Comparison of three different midurethral sling operations using urodynamic evaluation

Üç farklı midüretral sling operasyonunun ürodinamik inceleme kullanılarak karşılaştırılması

Comparison of midurethral slings

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Öz

Amaç: Stress üriner inkontinansı olan hastalarda modifiye midüretral sling, tension-free vajinal tape ve transobturator tape operasyonlarının ürodinamik inceleme ile etkinliklerininin karşılaştırılması amaçlanmıştır. Gereç ve Yöntem: Stres üriner inkontinansı olan ve 2003 ile 2012 yılları arasında midüretral sling operasyonu olan 65 hasta çalışmaya dahil edildi. Preoperatif ve postoperatif ürodinamik değerlendirmeler analiz edildi. Sistometri operasyonları kür oranlarını saptamak için kullanıldı. Valsalva kaçak noktası basıncı, objektif kür oranlarını değerlendirmek ve karşılaştırmak için belirlendi. Bulgular: Operasyon tipleri arasında belirgin farklılık saptanamamıştır. Objektif kür oranları; modifiye midüretral sling, tension-free vajinal tape ve transobturator tape için sırasıyla %83.3, %88.9 ve %91.3 olarak saptanmıştır. Tension-free vajinal tape, intrinsik sfinkterik yetmezlikte diğer operasyon tiplerine göre daha etkin bulunmuştur. Valsalva kaçak noktası basıncı operasyonların başarısını göstermek için kullanılmıştır. Basınç değerlerine göre, stres üriner inkontinans hastalarında objektif olarak tam kür veya iyileşme sağlandı. Sadece 8 hastada postoperatif valsalva sonrası kaçak tespit edildi, bu hastalarda da preoperatif düzeylere göre valsalva kaçak noktası basınçları daha yüksek değerlerde saptandı. Tartışma: Midüretral sling operasyonlarının etkinlikleri gruplar arasında farklı bulunmadı. Valsalva kaçak noktası basıncı objektif kür oranlarını belirlemek için önemli bir parametredir. Modifiye midüretral sling tekniği karşılaştırılabilir başarı oranı ile daha ekonomik bir yöntem olarak gözükmektedir.

Anahtar Kelimeler

Modifiye Midüretral Sling; Stres Üriner İnkontinans; Tension-Free Vajinal Tape; Transobturator Tape; Valsalva Kaçak Noktası Basıncı

Abstract

Aim: To use urodynamic evaluation to compare the effectiveness of modified midurethral sling, tension-free vaginal tape, and transobturator tape in the treatment of stress urinary incontinence. Material and Method: A total of 65 patients with stress urinary incontinence underwent midurethral sling operations between 2003 and 2012. Preoperative and postoperative urodynamic evaluation data were analysed. Cystometry was used to determine the cure rates of operations. Valsalva leak point pressure was obtained to assess and compare the objective cure rates. Results: No significant differences were noted between different operation types. Objective cure rates of procedures were established as 83.3%, 88.9%, and 91.3% for modified midurethral sling, tension-free vaginal tape, and transobturator tape, respectively. Tension-free vaginal tape was more effective in intrinsic sphincteric deficiency than other operation types. Valsalva leak point pressure showed the effectiveness of the operations. According to pressure values, stress urinary incontinence were cured or improved in patients objectively. Only 8 patients had positive Valsalva leak point pressure postoperatively and the mean of postoperative Valsalva leak point pressure values was higher than that of preoperative levels. Discussion: Effectiveness of midurethral sling operations did not differ between groups. Valsalva leak point pressure is an important marker to determine objective cure rates. Modified midurethral sling techniques are more economical with comparable success rates.

Keywords

Modified Midurethral Sling; Stress Urinary Incontinence; Tension-Free Vaginal Tape; Transobturator Tape; Valsalva Leak Point Pressure

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Introduction

Urinary incontinence (UI) is defined as the complaint of any involuntary leakage of urine [1]. Stress urinary incontinence (SUI), which mainly occurs during physical activity due to the urethral sphincteric insufficiency, may affect up to 60% of women with UI in a pure or mixed form accompanied by detrusor overactivity (DO) [2-4]. The mainstay of the treatment of SUI has been improving urethral sufficiency using a variety of types of operations. Minimally invasive midurethral sling operations developed in recent decades, including tension-free vaginal tape (TVT) and transobturator tape (TOT), have had high success and low complication rates and have been accepted as gold standard procedures for SUI [5-9]. However, the high cost of the sling devices and meshes is a significant burden for effective treatment of SUI in developing countries with limited healthcare sources. In response, many modified techniques have been developed to reduce the cost without decreasing the success [10]. In the literature there are only a few studies that compare TVT to pubovaginal sling and TOT to pubovaginal sling [11]. Additionally, there are no more studies about synthetic pubovaginal sling procedures.

