

## A META-ANALYSIS OF COMPLICATIONS ASSOCIATED WITH URETHRAL BULKING AGENTS IN THE TREATMENT OF STRESS URINARY INCONTINENCE

### Hypothesis / aims of study

Stress urinary incontinence (SUI) is a common issue that interferes with the quality of life in women. Periurethral injection of urethral bulking agents (UBA) has been a simple and cost effective treatment for these women. However, there are often complications associated with these bulking agents. The aim of this study is to critically assess the safety of the seven more commonly used bulking agent via a meta-analysis of reported complications.

### Study design, materials and methods

A meta-analysis of the scientific literature from 1996 to 2014 was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement to quantitatively summarize the complications and treatments of said complications of urethral bulking agents. A total of 4,326 patients from 78 studies/study samples were analyzed and were eligible for inclusion. Complications of injections were analyzed and incidence was recorded, along with complication treatment incidence and efficacy. Statistical analysis of complication incidence between each UBA was calculated as well.

### Results

A total of 1,999 complications were reported. 3.8% were considered serious (Clavien Grade III)—of these, 70.6% required incision and drainage (I and D), and 29.3% required a more invasive procedure. Reported major complication rates varied between available urethral bulking agents. Major complication rates for all complications were: dextranomer/hyaluronic acid (17.8%), carbon coated zirconium (11.4%), ethylene vinyl alcohol copolymer (10%), calcium hydroxylapatite (8.7%), collagen (1.8%), polyacrylamide hydrogel (0.8%) and polydimethylsiloxane (no Clavian Grade III complications reported). Odds ratio (OR) of any UBA complication compared to control (contigen) was 4.8 with  $p < 0.0001$ , and OR of major complication was 58.4 with  $p = 0.0042$ .

### Interpretation of results

The majority of urethral bulking agent complications are transient or do not require treatment, however, significant complications may require I&D or more invasive interventions including surgical treatment. Rates of significant complications associated with urethral bulking agents vary significantly between available UBAs.

### Concluding message

Urethral Bulking Agents have significant different rates of reported major complications. For currently commercially available UBAs, polydimethylsiloxane and polyacrylamide hydrogel appear to have the most favorable safety profiles in regards to major complications.

### Disclosures

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