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 development of a more natural and long-lasting repair. This study aimed to assess the long-term safety and efficacy of transobturator four-arms mesh in the surgical management of cystocele.
opment of stronger supporting tissue (Sand et al., 2001).

Despite the advanced current surgical techniques such as laparo-
scope 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 polypropyl-
ene 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 transobtu-
rator four-arm mesh surgery in the urology department of Chun-
gnam National University Hospital from January 2003 to De-
cember 2015. All procedures were performed by or under the su-
ervision 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 neu-
rological 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 aver-
age 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 outpa-
tient 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 be-
fore 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 collec-
tion of questionnaires, including: urodynamic investigations in-
cluded 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 1 cm 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 (Kolodybska et al., 2019).

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

**Surgical methods**

We used polypropylene mesh Gynemesh PS or ProliftTM sys-
tem (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-
lifeTM 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 fixing 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. Statistical analysis

RESULTS
The average age of the women when they had surgery was 61.7±0.8 years, BMI was 25.5±0.2 kg/m2, 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 rectoceles 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 cmH2O, 6.9±8.6 cmH2O, 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±94.6). 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/m2) | 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 (88.4)             |
| NSVD                 | 3.0±0.1 (0–7)          |
| Caesarean section    | 5 (2.5)                |
| Hysterectomy         | 42 (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 (cmH2O)        | 48.1±22.0    | -             | -       |
| Pdet Qmax (cmH2O)   | 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±152.6  | 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.
CIQ, Incontinence Questionnaire; KHQ, King’s Health Questionnaire; PPBC, patient perception of bladder condition; FSFI, Female Sexual Function Index assessment; SD, standard deviation; MUCP, maximum urethra closure pressure; Pdet Qmax, detrusor pressure at maximal urinary flow rate.
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;
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, despite the long-term 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.

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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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