

Transobturator Tape and Kelly's Plication Procedures Comparison: A Case-Control Study with One-Year Follow-Up

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Abstract

Objective: To investigate the factors that may affect urinary incontinence and compare the outcomes of surgical methods used to treat it, specifically Transobturator Tape (TOT) and Kelly's plication procedures.

Method: The data of 213 patients who underwent TOT and Kelly's Plication procedures for urinary incontinence at the Department of Obstetrics and Gynecology, Gaziantep University Faculty of Medicine, between January 2016 and December 2021, were retrospectively analyzed with consideration of their evaluations one year postoperatively. The patients' age, type of surgery, complete urinalysis, urea, creatinine results, chronic disease status, menopausal status, gravidity and parity, body mass index, type of urinary incontinence, whether the stress test was positive or not, degrees of vaginal prolapse, and whether urinary incontinence complaints persisted during postoperative follow-up were examined. The patients were divided into two groups: those who underwent TOT and those who underwent Kelly's's Plication. The differences between the two groups were evaluated. Subsequently, the urinary incontinence complaints of both groups were assessed one year later, and the risk factors for patients whose complaints persisted were examined using logistic regression analysis.

Results: One year postoperatively, the success of the TOT procedure was higher than that of the Kelly's's Plication. However, multivariate regression analysis revealed that patients who underwent the TOT procedure had a higher likelihood of persistent complaints compared to those who underwent Kelly's's Plication (OR: 2.07 [1.12-3.93], P=0.02). While there was a significant difference between the two groups in terms of parity and gravidity, no significant differences were observed in terms of age, BMI, menopausal status, type of urinary incontinence, and the presence of chronic diseases.

Conclusion: The success rate of the TOT procedure in terms of the improvement of urinary incontinence symptoms in patients was found to be higher compared to Kelly's plication. However, regression analysis indicated that patients who underwent the TOT procedure were more likely to have persistent urinary incontinence complaints.

Key words: Kelly's Plication, Urinary incontinence, Stress urinary incontinence, Transobturator tape

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Introduction

The International Continence Society (ICS) defines incontinence as the involuntary loss of urine under any condition (1). One in two women experience urinary incontinence, which causes a decline in quality of life for women both socially and hygienically. The prevalence increases with age, yet only a small fraction of women with urinary incontinence seek medical treatment (2-4).

The primary risk factors are gender and age. Aging and female gender are significant risk factors, with urinary incontinence being approximately three times more common in women than in men. The risk of incontinence is about 8% in women aged 40-50, while it increases to 28% in those over 65 years old (5-7). Some studies also list obesity, menopausal status, pelvic organ prolapse (POP), the number and type of deliveries, smoking, and race as risk factors for urinary incontinence (8). Among the types of urinary incontinence, the most common is stress urinary incontinence, which occurs with an increase in intra-abdominal pressure and is most frequently seen in women aged 45-49 (9, 10). Urge incontinence is defined as the involuntary loss of urine accompanied by a sudden urge to urinate, while mixed incontinence includes symptoms of both stress and urge incontinence. TOT and Kelly's plication are commonly performed surgical treatments

for urinary incontinence. TOT is a mid-urethral sling procedure that supports the urethra by placing a synthetic mesh through the obturator foramen. Kelly's plication is a traditional method that reinforces the urethral sphincter by suturing the bladder neck. These techniques aim to restore urinary continence by improving urethral support and function. Both conservative and surgical methods are used to treat urinary incontinence. Conservative treatments include pharmacotherapy, pelvic floor exercises, and behavioral therapy. In the presence of a true SUI condition, surgical treatment should be planned for moderate to severe SUI cases, cases that do not respond to medical treatment and conservative approaches, and especially for advanced incontinence cases where other treatment methods have failed (11). Despite the development of numerous surgical techniques, a gold-standard method with high success and low complication rates has not yet been identified.

In our research, we aimed to examine the effects of various variables on the success of Transobturator Tape (TOT) and Kelly's Plication surgery, as well as success rates and the reasons for patients' continuing complaints.

