Does tension-free vaginal tape and tension-free vaginal tape-obturator affect urodynamics? Comparison of the two techniques

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Summary

Aim: To evaluate the effects of tension-free vaginal tape (TVT) and tension-free vaginal tape-obturator (TVT-O) operations on urodynamics and subjective and objective outcomes. *Materials and Methods:* Thirty-six patients with stress or mixed urinary incontinence underwent TVT or TVT-O. Bristol Female Lower Urinary Tract Symptoms (BFLUTS) Questionnaire-Scored Form, one-hour pad test, Q-tip test, perineometer, and urodynamics were performed before and after the operations. Blaivas-nomogram was used for assessment of postoperative voiding difficulty. *Results*: Nineteen patients underwent TVT-O and 17 patients underwent TVT. Mean follow-up was 18.4 ± 6.8 months. There was no difference between two groups regarding demographic variables, degree of prolapse, type of incontinence, perineometer, Q-tip test, pad test, and urodynamics. There was a significant increase in the maximum urethral closure pressure (MUCP) and residual volume in TVT-O group. According to Blaivas-nomogram, five patients had mild, one had medium obstruction in the TVT-O group, whereas one had mild and three had medium obstruction in TVT group. Two bladder perforations occurred during TVT. One patient developed groin pain after TVT-O. *Conclusions:* TVT-O may lead to an increase in MUCP and residual urine volume. TVT-O is as efficient as TVT and leads to milder obstruction when compared to TVT.

Key words: Stress urinary incontinence; Urinary incontinence; Midurethral sling; Tension-free vaginal tape; Transobturator tape; Urodynamics.

Introduction

Stress urinary incontinence (SUI) is defined as incontinence secondary to increased abdominal pressure such as coughing, sneezing, and heavy lifting [1]. It affects approximately 30% of adult women. In the 20th century, more than 100 surgical techniques for the treatment of urinary incontinence were developed. The tension-free vaginal tape (TVT) procedure, initially described by Ulmsten *et al*. in 1996, was the first minimally invasive mid-urethral sling procedure with 84% cure and eight percent significant improvement rates at two years follow-up [2]. The complication rates are low for TVT and mainly include bladder injury, hematomas, and transient retention of urine with bladder injury being the most common and occurring in three to nine percent of cases [3-6]. There have been rare reports of bowel and vascular injury with TVT [7]. In order to overcome the bladder, bowel, and vascular injuries related to TVT, transobturator approach (TOT) was developed by Delorme, maintaining the efficacy of TVT and reducing or even eliminating the complications related to the penetration of the retropubic space [8]. In 2003, de Leval described the inside-out technique of transobturator approach (TVT-O) for better control of the vaginal passage [9].

Various studies have been conducted comparing the efficacy and complication rates of these two methods; however, literature lacks sufficient amount of reports concerning the effect of these methods on urodynamics and relationship with the success of these methods. In this study, the authors evaluated the effects of TVT and TVT-O operations on urodynamics and compared the two methods according to patient satisfaction and objective measures of success.

Materials and Methods

Thirty-six patients admitted to the present institution with the complaint of SUI or mixed urinary incontinence and operated were included in this prospective study. Informed consent was obtained from all patients. Ethics approval was obtained from the local ethics committee. The patients were randomly assigned and 19 patients underwent TVT-O and the remaining 17 underwent TVT operation.

Preoperative and postoperative evaluations included urinalysis, urine culture, urogynecologic symptom assessment and gynecologic examination, one-hour pad test, four-day bladder diary, stress test, Q-tip test, and urodynamics were performed. Pelvic organ prolapse was evaluated using Baden-Walker Halfway System. The Bristol Female Lower Urinary Tract Symptoms Questionnaire-Scored form (BFLUTS) was used to evaluate the effect of SUI on the patient's everyday life and for the quantification of the lower urinary tract symptoms [10]. Urodynamic studies (MMS UD-2000) included uroflowmetry, multichannel cystometry, and urethral pressure profile. In cases of grade 3 and more pelvic organ prolapse, normal anatomy was restored using a pessary or a vaginal tampon during the tests.

The same surgeon performed all of the surgical procedures. The operations were performed with spinal or general anesthesia according to patient preference in accordance with original techniques described by Ulmsten and De Leval. For TVT oper-

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ations Gynecare TVT, for TVT-O operations Gynecare TVT Obturator System tension- free support for incontinence was used. Cystoscopy was routinely performed in all of the TVT procedures and in suspected cases during TVT-O operations.

