



Original Article

Improvement of overactive bladder symptoms: Is correction of the paravaginal defect in anterior vaginal wall prolapse necessary?

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Abstract

Background: To explore the relationship between overactive bladder (OAB) symptoms and paravaginal defects (PVDs), and to identify the necessity of PVD repair by transvaginal mesh (TVM) for the treatment of OAB symptoms.

Methods: A retrospective clinical study of 30 women with advanced cystocele with limited apical and posterior vaginal wall prolapse was conducted to identify any changes in OAB symptoms following a single Perigee procedure. Prolapse was assessed using the pelvic organ prolapse quantification (POP-Q) system, and paravaginal defects were identified by sonography. Complete urodynamic examination was performed prior to and one year after operation. All patients completed the overactive bladder questionnaire pre- and postoperatively for a quantitative assessment of OAB symptoms.

Results: All patients showed a significant improvement at points Aa and Ba in the POP-Q system. The results of the administered questionnaire revealed statistically significant improvement postoperatively. The difference of OAB symptoms between the group with PVDs and that with central defects was not statistically significant ($p = 0.67$). Moreover, no statistically significant improvement of OAB symptoms in the group with repaired PVDs was observed postoperatively ($p = 0.42$).

Conclusion: Statistical improvements of symptoms exist after Aa and Ba points recovery as evaluated by POP-Q system regardless of PVD existence identified by sonography. Repairing PVD did not show significantly improve the severity of OAB symptoms in objective urodynamic data or subjective questionnaire data. The superiority of TVM in PVD repair to manage OAB symptoms seems not manifest.

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Keywords: Cystocele; Overactive bladder; Overactive detrusor; Surgical mesh; Urinary bladder prolapse; Vaginal prolapse

1. Introduction

In 2002, the Food and Drug Administration (FDA) cleared the first surgical mesh product specifically for use in pelvic organ prolapse (POP). However, in 2008 and 2011, the FDA issued a safety communication that warned physicians and consumers about an increase in adverse event reports related to the mesh used for urogynecological procedures. By convening an advisory panel and issuing orders to manufacturers to

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address specific safety and effectiveness concerns, the FDA reclassified transvaginal mesh (TVM) from class II (moderate risk) to III (high risk) in 2014. During this period, owing to the numerous lawsuits and the serious FDA warnings, some of the controversial products were taken off the market. This had caused a concern among urogynecologists because the products were unique and irreplaceable.

Before TVM was released to the market, successful treatment of paravaginal defects (PVD) was one of the most challenging aspects of pelvic reconstructive surgery. The technical difficulties in performing an effective PVD repair, as described by White in 1912,¹ have limited its widespread use in clinical practice.^{2,3} Thus, anterior colporrhaphy became the most popular surgical procedure to repair anterior vaginal prolapse, owing to its simplicity.² However, the recurrence rate was high associated with anterior colporrhaphy, which could be attributed to inadequate PVD repair, was an extremely significant limitation.⁴ The mesh of TVM connected with four anchors had adequate support to repair the paravaginal defect and was acclaimed because of its ability to repair a cystocele in one procedure regardless of the defect, i.e., whether central or paravaginal. The outcomes of advanced anterior vaginal wall prolapse repair by TVM have been cited in several studies.^{5–9}

Overactive bladder (OAB) symptoms, such as urinary frequency, urgency, and nocturia, are common among patients with vaginal anterior wall prolapse.^{10,11} Previous studies reported that patients with severe vaginal prolapse (cystocele grades 3 and 4) experience more urinary urgency and frequency.¹² Even, a significant decrease in detrusor overactivity following surgery was noted among patients with advanced prolapse.^{12,13} Nevertheless, the relationship between vaginal wall prolapse and OAB symptoms still remains controversial.^{14–16} This may be because, previously, anterior vaginal wall repair was inadequate, especially for PVDs.^{1,2,4}

In this study, we employed the Perigee™ system (Trans-obturator Anterior Prolapse Repair System, American Medical Systems Inc., Minnetonka, MN), which was a pioneer of TVM device and designed to repair central and bilateral PVDs simultaneously.^{5,17,18} A sonographic scan was performed, as described by Ostrzensky, to assess paravaginal wall defects precisely.¹⁹ Consequently, we could evaluate whether PVD repair by Perigee affects OAB symptoms.

The aim of this study was to explore the relationship between OAB symptoms and PVDs and to identify the necessity of PVD repair by TVM for the treatment of OAB symptoms.