Material and Methods

Patient Selection

This study was conducted with the ethical approval of the Gaziantep University Non-Interventional Clinical Research Ethics Committee, under approval number 2022/244, date:03.08.2022. Data were obtained using the high-security information management system and archives of Gaziantep University Şahinbey Research and Application Hospital. Initially, 253 patients who underwent surgery for urinary incontinence between January 2016 and December 2021 at the Department of Obstetrics and Gynecology, Gaziantep University Şahinbey Research and Application Hospital were identified. Among these, 30 patients underwent minisling procedures, eight had Burch colposuspension, and two patients with insufficient data were excluded. As a result, 213 patients remained, with 122 undergoing Kelly's plication and 91 undergoing the TOT procedure. Of these patients, 122 underwent Kelly's Plication, and 91 underwent Transobturator Tape (TOT). Archive records for each patient were reviewed, and if any data were missing, patients were contacted to obtain the necessary information. The recorded data included age, gravidity, parity, body mass index, type of urinary incontinence, stress test results, degree of pelvic organ prolapse,

presence of chronic diseases (DM, HT, CAD, asthma, goiter), and menopausal status.

Patients with incomplete data on the type of urinary incontinence and type of operation, those who underwent surgery for pelvic organ prolapse without urinary incontinence, those who had urinary incontinence complaints but received medical treatment, those who did not attend postoperative follow-ups, and those with insufficient information about the continuation of incontinence complaints were excluded from the study. Additionally, data from patients who met the inclusion criteria but were deceased were not included in the study.

Surgical Technique and Follow-Up

The surgical methods for incontinence surgery performed in our clinic adhere to standard procedures. Kelly's Plication is a surgical technique used in the treatment of stress urinary incontinence, typically performed under general or spinal anesthesia. In this procedure, a suprapubic or transvaginal incision is made, and tissues are carefully dissected to reach the pelvic floor muscles and connective tissue beneath the bladder neck and urethra. Then, the pelvic floor muscles and connective tissue beneath the bladder neck and urethra are tightened using sutures Kelly's plication, as described by Howard Kelly, begins with a

midline incision in the anterior vaginal mucosa at the level of the bladder neck. Through this incision, the bladder is carefully dissected. The lax tissues beneath the bladder neck are plicated using 2/0 absorbable sutures. Then, the excess vaginal tissue is excised, and the vagina is closed with 2/0 absorbable sutures (12).

The TOT procedure begins with a vertical incision made at the mid-urethral level of the anterior vaginal wall, followed by the dissection of the bladder. The cleavage is advanced to the ischiopubic rami. As described by Delorme, the trocars are inserted through the skin at 1 cm lateral to the ischiopubic rami at the level of the clitoris, advancing from outside to inside, and the mesh is brought out to the skin with the help of the trocars. A macroporous polypropylene mesh is attached to the eye of the trocar on both sides and placed beneath the bladder neck. Then, the excess vaginal tissue is excised, and the vagina is closed with 2/0 absorbable sutures (13).

Postoperatively, patients were evaluated at the end of one year to determine whether their urinary incontinence complaints persisted. Based on their feedback, patients were grouped into those whose urinary incontinence persisted and those whose complaints were resolved.

Statistical Methods

The Shapiro-Wilk test was used to determine whether the data were normally distributed. Descriptive statistics for normally distributed data were reported as mean \pm standard deviation (SD). Data that did not show normal distribution were presented as median (minimum-maximum). Categorical data were expressed as numbers (n) and percentages (%). For group comparisons, the independent samples t-test was used for normally distributed data, while the Mann-Whitney U test was used for data that did not show normal distribution. The chi-square test or Fisher's exact test was applied for the comparison of categorical data. All statistical analyses were performed using R version 4.4.1, and a p-value of <0.05 was considered statistically significant.

Results

In this study, the demographic and clinical characteristics of patients who underwent TOT (trans obturator tape) and Kelly's Plication procedures for urinary incontinence complaints were examined in detail. Logistic regression analysis was used to identify factors that might affect the persistence of urinary incontinence complaints postoperatively.

The analyses included variables such as the patient's age, gravidity, parity, body mass index (BMI), menopausal status, stress test results, type of incontinence, degree of

prolapse, and type of surgery performed. Table 1 compares the demographic data of patients who underwent Kelly's and TOT procedures.

