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Surgical Correction of Stress Urinary Incontinence Using Concurrent Cystocele Repair on Transobturator Tape: A Retrospective Cohort Study

Conflict of interest: nothing to declare.
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Abstract

Introduction. Stress Urinary Incontinence (SUI) is the most prevalent urinary problem in women; it affects their quality of life and results in several problems, including issues with sexual intimacy. Minimally invasive surgical procedures have developed over time to manage this health problem, including mid-urethral sling procedures such as transobturator tape (TOT) and transvaginal tape (TVT).
Purpose. To evaluate the effect of concurrent cystocele repair with the TOT procedure on improving the symptoms and quality of life in female patients with SUI.
Materials and methods. In a retrospective case-control study that included 98 participants, the women were split into two groups; the first group involved 49 women who received repair with TOT alone, and the second group involved 49 women who received cystocele repair done concurrently with TOT.
Results. After nine months of the initial surgical procedure, both groups showed significant improvement based on the Pelvic Organ Prolapse-Quantification (POP-Q) system; however, no significant differences were observed between treatments, no statistically significant difference between both groups in the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) score at baseline assessment; after nine months, TOT with cystocele corrections showed significantly lower scores. The cure rate was significantly higher in the TOT and cystocele repair compared to TOT only (77.6% vs. 53.1%).
Conclusion. Combined TOT with cystocele repair improved quality of life, severity, frequency, urinary continence effectiveness, and cystocele cure rate in the sampled patients.
Keywords: stress incontinence, cystocele, midurethral sling, transobturator tape, transvaginal tape

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Хирургическая коррекция стрессового недержания мочи с одновременным лечением цистоцеле с применением трансобтураторной ленты: ретроспективное когортное исследование

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Резюме

Введение. Стрессовое недержание мочи (СНМ) является наиболее распространенной проблемой мочеиспускания у женщин; оно влияет на качество жизни и приводит к ряду проблем, включая проблемы с сексуальной близостью. На протяжении многих лет для решения этой проблемы разрабатывались малоинвазивные хирургические процедуры, включая процедуры слинга в средней части уретры, такие как трансобтураторная лента (TOT) и трансвагинальная лента (TVT).
Цель. Оценить влияние сопутствующего лечения цистоцеле с выполнением процедуры TOT на облегчение симптомов и улучшение качества жизни у пациенток с СНМ.
Материалы и методы. В ретроспективном исследовании методом «случай-контроль», включавшем 98 участниц, пациенток разделили на две группы: в первую вошли 49 женщин, которым была выполнена только операция TOT, а во вторую – 49 женщин, которым было проведено лечение цистоцеле в сочетании с TOT.
Результаты. Через девять месяцев после первичного хирургического вмешательства в обеих группах было отмечено достоверное улучшение по международной системе оценки пролапса тазовых органов Pelvic Organ Prolapse-Quantification (POP-Q); при этом не было отмечено достоверных различий между результатами применения различных методов лечения, не выявлено статистически значимой разницы между группами в баллах по опроснику Международного совещания по вопросам инконтиненции – краткая форма (ICIQ-SF) при оценке исходного состояния; через девять месяцев в группе TOT с коррекцией цистоцеле показатели достоверно снизились. Частота излечения была значительно выше в группе с одновременным выполнением TOT и коррекцией цистоцеле по сравнению с группой, в которой выполняли только TOT (77,6% по сравнению с 53,1%).

Заключение. Сочетание ТОТ с лечением цистоцеле позволило улучшить качество жизни, уменьшить степень выраженности симптомов, частоту мочеиспускания, повысить эффективность поддержания непрерывности мочеиспускания и частоту излечения цистоцеле у пациентов, включенных в выборку.
Ключевые слова: стрессовое недержание мочи, цистоцеле, мидуретральный слинг, трансобтураторная лента, трансвагинальная лента

■ INTRODUCTION

Stress urinary incontinence (SUI) refers to the unintentional and abrupt release of urine caused by heightened pressure within the abdomen, which can be distressing or have a negative impact on the patient's overall well-being [1]. SUI greatly affects the quality of life (QoL) for numerous females. However, the prevalence of SUI is difficult to determine precisely due to variances in defining SUI and variations in the populations studied [2]. The frequency of stress urine incontinence tends to rise with increasing age, especially during menopause. A survey discovered that 41% of women aged 40 or above experience urine incontinence [3]. As a result of the possibility of urine leakage, females suffering from SUI may have difficulties in their sexual life. Much of the woman's and her family's income might be spent on symptom management. At a certain point in their lifetime, one-third of females aged 18 years and over will experience SUI [4].

