## GYNECOLOGY

# Can Video Enhance Confidence in Management of Vaginal Pessary: A randomized trial

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### ABSTRACT

- **Objectives:** To compare the confidence of women with pelvic organ prolapse (POP) in vaginal pessary management between those who had versus those who hadn't watched the teaching video.
- Materials and Methods: This randomized clinical trial was conducted at two urogynecological clinics in Khon Kaen, Thailand, from September 2017 to May 2018. Women with POP that require for vaginal pessary were included and were randomized into two groups: 1) treatment group received brochure and watched teaching video, and 2) control group received only educational brochure. Each participant's knowledge was tested before and after receiving construction from a trained nurse. A retest, which examined participants' knowledge retention, self-confidence, and satisfaction in pessary use, was conducted at a two-week follow-up visit.
- **Results:** A total of 50 subjects were enrolled: 25 in each video and non-video group. There was no statistically significant difference in median confidence scores between video (median; range = 10; 7-10) and non-video (median; range = 10; 5-10) groups, p = 0.917. There was statistically significant difference in mean pretest and posttest scores in both video and non-video group (3.72 [95%CI 2.98-4.46], p < 0.001 and 3.84 [95%CI 3.10-4.58], p < 0.001, respectively) but no significant difference between two groups (0.12 [-0.60-0.84], p > 0.999). However, the median time required to practice using pessary was significantly shorter in the video group (10 minutes [5, 30] and 15 minutes [7, 20], p = 0.001).
- **Conclusion:** Additional teaching video didn't affect confidence in vaginal pessary management. However, this tool enhanced patients' learning.

Keywords: confidence, pelvic organ prolapse, teaching video, vaginal pessary.

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## การใช้วีดีทัศน์ช่วยสอนสามารถเสริมความมั่นใจในการใช้อุปกรณ์พยุงช่องคลอดได้ หรือไม่? : การทดลองแบบสุ่ม

ศิวรุจน์ บัวขม, ธีระยุทธ เต็มธนะกิจไพศาล, โฉมพิลาศ จงสมชัย, มาลีชาติ ศรีพิพัฒน์กุล, ประนอม บุพศิริ

## บทคัดย่อ

**วัตถุประสงค์**: เพื่อเปรียบเทียบความมั่นใจในการจัดการเกี่ยวกับห่วงพยุงช่องคลอดในสตรีที่มีภาวะการหย่อนของอวัยวะใน อุ้งเชิงกรานในกลุ่มที่ได้ดูวีดีทัศน์เพื่อการสอนกับกลุ่มที่ไม่ได้ดู

วัสดุและวิธีการ: การทดลองแบบสุ่มนี้ดำเนินการที่คลินิกนรีเวชทางเดินปัสสาวะ 2 แห่ง ที่จังหวัดขอนแก่น ประเทศไทย ตั้งแต่ เดือนกันยายน พ.ศ.2560 ถึงเดือนพฤษภาคม พ.ศ.2561 ในสตรีที่มีภาวะอวัยวะอุ้งเชิงกรานหย่อน และต้องการใช้ห่วงพยุงช่อง คลอด โดยแบ่งเป็น 2 กลุ่ม กลุ่มรักษาได้รับเอกสารแผ่นพับความรู้และได้ดูวิดีทัศน์ ส่วนกลุ่มควบคุมได้รับเอกสารแผ่นพับความ รู้อย่างเดียว อาสาสมัครทุกคนได้รับการประเมินความรู้ก่อนและหลังฟังคำอธิบายจากพยาบาล มีการติดตามประเมินการคงอยู่ ของความรู้ ความมั่นใจของตนเองและความพึงพอใจในการใช้ห่วงพยุงช่องคลอดในอีก 2 สัปดาห์ถัดมา

