Original Article

Risk Factors for Mesh Exposure after Transvaginal Mesh Surgery

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Abstract

Background: Mesh exposure after surgery continues to be a clinical challenge for urogynecological surgeons. The purpose of this study was to explore the risk factors for polypropylene (PP) mesh exposure after transvaginal mesh (TVM) surgery.

Methods: This study included 195 patients with advanced pelvic organ prolapse (POP), who underwent TVM from January 2004 to December 2012 at the First Affiliated Hospital of Chinese PLA General Hospital. Clinical data were evaluated including patient's demography, TVM type, concomitant procedures, operation time, blood loss, postoperative morbidity, and mesh exposure. Mesh exposure was identified through postoperative vaginal examination. Statistical analysis was performed to identify risk factors for mesh exposure.

Results: Two-hundred and nine transvaginal PP meshes were placed, including 194 in the anterior wall and 15 in the posterior wall. Concomitant tension-free vaginal tape was performed in 61 cases. The mean follow-up time was 35.1 ± 23.6 months. PP mesh exposure was identified in 32 cases (16.4%), with 31 in the anterior wall and 1 in the posterior wall. Significant difference was found in operating time and concomitant procedures between exposed and nonexposed groups ($F = 7.443$, $P = 0.007$; $F = 4.307$, $P = 0.039$, respectively). Binary logistic regression revealed that the number of concomitant procedures and operation time were risk factors for mesh exposure ($P = 0.001$, $P = 0.043$).

Conclusion: Concomitant procedures and increased operating time increase the risk for postoperative mesh exposure in patients undergoing TVM surgery for POP.

Key words: High Risk; Polypropylene; Transvaginal Mesh

Introduction

Pelvic organ prolapse (POP) is a major healthcare problem in middle-aged and elderly women and is usually accompanied by pelvic floor dysfunction (PFD).[1] The number of patients with these disorders has increased as life expectancy has increased. The treatment of POP continues to be a clinical challenge for urogynecological surgeons. The introduction of mesh repair in vaginal prolapse surgery showed possible advantageous results in early reports.[2] However, pelvic floor structures progressively weaken in the elderly women,[3] contributing to the high rate of recurrence. It has been reported that more than 30% of patients undergoing prolapse repair need reoperation.[4] Recent announcements from the US Food and Drug Administration (FDA) describe increasing concern for complications after transvaginal mesh (TVM) surgery.[5]

The risk factors for mesh exposure have been explored for decades, but it remains unclear what leads to the mesh exposure and operation failure. We analyzed clinical data to identify possible risk factors for mesh exposure to reduce the TVM complication rate and to improve patients' quality of life.

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Methods

Research design and trial population

A retrospective study of patients undergoing TVM surgery between January 2004 and December 2012 was conducted in the Department of Obstetrics and Gynecology at the

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First Affiliated Hospital of Chinese PLA General Hospital. All procedures used Gynecare Gynemesh PS produced by Ethicon. The operative methods included Prosima anterior leaf fixation, Prolift anterior leaf fixation, small mesh fixation, Prosima posterior leaf fixation, Prolift total pelvic fixation, tension-free vaginal tape (TVT), and TVT-obturator. Clinical data were collected including age, menopause status, body mass index (BMI), gravidity and parity, stage of the POP, TVM types, concomitant procedures, operation time, blood loss, postoperative morbidity, and postoperative mesh exposure. Only patients with at least 3 months of follow-up time were included. The study was approved by the Institutional Review Board of First Affiliated Hospital of Chinese PLA General Hospital.

Statistical analysis

Quantitative data were expressed as mean ± standard deviation (minimum, maximum) while categorical data were expressed as absolute number and rate. Statistical analysis was performed to analyze the risk factors for mesh exposure using the SPSS 10.0 software (SPSS Inc., USA). Independent sample's *t*-test was used for comparisons between the two groups while binary logistic regression was adopted to explore the risk factors for mesh exposure. A value of $P < 0.05$ was considered statistically significant.