Table 1. Demographic Data of Patients Who Underwent Tot and Kelly's Plication.

Variables	Kelly's's Plication (n=122)	TOT (n=91)	p-value
Age			
Median (Min-Max)	51.0 (24-88)	50.0 (32-94)	0.895
Gravity			
Median (Min-Max)	4.0 (2-11)	5.0 (1-12)	0.012
Parity			
Median (Min-Max)	4.0 (1-11)	4.0 (1-12)	0.007
BMI			
Median (Min-Max)	27.27 (21.33-35.40)	27.68 (21.45-40.79)	0.513
Menopause Status			
Premenopause	45 (36.9%)	34 (37.4%)	1.0
Postmenopause	77 (63.1%)	57 (62.6%)	
Comorbidity			
None	66 (54.1%)	47 (51.6%)	0.352
DM	23 (18.9%)	12 (13.2%)	
Other	33 (27.0%)	31 (34.1%)	
Stress Test			
Negative	15 (12.3%)	6 (6.6%)	0.251
Positive	107 (87.7%)	85 (93.4%)	
Incontinence Type			
Stress	85 (69.7%)	69 (75.8%)	0.608
Urge	29 (23.8%)	5 (5.5%)	
Mix	8 (6.6%)	17 (18.7%)	
Degree of Prolapse	2(0-5)	2(0-5)	0.10

The median gravidity was 4.0 (min 2-max 11) in the Kelly's group and 5.0 (min 1- max 12) in the TOT group, with a significant difference between the groups in terms of gravidity ($p=0.01$). The median parity was 4.0 in both groups, but a significant

difference was observed in terms of parity ($p=0.007$). There was no significant difference in BMI ($p=0.51$). The success of the operations performed on the patients is shown in Figure 1.

