

An integrative review and severity classification of complications related to pessary use in the treatment of female pelvic organ prolapse

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Abstract

Introduction: Pessary use is the preferred non-surgical treatment option for female pelvic organ prolapse. As pessaries can be used chronically to alter pelvic floor anatomy, consideration of short- and long-term complications is important in patient management. We systematically reviewed articles describing the complications of pessary use to determine frequency and severity.

Methods: A systematic search via MEDLINE and PubMed using the key terms “complications,” “pessary,” “pelvic organ prolapse,” “side effects” was conducted for the years 1952 to 2014 inclusively. Selected articles cited in the publications identified were also considered. Only full-text material published in English was reviewed. All pessary-related complications described were collated; overall frequency within case reports and case series were calculated and severity was graded using the Clavien-Dindo classification.

Results: In total, 61 articles met the inclusion criteria. The most common complications reported were vaginal discharge/vaginitis, erosion, and bleeding. Complications were related to pessary shape and material, and duration in situ. Clavien-Dindo classification of complication severity found that all 5 grade levels were attributed to pessary use; serious grade 4 and 5 complications included cancer, adjacent organ fistula and death.

Conclusion: There are few detailed reports of complications of pessary use relative to the estimated frequency of pessary use worldwide. Prospective studies documenting complications by shape, material, and size, and objectively classifying complication severity are required. As serious grade 4 and 5 complications of pessary use occur, further development of clinical follow-up guidelines for long-term pessary users is justified.

Introduction

Pelvic organ prolapse (POP) is a widespread and troublesome condition related to loss of anatomic support of the

pelvic organs.^{1,2} Recognition of the condition can be traced back to Egypt in 1500 BC and treatment with pessary use was demonstrated by Hippocrates in 400 BC.^{3,4} The word “pessary” derives from the Greek word “peso” – an oval stone. The origin for all intrauterine devices is probably the use of oval stones inserted into the uterus in saddle camels to prevent conception during long desert journeys.⁵⁻⁸

The use of pessaries is common; more than 85% of gynecologists⁹ and nearly 98% of urogynecologists prescribe them.¹⁰ They provide anatomic support and can be used as a treatment of choice or in those who decline surgery (e.g., women who plan future childbearing, require temporary relief of prolapse while waiting for surgery or during pregnancy, or do not want surgical repair^{11,12}).

Pessaries have few complications, although some authors suggest that they require lifestyle modification,^{13,14} and the variety of shapes and sizes available affords choice and individual fitting.¹⁵ However, data on complications relevant to appropriate discussion of consent with patients and planning of long-term follow up strategies are limited. The side effects of pessary use are not obvious; moreover it is not clear whether the therapeutic impact is high enough to overlook possible risks or which patients benefit the most from pessary treatment.¹⁶ Few studies have tested the relative value of different practice models for pessary use, although pessaries have assumed growing importance in the treatment of POP.¹⁷

A 2004 Cochrane review of pessaries use for POP and updated in 2013^{13,18} found only 1 randomized controlled trial examining the efficacy of pessary use.¹³ Complications were described as rare and there was no consensus on complication management. Furthermore, there was no reference to complication severity grading.

In this study, we conducted an integrative review of reported complications related to pessary use, and classified them according to a standardized severity scale. Since pessaries were used as an alternative to surgical treatment, and are a

physical therapy akin to surgical therapy, the Clavien-Dindo¹⁹ complication severity grading system was used. Conceptually this provided a comparison to reported surgical complications and also provided a means to appropriately inform patients about complications in the context of informed consent. A secondary objective was to categorize complications according to pessary shape, size, and material used.

Methods

Systematic review search strategy

A systematic search via MEDLINE and PubMed using the key terms “complications,” “pessary,” “pelvic organ prolapse,” “side effects” was conducted for the years 1952 to 2014 inclusively. Included articles had to have been published in English, peer-reviewed journals, with the full-text available. Review articles were excluded because they either did not contain original material or duplicated extant reports.

