Stemming the tide of mild to moderate post-prostatectomy incontinence: A retrospective comparison of transobturator male slings and the artificial urinary sphincter

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Cite as: *Can Urol Assoc J* 2014;8(7-8):273-7. http://dx.doi.org/10.5489/cuaj.2108
Published online August 11, 2014.

Abstract

Introduction: The AUS remains the gold standard treatment for post-prostatectomy incontinence (PPI), although most patients with mild-moderate PPI prefer a sling without strong evidence of procedural equivalence. This study compares outcomes of 2 procedures for the treatment of mild-moderate PPI.

Methods: A retrospective review of 124 patients (76 transobturator sling, 48 AUS) with mild-moderate PPI requiring intervention over an 8-year period. The primary outcome was continence. Secondary outcomes included global patient satisfaction, improvement, and complication rates. Mild to moderate incontinence was defined as requiring ≤5 pads/day.

Results: There was no significant difference in age (66.2 vs. 68.1 years; $p = 0.17$) or prostate cancer characteristics for slings and AUS, respectively. AUS patients had higher Charlson comorbidity scores and were more likely to have previous radiotherapy. Median length of follow up was 24 months for slings and 42 months for AUS. There was no difference in continence rates, 88.2% vs. 87.5% ($p = 0.79$), rate of improvement, 94.7% vs. 95.8% ($p = 1.00$), or patient satisfaction, 93.4% vs. 91.7% ($p = 0.73$), for slings and AUS, respectively. Complication rates were equivalent (19.7% vs. 16.7%; $p = 1.00$), though a significantly higher proportion of complications with AUS were Clavien Grade 3 (0% vs. 75%; $p = 0.006$).

Conclusions: For mild to moderate PPI there is no difference in continence, satisfaction, or improvement rates, between AUS and slings. AUS complications tend to be more severe. Our study supports the use of slings as first-line treatment for mild-moderate PPI.

Introduction

Post-prostatectomy incontinence (PPI) is a devastating surgical complication, affecting about 1% to 57% of prostate surgeries.[1] The disparity in PPI rates between studies reflects the largest challenge of research in this area – a lack of a standardized definition of PPI.[2] About 10% of men will ultimately choose a surgical intervention for their PPI. The two most common surgical techniques are the male sling and artificial urinary sphincter (AUS).[3]

The AUS was introduced in 1972 (AMS, Minnetonka, MN).[4] It is still considered the current gold standard for the management of PPI with excellent long-term 5-year continence rates.[5] In 2006, the AdVance transobturator male sling was introduced as a minimally invasive alternative to the AUS (AMS, Minnetonka, MN).[6]

Mild to moderate PPI management presents a dilemma. Despite the AUS being more established, most of these patients select the male sling without evidence of procedural equivalence.[7] A study demonstrating the superiority of the AUS over the male sling in this group, justifying the cost, perioperative risk and invasiveness, could potentially alter the existing treatment paradigm. Our study aimed to retrospectively compare outcomes of the AUS and sling for mild to moderate PPI.

Methods

An institutional retrospective chart review (approved by an institutional ethics board) identified patients undergoing surgical treatment for mild to moderate PPI between August 2004 and March 2013. Patients were identified using the provincial fee codes for the procedures. All surgeries were performed by one of two surgeons. The inclusion criteria included men over 18, with a minimum of 1 year post-prostatectomy at the time of continence procedure, and with mild to moderate incontinence (defined as requiring ≤5 incontinence pads/day).[8] Prostate surgeries for both benign and malignant indications were included. We excluded patients with untreated overactive bladder symptoms at time of the continence procedure.

Preoperative and postoperative data collection

We collected baseline characteristics, which included age at prostatectomy, age at continence procedure, type of prostatectomy, body mass index (BMI), type 2 diabetes mellitus, Charlson comorbidity index (CCI), number of incontinence pads required, radiation therapy prior to continence procedure, previous sling procedure, previous AUS and previous urethroplasty (Table 1). If the prostatectomy indication was prostate cancer, the cancer characteristics were noted (Table 2). Postoperative data collected included number of incontinence pads required (determined by most recent follow-up visit), global patient satisfaction and complications (classified by Clavien grade).[9]

Outcome measures

Our primary outcome measure was continence defined by requiring ≤1 pad postoperatively for patients requiring ≥2 pads preoperatively, and 0 pads for those requiring 1 pad preoperatively. Secondary outcome measures included rates of improvement (defined as any improvement in the number of pads/day), and rates of global patient satisfaction.

