Improved artificial urinary sphincter outcomes using a transcorporal cuff placement in patients with a "fragile urethra"

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Abstract

Introduction: The artificial urinary sphincter (AUS) is the most effective treatment option for incontinence after prostate cancer treatment. However, patients with a "fragile urethra" (defined as prior radiotherapy, previous failed AUS, or previous urethroplasty) are at increased risk of AUS failure. The aim of this study was to evaluate outcomes using standard and transcorporal cuff placement in this group of patients.

Methods: A retrospective review was performed on patients with a fragile urethra who underwent AUS insertion between 2004 and 2017. The primary outcome was the need for AUS revision. Secondary outcome measures included change in pad use, patient satisfaction, continence (≤1 pad/day), improvement (≥50% change in pad use), and cuff erosion rates.

Results: Seventy-six patients met the criteria for inclusion, with a mean age of 71.6 years and a mean followup of 37.9 months. A total of 42.1% had prior radiotherapy, 56.6% had a history of failed AUS, and 19.7% had previous urethroplasty. Transcorporal cuff placement was performed in 31.6% (n=24). These patients had lower revision (20.8% vs. 36.5%; p=0.05) and erosion rates (8.3% vs. 17.3%; p=0.09). There was no significant difference in functional outcomes such as continence (66.7% vs. 73.1%; p=0.57), improvement (100% vs. 90.4%;p=0.17), or satisfaction (82.6% vs. 69.4%; p=0.26), nor for 90-day complications (4.2% vs. 9.6%; p=0.41).

Conclusions: AUS insertion is an effective treatment option for post-prostatectomy incontinence in the setting of a fragile urethra. Transcorporal cuff placement in this subset of patients may be recommended, as it is associated with lower revision and erosion rates compared to standard cuff placement.

Introduction

The artificial urinary sphincter (AUS) is considered the most effective treatment option for post-prostatectomy incontinence related to sphincter weakness. Various studies have confirmed high satisfaction rates and continence associated with the procedure.[1-3] However, the management of post-prostatectomy incontinence in the setting of a fragile urethra (defined as prior radiotherapy, previous failed AUS, or previous urethroplasty) is challenging, as these factors have been independently associated with poorer functional outcomes and higher revision rates.[4-6] Several maneuverers have been described that aim to minimize the risk of failure, including cuff downsizing,[7] insertion of 3.5 mm cuff,[8] tandem cuff insertion,[9-11] adjustment of the pressure regulating balloon,[12,13] and transcorporal cuff placement.[4,14-17] In spite of this, there is a paucity of studies that evaluate these techniques specifically in the setting of a fragile urethra, and very few studies provide a comparison with standard methods of AUS insertion.

The aim of this study was to evaluate the functional outcomes and durability of AUS insertion using standard vs. transcorporal cuff placement in patients with a fragile urethra. Our hypothesis is that using the transcorporal cuff technique will reduce revision rates without adversely affecting perioperative outcomes.

Methods

Patients with a fragile urethra who underwent implantation of an AUS by a single surgeon between 2004 and 2017 were identified from procedural billing codes. Fragile urethra was defined as those with a history of radiotherapy, previous failed AUS, or previous urethroplasty. A retrospective review of patient medical records was performed and AUS cuff placement technique recorded (standard cuff placement or transcorporal cuff placement [TC-AUS]). Other patient demographics included age, diabetes, obesity (body mass index [BMI] ≥35), Charlson comorbidity index (CCI), salvage/adjuvant radiotherapy, previous AUS, previous urethroplasty, and etiology of incontinence. The primary outcome was the need for AUS revision. Secondary outcomes included global patient satisfaction, change in pad use, continence (defined as requiring ≤1 pad), improvement (≥50% change in pad use), and cuff erosion rates. Patient satisfaction was

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assessed by a global patient satisfaction questionnaire asking: "Are you satisfied with your level of urinary control (continence)"? Collected data was tabulated using Microsoft Excel (Microsoft Office 2010). Results were imported to SPSS25 (IBM Corp, Armonk, NY, U.S.) for statistical analysis. Mean pad change was compared with t-tests. Patient satisfaction, continence, and improvement rates were evaluated with Chi-squared, tests while revision and erosion rates were compared using the log-rank test. A $p<0.05$ was considered statistically significant. Ethical approval was granted by the university health ethics review board.

Operative details

As previously described,[14] standard cuff placement is performed through a midline perineal incision. The bulbospongiosus is mobilized from the corpus spongiosum and proximal bulbar urethra is exposed circumferentially, after which cuff size is measured. A transverse lower abdominal incision is made, followed by dissection of the space of Retzius and then creation of a subdartos pouch in the hemiscrotum. The pressure-regulating balloon (PRB) is instilled with approximately 22 ml and is placed in the retropubic space, with subsequent placement of the urethral cuff and pump in the hemiscrotum. All patients had a 61–70 cm PRB placed. Once all components are connected, the device is cycled to ensure proper function and absence of leaks and deactivated.

