

## SAFETY OF NOVEL PERMANENT INJECTABLE BULKING AGENT 'UROLASTIC' FOR REFRACTORY STRESS URINARY INCONTINENCE IN MOST DEMANDING PATIENTS - RESULTS OF PHASE IV ONE-CENTER STUDY

### Aims of study

A well-known shortcoming of bulking agents for stress urinary incontinence (SUI) in women is their resorbable character [1]. On the top of that, one randomized controlled trial of autologous fat injection reported a case of fatality from pulmonary embolism [2]. In the present study, our objective was to prospectively evaluate short-term safety of a new nonresorbable injectable for otherwise hardly curable refractory SUI.

### Study design, materials and methods

We studied 21 Caucasian women with urodynamically proven SUI, injected at 4 defined sites of the mid-urethra with the recently introduced 'Urolastic' (extremely biocompatible rubbery compound) preparation according to the manufacturer's (Urogyn BV, Nijmegen, the Netherlands) instructions under local anesthesia. The application is not transurethral, but done parallelly to the urethral lumen. The exclusion criteria included: severe overactive bladder, urethral hypermobility, cystocele of any type and degree, post-void residual urine volume increased  $\geq 100$  mL, increased total bladder capacity  $\geq 600$  mL, and decreased detrusor contractility. The inclusion criteria were: history of recurrent SUI following at least 1 unsuccessful SUI surgery, and history of serious medical conditions, such as diabetes mellitus, unstable arterial hypertension, myocardial infarction, stroke, and grey matter involution. In other words, the recruited patients were women with medical contraindications for standard surgery, or for whom, in our setting, an artificial sphincter or no other procedure could be offered. Follow-ups were done at 6 weeks with a written questionnaire and pad test, when a possibility for an additional 2 injections for residual SUI was offered, and at 6 months.

### Results

Median age was 64 (range: 36-80) years, mean follow-up:  $4.2 \pm 0.3$  (1 SD) months. One patient had myocardial infarction 8 months before procedure, other two experienced mild stroke in the past, while some others had: morbid obesity (BMI of 47.4), chronic atrial fibrillation, chronic renal insufficiency, Parkinson's disease, severe asthma, emphysema, and active vertebral compression fracture at L<sub>2</sub>. The mean time required for the 4 primary injections was  $22 \pm 1.7$  minutes. All patients underwent the procedure uneventfully and all were continent in cough test with full bladder immediately post-injection. No local hematomas were observed, but there were displacements of 3 deposits to the bladder or vagina, which needed removal. One submucosal paravaginal deposit was also removed because it was irritating the patient. One patient reported short-term discomfort with sitting. Only 1 woman had one-day acute retention of urine after primary procedure and another had transient urine stream narrowing after repeat procedure. All cases of relapse were early and in relation to excessive physical exertion or strenuous cough. Ten (47.6%) patients required and agreed to repeat injections ( $10 \pm 1.2$  minutes) with a low-volume deposit at 6 weeks, whilst 2 refused additional injections. At follow-up, none of the patients reported worsening of her urinary continence, 6 (28.6%) - had no improvement, 1 (4.8%) - a slight improvement, 3 (14.3%) - a moderate improvement, 4 (19.0%) - a significant improvement, and 7 (33.3%) were completely continent. Thus, some form of improvement was observed in over two thirds of the patients, whereas the combined rate for significant improvement or cure was 52.3%.

### Interpretation of results

Injection therapy was considered useful as an option for short-term symptomatic relief in selected patients with comorbidities [1], but this review was written before the introduction of permanent injectable 'Urolastic'. The above procedure was well tolerated in these mostly very ill patients, even as early as 8 months after myocardial infarction. It is a truly minimally invasive procedure with no metabolic impact. The newly created mechanism of continence is of delicate nature. Our work concurs with a recent Swiss study which reported marked improvement in incontinence after resorbable bulking therapy according to subjective and objective outcome measures in an elderly population [3].

### Concluding message

In spite of the limited number of observations, 'Urolastic' injection can be considered as a viable option for medically compromised patients with recurrent SUI.

### References

1. Urethral injection therapy for urinary incontinence in women. Cochrane Database Syst Rev 2012; 2: CD003881.
2. Periurethral autologous fat injection as treatment for female stress urinary incontinence: a randomized double-blind controlled trial. J Urol 2001; 165: 153-158.
3. Bulking agents: an analysis of 500 cases and review of the literature. Int Urogynecol J Pelvic Floor Dysfunct 2013; 24: 241-247.

### Disclosures

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