
The transobturator suburethral sling: a safe and effective option for all degrees of post prostatectomy urinary incontinence

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Introduction: Male stress urinary incontinence (SUI) after radical prostatectomy (RP) is common. The surgical standard of care traditionally has been placement of an artificial urinary sphincter (AUS) but since its introduction the transobturator male sling has been shown to have particular unique advantages. Our aim was to assess outcomes of a consecutive series of suburethral sling insertions in men presenting with all degrees of post RP SUI.

Materials and methods: A consecutive cohort of men undergoing AdvVance sling insertion following RP were studied. Parameters assessed included pre and postoperative urinary function, 24 hour pad use, quality of life (QoL) outcomes, complications and further treatments. Degree of incontinence was categorized as mild (1-2), moderate (3-5) or severe (≥ 6) depending on daily pad use. Patients were reviewed at 1, 4 and 6

months. The International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF) was used to assess symptom severity and QoL outcomes.

Results: Seventy-seven patients were included, mean age 68 and mean time to sling post RP 34 (8-113) months. Preoperative degree of incontinence: mild 22%, moderate 58%, severe 20%. Fourteen percent had undergone post RP radiation therapy (RT). In total 73% experienced complete resolution of symptoms post sling, 12% significant improvement, 15% no reduction in pad use. Sixty percent with severe incontinence were classified as cured (no pad or 1 dry pad for security reasons). When patients with preoperative RT were excluded, cure rate rose to 82%. On follow up survey at 30 months (mean), the ICIQ-SF score decreased from baseline 17.7 (9-21.0) to 8.0 (0-20) ($p < 0.0001$), CI 95% (8-12).

Conclusions: Suburethral slings are effective and safe for all degrees of post RP incontinence, are associated with improved QoL parameters and with appropriate selection and counseling are a viable option for more severe degrees of post RP SUI.

Key Words: suburethral slings, male stress urinary incontinence, radical prostatectomy

Introduction

Male stress urinary incontinence (SUI) after radical prostatectomy (RP) is common, with reported rates varying between 7% to 33%.¹ Management options include conservative pelvic floor muscle training, behavioral therapies, pharmacotherapy and surgical intervention.² About 1 in 10 men will choose surgery

to rectify their post RP SUI³ with the most common procedures being artificial urethral sphincter (AUS) placement and suburethral sling insertion. The standard of care traditionally has been placement of an AUS⁴ but since the introduction of the transobturator male sling in 2007, there has been a growing weight of evidence supporting its use as an alternative with particular unique advantages.^{5,6}

These advantages of the male sling include shorter operative time, a non-mechanical device insertion and easier postoperative access to both bladder and upper genitourinary tract for subsequent unrelated pathology.⁷ To date, slings have mostly been chosen for patients with mild to moderate SUI,⁸ however they

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have been shown to be effective in more severe forms of SUI with the appropriate patient selection.^{6,8}

This analysis was performed to assess the outcomes of a consecutive series of suburethral sling insertions in a population of men with all ranges of post RP SUI.

Materials and methods

Patient population

A consecutive series of patients with SUI post RP were treated with the AdVance transobturator male sling (American Medical Systems, Minnetonka, MN, USA) by one surgeon at a single center. All patients had undergone failed conservative treatment with pelvic floor muscle training and required more than one incontinence pad per 24 hour period. Patients were seen in clinic preoperatively where a thorough review of previous treatments, prior radiation therapy (RT) and other relevant co-morbidities were assessed. All patients underwent preoperative cystoscopy and any men with an anastomotic or urethral stricture were treated as appropriate. They were followed up and had to be stricture free for 6 months prior to the placement of a sling.

The degree of incontinence was based on pad usage over a 24 hour period. We adhered to a previously well reported definition, with mild incontinence defined as pad usage of 1 or 2 pads per day, moderate between 3 and 5, and severe greater than 6.^{6,9} All patients also completed the International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF; score range: 0-21, minimal to maximum symptoms) which assesses severity of incontinence symptoms and impact on quality of life (QoL). Patients were surveyed both pre and postoperatively and a comparative analysis performed.

