

Transobturator tape for female stress urinary incontinence: short term results after surgical procedure

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Abstract

Objective. The aim of the present prospective study was to assess the success and safety of TOT Trans-Obturator-Tape (TOT) operation using the manipulation of 45 degree reverse trendelenburg position in lithotomy for adjusting the tension of vaginal tape for each patient. **Methods.** Between June 2005 and April 2006, a total of 80 patients underwent TOT operation in which intraoperative 45 degree reverse terendelenburg position for adjusting tension rate of tape was used at Zekai Tahir Burak Women Health and Research Hospital, Turkey. The pre- and postoperative assessments included medical history, pelvic examination, BMI (kg/m²), International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF, Turkish version), urine analysis, stress test (cough provocation), one-hour pad test, URA measurement via transperineal ultrasonography and urodynamic studies were conducted in all of preoperative cases in order to support diagnosis and in postoperatively unsuccessful cases in order to have a much adequate understanding of the machinery of this condition. The majority of patients (64/80, 80%) underwent one or more concurrent surgical procedures at the time of their TOT procedure. A non-elastic polypropylene monofilament tape was placed under the mid-urethra. **Results.** The mean follow-up period was 6.4 months (2-13). Success rate was 92.5%. The total perioperative complication rate was 3.75% (3/80). URA has changed in the range of 0°-50° (mean 16.5°). The postoperative complication rate was moderate (7.59%). None of the patients developed urinary retention. **Conclusions.** TOT is an effective and safe procedure for the treatment of genuine stress incontinence and the intraoperative adjustment of tension of vaginal tape using reverse terndelenburg position maybe helpful for improving success of operation.

Keywords: trans-obturator-tape, transperineal ultrasound, urinary incontinence

Introduction

Stress urinary incontinence (SUI) is a common functional pathologic condition for women⁽¹⁾. It is commonly believed that SUI is caused by anatomic defects and can be cured by the restoration of anatomy. Enhorning⁽²⁾ hypothesized that pressure transmission occurs because the urethra lies within the abdomen, above some theoretic pelvic floor. Tension free vaginal tape procedure (TVT) is one of the techniques used in the treatment of female SUI⁽³⁾. Although TVT has high success rates, its operative safety is questionable. This surgical technique called TOT was introduced by Delorme⁽⁴⁾. The original aspect of this technique described by Delorme in 2001 was to place the tape between the two obturator foramen, creating a real hammock⁽⁵⁾ supporting the urethra instead of a urethral suspension as with TVT. Ninety percent of the patients were cured with no perioperative complications or postoperative voiding difficulties.

The aim of the present prospective study was to assess the success and safety of transobturator tape (TOT) operation using the manipulation of 45 degree reverse trendelenburg position in lithotomy for adjusting the tension of vaginal tape for each patient.

The subjective (questionnaire short form (ICQI-SF)) and objective (stress test, one-hour pad test, transperineal ultrasound, urodynamic studies) parameters were evaluated.

Methods

Between June 2005 and April 2006, a total of 80 patients underwent TOT operation at Zekai Tahir Burak Women Health and Research Hospital, Turkey. Ethical approval was obtained from the local committee. All subjects were given an explanation of the study and written informed consents were obtained.

The study was designed as a prospective open observational study. This procedure was performed on a multiple surgeon's basis with the same method and in urogynecology department of the clinic in which this study was conducted. All patients included had been indicated for surgical treatment of their SUI with or without a combined procedure for prolapse. Main criteria for selection were: visible SUI and urethral hypermobility at the physical examination, absence of a contractile bladder or obstruction. Exclusion criteria were pure urge incontinence and absence of preoperative urodynamic testing.

The diagnosis of genuine stress urinary incontinence was made by a positive stress test during coughing in the absence of simultaneous detrusor contraction.

The pre- and postoperative assessments included medical history, pelvic examination, BMI (kg/m²), urine analysis, stress test (cough provocation), one-hour pad test, transperineal ultrasonography and urodynamic studies were conducted in all of preoperative cases in order

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to support diagnosis and in postoperatively unsuccessful cases in order to have a much adequate understanding of the machinery of this condition.

Urodynamic investigation consisted of uroflowmetry, filling cystometry, valsalva leak point pressure (VLPP) and post voiding residual urine (PVR) determination.

All of the patients completed the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF, Turkish version) preoperatively and postoperatively(6). ICIQ-SF is a new self-administered questionnaire that qualifies the symptoms and quality of life in adult patients with symptoms of urine loss(7).

