Journal of Pelvic, Obstetric and Gynaecological Physiotherapy, Spring 2022, **130,** 16–21

POGP CONFERENCE 2021

Filling the gap: the use of a vaginal pessary device in patient-centred care for the non-surgical management of prolapse

K. Lough & C. Brown
UK Clinical Guideline Group for the Use of Pessaries in Vaginal Prolapse and UK Continence Society Pessary Implementation Group

Abstract
Pessary management for pelvic organ prolapse should be considered for all women who have troublesome symptoms. Although there is a lack of high-quality evidence relating to pessary use and its effectiveness, various studies are now reviewing specific aspects of pessary care. The recently published *UK Clinical Guideline for Best Practice in the Use of Vaginal Pessaries for Pelvic Organ Prolapse* includes information that is intended to inform and empower pessary users, and allow them to manage their expectations. It also presents a multidisciplinary competency framework for training, and recommendations for levels of supervision, observation and assessment of competence. In accordance with the aims of the guideline group, emerging and future evidence will be reviewed for subsequent updates. Further work with national professional networks is required to finalize training pathways for physiotherapists.

Keywords: multidisciplinary competency framework, non-surgical management, patient-centred care, pelvic organ prolapse, vaginal pessary device.

Introduction

Vaginal or pelvic organ prolapse (POP) remains a considerable problem for women that affects their quality of life (QOL) and creates a significant economic burden for the health sector. Epidemiological studies and forecasting indicate that the prevalence of symptomatic prolapse is 5–15% (Altman *et al.* 2017). Further research has demonstrated that the likelihood of prolapse increases fourfold between 40 and 64 years of age (Åkervall *et al.* 2020), and the number of women in the USA experiencing POP was predicted to increase by nearly 50% between 2010 and 2050 (Wu *et al.* 2009). Pessaries have been used in the urogynaecological management of women with symptomatic prolapse for decades, but the high-quality evidence needed to support the use of these devices and direct clinical practice has been insufficient. Nevertheless, increasing numbers of pessary procedures are being recorded, and there has been an increase in the types of pessaries available from commercial medical product companies.

Correspondence: Dr Kate Lough, Lochside House, Lochwinnoch PA12 4JH, UK (e-mail: katelough@hotmail.co.uk).

The need for a UK guideline

The clinical application of pessary use for prolapse is being reassessed because the demand for non-surgical management options for this condition has increased. This is a result of the ongoing suspension of surgical procedures involving mesh following the publication of the *First Do No Harm* report (Cumberlege 2020). Recent systematic reviews have added to the amount of available evidence and knowledge, and these are summarized in Table 1.

Systematic reviews have consistently demanded that more high-quality studies with longer follow-up periods should be conducted prospectively, but one of the barriers to research has been the lack of digital health data and the inconsistency of pessary practice for POP (Lough 2020).

Recently published and ongoing studies have addressed some of the priority research

Table 1. Summary of recent systematic reviews of aspects of pessary use: (QOL) quality of life; (PFMT) pelvic floor muscle training; and (POP) pelvic organ prolapse

Reference	Aim	Participants and studies (*n*)	Key findings
de Albuquerque Coelho *et al.* (2016)	Impact on QOL	895 across seven studies	Women using a pessary have improved QOL Equal improvements in QOL with pessary use and after surgery Improvement in sexual function while using a pessary Reasons for discontinuation were pain, expulsion and discomfort
Bugge *et al.* (2020)	Effects and economic evaluations of pessaries	478 across four studies	Uncertainty regarding the effectiveness of a pessary versus no treatment or PFMT Pessaries in addition to PFMT probably improve women's POP symptoms and prolapse-specific QOL
Lough (2020)	Scoping review: evidence-based and woman-centred?	5262 across 24 studies	Any woman with symptomatic prolapse could be offered a pessary If a suitable pessary is fitted, brings about rapid symptom reduction and is comfortable, the woman is likely to continue with this form of treatment until her desire for an alternative management approach becomes a priority There is no evidence that one pessary is more effective than another, nor for the optimal management of complications
de Albuquerque Coelho *et al.* (2021)	Unsuccessful fitting factors	3601 across 21 studies	Higher body mass index Previous reconstructive surgery Advanced POP

questions identified by the James Lind Alliance Priority Setting Partnership examining pessary use for prolapse (Lough *et al.* 2018), i.e. self-management, the effects of pessary use, and optimal management and follow-up regimes.

