

Assessment of perioperative, early, and late postoperative complications of the inside-out transobturator tape procedure in the treatment of stress urinary incontinence

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Summary

Objective: To evaluate the complications of urinary incontinence surgery with transobturator tape (TVT-O) system and to describe its diagnosis and management. **Materials and Methods:** A total of 156 patients who were diagnosed as having stress incontinence and mixed incontinence with stress predominance underwent a TOT operation under spinal anesthesia by one surgeon or two surgeons (MB, AEY) from the team. TVT-obturator inside out material was used in the operation. Urodynamic tests and pad tests were done on all the patients. This is a prospective and retrospective study of the complications of TVT-O. The operation was performed under regional anesthesia, as described by Deval *et al.* Patients were excluded from the study if they had been operated under general or local anesthesia, had undergone any vaginal operations except for anterior repair (cystocele), wanted to have a baby, had severe systemic diseases or had been diagnosed as having urge incontinence in urodynamic tests. These situations may affect the rate of complications, the authors also excluded slings that had materials other than monofilament polypropylene, and patients who were suspected of having neurologic bladder conditions. The bladder and urethra were evaluated using cystoscopy. The durations of the TOT procedure, cystoscopy, and if performed, the cystocele operation, were recorded. Perioperative, early, and late postoperative complications were analyzed by follow-up visits (after two months to four years). **Results:** Of the 156 patients included in the study, 100 (64.1%) had pure stress urinary incontinence and 56 (35.9%) had mixed incontinence, 20 (12.8%) had previous incontinence surgery. The mean duration of follow up was 30.3 ± 7.4 (range 17-42) months. The mean age of the patients was found to be 48.43 ± 6.24 years (range 42-68). The mean parity of the patients was 5.24 ± 2.86 (range 2-13), and mean body mass index was found to be 23.7 ± 4.8 . Mean maximum detrusor pressure was 10.30 ± 4.08 and the mean ALP value was 80.80 ± 25.57 . Mean operative time was found to be 13.8 ± 5.16 min in patients who underwent only TOT and TOT-anterior repair. Vaginal injury including to the lateral fornix (4.4%), hemorrhaging of more than 200 ml (3.2%), vascular damage (1.9%), hematoma on the leg (1.9%), hemorrhaging of more than 500 ml (0.064%), and bladder perforation (1.2%) were detected as perioperative complications. Urethral injury and perioperative nerve and intestinal injury did not occur. The most common complication in early postoperative period was inguinal pain extending the legs (30.7%), followed by headaches (23.7%), fever (12.8%), urinary tract infection (5.7%), and urinary retention (3.2%), respectively. Late postoperative complications included vaginal erosion (4.4%), de novo urge incontinence (8.9%), de novo dyspareunia (7.1%), perineal pain (4.4%), and worsening urgency (8.9%). **Conclusion:** Although the TVT-O technique is a minimal invasive surgery method applied to treat the urinary incontinence surgically, it does not imply that it is a complication-free surgical procedure. Despite the low incidence of intraoperative complications, there is a mild risk of early and late postoperative complications. Fortunately these complications can be taken under control by either conservative and simple medical treatments or surgical procedures.

Key words: Urinary incontinence; Complications of TVT-O; Bladder injury; De novo urge incontinence; Mesh erosion.

Introduction

The inside-out transobturator tape (TVT-O) (a monofilament macroporous, knitted, polypropylene mesh with pore size >75 μ m) procedure, which is a simple and effective treatment modality for the treatment of female stress urinary incontinence, was first described by Deval *et al.* in 2003 [1]. Reduction of potential peri- and postoperative complications that may develop following the retropubic tension-free suburethral sling systems (TVT) widely used worldwide may be possible through newly developing surgical techniques (e.g. TVT-O) in treatment of female stress urinary incontinence. Complication rates

