

Bladder filling test, cystoscopy, or both for checking bladder perforation in tension-free-vaginal tape operations

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Ethics Committee Approval

This study was approved by the Acibadem Mehmet Ali Aydınlar University, Medical School, Board of Ethics (No: ATADEK 2020/26). A written informed consent was obtained from each participant.

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest

No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Tension-free-vaginal tape (TVT) has been widely used for treatment of stress urinary incontinence as a mid-urethral sling operation. Cystoscopy is routinely performed during tension-free-vaginal tape operations to check for bladder perforation or injury. This study aims to check the applicability and accuracy of the bladder filling test for predicting bladder perforation in tension-free-vaginal tape operations.

Methods: Between 2015 and 2020, 285 women who had TVT operations were subject to evaluation. Out of 285 cases, 23 cases were suspected subjectively by the operating surgeons to have visible or occult bladder perforation during the TVT procedure. A routine cystoscopy was performed at the end of all operations. Additionally, before the routine cystoscopy, in cases suspected of a visible or occult bladder perforation, the bladder was filled with 500 ml saline or diluted methylene blue dye through a urinary catheter (bladder filling test) to check for occult bladder perforation that might not be visualized by cystoscopy. Any fluid leakage through the paraurethral dissected canals or from the abdominal incisions was observed for the possibility of bladder perforation. The accuracy of the bladder filling test was compared to cystoscopy to diagnose bladder perforation in suspected cases. In addition, all cases were followed up for three months to record any cases with late or occult bladder perforations missed in the diagnosis using cystoscopy or the bladder filling test perioperatively.

Results: Out of 23 cases suspected subjectively by the operating surgeons to have visible or occult bladder perforation, 11 had visible bladder perforations (3.9%) confirmed by both cystoscopy and the bladder filling test. After the filling test, leakage at the abdominal incision site and/or para-urethral dissected canal was observed in all cases with bladder perforation. No leakage was observed in the remaining patients (n = 12) suspected of, but not diagnosed with bladder perforation by cystoscopy. The bladder filling test did confirm the same diagnosis revealed by cystoscopy in all suspected cases.

Conclusion: The bladder filling test was found to be very sensitive in predicting bladder perforation at tension-free-vaginal tape operations compared to cystoscopy. This test can decrease the need for routine cystoscopy at tension-free-vaginal tape insertion, and cystoscopy can be limited to cases with leakage in the bladder filling test.

Keywords: Stress urinary incontinence, Tension-free-vaginal-tape, Bladder perforation, Cystoscopy, Bladder filling test

Introduction

Stress urinary incontinence (SUI) is a common worldwide disorder affecting 15-80% of women [1]. When conservative strategies fail, the preferred treatment is surgery. Mid-urethral sling operations are the gold standard for the treatment of SUI with long-term cure rate of 77-90% [2, 3]. Since first described by Ulmsten and Petros [4], tension-free-vaginal tape (TVT) has been widely used for SUI with satisfactory long-term outcomes [3, 5]. As a routine procedure, cystoscopy is performed during TVT operations to check for bladder perforation (BP), which is one of the main complications occurring at a rate of 4.5% [6]. If unrecognized, BPs may lead to serious postoperative complications, such as hematuria, irritative bladder symptoms, pelvic pain, recurrent urinary tract infections, bladder stones, and sinus tract formation [7-10]. Although cystoscopy is an effective procedure for diagnosing bladder pathologies, it is operator-dependent, and occult BP during mid-urethral sling procedures may not always be visualized by cystoscopy [11, 12]. Inadequate filling of the bladder during cystoscopy and/or using 30° lenses instead of 70° can lead to a false normal cystoscopic evaluation. The improper placement of a trocar through the submucosa with no visible tape at cystoscopy may later turn into an occult BP. This possibly results from trauma by the rough edge of the tape when the trocars are extracted [11].

Cystoscopy is not a difficult or complex procedure, but it increases the costs, prolongs the surgical time, and requires access to a camera stack, light source, and cystoscope. Despite being a minimally invasive procedure, cystoscopy also has risks like urethral stricture or bladder injury in addition to its minor complications like urinary tract infection, hematuria, and dysuria [13].

This study aimed to reveal the applicability and diagnostic accuracy of a fast and simple method that can be performed routinely to predict the BPs during the TVT operations and to decrease the need for routine cystoscopy for each patient at TVT insertion.

