ORIGINAL RESEARCH

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Comparison of Transobturator Tape (TOT) and BURCH Colposuspension in the Surgical Treatment of Female Urinary Incontinence

Kadınlarda İdrar Kaçırmanın Cerrahi Tedavisinde Transobturator Bant (TOT) ve BURCH Kolposüspansiyonunun Karşılaştırılması

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Abstract

Objective: The aim of this prospective comparative study is to compare the outcomes of the transobturator tape (TOT) and Burch operations through clinical and quality of life analyses in women with urinary incontinence.

Method: The patients who presented with urinary incontinence symptoms to the obstetrics and gynecology clinic of a university hospital between June 2007 and June 2008 were included in the study. Patients diagnosed with stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) were scheduled for TOT or BURCH procedures. Preoperative urological and gynecological histories were obtained, along with gynecological examinations, ultrasonography and quality of life questionnaires. All patients were followed for 18 months in the postoperative period. Follow-up studies included stress tests, presence of incontinence and quality of life questionnaires, and postvoid residual volume measurements. Two treatment procedures and their outcomes were compared.

Results: Of the 50 patients, 37 (74%) had SUI, and 13 (26%) had MUI. The mean age of the patients was 47.42±9.48 years (similar within groups). Postoperative decreases in hemoglobin concentration were similar between groups. Postoperative complications occurred in 12 (48%) patients in the TOT group and 5 (20%) patients in the BURCH group (p=0.072). All quality of life scores showed significant improvement between pre-postoperative periods, with similar changes in both groups. Subjective improvement was observed in 88% of patients in the TOT group and 80% in the BURCH group.

Öz

Amaç: Bu prospektif karşılaştırmalı çalışmanın amacı, idrar kaçırma sorunu olan kadınlarda transobturator bant (TOT) ve BURCH operasyonlarının sonuçlarını klinik ve yaşam kalitesi analizleri yoluyla karşılaştırmaktır.

Yöntem: Haziran 2007 ile Haziran 2008 arasında bir üniversite hastanesinin kadın hastalıkları ve doğum kliniğine idrar kaçırma semptomlarıyla başvuran hastalar çalışmaya dahil edildi. Stres üriner inkontinans (SUI) veya karma üriner inkontinans (MUI) tanısı konulan hastalara TOT veya BURCH prosedürleri planlandı. Ameliyat öncesi ürolojik ve jinekolojik öyküler, jinekolojik muayeneler, ultrasonografi ve yaşam kalitesi anketleri alındı. Tüm hastalar ameliyat sonrası dönemde 18 ay boyunca takip edildi. Takip çalışmaları stres testleri, inkontinans varlığı ve yaşam kalitesi anketleri ve işeme sonrası kalan hacim ölçümlerini içeriyordu. İki tedavi prosedürü ve sonuçları karşılaştırıldı.

Bulgular: Elli hastanın 37'sinde (%74) SUI, 13'ünde (%26) MUI vardı. Hastaların ortalama yaşı 47,42±9,48 yıldı (gruplar içinde benzer). Ameliyat sonrası hemoglobin konsantrasyonundaki düşüşler gruplar arasında benzerdi. Ameliyat sonrası komplikasyonlar TOT grubunda 12 (%48) hastada ve BURCH grubunda 5 (%20) hastada meydana geldi (p=0,072). Tüm yaşam kalitesi skorları ameliyat öncesi ve sonrası dönemler arasında anlamlı iyileşme gösterdi ve her iki grupta da benzer değişiklikler oldu. TOT grubunda hastaların %88'inde ve BURCH grubunda hastaların %80'inde öznel iyileşme görüldü. TOT grubunda hastaların %84'ünde ve BURCH grubunda hastaların

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Abstract

Objective improvement was noted in 84% of the TOT group and 80% of the BURCH group. These results were statistically similar between the groups.

Conclusion: The success rate of BURCH is similar to the TOT procedure. TOT procedure is also a valuable alternative surgical method with a lower complication rate than the BURCH.

Keywords: BURCH, transobturator tape, urinary incontinence, women

Öz

%80'inde nesnel iyileşme kaydedildi. Bu sonuçlar gruplar arasında istatistiksel olarak benzerdi.