of mid-urethral sling operations are low, however it is known that complications are reported less than those occurring [2, 3]. The transobturator tape procedure may be performed inside-out and also outside-in. Two types of transobturator approaches have been performed over the past ten years: the inside-out (TVT-O) and outside-in transobturator tape (TOT). Anatomic dissections have indicated that performing the TOT procedure inside-out significantly reduces bladder, external iliac, and epigastric vein injuries through reducing the probability of reaching the inferior part of pelvis. However, studies have shown that TOT procedures may lead to

a risk to the obturator and vaginal vessels although they preserve the retropubic area [4, 5]. The TOT procedure is an effective surgical treatment for female stress urinary incontinence. However, data concerning its safety are rare, follow-up is frequent, and complications are probably under-reported. Several variables have an impact on the epidemiology of mid-urethral sling (MUS) related complications. Lack of worldwide national registers of all MUS procedures signifies that often investigators do not have the denominator for calculating the true incidence of complications; a discrepancy exists between complication rates in scientific reports and independent databases such as the Manufacturer and User Facility Device Experience (MAUDE), which monitors voluntary reporting of MUS-related complications. Deng *et al.* recently investigated the incidence of major MUS-related complications in the American population and found that they were under-reported. A significant discrepancy emerged between scientific reports in English and Food and Drug Administration (FDA)/MAUDE reports, which collected four times as many major complications [6].

The aim of this paper was to describe perioperative, early and late complications associated with TVT-O procedures.

Materials and Methods

Patient selection

A total of 156 patients who were admitted with stress incontinence to the Gynecology and Obstetrics Clinics of Taksim Research and Training Hospital and Şirnak İlil State Hospital between May 2005 and January 2010 were included in this prospective study.

Preoperative assessment

A detailed anamnesis including the duration and severity of stress incontinence was obtained from the patients. All patients had symptoms for more than four years. Symptoms were found to be grade 2 (grade 1-3) according to the Ingelman-Sundberg scale. Vaginal examination and transvaginal ultrasonography were performed on all patients. All menopausal patients were administered local estrogen treatment and 112 of the patients participating to the research were sexually active. For urogynecologic evaluation, a stress test was applied in standing and lying positions after the urinary bladder had been expanded with 300 ml isotonic solution. Twenty-four and 48 hour pad follow-ups were performed. Cystometry and urodynamic tests were used on all patients for the discrimination of stress and urge urinary incontinence. Urodynamic evaluation was done using a specific device. A sterile 8 French dual channel cystometry catheter was placed into the urethra and a rectal catheter with a five-ml balloon was placed into the rectum when the patient was in the lithotomy position. Cystometric assessment was done after the residual urine measurement had been taken. The urinary bladder was filled with saline solution at room temperature at a rate of 50 ml/min and the patient was asked to cough after each 100 ml filling. Urinary incontinence occurred in the while was detected and diagnosis of stress incontinence was made. Urodynamic diagnosis of detrusor instability (urge incontinence) was made upon detection of an elevation of 15 cm H₂O or above in basal detrusor pressure in cystometry.

All patients were administered two grams of parenteral cefazolin preoperatively for antibacterial prophylaxis. While the pa-

tients who underwent only TVT-O did not receive vaginal lavage, this procedure was applied preoperatively to the patients who underwent additional surgery (cystocele). TVT-O procedure was performed as described by Deval *et al.*

Exclusion criteria

Patients were excluded from the study if they had received general or local anesthesia, had undergone vaginal surgery except for anterior repair, desired to have a baby or if they had severe systemic diseases or mixed urinary incontinence with urge incontinence predominance in urodynamic tests. These situations may affect the rate of complications, the authors also excluded slings that had materials other than monofilament polypropylene, and patients who were suspected of having a neurologic bladder conditions.

Concomitant surgery

Thirty patients diagnosed with anterior wall defect (cystocele) according to the POP-Q staging, underwent anterior wall repair without mesh. Regional (spinal) anesthesia was applied to all patients.

