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## INTRODUCTION

Stress urinary incontinence (SUI) is among the most prevalent urogynecological disorders worldwide and significantly impairs women's quality of life. Population-based studies report its prevalence ranges from 25% to 45% (1). SUI is not only a physical health problem but also a significant public health issue with multifaceted consequences, including loss of

productivity, social isolation, depression, sexual dysfunction, and increased healthcare costs. Therefore, developing effective and safe treatment strategies is critically important for women's health.

In patients with SUI refractory to conservative management, surgical intervention becomes the primary treatment modality. Although Burch colposuspension and pubovaginal slings

# Comparison of clinical outcomes of TVT and TOT procedures and the role of the methylene blue test in detecting bladder perforation

## Abstract

**Aim:** Stress urinary incontinence is commonly treated with mid-urethral sling procedures such as tension-free vaginal tape (TVT) and transobturator tape (TOT). Cystoscopy is widely used to detect intraoperative bladder injury during retropubic sling placement, yet access and routine use vary between centers. We compared perioperative outcomes of TVT and TOT and described the pragmatic role of an intravesical methylene blue leak test as an intraoperative screening maneuver in settings where immediate cystoscopy is not available.

**Materials and Methods:** This retrospective two-center cohort included 131 women who underwent TVT (n=62) or TOT (n=69) between 2020 and 2025. Demographics, operative time, hemoglobin change, postoperative CRP, post-void residual urine, and complications were analyzed. Intraoperative bladder integrity assessment (cystoscopy and/or methylene blue leak test) followed center-based protocols and equipment availability, and postoperative cystoscopy practices were recorded.

**Results:** Demographic and perioperative parameters were similar between groups. Operative time, hemoglobin change, CRP levels, and residual urine showed no significant differences ( $p>0.05$ ). Complication rates were 6.5% in the TVT group and 1.4% in the TOT group ( $p=0.25$ ). One intraoperative bladder perforation occurred during TVT and was identified by dye leakage at the incision site during the methylene blue leak test; this event was documented in a supplementary video. Intraoperative and postoperative evaluation practices differed between centers and procedures.

**Conclusion:** TVT and TOT showed comparable short-term perioperative outcomes with low complication rates. In a single video-documented TVT case, an intravesical methylene blue leak test allowed immediate recognition of bladder perforation at the incision site. Although cystoscopy remains the reference standard this single illustrative observation suggests that the methylene blue leak test may provide a practical intraoperative warning sign when cystoscopy is unavailable. The diagnostic performance of this approach cannot be determined from this cohort and requires prospective evaluation.

**Keywords:** Midurethral sling, tension-free vaginal tape, transobturator tape, bladder perforation, methylene blue test

were long considered standard surgical procedures, their invasiveness and complication profiles have gradually led to their replacement by mid-urethral sling techniques. Owing to their minimally invasive nature, short learning curve, and high success rates, tension-free vaginal tape (TVT) and transobturator tape (TOT) are among the most commonly used surgical approaches for the treatment of SUI (2,3).

Randomized controlled trials and meta-analyses have shown that both techniques achieve comparable success rates in efficacy. However, their complication profiles may differ, particularly with higher bladder perforation rates reported for retropubic approaches and increased groin pain associated with transobturator techniques (4). The literature indicates that bladder perforation and voiding dysfunction occur more frequently with TVT, while groin and thigh pain are more commonly associated with TOT (2,5,6). Nevertheless, the incidence of serious complications remains low for both procedures, and long-term success rates have been reported to exceed 80% (3,7).

Early detection of intraoperative complications is essential for patient safety. Intraoperative cystoscopy is one of the most frequently used methods for this purpose. Cystoscopy provides direct assessment of bladder and urethral integrity and allows immediate identification of injuries that may occur during sling placement (8,9). However, cystoscopy may not be routinely available in all hospitals, requires technical expertise, and increases the cost of the procedure. Therefore, although it is highly effective in detecting acute intraoperative injuries, its use should be weighed against considerations of availability and cost. In some centers, simpler and more cost-effective alternatives, such as methylene blue testing, may be preferred (10,11). While cystoscopy is considered the gold standard, there is increasing discussion about the role of simple adjunctive methods that can provide intraoperative reassurance. Among these, the methylene blue test is an inexpensive, feasible, and easily applicable tool that may serve as a safety check in selected cases.

