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FEMALE UROLOGY
Original Article

Transobturator four arms mesh in the surgical management of stress urinary incontinence with cystocele

Sistoselin eşlik ettiği stres üriner inkontinansta cerrahi tedavi olarak dört kollu transobturator meş uygulaması

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ABSTRACT

Objective: This study aims to evaluate safety and efficacy of four arms polypropylene mesh in the long- term follow-up in the management of stress urinary incontinence (SUI) associated with cystocele.

Material and methods: This prospective study was conducted on 50 female patients with SUI associated with cystocele. Patients underwent placement of transobturator four-arms mesh implants. Stress incontinence was evaluated using cough stress test with and without prolapse reduction, Stamey's grading of SUI, the validated Arabic version of the International Consultation on Incontinence Questionnaire-Short Form and King Health Questionnaire forms. Perioperative parameters evaluated included age, body mass index, grade of SUI, time of procedure, hospital stay after surgery, difference between pre-, and postoperative serum hemoglobin values, and need for blood transfusion. Follow- up visits were planned at 3, 9 and 18 months after surgery.

Results: The mean operative time was 37.4±10.2 (25-60) minutes. Blood transfusion was not required. The mean hospital stay was 30.5±10 (24-48) hrs. Five (10%) patients had fever and urinary tract infections were noticed in five (10%) patients. Two (4%) women had urine retention after catheter removal and vaginal mesh erosion was present in one (2%) patient. Forty (80%) patients were cured from SUI, 8 (16%) patients were improved and 2 (4%) patients failed to respond.

Conclusion: Cystocele associated with SUI can be repaired with transobturator four-arms mesh with promising results, improved quality of life, and tolerable side effects.

Keywords: Cystocele; four arms; Mesh; stress urinary incontinence; transobturator.

ÖZ

Amaç: Bu çalışma, sistosele eşlik eden stres üriner inkontinans (SÜİ) tedavisinde dört kollu polipropilen meşin uzun dönemde tedavideki güvenlilik ve etkinliğini değerlendirmeyi amaçlamaktadır.

Gereç ve yöntemler: Bu prospektif çalışmaya eş zamanlı SÜİ ve sistoseli olan 50 hasta dahil edilmiştir. Hastalara dört kollu transobturator meş uygulanmıştır. Stres inkontinans prolapsun yerine konmasıyla birlikte veya yalnız başına öksürük stres testi, Stamey stres inkontinans derecelendirmesi, Arapça için geçerliliği onaylanmış Uluslararası İnkontinans Konsültasyonu Anketi –Kısa Formu (International Consultation on Incontinence Questionnaire-Short Form) ve King Sağlık Sorgulama Anketi (King Health Questionnaire (KHQ) ile değerlendirildi. Yaş, vücut kitle indeksi (VKİ), SÜİ derecelendirmesi, işlemin zamanı, postoperatif dönemde hastanede kalış süresi, ameliyat öncesi ve sonrası serum hemoglobin değerleri arasındaki farklılık, kan nakli gereksinmesi gibi perioperatif parametreler değerlendirildi. Ameliyat sonrası 3, 9 ve 18. aylarda hasta takibi yapıldı

Bulgular: Ortalama ameliyat süresi 37,4±10,2 (25-60) dakika idi. Hiçbir hastada kan transfüzyonu gerekmedi. Hastanede kalış süresi ortalama 30,5±10 (24-48) saat idi. Beş (%10) hastada ateş ve yine 5 (%10) hastada idrar yolu enfeksiyonları mevcuttu. İki (%4) kadında sonda çıkartıldıktan sonra idrar retansiyonu oldu ve bir (%2) hastada vajinal meş erozyonu görüldü. Kırk (%80) hastada SÜİ yönünden tam kür sağlandı, 8 (%16) hastada iyileşme gözlendi. İki (%4) hastada işlem başarısız idi.

Sonuç: SÜİ ile ilişkili sistosel dört kollu transobturator meş ile onarılabilir. Bu teknik sağladığı yaşam kalite iyileşmesi ve tolere edilebilir yan etkileriyle umut vadeden sonuçlar vermektedir.