Surgical technique

The anterior wall of the vagina was incised two cm sagittally and two cm below the urethra in the dorsal lithotomy position. The ischiopubic bone was approached digitally by separating the paraurethral areas with sharp and blunt dissections. The skin was incised on the line crossing the clitoris and one cm lateral to the ischiopubic ramus. A synthetic prolene band was placed (inside-out) using sloping trocars in order to pass from the suburethral area to near the medial part of the obturator foramen.

Cystoscopy was performed to evaluate the bladder and urethra after the procedure. Patients who had a cystocele operation underwent the additional intervention after the prolene band had been placed. Afterwards, a stress test was applied, the band level was adjusted and the operation was terminated. The duration of the TVT-O, cystoscopy and if performed, the additional operation, were recorded. All patients were monitored with a Foley catheter for bladder drainage for 24 hours. The catheter was removed if residual volume was below 100 ml at the end of 24 hours and intermittent catheterization was performed if post-voiding residual volume was above 100 ml. Similar protocols were applied for pre-, peri-, and postoperative assessments in both clinics. In terms of diagnosing the patients with postoperative urinary tract obstruction, conditions such as Qmax below 12 ml/s and pdetQmax above 60 cm H₂O have to be fulfilled. All surgical procedures were performed by one or two members (MB, AEY) of the surgical team.

Assessment of complications

An assessment of perioperative and postoperative complications was made for each patient. Perioperative complications were recorded after surgery by the surgeon. Immediate and late postoperative complications were also recorded during the patient's hospital stay and by the follow-up visit (after two and six months, one and two years up to 42 months). A great majority of the patients had regular follow-ups and medical examinations during which their complaints and vaginal examination findings were reported. In the later years, the patients who were missing their follow-ups were contacted by phone and questioned for late operative complications.

Statistical analysis

Statistical analyses were done using SPSS 15.0. Mean values were estimated using a *t*-test and ratios were estimated using a Chi-square test. Constant data were given as mean \pm standard deviation (SD).

Table 1. — Descriptive characteristics of the cases.

Mean age \pm SD (years) range	48.43 \pm 6.24 (36-63)
Mean parity	5.24 \pm 2.86 (2-13)
Mean body mass index	23.7 \pm 5.2

Table 2. — Diagnosis and distribution.

Stress incontinence	n = 100 (64.1%)
Mixed incontinence	n = 56 (35.9%)
Previous incontinence surgery	n = 20 (12.8%)
Concomitant surgery (only anterior repair)	n = 30 (19.2%)
Sexually active patients	n = 112 (71.7%)
Number of patients in menopause	n = 64 (41%)

n = patient number.

Results

The mean duration of follow up was 30.3 \pm 7.4 (range 17-42) months. The mean age of the patients was found to be 48.43 \pm 6.24 (range 42- 68) years. Mean parity of the patients was 5.24 \pm 2.86 (range 2-13) and mean body mass index was found to be 23.7 \pm 4.8 (Table 1). Diagnosis and distribution of the patients are shown in Table 2 and also diagnosis and distribution of the patients are shown as a graph in Figure 1.

Mean operative time was found to be 13.8 \pm 5.16 minutes in patients who underwent only TVT-O and TVT-O anterior

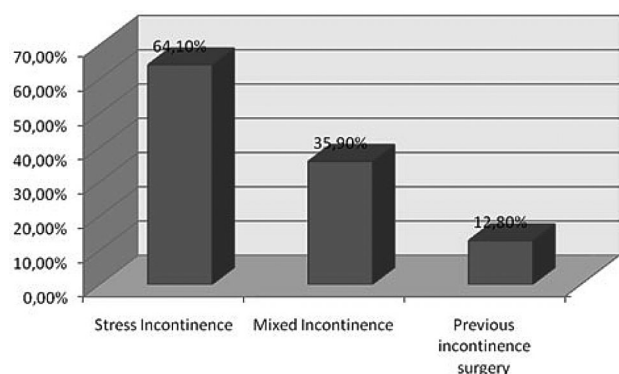


Figure 1. — Diagnosis and distribution.

