TRANSVAGINAL RADIO FREQUENCY TREATMENT OF THE ENDOPELVIC FASCIA: A PROSPECTIVE EVALUATION FOR THE TREATMENT OF GENUINE STRESS URINARY INCONTINENCE

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ABSTRACT

Purpose: We evaluate the safety and efficacy of a new treatment modality for genuine stress urinary incontinence which was a transvaginal radio frequency applicator to deliver radio frequency energy to the endopelvic fascia. The purported mechanism of effect for this therapy is shrinkage of the collagenated tissue which composes the endopelvic fascia that supports the bladder neck and proximal urethra, thus stabilizing the proximal urethra and bladder neck. In prior animal trials and early pilot studies this therapy was shown to cause a reproducible thermal effect manifested by fascial shrinkage. Preliminary human trials indicated a therapeutic benefit of this therapy for women with genuine stress urinary incontinence.

Materials and Methods: To our knowledge this is the first multicenter study of a transvaginal approach for radio frequency of the endopelvic fascia for treatment of genuine stress incontinence. Between June 1999 and June 2000, 120 consecutive women (mean age 49.9 years) at 10 sites underwent transvaginal radio frequency treatment in a prospective trial to evaluate the overall efficacy and safety profile of this therapy. All patients had preoperative urethral hypermobility (average cotton swab change 38 degrees). Detrusor instability was excluded by cystometry. In all procedures precisely controlled radio frequency energy was applied to the endopelvic fascia to heat and shrink the tissue. The patients were evaluated postoperatively at 1 week and at 1, 3, 6 and 12 months using objective and subjective measures. Primary end points consisted of physician assessment of continence, patient reported pad use and the number of patient reported episodes. Safety was determined for acute (immediate postoperative) and chronic time frames.

Results: Of the 120 patients 96 completed 1-year evaluation. Average operative time was less than 30 minutes, and all patients were treated as outpatients. Preoperatively 101 patients (84%) averaged 1 or more episodes of urinary incontinence per day. At 3, 6 and 12 months 57%, 66% and 59% of patients, respectively, averaged 1 or no daily episodes of urinary incontinence. At 12-month followup 79 of 109 patients (73%) reported being continent or improved. Preoperatively, 43% of patients reported using 1 or no pads daily. At 3, 6 and 12 months 69%, 70% and 72% of patients, respectively, required 1 or no pads daily. On urodynamic evaluation at 12-month followup 76.0% of the patients did not leak with a Valsalva maneuver. A total of 30 cases were classified as failures and 11 women were lost to followup. There were no intraoperative complications, 3 (4%) minor postoperative complications which resolved, and no device related complications.

Conclusions: The transvaginal radio frequency applicator demonstrated good efficacy and excellent safety at 1-year followup. Ongoing analysis of the data has indicated opportunities for improvement of this new surgical technique that could result in higher efficacy rates without compromising safety. Further long-term evaluation is being conducted to assess chronic durability of the procedure.

KEY WORDS: urinary incontinence, stress; surgery, fascia

It is reported that 10 million women worldwide and 6.5 million women in the United States suffer from genuine stress incontinence. Of the total number of women with genuine stress incontinence only a small portion are treated with surgical procedures (mostly Burch) in the United States and only 200,000 women annually seek surgical intervention. The remaining women afflicted with genuine stress incontinence use disposable absorbent products, with an estimated cost in the billions of dollars, to cope with (but not cure) the symptoms. Urinary continence in women is contingent on an intact urethral sphincter, which provides occlusive forces to the urethral lumen and prevents urinary loss by increasing abdominal pressures. Support by the endopelvic fascia also
provides stabilization and probable compression of the urethra during stress events.

Previously, a variety of methods existed to restore support to the urethral sphincteric mechanism, either from retropubic or transvaginal approaches, such as the Burch and Raz procedures. Retropubic suspensions have been determined to have therapeutic durability and are considered by many investigators to be the primary modality for surgical intervention for women with genuine stress incontinence who have adequate urethral function. Morbidity and convalescence issues associated with this genre of surgical interventions have caused a continued search for less invasive, equally efficacious and safe procedures as alternatives to these operations.