Sonuç: BURCH'nin başarı oranı TOT prosedürüne benzerdir. TOT prosedürü ayrıca BURCH'den daha düşük komplikasyon oranına sahip değerli bir alternatif cerrahi yöntemdir.

Anahtar kelimeler: BURCH, kadınlar, idrar kaçırma, transobturator bant

Introduction

Urinary incontinence (UI), defined by the International Continence Society, is the urine leaks without control that causes social or hygienic problems and can be objectively demonstrated (1,2). Stress urinary incontinence (SUI) is the most common subtype, occurring during physical activities that increase intra-abdominal pressure, such as coughing or lifting. It particularly affects many women in the postmenopausal period; while it is seen at a rate of 35% in Europe, it varies between 16.1% and 25.1% in Turkey, depending on age (3,4).

While conservative therapies—including lifestyle modifications, pelvic floor muscle training, and pharmacological interventions—are recommended as first-line management, a significant proportion of women experience persistent symptoms. In such cases, surgical intervention remains the standard of care (5). For decades, BURCH procedure was considered the gold standard surgical treatment for SUI (6). However, the introduction of minimally invasive mid-urethral sling procedures revolutionized surgical practice. Among these, the transobturator tape (TOT) technique, described by Delorme in 2001, has gained widespread acceptance due to its comparable success rates, shorter operative time, and lower risk of perioperative complications (7,8).

The primary aim of this study is to compare the effectiveness, complication rates, and quality-of-life outcomes between BURCH and TOT procedures, thereby providing evidence to guide clinical decision-making in SUI management. Importantly, unlike many prior studies limited by short-term follow-up or a predominant focus on objective cure rates, the present study emphasizes long-term outcomes and incorporates patient-reported quality-of-life measures. In doing so, it addresses a critical gap in the literature and contributes to a more comprehensive understanding of treatment effectiveness from both clinical and patient-centered perspectives.

Materials and Methods

This prospective study was conducted with patients who consecutively presented with UI symptoms to the Department of Obstetrics and Gynecology at Hatay Mustafa Kemal University Hospital between June 2007 and June 2008. The study included women aged ≥18 who agreed to participate in this study. Patients with predominant urge incontinence, diabetes, or neurological deficits were excluded. Following a preliminary evaluation of patients who consecutively presented to our clinic with UI symptoms, decisions were made regarding the appropriate surgical procedures. BURCH procedure were performed in patients who required open abdominal-pelvic surgery for other indications and patients who had not previously undergone open abdominal-pelvic surgery. The TOT procedure was preferred for patients who had previously undergone open abdominal-pelvic surgery. Additionally, patients' preferences for surgical methods were also taken into consideration. A total of 50 patients diagnosed with SUI or mixed urinary incontinence (MUI) were scheduled for either TOT or BURCH procedures. Each surgical procedure group consisted of 25 patients. This study was not randomized, and allocation to surgical procedures was based on clinical indications, prior surgical history, and patient preference. The effectiveness, feasibility, complication rates, and impact on quality of life were descriptively compared between the two groups; however, due to the non-randomized design, these comparisons should not be interpreted as causal.

In a chi-square model with a Type 1 error (alpha) of 0.05, a power ratio (1-beta) of 0.85, and an effect size (w) of 0.5 and degrees of freedom of 2, we predicted that a total of 44 cases would be included in the study. Because of the potential for data loss, we included a total of 50 patients who met the inclusion criterias and agreed to participate in the study. Informed consent was obtained from all participants. The study was approved by the Ethics Committee of Hatay Mustafa Kemal University Tayfur Ata Sökmen Faculty of

Medicine (approval number: 06/04, date: 25.06.2009). This approval was obtained for the analysis of prospectively collected institutional data.

Data Collection and Preorerative Assessment

Demographic characteristics, incontinence questionnaires, quality of life scores [incontinence quality of life scale (I-QOL), incontinence and prolapse symptom inventory-quality of life scale (PSI-QOLS)], clinical findings, neurological assessments (clitoral reflex, anal reflex, cough reflex), stress tests, Q-tip tests, postvoid residual volumes, hospital stay durations, catheterization times, ultrasonography results, materials used (tape, etc.), operation times, and outcomes were recorded.

