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Therapeutic Efficacy of a New Procedure for Male Urinary Incontinence Combining a Suburethral Polypropylene Mesh and Cardiovascular Patch

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Purpose: Stress urinary incontinence (SUI) in men is a complication secondary to prostatectomy or resulting from neurological lesions. This study presents our experiences with male suburethral slings over the past decade.
Methods: In this study, we considered patients who presented with SUI and were diagnosed with an intrinsic sphincteric deficiency due to postprostatectomy incontinence (PPI) or other causes (non-PPI). Patients who underwent the suburethral sling procedure using a polypropylene mesh and a cardiovascular patch were retrospectively included. An urodynamic study was performed before and after the operation. Global response assessment (GRA) and SUI grading were used for surgical outcome. The revision rate and the infection rate were also evaluated.
Results: A total 31 patients were enrolled in this study; the mean patient age was 59.5 ± 18.9 years, and the mean follow-up period was 36.9 ± 29.4 months. Fourteen patients comprised the non-PPI group and 17 were in the PPI group. The preoperative SUI of all patients were categorized as a moderate to severe problem according to the SUI grade, with a mean score of 2.32 ± 0.48 before the operation and 0.48 ± 0.57 after the operation. With a mean score of 2.35 ± 0.71, GRA showed that the patients were satisfied with the treatment. After the sling procedure, 4 patients (13%) reported a mild improvement, 12 (38.7%) a moderate improvement, while 15 (48.4%) reported an excellent improvement. Six patients (19.4%), including 5 from the non-PPI group (35.7%) and 1 (5.9%) from the PPI group (P = 0.037), underwent sling removal because of infection.
Conclusions: The male suburethral sling procedure using a polypropylene mesh and a cardiovascular patch is a safe, efficacious, and inexpensive surgical procedure for PPI. In cases of neurological incontinence, however, the higher infection rate in non-PPI patients means that they should be carefully managed.

Keywords: Male; Suburethral Sling; Urinary Incontinence

- **Research Ethics:** This study had been approved by the Ethics Committee of Buddhist Tzu Chi General Hospital, Hualien, Taiwan (approval number: IRB105-22-B). Informed consent was waived by the Ethics Committee of the Buddhist Tzu Chi General Hospital, Hualien, Taiwan, as the chart review involved a regular treatment and the study was retrospectively performed.
- **Conflict of Interest:** No potential conflict of interest relevant to this article was reported.

INTRODUCTION

Stress urinary incontinence (SUI) is defined by the International Continence Society as involuntary urine leakage on effort or exertion, such as sneezing or coughing [1]. This situation in men may occur due to an anatomical disruption of the external urinary sphincter after a radical prostatectomy or occasionally after a transurethral prostatectomy. Additionally, intrinsic sphinc-

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ter deficiency (ISD) may result from neurological lesions such as spinal cord injury (SCI), myelomeningocele (MMC), spinal bifida, or complicated urethral rupture associated with pelvic fracture [2].

Patients with SUI have a poor quality of life and may be ashamed of this condition. Conservative management includes an external appliance for urine collection, use of a penile clamp, behavioral modification, and pelvic floor exercises. Surgical procedures for male SUI include periurethral bulking agents, a sling procedure, an artificial urinary sphincter (AUS), a periurethral constrictor, or stem cell therapy.

Many patients with SUI require surgical intervention to address the problem of incontinence since nonsurgical modalities for postprostatectomy incontinence (PPI) offer limited and unsatisfactory improvement [3]. The male sling procedure was introduced more than 20 years ago as a surgical alternative to the AUS for patients with low-volume incontinence (1–3 pads per day). There are many differences between these 2 procedures. The most notable difference between male slings and the AUS is the absence of mechanical components, which reduces the potential risk of infection and device failure. Although many different sling designs have been developed, the following 3 types are described most commonly in the literature: suburethral bone-anchored slings (BAS), retrourethral transobturator slings (RTS), and adjustable retropubic slings (ARS). We developed a novel suburethral sling procedure for treating male SUI. In this study, we report the long-term outcomes at a mean of over 3 years of follow-up of 31 incontinent men who underwent the suburethral sling procedure [4].

