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### Original Article

# Risk factors and management of vaginal mesh erosion after pelvic organ prolapse surgery



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#### ABSTRACT

*Objective:* Mesh erosion is a serious and not uncommon complication in women undergoing vaginal mesh repair. We hypothesized that mesh erosion is associated with the patient's comorbidities, surgical procedures, and mesh material. The aims of this study were to identify the risk factors and optimal management for mesh erosion.

*Materials and Methods:* All women who underwent vaginal mesh repair from 2004 to 2014 were retrospectively reviewed. Data on patients' characteristics, presenting symptoms, treatment and outcomes were collected from their medical records.

Results: A total of 741 women underwent vaginal mesh repairs, of whom 47 had mesh erosion. The median follow-up period was 13 months (range 3–84 months). Another nine patients with mesh erosion were referred form other hospitals. Multivariate analysis revealed that concomitant hysterectomy (odds ratio 27.02, 95% confidence interval 12.35–58.82; p < 0.01) and hypertension (odds ratio 5.95, 95% confidence interval 2.43–14.49; p < 0.01) were independent risk factors for mesh erosion. Of these 56 women, 20 (36%) were successfully treated by conservative management, while 36 (64%) required subsequent surgical revision. Compared with surgery, conservative treatment was successful if the size of the erosion was smaller than 0.5 cm (p < 0.01). Six patients (17%) had recurrent erosions after primary revision, but all successfully healed after the second surgery.

*Conclusion:* Concomitant hysterectomy and hypertension were associated with mesh erosion. In the management of mesh erosion, conservative treatment can be tried as the first-line treatment for smaller erosions, while surgical repair for larger erosions. Recurrent erosions could happen and requires repairs several times.

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#### Introduction

Pelvic reconstructive surgery with mesh for pelvic organ prolapse (POP) has been reported to have a superior anatomical cure rate compared with traditional repair methods and for cystocele repair [1]. Therefore, many pelvic surgeons have adopted surgical mesh devices in recent years to repair POP. However, an increasing number of mesh-related adverse events have been reported

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worldwide [2,3]. The U.S. Food and Drug Administration warned in 2008 and 2011 about the mesh-related complications, including mesh erosion, pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems [2,3], and even stated in 2011 that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare" [3]. Of these adverse effects, mesh erosion is the most common, and mesh-related complications after vaginal mesh repair have been reported frequently [1,4]. Mesh erosion may require multiple surgeries to repair completely, it can be debilitating for patients, and it can take considerable time to resolve fully. Therefore, elucidating the risk factors for mesh erosion and thereby preventing its occurrence are important.

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Some studies have reported possible risk factors including hypertension, diabetes, and concomitant hysterectomy [5]. However, the results are inconsistent because of limited related data and small sample sizes. In addition, guidelines for the management of erosion have yet to be established. Some mesh erosions require surgical revision, while some heal spontaneously under conservative treatment [6]. To choose either conservative management or surgical revision, as the first-line treatment is unclear. As a result, the primary objective of this study was to analyze the risk factors for mesh erosion so that physicians can better advice patients who opt for vaginal mesh repair. The secondary objective was to elucidate under which situation conservative or surgical treatment is the best management option.

#### Materials and methods

This retrospective study used data on women who experienced mesh erosion after vaginal mesh repair for symptomatic POP quantification stage II or higher POP. All the women underwent mesh-reinforced repair at the same tertiary medical center from 2004 to 2014. The Institutional Review Board of the hospital approved this study.

Mesh erosion was defined as any visible vaginal mesh exposure identified on vaginal examination. Data were extracted from electronic medical records and charts. Baseline data including age, gravity, parity, comorbidities, smoking and hormone status, and mesh complications including dyspareunia, infection, urinary incontinence, or any other lower urinary tract symptoms, and how long the erosion had been present were collected. Characteristics of the mesh material, commercial kits, and all surgical records of patients were reviewed. Physical examination findings, including the size, site, and number of erosions, were also documented. Initially, at least 1 month of conservative treatment including topical estrogen cream, pain relief with analgesic agents, and enhanced local hygiene was advised. If the conservative treatment failed or the erosion did not improve, revision surgery was considered. Surgical revisions were all performed by two experienced attending urogynecologists. All the removed tissue specimens were proved via pathological examinations.

Descriptive data were presented as mean  $\pm$  standard deviation. The chi-square and Fisher's exact tests were used to compare categorical variables, while the paired t test and independent t test were used for continuous variables. The univariate analysis was performed to assess the possible factors associated with mesh erosion, and the multivariate analysis was then used to identify independent risk factors. A p value of <0.05 was considered to be statistically significant. All analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 17.0 for Window (SPSS, Chicago, IL, USA).