In addition, transperineal ultrasonography was carried out to examine the urinary bladder and bladder neck. The anatomic position and the dynamic mobility of bladder neck were evaluated with the patient in semi-supine position by transperineal ultrasonography with a bladder volume of 400 ml. A 3.5 MHz curved linear-array transducer (Aloka SSD 1200; Aloka Ltd., Tokyo, Japan) was positioned adjacent to the vaginal introitus, just underneath the external urethral orifice between the labia majora. A complete sagittal view of the bladder base, urethrovesical junction, urethra and whole pubic symphysis was scanned (Figure 1)(8).

The bladder neck position was measured using the rectangular coordinate system as described by Schaefer et al.(9) with the inferior border of the pubic bone as the reference point while the patient was resting. Patients were asked to perform straining slowly so that the bladder neck position at maximum straining could be measured. Patients were told to push as hard as necessary to produce urinary leakage. The displacement of bladder neck position between resting and maximum straining positions was calculated. By this way, the bladder neck mobility and its position before and after TOT were evaluated.

Success was defined as the absence of subjective complaints of urine leakage with the absence leakage on cough stress testing and the weight measurement on one-hour pad test less than 2 g. Patients were considered improved when they had a decrease of stress incontinence. Other cases were considered as failures.

Perioperative complications were also recorded on the case report form.

Surgical procedure:

A non-elastic mono-filament polypropylene tape was used in the TOT procedure (Gynecare, Johnson & Johnson, USA). The transobturator tape (TOT outside-in procedure) was carried out in all patients in the lithotomy position, thighs on abdomen, and buttocks over the end of the table to free the perineum. A Foley catheter was inserted to empty the bladder completely. General anesthesia was used for all patients.

In isolated TOT operations a 2-3 cm long sagittal incision was made in the anterior vaginal wall, starting 0.5 cm from the external urethral meatus. A bilateral para-urethral dissection of the vagina was made in the direction of the ischio-pubic ramus. This dissection allowed the surgeon to introduce his index finger and to palpate the posterior part of the ischio-pubic ramus and the internal obturator muscle.

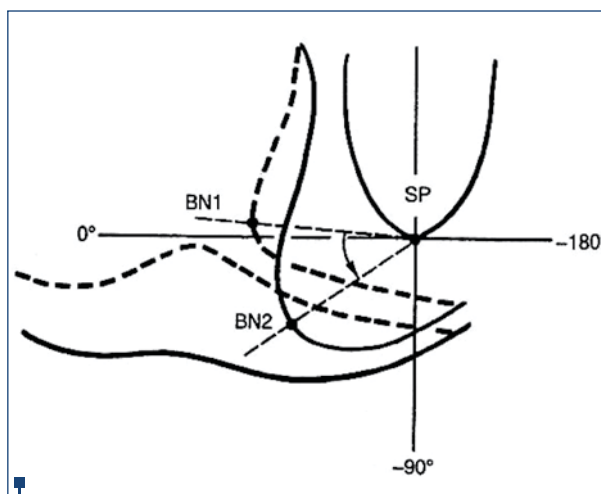


Figure 1. The position of the bladder neck in resting (BN1) and straining (BN2) conditions. The Y-axis is represented by the long axis of symphysis pubis (SP). The connection of SP and BN is regarded as the pubovesical ligament (PVL), and the angle of PVL is measured by taking the X-axis as 0 degree reference. The urethral rotational angle (URA) on straining is measured in a counterclockwise manner

Two minimal cutaneous incisions were made in the superior medial aspect of the obturator foramen. The tunneller was passed through the obturator membrane and its tip was located with the index finger placed in the vaginal dissection. Then the tunneller tip was brought out into the vaginal incision using the finger to guide its path. The urethra was protected with the finger. The tape was introduced into the eye of the tunneller and was exteriorized by pulling the tunneller out. An identical procedure was repeated on the other side(10).

While adjusting the tension of vaginal tape, the bladder was filled with 400 cc of saline solution and, in order to minimize bladder neck mobility, patients were given a 45 degree reverse trendelenburg position in lithotomy. The relationship between patient position and urethral mobility as described by Handa et al.(11) has shown that the proximal urethral mobility in a stress urinary incontinent patient is greater in the supine than in the standing position. Thus we believe these manipulations may have improved operation success.