Operative details

AdVance male sling

The sling is placed through a midline perineal incision. The bulbospongiosus is mobilized from the corpus spongiosum with at least a partial dissection of the perineal body. A space is developed laterally to the level of the pelvic floor. Incisions are made along the thigh by the insertion of the adductor longus. The obturator is placed through the deep fascia and obturator fossa. The sling is seated against the corpus spongiosum, and approximated to the bulbospongiosus muscle at four points. It is tensioned to coapt the urethra and compress the urethral bulb to the pelvic floor. Cystoscopy is performed to ensure urethral coaptation and lack of intrusion into urethra or bladder. A urethral catheter is placed and the layers closed anatomically. The sling is attached to the superficial fascia of the thigh. Patients are generally discharged on the same day and a urethral catheter is left in-situ for 2 to 5 days.

Artificial urinary sphincter

Cuff placement is performed through a midline perineal incision. The bulbospongiosus is mobilized from the corpus spongiosum and proximal bulbar urethra is exposed circumferentially. The cuff size is measured and soaked in bacitracin solution. A transverse lower abdominal incision is made, followed by blunt dissection of the space of Retzius and creation of a subdartos pouch in the left hemiscrotum. The AUS is then prepared with a pre-selected pressure reservoir and the cuff placed. The reservoir, instilled with approximately 22 mL, and pump are placed in the retropubic space and left hemiscrotum, respectively. The device is cycled to ensure no leaks and proper functioning. Patients are admitted and maintained on 48 hours of intravenous antibiotics.

Table 1. Baseline patient and prostate operation characteristics of the sling and AUS cohorts

Characteristic	Sling	AUS	*p* value
Total	76	48	-
Mean age at prostatectomy (yrs)	62.2	64.7	0.05*
Mean age at continence procedure (yrs)	66.2	68.1	0.17
RALP	31	4	0.001*
LRP	24	19	0.44
RRP	15	16	0.095
Other	9	9	0.30
BMI >35	2	1	1.00
CCI	3.1	3.9	0.0007*
Previous radiotherapy	3	7	0.045*
Previous sling	0	1	0.34
Previous AUS	0	1	0.39
Previous urethroplasty	0	3	0.056
Median follow-up (months)	24	42	0.0008*

AUS: artificial urinary sphincter; RALP: Robot-assisted laparoscopic radical prostatectomy; LRP: laparoscopic radical prostatectomy; RRP: radical retropubic prostatectomy; BMI: body mass index; CCI: Charlson comorbidity index *Denotes statistically significant *p* value.

Table 2. Prostate cancer characteristics for the sling and AUS cohorts

Characteristic	Sling	AUS	*p* value
Mean preoperative PSA	7.6	6.8	0.55
Mean preoperative Gleason score	6.4	6.4	0.91
Mean number of biopsy cores positive	3.6	3.5	0.49
Pathologic T stage	0	0	1.00
T1a	0	0	1.00
T1b	0	0	1.00
T2a	11	4	0.40
T2b	6	5	0.75
T2c	33	19	0.71
T3a	16	7	0.48
T3b	5	2	0.71
T3c	0	0	1.00
Unknown	4	0	0.16
N/A	1	0	1.00

AUS: artificial urinary sphincter; PSA: prostate-specific antigen.

Follow-up protocol

Patients were seen in clinic 6 weeks postoperatively, where the AUS cuff was activated if applicable. Patients were reviewed at 6 and 12 months, then annually.

Statistical analysis

Utilizing GraphPad Prism version 6.0 for Mac statistics software, non-normally distributed ordinal and continuous variables were compared with a Mann-Whitney test. Two-tailed Fisher's exact test was used to compare categorical variables. A p value <0.05 was statistically significant.