MATERIALS AND METHODS

Patients who presented with SUI, were diagnosed with ISD, and underwent the suburethral sling procedure at Hualien Tzu Chi General Hospital were retrospectively analyzed. All patients had been treated with pelvic exercises, biofeedback, and medications to increase urethral resistance before the operation, but those treatment modalities failed. For these patients, the suburethral sling procedure was advised. They underwent a complete history, physical examinations, videourodynamic study (VUDS), and cystoscopy before the operation. VUDS was performed to exclude patients with bladder outlet obstruction and to determine possible detrusor dysfunction. The leak point pressure (LPP) was measured to check the extent of ISD, and a urinary pressure-flow study was performed to evaluate bladder compliance and detrusor contractility. Cystoscopy was used to exclude the presence of an anatomic urethral stricture or incompetence. All patients had a documented videourodynamic demonstration of ISD.

All patients received cefradine-arginine (1 g) intravenously 15 minutes before the operation. After general anesthesia, the patients were placed in an extended lithotomy position. One 20-Fr Foley catheter was indwelled to facilitate urethral identification during periurethral dissection and to avoid complete urethral occlusion from extrinsic compression. A perineal longitudinal midline incision was made, centered over the bulbous urethra. The fascia of Colles was incised and left along the surrounding tissues to expose the bulbospongiosus muscle. We then identified the bilateral inferior pubic rami by direct palpation. Further dissection of the pubic bone was done until the periosteum was exposed. We used a nonabsorbable polypropylene mesh to create a 4-cm-wide double-folded sling after soaking the mesh in a gentamicin solution (10 mL of pure antibiotic). The sling was fixed as tight as possible with 3 1-0 nylon sutures bilaterally to the periosteum on the anteromedial aspect of the inferior rami. The suburethral pads were placed for additional support using a Bard cardiovascular patch (Bard, Murray Hill, NJ, USA) between the sling and the urethra (Fig. 1).

After the placement of the sling and the suburethral pads, a flexible cystoscope (17 Fr) was used for checking the urethral competence and maintaining the retrograde LPP around 60–80 mm H_2O. We then adjusted the number of suburethral pads used in order to reach the target retrograde LPP. The retrograde LPP was determined by measuring the pressure above the upper margin of the symphysis pubis that permitted saline to infuse into the bladder while clamping the anterior urethra by hand. The retrograde LPP was adjusted lower because of low detrusor contractility in some patients. Fig. 2A shows the wide-open external sphincter before the operation, and Fig. 2B shows the closed urethra after the operation. The operation was ended after inserting an 8-Fr Foley catheter to avoid extra force to the suburethral sling and spraying the remaining gentamicin on the sling before wound closure. The Foley catheter was removed the next morning for a voiding trial. Broad spectrum antibiotics were given for 3 days, and the drain tube was removed if only a minimal amount of fluid was present in it.

Regular direct interviews were conducted with patients for postoperative follow-up at the outpatient clinic. Their satisfaction with the long-term therapeutic results was assessed in December 2015. The severity of SUI was assessed using a range of

