Preoperative pad usage is independently associated with failure of non-adjustable male trans-obturator slings in otherwise well-selected patients

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Abstract

Introduction: Our objective was to determine which clinical factors are associated with failure to achieve continence after non-adjustable trans-obturator sling in otherwise well-selected men undergoing treatment for post-prostatectomy incontinence (PPI).
Methods: A retrospective review of Advance/Advance XP male sling procedures was performed from December 2006 to May 2017. Patients with known risk factors for sling failure, including severe incontinence (>5 pads), radiation therapy, or detrusor dysfunction, were excluded. The primary outcome was failure to achieve continence, defined as ≤1 pad per day when pad use was ≥2 preoperatively (or 0 pads if preoperative pad use was 1). Covariates included patient age, Charlson comorbidity index (CCI), diabetes, obesity (body mass index [BMI] ≥35), type of prostatectomy, and number of preoperative pads. Descriptive statistics and Cox regression analysis was performed.
Results: Of 158 patients, continence was achieved in 82.3% (n=130) with a mean followup of 42.7 months. Patient-reported satisfaction was 86.7% (n=137) and the 90-day complication rate was 12% (n=19). On univariate Cox regression analysis, increasing age (p=0.02), CCI (p=0.02), and preoperative pad use (p<0.0001) were associated with sling failure, whereas obesity (p=0.95), diabetes (p=0.49), and type of prostatectomy (p=0.88) were not. On multivariate analysis, only increasing preoperative pad use remained associated with sling failure (hazard ratio [HR] 1.3; 95% confidence interval [CI] 1.1–16; p=0.008). Patients wearing >3 pads per day were more likely to experience failure (35.5% vs. 13.4%; p=0.007).
Conclusions: Increasing preoperative pad use is independently associated with an increased risk of failure after non-adjustable sling for post-prostatectomy incontinence in otherwise well-selected patients.

Introduction

Post prostatectomy incontinence (PPI) is a well-known complication after radical prostatectomy and is estimated to occur in 8.4% of patients after treatment.[1] Although there is substantial disparity in the reported rates of PPI, Nam et al found in a population based study that approximately 5% of men after radical prostatectomy undergo surgical intervention for incontinence within 15 years of treatment.[2] The current surgical armamentarium for the treatment of post prostatectomy includes non-adjustable male slings, adjustable male slings, and the artificial urinary sphincter (AUS). Many consider the artificial urinary sphincter the gold standard of treatment for PPI but in mild to moderate cases of incontinence, slings may offer similar efficacy.[3] Additionally, when given a choice, 92% of men prefer a male sling over an AUS to avoid the use of a mechanical device and associated manipulation of a scrotal pump.[4]

In 2006, the AdVance™ transobturator male sling was introduced as a minimally invasive alternative to the AUS (AMS, Minnetonka, MN). After this non-adjustable male slings such as the Advance sling saw a large increase in use but were associated with lower success rates until the identification of obvious patient selection factors improved the treatment success.[5] These initial exclusion criteria included severe incontinence (>5 pads/day), concurrent radiation therapy, cryotherapy, untreated detrusor dysfunction, neurogenic incontinence and a standing cough test with grade 3-4 on the male stress incontinence grading scale.[6-9] Unfortunately, even in otherwise well selected patients' male slings fail in approximately 20-30% of cases.[10-12] Moreover, long-term results of non-adjustable male slings such as the Advance sling are not widely reported.[13] Our objective was to determine the clinical factors associated with failure to achieve continence after placement of an AdVance™ sling for the treatment of PPI in otherwise well-selected patients.

Methods

A retrospective review with approval from the regional institutional ethics board was performed on patients undergoing the AdVance™ or Advance XP™ trans-obturator male sling (American Medical Systems, Minnetonka, MN) between December 2006 and May 2017. Patients were identified using the surgical fee code for the procedure. Inclusion criteria included men over the age of 18, a minimum 1-year post radical prostatectomy at the time of continence procedure, and mild to moderate incontinence (defined as requiring ≤5 incontinence pads/day). All patients underwent cystoscopy, urinalysis, and urine culture. Urodynamics were selectively performed in patients with lower urinary tract symptoms, neurologic disease, abnormal urinalysis or prior incontinence treatment. Patients with known risk factors for sling failure including severe PPI (>5 pads/day), previous radiation therapy, untreated detrusor overactivity, neurogenic detrusor dysfunction and less than 6 months of follow-up were excluded from analysis.