Self-management

The TOPSY trial is a multicentre randomized controlled trial with nested process evaluation (Hagen *et al.* 2020). Its aim is to compare the clinical and cost-effectiveness of self-management of vaginal pessaries in the treatment of POP to standard care, and also assess improvements in women's QOL. The TOPSY trial involves over 20 sites in the UK and has an 18-month follow-up period (Hagen *et al.* 2020). In addition, Health Education England and the National Institute for Health Research have a funded a clinical doctoral research fellowship for the project, "Understanding factors which affect willingness to self-manage a pessary for pelvic organ prolapse: a mixed methods study aiming to improve access to pessary self-management" (NIHR 2021).

Effects of pessary use

In a recently published study of the effects and effectiveness of pessaries, Manzini *et al.* (2021) addressed pessary use on vaginal muscular function. These authors used ultrasound to look at the nature of the puborectalis muscle contraction in two groups of women, i.e. those with a complete levator avulsion and those without one, who were all undergoing pessary treatment. The effects of the contraction were compared with the displacement and hiatal area changes measured in both groups (Manzini *et al.* 2021). The authors concluded that pessary treatment does induce functional changes of the puborectalis muscle, a finding that was more noticeable in the group without complete avulsion. This study is an important contribution to the debate about whether vaginal muscle tone is affected by symptomatic prolapse.

A further study by Sahar *et al.* (2020) compared the relative effectiveness of pessaries, pelvic floor physiotherapy and surgery to address the problem of vaginal sound. Women were allocated to one of three treatment options (i.e. surgery, physiotherapy or pessary). The authors concluded that a pessary was better than surgery or physiotherapy for reducing vaginal noise, and had a significant effect on QOL and sexual relations (Sahar *et al.* 2020).

Finally, Nemeth *et al.* (2020) continued their exploration of the effect of the cube pessary by examining the correlation of vaginal space with prolapse stage and genital hiatus. The cube pessary offered symptomatic relief, and provided potentially useful data about the prolapse and vaginal anatomy (Nemeth *et al.* 2020).

Optimal management and follow-up regimes

The COVID-19 pandemic has provided an opportunity to extend our research into optimal follow-up regimes, which have traditionally been every 3–4 months for women who are not self-managing. Many recent studies have looked at extended follow-up intervals, and the complication and satisfaction rate (Tam *et al.* 2019; Propst *et al.* 2020; de Albuquerque Coelho *et al.* 2021; Micelli *et al.* 2021).

It is important to be cautious when interpreting the literature because of the heterogeneity of approaches that have been adopted. Inconsistent details of interventions and outcomes in studies exploring pessary use for prolapse do not always allow for robust comparisons to be made (Lough 2020).

Indications for use

Women may be offered a pessary if follow-up can be assured and there are no contraindications to its use. This may be as part of their prolapse management if they are not suitable for surgery, and is indicated in order to defer surgery if their family is not complete and assess the extent of the surgical procedures required. However, clinician influence is a key factor in women's awareness of and openness to a pessary trial (Sevilla *et al.* 2013; Brown *et al.* 2016), and anecdotal evidence suggests that barriers to women being offered one include clinician beliefs that are not supported by published studies (Fig. 1).

There is still uncertainty about how to guide clinical practice in the areas of pessary choice, length of treatment, adjuncts to pessaries and optimal management protocols. However, recent guidelines clearly advocate and recommend that every woman with symptomatic prolapse should be offered a pessary irrespective of prolapse stage or compartment (NICE 2019; Harvey *et al.* 2021; POGP & UKCS 2021).

