Transobturator male sling: is there a learning curve?

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Introduction: *A potential learning curve associated with AdVance (American Medical Systems, Minnetonka, MN, USA) sling placement has not been adequately reported.*
Materials and methods: *Retrospective analysis of our AdVance single surgeon database. Patients with a history of a radical prostatectomy, no past radiation or prior incontinence interventions and at least 12 months of follow up were included. A learning curve was evaluated by predicting patient outcomes using their order within the surgical log. Univariate and multivariate logistic regressions were performed.*
Results: *Sixty patients with mean age of 65 years and an average 28.2 months of follow up were included in the analysis. Surgical order was not significant on either univariate or multivariate analysis for predicting outcomes following sling placement. Patients with a history of a retropubic radical prostatectomy did enjoy improved incontinence results at all time points tested. Other variables were mixed.*
Conclusion: *Our data failed to demonstrate a significant surgical learning curve that would predict outcomes following AdVance sling placement.*

Key Words: suburethral slings, learning curve, prostatectomy, urinary stress incontinence

Introduction

Post-prostatectomy incontinence complicates the recovery of many men following radical prostatectomy, with widely varying rates reported in the literature.[1-3] When persistent, stress urinary incontinence can have devastating effects on quality of life and is a common concern in men considering treatment for prostate cancer. Many treatments are available, including fluid restriction, penile clamp, catheter drainage, anticholinergics, pelvic floor physical therapy, periurethral bulking agents and various bulbourethral slings; artificial urinary sphincters (AUS) continue to represent the gold standard treatment to which all others are compared.[4,5]

The AdVance male sling was introduced in 2006 by Rehder and Gozzi as a surgical alternative to the AUS for men with stress incontinence.[6] Mid term results have been encouraging with "cure" rates ranging between 51% and 73%.[7-11] Overall success has been even higher, depending on the definition used. More recently, 3 year outcome data is emerging that suggests a durable improvement in incontinence, though we await results from more centers to confirm these results. Indeed, some already have suggested a time dependent decrease in efficacy.[12,13]

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There are few risk factors that have consistently shown to be associated with poor outcomes following placement of an AdVance sling. Most are intuitive physiologically and anatomically, including poor coaptation of the membranous urethra, length of the coaptation zone, absence of sling tunneling and not affixing the body of the sling properly to the bulbar urethra. History of a surgery for a bladder neck contracture and history of pelvic radiation therapy have also been suggested as negative prognostic factors.[10,14] Two publications thus far have commented on the potential for a learning curve associated with performing an AdVance sling placement, both concluding that a significant learning curve did not exist.[10,15] We have reviewed our data specifically to evaluate for a potential learning curve associated with sling placement.

Materials and methods

After local institutional review board approval, we performed a retrospective review of patients at our institution that underwent placement of an AdVance sling for stress urinary incontinence from August 2006 through June 2012. All slings performed at our institution, including our initial surgical experience, were represented in the database. Recorded data points included preoperative clinicopathologic characteristics, perioperative outcomes, pre and postoperative pad usage, complications, subsequent continence procedures and urodynamic studies. Preoperative patient evaluation was consistent with what we have previously reported, including documented stress urinary incontinence, a bladder with adequate capacity and compliance on urodynamic testing, and adequate sphincter contraction visualized cystoscopically.[16] A single surgeon performed all the surgeries using a standard technique for each patient.[17] Other than tunneling the sling arms, which we instituted quickly after introduction of this procedure there have not been any major technical changes over time. All patients were kept overnight in the hospital for observation and were given a voiding trial on postoperative day one. If they were found to have significant urinary retention (post-void residual > 200 mL), a Foley catheter was replaced and they were sent home with a leg bag. All patients were strictly instructed to limit their activity for 6 weeks postoperatively.

In order to evaluate for a potential learning curve associated with performing the sling procedure we selected a subgroup of patients from AdVance database for comparison. All patients had a history of a radical prostatectomy. Patients were excluded if they had a history of pelvic radiation therapy, prior incontinence procedures, or less that 12 months of postoperative follow up available for review. This data censoring did not remove any patient from those within our first 10 slings performed and only one patient was excluded within the first 20 procedures. The learning curve was assessed using a continuous variable based on the patient's place in the operative log. We defined success as a safety pad or less per day postoperatively (cured) or both a greater than 50% improvement in pad use and patient satisfaction with the surgical outcome (improved). Pad counts were assessed at each clinic visit prior to, and following, AdVance placement. All patients requiring reoperation for incontinence were considered failures.

