384 Abstracts

 $P2X_4$ (8/118); $P2X_5$ (3/117); and $P2X_6$ (0/121). The SU and baby bladders exhibited very similar labelling patterns except that the density of the small P2X clusters unrelated to the SV2-labelled varicosities was much higher in the vicinity of the varicosities in SU as if they were being dissociated. The large numbers of small clusters of P2X receptors could be acting as autoreceptors in SU.

CONCLUSIONS: These results are the first indication of a selective down-regulation of P2X₃ and P2X₅ in IDI and an almost complete absence of purinergic nerve innervation in SU.

- Development of the distribution of single P2X homomeric and heteromeric receptor clusters on smooth muscle cells in relation to nerve varicosities in the rat urinary bladder J Neurocytol, 1999, 28, 3-15.
- Spontaneous contractility, atropine resistance and response to the tachykinin antagonist SR48968 in idiopathic detrusor instability. Neurourol & Urodyn, 1999, 18, 373-374

5A

Author(s): R. Dmochowski

Institution, city, countr

Harris Hospital, Dallas TX, USA

Title (type in CAPITAL LETTERS, leave one blank line before the text): A MINIMALLY INVASIVE TECHNIQUE TO SHRINK THE ENDOPELVIC FASCIA FOR THE TREATMENT OF SUI: INITIAL SAFETY AND EFFICACY PROFILE OF TWO SURGICAL APPROACHES

Aims of Study: The goal of this study is to evaluate the initial operative safety and short and intermediate term efficacy of radio frequency (RF) bladder neck suspension for the treatment of female stress urinary incontinence (SUI). The approach reported here evaluated a minimally invasive technique for providing support to the urethrovesical junction utilizing radio frequency induced tissue changes without the use of implantable materials, sutures, staples, or mesh. A similar technique is used by orthopedic surgeons in shoulder and spine surgery to support and lift other anatomic structures.

Methods: Two parallel, independent, prospective IDE approved, multi-center comparative studies of RF treatment were conducted on women with genuine SUI confirmed by objective urodynamics. Two access methods were used: the first uses a standard extraperitoneal laparoscopic (LP) approach and the second a bilateral transvaginal (TV) approach. In both procedures, the endopelvic fascia (EPF) was visualized and an instrument (SURx, Inc., Pleasanton, CA) was used to apply the low power RF energy directly to the EPF. The EPF was observed to shrink as a result of the heat generated by the RF. Success and complication rates were noted and compared to published sources to determine the safety profile of this new procedure.

Results: Complication rates were noted and compared to the American Urological Association 1997¹ report on surgical options for incontinence. Success rates were determined by standard urodynamics, pad usage, voiding diaries and patient satisfaction scores.

Complication/Risk		Retropubic Suspension ¹	Sling	TV (N=26)	LP (N=105)
Intra-operative (bladder, urethra perforation)		2%	3%	0%	2% ***
Transfusion		2	4	0	0
Retention (longer than 4 wks)		5	8	0	0
Comp. Requiring Surgery		2	3	0	0
Urgency		11	7	0	2
Wound Comp.		7	9	0	1
UT Infection		13	12	3	1
Total		42%	46%	3%	6%
Success Rate (%)	3 month	6 mont	h	12 month	
Transvaginal (TV)	78% (N =18)	100% (N	V = 10)	88% (N = 8)
Laparoscopic (LP)	80% (N =75)	80% (1	N = 61)	64% (N = 14	4) ***

^{***} No patients who have reached their 3 month follow-up interval have changed their continence status in subsequent follow-up periods. The lower 12-month success rate is due to initial physician learning curve and technique refinement. The two LP intraoperative perforations were due to difficult access and unrelated to the RF instrument.

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.

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M. Avon, R. Kaplan

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.

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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.

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