Outcomes of the artificial urinary sphincter among men with prior pelvic radiation

Device survival and impact of time since radiation

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INTRODUCTION

The artificial urinary sphincter (AUS) improves continence and quality of life for men with post-prostatectomy incontinence.[1] Many of these prostate cancer patients also receive radiation therapy as primary treatment or salvage therapy. The exact impact of radiation on outcomes of the AUS is still debatable but in general, studies suggest that radiation results in higher risk of erosion and reoperation.[2-4] Radiation disrupts the basement membrane of blood vessels, leading to microangiopathy and neovascularization, and subsequently causes fibroblast proliferation and scar formation. These effects typically manifest in a delayed and cumulative fashion, with reports of complications, such as fistulas, urethral strictures, and hemorrhagic cystitis, presenting decades after the completion of radiation therapy.[5]

Our objective was to describe our surgical outcomes in AUS patients with prior pelvic radiation, and determine if time since radiation is significantly related to reoperative device complications; our hypothesis was that increased time from radiation would be associated with increased AUS complications.

METHODS

This study is a retrospective case series. We used billing records to identify consecutive adult males who underwent a first-time AUS from 2012–2023 with a single surgeon. A two-incision technique was used, and a perineal incision was used for proximal bulbar cuff placement. A transcorporeal approach, or grafts/bulbospongiosus wraps were not used in any of these first-time AUS cases. We only included patients who had received pelvic radiation before AUS. Ethics approval was granted by Western University REB (120719).

We used a standardized data extraction sheet to collect data from the paper and electronic patient charts, and a sample of data was double-extracted to ensure accuracy. The primary outcome was an AUS complication requiring repeat surgical intervention. This included an erosion and/or device infection, revision surgery for recurrent urinary incontinence, or other device problems. Our secondary outcome was device reoperation due to infection/erosion (which may be more specific to a radiation-related mechanism). The primary exposure was time, in months, from completion of radiation to AUS insertion.

We performed exploratory analysis on secondary exposure variables, such as cuff size, learning curve, and American Society of Anesthesiologists (ASA) score. For all analyses, Cox regression analysis was used and patients were censored at last followup or death. Due to our limited sample size and low event rate, we could not create strong multivariable models. Therefore, we only reported univariable Cox regression models. SPSS version 26 was used for statistical analysis, and a $p<0.05$ was considered statistically significant.

RESULTS

We identified 99 men (out of 200 total first-time AUS placements) who met the inclusion criteria. Relevant baselines, intraoperative details, and outcomes are shown in Table 1. The most used cuff size was 4 cm (43%). Radiation dosage and fractions were available for 52/99 patients, and almost all men received 66 gray (Gy) in 33 fractions. The median time between radiation and AUS implantation was 90 (interquartile range [IQR] 41–129) months.

After AUS placement, 34 men (34%) had a Clavien ≤3 complication within 30 days (such as urinary retention, urinary tract infection, or gross hematuria), and 92% of men had social continence. After a median followup of 31 months, 15 men (15%) had a repeat surgical intervention on their AUS. The majority (12/15) were for device erosion/infection. The remaining three

KEY MESSAGES

- Patients undergoing AUS implantation often have received radiation; we did not find that the time since radiation impacts AUS complications that require reoperation.
- Despite the challenges with operating in radiated patients, the five-year AUS device survival was high.
- A larger AUS cuff size is significantly correlated with a lower risk of AUS complications that require reoperation.

were for mechanical failure (1) and recurrent incontinence (2). The five-year overall device survival was 87%.

Time in months from radiation was not significantly associated with all-cause device failure (hazard ratio [HR] 1.00, 95% confidence interval [CI] 0.99–1.01, p=0.63) or with our secondary outcome specific to infection/erosion (HR 1.0, 95% CI 0.99–1.01, p=0.44). We explored other exposure variables and found that a larger cuff size was significantly associated with a lower risk of all-cause AUS reoperation (HR 0.27, 95% CI 0.05–0.91, p=0.03), and a higher ASA class was significantly associated with a higher risk of all-cause AUS reoperation (HR 5.28, 95% CI 1.42–19.70, p=0.01). Of the 15 people with reoperation, 13 (87%) had a 4.0 or 3.5 cm cuff, and 12 (80%) were ASA 3 or 4. The univariate analysis of variables and their association with AUS reoperation is shown in Table 2.