Anahtar Kelimeler: Sistosel; dört kol; meş; stres üriner inkontinans; transobturator.

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Introduction

Pelvic organ prolapse (POP) is a common condition for women. It affects 30-50% of parous women and it may be concomitantly present with stress urinary incontinence in some women.[1,2] Cystocele [anterior vaginal wall prolapse (AVWP)] is the most common type of POP in women and is due to herniation of the bladder through anterior vaginal wall.[3] It may be lateral or central due to loss of support or weakness of the pubocervical facia between bladder and vagina.[4]

Female stress urinary incontinence (SUI) is a significant health problem which is considered to be a common condition for adult female with prevalence rates ranging from 12.8 to 46%.[5] Popular techniques for repair of stress urinary incontinence are implantation of midurethral slings (MUS) by placing transvaginal or transobturator tape made of polypropylene.[6] POP and SUI are most probably simultaneous conditions. Repair of the two conditions in the same operation has been a point of controversy.[7] When the two procedures are performed in the same session a midurethral sling is implanted after repair of cystocele.[8] One of the most popular procedures for the management of AVWP is anterior colporrhaphy (AC) which may be done alone or with sling operation.[9] Traditional methods for the repair of anterior wall prolapse using native tissue have a high recurrence rate.[10] Also, transabdominal or laparoscopic paravaginal repair have not yielded different results than anterior repair.[11]

Recently synthetic mesh has been widely used and proved its efficacy in the management of SUI and POP due to high recurrence rates and failure of native tissue.[2] Many procedures used polypropylene mesh on a large scale of patients suffered from SUI and POP with high success rates.[12] Four-arms mesh is designed to fix the mesh at four points to the pelvic side wall by passing the needle through four anatomic routes which is relatively easier and safer.[8] Double transobturator four arms polypropylene mesh was introduced for the management of SUI beside anterior compartment repair.[13] Complications related to placement of mesh or passage of needle entrance such as visceral or vascular injury, also pelvic pain or mesh extrusion were reported.[14]

This study aims to evaluate safety and efficacy of four arms polypropylene mesh in management of SUI associated with cystocele during the long term follow-up.

Material and methods

This prospective study was conducted on 50 female patients with SUI associated with cystocele who attended the outpatient clinic between June 2013 and September 2016. All procedures were approved by the local ethics committee. Informed written consent was obtained from all patients about operative details and purposes of research. Women suffered from SUI associated with cystocele were included in this study. Exclusion criteria included women with a history of previous transvaginal mesh surgeries, detrusor overactivity, malignancy of female genital system or urinary bladder, history of pelvic irradiation or presence of neurological disorders that caused voiding dysfunction.

Preoperative workup was performed which included complete medical, surgical and gynecological history. Also, physical examination including full neurological examination, routine laboratory investigations and pelviabdominal ultrasound were performed. Urodynamic investigations included flowmetry, cystometry to assess the maximum cystometric capacity, presence of detrusor overactivity and the Valsalva leak point pressure (VLPP). We used vaginal gauze pack for reduction of severe prolapsus during urodynamic studies.[15] Pelvic organ prolapse was described using pelvic organ prolapse quantification (POP-Q) system. Stress incontinence was evaluated using cough stress test with and without prolapse reduction, Stamey's grading of SUI, the validated Arabic version of the International Consultation on Incontinence Questionnaire-Short Form and King Health Questionnaire (KHQ) forms.[17]

Procedure

Patients subjected to transobturator four arms mesh implantation. We used monofilament polypropylene mesh of GYNECARE PROLIFT Pelvic Floor Repair System (Johnson and Johnson Co Somerville, New Jersey, USA) which included needle guide, cannula and retrieval device. Patients were placed in dorsal lithotomy position under spinal anesthesia and 16 Fr urethral catheter was inserted. Longitudinal midline incision was extended from bladder neck down to the cervix or vaginal cuff (Figure 1) then lateral right and left dissections were performed between bladder and vaginal wall in paravesical space to open the paravesical fossa reaching the ischial spine. Two right and left incisions were made in the genitofemoral crease at the level of clitoris just lateral to the ischiopubic ramus. Needle was passed with the cannula through

