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ORIGINAL ARTICLE

Prophylactic midurethral sling insertion during transvaginal pelvic reconstructive surgery for advanced prolapse patients with high-risk predictors of postoperative de novo stress urinary incontinence

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Abstract

Introduction and hypothesis Our aim was to evaluate the clinical outcome of continent women with high-risk predictors for de novo stress urinary incontinence (SUI) offered prophylactic midurethral sling (MUS) insertion during vaginal pelvic reconstructive surgery (PRS) for advanced pelvic organ prolapse (POP).

Materials and methods This was a prospective cohort study in patients with POP stage ≥ 3 and maximum urethral closure pressure (MUCP) <60 cmH_2O and functional urethral length (FUL) <2 cm. Patients were divided into PRS and PRS + MUS groups. Surgery commenced with vaginal hysterectomy, application of Uphold® and insertion of MUS to the PRS + MUS group. Main outcome measures were incidence of de novo urodynamic stress incontinence (USI), lower urinary tract symptoms (LUTS), quality of life (QoL), and topographic and anatomical relationship of implanted mesh.

Results Based on sample size calculation, 40 patients were recruited—20 in each group. Rate of de novo USI in PRS + MUS was 5% objectively and 10% subjectively, while in the PRS it was 50% objectively and 60% subjectively. No significant difference was noted in patient demographics. Intraoperative blood loss was greater for PRS + MUS but was not statistically significant. No organ injuries, mesh exposure, or infections occurred. Postoperatively, MUCP significantly increased from 43.3 ± 8.9 to 58.5 ± 19.2 cmH_2O and FUL from 17.2 ± 1.9 to 20.3 ± 3.1 mm in the PRS + MUS group. Residual urine significantly decreased. No patient had bladder outlet obstruction (BOO). Sonographic assessment showed no difference in mesh mobility with urethral kinking observed in 11 (55%) patients with MUS.

Conclusion Based on a validated small sample, prophylactic MUS for continent women at high risk for postoperative USI with advanced POP lowers its incidence to 5%. Continence is achieved in 95%. Concern for complications, LUTS, and QoL did not significantly differ.

Keywords De novo stress urinary incontinence · Continent women · Midurethral sling · Pelvic organ prolapse · Predictive factor

Introduction

Advanced pelvic organ prolapse (POP) and stress urinary incontinence (SUI) co-exist in up to 80% of women with pelvic floor dysfunction [1, 2]. POP leads to anatomical distortion and loosening of the endopelvic fascia that supports and maintains bladder position [1]. Corrective surgeries for POP can cure SUI; however, the procedure may induce SUI as a result.

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Lensen et al. [3] reports 40% of women developing postoperative SUI following surgery for POP, with the highest risk seen in patients with occult SUI. Wei et al. [4] concurrently reports the incidence of de novo SUI at 43% after prolapse surgery and 27% after combined surgery with sling insertion.

Several studies have been done to find predictive factors and preventive measures for women with de novo SUI. Forsgen et al. [5] considers patients with preoperative SUI, high body mass index (BMI), and chronic obstructive pulmonary disease (COPD) to be at high risk for de novo SUI. Wang et al. [6] noted an increased incidence in patients with obstructive lower urinary tract symptoms (LUTS) and a high score at point Aa. Lo et al. [7] reported an 11% incidence of de novo SUI on continent patients with advanced POP after pelvic reconstructive surgery. Predictive factors noted includes age > 66 years, diabetes mellitus, maximum urethral closure pressure (MUCP) <60 cmH_2O, and functional urethral length (FUL) <2 cm with de novo SUI rate at 18.5, 24.3, and 37.5%, respectively. In a separate study, Lo et al. [8] state that the use of certain vaginal mesh kits increases the incidence of de novo SUI, especially if it involves opening the paravesical space. Following the use of the Elevate™ system, 26.3% had de novo SUI in contrast to 8.3% with the Perigee system.

Currently, combination surgery with midurethral sling (MUS) insertion has been performed in women with occult SUI, decreasing the occurrence de novo SUI by 10–15% [9]. Marinus van der Ploeg et al. [10] report 86% of women with occult SUI were continent after combination surgery, with no difference in severe complication rates.

On the other hand, 25% of women negative for occult SUI will develop SUI after surgery [7], though Alas et al. [11] report a lower incidence at 9.9%. Certain continent women will possess predictive factors for de novo SUI, which adds up to the known risk during POP surgery that involves opening of the paravesical space. These women are classified as high risk and will most likely need a second surgery for MUS placement. The management protocol for this group of patients remains debatable at the present time, thus, a shared decision-making process between clinician and patient must be in place.

This study was conducted to evaluate the clinical outcomes of continent women at high risk (MUCP <60 cmH_2O and FUL <2 cm) for postoperative SUI with prophylactic MUS insertion during vaginal pelvic reconstructive surgery (PRS) for advanced POP. It is hypothesized that prophylactic MUS insertion lowers the occurrence of de novo USI.