Materials and methods

Two hundred eighty-five women who had a TVT procedure with or without coexistent surgery from 2015 to 2020 were subject to evaluation. This study was approved by the Acibadem Mehmet Ali Aydınlar University, Medical School, Board of Ethics (No: ATADEK 2020/26). A written informed consent was obtained from each participant. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The surgeries were performed in the Egemed Hospitals in Aydın, and Acibadem Health Group Hospitals in Istanbul by two surgeons experienced in urogynecological surgery (UK and MTE). The TVT procedures without coexisting surgeries were performed under spinal anesthesia. A 10x450 mm polypropylene mesh kit produced by Düzey Medikal Cihazlar San. Tic. Ltd. Şti, Istanbul, Turkey was used. The pre-surgical data of age, body mass index (BMI), parity, smoking, menopausal status, hormonal replacement therapy, previous hysterectomy, and relevant systemic diseases with medications were recorded.

The preoperative assessment included the Pelvic Organ Prolapse Quantification (POP-Q) System, cough stress test, Bonney's test, Q-tip test, post-void residual volume, urine analysis, and pelvic floor ultrasound. For cases with POP > stage 2 and/or for those having urgency symptoms or post-void residual volume > 150 cc, urinary stress incontinence was urodynamically confirmed (a stable detrusor, maximum urethral closure pressure (MUCP) < 30 cm H₂O, Valsalva leak point pressure (VLPP) < 90 cm H₂O, maximum flow rate (Q_{max}) > 17 ml/s). For rating urinary incontinence symptoms in the last four weeks, patients were asked to complete a Turkish validated ICIQ-SF form [14]. The cases diagnosed with urinary tract infection were re-assessed after the proper antimicrobial treatment. All cases received cefazolin 1 gr + metronidazole 500 mg iv as prophylaxis 30 minutes before the surgery.

Out of 285 cases, 23 cases were suspected subjectively by the operating surgeons to have visible or occult BP during the TVT procedure. A routine cystoscopy was performed at the end of all TVT operations. Additionally, before routine cystoscopy, in cases suspected of a visible or occult BP, the bladder was filled with 500 ml saline or diluted methylene blue dye through a urinary catheter (bladder filling test) to check for occult BP that might not be visualized by cystoscopy. Any fluid leakage through the paraurethral dissected canals or from the abdominal incisions was observed.

The urethral catheters were withdrawn six hours postoperatively unless a BP occurred. Duration of catheterization was 10 to 14 days for the patients with BP. The patients with postoperative voiding difficulty were re-catheterized and evaluated after three and ten days of re-catheterization.

In all cases, the duration of the TVT and cystoscopy procedures were recorded separately. Co-existing surgeries if present, duration of hospital stay, and perioperative and postoperative complications were also recorded.

The patients were evaluated one week, one month, and three months after the surgery unless they had any complaints and/or complications existed. The early post-operative period was defined as one week after surgery. The subjective cure rates were self-evaluated by the patients one and three months after the surgery according to the schedule proposed, and designated as cured, improved, failed, or worsened.

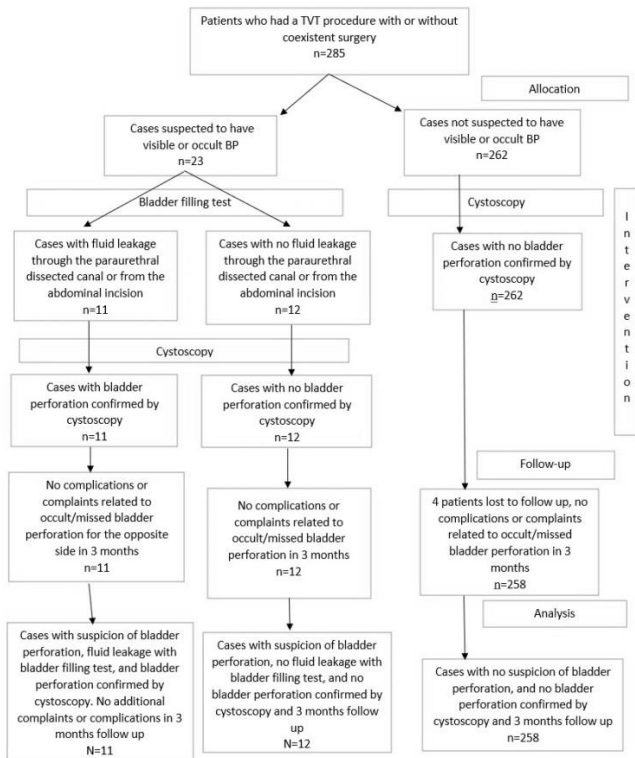
Statistical analysis

Statistical analysis was performed using the SPSS version V23 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean, standard deviation (SD), median (minimum-maximum) for quantitative data and in frequency (percentage) for qualitative data. Distribution of the variables was analyzed using the Shapiro-Wilk test. Analysis of quantitative independent variables was carried out using the Two-Sample Independent t-Test and Mann-Whitney U test depending on distribution of the data. The chi-square test and, when the assumptions of the chi-square test were not met, Fisher's exact test was performed for the analysis of qualitative independent data. Comparison of the dual categorized variables according to dual time was performed by McNemar test and for the comparison of more than two categorized variables, McNemar test was used. A *P*-value of <0.05 was considered statistically significant.

