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**Title:** COMPARISON OF SAFETY AND EFFICACY OF RADIO FREQUENCY BLADDER NECK SUSPENSION TO TRADITIONAL SURGICAL APPROACHES FOR THE TREATMENT OF GENUINE STRESS INCONTINENCE

**Aims of Study:**

We report on the results of two large studies treating over 200 patients at 16 study sites that were designed to evaluate the safety and efficacy of radio frequency (RF) bladder neck suspension procedures using either a laparoscopic approach or a transvaginal approach to gain access to the endopelvic fascia (EPF).

Methods: Two independent, overlapping, prospective multi-center comparative studies of RF treatment of the endopelvic fascia were conducted on women with genuine stress urinary incontinence (GSI) confirmed by objective urodynamics. Two methods of accessing the endopelvic fascia were used: the first method employed a standard extraperitoneal laparoscopic (LP) approach and the second method used a bilateral transvaginal (TV) approach. The laparoscopic study was conducted at six (6) US sites and the transvaginal study was conducted at ten (10) sites. Both procedures exposed the EPF so that an instrument (SURx, Inc, Livermore, CA) could be used to apply the bipolar RF energy directly to the endopelvic fascia. During each procedure, the EPF was observed to shrink because of the heat produced by the RF energy. Success rates were noted and complication rates were compared at follow-up intervals and to published literature to determine the safety profile of the new procedures. Success was determined using five criteria including the absence of leakage during a valsalva maneuver (VLPP) conducted using standard urodynamic test protocols. Many studies have been previously published on the success and complication rates of surgical treatments for GSI. Results from the RF bladder neck suspension procedure were compared to data on standard surgical techniques from large meta-analysis<sup>2</sup> of previously published literature.

**Results:**

Surgical Procedure	Open Burch <sup>2</sup>	Transvaginal Suspension <sup>2</sup>	<u>Laparoscopic</u> RF bladder	<u>Transvaginal</u> RF bladder
Number of patients	-----	-----	94	120
Follow up period	12-23 months	12-23 months	89pts.1yr follow up	88pts.6 mo.follow up
Success	85%	75%	81.2%	71.6%
Complications				
Transfusion	3%	7%	0%	0%
Cardiovascular	2%	7%	0%	0%
Pulmonary	3%	1%	0%	0%
Bladder,ureter,urethra	7%	6%	2%	0%
Perioperative Bleeding	7%	3%	0%	0%
Urinary Tract Infection	24%	14%	2%	0.8%
Pain	6%	2%	0%	3%
Sexual Dysfunction	5%	16%	0%	0%

Compl Requiring Surgery	5%	1%	0%	0%
Urinary Retention(>4wks)	5%	5%	0%	0%

**Conclusions:**

The success rates of the RF bladder neck procedures using either a laparoscopic or a transvaginal approach compare favorably with the standard open Burch procedure and the transvaginal suspension. However, the safety profile of the RF bladder neck suspension procedures in these two studies is substantially better than the traditional procedures. The RF bladder neck technique may offer an alternative to more traditional techniques and could be a promising first line intervention for the treatment of genuine stress incontinence. Further follow-up data collection is ongoing.

<sup>1</sup> Lead investigator for each study

<sup>2</sup> American Urological Association report on the Surgical Management of Stress Urinary Incontinence, 1997

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