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Authors

Wingate, Jonathan T
Erickson, Bradley A
Murphy, Gregory
et al.

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Multicenter Analysis of Patient Reported Outcomes Following Artificial Urinary Sphincter Placement for Male Stress Urinary Incontinence

Jonathan T. Wingate, Bradley A. Erickson, Gregory Murphy, Thomas G. Smith, III, Benjamin N. Breyer and Bryan B. Voelzke* for TURNS

From the Madigan Army Medical Center (JTW), Tacoma and University of Washington (BBV), Seattle, Washington, University of Iowa (BAE), Iowa City, Iowa, University of California-San Francisco (GM, BNB), San Francisco, California, and Baylor College of Medicine (TGS), Houston, Texas

Purpose: Patient centered data are lacking regarding functional and quality of life improvements after artificial urinary sphincter placement. We analyzed the degree of benefit from artificial urinary sphincter placement using ISI (Incontinence Symptom Index), a validated patient reported outcome measure assessing the severity and bother of urinary incontinence, and IIQ-7 (Incontinence Impact Questionnaire-7), a validated patient reported outcome measure assessing the impact and emotional distress of urinary incontinence.

Materials and Methods: We performed a retrospective review at 4 centers participating in TURNS (Trauma and Urologic Reconstruction Network of Surgeons). Data were available on 51 and 45 patients who underwent artificial urinary sphincter placement, and had preoperative and postoperative ISI and IIQ-7 data, respectively.

Results: Mean age was 64.8 years. Median time from surgery to followup questionnaires was 8.5 months. On ISI the median preoperative severity and bother scores were 24 (IQR 20–28.5) and 6 (IQR 4–7), and the median postoperative severity and bother scores were 10 (IQR 4.5–17) and 1 (IQR 0–3), respectively. Improvement on each ISI item was statistically significant. On IIQ-7 the median preoperative impact and distress scores were 9 (IQR 6–13) and 4 (IQR 2–6), and the median postoperative impact and distress scores were 3 (IQR 0–7) and 0 (IQR 0–3), respectively. Improvement on each IIQ-7 item was statistically significant.

Conclusions: Artificial urinary sphincter implantation significantly reduces the severity and bother of stress urinary incontinence symptoms. Longer followup and development are needed of a patient reported outcome measure targeting male stress urinary incontinence.

Key Words: urethra; urinary sphincter, artificial; urinary incontinence, stress; males; patient reported outcome measures

Abbreviations and Acronyms

AUS = artificial urinary sphincter

IIQ-7 = Incontinence Impact Questionnaire-7

ISI = Incontinence Symptom Index

PROM = patient reported outcome measure

QOL = quality of life

SUI = stress urinary incontinence

UUI = urge urinary incontinence

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* Correspondence: Department of Urology, Harborview Medical Center, 325 9th Ave., Box 359868, Seattle, Washington 98101 (telephone: 206-744-6384; FAX: 206-543-3272; e-mail: voelzke@uw.edu).

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STRESS urinary incontinence is a well described sequela of radical prostatectomy with rates as high as 65.6%.[1] SUI is a chronic urological condition that has a significant impact on the patient quality of social and emotional life.[2,3] The gold standard treatment of moderate to severe SUI is AUS with surgical success rates up to 88%.[4] Studies that have assessed patient satisfaction have shown that most patients are satisfied with the outcome with rates ranging from 73% to 90% with the volume of persistent leakage as the greatest driver of dissatisfaction.[5–7] However, the degree

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to which a successful AUS improves PROMs is largely unknown.

A PROM is a measurement tool completed by patients without external interpretation, which addresses the patient perspective on the health condition.[8] For SUI evaluating the patient perceptions of symptoms and how symptoms impact daily life is integral to determine the magnitude of the treatment benefit offered by an AUS.

The purpose of this study was to analyze PROMs completed by men who underwent AUS implantation, specifically looking at changes in patient QOL after surgically successful AUS placement. We hypothesized that significant improvement in patient QOL would strongly correlate to improvements in incontinence after AUS implantation.