2. Methods

The statistical data were from our previous study conducted from 2006 to 2010. This study was supported by the Medical Research Project (CMRPG250091) at Chang Gung Memorial Hospital in Keelung, Taiwan, and approved by the Institutional Review Board of the same institution. All patients had OAB symptoms for more than 6 months. Our diagnosis of OAB syndrome was consistent with the following definition proposed by the International Continence Society (ICS) in 2002: urinary urgency with or without urge incontinence, usually

with urinary frequency (voiding eight times or more in a 24-h period), and nocturia (awakening two or more times at night to void).²⁰ All patients with OAB symptoms had no history of anti-incontinence surgery, pelvic reconstructive surgery, or any urological surgery. The exclusion criteria also included the presence of symptoms related to voiding dysfunction with high residual urine volume, chronic pelvic pain, and painful bladder syndrome. Furthermore, patients on medication that could affect bladder function and those with hypertension, diabetes mellitus, diabetes insipidus, neurological disorders, stroke, and psychological problems, followed up on an outpatient basis, were also excluded. All patients underwent routine urinary and pelvic examinations. Patients with pathological conditions, such as urinary tract infection, urogenital tract malignancy, pelvic mass or malignancy, urethral diverticulum, urinary tract stone history, or intravesical lesion were also excluded. In addition, no patient showed a significant increase in uterine size or pelvic mass in sonographic examination.

Patients were screened according to the Baden–Walker system.^{18,21} Those with anterior wall prolapse of Grade 3 or above were enrolled. The prolapse in each vaginal segment was measured according to the pelvic organ prolapse quantification (POP-Q) system. A sonographic scan was performed, as described by Ostrzensky and Osborne, to assess PVDs (Fig. 1).¹⁹ A 27-Hz curved transducer was used with the patient having full bladder and lying supine. The images were in a transverse suprapubic view (Fig. 1).

A complete urodynamic examination was performed immediately prior to and one year after operation. This includes urodynamic studies, consisted of filling cystometry, urethral pressure profilometry, and free uroflowmetry, performed with the patient in supine position and using water media with a Duet Logic G2 manometer (Medtronic-Dantec™, Denmark). A triple-lumen urethral catheter (8 Fr.) was inserted into the urethra and then pulled at 2 mm/s. For uroflowmetry, the patients were seated on a micturition chair for the assessment, with sufficient gauze placed in the vagina during the test.

All patients were asked to complete the overactive bladder questionnaire (OAB-q, translated into Chinese, downloaded from the website: <https://www.pfizerpatientreportedoutcomes.com>, Copyright © 2004 Pfizer Inc.) for the quantitative assessment of symptoms before and one year after operation.²²

2.1. Operative procedures

The Perigee procedure, similar to that described by Palma et al., was performed in all patients by the same physician. The patients were placed under general endotracheal anesthesia. Dissection made the rollover of the anterior vaginal wall to the level of the bladder neck possible. Lateral dissection at the ischium–pubic level allowed four Perigee needles to pass through. Each needle was pulled back, and the mesh underneath the cystocele was kept in a tension-free manner. The mesh was drawn down to the lowermost portion of the cystocele and fixed at that point by suture.

