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## Patient Risk Factors Associated with Reported Urinary Quality of Life Following Artificial Urinary Sphincter Placement: A Paired Pre and Postoperative Analysis



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<b>OBJECTIVE</b>	To evaluate potential associations between patient risk factors and incontinence related patient-reported outcome measures (PROMs) preandpost artificial urinary sphincter (AUS) implantation. We hypothesize patient risk factors, including prior radiation and diabetes will have a negative association with post AUS PROMs.
<b>METHODS</b>	A review of prospectively collected preandpostoperative Incontinence Symptom Index [ISI] and Incontinence Impact Questionnaire-7 (IIQ-7)s from multiple institutions in the Trauma and Urologic Reconstruction Network of Surgeons was performed. Changes in preandpost AUS ISI and IIQ-7 scores were compared for the entire cohort then stratified by patients with prior AUS, obesity, diabetes, prior radiation, and mixed urinary incontinence.
<b>RESULTS</b>	A total of 145 patients, 67.2 (SD 10.9) years had complete preandpost AUS questionnaires (median follow up 186 days, IQR 136-362). Post AUS ISI and IIQ-7 scores improved significantly for the group at large. Prior radiation was associated with less improvement in total IIQ-7 scores, -25.5 (31.9) vs -39 (33.0), $P = .03$ . Obesity was associated with a greater reduction in incontinence severity -13.6 (SD 9.1) vs -9.2 (SD 8.9), $P < 0.01$ , urge -5.2(SD 4.2) vs -2.5(SD 4.5), $P < .01$ , and total ISI score -29.7(SD19.7) vs -21.2 (SD 19.9), $P = .02$ . Prior AUS, diabetes, and mixed incontinence were not associated with post AUS PROMs outcome.
<b>CONCLUSION</b>	Overall, patients reported a significant reduction in incontinence severity, bother, impact, and distress following AUS placement. Prior radiation was associated with less improvement in total IIQ-7 scores. In contrast, obesity demonstrated a greater reduction in ISI severity and urge scores compared to non-obese patients. UROLOGY 169: 226–232, 2022. © 2022 Elsevier Inc.

Numerous studies demonstrate the objective, clinical efficacy of the artificial urinary sphincter (AUS) for management of moderate to severe stress urinary incontinence (SUI).<sup>1-3</sup> However, increasing evidence supports the importance of subjective, patient

perceived impact of interventions on health related quality of life (HR-QOL) through patient-reported outcome measures (PROMs).<sup>4</sup> As such, recent studies incorporate patient-reported outcomes into the evaluation of AUS success.<sup>5-7</sup>

In 2018, a study was published by the Trauma and Urologic Reconstruction Network of Surgeons (TURNS) with 51 and 45 patients evaluating average preoperative and postoperative Incontinence Impact Symptom Index (ISI)<sup>8</sup> and Incontinence Impact Questionnaire-7 (IIQ-7)<sup>9</sup> surveys. This demonstrated a significant improvement (lower scores) for SUI severity and bother across domains for patients undergoing AUS. The study had recognized limitations, however, because of the use of pooled responses and a small sample size that prevented risk factor, subgroup analysis.

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Importantly, prior studies demonstrate risk factors including prior AUS placement,<sup>10</sup> diabetes,<sup>11</sup> obesity,<sup>12</sup> and pelvic radiation<sup>13-15</sup> are associated with poor objective clinical outcomes such as higher urethral cuff erosion, infection, and device revision rates.<sup>14,16-18</sup> It follows that patients with these risk factors may experience less subjective improvement in AUS related quality of life. However, few previous studies have evaluated the potential associations of these risk factors on patients' perceived benefit of AUS placement.<sup>6</sup>

The primary objective of this study is to perform an updated analysis of the TURNS prospective AUS database to evaluate the overall impact of AUS placement on PROMs in a larger cohort with complete, paired pre and postoperative survey data. The secondary outcome of this study is to determine if clinical risk factors for poor AUS outcome are associated with patients' perceived AUS placement efficacy. We hypothesize that PROMs will improve significantly overall following AUS placement, and that previously evaluated AUS risk factors will be associated with reduced PROM improvement.

