

# Predictors of improved overactive bladder symptoms after transvaginal mesh repair for the treatment of pelvic organ prolapse

## Predictors of Improved OAB after POP Repair

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### Abstract

**Introduction and hypothesis** The aim of this study was to identify the predictors of improved overactive bladder (OAB) symptoms after transvaginal mesh repair.

**Methods** Eighty women with pelvic organ prolapse (POP) stage II to IV reporting OAB symptoms were scheduled for transvaginal mesh procedures. Preoperative and postoperative assessments included a bladder diary, urodynamics, and a personal interview about urinary symptoms.

**Results** Sixty-three (78.8%) women experienced improvement of OAB symptoms (Improvement group), and 17 (21.2%) women remained unchanged or worsened (Persis-

tence group) postoperatively. A univariate analysis of patients' characteristics showed no difference between two groups regarding parity, diabetes, hypertension, prolapse status, preoperative urodynamic parameters, and urinary symptoms ( $P>0.05$ ). However, the age ( $P=0.042$ ) and preoperative detrusor overactivity (DO) ( $P=0.03$ ) were two significant predictors of postoperative OAB improvement. **Conclusions** Women with POP may experience improvement of their OAB symptoms after transvaginal mesh repair. Both age and DO were two predictors in our univariate analysis, and the latter was the only significant predictor of symptom relief after adjusting age factor.

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Cheng-Yu Long and Chun-Shuo Hsu has contributed equally to this work.

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**Keywords** Detrusor overactivity · Overactive bladder · Pelvic organ prolapse · Transvaginal mesh repair · Urgency

### Abbreviations

POP	Pelvic organ prolapse
OAB	Overactive bladder
DO	Detrusor overactivity
TVT	Tension-free vaginal tape
TVT-O	TVT-obturator
USI	Urodynamic stress incontinence
TOT	Transobturator tape

### Introduction

It has been estimated that 11% of all women will undergo some types of operation for pelvic organ prolapse (POP) or urinary incontinence in their lifetime, with 29% needing a second operation for recurrence within 5 years [1]. Women with POP often report overactive bladder (OAB) symptoms and may demonstrate detrusor overactivity (DO) on urodynamics [2, 3]. However, OAB symptoms may or may not be associated with prolapse and urodynamic results [4].

Traditionally, anterior and/or posterior colporrhaphies have been the established treatment for POP over the last century, but carry a higher rate of recurrence [1]. Therefore, the use of synthetic mesh has become increasingly popular over the last decade due to the excellent short-term cure and low morbidity rates [5]. Prolift (Gynecare Prolift, Ethicon, Inc., Piscataway, NJ, USA) and Perigee–Apogee (AMS, Inc., Minnetonka, MN, USA) are examples of surgical mesh kits recently developed and adopted in pelvic reconstruction. These non-absorbable meshes allow surgeons to reinforce the pubocervical and the rectovaginal fascia via minimally invasive approaches.

Previous studies have demonstrated that transvaginal surgery for correction of advanced POP can reduce the rate of DO and OAB simultaneously [6, 7]. Nonetheless, patients can also experience unchanged or de novo OAB symptoms following prolapse repair [8]. The relationship between POP and OAB symptoms remains controversial. In the literature, there are limited studies to evaluate preoperative clinical and urodynamic parameters in predicting which women are more likely to have improvement of irritative symptoms after POP surgery. It remains a critical issue that should be discussed with the patients during their preoperative counseling. The aim of our study is to identify predictors of improved OAB symptoms after transvaginal mesh repair.

### Methods

Between June 2004 and January 2009, 130 consecutive women with POP stage II to IV defined by the POP quantification staging system [9] were referred for transvaginal mesh procedures (70 Perigee and/or Apogee; 60 Prolift system) at our hospital. Concomitant midurethral sling operations, including tension-free vaginal tape (TVT; Gynecare TVT, Ethicon, Inc., Piscataway, NJ), TVT-O (Gynecare TVT-Obturator System, Ethicon, Inc., Somerville, NJ) and Monarc (AMS, Inc., Minnetonka, MN, USA), were performed in women with current or occult stress urinary incontinence. We excluded 18 patients due to various reasons, including incomplete medical records ( $n=8$ ) and current use of anti-muscarinic drugs ( $n=10$ ). Of the remaining 112 women, 80 who reported OAB symptoms before surgery were included in this study (41 Perigee and/or Apogee; 39 Prolift system).

