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Letter to the Editor

Popularization of tension-free vaginal mesh surgery for the treatment of pelvic organ prolapse in Japan: A retrospective review of the first 50 procedures performed by a gynecologist

Dear Editor,

As Japan becomes a super-aging society, with 1 in 5 people aged 65 years or older, the range of activities for the elderly is also becoming wider. Pelvic organ prolapse (POP) is a serious disease that carries an increased risk for surgery by the age of 80 years in up to 11% of the female population and it significantly affects women's quality of life (QOL).¹ Urinary incontinence (UI) is another urogynecologic disease that is closely associated with POP and increases in incidence with advancing age.^{2,3} Permanent cure of POP can be achieved surgically, and Japanese gynecologists have traditionally performed curative surgical procedures such as vaginal hysterectomy (VH), anterior or posterior colpoplasty, and circumferential suture of the levator ani muscle for POP, and especially for uterine prolapse. With a trend toward seeking less invasive surgical procedures, in the last decade a French group of gynecologists described tension-free vaginal mesh (TVM) surgery for the repair of POP using a mesh without hysterectomy.^{4,5} In Japan, this surgical procedure was first adopted by urologists,⁶ followed by gynecologists and is now becoming the first-line surgical option for POP—substituting VH in Japan. However, while surgical kits for TVM are commercially available in Western countries, such products have not received approval from the government in Japan, and surgeons must therefore cut a polypropylene mesh into the same shape as that provided in a commercially available kit which enables the mesh arms to penetrate through the obturator foramen and the sacrospinous ligament with a custom-made needle. Unlike VH, in which surgical manipulation is performed under macroscopic observation, TVM surgery consists mainly of blind techniques and is thus associated with not only procedure-specific complications, such as bladder and rectal injury, but also postoperative complications, such as dyspareunia and urinary incontinence. Indeed, a randomized controlled trial showed higher rates of surgical complications and postoperative adverse events in mesh surgery compared to that in conventional surgery.⁷

At the Department of Obstetrics and Gynecology, Shimane University School of Medicine, we have employed TVM surgery for the treatment of POP since September 2009. *Japanese government approved TVM surgery as a remedy for POP and the cost of treatment is covered by the public health insurance for the whole nation in our country.* We report here the clinical outcome of the first 50 patients with POP who underwent TVM surgery performed solely by the first author, a gynecologist who had no prior experience of

TVM surgery, with the intention of showing that the TVM technique can be performed relatively easily and safely, even by a first-time surgeon.

Of these 50 patients, 18 with cystocele underwent anterior TVM (A-TVM) in which a mesh was inserted into the anterior vaginal wall alone, 21 with cystocele underwent anterior and posterior TVM (AP-TVM) in which meshes were inserted into both the anterior and posterior vaginal walls, 9 with cystocele underwent total TVM (T-TVM) in which a mesh consisting of two parts for the anterior and posterior walls connected to each other was inserted into a vaginal vault prolapse following hysterectomy, and 2 patients with rectocele underwent posterior TVM (P-TVM) in which a mesh was inserted into the posterior vaginal wall alone. POP-Q stage, operation time, and intraoperative bleeding volume for patients who underwent the TVM procedure are summarized in [Table 1](#). Mean operation time was 72.23 ± 17.17 min for A-TVM, 106.70 ± 16.26 min for AP-TVM, 97.11 ± 22.77 min for T-TVM, and 66.5 ± 23.334 min for P-TVM. Intraoperative bleeding volume was not measurable and was therefore recorded as <30 ml, 30–50 ml, or 50–100 ml, or >100 ml. Four patients in total had >100 ml of bleeding during surgery, with 1 patient having 1800 ml of bleeding.

Antibiotic prophylaxis was administered until postoperative day (POD) 5. We removed the balloon catheter on the morning of POD2 and discontinued measurement of residual urine if the volume was <100 ml. Ten (21.6%) patients had >100 ml of residual urine at the initial measurement, but measurement was discontinued in all patients if volume decreased to <100 ml by discharge on POD3 ([Table 2](#)).

Possible intraoperative complications of TVM surgery include bladder and rectal injury caused by needle insertion, vaginal wall hematoma, and massive transfusion. Among the 50 cases, the only intraoperative complication encountered was 1800 ml of bleeding requiring transfusion in one patient. There were no cases of bladder injury, rectal injury, vaginal hematoma, or hydronephrosis. Postoperative complications were reviewed for all 50 patients who were followed for at least 3 months. Neither postoperative recurrence of uterine prolapse nor mesh exposure has occurred thus far. One (2.0%) patient complained of tightening of the lower abdomen at 1-month follow-up, but the symptom had resolved by the 3-month follow-up visit. Twelve (24.0%) patients experienced postoperative new onset of stress urinary incontinence (SUI) while 6 (12.0%) reported worsening of existing urinary incontinence.

