

Learning curve experience in tension-free vaginal tape and transobturator tape operations for the treatment of stress urinary incontinence

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Abstract: Objective: to compare short-term outcomes and intraoperative complications that arise within the learning period of tension-free vaginal tape (TVT) and transobturator tape (TOT) operations used in stress urinary incontinence. Material and method: In the present study, 50 patients were treated with TOT and 20 with TVT. An additional operation was performed on 32% of those who had TOT and 50% of those who had TVT. Results: No intraoperative complications have been encountered in TVT and TOT operations. Marked improvements were observed in both operation groups in IIQ-7 and UDI-6 quality of life surveys in the first and third postoperative months ($p < 0.05$). Operation duration of TOT was found significantly shorter than that of TVT ($p < 0.05$). There was not any significant difference between groups in terms of early postoperative complications like duration of hospital stay, urination dysfunction, leg pain and urinary tract infection ($p > 0.05$). One patient who had TOT developed mesh erosion and one who had TVT developed globe vesical on postoperative day one. Conclusion: TVT and TOT are operations which produce similar short-term outcomes and the learning period of which can be overcome without complications by surgeons experienced in pelvic anatomy and surgery.

Key words: Stress urinary incontinence (SUI); Tension-free vaginal tape (TVT); Transobturator tape (TOT); Short-term outcomes; Complication.

INTRODUCTION

Although a multitude of surgical techniques have been developed for the treatment of stress urinary incontinence (SUI), an ideal method with high success and low complications rate could not have been established yet. Recently, two methods based on the principle of midurethral support have been popularly utilized. These two techniques, both of which are applied vaginally, are Transobturator Suburethral Tape (TOT) and Tension-free Vaginal Tape (TVT).¹ Although these two are comparable in terms of treatment success, complication rates, long-term efficiency, ease of application and learning curve, there is a period of learning curve during which the rate of complications may be very high for both.² The present study was planned to compare the outcomes of the two operations, widely used in the surgical treatment of SUI, performed during the learning curve with regard to efficiency, complications and patient satisfaction.

MATERIAL AND METHOD

The study registered 70 patients who were diagnosed with stress urinary incontinence in the Obstetrics and Gynaecology Clinic of Firat University Medical School in a period of 18 months starting on June the 1st 2006. After approval from Ethics Committee of the Firat University Medical School was obtained, the study was planned prospectively. In the first 40 cases, all the patients were informed about both operations in the preoperative period and the choice of operation was made randomly by a different team in the operation room. After 20 TVT and 20 TOT operations, randomization was abandoned, due to the preference of the surgical team towards TOT. All the remaining cases were applied TOT and consequently, a total of 50 TOTs and 20 TVTs were conducted.

Cases who had diabetes, hypertension or another additional disease were not included in the study. Patients who described stress incontinence in the preoperative and postoperative controls were subjected to a stress test in order to objectively evaluate whether they actually had incontinence. When urge and stress incontinence could not be dis-

tinguished, an urodynamic examination was carried out. Cases who were shown not to have urge component by urodynamic examination were included in the study, while those with an urge component were not. The study evaluated operation duration, short-term success and complication rates of these two techniques performed within the learning period. In this context, preoperative and postoperative haematocrit levels, operation and anaesthesia durations, duration of catheterized hospital stays, as well as postoperative complaints and findings of the patients were recorded. Physical and pelvic examinations of the patients were carried out in the postoperative 1st and 3rd months in order to evaluate incision line wound infection, urinary infection, mesh erosion, *de novo* urge incontinence and patient satisfaction (IIQ-7 and UDI-6 survey forms).

The operations were started by a gynaecologist oncologist who participated as an assistant in about 5 live operations performed on patients by experienced incontinence surgeons in a course organized by the Turkish Association of Urogynaecology and Pelvic Reconstructive Surgery in the operation room of our hospital. All operations in the study were conducted by this surgeon and his team. Monofilament mesh (I-STOP) was used in the operations.

Statistical analysis: Data were presented as mean \pm standard deviation (SD). Wilcoxon signed rank and Mann Whitney U tests were used in comparisons. Categorical data were expressed as numeric value and percentage. Values for which $p < 0.05$ were accepted statistically significant.