Statistical analysis was performed using SPSS v. 20 software. All statistics are reported as mean ± standard deviation unless otherwise indicated and p values of < 0.05 were considered statistically significant.

Results

Two hundred and thirty three slings were placed in 214 patients at our institution during the 6 year period reviewed. Sixty patients met our inclusion criteria and had adequate data available for analysis. Their demographics and overall results are shown in Table 1. Average age at sling placement was 65 years. The majority (67%) were Caucasian, 56.7% had undergone a robotic prostatectomy and 16.7% had a history of

TABLE 1. **Demographics and results, n = 60 patients**

Age at AdVance (years)	65 ± 7
Body mass index (kg/m^2)	28.8 ± 3.5
Race (%)	
White	66.7
Black	26.7
Other	6.7
Diabetes mellitus (%)	78
Time RP to AdVance (years)	4.4 ± 4.0
History of BNC (%)	16.7
Follow up (months)	28.2 ± 13.1
Outcomes (%)	
12 month success	73.3
12 month cure	58.3
Overall success	63.3
Overall cure	43.3

RP = radical prostatectomy; BNC = bladder neck closure

TABLE 2. **Surgical order univariate logistic regression, n = 60 patients**

	Odds ratio	p value
12 month success	1.005	0.775
12 month cure	0.999	0.958
Overall success	1.004	0.805
Overall cure	1.018	0.256

a bladder neck contracture. The average time from prostatectomy to AdVance placement was 4.4 years. At 12 months postoperatively 58.3% of patients were cured and 15% were improved for an overall success rate of 77.3%. At a mean follow up of 28.2 months these numbers changed to 43.3%, 20% and 63.3%, respectively.

In order to test our hypothesis that there was no appreciable surgical learning curve associated with this procedure, we used patient order within the surgical log as a surrogate variable. On univariate analysis including all 60 patients, surgical order failed to predict outcomes following advance placement at either 12 months or final follow up, Table 2.

We then performed a multivariate logistic regression analysis, Table 3 evaluating outcomes in terms of success and cure at both 12 months and final follow up. Twenty patients were missing some demographic and preoperative data and therefore by definition necessitated exclusion from this portion of the analysis. On multivariate regression with the remaining 40 patients, surgical order failed to predict success or failure following AdVance placement. The only tested variable found to predict outcomes at each time point tested was the type of prostatectomy a patient had received. At both 12 months and overall, patients with a history of a robotic prostatectomy experienced worse outcomes following AdVance placement than those who had undergone an open retropubic approach (OR 0.029-0.178, $p < 0.05$ for all, Table 3). Looking specifically at the likelihood for a cure at 12 months, a higher preoperative peak flow and Valsalva leak point pressure (VLPP) predicted slightly improved outcomes. Detrusor overactivity negatively predicted overall success, but was not significant at other endpoints tested. No other variables were statistically significant at predicting surgical outcomes.

Perioperative complications were similar to what we and others have previously reported following AdVance placement. Five patients (8.3%) experience transient urinary retention requiring intermittent catheterization or indwelling Foley catheter placement postoperatively. This retention resolved in each within

TABLE 3. **Multivariate logistic regression, n = 40 patients**

	12 month success		12 month cure		Overall success		Overall cure	
	Odds ratio	p value	Odds ratio	p value	Odds ratio	p value	Odds ratio	p value
Surgical order	0.973	0.52	0.965	0.458	0.986	0.7	0.995	0.904
Follow up	--	--	--	--	1.018	0.713	0.969	0.556
Age at AdVance	0.851	0.118	0.846	0.118	0.946	0.627	0.895	0.39
Caucasian race	11.418	0.12	85.285	0.073	13.316	0.079	17.095	0.097
Body mass index	1.07	0.647	1.138	0.464	1.215	0.21	1.434	0.127
History of robotic prostatectomy	0.029	0.035	0.034	0.038	0.178	0.147	0.035	0.041
History of BNC	1.01	0.995	0.194	0.38	0.415	0.55	0.087	0.151
Preop pad count	1.851	0.104	1.27	0.463	1.868	0.054	1.671	0.218
Detrussor overactivity	0.193	0.387	23.252	0.146	0.014	0.038	0.026	0.15
Valsalva leak point pressure	1.047	0.135	1.098	0.048	1.04	0.144	1.07	0.103
PdetQmax	0.935	0.141	0.92	0.057	0.98	0.628	0.891	0.16
Peak flow	1.168	0.081	1.206	0.048	1.113	0.161	1.03	0.634
PVR	1.068	0.346	0.899	0.074	1.077	0.191	0.914	0.168

BNC = bladder neck contracture, PVR = post-void residual

the first month following surgery. Transient scrotal/perineal pain was reported by two patients (3.3%) and one (1.7%) complained of mild hip pain, likely secondary to positioning. A surgical site infection did develop in one patient (1.7%). We attempted to manage this conservatively with antibiotics, but he eventually underwent sling excision. No patient experienced any intraoperative complications and there were no postoperative mesh erosions identified.

