The Role of Urethral Ligation with Suprapubic Tube Placement in the Treatment of Refractory Stress Urinary Incontinence

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Introduction

The persistence of stress urinary incontinence (SUI) in adults carries physical, financial, and psychosocial ramifications for those unfortunate individuals. SUI in adult males is most commonly caused by prostate surgery, but can also be secondary to spinal cord injury and disease or medications. A population-based study of more than 25,000 individuals who underwent radical prostatectomy reported that 5% of patients will undergo surgical intervention for urinary incontinence in the following 15 years.[1] This intervention for incontinence took place at a median of 2.9 years following the radical prostatectomy. Other surgical manipulations of the prostate have reported varying levels of SUI thereafter: 5.4% in holmium enucleation of the prostate[2]; <0.5% in transurethral resection of the prostate[3]; and up to 8% in simple open prostatectomy.[4] SUI is also a common problem for individuals with spinal cord disease or following spinal cord surgery. A study of young adults with spina bifida identified a 60.9% rate of urinary incontinence.[5] Medications make up the third major category of causes contributing to SUI. The most commonly implicated medications include $alpha_1$ antagonists due to their effect in decreasing urethral sphincter tone, but other drugs have been shown to have this effect as well.[6-8]

Various surgical treatments are available for these adults with SUI. While transurethral bulking agents and perineal slings may be effective in some patients, the artificial urinary sphincter (AUS) remains the gold standard of treatment.[9] In a side-by-side comparison of AUS and sling procedures, one study of 179 patients with moderate SUI identified a significantly higher success rate in those treated with AUS (80%) to those treated with a sling procedure (63%).[10] It is important to note, however, that the success rate of these procedures is often dependent upon the studies' definitions of success. One study of 309 men who underwent AUS placements found that 87% of respondents felt "much better" after the AUS placement, but only 15% reported zero pad use.[11]

While AUS placement appears to be the next step-up in treatment for patients with SUI, it is not without its share of morbidity implications. It has been documented that around 50% of patients with an AUS will require a revision operation due to cuff erosion or mechanical failure.[12,13] Furthermore, continual AUS erosion and revision can only carry-on for so long before the fragility of the urethra prevents any further renovation. Many patients in this position, deemed end-stage urethra (ESU), have numerous comorbidities or are advanced enough in age that they are poor surgical candidates for more invasive formal urinary diversion.[14] In this subset of patients with refractory SUI, very few surgical options remain.

Van Dyke *et. al.* have demonstrated the possibility of treating this patient population with permanent urethral ligation (PUL) and suprapubic tube (SPT) placement.[15,16] Their case series has demonstrated continence in 90% of the 20 patients treated via this approach, while also showing moderate rates of post-operative complications (55.5%). The purpose of this single-center study is to provide our experience with and approach to refractory SUI with PUL and SPT placement, in hopes of contributing to the limited body of research surrounding this effective approach.

Methods

Patient Selection

All patients undergoing PUL with SPT placement from 01/01/2018 to 04/30/2022 were identified from an institutional database. Institutional Review Board exempt status was granted for the conduct of this study. Urethral ligation with SPT placement was performed by MJ Mellon.

Preoperative evaluation, surgical technique, and postoperative management
The benefits, risks, and alternatives of this procedure were discussed with all patients prior to the operation and informed consent for all aspects of the procedure were obtained.

After the induction of anesthesia, patients were placed in the lithotomy position with the abdomen and perineum prepped and draped in the standard fashion. A cystoscope was inserted up to the level of the cuff, which would oftentimes show AUS cuff erosion. A perineal incision above the anus and below the scrotal verge was made and dissected down onto the AUS. The cuffs were removed in their entirety. A small counter-incision was made in the infrapubic space, and dissected down until the connecting tubing and reservoir were visualized; these pieces were subsequently removed as well. If there was concern for or evidence of infection or frank purulence, the wounds were adequately cleaned and irrigated. Cystostomy was then performed in the standard fashion, with placement of a SPT that was adequately secured. Attention was then returned to the urethra. The urethra was divided at the proximal cuff, and typically 2 to 3 cm of bulbar urethra was resected back until healthy tissue was exposed. The urethra was closed here and imbricated upon itself with multiple layers of 3-0 Vicryl, closing the bulbocavernosus muscle over top of the stump of the urethra as well in this area. The remaining wounds were copiously irrigated and closed appropriately.

Postoperatively, patients were typically seen back in clinic one month following surgery. If there were any concerns of incontinence, a retrograde urethrogram via the SPT was performed. If no concerns were present at the monthly visit, patients were seen again at a 1-year mark following their operation. Continence was assessed at both visits.

Statistical analysis
Descriptive statistics were used to evaluate patients undergoing permanent urethral ligation with SPT placement.

Results

Seven patients met criteria and were included in our study. Patients had a mean age (SD) of 69 ± 14.6 years at the time of surgery. All patients that underwent PUL with SPT placement had comorbidities: diabetes (43%), hypertension (57%), coronary artery disease (29%), and heart failure (43%) were the most common (**Table 1**). The majority of patients had SUI following prostate surgery. One of the seven patients had SUI secondary to myelomeningocele. All patients had previously had an AUS placed, and two patients had a urethral sling previously placed.

