Postoperative Outcomes Following Tension-Free Vaginal Mesh Surgery for Pelvic Organ Prolapse: A Retrospective Study

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Purpose: We retrospectively reviewed the postoperative outcomes of patients who underwent tension-free vaginal mesh (TVM) surgery in our institution.

Methods: In total, 195 TVM surgeries were performed at the Shimane University School of Medicine from January 2010 to May 2016 in patients with Pelvic Organ Prolapse–Quantification (POP-Q) stage II or higher. Perioperative complications and problems arising following surgery were assessed from medical charts.

Results: Among the 195 patients, only 1 patient required blood transfusion due to massive intraoperative blood loss. None of the patients experienced intraoperative complications, such as injury to the bladder or rectum during surgery. Mesh exposure was observed in 10 patients (5.1%). Overall, 6 of these 10 patients were asymptomatic, and surgical treatment was required in only 1 patient. Mesh exposure occurred at significantly higher frequencies in patients aged less than 60 years. Postoperative recurrence of POP, which was defined as recurrence over POP-Q stage 2, was noted in 13 of the 195 patients (6.6%). Re-operation was performed in 1 patient in whom recurrence was observed within 3 months postoperatively. Recurrence of POP was likely to occur in patients with higher POP-Q stages. Overall, 31 of the 195 patients (15.9%) required medication for postoperative stress urinary incontinence (SUI) after surgery. Among these, 2 patients underwent surgical treatment for SUI.

Conclusion: Outcomes following the TVM procedure were satisfactory. However, caution should be exercised against mesh exposure in younger patients and recurrence of POP in patients with advanced POP-Q stage.

Keywords: TVM; mesh surgery; pelvic organ prolapse; mesh exposure; stress urinary incontinence

INTRODUCTION

In the super-aging society of Japan, pelvic organ prolapse (POP) is a major healthcare problem, and the number of patients with this disorder has increased in recent years. Although Japanese gynecologists have traditionally performed vaginal hysterectomy (VH), anterior and posterior colpoplasty, and circumferential suturing of the levator ani muscles as curative surgery for POP, a gold standard operation for POP is yet be established worldwide. Thus, the surgical treatment of POP continues to be a clinical challenge for gynecologists. After the development of tension-free vaginal mesh (TVM) surgery for the repair of POP in France, this new transvaginal technique has been adopted in many countries[1]. TVM surgery, which does not require hysterectomy, is associated with favorable cure rates and a low frequency of complications[1], and many gynecologists in Japan have now switched to using this new technique as the first-line surgical option for POP. The procedure of TVM surgery is simple and easy to learn. However, there exist certain TVM surgery-specific peri- and postoperative complications, such as mesh exposure, wound granulation, infection, dyspareunia, and stress urinary incontinence (SUI)[2,3]. For example, in a recent review, the overall mesh exposure rate has been reported to be 10.3% [2], and the recurrence rate following TVM operation has been reported to be low but significant at 7.0% [1]. Indeed, the US Food and Drug Administration (FDA) expressed concerns about the safety and effectiveness of TVM surgery in 2008 and 2011[4].

We have employed TVM surgery as the first-line surgical treatment for POP in our institution since 2010. To evaluate the postoperative outcomes and complications of this transvaginal surgery, we retrospectively reviewed cases of POP treated with TVM surgery in our institution.

MATERIALS AND METHODS

Between January 2010 and March 2016, 195 women with POP underwent TVM surgery in Shimane University Hospital. Women with asymptomatic prolapse designated Pelvic Organ Prolapse Quantification System (POP-Q) stage II (leading edge of the prolapse > -1 cm) or higher were candidates for TVM surgery. Exclusion criteria were premenopausal women, diabetes mellitus, and very low activities of daily living. Patients were provided preoperative counseling regarding uterine preservation procedures, safety, efficacy, and potential complications. Moreover, we also provided explanations about alternative measures such as the use of pessary ring, native tissue repair, and sacrocolpopexy.