Results

We identified 76 patients undergoing a male sling and 48 receiving an AUS. There was no difference in age at the time of the procedure ($p = 0.17$). Other similar baseline characteristics included BMI and type 2 diabetes mellitus. AUS patients had significantly higher CCI scores (3.1 vs. 3.9; $p = 0.0007$) (Table 1). Rates of robotic-assisted radical prostatectomy (RALP) were significantly higher in the sling group at 40.8% versus 8.3% in the AUS group ($p < 0.0001$). Rates for laparoscopic prostatectomy ($p = 0.44$), radical retropubic prostatectomy (RRP) ($p = 0.095$), and the "other" category ($p = 0.30$), including cystoprostatectomy with neobladder, cryoprostatectomy, transurethral resection of the prostate, and GreenLight laser prostatectomy, all demonstrated no difference between the groups (Table 1).

Patients in the AUS group were more likely to have undergone previous radiation therapy (brachytherapy or external beam) (14.6% vs. 3.9%; $p = 0.045$), though no difference was noted with respect to previous sling ($p = 1.00$), previous AUS ($p = 0.39$), or previous urethroplasty ($p = 0.056$). Table 2 demonstrates the baseline prostate cancer characteristics between the two groups. There was no significant difference with respect to any of the characteristics analyzed.

At a median follow-up of 24 months (range: 1-61) and 42 months (range: 9-86) ($p = 0.0008$), no statistical differences were noted for continence rates (88.2% [67/76] vs. 87.5% [42/48]; $p = 0.79$), improvement rates (94.7% [72/76] vs. 95.8% [46/48]; $p = 1.00$), or overall satisfaction rates (93.4% [71/76] vs. 91.7% [44/48]; $p = 0.73$) in the sling and AUS groups, respectively.

Overall complication rates were 19.7% (15/76) for slings and 16.7% (9/48) for AUS ($p = 1.00$). Most (14/15, 93%) of the sling complications were Clavien grade 1, compared to 0 of the AUS complications ($p = 0.008$). All of these cases were acute urinary retention requiring catheterization. One sling complication and 3 of the 9 (33%) AUS complications were Clavien grade 2 localized infections requiring antibiotics ($p = 0.30$). The other 6 AUS complications were a more serious grade 3, requiring surgical explantation/revision ($p = 0.003$). Two patients had a malpositioned or migrated cuff. One had erosion into the urethra, 2 had an infection, and 1 had erosion necessitating a replacement AUS, which subsequently got infected and required explantation.

Discussion

To date, a direct comparison between the 2 procedures has not been reported. A randomized study is difficult, owing to a typically strong patient preference to self-select the procedure desired.

The baseline characteristics between the 2 groups are relatively comparable, except for rates of radiation therapy, RALP and CCI scores. The increased incidence of RALP reflects the contemporary nature of the AdVance technology and robotic surgery. Thiel and colleagues evaluated the clinical predictors of successful AUS and determined that age, diabetes and neurological diagnosis were not predictive of failure.[10] This study suggests that many of the main factors included in the CCI do not affect outcomes and thus, the difference in comorbidity indices should not affect our analysis.

It has been shown that prior radiation therapy, previous AUS placement and explantation are factors predictive of sling failure.[11] The common pathophysiologic mechanism is hypothesized to be urethral fibrosis with subsequent failure of adequate coaptation. Similar prognostic factors have not been identified with the AUS, though previous radiation remains a contentious issue. A literature review noted complication rates and continence outcomes were not affected by previous radiation.[5] Thus it is reasonable to conclude that the increased incidence of radiation in the AUS group, though making it more technically challenging, may not significantly affect our comparison.