The tape was adjusted such that no contact was made with the urethra and no tension was applied on the urethra: there was visible space between the urethra and the tape. No intra-operative cough test was performed. The excess tape was cut off at the obturator incisions. Vaginal incision was closed with interrupted sutures of gradually resorbable thread. Obturator incisions were closed with one resorbable suture. Cystoscopy was not performed.

A urinary catheter was inserted and it was left in place for 24 hours postoperatively for all patients. The catheter was removed on the next day following surgery and postvoidal residual volume was measured before the patient was discharged from the hospital. In cases of poor bladder emptying (i.e. >100 ml residual urine), hospitalization was prolonged until a postvoid residual volume of <100 ml was obtained.

The data was evaluated using the SPSS 11.5 program. In the comparison of the pre-operational and post-operational values the paired t-test was used for ICIQ-SF and transperineal ultrasonography, the Mc Nemar test was used for the Stress Test, and the Wilcoxon test was used for the one-hour pad Test.

For the groups formed with different characteristics, the t test for independent samples was used to compare the ICIQ-SF and Transperineal Ultrasonography values in the pre-operational and post-operational periods. Additionally the Chi-square test was used for the inter-group comparisons of the one-hour pad Test and Stress Test values in the post-operational period.

Results

TOT operation was performed under general anesthesia in all 80 patients. The mean follow-up period was 6.4 months^(2,13). The mean hospitalization time was 1.4 days⁽¹⁻⁵⁾. All postoperative patients voided spontaneously. No patient required urethral catheterization for more than 24 hours. Preoperative patient characteristics are summarized in Table 1.

We performed an urodynamic test in all cases in the pre-operative period, and it was performed postoperatively only for the 5 patients in whom the surgery was unsuccessful. In all of these 5 patients, there was no change between pre-operative and post-operative urodynamic parameters (in one patient <60 cm water pressure, in four patients > 60 cm water pressure). Symptoms of urgency and urge incontinence disappeared postoperatively in 24 of 28 patients (85.71%) with mixed incontinence (subjectively). Differences between the preoperative residual urine volume (28.01 ±36.44) and the postoperative volume (33.75 ±23.34) were not statistically significant.

Vaginal erosion occurred in one of the two patients who had continuing detrusor over-activity postoperatively. In this patient the prolene mesh was cut.

The majority of patients, 64/80 (80%), underwent one or more concurrent surgical procedures at the time of their TOT procedure (Table 1). Isolated TOT operation was performed in 16/80 (20%) patients and 9/80 (11.25%) patients have had previous surgery for stress urinary incontinence (SUI) (Table 1).

There were few perioperative complications: one lateral vaginal perforation (sulcus), one perineal hematoma, and one bladder perforation in a patient who underwent an associated prolapse surgery. This perforation had been repaired appropriately at the time of operation. The total perioperative complication rate was 3.75% (3/80) as listed in Table 2. No urethral perforation, bleeding, nerve and bowel injury was reported.

Postoperative complications were presented in Table 2. About 2 of 52 (3.84%) patients with pure stress incontinence developed de-novo-urge symptoms. One patient complained for 3 weeks of a transient perineal pain. One patient had an obturator skin infection at the surgical incision site. This patient was treated with appropriate antibiotics. In one patient vaginal erosion and infection developed postoperatively in the first

month. Prolene mesh was cut and after taking cultures from the infection site the patient was treated with appropriate antibiotics. None of the patients developed urinary retention, urethral erosion or obturator hematoma formation. Postoperative complication rate was moderate (7.59%) (Table 2).

According to ICIQ-SF, the total score differences between pre-menopausal and post-menopausal patients, BMI type I and type II, isolated TOT and combined operations, primary and secondary incontinence operations are not statistically significant (Table 3). The total scores on the ICIQ-SF declined from 17±3.74 before surgery to 4.16±4.4 approximately 6.4 months after surgery, indicating improvement in urinary symptoms ($p < 0.05$).

Preoperative 1-hour pad test results were 2-10 g in 68 patients and >10 g in 12 patients. Postoperatively 1-hour pad test results were <2 g in 73/80 (91.25%) patients. If 1-hour pad test is accepted as a success criteria, the success rate in our study becomes 91.25% and improvement and failure rates together add up to 8.75% (Table 4).

When all patients are separated into different categories according to different criteria such as: premenopausal and postmenopausal, BMI type I and BMI type II, isolated TOT and concurrent surgery, primary and secondary SUI surgery and all subcategories in the same category are compared in terms of ICIQ-SF, stress test and 1-hour pad test no statistically significant differences between subcategories are found (Tables 3, 4 and 5).

