Use of flexible cystoscopy at time of artificial urinary sphincter placement

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Introduction: *Artificial urinary sphincters (AUS) are used to treat significant urinary incontinence. Flexible cystoscopy at the time of AUS placement provides relevant intraoperative feedback including confirmation that the AUS is functioning, visualization of coaptation, and evaluation for urethral injury. Current guidelines for placement of an AUS do not include flexible cystoscopy. The objective was to evaluate whether flexible cystoscopy at time of AUS placement changed cuff size at the time of surgery.*

Materials and methods: *A retrospective cohort study was performed to evaluate all patients undergoing AUS placement by a single surgeon between March 2013 and March 2017. The primary endpoint of the study was change in cuff size based on cystoscopy.*

Results: *A total of 109 AUS were placed in 96 patients. In five (4.6%) cases flexible cystoscopy identified a lack of coaptation of the urethra despite appropriate sizing which resulted in down-sizing of the cuff. Five patients were identified as having a bladder neck contracture that was previously unrecognized as clinic cystoscopy was performed by the referring urologist and was reportedly normal. Three patients developed postoperative infections, two of these patients had a history of multiple AUS placement and revisions and the third patient had a history of cystectomy and neobladder.*

Conclusions: *Flexible cystoscopy at time of AUS placement changed the cuff size in nearly 5% of cases. Flexible cystoscopy at time of AUS placement provides valuable feedback and should be recommended for low volume prosthetic surgeons.*

Key Words: AUS, cystoscopy, artificial urinary sphincter, incontinence

Introduction

Urinary incontinence impacts up to 32% of men in the United States.[1,2] The most common etiology of significant urinary incontinence is post-surgical, particularly following radical prostatectomy, cystectomy with neobladder creation, transurethral resection of the prostate (TURP), and holmium laser enucleation of the prostate (HoLEP). Management of urinary incontinence depends on the severity of symptoms and includes pads for minimal incontinence, midurethral slings for moderate incontinence, and artificial urinary sphincters (AUS) for severe urinary incontinence.

Artificial urinary sphincters have been used over the past 45 years as an option for management of severe urinary incontinence with studies reporting that the majority of patients use 0-1 pads per day after AUS placement compared with preoperative pad use of 5 or more pads.[3-8] At the time of insertion of the AUS, the urethral cuff is measured and placed based on the outer diameter of the urethra. Flexible cystoscopy is optional to confirm that the AUS is functioning without a cuff leak, visualize appropriate coaptation of the urethra, and to ensure no injury to the urethra occurred during prosthetic placement. Based on American Board of Urology case reports from 2003 to 2013, the median number of AUS placed was one annually.[9] Recognizing that the majority of AUS placement occurs by low volume surgeons, we sought to evaluate whether flexible cystoscopy at time of AUS placement changed cuff size at the time of surgery.

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Materials and methods

A retrospective cohort study was performed to identify all adult male patients who underwent placement of an American Medical Systems (AMS) 800 device (Minneapolis, MN, USA) (now Boston Scientific AMS 800) between March 2013 and March 2017 by a single surgeon. All surgeries were performed for urinary incontinence and patients were included regardless of whether the surgery represented the initial device placement or a removal and replacement. Flexible cystoscopy was performed prior to incision closure to evaluate the urethra in all cases. All patients are sent home on 2 weeks of antibiotics after surgery.

The primary outcome of the study was change in cuff size based on intraoperative flexible cystoscopy. Variables collected included demographics, prior urologic surgeries, history of AUS placement, and details specific to the current procedure including cuff size, need for cuff revision at time of surgery, postoperative infection, and follow up. Patient characteristics were described for the individual patients (n = 96) but surgical characteristics were described when considering each urethra that was operated upon (n = 109).

Descriptive statistical analysis was undertaken to evaluate patients undergoing AUS placement. Fishers exact test was used to compare differences among categorical variables with $p < 0.05$ set a priori as the level of statistical significance. IRB exempt status approval was obtained for the conduct of the study.

