
GYNAECOLOGY

Quality of Life after Treatment by Vaginal Pessary versus Surgery in Symptomatic Pelvic Organ Prolapsed Thai Patients

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ABSTRACT

Objectives: To compare the change in quality of life of Thai patients with symptomatic pelvic organ prolapse treated with vaginal pessary or surgery using validated prolapse quality of life (P-QOL) questionnaire.

Materials and Methods: The study recruited patients in one by one stratified simple random sampling in the same prolapse stages of forty patients in the pessary group and forty patients in the surgery group from the urogynecology clinic between January 2018 and August 2019. The data were collected using the P-QOL questionnaire before the treatment and 3 months and 6 months after the treatment.

Results: The mean age was 65.7 ± 7.7 years and body mass index was 24.9 ± 3.7 kg/m². After treatment with either pessary or surgery, almost all P-QOL domains significantly improved at 3 months and 6 months except in the personal relationships and sleep/energy domains in the pessary group in which the domains were not different from the baseline. General health perceptions and sleep/energy domains significantly improved more in the surgery group at 3 months ($p = 0.01$ and $p = 0.023$) and 6 months ($p = 0.024$ and $p = 0.007$) after treatment. The mean \pm standard deviation of satisfaction scores after treatment in pessary and surgery at 3 months (8.9 ± 1.4 and 9.3 ± 1.0 ($p = 0.509$), and 6 months (9.4 ± 1.2 and 9.3 ± 1.1 ($p = 1.000$) were not statistically different.

Conclusion: The quality of life in symptomatic prolapse after treatment with vaginal pessary or surgery improved. The majority of patients were very satisfied with the outcomes of either treatment.

Keywords: pelvic organ prolapse, pessary, quality of life, surgery.

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คุณภาพชีวิตหลังได้รับการรักษาด้วยอุปกรณ์พยุงช่องคลอดเปรียบเทียบกับการผ่าตัดในผู้ป่วยไทยที่มีอุ้งเชิงกรานหย่อน

ศุภกิตต์ ปัญางษ์, ประนอม บุพศิริ, โฉมพิลาส จงสมชัย, อธิยุทธ เต็มธนะกิจไพศาล

บทคัดย่อ

วัตถุประสงค์: เพื่อเปรียบเทียบคุณภาพชีวิตที่เปลี่ยนแปลงในผู้ป่วยไทยที่มีภาวะอุ้งเชิงกรานหย่อนหลังได้รับการรักษาด้วยอุปกรณ์พยุงช่องคลอดกับการผ่าตัดโดยใช้แบบสอบถามคุณภาพชีวิต P-QOL ฉบับภาษาไทย

วัสดุและวิธีการ: สุ่มตัวอย่างแบบชั้นภูมิเปรียบเทียบผู้ป่วยที่มีระดับอุ้งเชิงกรานหย่อนระดับเดียวกัน ได้รับการรักษาโดยใช้อุปกรณ์พยุงทางช่องคลอด หรือผ่าตัด กลุ่มละ 40 คน จากคลินิกนรีเวชทางเดินปัสสาวะระหว่างเดือนมกราคม 2561 ถึง สิงหาคม 2562 ด้วยแบบสอบถามคุณภาพชีวิต P-QOL ฉบับภาษาไทย ทั้งก่อนรับการรักษา และหลังการรักษาที่ 3 เดือน และ 6 เดือน

