



## Risk factors of surgical failure following transvaginal mesh repair for the treatment of pelvic organ prolapse

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### ABSTRACT

**Objective:** To identify the factors associated with pelvic organ prolapse (POP) recurrence after transvaginal mesh (TVM) repair.

**Study design:** One hundred and thirteen women with symptomatic POP stage II to IV were scheduled for TVM procedures. All subjects underwent urinalyses and pelvic examination using the POP quantification (POP-Q) staging system before and after surgery.

**Results:** Seven (6.2%) of 113 women reported POP recurrence after a mean follow-up time of 30 months. We performed a univariate analysis of patients' characteristics to identify the predictors of surgical failure after TVM. There was no difference between two groups as to body mass index, POP stage, mesh type, and preoperative urinary symptoms and urodynamic parameters ( $P > 0.05$ ). However, we found that uterine prolapse ( $P = 0.016$ ) and surgical experience ( $P = 0.043$ ) were two significant predictors of surgical failure. Multivariate logistic regression showed similar results.

**Conclusion:** Advanced uterine prolapse and lack of surgical experience were two significant predictors of failure following TVM. POP recurrence after mesh repair appears to be unlikely beyond the learning curve.

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## 1. Introduction

Nearly 11% of all women need some type of operation for pelvic organ prolapse (POP) or urinary incontinence in their lifetime, with 29% needing a second operation for recurrence within five years [1]. Repair involving anterior and/or posterior colporrhaphy has been the established treatment for POP over the past decades, but may carry a higher rate of recurrence [1]. Therefore, the use of synthetic mesh has become increasingly popular over the last decade due to the excellent short-term cure rate [2].

Recently a number of mesh devices have been designed by different companies, including Prolift (Gynecare Prolift, Ethicon, Inc., Piscataway, NJ, USA) and Perigee-Apogee (AMS, Inc., Minnetonka, MN, USA), etc. These non-absorbable meshes could permanently reinforce the pubocervical and the rectovaginal fascia via minimally invasive approaches, and yield promising results [3].

Although these procedures initially seemed to be reasonable by replacing or reinforcing damaged supportive vaginal tissue, recurrent cases still occurred. To date, there are limited studies to evaluate preoperative clinical and urodynamic parameters in predicting which women are more likely to experience surgical failure after transvaginal mesh repair. An exploration of these possible factors for surgical failure was, therefore, thought to be of interest. The aims of this study were to review the efficacy of commercial mesh kits employed in our practice and to identify factors associated with recurrent POP.

## 2. Materials and methods

From June 2004 through March 2009, one hundred and thirty-six consecutive women with POP stage II to IV defined by the POP quantification (POP-Q) staging system [4], were referred for transvaginal mesh (TVM) procedures (74 Perigee and/or Apogee; 62 Prolift system) at our hospital. Women with uterine pathology were scheduled for simultaneous hysterectomy with TVM, and preservation of the uterus could be considered in women with an intact uterus. Concomitant midurethral sling operations, including tension-free vaginal tape (TVT) (Gynecare TVT, Ethicon, Inc., Piscataway, NJ), TVT-O (Gynecare TVT-Obturator System, Ethicon,

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Inc., Somerville, NJ) and Monarc (AMS, Inc., Minnetonka, MN, USA), were performed in women with current or occult urodynamic stress incontinence (USI), unless they did not desire additional surgery. The preoperative diagnosis of occult USI was made by a positive cough stress test with prolapse reduction by vaginal packing during cystometry. Twenty-three patients were excluded due to incomplete medical records (eleven women in the Perigee group and 12 in Prolift group). Finally, the remaining 113 women were included in this study (63 Perigee and/or Apogee; 50 Prolift system).

The Perigee–Apogee and Prolift systems are similar with only a slight difference in the posterior procedure involved. In the Prolift procedure for apical and posterior prolapse, the trocar is inserted 3 cm lateral and inferior to the anus. The needle is designed to pass through the sacrospinous ligament at a level of 2 cm posterior and medial to the ischial spine. Using the same insertion wound, a more helical trocar of Apogee penetrates the ileococcygeus muscle rather than the sacrospinous ligament at the level of the ischial spine.

During anterior mesh repair, the superior trocars of both devices are inserted through the upper medial angle of the obturator foramen at the level of urethral orifice, while the inferior trocars are inserted 2 cm inferior and 1 cm lateral to the upper wounds [3]. All trocars are designed to pass through the arcus tendineus fascia of the pelvis and emerge in the vaginal incision. All patients were given prophylactic antibiotics (intravenous cefazolin 1 g; Cefamezin, Fujisawa, Tokyo, Japan) administered before surgery. The operation was carried out with the patient under epidural or general anesthesia. The uterus was preserved unless ultrasonography showed pelvic pathology.