Foley catheter was introduced during all of the operations and kept for 24 hours in cases of isolated midurethral sling operations, and kept for three days if anterior colporrhaphy was included. The residual urine volume was measured after the Foley catheter was removed and the patients were discharged when the residual urine volume was < 100 ml. In case of urinary retention, the catheter was inserted and kept in place for an additional 24 hours. Perioperative and postoperative complications were noted in all of the cases.

Patients were re-evaluated at three to 12 months after surgery. Groups were compared according to demographic variables, urinary leakage, pad usage, voiding problems, Q-tip test, stress test, pad test, uroflowmetry, cystometry, and urethral pressure profile. For the determination of postoperative bladder outlet obstruction, Blaivas nomogram was used [11].

Statistical analysis

Statistical analysis was performed with the computer program Statistical Package for the Social Sciences (SPSS) 11.0 for Windows by a professional statistician. Data are expressed as mean ± standard deviation.

All univariate comparisons were performed using Student's t-test in cases where the data were normally distributed. Normality assumption was performed and Mann Whitney U test, Wilcoxon signed rank test, Spearman correlation, chi-square test, and McNemar chi-square test were used for abnormally distributing data. All outcome comparisons were one-sided to compare the methods used in each group to assess the improved outcomes. Comparisons of patient characteristics were two-sided. A p value less than 0.05 was considered statistically significant.

Results

Thirty-six patients were included in the study. TVT-O was performed in 19 patients and 17 patients underwent TVT. The demographic variables of patients are summarized in Table 1. There was no statistically significant difference between the groups for age, body mass index, menopausal state, hormone treatment, and surgical history. One patient in the TVT-O group had a history of periurethral injection, which was unsuccessful.

Five patients (26%) in the TVT-O group and four patients (24%) in the TVT group had genuine SUI. Fourteen patients (74%) in the TVT-O group and 13 patients (76%) in the TVT group suffered from mixed urinary incontinence. Eighteen (96%) of the patients in the TVT-O group and all of the patients in the TVT group had a cystocele, two patients in the TVT-O group, and three patients in the TVT group had a rectocele, nine patients in the TVT-O group, and eight patients in the TVT group had uterine prolapse. The types of the operations performed are summarized in Table 2. Four patients in the TVT-O group and three patients in the TVT group did not have pelvic organ prolapse and underwent sling operation only.

No significant difference was observed between the TVT and TVT-O groups in terms of preoperative pad test, Q-tip test, perineometer results, and bladder diaries. All of the patients had urethral mobility before the operation. Only five patients in the TVT-O group and two patients in the TVT group had negative pad test results before the opera-

Table 1. — *Demographic variables of the two groups.*

	TVT-O (n = 19)	TVT (n = 17)	p
Age	51.1 ± 9.3	50.6 ± 8.0	> 0.05*
Body mass index (kg/m^2)	30.9 ± 4.9	30.4 ± 4.3	> 0.05*
Parity	3.58 ± 1.54	3.06 ± 1.30	> 0.05†
Menopause	9 (47%)	9 (52%)	> 0.05°
Hormone replacement treatment	3 (16%)	3 (17%)	> 0.05°
Previous anti-incontinence surgery	1 (0.05%)^	0	> 0.05°
Previous hysterectomy	2 (10.5%)	3 (17.6%)	> 0.05°
Previous prolapse surgery	2 (10.5%)	1 (5.8%)	> 0.05°

*Student-t test; †Mann-Whitney U-test; °Fischer chi-square test.

Table 2. — *Operations performed in the two groups.*

Operation	TVT-O (n = 19)	TVT (n = 17)
Sling operation only	4	3
Prolapse operation included	15	14
Vaginal hysterectomy + colporraphy anterior + posterior	6	5
Colporrhaphy anterior	1	0
Colporrhaphy posterior	3	0
Colporrhaphy anterior + posterior	1	3
Manchester operation	1	0
Vaginal hysterectomy	2	1
Total abdominal hysterectomy	1	3
Vaginal hysterectomy + colporrhaphy anterior	0	2

Chi square test, $p > 0.05$.

