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## GYNAECOLOGY

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# Overactive Bladder Symptom Score Changes after Pessary Insertion in Women with Pelvic Organ Prolapse and Overactive Bladder

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### ABSTRACT

**Objectives:** To determine the overactive bladder symptom score (OABSS) change after pessary insertion in patients with symptomatic pelvic organ prolapse and overactive bladder at 3 months after treatment.

**Materials and Methods:** During May 2020 and May 2021, 27 patients diagnosed as having pelvic organ prolapse with overactive bladder and treated by vaginal pessary were recruited in the study. The Thai-version Overactive Bladder Symptom Scores (OABSS) Questionnaire was used to assess the overactive bladder symptom before and after pessary treatment at 3 months follow-up.

**Results:** The mean total OABSS scores at pre- and post- treatment were  $6.9 \pm 3.3$  and  $4.4 \pm 3.1$ , with significant difference at  $p < 0.05$ . The patients with improved OABSS score were 85.2% (23/27) after pessary insertion. OABSS significantly improved in all subcategories including frequency, nocturia, urgency, and incontinence. After performing the univariate analysis, there was no significant relationship between OABSS outcome and various factors such as age, weight, height, BMI, parity, and POP-Q stages.

**Conclusion:** The overactive bladder symptom score (OABSS) changed significantly after pessary treatment in women diagnosed with symptomatic pelvic organ prolapse and overactive bladder.

**Keywords:** pelvic organ prolapse, overactive bladder, overactive bladder symptom score (OABSS), pessary .

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# อาการกระเพาะปัสสาวะไวเกินในผู้ป่วยที่มีภาวะอุ้งเชิงกรานหย่อน ภายหลังจากการรักษาด้วยห่วงพยุงช่องคลอด

สุชาธิ์ ณะระนันท์ กิรติ เชียงทอง ปุริม เรือนภู สุวิทย์ บุญยะเวชชีวิน

## บทคัดย่อ

**วัตถุประสงค์:** เพื่อประเมินคะแนนของแบบสอบถามอาการโรคกระเพาะปัสสาวะไวเกิน (OABSS) ที่เปลี่ยนแปลงไปหลังจากการรักษาผู้ป่วยที่มีภาวะอุ้งเชิงกรานหย่อนและภาวะกระเพาะปัสสาวะไวเกินด้วยห่วงพยุงช่องคลอด

**วัสดุและวิธีการ:** ระหว่างเดือน พฤษภาคม พ.ศ. 2563 ถึง พ.ศ.2564 สตรีไทยจำนวน 27 ราย ที่ได้รับการวินิจฉัยว่ามีภาวะอุ้งเชิงกรานหย่อนและภาวะกระเพาะปัสสาวะไวเกินและได้รับการรักษาด้วยห่วงพยุงช่องคลอดได้คัดเลือกเข้ามาในการศึกษา โดยมีการประเมินอาการของกระเพาะปัสสาวะไวเกินก่อนและหลังการรักษาด้วยห่วงพยุงช่องคลอดที่ระยะเวลา 3 เดือน ด้วยแบบสอบถามอาการโรคกระเพาะปัสสาวะไวเกินฉบับภาษาไทย (Thai-version OABSS)

