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# Prediction of Mid-Urethral Sling Failure with Clinical Findings and Urodynamics

Serdar AYDIN,[1]* Çağrı ARIOĞLU AYDIN,[2] and Fırat ERSAN[3]

[1]Department of Obstetric and Gynecology, Bezmialem Vakif University, İstanbul, Turkey, [2]Department of Obstetric and Gynecology, Liv Hospital, İstanbul, Turkey, and [3]Department of Obstetrics and Gynecology, Kanuni Sultan Süleyman Research and Training Hospital, İstanbul, Turkey

**Objective:** Mid-urethral slings (MUS) become a standard, minimally invasive surgery to treat urinary stress incontinence. Our aim is to investigate the contribution of preoperative urodynamics to mid-urethral slings success and determine predictors for choosing mid-urethral sling route.

**Methods:** Women with stress urinary incontinence and who desired surgical correction of their incontinence were included in the study. The selection of the procedure was according to an algorithm used in an institution. Urodynamic and baseline factors that may be associated with surgery failure were analyzed.

**Results:** A total of 159 patients in the tension free transvaginal tape (TVT) group and 83 patients in the transobturator tape (TOT) group were included in the present study. Urodynamic findings of subjects who were considered MUS failure were not significantly different from those women who were continent after 1 year of surgery. Detrusor overactivity was present on urodynamics in 23 of 37 women (62.2%) with MUS failure, 81 of 205 women (39.7%) with no stress test positivity with the cough stress test ($P < 0.05$). A vaginal hysterectomy had been performed on 13 of 37 (35.1%) subjects with MUS failure 1 year after operation, and 20 of 205 subjects (9.8%) in the stress urinary incontinence (SUI) continent group ($P < 0.001$).

**Conclusions:** Preoperative detrusor overactivity (DO) was the only urodynamic finding that negatively affected the success of surgery in both TOT and TVT groups. Our study demonstrated an increased risk of surgery failure for those who underwent a concurrent hysterectomy for pelvic organ prolapse.

**Key words** midurethral sling, stress urinary incontinence, tension free transvaginal tape, transobturator tape, urodynamics

## 1. INTRODUCTION

Stress urinary incontinence (SUI) is a common form of urinary incontinence in women. The lifetime risk that women will have surgical treatment for SUI is about 4%.[1] A standard, minimally invasive surgery to treat urinary stress incontinence, tension-free vaginal tape (TVT), was first described by Ulmsten in 1995.[2] Despite the fact that success ranges from 84 to 95%, described complications have included bladder, bowel and major blood vessel injuries as well as postoperative voiding difficulties, de novo urgency and urge incontinence.[3] To minimize these complications, an alternative procedure called transobturator tape (TOT) was developed by Delorme in 2001, where tape was introduced through the obturator foramen.[4] Delorme showed that there was a high success rate, no bladder perforations, and few perioperative complications via the transobturator route; this procedure was subsequently widely adopted before proper evaluation of its effectiveness.

Identifying predictors for treatment failure would facilitate improved counseling for women considering surgery to manage their SUI, and potentially allow surgeons to modify their approach to improve the outcome for individual patients. There are, however, few scientific studies on clinical or urodynamic predictors of treatment success or failure after these procedures. A urodynamic study (UDS) before considering surgical treatment of SUI is a recommended strategy, according to both gynecological and urological guidelines. Urodynamics try to enhance the understanding of lower urinary tract function and reveal the underlying pathophysiology responsible for the patient's complaints. The information gained from urodynamics may confirm or alter the clinical diagnosis based on office evaluation and medical history, and may influence the choice of the intervention. On the other

*__Correspondence:__ Serdar Aydın, MD, Obstetric and Gynecology Department, Bezmialem University, Adnan Menderes Bulvarı, 34093 Fatih, İstanbul, Turkey. Tel: +905327097179; Fax: +902124531870. Email: serdariks@yahoo.com

A Serdar: Project development, Data Collection, Manuscript writing.
AA Çağrı: Data collection, Manuscript writing.

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hand, UDS is associated with a risk of causing urinary tract infections, and many women perceive urodynamics as painful or embarrassing. Furthermore, UDS is time-consuming and costly. The aim of this prospective study is to investigate the contribution of preoperative urodynamics to mid-urethral slings success and determine predictors for choosing mid-urethral sling route.

