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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
The efficacy of TUI was evaluated 3 months (±1week) and an average of 22 months (minimum - 6 months; mean number of days 660; median 655) after the procedures. Five patients had a reinjection of Bulkamid®. We enrolled patients whose predominant symptom was SUI. Forty patients had previously undergone anti-incontinence surgery; twenty nine women from this group were treated with TVT, TVT-O or TVT-S procedures. Twelve patients who had not had previous anti-incontinence surgery were selected for this procedure because they had ISD (MUCP - maximal urethral closure pressure < 20 cm H_2O). Three patients had previous anti-incontinence surgery and ISD as well. 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 the bladder neck at 2, 6 and 10 o'clock positions. At each position an average of 0.46; 0.48 and 0.44 ml of Bulkamid was injected, so the total mean mass of Bulkamid was 1.39 ml (SD-0.28). Before the injections the women received prophylactic antibiotic treatment in the form of an intravenous dose of Sulbactamum 0.5g+ Ampicillinum 1g (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 - 22 months after the surgery. Improvement in urinary incontinence by ICIQ-UI SF was defined as a drop in the score of more than 50% compared to before the operation. Objective assessment of leakage of urine was assessed by cough test. The cure effect was evaluated by VAS (Visual Analogue Scale) (VAS score 0-100; 100 - without leakage of urine, dry) and by using the five-point Likert score (5-cured, 4-improved, 3-no change, 2-worse, 1-significantly worse).
Ethical committee approval was obtained, and all subjects gave written consent to participate in the study. The statistics were calculated using the software STATISTICA 10 – StatSoft.Inc software (Tulsa, USA).

Results
A retrospective study was performed on 52 women with urinary incontinence (stress 43; mixed 9), and 51 patients completed the study. One patient with stress urinary incontinence died during this study. Their mean age was 70 (SD-13.98; range 18-90) years, mean body mass index (BMI) was 28.65 (SD-4.30), and mean parity was 1.76 (SD-0.83). Objective assessment by cough test showed that 19/51 (37.3%) of patients had negative results for this test 3 months and 10/51 (19.6%) 22 months after the operation. Subjective assessment by the ICIQ-UI SF questionnaire showed that 16/51 (31.4%) of our patients were completely dry 3 months after the operation and 8/51 (15.7%) 22 months after the operation. 41/51 (80.4%) of patients were dry or improved 3 months after the operation and 23/51 (45.1%) 22 months after the operation. The mean score before the operation was 17.59 (SD 2.67), median 17; 3 months after the operation it was 5.66 (SD 5.25), median 5; and 22 months after the operation it was 10.55 (SD 6.48), median 10. The changes in the score 3 months and 22 months after the operation are statistically significant, 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 2.49 (SD 2.69), while 22 months after the operation it was 5.37 (SD 3.73).
The mean cure effect evaluated by VAS score 3 months after the operation was 72 (SD 31.3), while 22 months after the operation it was 51.3 (SD 38.3). The changes in the score 3 months and 22 months after the operation are statistically significant.
The five-point Likert score was 5 or 4 (the evaluation of the cure effect was "cured or improved") three months after the operation in 40/51(78.4 %) patients and 28/51 (54.9%) patients 22 months after operation.

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, evaluated by the ICIQ-UI SF score, decreased significantly from 80.4% 3 months after operation to 45.1% 22 months after operation, i.e. by about 35%. We can conclude from the objective assessment of SUI by cough test that this test was negative in 37.3% of patients 3 months and in 19.6% 22 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.

Disclosures
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