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Treatment Outcomes of Transurethral Macroplastique Injection for Postprostatectomy Incontinence

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Purpose: We investigated the efficacy of transurethral injection of Macroplastique bulking agent (Uroplasty) for male stress urinary incontinence (SUI) after prostate surgery.

Materials and Methods: This retrospective review included men with SUI treated by transurethral injection for symptoms resulting from prostate surgery. Patients were evaluated at 1 month and 6 months after injection by determining the number of pads used per day and changes in incontinence symptoms. Treatment success was defined as use of 1 pad or fewer per day combined with subjective symptom improvement.

Results: The study population comprised 30 men with a mean age of 66.1±5.3 years. Of the 30 patients, 24 (80.0%) underwent prostate cancer surgery and the remaining 6 (20.0%) underwent surgery for benign prostatic hyperplasia. The preinjection pad number was 2.9±1.9 pads per day. After injection treatment, the mean follow-up period was 9.3±12.7 months and the success rate was 43% (13/30) at 1 month and 32% (6/19) at 6 months. Injection was more likely to result in a successful outcome in patients with no preinjection radiation treatment history and higher abdominal leak point pressure (ALPP) than in those with a previous history of radiation treatment and lower ALPP, although this result was not statistically significant. Acute urinary retention occurred in 5 patients (17%).

Conclusions: Transurethral Macroplastique injection treatment is a relatively non-invasive treatment method for male SUI with a success rate of 43% at 1 month and 32% at 6 months. Patients with a higher ALPP and no previous history of radiation therapy may experience better treatment outcomes.

Keywords: *Dimethylpolysiloxanes; Male; Prostate; Urethra; Urinary incontinence*

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INTRODUCTION

In recent years, the incidence of prostate cancer has increased rapidly, and prostate cancer is now the fifth most common type of malignancy among Korean men [1]. Increased screening for prostate-specific antigen during health check-ups has contributed to increased detection of early prostate cancer, and the number of radical prostatectomies has increased correspondingly. In the case of benign prostatic hyperplasia (BPH), patients with lower urinary tract symptoms often report that their symptoms reduce quality of life. Thus, the number of BPH surgeries is also on the rise.

Male stress urinary incontinence (SUI) is one of the complications of prostate surgery. The first treatment approach for this condition is conservative management, which involves behavioral modifications, pelvic floor muscle training, and biofeedback. If conservative treatment fails, surgical treatment, including injection, male sling surgery, or creation of an artificial urinary sphincter (AUS)

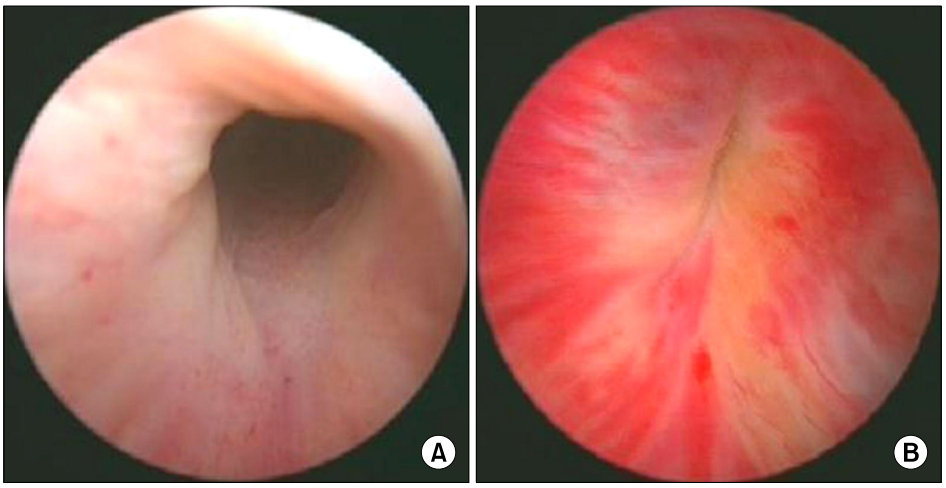

FIG. 1. Pre- and postinjection state of the urethral sphincter. (A) Preinjection state. The urethral lumen is wide open. (B) Postinjection state. The urethral lumen is coaptated.

can be considered. Compared with other types of surgery, bulking agent injection therapy is less invasive, requires no skin incision, and can be converted to another type of incontinence surgery if necessary [2].