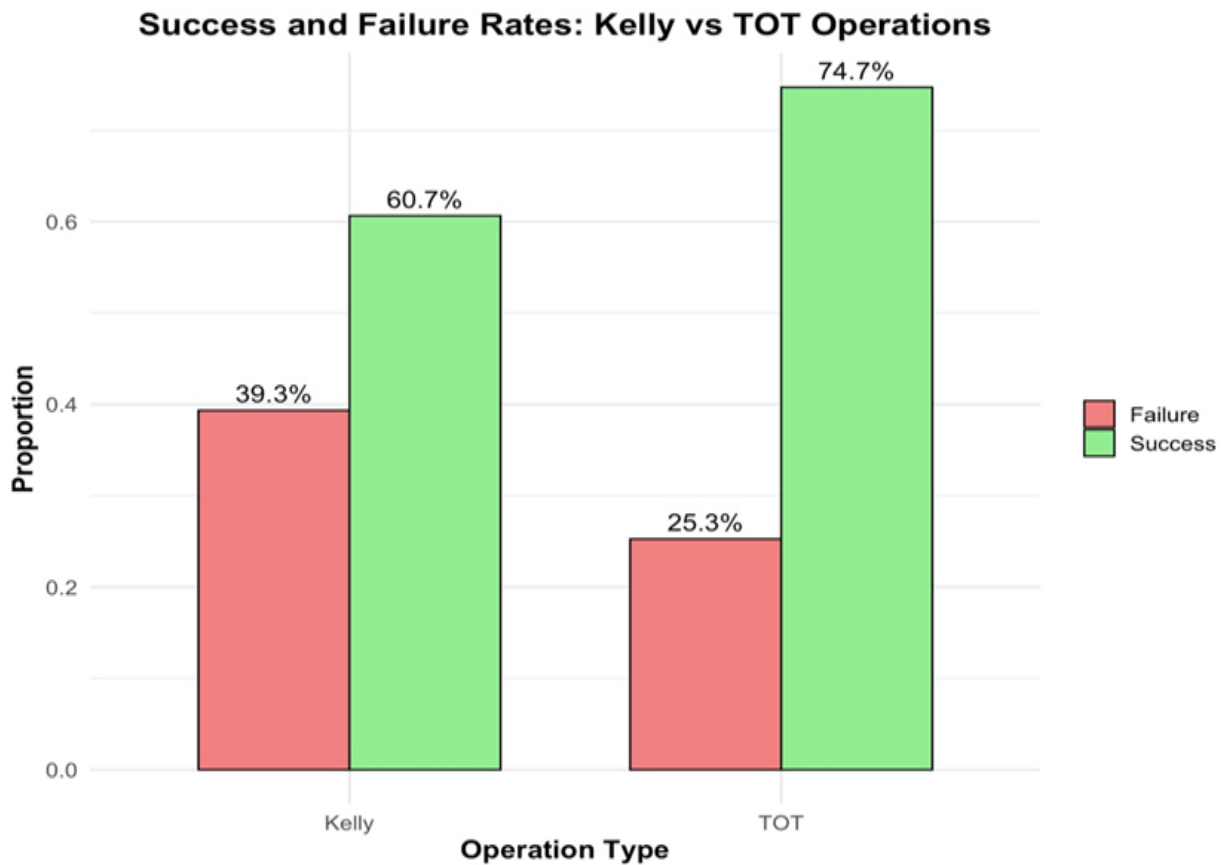


Figure 1. Success and Failure Rates: Kelly's vs TOT Operations.

Table 2 presents the demographic and clinical data of patients in the Kelly's group

regarding the status of urinary incontinence complaints at the end of the first year.

Table 2. Evaluation of Urinary Incontinence Complaints in Patients Underwent Kelly's's Plication.

Variables	Persistent Symptoms (n=48)	No Symptoms (n=74)	p-value
Age			
Median (Min-Max)	52.56 ±13.60	52.62 ± 13.85	0.98
Gravity			
Median (Min-Max)	4 (2-11)	4 (2-11)	0.59
Parity			
Median (Min-Max)	4.0 (1-11)	4.0 (2-11)	0.89
BMI			
Median (Min-Max)	26.8 ±62.52	27.95±3.47	0.06
Comorbidity			
None	24 (%50.00)	30 (%40.00)	0.22
DM	16 (%33.33)	22 (%29.33)	
Other	8 (%16.67)	23 (%30.67)	
Menopause Status			
Premenopause	16 (%33.33)	29 (%39.19)	0.64
Postmenopause	32 (%66.67)	45 (%60.81)	
Stress Test			
Negative	5 (%10.42)	8 (%10.81)	0.43
Positive	43 (%89.58)	66 (%89.19)	
Incontinence Type			
Stress	29 (%60.42)	48 (%64.86)	0.68
Urge	10 (%20.83)	12 (%16.22)	
Mix	9 (%18.75)	14 (%18.92)	
Degree of Prolapse	2.0 (0-5)	2.0 (0-5)	0.76

These findings indicate that demographic and clinical factors do not have a decisive effect on the persistence of urinary incontinence complaints in patients who underwent the Kelly's procedure.

Table 3 summarizes the urinary incontinence complaint status of patients in the TOT group.

Table 3. Evaluation of Urinary Incontinence Complaints in Patients Undergoing TOT.

Variables	Persistent Symptoms (n=23)	No Symptoms (n=68)	p-value
Age			
Median (Min-Max)	53.22±11.02	52.34±13.52	0.77
Gravity			
Median (Min-Max)	6.0(3-11)	5.0(1-12)	0.39
Parity			
Median (Min-Max)	5.0 (3-10)	4.0(1-12)	0.27
BMI			
Median (Min-Max)	27.38, ±2.30	27.99±3.64	0.45
Comorbidity			
None	10(%43.48)	31 (%42.47)	0.88
DM	8(%34.78)	20 (%27.40)	
Other	5 (%21.74)	22 (%30.14)	

Table 3. Evaluation of Urinary Incontinence Complaints in Patients Undergoing TOT (continued).

Menopause Status			
Premenopause	13 (%56.52)	41 (%56.16)	0.96
Postmenopause	10 (%43.48)	32 (%43.84)	
Stress Test			
Negative	1 (%4.35)	2 (%2.74)	0.98
Positive	22 (%95.65)	71 (%97.26)	
Incontinence Type			
Stress	15 (%65.22)	45 (%61.64)	0.32
Urge	4 (%17.39)	15 (%20.55)	
Mix	4 (%17.39)	13 (%17.81)	
Degree of Prolapse	2.0 (0-5)	2.0 (0-5)	0.20

Various demographic and clinical characteristics were compared between the group with persistent complaints and the group without complaints. No significant differences were found between the groups in terms of comorbidities, BMI, menopausal status, stress test results, type of incontinence, and degree of prolapse. These findings suggest that demographic and clinical factors do not play a decisive role in the persistence of urinary incontinence complaints in patients who underwent the TOT procedure.

