Prognostic value of postoperative urinary retention after male sling insertion

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Introduction: *While urinary retention is a known complication of AdVance male sling (AMS) placement for post-prostatectomy incontinence (PPI), there is minimal data regarding ultimate continence outcomes for patients who experience this complication. The purpose of this study was to determine the rate of continence after AMS placement in patients who had postoperative urinary retention as compared with those patients who did not.*
Materials and methods: *A retrospective review was conducted of patients who underwent AMS placement for PPI between 2008 and 2011 with postoperative void trial (TOV). Preoperative factors such as urodynamic findings, daily pad number (PPD) and weight were recorded. Follow up data included pad use, need for catheterization and complications. Statistical analysis compared patients with and without postoperative urinary retention.*
Results: *Thirty-five patients were included with a mean follow up of 11.8 months. Complete continence was 60%, while 83% of patients were improved. PPD improved from 2.9 pads to 0.8 pads after AMS placement. Sixteen patients (46%) had postoperative urinary retention requiring clean intermittent catheterization (CIC). Of the 16 patients in postoperative retention, 100% were completely continent (PPD = 0), compared to 5 of 19 patients (26%) who passed first TOV ($p < 0.00001$). All patients who required CIC were able to void within 7 days.*
Conclusions: *Postoperative urinary retention after AMS placement for PPI occurs in about 50% of patients and is short-lived. Patients who experienced postoperative urinary retention had good continence outcomes.*

Key Words: urinary incontinence, prostatectomy, advance male sling, retention

Introduction

The most common complications after radical retropubic prostatectomy (RRP) are post-prostatectomy incontinence (PPI) and erectile dysfunction (ED).[1,2] PPI has a highly variable reported prevalence (0.8%-87.0%) due to variable definitions of incontinence, length of follow up and lack of reporting standardization.[3] Management options for PPI include conservative treatments such as behavior modification, pelvic floor stimulation or biofeedback, medical management and surgical management including use of bulking agents, compressive adjustable balloons, artificial urinary sphincters (AUS), as well as urethral slings.[4-6]

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Although AUS is the gold standard for PPI, it has substantial failure and reoperation rates and requires manual dexterity to operate the device.[7] For men with mild to moderate stress urinary incontinence (SUI), the male sling is a relatively safe alternative to AUS with moderate success rates of 37% to 87%.[4] The AdVance male sling (AMS), (American Medical Systems, Minnetonka, MN, USA) is a polypropylene mesh sling placed via the transobturator approach.[8] Its mechanism of action is believed to be a repositioning of the external sphincter and lengthening of the functional membranous urethra without compression.[8] There are some adjustable slings, such as the REMEEX and the Argus Adjustable Male Sling System, in which one can augment the amount of urethral compression. While urinary retention is a known complication of AMS placement for PPI with a prevalence of 5.0%-34.6%, there is minimal data regarding ultimate continence outcomes for patients who experience this complication.[4,9,10] Because patients at our institution

were most bothered by the foley catheter in the initial postoperative days, it became our practice to remove the foley catheter in the recovery room. The purpose of this study was to determine the rate of continence after AMS placement in patients who had postoperative urinary retention as compared with those patients who did not. We hypothesized that postoperative urinary retention patients would have improved continence.

Materials and methods

A retrospective review was conducted of all patients who, after open or robot-assisted radical retropubic prostatectomy, underwent AMS placement for incontinence between 2008 and 2011 at our institution by a single surgeon. A minimum time interval of 6 months from prostatectomy, and failure of conservative and medical management, was required for inclusion. Medical history, physical exam, prior medical and surgical treatments, cystoscopy, preoperative video urodynamics, preoperative pad weight (POPW) and preoperative pad number (POPN) were abstracted from patient medical records. Preoperative urodynamics was performed to assess Valsalva leak point pressure (VLPP), detrusor activity (Pdet at Qmax), maximum flow rate (Qmax) and post-void residual (PVR). Each patient had a preoperative cystoscopy to ensure coaptation of the sphincter and to assess for bladder neck contracture or urethral stenosis. Patients with bladder neck contracture, history of radiation, POPW > 500 mL and use of five or more pads per day were discouraged from AMS placement, although not excluded from this study, as understanding outcomes in this group of patients is valuable. Immediate preoperative urine examination was performed to ensure urine sterility in all patients. All patients received preoperative clean intermittent catheterization (CIC) training.

The technique used for AMS placement was previously described by Rehder.[8] No tensiometer or retrograde leak point pressure was performed during AMS insertion in the current study.

All patients were given an active TOV in the recovery room. The bladder was filled with 300 cc of normal saline and the patient given on average 2 hours to void. If the patient failed this TOV, CIC was performed by the patient and he was discharged home with plans to continue CIC until minimal PVR was achieved (PVR < 50 mL).

