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Transobturator four-arms mesh in the surgical management of cystocele: a long-term follow-up

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We studied the long-term efficacy and safety of cystocele operation by polypropylene mesh. A total of 198 women with stage ≥2 cystocele who had anterior vaginal wall repair with transobturator four-arm polypropylene mesh during 2003 to 2015 were evaluated. Outcomes including clinical characteristics and complications were reviewed by extracting patient data from electronic medical records. In addition, telephone interviews were conducted using a validated questionnaire along with physical examination. The follow-up period was 9.3±0.3 years. The cystocele stage in patients was significantly decreased post-operation compared to that preoperation. The anatomical cure rate for cystocele was 93.4%, and that for stress urinary incontinence was 95%. Comparing the three questionnaires indicated overall average score was improved significantly, except for Female Sexual Function Index Assessment. Early complications were either resolved spontaneously or controlled medically in four cases of hematoma or abscess, three cases of vaginal infection and urinary tract infection, and four cases of difficult micturition. In late complications, four cases of pain were managed, five cases of recurrence were observed and two cases of mesh exposure were treated with ointment and local excision. Transobturator four-arms mesh is an effective and safe method for cystocele repair with low rate of recurrence and complications. We suggest that the use of transobturator four-arm mesh is a still good choice for the old patients with cystocele who are not suitable for general anesthesia and reside in areas where laparoscopy and robots are not available.

Keywords: Cystocele, Surgical mesh, Long-term follow-up

INTRODUCTION

Pelvic organ prolapse (POP) is a common disease in women, which is usually accompanied by the stress urinary incontinence (SUI), and affects both physical and psychological well-being (Patel et al., 2009). Among the types of POP, anterior vaginal wall prolapse, a cystocele, is the most common condition that occurs due to herniation of the bladder through the anterior vaginal wall (Rane et al., 2012). The weakening and loss of support of the pubocervical fascia between the bladder and vagina due to aging, obesity, and previous pelvic surgery causes lateral or central defects. However, the repair of anterior genital prolapse with or without SUI still remains a challenging vaginal surgery, with recurrence rates of 30%–50% depending on the technical methods and reporting authors (Debodinance et al., 2007). As the traditional colporrhaphy only corrects the central defects and adds a suture under tension to the poor quality of native tissues, more than a third of patients formerly managed by the simple subvesical plication or anterior colporrhaphy recur. These disadvantages have led to the development of more reliable and durable surgical techniques resulting in the use of various types of mesh in vaginal prolapse surgery. These materials act as frames, guiding the devel-

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opment of stronger supporting tissue (Sand et al., 2001).

Despite the advanced current surgical techniques such as laparoscopic sacrocolpopexy and robotic paravaginal cystocele repair, transvaginal repair with the use of a mesh is still the preferred method in many countries because of its cost-effectiveness and usefulness for patients with high operative risk.

In this study, we evaluated the long-term safety and efficacy of cystocele treatment using a transobturator four-arm polypropylene mesh and explored whether it is applicable in a wide range of cystocele patients.

MATERIALS AND METHODS

Subjects and study design

We systematically reviewed patients who underwent transobturator four-arm mesh surgery in the urology department of Chungnam National University Hospital from January 2003 to December 2015. All procedures were performed by or under the supervision of a single surgeon under regional or general anesthesia with administration of prophylactic antibiotics.

Inclusion criteria for patients were cystocele stage ≥2 according to the classification of Pelvic Organ Prolapse Quantification (POP-Q) either associated with SUI or not. Because of the need to obtain longer follow-up data, our exclusion criteria included women with a history of previous transvaginal mesh surgeries, recurrent urinary tract infections, gestation, malignancy of the female genital system or urinary bladder, history of pelvic irradiation, or presence of neurological disorders that caused voiding dysfunction.

Preoperative assessments

A total of 198 patients met the inclusion criteria and agreed to the Institutional Review Board (IRB) (IRB No. 2020-04-150) permission. First, the short-term follow-up information (an average of 2.0±0.8 months) after the operation was reviewed. It was evaluated through the electronic medical records which include: history, physical examination, self-administered questionnaires, 1-hr pad test, urodynamics (UDS), admission record, and outpatient record.

Postoperative assessments

For the postoperative assessments, we reviewed the information of all patients from the electronic medical records in accordance with routine follow-up schedule, including postoperative physical examination, urine flow rate, and complications. Afterward, we followed the health status of these patients for a long period of time by reviewing all their outpatient visits related to surgery. A standardized interview over the phone was conducted for obtaining long-term follow-up information (a mean of 9.3±0.3 years). It included questionnaires regarding the presence of relapse, pain, mesh exposure, *de novo* urgency, cystocele stage, and SUI grade. Of these patients, only 152 agreed or accepted to revisit hospital for further evaluation and physical examination within 2 weeks.

