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EVEN UNEXPOSED, TEGRESS™ URETHRAL BULKING AGENT MAY INITIALLY INCREASE URINARY INCONTINENCE

Hypothesis / aims of study

To review our initial experience in the use of transurethral injection of the Tegress™ (also known as URYX™) Implant solution of Ethylene Vinyl Alcohol copolymer (EVOH) in Dimethyl Sulfoxide (DMSO). To review and compare complications obtained from the Federal Drug Aministration Manufacturer and User Facility Device Experience Database (MAUDE) and a previous multicenter study [1].

Study design, materials and methods

A retrospective chart review was performed on the first nine patients who underwent endoscopic injections by two surgeons experienced in transurethral injection of bulking agents. One surgeon underwent training on pig bladders. The other completed online training. Injections were performed using the 1-1-1 rule as described on the product's website. MAUDE was reviewed from the time of FDA approval.

Results

Patient characteristics:
Average age was 56 (range 40-50); average BMI 34 (range 26-43); previous bladder neck surgery, 4 (44%); previous bulking agents, 3 (33%).

Distribution of pelvic organ prolapse	
Procidentia	1
Anterior wall prolapse ≤ Stage 1	7
Anterior wall prolapse, Stage 2	1
Posterior wall prolapse ≤ Stage 1	6
Anterior wall prolapse Stage 2	2
Apical prolapse ≤ Stage 1	8

Four patients exhibited pure urodynamic stress incontinence, two with intrinsic sphincter deficiency. The remainder exhibited mixed incontinence and were treated with antimuscarinic medications prior to Tegress™ injection.

Posttreatment:
Three patients subjectively improved after one or two injections.

One with scleroderma improved experienced no improvement after two injections, but improved after a sling.

Four patients experienced extrusion of material, not necessarily evident at the time of injection: one with minimal extrusion improved. One has not returned for follow-up. Two patients with extrusions worsened: Because no re-repithelization occurred over one month with vaginal estrogen, they required cystoscopic removal of the material over one and three visits: one improved with Contigen™; one improved with rectus fascial sling. Histologic examination of the implant plus tissue removed from one patient demonstrated foreign body granulomas.

Two patients developed unconscious, unpredictable incontinence of large amounts of urine without evidence of infection during the first month following injection. Cystourethroscopy demonstrated no extrusion of material in these patients. One of these improved with office injection of Contigen™. The other improved with Contigen™ injection at the time of posterior vaginal wall prolapse repair.

MAUDE: Forty five of 47 patients (96%) experienced complications related to exposure of material. The remaining two patients experienced urinary retention without reported exposure.

Interpretation of results

Tegress™ injection may present technical difficulties during the learning curve. Extrusion may not be visualized at the time of injection. Even in the absence of erosion or extrusion of Tegress™, patients may worsen during the first month postinjection. If re-epithelialization does not occur, the material may be removed by office cystoscopy and does not preclude alternative treatment. This worsening of incontinence in the absence of extrusion has not been specifically described. [1]

Concluding message

Tegress™ may not only cause irritative urinary symptoms, it may worsen incontinence, at least in the short-term. Patients should be extensively counselled about this emotionally distressing possibility before treatment.

Reference: 1. Multicenter Randomized Controlled Trial To Evaluate Uryx Urethral Bulking Agent In Treating Female Stress Urinary Incontinence: Comparison Of Initial And Expansion Phases Of Trial. Read by title: Abstract ICS Meeting 2004.

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HUMAN SUBJECTS: This study was approved by the UTMB Instituional Review Board and followed the Declaration of Helsinki Informed consent was not obtained from the patients.