Does self-management of vaginal pessaries improve care for women with pelvic organ prolapse?

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Title: 'Uncertainties: Is self-management of vaginal support pessary for pelvic organ prolapse safe and does it improve women's quality of life?'

Introduction

Pelvic organ prolapse is the symptomatic downward displacement of the pelvic organs which affects approximately 40% of women over the age of 50 and has a negative impact on quality of life [1]. The NICE guideline on the management of urinary incontinence and pelvic organ prolapse in women recommends that all options for treating prolapse should be discussed with women including lifestyle modification, pelvic floor muscle training, pessaries and surgery [2]. The NICE guidance recommends that the pessary is removed at least every 6 months but does not recommend where or who should do this; however it is recommended that women who have cognitive or physical impairments that might make it difficult for them to manage their pessary are to receive 6 monthly clinic appointments. The guidance does not mention pessary self-management. A vaginal pessary is a support device inserted into the vagina to hold up the vaginal walls and pelvic organs to relieve symptoms of pelvic organ prolapse. Pessaries are used by many women as an alternative to surgery. A pessary needs to be changed regularly to prevent and detect complications such as vaginal ulceration. Neglected pessaries can result in incarceration or the development of vesicovaginal or rectovaginal fistulae. There are two types of pessary in common use: support pessaries such as rings and space-occupying pessaries such as gellhorn or shelf pessaries (see Figure 1 for examples of different pessary types). They are made from a variety of materials including PVC, vinyl, silicone and latex. Pessaries can be inserted by GPs, practice nurses, gynaecology nurses, specialist physiotherapists and gynaecologists. This paper focusses on the uncertainty about the best care pathway for women using a vaginal pessary for prolapse. Specifically, whether self-management is more effective than clinic-based pessary care in ensuring safety and maximising quality of life for women with prolapse.

Two thirds of women will opt to try a pessary instead of surgery for prolapse symptom relief [3]. Pessaries are most commonly inserted by gynaecologists in a hospital setting although follow-up pessary changes are carried out in different settings including GP practices and community clinics and by a range of health professionals. Current evidence suggests that, in the UK, women most commonly receive follow up pessary care in a hospital outpatient clinic [3] which has significant cost implications for the service. However, it is possible that a woman could remove, clean and re-insert the pessary herself, after receiving appropriate instruction from a healthcare professional: this is called self-management.

Surveys carried out in the UK [4] and North America [5] showed that the rate of self-management for pessaries is much lower in the UK than in North America (17% vs. 57% respectively). It is unclear whether the lower rates for self-management in the UK are due to the prevailing uncertainties about its safety and effectiveness.

What you need to know

Pessaries are commonly used in the treatment of pelvic organ prolapse to relieve symptoms. Pessaries can be used as a conservative management for pelvic organ prolapse, where women would like to avoid surgery, or while awaiting surgery. Pessaries can be used for a variety of prolapse types and stages.

Clinic based care involves women attending an appointment every 4-6 months to have their pessary removed, their vaginal tissues inspected and a new pessary inserted by a GP or specialist nurse or Gynaecologist [3].The frequency of pessary changes varies across different clinical environments and pessary types.

The key benefit of clinic-based care compared to self-care is that the woman's vaginal tissues are inspected and hence pessary complications (such as erosions) can be identified and treated early. The disadvantages are that women need to attend clinic appointments regularly, possibly over many years and they may not be able to remove the pessary to have sexual intercourse (depending on pessary type).

Pessary self-management allows women the flexibility of removing/reinserting their pessary as they wish, but at least once every 6 months. Women are usually provided with a telephone number to call if they experience any problems, and are seen in clinic for a visual examination. Not all clinical areas offer pessary self-management to their patients. The main advantages of self-management are convenience for the woman and fit to her lifestyle choices (e.g. ability to remove pessary when it suits her). The main disadvantage of pessary self-management is that if a woman is not seen in clinic regularly it is possible that complications may be missed.

