

# Safety and Effectiveness of Transvaginal Mesh Placement in Treating Pelvic Organ Prolapse

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## Research article

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# Abstract

To observe the clinical effect and complications of transvaginal mesh (TVM) placement on treating pelvic organ prolapse (POP).Methods From May 2014 to June 2017, 89 patients with moderate to severe pelvic organ prolapse and pelvic floor defect (PFD) had received TVM pelvic reconstruction at our hospital. The operation time, intraoperative blood loss and intraoperative complications of all patients were recorded, and the incidence of postoperative complications was also observed. In addition, the POP-Q was utilized to evaluate the severity of POP in patients before surgery, as well as at 6 weeks, 6 months, 12 months and 24 months after surgery, respectively; besides, the Pelvic Floor Influence Questionnaire-7 (PFIQ-7), Pelvic Floor Dysfunction Inventory 20 (PFDI-20), and Patient Global Impression of Improvement (PGI-I) were adopted to evaluate the quality of life of patients.Results All the 89 cases had successfully completed the surgery, with the operation time of  $60.0 \pm 13.0$  min and the intraoperative blood loss of  $57.2 \pm 21.9$  mL. All patients had no bladder or rectal injury during the surgery. 2 patients displayed asymptomatic recurrence, 10 cases had postoperative fever, while 3 had mesh exposure, and all of them were improved after symptomatic treatment. Upon discharge, the lumbosacral and pubic discomfort, as well as pelvic organ dragging sensation had disappeared in all patients. In the final follow-up, the PFIQ-7 and PFDI-20 scores in the 89 cases were reduced compared with those before surgery ( $P < 0.05$ ).Conclusions TVM placement is effective on treating moderate to severe POP, which is associated with a lower complication rate and higher postoperative satisfaction.

## Background

Pelvic floor dysfunction is a disease that severely affects the physical and mental health of middle-aged and old-aged women. Data suggest that, the risk of incidence is as high as 50% in women that have given birth to a baby<sup>1</sup>. At present, transvaginal mesh (TVM) placement is an effective surgical procedure with little trauma for pelvic organ prolapse (POP), which has been extensively applied in moderate and severe patients<sup>2,3</sup>. However, TVM placement is also associated with the complications such as mesh corrosion/exposure, dysuria, pelvic and vaginal pain, and dyspareunia<sup>4</sup>. As a result, the FDA has raised two safety warnings regarding the TVM placement-induced complications in 2008 and 2011. Recently, the FDA has issued a command in 2016 to re-classify the TVM used for POP from class II (special control) to class III (pre-market approval)<sup>5</sup>. Notably, these warnings and reclassification have highlighted the potential severe risks of TVM-related complications.

This study aimed to analyze the safety and effectiveness of TVM in treating moderate and severe POP at our hospital, particularly in postoperative recurrence rate, complications and patient subject satisfaction.

## Methods

From December 2014 to June 2017, the clinical data, as well as mid- and long-term follow-up data of patients with POP treated with TVM placement at the Affiliated Hospital of Xuzhou Medical University were systemically reviewed. Typically, women that had given birth to a baby or the postmenopausal