METHODS

Study Subjects

Four centers in TURNS (Trauma and Urologic Reconstruction Network of Surgeons) prospectively enrolled men in a longitudinal AUS registry that evaluated patient reported outcomes related to SUI and surgery intended to improve SUI. All men at these 4 centers who completed preoperative and postoperative questionnaires were included in study. Preoperative evaluation of the patient, such as the need for cystoscopy or urodynamic testing, was left to the discretion of the operative provider as dictated by the clinical situation.

Outcomes Assessment

The primary outcome of this retrospective study was the postoperative change in PROM scores after AUS placement. We used 2 PROM instruments in this study, including ISI and IIQ-7. These questionnaires were completed preoperatively and then at all subsequent postoperative visits after the AUS had been activated. In this particular study if multiple postoperative questionnaires were completed, only the most recent questionnaire was used for comparison to preoperative answers.

ISI is a validated instrument designed to discern incontinence type (stress incontinence vs UUI) and severity/bother due to urinary incontinence.[9] It includes 10 items, consisting of an incontinence domain (questions 1 to 8) and a bother domain (questions 9 and 10). The incontinence domain is further divided into 3 subdomains, including questions 1 to 3 on SUI, 3 to 6 on UUI, and 7 and 8 on pad use. All 10 items have Likert response options (range 0 to 4) with higher values representing greater symptoms or bother.[9]

IIQ-7 is a validated instrument designed to evaluate the impact and symptom distress due to urinary incontinence on quality of life.[10] It is 7 items, consisting of an impact domain (questions 1 to 5) and a distress domain (questions 6 and 7). The impact domain lists specific activities and measures the effect of urinary incontinence on the patient ability to perform those tasks. The distress domain asks patients how urinary incontinence has affected emotional health or whether urinary incontinence was making them frustrated. All items have Likert response options, including 0—not at all, 1—slightly, 2—moderately and 3—greatly.

Statistical Analysis

Descriptive statistics were generated on all demographic data with the mean ± SD for continuous variables, and the frequency and percent for categorical variables. Likert scores were treated as ordinal variables, and are reported as the median and IQR. Differences between ISI and IIQ-7 before and after treatment were analyzed by the Wilcoxon signed rank test. All statistical analyses were performed with R, version 3.2.1 (https://www.r-project.org/). Statistical significance was considered at $p < 0.05$.

RESULTS

A total of 51 and 45 patients had preoperative and postoperative ISI and IIQ-7 questionnaires available, respectively, and were included in analysis. Mean ± SD time from surgery to the followup questionnaire was 8.53 ± 6.02 months. Table 1 lists baseline patient demographics. Notably the cohort consisted of 62.7%, 23.5% and 9.8% of patients with prior pelvic radiation, prior urethroplasty and/or revision AUS, respectively. Given the complexity of these cases, 45.1% of AUS placements were done in a transcorporeal manner.

Urinary Incontinence Patient Reported Outcomes Measure Assessment

Severity. Significant improvement was seen in the SUI severity scores of ISI after successful AUS

Table 1. *Baseline patient demographics*

Mean ± SD age	64.8 ± 12.1
No. comorbidity (%):	
Diabetes	7 (13.7)
Hypertension	29 (56.9)
Hyperlipidemia	22 (43.1)
Coronary artery disease	10 (19.6)
Current smoker	5 (9.8)
No. surgical risk factor (%):	
Prior pelvic radiation	32 (62.7)
Prior urethroplasty	12 (23.5)
Revision AUS	5 (9.8)
No. cm cuff size (%):*	
3.5	4 (7.8)
4	21 (42.1)
4.5	9 (17.6)
5	5 (9.8)
5.5	2 (3.9)
7.5	1 (2.0)
Unknown	9 (17.6)
No. transcorporeal cuff (%):	
Yes	23 (45.1)
No	20 (39.2)
Unknown	8 (15.7)
No. surgical approach (%):	
Perineal	42 (82.4)
Penoscrotal	1 (2.0)
Abdominal	2 (3.9)
Unknown	6 (11.8)
No. anticholinergic (%):	
Yes	6 (11.8)
No	45 (88.2)

*Unlisted sizes not used.