Analytic process

The authors reviewed each article to extract the following: complication(s) of pessary use, number of subjects, age, type

of pessary (ring, shelf, Gellhorn, and cube), size, and material composition (silicon, polythene, gold, and metallic). In papers in which the nature or management of the complication was described, we categorized complication severity according to the Clavien-Dindo system.¹⁹ In the instance of multiple reports of a single complication, we reported the severity of the outcome in more than 1 grade based on description of the management. Removal of a pessary as a management strategy, or a change from the treatment plan of self-care to dependent care was classified as a Grade 1 complication. This was felt to be akin to deviation from a standard protocol in the surgical setting.

Results

In total, we identified 99 full-text articles. Of these, 61 met the inclusion criteria (Fig. 1): 25 original case studies and 36 case reports. We excluded 21 review articles and 17 additional articles due to duplication or unrelated content (Fig. 1).

In 34 papers, we were able to assess type, shape, size or composition of the pessary with complications (Table 2). Thirteen papers discussed complications related to pessary size.²⁰⁻³¹ By combining the data in both case reports and case studies, we found that the most frequent complications

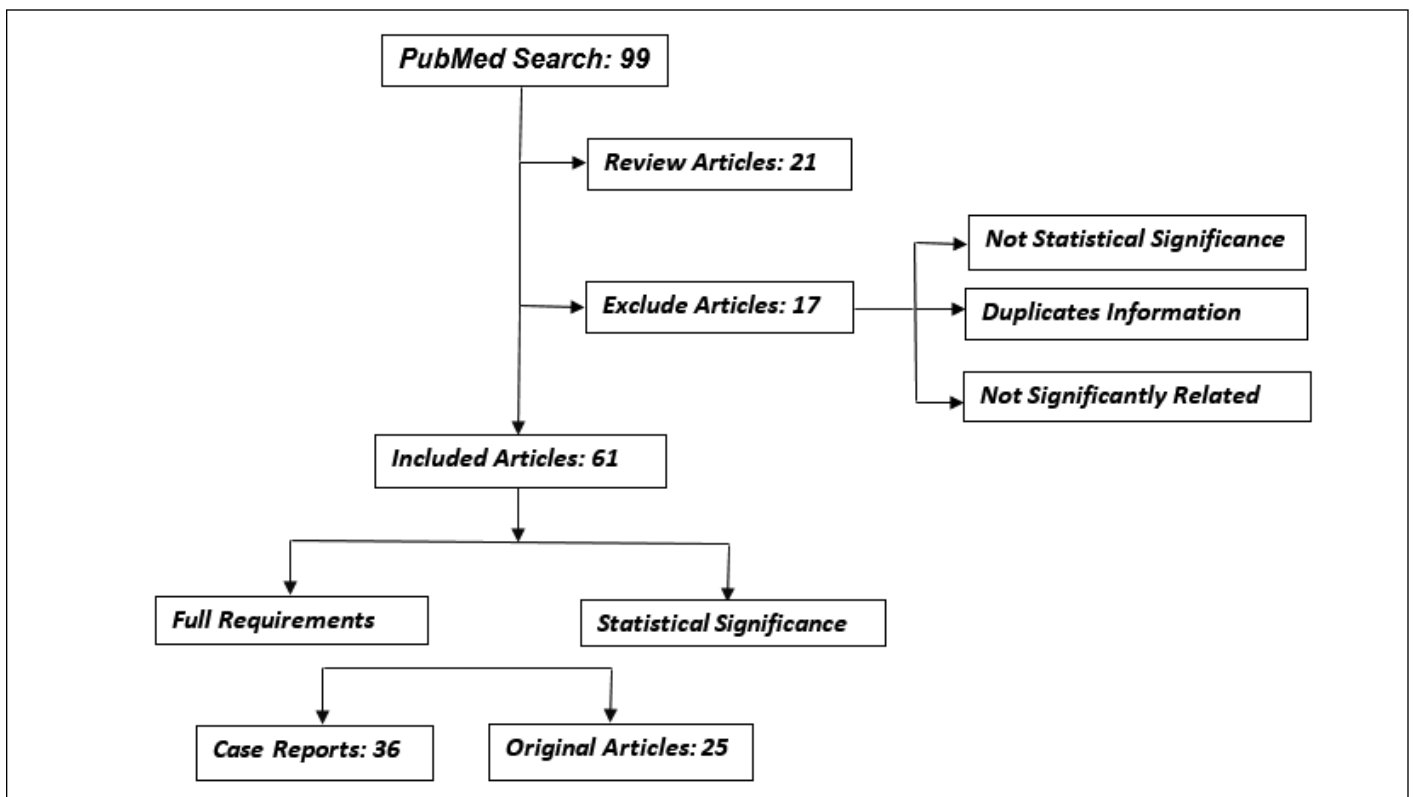


Fig. 1. Flowchart of citation review and inclusion strategy.

were: vaginal discharge, bleeding, vesicovaginal fistula, erosion, ulceration, and foul odor (Table 1). We graded the reported complications using the Clavien-Dindo classification (Table 3).

Discussion

We systematically reviewed the complications of pessary use to treat POP. The frequency of complications varied widely between individual reports and between case series and case reports. Vaginal discharge, bleeding, and odor were frequently reported; however in rare instances, dangerous complications included death, particularly if the pessary was neglected.