women with the POP-Q grade<sup>6</sup>  $\geq \text{III}$  were enrolled into this study, while those with urinary incontinence, or those undergoing hysterectomy or prior TVM placement were excluded from this study. The basic information of all patients is presented in Table 1. The meshes used in the surgery were Avaulta® (Bard, Murry Hill, NJ, USA) and POP-UP System® (Prestige Medical, Jungwon-gu Seongnam-si, Gyeonggi-do, KOREAN), which was selected based on the economic condition of patients. The previously reported technique was adopted in the surgical procedure<sup>7,8</sup>; at the same time, the operation time, intraoperative blood loss, and intraoperative complications of all patients were recorded to evaluate the operation safety. Afterwards, patients were followed up at 6 weeks, 6 months, 12 months and 24 months after surgery, of them, 83 cases had completed the 2-year follow-up, while 4 were lost to follow-up after 1-year of follow-up, and the remaining 2 were lost after 6 months of follow-up. The objective manifestation of healing was the POP-Q grade of  $\leq \text{I}$  in the last follow-up in which patients were asked to conduct the Valsalva manoeuvre in standing position. Moreover, the postoperative complications in patients were followed up by means of clinic physical examination and, Typically, the questionnaires used in this study were the Chinese version of PFDI-20 and PFIQ-7<sup>9,10,11</sup>, among which, PFDI included the POP distress inventory 6 (POPDI-6), the Colorectal-anal distress inventory 8 (CRADI-8) and the Urinary distress inventory 6 (UDI-6); while Patient global impression of improvement (PGI-I)<sup>12</sup> was utilized to quantify the subjective patient symptoms after surgery. PGI-I is single question of a 7-point Likert scale, which asks the patients to compare their illness at the time of answering the question with their feeling before surgery, and it ranks from 1 point (extremely good) to 7 points (extremely bad). Additionally, PGI-I was also adopted in patients developing a second prolapse or those requiring a second operation due to severe complications, so as to compare the effects before and after surgery.

The SPSS®20.0 (IBM Corporation, Armonk, NY, USA) was used for statistical analyses. Results of qualitative variables were expressed as percentage, while results of quantitative variables were expressed as means and standard deviation. The quantitative variables were compared using independent sample or paired sample t-test, while chi-squared test was adopted to test the qualitative variables. A P-value  $<0.05$  was deemed as statistically significant.

## Results

The average age of the 89 POP patients receiving TVM was  $65.7 \pm 8.2$  years, with the average parity of  $2.2 \pm 1.1$  times. Meanwhile, 83 of them (93%) had completed the 24-month postoperative follow-up, while only 4 (4.5%) were followed up for 12 months, and the remaining 2 (2.2%) were only followed up for 6 months due to personal reasons. As shown in Table 1, the basic conditions of patients selecting the Avaulta and the Pop-up meshes for operation were similar, and no statistically significant difference was observed ( $P > 0.05$ ). Similarly, preoperative POP-Q grade, as well as PFDI-20 and PFIQ-7 scores, between two mesh groups was quite close ( $P > 0.05$ ), and a vast majority of cases had anterior prolaps (95.5%).

In the last follow-up, 3 patients displayed asymptomatic recurrence, while 9 cases (10.1%) required a second treatment after surgery. The average operation time was  $60.0 \pm 13.0$  min, the intraoperative blood loss was  $57.2 \pm 21.9$  ml, the average length of hospital stay was  $8.4 \pm 3.5$  days, and no obvious difference

was detected in the above data between two mesh groups ( $P>0.05$ , Table 2). No bladder or intestinal tract injury was observed in all patients intraoperatively and postoperatively; Two patients had anterior wall recurrence at 12 months and 1 had posterior wall recurrence at 24 months, and all were in the Avaulta group. Due to their old age and quality of life improved after surgery, the patients with recurrence did not choose further surgery. 16 (18%) of the enrolled patients had developed TVM placement-related complications, and 3 had mesh exposure at 6 months, 2 of them with obvious symptoms were treated through surgery (removal of the exposed mesh), while the other 1 with no obvious symptom was given topical application of estrogen ointment for conservative treatment. 2 patients had urinary incontinence manifestation at 6 weeks after surgery, and the symptoms were gentle, which required no further treatment. During the postoperative hospital stay, 3 patients had delayed wound healing and 9 had urinary tract infection, and no further treatment was required after the application of antibiotics and nutrition.

There were no statistical differences in the preoperative PFDI and PFIQ scores between two mesh groups (Table 1). At the last follow-up, the PFDI and PFIQ scores in all patients were markedly improved compared with those before surgery ( $P<0.005$ ), and PFDI had reached the least significant difference of 45 points<sup>13</sup>. In addition, the changes in postoperative score between two groups were not statistically significant (Table 3), and both groups had attained favorable mid-term prognosis, with the average postoperative PGI-I score of  $1.31\pm 0.59$ . Importantly, patients had extremely high self-evaluation satisfaction on the operation, among them, 73% suggested that their symptoms were greatly improved (PGI-I of 1), and 100% had attained overall improvement (PGI-I of 1-3). It was suggested that the symptoms were remarkably improved compared with those before surgery.