**ผลการศึกษา**: อาสาสมัครจำนวน 50 คน แบ่งเป็น 25 คน ในแต่ละกลุ่ม พบว่าไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ของค่ามัธยฐานความมั่นใจในการจัดการกับห่วงพยุงช่องคลอดของกลุ่มที่ดูวิดีทัศน์ (10; 7-10) และกลุ่มที่ไม่ได้ดูวิดีทัศน์ (10; 5-10), p = 0.917 พบว่ามีความแตกต่างอย่างมีนัยสำคัญทางสถิติของค่าเฉลี่ยของคะแนนด้านความรู้ก่อนและหลัง การรับคำแนะนำในกลุ่มที่ดูวิดีทัศน์และกลุ่มที่ไม่ได้ดู (3.72 [95%CI 2.98-4.46], p < 0.001 and 3.84 [95%CI 3.10-4.58], p<0.001) แต่ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่าง 2 กลุ่ม อย่างไรก็ตามพบว่า ค่ามัธยฐานของระยะเวลาที่ อาสาสมัครใช้ในการฝึกการใส่และถอดห่วงพยุงช่องคลอดสั้นกว่าอย่างมีนัยสำคัญทางสถิติในกลุ่มที่ได้ดูวิดีทัศน์ (10 [5, 30] และ 15 [7, 20], p = 0.001)

**สรุป**: การเสริมการสอนด้วยวิดีทัศน์ไม่ได้มีผลกระทบต่อความมั่นใจในการจัดการกับห่วงพยุงช่องคลอด แต่ช่วยเสริมการเรียนรู้

**คำสำคัญ:** ความมั่นใจ, อวัยวะในอุ้งเชิงกรานหย่อน, วีดิทัศน์การสอน, ห่วงพยุงช่องคลอด

## Introduction

Pelvic organ prolapse (POP) is a condition in which any of the pelvic organs, such as the uterus, vaginal wall, bladder, or rectum, descend from their normal position<sup>(1)</sup>. It can cause various symptoms such as pelvic pain, vaginal pain, urinary incontinence, constipation, and a feeling that something is falling out of the vagina. Although POP is not a life-threatening condition, it is closely associated with impaired quality of life. The prevalence of this condition is higher in the elderly<sup>(2)</sup>. Previous studies have found the prevalence of POP to be 30.8% in Swedish women age 20-59 vears<sup>(3)</sup> and 43.3% in postmenopausal women in Thailand<sup>(4)</sup>. There are many options for POP treatment. Nonsurgical treatments are considered the first line of management and including pelvic floor muscle exercises and use of a vaginal pessary. Surgical treatments are offered when conservative management is ineffective<sup>(5)</sup>. Vaginal pessaries are widely used to support the pelvic organs. The advantages of pessaries are their ability to improve prolapse symptoms and that they can be used in cases in which the patient suffers from frailty or has a severe medical condition that precludes surgical intervention, or in which surgery has failed to remedy the condition<sup>(5)</sup>. It has been reported that a combination of vaginal pessary use and pelvic floor muscle training significantly improves the quality of life in women with POP to a greater degree than pelvic floor muscle training alone<sup>(6)</sup>.

Providing instruction and demonstration of selfinsertion and removal of the vaginal pessary is timeconsuming. In our practice, we spent 20-25 minutes to teach in each patient. Therefore, instructional media such as pictures, brochures, and videos may play an important role in helping patients to understand and use vaginal pessaries with greater confidence and more effectively. A previous study found that half of the women with pelvic organ prolapse in the United States knew about vaginal pessary<sup>(7)</sup>. Another report found that women with pelvic organ prolapse who were taught how to use the pessary as well as being given the instructional media, such as brochures, had more confidence in their ability to use these devices<sup>(8)</sup>. In this study, we aimed to compare the confidence, knowledge and satisfaction of women with POP regarding vaginal pessary selfmanagement between those who had versus those who had not watched a teaching video. We hypothesized that watching the video would make the patients more confident in pessary management.

