Long-Term Durability and Functional Outcomes Among Patients With Artificial Urinary Sphincters: A 10-Year Retrospective Review From the University of Michigan

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Purpose: The artificial urinary sphincter continues to be one of the most effective and commonly used surgical treatments for severe urinary incontinence. The long-term durability and functional outcome remains unclear. This study sought to report the artificial urinary sphincter complication rates, associated risk factors with complications, and long-term quality of life and durability.

Materials and Methods: This single institution study reports the outcomes of 124 consecutive index cases of artificial urinary sphincter from 1996 to 2006 for complications (infection, erosion, and mechanical failure). Bivariate statistics and multivariable logistic models were used to identify patient and artificial urinary sphincter characteristics associated with complications. Functional outcomes and long-term durability were assessed using a cross sectional analysis of a validated health related quality of life survey and a product limit estimates, respectively.

Results: Among the 124 male patients median followup was 6.8 years. The overall complication rate for patients undergoing an artificial urinary sphincter was 37.0%, with mechanical failure the most common cause (29), followed by erosion (10) and then infection (7). Significant differences between complications and specific patient and artificial urinary sphincter characteristics risk factors were not found. Functional outcomes appeared stable with similar mild-moderate urinary incontinence severity and 0 to 1 daily pad use at intervals of 0 to 4 years, 4 to 8 years and more than 8 years. Long-term durability was notable with 36% having complications (requiring surgical revision or removal) within 10 years and most events occurring within the first 48 months.

Conclusions: Long-term durability and functional outcomes are achievable for the AMS 800, but there are appreciable complication rates for erosion, mechanical failure and infection in the first 48 months from implantation.

Key Words: treatment outcome; quality of life; urinary sphincter, artificial

Implementation of the artificial urinary sphincter to treat urinary incontinence was first described with the AMS 721 in 1974 (American Medical Systems). Evolution of the AUS and its improvements in urinary continence came with the development of a 3-part AMS 800 device. An estimated 20,000 AUSs were implanted in men and women for the treatment of urinary incontinence since its introduction.[1,2] It remains a common surgical treatment with approximately 4,000 units implanted in 2005 and most commonly applied to post-prostatectomy incontinence.[3] Urinary incontinence remains an increasingly common urological problem, with a prevalence ranging from approximately 2.5% to 40% and an estimated annual cost to United States health care at $19.5 to $32 billion.[4–7] Moreover, urinary incontinence is a chronic urological condition that adversely affects patient hygiene, quality of life, social and emotional well-being, and mental health.[8,9]

Treatment of urinary incontinence involves pharmacological interventions, behavioral modifications and surgery. Treatment decisions are often based on quality of life considerations and relief of symptoms. The AUS remains a surgical option for patients with severe urinary incontinence, especially for those who have failed other pharmacologic and behavioral treatments. Several studies report varying treatment efficacy with decreased symptom severity and improved quality of life from urinary incontinence due to radical prostatectomy, radiation, neurogenic bladder due to spinal cord injury and stress urinary incontinence.[2,10–14] Although there is often an immediate treatment benefit from implantation of the AUS, long-term durability and functional outcomes for health related quality of life remains unclear. There has been marked variation in the complica-

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tion rates from the AUS from 3% to 40%.[2,15–17] Complications from this device have been divided into mechanical failure such as inadequate balloon pressure or blockage of tubing, infection, erosion and recurrent incontinence. Early and late complications, surgical revision, explantation and risk factors such as comorbid illnesses and previous radiation have differed, with some studies reporting associations with poor surgical outcomes from the AUS.[17,18]

In this study we evaluated the long-term outcomes of the AUS from a retrospective review of 10 years experience at a large academic tertiary medical center. We report our experience with complications, functional outcomes for health related quality of life and long-term durability with AUS. The objectives of this study were to 1) report the complication rates for mechanical failure, erosion and infection, and identify risk factors associated with these complications; 2) evaluate the long-term functional outcome for health related quality of life after AUS implantation and 3) assess the long-term durability of AUS.