ผลการศึกษา: อายุเฉลี่ยและน้ำหนักเฉลี่ยของผู้ป่วยส่วนใหญ่อยู่ที่ 65.7 ± 7.7 ปี และ 24.9 ± 3.7 กิโลกรัม/เมตร² หลังรับการทั้งสองกลุ่มมีคุณภาพชีวิต (P-QOL) ดีขึ้นอย่างมีนัยสำคัญทั้งใน 3 เดือนและ 6 เดือน ยกเว้นหมวดความสัมพันธ์ส่วนบุคคลและหมวดคุณภาพชีวิตการนอน/พลังในการทำงาน หลังรับการผ่าตัดเมื่อเทียบกับการใส่อุปกรณ์พยุงช่องคลอด คุณภาพชีวิตในหมวดสุขภาพทั่วไปและหมวดคุณภาพชีวิตการนอน/พลังในการทำงานดีขึ้นอย่างมีนัยสำคัญทั้งใน 3 เดือน ($p = 0.01$ และ 0.023 ตามลำดับ) และ 6 เดือน ($p = 0.024$ และ 0.007 ตามลำดับ) ค่าเฉลี่ยความพึงพอใจหลังรับการรักษาด้วยอุปกรณ์พยุงช่องคลอด และการผ่าตัดที่ 3 เดือน (8.9 ± 1.4 และ 9.3 ± 1.0 ($p = 0.509$)) และ 6 เดือน (9.4 ± 1.2 และ 9.3 ± 1.1 ($p = 1.000$)) ไม่พบความแตกต่างอย่างมีนัยสำคัญ

สรุป: หลังการรักษาผู้ป่วยที่มีภาวะอุ้งเชิงกรานหย่อนด้วยอุปกรณ์พยุงช่องคลอดหรือได้รับการผ่าตัดพบว่ามีคุณภาพชีวิตดีขึ้น และมีความพึงพอใจอย่างมากหลังการรักษาทั้งสองกลุ่ม

คำสำคัญ: ภาวะอุ้งเชิงกรานหย่อน, อุปกรณ์พยุงช่องคลอด, คุณภาพชีวิต, การผ่าตัด

Introduction

Pelvic organ prolapse (POP) is the downward descent of one or more compartments of vagina and uterus into vagina or protruding through the hymen⁽¹⁾. It is a benign condition probably leading to vaginal bulge, pelvic pressure, voiding dysfunction, defecatory dysfunction and sexual dysfunction⁽¹⁾. A negative impact on quality of life (QoL) may be attributed to these symptomatic prolapses⁽²⁾. The risk factors accounting for the development of POP are age, parity, vaginal delivery, obesity, connective tissue diseases, chronic constipation and menopausal status.

In addition to lifestyle modifications, a vaginal pessary is a non-surgical option to relieve the POP symptoms and is considered to be the first offer rather than surgery⁽³⁾. Nevertheless, the prolapse surgery is essentially required to correct all affected vaginal compartments to restore the vaginal anatomy with operation techniques that primarily rely on the physicians' discretion and expertise⁽¹⁾.

Although POP surgery has considerable advantages over pessary use, the risk of complications after surgery and the cost-effectiveness are required to be taken into account⁽⁴⁾.

Given the improvement of the symptoms after treatment with either treatment, however, two prospective studies showed similar improvement in prolapse, urinary, bowel symptoms, sexual function as well as the QoL^(3,5).

As for the cultural differences, to the knowledge of present investigators, few studies have compared the outcomes of both treatments among Thai women. The aim of the study was, therefore, to evaluate and compare the changes in QoL of Thai women with symptomatic POP who were treated with vaginal pessaries and surgery after 3 and 6 months, in which the validated prolapse quality of life (P-QOL) questionnaire and satisfaction scores were used to collect data.

Materials and methods

This was a quasi-experimental study that pelvic organ prolapsed patients selected the treatment by pessary or surgery depending on their preference and

co-morbidities. The study protocol was approved by the Human Research Ethics Committee, Khon Kaen University (HE621008). After obtaining a written informed consent from each participant, data collection began from the participants attending an urogynecology clinic at the tertiary hospital between January 2018 and August 2019. As for the inclusion criteria, the participants were required to be 18 years of age or over, have developed prolapse stage II or more (POP-Q system), and were to have been treated with either vaginal pessary or surgery. Patients illiterate in Thai language and who did not follow-up for 6 months were excluded from the study. Patients who changed the treatment from pessary to surgery were considered as a failed pessary and the P-QOL scores were not evaluated. The pelvic organ prolapsed patients selected the treatment using their own discretion after the physicians gave them the information regarding treatment options. For care of the pessaries, patients were advised, if possible, to remove and clean every night. Once a week, however, was considered acceptable. Participants were enrolled with one by one stratified simple random sampling in the same prolapse stage. In cases who could not follow-up in person were contacted by phone.