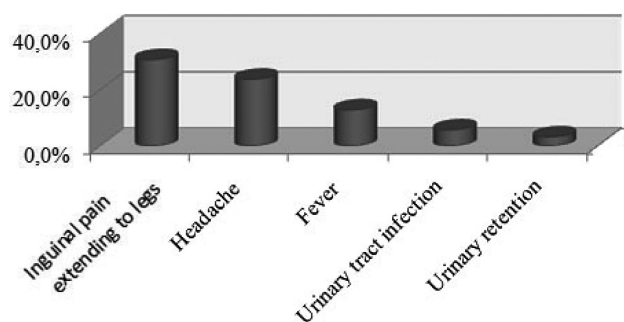


Figure 3. — Early postoperative complications.

Table 3. — Perioperative complications.

Vaginal injury concerning lateral fornix	7 (4.4%)
Haemorrhage more than 200 ml	5 (3.2%)
Vascular damage	3 (1.9%)
Haematoma on the leg	3 (1.9%)
Haemorrhage more than 500 ml	1 (0.6%)
Bladder perforation	2 (1.2%)
Urethral damage	-
Intestinal injury	-
Nerve injury	-

Table 4. — Early postoperative complications.

Inguinal pain extending to legs	48 (30.7%)
Headache	37 (23.7%)
Fever	20 (12.8%)
Urinary tract infection	9 (5.7%)
Urinary retention	5 (3.2%)

Table 5. — Late postoperative complications.

Dyspareunia	8 (7.1%)
De novo urge incontinence	14 (8.9%)
Worsening urgency	14 (8.9%)
Vaginal erosion	7 (4.4%)
Perineal pain	7 (4.4%)
Obturator abscess	-

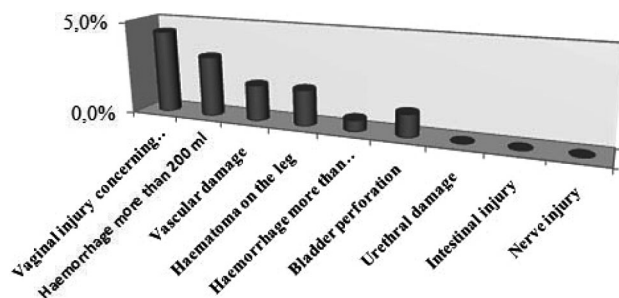


Figure 2. — Perioperative complications.

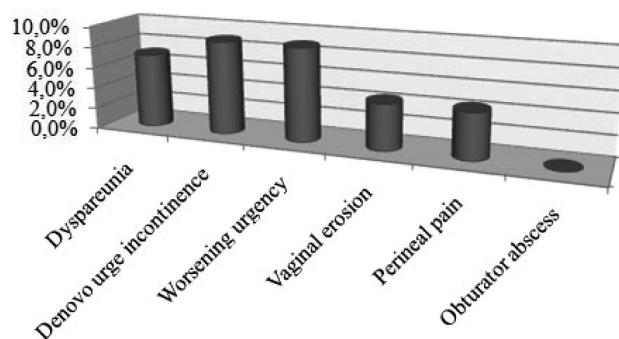


Figure 4. — Late postoperative complications.

repair. Perioperative, early, and late postoperative complications are shown in Tables 3, 4, 5, and Figures 2, 3, and 4.

Although IUGA/ICS classifications did describe a specific terminology particularly for mesh erosions (mesh erosion into the urinary tract, mesh exposure through the original incision, and mesh extrusion through the vagina other than the incision) in this research, the authors decided to use the most commonly utilized definition, the “mesh erosion” to specify the mesh complications.

Discussion

Retropubic and transobturator midurethral synthetic slings are now considered gold standard procedures for primary surgical treatment of stress urinary incontinence in women. The less invasive nature of MUS has significantly reduced many forms of surgical morbidity. Unfortunately, minimal invasive incontinence surgery does not necessarily guarantee minimal risks. Although the transobturator midurethral sling was designed to minimize bladder and bowel perforation, complications such as thigh pain and neurological pain are known to occur. Bladder perforation is one of the more common intraoperative problems encountered with retropubic midurethral sling placement, occurring in 2.7%–6% of a large series [7–9].

