ABSTRACT

Introduction Pelvic organ prolapse (POP) can be managed with a pessary; however, regular follow-up may deter women from pessary management due to the inconvenience of frequent appointments, as well as preventing pessary users from autonomous decision-making. Pessary self-management, whereby the woman removes and inserts her own pessary may be a solution to these issues. However, there remains a number of uncertainties regarding the potential benefits and risks of pessary self-management. This scoping review aims to map available evidence about the subject of pessary self-management for POP to identify knowledge gaps providing the basis for future research.

Methods and analysis The scoping review will be conducted using the Joanna Briggs Institute scoping review methodology and reported in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews guidelines. A search of Medline, CINAHL, Embase and PsycInfo will be undertaken to identify relevant articles which meet the eligibility criteria using the search terms ‘pessary’ and ‘self-management’ or ‘self-care’. A hand search of the reference list of non-original research identified during the search but excluded, will be conducted for additional publications which meet the inclusion and exclusion criteria. Data relevant to the topic of pessary self-management will be extracted and critical appraisal of all included publications undertaken.

Ethics and dissemination No ethical or Health Research Authority approval is required to undertake the scoping review. However, it has been registered with The Open Science Framework (DOI 10.17605/OSF.IO/DNGCP). The findings will inform future research exploring pessary self-management and be disseminated via both a presentation at a national conference and publications in peer reviewed journals.

INTRODUCTION

Pelvic organ prolapse (POP) is defined as the downward displacement of one or more of the pelvic organs including the uterus, vaginal compartments, bowel or bladder. Common POP symptoms reported by women include seeing or feeling a vaginal bulge, a heaviness or a dragging sensation, difficulties voiding or defecating and sexual dysfunction, all of which can significantly negatively impact a woman’s quality of life.

A pessary is a medical device which can be inserted into the vagina to provide mechanical support to the prolapsed organs. Pessary management offers women with prolapse comparable treatment outcomes to surgery in terms of reported symptoms and quality of life and absence of bulge and no desire for further treatment. This may be a particularly desirable option for women who have not completed their family, are unfit for surgical management or would simply prefer to avoid the risks that POP surgery entails. There are a wide variety of pessaries available, offering a conservative, long-term management option to women. Pessary follow-up is required, tending to be 3–6 monthly. At each appointment, the pessary is removed, the vaginal tissues examined and either a new pessary, or the same pessary replaced after cleaning. The need for regular follow-up is often cited as a reason why women opt for surgical management of POP due to the inconvenience of frequent appointments. Moreover, clinician management means women are denied autonomy in how and when to use their
pessary. Furthermore, the cost of regular pessary follow-up appointments is not insignificant, with over 86000 pessaries inserted annually in English NHS services alone.9

A solution to these frequently cited issues with pessary care may be pessary self-management. This entails the woman removing and reinserting her own pessary as required or desired. There remains a number of uncertainties regarding the benefits and possible risks of pessary self-management.10 A preliminary search in May 2021 identified a recent review of the published evidence related to pessary self-management, which highlighted current uncertainties within the subject area.19 These include whether pessary self-management improves a woman’s satisfaction, quality of life and therefore long-term use of a pessary; whether pessary self-management is safe and what follow-up requirements are for women self-managing their pessary.10 However, the review was limited to searching PubMed and had a focus on patient safety as indicated by the search terms used. Therefore, only five eligible studies were identified. A preliminary search of Medline, the Cochrane Database of Systematic Reviews and JBI Evidence Synthesis was conducted and no further systematic or scoping reviews on the topic were identified as being currently underway.

It is acknowledged that there is a lack of robust evidence regarding the risks and benefits of pessary self-management due to the small-scale, non-randomised nature of much of the evidence.10 While there is currently a lack of robust evidence regarding the benefits of self-management, there is qualitative and observational evidence from women using pessaries about the benefits pessary self-management offers to them, including flexibility in how and when they use the pessary.5,11

This scoping review aims to map available evidence about the subject of pessary self-management for POP to identify knowledge gaps12 providing the basis for future research. The following research question was formulated: What is known from the literature about pessary self-management for women with POP?

METHODS AND ANALYSIS

Types of sources

The scoping review will be conducted using the Joanna Briggs Institute scoping review methodology13 and reported in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines (Supplementary material).14 As advocated by PRISMA-ScR guidelines, the review has been registered with The Open Science Framework (OSF) (DOI 10.17605/OSF.IO/DNGCP) and the protocol published to ensure transparency and reproducibility.

