A Randomized, Controlled Clinical Trial of an Intravesical Pressure-Attenuation Balloon System for the Treatment of Stress Urinary Incontinence in Females

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Aims: Evaluate the efficacy, safety, and tolerability of a novel 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. **Methods:** 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 ≥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 PGII assessment. **Results:** In an ITT analysis, 63% of women in the treatment group achieved the composite endpoint, compared to 31% in the Control Group ($P = 0.0200$). In a per protocol analysis, 81% of women in the treatment arm had a 50% decrease in pad weight test vs. 45% in the Control Group ($P = 0.0143$); 41.6% of the treatment patients were dry on pad weight test (≤1gram) vs. 0% in the Control Group ($P < 0.001$), and 58% of treated patients reported improvement on a PGII assessment versus 25% of women in the Control Group ($P = 0.025$). Adverse events in the treatment group included dysuria (14.6%), gross hematuria (9.8%), and UTI (7.3%). **Conclusions:** This minimally invasive treatment for female SUI with an intravesical pressure-attenuation balloon was safe and effective. The concept of pressure attenuation as a therapy for SUI is valid and feasible for those patients that can tolerate the balloon. *Neurourol. Urodynam.*

Key words: balloon; bladder control; intravesical; pressure-attenuation; stress urinary incontinence; urinary incontinence

INTRODUCTION

Stress urinary incontinence (SUI) typically results from dysfunction of the urethral sphincter closure mechanism and/or surrounding tissues, such that the urethra cannot resist antegrade urine flow during periods of increased intra-abdominal pressure.[1] 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.[2] This paper 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.

Because gas is highly compressible relative to most liquids, it can act as a kind of hydraulic "shock-absorber."[3] This concept is fundamental to a wide range of air-filled pulsation dampeners for minimizing hydraulic shock in industrial or civic plumbing and fluid-handling systems. The capacity of a volume of gas to absorb a pressure pulse in a closed hydraulic system is proportional to the volume of gas, as expressed by Boyle's Gas Law.[4] In industrial hydraulic systems, the compressible gas is contained within some type of hydropneumatic attenuator. In the system described in this paper, the gas is contained in an intravesical balloon attenuator that is placed in the bladder to directly attenuate the transient spikes in intravesical pressure related to the increases in abdominal pressure. The fundamental mechanism of action for this intravesical application has been described in previous published studies,[5,6] including a previous prospective, randomized, single-blind, multicenter study on a different patient population.[7]

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This paper discusses the SOLECT trial, the second multicenter, prospective, randomized, concurrently controlled and single blinded study of an intravesical balloon to treat female patients with predominate SUI (Vesair(TM), Solace Therapeutics, Framingham, MA). The goals of this study are to evaluate the efficacy and safety of the balloon therapy against a control sham procedure at three months. After the three-month data is collected, the patients are unblinded and control patients are offered to crossover and receive the balloon. Patients have the option to continue with the balloon therapy and follow-up for up to three years.

This article discusses the 3-month endpoint results comparing treatment vs. control groups. Longer-term efficacy and safety data for patients in the Treatment Group will be reported when available.

PATIENTS AND METHODS

This study was conducted at seven sites in the European Union under a clinical research protocol that was approved by ethics committees for each site, and the devices are authorized for sale in the European Union (CE Mark). Informed consent was obtained from all subjects.

Prior to enrollment, all potential subjects were evaluated using the following assessments: history and physical examination; laboratory urinalysis (including culture and sensitivity, if urinalysis was positive); provocative pad weight test; urodynamic evaluation, including VLPP; one seven-day voiding diary; I-QOL; ICIQ-FLUTSsex; ICIQ-SF and cystoscopy.

The pad test was performed with controlled fill volumes and activity levels. The patient voided normally and a weighed pad was then placed. The patient then drank 500cc of fluid within 15 min. The bladder volume was monitored by bladder scan until the measured volume was between 250 and 300 cc. The patient underwent 30 min of walking and a specific series of physical exercises while monitored by a blinded assessor. Upon completion of the physical activity, the pad was immediately removed and weighed. Patients are considered ''dry'' if their post-test pad weight increase is $\leq$1g.