The validated P-QOL questionnaire in Thai version⁽⁶⁾ was administered before treatment and 3 months and 6 months after treatment. A lower score indicates better quality of life; meanwhile, a higher score indicates detrimental effects on quality of life. Moreover, the satisfaction with the treatments using the visual analog scale at 3 months and 6 months after treatment, were also investigated.

According to the pilot study, the mean difference \pm standard deviation (SD) of P-QOL after the treatment with pessary was 23.50 ± 31.68 and 36.8 ± 42.85 in surgery. It was assumed that there were at least 25 points of mean differences in the treatment group. In order to achieve a power of 80% and a level of significance of 5%, 40 patients per treatment were required.

Statistical analysis was performed using STATA/SE version 10.1, and a test of normality was conducted

using Kolmogorov-Smirnov testing. The collected data were presented as percentages, means, and medians. The student's t-test, chi-square, Fisher's exact and Mann-Whitney U tests were used to assess the appropriateness to compare between pessary and surgical groups. A generalized estimating equation (GEE) was used to compare the mean difference of QoL scores between two groups. A p value of < 0.05 was considered statistically significant.

Results

One hundred eighteen patients were recruited, seventy-five were in the pessary group and forty-three patients were in the surgery group. Patients were enrolled by stratified simple random sampling in the same prolapse stage. Forty of them were assigned in the pessary group (50%) and forty in surgery group (50%). The data were collected during the follow-up period. In case of loss of in-person contact follow-up (46.3%) (15 patients in pessary group and 22 patients in surgery group), they were all contacted by phone. Thirty-nine patients (97.5%) in the pessary group were fitted with support pessaries, while only one (2.5%) was fitted with space occupying pessary (Donut

pessary). There were two surgical routes to restore pelvic floor anatomy in this study depending on physician experience and preference; a vaginal approach in 31 patients (77.5%) which was vaginal hysterectomy with sacrospinous ligament fixation with anterior and posterior colporrhaphy and the laparoscopic approach in 9 patients (22.5%). Six patients underwent laparoscopic sacrocolpopexy; 5 cases had vaginal vault prolapse and another one case was prolapsed with a paravaginal defect. Three patients had undergone laparoscopic high uterosacral ligament suspension. In cases who had the uterus in situ, they had laparoscopic hysterectomy performed as an additional procedure.

The mean age \pm SD was 65.7 ± 7.7 years and their mean body mass index (BMI) \pm SD was 24.9 ± 3.7 kg/m² and menopausal status was 96.3%. There was no statistical difference between the pessary and surgery groups in respect of age, BMI, occupation, marital status, parity, menopausal status and POP-Q stage (Table 1). For the underlying diseases, 5 patients suffered from ischemic heart disease and all of them were in the pessary group ($p = 0.021$). No one in the pessary group changed to the surgery group.

Table 1. Patient baseline characteristics (n = 80).

Variables	Pessary group (n = 40)	Surgery group (n = 40)	Total	p value
1. Age (years), mean \pm SD	67.25 \pm 7.48	64.23 \pm 7.61	65.74 \pm 7.65	0.077
2. BMI (kg/m ²), mean \pm SD	24.11 \pm 3.86	25.61 \pm 3.42	24.86 \pm 3.70	0.071
3. Occupation, n = yes (%)				0.23
3.1 Agricultural workers	19 (47.5)	10 (10)	29 (36.25)	
3.2 Self-employed	6 (15)	13 (32.5)	19 (23.75)	
3.3 Trader	7 (17.5)	6 (15)	13 (16.25)	0.83 ^a
3.4 Office worker	1 (2.5)	1 (2.5)	2 (2.5)	0.12 ^a
3.5 Civil servant	3 (7.5)	6 (15)	9 (11.25)	0.26 ^b
3.6 None	4 (10)	4 (10)	8 (10)	
4. Marital status, n = yes (%)				0.79
4.1 Single	0	0	0	
4.2 Married	29 (72.5)	32 (80)	68 (85)	
4.3 Divorced	1 (2.5)	1 (2.5)	2 (2.5)	
4.4 Widowed	10 (25)	7 (17.5)	17 (21.25)	
5. Parity, mean \pm SD	3.43 \pm 1.26	3.25 \pm 1.45	3.34 \pm 1.35	0.565
6. Menopause, n (%)	39 (97.5)	38 (95)	77 (96.25)	0.999
7. History of vaginal birth, n (%)	38 (95)	36 (90)	74 (92.50)	0.675

Table 1. Patient baseline characteristics (n = 80). (Cont.)

