Original Article

Radiotherapy is associated with reduced continence outcomes following implantation of the artificial urinary sphincter in men with post-radical prostatectomy incontinence

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Abstract

Objectives: The objective of this study is to present the outcomes of men undergoing implantation of artificial urinary sphincter, after treatment for prostate cancer and also to determine the effect of radiotherapy on continence outcomes after artificial urinary sphincter (AUS) implantation.

Materials and Methods: A prospectively acquired database of all 184 patients having AUS insertion between 2002 and 2012 was reviewed, and demographic data, mode of prostate cancer treatment(s) before implantation, and outcome in terms of complete continence (pad free, leak free) were assessed. Statistical analysis was performed by Chi-squared and Fisher's exact tests.

Results: A total of 58 (32%) men had bulbar AUS for urodynamically proven stress urinary incontinence consequent to treatment for prostate cancer in this period. Median follow-up post-AUS activation was 19 months (1–119). Forty-eight (83%) men had primary AUS insertion. Twenty-one (36%) men had radiotherapy as part of or as their sole treatment. Success rates were significantly higher in nonirradiated men having primary sphincter (89%) than in irradiated men (56%). Success rates were worse for men having revision AUS (40%), especially in irradiated men (33%).

Conclusion: Radiotherapy as a treatment for prostate cancer was associated with significantly lower complete continence rates following AUS implantation.

Keywords: Artificial urinary sphincter, postprostatectomy incontinence, prostate cancer, radiotherapy

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INTRODUCTION

Urinary incontinence following all modalities of prostate cancer treatment confers a significant socioeconomic burden worldwide.[1,2] This problem will only increase with the increasingly aged population. Advances in prostate cancer diagnostics mean that more men, in particular more elderly men are receiving this diagnosis. We are now treating an aging population that is more active and healthier than the traditional cohort of elderly patients. Most are

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functionally independent and have a longer life expectancy, and they expect and demand curative treatments for both their prostate cancer and the consequences of its treatment.[3-6]

The artificial urinary sphincter (AUS) remains the gold standard for the surgical treatment of stress urinary incontinence (SUI) in men.[7] Male SUI occurs in between 3% and 87% following treatment for prostate cancer, depending on the definition of incontinence used.[8-11] SUI is reported in 1.5%–72% of men following radical prostatectomy alone,[12,13] 0%–10% following high-intensity focused ultrasound (HIFU),[14,15] and 0%–14% following radiotherapy alone.[16]

There is controversy as to whether neoadjuvant or adjuvant radiotherapy adversely affects the functional outcome of the AUS in men who have had treatment for prostate cancer. Resnick *et al*. reported no significant difference in the odds of urinary incontinence between irradiated and nonirradiated patients 15 years posttreatment.[17] This is supported by Ravier *et al*.,[18] Sathianathen *et al*.,[19] and other studies showing similar findings.[20,21] Conflicting evidence was detailed in the studies by Pérez *et al*.[22] and Walsh *et al*.[23] who found worse continence rates in patients who received radiotherapy before AUS. Indeed, Bates *et al*.[8] in a recent systematic review and meta-analysis of 949 patients concluded that persistent urinary incontinence is more common in men having radical prostatectomy and radiotherapy than those having radical prostatectomy alone.

We have assessed the outcomes and complications of men having bulbar AUS for SUI following treatment of prostate cancer to determine whether radiotherapy affects continence outcomes

MATERIALS AND METHODS

We have retrospectively reviewed our prospectively acquired database of all patients having an AUS insertion between the years 2002 and 2012. The dermographic data, mode of prostate cancer treatment(s) and continence outcomes following AUS implantation were assessed.

A total of 184 men had an AUS implanted in this period. Of these, 58 had bulbar AUS implanted for SUI consequent to the treatment of their prostate cancer. Of the 21 (36%) irradiated patients, 19 were treated initially with radical prostatectomy and 2 had external beam radiotherapy (EBRT) as sole therapy. Of the remaining 37 patients, 35 were treated solely with radical prostatectomy and 2 had HIFU.

All bulbar AUS implantations (primary and revision) in a uniform manner during the study period using proximal-mid bulbar extracorporeal cuff placement, iliac fossa extraperitoneal balloon placement, and subdartos pouch control pump location. No cuff size smaller than 4.0 cm was used and all had a 61–70 cm H_2O pressure regulating balloon. Standard preoperative assessment was carried out for each patient including a midstream urine sample to exclude active infection as well as video-urodynamic assessment. All AUS were activated 6 weeks postoperatively (Do we have data on capacity, etc.).

Patients were followed up by a consultation 3 months postoperatively and annually thereafter. The initial consultation included a physical examination and evaluation of clinical outcomes in terms of continence and patient satisfaction. Complete continence was defined as being dry without the use of any pads (pad free, leak free) by both patient and clinician.

Statistical analyses were performed by Chi-squared and Fischer's exact tests. $P < 0.05$ was considered to be statistically significant.

RESULTS

The median duration of follow-up post-AUS activation was 19 months (1–119). The patient cohort was divided into two groups: those having primary implantation of AUS versus those having a revision procedure [Table 1].

