EVIDENCE BASED CASE REPORT

The Use of Vaginal Pessary for Pelvic Organ Prolapse's Treatment

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Received 21 August 2019; Accepted 31 December 2019
DOI: 10.23886/ejki.7.11157.

Abstract

Pelvic organ prolapse (POP) is the descent of the anterior and/or posterior vaginal wall or vagina apex (uterus or vaginal apex after a hysterectomy) and has negative effects on woman's daily activities and reduces her quality of life. One of the treatments of POP is pessary that has limited evidence but still commonly used for treatment of genital prolapse and considered as the first line treatment by the American Urogynecologic Society (AUGS). This evidence-based case report (EBCR) is made to critically analyze from the current studies whether the use of pessary improves the symptoms of pelvic organ prolapse or not. A search of literature was performed in two databases, MEDLINE and Cochrane. Eligible articles were observational studies, clinical trials, systematic reviews, or meta-analyses that published within the last 5 years. All studies showed symptoms improvement with four studies using Pelvic Organ Prolapse Distress Inventory (POPDI) score and one study using International Consultation on Incontinence Questionnaire – Vaginal Symptoms (ICIQ-VS).
***Keywords**: pelvic organ prolapse, pessary, treatment.*

Penggunaan Pesarium Vagina untuk Penatalaksanaan Prolaps Organ Pelvik

Abstrak

Prolaps organ pelvik (POP) adalah penurunan dinding anterior dan atau posterior vagina atau apeks vagina (uterus atau apeks vagina setelah histerektomi) yang memiliki dampak negatif terhadap aktivitas sehari-hari dan menurunkan kualitas hidup. Salah satu tata laksana POP adalah pesarium yang memiliki bukti ilmiah terbatas tetapi masih digunakan untuk tata laksana prolaps genitalia dan dipertimbangkan sebagai terapi utama menurut American Urogynecologic Society (AUGS). Evidence-based case report (EBCR) dibuat untuk menganalisis secara kritis dari studi yang sudah ada apakah penggunaan pesarium dapat memperbaiki gejala dari prolaps organ pelvik atau tidak. EBCR ini dilakukan dalam dua databases, MEDLINE dan Cochrane. Artikel yang memenuhi syarat merupakan studi observasional, percobaan klinis, ulasan sistematis, atau meta-analisis yang telah dipublikasi pada 5 tahun terakhir. Semua studi menunjukan bahwa terdapat perbaikan dari gejala (POP) dengan empat studi menggunakan pelvic organ prolapse distress inventory (POPDI) score dan satu studi lainnya menggunakan International Consultation on Incontinence Questionnaire – Vaginal Symptoms (ICIQ-VS).
***Kata kunci:** prolapse organ pelvik, pesarium, penatalaksanaan.*

Introduction

Pelvic organ prolapse is an important and common medical condition. The International Continence Society (ICS) defines female pelvic organ prolapse as the descent of the anterior and or posterior vaginal wall or vagina apex (uterus or vaginal apex in women after a hysterectomy).[1]randomized, multicenter trial evaluated the 6-month success rate of sacral neuromodulation (SNM The prevalence of pelvic organ prolapse is uncertain due to the large number of women who do not seek medical care.[2] It is estimated that 50% of parous women lose pelvic floor support; as a result, develop prolapse but only 20-30% of these women are symptomatic.[3]

Symptomatic prolapse has been shown to have a negative impact on woman's daily activities and her quality of life.[2] Currently, treatment modalities include pelvic floor muscle training, vaginal pessaries, and surgery. Surgical treatment features high recurrence rates and reoperation is required in 30-56% of cases in certain populations, making it a costly procedure.[4,5] In addition, surgery is also contraindicated for older women and those with comorbidities such as cardiac problems and uncontrolled high blood pressure. As an alternative, conservative treatment such as vaginal pessary is still commonly used and indicated for all pelvic prolapse stages.[6]there has been a renewed interest in pessaries as a conservative alternative to surgical repair for pelvic organ prolapse (POP