²⁰ We have documented that all 5 Clavien-Dindo grades of complication occurred as a consequence of pessary use. The Clavien-Dindo approach is based on the type of therapy used to correct a specific complication, and is a form of classification used increasingly in surgical research to provide an objective and reproducible ranking for the reporting of complication severity. Hence, extrapolation to pessary use was considered justified, because, like surgery, pessaries offer a physical treatment which makes this type of classification more suitable than those used for pharmacologic treatments.

Despite the frequency of pessary use, complication reports predominantly came from case reports rather than case series.³² Some authors described pessaries as “outdated” and “risky;”^{33,34} there was even reference to the “dangerous pessary.”⁷ We felt it was not appropriate to state the overall frequency of complications related to pessaries from the reviewed literature. As the denominator is either small or unknown in most studies, we were cautious in our data interpretation. Others have reported that complications

Table 1. Nature of complications of pessary use and frequency of reporting classified by type of report⁷⁰⁻⁸⁰

Type of study	Case report	Case series	Total
No. studies	34	25	61
No. total subjects	52	1138	1190
Erosion	11	44	55
Infection	6	13	18
Vesicovaginal fistula	16	18	34
Bleeding	19	10	29
Ulceration	10	4	14
Death	4	5	9
Pain and discomfort	2	60	62
Vaginitis	3	14	17
Vaginal discharge	21	35	56
Foul odor	9	18	27
Cancer	9	0	9
Fibrosis	2	0	22
Rectovaginal fistula	2	0	2
Bilateral hydronephrosis with urosepsis	1	0	1
Bowel obstruction	1	0	1
Unilateral hydronephrosis	1	0	1
Ureteric obstruction	1	0	1
Hydronephrosis	1	0	1

affect <10% of patients.^{35,36} Overall, very few reports defined pessary complications by type, shape, material, or size and objective classification of severity was lacking. This information is important to ensure patients are properly informed and to ensure proper patient consent in patients undertaking long-term pessary use and in their follow-up care.