Before and 6 months after surgery, patients underwent urinalysis, pelvic examination, 3-day bladder diary, multi-channel urodynamic testing, and a personal interview to identify how they were bothered by urinary symptoms on a scale of 0 to 5 (0=not at all; 1=a little bit; 2=somewhat; 3=quite a bit; 4=a great deal; 5=a very great deal) with a standardized OAB V8 questionnaire [10]. OAB was defined as “the presence of urgency with or without urge incontinence and usually with frequency and nocturia” [11]. During the first visit, the diagnosis of OAB was made when the patient answered “somewhat” or more to any one of the three urge questions in OAB V8 questionnaire (question 2, An uncomfortable urge to urinate?; question 3, A sudden urge to urinate with little or no warning?; question 7, An uncontrollable urge to urinate?), once we had excluded any obvious etiology. The contents of 3-day voiding diary, including daily fluid intake, maximum voided volume, micturition numbers per day, urgency and incontinence episodes per day, were recorded prior to the second visit. Therefore, the baseline of OAB symptoms come from the OAB V8 questionnaire and 3-day voiding diary. Following POP surgery, women reporting a lower score to any one of the three urge questions were placed into the “Improvement” group. Those who answered the same or greater scale were classified into the “Persistence” group.

Urodynamic studies, including spontaneous uroflowmetry, filling and voiding cystometry, and urethral pressure profilometry, were performed according to the recommendations by the International Continence Society [12] with a 6-channel urodynamic monitor (MMS; UD2000, Enschede, The Netherlands). Any uninhibited detrusor contraction during filling cystometry was deemed positive for idiopathic DO. Urodynamic stress incontinence (USI) was defined as involuntary urine leakage with cough in the absence of detrusor contraction during cystometry. The preoperative

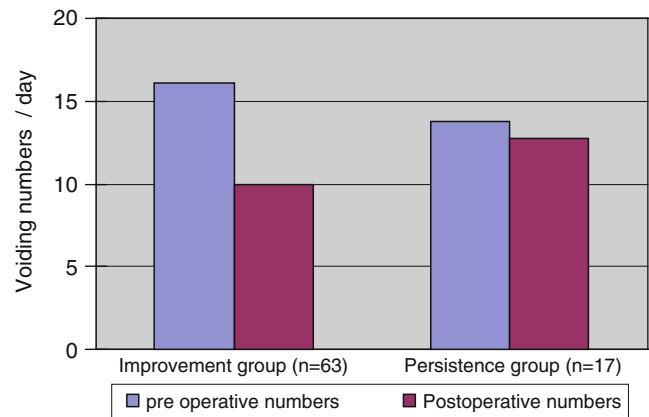
diagnosis of occult USI was made by a positive cough stress test with the prolapse reduction by a vaginal packing during the cystometry.

Perigee–Apogee and Prolift systems are similar with only subtle differences in the posterior procedure involved. In the Prolift procedure for apical and posterior prolapse, the trocar is inserted 3 cm lateral and inferior to the anus. The needle is designed to pass through the sacrospinous ligament at a level of 2 cm posterior and medial to the ischial spine. The Apogee system uses the same insertion location, but with a more helical trocar that pierces the ileococcygeus muscle rather than the sacrospinous ligament at the level of the ischial spine. During anterior mesh repair, superior trocars of both devices are inserted through the upper medial angle of the obturator foramen at the level of clitoris, while the inferior trocars are inserted 2 cm inferior and 1 cm lateral to the upper incisions [13]. All trocars are designed to pass through the arcus tendineus and emerge with the vaginal incision. All patients were given antibiotic prophylaxis (intravenous Cefazolin 1 g; Cefamezin, Fujisawa, Tokyo, Japan) administered before surgery. The operation was carried out with the patient under epidural or general anesthesia. All surgeries were performed mainly by the first author (C.Y.L.), with individual experience of more than 100 transvaginal POP repairs.

Ethics approval by the institutional review board of our hospital had been obtained for this study. Potential predictors that were analyzed for the improvement of OAB symptoms after POP surgery included the past gynecologic history, sling type, urinary symptoms as well as preoperative urodynamic parameters. A statistical analysis was performed using Student's *t* test or Wilcoxon's signed-rank test for parametric or non-parametric continuous variables, and the McNemar's test, Chi-square, or Fisher's exact test for categorical variables. A logistic regression model and odds ratios (with 95% confidence intervals) were used to assess the independent prognostic value of the variables associated with OAB improvement. A difference was considered statistically significant when  $P < 0.05$ .