Materials and methods

This prospective cohort study was performed in a tertiary referral center from August 2015 to July 2018 after gaining Institutional Review Board approval (No.104-9971B). Patients with symptomatic anterior- and apical-compartment prolapse stage ≥ 3, continent with high-risk predictors of de novo SUI specifically, MUCP <60 cmH_2O, and FUL <2 cm on urodynamic study were enrolled. POP was assessed with the patient in the semilithotomy position and staged according to the Pelvic Organ Prolapse Quantification (POP-Q) system [12]. Patients with preoperative overt and occult urodynamic stress incontinence (USI), prior POP mesh-augmented surgeries, previous anti-incontinence procedure, detrusor underactivity, or medically unfit for surgery were excluded. Patients were divided into two groups of 20 patients: PRS and PRS + MUS. Grouping depended on the patient's surgical procedure of choice. Thorough counseling of treatment options, such as potential benefits, risks, and complications of having concurrent MUS surgery, was done. Specific details, such as the odds of developing de novo USI after vaginal PRS being 3.5 [7] and of having voiding dysfunction after concurrent MUS surgery being 3.12 [13], were all explicitly explained. Informed written consent was obtained from each patient prior to surgical procedure.

Patients were considered continent when no leakage of urine was demonstrated during cough stress test, urodynamic evaluation, and when the prolapse was reduced, e.g., no overt and occult USI/SUI. USI was defined as involuntary leakage of urine during increased abdominal pressure in the absence of detrusor contraction on filling cystometry [14]. Occult USI was considered for patients with urine leakage when the prolapse was reduced during urodynamic evaluation without symptomatic SUI. Bladder outlet obstruction (BOO) was diagnosed with $P_{det}Q_{max} \geq 20$ cmH_2O and $Q_{max} \leq 15$ ml/s together with high clinical suspicion of obstruction [15]. Detrusor overactivity (DO) was defined as spontaneous or provoked involuntary detrusor contraction during filling cystometry producing a waveform pattern of variable duration and amplitude on cystometrogram [14]. Detrusor underactivity was defined as detrusor pressure at maximum flow ($P_{det}Q_{max}$) of ≤ 10 cmH_2O and peak flow rate (Q_{max}) of ≤ 12 ml/s on urodynamic study [16].

Baseline preoperative clinical evaluation included medical history and physical examination (pelvic exam, cough stress test, 1-h pad test, urine analysis, 72-h voiding diary, multichannel urodynamic testing, and 2D introital ultrasonography). All patients also completed the validated questionnaires: Incontinence Impact Questionnaire (IIQ-7), Urinary Distress Inventory Questionnaire (UDI-6), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), and Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6) at baseline and 12-month follow-up. The IIQ-7 assesses the impact of UI on activities, social relationships, travel, and emotional health [quality of life (QoL)], UDI-6 evaluates LUTS, the POPDI-6 assesses how symptoms of bladder, pelvic, and bowel prolapse affects the patient's daily life, and the PISQ-12 assesses the sexual function of women with POP and UI.

Multichannel urodynamic study was performed following the standardized protocol set by the International Continence Society (ICS) [17] using the Solar Gold system (Medical Measurement Systems, Dover, NH, USA). An appropriately sized pessary was inserted to reduce the prolapse and unmask occult USI if present. The pessary was removed when $P_{det}Q_{max}$ and Q_{max} were measured.

Operative procedure

Surgical procedures were carried out under regional or general anesthesia. The sequence of site-specific prolapse repair was performed as follows: vaginal hysterectomy, application of Uphold® LITE Vaginal Support System with Capio SLIM™ Suture Capturing Device (Boston Scientific, MA, USA), posterior colporrhaphy, and insertion of MUS (transobturator tape) to PRS + MUS group. The use of the Uphold® LITE was done as described by Letouzy [18], with modifications made on mesh fixation. Three to five simple interrupted sutures were added on the distal tips of the mesh and vaginal mucosa under the bladder neck to immobilize the mesh and improve distal support. For the PRS + MUS group, concomitant MUS using the transobturator tape technique (Obtryx®, Boston Scientific) was done as described by Latthe et al. [19]. Intraoperative cystoscopy was performed in all patients to evaluate lower urinary tract integrity. Prophylactic antibiotic—Cefazolin 500 mg—was given IV prior to surgery then every 6 h thereafter for 24 h. Vaginal packing was done, with the gauze left in situ for 24 h. A Foley catheter was also maintained for 24 h, and after its removal, postvoid residual (PVR) urine volume was assessed every 4 h using the bladder scan (BVI 3000; Diagnostic Ultrasound Corp., Bothell, WA, USA). For PVR urine volume of >150 ml, sterile intermittent catheterization was done. If the ideal PVR of <20% from the voiding volume ws not attained in 3 days, clean intermittent self-catheterization was taught.

Outpatient follow-up evaluations were scheduled at 1 week; 1, 3, and 6 months; and annually thereafter. Subjective and objective assessment included pelvic examination, POP-Q measurement, PVR using sterile catheterization, 2D introital ultrasonography, 72-h voiding diary, and validated questionnaires. Multichannel urodynamic study and 1-h pad test were done at 6 months to 1 year. Nurses and examiners performing the in-person and telephone follow-ups were blinded as to which group the participant was in. The primary outcome measure was the incidence de novo USI assessed objectively through multichannel urodynamic study and 1-h pad test and subjectively based on negative response to UDI-6 question 3 (no leakage on coughing, sneezing, or laughing). Secondary outcome measured LUTS, changes in QoL according to validated questionnaires, and topographic and anatomical relationship of the implanted mesh through 2D introital ultrasonography. Cure for POP was defined as POP-Q ≤ 1 on all compartments.