Discussion

The surgical learning curve for physicians performing AUS placement has been suggested to be lengthy, with a gradual slope towards improved outcomes over time. Sandhu and colleagues evaluated surgeon data maintained by American Medical Systems, who manufactures the current AUS, to assess outcomes following its placement.[18] They analyzed data from 6868 surgeons placing an AUS in 40347 patients. Using reoperations within 5 years as a surrogate for success or failure, they found that even experienced surgeons continue to progress on their learning curve with improved outcomes up to and beyond 200 cases. Unfortunately, despite American Medical Systems also manufacturing the AdVance male sling, similar reporting data has not been collected on patients undergoing sling placement. Therefore, a similar analysis in this patient population is not likely to be possible.

Placement of an AUS requires intimate knowledge of the surgical components: the pressure-regulating balloon, urethral cuff, and the mechanical pump. Additionally, the procedure requires urethral sizing, selecting the appropriate size cuff and filling the balloon to an appropriate pressure. All these factors may contribute to a surgical learning curve. Conversely, an AdVance sling is not associated with as many "moving parts," and thus should theoretically shorten the learning curve.

Few publications have evaluated the learning curve associated with AdVance sling placement. Soljanik and associates reported on 178 of their patients and on univariate analysis found a significant improvement in outcomes from slings placed by more experienced surgeons (> 25 slings placed).[15] When controlling for other factors that were identified to affect sling outcome, however, surgeon experience was no longer predictive. Notably, more experienced surgeons were also assisting the less experience surgeons in the operating room, diminishing their ability to evaluate the surgical learning curve.

Cornu and colleagues also analyzed their outcomes from AdVance sling placement in an effort to clarify prognostic factors for success.[10] They used the patient's surgical order to predict outcomes. No significant association was found between the patient's rank in the potential learning curve and incontinence outcomes. The only factors they found to be negatively predictive were history of radiation, previous bladder neck contracture and more severe incontinence. While no learning curve was found, this series was a single surgeon experience and reportedly the procedure was performed in exactly the same fashion for each patient.

In this study we have reviewed data from our AdVance database specifically to determine the presence of a surgical learning curve associated with the procedure. Surgical case order was used as a marker for each patient's location on the potential learning curve. Analyzing surgical learning curves for anti-incontinence procedures using this statistical method has been previously reported.[10,18] On both univariate and multivariate analysis, we found that surgical order did not predict outcomes in terms of success or cure at any time point tested. These results would suggest that if present, a surgical learning curve in our data is likely small and contributes little to overall outcomes. We did find that patients with a history of a robotic prostatectomy did significantly worse compared to their open counterparts following sling placement. This is something that has never been reported before and the etiology of this finding is unclear.

At 12 months we did find that patients with preop urodynamics showing higher VLPP and peak flow rates had improved cure rates. Additionally there was a trend towards improved rates of cure with lower detrusor pressure at peak flow (OR 0.92, p = 0.057, Table 3). This combination of findings are intuitive and would suggest that those patients with unobstructed volitional voiding and a more substantial continence mechanism prior to surgery (higher VLPP) fair better at 12 months. However, odds ratio for 12 month cure with each of these variables was modest and none were significant at other endpoints tested, suggesting little impact on overall results following AdVance placement. This would be more consistent with previous reports, as preoperative urodynamics parameters have not been shown to significantly predict postoperative outcomes.[19]

There are several limitations to this study. It is retrospective in design and therefore is at risk for those inherent biases. It is a single surgeon experience, making it difficult to evaluate a large number of patients that received a sling during the theorized timeframe of a "learning curve." This is especially true given that the learning curve associated with AdVance placement is presumed to be relatively short

compared to other procedures, such as the AUS. Our surgical outcomes are based on patient reported pad use that was obtained in the surgeon's office, which may be associated with under, or over-reporting of pad counts depending on potential secondary gain. Patients may under-report in an effort to appease the surgeon, or over-report if they are simply unhappy with their outcome or surgical experience. Finally, an experienced reconstructive surgeon performed all the procedures. This may have shortened the learning curve compared to with what would be expected from other urologists performing the same procedure. Limitations notwithstanding, we are consistent with other reports in that our data does not support the presence of a substantial learning curve with AdVance placement.

