

#615 Prevention of recurrence in transvaginal mesh surgery using polytetrafluoroethylene mesh for anterior POP : Can barb formation on the mesh arms prevent recurrence?



Takeyama M¹, Kuwata T¹, Kashihara H¹, Kato C¹, Watanabe M², Saito Y³

1. First Towakai hospital, 2. Kitasaito hospital, 3. Kyoto prefectural university of medicine

Hypothesis / aims of study

Hypothesis: the use of transvaginal mesh surgery (TVM) with polypropylene (PP) mesh in the U.S. and Europe has declined drastically due to the high number of mesh-related complications leading to its ban by the FDA in 2019.

In Japan, a unique version of TVM procedure, utilizing a self-cut mesh based on the Prolift™ technique has been developed and performed with low complication rates and favorable outcomes (1). However, also in Japan, the use of PP mesh was banned in April 2019 and currently only polytetrafluoroethylene (PTFE) mesh ORIHIME® can be used for TVM. Although PTFE is a safe material, its low coefficient of friction and insufficient adhesion to the surrounding tissue make it difficult to maintain the mesh position when it is used in the TVM. The results of a prospective comparative study of Polyform™ and ORIHIME® showed that recurrence was significantly higher with ORIHIME® than with Polyform™ up to the fourth year.

Therefore, we devised the TVM-uphold barb technique (TVM-UPB), a method to mechanically fix the mesh arm to the sacrospinous ligament (SSL) without the expectation of adhesion of the mesh to the surrounding tissues.

The aim of the study was to evaluate the safety and efficacy of TVM-UPB for preventing recurrence of POP.

Study design, materials and methods

Study design was retrospective study based on the patient records. Materials were 52 consecutive patients with anterior POP stage II or higher without high stage uterine prolapse nor posterior POP who underwent surgery between August 2022 and February 2023. As controls, 50 patients treated with TVM-A2 procedure (2) using ORIHIME®(ORI), a conventional technique for anterior pelvic organ prolapse, and 50 patients treated with TVM-A2 using Polyform™ (PP), a PP mesh were listed. These control patients were underwent surgery between February in 2018 to September in 2018. The two control groups were the cases from a randomized prospective trial of Polyform™ versus ORIHIME® for TVM-A2.

Methods; Operation: TVM-UPB (UPB). After placing longitudinal incision in the anterior vaginal wall and dissecting between the full thickness vaginal wall and urinary bladder, exposed the sacrospinous ligament (SSL) from the paravesical space. Using special needle we penetrate SSL through the transgluteal route, and pull through the mesh arms from paravesical space to the buttock using nylon-loops. Anchoring points are uterine cervix, distal vaginal wall and both side SSL. Mesh shape is shown in Fig.1. The right and left mesh arms were wrapped with mesh stripe and squeezed with non-absorbable thread to form a barb-like nodule to achieve mechanical fixation of the mesh arms to SSL. After the median ends of the mesh were suture-fixed to the cervix and distal vaginal wall with 3-5 stitches of non-absorbable thread, the left and right mesh arms were covered with "arm-through" to improve slippage and allow passage of the SSL on both sides. The mesh arms are fixed when the "arm-through" is removed. The excess vaginal wall is not removed, and the procedure is terminated by closing the vaginal wall using continuous sutures with absorbable threads.

Perioperative complications, mesh-related complications including postoperative mesh exposure, and the number of pelvic organ prolapse recurrences up to 12 months were tabulated. All values were expressed using the mean ± standard deviation(SD) and analyzed with EZR, which is a graphical user interface for R. For continuous variables, Student's t-test was used for analysis. The significance level was set at p-value <0.05.