RESULTS

Sociodemographic characteristics of the cases in TOT and TVT groups are presented in Table 1. Of the TOT cases, 4 had previous colporrhaphy anterior and 5 had a history of hysterectomy. None of the TVT group cases had a history of urogynaecological operation. An additional procedure was applied to 32 out of 50 TOT operation cases and 10 out of 20 TVT operation cases. All the operations were performed under general anaesthesia.

In addition to TOT operation, three cases were applied vaginal hysterectomy (VAH), five were applied vaginal hysterectomy + bilateral salpingoopherectomy (VAH-

TABLE 1. – Demographic characteristics of the patients.

	TOT (n:50)	TVT (n:20)
Age (years)	47.2±9.9	47.8±9.1
BMI (kg/m ²)	29.5±4.1	29.3±2.2
Parity (n)	5.0±2.8	5.5±2.8
Incontinence duration (years)	6.3±5.3	5.7±3.7
Menopause	17 (%34)	6 (%30)
History of gynaecologic operation	9 (%18)	0 (%0)

BSO), four were applied total abdominal hysterectomy (TAH), eight were applied total abdominal hysterectomy + bilateral salpingoophorectomy (TAH-BSO), seven were applied colporrhaphy anterior, six were applied colporrhaphy posterior, four were applied perinoplasty, one was applied sacrocolpopexy, three were applied tubal ligation, one was applied hysteroscopic polyp extirpation, one was applied cervical conisation and one was applied Bartholin's cyst extirpation. In the TVT group, in addition to TVT, two cases were applied VAH, two were applied TAH-BSO, three were applied laparoscopy-assisted vaginal hysterectomy, one was applied colporrhaphy anterior, two were applied colporrhaphy posterior, one was applied perinoplasty, one was applied sacrospinous fixation, one was applied office hysteroscopy (H/S), and one was applied tubal ligation with laparoscopy (L/S). The mean duration of TOT operation was found 14.3±1.9 minutes and that of TVT was found 18.4±2.7 minutes. The difference between these two operation durations was statistically significant (p<0.05). The duration of hospital stay was 1.1±0.3 day in the group who had TOT only and 1.0±0 day in the group who had TVT only (p>0.05). Durations of hospital stay in the groups in which operations other than TOT and TVT were performed were 3.3±1.1 and 3.0±0.4 days respectively, and the difference between these values was insignificant (p>0.05). Duration of catheterized hospital stay was 12.2±4.2 hours in the TOT group and 12.5±3.8 hours in the TVT group (p>0.05). In the postoperative subjective evaluation, 80% of TOT patients said that they were satisfied with the operation, 10% said they felt better, relative to preoperative period, and 10% reported that they were not satisfied. Of the TVT cases, 85% expressed satisfaction, 5% said they felt better, compared to the preoperative period, and 10% said they were not satisfied.

Scores of IIQ-7 and UDI-6 surveys, which were responded by patients in the preoperative periods and postoperative 1st and 3rd months and which evaluated the patients' incontinence complaints and mental states in their social life, displayed statistically significant improvements (Appendix 1). TOT patients showed significant improvements in the 1st and 3rd postoperative months, compared to the preoperative period (p<0.05), but there was no difference between postoperative 1st and 3rd months (p>0.05). In the TVT group, however, significant improvements were found in the 1st and 3rd postoperative months, relative to the preoperative period, and between the postoperative 1st and 3rd months (p<0.05) (Table 2).

There was not any statistically significant difference between TOT and TVT groups in terms of urination dysfunction, leg pain and urinary tract infections (p>0.05) (Table 3). None of the TOT or TVT patients had intraoperative complications. A patient who had TOT operation developed mesh erosion in the 1st postoperative month. The patient was re-operated and the mesh was removed. The patient's incontinence complaint did not recur after the removal of the mesh. A patient who had TVT operation developed globe vesical at the postoperative 24th hour. The patient was recommended bladder training after catheterization, on the second day of which, the urination function was restored. It was found by urodynamics that one patient (5%) who had undergone TVT continued to experience stress incontinence. TOT operation was conducted in this patient and her symptoms resolved.

DISCUSSION

Our study demonstrated that TOT and TVT operations used in stress urinary incontinence were easily applied operations with a short learning period. No intraoperative or postoperative complications developed in any of the groups.

