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LONG-TERM EFFICACY OF MACROPLASTIQUE INJECTION FOR THE TREATMENT OF URINARY INCONTINENCE IN MALES AND FEMALES

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Objective To evaluate the long-term efficacy of endoscopic injection of Macroplastique (Polydimethylsiloxane, PDMS) in male and female urinary incontinence (UI).

Patients and Methods A total of 87 patients with different causes of urinary incontinence have been treated by endoscopic injection of PDMS at our department between 1997 and 2001. The group consisted of 39 male and 48 female patients with a mean age of 58 and 44 years, respectively. All patients underwent a sophisticated history taking including urodynamics and were instructed to complete a pre- and postoperative voiding diary. The results were evaluated by questionnaire at 1, 6, 12 and 24 months after injection. The outcome was classified as dry in all circumstances, improved or failed.

Results At one month, 5 male (13%) and 10 female (21%) patients were dry, while 27 males and 29 females had improved and treatment had failed in 7 males (18%) and 9 females (19%). At the last follow-up (mean injections = 2.5), 12 males patients (31%) and 27 female patients (56%) were classified as dry, 18 males (46%) and 14 females (29%) were improved, while in 9 males (23%) and 7 females (15%) the procedure had failed. The overall success rate (dry and improved) was 77% for the males and 85% for the females.

Conclusion The use of PDMS (Macroplastique) is a good and effective alternative for the treatment of intrinsic sphincter deficiency in male and female patients. The implants do not lose volume over time and have a good long-term effect.

Key Words urinary incontinence, stress, injection therapy, Macroplastique (PDMS)

INTRODUCTION

Urinary incontinence (UI) following radical prostatectomy has a reported incidence of 5 to 12% and can significantly diminish the quality of life[1-4]. Urethral incompetence usually requires interventional therapy. Increasing urethral outflow resistance by submucosal injection of a bulking agent was used as a treatment option in the past. In the 1960s and 1970s, good results were also reported with the use of polytetrafluoroethylene[5,6].

Stress urinary incontinence (SUI), which is the involuntary loss of urine during stressful activities, develops in 10 to 30% of women of all ages[7]. In women, two types of sphincter abnormality are diagnosed: bladder neck hypermobility and intrinsic sphincter deficiency (ISD). ISD may account for a higher failure rate of surgical procedures performed to treat stress urinary incontinence.

Historically, sling procedures have been used as the first line of treatment however such procedures may increase and/or produce a significant incidence of urinary retention.

More recently, periurethral bulking agents, which are less invasive, have been used to treat ISD thus avoiding recurrent surgical procedures. Bulking agents, such as polytetrafluoroethylene paste and collagen are able to coapt the urethral mucosa and as a consequence cause a higher resistance to increased abdominal pressure.

However, polytetrafluoroethylene paste consists of microparticles that vary in size from 1 to 100 µm, with 90% being smaller than 40

Table 1: Patient Characteristics

	Male Patients (n = 39)	Female Patients (n = 48)
Incontinence Grade:		
Grade 1	3	4
Grade 2	11	13
Grade 3	25	31
Previous Surgery:		
Sling procedure	3	6
Injection therapy	3	7
Resected artificial sphincter	1	
Kelly plication		9
Open Burch procedure		4
Laparoscopic Burch prodecure		3
Aetiology:		
Radical prostatectomy	12	
Pelvic irradiation (radical prostatectomy group)	3	
Radical cystectomy	4	
Resection of rectal carcinoma	1	
TURP	14	
Open prostatectomy	5	
Posterior urethral rupture	2	
Post-visual internal urethrotomy	1	
Uncomplicated stress urinary incontinence		40
Urethral diverticulectomy		3
Pelvic fracture trauma		5

µm, resulting in distant migration and granuloma formation[8]. The long-term results have been disappointing. Kiilholma and Mäkinen reported that only 18% of their patients were continent five years after polytetrafluoroethylene injection[9].

Collagen, on the other hand, is expensive and may cause allergic reactions in around 3% of patients[10]. In most studies incontinence returned gradually with a median continence duration of 23 months[11]. Repeat injections are necessary to achieve sustained continence, which increases the cost.

The main disadvantages of using autologous fat relate to the variability of resorption as well as repeated injections. At 1-year follow-up only 28% of patients are cured with this therapy[12].