The study enrolled patients with SUI or MUI where stress incontinence was the predominant component. Investigators based this diagnosis by visually confirming stress incontinence with physical maneuvers (stress test), urodynamics, and a focused incontinence history/interview, all of which indicated the predominance of a stress component. Additional inclusion and exclusion criteria used during study recruitment are seen in Table I. Randomization was sequential at each site using a card-based randomization scheme. Patients were randomized using a 2:1 randomization scheme in which one-third of subjects (N = 22) were initially assigned to a Control Group receiving a sham procedure, and two-thirds (N = 41) were assigned to the Treatment Group (Fig. 1).

The study was powered to ensure adequate sample size for testing the composite effectiveness endpoint. The PASS Power Analysis and Sample Size software, 2011, by NCSS, was used for computation of sample size requirements for the study hypothesis. A level of 80% power was sought, using a two-tailed test with alpha of 0.05. The estimate for proportion of patients in the treatment group with this composite endpoint is approximately 50%. The proportion of patients in the control group for this trial (e.g., patients undergoing the sham procedure) is estimated to be 12%. Using a two-sided Fisher's Exact test of the difference between two independent proportions at the 0.05 level of significance and a 2:1 randomization ratio, a total of 56 patients are required to detect an expected difference in proportion of patients with this composite endpoint at 3 months of the magnitude described above with 80% power. The sample size was increased to 63 to offset loss to clinical follow-up.

Subjects in the treatment arm had the pressure attenuation balloon inserted into the bladder on Day 0. For subjects in the control arm, the identical procedure was used except a balloon was not deployed from the balloon delivery system (subjects were blinded as to whether they were in the treatment or control arms; practitioners were necessarily unblinded). A blinded assessor administered the endpoint instruments (pad test and questionnaires) at the one-month and three-month visits.

At one month, subjects in both arms completed the following: 7-day voiding diary; I-QOL, PGII, ICIQ-SF and ICIQ-FLUTSsex questionnaires. At three months, subjects in both arms completed the following: provocative pad weight test; 7-

TABLE I. Inclusion and Exclusion Criteria

Inclusion Criteria:	Females age 18 and older with SUI
	Positive provocative pad weight test of $\geq$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 $\geq$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 baselineI-QOL score of $\leq$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 $\geq$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

