

BULKAMID TREATMENT OF STRESS INCONTINENCE IN WOMEN WITH URINARY STRESS INCONTINENCE AND NOT SUITABLE TO TVT-PROCEDURE. A PROSPECTIVE RANDOMIZED STUDY

Hypothesis / aims of study

Some patients those are not suitable for TVT procedure either because they already have been operated or have other contraindications for surgery. For these patients we have very few therapeutic options to offer. We have performed a study where we have treating these women with bulking agents.

Study design, materials and methods

We have performed a prospective consecutive randomized study of patients not suitable for TVT operations. At inclusion women filled in the questionnaire UDI-6 (lower urinary tract symptoms) and IIQ-7 (quality of life) and had to have at least a positive pad-test (after coughing 10 times) with a of minimum of 10 grams of urine with 300 ml in the bladder or a 24 h pad-test of more than 50 mg.

The patients were randomized first to treatment or non-treatment. All patients were followed up after 2 months. The women not treated were then offered a treatment and then followed up again after 2 months. Then a 1-year follow up was performed for all patients. If patient were not completely dry at follow up a new treatment was performed and the patients were follow up again after 1 year.

The same UDI-6 questionnaire and IIQ-7 questionnaire and PAD test were used for test of cure.

The procedure is an outpatient treatment that takes around 15 min under endoscopic control using the special urethroscope (Bulkamid® Urethral Bulking System). The bulking agents is a homogenous hydrophilic gel consisting of 2.5% polyacrylamide and 97.5% water, that will be injected under local anesthesia at three to four different sites. The patient is discharged after normal voiding with residual urine of less than 100 ml.

Results

Since 2009 we have treated 54 women with a mean age of 71. The reason for not having a TVT procedure was for 29 women that they have been operated with at least one TVT operation and 7 had been done other incontinence procedures. Of the other women 7 had a diagnosis of internal sphincter deficiency (ISD) and 6 was to sick for surgery because of other diseases. At baseline a mean score for the IIQ7 was 51.0 and UID7 60.5 and PAD test was 28.7 gram

Twenty-one women were randomized to expectance. The 2-month follow-up showed little difference as the IIQ 7 decreased only with mean of 4.2 and UID7 with mean of 3.3 but the pad-test increased with 4 gram.

The 2-months follow-up treated women showed that IIQ7 decreased with 19,2 and UID7 with 22,6 and the pad test decreased with 28 gram. 10 patients were treated with 2 injections.

The 1 year follow-up was possible to perform on 36 with a decrease of the IIQ7 with a mean of 24.8 and UID7 decreased with a mean of 17.6. The pad test decreased with mean of 25.0 gram. Of the 36 women 18 (50%) was completely dry with 0 gram at the PAD test. The subjective one year result for 44 women showed that they were better or much better in 63,5%. No change for 29,5 and worse for 7%,

For 2 patients a new TVT procedure was performed after 1 year follow up. One patients aged 87 had been to sick for surgery and one patient aged 58 that had done one TVT before and 3 bulking agents were given a new TVT

Only one patients could not void sufficient after the procedure and had to use intermittent cauterization for one night.

Interpretation of results

The results injecting Bulkamid intraurethral are much better than we expected with a 60% subjective improvement and 50% objective cure. The result also shows that the effect that has been achieved at 2 months will in most cases be as good at the 1-year follow-up. Bulking agents can be an alternative therapeutic alternative for these patients.

Concluding message

Bulkamid could be offered to women not cured after an TVT procedure and will increase these women's quality of life.

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Clinical Trial: Yes **Registration Number:** <https://register.clinicaltrials.gov>, NCT00984958 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Gothenburg ethics committee, in Sweden **Helsinki:** Yes **Informed Consent:** Yes