In a multi-center study carried out by Costa *et al.*, the overall perioperative complication rate of the TOT operation was found to be 2.2%. Vascular damage, nerve, and intestinal injury did not occur. Postoperative urinary retention was detected at a rate of 3.3% [10]. Urinary retention was found to be 2.4% in another study and vascular damage, nerve, and intestinal injury did not occur either in this study [11]. In order to definitely ensure that no bladder injury has occurred during the TVT-O procedure a cystoscopy would be necessary and can be recommended although is not the current practise with TVT-O users. The present authors performed a cystoscopic examination in all of their patients to assess the urethra and bladder.

Two perioperative bladder injuries occurred in the present study (0.12%). One of these cases was 64-years-old and had severe atrophic vaginitis and bladder injury occurred during creation of the lateral dissection towards the right obturator area. This case was associated with marked cystocele secondary to a lateral defect and was injury discovered during the cystoscopic examination done for bladder injury. The other patient had a history of previous incontinence surgery and diagnosis was made with urine originating from the vagina. As for the two patients in the present study, bladder perforation usually does not need any further therapy except catheter drainage for two to four days. Concomitant procedures and previous vaginal surgery appear to be risk factors for low urinary tract (LUT) injuries with TVT-O and therefore extra care should be taken during incision and dissection. It should be kept in mind that

bladder injury cannot always be detected in cystoscopic examinations; some of these patients may be admitted to the clinic with complaints of urinary tract infection or chronic pelvic pain. LUT injury is seen at a rate of around 1% in the literature and distributed as 0.5% urethral injury and 0.5% bladder injury. Bladder injury was mostly seen in cases operated on using the outside in the technique [12]. None of the present patients developed urethral damage, nor did they experience intestinal or nerve injury. There are multiple reports of bowel injury during urinary incontinence surgery [13, 14]. Fortunately, this is a rare complication. Bowel injury may occur during entry into the retropubic space during an autologous pubovaginal sling or urethrolisis, or during passage of needle passers or trocars during midurethral slings. These can be devastating complications leading to sepsis, abscess, and even death [13].

Sivanesan *et al.* did not encounter bladder or urethra injury in the 167 cases that underwent TOT. The mean operative time (14.7 min., range 12–28 min, median 14 min.) was similar to that found in the present study (13.8 min). Blood loss was found to be less than 100 ml in 97.8% of the patients [15]. While hemorrhaging more than 200 ml was 3.2%, hemorrhaging more than 500 ml was found to be 0.64% in the present TVT-O procedures. Hemorrhaging is relatively rare in TVT-O applications. Hemorrhage, defined as blood loss greater than 200 ml or postoperative hematoma, occurs in approximately 2% of patients and can usually be managed by observation or local compression. When the causes of hemorrhaging were analyzed in the present study, vaginal plexus injury or absence of a dissection line between the vaginal wall and bladder, or both were seen. One of the intraoperative complications was vaginal bleeding and intramuscular hematoma due to vascular injury. In the present research, vascular injury bleeding cases were higher than the expected, a total number of three patients bled during surgery due to the vascular injury; two of these patients received erythrocyte suspension treatment and the parenteral iron supplementation was adequate to treat the third patient.

In a study by Krauth *et al.*, 0.5% bladder injury, 0.3% vaginal wall injury, 0.8% hemorrhage of 200–300 ml, and 0.33% perineal hematoma were detected. Urethral wall injury was not seen. In the postoperative period, temporal retention (1.5%), temporal pain (2.3%), urinary tract infection (2.5%), and temporal dysuria (1.3%) were detected [16]. In the present series, urinary retention occurred in seven cases (4.4%).