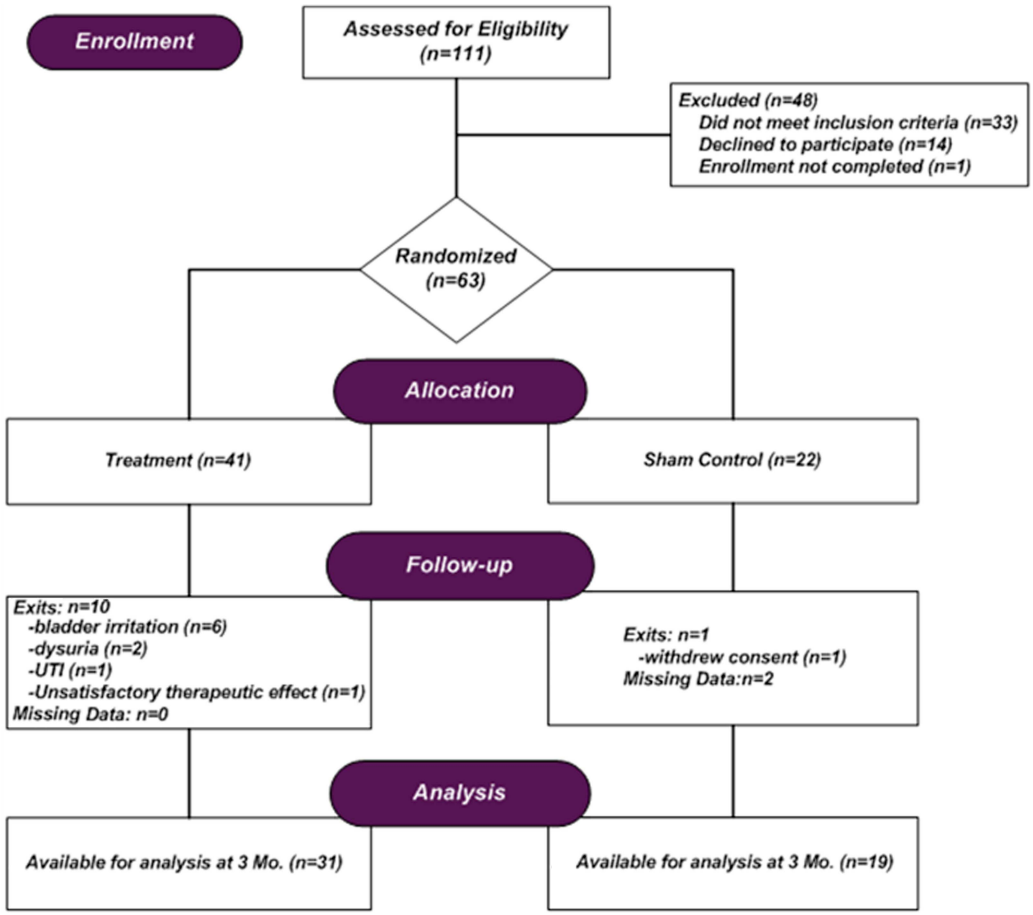

Fig. 1. CONSORT (CONsolidated Standards of Reporting Trials) Flow Diagram of SOLECT Study.

day voiding diary; I-QOL, PGII, ICIQ-SF and ICIQ-FLUTSsex questionnaires. Endpoints were collected by a blinded assessor. After all data was collected at the three month visit, all subjects were unblinded as to their treatment group and patients in the control group were offered to crossover and receive the balloon.

Prior to the 63 patient study reported herein, 17 patients were enrolled at three centers. This enrollment was halted due to the premature deflation of the balloon. Enrollment was reset and the study was then started under the modified protocol and device. All data and analysis herein includes only the 63 patients that were enrolled under the new protocol and device.

The composite endpoint of a $\geq$50% reduction in provocative pad weight and a $\geq$10 point increase in I-QOL score was evaluated at three months. Results were analyzed on both an Intent-To-Treat (ITT) and Per Protocol (PP) basis with Student's *t* test used for comparison of means and Fisher's Exact test for comparison of proportions.

Adverse events were recorded at each follow-up visit whenever reported by a patient or elicited by the site. "Urinary Tract Infection" was defined as the presence of leukocytes and/or bacteria in a urine specimen and/or urine cultures demonstrating 100,000 or more colony forming units (CFU) per ml of urine of a single bacterial species from a clean catch mid-stream voided sample concurrent with dysuria, excessive urinary frequency, excessive urge, purulent discharge from the meatus, new onset of bladder symptoms, or gross hematuria.

Procedure

Balloon placement. For patients in the Treatment Group, the Guardian Urethral Sheath ™ is placed through the urethra to provide access to the bladder while protecting the urethra (Fig. 2a). A scope is placed through the sheath to investigate the bladder and then removed. The deflated balloon is pre-inserted inside the tip of a 19 F delivery system. The delivery system is inserted through the sheath and the deflated balloon is then inflated with 0.5 cc of AirLoc™ and 30 cc of air via two attached syringes (Fig. 2b). AirLoc is a perfluorocarbon liquid used to maintain inflation of the balloon. The inflated balloon is released into the bladder and the insertion device is removed from the sheath. Proper inflation of the balloon is verified visually with a cystoscope through the sheath.

For patients in the Control Group, the Guardian Urethral Sheath is placed through the urethra. A scope is placed through the sheath to investigate the bladder and then removed. The delivery system (without a deflated balloon at the distal tip) is inserted through the sheath and the two syringes are deployed to simulate balloon inflation. The release mechanism on the delivery handle is deployed to simulate balloon release into the bladder and the insertion device is removed from the sheath. The lack of a balloon is then verified visually with a cystoscope through the sheath.

