Low Serum Testosterone is Present in Nearly Half of Men Undergoing Artificial Urinary Sphincter Placement

Maxim J. McKibben, Jorge Fuentes, Nabeel Shakir, Joceline S. Fuchs, Boyd R. Viers, Travis J. Pagliara, Mattias D. Hofer, Jeremy Scott, and Allen F. Morey

OBJECTIVES To report the prevalence of low serum testosterone (LST) in men undergoing artificial urinary sphincter (AUS) placement at a single high-volume institution.

METHODS We retrospectively reviewed all men undergoing AUS procedures by a single surgeon from January 2015 to January 2018 to identify men with pretreatment total serum testosterone levels. LST was defined as less than 280 ng/dL. Patients with only posttreatment testosterone levels were excluded. Demographic characteristics and clinical outcomes were compared between men with and without LST.

RESULTS Among 113 patients who underwent AUS with pretreatment serum testosterone levels drawn an average of 2.2 months before AUS surgery, 45.1% (51 of 113) met criteria for LST, including 18 patients on androgen deprivation therapy. The rate of primary LST was 34.7% (33 of 95). The median total serum testosterone level among men with LST was 118 ng/dL (interquartile range 6-211), and 413 mg/dL (interquartile range 333-550) in the normal serum testosterone group. There were no differences in patient age, history of radiation, erectile dysfunction, or other comorbidities between the groups. Body mass index was higher in the LST group compared to normal serum testosterone (30 vs 27 kg/m^2, P = .001). Cuff size and rates of transcorporal cuff placement were similar between groups.

CONCLUSION Nearly one-half of men with stress urinary incontinence undergoing AUS placement present with LST. While AUS cuff erosion appears to be more common in men with LST, further study is needed to determine if treating LST will reduce cuff erosion rates. UROLOGY ■■: ■■–■■, 2018. © 2018 Elsevier Inc.

The artificial urinary sphincter (AUS) is the gold standard treatment for moderate-to-severe stress urinary incontinence (SUI) after prostatectomy, which dramatically improves quality of life in most recipients. However, AUS placement is not without risks, the most devastating of which are device infection and cuff erosion, necessitating device explant.[1] In contemporary series, rates of cuff erosion typically range from 6% to as high as 21% depending on risk factors.[2,3]

Cuff erosion risk factors that may adversely affect periurethral tissue integrity include pelvic radiation, prolonged time from prostate cancer surgery to AUS placement, urethroplasty, and prior cuff erosion.[4-6] While the majority of cuff erosion risk factors are not modifiable, we have recently demonstrated that low serum testosterone (LST) is an independent predictor of AUS cuff erosion.[7] From a mechanistic standpoint, in vivo data link LST to decreased periurethral vascularity, as well as lower levels of androgen receptors in the urethral tissue.[8] These preliminary data raise the important clinical question of whether LST may be a modifiable risk factor for AUS cuff erosion.

Although the prevalence and risk factors for LST in the general population have been well established, the prevalence of LST among men undergoing AUS implantation for SUI is currently unknown.[9] Identifying LST prior to AUS placement may prove to be an effective preemptive intervention strategy in high-risk patients. We sought to identify the prevalence of LST in our single-institution series of patients undergoing AUS; we hypothesize that this is a common, unrecognized clinical condition in this population of men that may be a risk factor for AUS cuff erosion.

METHODS

After obtaining institutional review board approval, we retrospectively reviewed the medical records of all patients

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From the Department of Urology, UT Southwestern Medical Center, Dallas, TX; the Department of Urology, Mayo Clinic, Rochester, MN; Hennipin County Medical Center, Minneapolis, MN; and the Department of Urology, Northwestern University Feinberg School of Medicine, Chicago, IL

Address correspondence to: Allen F. Morey, M.D., Department of Urology, UT Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390-9110. E-mail: allen.morey@utsouthwestern.edu

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who underwent AUS placement at our institution by a single surgeon (A.F.M.) between January 2015 and January 2018 using a uniform 2-incision technique as previously described.[2] Serum testosterone measurements were drawn in the morning and LST was defined as serum testosterone <280 ng/dL, per the reference range at the University of Texas Southwestern Medical Center clinical laboratory. All patients without serum testosterone values and those who had testosterone drawn after AUS surgery were excluded from analysis. Patients on androgen deprivation therapy (ADT) for prostate cancer treatment were included in the LST cohort.

Prior to 2015, serum testosterone levels were drawn primarily in men presenting with AUS cuff erosions at the time of explant or reimplantation. Over time, as we became aware of the possible importance of LST in patients who underwent AUS, testosterone levels were assessed in all AUS cases when feasible regardless of prior history (2015-2018). Because of the change in our collection protocol, prevalence of LST is calculated based only on the cohort from 2015 to 2018, thus should be a representative cross section of our AUS population. Patients who underwent AUS with serum testosterone collected prior to 2015 were excluded from the analysis.

