AdVance male sling in irradiated patients with stress urinary incontinence

Jack M. Zuckerman, MD, Britton Tisdale, MD, Kurt McCammon, MD
Department of Urology, Eastern Virginia Medical School, Norfolk, Virginia, USA

ZUCKERMAN JM, TISDALE B, MCCAMMON K. AdVance male sling in irradiated patients with stress urinary incontinence. The Canadian Journal of Urology. 2011;18(6):6013-6017.

Introduction: *Evaluate the complication rate and efficacy of the AdVance sling (American Medical Systems, Minnetonka, MN, USA) in patients with stress urinary incontinence (SUI) and a history of pelvic radiation.*
Materials and methods: *A retrospective chart review of all men at our institution with a history of prostate cancer and subsequent radiation therapy treated with an AdVance sling for SUI.*
Results: *Between 2007 and 2009 an AdVance sling was performed in 27 patients with prior pelvic radiation therapy. The mean patient age was 73.2 years. At an average follow up of 15.8 months 19 patients (70%) were claiming benefit from the operation. Average pre and postoperative pad use per day was 4.2 and 1.1, respectively. One patient had worsening symptoms, and two had no change. Intraoperative complications occurred in two patients (7.4%), both of which were urethral injuries during needle passage and both were repaired primarily and the procedure completed. Early complications included a urinary tract infection in one and urinary retention requiring intermittent catheterization in another. Two late complications occurred, including continued retention in the previously mentioned patient and hematuria (negative cystoscopy) in one of the patients with an intraoperative urethral injury. There were no mesh erosions or infections. Nine patients (38%) had some decreased efficacy over time and four patients underwent subsequent incontinence procedures.*
Conclusions: *The AdVance male sling can be safely and effectively performed in men who have had previous radiation therapy. Our results are encouraging but long term follow up is needed especially in light of the decrease efficacy in 38% of our patients.*

Key Words: urinary stress incontinence, suburethral slings, radiation, brachytherapy, prostatectomy

Introduction

Post-prostatectomy incontinence (PPI) complicates the recovery of many men following radical prostatectomy (RP), with widely variable rates reported in the literature.[1-3] When persistent, stress urinary incontinence (SUI) can have devastating effects on quality of life (QoL) 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, initially introduced by Rehder and Gozzi, is increasingly accepted as an effective, well-tolerated, minimally invasive treatment option with encouraging results for men with SUI.[6-10] Short and mid term complications are exceedingly rare.[11] Its use in men with PPI who have undergone adjuvant or salvage radiation therapy has been sparsely reported and efficacy has been mixed.[8,12] The expected complications in this patient population are largely unknown. Here we present the outcomes of our patients who underwent placement of an AdVance sling following pelvic radiation.

Accepted for publication September 2011

Address correspondence to Dr. Kurt McCammon, Department of Urology, Eastern Virginia Medical School, 6333 Center Drive, Norfolk, VA 23502 USA

Materials and methods

This is a retrospective review of all men at our institution with a history of prostate cancer and subsequent radiation therapy that were also treated with an AdVance sling for stress urinary incontinence. The list of men included in the study was generated from our patient-billing database, which was queried for those patients who underwent placement of an AdVance sling. The results were then refined to include only those men with a history of pelvic radiation (external beam [EBRT] or brachytherapy) prior to sling placement. Local institutional review board approval was obtained prior to chart review.

Recorded data points included preoperative clinicopathologic characteristics, perioperative outcomes, pre and postoperative pad usage, complications, subsequent continent 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.[7] Postoperative recovery was similar for all patients and all were discharged from the hospital within 24 hours. Patients were instructed to abstain from heavy lifting, strenuous exercise and leg abduction for at least 6 weeks. Patient follow up was standardized, including a 3-4 week postoperative visit, 3, 6, and 12 month office visits and then annual follow up. Patients doing well often chose to return to the care of their primary urologist.