Table 1 Patient Characteristics

	n=7
Demographics	
Mean age at surgery, years (SD)	69 ± 14.6

Mean BMI, kg/m^2 (SD)	30.1 ± 5.3
Medium ASA (range)	3 (3-4)
Diabetes, no. (%)	3 (43)
Hypertension, no. (%)	4 (57)
Coronary artery disease, no. (%)	2 (29)
Heart Failure, no. (%)	3 (43)
Myelomeningocele, no. (%)	1 (14)
Etiology of Incontinence	
Radical Prostatectomy, no (%)	6 (86)
Radiation Therapy, no. (%)	1 (14)
BPH Surgery no. (%)	
Spinal Cord injury or disease, no. (%)	1 (14)
Prior Urethral Surgeries	
AUS Surgery, no. (%)	7 (100)
Number of AUS Placements, average (range)	2 (1-3)
Urethral Slings, no. (%)	2 (29%)

The median operative time was 70 minutes (interquartile range [IQR]: 62-90). Median estimated blood loss was 20 mL (IQR: 2.5-27.5). The majority of cases were performed in the outpatient setting and did not require any hospitalization. Only 1 of the 7 cases required hospitalization, and was only there for a single day. Postoperatively, only 1 patient has had no complications as of their most recent follow-up. Three patients had bladder spasms, 1 patient had bladder/kidney stones, and 1 patient had a urinary tract infection requiring hospitalization. Of the 7 patients, 5 have reported continence at their most recent follow-up (**Table 2**). One patient has continued leakage and is awaiting a retrograde urethrogram. The final patient has not presented yet to their follow-up appointment due to the recency of their surgery.

Table 2 Operative and Postoperative Characteristics

Median length of surgery, min. (IQR)	70 (62-90)
Median estimated blood loss, mL (IQR)	20 (2.5-27.5)
Median size of SPT placed, French (range)	18 (18-20)
Median postoperative length of stay, days (IQR)	0 (0-1)
90-day complications, no. (%)	
Bladder Spasms	3 (43%)
Urinary Tract Infection	1 (14%)
Bladder/Kidney stones	1 (14%)
Continence through follow-up, no. (%)	5 (83%)

Discussion

In this case series, we identify PUL with SPT placement to be a viable surgical approach for patients with refractory SUI and ESU. This subset of incontinence patients present to the reconstructive urologist with the following conundrum: they require surgical management, but are oftentimes poor surgical candidates. The patients studied above are no exception. Those undergoing PUL with SPT placement are typically older adults with multiple comorbidities. This combination of characteristics make them poor surgical candidates for more formal approaches to urinary diversion, such as a cystectomy with ileal conduit or Indiana pouch creation. Van Dyke *et. al.* identified a similarly aged, relatively unhealthy cohort in their examination of PUL with SPT.[16] Simultaneously, these patients are unable to be managed with further AUS revision. All of the patients studied had a former AUS placed; two patients had undergone 3 previous AUS surgeries before undergoing final PUL with SPT. For patients with SUI, AUS appears to be the appropriate initial step-up in therapy for individuals that cannot be managed non-operatively. However, AUS is not always a permanent solution. Patients with erosions that require multiple revisions may eventually have friable urethral tissue that is not amendable to further revision; in other words, end-stage urethra (ESU).

When patients arrive at this stage of incontinence with ESU, PUL with SPT gives these individuals an alternative option. This procedure is commonly done on an outpatient basis, with limited intraoperative complications and relative short surgery times. In the 7 patients studied, 6 had this operation done on an outpatient basis. Only 1 patient required a hospital stay, and even that was only for a single day. Median surgery length was 1 hour and 10 minutes. Comparatively, average operative time for cystectomy and ileal pouch creation has been reported at 5 hours and 27 minutes, with an average blood loss of 1,290 mL.[17] For an Indiana pouch creation, average operative time was 5 hours and 30 minutes, with 1,201 mL of blood loss[17]. The patients studied above are simply not ideal candidates for such prolonged, invasive procedures. Our case series identifies a high rate of continence in a patient population actively seeking this outcome, while also demonstrating limited morbidity. This continence rate has been previously identified in the literature as well.[16] As such, it appears that PUL with SPT placement may be a viable alternative presented to patients wishing to avoid more invasive procedures.

This currently presented study has multiple limitations. First, it is a small, retrospective study with a limited number of participants described. Therefore, no statistical significance can be drawn from a study of this size. Furthermore, it entails limited follow-up. Due to the recent use of this approach, we were unable to identify the long-term (i.e. >10 year) success or complication rate of it beyond our study period. Additionally, we are dependent upon the patients following up in our clinic regarding any complications or voiding issues to-date. Prior to our study, only 20 cases of this approach have been described in the literature. Further study of this technique, likely involving the collaboration of multiple institutions, would be a reasonable next step in demonstrating the feasibility of this surgical approach for patients with refractory SUI.

Conclusions

This initial data suggests that PUL with SPT placement may be a viable surgical approach to treating refractory SUI, especially for patients with ESU who wish to avoid the morbidity associated with more formal supravesical diversion. Further study of this technique and longer follow-up is required to determine its long-term efficacy and tolerability for patients. Every case

is unique, and the appropriate technique must be selected based on patient characteristics, patient preferences, and a surgeon's professional judgement. We intend for this study to build upon and corroborate the existing data suggesting that PUL with SPT should added to the reconstructive urologist's toolkit.

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None.

Footnote
Conflicts of Interest: The authors have no conflicts of interest to disclose.

Ethical Statement: The Indiana University School of Medicine Institutional Review Board exempt status was granted for the conduct of the study. As this was performed as a retrospective review of outcomes, patients did not undergo separate consent from the procedural consent prior to surgery.

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