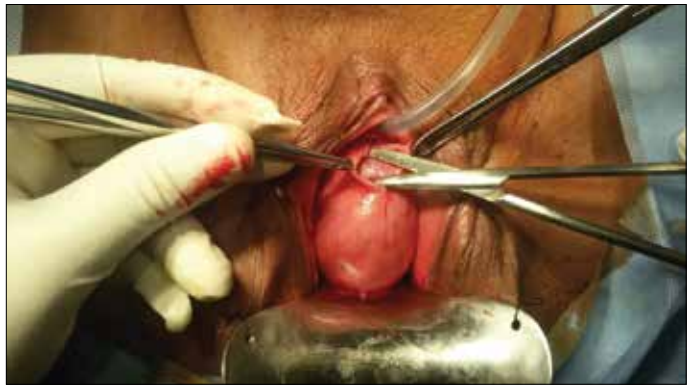

Figure 1. Midline vaginal mucosa incision

the incised skin, and advanced up to the obturator muscle and membrane. Then it was inserted through obturator foramen around ischiopubic ramus till vaginal incision was approached under guidance of index finger (Figure 2). Then needle was removed leaving the cannula, in which the retrieval device was passed from the incised skin to the vaginal incision. Then the loops of the retrieval device were passed through the cannula and the upper arm of the mesh was fixed to it, and brought out through the cannula which then removed. The same procedure was repeated on the other side. The other two skin incisions were done 2 cm lateral and 3 cm inferior to the previous incisions then the procedure was repeated using the lower arms of the mesh as was performed with upper arms. Then the four arms of the mesh were used to adjust it in tension- free method to cover the prolapsed area (Figures 3-5). Finally, vaginal and groin incisions were closed with absorbable 2/0 sutures followed by vaginal pack placed for 24 hour and the catheter was removed after 24 hours. On discharge the patient was given oral ciprofloxacin at a dose of 500 mg at every 12 hours for 5 days, in addition to a non-steroidal anti-inflammatory drug (NSAID) and vaginal antiseptic. Patients were instructed to avoid sexual intercourse for 4 weeks postoperative.

Figure 2. Outside-in cannula

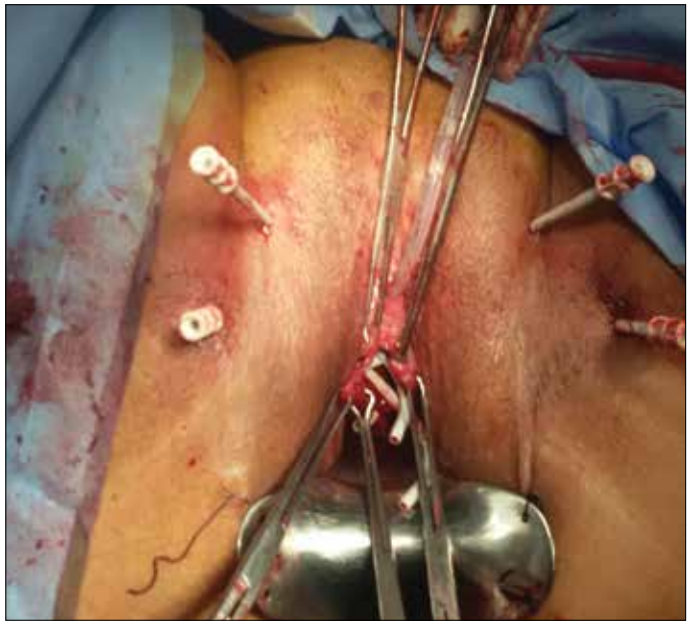

Figure 3. Cannulas through the obturator membrane

Follow-up

The following perioperative parameters were evaluated: age, body mass index (BMI), grading of SUI, time of procedure, hospital stay after surgery, difference between serum hemoglobin levels before and after surgery, and need for blood transfusion. Patients were seen 2 weeks postoperatively to be assessed for any complications. Follow-up visits were planned at postoperative 3, 9 and 18 months and, ICIQ-SF questionnaire, KHQ, Cough test, POP-Q system were administered, as well as

