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TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN WITH INTRAURETHRAL INJECTIONS OF A POLYACRYLAMIDE HYDROGEL (BULKAMID®): A ONE YEAR FOLLOW-UP STUDY

Hypothesis / aims of study

Peri- and intraurethral injections of bulking agents for the treatment of female urinary incontinence have been advocated for many years and finds its main indication in women suffering from intrinsic urethral sphinteric deficiency. The ideal bulking agent, however, is still to be discovered. Polyacrylamide hydrogel seems to fulfil many of the characteristics of the ideal bulking agent and some studies seem to support its efficacy (1,2). Aim of this study was to evaluate the efficacy and safety of Bulkamid® in the treatment of type III female stress urinary incontinence (SUI) with intrinsic urethral deficiency.

Study design, materials and methods

This was a prospective study on women with type III SUI. Inclusion criteria were: maximal urethral closure pressure ≤ 60 cmH_2O; exclusion criteria were: isolated or predominant urge incontinence, prolapse of genital organs ≥ 2 stage according to PoP-Q scoring system, detrusor instability at urodynamics; urethral hypermobility as evaluated by Q-tip test. All patients signed an informed consent. We evaluated 25 patients that, before entering the study underwent a complete general, gynaecologic and urologic clinical exam with PoP-Q staging, urodynamic testing with evaluation of MUCP, and pelvic ultrasonography. The subjects participating to the study also completed the ICIQ questionnaire and a 3-day urinary diary. Patients were evaluated 6 and 12 months after the procedure, when they underwent clinical examination and urodynamic testing and completed the ICIQ questionnaire and score their satisfaction with the procedure on a VAS scale ranging from 0 to 10 and returned a 3-day urinary diary regarding the month preceding the follow-up visit. Data distribution for continuous variables was assessed with the Shapiro-Wilk's test and all variables displayed a normal distribution.

Results

One patient was not available at the follow-up visit, leaving a total of 24 patients. Mean age was 56 years (mean 36-79), with a mean parity of 2.2 (range 1-7). Fifteen patients (62.5%) were postmenopausal and four of them (26.6%) were hormonal replacement therapy users. Seven patients (29.2%) previously underwent hysterectomy and six (25%) tension-free vaginal tape positioning with recurrent SUI. Sixteen patients (66.7%) had a stage I anterior vaginal wall prolapse and 15 (62.5%) mixed urinary incontinence. All procedure were performed under local anesthesia and conscious sedation and no intraoperative complication was observed. Mean operative time was 6.4 ± 2.1 minutes. We observed two cases of strangury and one case of urinary retention (PVR > 100 cc.) that recessed sponatenously. Twelve months after the procedure, we observed 6 objective failures (25%) and 2 case of improvement (8.3%) with a cure rate of 66.7%. MUCP was significantly increased 12 months after the procedure (mean MUCP 95 ± 15 cmH_2O). ICIQ scores showed a significant increase already 6 months after procedure (9.4 ± 3.2 vs 18.7 ± 5.3) and 19 (79.9%) patients subjectively reported to be cured (16, 66.7%) or improved (3, 12.5%). Mean satisfaction VAS score was 8.9 ± 2.1.

Interpretation of results

No significant intraoperative or postoperative complications were observed, indicating that intraurethral injection of polyacrylamide hydrogel seems to be safe. Operative times were limited and mid-term results, in particular subjective cure rates, are acceptable for this very minimally invasive technique. This cohort of patients was very homogeneous in that all women suffered of type III SUI and all reports published studied eterogeneous populations. Larger studies are needed to confirm these data.

Concluding message

Bulkamid seems to be an effective, safe and minimally invasive treatment for the treatment of type III SUI. This technique seems to be very well tolerated by patients that showed a high satisfaction with this procedure.

References

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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?	**No**
This study did not require ethics committee approval because	**Patients underwent a diagnostic and surgical procedures indicated for their pathology**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**