Pelvic organ prolapse (POP) is a prevalent condition, particularly among women who have undergone childbirth and are in the postmenopausal stage. POP refers to the downward displacement of organs such as the uterus, bladder, colon, and vagina, both inside and outside the vaginal opening; POP is frequently associated with SUI [5]. Around 55% of women with stage 2 POP (prolapse to the hymen ±1 cm) experience concomitant SUI, while only 33% of women with stage 4 POP have SUI [6]. When the prolapse is manually corrected, using a pessary or speculum during a clinical examination, SUI may be observed in as many as 68% of cases [7, 8].

The causes of POP and SUI are intricate and multifactorial. Potential risk factors encompass pregnancy, childbirth, congenital or acquired connective tissue abnormalities, denervation or weakening of the pelvic floor, aging, hysterectomy, menopause, and variables linked to chronically elevated intra-abdominal pressure [9].

The surgery to repair SUI has become less invasive over time [10]. Midurethral sling procedures are among these various surgical operations (which involve transobturator tape (TOT) and transvaginal tape (TVT)) [11]. These procedures are appropriate for both first-time surgical patients and those with a history of failed surgeries. During a mid-urethral sling procedure, tape is placed beneath the urethra. Whenever the female patient coughs, the tape supports preventing urinary flow by compressing the urethra [12].

It remains uncertain which treatment is the most effective in decreasing POP. Both reduction with speculum and pessary have not yielded satisfactory positive predictive values in identifying women who would benefit from a concomitant continence therapy after POP surgery.

The objective of POP surgery is to rectify the support deficit or integrate surrogate tissues to restore pelvic floor anatomy and function. While there are several surgical

options for treating POP with or without SUI, it is currently unclear which treatment is best for each case, especially when considering the presence of symptomatic SUI or hidden SUI detected during testing.

The optimal timing for performing continence procedures in conjunction with or after a two-stage POP surgery, and which specific POP operations can effectively support the urethra or bladder neck to treat or prevent postoperative symptomatic SUI in women with preoperative symptomatic or hidden SUI and symptomatic POP, remains uncertain. Concurrent SUI frequently occurs in women with POP due to the shared underlying mechanisms of these two disorders.

■ PURPOSE OF THE STUDY

To evaluate the effect of concurrent cystocele repair with the TOT procedure on improving the symptoms and quality of life in female patients with SUI.

■ MATERIALS AND METHODS

Study Design

We undertook a retrospective cohort analysis of patients undergoing surgical repair of SUI. Our center is a tertiary referral center that annually receives 80 – 120 SUI operations. As part of an ongoing hospital registration system for our surgical center, the data of the involved patients were obtained. In our center, there were two surgical repairs for SUI: 1) TOT alone and 2) cystocele repair is done concurrently with TOT; thus, the patients were divided accordingly based on these two surgical procedures. The study involved 98 SUI patients, 49 of whom were treated with TOT alone and 49 with cystocele repair. All patients were assessed before the surgical procedure, after six months, after one year, and after two years of their index surgery.

At admission to the hospital, the surgical team obtained a comprehensive medical, surgical, and gynecological history during the preoperative workup as part of their usual routine. A complete neurological examination, standard laboratory examinations, and a pelviabdominal ultrasound were also conducted.

The Pelvic Organ Prolapse Quantification (POP-Q) System was used to characterize pelvic organ prolapse. Utilizing the validated Arabic versions of the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and King Health Questionnaire (KHQ) forms, stress incontinence (SUI) was evaluated using a cough stress test with and without reduction of the prolapsed viscera [13].

Study Setting

The study was conducted at Al-Sadr Teaching Hospital in the Misan governorate between September 2020 and September 2023 [a teaching hospital associated with the College of Medicine / Misan University]. Written and informed consent was obtained from all the patients participating in this study. All patients were followed with a maximum of two years postoperatively per American Urology Association (AUA) guideline – statement 24 [14].

