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Original Article

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

Yung-Wen Cheng [a], Tsung-Hsien Su [a, b, c, d], Hsuan Wang [a], Wen-Chu Huang [a, b, d], Hui-Hsuan Lau [a, b, c, d, *]

[a] Division of Urogynecology, Department of Obstetrics and Gynecology, Mackay Memorial Hospital, Taipei, Taiwan
[b] Mackay Medicine, Nursing and Management College, Taipei, Taiwan
[c] Taipei Medical University, Taipei, Taiwan
[d] Mackay Medical College, Taipei, Taiwan

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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.

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 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.

* Corresponding author. Division of Urogynecology, Department of Obstetrics and Gynecology, Mackay Memorial Hospital, Number 92, Section 2, Chung-Shan North Road, Taipei 104, Taiwan.
E-mail address: huihsuan1220@gmail.com (H.-H. Lau).

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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 ± 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 ($n = 649$)	p
Age, y	63.3 ± 11.0	63.3 ± 10.9	0.97
Parity, n	3.5 ± 1.5	3.7 ± 1.5	0.28
Body mass index, kg/m^2	24.5 ± 3.0	24.5 ± 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,[a] 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, Prosima, Apogee, Perigee)	13 (32)	105 (16)	0.23

[a] Other disease includes malignancies, autoimmune disease, and cardiovascular disease.

Table 2
Risk factors for mesh erosion.

Variable	Univariate analysis		Multivariate analysis	
	Odds ratio (95% CI)	*p*	Odds ratio (95% CI)	*p*
Age ≥65 y (reference: <65 y)	1.02 (0.97–1.03)	0.88		
Menopause (reference: premenopause)	1.37 (0.61–3.09)	0.45		
Concomitant hysterectomy (reference: none)	30.3 (13.89–66.67)	<0.01	27.02 (12.35–58.82)	<0.01
Comorbid hypertension (reference: none)	7.30 (3.80–14.08)	<0.01	5.95 (2.43–14.49)	<0.01
Comorbid diabetes mellitus (reference: none)	5.08 (1.87–13.07)	<0.01	1.76 (0.46–6.72)	0.41
Mesh material factor (reference: lightweight type I mesh[a])	1.23 (0.59–2.56)	0.57		

CI = confidence interval.
[a] Lightweight type I mesh is IntePro Lite mesh with a density of 25.2 g/m^2.

Table 3
Characteristics of mesh erosion between those healed with conservative treatment and those requiring subsequent surgical revision.

	Conservative treatment (n = 20)	Surgical revision (n = 36)	*p*
Age, y	64.5 ± 11.1	62.5 ± 11.2	0.50
Postmenopausal, *n* (%)	20 (100)	25 (69)	0.27
Parity, *n*	3.5 ± 1.5	3.5 ± 1.5	0.86
Body mass index, kg/m^2	23.9 ± 2.3	25.4 ± 3.5	0.07
Any comorbidity, *n* (%)	12 (60)	18 (50)	0.79
Mesh erosion size, *n* (%)			
<0.5 cm	20 (100)	14 (39)	<0.01
0.5–1 cm	0 (0)	8 (22)	<0.01
>1 cm	0 (0)	14 (39)	<0.01
≥2 mesh erosions, *n* (%)	0 (0)	2 (6)	0.50
Mesh erosion site, *n* (%)			
Anterior vaginal wall	12 (60)	15 (42)	0.15
Vaginal cuff	7 (35)	18 (50)	0.19
Posterior vaginal wall	1 (5)	3 (8)	0.63
Mesh material,[a] *n* (%)	11 (55)	10 (28)	0.15

[a] Lightweight type I mesh (mesh density of 25.2 g/m^2).

Table 4
Characteristics of mesh erosion between those successfully treated with primary surgical revision and those requiring a second surgical revision.

	Primary surgical revision (n = 30)	Second surgical revision (n = 6)	*p*
Age, y	63.4 ± 11.3	63.7 ± 3.8	0.02
Postmenopausal, *n* (%)	25 (83)	4 (67)	0.11
Parity, *n*	3.6 ± 1.5	2.3 ± 0.6	0.17
Body mass index, kg/m^2	25.6 ± 3.6	23.0 ± 1.3	0.22
Any comorbidity, *n* (%)	17 (57)	1 (17)	0.79
Mesh erosion size, *n* (%)			
<0.5 cm	12 (40)	2 (33)	0.22
0.5–1 cm	5 (17)	3 (50)	0.56
>1 cm	13 (43)	1 (17)	0.99
≥2 mesh erosions, *n* (%)	1 (3)	1 (17)	0.26
Mesh erosion site, *n* (%)			
Anterior vaginal wall	13 (43)	2 (33)	0.27
Vaginal cuff	14 (47)	4 (67)	0.24
Posterior vaginal wall	3 (10)	0 (0)	0.99
Mesh material,[a] *n* (%)	10 (33)	0 (0)	0.27

[a] Lightweight type I mesh (mesh density of 25.2 g/m^2).

is unaware of a complication or does not receive regular follow-up, the incidence of mesh erosion may be underestimated, and identification of risk factors becomes difficult. However, identification of risk factors is important for preoperative counseling and modification of surgical options. Similar to some other studies, hysterectomy was a risk factor for mesh erosion [5,7]. Mesh erosion may be associated with a combination of bacterial infection and devascularization of the vaginal cuff [8]. The concurrent hysterectomy involves a wider tissue incision and dissection, and the opening of the vaginal cuff with exposure to vaginal flora may lead to subsequent mesh erosion [8]. Besides surgical procedures, patient characteristics also influence the risk of mesh erosion. We observed that hypertension and diabetes mellitus were also potential risk factors for mesh erosion. Both hypertension and diabetes are associated with peripheral vascular disease. Denervation and devascularization make decreased nutrients and oxygen be delivered at the cellular level, which may impede wound healing and consequently cause the development of mesh erosion. With regard to mesh materials, it is documented that mesh properties play a role in the relative risk of developing mesh erosion. However, the results of previous studies remain inconsistent. Barski et al [5] reported that a light weight and collagen coating were positive factors to prevent erosion, while other studies have reported that the mesh material had no association with mesh erosion [9,10]. Moore and Lukban [10] compared the mesh extrusion rate in patients using lower density type I polypropylene mesh (IntePro Lite mesh, 25.2 g/m^2) versus heavier mesh (IntePro mesh, 50 g/m^2). Although 46% reduction in the rate of mesh exposure was observed in the lighter and softer mesh group, there was no statistical significance. Similarly, we did not observe that a heavier mesh material was a significant risk factor of mesh erosion compared with a softer mesh material, indicating that mesh erosion can take place regardless of the type of material used.

Some studies have reported the experience of mesh erosion management [6,11,12]. In 2008, Ridgeway et al [11] reported their early experience of mesh revision in 19 patients. All these patients underwent surgical intervention with only a few reported complications related to the mesh removal and significant relief of symptoms. They reported that surgical removal of mesh removal was a safe procedure with few complications and significant relief of symptoms [11]. Crosby et al [6] also reported their surgical experience in 84 patients with a median of 4-month follow-up. The success rate for surgical mesh revision was 95%, with 51% of the patients having resolution of all presenting symptoms. They concluded that surgical removal of exposed mesh is always successful and helpful in relieving symptoms. Abbott et al [12] reported their experience in 347 patients who had mesh-related complications after vaginal mesh repairs and/or sling surgeries with a median of 5.8-month follow-up in a multicenter, retrospective study. They reported that 51% of the patients were initially managed conservatively, and 59% of them were shifted to surgical intervention due to failed nonsurgical management. Our study showed a similar prevalence, in that 64% (36/56) of the patients

needed subsequent surgical treatment. Only erosions smaller than 0.5 cm in size healed spontaneously under conservative treatment, and those larger than 0.5 cm required a surgical intervention. Of 34 patients with erosions smaller than 0.5 cm, 20 (59%) healed after conservative treatment, and the remaining 14 (41%) patients as well as those with larger or multiple erosions required surgical revision. This result indicates that the size of the erosion is an important factor. The success rate of the first surgical revision surgery was 83% (30/36), and the 17% (6/36) patients with recurrent erosions were all successfully repaired by a second surgical intervention without complications. We compared the characteristics of the patients who were successfully treated after only one surgery and those required two or more interventions, and found no significant differences. This suggests that age, menopausal status, size and location of erosion, and mesh material are not risk factors for recurrent erosions, and this information should be provided to the patients who undergo mesh revision surgery. Unlike other studies in which a few patients had chronic pelvic pain and dyspareunia, all our patients had improvements in or relief of their symptoms after either conservative treatment or surgical revision. This result indicates that in most cases, mesh erosion may be a serious but resolvable problem with careful and successful management.

The limitations of this study include its retrospective design, relatively small sample size, and short-term follow-up. In addition, the median follow-up period was 13 months; however, Marcus-Braun and von Theobald [13] reported that delayed mesh erosion may occur more than 2 years after the primary operation. Another study reported delayed mesh erosion mainly in the 4th year of follow-up [14]. Therefore, further studies are needed with a longer follow-up period to clarify this issue, and it is possible that some of the risk factors, which were not found to be significant, may actually be associated with mesh erosion, which may be observed with a longer follow-up period. Smoking and sexual activity have also been reported to be risk factors in some studies [5,8,15]. However, none of our patients smoked and data on sexual activity were incomplete, and therefore we were unable to analyze these risk factors in this study.

In conclusion, the risk factors for mesh erosion were diabetes mellitus, hypertension, and concomitant hysterectomy. All physicians should inform these patients about the risks before vaginal mesh procedures. In addition, all patients receiving mesh procedures should receive regular follow-up. Once erosion has been noted, conservative treatment may be used initially for smaller erosions; however, for larger or multiple erosions, surgical revision is indicated as the treatment of choice.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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