3.5 cm Artificial Urinary Sphincter Cuff Erosion Occurs Predominantly in Irradiated Patients

Jay Simhan, Allen F. Morey,*,† Nirmish Singla, Timothy J. Tausch, J. Francis Scott, Gary E. Lemack‡ and Claus G. Roehrborn

From the Department of Urology, University of Texas Southwestern Medical Center, Dallas, Texas

Purpose: We analyzed our initial 100-case experience with the 3.5 cm artificial urinary sphincter cuff to identify risk factors for cuff erosion.

Materials and Methods: We reviewed the records of a single surgeon, consecutive series of patients treated with 3.5 cm artificial urinary sphincter cuff placement from September 2009 to August 2013. Each patient underwent single perineal cuff placement via standardized technique. Preoperative characteristics, technical considerations and postoperative outcomes were analyzed and compared to those in a cohort of patients in whom a larger (4.0 cm or greater) artificial urinary sphincter cuff was placed during the same period. We identified clinical factors associated with an increased risk of 3.5 cm artificial urinary sphincter cuff erosion.

Results: Of the 176 men who met study inclusion criteria during the 4-year period 100 (57%) received the 3.5 cm artificial urinary sphincter cuff and 76 (43%) received a larger cuff (4.0 cm or greater). The continence rate (83% vs 80%, p = 0.65) and mean followup (32 vs 25 months, p = 0.14) were similar in the 2 groups. Erosion developed in 16 of the 176 patients (9%) during the study period, of whom 13 had the 3.5 cm cuff. Of the 100 patients with the 3.5 cm cuff 52 (52%) had a history of radiation, including 11 (21%) with erosion. Cuff erosion developed only rarely in nonirradiated men (2 of 48 or 4%, p = 0.01). A history of radiation was the only significant risk factor associated with 3.5 cm cuff erosion (OR 6.2, 95% CI 1.3–29.5).

Conclusions: Men with a history of radiation who underwent placement of a 3.5 cm artificial urinary sphincter cuff experienced an increased (21%) risk of cuff erosion.

Key Words: urinary bladder; urethra; urinary incontinence, stress; urinary sphincter, artificial; complications

Abbreviations and Acronyms

AUS = artificial urinary sphincter

SUI = stress urinary incontinence

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* Correspondence: Department of Urology, University of Texas Southwestern, 5323 Harry Hines Blvd., Dallas, Texas 75390 (telephone: 214-648-5698; FAX: 214-648-8786; e-mail: allen.morey@utsouthwestern.edu).

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‡ Financial interest and/or other relationship with Afferent and Allergan.

THE AUS, first developed more than 40 years ago, remains the gold standard treatment for men with SUI.[1] Although numerous modifications have been made to the AUS to provide better urinary continence and improved device safety, almost a third of the patients with an artificial sphincter require device revision within 5 years.[2,3] The introduction of the 3.5 cm AUS cuff in September 2009 is the most recent device enhancement.

Because patients with prostate cancer are now living longer[4] and healthier men with milder forms of incontinence are being treated with transobturator slings,[5] contemporary

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patients with an AUS often have spongiosal atrophy and a urethral circumference of less than 4.0 cm.[6] Although our initial 2011 report of the new 3.5 cm cuff demonstrated promising findings,[7] use of the smaller cuff continues to be underreported elsewhere,[8–13] possibly due to concern over an increased risk of erosion. We present an updated experience with the 3.5 cm AUS cuff including an investigation of risk factors for erosion with the smaller cuff in a tertiary care patient population.

MATERIALS AND METHODS

We reviewed a prospectively maintained, institutional review board approved database of AUS cases performed by a single surgeon from September 2009 (the date of 3.5 cm AUS cuff premarket availability) to August 2013. All patients who underwent 3.5 cm AUS cuff placement were retrospectively identified and compared to a cohort of patients who received a larger cuff (4.0 cm or greater) during the same period. Tandem cuff[2] or urethral buttressing[11] procedures were not performed during this study interval at our institution.

