

# Factors Affecting Successfulness of Vaginal Pessary Use for the Treatment of Pelvic Organ Prolapse

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**Background:** Pelvic organ prolapse can cause adverse events affecting the lives of the women. Vaginal pessary is a conservative treatment, which is not expensive and safe. For the patient with medical condition, vaginal pessary would be the first choice of treatment.

**Objective:** To study the factors those affect the success of the vaginal pessary use for treatment of pelvic organ prolapse.

**Material and Method:** Historical data of patients who visited urogynecology clinic, Thammasat University hospital from January 2009 through December 2013, were collected. The SPSS program was used for statistical analysis with p-value <0.05.

**Results:** Of 252 women with pelvic organ prolapse, median age was 67 years (range 29-92 years). Most patients, 78.2%, had severe POP (stage 3-4). 194 women were treated with vaginal pessary. 83.5% of these patients could use continuously more than 3 months. The open ring was the most common using pessary. 48.1% of the patients who could use pessary continuously can self-remove and insert the device. Anterior vaginal wall and the vaginal length were significantly higher with the successful users. The most common complication was the presence of abnormal vaginal discharge, and more common in the patient with donut pessary.

**Conclusion:** The open ring is the device that can be used easily and has fewer complications, followed by ring with support. Short vaginal length is a factor that cannot use the pessary. It seems that relaxed anterior wall and longer vaginal length might help hold the pessary in the vagina.

**Keywords:** Pelvic organ prolapse, Menopause, Vaginal pessary

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Changes in socioeconomic and advances in technology particularly medical technology, lead to increase the longevity of Thai population. The structure of Thai population is changing constantly as a result in the reduction of births. The data from the National Statistical Office show that over the last 20 years, the childhood population in Thailand decreased from 38.3% in 1980 to only 24.4% in 2000. While the aging population trends to increase steadily from 5.5% in 1980 to 9.5% in 2000. Thailand has entered an aging society since 2005 with 10.5% of the population aged 60 and over. And from expectation, in 2030, the aging population in Thailand could increase to 15.7%. With this aging population, health care and prevention are important to help the elderly maintain a good quality of

life and not become a burden on society<sup>(1)</sup>.

Pelvic organ prolapse is a group of symptoms caused by the disorder of pelvic floor which consists of muscle and connective tissue. The factor that affects the injury and destruction of the muscle or connective tissue in this area is vaginal birth. This factor is confirmed to be an important risk factor of pelvic floor relaxation especially due to prolonged labor or high birth weighed babies, which can cause more severe injury and destruction to the pelvic support<sup>(2)</sup>. Pelvic organ prolapse can cause adverse symptoms such as pelvic discomfort, vaginal bulging and lumping, voiding and defecation dysfunction. Particularly in elderly women<sup>(3)</sup>, due to decreasing in estrogen level, they will have more severe pelvic floor relaxation and experience more problems in their daily activities.

The treatment of pelvic organ prolapse can be divided into two main methods. First is the conservative treatment and second is the surgical treatment. The treatment option for pelvic organ prolapse depends on many factors. Menopausal women

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tend to have chronic health problems such as diabetes, high blood pressure and heart disease. Surgical treatment for these patients may cause high risk surgical complications. Therefore, conservative treatment by vaginal pessary gains increasing popularity. But in Thailand, this vaginal pessary is not well known and most of the gynecologists are not familiar and not skilled in selection and monitoring patients. Also, there are a very small numbers of the studies about the vaginal pessary in Thailand. But in other countries, especially European countries, there are many studies confirming the high effectiveness and low complication rate of the conservative treatment by vaginal pessary<sup>(4-6)</sup>. This technique was recommended the one of choice for pelvic organ prolapse that can help improve the quality of life of the patients<sup>(7,8)</sup>.

The aim of this study was to study the factors that affect the successfulness in the treatment of pelvic organ prolapse by vaginal pessary at Urogynecology clinic, Thammasat University Hospital.

#### Material and Method

At the urogynecology clinic in Thammasat University Hospital from January 2009 to December 2013, the historical data of the all patients attending the clinic were collected but only the data of patient who had pelvic organ prolapse and treated with vaginal pessary were used for analysis. The patients who lost to follow-up before 3 months after the first time pessary insertion were excluded. The data sheet form of our clinic consists of the general information, the presenting symptom and its' severity, the physical exam's data including POP-Q (Pelvic organ prolapse quantitative), type and size of pessary and the impact of quality of life questionnaire. The follow-up data sheet has questions about how to be satisfied in using pessary, co-morbidity or complications of pessary use, and how they care for their pessary. The success of treatment means the continued use of the vaginal pessary more than 3 months. The unsuccessfulness means discontinuation of pessary using during first three months of the treatment, for which the reasons were recorded as the main outcome. All complications from using pessary were recorded as secondary outcome.