Results

During the study period, 109 artificial urinary sphincters were placed in a total of 96 patients. Descriptive statistics are shown in Tables 1 and 2. Eleven patients underwent removal and replacement of an AUS and one patient underwent removal and replacement twice.

TABLE 2. **Characteristics of artificial urinary sphincter surgeries (n = 109)**

	n (%)
Concurrent IPP placement	13 (11.9%)
Revision procedure	56 (51.4%)
Urethral injury	0 (0%)
Median cuff size (range), cm	4 (3.5-5.5)
Placement of two simultaneous cuffs	12 (11.0%)
Transcorporal cuff placement	14 (12.8%)
Post-op infection	3 (2.8%)
Urethral erosion	0 (0%)
Median pads per day at follow up (IQR)	0 (0-1)
Median follow up (IQR), months	22 (12-30)
Median pads per day at follow up (IQR)	0 (0-1)

Of the 96 individual patients, 29% had a history of radiation and all had prior urologic surgery. Eighty-four previously underwent radical prostatectomy, 47 had a prior AUS, 9 had prior urinary diversion with neobladder or monti-channel, and 3 had either HoLEP or TURP, Table 1.

Intraoperative flexible cystoscopy identified five (4.6%) cases in which the AUS cuff did not adequately coapt, necessitating down-sizing of the urethral cuff, Table 3. There was no difference in this occurring between patients with a prior AUS and primary AUS placement (n = 2/52 prior AUS versus n = 3/57 primary AUS; p = 0.544). Additionally, there was no difference in patients with transcoporal cuff placement (p = 0.504) or history of radiation (p = 0.999), Table 3. In each of these cases, the cuff was down-sized by 0.5 cm. There were no urethral injuries noted. Five patients were identified to have a bladder neck contracture at time of surgery during flexible cystoscopy, Table 2. Each of these patients

TABLE 1. **Characteristics of patients undergoing artificial urinary sphincter placement (n = 96)**

	n (%)
Mean age (SD), years	67.3 (11.8)
History of radiation	28 (29.2%)
Prior surgery	
Radical prostatectomy	84 (87.5%)
Artificial urinary sphincter	47 (49.0%)
Urinary diversion (monti, neobladder)	9 (9.4%)
Holmium laser enucleation of the prostate/transurethral resection of the prostate	3 (2.8%)

TABLE 3. **Description of the five patients requiring AUS cuff downsizing**

Patient	Age	Prior prostectomy	Revision surgery	History of size radiation	Initial cuff size	Final cuff size	Double cuff	Transcorporal cuff placement	Wound infection	Pads per day
1	76	Yes	Yes	Yes	5.5	5	No	Yes	No	0
2	64	Yes	Yes	No	4.5	4	No	No	No	1
3	67	Yes	Yes	No	5	4.5	No	No	No	0
4	60	No	No	No	4.5	4	No	No	No	0
5	63	Yes	Yes	No	4.5	4	Yes	No	No	0

had their preoperative clinic cystoscopy performed by referring physicians. These patients underwent dilation of the contracture intraoperatively without post-operative sequelae. None required a change in AUS cuff size. Three patients in the cohort developed postoperative infections, two of these patients had a history of multiple AUS placement and revisions and the third patient had a history of cystectomy and neobladder. Median follow up for the cohort was 22 months. Mean (SD) pads per day at follow up was 0.68 (1.13).

Discussion

Intraoperative flexible cystoscopy prompted cuff changes in 4.6% of patients undergoing AUS placement by a high volume, experienced prosthetic surgeon. Performing flexible cystoscopy provides an opportunity to confirm a functioning cuff, appropriate coaptation, and identify urethral injury. The added time to the case is minimal and, in our practice, provides valuable feedback for the urologist at the time of surgery.

