

ARTICLE

The AdVance™ male sling: does it stand the test of time?

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ABSTRACT

Introduction: There is minimal data published on the longevity of the transobturator retrobulbar male sling (AdVance™). We aimed to determine the efficacy, the complication rate and need for salvage SUI surgery in the medium to long term for male sling insertion.

Materials and methods: We performed a retrospective review of all patients undergoing male sling insertion at a single centre between 2009 and 2018. Data on patient demographics, pre and post-operative International Consultation on Continence Questionnaire – Urinary Incontinence (Short Form) (ICIQ-UI(SF)) scores and 24 h pad usage were collected. Success was calculated as a combination of the cured rate (0–1 security pad use) and the improved rate (>50% reduction in pad usage). Data was also collected on complications, patient satisfaction as well as need for further SUI surgery.

Results: A total of 91 patients underwent male sling insertion in the period specified; median follow up was 69 months. Success rates at 3 months in mild SUI, moderate SUI and severe SUI groups were 96, 86 and 80%, respectively. In the medium to long term, this drops to 65, 62 and 47%, respectively. The overall rate of artificial urinary sphincter (AUS) implantation was 15%. Common complications included groin pain (3%), infection (3%), urinary retention (10%) and de novo overactive bladder (OAB) (11%). The only factor predicting success or failure was pre-operative ICIQ-UI(SF) score.

Conclusions: AdVance™ male sling success rates deteriorate from 89% at 3 months to 61% at 5 years. The risk of complications is low and, for the most part, transient. Sling insertion remains a reasonable treatment option for male patients suffering with stress urinary incontinence (SUI).

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Introduction

Radical prostatectomy (RP) represents the most common cause of stress urinary incontinence (SUI) in men [1]. Current rates are cited as 21.3% after robotic RP and 20.2% after open RP at 12 months with the definition used being patients requiring at least one pad change in 24 h [2]. Other causes of SUI in men include radical cystectomy with neobladder, transurethral resection of prostate as well as laser enucleation of prostate. There are a number of commercially available devices to surgically treat the condition. The artificial urinary sphincter (AUS) is considered the gold standard, achieving continence rates of 82–92% (0–1 pad/24 h) but there is a growing number of male sling devices on the market [3].

Rehder and Gozzi initially demonstrated the transobturator retrobulbar AdVance™ male sling (Boston Scientific, formerly American Medical Systems, Marlborough, MA) in a proof-of-concept study in 2007 [4]. They described a technique for inserting a polypropylene mesh tape in a transobturator fashion resulting in 3–4 cm proximal relocation of the urethral bulb into the pelvic outlet with consequent lengthening of the membranous urethra. The sling was tensioned to achieve a retrograde leak point pressure of 60 cm H₂O. This was initially performed in cadavers followed by a group of 20 patients, the majority of which were post-RP. Initial

results were encouraging with a 40% dry rate, 30% improved rate (1–2 pads/24 h) and 60% satisfaction rate at 6 weeks post-procedure.

A second generation AdVance XP™ sling was introduced in 2010. This incorporated polypropylene barbs onto the tape to prevent slippage. Success rates of 60–89% (using both iterations) have been reported by several groups in cohorts of post-prostatectomy patients, post-TURP patients [5] and irradiated patients [6]. The majority of studies are retrospective case series and have limited long-term follow up, although this is now changing as data matures [7]. It is important to note that there are also differing definitions of success between groups with some using different combinations of pad usage and others using pad weight criteria [8].

Using the definition of success as 0–1 security pad (also the cured rate) or improved (1–2 pads/24 h and 50% reduction in pad usage), Rehder et al. [9] reported durable success rates of 76% at 12 and 36 months. Cure rates were lower at 53% but still persisting at 36 months. Li et al. [10] could not reproduce this durability with a success rate that decreased from 87 to 62% at 2 years. Patient satisfaction however was maintained in the latter study and in a review of the literature by Doudt [11], the author suggests that patient expectations may have a subjective role to play in this outcome measure.

