

Original Article

The treatment of male stress urinary incontinence with polydimethylsiloxane in compliant bladders following spinal cord injury

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Study design: Retrospective analysis.

Objectives: To evaluate the safety and efficacy of polydimethylsiloxane (PDS, Macroplastique™) submucosal injections, in the treatment of male genuine stress urinary incontinence secondary to spinal cord injury (SCI).

Setting: London Spinal Injuries Unit, Stanmore, UK and Institute of Urology and Nephrology, London, UK.

Patients and methods: A retrospective analysis identified 14 patients treated with PDS for stress urinary incontinence secondary to SCI between 1997 and 2001. A single surgeon at a specialist spinal injuries unit managed all patients. A total of 13 patients had suffered a traumatic SCI (T11:n=2; T12:n=5; L1:n=5; L2:n=1), while one developed stress incontinence after spinal surgery. The mean age was 41 years (range 26–69 years) and the mean duration of injury was 9.6 years (range 1.5–48 years). The preoperative investigations included video cystometrogram (VCMG) confirming the presence of urodynamically proven stress incontinence without evidence of urge incontinence. Complete cure was defined as a cessation of pad usage with no evidence of leakage on VCMG. Incomplete cure with improvement was defined as a >50% reduction in the number of pads used, with incontinence present on VCMG.

Results: The follow-up ranged from 12 to 58 months (mean 34.7 months). Five patients (36%) reported complete success, confirmed by VCMG. Three patients (21%) reported improvement with >50% reduction in the use of pads. The procedure failed completely in six patients (43%). No immediate or late complications were noted with the procedure.

Conclusions: The use of PDS is a safe and minimally invasive treatment for genuine stress urinary incontinence in males following SCI with a stable compliant bladder. We achieved complete cure in 36% of our patients with confirmation on VCMG. A further 21% reported greater than 50% reduction in usage of pads; however, on VCMG stress incontinence was demonstrated in these patients. We suggest that PDS can be used as the first line of treatment in this difficult group of patients with complex problems.

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Keywords: male; genuine stress urinary incontinence; stable complaint bladder; polydimethylsiloxane

Introduction

The international continence society has defined genuine stress incontinence (GSI) as the complaint of involuntary urine leakage on effort or exertion, or on sneezing or coughing.¹ The prevalence of urinary incontinence in men ranges from 6.6 to 8.9%.^{2,3} The reported rate of stress incontinence in males after transurethral resection of prostate is 1–5%,⁴ and after radical retropubic prostatectomy is approximately 30%.^{5,6} There are no

figures available for the incidence of male stress incontinence after spinal cord injury (SCI). More than 80% of SCI are in males and two-thirds of these are in individuals less than 30 years of age.⁷ In this young patient group, stress incontinence can be a particularly distressing problem and result in low self-esteem. In turn social interactions, particularly sexual relations, can be difficult to establish.

Conservative management of GSI has not been particularly successful.⁴ Surgical treatment in males is limited to either an artificial urinary sphincter or urinary

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diversion, both of which are major undertakings for the patient and surgeon. During the last two decades minimally invasive procedures, particularly endoscopic periurethral injections, have been described to treat GSI (male or female), but none have gained universal approval. Periurethral injections of sclerosing agents (paraffin, dondren) have been used to treat incontinence since 1938.⁸ In the 1970s, polytetrafluoroethylene was used with initial success, but migration of particles to distant sites (eg lungs, brain) raised concerns.^{9,10} Collagen was used in the early 1980s, but problems included allergic reactions and absorption over time.¹¹ Autologous fat encountered similar problems of absorption.¹² Polydimethylsiloxane (PDS, Macroplastique™) that has been in use since 1991 is a nontoxic and hypoallergenic substance. It comprises silicone particles ranging in size from 100 to 600 μm (average 150 μm), which do not migrate.^{13–15} There are some reports in the literature evaluating the efficacy of PDS in the treatment of male GSI secondary to prostatectomy, with a success rate varying from 26 to 100% after 1 year.^{16,17} However, there are no published reports for the use of PDS in male stress incontinence of neurogenic origin.