We defined success as 0-1 pads per day postoperatively (cured) or both a greater than 50% improvement in pad use and patient satisfaction with the surgical outcome (improved). For patients only requiring one pad per day preoperatively, we defined success more stringently as either no pads or a dry "safety pad" postoperatively. Pad counts were assessed at each clinic visit both prior to, and following AdVance placement. These numbers were acquired during the patient interview conducted by the primary surgeon at these visits. Pre and postoperative pad counts were compared using a paired, two-tailed t-test. All statistics are reported as mean ± standard deviation unless otherwise indicated and p values of < 0.05 were considered statistically significant.

Results

From February 2007 through July 2009 a single reconstructive urologist at our institution performed an AdVance sling in 27 patients with prior radiation therapy for prostate cancer, Table 1. Twenty-three patients had received external beam radiation, two had radioactive seed placement (i.e. brachytherapy) combined with EBRT and two had brachytherapy alone. All patients had documented SUI and in 21 patients (78%) this was caused by radical prostatectomy: 14 after radical retropubic prostatectomy (RRP), five after da Vinci robotic prostatectomy (DVP) and in two patients the type of prostatectomy was unknown. Among these 21 patients with PPI, the AdVance sling was placed an average (standard deviation) of 9.3 ± 6.9 years following RP. In the remaining cohort, the onset of SUI followed radiation in four (3 EBRT, 1 brachytherapy), transurethral resection of the prostate (TURP) in one and laser photovaporization of the prostate (PVP) in the last patient. Two patients had previous artificial urinary sphincters, one of which was explanted for erosion prior to the AdVance sling. All patients failed conservative management.

TABLE 1. **Patient characteristics**

Patient characteristics (n = 27)	**Mean ± SD**
Age	72.6 ± 9.4
Body mass index	27.7 ± 3.3
SUI etiology	
Post-prostatectomy	21
Radiation	4
TURP	1
Laser PVP	1
Radiation type	
EBRT	23
EBRT + brachytherapy	2
Brachytherapy alone	2
XRT to AdVance, yrs	8.0 ± 6.5
RP to AdVance, yrs	9.3 ± 6.9

Patients underwent sling placement an average 8 ± 6.5 years following their radiation therapy. Mean patient age at the time of AdVance placement was 72.6 ± 9.4 years and the cohort had a mean body mass index (BMI) of 27.7 ± 3.3 kg/m^2. At initial postop follow up 24 patients (89%) were claiming benefit from the procedure and mean pre and early postoperative pad counts were 4.2 ± 2.2 and 1.1 ± 1.6, respectively ($p = 7.5^{-7}$, Table 2). One patient had worse symptoms and two had no change following sling placement. Of those with initial success, nine patients (38%) did experience a decline in sling efficacy in terms of urinary control over time, which happened at an average 14.6 months. Only two (7.4%) of those

TABLE 2. **Results**

Results (n = 27)	**Mean ± SD**	**p value**
Follow up	15.8 ± 12.6	
Success		
Early postop	24 (89%)	
Final follow up	19 (70%)	
Decreased efficacy	9 (38%)	
Pad count		
Preop	4.2 ± 2.2	
Early postop	1.1 ± 1.6	0.00005
Final follow up	1.8 ± 2.0	0.0000007

patients had a notable event that may have caused the decrease in efficacy. This mid term decrease in continence led to a 2.1 ± 1.5 pads per day increase compared to nadir postop pad use in these patients (p = 0.01). Despite this, 5 of these 9 patients (56%) were still satisfied with the outcome and continued to have greater than a 50% decrease from their preoperative pad use.

Our mean follow up for this cohort was 15.8 months (range 0.6-42.6 months) and median follow up was 13.4 months. At final follow up, 19 patients (70%) continued to have a successful outcome from AdVance placement; 13 (48%) of these patients were considered "cured" and 6 (22%) "improved". Mean pad use per day at this time was 1.8 ± 2.0, accounting for those patients with a decline in efficacy over time. Compared to the preoperative numbers, however, patients did continue to demonstrate a statistically significant reduction in pads used per day through the final follow up (p = 0.00005). Looking specifically at the 18 patients with at least 3 months of follow up, we found the average pad counts to be slightly higher than entire cohort at 1.9 ± 2.1 pads per day. This is not entirely surprising given the slight decrease in efficacy that we have demonstrated during our follow up period.