The aim of this study is to assess the objective success, cure and improved rates of the AdVance male sling for SUI. Success was defined as 0–1 security pad usage post-operatively (also the cure rate) or a 50% reduction in pad usage compared to baseline (the improved rate). Secondary outcomes included the need for further SUI surgery, the complication rate and whether the success and patient satisfaction rates were maintained in the medium-long term. We also aimed to identify predictors of long-term success or failure for male sling insertion.

Materials and methods

Subjects and setting

All patients who underwent AdVance™ or AdVance XP™ male sling insertion by two surgeons at a single centre between 2009 and 2018 were assessed. Previous radiotherapy was the only relative (but not absolute) exclusion criteria. All patients underwent a detailed pre-operative history taking, examination and investigations which included videourodynamics (VUDS), flexible cystoscopy, bladder diary and latterly pad weight testing. Data were prospectively collected on patient demographics, pre- and post-operative International Consultation on Continence Questionnaire – Urinary Incontinence (Short Form) (ICIQ-UI(SF)) scores and 24 h pad usage pre-operatively and at 3 months post-operatively. At this point, the majority of patients were discharged if they had satisfactory results and no complications.

Patient notes were retrospectively assessed for surgical complications and need for further surgical intervention for SUI. In order to assess the longevity of results, all patients were contacted at the time of the study (January 2020) and data on ICIQ-UI(SF) scores and pad usage collected again along with a subjective patient-reported overall satisfaction with the procedure. Preoperative severity was categorised as mild SUI (1–2 pads/day), moderate SUI (3–4 pads/day) or severe SUI (5 or more pads/day).

Analysis

Quantitative analysis of results was undertaken using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp, Armonk, NY). Categorical data were compared using a chi-squared test, while continuous variables were compared using an unpaired T-test. Fisher's exact test was utilised for smaller sample sizes and multivariate analysis performed to identify factors predictive of success or failure; $p \leq .05$ was considered statistically significant.

Results

A total of 91 patients underwent male sling insertion in the period 2008–2018 at a supra-regional referral centre for male incontinence. The mean patient age at the time of the procedure was 67.3 (range 51–71). The average BMI was 27.5 (range 20.8–41.4). All but two patients had previously undergone RP (one post-HOLEP, one post-TURP). There was an

almost equal split between open RP and minimally invasive methods; 42 patients (46%) had undergone open RP while another 42 underwent a laparoscopic procedure and 5 (5%) underwent a robotic procedure. Median time from initial surgery to sling insertion was 33 months (2.7 years, range 16–135 months). Average inpatient stay was 2.2 days (range 1–4). Procedures were performed by two surgeons (surgeon A and surgeon B) in a ratio of 61:30 (A:B). This information is detailed in Table 1.

All patients demonstrated stress incontinence on VUDS; in addition, three patients demonstrated detrusor overactivity (DOA) and were counselled on possible worsening symptoms post-operatively (3%). Three patients had undergone adjuvant or salvage radiotherapy prior to sling insertion (3%).

Short-term outcomes

Mean pre-operative ICIQ-UI(SF) score was 16.5 (range 5–21). Mean pre-operative pad usage was 3.3 (range 1–10) in 24 h. At 3 months, mean ICIQ-UI(SF) score was 5.3 (range 0–21). Mean post-operative pad usage had reduced to 0.6 (range 0–4). Average change in ICIQ-UI(SF) was –11.2 points while average change in pad usage was –2.7. The overall success rate at this stage was 89% while the improved rate was 2% and the cure rate was 87%. Breakdown of this data by pre-operative severity is shown in Table 2.