The major reason why intraoperative complications that are common particularly in the learning period were not encountered in our series can be explained by the fact that the surgical team was experienced in pelvic surgery and anatomy, although not in TOT and TVT. However, intraoperative wounds have been reported at a certain rate in the literature and require attention. Raffi et. al. reported bladder perforation in 9.6% of the cases who had TVT in their study. This risk was shown to increase in hysterectomy of pelvic reconstructive surgery, which was conducted concurrently.³ In the same vein, Grise et. al. noted that bladder perforation occurred generally in situations where the operation was accompanied by hysterectomy or prolapsus repair, and recommended cystoscopy only in patients who had previous or simultaneous prolapsus operation, as bladder perforation is rare during TOT.⁴ In our study, there was no complication even in the operations conducted simultaneously with TVT and TOT. In line with our routine procedures, operations like TVT and TOT are performed after pelvic surgery. We cannot claim that this approach is standard, but in this way, it is easy to show whether the bladder injury is associated with incontinence surgery or reconstructive surgery. The fact that additional surgical procedures were applied in about 32% of TOT cases and 50% of TVT cases indicates that a gynaecologist who operates on stress urinary incontinence cases needs to have substantial knowledge of pelvic reconstructive surgery as well.

Cystoscopy was not used in our cases in the present study or in other cases in our routine procedures. When the urine has a clear colour, it is an important sign that at least the bladder mucosa is intact. However, it should be noted that there may be some drawbacks at this point. One of these drawbacks is that in cases who do not have enough urinary discharge, the urine may be haematuric, but there may not be enough urine discharge from the catheter to see haema-

TABLE 2. – Evaluation of TOT and TVT treatment outcomes.

	TOT (n:50)				TVT (n:20)			
	Preop	Post-1	Post-3	p	Preop	Post-1	Post-3	p
IIQ-7	10.3±5.3	1.6±0.6*	0.9±0.4*	0.0001*	10.8±1.3	2.3±1.2*	1.4±0.9*	0.0001*
UDI-6	4.8±0.5	1.5±0.4*	0.9±0.3*	0.0001*	4.4±0.7	2.0±0.7**	0.9±0.4*	0.0001* 0.004**

TOT: Trans-obturator Suburethral Tape, TVT: Tension-free vaginal tape, preop: preoperative, post-1: postoperative day 1, post-3: postoperative day 3.

TABLE 3. – Early postoperative complications in TOT and TVT groups.

	TOT (n:50)	TVT (n:20)	P
Urinary disfunction	0.14±0.05	0.1±0.06	0.65
Leg pain	0.08±0.04	0.1±0.06	0.79
Urinary infection	0.08±0.04	0.15±0.08	0.38

turia. This may be the case in cases with haemorrhage or in hypotensive patients who were not provided with enough anaesthesia support. In order to eliminate this suspicion, it is sufficient to wait for a few minutes, until regular urinary discharge is observed. Another possibility is that haematuric appearance may not always indicate bladder laceration. The urine colour may change due to partial bladder mobilisation during additional surgical procedures. It can be stated in the light of this information that the risk of bladder injury may be minimized by taking the necessary care during surgery and having sound knowledge of anatomic landmarks. However, if the surgeon has suspicions that something may be wrong, cystoscopy should be performed. In this way, all the injuries that impair the mucosal integrity of the bladder may be revealed. Still, it should be born in mind that close submucosal passes that can lead to perforations in later periods, also known as late perforation, cannot be identified by cystoscopy.⁵

Another important complication is urination dysfunction. Raffi et. al. reported in their study that the concerned complication was observed in 9.1% of TVT patients.⁶ In our study only one patient (5%) who had TVT developed globe vesical on the first postoperative day and recovered after a short catheterization and bladder training period. In cases where urination dysfunction is observed, mesh tension should be re-arranged postoperatively in the shortest time possible. It is recommended to re-open the old incision site and to pull the mesh about 5 mm downwards or to close the vaginal tissue individually. If this procedure is delayed, the mesh may merge with the tissue and cannot be loosened, and then it may be necessary to cut the mesh.⁷ In our case who developed globe vesical, the catheter passed easily from the urethra, and consequently there was no problem and no need to loosen the mesh. However, easy passage of the catheter from the urethra should not be considered an objective indicator of the urethral narrowing caused by the mesh in the urethral compartment. It is also possible for the impaired urethral angle to prevent urinary discharge, despite the lack of any narrowing.⁸ Similarly, it should be kept in mind that globe vesical may result from the general anaesthetics administered, postoperative pain and oedema. If the problem continues in spite of catheterization and bladder training, then complications associated with mesh application can be considered. Almost all meshes allow loosening at any time within the first 7 days of placement.