Two-dimensional introital ultrasonography was performed as described by Lo et al. [20] to determine position, relationship, and mobility of mesh implants. Mesh thickness (TVM-T) and length (TVM-L), together with the thickness of the vaginal mucosa (Vag-T) and distance of the bladder neck to the distal end of the mesh (TVM-D) were all measured at rest. Mesh mobility (TVM-M) was measured during rest and maximum Valsalva using the formula $[\sqrt{(\delta xm)^2 + (\delta ym)^2}]$, where *xm* is the distance between the mesh and parallel plane on the central symphysis pubis line and *ym* is the distance in the perpendicular plane. Mesh displacement value was calculated as ($\delta xm = x_{strain} - x_{rest}$; $\delta ym = y_{strain} - y_{rest}$). Observance of urethral kinking, defined as sling angularity noted during maximum Valsalva without any specific angle degree, was recorded [21].

Statistical analysis

The sample size of 20 patients was required for each study arm to detect a 40% difference in postoperative USI with 95% confidence interval (CI); statistical power of 80% was computed based on the incidence of postoperative USI in the study by Lo et al. [8]. Descriptive statistics were used for demographics and perioperative data. Paired-samples *t* test and chi-square or Fischer's exact tests were applied for comparison of pre- and postoperative continuous and categorical data, respectively. $P < 0.05$ were considered statistically significant for all comparisons. All statistical methods were performed using the commercial software SPSS, version17.

Results

There were 43 consecutive patients eligible for the study, but three were excluded for unwillingness to participate during follow-up; thus, 40 patients were evaluated. Baseline demographic data are represented in Table 1. No significant difference was noted in terms of age, parity, BMI, medical disease, prior pelvic surgeries, and topical hormone use. Significantly, operative time was longer for the PRS + MUS group, lasting 75.3 ± 13.0 min, in contrast to PRS, lasting 63.6 ± 16.9 min. Intraoperative blood loss for PRS + MUS was greater, at 70.0 ± 60 ml vs 60 ± 50 ml, with no significant difference. Hospital stay averaged 3 days for both groups.

Surgical outcomes are outlined in Table 2. Follow-up period for PRS + MUS was 14.8 ± 7.5 months and 15.1 ± 6.7 months for PRS. Prolapse was corrected for both groups at 95 and 90%, respectively.

Objectively, one (5%) patient had de novo USI in the PRS + MUS group and ten (50%) in the PRS group. Subjectively, two (10%) patients in the PRS + MUS group

Table 1 Baseline demographics of patients

	PRS + MUS ($n = 20$)	PRS ($n = 20$)	P value
Mean age (year)	65.2 ± 7.2 (61.8–68.6)	64.2 ± 7.5 (60.7–76.7)	0.670 *
Median parity (range)	3 (1–5)	3 (1–4)	0.616 *
Mean BMI (kg/m^2)	24.3 ± 3.4 (22.7–25.9)	25.1 ± 2.5 (23.9–26.3)	256 *
Postmenopausal status	19 (95.0%)	19 (95.0%)	0.500***
Hormone therapy	15 (75.0%)	14 (70.0%)	0.500**
Systemic	0 (0%)	1 (7.1%)	0.756***
Topical	15 (100%)	13 (92.9%)	0.363**
Prior pelvic surgery	1 (5%)	1 (5%)	0.756***
C/S	1 (5%)	0	0.756***
Myomectomy	0	1 (5%)	0.756***
Medical disease	10 (50%)	12 (60%)	0.376**
Cardiovascular diseases	2 (10.0%)	3 (15.0%)	0.500***
Coronary heart disease	1 (5.0%)	2 (10.0%)	0.744***
Cardiac dysrhsythmias	1 (5.0%)	1 (5.0%)	0.756***
Hypertension	6 (30.0%)	7 (35.0%)	0.500**
Diabetes	1 (5.0%)	2 (10.0%)	0.500***
Brest cancer	1 (5.0%)	0 (0%)	0.500***
Smoking	0	0	
Primary surgery			
VH + TVM + P + MUS	20	0	
VH + TVM + P	0	20	
Operative time, (min)	75.3 ± 13.0 (69.2–81.4)	63.6 ± 16.9 (55.7–71.4)	**0.018***
Intraoperative blood loss (ml)	72.0 ± 58.6 (44.6–99.4)	58.8 ± 54.0 (33.5–84.0)	0.462*
Hb difference (g/dl)	−1.3 ± 0.6 (−1.57 to −0.9)	−1.3 ± 0.7 (−1.6 to −0.9)	0.980*
Hospital stay (days)	3.1 ± 0.2 (2.9–3.2)	3.2 ± 0.4 (2.9–3.3)	0.304*

