

Double sling with polyvinylidene fluoride implant: Evaluation of functional and anatomical outcomes of concomitant retropubic sling and anterior vaginal wall prolapse repair

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Background: Several kinds of procedures have been introduced for surgical rectification of pelvic organ prolapse (POP) and/or stress urinary incontinence (SUI) using various synthetic meshes such as polypropylene (PP) material. Polyvinylidene fluoride (PVDF) meshes have been proven to have higher biocompatibility, lower morbidity, and also less inflammatory and fibrotic reactions in comparison with PP meshes. Here, we intend to report a 2-year follow-up report of patients who had undergone transvaginal surgery using PVDF meshes to rectify POP and concomitant SUI. **Materials and Methods:** Between August 2015 and May 2024, 38 peri- or postmenopausal women with high-grade anterior compartment prolapse and concomitant SUI, who were nonresponsive to conservative management, were scheduled and underwent double-sling (anterior retropubic mid-urethral sling and posterior transobturator tape) surgery using a four-arm PVDF mesh. The patients were followed up for at least 24 months. **Results:** Thirty-eight patients were enrolled in the study and followed for an average of 5.7 years. A statistically significant subjective improvement was observed after 2 years ($P = 0.029$) regarding the vaginal symptom score and SUI. Two-year outcomes for all these patients revealed an 83% anatomical success rate. Two mesh exposures were observed (5.2%) after 4 years. No other severe mesh-related complications were registered. **Conclusion:** Double sling with PVDF implant is a safe and convenient procedure for the selected women with high-grade anterior compartment prolapse and symptomatic concomitant stress urine incontinence (SUI).

Key words: Mesh, pelvic organ prolapse, polyvinylidene fluoride, stress urinary incontinence

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INTRODUCTION

Pelvic organ prolapse (POP) is defined as the descent of one or more of the pelvic organs through the genital hiatus.^[1] POP has an estimated lifetime surgery risk of 11%.^[2] Stress urinary incontinence (SUI) and POP may coexist and are seen in more than 50% of patients.^[3] Several procedures have been used for the

synchronized surgical treatment of POP and/or SUI.^[4] Transobturator tape (TOT) and tension-free vaginal tape are among the most effective techniques for the treatment of SUI.^[5] The double-sling (D-sling) operation was planned at the base of tissue fixation system (TFS) according to “integral theory” (IT) and defined as the simultaneous use of retropubic mid-urethral and posterior transobturator slings with a four-arm designed

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mesh for the treatment of major anterior compartment prolapse. Polypropylene (PP) material has been used in this procedure already.^[6] Since 2019, the routine use of large PP meshes for vaginal POP repair has been prohibited by the United States Food and Drug Administration (FDA) due to the high incidence of postoperative complications. Polyvinylidene fluoride (PVDF) mesh as a synthetic material has higher biocompatibility, reduced morbidity, and less inflammatory and fibrotic reactions compared to PP.^[7] PVDF material can also be visualized by different imaging modalities, including magnetic resonance imaging (MRI) and ultrasound (US),^[7] which is an advantage during the follow-up of the patients. This unique characteristic of the mesh provides the possibility of localizing postoperation-related complications.^[8] Although native tissue repair is preferred in pelvic reconstructive surgery, its success rate may decline over time, especially in high-stage POPs.^[9,10] In the present study, we evaluate the mid-term outcome including success rate, functional results, and possible complications regarding the use of PVDF mesh in the surgical treatment of concomitant POP and SUI.

MATERIALS AND METHODS

Study design

The inclusion criteria were the peri- or postmenopausal patients with high-grade anterior compartment prolapse and concomitant SUI, nonresponsive to conservative management. The exclusion criteria included any previous history of transvaginal surgery with synthetic materials, lithotomy position limitations or contraindications, and every manifestation of neurogenic lower urinary tract dysfunction.

