

Author(s) D Galen ¹ , K Abbott ² , D. Albala ³ , T Turk ³ , J. Presthus ⁴													
Institution, city, country Reproductive Science Center of the San Francisco Bay Area, San Ramon, CA ¹ , Physician's Surgery Center, Daly City CA ² , Loyola University, Dept. of Urology, Maywood, IL ³ , University of Minnesota, Minneapolis MN ⁴ USA													
Title (type in CAPITAL LETTERS, leave one blank line before the text) RADIO FREQUENCY BLADDER NECK SUSPENSION: LONGITUDINAL ANALYSIS OF 50 PATIENTS USING A LAPAROSCOPIC APPROACH													
<p>Aims of Study: To evaluate the short term success rate of a new technique to treat stress urinary incontinence (SUI) by elevating the endopelvic fascia <u>without implantable sutures or mesh</u> using objective and subjective measures. A total of 105 women were enrolled in the study. We report on the first 50 patients to reach 6-month follow-up.</p> <p>Methods: Women with SUI, confirmed by urodynamic evaluation were enrolled in this multi-center prospective comparative IDE investigational study. Patients average 48.3 ± 7.3 years of age and suffered an average of 6.9 ± 5.2 years with SUI symptoms. All patients were found to have positive valsalva leak point pressures. Over 60% of the patients used one or more pads per day and 80% of the patients averaged one or more episodes of SUI per day. Using a standard extraperitoneal laparoscopic approach, the endopelvic fascia (EPF) is exposed and directly visualised. A bipolar probe (SURx, Inc, Pleasanton, CA) was used to deliver precisely controlled RF energy to heat the EPF. As the EPF was heated to above 85°C, tissue shrinkage with corresponding bladder neck elevation was apparent. Once the EPF was completely treated, the probe was removed and the access sites closed.</p> <p>Results: Operative time was approximately 40 minutes. Total RF application time was approximately 3-5 minutes. Patients were discharged 2-4 hours after the procedure without a Foley catheter. Two (4%) intraoperative events (bladder perforations unrelated to device due to difficult access) were reported. Normal ambulatory activities excluding strenuous physical activities were possible the day following surgery. Two (4%) postoperative events (1 urinary infection, 1 nausea related to anesthesia) were reported. Two (4%) cases of de novo urge incontinence were also reported.</p> <p>A total of 50 patients have been followed for 6 months. Success rates are as follows:</p> <table border="1"> <thead> <tr> <th>Criteria</th> <th>Success rate at 6 month follow-up</th> </tr> </thead> <tbody> <tr> <td>Reduced SUI episodes per day</td> <td>81.6%</td> </tr> <tr> <td>Reduced Daily pad use</td> <td>71.4%**</td> </tr> <tr> <td>Negative valsalva leak point</td> <td>59%</td> </tr> <tr> <td>Patient self reported satisfaction</td> <td>82%</td> </tr> <tr> <td>Improved patient quality of life score</td> <td>78%</td> </tr> </tbody> </table> <p>** 16% of patients suffered from SUI but used no pads prior to treatment.</p> <p>Conclusion: Treatment of SUI using RF bladder neck suspension appears to yield success rates comparable to most traditional surgical procedures. Because the RF bladder neck procedure does not use artificial implantable materials, it may offer advantages over suspension and sling procedures. Longer term follow-up on a larger number of patients is required to confirm these early results.</p> <p>This study sponsored by SURx, Inc</p>		Criteria	Success rate at 6 month follow-up	Reduced SUI episodes per day	81.6%	Reduced Daily pad use	71.4%**	Negative valsalva leak point	59%	Patient self reported satisfaction	82%	Improved patient quality of life score	78%
Criteria	Success rate at 6 month follow-up												
Reduced SUI episodes per day	81.6%												
Reduced Daily pad use	71.4%**												
Negative valsalva leak point	59%												
Patient self reported satisfaction	82%												
Improved patient quality of life score	78%												

Type your text within this frame. If 2nd page is needed use Abstract Form A-2