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TRANSURETHRAL INJECTION OF POLYACRYLAMIDE HYDROGEL (BULKAMID®) FOR TREATMENT OF RECURRENT STRESS URINARY INCONTINENCE AFTER FAILURED REPEATED ANTI-INCONTINENCE SURGERY

Hypothesis / aims of study
The objective of this study was to evaluate the cure effect of a transurethral injection (TUI) of Bulkamid® for recurrent female stress urinary incontinence after two and more anti-incontinence surgical procedures had failed. The last procedure was tape surgery. The hypothesis was that the cure effect of Bulkamid® is positive in patients who have undergone previous unsuccessful anti-incontinence surgery at least twice.

Study design, materials and methods
We enrolled 25 patients whose predominant symptom was SUI and who had undergone previous anti-incontinence surgery at least twice. Their mean age was 73.7 (SD 9.38; range 57-92) years, mean body mass index (BMI) was 28.91 (SD 4.15), and mean parity was 2.08 (SD 0.81). 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 an average of 30 months (minimum – 6 months; mean number of days 890) after the Bulkamid® surgery. 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. 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). Six patients had a reinjection of Bulkamid® after a check-up 3 months after the operation which established that the procedure had failed; the Bulkamid® was reapplied submucously, and the cure effect of Bulkamid® was evaluated minimally 6 months after the second operation. 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 positions. At each position an average of 0.44; 0.48 and 0.48 ml of Bulkamid was injected, so the total mean mass of Bulkamid was 1.41 ml (SD-0.12). Before the injections the women received prophylactic antibiotic treatment, an iv dose of Unasyn (1.5g). 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.

Results
A retrospective study was performed on 25 women with recurrent stress urinary incontinence, and all patients completed the study. The procedure was performed on patients who had undergone previous unsuccessful anti-incontinence surgery twice (n=19) or more often (n=6). The last procedure was tape surgery. Objective assessment by cough test showed that 4/25 (16%) of patients had negative results for this test, and in 21/25 (84%) of patients leakage of urine persisted 30 months after the operation. Subjective assessment by the ICIQ-UI SF questionnaire showed that 8/25 (32%) of our patients were completely dry or improved, and in 17/25 (68%) of patients leakage of urine remained the same as before the operation or declined to a score of lower than 50%.The mean score before operation was 17.24 (SD 3.28), while after the operation it was 10.20 (SD 4.31). There is a statistically significant decline in the score of the ICIQ-UI SF. Answers to the question "Overall, how much does leaking urine interfere with your everyday life?" showed the mean score before the operation was 9.15 (SD 1.35), while 30 months after the operation it was 4.41 (SD 2.39). The decline in the score is statistically significant. On the Likert scale the cure effect was evaluated as 5 or 4 ("cured" or "improved") in 22/25 (88%) of patients, and the mean VAS score was 59.8 (SD 26.16). On the VAS score the cure effect was evaluated more or equal than 50 in 20/25 (80%) of patients.

Interpretation of results
The hypothesis that the cure effect of Bulkamid® is positive was confirmed, although there are large differences between individual methods of subjective assessment of the effect of the operation (VAS, Likert score, the ICIQ-UI SF score), which suggests that a better correlation between these methods will have to be found. To assess the effect of the operation as improved, according to the Likert score, we may have to determine other values of VAS or the ICIQ-UI SF score. This surgical procedure may be useful in addressing some complicated cases where repeated operations have been carried out and it is not clear which way to proceed.

Concluding message
The hypothesis that the cure effect of Bulkamid® is positive in patients who have undergone previous unsuccessful anti-incontinence surgery at least twice was confirmed. The procedure was minimally invasive and is an option for repeatedly failed anti-incontinence surgery, although the cure effect is lower when the Bulkamid® procedure is performed on patients who have undergone previous unsuccessful anti-incontinence surgery twice or more often.

Disclosures
Funding: This work was supported by the Grant Agency of the Ministry of Health of the Czech Republic, grant NT 13509-4/2012 and by Charles University in Prague - UNCE 204024 **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** This study was approved by the local Ethics Committee of Gen. Faculty Hospital as part of a national grant application / Grant NT 13509-4/2012 **Helsinki:** Yes **Informed Consent:** Yes