Clinical and cost-effectiveness of pessary self-management versus clinic-based care for pelvic organ prolapse in women: the TOPSY RCT with process evaluation

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Scientific summary

Clinical and cost-effectiveness of pessary self-management versus clinic-based care for pelvic organ prolapse in women: the TOPSY RCT with process evaluation

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Scientific summary

Background

Pelvic organ prolapse (hereafter prolapse) is the descent of some, or all, of the female pelvic organs from their usual position in the pelvis into the vagina. Prolapse is a common problem, with studies suggesting that up to 65% of women may be affected. Prolapse incidence increases with age. As the population ages, prolapse presents a growing health problem. Women who experience prolapse report bothersome symptoms that negatively affect their quality of life and body image. Symptoms include a feeling of 'something coming down' into the vagina; urinary, bowel and sexual symptoms; and pain.

Prolapse can be treated conservatively or surgically. Between 10% and 30% of women who have prolapse surgery may need repeat surgery, and the controversy around the use of surgical mesh has brought the focus onto conservative treatment options. One conservative treatment option is vaginal pessary. The pessary is an inexpensive mechanical device that is inserted into the vagina to support the pelvic organs. Pessaries are widely used in the NHS, with two-thirds of women initially choosing a vaginal pessary to treat their prolapse symptoms.

The current UK care pathway for women who use a pessary as treatment for prolapse is that the pessary is usually fitted at a gynaecological clinic, or occasionally at a general practitioner surgery, and the woman returns approximately every 6 months to have it removed and replaced with a new one. However, having to return to clinic every 6 months may be inconvenient for women, having a pessary permanently in situ may interfere with sexual intercourse, and the patient may require a review in clinic before 6 months because the pessary has fallen out or because of pessary complications (e.g. vaginal discomfort). An alternative to clinic-based pessary care is pessary self-management, whereby a woman removes and reinserts the pessary herself at home, thus offering her more control over her ability to maintain and improve her own health. Research in other clinical domains suggests that self-management is beneficial because people improve their self-efficacy (confidence) in looking after their own health. To the best of our knowledge, there is no current evidence on the effectiveness of pessary self-management for women with prolapse. The treatment of prolapse with self-care pessary (TOPSY) study aims to fill that evidence gap.

Objective

The TOPSY trial aimed to evaluate the clinical effectiveness and cost-effectiveness of self-management of a vaginal pessary on the prolapse-specific quality of life of women with pelvic organ prolapse when compared with clinic-based care. Clinic-based care is the standard operating model for many pessary services across the UK. The process evaluation undertaken concurrently with the trial aimed to assess, using a mixed-methods design, intervention acceptability, pathways to effectiveness, adherence to treatment and fidelity.

Methods

We undertook a parallel-group, multicentre, randomised controlled trial, with individual randomisation, which assessed the superiority of self-management compared with clinic-based pessary care for women who used a pessary for prolapse. Allocation was carried out remotely via a web-based computer system, with minimisation by age (< 65/≥ 65 years), pessary user type (new user/existing user) and centre. A sample size of 330 women (165 per group) was required to provide 90% power to detect a difference of 20 points in the Pelvic Floor Impact Questionnaire-7 score (which measures prolapse-specific quality of

life) at 18 months after randomisation, assuming a standard deviation of 50, two-sided alpha of 0.05 and 20% loss to follow-up.

Participants were recruited from 21 UK centres where pessary care was routinely provided. Women who were new pessary users (had used a pessary for ≤ 3 months) and existing users (had used a pessary for > 3 months) were identified by centre staff and via patient notes, clinic lists, caseloads and referral letters. Potentially eligible women were sent an invitation letter or approached in clinic by centre staff. Women were eligible for inclusion if they were aged ≥ 18 years, were using a pessary of any material or type (except shelf, Gellhorn or cube pessaries) and had retained the pessary for at least 2 weeks. Women were excluded if they had limited manual dexterity that would affect their ability to remove and replace their pessary; were judged by their healthcare team to have a cognitive deficit such that it was not possible for them to provide informed consent or to self-manage; were pregnant; or had insufficient understanding of the English language (the self-management intervention was only available in English).