The pessaries are intravaginal devices made of hypoallergenic plastic or silicone that is introduced into the vagina for the purpose of supporting the pelvic organs.[6]there has been a renewed interest in pessaries as a conservative alternative to surgical repair for pelvic organ prolapse (POP Several studies reported significant improvements in vaginal, urinary, bowel, and sexual symptoms.[7–9]health-related quality of life in women with pelvic organ prolapse. After a Medline search using the Mesh term 'pessary' and critical appraisal, 41 articles were selected and used in this review. Pessaries are widely used to treat pelvic organ prolapse. It is minimally invasive and appears to be safe. Although there is evidence that the use of pessaries in the treatment of pelvic organ prolapse is effective in alleviating symptoms and that patient satisfaction is high, the follow-up in many published papers is short, and the use of validated urogynaecological questionnaires is limited. Comparison with surgical treatment of pelvic organ prolapse is rare and not assessed in a randomised controlled trial.","author":[{"dropping-particle":The objective of the study was to compare pelvic floor symptom changes in patients who continue vs discontinue pessary use, and determine whether changes predict pessary continuation. Study Design: Women fitted with pessaries completed the Pelvic Floor Distress Inventory-20 (PFDI-20 However, there is still a lack of comparing trial in the setting of vaginal pessary as an intervention. Despite its limited evidence, the pessary is still commonly used in the treatment of genital prolapse and considered as the first line treatment by the American Urogynecologic Society (AUGS).[6,10]there has been a renewed interest in pessaries as a conservative alternative to surgical repair for pelvic organ prolapse (POP The aim of this evidence-based case report (EBCR) is to critically analyzed using newer studies whether the use of pessary improves the symptoms of pelvic organ prolapse compared to not using one.

Case Illustration

A 62-year old woman came to the gynecologic clinic with complaint of feeling a bulge in her vagina. It has happened in the last 6 months and sometimes she could saw something coming out from her vagina, especially when she was coughing. She was a housewife with 6 children with no cesarean history. No history of contraception and she had her menopause around 7 years before. The patient was diagnosed with uterine prolapse stage II and had pelvic exercise as the therapy from her doctor. As she felt very uncomfortable with the bulging sensation, the doctor also suggested the additional use of vaginal pessary.

As the doctor explaining how the pessary worked, she was afraid of the thought of inserting a foreign object into her body. She was wondering how effective it was compared to not using one as she already thought that maybe diet and exercise would be sufficient enough for herself. In woman who newly diagnosed uterine prolapse, does the pessary intervention improve the symptoms?

Methods

Formulation of Research

How is the effectiveness of pessary for improving the symptoms of pelvic organ prolapse?

Evidence Research Strategy

A search of literature was performed on May, 2019 in two databases namely MEDLINE and Cochrane. The keywords were "pessary", "pelvic

organ prolapse", and "uterine prolapse" with their synonyms and related terms (Table 1). Eligible articles were observational studies, clinical trials, systematic reviews, or meta-analyses that published within the last 5 years. The search strategy, results, and the inclusion-exclusion criteria are shown in Figure 1. After literature selection, critical appraisal was done by consensus of all authors using several aspects based on Center of Evidence-Based Medicine, University of Oxford for therapy study.

Table 1. Terminology Used in Two Databases

Database	Terminology	Hits
MEDLINE	((((“Pessaries”[Mesh]) OR pessary[Title/Abstract]) OR pessaries[Title/Abstract])) AND ((((“Pelvic Organ Prolapse”[Mesh]) OR “Uterine Prolapse”[Mesh]) OR pelvic organ prolapse[Title/Abstract]) OR uterine prolapse[Title/Abstract])	533
Cochrane	((MeSH descriptor: [Pessaries] explode all trees) OR (pessary):ti,ab,kw OR (pessaries):ti,ab,kw) AND ((MeSH descriptor: [Pelvic Organ Prolapse] explode all trees) OR (pelvic organ prolapse):ti,ab,kw OR (uterine prolapse):ti,ab,kw)	79

