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TRANSURETHRAL RADIOFREQUENCY ENERGY TISSUE REMODELING FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Aims of Study

This pilot study was performed to determine the safety and quality of life impact of radiofrequency energy (RFe) tissue remodeling of the proximal urethra and distal bladder outlet in the treatment of women suffering from stress urinary incontinence (SUI). Unlike RFe tissue ablation, which grossly shrinks tissues, visibly altering tissue length and/or shape, RFe tissue remodeling leads to microscopic changes as submucosal collagen is denatured and subsequently heals, resulting in altered tissue compliance. Thus no gross shrinkage or anatomic change results from RFe tissue remodeling.

This investigational procedure is unique in terms of device placement and positioning. The device is placed transurethrally, without the need for any incisions. The device is positioned by palpation of a balloon anchoring within the bladder outlet (as with a standard indwelling urinary catheter) and without the requirement for either cystoscopy or fluoroscopy.

Methods

41 women suffering from SUI and with physical examination evidence of bladder outlet hypermobility were sequentially enrolled into four treatment groups. The groups differed in number of RFe lesions created (range 24-60), total duration of RFe treatment (7.5-15.0 minutes), and target of RFe remodeling (proximal urethra ± vesicourethral junction ± distal bladder outlet). All treatments were delivered in the outpatient setting utilizing intravenous conscious sedation.

The 21F device was passed through the urethra, and a 10cc balloon at the device tip was insufflated within the bladder lumen. Four 23 gauge needle electrodes were deployed into the targeted submucosa, and RFe was delivered in 60-90 second intervals while sterile water simultaneously irrigated and protected the overlying mucosa from thermal injury. Device rotation and alterations in needle deployment allowed for predictable and reproducible variations in the anatomic location of RFe remodeling (proximal urethra, vesicourethral junction, or distal bladder outlet).

Prior to and at 6 months following treatment, patients completed a urinary incontinence quality of life questionnaire (I-QOL) [1]. The I-QOL has previously demonstrated associations between specific numerical score elevations and clinically meaningful improvement in patient quality of life: $\geq$ 10 point elevation in overall I-QOL score is associated with $\geq$ 25% reduction in incontinence episodes, $\geq$ 25% reduction in urinary pad weight, and a “much better” urinary incontinence-related patient global perception relative to pre-treatment [2]. The I-QOL also generates three subscale scores: Avoidance and Limiting Behavior (ALB), Psychosocial Impact (PSI), and Social Embarrassment (SE). Incontinence frequency and urinary pad use were also recorded.

Results

Four patients were retrospectively excluded from analysis for exclusion criteria violations, and a fifth was lost to follow-up. Data from 36 patients was available for analysis.

All patients were discharged on the day of treatment. No patient was discharged requiring urinary catheterization. No Serious Adverse Events were noted in any patient at treatment or at any time in the 6 month follow-up period. All Adverse Events were anticipated, and all are commonly associated with lower urinary tract instrumentation. With the exception of one patient, no patient’s symptoms disturbed her enough to request an unscheduled physician evaluation.

At 6 months following treatment, 63%-78% of women in the four treatment groups demonstrated clinically meaningful improvement ($\geq$ 10 point elevation) in their I-QOL score. 50%-80% demonstrated improvement in their ALB subscale score, 70%-78% in their PSI subscale score, and 63%-89% in their SE subscale score. The two groups in which both vesicourethral junction and proximal urethral submucosal tissue was remodeled both demonstrated statistically significant improvement in overall I-QOL score and in all three subscale scores. These two groups also demonstrated statistically significant reduction in incontinence frequency.

Cure (dry) rates for the four groups ranged from 22%-78% at 6 months following treatment.

[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

[2] Patrick DL, Martin, Bushnell DM et al. Quality of Life of Women with Urinary Incontinence: Further Development of the Incontinence Quality of Life Instrument (I-QOL). *Urology* 53:71-6, 1999

Conclusions

This pilot study of transurethral RFe tissue remodeling demonstrated safety and effectiveness in improving the quality of life for women suffering from stress urinary incontinence. A majority of women within each of the four treatment groups demonstrated clinically meaningful improvement in I-QOL scores at 6 months following treatment, and this improvement, along with a reduction in incontinence frequency, reached statistical significance in two groups.

This novel RFe treatment is entirely non-surgical. Furthermore, the treatment requires no endoscopic or fluoroscopic imaging assistance, utilizing technically simple, familiar, reliable palpation of a balloon anchoring within the bladder outlet. The results of this initial investigation suggest that transurethral RFe tissue remodeling may offer physicians and SUI patients a safe, rapid, and effective non-surgical treatment option.