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Permanent urethral ligation after AUS cuff erosion: Is it ready for prime time?

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Abstract

Aims: Although artificial urinary sphincter (AUS) has long been the gold standard treatment for severe stress urinary incontinence, poor tissue quality in patients with prior cuff erosions may preclude this option. Formal supravesical diversion and/or bladder neck closure comprise alternative salvage options but are associated with significant morbidity and mortality. We review our experience with permanent urethral ligation (PUL) among patients deemed not to be candidates for AUS replacement following cuff erosion.

Methods: From a single-center database of 396 patients undergoing AUS from 2014 to 2020, 20 men underwent PUL with suprapubic tube (SPT) diversion. Clinical characteristics and outcomes were evaluated. Quality of life (QOL) was assessed using chart review, Michigan Incontinence Symptom Index (M-ISI), and Patient Global Impression of Improvement (PGI-I).

Results: PUL resulted in continence in 18 (90%) men; 15 after the initial surgery and three after repeat ligation. Patients were elderly (average age 75) with significant comorbidities. A total of 11 (55.5%) patients experienced complications in the 90-day postoperative period (seven Clavien-Dindo Grade II, four Grade III). Over an average follow-up of 30.3 months (interquartile range: 15.75–48.75), four patients underwent cystectomy and one underwent perineal urethrostomy. In the remaining patients managed by PUL, 13 had satisfactory M-ISI scores and indicated overall improvement on PGI-I.

Conclusions: For men with AUS cuff erosion who are poor candidates for replacement, PUL with chronic SPT drainage represents an acceptable alternative option to restore continence and improve QOL. Though complications are not uncommon, the morbidity profile still compares favorably to more invasive formal urinary diversion.

KEYWORDS

artificial urinary sphincter, end-stage urethra, stress urinary incontinence

1 | INTRODUCTION

Stress urinary incontinence (SUI) carries a significant financial and psychosocial burden and is associated with decreased health-related quality of life.[1,2] While the artificial urinary sphincter (AUS) remains the gold standard for severe SUI, nearly half of AUS patients will require revision due to mechanical failure or cuff erosion.[3,4] Salvage strategies such as cuff repositioning, tandem cuff placement, or transcorporal cuff placement have all been well established in the reoperative setting.[5,6] Over time, however, cuff erosions occurring in a frail, reoperative urethra may preclude any hope of urethral restoration or AUS replacement.[7] The goals of eliminating incontinence while ensuring reliable urinary drainage may become elusive in end-stage elderly patients.

Creation of a continent catheterizable channel has been proposed for selected cases with formal bladder neck closure.[8–10] Alternatively, cystectomy with ileal conduit provides a controlled urinary diversion.[11,12] These abdominal procedures are associated with significant morbidity, with over half of all patients developing postoperative complications.[13,14] For men faced with the extreme, suboptimal choices of severe lifelong SUI and aggressive abdominal surgical options, we have proposed the intermediate option of permanent bulbar urethral ligation (PUL) with chronic suprapubic tube (SPT) drainage.

In 2017, we reported our initial experience with this technique in 10 patients.[15] Herein we report our updated experience with PUL in this challenging population, including additional detail on long-term patient-reported outcomes, complication management, and reoperative cases. We hypothesize that PUL with chronic suprapubic tube drainage represents a viable alternative treatment strategy for frail men bothered by severe SUI when urethral tissue damage precludes hope for AUS replacement.

2 | MATERIALS AND METHODS

2.1 | Data collection

Data were retrospectively collected on patients with "end-stage urethra" (ESU) undergoing bulbar urethral ligation between January 2014 and December 2019. We defined ESU as those with two or more prior failed urethral interventions who were felt to not have adequate healthy urethra to allow subsequent AUS cuff placement. Patient characteristics were obtained by systematic chart review including comorbidities, etiology of incontinence, and prior reconstructive procedures. Surgical data including the length of procedure, estimated blood loss (EBL), duration of inpatient stay, and incidence of 90-day complications were also obtained.