Operative procedure

Implantation of the AdVance sling was performed under general anesthesia and using an operative technique previously described.¹⁰ Cystourethroscopy was performed at the time of sling tensioning to ensure an intact urethra and proper urethral repositioning. A 14Fr urethral catheter remained in place during the surgery and was then removed.

For the initial 15 patients in this series no suprapubic catheter (SPC) was inserted, however all subsequent patient had one placed at the beginning of the procedure and were discharged home with the catheter to a flip flow valve. They were encouraged to void spontaneously and then measure residual volume via SPC. They were followed up by telephone by urology specialist nurses and when residual volumes fell below 100 cc the SPC was removed.

Follow up and statistical analysis

Patients were reviewed at 1, 4 and 6 months postoperatively and thereafter as needed. Primary outcome was pad usage over a 24 hour period at their 6 month clinic visit. As with previous studies^{6,9} we considered patients cured if they used no pad or one dry pad for security reasons, as improved if one or two pads per day were used and if there was a reduction in daily pad usage of 50%. All other pad usage as well as those patients who required an additional procedure were classified as failures. The secondary study outcome was patient satisfaction using the ICIQ-SF questionnaire. Peri and postoperative complications were recorded using the Clavien–Dindo classification.¹¹ Local institutional ethics committee approval was obtained for evaluation of all data. The results were collated on a secure protected database (Microsoft Excel, WA, USA) and analyzed using SPSS (IBM, NY, USA). Paired t-tests were used to compare pre and postoperative ICIQ survey results.

Results

Seventy-seven patients were included in the analysis, all of which were status post RP. Patient demographics and baseline incontinence data are reported in Table 1. The mean time from RP to sling insertion was 38.5 ± 33.6 (mean \pm SD) months (m) for the whole group. There was no significant difference regarding time to sling between the minimally invasive (MIS) ($n = 44, 32.5 \pm 29.6$ m) and open ($n = 33, 48.2 \pm 37.8$ m) groups ($p = 0.067$). Pad use

TABLE 1. Patient baseline characteristics

Characteristic (n = 77)	Mean (range) or n (%)
Age at diagnosis (years)	68 (51-80)
Type of prostatectomy	
Open	33 (43%)
Minimally invasive (laparoscopic/robotic)	44 (57%)
Time interval between RP and sling (months)	34 (8-113)
Previous pelvic radiation	11 (14%)
Preoperative degree of incontinence	
No. of pads used per day	4 (1-9)
No. of patients with:	
Mild (1-2 pads)	17 (22%)
Moderate (3-5 pads)	45 (58%)
Severe (≥ 6 pads)	15 (20%)

RP = radical prostatectomy

before surgery was 3.7 ± 1.7 for the 77 men, MIS: 3.4 ± 1.6 and open: 4.0 ± 1.9 ($p = 0.158$). Fourteen percent of patients had received RT prior to sling insertion. Fifty-eight percent of patients were graded as having moderate incontinence preoperatively with a further additional 20% classed as severe. In the severe grouping average daily pad use was 6.7 (range 6-9).

At 6 months post sling insertion 73% of all patients experienced complete resolution of symptoms, 12% had a significant improvement, with 15% having no reduction in pad use. Postoperative outcomes are shown in Table 2. Nine of 15 patients (60%) with severe incontinence were classified as cured, with an additional patient have a greater than 50% drop in pad use (7 to 3 pads per day). When patients with post RP RT were removed from the analysis 82% (54/66) of men were considered cured, with a further 12% improved and 8% reporting no improvement. Of the 5 patients (8%) without RT that found no benefit from sling insertion, 3 of them had severe incontinence (7, 8

and 9 pads respectively). Overall pad use significantly decreased from 3.7 ± 1.7 pads before to 0.83 ± 1.6 after sling insertion ($p < 0.001$). There was no difference seen between MIS and open groups.