I-QOL was developed to determine the QOL of patients with UI. The questionnaire items are in the five-category Likert type. The calculated total score is converted to scores between 0 and 100 and consists of three subdimensions (limiting behaviors, psychological impact, limiting social life). Higher scores indicate a better QOL (9). The Turkish validity and reliability study was conducted by Eyigor et al. (10). We used the PSI-QOL, which contains 11 items for prolapse symptoms and 4 items for life domains of social, physical and entertainment activities, and sexual function (11). The Turkish validation and reliability study of PSI-QOL was conducted by Cam et al. (12). Percentage changes in quality-of-life scores were calculated using the formula: (postoperative score-preoperative score)/preoperative score ×100. High percentage changes may occur when baseline scores are low and should therefore be interpreted with caution.

Pelvic examination was performed using the Baden-Walker classification system. Preoperative and postoperative hemoglobin levels, urine cultures, and urinalyses were obtained. SUI diagnosis was confirmed by observing urine leakage during Valsalva maneuver and coughing after bladder filling with 300 mL saline. Bladder neck mobility was considered positive when the Q-tip test demonstrated an angle change greater than 30°. Patients with urinary tract infection were treated and re-evaluated prior to surgery.

Follow-up Schedule

Postoperative evaluations were performed at 1 week, 1 month, 3 months, 6 months, 12 months, and annually thereafter. Follow-up assessments included stress tests, symptom evaluation, quality of life questionnaires, postvoid residual volume, and complication monitoring. Mean follow-up duration was 15.8±5.9 months (range, 6-24 months).

Surgical Procedures

All patients received antibacterial prophylaxis (cefazolin 1 g intravenously preoperatively and postoperatively) and a vaginal suppository (Biokadin®) one day before surgery.

• **TOT procedure:** After bladder emptying, the TOT technique was performed using I-STOP® polypropylene tape (CL Medical). An 18F Foley catheter was inserted at the end of surgery and removed 36 hours later. Spinal anesthesia was used in 32% of patients and general anesthesia in 68%.

• **BURCH procedure:** Performed according to the Petri technique, using non-absorbable sutures (size 0 or 1). All patients received general anesthesia. A 16F Foley catheter was removed 24 hours postoperatively.

Perioperative data included operative time, hospital stay, catheterization duration, and postoperative residual urine volume. Patients were discharged when postvoid residual volume was <100 mL.

Outcomes and Complications

Surgical success was defined as a negative stress test, postvoid residual volume <100 mL, and complete continence. Failure was defined as persistent leakage or positive stress test. Complications within 15 days were classified as early postoperative complications, and those occurring after 15 days as late complications

Statistical Analysis

Statistical analysis was performed using SPSS for Windows 10.0. Descriptive statistics (mean, standard deviation, frequency) were used. Bonferroni-corrected Friedman and Mann-Whitney U tests were used to compare preoperative and postoperative changes between groups. Wilcoxon tests were applied to compare absolute values before and after surgery. Pearson chi-square and Fisher's exact tests were used for categorical data. Statistical significance was set at $p<0.05$ with a 95% confidence interval.

Results

A total of 50 patients were included in the study. Of these, 37 (74%) were diagnosed with SUI, while 13 (26%) had MUI. Among the SUI patients, 22 underwent TOT surgery, and 18 underwent BURCH procedures. For MUI patients, 3 underwent TOT and 7 underwent BURCH procedures. General anesthesia was used in 17 (68%) TOT cases, while spinal anesthesia was applied in 8 (32%). All BURCH procedures were performed under general anesthesia.

Patient Characteristics

The patients' ages ranged from 27 to 70 years, with a mean age of 47.42±9.48. In the TOT group, the mean age was 49.4±10.73, while in the BURCH group, it was 45.44±7.77, with no statistically significant difference (p=0.177). The body mass index (BMI) of all patients ranged from 20.80 to 39.80 (mean 28.66±4.46), with similar mean BMI values in the TOT (29.73±4.54) and BURCH (27.58±4.20) groups (p=0.071).