In this study, we describe our surgical experience with transurethral injection treatment of Macroplastique bulking agent (Uroplasty, Minnetonka, MN, USA) for male SUI after prostate surgery. We investigated the efficacy of transurethral Macroplastique injection for male SUI after prostate surgery, and we determined the factors that affected outcomes.

MATERIALS AND METHODS

1. Study design and patients

This retrospective review included men with SUI treated by transurethral injection of Macroplastique bulking agent from March 2006 to November 2012 at Samsung Medical Center. All SUI symptoms had occurred as complications of surgery for prostate disease. A urodynamic study was performed in all patients before injection treatment, and all procedures were performed by a single experienced surgeon (K.S.L.). A retrospective medical record review and telephone interview were performed to obtain the following clinical data: age at injection treatment, type of previous prostate surgery, preinjection radiation treatment history, time interval between prostate surgery and injection treatment, number of preinjection pads per day, abdominal leak point pressure (ALPP), detrusor overactivity (DO) on preinjection urodynamic study, and injected volume. Treatment outcomes after injection were evaluated at postoperative 1 month and 6 months. We analyzed factors affecting treatment success. Complications associated with injection treatment were also recorded.

2. Patient preparation and transurethral injection procedure

Injection procedures were performed in the lithotomy position by using intraurethral lidocaine jelly injection. A 0-degree 24-Fr urethroscope was used. A syringe containing 2.5 mL of Macroplastique was attached to a 5-Fr injection catheter with a 20-gauge needle. The bulking agent was delivered to the 3, 6, 9, and 12 o'clock points of the urethra in the proximal position of the remnant urethral sphincter, creating a bleb under the urethral mucosa that protruded into the urethral lumen. Special care was taken to not inject the material into the external urethral sphincter because this can produce pudendal nerve irritation, resulting in sphincter spasm and discomfort. After injection, the urethral lumen was confirmed to be coaptated (Fig. 1). When proper coaptation was achieved, residual urine was evacuated with a thin urethral catheter to avoid displacement of the implant. Patients were discharged after successful voiding without significant residual urine ($\leq$100 mL).

3. Measurement of treatment outcomes

Patients were evaluated at 1 month and at 6 months after injection treatment by determining the number of pads used per day (objective parameter) and improvement in incontinence symptoms from before to after injection according to the Sandvik severity index (SSI) [3] and the benefit, satisfaction, and willingness to continue questionnaire [4] (subjective parameters). Dryness was defined as no wetting. Improvement was defined as use of one or fewer postinjection pads per day. Success was defined as dryness or subjective symptom improvement.

4. Statistical analysis

Statistical analyses were performed with PASW ver. 18.0 (SPSS Inc., Chicago, IL, USA). Chi-square tests were used to compare pre- and postoperative changes in the SSI score and factors affecting the outcomes of transurethral injection treatment. A p-value of less than 0.05 was considered statistically significant.

5. Ethics statement

This study was approved by the Institutional Review Board of Samsung Medical Center, which waived the require-

ment for written informed consent.

RESULTS

The study population comprised 30 men with a mean age of 66.1±5.3 years (range, 55–79 years). Of the 30 patients, 24 (80.0%) had undergone previous prostate cancer surgery (12 laparoscopic robot-assisted radical prostatectomies, 8 radical retropubic prostatectomies, 3 radical perineal prostatectomies, and 1 high-intensity focused ultrasound treatment), whereas the remaining 6 (20.0%) had undergone previous BPH surgery (3 holmium laser enucleations of the prostate, 2 transurethral resections of the prostate [TURP], and 1 photoselective vaporization of the prostate) (Table 1). Four patients (13.4%) had a history of radiation therapy for prostate cancer treatment. The mean preinjection number of pads was 2.9±1.9 pads per day. On the basis of the urodynamic findings, the mean preinjection ALPP was 109.7±41.9 cm H_2O. The ALPP was less than 80 cm H_2O in eight patients (26.7%). DO was observed in eight patients (26.7%). The mean time interval between prostate surgery and injection treatment was 35.8±25.2 months (range, 9–108 months). The mean injection volume was 5.3±2.1 mL, and no intraoperative complications occurred.