Results

Patient characteristics

Data from 218 patients who had received reconstruction pelvic surgery (RPS) due to PFD from January 2004 to December 2012 data were collected. A total of 195 (89.4%) subjects were enrolled and 150 (68.8%) subjects were followed up for more than 2 years. The median follow-up time was 35.1 ± 23.6 months (range: 2.0–104.0 months). The average age was 63.9 ± 11.2 years (43.0–89.0 years, mean age 65.0 years). The median duration of menopause was 14.8 ± 10.7 years (range: 0–35.0 years). The average gravidity was 3.6 ± 1.6 times (range: 1–11 times) and the average parity was 2.6 ± 1.5 times (range: 1–9 times). Fifty-three patients had diabetes and 108 patients had hypertension. Seven patients had a history of pelvic surgery, including 3 with hysterectomy plus anterior wall colporrhaphy, 1 with posterior wall colporrhaphy, and 1 with hysterectomy.

Surgery

A total of 195 patients underwent transvaginal RPS with polypropylene (PP) mesh; 180 (92.3%) received anterior prolapse surgery, 1 (0.5%) received posterior prolapse surgery, and 14 (7.2%) received combined anterior and posterior prolapse surgery. A total of 209 transvaginal PP meshes were placed; 194 in the anterior wall and 15 in the posterior wall. Concomitantly, transvaginal hysterectomy was performed in 189 (96.9%) cases, high uterosacral ligament suspension in 176 (90.2%), sacrospinous ligament fixation in 5 (2.5%), posterior wall colporrhaphy in 130 (66.7%), perineal repair in 160 (82.1%), and TVT in 61 (31.3%). The mean operative time was 2.4 ± 1.1 h (range: 1.0–4.0 h). The mean blood loss was 172.4 ± 75.3 ml (90.0–300.0 ml). The mean body temperature in the first 3 days after the operation was 37.1 ± 0.3°C (range: 36.8–38.2°C). No perioperative complications were observed.

Postoperative follow-up

The average follow-up time was 35.1 ± 23.6 months (range: 2–104 months). A successful operation was defined as Stage 2 or less by POP quantification (POP-Q) examination. Two patients had recurrence 3 months after surgery. All other patients were found by POP-Q to be Stage 2 or less up to half a year after the surgery. The objective success rate was 98.9%, and no patient was reoperated because of recurrence. Mesh exposure was defined by criteria established by the International Urogynecological Association and the International Continence Society[6] [Figure 1a and 1b]. Mesh exposure was found in 32 patients, whose age ranged from 43 to 81 years. Most of the patients with mesh exposure were between 60 and 70 years old. The mean exposure diameter was 0.6 ± 0.3 cm (range: 0.3–1.5 cm) [Table 1]. The main clinical symptom of mesh exposure was vaginal discharge. The management of vaginal mesh exposure included regular observation, local application of estrogen ointment and metronidazole suppositories, and removal of exposed mesh. Most cases gradually healed in half a year. No mesh exposure progression was detected. There were eight patients who were admitted for removal of exposed mesh and after mesh resection the vaginal mucosa healed completely.

Comparison of risks factors between the two groups

Thirty-two patients with mesh exposure were recruited into the exposed group and the other 163 patients were recruited into the nonexposed group.

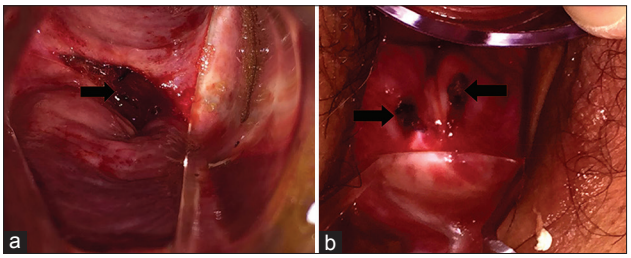

Figure 1: (a and b) Mesh exposure was found in the follow-up checkup, as the black arrows show.

Table 1: Demography of patients with MESH exposure (n = 32)

Variables	Range	Mean ± SD	95% *CI*
Age (years)	43.0–81.0	64.3 ± 8.8	61.1–67.5
Menopausal status (years)	0–35.0	14.6 ± 9.4	11.2–18.0
Gravidity (times)	1.0–7.0	3.3 ± 1.4	2.8–3.8
Parity (times)	1.0–6.0	2.3 ± 0.2	1.8–2.7
BMI (kg/m^2)	20.0–33.3	25.0 ± 2.6	24.0–25.9
Exposure time (months)	1.0–24.0	5.2 ± 4.7	3.5–7.0
Diameter (cm)	0.3–1.5	0.6 ± 0.3	0.5–0.7
Operative time (h)	1.0–3.0	1.6 ± 0.7	1.2–1.7
Blood loss (ml)	90.0–300.0	172.4 ± 75.3	142.7–216.4

BMI: Body mass index; *CI*: Confidence interval; SD: Standard deviation.