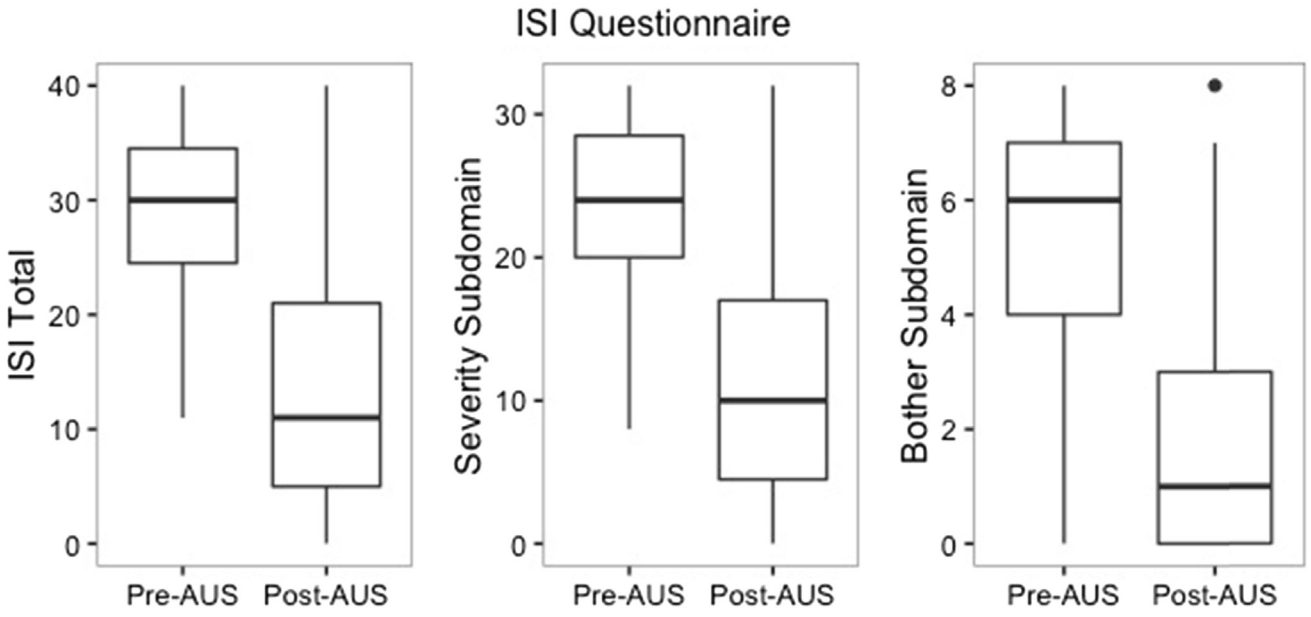

Figure 1. Median total ISI Likert scores, and severity and bother subdomain scores with IQR and outliers before and after AUS

implantation (fig. 1). The correlation of each ISI item before vs after AUS surgery was statistically significant ($p < 0.05$). The median overall incontinence subdomain improved significantly from 24 (IQR 20–29) to 10 (IQR 5–17), reflecting specific improvements in the stress incontinence subdomain (10, IQR 8–12 to 3, IQR 2–7) and the urge incontinence subdomain (9, IQR 6–12 to 3, IQR 2–7) (table 2).

There was also a statistically significant decline in pad use and pad type. When asked, "What form of protection do you use to protect against wetness during the day?" the median Likert score was 3 (IQR 3–4) for "large/maxi pad" preoperatively and 1 (IQR 1–2) for "thin pad or tissue" postoperatively. Average pad use also decreased from a median Likert score of 4 (IQR 3–4) for "4 or more pads per day" to 1 (IQR 1–3) for "1 pad per day or less, or only for security."