The aim of our study is to compare cure rates, efficacy rates, and complication rates among patients who underwent TVT, TOT, and modified midurethral sling operations for anti-incontinence surgery.

Material and Method

The study population consisted of patients who underwent midurethral sling operations for stress urinary incontinence (SUI) and mixed urinary incontinence (MUI) between April 2003 and April 2012. The study was approved by the Ethics Review Board and conducted in Eskisehir Osmangazi University, Department of Obstetrics and Gynecology.

Eigthy-six patients were evaluated retrospectively. Urogynecological evaluation and urodynamic studies were performed preoperatively for all patients. Twenty-one patients who did not come to their follow-ups and whose medical information couldn't be gained or had missing data were excluded from the study population. We assessed age, number of parity, and type of delivery (spontaneous vaginal or caesarean section) as demographic parameters.

Urodynamic studies (cystometry), which were routine procedure for SUI operations in our clinic, were performed on all patients preoperatively. Urine testing and culture were obtained before the urodynamic test. Postvoiding residual volume (PVR) was assessed before starting the urodynamic testing by sterile catheterization. Maximum bladder capacity, maximum vesical pressure, VLPP (valsalva leak point pressure), and maximum detrusor pressure were evaluated by the urodynamic test and were recorded with a computer program. VLPP was obtained with the subject seated when the total infused volume reached 200 mL by asking the patient to perform a Valsalva maneuver until urine loss was directly observed. We retrospectively analysed the data obtained from these recordings.

According to patients' complaints and urodynamic test results we categorized them into two groups: SUI and MUI. We diagnosed the SUI by confirmation of positive stress test during the urodynamic test. For patients who had MUI and who had no response to any medications, we recommended and performed surgery for SUI.

We performed three different operation types during the study period. 'Modified midurethral sling (MMUS)' operations were performed using the abdominovaginal route with synthetic mersilene mesh. In this technique, first an pfannenstiel incision was performed and a trocar was directed top-to-bottom to the vaginal incision. Then synthetic mersilene mesh was fixed to the trocar and pulled out by the trocar from the abdominal incision. After that, sutures of the mesh were adjusted and then tied. The second operation type was TVT. In this technique we used the bottom-to-top technique (from the vaginal incision to pubic bone). The third operation type was TOT. We performed an inside-to-outside technique named TVT-O and developed by de Leval, hereafter referred to as TOT. All of the operations were performed by a single experienced surgeon. Intraoperative complications were identified. Patients who had mesh erosion were recorded.

Patients were invited to the hospital with a telephone call asking them to come for evaluation. They were informed about this study and informed consent was obtained. Present complaints, particularly those related to stress urinary incontinence, were questioned as 'present or absent.' Urodynamic tests were performed to detect objective cure rates. Before the urodynamic tests, PVR was established by sterile catheterization. As with the preoperative procedure, test data was recorded with a computer program.

After these evaluations 'subjective cure rates' and 'objective cure rates' were determined. The absence of involuntary urine leakage was designated 'subjective cure' and negative stress test and no VLPP in the urodynamic test was designated 'objective cure.'

Statistical analysis was performed to compare operation types and to detect differences between preoperative and postoperative data. Statistical analysis was conducted using SPSS version 20.0. One-way ANOVA, Independent Samples Kruskal-Wallis Test, Pearson Chi-Square Test, Paired-sample t-Test, and Related-samples Wilcoxon Test were used. A p value <0.05 was considered statistically significant.