During follow up, data on pad-use, need for catheterization and complications were recorded. After the initial postoperative visit at 2 weeks, patients were followed every 3 months. Mean follow up was 11.8 months (range 6-42). At follow up visits, patient reported data on pad use and pad weight was recorded and all patients underwent post-micturition bladder scans to assess for PVR. All complications were recorded. Complete continence was defined as no pad usage. Improvement was defined as reduction from POPN by at least 50% and fewer than two pads per day postoperatively.

Statistical analysis was performed using SAS v9.2. The Fisher exact test was used for the analysis of categorical variables. A two-sample t-test was used for the analysis of continuous variables. All analyses were performed at the 0.05 significance level.

Results

A total of 35 patients were included in this study. Patient characteristic are listed in Table 1. Mean age for the cohort was 63.5 years (range 47 to 76). Mean follow up time was 11.8 months (range 6-42). Mean time interval between prostatectomy and AMS placement was 3.5 years (range 1-18 years). Mean preoperative

TABLE 1. **Patient characteristics (n = 35)**

Variable	Data
Age (years)*	63.5 ± 7.2 (47-76)
Postoperative retention†	16 (45.7)
Continence (zero PPD)†	21 (60)
BNC†	2 (5.7)
XRT†	3 (8.6)
POPW (g)*	181.7 ± 151.3 (7-550)
POPN*	2.9 ± 2.0 (1-10)
PPN	0.8 ± 1.2 (0-5)
TFS (years)*	3.5 ± 4.0 (1-18)
Qmax (mL)*	20.7 ± 10.0 (6-55)
PVR (mL)*	12.2 ± 32.1 (0-150)
VLPP (mmHg)*	65.8 ± 21.0 (34.0-117.0)
Pdet@Qmax (cm H_2O)*	24.3 ± 20.5 (0-87)

BNC = bladder neck contracture; XRT = radiation therapy; POPW = preoperative pad weight; POPN = preoperative pad number; PPN = postoperative pad number; TFS = time from surgery; Qmax = maximum flow rate; PVR = post-void residual; VLPP = Valsalva leak point pressure; Pdet@Qmax = detrusor pressure at maximum flow

*results are given as mean plus or minus standard deviation (range)

†results are given in numbers of patients with percentages in parenthesis

TABLE 2. **Pad usage pre and postoperatively after AdVance male sling implantation in 35 men with stress urinary incontinence after prostatectomy**

Number of pads	Preoperatively n (%)	Postoperatively n (%)
0	0 (0)	21 (60)
1-2	19 (54.2)	10 (28.5)
3-4	11 (31.4)	3 (8.6)
5-6	2 (5.7)	1 (2.8)
7+	3 (8.6)	0 (0)

pad usage was 2.9 ppd (range 1-10). Mean POPW was 181.7 g over 24 hours (range 7-550). Preoperative urodynamics revealed mean Qmax of 20.7 mL (range 6-55), mean Valsalva leak point pressure of 65.8 cm H_2O (range 34-117) and mean Pdet at Qmax of 24.4 cm H_2O (range 0-87). Mean PVR was 12.2 mL (range 0-150). Two patients had preoperative bladder neck contractures with concurrent radiation therapy, one patient had undergone radiation prior to AMS placement.

Mean pad usage over the entire cohort decreased from 2.9 ppd to 0.8 ppd postoperatively. Eighty-three percent of all patients were improved and 60% were completely continent, Table 2. Sixteen patients (46%) experienced postoperative urinary retention requiring CIC. All of these patients had resolution of their urinary retention within the first week after surgery; and all were completely continent. Nineteen patients (54%) had successful first TOV, of these only five (26%) were completely continent. When excluding the patients who had undergone radiation there were a total of 16 patients with successful first TOV and five were completely continent (31%). Thus there was a statistically significant difference in continence between those patients with urinary retention and those who passed their first TOV ($p < 0.00001$). The 14 patients who were not completely continent required on average, 2 ppd (range 1-5), among this group however, 57% were improved.