Mean ± SD (95% CI or percentile); bolded data statistically significant

PRS pelvic reconstructive surgery, *VH* vaginal hysterectomy, *TVM* transvaginal mesh, *P* posterior colporrhaphy, *MUS* midurethral sling, *TOT* transobturator tape, *C/S* Cesarean section/midurethra sling, *Hb difference* Pre- and postoperation hemoglobin, *SD* standard deviation, *CI* confidence interval

*Unpaired *t* test; **chi-square test; *** Fisher's exact test

Table 2 Surgical outcomes

	PRS + MUS ($n = 20$)	PRS ($n = 20$)	P value
Follow-up (months)	14.80 ± 7.5 (12.6–16.7)	15.1 ± 6.7 (13.1–17.6)	0.105*
Complications	2 (10.0%)	2 (10.0%)	1.00**
Organ injury	0	0	
Mesh exposure, vagina	0	0	
Infection	0	0	
Hb difference > 2 (g/dl)	2 (10%)	2 (10%)	1.00**
Anemia with transfusion	0	0	
Secondary surgery			
MUS/TOT sling	0 (0%)	1 (5.0%)	0.756**
De novo USI (objective, 1st year):	1	10	0.003**
De novo SUI (subjective, 1st year):	2	12	**0.001****
Prolapse cure (objective, 1 year)	19/20 (95%)	18/20 (90%)	0.744**
Anterior	20/20 (100%)	20/20 (100%)	1.00**
Apex	20/20 (100%)	20/20 (100%)	1.00**
Posterior	19/20 (95%)	18/20 (90%)	0.744**
Prolapse cure (subjective, 1 year)	19/20 (95%)	18/20 (90%)	0.744**

Mean ± SD (95% CI or percentile); bolded data statistically significant

PRS pelvic reconstructive surgery, *MUS* midurethral sling, *TOT* transobturator tape, *Hb difference* Pre- and postoperation hemoglobin, *USI* urodynamic stress incontinence, *SUI* stress urinary incontinence, *SD* standard deviation, *CI* confidence interval

*Unpaired *t* test, **chi-square test

and 12 (60%) in the PRS group complained of SUI, with notable significant difference. One patient had second surgery for MUS insertion in the PRS group. Postoperative complication was hemoglobin difference of >2 g/dl at 10% in each group. No organ injuries, mesh exposure, or infections were noted in either group. Table 3 shows pre- and postoperative urodynamic data at 6–12 months. Postoperatively, the PRS group showed significant increase in de novo USI ($p = 0.003$), and 1-h pad test preoperatively of 0.4 ± 0.3–6.9 ± 16.9 g ($p < 0.001$). Urodynamic parameters, such as MUCP and FUL significantly increased in the PRS + MUS group, with MUC*P* value 43.3 ± 8.9–58.5 ± 19.2 cmH_2O and FUL 17.2 ± 1.9–20.3 ± 3.1 mm. DO was noted in one patient in each group. There were no significant cases of BOO, and residual urine significantly decreased in both groups. Comparison of postoperative POP-Q measurements on anterior, apical, and posterior compartments between PRS and PRS + MUS groups showed no statistical significance (Table 4).Subjective assessment according to validated questionnaires regarding LUTS, QoL, prolapse symptoms, and sexual function showed significant improvement ($p < 0.001$) for both groups, as reflected in Table 5. Yet, comparison between groups showed significantly higher postoperative LUTS (UDI-6), especially de novo SUI, in the PRS group ($p = 0.006$).Table 6 shows the topography and anatomical measurements of the mesh at 1 year. Comparison of the 2 groups with regard to the status of the transvaginal mesh with and without addition of MUS showed no significant difference in terms of the distance of the mesh to the bladder neck, thickness and length of the mesh, thickness of the vaginal mucosa, and mobility of the mesh. Urethral kinking was observed in 11(55%) patients in the PRS + MUS group.

Discussion

In this prospective study, continent women with predictive factors for postoperative SUI showed a high incidence (50%, 10/20) of de novo USI after PRS alone. Insertion of MUS during PRS lowered the incidence to 5% (1/20), attaining a continence rate of 95% (19/20). The significant increase in MUCP and FUL noted in the PRS + MUS group implies improvement in urethral function that increased urethral competence. Subjectively, patients were satisfied with the outcome. The significant improvement in their QoL was remarkably noted in all validated subjective questionnaires. However, patients in the PRS group were significantly bothered by the incontinence they developed postoperatively.