Complications were characterized according to the Clavien-Dindo classification system.[16] Patient-reported outcomes were assessed using the validated Michigan Incontinence Symptom Index (M-ISI) and Patient Global Impression of Improvement (PGI-I) questionnaires.[17,18] Updated questionnaires were obtained from the 10 patients reported in our initial 2017 series. All surveys were administered via clinic visit or telephone follow-up.

The M-ISI questionnaire uses eight initial questions to evaluate three incontinence subdomains—SUI (score: 0–12), urge urinary incontinence (UUI, score: 0–12), and pad use (score: 0–8)—which are summed to yield a total severity score of 0–32. The final two questions yield a total bother score of 0–8. Each question is answered using Likert response options (0–4 points), where higher values for each respective domain are indicative of more severe symptoms.

2.2 | Surgical approach

PUL is performed via a perineal approach, with dissection carried out circumferentially around the bulbar urethra, which is then completely transected. When performed concurrently with AUS explantation for erosion, transection is completed at the site of the urethral defect. In all other patients, the urethra is transected proximal to the urethral abnormality. At this point, cystoscopy is performed and 200 units of Onabotulinum Toxin A, reconstituted in 20 ml of injectable saline, is injected intravesically in 20 distinct sites. If not already present, a 16 French SPT is then introduced via trocar under direct vision. The mucosa of the proximal urethral stump is closed in a running fashion with 4–0 poliglecaprone 25 suture. A series of multiple 2–0 polyglycaprone figure-of-eight sutures are used to imbricate the proximal urethral stump (Figure 1). Multiple layers of tissue including bulbospongiosus muscle are interposed over the proximal stump using 2–0 polyglycaprone.

The distal urethral stump is left open so that it may enable drainage if fistulization or abscess occurs at the proximal site closure. Oxidized Regenerated Cellulose (ORC; Surgicel Fibrillar, Ethicon Inc) is packed in the surgical field before the superficial layers are closed to provide enhanced hemostasis. For reoperative PUL cases, antegrade cystoscopy with wire placement through the fistulous site may facilitate identification and dissection of the leaking site. The scope light itself also helps

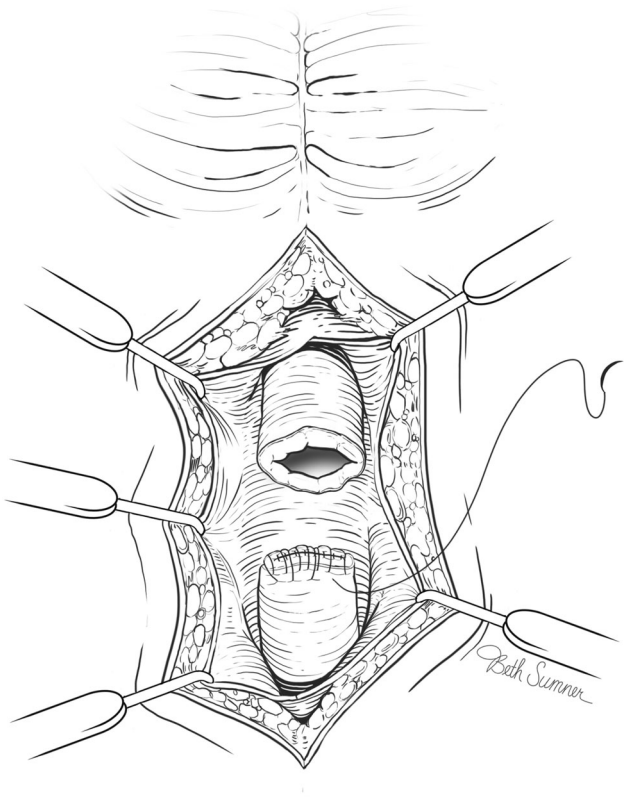

FIGURE 1 View of dissected bulbar urethra after transection. The proximal urethral stump is closed in a running fashion with a series of imbricating sutures. The distal urethral stump is left open to allow drainage from the surgical site

identification of the proximal stump deep in the scarred operative field.