TABLE 1. Demographic and baseline characteristics of the patients

Variable	Value
No. of patients	30
Age (y)	
51–60	7 (23.3)
61–70	18 (60.0)
>70	5 (16.7)
Mean±SD	66.1±5.3
Previous prostate surgery	
Prostate cancer surgery	24 (80.0)
BPH surgery	6 (20.0)
Preinjection radiation therapy history	
Absent	26 (86.7)
Present	4 (13.3)
Preinjection pad	
<3 per day	15 (50.0)
≥3 per day	15 (50.0)
Mean±SD	2.9±1.9
Preinjection ALPP (cm H_2O)	
<80	8 (26.7)
≥80	22 (73.3)
Mean±SD	109.7±41.9
Preinjection detrusor overactivity	
Absent	22 (73.3)
Present	8 (26.7)
Interval between prostate surgery and injection treatment (mo), mean±SD	35.8±25.2

Values are presented as number (%) unless otherwise indicated. SD, standard deviation; BPH, benign prostatic hyperplasia; ALPP, abdominal leak point pressure.

The mean follow-up duration after injection treatment was 9.3±12.7 months (range, 1–63 months) and 19 patients had follow-up periods longer than 6 months. The mean pad number at follow-up was 1.7±1.7 pads per day. Thirteen patients (43%) were successfully treated at 1 month, consisting of 3 patients (10.0%) with dryness and 10 patients (33.3%) with improvement. Of them, five patients had follow-up times shorter than 6 months and two patients showed recurrence of incontinence symptoms. Six of 19 patients (32%) were successfully treated at 6 months, consisting of 1 patient (5.3%) with dryness and 5 patients (26.3%) with improvement.

Table 2 summarizes the changes in pre- and postinjection SSI score at the 1-month time point, which consists of four levels of severity. The number of patients who had a severe (8–9 points) or very severe (12 points) symptom score was 27 (90.0%) before injection and 14 (46.7%) after injection. However, this change was not statistically significant (p=0.361) (Table 2). Fifteen patients (50%) benefited from the treatment, whereas 13 patients (43%) reported some benefit. Fifteen patients (50%) were satisfied with the treatment and only five patients (17%) were "very dissatisfied" with the treatment (Fig. 2).

Univariate analysis of several factors at the 1-month time point revealed that patients who had no previous history of radiation treatment or a higher ALPP were more likely to experience successful injection treatment. However, this relationship was not statistically significant, nor was there any statistically significant relationship between success and any of the other factors evaluated (Table 3).

Acute urinary retention (AUR) occurred in five patients (17%) as a complication of surgery. Two patients with AUR were treated by suprapubic catheter insertion. One patient

TABLE 2. Pre- to postoperative changes in the sandvik severity index score

Sandvik severity index score	Preoperative (n=30)	Postoperative (n=30)	p-value
Categorized by the four-level severity index			0.361[a]
Dry (0)	0 (0)	3 (10.0)	
Slight (1–2)	0 (0)	1 (3.3)	
Moderate (3–6)	3 (10.0)	12 (40.0)	
Severe (8–9)	17 (56.7)	8 (26.7)	
Very severe (12)	10 (33.3)	6 (20.0)	

[a]:Chi-square test.