Table 3. — *One-hour pad test, Q- tip Test, and perineometer results of the two groups before and after surgery.*

	TVT-O (n = 19)		TVT (n = 17)		p
	Preoperative	Postoperative	Preoperative	Postoperative	
One-hour pad test (gr)	16.1 ± 26.8 (5.0) (0-100)	0 (0-85)	29.1 ± 28.4 (0-70)	6.46 ± 19.32	> 0.05*
Q-tip Test (°)	62.5 ± 17.5 (35-90)	45.0 ± 20.4 (20-90)	59.1 ± 18.0 (35-85)	48.5 ± 19.3 (15-80)	> 0.05*
Perineometer (cm H_2O)	24.4 ± 13.4 (4-51)	25.4 ± 13.5 (3.0-45.0)	20.1 ± 10.7 (4-44)	25.0 ± 14.0 (6-49)	> 0.05*

*Mann-Whitney U test.

Table 4. — *Comparison of the preoperative and postoperative bladder diaries.*

	TVT-O (n = 19)		TVT (n = 17)		p
	Preoperative	Postoperative	Preoperative	Postoperative	
Mean amount of fluid intake/day (ml)	1793 ± 494 (600-2800)	1808 ± 594 (600-2566)	2181 ± 658 (837-3219)	1975 ± 612 (925-2887)	0.05
Mean daytime number of micturition	8.5 ± 2.6 (5-14)	6.5 ± 2.4 (4-12.5)	9.3 ± 3.4 (4-17)	7.6 ± 2.4 (4-11)	0.05
Mean number of urgency episodes/day	4.6 ± 4.7 (0-15)	1.8 ± 4.4 (0-14)	3.6 ± 4.2 (0-16)	1.1 ± 1.8 (0-5)	0.05
Mean number of leakage/day	2.2 ± 2.7 (0-8.5)	0.5 ± 0.9 (0-2.5)	2.5 ± 3.5 (0-14)	0.8 ± 1.8 (0-6)	0.05

Table 5. — *Comparison of uroflowmetry, cystometry, and urethral pressure profile before and after surgery.*

	TVT-O (n = 19)			TVT (n = 17)			
	Preoperative	Postoperative	*p*	Preoperative	Postoperative	*p*	*p*
Uroflowmetry							
Maximum flow rate (ml/s)	28.3 ± 8.3 (13-43)	17.8 ± 6.1 (11-42)	> 0.05*	28.9 ± 10.8 (17-60)	23.5 ± 9.1 (10-45)	> 0.05*	> 0.05*
Time to maximum flow (s)	8.6 ± 8.2 (2-33.6)	8.9 ± 3.9 (4-15)	> 0.05*	11.6 ± 8.9 (2.4-31.2)	9.9 ± 9.4 (2.4-40)	> 0.05*	> 0.05*
Residual urine volume (ml)	20.6 ± 21.4 (0-80)	38.9 ± 52.4 (0-90)	= 0.047*	19.7 ± 23.9 (0-70)	23.1 ± 24.6 (0-80)	> 0.05*	> 0.05*
Micturition time (sn)	30.5 ± 11.6 (14-55)	42.0 ± 24.5 (18-96)	> 0.05*	39.1 ± 17.1 (12.8-73)	38.5 ± 11.8 (20-61)	> 0.05*	> 0.05*
Cystometry							
First sensation of urine (ml)	187 ± 57 (125-319)	175 ± 45 (121-391)	> 0.05*	191 ± 75 (83-351)	154 ± 77 (40-326)	> 0.05*	> 0.05*
Strong sensation of urine (ml)	323 ± 256 (no-699)	496 ± 131 (251-658)	> 0.05*	516 ± 119 (227-660)	504 ± 131 (316-709)	> 0.05*	> 0.05*
Maximum bladder capacity (ml)	595 ± 177 (184-720)	609 ± 153 (317-717)	> 0.05*	629 ± 141 (354-717)	589 ± 135 (337-725)	> 0.05*	> 0.05*
Compliance (ml/cmH_2O)	75.9 ± 56.6 (13-210)	124 ± 156 (13-450)	> 0.05*	73.9 ± 44.1 (13-150)	92.7 ± 56.5 (15-159)	> 0.05*	> 0.05*
Maximum detrusor pressure (cm H_2O)	10.3 ± 8.5 (3-36)	14.5 ± 10.6 (3-85)	= 0.021*	10.3 ± 6.5 (2-25)	25.0 ± 28.6 (3- 87)	> 0.05*	> 0.05*
Abdominal leak point pressure (cm H_2O)	78.8 ± 29.3 (40-131)	–		85.2 ± 41.5 (22-141)	92.7 ± 42.5 (47-131)		> 0.05*
Detrusor leak pressure (cm H_2O)	27.0 ± 11.9 (15-47)	25.0 ± 7.3 (15-31)	> 0.05*	30.6 ± 14.8 (13-52)	30.3 ± 16.5 (20- 54)	> 0.05*	> 0.05*
Detrusor pressure at micturition (cm H_2O)	35.7 ± 23.5 (5-85)	25.0 ± 7.5 (12-33)	> 0.05*	27.4 ± 12.2 (10-48)	33.5 ± 18.7 (2- 64)	> 0.05*	> 0.05*
UPP							
Maximum urethral pressure (cm H_2O)	48.7 ± 25.8 (25-115)	68.1 ± 34.0 (23-131)	> 0.05*	63.7 ± 33.6 (8-117)	44.9 ± 18.4 (13- 46)	> 0.05*	>0.05*
Maximum urethral closure pressure (cm H_2O)	43.4 ± 30.8 (0-115)	63.1 ± 25.8 (23-107)	= 0.031*	57.7 ± 31.2 (8-116)	45.1 ± 18.4 (11- 86)	> 0.05*	= 0.01*
Functional urethral length (cm)	3.1 ± 0.5 (2.2-3.9)	2.9 ± 0.6 (1.5-3.7)	> 0.05*	2.9 ± 0.5 (1.7-3.8)	2.8 ± 0.7 (1.4- 4.0)	> 0.05*	> 0.05*