Best practice in the use of vaginal pessaries for pelvic organ prolapse

A group of multidisciplinary professionals representing nursing, physiotherapy, urogynaecology, obstetrics and gynaecology, urology, and colorectal surgery worked with women with experience of prolapse to produce the first UK guideline to address universal management strategies, and consistent patient information and advice (POGP & UKCS 2021). Over 2 years, the group took the available evidence into account and gathered

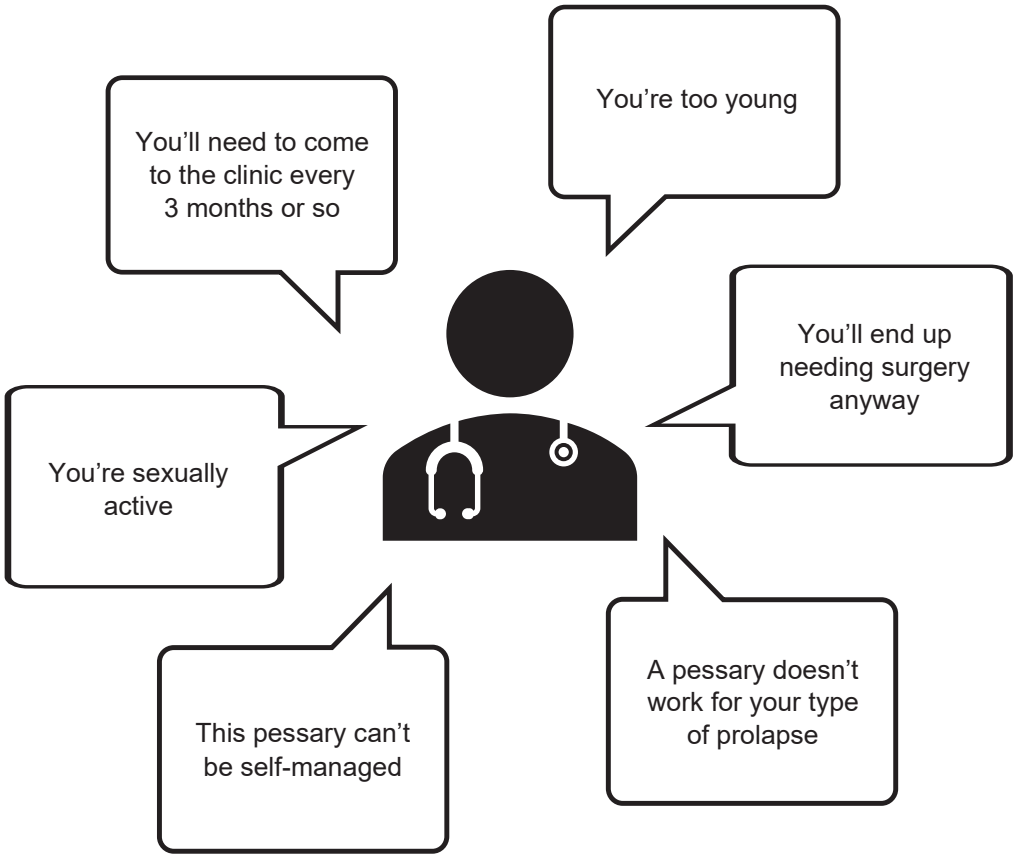

Figure 1. "A pessary is not for you. . ." Common myths.

new data. The latter included updates to service information projects, including a survey of pessary practice across the UK (Brown *et al.* 2021) and Freedom of Information requests made to 128 organizations providing pessary provision (Dwyer *et al.* 2021). The group prepared a consensus document to: offer clinical support to those involved with the provision, fitting and management of pessaries; and produce consistent patient information to help inform women seeking non-surgical management of symptomatic prolapse. The key components of the guideline include a clinical pathway algorithm, patient information sections, a section on pessary types with fitting tips, and a guide to risks and complications. Healthcare professionals can also access fitting videos for commonly used pessary types. *The UK Clinical Guideline for Best Practice in the Use of Vaginal Pessaries for Pelvic Organ Prolapse* was launched in March 2021 (POGP & UKCS 2021), and the full document is available to view and download on the POGP website.