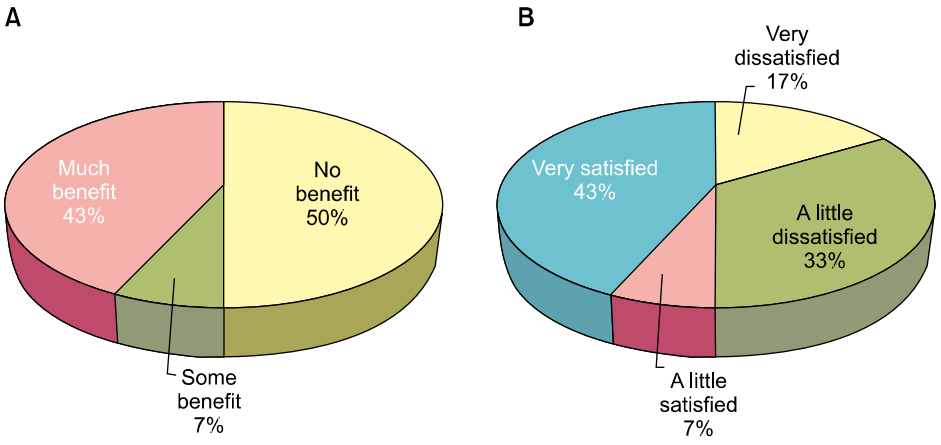

FIG. 2. Benefit and satisfaction measurements for transurethral injection treatment. (A) Fifteen patients (50%) benefitted from the treatment and 13 patients (43%) reported much benefit. (B) Fifteen patients (50%) were also satisfied with the treatment, whereas only five patients (17%) were "very dissatisfied."

TABLE 3. Univariate analysis of prognostic factors in the injection treatment of male incontinence at 1 month

Variable	Success		p-value
	No	Yes	
No. of patients	17	13	
Age (y)			0.616[a]
51–60	5 (71.4)	2 (28.6)	
61–70	9 (50.0)	9 (50.0)	
>70	3 (60.0)	2 (40.0)	
Mean±SD	65.8±6.1	66.5±4.2	0.726[b]
Previous prostate surgery			0.580[a]
BPH surgery	4 (66.7)	2 (33.3)	
Prostate cancer surgery	13 (54.2)	11 (45.8)	
Preinjection radiation treatment history			0.427[a]
Absent	14 (53.8)	12 (46.2)	
Present	3 (75.0)	1 (25.0)	
Preinjection pad			0.713[a]
<3 per day	8 (53.3)	7 (46.7)	
≥3 per day	9 (60.0)	6 (40.0)	
Preinjection ALPP (cm H_2O)			0.222[a]
<80	6 (75.0)	2 (25.0)	
≥80	11 (50.0)	11 (50.0)	
Mean±SD	103.9±37.8	117.3±47.1	0.394[b]
Preinjection detrusor overactivity			0.201[a]
Absent	14 (63.6)	8 (36.4)	
Present	3 (37.5)	5 (62.5)	
Injection volume (mL)	5.18±2.29	5.38±2.53	0.816[b]

Values are presented as number (%) unless otherwise indicated.
BPH, benign prostatic hyperplasia; ALPP, abdominal leak point pressure.
[a]:Chi-square test; [b]:Paired t-test.

kept the catheter for 1 month and the other the others kept catheter for 2 days. The remaining three AUR patients were treated by clean intermittent catheterization (CIC). One patient underwent CIC for 1 day and two patients underwent CIC for 2 days. One of the patients who underwent CIC for 2 days had a persistent weak stream. Therefore, after 6 months, we performed a urethroscopic examination of this patient. No abnormal narrowing or strictures were found; this patient is being closely observed.

DISCUSSION

The incidence of SUI after radical prostatectomy has been reported to range from 8% to 47% [5,6], whereas the incidence of SUI after TURP has been reported to be 0.5% [7]. The mechanism for male SUI after prostate surgery appears to be internal sphincter deficiency. The probable mechanism for internal sphincter deficiency after prostate surgery includes rhabdo-sphincter injury during apical dissection, large and deep sutures during vesico-urethral anastomosis, or injury of the neurovascular bundles.

Urinary incontinence causes problems, such as poor hygiene and loss of self-confidence, that directly affect the quality of life of patients. When conservative treatment fails, surgical treatment should be considered. AUS is considered the gold standard treatment for male SUI, with a success rate ranging from 59% to 90% [8,9] and a patient satisfaction rate of 76% [8]. However, the revision rate for AUS is relatively high (20% to 29%) owing to infection, urethral erosion, and mechanical failure [8,9]. Compared with AUS, a male sling operation has several advantages, including the absence of mechanical problems, no need for device training, immediate efficacy, and an overall reduced revision rate. The success rate of a male sling operation ranges from 54% to 83% [10,11]. However, urinary retention, erosion, infection, system dislocation, and persistent pain are possible complications of a male sling operation, whereas technical difficulty is another problem in patients who have undergone radical pelvic surgery [12]. Compared with other surgical treatments, bulking agent injection is less invasive but has a lower success rate, and multiple injections are usually needed to maintain continence [2]. The therapeutic mechanism of bulking agent injection therapy in male SUI patients is urethral sphincter obstruction or the sealing effect afforded by the bulking agent. Histologically, the bladder neck and posterior urethra consist of four layers, namely the mucosa, lamina propria, muscle layer, and adventitia. Of the four layers, the lamina propria has the potential space for bulging. If the bulking agent is inserted into the lamina propria, dissecting and urethral bulging between the mucosa and muscle layer can occur and result in sealing [12].

