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## **EFFECTIVENESS OF URETHRAL BULKING PROCEDURE WITH POLYACRYLAMIDE GEL FOR PATIENTS WITH URETHRAL HYPERMOBILITY**

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### **Hypothesis / aims of study**

Introduction: Urethral bulking is a minimally invasive in-office procedure used to treat Stress Urinary Incontinence (SUI) or stress predominant Mixed Urinary Incontinence (MUI) in the setting of urethral hypomobility and/or intrinsic sphincteric deficiency. Multiple agents are used in this treatment modality. Bulkamid® (Axonics Inc.) is an FDA approved polyacrylamide hydrogel (PAHG; 2.5% polyacrylamide and 97.5% water) that is a non-biodegradable homogeneous gel free of particles. This data reports outcomes of treatment with PAHG on SUI and MUI predominantly for those with urethral hypermobility. Study aims: The aim of this quality improvement project is to report on the patient centered efficacy of urethral bulking with polyacrylamide hydrogel for stress urinary incontinence. Patients are predominantly those with urethral hypermobility, a less reported application of this modality.

### **Study design, materials and methods**

This is single-center retrospective data of female patients with SUI or stress-predominant MUI, who underwent injection with PAHG from March 2021, when this modality was implemented in our institution as standard of care. The primary endpoint was patient satisfaction measured on a four-point scale as cured, improved, unchanged, or worse. Secondary outcomes included the Visual Analog Scale Quality of Life (VAS QoL), reinjection rates, and perioperative and postoperative complications. Patients with active UTI, and elevated urine post-void residual (PVR > 100mL on bladder ultrasound during follow up visits) were excluded from the data. Patients were confirmed to have stress urinary incontinence with positive cough stress test and/or urodynamic testing. Urethral hypermobility was defined as urethral Q-tip > 30 degrees from resting position. Urethral bulking was performed in the office after peri-urethral local anesthetic injection of 10mL 1% lidocaine, and 2mL total PAHG solution was injected trans-urethrally at 2, 4, 8 and 10 o'clock in the urethral submucosa in the proximal urethral 0.5-1 cm distal to the bladder neck. Successful treatment was defined as patient report of a consistent cure, or improvement of SUI symptoms at the follow-up visits.

### **Results**

Between March 2021 and February 2022, 52 patients underwent in-office urethral bulking procedure with PAHG. Follow-up of patients ranged between 4 weeks to 2 years. 50 patients had urethral hypermobility, and 2 patients had urethral hypomobility (urethral Q-tip < 30 degrees from resting position). For patients with urethral hypermobility, 39 patients (78%) experienced successful treatment outcome with PAHG with regards to SUI symptoms at the follow-up visits. Success rate for SUI patients with urethral hypomobility was 100%. Elevated urine PVR after the procedure occurred in 5 (9.6%)

patients within 1 week after the procedure, median PVR value was 150 ML, all patients were asymptomatic, and PVR normalized at subsequent follow-up visits. One patient required indwelling urinary catheterization with a Foley catheter for 4 days after urethral bulking procedure, followed by complete return of urinary function. Two patients experienced recurrence of SUI symptoms within one month after procedure, and chose to proceed with a repeat urethral bulking with PAHG. One patient developed a UTI, and was successfully treated with antibiotics.

### Interpretation of results

This data suggest that urethral bulking with polyacrylamide gel is an effective patient centered minimally invasive option for patients with SUI and urethral hypermobility

### Concluding message

This study suggest that urethral bulking with polyacrylamide gel is an effective patient centered minimally invasive option for patients with SUI and urethral hypermobility. Additional data is needed to confirm our results in the long-term, however urethral bulking procedure with polyacrylamide gel may be considered a safe and effective first line option for management of stress urinary incontinence, especially for poor surgical candidates.

### Figures:

Fig 1 Urethral Bulking with Bulkamid Procedure

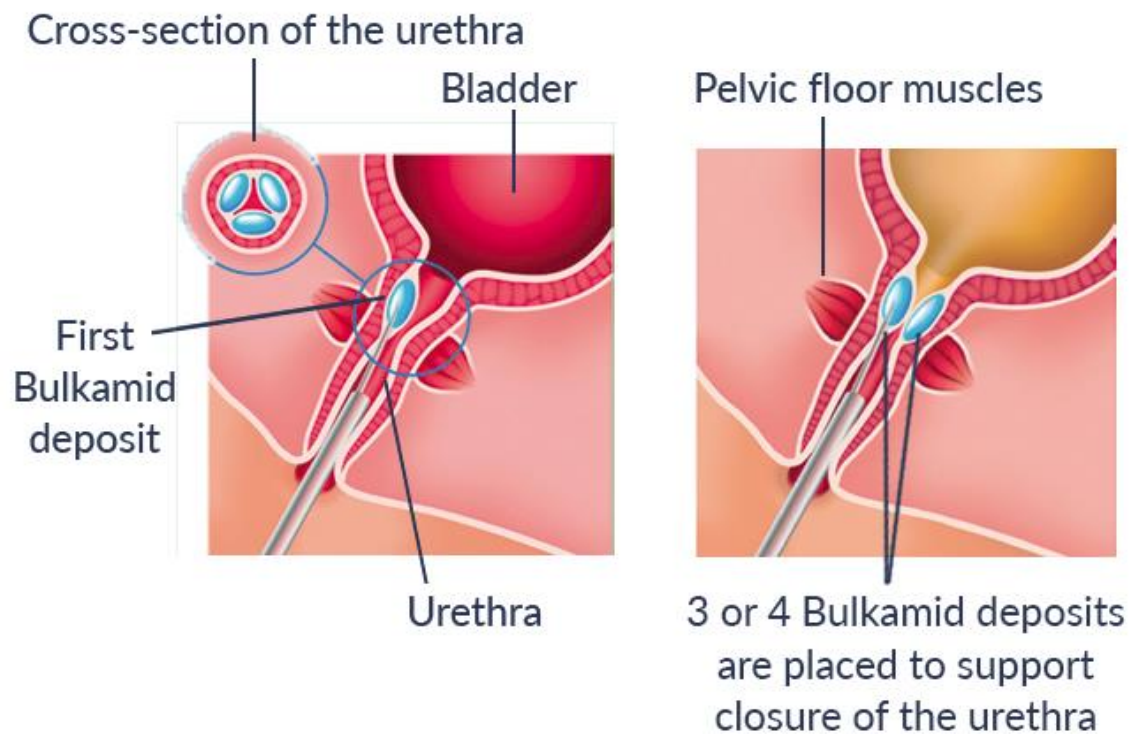


Figure 2.

Urethral Mucosa Coaptation during Urethral Bulking Procedure with Bulkamid