Beyond comparative perioperative outcomes, there is ongoing heterogeneity in intraoperative safety assessment during mid-urethral sling surgery, particularly across centers with differing resources and equipment availability. While cystoscopy is widely regarded as the reference standard for detecting intraoperative bladder injury—especially during retropubic sling placement—its routine use may be limited by logistical, technical, or economic constraints in some settings. Consequently, pragmatic adjunctive screening maneuvers continue to be used in real-world practice, despite limited formal evaluation.

Intraoperative safety assessment during mid-urethral sling surgery remains heterogeneous across centers, particularly in settings with differing resources and equipment availability. In this context, we aimed to compare the short-term perioperative

outcomes of TVT and TOT procedures. We also aimed to describe real-world intraoperative and postoperative evaluation patterns and to present an illustrative intraoperative warning sign observed during an intravesical methylene blue leak test in a resource-constrained setting.

## MATERIALS AND METHODS

### Study Design and Setting

This study was designed as a retrospective, two-center cohort analysis. Female patients who underwent surgery for stress urinary incontinence between 2020 and 2025 at Gaziosmanpaşa Education and Research Hospital and Simav Doç. Dr. İsmail Karakuyu State Hospital were included. Ethical approval was obtained from the Ethics Committee of Gaziosmanpaşa Education and Research Hospital (Approval no: 42, dated: 06/11/2024). Additional approval for the two-center design was granted by the same committee on 17/09/2025. The research was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all patients at hospital admission, including permission for the use of their anonymized clinical data in future research.

### Study Population

Patients were included if they had a confirmed diagnosis of stress urinary incontinence based on clinical and urodynamic evaluation, had undergone surgery using either TOT or TVT technique, and had sufficient information in their medical records regarding intraoperative and postoperative outcomes. Patients were excluded if they had a history of prior anti-incontinence surgery, a diagnosis of neurogenic bladder, advanced pelvic organ prolapse, mixed urinary incontinence, or insufficient follow-up data.

### Surgical Procedures and Intraoperative Assessment

TVT and TOT procedures were performed using standard techniques as described in the literature (2,12). Intraoperative bladder integrity assessment was not standardized by the study protocol; instead, it was performed according to local center practice, surgeon preference, procedural risk profile, and equipment availability. Where intraoperative cystoscopy was available, cystourethroscopy was used to assess bladder and urethral integrity after sling placement. In settings where immediate cystoscopy was not available, an intravesical methylene blue leak test was performed as a screening maneuver: a diluted methylene blue solution was instilled retrograde through the Foley catheter after sling placement and before closure, and the vaginal incision, peri-mesh tissues, and mesh exit sites/skin incisions (e.g., suprapubic/pubis or groin incisions depending on the technique) were inspected for blue dye leakage suggesting bladder perforation. Because these intraoperative assessment strategies varied between centers and according to procedural context, surveillance intensity may have differed between TVT and TOT cases and may have influenced complication detection.

## Data Collection and Outcome Measures

Postoperative cystoscopy practices (routine postoperative cystoscopy versus symptom-triggered cystoscopy, including postoperative day 1 cystoscopy when used by local protocol) were recorded for each patient. Complications occurring during the study period (e.g., bladder perforation, fistula, mesh erosion, urinary retention) were also recorded. It should be noted that intraoperative and postoperative evaluation strategies were not standardized across centers and were influenced by local protocols, surgeon preference, and equipment availability. As a result, the intensity of intraoperative surveillance differed between procedures and centers, which may have influenced the detection of complications.

## Statistical Analysis

Data were analyzed using SPSS software. Continuous variables were expressed as mean  $\pm$  standard deviation, while categorical variables were presented as frequencies and percentages. The Shapiro–Wilk test was used to assess the normality of data distribution. Due to low frequencies, Fisher’s exact test was

applied for the comparison of complications. Comparisons between groups were performed using the Student’s t-test for continuous variables and Fisher’s exact test for categorical variables. A p-value of  $<0.05$  was considered statistically significant.

## RESULTS

A total of 131 patients who underwent surgery between 2020 and 2025 and whose data were retrospectively accessible were included in the study. Of these, 62 patients were treated with the TVT technique and 69 with the TOT technique. All patients were followed for at least six months postoperatively.

Demographic and clinical variables are summarized in Table 1. The mean age was  $48.6 \pm 8.0$  years in the TVT group and  $48.3 \pm 6.2$  years in the TOT group, with no statistically significant difference ( $p=0.81$ ). Parity, number of cesarean sections, BMI, and history of abdominal surgery were also comparable between the two groups ( $p=0.06$ ,  $p=0.75$ ,  $p=0.42$ , and  $p=0.70$ , respectively) (Table 1).

