

Pessary treatment for pelvic organ prolapse and health-related quality of life: a review

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Abstract Pessaries have been used to treat women with pelvic organ prolapse (POP) since the beginning of recorded history. This review aims to assess the effect of pessary treatment on the disease-specific, 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.

Keywords Pelvic organ prolapse · Pessaries · Pessary · Quality of life · Surgery · Urogenital

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Introduction

Pessaries have been used to treat women with pelvic organ prolapse since the beginning of recorded history. Hippocrates described reduction of vaginal prolapse by placing a halved pomegranate soaked in wine into the vagina (Fig. 1) [1].

A variety of devices has been described over time [2]. Nowadays, most pessaries are made of silicone and are ring type pessaries with or without central support, Gellhorn pessaries and donut pessaries (Fig. 2) [3]. Pessaries are used in daily practice by more than 86% of gynaecologists and 98% of urogynaecologists [4, 5]. The ring with central support and the Gellhorn pessary are most frequently used and appear equally effective in relieving symptoms of genital prolapse and voiding dysfunction [6].

It is not clear which patients particularly benefit most from pessary treatment, what the side effects are and whether the therapeutic effect is high enough to condone possible side effects. Most important is whether pessary treatment reduces urogenital bother symptoms and which impact it has on health-related quality of life [7]. In the end, it is not the doctor's but the patient's opinion about the treatment that is most important. Health-related quality of life is one of the patient outcome measures (POM) and is measured and quantified in domain scores of validated urogynaecological questionnaires. The use of these validated questionnaires to assess health-related quality of life in surgery of pelvic organ prolapse (POP) is well established. Although pessary treatment is widely used for the treatment of pelvic organ prolapse as well, a (systematic) review on the quality of life following pessary treatment has not yet been published.

This review aims to assess the effects of pessary treatment on disease-specific health-related quality of life in women with POP.



Fig. 1 Reduction of vaginal prolapse by placing a halved pomegranate soaked in wine into the vagina described by Hippocrates

Search strategy and selection criteria

We searched Medline (1966 to December 2010) using the Mesh term ‘pessary’ and limits ‘female’ AND ‘human’. This resulted in 726 articles. An additional search on Embase using the term ‘pessary’ and limits ‘human’ resulted in 633 articles. After screening of both title and abstract, we were left with 159 articles related to pelvic organ prolapse and pessary. This review focused solely on pessary treatment in pelvic organ prolapse. Therefore, articles regarding pessary treatment in urinary incontinence or other conditions were excluded. Guidelines on how to fit a pessary, case reports describing rare complications without any literature review and experts’ letters were excluded. From the remaining 41 articles which were considered useful, 13 articles were a review [2, 5, 8–18], and 28 articles were original research articles [3, 4, 6, 7, 19–43]. Only 10 articles [6, 19–21, 25, 27, 32, 34, 35, 41] met the exact criteria of the reviewers’ aim to assess the health-related quality of life in women with pelvic organ prolapse. Although the other articles did not meet these pre-specified criteria, they were considered useful in additional analyses, such as for example which women are most suitable for pessary treatment, successful fitting, dropout rates and management of pessary treatment. Table 1 shows a description of papers included in this review. This review

was originally set up as a systematic review. After reviewing the articles, there was inconsistency in definitions such as successful fitting and dropout rates, sample sizes, and follow-up periods, and there was shortage of studies that met the exact criteria. Therefore, the goal of a systematic review could unfortunately not be achieved, but the available (or lack of) research articles did, to our opinion, justify the present review.

Patient suitability

Which patients are considered suitable for pessary treatment remains unclear from the literature. Patients themselves may have preconceived ideas, and both beliefs and attitudes regarding the aetiology and success of pessary treatment may influence their choice of treatment [3, 22, 31, 33].

