12 AND 24 MONTH FOLLOWUP OF PATIENTS IN THE SOLECT TRIAL FOR SUI

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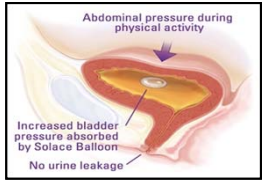
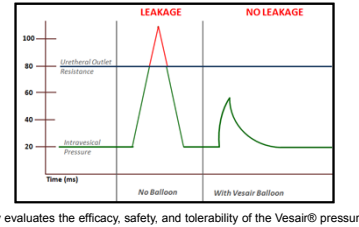
OBJECTIVES

- This poster describes a novel technique for treating SUI that focuses 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." This fundamental mechanism of action has been published previously, including a prospective, randomized, single blind, multi-center study on a different patient population.[1]



- 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 design, evaluated at 3 months and again at 6 months.

MATERIALS & METHODS

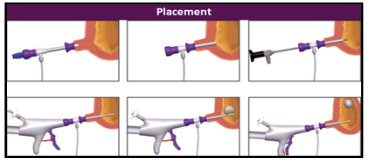
The Vesair ® Balloon

- **The balloon is thin and has a low mass**. It is constructed of polyurethane film - a material with a long history of biocompatibility, including use in the urinary tract. A one-way valve seals the balloon after filling with air.

MATERIALS & METHODS (CONT'D)

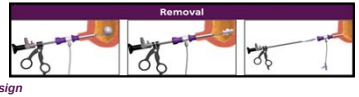
Placement

- A sheath is placed through the urethra, and cystoscopy is performed. The deflated balloon is pre-inserted inside the tip of a 19 French (Fr) 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.



Study Design

- 63 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.

Patients and Methods

- All patients had the option to continue beyond 3 months. For those women in the control arm that chose to continue, a balloon was placed during cystoscopy at the 3-month visit. The balloon is removed under direct visualization every 12 months (or earlier if needed) using a custom optical grasper through a sheath.

Inclusion Criteria

- Females age 18 and older with SUI
- Positive provocative pad weight test of ≥5 g
- Experienced SUI for at least 12 months and failed prior noninvasive treatment
- Willing to undergo cystoscopic and urodynamic procedures during the course of the study
- Valsalva leak point pressure (VLPP) of ≥60 cm H_20
- Free of local genital skin infection, impassable urethral strictures, trauma or necrosis
- Alert, oriented, mentally competent, and capable of determining their need to void by sensing and responding to an urge to void
- A baseline I-QOL score of ≤ 80

Exclusion Criteria

- Pregnant or planning pregnancy during study period
- Urosepsis, Bladder infection, urethral inflammation, urethral edema, urinary tract infection or asymptomatic bacteriuria within previous 3 months
- Recurrent UTIs (2 or more in past 12 months)
- Urinary incontinence due to intrinsic sphincter deficiency or of neurogenic etiology
- Surgical procedure for incontinence in the past 6 months
- History of artificial sphincter placement
- Cystocele with bladder descent below mid-vagina during straining (PoP-Q grade ≥3)
- Undergoing or anticipating a course of pelvic radiation therapy
- Non-ambulatory or bedridden or physically unable to perform pad weight test
- Presence of gross hematuria and/or blood clots in the urine
- History of kidney stones
- Detrusor overactivity or interstitial cystitis

Reference

1. Rovner et al, 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

RESULTS

This poster reports on the 23 patients that completed a 12 month visit.

