Does Pressure Regulating Balloon Location Make a Difference in Functional Outcomes of Artificial Urinary Sphincter?

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Abbreviations and Acronyms

AUS = artificial urinary sphincter
BMI = body mass index
HSM = high submuscular
IPP = inflatable penile prosthesis
PRB = pressure regulating balloon
SOR = space of Retzius
SUI = stress urinary incontinence

Accepted for publication January 27, 2015.
Study received institutional review board approval.

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† Financial interest and/or other relationship with American Medical Systems and Coloplast.

Purpose: We compared functional outcomes in patients who received an artificial urinary sphincter in the space of Retzius vs the same device placed at a high submuscular location.

Materials and Methods: We reviewed a prospectively maintained database of patients who received an artificial urinary sphincter between July 2007 and December 2014. After cuff placement was completed via a perineal incision, a 61 to 70 cm H_2O pressure regulating balloon was placed through a separate high scrotal incision in the space of Retzius or in a high submuscular tunnel. Demographics, perioperative comorbidities and functional outcomes were compared between the groups.

Results: A total of 294 consecutive patients underwent artificial urinary sphincter placement. Mean followup was 23 months. Space of Retzius and high submuscular placement was performed in 140 (48%) and 154 patients (52%), respectively. Functional outcomes were similar between the groups, including the continence rate (defined as 0 or 1 pad daily) in 81% vs 88% ($p = 0.11$), the erosion rate in 9% vs 8% ($p = 0.66$) and the explantation rate in 10% vs 11% ($p = 0.62$). Artificial urinary sphincter revision for persistent incontinence was required in a similar proportion of the 2 groups (13% vs 8%, $p = 0.16$) with a comparable mean followup (24 vs 23 months, $p = 0.30$). Kaplan-Meier analysis revealed no difference between the groups in the rate of explantation ($p = 0.70$) or revision ($p = 0.06$).

Conclusions: High submuscular placement of a pressure regulating balloon at artificial urinary sphincter surgery is a safe, effective alternative with functional outcomes equivalent to those of traditional placement in the space of Retzius.

Key Words: urinary bladder; urinary sphincter, artificial; urinary incontinence, stress; rectus abdominis; outcome and process assessment (health care)

The AUS remains the gold standard treatment for male SUI. Although the AUS has evolved from its original description more than 40 years ago,[1] its basic function as a fluid filled cuff that maintains urethral coaptation by saline from an abdominal reservoir or PRB has remained the same. The PRB has traditionally been placed in the retropubic SOR as performed by puncture through the transversalis fascia. However, complications may result because of proximity to surrounding blood vessels and organs.[2–16] Furthermore, prior pelvic surgery, such as robotic radical prostatectomy, scarring or complete obliteration of the SOR, increases the technical difficulty of PRB placement.[17]

0022-5347/15/1941-0202/0
THE JOURNAL OF UROLOGY®
© 2015 by American Urological Association Education and Research, Inc.
http://dx.doi.org/10.1016/j.juro.2015.01.115
Vol. 194, 202-206, July 2015
Printed in U.S.A.

We recently reported a novel technique for HSM placement of the AUS PRB beneath the rectus abdominis.[18] However, concern has been raised about the potential effects of chronic increased pressure on the PRB at that location (J. Mulcahy, personal communication). In the current study we report our longitudinal experience with the HSM technique of PRB placement and compare functional outcomes to those of traditional PRB placement in the SOR.

MATERIALS AND METHODS

Patient Selection

We reviewed a prospectively maintained, institutional review board approved AUS database from July 2007 to December 2014. A consecutive series of men who underwent AUS implantation within this time frame were included in analysis. Patients treated with HSM placement of the PRB were identified and compared to a cohort of patients in whom traditional SOR placement was performed. Patients with less than 3 months of followup were excluded from study but no patient with a complication was excluded regardless of followup duration. Followup of SOR cases was truncated to a maximum of 24 months. We recorded demographic information, including patient age, any prior SUI procedure, history of tobacco use, and history of radiation and medical comorbidities, including hypertension, diabetes mellitus, coronary artery disease, BMI and erectile dysfunction with or without penile prosthesis implantation.