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Table 1. Baseline characteristics of the 195 patients.

Age (at the time of surgery)	**69.0 ± 8.5**
Surgery	
A-TVM, n (%)	34 (17.4)
AP-TVM, n (%)	128 (65.6)
P-TVM, n (%)	29 (14.9)
T-TVM, n (%)	4 (2)
POP-Q stage	
II, n (%)	32 (16.4)
III, n (%)	135 (69.2)
IV, n (%)	28 (14.4)

Abbreviations: TVM: anterior TVM, P-TVM: posterior TVM, AP-TVM: anterior and posterior TVM, T-TVM: total TVM

Patients who had provided written informed consent were scheduled for TVM surgery. Data were collected retrospectively from the patients' medical records, and ethical approval for this study was obtained from the Ethical Committee of Shimane University Hospital.

All procedures were performed by two experienced gynecologists in our hospital. The surgery was performed under general or lumbar spinal anesthesia in the lithotomy position. The conventional TVM technique has been described previously[5]. We used monofilament polypropylene mesh (Polyform™; Boston Scientific, Natick, MA) cut into a shape similar to that used with the Prolift system (Ethicon, Somerville, NJ) before each operation, because mesh kits for TVM surgery are not available in Japan. The anterior TVM (A-TVM) procedure starts with anterior colpotomy after local infiltration. Repair of a cystocele requires two arms of transobturator mesh to be passed on both sides in order to suspend the cystocele. On either side, both arms of the mesh are passed into the paravesical region using a modified Emmet needle. The anterior subvesical strap is inserted into the tendinous arch of the pelvic fascia. The posterior subvesical strap is inserted in the tendinous arch 1 cm from the ischial spine using a gently curved needle. In the posterior TVM (P-TVM) procedure, posterior colpotomy is performed longitudinally and the mesh is placed under the vaginal wall. On each side, one strap of the mesh is passed into the pararectal space through the sacrospinous ligament and exteriorized via incisions located outside and below the anus. After cystoscopy and digital examination of the rectum, the colpotomy is closed with a 2-0 PDS running suture without additional colpectomy.

In our institution, patients with anterior vaginal wall prolapse underwent A-TVM, patients with both anterior and posterior vaginal wall prolapse underwent a combined A-TVM and P-TVM (AP-TVM) procedure, and patients without a uterus underwent total TVM (T-TVM). For T-TVM, we connected the A-TVM mesh and P-TVM mesh, and created a one-piece mesh with six arms. We then created a tunnel under the mucous membranes of the vaginal stump through which the mesh was passed and inserted in the anterior and posterior walls.

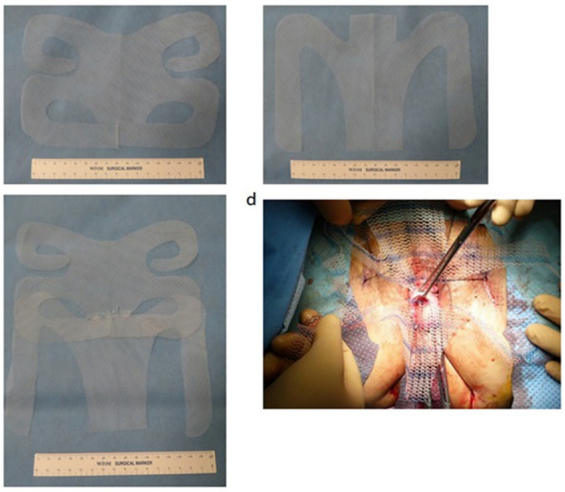

Figure 1. Shape of mesh and a intraoperative picture of T-TVM. **(a)**A-TVM mesh, **(b)** P-TVM mesh, **(c)** T-TVM mesh, **(d)** Insertion of T-TVM mesh into a tunnel of vaginal stump

Perioperative and postoperative complications, including mesh extrusion, dyspareunia, SUI, and recurrence of POP were evaluated according to patient age and preoperative stage of POP-Q. Recurrence of POP was defined as POP-Q stage II or higher after the initial operation. Patients were discharged 3 days after surgery and monitored for postoperative complications in the outpatient clinic at 1, 3, 6, and 12 months and then annually after the surgery.