After consulting with patients, written informed consent was obtained from all patients, and the study received ethical approval from the institutional research ethics committee (IR.SBMU.UNRC.REC.1401.001). Prophylactic antibiotics were administered ½ h before the surgery and continued for 3 days postoperatively. Anatomical success or cure was defined as anterior descent at or above the hymen cervix above mid-vagina and no reoperation or symptomatic vaginal mass sensation. Prolapse Quantification examination and validated questionnaires were collected before operation and every year including the International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS).

Primary outcomes for SUI treatment were both objective (stress test and Pad test) and subjective (no leakage episodes) success after a median follow-up of 24 months. At each visit, the patient was referred for urine culture results, and in case of UTI, treatment of urinary tract infection was performed based on the antibiogram. In addition to bladder examination, patients experiencing refractory or

obstructive urinary symptoms were also checked with catheterization or bladder scanning with US for residual urine. If post voiding residual (PVR)>100, clean intermittent catheterisation (CIC) was recommended.

Operative technique

All surgeries were done by one experienced urologist. A total of 38 patients underwent D-sling surgery using four-arm PVDF mesh implants. The surgical procedure was as follows:

Step A: 3-cm vertical anterior vaginal wall incision and implantation of the anterior arms of the mesh through craniocaudal retropubic approach, Step B: infra-sacrocolpopexy through transobturator root using posterior arms of the PVDF mesh, Step C: fixation of the central part of the four-arm mesh implant to arcus tendineus of endopelvic fascia and uterosacral ligament with absorbable suture, Step D: double-layer vaginal wall epithelium closure with overlap technique, and Step E: proper adjustment of the mesh to prevent overcorrecting [Figure 1].

Statistical analysis and sample size calculation

Considering an improvement of vaginal symptoms in 90% of the patients (95% confidence interval: 80–100), a sample size of 35 patients was calculated. Data were analyzed using SPSS statistical software version 26 (SPSS Inc., Chicago, IL, USA). Categorical variables are reported as percentages and numbers. Continuous variables are presented as means and standard deviations. The normality of data was assessed using the Kolmogorov–Smirnov test. $P < 0.05$ was considered statistically significant. A paired-sample t -test was utilized for comparing the vaginal symptom scores between preoperative and postoperative periods.

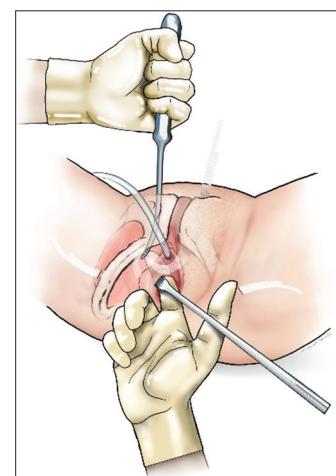


Figure 1: Double-sling repair. Large cystocele repaired with PR4 secured posteriorly transobturator tape sling and anteriorly by retropubic mid-urethral sling (the image was painted by Ms. Ghazaleh Hosseini, a photographer with experience in the field of pelvic anatomy)