**ผลการศึกษา:** ค่าเฉลี่ย  $\pm$  ค่าเบี่ยงเบนมาตรฐานของคะแนนของแบบสอบถามอาการโรคกระเพาะปัสสาวะไวเกิน (OABSS) ก่อน และ หลัง การรักษาคือ  $6.9 \pm 3.3$  และ  $4.4 \pm 3.1$  ตามลำดับ โดยค่า  $p < 0.05$  แสดงถึงความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ในงานวิจัยนี้ผู้ป่วยทั้งหมดร้อยละ 85.2 (23/27) มีคะแนนของแบบสอบถามลดลง (อาการกระเพาะปัสสาวะไวเกินดีขึ้น) หลังจากการรักษาด้วยห่วงพยุงช่องคลอด ซึ่งคะแนนของแบบสอบถาม OABSS ลดลงอย่างมีนัยสำคัญทางสถิติในทุกหัวข้อของแบบสอบถาม ซึ่งได้แก่ อาการปัสสาวะบ่อย ปัสสาวะตอนกลางคืน ปัสสาวะเร่งรีบ รวมไปถึงอาการกลั้นปัสสาวะไม่ได้ จากการศึกษาระบบ Univariate analysis ของปัจจัยที่อาจจะส่งผลต่อคะแนนของแบบสอบถาม OABSS ที่ไม่ดีขึ้น พบว่าไม่มีความสัมพันธ์ระหว่างผู้ป่วยที่อาการไม่ดีขึ้นและปัจจัยเหล่านี้ได้แก่ อายุ น้ำหนัก ส่วนสูง ค่าดัชนีมวลกาย จำนวนการคลอด และ POP-Q stage

**สรุป:** คะแนนของแบบสอบถามอาการโรคกระเพาะปัสสาวะไวเกิน (OABSS) เปลี่ยนแปลงไปในทางที่ดีขึ้นอย่างมีนัยสำคัญทางสถิติ เมื่อเปรียบเทียบก่อนและหลังการรักษาผู้ป่วยที่มีภาวะอุ้งเชิงกรานหย่อนและภาวะกระเพาะปัสสาวะไวเกินด้วยห่วงพยุงช่องคลอด

**คำสำคัญ:** ภาวะอุ้งเชิงกรานหย่อน, ภาวะกระเพาะปัสสาวะบีบตัวไวเกิน, ความเที่ยงตรงของแบบสอบถามอาการโรคกระเพาะปัสสาวะไวเกิน, ห่วงพยุงทางช่องคลอด

## Introduction

The prevalence of pelvic organ prolapse (POP) increased with age and it doubled in women aged 80 years and older<sup>(1)</sup>. Overactive bladder (OAB) is a symptom often seen in women who experienced pelvic organ prolapse. These were confirmed in several studies that the incidence of overactive bladder was significantly higher in patients with symptomatic POP. Furthermore, many factors such as bladder outlet obstruction, bladder distension and prominent cystocele were found to be the significant risk factors of OAB in women with POP<sup>(2, 3)</sup>.

Vaginal pessary is a treatment of choice for POP. There was the evidence that the three-day micturition/incontinence diary and the urgency and urge incontinence improved in women diagnosed as having OAB with POP after pessary treatment<sup>(4, 5)</sup>. Using standard questionnaires for the diagnosis and follow-up for the response of treatment was introduced as the instrument for the patient reported outcome measurement<sup>(6)</sup>. The standard questionnaires such as overactive bladder symptoms score (OABSS) questionnaire is recommended by the International Consultation on Incontinence<sup>(7)</sup> for the assessment of changes in overactive bladder symptoms. The OABSS questionnaire had already been translated and validated into Thai language<sup>(8)</sup>. Although there were evidences of clinical OAB symptom improvement in POP patients after pessary treatment, no studies regarding the utilization of standard symptom questionnaire to assess and compare clinical improvement after different treatment modalities for future research were reported. In order to fill this research gap, this research was primarily designed to evaluate overactive bladder symptoms before and after treating patients having symptomatic POP with vaginal pessary by applying the Thai version of OABSS. The secondary objective was to identify the risk factors in the cases that OABSS were not improved after pessary management.

## Materials and Methods

This study was carried out as the before and after

study at the Female Pelvic Medicine and Reconstructive Surgery clinic of King Chulalongkorn Memorial Hospital, Bangkok, Thailand, between May 2020 and May 2021. The research protocol was approved by the Institutional Review Board of the hospital. This study followed the STROBE guideline for prospective and observational study<sup>(9)</sup>.

