

Medical Policy Manual

Topic: Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

Date of Origin: December 2003

Section: Surgery

Last Reviewed Date: December 2013

Policy No: 130

Effective Date: March 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION^[1]

Radiofrequency tissue remodeling with specially designed devices has been explored as a minimally invasive treatment option for urinary stress incontinence. It involves using nonablative levels of radiofrequency energy to shrink and stabilize the endopelvic fascia.

Urinary stress incontinence, defined as the involuntary loss of urine from the urethra due to an increase in intra-abdominal pressure, is a common condition, affecting 6.5 million women in the U.S. Conservative therapy usually includes pelvic floor muscle exercises. Biofeedback, pelvic electrical stimulation, or periurethral bulking agents such as collagen might also be tried. Various surgical options are considered when conservative therapy fails, including most prominently various different types of bladder suspension procedures, which intends to reduce bladder neck and urethra hypermobility by tightening the endopelvic fascia. For example, for colposuspension (i.e., the Burch procedure), sutures are placed in the endopelvic fascia and fixed to Cooper's ligament or retropubic periosteum, which in turn creates a floor or hammock underneath the bladder neck and urethra.

Recently, the use of nonablative levels of radiofrequency energy has been investigated as a technique to shrink and stabilize the endopelvic fascia, thus improving the support for the urethra and bladder neck. Two radiofrequency devices have been specifically designed for the treatment of urinary stress incontinence, which may be performed as outpatient procedures under general anesthesia.

SURx® Transvaginal System: This involves making an incision through the vagina lateral to the urethra, exposing the endopelvic fascia. Radiofrequency energy is then applied over the endopelvic fascia in a slow sweeping manner, resulting in blanching and shrinkage of the tissue.

The Lyrette™ Transurethral SUI System: Previously known as Renessa® Procedure, this procedure involves passing a specially designed 4-needle radiofrequency probe through the urethral opening into the urethra and then into the bladder. Once the probe is in position, a small balloon is inflated to keep it stationary during the procedure. Radiofrequency energy is then delivered for 60 seconds to the 4 needles, which are deployed from the probe into the tissue of the bladder neck and upper urethra. Tissue temperatures of 65 to 75 degrees Celsius are generated; at this temperature, focal microscopic denaturation of collagen occurs. The procedure is repeated 9 times so that collagen is denatured at 36 tissue sites.

Regulatory Status

In 2002, the SURx Transvaginal System received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) process. According to the FDA, the device “is indicated for shrinkage and stabilization of female pelvic tissue for treatment of Type II stress urinary incontinence due to hypermobility in women not eligible for major corrective surgery.” As of 2006, the SURx is no longer marketed in the U.S.

In 2005, Novasys Medical received clearance to market the Renessa® transurethral radiofrequency system through the FDA 510(k) process. The device is indicated for the transurethral treatment of stress urinary incontinence due to hypermobility. In 2013, Verathon acquired Renessa® by Novasys Medical®, and rebranded it as the Lyrette™.

MEDICAL POLICY CRITERIA

The following treatments of urinary stress incontinence are considered **investigational**:

1. Transvaginal radiofrequency bladder neck suspension
2. Transurethral radiofrequency tissue remodeling

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of urinary stress incontinence include the resolution of urinary leaks or a decrease in the frequency and volume of leaks. In order to understand the impact of transvaginal or transurethral radiofrequency tissue remodeling for treatment of incontinence, well-designed randomized controlled trials (RCTs) that compare this therapy to standard medical treatment, such as pelvic floor muscle exercises, are needed.

Transvaginal Radiofrequency Tissue Remodeling

Randomized Controlled Trials (RCTs)

A literature review failed to identify RCTs of transvaginal radiofrequency tissue remodeling.

Nonrandomized Studies

- Dmochowski and colleagues reported on a multi-institutional prospective case series of 120 consecutive women with urinary stress incontinence who underwent transvaginal radiofrequency bladder neck suspension.^[2] Enrolled patients had failed at least a 3-month trial of conservative therapy, including most commonly pelvic floor muscle exercises or pelvic floor stimulation. Follow-up examinations at 1, 3, 6, and 12 months consisted of a history, physical examination, and urodynamic studies. In addition, each patient completed a voiding diary and quality of life questionnaire. A cure was defined as a negative Valsalva maneuver; improvement was defined as decreased daily episodes of pad use. A total of 73% of patients were considered cured or improved at 12 months. More than 68% of patients reported satisfaction with the treatment. The authors conclude that the results were encouraging and that a 73% 12-month success rate suggested that this procedure has applicability for women with refractory incontinence who do not wish to undergo a more complicated surgical procedure.
- Ross and colleagues conducted a multicenter, prospective single-arm study that included 94 women with stress incontinence.^[3] At 1 year, the objective cure rate was 79%, based on a negative leak point pressure. Assessment of quality of life was also significantly improved. Larger controlled studies with longer follow-up were needed to further evaluate this procedure. In a review of laparoscopic bladder neck suspension, McDougall et al. noted that initial promising results at 12 months declined to a 30% success rate at 45 months.^[4] These authors suggest that any new surgical technique for the treatment of stress incontinence should have more than 2 years of follow-up.
- Buchsbaum et al. retrospectively reviewed the charts of 18 patients (11 with genuine stress urinary incontinence and 7 with mixed incontinence) who underwent transvaginal radiofrequency bladder neck suspension procedure.^[5] At an unspecified time greater than 3 months following treatment, 6 of the 18 patients reported no urine loss and were satisfied with the outcome, 2 patients were lost to follow-up, and 10 reported continuing symptoms of incontinence. The relation between diagnosis (i.e., genuine stress-induced or mixed incontinence) and outcome was not presented.