A variety of bulking agents have been used to treat male SUI. Polytetrafluoroethylene (Teflon) was widely used in the past, but was shown to cause several problems, including urethral irritation and perineal discomfort; small particle migration to the regional lymph nodes, lungs, and brain; and in animal experiments, polytetrafluoroethylene sarcoma formation [13]. Therefore, polytetrafluoroethylene is not currently in use. One of the most commonly used materials is collagen, which does not migrate to other sites. However, collagen is rapidly resorbed, so repeated injections are needed to maintain continence. A hypersensitivity reaction can also occur during collagen use [14]. Similar to collagen, autologous fat shows rapid resorption and is associated with a relatively low success rate. An adequate blood supply is essential for the maintenance of autologous fat; thus, the success rate is low when periurethral vascular injury is present after prostate surgery [15]. The Macroplastique used in this study is composed of textured silicon particles (polydimethylsiloxane) in a liquid gel. These particles have a low migration rate because they are larger than 100 μm, the injection material is encapsulated by nearby tissue, and there is a quiescent foreign body reaction that is maintained for 9 months [16]. Compared with other bulking agents, Macroplastique has stable characteristics.

Studies that have investigated transurethral injection treatment for male SUI have reported widely different success rates [2,12,16-27] (Table 4). This wide variation in success has several possible explanations. First, there is no common definition of success across studies. Studies also differed in terms of patient characteristics, injected materials, number of injections, and length of the postoperative follow-up period. In general, the results of previous studies indicate that treatment with an injection agent has a lower success rate than does AUS or a male urethral sling. Several factors may affect the success rate of injection. During radical prostatectomy, extensive scarring owing to multiple anastomotic incisions and scarring of the mucosal layer after radiation therapy can cause tight adhesion of the mucosa and muscle layer, or a "rigid urethra." Rigid urethra interferes with bulging and causes extravasation of materials [12]. The long length of the male urethra compared with the female urethra and technical failure owing to bulking agent migration may also contribute to the lower success rate of injection treatment [18].

In our study, the success rate was 43% at 1 month and 32% at 6 months. Our success rate was slightly lower than that reported in previous studies, perhaps because our definition of success was stricter than that used in previous studies and because of the low injection volume of our study. We considered success if the pad count was less than one pad per day with subjective symptom improvement. We believe our definition of success is more appropriate than that of previous studies because social continence is generally accepted to be less than one pad per day. Compared with the injection volume of the other study (range, 7.1–11.9 mL), the injection volume of our study was 5.3 mL (Table 4). We could not exclude the possibility of a relationship between a low injection volume and a low success rate. In addition, our study included patients who received only a single injection and excluded patients who received repeated injections because this approach yields more practical information for clinical practice. When injection treatment fails, most patients want a different surgical treatment rather than a repeat injection. Thus, determining the success rate after a single injection provides more useful data than determining the success rate after multiple injections when planning further treatment.

When we assessed incontinence by using the four-level SSI score, we found that the number of patients with severe or very severe incontinence decreased after surgery (before, 90%; after, 46.7%), but this change was not statistically significant. We believe that this result demonstrates improvement in subjective symptoms after Macroplastique injection treatment, although further study is needed.

