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A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence

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KEY WORDS
Prolapse
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Objective: The purpose of this study was to compare 2 anti-incontinence procedures in women who had severe genital prolapse and potential stress incontinence.

Study design: In addition to vaginal reconstructive surgery, 50 patients with stage II or higher anterior defect and a positive stress test result with prolapse reduction received either tension-free vaginal tape or plication of the endopelvic fascia. Preoperative evaluation included history, physical examination, stress test, and urodynamic assessment. Data were analyzed with the Student *t* test, the Fisher's exact test, and the Wilcoxon signed-rank test.

Results: The median follow-up time was similar for both groups, 26 and 24 months. Subjective (96% vs 64%; $P = .01$) and objective (92% vs 56%; $P < .01$) continence rates were higher after the tension-free vaginal tape procedure. Time for the resumption of spontaneous voiding, rates of urinary retention, or de novo urge incontinence were similar in the 2 groups.

Conclusion: Tension-free vaginal tape can be recommended for patients with prolapse and occult stress incontinence.

Women with severe genital prolapse may also have clinical stress urinary incontinence (SUI), but more often they are continent subjectively because of urethral kinking or compression.[1,2] Reduction of the prolapse during preoperative urodynamic evaluation may reveal occult SUI in 36% to 80% of women with severe genitourinary prolapse.[3-5] In these circumstances on the basis of a positive preoperative barrier test, it is suggested that a prophylactic anti-incontinence procedure should be performed during prolapse repair to prevent postoperative SUI.[5-8] However, there is still no consensus on the optimal prophylactic procedure with respect to postoperative continence rates and morbidity.

The aim of this randomized clinical trial was to compare outcomes of 2 anti-incontinence procedures (tension-free vaginal tape [TVT] and bladder neck endopelvic fascia plication, in a group of women with occult SUI, who were undergoing reconstructive surgery for severe pelvic organ prolapse.

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Material and methods

Since February 2000, all women who are admitted to the urogynecology unit of our department for the surgical correction of symptomatic pelvic organ prolapse have been considered for enrolment. Patient evaluation included history, urine culture, physical examination, stress test, cotton swab test, and urodynamic assessment. At physical examination, pelvic floor defects were determined with the use of the standardized system of the International Continence Society.[9] Measurements were made at different vaginal sites (anterior and posterior vagina and cervix) with the patient recumbent and straining down. The standardized system defines each vaginal site as normal (stage 0), protruding within 1 cm above the level of the hymen (stage I), between ≤ 1 cm proximal or distal to the plane of the hymen (stage II), protruding >1 cm below the plane of the hymen but no further than 2 cm less than the total vaginal length (stage III), or complete eversion of the total length of the affected site (stage IV). The urethral axis and urethrovesical junction mobility were assessed by a cotton swab test. Urethral hypermobility was defined as a maximum straining angle of more than 30 degrees.

All patients underwent a stress test in the supine position at bladder volumes of 150 and 300 mL, before and after a posterior blade of a Sims' speculum had been placed in the anterior vaginal fornix, as described by Bump et al[2]; care was taken to avoid overstretching these structures. The test was considered positive if leakage occurred concurrent with a cough or Valsalva maneuver. Patients who only had urinary leakage when the prolapse had been repositioned (occult SUI) were considered eligible for the study. They underwent a multichannel urodynamic evaluation that included uroflowmetry, provocative twin-channel subtracted cystometry at a filling rate of 100 mL/min, and urethral profilometry. The urethral pressure profile was taken with the patient in the supine position, at a bladder volume of 300 mL, and with the prolapse reduced by the Sims' speculum, with the use of a dual-sensor microtip catheter.

Data were recorded and analyzed with a Duet MultiP (Medtronic, Copenhagen, Denmark) diagnostic system. Urodynamic techniques and measurements, terms, and diagnostic criteria conform to the recommendations of the International Continence Society.[10]

Women with any of the following characteristics were excluded from enrolment: age >75 years, obesity (body mass index, ≥ 30 kg/m^2), diabetes mellitus, previous pelvic and anti-incontinence surgery, symptoms of SUI, cotton swab test <30 degrees, and uninhibited detrusor contraction of any size during bladder filling.