## Results

Postoperatively, 63 (78.8%) women experienced absence or improvement of OAB symptoms (Improvement group), and 17 (21.2%) women remained unchanged or worsened (Persistence group). When analyzing the data for bladder diaries, the number of voids over 24 h in the Improvement group significantly decreased from  $15.8 \pm 4.3$  preoperatively to  $10.0 \pm 4.0$  postoperatively (paired *t* test;  $P = 0.02$ ). In the Persistence group, the corresponding figures were  $13.8 \pm 2.2$  and  $12.7 \pm 2.2$ , respectively (Wilcoxon signed-rank test;  $P = 0.83$ ; Fig. 1)



**Fig. 1** Voiding numbers per day in both groups of women with prolapse reporting overactive bladder symptoms before and after surgery

The demographic characteristics of these 80 women are summarized in Table 1. Study participants had their POP and/or USI treated surgically with over one transvaginal procedures (Table 2). As for the POP-Q analyses of these 80 women, there was a significant improvement at points Aa, Ba, C, Ap, and Bp ( $P < 0.001$ ) except for total vaginal length ( $P = 0.36$ ; Table 3).

We performed a univariate analysis of patients' characteristics and preoperative urodynamic parameters to identify potential predictors of OAB improvement after transvaginal mesh repair. There was no difference between the two groups with regards to parity, body mass index, diabetes, hypertension, prior surgery, prolapse status, mesh device, concomitant sling procedures, mesh erosion, 24-h voiding numbers, and a variety of preoperative urinary symptoms and urodynamic parameters ( $P > 0.05$ ; Tables 4 and 5).

However, we found that the age (Fisher's exact test;  $P = 0.042$ ) and DO (Fisher's exact test;  $P = 0.03$ ) were

**Table 1** Demographic characteristics of women ( $n = 80$ ) with pelvic organ prolapse and overactive bladder symptoms

Age (years)	58.6 ± 12.0
Parity	3.5 ± 1.6
BMI (kg/m <sup>2</sup> )	24.9 ± 3.4
Menopause	61 (76.3)
Current hormone therapy	19 (23.8)
Current smokers	2 (2.5)
Diabetes Mellitus	10 (12.5)
Hypertension	32 (40.0)
History of hysterectomy	12 (15.0)
History of POP and/or SUI Surgery	4 (5.0)

Data are given as mean ± standard deviation or *n* (%).

BMI body mass index, POP pelvic organ prolapse, SUI stress urinary incontinence

**Table 2** Surgical procedures performed in all participants ( $n=80$ )

Procedures	$n$ (%)
Anterior repair with mesh	42 (52.5)
Anterior and posterior repair with mesh	38 (47.5)
Concomitant procedures	
Vaginal hysterectomy	8 (10.0)
Midurethral sling	
TVT	3 (3.8)
TVT-O	42 (52.5)
Monarc	3 (3.8)
Posterior colporrhaphy	2 (2.5)

POP pelvic organ prolapse

significant predictors of postoperative OAB improvement. The women with OAB improvement were younger (age under 60 years; odds ratio, 3.23; 95% confidence interval, 1.01–10.0) and more likely to have a DO during the preoperative urodynamics (odds ratio, 4.22; 95% confidence interval, 1.10–16.22; Tables 4 and 5). DO was documented in 32 subjects (40%), and 29 of them (90.6%) reported subjective improvement of OAB symptoms after POP surgeries. After adjusting the age factor, we found that DO was the only significant predictor of postoperative relief of OAB (odds ratio, 5.26; 95% confidence interval, 1.49–25.0).

When evaluating the changes in the urodynamic parameters of both groups, including residual urine, maximum cystometric capacity, detrusor pressure at peak flow, maximum urethral closure pressure, and urethral closure pressure area, these were not significantly different following POP surgery ( $P>0.05$ ). However, maximum flow rate, volume at first sensation to void, and functional urethral length increased significantly in the Improvement group after surgery ( $P<0.05$ ), but this was not the case in the Persistent group ( $P>0.05$ ). Similarly, the rate of DO decreased significantly postoperatively only in the Improvement groups ( $P<0.01$ ; Table 6).