Impact, Distress and Bother. We used IIQ-7 to evaluate the impact of incontinence on the patient. This revealed significant postoperative improvement in the ability to perform activities of

Table 2. *Patient responses to ISI*

Subdomain (question)	Median before AUS (IQR)	Median after AUS (IQR)
SUI:*	10 (8–12)	3 (2–6)
How often has urine leakage occurred in association with any physical activity?	4 (3–4)	2 (1–3)
How often has lifting light objects caused you to leak urine?	2 (2–4)	1 (0–1)
How often has walking or light exercise caused you to leak urine?	4 (2–4)	1 (0–2)
UUI:*	9 (6–12)	3 (2–7)
How often have you leaked urine because you could not wait to empty your bladder?	4 (2–4)	1 (1–3)
How often has sudden urge to urinate caused you to leak urine?	3 (1–4)	1 (0–3)
How often have you leaked urine because you could not reach bathroom in time?	3 (1–4)	1 (0–2)
Pad use:	7 (6–7)	3 (2–5)
On average what form of protection do you use to protect against wetness during day?†	3 (3–4)	1 (1–2)
On average how many of these would you use to protect against wetness during day?‡	4 (3–4)	1 (1–3)
Total severity	24 (20–29)	10 (5–17)
Bother:	6 (4–7)	1 (0–3)
How often have you needed to change your daily activities because of your urinary incontinence?§	3 (2–4)	0 (0–1)
How big of social problem has your urinary incontinence been for you during past month?¶	3 (2–4)	1 (0–2)

All $p < 0.001$.
* Likert scale 0—never, 1—rarely, 2—occasionally, 3—about half of time, 4—most or all of time.
† Likert scale 0—never, 1—thin pad or tissue, 2—medium/regular pad, 3—large/maxi pad, 4—absorbant, disposable undergarments.
‡ Likert scale 0—never, 1—1 per day or less or only for security, 2—1 per day and it is usually wet, 3—2 to 3 per day, 4—4 or more per day.
§ Likert scale 0—never, 1—rarely, 2—sometimes, 3—most of time, 4—all of time.
¶ Likert scale 0—no problem, 1—very small problem, 2—small problem, 3—moderate problem, 4—big problem.

Table 3. *Patient responses to IIQ-7*

Questions	Median before AUS (IQR)	Median after AUS (IQR)	p Value
Incontinence impact subdomain			
Has urine leakage affected your:	9 (6,13)	3 (0,7)	<0.001
Ability to do household chores?	2 (0,3)	0 (0,1)	0.001
Physical recreation such as walking, swimming or other exercise?	2 (1,3)	0 (0,2)	<0.001
Entertaining activities?	2 (1,3)	0 (0,2)	0.001
Ability to travel by car or bus more than 30 mins from home?	2 (1,3)	0 (0,2)	0.017
Participation in social activities outside your home?	2 (2,3)	1 (0,2)	<0.001
Incontinence distress subdomain			
Has urine leakage affected your:	4 (2,6)	0 (0,3)	<0.001
Emotional health (nervousness, depression)?	2 (1,3)	0 (0,1)	<0.001
Feeling frustrated?	2 (1,3)	0 (0,2)	<0.001

Likert scale 0—not at all, 1—slightly, 2—moderately, 3—greatly.

daily living, including household chores, physical recreation, entertaining, driving a car and other social activities (table 3). The overall median subdomain score decreased from 9 (IQR 6–13) to 3 (IQR 0–7) (fig. 2).

Distress was also evaluated using IIQ-7, which revealed significant improvement in postoperative emotional health and frustration as they related to incontinence. The overall median subdomain score decreased from 4 (IQR 2–6) to 0 (IQR 0–3) (table 3).