Balloon removal. The balloon is removed when necessary under direct visualization using a custom optical grasper through the

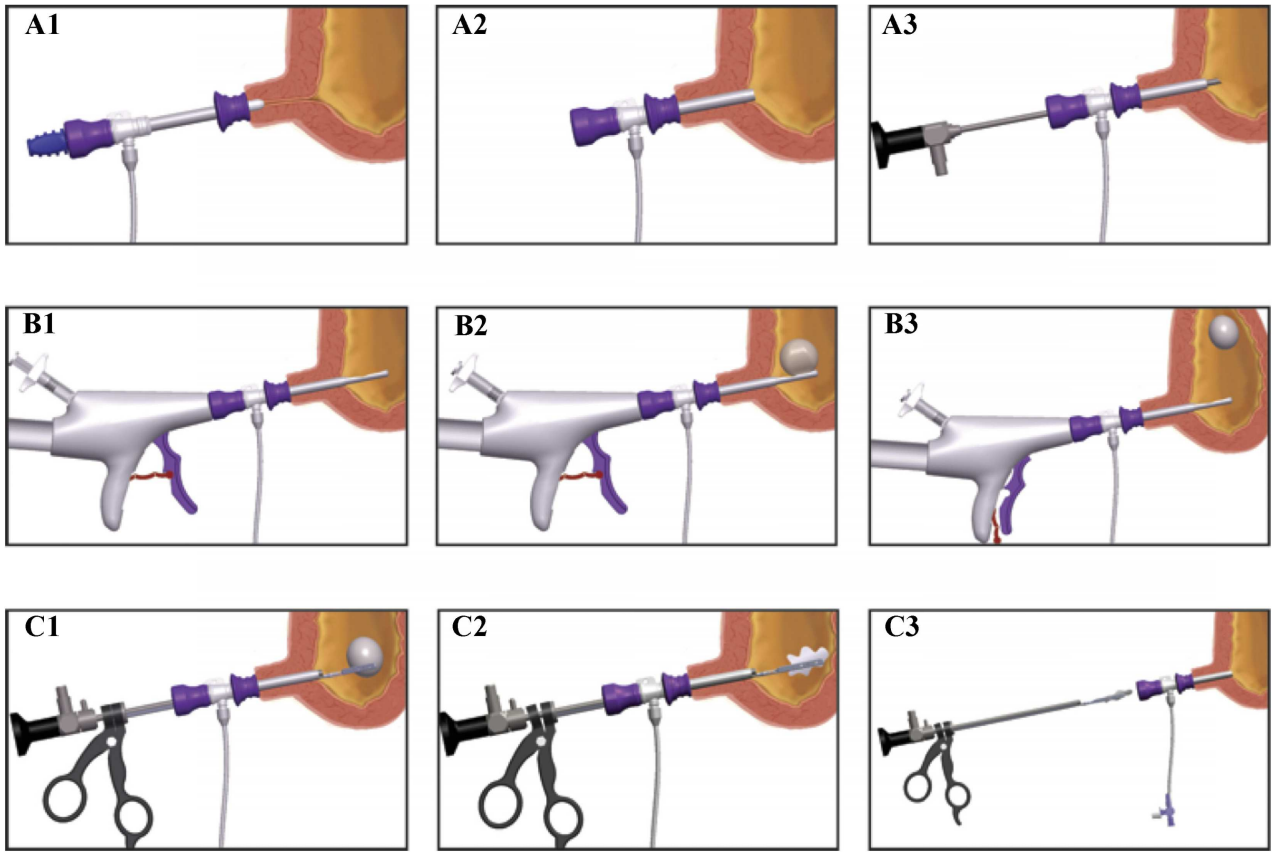

Fig. 2. Solace procedure steps. **A:** Bladder access and fluid management A1: Insert tip of Guardian Urethral Sheath™ into the urethra at the meatus. A2: Advance Sheath into bladder, remove obturator, and fill bladder. A3: Insert scope through Sheath to visualize bladder. **B:** Balloon Delivery B1: Advance Solace Balloon Delivery System (with deflated balloon at the tip) through Sheath and into bladder. B2: Inflate balloon with AirLoc™ and air. B3: Squeeze trigger to release balloon and remove Delivery System. Insert scope through Sheath to inspect balloon. **C:** Balloon Removal C1: Insert Solace Balloon Removal System through Guardian Urethral Sheath and visualize balloon. C2: Squeeze removal handle to grasp and deflate balloon. C3: Pull Removal System and deflated balloon through the Guardian Urethral Sheath. Insert scope through Sheath and visualize bladder.