Before enrolment, a power calculation was performed on the basis of a 50% to 60% success rate (the midpoint of this span was 55%) in the cure of SUI that was observed with anterior vaginal repair,[11-13] compared with a reported cure rate of 90% with TVT.[14,15] This calculation indicated that 50 patients (25 in each arm) would be needed to achieve 80% power for the detection of a 30% to 40% difference in cure rates between the 2 groups.

Patients underwent either a TVT procedure as described by Ulmsten et al[16] or plication of the urethrovesical junction endopelvic fascia as described by Hurt.[17] These 2 anti-incontinence procedures were assigned according to a computer-generated random list. Envelopes that contained the study assignment were prepared in advance and sequentially labeled by a third party who was not involved in the study. For the treatment of pelvic floor defects, all patients underwent vaginal hysterectomy, McCall culdoplasty, and cystocele repair; 20 women (80%) in the TVT group and 23 (92%) in the fascia plication group also underwent rectocele repair. Sacrospinous ligament fixation was not performed, even in patients with stage IV uterine prolapse. The TVT procedure was performed with the use of epidural anesthesia; the Prolene tape (Ethicon Inc, Sommerville, NJ) was placed under the mid portion of the urethra, through a separate small sagittal vaginal incision, before the prolapse was repaired. The tape was adjusted once the reconstructive surgery was completed, with the patient coughing with a bladder volume of approximately 300 mL.

Endopelvic fascia plication at the level of the urethrovesical junction was carried out with the use of 2-0 permanent-braided polyester sutures. Anterior repair was done in both groups in the standard manner using a series of interrupted 2-0 delayed absorbable sutures (polydiaxonone).

Approval for this study was granted by the local Human Institutional Investigation Committee. All patients were informed about the trial aim and procedures and gave their informed consent.

Data on intra- and postoperative morbidity, on length of hospital stay, and time to spontaneous voiding were collected. All patients had an indwelling Foley catheter for bladder drainage for the first 48 hours, with voiding trials starting the day the catheter was removed. Time to spontaneous voiding, with residuals <100 mL or less than one third of the voided volumes, was calculated from the day of surgery. Follow-up visits were scheduled every 6 months after surgery and included a detailed urogynecologic history, urine culture, pelvic examination, and a stress test. The primary outcome measure was occurrence of de novo SUI after operation. The secondary outcome measure was rate of prolapse recurrence for each vaginal site. The anatomic outcomes were assessed according to the standardized terminology for research in female pelvic floor disorders.[18] Urodynamic assessment was repeated 6 months after surgery.

The Statistical Package for Social Sciences (SPSS Inc, Chicago, Ill) was used for data analysis. Differences in urodynamic and demographic parameters between the

2 surgical groups were assessed by the Student t test. Continuous data were reported as mean ± standard deviation. Categoric relationships were analyzed by the χ^2 test with Yates' correction or Fisher's exact test, as appropriate. Because the length of hospital stay and time to resumption of spontaneous voiding were skewed, differences were analyzed with the nonparametric Wilcoxon signed-rank test. Probability values of $<.05$ were considered statistically significant.

Results

Between February 2000 and June 2001, 50 women with severe genital prolapse and occult SUI were enrolled. They had mean age of 65 ± 8 years (range, 50-75 years), body mass index of 25 ± 3 kg/m^2, and vaginal parity of 2.2 ± 0.8 pregnancies (range, 1-5 pregnancies). All of the women were postmenopausal, and none of the women were using hormone replacement therapy at the time of operation. There were no significant differences between the 2 surgical groups with respect to any of these parameters and no difference in the severity of genital prolapse. Intra- and early postoperative data are shown in Table I. Average time to resumption of spontaneous voiding was only slightly longer in the TVT group than in the fascia plication group. Four women (2 in each group) had postoperative urinary retention that resolved spontaneously after 8 of 9 and 7 of 10 days, respectively. In the TVT group, 1 patient had a uneventful bladder perforation, and 1 patient experienced a retropubic hematoma that resolved spontaneously. The median follow-up time for the TVT and fascia plication groups was 26 months (range, 15-31 months) and 24 months (range, 15-31 months), respectively.