A key component to achieving continence is attributed to the synergistic action between transvaginal mesh, bladder neck, and sling. Transvaginal mesh mobility could affect surgical outcomes of the MUS. Dynamic urethral kinking and urethral compression both play a significant role in postoperative continence

Table 3 Urodynamic data pre- and postoperatively at 6–12 months

	Preoperative			Postoperative			Within group	
	PRS + MUS, ($n = 20$)	PRS ($n = 20$)	*P* between groups	PRS + MUS ($n = 20$)	PRS ($n = 20$)	*P* between groups	*P*	*P*
Q_{max}	15.4 ± 9.1 (11.1–19.6)	15.1 ± 8.9 (10.9–19.2)	0.902*	18.1 ± 7.0 (14.8–21.4)	18.0 ± 7.6 (14.5–21.6)	0.961*	**0.039****	**0.020****
RU	89.7 ± 72.1 (55.9–123.4)	98.7 ± 109.7 (47.1–149.7)	0.767*	46.4 ± 32.9 (30.9–61.8)	43.9 ± 33.4 (28.2–59.5)	0.813*	**0.031****	**0.024****
CC	409.3 ± 79.6 (371.9–446.5)	397.4 ± 98.4 (351.3–443.4)	0.679*	369.4 ± 95.8 (324.5–414.2)	351.2 ± 76.1 (315.6–386.8)	0.511*	**0.047****	**0.013****
MUCP	43.3 ± 8.9 (39.1–47.4)	42.3 ± 10.9 (37.2–47.4)	0.765*	58.5 ± 19.2 (49.5–67.4)	39.6 ± 15.2 (32.5–46.7)	**.0.011***	**0.007****	0.408**
FUL	17.2 ± 1.9 (16.3–18.1)	16.7 ± 2.9 (15.3–18.1)	0.520*	20.3 ± 3.1 (18.8–21.8)	16.9 ± 6.5 (14.5–19.3)	**0.015***	**<0.001****	0.870**
D_{max}	24.4 ± 17.2 (16.3–32.9)	23.8 ± 14.0 (17.3–30.4)	0.906*	15.4 ± 9.7 (10.8–19.9)	16.4 ± 9.8 (11.8–21.0)	0.735*	**0.038****	**0.024****
USI	0	0		1 (5%)	10 (50%)	**0.003****		
DO	1 (5%)	0	0.500****	1 (5%)	1 (5%)	0.100****	0.100****	0.500****
BOO	7 (35%)	8 (40%)	0.500****	0	0		**0.008****	**0.003****
Pad test	0.4 ± 0.4 (0.21–0.55)	0.4 ± 0.3 (0.25–0.54)	0.889*	0.2 ± 0.3 (0.92–0.24)	6.9 ± 16.9 (−1.05 to 14.79)	**<0.001***	0.109**	**0.003****

Mean ± SD (95% CI); bolded data statistically significant

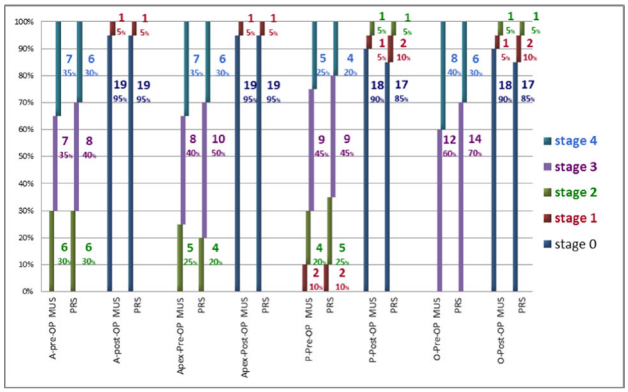
PRS pelvic reconstructive surgery, *MUS* midurethral sling, *RU* residual urine, *CC* cystometric capacity, *MUCP* maximal urethral closure pressure, *FUL* functional urethral length, D_{max} detrusor pressure at maximum flow, *USI* urodynamic stress incontinence, *DO* detrusor overactivity, *BOO* bladder outflow obstruction, *SD* standard deviation, *CI* confidence interval

*Unpaired *t* test, **paired *t* test, ***chi-square test, ****Fisher's exact test

Table 4 Pelvic Organ Prolapse Quantification system measurement and staging at pre- and postoperative follow-up according to surgical methods