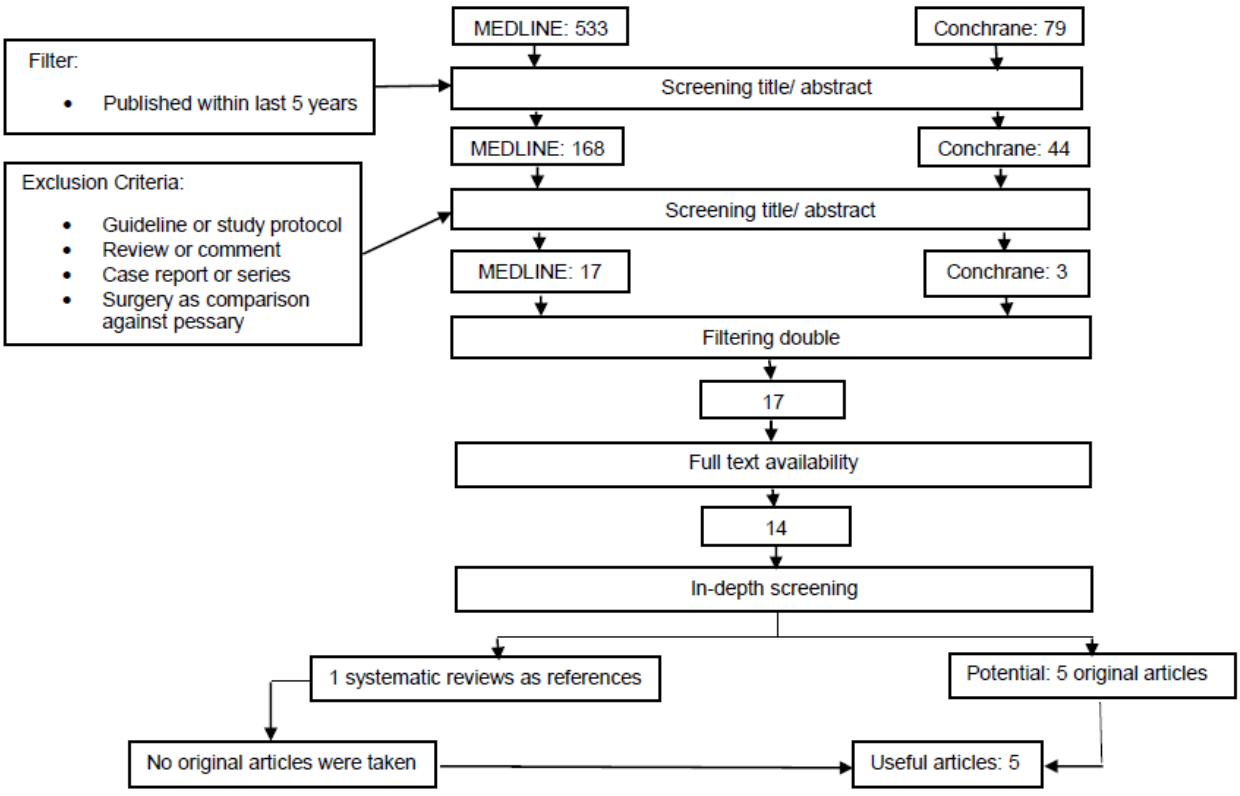

Figure 1. Flowchart of Search Strategy

Results

Following the search strategy, five original articles were eligible for this EBCR.[11,12] The design and summary of result is available on Table 2. The critical appraisal is shown on Table 3. Two articles were randomized controlled trial with level of evidence 1c and three observational cohort studies with level of evidence 2b.

Tabel 2. Design and Results of Selected Articles

	Cheung et al[11]	Panman et al[12]	Coelho et al[13]	Mao et al[14]	Shayo et al[15]
Study Design	RCT	RCT	Cohort study	Cohort study	Pre-post intervention (cohort) study
Sample Characteristic					.
Symptomatic POP Staging	I-III, without previous treatment.	II-III, without previous treatment.	III-IV with no cognitive dysfunctions.	Unknown with no physical or mental disability.	Unknown
Age	Mean age 62 y.o	Mean age 65 y.o	Mean age 76 y.o with 27 patients.	Mean age 68 y.o with 218 patients.	Mean age 48 y.o with 71 patients
	137 patients	80 patients.	-	-	-
Control group	139 patients	82 patients.	-	-	-
Pessary group					
Intervention	PFMT with 8-10 exercises/ session with 8-12 repetitions each, performed at least 2x/ day and 3 days/ week. PFMT + ring pessary for 6-12 months.	PFMT 2-3x/ day and 3-5x/ week, ring pessary for 12-24 months,	Ring pessary for 6 months. No comparison/control group.	Ring or gellhorn pessary for at least 12 months. No comparison/control group.	Ring pessary for at least 12 months. No comparison/control group.
Main Outcomes					
- Primary outcome	PFDI and PFIQ.	PFDI-20.	QoL measured with ICIQ-VS&SF-36.	Changes in prolapse and urinary symptoms and quality of life, measured using PFDI-20 and PFIQ-7.	POPDI-6 and POPIQ-7 to measure information on POP symptoms and POP-related QoL.
- Secondary outcome	VAS for prolapse	POPDI-6, CRADI-8, UDI-8, PFIQ-7, PCS-12, MCS-12, and PISQ-12.	Satisfaction, sociodemographic and clinical data, complications, and urinary symptoms.		
Main Results	-94% (control group) comfortable with the treatment, at 6 and 12 months 88% remained on conservative treatment. Pessary group: 66% comfortable with the pessary, after 6 months 63% of them maintained the pessary, after 12 months 60 decreased in the pessary at 12 months ($p < 0.01$) but no difference in the control group.	(Control group): at 12 and 24 months 79% and 78% remained on conservative treatment at 12 and 24 months respectively. Pessary group: 41.5% did not receive pessary as randomised due to unsuccessful fit.	ICIQ-VS improved for the subscale of vaginal symptoms and QoL (both $p < 0.01$). reported vaginal discharge and no case of severe complication. No difference in urinary symptoms.	About 65% patients successfully continued to use the pessary at the endpoint. Both of the PFIQ-7 and PFDI-20 scores decreased significantly ($p < 0.01$ each).	Only 42% continued the treatment until the endpoint. The overall POPDI score was reduced to 45% of the baseline score. The overall POPIQ score was reduced to 44% of the baseline score.

