Transobturator sling for post-prostatectomy incontinence: radiation's effect on efficacy/satisfaction

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Introduction: *We review our experience with the AdVance sling in patients with post- prostatectomy incontinence, comparing the role that adjuvant radiation therapy plays in sling success and patient satisfaction at short and long term follow ups.*

Materials and methods: *Men who underwent AdVance sling placement for post-prostatectomy incontinence from 2007 to present were identified using Current Procedural Terminology (CPT) codes. Manual chart review was performed. Level of incontinence was assessed using Expanded Prostate Cancer Index Composite (EPIC) and pads per day (PPD) use. Satisfaction was assessed by willingness to recommend the procedure to a friend. Outcomes in men who received radiation were compared to radiation-naïve men.*

Results: *Fifty-two men underwent AdVance sling placement. Eighteen men received adjuvant radiation. Thirty-six men were available for short term (19.4 months) and 16 men for long term (61.5 months) follow up. Overall, significant improvement was seen in post-sling EPIC score (24.6, $p < 0.001$), EPIC incontinence score (39.1, $p < .001$), and pad use (3.2 PPD to 1.4 PPD, $p < .001$). Greater improvement in EPIC scores and PPD use was seen in radiation-free men. Irradiated men were less satisfied with the procedure at both short and long term follow up. Diminished efficacy and satisfaction occurred at extended follow up for both groups but was more pronounced with radiation.*

Conclusions: *The majority of patients undergoing the AdVance sling procedure for post-prostatectomy urinary incontinence saw a significant reduction in pad use, and were overall satisfied in both radiated and non-radiated groups at short and long term follow up. However, improvements were greater in the non-radiated groups and diminished with time.*

Key Words: patient satisfaction, transobturator sling, urinary incontinence, radiation, post-prostatectomy incontinence

Introduction

Prostate cancer is a growing issue, comprising 15% of all new cancer in males and 8% of all new cancers overall, with almost 3 million men living with the disease in the United States alone.[1] With the high number of prostate cancer diagnosed annually, a growing number of interventions are being offered in an effort to battle the disease. Most commonly, the non-surveillance interventions are comprised of radical prostatectomy, radiation therapy, or a combination of the two modalities.

While the mortality rates following prostate cancer intervention have continued to decline, sustained morbidity rates persist following the cancer treatment.[2] Most notably, erectile dysfunction and stress urinary incontinence (SUI) remain common following both

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prostatectomy and radiation therapy (XRT). Post-prostatectomy SUI has been reported to approach 84%[3] with 6%-9% of patients seeking treatment for their SUI symptoms.[4]

While conservative treatments for SUI range from lifestyle interventions, pelvic floor muscle training, biofeedback, and bladder training, those interventions are generally most effective within the first year following surgery.[5] For more severe cases of SUI, and incontinence refractory to conservative management, treatment options include artificial urinary sphincter, urethral bulking, adjustable balloons, and male slings. The various sling options include bone- anchored, readjustable and retrourethral transobturator systems.[6] Although the sling systems have demonstrated substantial improvement in continence rates, risk factors for failure, notably prior XRT, remain a relative contraindication.[7,8]

However, limited data currently exists on the efficacy of the AdVance sling (Boston Scientific, Marlborough, MA, USA) in the treatment of post-prostatectomy in patients with a history of radiation, with only limited follow up available. With the concern of diminishing sling efficacy with time, especially in patients with radiation, we conducted a study that compares the objective and subjective outcomes of sling placement in irradiated and radiation-naïve patients at both short and long term follow up.

Materials and methods

Following IRB approval, we performed a retrospective cohort study of patients undergoing AdVance sling placement for post-prostatectomy incontinence from 2007 to the present. Patients undergoing the procedure were noted in a prospectively maintained database. Confirmation that target patients were not omitted was performed using the Current Procedural Terminology (CPT) code 53440 and 53442.

Inclusion criteria consisted of all men receiving and failing prior conservative treatment in the form of pelvic floor exercises and behavioral modification as well as a recorded positive pad test. Urodynamic testing was not performed. Exclusion criteria included incomplete records.

All patients underwent preoperative cystoscopy with confirmation of normal bladder capacity and evaluation of external urethral sphincter (EUS) function. Patients who underwent post-prostatectomy radiation had their treatment before sling placement. Patient charts were manually reviewed for pre and postoperative pads per day (PPD) use, complications, comorbidities and history of XRT.

Preoperative incontinence was assessed in clinic using the EPIC questionnaire and PPD use. Following the sling placement, short term follow up was evaluated using a chart review. Objective outcomes include quantifying PPD use. Subjective outcomes include the EPIC questionnaire. These were conducted during postoperative clinic visits at a minimum of 2 months and up to 52 months where clinic follow up was available. Long term follow up was performed via a phone interview conducted by a urology resident at a minimum of 33 months and up to 92 months following sling placement. Long term follow up questions included "Would you recommend this procedure to a friend?" and "How many pads per day are you currently using?" No long term follow up EPIC scores were available.

