413

de Vries A[1], van Breda H[1], Heesakkers J[1]
1. *Radboud University Medical Centre Nijmegen*

SUBJECTIVE IMPROVEMENT AND SAFETY OF UROLASTIC® AS AN INJECTABLE FOR FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Female stress urinary incontinence (SUI) is a common medical condition with a significant impact on quality of life [1]. According to most guidelines, after more conservative measures, a midurethral sling procedure is treatment of first choice. For patients who do not respond to slings or who are unfit for surgery, options are limited. Urethral bulking agents offer an alternative treatment option, albeit with questionable clinical success rates. If a treatment with a bulking agent can combine a good and durable clinical success rate with a low complication rate, it might be a viable alternative to more invasive treatments for certain patient groups. Since 2013 Urolastic® has been used as an injectable treatment for female stress urinary incontinence. Although results seem promising, not much data is available on the efficacy and safety of this procedure[2,3]. We therefore retrospectively assessed the subjective improvement and the complications in patients treated with Urolastic® in two Dutch hospitals.

Study design, materials and methods

In this study 65 females with predominant SUI were included. Of this group, 38 patients were consecutively treated in a general hospital and 27 in a tertiary referral centre, both in The Netherlands. All received 4 paraurethral injections at the level of the midurethra with on average a total of 3.6-4.2ml of vinyl dimethyl polydimethylsiloxane (Urolastic®). If the outcome was not satisfactory after the first procedure, additional injections were given. Follow-up started after the last injections. All procedures were performed by urologists who had performed at least five procedures.
In February and March 2016 we retrospectively analyzed the charts for complications that had occurred due to the procedure. Complications were subsequently rated using the Clavien Dindo classification.
Subjective improvement was assessed by telephone survey. All patients were asked for the perceived percentage of improvement. In addition we asked for the patient global impression of improvement (PGI-I). This is a transition scale that ranges from 1 (very much better) to 7 (very much worse). This scale has been tested for use in stress urinary incontinence and was found to have a good construct validity[4].

Results

In the group from the general hospital 38 women were included, 15 of which were primary patients. Three women could not be reached by phone, one woman had Urolastic® removed because of permanent retention. In the remaining 34 patients a median follow-up of 12 months was reached, with a median subjective improvement of 70.0% (table 1). Improvement of incontinence was reported in 29 out of 34 patients (85%). No patients reported a worsening of their symptoms (table 2). The most serious complication was exposure of the material through the anterior vaginal wall and postoperative pain. In 7 out of 38 patients (18%) this led to (partial) removal under local or general anaesthesia, which in turn led to a Clavien score of IIIA or B (table 3).

In the group from the tertiary referral centre 27 patients were included. This group consisted of very difficult to treat patients, with a total of 71 previous procedures for incontinence or prolapse. Most patients had a fixed urethra and 2 patients underwent radiotherapy.
In 5/27 patients the material was removed, 3 times because of pain or erosion, 2 times in order to make other procedures possible. One patient died due to an unrelated malignancy. In the remaining 21 patients a median follow-up of 25 months was reached. The subjective improvement reported was 50.0%(table 1). Improvement on PGI-I was found in 16 out of 21 patients (76%). Two patients in this group had worsened symptoms of incontinence after the procedure(table 2). A sub analysis of 12 patients who reported an improvement of 80-100% after 2 months, showed a median subjective improvement of 85% after 25.5 months.

The complication encountered mostly in this centre was again erosion or pain. This resulted in a Clavien score of IIIA or B because of a (partial) removal of injected material under local or total anaesthesia in 7/27 patients (26%) (table 3).

Table 1: Patient characteristics

	General hospital (N=38)	Tertiary centre (N=27)
Age (median, years)	64.5 (±15.2, 23.3-89.9)*	61.4(±15.6, 22.0-89.6)
Follow-up (median, months)	12.0 (±7.4, 2-28)	25.0(±9.4,2.0-30)
Previous Treatments (median) - sling - bulking agent - adjustable continence therapy - prolapse surgery - urge (botox/neurostimulation) - other pelvic surgery	1.0 (±2.2, 0-11) 5 3 0 12 7 18	2.0(±2.7,0-13) 28 15 2 11 6 9
Injected volume (mean, millilitres)	4.2 (±1.0, 2.3-6.8)	3.6 (±0.7, 2.4-4.8)
Re-injections (no. of patients)	8 (21.1%)	4 (14.8%)
Subjective improvement (median)	70.0% (±30.8)	50.0% (±40.1)

* (± SD, range)

Table 2: Patient global impression of improvement

PGI-I score	General hospital	Tertiary centre
1 *very much better*	8	5
2 much better	12	4
3 *little better*	9	7
4 *no change*	4	3
5 *little worse*	0	1
6 *much worse*	0	1
7 *very much worse*	0	0

Table 3: complications

Clavien Dindo grade	General hospital	Tertiary centre
0	12 (31.6%)	9 (33.3%)
I	14 (36.8%)	9 (33.3%)
II	2 (5.3%)	2 (7.4%)
IIIA	6 (15.8%)	2 (7.4%)
IIIB	1 (2.6%)	5 (18.5%)

Interpretation of results

Although these results are limited by the retrospective character of the study and the sole use of patient reported outcomes, some conclusions can be drawn. In the general hospital the impression of improvement tends to be bigger and the number of complications is relatively low compared to the tertiary referral centre. This can be explained by the fact that more severe cases are treated in the tertiary centre, with twice as many previous procedures for SUI and/or prolapse.

In the tertiary clinic satisfactory results can also be found after a follow-up of >2 year in a significant number of patients that had good initial results. This implies that careful patient selection can lead to good results with Urolastic® and that durable results can be obtained as well.

The high number of Clavien grade III scores is a point of concern. More research is needed to find the cause of the vaginal exposures.

Concluding message

Paraurethral injections with Urolastic® do give complications, but with careful patient selection a good and durable patient satisfaction can be achieved.

References

1. 1. Coyne, K.S., et al., Urinary incontinence and its relationship to mental health and health related quality of life in men and women in Sweden, the United Kingdom, and the United States. Eur Urol, 2012. 61(1): p. 88-95
2. 2. Zajda, J. and F. Farag, Urolastic-a new bulking agent for the treatment of women with stress urinary incontinence: outcome of 12 months follow up. Advances in urology, 2013. 2013: p. 724082.
3. Futyma, K., et al., An Open Multicenter Study of Clinical Efficacy and Safety of Urolastic, an Injectable Implant for the Treatment of Stress Urinary Incontinence: One-Year Observation. Biomed Res Int, 2015. 2015: p. 851823.

Disclosures

Funding: This study was supported by an unrestricted grant from Urogyn BV, Nijmegen, The Netherlands **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** there was no approval necessary. **Helsinki:** Yes **Informed Consent:** No