The objective of the study was to assess surgical efficacy and predictors of POP recurrence for the TVM repair. All subjects underwent urinalyses and pelvic examination using the POP-Q system before and after surgery. Postoperative follow-up was at 1, 2, 3, 6, and 12 months and then semiannually beyond one year. Recurrence was defined as most dependent portion of POP stage II or greater (leading edge of the prolapse  $\geq -1$  cm).

Ethics approval by the institutional review board of our hospital had been obtained for retrospective data analysis. The analysis of the potential risk factors involved in surgical failure after mesh surgery included the demographics, mesh type, urinary symptoms as well as preoperative urodynamic parameters. Statistical analysis was performed with chi-square or Fisher's exact test for categorical variables. A logistic regression model was used to assess the independent predictive value of the variables. A difference was considered statistically significant when  $P$  was  $<0.05$ .

We assessed the power of tests for differentiating the surgical outcome between groups. Despite the limited numbers in the failure group, we used multiple parameters such as rates of uterine prolapse and surgical experience to evaluate the discrepancies between the two groups. We found the power of more than 90% for discrimination in these two significant predictors.

### 3. Results

Participant demographics of these 113 women are summarized in Table 1. The ages of the participants ranged from 35 to 80 years, with an average of 58 years; parity ranged from 1 to 10, with a mean of 3.4. Eighty-two (72.6%) patients were postmenopausal and 15 (13.3%) had a previous history of hysterectomy. Fifty-one (45.1%) participants were treated simultaneously with transvaginal anterior and posterior procedures for POP. Concomitant vaginal hysterectomy was performed in 10 (8.9%) women. Sixty-nine (61.1%) patients required midurethral sling procedures for the treatment of USI (Table 2).

**Table 1**

Demographic characteristics of women ( $n=113$ ) with pelvic organ prolapse undergoing transvaginal mesh repair.

Mean age (years)	58.0 $\pm$ 11.4
Mean parity	3.4 $\pm$ 1.5
Mean BMI (kg/m <sup>2</sup> )	25.2 $\pm$ 3.6
Menopause	82 (72.6)
Current hormone therapy	19 (16.8)
Current smokers	3 (2.7)
Diabetes mellitus	16 (14.2)
Hypertension	42 (37.2)
History of hysterectomy	15 (13.3)
History of POP and/or SUI surgery	8 (7.1)
Follow-up (months)	30.1 $\pm$ 13.7

Data are given as mean  $\pm$  standard deviation or  $n$  (%).

BMI, body mass index; POP, pelvic organ prolapse; SUI, stress urinary incontinence.

**Table 2**

Surgical procedures in this study ( $n=113$ ).

Procedures	$n$ (%)
Anterior repair with mesh	62(54.9)
Anterior and posterior repair with mesh	51(45.1)
Vaginal hysterectomy	10(8.9)
Mid-urethral sling	69(61.1)
Posterior colporrhaphy	2(1.8)

POP, pelvic organ prolapse.

Seven (6.2%) women reported POP recurrence after a mean follow-up time of 30 months: four had uterine prolapse (intervals: 2–12 months), two had enterocele (intervals: 6 months), and one had anterior vaginal wall prolapse (intervals: 3 months). The mean time from initial surgery to recurrence was 5.3 months. Three of the four cases of uterine prolapse underwent vaginal hysterectomy, and the remaining four women did not desire additional surgery as the recurrence was asymptomatic. The overall vaginal erosion rate was 12.4% (14/113) in our study, and a higher rate of vaginal erosion (50%) was noted when we performed hysterectomy together with TVM surgery (Table 3).

We performed a univariate analysis of patients' demographics and preoperative urodynamic parameters to identify the potential risk factors for POP recurrence after TVM repair, and the results are shown in Tables 3 and 4. There was no difference between the two groups with regard to parity, body mass index, diabetes, hypertension, prior surgery, POP status, mesh type, concomitant sling procedures, and a variety of preoperative urinary symptoms and urodynamic parameters ( $P > 0.05$ ). However, we found the presence of uterine prolapse and the surgical experience were two significant predictors of surgical failure. The majority of women with POP recurrence reported significant uterine prolapse preoperatively (Fisher's exact test;  $P = 0.016$ ) and recurrence occurred in the first 50 cases (Fisher's exact test;  $P = 0.043$ ).

Multivariate logistic regression revealed that women with significant uterine prolapse were 10.67 times (95% confidence interval (CI): 2.00–83.29) more likely to report TVM failure than women with other compartment prolapse, and women in the first 50 cases were 11.93 times (95% CI: 1.79–240.1) more likely than women in the 51st to 113th cases (Table 3).

### 4. Comments

With the advance of kits and materials for the treatment of female POP, non-absorbable synthetic mesh has the advantages of strength and durability over traditional anterior and posterior colporrhaphies [5]. Biological grafts were claimed to reduce the possibility of erosion and rejection, but a concern is the ability to provide long-term support to the weakened fascia. Recently Ramanah et al. [6] found that absorbable porcine dermal graft was

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