## METHODS

### Study Participants

Adult men undergoing AUS placement or revision at one of 7 TURNS centers were prospectively enrolled in an outcomes database and completed pre and postoperative ISI and IIQ-7 questionnaires. All participants with complete pre and postoperative PROMs were included in the study. In general, contributing surgeons performed AUS placements via a perineal approach with the cuff placed around the bulbar urethra using either a standard or transcorporal technique. The decision to perform standard vs transcorporal cuff placement was left to the discretion of the surgeon and typically reserved for cases where the urethra was felt to be compromised<sup>13</sup> or "fragile" due to factors including but not limited to prior radiation, urethroplasty, or prior AUS.<sup>19</sup>

### Outcomes Assessment

The primary outcome was overall change in paired pre- and post-operative ISI and IIQ-7 scores in men undergoing AUS placement. Secondary outcomes included the same comparisons stratified by (1) index vs revision AUS placement; (2) prior radiation treatment; (3) diabetes; (4) obesity (defined as a BMI>30); and (5) mixed incontinence. Mixed incontinence was surgeon reported based on the presence of stress urinary incontinence with concomitant urinary urgency or urge incontinence defined as patient use of overactive bladder (OAB) therapy (anticholinergic, beta agonist, botulinum toxin, etc.) or urodynamic findings.

### Statistical Analysis

Group characteristics were summarized with mean and standard deviation for continuous variables and percentages for categorical variables. Differences between the group demographics were compared using Student's t-test and chi-squared goodness of fit tests. Preoperative and postoperative AUS PROM scores for the entire cohort were presented as

medians and interquartile range (IQR) and compared using Wilcoxon signed-rank nonparametric test. Secondary outcome groups were then compared by the mean change in PROM scores using Student's t-test. Statistical significance was defined as a 2-tailed P-value <.05 for all statistical tests. All analyses were performed using Stata 15 (StataCorp. 2017, College Station, TX.).

## RESULTS

A total of 145 patients, mean age (SD) 67.2year (10.9year) had complete preoperative and postoperative ISI and IIQ-7 questionnaires available and were included in the analysis. Participants had an average follow up of 186 days (IQR 136-362days) between initial and postoperative surveys. Overall, patient comorbidities and potential risk factors included diabetes 29/145 (20%), obesity 52/145 (36%), and mixed incontinence 13/145 (9%). More than half of patients in the total cohort had prior radiation treatment 79/145 (55%), and 50/145 (34%) had undergone prior AUS (Table 1).

### Patient Outcomes

We found a significant improvement in the overall ISI score change with both stress and urgency components as demonstrated in (Fig. 1). Following AUS placement, patients reported using thinner pads with an average reduction in pads per day (PPD) from 4.0 (IQR 3.0-4.0) to 2.0 (IQR 1.0-3.0),  $P<.001$ . The total severity subdomain score was reduced from 24.0 (IQR 20.0-29.0) to 10.0 (IQR 7.0-19.0),  $P<.001$  as well as bother subdomain from 6.0 (IQR 4.0-7.0) to 1.0 (IQR 0.0-5.0)  $P<.001$  postoperatively.

Similar to the ISI, the IIQ-7 demonstrated an overall significant improvement in postoperative scores for all measures (Fig. 2). Notably, the impact scores from 9.0 (IQR 5.0-12.0) to 3.0 (IQR 0.0-7.0),  $P <.01$ , and distress from 4.0 (IQR 2.0-5.5) to 1.0 (IQR 0.0-3.0),  $P<.01$ .

