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LONG TERM OUTCOMES OF THE TREATMENT OF MALE STRESS URINARY INCONTINENCE WITH POLYDIMETHYLSILOXANE FOLLOWING SPINAL CORD INJURY.

Hypothesis / aims of study

To evaluate the long-term outcomes of Polydimethylsiloxane (PDS, Macroplastique™) perisphincteric injections in the treatment of male stress urinary incontinence (SUI) secondary to spinal cord injury (SCI).

Study design, materials and methods

Thirteen SCI patients (T11: n=2; T12: n=5; L1: n=5; L2: n=1) with urodynamic SUI, without urge incontinence, were retrospectively identified. All were managed by a single surgeon at a spinal specialist unit and had perisphincteric PDS injections between 1997 and 2002. The mean age was 49.6 years (range 32 to 79 years) and the mean duration from injury to first injection was 7.1 years. Outcome measures were changes in incontinence objectified by pad usage and post-procedural Video-urodynamics (VCMG). Complete cure was defined as cessation of pad usage with no evidence of leakage on VCMG. Partial cure with improvement was defined as >50% reduction in the number of pads used, with incontinence present on VCMG.

Results

The follow-up ranged from 6.1 to 11.2 years (mean 7.8 years). Overall cure rate was 27.3%. After a single injection, one patient remained completely dry at 6.8 years and another achieved partial cure at 10.5 years. One achieved partial cure following repeat injections at 11 months and 1.5 years. Of the remaining eight, four eventually achieved continence with artificial urinary sphincters (AUS) insertion. One was lost to follow-up at 2 years and one patient had died at 19 months due to an unrelated chest infection.

Interpretation of results

The long-term efficacy of PDS analysed in this series follows a previous short-term analysis of its efficacy and safety [1]. The initial review had demonstrated a 57% success rate (36% complete cure, 21% partial cure) at a mean follow-up duration of 34.7 months (2.9 years). This compares to only 27.3% (9% complete cure, 18.2% partial cure) at a mean 7.8 years in this study indicating a probable diminution in the effectiveness of PDS bulking capacity with time.

Concluding message

The use of PDS should be contemplated as a first-line treatment in urodynamic SUI in SCI patients. Although its long-term effects are not durable, it can be effective in select cases with or without repeat injections in the short term. This is particularly significant as an alternative definitive operative intervention such as AUS insertion may not appeal to all patients and may result in major complications.

References

1. Spinal Cord 2003; 41, 286-289.

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require eithics committee approval because	retrospective analysis of established practice
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes