Urologic Nursing

AUGS-SUNA Joint Clinical Consensus Statement

Vaginal Pessary Use and Management for Pelvic Organ Prolapse

Developed by the Joint Writing Group of the American Urogynecologic Society and the Society of Urologic Nurses and Associates

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Abstract

Over the past 50 years, pessary use has increased in popularity and has become an essential pelvic organ prolapse (POP) management tool. However, evidence is lacking to define care standardization, including pessary fitting, routine maintenance, and management of pessary-related complications. This clinical consensus statement (CCS) on vaginal pessary use and management for POP reflects statements drafted by content experts from the American Urogynecologic Society and Society of Urologic Nurses and Associates. The purpose of this CCS is to identify areas of expert consensus and nonconsensus regarding pessary fitting, follow-up, and management of pessary complications to improve the safety and quality of care where evidence is currently limited. The American Urogynecologic Society and Society of Urologic Nurses and Associates' vaginal pessary for POP writing group used a modified Delphi process to assess statements that were evaluated for consensus after a structured literature search. A total of 31 statements were assessed and divided into 3 categories: (1) fitting and follow-up, (2) complications, and 3) quality of life. Of the 31 statements that were assessed, all statements reached consensus after 2 rounds of the Delphi survey. This CCS document hopefully serves as a first step toward standardization of pessary care, but the writing group acknowledges that improved research will grow the base of knowledge and evidence providing clinicians a foundation to manage pessary care effectively and confidently.

Why This Matters

- At present, guidance for pessary management has fallen to pessary manufacturers and the opinion of expert clinicians, leading to significant variation in recommendations for care.
- The purpose of this clinical consensus statement is to identify areas of expert consensus and nonconsensus regarding pessary fitting, follow-up, and management of pessary complications to improve the safety and quality of care where evidence is currently limited.
- The recommendations, developed by the writing group, may support these efforts by providing consistent care guidelines and statements on pessary fitting and management, while highlighting areas for further research for current practitioners or those new to the use of pessaries.

Vaginal support pessaries are considered first-line treatment in the nonsurgical management of women with pelvic organ prolapse (POP),[1] given that pessaries have been demonstrated to improve quality of life (QoL) by reducing bothersome POP symptoms associated with pelvic floor disorders.[2–9] Despite their common use, a recent Cochrane review demonstrated only 4 high-quality articles of their efficacy.[10] Physicians and advanced practice providers in various specialties in the United States fit and manage pessaries. The American Urogynecologic Society (AUGS) and the Society of Urologic Nurses and Associates (SUNA) recommend that expert guidance and insight into pessary practices should be used when the quality and quantity of high-level evidence are insufficient to develop multidisciplinary clinical guidance documents. To improve quality of care, clinical consensus statements (CCSs) are used as a bridge to summarize experts' views on care that requires interpretation and value judgment. Authors of CCSs use explicit methodology to draft experts' opinions to identify areas of agreement and disagreement regarding care in situations where high-level evidence is limited.[11] Although pessaries may be used for other indications such as stress urinary incontinence or preterm labor, the scope of this CCS is limited to pessaries used for the treatment of prolapse.

A panel of experts in pessary care from both the AUGS and SUNA membership was convened by the AUGS Publications Committee to draft a CCS regarding use and management of vaginal pessaries for POP. This panel of experts is referred to in this document as "the writing group." The purpose of this CCS is to identify areas of expert consensus and nonconsensus regarding pessary fitting, follow-up, and management of pessary complications to improve the safety and quality of care where evidence is currently limited.

Note: Author affiliations, conflicts of interest, and article information are provided at the end of this article.

Background

Over the past 50 years, pessary use has increased in popularity and has become an essential POP management tool. Benefits for women using pessaries include reducing bothersome POP symptoms, enhancing body image, and improving QoL.[2] However, evidence is lacking to define care standardization, including placement strategies, routine maintenance, and management of pessary-related complications.[10,12] At present, guidance for pessary management has fallen to pessary manufacturers and the opinion of expert clinicians, leading to significant variation in recommendations for care.[13] There are many nuances to pessary care, and clinicians must counsel patients regarding a variety of topics, including who will manage pessary care (clinician vs patient), use of intravaginal estrogen, and recommendations for timing of care.