Table 2: Comparison of risk factors between groups

General information	Nonexposed group (n = 163)	Exposed group (n = 32)	Statistical value	P
Age (years)	63.6 ± 11.4	64.1 ± 9.6	0.062*	0.803
Menopausal status (years)	14.6 ± 10.8	14.7 ± 9.7	0.005*	0.942
Gravidity (times)	3.6 ± 1.6	3.1 ± 1.4	2.068*	0.152
Parity (times)	2.7 ± 1.5	2.1 ± 1.4	3.401*	0.067
BMI (kg/m^2)	24.6 ± 3.5	25.0 ± 2.6	0.321*	0.572
POP-Q stage				
II	4	2		0.514
III	144	27	1.330†	
IV	17	3		
Operation year				0.866
2004–2009	41	7	0.029†	
2010–2012	122	25		
Repair material				
Prosima	76	18		
Mesh	50	7	1.231†	0.541
Prolift	37	7		
Concomitant surgical procedures				
HUS	150	26	2.412†	0.120
TVH	159	30	0.333†	0.564
Perineal repair	131	29	1.278†	0.258
TVT	26	4	0.051†	0.821
TVT-O	20	11	8.192†	0.004
Concomitant procedures (n)	3.8 ± 1.1	4.3 ± 1.0	7.443*	0.007
Operative time (h)	1.7 ± 1.1	2.1 ± 0.5	4.307*	0.039
Blood loss (ml)	157.2 ± 69.2	171.3 ± 74.3	1.093*	0.297
Postoperative temperature (°C)	37.1 ± 0.2	37.2 ± 0.4	1.632*	0.203

*F values; †χ^2 values. SSLF: Sacrospinous ligament fixation; HUS: High uterosacral ligament suspension; TVT: Tension-free vaginal tape; TVT-O: Tension-free vaginal tape obturator technique; POP-Q: Pelvic organ prolapse quantification.

As shown in Table 2, the median age, the operative time, and the blood loss were comparable in the nonexposed and exposed groups. Statistical analysis revealed no significant difference for menopausal status, gravidity and parity, BMI, blood loss, age, or postoperative morbidity. However, the number of concomitant procedures in the nonexposed group was significantly lower than those in the exposed group. The postoperative morbidity in the two groups was 2% and 3%, respectively. The difference was not significant.

Logistic regression analysis of the risk factors for mesh exposure

Logistic regression analysis of the risk factors for mesh exposure was performed in 195 patients [Table 3]. Risk factors for mesh exposure in our analysis included operative duration and the concomitant procedures (P = 0.043, P = 0.001). The relative risk was 1.899 and 0.376, respectively, for operative time and number of operations. Other factors such as age, menopausal status, gravidity, parity, BMI, and blood loss were not related to mesh exposure.

Table 3: Risk factors for mesh exposure

General information	P	OR	95% CI
Age	0.457	1.045	0.931–1.173
Menopausal status	0.456	0.960	0.862–1.069
Gravidity	0.840	0.953	0.598–1.520
Parity	0.159	1.539	0.845–2.805
BMI	0.978	1.002	0.978–1.002
Operative duration	0.043	1.899	1.543–2.341
Blood loss	0.374	1.003	0.996–1.011
Postoperative temperature	0.680	0.696	0.124–3.898
Diabetes	0.645	0.780	0.270–2.249
Amount of procedures	0.001	0.376	0.209–0.676

BMI: Body mass index; *CI*: Confidence interval; *OR*: Odds ratio.

Discussion

Mesh exposure rate after RPS with transvaginal mesh

Epidemiological studies have shown that 29.2% of the POP patients need to be reoperated after traditional operation, especially in advanced POP. Some patients may even need several operations.[7] The synthetic PP mesh has been used more widely in pelvic reconstructive surgery for the past 10–20 years. However, the related complications of PP mesh have been reported occasionally and some of them are serious and life-threatening. Mesh exposure was most often seen in PP mesh-related complications. Its occurrence varies significantly among different studies. In 2007, Falagas reported that the incidence of mesh exposure rate ranged from 0% to 33%.[8] PP mesh erosion was reported in 20% of the patients by Deffieux *et al*., 11.3% by Caquant from France, and 20% by Antoine Béclère Hospital.[9-11] Recently,

a meta-analysis of 110 studies comprising 11,785 patients reported 10.3% overall rate of mesh exposure. In this study, we have found a higher mesh exposure rate in TVM of 15.8%.