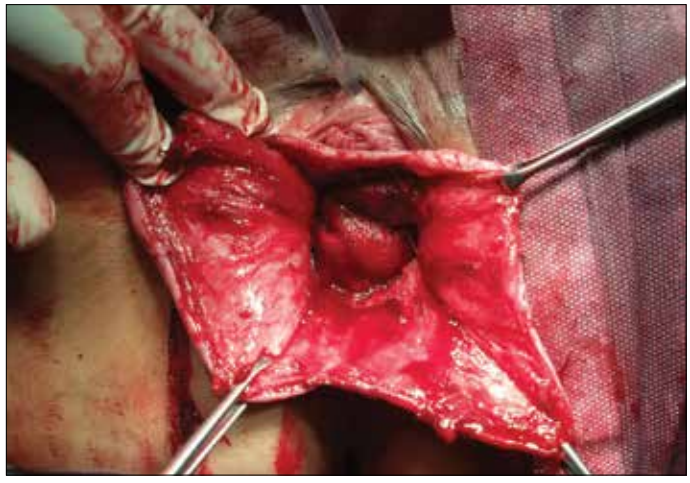

Figure 4. Mesh under the bladder

Figure 5. Four arms mesh

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severity assessment of SUI, visual analogue scale (VAS) for satisfaction, measurement of PVR were performed. Urodynamic studies were realized at postoperative 9 and 18 months.

Statistical analysis

The collected data were tabulated and analyzed using Statistical Package for the Social Sciences version 16 software (SPSS Inc.; Chicago, IL, USA) and Microstat W software (India, CNET Download.com). Categorical data were presented as number and percentages while quantitative data were expressed as mean±standard deviation, and range. Categorical variables were analyzed using "Z" test and Mc Nemer's test. Quantitative data proved to be non-parametric were tested for normality using Shapiro-Wilks test, Friedman test was used to test the differences between matched variables considering p value of 0.05 as statistically significant. Friedman test was followed by post-hoc multiple comparison test using Wilcoxon test with Bonferroni correction to detect the significant pairs at adjusted p=0.008 if four variables, or 0.017 if 3 variables were compared.

Results

Fifty women were included in this study and their demographic data are shown in Table 1. Preoperative data of the patients are shown in Table 2. Two patients at postoperative 9, and another two patients at postoperative 18 month were lost to follow-up.

The mean operative time was 37.4±10.2 (25-60) minutes. Blood transfusion was not required by any patient as mean blood loss was 83.6±62.7 (50-400) mL. The mean hospital stay was 30.5±10 (24-48) hrs. Intraoperatively, no patient had bladder or urethral injury. Five (10%) patients had fever and urinary tract infections (UTIs) were noticed in five (10%) patients during early postoperative period who were improved using antibiotics and antipyretics.

Table 1. Sociodemographic characteristics of the patients

Variable		Mean±SD	Range
Age (years)		47.6±6.4	35-65
BMI (kg/m^2)		26.2±4.1	20-36
Parity		3.7±1.1	2-7
Mode & number	NVD	3.2±1.1	1-7
of delivery	CS	0.5±0.6	0-2
		No.	%
Menopause	No	15	30.0
	Yes	35	70.0

BMI: body mass index; NVD: normal vaginal delivery; CS: cesarean section

Two of the 50 (4%) women had urine retention after catheter removal. They were treated by indwelling catheter for two weeks. One of them improved but the other retained urine again and treated by clean intermittent catheterization for another 2 weeks. Four (8%) patients developed groin and thigh pain that were relieved with analgesics.

Vaginal mesh erosion presented in one (2%) patient who required local estrogen cream for improvement without any need for operative intervention. Dyspareunia was reported in 4 (8%) patients who required topical estrogen cream for relief. Two (4%) patients had recurrent cystoceles which were discovered during local examination at 3 months follow-up in the form of grade II and III cystoceles according to POP-Q, but the patients refused any further surgical intervention.