### Secondary Outcomes

Baseline characteristics of patients with preoperative and postoperative surveys were similar when stratifying by patient risk factors except for a lower rate of prior AUS for patients post radiation (Table 1). When analyzing the PROMS stratifying by patient AUS risk factors in the total cohort (Table 2), obesity was associated with improved pre and postoperative change in severity reduced from -13.6 (SD 9.1) to -9.2 (SD 8.9)  $P<.01$ , urge from -5.2 (SD 4.2) to -2.5 (SD 4.5)  $P <.01$ , and total ISI score from -29.7 (SD 19.7) to -21.2 (SD 19.9)  $P = .02$ . Radiation, mixed incontinence, diabetes, and prior AUS did not have a reduced change in ISI scores compared to controls.

In contrast, for the IIQ subgroup analysis, radiation demonstrated significantly reduced change (less improvement) in total IIQ-7 score for the total cohort (Table 2), -25.5 (31.9) vs -39 (33.0),  $P = .03$ . Obesity, mixed incontinence, diabetes, and prior AUS were not associated with significant reduction in perioperative PROMs.

## DISCUSSION

This study demonstrates overall significant improvement in urinary function and patient-reported QOL after undergoing AUS placement. A history of prior radiation treatment demonstrated a reduced change in

**Table 1.** Baseline patient characteristics of all patients with preoperative and postoperative surveys stratified by risk factor

Factor	N N=145	Prior AUS			Prior Radiation			Obese			Mixed Incontinence			Diabetes		
		No N=95	Yes N=50	P	No N=51	Yes N=79	P	No N=80	Yes N=53	P	No N=123	Yes N=13	P	No N=112	Yes N=29	P
Age, mean y (SD)	67.2 (10.9)	66.2 (10.1)	68.8 (12.1)	.18	67.6 (10.9)	67.6 (9.1)	.99	69.5 (9.3)	63.6 (12.5)	.003	67.0 (10.8)	68.5 (12.2)	.57	66.7 (11.3)	68.8 (9.4)	.35
Comorbidity N (%)																
Diabetic	29 (20.0)	19 (20.0)	10 (20.0)	.90	10 (19.6)	18 (22.8)	.67	14 (17.5)	15 (28.3)	.14	25 (21.4)	4 (21.1)	.98	—	—	—
Prior Pelvic Radiation	79 (54.5)	57 (60.0)	22 (44.0)	.02	—	—	—	44 (58.7)	33 (66.0)	.41	68 (59.6)	10 (71.4)	.39	61 (59.8)	18 (64.3)	.67
Obesity	52 (35.9)	35 (36.8)	17 (34.0)	.63	17 (35.4)	33 (42.9)	.41	—	—	—	44 (39.3)	9 (47.4)	.51	38 (36.5)	15 (51.7)	.14
Mixed Incontinence	13 (9.0)	9 (9.5)	4 (8.0)	.53	3 (6.0)	7 (9.0)	.54	6 (7.7)	7 (13.2)	.3	—	—	—	10 (9.3)	3 (10.3)	.87
Transcortical Approach	40 (27.6)	24 (25.3)	16 (32.0)	.22	8 (17.4)	27 (36.0)	.02	19 (25.7)	17 (34.0)	.32	32 (29.6)	6 (31.6)	.86	31 (29.8)	7 (25.0)	.62
Urethral Cuff Size mean (SD)	4.5 (0.6)	4.5 (0.5)	4.6 (0.7)	.18	4.6 (0.7)	4.4 (0.5)	.05	4.5 (0.6)	4.6 (0.6)	.54	4.5 (0.6)	4.6 (0.6)	.71	4.6 (0.6)	4.3 (0.4)	.086

IIQ-7 scores; however, no other patient clinical risk factor had a significant association change in post AUS PROMs. Conversely, obesity demonstrated greater PROM improvement with reduced ISI severity and urgency scores.

### Prior AUS Surgery

We found no significant association between prior AUS on pre and postoperative ISI and IIQ-7 scores. Additional studies have compared HR-QOL measures following AUS placement between index and revision AUS placement including a prior cross sectional, postoperative analysis<sup>7</sup> with a median follow up of 8.3 years (IQR 5.8-11.4). Similar to our findings, using a non-validated questionnaire as well as the Expanded Prostate Cancer Index Composite Urinary Assessment Urinary Domain (EPIC),<sup>20</sup> they found a similarly good post-operative quality of life score for both index and revision AUS [74 vs 74 (100 being the best score)]. In contrast, this study did not include a pre-operative assessment.