Intraoperative complications occurred in two patients (7.4%), both of which were urethral injuries during needle passage and both were repaired primarily and the procedure completed. These injuries were both located lateral on the urethra and were not in direct contact with mesh, therefore we felt it safe to continue the procedure. There were two (7.4%) early complications, including a urinary tract infection (successfully treated) in one and urinary retention requiring clean intermittent catheterization (CIC) in another. Two late complications occurred (7.4%), including continued retention requiring catheterization in the previously mentioned patient and gross hematuria (negative cystoscopy) in one of the patients with an intraoperative urethral injury. The patient with persistent urinary retention was an elderly man with multiple medical problems and we determined it prudent to continue intermittent catheterization rather than undergo further interventions. He was considered a "failure" in the both the early and final follow up periods. We did not encounter any mesh erosions or infections. Four patients underwent subsequent incontinence procedures (AUS in 3 and redo AdVance in 1). The patient with worse incontinence after his AdVance placement eventually had an explant and subsequent botulinum toxin bladder injections for urge symptoms.

Discussion

Radical prostatectomy continues to represent a common treatment for clinically localized prostate cancer, especially in younger patients. Unfortunately, a significant portion of these patients will struggle with post-prostatectomy incontinence.[2,3,13] For decades the artificial urinary sphincter has been the gold standard treatment for SUI with success rates reported to be 60%-90% and high rates of patient satisfaction.[4,5] In 2007 Rehder and Gozzi proposed a minimally invasive incontinence procedure utilizing a transobturator retrourethral sling. Subsequently, numerous reports have been published documenting the efficacy and safety of the AdVance male sling for stress urinary incontinence with success rates approaching those seen following AUS placement.[6-11] Additionally, it is now becoming clear that despite high rates of satisfaction with an AUS, if given a choice patients will more often choose a sling procedure. This phenomenon seems to be primarily related to concerns with the manual dexterity required to operate the AUS and the perceived invasiveness of the operation relative to the sling.[14]

Placement of AdVance slings in patients with a history or pelvic radiation has been sparsely reported in the literature. In 2009 Cornu et al reported their results placing AdVance slings with a mean follow up of 13.4 months.[8] Seventeen of these patients had previous external beam radiation for prostate cancer. In this cohort they reported a 59% success rate (9 cured, 1 improved) and failure (no change in pad use) in 41% of patients at final follow up. This was a statistically significant difference from the 85% success rate in patients without a history of radiation. No increased rate of complications in the radiated patients was reported.

Soljanik et al reported their prospective results in 35 patients undergoing a repeat AdVance placement after failing an initial retrourethral sling.[12] They report high

rates of success with the second procedure without increased complications. Among the 35 patients treated were 7 with a history of adjuvant radiation for prostate cancer. Although small numbers, univariate analysis did not show any difference in outcomes in radiated patients compared to those without a history of pelvic radiation. Success rates of around 80% were achieved in both patient groups.

Most recently, Bauer et al published their results placing an AdVance sling in 24 patients with PPI who had also undergone adjuvant radiation therapy.[15] At a mean follow up of 18.8 months they report a 50% success rate (25% cured, 25% improved, 50% failure). Mean 1 hour pad weights improved from 84.4 grams to 47.0 grams ($p = < 0.001$) and there was a significant improvement in QOL using validated self-report patient questionnaires. They did not experience any wound infections or erosions over the follow up period.

Here we present the outcomes of our patients who underwent placement of an AdVance sling for SUI following pelvic radiation. To our knowledge, this represents the largest cohort in this patient population. Many urologists are uncomfortable placing retrourethral slings in irradiated patients secondary to concerns with intra and postoperative complications. To be fair, urethral erosion following AdVance placement in an irradiated patient has been reported.[16] In this retrospective series, our complication rate compares with what has been previously reported in non-radiated patient and no patients experienced serious postoperative infections or mesh erosions.[11]

There were two (7.4%) urethral injuries intraoperatively, but both were recognized and repaired at the time of injury and neither caused long term morbidity. Similar urethral injuries have been previously reported, also during trocar passage.[9,12] The placement of an AdVance sling is essentially the same in both irradiated and non-radiated patients as has been previously published.[17] Although the technique is similar there are a few differences noted. The radiation does not cause any significant scarring in the perineum but the bulbospongiosal muscle is usually thinner which if not known could lead to a corpus spongiosum injury. There is also significantly more scarring in the obturator fossa, which makes needle passage more difficult likely leading to our two urethral injuries.