sheath (Fig. 2c). The balloon is pierced to allow the air to escape, then removed through the sheath. At the patient's option, a new balloon can be inserted through the sheath. At the end of the procedure, the sheath is removed. All patients are given prophylactic antibiotics prior to and after performing cystoscopy, balloon insertion, sham balloon insertion or removal.

RESULTS

Baseline characteristics between the treatment and control groups were comparable for most parameters (Table II). The composite endpoint was defined as the number of women in either study arm who had both a $\geq$50% reduction in provocative pad weight and a $\geq$10 point increase in their I-QOL scores. Women in the treatment arm had significantly improved symptoms when analyzed on both an ITT analysis (63.4% in Treatment Group vs. 31.8% in Control Group; $P = 0.0200$) (Fig. 3), and a per protocol analysis (67.7% in treatment group vs. 31.6% in sham group; $P = 0.0195$). Evaluable results for the composite endpoint were obtained from 31 patients in the treatment arm and 19 patients in the control arm (total = 50) (Fig. 1). Per the Statistical Analysis Plan approved before the study began, the ITT analysis used imputation for missing data.

Improvements were also observed in other endpoints, analyzed on a Per Protocol basis (Table III). For example, a statistically significant improvement in the percentage of women with a greater than 50% reduction in their provocative pad weight (80.7% of treated patients vs. 45% of the control patients, $P = 0.0143$) was observed at three months. Furthermore, 41.9% of patients in the Treatment Group were "dry" on their provocative pad weight test at three months compared to 0% of those who received the sham procedure ($P = 0.0006$). A statistically significant improvement in symptoms was reported on the patients PGII questionnaire, with 58.1% of treatment patients reporting improvement versus 25% of the control patients ($P = 0.0249$).

Eleven of 63 total enrolled subjects (17.4%) withdrew from the study before the 3-month follow-up visit. Balloons were removed from patients in the Treatment Group at the time of withdrawal. The most significant reason for withdrawals was related to issues of bladder irritation and tolerability of the balloon and procedure. Six patients withdrew due to bladder irritation, five of which exited before or during the 1-month visit. Two patients exited due to dysuria, one of which occurred 5 days after balloon placement. One patient withdrew because of concerns relating to UTI. One patient exited due to an unsatisfactory therapeutic effect. In the control arm, one patient exited due to a physical relocation to a foreign country.

TABLE II. Baseline Characteristics

Subject baseline characteristics	Treatment N = 41	Control N = 22	*P*-value
Mean Age (years)	49.3	48.7	0.8638
Mean BMI	25.73	25.76	0.9761
Length of symptoms (Months)	90.9	78.5	0.5432
SUI Type			0.6104
Stress Only	95.0%	91.9%	
Mixed	5.0%	9.1%	
Cause of SUI			1.000
Hypermobility	88%	91%	
ISD and Hypermobility, Predominant Hypermobility	12%	9%	
Menopausal Status			0.0926
Pre-menopausal	46.3%	59.1%	
Peri-menopausal	14.6%	27.3%	
Post-menopausal	39.1%	13.6%	
Number of Live Births (mean)	1.83	1.77	0.8170
Number of Vaginal Deliveries (mean)	1.80	1.77	0.8997
Other Symptoms Reported			
Frequency	4.9%	9.1%	0.6063
Urge Incontinence	7.3%	0%	0.5457
Poor Stream	0%	4.6%	0.3492
Nocturia	7.3%	18.2%	0.2264
Urgency	9.8%	4.6%	0.6497
Straining	2.4%	0%	1.000
Hesitancy	7.3%	0%	0.5457
Mean Valsalva Leak Point Pressure	113.5	139.6	0.0235
Prior Treatments			
Prior Pelvic Surgery (Any)	34.2%	22.7%	0.4011
Prior Hysterectomy	17.1%	4.5%	0.2425
Prior Failed Sling Procedure	9.8%	0%	0.2883
Prior Failed Bladder Training	43.9%	45.5%	1.000
Prior Failed Kegel Exercises	43.9%	50.0%	0.7917
Prior Failed Biofeedback	4.9%	13.6%	0.3327
Prior Failed Electrical Stimulation	7.3%	4.6%	1.000
Currently on Estrogen Replacement	0%	9.1%	0.1183
Current Tobacco User	17.1%	18.2%	1.000
Mean Packs/Day	1.0	1.0	1.000
Current Alcohol User	43.9%	54.6%	0.4418
Mean Drinks/Week	3.7	2.5	0.2131
Mean Baseline Measures			
Pad Weight	27.2	24.9	0.7705
IQOL	51.8	51.1	0.8540
Leaks per day	3.1	2.4	0.2513
ICIQ FLUTSsex	3.8	3.4	0.5438
Voids/Day	7.3	6.7	0.2395