Key Issues to discuss with women before pessary use [2]

- All options for management of symptoms including lifestyle modifications, PFMT, pessary and surgery.
- Explain pessary use requires regular changes
- Ensure the pessary is appropriate for sexual activity if the woman wishes to be sexually active
- Treating atrophic vaginitis with vaginal oestrogen may make pessaries more comfortable
- Explain it may take more than one fitting to achieve a successful pessary fit and it is not always possible to find a suitable pessary
- Ensure women can void after first fitting before leaving the clinical area
- Advice on common complications include vaginal discharge, ulceration, bleeding and expulsion and on less common complications which may occur if a pessary is not changed regularly such as incarceration requiring removal under anaesthetic, rectovaginal or vesicovaginal fistula and very rarely cancer.
- Ensure failsafe netting is in place for women with physical or cognitive barriers to attending for pessary changes to prevent serious complications of neglected pessary.

"What is the evidence of uncertainty?"

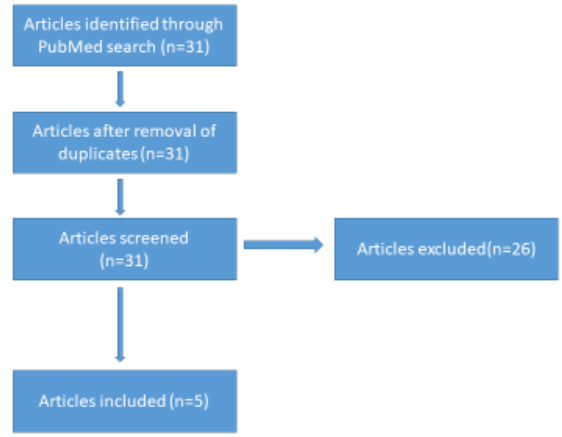
To date no completed trials have been identified on pessary self-management. The current search, outlined in Box 1, identified five small non-randomised studies, which focused on pessary self-management (Table 1).

The five studies were carried out in the UK [6], Hungary [7], Thailand [8], Taiwan [9] and the Netherlands [10] and four [6-9] focused mainly on pessary continuation. Three of the studies had sample sizes of less than 100 participants [6,7,9], one had a sample size of 289 women [8] and the other a sample size of 163 [10]. The combination of this observational evidence suggests that pessary self-management may enhance pessary continuation rates, patient satisfaction and quality of life without increasing complication rates or adverse events. A major limitation is the lack of comparison groups in four studies [6-9] for their primary and secondary outcomes. Kearney and Brown [6] report comparative data for improved levels of convenience, accessibility, support and comfort in the self-management group but for a non-randomised population.

Box 1: Search strategy, terms and flow diagram

Search strategy and terms

We searched the PubMed database using the following search terms:
"pessary" AND "safety" AND "self-management" AND "prolapse".



"Is ongoing research likely to provide relevant evidence?"

The US National Library of Medicine database and ISRCTN and ANZCTR registries for registered trials were searched on 19th August 2019 for ongoing trials focusing on pelvic organ prolapse. Two trials were identified that have relevance to pessary self-management.

The TOPSY trial (ISRCTN62510577, registered on 06/10/2017] is an ongoing randomised controlled trial (RCT) comparing standard clinic-based care with a self-management intervention for women with any type and stage of prolapse who are using a ring or shaatz pessary and have the necessary manual dexterity and cognitive functioning to self-manage. The primary outcome measure is prolapse-specific quality of life at 18 months. Data on complications and adverse events is also collected, and an economic evaluation is to be performed [11].

The second study is an ongoing RCT [ACTRN12618000416291, registered on 21/03/2018]. It compares treatment success for women who are first-time pessary users. One group is instructed in self-management, receiving a PVC ring pessary and the second group received instructions for self-managing a silicon irregular hexagon pessary. The primary outcome is retention of the pessary at 6- and 12-months post-randomisation.

TOPSY will provide evidence about the safety and effectiveness of self-management for pessaries, and the second trial on pessary type for women who are self-managing. These trials will provide some evidence toward the safety of self-management and acceptability, but do not address all uncertainties such as optimal follow-up times or potential differences in managing pessaries made of different materials.

Recommendations for further research

These recommendations are informed by the evidence reviewed in the 6th International Consultation on Incontinence [12] and a recent James Lind Alliance Priority Setting [13]:

Large, multicentre trials are needed to examine:

Long term follow up of women who self-manage to assess pessary continuation rates linked to women's quality of life and safety

The optimal management protocols for pessary self-management (e.g. optimal clinical follow-up timelines) to support women's best quality of life and safety. This could be via a trial comparing different follow-up timelines.