Participants were women aged more than 18 years old with (1) symptomatic POP diagnosed by clinical symptoms, pelvic examination and POP-Q staging classification (2) overactive bladder symptoms, and (3) vaginal pessary as the treatment of choice for prolapse. The exclusion criteria were women with undiagnosed vaginal discharge, abnormal uterine bleeding, vaginal or cervical cancer, impaired mental capacity, noncompliance in follow-up, infection, and intermittent catheter usage. Information regarding demographic data, patient characteristics, and OABSS were extracted for analysis. POP was defined as the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix), or the apex of the vagina (vaginal vault or cuff scar after hysterectomy), correlated with symptoms<sup>(10)</sup>. Overactive bladder (OAB) is diagnosed primarily by symptoms such as urgency with or without urge incontinence, usually with frequency and nocturia, and other causes such as infection or other pathology needed to be ruled out<sup>(11)</sup>. Clinical risk factors that were evaluated in this study included age, weight, height, body mass index (BMI), parity, and POP-Q stage. At 0 and 3 months of pessary treatment, the participants were asked to self-complete the Thai version of OABSS questionnaires. The clinical data including the side effect or complications of pessary were recorded at 3 months follow-up.

The OABSS questionnaire is the self-reported questionnaire to quantify OAB symptoms<sup>(12)</sup>. It consists of 4 questions, including daytime frequency, night-time frequency, urgency, and urgency incontinence. The severity of each symptom is rated on the Likert scale from 0-2 for day time frequency, from 0-3 for night-time frequency, from 0-5 for urgency incontinence, respectively. The total score of the OABSS ranges from 0 to 15, indicating the higher the score, the more severe

the symptoms. Patients were defined as improved if the post-treatment score of OABSS decreased more than or equal to 1, and were defined as not improved if the score did not change.

The sample size was calculated from the mean difference of the pre- and post-treatment OABSS scores obtained during the 10-case pilot study with add on drop out of 20%. Thus, the formula for sample size calculation for two dependent means study was  $(Z_{1-\alpha/2} + Z_{1-\beta})^2 * \sigma^2 / d^2$ . The pool variance ( $\sigma$ ) was 3.4 and the delta (mean difference of OABSS score = d) was 2.0 ( $\alpha = 0.05$  and  $\beta = 0.2$ ).  $N = (1.96 + 0.84)^2 \times (3.4)^2 / (2)^2 = 23$ . With the add on drop out of 4 cases, 27 participants were required.

The numbers and percentages were used for categorical data presentation. The mean and standard deviation were used for the continuous data presentation. The difference between pre- and post-treatment OABSS

was analyzed by the paired t-test. The univariate analysis by independent t-test and multivariate analysis by logistic regression analysis were used for the factors affecting the OABSS outcomes in this study. Statistical analysis was carried out by IBM SPSS Statistics for Windows, version 22.0 with statistical significance at p value less than 0.05.

## Results

Of 27 women, the mean age was  $71.8 \pm 8.7$  years. Most women demonstrated advanced stage (stage III-IV) POP in both anterior (70.3%) and apical (59.2%) compartments, except posterior compartment (29.6 %) (Table 1). Successful pessary fitting was achieved at the first visit and pessary use was continued without complications until the 3-month follow-up. No treatment failure, such as pessary change and switching to another treatment modality, was reported.

**Table 1.** Patients' Characteristics (n = 27).

Characteristics	Mean $\pm$ SD
Age (yr)	71.8 $\pm$ 8.7
Weight (kg)	58.3 $\pm$ 7.9
Height (cm)	151.3 $\pm$ 4.8
BMI (kg/m <sup>2</sup> )	24.6 $\pm$ 3.7
Parity	3.0 $\pm$ 1.6
POP-Q stage	<b>n (%)</b>
Anterior compartment	
Stage 0	2 (7.4)
Stage I	2 (7.4)
Stage II	4 (14.8)
Stage III	12 (44.4)
Stage IV	7 (25.9)
Apical compartment	
Stage 0	2 (7.4)
Stage I	4 (14.8)
Stage II	5 (18.5)
Stage III	4 (14.8)
Stage IV	12 (44.4)
Posterior compartment	
Stage 0	4 (14.8)
Stage I	8 (29.6)
Stage II	7 (25.9)
Stage III	5 (18.5)
Stage IV	3 (11.1)

SD: standard deviation, BMI: body mass index, POP-Q: Pelvic Organ Prolapse Quantification system, OABSS: overactive bladder symptom score

The majority of women (48.1%) demonstrated the total OABSS between 6-11 prior to treatment,

whereas 40.7% showed lower scores between 3-5 after treatment (Table 2).