We collected pre-operative patient characteristics including patient age, Charlson comorbidity index (CCI), type 2 diabetes, obesity (BMI≥35), prior incontinence procedure, type of prostatectomy and type/number of pre-operative pads. Postoperative data collected included number of incontinence pads required per day (determined by most recent follow-up visit), global patient satisfaction and 90-day complications (classified by Clavien grade). Our primary outcome measure was failure to achieve continence defined as 1 or less pads postoperatively if preoperative pads were equal or greater than 2 or no pads if preoperative pads used was 1. Secondary outcome measures included change in the number of postoperative pads and patient satisfaction based on a global assessment question ("Are you satisfied with the results of your surgery?").

Operative technique and followup

The Advance/Advance XP^{TM} 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 then made along the medial aspect of the thigh 2cm inferior to and just lateral to the insertion of the adductor longus muscle. The obturator is placed through the deep fascia and obturator fossa. The sling is seated against the corpus spongiosum, and approximated to the corpus spongiosum at four points. The sling is tensioned to achieve coaptation of the urethra and compress the bulb of the urethra to the pelvic floor. Cystoscopy is performed to ensure appropriate urethral coaptation and lack of mesh intrusion into the urethra or bladder. A urethral catheter is placed and the layers closed anatomically. The sling is additionally secured with an interrupted absorbable suture to the superficial fascia of the thigh. Patients are generally discharged on the same day and a urethral catheter is left in-situ for approximately 2 days. Patients were seen in clinic 6 weeks postoperatively, reviewed at 6 and 12 months, then annually thereafter.

Statistical analysis

Descriptive statistics, univariate and multivariate Cox regression analysis was performed using SPSS24 when appropriate.

Results

158 patients with at least 6 months of postoperative follow-up data were identified with an Advance/Advance XP sling placement between December 2006 and May 2017. Patient demographics and outcomes are described in Table 1. The mean age at sling placement was 66.1 ± 7.9 years of age with a mean Charlson comorbidity index of 1.8 ± 1.3. The rates of diabetes mellitus and obesity (BMI >35kg/m^2) were 10.8% (n=17) and 3.8% (n=6) respectively. The etiology of incontinence was most commonly robotic assisted radical prostatectomy (35.4%) followed by retropubic radical prostatectomy

(20.3%). The mean preoperative pad use was 2.8 ± 1.5 pads per day with a distribution of 49.4% (n=78), 39.8% (n=63), and 10.8% (n=17) requiring 1-2 pads/day, 3-4 pads/day and 5 pads/day respectively.

Continence was achieved in 82.3% (n=130) of patients with a mean follow-up of 42.7 ± 30.0 months (Figure 1). Postoperatively there was a mean change of 2.1±1.3 pads per day. Of the 28 patients failing to achieve continence postoperatively, 15 of these (53.5%) opted for further operative intervention including either an artificial urinary sphincter in 9 patients (32.1%) or an adjustable male sling (Adjustable Transobturator Male System) in 6 (21.4%). The remaining 13 patients opted for conservative treatment including either observation (n=12) or an indwelling catheter (n=1). Patient reported global satisfaction was 86.7% (n=137) and 90-day complications occurred in 12% (n=19) (Table 1). Clavien grade I (n=11) complications consisted of patients who experienced transient post-operative retention requiring a temporary urinary catheter reinsertion. These patients typically had a catheter for an additional 3-5 days. Clavien grade II (n=7) consisted of wound infections (n=4) and urinary tract infections requiring antibiotics (n=3). Finally, the only Clavien grade III occurred in a patient who presented with syncope 1 month postoperatively and required a pacemaker. This complication is unlikely related to his sling insertion but was included for completeness. No patients complained of persisting wound pain or scrotal paresthesia lasting more than 90 days and no sling erosion or explanations occurred. No grade IV or V complications occurred.

On univariate Cox regression analysis (Table 2), increasing age (p=0.02), CCI (p=0.02) and pre-operative pad use (p<0.0001) were associated with failure to achieve continence whereas obesity (p=0.95), diabetes (p=0.49), and type of prostatectomy (p=0.88) were not (Table 3). On multivariate analysis (Table 3) increasing preoperative pad usage remained associated with failure to achieve continence (p=0.008; H.R. 1.3; 95% 1.1-16) while patient age (p=0.29) and CCI (p=0.10) did not (Table 4). On log rank analysis patients wearing more than 3 pads per day (the approximate pre-operative mean of the cohort) were more likely to experience failure (35.5% versus 13.4%; p=0.007) (Figure 1).