Some factors contributing to patient’s choices appear to be independently associated with treatment choices of patients in a fairly predictable way. The probability of choosing pessary treatment over surgery increases as patients’ age rises and respectively decreases as stage of POP increases [31]. Women who already have undergone prior POP surgery are more eager to choose POP surgery again [31]. Women preferring surgery to pessary treatment for POP reported more bothersome symptoms related to POP and felt more affected by POP in their general well-being [33]. Furthermore, the majority of patients who were sexually active tended to prefer surgery above conservative treatment [33].

Failure of fitting and continuation of pessary use

Most papers reported that there are certain groups of patients that drop out. There are patients who initially do



Fig. 2 Pessary most prescribed. Donut, Gellhorn, ring with and without support (Milex Products, Inc.)

Table 1 Description of papers used in the review

Description of research	Number of articles, <i>n</i> =41	References
Quality of life changes in pessary use in pelvic organ prolapse	10	[4, 6, 19–21, 25, 27, 32, 34, 35]
Successful fitting pessary and dropout rates in pelvic organ prolapse	20	[6, 19–25, 27, 28, 30, 32, 34, 35, 37, 39–43]
Continuation rate long-term pessary use	3	[23, 27, 43]
Patients suitability	6	[3, 14, 20, 22, 31, 33]
Anatomical changes after pessary use	3	[29, 32, 38]
Complication and discomfort	6	[1, 9, 18, 23, 27, 43]
Management of pessary treatment	11	[1, 3, 5, 10, 14–18, 21, 30]
Research design		
Review	13	[2, 5, 8–18]
Retrospective study	10	[3, 20, 22, 23, 28, 30, 37, 39, 42, 43]
Prospective study	13	[7, 19, 21, 24–27, 29, 33–36, 41]
Randomised and quasi-randomised trials	3	[4, 6, 40]
Cross-sectional	1	[31]
Observational cohort	1	[32]
Case report	1	[38]

not comfortably retain a pessary (mostly at their first visit). There is an additional group of patients who abandon pessary treatment after some weeks because of discomfort or repeated expulsions [30]. There is no agreement in the literature on what is considered successful pessary fitting. Some authors considered fitting successful if a pessary was perceived comfortable by a patient when retained during Valsalva and voiding, at the initial patient visit, while others considered fitting successful if a patient continued to use the pessary until the following doctor's appointment [40]. Therefore, the rate of unsuccessful fitting and dropout ranges widely. Table 2 offers an overview of successful fitting and dropout rates of studies included in this review. In this review, we considered fitting to be successful if a patient comfortably retained a pessary at their first visit. A patient was considered to drop out if they abandoned pessary use at the following doctors' appointment.

Most studies reported successful fitting rates to be over 85%. Risk factors that are reported to be responsible for unsuccessful pessary fitting are short vaginal length, a large genital hiatus, prior history of hysterectomy and prior surgical repairs of POP [37, 39].

The compartment and stage of POP have not been reported to have any influence on successful pessary fitting and should therefore not be a factor of patient selection for pessary treatment [39]. Continuation rates on the short-term range from 50% to 80% after 3 or 4 months. After 1 year of use, the continuation rates

remain unchanged: 50–80%. Only two studies reported long-term continuation of pessary use over more than 1 year. One study reported a continued pessary use in 48% of patients for an average duration of 5.4 years [23]. A more recent study on the long term reported a 14% continued pessary use with a mean duration of 7 years [43].

An independent factor associated with the continued use of a pessary is age above 65 years. Sexually active women were more likely to continue wearing a pessary for a longer period of time [22, 26, 28].

Improvement in POP-related bother and health-related quality of life

POP causes symptoms that have impact on patients' daily activities and quality of life. Women with POP seem to have a negative body image compared to women without POP [44]. Women who seek medical advice perceive these symptoms bothersome enough to opt for treatment and strive to improve their perceived quality of life [44].