One of the early postoperative complications was urinary system infections. A urinary tract infection occurred in nine (5.7%) and was managed with oral antibiotics. None of the present patients ever suffered from surgical site infections. The low rate of surgical site infection is due the preoperative antibiotic administration, meticulously applied hemostasis, and overall high fidelity to the antisepsis rules. Postoperative obstruction and urinary retention are another

challenging complication. Urinary retention may first be recognized when the patient fails to empty her bladder at the first voiding trial after MUS surgery.

While urinary retention rate is 8-17% in TVT, this rate is around 1-3% in TOT [11]. However, high rates as 13.3% which were considered to develop due to urinary retention have also been reported [16]. Of these cases, while four recovered with intermittent catheterization, urethral dilation was needed in two patients and mesh removal was needed in one patient [16]. The most important factor for urinary retention development is thought to be extensive stretching of the suburethral sling system [17]. When the patient cannot void after MUS surgery, many surgeons prefer indwelling bladder catheterization up to one week (three to seven days) and retesting the patient after catheter removal.

In the present study, urinary retention, which the authors evaluated in the postoperative early complications, occurred in five cases (3.2%). While three of these cases recovered with intermittent catheterization, urethral dilation was required in one and mesh removal was required in another. A clinical improvement was obtained in the latter case although the mesh was removed partially. Urinary retention is temporary in most cases as in three cases in the present study.

Subcutaneous and intramuscular hematoma in the inguinal region occurred in three patients (1.92%). Multiple manipulation of the guide and manipulations that cannot be made towards the targeted outlet site have led to this condition.

Some of the most common early postoperative complications can be listed as inguinal pain radiating to the leg, headache, and fever. In the present research, headaches related to the spinal anesthesia can be taken under control by the administration of caffeinated drinks and increased fluid intake. To alleviate the leg pain and fever non-steroidal anti-inflammatory drugs were administered to the patients.

Persistent groin or thigh pain is one of the most important complications of the transobturator route and its incidence after TOT ranges from 8% to 17% [18-20]. A higher incidence of pain in the transobturator approach could be due to the passage of trocars through the tissues (muscles, tendons, and sometimes nerves) in case of TVT-O. The reasons explained for pain in TOT tapes are adductor muscle injury/strain, osteitis pubis, obturator/groin abscess, inflammation, and edema or nerve entrapment of the anterior branch of the obturator nerve, and structural adhesions [21]. To explain the possible reason and pathophysiology of perineal and groin pain, they are associated to recent operation related pain which persists and exist initially or may develop years after the operation.

Postoperative inguinal pain was reported at a higher rate than other complications in TOT procedures. Inguinal pain was reported to disappear within few weeks and two months [11, 18]. In the present study, the most common early postoperative complication was inguinal pain that ex-

tended to the legs. Patients experience pain particularly with movements. In the present authors' opinion, this condition may be explained with the proximity of the band outlet site to the origin of the gracilis and adductor muscles. This unwanted condition, seen in 48 of 156 patients (30.7%), was the most common condition requiring analgesic together with headaches which are a complication of spinal anesthesia.

Pain in the upper part of the thigh was seen in 5% - 26% in the literature [19, 22]. This pain is a subjective finding - pain scales often thought to be objective may vary between individuals - may explain the variability of complication rates.

A regional or local anesthesia is often preferred in retropubic operations and the ones who received spinal anesthesia were analyzed in the present study. Spinal anesthesia-related headache was seen at a rate of 23.7%. Headache was controlled by increasing fluid intake and caffeine containing analgesics. In the present authors' opinion, use of local anesthesia will lead to a reduction in headache complications.

Vaginal erosion seen in broad range and its incidence is reported to range from 1.7% to 20% in the literature [23-25]. Some possible reasons for vaginal extrusion have been suggested to be wound infection, impaired wound healing, an improper vaginal dissection plane, and vaginal atrophy. Symptoms of vaginal erosion include vaginal discharge, a palpable rough surface in the vagina, sexual discomfort (usually partner related), and lower urinary tract symptoms including hematuria. The mean time to erosions varies, which emphasizes the need to pay attention when symptoms like vaginal discharge, pain or dyspareunia occur even after a long period.