Pad weights

There was complete pad weight data available for 34/91 patients recorded pre-operatively and at 3-month follow up (37%). All had undergone RP – 21 open, 8 laparoscopic and 5 robotic. All patients were diagnosed with stress incontinence on VUDS and 1 had additional DOA. Mean ICIQ-UI(SF) score pre-operatively was 16.2 (range 10–21), mean pad usage was 2.7 in 24 h (range 1–5) and mean pad weight was 277 ml in 24 h (range 30–1400 ml). At 3 months, mean ICIQ-UI(SF) score was 4.3 (range 0–19), mean pad usage was 0.5 (range 0–4) and mean pad weight was 64 ml (range 0–1400 ml).

Short-term complications

There were no intra-operative complications. One patient reported testicular numbness and three reported groin pain that was managed with analgesia (3%) (Clavien–Dindo I). Three patients reported wound infections (3%) and were treated with intravenous antibiotics (Clavien–Dindo II); no slings were explanted. Nine patients reported urinary retention post-procedure (Clavien–Dindo IIIa); all but one had resolved by the 3-month follow up appointment (10%). One patient continued to self-catheterise twice a week but was otherwise dry and happy to continue (1%).

Patient satisfaction

At 3 months, 78 patients reported that they were happy with the outcome of their sling procedure (86%). Seventy-six of these patients were on 0 or 1 security pad a day, 1 was

Table 1. Patient demographics.

	Surgeon A	Surgeon B	Total
Number of patients	61	30	91
Age, years, mean (range)	66 (51–80)	70 (57–80)	67.3 (51–80)
BMI, mean (range)	27.7 (20.8–41.4)	27.2 (21–37.6)	27.5 (20.8–41.4)
Previous prostate surgery			
TURP	1	0	1
HOLEP	0	1	1
Open RP	22	20	42
Lap RP	38	4	42
Robotic RP	0	5	5
Time (months) between original surgery and sling insertion, median (range)	33 (18–135)	35 (16–114)	33 (18–135)
Average inpatient stay, days (range)	2.2 (1–4)	2.2 (1–4)	2.2 (1–4)

Table 2. Short-term success, cured and improved rates.

Pre-operative severity	Success rate at 3 months (%)	Cure rate at 3 months (%)	Improved rate at 3 months (%)	Patient satisfaction at 3 months (% happy)
Mild incontinence (1–2 pads)	30/31 (96%)	30/31 (96%)	0/31 (0%)	30/31 (96%)
Moderate incontinence (3–4 pads)	39/45 (86%)	38/45 (84%)	1/45 (2%)	37/45 (82%)
Severe incontinence (5 or more pads)	12/15 (80%)	11/15 (73%)	1/15 (6%)	11/15 (73%)
All patients	81/91 (89%)	79/91 (87%)	2/91 (2%)	78/91 (86%)

Table 3. Medium-long term success, cured, improved and patient satisfaction rates.

Pre-operative severity	Mean pre-op ICIQ-UI(SF) score (range)	Median length of follow-up in months (range)	Mean post-op ICIQ-UI(SF) score at medium-long term (range)	Success rate in medium-long term (%)	Cure rate in medium-long term (%)	Improved rate in medium-long term (%)	Patient satisfaction in medium-long term (% happy)
Mild incontinence (1–2 pads)	15.9 (5–21)	69 (15–130)	8.2 (0–21)	20/31 (65%)	20/31 (65%)	0/31 (0%)	21/31 (68%)
Moderate incontinence (3–4 pads)	16.2 (8–21)	64 (15–125)	9.8 (0–21)	28/45 (62%)	25/45 (56%)	3/45 (6%)	25/45 (56%)
Severe incontinence (5 or more pads)	18.5 (16–21)	70 (15–98)	13.4 (4–21)	7/15 (47%)	7/15 (47%)	0/15 (0%)	6/15 (40%)
All patients	16.5 (5–21)	68 (15–130)	9.9 (0–21)	56/91 (61%)	53/91 (58%)	3/91 (3%)	52/91 (57%)

using half the number of pads compared to pre-operatively and one was using fewer pads compared to pre-operatively (but not >50% reduction). Thirteen patients (14%) stated that they were unhappy with the outcome of their sling procedure and further work-up was then undertaken. This involved an assessment of symptoms, flexible cystoscopy and VUDS. The mean post-operative ICIQ-UI(SF) in the unhappy group was 12 (range 5–19) and mean pad usage was 2.5 in 24 h (range 1–4). All except 1 had moderate-severe incontinence pre-operatively.