Table 1 provides an overview of the demographic and clinical characteristics of TOT and BURCH patients. Eighteen patients (36%) were postmenopausal, while 32 (64%) were in their reproductive period. Parity ranged from 2 to 12, with a mean of 4.82±2.11 across all patients. Parity averages were comparable between the TOT (4.76±2.04) and BURCH (4.88±2.22) groups (p=0.953).

Preoperative Q-tip test positivity (>30 degrees) was observed in 20 patients (40%), with 52% positivity in the TOT group and 28% in the BURCH group. The difference in Q-tip positivity was not statistically significant (p=0.086).

Pelvic Organ Prolapse and Surgical History

All patients had some degree of pelvic organ prolapse. Uterine descent was Grade I in 38 (76%) and Grade II in 12 (24%) patients. Figure 1 illustrates the distribution of cystocele, rectocele, and uterine descent grades across the groups. Cystocele grades were distributed as Grade I in 21 (42%), Grade II in 24 (48%), and Grade III in 5 (10%) cases. Rectocele grades were Grade I in 29 (58%), Grade II in 19 (38%), and Grade III in 2 (4%) patients.

Sixteen patients (32%) had a history of gynecological surgeries, including one incontinence surgery. Figure 2 highlights the distribution of prior surgeries by groups. Table 2 shows the distribution of surgical histories and combined gynecological procedures. Additional gynecological surgeries were performed concurrently in 38 patients (76%), with 68% in the TOT group and 84% in the BURCH group.

Operative and Postoperative Findings

The mean operative time was significantly shorter for TOT (20.03±2.83 minutes) compared to BURCH procedures (36.66±9.24 minutes, p<0.001). The mean catheterization

Table 1. Characteristics of patients in TOT and BURCH groups

Characteristic	All patients (n=50)	TOT group (n=25)	BURCH group (n=25)	p-value
	Mean	Mean	Mean	
Age (years)	47.42	49.40	45.44	0.177
Parity	4.82	4.76	4.88	0.953
BMI (kg/m²)	28.66	29.73	27.58	0.071

TOT: Transobturator tape, BMI: Body mass index

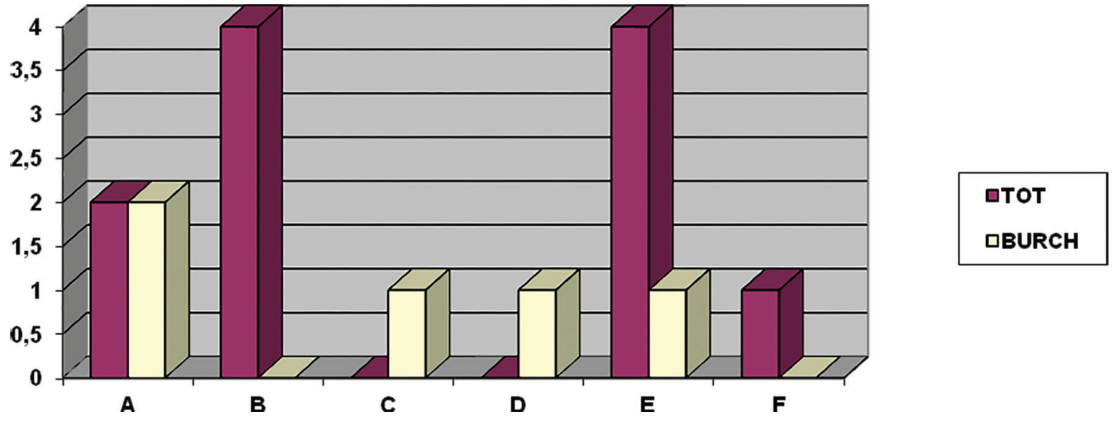

Figure 1. Distribution of prior surgeries by groups

A: Total abdominal hysterectomy with bilateral salpingo-oophorectomy (TAH+BSO); B: Cesarean section; C: Tubal ligation; D: Oophorectomy; E: Colporrhaphy; F: BURCH colposuspension

TOT: Transobturator tape

time was longer in the TOT group (40.64±21.63 hours) compared to the BURCH group (28.44±14.28 hours, p<0.001). Longer catheterization time in the TOT group compared to the BURCH group was observed; however, this finding should be interpreted cautiously and does not necessarily indicate a clinically meaningful disadvantage. The mean hospital stay was also shorter for TOT (2.23±1.01 days) than BURCH (2.54±0.59 days, p<0.001).

