

THE CLINICAL EFFECTIVENESS OF URETHRAL, NONABSORBABLE BULKING AGENT IN THE TREATMENT OF RECURRENT STRESS URINARY INCONTINENCE - 6 MONTHS OF FOLLOW-UP – 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. Urethral bulking agents with specially designed injection devices are one of the minimally invasive options in the treatment of recurrent stress urinary incontinence (RSUI). There are few techniques as well as many different types of materials injected into the tissues surrounding female urethra. 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 radio-pacifying agent - Urolastic - in the treatment of 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 October 2012 82 patients with RSUI were treated with Urolastic (Urogyn BV, Nijmegen, Netherlands) in two 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 (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). Statistical analyses were performed with Statistica package version 8.0 (StatSoft Inc., Tulsa, OK, USA).

Results

Objective success rate (cured and improved) was found in 52 patients (71,2%) 6 months after primary procedure. In 12 patients in whom primary injection was unsuccessful a second attempt was performed and marked improvement was observed in 6 of them. In 8 patients bladder outlet obstruction (BOO) was observed after injection requiring catheterization for 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. One patient experienced recurrent urinary tract infections and was admitted at urology department one year after procedure in order to remove the material from the bladder. Portion of Urolastic 5 cm in length was found incorporated in the bladder wall surface. No 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 RSUI. After 6 months the results are very promising as more than 70% of patients are satisfied with the procedure efficacy. One should remember that this group include only patients previously treated with MUS in whom 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 RSUI without urethral hypermobility.

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

PARAMETER	CURED AND IMPROVED (n=53)	FAILURES (n=20)	p value
Age (years)	65,2	64,3	NS
Parity (n)	2,7	2,8	NS
BMI (kg/m ²)	29,3	30,2	NS

Disclosures

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