**Table 1. Comparison of the patient group and control group in terms of sociodemographic data**

| Variable                     | TVT (n=62)       | TOT (n=69)       | p-value |
|------------------------------|------------------|------------------|---------|
| Age (years)                  | $48.6 \pm 8.0$   | $48.3 \pm 6.2$   | 0.81    |
| Parity                       | $2.9 \pm 1.3$    | $3.3 \pm 1.4$    | 0.06    |
| Number of cesarean sections  | $0.3 \pm 0.7$    | $0.4 \pm 0.7$    | 0.75    |
| BMI (kg/m <sup>2</sup> )     | $27.42 \pm 3.06$ | $26.98 \pm 3.13$ | 0.42    |
| History of abdominal surgery | 30/62 (48.4%)    | 30/69 (43.5%)    | 0.70    |

Data are presented as mean  $\pm$  standard deviation for continuous variables and as numbers with percentages for categorical variables. p-values were calculated using the Student’s t-test for continuous variables and Fisher’s exact test for categorical variables. Abbreviations: BMI; Body mass index

Perioperative outcomes are presented in Table 2. The mean operative time was  $29.8 \pm 6.4$  minutes in the TVT group and  $29.5 \pm 6.4$  minutes in the TOT group, with no significant difference ( $p=0.81$ ). Preoperative and postoperative hemoglobin values were also similar ( $p=0.95$  and  $p=0.80$ , respectively), and no statistically

significant difference in hemoglobin change was observed between the groups ( $p=0.72$ ). Postoperative day 1 CRP levels were  $11.5 \pm 8.1$  mg/L in the TVT group and  $11.2 \pm 8.3$  mg/L in the TOT group ( $p=0.79$ ). Residual urine volumes were similar, with no significant difference between groups ( $p=0.90$ ) (Table 2).

**Table 2. Comparison of perioperative outcomes between TVT and TOT groups**

| Variable                | TVT (n=62)       | TOT (n=69)       | p-value |
|-------------------------|------------------|------------------|---------|
| Operative time (min)    | $29.8 \pm 6.4$   | $29.5 \pm 6.4$   | 0.81    |
| Preoperative Hb (g/dL)  | $12.24 \pm 1.34$ | $12.26 \pm 1.56$ | 0.95    |
| Postoperative Hb (g/dL) | $10.79 \pm 1.22$ | $10.85 \pm 1.46$ | 0.80    |
| Hb change (g/dL)        | $1.45 \pm 0.66$  | $1.41 \pm 0.75$  | 0.72    |
| CRP (postop day 1)      | $11.5 \pm 8.1$   | $11.2 \pm 8.3$   | 0.79    |
| Residual urine (mL)     | $45.2 \pm 47.6$  | $46.0 \pm 25.0$  | 0.90    |

Data are presented as mean  $\pm$  standard deviation. p-values were calculated using the Student’s t-test. Abbreviations: Hb; Hemoglobin, CRP; C-reactive protein

Complications and intraoperative evaluation methods are summarized in Table 3. Complications occurred in 4 of 62 patients (6.5%) in the TVT group and in 1 of 69 patients (1.4%) in the TOT group, with no statistically significant difference ( $p=0.25$ ). In the TVT group, complications included one intraoperative bladder perforation, one vesicovaginal fistula, and two cases of mesh-related reaction (pain, irritation, erythema). In the TOT group, the only complication was postoperative leg pain in a single patient. Methylene blue testing and/or cystoscopy were performed more frequently in TVT cases than in TOT cases ( $p<0.001$ ). Postoperative cystoscopy was performed according to local protocol and clinical indication, and was more common after TVT than after TOT (Table 3). These differences in intraoperative and postoperative surveillance intensity may have affected the observed distribution and detection of complications between the two procedure groups.

The most noteworthy intraoperative event in this cohort was a single bladder perforation in the TVT group, recognized by the appearance of blue dye at the incision site during the methylene blue leak test (Video 1). The event is documented in Supplementary Video 1, (Figure 1).

