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Brief communication (Original)

Impact of a vaginal pessary on the quality of life in women with pelvic organ prolapse

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Background: Vaginal pessaries have been used as an option for conservative treatment of pelvic organ prolapse.
Objectives: To determine if vaginal pessaries improve vaginal symptoms, quality of life, and satisfaction in women with pelvic organ prolapse after 3 to 6 months of pessary use.
Methods: This was a prospective observational study in a cohort of women presenting for a vaginal pessary fitting for pelvic organ prolapse. The women were asked to complete an International Consultation on Incontinence Modular Questionnaire-Vaginal Symptoms and evaluate their satisfaction using visual analog satisfaction scale before being fitted for the vaginal pessary, and after 3 and 6 months of treatment.
Results: Of the 40 women eligible to be included in this study, all vaginal symptoms and overall quality of life scores significantly improved after 3 and 6 months of treatment ($P < 0.001$). Moreover, the satisfaction scale increased significantly ($P < 0.001$).
Conclusions: The use of a vaginal pessary for up to 6 months improved vaginal symptoms, quality of life and satisfaction in women with pelvic organ prolapse.

Keywords: Quality of life, satisfaction vaginal pessary, vaginal symptoms

Pelvic organ prolapse is a common condition of postmenopausal and elderly women worldwide [1, 2]. The prevalence is 43% in Thai postmenopausal women attending a menopause clinic [3]. This condition affects their daily lives, such as decrease their confidence, limits their activities because of urinary symptoms, and affects their sexual activities. There are many options for treatment of pelvic organ prolapse, including observational, nonsurgical, and surgical treatments. Most elderly women have comorbidities such as hypertension, diabetes, and cerebrovascular disease that make them poor candidates for pelvic reconstructive surgery. Vaginal pessaries have been used as an option for conservative treatment. They immediately relieve symptoms and have minimal risks.

Most studies about pessaries use have focused on adverse events and continuation rate [4-9]. There are a few studies evaluating the impact of a vaginal pessary on quality of life [10-12]. There is no study in Thai women that focuses on quality of life and stage of prolapse after 6 months of pessary use. This study was aimed to evaluate impact of vaginal pessary on quality of life and the women's satisfaction after 3 and 6 months of pessary use.

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Materials and Methods

We conducted this observational study from January 2011 to December 2011. The study protocol was approved by the Institutional Ethical Committee and Review Board of Faculty of Medicine Ramathibodi Hospital, Mahidol University (approval No. 2553/567). Forty women with pelvic organ prolapse attending the Urogynecology Clinic willing to use a vaginal pessary and were recruited into this study. All women provided their written informed consent to participate. Their anonymity was protected. Participant's age, number of vaginal deliveries, body mass index, and menopausal status were collected as demographic data. Their history of medical comorbidities, reconstructive pelvic surgery, and other treatments for pelvic organ prolapse were recorded. Women who could not complete the questionnaire or assume a lithotomy position and women who were lost to follow-up at 3 and 6 months were excluded from this study.

The participants and their relatives were educated in how to take care of pessaries according to a standard protocol. The pessaries were inserted participants who had appointments scheduled for 1 week later to recheck the pessaries. Then, they had follow up appointments scheduled at 3 and 6 months. Vaginal estrogen cream was prescribed if there was evidence of vaginal atrophy.

All participants were asked to complete a Thai version of the International Consultation on Incontinence Modular Questionnaire or ICIQ – Vaginal Symptoms (ICIQ-VS) [13] at visit 1 (baseline), visit 2 (month 3), and visit 3 (month 6). The ICIQ-VS is composed of 14 questions divided into 3 parts, each with an independent score. The first part contains 8 items related to vaginal symptoms; the vaginal symptom score (VSS), and has a possible minimum of 0 and maximum of 53 items. The second part contained 3 items related to sexual matters; the sexual matters score (SMS), and has a possible minimum of 0 and a maximum of 58. The third part contained 1 item related to quality of life; the quality of life score (QoLS), and has a possible minimum of 0 and maximum of 10. The score increases with the severity of symptoms. A decrease in QoLS indicates improvement in the quality of life. The Thai version of ICIQ-VS questionnaire was successfully validated for Thai women and was used in this study.

Satisfaction was evaluated by using a visual analog satisfaction scale (VASS) [14] at the initial visit, visit 2 (month 3) and visit 3 (month 6). It was composed of a 100 mm vertical line with most satisfied at the top of the line and least satisfied at the bottom. Participants were asked to mark the level of their satisfaction on the scale.