A clinical trial of women self-managing their pessary using the same type of pessary but different pessary materials to assess if there is a difference in acceptability and pessary complications.

Clinical trials comparing self-management of two different types of pessary to assess safety acceptability and quality of life.

Clinical trials comparing self-management of vaginal pessaries between women with different stages of prolapse to assess effectiveness, safety and quality of life.

"What should we do in the light of the uncertainty?"

Given the lack of evidence on all models of pessary care, options of self-management and clinic-based care should be discussed with women considering pessary use. Self-management is unsuitable for women with cognitive impairment or those who have a physical difficulty that means that she does not have the manual dexterity required for pessary handling. Women should be advised that self-management of space occupying pessaries is more difficult than for ring and sieve pessaries. If a woman wishes to self-manage her pessary, appropriate teaching is required and might include: instruction on removal and re-insertion technique (ensuring she understands her pelvic anatomy); cleaning of the pessary (with a short explanation of the material of the pessary); how to receive a replacement pessary and access to support if she experiences problems (such as a phone number to call). When discussing self-management the clinician should discuss potential benefits of being able to remove and insert the pessary, for example before intercourse, flexibility to use when required, cleaning pessary to reduce discharge and reducing the need to attend clinic appointments. There is no evidence-based timeframe for clinician's review if a woman is self-managing and not experiencing problems. However, a follow-up appointment every 2 years is reasonable in the absence of further guidelines.

For all women using pessaries it is crucial to discuss the importance of pessary removal and re-insertion to reduce the risk of pessary complications such as vaginal ulceration, pessary incarceration and, less commonly, vesicovaginal or rectovaginal fistula. One very small trial has recently reported lower (but not significantly) complication rates in women followed up every three months compared to six months [14]. Usual UK practice is for 3-6 monthly follow-

up if care is clinic-based. Common complications of vaginal discharge, pessary dislodgement or expulsion and vaginal bleeding should be discussed. The clinician should consider whether peri or postmenopausal women would benefit from treatment with vaginal oestrogen preparations to reduce the risk of discharge and ulceration. There is little robust evidence to support this although it is widely used in practice. The woman should be encouraged to seek medical care if she is experiencing excessive discharge or bleeding. The effect of pessary use on sexual activity depending on the type of pessary should also be discussed.

What patients need to know

There are options of regular pessary appointments for removal and re-insertion, or learning to self-manage with access to support when required. Although there is no current evidence to guide whether self-management or clinic-based care is better, an individual woman may wish to decide on her preferred pathway.

It may take more than one appointment to find a suitable pessary and a pessary must be removed and cleaned or replaced at least once every 6 months.

Medical advice should be sought if the pessary is uncomfortable or if a woman is experiencing non-menstrual vaginal bleeding, excessive vaginal discharge, urinary or bowel problems.

Education into practice

Do you currently offer women using pessaries the option of self-management?

Do you discuss common problems that women may experience with pessary use before offering pessary care?

Consent from patients

No patient data was used for this article. Patient consent does not apply.

How patients were involved in this article

A patient reviewed and commented on the manuscript. She highlighted the importance of having telephone support available when self-managing a pessary; this was crucial to her as it eased her concerns in the time between vaginal examinations every two years. Telephone support as a component of self-management has been included in the manuscript. We are grateful for her involvement and input.

Competing interest statement

We have read and understood the BMJ Group policy on declarations of interest.

CB, SH and MD declare that there are none. RK was the topic lead for prolapse on the NICE guidelines (National, Guideline Alliance UK. Urinary incontinence and pelvic organ prolapse in women: management. 2019).

Copyright statement

Contributorship statement and guarantor

CB acts as guarantor and takes overall responsibility for the content of the paper; RK is responsible for the clinical content. MD and RK initially drafted the manuscript. CB, SH and RK conceptualised and developed the TOPSY study. All authors contributed substantially to the paper content, reviewed and edited the manuscript.

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Dissemination Declaration

There are no study participants data contained within the paper, therefore dissemination to these groups is not applicable.

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