## Discussion

Various surgical procedures are available for pelvic floor reconstruction in women, including the transvaginal approach, laparotomy, laparoscopic or robot-assisted approach. Among them, the transvaginal approach is associated with short operation time, length of stay and recovery time<sup>14,15</sup>. The synthesized mesh has attracted high attention and dispute in recent years, but it is the reconstruction technique that best corresponds with anatomy in pelvic floor surgery, since the mesh shape accords with the human pelvic floor. In addition, the application of mesh in pelvic floor reconstruction also conforms to the findings by Gutman R et al. in literature that the uterine preservation technique is the feasible surgical treatment option for prolapse of uterus, because it can best preserve the original anatomical structure and statics of the pelvic floor<sup>16</sup>.

In a study that applies TVM placement to treat POP, a conclusion is drawn through two sets of parallel, multi-center randomized controlled trials that, neither mesh or transplant material can greatly improve the postoperative effect, quality of life and adverse reaction within a short period of time; at the same time, over 1/10 patients have developed mesh placement-related complications<sup>17</sup>. However, that research includes not only the POP patients, but also patients with urinary incontinence. By contrast, only patients with POP alone were enrolled in this study, which could eliminate the selection bias to some extent.

Mesh exposure and invasion are the most common complications after TVM placement. According to previous literature report, the mesh exposure rate ranges from 1.4% to 36%<sup>18,19,21,22</sup>, while in the Cochrane review<sup>1</sup>, the mesh exposure rate is 12%, and 8% patients require further surgical treatment. In our study, only 2 (2.2%) patients had asymptomatic recurrence during postoperative follow-up, but no further treatment was selected owing to little impact on quality of life. Another 3 (3.6%) patients had mesh exposure, all of them were diabetics whose blood glucose could not be well controlled after surgery; among them, 2 patients had obvious symptoms, who had improved after surgical removal of the exposed mesh and topical application of estrogen ointment. It is generally believed that, the incidence of mesh exposure is related to the thin vagina mucosa separation, excessive tension, infection, vaginal wall atrophy, and early sexual life. Similarly, some research indicates that, diabetes will increase the mesh exposure rate by 7 folds; besides, the anterior vaginal wall is subject to a higher risk of mesh exposure than the posterior wall<sup>23</sup>. Therefore, internal medicine complications such as diabetes and hypertension were strictly controlled before surgery in this study, and the internal medicine diseases were positively controlled during the perioperative period, which were of great significance to the expected surgical wound healing, prevention of wound infection and reduction of mesh exposure rate. The surgical procedure of Avaulta and Pop-Up has no significant difference. In the design of the puncture needle, Avaulta only uses the wire lasso connection method, while the application of Pop-Up is lock connection which was easier in practice. There is a plastic film covering outside the Pop-Up. Although it can reduce the tissue injury during the puncture process, there is no conspicuous difference in postoperative recurrence and complications.

Postoperative dyspareunia is a symptom affected by multiple factors. Typically, any transvaginal surgical procedure, regardless of the use of mesh or not, will lead to vaginal scar formation, which will subsequently result in loss of elasticity and vaginal malformation, thereby causing dyspareunia. According to the Cochrane review, the incidence of dyspareunia after surgery is 4-5%, while the use of mesh will make little difference, which may be related to the vaginal approach<sup>1</sup>. In this study, only 2 (2.2%) patients had postoperative dyspareunia, which was suggested to be related to early sexual life of patients.

