THREE AND SIX MONTH RESULTS FROM A RANDOMIZED, CONTROLLED CLINICAL TRIAL OF AN INTRAVESICAL PRESSURE-ATTENUATION BALLOON SYSTEM FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI)

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OBJECTIVES
- This study evaluates the efficacy, safety, and tolerability of the Vesair® pressure-attenuation balloon for the treatment of female SUI using a prospective, randomized, single-blind, multi-center study on a different patient population. 1

MATERIALS & METHODS

Placement
- A sheath is placed through the urethra, and cystoscopy is performed. The deflated balloon is pre-inserted inside the tip of a 19 Franch (F) delivery system and inserted into the bladder through the sheath, inflated and released.

Removal
- The balloon is removed under direct visualization using a custom optical grasper through a sheath. Subjects that received the sham procedure at enrollment had a balloon placed at 3 months.

Endpoints – 3 Month
- Composite Endpoint: 210 g improvement in m-QOL and >50% Reduction in Provocative Pad Weight Test

Endpoints – 6 Month
- Safety
  - Adverse Events 3 Months and Beyond – Treatment Group
  - No patients discontinued the study due to treatment-related adverse events.

RESULTS

Effectiveness Endpoints at 3 months
- Treatment vs. Control

Endpoints – 6 Months
- SOLECT Six Month Results
  - Effectiveness Endpoints (Per Protocol) – Demonstrating Superiority

Safety
- No adverse events reported in the control group.

CONCLUSIONS
- Results from the trial show statistically significant improvements at 3 months in clinically relevant objective and subjective measures of SUI. The pressure attenuation system was safe and caused no urinary retention during the follow-up period. Six-month evaluation of the patients in the treatment group demonstrated durability of the therapy. Additional follow-up is warranted to assess the longer-term durability of this therapy.

Reference

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