Statistical evaluation was performed by using SPSS 17.0 for windows (SPSS Inc, Chicago, Illinois). Normality was tested by using Kolmogorov-Smirnov testing. Chi-square test and Fisher's exact test were used for non-parametric data and Student's t-test was used for parametric data. A *p*-value <0.05 was considered significant.

This study was approved by the local ethical committee of faculty of medicine, Thammasat University.

#### Results

From January 2009 to December 2013, there were 293 patients attending urogynecology clinic in Thammasat university hospital. 41 patients presenting with lower urinary tract symptoms had no pelvic organ prolapse. There remain 252 data files for analysis. The median age was 67 years (range 29-92 years) and the median parity was 3 (range 0-11). Mean weight was 58.1±9.8 kilograms. There were 240 patients (95.2%) in menopausal period. Most patients (206 patients, 81.7%) had come with a lump protruding from the vagina and of these patients, 54 patients (21.4%) had voiding dysfunction. The presenting symptoms of all patients attending the clinic were shown in the Table 1. 78.2% of the patients had severe pelvic organ prolapse (stage III-IV) and 46 patients (18.3%) had procidentia uteri. There were only 55 patients (21.8%) with second stage of pelvic organ prolapse. Most of the patients with all stage of pelvic organ prolapse had significant impact on quality of life. There were 45 patients (17.9%) with second stage of prolapse did not have any effect on quality of life and one patient required surgery due to sexual problem. The patients who did not prefer to treat with pessary at the first time of counselling were 13 patients (5.2%) and all were treated with reconstructive surgery. Only 194 patients remained for complete analysis (Fig. 1).

From 194 patients who were treated with vaginal pessary, 162 patients (83.5%) could continuously use pessary for more than 3 months. Open Ring Pessary was the most common type of pessary used for treatment of pelvic organ prolapse (74 patients, 45.7%) followed by ring support (35 patients, 21.6%) as shown in Table 2.

From all 162 patients who continuously used

**Table 1.** The presenting symptoms of all patients

Symptom	Number	Percent
Protruding mass from vagina	146	57.9
Lower urinary tract symptoms	35	13.9
Pelvic discomfort	5	2.0
Abnormal bleeding	2	0.8
Vaginal mass with voiding symptom	54	21.4
Vaginal mass with abnormal bleeding	6	2.4
Sexual related symptom	4	1.6

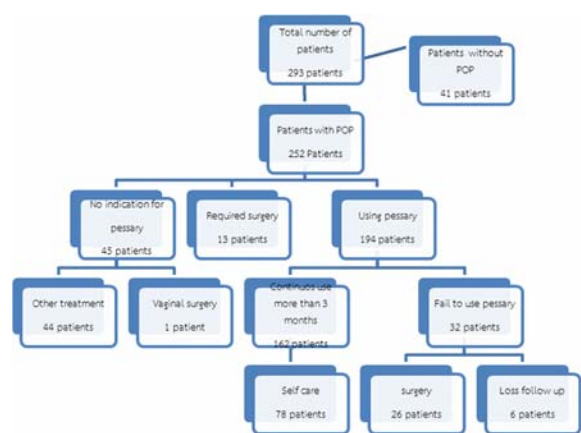
pessary, 78 patients (48.1%) could remove and insert the pessary by themselves or their caregivers and mostly using open ring (50 patients, 64.1%) following by ring with support (21 patients, 26.9%). Patient's characteristics and POP-Q measurements which expected to affect the success of pessary use were shown in Table 3.

The most common complication was abnormal leucorrhea (38.9%), particularly in the patients using Donut pessary (14.8%) and Gelhorn pessary (11.1%). All patients who had abnormal leucorrhea (63 patients) were unable to remove and insert the pessary by themselves. Pressure ulcers were the second most common complication, found in 42 patients (25.9%). 18 patients (11.1%) from these 42 patients used Donut pessary and could not self-remove and care. With 15 patients (9.3%) used Gelhorn pessary and also could

not self-care. There were 3 patients (1.9%) had abnormal bleeding. After evaluation by transvaginal ultrasound of the endometrial thickness and not suspecting endometrial hyperplasia, all patients with bleeding were reassured and could continue use pessary.