Results

We evaluated 65 patients; modified midurethral sling (MMUS), TVT, and TOT operations were performed for 24, 18, and 23 patients, respectively. Demographic characteristics of patients and preoperative urodynamic results were assessed (Table 1). In the preoperative diagnoses of patients, 28 patients (43.1%) had pure stress urinary incontinence and 37 patients (56.9%) had mixed urinary incontinence. One bladder perforation was seen as an intraoperative complication; it occurred during the MMUS procedure. Among all patients, the rate of bladder perforation was evaluated as 1.5% but for the MMUS procedure this rate was evaluated as 4.1%. Bladder perforation was determined intraoperatively by cystoscopy. The patient was followed with 168 hours of bladder catheterization. After catheterization there was no problem and the patient was discharged from hospital. We did not see any major complications, such as major vessel and nerve injury, other than the bladder perforation. Follow-up duration of our patients was in a wide range, from 11

Table 1. Demographic characteristics and preoperative Urodynamic results of patients

	MMUS (n=24)	TVT (n=18)	TOT (n=23)	p
Age (years)	52.04±10.25	51.72±8.29	57.43±12.12	>0.05
Parity (numbers)	3.75±2.11	3.05±1.43	3.69±1.60	>0.05
Number of SVD	3.82±2.12	2.88±1.53	3.65±1.64	>0.05
Capacity of bladder (ml)	411.33±66.74	391.27±80.24	395.00±80.38	0.646†
Maximal Vesical Pressure (cm H_2O)	19.20±9.35	26.27±14.73	18.30±9.20	0.186‡
Maximal Detrusor ressure (cm H_2O)	13.75±7.21	22.50±14.07	16.04±8.14	0.083‡
PVR (ml)	16.45±15.70	9.44±11.99	15.21±24.83	0.031‡
VLPP (cm H_2O)	72.61±97.38	78.28±103.15	79.87±114.21	0.449†

†, Oneway ANOVA Test ‡ Independent Samples Kruskal-Wallis Test Values are given as mean ±SD, MMUS, modified midurethral sling PVR, Postvoiding residual volume SD, Standard deviation SVD, spontaneous vaginal delivery TVT, tension-free vaginal tape TOT, transobturator tape VLPP, valsalva leak point pressure

months to 114 months. Mean evaluation durations in postoperative period were 76.04, 46.11, and 25.78 months for MMUS, TVT, and TOT respectively (p>0.05).

We did not determine any statistical significance for VLPP values postoperatively. There were only 8 cases that had positive VLPP postoperatively so the statistical analysis was not applicable for VLPP.

Preoperative and postoperative urodynamic test results were evaluated. When we compared maximum vesical pressure and maximum detrusor pressure between preoperative and postoperative urodynamic tests, we determined that the values of both parameters decreased after the operations and these decreases were statistically significant (p<0.05). In the analysis of VLPP values, the mean of postoperative values was higher than that of preoperative values and this was statistically significant (p<0.05).

Eight patients had VLPP postoperatively. We determined that significant improvement and satisfaction were obtained postoperatively for most of these 8 patients.

VLPP, a parameter for objective diagnosis of stress urinary incontinence, was used to detect response of the treatment postoperatively. Preoperative and postoperative mean values of VLPP were compared between operation types (Table 2). Among postoperative urodynamic evaluation of 13 patients who had <60 cm H2O pressure of VLPP preoperatively, 11 of them (84.6%) had no VLPP and only 2 had positive VLPP (15.4%) postoperatively. These two patients had higher VLPP levels than their preoperative levels; the increase in VLPP may demonstrate the effectiveness of operations so we determined these results as improvement. We established improvement in patients who had 60-100 cm H2O pressure of VLPP and >100 cm H2O pressure of VLPP with a rate of 84.6% and 92.3%, respectively. We compared the classification of postoperative VLPP values and we did not find any significant differences between operation types (p>0.05) (Table 3). Evaluation of postoperative VLPP values are significant and important in terms of 'objective cure' assessment. Comparative analysis of operation types showed that 'objective cure' rates were 83.3%, 88.9%, and 91.3% for MMUS, TVT, and TOT respectively (Table 3).

In the follow-up process 3 patients experienced mesh erosion. The rate of erosion was 4.6% among all patients; 8.3% (n=2) in the MMUS group; 0% (n=0) in the TVT group; and 4.3% (n=1) in the TOT group. When we compared rate of mesh erosion between operation types, there was no statistical significance (p>0.05).

Discussion

We compared sling operations for patients with SUI or MUI and evaluated subjective and objective cure rates. We found that subjective cure rates for MMUS, TVT, and TOT were 79.1%, 94.4%, and 91.4% respectively. Objective cure rates for MMUS, TVT, and TOT were 83.3%, 88.9%, and 91.3% respectively. We did not determine any significant differences between operation types in terms of objective and subjective cure rates.