POP recurrence and mesh exposure were diagnosed based on gynecological examination. De novo SUI was determined based on the presence of both the patient's complaints and a positive stress test.

Statistical analysis was performed to determine significant differences between the groups using the Chi-squared test and the Fisher exact test with $P < 0.05$ indicating statistical significance. The data were finalized in December 2016.

RESULTS

The characteristics of the 195 patients who underwent TVM surgery between January 2010 and March 2016 are shown in **Table 1**. The mean follow-up duration was 12 ±15 (range 3 to 60) months. Regarding TVM surgery, the combined AP-TVM was the most commonly performed surgery in patients with POP, and this was performed in 128 women. The number of A-TVM, P-TVM, and T-TVM surgeries were 34, 29, and 4, respectively. Stage III was the most commonly diagnosed POP-Q stage (n = 135), followed by stage II (n = 32) and stage IV (n = 28). Also, the age distribution is shown in Table 2. About 77% of women who underwent TVM surgery were aged between 61 and 80 years; 13 wom-

Table 2. Age distribution of patients.

	41-60 y	61-70 y	71-80 y	81-90 y	Total (%)	Mean of age (± SD)
TVM-A	11	10	9	5	34 (17.4)	67.9 (± 10.8)
TVM-AP	17	59	44	7	128 (65.6)	68.7 (± 8.0)
TVM-P	3	6	19	1	29 (14.9)	71.4 (± 8.0)
T-TVM	1	1	2	0	4 (2)	68.3 (± 6.0)
	32	76	74	13	195	69 (± 8.6)

Table 3. Age and POP-Q stage distribution of 10 patients with mesh exposure.

Age (years)	mesh exposure		*P* value
	Yes n (%)	No n (%)	
41-50	1 (50)	1 (50)	
51-60	4 (13.3)	26 (86.7)	
61-70	1 (1.3)	75 (98.7)	$p = 0.0071$
71-80	4 (5.4)	70 (94.6)	
81-90	0 (0)	13 (100)	
POP-Q stage			
II	3 (9.4)	29 (90.6)	
III	6 (4.4)	129 (95.6)	
IV	1 (3.6)	27 (96.4)	

The percentage is the proportion of patients of the same age or at the same disease stage who developed mesh exposure following TVM surgery. The Chi-squared test was performed to compare two groups divided by age ≤ 60 years and > 60 years. The incidence of mesh exposure was significantly higher in patients over 60 years. The percentage of mesh exposure did not differ between POP-Q stages.

Table 4. Age and POP-Q stage distribution of 13 patients with recurrent POP.

Age (years)	Recurrent POP		*P* value
	Yes n (%)	No n (%)	
41-50	0 (0)	2 (100)	0.06
51-60	1 (3.3)	29 (96.7)	
61-70	7 (9.2)	69(90.8)	
71-80	5 (6.8)	69 (93.2)	
81-90	0 (0)	13 (100)	
POP-Q stage			0.66
II	0 (0)	32 (100)	
III	8 (5.9)	127 ((94.1)	
IV	5 (17.9)	23 (82.1)	

The percentage is the proportion of patients of the same age or at the same disease stage whose POP recurred following TVM surgery. The Fisher's exact test was performed to make comparisons within each group. The recurrence rate was not related to the patient's age and POP-Q stage.

en were aged over 81 years, and 32 women were aged below 60 years. Only 2 of the 195 patients had vaginal hysterectomy due to uterine fibroid. No other patients had undergone previous vaginal surgery.

Among 195 cases, only 1 intraoperative complication occurred, wherein over 1800 mL of intraoperative bleeding required transfusion in a patient. There were no cases of bladder injury, rectal injury, or injury to the ureters.