Statistical analysis was performed with STATA (version 12.1 StataCorp LP TX, USA) using Student's t-test with significance defined as $p < 0.05$. Data was summarized using means and standard deviations for continuous variables and frequencies and percentages for categorical variables.

TABLE 1. **Demographic data of patients with and without history of pelvic radiation**

	XRT (n = 14)	**No XRT (n = 22)**
Average age	69.8	69.0
Age range	55-81	54-86
Race		
Caucasian	9	21
African American	6	5
Unknown	1	6
Smoker		
Former	10	7
Current	1	1
Never	5	22
Comorbidities		
None	2	2
CAD	2	3
HTN	11	18
Other cancer	2	3
Diabetes	5	3
Parkinson's	2	
Sexually active		
Yes	11	25
No	5	8

XRT = radiation therapy; CAD = coronary artery disease; HTN = hypertension

Results

A total of 52 men underwent AdVance sling placement for post-prostatectomy incontinence at our institution from 2007 to present, 16 (31%) men received adjuvant XRT. Thirty-six men (14 with history of and 22 without history of radiation) were available for short term follow up. Sixteen men (6 with history of and 10 without history of radiation) were available for a long term postoperative phone interview. Mean short term follow up was 19.4 months (range 2-52 months) and long term follow up was 61.5 months (33-92 months).

In the cohort receiving prior radiation, 2 patients had undergone prior surgery for bladder neck contracture. The average time to sling-placement following prostatectomy was 91.9 months. Smoking history was preset in 64.3% of this cohort, Table 1.

In the radiation-naïve cohort, 3 patients had undergone prior surgery for bladder neck contracture. The average time to sling-placement following prostatectomy was 81.8 months. Only 13.6% on this cohort had a positive smoking history.

Subjective outcomes

The improvement in overall EPIC score in the non-irradiated group was 30.5 in comparison to 15.4 in the irradiated group ($p < 0.05$). In addition, while the preoperative EPIC incontinence score was similar between the non-irradiated and irradiated groups (14.1 and 15.1, respectively), the postoperative EPIC incontinence scores were better in the non-irradiated (63.7) versus irradiated (37.8) groups. This resulted in a statistically significant difference in overall EPIC incontinence score between the non-irradiated (49.6) and irradiated (22.2) groups ($p < 0.05$). There was also a large discrepancy observed in both short and long term patient satisfaction. In the group receiving radiation 64% reported short term satisfaction and 33% reported long term satisfaction. Conversely, the radiation-free group reported 95% short term and 80% long term satisfaction rates, Table 2.

Objective outcomes

Improvement in short term PPD use was 2.3 versus 1.1 in the non-irradiated versus irradiated groups, respectively ($p < 0.01$). Long term PPD use was 1.55 versus 0.8 in the radiated versus non-radiated groups, respectively. However, long term PPD improvement was not statistically significant ($p = 0.9$).

Few adverse events were observed: 5 patients experienced postoperative urinary retention in the non-radiation group; only 1 patient experienced prolonged retention. Perineal pain occurred in 5 patients (1 radiated, 4 non-radiated) and mesh extrusion (resolved with outpatient mesh trimming) was observed in 2 patients in the non-radiated group.

Discussion

Initially clinically described in 2007,[9] the Advance retrourethral sling has become an important tool in the treatment of post-prostatectomy incontinence. The AdVance sling system, using a transobturator outside-in approach, improves continence through the postulated mechanism of cranial urethral displacement without respective urodynamic obstruction.[10]

TABLE 2. **Short and long term effects of radiation on sling efficacy and patient satisfaction**

	Radiation (n = 14)	**Non-radiation (n = 22)**	**p value**
Short term improvement in PPD	1.1 (3 to 1.9)	2.3 (3.3 to 1)	< 0.001
Improvement in overall EPIC	15.4	30.5	< 0.05
Preop EPIC incontinence	15.1	14.1	
Postop EPIC incontinence	37.8	63.7	
Improvement in EPIC incontinence	22.2	49.6	< 0.05
Patient satisfaction	64%	95%	< 0.05
	Radiation (n = 6)	**Non-radiation (n = 10)**	
Long term improvement in PPD	0.8 (3 to 2.2)	1.55 (3.3 to 1.75)	0.09
Patient satisfaction	33%	80%	0.06

PPD = pads per day; EPIC = Expanded Prostate Cancer Index Composite

The efficacy of the AdVance sling varies greatly in reported efficacy, with "cure" rates reported in 9%-74%.[11-13] Most of the variability in outcomes is due to the differences among the cohorts. Several studies, by including patients with prior radiation (Cornu et al with 17%[14] and Rehder et al with 3%[15]) have demonstrated that history of radiation was a risk factor for failure via secondary analysis. And although a study by Zuckerman et al of 27 patients with prior history of radiation therapy undergoing AdVance sling placement revealed good initial success rates with diminishing efficacy over time,[16] comparisons of irradiated versus non-irradiated patients by Torrey et al revealed significantly poorer outcomes in irradiated patients.[17] Similarly, Bauer et al reported a 50% efficacy rate and 46% satisfaction rate following AdVance sling placement in patients with adjuvant XRT.[18]

