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AUTOLOGOUS FASCIAL SLING VS POLYPROPYLENE TAPE AT SHORT-TERM FOLLOWUP: A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT

Purpose: The incidence of urinary incontinence in women of childbearing age is about 30%. Around half have stress incontinence. Many treatment modalities have been elucidated to treat stress incontinence, and among the most popular are rectus fascia sling and tension-free vaginal tape (TVT). The introduction of TVT to the urological armamentarium put a multiplicity of synthetic materials into use in the correction of stress urinary incontinence. A comparison of the impact of these 2 commonly used techniques is needed.

Materials and Methods: A total of 53 female patients older than 21 years (mean age 45.09) were randomized, using closed envelopes, to undergo TVT or rectus fascia sling. Randomization was performed after patients received spinal anesthesia. One surgeon performed the 2 types of treatment. Associated grade 2 cystocele was simultaneously corrected. Patients with bladder or urethral pathology, as well as those with cystocele greater than grade 2, were excluded from analysis.

Results: All 53 patients completed 6 months of followup and all had stress urinary incontinence. There were 15 patients who underwent sling surgery and 17 who underwent TVT who had concomitant grade 1 or 2 cystocele. No statistically significant difference was found between the 2 groups at baseline. Cure was accomplished in 23 of 25 (92%) with sling and in 26 of 28 (92.9%) with TVT at first followup visit (1 week). There were 7 patients who needed at least 1 extra week of catheterization in the sling group and 3 in the TVT group. No significant difference was detected in terms of post-void residual urine, symptom score, and filling and voiding parameters. At 6 months 1 patient had de novo detrusor overactivity and 7 had wound pain. Compared to those with TVT, 2 cases of sling were considered treatment failures, none had de novo overactivity and 2 had wound pain. None of the patients had symptoms suggestive of urethral erosion.

Conclusions: Rectus fascia sling and TVT seem to be equally effective regarding primary outcome measure (ie cure of stress incontinence). Symptom score related to incontinence surgery as well as simultaneous correction of cystocele are comparable in the 2 groups. Fascial sling is a longer treatment process yet it is more economical. Longer followup is vital before rigorous conclusions can be drawn.

KEY WORDS: urinary incontinence, stress; fascia, surgical procedures, prospective studies, randomized controlled trials

In the last decade autologous fascial slings became the gold standard in the treatment of genuine stress incontinence. In 1996 a synthetic material sling was introduced to the urogynecological literature known as tension-free vaginal tape (TVT), and it has gained ground rapidly. Nevertheless, to our knowledge no prospective randomized evaluation of the safety and efficacy of these 2 methods has been reported to date. Our ongoing study reports the short-term results of TVT vs rectus fascia sling.

PATIENTS AND METHODS

Women seen in our outpatient department with a principal complaint of stress urinary incontinence (SUI) were potential candidates for this study. Inclusion and exclusion criteria are summarized in the appendix. All patients underwent physical examination including stress test. The degree of pelvic organ prolapse was assessed and grading according to Baden et al was adopted.[1] A brief neurourological examination was conducted including sensation at the perineum, knee and ankle jerks, and tone of anal sphincter muscle.

Basal laboratory investigations (serum creatinine, liver functions, complete blood count, chemical and microscopic urinalysis, urine culture), renal ultrasound, and plain x-ray of the kidneys, ureters and bladder were all routinely performed. An ascending cystogram was performed with the patient standing, resting and straining. Images were taken with the patient in a dead lateral position, at rest and on straining, with demonstration of urinary leakage. The degree of urethral hypermobility was documented. Cystoscopy was performed at the time of surgery.

Urodynamic testing included filling cystometry. Medium fill water cystometry (50 ml per minute) using a dual lumen 8Fr catheter was performed. The technique, definitions and units of urodynamic measurement conform to the standards proposed by the International Continence Society.[2] Compliance was calculated at maximum cystometric capacity/detrusor pressure at maximum capacity. At the end of the filling phase the patient was allowed to void in the sitting position in privacy. Voiding cystometry was interpreted by Schafer's pressure flow nomo-

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***Editor's Note*: This article is the fifth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 1160 and 1161.**

gram, with measurement of detrusor pressure at maximum flow (PdetQmax). Bladder outlet obstruction was considered when pressure flow was grade 3 or more (as used in previous reports[3]) or PdetQmax was more than 20 cm H_2O with maximum flow (Qmax) less than 12 ml per second.[4]

Stress incontinence was defined as involuntary leakage on effort or exertion.[2] Surgery was performed with the patient under spinal anesthesia, 2 to 3 ml of heavy (hyperbaric, 2.5%) bupivacaine hydrochloride were injected in the subarachnoid space. After patients were anesthetized they were randomized using closed envelopes delivered to the surgeon by a third party (operating room secretary) who kept the envelopes in a safe place. An envelope was released anonymously for each patient after spinal anesthesia was administered.

Operative technique. For fascial sling a technique similar to that previously described was used with some modifications.[5] Free ends of the flap are fixed by a 1-zero polyglactin suture (double string), and the sling is fixed to the underlying periurethral fascia using 4-zero polyglactin sutures at the 6 and 12 o'clock positions. Urethral catheter was left indwelling for 48 hours unless anterior colporrhaphy was performed, in which case the catheter was left for 5 days. For TVT a technique similar to that proposed by Ulmsten et al was adopted.[6] In terms of cystocele repair only grade 2 cystocele was repaired with the classic colporrhaphy technique. Anterior colporrhaphy was performed using 3 sutures of 2-zero polydioxanone, approximating the pubocervical fascia in the midline. Foley catheter was left indwelling for 5 days after cystocele repair.