Medium-long term outcomes

Data for medium-long term outcomes were obtained by telephoning patients at the time of the study (January 2020). Six patients were unable to be contacted (93% follow-up rate). Median follow up was 69 months (5.7 years, range 15–130 months). Mean ICIQ-UI(SF) scores had risen to 9.9 (range 0–21) while mean pad usage had risen to 1.8 in 24 h (range 0–10). The overall success rate at this stage had fallen

to 61% while the cure rate was 58%. Breakdown of this data on an intention-to-treat basis is shown in Table 3.

Medium-long term complications

Twelve patients reported overactive bladder (OAB) symptoms following sling insertion; two of these had DO diagnosed on pre-operative VUDS. The majority of these were satisfactorily treated with anticholinergics or beta-3 agonists (Clavien–Dindo II). Two patients were offered intravesical botulinum toxin for their refractory symptoms but declined. This represents a de novo OAB rate of 11%.

Twenty-two patients had refractory SUI and were offered an AUS (24%). This comprised of patients who were unhappy at their three-month post-operative visit and those who had been re-referred with recurrent symptoms. All three patients who had a background of radiotherapy pre-operatively were in this cohort. Ten patients went on to have one implanted and four are currently on the waiting list while the rest declined. Salvage SUI surgery rates categorised by pre-operative SUI severity is demonstrated in Table 4.

Patient-reported satisfaction

Fifty-two patients reported being happy with the outcome of their sling surgery (57%) in the medium-long term. Thirty-three patients (36%) reported that they were unhappy. Mean ICIQ-UI(SF) score of the unhappy patients was 16.6 (range 4–21) and mean pad usage was 3.6 in 24 h (range 1–10). At 3 months, this group had reported a mean ICIQ-UI(SF) score of 7.1 (range 0–19) and mean pad usage of 1.1 (range 0–4).

Length of time since sling insertion

Those who had their sling implanted less than 5 years ago had a success rate of 80% (24/30) with a cure rate of 73% (22/30) at the time of the study (median follow up 2 years). The success rate in patients who had their sling implanted 5 or more years ago was 52% (32/61) with a cure rate of 51% (31/61) (median follow up 7 years). Breakdown of outcomes in this group is shown in Table 5.

Factors predictive of success or failure

We performed a multivariate analysis to assess risk factors for success or failure. At 3 months, the only predictor of success or failure was pre-operative SUI severity ($p = .04$), whereby a lower severity was associated with a higher degree of success. In the long term, the only significant predictor of success or failure was pre-operative ICIQ-UI(SF) ($p = .01$), whereby a lower pre-operative ICIQ-UI(SF) score was associated with a greater chance of success. The mean pre-operative ICIQ-UI(SF) in the medium-long term treatment success group was 16 while the mean pre-operative ICIQ-UI(SF) in the group deemed treatment failures was 18. There were no significant associations with age, BMI and time between prostatectomy and sling surgery; this is demonstrated in Table 6.

Table 4. Salvage SUI surgery rates.

