 or 6 port transperitoneal approach. Daily quarter dose phosphodiesterase type 5 inhibitors (sildenafil or tadalafil) were advised for the first postoperative year for potency, and after 1 year, were taken on a pro re nata basis.

All patients were given prospective validated International Prostate Symptom Score (AUA symptom score [AUAss] and QOL score) questionnaires.<sup>22</sup> Baseline AUAss and QOL score were queried prior to their first clinic consultation, generally <30 days prior to surgery, and reflect the patient's general preoperative urinary health status. Self-reported responses at postoperative times occurred via mail or clinic visits. Continence was defined as pad free<sup>23</sup> and time to continence was recorded by postcards returned by patients on the date they became pad free. Incontinent men were identified by secondary questionnaires or phone contact. Incontinent men with multiple pads were treated ad hoc primarily with tolterodine. Overall, 16 men presented with acute symptoms of either a visually confirmed bladder neck contracture (n = 6) or fossa stricture (n = 10), and were included after resolution of

symptoms. Six men with preoperative transurethral resection of the prostate were also included. However, preoperative men with indwelling catheters were excluded.

Overall, 97% of the 666 men completed both an AUAss and QOL score at baseline. Of the 174 long-term responders, more than 77% of patients filled out a minimum of 5 or more postoperative questionnaires, and 87% gave 4 responses. Patients were categorized into 3 groups by AUA scores: mild LUTS (0–7) (n = 355), moderate LUTS (8–19) (n = 257), and severe LUTS (20+) (n = 53), based upon their preoperative self-reported questionnaire.<sup>22</sup> Definitions for subjective improvement in LUTS scores were defined as AUA score reduction: marked. 8.8 points, moderate 5.1, and slight 3.0 points, unchanged –0.7, or decline/worse +2.7.<sup>24</sup> Statistical analyses were performed with SAS software (SAS institute Inc, Cary, NC). Differences between subgroups defined by LUTS were compared at baseline and subsequent follow-up points using analysis of variance methods. Differences in change over time between subgroups were tested using analysis of variance for repeated measures. Univariate and multivariate logistical regression models were performed to test the association of preoperative characteristics in predicting AUAss improvement.

## RESULTS

### Baseline Characteristics of All Men Combined

We compared subgroups with complete, incomplete, and no follow-up with respect to baseline patient characteristics and found no significant differences in age, AUAss, QOL score, body mass index, prostate-specific antigen, International Index of Erectile Function-5, prostate weight, Gleason sum, or 0-pad continence at 1 year (Table 1). A subgroup with complete data at baseline, 3 months, and 9 months also did not differ significantly from those without follow-up ( $P > .10$ ) (Table 1). The baseline distributions of LUTS were mild (53%), moderate (39%), and severe (8%). Preoperative demographics of the respective LUTS cohorts are presented in Table 2.

### Postoperative Results of Entire Cohort

The proportions of responses at follow-up times were as follows: 3 months (78%), 9 months (55%), 15 months (30%), and 4 years (26%) (Table 3), with mean and median follow-up of 3.0 and 2.4 years (range 0.1–10.3 years). Overall, the AUAss for all men combined significantly improved from a preoperative mean of 8.6 to 7.3 at 3 months and to 5.8 at 9 months, with no significant change from 9 months to long term (4+ years) (Fig. 1A). Further breakdown of the AUA symptom score into Voiding and Storage totals at preoperative and after surgery is presented in Supplementary Table S1. Supplementary Table S2 presents adjusted odds ratios of preoperative variables in that younger men and men with greater baseline AUA scores will improve the greatest (8.8 points) after surgery. QOL scores for all men slightly worsened at 3 months (1.7 to 2.0) but then stabilized at 9 months until long term (Fig. 1B). At 1 year, 89% (521/583) of men were continent (self-reported use of 0 pads) (Table 1). For long-term responders (n = 172) at 4+ years, 150 (87%) reported wearing 0 pads, 7 patients (4%) reported wearing a security pad, 11 patients (6%) used a single pad, and 4 patients (2%) reported using multiple pads per day.