	PRS+MUS, (n=20)		PRS, (n=20)		
	Pre-	Post-OP immediate Post-OP 1 year *Difference between post-OP 1st year and post-OP immediate*	Pre-	Post-OP immediate Post-OP 1 year *Difference between post-OP 1st year and post-OP immediate*	P value[a]
Aa	0.6 ± 1.1 (0.6-1.1)	-3.0 ± 0.1 (-3.0–-2.9) -2.6 ± 1.4 (-3.2—1.9) *0.4 ± 1.4 (-1.1-0.2)*	0.5 ± 1.2 (-0.6-1.0)	-2.9 ± 0.3 (-3.0–-2.3) -2.6 ± 0.5 (-2.8—2.4) *0.3 ± 0.6 (-0.6—0.0)*	0.675 0.246 0.878 0.710
Ba	7.6 ± 1.8 (6.7-8.4)	-3.0 ± 0.1 (-3.0–-2.9) -2.8 ± 0.4 (-3.0—2.6) *0.2 ± 0.4 (-0.4-0.0)*	7.2 ± 1.3 (6.6-7.8)	-2.9 ± 0.3 (-3.0—2.8) -2.7 ± 0.5 (-2.9—2.5) *0.2 ± 0.5 (-0.4-0.0)*	0.495 0.246 0.478 0.867
C	7.6 ± 2.5 (6.4-8.7)	-7.8 ± 0.6 (-8.1—7.5) -8.1 ± 0.8 (-8.4—7.7) *-0.3 ± 0.6 (-0.1-0.6)*	7.0 ± 1.5 (6.3-7.7)	-7.8 ± 0.6 (-8.0—7.5) -8.2 ± 0.7 (-8.5—7.8) *0.4 ± 0.7 (0.1-0.7)*	0.400 0.788 0.677 0.477
Ap	-0.1 ± 1.0 (-0.6-0.4)	-3.0 ± 1.1 (-3.0–-2.9) -2.7 ± 0.6 (-2.9—2.4) *0.3 ± 0.5 (-0.6—0.1)*	-0.4± 1.0 (-0.9-0.7)	-2.9 ± 0.3 (-3.0—2.8) -2.6 ± 0.7 (-2.9—2.3) *0.3 ± 0.5 (-0.5—0.1)*	0.340 0.246 0.805 0.877
Bp	6.2 ± 2.1 (5.2-6.1)	-3.0 ± 0.2 (-3.0–-2.9) -2.7 ± 0.8 (-2.9—2.1) *0.5 ± 0. 7 (-0.8—0.1)*	5.9 ± 1.5 (5.2-6.5)	-2.9 ± 0.3 (-3.0—2.8) -2.4 ± 0.9 (-2.8—1.9) *0.5 ± 0.8 (-0.9—0.2)*	0.543 0.294 0.581 0.744
D	6.4 ± 2.2 (5.3-7.4)	n=0	5.95 1.57 (5.21-6.69)	n=0	0.513
TVL	9.5 ± 1.9 (8.6-10.4)	8.0 ± 0.9 (7.5-8.4) 8.3 ± 1.2 (7. 0-8.8) *0.3 ± 1.0 (-0.8-0.2)*	9.7 ± 1.3 (9.1-10.2)	7.9 ± 0.9 (7.5-8.3) 8.2 ± 1.1 (7.7-8.7) *0.3 ± 0.8 (-0.6-0.1)*	0.773 0.857 0.834 0.929
Gh	4.7 ± 0.5 (4.5-4.9)	4.7 ± 0.5 (4.5-4.2) 4.8 ± 0.6 (4.50-5.04) *-0.1 ± 0.4 (-0.3-0.1)*	4.8 ± 0.4 (4.5-5.0)	4.8 ± 0.4 (4.6-5.0) 4.7 ± 0.7 (4.4-5.0) *0.1 ± 0.7 (-0.2-0.4)*	0.731 0.478 0.720 0.349
Pb	2.4 ±0.5 (2.2-2.6)	2.5 ± 0.1 (2.1-2.7) 2.3 ± 0.5 (2.1-2.5) *0.2 ± 0.4 (-0.0-0.4)*	2.5 ± 0.5 (2.3-2.8)	2.3 ± 0.5 (2.1-2.6) 2.3 ± 0.5 (2.0-2.5) *0.8± 0.2 (-0.0-0.2)*	0.457 0.448 0.868 0.322

POP-Q staging		*PRS+MUS* *Pre-*	*Post-OP 1 year*	*PRS* *Pre-*	*Post-OP 1 year*
Overall	*0*	*0*	*18*	*0*	*17*
	1	*0*	*1*	*0*	*2*
	2	*0*	*1*	*0*	*1*
	3	*12*	*0*	*14*	*0*
	4	*8*	*0*	*6*	*0*
Anterior	*0*	*0*	*19*	*0*	*19*
	1	*0*	*1*	*0*	*1*
	2	*6*	*0*	*6*	*0*
	3	*7*	*0*	*8*	*0*
	4	*7*	*0*	*6*	*0*
Apical	*0*	*0*	*19*	*0*	*19*
	1	*0*	*1*	*0*	*1*
	2	*5*	*0*	*4*	*0*
	3	*8*	*0*	*10*	*0*
	4	*7*	*0*	*6*	*0*
Posterior	*0*	*0*	*18*	*0*	*17*
	1	*2*	*1*	*2*	*2*
	2	*4*	*1*	*5*	*1*
	3	*9*	*0*	*9*	*0*
	4	*5*	*0*	*4*	*0*



Data listed as mean ± standard deviation with 95% CI in parentheses

A-PreOP, anterior compartment at preoperative POP-Q stage; A-PostOP, anterior compartment at postoperative POP-Q stage at 1 year; Apex-PreOP, apical compartment at preoperative POP-Q stage; Apex-PostOP, apical compartment at postoperative POP-Q stage at 1 year; P-PreOP, posterior compartment at preoperative POP-Q stage; P-PostOP 5 posterior compartment at postoperative POP-Q stage at 1 year; O-PreOP, overall at pre-operative POP-Q stage; O-PostOP, overall at post-operative at 1 year; MUS, pelvic reconstructive surgery with midurethral sling (study); PRS, pelvic reconstructive surgery (control)

Objective cure rate (by POPQ ≤ stage 1);

MUS: anterior = 100% (20/20); Apical = 100% (20/20); Posterior = 95% (19/20); Overall = 95% (19/20)

PRS: anterior = 100% (20/20); Apical = 100% (20/20); Posterior = 90% (18/20); Overall = 90% (18/20)