Improvement was defined as having a lower stage than that before the surgery, and not above stage III, as established either by physical examination in the clinical setting or by a standardized interview by phone. Recrudescence was defined as having the same or higher stage than that before the surgery. In addition, the anatomical cure was defined as having less than stage I.

Patients' medical data included: age, body mass index (BMI), normal vaginal delivery (Caesarian section), hysterectomy, et al. In addition, after the patient's consent, a detailed record and collection of questionnaires, including: urodynamic investigations included flowmetry, cystometry to assess the maximum cystometric capacity, presence of detrusor overactivity, and the Valsalva leak point pressure.

Classification of cystocele stage according to POP-Q method: stage 0, no prolapse was found; stage I, most of the distal part of prolapse was more than 1 cm above the hymen; stage II, the distal part of prolapse was mostly within 1cm above and below hymen; stage III, most distal portion of prolapse is >1 cm below hymen but protrudes 2 cm; stage IV, complete vaginal eversion (Persu et al., 2011).

The grades of SUI are as follows: grade 1, urinary outflow will occur only when negative pressure is increased such as laughter, coughing, sneezing, etc.; grade 2, urine outflow occurs during nonviolent normal activities such as standing and walking; grade 3, under rest, bed rest, and other resting states, urine flows out spontaneously (Kołodyńska et al., 2019).

Self-administered questionnaires we used were: Incontinence Questionnaire (ICIQ) (Avery et al., 2004), King's Health Questionnaire (KHQ) (Kelleher et al., 1997), patient perception of bladder condition-2006 (PPBC) (Coyne et al., 2006), Female Sexual Function Index assessment (FSFI) (Rosen et al., 2000).

Surgical methods

We used polypropylene mesh Gynemesh PS or ProliftTM system (Ethicon Inc., Somerville, NJ, USA) with a same surgical method under regional or general anesthesia. A midline incision is carried out on the anterior vaginal wall and the pubocervical fascia is dissected as for anterior colporrhaphy. Whereas the Pro-

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liftTM mesh has already tailored to transobturator four-arms, the sheet of Gynemesh PS need to be trimmed to an identical rounded shape, with two lateral wings. In each operation, the central, rounded part of the graft is positioned under the urinary bladder in a tension-free fashion, while its arms are inserted deep into the periurethral tissue on both sides towards the pubic bone. A single fixating monocryl 2/0 suture is performed at the base of one wing of the mesh, at the periurethral level.

Statistical analysis

IBM SPSS Statistics ver. 23.0 (IBM Co., Armonk, NY, USA) was used for statistical analyses. The Wilcoxon signed-rank test was used for evaluation of pre- and postoperative variables between the two groups. Mean and error are expressed by mean±standard error of the mean.

RESULTS

The average age of the women when they had surgery was 61.7±0.8 years, BMI was 25.5±0.2 kg/m^2, and average follow-up time was 9.3±0.3 years. The patients who underwent hysterectomy before the surgery accounted for 2.0% and 63.1% combined with rectocele repair. We also performed UDS and 1-hr pad test, with an average value of 17.0±1.9. The values of maximum urethra closure pressure, detrusor pressure at maximal urinary flow rate, and detrusor pressure max flow were 48.1±22.0 cmH_2O, 6.9±8.6 cmH_2O, and 13.9±14.8 mL/sec, respectively. We compared voiding time, voided volume, and residual urine volume before and after the operation. Their mean±standard deviation values were: voiding time (50.5±38.4, 46.9±45.8), voided volume (330.5±162.6, 268.9±143.7), and residual urine volume (61.3±90.8, 57.7±94.61). However, none of these showed statistical significance ($P>0.05$) (Table 1).

After an average follow-up of 9.3±0.3 years, 152 patients underwent physical assessment and telephone interview to complete the self-administered questionnaires. The ICIQ, KHQ, and PPBC questionnaire scores showed improvements. The total ICIQ scores before and after the surgery were 15.5±0.2 and 1.7±0.4, respectively; the total scores of KHQ before and after the surgery were 69.6±1.1 and 17.1±2.1, respectively; and the PPBC scores before and after the surgery were 3.7±0.1 and 0.8±0.1, respectively; as shown in Table 2. Comparison of the three questionnaires before and after the surgery showed a significant difference in the overall average score ($P<0.001$). However, in the FSFI questionnaire, there was no statistically significant difference between preoperative and postoperative values ($P>0.05$) (Table 2).