* Mann-Whitney U test; Wilcoxon signed rank test.

tion. Stress test was positive in five patients in the TVT-O group and four patients in the TVT group (Tables 3 and 4).

There was no significant difference in the preoperative urodynamic parameters between the two groups. Six patients (32%) with mixed urinary incontinence and two patients (10%) with SUI in the TVT-O group, and five patients (30%) with mixed urinary incontinence in the TVT group had detrusor overactivity during cystometry. SUI was observed in eight patients (42%) in the TVT-O and seven patients (41%) in the TVT group. There was no difference in the mean abdominal leak point pressure between the two groups. The results are summarized in Table 5.

The mean follow-up period was 18.4 ± 6.8 months. Cure was accomplished in 89.5% of the TVT-O group, 65% of the TVT group and 10.5% of the TVT-O group, and 35% of the TVT group improved ($p = 0.002$). Stress test was negative in all of the patients. Only one patient in the TVT group and one patient in the TVT-O group did not have urethral mobility in the postoperative evaluation (Table 3). None of the patients who underwent TVT-O complained of SUI in the postoperative period, but two patients (10.5%) suffered from urge urinary incontinence. One had mixed urinary incontinence before the operation, and the other one developed de novo. One patient (5.8%) in the TVT group suffered from SUI, four patients (23.5%) had urge urinary incontinence, and one patient (5.8%) had mixed urinary incontinence. There was a significant difference between the two groups in total number of incontinent patients. When the postoperative pad test results were compared, none of the patients in the TVT-O group and only two patients in the TVT group had a positive pad test ($p > 0.05$).

BFLUTS results revealed no significant difference in the symptoms of obstructed voiding between the two groups, but in both groups, postoperative voiding dysfunction increased; 41% of the TVT group and 42% of the TVT-O group noted changing in the voiding pattern and hesitancy during voiding. Frequency of micturition and pad usage decreased (Table 6).

Table 6. — *Comparison of the symptoms of voiding difficulty of the two groups before and after surgery.*

	TVT-O		TVT		*p*
	Preoperative	Postoperative	Preoperative	Postoperative	
Slow stream	6 (31%)	11 (58%)	6 (35%)	11 (65%)	> 0.05
Straining for voiding	5 (26%)	11 (58%) De novo: 7 (37%)	6 (35%)	9 (53%) De novo: 4 (23.5%)	
Difficult voiding	3 (16%)	11 (58%)$^+$ De novo: 8 (42%)	6 (35%)	13 (76%)$^+$ De novo: 7 (41%)	> 0.05
Pad usage	14	0$^+$	13	5$^+$	> 0.05
Frequency	11 (58%)	1 (5%)$^+$	9 (53%)	5 (29%) De novo: 2 (12%)	> 0.05

*McNemar Chi square test; ^Chi square test; ^+p for TVT-O < 0.05; *p* for TVT < 0.05.

