The Impact of Prior Radiation Therapy on Artificial Urinary Sphincter Device Survival

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Purpose: The literature on artificial urinary sphincter device survival in individuals with a history of radiation therapy is conflicting. We assess device survival outcomes among individuals after prior radiation therapy exposure undergoing primary artificial urinary sphincter placement.

Materials and Methods: An institutional review board approved database of all patients who underwent artificial urinary sphincter surgery from 1999 to 2011 was used to assess device survival in patients treated with radiotherapy compared to individuals without radiotherapy exposure. Hazard regression and competing risk analysis were used to determine the association between radiation therapy and device outcomes.

Results: From 1999 to 2011 a total of 872 patients underwent artificial urinary sphincter surgery at our institution. Of these patients 489 underwent primary artificial urinary sphincter placement, with 181 of 489 (37%) having received radiation therapy. Patients with prior radiation therapy were older (median age 72.0 vs 70.1 years, $p < 0.01$) and had a higher median body mass index (29.4 vs 28.6 kg/m^2, $p < 0.03$) than those without radiation exposure. Rates of diabetes mellitus and hypertension were similar between the 2 groups. There was no significant difference in overall device survival between individuals who received radiation therapy and those without radiation therapy exposure, with 1 and 5-year device survival rates of 92% vs 90% and 77% vs 74%, respectively ($p=0.24$).

Conclusions: While individuals who underwent radiation therapy were significantly older and had a higher body mass index, device survival was not significantly different between the 2 groups when using a cuff size greater than 3.5 cm. These findings will assist the urologist with the preoperative counseling of men undergoing primary artificial urinary sphincter placement with a history of radiation therapy.

Key Words: urinary sphincter, artificial; treatment outcome; radiotherapy; urinary incontinence

Abbreviations and Acronyms

AUS = artificial urinary sphincter
BMI = body mass index
CAD = coronary artery disease
HTN = hypertension
RP = radical prostatectomy
SUI = stress urinary incontinence
XRT = external beam radiation therapy

Accepted for publication October 2, 2015.

No direct or indirect commercial incentive associated with publishing this article.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

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Editor's Note: This article is the fifth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 1176 and 1177.

Originally introduced in 1972, the artificial urinary sphincter is considered the preferred therapy for moderate to severe SUI.[1] The majority of patients undergoing AUS placement have undergone radical prostatectomy or prostate surgery for benign pathology as the cause of SUI.[2–5]

Notably, approximately 40% of men who undergo AUS placement after RP have received external beam radiation therapy, and exposure to

0022-5347/16/1954-1033/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2015.10.119
Vol. 195, 1033-1037, April 2016
Printed in U.S.A.

radiotherapy has been proposed as a risk factor for adverse AUS outcomes in terms of infection and erosion rates as well as urethral atrophy.[6–10] In fact, a recent meta-analysis concluded that AUS after RP and XRT presented an increased risk of device erosion compared to RP without XRT exposure.[9] However, there are disparate reports regarding the impact of radiation therapy on AUS outcomes.[2,8,11] Due to the conflicting nature of multiple small, underpowered studies, we assessed device survival outcomes among individuals with prior radiation therapy exposure undergoing AUS placement in a large patient cohort with long-term followup.

METHODS

After obtaining institutional review board approval we identified 872 consecutive male patients undergoing AUS implantation at Mayo Clinic (Rochester, Minnesota) from 1999 to 2011. We purposely limited our study group to AUS procedures performed up to 2011 to allow for adequate patient followup. Of the 872 procedures 489 (56%) were primary implantations and 181 (37%) of the primary implantations had radiation exposure before AUS placement, thereby comprising the study cohort. Patients were excluded from analysis if they underwent AUS placement secondary to neurogenic bladder, were younger than 18 years old, were female or declined research consent.