## Discussion

The prevalence of pelvic organ prolapse in developing countries is about 19.7% (3.4-56.4%)<sup>(9)</sup>. The wide range of the prevalence is due to the variation in definition and assessment. In the present study, the authors collected the data from urogynecology clinic so the prevalence of pelvic organ prolapse could be high as 86%. Most (82.1%) need the treatment. More than 80% of the patients presented with vaginal mass with or without voiding dysfunction. All abnormal bleeding caused by the pressure sores on the vaginal surface outside the vagina which could be treated by applying local estrogen. Almost all patients were menopausal (95.2%). According to other studies, estrogen depletion can increase risk of pelvic floor



**Fig. 1** Number of the patients according to the treatment line.

**Table 2.** The number of the patient using pessary continuously more than 3 months according to type of pessary

Type of vaginal pessary	Number	Percent
Open ring	74	45.7
Ring with support	35	21.6
Donut	29	17.9
Gelhorn	21	13.0
Pingpong ball	3	1.9

**Table 3.** Comparison of the patient's characteristics and POP-Q measurements between success and failure treatment

Patient's characteristics and factors	Success (162 patients)	Failure (32 patients)	p-value
Age (median, range) years	69.1 (39-92)	66.6 (51-82)	0.130
Weight (median, range) kilograms	57.4 (33-82.5)	59.0 (42-76)	0.300
Parity (median, range)	4.2 (0-11)	3.9 (2-9)	0.570
POP-Q measurement (mm)			
Laxity of anterior vaginal wall, Ba (median, range)	3.0 ((-2)-10)	1.8 ((-2)-8)	0.003
Laxity of posterior vaginal wall, Bp (median, range)	1.4 ((-3)-10)	0.4 ((-2)-8)	0.140
Total vaginal length, (TVL) (mean ± SD)	6.3±1.4	5.1 ± 0.9	<0.001a
Length of perineal body (median, range)	1.9 (0.5-3)	2.0 (1-3)	0.530
Genital hiatus (GH) (median, range)	5.0 (3-7)	4.9 (3-6)	0.660

Mann-Whiney test, a = student's t-test  
p-value <0.0

relaxation. Some studies found the correlation between estrogen and progesterone levels at Uterosacral ligament and Pubocervical fascia<sup>(10-12)</sup>. Vaginal pessary is a conservative treatment. It can decrease the risk of surgical complications. Since Greek history, vaginal pessaries have been used to manage pelvic organ prolapse and develop shape and size to suit the unusual conditions of the patient<sup>(13)</sup>. Vaginal pessary is a low-risk option for treatment of pelvic floor relaxation. Main indications are to relieve prolapse symptoms by supporting and adjusting the position of the prolapse organ. Recent studies have reported the success in pessary treatment of pelvic organ prolapse about 56-89% at 2-3 months<sup>(4,14)</sup>. Open ring has been the most frequently selected type for treatment of pelvic organ prolapse with an excellent success rate due to ease of use and few complications<sup>(15)</sup>. The authors found that nearly half of the patients with continuous pessary-using, could remove and insert pessary by themselves or by their caregivers. So they would have lower complications especially abnormal leucorrhea and pressure ulcers than the others who could not take care of their pessary. However, we found that more than 50% of the patients, who could not take care of their pessary, had been using Donut or Gelhorn pessary, which are quite difficult to remove and insert. In the other hand, the patients who could take care of their pessary, they had been using open ring 64.1% and ring with support 26.9%. Therefore, the ability to take care of the pessary should be an important factor for the success of pessary use.

For the study using POP-Q measurement, short vaginal length was a significant factor that caused unsuccessful pessary use<sup>(15,16)</sup>. In the present study, the authors also found a significant correlation between the length of relaxed anterior vaginal wall (Ba) and the pessary use. The patient who had high Ba would have a successful fit with the pessary. It seems that the patient who had severe relaxation of the anterior vaginal wall, the concave area on the anterior wall might help in holding the pessary in a suitable fitting position. However, this needs more study to find out the correlation between the laxity of the anterior vaginal wall and pessary use.

### **Conclusion**

Menopausal women have high incidence of pelvic organ prolapse which can have a significant impact on their quality of life. To avoid surgery in some elderly women with chronic health disease, vaginal pessary is the low-risk option with low complication.

Age, parity, weight were not have any effect on the success of pessary use. Only total vaginal length and the laxity of anterior vaginal wall were found to be related with successfulness. Open ring pessary is the most common selected type with good compliance and continuation rates of use. Donut and Gelhorn pessary can cause more complications especially foul smell-leucorrhea and pressure ulcers and difficulty to remove and insert. This is a retrospective study, so lack of some data that would have been important factors such as the strength of levator ani, the width of introitus etc, were not available. There should be a further cohort study for more complete evaluation of data.

### **What is already known on this topic?**

Pelvic organ prolapse is caused by the injury of the pelvic support. The most common risk factor is vaginal delivery. The drop in estrogen during menopausal period reduces the strength of the pelvic floor. So pelvic organ prolapse are more common in menopausal women. Conservative treatment for pelvic organ prolapse by using vaginal pessary is a low-risk treatment. It should be used for women who are not suitable for surgery. In Thailand, most of the gynecologist are not familiar with this pessary. Only one paper from a Tarinee, Mancana, Chulalongkorn University in 2011, which reported about ring pessary and its benefits. She found that ring pessary can be used at any stage and type of prolapse with few complications. A short vaginal length affects the success rate of pessary fitting.