During postoperative routine follow-up examinations, we found mesh exposure in 10 of the 195 patients (5.1%). Furthermore, 6 of these 10 patients were asymptomatic, and 4 patients complained of abnormal vaginal bleeding during follow-up hospital visits. Mesh exposure was identified at various intervals following surgery, between 6 months and 2 years and among patients whose age ranged from 49 to 79 (average age, 73.8 ± 11.0) years. The age distribution of patients with mesh exposure demonstrated that younger patients who underwent TVM surgery were more likely to have mesh exposure postoperatively. When patients were divided into two groups by age ≤ 60 years and > 60 years, we noted that the occurrence of mesh exposure was significantly higher in those aged ≤ 60 years of age ($P < 0.007$) (**Table 3**). Among the 10 patients with mesh exposure, only 1 patient underwent additional surgical treatment, which included removal of the exposed mesh and re-suturing of the vaginal wall to control abnormal bleeding. Among the 195 patients who underwent TVM surgery, 13 patients were diagnosed with recurrent prolapse (6.6%). Recurrence was diagnosed based on physical indications, not patient's complaints. The time points at which recurrence of POP was diagnosed varied from 3 months to 3 years postoperatively, and the average time was 13.6 ± 10.3 months after the initial TVM surgery. POP-Q stages at the time of initial operation were compared among the recurrent cases. Overall, 8 patients with recurrence were initially diagnosed as POP-Q stage III (8/135, 5.90%), while the remaining 5 patients had POP-Q stage IV (5/24, 17.90%). The recurrence rate of POP was thus significantly higher in patients with POP-Q stage IV than those with POP-Q stage III at initial diagnosis. There was no significant difference between age groups and POP-Q stage. Among these 13

Table 5. Occurrence of SUI after TVM surgery.

	Patients with SUI after TVM		
	Yes n (%)	No n (%)	
	31 (15.9)	164 (84.1%)	
Age (years)			*P* value
41-50	0 (0)	2 (100)	0.200
51-60	1 (3.3)	29 (96.7)	
61-70	14 (18.4)	62 (81.6)	
71-80	15 (20.3)	59 (79.7)	
81-90	1 (7.7)	12 (92.3)	
POP-Q stage			
II	7 (21.9)	25 (78.1)	0.29
III	22 (16.3)	113 (83.7)	
IV	2 (7.1)	26 (92.9)	
	Yes n (%)	**No n (%)**	
Consultation to urologists	7 (3.6)	188 (96.4)	
TVT surgery	2 (1.0)	193 (99.0)	

Abbreviations: SUI: stress urinary incontinence; TVT: tension-free vaginal tape

The percentage is the proportion of patients of the same age or at the same disease stage who developed SUI following TVM surgery. The Chi-squared test was performed to make comparisons within each group. The occurrence of SUI was not related to the patient's age and POP-Q stage.

patients who presented with recurrent POP, only 1 patient underwent a second surgery at her request (**Table 4**).

Finally, we analyzed the occurrence of postoperative SUI in the 195 patients who underwent TVM surgery; 15 of 31 patients who developed postoperative SUI had preoperative SUI. During postoperative follow-up, 31 patients (15.9%) received medication for complaints of onset or worsening of SUI; These included transient or continuous medication. The majority of patients who complained of SUI following TVM surgery recovered or did not consider the problem serious enough to warrant further treatment. However, 7 of the 31 patients (22.5%) consulted a urologist to request further examination and treatment. Of these, 2 patients underwent tension-free vaginal tape surgery for SUI (**Table 5**). Patients' symptoms associated with de novo SUI improved after surgery. No patients complained of postoperative recurrent urinary tract infection or deterioration of sexual function including dyspareunia and vaginismus. There was no evidence of wound granulation or infection at the postoperative examination.