Overall, success and improvement-failure rates in terms of the stress test performed at a stand-up position were 95% and 5%, respectively, and when the test was performed at a lithotomy position these rates were 93.75% and 6.25%, respectively (Table 5).

The median values of URA on rest (BN1) determined by using a particular transperineal ultrasonographic method were 126.85 degrees pre-operatively and 120.5 degrees postoperatively. The postoperative BN1 angle value decreased by 5.5 degrees compared to the preoperative value. The median values of URA on valsalva (BN2) were 162 degrees pre-operatively and 140.5 degrees postoperatively and postoperatively a 21.5 degrees was obtained compared to the preoperative value (Figure 1 and Table 6).

The median values of URAs preoperatively and postoperatively were 32 degrees and 16.5 degrees, respectively. The URA values decreased up to 50 degrees (mean 15.5) by isolated TOT and combined procedures performed by our group.

Discussion

Delorme et al. reported that TOT is a safe and effective surgical technique for the treatment of female stress urinary incontinence^(4,10). TOT is an easily performed and reproducible procedure. De Lancey's theories on pelvic support for the bladder and urethra help explain the mechanism of action of urethral suspension in the treatment of stress urinary incontinence^(12,13). With the TOT procedure, the tape forms a neo-hammock under the urethra. The trans-obturator route appears to achieve gains in terms of morbidity and safety combined with a low rate of de novo symptoms.

Table 1 General patient characteristics

Patient Characteristics		
	Mean	Range
Age at procedure (years)	49.4	(22-67)
Parity	4.1	(1-12)
Body mass index (BMI) (kg/m ²)	29.4	(21.4-48.3)
Percent		
Menopausal status	48/80 (60%)	
Previously operated for incontinence	9/80 (11.25%)	
VLPP		
< 60 cm water	12 (15%)	
>60 cm water	68 (85%)	
Detrusor overactivity	4 (5%)	
Type of incontinence		
Stress	52/80 (65%)	
Mixed	28/80 (35%)	
Mean weight of pad test (grams)	10.9 (0-57)	
Concurrent Surgical Procedures Performed at the Time of TOT		
Type of procedure	Number of patients	%
Anterior colporraphy	55/80	68.7
Posterior colporraphy	24/80	30
Paravaginal repair	20/80	25
VAH	18/80	22.5
SSLP	9/80	11.25
TAH	6/80	7.5
Previous SUI surgical procedures		
Operations	Number of patients	
Burch	3	
Kelly	3	
TVT	1	
Others	2	

VLPP, Valsalva Leak Point Pressure; VAH, Vaginal Hysterectomy; SSLP, Sacrospinous Ligamentopexy; TAH, Total Abdominal Hysterectomy; SUI, Stress Urinary Incontinence; TVT, Tension - Free vaginal Tape

Table 2 Perioperative complications

Peri-operative complications						
Surgical complications	Isolated TOT (N=16)	Associated surgery (N =64)			Total (N= 80)	
Lateral Vaginal perforation	1 (%6.25)	-				
Perineal hematoma	-	1 (%1.56)			3 (%3.75)	
Bladder perforation	-	1 (%1.56)				
Post-operative complications						
	N	De novo urge	Transient perineal pain	Skin infection	No improvement	Vaginal erosion
Isolated TOT	16	1	-	-	2	-
Associated surgery	64	1	1	1	3	1
Total	80	2/52 (3.84%)	1 (1.25%)	1 (1.25%)	5 (6.25%)	1(1.25%)

Other studies^(10,14,15) reported short term success rates as of 90.6%, 80.5%, 85.5% and improvement rates as of 9.4%, 7.5%, 14.5% in their studies respectively. The additional surgical procedures was performed concurrently in 26 of 183 and 48 of 604 patients by Costa et al.⁽¹⁴⁾ and Krauth et al.⁽¹⁵⁾, respectively. However, TOT operation was performed alone without additional surgical procedure by Delorme et al. In our study, as the success rate was 93.75% and the improvement and failure

rates added together was 6.25%. Also, in our study combined surgical operation was performed in 64 of 80 patients.

De Tayrac et al.⁽¹⁶⁾ (only TOT) reported no major complications in their study (n=30). Krauth et al. 15 in their multicentered study reported a 2.15% rate of perioperative complications (n=604). In our study intra-operative complication rate was 3.75% (one bladder perforation, one lateral vaginal perforation, one perineal hematoma).