Evaluated patient information included age, SUI etiology, prior SUI procedures, history of tobacco use and medical comorbidities, including hypertension, diabetes mellitus and erectile dysfunction with or without implantation of a penile prosthesis. AUS candidates were evaluated preoperatively by history, pad count and physical examination with a standing cough test. Cystoscopy was performed, and flow rate and post-void residual urine volume were measured in men with a history of obstructive voiding symptoms, bladder neck obstruction, urethral stricture or prior urethral surgery, including urethroplasty or placement of an AUS or male sling. Urodynamic studies were performed in the context of mixed incontinence or persistent/recurrent SUI despite adequate cuff coaptation. Urinary continence was assessed by history at all followup examinations in the office. Patients were deemed socially continent if they used 0 or 1 pad per day.

All 3.5 cm AUS cuffs were implanted using a uniform perineal surgical approach for cuff placement. The proximal bulbar urethra was measured using the standard 3.5 to 11 cm measuring tape included in the kit. Cuff size was selected based on precise tape measurement using a push-pull technique without creating spongiosal deformity or laxity beneath the tape.[7] A 61 to 70 cm pressure regulating balloon was placed via a 2 cm upper scrotal incision, as previously described.[14] No other pressure regulating balloon type was used in this study. We selected cuff size based on the urethral measurement obtained and then rounded up or down to the nearest 0.5 cm measurement.

Patients returned to the office for device training and activation 6 weeks postoperatively. Routine followup visits were made 3 and 12 months postoperatively, and annually thereafter. At these visits continence (defined as using 0 or 1 pad per day) was assessed.

All patients who received a 3.5 cm AUS cuff were compared to those who received a larger cuff (4.0 cm or greater). Demographic and perioperative data were analyzed and compared between the groups. Patients who experienced erosion were then compared to those without erosion using the chi-square test for categorical variables and the Student t-test for continuous variables. Kaplan-Meier analysis was done to compare erosion events between patients based on cuff size and radiation history using the Cochran-Mantel-Haenszel log rank test. Logistic regression analysis was used to identify univariate predictors of erosion events after 3.5 cm AUS cuff placement. All analysis was done with SPSS®, version 19.0.

RESULTS

Demographics

During the study period we compared outcomes in 100 of 176 men (57%) who received a 3.5 cm AUS cuff to those in 76 of 176 (43%) who received a larger AUS cuff (4.0 cm or greater) (table 1). Mean age was 69.8 and 70.4 years, respectively ($p = 0.96$). Of the 76 patients with a larger cuff size 62 (82%), 11 (14%), 1 (1%) and 2 (3%) received a 4.0, 4.5, 5.0 and 5.5 cm cuff, respectively. In the 3.5 cm AUS cohort 52% of the men had a history of radiation treatment before cuff implantation while 30 of 76 (39%) had a radiation history in the 4.0 cm or greater AUS cuff cohort. Prior incontinence procedures were performed in most patients who received a 3.5 cm cuff (51 of 100 or 51%), or a 4.0 cm or greater cuff (43 of 76 or 57%). There was no difference in the rate of social continence, defined as 0 or 1 pad per day (83 patients or 83% vs 61 or 80%, $p = 0.65$), or in mean followup (32 vs 25 months, $p = 0.14$) between the groups. Of the 176 patients 146 (83%) had SUI due to radical prostatectomy,

Table 1. *Demographics and outcomes in patients with AUS by cuff size*

	No. 3.5 cm (%)	No. 4.0 cm or Greater (%)	p Value
Overall	100	76	
SUI etiology:			
Radical prostatectomy*	86 (86)	60 (79)	0.23
Pelvic crush injury	2 (2)	3 (4)	0.46
Transurethral prostatectomy	5 (5)	9 (12)	0.12
External beam radiation	3 (3)	0	0.09
Cryoablation	4 (4)	2 (3)	0.61
Other pelvic surgery	0	1 (1)	0.99
Congenital	0	1 (1)	0.99
Prior incontinence surgery:			
AUS	25 (25)	30 (40)	0.04
Male sling	19 (19)	13 (17)	0.75
AUS + male sling	7 (7)	0	0.01
Other history:			
Erectile dysfunction	80 (80)	56 (74)	0.33
Penile prosthesis	34 (34)	20 (26)	0.27
Diabetes mellitus	21 (21)	15 (20)	0.84
Coronary artery disease	12 (12)	16 (21)	0.11
Smoking	57 (57)	48 (63)	0.41

*With or without adjuvant radiation.