### Diabetes

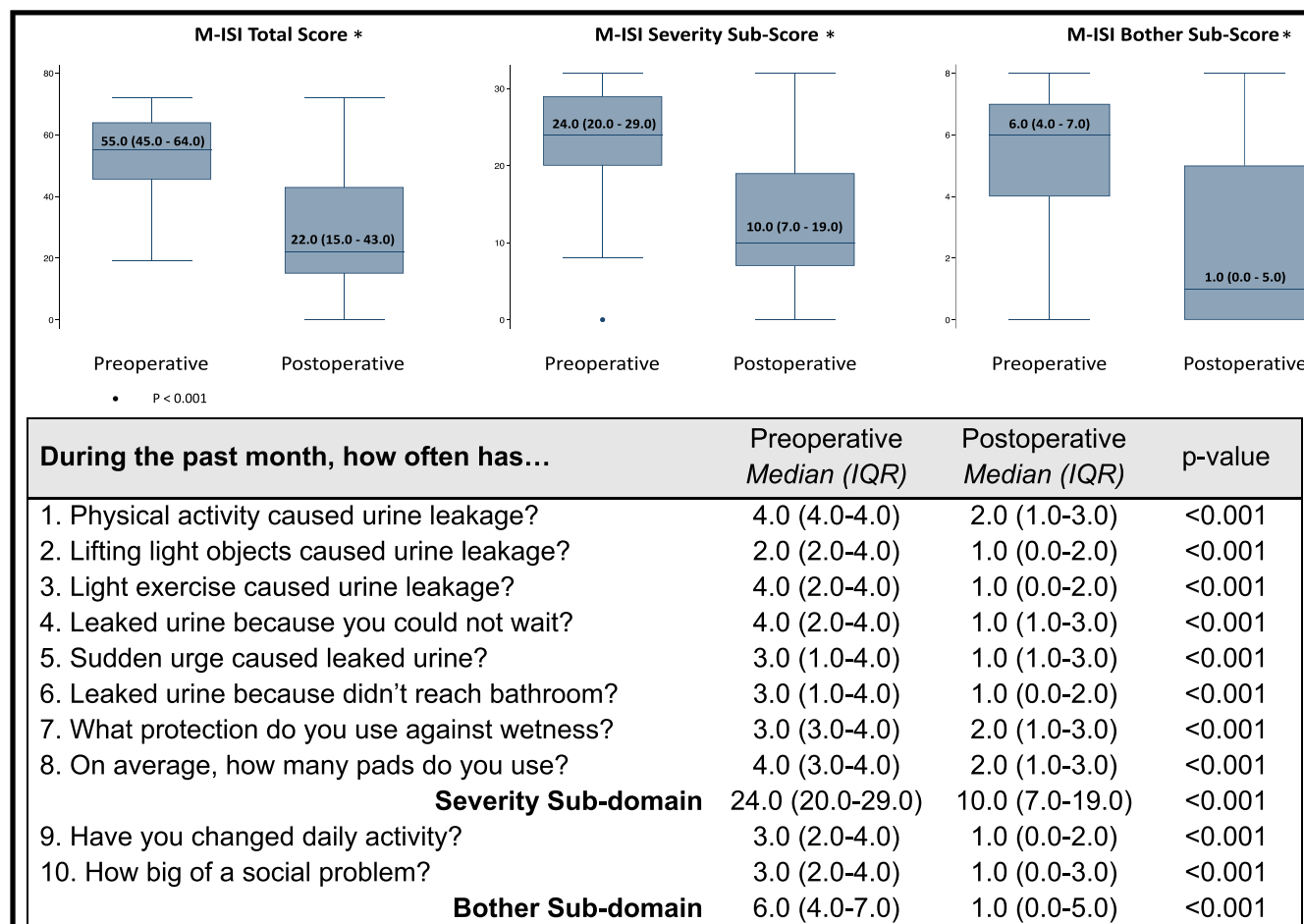
Prior studies demonstrate diabetes is associated with poor AUS clinical outcomes including infection and erosion,<sup>18</sup> however, no study has evaluated potential impact on PROMs. Although patients with diabetes demonstrated reduced (worse) overall ISI score from the total cohort, there was no significant impact on the change in pre and postoperative PROMs. This suggests that despite a higher risk for AUS revision, patients perceive improved incontinence outcomes following AUS placement comparable to patients without diabetes.