Patient demographics and surgical and clinical outcomes were determined by medical record review. Cuff erosion was first identified based on patient symptoms and confirmed using cystoscopy and during surgical explant. Continuous variables were compared with the Mann-Whitney *U* test. Categorical variables were compared with Fisher's exact test. All analyses were performed in SAS JMP 13.0 (SAS Institute, Cary, NC).

RESULTS

Patient Demographics and Testosterone Levels in AUS Patients (2015-2018)

Serum testosterone levels drawn an average of 2.2 months prior to AUS placement were available for 113 patients who underwent AUS. Of the 113 patients analyzed, 51 met criteria for LST (45.1%). Overall median serum testosterone was 296.5 mg/dL among all patients who underwent AUS, with a median of 118.6 mg/dL (interquartile range [IQR] 6-211) in the LST cohort, and 413.0 mg/dL (IQR 333-550, P <.0001) in normal serum testosterone (NST) patients. Of 51 LST patients, 18 were on ADT for prostate cancer, thus 34.7% of patients (33 of 95) had primary LST.

Patients with LST had a higher average body mass index (30 kg/m^2, IQR 27-33) than those patients with NST (27 kg/m^2, IQR 24-30). There were no differences in patient age, history of radiation, time from cancer treatment, erectile dysfunction, smoking history, or other comorbidities between patients who underwent AUS with LST and those with NST levels. (Table 1). The size of AUS cuffs used did not differ between the 2 groups, with the majority of patients in each group receiving either the 3.5 cm or 4.0 cm cuff (82% in LST, 71% in NST, P = .2). Rates of transcorporal cuff placement were consistent between LST and NST groups as well (9% vs 10%, respectively. P = .9). Rates of AUS cuff erosion were consistent between the LST and NST groups (6% vs 8%, respectively; P = .7).

Table 1. Patient demographics and AUS cuff characteristics of 2015-2018 cohort

	LST (N = 51)	NST (N = 62)	*P* value
Age, y	71 (66-76)	73 (68-79)	.4
BMI, kg/m^2	30 (27-33)	27 (24-30)	**.001**
Prior ADT, no. (%)	18 (35%)	0	**<.0001**
Serum testosterone, ng/dL	118 (6-211)	413 (333-550)	**<.0001**
ED, no. (%)	35 (70%)	43 (70%)	.9
Prior IPP, no. (%)	8 (16%)	6 (10%)	.4
Radiation, no. (%)	26 (52%)	28 (46%)	.6
CAD, no. (%)	11 (22%)	7 (11%)	.2
DM, no. (%)	14 (28%)	11 (18%)	.3
HTN, no. (%)	33 (66%)	39 (64%)	.8
Smoking, no. (%)	26 (51%)	31 (50%)	.9
Cuff size, no. (%)			
3.5 cm	13 (25%)	18 (29%)	.2
4.0 cm	29 (57%)	26 (42%)	
4.5 cm	4 (8%)	13 (21%)	
5.0 cm	0	1 (2%)	.2
5.5 cm	2 (4%)	2 (3%)	.9
Unknown	3 (6%)	2 (3%)	
Transcorporal, no. (%)	4 (9%)	6 (10%)	
Erosion, no. (%)	3 (6%)	5 (8%)	.7

ADT, androgen deprivation therapy; AUS, artificial urinary sphincter; BMI, body mass index; CAD, coronary artery disease; DM, diabetes mellitus; EP, erectile dysfunction; HIN, hypertension; IPP, inflatable penile prosthesis; LST, low serum testosterone; NST, normal serum testosterone.
Bold values denote statistical significance (*P* values <.05).

DISCUSSION

The present study highlights the prevalence of LST in men undergoing AUS implantation, which may be an unrecognized risk factor for AUS cuff erosion. In our series, nearly half (45.1%) of patients who underwent AUS had LST (total testosterone <280 ng/dL), about a third of whom were on ADT for prostate cancer. Our prior work suggests that LST is independently associated with AUS cuff erosion, even after controlling for radiation history.[7] To our knowledge, this is the first study evaluating the prevalence of LST in the AUS population. With emerging evidence supporting LST as a risk factor for AUS cuff erosion, this high rate of LST should prompt further study.

LST Demographics and Symptoms

A recent community survey found a 27% prevalence of LST in randomly selected men between the age of 70 and 79.[10] The prevalence of LST in our cohort was 45.1%, partially due to "enrichment" by those on ADT for prostate cancer. However, this likely represents a true prevalence of LST for AUS patients, as ADT is commonly a lifelong reality for many patients with prostate cancer. Additionally,

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