## **Materials and Methods**

This randomized clinical trial was approved by the Khon Kaen University Ethics Committee in Human Research (HE601252) and was conducted at two urogynecological clinics (Srinagarind hospital and Khon Kaen Regional hospital) from September 2017 to May 2018. The clinical trial registration number was TCTR20170906001. The inclusion criteria were that the patient had POP, required vaginal pessary treatment, and able to self-insert and remove pessary. After vaginal pessary fitting was performed by the physician and written informed consent was obtained, the participants had to complete a pretest questionnaire to test their knowledge of POP. They were then divided into two groups by using a block of 8 randomizations in sealed envelopes fashion by researcher nurse. Participants in the treatment group individually watched the educational video twice. The video consisted of basic POP knowledge, risk factors, treatment, and how to cope with common side effects (the same content covered in the educational brochure). In addition, it gave step-by-step visual instructions for pessary insertion, removal, and care. The control group did not watch this video. Next, participants in both groups were given basic knowledge regarding POP and trained in pessary insertion, removal, and care by trained nurse. They were then instructed to practice for themselves until they were familiar with the pessary. The duration of practice until each participant was able to use the pessary on their own was recorded. After this, the posttest was conducted. An educational brochure was given to all patients before leaving the clinic and an appointment was made for a two-week follow up. All patients were instructed to remove the pessary every night and reinsert it the morning. At a two-week follow-up, the same posttest was conducted, and patients were asked to rate their confidence, and overall satisfaction in vaginal pessary management and use.

#### Two educational brochures

The brochures were provided to each participant. The first one was a leaflet containing basic knowledge about POP, risk factors, treatment options, coping with common side effects, and POP prevention. The another one was a leaflet explaining the vaginal pessary and contained instructions in pessary use and management. The brochures were based on translated leaflets in Thai distributed by the Urogynecological Association (IUGA) <sup>(1)</sup> and the Thai Urogynecological Society (TUGS).

#### Preparation of the questionnaire

The questionnaire consisted of three parts. The first part consisted of questions about demographic data (age, parity, body mass index (BMI), educational level, and menopausal status). The second part consisted of 10 questions (10 scores) regarding the basic POP knowledge that was documented in the brochure (the definition of POP, the role of the pessary, use of lubricant gel, cleaning the pessary, and coping with vaginal or bloody discharge), each with four options (correct, incorrect, not sure, and unknown). The third part of the questionnaire evaluated self-confidence in pessary management using a 1-10 visual analog scale (VAS), with a higher score representing greater confidence. In addition, a five-level (1-5) questionnaire regarding overall satisfaction in pessary use was administered at the two-week follow-up. Answers were presented using five facial expressions, which represented very unhappy or very unsatisfied<sup>(1)</sup>, unsatisfied, fair, satisfied, and very satisfied or very happy<sup>(5)</sup>.

#### Preparation of the teaching video

The video was eight-minute long and covered

basic POP knowledge, step-by-step instructions on pessary insertion and removal, pessary care, and coping with common side effects. The content of the video corresponded with the data in the brochure.

For sample size calculation, there was no data regarding to the effect of video on confidence in pessary management. Murray<sup>(8)</sup> reported that providing an education brochure was found to increase confidence in pessary management three point from ten compared to control group. We hypothesized that adding the video might increase confidence in pessary management at least equal to only educational brochure. We, thus, decided that 22 participants per group would be required to achieve 80% of the power of calculation.

Statistical analyses were performed using STATA version 10.0 (StataCorp, College Station, TX, USA). Confidence in pessary self-management, satisfaction in pessary use, and time required to practice pessary use were analyzed using a Mann-Whitney two-sample test. Events during pessary use were analyzed using a Fisher's exact test and chi-square test. Knowledge about pelvic organ prolapse and vaginal pessary were analyzed with a Bonferroni post-hoc test using Generalized Estimating Equations. A p value of less than 0.05 was considered statistically significant.

## Results

A total of 50 subjects were enrolled in the study: 25 in the video group and 25 in the non-video group. There were four participants lost to follow-up at two weeks, (two in each group). There were 23 participants in the final analysis in each group, as shown in Fig. 1.