#### **Results**

A total of 741 patients who underwent vaginal mesh reinforced repair in our hospital were retrospectively reviewed, of whom 47 (6.3%) had mesh erosion. The mesh kits included Anterior/Posterior Elevate (AMS, Minnetinka, NM, USA), Prolift (Ethicon, Somerville, NJ, USA), Gynemesh (Ethicon), Apogee/Perigee (AMS), and Prosima (Ethicon). Baseline demographic data of all patients are shown in Table 1. Except for concomitant hysterectomy, hypertension, and diabetes mellitus, there were no significant differences between patients with and without mesh erosions regarding age, parity, body mass index, menopausal status, and mesh kits. The mean duration from the onset of initial symptoms to the patient's first visit was 5 months (range, 1–84 months). The most common symptoms were abnormal vaginal spotting and discharge (23%);

however, the majority of the patients (63%) remained asymptomatic, and the mesh erosion was observed during pelvic examinations. Univariate analysis showed that the potential risk factors for mesh erosion were concomitant hysterectomy [odds ratio (OR) 30.03, 95% confidence interval (CI) 13.59–66.67; p < 0.01], hypertension (OR 7.30, 95% CI 3.80–14.08; p < 0.01), and diabetes mellitus (OR 5.08, 95% CI 1.87–13.07; p < 0.01) (Table 2). Multivariate analysis showed concomitant hysterectomy (OR 27.02, 95% CI 12.35–58.82; p < 0.01), and hypertension (OR 5.95, 95% CI 2.43–14.49; p < 0.01) were independent risk factors.

Of the 56 women (including referral patients), 20 (36%) were successfully treated conservatively, while 36 (64%) required surgical revision after failing 1-3 months of conservative management or after recurrent erosions after conservative treatment. Of these 36 women, six (17%) had recurrent erosions, all of whom underwent successful second revision surgery. All the patients with more than two sites of erosions required surgical revision. There were no significant differences between patients who underwent successful conservative treatment or those who needed surgical revision regarding age, parity, body mass index, menopausal status, mesh material, or site of mesh erosion (Table 3). Only the size of erosion smaller than 0.5 cm healed spontaneously under conservative treatment (p < 0.01). Table 4 compares the characteristics between patients who had a successful surgical revision and those who required a second surgical revision. There were no significant differences in the size of mesh erosion, age, parity, body mass index, menopausal status, mesh material, or site of mesh erosion.

#### Discussion

This study demonstrates that mesh erosion is associated with concomitant hysterectomy, hypertension, and diabetes mellitus. Only 36% of patients responded to conservative therapy alone, while the others needed surgical revision. Furthermore, 16% of patients who had recurrent erosions needed repeated repairs. Although the standard management for mesh erosion has yet to be established, we noted that conservative treatment may be suitable for patients with an erosion size smaller than 0.5 cm, while surgical revision is indicated for those with larger or multiple erosions.

In this study, some patients were asymptomatic, and in the other patients, the symptoms involved infection, dyspareunia, bleeding, pelvic pain, or lower urinary tract symptoms. If a patient

**Table 1**Baseline clinical demographic data.

Erosion case	Erosion $(n = 47)$	No erosion $(n = 649)$	р
Age, y	63.3 ± 11.0	63.3 ± 10.9	0.97
Parity, n	$3.5 \pm 1.5$	$3.7 \pm 1.5$	0.28
Body mass index, kg/m <sup>2</sup>	$24.5 \pm 3.0$	$24.5 \pm 3.1$	0.92
Postmenopausal, $n$ (%)	37 (78)	554 (85)	0.18
Concomitant hysterectomy, $n$ (%)	34 (72)	331 (51)	< 0.01
Comorbidity			
Hypertension, $n$ (%)	17 (36)	48 (7)	< 0.01
Diabetes mellitus, $n$ (%)	7 (15)	15 (2)	0.01
Other disease, n (%)	2 (4)	5 (1)	0.20
Mesh procedure			
Anterior repair, $n$ (%)	15 (32)	187 (29)	0.71
Posterior repair, n (%)	2 (4)	13 (2)	0.34
Combined repair, $n$ (%)	30 (64)	449 (69)	0.79
Mesh type			
Elevate	19 (40)	331 (51)	0.19
Prolift	15 (32)	213 (33)	0.46
Others (Gynemesh,	13 (32)	105 (16)	0.23
Prosima, Apogee, Perigee)			

<sup>&</sup>lt;sup>a</sup> Other disease includes malignancies, autoimmune disease, and cardiovascular disease.

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