The experience, skills and number of operation of the surgeon are the key factors determining whether the operation will success. As proved by Kelly<sup>24</sup> et al., about 5% POP women undergoing TVM placement required a second operation within 10 years to treat the mesh complications. For surgeons that carry out at least 14 operations annually, the risk of a second operation can be minimized<sup>24</sup>. Nonetheless, it should be pointed out that, surgical technique plays a crucial role in mesh corrosion, since the incidence of mesh corrosion varies from studies. For instance, a multi-center randomized controlled trial about TVM suggested that, the incidence of mesh exposure varied from 0% to 100%<sup>3</sup>. In order to avoid complications and reduce the risk of recurrence, we summarized some key points during TVM. Hydrodissection beneath vaginal adventitia is crucial to preserve the capillary network within the vaginal adventitia and for well separating the anterior wall of the vagina from the bladder and ureter, thereby reducing the risk of bladder or uterine damage. At the same time, attention should be paid to the flat

placement of the mesh to avoid the formation of folds, otherwise it is easy to form a local cavity causing infection; and we use normal saline instead of diluted adrenaline, so as to avoid the increase of intraoperative blood pressure and increase the burden of the heart. After operation, the vagina was filled with Iodophor gauze for 48 hours to prevent hematoma. The surgical procedure becomes easier and more feasible thanks to the application of mesh box, which has reduced the experience requirement on surgeons in such pelvic floor surgery. However, only after completing sufficient theoretical and technical training, and being experienced in vaginal surgery, can the surgeons perform the pelvic floor surgery. Given that TVM use has dropped precipitously in the USA due to medicolegal issues related to class action lawsuits against the manufacturers of the TVM kits, the use of TVM can be further optimized through the following aspects: First, the indications of TVM should be further refined. For patients with relatively high risk of anesthesia and surgery, TVM should be given priority to avoid re-surgery due to recurrence. In addition, 3D printing technology<sup>25</sup> can be used when training young doctors and patients for pre-operative communication. The printout of the patient's pelvic floor structure not only allows the patient to understand the surgical procedure and risks more directly, but also allows young doctors to re-learn the pelvic floor organ structure from 2D to 3D

Our study has some limitations. We acknowledge the limited number of patients included in this study and its retrospective nature. Due to the influence of traditional concepts, the sexual activity of elderly women seems lower than other regions, and preoperative sexual life only accounts for 5.6%. The limited number of patients could not fully reflect the influence of TVM on dyspareunia. In addition, not all women undergoing pelvic organ prolapse repair at our institution enrolled in the database

## Conclusions

Findings of this study suggest that, TVM placement is effective on repairing POP, which can also achieve high satisfaction. Altogether it is associated with potential operation-related and mid-term complications, they can be treated through some conventional methods and attained favorable results. Therefore, we believe that it is safe to treat POP through TVM in the hands of experienced surgeons.

## Abbreviations

TVM: transvaginal mesh; POP: pelvic organ prolapse; PFD: pelvic floor defect; POP-Q: pelvic organ prolapse Questionnaire; PFIQ-7: Pelvic Floor Influence Questionnaire-7; PFDI-20: Pelvic Floor Dysfunction Inventory 20; PGI-I: Patient Global Impression of Improvement; FDA: Food and Drug Administration; POPDI-6: pelvic organ prolapse distress inventory-6; CRADI-8: Colorectal-anal distress inventory-8; UDI-6: Urinary distress inventory 6

## Declarations

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Not applicable

## Availability of data and materials

Not applicable

## Authors Contributions

Zeyu Chen: Project development, Data Collection, Manuscript writing

Wensheng Du: Project development

Haitao Zhu: Data collection, Project development

## Ethics approval and consent to participate

This project was submitted and approved by approved by the IRB of the of Affiliated Hospital of Xuzhou Medical University under the number XYFY2019-KL093.

## Consent for publication

To participate, the women signed the Free and Informed Term of Consent.