## 2. METHODS

This study was carried out from June 2010 to February 2014. Included patients suffering from stress urinary incontinence and who desired surgical correction of their incontinence. Written informed consent was obtained from all patients before enrolment. This study was approved by the institutional review board.

Eligibility requirements included documented pure or predominant SUI symptoms for at least 3 months, along with a positive standardized urinary stress test. Subjects were excluded if they demonstrated the following: prior incontinence surgery, post-void residual volumes of greater than 100 mL, a history of chronic inguinal or vulvar abscess, hidradenitis suppurativa, genitourinary fistula or urethral diverticulum, reversible cause of incontinence or any contraindication to surgery. Subjects requiring concurrent surgery for pelvic organ prolapse were eligible for the study.

At baseline, a multichannel urodynamic investigation was performed in all women according to the recommendations of the International Continence Society.[5] Leak point pressures (LPPs) were obtained during filling cystometry with the patient upright and sitting. Cough and Valsalva LPP measurements were obtained in a standard fashion at multiple bladder volumes beginning at 150 mL, and again at every 50 mL incremental increase until maximal functional bladder capacity was reached. Pressure-flow studies, cystometry and urethral pressure measurements had been performed with Solar-Blue (MMS, Netherlands) urodynamic device, using seven French urethral catheters.

We used the Turkish version of the Urogenital Distress Inventory-6 (UDI-6) to quantify lower urinary tract symptoms before surgery and evaluation of surgery success after 1 year.[6] After the urodynamic investigation and completion of several questionnaires, the chief clinician of the institution conducted all examinations, surgery choice, perineal ultrasound, and post-residual volume calculation. Bladder neck descent (BND) is determined by measuring the vertical distance between inferoposterior margin of the symphysis pubis and the bladder neck, at rest and maximal Valsalva via perineal ultrasound. The difference between those two measurements yields BND on Valsalva. We select the TVT when BND $<30$ mm and TOT for BND over 30 mm. The argument for choosing sling route is a lack of urethral hypermobility may be a risk TOT failure.[7]

All procedures conformed to those described in the manufacturer's guidelines, and were performed by one skilled urogynecologist. Concomitant surgery was performed at the discretion of the chief decision-maker who was blind to urodynamic findings. The types of urinary incontinence were classified as detrusor overactivity (DO) and Urodynamic stress incontinence (USI), according to the definitions recommended by the Joint International Urogynecological Association (IUGA)/ International Continence Society (ICS) terminology report.[8] Postoperatively, subjects were evaluated at 1, 3, and 12 months after surgery. The focus of this analysis was treatment success 12 months after surgery. At 12 months, all patients were evaluated for follow up by one independent physician, blind to the different procedures and urodynamics; postoperative UDI-6 questionnaire scores were recorded.

The definition of cure after the TVT or TOT procedure was that the patient had negative findings on the cough stress test result, and no reports of urine leakage during stress. Cough stress test performed with approximately 300 mL bladder filling, volume calculated via transabdominal ultrasound formulated as $a \times b \times c \times 0.7$. Improvement was defined as negative findings on the cough stress test result, but occasional urine leakage during stress with a reduction of stress incontinence episodes $>50\%$ than that before surgery. Patients who did not meet these definitions of cure or improvement were considered to have treatment failure.

Descriptive statistics were computed; nonparametric statistics were presented for non-normally distributed variables. The Mann Whitney U test and *t*-test were used for the comparison of continuous variables; $\chi^2$ test and Fisher's exact tests were used to compare categorical variables. Data were analyzed by using IBM SPSS version 21 for all statistical tests, and differences were considered significant $P < 0.05$.

## 3. RESULTS

A total of 159 patients who underwent the TVT procedure and 83 patients who underwent the TOT procedure were included in the study. Baseline demographic characteristics were not significantly different between the TOT and TVT groups, although women in the TVT group had a higher menopause ratio (39.6% in the TVT group, 22.9% in the TOT group). Mean age was 52.3 years, ranging from 37 to 72. Mean age was similar in both groups: 51.9 (37–72) in the TVT group, and 53.1 (39–70) in the TOT group. Also, there was no age difference between treatment failure and success groups. Baseline characteristics and urodynamic parameters of TVT and TOT groups are shown in Table 1.