Surgical Procedure

Under spinal anesthesia, sampled patients were positioned in a dorsal lithotomy position followed by the insertion of a 16 French catheter in the urethra. A midline

longitudinal incision was established and then extended from the "bladder neck" region ending just at the level of the "cervix" or "vaginal cuff". The focus then is put on the "paravesical space" between the "bladder" and "the vaginal wall" Lateral right and left dissections were performed for the sake of opening the "paravesical fossa" and reaching the "ischial spine". Two right and left incisions are then established in the "genitofemoral crease" skin just lateral to the "ischiopubic ramus" exactly at the level of the "clitoris". Following that incision, a trocar was passed through the incision and navigated and inserted through the "obturator foramen" around the "ischiopubic ramus" until reaching the recently mentioned vaginal incision guided by the index finger. After that, the trocar was removed, leaving the cannula in place; this was used to pass the retrieval device from the incised skin to the vaginal incision. The loops of the recently passed retrieval device were fed through the cannula, after which the upper arm of the mesh was attached to these loops and pulled out via the cannula, which was removed at the end of the operation leaving the sling under mid-urethra.

Patients' Assessment

The Pelvic organ prolapse quantification system (POP-Q) was utilized to describe and assess the degree of Pelvic organ prolapse [15, 16]. Stress urinary incontinence (SUI) was evaluated by utilizing the "cough stress test" with and without reducing the prolapsed viscera and the ICIQ-SF, which we used its validated Arabic version [14].

Sample Size Calculation

According to a previous study by Onarımının [17], they reported the Postoperative ICIQ-SF in the TOT group to be 3.28±0.78 assuming an improvement by 15% from the previous study we arrived at a sample size of 49 for each group (at type I error 1%, and type II error 5%), MedCalc Statistical Software version 14.8.1 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2014).

Inclusion Criteria

Female patients with age ranged between 40–60 years, with "pure stress incontinence" and/or "stress-predominant mixed urinary incontinence" (MUI) associated with cystocele that had not undergone a previous SUI surgery before and with BMI less than 35 kg/m^2.

Exclusion Criteria

Female patients with age below 40 years, patients who refused to participate in the study, patients with Severe comorbid disease, patients with a previous surgical operation of transvaginal mesh, patients suffering "detrusor overactivity", and patients diagnosed with Female genitourinary Malignancies of or with the presence of neurological disorders that caused voiding dysfunction.

ICIQ-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form) [18]

The ICIQ-SF is a questionnaire for assessing the frequency, severity, and effect of urine incontinence on quality of life (QoL) in men and women; the score runs from 0 to 21, with higher values indicating more severe illness.

King Health Questionnaire (KHQ) [19]

This questionnaire "assesses the impact of lower urinary tract symptoms including UI on health-related quality of life", copyright Mapi Research Trust, ePROVIDE™ (license number 82960).

Furthermore, it contains ten patient-rated domains to assess their quality of life related to SUI. Overall, there are 21 items in the score, each score ranging in value from 0% (best outcome) to 100% (worst outcome), except for Q10, which ranges from 0 to 30 with Zero score being the best and 30 being the worst [20].

If the domain scores on the KHQ go down, life satisfaction increases. Subjects report a minimum meaningful difference (MID) of 3 points on the symptom severity scale (i.e., Q10) and 5 points on all other KHQ categories [20].

Statistical Analysis

The present study analysis used GraphPad Prism version 9.5.1 (733) [Serial number: GPS-2278869-E, MachineID: 1CDE66854DB]. The chi-square test was used for categorical variables. Independent t-tests and paired t-tests were used for continuous variables that followed normal distribution. While the Mann-Whitney U test for continuous variables did not follow the normal distribution, the p-value was considered significant if <0.05 and was two-tailed.

■ RESULTS

The total number of female participants in this study was 98; they were split according to surgical procedure, each having 49 patients. The demographic data is illustrated in Table 1.

After two years of follow-up, both groups showed significant improvement in the Pelvic Organ Questionnaire (POP), particularly after 6 months of improvement; this improvement stabilized after 12 months and 2 years of follow-up; however, no significant differences were observed between the two treatments after 6 months, 12 months, and 2 years, as illustrated by Table 2.