## Outcomes Grouped by Baseline LUTS

**Mild LUTS (AUAss 7)**—Patients with mild LUTS at baseline experienced increases in AUAss at 3 months (3.5 to 5.8) but then improved back to baseline level at 15 months and remained stable over time (Fig. 1A). Bother score (aka urinary QOL score) doubled from baseline of 0.9 to 1.8 at 3 months ( $P < .001$ ), but returned to clinical baseline at 9 months (Fig. 1B).

**Moderate LUTS (AUAss 8–19)**—Individuals with moderate preoperative LUTS experienced a 34% decline at 3 months in AUAss, decreasing by an average of 4 points (12.4 to 8.2). Thereafter, total AUAss improved by approximately 50% compared to baseline and remained stable long term (Fig. 1A). Bother scores did not change significantly from baseline to 3 months (2.4 to 2.3,  $P = .20$ ), but improved thereafter, and stabilized at a 9-month average of 1.5 (Fig. 1B).

**Severe LUTS (AUAss 20–35)**—For men with preoperative severe LUTS (AUAss 20), an average reduction in AUAss of approximately 15 points (24.8 to 9.0) occurs as early as 3 months ( $P < .001$ ), with incremental but non-significant improvement down to 7.3 long term (Fig. 1A). Overall, the QOL/Bother score in the Severe LUTS group declined by 1.5 points immediately and this continued long term (4.0 to 2.0,  $P < .05$ ) (Fig. 1B).

**Long-term AUA Scores**—We examined 174 men with data at baseline long-term follow-up (mean 5.8 years; range 4.0–10.3 years) (Fig. 2A,B). For these long-term men, the total AUAss declined at 5-year follow-up by 3.8 points (8.6 to 4.8,  $P < .05$ ). Trends in AUAss over time differ with baseline levels of LUTS. LUTS groups differed significantly ( $P = .02$ ) with respect to mean AUAss at each time point except at year 2 (Fig. 1A). Total AUAss were stable from 15 months through 4 or more years of follow-up in all 3 LUTS groups, that is, averaging from baseline: mild (no change), moderate (−7.5), and severe (−16.4) (Fig. 1A). Figure 2A shows the change (improvement) in individual AUAss items between baseline and 5 years for the 174 men in each of the 3 LUTS categories. Both voiding symptoms (residual, intermittency, weak stream, straining) and storage symptoms (frequency, urgency, nocturia) improved within the moderate and severe LUTS groups; however, voiding symptoms decreased nearly 2-fold more than storage symptoms.

Figure 2B demonstrates the migration of symptoms from baseline to 5-year follow-up in the 174 men stratified by LUTS group. In men with mild preoperative LUTS ( $n = 96$ ), 89% continued to have only mild symptoms at the 5-year follow-up, suggesting minimal clinical deterioration. Of the 11 men with mild LUTS who worsened in their AUAss, only 3 had AUAss scores  $\geq 12$ . For men with moderate and severe LUTS ( $n = 78$ ), 68% improved to a mild LUTS category, 24% continued to have moderate symptoms, and 4% deteriorated to a more symptomatic category. In 13 men with preoperative severe LUTS, 92% improved, 69% were in the mild category and 23% were in the moderate symptoms category, whereas only 8% continued to have severe symptoms.

### Long-term QOL Scores

QOL scores for all men modestly improved by 0.47 (1.7 to 1.2,  $P < .05$ ) (Fig. 1B). Subgroup analyses by LUTS group revealed that men with mild baseline LUTS and baseline QOL of 0.9 generally remained “*Pleased*,” with an average score of 1.0 at long-term follow-up. Ninety percent of men with mild LUTS preoperatively reported similar (+1 point) or improved QOL long term postsurgery.

