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RESULTS OF USING POLYACRYLAMIDE HYDROGEL (BULKAMID®) FOR THE THERAPY OF STRESS URINARY INCONTINENCE IN SELECTED POPULATION OF WOMEN

Hypothesis / aims of study
The aim of this study was to assess one-year outcome of the polyacrylamid hydrogel (PAHG) transurethral injection in selected risk group of women with stress urinary incontinence (SUI).
Background:Injection of bulking agents (BA) into the urethral wall can improve urethral coaptation. If conservative management fails, BA is the most minimal invasive therapy for stress urinary incontinence.

Study design, materials and methods
This is an open, prospective, observational study of patients operated with the PAHG (Bulkamid®) technique at one center between September 2008 and December 2009. A total of 41 women with urodynamic stress incontinence with previous ineffective anti-incontinence surgery and/or comorbidities that precludes anaesthesia were prospectively assigned to this study (drop out at 12 months follow-up = 0 patients). Only 36% of patiens was without previous surgery for SUI and the reason for hydrogel application was presence of severe comorbidities. The majority of women (64%) underwent 1 - 3 ineffective procedures for SUI in the past. Exclusion criteria were: 1) post-void residual volume (PVR) greater than 100 mL, 2) women with stage II, III or IV pelvic organ prolapse according to the International Continence Society pelvic organ prolapse quantification system, 3) Q max < 15 ml/s. Prior to the surgery and at 12 month follow-up cystometry, maximum urethral closure pressure (MUCP), functional urethral length (FUL), maximum flow rate and cough test were performed. All patients self-evaluated the severity of their incontinence symptoms with the use of a visual analog scale (VAS). Quality of life (QoL) assessment was performed using the International Consultation on Incontinence Questionnaire-Short form (ICIQ-UI SF). Criteria of Cure: An objective cure was defined as a negative cough stress test with 300 mL of saline solution in the bladder during the multichannel urodynamic examination. Subjective evaluation of the procedure was made using the ICIQ-UI SF questionnaire. Subjective cure was defined by no leakage of urine after surgery (tick-box “never“ was checked after surgery). Subjective improvement was experienced if assessment of frequency of urine leakage after the surgery was lower than before. Subjective failure occurred if the urine leakage frequencies before and after the surgery were identical or worse. Surgical procedures: For all patients, the procedure was performed under local paraurethral anaesthesia supplemented by intravenous analgosedation. Minimally three deposits at Nr. 6, 10 and 2 were placed 1 cm distal to the bladder neck. After satisfactory urethral occlusion the bladder was emptied via the endoscope.

Results
The mean age was 69 years (42-88), mean BMI 28.8 kg/m^2 (21.3-39.6), and mean parity was 2.4 (1-8). The mean operating time was 21.4 min. (10-45), the median injected volume per treatment was 1.28 ml (1-2.2.5).There were no major peroperative complications. Early postoperative complications (day 0-7):urinary tract infection - 4.9%, febrile morbidity - 2.4%, urinary retention - 4.9%. There was no clinical hematoma or bleeding in the early postoperative period. Late postoperative complications (day 8-28): urinary tract infection - 12,2%, febrile morbidity - 4.9%, urinary retention - 2.4%. At the 12-month follow-up 63% women were objectively cured. Regarding the parameters of subjective cure, where we analyzed the questionnaire parameters before and after surgery in each patient, we found following results: 10% women were subjectively dry and 68% were improved, 22% of patients evaluated their continence status without change or worse. The mean VAS score significantly decreased from a mean of 7.95 ± 1.83 to a mean 3.89 ± 1.45 (p). The ICIQ-SF questionnaire symptoms score also statistically significantly decreased from a mean of 15.00 ± 3.57 before surgery to 10.65 ± 4.65 at the 12-month follow-up evaluation. Urodynamic parameters at the 12-month follow-up showed statistically significant change in case of MUCP and FUL. PVR changes were not significant. PAHG can be visualized by transvaginal ultrasound. In the objective cured group (63%) PAHG deposits were visible by all patients. In the objective failure group (37%) the PAHG deposits were not visible by three patients. The possible reason for this phenomenon is leakage from the puncture holes or mucosal defect when the PAHG deposits are placed too superficially and/or the deposits are too large.

Interpretation of results
The procedure is quick and easy to perform and therefore well accepted by risk group of patients (obesity, comorbidities). The objective cure rate of 63% at 12 months follow-up in this selected group is acceptable.

Concluding message
The current study proves that transurethral PAHG injection in selected group of women with SUI improve significantly the patients satisfaction and their continence.

Specify source of funding or grant	**NONE**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Local Ethics Committee of The Institute for the care of mother and child**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**