

FEASIBILITY OF PERFORMING NON-SURGICAL RADIOFREQUENCY ENERGY TISSUE MICRO-REMODELING IN WOMEN WITH STRESS URINARY INCONTINENCE USING ORAL AND LOCAL ANESTHESIA**Hypothesis / aims of study**

Non-surgical radiofrequency energy (RF) tissue micro-remodeling for the treatment of stress urinary incontinence (SUI) is rapidly and safely performed on an outpatient basis using intravenous conscious sedation to assure patient comfort. This Pilot Clinical Trial was undertaken to assess the feasibility of performing non-surgical RF tissue micro-remodeling using only oral and local anesthesia in women suffering from SUI.

Study design, materials and methods

Sixteen women with a history of SUI for ≥ 12 months, a clinical diagnosis of genuine SUI, and bladder outlet hypermobility on physical examination were enrolled in this prospective, open-label, single arm Pilot Trial.

All women underwent identical non-surgical RF micro-remodeling of 36 microscopic, circumferential sites within the bladder neck and proximal urethral submucosa. This procedure has demonstrated safety and improvement in patient quality of life in previous trials when performed under conscious sedation [1,2].

Prior to treatment, all women received 250mg levofloxacin orally. All women received oral sedatives and/or analgesics 30-60 minutes prior to RF micro-remodeling treatment, and all underwent a simple bilateral peri-urethral local anesthetic block to the level of the bladder outlet using 2% lidocaine with epinephrine prior to transurethral passage of the RF micro-remodeling probe, as detailed in the table below. The trial progressed with the aim of reducing anesthetic requirements while maintaining patient safety and comfort. Anesthetic failure was defined as either the patient requesting conversion to conscious sedation (due to discomfort) or the physician determining that conversion to conscious sedation was required for safe and comfortable completion of the procedure.

Number of Patients (%)	Oral Medications	Total Local Anesthetic Volume (2% Lidocaine with Epinephrine)
2 (13%)	midazolam 15.0mg tramadol/paracetamol 2 tablets	20cc
2 (13%)	midazolam 7.5mg tramadol/paracetamol 2 tablets	20cc
1 (6%)	midazolam 7.5mg	20cc
1 (6%)	tramadol/paracetamol 2 tablets	10cc
10 (63%)	midazolam 7.5mg	10cc

Results

The anesthetic failure rate was 0%, as no procedure required conversion to conscious sedation for completion either at the request of a patient or at the determination of the physician that conscious sedation was required. Initial experience demonstrated that the level of patient anxiety and discomfort was minimal, allowing for a rapid reduction in oral

sedation and local anesthetic administration. Thus the final 63% of women required only a single 7.5mg midazolam tablet and a total of 10cc local anesthetic.

Mean total procedure time (from initial catheterization to completion of the procedure) was 29 ± 4 minutes. In the subpopulation who received only 7.5mg midazolam and 10cc local anesthetic, mean total procedure time was 28 ± 4 minutes.

Following treatment, all women were discharged home after spontaneous urination.

Interpretation of results

The results of this Pilot Trial indicate that RF micro-remodeling of the bladder neck and proximal urethral submucosa was well tolerated when performed using only oral and local anesthesia. Unlike RF ablation, in which higher temperatures are achieved to produce tissue necrosis on a gross scale (as in transurethral needle ablation for the treatment of benign prostatic hyperplasia), RF micro-remodeling likely required minimal anesthesia because of (1) the lower target temperature (65°C), (2) the short duration of treatment at target temperature (≤ 50 seconds), and (3) the microscopic rather than gross scale of tissue treatment.

Subjectively, relative to more than 150 women who have previously undergone RF micro-remodeling using conscious sedation, the 16 women in this Pilot Clinical Trial appeared to have superior anesthetic results using the oral sedative plus the local anesthetic, while also benefitting from the rapid anesthetic recovery and avoidance of intravenous line placement associated with this minimal regimen.

Concluding message

The patient comfort demonstrated in this feasibility study of RF tissue micro-remodeling performed under minimal oral and local anesthesia further increases the usefulness of this non-surgical, safe, outpatient treatment from both the SUI patient and physician perspective.

References

[1] Transurethral delivery of radiofrequency energy for tissue micro-remodeling in the treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 14:373-379, 2003.

[2] Non-Surgical, Palpation-Based Outpatient Treatment for Stress Urinary Incontinence. *International Continence Society, 2003 Annual Meeting* [Abstract].

FUNDING: Novasys Medical, Inc. sponsored this IRB approved trial