Table 5 UDI-6, IIQ-7, POPDI-6, and PISQ-12 scores pre- and postoperatively at 1 year

		PRS + MUS ($n = 20$)	PRS ($n = 20$)	P value (between groups)*
UDI-6	Pre	12.4 ± 2.4 (12.3–14.4)	12.9 ± 3.1 (11.8–13.6)	0.575 *
	Post	8.5 ± 2.71 (9.7–11.1)	11.2 ± 3.7 (11.8–9.2)	0.006*
P value (within groups)		**<0.001****	**0.193****	
IIQ-7	Pre	11.8 ± 4.1 (11.4–13.6)	10.3 ± 4.5 (11.7–13.6)	0.277 *
	Post	5.5 ± 2.7 (6.4–7.6)	7.1 ± 4.8 (6.9–7.9)	0.202 *
P value (within groups)		**<0.001****	**0.039**	
POPDI-6	Pre	7.6 ± 3.8 (12.9–14.2)	8.1 ± 5.0 (12.1–16.3)	0.244 *
	Post	9.1 ± 2.9 (8.3–9.9)	9.5 ± 2.9 (8.8–10.3)	0.550 *
P value (within groups)		**<0.001****	**0.027****	
PISQ-12	Pre	24.2 ± 3.1 (19.8–27.5) $n = 6$ (33.3%)	26.3 ± 5.5 (18.9–33.3) $n = 6$ (33.3%)	0.421 *
	Post	29.7 ± 2.5 (25.4–33.1) $n = 6$ (33.3%)	30.7 ± 4.2 (27.3–32.5) $n = 6$ (33.3%)	0.629 *
P value (within groups)		**0.001****	**0.029****	

Mean ± SD (95% CI); bolded data statistically significant

PRS pelvic reconstructive surgery, *MUS* midurethral sling, *UDI-6* Urinary Distress Inventory (score 0-18); *IIQ-7* Incontinence Impact Questionnaire (score 0-21); *POPDI-6* Pelvic Organ Prolapse Distress Inventory (score 0-24); *PISQ-12* Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (score 0-48), *SD* standard deviation, *CI* confidence interval

*Unpaired *t* test; **paired *t* test

[20]. Yang et al. [22] reported extremes of postoperative mechanical interaction resulting in functional impairment of the tape. A larger range of movement is needed for urethral kinking to occur, which closes the urethra to provide continence. The MUS acts as a hammock to suspend the urethra. Functional closure is achieved because the MUS serves as a fulcrum during straining. The downward pull of the anus muscles during straining indirectly pulls down the bladder base and proximal urethra against the pubourethral ligament, making the urethra kink in the immobilized segment [21]. Yet, our study demonstrated urethral kinking in 55% of patients only. The other half achieved continence through compression of the urethra by a tight MUS when bladder-neck mobility was limited [20, 21].

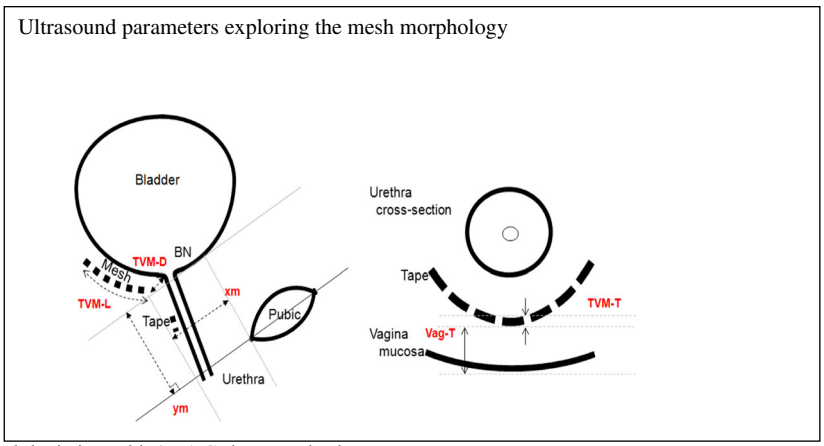
Our study ultrasonographically compared mesh morphology and behavior with the addition of an MUS. No significant changes were noted between groups, which implied that the addition of MUS does not effect changes to transvaginal mesh in terms of distance, thickness, length, and mobility. Several reports noted mesh elongation, especially with kits having the four-point fixation system, and mesh folding or retraction for anterior compartment fixation [8]. Adjustments to the surgical technique for mesh fixation have been suggested. The three- to five-point suture fixation of transvaginal mesh to the vaginal mucosa stemmed from these observations. Whether the Uphold mesh lengthened or shortened was not the focus of this study.

It has been proposed that combination surgery for POP leads to voiding dysfunction. The incidence ranges from 2.4 to 24% [23]. Excessive elevation of the bladder neck during colposuspension or undue tension on the sling causes postoperative voiding difficulty [24]. Lo et al. [13] reported that concomitant MUS insertion with advanced POP surgery was a contributing factor for increased risk of postoperative voiding dysfunction (3.12 times in odds ratio). Other contributing factors include diabetes mellitus, $D_{max} < 10$ cmH_2O, and PVR ≥ 200 ml. Yet, no patient had voiding dysfunction. Residual urine significantly decreased in both groups, and no patient had BOO. Similarly, Marinus van der Ploeg et al. [10] found no signs of obstruction or symptoms of overactive bladder following combined surgery for POP but had a high incidence of prolonged bladder catheterization.