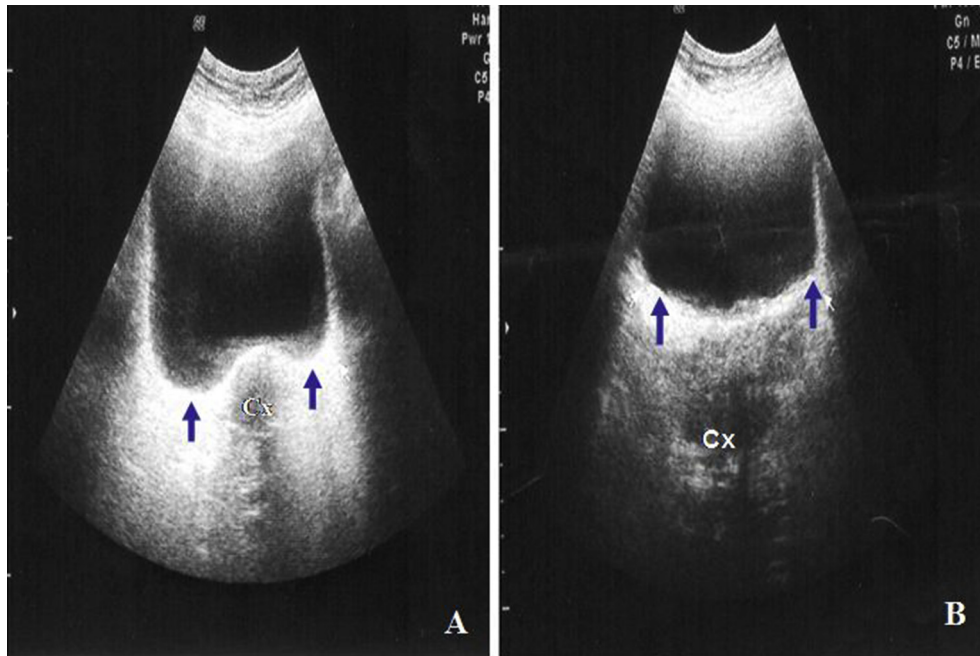


Fig. 1. The sonographic pictures of paravaginal defects (A) Blue arrow showed the paravaginal defects prior to and after operation (B) Blue arrow showed there is no paravaginal defects prior to and after operation. Cx: cervix of uterus.

2.2. Statistical analysis

All analyses were performed using SPSS for Windows version 17.0 (SPSS Inc., Chicago, IL). Statistical significance was considered at $p < 0.05$. The demographics of the patients and their operative results were summarized using descriptive statistics (median and range). Continuous variables were compared using non-parametric testing (Wilcoxon signed-rank test) for data that were not normally distributed. All probability values were two-sided. To investigate the effectiveness of transvaginal surgery for advanced vaginal wall prolapse in relieving OAB symptoms, the paired t-test and Wilcoxon signed-rank test were employed to compare the “health-related quality of life”, symptom bother scores, and POP-Q values of all patients before and after transvaginal surgery. Moreover, the Wilcoxon signed-rank test and the McNemar test were employed to compare the pre- and postoperative urodynamic data and to detect any PVD before and after transvaginal surgery, respectively.

3. Results

A total of 36 women underwent single Perigee procedure for advanced vaginal wall prolapse and completed the sonographic examination during the study period. Only the complete data records of 30 cases were analyzed as we lost contact with three of the patients and another three patients dropped out of the study. The mean age was 61.9 years. The average number of children to which the patients had given birth was 3.67. The mean operation time, blood loss, and postoperative hospital stay was 90 min, 65 mL, and 4.6 days, respectively shown in Table 1.

Table 2 presents both the pre- and postoperative POP-Q values. A comparison between the two values can shed light on the effectiveness of the operation in the treatment of an advanced cystocele. Statistical analysis showed statistically significant improvements after operation at points Aa and Ba ($p < 0.001$). The natural length of the vagina, denoted by Tv1, points C and D was found to increase slightly after operation; however, it was not statistically significant. This means that the Perigee procedure could not affect vaginal length; as we know, it could not significantly improve the vault prolapse when there is abdominal strain.

Table 3 shows all of the patients' response to the questionnaire and the results of the urodynamic studies in relation to OAB symptoms both before and after operation.

Table 1
Demographics of subjects.

Variable	Value ^a
Age (y)	61.90 (43–76)
BMI (kg/m ²)	24.82 (17.90–31.96)
Prior vaginal deliveries, no.	3.67 (1–7)
Operating time (mins)	90.40 (60–110)
Blood loss (mL)	65.00 (50–150)
Postoperative stay (days)	4.63 (3–8)
Symptoms, no. (%)	
Frequency	15 (50.0)
Urgency	13 (43.3)
Nocturia	11 (36.7)
UUI	6 (20.0)
SUI	12 (40.0)

BMI = Body Mass Index.

UUI = Urge Incontinence.

SUI = Stress Urinary Incontinence.

^a Values are presented as median (interquartile range).

Table 2
Pelvic organ prolapse quantification (POP-Q) values prior to and one year after operation.

POP-Q measurements (cm)	Pre-operative	Post-operative	<i>p</i>
Aa	0.90 (–1~3)	–2.80 (–3~-1)	<0.001
Ba	1.05 (–1~4)	–2.80 (–3~-1)	<0.001
C	–2.86 (–8~7)	–6.24 (–8~-4)	0.001
gh	3.33 (2~4)	3.25 (2~5)	0.682
pb	3.93 (3~6)	4.17 (2~7)	0.122
tvI	8.32 (6~11)	8.48 (7~11)	0.710
Ap	–1.43 (–3~1)	–2.30 (–3~-1)	0.002
Bp	–1.53 (–3~1)	–2.28 (–3~-1)	0.003
D	–3.43 (–9~8)	–6.62 (–10~9)	0.001

Table 3
The patients' response to the questionnaire and the results of the urodynamic studies in relation to OAB symptoms both before and after operation.