We found only few articles in which validated urogynaecological questionnaires were used to assess treatment effects on health-related quality of life [6, 19, 21, 27, 32, 34, 35, 41]. Two articles did not use validated questionnaires but measured improvement of POP symptoms and satisfaction in pessary users with questionnaires that

Table 2 Successful fitting and dropout rates

Author publication year [reference]	Number	Study design	Initially successful fitting, <i>n</i> (%) ^a	Dropout at follow-up, <i>n</i> (%) ^b	Follow-up in months
Clemons 2004 [24]	100	Prospective	94 (94)	21 (22)	0.5
Brincat 2004 [22]	136	Retrospective	Unknown	54 (40)	4
Clemons 2004 [26]	59	Prospective	Unknown	16 (27)	12
Mutone 2004 [39]	407	Retrospective	288 (71)	120 (42)	0.75
Powers 2004 [42]	32	Retrospective	Unknown	20 (63)	Unknown
Broens-Oostveen 2004 [23]	192	Retrospective	Unknown	107 (52)	64
Bai 2005 [20]	104	Retrospective	Unknown	20 (19)	Unknown
Hanson 2005 [30]	1,216	Retrospective	1,043 (86)	299 (29)	3
Fernando 2006 [27]	203	Prospective	203 (100)	106 (52)	4
Barber 2006 [21]	42	Prospective cross-over	42 (100)	0 (0)	3
Maito 2006 [37]	120	Retrospective	103 (86)	11 (11)	6
Cundiff 2007 [6]	134	Randomised cross-over	123 (92)	49 (40)	3
Komesu 2007 [34]	64	Prospective cohort study	Unknown	28 (44)	12
Jones 2008 [32]	90	Prospective cohort study	Unknown	48 (53)	3
Nager 2009 [40]	255	Randomised controlled trial	235 (92)	No follow-up	No follow-up
Kuhn 2009 [35]	73	Prospective cohort study	Unknown	40 (55)	3
Sarma 2009 [43]	273	Retrospective	167 (61)	144 (86)	84
Friedman 2010 [28]	150	Retrospective	Unknown	35 (23)	12
Patel 2010 [41]	75	Prospective cohort study	70 (93)	21 (30)	3
Abdool 2010 [19]	359	Prospective	359 (100)	116 (32)	12

^a Initially fitting^b Dropout at follow-up

were not validated [20, 25]. Other questionnaires that were used were the Female Sexual Function Index Questionnaire (FSFI), the Pelvic Floor Distress Inventory (PFDI), the Pelvic Floor Impact Questionnaire (PFIQ), the Body Image Scale, the Sheffield Pelvic Organ Prolapse Symptom Questionnaire and the King's Health Questionnaire. The PFDI and PFIQ have been validated for use in women with POP [41]. The body image scale evaluates a woman's self-perception of her physical appearance, attractiveness, and satisfaction with her body. This questionnaire has been used in research on women with cancer and was considered valid and reliable for that group of patients, but is not yet validated for use in women with POP [45]. The FSFI is a validated questionnaire that refers to the domains of desire, arousal, lubrication, orgasm and satisfaction in sexual functioning [46]. The Sheffield prolapse questionnaire relates to the severity of POP specific symptoms, while the King's Health Questionnaire evaluates domains of health-related quality of life [35]. The results of 10 available studies are shown in Table 3. Consistent in most papers is the improvement gained in both bulge and irritative bladder symptoms following pessary treatment. Two studies

reported de novo stress urinary incontinence [25, 35]. Women who were sexually active and wore a pessary reported a significant increase in both frequency and satisfaction of sexual activity [19, 27]. There were significant improvements in desire, lubrication and sexual satisfaction after treatment of POP with a pessary [35]. These findings may have resulted of improvements in general well-being which may have altered patients' self-esteem. These data are suggestive that a vaginal pessary does not negatively interfere with sexual activity and may even improve sexual functioning as a whole.

Patients' satisfaction rates with medium-term pessary use are high (70–92%) [20, 25]. Pessary treatment for 3 months not only reduced POP-related bother symptoms but also caused improvement in quality of life and women's perception of their body image [41].