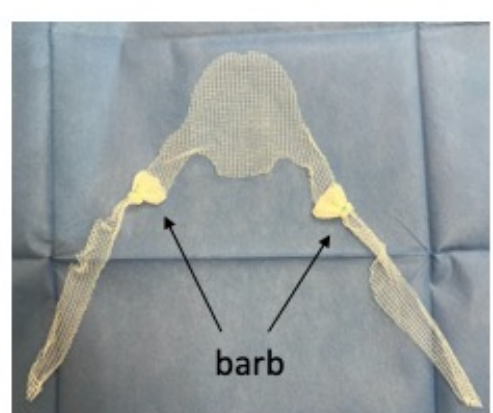
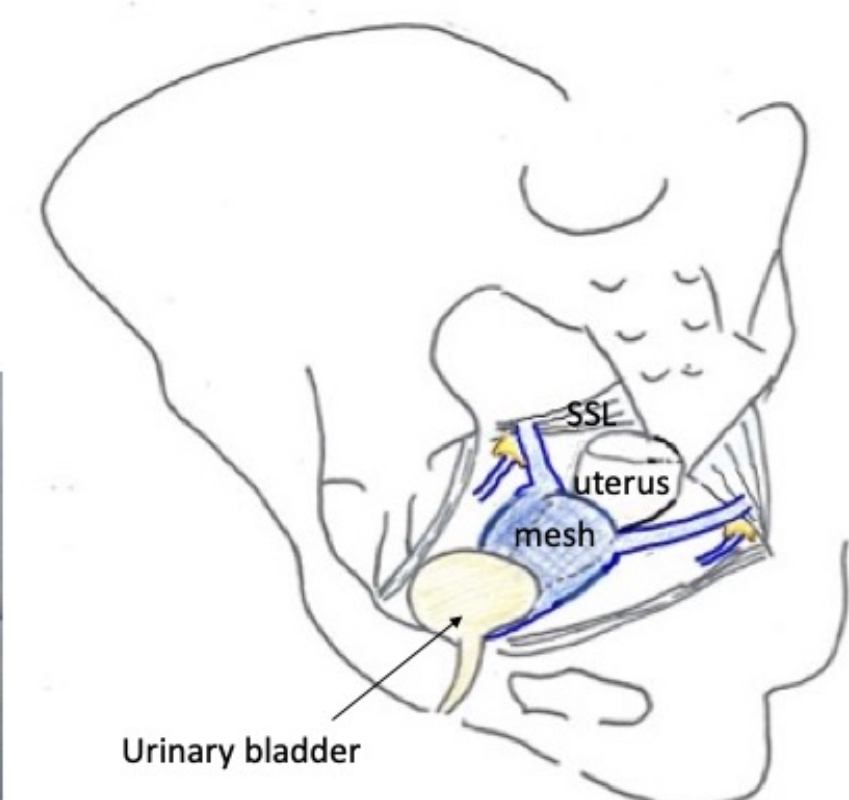
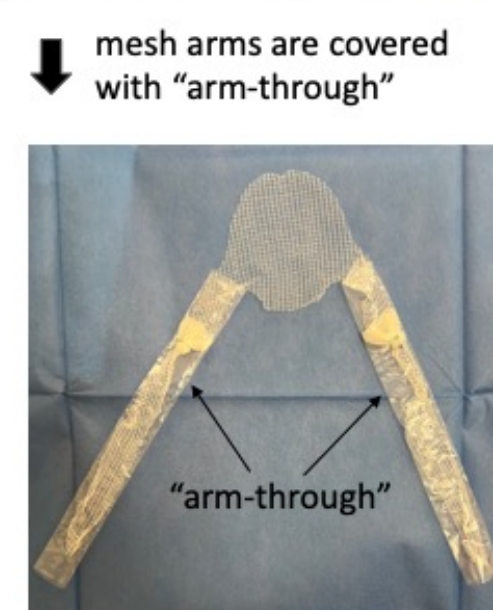


Fig.1 mesh shape and mesh position in the pelvis



Results and interpretation

Results

Baseline characteristics	UPB n=52	PP n=50	ORI n=50
Age (years) , (Mean ± SD)	73.0 ± 6.3	74 ± 6.1	73.7 ± 5.8
BMI (kg/m ²), (Mean ± SD)	25.2 ± 3.6	25.0 ± 3.3	24.7 ± 3.1
Parity (n), (Mean ± SD)	2.3 ± 0.8	2.2 ± 0.9	2.2 ± 0.9
Most descending compartment(s)			
Anterior, n(%)	48 (92)	49 (98)	49 (98)
Anterior and apical, n(%)	4 (7.6)	1(2)	1(2)
Apical, n(%)	0 (0).	0(0)	0(0)
POP-Q stage			
Stage II, n(%)	2 (3.8),	1(2)	1(2)
Stage III, n(%)	50 (96).	49 (98)	49 (98)

Summary of the operation

	TVM-UPB ORIHIME n=52	TVM-A2 ORIHIME n=50	TVM-A2 Polyform n=50
Ope time (min.)	45.6 ± 9.5 (22-70)	28.6 ± 4.5 (22-45)	28.3 ± 4.4 (21-42)
Blood loss (gr)	21.2 ± 21.3 (5-150)	18.4 ± 14.0 (5-80)	22.7 ± 14.2 (5-100)
Concomitant operation	Posterior repair 2 Cerviectomy 1	Posterior repair 2 Cervical polypectomy 1	None
Intraoperative complication	None	None	None

Recurrence in in the operated compartment

TVM-A2 ORIHIME (n=50)	3M after operation	12M after operation
Recurrence	3/47 (6.4%)	5/46 (10.9%)
Stage II	1	2
Stage III	2	3
TVM-A2 PP (n=50)	3M after operation	12M after operation
Recurrence	2/46 (4.3%)	2/42 (4.8%)
Stage II	2	2
Stage III	0	0
TVM-Uphold barb method (n=78)	3M after operation	12M after operation
Recurrence	1/52(1.9%)	1/47(2.1%)
Stage II	1	1
Stage III	0	0