All patients are discharged on anticholinergic or beta-3 receptor agonist to be taken on a scheduled basis. The suprapubic tube is left to continuous gravity drainage for a minimum of 3 months to promote healing and reduce the risk of ligation failure. Patients are evaluated at monthly intervals postoperatively in the clinic for suprapubic catheter exchange. If perineal inflammation or recurrent urethral discharge is noted, this is initially managed with broad-spectrum antibiotics and perineal compression. If the wound remains dry at the 3-month mark, the SPT may be converted to a capping trial with intermittent drainage. If fistulation persists beyond 3 months, religation may be offered.

3 | RESULTS

3.1 | Patient population

A total of 20 patients underwent PUL at our institution during the study period, with demographics outlined in Table 1. Compared to patients undergoing AUS, patients undergoing PUL were older and had more coronary artery disease. PUL patients had multiple comorbidities including smoking history (75%), hypertension (70%), and coronary artery disease (55%), yielding an average American Society of Anesthesiologists rating of 3, indicating severe systemic disease which limits activity. The majority of patients (16/20, 80%) had a history of prostate cancer. Of these, 5 (31.3%) underwent primary radiation therapy, while 11 (68.8%) underwent primary radical prostatectomy. In all, 14 (87.5%) patients with prostate cancer underwent radiation during the course of their treatment, and 7 (43.8%) received androgen deprivation therapy. Of the remaining three patients, one developed SUI secondary to spinal cord injury, and three were incontinent following endoscopic intervention for BPH.

Among the 18 men having AUS cuff erosion, 10 (55.6%) had multiple erosion events and 8 (44.4%) had transcorporal cuff erosion. The remaining two had severe SUI but also had extensive perineal scar from long-standing proximal stricture disease, thus precluding any hope for AUS cuff placement. Most men (10/18, 55.6%) had urethral ligation as a staged procedure, subsequent to AUS cuff removal; the remaining eight (44.4%) underwent synchronous urethral ligation in conjunction with device explantation.

3.2 | Surgical outcomes

The median operative time was 74 min (interquartile range [IQR]: 60–93), median EBL was 75 cc (IQR: 50–80), and the majority of cases were performed in the outpatient setting (median length of stay 0 days, IQR: 0–1; Table 2). During a median follow-up of 27.5 months (IQR: 15.75–48.75), 15 men (75%) reported being dry per urethra after initial PUL surgery. Of the five patients who reported persistent or recurrent urethral leakage, three were dry after repeat PUL performed at an average of 4-month postop (range: 3–5 months), and another is currently scheduled for repeat PUL. The fifth ultimately underwent perineal urethrostomy at outside hospital, stating that he would rather be diaper-dependent than continue with suprapubic tube or undergo extensive abdominal surgery.

A total of 11 (55%) patients experienced postoperative complications in the 90-day postoperative period including seven Grade II complications and four Grade III b complications. The most common 90-day complication was bladder spasm in 8 (40%) patients, which was managed initially by anticholinergics and/or beta-3 adrenergic receptor agonists.

TABLE 1 Characteristics of patients undergoing PUL versus AUS

	PUL ($n = 20$)	AUS ($n = 396$)	p Value
Demographics			
Mean age at surgery (*SD*)	75 ± 8.2	71 ± 8.8	**.045**
Mean BMI (*SD*)	26 ± 4.7	29 ± 5.1	**.010**
Diabetes, no. (%)	5 (25)	91 (23)	.834
Hypertension, no. (%)	14 (70)	245 (62)	.464
Coronary artery disease, no. (%)	11 (55)	49 (12)	**<.001**
Smoking history, no. (%)	15 (75)	209 (53)	.052
Etiology of incontinence, no. (%)			
Radical prostatectomy	11 (55)		
Radiation therapy	5 (25)		
BPH surgery	3 (15)		
Spinal cord injury	1 (5)		
Prior urethral surgeries			
Artificial urinary sphincter surgery, no. (%)	19 (95)		
History of cuff erosion, no. (%)	18 (100)		
Average no. erosions (range)	2 (1–3)		
Average no. AUS cuff implantations (range)	2 (1–4)		
History of transcorporal placement (No, %)	8 (44.4)		
Dilation of stricture, no. (%)	9 (45)		
Urethroplasty, no. (%)	6 (30)		
Urethral Sling, no. (%)	3 (15)		
Urethral Stent, no. (%)	2 (10)		