Careful evaluation was conducted on those pressure-attenuation balloons that were removed during the 3-month evaluation period to evaluate the balloons for evidence of encrustation or sediment formation. Twelve balloons were evaluated with a mean dwell time of 44.5 days (range from 5 days to 103 days) and were analyzed by visual inspection. Some of the balloons changed color, and some sediment was noticeable in the valve port of the balloon, but no balloon had any measurable sediment formation on the surface of the balloon. Chemical analysis of a representative sample of the sediment indicated that it was calcium oxalate. The twelve evaluated balloons included one balloon removed from each of the 10 treatment patients that withdrew, and one balloon removed from each of two patients that had a balloon exchange at the discretion of the investigator.

There was no observation of urinary retention or obstruction and no patient complaints of incomplete emptying in either study arm. No serious adverse events occurred during the 3-month evaluation period. During the initial 3-month period, device or procedure related adverse events were reported in 18 subjects in the Treatment Group (43.9%) compared with one subject (4.6%) reporting a procedure-related adverse event in the control group (Table IV). Three patients in the Treatment Group had a UTI, all occurring within 22 days of balloon placement. The UTI was resolved in one patient without balloon removal. The other two patients had the balloon removed by physician's choice and the UTI resolved. One of these patients exited the study, and the other had a new balloon inserted after resolution of the infection. One patient voided the fully inflated balloon at the end of micturition shortly after balloon placement. A new balloon was replaced, and the patient was instructed not to "bear down" to evacuate all urine upon completion of voiding.

The presence of the balloon in the bladder did not result in any clinical significant differences in the number of voids per day. Patients in the Treatment Group had a mean voids/day percent change of 6.0%, while the mean voids/day percent change in the Control Group decreased 1.2% ($P = 0.3604$).