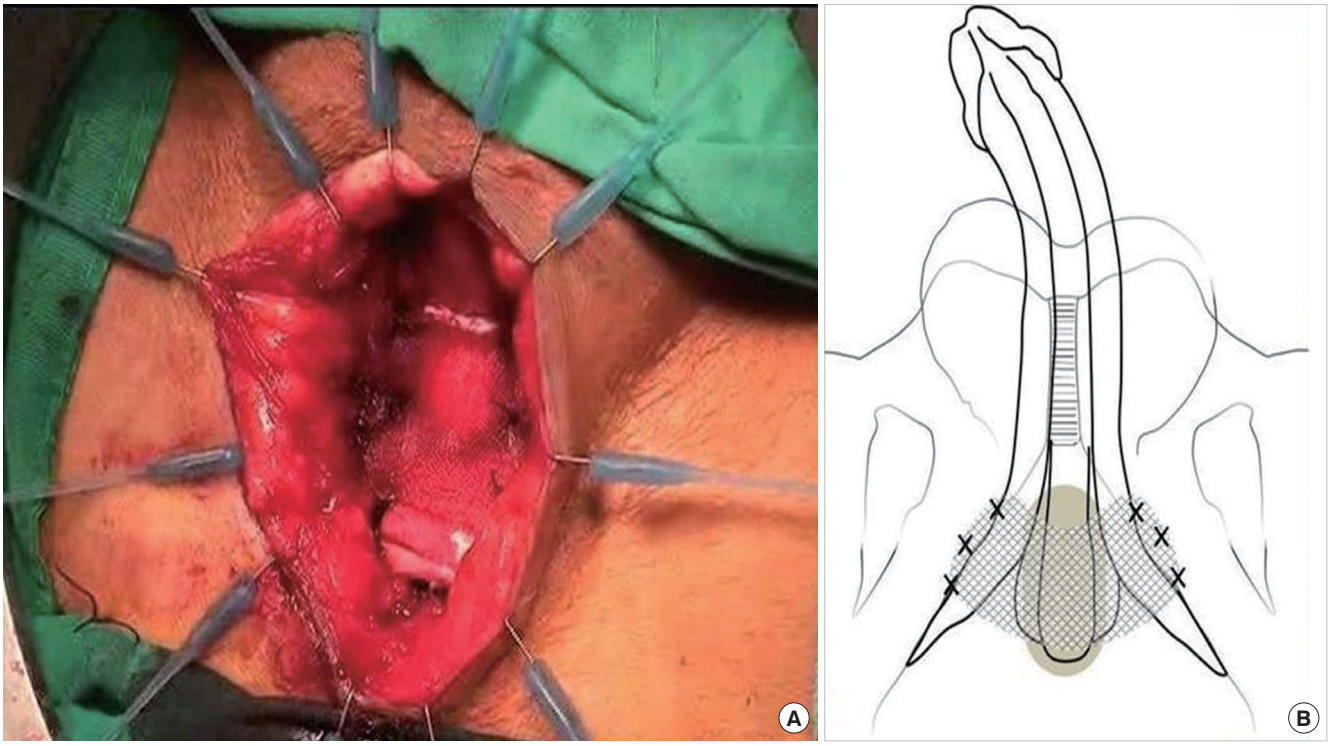

Fig. 1. Photograph (A) and graphical illustration (B) of the suburethral sling and the suburethral pads.

