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Koski M[1], Padmanabhan P[1], Kaufman M[1], Scarpero H[1], Dmochowski R[1]
1. *Vanderbilt University Medical Center*

SAFETY AND EFFICACY OF SLING AFTER BULKING INJECTION FOR PERSISTENT STRESS URINARY INCONTINENCE

Hypothesis / aims of study
Periurethral bulking agents are a widely employed, minimally-invasive treatment option for stress urinary incontinence (SUI), but often lack durability necessitating further surgical intervention. This study aims to assess the impact of injectable agents on subsequent incontinence surgery outcomes to assess safety and efficacy of this treatment combination.

Study design, materials and methods
IRB approved retrospective review of medical records of 57 patients with SUI post-bulking agent who underwent sling between 11/2000 and 8/2009 were evaluated for demographics, voiding symptoms, urodynamics (UDS), bulking agent characteristics, concomitant procedures, pads per day (PPD), outcomes, and complications.

Results
Mean patient age was 66.5 years (46 - 91) with mean follow-up of 23.8 months (0 - 80). 80.7% presented with mixed incontinence (MUI) with 100% demonstrating SUI on clinical exam or UDS. Mean valsalva leak point pressure was 70.9 cm H20 (15-150) and detrusor overactivity was seen in 25%. 55% had prior anti-incontinence procedures or injections. A mean of 3 injections with commonly utilized agents was performed. Subsequent procedures included 33 autologous fascia pubovaginal slings (58%), 18 midurethral slings (32%), and 6 biologic pubovaginal slings (11%). 31.6% of patients underwent concomitant pelvic surgery. There was a marked clinical reduction in mean PPD, from 4.8 to 0.59 (p=0.2833). 61% subjectively described complete cure. 63% with MUI noted improvement or cure. No association was seen between number or type of injection or type of sling on outcomes. However, results were significantly related to concomitant surgery with only a 33% cure rate in patients undergoing simultaneous procedures, and 6% showing worsened incontinence (p=0.0016). 16% of patients had recurrent SUI, which was not associated with any injection, UDS, or concomitant surgery parameter. Complications included 10 episodes of urinary retention (only one of which persisted, due to a planned overtight sling), 2 patients with de novo urgency (18.2% of patients with pure SUI preoperatively) and a 7% incidence of urinary tract infections. One patient had an intraoperative cystotomy in an area of scarring where an eroded sling had previously been removed.

Interpretation of results
Our patient group was particularly complicated, 49% having previously undergone one or more anti-incontinence procedures. Despite this, our rates of subjective improvement and cure are fairly comparable to published data. In our experience, prior injections did not change the complication profile of sling placement. There were no incidences of sling erosion, persistent unintended urinary retention, or particle migration. Patients who required concomitant procedures at the time of sling showed significantly worse subjective outcome than patients undergoing sling alone, although most reported improvement and they did not have higher rates of recurrent SUI. In our experience, sling placement for persistent SUI after bulking agent has been safe and efficacious, even in a complex patient population.

Concluding message
Treatment algorithms for SUI are continually evolving with injectable agents increasingly utilized in clinical practice. We provide insight into this complex patient population and demonstrate the safety and efficacy of this adjunct modality for the management of SUI, which does not appear to alter outcomes for future anti-incontinence surgery.

Specify source of funding or grant	**There was no funding required for this study**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Vanderbilt University IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**