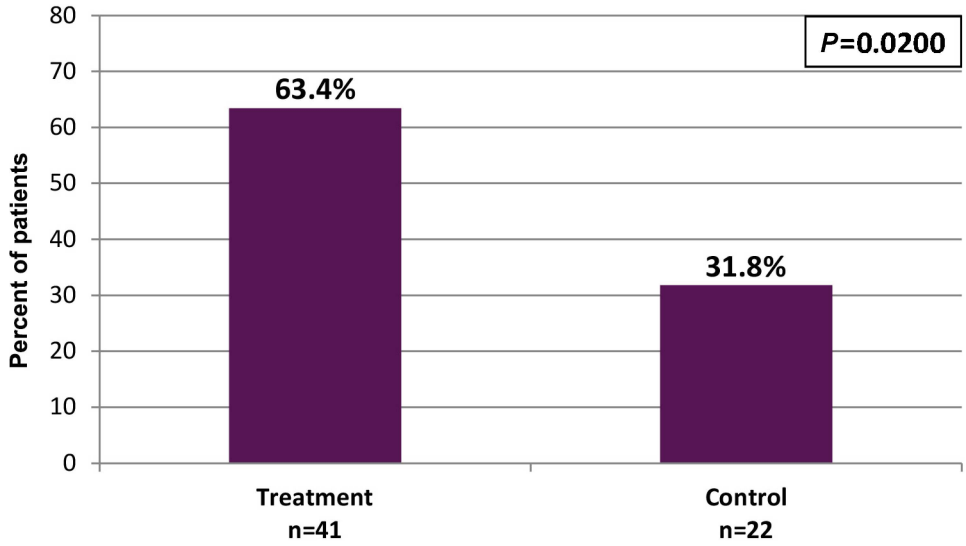

Fig. 3. Composite endpoint at 3 months (ITT analysis).

DISCUSSION

Current SUI treatments focus on improving the urethral closure forces such that the bladder outlet can better withstand transient increases in intravesical pressure associated with coughing, sneezing, exertion, or other actions that increase intra-abdominal pressure. Despite a wide range of current options, however, there remains a significant unmet clinical need for non-surgical treatments that are effective across a range of etiologies, and which are reversible, safe, relatively inexpensive, and with low morbidity. The current study suggests that this novel treatment focused on reducing rapid changes in intravesical pressure may provide a clinically valuable option that could be used alone or in combination with existing therapies directed at urethral function.

The pressure attenuation balloon used in this study is constructed of polyurethane, a material with a long history of biocompatibility, including use in the urinary tract. A one-way valve seals the balloon after being filled with 30 cc of air and Airloc. AirLoc is a liquid perfluorocarbon used to maintain inflation of the balloon. Liquid perfluorocarbons have been used extensively in a number of FDA-approved medical devices because they are inert, non-toxic, and safe.[8] The balloon's low mass (0.2g) and inherent buoyancy causes it to float naturally at the dome of the bladder, thus preventing occlusion of the bladder outlet during voiding. By protocol and product labeling

TABLE III. Improvement at Endpoints

	One Month			Three Month		
Follow-up measures (Change is from baseline)	**Treatment**	**Control**	***P*-value**	**Treatment**	**Control**	***P*-value**
Provocative Pad Weight				N = 31	N = 20	
w/50% Reduction				80.7%	45.0%	0.0143
Dry (≤2 gm)				51.6%	15%	0.0164
Dry (≤1 gm)				41.9%	0%	0.0006
Mean Change (gm)				−19.4	−7.8	0.1830
Mean % Change				−66.6%	15.9%	0.0072
I-QOL	N = 38	N = 22		N = 31	N = 20	
w/10 pt improvement	68.4%	59.1%	0.5766	74.2%	55.0%	0.2250
Mean Change	19.7	15.0	0.3873	22.7	13.3	0.1089
Mean % Change	53.3%	37.8%	0.3920	57.9%	35.5%	0.3223
Episode Frequency	N = 32	N = 22		N = 31	N = 19	
w/50% Reduction	59.4%	27.3%	0.0275	61.3%	31.6%	0.0792
Mean Change (leaks/day)	−1.57	−0.75	0.0816	−1.28	−0.44	0.2088
Mean % Change (leaks/day)	−18.4%	−9.4%	0.8117	−41.7%	7.49%	0.0242
Dry (0 leaks/day)	12.5%	4.6%	0.6377	19.4%	0%	0.0707
Mean Change (Voids/day)	0.234	−0.239	0.2228	0.373	−0.113	0.3960
Mean % Change (Voids/day)	6.0%	−1.8%	0.1862	5.7%	−1.2%	0.3604
PGI-I	N = 38	N = 22		N = 31	N = 20	
Reporting Improvement	68.4%	36.4%	0.0294	58.1%	25.0%	0.0249
ICIQ-FLUTSsex	N = 37	N = 21		N = 28	N = 19	
Mean Change	−0.97	2.86	0.0694	−0.58	−1.12	0.7360
Mean % Change	−23.9%	8.8%	0.1297	−38.1%	−18.0%	0.3235

TABLE IV. Adverse Events

Adverse Events Type Patients Reporting Through 3 Months	Treatment N = 41	Control N = 22
Any Adverse Event	43.9%	4.6%
Dysuria	14.6%	4.6%
Gross Hematuria	9.8%	0%
Cystitis	7.3%	0%
Suprapubic Pain	4.9%	0%
Urinary Tract Infection (Symptomatic)	7.3%	0%
Vaginal Irritation	0%	4.5%
Balloon Voided (intact)	2.4%	—

(CE Mark), the balloon can be removed and replaced at any time and has a recommended dwell time of up to 1 year. Longer follow-up is required to determine the actual in-dwelling times of balloons in this study.