DISCUSSION

In this study, we reviewed the records of patients who underwent TVM surgery for POP and analyzed the postoperative outcomes. As previously reported, we concurred that TVM surgery can be performed safely and that it is associated with a relatively low rate of complications[6]. We have not encountered severe complications during the TVM surgeries that we have performed so far, except in 1 case where blood transfusion was required following heavy bleeding. This was our 24th case after starting TVM surgery in our institution, and the unexpected blood loss probably occurred due to poor surgical technique when opening the paravesical space by blunt dissection.

As expected, this study revealed that mesh exposure was one of the major postoperative complications of TVM surgery. Our mesh exposure rate was 5.1%. The occurrence of mesh exposure has varied significantly among different studies. In 2007, Falagas et al. reported that the incidence of mesh exposure ranged from 0% to 33% [7]. In 2016, Niu et al. reported a series of 195 patients in which the incidence of mesh exposure was 16.4% [8]; they assumed that the number of concomitant procedures and the operation times were risk factors for mesh exposure. Indeed, a report by Heinonen et al. in 2016 demonstrated a mesh exposure rate of 23% and noted that the complications in the first half and second half of patients sampled revealed a reduction in mesh exposure from 14% to 5%. Luo et al. reported that the mesh exposure rate will be close to zero if TVM surgery is performed using the anatomical implant technique [9]. We did not evaluate the cases of mesh exposure in detail because our study had only 10 such cases; however, mesh exposure was more likely to occur in patients younger than 60 years of age. Sexual activity may also be a risk factor for mesh exposure as previously suggested[10,11]. However, several studies have shown no significant difference in patient age between mesh exposure and non-exposure groups[8,12]. Considering that more than half of the patients with mesh exposure were asymptomatic and only 1 patient (0.5%) required reoperation due to repeated abnormal bleeding, which implied that most cases with mesh exposure and abnormal bleeding were easily cured by medical intervention with local vaginal estrogen tablets), TVM surgery should not be excluded based on patient age. Nevertheless, since mesh exposure was noted as late as 2 years postoperatively, longer follow-up durations may increase the incidence rate of mesh exposure in the future.

Recurrence of POP after TVM surgery occurred in 13 patients (13/195, 6.6%) in our evaluation. Of the 13 patients, only 1 patient underwent reoperation, while the remaining 12 patients either did not notice POP recurrence or did not find it inconvenient. In 2008, Caquant et al. reported a recurrence rate at 6-18 months of 6.9% after TVM surgery[13]. Sho et al. retrospectively reviewed 526 TVM operations in 2014 and indicated a recurrence rate of 7.0%[14]. Similar to our results, these reports also described low rates of reoperation among cases of recurrent POP. Since the recurrence rate of POP was higher in patients with advanced stages of preoperative POP, such patients should be followed up carefully.

Although children might also develop SUI , SUI and POP are common diseases in postmenopausal women. Some reports state that SUI is observed in approximately 40% of women aged 51 or over. Changes in certain neuropeptides such as vasoactive intestinal peptide and neuropeptide Y, and neuronal nitric oxide in the vaginal wall have been observed in SUI and POP patients . Postoperative SUI is a well-known complication of TVM surgery. We have previously reported that 47.3% of patients without preoperative SUI experienced de novo postoperative SUI after TVM surgery[3]. In the present study, not all women who complained of postoperative SUI wished to receive medication, because their SUI symptoms were not severe. Treatment was prescribed to 31 of 195 patients for SUI using clenbuterol hydrochloride and/or propiverine hydrochloride after TVM surgery. In most patients, the symptoms resolved or subsided over time, and only 7 of 31 patients were referred to the urologist for further expert examination and treatment. Ultimately, only 2 patients who underwent TVM surgery underwent surgical treatment for SUI by the urologist. SUI can result from resolution of urethral obstruction by anatomical reconstruction. Interestingly, TVM surgery can improve SUI in some cases[3]. Thus, even when postoperative SUI occurred, most cases were transient. However, a small number of serious cases may require surgery.

Limitations of our study are its retrospective and single-center design. Additionally, although the study duration was 3 years at the longest, the follow-up period for some patients was too short for any complications to have been observed.