It is important to discuss the following points with patients. A superficial vaginal mucosal erosion is the most frequently

Table 2. Reported complications of individual pessary types^{12,20-31,35,38,42,48,49,52,53,60-69}

Type of pessary	Gellhorn	Ring	Shelf	Porcelain	Doughnut	Cube	Metallic ring	Total
No. studies	6	15	8	1	1	1	2	34
No. patients	7	397	9	1	1	1	3	419
Erosion	2	40	2	0	0	0	0	
Vesicovaginal fistula	6	2	4	1	0	0	0	
Infection	3	13	0	0	0	0	0	
Ulceration	0	4	1	0	0	1	0	
Bleeding	1	28	3	1	0	0	1	
Death	0	0	2	0	0	0	0	
Discomfort	1	10	1	0	0	0	0	
Vaginal discharge	1	47	2	0	1	1	2	
Fibrosis	1	1	1	0	0	0	0	
Foul odor	1	23	0	0	0	0	0	
Slipped	0	16	0	0	0	0	0	
Ureteric obstruction	0	2	2	0	1	0	0	
Cancer	1	6	0	0	0	0	0	
Vaginitis	0	18	2	0	0	0	0	
Rectovaginal fistula	0	0	1	0	0	0	1	

Table 3. Classification of complications using the Clavien-Dindo system based on management strategies reported in the literature

Grades (Contracted form)	Definition	Complications
Grade I	Deviation from the standard course of therapy. Allowed therapeutic regimens including drugs: (antiemetics, antipyretics, analgesics, diuretics, electrolytes) and physiotherapy.	Vaginal Discharge Ulceration Pain Bleeding Constipation Material Allergy Inability to self-replace or insert
Grade II	Requiring pharmacological treatment (drugs other than allowed for grade I complications), blood transfusions, total parenteral nutrition.	Vaginal discharge Erosion Vaginitis Ulceration Acute pyelonephritis Vesicovaginal fistula Rectovaginal fistula Ureteric obstruction
Grade III	Surgical, endoscopic or radiological interventions	Retained pessary requiring surgical removal Decubitus ulceration of the uterus Hydronephrosis – unilateral and bilateral Bowel obstruction Vaginal fibrosis
Grade IV	Life-threatening complication. Single or multi-organ dysfunction.	Vaginal cancer Cervical cancer Small bowel incarceration
Grade V	Death of a patient	Incarceration Enterovesical Fistula Obstructive uropathy Urosepsis

In the case where multiple instances of a single complication was reported, the complication may appear in more than 1 grade based on how the complication was managed as reported in the literature.

reported complication of a pessary,^{33,34,37-41} presenting as foul odor, purulent discharge, irregular blood stained discharge, and increased vaginal fluid. Localized pressure effects can result in ulceration and abrasions of the vaginal mucosa,^{42,43} and in rare cases reduced local blood flow secondary to chronic pressure has caused decubitus ulceration of the uterus.⁴⁴ Reported risk factors for erosion include long-term uninterrupted use or placement of a pessary that was too large.³¹ Recommendations associated with this literature stress the need for proper sizing and performance of periodic examination.^{28,43}

Vaginal flora are affected by pessary use. Many patients have a physiologic watery discharge; this finding is not considered an infectious process unless accompanied by other symptoms (e.g., itching, burning, or foul odor).⁴³ Vaginal discharge and infection may affect as many as one-third of users;⁴⁵ bleeding, pain, and constipation were also often reported.^{16,46} These issues have led to changes in pessary shape design.^{4,47}

Serious complications include fistulae. Unlike minor complications which occur across all design types and materials, fistula frequency and location vary depending on pessary shape and material. Vesicovaginal fistulas (VVF), although uncommon, are among the most serious complications of neglected pessaries.⁴⁸ The reports identify Gellhorn

and shelf designs most often;¹² rectovaginal fistula and VVFs appear more common with rubber or PVC pessaries when compared with polythene pessaries.³⁵ Fistula formation may also be associated with fecal impaction, hydronephrosis, and urosepsis,³² however, these complications were generally reported in the setting of neglect.^{22,23} Although serious complications caused by neglected pessaries are rare,⁴⁹ in case reports describing VVFs, bowel fistulae, and incarcerated pessaries, 91% were correlated to neglected pessaries,¹² and patients with dementia and nursing home residents could be at higher risk.³⁹