Table 3 Preoperative and postoperative values and comparison of ICIQ-SF scores.

	Preoperative	Postoperative	p*
	Mean±SD	Mean±SD	
Premenopausal (n=32)	16,80±3,54	4,01±4,1	<0,001
Postmenopausal (n=48)	17,13±3,98 NS**	4,26±4,98 NS**	<0,001
BMI <35 I (n=68)	16,90±3,18	4,06±4,12	<0,001
BMI >35 II (n=12)	17,57±4,12 NS**	4,72±4,67 NS**	<0,001
Isolated TOT (n=16)	16,62±4,12	3,88±3,88	<0,001
Combined surgery (n=64)	17,10±3,09 NS**	4,23±3,47 NS**	<0,001
Primary SUI op. (n=71)	16,94±3,34	4,14±3,82	<0,001
Secondary SUI op. (n=9)	17,47±4,30 NS**	4,32±4,55 NS**	<0,001
Total (n=80)	17,00±3,74	4,16±4,40	<0,001

Op, Operation; * Paired t test, ** t test for independent samples

Table 4 | Pad test

Preoperative	Postoperative		Total	P*	Postoperative**
	<2 g	2-10 g			
All Patients					
2-10 g	68 (100%)	0 (0%)	68	<0,001	
>10 g	5 (42%)	7 (58%)	12		
Premenopausal					P>0,05
2-10 g	30 (100%)	0 (0%)	30	<0,001	
>10 g	2 (100%)	0 (0%)	2		
Postmenopausal					
2-10 g	38 (100%)	0 (0%)	38	<0,001	
>10 g	3 (30%)	7 (70%)	10		
BMI Type I					P>0,05
2-10 g	59 (100%)	0 (0%)	59	<0,001	
>10 g	5 (55%)	4 (45%)	9		
BMI Type II					
2-10 g	9 (100%)	0 (0%)	9	<0,001	
>10 g	0 (0%)	3 (100%)	3		
Isolated TOT					P>0,05
2-10 g	15 (94%)	1 (6%)	16	<0,001	
>10 g	0 (0%)	0 (0%)	0		
Combined TOT					
2-10 g	52 (100%)	0 (0%)	52	<0,001	
>10 g	6 (50%)	6 (50%)	12		
Primary					P>0,05
2-10 g	64 (100%)	0 (0%)	64	<0,001	
>10 g	2 (29%)	5 (81%)	7		
Secondary					
2-10 g	4 (100%)	0 (0%)	4	<0,001	
>10 g	3 (60%)	2 (40%)	5		

* Wilcoxon Test; ** Chi square test to compare different groups for postoperative time

Krauth et al.⁽¹⁵⁾ reported the overall post-operative complication rate as 7.5%. In our study this rate was 7.59%.

Handa et al.⁽¹¹⁾ reported that patient position has a significant effect on mobility of the urethrovesical junction, in that the female urethra is more mobile in the supine than in the standing position. In our opinion, the tension of vaginal tape in TOT operation may be adjusted to increase the success rate of surgery while taking in mind that each of patients has different urethral mobility.

We had no patients with urinary retention among the patients with postoperative complications. In our opinion, the explanation for this is the following: the patient position has a significant effect on the mobility of the urethrovesical junction, in that the female urethra is more mobile in the supine than in the standing position⁽¹¹⁾. Therefore, before adjusting the tension of the tape the bladder was filled with 400 cc of saline solution and the patients were given an inverse 45 degree of trendelenburg position. Through such an

Table 5 Stress test

Preoperative	Postoperative		Total	P*	Postoperative	
	-	+			Standing	Lithotomy
All patients						
Standing +	76 (95%)	4 (5%)	80	<0,001		
Lithotomy +	75 (93.75%)	5 (6.25%)	80	<0,001		
Premenopausal					P>0,05	P>0,05
Standing +	31 (97%)	1 (3%)	32	<0,001		
Lithotomy +	31 (97%)	1 (3%)	32	<0,001		
Postmenopausal						
Standing +	45 (94%)	3 (6%)	48	<0,001		
Lithotomy +	44 (92%)	4 (8%)	48	<0,001		
BMI Type I					P>0,05	P>0,05
Standing +	66 (97%)	2 (3%)	68	<0,001		
Lithotomy +	66 (97%)	2 (3%)	68	<0,001		
BMI Type II						
Standing +	10 (83%)	2 (17%)	12	<0,01		
Lithotomy +	9 (75%)	3 (25%)	12	<0,01		
Isolated TOT					P>0,05	P>0,05
Standing +	15 (94%)	1 (6%)	16	<0,001		
Lithotomy +	15 (94%)	1 (6%)	16	<0,001		
Combined TOT						
Standing +	61 (95%)	3 (5%)	64	<0,001		
Lithotomy +	60 (94%)	4 (6%)	64	<0,001		
Primary					P>0,05	P>0,05
Standing +	69 (97%)	2 (3%)	71	<0,001		
Lithotomy +	69 (97%)	2 (3%)	71	<0,001		
Secondary						
Standing +	7 (78%)	2 (22%)	9	<0,001		
Lithotomy +	6 (67%)	3 (33%)	9	<0,001		

