Artificial Urinary Sphincter Placement in Compromised Urethras and Survival: A Comparison of Virgin, Radiated and Reoperative Cases

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Abbreviations and Acronyms

AUS = artificial urinary sphincter
BMI = body mass index
CAD = coronary artery disease
EBR = external beam radiation
SUI = stress urinary incontinence

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Purpose: Although long-term outcomes after initial placement of artificial urinary sphincters are established, limited data exist comparing sphincter survival in patients with compromised urethras (prior radiation, artificial urinary sphincter placement or urethroplasty). We evaluated artificial urinary sphincter failure in patients with compromised and noncompromised urethras.

Materials and Methods: We performed a retrospective analysis of 86 sphincters placed at a single institution between December 1997 and September 2012. We assessed patient demographic, comorbid disease and surgical characteristics. All nonfunctioning, eroded or infected devices were considered failures.

Results: Of the 86 patients reviewed 67 (78%) had compromised urethras and had higher failure rates than the noncompromised group (34% vs 21%, p=0.02). Compared to the noncompromised group, cases of prior radiation therapy (HR 4.78; 95% CI 1.27, 18.04), urethroplasty (HR 8.61; 95% CI 1.27, 58.51) and previous artificial urinary sphincter placement (HR 8.14; 95% CI 1.71, 38.82) had a significantly increased risk of failure. The risk of artificial urinary sphincter failure increased with more prior procedures. An increased risk of failure was observed after 3.5 cm cuff placement (HR 8.62; 95% CI 2.82, 26.36) but not transcorporal placement (HR 1.21; 95% CI 0.49, 2.99).

Conclusions: Artificial urinary sphincter placement in patients with compromised urethras from prior artificial urinary sphincter placement, radiation or urethroplasty had a statistically significant higher risk of failure than placement in patients with noncompromised urethras. Urethral mobilization and transection performed during posterior urethroplasty surgeries likely compromise urethral blood supply, predisposing patients to failure. Patients with severely compromised urethras from multiple prior procedures may have improved outcomes with transcorporal cuff placement rather than a 3.5 cm cuff.

Key Words: urinary sphincter, artificial; urinary incontinence; radiation

Soon after its introduction in 1972, the artificial urinary sphincter became a mainstay of treatment of male stress urinary incontinence. After several advances in mechanical design, the AMS 800™ was released in 1983 and remains the primary AUS used today. Although various continence promoting devices, most notably bone anchored,[1] transobturator[2] and adjustable male slings,[3] have been used as a treatment modality for mild

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to moderate SUI, the AUS is considered the gold standard for the treatment of severe SUI.[4]

Acceptable long-term patient satisfaction and device durability have been demonstrated in multiple cohorts chiefly comprised of uncomplicated patients, with 63% to 77% of original sphincters still in place with long-term followup.[5–8] Outcome data from these cohorts may not be applicable to patients with a history of pelvic radiation, AUS explant or urethroplasty.

More post-prostatectomy cases are now receiving adjuvant radiation due to the trend toward multimodal treatment of aggressive prostate cancer.[9] Radiation causes small vessel obliteration and endarteritis, resulting in localized ischemic tissue changes such as fibrosis and necrosis.[10] Although the bulbar urethra is outside the radiated field, urethral blood supply may be compromised during its pelvic course, which could predispose these patients to urethral erosion after AUS placement.[11–13] Although several studies showed little difference in sphincter survival between the radiated and nonradiated groups,[14–16] others have reported a significantly higher failure rate, primarily from atrophy and infection/erosion, in radiated cases.[11,12,17–19]

The number of patients undergoing revision and reimplantation procedures is increasing.[11] Simple revision operations to replace older malfunctioning devices or downsize the cuff appear to have durability similar to that of the initial placement.[20,21] The recent availability of the 3.5 cm cuff has allowed physicians to achieve functional success in patients who have spongiosal atrophy with acceptable 1-year erosion rates (9%).[10] Patients undergoing secondary AUS reimplant after removal of an eroded/infected AUS are more likely to experience re-erosion.[11,20] Since cuff placement around the poorly perfused scar tissue at the prior erosion site will likely re-erode, further mobilization of the urethra and placement of the new cuff in an alternate location are recommended.[22] In addition to the negative impact this has on collateral blood flow, longitudinal blood flow through the scarred, previously eroded portion of the urethra is likely impaired in these patients.[11] Also, a smaller cuff often has to be placed around the less robust distal bulbar urethra since the initial cuff is generally placed around the thicker, proximal bulbar urethra.[11,20]

In this analysis we compared compromised (prior AUS, radiation or urethroplasty) and noncompromised AUS cases to determine risk factors for AUS failure. We hypothesized that conditions which negatively impact spongiosal blood supply, including urethroplasty, would lead to increased AUS failure.

MATERIALS AND METHODS

After institutional review board approval was granted we evaluated all male patients who underwent bulbar urethra AUS placement at the University of California, San Francisco from December 1997 through September 2012. A retrospective chart review was conducted to identify patient demographics and surgical variables including age at implantation, BMI (kg/m^2), medical comorbidities by patient self-report including CAD, diabetes and smoking, prior urethroplasty, AUS placement or radiation (EBR and/or brachytherapy), cuff size (3.5, 4, 4.5, 5 cm) and placement technique (single vs double cuff, transcorporal). All patients were contacted by telephone by a single surgeon (JBM) and were asked if they still had a functioning artificial urinary sphincter in place. Failure was defined as sphincter explant. To account for tissue atrophy, explant for nonfunctioning devices was also considered a failure. Postoperative variables including continued sphincter function, time to failure (explant) and etiology of failure were gathered. We included patients with at least 6 months of followup and all patients who experienced failure before 6 months. Followup time was defined as the last clinic visit or telephone contact, whichever was later. Patients with clinical signs of erosion or infection underwent confirmatory office cystoscopy and subsequent AUS explantation.

All patients in the study underwent placement of the AMS 800 with a 61 to 70 cm reservoir for the treatment of SUI. A single surgeon (JWM) placed the majority of sphincters (97%, 83 of 86), and the remainder were placed by another faculty member and former fellow (BNB) using the same surgical technique through separate perineal and suprapubic incisions. Patients with noncompromised urethras were compared across categories of demographic and clinical characteristics with those who had compromised urethras, using Fisher's exact test for categorical variables. The t-test was used for continuous variables to compare means across groups. We enumerated the reasons for failures by those with noncompromised vs compromised urethras. In all patients Cox proportional hazards models were used to analyze associations between demographic indicators, clinical characteristics and history, and time to failure. All Cox proportional hazards models were adjusted for age at surgery. Hazard ratios and 95% CIs were calculated. In the analysis of time to failure, patients were evaluated from time of surgery to date of last followup. We used a Kaplan-Meier plot to illustrate failure-free survival. All analyses were performed using SAS® version 9.3 and results with a 2-sided $p < 0.05$ were considered statistically significant.

RESULTS

The study population included a total of 86 sphincters placed in 69 patients. Of these, 19 (22%) were placed in patients with noncompromised urethras and 67 (78%) were placed in patients with compromised urethras. There was no significant difference in demographics between these groups (table 1). Median followup was 39.2 months (range 1 to 126).