308

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Title: SAFETY AND EFFICACY OF THE TRANSVAGINAL RADIO FREQUENCY BLADDER NECK SUSPENSION PROCEDURE

Aims of Study:

To evaluate the safety and effectiveness of the transvaginal radio frequency (RF) bladder neck suspension to treat female stress urinary incontinence (SUI). This easily performed procedure does not use implantable materials such as mesh or sutures but instead shrinks the endopelvic fascia (EPF) and lifts the urethrovesical junction to a more anatomically correct position thereby restoring continence.

Methods:

In this prospective, IDE approved, study, 120 women with genuine stress incontinence (GSI) were enrolled at ten (10) study sites between June 1999 and June 2000. All patients had positive valsalva leak point pressures. Average patient age was 49.5 ± 9.9 years and symptom duration was 6.4 ± 5.9 years. Twenty one percent (21.7%) of patients had prior pelvic surgery. Over 83% of patients experienced one or more GSI episodes and over 57% used more than one pad per day. Transvaginal paraurethral incisions and reflection of the vaginal epithelial surface were most frequently used to directly visualize the EPF. Precisely controlled bipolar RF energy was applied with an instrument (SURx, Inc., Livermore, CA) to the EPF causing it to heat and shrink. This shrinkage was easily observed during the surgery. The incisions were closed using conventional techniques. Safety, tolerability and efficacy data were collected using standardized methods. Follow-up intervals for urodynamic testing were performed at 3, 6 and 12 months.

Results:

All patients were treated on an outpatient basis and discharged 2-4 hours following the procedure. RF treatment time ranged from 2 to 5 minutes. Operative time typically ranged from 30-45 minutes. There were no operative or device related complications and no patients required a catheter. Postoperative complications were minor and none were related to the RF device. One (1/120) patient experienced a suture break at 3 weeks and 1/120 experienced de novo urge incontinence. Patients typically returned to normal ambulatory activities (excluding strenuous exercise) within 1-2 post-operative days. At the three and six month follow-up periods, 103 and 89 patients respectively have been examined. Cured/improved rates are 74.8% and 71.6% at 3 and 6-month follow-up periods respectively.

Conclusions:

RF Bladder Neck Suspension appears to be safe and well tolerated by patients. Because this procedure has a good success rate, an excellent safety profile, does not use implantable materials, is straightforward to perform and an outpatient procedure, it holds promise as an alternative to more invasive or difficult to perform procedures. Long-term efficacy data collection is ongoing and one-year follow-up data will be presented.

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