Variables	Pessary group (n = 40)	Surgery group (n = 40)	Total	p value
8. Underlying disease, n (%)	21 (52.5)	27 (67.5)	48 (60)	0.171
8.1 Hypertension	15 (37.5)	20 (50)	35 (43.75)	0.260
8.2 Diabetes mellitus	10 (25)	9 (22.5)	19 (23.75)	0.793
8.3 Dyslipidemia	5 (12.5)	10 (25)	15 (18.75)	0.152
8.4 SLE	0	1 (2.5)	1 (1.25)	0.314
8.5 Ischemic heart disease	5 (12.5)	0	5 (6.25)	0.021
8.6 CKD	0	1 (2.5)	1 (1.25)	0.314
8.7 GERD	0	1 (2.5)	1 (1.25)	0.314
8.8 Gout	0	1 (2.5)	1 (1.25)	0.314
8.9 Osteoarthritis of knee	0	1 (2.5)	1 (1.25)	0.314
8.10 Spinal stenosis	1 (2.5)	0	1 (1.25)	0.314
8.11 Hyper/hypothyroid	2 (5)	1 (2.5)	3 (3.75)	0.556
8.12 Breast cancer	0	1 (2.5)	1 (1.25)	0.314
9. History of hysterectomy, n (%)	4 (10)	5 (12.50)	9 (11.39)	1.000
10. Overall stage of pelvic organ prolapse Quantification system (POP-Q), n (%)				
Stage II	12 (30)	12 (30)	24 (30)	1.000
Stage III	21 (52.5)	21 (52.5)	42 (52.50)	1.000
Stage IV	7 (17.5)	7 (17.5)	14 (17.50)	1.000

SD: standard deviation, BMI: body mass index, SLE: systemic lupus erythematosus, CKD: chronic kidney disease, GERD: gastroesophageal reflux disease

The P-QOL scores at baseline before treatment in each group are shown in Table 2. The patients with symptomatic prolapse were affected adversely by the disease, including general health perceptions, impacts of prolapse, role limitations, physical limitations, emotions and severity measures which were not different at the baseline between two groups. In the

sleep/energy domain, patients in the surgery group significantly suffered more than the pessary group ($p = 0.023$). After treatment with either pessary or surgery, all P-QOL domains significantly improved at 3 months and 6 months except for personal relationships and sleep/energy domains in the pessary group.

Table 2. Patient quality of life score before treatment between pessary and surgery groups (n = 80).

P-QOL domain	Baseline of pessary median (IQR)	Baseline of surgery median (IQR)	p value
1. General health perceptions	50 (25, 75)	50 (50, 75)	0.095
2. Prolapse impact	67 (67, 100)	67 (33, 100)	0.556
3. Role limitations	33 (0, 67)	33 (17, 67)	0.477
4. Physical limitations	17 (0, 58.5)	33 (17, 91.5)	0.055
5. Social limitation	0 (0, 27.5)	5.5 (0, 44)	0.241
6. Personal relationships	0 (0, 0)	0 (0, 0)	0.477
7. Emotions	44 (22, 67)	33 (11, 56)	0.586
8. sleep/energy	0 (0, 0)	0 (0, 50)	0.023
9. Severity measures	33 (17, 37.5)	25 (12.5, 37.5)	0.763
10. Total score	28.5 (19.5, 39)	31.5 (25, 51)	0.202

P-QOL: Validation of the prolapse quality of life questionnaire, IQR: Interquartile range

When comparing the two groups, general health perceptions and sleep/energy domains significantly improved more in the surgery group at 3 months ($p = 0.01$ and $p = 0.023$) and 6 months ($p = 0.024$ and $p = 0.007$) after treatment (Table 3).

