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Original Article

Comparing the midterm outcome of single incision vaginal mesh and transobturator vaginal mesh in treating severe pelvic organ prolapse

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ABSTRACT

Objective: The aim of this study is to compare perioperative parameters and midterm clinical outcomes using two different mesh kits: transobturator vaginal mesh (TVM) (both Perigee and Apogee), versus single incision vaginal mesh (SIM) (combined Elevate anterior/apical system and Elevate posterior/apical system) in treating severe pelvic organ prolapse (POP).

Materials and Methods: This is a retrospective cohort study. During 2008 and 2013, those women with severe POP [POP quantification system (POP-Q), Stage III and Stage IV], who received either TVM or SIM operation, were enrolled for cohort comparison. There were 111 patients in the TVM group, and 136 in the SIM group. Those with an incomplete POP-Q record, or who did not complete postoperative urodynamic study were excluded. Perioperative characteristics and outcomes, postoperative urinary symptoms, urodynamic parameters, prolapse recurrence (defined as the leading edge > 0 using the POP-Q system), and mesh extrusion rate were compared.

Results: There were no differences in the operation time, blood loss, hospital stay, and the postoperative visual analog scale for pain. Urodynamic studies showed improvement in bladder outlet obstruction in both groups. The postoperative stress urinary incontinence was significantly higher in the SIM group. The recurrence of prolapse was comparable between the two groups at a median follow-up of 2 years. The mesh extrusion rate was significantly lower in the SIM group.

Conclusion: At an average of 2 years of follow-up, the mesh extrusion rate was lower in the SIM group than in the TVM group, but there was no difference in postoperative visual analog scale for pain. The postoperative stress urinary incontinence was higher in the SIM group.

Introduction

Pelvic organ prolapse (POP) is characterized by the abnormal descent or herniation of the pelvic organs, and its incidence increases with age. With the gradual increase in life expectancy, POP has become a common problem of adult women. Vaginal mesh for POP repair was first introduced due to the high recurrence following traditional transvaginal repair. Previous population-based epidemiological studies demonstrated that 11–18.7% of women underwent at least one surgery for POP in their lifetime, with a repeat operation rate of 12–30% [1,2]. According to the Cochrane database in 2013, permanent mesh has superior outcomes and lower recurrence rates in treating anterior compartment prolapse compared to traditional native tissue repair [3]. However, there are also drawbacks to these artificial materials. The US Food and Drug Administration issued a formal warning of complications of vaginal mesh procedures in 2008 [4]. The warning was reiterated and emphasized in 2011, with the most frequent complications being mesh exposure, pain, and urinary problems [5].

The Perigee/Apogee (transobturator vaginal mesh, TVM) system (American Medical Systems, Minnetonka, MN, USA) is a trocar-guided transobturator, type 1 polypropylene vaginal mesh for treating POP. The anterior/apical and posterior/apical Elevate repair system (American Medical Systems) applies a single incision vaginal mesh (SIM) using lighter, softer type 1 polypropylene mesh. Previous studies confirmed the efficacy of both the Perigee/Apogee and Elevate vaginal mesh systems for treating POP [6–10]. However, only a few studies directly compare these two types of mesh procedures [11].

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A recently published study [11] compared the Elevate anterior/apical system with the Perigee system plus sacrospinous ligament fixation (SSF). The investigators concluded that both have comparable anatomical outcomes in treating POP, with the Elevate system provoking more postoperative *de novo* stress urinary incontinence (SUI). All of the recurrences in the study occurred in the posterior compartment.

We compared the TVM and SIM systems for treatment of both the anterior and posterior compartment POP for an average of 2 years. We hypothesize that the SIM has less mesh-related complications with similar anatomical support compared with the TVM at a median of 2-year follow up. The perioperative outcomes, anatomical outcomes, recurrence of prolapse, and mesh extrusion rates were analyzed.

Materials and methods

After obtaining ethical approval from the hospital Institutional Review Board, we conducted a retrospective chart review of patients who received the TVM system from May 2008 through December 2010, and those who received the SIM system from November 2010 through October 2013. The average follow-up times were 32 months (14–73 months) in the TVM group and 25 months (15–47 months) in the SIM group. The inclusion criteria were severe POP, defined as Stage III or Stage IV in the POP quantification system (POP-Q) [12], and having undergone TVM or SIM for prolapse repair. We excluded patients who underwent only single-compartment vaginal mesh repair, patients with incomplete POP-Q assessments during follow-up, and patients who did not complete the postoperative urodynamic studies. Two experienced urogynecologists performed all operations.

All patients received thorough preoperative evaluations including detailed medical histories, physical examinations, pelvic examinations, preoperative pelvic ultrasounds, Pap smears, and urodynamic studies. Prolapse staging was recorded using the POP-Q system. Perioperative parameters included operative time, blood loss, length of hospital stay, and postoperative visual analog scale (VAS) pain score on postoperative Day 1. The frequency of postoperative transient, intermittent catheterization procedures (ICP) was recorded.