Relevance of the UK guidelines to pelvic health physiotherapists

Prior to the publication of the UK pessary training document and Australian standards (Neumann *et al.* 2021), no framework existed for training or competency in this area. The *UK Clinical Guideline for Best Practice in the Use of Vaginal Pessaries for Pelvic Organ Prolapse* (POGP & UKCS 2021) contains a pessary-specific training document that presents eight standards:

(1) removal and insertion of pessaries for routine changes;
(2) knowledge of the indications and management involved in pessary care;
(3) knowledge of how to manage the complications of pessaries;
(4) prolapse assessment;
(5) assessment for fitting the first pessary;
(6) knowledge of alternatives to pessaries;
(7) pessary self-management; and
(8) reflective practice.

The training document is intended to represent the benchmark of the skills a pessary clinician in the UK should have, but the standards are flexible. For example, to fulfil a job role that solely involves changing pessaries, only the first three will be applicable to that clinician. However, the remaining criteria are designed to help inspire the clinician to complete all eight standards. The training document highlights a level of prerequisite knowledge and provides the clinician with a self-declaration box.

For each learning objective within each standard, the clinician should show evidence of their learning and clinical competence. An assessor should sign off on which competency level that he or she deems the clinician to be practising at for each particular objective. The levels have been modified from Benner's (1982) stages of clinical competence, and amalgamated with the core curriculum sign-off requirements stipulated by the Royal College of Obstetricians and Gynaecologists (RCOG 2021). Level 1 is observational, level 2 is supervised practice and level 3 is independent practice.

Some clinicians have limited means for assessment, but they can demonstrate their clinical aptitude in other ways, such as attendance at a course, completion of an e-learning module or a reflective account of a particular case. The present authors suggest that, if a standard is being achieved with other methodologies, there should be a minimum of three different types of evidence to support this.

The assessor can be a clinician who has prior knowledge of and experience in pessary management. These levels of competence can be signed off in the logbook provided in the training document.

Physiotherapy-specific competency standards in pessary management that were derived from an e-Delphi study have been recently published by a research group in Australia (Neumann *et al.* 2021). The e-Delphi study enabled the publication of three domains of a competency framework. The first domain states that knowledge of the conservative management of pelvic floor dysfunction is an essential prerequisite for pessary management. The second domain lists entrustable professional activities, which include: skills required for specific pessary types; speculum examination; and pessary management in complex patients and women who cannot self-manage. The third domain lists 10 roles to support competency in these entrustable professional activities.

For a skill to be within the scope of practice of physiotherapists, education and training must be undertaken so that they can be deemed competent (CSP 2019). Only individuals can decide if they believe that they are proficient in a certain skill set. The UK pessary training document (POGP & UKCS 2021) and the Australian

standards (Neumann *et al.* 2021) provide physiotherapists with resources to create training opportunities and document the tuition received.

Training physiotherapists in pessary skills still presents some challenges. Many will work alone in the community or in private practice, and will not have the support of a multidisciplinary team, or a pessary clinic to observe and participate in.

Pelvic health physiotherapy lends itself well to learning through mentorship and competency assessment in a clinical setting (Guyatt 2019). This suggests that a single study day may not be the best way to train physiotherapists. A mentorship programme can help to transfer skills learned in training to clinical practice (Frawley *et al.* 2019). The present authors recognize that more work is needed to create a clear training pathway for the profession.

Conclusion

The present authors are members of a United Kingdom Continence Society pessary use for prolapse guideline implementation group that aims to: roll out the recommendations from the guideline nationally; help finalize training for pessary clinicians in the UK; and ensure that the extension of the scope of physiotherapy practice to include pessary provision is delivered within a robust, evidence-based and rigorous skills framework. They firmly believe that there is a clear role for physiotherapists in pessary provision as an adjunct to existing evidence-based non-surgical management for symptomatic prolapse. The authors believe that this will be an important step in helping women to maintain their QOL, and remain active with a prolapse. It is important that this delivers a benefit for women seeking help for prolapse, and with additional research, adds to the evidence base for optimal pessary use.

References

Åkervall S., Othman J. A.-M., Molin M. & Gyhagen M. (2020) Symptomatic pelvic organ prolapse in middle-aged women: a national matched cohort study on the influence of childbirth. *American Journal of Obstetrics and Gynecology* **222** (4), 356-e1–356-e14.