A recently published study compared the effectiveness of pessaries with surgery in women with symptomatic POP [19]. The authors reported similar improvements in urinary, bowel, sexual function and quality of life parameters in both treatment arms. That suggests that pessary treatment in POP might be as effective as surgery in improving health-related quality of life.

Table 3 Studies on effect of pessary treatment on health related quality of life

Author year [reference]	Number	Study design	Dropout, n (%)	Dropout, reasons	Follow-up in months	Questionnaires used	Improved symptoms with pessary treatment	Worsened symptoms	Satisfaction rate
Clemons 2004 [25]	100	Prospective study	27 (27)	Failure to retain pessary, Discomfort	2 months	Questionnaire not further assessed	Bulge, Pressure, Discharge, Voiding, Urge incontinence, Stress incontinence	De novo stress urinary incontinence	92%
Bai 2005 [20]	104	Retrospective study	20 (19)	Failure to retain pessary, Discomfort, Inflammation	Unknown	Questionnaire not further assessed	Not measured	Bleeding, foul odour, Erosion	70%
Fernando 2006 [27]	203	Prospective observational cohort study	106 (52)	Failure to retain pessary, Pain/bleeding/discomfort, Worsening symptoms	4 months	SPQ	Bulge, Pressure, Voiding, Urinary urgency, Sexual activity		
Barber 2006 [21]	42	Prospective cross-over study	0	Worsening symptoms	3 months	PFDI, PFIQ	Bulge, Urinary		
Cundiff 2007 [6]	134	Randomised crossover study	49 (37)	Failure to retain pessary, Quit study due to failure of pessary	3 months ring, 3 months Gellhorn	PFIQ, PFDI	Bulge, Urinary, Life impact urinary symptoms, Life impact pelvic organ prolapse		
Komesu 2007 [34]	64	Prospective observational cohort study	28 (44)	Failure to retain pessary, Discomfort	12 months	PFDI	Bulge, Pressure, Voiding, Urge incontinence, Stress incontinence		
Jones 2008 [32]	90	Prospective Observational Cohort study	48 (53)	Failure to retain pessary, Inadequate relief of symptoms	3 months	PFDI	Bulge, Urinary		
Kuhn 2009 [35]	73	Prospective observational cohort study	40 (55)	Loss of pessary during daily activities or bowel emptying, Pain/discomfort, Desire for surgery, Worsening symptoms, Inability to remove insert/remove pessary	3 months	SPQ, FSFI, KHQ	General health, Role limitations, Physical and social limitations, Incontinence impact, Personal relationships, Sexual desire, Lubrification, Sexual satisfaction, Bulge, Stool outlet problems	De novo stress urinary incontinence	
Patel 2010 [41]	75	Prospective observational cohort study	21(28)	Failure to retain pessary, Desire for surgery, Discomfort	3 months	PFDI, PFIQ, BIS	Body image, Quality of life, Bulge		
Abdool 2010 [19]	359	Prospective study	116 (32)	Opted for surgery	12 months	SPQ	Bulge, Pessary-related problems, Pressure, Urinary, Sexual function, Stool outlet problems		

Questionnaires used were Female Sexual Function Index (FSFI), Sheffield Prolapse Questionnaire (SPQ), King's Health Questionnaire (KHQ), Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ), and body image scale (BIS). Questionnaire not further assessed

Improvement in POP-Q measurement

There may be a decrease in the size of the genital hiatus with continued pessary use. This decrease is detected even after 2 weeks of continuous pessary wearing [32]. There may also be an improvement in POP stage after 1 year of pessary treatment [29]. Such improvements may have been due to a transient effect of pessary use [29, 38]. Limitations of these papers are the small sample sizes. Whether this reduction in POP stage sustains at the long term and whether it is clinically relevant need further research.