The outcomes of the procedures were as follows: 40 (80%) patients were cured from SUI, 8 (16%) patients were improved and 2 (4%) patients with recurrent cystoceles failed to respond to the treatment. In 40 patients with ICIQ-SF=0 subjective cure was achieved. Subjective improvement with ICIQ-SF ≤12 was realized in 8 patients. Forty-eight patients achieved objec-

Table 2. Preoperative data of the patients

Variable		n=50 (%)
Cough test	Negative	0 (0)
	Positive	50 (100)
Stamey's grading	Grade I	24 (48)
	Grade II	20 (40)
	Grade III	6 (12)
PVRU (mL)	Mean±SD (Range)	18.4±23.1 (0-95)
VLLP (cm H_2O)	≥90	12 (24)
	60-90	34 (68)
	<60	4 (8)
Q-max (mü/sec)	Mean±SD (Range)	24.8±2.5 (20-30)
ICIQ-SF	Slight	0 (0)
	Moderate	12 (24)
	Severe	28 (56)
	Very severe	10 (20)
	Mean±SD (Range)	14.8±4.1 (6-21)
POP-Q	Grade II	21 (42)
	Grade III	26 (52)
	Grade IV	3 (6)
	Mean±SD (Range)	2.6±0.6 (2-4)

PVRU: Post-void Residual Urine; VLLP:Valsalva leak point pressure; Q-max: Maximum urine flow rate; ICIQ-SF: Arabic version of the International Consultation on Incontinence Questionnaire-Short Form; POP-Q: Pelvic Organ Prolapse-Questionnaire

tive cure with negative cough stress test results, while in two patients objective cure could not be attained.

Anatomical success: In 48 patients POPQ was ≤1 at 3rd month of postoperative follow-up period. Anatomical failure was observed in 2 patients with POPQ II and III. Comparative grades of pelvic organ prolapsus over the period of the study are shown in Table 3. Table 4 does not demonstrate any significant difference regarding PVRU and maximum flow rates during follow-up period, while there was a significant improvement in the mean values of ICIQ-SF and POP-Q scale scores. Table 5 shows changes in KHQ that assess quality of life which reveals significant improvements at postoperative 3, 9 and 18 months in comparison to baseline data.

Discussion

This study assessed the results of transobturator four-arms mesh technique in the management of cystocele associated with SUI. Early reports were controversial regarding the repair of pelvic organ prolapse that may affect bladder neck mobility, results of SUI or obstructive complications, while others reported no effect.[18] Sergent et al.[18] reported 97% and 81% (69% cure and 12% improvement) success rates for the treatment of cystocele and SUI, respectively. Also, Önol et al.[19] noticed a cure rate of 86.4% and improvement rate of 9% for SUI. These data matched with our results as we had cure rate of 96% based on SUI sum, according to ICIQ-SF. Also, the anatomical success rate in our study was 96%, according to POP classification similar to that found in the study by Yonguc et al.[20] which was 96% in medium term follow-up with double sling procedure. This outcome was better than that was found in another study[13] in which anatomical and subjective success rates were 87.5% and 92.1%, respectively.

Only 2 patients showed recurrent cystoceles at follow- up visits in this study which were associated with SUI but the patients refused to undergo any further intervention. Likewise, Eboue et al.[21] reported a 2.4% symptomatic cystocele recurrence after transobturator 4-arms mesh repair in 123 patients. Also, Stanford et al.[22] reported an overall 2.6% failure rate at a mini-

Table 3. Comparing the grades of pelvic organ prolapsus occurred during the study period

	Before intervention (n=50)	Postoperative 3. month (n=50)	Postoperative 9, month (n=48)	Postoperative 18. month (n=46)
POP[1]	**n (%)**	**n (%)**	**n (%)**	**n (%)**
None	0 (0)	28 (56)	26 (54.2)	25 (54.3)
Grade I	0 (0)	20 (40)	20 (41.7)	19 (41.3)
Grade II	21 (42)	1 (2)	1 (2.1)	1 (2.15)
Grade III	26 (52)	1 (2)	1 (2.1)	1 (2.15)
Grade IV	3 (6)	0 (0)	0 (0)	0 (0)
p	Ref	<0.001 (S)	<0.001(S)	<0.001(S)
		Ref	0.32 (NS)	0.32 (NS)
			Ref	1.0 (NS)

[1]POP: pelvic organ prolapsus; Mc Nemar's test was used.