All patients with a fragile urethra are consented for a possible TC-AUS. However, the decision is ultimately made intraoperatively, where the surgeon feels dorsal dissection of the corpus spongiosum would be inappropriate due to an increased risk of urethral injury or excessive atrophy of the spongiosal tissue. As described previously,[14] the initial dissection mirrors that of a standard cuff placement. Once the ventral aspect of the corpus spongiosum is exposed, an approximate 3 cm incision is made into the tunica albuginea of both corporal bodies on either side of the lateral aspect of the corpus spongiosum. The space of Smith is then developed to accommodate a "sail" of tunica albuginea dorsally. The urethral circumference incorporating this is measured and an appropriate-sized cuff is selected and placed. The lateral wall of the tunica albuginea is closed with a running horizontal mattress for hemostasis. The wound is then irrigated, and the rest of the procedure completed, as in the standard cuff placement.

Patients are assessed in clinic at six weeks postoperatively, at which point the AUS is cycled and activated. Patients are reviewed in clinic at six and 12 months, and annually thereafter.

Results

A total of 76 AUS devices were placed in fragile urethras during the study period. The mean age of the group was 71.6±6.2 years, with a mean follow up 37.9±28.5 months. Incontinence etiology was characterised as post-radical prostatectomy in 68 cases (89.5%), post-transurethral resection of prostate in five cases (6.6%), simple prostatectomy in two cases (2.6%), and post-cryotherapy (with radiation) in one case (1.3%). Reasons for a fragile urethra included prior radiotherapy (42.1%), prior AUS (56.6%), and previous urethroplasty (19.7%). Of those with prior AUS, the reasons for revision were progressive incontinence due to urethral atrophy (22/43, 51.2%), cuff erosion (17/43, 39.5%), infection (3/43, 7.0%), and mechanical failure (1/43, 2.3%). Transcorporal placement of the AUS was performed in 31.6% of cases (24/76). Other patient demographics are further outlined in Table 1. Patients who underwent TC-AUS were more likely to have prior urethroplasty (50% vs. 5.8%, $p<0.001$) and reported a higher preoperative mean pad use (7.5 vs. 5.9, $p=0.02$). There were no other significant differ-

Table 1. Patient demographics

Demographic	Overall (n=76)	Transcorporal cuff (n=24)	Standard cuff (n=52)	p
Age (years)	71.6±6.2	72.2	71.3	0.57
Mean Charlson comorbidity index	2.4±0.5	2.9	2.2	0.17
BMI ≥35	14 (18.4%)	5 (20.8%)	9 (17.4%)	0.76
Diabetes	17 (22.4%)	4 (16.7%)	13 (25.0%)	0.56
Previous radiotherapy	32 (42.1%)	9 (37.5%)	23 (44.2%)	0.63
Previous vesicourethral stenosis	21 (27.6%)	10 (41.7%)	11 (21.2%)	0.10
Previous artificial urinary sphincter	43 (56.6%)	13 (54.2%)	30 (57.2%)	0.81
Previous male sling	7 (9.2%)	2 (8.3%)	5 (9.6%)	0.86
Previous urethroplasty	15 (19.7%)	12 (50.0%)	3 (5.8%)	<0.001
Transecting anastomotic	10/15	9/12	1/3	
Non-transecting anastomotic	4/15	3/12	1/3	
Penile urethroplasty with fasciocutaneous flap	1/15	0	1/3	

BMI: body mass index.

Table 2. Comparison of outcomes in patients receiving AUS with transcorporal and standard cuff placement

Outcome	Overall (n=76)	Transcorporal cuff (n=24) (%)	Standard cuff (n=52) (%)	p
Cuff size	4.3±0.4 cm (3.5–5.5)	4.6±0.4 cm (4–5.5)	4.1±0.3 cm (3.5–5)	**<0.001**
90-day complication	6 (7.9%)	1 (4.2%)	5 (9.6%)	0.41
Followup (months)	37.9	42.0	36.9	0.41
Patient satisfaction	53/72 (73.6%)	19/23 (82.6%)	34/49 (69.4%)	0.26
Continence rate	54 (71.1%)	16 (66.7%)	38 (73.1%)	0.57
Improvement rate	71 (93.4%)	24 (100%)	47 (90.4%)	0.17
Preoperative pad use	6.4±2.6	7.5	5.9	**0.02**
Postoperative pad use	0.9±1.1	0.9	0.9	0.95
Mean change in pad use	5.5±2.6	6.5	5	**0.02**
Revision rate	24 (31.6%)	5 (20.8%)	19 (36.5%)	**0.05** (log-rank)
Erosion rate	11 (14.5%)	2 (8.3%)	9 (17.3%)	0.09 (log-rank)

AUS: artificial urinary sphincter.

ences in baseline demographics between the two groups, including duration of followup.