TABLE 3. **Retention versus passed postoperative void trial (n = 35)**

Variable	Postoperative retention	Passed postoperative void trial	p value
Age (years)*	64.5 ± 5.9 (54-74)	62.6 ± 8.2 (47-76)	0.2082
Complete continence†	16/16 (100)	5/19 (26.3)	0.00001
BNC†	0/16 (0)	2/19 (10.5)	0.4891
XRT†	0/16 (0)	3/19 (15.8)	0.2336
POPW (g)*	175.0 ± 140.4 (25-464)	187.3 ± 163.6 (7-550)	0.5555
POPN*	3.13 ± 1.78 (1-7)	2.78 ± 2.16 (1-10)	0.4650
TFS (years)*	2.53 ± 1.81 (1-5)	4.21 ± 5.15 (1-18)	< 0.001
Qmax (mL)*	18.9 ± 7.78 (6-33)	22.1 ± 11.5 (11-55)	0.2194
PVR (mL)*	22.1 ± 45.8 (0-150)	3.8 ± 7.51 (0-20)	< 0.0001
VLPP (mmHg)*	57.8 ± 17.3 (34-94)	73.8 ± 22.1 (44-117)	0.4497
Pdet@Qmax(cm H_2O)*	13.4 ± 10.5 (0-30)	34.0 ± 22.8 (8-87)	0.0404
PPN*	0 ± 0 (0)	1.47 ± 1.50 (1-5)	0.0003

Complete continence = 0 pads per day
BNC = bladder neck contracture; XRT = radiation therapy; POPW = preoperative pad weight; POPN = preoperative pad number; TFS = time from surgery; Qmax = maximum flow rate; PVR = post-void residual; VLPP = Valsalva leak point pressure; Pdet@Qmax = detrusor pressure at maximum flow; PPN = postoperative pad number
*results are given as mean plus or minus standard deviation (range)
†results are given in numbers of patients with percentages in parenthesis

No intraoperative complications occurred; no sling erosions or postoperative infections occurred during the course of follow up. No patient required sling lysis for urinary retention. No improvement was seen during follow up. One patient had a worsening of symptoms from one to two pads per day.

Table 3 compares the cohort of patients who had postoperative urinary retention in the recovery room necessitating CIC with those who passed the initial voiding trial. There was no difference between groups with regard to age (64.5 versus 62.9), preoperative Qmax (18.9 versus 22.1) or VLPP (57.8 versus 73.8). There was no difference in preoperative pad weight between the groups 175.0 g versus 187.3 g per 24 hours or preoperative pad number 3.1 versus 2.8 in the urinary retention group and the successful TOV group respectively. Time from surgery was significantly longer in the successful TOV group 4.2 years versus 2.5 years ($p < 0.001$). There was a statistically significant difference in preoperative Pdet at Qmax between the groups, 13.4 cm H_2O for the urinary retention group and 43.0 cm H_20 for the successful TOV group ($p < 0.05$), as well as a statistically significant difference in preoperative PVR 22.1 mL versus 3.8 mL for the urinary retention group and the successful TOV group respectively ($p < 0.0001$). All three patients with a history of radiation, two of whom had bladder neck contracture, had successful TOV and were incontinent at follow up, although on statistical analysis radiation was not significantly associated with successful TOV.

Discussion

Rehder and colleagues first described AMS insertion for PPI in 2007 in both a cadaver study and a clinical trial.[8] Unlike the AUS, which works by concentric compression of the urethra for treatment of sphincter deficiency, the transobturator sling is hypothesized to restore the urethra to its pre-prostatectomy anatomic position, thereby augmenting residual sphincter function without causing obstruction. After prostatectomy, there is shortening of the membranous urethral and caudal descent of the sphincter complex. After AMS placement, the membranous urethra is brought into a cranial and posterior position with the proximal bulb in the pelvic outlet. Video urodynamic studies have shown an increase in urethral closure pressures with AMS 13.2 cm H_2O to 86.4 cm H_2O, with no change in Qmax or PVR supporting the hypothesis that sling placement does not cause obstruction.[8] In a study of 13 patients undergoing AMS placement for PPI with pre and postoperative urodynamic measurements, no difference was observed in Pdet at Qmax, Qmax or PVR.[9] VLPP was seen to be increased from 29.3 mm Hg to 46.6 mm Hg.[9] The authors conclude that no significant obstructive component was detectable on urodynamics after AMS placement. Our study however suggests an obstructive component to the mechanism of action.

In our study, 21 of 35 patients were completely continent, a cure rate of 60%. This cure rate is within the range (9%-85%) seen for previous studies evaluating the AMS.[6,9,11,12-14] The success rate (improvement or cure rate) of 83% is comparable to other studies with success rates of 54%-90%.[6,8,9,13] Our study was the first to our knowledge to assess postoperative urinary retention. We found that patients who experienced postoperative urinary retention compared to the patients who passed initial TOV had a significantly higher rate of complete continence ($p < 0.00001$). In the group passing the initial TOV, only five patients were completely continent, although an additional eight patients were improved. The results of this study suggest that there may be a compressive component to the mechanism of action by which the AMS establishes continence, making those patients with postoperative urinary retention more likely to be continent at later follow up.