There was no significant difference in hemoglobin decline postoperatively between the TOT (14.61±8.33%) and BURCH (16.15±6.73%) groups (p=0.383). No major intraoperative complications such as vaginal perforation or nerve injury occurred in TOT cases. However, three BURCH cases experienced intraoperative bleeding managed by suture placement and compression. Table 3 shows the distribution of postoperative complications in TOT and BURCH groups.

Postoperative Complications

Complications included urinary retention in one patient from each group, urinary tract infections in 5 patients (3 TOT, 2 BURCH), and transient groin pain in 5 patients (4 TOT, 1 BURCH), all managed successfully.

Objective and Subjective Outcomes

Objective success was defined as negative stress tests, postvoid residuals <100 mL, and full continence at 3 and 12 months postoperatively. Success rates were similar between the groups (TOT 84% vs. BURCH 80%, p>0.05). Subjective success, assessed using patient-reported improvement scales, was also comparable (TOT 88% vs. BURCH 80%, p>0.05).

Quality of Life

Quality of life improvements were assessed using the I-QOL and PSI-QOLS. Significant postoperative improvements were noted in both scales for both groups (p<0.01). The percentage changes in I-QOL scores from baseline to 12 months were 101.54% for TOT and 57.86% for BURCH. PSI-QOLS scores showed similar trends, with mean improvements of 26.33% for TOT and 31.56% for BURCH, with no significant differences between the groups (p=0.844). Table 4 summarizes the changes in I-QOL and PSI-QOLS survey results.

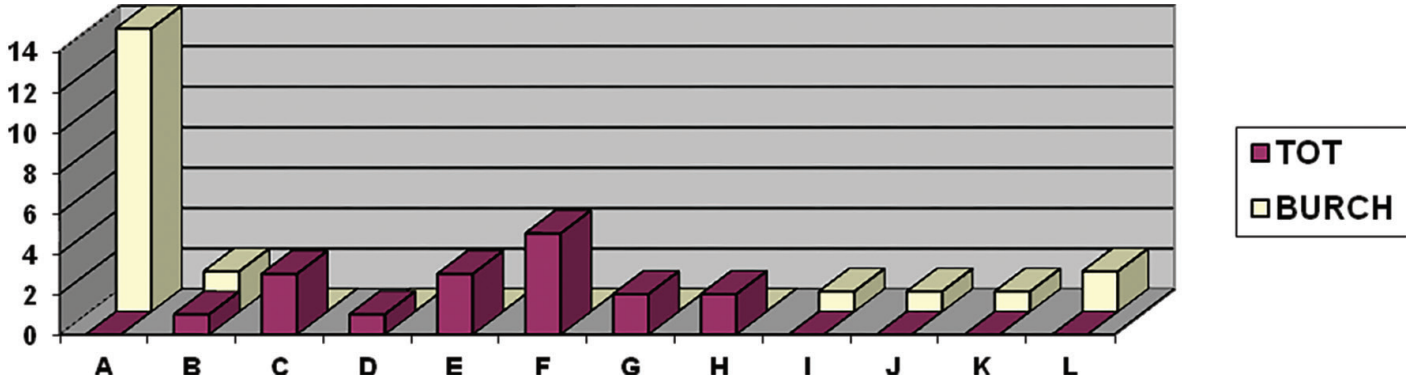

Figure 2. Additional gynecological procedures performed concurrently with transobturator tape (TOT) and BURCH surgeries

***A**: Total abdominal hysterectomy with bilateral salpingo-oophorectomy and culdeplasty (TAH+BSO+culdeplasty); **B**: Total abdominal hysterectomy with bilateral salpingo-oophorectomy (TAH+BSO); **C**: Vaginal hysterectomy with colporrhaphy (VH+CAP); **D**: Colporrhaphy (CAP); **E**: Anterior colporrhaphy (CA); **F**: Posterior colporrhaphy (CP); **G**: Laparoscopic tubal ligation with colporrhaphy (L/S T/L+CAP); **H**: Colpotomy with tubal ligation and colporrhaphy (colpotomy T/L+CP); **I**: Myomectomy with tubal ligation and colporrhaphy (myomectomy T/L+CP); **J**: Oophorectomy; **K**: Mini-laparotomy with tubal ligation (mini laparotomy T/L); **L**: Sacrocolpopexy with culdeplasty*