RESULTS

From 2015 to 2024, we prospectively enrolled a total of 38 women with a mean age of 58.91 (± 10.73) years, complaining of POP and concomitant stress urine incontinence (SUI). The baseline characteristics of participants are summarized in Table 1. The vaginal symptoms, intensity, and type of urinary incontinence and prolapse stage were recorded preoperatively using ICIQ-VS, the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF), and the POP Quantification (POP-Q) system, respectively. SUI grade 1 was defined as an ICIQ-UI-SF score of 1–5 (mild SUI), grade 2 was defined as an ICIQ-UI-SF score of 6–12 (moderate SUI), and SUI grade 3 was defined as an ICIQ-UI-SF score of 13–21 (severe and very severe). The postsurgical data are depicted in Table 2. eight patients had a history of diabetes mellitus, and nine of them had a documented history of lumbar disc herniation. All patients had a history of normal vaginal delivery ranging from 1 to 7, and four patients had undergone abdominal hysterectomy. In terms of SUI, 4 patients had grade 1, 24 of them had grade 2, and 10 of them had grade 3. Sixteen patients required additional surgery, such as levatorplasty, and out of those, two patients experienced intraoperative hemorrhage and one of them needed blood transfusion. The mean operative time was 95 (± 10.2) min, and the average hospital stay was 2 (1–4) days, as for perioperative complications, severe early-onset pain was assessed using a 5-point Likert scale and was observed in 18.42% of patients. However, during the 6- and 12-month follow-up visits, only one patient was reported to suffer from persistent pelvic pain (2.6%). Persistent urinary retention, defined as the inability to voluntarily pass urine, postvoid residue of more than 100 ml, and a sense of incomplete voiding, was observed in two patients (5.26%). Early postoperative vaginal bleeding was noted in 10.52% of patients. Postoperative complications included SUI recurrence (15.78%), the need for further anti-incontinence surgery (10.52%), *de novo* urge urinary incontinence (7.8%), temporary urinary retention after being discharged from the hospital (7.89%), and recurrent urinary tract infections (21.05%). No mesh-related complications, such as infection, protrusion to the bladder, urethra, vagina, or dyspareunia, were detected during a mean follow-up period of 42 months (range: 24–60). The vaginal symptom score was also recorded preoperatively at 6, 12, and 24 months after surgery. As shown in Table 3, there was a statistically significant improvement after 2 years ($P = 0.029$). Two cases of vaginal mesh protrusion were reported. the first one with persistent vaginitis and vaginal discharges 4 years after initial operation was treated conservatively with intravaginal antibiotics and hormone replacement therapy (Clavien–Dindo II). Since the second patient suffered from severe dyspareunia, dysuria, and atrophic vaginitis after 7 years, mesh removal under

Table 1: Baseline characteristics of 38 patients undergoing double sling with Polyvinylidene fluoride -mesh and preoperative data

Outcomes	Mean \pm SD or n (%)
Age	58.91 \pm 10.73
History of former medical condition	14 (48.2)
History of former pelvic surgery	5 (17.2)
History of hysterectomy	4 (13.8)
Normal vaginal delivery	4.35 \pm 2.29
SUI grade 1	4 (10.5)
SUI grade 2	24 (63.15)
SUI grade 3	10 (26.31)
Mean vaginal symptom score	31.21 \pm 0.78
Mean POP-Q stage (range)	
Stage II	2 (5.2)
Stage III	32 (84.4)
Stage IV	4 (10.4)

SUI=Stress urinary incontinence; POP-Q=Pelvic organ prolapse quantification; SD=Standard deviation

Table 2: Intra-, peri-, and postoperative events and double-sling-related complications between hospital stay and at least 7-year follow-up, number of patients (%)

Outcomes	n=38, n (%)
Intraoperative events	
Need for concomitant surgery	16 (42)
Intraoperative bleeding	2 (5)
Need for blood transfusion	1 (2)
Perioperative events	
Pain	7 (18)
Urinary retention before discharge	2 (5)
Postoperative bleeding	4 (10)
Postoperative events	
SUI recurrence	6 (15)
Need for further anti-incontinence surgery	4 (10)
Urinary retention after discharge	3 (7)
Persistent urinary retention	2 (5)
Postoperative UTI	8 (21)
Need for prolapse recurrences* treatment	
Hystero/cystocele or cuff prolapse	2 (5)
Cystocele recurrence	1 (2.5)
Mesh erosion (years)	
After 2	0
After 4	1 (2.6)
After 8	2 (5.2)

*Recurrence definition is ant or apical; prolapse more than stage 1 of POPQ.