Discussion

Post prostatectomy incontinence occurs in up to 10% of patients who have undergone radical prostatectomy [2]. The occurrence of incontinence is associated with decreased patient reported quality of life and regret after radical prostatectomy.[14] Herr et al. reported that only 53% of men with incontinence after radical prostatectomy would again choose radical prostatectomy when assessed at 5 years or more after treatment.[14] Patient regret associated with post-prostatectomy incontinence is an important aspect of prostate cancer survivorship that cannot be dismissed and speaks to the long-term quality of life implications in patients with incontinence after radical prostatectomy.

The Artificial urinary sphincter (AUS) was introduced in in 1972 and has been considered the gold standard for treatment of PPI.[15] Although broadly considered the most effective treatment, the AUS is not without complication or downside. Complications may arise from infection, urethral atrophy or erosion, or mechanical failure. In a large single center report of 218 patients who had an AUS implanted, 27.1% required surgical revision or explantation within 5 years.[16] Patient factors such as manual dexterity and worsening cognition can also greatly influence patient selection.

American Medical Systems introduced the AdVance™ sling in 2006 for the treatment of PPI. The AdVance™ sling had certain advantages from a patient perspective, there are no mechanical components and it does not rely on patient related dexterity or cognition to function. After the initial learning curve and subsequent more selective use, results of the AdVance sling were favorable with early continence rates ranging from 60-91%.[6,17,18] Established risk factors for Advance sling failure include concurrent radiation therapy and untreated detrusor dysfunction. Other risk factors associated with failure are poorly understood. We currently report continence rates of 82.3% in patients with no known risk factor for Advance sling failure with a mean follow up of 42.7 months. While some variability may exist due to of a lack of standardization in reporting outcomes.[19] We feel that our definition of zero postoperative pads if preoperatively the patient required 1 pad or ≤1 postoperative pads if the patient was wearing ≥2 pads preoperatively is justified by the strong correlation the patient satisfaction (86.7%). Thus, even in well selected candidates without risk factors for failure approximately 20% of patients fail to achieve continence. It seems prudent to explore factors associated with sling failure.

While the Advance sling has shown effectiveness in treating mild to moderate post-prostatectomy incontinence.[3] This current work builds on the concept of further delineating which patient should or should not be offered a male sling. The most important association our study adds to the literature is that for those otherwise well selected patients preoperative pad usage is the most important predictor of sling success. The male sling survival curve demonstrates that patients who only require 1-3 versus 4-5 preoperative pads had improved sling outcomes with regard to continence. This cut-point was chosen as it closely approximates the pre-operative mean number of daily pads used. This data suggests that slings should potentially be reserved for men who have not undergone previous radiation therapy and only require 1-3 preoperative pads. In this group continence approaches almost 90%. We suggest that for those men who require 4-5 preoperative pads an alternative another tool in the PPI surgical armamentarium, such as newer adjustable male slings or the AUS, be used.[20] Other than preoperative pad use other readily identifiable risk factors for sling failure remain elusive. In particular

diabetes, obesity and other comorbidities were not associated with failure to achieve continence which is in itself also a novel finding.

There are several limitations to our study. First, this is a single center retrospective review that may introduce some bias on the basis of methodology, limiting its generalization. However, most variables in our patient population are easily obtained in most clinical settings and are easily reproducible. Second, with no universally accepted standardized method of reporting incontinence outcomes we used a reduction in the number of daily pads instead of exact pad weight. However, pad count as a measure has been shown to be an accurate surrogate marker for incontinence severity and is thus a very relevant and easily obtainable clinical measure which helps increase relevance of our study.[21] Also, we lacked the use of standardized incontinence questionnaires as an objective marker in this study but did provide overall patient satisfaction.

Conclusions

The AdVance™ non-adjustable sling remains a viable tool in the post-prostatectomy incontinence surgical armamentarium. However, increasing pre-operative pad usage is independently associated with an increased risk of failure in otherwise well selected patients. In particular, over 1/3 of patients using more than 3 pads per day failed to achieve continence and may be better managed by other means such as an adjustable sling or an artificial urinary sphincter.