A high index of suspicion is required. The management options are not standardized and range from observation to partial and complete tape excision and reapproximation of the vaginal mucosa over the exposed tape. Mesh erosion that the present authors evaluated in postoperative late complications occurred in seven out of 156 cases (4.4%). One of these patients wanted the mesh to be removed. In six other patients, vaginal repair had been realized using vaginal rhomboid flap technique.

Gambriosio *et al.* applied TOT to 233 cases and followed up for 27 months. Mesh erosion was found at a rate of 7.6% in this series. The rate of mesh erosion varied between 0% and 17% with varying brands of mesh use [25]. Comparisons with other mesh types could not be made as the same type of mesh was used in the present study.

Another important concern is emergence of de novo urgency after TVT-O procedure. De novo urgency, although claimed to be the complication with the strongest negative impact on quality of life, is sometimes self-limiting. When a patient complains of urgency after surgery, the surgeon must rule out and remove specific causes of urgency, such as urethral erosion, intravesical tape, urinary retention, or

recurrent urinary tract infections. If urgency and urinary urge incontinence persist, oral antimuscarinic agents are first-line therapies. Should they fail, alternatives (intravesical vanilloids, intradetrusor injection of botulinum toxin, and sacral neuromodulation) may be proposed. The hypothesis that tape location closer to the bladder neck correlated with a higher risk of dysfunction.

De novo urge incontinence was investigated by Juma and Brito. In their study, while a persistent urge was detected in 21 out of 130 patients (16%), de novo urge incontinence developed in only one (2%) patient [26].

De novo urge incontinence was found to be 2% - 22.1% in the different series in the literature [26-28]. In another study done in 2011, de novo urge incontinence was reported to be seen 13.4% in the first six months, 19.3% at the 12th month, and 22.1% at the 36th month in patients who had undergone TOT and TVT. De novo urge incontinence was found to be significantly higher in the TVT group compared to the TOT group. De novo urgency was significantly more frequent in the TVT group than in the TOT group at 12 (22.2% vs. 11.2%, $p = 0.025$), 24 (24.8% vs. 12.3%, $p = 0.033$), and 36 (0% vs. 24.7%, $p = 0.034$) months [28]. This study indicates that frequency of de novo urge incontinence increases in parallel with postoperative periods. Recognition of this condition requires subjects to be examined meticulously in postoperative checks. De novo urge incontinence was found to be 8.9% in the present study. Worsening injury was found to be 8.9%. Worsening urgency was reported to be 5-25% following mid-urethral sling surgery [29]. Given that 35.9% of the patients in the present study group had mixed incontinence, 8.9% is an acceptable rate. Mixed incontinence is a risk factor for de novo urge incontinence. In four other patients, the present authors had to prescribe anticholinergic treatment. The symptoms improved in all these four patients who had a good compliance to treatment.

Persistent urge rate was found to be 16.4% in patients who underwent a mid-urethral sling procedure for mixed incontinence [30]. In a review it was reported that mixed incontinence could be treated successfully with a mid-urethral sling however persisting urge symptoms could significantly affect the quality of life of the patients [31].

One of the postoperative complications that impair the quality of life after the mid urethral sling technic is sexual dysfunction. Dyspareunia is only one form of sexual dysfunction but it may occur following anti-incontinence surgery as vaginal anatomy is altered by these types of treatments. The vaginal axis can be shifted, changing the angulation of the vaginal canal, and narrowing of the vagina may occur as a result of aberrant scarring. Dissection along the anterior vaginal wall may result in nerve injury and neuroma formation. In the present study, most women were sexually active (71.8%) and among them 7.1% reported de novo dyspareunia after the operation. In a retrospective cohort study, Chohan *et al.* found that none