Results

Out of 285 women who had a TVT procedure with or without coexistent surgery, 23 were allocated for evaluation with a preliminary diagnosis of occult or visible BP. After the bladder filling test, 11 suspected cases had fluid leakage through the paraurethral dissected canals and/or from the abdominal incisions, and 12 of the suspected cases had no leakage. Routine cystoscopy that was performed after the bladder filling test revealed BP in all cases with fluid leakage and no BP in any of the cases without leakage. No complications or complaints related to occult/missed BP were recorded at the three-month follow-up period (Figure 1).

Figure 1: Flow diagram of case series.



Mean age and BMI of the suspected cases were 56.83 (13.49) and 26.92 (5.34), respectively. The characteristics of the cases are presented in Table 1.

There were no intraoperative complications other than BP that occurred in 11 patients (3.9%). Early postoperative complications other than BP were subcutaneous hematoma (n = 1), urgency (n = 2), urinary tract infection (n = 2) and voiding difficulty (n = 12). Subcutaneous hematoma and urgencies resolved spontaneously in the follow-up period. Urinary tract infections were treated with proper antibiotic administration. Voiding difficulties were resolved by short-term (three to ten days) catheterizations and none of the patients required a mesh release intervention. None of these complications occurred in the patients with BP.

There were no correlations between the occurrence of BP or early post-operative complications, and the characteristics of cases, such as age, BMI, parity, number and type of deliveries, menopausal status, smoking, chronic systemic illnesses, medication, hormone therapy, previous hysterectomy, and co-existing surgery (Table 1).

Table 1: The characteristics of the cases.

	Cases with bladder perforation n = 11	Cases with no bladder perforation n = 12	P-value
Age	55.27 (13.93) [‡]	58.25 (13.53) [‡]	0.609 [†]
BMI	25.88 (6.30) [‡]	27.87 (4.34) [‡]	0.385 [†]
Parity	2.00 (1.00 - 5.00) [†]	2.00 (0.00 - 4.00) [†]	0.880 ^U
Normal deliveries	2.00 (1.00 - 5.00) [†]	1.00 (0.00 - 4.00) [†]	0.190 ^U
Cesarean deliveries*			
No	10 (90.9)	8 (66.7)	0.317 ^F
Yes	1 (9.1)	4 (33.3)	
Menopause*			
No	3 (27.3)	4 (33.3)	1.000 ^F
Yes	8 (72.7)	8 (66.7)	
Smoking*			
No	8 (72.7)	8 (66.7)	1.000 ^F
Yes	3 (27.3)	4 (33.3)	
Systemic diseases*			
No	3 (27.3)	4 (33.3)	1.000 ^F
Yes	8 (72.7)	8 (66.7)	
Medication*			
No	4 (36.4)	3 (25)	0.667 ^F
Yes	7 (63.6)	9 (75)	
Hormone Therapy*			
No	10 (90.9)	11 (91.7)	1.000 ^F
Yes	1 (9.1)	1 (8.3)	
Previous hysterectomy*			
No	9 (81.8)	10 (83.3)	1.000 ^F
Yes	2 (18.2)	2 (16.7)	
Co-existing surgery ^{§,*}			
Anterior colporrhaphy	7 (87.5)	5 (83.3)	0.672 ^X
Pectopexy	2 (25)	1 (16.7)	
Posterior colporrhaphy	2 (25)	2 (33.3)	
Laparoscopic subtotal hysterectomy	0 (0)	1 (16.7)	
Sacrocopexy	0 (0)	1 (16.7)	
Sacrocolpopexy	0 (0)	1 (16.7)	

†: Independent-samples t-test. ^U: Mann-Whitney U test. ^X: Chi-square test. ^F: Fisher's Exact test. [‡]: Median (Minimum-Maximum); [†]: Mean (Standard Deviation). [§]: Multiple response. ^{*}: Number of patients (percentage)

Comparative analysis of data demonstrated that only total operation time ($P < 0.001$), duration of cystoscopy ($P < 0.001$), and mean hospitalization time ($P = 0.007$) increased in the cases with BP (Table 2).