Fifty-nine of 77 patients (77%) responded to the follow up ICIQ-SF survey. Respondents were a mean of 30 months (6-70) post sling insertion. Of the individuals who responded to this survey 78% were cured, 12% improved and 10% had failed post sling insertion. The ICIQ-SF score decreased from a baseline 17.7 (9-21.0) to 8.0 (0-20) ($p < 0.0001$), CI 95% (8-12).

In total 14 complications occurred, (6 Clavien grade I, 4 Clavien grade II, 3 Clavien grade IIIa and 2 Clavien grade IIIb). Complications included mild perineal pain (<3months) ($n = 4$), urinary urgency / minor LUTS ($n = 4$), transient urinary retention ($n = 3$), sling explantation ($n = 2$), superficial wound infection ($n = 1$). Nine of the 12 patients who did not gain any benefit from sling insertion underwent a subsequent AUS. One additional patient had an ileal conduit urinary diversion, while one patient underwent a second sling which was successful.

TABLE 2. Postoperative outcomes

Variable	Post sling n (%)
Overall outcome (n = 77)	
Cured	56 (73%)
Improved	9 (12%)
Failed	12 (15%)
According to baseline severity of incontinence	
Mild (n = 17)	
Cured	14 (82%)
Improved	2 (12%)
Failed	1 (6%)
Moderate (n = 45)	
Cured	33 (73%)
Improved	6 (13%)
Failed	6 (13%)
Severe (n = 15)	
Cured	9 (60%)
Improved	1 (7%)
Failed	5 (33%)
According to previous radiation therapy	
Radiation (n = 11)	
Cured	2 (18%)
Improved	2 (18%)
Failed	7 (64%)
No radiation (n = 66)	
Cured	54 (82%)
Improved	7 (11%)
Failed	5 (8%)

Discussion

SUI is a common issue for patients post RP.¹ It is well established that it is a significant source of bother and treatment dissatisfaction for both patients and partners after surgery for prostate cancer.^{12,13}

Options for management of post RP SUI include conservative measures such as pelvic floor muscle training and behavioral modifications.¹⁴ If these measures fail surgical intervention can be offered in the form of a AUS or suburethral sling.⁶ The AUS is recognized as the reported treatment of choice¹⁵ especially for more severe degrees of incontinence, however since its introduction in 2007, the suburethral sling has become an acceptable alternative for many patients.^{3,6,16-18}

In this analysis we have reviewed our series of sling insertions, which included men with all degrees of post RP SUI. We defined the degree of incontinence as pad usage over 24 hours and adhered to well described definitions.^{6,9} Over 75% of patients had moderate to severe SUI and as this analysis such provides information of the effectiveness of a sling for more significant urinary leakage. Our primary outcome of patient reported pad use at 6 months revealed that 73% of individuals were considered cured (no pads or 1 single dry pad for security), with an additional 12% having a significant improvement, comparing vary favorably with other similar single and multi-center studies, Table 3. Of particular interest was that 73% and 60% of the moderate and severe groupings respectively

TABLE 3. Comparisons of results from previous similar Advance sling studies

	Current study (n = 77) at 6 months	Bauer et al²¹ (n = 113) at 6 months	Rehder et al⁶ (n = 151) at 3 years	Siegler et al²⁴ (n = 69) at 16 months
Overall outcome				
Cured	73%	55.8%	53%	21.8%
Improved	12%	27.4%	23.8%	50.7%
Failed	15%	16.8%	23.2%	17.5%
Severe (≥ 6 pads)	(n = 15)	(n = 34)	(n = 52)	(n = 14)
Cured	60%	42.4%	42.3%	14.2%
Improved	7%	33.4%	25%	7.8%
Failed	33%	24.2%	32.7%	78%
	Berger et al²⁵ (n = 26) at 1 year	Cornu et al¹⁷ (n = 136) at 18 months	Cornel et al¹⁶ (n = 36) at 3 months	Kowalik et al²⁶ (n = 31) at 3 years
Overall outcome				
Cured	61.5%	62%	14.3%	60%
Improved	26.9%	16%	40%	13%
Failed	11.5%	22%	42.8%	27%
Severe (≥ 6 pads)				
Cured	Did not	Did not	Did not	Did not
Improved	clearly report	include	clearly report	clearly report
Failed	severe	severe	severe	severe