No significant variation existed between the two groups in ICIQ-SF score at baseline assessment; after nine months of follow-up, TOT with cystocele corrections showed

Table 1
Demographic data and general information about the patients

Variables	Value
Number	98
Age (year), mean±SD	50.4±6.3
BMI (kg/m2), mean±SD	28.4±3.4
Mode of delivery, no (%)	
CS	27 (27.6%)
VD	71 (72.4%)
Parity, mean±SD	2.5±1.8
History of gynecological surgery (abdominal or vaginal)	35 (35.7%)
Presence of rectocele, no (%)	76 (77.6%)

Notes: SD – standard deviation, kg – kilogram, m – meter, CS – caesarian delivery, VD – vaginal delivery, no – number, TOT – Transobturator Tape.

Table 2
Assessment of the grades of pelvic organ prolapsus pre- and postoperatively

Parameters	Preoperative	After 6 months	After 12 months	After 2 years
TOT alone				
Grade 0	0 (0.0%)	20 (40.8%)	21 (42.9%)	22 (44.9%)
Grade I	0 (0.0%)	26 (53.1%)	26 (53.1%)	26 (53.1%)
Grade II	17 (34.7%)	2 (4.1%)	2 (4.1%)	1 (2.0%)
Grade III	26 (53.1%)	1 (2.0%)	0 (0.0%)	0 (0.0%)
Grade IV	6 (12.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TOT with cystocele				
Grade 0	0 (0.0%)	27 (55.1%)	27 (55.1%)	28 (57.1%)
Grade I	0 (0.0%)	18 (36.7%)	18 (36.7%)	20 (40.8%)
Grade II	17 (34.7%)	2 (4.1%)	2 (4.1%)	1 (2.0%)
Grade III	24 (49.0%)	2 (4.1%)	2 (4.1%)	0 (0.0%)
Grade IV	8 (16.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
p-value[$]	0.833	0.418	0.258	0.499

Notes: TOT – Transobturator Tape; [$] Chi square test.

Table 3
Comparison of ICIQ-SF scores in both groups pre- and postoperatively

Variables	TOT alone	TOT with cystocele	p-value[$]
Number	49	49	–
Preoperative	14.98±3.40	14.65±3.44	0.612
After 6 months	1.61±2.11	1.06±2.00	0.116
After 12 months	0.37±0.81	0.43±0.94	0.920
After 2 years	0.16±0.51	0.22±0.59	0.545
p-value [#]	<0.001	<0.001	

Notes: [#] Friedman ANOVA, [$] analysis done with Mann-Whitney U test.

significantly lower scores; in addition, 38 (77.6%) in TOT and cystocele while 26 (53.1%) for TOT only group had ICIQ-SF equal to zero (and considered to be cured), as illustrated by table 3 and Fig. 1.

Two-way ANOVA was performed to assess the overall effect of surgical procedures during the 2-year follow-up period, and it showed that time versus surgical procedures showed a significant difference (p-value of interaction <0.001).

Anatomical success was achieved in 93.9% and 92.8% of patients who had undergone TOT alone and TOT with cystocele (anatomical success is defined as a POP score of less than or equal to one at six months of follow-up), as illustrated by Fig. 2A. The procedure outcomes were 89.8% of those who had undergone TOT alone showed a cure from SUI. In comparison, 85.7% of those who had undergone TOT with cystocele showed improvement (a value of ICIF-SF = 0 indicates cure), and the rest of the patients showed improvement of SUI (defined as ICIF-SF ≤12), as illustrated by Fig. 2B.