**Table 3** Pelvic organ prolapse quantification (POP-Q) values before and after surgery

Data are given as median (range) or  $n$  (%)

Pre-op preoperative,  
Post-op postoperative,  
Tvl total vaginal length

<sup>a</sup> Wilcoxon signed-rank test

POP-Q parameters (cm)	Pre-op ( $n=80$ )	Post-op ( $n=80$ )	$P$ values <sup>a</sup>
Aa	2 (0~3)	-2 (-1~-3)	<0.001
Ba	3 (-1~6)	-2 (-5~0)	<0.001
C	0 (-4~6)	-6 (-7~-3)	<0.001
Ap	-1 (-2~3)	-2 (-3~0)	<0.001
Bp	0 (-3~4)	-2 (-5~0)	<0.001
Tvl	8 (6~9)	8 (6~9)	0.36
Recurrent POP		3 (3.8)	

## Discussion

In our study, 78.8% of women experienced absence or improvement of OAB symptoms after transvaginal POP repairs, which is in accordance with previous studies [6, 7]. Interestingly, we did not find a correlation between increasing stage of POP and OAB improvement. The mechanism that is responsible for symptom relief after POP surgery is still not well understood. Some may take concern with our use of the term “OAB” in this study since the definition excludes proven pathology [11]. However, there is no consensus in the literature as to whether POP is a true etiology for OAB.

In an attempt to improve outcome of traditional surgery, synthetic materials are increasingly being used to augment POP repair despite insufficient evidence on the long-term safety. The effects of Perigee and Prolift (anterior system) devices should theoretically be similar on urinary symptoms due to the similar mesh materials and wound locations. Therefore, women undergoing either procedure were enrolled together for analyses. As expected, we observed no association between the improvement of OAB and different surgical kits.

Nearly half of our patients undergoing POP surgery will have multi-compartmental prolapse requiring repair of each. Dysfunctional voiding in itself can be multifactorial and should not be considered to be solely related to anterior vaginal wall prolapse. As such, the inclusion of repairs from other compartments may be an additional advantage and results in a higher resolution of voiding dysfunction [14]. The vaginal erosion rate (8/80; 10%) in our study was much higher than the 4.7% reported by Fatton et al. [15], yet it was similar to the figure of 12.7% reported by Collinet et al. [16].

There is a high prevalence of changeable OAB symptoms in postmenopausal women, while most women undergoing POP surgery falling into this age group. Previous studies have also shown the aging process as a significant etiologic factor of OAB [17]. Postoperative changes in urinary symptoms therefore were assessed within a short-term interval (6 months) in our study to

**Table 4** Analysis of clinical features in both groups

	Improvement (n=63)	Persistence (n=17)	P value	OR (95%CI) <sup>a</sup>
Age (years)				
<60	36 (57.1)	5 (29.4)	0.042	1
≥60	27 (42.9)	12 (70.6)		3.23 (1.01~10.0)
Parity				
<4	39 (61.9)	10 (58.8)	0.91	1
≥4	24 (38.1)	7 (41.2)		1.14 (0.37~3.37)
BMI				
Healthy<25	35 (55.6)	8 (47.1)	0.69	1
Overweight 25–30	24 (38.1)	7 (41.2)		1.28 (0.40~4.02)
Obese>30	4 (6.4)	2 (11.8)		2.19 (0.27~13.45)
Past history				
HRT	15 (23.8)	4 (23.5)	0.98 <sup>b</sup>	0.92 (0.23~3.09)
Menopause	48 (76.2)	13 (76.5)	0.98	1.02 (0.30~4.02)
H/T	25 (39.7)	7 (41.2)	0.91	1.06 (0.35~3.14)
DM	7 (11.1)	3 (17.7)	0.47	1.71 (0.34~7.07)
Hysterectomy	8 (12.7)	4 (23.5)	0.27 <sup>b</sup>	2.12 (0.50~7.88)
Previous pop or SUI Sx	2 (3.2)	2 (11.8)	0.19 <sup>b</sup>	4.06 (0.46~36.20)
Prolapse				
stage II	20 (31.8)	6 (35.3)	0.78	1.17 (0.36~3.55)
stage III–IV	43 (65.1)	11 (64.7)		
Anterior wall prolapse	52 (82.5)	14 (82.4)	0.99	0.99 (0.26~4.79)
Uterine prolapse	16 (25.4)	8 (47.1)	0.08	2.61 (0.85~8.01)
Vault prolapse	6 (9.5)	4 (23.5)	0.21 <sup>b</sup>	2.92 (0.69~11.80)
Posterior wall prolapse	4 (6.4)	1 (5.9)	0.94 <sup>b</sup>	0.92 (0.05~6.79)
Device				
Perigee	32 (50.8)	9 (52.9)	0.88	1
Prolift	31 (49.2)	8 (47.1)		0.92 (0.31~2.70)
Concomitant procedures				
Hysterectomy	8 (12.7)	0	0.12 <sup>b</sup>	—
Midurethral sling	35 (55.6)	13 (76.5)	0.12	2.60 (0.82~10.03)
TVT	2 (3.2)	1 (5.9)		
TVT-O	31 (49.2)	11 (64.7)		
Monarc	2 (3.2)	1 (5.9)		
Mesh erosion	6 (9.5)	2 (11.8)	0.68 <sup>b</sup>	1.27 (0.17~6.17)
Pre-op symptoms				
SUI	38 (60.3)	10 (58.8)	0.91	0.94 (0.32~2.86)
UI	29 (46.0)	6 (35.3)	0.43	0.64 (0.20~1.90)
Nocturia	37 (58.7)	12 (70.6)	0.37	1.68 (0.55~5.83)
Bladder diary				
Voiding numbers/day				
<12	19 (30.2)	7 (41.2)	0.39	1
≥12	44 (69.8)	10 (58.8)		1.62 (0.52~4.88)