* Mc Nemar Test; ** Chi square test to compare different groups for postop. time.

Table 6 Preoperative and postoperative URA values measured by transperineal ultrasonography

	Pre-operatively		Post-operatively		P*
	Mean±SD	Median	Mean±SD	Median	
Resting	126,85±10,19	126,0	121,32±6,83	120,5	<0,001
Valsalva	162,45±13,48	162,0	139,92±0,65	140,5	<0,001
Mobility	34,88±15,35	32,0	18,05±8,71	16,5	<0,001

* Paired t test

inverse 45 degree of trendelenburg position and filling the bladder with 400 cc saline solution, naturel miction environment was constituted and the relationship between mesh and urethra was regulated within this context. These manipulations minimized the differences in bladder neck mobility seen among the patients and the contribution of these differences in mobility to the inconsistencies of tape tension adjustments. The position given to the patients during the adjustment of the tape tension decreased the possibility of creating over-tense or loose tapes in the adjustment procedure. Thus while preventing the development of post-operative urinary retention, it did not have any negative effects on the success rates on the contrary, in our opinion, even improved the rate of success.

Stress incontinence is frequently associated with coexisting genital prolapse, therefore it is important that pelvic reconstructive surgery can be done at the time of incontinence surgery⁽¹⁷⁾. In this study in 64 patients who underwent a combined procedure, the success rate was 60/64 (93.75%). Therefore, TOT was combined with a variety of pelvic reconstructive procedures without observing a difference in the success rate. In the study reported by Costa et al.⁽¹⁴⁾ success and failure rates for combined procedures were 92% and 8% respectively.

Although Mouritsen and contributors⁽¹⁸⁾ have defined an anatomical defect ultrasonographically as BN1 >95 and URA >20, we could not find any study that has evaluated URA in TOT operations. In our study, URA has changed in the range of 0°-50° (mean 16.5). In the majority of the patients URA has not changed or changed slightly. This means, for these patients hypermobility of the bladder neck has been persistent, although urinary continence was achieved for all of them. In spite of the persistence of dynamic structural relationships, the conversion into continence state can be explained by integral hammock

theory which is first described by Petros and Ulmstein in 1993⁽¹⁹⁾. Normally, mid-urethra is fixed by the pubourethral ligament and proximal urethra rotates around this fixed point. Urethral coaption occurs as a result of the kinking effect of urethra, which is due to the rotation of urethra around the tape that is fixed in a horizontal position^(20,21). Sarlos et al.⁽²²⁾ reported that two points seem to be important for the functioning of the tension-free vaginal tape: a dynamic kinking of the urethra during stress, and the movement of the tape against the symphysis, compressing the tissue between the tape and the symphysis. Dietz et al. reported that the curative effect of the TVT on stress incontinence is likely to be due to mechanical compression of the urethra between implant and symphysis pubis⁽²³⁾.

In these functional and structural interactions, the tape is placed at the operation as a substitute to the pubourethral ligament.

Conclusions

TOT operation is an efficient and safe procedure in stress incontinence. It has high success and low morbidity rates. A factor that may improve success rates is the adjustment of tension of tape depending on patient's position. The manipulation of intraoperative reverse 45 degree trendelenburg positioning maybe helpful for minimizing the differences in bladder neck mobility seen among the patients. We were studied to render the point applicable that was reported by handa et al which was in contradistinction to other studies. The main point of success in this operation is to achieve the essential components of integral theory of hammock. We are of the conviction that continence is managed by the provision of dynamic kinking through the compression of urethra during the stress and by the resulting urethral coaptation. However randomized controlled studies in large series are needed. ■

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