There are many limitations to this study. First, this is a retrospective review and is therefore subject to those inherent biases. We do not routinely use standardized metrics (i.e. questionnaires) in our practice to assess patient satisfaction and therefore this was not included in our analysis. Additionally, we use subjective, patient reported, pads counts to track efficacy postoperatively. This is obviously less accurate than 1 hour or 24 hour pad weights. That being said, we have found subjective pad counts to be a useful tool to track patients over time as they can be a marker of individual improvement, or lack thereof. Finally, all of our patient data was derived from office follow up and primarily from patient interviews with the primary surgeon. This does introduce a positive reporting bias in that some patients may have not felt comfortable giving true estimates of their relative success or failure.

Though seemingly safe to perform, the efficacy of AdVance slings in irradiated patients has been questioned.8 In our series we report a 70% success rate at an average 15.8 months follow up. This is lower than reports of AdVance slings in non-irradiated patients, including what we have previously reported.[7-9] That being said, a 70% success rate may be acceptable to many of these patients, especially when morbidity can be expected to be consistently low despite a history of radiation. We also report that 38% of our patients had a decline in efficacy an average 14.6 months after AdVance placement, which is concerning and a phenomenon that has not been seen to such an extent in non-irradiated patients. Over half of those patients were still considered a "success", but it is unknown if that decreased efficacy will continue to decline over time. Longer term studies evaluating slings in this patient population will help to further characterize outcomes.

Conclusion

The AdVance male sling can be safely and effectively performed in men who have had previous radiation therapy. Postoperative complications rates are comparable to men without a history of radiation, though the rate of operative urethral injuries is higher than what has been seen in non-irradiated patients. Our initial results are encouraging but long term follow up is needed especially in light of the decreased efficacy in some of our patients.

Disclosure

Dr. Kurt McCammon is a consultant and proctor for 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. Davies TO, Bepple JL, McCammon KA. Urodynamic changes and initial results of the AdVance male sling. *Urology* 2009;74(2): 354-357.
8. Cornu JN, Sebe P, Ciofu C et al. The AdVance transobturator male sling for postprostatectomy incontinence: clinical results of a prospective evaluation after a minimum follow-up of 6 months. *Eur Urol* 2009;56(6):923-927.
9. 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.
10. Gill BC, Swartz MA, Klein JB et al. Patient perceived effectiveness of a new male sling as treatment for post-prostatectomy incontinence. *J Urol* 2010;183(1):247-252.
11. Bauer RM, Mayer ME, May F et al. Complications of the AdVance transobturator male sling in the treatment of male stress urinary incontinence. *Urology* 2010;75(6):1494-1498.
12. Soljanik I, Becker AJ, Stief CG, Gozzi C, Bauer RM. Repeat retrourethral transobturator sling in the management of recurrent postprostatectomy stress urinary incontinence after failed first male sling. *Eur Urol* 2010;58(5):767-772.
13. Bauer RM, Bastian PJ, Gozzi C, Stief CG. Postprostatectomy incontinence: all about diagnosis and management. *Eur Urol* 2009; 55(2):322-333.
14. Kumar A, Litt ER, Ballert KN, Nitti VW. Artificial urinary sphincter versus male sling for post-prostatectomy incontinence--what do patients choose? *J Urol* 2009;181(3):1231-1235.
15. Bauer RM, Soljanik I, Fullhase C et al. Results of the AdVance transobturator male sling after radical prostatectomy and adjuvant radiotherapy. *Urology* 2011;77(2):474-479.
16. Harris SE, Guralnick ML, O'Connor RC. Urethral erosion of transobturator male sling. *Urology* 2009;73(2):443 e419-420.
17. McCammon KA, Haab F. AdVance male sling: surgical technique and postoperative patient management. *Eur Urol* 2011; 10(4):395-400.