Management and follow-up

Evidence is lacking on the type of pessary that is chosen, or who should be responsible for cleaning and changing pessaries and how often this should be performed [14, 30]. Ideally, the physician can teach a patient how to remove and replace the pessary herself. This increases patients' autonomy, allowing her to use it and clean it when needed [5, 18]. In such a setting, follow-up could be on an annual basis [18]. Patients who are not willing or able to manage pessary care themselves require more frequent doctors (or nurse practitioner) visits. There is a lack of evidence on whether a pessary should be used in combination with hormone replacement therapy or pelvic floor exercises [3]. If HRT is prescribed, local HRT seems to be more beneficial in reducing side effects than systemic HRT or a combination of both [30]. HRT is particularly used to prevent vaginal irritation and ulceration due to pressure of the pessary in an older and atrophic vagina [17]. There is some evidence that local HRT plays a significant role in the initial success of fitting [30].

Complications and discomfort

The most common side effects of pessary use are a foul smell, vaginal discharge, bleeding, pain and constipation [43]. A recent study reported that 56% of women wearing a pessary reported one of these side effects [43]. Changing a pessary at frequent intervals could prevent this vaginal irritation. Therefore, it is helpful if the patient is willing and able to remove, clean and replace the pessary herself [18].

Rarely, pessaries cause major urinary, rectal and genital complications such as fistula, faecal impaction, hydro-nephrosis and urosepsis [1]. These rare complications are almost exclusively related to a long period of use and negligence of care. With regular follow-up, the majority of

pessary complications can be avoided and kept to a minimum [9].

Conclusion

Pessary treatment is widely used for the treatment of pelvic organ prolapse. It can be considered a patient-friendly, minimally invasive treatment and appears to be safe. Most studies reported successful fitting trial over 85%. Risk factors responsible for unsuccessful pessary fitting are short vaginal length, a large genital hiatus, prior history of hysterectomy and prior surgical repairs of POP. The compartment and stage of POP have not been reported to have any influence on successful pessary fitting. Fifty percent to 80% of women who were initially successfully fitted continued to use pessary at 1 year. Continuation rates at greater than 5 years range from 14% to 48%. Consistent in most reports though are the improvements in both bulge and irritative bladder symptoms and the high satisfaction rates.

Sexual activity appears not to be a contraindication for pessary treatment; on the contrary, it seems to have a positive effect on sexual functioning. In comparison with POP surgery, 1-year outcomes in terms of prolapse symptoms, sexual functioning and quality of life seem similar with pessary use.

Discussion

The aim of this review was to set up a systematic review on articles that address health-related quality of life in pessary treatment of pelvic organ prolapse. The limitation of this review is the limited availability of published studies on that issue. Another limitation is that in most published papers, follow-up periods were short, usually less than 12 months. Long-term outcomes on the other hand were inconsistent.

The use of validated urogynaecological questionnaires in pessary treatment is still limited. In POP surgery, the use of these validated tools is well established. The few papers in which urogynaecological questionnaires were used do suggest improvements in health-related quality of life following pessary treatment. Comparison with other prolapse therapies is rare and, if so, not yet assessed in a randomised controlled trial.

More research is indicated, and it is our opinion that a randomised controlled trial comparing pessary use with surgical treatments of POP should be undertaken to determine its therapeutic position in the management of pelvic organ prolapse. Outcome measures of such a trial

should be the change in urogenital bother and quality of life scores.

- Gelhorn and ring with support prescribed most frequently
- Sexual activity or degree of prolapse should not be a contraindication of pessary treatment
- Failure to fit 15%
- If HRT is prescribed, local HRT is sufficient
- Common side effects are bleeding, vaginal discharge, pain, constipation and odour.
- Side effects appear in 56% of women with long term pessary use.

Effect of pessary treatment

- Improvement in bulge symptoms
- Improvement in irritative bladder symptoms
- Increase in frequency and satisfaction of sexual behaviour
- Improvement in perception of body image
- Reported satisfaction rate 70-92%
- Comparison with surgery similar outcomes after 1 year follow up.

Conflicts of interest None.

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