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MULTICENTER RANDOMIZED CONTROLLED STUDY TO EVALUATE URYX® URETHRAL BULKING AGENT IN TREATING FEMALE STRESS URINARY INCONTINENCE.

Aims of Study

One approach for managing genuine SUI involves injecting bulking agents into the periurethral tissue. This study evaluated URYX in treatment of female urinary incontinence. URYX is an injectable solution of ethylene vinyl alcohol (EVOH) dissolved in dimethyl sulfoxide (DMSO) carrier. Upon contact with an aqueous environment the DMSO dissipates and the EVOH solidifies as a soft spongy mass, creating a bulking effect. The final volume is equivalent to the injected solution, and does not change over time.

Methods

One hundred eighty-three (183) females with genuine SUI were randomized and prospectively treated with either URYX or Contigen®, then followed for one year. A maximum of three treatments was allowed in the first 90 days. Mean age was 60 years. All patients had failed previous urinary incontinence treatment, with 44% failing at least one surgery. Efficacy was assessed at 12 months following the last treatment using pad weight, Stamey grade and the Incontinence Quality of Life (I-QOL) survey. Safety analysis was comprehensive.

Results

Mean total volume injected per patient was 4.6ml URYX; 6.9ml Contigen. One-year pad weights were "dry" (no leakage) in 61% URYX vs. 35% Contigen. Pad weights for treated patients having only 1 or 2 injections were dry or improved in 75% URYX vs. 50% Contigen. Dry or Improved Stamey grade was achieved in 58% URYX vs. 57% Contigen at one year. Stamey grade for patients treated with 1 or 2 injections dry or improved were URYX 59% vs. Contigen 56%. Improvement >50% in I-QOL scores at one year was achieved in 36% URYX vs.13% Contigen. The majority of complications occurred early and resolved rapidly. The three most prevalent complications in both treatment arms were delayed voiding, dysuria and frequency. No unanticipated adverse events have been reported in either treatment group.

Conclusions

URYX demonstrated ‘dry’ outcomes more often than Contigen while injecting less mean volume. There were no significant clinical or safety issues when comparing URYX to Contigen. URYX was easily injected through a 25gauge needle. Study follow-up is continuing and updated results will be provided in the presentation.