Men with moderate and severe LUTS, however, demonstrated overall improvement from baseline QOL scores of 2.4 and 4.0 to scores of 1.4 and 2.0 at long-term follow-up, respectively. In men with moderate and severe LUTS, 63% improved their QOL, 31% remained static (+1 point), and 6% waned with long-term bother scores 4, “*Mostly Dissatisfied*” to “*Terrible*” urinary satisfaction. At long-term follow-up, specifically in men with preoperative severe LUTS, 77% (4-fold) reported long-term QOL scores 2 (*Mostly Satisfied, Pleased, or Delighted*), vs only 15% at baseline ( $P = .01$ ). Conversely, 23% now reported a long-term QOL score of 3 “*Mixed*,” with no 4, 5, or 6s (“*Mostly Dissatisfied*,” “*Unhappy*,” or “*Terrible*”) in contrast to 85% reported baseline rate.

## DISCUSSION

Intuitively, removal of the prostate by radical prostatectomy should provide relief from obstructive prostatic symptoms, but surgery does carry the potential risks of irritative symptoms and incontinence. In this study, the 53% of men with generally nonsymptomatic baseline mild LUTS found transient increases in LUTS at 3 months but were back to baseline by 1 year. For men with baseline “mild” LUTS, 89% remained so long term. We note that of the 11 baseline mild LUTS men who did digress to moderate LUTS, 75% migrated to an AUAss of 8–11 (Fig. 2B). Regrettably, 2% did experience long-term bother scores 4.

Although the indication for RARP is oncologic control, the secondary effect of total prostate removal appears to provide significant relief of LUTS in men with more severe symptoms preoperatively.<sup>21</sup> After RARP, the 47% of men with moderate and severe LUTS found significant improvement in QOL, with AUAss declining by 7.9 points (14.5 to 6.6,  $P < .001$ ) beginning at 3 months and persisting through 5 years (Fig. 1A). Urinary QOL scores (Fig. 1B) significantly improved at 3 months from 2.7 to 2.3 ( $P = .002$ ), stabilizing at 15 months to 1.5, or between “*Pleased*” and “*Mostly satisfied*.” These results are comparable to 1-year improvements in AUA 8 scores of 6.4 for open RP<sup>14</sup> and 11.2 for RARP.<sup>19</sup>

This is the first observational long-term RARP study to track AUA and QOL scores in each of the 3 preoperative LUTS categories. Notably, as shown in Figure 1A, clinical stability or improvements in AUAss are durable long term in all three LUTS groups, that is, averaging from baseline: mild (no change), moderate (−7.5), and severe (−16.4). QOL improvement is durable as well, as only 5% of men have QOL outcomes of “*Mostly Dissatisfied*” or worse at 5 years, compared to the baseline rate of 11%. To our knowledge, there are only a few long-term evaluations of AUAss and QOL after RP.<sup>15,16</sup> In a 10-year RP study of 242 subjects, Prabhu et al<sup>16</sup> demonstrated a 1.8-point rise in AUAss for men with mild LUTS and a decrease in men with moderate and severe LUTS of 4.7 points through 10 years. Our

study shows that men in each of the 3 LUTS groups can be counseled preoperatively that they will likely experience stability for mild LUTS or improvements for moderate and severe LUTS extending at least 4 years after RARP. Conversely, untreated men with minimal to no LUTS should expect a decline in their urination after 2–4 years.<sup>10,25</sup> Importantly, for men with prostate cancer and moderate to severe LUTS, RARP reverses these symptoms in 68%, with a return to mild LUTS within 9 months and persisting through 4 or more years.

A concern faced by patients undergoing RARP is regaining baseline urinary continence. Continence, in this study, was defined by the self-reported use of 0 pads. Eighty-nine percent (521/583) were continent by 12 months. We previously analyzed a large subset of this cohort and found that age, International Index of Erectile Function-5 score, and body mass index were significant predictors of continence at 1, 3, and 12 months after surgery.<sup>26</sup> Of the men in this study at long-term follow-up, 87% reported wearing 0 pads, 10% reported wearing 1 single pad, and 2% reported using multiple pads per day. For all 3 LUTS groups, 95% of men reported either total control or only very occasional dripping. Although incontinence was 11%, of the majority of men who used pads, 84% reported drippage ratings of “Not at all” to “About once a week.” Of the 3.5% of all men in the study who leaked every day, only 5 did so to a significant degree and only 1 had no control.

Limitations of the study include the attrition rate of responses, retrospective analysis of data, and absence of comorbidity data. Unpaired statistical analyses such as this study are not as strong as repeated measure studies. Finally, our results represent the experience of a single, high-volume surgeon, and may not be characteristic of smaller-volume centers. Men receiving postoperative radiation treatment were included in this study, which could have affected their long-term results. In regard to cancer outcomes, we previously published biochemical recurrence-free rates of 88% at 3 years and 85% at 5 years for a subgroup of 435 men.<sup>27</sup>

Strengths of the study include the length of follow-up and use of validated questionnaires at preoperative and multiple postoperative time points. Of the long-term responders, greater than 77% of patients filled out a minimum of 5 postoperative questionnaires (87% 4). We also found no differences in preoperative characteristics of long-term responders compared to nonresponders, limiting selection bias (Table 1).

An important clinical implication is that prostate cancer patients with moderate to severe LUTS should be counseled regarding the potential QOL benefits and improved AUAs after RARP in comparison to other treatment options.<sup>21,28</sup> RARP additionally contributes to improved urinary peak flow rates across all 3 LUTS groups.<sup>29</sup> Men who choose an active monitoring protocol, radiation,<sup>30</sup> or hormonal therapies remain at risk for declining urinary function in the form of reduced daily QOL and the subsequent risk of treatment by transurethral resection of the prostate or chronic  $\alpha$ -blocker therapy. These findings should be shared with prostate cancer patients whose LUTS already have a negative impact on their daily QOL. These men should be aware of the potential negative urinary or sexual outcomes associated with other potential treatments. The present study shows that RARP mitigates LUTS progression in 89% of men, and reverses it in 68%. We note that outcome instruments

that measure return to baseline status, for example, the Expanded Prostate Cancer Index Composite scale, may not accurately reflect postoperative benefits.

## CONCLUSION

RARP lowers urinary symptom and bother scores in those men who have moderate and severe LUTS (AUA  $\geq 8$ ). These men should be counseled that RARP confers a very significant long-term QOL benefit with regard to relief of LUTS. The fact that most men with mild LUTS seem to maintain their baseline AUA scores for at least 5 years following RARP is also reassuring.