DO and BOO are often associated. Preoperatively, BOO was noted in 15 patients in both groups and DO in one patient in the PRS + MUS group. BOO causes DO through denervation of the bladder, decrease in the number of muscle contractile units, and reduced cell-to-cell propagation of membrane potential. The bladder then becomes overactive and irritable, losing synchronization [25, 26]. Generally, eliminating the obstructive element improves bladder and voiding function. However, DO persisted in one patient in the PRS + MUS group, and one patient had de novo DO in the PRS group. The persistence of DO could have been due to extensive paravesical dissection that damaged motor parasympathetic nerves, and to impaired detrusor contraction [8]; long-standing BOO may have induced changes in the bladder receptor urothelium [27]. Concomitant MUS insertion has no significant association with the risk for DO. Instead, age > 66 years, neurologic factors (e.g., Parkinson's disease and cerebrovascular accident), preoperative MUCP ≥ 60 cmH_2O, maximum flow rate < 15 ml, and $D_{max} \geq 20$ cmH_2O are known to increase the risk for postoperative DO [27].

Table 6 Topography and anatomical measurements by introital ultrasonography at 1 year

Parameter (mm)	PRS+ MUS	n=20	PRS	n=20	*p* value
TVM-D,	10.13 ± 5.67	(9.02-12.03)	10.50 ± 5.33	(8.74-11.37)	0.437
TVM-L,	31.74 ± 4.82	(29.10-32.41)	32.10 ± 5.65	(31.71-33.64)	0.221
TVM-T,	2.56 ± 1.52	(2.17-2.94)	2.60 ± 1.71	(2.21-3.00)	0.513
Vag-T,	4.41 ± 4.13	(3.81-5.45)	4.26 ± 3.01	(3.41-4.98)	0.522
TVM-M	6.65 ± 3.41	(5.67-7.44)	6.71 ± 2.56	(6.05-7.19)	0.247
Urethral kinking (%)	11	(55%)			



Data listed as mean ± standard deviation with 95% CI in parenthesis

TVM-D, distance from bladder neck to distal end the mesh; **TVM-L**, length of the mesh; **TVM-T**, thickness of the mesh; **Vag-T**, thickness of vagina mucosa; **TVM-M**, mobility of the mesh (TVM-M = $\sqrt{}$ (δxm)2 + (δym)2; xm = distance between mesh and axis perpendicular to central line of symphysis (cephalocaudal position); ym = distance between mesh and central line of symphysis (ventrodorsal position); δxm = mesh displacement on cephalocaudal direction (x strain - x rest);δym = mesh displacement on ventrodorsal direction (y strain - y rest); **Urethral kinking**, presence of urethral kinking seen as sling angularity or angle configuration of the urethra

p value, for the comparison between third month and first year postoperatively to the first month postoperatively

Complication rates for both groups were similar: 10% (2/10). One would expect more trocar-related complications in combined surgeries to include bladder perforation, prolonged catheterization, urinary tract infection, voiding dysfunction, and greater amount of blood loss [4, 10]. Yet, no patient had any organ injury. Blood loss was greater for the PRS + MUS group but was not significantly different from the PRS group. The significantly longer operative time for the PRS + MUS group increased anesthetic risk; nevertheless, no associated complications were noted. Neither mesh exposure nor infection posed any significant risk. That no such complications were noted could be explained by careful patient selection, limited sample size and study time, lack of power, good surgical technique, and surgeon expertise.

Anatomical outcomes in POP repair showed no significant difference in specific and overall compartments in either group. Objective and subjective cure for POP was 95% for PRS + MUS and 90% for PRS. Cure rates were comparable with several published studies. Rivaux et al. [28] reported an anatomical cure in both anterior and apical compartments at 93% in a mean follow-up of 12 months. In a longer follow-up study by Letouzy et al. [18], anatomic success was achieved at 93% in a mean follow-up of 23 months, with patient satisfaction of 95%.

Strengths and limitation

The strength of our study includes its prospective two-arm cohort study design, homogenous groups, judicious

patient selection, and standard pre- and postoperative evaluation protocol following ICS recommendations. All operative procedures were the same and were performed by one surgeon, thus reducing bias. Limitations of the study include small sample size, short-term assessment, and nonrandomized selection of respondents.

Conclusion

In conclusion, prophylactic MUS insertion during vaginal PRS for advanced POP in continent women with predictive factors for de novo USI lowers USI incidence to 5%, at least in our small sample. It provided continence to 95% of patients when offered with prophylactic treatment. Likewise, complication and LUTS rates were no different in patients who underwent PRS alone. Patient satisfaction with regard to SUI was more pronounced in women offered a concomitant MUS. Ergo, offering prophylactic MUS insertion to this group of patients is an option to be considered.

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Compliance with ethical standards

Conflicts of interest None.

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