Intrinsic sphincter deficiency is thought to be a major cause of GSI in males following neural damage during radical prostatectomy.^{18,19} Similarly, neural damage after SCI may result in intrinsic sphincter deficiency leading to GSI. This may be managed by injection of bulking agents, such as PDS to raise submucosal cushions and thereby increase outflow resistance. We report our experience with PDS used exclusively to treat male GSI secondary to SCI.

Patients and methods

A retrospective analysis identified 14 male patients with GSI secondary to SCI, and treated with endoscopic

injection of PDS between September 1997 and July 2001. All patients had GSI demonstrated on preoperative video cystometrogram (VCMG). Neurogenic detrusor overactivity (NDO) was noted on VCMG in two cases with thoracic level injuries in spite of being on anticholinergics, but they did not demonstrate evidence of urge incontinence. The remaining patients had either completely suppressed NDO (by anticholinergic medication) not manifested on VCMG or acontractile bladders.

Patients

A total of 13 patients had a SCI affecting the sacral spinal micturition centre located near the termination of spinal cord (T12–L1 vertebral level) (see Table 1).^{20,21} Seven had thoracic level injuries (T11: $n=2$; T12: $n=5$), while six had lumbar spinal injuries (L1: $n=5$; L2: $n=1$). One patient had developed neuropathic bladder dysfunction after spinal surgery. The mean age was 41 years (range 26–69 years) and the mean duration of injury was 9.6 years (range 1.5–48 years). Five patients performed clean intermittent self-catheterization (CISC) to empty their bladder, while one had a sacral anterior nerve root stimulator implanted with posterior rhizotomy. Eight were using a suprapubic catheter (SPC) as a means of bladder drainage. All patients were using pads preoperatively to keep themselves dry. Two patients had previously failed surgery with endoscopic injection of collagen.

Initial follow-up was at 6 weeks postoperation for subjective evaluation. A VCMG was organised at 3 months to assess objectively the outcome of the operation. Thereafter, annual follow-up was performed with VCMG. Routine serum electrolytes were monitored on each visit. Any further surgical procedure performed and all complications were documented.

Table 1 Patient demographics and VCMG results

Patient no/ age	Aetiology	Time from SCI (years)	Preop VCMG (grade)	Postop VCMG (grade)	Follow-up (months)
1/47	L1 SCI	5.66	3	NI	58
2/44	T11 SCI	10.25	3	NI	12
3/31	T12 SCI	1.5	3	NI	21
4/56	Spinal surg ^a	5.75	3	NI	33
5/53	L1 SCI	8.08	3	NI	24
6/42	T12 SCI	2.33	3	3	18
7/29	L1 SCI	7.25	3	3	13
8/48	L1 SCI	4.33	3	3	36
9/26	L1 SCI	6.58	3	3	36
10/41	T12 SCI	16.0	3	3	57
11/31	T12 SCI	6.08	3	3	38
12/69	T12 SCI	48.0	3	3	36
13/26	L2 SCI	5.17	3	3	47
14/44	T11 SCI	8.25	3	3	57

VCMG: video cystometrogram; SCI: spinal cord injury; NI: no incontinence

^aSpinal surgery for sacral cordoma

Table 2 Summary of results

Postoperative outcome management	No. of treatment episodes: no. of patients	Bladder
Completely dry (<i>n</i> = 5)	1:5	4 pts. SPC 1 pt. CISC
Improved (<i>n</i> = 3)	1:2 2:1	2 pts. SPC 1 pt. CISC
Failed (<i>n</i> = 6)	1:3 2:2 3:1	3 pts. SPC 2 pts. CISC 1 pt. SARS

SPC: suprapubic catheter; CISC: clean intermittent self-catheterization; SARS: sacral anterior root stimulator; pts: patients

We defined cure as cessation of using pads along with confirmation of dryness on VCMG. Improvement was described as >50% decrease in number of pads but evidence of leakage on VCMG.