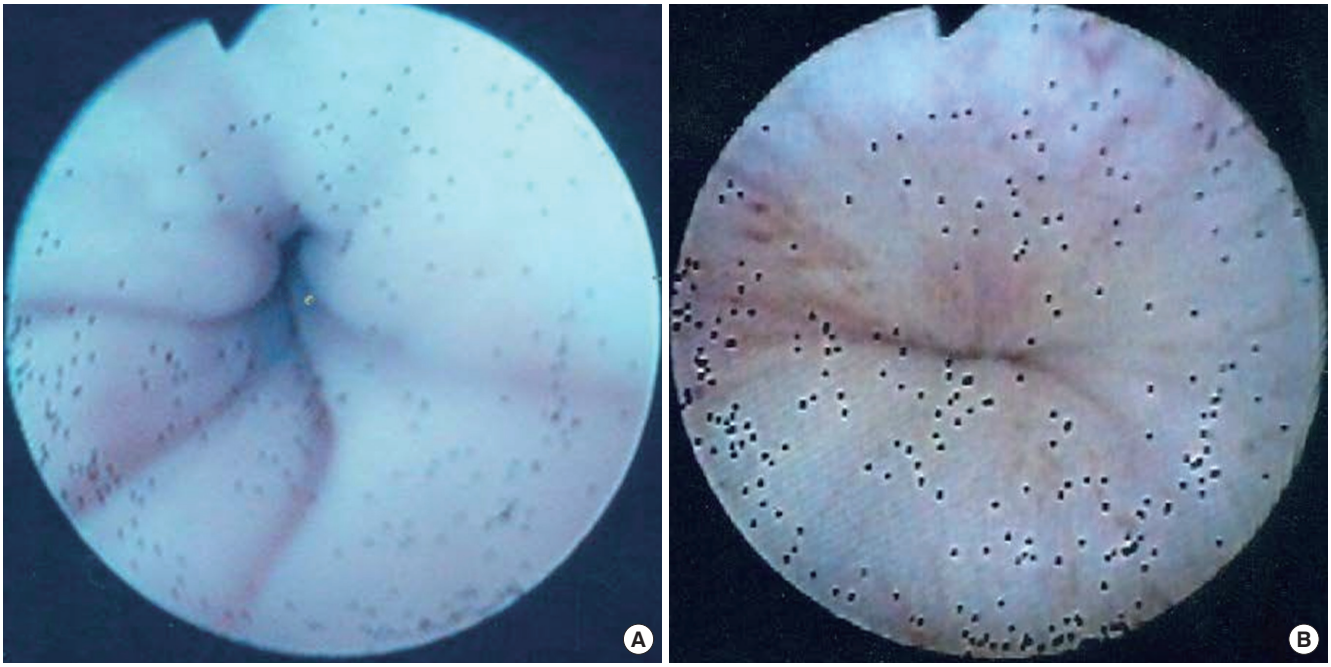

Fig. 2. Cystoscopic finding of a urethral external sphincter before (A) and after (B) the operation.

1 to 3 by using the Stamey classification [5]. If no SUI was present, a score of 0 points was given. Global response assessment (GRA) was also used to assess satisfaction on a scale of 0 to 3, with 0 indicating no change; 1, mildly satisfied; 2, moderately

satisfied; and 3, markedly satisfied. We further divided these patients into 2 subgroups: the PPI and non-PPI groups. Outcomes and complication rates were compared between these groups. A statistical analysis was performed using 1-way analysis of variance and the paired t-test. All analyses were performed using SPSS ver. 12 (SPSS Inc., Chicago, IL, USA).

RESULTS

A total of 46 patients met our criteria for SUI with ISD and underwent the suburethral sling procedure between December 2005 and November 2015. During the follow-up period, 4 patients passed away, 10 were lost to follow-up, and 1 was lost to dementia and was not able to answer our questions. The other 31 patients were enrolled into this study; their mean age was 59.5 ± 18.9 years (range, 14–85 years), and the mean follow-up period was 36.9 ± 29.4 months (range, 2–131 months). Fourteen patients comprised the non-PPI group (mean age, 43.0 ± 14.5 years) and 17 were in the PPI group (mean age, 73.1 ± 8.42 years). In the non-PPI group, 3 patients had a pelvic fracture and urethral sphincter denervation, 4 had MMC, 3 had a SCI, and 4 had SUI after radical surgery for rectal cancer. In the PPI group, 5 patients had previous transurethral resection of the prostate and 12 had undergone radical prostatectomy. Additionally, 3 out of those 12 patients received adjuvant external beam radiation therapy after radical prostatectomy (Table 1).

Demographic and VUDS parameters of the patients are presented in Table 1. Preoperatively, all patients reported normal bladder compliance without bladder outlet obstruction. Of the 31 patients, 8 (25.8%) had detrusor overactivity (DO), 10 (32.3%) had detrusor underactivity (DU), 10 (32.3%) had hypersensitive bladder (HSB), and 3 (9.7%) had normal detrusor function. All patients had VUDS-documented ISD; 13 had genuine SUI without urine leakage during the cough leak point pressure (CLPP) test, and the remaining 18 had a mean preoperative CLPP of 59 cm H_2O (range, 11–123 cm H_2O). The preoperative Abrams-Griffiths nomogram showed that all patients had a nonobstructive flow pattern.

The preoperative SUI of all the patients was moderate to severe according to the SUI grading. The mean SUI grade was 2.32 ± 0.48 preoperatively and 0.48 ± 0.57 postoperatively. With a mean score of 2.35 ± 0.71 after the operation, GRA showed that all the patients were well satisfied with the procedure. Overall, 4 patients (13%) reported a mild improvement, 12 (38.7%) reported a moderate improvement, while 15 (48.4%) reported an excellent improvement after the operation (Table 2).