Table 1. Characteristics of the study population (n=198)

Characteristic	Value
Age (yr)	61.7±0.8
Follow-up time (yr)	9.3±0.3 (0.6–18)
Body mass index (kg/m^2)	25.5±0.2 (16.3–38.3)
Smoking	5 (2.5)
Diabetes mellitus	22 (11.1)
Hypertension	71 (35.9)
Cardiovascular diseases	11 (5.6)
Menopause	21 (10.6)
No	21 (10.6)
Yes	177 (89.4)
NSVD	3.0±0.1 (0–7)
Caesarean section	5 (2.5)
Hysterectomy	4 (2.0)
Repair of rectocele	125 (63.1)
1H pad test (g)	17.0±1.9 (0–80)

Values are presented as mean±standard error of the mean (range) or number (%).
NSVD, normal vaginal deliver.

Table 2. Assessments using questionnaire forms and urodynamics (UDS)

Questionnaire	Preoperative	Postoperative	*P*-value
ICIQ (total score)	15.5±0.2	1.7±0.4	<0.01
Slight	0 (0)	87 (82.1)	
Moderate	27 (25.0)	12 (11.3)	
Severe	58 (55.0)	5 (4.7)	
Very severe	21 (20.0)	0 (0)	
KHQ (total score)	69.6±1.1	17.1±2.1	<0.01
General health perception	3.7±0.1	1.4±0.1	
Incontinence impact score	2.7±0.1	1.2±0.1	
Role limitations	5.5±0.2	2.5±0.1	
Physical limitations	5.4±0.2	2.5±0.1	
PPBC (total score)	3.7±0.1	0.8±0.1	<0.01
FSFI (total score)	24.7±2.3	21.5±0.9	>0.05
UDS, mean±SD			
MUCP (cmH_2O)	48.1±22.0	-	-
Pdet Qmax (cmH_2O)	6.9±8..6	-	-
Pdet max flow (mL/sec)	13.9±14.8	-	-
Voding time (sec)	50.5±38.4	46.9±45.8	>0.05
Voding volume (mL)	300.5±162.6	268.9±143.7	>0.05
Residual urine volume (mL)	61.3±90.8	57.7±94.61	>0.05

Values are presented as mean±standard error of the mean or number (%) unless otherwise indicated.
ICIQ, Incontinence Questionnaire; KHQ, King's Health Questionnaire; PPBC, patient perception of bladder condition; FSFI, Female Sexual Function Index assessment; SD, standard devation; MUCP, maximum urethra closure pressure; Pdet Qmax, detrusor pressure at maximal urinary flow rate.

Table 3. Stages of POP-Q system and SUI in patients before and after surgery

Variable	Preoperative	Postoperative	*P*-value
POP-Q	n=198	n=152	<0.01
Cystocele stage 0	0 (0)	130 (85.5)	
Cystocele stage I	0 (0)	13 (8.6)	
Cystocele stage II	53 (26.8)	7 (4.6)	
Cystocele stage III	135 (68.2)	1 (0.5)	
Cystocele stage IV	10 (5.1)	1 (0.5)	
SUI grade	n=105	n=152	<0.01
Grade 0	26 (24.8)	134 (88.2)	
Grade I	18 (17.0)	13 (12.3)	
Grade II	17 (16.0)	2 (2.0)	
Grade III	44 (41.5)	3 (3.0)	

Values are presented number (%).
POP-Q, Pelvic Organ Prolapse Quantification; SUI, stress urinary incontinence.

Table 4. Scale of the early and late postoperative complications

Complication	Value
Early (mo)	2.0±0.8
Hematoma or abscess	4 (2.0)
Spontaneous regression	3 (1.5)
Treatment	1 (0.9)
Urinary retention	0 (0)
Difficult micturition	4 (2.0)
Vaginal infection	3 (1.5)
Urinary tract infection	3 (1.5)
Denovo urgency	16 (8)
Disappear spontaneously	10 (5.0)
Received medication	6 (0.3)
Late (yr)	9.1±0.3
Pain location	4 (3.6)
Thigh pain	1 (0.9)
Vaginal pain	1 (0.9)
Nonvaginal pelvic pain	2 (1.8)
Difficult micturition	4 (2.0)
Mesh exposure	2 (1.9)
Topic treatment	1 (0.9)
Repeat for mesh exposure	1 (0.9)
Recrudescence	5 (4.7)
Other*	1 (0.9)

Values are presented number (%).
*Other: vaginal bleeding.