Follow-up visits were scheduled for postoperative Week 1, the 1st, 3rd, 6th, and 12th months, and then annually after that. Symptoms of SUI and overactive bladder were recorded, and pelvic examinations were performed in our outpatient department at every postoperative visit. The follow-up POP-Q score and exposure of any mesh including size, location, and exposure management were also recorded. Postoperative urodynamic studies were done 6 months after the operation.

The TVM system was applied using the techniques described by Erickson [13], with only subtle modification. Instead of inserting the needle into the iliococcygeus muscle, we penetrated the sacrospinous ligament to achieve Level I support. The SIM system was applied using the techniques previously described by Huang et al [14].

The vaginal wall was closed in two layers using 2-0 Vicryl (Ethicon, Somerville, NJ, USA). Cystoscopy and digital rectal examination were performed after the placement of the mesh. A Foley catheter and vaginal gauze were placed after the operation and removed on postoperative Day 2. Postoperative, transient ICP was performed after the removal of the Foley catheter when the postvoid residual volume was more than 100 mL on the bladder scan.

The Chi-square test was used to compare binomial variables while the Student paired *t* test was used to compare the preoperative and postoperative data. Additionally, the independent *t* test was used to compare continuous unpaired data. A Kaplan–Meier analysis with a log-rank test was used to compare assumed time-related variables such as recurrence and mesh exposure rates. All the statistical analyses were performed using IBM SPSS Statistics 22 (IBM Corp., Armonk, NY). Differences were considered statistically significant when $p < 0.05$.

Results

During the study period, 274 patients met the inclusion criteria of undergoing both the anterior/apical and posterior/apical Elevate procedure, or both the Perigee and Apogee procedures for POP repair. Of these, 253 patients had Stage III or Stage IV POP, and among them, eight had incomplete POP-Q records or did not complete the postoperative urodynamic studies. Finally, there were 111 patients in the TVM group and 136 patients in the SIM group.

Table 1 shows the patients' demographic data. There were no differences between the groups in terms of body weight, body mass index, parity, diabetes, menopausal status, or previous related surgeries. The mean patient age in the SIM group was slightly older than in the TVM group (65.8 vs. 63.1 years, $p = 0.03$). Of all patients, 45% in the TVM group and 16.9% in the SIM group underwent uterus-sparing operations. Concurrent vaginal hysterectomies were performed in 33.4% of patients in the TVM group and 64.7% in the SIM group. Concurrent midurethral sling operations were performed in 58.6% of the patient in the TVM group and 22.8% in the SIM group.

The preoperative POP-Q measurement showed more severe prolapse in the posterior compartment in patients treated using the Elevate system (Table 2). Nonetheless, no significant differences in the postoperative anatomical outcomes between the TVM and SIM groups occurred. The urodynamic parameters showed improved bladder outlet obstruction in both groups (Table 3). The maximal urethral closure pressure (MUCP) in both groups decreased postoperatively. The preoperative maximal urine flow rate was higher in the SIM group; otherwise, there were no significant differences in either group when comparing the preoperative and postoperative urodynamic parameters (Table 3).

Table 4 shows the perioperative outcomes. To avoid the inherent, time-consuming nature of combined surgeries that could

Table 1
Patient demographic data.

	TVM[a] ($n = 111$)	SIM[b] ($n = 136$)	p
Mean age (y)	63.1 ± 9.49	65.8 ± 9.84	0.032
Mean BMI	24.8 ± 2.99	24.9 ± 3.63	0.830
Mean parity	3.6 ± 1.36	3.4 ± 1.34	0.248
Diabetes (n)	22 (19.8%)	33 (24.2%)	0.421
Menopausal status (n)	98 (88.2%)	123 (90.4%)	0.707
Previous related surgery (n)	25 (22.5%)	27 (19.9%)	0.600
STH	3	2	
ATH	4	17	
LAVH	9	4	
VTH	7	2	
Anterior/posterior repair	9	1	
Without mesh	8	0	
With mesh	1	1	
Any other prolapse surgery[c]	2	1	
Incontinence surgery[d]	2	2	
Preserve uterus (n)	50 (45.0%)	23 (16.9%)	<0.001
Combined VTH (n)	38 (34.2%)	88 (64.7%)	<0.001
Combined sling (n)	65 (58.6%)	31 (22.8%)	<0.001

Mean ± standard deviation (95% confidence interval or percentile).
ATH = abdominal total hysterectomy; BMI = body mass index; LAVH = laparoscopic-assisted vaginal hysterectomy; SIM = single incision vaginal mesh; STH = subtotal hysterectomy; TVM = transobturator vaginal mesh; VTH = vaginal hysterectomy.
[a] TVM: Perigee + Apogee.
[b] SIM: anterior Elevate + posterior Elevate systems.
[c] Any other prolapse surgery: Right side sacrospinous ligament suspension, hysterocolpopexy, or unknown.
[d] Incontinence surgery: Burch or sling operation.