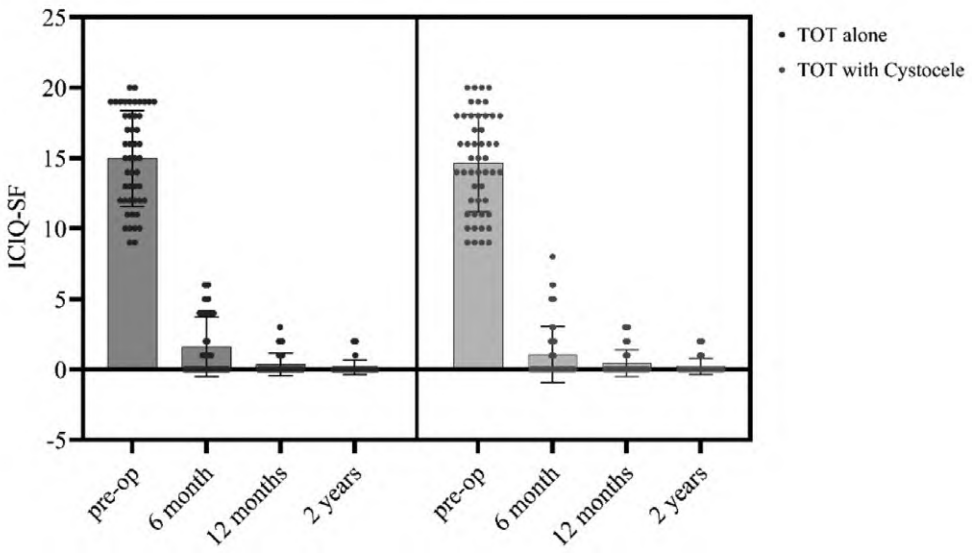

Fig. 1. Assessment of ICIQ-SF

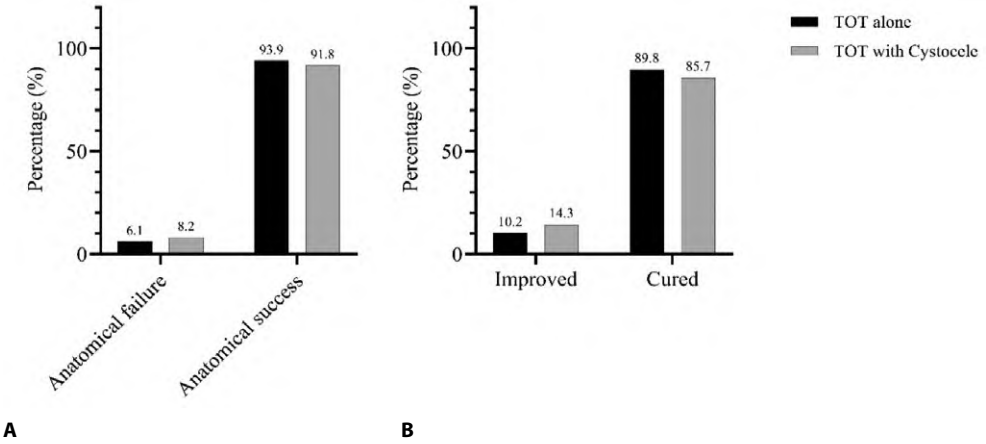

Fig. 2. Assessment of surgical outcomes: A – POP outcomes, B – ICIQ outcomes

Table 4 shows the difference between surgical modalities and quality of life (QOL). TOT with cystocele showed better improvement in several domains of the QOL, which includes Incontinence impact, Role limitations, Physical limitations, Social limitations, Personal relationships, Sleep/energy, Severity measures, and Symptom severity scale.

Table 4
King Health Questionnaire (KHQ) forms evaluation and assessment over the study period for each group.