Demographic data including age, BMI, occupation, education, and menopausal status, are shown in Table 1. The mean (SD) ages of participants in the video group and non-video group were 68.24 (9.42) and 67.28 (7.55) years,

respectively. Most of the participants were the farmers, had a primary school education, had undergone vaginal delivery, were menopausal, and had POP stage III. The most common type of pessary use was ring pessary.

**Table 1.** Demographic data of patients in each group (N = 50).

Characteristics	Video group (n = 25)	Non-video group (n = 25)
Age, mean (SD), years	68.24 (9.42)	67.28 (7.55)
BMI, mean (SD), kg/m <sup>2</sup>	23.14 (3.47)	24.32 (4.23)
Occupation, n (%)		
- Farmer	18 (72)	16 (64)
- Merchant	4 (16)	1 (4)
- Government officer	1 (4)	5 (20)
- None	2 (8)	3 (12)
Education level, n (%)		
- Primary	20 (80)	19 (76)
- Secondary	4 (16)	2 (8)
- Vocational/Technical	0(0)	1(4)
- Bachelor's degree or more	1 (4)	3 (12)
Parity, median (min, max)	3 (0,8)	3 (1,7)
Route of delivery, n (%)		
- Vagina	23 (92)	25 (100)
- Caesarean section	0 (0)	0 (0)
- Both	1 (4)	0 (0)
- None	1 (4)	0 (0)
Menopause, n (%)	24 (96)	24 (96)
Duration of POP, years, median (min, max)	2 (0.08, 20)	1 (0.08,10)
Stage of POP, n (%)		
I	0 (0)	0 (0)
II	6 (24)	9 (36)
III	13 (52)	12 (48)
IV	6 (24)	4 (16)
Type of pessary, n(%)		
Ring	18 (72)	17 (68)
Ring with support	7 (28)	7 (28)
Donut	0 (0)	1 (4)

SD: standard deviation, BMI: body mass index, POP: pelvic organ prolapse

Participants in both groups showed significant improvement in terms of their knowledge evaluation scores on the posttest compared to the pretest [5.40 (1.19) and 9.12 (1.01), p < 0.001 in the video group vs

5.16 (0.99) and 9.00 (1.12), p < 0.001 in the control group]. However, there was no statistically significant difference in the mean scores of the two groups (p > 0.999) (Table 2).

	Video group (Total score 10)	Ν	Non-video group (Total score 10)	Ν	Mean difference (95%Cl), p
Pretest score, mean (SD)	5.40 (1.19)	25	5.16 (0.99)	25	0.24 (-0.48-0.96), > 0.999
Posttest score, mean (SD)	9.12 (1.01)	25	9.00 (1.12)	25	0.12 (-0.60-0.84), > 0.999
2-week score, mean (SD)	9.00 (1.04)	23	8.96 (1.15)	23	0.04 (-0.71-0.79), > 0.999
Mean difference					
- Pre-Posttest (95%Cl), p	3.72 (2.98-4.46),		3.84 (3.10-4.58),		
	< 0.001		< 0.001		
- Pretest-2 weeks (95%Cl), p	3.60 (2.85-4.36),		3.80 (3.05-4.55),		
	< 0.001		< 0.001		

 Table 2.
 Pretest and posttest knowledge scores.

SD: standard deviation, CI: confidence interval

Participants' confidence in pessary selfmanagement and the overall satisfaction regarding pessary use were high, and neither differed significantly between the two groups (Table 3). There was also no difference in terms of adverse events or side effects of pessary use between the two groups. However, the required practice time for vaginal pessary self-insertion and removal was significantly shorter in the video group [10 minutes (5, 30) vs 15 minutes (7, 20), p = 0.001] (Table 3).