When we analyze the findings according to surgery failure or success, demographic and characteristics at baseline for women with primary outcome data available were generally similar between the two groups. Mean age and body mass index (BMI) were similar. The baseline characteristics and urodyamic findings of the women with MUS failure after 1 year compared with continent women are shown in Table 2. Urodynamic findings of subjects who were considered MUS failure were not significantly different from those women who were continent after 1 year of surgery except DO. Mean VLPP was not significantly lower in the

**TABLE 1.** Baseline characteristics and urodynamic parameters of tension-free vaginal tape (TVT) and transobturator tape (TOT) groups

| | TOT ($n=83$) | TVT ($n=159$) | $P$ |
|---|---|---|---|
| VLPP ($cmH_2O$)† | 102.4 ± 12.5 | 142.1 ± 11.3 | 0.03* |
| MUCP ($cmH_2O$)† | 88.5 ± 6.0 | 94.9 ± 4.7 | 0.4 |
| FUL (mm)† | 25.9 ± 1.2 | 24.50 ± 1.0 | 0.4 |
| Compliance ($mL/cmH_2O$)† | 75.4 ± 13.1 | 78.4 ± 8.4 | 0.8 |
| LPV (mL)† | 201 ± 17.8 | 210 ± 12.3 | 0.6 |
| VLP$P < 60$ $cmH_2O$† | 24 (28.9%) | 39 (29.5%) | 0.5 |
| DO‡ | 38 (46.5%) | 66 (41.5%) | 0.4 |
| Age† | 53.1 ± 0.7 | 51.9 ± 0.6 | 0.2 |
| BMI† | 25.1 ± 0.3 | 24.9 ± 0.3 | 0.6 |
| Parity† | 2.7 ± 0.1 | 2.8 ± 0.1 | 0.1 |
| Gravidy‡ | 3.3 ± 0.1 | 3.6 + 0.1 | 0.8 |
| Menopause status‡ | 19 (22.9%) | 63 (39.6%) | 0.009* |
| Hormone replacement‡ | 14 (16.9%) | 22 (13.8%) | 0.5 |
| Additional cystocele operation‡ | 65 (78.5) | 115 (72.3%) | 0.3 |
| Concomitant hysterectomy‡ | 12 (14.5) | 21 (13.2%) | 0.8 |
| Smoking‡ | 19 (22.9%) | 41 (25.8%) | 0.6 |
| Pre-surgery UDI-6† | 6.5 ± 0.3 | 6.4 ± 0.2 | 0.8 |
| Post-surgery UDI-6† | 2.1 ± 0.1 | 2.1 ± 0.1 | 0.8 |

*$P < 0.05$. †Mean ± SEM. ‡Number of patients (%). BMI, body mass index; DO, detrusor overactivity; FUL, functional urethral length; LPV, leak point volume; MUCP, maximum urethral closure pressure; UDI-6, urinary distress inventory-6; VLPP, Valsalva leak point pressure.

**TABLE 2.** Baseline characteristics and urodyamic findings of the women with mid-urethral sling (MUS) failure after 1 year compared with continent women

| | Continent ($n=205$) | MUS failure ($n=37$) | $P$ |
|---|---|---|---|
| VLPP ($cmH_2O$)† | 138.5 ± 10.5 | 96 ± 12.1 | 0.05 |
| MUCP ($cmH_2O$)† | 94.3 ± 4.0 | 83.8 ± 9.8 | 0.3 |
| FUL (mm)† | 25.1 ± 0.9 | 24.5 ± 2.1 | 0.7 |
| Compliance ($mL/cmH_2O$)† | 77.6 ± 7.8 | 76.1 ± 16.3 | 0.9 |
| LPV (mL)† | 212.4 ± 11.3 | 189.2 ± 22.7 | 0.3 |
| VLP$P < 60$ $cmH_2O$† | 49 (23.9%) | 14 (37.8%) | 0.07 |
| DO‡ | 81 (39.7%) | 23 (62.2%) | 0.01* |
| Age† | 52.3 ± 0.5 | 52.5 ± 1.1 | 0.9 |
| BMI† | 24.9 ± 0.2 | 25.4 ± 0.4 | 0.3 |
| Parity† | 2.7 ± 0.1 | 3 ± 0.2 | 0.2 |
| Gravidy‡ | 3.4 ± 0.1 | 3.8 ± 0.2 | 0.2 |
| Menopause status‡ | 68 (33.2%) | 14 (37.8%) | 0.5 |
| Hormone replacement‡ | 33 (16.1%) | 3 (8.1%) | 0.2 |
| Additional cystocele operation‡ | 151 (73.7%) | 29 (78.4%) | 0.5 |
| Concomitant hysterectomy‡ | 20 (9.8%) | 13 (35.1%) | <0.001* |
| Smoking‡ | 51 (24.9%) | 9 (24.3%) | 0.9 |
| Pre-surgery UDI-6† | 6 ± 0.2 | 8.7 ± 0.4 | <0.001* |
| Post-surgery UDI-6† | 1.6 ± 0.2 | 4.7 ± 0.2 | <0.001* |

