

## TRANSURETHRAL INJECTION OF POLYACRYLAMIDE HYDROGEL (BULKAMID®) FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE AND CHANGES IN THE CURE RATE OVER TIME

### Hypothesis / aims of study

The objective of this study was to evaluate the efficacy of a transurethral injection (TUI) using bulking agent Bulkamid® for female stress and mixed urinary incontinence. The hypothesis was that the cure effect of Bulkamid® may slowly decrease and that changes in the cure rate are in correlation with the time that elapses after the operation.

### Study design, materials and methods

A retrospective study was performed on 25 women with urinary incontinence (stress, 18; mixed 7), and 24 patients completed the study. One patient with stress urinary incontinence died during this study. The efficacy of TUI was evaluated 3 months and an average of 13 months after surgery. One patient had a reinjection of Bulkamid®. Their mean age was 69.7 (SD-16.22) years, mean body mass index (BMI) was 27.56 (SD-3.42), and mean parity was 1.73 (SD-0.7). We enrolled patients whose predominant symptom was SUI. Nineteen patients had previously undergone anti-incontinence surgery; fifteen women from this group were treated with TVT, TVT-O or TVT-S (Gynecare) procedures. Six patients who had not had previous anti-incontinence surgery were selected for this procedure because three had ISD (MUCP - maximal urethral closure pressure < 20 cm H<sub>2</sub>O) and immobile urethra. Three had serious concomitant disease. The injections of Bulkamid® were given after local anesthesia under urethroscopic control. The bulking agent was injected into the submucosa through the urethra using a 23G needle. Three deposits were placed at positions 1 cm distal to bladder neck at 2, 6 and 10 o'clock position. At each position an average of 0.42; 0.45 and 0.44 ml of Bulkamid was injected, so the total mean mass of Bulkamid was 1.31 ml (SD-0.28). Before the injections the women received a prophylactic antibiotic treatment, an iv dose of Unasyn (1.5g). Subjective assessment of the leakage of urine was based on the International Consultation on Incontinence Questionnaire - Short form (ICIQ-UI SF) filled in before and three and - on average - 13 months after the surgery (mean days after operation – 413, median 416; minimum 6 months after operation). Improvement in urinary incontinence was defined as a drop in the score of more than 50%. Objective assessment of leakage of urine was assessed by cough test. Ethical committee approval was obtained, and all subjects gave written consent to participate in the study.

Data were processed and statistical analysis performed by internal functions of OpenOffice CALC3.1.0 (average, median, SD, F-test, T-test). Changes in time and differences between groups were compared using t-test, Wilcoxon test or Fischer exact test; the level of significance was set to 0.05.

### Results

Objective assessment by cough test showed that 9/25 (36%) of patients had negative results for this test 3 months and 4/24 (16.7%) 13 months after the operation, while in 16/25 (64%) of patients leakage of urine persisted 3 months after the operation and 20/24 (83.3 %) 13 months after the operation. Subjective assessment by the ICIQ-UI SF questionnaire showed that 7/25 (28%) of our patients were completely dry 3 months after the operation and 3/24 (12.5 %) 13 months after the operation. 20/25 (80%) of patients were dry or improved 3 months after the operation and 14/24 (58.3%) 13 months after the operation. In 10/24 (41.7 %) of patients leakage of urine remained the same as before the operation, or the drop in the score was lower than 50% (a small improvement). The mean score before the operation was 17.56 (SD 3.44), median 18; 3 months after the operation it was 5.68 (SD 5.51), median 5; and 13 months after the operation it was 8.25 (SD 5.49), median 7.5. The changes in the score 3 months and 13 months after the operation are statistically significant (Wilcoxon test), and the answer to the question "Overall, how much does leaking urine interfere with your everyday life?" showed a worsening of the situation to a statistical significant degree: 3 months after the operation the mean score was 2.38 (SD 2.28), while 13 months after the operation it was 3.79 (SD 2.96).

### Interpretation of results

The hypothesis that the cure rate of Bulkamid® may slowly decrease as time passes after the operation was confirmed. The mean curative effect, the ICIQ-UI SF score, decreased significantly by about 22%. We can conclude from the objective assessment of SUI by cough test that this test was negative in 36% of patients 3 months and in 16.7% 13 months after the operation.

### Concluding message

The cure rate of Bulkamid® operation slowly decreases, although this procedure is minimally invasive and is an option in cases where anti-incontinence surgery has failed.

<b>Specify source of funding or grant</b>	None
<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	No
<b>Is this a Randomised Controlled Trial (RCT)?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	Ethical committee of Gen. Faculty Hospital, Prague, Czech Republic
<b>Was the Declaration of Helsinki followed?</b>	Yes

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*Was informed consent obtained from the patients?*

Yes

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