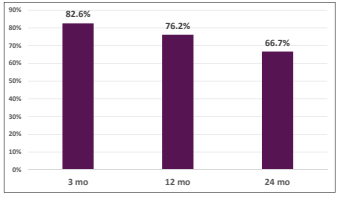
Baseline

Subject Baseline Characteristics	Treatment N=23
Mean Age (years)	51.9
Mean BMI	27.6
Length of symptoms (Months)	83.2
SUI Type	
Stress Only	91.3%
Mixed	8.7%
Cause of SUI	
Hypermobility	91.3%
ISD and Hypermobility, Predominant Hypermobility	8.7%
Menopausal Status	
Pre-menopausal	39.13%
Peri-menopausal	21.74%
Post-menopausal	39.13%
Number of Live Births (mean)	1.61
Number of Vaginal Deliveries (mean)	1.57
Other Symptoms Reported	
Frequency	8.7%
Urge Incontinence	7.3%
Poor Stream	0%
Nocturia	21.74%
Urgency	8.7%
Straining	0%
Hesitancy	8.7%
Mean Valsalva Leak Point Pressure (cm H_2O)	135.33
Prior Treatments	
Prior Pelvic Surgery (Any)	30.43%
Prior Failed Sling Procedure	8.7%
Prior Failed Bladder Training	47.83%
Prior Failed Kegel Exercises	56.52%
Prior Failed Biofeedback	0%
Prior Failed Electrical Stimulation	4.35%
Currently on Estrogen Replacement	4.35%
Current Tobacco User	17.39%
Mean Packs/Day	1.0
Current Alcohol User	39.13%
Mean Drinks/Week	3.89
Mean Baseline Measures	
Pad Weight (gm)	15.2
IQOL	56.0
Leaks per day	3.1
ICIQ FLUTSsex	3.3

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 a ≥50% decrease in provocative pad weight. Additional endpoints included incontinence episode frequency and PGI-I assessment.

Endpoints

- ***Composite Endpoint***
  ≥10 pt Improvement in I-QOL and >50% Reduction in Provocative Pad Weight Test



RESULTS (CONT'D)

- ***Effectiveness Endpoints at 3, 12 and 24 months.***

	1 Months N=23	3 Months N=23	12 Months N=23	24 Months N=13
Provocative Pad Weight	NA		N=20	N=12
w/50% Reduction		82.6%	85.0%	83.3%
Dry (≤2 gm)		69.6%	75.0%	66.7%
Dry (≤1 gm)		65.2%	45%	41.7%
Mean Reduction (gm)		12.3	12.5	13.2
Mean % Reduction		73.9%	75.9%	62.35
I-QOL	N=23	N=23	N=22	N=13
w/10 pt improvement	91.3%	95.7%	77.3%	69.2%
Mean Change	28.5	28.6	22.5	19.8
Mean % Change	67.1%	65.3%	48.9%	39.2%
Episode Frequency	N=22	N=22	N=20	N=11
w/50% Reduction	68.2%	77.3%	65.0%	63.6%
Mean Reduction (leaks/day)	1.6	2.2	1.7	1.7
Mean % Reduction (leaks/day)	61.4%	69.1%	54.8%	49.9%
Dry (0 leaks/day)	18.2%	27.3%	10.0%	18.2%
Mean Change (voids/day)	0.5	0.3	0.7	0.8
PGI-I	N=23	N=23	N=22	N=9
Reporting Improvement	87.0%	87.0%	68.2%	69.2%
Composite		N=23	N=21	N=12
Reporting Improvement		82.6%	76.2%	66.7%
ICIQ-FLUTSsex	N=23	N=20	N=21	N=13
Mean Improvement	1.2	1.4	1.1	0.3

Safety

- Adverse Events

Adverse Events by Type during the first 12 months	N	%
Any Adverse Event	14	60.9%
Hematuria (Gross)	6	26.1%
Balloon Deflation	3	13.0%
Urgency/Urge Incontinence	3	13.0%
Suprapubic Discomfort	3	13.0%
Cystitis	2	8.7%
Dysuria	2	8.7%
Bladder Wall Irritation	2	8.7%
Urinary Tract Infection	1	4.3%
Bladder Stone	1	4.3%
Other*	6	26.1%

**Voided Balloon, Sensation of pressure in bladder, awareness of balloon, intermittent voiding difficulty, incomplete voiding sensation .*

Adverse Events by Type Between 12 and 24 Months	N	%
Any Adverse Event	3	23.1%
Hematuria (micro)	2	15.4%
Urgency/Urge Incontinence	1	7.7%
Suprapubic Discomfort	1	7.7%
Urinary Tract Infection	1	7.7%
Bladder Wall Irritation	1	7.7%

- Encrustation
  - A measurable deposit of less than 1 mm was discovered on 3 balloons.
- Urinary Tract Infection
  - One UTI reported during the first 12 months on one patient and a second UTI reported in the second 12 months on another patient. Both were resolved without balloon removal.
- Retention
  - No reports of urinary retention.

CONCLUSIONS

- Results from the trial continue to demonstrate the durability of the balloon 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. Additional studies are warranted to assess the longer-term durability of this therapy.

This Study was Sponsored by Solace Therapeutics, Inc.
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