Data are given as n (%)

OR odds ratios, CI confidence intervals, BMI body mass index, HT hormone therapy, H/T hypertension, DM diabetes mellitus, POP pelvic organ prolapse, SUI stress urinary incontinence, TVT tension-free vaginal tape, TVT-O TVT-obturator system, Pre-op preoperative, UI urge incontinence

<sup>a</sup> Univariate logistic regression<sup>b</sup> Fisher's exact test

— cannot be calculated

control for this confounding factor. After a univariate analysis, age under 60 years is an important factor for OAB improvement following POP repair. A possible explanation may be that “aged” bladders of elder women are less likely to be reversed by anatomical correction. This finding also accounts for the higher rate of OAB improve-

ment in our younger patients than the report of Foster et al. [6].

Both neurogenic and myogenic theories have also suggested that DO increases with age [18]. However, in our study, the rate of DO was observed to be significantly higher in “younger” Improvement group. An alternate

**Table 5** Comparison of preoperative urodynamic parameters in both groups

	Improvement (n=63)	Persistence (n=17)	P value	OR (95%CI) <sup>a</sup>
DO	29 (46.0)	3 (17.7)	0.03 <sup>b</sup>	4.22 (1.10–16.22)
Qmax (ml/s)				
<15	22 (34.9)	6 (35.3)	0.73	1
15–25	31 (49.2)	7 (41.2)		0.83 (0.24~2.89)
>25	10 (15.9)	4 (23.5)		1.47 (0.32~6.36)
RU (ml)				
<50	38 (60.3)	12 (70.6)	0.73	1
50–150	19 (30.2)	4 (23.5)		0.67 (0.17~2.21)
>150	6 (9.5)	1 (5.9)		0.53 (0.03~3.54)
FS (ml)				
<100	18 (28.6)	3 (17.7)	0.36	1
≥ 100	45 (71.4)	14 (82.4)		1.87 (0.53~8.79)
MCC (ml)				
<300	40 (63.5)	7 (41.2)	0.10	1
≥ 300	23 (36.5)	10 (58.8)		0.40 (0.13~1.19)
Pdet (cmH <sub>2</sub> O)				
<15	11 (17.5)	0	0.17	—
15–25	16 (25.4)	6 (35.3)		
>25	36 (57.1)	11 (64.7)		
FUL (mm)				
<25	24 (38.1)	9 (52.9)	0.67	1
≥25	39 (61.9)	8 (47.1)		0.55 (0.18~1.62)
MUCP (cmH <sub>2</sub> O)				
<40	10 (15.9)	1 (5.9)	0.29	1
≥40	53 (84.1)	16 (94.1)		3.02 (0.52~57.51)
UCA (mmcmH <sub>2</sub> O)				
<1000	36 (57.1)	11 (64.7)	0.57	1
≥1000	27 (42.9)	6 (35.3)		0.73 (0.23~2.16)

Data are given as n (%)  
OR odds ratios, CI confidence intervals, DO detrusor overactivity, Qmax maximum flow rate, RU residual urine, FS first sensation to void, MCC maximum cystometric capacity, Pdet detrusor pressure at peak flow, FUL functional urethral length, MUCP maximum urethral closure pressure, UCA urethral closure area  
<sup>b</sup> Fisher's exact test  
<sup>a</sup> Univariate logistic regression  
— cannot be calculated