PDMS implants are the most recently developed injectable material. Numerous reports on PDMS for the treatment of female SUI have been published with encouraging results for follow-up periods of up to five years[13-17].

In our study, the long term efficacy of PDMS injection therapy for the treatment of both male and female UI was evaluated.

PATIENTS AND METHODS

Between April 1997 and March 2001, a total of 87 patients (39 males and 48 females) with different aetiologies of UI were enrolled in the study.

A total of 39 males with UI with a mean age of 58 years (range 45 to 70 years) underwent transurethral submucosal PDMS injections for ISD. The patients had developed UI for the following reasons: secondary to radical prostatectomy (12 patients), pelvic irradiation (3 patients of the radical prostatectomy group), radical cystectomy and orthotopic diversion with ileal neobladder (4 patients), as a complication of abdomino-perineal resection of a rectal carcinoma (1 patient), as a complication of transurethral resection of the prostate (14 patients), following open prostatectomy (5 patients), following urethroplasty after traumatic rupture of the posterior urethra (2 patients) and following visual internal urethrotomy (1 patient). Seven of these patients had a history of previous surgery to treat their incontinence. Three patients had undergone a sling procedure, three had undergone endoscopic injection elsewhere (two polytetrafluorethylene and one with collagen) and the remaining patient suffered from complications caused by an artificial sphincter; the device was removed due to infection and urethral erosion. (Table 1)

Forty-eight females with either UI or total urinary incontinence due to ISD were enrolled in the study. Their mean age was 44 years (range 36 to 54). Eight patients developed incontinence as a complication of surgery or trauma. Three patients had a history of urethral diverticulectomy for multiple urethral diverticulae. Five patients had a history of urethral and vaginal reconstructive surgery after pelvic fracture trauma. Forty patients had uncomplicated stress incontinence of variable degrees up to total incontinence. Twenty eight of those patients had a history of previous incontinence surgery: transvaginal surgery (Kelly plication) (9 patients), open Burch procedure (4 patients), laparoscopic Burch procedure (3 patients), endoscopic polytetrafluorethylene injection (7 patients) and sling operation (6 patients, 2 of them TVT). Three of the slings failed and three caused difficulty and retention of urine; one was extracted and two were incised in situ to relieve the patients. (Table 1)

The degree of incontinence was graded according to Stamey on a scale of 0 to 3: 0 = continent with no urinary leakage, 1 = urine leakage with severe stress on heavy lifting or coughing, 2 = urine leakage with minimal to modest activity, shifts in posture, standing or walking, and 3 = constant urine leakage regardless of posture or activity[18].

Each patient maintained a 7-day voiding diary before and after treatment. The number of pads used by the patient each day before and after treatment was recorded. Every patient underwent a thorough physical examination and urinalysis. If there was an infection an appropriate antibiotic, determined according to urine culture and sensitivity, was prescribed. The patients were re-scheduled for treatment on negative urine culture.

Urodynamics with the assessment of the abdominal leak point pressure (ALPP) were performed in all patients prior to treatment. The parameters obtained were bladder capacity, early sense of urge, presence or absence of intravesical abnormal contractions and ALPP.

Diagnosis of ISD was based on a low ALPP (< 60 cm H_2O). In females, bladder neck mobility was assessed by lateral cystourethrography while the patient was at rest and during stress, and clinical examination, including a cotton swab test (< 30°).

The material used for injection was "Macroplastique" consisting of soft irregularly textured, vulcanized, medical grade PDMS particles suspended in a carrier gel of pharmaceutical grade, water soluble, low molecular weight polyvinylpyrrolidone. All injections were performed under local, spinal or general anaesthesia. A routine intravenous dose of broad-spectrum antibiotics was given to all patients one hour before the procedure. After injection a course of oral antibiotics was continued for 5 days. Injections were performed transurethrally. After inspection of the urethra and bladder, a 5 Fr. needle-tipped catheter was introduced through the working channel of the cystoscope. The needle was then inserted just beneath the surface of the mucosa, piercing the lamina propria but not the muscularis layer. In some males with urethral strictures a visual internal urethrotomy (VIU) was performed and the injection was postponed for a month.

