Prior Radiation Therapy Decreases Time to Idiopathic Erosion of Artificial Urinary Sphincter: A Multi-Institutional Analysis

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Purpose: Substantial controversy and conflicting data exist regarding the survival of the artificial urinary sphincter in patients with prior radiation therapy. We present data from a multi-institutional analysis examining the effect of prior radiation for prostate cancer on device survival.

Materials and Methods: A database was compiled of patients with artificial urinary sphincter cuff erosion, which included demographic and comorbid patient characteristics, functional analyses and interventions. We identified 80 patients with iatrogenic or idiopathic artificial urinary sphincter erosion. Idiopathic erosion cases were further analyzed to determine factors influencing device survival with specific stratification for radiation therapy.

Results: A total of 56 patients were identified with idiopathic artificial urinary sphincter erosion. Of those men 33 (58.9%) had not undergone radiation treatment while 23 (41.1%) had a history of brachytherapy or external beam radiotherapy. In patients without radiation erosion-free median device survival was 3.15 years (95% CI 1.95–5.80), in contrast to the median device survival of only 1.00 year (95% CI 0.36–3.00) in irradiated patients. The erosion-free survival experience of patients with vs without radiation differed significantly (Wilcoxon-Breslow test for equality of survivor functions $p = 0.03$).

Conclusions: Radiation therapy in patients with known idiopathic cuff erosion in this contemporary analysis correlated with significantly increased time to erosion. Mean time to idiopathic cuff erosion was accelerated by approximately 2 years in irradiated cases. To our knowledge these data represent the first demonstration of substantial outcome differences associated with radiation in patients with an artificial urinary sphincter who present specifically with cuff erosion.

Key Words: prostatic neoplasms; urethra; urinary sphincter, artificial; radiotherapy; treatment outcome

Abbreviations and Acronyms

AUS = artificial urinary sphincter

PCa = prostate cancer

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The hydraulic AUS was first introduced in 1972 by Scott et al.[1] The AMS 800® debuted in 1983 and has undergone multiple technical advancements in the intervening decades. These enhancements include a narrow backed cuff, infection retardant coatings, tubing modifications and the availability of smaller cuff sizes.[2,3] The AUS endures as the gold standard for moderate to severe male stress urinary incontinence after radical prostatectomy.[4] The AUS has also been useful in patients with incontinence after transurethral resection of the prostate as well as those with an orthotopic neobladder following cystoprostatectomy and with neurogenic bladder due to spinal cord injury or spina bifida.[5–7] As a result of the durability and efficacy of these adaptations the complication rate after AUS implantation has declined significantly in the last 3 decades.[8–10]

Primary AUS implantation requires thoughtful patient selection and regular followup to monitor for long-term complications, including mechanical malfunction, infection and cuff erosion. Erosion has been estimated to develop in 2% to 15% of patients after AUS implantation with an average of 6% at most high volume centers.[8,11,12] Outcomes after cuff erosion are often devastating, including mandatory device removal, short-term urinary diversion with a urethral or suprapubic catheter, the risk of urethral stricture, recurrent incontinence and delayed reimplantation months following explantation. A significant amount of literature exists regarding AUS cuff erosion, primarily focused on risk factors leading to erosion or the feasibility of subsequent reimplantation.[10,12] It has also been demonstrated that cuff erosion is a risk factor for subsequent erosion at reimplantation even when advanced maneuvers such as transcorporeal cuff placement are used.[12,13]

Discordant data exist on pelvic radiotherapy and AUS cuff erosion risk in PCa survivors. Early, single institution series revealed no difference in AUS complication rates when accounting for extensive variables, including radiation.[8] Exceptionally large series have additionally demonstrated that radiation carries no significant risk on multivariate analysis with regard to cuff erosion, although radiation and cuff size correlated on univariate analysis.[9] Indeed, specific interrogation of a subset of these patients determined that there was no difference in overall AUS survival in those with radiation exposure.[14]

However robust, data from retrospective, single institution series during decades may limit general applicability. In contrast, a contemporary multicenter analysis from 8 high volume institutions clearly demonstrated that prior radiation was a risk factor for cuff erosion (OR 4.872).[10]

In this study we sought to use a reverse paradigm beginning with a known event to characterize factors influencing AUS device survival with emphasis on the risks of radiotherapy. To do so we compiled a database of patients with erosion exclusively from 6 high volume male continence centers.

MATERIALS AND METHODS

Following institutional review board approval at each study site we performed a retrospective, multi-institution data analysis of 80 patients who underwent AUS implantation between 1991 and 2014, and subsequently experienced idiopathic or iatrogenic cuff erosions. No external funding was obtained for this study.

Patient data were procured via extensive review of individual site medical records, including operative reports, nursing operative data, inpatient notes, consultation notes and followup visits. Collaborating investigators compiled 85 data points on each patient when available, including demographic information, pertinent comorbid characteristics, additional interventions for incontinence and outcomes as defined by the individual clinical practice. These data were compiled into an Excel® database.

Patient demographic and clinical data measured in the nominal or the ordinal scale are summarized as the count and percent, and compared across radiation history groups using the Fisher exact test. Patient demographic and clinical data measured in the interval scale are summarized as the mean ± SD or the median and IQR and compared across age groups using the nonparametric rank sum test. Erosion-free survival was calculated and plotted using the Kaplan-Meier product limit method and survival trajectories were compared by the Wilcoxon-Breslow test. Data were analyzed and processed with Stata®, version 14 with $p < 0.05$ considered statistically significant.

RESULTS

The supplementary table (http://jurology.com/) lists patient demographic and clinical characteristics. Mean patient age at cuff erosion was 73.9 years (range 20 to 92). Idiopathic cuff erosion developed after AUS placement in 56 cases with the remainder deemed iatrogenic cases secondary primarily to catheterization. Of the 80 patients 93.3% were Caucasian. Three African American and 2 Hispanic patients were included in study. At the time of AUS implantation 18 men (23%) had been diagnosed with diabetes.

Of the 80 patients 71 (89%) had a history of PCa, including 54 (76%) who underwent radical retropubic prostatectomy and 7 (10%) who underwent robot-assisted radical prostatectomy. Four patients (6%) with PCa were treated with brachytherapy combined with external beam radiation. In 2 patients (3%) PCa was discovered at transurethral resection. One of these men was later treated with brachytherapy alone while the other received brachytherapy combined with external beam radiation. In 29 of these primary surgical cases salvage external beam radiation was later performed, including in 28 after radical retropubic prostatectomy and in 1 after robot-assisted radical prostatectomy. PCa treatment information was unknown in the other 4 cases. The remaining patients