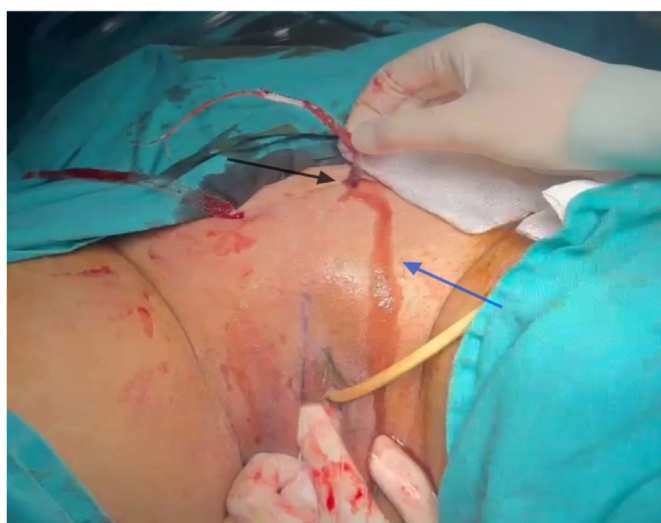
**Video 1.** *The surgical procedure of the modified lower one-third calf amputation is presented as supplementary material.*

Procedural practices are described in Table 3. In the TVT group, intraoperative evaluation (cystoscopy and/or methylene blue leak test) was performed in nearly all cases, reflecting local protocols and equipment availability. In the TOT group, intraoperative evaluation was performed less frequently due to the lower expected risk of bladder injury. Postoperative cystoscopy was performed either routinely or in response to symptoms, depending on center policy and clinical indication.

**Table 3. Complications and intraoperative/postoperative bladder evaluation methods in TVT and TOT procedures**

| Variable                           | TVT (n=62)    | TOT (n=69)    | p-value          |
|------------------------------------|---------------|---------------|------------------|
| Complication ( $\geq 1$ )          | 4 (6.5%)      | 1 (1.4%)      | 0.25             |
| • Bladder perforation              | 1 (1.6%)      | 0             | -                |
| • Vesicovaginal fistula            | 1 (1.6%)      | 0             | -                |
| • Mesh reaction                    | 2 (3.2%)      | 0             | -                |
| • Leg pain                         | 0             | 1 (1.4%)      | -                |
| Intraoperative methylene blue test | 60/61 (98.4%) | 32/69 (46.4%) | 12.26 $\pm$ 1.56 |
| Intraoperative cystoscopy          | 61/62 (98.4%) | 1/69 (1.4%)   | 10.85 $\pm$ 1.46 |
| Postoperative cystoscopy           | 62/62 (100%)  | 0/69 (0%)     | 0.79             |

Data are presented as numbers with percentages. p-values were calculated using Fisher's exact test



**Figure 1.** Bladder perforation during a TVT procedure. Following instillation of methylene blue through a catheter, leakage of dye is observed at the site of perforation (blue arrow). The exit point of the mesh at the pubis is indicated by the black arrow

## DISCUSSION

In this two-center retrospective study, TVT and TOT showed comparable short-term perioperative outcomes, with no significant differences in demographic characteristics, operative time, hemoglobin change, postoperative CRP levels, or residual urine volumes. Although complications were numerically more frequent in the TVT group, the difference was not statistically significant. These findings should be interpreted cautiously, as intraoperative and postoperative surveillance intensity differed between procedures and centers and may have influenced complication detection.

The most notable observation in this cohort was a single intraoperative bladder perforation in the TVT group, recognized during the methylene blue leak test when dye leakage was seen at the incision or mesh exit site (Video 1). This finding should be interpreted as illustrative rather than definitive, since no conclusion regarding diagnostic accuracy or clinical effectiveness can be drawn from a single event. Nevertheless, in settings where intraoperative cystoscopy is not immediately available, an intravesical dye leak test may provide a practical intraoperative

warning signal that prompts immediate reassessment of sling placement and early cystoscopic confirmation when feasible.

Bladder perforation is known to occur more frequently with the retropubic approach than with the transobturator route, and our cohort followed this expected pattern. This finding is consistent with recent meta-analyses demonstrating comparable efficacy between TVT and TOT procedures, with differences mainly observed in complication profiles related to the surgical approach (13). The originality of the present report lies in the video-documented illustration of dye leakage at the incision site during a confirmed bladder perforation, rather than in the evaluation of a diagnostic method.

Across the literature, the role of routine cystoscopy during mid-urethral sling surgery remains heterogeneous. Some recommendations support cystoscopy to rule out bladder injury during retropubic sling procedures (7), whereas others suggest it may be unnecessary in routine transobturator cases (14). This variation provides the clinical context for exploring pragmatic screening maneuvers—such as an intravesical dye leak test—when cystoscopy is not readily available.