But with assigning risk factors for failure in quality of life intervention, the inevitable question becomes how, exactly, do we measure success and failure. Generally speaking, the efficacy of an incontinence procedure is measured by the degree of dryness. That degree, objectively assessed by pad weight or self-reported PPD use, has been the preferred metric in the majority of major AdVance studies to date.[11,12,18-22] The recent emphasis on patient satisfaction has prompted inquiries into patient satisfaction via perceived improvement and satisfaction scores.[23]

A 2014 study by Sturm et al of "ideal" versus "nonideal" AdVance sling candidates took this concept one step further, posing the question of whether a patient would undergo the procedure again, thereby shifting the idea of success from the objective to the subjective realm.[24] This study grouped degree of incontinence, volitional external sphincter control, history of radiation and cryotherapy, the history of prior anti-incontinence procedures, volitional detrusor control, and post-void residual (PVR) volumes in the segregation of patients into the two cohorts. Only 2 patients had a prior history of radiation; the risk factors were not independently isolated.

Therefore, little is truly known about the difference in both objective and subjective outcomes between irradiated and non-irradiated patients following sling placement. Furthermore, despite the concern that the efficacy of the transobturator sling decreases with time, limited long term follow up data exists. Our review of the literature revealed that at 61.5 months, our follow up appears to be the longest available. The longest previously reported follow up for a cohort receiving a transobturator sling for a history of incontinence associated with prior prostatectomy and pelvic radiation was 40.1 months (range 13-40.1 months), Table 3. The number of patients with a history of radiation was likewise generally limited. Overall, the larger cohorts demonstrated improvement in half of the patients with a history of radiation in whom a slings was placed. More importantly, despite the growing interest in patient-centered outcomes, patient satisfaction has generally been overlooked as a vital outcomes measure.

Objective outcomes in our patient population demonstrate that the majority of patients undergoing the AdVance sling procedure for post-prostatectomy urinary incontinence saw a statistically significant reduction in short term PPD use. While there was not a statistically significant difference in long term PPD use, there was

TABLE 3. **Previously reported sling efficacy and patient satisfaction in patients with and without history of pelvic radiation**

Study	# of patients	# with h/o radiation	Mean follow up (mos)	% irradiated improvement/ would recommend to a friend	% irradiated no improvement/ would not recommend to a friend
Cornu et al[21]	102	17	13	59	41
Zuckerman et al[16]	27	27	15.8	70	30
Cornu et al[14]	136	23	21	-	-
Bauer et al[18]	24	24	18	50	50
Berger et al[25]	26	5	22	60	40
Rehder et al[15]	156	22	40.1	54.6	45.4
Soljanik et al[26]	189	27	20.8	59.3	40.7
Serra et al[27]	61	3	26	-	-
Torrey et al[17]	37	7	17.3	28.6	71.4
Sturm et al[24]	95	2	28	0	100

an overall trend toward improvement. Patients without a history of pelvic XRT had a greater improvement in both short and long term PPD use – a finding consistent with results from prior studies, Table 3.

Subjective outcomes in our patient population demonstrate that while both groups had similar preoperative EPIC incontinence scores, and likely similar baseline incontinence, a greater degree postoperative improvement was observed in the non-irradiated group. Additionally, and perhaps most importantly, non-irradiated patients were more likely to recommend the procedure to a friend. These findings bring attention to the concern that both sling efficacy and patient satisfaction in irradiated patients diminishes to a greater degree in both short and long term follow up. However, despite this, the AdVance male sling should still be considered an effective and durable method of treating post-prostatectomy incontinence.

The limitations of this study include its retrospective design and the fact that long term follow up is limited in the response rate: only16 of 36 patients were available for long term follow up interview. We did not use a validated questionnaire to assess the patients' quality of life. Finally, none of our patients underwent pre or post-intervention urodynamics, so we cannot confidently conclude whether or not our patients had pure stress urinary incontinence or had a component of urge incontinence.

The strengths of this study include its design as a retrospective cohort study with prospective follow up, the large size of the cohort, its use of validated surveys as outcome measures (EPIC), the prospective follow up and the longest length of follow up reported in the current literature.

Conclusion

The AdVance transobturator sling appears to be a safe and effective short and long term method of treating post-prostatectomy incontinence in patients without a history of pelvic radiation. However, while the treatment appears effective in treating post-prostatectomy incontinence in irradiated patients in short term follow up, follow up at 5 years reveals a decreased efficacy and patient satisfaction. These factors should to be considered in selecting the population that would most greatly benefit from transobturator sling placement in post-prostatectomy incontinence. □

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