

Dmochowski R<sup>1</sup>, Herschorn S<sup>2</sup>, Corcos J<sup>3</sup>, Karram M<sup>4</sup>, Pommerville P<sup>5</sup>, Berger Y<sup>6</sup>, Radomski S<sup>7</sup>, Jacoby K<sup>8</sup>, Foote J<sup>9</sup>, Cornella J<sup>10</sup>, Bent A<sup>11</sup>, Chaikin D<sup>12</sup>

1. Vanderbilt University Medical Center Dept. of Urologic Surgery, 2. University of Toronto, 3. Jewish General Hospital, 4. Good Samaritan Hospital, 5. Can-Med Clinical Research, 6. Associates in Urology, 7. Toronto Hospital, Western Div., 8. Northwest Outpatient Med Ctr, 9. Shepherd Center, 10. Mayo Clinic Scottsdale, 11. Greater Baltimore Med Ctr, 12. Morristown Urology Assoc

## **MULTICENTER RANDOMIZED CONTROLLED STUDY TO EVALUATE URYX<sup>®</sup> URETHRAL BULKING AGENT IN TREATING FEMALE STRESS URINARY INCONTINENCE**

### **Aims of Study**

Multiple approaches have been described for the management of genuine stress urinary incontinence (SUI). One such approach involves the injection of bulking agents into the periurethral tissues to increase resistance to urinary outflow. The most commonly used urethral bulking agent to date is cross-linked bovine collagen for injection (Contigen<sup>®</sup> Collagen Implant). This study was undertaken to evaluate the safety and efficacy of Uryx Urethral Bulking Agent in treatment of female urinary incontinence and to compare this device to Contigen Collagen Implant. Uryx is an injectable solution of ethylene vinyl alcohol copolymer (EVOH) dissolved in dimethyl sulfoxide (DMSO) carrier. Upon contact with an aqueous environment, such as the submucosal tissues of the urethra, the DMSO solvent diffuses away, resulting in precipitation of the polymer, which forms a cohesive spongy mass creating a bulking effect. The low viscosity of Uryx enables easy hand injection through a fine (25g) needle. The precipitated polymer mass volume is essentially equivalent to that of the injected solution, and does not change over time.

### **Methods**

Two hundred ten (210) females with genuine SUI confirmed by clinical urodynamic evaluation were prospectively treated with either Uryx or Contigen using a randomization ratio of 2:1 in favor of Uryx. Average patient age for both groups was 60 years + 13 years. Historical symptom duration for both groups was 9.7 years + 8.8 years (Uryx) and + 8.6 years (Contigen). Patients were assessed post-treatment with objective urodynamic testing and subjectively with patient questionnaires. Pad weights and Stamey Scores are presented on all available patients at 6 months post-treatment. Safety analysis is comprehensive. All available patients will be followed to 12 months.

### **Results**

Mean total volume injected per patient was 4.2 cc Uryx; 7.0 cc Contigen. Six-month pad weight success rates were "dry" in 24/38 (63%) Uryx; 9/20 (45%) Contigen; and "improved" in 5/38 (13%) Uryx; 6/20 (30%) Contigen. Overall dry/improved results were Uryx 29/38 (76%); Contigen 15/20 (75%). Stamey Grade success was defined as improvement of at least 1 grade post-treatment. At six months the Uryx group achieved 26/39 (67%) improved; Contigen 13/21 (62%). In reviewing safety information, the majority of complications occurred early (within 28 days of treatment) and resolved rapidly. The two most prevalent complications in both treatment groups were urge (22% Uryx; 21% Contigen) and dysuria (16% Uryx; 15% Contigen). No serious unanticipated events have been reported in either treatment group. [12-month data available prior to presentation will be tabulated and presented].

### **Conclusions**

The physical characteristics of Uryx bulking agent allow delivery of the desired volume through a small gauge needle. The injected volume remains fixed and a durable cohesive mass is formed. These properties appear to offer promising clinical advantages. Overall, the data to date indicate no significant clinical or safety issues when Uryx is directly compared to Contigen. Further study and follow-up are ongoing.