### Obesity

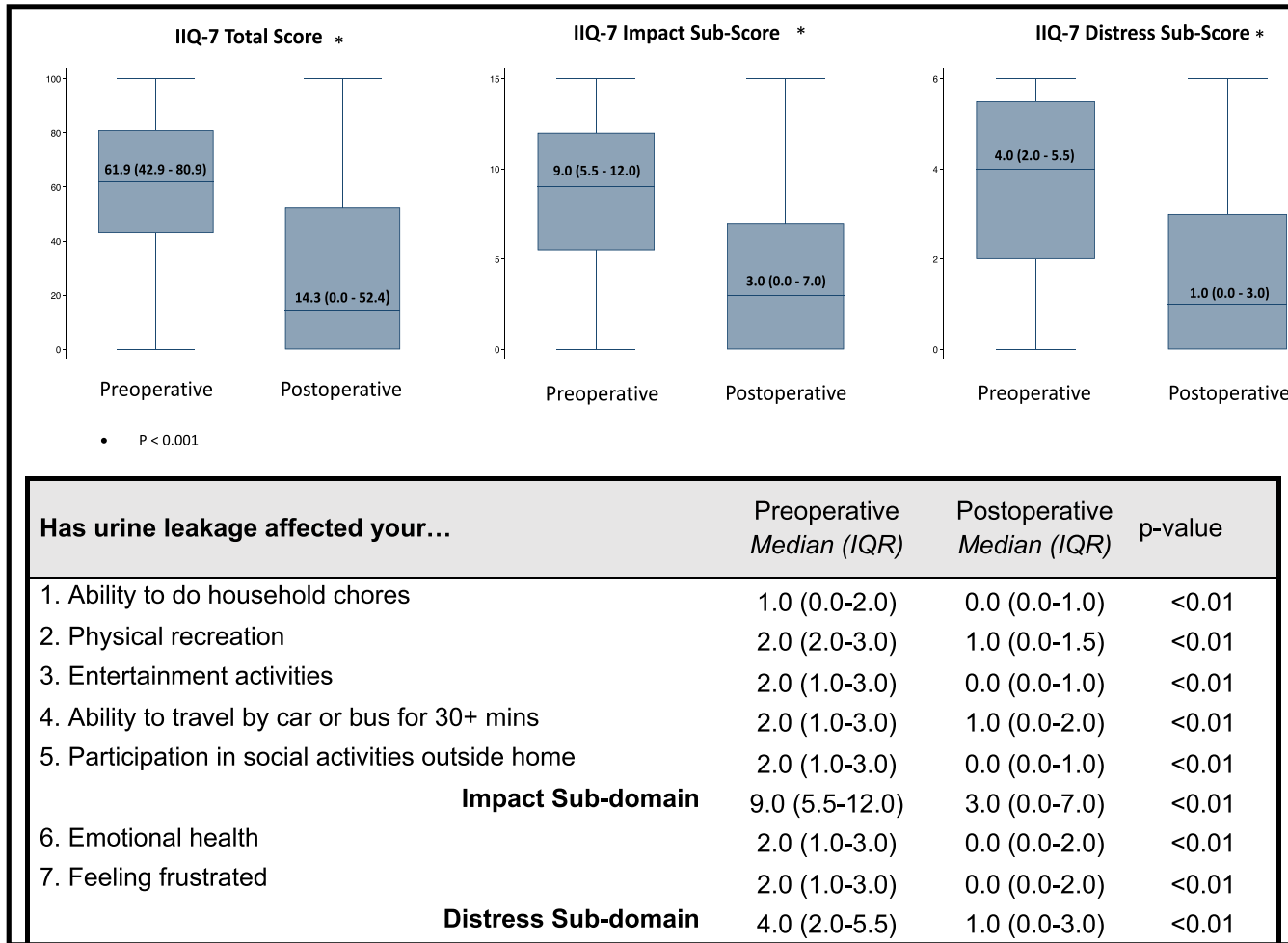
Obesity is associated with a reduced rate of AUS erosion<sup>18</sup> however, has also been linked to higher post AUS PPD utilization<sup>18</sup> and higher rates of mechanical failure,<sup>12</sup> possibly due to increased mass effect on the system. No studies to our knowledge have specifically evaluated the effects of obesity on PROMs after AUS placement. In this study, we found obesity was associated with a greater reduction incontinence severity, urgency, and total ISI score. Further, there was no significant difference in pad utilization as compared to non-obese patients. This may be due to the relatively high proportion of patients with obesity in this cohort, however the reason for the association between obesity and improved PROMs remains unclear.