Table 2. Distribution of cystocele, rectocele, and uterine descent grades

	Grade I n (%)	Grade II n (%)	Grade III n (%)
Cystocele	21 (42%)	24 (48%)	5 (10%)
Rectocele	29 (58%)	19 (38%)	2 (4%)
Uterine descent	38 (76%)	12 (24%)	-

Table 3. Distribution of postoperative complications

	TOT		BURCH	
	Observed n (%)	**Not observed n (%)**	**Observed n (%)**	**Not observed n (%)**
Urinary tract infection	3 (12%)	22 (88%)	2 (8%)	23 (92%)
Urinary retention	1 (4%)	24 (96%)	1 (4%)	24 (96%)
Vaginitis	2 (8%)	23 (92%)	-	25 (100%)
Groin pain	4 (16%)	21 (84%)	1 (4%)	24 (96%)
Dyspareunia	2 (8%)	23 (92%)	-	25 (100%)
***De novo* urge symptoms**	-	25 (100%)	1 (4%)	24 (96%)
Fever	-	25 (100%)	-	25 (100%)
Erosion	-	25 (100%)	-	25 (100%)

TOT: Transobturator tape

Table 4. Changes in I-QOL and PSI-QOLS questionnaire results

	TOT		p**	BURCH		p**
	Preoperative Mean ± SD	**Postoperative 12th month Mean ± SD**		**Preoperative Mean ± SD**	**Postoperative 12th month Mean ± SD**	
*I-QOL	54.26±24.21	92.15±19.10	0.001	58.60±20.24	80.95±19.02	0.001
*PSI-QOLS	50.94±9.77	62.26±7.70	0.001	51.15±13.84	61.95±8.87	0.001

TOT: Transobturator tape, I-QOL: Incontinence quality of life scale, PSI-QOLS: Prolapse symptom inventory-quality of life scale, SD: Standard deviation, *: Friedman test, **: p<0.05

Discussion

UI is a big public health issue with increasing awareness and aging population driving the demand for treatment. Despite many surgical techniques developed, there is no universally accepted gold standard exists for all cases. Among the various types of UI, SUI is the most common and has the most options. But success of these interventions depends on accurate diagnosis of the underlying pathophysiology and choosing the right surgical technique. Our study compared TOT and BURCH procedure, two common surgical methods for SUI, on their effectiveness, safety and patient reported outcomes. TOT appeared to be more frequently preferred in patients with urethral hypermobility, while BURCH was more commonly used in patients requiring concurrent pelvic surgery. This is in line with previous studies that TOT is good for urethral hypermobility and BURCH for complex pelvic floor dysfunction (13,14).

Similar to the literature, TOT had significantly shorter operative time and hospital stay compared to BURCH procedure (15-17). However, unlikely, we found a longer postoperative catheterization time in the TOT group than the BURCH group. Sharma et al. (16) presented a mean of 1.2 day, Roumeguère et al. (17) presented a mean of 0.9 day for postoperative catheterization time in TOT patients. We think that our conflictive result about this issue is likely due to transient voiding dysfunction associated with sling positioning.

In this study, the overall complication rate was similar between the two groups, TOT had slightly higher postoperative complication rate (48% vs 20%). Although the complication rate was numerically higher in the TOT group, this difference did not reach statistical significance and therefore cannot be interpreted as a meaningful clinical difference. Most of the complications like UTI and transient groin pain were minor and managed conservatively. No major intraoperative complications like bladder perforation or nerve injury occurred in either group. This is in line with previous studies showing the safety of both procedures (18,19).

