

## TREATMENT OF STRESS URINARY INCONTINENCE IN NEUROGENIC PATIENTS BY AN INJECTABLE ELASTOMER PROSTHESIS: PRELIMINARY RESULTS

### Hypothesis / aims of study

Stress urinary incontinence is a common burden which finds many treatments ranging from bulking agents to artificial sphincters. However these options are difficult to transfer to neurological patients where mixed disorders usually coexist.

In spite of these considerations new products have been designed with a prime indication in women mild stress urinary incontinence or in male after prostate surgery. According to various studies which analysed over 100 procedures, this new product Urolastic® is safe, effective, reversible and easy to perform.

The aim of this study is to present preliminary data of this device in the setting of neurological patients.

### Study design, materials and methods

Urolastic® is composed a Vinyl dimethyl polydimethylsiloxane PDMS, titanium coated, non bioabsorbable elastomer. Precise injection sites are identified thanks to a dedicated device placed on cystoscope: at level of bladder neck (4 sites) in women at level of membranous urethra in men (2 sites). Injection is the performed under local anesthesia.

5 patients were considered for a preliminary trial: 2 men and 3 women. All patients presented urinary stress incontinence in the context of spinal injury (infectious, vascular or traumatic). Incontinence was defined as complete when patient showed loss of urine equal to its entire bladder capacity. Partial incontinence was defined as the loss of the equivalent of 50 % of patients bladder capacity.

To evaluate the efficacy of the device all patients were evaluated preoperatively and postoperatively monitoring voiding diary data and the use of auxiliary devices and dryness between self catheterization as main indicator of continence.

### Results

<u>Gender</u>	<u>Age (years)</u>	<u>Neurogenic disorder</u>	<u>Incontinence grade</u>	<u>Pre-treatment</u>	<u>Post treatment mean follow-up: 4.8 months</u>
Female	65	Medullary ischemia	Complete	Diaper	Small pad (1/day)
Female	40	Spina-Bifida	Partial	Diaper	Small pad (1/day)
Female	45	Myelitis	Complete	Diaper	No progress
Male	40	Spine lesion L1 ASIA C	Partial	Condom	Dry
Male	50	Medullary ischemia	Partial	Condom	Dry (self cath up to 500 ml)

No complications were registered. Median operative time was 20 minutes

After a mean follow-up of 4.8 months, one patient showed no response to treatment. This failure occurred in a low compliance bladder who then needed detrusor botulinum toxin injection to increase bladder capacity.

### Interpretation of results

Stress urinary incontinence is a common matter addressed in general urology. Its high frequency has stimulated the development of various devices and techniques ranging from injectable agents to prosthetics. Unfortunately, neurological patients present specific features which impede the translation of these techniques. In fact, the classic combination in sub-sacral lesion patient consists in underactive bladder and incontinence due to sphincter insufficiency. In this context, hydraulic prosthetics are of difficult management mostly due to the higher risk of erosions and to the frequent need of self catheterization. On the other hand classic injectable agents either do not ensure enough bulking, or migrate in time from their infiltration position. Furthermore as all injectable products they can determine allergic inflammatory reactions but can not be removed.

Urolastic® from a practical point of view can be defined as an hybrid between bulking agent as it is injected at mid urethra but creates a soft cuff effect as it solidifies around it and therefore remains in the instillation site.

Furthermore, it is radiolucent, enabling to verify the objective correct positioning by imaging

These preliminary results show that this procedure is feasible, safe and effective in neurological patients. The main advantages that we observed in contrast to other options are: creation of a “ soft cuff effect ” easily and completely removable ( due to product consistency and radioopacity); low risk of migration (due to solidification after injection) ; minimal invasiveness. It is clear however that this case series is small and with a short follow-up. A larger number of patients is required to fully confirm its advantage in this setting and should be subject of a randomized control trial.

#### Concluding message

Urolastic® represents today a possible alternative for treatment of stress urinary incontinence in neurological patients as preliminary results demonstrate that the procedure is safe , effective, reversible and easy to perform. However it should be emphasized that larger series are needed to confirm these preliminary considerations.

#### Disclosures

**Funding:** None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** It was not an experimental study but the use of a new device already approved **Helsinki:** Yes **Informed Consent:** Yes