## Supplementary Material

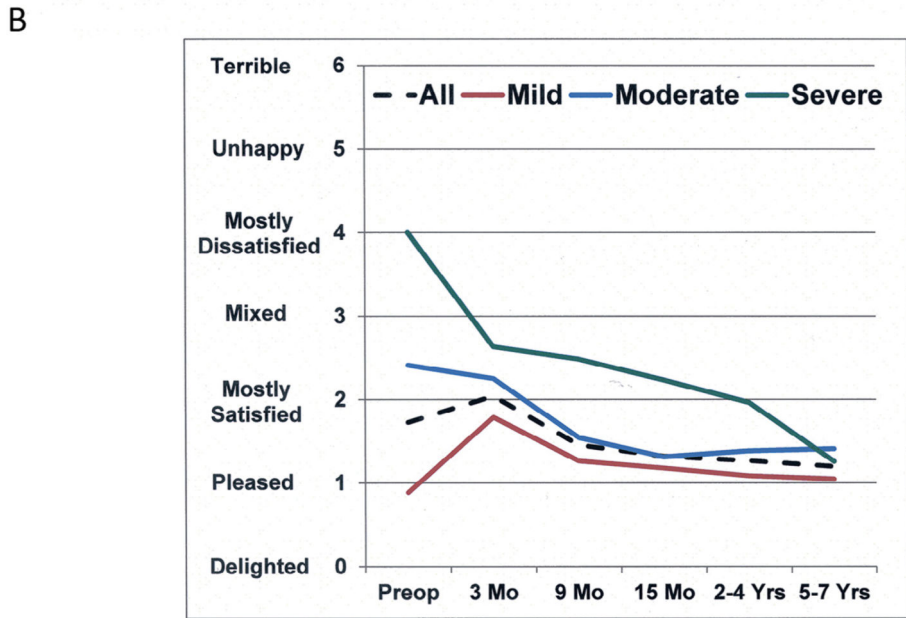
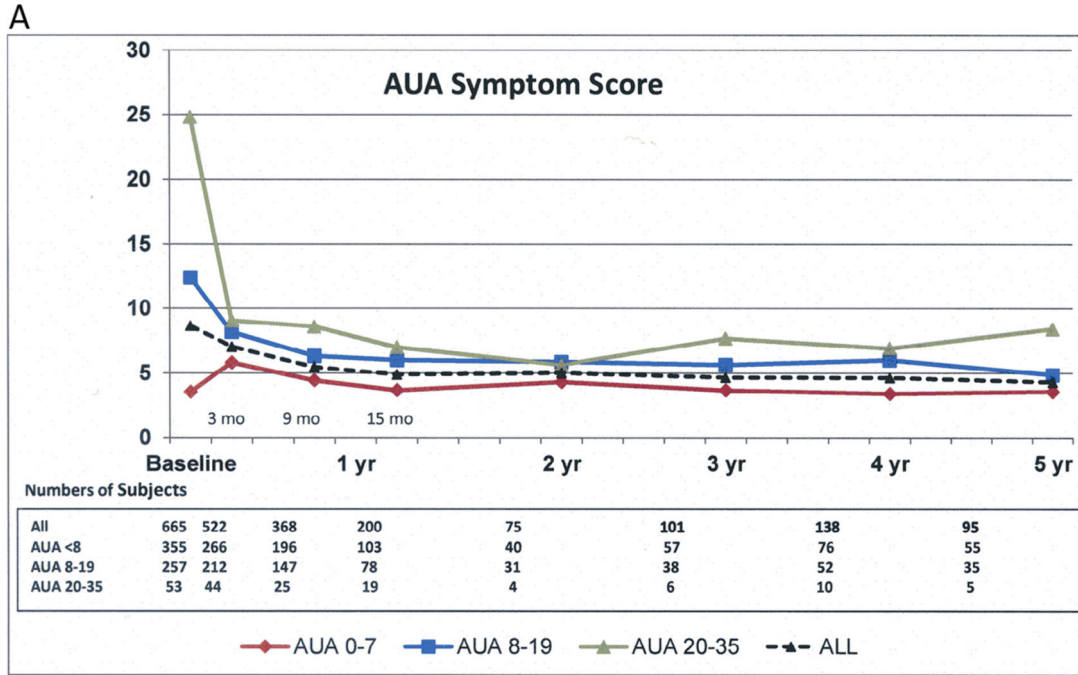
Refer to Web version on PubMed Central for supplementary material.