Table 4 presents the results of the logistic regression analysis, including the coefficients, standard errors, z-values, and p-values for the independent variables affecting the persistence of urinary incontinence complaints. Age did not have a significant effect. The likelihood of persistent urinary incontinence complaints increased with higher BMI (OR=1.10, 95% CI: 1.00-1.22)

Table 4. Logistic Regression Analysis Results of Patients Underwent Incontinence Surgery.

Variables	Estimate	SE	z value	OR (%95 CI)	P value
Age	0.006	0.0195	0.312	1.006(0.968-1.046)	0.75
Gravidity	-0.127	0.1132	-1.123	0.881(0.705-1.103)	0.26
Parity	0.049	0.139	0.352	1.05(0.797-1.38)	0.72
BMI	0.103	0.049	2.101	1.108(1.009-1.224)	0.03
(Ref: Premenopause)					
Postmenopaz	-0.402	0.4602	-0.875	0.668(0.269-1.644)	0.38
Stress Test	-0.078	0.5081	-0.155	0.924(0.325-2.448)	0.87
Incontinence Type	0.162	0.19	0.854	1.176(0.817-1.727)	0.39
Prolapse Degree	0.102	0.1434	0.716	1.108(0.838-1.476)	0.47
(Ref: Kelly's's Plication)					
TOT	0.73	0.3189	2.289	2.075(1.121-3.931)	0.02

Additionally, patients who underwent the TOT procedure had a higher likelihood of persistent urinary incontinence complaints compared to those who underwent the Kelly's procedure (OR=2.07, 95% CI: 1.12-3.93). Other variables, such as age, gravidity, parity, menopausal status, stress test results, type of incontinence, and degree of prolapse, did not significantly affect the persistence of urinary incontinence complaints.

Discussion

Urinary incontinence is a common health problem that can be seen at any age. While it is not life-threatening, it significantly impairs the quality of life. Patients who underwent anti-incontinence surgery over a 5-year period in our clinic were evaluated. We assessed the study results by considering certain values. The relationships between pre-treatment variables such as age, height, weight, BMI comorbidities (DM, HT, and other diseases such as CAD, goiter, asthma), gravidity, parity, and menopausal status with post-treatment success were examined for statistical significance.

In a study conducted in Norway investigating the prevalence of urinary incontinence in the female population, it was observed that 25% of women experienced incontinence. Among those with incontinence complaints, 50% had

stress incontinence, 11% had urge urinary incontinence, and 36% had mixed urinary incontinence (14). In our study, examining patients who underwent surgery for urinary incontinence over a five-year period, the most common type of urinary incontinence was stress urinary incontinence, followed by mixed type urinary incontinence. While non-surgical treatment methods are initially tried for stress urinary incontinence, surgical treatment is often required (15). Studies have shown that urinary incontinence increases with advancing age (2, 16). A retrospective study found that the incidence of incontinence or prolapse surgery increases with age, with a lifetime risk of 11.1% up to the age of 80 (17). Another study indicated that, although the rate of increase is not constant, the incidence of urinary incontinence peaks post-menopause and begins to decrease after the fifth decade, while urge incontinence shows a bimodal distribution, peaking twice in early and late adulthood (18). The logistic regression results obtained in our study indicate that the effect of age on urinary incontinence is not statistically significant (OR:1, 95% CI: 0.96-1.04, $p=0.75$). This finding suggests that age alone is not a determinant of urinary incontinence and that other factors should also be considered. Consistent with the existing literature, while an increase in the incidence of urinary incontinence is

observed with advancing age, the results of our study suggest that age alone is insufficient to explain this condition.