Radio frequency energy is a distinctly unique form of electromagnetic energy that induces reproducible thermal changes in soft tissue, manifested by well-defined areas of tissue heating and coagulation. This energy delivery method has been used extensively in dermatological and orthopedic surgery for tissue shrinkage and ablation. Recently, laparoscopic radio frequency treatment of the endopelvic fascia has been shown to provide therapeutic benefit by inducing fascial shrinkage or contraction with minimal safety concerns in women with genuine stress urinary incontinence in a prospective trial. Transvaginal radio frequency treatment has undergone extensive pre-clinical testing and early pilot evaluation, and appeared to mimic the results obtained with the laparoscopic approach. We present data from the first multicenter prospective study of the new transvaginal device and procedure based on the SURx Transvaginal System (SURx, Inc., Livermore, California).

MATERIALS AND METHODS

We performed a prospective, multicenter, single-arm, non-randomized, longitudinal investigational device exemption study of 120 women who presented with a history of genuine stress incontinence due to type I or II hypermobility on urodynamic and physical evaluation. The primary study objectives were to establish the safety and efficacy of the SURx Transvaginal System. Patient enrollment for this trial started in June 1999 and was completed in June 2000. Convenience sampling was used to enroll study participants. Patients were treated at 10 United States investigational sites and represented a broad geographic accrual distribution.

Preoperative evaluations included criteria similar to those for most incontinence trials, and consisted of a history and physical examination, voiding diary, quality of life questionnaire and urodynamics. All study participants had normal neurological examinations. Patients who were on antidepressants, or α-adrenergic and anticholinergic medications as well as those with grade III or IV cystoceles or other vaginal support defects (that is, enterocele, rectocele or uterine prolapse and mixed incontinence were excluded from study). All patients had clinically demonstrated evidence of urethral hypermobility with an abnormal cotton swab test (greater than 30 degrees) and a Valsalva leak point pressure greater than 90 cm./H2O at a bladder capacity of 250 ml. Detrusor instability was excluded by cystometry. Patients included in the study had had previous unsuccessful outcomes after at least 3 months of conservative, noninvasive therapies, such as Kegel exercises or electrical stimulation of pelvic floor muscles. No patient was concurrently receiving any active incontinence therapy.

The SURx Transvaginal System is composed of a small bipolar radio frequency generator and a sterile, single use disposable bipolar applicator that allows application of radio frequency energy to the tissue. The applicator has a handle, trigger and a 270-degree rotational tip with microbipolar electrodes and a saline drip at the distal end of the probe (see figure). Additionally, there is a thermistor located between the electrodes for accurate monitoring of treatment tissue temperatures. An electronic data collection device was used to collect automatically real-time device performance on 26 different treatment parameters during each procedure.

All patients were treated as outpatients using general anesthesia. After being placed in the dorsal lithotomy position a Foley catheter was inserted into the bladder, the bladder was emptied and the balloon was inflated. Hydrourethrosis of the anterior vaginal wall was performed using sterile injectable saline or an appropriate dilute vasostrictive solution (20 U vasopressin in 50 ml. injectable saline or epinephrine at a 1:20,000 dilution in injectable saline) to minimize excess bleeding. A 2 to 3 cm. incision was made 1 cm. lateral to the urethra through the full thickness of the vaginal mucosa to (1 to 2 mm.) at the level of the mid urethra between the urethral meatus and bladder neck. The surgeon then laterally dissected the anterior vaginal wall, exposing an area approximately 1.5 × 2 cm. of the inferior aspect of the endopelvic fascia. Care was taken not to disrupt the underlying fascial layer. In most cases similar dissection was performed on the contralateral side before radio frequency treatment was initiated to prevent undue stress from compromising previously treated tissues. The bladder neck was identified by palpation of the transurethral Foley catheter. The area to be treated was irrigated with saline and dried using continuous suction. The maintenance of a dry surgical field and hemostasis varied from investigator to investigator and was later found to be a predictor of procedural outcome.

After dissection the tip of the applicator was applied to the underlying endopelvic fascia with enough pressure to cause deflection of the tissue. Medial application of radio frequency energy was accomplished by drawing the radio frequency applicator tip over the fascia in a slow sweeping manner along the longitudinal axis, making sure that both times of the applicator tip were equally in contact with the tissue until all of the endopelvic fascia was treated. Care was taken throughout the procedure to remain 1 cm. lateral to the urethra. Thermal effect within the tissue was evidenced by blanching and shrinkage. Treatment was then repeated on the contralateral side.