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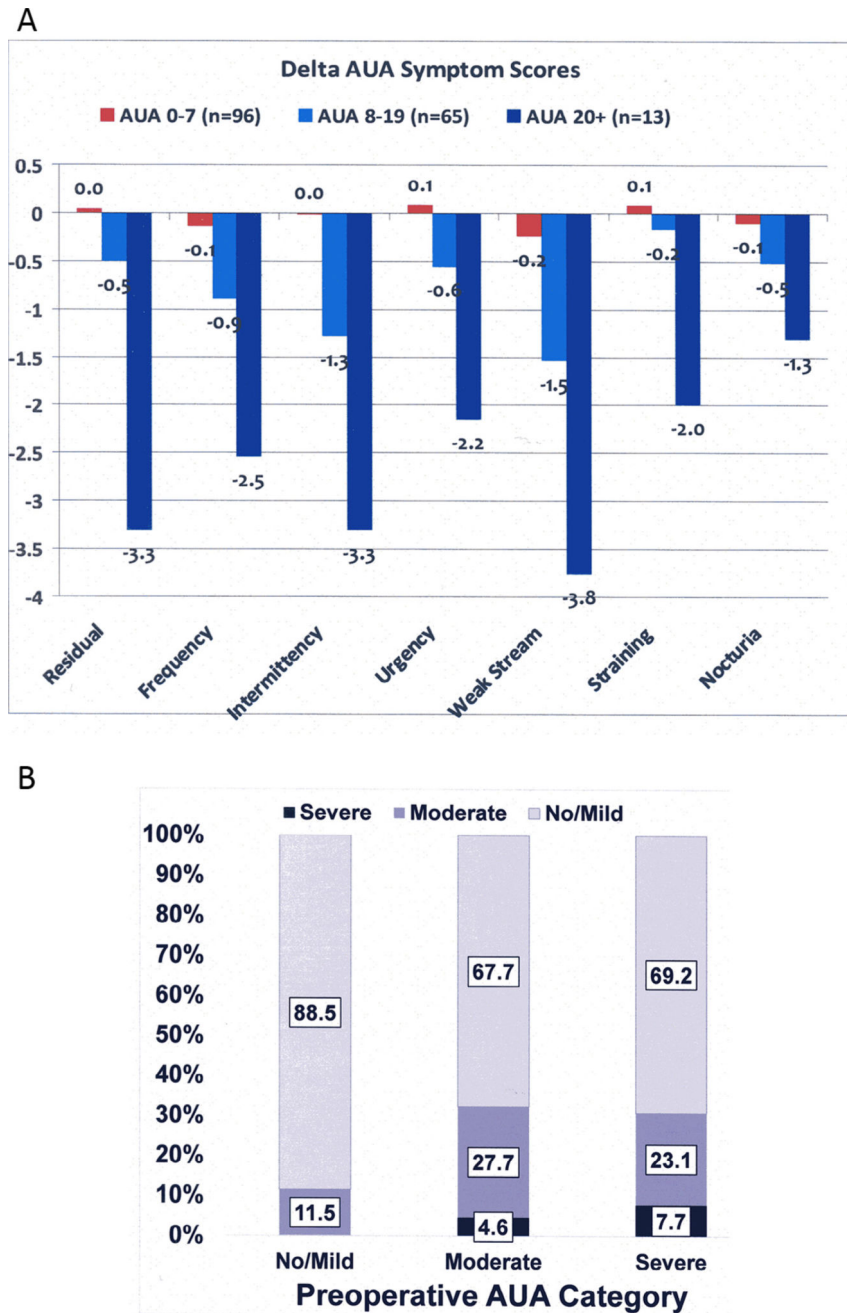
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**Figure 1.** (A) The change in baseline AUA score is shown across time for each of the 3 LUTS categories. (B) Individuals with mild LUTS remained nearly identical (0.9 to 1.1,  $P = .43$ ) long term with their urinary QOL scores. In individuals with moderate preoperative LUTS, Bother scores were statistically unchanged at 3 months (2.4 to 2.3,  $P = .20$ ) and stabilizing at 9 months to 1.5. Overall, the Bother score in the severe LUTS group declined by 2 points long term (4.0 to 2.0, all  $P < .05$ ). AUA, American Urological Association; LUTS, lower urinary tract symptoms.



**Figure 2.** (A) Change in AUA symptom indices from baseline to 5 year follow-up for 174 Men. All average AUA scores remained similar for men with preoperative Mild LUTS, and changes were not statistically significant ( $P > .05$ ). Men with preoperative severe LUTS showed the largest improvement in the 4 voiding domains (residual, intermittency, weak stream, and straining), with an average improvement of 12.4 points. (B) AUAss migration of 174 men with long term follow-up. X axis indicates preoperative LUTS category. AUA, American Urological Association; AUAss, AUA symptom score; LUTS, lower urinary tract symptoms.