The abovementioned 31 patients were asked to void after the removal of the Foley catheter the next day. Moderate to large amounts of postvoid residual urine were recorded in some patients. Six patients (19.4%, all from the PPI group) had new-onset urine retention after Foley catheter removal, and a revision of the suburethral pad volume was necessary during the same

Table 1. Patient demographics and treatment outcome

Variable	PPI (n = 17)	Non-PPI (n = 14)	P-value
Causes of SUI	Transurethral resection of prostate (n = 5)	Pelvic fracture (n = 3)	
	Radical prostatectomy (n = 12)	Myelomeningocele (n = 4)	
		Spinal cord injury (n = 3)	
		Rectal cancer (n = 4)	
Bladder function	DO (n = 3)	DO (n = 5)	
	DU (n = 2)	DU (n = 8)	
	HSB (n = 10)	Normal (n = 1)	
	Normal (n = 2)		
Treatment outcome, n (%)			
Moderate/excellent satisfaction	17 (100)	10 (71.4)	0.017
Simple revision	7 (41.2)	2 (14.3)	0.107
Repeat procedure	1 (5.9)	5 (35.7)	0.037
Mesh infection	1 (5.9)	5 (35.7)	0.037

PPI, postprostatectomy incontinence; SUI, stress urinary incontinence; DO, detrusor overactivity; DU, detrusor underactivity; HSB, hypersensitive bladder.

Table 2. Measured parameters between patients with postprostatectomy incontinence and nonpostprostatectomy incontinence

Variable	Non-PPI (n = 14)	PPI (n = 17)	P-value
Age (yr)	43.1 ± 14.5	73.1 ± 8.42	0.000
Body mass index (kg/m^2)	24.4 ± 5.61	25.8 ± 2.38	0.364
Operation time (min)	45.4 ± 36.8	30.0 ± 20.1	0.151
Preoperative LPP (cm H_2O)	56.9 ± 39.6	60.6 ± 28.1	0.818
RLPP (cm H_2O)	60.6 ± 10.1	43.6 ± 16.4	0.013
Preoperative CBC (mL)	310 ± 169	248 ± 98.5	0.220
Preoperative PdetQmax (cm H_2O)	20.2 ± 15.8	11.1 ± 9.18	0.059
Qmax			
Preoperative	15.8 ± 6.01	14.2 ± 5.46	0.537
Postoperative	10.6 ± 5.53	10.5 ± 5.91	0.963
SUI grade			
Preoperative	2.29 ± 0.47	2.35 ± 0.49	0.702
Postoperative	0.50 ± 0.65	0.47 ± 0.51	0.889
GRA	2.00 ± 0.78	2.65 ± 0.49	0.009

Values are presented as mean ± standard deviation.
PPI, postprostatectomy incontinence; LPP, leak point pressure; RLPP, retrograde LPP; CBC, cystometric bladder capacity; Pdet: detrusor pressure; Qmax: maximal flow rate; SUI, stress urinary incontinence; GRA, global response assessment.

period of hospitalization. They received a repeat operation to expose the mesh and the suburethral pads. The number of suburethral pads was adjusted, and some of the pads were removed. After revision, flexible cystourethroscopy was performed to check the new retrograde LPP. Three patients (9.7%; 1 from the PPI group and 2 from the non-PPI group) had persistent SUI immediately after catheter removal and received mesh enhancement by the addition of more suburethral pads during the same admission. Six patients received a repeat suburethral sling due to recurrent SUI (only 1 patient in the PPI group). Four of them received a second sling, 1 underwent a third sling procedure, and 1 underwent second sling procedure and bladder neck reconstruction. The overall simple revision rate was 29.0% (14.3% in the non-PPI group; 41.2% in the PPI group; P = 0.107). Five patients in the non-PPI group needed clean intermittent catheterization (CIC) after the operation; all of them had DU before the operation.

All patients had minimal blood loss and no complications during the operation. Immediately after surgery, all patients reported mild and tolerable wound pain. The main complication was mesh infection, and extraction of the mesh/suburethral pads was needed. Six patients had the sling removed because of infection; of these, 5 were from the non-PPI group (35.7%) and 1 from the PPI group (5.9%) (P = 0.037).

No significant differences were found in the surgical outcomes between the different causes of SUI according to SUI grade (P = 0.702). The mean maximal flow rate (Qmax) after the suburethral sling procedure (11.3 ± 5.3 mL/sec) was significantly lower than the preoperative Qmax (14.6 ± 5.6 mL/sec) (P = 0.013). Compared with the patients in the PPI group, the patients in the non-PPI group had a lower revision rate but a significantly higher mesh infection rate, and were less likely to require a repeat sling procedure or other surgical procedure to treat incontinence, such as bladder neck reconstruction.