Many studies have shown that the rate of urinary incontinence is higher in women who have had one or more births compared to those who have never given birth. It is particularly noted that the rate increases with each additional birth after the first (19). A community-based cohort study evaluating the mode and number of births in 15,307 women found that the age-standardized prevalence of incontinence was 10.1% in nulliparous women, 15.9% in the cesarean section group, and 21% in the vaginal birth group. Consequently, the risk of urinary incontinence was highest with vaginal delivery, while it was still higher in cesarean deliveries compared to nulliparous women (20). Our study also examined the effects of gravidity and parity on urinary incontinence. However, neither variable was found to be statistically significant, indicating that they did not independently contribute to the risk of urinary incontinence in our study population. While previous research has consistently identified gravidity and parity as significant risk factors, our findings did not confirm this association. This discrepancy may be due to differences in study populations and sample sizes.

One of the risk factors strongly associated with incontinence is obesity. Obesity increases intra-abdominal pressure, exacerbating stress incontinence. Women with true stress incontinence and detrusor instability are more likely to be obese compared to continent women (21). In a study of 148 patients who underwent urinary incontinence surgery, BMI values were examined, and higher surgical failure rates were observed in obese patients (22). Conversely, another study investigating whether BMI affects the outcomes of urethral sling procedures for SUI found no significant difference in success rates among 285 women classified as normal weight (18.5-23 kg/m²), overweight (23-27.5 kg/m²), and obese (over 27.5 kg/m²), and no significant difference in postoperative voiding symptoms was observed (23).

The logistic regression results obtained in this study evaluated the effects of BMI on urinary incontinence. The BMI variable was found to be statistically significant (OR: 1.10, 95% CI:1.00-1.22, p=0.03). This finding indicates that an increase in BMI increases the risk of urinary incontinence. Despite differing results in the literature regarding the impact of obesity on urinary incontinence, our study determined that BMI has a significant impact as an independent risk factor. This result

underscores that obesity is a factor that should be considered in the development of urinary incontinence.

A recent study examined 60 patients undergoing surgery for stress urinary incontinence (SUI) in two groups: TOT and anterior colporrhaphy combined with Kelly's plication. The success rates in the TOT group were reported as 86.7%, 80%, and 80% at 1, 6, and 12 months, respectively, while in the anterior colporrhaphy and Kelly's plication group, the rates were 80%, 70%, and 66.7%, respectively. This study highlighted that while there was no significant difference in success rates between the two surgical methods in short-term follow-ups, long-term results could differ (24).

In our study, the overall success rate of urinary incontinence treatment in the follow-up of 253 operated patients was found to be 65.12%. Patients followed for one year in three-month periods were observed to need longer follow-ups. When patients were examined in two groups-TOT and Kelly's plication—the success rate in those who underwent the TOT procedure (75%) was statistically significantly higher compared to those who underwent Kelly's plication (61%) ($p=0.03$). However, the likelihood of persistent urinary incontinence complaints was significantly higher in patients who underwent the TOT

procedure compared to those who underwent Kelly's plication (OR: 2.07, 95% CI: 1.12-3.93, $p=0.02$).

These results suggest that while the TOT procedure has higher success rates in the short term, the likelihood of persistent urinary incontinence complaints is higher in the long term compared to Kelly's plication. In our study, we examined some factors that might affect the treatment success in patients who underwent Kelly's plication and TOT procedures for the treatment of SUI and the etiology of urinary incontinence.

This study has several limitations. The single-center design may limit the generalizability of the findings. Additionally, its retrospective nature imposed data constraints, making it challenging to access all desired information. The absence of urodynamic and uroflowmetry tests, as well as the lack of pre- and post-operative anxiety and satisfaction surveys, may have concealed factors influencing surgical outcomes. Furthermore, the short-term follow-up period is another limitation, preventing a comprehensive evaluation of long-term success and complications.

Conclusion

In conclusion, this study compared the outcomes of TOT and Kelly's plication

procedures for urinary incontinence, showing that while TOT had higher short-term success rates, it was associated with a greater likelihood of persistent urinary incontinence complaints in the long term. Additionally, BMI was identified as a factor influencing the persistence of symptoms, whereas other demographic and clinical variables did not show a significant effect. Further prospective, multi-center studies with extended follow-up periods are needed to confirm these results and provide more robust clinical guidance.

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Conflict of Interest:

The authors report no conflicts of interest.

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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