Table 2: Preoperative, intraoperative, and postoperative evaluation of the cases.

	Cases with bladder perforation n = 11	Cases with no bladder perforation n = 12	P-value
ICIQ-SF score at first visit	15.45 (1.75) [‡]	15.17 (1.99) [‡]	0.880 ^U
Preoperative post-void residual volume (ml)	15.00 (12.00 - 18.00) [†]	15.50 (11.00 - 17.00) [†]	0.608 ^U
Cough stress test [†]	107.27 (51.98) [‡]	115.83 (48.14) [‡]	
Negative	80.00 (60.00 - 200.00) [†]	100.00 (60.00 - 200.00) [†]	0.317 ^F
Positive	1 (9.1)	4 (33.3)	
Bonney's test*			
Leakage	10 (90.9)	8 (66.7)	0.371 ^F
No leakage	2 (18.2)	5 (41.7)	
Q tip test angle*			
≤30	9 (81.8)	7 (58.3)	1.000 ^F
>30	4 (36.4)	4 (33.3)	
Preoperative urgency symptoms*			
No	7 (63.6)	8 (66.7)	0.590 ^F
Yes	10 (90.9)	9 (75)	
Preoperative urine analysis*			
Normal	1 (9.1)	3 (25)	N/A
Patients undergone for preoperative urodynamic*			
No	11 (100)	12 (100)	1.000 ^F
Yes	6 (54.5)	6 (50)	
Surgical time for TVT (minutes)	43.45 (4.89) [‡]	34.58 (3.99) [‡]	<0.001 [†]
Surgical time for cystoscopy (minutes)	44.00 (36.00 - 52.00) [†]	33.50 (28.00 - 40.00) [†]	
Hospitalization time (hours)	11.27 (1.10) [‡]	8.25 (1.60) [‡]	<0.001 ^U
Subjective cure of SUI at 1 st month*	11.00 (10.00 - 13.00) [†]	8.50 (6.00 - 10.00) [†]	
Cure	56.09 (9.06) [‡]	41.33 (14.00) [‡]	0.007 [†]
Improvement	54.00 (45.00 - 74.00) [†]	36.50 (27.00 - 74.00) [†]	
Subjective cure of SUI at 3 rd month*			
Cure	10 (90.9)	12 (100)	N/A
Failure	1 (9.1)	0 (0)	
Subjective cure of SUI at 3 rd month*			
Cure	9 (81.8)	12 (100)	0.217 ^F
Improvement	2 (18.2)	0 (0)	

†: Independent-samples t-test. ^U: Mann-Whitney U test. ^F: Fisher's Exact test. [‡]: Mean (Standard Deviation). [†]: Median (Minimum-Maximum); ^{*}: Number of patients (Percentage), N/A: not applicable

Subjective cure rates at the first and third months were described as cured, improved, or failed, and these are presented in Table 2. There was no statistically significant difference between subjective cure rates of the cases with BP and no BP at the first month and third month evaluations. Only two patients

presented with de novo urgency symptoms postoperatively, and cystoscopy of these patients was normal with no submucosal mesh.

The observed accuracy of the bladder filling test to diagnose BP was high. All patients without any observed leakage during the bladder filling test fell outside the BP complication confirmed by the following cystoscopy (Table 3).

Table 3: The observed accuracy of the bladder filling test.

		Bladder perforation diagnosed by cystoscopy*		P-value	Kappa (P)
		No	Yes		
Leakage after bladder filling test*	No	12 (100)	0 (0)	1.000 ^M	1.000 (<0.001)
	Yes	0 (0)	11 (100)		

M: McNemar test. *: Number of patients (Percentage)

Discussion

In this study, the evaluation of the case series with bladder perforation in TVT operations revealed that the bladder filling test was highly accurate in predicting bladder perforation.

SUI is a common worldwide disorder affecting 15-80% of women [7] and one in three women over the age of 18 will be affected by it at some point in their lifetime [6]. TVT has a high success rate of up to 90% for the surgical treatment of SUI confirmed by long-term follow-up data [3, 7]. The TVT procedure is associated with some complications, and BP is one of the most reported problems [7, 8]. The incidence of BP after TVT insertion is between 3.6 to 4.5% according to the literature [6]. The rate of BP in our case series, which was 3.9%, is consistent with the reports.