Table 7. — *Comparison of the complications encountered during or after TVT-O and TVT procedures.*

Complications	TOT (n = 19)	TVT (n = 17)	*p*
Urinary retention	2	2	> 0.05*
Bladder perforation	0	2	> 0.05*
Postoperative pain	1	0	> 0.05*
De novo UI	1	0	> 0.05*
Fever	2	2	> 0.05*

Chi square test, $p > 0.05$.

When the postoperative urodynamic parameters were compared, there was no significant difference in maximum flow rate, the time to reach maximum flow, micturition volume, residual urine volume, compliance, maximum detrusor pressure, abdominal leak point pres-

sure, detrusor pressure at micturition, maximum urethral pressure, and functional urethral length. The results are summarized in Table 5. The mean maximum urethral closure pressure was 63.1 ± 25.8 cm H_2O (23-107 cm H_2O) in the TVT-O group and 45.1 ± 18.4 cm H_2O (11-86 cm H_2O) in the TVT group. There was a significant increase in the maximum urethral closure pressure and residual urine volume in patients who underwent TVT-O operation (Table 4).

As shown in Figure 1, none of the patients in the TVT-O group had severe obstruction according to Blaivas nomogram. One patient (5.2%) was in the moderate and five patients (26%) were in the mild obstruction group. In the TVT group, three patients (17%) were in the moderate obstruction group and one patient (26%) was in the mild obstruction group.

Intraoperative and postoperative complications are summarized in Table 7. Postoperative urinary retention developed in two patients in both groups, but resolved completely shortly after. Groin pain developed in one patient in the TVT-O group. De novo urge incontinence was seen in one patient in the TVT-O group. Bladder perforation occurred in two patients in the TVT group.

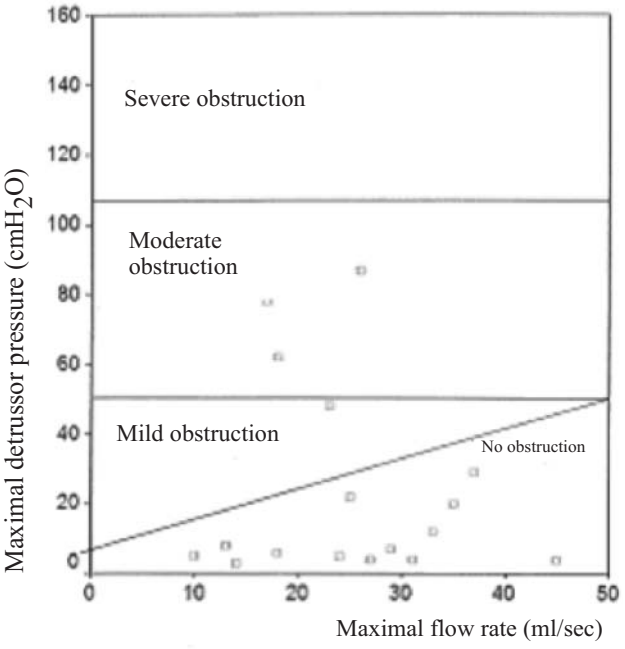

Figure 1. — Blaivas nomogram a) for TVT-O; b) for TVT.

Discussion

In this study, the effect on urodynamics and subjective and objective outcomes of TVT and TVT-O procedures have been evaluated. Subjective and objective criteria including urodynamics were used to compare the TVT and TVT-O operations. There was no difference between the two groups regarding age, parity, menopausal state, and the prevalence of mixed urinary incontinence; therefore the two groups were suitable for comparison in this study.