**Table 3.** Confidence and satisfaction in vaginal pessary use at a two-week follow-up (N = 46).

Subject	Video group (n = 23)	Non-Video group (n = 23)	p value
Confidence in self-management of pessary			
- Median (min, max)	10 (7, 10)	10 (5, 10)	0.917
Satisfaction in using the pessary			
- Median (min, max)	4 (2, 5)	5 (3, 5)	0.209
Practice time required (minute)			
- Median (min, max)	10 (5, 30)	15 (7, 20)	0.001
Events during pessary use, n (%)			
- Pessary slippage	6 (26.09)	4 (17.39)	0.475
- Difficulty in pessary insertion and removal	5 (21.74)	2 (8.70)	0.414
- Failure to insert /discontinuing usage	0 (0)	0 (0)	
Side effect, n (%)			
- Pain, irritation	4 (17.39)	3 (13.04)	> 0.999
- Abnormal vaginal discharge	0 (0.00)	2 (8.70)	0.489
- Constipation	1 (4.35)	0 (0.00)	> 0.999

## Discussion

Participants' confidence in vaginal pessary self-management was high in our study. This result was consistent with those of other studies, which found that teaching patients vaginal pessary management improved comfort and made the patients more likely to continue using the device<sup>(9, 10)</sup>. Palumbo<sup>(11)</sup> reported that patient education plays a vital role in successful pessary use. Studies have also shown that health literacy leads to patients being more aware of the importance of individual health maintenance<sup>(12,13)</sup>. Elderly patients are known to have difficulty in recalling information given to them by healthcare staff, particularly doctors. Additional media such as brochures, pictures/graphics, and videos, may enhance patients' understanding of their diseases and improve information retention and treatment plans<sup>(8-10)</sup>.

In our study, we used a teaching video to enhance understanding of insertion and removal of a vaginal pessary. However, this did not affect patients' confidence in pessary self-management when compared with face-to-face consultation alone. The explanation for this might be that all patients were given slow verbal step-by-step instructions by a trained nurse, which helped them to become familiar with pessary use, which led to higher patient confidence in both groups. Thus, instruction performed by trained nurses and the provision of time for patients to practice pessary use and maintenance in the POP clinic are essential to pessary care<sup>(1-3, 14-16)</sup>.

However, patients in the video group required significantly less time to practice self-insertion and removal of the pessary. This might be because the video provided patients with clearer picture as to how these devices should be used and managed. In addition, we showed participants the video prior to face-to-face consultation (verbal instruction), which served to enhanced patient's learning. Therefore, video presentation is useful and necessary to add in educating the POP patients that require pessary in both individual or group learning and it might reduce instruction time for health care personnel. Patients' knowledge scores were significantly higher at post instruction. Retention at a follow-up visit at least two weeks later might also be an important indicator of awareness of the patients.

Time is needed to learn skill of self-insertion and removal of the vaginal pessary. If patients are skilled in this procedure, the continuation rate of pessary use will likely be high. Moreover, a two-step approach, in which information and advice regarding pessary use is first provided by the physician and then followed-up on by a trained nurse, enables prolapse patients to more effectively use the device and leads to a low rate of discontinuation<sup>(17)</sup>. However, Duenas<sup>(18)</sup> noted that most discontinuation occurs within the first week after device insertion. Brown<sup>(7)</sup> reported that lower levels of education tend to be correlated with declined pessary use. However, although most of our participants graduated from the primary school which contrast to Brown's reported a lower level of education trend to decline pessary use<sup>(7)</sup>. The Patients' self-confidence scores in vaginal pessary self-care were high in both groups. Overall satisfaction with pessary use was also high, which was consistent with results found in others reports<sup>(19,</sup> 20)

The strength of this study was the study design, the limitation of the study was a short time follow-up and the included participants were only the patients who were able to self-practice. Therefore, our data cannot apply in the dependent patients. Furthermore, a long time follow-up for retention rate evaluation of using the vaginal pessary, or develop new appropriate teaching media is required in the future research.

## Conclusion

Additional teaching video did not affect confidence in self-management of the vaginal pessary. However, this tool enhanced understanding and led to a shorter time being required to practice pessary use.

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## Potential conflicts of interest

The authors declare no conflict of interest.

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