Note: Bold values are statistical significance.
Abbreviations: AUS, artificial urinary sphincter; BMI, body mass index; BPH, benign prostatic hyperplasia; PUL, permanent urethral ligation.

Three patients ultimately underwent chemodenervation via intravesical botulinum toxin A injection. Of these, one was successfully salvaged, and two ultimately underwent cystectomy. A total of 3 (15%) patients developed urinary tract infections and 4 (20%) developed wound infections, including cellulitis managed by antibiotics in three patients and abscess requiring in-office drainage in one. Urethrocutaneous fistulas developed in two patients (Figure 2), both of whom had a history of radiation and postoperative bladder spasms. In the subset analysis of patients with testosterone levels available, 10/13 (77%) were hypogonadal, defined as total testosterone less than 300 ng/dl. Hypogonadism was significantly associated with risk of developing complications within the 90-day window (70% vs. 0%, $p = .0329$).

TABLE 2 Operative and postoperative characteristics

Median length of surgery, min (IQR)	74 (60–93)
Median estimated blood loss, ml (IQR)	75 (50–80)
Median postoperative length of stay, days (IQR)	0 (0–1)
90-day complications, no. (%)	11 (55)
Bladder spasms	8 (40)
Urinary tract infection	3 (15)
Cellulitis	2 (10)
Abscess	2 (10)
Urethral recanalization	4 (20)
Fistula	**2 (10)**

Note: Bold value are statistical significance.
Abbreviation: IQR: Interquartile range.

Nine patients who were doing well at the 3-month mark elected to convert from continuous SPT drainage to capping with intermittent drainage every 3 h, as mentioned in Table 3. Six of these patients tolerated capping well, while one had worsening bladder spasms, one developed urethrocutaneous fistula, and one developed urethral recanalization. Most patients elected to alternate between continuous drainage overnight, with capping when they were active outside their homes.

FIGURE 2 Voiding cystourethrogram shows small-caliber fistula after PUL amenable to repeat ligation. A remotely placed urethral stent (left in situ) is noted. PUL, permanent urethral ligation

3.3 | Extended follow-up

During the median follow-up of 27.5 months, the most common complaint was bladder spasm, which occurred in 13/20 (65%) of patients. Nine of these were successfully managed by medication alone, while four patients ultimately went on to receive intravesical botulinum toxin A injections. Stone formation requiring treatment occurred in one patient (5%). Of the 20 men who underwent PUL, 19 were alive at the time of this study; of these, 14 were still managed by ligation and SPT. Four patients ultimately elected cystectomy at an average of 26-month postligation (Figure 3) due to severe pain and refractory urgency relating to the chronic SPT.

Thirteen of the 14 men still alive and managed by PUL long-term were reached to complete updated M-ISI and PGI-I evaluations. All patients had excellent incontinence domain scores with average SUI domain score of 0.5 (range: 0–3, of 12 possible) and UUI domain score of 0.3 (range: 0–3, of 12 possible). Average total severity score was 1.4 of 32 possible points (range: 0–8). Only one patient had unsatisfactory total severity score of 8/32 due to persistent urethral leakage; this patient is currently scheduled for repeat PUL. Average total bother score was 0.6 (range: 0–4, of 8 possible points), with only 1 (7.7%) patient reporting an unsatisfactory total bother score of 4 as he reported embarrassment from the catheter bag. All patients reported improved quality of life after PUL on PGI-I, with 11 (84.6%) patients reporting their quality of life to be "very much better," one as "much better" and one as "a little better." All stated that they would recommend the procedure to others.