Patients were seen 1 week and 1, 3, 6 and 12 months postoperatively. Followup evaluations consisted of a history, physical examination and urodynamic studies. In addition, each patient completed a voiding diary and quality of life questionnaire. The primary end points were safety of the procedure, physician and patient assessment of continence, and patient reported daily incontinence episodes. Cured was defined "objective cure" (negative Valsalva) and improved was defined as decreased daily episodes or pad use.
Pretreatment and posttreatment matched pairs were used for all analyses. When data were scaled ordinally, likelihood ratio and log linear statistics were generated. However, due to periodic cell sparseness, tables were collapsed to create $2 \times 2$ contingency tables for most analyses. These reduced tables were conducive to generating Fisher's exact statistics, continuity adjusted chi-square statistics and other measures of association. The matched paired t test and nonparametric Wilcoxon rank sums test were used to evaluate quality of life scores before and after treatment. All analyses were performed using Statistical Analysis System, version 8 (SAS, Cary, North Carolina).

RESULTS

A total of 120 women underwent genuine stress incontinence surgery at 10 centers (table 1). Average duration of symptoms ± SD was 7.2 ± 3.7 years. All patients presented with genuine stress incontinence symptomatology that typically characterized type II incontinence and by inclusion criteria all patients had Valsalva leak point pressure greater than 90 cm H$_2$O. Of the patients 26 (21%) had undergone prior abdominal and/or pelvic surgery (that is hysterectomy and laparoscopy). Average preoperative cotton swab test angle was 38 degrees which decreased to 21 degrees postoperatively. Postoperative examination of the vaginal mucosa showed no tissue abnormalities. Average operative time was 30 minutes and average radio frequency treatment time per side was 2 to 3 minutes. In each case tissue impedance averaged 204 ± 66 ohms with an average treatment temperature of 82 ± 8°C.

There were no intraoperative complications and 3 (4%) minor postoperative complications, which included vaginal bleeding due to vaginal incision dehiscence at 3 weeks, urinary tract infection at 1 month and urgency at 1 month. All minor complications resolved, and there were no device related complications.

Of the 120 patients 96 presented for the 12-month followup examination. Successful outcome (defined by cured or improved) was 73% at 12 months (79 of 109, including patients with known treatment failures lost to followup at the 12-month interval). Of the 109 patients 66 (61%) had a negative Valsalva leak point pressure on urodynamic evaluation at 12 months, including those who did not submit to urodynamics at 12 months (even if other measures indicated a successful outcome) and those with known treatment failure at previous followup visits and who failed to undergo urodynamics evaluation. Of those patients who underwent urodynamics 12 months 76% had a negative Valsalva leak point pressure.

Improvement in daily incontinence episodes was significant from preoperative status (table 2). Comparing baseline to 12-month observations 64% of the patients reported reduced episodes as measured by movement of 1 category on a 4-point scale or remained stable with mild episodes, and 19% (21 patients) had an increased frequency of episodes. A significant number of patients demonstrated a decrease in daily pad use at 12-month followup compared to preoperative status (table 3). Before the procedure 57% of patients used 1 or more pads a day while only 28% used 1 or more pads a day at 12 months.

All patients presented with positive Valsalva leak point pressure before treatment. They were instructed to generate maximal effort and were only deemed to have a negative leak point (no leak) if no urinary loss occurred related to this effort. Based on data available for 86 patients at preoperative and 12-month intervals 24% had demonstrable Valsalva leak point pressures 12 months after treatment, representing a statistically significant (p < 0.05) improvement in urodynamics for 76% of the patients.

Patients were asked to record on a Likert type scale their satisfaction with the treatment results (table 4). Results were scored from 1 (extreme satisfaction) to 5 (complete dissatisfaction). More than 68% of patients reported satisfaction with the outcome of the procedure at 12 months. Of the patients 95 completed preoperative and 12-month postoperative quality of life questionnaires using the previously validated Wagner quality of life instrument. Matched pairs t test indicated significantly (p < 0.05) improved quality of life scores over baseline at the 12-month evaluation.

DISCUSSION

Tissue responses induced by radio frequency thermal energy are well described and reproducible. Acute effects include denaturation of collagen fibers, which results in loss of collagen fibril integrity. At 1 week a more generalized granulation response is seen and by 21 days after treatment fibroplasia and fibrosis response are predominant. By 6 weeks after treatment the expected fibrotic healing response continues to progress and inflammatory cellular components are minimal. The final histological result is fibrotic tissue that replaces the elastic endopelvic fascia. This process shortens, stiffens and thickens the fascia increasing support of the bladder neck and changes the collagen structure of the tissue. Radio frequency thermal tissue treatment has been used in dermatology, in orthopedics and for varicosce veins. The contractile response to radio frequency energy has also been applied to the treatment of tissue within joints to shorten and strengthen tendineous or ligamentous attachments.