Overall outcomes and outcomes by cuff technique are demonstrated in Table 2. Implanted cuff size was larger in the transcorporal group (4.6 vs. 4.1 cm, p<0.001). Ninety-day complications occurred in six patients (7.9%), including transient retention (n=2), hematuria (n=1), and acute infection (n=3), which did not differ by cuff technique (p=0.41). Overall patient satisfaction, improvement (≥50% reduction in pad use), and continence rates following surgery were 73.6%, 93.4%, and 71.1%, respectively. There were no significant differences in satisfaction (82.6% vs. 69.4%, p=0.26), improvement (100% vs. 90.4%, p=0.17), or continence (66.7% vs. 73.1%, p=0.57) between those who had TC-AUS vs. standard cuff placement. However, TC-AUS was associated with a greater change in pad use (6.5 vs.5.0, p=0.02). The overall revision rate was 31.6% and cuff erosion rate was 14.5%. Patients who had TC-AUS had significantly lower revision rates (20.8% vs. 36.5%, p=0.05) and a trend towards lower erosion rates (8.3% vs. 17.3%, p=0.09). The indications for revision surgery in this cohort were cuff erosion (11/24, 45.8%), progressive incontinence due to urethral atrophy (8/24, 33.3%), infection (3/24, 12.5%), mechanical failure (1/24, 4.2%) and urethral stricture at the cuff site (1/24, 4.2%).

Discussion

Despite a number of device[18] and peri-procedural modifications[3] since the AUS was first introduced in the 1970s,[19] the risk of revision surgery due to infection, device malfunction, or erosion remains high, particularly in the fragile urethra.[4,20] Several techniques have been described to enhance the success of the procedure, including transcorporal positioning of the cuff. Incorporation of the corporal bodies as a means to reduce the risk of cuff erosion was first proposed by Nelson in 1986.[21] Guralnick et al later described transcorporal placement of the cuff,[15] a technique that has been more widely adopted in modern practice. Several papers have reported on the success of this technique; however, the majority of studies have been limited by small numbers, the use of diverse population groups, or lack of functional outcomes.[4,14-17] To our knowledge, this is the first study to directly compare the long-term functional outcomes and device durability of TC-AUS with standard cuff placement in the fragile urethra.

Our study found acceptable satisfaction, improvement, and continence rates in both groups. The position of cuff placement did not appear to affect functional outcomes. There was a significant difference in the change in pad use between the groups; however, this may be explained by the difference in preoperative pad use. Both groups reported identical postoperative pad use. The effect of transcorporal cuff placement on erectile function was not assessed in our study, as the vast majority of patients had severe pre-existing erectile dysfunction owing to treatment of their prostate cancer. While studies have failed to show a significant change in erectile function with transcorporal cuff placement,[16,17] it is important that patients are appropriately counselled regarding the potential effect of corporal dissection on remaining erectile function. The 90-day complication rate was low in both groups, and there was no increased risk of bleeding or hematoma associated with dissection of the corpora.

The increased failure rate associated with the placement of AUS in patients with a fragile urethra is well-recognized.[22-24] Radiotherapy, previous failed AUS, and previous urethroplasty all have the same potential to compromise the integrity of the uretha, with devastating consequences. Urethral fibrosis from radiation or previous urethral surgery increases the complexity of dissection, which may compromise both the integrity and coaptive ability of the urethral tissue. Disruption of the anatomical blood supply to the urethra from previous dissection, transection, or as a result of post-radiotherapy microangiopathy may impair wound

healing, limit support of the sphincter cuff, and increase the risk of infection or erosion. Our study found that transcorporal cuff placement was associated with a significantly lower revision rate and a trend towards lower erosion rates compared to standard cuff placement. This technique minimizes dorsal dissection of the urethra, likely reducing the risk of dissection injury. Additionally, the inclusion of tunical tissue enhances the cuff fit by increasing the urethral girth; may prevent atrophy of the corpus spongiosum, which is already deficient in this distal location; and ultimately may provide a greater margin of safety against cuff erosion. Despite this more extensive surgical dissection, transcorporal cuff placement did not appear to adversely impact the rate of perioperative complications.

The most significant limitation of this study is its retrospective design. There were notable differences in baseline characteristics between the two groups in our study, which reflects our inherent bias that TC-AUS placement is preferable in patients with a fragile urethra. Nevertheless, these differences appeared to favor the group that underwent standard cuff placement and, therefore, may have underestimated the benefit of TC-AUS. Previous attempts at a randomized controlled trial to compare TC-AUS vs. standard cuff placement were unsuccessful due to inadequate enrolment.[25] In light of our study and others, the possibility of a future randomized controlled trial is difficult to envisage, given the ethical considerations of randomizing patients with a fragile urethra to standard cuff placement.

Conclusions

Insertion of an AUS in patients with a fragile urethra is associated with a higher risk of erosion and revision. Our study found lower revision and erosion rates in patients who underwent transcorporal cuff placement. Therefore, we recommend transcorporal placement of the AUS cuff in these patients, as this may reduce the risk of device failure without compromising functional outcome or increasing perioperative adverse events.

Competing interests: Dr. Rourke has been an advisory board member for and is a shareholder in Boston Scientific; and has participated in clinical trials supported by Red Leaf Medical. The remaining authors report no competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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