Table 4. Pre-and postoperative PVRU, Q-Max, ICIQ-SF and POPQ values

	Before intervention	Postoperative 3. month	Postoperative 9. month	Postoperative 18. month
Variable	**Mean±SD**	**Mean±SD**	**Mean±SD**	**Mean±SD**
PVRU (mL)	18.4±23.1	18.0±18.03	18.0±18.01	16.3±15.51
Q-max (mL/sec)	22.8±2.52	---	21.3±2.23	20.4±1.73
ICIQ-SF	14.8±4.1	3.9±4.34*	3.1±3.99*,†	2.9±4.14*,†
POP-Q score	2.6±0.6	0.50±0.64*	0.54±0.71*	0.56±0.72*

*Statistically significant when compared to preoperative values, †Statistically significant when compared to postoperative 3. Month. Bonferroni adjusted Wilcoxon test was used.

PVRU: Post-void Residual Urine; Q-max: Maximum urine flow rate; ICIQ-SF: Arabic version of the International Consultation on Incontinence Questionnaire-Short Form; POP-Q score: Pelvic Organ Prolapse-Questionnaire Score

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Table 5. Assessments using King Health Questionnaire (KHQ) forms over the study period

	Before intervention	Postoperative 3. month	Postoperative 9. month	Postoperative 18. month
Variable	**Mean±SD**	**Mean±SD**	**Mean±SD**	**Mean±SD**
General health perception	52.1±28.29	28.8±18.97*	11.4 ± 12.59*†	8.1±1189*†
Incontinence impact score	52.8±22.85	27.5±20.23*	6.5±13.35*†	4.3±11.33*†
Role limitations	60.8±17.63	45.6±17.72*	18.5±17.27*†	18.4±17.29*†
Physical limitations	60.4±20.59	39.4±19.35*	19.8±10.89*†	18.0±12.57*†
Social limitations score	60.4±20.59	21.7±15.26*	7.2±10.89*†	5.4±10.55*†
Personal relationships score	16.2±19.71	7.5±12.50*	2.5±6.02*†	0.00±0.00*†‡
Emotions score	25.8±17.36	14.9±14.84*	4.1±5.41*†	4.1±5.41*†
Sleep/energy score	3.6±6.92	1.4±4.72	0.0±0.00*	0.0±0.00*
Severity measures	58.8±25.18	28.0±17.07*	9.7±10.29*†	7.3±6.82*†‡
Symptom scale	17.5±3.75	5.8±2.33*	2.0±1.16*†	1.4±1.27*†‡

Bonferroni adjusted Wilcoxon test was used. *→ significant in comparison to "before intervention", † → significant in comparison to "3 months later", ‡→ significant in comparison to "9 months later"

mum 2 years' follow-up in a cohort of 154 women treated with transvaginal and abdominal custom-shaped polypropylene mesh for POP.

In our study, there was no intraoperative complications as bladder or urethral injury. Likewise, no patient required blood transfusion as the mean blood loss was (83.6±62.7) mL which was in concordance with the study by Moez and Fethi.[23] In other studies performed by Moore et al.[24] and Yonguc et al.[20] one case in each study required blood transfusions. On the other hand, in a study by Sharifiaghdas et al.[13] two patients had required one unit of blood postoperatively. Blood transfusions during POP repair were required due to lateral vaginal wall dissection not related to the passage of the needle.[24]

Vaginal mesh erosion is one of the most common complications after POP repair whose incidence rtates ranged from 4% to 30%[13,21,22,25-29] while in the study done by Yonguc et al.[20] any mesh erosion had not been observed. In our study, vaginal mesh erosion was observed in one patient (2%) that was improved on local estrogen cream without operative intervention. Size and location of vaginal incision, depth of dissection, sexually active and younger aged women are seen as prognostic factors for mesh erosion.[30] Also limited experience may be a factor in the high incidence of mesh erosion.[27]