In male patients the injection was performed at the 4 and 8 o'clock position just proximal to the external sphincter and distal to

the bladder neck. When the needle was placed into the correct submucosal space, the PDMS spread circumferentially, producing a nice and smooth bulge that narrowed the lumen. However, in some cases, injection in multiple sites was needed if coaptation of the bulges was unsatisfactory.

Injection was performed slowly to allow the substance to raise the mucosa forming blebs until we observed coaptation of the urethral lumen. Occasionally, injections at the area of the external sphincter or just distally were performed when the area of the prostatic fossa was severely scarred due to the previous failed surgical procedures. In such cases, it is justified to inject at any site with a sound mucosa that can hold the injected substance to form the occluding bulge.

In female patients, the injection was performed at the 3 and 9 o'clock position just distal to the bladder neck, until the creation of two well occluding bulges that created lateral lobes. In patients with extensive urethral fibrosis, due to previous vaginal or urethral surgery, the injection was performed at any part of the urethral circumference so as to achieve the required narrowing of the lumen.

Once the injection was completed, cystoscopic maneuvers were minimized to prevent molding of the urethra. The bladder was drained for 3-4 hours postoperatively with a 6 Fr. ureteric catheter that was introduced through the cystoscope keeping it distal to the injection site. The ureteric catheter was fixed by adhesive band to the penis in males or to the thigh in females. All patients were discharged home on the same day of injection and kept on oral antibiotics for 5 days. Patients who developed any degree of urgency and/or urge incontinence after injection were given anticholinergic therapy for 2-4 weeks. When the patient was not satisfied with the results, an additional injection was considered after three months. A maximum of three injections was given to patients who showed no improvement, although the number of injections could exceed three if slow improvement was encountered.

When symptoms stabilized and no further injections were needed, the patients made regular visits after 1, 6, 2 and 24 months to evaluate their state of continence. Urodynamics were performed only when indicated.

In this study cure implied no incontinence at all, improvement meant a change from one grade to a lower grade, and failure meant no change from the baseline values.

RESULTS

All patients presented their pre- and post injection voiding diaries, and the subjective results of treatment were evaluated. Twenty-one patients (15 males and 6 females) had recurrent urinary tract infections (UTI) and were treated according to their urine analysis with culture and sensitivity test. Involuntary bladder contractions and/or sensory instability were noted in 11 patients (all females without UTI); all were given anticholinergic therapy. The mean follow-up was 32 months after the last injection (range 22 to 50 months).

In the male group the average pre-treatment number of pads used was 5 daily (range 2 to 10). The severity of incontinence was: grade 1 in 3, grade 2 in 11 and grade 3 in 25 patients. The average pre-treatment ALPP was 58 cm/H_2O (range 32 to 95 cm/H_2O), while the average bladder capacity was 315 ml (range 180 to 430 ml). In five cases the injection was postponed for one month because VIU was performed to release mild urethral strictures that were found during initial urethroscopy.

The treatment results in the male patient group were as follows: One month after the procedure, 5 patients (13%) were classified as dry, 27 (69%) as improved and treatment had failed in seven patients (18%). At six months, 11 patients (28%) were considered completely dry, 15 (38%) were improved, and treatment had failed in 13 (34%). At 12 months, 13 patients (34%) were considered completely dry, 19 (48%) were improved, and treatment had failed in 7 (18%) patients. At 24 months, 12 patients (31%) were classified as dry, 18 (46%) were improved and treatment had failed in 9 (23%). The total success rate (dry and improved) was 77%. (Table 2)

Of the 40 women in the female group who had urodynamic stress incontinence, 18 had bladder neck hypermobility and 5 had a patulous urethra but all of them had variable degrees of intrinsic sphincteric deficiency.

In the female patient group, the average pre-treatment number of pads used was 4 daily

Table 2: Results in the Male Patients

	1 Month		6 Months		12 Months		24 Months	
	No.	%	No.	%	No.	%	No.	%
Dry	5	13%	11	28%	13	34%	12	31%
Improved	27	69%	15	38%	19	48%	18	46%
Failed	7	18%	13	34%	7	18%	9	23%
Success	32	82%	26	66%	32	82%	30	77%

Table 3: Results in the Female Patients

	1 Month		6 Months		12 Months		24 Months	
	No.	%	No.	%	No.	%	No.	%
Dry	10	21%	19	40%	25	52%	27	56%
Improved	29	60%	21	44%	16	33%	14	29%
Failed	9	19%	8	16%	7	15%	7	15%
Success	29	81%	40	84%	41	85%	41	85%

(range 2 to 8). The severity of incontinence was grade 1 in four, grade 2 in 13 and grade 3 in 31 patients. The average pre-treatment ALPP was 46 cm/H_2O (range 26 to 75 cm/H_2O), while the average bladder capacity was 340 ml (range 165 to 530 ml).