The objective success results are shown in Table 3. After an average follow-up of 9.3±0.3 years, the cystocele stage between preoperative and postoperative was significantly decreased ($P<0.01$). The anatomical cure rate for cystocele was 94.4%, of which 152 patients (85.5%) had no cystocele and 13 (6.6%) had stage I cystocele. Although most patients showed an improvement in stage compared to the preoperative stage, only two patients showed postoperative stages III and IV and had a reoperation. SUI grade decreased as well; the number of patients with high-grade SUI was significantly decreased ($P<0.01$) (Table 3).

The early and last postoperative complications are shown in Table 4. The surgery was feasible and secure, and there were no intraoperative complications, such as hemorrhage or organ injuries. The early postoperative complications were reviewed using electronic medical records within an average time of 2.0±0.8 months after the surgery. There was no urinary retention. Hematoma and abscess were found in four patients, three of which had self-regressed, and another one through medical treatment. No one had overactive bladder to preoperative UDS, but there has *de novo* urgency occurred in 8% of the patients, it either resolved spontaneously or after applying anticholinergic medications.

The average assessment time of late postoperative complications was 9.3±0.3 years. Six patients complained of mild pain after the operation; only three of the patients took the analgesics occasionally. Four patients experienced difficult micturition and underwent UDS. No obstruction was detected, but detrusor underactivity was observed, and patients were treated with cholinergics and alpha-blockers. Two patients (1.9%) had mesh exposure after 2.7 and 5 years, respectively. While local treatment was sufficient for one patient, the other patient required minimum operation under local anesthesia to remove the exposed mesh. Five patients (4.7%) had relapse, all of whom were over 75 years old. Two of them, with the change in cystocele from preoperative stage IV to postoperative III and IV, underwent a second operation. Others with postoperative stage II were observed. We also report a case of periodic vaginal bleeding without erosion of the mesh (Table 4).

DISCUSSION

Transvaginal, transabdominal (open), and laparoscopy are the generally accepted methods used to repair the cystocele. Transvaginal and laparoscopic surgery is the preferred methods (Hiltunen et al., 2007; Maher and Baessler, 2006), while open surgery is not recommended because of its severe complications such as bleeding (Raz et al., 1991). The advantage of the laparoscopic method is that it allows clear visualization and access to the paravaginal spaces with lower morbidity than that of the open approach and fewer complications than those of the transvaginal approach (Young et al., 2001). However, Baines et al. (2019) studied 660 patients who underwent laparoscopic sacrocolpopexy between 2005 and 2017;

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5.3% of patients required further reoperation for prolapse, and there was no difference compared to the transvaginal approach. They reported several intraoperative complications such as bladder injury (0.8%), bowel injury, and pneumonia with an average 90-min operating time. However, in our study, patients were older and had several underlying diseases; thus, the operative risk for general anesthesia was high and transvaginal approach under regional anesthesia was considered more suitable and secure than laparoscopic surgery.

In earlier studies, the cure rate of anterior colporrhaphy seemed favorable, with only a 3% recurrence rate reported by Shull et al. (1994). However, in later studies that compared augmented repairs, such as synthetic meshes, cadaveric fascia, and porcine dermis, the reported recurrence rates for standard anterior colporrhaphy were remarkably higher. Sand et al. (2001) reported that 43% of the patients who underwent plication with suture alone had recurrence, compared with those treated with vicryl mesh inlay, which had a failure rate of 25%. In a 2016 Cochrane review by Maher et al. (2016) who analyzed 33 trials and 3,332 patients, it was concluded that native tissue repair without mesh increased the risk of recurrence, when compared with polypropylene mesh. Stanford et al. (2011) reported an overall 2.6% failure rate after using a transobturator four-arms mesh over 2 years of the follow-up. Kdous and Zhioua (2014) reported 93% of an anatomical success rate after a 3-year investigation. In our study, despite the long-term follow-up, the anatomical cure rate for cystocele was 94.4%, and only two patients needed reoperation.