Altman D., Cartwright R., Lapitan M. C., *et al.* (2017) Epidemiology of urinary incontinence (UI) and other lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP) and anal incontinence (AI). In: *Incontinence*, 6th edn (eds P. Abrams, L. Cardozo, A. Wagg A. & A. Wein), pp. 1–141. International Continence Society, Bristol.

Benner P. (1982) From novice to expert. *American Journal of Nursing* **82** (3), 402–407.

Brown C. A., Pradhan A. & Pandeva I. (2021) Current trends in pessary management of vaginal prolapse: a multidisciplinary survey of UK practice. *International Urogynecology Journal* **32** (4), 1015–1022.

Brown L. K., Fenner D. E., DeLancey J. O. & Schimpf M. O. (2016) Defining patient knowledge and perceptions of vaginal pessaries for prolapse and incontinence. *Female Pelvic Medicine & Reconstructive Surgery* **22** (2), 93–97.

Bugge C., Adams E. J., Gopinath D., *et al.* (2020) Pessaries (mechanical devices) for managing pelvic organ prolapse in women. *Cochrane Database of Systematic Reviews*, Issue 11. Art. No.: CD004010. DOI: 10.1002/14651858.CD004010.pub4.

Chartered Society of Physiotherapy (CSP) (2019) *Code of Members' Professional Values and Behaviour 2019.* [WWW document.] URL https://www.csp.org.uk/system/files/publication_files/000529_Code%20of%20Members%20Professional%20Values%20and%20Behaviours%202019.pdf

Cumberlege J. (2020) *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review.* [WWW document.] URL https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

de Albuquerque Coelho S. C., de Castro E. B. & Juliato C. R. T. (2016) Female pelvic organ prolapse using pessaries: systematic review. *International Urogynecology Journal* **27** (12), 1797–1803.

de Albuquerque Coelho S. C., Pereira G. M. V., Brito L. G. O. & Juliato C. R. T. (2021) Cross sectional study on assessment of ring pessary cleaning and removal every six months: adverse events and complications. *International Urogynecology Journal*, online ahead of print. DOI: 10.1007/s00192-021-04775-1.

Dwyer L., Stewart E. & Rajai A. (2021) A service evaluation to determine where and who delivers pessary care in the UK. *International Urogynecology Journal* **32** (4), 1001–1006.

Frawley H. C., Neumann P. & Delany C. (2019) An argument for competency-based training in pelvic floor physiotherapy practice. *Physiotherapy Theory and Practice* **35** (12), 1117–1130.

Guyatt S. (2019) *Another Pathway for Competency-Based Training in Pelvic Floor Physiotherapy Practice – Through Experiential Learning, Clinical Mentorship and Competency Assessments.* [WWW document.] URL https://tinyurl.com/4cz85cfw

Hagen S., Kearney R., Goodman K., *et al.* (2020) Clinical and cost-effectiveness of vaginal pessary self-management compared to clinic-based care for pelvic organ prolapse: protocol for the TOPSY randomised controlled trial. *Trials* **21:** 837. DOI: 10.1186/s13063-020-04738-9.

Harvey M.-A., Lemieux M.-C., Robert M. & Schulz J. A. (2021) Guideline No. 411: Vaginal pessary use. *Journal of Obstetrics and Gynaecology Canada* **43** (2), 255.e1–266.e1.

Lough K. (2020) *Making Pessary Use for Prolapse Woman-Centred and Evidence-Based.* PhD thesis, Glasgow Caledonian University, Glasgow.

Lough K., Hagen S., McClurg D. & Pollock A. (2018) Shared research priorities for pessary use in women with prolapse: results from a James Lind Alliance Priority Setting Partnership. *BMJ Open* **8:** e021276. DOI: 10.1136/bmjopen-2017-021276.

Manzini C., van den Noort F., Grob A. T. M., Withagen M. I. J. & van der Vaart C. H. (2021) The effect of pessary treatment on puborectalis muscle function. *International Urogynecology Journal* **32** (6), 1409–1417.

Miceli A., Fernández-Sánchez M. & Dueñas-Díez J.-L. (2021) How often should ring pessaries be removed or changed in women with advanced POP? A prospective observational study. *International Urogynecology Journal* **32** (6), 1471–1478.