	Pre-operative (n = 30)	Post-operative (n = 30)	<i>p</i>
HRQL (total)	65.5 ± 26.9	42.3 ± 22.6	<0.001
Symptom severity	22.2 ± 9.4	13.8 ± 6.0	<0.001
Coping	21.9 ± 9.4	14.7 ± 9.8	0.005
Concern	20.0 ± 9.3	11.7 ± 7.5	<0.001
Sleep	13.5 ± 6.1	9.2 ± 4.4	0.003
Social activity	10.2 ± 5.1	6.7 ± 3.3	0.003
Normal Desire (ml)	240.3 ± 122.7	196.0 ± 97.6	0.13
Cystometric Capacity (ml)	445.1 ± 121.7	398.1 ± 142.2	0.17

Data are given as average ± SD.

HRQL = health-related quality of life (in questionnaire).

Data of Normal desire and Cystometric Capacity were original from urodynamic study.

A significant improvement was noted in the overall outlook after the operation in almost all patients, both in their physical condition and general daily lives, including their coping with the symptoms, their concerns, and even their sleeping patterns. Thus, based on the results of the administered questionnaire, statistically significant improvements of symptoms exist after anatomic recovery as evaluated by POP-Q system regardless of PVD existence identified by sonography. Of interest, urodynamic study results revealed that the average urine volume

of normal desire to void and maximum cystometric capacity after operation were decreasing. However, no statistical significance before and after operation (*p* = 0.13 and *p* = 0.17, respectively) was noted. Therefore, the urodynamic study results were not compatible with clinical symptoms.

The 30 patients grouped according to the sonography results before and after operation are listed in Table 4. Patients in group A (seven cases, 23.3%) had PVD before and after operation, which means that the Perigee procedure failed to repair the PVD. Patients in group B (15 cases, 50%) had PVD before operation, but the PVD could not be detected by sonography after operation, which means that the PVD was repaired by the Perigee procedure. Patients in group C (eight cases, 26.7%) had no PVD before and after operation; these patients had a single central defect.

Table 4 also showed the difference in symptom severity between PVD and a single central defect. The patients in groups A and B had PVD while those in group C had a single central defect before operation. The OAB symptom severity in group C was higher than that in groups A and B. However, no statistical significance between the PVD group and single central defect group was observed (*p* = 0.67). Furthermore, the single central defect caused more severe OAB symptoms than PVD; however, no conclusive evidence was found.

The comparison between the OAB symptoms of patients with persistent PVD and those of patients without PVD after operation is shown in Table 4. The patients in group A showed higher severity of OAB symptoms than those in group B and C. Thus, PVD repair could reduce OAB symptom severity. However, no statistical significance between the two groups was observed (*p* = 0.42). Of interest, the urine volume of normal desire after PVD repair increased, which showed statistical significance (*p* = 0.01). In this case, the urodynamic study results were compatible with clinical findings. Furthermore, the maximum cystometric capacity in group B was higher than that in group A. Therefore, PVD repair could improve the maximum cystometric capacity; however, no statistical significance between two groups were noted (*p* = 0.32).

Table 4
Patients were grouped according to with or without PVD checked by the sonography results before and after operation.

	Pre-operative			Post-operative		
	Existence of PVD (Group A + B, n = 22)	Single central defect (Group C, n = 8)	<i>p</i>	PVD not corrected (Group A, n = 7)	Single central defect + PVD corrected (Group B + C, n = 15)	<i>p</i>
HRQL	64.1 ± 26.3	69.4 ± 29.9	0.67	48.0 ± 19.6	40.6 ± 23.6	0.42
Symptom severity	20.9 ± 8.4	25.6 ± 11.7	0.32	12.4 ± 4.6	14.3 ± 6.3	0.41
Coping	21.8 ± 9.5	22.3 ± 9.6	0.91	18.4 ± 10.5	13.7 ± 9.6	0.34
Concern	19.2 ± 8.3	22.1 ± 12.0	0.54	12.9 ± 5.4	11.3 ± 8.1	0.58
Sleep	13.2 ± 5.5	14.3 ± 7.9	0.73	10.1 ± 5.8	8.9 ± 4.0	0.62
Social activity	10.0 ± 5.3	10.8 ± 4.7	0.70	6.9 ± 2.9	6.7 ± 3.5	0.88
Normal desire (ml)	259.6 ± 125.4	187.1 ± 103.7	0.13	137.4 ± 50.6	213.8 ± 102.1	0.01*
Cystometric Capacity (ml)	455.2 ± 130.8	417.4 ± 93.7	0.40	332.0 ± 205.4	418.2 ± 115.5	0.32

Data are given as average ± SD.

HRQL = health-related quality of life.