There are several studies that compare the effectiveness of sling operations. In the Cochrane meta-analysis that evaluated cure rates of TVT and TOT, cure rates were reported as 73% for both operations [12]. In a randomized study, Richter et al. showed no significant differences for objective cure rates between TVT and TOT operations (TOT-77.7% vs TVT-80.8%) [13]. Hung et al. compared TVT and pubovaginal sling with synthetic mesh, finding 91.3% and 93% improvement in TVT and pubovaginal sling with synthethic mesh, respectively [14].

We determined objective cure rates using urodynamic evaluation (cystometry). Urodynamic evaluation provides some data to detect the stress component of urinary incontinence. In particular, VLPP values give more information to clinicians in understanding of ISD (intrinsic sphincteric deficiency). Although there are some differences among patients, most clinicians

Table 2. Comparison of preoperative and postoperative urodynamic outcomes according to operation types

		MMUS (n=24)	p	TVT (n=18)	p	TOT (n=23)	p
Bladder Capacity (ml)	Preoperative	411.33±66.74	0.201†	391.27±80.24	0.429†	395.00±80.38	0.136†
	Postoperative	390.29±72.67		404.22±56.14		414.43±79.25	
Maximal Vesical Pressure (cm H_2O)	Preoperative	19.20±9.35	0.278†	26.27±14.73	0.003†	18.30±9.20	0.113‡
	Postoperative	17.20±7.30		17.94±12.68		13.69±6.81	
VLPP (cm H_2O)	Preoperative	71.00±18.52	0.068‡	108.50±33.23	§	74.00±41.01	§
	Postoperative	121.75±15.10		105.00±14.14		128.00±2.82	
Maximal Detrusor Pressure (cm H_2O)	Preoperative	13.75±7.21	0.445‡	22.50±14.07	0.008‡	16.04±8.14	0.092‡
	Postoperative	14.54±6.23		16.16±12.19		12.21±7.10	
PVR (ml)	Preoperative	16.45±15.70	0.104‡	9.44±11.99	0.500‡	15.21±24.83	0.350‡
	Postoperative	11.95±13.55		6.66±8.40		10.43±18.02	

†Paired Samples t-Test, ‡Related-Samples Wilcoxon Test §, statistical significant was not evaluated Values are given as mean ±SD, MMUS, modified midurethral sling PVR, Postvoiding residual volume SD, Standard deviation TVT, tension-free vaginal tape TOT, transobturator tape VLPP, valsalva leak point pressure

Table 3. Postoperative VLPP and Objective Cure rates between operation types

		MMUS n (%)	TVT n (%)	TOT n (%)	p
Postoperative VLPP (cm H2O)	Absent	20 (83.3)	16 (88.9)	21 (91.3)	0.834
	<60	0 (0)	0 (0)	0 (0)	
	60-100	1 (4.2)	1 (5.6)	0 (0)	
	>100	3 (12.5)	1 (5.6)	2 (8.7)	
Objective Cure Rate		20(83.3)	16 (88.9)	21 (91.3)	>0.05

Pearson Chi-Square Test MMUS, modified midurethral sling TVT, tension-free vaginal tape TOT, transobturator tape VLPP, valsalva leak point pressure

think that a VLPP value below 60 cmH2O confirms the diagnosis of ISD [15]. We classified VLPP values according to the pressure levels and compared postoperative findings between operation types. When we evaluated the patients who had VLPP values below 60 cm H2O, a complete cure was obtained in 84.6% of patients. Higher pressure values of VLPP (>100 cm H2O) raised the success rate to 92.3% in the present study. Similarly, Young et al. found significant differences between patients according to whether they had ISD and they showed significantly higher cure rates in the no-ISD group (p<0.001) [16]. Another study indicated that low VLPP values (<60 cm H2O) may be an independent marker for treatment failure [17]. Rechberger et al. showed that low VLPP levels lead to poor treatment response in TOT operations but not in TVT operations [18]. The success rates of our study for ISD patients was 100% in the TVT group and 75% in the TOT group. Similar to our study, Kim et al. established that the success rate of TVT was significantly higher than for TOT in patients who had ISD (TVT, 95.2% vs TOT, 82.7%) [19]. They showed risk factors of treatment failure and found that TOT is the only risk factor associated with treatment failure after 12 months follow-up. Therefore TVT is considered the preferred method in patients with ISD because it is a more obstructive technique than TOT [20]. Contrary to these studies, some authors have concluded that TOT is comparable to TVT in ISD [13,21]. Another study which compared pubovaginal sling, TVT, and TOT observed similar complication rates among operations for ISD; however, cure rates for TOT were lower (34.9%) than for TVT (87%) and pubovaginal sling (87.3%) [22]. When we evaluated the objective cure rates of patients according to VLPP values, we did not find any significant differences between operation types (MMUS, TVT, and TOT; 83.3%, 88.9%, and 91.3% respectively) (p=0.834).