One woman (4%) who received TVT and 9 women (36%) who had fascia plication reported postoperative symptoms of SUI ($P = .01$). All women reported SUI within the first year of follow-up. In one half of the patients, SUI was classified as mild according to the Ingelman-Sundberg symptoms score and required no treatment. The other 5 women, all in the fascia plication group, had moderate or severe SUI; 3 of the women underwent reoperation (1 periurethral silicone injection and 2 TVT procedures, between 8 and 14 months after the original operation). Two patients who refused repeat surgery were enrolled in a pelvic floor muscle training program. Objectively, 23 patients (92%) in the TVT group were stress continent during the postoperative cough provocation test compared with 14 patients (56%) in the fascia plication group ($P<.01$). De novo urge incontinence was reported by 3 women (12%) in the TVT group and only 1 woman in the other group (4%; $P = .66$). At follow-up visits, 4 women complained of voiding difficulties with recurrent urinary tract infections; 3 women had undergone the TVT procedure ($P = .61$). All patients underwent urodynamic evaluation 6 months after surgery. Pre- and postoperative urodynamic data by surgical group are shown in Table II.

Table I Intraoperative and early postoperative data

	TVT	Fascia plication	P value
Operation time (min)	131 ± 13	112 ± 21	<.001
Blood loss (mL)	188 ± 77	177 ± 102	.66
↓Hemoglobin (g/dL)*	1.8 ± 1.6	1 ± 1.2	.08
Surgical complications†	2 (8%)	0 (0%)	.49
Time to spontaneous voiding (d)	4.4 ± 1.7	3.8 ± 2	.26
Hospital stay (d)	6.4 ± 1.5	6.1 ± 1.5	.44
Delayed voiding	2 (8%)	2 (8%)	1.0

* Postsurgical hemoglobin concentrations were measured the day after operation.

† One case of bladder perforation and 1 case of retropubic hematoma.

After surgery, prolapse-related symptoms were reported by 12 patients (24%), 4 patients in the TVT group and 8 patients in the fascia plication group.

The median cotton swab angle dropped after surgery from 50 degrees (range, 30-90 degrees) to 15 degrees (range, 0-40 degrees) and from 60 degrees (range, 30-90 degrees) to 25 degrees (range, 10-50 degrees) in the TVT and in the fascia plication groups, respectively ($P<.001$ for both groups). Table III summarizes the stages of prolapse by anterior, posterior, and apical vaginal sites and by procedure before and after operation. The anatomic outcome was unsatisfactory in 15 women (30%), 7 women in the fascia plication group and 8 women in the TVT group. Eleven women had an isolated stage II prolapse of the anterior (9 cases) and posterior (2 cases) vaginal segment. Two women had a stage II prolapse in >1 vaginal segment, and only 2 patients had a clinically relevant anatomic recurrence with anterior and apical stage III prolapse. One of these women underwent a subsequent prolapse repair that included sacrospinous fixation and vaginal/paravaginal repair, whereas the other, who refused surgery, was treated conservatively with the insertion of a pessary.

Comment

Many women with mild to moderate pelvic organ prolapse also have SUI; however, women with high-grade anterior vaginal wall prolapse or severe uterovaginal prolapse may be continent paradoxically, as a result of urethral kinking or compression. Unfortunately, after anatomic repair of the high-grade prolapse, 22% to 80% of these patients will present de novo SUI, which can be distressing to the physician and patient.[1,19]

Table II Preoperative and postoperative urodynamic variables

Variable	TVT			Fascia Plication		
	Before surgery	After surgery	*P*	Before surgery	After surgery	*P*
First desire (min)	208 ± 82	175 ± 51	0.09	184 ± 98	183 ± 59	.96
Very strong desire (mL)	359 ± 58	347 ± 67	0.50	340 ± 61	343 ± 45	.84
Maximal urethral closure pressure (cm H_2O)	36 ± 14	39 ± 17	0.49	35 ± 15	34 ± 13	.80
Functional length (mm)	23 ± 4	22 ± 6	0.49	25 ± 4	25 ± 6	1
Average flow rate (mL/sec)	10 ± 5	11 ± 6	0.52	11 ± 6	14 ± 5	.06
Voiding time (sec)	42 ± 20	48 ± 178	0.25	42 ± 18	31 ± 12	.01

Values are given as mean ± SD.