In terms of technique all implanted AUS devices were AMS 800™. We use a standard surgical technique for AUS placement in males including a perineal approach. Since 1983 it has been standard at our institution to preserve the bulbospongiosus muscle during perineal dissection and to place the cuff around the muscle, not in direct contact with the urethra, as this may decrease direct pressure on the corpus spongiosum tissue and prevent urethral atrophy. Therefore, all patients in this series had cuffs placed in this manner.

After circumferential dissection of the proximal bulbar urethra between the corpora cavernosum and corpora spongiosum, the appropriate size cuff is selected. In cases of severely atrophic urethral tissues (measurement less than 4.0 cm) or difficult dissection planes (eg in some cases with prior pelvic radiation therapy or urethral sling placement), we use a transcorporal approach as previously described.[12] In addition, we prefer to implant a 61 to 70 cm abdominal reservoir through a separate abdominal incision. The reservoir is filled with 22 cc iso-osmotic contrast to assist with the identification of mechanical failure during future evaluations.

Individual charts were reviewed to evaluate pertinent clinical and surgical comorbidities, in particular radiation therapy before AUS placement, details of the implanted device and device outcomes including reoperations (ie explantation for urethral erosion or device infection, revision for device malfunction, urethral atrophy, tubing or pump complications). The retrospective nature of this study precluded a standardized followup protocol in all patients. Rather all patients were evaluated at 6 weeks postoperatively for device activation and instruction on device use. All participating patients were then followed via office evaluation on an as needed basis as determined by continence or other device concerns and by mailed patient questionnaires. In addition, the Mayo Clinic AUS registry, which includes patients treated with AUS from 1983 to the present, monitors outcomes periodically by correspondence with the patient. All patients were contacted with written correspondence regarding device outcomes. Details regarding device survival were obtained from the last office examination, any available subsequent operative report, or written or telephone correspondence.

Statistical analysis was performed using the SAS® software package. Continuous features were summarized with medians and IQRs, and categorical features were summarized with frequency counts and percentages. Device survival was estimated as time from AUS implantation to subsequent repeat surgery (including explantation or device revision for any reason) using the Kaplan-Meier method. In terms of the AUS related failures of infection/erosion and atrophy, we used a survival analysis based on competing risks. All statistical tests were 2-sided, with $p < 0.05$ considered statistically significant.

RESULTS

From 1999 to 2011 a total of 872 patients underwent AUS surgery at our institution. Of these patients 489 underwent primary AUS placement. Of the total primary AUS cohort 181 (37%) patients had received radiation therapy before AUS placement. Patients with prior radiation therapy were older (median age 72.0 vs 70.1 years, $p < 0.01$), had a higher median BMI (29.4 vs 28.6 kg/m^2, $p < 0.03$) and were more likely to have received androgen deprivation therapy (33% vs 6.6%, $p < 0.0001$) than those without prior radiation exposure. Rates of diabetes mellitus, HTN, CAD and myocardial infarction were similar between the 2 groups, as were the rates of open radical prostatectomy as the cause of SUI (87% vs 83%, p=0.27, table 1).

In terms of cuff size 95% of patients received a 4.5 cm cuff. The remaining 5% had a 4.0 or 5.0 cm cuff. In particular, no patient was treated with a 3.5 cm cuff during the study duration time that the 3.5 cm cuff was available.

Median followup for the 489 primary implantations was 4.3 years (IQR 1.3, 7.8). On univariate

Table 1. *Clinical and demographic information for patients undergoing primary AUS placement*

	No Radiation Therapy	Radiation Therapy	p Value
No. pts	308	181	
Mean pt age at AUS (SD)	70.1 (7.9)	72.0 (7.8)	0.002
Mean kg/m^2 BMI (SD)	28.6 (4.2)	29.4 (4.3)	0.03
No. diabetes (%)	42 (13.7)	35 (19.4)	0.09
No. HTN (%)	192 (62.5)	122 (68.2)	0.21
No. CAD (%)	73 (23.9)	54 (29.8)	0.15
% Urethral cuff size 4.5 cm	89.5	85.6	0.37