Significant improvement in the median bother score was noted in the ISI bother subdomain, which decreased from 6 (IQR 4–7) to 1 (IQR 0–3). Specifically answers on this subdomain revealed that patients reported a decrease in the "need to change daily activities" and "incontinence being a social problem" less often (fig. 1 and table 2).

DISCUSSION

Our study highlights that the AUS significantly reduces the severity and bother of urinary incontinence. Applying the validated ISI questionnaire in the preoperative and postoperative settings, we quantified improvement across its severity and bother subdomains and found that the subjective patient reported improvements in these subdomains were statistically significant. By examining the IIQ-7 questionnaire we also found that the AUS significantly reduced the impact and emotional distress associated with urinary incontinence.

SUI is a common sequela following radical prostatectomy and urinary incontinence significantly affects patient QOL.[2,3,11] Many groups have described excellent patient satisfaction, durability and functional outcomes with the AUS.[5,12–15] Although many prior studies have preoperative and postoperative pad use data, a granular assessment of the patient subjective assessment of overall improvement is lacking. By not assessing and comparing consistent PROMs in the preoperative and postoperative settings, urologists cannot accurately know the subjective impact of AUS surgery on patient daily life. To our knowledge no group has

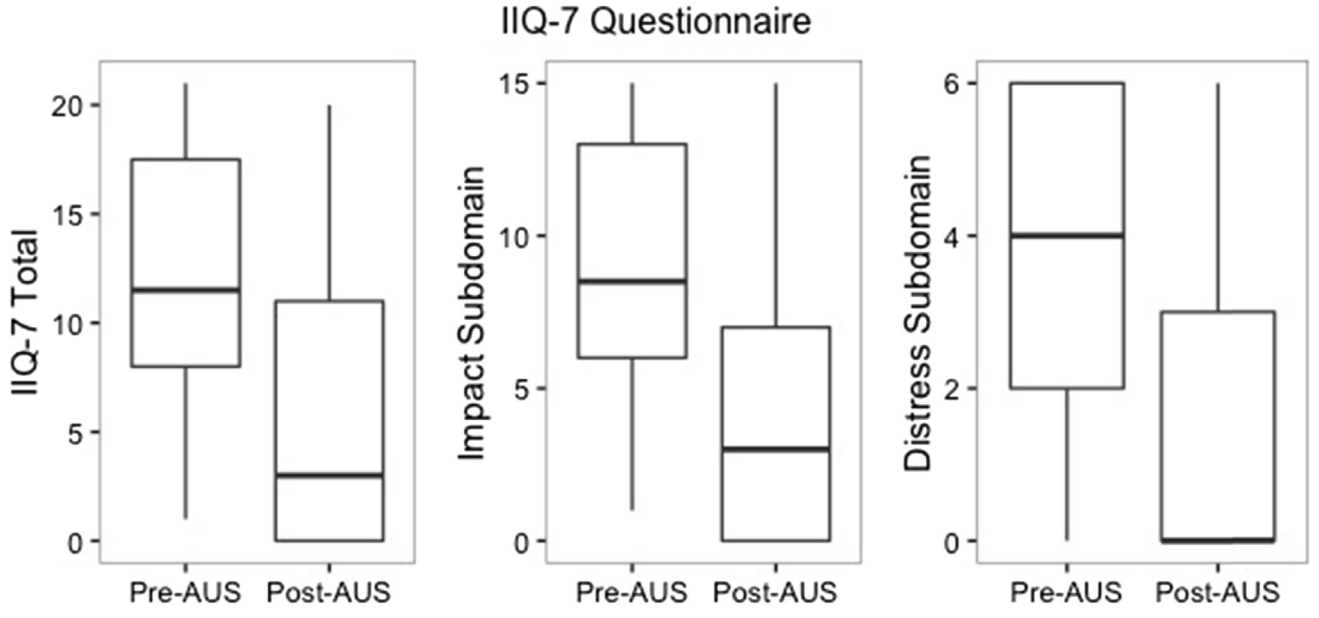

Figure 2. Median IIQ-7 Likert scores, and impact and distress subdomain scores with IQR and outliers before and after AUS

previously used PROMs to evaluate the impact of urinary incontinence in the preoperative and postoperative settings.