Table III Stages of prolapse by vaginal sites and by procedure

Stage	Before surgery		After surgery	
	TVT	Fascia plication	TVT	Fascia plication
Anterior defect				
Stage IV	8	12	0	0
Stage III	13	11	0	2
Stage II	4	2	6	5
Stage 0-I	0	0	19	18
P	.42		.35	
Posterior defect				
Stage IV	0	1	0	0
Stage III	4	4	0	0
Stage II	11	7	3	3
Stage 0-I	10	13	22	22
P	.55		1.0	
Apical defect				
Stage IV	5	9	0	0
Stage III	10	8	0	2
Stage II	10	7	0	1
Stage 0-I	0	1	25	22
P	.43		.24	

Data refer to the last follow-up visit.

A preoperative evaluation that allows the reduction of the prolapse can help to identify patients who are at high risk of incontinence after prolapse surgery.[3,7] However, reduction maneuvers are not standardized, and the use of a pessary or a posterior blade of a Sim's speculum may not be reliable in the prediction of the need for anti-incontinence surgery in continent women who undergo repair of severe urogenital prolapse.[5,20] Klukte and Ramos[5] suggested that a negative barrier test result is reliable in the prediction of patients who will be stress continent after prolapse repair without a suspending urethropexy, but they did not measure the positive predictive value of the pessary test. In a prospective study, Gordon et al[21] reported that 50% of clinically continent women with severe pelvic organ prolapse, who had a preoperative positive barrier test, experienced de novo SUI after prolapse repair and prophylactic Kelly plication.

Few randomized trials have proved that an anti-incontinence procedure that is done at the time of prolapse repair in patients with occult incontinence is advantageous for the prevention of postoperative SUI. Colombo et al,[6] who compared the results of posterior pubourethral ligament plication and Pereyra needle suspension in 73 women with genital prolapse and potential SUI, showed that 50% and 76% of them were objectively continent after surgery ($P = .04$). However, Bump et al,[20] in a group of 29 women with occult SUI who underwent either needle suspension or endopelvic fascia plication at the time of prolapse repair, found that 14% of the former and 7% of the latter group had SUI 6 months after surgery. Gordon et al[8] and Chaikin et al,[7] in nonrandomized series of patients with occult SUI, reported that prophylactic TVT or pubovaginal sling resulted in 0% and 14% of postoperative clinical SUI.

Our data show that women who underwent plication of the endopelvic fascia at the urethrovesical junction are at greater risk of clinical SUI after the operation than women who received TVT as an anti-incontinence procedure (36% vs 4%; $P = .01$). Moreover, urinary leakage was demonstrated objectively in 44% and 8% of patients, respectively ($P < .01$).

One can debate the justification of any additional anti-incontinence surgery other than simple anterior vaginal repair in patients with occult SUI on account of the risk of increased perioperative morbidity, especially voiding dysfunction and urinary retention. A significant rate of such problems could outweigh the potential benefits of the prevention of the incontinence. Figures on the incidence and duration of urinary retention and incomplete emptying after prolapse surgery alone are scarce. In a survey among Dutch teaching hospitals, the duration of catheterization after prolapse repair ranged from 1 to 7 days (median, 5 days).[22] We found no difference either in the time to resumption of spontaneous voiding or in the incidence of urinary retention between the 2 groups, which suggests that the loose positioning of the Prolene tape under the mid urethra does not increase the need for prolonged catheterization.

Voiding dysfunction may also take the form of de novo urge incontinence. Data on its occurrence after prolapse repair alone are scarce, although there is plenty of information in the literature for anti-incontinence surgery with or without prolapse repair. In our study 3 patients (12%) in the TVT group reported postoperative symptoms of de novo urge incontinence compared with 4% of the women who underwent fascia plication ($P = .66$); however, urodynamically there were no signs of detrusor overactivity in these patients.

Another concern that is related to additional TVT in patients with occult incontinence is the possibility of a higher rate of intraoperative complications. Complications of this procedure are associated mainly with the risk of bladder perforation, but the recent literature provides increasing evidence that more serious complications may arise, such as hemorrhage in the space of Retzius, laceration of external iliac vessels, bowel perforation, or even obturator nerve injury.[23] In our series, we had only 1 uneventful bladder perforation and 1 retropubic hematoma that resolved spontaneously. On the basis of this evidence, we can suggest that all women with severe pelvic organ prolapse and occult stress urinary incontinence should undergo TVT at the time of prolapse repair. However, data from larger series are required to define the risks and benefits precisely that are associated with the addition of TVT to reconstructive pelvic surgery.

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