**Table 6** Urodynamic changes in both groups before and 6 months after surgery

Parameters	Improvement (n=63)			Persistence (n=17)		
	Pre-op	Post-op	P value	Pre-op	Post-op	P value
DO	29 (46.0)	8 (12.7)	<0.01 <sup>a</sup>	3 (17.7)	3 (17.7)	1.0 <sup>a</sup>
Qmax (ml/s)	17.5±9.1	20.1±8.2	0.047 <sup>b</sup>	16.8 (4.9-32.9)	16 (7.8-31.8)	0.72 <sup>b</sup>
RU (ml)	64.6±35.4	49.7±30.6	0.18 <sup>b</sup>	32 (0-225)	38 (0-185)	0.09 <sup>b</sup>
FS (ml)	143.9±71.8	167.5±65.4	0.02 <sup>b</sup>	123 (40-310)	151 (16-252)	0.87 <sup>b</sup>
Pdet (cmH <sub>2</sub> O)	32.5±14.1	28.7±17.2	0.11 <sup>b</sup>	30 (15-52)	27 (12-46)	0.79 <sup>b</sup>
MCC (ml)	355.4±97.2	361.1±104.0	0.67 <sup>b</sup>	321 (100-535)	295 (182-562)	0.46 <sup>b</sup>
FUL(mm)	25.3±7.8	27.6±5.3	0.024 <sup>b</sup>	25 (18-34)	28 (14-32.8)	0.76 <sup>b</sup>
MUCP (cmH <sub>2</sub> O)	58.4±25.6	61.4±24.3	0.23 <sup>b</sup>	62 (38-134)	63 (16-123)	0.25 <sup>b</sup>
UCA (mm.cmH <sub>2</sub> O)	902.7±500.5	1017.1±508.6	0.07 <sup>b</sup>	780 (286-2110)	870 (124-2150)	0.39 <sup>b</sup>

Data are given as n (%) or mean±standard deviation

DO detrusor overactivity, Qmax, maximum flow rate, RU residual urine, FS first sensation to void, Pdet detrusor pressure at peak flow, MCC maximum cystometric capacity, FUL functional urethral length, MUCP maximum urethral closure pressure, UCA urethral closure pressure area

<sup>a</sup> McNemar's test

<sup>b</sup> Wilcoxon's signed rank test

explanation would be that severe POP could cause bladder outlet obstruction by urethral kinking or external compression [4], which can promote uninhibited detrusor contractions. Our findings of postoperative OAB improvement after mesh repair can be simply related to the release of urethral obstruction.

The urodynamic parameters, including maximum flow rate, volume at first sensation to void, and functional urethral length increased significantly after surgery only in the Improvement group, also indicating the effects of POP correction on urethral obstruction. However, all preoperative urodynamic parameters were not significant predictors of the OAB improvement in our analyses. In addition, significant reduction in the number of voids over 24 h within the Improvement group emphasizes the importance and consistency of both symptom questionnaires and bladder diaries in our series.

Although previous studies reported that the incidence of OAB increased significantly when POP repair and TVT were performed together [8], we observed no significant association between the incidence of OAB and concomitant midurethral sling procedures. This may be due to the fact that the majority of our patients underwent transobturator tape (TOT) rather than TVT procedure. The horizontal orientation of the TOT tape may be less obstructive [19–23], and causes less-irritative symptoms. However, whether the TOT is more suitable in women with preoperative OAB symptoms remains unclear.

A strength of our study is the simplicity and effectiveness of surgical procedures. All subjects underwent a transvaginal reconstructive surgery using non-absorbable mesh although some women required repairs of more than one compartment. The excellent short-term success rate of synthetic mesh could reflect the true effect of anatomical restoration on OAB symptoms [5]. In spite of limited cases, all of our data were collected prospectively as standard survey for patient care visits. We believe this can minimize the study bias.

In conclusion, the results of our study suggest that women with advanced POP can expect significant resolution of OAB symptoms after transvaginal mesh repair. Both age and DO were two predictors in the univariate analysis, and the latter was found to be the only significant predictor of symptom relief after adjusting age factor. However, all women undergoing surgery for POP still need to be informed that OAB symptoms might persist postoperatively. Future research in POP repair evaluating different techniques and mesh materials are needed to identify more predictors and confirm our findings. Then physicians could tailor an appropriate procedure in individual patient.

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**Conflicts of interest** None.

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