### AUS and Prior Radiation

Although radiation has been associated with higher rates of AUS erosion and failure,<sup>13,15,17,21</sup> studies demonstrate comparable postoperative pad utilization and perceived satisfaction.<sup>16</sup> Similarly, we found a similar reduction in patient reported urinary stress, urge, and pad utilization between patients with and without prior radiation exposure. Conversely, we found a less improvement in total impact and distress IIQ scores for irradiated patients



**Figure 1.** Overall and question-specific preoperative versus postoperative Incontinence Symptom Index (ISI) responses in the study population, n=145 patients. (Color version available online.)



**Figure 2.** Overall and question-specific preoperative versus postoperative Incontinence Index Questionnaire -7 (IIQ-7) responses in the study population, n=145 patients. (Color version available online.)

**Table 2.** Average change in incontinence severity index (ISI) survey score and incontinence index questionnaire (IIQ) scores pre and post AUS stratified by patient factor

ISI Domain mean Δ(SD)	Radiation						Mixed Incontinence						Diabetes						Prior AUS											
	No N=51		Yes N=79		P-value		No N=80		Yes N=53		P-value		No N=117		Yes N=19		P-value		No N=112		Yes N=29		P-value		No N=95		Yes N=50		P-value	
	Overall N=145																													
Severity	-11.1 (9.4)	-12.1 (9.3)	-10.6 (9.2)	.40	-9.2 (8.9)	-13.6 (9.1)	≤.01	-11.2 (8.9)	-9.9 (11.6)	.58	-11.7 (8.7)	-8.4 (11.5)	.12	-11.1 (10.2)	-11.0 (8.0)	.96														
Bother	-3.0 (3.0)	-2.8 (3.2)	-3.2 (2.8)	.44	-2.8 (3.0)	-3.4 (2.8)	.30	-3.0 (3.0)	-2.8 (2.9)	.74	-3.2 (2.8)	-2.3 (3.4)	.19	-3.3 (3.0)	-2.5 (2.8)	.16														
Stress	-4.9 (4.3)	-5.2 (4.0)	-4.8 (4.2)	.68	-4.2 (4.3)	-5.6 (3.7)	.06	-4.9 (4.1)	-4.3 (4.9)	.59	-5.1 (3.9)	-3.7 (5.3)	.15	-4.9 (4.6)	-4.8 (3.7)	.87														
Urge	-3.6 (4.6)	-4.4 (4.3)	-3.0 (4.5)	.12	-2.5 (4.5)	-5.2 (4.2)	≤.01	-3.7 (4.3)	-3.1 (5.8)	.64	-3.8 (4.3)	-2.3 (5.5)	.14	-3.3 (4.9)	-4.0 (3.9)	.47														
Pad Use	-2.5 (2.6)	-2.4 (2.7)	-2.6 (2.7)	.76	-2.5 (2.3)	-2.4 (3.0)	.88	-2.5 (2.6)	-2.5 (2.7)	.98	-2.5 (2.5)	-2.4 (3.1)	.80	-2.7 (2.7)	-2.1 (2.5)	.24														
<b>TOTAL</b>	<b>-24.7 (20.7)*</b>	<b>-26.6 (20.9)</b>	<b>-23.9 (19.8)</b>	<b>.48</b>	<b>-21.2 (19.9)</b>	<b>-29.7 (19.7)</b>	<b>.02</b>	<b>-24.9 (19.6)</b>	<b>-22.6 (25.5)</b>	<b>.65</b>	<b>-25.9 (19.0)</b>	<b>-19.1 (25.4)</b>	<b>.14</b>	<b>-25.0 (22.3)</b>	<b>-24.1 (17.7)</b>	<b>.82</b>														