One month after the procedure,10 of our female patients (21%) were dry, 29 (60%) had improved and treatment had failed in 9 cases (19%). At six months, 19 patients (40%) were completely dry, 21 (44%) were improved and treatment had failed in eight (16%). At 12 months, 25 patients (52%) were completely dry, 16 (33%) were improved and treatment had failed in 7 (15%). At 24 months, 27 patients (56%) were dry, 14 (29%) were improved and in 7 (15%) the treatment has failed. The total success rate (dry and improved) was 85%. (Table 3).

One injection was performed in 19 patients (6 males and 13 females), two in 31 (10 males and 21 females) and 3 or more in 37 patients (23 males and 14 females). The mean volume at each injection was 4.5 cc (5.5 cc for males and 3.5 cc for females) and the mean total volume injected for a patient was 9.5 cc (11.5 cc for males and 7.5 cc for females). The mean interval between two injections was 4.8 months (range 3 to 12).

Of the failed cases six males and five females received two injections due to lack of response to the treatment. The remaining failed cases were treated three times as they had shown an initial improvement but had relapsed on the last follow up. Mild to moderate urgency following the treatment was noted in 20 patients (7 males and 13 females) and was treated with anticholinergics for 2-6 weeks until an improvement was achieved.

All patients tolerated the procedure well without any significant side effects, although 6 patients (4 males and 2 females) developed

retention postoperatively. An 8 Fr. Nelaton catheter was used to drain the bladder (needed only once).

DISCUSSION

The treatment of ISD in men after radical prostatectomy is a technically challenging procedure. Post-prostatectomy incontinence and other forms of male urinary incontinence have a significantly negative impact on the quality of life[19]. Treatment options are limited and include artificial sphincter, injection of bulking material or sling operations.

The artificial urinary sphincter is a known effective solution in managing ISD. However, it carries the risk of disturbed bladder compliance and function to a degree that may affect the upper urinary tract. Moreover, there is the possibility of urethral erosion, especially in patients with a history of difficult pelvic operation and/or significant blood loss. Complications such as infections and mechanical problems, requiring revisions are additional disadvantages[20].

Sling operations have proved to be technically difficult in males, especially after radical pelvic surgery[21]. Extensive fibrosis associated with male incontinence after surgery or trauma, and pelvic irradiation after radical prostatectomy may further complicate the procedure; for this reason, it is rarely performed.

Alternatively, injection therapy has the advantages of being easily performed as an outpatient procedure because of the use of local anesthesia and a low complication rate, which makes it suitable especially in the elderly incontinent population[22].

In this study, patients with variable and different aetiological factors causing incontinence were included because the main message of the study was to show the usefulness of injection therapy as a first line simple treatment for all cases of urinary incontinence especially those of intrinsic sphincteric deficiency.

The best results were obtained in patients who had developed UI after radical prostatectomy and radical cystectomy and had not previously been operated upon for incontinence, due to the better field and better tissues available for injection. On the contrary, post-TURP and open prostatectomy patients presented with an extensively scarred and fibrotic mucosa and submucosa complicating the injection of the substance. The PDMS was easily extruded out off the mucosa, as there was no pliant submucosal space that could hold the injected material.

The same was apparent in the female group. Best results were obtained in those patients who had not undergone a previous failed surgical intervention (primary). The least improvement was obtained in those with transvaginal procedures as compared to the abdominal approach.

In this study, 18 patients (37%) demonstrated bladder neck hypermobility which was expected to increase the failure rate as reported in other studies[23]. On the contrary, good results were achieved with these patients (seven became completely dry, nine improved and two were considered failures), although six patients in this group had a history of previously failed sling operation and TVT. These results are in accordance with the results of Bent and associates whose data showed that collagen injection was effective for treating patients with urethral hypermobility associated with SUI[24].