TABLE 3 Analysis of patients ultimately undergoing cystectomy

	Cystectomy ($n = 4$)	No cystectomy ($n = 16$)	p Value
Demographics			
Age (average, range)	76.0	76.4	.9271
BMI (average, range)	27.1	25.3	.5059
ASA score (average, range)	2.5	2.75	.4486
History of radiation (no., %)	3 (75)	11 (69)	.9192
History of ADT (no., %)	3 (75)	4 (25)	.2350
No. AUS cuffs (average, range)	2.0	2.0	1.000
No. AUS erosions (average, range)	1.3	1.6	.5101
Postoperative factors			
Bladder spasm	3 (75)	10 (16)	.8327
Intravesical botox	2 (50)	2 (13)	.2059
Use of SPT capping technique	2 (50)	7 (44)	.8913

Abbreviations: ADT, androgen deprivation therapy; ASA, American Society of Anesthesiologists; AUS, artificial urinary sphincter; BMI, body mass index; SPT, suprapubic tube.

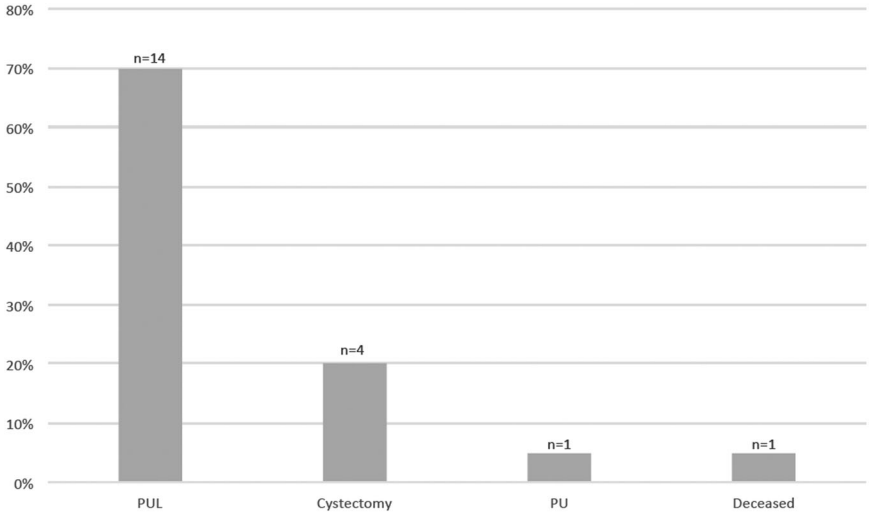

FIGURE 3 Representation of long-term bladder management technique over follow-up period. PU, perineal urethrostomy; PUL, permanent urethral ligation

4 | DISCUSSION

4.1 | Patient selection

Patients with severe SUI and concomitant complex urethral pathology represent a challenging population for the reconstructive urologist. AUS remains the standard of care for severe SUI, even in the setting of cuff erosion ordinarily; most may be successfully reimplanted after healing.[19] However, a challenging minority will consistently present with such poor periurethral tissue quality that further efforts at restoring continence in a conventional manner are precluded. These patients have traditionally been offered two unsatisfactory choices—(a) lifelong severe SUI with noninvasive options such as Cunningham clamp, condom catheter, and incontinence pads, all associated with poor quality of life,[1,2,7] or (b) aggressive abdominal urinary diversion procedures which have significant associated morbidity in this debilitated population.[13,14] To our knowledge, this is the largest reported series of PUL, which appears to offer promise as a viable intermediate treatment strategy to restore continence and improve quality of life for those not suitable for AUS replacement.

4.2 | Benefits of the PUL approach

Performed via a perineal approach, PUL is technically less demanding than bladder neck closure or supravesical diversion. It also obviates the risk of intra-abdominal complications including small bowel obstruction and bowel injury. With an average operative length of just over an hour, ligation can readily be performed in the outpatient setting. Most patients remained dry per urethra after initial PUL, although three others underwent repeat PUL, four cystectomy, and one perineal urethrostomy. The most common driver for cystectomy or urethrostomy was issued with the SPT.