Prior to the 63 patient study reported herein, 17 patients were enrolled at three centers. This enrollment was halted due to the premature deflation of the balloon. In five patients, the balloon ruptured and deflated. In each case the balloon was voided by the patient without incident. The balloon was strengthened with an increase in wall thickness. Several protocol modifications were made to further exclude patients with predominate urge symptoms, including the use of a completed 24 hr voiding diary at patient evaluation and elimination of the hand washing procedures during the provocative pad test. Enrollment was reset and the study was then started under the modified protocol and device. All data and analysis herein includes only the 63 patients that were enrolled under the new protocol and device.

The AE rates described herein are consistent with published studies of bulking agents, with the added benefit of simple removal of the implant at any time. The requirement of both bacteria and symptoms in the definition of UTI was in the protocol since the presence of a foreign body in the urinary tract can result in symptoms such as pyuria and/or bacteriuria but not necessarily infection. The adverse event rates, including UTI, in this study were lower than those in a previous randomized controlled trial of this technology reported by Rovner et al in 2013.[7] Device changes incorporated after the previous study include the use of a seamless 30 cc balloon, simplified delivery and removal instrumentation and procedures, and the addition of a urethral sheath to minimize urethral trauma and reduce the introduction of bacteria into the bladder during balloon delivery and removal.

Limitations of the study include the unavoidable lack of clinician blinding and a dropout rate in the treatment arm that indicate that not all patients tolerate the balloon in their bladder. All tolerability issues were resolved upon balloon removal. Further study of those patients that didn't tolerate the balloon is underway to help further screen out patients that are not good candidates for this therapy and to provide guidance for future balloon modifications. The withdrawal rate should be considered in the context that this approach is reversible, with a very straightforward office procedure, at the patient's option at any time, and does not preclude any other subsequent therapy options for the patient. The withdrawal rate herein is consistent or better than other anti-incontinence products such as pessaries[9] and urethral plugs.[10] The rigor of this trial, requiring multiple visits and time consuming tests and interventions, increased the patient burden beyond what would be required in commercial use.

Statistical significance was achieved in the challenging composite endpoint of this study, but the withdrawal rate did have an impact on the statistical power of the study. Imputation for missing data from withdrawn patients was appropriate for the ITT analysis as withdrawals were primarily due to lack of tolerability of the balloon, even though in many cases the subjects reported an improvement in symptoms. It would be misleading to negatively impact the assessment of efficacy by imputing all withdraws as failures. Future studies should include larger patient populations to minimize the impact of early withdrawals.

A "perfect" therapy for SUI would be 100% effective, durable, simple to implement, minimally invasive, completely reversible, applicable for all types of SUI, relatively inexpensive, and be associated with low morbidity and/or complications.[11] Unfortunately, this "perfect" therapy does not exist. However, the pressure attenuation system described herein moves us closer to these ideals. For example, the inherent risks of surgery, a permanent implant, and mesh are eliminated when compared to mid-urethral slings.[12] Given that the worldwide number of patients with SUI is projected to grow to 167 million by 2018,[13] such a novel treatment option for SUI could have wide applicability.

CONCLUSIONS

This randomized, controlled, sham trial compared efficacy and safety outcomes for a novel intravesical pressure-attenuation system designed to reduce or eliminate symptoms of SUI. Results from the trial show statistically significant improvements in clinically relevant objective and subjective measures of SUI. The pressure attenuation system was safe and caused no urinary retention during the 3-month follow-up period. This therapy provides a useful alternative therapeutic option for women with stress incontinence. Continued follow-up is warranted to assess the long-term durability of this therapy.

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