To be eligible for inclusion in the review, papers must include original research data regarding pessary self-management for women with POP. Pessary self-management and what it entails is poorly defined. However, for the purpose of this scoping review women who remove or insert their pessary independently will be classed as self-managing. There will be no time limit set as it is acknowledged pessary management of prolapse is a long-standing treatment option and therefore self-management of pessaries may also be. All identified studies will be included regardless of the methodology used to ensure the different aspects and perspectives of pessary self-management for POP will be explored. Non-original articles such as reviews will be excluded to avoid duplication of evidence. However, the reference list of all review articles identified in the search will be checked and all relevant original research cited will be included within this review.

The search aims to include publications from different methodological perspectives and to scope the available evidence related to pessary self-management for POP without presuming what the important outcomes may be. Therefore, rather than the PICO tool which is typically used for systematic reviews of quantitative evidence, the population, concept and context of the research question will be used to structure the search.15

Population

The population in focus are women with POP who use a pessary. It is recognised that the prevalence and severity of POP increases significantly with increasing age. However, women of all ages develop prolapse, with 77% of 18–29-year-old women examined in a routine gynaecological clinic having stage one or two prolapse.15 Therefore, no limits will be placed on the age of the study population. POP is typically measured using the POPQ system,17 the measurements of which can be used to determine the stage of prolapse.17 It is acknowledged the anatomical extent of a prolapse as measured by staging may not correlate with the severity of a woman’s symptoms.18 Therefore, it is advocated women be treated based on the bothersomeness of their symptoms. It can thus be assumed women managing their prolapse symptoms with a pessary were sufficiently bothered to consent to treatment, and the stage of their prolapse is of less significance than this. Therefore, the review will not exclude women based on the stage of their prolapse.

Concept

The concept to be explored is specifically those who self-manage their pessary for POP. That included studies must relate to this type of pessary is an important distinction, as pessaries can be for either structural or medicinal purposes.19 Pharmaceutical pessaries are solid tablets containing medicinal products for insertion into the vagina and are typically prescribed when a local effect is desired.19 While there is limited evidence supporting the use of vaginal oestrogen as a treatment for POP,20 National Institute for Health and Care Excellence guidelines suggest clinicians consider the use of local oestrogen cream or pessaries for women with symptomatic prolapse and vaginal atrophy.21 Therefore, there is potential for articles with a focus of pharmaceutical
pessaries for women with POP to be identified during the
search. The term mechanical pessaries includes devices
designed to manage symptoms of urinary incontinence,22
with some devices having a dual purpose for manage-
ment of prolapse and urinary symptoms.22 Studies will
be excluded if the pessaries are solely for urinary incon-
tinence; however, studies with a sample population that
includes women using dual purpose pessaries are eligible
for inclusion. There is a broad range of pessaries available
to manage POP and these are typically classed as either
a support or space occupying pessary.17 While the pessa-
ries have different mechanisms of working, both have the
same purpose of reducing the descent of, and symptoms
associated with, prolapse. Therefore, studies including
both types of pessaries will be included.

Context
Whether there are differences in the extent to which
pessary self-management is offered to, or accepted by
women, depending on the country they live in, health-
care provision, or the culture they belong to, is of particu-
lar interest to the authors. Therefore, there is no specific
context to the question as the authors are interested in
evidence related to pessary self-management for POP
regardless of the setting where self-management was initi-
atated, or within what country.

Articles will be excluded if they are not accessible in the
English language due to feasibility issues, it is acknowl-
edged this may limit the scope and generalisability of
findings. Relevant conference abstracts will be included
if the full data set has not subsequently been published.
While this prevents the authors from appraising the full
dataset and detailed description of the study processes,
it enables the inclusion of recent research studies which
have not yet been published as well as findings which may
not be deemed sufficiently significant by the authors to
publish.

The search strategy will aim to locate published studies
related to pessary self-management. A search of Medline,
CINAHL, Embase and PsycInfo will be undertaken to
identify articles on the topic. The search terms which will
be used for all databases are pessary and self-management
or self-care. Searches of all databases will be undertaken
between 5 and 7 May 2021. Hand searches will be under-
taken throughout May 2021. Data extraction, critical
appraisal and synthesis of the results will be undertaken
following this.

Inclusion criteria
► Original research.
► Pessary for POP.
► Published in English language.
► Focuses on self-management of pessary for POP.

Exclusion criteria
► Not relevant to subject area.
► Not published in English language.
► Not original research including case reports.