RCT: randomized controlled trial; POP: pelvic organ prolapse; PFMT: pelvic floor muscle training; PFDI: pelvic floor distress inventory; PFIQ: pelvic floor impact questionnaire; VAS: visual analog scale; POPDI: pelvic organ prolapse distress inventory; UDI: urinary distress inventory; CRADI: colorectal-anal distress inventory; POPIQ: pelvic organ prolapse impact questionnaire; UIQ: urinary impact questionnaire; CRAIQ: colorectal-anal impact questionnaire; PISQ: pelvic organ prolapse/incontinence sexuality questionnaire; PCS: physical component health summary; MCS: mental component health summary; ICIQ-VS: International Consultation on Incontinence Questionnaire – Vaginal Symptoms; SF-36: short form 36 health survey.

Table 3. Critical Appraisal for The Two Selected Studies Based on Criteria by Center of EBM, University of Oxford

	Cheung et al[11]	Panman et al[12]	Coelho et al[13]	Mao et al[14]	Shayo et al[15]
Level of evidence	1b	1b	2b	2b	2b
Number (n)	276	162	27	218	71
Validity					
Randomization	+	+	-	-	-
Similar group	+	+	n/a	n/a	n/a
Loss to follow-up and/or dropout (%)	26	36	30	35	58
Equal treatment	+	-	n/a	n/a	n/a
Intention-to-treat analysis	+	+	-	-	-
Blind	S[a]	S[a]	-	-	-
Importance					
Mean score pessary vs control	POPDI[b] = 32,1 vs 49,4	POPDI[c] = 12,8 vs 16,4	ICIQ-VS[e] (endpoint vs baseline) = 2,1 vs 30,1	POPDI[c] (endpoint vs baseline) = 9 vs 38,2	POPDI [b] (endpoint vs baseline) = 25 vs 55
Mean difference (95% CI)	POPDI = -25 (p < 0,01)	POPDI = -3,6 (-8,3 – 1,1)	ICIQ-VS (endpoint vs baseline) = -28 (-31,4 – (-24,6))	POPDI (endpoint vs baseline) = -29,2 (-32,7 – (-25,7)	-
Applicability					
Patient similarity	+	+	-	+	-
Feasible	+	+	+	+	+

[a]S: single blind
[b]data presented as median, higher score indicates more distress
[c]data presented as mean, higher score indicates more distress
[d]95% CI could not be calculated
[e]data presented as mean, higher score indicates more distress

Two clinical trial studies had similar validity.[11,12] The groups were randomized and similar. Owing to the nature of the intervention, it was not possible to blind patients in these studies. Hence, only the investigators that were unaware of the treatment allocation (i.e. single-blinded). All studies had more than 20% number of loss to follow-up and/or drop-out, based on initial randomization. Cheung et al[11] had equal treatment as all of its patients had pelvic exercises with no additional treatment except for the pessary in the intervention group. Both studies were using intention-to-treat analysis. Three observational studies were prospective cohort with no comparison or control group.[13–15] Thus, no validity criteria could be fulfilled.

