Original Study

Durability of Artificial Urinary Sphincter With Prior Radiation Therapy

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Abstract

The data on the effect of prior radiation therapy on the durability of artificial urinary sphicter lacks consistency and long-term follow-up. We found no significant difference in incontinence rates or rates of revision, erosion, infection, and removal of artificial urinary sphicter with or without prior radiation therapy in our study comprising 94 men at a median follow-up of 62 months.

Background: The aim of this study was to investigate the effect of prior radiation therapy on artificial urinary sphincter. **Methods:** Group 1 was comprised of 63 men who underwent prior radical prostatectomy, and Group 2 was comprised of 31 men who received prior radiation therapy with or without prior radical prostatectomy. Social incontinence was defined as requiring to use $>$ 1 pad per day and/or catheter-dependent at the time of last follow-up. **Results:** The median age at artificial urinary sphincter placement was 71 years (interquartile range, 55-74 years). The median and mean follow-up was 62 months (interquartile range, 37-106 months) and 75 months (range, 2-205 months), respectively. At the time of last follow-up, 67% (63 of 94) of the men in the entire cohort (73% [46 of 63] and 55% [17 of 31] in Group 1 and Group 2, respectively [$P = .078$]) were socially continent. Sphincter revision, erosion, infection, and removal rates were 20%, 20%, 7%, and 10%, respectively, in Group 1, and 26%, 13%, 7%, and 23%, respectively, in Group 2. The differences in these rates were not statistically significant between the 2 groups. **Conclusion:** We found no significant difference in functionality (incontinence rates) and outcomes (rates of sphincter revision, erosion, infection, and removal) between the 2 groups. The message for patients is that prior radiation does not significantly alter the outcomes of artificial urinary sphincter.

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Introduction

Urinary incontinence can be a significant complication after radical prostatectomy.[1] Surgical insertion of an artificial urinary sphincter (AUS) is the ultimate treatment for this and provides excellent outcomes.[2] The effect of prior radiation therapy (XRT) on the functionality and outcomes of AUS have been reported; however, the data lacks consistency and long-term follow-up. We investigated the durability and outcomes of AUS after XRT and compared them with outcomes in men who did not have XRT.

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Methods

This study was approved by the institutional review board. We identified 107 men who underwent AUS placement for urinary incontinence after prostate cancer treatment between 1997 and 2012. The final dataset comprised 94 men after 13 were excluded owing to lack of follow-up data. Their charts were retrospectively reviewed to identify men who did or did not receive XRT prior to AUS placement. We also identified 3 patients who received XRT but had AUS placed prior to XRT and reviewed the functionality and outcomes in them separately. Our goal was to investigate and compare the durability (continence rates) and operative outcomes (AUS revision surgery, erosion, infection, and AUS removal rates) after AUS placement in these 2 groups. AUS revision included balloon revisions, pump revisions (replacement, adjustment), and cuff revisions (replacement, adjustment, etc). Erosions and infections occurring after AUS revision surgery subsequent to initial sphincter placement were defined as secondary. Erosions and infections occurring in patients not requiring AUS revision surgery

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after initial sphincter placement were defined as primary. Social incontinence was defined as requiring the use of > 1 pad per day with the sphincter in place and/or catheter-dependent with or without AUS in place at the time of last follow-up.

Owing to the retrospective nature of the study, there was no predetermined standardized follow-up surveillance policy. Based on individual physician preference, patients were generally followed up at 3- to 6-month intervals in their first year and then 6 months to yearly thereafter. There was no predetermined duration of follow-up. Incontinence was established using either questionnaire, phone call, or office visit. The data on revision, erosion, infection, or removal was unavailable in 4 patients, all of them in Group 1.

Statistical Methods

The dataset was imported into SAS and R for analysis. Statistical analysis was performed in SAS 9.4. Plots were created in R v. 3.1.1. Descriptive statistics are provided for all variables of interest. Means and standard deviations are reported for continuous variables; frequencies and percentages are reported for categorical variables. The χ^2 test and the Fisher exact test are used to compare rates of continence, erosion, infection, and revision between the treatment groups.

Results

Of the 94 men analyzed, 63 (67%) did not receive XRT prior to AUS placement. This group of 63 men had undergone radical prostatectomy (RP) alone and were assigned to Group 1. The remaining 31 (33%) men had received XRT with or without RP as initial treatment for prostate cancer and were assigned to Group 2. Six men in Group 2 (19%) had prior XRT alone without RP. Five of these 6 men had cryotherapy and/or trans-urethral resection of the prostate at various time points after completion of XRT and prior to AUS placement. Owing to the similar functionality and outcomes after AUS placement in these 6 men, they were included in Group 2 along with the 25 men who received prior-XRT and RP (Table 1). The AMS 800 (American Medical Systems, Minnetonka, MN) sphincter was used in the majority of patients, except for AMS 600 and AMS 700 in 1 patient each. Time between AUS placement and activation of the pump was 4 to 6 weeks. The median time between RP and AUS placement was 3 years in Group 1 and between XRT and AUS placement was 7.4 years in Group 2. The descriptive statistics and results are detailed in Table 1.

The median age at AUS placement was 71 years (interquartile range, 55-74 years). The median follow-up was 62 months (interquartile range, 37-106 months). The mean follow-up was 75 months (range, 2-205 months). Information on continence was available on all 94 men. Information on AUS revision surgery, erosion, infection, and AUS removal was unavailable on 4 men in Group 1.

At the time of last follow-up 67% (63 of 94) of the men in the entire cohort (73% [46 of 63] in Group 1 and 55% [17 of 31] in Group 2) were socially continent. The difference between the continence rates between Group 1 and Group 2 was not statistically significant (χ^2 test; $P = .078$).

AUS revision surgery was required in 22% (20 of 90) of the men in the entire cohort (20% [12 of 59] and 26% [8 of 31] in Group 1 and Group 2, respectively [$P = .55$]). Notably, none of the 6 men within Group 2 who received XRT alone required AUS revision surgery.

Table 1 Descriptive Statistics and AUS Functionality and Outcome Results

	All	RP Alone (Group 1)	RP + XRT	XRT Alone	XRT Group (Group 2)	*P* Value
Number of men	94	63	25	6	31	–
Mean age at RP, years (range)	–	63.3 (51-77)	63.8 (53-72)	–	–	–
Median age at RP, years (IQR)	–	63.5 (52-68)	64.7 (54.4-67.3)	–	–	–
Mean age at XRT, years (range)	–	–	–	–	65.5 (55-73)	–
Median age at XRT, years (IQR)	–	–	–	–	65.3 (55.4-70.6)	–
Mean age at AUS placement, years	69.6	–	–	–	–	–
Median age at placement, years	70.5	–	–	–	–	–
Average follow-up, years	6.3	–	–	–	–	–
Median follow-up, years	5.1	–	–	–	–	–
Median cuff size	–	4 cm	–	–	4 cm	–
Socially continent	63 (67%)	46 (73%)	14 (56%)	3 (50%)	17 (55%)	.07
AUS revision surgery	20 (22%)	12[a] (20%)	–	–	8 (26%)	.55
Erosions	16 (18%)	12[a] (20%)	–	–	4 (13%)	.5
Infections	6 (7%)	4[a] (7%)	–	–	2 (7%)	.95

Abbreviations: AUS = artificial urinary sphincter; IQR = interquartile range; RP = radical prostatectomy; XRT = radiation therapy.
[a]Data unavailable on 4 patients.