Variables	TOT alone	TOT with cystocele	p-value#	Variables	TOT alone	TOT with cystocele	p-value#
General health perception				**Personal relationships**			
Preoperative	72.96±21.55	72.96±18.98	0.952	Preoperative	49.30±24.78	48.96±22.94	0.933
After 6 months	16.33±19.47	15.31±18.97	0.804	After 6 months	20.73±19.10	10.18±13.94	0.004
After 12 months	4.59±12.16	7.14±14.43	0.304	After 12 months	16.30±17.83	7.46±11.80	0.008
After 2 years	2.55±7.65	4.59±11.03	0.358	After 2 years	10.87±16.15	4.07±9.32	0.017
Incontinence impact score				**Emotions**			
Preoperative	67.31±25.91	64.59±26.72	0.605	Preoperative	37.38±20.35	41.23±20.01	0.352
After 6 months	10.87±20.83	15.63±25.53	0.407	After 6 months	13.82±15.78	10.65±13.01	0.474
After 12 months	6.12±16.19	0.68±4.76	0.027	After 12 months	10.87±14.42	8.16±12.15	0.365
After 2 years	4.76±13.59	0.68±4.76	0.049	After 2 years	7.48±11.86	6.12±11.11	0.397
Role limitations				**Sleep/energy**			
Preoperative	65.64±22.93	67.00±22.95	0.787	Preoperative	17.31±14.00	18.68±14.67	0.617
After 6 months	31.61±23.88	21.07±21.73	0.028	After 6 months	13.23±13.15	17.23±13.15	0.623
After 12 months	25.83±24.55	16.31±20.83	0.035	After 12 months	7.80±11.31	9.50±12.25	0.493
After 2 years	17.67±21.09	12.91±17.43	0.273	After 2 years	2.37±5.87	6.44±9.49	0.017
Physical limitations				**Severity measures**			
Preoperative	70.06±21.78	62.91±25.07	0.139	Preoperative	63.07±12.38	57.44±14.26	0.030
After 6 months	28.90±26.09	19.71±21.70	0.078	After 6 months	37.56±12.74	24.79±15.16	<0.001
After 12 months	23.45±24.04	14.61±18.82	0.058	After 12 months	16.81±11.96	4.24±7.99	<0.001
After 2 years	19.37±21.34	10.19±15.13	0.021	After 2 years	7.12±9.61	1.19±4.49	<0.001
Social limitations				**Symptom severity scale**			
Preoperative	66.67±21.79	66.32±23.45	0.991	Preoperative	16.49±2.99	16.35±2.64	0.850
After 6 months	43.19±24.76	22.09±20.52	<0.001	After 6 months	11.96±3.26	10.55±3.12	0.055
After 12 months	33.66±23.45	16.30±17.51	<0.001	After 12 months	7.53±3.65	5.00±3.01	<0.001
After 2 years	28.21±21.58	12.23±17.27	<0.001	After 2 years	3.61±2.97	1.71±2.09	0.001

Notes: TOT – transobturator tape; # Mann-Whitney U test.

■ DISCUSSION

Cystocele and SUI are only two of the many anatomical issues that become more common as women age and often necessitate surgical intervention. In women over the age of 80, SUI accounts for 11% of all surgical procedures. 29% of these female patients undergo multiple surgical treatments [21]. Most people who have SUI and need surgery also have cystocele, which also must be surgically repaired [22, 23].

Patients undergoing cystocele correction and a mid-urethral sling procedure should carefully weigh surgery's potential risks and advantages. As was previously indicated, cystocele may influence micturition function and, hence, the effectiveness of a mid-urethral sling procedure [24].

In the present study, simultaneous correction of cystocele with TOT showed significant improvement in terms of ICIQ-SF, which indicates improvement in frequency, severity, and effect of urine incontinence on quality of life (QoL). After nine months of follow-up, there was a cure rate of 38 (77.6%) in TOT and cystocele and 26 (53.1%) for TOT, which was significant.

Several authors have controversial reports regarding the repair of pelvic organ prolapse. Sergent et al. [25] reported that 97% were cured of their prolapse (cystocele reparation), and 69% were cured of their SUI after a median follow of 45 months. In addition, Önol et al. observed a curing rate of 86.4%, 81% for SUI, and concomitant pelvic organ prolapse repair. Pelvic organ prolapse was cured in 99% of patients, with a significant improvement in all domains of the P-QO" questionnaire at the last follow-up; however, contrary to the present study findings, no significant difference between both procedures was observed [26]. The study by Sherif et al. possessed a 96% cure rate based on SUI sum, according to the ICIQ-SF [27].

In terms of anatomically based POP classification, TOT only showed 93.9% and 91.8% for combined TOT cystocele repair, which was similar to the Sherif et al. study with a success rate of about 96% [27], Yonguc et al. exhibited similar findings in the medium-term follow-up of double sling procedure which was 96% success rate[28]. This outcome was superior to previous research in which anatomical and subjective success rates were measured at 87.5% and 92.1%, respectively [29].

In the present study, intraoperative complications, including bladder or urethral injury, were absent, like other studies [18, 21, 22], and minor surgical complications were reported [28–30].

In the present study, QoL was assessed using KHQ, which showed that TOT with cystocele operation improved in several components of the KHQ score compared to TOT alone; this agreed with several reports [27, 31, 32].

The strength of this study lies in its prospective comparison of the difference between TOT alone and TOT with cystocele, which, to our knowledge, is the first to attempt this; in addition, we assess both functional improvement and the patient's perspective and it revealed better outcomes for combined TOT with cystocele.

■ CONCLUSION

Combined TOT with cystocele led to an improved quality of life, severity, frequency, effectiveness of urinary continence, and better cure rate of cystocele in the sampled patients.

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