Our study quantified the severity, bother and distress associated with urinary incontinence using the ISI and IIQ-7 urinary incontinence questionnaires. We then assessed patient urinary incontinence after AUS placement, thus, quantifying the impact of the AUS on patient QOL due to urinary incontinence. Furthermore, we used the ISI questionnaire, which has been validated to measure the impact of urinary incontinence.[9] With the PROMs we identified and measured specific symptoms and how improvement in each of these domains ultimately impacted patient QOL. Although overall patient satisfaction is an important metric to determine surgical success, as described in many prior series, our study describes the specific effects of SUI that affect patient QOL, how the AUS improves those symptoms and what drives the global improved QOL and satisfaction.

These improvements were achieved in a complex patient cohort with a high rate of prior pelvic radiation, prior urethroplasty and/or AUS revision surgery. Since the surgical approach was left to the discretion of the operative surgeon, we suspect that the high rate of transcorporeal cuff placement reflects the complexity of the patient cohort as the transcorporeal technique is an accepted modification for this particular patient cohort.[16] Interestingly patients had significant and unexpected improvements in the urinary urge incontinence subdomains. A prior study demonstrated that patients may actually have worse urinary urgency after AUS placement as this patient population may have underlying detrusor overactivity.[14] As only 6 of the 51 patients (11.8%) in our cohort were on anticholinergic medications, we suspect that the improvement in UUI may have been due to a global effect of improved SUI and overall QOL rather than to a direct effect of the AUS on UUI. Future studies to validate our hypothesis would be necessary.

There are several limitations to our study. Although ISI was administered to men in the validation studies, men comprised a small proportion of the cohort and ISI has not been validated to assess male urinary incontinence.[9] As to our knowledge there are no specific questionnaires available to assess urinary incontinence in men, we decided to use ISI since it has excellent content and face validity.

Another limitation is the median followup of 8.5 months. Long-term followup studies have demonstrated that AUS mechanical failure and revision rates range between 12.4% and 36%, which may affect the durability of subjective QOL improvements.[13,15] Of note, a long-term QOL followup study demonstrated that revision AUS surgery is not associated with decreased QOL or continence outcomes so that patients who require revision presumably will have similar improvements in the severity, bother and distress of urinary incontinence.[12]

Patients demonstrate decreased AUS QOL, decreased perceived urinary control and increased urinary bother with time.[12,13] Consequently we theorize that responses to the 2 PROMs will be fluid since dissatisfaction may become more prevalent with time following AUS. Because the rate of long-term continence of 0 or 1 pad per day 5 to 10 years after AUS placement ranges from 53% to 60%, our study reinforces the importance of adequate patient counseling and better long-term outcomes data on subjective bother.[6,12]

These limitations notwithstanding, our study has significant clinical impact as it quantifies QOL improvements after AUS implantation and describes what drives those improvements in patient satisfaction. Using questionnaires in the preoperative and postoperative settings that have excellent content validity, we not only described the impact of urinary incontinence but also measured the impact that an AUS can have on subjective QOL. These tools can help aid in counseling patients and establishing expectations. However, we acknowledge that to our knowledge no validated questionnaires exist for male SUI, especially after AUS placement. As these metrics drive outcomes and define surgical success, a validated PROM for men with SUI should be further investigated and developed.[17]

CONCLUSIONS

AUS implantation was associated with significant improvement in severity, bother and distress due to urinary incontinence at short-term followup on pre-AUS and postAUS questionnaires. These findings quantify the expected QOL improvements, although further research is needed to examine durability and consistency during a longer followup. The subjective state dominates male SUI. As such, further research to develop a PROM for men with SUI is paramount. Affected men should be involved at every aspect of development to create a PROM that comprehensively addresses the impact of male SUI. Until the creation of such a PROM gaps will remain in our understanding of this disease state.

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