Objective success defined as negative stress test and postvoid residual under 100 mL, was comparable between the TOT (84%) and BURCH (80%) groups, with no statistically significant difference. Similarly, subjective success, assessed through patient-reported improvement scales, showed nearly equivalent outcomes (88% for TOT vs. 80% for BURCH). These findings reinforce that both surgical techniques yield robust and consistent efficacy in appropriately selected patients, in line with prior reports

demonstrating that the choice of procedure does not substantially alter cure rates when clinical indications are carefully considered (7,20).

Quality-of-life outcomes followed a similar pattern. Both groups experienced significant improvements in I-QOL and PSI-QOL scores postoperatively, reflecting meaningful patient-perceived benefits. Although TOT demonstrated a numerically higher percentage improvement in I-QOL scores, this may be influenced by lower baseline values, and no statistically significant difference was observed between the groups. This indicates that while minor variations in effect size may exist, both procedures contribute meaningfully to patient-reported quality of life improvements (21,22). The lack of significant divergence across both objective and subjective measures highlights the clinical equivalence of TOT and BURCH in terms of overall treatment success.

TOT and BURCH procedures have unique benefits that make them suitable for different patient groups. TOT is minimally invasive, has a shorter surgery time, and can be done under regional anesthesia, making it a good option for older and obese patients. On the other hand, BURCH procedure is better suited for patients who need additional pelvic procedures or have anatomical issues that make TOT unsuitable. These observations are consistent with studies that highlight the need for personalized treatment plans based on individual patient characteristics and clinical situations (14,23). Although TOT had higher rates of postoperative complications, most were minor and temporary. Common issues included urinary retention and groin pain, both of which resolved with conservative treatment. BURCH procedure had a lower complication rate but showed a slightly higher occurrence of urinary retention that required catheterization. Both techniques had low rates of severe complications, such as urethral or bladder injuries, which aligns with established safety profiles (23).

Recent long-term studies indicate that while TOT shows better short-term outcomes in terms of surgery time and reduced hospital stays, the modified laparoscopic BURCH procedure provides durable benefits for selected patient groups with specific anatomical considerations. Our findings support these observations, showing comparable objective success rates between both methods, which highlights the need for tailoring surgical choice to individual patient profiles rather than adopting a universal approach (24).

Clinical considerations also point to the importance of minimizing complications such as mesh erosion and chronic pain. Although TOT was associated with more transient minor complications, the modified BURCH approach demonstrated lower rates of dyspareunia and chronic pelvic pain, consistent with prior reports (25). These patterns reinforce that both procedures remain viable options, with distinct strengths that should be matched to patient-specific factors.

Study Limitations

This study has several limitations. First, the study design was non-randomized, and allocation to surgical procedures was influenced by clinical indications, prior surgical history, and patient preference. Therefore, selection bias cannot be excluded, and the two groups may not be fully comparable. Accordingly, direct comparative or causal interpretations between TOT and BURCH procedures should be made with caution. Furthermore, the relatively small sample size limits the statistical power of the study and the generalizability of the findings.

Conclusion

In conclusion, both TOT and BURCH procedure are effective and safe surgical options for managing SUI, with similar objective and subjective success rates. TOT may be considered a suitable option for patients seeking a minimally invasive procedure with faster recovery, while BURCH is more suitable for those requiring concurrent pelvic surgery or at higher risk of mesh-related complications. While both techniques are effective and safe, patient-specific anatomical and clinical features should guide surgical choice. Surgical decision-making should therefore be guided by patient anatomy, comorbidities, and treatment priorities. Future randomized studies with longer-term follow-up may further clarify optimal patient selection criteria.

Ethics

Ethics Committee Approval: The study was approved by the Ethics Committee of Hatay Mustafa Kemal University Tayfur Ata Sökmen Faculty of Medicine (approval number: 06/04, date: 25.06.2009).

Informed Consent: Informed consent was obtained from all participants.

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Footnotes

Authorship Contributions

Surgical and Medical Practices: Ç.Y., A.U.H., Concept: Ç.Y., A.U.H., Design: Ç.Y., A.U.H., Data Collection or Processing: Ç.Y., A.U.H., Analysis or Interpretation: Ç.Y., A.U.H., Literature Search: Ç.Y., Writing: Ç.Y., A.U.H.

Conflict of Interest: No conflict of interest was declared by the authors.

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