PDS injection technique

The type of anaesthesia used (none, spinal, general) was dependent on the level and completeness of the injury. All patients received a single dose of antibiotics on induction of anaesthesia. We employed the PDS injection technique described by Politano²² using a prefilled syringe on a piston gun. Following a preliminary cysto-urethroscopy, approximately 2.5–5.0 ml (mean 4.0 ml) of PDS was injected submucosally in the region of external urethral sphincter. The bulking agent was injected between 2 and 5 O'clock on the left and 7 and 10 O'clock on the right. Additional injection was performed at 12 O'clock if adequate coaptation was not achieved. At the end of the procedure, the bladder was completely emptied either with the patient's existing SPC or with a size 10F urethral catheter. The latter group continued CISC postoperatively.

Results

All procedures were completed successfully. No intra-operative complications were noted other than some leakage of PDS at the injection sites. The follow-up ranged from 12 to 58 months (mean 34.7 months). In all, 10 patients had a single injection, three had two and one had three repeat injections (see Table 2 for summary of results).

Five (36%) patients reported complete success at 3 months becoming continent without any leakage either at rest or on transferring. This was confirmed on VCMG and has been maintained at a mean follow-up of 20 months (range 6–48 months). All these patients required only a single injection and four (80%) of them had been using an SPC for bladder drainage, while one had been performing CISC.

Three (21%) patients at 6 months follow-up reported symptomatic improvement with >50% decrease in the use of pads, but had continuing evidence of GSI on VCMG. Of these, one had a repeat injection without additional benefit. The remaining two refused further intervention.

The procedure failed completely in six (43%) patients of whom three underwent a repeat procedure again without improvement. Of the others, two had an artificial urinary sphincter implanted and one is continuing to use pads, but is contemplating further surgery.

Both the patients with NDO on VCMG (but without evidence of urge incontinence) failed PDS injection therapy.

Discussion

In the present retrospective series, 36% of patients were cured of GSI after endoscopic submucosal injection of PDS confirmed on VCMG studies. This compares favourably with long-term results reported in the literature for non-neuropathic patients with cure rates ranging from 30 to 40%.^{23,24} A further 21% reported improved continence rates and >50% reduction in pad usage. However, VCMG showed no detectable difference pre- and postPDS treatment. Interestingly, this may have been a placebo effect, but they were all willing to undergo the procedure again if offered.

In our experience, all cured patients needed only a single treatment episode. Of those patients who initially failed treatment or reported improvement none gained any further benefit from repeat injections, which was also noted by Guys *et al*²⁵ in their study of incontinence in children with neurogenic bladders. In our group, two patients who completely failed PDS injection therapy subsequently had successful insertion of an AUS. In both cases there was no problem during dissection in the region of the bladder neck, close to the area of PDS injection, which is in agreement with the experience of other surgeons.^{26,27}

Postoperatively two of the four patients (50%) employing CISC for bladder drainage completely failed treatment, whereas three of eight (37%) using SPC drainage were unsuccessful. It is presumed that the mode of action of bulking agents is to restore the submucosal cushions in the urethra, which may be lost in neurogenic damage to the external sphincter.²⁸ We suggest that CISC causes a recurrent dilatatory effect in the early postoperative period, thus permanently disturbing the urethral indentations caused by the PDS. Therefore, all patients should ideally be managed after injection by SPC bladder drainage in the initial period after surgery, but we acknowledge that this hypothesis needs to be confirmed by larger studies.

Both patients with NDO did not have any benefit from repeated PDS treatment, which is in agreement with previous reports of children with congenital neuropathic bladders.²⁵ Thus, endoscopic injection of

bulking agents should preferably be performed in those patients with stable compliant bladders.^{23,25}

In all patients there was no evidence of local or systemic allergic reactions or of particle migration. This is because local reaction to PDS consists of the recruitment of monocytes which are transformed into giant cells and subsequently encapsulated by fibroblasts, thus forming a three-dimensional matrix without tissue necrosis. Furthermore, as the majority of PDS particles are greater than 60 μm in size, this eliminates lymphatic migration to distant sites as has been demonstrated with other bulking agents.^{9,10}

To our knowledge this is the first series analysing the efficacy of PDS in the treatment of adult male stress urinary incontinence in SCI. As the results compare favourably with its use in non-neuropathic patients, we suggest this minimally invasive method be considered as a first-line treatment modality in this complex patient group.

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