A total of 48 (83%) patients had a primary bulbar AUS implantation during this period. Twenty-eight of these patients had had radical prostatectomy as their only prostate cancer treatment and 25 (89%) achieved complete continence following AUS implantation. Sixteen patients had their prostate cancer treated with adjuvant radiotherapy due to biochemical failure following radical prostatectomy and only 9 (56%) were completely continent following AUS implantation. This was a statistically significantly

Table 1: Outcomes in irradiated versus nonirradiated patients, in the primary and revision settings

Etiology of USUI	Adjuvant radiotherapy	Primary or revision AUS	*n*	Dry (%)
Radical prostatectomy	No	Primary	28	25 (89)*
		Revision	7	3 (43)
	Yes	Primary	16	9 (56)*
		Revision	3	1 (33)
EBRT	No	Primary	2	1 (50)
HIFU	Yes	Primary	2	0

Statistical analysis was performed by Chi-squared and Fisher's exact tests and *$P<0.05$. EBRT: External beam radiotherapy, HIFU: High-intensity focused ultrasound, USUI: Urodynamically proven stress urinary incontinence, AUS: Artificial urinary sphincter

lower complete continence rate than in the nonirradiated group ($P < 0.05$) [Table 1].

Ten patients had a second bulbar AUS implanted as a revision procedure during the study period. Seven had their prostate cancer treated with radical prostatectomy alone. Three (43%) of these men achieved complete continence. Three men had adjuvant radiotherapy following radical prostatectomy for the treatment of their prostate cancer and only 1 (33%) was completely continent post-AUS implantation.

Two patients were treated with EBRT only. One (50%) was completely continent post-AUS insertion. Neither of the two patients treated with HIFU achieved continence.

DISCUSSION

Radiotherapy was associated with significantly lower complete continence rates in all AUS patients and primary AUS patients in particular. Repeat AUS implantation was associated with poorer continence outcomes than primary AUS implantation.

SUI following treatment for prostate cancer causes significant negative impact on quality of life (QOL). Implantation of a bulbar AUS is the gold standard treatment for SUI in this situation, providing high rates of long-term continence and acceptable morbidity. The effect of adjuvant radiotherapy on the outcomes of AUS implantation is still undecided. Several studies report conflicting results. While Jhavar *et al*. concluded that prior radiation did not alter AUS postoperative outcomes,[24] Suardi *et al*. reported that at 1 and 3 years after adjuvant radiotherapy, urinary continence recovery was 51% and 59% as opposed to 81% and 87% for those not receiving adjuvant radiotherapy.[25] This is confirmed in the reports of higher rates of persistent urinary incontinence post-AUS implantation in those men treated with adjuvant and neoadjuvant radiotherapy, with rates ranging from 5% to 48%.[19,23-34]

Radiation causes ischemic fibrosis of the urethra resulting in hypovascularity and subsequent tissue atrophy. As a consequence, irradiated patients exhibit a higher incidence of urethral stricture disease.[19,23] Sathianathen *et al*. reported a urethral stricture rate of 62.1% in irradiated patients compared with only 10.4% in the nonirradiated surgery only group.[19] If radiation is sufficient to cause ischemia and fibrosis in the region of the bladder neck, it does not require too much of an extension of thought and irradiation field for it to cause similar effects on the bladder – producing the adverse continence outcomes described in our and other studies and confirmed in Bates *et al*'s meta-analysis.[8]

Persistent urinary incontinence following AUS implantation may not be consequent to persistent intrinsic sphincter deficiency secondary but due to bladder factors such as *de novo* detrusor overactivity, loss of compliance, or loss of capacity.[26-28] All which are known to occur following radiotherapy to the bladder. The variation in continence outcomes described in the literature is consequent to variation in radiotherapy dose and techniques, patient selection bias, and variation in the definition of continence, outcomes measures and follow-up.

High complication rates with AUS implantation in irradiated patients have been reported by Manunta *et al*., with 8 of 15 patients with pelvic radiation requiring further surgical intervention.[23] Other studies have also reported increased rates of postoperative complications and surgical revision rates after adjuvant radiotherapy.[8,27] Conversely, surgical revision rates are not uniformly low in nonirradiated patient cohorts. Reports vary widely, ranging from 5% to 40%.[2,23,28-34] The varying rates may well be due to small cohort numbers, incomplete data, and/or inconsistent follow-up particularly with patient satisfaction and QOL questionnaires. Certainly, the surgical revision rates reported for irradiated patients are consistently higher than those in nonirradiated patients. This is well demonstrated in Bates *et al*'s meta-analysis of 15 studies, where the reported surgical revision rates in the irradiated group are 37.3% ± 6.1%, whereas those for the nonirradiated group were 19.8% ± 3.6% at 95% confidence intervals, respectively. Urethral atrophy accounted for 36.7% ± 10.9% and infection and erosion accounted for 52.3% ± 10.6% of surgical revisions.[8]

CONCLUSION

The bulbar AUS remains the gold standard for the treatment of postprostatectomy SUI making 89% of men with SUI following radical prostatectomy only dry on primary insertion. Results for men treated with both radical prostatectomy and radiotherapy are not as good, with only 56% of men becoming dry following AUS implantation. All men, regardless of their prostate cancer treatment modality, having repeat AUS implantation do not have as satisfactory continence outcomes as those having primary AUS implantation. Care should be taken when managing and counseling those who have received radiotherapy as well as surgery and those having repeat procedures.

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Conflicts of interest

There are no conflicts of interest.

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