Pelvic organ prolapse severity was classified by the Pelvic Organ Prolapse Quantification system (POP-Q) [15] and was evaluated by the principal investigator (TA) at the initial visit and visit 3 (month 6).

All had appointments scheduled for after 3 and 6 months of pessary use. At 3 months the subjects were asked to complete the ICIQ-VS and VASS again. At 6 months, besides the ICIQ-VS and VASS, the POP-Q staging system was re-examined.

The sample size required in this study was calculated for type I and type II errors <0.05 and calculated for further data loss of 20%. The total sample size was 40. A repeated measures ANOVA was used in this study to compare the results at 3 and 6 months by using the mean score and a Wilcoxon signed-rank test.

Results

Patient characteristics of the 40 participants completing are shown in **Table 1**.

Support pessaries were used in 85% of participants were fitted with a ring; 5% were fitted with Gellhorn pessaries. Three participants did not complete data collection at the end of this study. One quit the Gellhorn pessary because her caregiver could not remove it. Another two were unhappy with the rings and quit. All 40 participants were included in intention-to-treat analysis.

The vaginal symptoms score decreased significantly at both 3 and 6 months after pessary use. The overall quality of life score decreased significantly at both 3 and 6 months after pessary use. The sexual matters score decreased significantly only at 6 months after pessary use (**Table 2**).

The satisfaction scores increased significantly at both 3 and 6 months after treatment (**Table 3**).

The prolapse stage did not change in almost all participants. Only 2 cases improved 1 stage, and 1 case improved 2 stages as shown in **Table 4**.

There were few complications from using pessaries in this study. Three participants (8%) had vaginal erosion and one (3%) had bacterial vaginosis at 3 months after treatment. They were treated successfully and no complication was found at six months.

Table 1. Patient Characteristics

Age (y), mean (SD)	68.7 (7.6)
BMI (kg/m^2), mean (SD)	23.5 (3.3)
Vaginal delivery, median (range)	3 (0–8)
POP-Q stage, n (%)	
II	11 (28%)
III	20 (50%)
IV	9 (23%)
Comorbidities, n (%)	
Hypertension	25 (63%)
Diabetes	13 (33%)
Dyslipidemia	12 (30%)
Thyroid diseases	5 (13%)
Breast cancer	1 (3%)
Previous hysterectomy, n (%)	5 (13%)
Previous prolapse surgery, n (%)	2 (5%)
Menopause, n (%)	40 (100%)
Sexually active, n (%)	5 (13%)

Table 2. Comparison of quality of life scores before and after pessary use at 3 and 6 months

Domains		After pessary 3 months mean score (SD)	After pessary 6 months mean score (SD)	*P*
Vaginal symptoms	24.3 (7.7)	10.8 (8.7)	6.8 (6.5)	<0.001**
Sexual matters score	32.0 (18.9)	18.0 (18.3)	12.8 (12.4)	0.042*
Quality of life overall	7.7 (2.2)	2.9 (2.4)	1.7 (1.9)	<0.001**

Table 3. Comparison before and after pessary use satisfaction at 3 and 6 months

	Before pessary Mean score (SD)	After pessary 3 months Mean score (SD)	After pessary 6 months Mean score (SD)	*P*
VASS	22.9 (19.3)	78.9 (18.7)	88.2 (16.2)	<0.001**

Table 4. Changes in POP-Q stage

Change in POP-Q stage	After pessary 6 months, n (%)
No change	34 (92)
1 stage improvement	2 (5)
2 stages improvement	1 (3)
Worsen	0 (0)

Discussion

A vaginal pessary is one type of nonsurgical treatment for pelvic organ prolapse. Pessaries are suitable for women who are poor candidates for surgery because of multiple comorbidities or old age. Previous studies show that pessary use can improve patient's quality of life by using other questionnaires such as Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) [10-12]. Most patients with pelvic organ prolapse had a favorable outcome in terms of satisfaction with the pessary use, and continued to use a pessary to control pelvic floor symptoms [16]. This finding was similar to that we reported previously [17]. Improvements in prolapse-related symptoms and satisfaction were demonstrated with use of a pessary up to 6 months after initial fitting in this study. These findings confirmed earlier data that showed significant improvements in prolapse-related symptoms, quality of life, and body image with use of vaginal pessary [11]. In Thai culture, there are very few elderly women still sexually active. Even though there were improvements in the sexual matter domain after pessary treatment, the group was too small to determine if pessaries really improved sexual health.