**Table 1**

Descriptive characteristics for cohort

	All Subjects			Complete Follow-up*			Incomplete Follow-up <sup>†</sup>			No Follow-up			F-test
	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	
Age	666	61.4	7.4	330	61.8	7.5	252	60.9	7.1	84	61.2	7.6	.272
AUA	665	8.6	6.9	330	8.6	6.6	252	9.1	7.3	83	7.3	6.9	.105
Bother	646	1.7	1.5	326	1.8	1.4	241	1.8	1.5	79	1.5	1.5	.342
BMI	666	26.9	3.5	330	26.6	3.3	252	27.2	3.6	84	26.8	3.4	.085
PSA	666	6.8	6.3	330	7.1	7.1	252	6.4	5.3	84	7	5.4	.486
IIEF-5	660	18.9	7.4	328	19.0	7.4	248	19.1	7.2	84	17.9	8.3	.432
Prostate weight	659	51.9	21.1	327	53.3	22.8	248	50.6	19.4	84	50.1	18.9	.233
Gleason sum	661	6.8	0.8	329	6.8	0.8	252	6.8	0.9	80	6.7	0.9	.756
12-month 0-pad continence	N	%		N	%		N	%		N	%		
No	62	11		27	9		31	14		4	7		.101
Yes	521	89		280	91		189	86		52	93		
Positive margin													
No	572	86		285	86		216	86		71	85		.906
Yes	94	14		45	14		36	14		13	15		
Nerve sparing													
No	39	6		13	4		19	8		7	8		.207
Unilateral	171	26		92	28		57	22		22	26		
Bilateral	456	68		225	68		176	70		55	65		

AUA, American Urological Association; BMI, body mass index; IIEF-5, International Index of Erectile Function-5; PSA, prostate-specific antigen; SD, standard deviation.

\* Follow-up data at 3 and 9 months.

<sup>†</sup> Some follow-up data over 8 years but not both 3 and 9 months.

**Table 2**

Preoperative demographics by 3 LUTS groups

	Mild LUTS		Moderate LUTS		Severe LUTS		P Value <sup>‡</sup>
	Mean	Count	Mean	Count	Mean	Count	
Age	60.3	355	62.4	257	63.8	53	<.001
Preoperative PSA	6.4		7.4		7.0		.103
BMI	26.7		26.9		26.7		.797
Preoperative HGB	15.1		14.9		15.0		.15
LOS	26		27		29		.461
Prostate weight	47.2		55.7		65.6		<.001
Path Gleason cohorts*	6	135		101		25	.765
	7	179		125		24	
	8	40		28		4	
Pathological staging*	pT2	248		195		37	.241
	pT3	107		62		16	

HGB, hemoglobin; LOS, length of stay; LUTS, lower urinary tract symptoms; other abbreviations as in Table 1.

\* Categorical variables may not reflect total count due to missing data.

<sup>‡</sup> One-way analysis of variance with Games-Howell post hoc for group comparisons. Chi-squared test for categorical variables.

**Table 3**

Total AUA symptom score results by 3 LUTS groups

	Mild LUTS			Moderate LUTS			Severe LUTS			F-test
	N	Mean	SD	N	Mean	SD	N	Mean	SD	
All										
Baseline	355	3.53	0.11	257	12.39	0.21	53	24.78	0.54	<0.0005
3 months	266	5.80	0.28	212	8.16	0.37	44	9.02	0.75	<0.0005
9 months	196	4.42	0.27	147	6.31	0.41	25	8.58	1.30	<0.0005
15 months	103	3.66	0.32	78	6.00	0.48	19	6.97	1.15	<0.0005
2 years	40	4.29	0.57	31	5.86	1.02	4	5.63	1.60	0.349
3 years	57	3.66	0.33	38	5.63	0.82	6	7.67	1.69	0.007
4 years	76	3.40	0.37	52	5.99	0.74	10	6.90	2.12	0.002
5 years	55	3.56	0.49	35	4.86	0.60	5	8.40	2.06	0.012
Complete data	175	3.83	0.20	131	11.96	0.24	24	25.19	0.55	<0.0005*
Baseline	175	5.61	0.37	131	7.93	0.43	24	9.71	1.00	
3 months	175	4.40	0.33	131	6.13	0.39	24	8.75	0.90	
9 months										

Abbreviations as in Tables 1 and 2.

\* F-test for difference between groups in change over time using repeated measures analysis of variance.