In that respect, an important controversy exists concerning the anterior vaginal wall repair, and its relation to sexual activity. In recent studies any difference between mesh repair, and traditional methods for the repair of anterior vaginal wall prolapse with respect to sexual activities.[31,32] At follow-up visits 4 (8%) patients developed dyspareunia that was improved on local estrogen cream which was in accordance with the results of Palma et al.[29] who used the Nazca-Tc mesh kit and the rate of dyspareunia in their study was reportedly 2.7%. In a study by Sharifiaghdas et al.[13] 68.9% of the patients who were sexually active reported improvement in their sexual function after surgery and only 6.8% of them complained of worsening of dyspareunia, similarly Yonguc et al.[20] reported that their 2 patients developed dyspareunia.

Urologists have believed that dyspareunia is not related to the mesh itself, but may be due to some points in the technique. Many studies have demonstrated that vaginal mesh does not seem to cause a negative impact on sexual function, and prospective comparative studies assessing mesh and traditional repair for the anterior compartment defects have not demonstrated any substantial deviation in the rate of dyspareunia.[31,32] To cut down the risk of dyspareunia after the operation, the surgeon must sure that mesh is tension free and the mesh arms haven't pulled tight to get sexual activity improved after repair of POP.[32]

In our study 4 (8%) patients developed groin and thigh pain that improved on analgesics in parallel with results of Moore et al.[24] where 4.4% of their patients had postoperative vaginal, groin, buttock or leg pain. Vaiyapuri et al.[33] reported that 10.4% of their patients had vaginal and groin pain and 22.6% of their patients had pain in the inner side of the thigh which they attributed this pain to inadvertent passage of needle through adductor muscle. For decreasing postoperative groin or thigh pain some steps should ber followed in passing the needle, as passing it from outside-in, below the tendon of adductor longus and as medially as possible to the ischiopubic ramus.[34]

Infection may be considered as an additional complication in vaginal repair either using mesh or another traditional method.[35] In our study 5 patients developed UTI and treated by antibiotics. Two patients had urinary retention after catheter removal and were treated by indwelling catheter for 2 weeks. One of them improved, but the other retained urine again and treated with clean intermittent catheterization for another 2 weeks. This was also similar to other studies which had the same ratio[19,24] reportedly only one case of urinary retention. In other studies[13,23] 11 and 6 patients had postoperative urine retention, respectively. Yonguc et al.[36], reported postoperative urinary retention in nine women (11.3%) in Group 1 (repairing cystocele through one incision), which required an indwelling catheterization for 7–14 days. There was no UR in Group 2 (cystocele repaired through two incisions). This problem was not reported by Sergent et al.[18] in his work.

Many questionnaires were used to assess quality of life, improvement and satisfaction after cystocele repair.[24] In our study, all the scores of KHO which is used to assess quality of life, improvement and the overall satisfaction was 88.4%, according to VAS in agreement with others[23,36] in which improvement, and overall satisfaction scores of VAS were 71.4% and 86.4%, respectively. Leanza et al.[37] found a significant difference in VAS scores and in the majority of the main domains in the King's health questionnaire when compared pre- and post-operative data ($p<0.001$). On the other hand, other questionnaires used as Pelvic Floor Distress Inventory short form (PFDI-20), the Pelvic Floor Impact Questionnaire short form (PFIQ-7), Pelvic Organ Prolapse Urinary Incontinence, Sexual Questionnaire (PISQ-12), Pelvic Floor Distress Inventory (PFDI) indicated significant improvements.[1,13,19] Also, there was a significant improvement in all domains of prolapse quality of life (P-QOL) questionnaire.[19]

Main limitation of our study is, it is a single arm, single-centered study with small number of patients and midterm follow up. However, our findings contributed to current literature with detailed examination and validated questionnaire based assessment. Nevertheless, cystocele associated with SUI can be repaired with transobturator four-arms mesh giving better results with improved quality of life and tolerable complications. To further improve the outcomes and reduce associated complications related to mesh use in pelvic floor reconstruction, more randomized and multicentered studies using standardised techniques and validated instruments are needed.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Benha University.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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