**Table 2.** Pre and Post treatment of the OABSS score (n = 27).

OABSS score	Pre-treatment OABSS score n (%)	Post-treatment OABSS score n (%)
Pre-treatment OABSS: total score		
Less than 3	2 (7.4)	7 (25.9)
3 to 5	9 (33.4)	11(40.8)
6 to 11	13 (48.1)	7 (25.9)
12 or more	3 (11.1)	2 (7.4)
Pre-treatment OABSS: frequency score		
0	13 (48.1)	20 (74.2)
1	13 (48.1)	6 (22.2)
2	1 (3.7)	1 (3.7)
Pre-treatment OABSS: nocturia score		
0	1 (3.7)	2 (7.4)
1	5 (18.5)	8 (29.6)
2	9 (33.4)	12 (44.5)
3	12 (44.4)	5 (18.5)
Pretreatment OABSS: urgency score		
0	0 (0)	12 (44.5)
1	9 (33.4)	3 (11.1)
2	7 (25.9)	6 (22.2)
3	0 (0)	1 (3.7)
4	7 (25.9)	4 (14.8)
5	4 (14.8)	1 (3.7)
Pretreatment OABSS: incontinence score		
0	13 (48.1)	16 (59.3)
1	0 (0)	3 (11.1)
2	9 (33.4)	5 (18.5)
3	0 (0)	1 (3.7)
4	3 (11.1)	1 (3.7)
5	2 (7.4)	1 (3.7)

OABSS: overactive bladder symptom score

When statistically comparing, the mean OABSS between pre- and post-pessary treatment, significant

improvement was observed in both total scores ( $6.9 \pm 3.3$  vs  $4.4 \pm 3.1$ ,  $p < 0.05$ ) and all subcategories (Table 3).

**Table 3.** The Mean  $\pm$  SD of the Pre and Post treatment OABSS (n = 27).

OABSS items	Pre-treatment		Post-treatment		p value
	mean $\pm$ SD	min-max	mean $\pm$ SD	min-Max	
Frequency	0.6 $\pm$ 0.6	0-2	0.3 $\pm$ 0.5	0-2	0.017*
Nocturia	2.2 $\pm$ 0.9	0-3	1.7 $\pm$ 0.9	0-3	0.020*
Urgency	2.6 $\pm$ 1.5	1-5	1.4 $\pm$ 1.6	0-4	0.001*
Incontinence	1.5 $\pm$ 1.7	0-5	0.9 $\pm$ 1.4	0-5	0.037*
<b>Total</b>	<b>6.9 <math>\pm</math> 3.3</b>	<b>2-14</b>	<b>4.4 <math>\pm</math> 3.1</b>	<b>1-12</b>	<b>&lt; 0.001*</b>

\*statistically significant at p-value < 0.05. SD: standard deviation, OABSS: overactive bladder symptom score

There were 23 cases with OABSS score improvement and 4 cases of non-improvement. For women with OABSS improvement (n = 23), the mean total scores prior to and after pessary treatment were  $7.3 \pm 3.3$  and  $4.1 \pm 3.2$ , respectively, whereas those with no improvement (n = 4) demonstrated similar

outcomes between pre-and post-treatment scores ( $4.2 \pm 1.7$  vs  $5.8 \pm 2.1$ ). By using univariate analysis, there was no difference in terms of the age, weight, height, BMI, parity, and POP-Q stage when compared between women with and without improved OABSS (Table 4).