Pre-operative severity	AUS implanted/awaited
Mild incontinence (1–2 pads)	2/31–6%
Moderate incontinence (3–4 pads)	7/45–15%
Severe incontinence (5 or more pads)	5/15–33%
All patients	14/91–15%

Discussion

In the UK, the National Institute for Clinical Excellence (NICE) has recognised that some patients may consider the AUS too invasive or prone to complications; this concern then results in them being reliant on pads alone [12] hence the advent of minimally invasive non-mechanical options, such as the AdVance™ sling. The level of evidence supporting the use of male slings in general is low based primarily on single or multicentre case series with limited follow up beyond 3 years. The MASTER study has recently examined the AUS and the AdVance™ sling in a randomised controlled trial; the results are awaited and may give us a better idea of relative efficacy and of which patient cohorts may better suit one treatment modality or other [13]. The controversies around the use of mesh for female SUI have also put the future of the male sling into question. The mesh ban in the UK has not included the male sling however anecdotal data has suggested that some clinicians have also put this on pause. With this backdrop, real-world long-term data on the outcomes of male sling is a priority for those involved in treating male SUI.

This is the first article to report outcomes in patients undergoing AdVance™ male sling insertion at a median of 69 months. The demographics of our patient cohort were not dissimilar to other studies as was our definition of successful, cured and improved [11]. Our 3-month overall success rate of 89% and cure rate of 87% is comparable to the literature. Cornel et al. [14] reported 3-month success rates with AdVance™ sling insertion of 54% with 14% cured and 40% improved. Bauer et al. [8] reported 36-month outcomes with 115 patients undergoing AdVance XP™ sling insertion; at 3 months, 96% of patients were deemed cured or improved. The latter group had a much stricter definition of success by utilising post-operative pad weight data. We did not use pad

Table 6. Multivariate analysis of factors predictive of success.

	Short-term follow up	Medium-long term follow up
Age	0.602	0.149
BMI	0.092	0.815
Lower pre-operative ICIQ-UI(SF)	0.577	0.016
Time between prostatectomy and sling insertion	0.351	0.868
Lower pre-operative SUI severity	0.045	0.421

Variables where $p < 0.05$ are shown in bold.

Table 5. Comparing outcomes of patients with less than 5 years since sling implantation vs. more than 5 years.

	Less than 5 years	5 or more years	p Value
Number of patients, n	30	61	–
Median follow up, range	34 months (15–59)	88 months (60–130)	–
Mean ICIQ-UI(SF) pre-operatively	16.3	16.5	0.73
Mean ICIQ-UI(SF) at 3 months	5.7	5.0	0.59
Mean ICIQ-UI(SF) now	7.3	11.2	0.0114
Mean pad usage/24 h pre-operatively	2.9	3.5	0.08
Mean pad usage/24 h at 3 months	0.5	0.7	0.06
Mean pad usage/24 h now	1.3	2.0	0.1076
No of patients happy now	21/30–70%	31/61–51%	0.022
No of patients unhappy now	8/30–27%	25/61–41%	
No of patients offered AUS	6/30–20%	16/61–26%	
No of patients with AUS inserted (or awaited)	4/30–13%	10/61–16%	1.000
No current data	1/30	5/61	

Variables where $p < 0.05$ are shown in bold.

weights in our definition of success due to the fact that we did not have comprehensive data for all the patients in our series, although it is now being consistently collected.

In our study, initial success rates in patients with mild-moderate incontinence pre-operatively were better than those with severe incontinence (86–96 vs. 80%). It has previously been shown that pre-operative pad usage and incontinence severity were independent predictors of success at 3 years [9,15]. This is also reflected in a multivariate analysis of our data when looking at those deemed treatment successes or failures at 3 months. From a subjective patient point of view, 86% reported that they were happy with the outcome of their sling procedure; almost all these patients were on no pads or 1 security pad a day. Reporting of subjective patient-reported outcome measures is patchy in the literature. Bauer et al. used a patient-reported global improvement (PGI-I) scale, reporting a mean of 1.5 at 3 months while others have used the Incontinence Impact Questionnaire (IIQ) [8,16]; this makes comparison difficult.