Pessary complications include vaginal discharge, infection, abrasions, erosions/ulcerations (erosion and ulceration are used synonymously throughout), incarceration (or embedment of the device into the vaginal epithelium), and fistulas (such as vesicovaginal or rectovaginal fistulas).[14] Abrasions and erosions/ulcerations represent varying degrees of damage to the epithelium. The severity of epithelial damage and breakdown is ill-defined, but recent work by Propst et al[15] has begun to provide a clearer system to describe the depth and size of epithelial injury from pessary use. Furthermore, the lack of consistent data regarding strategies for treating complications, including altering pessary type and size, use and timing of local estrogen, or providing a pessary holiday, limits clinicians' ability to provide optimal care and counseling to their patients.[13,16]

With few data to guide practice, it is challenging to educate new clinicians on the nuances of pessary care. Recent evidence indicates insufficient pessary education and comfort with pessary management among obstetrics among gynecology residents.[17] Furthermore, O'Dell and Atnip[12] found that most pessary education and practice knowledge were achieved through on-the-job training and mentorship. High-quality, well-designed research trials are needed to provide robust educational support and definitive answers to define best practices for patients who use pessaries.[18] The recommendations, developed by the writing group, may support these efforts by providing consistent care guidelines and statements on pessary fitting and management, while highlighting areas for further research for current practitioners or those new to the use of pessaries.

Methods

The *Vaginal Pessary Use and Management for Pelvic Organ Prolapse* CCS topic was proposed by representatives from the SUNA Board of Directors to the AUGS Board of Directors as a means for the 2 organizations to collaborate on this important clinical topic. A formal proposal was reviewed for feasibility and importance by the AUGS Publications Committee and recommended to the board for further development. This CCS was developed using the following established methods to reach consensus on pessary use for the nonsurgical treatment of POP.

A call for applications for participation in the writing group was issued to the AUGS membership. Applications, including conflicts of interest, were reviewed, and a writing group chair was identified. The SUNA members were appointed by SUNA, and the AUGS members of the writing group were chosen with input from the AUGS Publications Committee from the pool of applicants and by invitation to ensure a wide range of expertise. A systematic review subcommittee was formed. A consultant from the AUGS Publications Committee served as a resource and liaison for the writing group, and administrative support was provided by AUGS.

Types of Studies

The writing group searched published original research or review articles on the topic of pessary utilization for POP. Studies on pessary use for stress incontinence and pregnancy were not included. Studies on pessary use for POP and stress incontinence were included only if the data on POP could be specifically identified. Studies were excluded if animal models were involved, they were not published in English, or they did not cover the topic area of interest. Studies in which data were reported only in abstract form were also excluded.

As stated previously, there is good evidence to demonstrate that pessaries reduce bothersome POP symptoms and improve QoL.[2–9] However, evidence is limited regarding pessary placement strategies, selection of pessary type and size, routine maintenance, timing of care, use of intravaginal estrogen, and management of pessary-related complications.[10,12] Therefore, we excluded the QoL studies and focused on the pessary fitting, management, and complication studies.

Types of Interventions

Meta-analysis was not appropriate because of the heterogeneity of the topics discussed, patient populations, and outcome reporting. Study results were summarized and graded qualitatively.

Search of Other Resources

References cited in the articles that were identified by the initial literature search were also reviewed to identify additional publications that met the guideline objectives (Appendix A, http://links.lww.com/FPMRS/A363). All studies meeting the inclusion and exclusion criteria were examined for data supporting the objectives and were included if appropriate. The search of all databases mentioned yielded 13,294 articles.

Identification of Included Studies

The initial title results were screened by a systematic review subcommittee (ie, 3 appointed writing group members) and the librarian to remove duplicates or references not relevant to pessary use for POP. Two writing

group members independently screened titles and abstracts of the studies identified by the search strategy described above to assess potential eligibility for inclusion. Each potentially relevant full-text article was then reviewed for eligibility by 2 writing group members. Any disagreements on the abstract or full-text articles were resolved by consensus during video meetings. A writing group member used the full-text article to record author name, study type, population, comparison population (if applicable) intervention, and whether it supported one of the topic statements. Ultimately, 95 articles were retained to inform this CCS.