Dye-based adjuncts have been described to facilitate intraoperative evaluation of the lower urinary tract and ureters in selected contexts (9,10). In our setting, intravesical methylene blue instillation was used as a practical leak screen when immediate cystoscopy was unavailable.

Importantly, the methylene blue leak test should not be presented as a replacement for cystoscopy. Rather, it may be described as a low-cost screening step that could be integrated into a safety algorithm: (1) intravesical dye instillation and inspection for leakage at the vaginal incision, peri-mesh tissues, and mesh exit sites/skin incisions; (2) low threshold for immediate reassessment/repositioning of the sling placement if leakage is present; and (3) cystoscopic evaluation intraoperatively when available or postoperatively when indicated by symptoms or local protocol.

Preoperative urodynamic measures—particularly maximal urethral closure pressure (MUCP)—may influence surgical planning and outcomes, especially in women with suspected intrinsic sphincter deficiency. MUCP data were not consistently available across centers in this retrospective cohort; therefore, we could not evaluate its predictive value. Future prospective studies incorporating standardized urodynamic parameters may help refine patient selection and contextualize perioperative outcome comparisons between sling techniques.

The rate of mesh-related complications in our study was 3.2%, which is consistent with the 2–10% range reported in the literature (15,16). In addition, one patient developed a postoperative vesicovaginal fistula. Although fistula formation following sling surgery is rare, similar case reports have been described in the literature (17,18). This finding further underscores the importance of long-term follow-up for the detection of complications.

The strengths of our study include the presentation of real-world data obtained from two different levels of healthcare delivery and the incorporation of a supplementary video documenting the intraoperative diagnosis of bladder perforation using the methylene blue test.

In recent years, the use of mesh materials in mid-urethral sling surgery has become a subject of international debate, leading to regulatory actions in some countries (7,19,20). Although our findings are not of a magnitude to alter the course of these debates, they demonstrate the critical role of intraoperative evaluation methods in the early diagnosis and management of complications. These findings primarily contribute to the understanding of real-world intraoperative safety practices across heterogeneous clinical settings and highlight an illustrative intraoperative warning sign rather than providing evidence for a diagnostic strategy. This observation should be interpreted as an illustrative intraoperative warning sign rather than as evidence of diagnostic effectiveness. Accordingly, the higher number of detected complications in the TVT group should be interpreted with caution, as more intensive intraoperative and postoperative assessment may have increased the likelihood of identifying adverse events in that group.

### Study Limitations

This study has several limitations. First, its retrospective design may introduce selection bias and unmeasured confounding. Second, differential intensity of intraoperative and postoperative surveillance between TVT and TOT procedures may have introduced detection bias, potentially influencing the observed distribution of complications. Third, the relatively small sample size and the very low event rate (only one bladder perforation) preclude any meaningful assessment of diagnostic performance for the methylene blue leak test. No *a priori* power calculation was performed; therefore, all statistical comparisons should be considered exploratory. Finally, the short follow-up period restricts evaluation of long-term functional outcomes, quality of life, and late mesh-related complications.

### CONCLUSION

In this two-center retrospective cohort, TVT and TOT demonstrated comparable short-term perioperative outcomes with low overall complication rates. A single bladder perforation occurred during TVT and was recognized intraoperatively by dye leakage during an intravesical methylene blue leak test (supplementary video). Given the single-event nature of this observation and the heterogeneity of evaluation pathways, these findings should be interpreted cautiously and should not be construed as evidence of diagnostic effectiveness or as support for replacing cystoscopy. When intraoperative cystoscopy is not immediately available, an intravesical dye leak test may be a pragmatic screening step that prompts early corrective action and/or timely cystoscopic confirmation. Larger prospective studies using standardized protocols are required.

**Conflict of Interests**

The authors declare that there is no conflict of interest in the study.

**Financial Disclosure**

The authors declare that there is no financial support.

**Ethical Approval**

The study protocol received approval from the Ethics Committee of Gaziosmanpaşa Education and Research Hospital (Approval no: 42, dated: 06/11/2024). Additional approval for the two-center design was granted by the same committee on 17/09/2025.

**Informed Consent**

Written informed consent was obtained from all participants prior to surgery, including permission for the use of anonymized clinical data as well as the publication of accompanying images and video materials. All identifying information has been removed to ensure patient confidentiality.

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