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

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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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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.