Previous studies have identified several factors that influence the success of injection treatment. Increasing age is associated with problems such as low tissue quality, loss of ureter dexterity, and increased overactivity of the bladder [28]. Radiation therapy is associated with long-term consequences, such as obliteration of small vessels with subsequent endarteritis resulting in fibrosis, tissue ischemia, necrosis, and aberrant tissue repair [29]. Local ana-

TABLE 4. Summary of studies on injection treatment for male stress urinary incontinence after prostate surgery

Study	Year	No. of patients	Material	Mean follow-up (mo)	Mean injection no.	Mean injection volume (mL)	Definition of improvement	Treatment outcomes		
								% Dryness	% Improvement	% AUR
Cummings et al. [17]	1996	19	Col	10.4	2.1	17.4	>75% symptom reduction	21.1	36.8	10.5
Klutke et al. [18]	1996	20	Col	8.5	1.0	14.5	≥1 reduction in SUI Grade	25.0	45.0	5.0
Martins et al. [19]	1997	46	Col	26	2.8	31.0	>75% symptom reduction or ≤2 PPD	23.9	45.7	4.3
Colombo et al. [20]	1997	6	Macro	15.5	1.5	7.5	Subjective symptom improvement	83.3	16.7	16.7
Griebling et al. [21]	1997	25	Col	13	2.6	27.5	>50% PPD reduction	8.0	32.0	16.0
Faerber and Richardson [22]	1997	68	Col	38	5.0	36.0	>50% PPD reduction	10.3	76.5	11.8
Elsergany and Ghoniem [12]	1998	35	Col	17.6	1.9	8.5	≥1 reduction in SUI Grade	20.0	31.4	2.9
Smith et al. [23]	1998	62	Col	29	4.0	20.0	≤1 PPD	8.1	30.6	4.8
Tiguert et al. [24]	1999	21	Col	24.5	2.9	18.4	≥1 reduction in SUI Grade	4.8	57.1	0
Kylmala et al. [16]	2003	50	Macro	7.3	3.0	7.1	Improvement in 1 hour pad test and subjective symptoms	60.0	24.0	0
Westney et al. [2]	2005	322	Col	40	4.4	35.0	>50% PPD reduction	17.1	27.0	3.4
Schneider et al. [25]	2005	44	NR	32	1.4	5.2	Symptom improvement	43.2	40.9	13.6
Imamoglu et al. [26]	2005	23	Macro	48	1.2	11.9	≤1 PPD	47.8	26.1	4.3
Onur and Singla [27]	2006	34	Col	15	2.1	8.8	>50% PPD reduction or ≤2 PPD	14.7	14.7	2.9
Present study		30	Macro	9.3	1.0	5.3	≤1 PPD and subjective symptom improvement	10.0	33.3	16.7

AUR, acute urinary retention; NR, not reported; SUI, stress urinary incontinence; PPD, pad use per day; Col, collagen; Macro, Macroplastique.

tomical distortion and tissue hypovascularity influence the results of surgery. Preoperative DO or low ALPP are also known to be negative risk factors for treatment success [30]. In the current study, patients who had a history of radiation therapy had a lower success rate (25%) than did those who did not (46.2%, p=0.427). Likewise, patients with an ALPP lower than 80 cm H_2O had a lower success rate (25%) than did those whose ALPP was equal to or greater than 80 cm H_2O (50%, p=0.222). However, these differences were not statistically significant, most likely owing to the small number of cases evaluated.

A potential limitation of this study was the retrospective cohort design. However, during the study period, our measurement and interpretation of clinical parameters such as pad number, SSI score, and urodynamic findings were consistent. Another limitation of this study was the small number of patients evaluated. Although our study period was longer than 6 years, only 30 patients who were treated during this period met the enrollment criteria.

Several studies have assessed the outcomes of bulking agent injection therapy with collagen, but few studies have examined outcomes after injection therapy with Macroplastique bulking agent for male SUI. To our knowledge, this is the first study to report outcomes of Macroplastique injection therapy to treat SUI in Korean men.

CONCLUSIONS

Injection therapy with Macroplastique bulking agent is a simple and relatively noninvasive surgical treatment for male SUI after prostate surgery with a short-term success rate of 43% and a longer-term success rate of 32%. There was a nonsignificant tendency for the treatment to be successful when patients had no preinjection radiation treatment history or when they had a higher ALPP. Our study provides useful information regarding the treatment options for male SUI after prostate surgery.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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