Transurethral Radiofrequency Tissue Remodeling

Randomized Controlled Trials

- In a company-sponsored randomized controlled trial of the transurethral radiofrequency procedure, Appell et al. did not find a difference in quality of life measures between the radiofrequency (110 subjects) and the sham control group (63 subjects) at 12 months.^[6] However, a subgroup analysis showed benefit in patients with moderate to severe stress urinary incontinence. This study is limited by the post hoc subgroup analysis, loss to follow-up of nearly 20%, and lack of investigator blinding. Longer term follow-up, identification of the patient population that might benefit from this procedure, and independent replication was needed. In the 3-year follow-up of this trial, only 26 (24%) of the original 110 treated patients were available for evaluation.^[7] Control subjects were not contacted. Of the 26, five had obtained other treatments and were not included in the analysis (not counted as failures). An additional 3 patients were not included since they had no episodes of incontinence at baseline. The authors report that of the 18 (16%) included patients, 50% had reductions in incontinence episodes of greater than 50% (average of 3.5 daily incontinence episodes at baseline to 1.8 at 3 years after treatment). It should be noted that inclusion of all of the 26 subjects who had been contacted would result in a positive response rate of 38%. Interpretation of this study is limited due to the absence of the control group and inadequate numbers of treated patients in follow-up, along with excluding some patients from data analysis.

Nonrandomized Studies

- Elser et al. reported interim (12-month) findings from the industry-sponsored, prospective, single-arm study of transurethral radiofrequency remodeling.^[8] 136 women with stress urinary incontinence caused by bladder outlet hypermobility who had failed nonsurgical treatment and were not candidates for

surgical therapy were enrolled in the study. Exclusion criteria included urge incontinence or stress urinary incontinence caused by intrinsic sphincter deficiency. By 12 months, 25 patients withdrew consent, 19 were lost to follow-up, and 17 reported lack of response, resulting in 75 patients (55%) who were evaluated at the 12-month follow-up. Efficacy, based on the percentage of patients with a 50% or greater reduction from baseline in daily incontinence episodes, was reported in 68 (50%) patients. Of the 75 evaluated at 12 months, 69% (38% of 136) reported at least a 50% reduction in leaked urine (median of 15 g) from baseline, and 45% (25% of 136) were dry. One patient reported increased leaking. No serious adverse events were reported. The most common adverse events at day 3 included dysuria (5%), urinary retention (4%), post-procedure pain (3%), and urinary tract infection (3%). This study is limited by the large losses to follow-up and the evidence is insufficient to alter the conclusions reached above.

At eighteen months, the data were available for 60 of the 136 women (44%).^[9] Thirty-one of the 60 evaluable women (61.7%) reported a reduction of at least 50% from baseline in leaks due to activity. In an intention-to-treat analysis of data from all 136 participants (last observation carried forward), 46.7% reported at least a 50% reduction in leaks from baseline. The 60 evaluable patients reported a median improvement of 9.5 stress leaks per week. In the report based on the 36-month follow-up data, significant and durable quality of life improvements were reported; however, of the 136 women included in the ITT analysis at 36-months, only 76 (55.9%) actually responded to the quality of life questionnaires (20 proceeded to surgery, 37 lost to follow-up, 3 discontinued participation due to study site closure).^[10] Both 18- and 36-month follow-up studies had significant attrition rates. In addition, single-arm studies lack an adequate comparison/control group. Therefore the findings from these studies must be interpreted with caution.

Clinical Practice Guidelines

The American College of Obstetricians and Gynecologist (ACOG) guideline on urinary incontinence in women is silent on transvaginal and transurethral radiofrequency remodeling.^[11]

Summary

Evidence from well-conducted, randomized, controlled trials on transvaginal and transurethral radiofrequency tissue remodeling for urinary stress incontinence remains limited in quantity and quality. It is not known whether either of these treatments leads to long-term improvements in net health outcomes compared with a sham procedure or another treatment for stress urinary incontinence; therefore both transvaginal and transurethral radiofrequency tissue remodeling for urinary stress incontinence are considered investigational.

REFERENCES

1. BlueCross BlueShield Association Medical Policy Reference Manual "Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence " Policy No. 2.01.60
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11. American College of Obstetricians and Gynecologists (ACOG). Urinary incontinence in women. ACOG Practice Bulletin, No. 63. Available online at the National Guideline Clearinghouse website. Reaffirmed 2009. [cited 12/03/2013]; Available from: <http://www.guideline.gov/content.aspx?id=10931&search=urinary+incontinence+in+women.+acog>

CROSS REFERENCES

[Pelvic Floor Stimulation as a Treatment of Urinary Incontinence](#), Allied Health, No. 4

[Biofeedback as a Treatment of Urinary Incontinence in Adults](#), Allied Health, No. 32

[Transanal Radiofrequency Treatment of Fecal Incontinence](#), Surgery, No. 129

[Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction](#), Surgery, No. 134

CODES	NUMBER	DESCRIPTION
CPT	53860	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
	53899	Unlisted procedure, urinary system
HCPCS	None	