After treatment with either pessary or surgery, vaginal bulging, urinary frequency, urinary urgency and voiding difficulty improved significantly. The improvement

of urgency urinary incontinence symptoms was observed solely in the surgery group ($p = 0.025$); however, after both pessary and surgical treatment, neither stress urinary incontinence nor constipation improved. The improvement of symptoms in relation to the symptoms of pelvic organ prolapse were not statistically different at 6 months after treatment in both pessary and surgery groups (Table 4).

Table 3. Comparison of P-QOL domain score between pessary and surgery groups ($n = 80$).

Domains	3 months after treatment					6 months after treatment				
	Pessary		Surgery		difference between group (p value)	Pessary		Surgery		difference between group (p value)
	mean change from baseline	p value	mean change from baseline	p value		mean change from baseline	p value	mean change from baseline	p value	
1. General health perceptions	- 14.38	0.001	- 31.23	0.001	- 16.85 (0.010)	- 15	< 0.001	- 30	< 0.001	- 15 (0.024)
2. Prolapse impact	- 53.47	< 0.001	- 59.23	< 0.001	- 5.77 (0.922)	- 63.47	< 0.001	- 60.90	< 0.001	2.57 (1.000)
3. Role limitations	- 37.48	< 0.001	- 40.84	< 0.001	- 3.37 (1.000)	- 36.64	< 0.001	- 42.93	< 0.001	- 6.28 (0.816)
4. Physical limitations	- 29.62	< 0.001	- 42.16	< 0.001	- 12.54 (0.256)	- 27.95	< 0.001	- 42.58	< 0.001	- 14.63 (0.154)
5. Social limitations	- 14.96	< 0.001	- 21.06	< 0.001	- 6.10 (0.624)	- 14.68	< 0.001	- 21.62	< 0.001	- 6.94 (0.501)
6. Personal relationships	- 4.55	0.229	- 6.67	0.021	- 2.12 (1.000)	- 3.72	0.482	- 6.25	0.036	- 2.53 (1.000)
7. Emotions	- 34.92	< 0.001	- 35.51	< 0.001	- 0.59 (1.000)	- 37.42	< 0.001	- 37.18	< 0.001	0.24 (1.000)
8. Sleep/ energy	- 6.68	0.147	- 20.41	< 0.001	- 13.73 (0.023)	- 4.18	0.765	- 19.99	< 0.001	- 15.81 (0.007)
9. Severity measures	- 20.15	< 0.001	- 25.93	< 0.001	- 5.78 (0.324)	- 23.90	< 0.001	- 26.56	< 0.001	- 2.66 (1.000)
10. Total	- 23.96	< 0.001	- 31.49	< 0.001	- 7.53 (0.116)	- 25.16	< 0.001	32.04	< 0.001	- 6.88 (0.166)

P-QOL: Validation of the prolapse quality of life questionnaire

Table 4. The changes of pelvic organ prolapse related symptoms between pessary and surgery groups.

Symptoms	Pessary			Surgery			p value between two groups at 6 months
	Baseline n (%)	6 months n (%)	p value	Baseline n (%)	6 months n (%)	p value	
1. Vaginal bulge or lump	37 (92.5)	7 (17.5)	< 0.001	35 (87.5)	4 (10)	< 0.001	0.330
2. Frequency of urination	20 (50)	8 (20)	0.006	30 (75)	5 (12.5)	< 0.001	0.363
3. Urgency	21 (52.5)	12 (30)	0.045	21 (52.5)	8 (20)	0.002	0.302
4. Urgency urinary incontinence	16 (40)	14 (35)	1.000	20 (50)	9 (22.5)	0.025	0.217
5. Stress urinary incontinence	15 (37.5)	17 (42.5)	1.000	17 (42.5)	9 (22.5)	0.071	0.056
6. Voiding dysfunction	18 (45)	2 (5)	< 0.001	20 (50)	1 (2.5)	< 0.001	1.000
7. Constipation	14 (35)	10 (25)	0.529	19 (47.5)	11 (27.5)	0.072	0.799

The mean \pm SD of satisfaction score (0-10) after treatment in pessary and surgery groups at 3 months (8.9 ± 1.4 and 9.3 ± 1.0 ($p = 0.509$), and 6 months (9.4 ± 1.2 and 9.3 ± 1.1 ($p = 1.000$) were not statistically

different.