For the AUS, our continence rate compares favourably with the literature. In the largest series to date, 435 patients underwent primary AUS for PPI and 90% achieved continence, using ≤1 pad/day.[12] A review of the literature is documented in Table 3, with continence rates ranging from 59-90%.[12-20] To make a more meaningful comparison, only studies defining continence as requiring ≤1 pad/day were included. Sacco and colleagues demonstrated that the criterion of pad usage discriminates well between a limited reduction and markedly affected quality of life, noting that it is clinically valid to consider ≤1 pad/day as continent.[21] Undoubtedly, the exclusion of severely incontinent patients in our analysis contributed to higher continence rates. As well, not all studies included only narrow-back cuffs, which was a major improvement to the AUS design introduced in 1987.[22]

Our 88.2% sling continence rate also compares favourably with the literature. Bauer and colleagues reported a 52% cure rate (0 pads or 1 prophylactic pad/day) at a median follow-up of 27 months.[23] Similar to AUS, valid com-

Table 3. Summary of literature continence rates after AUS placement

Study	No. patients	Continence rate
Raj et al.[12+]	435+	90
Montague et al.[13]	113	64
Gomha and Boone[14]	86	62
Manunta et al.[15]	72	81
Gousse et al.[16]	71	59
Haab et al.[17]	68	80
Kim et al.[18^]	47^	77
Trigo Rocha et al.[19]	40	90
O'Connor et al.[20]	29	83

+Excluded patients undergoing secondary AUS implantation; ^Excluded patients who did not have postoperative pad usage data reported.

parisons are hindered by varying definitions of continence. The most recent prospective study of 100 mild-moderate PPI patients showed a 59% continence rate.[1] This study provides the most meaningful comparison given the relatively similar inclusion criteria and continence outcomes. Though the 59% rate seems much lower, this reflects a stricter continence definition of 0 or 1 security pad/day. Patients requiring 1 to 2 pads/day were considered improved and the combined cure and improved rate is 82%, which is closer to the rate seen in our cohort.

One of the most significant deterrents to the use of AUS in all PPI patients is the complication profile. James and McCammon reviewed 9 studies and found an infection rate of 0.5% to 10.6%, comparable to the 4.2% infection rate in this study.[5] The introduction of an antibiotic InhibiZone coating to the AUS was intended to decrease the infection rate. However, a study retrospectively comparing 426 patients evenly treated with and without InhibiZone coated AUS found no difference in infection rates, but a significantly increased cost associated with the coating (about $1300/device).[24]

Mechanical dysfunction has been analyzed with Kaplan-Meier freedom from re-operation analyses. In the largest series of 530 men, the 5-year rate was 79% for primary implantation.[12] A much lower rate was observed in this series, potentially because of the use of only narrow-back cuffs, which decreased the malfunction rate from 21% to 7.6%, and the shorter length of follow-up.[22] Re-operation represents a severe potential consequence of the AUS and rates range from 5% to 61%.[5] The most common indications for revision include erosion, infection, mechanical dysfunction or worsening incontinence.

Contrastingly, the complications seen with the male sling are relatively uncommon and minor. Acute urinary retention occurs in 3% to 21%, and was the most common complication seen in our series (18.4%).[25] Causes of retention include perineal pain, urethral manipulation, urethral compression and postoperative swelling.[25] To date, only 5 severe complications (persistent retention, wound infection, osteitis pubis, sling placed through urethra and urethral erosion) requiring removal or revision have been reported.[26-28]

The limitations of this study include its retrospective nature, lack of exact pad weights, heterogeneous follow-up, and lack of standardized quality of life improvement questionnaire. Given the significant side effect profile of the AUS and the fact that a trial of the male sling does not preclude AUS insertion, a prospective, randomized trial is unlikely to receive ethics approval.

Conclusion

For the treatment of mild-moderate PPI (≤5 continence pads daily), transobturator male slings and AUS are equal with respect to continence rates (88.2% vs. 87.5%), patient improvement (94.7% vs. 95.8%) and patient satisfaction (93.4% vs. 91.7%). Though overall complication rates are equivalent, AUS has a higher proportion of Clavien grade 3 complications requiring surgical intervention. The widespread use of transobturator slings as first-line therapy for mild-to-moderate PPI is justified.

Acknowledgements: This is the completed manuscript for the CUA Prize Essay Competition 2014. This was the winning essay.

Competing interests: Dr. Hoy and Dr. Rourke declare no competing financial or personal interests.

This paper has been peer-reviewed.

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