METHODS

This retrospective study focused on 124 consecutive index cases of AUS performed at the University of Michigan from 1996 to 2006. After obtaining institutional review board approval, index AUS cases were identified through hospital claims data. Through electronic medical chart abstraction, data were collected for clinical information on patient sociodemographics (age at the time of procedure and race), patient comorbidities (diabetes, hypertension and vascular disease [peripheral vascular occlusive disease or coronary artery disease]), history of pelvic radiation, smoking status (current or previous smoker and nonsmoker) and preoperative urodynamics. Other study variables included indications for AUS placement (radical prostatectomy, robotic prostatectomy, TURP, neurogenic bladder and other pelvic surgery), estimated blood loss (greater than 150 vs 150 or less) and index AUS device specifics (cuff size and pump location in scrotum).

The primary surgical outcome measures in this study were to determine the overall AUS complication rates, and report functional outcomes with health related quality of life after placement of AUS and long-term durability. We defined AUS specific complications as postoperative infections, mechanical failures requiring revision and erosions requiring surgical removal. We hypothesized that older age (more than 65 years), certain comorbid conditions (diabetes), history of pelvic radiation and smoking exposure would be associated with higher rates of postoperative AUS complications.

Assessment of symptom improvement from urinary incontinence and functional outcome after placement of an AUS was measured cross-sectionally by a validated, health related quality of life instrument, that is the Incontinence Severity Index. The ISI survey has 10 item questions that focus on 2 domains of symptom severity and impairment.[19] Briefly, for symptom severity 8 items assessed patient stress incontinence, urge incontinence and pad use. The impairment aspect includes 2 items that queries patients about changes in daily activities and social anxiety as measures for adaptation and bother, respectively. The severity of urinary incontinence was categorized into 3 levels by aggregate ISI score of mild (0 to 8), moderate (9 to 20) and severe (greater than 20). Study patients completed the ISI questionnaire at the time of the study by mail or telephone.

Statistical Analysis

Bivariate statistics were examined to determine potential risk factors associated with the different types of AUS complications, erosion, mechanical failure and infection. Three multivariable logistic models were used to determine risk factors for each type of complication. Long-term functional quality of life outcomes were assessed for patients who had an index AUS who experienced no operative complications. These patients were divided into postoperative intervals of more than 4 years, 4 to 8 years and more than 8 years. Mantel-Haenszel statistics were used to assess statistically significant variation in severity of urinary incontinence as measured by the ISI. The study sample precluded further multivariable analysis for differences in ISI score. Durability of the AUS was measured as time from initial implant of the AUS to the time of the complication, mechanical failure or erosion, resulting in surgical removal or revision. Long-term durability was analyzed using product limit estimates and plotted.

RESULTS

Table 1 provides the descriptive characteristics for patient sociodemographics, comorbid illnesses, indications, estimated blood loss and AUS device specifics (cuff size and pump location). Among the 124 participants the most common indication for AUS was radical prostatectomy, followed by TURP and neurogenic bladder. Although robotic prostatectomies accounted for only 4.0% of this patient sample, it is noteworthy that robotic prostatectomies now represent the most common surgical procedure for prostate cancer at our institution.

The overall complication rate for patients undergoing an AUS was 37.0%, with mechanical failure the most common

TABLE 1. *Sociodemographic, comorbid and AUS characteristics of male patients with urinary incontinence treated with an AUS*

Mean pt age at index surgery (SD)	65.9	(11.4)
No. race (%):		
White	107	(86.3)
Black	6	(4.8)
Other	11	(8.9)
No. comorbidities (%):		
Diabetes	8	(6.5)
Hypertension	57	(46.0)
Vascular disease*	44	(35.5)
Current or prior smoker	42	(35.0)
No. preop flurourodynamics (%)	41	(33.1)
No. surgical indications for AUS placement (%):		
Open prostatectomy	98	(79.0)
TURP	12	(9.7)
Neurogenic bladder	9	(7.3)
Robotic prostatectomy	5	(4.0)
No. AUS cuff size (%):		
4.0–4.5	100	(81.3)
5.0–7.5	24	(18.7)
No. tandem cuff (%)	4	(3.2)
No. pump location (%):†		
Rt	103	(85.1)
Lt	17	(14.1)

* Vascular disease includes coronary artery disease and peripheral vascular disease.
† Four patients missing pump locations.