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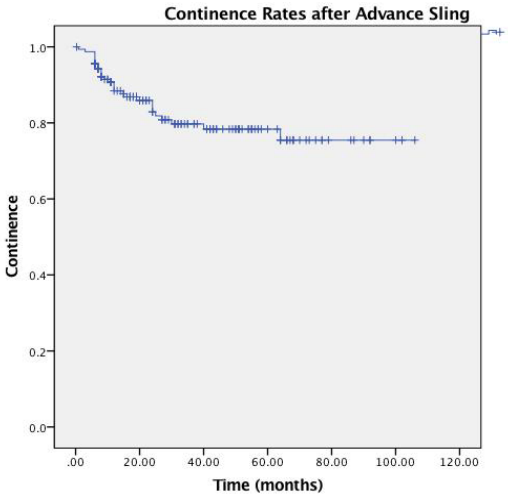
Figures and Tables

Fig. 1. Kaplan-Meier curve of ***(A)*** overall postoperative continence after Advance/Advance XP male sling; and ***(B)*** survival curve of postoperative continence rates stratified by preoperative pad number ≤3 pads per day (blue) or 4–5 pads per day (green). Long rank p=0.007.



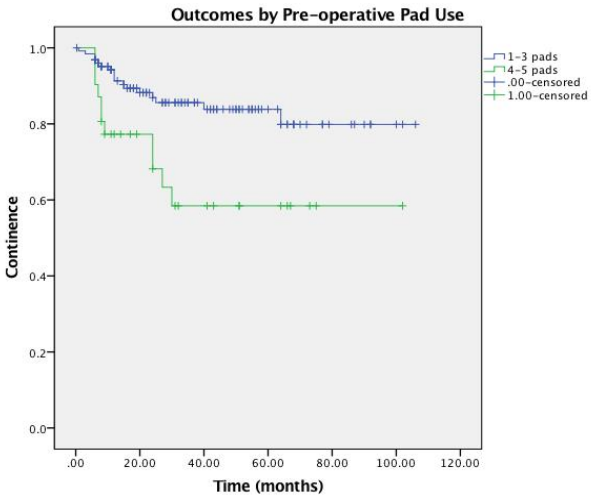


Table 1. Patient demographics and postoperative outcomes of the Advance/Advance XP male sling	
	n (%)
Number of patients	158
Patient age	66.1±7.9 (47–93)
Diabetes	17 (10.8%)
Mean Charlson Comorbidity Index	1.8±1.3 (0–8)
Obesity (BMI ≥35)	6 (3.8%)
Etiology of incontinence	
Open radical prostatectomy	32 (20.3%)
Robotic-assisted radical prostatectomy	56 (35.4%)
Laparoscopic prostatectomy	28 (17.7%)
Unspecified radical prostatectomy	38 (24.1%)
Transurethral resection of prostate	4 (2.5%)
Previous continence surgery	1 (0.6%)
Preoperative continence status	
1–2 pads	78 (49.4%)
3–4 pads	63 (39.8%)
5 pads	17 (10.8%)
Mean preoperative pad use	2.8±1.5 (0–5)
Mean postoperative pad use	0.7±1.5 (1–6)
Mean change in pad use	2.1±1.3
Continence rate (≤1 pad)	130 (82.3%)
Postoperative pad use	
No pads or rescue pad	109 (70.0%)
1 pad	25 (15.8%)
2–3 pads	19 (12.0%)
4–5 pads	5 (3.2%)
Patient satisfaction	137 (86.7%)
Length of followup (months)	42.7±30.0 (6–106)
Complications (any grade)	19 (12.0%)
Grade I: Transient urinary retention	11 (7.0%)
Grade II: UTI or wound infection requiring antibiotics	7 (4.4%)
Grade III: Syncope	1 (0.6%)

BMI: body mass index; UTI: urinary tract infection.

Table 2. Univariate Cox regression analysis of factors associated with failure to achieve continence	
Variable	**p**
Age (years)	**p=0.02**
Preoperative pad use	**p≤0.0001***
BMI ≥35	p=0.95
Diabetes	p=0.49
Charlson Comorbidity Index	**p=0.02**
Etiology of incontinence	p=0.88

*Indicates p<0.05. BMI: body mass index.

Table 3. Multivariate associations of failure to achieve continence after Advance/Advance XP male sling		
Variable	**p**	**Odds ratio (95% CI)**
Age (years)	p=0.29	1.0 (0.98–1.1)
Preoperative pad use	**p=0.008***	1.3 (1.1–1.6)
Charlson Comorbidity Index	p=0.10	1.2 (0.96–1.5)

*Indicates p<0.05. CI: confidence interval.