## Competing interests

The authors declare that they have no competing interests

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## Tables

Table 1. *Patient baseline characteristics*

	Total	Avaulta ®	Pop-UP®	P value
Patients, <i>n</i>	89	52	37	
Age,years	65.7±8.2	64.9±8.4	66.7±7.9	0.33
BMI,Kg/m <sup>2</sup>	23.0±2.7	22.8±2.5	23.2±2.9	0.45
Smoking	3(3.3%)	1(2.0%)	2(5.4%)	0.37
Paturition(time)	2.2±1.1	2.2±0.8	2.3±1.3	0.54
Sexually active	5(5.6%)	3(5.8%)	2(5.4%)	0.94
Anterior prolapse	85(95.5%)	50(96.2%)	35(94.6%)	
POP-Q stage ≥3	67(75.3%)	40(76.9%)	27(30.3%)	0.67
Apical prolapse	60(67.4%)	36(69.2%)	24(27.0%)	
POP-Q stage≥3	17(19.1%)	13(25.0%)	4(7.7%)	0.93
Posterior prolapse	36(40.4%)	23(44.2%)	13(35.1%)	
POP-Q stage≥3	11(12.4%)	8(15.4%)	3(8.1%)	0.30
PFDI-20	86.0±26.9	86.9±27.0	84.9±27.1	0.73
POPDI	42.8±15.8	42.2±16.1	43.7±15.7	0.67
CRADI	10.2±9.6	10.8±9.6	9.3±9.6	0.47
UDI	33.0±10.2	33.8±10.5	31.9±9.8	0.37
PFIQ-7	64.4±20.9	64.5±21.0	64.3±20.9	0.96

BMI=body mass index

Values are presented as mean ±SD or number of cases (and %) in each group.

Chinese version of the Pelvic Floor Distress Inventory(PFDI-20) and Chinese validation of the Pelvic Floor Impact Questionnaire Short Form(PFIQ-7) were used to quantify the outcomes and both have the perfect score of 300

Table 2 .Operative outcomes

	Total	Avaulta ®	Pop-Up®	P value
Surgical procedure				
Opreating time(min)	60.0±13.0	61.1±12.6	58.4±13.6	0.34
Blood loss(mL)	57.2±21.9	60.4±26.2	52.7±12.8	0.07
Length of stay(day)	8.4±3.5	10.3±2.0	7.6±2.8	0.28
Surgical complications*				
Bladder injury	0	0	0	
Bowel injury	0	0	0	
Transvaginal incision delayed healing	3	2	1	
Mesh exposure				
Urinary infaction	3	1	2	
urinary incontinence	8	5	3	
Dyspareunia	2	1	1	
	2	2	0	

Continuous variables are expressed with mean±SD and quaitative variables with *n*(%)

\*Complications range from postoperative to last follow-up

Table 3. 2 years follow-up of patient and retreatment outcomes

	Total	Avaulta	Pop-Up	<i>P</i> value
PFDI-20	25.3±10.7	25.7±11.1	24.7±10.3	0.73
POPDI-6	9.4±5.1	9.9±5.0	8.7±5.2	0.67
CRADI-8	3.7±5.2	3.5±4.6	4.1±5.9	0.47
UDI-6	12.2±6.7	12.4±7.1	11.9±6.1	0.37
PFIQ-7	17.3±7.5	17.8±7.6	16.7±7.4	0.96
PGI-I	1.31±0.59	1.35±0.82	1.27±0.84	0.53
	Total	Avaulta	Pop-Up	<i>P</i> value
ΔPFDI-20	60.8±24.2	61.2±22.8	60.1±26.2	0.86
ΔPOPDI-6	33.5±15.8	32.3±15.4	35.1±16.1	0.44
ΔCRADI-8	6.5±6.2	7.3±6.9	5.5±4.9	0.12
ΔUDI-6	20.8±10.0	21.5±9.2	19.5±11.1	0.48
ΔPFIQ-7	47.1±20.0	46.8±18.6	57.6±20.8	0.22
Any retreatment	9(10.1)	6(11.5)	3(6.1)	0.60

Continuous variables are expressed with mean±SD and qualitative variables with *n*(%)

Any retreatment includes midurethal sling placement, excision the exposed mesh, medication for vaginal infection, and other complication management.