In the current study, nearly half of the patients were undergoing revision AUS placement. Prior studies have suggested that anywhere from 21% to 32% of patients will require revision surgery within the first few years of surgery.[10-13] These patients are more complicated surgically due to scar tissue from the initial AUS placement. We reported that there was no difference in the proportion of patients undergoing primary versus revision AUS placement that required a change in cuff size based on flexible cystoscopy. This may be related to urethral characteristics or small numbers.

While overall social continence was excellent, Kaiho et al reported that there is a deterioration in urinary continence within the first year after AUS placement.[5] Similarly, Viers et al reported decreased continence following surgery which was worse in the greater than 10 years compared with less than 5 years after surgery cohorts.[14] The etiology of this deterioration is poorly understood but has been proposed to be potentially related to edema from the surgery falsely improving results in the immediate postoperative period.[5] Collado Serra et al has proposed using a bulbocavernosus muscle sparing approach which may decrease the edema and help prevent urethral erosion.[15] Whether flexible cystoscopy at the time of surgery may have led to better cuff selection is unclear, but we theorize that optimal cuff size placement as confirmed by flexible cystoscopy could prevent some early deterioration of continence.

Urethral erosion occurs in up to 12% of patients following AUS placement.[3,6,7,16] It is proposed that early urethral erosion occurs secondary to unrecognized injuries to the urethra during AUS placement.[3] In the majority of cohorts, urethral erosion rates do not differ between radiation and no radiation cohorts[6,17] or in primary versus revision AUS cases.[7] No patients in the current cohort were identified as having a urethral erosion during the study period.

The mechanics of occluding the urethra using a device such as the AMS 800 are complicated. Attempts at modeling have been made with varying success.[18-21] A three dimensional model was recently proposed by Natali et al which attempted to characterize different phases of urethral occlusion and to determine whether the conformation of the cuff could be changed to accommodate urethral differences.[19] One of the challenges of studying urethral occlusion is incorporating the impact of prior urethral procedures leading to fibrosis. We propose that performing flexible cystoscopy after cuff placement offers the surgeon an opportunity to evaluate the coaptation of the urethra from the cuff prior to concluding the procedure. In our study, nearly 5% of cases underwent revision of the cuff at the time of surgery to provide better coaptation.

According to the American Board of Urology Case Numbers for 2004-2010, of urologists performing AUS placement, the median number of AUSs placed annually was two and less than 4% placed ten or more

AUS annually.[22] Examining the data from 2003-2013, Liu et al reported that the median number of AUSs placed annually was one, suggesting that the majority of urologists are not increasing their placement of AUSs.[9] Yafi et al used the AMS database and reported that being a high volume surgeon, defined as 10 or more AUS annually, was protective against cuff erosion (HR 0.730, p = 0.001) and that it approached statistical significance for protecting against needing a pump revision (HR 0.923, p = 0.079).[13] Eighty-three percent of the surgeries in the Yafi et al study were performed by low volume surgeons. Should Yafi et al had used a different cut off for high volume surgeon, the results may have been more dramatic. Given that the majority of AUS implantations are being performed by surgeons performing two or less cases annually, all safeguards to ensure patient safety should be encouraged.

There are multiple limitations worth considering in the current study. This is a retrospective study and therefore subject to biases from its retrospective nature. Nearly half of the cohort was composed of revision surgeries and half of the cohort previously underwent radiation, both of which make the population a more challenging surgical cohort. We do not routinely use validated questionnaires in follow up, so are only able to present pad per day outcomes for continence. However, this large cohort of AUS patients, both straightforward and complicated, offers a unique opportunity to examine the role of cystoscopy at time of AUS placement by a high volume prosthetic surgeon.

Conclusions

Performing flexible cystoscopy to evaluate urethral cuff placement during placement of an AUS led to a change in cuff size in nearly 5% of AUS placements by a high volume prosthetic surgeon. Given the fact that the majority of AUS placements are performed by low volume urologists, there may be a role in recommending flexible cystoscopy at time of placement to ensure appropriate urethral copatation and to confirm no injury to the urethra. □

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