IIQ Domain mean Δ(SD)	Radiation						Mixed Incontinence						Diabetes						Prior AUS											
	No N=51		Yes N=79		P-value		No N=80		Yes N=53		P-value		No N=117		Yes N=19		P-value		No N=112		Yes N=29		P-value		No N=95		Yes N=50		P-value	
	Overall N=145																													
Impact	-4.3 (5.4)	-5.6 (5.1)	-3.7 (5.6)	.05	-4.2 (4.7)	-5.1 (5.8)	.32	-4.5 (5.6)	-3.8 (4.3)	.61	-4.3 (5.4)	-4.2 (5.6)	.97	-4.6 (5.2)	-3.7 (5.9)	.30														
Distress	-2.0 (2.4)	-2.4 (2.3)	-1.8 (2.4)	.16	-2.0 (2.2)	-2.1 (2.3)	.89	-2.0 (2.4)	-1.9 (2.1)	.84	-2.0 (2.4)	-1.7 (2.4)	.46	-2.1 (2.4)	-1.7 (2.4)	.35														
<b>TOTAL</b>	<b>-30.5 (33.1)</b>	<b>-39.0 (33.0)</b>	<b>-25.5 (31.9)</b>	<b>.03</b>	<b>-30.1 (29.5)</b>	<b>-32.1 (36.2)</b>	<b>.73</b>	<b>-31.3 (33.8)</b>	<b>-31.4 (24.8)</b>	<b>.99</b>	<b>-31.6 (32.6)</b>	<b>-24.9 (34.6)</b>	<b>.35</b>	<b>-31.8 (33.4)</b>	<b>-27.7 (32.7)</b>	<b>.49</b>														

compared to non-radiated patients. This may be due to other factors contributing to poor urinary QOL, such as radiation cystitis or increased co-morbidities.

### Limitations

Despite a larger cohort size as compared to the 2018 publication,<sup>22</sup> there were relatively small proportions of patients with risk factors of interest, including diabetes, which limited the power of the study to detect potential impact on the ISI and IIQ-7. Additionally, there are no validated AUS PROMs, thus the existing surveys may not accurately capture the full, patient perceived impact of AUS on HR-QOL. However, the ISI has been used in prior studies evaluating AUS outcomes<sup>23</sup> and has standard measures that extrapolate well to this context. Although we were able to complete a repeated measure analysis, the average follow-up was less than one year for many in the cohort. This may not have captured the potential impact of a revision rate approaching 50% at 5 years.<sup>24</sup>

### CONCLUSION

This study demonstrated overall significant reduction in patient reported incontinence severity, bother, impact, and distress following AUS placement. Prior radiation was associated with less improvement in postoperative IIQ-7 scores, however, diabetes, mixed incontinence, and prior AUS placement did not have a significant association. Conversely, obesity was associated with a greater reduction ISI severity and urge. Validated, specific AUS PROMs are lacking and required to completely capture outcomes. Further, longitudinal follow up is required to evaluate the durability of these results.

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