DISCUSSION

This study found that, for male high-grade SUI, a suburethral polypropylene mesh combined with a cardiovascular patch to increase urethral resistance effectively improved or cured SUI without compromising voiding efficiency. However, patients in the non-PPI group had a higher rate of infection and a greater need for sling explantation.

SUI in men can occur as a bothersome complication after radical prostatectomy, transurethral prostatectomy, or neurogenic lesions causing urethral sphincter denervation and ISD, such as SCI or traumatic urethral injury [2]. After the initial evaluation, patients can receive noninvasive first-line treatment based on pelvic floor muscle training. Behavioral therapies are also recommended, even though reliable evidence to prove their efficacy is still lacking [6,7].

The most frequently prescribed medications are antimuscarinic agents such as oxybutynin, propiverine, and tolterodine. They are effective in treating DO-caused urinary incontinence, even dry mouth, but may cause other side effects [8]. However, antimuscarinic agents are not useful in the treatment of male ISD. In case of refractory SUI after conservative treatment, invasive management is recommended [9].

Surgical procedures for male SUI include periurethral bulking agents, stem cell therapy, a tape procedure, an AUS, or a periurethral constrictor. Three principal slings have been reported in the literature for patients with PPI, including the BAS, RTS, and ARS [4]. BAS involve the use of a synthetic or organic mesh that is tightly fixed to the bilateral inferior pubic ramus with screws or sutures to support and compress the bulbous urethra. They have a success rate of 40%–88%, with some series having

a mean follow-up duration of 36–48 months. A mesh infection rate of 2%–12%, in which case explantation is necessary, has been reported. RTS involve the use of a self-anchored polypropylene mesh with bilateral arms through the obturator foramen. The sling part is placed at the level of the proximal bulbous urethra, and continence is achieved through elevation of the bulbous urethra. They have been reported to have a success rate of 76%–91% in previous studies with a follow-up duration of 12–27 months and a low explantation rate. ARS involve the use of a retropubic traction suture to the pubic area. The sling is also placed at the proximal bulbous urethra. Several sutures are made to the rectus fascia to provide adequate tension for urethral compression. ARS have a success rate of 72%–79% with a follow-up duration of 26–45 months. The mesh erosion rate was found to be 3%–13% and the infection rate was reported to be 3%–11% in recent reports, with both complications leading to explantation [4,10].

The AUS has become the gold-standard therapy for male SUI since its popularization in 1978. A set of European Association of Urology guidelines stated that the AUS (AMS 800, American Medical Systems, Minnetonka, MN, USA) could be the treatment of choice in patients with moderate to severe SUI because it had a higher success rate than the other treatment options [11]. The long-term success rate was up to 90%. However, it has some disadvantages, such as a high cost and risks of erosion, infection, and mechanical failure. The revision rates due to mechanical failure have been reported to be 8%–45%; and the rates of revision due to nonmechanical failure for reasons such as erosion, urethral atrophy, and infections were 7%–17% [12]. Patients who received radiotherapy showed a lower AUS success rate and higher revision rate due to erosion and infection [11].

A readjustable system called the ProACT system (Uromedica, Plymouth, MN, USA) was introduced in 2001. Two balloons are placed at the bladder neck bilaterally and provide urethra compression. This device contains titanium ports, which are placed in the scrotum for adjusting the balloon size. The dry rate has been reported to be as high as 67% after several readjustments. High rates of complications such as erosion, infection, balloon deflation, and balloon migration were also reported in the previous studies. These complications may lead to device removal (10%–30%) [11]. The other adjusting sling systems include the Reemex system, the Argus sling, and the tissue expander. All these systems require additional wounds for the regulator and may induce a foreign body reaction. Moreover, tissue damage, including bladder injury, may occur during the sling procedure. Our procedure prevents the above disadvantages and provides a direct vector towards the urethra.