Delorme et al. (2004) applied the transobturator pathway for SUI in 2001, and a genital prolapse was treated as well with a similar concept, sparing the pelvic fasciae because of its good security for major organs, vessels, and nerves. Two-arms mesh was previously used, but soon reported many complications related to unfixed mesh such as exposure, pain, and dyspareunia with high recurrence rate (Mourtialon et al., 2012). To compensate for these disadvantages, Palma et al. (2005) first suggested a four-arms mesh technique, which was revised to cover the entire bladder so that the mesh maintained its proper location to support the tissue. In the present study, there were no major intraoperative injuries such as injury of the urethra, bladder, and other pelvic organs. Furthermore, mesh-related long-term complication rates were low and treated well with only 4.7% of recurrence rate (Carey et al., 2009).

Most studies have shown a significant improvement in functional symptoms after using the four-arms mesh technique. After 3 years of operation, Kdous and Zhioua (2014) reported that the subjective success rate was 73% and the overall satisfaction score was 71%. In the present study, using self-administered questionnaires, we evaluated subjective satisfaction, and most of the scores showed improvement after operation, except for FSFI.

Vaginal exposure of the mesh is an annoying complication that has been occurred mostly during the second month after the surgery. It can cause bleeding and discharge from the vagina, but it is usually asymptomatic. In a Cochrane review, the mean mesh extrusion rate was 11.4%, with 6.8% undergoing surgical intervention for extrusion (Maher et al., 2016). In the present series, only two patients (1.9%) showed mesh exposure and were treated under the local anesthesia to remove the exposed mesh. No patient required complete removal of the mesh. This would be the proficiency for this operation, which is closely related to the incidence of mesh erosion.

Mesh-related infection was the complication accompanied either with or without exposure and showed 0%–8% of incident rate (Menefee et al., 2011). More than half of the infections are medically treated, and few cases require excision of the graft or aggravated to abscess formation (Flood et al., 1998; Niro et al., 2010; Rardin and Washington, 2009). In our study, three cases of mesh-related infection were observed during the long period of follow-up and treated well with antibiotics without secondary surgical interventions.

SUI is generally accompanied with cystocele because the shared pathophysiology weakens the support of the pelvic floor. Incontinence seemed asymptomatic with high-grade cystocele due to urethral obstruction by cystocele. Long et al. (2011) reported significant improvement of SUI after using combined tension-free vaginal tape or transobturator tape (TOT). In our center, we mainly used TOT in patients with SUI, and significant improvement was reported. However, five patients complained of SUI grades II and III, which was related to the recurrence of cystocele.

Rusavy et al. (2013) surveyed postoperative voiding difficulties after vaginal mesh cystocele repair with SUI treatment. They reported that postoperative urinary retention was significantly more frequent in the anterior compartment repair by the mesh anchored to the sacrospinous ligament from an anterior position compared to that in the TOT group (17 [27%] vs. 2 [6.25%]). No urinary retention occurred in the short-term investigation, and four patients experienced difficulties in voiding after a mean of 9 years of the follow-up. However, no obstruction was found in the UDS, but in bladder underactivity. In addition, *de novo* urgency occurred in 16 patients within 2 months but it either resolved spontaneously or was treated with medication.

Chronic pain due to grafts is a frequently reported complication.

Vaiyapuri et al. (2011) reported 10.4% incidence of the buttock pain and 22.6% of the inner thigh pain. In the study by Sherif et al. (2017) 8% of the patients had pain in the groin and thighs, of which 4.4% had pain in the vagina, buttocks, groin, or legs after the surgery. In the long series of studies, thigh pain, vaginal pain, and nonvaginal pelvic pain accounted for a total 0.9% pain cases reported among patients. Thus, the incidence of postoperative long-term pain was slightly lower than that reported by other researchers.

Recently, the surgical mesh for POP is still controversial after the U.S. Food and Drug Administration ordered to reclassify POP vaginal mesh to class III in 2014 due to accompanying complications. However, long-term data have not been researched yet and in many developing countries, surgical mesh is preferred because of its cost-effectiveness. Despite the limitations of our study, it supports the efficacy and safety of the transobturator four-arms mesh from a long-term perspective. Nevertheless, cystocele associated with SUI can be repaired with transobturator four-arms mesh, providing better results with improved quality of life and tolerable complications. To further improve the outcomes and reduce associated complications related to mesh use in the pelvic floor reconstruction, more randomized and multicenter studies with higher stage cystocele using standardized techniques and validated instruments are needed.

In conclusion, with a mean 9.3 years of follow-up transobturator four-arms mesh was deemed cost-effective and safe in the treatment of cystocele, showing only a few complications and a low incidence of secondary surgery. Moreover, it would be preferable for old patients with high operative risk who cannot receive general anesthesia, especially in countries with difficult access to laparoscopic and robotic treatment.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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