Our results do however show that early success rates are not durable in the medium-long term. Data was recorded for 93% of our cohort. Success rates declined to 61% with a cured rate of 58%. Patient satisfaction also declines to 57%. This phenomenon has also been observed in some case series although there is minimal 5-year data available [10,17]. Comparing patients who had slings implanted in the last 5 years to those with slings in longer than 5 years, there were statistically significant differences in ICIQ-UI(SF) scores and patient satisfaction but this did not appear to translate to pad usage. As the ICIQ-UI(SF) does not differentiate between SUI or urge incontinence, we have to consider the possibility that a rising score could be secondary to incontinence caused by de novo OAB rather than recurrent SUI (or a combination of both). Despite this, there was no significant difference in AUS implantation rate. While one would expect a higher AUS implantation rate as pad efficacy deteriorates over time, in reality, these patients may not have actively sought re-referral for their incontinence.

In examining the risk factors for long-term success or failure, the only predictive factor was pre-operative ICIQ-UI(SF) score. The mean pre-operative ICIQ-UI(SF) score of those deemed a success at 5 years is 16, while the mean pre-operative score of the failure group is 18. We did not find any statistical significance of pre-operative SUI severity as a risk factor in the long-term but did in the short term, which may reflect the significance of patient expectation/bother which is accounted for in the ICIQ-UI(SF) score. This would therefore infer that patients who are less bothered by their SUI are happier with a successful result (which has been shown in other studies). We did not feel able to reach meaningful conclusions on a pad weight cut-off for male sling failure due to small numbers of complete data.

A quarter of patients undergoing AdVance™ male sling insertion are ultimately offered AUS insertion and the subsequent overall AUS implantation rate was 15%, doubling dependent on pre-operative SUI severity. Specifically, a third of patients with severe incontinence pre-operatively went on to have an AUS implanted. Conversely, two-thirds did not.

Patient expectations can have a role to play in any procedure aimed at improving quality of life; patients starting off with severe SUI may have felt satisfied with the outcome of their sling surgery although their outcome may not have fit our objective definition of success. All patients with a history of radiotherapy were unhappy with the results of their sling surgery and went on to have an AUS implanted; this is consistent with evidence that suggests poorer outcomes in irradiated patients [6].

There were no Clavien–Dindo IV and V complications in our cohort. Early complications included groin pain (3%), infection (3%) and urinary retention (10%) although the majority of these were self-limiting. One patient had to perform ISC long-term representing 1% of our patients. Our infection and retention rates fall within the range reported by a number of studies, while our groin pain incidence is lower [18]. There was a de novo OAB rate of 11%; this is higher than reported in other studies. For example, Bauer et al. [8] reported 2 out of 115 patients had de novo OAB, however only 40% of patients reached 3-year follow up. Transection of one of the sling arms has been described as a treatment of de novo OAB, although in our series, this was never performed and patients were managed medically.

There are several limitations to our study. It is a retrospective case series, although much of the data was collected and recorded prospectively. It would have been useful to assess pain scores using a validated questionnaire, particularly in view of recent controversies around mesh. Complete pad weight data would be helpful to form a robust definition of success and this information now being recorded prospectively. The results of the MASTER trial will help to establish how the male sling compares with the AUS but long-term efficacy will not be elucidated for some time. Our follow-up rate is high and therefore accurately reflects male sling outcomes in the medium-long term in a non-trial setting.

Conclusions

Male sling success rates deteriorate from 89% at 3 months to 61% at 5 years. 15% will eventually have an AUS inserted to manage their symptoms. The risk of complications is low and, for the most part, transient. Patients with higher pre-operative ICIQ-UI(SF) are more likely to become treatment failures. Sling insertion remains a reasonable treatment option for male patients suffering with SUI who may not want or be suitable for AUS insertion. The data we have presented can be used to accurately counsel patients and manage their expectations, allowing them to make a fully informed decision.

Previous presentation

This work was previously the subject of a poster presentation at the American Urological Association annual meeting 2020 and published in abstract form.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Author contributions

IGR, TK and MB conceived the study. IGR and MP collated the results. PR and RS analyzed the data. PR wrote the manuscript. All authors reviewed and amended the manuscript before submission.

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