Many autologous or artificial materials, such as collagen, Teflon, silicone, autologous fat, autologous chondrocytes, dextranomer/hyaluronic acid copolymer, pyrolytic carbon microspheres, and polydimethylsiloxane, have been used as bulking agents. The dextranomer/hyaluronic acid copolymer and polydimethylsiloxane are the most commonly used bulking agents. However, they have a high early failure rate of approximately 50%, and the therapeutic effect of continence decreases with time. In comparative studies, the AUS (continence, 75% vs. 20%) and male slings (failure rate, 24% vs. 70%) showed significantly better efficacy compare to the bulking agent treatments. Patients may require a repeat injection to maintain satisfaction. However, repeat procedures may induce a local inflammatory reaction, resulting in a change in urethral elasticity and possibly a "frozen urethra," which can lead to severe urethral incompetence [13-15]. The use of Teflon injections in humans was discontinued because migration of Teflon to the lymph nodes, spleen, lung, and brain after an external sphincter injection was noted in animal tests. In addition, collagen injections may induce severe anaphylactic reactions. In general, bulking agents have limited efficacy and can induce a frozen urethra. They should only be used carefully in highly selected patients with mild PPI [16].

In this study, we used the bone-anchored sling technique. In addition to the polypropylene mesh, we used suburethral pads with a cardiovascular patch for increasing urethral resistance. The success rate was 77.4%, as measured by patient satisfaction, even though 6 of 31 patients received a repeat procedure. The success rate was similar to that of previous studies, but there was a higher infection rate (19.4%) in our study, particularly in the non-PPI patients. It is possible that in our study, we included high-risk patients (SCI and neurogenic urethra) who were vulnerable to perineal wound infections. However, the most prominent advantage of our method of choice was a low technical threshold and the ease of revision. The supporting pressure could be easily adjusted by changing the number of suburethral pads used. Removing and redoing the bone anchored mesh was unnecessary. Therefore, in select patients, such as PPI patients, it was a better choice than traditional methods.

The effect of these procedures on voiding parameters has seldom been discussed in previous studies. In this study, the Qmax after the operation was significantly lower than the preoperative value. Since the goal of this operation was continence, the result

was acceptable. Six patients presented with acute urine retention immediately after the operation, but their condition improved after the pad volume was adjusted. In all 6 patients who had HSB or DO in preoperative VUDS, no DU was noted postoperatively. Since most of the PPI patients had normal bladder function before the sling procedure, it is likely that urinary retention or dysuria was caused by a considerable increase in the urethral resistance after the suburethral sling procedure. Persistent CIC after the operation was necessary in 5 patients with preoperative DU in the non-PPI group. Since all patients provided complete informed consent, and were informed of the possibility of urine retention and the need for CIC before the operation, the subjects (particularly patients with DU) accepted this treatment outcome and were satisfied with the dryness. Most patients still chose to undergo the operation even when there was a risk of acute urinary retention. They preferred performing CIC and keeping dry, rather than experiencing incontinence. Nevertheless, even when the Qmax value was significantly lower and CIC was needed after the operation, the patients were satisfied with the surgical outcome after the suburethral sling procedure.

The age of the patients in the PPI group was significantly higher than that of the patients in the non-PPI group; this difference could be attributed to their different diseases. However, the satisfaction rate was not affected by age. Although revision was required in 10 patients, the final success rate measured, bearing in mind the moderate to excellent GRA results, was 100% in the PPI group. A previous study reported that efficacy may decrease in patients who received radiation therapy, perhaps because of periurethral fibrosis that prevents urethra coaptation and mesh compression [17]. Of the 3 patients in the PPI group who received radiation therapy, only 1 needed simple revision and the treatment was successful. In the non-PPI group, patients with SCI, MMC, and urethral rupture also had a fair success rate. However, infection due to the repeat procedure resulted in sling failure and sling explantation, which are serious problems. The high infection rate could be attributed to the implantation of the suburethral pads. In these neurogenic ISD patients, success should be achieved in the first sling to prevent infections after revision.

The main limitations of the present study are the small number of cases and the lack of appropriate objective parameters. Furthermore, the patients in the non-PPI group had several complications. Nevertheless, patients in both groups were highly satisfied after the operation.

In conclusion, the male suburethral sling using a polypropylene mesh and suburethral pad compression is a safe, efficacious, and inexpensive surgical procedure for PPI and neurogenic ISD. In patients with neurological incontinence, the relatively high infection rate means that they should be carefully managed. Nevertheless, in our series, the suburethral sling for male SUI not only resulted in significant self-reported improvement, but also showed a tendency to promote quality of life.

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