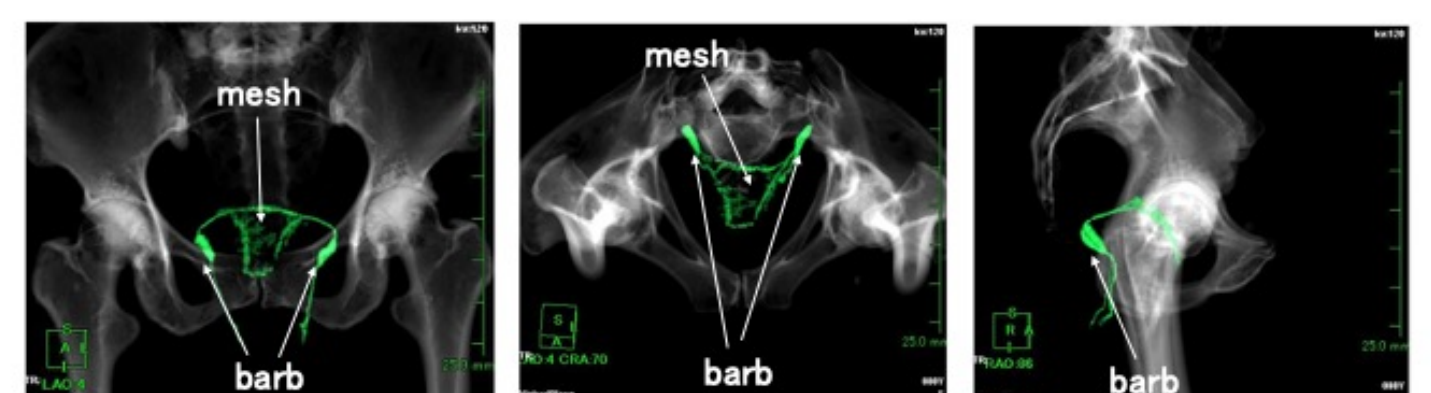
(recurrence : POPQ> Stage II)

INTERPRETATION OF RESULTS

Although PTFE mesh ORIHIME® is a safe material that is hardly degraded in vivo and does not cause much inflammation, the mesh may shift and POP may recur even after more than one year due to insufficient adhesion to the surrounding tissue when used for TVM. In the TVM-A2 technique, which omits the anterior arms of the Prolift™ type anterior TVM, TVM-A2 using ORIHIME® had a significantly higher recurrence rate than TVM-A2 using Polyform™, indicating that the mesh arms were not sufficient to maintain the mesh position. We hypothesized that a more mechanical method of anchoring the mesh without expecting adhesion to the surrounding tissue might be effective in maintaining the position of the mesh by using the mesh arms. We developed a barb-like anti-reversal device by wrapping the mesh around the mesh arms and passing through the sacrospinous ligament, which is a tough tissue. A plastic cover called an "arm-through" was used to minimize the damage to the SSL to reduce friction when the SSL was passed, and the barb was caught on the SSL by removing the arm-through after the SSL was passed. Compared to the control TVM-A2 procedure with ORIHIME®, TVM-UPB was considered to be a safe technique, with no significant difference in blood loss and no intraoperative complications although the operation time was significantly longer than those of the TVM-A2 technique. The absence of mesh exposure and other mesh-related complications is thought to be due to the fact that the mesh causes little inflammation with the surrounding tissue. The results showed the recurrence rate in UPB was significantly lower than the controls. So this technique may become the standard technique for the anterior TVM using the PTFE mesh.

Previous study reported that CT imaging made ORIHIME® visible(3). The location and shape of the mesh could be identified in the CT images that were accidentally taken at 3 months postoperatively (Fig.2). The CT images suggested that the barb created in the mesh arms would not regress postoperatively. The fact that ORIHIME® can be visualized on CT images is a powerful property to infer the cause when recurrence is suspected.

Fig.2 Mesh shape and position in the pelvis 3 month after surgery



Conclusions

TVM-UPB was suggested to be a effective and safe procedure for anterior POP with a low recurrence rate. Barb formation on the mesh arms can prevent recurrence of POP in the anterior TVM using PTFE mesh ORIHIME®.

References

- (1). Takeyama M, Kuwata T, Kato C, Kashihara H, Watanabe M, Kinoshita R, et al. Is transvaginal mesh procedure a potential measure for pelvic organ prolapse repair when performed by expert surgeons? Int J Urol. 2022;29: 435–40.
- (2). Watanabe M, Takeyama M, Kuwata T, Kashihara H, Kato C, Hirota M. Are anterior mesh arm necessary in Japane-style transvaginal mesh surgery for cystocele? J Obstet Gynaecol Res 48; 2466-2473 2023
- (3). Yamaguchi A, Miwa K, Nakahira K, Moriyama Y, Kitagawa Y. Visualization of mesh on computed tomographic images after pelvic organ prolapse surgery. Int J Urol. 2022 Apr;29(4):360-361. doi: 10.1111/iju.14762. Epub 2021 Dec 8.