Conclusions

Based on this analysis of our AdVance database a potential surgical learning curve was not found to be predictive of incontinence outcomes following AdVance placement. A multi-institutional, multi-surgeon analysis would allow a larger group of patients on the learning curve to be evaluated and would have more statistical power to identify the duration of the presumed short learning curve associated with this procedure. This is an area of needed future research.

Disclosure

Kurt McCammon, MD - Consultant and proctor American Medical Systems. □

References

1. Penson DF, McLerran D, Feng Z et al. 5-year urinary and sexual outcomes after radical prostatectomy: results from the prostate cancer outcomes study. *J Urol* 2005;173(5):1701-1705.
2. McCammon KA, Kolm P, Main B, Schellhammer PF. Comparative quality-of-life analysis after radical prostatectomy or external beam radiation for localized prostate cancer. *Urology* 1999;54(3):509-516.
3. Kao TC, Cruess DF, Garner D et al. Multicenter patient self-reporting questionnaire on impotence, incontinence and stricture after radical prostatectomy. *J Urol* 2000;163(3):858-864.
4. Petrou SP. Treatment of postprostatectomy incontinence: is the bulbourethral sling a viable alternative to the artificial urinary sphincter? *Curr Urol Rep* 2002;3(5):360-364.
5. Litwiller SE, Kim KB, Fone PD, White RW, Stone AR. Post-prostatectomy incontinence and the artificial urinary sphincter: a long-term study of patient satisfaction and criteria for success. *J Urol* 1996;156(6):1975-1980.
6. Rehder P, Gozzi C. Transobturator sling suspension for male urinary incontinence including post-radical prostatectomy. *Eur Urol* 2007;52(3):860-866.
7. Bauer RM, Mayer ME, Gratzke C et al. Prospective evaluation of the functional sling suspension for male postprostatectomy stress urinary incontinence: results after 1 year. *Eur Urol* 2009;56(6):928-933.
8. Rehder P, Mitterberger MJ, Pichler R, Kerschbaumer A, Glodny B. The 1 year outcome of the transobturator retroluminal repositioning sling in the treatment of male stress urinary incontinence. *BJU Int* 2010;106(11):1668-1672.
9. Bauer RM, Soljanik I, Fullhase C et al. Mid-term results for the retroluminar transobturator sling suspension for stress urinary incontinence after prostatectomy. *BJU Int* 2011;108(1):94-98.
10. Cornu JN, Sebe P, Ciofu C et al. Mid-term evaluation of the transobturator male sling for post-prostatectomy incontinence: focus on prognostic factors. *BJU Int* 2011;108(2):236-240.
11. Rehder P, Haab F, Cornu JN, Gozzi C, Bauer RM. Treatment of postprostatectomy male urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3-year follow-up. *Eur Urol* 2012:62(1):140-145.
12. Suskind AM, Bernstein B, Murphy-Setzko M. Patient-perceived outcomes of the AdVance sling up to 40 months post procedure. *Neurourol Urodyn* 2011;30(7):1267-1270.
13. Li H, Gill BC, Nowacki AS et al. Therapeutic durability of the male transobturator sling: midterm patient reported outcomes. *J Urol* 2012;187(4):1331-1335.
14. Zuckerman JM, Tisdale B, McCammon K. AdVance male sling in irradiated patients with stress urinary incontinence. *Can J Urol* 2011;18(6):6013-6017.
15. Soljanik I, Gozzi C, Becker AJ, Stief CG, Bauer RM. Risk factors of treatment failure after retrourethral transobturator male sling. *World J Urol* 2012;30(2):201-206.
16. Davies TO, Bepple JL, McCammon KA. Urodynamic changes and initial results of the AdVance male sling. *Urology* 2009;74(2):354-357.
17. McCammon KA, Haab F. AdVance male sling: surgical technique and postoperative patient management. *Eur Urol* 2011;10(4):395-400.
18. Sandhu JS, Maschino AC, Vickers AJ. The surgical learning curve for artificial urinary sphincter procedures compared to typical surgeon experience. *Eur Urol* 2011;60(6):1285-1290.
19. Soljanik I, Becker AJ, Stief CG, Gozzi C, Bauer RM. Urodynamic parameters after retrourethral transobturator male sling and their influence on outcome. *Urology* 2011;78(3):708-712.