

CLINICAL EFFECTIVENESS OF A NEW GENERATION PARA-URETHRAL BULKING INJECTION (PBI) IN WOMEN WITH STRESS URINARY INCONTINENCE (SUI) AND POOR PROGNOSTIC PROFILE

Hypothesis / aims of study

In recent history new treatment modalities have been introduced and implemented within urogynecology without proper evaluation of effectiveness and safety prior to market introduction.

Recently an innovative PBI for the treatment of SUI has been introduced to the market. This PBI is a bulking agent made of vinyl dimethyl terminated polydimethylsiloxane (PDMS), (Urogyn BV, NL). The unique feature of this PBI is that this material polymerises in situ, forming a uniform elastomer that adapts itself to the environment during injection. This results in a large, non-biodegradable homogeneous mass that becomes encapsulated by the surrounding tissue and for that reason has a minimal risk on migration. Small-sample studies have been performed with this PBI claiming overall success rates (defined as a decrease in the Stamey Score by 1 grade compared to the baseline continence status) of 89% after 12 months follow up and 66% after 24 months follow up, whereas 68% respectively 45% of patients were dry after 1 respectively 2 years follow-up [1, 2]. These success rates were reported in a group of women that were predominantly treated for primary SUI.

The optimal indication for PBI is not evidence based. In our clinic we treat patients with mild to moderate SUI with pelvic floor physiotherapy, moderate to severe SUI with a sling, and preserve PBI for those who have a poor prognostic profile to be cured. The above mentioned success rates would be very acceptable for a poor prognostic group, but it is questionable whether these success rates can be realized in the group of patients that we offer PBI to.

To evaluate whether in this subcategory of patients the cure rates are similar as those with a better prognostic profile, we performed a prospective study.

Study design, materials and methods

A prospective study was performed evaluating women with SUI who were treated with a new PBI in two Dutch teaching hospitals with a special interest in urogynaecology. Participants were women aged 18 years or older, with symptoms of SUI, belonging to one of the following categories: (1) recurrent SUI after a previous SUI surgical procedure, (2) a history of oncologic gynaecological surgery, (3) a history of neurologic disease resulting in voiding problems (defined as a maximum flow rate of less than 15 mL/sec), (4) a maximum flow rate of less than 15 mL/sec or (5) women with a contraindication for surgery under general or regional anaesthesia.

Intervention

All women were treated with PBI using PDMS. Some women required two procedures, because of persisting SUI. PBI was performed using local analgesia with Lidocaine 1% at the intended injection sites. The compound was injected para-urethral at 4 defined sites (10, 2, 5 and 7 o'clock) of the mid-urethra by use of a special device and at 2 defined sites (3 and 9 o'clock) in case of a second procedure.

The primary outcome was subjective cure defined as responding "very much better" or "much better" to the PGI-I at 6 months after surgery. Objective cure was defined as a negative cough stress test (CST) at 6 months after surgery. Adverse events were prospectively monitored. We felt a cohort of 20 patients would provide sufficient information about the performance of PBI in this specific group.

Results

Of the 20 women included, 7 women had prior surgery for SUI, 1 had a prior bulking agent treatment with Polyacrylamidehydrogel (Bulkamid), 7 women had a history of gynaecologic oncologic surgery, 2 women had neurologic disease, 2 women a flow rate of less than 15mL/sec and 1 woman had a relative contraindication for general anaesthesia.

15 women were treated in one session, 5 of them needed an additional procedure because of persisting SUI. The volume of injected PDMS was 3.2-4.8 mL for the first procedure and 0.8-1.6 mL for the second procedure.

At 6 months follow up 9 (45%) women were subjectively cured. 90% (18/20) of women reported improvement. One woman had mixed urinary incontinence and preferred to have a permanent indwelling catheter, one was lost to follow up. A negative CST was observed in 65% of women, 20% had a positive CST, in 15% of women the CST was not correctly reported.

Adverse events directly related to surgery were seen in 3 women. In these women the material was located too superficially under the epithelium at the injection site and was removed directly.

Short term complications, following immediately after treatment were temporary urinary retention in 8 (40%) women. Urinary retention could conservatively be treated with an indwelling catheter and CIC and resolved spontaneously with a median of 10 (2-16.5) days in 6 (75%) of these women. One woman had to undergo partial removal of the PBI to solve bladder retention and one woman preferred to continue CIC as she was afraid to get SUI again if the PBI would be removed. One woman mentioned spontaneous extrusion of a part of the bulking material.

Interpretation of results

This study shows the effectiveness of treatment with a new PBI that has a limited risk to migrate in women with SUI who have a poor prognosis to be cured. Even in this very challenging group of patients 90% of women reported subjective improvement.

Urinary retention was the most common complication, however this was transient and resolved spontaneously in the majority of patients. One has to bear in mind that most of these women had a high chance of developing urinary retention prior to treatment and that this risk of retention was the primary reason for treating them with PBI.

Concluding message

PBI with PDMS is a valuable and innovative treatment modality in women with a poor prognostic profile. Post treatment urinary retention is common in these particular patients but resolves spontaneously in the majority of them. Prior to implementing this treatment for women with a different prognostic profile the efficacy and safety should be subject of further study.

References

1. 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;2013:724082.
2. Zajda J, Farag F. Urolastic for the treatment of women with stress urinary incontinence: 24-month follow-up. Cent European J Urol. 2015;68(3):334-8.

Disclosures

Funding: Unrestricted research grant Urogyn **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** the Medical Research Involving Human Subjects Act (WMO) does not apply to the study and therefore official approval of this study was not required. **Helsinki:** Yes **Informed Consent:** Yes