In other studies applying PDMS, no major complications or incidences of distant migration were reported, only a few minor complications, including transient urinary retention requiring urethral catheterization and urinary tract infection[15,25,26]. This is similar to our results which are even superior to many other reports for both males and females. In our view, this may be attributed to technical aspects and is not associated with patient selection. All the procedures were performed using the transurethral approach which offers a better selection of the injection site, a direct evaluation of mucosal coaptation and immediate monitoring of product extrusion allowing additional injection. Performing the procedure as described is more economic than the transperineal or periurethral approaches.

The real challenging and complex cases are those that had previous failed surgery. In these patients the injection was performed without adhering to the predetermined implantation sites along the urethra or the circumference. The material was placed wherever the submucosa was compliant, starting just distal to the bladder neck to the level of the external sphincter or more distal in very scarred ure-

thras. Targeted sites at 5 and 7, 4 and 8 or 3 and 9 were used in non operated patients, while in the difficult and complicated cases it is justified to inject any part of the circumference until obtaining coaptation at 2, 3 or 4 sites, in an attempt to create a continent urethral outlet.

In this study postoperative drainage was done by introducing a 6 Fr. ureteric catheter through the cystoscope which was left in place for a few hours without using a Foley catheter. Fixation of the ureteric catheter was performed as previously described. This drainage procedure minimizes the risk of moulding of the implanted material around a larger bore catheter (Foley) immediately after injection, and prevents disruption of the bulges. In general the best results are obtained when a very wide bladder neck is avoided because of the volume needed to reach coaptation, to avoid fibrotic tissue, to inject under a sound and compliant mucosa in order to achieve well coapted mucosal bulges.

Although the price of the material used is expensive, yet, it is still cost effective when compared to open surgery and sling operations, because the procedure is done on an outpatient basis, thus avoiding hospital expenses.

In conclusion, transurethral injection of PDMS implants (Macroplastique) is a good, safe and effective alternative for the treatment of intrinsic sphincter deficiency in male and female patients with or without bladder neck hypermobility. It can be easily repeated when needed, and does not jeopardize further surgical procedures. The implants do not lose volume over time and have a good long-term effect.

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RESUME

Efficacité à Long Terme de l'Injection de Macroplastique pour le Traitement d'Incontinence Urinaire chez les Sujets de Sexe Masculin et Féminin

Objectif : D'évaluer l'efficacité à long terme de l'injection endoscopique de Macroplastique (Polydimethylsiloxane, PDMS) chez les patients présentant une incontinence urinaire (UI). **Patients et Méthodes :** Un total de 87 patients, présentant différentes causes d'incontinence urinaire, ont été traités par l'injection endoscopique de PDMS entre avril 1997 et mars 2001. Le groupe s'est composé de 39 hommes et 48 femmes avec un âge moyen de 58 et 44 ans, respectivement. Tous les patients ont subi un examen complet, une étude urodynamique, et ont été chargés de tenir un journal intime pré et postopératoire. Les résultats ont été évalués par le questionnaire à 1, 6, 12 et 24 mois après injection. Les résultats ont été classés comme secs dans toutes les circonstances, améliorée ou échec. **Résultats :** À 1 mois, 5 hommes (13%) et 10 femmes (21%) étaient secs avec 27 hommes et 29 femmes améliorées, le traitement a échoué chez 7 hommes (18%) et 9 femmes (19%). Enfin de suivi (injections moyennes = 2.5) 12 hommes (31%) et 27 femmes (56%) ont été classés en tant que secs, 18 hommes (46%) et 14 femmes (29%) ont été améliorés tandis que 9 hommes (23%) et 7 femmes (15%) étaient considérés comme des échecs. Le taux de succès (sec et amélioré) était de 77% pour les hommes et 85% pour les femmes. **Conclusion :** L'utilisation de PDMS (Macroplastique) est une bonne et efficace alternative pour le traitement de l'insuffisance intrinsèque du sphincter chez les patients masculins et féminins. Les implants ne perdent pas de volume avec le temps et ont un bon effet à long terme. Le coût élevé de Macroplastique doit, cependant, être pris en considération en déterminant l'efficacité d'un tel traitement par rapport à d'autres options potentielles.

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