Conclusions: RF bladder neck suspension appears to have acceptable short and intermediate term success rates and a low complication rate. However, further study is required with more patients and longer follow-up time.

[1] Report on the surgical management of female stress urinary incontinence, 1997, American Urological Association.
This study sponsored by SURx, Inc.

5B

Author(s):
M. Avon, R. Kaplan
Institution, city, country:
San Ramon Regional Medical Center, San Ramon CA

Title (type in CAPITAL LETTERS, leave one blank line before the text): RADIO FREQUENCY BLADDER NECK SUSPENSION FOR STRESS URINARY INCONTINENCE: INITIAL SAFETY AND SHORT TERM EFFICACY OF A TRANSVAGINAL APPROACH

Aims of Study: To evaluate the safety and effectiveness of a new method to treat female stress urinary incontinence (SUI). This easily performed procedure shrinks the endopelvic fascia EPF and lifts the urethrovesical junction to a more anatomically correct position thereby restoring continence. This treatment does not use implantable materials such as mesh or sutures.

Methods: It is well documented in other medical specialities such as orthopaedics, vascular surgery, and neurology that heating collagenous tissue from 60°C to 100°C causes the collagen to denature and the tissue to shrink. It is postulated that shrinking the previously stretched EPF lifts the area around the urethra and bladder neck in a way similar to conventional sling and suspension procedures. A prospective IDE study was conducted on 26 women with genuine SUI confirmed by urodynamics. All patients had positive valsalva leak point pressures. Symptom duration was 10.4 ± 8.9 years. Over 80% of the subjects used one or more pads per day; all of the subjects averaged one or more episodes per day. Using transvaginal paraurethral or "U" shaped incisions, and reflection of the vaginal epithelial surface, the EPF was directly visualized. Precisely controlled radio frequency energy was applied with an instrument (SURx, Inc., Pleasanton, CA) to the EPF causing it to heat and shrink. The incisions were closed using conventional techniques. Initial safety, tolerability and short-term efficacy data were collected using standardized methods.

Results: All patients were treated on an outpatient basis and discharged 2-4 hours following the procedure. RF treatment time did not cumulatively exceed five minutes. Operative time ranged from 30-45 minutes. There were no operative complications. One patient had a urinary tract infection that resolved with antibiotic treatment. All patients returned to normal ambulatory activities (excluding strenuous exercise) on the first post-operative day. Success was defined as negative valsalva, reduction in daily SUI episodes, reduction in pad use, improved quality of life score, and patient satisfaction.

Success Rates (%)	3 month	6 month	12 month
	14/18	9/10	7/8
	(77.8%)	(90.0%)	(87.5%)

Conclusions: Lifting the urethrovesical junction and urethra by shrinking the endopelvic fascia without the use of implantable sutures or mesh appears to be safe and well tolerated by patients. The early efficacy data are promising. Data collected on a larger number of patients and for a longer follow-up period is ongoing.

This study was sponsored by SURx, Inc.

6

A. Liapis, P. Bakas, G. Creatsas.

2ND Department of Obstetrics and Gynecology, Aretaieio Hospital, Urogynecology Unit, University of Athens, Greece.

COMPARISON OF OPEN RETROPUBIC COLPOSUSPENSION WITH TENSION-FREE VAGINAL TAPE FOR THE TREATMENT OF GENUINE STRESS INCONTINENCE IN WOMEN.

Aim of the study: The Tension-free Vaginal Tape (TVT), has been used extensively over the last 5 years, as a minimal invasive technique for surgical treatment of stress urinary incontinence(1). The Burch colposuspension (BC) is an invasive technique that has been used over the last two decades with good results as well. Objective of the study was to compare the efficacy of TVT and Burch colposuspension in the treatment of genuine stress incontinence, the complications and the urodynamic findings.

Methods. In this prospective study, participated 35 patients who underwent Burch colposuspension and 36 patients that underwent TVT procedure for the treatment of genuine stress incontinence. Both groups of patients were comparable in relation to their age, number of deliveries and Body mass index(BMI). Mean age for TVT was 46.5 years (range 32-62) and mean age for BC was 48.4 years (range 35-64).Mean parity for TVT was 1.9 +0.8 and for BC was 2.1 +1.1, while mean BMI for TVT was 26.6 + 2.1 and mean BMI for BC was 27.2+2.2. All patients had a full history taken and a complete gynecological examination performed at initial visit and Frequency-Volume charts were completed for 3-4 days. Preoperative urodynamic investigations included filling and voiding cystometry, urethral profilometry and uroflow. Genuine stress incontinence diagnosis was based on the findings of urodynamic investigations and in all patients the severity of GSI was stage II (2). Patients with prolapse more than first degree, previous surgical treatment of stress urinary incontinence, maximal urethral closure pressure less than 30cmH2O and detrusor instability were excluded from the study.

Results. All the patients were operated under epidural anesthesia. The mean follow-up time was 22 months for TVT and 24 months for Burch colposuspension. The operative time for TVT was significantly shorter compared to BC (mean operative time for TVT 20 minutes, and for BC: 58mins). The severity and duration of postoperative pain for TVT was significantly less compared to BC (Mean duration of pain for TVT: 2.1+1.2 and for BC: 7.4+2.3).Therefor, the need for postoperative analgesia was much less for TVT than for BC. The hospitalisation time for TVT was 2.1+1.1 and was significantly shorter compared to BC(5.7+2.2). The necessary time for return to normal activity was 10 days for TVT and 21 days for BC. The cure rate after 22 months of follow-up for TVT and 24 months for BC were as following: TVT :84% and BC:86%, while the improvement was 7% for TVT and 10% for BC. The incidence of postoperative de novo detrusor instability at 6 months follow-up was 14% for Burch colposuspension and 11% for TVT.

Conclusion: The results of the present study suggest that both TVT and Burch colposuspension are almost equally effective in the management of genuine stress incontinence at two years follow-up. TVT procedure requires much less operative time, has much shorter hospitalization time, with significantly less postoperative pain and faster return to normal daily activities than Burch colposuspension(3). The present study is the first comparing TVT with Burch colposuspension in the management of genuine stress incontinence. It seems that TVT could replace Burch colposuspension in the management of genuine stress incontinence in female patients without significant genital prolapse, but more studies including a larger number of patients with a follow-up period at 5 and 10 years postoperatively are required for safer conclusions to be made.

References:

1. Br J Obstet Gynecol 1999; 106:345-350.
2. Contr Gynecol Obstet 1983; 10: 51-69.
3. The J Reprod Med 1998; 43: 429-433.

7A

Author(s): Ward, KL;[1] Hilton, P;[1] Browning, J.[2] (On behalf of the UK & Ireland TVT trial group)

Institution, city, country: [1]University of Newcastle upon Tyne and the Royal Victoria Infirmary, Newcastle upon Tyne, England; [2] Ethicon, Edinburgh, Scotland.

Title (type in CAPITAL LETTERS, leave one blank line before the text):

A RANDOMISED TRIAL OF COLPOSUSPENSION AND TENSION-FREE VAGINAL TAPE (TVT) FOR PRIMARY GENUINE STRESS INCONTINENCE