Data of Normal desire and Cystometric Capacity original from urodynamics.

4. Discussion

OAB symptoms are closely related to vaginal anterior wall prolapse.^{10,11} This study shows that the Perigee procedure can adequately resolve advanced cystocele as measured by POP-Q system, with points Aa and Ba almost returning to their original anatomical positions shown in Table 2. This allowed us to deeply explore the relationship between cystocele and OAB symptoms.

After the recovery of cystocele measured by POP-Q system, a statistically significant improvement of OAB symptoms based on the responses to the OAB-q after the operation was shown in Table 3. The relationship between cystocele and OAB symptoms was statistically significant in our study. Yet, the cystocele was confirmed by pelvic examination but instrument diagnosis.

Further, we evaluated the relationship between PVDs and OAB symptoms. Interestingly, there was no statistically significant difference in OAB symptoms in the group with PVDs and no statistically significant improvement of OAB symptoms in the group with repaired PVDs after operation, as shown in Table 4. Thus, the relationship between PVDs and OAB symptoms seems to be unclear. However, the existence of PVDs was identified by sonography but pelvic examination.

The mesh of TVM connected with four anchors theoretically had adequate support to repair the paravaginal defect and central defect in one procedure. In our study, sonography showed that 22 of 30 patients (73.3%) already had a significant angle of PVDs prior to surgery. This result was compatible with the high percentage of PVDs in advanced cystocele. Some article showed that the TVM indeed yielded favorable outcomes for the repair of advance cystocele, especially with PVDs.^{6–9} In our study, all the eight cases (100%) with single central defect improved. Relatively, only 15 of 22 cases (68.2%) with PVD improved after operation. Perigee kits for PVD repair seem insufficient. We supposed that the results were attributed to inadequate width of mesh or mesh shrinking after operation.

Although the group without PVD had no statistically significant improvement of OAB symptoms compared with that with persistent PVD (Table 4), the former had a higher and statistically significant urine volume of normal desire to void and maximum cystometric capacity than the latter based on the urodynamic study results. The role of urodynamics in the evaluation of patients with OAB symptoms is controversial. In contrast to the subjective data from the OAB-q, several tables in our study show a number of contrasting urodynamic results. This could be a reason for the question on the effectiveness and accuracy of urodynamics in assessing OAB symptoms.

The components of a PVD are hard to evaluate by pelvic examination alone; thus, magnetic resonance imaging is advisable. However, sonographic scanning, as first described by Ostrzensky and Osborne, is an acceptable alternative.¹⁹ Several studies confirmed that scanning provides useful feedback to surgeons and helps evaluate the anatomical recovery of PVDs.^{23,24} In our study, no statistically significant difference of OAB symptoms between a single central defect and PVDs before operation was observed (Table 4). Furthermore, no statistically significant difference of OAB symptoms

was noted regardless of the PVD status after operation. In summary, identifying PVDs by sonography seems a redundant process in clinical practice; hence, it has no practical value. It also meant that PVD repair might not be a key to treat OAB symptoms in patients with cystocele.

Currently, POP-Q system is the most popular way to assess the degree of pelvic organ prolapse. The POP-Q system is simple to use, and no instrument is required to clearly determine the prolapse severity in clinical practice. In this study, the assessment results using POP-Q system clearly revealed the relationship between cystocele and OAB symptoms (Table 3). Thus, POP-Q system is an appropriate tool to assess the status of the prolapse.

TVM procedures (e.g., Perigee kit) were considered an effective way to treat cystocele with PVDs. This study showed that seven of 22 cases (31.8%) still had a persistent angle of PVD as identified by sonography after operation, though the evidence of PVDs could not be found by the POP-Q system. Moreover, no statistically significant difference of OAB symptoms with the recovery of PVD after operation was noted. In our study, the necessity for PVD repair employing TVM for the treatment of OAB symptoms was greatly reduced.

This study has several limitations. The sample size was small because we particularly emphasized that a single Perigee procedure was performed for predominate cystocele with limited vault and posterior vaginal wall prolapse, with the aim to reach a more precise assessment of the relationship between cystocele and OAB symptoms before or after operation. Nevertheless, we still could get an effective statistical analysis given the limited case number.

The urogynecologists are concerned about the production of TVMs. However, this study proposes that the superiority of TVM in PVD repair to manage OAB symptoms seems not so manifest. Thus, the necessity of PVD repair for the improvement of OAB symptoms remains unclear. Nevertheless, we still have opportunities to find a better procedure and a more appropriate pessary to replace TVMs. Further studies with a larger sample and a longer follow-up period are needed to verify our results.

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