Overall, we were satisfied with the outcomes of TVM surgery performed in our institution in the past 6 years. However, the US FDA has described increasing concerns regarding complications after TVM surgery[15]. Furthermore, two recent studies from Scotland and the UK took a stand against mesh surgery for POP because their investigations revealed that vaginal repair with mesh material did not improve outcomes for women [16,17]. Therefore, this surgical technique needs further consideration, and patients undergoing TVM surgery should be followed up carefully.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of inter-

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REFERENCES

1. Debodinance P, Berrocal J, Clave H, et al. [Changing attitudes on the surgical treatment of urogenital prolapse: birth of the tension-free vaginal mesh]. J Gynecol Obstet Biol Reprod (Paris). 2004;33:577-88.
2. Abed H, Rahn DD, Lowenstein L, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J. 2011;22:789-98.
3. Kanasaki H, Oride A, Mitsuo T, Miyazaki K. Occurrence of pre- and postoperative stress urinary incontinence in 105 patients who underwent tension-free vaginal mesh surgery for pelvic organ prolapse: a retrospective study. ISRN Obstet Gynecol. 2014;2014:643495.
4. Costantini E, Lazzeri M. What part does mesh play in urogenital prolapse management today? Curr Opin Urol. 2015;25:300-4.
5. Collinet P, Belot F, Debodinance P, Ha Duc E, Lucot JP, Cosson M. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. Int Urogynecol J Pelvic Floor Dysfunct. 2006;17:315-20.
6. Takahashi S, Obinata D, Sakuma T, et al. Tension-free vaginal mesh procedure for pelvic organ prolapse: a single-center experience of 310 cases with 1-year follow up. Int J Urol. 2010;17:353-8.
7. Falagas ME, Velakoulis S, Iavazzo C, Athanasiou S. Mesh-related infections after pelvic organ prolapse repair surgery. Eur J Obstet Gynecol Reprod Biol. 2007;134:147-56.
8. Niu K, Lu YX, Shen WJ, Zhang YH, Wang WY. Risk Factors for Mesh Exposure after Transvaginal Mesh Surgery. Chin Med J (Engl). 2016;129:1795-9.
9. Luo DY, Yang TX, Shen H. Long term Follow-up of Transvaginal Anatomical Implant of Mesh in Pelvic organ prolapse. Sci Rep. 2018;8:2829.
10. Achtari C, Hiscock R, O'Reilly BA, Schierlitz L, Dwyer PL. Risk factors for mesh erosion after transvaginal surgery using polypropylene (Atrium) or composite polypropylene/polyglactin 910 (Vypro II) mesh. Int Urogynecol J Pelvic Floor Dysfunct. 2005;16:389-94.
11. Kaufman Y, Singh SS, Alturki H, Lam A. Age and sexual activity are risk factors for mesh exposure following transvaginal mesh repair. Int Urogynecol J. 2011;22:307-13.
12. Kim J, Lucioni A, Govier F, Kobashi K. Worse long-term surgical outcomes in elderly patients undergoing SPARC retropubic midurethral sling placement. BJU Int. 2011;108:708-12.
13. Caquant F, Collinet P, Debodinance P, et al. Safety of Trans Vaginal Mesh procedure: retrospective study of 684 patients. J Obstet Gynaecol Res. 2008;34:449-56.
14. Sho T, Yoshimura K, Hachisuga T. Retrospective study of tension-free vaginal mesh operation outcomes for prognosis improvement. J Obstet Gynaecol Res. 2014;40:1759-63.
15. Stanford E, Moen M. Patient safety communication from the Food and Drug Administration regarding transvaginal mesh for pelvic organ prolapse surgery. J Minim Invasive Gynecol. 2011;18:689-91.
16. Morling JR, McAllister DA, Agur W, et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997-2016: a population-based cohort study. Lancet. 2017;389:629-40.
17. Glazener CM, Breeman S, Elders A, et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). Lancet. 2017;389:381-92.