National Institute for Health and Care Excellence (NICE) (2019) *Urinary Incontinence and Pelvic Organ Prolapse in Women: Management.* [WWW document.] URL: https://www.nice.org.uk/guidance/ng123/resources/urinary-incontinence-and-pelvic-organ-prolapse-in-women-management-pdf-66141657205189

National Institute for Health Research (NIHR) (2021) *Understanding Factors Which Affect Willingness to Self-manage a Pessary for Pelvic Organ Prolapse: A Mixed Methods Study Aiming to Improve Access to Pessary Self-management.* [WWW document.] URL https://fundingawards.nihr.ac.uk/award/NIHR300519

Nemeth Z., Farkas N. & Farkas B. (2020) Can we define excess vaginal space? – Genital hiatus size and prolapse severity are correlated with cube pessary size. *European Journal of Obstetrics & Gynecology and Reproductive Biology* **253** (October), 61–64.

Neumann P. B., Radi N., Gerdis T. L., *et al.* (2021) Development of a multinational, multidisciplinary competency framework for physiotherapy training in pessary management: an E-Delphi study. *International Urogynecology Journal*, online ahead of print. DOI: 10.1007/s00192-021-04843-6.

Pelvic, Obstetric and Gynaecological Physiotherapy (POGP) & United Kingdom Continence Society (UKCS) (2021) *UK Clinical Guideline for Best Practice in the Use of Vaginal Pessaries for Pelvic Organ Prolapse.* [WWW document.] URL https://thepogp.co.uk/_userfiles/pages/files/resources/uk_pessary_guideline_final_april21.pdf

Propst K., Mellen C., O'Sullivan D. M. & Tulikangas P. K. (2020) Timing of office-based pessary care: a randomized controlled trial. *Obstetrics and Gynecology* **135** (1), 100–105.

Royal College of Obstetricians and Gynaecologists (RCOG) (2021) *Sign-off of Competency Acquisition.* [WWW document.] URL https://www.rcog.org.uk/en/careers-training/about-specialty-training-in-og/assessment-and-progression-through-training/Sign-off-of-competency-acquisition/

Sahar T., Fatemeh M., Parvin B. & Reza S. M. (2020) The comparison of the effects of pessary, pelvic floor physiotherapy, and corrective surgery methods in correction of vaginal sound in patients with pelvic floor disorders. *Journal of Biochemical Technology* **11** (1), 85–91.

Sevilla C., Wieslander C. K., Alas A., *et al.* (2013) The pessary process: Spanish-speaking Latinas' experience. *International Urogynecology Journal* **24** (6), 939–946.

Tam M.-S., Lee V. Y. T., Yu E. L. M., *et al.* (2019) The effect of time interval of vaginal ring pessary replacement for pelvic organ prolapse on complications and patient satisfaction: a randomised controlled trial. *Maturitas* **128** (October), 29–35.

Wu J. M., Hundley A. F., Fulton R. G. & Myers E. R. (2009) Forecasting the prevalence of pelvic floor disorders in U.S. Women: 2010 to 2050. *Obstetrics and Gynecology* **114** (6), 1278–1283.

Dr Kate Lough has worked in pelvic health for over 25 years, and currently practises privately. She also works for the NHS Greater Glasgow and Clyde health board as an advanced practice physiotherapist, and her remit includes the Complex Pelvic Mesh Removal Surgical Service. Kate completed a doctorate in October 2020 on making pessary use for prolapse woman-centred and evidence-based (Lough 2020). She has been involved with POGP since 2008, and took over as chair in October 2020.

Claire Brown works as a clinical specialist physiotherapist at Cambridge University Hospital NHS Foundation Trust, Cambridge, UK, and has been a pelvic health physiotherapist for 12 years. In 2013, she was employed to teach women how to manage their own pessaries in a quality improvement programme, and uses pessaries in her current clinical physiotherapy caseload. Claire was also part of the UK Clinical Guideline Group for the Use of Pessaries in Vaginal Prolapse, leading the sub-training group, and has published work on the current management of pessary care in the UK. She is also a tutor on the POGP prolapse course.

