

## A RANDOMIZED, CONTROLLED CLINICAL TRIAL OF A INTRAVESICAL PRESSURE-ATTENUATION BALLOON SYSTEM FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN FEMALES.

### Hypothesis / aims of study

Current SUI treatments attempt to either increase intrinsic urethral closure forces or increase urethral support such that the urethra can better withstand transient increases in intravesical pressure during stress maneuvers. This abstract describes a novel technique for treating SUI that focuses, instead, on directly reducing the transient spikes in intravesical pressure that are common to all forms of SUI, regardless of their etiology. The reduction in transient spikes in intravesical pressure is accomplished by insertion of a free-floating, non-occlusive intravesical balloon filled with compressible gas. Since gas is highly compressible relative to most liquids, it can act as a hydraulic "shock-absorber."<sup>1</sup> This fundamental mechanism of action in an intravesical application has been described in previous published studies,<sup>2</sup> including a previous prospective, randomized, single blind, multicenter study on a different patient population.<sup>3</sup>

### Study design, materials and methods

This study evaluated the efficacy, safety, and tolerability of the Vesair® pressure-attenuation balloon for the treatment of female stress urinary incontinence (SUI) using a prospective, randomized, single-blind, multi-center design, evaluated at 3 months. Additionally, 6 month and 12 month data was collected.

Sixty-three females with SUI were randomized 2:1 to treatment with a balloon (N=41) or sham procedure (N=22). The sham (control) entailed the same procedure without the deployment of a balloon. Endpoints were evaluated at 3 months and included a composite endpoint that required both a ≥10 point increase in the 22-item Incontinence Quality of Life Survey (I-QOL) and ≥50% decrease in provocative pad weight. Additional endpoints included incontinence episode frequency and PGI-I assessment.

The deflated balloon is placed inside the tip of a 19 French (Fr) delivery system and inserted into the bladder through a sheath, inflated and released. The balloon is removed under direct visualization using a custom optical grasper through a sheath.

### Results

In an ITT analysis, 63% of women in the treatment group achieved the composite endpoint at 3 months, compared to 31% in the Control Group (P=.0200). In a per protocol analysis at 3 months, 81% of women in the treatment arm had a 50% decrease in pad weight test vs. 45% in the Control Group (P = .0143); 51.6% of the treatment patients were dry on pad weight test (≤2 gram) vs. 15% in the Control Group (P=.0164), and 58% of treated patients reported improvement on a PGI-I assessment vs. 25% of women in the Control Group (P=.023). Adverse events in the treatment group included dysuria (12.2%), gross hematuria (9.8%), and UTI (7.3%). At the six-month evaluation of the treatment group, 45.5% of patients were dry on pad weight test (≤2gram) and the percentage of patients reporting improvement on a PGI-I assessment increased from 58% at 3 months to 64% at 6 months. Late-Breaking 12-month data will be presented when available.

### Interpretation of results

Results from the trial show statistically significant improvements in clinically relevant objective and subjective measures of SUI.

### Concluding message

The pressure attenuation system was safe and caused no urinary retention during the 3-month follow-up period. 6-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.

### References

1. Fluid Transients in Systems. 1993. Prentice Hall Publishers, Englewood Cliffs, NY, USA. p125.
2. Can an air-filled intravesical device in vivo attenuate pressure and raise the abdominal pressure at which stress urinary incontinence related leakage occurs? *Neurourology Urodyn.* 2009;28(7):781-783.
3. A Randomized, Controlled Clinical Trial of a Novel Intravesical Pressure-Attenuation Device for the Treatment of Stress Urinary Incontinence. *J Urol* 2013; 190; 2243-50.

### Disclosures

**Funding:** The study was funded by Solace Therapeutics, Inc. **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov registration number NCT01676662 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** The University of Antwerp, Maastricht University Medical Centre, and Universita Degli Studi Di Napoli **Helsinki:** Yes **Informed Consent:** Yes