Some participants experienced complications from pessary treatment. All complications were minor such as erosion of the vaginal wall or vaginal discharge. They were improved by adequate lubrication and vaginal estrogen treatment. The continuation rate was high at 93%; this might result from the satisfaction in using pessaries. One strength of this study was a prospective evaluation of subjects as they were treated with pessaries over 6 months. Secondly, the official validated Thai version of the ICIQ-VS and an simple VAS tool to interpret patient's satisfaction were used. Thirdly, the stage of pelvic organ prolapse, using the standard classification, was used and a single examiner performing all POP-Q exams. Finally, all interviewers were standardized because of the QoL questionnaire and satisfaction evaluation. The limitations of this study were its small sample size and that sexual satisfaction improvement could not be demonstrated. Further studies with a larger sample size and an appropriate number of sexually active women should be conducted. In conclusion, the use of a vaginal pessary for up to 6 months improved vaginal symptoms, QoL, and satisfaction in women with pelvic organ prolapse. The stages of prolapse did not change after 6 months of pessary treatment.

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Conflict of interest statement

The authors declare that there is no conflict of interest in this research.

References

1. Tegerstedt G, Maehle-Schmidt M, Nyren O, Hammarstorm M. Prevalence of symptomatic pelvic organ prolapse in a Swedish population. Int Urogynecol J Pelvic Floor Dysfunct. 2005; 16:497-503.
2. Woodman PJ, Swift SE, O'Boyle AL, Valley MT, Bland DR, Kahn MA, et al. Prevalence of severe pelvic organ prolapse in relation to job description and socioeconomic status: a multicenter cross-sectional study. Int Urogynecol J Pelvic Floor Dysfunct. 2006; 17:340-5.
3. Chuenchompoonut V, Bunyavejchevin S, Wisawasukmongchol W, Taechakraichana N. Prevalence of genital prolapse in Thai menopausal women (using new standardization classification). J Med Assoc Thai. 2005; 88:1-4.
4. Jones KA, Harmanli O. Pessary use in pelvic organ prolapse and urinary incontinence. Rev Obstet Gynecol. 2010; 3:3-9.
5. Cundiff GW, Weidner AC, Visco AG, Bump RC, Addison WA. A survey of pessary use by members of the American Urogynecologic Society. Obstet Gynecol. 2000; 95:931-5.
6. Clemons JL, Aguilar VC, Tillinghast TA, Jackson ND, Myers DL. Patient satisfaction and changes in prolapse and urinary symptoms in women who were fitted successfully with a pessary for pelvic organ prolapse. Am J obstet Gynecol. 2004; 190:1025-9.
7. Manchana T. Ring pessary for all pelvic organ prolapse. Arch Gynecol Obstet. 2011; 284:391-5.
8. Lamers BHC, Broekman BMW, Milani AL. Pessary treatment for pelvic organ prolapse and health-related quality of life: a review. Int Urogynecol J. 2011; 22: 637-44.
9. Manchana T, Bunyavejchevin S. Impact on quality of life after ring pessary use for pelvic organ prolapse. Int Urogynecol J. 2012; 23:873-7.
10. Barber MD, Walters MD, Cundiff GW. Responsiveness of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) in women undergoing vaginal surgery and pessary treatment for pelvic organ prolapse. Am J Obstet Gynecol. 2006; 194:1492-8.
11. Patel M, Mellen C, O'Sullivan DM, LaSala CA. Impact of pessary use on prolapse symptoms, quality of life, and body image. Am J Obstet Gynecol. 2010; 202: 499e1-4.
12. Abdool Z, Thakar R, Sultan AH. Prospective evaluation of outcome of vaginal pessaries versus surgery in women with symptomatic pelvic organ prolapse. Int Urogynecol J. 2011; 22:273-8.
13. Price N, Jackson S, Avery K, Brookes S, Abrams P. Development and psychometric evaluation of the ICIQ Vaginal symptoms Questionnaire: the ICIQ-VS. BJOG. 2006; 113:700-12.
14. Singer AJ, Thode JR HC. Determination of the minimal clinically significant difference on a patient visual analog satisfaction scale. Acad Emerg Med. 1998; 5: 1007-11.
15. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JOL, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol. 1996; 175:10-7.
16. Tenfelde S, Tell D, Thomas TN, Kenton K. Quality of life in women who use pessaries for longer than 12 months. Female Pelvic Med Reconstr Surg. 2015; 21: 146-9.
17. Sitavarin S, Wattanayingcharoenchai R, Manonai J, Sarit-apirak S, Chittacharoen A. The characteristics and satisfaction of the patients using vaginal pessaries. J Med Assoc Thai. 2009; 92:744-7.