Data Extraction and Management

The literature search was completed by a bio-librarian who was compensated by AUGS. Titles, abstracts, and full texts were reviewed using Covidence software (Covidence Systematic Review Software. Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org).

Data Analysis

The writing group was unable to complete a meta-analysis because of the low number of studies and heterogeneity of participants, outcomes, and interventions. However, a list of topic statements was created to perform a Delphi process. As described by Barrett and Heale,[19] the Delphi process uses rounds of discussions where a group of experts is asked their opinions on a topic. The questions for each round are based on the findings of the previous round, allowing the study to evolve over time in response to earlier findings. Participants can see the results of previous rounds, allowing them to reflect on the views of others and adjust their opinions as needed. This framework of rounds of expert opinion is designed to allow the development of a consensus view that answers the research question.

The writing group outlined the scope of the CCS before initiating the Delphi process based on topic themes identified in the literature. The following topics were identified as pertinent for clinical care of women utilizing a pessary for POP: pessary fitting, follow-up of patients, and management of complications; we then added 2 statements regarding quality-of-life impact.

Each writing group member selected a category for which he/she developed a list of topics to be considered for inclusion in the Delphi process. These topic statements were initially discussed to determine if the group supported its inclusion in the Delphi survey and to develop them into the final statements.

A total of 31 statements were evaluated with a modified Delphi survey method and were further refined by the writing group. Web-based software (www.surveymonkey.com) was used to administer confidential surveys to writing group members. Survey questions used a 5-point Likert scale that ranged from "strongly agree" to "strongly disagree" to inform the Delphi survey. Consensus was defined as 80% or more of the members voting "strongly agree" or "weakly agree." A total of 100% survey completion by the writing group was required. For statements that did not initially reach consensus, wording was adjusted to allow these statements to reach consensus in a second survey.

Once the statements reached consensus, they were assigned to the writing group to provide a brief rationale, supported by published literature where available. The writing group members were asked to limit their comments to a short paragraph, and where applicable, these comments were further refined by the writing group chair to fit the writing format.

Results

A total of 31 statements were reviewed by the writing group during the first Delphi round, reaching consensus on 29. The 2 statements that did not reach consensus were discussed and revised during the second Delphi round where a consensus was reached. The statements were then organized into 2 categories: (1) fitting and follow-up and (2) complications. Details regarding each of the 31 statements are provided in the text beneath each statement.

Fitting and Follow-up

Q1. Given the potential for improved QoL, all women with symptomatic POP should be offered a pessary among their initial therapeutic options.

There is significant evidence to support an improvement of QoL and the chance to avoid surgery in women who are offered a pessary for symptomatic prolapse.[20,21]

Consensus was reached in the Delphi survey; 100% (8 participants) strongly agreed with this statement.

The writing group recommends that all patients with symptomatic POP be offered a pessary. The writing group recommends that clinicians review the risks and benefits of each prolapse treatment option (observation, pessary, surgery).

Q2. Although several risk factors predict unsuccessful pessary fitting, all women who desire a pessary trial should be offered a pessary fitting. (These risk factors include prior hysterectomy, prior prolapse surgery, high body mass index, presence of stress urinary incontinence, and the anatomic variables of short total vaginal length, large introitus, and large hiatal area on Valsalva.)

Multiple studies have evaluated the risk factors that predict unsuccessful pessary fitting or long-term use.[12,21–33] However, the writing group agreed that a pessaries should be offered to all women with prolapse, even if 1 or more of these risk factors is present.

In the Delphi survey, 100% (8 participants) strongly agreed with this statement.

Q3. At the initial pessary fitting, we recommend assessment of the postvoid residual volume (PVR) in women with urinary symptoms such as voiding dysfunction, incomplete bladder emptying, or urinary retention. At follow-up visits, we recommend assessment of the PVR in women with unresolved or new voiding symptoms.

There are no clinical trials or guidelines that support assessment of the PVR after pessary fitting. This recommendation is based on best practices in the management of women with POP, especially in women who have voiding dysfunction before or during treatment, given that there is evidence for an increased PVR in women with prolapse.[34,35] In a retrospective case-control study of women with prolapse, matched by age and body mass index, anterior or apical vaginal prolapse to or past the introitus was associated with an elevated PVR of 100 mL or more.[36] In a study of nurses who manage pessaries, there was 100% consensus for obtaining a PVR before and after fitting a pessary.[37] The reasoning is that although vaginal pessary is likely to resolve urinary retention by relieving a kinked urethra and restoring normal anatomy, that urethral obstruction can still occur; therefore, clinicians should assess the PVR after a pessary fitting in symptomatic or at-risk women.