Modifications in TVT techniques to eliminate BP have been developed. However, BP is still inevitable for all modified techniques with varying rates [15, 16]. For all techniques, slinging the urethra requires a close operational space to the bladder, and the placement of the trocars is performed by blind movements out of the operator's sight. Therefore, elimination of this complication is difficult. A randomized clinical trial demonstrated that the route of retropubic trocar insertion, whether top to bottom or bottom to top, did not affect the BP rates [17], although some moderate quality evidence claimed the opposite [6]. The efforts to switch the insertion of tape to the groin (trans-obturator) instead of the abdomen (retropubic) decreased the complication rates; however, the BP rates, despite being lower, remained significant [8, 18]. An incidence of BP as high as 24% was also reported [17]. Reversing the trocar route (outside-in or in-outside) did not change the complication rates [19]. Moreover, the BP rates may be underreported due to unrecognized cases [7, 20]. Thus, in TVT and in trans-obturator tape (TOT) operations or even in the latest mini sling operations, routine cystoscopy is recommended for early detection of BPs [10, 12].

Recommendations for routine cystoscopy mainly depend on early recognition of BPs intraoperatively. Cetinel et al. [21] emphasized that cases of missed diagnosis would later require open or endoscopic surgery for removal of the tape inside the bladder. Otherwise, reinsertion of the tape intraoperatively and a few days of urethral catheterization postoperatively would be an adequate and timely solution.

However, cystoscopic evaluation may not detect all BPs [12, 21-22]. Cases with normal cystoscopic evaluation may still have perforated bladders diagnosed mostly by the related

postoperative symptomatology. The misdiagnosis may be due to inadequate filling of the bladder during cystoscopy and/or using 30° lenses instead of 70°, which may result in not seeing the perforation site that mostly occurs anteriorly. Shobeiri et al. [23] suggested that the improper placement of a trocar through the submucosa with no visible tape at cystoscopy may later turn to an occult bladder injury when the trocars are extracted due to trauma from the rough edge of the tape. In our study, we checked the fluid leakage after the extraction of the trocar, a technique that may exclude this probable injury and may eliminate all the imperfections of cystoscopy. Another study reported an undiagnosed occult perforation even using a 70° cystoscope, which was only detected by flexible cystoscopy soon after the operation [24]. Cetinel et al. [21] reported two patients who had BP with normal cystoscopy and the perforation was determined only by fluid leakage at the abdominal incision site after the trocars were removed. Buchsbaum et al. [25] reported a case of occult BP that could not be identified by cystoscopy, but was suspected after clear fluid leakage at the abdominal incision site. In another case report, missed perforation was diagnosed by vulvar edema presented four hours after the operation and confirmed by repeated cystoscopy [26]. All these case reports indicate the possible effectiveness of the method presented in this study, and to the best of our knowledge, there is no study in the literature that has investigated bladder filling technique systematically in a case series.

No patients from our study group presented with occult perforation during the follow-up period. Although we believe that our method could detect it intra-operatively, large scale, prospectively randomized studies are required to test the accuracy of the bladder filling test for occult BPs.

Along with the known risk of complications, cystoscopy increases costs and prolongs the surgical time. In addition, it requires access to a camera stack, light source, and cystoscope. Additional time due to cystoscopy was only mentioned in the literature at comparative studies between TVT and TOT reporting that surgical time for TOT operations was shorter. This outcome was postulated to be due to the surgical time saved from not performing routine cystoscopy in TOT operations [27, 28]. The mean cystoscopy time was 8.4 (1.14) minutes for our study group with a range of 5-13 minutes and mean total operation time was 34.8 (5.3) minutes. Cystoscopy took approximately 20% of mean total operation time, which supports the fact that the procedure significantly prolongs the operation when compared to the bladder filling test that usually takes 1-2 minutes. Therefore, the method we present in this study may help to shorten the surgical time and eliminate the requirement of cystoscopy instrumentation in most of the TVT procedures.

The cases with BP had longer operation, cystoscopy, and hospitalization times. However, statistical power was not sufficient to draw a firm conclusion due to the small number of perforated cases (n = 11).

Success and complication rates of this study were consistent with the current literature [29]. Although the outcomes of three months follow-up are not sufficient for a complete comparison, this follow-up period fills the requirements for the objective of this study.

This study has some limitations. Although specificity and sensitivity of the bladder filling test for diagnosing BP in TVT procedures were 100% in our study, large scale studies must be performed to validate these results for safely excluding cystoscopy in cases without leakage after the bladder filling test. No patients presented with occult BP in our study group; therefore, it was not possible to test the diagnostic performance of the bladder filling test for occult BPs.

Conclusion

Presence or absence of fluid leakage through paraurethral or abdominal incision sites following the bladder filling test accurately determined the existence or absence of BPs during TVT operations. Large-scale studies are required to validate these results, which may end in limiting the routine cystoscopy only to cases with leakage after the bladder filling test, thus, decreasing the total surgical time and the cost.

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