

PROSPECTIVE ONE-YEAR CLINICAL EVALUATION OF THE EFFICACY AND SAFETY OF UROLASTIC, A NEW BULKING AGENT, FOR THE TREATMENT OF STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

Although midurethral slings are currently the mainstay of surgery for SUI, some patients experience MUS failures. Injection of bulking agents as an alternative treatment for SUI has been attempted for years but so far results are disappointing. Every practitioner treating SUI feels that there is a need for satisfying bulking agents. The ideal bulking agent should be easily injectable under local anesthesia, permanent and maintain its shape, volume and therefore its mechanical effect. It should be hypoallergenic and non-immunogenic. We present the data on efficacy and safety of a new injectable, Urolastic in a prospective trial with one-year follow up. Primary objective was to evaluate the improvement of Stamey incontinence grade from baseline to 3 months post treatment. Afterwards the study was extended to one year. Secondary objectives were to evaluate other efficacy endpoints and to evaluate the frequency and severity of complications related to Urolastic for use as an injectable implant.

Study design, materials and methods

Twenty patients with SUI were enrolled in the study. All patients were determined eligible upon screening following the inclusion and exclusion criteria. Diagnosis was performed through gynecological examination, positive cough test with comfortable full bladder, 1-hour pad test and urodynamics when indicated. All patients signed the informed consent and the study was approved by the Ethics Committee.

All patients were treated with Urolastic (Urogyn BV, Nijmegen, The Netherlands) under local anesthesia with 1% lidocaine. Urolastic is a proprietary LSR elastomer composition consisting of vinylidimethyl terminated polydimethylsiloxane (PDMS) polymer. It is presented in a pre-filled, sterile, 5 ml dual syringe with 2 x 2.5 ml, supplied with a static mixer that allows for adequate pre-mixing of the syringe contents. The product will remain flexible and adapt itself to the shape of the environment during injection, thus reducing the chances of migration. Urolastic is biocompatible and not biodegradable, resulting in a long-term effect. It is injected paraurethrally in the submucosal tissue at the midurethra. The bulk product was injected at the 6 o'clock position and at the 2 and 10 o'clock positions. After the injection a cough test was performed, with the bladder filled with 200 ml of saline solution. In case a repeated treatment was needed, it was performed 6 weeks after the primary procedure. Ciprofloxacin 500 mg was prescribed for 5 days. Study follow-up visits were scheduled at 6 weeks (n=20) 3 months (n=20) and one year (n=18) follow up. During these visits the efficacy of the procedure was assessed by means of a cough test in the supine and standing positions with a comfortably full bladder. The Stamey grade of incontinence was also assessed as well as a standard one-hour pad test. A pad count was calculated at each visit as well as the number of incontinence episodes per 24 hours. Quality of life was assessed with the I-QoL. Complications were noted and treated.

Results

20 women with a mean age of 56 years (sd 11,8) were treated. Three of them had had other surgical procedures for SUI. 65% Had one treatment session, 35% had two treatment sessions. The average volume of injected Urolastic was 2,1 ml after during the first treatment session and in addition 0,35 ml was extra injected during the second session. The Stamey incontinence grade significantly decreased from 1.9 at baseline to 0.75 (61%) at 6 weeks, to 0.2 (89% improvement) at 3 months and to 0,39 after one year (all p<0.001). The one hour pad test decreased for 20,2 g at baseline, to 5,5 g at 6 weeks; 1,6 g at 3 months and 8 g at one year (all p<0.001). The mean number of incontinence episodes per 24 hr went from 6 a baseline to 2,5 at 6 weeks, to 1,7 at 3 months and to 1,8 at one year FU. The development of number of pads used per 72 hours went from 17 to 5 to 7 at baseline, 6 weeks, 3 months and 12 months respectively (all p<0.001). The percentage of patients that were dry were 0% at baseline, 45% at 6 weeks, 80% at 3 months and 72% at one year (fig 1). The I-QoL score increased from 51, to 64, 82 and 76 at baseline, 6 weeks, 3 months and 12 months respectively (all p<0.001). Six patients (30%) had adverse events from the procedure. Side effects were rated moderate by patients. The occurred complications were:

- small hematoma after first injection in one patient
- urinary retention due to bladder outlet obstruction and urinary tract infection in three patients
- dyspareunia and vaginal pain in two patients. In the last two patients, the implant was removed from the 6 o'clock position to provide comfort.

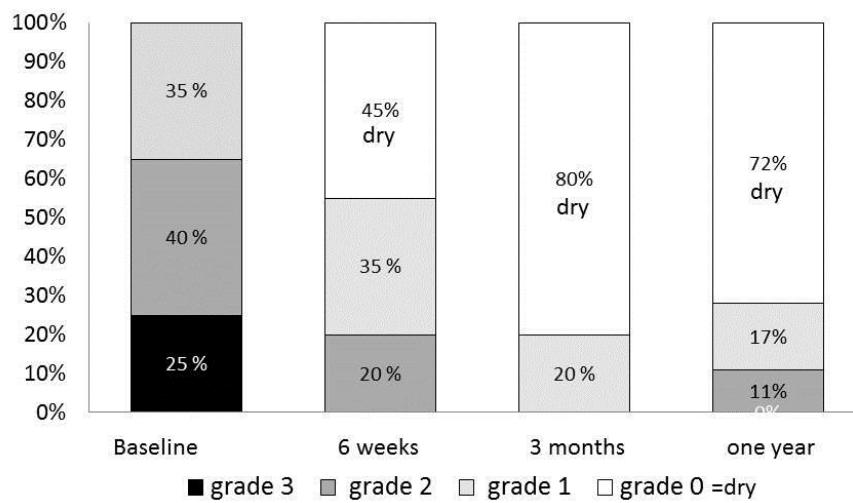


Figure 1. Stamey grade at follow-up

Interpretation of results

Our results after Urolastic injection indicate the product is a safe and effective novel bulking agent. Moderate complications occur but can be treated fairly easily. After one year 72% was still dry whereas the Stamey continence grade, one hour padtest, total pad count, number of incontinence episodes and QoL measures improved significantly.

Concluding message

Urolastic is a promising, safe and longlasting bulking agent for SUI.

Disclosures

Funding: This study was funded by Urogyn BV, The Netherlands **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Warsaw bioethical committee (ref. Decision No. 53/11 on project KB/797/11) **Helsinki:** Yes **Informed Consent:** Yes