SUI=Stress urinary incontinence; UTI=Urinary tract infection; POPQ=Pelvic organ prolapse quantification

Table 3: Comparison of pre- and postoperative vaginal symptom score

Vaginal symptom score	Mean	P
Preoperative	31.21	-
Month 6	10.72	0.357
Month 12	9.03	0.213
Month 24	8.54	0.029

anesthesia was inevitable (Clavien–Dindo III), and like all patients, she was advised to use hormone replacement therapy and finally she underwent reoperation and transvaginal mesh excision. Two patients presented with hystero-cystocele and cuff prolapse and complicated from POP-Q grade III recurrence 8 and 37 months after surgery and one underwent vaginal hysterectomy and the other chose to use pessary. The third case of prolapse recurrence was a 67-year-old woman who returned 3 years after double sling with stage 2 of lateral cystocele and was advised to Kegel exercise. Overall, 22.2% of patients presented with grade II or more of Clavien–Dindo complications and 15% needed a reoperation for POP or SUI during the median follow-up.

DISCUSSION

Implants have increasingly played a significant role in pelvic floor reconstruction in the last few decades, aiming to substitute or support in cases of tissue deficiency.^[11] From 1990, the IT stated that SUI and POP mainly arise from flaccid pelvic ligaments.^[12] According to IT, repair of attenuated ligaments will restore the function of pelvic organs. According to IT as a ligament-based system of urogynecology surgeries, there are three main ligaments that can be reinforced while fixation of both cystocele and stress urine incontinence: (1) pubourethral ligament (PUL), (2) arcus tendinous facial pelvic, and (3) cardinal ligament (CL).

After 1996, the use of various types of PP vaginal mesh implants for anti-incontinence surgeries and POP repair became popular.^[13,14] Otto *et al.*^[11] concluded that indications for pelvic floor devices should be focused on patients with low risk for mesh complications and high risk for failure of mesh-free procedures. Based on evidence, the FDA believes that the risks of transvaginal surgical mesh placement to treat POP outweigh the benefits.^[15] In 2008, the FDA issued a safety warning regarding transvaginal mesh procedures.^[16] However, as we noted earlier, not all patients, especially those with previous failed anti-prolapse surgeries, advanced-stage with multi-compartment defects and POP, will experience a lasting cure from native tissue repair alone without the use of mesh. D-sling operation is applied in this study for patients with major cystocele and SUI. By using PR4 ,PUL(pubourethral ligament) repaired by anterior arms through retropubic mid-urethral sling and CL (cardinal ligament)reinforced with posterior arms with a TOT (tarnsobtrurator tape)as the second TFS. In 2002, Klinge *et al.*^[17] introduced PVDF mesh as a highly nonreactive thermoplastic fluoropolymer and used it for hernia repair. They also showed a significant reduction in inflammatory reactions in PVDF mesh in comparison to PP mesh. This may explain why PVDF is more biocompatible and safer than PP.^[7] In comparison to PP mesh, PVDF mesh exhibits