*$P < 0.05$. †Mean ± SEM. ‡Number of patients (%). BMI, body mass index; DO, detrusor overactivity; FUL, functional urethral length; LPV, leak point volume; MUCP, maximum urethral closure pressure; UDI-6, urinary distress inventory-6; VLPP, Valsalva leak point pressure.

MUS failure group than in the SUI continent group (96 $cmH_2O$ in MUS failure group, and 138.5 $cmH_2O$ in the SUI continent group, $P=0.05$). Fourteen (37.8%) subjects in the MUS failure group and 49 (23.9%) subjects in SUI continent group had VLPP less than 60 $cmH_2O$.

Detrusor overactivity was the only urodynamic parameter that was independently associated with the risk for postoperative persistence of incontinence. DO was present on UDS in 23 of 37 women (62.2%) with MUS failure, and 81 of 205 women (39.7%) with no stress test positivity with the cough stress test. Other parameters that significantly affected the outcome were concurrent hysterectomy. Vaginal hysterectomy for uterine prolapse had been performed on 13 of 37 (35.1%) subjects with MUS failure 1 year after operation; however, only on 20 of 205 subjects (9.8%) in the SUI continent group ($P < 0.001$). A total of 33 concurrent hysterectomy and anterior colporrhaphy were performed on 12 (14.5%) subjects with TOT procedure and 21 (13.2%) subjects with retropubic sling procedure. Besides vaginal hysterectomies, 65 (78.5%) anterior colporrhaphies were performed with TOT and 115 (72.3%) anterior colporrhaphies with TVT. Subgroup analysis of TVT and TOT groups showed a strong association with DO and concomitant hysterectomy. Table 3 shows the demographic factors and urodynamic findings in both the TVT and TOT SUI failure groups. DO inversely affects the success of the sling surgery. Ten of 14 (71.4%) subjects in the TOT failure group, and 13 of 23 (56.5%) subjects in retropubic sling surgery failure group had detrusor overactivity ($P < 0.05$ in the TOT group, and $P=0.001$ in the TVT group). Also, the concomitant hysterectomy ratio was higher in both TVT and TOT groups: 5/14 (35.7%) versus 7/69 (10.1%) $P=0.02$ in the TOT group, and 8/23 (34.8%) versus 13/136 (9.6%) $P=0.001$ in TVT group. In both the TOT failure and TVT failure subgroup, and in the MUS failure group, preoperative UDI-6 scores were significantly higher than control groups: (8.7 ± 0.4 in MUS failure versus 6.4 ± 0.2 in the continent group, 8.6 ± 0.4 in TVT failure versus 6 ± 0.2 in continent group, and 9 ± 0.6 in TOT failure versus 5.9 ± 0.3 in continent group).

Four women who underwent a TVT operation had large ecchymosis and retropubic hematoma that spontaneously resolved without any intervention and blood transfusion. Two bladder perforations that were immediately detected with cystoscopy then mesh had been withdrawn and replaced again without complications. These two patients were SUI continent at the end of 1 year. There were no complications from the TOT operations other than minor hemorrhages that were controlled with conservative methods. No mesh erosion was determined at the end of 1 year.