There was a significant difference in patient satisfaction and cure rates in the two groups with more patients cured in the TVT-O group. In this study, cure was defined as no leakage episodes after surgery. In another study regarding the success rate of TVT operation from the present institution with mean follow-up period of 11 months (1-24 months), the cure rate was 90% and 10% of the patients had improved [12]. The mean age of the population studied and the inclusion of other vaginal surgical procedures were similar to the present study group. Various other reports presented 90% cure-rate in the first year after surgery using TVT with reduction in the success rate when cases with intrinsic sphincter deficiency and pelvic organ prolapse were included [13-15]. In most of the studies evaluating the success rate of TVT operations, patients with pelvic organ prolapse and pelvic reconstruction surgery and previous anti-incontinence surgery have been excluded. Tsivian *et al*. [16] reported that when these cases are included, the cure rate declines to 78.9%. In a recent systematic review, retropubic procedures have shown greater objective success, but no difference in subjective outcomes [17]. The current authors did not accept the patients as cured when there were still symptoms (loss, urge, high residual urine volume), even if they had a negative pad test and stress test result and no leakage in uroydnamics. However, this study demonstrates that TVT-O is as successful as TVT operation and the rate of complications is very low. In a study evaluating the patient perceptions of success after TOT and TVT, 65.5% of the patients in the TVT group and 63.4% of the TOT group reported no stress incontinence [18]. Similarly, in a recent multicenter randomized controlled trial using both objective and subjective outcomes, the success rate for TVT was 80.8% and for TOT was 77% [19] However, for subjective outcomes, success rates were 62.6% and 55.5% for TVT and TOT, respectively.

These two operations do not aim at correcting the urethral hypermobility. On the contrary, the persistence of urethral hypermobility after surgery is important for the dynamic movement of the urethra during increases in intra-abdominal pressure [20]. It was shown that urethral mobility was not affected after TVT [21, 22]. The continence mechanisms of TVT and TOT and TVT-O are similar. Fellipi showed the persistence of urethral mobility after TOT operation using cystography [23]. In another study using a Q-tip test, no effect of TOT on urethral mobility was found [24]. According to the present study, neither TVT nor TVT-O affected the urethral mobility in the postoperative period.

One of the major complications of both procedures is voiding difficulty, which may be observed after incontinence procedures. Significant portion of the patients began to suffer from hesitancy and voiding difficulty after the operations in both groups. Porena *et al*. reported voiding difficulty in 44% and 24% following TVT and TOT, respectively [24]. However, in other studies lower rates of voiding dysfunction were reported. Definitions of voiding difficulty vary between studies, so it is difficult to draw conclusions.

Persistence of urge incontinence or de novo urge incontinence may occur following the aforementioned procedures. In the present cohort, urge incontinence and de novo urge incontinence was not observed in the TVT group. One patient suffered from de novo urge incontinence in the TVT-O group. Thirteen patients in the TVT group had mixed urinary incontinence symptoms before surgery and this was reduced to five patients after surgery. Similarly, 14 patients had mixed urinary incontinence symptoms before the operation and only one patient after surgery had mixed symptoms in the TVT-O group. Segal *et al*. [25] studied the effect of TVT on urge urinary incontinence and detrusor overactivity. In this study, urge incontinence symptoms disappeared in 63.1% of the mixed urinary incontinence cases in the TVT group and 57.7% could stop their anticholinergic drugs. The present findings are in parallel. Similarly TVT-O leads to a reduction in urge incontinence symptoms in patients with mixed urinary incontinence.

Both TVT and TVT-O have high rates of success in the treatment of SUI and one would anticipate changes in the urodynamic parameters after these procedures. However; there was no significant difference in the urodynamics between TVT and TVT-O. There was a significant increase in the maximum urethral closure pressure in the postoperative evaluation in the TVT-O group. According to the present study, TVT-O might as well be effective in the treatment of intrinsic sphincter deficiency together with urethral hypermobility in patients. There was also a slight increase in the residual urine volume and micturition time. In the Blaivas nomogram, which shows voiding difficulty based on maximum detrusor pressure and maximum flow rate, there was no significant difference between the two groups. None of the patients in the TVT-O group had severe obstruction. Higher rates of voiding difficulty have been reported with TVT compared with TOT operation [16], possibly because it is more obstructive; but this was not seen in the study by Richter *et al*. (2.7% for TVT and 0% for TOT) [19].

The other complications following both techniques include bladder perforation, vascular injuries, hematomas, vaginal perforations, and groin pain [3-7]. In this study, there was a low rate of complications (Table 7). Two bladder perforations developed in the TVT group during the operations and the inserted needle was removed and re-inserted. No bladder perforations, vaginal sulcus injury or vascular injury developed in the TVT-O group, but one patient suffered from groin pain.

Conclusion

This study demonstrates that TVT and TVT-O procedures have high success rates with minimal effect on bladder storage and voiding functions. Both work well in patients with mixed urinary incontinence and pelvic organ prolapse. However, TVT-O procedure resulted in a higher cure rate with a significant increase in maximum urethral closure pressure than did the TVT procedure.

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