lower foreign body reaction, stiffness, and scar formation in the surrounding tissue. It also provides enhanced stability of the structural position.^[6,18,19] The PVDF mesh has been introduced and utilized for mid-urethral slings and hernia repair, proving to be an effective material with low complication rates.^[15,20,21] Eslami *et al.*^[22] showed that using PVDF mesh in the double TOT technique for anterior vaginal wall prolapse repair is a safe procedure with a high anatomic and functional success rate and acceptable complication rate in mid-term follow-up. There was a significant improvement in patients' vaginal symptoms, quality of life scores, and urinary incontinence postoperatively ($P < 0.0001$). Only six patients (5.5%) had mesh extrusion. Joukhadar *et al.*^[23] proposed a modified laparoscopic bilateral sacrocolpopexy using an MRI-visible PVDF mesh implant as a novel technique. They studied surgery-related morbidity, as well as anatomical and functional outcomes. The researchers found this technique to be feasible and safe, with a good outcome and no mesh-related complications. Furthermore, Barski *et al.*^[24] who proposed the first report on the efficacy and safety of using PVDF in transvaginal surgery reported no severe complications in their cohort study. Balsamo *et al.*^[25] suggested that both PVDF and PP meshes can be safely and effectively used with good anatomical outcomes, and interestingly, PVDF use was associated with significantly less storage symptoms and sexual dysfunction. In a recent study, Lin *et al.*^[26] used PVDF mesh with a combined transobturator and sacrospinous fixation technique in 27 patients with high-stage POP. The results showed that 85.2% of patients achieved anatomic success, while 14.8% experienced recurrent stage II cystocele. No recurrence of apical prolapse was observed. In one case (3.7%), an asymptomatic mesh protrusion was noted. Schmitz *et al.*^[27] implanted PP and PVDF meshes in the subcutaneous abdominal position of a total of 56 male Sprague-Dawley rats. The meshes were infected with *Staphylococcus aureus* during the implantation. After 7 and 21 days, the meshes were explanted, and the early and late tissue responses to infection were histologically evaluated. It was proposed that PP meshes show a higher inflammatory response than PVDF. As we know, the most common complications associated with mesh include erosion of the vaginal mucosa, shrinkage of the mesh, infection, urinary tract disorders, pain, and recurrence of prolapse.^[27] In our study, 38 patients suffering from SUI and POP underwent D-sling surgery, which involved the use of four-arm PVDF mesh implants through transobturator and retropubic routes. During a mean follow-up period of 7 years, two cases of vaginal mesh protrusion were observed. One of the troublesome and potentially disastrous complications of vaginal mesh surgeries is the protrusion of the mesh into the bladder or urethra. One patient managed with conservative management using hormone replacement therapy and topical antibacterial vaginal cream and another

one needs reoperation. Short anterior wall incision was done and damage of the vaginal mucosa, was repaired by an overlap technique in the closure of the vaginal wall, and using topical estrogen. We did not observe any persistent infection, shrinkage of the PVDF material, or recurrence of the POP. Transient voiding dysfunction following transvaginal POP repair is common.^[28] However, we reported persistent urinary retention in 5.26% of the patients, which is expected in POP surgeries regardless of the mesh material.^[22] Regarding *de novo* urge urinary incontinence, only three patients with a previous history of diabetes mellitus and herniation of the lumbar disk experienced this situation, which was managed with oral anticholinergics. The rate of *de novo* urinary symptoms was consistent with the available literature.^[29] The most commonly reported complication of synthetic meshes in POP repair is postoperative pelvic pain.^[30] Most previous studies in this area have focused on mid-urethral slings, which have reported an incidence of pain ranging from 1% to 3% after pelvic floor repair procedures with mesh kits.^[31-34] The relatively high incidence of early postoperative pain in the present study may be due to the larger size of the mesh material and the increased dissection of the vaginal wall compared to mid-urethral slings. However, the long-term results are consistent with the literature and show promise.

As far as the POP repair with PVDF mesh in a D-sling procedure is concerned, this is the first paper reporting the medium term both subjective and objective outcomes on it using validated questionnaires and regular genital exam. A growing number of articles provided evidence that the PVDF implants in SUI/POP treatments could be a valid alternative to PP meshes. However, further research would contribute to the best pelvic surgical reconstruction.^[33]

This article contains at least two limitations. The first one is its relatively small sample size and single-surgeon series. Although due to the novelty in using new material for reconstructive method and due to the many characteristics that were required in the patients' selection, these limitations are inevitable in the first articles. The second one is that the current study lacks urodynamics, as urodynamics is requested only in certain patients with UDS indication according to the Iranian Incontinence Guideline.

Designing a prospective study with a larger sample size and UDS findings would provide a more comprehensive evaluation of the outcomes, efficacy, and safety of PVDF mesh. This could potentially introduce a relatively safe synthetic material for vaginal POP repair in the near future.

CONCLUSION

We have observed high success and few complications rates when using a four-arm PVDF mesh in the D-sling procedure

for treating POP and concomitant SUI. Transvaginal reconstruction with PVDF mesh could be considered as an alternative to the FDA-disapproved PP meshes. However, further evaluation and more comprehensive studies with larger sample size and long-term follow-up are essential for substantiating this claim.

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Conflicts of interest

There are no conflicts of interest.

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