## 4. DISCUSSION

Although the number of studies considering these operations is limited, some studies reported an 84% success rate for women with no previous surgery for incontinence.[9,10] Our overall cure rate was 84.7%, which correlates with other reports. In a recent randomized clinical trial (RCT), Nager et al. defined treatment success as a reduction in the UDI score from baseline to 12 months of 70% or more, and a Patient Global Impression of Improvement response of ''very much better'' or ''much better'' at 12 months.[11] They reported a rate of treatment success of 76.9% in the urodynamic-testing group compared with 77.2% in the evaluation-only group. When

**TABLE 3.** Baseline characteristics and urodyamic findings of the women with transobturator tape (TOT) and tension-free vaginal tape (TVT) failure

| | TOT ($n=83$) | | | TVT ($n=159$) | | |
|---|---|---|---|---|---|---|
| | Continent ($n=69$) | TOT failure ($n=14$) | $P$ | Continent ($n=136$) | TVT failure ($n=23$) | $P$ |
| VLPP ($cmH_2O$)† | 109.2 ± 15.8 | 80.3 ± 13.1 | 0.3 | 151.3 ± 13.2 | 104.6 ± 17.1 | 0.1 |
| MUCP ($cmH_2O$)† | 87.2 ± 6.7 | 80.3 + 14.6 | 0.6 | 97.9 ± 5.0 | 76.5 ± 13.2 | 0.1 |
| FUL (mm)† | 26.1 ± 1.3 | 24.8 ± 3.8 | 0.7 | 24.5 ± 1.1 | 24.2 ± 2.4 | 0.9 |
| Compliance ($mL/cmH_2O$)† | 73.5 ± 14.7 | 83.7 ± 28.6 | 0.7 | 79.6 ± 9.2 | 70.8 ± 19.6 | 0.7 |
| LPV (mL)† | 214.2 ± 22.2 | 167.7 ± 26.3 | 0.3 | 112.7 ± 13.1 | 128.4 ± 34.3 | 0.8 |
| VLP$P < 60$ $cmH_2O$† | 18 (26.1%) | 6 (42.9%) | 0.2 | 31 (22.8%) | 8 (34.8%) | 0.2 |
| DO‡ | 28 (40.6%) | 10 (71.4%) | <0.05* | 53 (39%) | 13 (56.5) | 0.001* |
| Age† | 52.9 ± 0.7 | 54.2 ± 1.7 | 0.5 | 52.0 ± 0.6 | 51.4 ± 1.5 | 0.7 |
| BMI† | 25.2 ± 0.3 | 24.8 ± 0.8 | 0.6 | 24.7 ± 0.3 | 25.8 ± 0.5 | 0.1 |
| Parity† | 2.7 ± 0.1 | 3.1 ± 0.3 | 0.1 | 2.8 ± 0.1 | 2.9 ± 0.2 | 0.6 |
| Gravidy‡ | 3.2 ± 0.1 | 3.7 ± 0.2 | 0.1 | 3.5 ± 0.1 | 3.8 ± 0.2 | 0.3 |
| Menopause status‡ | 15 (21.7%) | 4 (28.6%) | 0.7 | 53 (39.0%) | 10 (43.5%) | 0.7 |
| Hormone replacement‡ | 13 (18.8%) | 1 (7.1%) | 0.4 | 20 (14.7%) | 2 (8.7%) | 0.7 |
| Additional cystocele operation‡ | 53 (76.8%) | 12 (85.7%) | 0.7 | 98 (72.1%) | 17 (23.9%) | 0.8 |
| Concomitant hysterectomy‡ | 7 (10.1%) | 5 (35.7%) | 0.02* | 13 (9.6%) | 8 (34.8%) | 0.001* |
| Smoking‡ | 16 (23.2%) | 3 (21.4%) | 0.8 | 35 (25.7%) | 6 (26.1%) | 0.9 |
| Pre-surgery UDI-6† | 5.9 ± 0.3 | 9.0 ± 0.6 | <0.001* | 6.0 ± 0.2 | 8.6 ± 0.4 | <0.001* |
| Post-surgery UDI-6† | 1.6 ± 0.1 | 4.7 ± 0.2 | <0.001* | 1.7 ± 0.1 | 4.7 ± 0.3 | <0.001* |

*$P < 0.05$. †Mean ± SEM. ‡Number of patients (%). BMI, body mass index; DO, detrusor overactivity; FUL, functional urethral length; LPV, leak point volume; MUCP, maximum urethral closure pressure; UDI-6, urinary distress inventory-6; VLPP, Valsalva leak point pressure.

they expanded the definition of success to include a negative stress test at a bladder volume of 300 mL at 12 months, success rates were 69.4% in the urodynamic testing group and 72.9% in the evaluation-only group ($P = 0.42$).