The primary outcome of effectiveness was prolapse-specific quality of life, measured using the Pelvic Floor Impact Questionnaire-7, and of cost-effectiveness was incremental cost per quality-adjusted life-year at 18 months post randomisation. Interim follow-ups were undertaken at 6 and 12 months. Secondary outcome measures included generic quality of life [measured using the EuroQol-5 Dimensions, five-level (EQ-5D-5L)]; pelvic floor symptoms (measured using the Pelvic Floor Distress Inventory-20); sexual function (measured using the prolapse/incontinence sexual questionnaire-IUGA-Revised); self-efficacy (measured using the General Self-efficacy Scale); pessary complications; pessary use; and pessary confidence. Resource use data were collected using a specifically developed health Resource Use Questionnaire.

Study centres received a training visit during which the principles of self-management were explained and the intervention delivery staff were trained in the components of the intervention. Each centre also received a training manual that provided written guidance on the intervention. Women randomised to self-management received:

- a 30-minute self-management teaching appointment where they were taught to, and given the opportunity to try to, remove, clean and reinsert their own pessary
- a self-management information leaflet that provided written and diagrammatic information on pessary self-management
- a 2-week follow-up telephone call to assess if they had been able to remove, clean and reinsert their pessary since the teaching appointment and to assess any difficulties they experienced
- a telephone helpline number for their local clinical centre.

Women in the clinic-based care group received routine appointments at which their pessary was removed and cleaned, or changed for a new one, and replaced by a healthcare professional. The interval between the appointments was determined by the usual practice of the centre.

A concurrent mixed-methods process evaluation was undertaken to assess intervention acceptability, pathways to effectiveness, adherence to treatment and fidelity. Recruiting staff at centres were asked to audio-record a sample of their recruitment discussions. Staff delivering the intervention were asked to record a sample of self-management teaching appointments and 2-week follow-up telephone calls and to complete a checklist for every self-management teaching session undertaken to allow assessment of fidelity to the intervention. A subsample of women who were randomised in the trial and consented to take part in an additional interview study were interviewed at baseline and 18 months. Eligible women who declined to be randomised but were willing to take part in an interview study were also interviewed at baseline and 18 months. The Pessary Use Questionnaire included an open question about women's experiences of their trial group. The interviews and open questions aimed to assess acceptability, adherence and pathways to effectiveness. Finally, recruiting centre staff and healthcare professionals who delivered the intervention were invited to take part in an interview to increase understanding of pathways to effectiveness and fidelity.

A within-trial economic evaluation was conducted to compare the costs and benefits, measured in quality-adjusted life-years, of self-management with clinic-based care over the 18 months post randomisation. In addition, a decision-analytic model was developed using the trial data to extend the analysis over a 5-year period. Healthcare resource use data were collected from the clinic visit and telephone support case report forms and from the participant-completed Resource Use Questionnaire. Costs were attached to resource use from published sources. Health state utility values were elicited from responses to the EQ-5D-5L to estimate the difference in quality-adjusted life-years between the trial groups. The trial analysis followed the intention to treat principle, and the analyses of all study elements were documented in prespecified analysis plans. The qualitative analysis for the process evaluation followed framework analysis methods and, where appropriate, case study analytic methods.

Results

Key results: trial

Three hundred and forty women were randomised: 169 to the self-management group and 171 to the clinic-based care group. At 18 months post randomisation, 291 questionnaires with valid primary outcome data were available: 139 (82.2%) in the self-management group and 152 (88.9%) in the clinic-based care group.

There was no evidence of a difference between the groups in prolapse-specific quality of life (measured using the Pelvic Floor Impact Questionnaire-7) at 18 months (adjusted mean difference −0.03, 95% confidence interval −9.32 to 9.25). Sensitivity analysis of the primary outcome showed no significant difference between the groups under a range of different assumptions and prespecified sensitivity analyses. A subgroup analysis of the primary outcome showed no significant effect of trial group by subgroup interactions (subgroups were age < 65 vs. ≥ 65 years, new vs. existing pessary user and hysterectomy vs. no hysterectomy at baseline).

At the 18-month follow-up, a greater proportion of pessary complications were reported in the clinic-based care group than in the self-management group (adjusted mean difference 3.83, 95% confidence interval 0.81 to 6.86). There was no difference between the groups in general self-efficacy, but women in the self-management group were more confident in their ability to manage pessary-related problems and to insert and remove their pessary.

An analysis adjusting for clinic-based care appointments cancelled due to the COVID-19 pandemic did not alter the findings.