Several reports implicated pessaries as a causal mechanism for both vaginal and cervical cancer.²⁵ Chronic inflammation in association with viral infections has been suggested to predispose patients to such cancers as the tumours appeared at the site of pessary placement.⁵⁰ It has been proposed that wearing a vaginal ring or cup-and-stem pessary for a long time may cause cancer of the vagina, ulcerative vaginitis, or fistulae. Primary cancer of the vagina was reported in 6 women among a group of 13 with major pelvic complications correlated to long-term pessary use,³⁸ and in a woman who developed vaginal and cervical cancer after 18 years of pessary use.⁵⁰ Other mechanisms proposed included the generation of metaplastic and subsequent dysplastic change of the squamous mucosa,⁵¹ and the potential

for personal cleanliness to play a role in carcinogenesis.⁵² Although, primary vaginal cancers are uncommon (1%–2% of gynecological malignancies⁵¹) Jain and colleagues reported that two vaginal cancers occurred in users of shelf pessaries among 9 cases of vaginal carcinoma reported between 2003 and 2005.⁵²

Death has resulted from pessary use. An 82-year-old woman with a ring pessary developed vaginal bleeding; biopsies showed extensive surface ulceration, necrosis, and suppurative inflammation, and she died from acute pyelonephritis with hydronephrosis.²⁰ A 77-year-old using a shelf pessary for 18 years reported vaginal bleeding and a foul-smelling discharge; examination revealed a vesicovaginal and a rectovaginal fistula, and she also died from acute pyelonephritis and hydronephrosis.³⁸ Also, an 88-year-old patient died following erosion of a pessary into the upper rectum.⁵³

The literature reviewed contained sparse information regarding the materials used in pessaries causing complications. This is an omission as pessaries are manufactured from an assortment of materials, including fruit, metal, porcelain, rubber, and acrylic,⁵⁴ with each material having certain advantages and disadvantages. Most are made of medical grade silicone covering components of surgical steel;⁵⁵ some pessaries are radiolucent with elements of silicone, rubber, acrylic, latex, or plastic.⁵¹ Medical-grade silicone pessaries are long-lasting, biologically inactive, do not cause allergy, and are not carcinogenic. Patients find them easy to wash and disinfect, using autoclave, boiling water, or a cold sterilization product.^{47,56,57} Pessaries rarely cause an allergic reaction. They may change colour with use and their material rarely fails or breaks, which would necessitate replacement.⁵⁸

No single pessary design was complication free. Historically, a large number of physical shapes exist; the American Medical Association had identified 123 types of pessaries by 1867.⁵⁵ Pessary shapes can be classified as supportive or space-occupying, with or without mechanisms to reduce urinary incontinence. Supportive pessaries consist of ring and lever designs, including the Smith, Hodge, Risser, and Gehring. Space-occupying pessaries for advanced prolapse include Gellhorn, doughnut, and cube designs. Ring pessaries are generally easy to displace and Gellhorn/shelf pessaries can be more difficult to remove, resulting in pain and bleeding.⁵⁷ Sometimes anesthesia is required.⁵⁹

Our review has its limitations. It is limited to English literature. The overall frequency of individual complications of pessary use is unclear as the literature consists principally of case reports rather than prospective randomized studies. Although literature from over 50 years was reviewed, the number of patients studied is not large; hence the frequency of complications from pessary use may be underreported.

Conclusions

There are few detailed reports of complications of pessary use relative to the estimated frequency of pessary use worldwide. High-grade complications appear related to longevity of pessary use and lack of appropriate maintenance care. The incidence of complications in general also mandates follow-up of all women using pessaries in the long-term. Prospective studies documenting pessary complications by shape, material, and size, and objective classification of severity are required to further the scientific literature related to pessary use. Death, although rare, is a reported complication and should be included in the informed consent of patients undertaking long-term pessary use.

Competing interests: The authors declare no competing financial or personal interests.

This paper has been peer-reviewed.

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