

## TREATMENT OF STRESS URINARY INCONTINENCE USING POLYACRYLAMID HYDROGEL IN FEMALE PATIENTS WITH AND WITHOUT PREVIOUS PELVIC RADIOTHERAPY – 1 YEAR FOLLOW-UP

### Hypothesis / aims of study

The experience with urethral bulking therapy in female patients after previous pelvic radiotherapy is lacking. The aim of this study was to compare the safety and efficacy of polyacrylamid hydrogel (Bulkamid®) injections in patients with severe stress urinary incontinence (SUI) with and without previous radiotherapy. This is the first study designed to test urethral bulking therapy in previously irradiated patients.

### Study design, materials and methods

This study was designed as a prospective, multicenter study. Forty six patients with severe SUI were enrolled. Group A consisted of 24 patients who underwent previous external beam radiotherapy and/or brachytherapy to their pelvic region due to gynecological malignancy. The average interval between the radiotherapy and Bulkamid® injection was 92.9 months. Group B included 22 female patients with severe SUI after at least 1 failed anti-incontinence procedure. The average interval between the last anti-incontinence procedure and Bulkamid® injection was 68.6 months.

All subjects were informed about the risks associated with the study and each signed a consent form. The study protocol was approved by the Institutional Ethics Committee. Prior to the procedure, each patient received prophylactic antibiotic treatment. All patients were treated by transurethral injection of Bulkamid® under local anesthesia. Three injections were administered submucosally approximately 1 cm distal to the bladder neck at the 2, 6 and 10 o'clock position using a 23 G needle. The bulks were created under visual urethroscopic control. The total mass of Bulkamid® injected per procedure was 1.113 mL (Group A) and 1.384 mL (Group B).

Subjective and objective parameters were evaluated immediately prior to injection and 3, 12, and 24 months after treatment. The average follow-up was 12.4 months. A paired Wilcoxon test was used to compare the parameters before and after the procedure within groups, and a two-sample Wilcoxon test was used to conduct a comparison between the two study groups. A p value of <0.05 was considered statistically significant.

### Results

Complete continence was achieved in 6 out of 24 patients (25%) in Group A and 8 out of 22 patients (36.4%) in Group B. Using a 24-hours pad weight test, we observed a significant reduction in urine leak in both groups (-61.5 mL in Group A, p=0.0164; -197.5 mL in Group B, p=0.0002). The difference between the groups did not reach statistical significance (p=0.0713). Self-assessment using ICIQ-UI questionnaire showed a decrease in the total score by 5.2 in Group A (p=0.0000) and by 6.36 in Group B (p=0.0001). This outcome did not reach statistical difference between the groups (p=0.5079). Subjective assessment using the patient perception of bladder condition (PPBC) scale showed a significant decrease in the total score by 1.54 in Group A, p=0.0001, and a decrease by 2.59 in Group B, p=0.0000, reaching statistical significance between groups (p=0.0224). Voided volume (-61.7 mL in group A, p=0.0069; -110.1 mL in Group B, p=0.0045; difference between groups p=0.3557) and normal desire to void (-6.1 mL in Group A, p=0.7861; -32.1 mL in Group B, p=0.0261; difference between groups p=0.0883) were the only urodynamic parameters where changes reached statistical significance. There were no significant changes observed in any of the other urodynamic parameters before and after treatment. No severe adverse events were noted post procedure. In total, 6 adverse events were observed in Group A (2 cases of urinary tract infection, 3 patients developed de novo urgency, 1 episode of hematuria) and 6 adverse events in Group B (2 cases of urinary tract infection, 3 patients developed de novo urgency, 1 patient developed temporary incomplete bladder emptying).

### Interpretation of results

Radiotherapy worsens the vascularization of tissues resulting in damage to peripheral innervation and fibrotic remodeling (1). These pathological changes to the urethral wall generally led to the conclusion that radiotherapy should be considered exclusion criteria for submucosal injection of urethral bulking agents (2). In our study, the efficacy and safety of urethral bulking therapy using Bulkamid® in female patients with severe SUI, with and without previous pelvic radiotherapy, were comparable. The low complication rate recorded in both study groups suggests that pelvic radiotherapy should not be considered a contraindication for the use of urethral bulking therapy.

### Concluding message

Based on the results of this study we conclude that urethral bulking therapy represents a valuable treatment option for previously irradiated patients suffering from severe SUI.

### References

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- Ghoniem G, Corcos J, Comiter C, et al.: Cross-linked polydimethyl siloxane injection for female stress urinary incontinence : results of a multicenter, randomized controlled , single-blind study. *J Urol*. 2009; 181: 204-210

Disclosures

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