of the 25 patients undergoing retropubic tapes reported dyspareunia whereas four of 17 (24%) of the patients in the TOT group complained of de novo dyspareunia [32]. Chohan *et al.* reported the finding of paraurethral bands— anterior vaginal wall banding in the paraurethral folds immediately adjacent to the midurethral placement of the sling in all patients in the TOT group complaining of dyspareunia and in none of the patients in the retropubic group. Contrary to the studies reporting that dyspareunia did not develop following the TOT procedure, studies are also available reporting relatively high rates such as 24% [33, 34]. The importance of the duration of the follow-up period on determining postoperative late complications is clear. Complication rates may increase as the follow up period prolongs. Of the postoperative late complications, perineal pain is reported to occur in 2.3% to 5% after transobturator surgery, to be transient, resolving within the first month [16, 22]. The present authors also found similar results in this study (4.8%).

Finally, in another study investigating complications similar to the present study, 363 patients were followed up for 36 months and 50 (13.8%) patients were seen to develop complications. Twenty-one patients (42%) developed irritative symptoms of the lower urinary tract, ten (20%) developed externalization of the mesh to the vagina, three (6%) developed necrotizing fasciitis, three (6%) developed obturator or vaginal abscesses, five (10%) developed chronic pelvic pain (thigh pain or dyspareunia), two (4%) experienced bruising and bleeding, three (6%) experienced urinary tract infection, and one (2%) mesh entering the bladder, which showed signs ten months after surgery [35]. Urinary tract infection rates were also similar in the present study (5.7%).

Tape-related infections include swelling, redness, and pus formation in the skin puncture area; abscess formation in the skin, retropubic space, deep tissues around the obturator membrane, and adductor compartment of the thigh; and necrotizing fasciitis. Infections in the deep tissues around the obturator membrane are particularly dangerous because of the presence of a foreign body, confined space, and relatively low oxygen tension can lead to rapid abscess formation resulting in necrotizing fasciitis [21]. Inguinal abscess was reported in TOT and it is more frequent with certain sling materials [19, 36]. Obturator abscess which is one of the late postoperative complications did not develop in the present series.

In the present research, identifications of some complications in a retrospective manner, subjective evaluation of perioperative complications as headache, pain radiating to the leg, and postoperative complications as dyspareunia and perineal pain are the limitations of the present research. Another limitation of this research is the admission of patients with previous incontinence surgery to the research; in this way the present authors attempted to form relatively heterogeneous patient groups and ensure the admission of pa-

tients with concomitant surgery. Because of the aforementioned reasons, the severity and degree of the patient complaints cannot be evaluated and the research results may present high complication rates due to the heterogeneity of the patient group. Although aforesaid limitations of the research, long patient follow-ups, determination of complications by clinical follow-ups, being a prospective study, realization of the research only in two centers, execution of the surgeries by two surgeon experienced in urogynecology either side by side or one by one, admission of patients with similar demographic background, utilization of one type mesh, and same type of surgical kit are the main factors that increase the validity of this research. As a result, although TVT-O is a minimal invasive technique, contrary to the common belief, the complication rates of the surgery are not low. As seen in this research, urinary bladder and vascular injury were minimal/lower than expected; it has been also shown that major perioperative complications are rare with TVT-O surgery: in the present research urethral, intestinal, and neural injuries never took place. However this research revealed that early and late postoperative complications are not a rare case. It is very important to evaluate the patients meticulously and frequently to elicit the late complications. Most of the early and late postoperative complications can be cured or treated with simple applications and medical treatments or surgical interventions, therefore omission of these complications can be facilitated. According to the present authors, perioperative complications can be minimized with the experience and suspiciousness of the surgeon although it is impossible to state the same for early and late postoperative complications. The authors recommend that patients be thoroughly informed preoperatively about the possible complications of TVT-O surgery.

Conclusion

Although the TVT-O technique is a minimal invasive surgery method applied to treat urinary incontinence surgically, it does not signify that it is a complication-free surgical procedure. Despite the low incidence of intraoperative complications, there is a mild risk of early and late postoperative complications. Fortunately these complications can be taken under control by either conservative and simple medical treatments or surgical procedures.

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