

THE EFFICACY AND SAFETY OF BULKAMID INJECTED INTO THE SUBMUCOSA OF THE MID-URETHRA

Hypothesis / aims of study

Urethral bulking has traditionally been performed in the proximal half of the urethra and often close to the neck of the bladder. However during the post operative ultrasound we often observed Bulkamid deposits in the bladders of patients that did not respond to treatment.

Since May 2008 surgeons at the DRK hospital Chemnitz-Rabenstein have injected Bulkamid in the middle of the urethra (Figure 1) after measuring the urethral length during the procedure in an attempt to prevent accidental injection of Bulkamid into the bladder and ensure accurate injections. Follow-up data from our online database for 275 patients treated mid-urethrally from May 2008 until March 2010 are presented here.



Figure 1: Cystoscope positioned for mid-urethral injection.

Study design, materials and methods

The patients average parity was 1.9 (range 0 to 6), the average age was 67.7 years (range 34 to 89 years). Body Mass Index (BMI) varied from 20.3 to 50.6. There were a number of elderly patients with significant comorbidities. On the day of admission, the results from the urogynaecological consultation were reviewed again, the residual urine was sonographically determined, and the required laboratory tests were conducted.

According to our experience the following contraindications should be considered: Urinary infections; Infections of the genitalia; Uroflow less than 10 ml/s; Intravesical obstruction; Connective tissue diseases; Urethral fibrosis; Hypersensitivity or allergy to Bulkamid; Active *Herpes genitalis*; Systemic corticosteroid treatment.

Depending on request from the patient, the procedure was done under local anaesthesia or with an i.v. short acting anaesthetic. 2 x 5 ml 1% Xylonest[®] local anaesthesia was used para-urethrally. Additionally Installagel[®] was administered in the urethra. Antibiotics (1.5g Cefazolin and 500mg Metronidazol) were administered prophylactically as single dosages.

Bulkamid was injected transurethrally into the submucosa under urethroscopic control (Bulkamid[®] rotatable sheath) using a 23G x 120 mm needle with 1 cm markings to enable correct placement of the injection. Two or three deposits (0.2-0.8 ml each) were placed, usually at 3, 6 and 9 o'clock. After satisfactory urethral occlusion, the bladder was emptied via the endoscope.

At each follow-up visit patients were asked how they perceived their incontinence compared to before the treatment: cured; improved; unchanged (same); or worsened. For the objective follow-up, patients performed a cough test and results were compared to the cough test performed prior to treatment.

Results

Forty-nine patients (18%) received a single re-injection and 2 patients (0.7%) received 2 re-injections. Mean injection volume was 1.7ml (range 0.7 to 3ml) per treatment.

Patient satisfaction at 6 and 12 months (Table 1) is similar with approximately 77% of patients either improved or cured. Only 1 patient perceived their incontinence was worse after the bulking procedure. Satisfaction is slightly lower at 18 months but this may be due to the low number of patients.

The Objective assessment of patients is similar at 6, 12 and 18 months (Table 1) with approximately 71-76% of patients measured as either improved or cured.

Very few complications have been observed following Bulkamid injection. Only 3 UTIs and 2 incidences of post operative pain have been reported following the 328 surgical procedures. In addition 16 patients reported prolonged urination and 10 patients had increased frequency of urination after the procedure.

Table 1: Results of the most recent follow-up visit (n=223). Fifty-two patients have not yet attended a 6 month follow-up visit

| Time Period (months) | Patients (n) | Patient Satisfaction | | | | Objective Assessment | | | |
|----------------------|--------------|----------------------|----------|------|-------|----------------------|----------|------|-------|
| | | Cured | Improved | Same | Worse | Cured | Improved | Same | Worse |
| | | % | % | % | % | % | % | % | % |
| 6 | 120 | 40.8 | 36.7 | 21.7 | 0.8 | 45.8 | 28.3 | 20 | 5.8 |
| 12 | 81 | 53.1 | 23.5 | 23.5 | 0 | 59.3 | 17.3 | 18.5 | 4.9 |
| 18 | 21 | 42.9 | 14.3 | 42.9 | 0 | 57.1 | 14.3 | 23.8 | 4.8 |
| 24 | 1 | 100 | 0 | 0 | 0 | 0 | 100 | 0 | 0 |

Interpretation of results

The data shows that bulking with Bulkamid is an effective treatment in elderly patients, patients with a high BMI and patients with comorbidities. The procedure is relatively complication-free, has a high acceptance rate and can be used as a primary intervention before other surgical measures.

Concluding message

Bulkamid is an effective and safe method for the treatment of female stress and mixed incontinence.

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| <i>Is this a clinical trial?</i> | No |
| <i>What were the subjects in the study?</i> | HUMAN |
| <i>Was this study approved by an ethics committee?</i> | No |
| <i>This study did not require ethics committee approval because</i> | data is taken from an online database. This data was compiled by the author and colleagues during routine patient visits at the Hospital DRK-Chemnitz Rabenstein. |
| <i>Was the Declaration of Helsinki followed?</i> | Yes |
| <i>Was informed consent obtained from the patients?</i> | No |