In the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with this statement.

Q4. After the initial pessary fitting, an outpatient clinic follow-up visit is recommended within 4 weeks.

There are no clinical trials or guidelines regarding optimal timing of follow-up office visits after an initial pessary fitting. However, most studies that examined the use of pessaries scheduled women for their first follow-up visit within 1–4 weeks of insertion.[21,23,38] One long-term prospective study found that most pessary-related failures occurred within 4 weeks of insertion.[39] The first follow-up visit is important in determining continuation of the pessary or a need for a different pessary size or shape. At this visit, patients can provide feedback regarding problems encountered and/or benefits derived from pessary use. Instructions on removal and pessary care can also be discussed.

In the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with this statement.

Q5. Pessary maintenance clinic visits for patients requiring provider care are recommended every 1 to 6 months. (Most do this every 3–6 months.)

Among the available literature, the frequency of follow-up visits for women who require outpatient clinic provider care for their pessaries varies, with intervals ranging from every 3 months to 2 years. (Note that self-care is defined as management for women who remove and reinsert the pessary themselves. Conversely, provider care is defined as management for women who are unable to remove and reinsert the pessary and, therefore, pessary removal and reinsertion are done by a health care provider in the outpatient clinic setting.) There is no evidence that shorter visit intervals improve long-term success rates or reduce the frequency of serious complications.[13,15,40] In addition, shorter visit intervals could increase costs, for both the patient and the health care system.[41]

Two randomized controlled trials (RCTs) of women receiving office care for a pessary provide support for this statement. Gorti et al[42] found complication rates with a ring pessary did not vary between 3- and 6-month follow-up intervals. Propst et al[15] found that follow-up intervals of 12 versus 24 weeks were equivalent, based on the incidence of vaginal epithelial abnormalities, in women using a ring, Gellhorn, or incontinence dish pessary.

The type of pessary used may influence follow-up interval recommendations. In women with grades 3 and 4 POP, space-occupying pessaries such as the Gellhorn or cube are often used. The cube pessary, although highly effective in supporting the prolapse, may require closer follow-up because of the potential for vaginal erosions and bleeding. Some members of the writing group did have concerns as to the cost and burden associated with follow-up. Because most patients requiring a pessary are older women, and more likely to be on a fixed income, and more likely to rely on assistance with transportation to the office, frequency of follow-up is an important consideration.

In the Delphi survey, 75% (6 participants) strongly agreed and 25% (2 participants) weakly agreed with this statement. Based on the available evidence, the writing group recommends pessary maintenance visits every 3–6 months, considering the patient's history and pessary type.

Q6. For women who manage their pessaries with self-care, recommended removal and cleaning intervals range from nightly to every 6 months.

There are no clinical trials or guidelines for an optimal interval of pessary removal for women who self-manage their pessaries. Lone et al[39] and Fregosi et al[43] found that the frequency of pessary removal did not affect a patient's experience of using the pessary and that patients should be encouraged to manage their pessaries based on their own preferences. A potential risk of removing the pessary too frequently (ie, nightly) is discomfort, whereas a potential risk of changing the pessary too infrequently (ie, every 3–6 months) is increased discharge and odor. However, some women have neither pain nor excessive discharge or odor. In a clinical pathway developed by members of the UK Clinical Guideline Group,[44] members reported that frequency of removal depends on the pessary type and patient choice, giving the example of the cube pessary as one that should be taken out daily and left out overnight.

In the Delphi survey, 75% (6 participants) strongly agreed and 25% (2 participants) weakly agreed with this statement. The writing group recommends counseling women to remove their pessaries as needed.

Q7. For women who manage their pessaries with self-care, follow-up examination with their clinician is recommended every 6–12 months. (Most do this every 12 months.)