Table 1
Surgical characteristics of the tension-free vaginal mesh (TVM) procedure.

	n = 50	POP-Q			Operation time (min)	Blood loss (ml)			
		II	III	IV		<30	30–50	50–100	>100
Anterior TVM	18	8	10	0	72.23 ± 17.17	14	2	1	1 (330)
Anterior and posterior TVM	21	4	15	2	106.7 ± 16.26	11	5	2	3 (100, 130, 1800)
Total TVM	9	3	6	0	97.11 ± 22.77	5	1	3	0
Posterior TVM	2	2	0	0	66.5 ± 23.33	2	0	0	0

We also examined whether there was a possible correlation between preoperative urinary symptoms and postoperative complications. Of the 23 (46.0%) patients without preoperative incontinence, 12 (52.2%) experienced postoperative onset of SUI. On the other hand, 6 of 27 (22.2%) patients with preoperative SUI reported resolution after TVM surgery. The remaining 21 (77.8%) continued to experience urinary incontinence even after surgery, of whom 15 (71.4%) reported unchanged symptoms and 6 (28.6%) reported worsening of urinary incontinence symptoms (Table 3).

The data presented here are from the first 50 cases performed solely by the first author and provide helpful information for surgeons who are interested in employing this surgical procedure. A randomized controlled trial to compare the TVM procedure with conventional VH surgery demonstrated the significant superiority of TVM in terms of cure rate.⁸ TVM is also associated with relatively few complications and can thus be performed safely.⁶ This is likely why TVM is becoming popular among Japanese gynecologists and is considered by many to be a suitable first-line option for POP patients. At the same time, however, there have been reports of TVM-specific intraoperative and postoperative complications, such as unexpected bleeding, pelvic hematoma formation, injury to the urinary bladder and rectum, mesh exposure, and dyspareunia, which led to an FDA warning issued in 2008 (Vaginal Mesh FDA Warning: Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence, 2008). As part of the informed consent process, patients need to be fully informed of the risk for postoperative onset of SUI. Among our 50 patients who underwent surgery for POP and were followed for at least 3 months, 27 (54.0%) had SUI prior to surgery. Among them, 6 (22.2%) reported improvement and 6 (28.6%) reported worsening of incontinence after surgery. Moreover, 12 of 23 (52.2%) patients without preoperative incontinence reported postoperative onset. These findings suggest, albeit based on a small number of cases in this preliminary study, that TVM surgery does not improve but may rather induce urinary incontinence. In all cases of postoperative new onset or worsening of urinary incontinence, however, symptoms were improved or resolved without the need for surgical intervention by urologists, such as by using tension-free vaginal tape and trans-obturator tape. Further studies are needed to identify subgroups of patients likely to undergo improvement or new onset or worsening of urinary incontinence after surgery.

Table 2
Residual urine volume after removal of uterine catheter.

Residual urine volume (ml)	No. of patients
<50	22
<100	16
<150	5
<200	2
<300	3

Table 3
Status of postoperative stress urinary incontinence (SUI).

Pre-operation	SUI (absent) 23 (46.0)	SUI (present) 27 (54.0)
Post-operation		
SUI (absent)	11 (47.8)	6 (22.2)
SUI (present)	12 (52.2)	21 (77.8)
		no change 15 (71.4) worsened 6 (28.6)

Based on the experiences of the first author who undertook all 50 TVM procedures reported on herein, TVM can be performed relatively easily, even by a surgeon inexperienced in the procedure. Moreover, as we reported previously in a review of the first 20 procedures undertaken by the first author, the TVM technique is not experience-dependent in regard to operation time.⁹ We therefore expect that this technique will become increasingly accepted by obstetricians and gynecologists as a standard surgical procedure for POP, replacing the conventional procedure. In another Japanese study, quality of life (QOL) parameters such as short Form-36 and prolapse-QOL scores were significantly improved among Japanese women who underwent TVM procedure, although a number of postoperative complications were reported.⁶ Because we have reviewed our first 50 cases of TVM surgery which were followed for a minimum of 3 months only at this stage, we plan to gather and report on longer follow-up data, including QOL, over time.

Since TVM is associated with the risk of inducing SUI, a condition not usually treated by obstetricians and gynecologists, such professionals should improve their understanding of the pathogenesis of various types of urinary incontinence and of specific tests, such as urodynamic study, and cooperate with urologists in treating POP. Although we expect that TVM surgery will continue to be adopted by an increasing number of obstetricians and gynecologists, including those inexperienced in the procedure, it is needless to add that surgeons who attempt to apply this procedure clinically should have a full understanding of pelvic anatomy and POP. Cadaver model training and observing or assisting experienced surgeons would be valuable for the inexperienced and they should receive guidance from an experienced surgeon prior to practical training.

Ethical approval

None declared.

Author contribution

Haruhiko Kanasaki – data collection, writing.

Aki Oride – data collection.

Kohji Miyazaki – review of the article.

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Conflict of interest

No conflicts of interest.

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