Study/source of evidence selection
Following the search, all identified citations will be collated
and uploaded and duplicates and non-original research
publications removed. The abstracts will then be reviewed
for relevance to the review question. In
the instance of abstracts which do not explicitly refer
to pessary self-management but are relevant to pessaries
for prolapse, the full text will be reviewed to check for
references to pessary self-management which may not
have been deemed as sufficiently significant to include
within the abstract. All data identified which is relevant
to pessary self-management will be extracted regardless
of the overall aim of the publication, the care setting and
the level of focus on pessary self-management. A sample
of 20% of abstracts will be screened by an independent
reviewer to ensure agreement with inclusion or exclu-
dion decision. In the instance of disagreement regarding
included or excluded studies not resolved through discus-
sion, a third reviewer will be asked to make the final
decision. Potentially relevant sources will be retrieved in
full and assessed in detail against the inclusion criteria.
Reasons for exclusion of sources of evidence that do not
meet the inclusion criteria will be recorded and reported
in the scoping review.

Data extraction
Data will be extracted from papers included in the
scoping review using a data extraction tool developed
by the reviewers based on scoping review guidance.13
The extracted data will be entered into the tool elec-
tronically via Microsoft Excel. The data extraction form
will include details of the author(s), year of publication,
population studied, context, methodology used and key
findings relevant to pessary self-management. A second
reviewer will perform data extraction from a subset of
10% of included articles to ensure a standardised process.
If there are discrepancies between both extractions, the
potential reasons for this will be explored and the data
extraction tool modified accordingly to reduce the like-
lihood for future discordance. Any amendments to
the data extraction tool will be recorded including the
reasons for this, for transparency. The final version of the
data extraction tool will be included in the scoping review
to ensure reproducibility.

Quality appraisal
Appraising the quality of included studies and the subse-
quent findings is not typically performed during a scoping
review.15 However, for the purpose of this review, quality
will be assessed to determine the weighting of included
research findings, as well as identifying potential method-
ological strengths and limitations of the current evidence
base. As identified studies will be included regardless
of the methodology used, it is important to identify a
quality appraisal tool which can assess qualitative, quan-
titative and mixed methods research. Therefore, the
updated Mixed Methods Appraisal Tool (MMAT) will be
used.23 The MMAT was initially developed in 2006 and

Dwyer L, et al. BMJ Open 2022;12:e055587. doi:10.1136/bmjopen-2021-055587
has subsequently been revised to facilitate more efficient quality assessment; therefore, the most recently developed 2018 MMAT will be used for this review.23 The authors of the revised MMAT discourage reviewers from calculating a single overall score to determine the methodological quality of a paper as it prohibits readers from understanding the specific strengths and limitations of a study.23 Therefore, the quality appraisal of each included study will be presented in a tabular format (figure 1), detailing the rating for each criterion assessed using the MMAT. The same subsample of studies randomly selected by the second reviewer for data extraction quality assurance will be quality appraised by the second reviewer to ensure agreement in the assessment process. The 2018 version of the MMAT has improved content validity compared with previous versions; however, the inter-rater reliability has yet to be established.24 Therefore, ensuring that there is concordance between both reviewer’s assessment of quality will be an important step in the scoping review process.

Patient and public involvement
Members of the public and pessary users have not directly been involved with development of this protocol or review process. However, the need for research exploring pessary self-management was highlighted by The James Lind Alliance (JLA) Priority Setting Partnership for pessary and prolapse.25 Several women with experience of pessaries participated in this partnership either as members of the steering group, by attending the consensus workshop or completing questionnaires. Understanding more about self-management was ranked third out of 20 priorities by the JLA Priority Setting Partnership for pessary and prolapse. The 2018 version of the MMAT has improved content validity compared with previous versions; however, the inter-rater reliability has yet to be established.24 Therefore, ensuring that there is concordance between both reviewer’s assessment of quality will be an important step in the scoping review process.

Data analysis and presentation
The data will be analysed and presented in numerical and tabular format to describe the current evidence base, for example, the extent of identified literature, the context of included research such as the country of origin and the nature of the research. This will provide a scope of the existing evidence related to pessary self-management as a key objective of this review. Furthermore, the key findings of included research will be analysed for emerging themes. A narrative description of the themes and a summary of the evidence related to this will be presented in text and numerical format as appropriate.

Ethics and dissemination
No ethical or Health Research Authority approval is required to undertake the scoping review. However, it has been registered with The OSF (DOI 10.17605/OSF.IO/DNGCP) to ensure quality through transparent reporting and to prevent overlapping or duplicate work being undertaken prior to publication of the review findings.26 The scoping review will be disseminated by publication in a peer reviewed journal and submitted for presentation at a national conference. The findings will also inform subsequent exploratory work regarding pessary self-management.

Contributors LD devised the scoping review question, methodology and drafted this manuscript. RK and DD substantively contributed to the development of the scoping review question, methodology and revised and approved this manuscript.

Funding Lucy Dwyer, Clinical Doctoral Research Fellow, NIHR300519 is funded by Health Education England (HEE)/National Institute for Health Research (NIHR) for this research project.

