

## NONABSORBABLE URETHRAL BULKING AGENT - CLINICAL EFFECTIVENESS IN THE TREATMENT OF PRIMARY AND RECURRENT STRESS URINARY INCONTINENCE AFTER 1 YEAR – MULTICENTER STUDY.

### Hypothesis / aims of study

Midurethral slings (MUS) are currently the mainstay of surgical anti-incontinence therapy. Patients who experience MUS failures (despite the proper tape position at midurethra found during post-op ultrasound examination) are appropriate candidates for this highly effective and minimally invasive salvage therapy. On the other hand it is method which should be considered as a primary procedures in patients with serious contraindications for more invasive procedures. Urethral bulking agents with specially designed injection devices are one of the minimally invasive options in the treatment of stress urinary incontinence (SUI). There are few techniques as well as many different types of materials injected into the tissues surrounding female urethra. Bulking agents can be injected either through the urethra or periurethrally. There is no consensus where the material should be injected: at midurethra or bladder neck [1]. In the recently published study with Urolastic therapy 68% patients were dry at 12 months follow up [2]. The primary aim of our study was to investigate mid-term (6 months) clinical effectiveness of non-absorbable periurethral bulking agent – (polydimethylsiloxane (PDMS) polymer, tetrapropoxysilane cross-linking agent and titanium dioxide radiopacifying agent - Urolastic - in the treatment of primary and recurrent stress urinary incontinence (RSUI) in females. The secondary aim was to investigate the safety as well as early and late complications profile of this procedure.

### Study design, materials and methods

Between February 2012 and March 2013 105 patients with SUI (including 95 patients with RSUI) were treated with Urolastic (Urogyn BV, Nijmegen, Netherlands) in three tertiary gynecological clinics. The demographic patients' data are given in Table 1. Urolastic was injected under local anesthesia with 1% Lignocaine according to the instructions given in the device manual at 10, 2, 4 and 8 o'clock positions with 0.5 to 0.75 ccm per one spot. If the second injection was needed it was performed 6 weeks after primary procedure and Urolastic was injected only at 4 and 8 o'clock with 0.75 ccm per spot. All injections were performed only by one investigator on each center (MJ, JD and KF). Immediately after the injection cough test was performed with 200 ccm. Routinely, ciprofloxacin 500 mg bid for 5 days in order to minimize the risk of infection was prescribed. Follow-up visits were scheduled two, six weeks and three and six months after primary procedure. Seventy three patients were available for 6 months follow-up. Efficacy of the procedure was assessed objectively on the follow-up visits. The outcome was considered as cured (no urine leakage), failure (urine leakage during increases of intra-abdominal pressure, positive cough tests or pad test weight gain >1g) or improved (pad test weight gain <1g or subjective occasional urinary leakage with minimum 50% of improvement declared by the patients on visual analog scale (VAS)). Statistical analyses were performed with Statistica package version 8.0 (StatSoft Inc., Tulsa, OK, USA).

### Results

Objective success rate in patients with SUI (cured and improved) was found in 54 patients (59.3%) including 45 (49.5%) patients completely dry 12 months after primary procedure. In 14 patients with primary SUI improvement after 1 year was found in 10 patients (71.4%) including only 3 patients totally dry (21.4%). In 10 patients bladder outlet obstruction (BOO) was observed after injection requiring catheterization for maximum 7 days. Four of them required partial removal of the Urolastic material after that period. In 4 other patients some material had to be removed due to its displacement under the urethra causing pain and dyspareunia. Three patients experienced recurrent urinary tract infections and were admitted at urology department in order to remove the material from the bladder. No other serious complications including hemorrhage, periurethral abscess or vaginal wall erosion were observed.

### Interpretation of results

This multicenter study was designed to assess long term (1 year) efficacy of nonabsorbable periurethral bulking agent in the treatment of primary SUI and RSUI. Although the primary SUI group is significantly smaller than RSUI disproportions among the results can be seen. Improvement is much higher in patients with primary incontinence (71.4% vs 59.3 %;  $p=0.02$ ) but full recovery rate is much higher in RSUI group 49.5% vs 21.4%;  $p=0.005$ ). The primary endpoint of this study was to evaluate the efficacy of this treatment option in patients with the history of SUI management. One should remember that placing another sling in the periurethral area may neither be safe nor effective. This procedure is also safe as no serious complications occurred in the study group.

### Concluding message

Although cure rates after MUS are up to 90% there is still place for less invasive treatment option like periurethral injection of bulking agents, especially in patients with previous RSUI surgical management. Advantage of this method is minimal invasiveness and safety of the procedure.

Table 1. Patients' demographic data and procedure outcome after 6 months.

PARAMETER	SUI (n=91)	RSUI (n=14)	p value
Age (years)	63,6	63,3	NS

Parity (n)	2,8	2,8	NS
BMI (kg/m <sup>2</sup> )	30,1	30,7	NS

#### References

1. Kuhn A, Stadlmayr W, Lengsfeld D, Mueller MD. Where should bulking agents for female urodynamic stress incontinence be injected? *Int Urogynecol J Pelvic Floor Dysfunct.* 2008; 19:817-21.
2. Zajda J, Farag F. Urolastic-a new bulking agent for the treatment of women with stress urinary incontinence: outcome of 12 months follow up. *Adv Urol.* 2013; 724082. doi: 10.1155/2013/724082.

#### Disclosures

**Funding:** Study was supported by Urogyn BV **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Medical University of Lublin Ethics Committee, Poland **Helsinki:** Yes **Informed Consent:** Yes