Difference between Urethral Circumference and Artificial Urinary Sphincter Cuff Size, and its Effect on Postoperative Incontinence

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Abbreviations and Acronyms

ΔC = difference between implanted AUS cuff size and measured urethral circumference

ALPP = abdominal leak point pressure

AUS = artificial urinary sphincter

BMI = body mass index

RRP = radical retropubic prostatectomy

TURP = transurethral prostate resection

XRT = external beam radiation therapy

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Purpose: We assessed whether a difference between intraoperative urethral circumference and artificial urinary sphincter cuff size affects postoperative outcomes.

Materials and Methods: We evaluated the medical records of 87 males who underwent implantation of an artificial urinary sphincter between January 2006 and May 2010. A validated questionnaire was completed by 59 patients for long-term followup. The difference between urethral circumference and artificial urinary sphincter cuff size was calculated. Incontinence was recorded as daily pad use. The primary outcome variable was the postoperative decrease in incontinence. Multivariable linear regression was used to model the effect on postoperative incontinence of the difference between urethral circumference and cuff size.

Results: Mean long-term followup was 4.2 years. Median preoperative incontinence was 8 pads per day and median abdominal leak point pressure was 50 cm H_2O. Median urethral circumference was 38 mm and the median difference between urethral circumference and artificial urinary sphincter cuff size was 2.5 mm. Median postoperative incontinence was 1 pad per day. A 1 mm increase in the difference between urethral circumference and cuff size resulted in a 1.6% increase in incontinence by 4.5 months postoperatively (95% CI −3.1–6.2, p = 0.487). Paradoxically, each 1 mm increase improved postoperative continence at long-term followup by 29% (95% CI −15–56, p = 0.162).

Conclusions: At 4.5-month followup there was no statistical difference in pad use or patient satisfaction when the difference between urethral circumference and artificial urinary sphincter cuff size was less than 4 mm vs 4 mm or greater. However, at long-term followup the 4 mm or greater group reported statistically significantly better continence and satisfaction than the less than 4 mm group. This study does not support efforts to improve continence by minimizing cuff size but rather suggests that modestly up-sizing the cuff may produce improved long-term outcomes.

Key Words: urethra; urinary incontinence; urinary sphincter, artificial; male; outcome and process assessment (health care)

Introduced in 1972, the AUS has emerged as the gold standard treatment for male urinary incontinence secondary to intrinsic sphincter deficiency.[1] The AUS has demonstrated long-term efficacy and durability,[2]

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and can be applied to multiple clinical scenarios, including post-prostatectomy incontinence. The most widely implanted AUS device is the AMS 800™ with a urethral cuff that is individually chosen according to measured urethral circumference. There are no standardized methods to size the urethra or choose the appropriate cuff size, although they were proposed.[3,4] However, it is generally accepted that too small a cuff may predispose to urethral erosion or atrophy, while too large a cuff may result in inadequate urethral coaptation and subsequent ongoing incontinence.

Few groups have analyzed the association between cuff size and postoperative incontinence or complications. A retrospective study showed that men with a larger cuff size (5.0 to 7.0 cm) had a lower percent of using 2 or more pads per day compared to men with a cuff size of less than 5 cm at a median followup of 6.8 years (9.1% vs 20.5%, $p = 0.07$).[5] In addition, AUS cuff size did not significantly affect the complication risk. In another retrospective study in 67 men a group evaluated the impact of the introduction of the 3.5 cm cuff size on primary and revision surgery after repeatedly observing that loose AUS cuffs led to worse postoperative incontinence.[3] In this study a similar proportion of men with a 3.5 cm vs a larger cuff (4 of 45 vs 2 of 22) required explantation due to infection and/or erosion at a mean 12-month followup. Therefore, the literature paradoxically supports larger and smaller cuff sizes for optimal outcomes. Moreover, there is limited knowledge about the actual relationship between cuff size and urethral circumference, and its impact on outcomes.

Groups have discussed cuff size but to our knowledge have not addressed the relationship between cuff size and urethral circumference. What effect does placing a cuff tightly vs loosely around the urethra have on outcomes? We addressed this question by assessing the association of the difference between urethral circumference and the chosen cuff size, and its effect on postoperative incontinence.

MATERIALS AND METHODS

The Vanderbilt institutional review board approved this retrospective study. We reviewed the medical records of all male patients who underwent AUS implantation at Vanderbilt University Medical Center between January 2006 and May 2010. Study exclusion criteria included less than 3 months of followup after AUS activation, neurogenic bladder since detrusor overactivity could significantly affect postoperative incontinence, tandem cuff placement to eliminate any effect of the interaction between the 2 cuffs or transcorporeal cuff placement.

All patients underwent a standardized urological evaluation, including history, physical examination, urodynamics and cystoscopy. Patient data were collected from the initial evaluation, intraoperative findings, postoperative clinic visits and validated questionnaire survey results. Preoperative incontinence, ALPP, BMI, intraoperative measured urethral circumference, implanted AUS cuff size, postoperative incontinence 3 months after AUS activation and questionnaire results were compared. Incontinence was recorded as self-reported daily pad use, including light (light pad, liner, thin or small), medium (no further description) or heavy (descriptive term such as heavy or diaper). ΔC is reported in mm. Outcomes were defined as socially continent (0 or 1 pads per day) or incontinent (2 or more pads per day).

The AUS was implanted using a standard midline perineal approach with cuff placement at the proximal portion of the bulbospongiosum. All cuffs were placed over the bulbospongiosum muscles, preserving the muscle complex. Urethral circumference at the proposed cuff site was measured intraoperatively using the graduated silicone tape provided in the AMS 800 accessory kit, such that the tape fit around the urethra without forming a waist with a 12Fr Foley catheter in place. This was done using the push-pull measurement technique previously described in the literature.[3] AUS cuff size was chosen by rounding up from the measured urethral circumference. After introducing the 3.5 cm cuff 1 patient with a less than 3.5 cm measured urethral circumference was implanted with a 3.5 cm cuff. The 61 to 70 cm water pressure regulating balloon used in all cases was placed in the prevesical space and the pump was placed in a dependent subdartos pouch in the scrotum. No patient received a low pressure reservoir.

Patient followup involved a clinic visit at 2 weeks, and a visit at 6 weeks for device activation and at 4.5 months (3 months after activation). Long-term followup was obtained through a questionnaire survey done in September 2012. Mean followup was 4.2 years (range 2.5 to 6.3). The survey included questions on AUS device modifications (revision, replacement and removal), the current number and size of pads, and validated questions on overall satisfaction with AUS placement. The questionnaire also included 2 validated scales to assess urinary incontinence severity, that is the Revised Urinary Incontinence Scale (RUIS) and Incontinence Severity Index (ISI) scale.[6,7]

Long-term incontinence severity was evaluated with a validated 2-item ISI scale incorporating incontinence frequency and volume. An index value of 1 to 12 was obtained by multiplying the responses, including score 1 to 2—mild or slight, 3 to 6—moderate, 8 or 9—severe and 10 to 12—very severe incontinence.[7] The index was validated against a 48-hour pad weight test in which incontinence severity was correlated with mean pad weight (95% CI).[7] Although the ISI was validated in a female population, the scale was used previously in men with lower urinary tract symptoms.[8,9]

Descriptive statistics are shown as the median and range or mean ± SD for continuous variables and the number and percent for categorical variables. The Wilcoxon rank sum and Pearson chi-square tests were used to compare the groups with ΔC less than 4 and 4 mm or greater. A multivariable linear regression model was fit to assess the association between ΔC and the