Key results: process evaluation

Self-management was reported to be an acceptable intervention to women and to healthcare professionals. Women (whether they received self-management or not) and healthcare professionals reported benefits from pessary self-management to women and the NHS and valued the possibilities provided to women who could self-manage their pessary, such as flexibility and independence in using the pessary as needed.

There was fidelity to self-management intervention delivery and there was minimal variance in the delivery of clinic-based care across the study centres. Self-management delivery can be integrated within existing service structures.

Interview data demonstrated that women's adherence to their allocated group ranged from not adherent at all to completely adherent in all aspects, and this was the case in both groups. The COVID-19 pandemic did have an impact on adherence, especially among those in the clinic-based care group when clinic appointments were suspended, which led some women to remove their own pessary. Although the

pandemic might have had some effect on adherence, multiple other contextual factors influenced adherence, such as good general health, which influenced it in both groups.

Multiple contextual factors impacted on pathways to effectiveness for both trial groups. There was variance in women's quality of life in both groups across the 18 months' follow-up. The pessary itself influenced women's quality of life, regardless of trial group. There was at least the potential for self-management to further enhance that quality of life over and above the influence of the pessary itself. Women in the self-management group had different self-efficacy from those in the clinic-based group. Women in the self-management group felt more confident in addressing common problems with their pessary, such as discharge or slippage, on their own without the need for additional clinic appointments.

Key results: economic evaluation

The within-trial economic analysis indicated that clinic-based care was dominated by self-management. There was no significant difference in the mean number of quality-adjusted life-years gained between self-management and clinic-based care (0.021), but the mean cost was lower for self-management than for clinic-based care (£578 vs. £728). The incremental net benefit estimated at a willingness-to-pay threshold of £20,000 per quality-adjusted life-year gained was £564, with an 80.8% probability of cost-effectiveness. The modelling results are consistent with the trial analysis. The incremental net benefit at 5 years was estimated as £4221 and the probability that self-management is a cost-effective intervention was estimated as 69.7%.

Key results: synthesis

There was no evidence that self-management improved prolapse-specific or general quality of life more than clinic-based care. Although qualitative findings suggested that quality of life had the potential to be improved more in the self-management group, this did not translate beyond participant-level data. The proposed mechanism of action for the intervention was self-efficacy. General self-efficacy did not differ between the groups at 18 months. Women who self-managed were more confident in their abilities to insert and remove their pessary and to manage problems experienced with their pessary than women in the clinic-based care group.

There was fidelity to the self-management and clinic-based care intervention delivery, with the groups receiving different interventions, confirming that the trial was a true test. There was variance in adherence to trial group by the women; approximately 40% of the clinic-based care group removed the pessary themselves at least once at some point during follow-up, and 34 women in the self-management group crossed over to clinic-based care.

Women in the self-management group reported fewer complications than women in the clinic-based care group. Experience of complications led to a greater likelihood of women discontinuing pessary use.

Conclusions

Implications for health care

- Healthcare professionals and policy-makers can be confident that in offering self-management as an option to women who use a vaginal pessary to manage pelvic organ prolapse they are offering an acceptable intervention that will not make women's quality of life better or worse than clinic-based care. Self-management will, however, reduce the pessary-related complications that women experience and will cost the NHS less to deliver than standard clinic-based care models. Self-management of vaginal pessaries should be offered as part of NHS services from the outset of pessary care and as part of routine, ongoing care.
- In offering self-management to women, healthcare professionals should explain the lower complication rates experienced by women who self-manage and the possible mechanisms

that may lead to that reduction (such as women's confidence in removing the pessary when experiencing discomfort).
- Healthcare professionals who deliver self-management training may wish to add further information about options for pessary removal into that training, as women found pessary removal more difficult than pessary insertion.

Recommendations for research (in priority order)

- Future research is needed to identify constructs that are important to women in measuring their prolapse-specific quality of life. This may necessitate the generation of a new measure that has greater sensitivity to quality-of-life constructs beyond the symptomatic changes linked to the pessary itself.
- Future trials of self-management should test the effectiveness of self-management with a wide range of ethnic groups and with women of different abilities to assess its effectiveness in these populations. This may include the testing of devices that support pessary removal or insertion.
- Future research is needed that focuses on self-management follow-up. For example, can follow-up be women-initiated, or does it need to be planned at specific intervals?
- Future research on pessary self-management is needed to look at possible links between pessary continuation and complications, including which specific complications are more likely to lead to discontinuation.

Study registration

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