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NON-SURGICAL, PALPATION-BASED OUTPATIENT TREATMENT FOR STRESS URINARY INCONTINENCE

Aims of Study

Microscopic submucosal radiofrequency energy (RF) tissue remodeling alters the structure and compliance of targeted collagen without grossly narrowing luminal structures. Proven safe and effective for the treatment of both fecal incontinence and GERD, RF tissue remodeling within the lower urinary tract may improve SUI. This 12 month pilot study was performed to demonstrate the safety, effect on quality of life, and effectiveness durability of a novel, non-surgical, transurethral RF treatment for SUI which does not require cystoscopy.

Methods

52 women with SUI and bladder outlet hypermobility were sequentially enrolled into 5 treatment groups which differed in exact targets of remodeling, number of RF lesions, and total RF delivery time (Table 1). All women were treated under conscious sedation in lithotomy position and were discharged home on the day of treatment. The 21F device is passed through the urethra and a balloon at the tip of the device is then inflated. The balloon is palpably anchored within the bladder outlet, similar to the positioning of a Foley™ catheter. Four 23 gauge electrodes are deployed into the submucosa and RF briefly delivered. Simple device rotations and variable ordering of electrode deployment/balloon anchoring allows for reproducible RF remodeling in the varying lower urinary tract locations. Automatic RF generator safety features protect the mucosa while rapidly achieving and maintaining submucosal collagen remodeling temperatures. Safety was assessed through adverse event (AE) recording. Effect on quality of life was assessed using an Incontinence Quality of Life questionnaire (I-QOL) which generates a 100-point score [1]. The women completed the I-QOL prior to (baseline) and at 6 and 12 months following treatment.

Table 1. Treatment Group Characteristics

Treatment Group (n)	RF Remodeling Targets and Lesion Number				Total RF Delivery Time
	Proximal Urethra	Vesicourethral Junction	Distal 2mm of Bladder Outlet	Total RF Lesions	
I (10)	24	0	0	24	7.5 min
II (10)	24	12	0	36	10.5 min
III (11)	24	0	24	48	12.0 min
IV (10)	24	12	24	60	15.0 min
V (11)	60	0	0	60	15.0 min

Results

There were no serious AEs, and all related AEs mimic those typically seen with lower urinary tract instrumentation. No woman required catheterization at discharge, and recovery was rapid. At 6 months, the 5 groups demonstrated incidences of I-QOL score improvement ranging from 78%-82%, and statistically significant mean score improvement was demonstrated by 3 groups. At 12 months, the 5 groups demonstrated incidences of I-QOL score improvement ranging from 70%-82%, and statistically significant mean score improvement was demonstrated by 4 groups. Furthermore at 6 months and at 12 months, 3 groups demonstrated statistically significant reduction in mean incontinence frequency (Table 2). Treatment group incidence of “dry” women at 12 months ranged from 22%-67%.

Table 2. Treatment-Based I-QOL Improvement

Treatment Group	Baseline Mean Score	6 Month Post-Procedure		12 Month Post-Procedure	
		Mean Score *(p-value)*	↑ Score Incidence	Mean Score *(p-value)*	↑ Score Incidence
I	45	63 *(NS)*	78%	68 *(NS)*	75%
II	54	77 *(0.004)*	78%	70 *(NS)*	78%
III	55	66 *(NS)*	80%	72 *(0.04)*	70%
IV	54	81 *(0.02)*	78%	77 *(0.03)*	78%
V	34	56 *(0.04)*	82%	58 *(0.02)*	82%
all patients	48	68 *(< 0.001)*	79%	69 *(< 0.001)*	77%

Treated patients may also be analyzed based on baseline incontinence severity, without regard to treatment group. If the 100 point I-QOL scale is equally divided into thirds, incontinence can be defined as “severe” for baseline scores of 0-33, “moderate” for scores of 34-67, and “mild” for scores of 68-100. The results of such an analysis suggest a high incidence of improvement, durability of improvement, and statistically significant improvement following RF treatment for women with all levels of incontinence severity (Table 3).

Table 3. Severity-Based I-QOL Improvement

Incontinence Severity (n)	Baseline Mean Score	6 Month Post-Procedure		12 Month Post-Procedure	
		Mean Score *(p-value)*	↑ Score Incidence	Mean Score *(p-value)*	↑ Score Incidence
severe (12)	21	55 *(0.001)*	92%	50 *(0.007)*	75%
moderate (29)	52	69 *(0.001)*	76%	72 *(0.0003)*	75%
mild (7)	76	87*(NS)*	71%	87*(0.02)*	86%

Conclusions

This pilot study demonstrated the safety, quality of life improvement, and effectiveness durability of transurethral RF tissue remodeling for the treatment of women with SUI. The results suggest that improvement may require only a limited number of lesions created over a narrow target range, and that RF tissue remodeling may safely improve the quality of life for women with mild, moderate, and severe SUI. This novel, non-surgical, outpatient procedure may offer physicians and SUI patients a safe, rapid, and effective therapeutic option. Furthermore, because this simple procedure does not require cystoscopic assistance, it may allow a larger number of physicians to provide treatment for this common disorder.

References

[1] Wagner TH, Patrick DL, Bavendam TG et al. Quality of Life of Persons with Urinary Incontinence: Development of a New Measure. *Urology* 47:67-72, 1996