There are no clinical trials of the optimal visit interval for women who self-manage their pessaries. A survey of nurse providers recommended a follow-up visit every 3–12 months[37] whereas a survey of AUGS members recommended an annual visit.[45] The rate of self-care was

31% in a retrospective review of women using a pessary for POP.[46] These women were more likely to be premenopausal, have a lower stage POP, and were more likely to be sexually active, indicating a younger group of women. Poor hand function due to arthritis, dementia, obesity, and back injuries can prevent women from being able to remove their pessaries.

Some pessaries are less amenable to self-care removal and reinsertion. Gellhorn, shelf, and cube pessaries can be difficult even for clinicians to remove, as they are designed to support the prolapse by exerting a suction effect.

Kearney and Brown[47] examined the feasibility of teaching women to manage their own pessaries and providing follow-up by phone call. This practice model also reduced health care costs and allowed clinicians more clinic time, and women preferred this alternative.

In the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with this statement. The writing group recommends an annual office visit for those self-managing pessaries.

Q8. Pessaries may safely be left in place during vaginal sexual intercourse if it is comfortable for both partners.

There are no clinical trials or guidelines regarding the need to remove a pessary for sexual activity. Many women who wear a pessary would like to remain sexually active and may not be able to remove the pessary on their own. Ring and dish shape pessaries are less likely to obstruct penetrative sexual activity. However, there is no research regarding sexual intercourse in women who use other types of pessaries.[48,49]

Sexual activity and satisfaction were found to improve in women who used pessaries in 2 studies.[50,51] The International Society for Sexual Medicine found that pessary use can improve self-confidence and body image and enhance sexual arousal and satisfaction, with women reporting that their ability to reach orgasm did not change. They caution, however, that not all pessaries can be worn during intercourse.[52]

In the Delphi survey, 75% (6 participants) strongly agreed and 25% (2 participants) weakly agreed with this statement. The writing group recommends counseling women that sexual intercourse is safe to attempt with a pessary in place, but there are no data regarding the effects on their sexual partners.

Q9. Disinfection and sterilization of pessaries intended for reuse in the clinic should follow manufacturer and institutional recommendations.

There are no clinical trials of disinfection and sterilization processes for pessaries intended for reuse. Pessary fitting kits are commonly used in clinical practice and are available from most manufacturers. However, pessary fitting kits may not include every shape and size of pessary, which leads to questions about how to manage pessaries that are used during fitting but not sent home with the patient and thus available for use with a future patient. At a minimum, used pessaries require cleaning and high-level disinfection or sterilization.[12]

In the Delphi survey, 100% (8 participants) strongly agreed with this statement. The writing group recommends following manufacturer or institutional recommendations for best practices regarding reuse of pessaries and pessary fitting kits.

Q10. During office examinations, after removal, the pessary should be cleaned with soap and water, and a cytobrush if needed, and then reinserted.

There are no clinical trials or guidelines to guide how pessaries should be handled during office examinations. When pessaries are removed and reinserted during an outpatient provider care visit, the pessary may be cleaned with soap and water, or water only; a cotton-tipped applicator or cytology brushes can help to clean pessaries with drainage holes.[12,38,53,54]

In the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with this statement. The writing group felt that any of these cleaning methods are acceptable and that more aggressive cleaning methods are not necessary. The writing group recommends counseling patients who self-manage their pessaries to wash their pessaries in a similar fashion.

Q11. During office examinations, there is no benefit to routine vaginal cleaning, unless there is excess or abnormal vaginal discharge, bleeding, or odor.

There are no clinical trials or guidelines regarding the use of cleansing agents in the vagina for women who wear a pessary. Some clinicians use a dilute mixture of a cleansing agent, such as povidone-iodine or chlorhexidine, to swab out the vagina as part of routine in-office pessary care. However, cleansing agents have not been shown to reduce pessary-related complications, and there is no evidence that cleansing the vagina during a pessary visit is helpful.[55] Furthermore, vaginal cleaning could potentially incur an additional outpatient office charge for the patient.[37] In addition, several trials have failed to show a benefit of more frequent office visits in preventing vaginal discharge and infection.[15,40,56]

In the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with this statement. The writing group recommends that if there is excess or abnormal vaginal discharge, the use of dry swabs is usually adequate, and saline or water is preferred to cleansing agents for use in the vagina.

Q12. There may be a therapeutic benefit of pessaries in the prevention of prolapse progression.