The primary outcome measure was cure of stress incontinence. Cure was defined as complete dryness with no usage of pads, anti-incontinence surgery response score of 0 and negative stress test, while failure was defined as visible leakage on stress test and a total score of 6. Cure was reported at first visit 1 week after surgery, at which point the wound condition was also checked, a stress test was performed, and post-void residual urine (PVR) and symptom score were recorded (a physician administered score). Per vaginum was performed at this visit as well as at 6 months to assess the integrity of the vaginal wound. At 6 and 12 months, as well as annually thereafter, a stress test was performed with the patient in the lithotomy position with the bladder containing at least 200 ml (using Bladder Scan®) in which the patient asked to cough maximally. Filling and voiding cystometry were repeated, and Valsalva leak point pressure was tested (ie patient was asked to strain maximally at 200 ml bladder volume or 300 ml if leakage was detected preoperatively only at this volume).

As suggested by Groutz et al,[7] the anti-incontinence surgery response score was used after due translation and modifications. Forward and backward translation was conducted by 3 different parties, and the most accepted Arabic version was used. Pad weighing was replaced by the number of the same type of pads that were used preoperatively. A patient using no pads at all was given a 0, a patient using a lower number of the same type pads was given a 1 and a patient using the same number of the same type of pads was given a 2. This was mandatory in our location since patients do not regularly keep balances at home capable of weighing pads.

Statistical methods. Comparison of the 2 groups regarding success was performed using the chi-square test. Comparison of baseline patient characteristics as well as baseline urodynamic variables was made by the 2-tail, t test and chi-square test. Survival analysis throughout followup was performed and the Kaplan-Meier survival curve was depicted.

RESULTS

In terms of baseline parameters, thus far 53 patients completed 6 months of followup. Mean patient age was 45.12 years (range 30 to 60). All had stress urinary incontinence as a primary complaint and 19 (35.8%) had previous surgery, 9 of whom had pelvic (7 cesarean section, 1 tubal ligation and 1 herniorrhaphy) while the other 10 had vaginal surgery (6 anterior colporrhaphy, 2 vaginal hysterectomy and 2 previous incontinence procedures). A total of 15 patients who had sling and 17 who had TVT had a concomitant grade 1 or 2 cystocele. Baseline clinical variables are illustrated in tables 1 and 2 with the differences between the 2 groups.

Table 3 demonstrates baseline urodynamic parameters of both groups. Notably no statistically significant difference was found between the 2 types. This was true for parameters including bladder capacity, compliance, maximum detrusor pressure, Qmax and PVR.

Cure was accomplished in 23 of 25 (92%) and in 26 of 28 (92.9%) having sling at first followup visit (1 week). Wounds were checked for any adverse event. One patient with TVT had a stitch sinus and another complained of vaginal bleeding that was proved to be menstrual in origin. PVR was also measured at 1 week. If urine volume was greater than 200 ml, a Foley catheter was refixed for an extra week. There were 7 patients who needed at least 1 extra week of catheterization in the sling group and 3 in the TVT group. Table 4 demonstrates the differences between the 2 groups in terms of operative and immediate postoperative course and complications.

TABLE 1. *Baseline clinical parameters*

	Mean ± SD		p Value*
	Sling (25 pts)	TVT (28 pts)	
Age	45.32 ± 6.3	44.9 ± 9	0.094
Body mass index	31.6 ± 4.2	29.7 ± 4.2	0.88
Hemoglobin (gm/dl)	12.66 ± 1.1	12.5 ± 1.6	0.09
Gravidity	5.6 ± 2.9	5.1 ± 2.4	0.43
Parity	5.2 ± 2.6	4.1 ± 1.8	0.07

* Test for independent samples.

TABLE 2. *Differences between the 2 groups by SUI type and grade, and cystocele grade*

	No. Sling (%)	No. TVT (%)	p Value*
Type:			
1	4 (16)	9 (32.1)	
2	21 (84)	18 (64.3)	
3	0 (0)	1 (1.9)	0.22
Grade:			
1	9 (36)	10 (35.7)	
2	10 (40)	14 (50)	
3	6 (24)	4 (14.3)	0.62
Cystocele:			
G1	2 (15.4)	6 (35)	
G2	13 (84.6)	11 (64.7)	0.06
Success:			
Cure	23 (92)	26 (92.9)	
Failure	2 (8)	2 (7.1)	0.9

* Chi-square test.

TABLE 3. *Baseline urodynamic parameters*

	Sling	TVT	p Value*
No. pts	25	28	
Mean ml PVR ± SD	28.7 ± 16	26.5 ± 13	0.83
Mean ml cystometric capacity ± SD	392 ± 104	404 ± 79	0.8
Mean ml/cm H_2O compliance ± SD	53.3 ± 30	67 ± 40	0.12
No. detrusor overactivity	2	4	–
Mean cm H_2O abdominal leak point pressure ± SD	84.3 ± 26	84.2 ± 28	0.99
Mean ml/sec Qmax ± SD	17.2 ± 9	16.5 ± 8	0.75
Mean cm H_2O PdetQmax ± SD	22.5 ± 12	25.4 ± 15	0.99

* t Test for independent variables.