were dry. The severe group having an average pre sling pad use of 6.7⁶⁻⁹ per 24 hours. This rate of success in the severe grouping correlates with other series, with Van Bruwaene et al in a recent pooled analysis quoting a success rate of 56%.⁸ When patients with preoperative RT were removed the overall study cure rate rose to 82%.

The conventional approach in treating post RP SUI has been to avoid sling insertions in patients with more severe incontinence in favor of an AUS as the weight of evidence to date would suggest the AUS is more effective overall in this grouping.⁸ We would challenge this and recommend that a sling can also be offered as a first line treatment option. The reason for patients favoring a sling over the AUS is that it is felt to be less invasive, with the return to a more normal voiding pattern without the need for deflating a sphincter. In a survey of patients with a moderate degree of SUI who were considering surgical management and offered an AUS or sling, 92% chose the sling and cited the main reason being the avoidance of insertion of a mechanical device.¹⁹ Comiter et al reported that despite their surgeon recommending otherwise, up to 25% of men with severe SUI had a preference for a sling.²⁰ We believe our data in addition to other groups,^{6,21} provides evidence that a sling should be offered as an alternative to the AUS in this group of patients.

Although the literature would appear to favor the AUS as the treatment of choice for severe incontinence, there are certain advantages to a suburethral sling. Firstly, significantly lower revision rates (23% versus 0.7%).⁸ Additionally, as mentioned, a less invasive approach, and importantly, the fact that an AUS can be placed post sling but the reverse not being applicable.

Previous analyses have shown a link between RT and sling failure.^{8,17,18,22} In this study we also saw a correlation with higher sling failure rates in patients post salvage RT, with 64% of post RT patients failing in comparison to a failure rate of 8% without salvage RT.

It has been proposed previously that these higher failure rates are directly related to radiation damage to the internal sphincter and surrounding tissue resulting in decreased ability to mobilize the urethra.²³ Our observations along with other reports cited above suggest that in irradiated patients the AUS is a better alternative.

We noted in our series, postoperative improvement in lower urinary tract urgency and frequency symptoms in the cohort of patients who has a SPC placed intra operatively. After patient number 15 in the series, all patients had a SPC sited at the beginning of the procedure. We reason, in the former grouping, that these individuals were initially holding onto to

significant postvoid residuals. After adopting the policy of a clamped SPC patients reported significantly less lower urinary tract symptoms. The majority of the catheters were removed within 10 days.

The suburethral sling and AUS have both advantages and disadvantages, the key is to choose the correct surgical strategy for each individual patient. We suggest that proposing a male sling as an initial procedure, even in men with severe SUI is viable, especially in view of the fact that AUS can be offered after sling failure. It is critical however, that the patient is fully informed as to rates of success and possible need for re-intervention.

As it stands the AUS still gives the best results for severe post RP SUI, however, in time this view may change. Randomized controlled trials comparing both sling and AUS insertion in this cohort are lacking and may well reveal a broadening of the accepted indications for sling placement.

The strengths of this study are that it is from one surgeon in a single center with all degrees of incontinence being treated in comparison to other series where the majority of patients had less severe incontinence.

Conclusion

Male suburethral slings are an effective and safe option for patients with post RP SUI. We believe that in certain appropriate and well selected patients they are an effective alternative with particular advantages over the AUS and should perhaps be offered as the first surgical option. □

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