Although half of the patients in our cohort experienced complications within the 90-day window, this morbidity profile of PUL compares favorably to more involved surgical options. The 30-day readmission rate for ileal conduit, for example, approaches 30% with 90-day mortality rate as high as 7.5%.[13,14] For elderly patients the risk is even higher, with 90-day mortality rates published as high as 19.3% in octogenarians.[20] Moreover, patients with ASA ≥3 have been shown to be nearly twice as likely to require perioperative reintervention (23.5% vs. 13.1%, $p < .001$), and to have more than twice the 90-day mortality rate (7.6% vs. 3.2%, $p < .002$) compared to those with ASA ≤2.[21] When considering cystectomy with diversion for purely benign disease, complication rates as high as 67% have been reported, with 57% experiencing Grade 2 or higher complications and similar complication rates between those undergoing supratrigonal and simple cystectomies.[11] Similarly, for patients opting for formal bladder neck closure with creation of continent catheterizable stoma, initial success rates have been reported as only 54%–87%, with reoperation rates as high as 31%.[10,22–24]

4.3 | Modifications from the original technique

We have found that the most common complication after urethral ligation was refractory bladder spasm, which clearly jeopardizes the integrity of the urethral ligation. Due to the absolute importance of maintaining low bladder pressures during the initial healing process, we now discharge all patients on scheduled anticholinergics

or beta-3 agonists. The suprapubic tube is also maintained to continuous gravity flow for 3 months after PUL, and if there is any concern for debris formation or intermittent obstruction, patients are taught to gently irrigate to maintain patency. We have begun injecting intravesical botulinum toxin A at the time of surgery to maximize detrusor quiescence during the first 90 days, which has been successful thus far in preventing complications. Injection of 200 units of botulinum toxin A has been shown to increase bladder capacity from 105 to 250 ml with decrease in urinary frequency episodes from 14 to 11 episodes per day in radiation cystitis cases.[25]

We also now leave the distal urethral stump open at the time of surgery to facilitate drainage from the wound bed. Anecdotally, we have found this to be preferable, as neither of these two patients has developed wound complications; however, our sample size is clearly too small to make statistically significant conclusions at this time. If there is concern for infection at the time of AUS explantation, it is now our practice to perform a staged closure to decrease postoperative infection risk. Large-bore SPT (22 French rather than 16 French) are also now favored at the time of PUL to enhance drainage and facilitate irrigation if needed. Further follow-up will be required to assess the impact of these interventions.

Our study shows that PUL may not always be a definitive treatment—with four patients requiring repeat ligation and four patients ultimately undergoing cystectomy. However, it is a viable option to postpone—and in most cases avoid—major surgery with its associated potential high morbidity in such an elderly and frail patient population. Patients reported significant improvement in quality of life following PUL, and all stated that they would recommend the procedure to others in a similar position.

4.4 | Limitations

Our study is limited by its retrospective nature. It represents an update of our previously published pilot study with increased patient numbers and longer follow-up, but still remains a small series. It is notable that it took 5 years at our high-volume tertiary center to acquire this experience. This update has nonetheless given us a chance to provide extended follow-up and capture long-term outcomes like cystectomy and reoperative ligation procedures. Additional studies—ideally across multiple institutions—would provide more robust data, though we recognize that given our own low numbers of patients this is unlikely. Finally, while our initial experience has been positive, the role of onabotulinum A injections as an adjunct to PUL requires further investigation.

5 | CONCLUSIONS

For debilitated men with ESU and SUI, PUL with SPT drainage represents a viable option to restore continence and improve quality of life in the outpatient setting. While our results show that PUL may not always represent a definitive treatment, it is often an effective alternative to postpone and often to avoid formal supravesical diversion with its associated high morbidity and mortality.

CONFLICT OF INTERESTS

Allen Morey receives honoraria for being a guest lecturer/meeting participant for Boston Scientific and Coloplast Corp.

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