Competing interests LD and RK are co-applicants of the NIHR/HTA funded Treatment of Prolapse with Self-Care Pessary (TOPSY) study.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

ORCID iD
Lucy Dwyer http://orcid.org/0000-0002-0284-873X

REFERENCES
1 Haylen BT, Maher CF, Barber MD, et al. An international Urogynaecological association (IUGA) / International Continence Society (ICS) joint report on the terminology for female pelvic organ prolapse (POP). Int Urogynecol J 2016;27:165–94.
2 Lone F, Thakar R, Sultan AH. One-Year prospective comparison of vaginal pessaries and surgery for pelvic organ prolapse using the validated ICIQ-VS and ICIQ-UI (SF) questionnaires. Int Urogynecol J 2015;26:1305–12.
Miceli A, Dueñas-Diez J-L. Effectiveness of ring pessaries versus vaginal hysterectomy for advanced pelvic organ prolapse. A cohort study. *Int Urogynecol J* 2019;30:2161–9.

Kapoor DS, Thakar R, Sultan AH, et al. Conservative versus surgical management of prolapse: what dictates patient choice? *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:1157–61.

Gorti M, Hudelist G, Simons A. Evaluation of vaginal pessary management: a UK-based survey. *J Obstet Gynaecol* 2009;29:129–31.

Kearney R, Brown C. Self-management of vaginal pessaries for pelvic organ prolapse. *BMJ Qual Improv Rep* 2014;3:u206180. w2533.

pp.Basu M, Wise B, Duckett J. A qualitative study of women’s preferences for treatment of pelvic floor disorders. *BJOG* 2011;118:338–44.

Nguyen JN, Jones CR, Krissovich M. Pessary treatment of pelvic relaxation. *J Wound Ostomy Continence Nurs* 2005;32:255–61.

Secondary Care Analytical Team, NHS Digital. Hospital outpatient activity 2019-20, 2020. Available: digital.nhs.uk/data-and-information/publications/statistical/hospital-outpatient-activity

Bugge C, Dembinsky M, Kearney R, et al. Does self-management of vaginal pessaries improve care for women with pelvic organ prolapse? *BMJ* 2021;372:n310.

Storey S, Aston M, Price S, et al. Women’s experiences with vaginal pessary use. *J Adv Nurs* 2009;65:2350–7.

Munn Z, Peters MDJ, Stern C, et al. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMJ Med Res Methods* 2018;18. 2018.

MDJ P, C G, P M. Chapter 11: Scoping Reviews (2020 version). In: *Aromataris E, Munn Z*, eds. *JBI manual for evidence synthesis*, 2020.

Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation, *Ann Intern Med* 2018;169:467–73.

Peters MDJ, Godfrey CM, Khalil H, et al. Guidance for conducting systematic scoping reviews. *Int J Evid Based Healthc* 2015;13:141–6.

Swift SE. The distribution of pelvic organ support in a population of female subjects seen for routine gynecologic health care. *Am J Obstet Gynecol* 2000;183:277–85.

Dwyer L, Kearney R. Conservative management of pelvic organ prolapse. *Obstet Gynaecol Reprod Med* 2021;31:35–41.

Gutman RE, Ford DE, Quiroz LH, et al. Is there a pelvic organ prolapse threshold that predicts pelvic floor symptoms? *Am J Obstet Gynecol* 2008;199:683.e1–7.

Watson J, Rees JA, Smith I, eds. *Pharmaceutical practice*. Elsevier Health Sciences, 2014.

Ismail SI, Bain C, Hagen S, et al. Oestrogens for treatment or prevention of pelvic organ prolapse in postmenopausal women. *Cochrane Database Syst Rev* 2010;15:CD007063.

National Institute for Health and Care Excellence,. Urinary incontinence and pelvic organ prolapse in women: management, 2019. Available: www.nice.org.uk/guidance/ng123

Amir-Khalikhali B, Farell SA. Selection of pessaries for urinary incontinence. In: *Pessaries in clinical practice*. London: Springer, 2006: 46–53.

Hong QN, Fábregues S, Bartlett G, et al. The mixed methods appraisal tool (MMAT) version 2018 for information professionals and researchers. *Educ Inform* 2018:34:285–91.

Hong QN, Pluye P, Fábregues S, et al. Improving the content validity of the mixed methods appraisal tool: a modified e-Delphi study. *J Clin Epidemiol* 2019;111:49–59.

Lough K, Hagen S, McClurg D, et al. Shared research priorities for pessary use in women with prolapse: results from a James Lind alliance priority setting partnership. *BMJ Open* 2018;8:e021276.

Tawfik GM, Giang HTN, Ghozzy S, et al. Protocol registration issues of systematic review and meta-analysis studies: a survey of global researchers. *BMJ Med Res Methods* 2020;20:213.