**Table 4.** Univariate analysis of the factors affecting the OABSS outcome (n = 27).

Factors	Improved OABSS group (n = 23)	Not improved OABSS group (n = 4)	p value
	mean $\pm$ SD	mean $\pm$ SD	
Age (yr)	72.0 $\pm$ 8.2	69.5 $\pm$ 12.2	0.573
Weight (kg)	58.0 $\pm$ 7.9	59.7 $\pm$ 9.3	0.700
Height (cm)	151.5 $\pm$ 3.8	150.3 $\pm$ 9.3	0.653
BMI (kg/m <sup>2</sup> )	25.5 $\pm$ 3.9	26.5 $\pm$ 3.3	0.630
Parity	3.3 $\pm$ 1.3	3.0 $\pm$ 2.0	0.961
	n (%)	n (%)	p value
POP-Q stage			
1 and 2	5 (18.5)	0 (0)	0.320
3 and 4	18 (66.7)	4 (14.8)	0.320

SD: standard deviation, BMI: body mass index, POP-Q: Pelvic Organ Prolapse Quantification system, OABSS: overactive bladder symptom score

## Discussion

Results from our study have confirmed that POP-related OAB symptoms, which were quantified by the OABSS questionnaire, significantly improved after ring pessary treatment. There were many similar reports showing that OAB symptom significantly improved after using a pessary as the treatment for POP<sup>(5, 13, 14)</sup>. Clemons et al reported that 73 women with successful pessary fitting had the urge incontinence improvement by 46% after 2 months of treatment<sup>(13)</sup>. Fernando et al demonstrated that 79 patients had significant improvement in both urgency (38%,  $p < 0.001$ ) and urge urinary incontinence (29%,  $p < 0.015$ )<sup>(14)</sup>. According to Kuhn et al, 73 women evaluated by the Sheffield POP symptom questionnaires were also found to have significant OAB improvement after the pessary treatment<sup>(5)</sup>. Using the OABSS to measure the OAB symptom improvement is considered beneficial due to the quantitative measurement which makes it easy for objective comparison of OAB symptoms before and after treatment. The use of OABSS questionnaire required more time in the outpatient clinic for both medical personnel and the patients. This might limit

the use of OABSS in clinical practice. Because the major symptom for the diagnosis of OAB is the urgency, the use of urgency questionnaire such urgency distress inventory (U-UDI) is advocated for future research<sup>(15)</sup>.

The pessary can improve symptoms of overactive bladder in POP patients by the reduction of bladder outlet obstruction/bladder distension which occurred as a consequence of the prominent cystocele<sup>(3)</sup>. We noticed that OAB symptoms improved in 85.2%, (23 out of 27) of the patients, whereas the remaining 14.8% reported unchanged or worsened symptoms. Among patients whose symptoms were not improved after the pessary use, the mean total OABSS were relatively low before treatment with the average score of 4.3. Fortunately, no patient required any additional treatments. This can be assumed that pessary can significantly relieve OAB symptoms in patients with more severity (higher OABSS scores).

From our results, the use of pessary was found to significantly improve OAB symptoms. With the advantages of low cost and low complication rates, vaginal pessary should be recommended as a first-line treatment option for women with POP-related OAB

symptoms. If symptoms do not improve after pessary insertion, additional treatments for OAB may be considered.

### **Strengths of this study**

This study used the validated Thai-version OABSS as the standard questionnaire with proper selection criteria. The good compliance in the pessary treatment and follow-up were noted in this study.

### **Limitations of this study**

The sample size calculation for the secondary outcome was not carried out. The future studies with larger sample size with longer follow-up period are advocated. Further comparative studies of OAB symptoms between different treatment modalities, such as pessary only vs pessary with vaginal estrogen, pessary vs surgery, and pessary vs other conservative management should be considered.

## **Conclusion**

The prolapse-related OAB symptoms can be significantly improved after pessary treatment for prolapse as quantified by the validated Thai-version OABSS.

## **Potential conflicts of interest**

The authors declare no conflicts of interest.

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