DISCUSSION

While the increased risk of complications and need for surgical revision following AUS implantation in previously radiated patients has been described, predicting this risk remains elusive. The delayed complications of radiation therapy can be severe, and the resulting fibrosis, tissue atrophy, and impaired wound healing increase the potential risk of surgery. The onset of these complications typically manifests between six months to several years post-treatment, particularly with doses ≥65 Gy, which is common in prostate cancer.[6] The purpose of this study was to explore if there was an ideal window after radiation during which to place an AUS; to our knowledge, this has not been investigated previously. We did not find that the length of time since radiation impacts the risk of an AUS complication.

Table 1. Patient demographic details

	Median (IQR) or n
Age (years)	72 (69–76)
BMI (kg/m²)	29 (26–31)
ASA class	
1	2
2	29
3	63
4	5
Etiology of incontinence	
EBRT alone	1
EBRT + RRP	89
Brachy + TURP	6
RT + Other	3
Patients with prior non-AUS incontinence procedures	4
Time between radiation and AUS placement (months)	90 (41–129)
Patients with vesicourethral anastomotic stricture (defined as <12 Fr)	13
Patient-reported pads per day prior to the AUS	5.0 (3.0–7.3)
Cuff size (cm)	
3.5	3
4	43
4.5	37
5	10
>5	6
30-day postop complications	
Clavien 1–2	22
Clavien 3	12
Clavien 4–5	0
Social continence after activation (defined as ≤1 pad per day)	92
Total followup time (median, IQR)	31 (12–60)

ASA: American Society of Anesthesiologists; AUS: artificial urinary sphincter; BMI: body mass index; EBRT: external beam radiation therapy; IQR: interquartile range; RRP: retropubic radical prostatectomy; RT: radiation therapy; TURP: transurethral resection of the prostate.

In general, radiation has been shown to accelerate time to cuff erosion. In a multicenter series, the mean overall time from AUS implant to erosion was short-

Table 2. Univariate analysis of variables and their association with AUS reoperation		
	HR (95% CI)	p
Impact of time from radiation on any AUS reoperation	1.00 (0.99–1.01)	0.63
Impact of time from radiation on AUS reoperation for erosion/infection	1.00 (0.99–1.01)	0.44
Exploratory analyses of variables and their relationship to any AUS reoperation		
Age (per year increase)	1.02 (0.93–1.13)	0.64
BMI (per kg/m^2 increase)	0.92 (0.78–1.09)	0.33
Vesicourethral anastomotic stricture (relative to those without VUAS)	2.31 (0.68–7.88)	0.18
Cuff size (per cm increase)	0.27 (0.05–0.91)	0.03
ASA class (per unit increase)	5.28 (1.42–19.70)	0.01
Learning curve (per case number)	1.02 (0.99–1.06)	0.13

ASA: American Society of Anesthesiologists; AUS: artificial urinary sphincter; CI: confidence interval; HR: hazard ratio.

ened to one year with radiation compared to three years in patients with no prior radiation.[7] The risk of AUS complication seems to increase with pelvic radiation, and may be more likely if the AUS is placed after radiation rather than before radiation.[8] This suggests that the ideal time to place an AUS may be prior to the radiation therapy, when tissue changes have not yet occurred, and once a patient has been radiated; according to our results, the timing of AUS placement does not impact significant device complications.

We found that larger AUS cuff size was protective against reoperation complications in radiated patients. This is similar to the results of a large retrospective study of 1020 patients that found that cuff size (but not history of radiation) was significantly related to device failure.[9] Other studies have demonstrated that a very small cuff size (3.5 cm), in combination with radiation, leads to an unacceptably high erosion risk of 85% (or 6.2-fold higher).[10]

The larger cuff size likely represents a healthier urethra, which explains the association between smaller cuff size and urethra erosion/infection. We abandoned the 3.5 cm cuffs early in practice, so we are unable to study this cuff size specifically. We also found that higher ASA score was significantly associated with AUS complications, which is likely driven by poor wound healing and impaired circulatory function that often accompanies patients with a higher ASA score.

Limitations

The current study is limited by its retrospective nature. It is not possible to determine the impact of very early AUS placement after radiation, as it not our practice to place an AUS until at least six months after radiation therapy is completed. The risk of surgical complications was low, and thus, we had limited power to assess our primary outcome and could not do multivariable modeling. This study represents data from a single surgeon at a single institution and findings may not be generalizable to other settings.

CONCLUSIONS

Patients with prior radiation have a high device survival at five years. Time since radiation is not a significant predictor of device failure; however, a larger cuff size and lower ASA score may reduce the risk of repeat surgical intervention.

COMPETING INTERESTS: The authors do not report any competing personal or financial interests related to this work.

This paper has been peer reviewed.

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