At the six-month follow-up, abnormal vaginal discharge was detected in one case and frequent pessary expulsion was observed in three cases. One

case was reported to have pelvic pain after laparoscopic surgery.

Discussion

This study compared the QoL of Thai patients with symptomatic POP who were treated with pessary and with surgery. It was found that both treatments significantly improved in almost all domains of the P-QOL questionnaire. Numerous studies have claimed that the QoL in pelvic organ prolapsed patients significantly improved after pessary⁽⁷⁻¹⁰⁾ and surgery^(11,12) treatments. These current study findings were consistent with those by Abdool et al⁽¹³⁾ and by Lone et al studies⁽⁵⁾, who employed both the Sheffield questionnaire and the validated International Consultation on Incontinence Questionnaire Vaginal Symptoms Module (ICIQ-VS) and the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI (SF)) questionnaires and found that the QoL after both treatments (pessary and surgery) significantly improved. In addition, considering each domain, this current study found personal relationships in the pessary group did not significantly improve from the baseline, similar to the report of Lone et al and Abdool et al.^(5,13) The possible explanation might be because the patients with pessary use are required to remove the pessary regularly during night time to prevent complications; consequently, prolapse may protrude during the night and may interfere with sexual activity. Moreover, the current study revealed that the sleep/energy domains did not improve in the pessary group. This may be due to prolapse-related symptoms during removal of pessary such as the symptoms of urinary urgency or incomplete emptying that can cause urinary frequency during nighttime, which may cause sleep disturbance. In contrast, in the surgery group, according to the P-QOL questionnaire, all domains improved significantly. Therefore, surgery has more advantages over pessary in this aspect.

As for the changes of prolapse symptoms, it was found that stress urinary incontinence did not improve after pessary or surgery, and urgency urinary

incontinence did not improve after pessary use but significantly improved after surgery. Moreover, the improvement of prolapse symptoms such as vaginal bulging, urinary frequency, urinary urgency and voiding difficulty significantly improved after both treatments. Such improvement could be due to relief of obstructive symptoms. These findings corresponded to the Abdool et al study⁽¹³⁾.

The satisfaction scores in pessary and surgery at 3 months and 6 months after treatment were high, but there was no statistical difference between two groups. In contrast to the study from Peking University⁽¹⁴⁾, in which the satisfaction score was relatively higher in surgery than the pessary group (4.9 ± 0.4 and 4.0 ± 1.3 scores, $p < 0.01$). The differences in the satisfaction scores may be because Chinese people have higher expectations. The pessary was used solely to support the pelvic organ rather than cure; thus, the satisfaction score was lower than that of surgery.

Patients' preference influences a selection of treatment⁽¹³⁾. One study from the Netherlands⁽¹⁵⁾ reported that 48% of patients with POP symptoms preferred surgery, 36% preferred pessary and 16% preferred neither. Therefore, in addition to the treatment options and complications, the data on the QoL particularly in the same cultures are of importance in the counseling process to guide patients' decisions.

The current study had some limitations since the study was conducted as a quasi-experiment and did not randomize the patients due to patient preferences, co-morbidities and the course of follow-up was short. Patients were enrolled by determining the number of patients in the same stage and the baseline characteristics between two groups were similar; thus, the scores of the QoL were not unduly affected by the study; all ischemic heart disease (IHD) patients who ultimately selected pessary use after the physician gave them advice with the consideration of the underlying disease, then did so. This enrolment reflected the daily practice in the real setting, which was a strength of the current study.

According to the P-QOL questionnaire, the QoL

in symptomatic prolapse after treatment with vaginal pessary or surgery improved. The majority of prolapse patients were very satisfied with the outcomes of either treatment.

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Potential conflicts of interest

The authors declare no conflict of interest.

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