In TOT operations in particular, when vaginal wall dissection cannot be performed at a proper depth to reach the lower Halban fascia due to the differences in the depth of the vaginal sulcus and the strength of the vaginal tissue, there is increased risk of vaginal perioperative perforations and secondary erosion. In case of perioperative sulcus perforation, it can be recommended to open a new and deeper sulcus for the mesh and to have an extended period of sexual abstinence in the postoperative period.

The mean duration by which vaginal erosion manifests itself is 9 months.⁹ The patients may be asymptomatic or they may present with symptoms such as vaginal discharge, pain during intercourse or at other times, or oedema in labia major.^{9,10} Vaginal tape may be seen during vaginal examination or in some cases it may be coated with granuloma and may become invisible. When the tape is removed, most pa-

tients have become asymptomatic and remain in continent situation, without any recurrence of incontinence. Some authors recommend partial removal of the tape,¹⁰ while others suggest total removal of non-woven tape.⁹ Vaginal erosion in our patient occurred in the first postoperative month. The patient who felt uncomfortable during coital activity found in her self-examination a foreign body in the vicinity of the right vaginal sulcus. She had no other symptom like bleeding, discharge or vaginitis. Vaginal examination of the patient revealed that the mesh became visible in a 1 cm square area in the vicinity of the right vaginal sulcus. This area was partially amplified with an incision under local anaesthesia and that part of the mesh was completely removed. The remaining tissues were primarily sutured using an absorbable material. The patient did not develop any symptoms related to incontinence. Croak et. al. reported a recurrence rate ranging between 33% and 39% in patients in whom the TVT mesh was cut between postoperative weeks 2 and 69 due to urination dysfunction.^{11,12} This condition may be associated with the area where the mesh was placed and cut. In our case, the removed part of the mesh is about 1 cm from the urethra and the fibrous tissue that developed adequately maintained continence, despite the partial removal of the mesh.

In a study where they performed TOT operations on 206 cases, Grise and colleagues reported 4 vaginal erosions, which occurred in months 2, 8, 13 and 25.4 In the present study, the cases have been followed up for 3 years and there has been no complications reported to us. Haemorrhage is a common condition during the operations, as pelvic tissues are rich in blood circulation and due to the injury to periurethral venous flexi. Although they worry the new beginners within the learning curve, life-threatening haemorrhages are very rare. In a study by Krauth and colleagues, haemorrhage was reported in 0.8% of TOT patients and was treated only by compression.¹³ TVT is no different than TOT in this respect, as although clinical hematoma was reported at a rate of 2.4%, operation was needed in only 0.2% of these patients.⁵ It was also reported that a re-operation was required in 0.7% of TVT cases due to hematoma.¹⁴ However, two mortalities were reported as a result of major vessel injuries associated with TVT, a retropublic hematoma requiring blood transfusion and catastrophic haemorrhages necessitating surgical intervention.^{11,12,15-18}

It was noted that the major vascular structures in the retropublic area and anterior abdominal wall are located at the 0.9-6.7 cm lateral side of TVT needles.⁷ Therefore, the risk of a major haemorrhage is high in case the needle is oriented towards the lateral part due to worries about urinary bladder perforation or the movement of the patient under local anaesthesia.^{7,19} In order to avoid vascular injuries, the surgeon should thrust the TVT needle in the direction of a line drawn from the mid labia major towards the shoulder on the same side and in the back of the pubis bone.⁵ Using the needle in this manner should significantly reduce the risk of haemorrhage. Intense bleedings observed particularly during incisions and opening of tunnels in both TOT and TVT operations show a marked decrease after the placement of mesh. Thus, in order to minimize unnecessary bleedings, it shall be useful to place the mesh immediately after the opening of the tunnel, without losing time, which shall be possible by preparing everything in advance.

In conclusion, the learning periods of surgical teams who have previous experience in pelvic anatomy and surgery can be overcome by a 0% intraoperative complication rate, on condition that surgical principles are closely followed. This result of ours has been supported by lack of any complications in about 100 cases in whom we performed TOT after the completion of this study.

The authors report no conflicts of interest.

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