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MULTICENTER RANDOMISED CONTROLLED TRIAL TO EVALUATE MACROPLASTIQUE® URETHRAL BULKING AGENT FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

This study evaluated Macroplastique Implants in a pivotal trial to determine its safety and effectiveness as a minimally invasive, endoscopic treatment of female stress urinary incontinence due to intrinsic sphincter deficiency.

Study design, materials and methods

Two hundred forty-eight females diagnosed with intrinsic sphincter deficiency were randomized 1:1 and treated with either Macroplastique or Contigen and followed for one year. Only one retreatment was allowed after the 3-month follow up. Efficacy was determined at 12 months after last treatment using Stamey grading, pad weight and Incontinence Quality of Life (I-QoL) scores. Safety assessment was recorded throughout the study.

Results

For both study arms, the mean age was 61 years with average incontinence duration of 11 years; all patients had received prior incontinence treatment; 23% had prior incontinence surgery. Mean implanted volumes were 6.9 ml and 7.2 ml, with 53% and 59% retreatment rates for the Macroplastique and Contigen groups, respectively. At 12 months, 219 patients were evaluable and the percentage of patients improving $\geq$ one Stamey grade was 68% (75/111) for Macroplastique and 56% (60/108) for Contigen (p=0.07). In the Macroplastique group, the dry/cure rate was 41% (45/111) compared to 29% (31/108) for Contigen (p=0.07). Pad weight improvement ($\geq$ 50% from baseline) was 74% and 65% (p=0.13), and mean improvement in I-QoL score was 29 and 27 (p=0.57) for the Macroplastique and Contigen groups, respectively. The most common transient symptoms lasting $\leq$ 48 hours after treatment were delayed voiding, pain at implantation site, dysuria and hematuria. There was no significant difference between the most prevalent side effects reported for the Macroplastique and Contigen groups, urgency (7% vs. 2%) and frequency (6% vs. 3%). No unanticipated treatment-related adverse effects were reported in either treatment group.

Interpretation of results

Substantial improvement of incontinence symptoms was observed with Macroplastique as a minimally invasive treatment for female stress urinary incontinence in terms of improvement of at least one Stamey grade at 12 months compared to baseline. This is further supported with pad weight reduction and Quality of Life score improvement.

Concluding message

Based upon these results, Macroplastique has been shown to be a safe and effective urethral tissue bulking treatment for female stress urinary incontinence.

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