From the aspect of importance, all studies showed symptoms improvement with four studies using pelvic organ prolapse distress inventory (POPDI) score and one study using International Consultation on Incontinence Questionnaire – Vaginal Symptoms (ICIQ-VS). Study from Cheung et al[11] and Panman et al[12] had better symptoms score in the pessary group compared to the control. The cohort studies also gave similar score but only able to compare before and after the use of pessary. Confidence interval (CI) was used to assess the clinical significance of the results with Coelho et al[13] and Mao et al[14] showing good 95% CI. Cheung et al[11] provided us with the data of mean difference but not enough data for calculating the 95% CI, while Shayo et al[15] presented the data as median with no possibility to calculate the CI manually.

Discussions

All studies reported a tendency of symptoms improvement with the use of pessary. POPDI score was used as a validated score to assess the symptoms related to the pelvic organ prolapse. The score consisted of 16 questions for the long version or 6 questions for the short versions, both with similar reliability and overall responsiveness.[16,17] The questionnaire is widely referred to in the literature.[9,18,19]Another validated score, ICIQ-VS, was also used for the assessment of pelvic symptoms related to pelvic organ dysfunction.[20]

Based on the validity components, the use of pessary as the intervention made it not possible to create a double-blind trial. Therefore, the risk of

response bias could not be omitted from the results. No study had small number of loss to follow-up and/or drop-out. This was due to quite a large number of unsuccessful pessary fitting and failure of pessary continuation for the given time. There are many shapes and sizes of pessaries available to suit the needs of patients, with ring and gellhorn pessaries as the most widely used in the selected studies. Three studies from Coelho et al,[13]Mao et al[14] and Shayo et al[15] were observational cohort, thus making it less valid compared to the two RCTs. The intervention from Panman et al[12] was pessary alone against pelvic exercise, thus making it less equally treated compared to Cheung et al.[11] Therefore, Cheung et al[11] is the best evidence we have at this time.

To provide similar comparison, we used the 12 months period of follow-up from most studies as the calculating point for the importance components, except for Coelho et al.[13] Study from Cheung et al[11]was statistically significant ($p<0.01$) yet did not provide the data we needed to calculate the 95% CI to assess the clinical significance.[11] On the other hand, Panman et al[12] had inaccurate 95% CI probably due to the large number of loss to follow-up and drop-out. From the three cohort studies, Coelho et al[13] and Mao et al[14] had accurate 95% CI with the latter gave us better clinical significance with larger sample and similar outcome measurement compared with Cheung et al.[11]

For the application in our case, the study from Cheung et al,[11]Panman et al[12] and Maoet al,[14] had the better similarity compared with the other two based on the mean patients' age. The mean age was too old in Coelho et al[13] and too young in Shayo et al.[15] All of the studies used the ring and gellhorn pessaries. Both pessaries are also widely available for our patient situation.

Pessary can be divided as support type and space-occupying type.[6] Several studies have evaluated the success of pessary fitting, with success rates ranging from 41% to 74%.[9,21,22] The definition of successful fitting is also varied considerably with variable lengths of follow-up, from a week to 36 months. Most protocols for pessary fitting were similar, with initial fitting using a ring pessary and transition to a space-occupying type if the ring failed. On average, 2 to 3 fittings were required until the appropriate pessary was found.[9,23,24] In addition, a lot of factors associated with unsuccessful fitting such as short vagina, wide introitus, young age, sexual activity, and symptom of incontinence.[6,21,23] This situation leads to a difficult standardized model of pessary.

Despite its internal use, it does not present serious adverse effect, proving to be safe.[6,7,11] However, high rate of discontinuation for lengthy usage still become the major challenge for applying pessary as the preferable treatment of pelvic organ prolapse. Common side effects include vaginal discharge and odor. Serious complications like fistula and erosion have all been reported but rare.[6]

These limitations have made it difficult to run a high-quality clinical trial with small number of drop-out. There is also still lack of studies comparing the effectiveness of pessary with other conservative treatment whose main outcomes would be the symptoms improvement, quality of life, and the satisfaction with the device usage.

Conclusions

Pessarium is one of the tool that can be used for conservative treatment for pelvic organ prolapse. Based on the several studies, the goal of pessarium use were to reduce symptoms that can be caused from pelvic organ prolapse. From these studies, pessarium was an effective and efficient way for pelvic organ prolapse. In one study, it was reported that over 90% patients were comfortable with the treatment and continued treatment until 6-12 months. After 24 months treatment, it was also stated that the use of pessarium correlates with the improvement of the symptoms in pelvic organ prolapse. The most common complaints from the therapy was vaginal discomfort, pain, and bleeding. To answer our patient, we should explain that there is a tendency that pessary usage improves the symptoms of uterine prolapse compared to not using it based on the research publications.

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