The endopelvic fascia may demonstrate loss of integrity which generally is caused by pregnancy and childbirth. However, other women, such as athletes, can also suffer from genuine stress incontinence. This resultant loss of integrity is manifested by bladder descensus with resultant urethral hypermobility during stress events, such as coughing or other activities, which increases abdominal pressures. Accepted treatments that stabilize the bladder neck include retropubic suspension and pubovaginal sling. As noted in the literature, the Burch and Raz procedures are associated with higher complication rates than the radio frequency transvaginal approach. The radio frequency suspension shrinks the endopelvic fascia and replaces elastic tissue with inelastic tissue. This shrinkage decreases the elasticity of the endopelvic fascia and stabilizes the proximal urethra and bladder neck, recapitulating the suburethral tissue used as a backboard for urethral closure.

The efficacy or cure rates for the Burch, transvaginal sling, SURx laparoscopic approach and SURx transvaginal approach are reflective of varying reporting criteria. These criteria include a reduction in daily pad use and daily genuine stress incontinence episodes as well as improved quality of life score, satisfaction with procedural outcome and/or negative Valsalva, and investigator assessment of outcome parameters. The success rates of the Burch, traditional transvaginal suspension and SURx laparoscopic and transvaginal procedures are 85%, 75%, 81% and 73%, respectively. The success rate for the SURx transvaginal procedure was lower than anticipated in earlier smaller studies or the larger multi-center study using a laparoscopic approach to treat the

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endopelvic fascia. Post hoc analysis revealed that 2 treatment variables were associated with diminished efficacy at 12 months. Fluid in the surgical field was noted to cause energy dissipation and resultant superficial treatment of the surgical field. The second factor that affected results was the quality of radio frequency application to the underlying tissues, with optimal results being obtained with continuous radio frequency delivery applied with light pressure as opposed to numerous intermittent energy applications. In a subset of 45 cases in which these 2 variables were within the recommended parameters a success rate of 87% was achieved.

No patients were identified with de novo intrinsic sphincter deficiency or indications of urethral denervation. With the transvaginal radio frequency procedure no dissection is performed beneath the urethra. During treatment the tip of the radio frequency applicator is always kept a minimum of 1 cm. from the urethra to avoid any injury to the nerve bundles adjacent to the urethra. In addition, the bipolar tip of the applicator is designed so that the radio frequency energy is localized. Heating of the tissue only occurs between the electrodes and extends to a depth of 1.5 to 2.0 mm. maintaining a safety zone between the treated tissue and periurethral nerves.

The results obtained from transvaginal radio frequency bladder neck suspension are encouraging. The 12-month data incorporating an overall 73% success (cured/improved) rate suggest that this procedure has definite applicability for women with bothersome incontinence who do not want to undergo a more complicated procedure. Most significant is the issue of patient tolerance and satisfaction, which were substantial despite the absence of improvement in 27% of the patients. This finding must be gauged against patient expectations of results weighed against the morbidity of incontinence. It is apparent that many patients were satisfied with simply having significant improvement in the incontinence.

The limitations of this study are underscored by the post facto analysis, which revealed an incomplete understanding of the importance of the surgical tenets described previously. It is anticipated that optimization of thermal delivery will result in better continence results. The transvaginal radio frequency procedure represents another alternative for minimally invasive incontinence therapy. A second limitation of this study is treatment durability. Promising short-term results do not always equate to long-term benefit for the patient, but this must be balanced against the minimal morbidity associated with the procedure. If therapy is durable for 6 to 12 months and can be accomplished as a minimally invasive, office based procedure, repeat interventions could possibly be performed to keep symptoms controlled.

CONCLUSIONS

The SURx transvaginal approach provides safe and effective treatment for genuine stress incontinence. Experience gained during the trial showed that optimal therapy was delivered in a controlled surgical field with little excess fluid (blood or serum) and best results were obtained with delivery that minimized radio frequency on/off cycles. The procedure demonstrated superior comparative safety parameters while inducing either cure or improvement in the majority of patients. Further investigation into radio frequency delivery and procedural modification is ongoing.

REFERENCES


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