Different definitions of failure such as objective, subjective, various scales and scores and timing of evaluation are responsible for these incompatible failure rates. Our definition of cure after the TVT or TOT procedure was that the patient had a negative result on the cough stress test and no reports of urine leakage during stress. This competitive failure rate, by using an objective definition, ascribed to the dominance of the TVT operation that may have better results in internal sphincter deficiency. We found higher UDI-6 scores in both the TOT failure and TVT subgroup, as well as in the MUS failure group, than in the control groups. These findings suggest that more severe defects or disease are associated with higher failure rates.

Our findings suggest that no urethral profilometry parameter can help the decision on surgery for a woman with predominant stress incontinence. This is not a study that compares office evaluation and urodynamics. This study looks to answer the question of whether urodynamics parameters can predict surgery failure or help with the selection of the patient for surgery. In contrast to Fletcher et al., our study shows that the factors identified in the preoperative urodynamic study that traditionally have been considered to increase the risk of MUS surgery failure, such as MUCP and VLPP, may not be predictive of a poor outcome.[12]

In our study, preoperative DO was the only urodynamic finding that negatively affect the success of surgery in both TOT and TVT groups. It is well documented that women with preoperative DO are more likely to experience treatment failure MUS, and there is much to indicate that urodynamic quantification of DO would be a convenient predictor of surgery outcome.[13] Persistence or worsening of the DO after surgery inversely affects the outcome of MUS procedures.[12] Furthermore, DO might play a role in predicting post-operative overactive bladder symptoms.[14] Consequently, the preoperative determination of DO contributes to the counseling of patients on the options, but it is questionable whether DO should have a major influence on the management.

Up to 80% of urinary incontinent women have coexisting pelvic organ prolapsed.[15] Among them, anterior vaginal wall prolapse and uterine prolapse is common and treatment becomes indicated as symptomatic prolapse develops. Our study demonstrated an increased risk of surgery failure in those who underwent concurrent hysterectomy for pelvic organ prolapse. Concurrent cystocele repair was not associated with MUS failure. This agrees with a number of other studies that have demonstrated an increased risk of failure in patients with pelvic organ prolapse and/or who received concurrent surgery for prolapse at the time of MUS procedure.[16] Possible explanations of SUI surgery failure are urethral denervation resulting from the vaginal dissection during prolapse surgery, and women with both pelvic organ prolapse and SUI represent a group with more severe pelvic floor dysfunction than those with SUI alone.[17] Barber et al. reported that a previous hysterectomy is not associated with failure, but concurrent hysterectomy and POP surgery negatively affect success of retropubic or transobturator mid-urethral slings 1 year after surgery.[18] Uncertainty persists about whether staging procedures, SUI surgery first followed by pelvic organ prolapse surgery at another time or performing at the same session. Randomized controlled trials are certainly needed to identify the optimal approach for common co-morbid conditions to manage patients with both SUI and pelvic organ prolapse.

This study has several weaknesses; for example, there was no control group or evaluation of postoperative voiding dysfunction. Studies can be found were urodynamic parameters are restricted for evaluation, these measures are selected from previous reports that may correlate with SUI surgery failure. The strengths of our study include its prospective study design, along with our eligibility criteria that more broadly reflects the characteristics of women with stress incontinence and who are seen in a clinical practice and a single, quality controlled center. Having one decision-maker and one surgeon reduced the bias of multi-center, multi-operator trials. Our study design is similar to a clinical practice, which makes our results applicable to patients in daily clinical practice.

## 5. CONCLUSION

Until the point in time under discussion, there has been no consensus as to whether urodynamics enhances surgical outcome of MUS by improving case selection or alters the surgical method based on urodynamic findings. Our findings on the success of MUS surgery in this study are in line with previous studies on the value of urodynamics in SUI patients.[19,20] Preoperative DO was the only urodynamic finding that negatively affected the success of surgery in both TOT and TVT groups. Our study demonstrated an increased risk of surgery failure in those who underwent concurrent hysterectomy for pelvic organ prolapse. Concurrent cystocele repair was not associated with MUS failure. This study addressed the role of office evaluation in planned concomitant surgery for pelvic organ prolapse. There is a need for RCT that evaluates the role of urodynamics in patient selection with concomitant pelvic organ prolapse surgery with MUS.

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### Disclosure

The authors declare no conflict of interest.

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