In this study, we identified risk factors for PP mesh exposure. We analyzed the onset of the exposure and found that 59% occurred within 1 year after the operation and 41% beyond 1 year.[11] It was also found that 72.7% (24/33) of mesh exposure occurred within half a year. Among them, 39.4% (13/33) happened within 2 months. One year after the operation the onset of exposure was rather low (1/31).

Age and mesh exposure

According to the literature, mesh exposure is more likely to occur in patients older than 70 years due to thinner vaginal mucosa caused by the low estrogen level. In 2005, Achtari *et al*. reported that patient age was a risk factor for mesh exposure.[12] Deffieux *et al*. found that age >70 years was an independent predictive factor.[9] Kaufman found that sexual activity was also a risk factor for mesh exposure.[13] Kim *et al*. reported that the rate of mesh erosion was not related to patient age when comparing a group >70 years of age to a group <70.[14] In two recent retrospective cohort studies, which included patients over 80 with POP, no mesh exposure was found after the operation.[15,16] In our study, mesh exposure was found to occur mainly in patients between 50 and 75 years old. Age between the exposed group and nonexposed group did not reveal any significant difference. The subsequent regression analysis has also not revealed any effect of age for mesh exposure. There are several possible reasons age was not a factor in our study. First, we tried to reserve the vaginal mucosa as much as possible during our operation. Second, we used estrogen ointment locally before and after the operation. Third, our sample may not be large enough to reveal a difference.

Operation type, concomitant procedure, and mesh exposure

The number of concomitant operation procedures is another contributing factor for mesh exposure. In 2004, Thompson *et al*. reported abdominosacral fixation combined with total hysterectomy led to higher rate of mesh exposure.[17] Collinet *et al*. believed that risk factors for mesh exposure were concomitant hysterectomy and inverted T colpotomy[18,19] while Ganj *et al*. thought the most important factor was the length of the incisions in vagina mucosa and the tension on the incision line.[20] Controversially, Stepanian *et al*. found that concomitant hysterectomy would not increase the risk of mesh exposure.[21] In our experience, inverted T colpotomy is more invasive. Exposure was significantly higher in patients who received posterior vaginal wall colporrhaphy, perineorrhaphy, and vaginal tape. Binary logistic regression analysis showed that the number of concomitant procedures and operative time were risk factors for mesh exposure. As the number of concomitant procedures increased, the rate of mesh exposure increased, possibly due to a longer operative time. In this study, we used 3 different types of meshes. Prolift usually is placed as a whole sheet without adjusting. It can be stretched evenly with puncture needle going through the skin. Prosima was smaller and can be adjusted by clipping but is not as evenly placed as Prolift. Ventricular septal defect is maintained for 28 days after Prosima placement, which may arouse a local inflammation reaction. It is placed in vaginal wall without puncture needle guidance. Our results showed that Prosima, Prolift, and Mesh had an exposure rate of 19.1%, 15.9%, and 12.3%, respectively. Although Prosima showed a higher exposure occurrence, statistical analysis did not reveal any difference among them, indicating they share similar exposure hazards.

It was reported that surgeon's experience is also related with mesh exposure.[22-24] In our hospital, the rate of mesh exposure was 14.6% in the first 5 years and 17% in the following 3 years. The surgeons did not change during these years. This indicated that the surgeon's experience might not be a strong protective factor for mesh exposure. In addition, it was found that the exposure rate of vaginal tape was only 1.6%, which indicated vaginal tape was safer and less likely to have mesh exposure. The warning from US FDA regarding TVM indicates improper use of mesh may cause serious safety problems.[25] Thus, close follow-up needs to be performed after the operation. The surgeons' professional skills should be strengthened to reduce the incidence of complications. Candidates should be carefully chosen, usually patients with advanced POP. Furthermore, alternative nonsurgical treatment or autologous tissue reconstructive surgery should be explored. Access system should be implemented to select eligible surgeons, and a standardized management system should be established for pelvic surgery.

In general, our results showed that TVM surgery is beneficial for patients with advanced POP. Although exposure may occur after surgery, exposure rate was low and easy to manage. At the same time, patients should be cautiously evaluated before mesh surgery.

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Conflicts of interest

There are no conflicts of interest.

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