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Dmochowski R¹, Ross J², Levy B³, Lucente V⁴

1. Vanderbilt University Department of Urology, 2. University of California Los Angeles, 3. University of Washington, 4. Pennsylvania State University

DURABILITY OF THERAPEUTIC EFFECTS OF A RADIO FREQUENCY ENERGY PROCEDURE FOR MILD-TO-MODERATE GENUINE STRESS INCONTINENCE AT THREE-YEAR FOLLOW-UP

Hypothesis / aims of study

To study the durability of therapeutic effects in patients receiving a direct application of bipolar radio frequency energy to the endopelvic fascia for the treatment of genuine stress incontinence. A cohort of 120 patients were treated using a minimally invasive transvaginal surgical approach and followed to three years.

Study design, materials and methods

One hundred twenty women presenting with symptoms of mild or moderate genuine stress incontinence with urethral hypermobility were enrolled at 10 U.S. clinical sites. At baseline, 66% of patients reported 1 to 3 incontinence episodes per day, and 18% reported 4 or more episodes daily. Mean duration of symptoms was 7.2 ± 7.3 years. All patients demonstrated a positive Valsalva with LPP >90 cmH₂O at 250 cc.

Treatment was performed in an outpatient setting using a low-power, bipolar radio frequency energy device to deliver a controlled thermal effect to the periurethral endopelvic fascia to create tissue shrinkage and tightening. Patients were placed under either general anesthesia or local anesthesia with conscious I.V. sedation.

Shallow bilateral transvaginal incisions 2-3 cm in length were made in the vaginal mucosa, centered at the level of the mid-urethra. Lateral blunt dissection of the anterior vaginal wall was used to expose two treatment areas on the underlying endopelvic fascia, each approximately 15mm x 20mm. RF energy was delivered to the tissue using sweeping passes with the applicator tip in direct contact with the tissue. Energy output, tissue temperature and impedance were monitored by the device and recorded using a computerized data collection tool. The incisions were closed, the catheter was removed, and the patient was transferred to recovery until the anesthesia effects were no longer present and she was able to void spontaneously.

Results

At 30 months, follow-up was attempted with all patients in the original cohort except for 12 patients (10%) who had undergone a second surgical procedure for incontinence subsequent to the transvaginal RF energy procedure. The percent of patients demonstrating a negative Valsalva (no leak with maximal effort) was analyzed using a Kaplan-Meier technique. Greater than 60% of patients maintained an objective cure by this criteria at 30 ± 3.3 months.

No intraoperative complications occurred in 120 cases. Post-operatively, three minor complications (3%) were reported: one urinary tract infection, one case of post-operative urgency, and one instance of vaginal bleeding due to a suture break. All complications resolved, and none were related to the RF energy device. There were no cases of post-operative urinary retention, voiding difficulties, or chronic *de novo* urgency.

Interpretation of results

The transvaginal RF energy procedure has demonstrated clinical efficacy in the treatment of genuine stress incontinence for the majority of patients and is accompanied by a distinctly low rate of complications as compared to other GSI surgical procedures such as suburethral slings and retropubic suspensions. The RF energy approach uniquely avoids the blind passage of needles or trocars into the retropubic space; notably, there were no injuries to the bowel, bladder or major vessels in 120 patients. No cases of fistula formation were reported. All patients were discharged to home of the day of the procedure without requiring a catheter; patients seeking to minimize the impact of treatment on their normal routines may consider this a key attribute of the procedure.

A secondary analysis of the data was performed using variations in RF energy application technique as stratification criteria. This analysis revealed two technique variables that correlated to clinical results, namely, the degree of excess fluid in the surgical field, and the

use of continuous versus interrupted energy delivery to the tissue. These technique variations were evident from the power, temperature and impedance data collected throughout each procedure. When the two technique variables were optimized to maximize the delivery of thermal energy to the tissue (i.e., fluid was minimized and energy was delivered continuously), improved clinical efficacy was observed. At 12 months, a cured/improved rate of 87% was achieved in 45 cases performed using the optimized technique. By this same criteria, a 76% success rate was noted at 30 months.

Concluding message

The three-year follow-up data from this early study suggests that the objective cure rate of the RF energy procedure maintains good durability. The data also indicate that two aspects of the surgical technique can be controlled to optimize clinical results. Long-term subjective outcomes such as quality of life and incontinence episode frequency must also be studied as further indicators of the procedure's viability in the spectrum of minimally invasive therapies for GSI.

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