In several studies, similar cure rates were reported but in the present study we determined higher objective cure rates than in other studies. Some studies that approved VLPP values as objective criteria showed lower cure rates compared to our study [13,23].

The most important complication of midurethral sling operations is bladder perforation. It is also the most common complication of TVT at a rate of 3.5-6.6% [24-27]. In a study that compared TVT and pubovaginal sling with synthetic mesh, the rate of bladder perforation was 4.3% in TVT patients and 0% in pubovaginal sling patients (p=0.287) [14]. Castillo-Pino et al. found that bladder injuries occurred in the TVT group at a rate of 5.5% and no bladder perforation was shown in the TOT group (p=0.14) [23]. In our study, one bladder injury occurred, and it was in the MMUS group. The rate of bladder injury was 4.1% in the MMUS group and there was no bladder complication in the TVT and TOT groups.

Another important complication is mesh erosion, which develops in the late postoperative period. A meta-analysis by Novara et al. did not find any significant differences between TOT and TVT with regard to mesh erosion [28]. Abouassaly et al. found that mesh erosion occurred at a rate of 0.4% and 1.4% in TVT and TOT operations, respectively [26]. Some researchers think that the hammock-shaped structure of TOT creates more contact area than the U-shaped structure of TVT, leading to increased inflammation and erosion rates in TOT operations [29]. In the present study, we established mesh erosions in 3 patients, 2 of them in the MMUS group (8.3%) and the other one in the TOT group. There was no mesh erosion in the TVT group. These rates are high compared to the literature, but may be explained by the small sample size.

According to the cost-effectiveness analysis of our study, TOT and TVT operations have higher costs because they use special materials. Only prolene or mersilene mesh is required for modified sling operations and this decreases the operation cost. Average costs of TOT and TVT currently are $300-400 (USD), whereas the cost of mesh for modified sling operations is approximately $10-15. As we have seen, modified sling operations have significantly lower materials costs than TVT and TOT operations. In one study, the cure rate was determined as 81.3% for pubovaginal sling operations with polypropylene mesh, and their low cost was also established [30]. ElSheemy et al. compared surgeon-tailored modified technique (STM) with original TVT-O [31]. There was no significant difference in cure rates between operation types (p=0.654), but surgical cost decreased significantly from $500 to $10. They also found MUI and urgency improvement similar to our study. Polypropylene self-tailored mesh has been used by many surgeons and costs of surgery have decreased significantly [32-34]. When TVT-O (with STM) was compared to TVT in one study, it was reported that cure rates did not show any significant difference, while surgical costs were significantly reduced by the STM method [35]. The surgeon-tailored mesh method has an advantage in developing countries with few financial resources and it may be considered as a low-cost alternative for treating SUI patients. We performed MMUS operations as a cost-effective method with similar cure rates compared to TVT and TOT.

Our study has several limitations. Firstly, this study is not a randomized controlled study. Non-random patient selection method is the main limitation. Heterogenous study groups with SUI and MUI is another limitation of our study. Follow-up duration is in a wide range and it is variable in our study. Objective questionnaires were not used to determine subjective cure rates in the present study. However, the strengths of our study include that it is single experienced surgeon data and VLPP is used to detect the objective cure rate of operations. There are few studies using single surgeon data and VLPP is not commonly used to demonstrate the objective cure rates of operations.

In conclusion, the subjective and objective cure rates of patients treated with MMUS, TVT, and TOT were similar and there was no statistically significant differences. VLPP provides a quantitative component of urodynamic evaluation that is useful in SUI

patients and especially for ISD. Modified sling operations may be preferred in some situations instead of TVT or TOT because of low costs. Further prospective randomized controlled trials are required to confirm our results.

Competing interests

The authors declare that they have no competing interests.

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