AUS candidates were evaluated preoperatively by history, pad count and physical examination with a standing cough test. Uroflowmetry and cystoscopy were performed in men with a history of obstructive voiding symptoms, bladder neck obstruction, urethral stricture or prior urethral surgery, including urethroplasty, or placement of a prior AUS or male sling. Urodynamics were performed in the context of mixed incontinence or persistent/recurrent SUI despite adequate cuff coaptation.

Patients who underwent HSM placement of the PRB were counseled on the possibility of device palpability before AUS implantation. Each patient underwent perineal cuff placement before PRB placement and received a 61 to 70 cm H_2O balloon filled with 24 cc injectable saline. Patients returned to the office for device training and activation at 6 weeks postoperatively. Routine followup visits were made 3 and 12 months postoperatively, and annually thereafter. Continence was assessed at each followup appointment and defined as using 0 or 1 pad per day.

PRB Placement Technique

All AUS PRBs were placed in the SOR or at a HSM location beneath the rectus abdominis muscle using an upper scrotal counter-incision after perineal cuff placement. In patients with HSM placement a long submuscular tunnel was created intraoperatively using a Foerster lung grasping clamp (Scanlan International, St. Paul, Minnesota) as previously described.[18] SOR placement was done in standard fashion with the transversalis perforated by face-lift scissors at the level of the external inguinal ring through a similar 2 cm upper scrotal counter-incision.

Statistical Analysis

Demographic and perioperative data on all men treated with SOR vs HSM PRB placement were tabulated in Excel® and analyzed with SPSS®, version 19.0. The 2 groups were compared in regard to continence and erosion rates, need for revision or explantation and time to revision or explantation. One-way ANOVA was used to compare continuous variables and the Fisher exact test was used for categorical variables. All reported p values are 2-sided with statistical significance considered at $p < 0.05$.

RESULTS

During the study period 294 consecutive men with a mean age of 70.0 years (range 31 to 90) underwent AUS placement. Mean followup was 23 months. Ten patients were excluded from analysis due to less than 3-month followup. SOR and HSM placement was performed in 140 (48%) and 154 patients (52%), respectively. More patients in the HSM group had diabetes (13% vs 22%, $p = 0.04$). Otherwise we noted no significant difference between the groups in mean age ($p = 0.73$), BMI ($p = 0.23$), hypertension ($p = 0.20$), coronary artery disease ($p = 0.57$), erectile dysfunction ($p = 0.11$), smoking history ($p = 0.37$), penile prosthesis placement ($p = 0.20$), cuff size ($p = 0.20$), prior AUS/sling procedure ($p = 0.97$) or prior radiation ($p = 0.23$, see table).

In the SOR and HSM groups we noted equivalent continence rates (113 of 140 patients or 81% vs 135 of 154 or 88%, $p = 0.11$) and a similar revision rate overall (18 or 13% vs 12 or 8%, $p = 0.16$, see table). Overall erosion rates did not significantly differ between the groups (13 of 140 patients or 9% vs 12 of 154 or 8%, $p = 0.66$). Mean followup was comparable (24 vs 23 months, $p = 0.30$). Kaplan-Meier analysis revealed no significant difference between the groups in explantation and revision rates ($p = 0.70$ and 0.06, respectively, see figure).

No patient experienced bowel or vascular injury. In 1 patient with SOR placement the bladder spontaneously ruptured due to inability to operate the AUS device secondary to progressive dementia. No patient in the HSM group experienced bladder or visceral organ injury. Although the PRB did not migrate in any patient with HSM placement, PRB inguinal herniation developed in 1 patient with SOR placement.

DISCUSSION

Our initial experience with HSM placement of the PRB during AUS and/or IPP implantation offered

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