### **What this study adds?**

Open ring pessary is easy to use with few complications. The patients who can remove and insert the pessary by themselves or their caregivers tend to continue use the pessary. Donut and Gelhorn pessary are hard to remove and insert and create more complications such as abnormal leucorrhea and pressure sores. Patients with high grade cystocele or relaxation of the anterior vaginal wall seem to fit with pessary than the patient whose anterior vaginal wall is intact.

### **Potential conflicts of interest**

None.

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## ปัจจัยที่มีผลต่อความสำเร็จในการใช้อุปกรณ์ช่วยพยุงในช่องคลอดเพื่อรักษาภาวะหย่อนของอวัยวะในอุ้งเชิงกราน

อรวรรณ เล็กสกุลไชย, ปรีชา วานิชยเศรษฐกุล

ภูมิหลัง: ภาวะหย่อนของอวัยวะในอุ้งเชิงกรานสามารถทำให้เกิดอาการไม่พึงประสงค์ที่มีผลต่อการดำเนินชีวิตของสตรี การใช้อุปกรณ์ช่วยพยุงในช่องคลอดเป็นการรักษาแบบอนุรักษ์ที่ไม่แพงและปลอดภัยสำหรับผู้ป่วยที่มีภาวะทางอายุรกรรม การใช้อุปกรณ์ช่วยพยุงในช่องคลอดน่าจะเป็นวิธีทางเลือกแรกสำหรับการรักษา

วัตถุประสงค์: เพื่อศึกษาถึงปัจจัยที่มีผลต่อความสำเร็จในการใช้อุปกรณ์ช่วยพยุงในช่องคลอดเพื่อรักษาภาวะหย่อนของอวัยวะในอุ้งเชิงกราน

วัสดุและวิธีการ: ข้อมูลเวชระเบียนของผู้ป่วยที่มีรับการรักษาที่คลินิกเวชศาสตร์เชิงกรานและศัลยกรรมช่องเสริม โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ มหาวิทยาลัยธรรมศาสตร์ ตั้งแต่ เดือนมกราคม พ.ศ. 2552 ถึง ธันวาคม พ.ศ. 2556 ได้ถูกเก็บรวบรวมการคำนวณทางสถิติใช้โปรแกรม SPSS และ p-value <0.05.

ผลการศึกษา: สตรีที่มีภาวะหย่อนของอวัยวะในอุ้งเชิงกรานจำนวน 252 คน มีค่ามัธยฐานอายุเท่ากับ 67 ปี (ช่วงอายุ 29-92 ปี) ผู้ป่วยส่วนใหญ่ 78.2% มีการหย่อนในระดับรุนแรง (ระดับ 3-4) สตรีจำนวนคนได้รับการรักษาด้วยอุปกรณ์ช่วยพยุงในช่องคลอดโดยในผู้ป่วยเหล่านี้ 83.5% สามารถใช้อุปกรณ์ได้อย่างต่อเนื่องมากกว่า 3 เดือน ห่วงแบบเปิดเป็นอุปกรณ์ช่วยพยุงที่ถูกใช้มากที่สุด 48.1% ของผู้ป่วยที่สามารถใช้อุปกรณ์อย่างต่อเนื่องสามารถถอดและใส่อุปกรณ์เองได้ ความยาวของผนังช่องคลอดส่วนหน้าและความยาวของช่องคลอดมีค่าสูงกว่าอย่างมีนัยสำคัญทางสถิติ ในผู้ที่ประสบความสำเร็จในการใช้อุปกรณ์ ภาวะแทรกซ้อนที่พบมากที่สุดคือการมีสารคัดหลั่งผิดปกติจากช่องคลอดที่พบมากขึ้นในผู้ป่วยที่ใช้อุปกรณ์ช่วยพยุงแบบโดนัทสรุป: ห่วงช่วยพยุงแบบมีรูเปิดเป็นอุปกรณ์ที่สามารถใช้ได้ง่ายและมีภาวะแทรกซ้อนน้อย รองลงมาคือห่วงช่วยพยุงแบบมีแผ่นรองรับความยาวของช่องคลอดที่สั้นจะเป็นปัจจัยที่ทำให้ไม่สามารถใช้อุปกรณ์ช่วยพยุงได้ ดูเหมือนว่าผนังช่องคลอดส่วนหน้าที่มีการหย่อนมากและช่องคลอดที่มีความยาวมากกว่าจะช่วยให้อุปกรณ์ช่วยพยุงจะถูกกระชับไว้ในช่องคลอดได้

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