Examination of preoperative factors which were associated with postoperative urinary retention revealed that there was no difference between groups with regard to age, preoperative Qmax, VLPP or preoperative pad weight or number. Time from prostatectomy to AMS placement was significantly greater in the successful TOV group 4.2 years compared to 2.5 years ($p < 0.001$). One patient in the successful TOV group had an 18 year span between prostatectomy and AMS placement, which contributed to this difference. The clinical relevance of this is not fully understood, although it may be related to worsening detrusor function with time from prostatectomy. A review of data analyzing the relationship between prostatectomy and urodynamic bladder dysfunction found that bladder function may change with time from prostatectomy.[15] There was a statistically significant difference in preoperative Pdet at Qmax between the groups, 13.4 cm H_2O for the urinary retention group and 43.0 cm H_20 for the successful TOV group ($p < 0.05$). The postoperative urinary retention group had a greater PVR preoperatively, 22.1 mL versus 3.8 mL ($p < 0.0001$), which may be related to an inability to mount sufficient detrusor pressure to empty the bladder. Although this is statistically significant, a mean difference of 18.3 mL may not have clinical significance. Furthermore, a slightly elevated preoperative PVR should not discourage sling placement as Davies demonstrated that AMS placement does not affect PVR.[9]

Surgical manipulation and subsequent swelling of the urethral mucosa as well as recent anesthetics might contribute to the temporary retention accounting for the higher retention rate seen in our series 46%, as compared to other series of AdVance sling placement in which foley catheter was left for up to 3 days, 15%-34.6 %.[4,9,10] All patients who experienced urinary retention postoperatively were continent. Intermittent catheterization rather than foley catheter placement allows for observation of voiding sooner and may decrease risk of urinary tract infection from indwelling foley. Intermittent catheterization allows bladder cycling without unnecessary urethral pressure after sling placement. In our study, the maximum time of CIC was 1 week.

Ideally patients undergoing AMS placement should have a working sphincter and a mobile urethra. Bladder neck contracture and prior radiation are relative contraindications to AMS. In our study, three patients had radiation and two of these had bladder neck contracture; these patients were included because understanding outcomes in this challenging group of patients is valuable. Other authors have reported decreased success in patients with prior radiation.[6,13] In a study by Cornu and colleagues of 102 patients undergoing AMS for PPI, 17 patients had preoperative radiation with a cure or improvement in only 59% versus 85 patients without preoperative radiation having a cure or improvement in 85%.[6] In our study, cure or improvement was seen in 83% of all patients. Although no statistical difference was seen in the patients with radiation or bladder neck contracture, this was likely due to the small number of these patients, as all three patients had incontinence at follow up. Two of these patients have subsequently undergone AUS placement and are continent at recent follow up.

No complications such as bladder perforation, intraoperative bleeding or nerve, bowel, or vascular injury occurred during AMS placement. One case of ongoing mild urgency was observed and the patient was continued on anticholinergics postoperatively, consistent with a Grade II complication. No erosion or postoperative infections were observed. One patient had a worsening of symptoms from 1 to 2 ppd over the course of the study. In a larger study by Cornu and colleagues, no major complications occurred in 102 patients, although there were two superficial perineal wound infections, four cases of perineal pain, two cases of perineal parathesia and ten cases of transient mild dysuria.[6] In the Bauer study discussed previously, overall complication rate of the AdVance sling was 23.9%.[10] Forty-nine patients (21.3%) experienced urinary retention post-surgery. Two slings were explanted (0.9%), one due to initial wrong placement and the other due to a symphysitis, attributed to a Guillain-Barre syndrome rather than sling infection. One sling was transected (0.4%) due to slippage of the sling with resultant urethral obstruction. Other complications included local wound infection (0.4%), urinary infection with fever (0.4%), and persistent moderate perineal pain (0.4%). Adjustable slings, as compared to the nonadjustable slings described here, typically require reintervention (38.6% for the Argus, > 80% for the REMEEX), and complications are relatively common. Sling removal because of urethral erosion or infection has been described in 5.9%-15.8% of patients.[15,16]

Limitations of this study include its retrospective nature, limited number of patients and lack of postoperative urodynamic data. However, our findings suggest that of patients who experience postoperative urinary retention, approximately 50%, have good continence outcomes. Further prospective studies of AMS placement in patients with PPI will allow us to predict which patients are at higher risk for developing postoperative urinary retention, so that we may better counsel our patients, and which patients are more likely to be continent at long term follow up, so that we may most appropriately select patients for this procedure.

Conclusions

Postoperative urinary retention after AMS placement for PPI occurs in about 50% of patients and is short-lived. Patients who experienced postoperative urinary retention had good continence outcomes. Further evaluation is needed to assess long term efficacy and precise indications for this procedure for the management of post-prostatectomy incontinence. □

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