There are several small studies that have evaluated the benefit of pessaries in the prevention of prolapse progression.[21,57,58] However, data from these studies are insufficient to conclude that pessary use definitively helps to prevent prolapse progression. Randomized controlled trials would be beneficial in providing evidence for improvement in POP with use of a pessary. (See also Q29 for a related topic.)

In the Delphi survey, 37.5% (3 participants) strongly agreed and 50% (4 participants) weakly agreed with this statement, whereas 12.5% (1 participant) were neutral. The writing group agreed that, based on collective expe-

rience, pessaries may help to prevent prolapse progression. However, additional studies are needed.

Q13. There are limited data to guide clinicians in selection of pessary type or size.

No clinical trials or guidelines exist regarding how to choose a pessary; instead, clinical experience is relied upon. Although pessary manufacturers provide guidelines as to which pessary is best for each type and stage of prolapse, these guidelines are not based on evidence. Multiple authors agree that pessary fitting is an imprecise procedure.[42,59,60] The best strategy is to try the smallest possible pessary that supports the prolapse, is comfortable, and is retained by the wearer. The ring pessary is the most commonly used pessary and can be used in women with all types and stages of prolapse.[23,61–63] In 2 studies, 3 sizes of ring pessaries (#3, #4, and #5) accounted for most of the successful pessary fitting trials.[23,38] Space-filling pessaries (Gellhorn, donut, or cube) are often successful in women who were unsuccessfully fitted with a support pessary (ring). The severity of POP does not influence the likelihood of a successful pessary fitting trial.[23,64,65]

In the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with this statement. The writing group agreed that it is reasonable to try the smallest possible pessary that holds in the prolapse, is comfortable, and is retained in the vagina with Valsalva.

Q14. There is no evidence to support a beneficial effect of hydroxyquinoline-based gel for pessary use.

Hydroxyquinoline gel is a vaginal acidifier offered with pessaries from CooperSurgical and is marketed as a treatment to maintain normal vaginal pH and reduce vaginal odor associated with pessary use, but there are no data to support its use. One clinical trial found no difference in the incidence of vaginal symptoms or desire to continue pessary use during the first 3 months between women who used hydroxyquinoline-based gel and those who did not.[66]

In the Delphi survey, 100% (8 participants) strongly agreed with this statement. The writing group agreed that hydroxyquinoline-based gel is unlikely to improve satisfaction with pessary use.

Q15. Vaginal estrogen may be considered for women who wish to optimize their long-term use of a pessary.

Vaginal estrogen often is recommended for women who use pessaries as a means of reducing the risk of epithelial abrasions and vaginal bleeding. Vaginal estrogen is typically delivered as a cream or a tablet, but also comes as an estrogen ring, and all of these can be used concurrently with a pessary. However, several well-designed studies did not find a significant difference in the rate of pessary-related epithelial abrasions between women who used vaginal estrogen and those who did not.[15,67,68] One study did find that women who used vaginal estrogen were less likely to discontinue use of their pessaries.[67]

In the first Delphi survey, 75% (6 participants) strongly agreed and 25% (2 participants) weakly disagreed with this statement: "Vaginal estrogen may be considered for women using pessaries." After some discussion, the topic statement was revised from the original statement to "Vaginal estrogen may be considered for women who wish to optimize their long-term use of a pessary." In the second Delphi survey, 87. 5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with the revised statement. The writing group agreed that the data conflict with the cost-benefit ratio of vaginal estrogen, especially in cases where the cost of estrogen is significant. In addition, there was agreement that regional differences in practice style, prescription costs, and patient attitudes can influence decisions on vaginal estrogen use.

Q16. For women with pain related to pessary removal and insertion, the use of lidocaine-prilocaine cream can reduce patient-reported pain. Other techniques and tools for provider care of the pessary include the use of a ring forceps, Kelly clamp, or dental floss/dental tape, to help gain traction on the pessary during removal.

Pessary removal and insertion can be painful, especially for women with a narrow introitus or vulvovaginal atrophy. There are few studies of tools and techniques that can help to reduce this discomfort. The use of lidocaine-prilocaine cream was found to reduce patient-reported pain scores in a trial that compared it with the use of a placebo.[69] Other techniques and tools for provider care of the pessary include the use of a ring forceps, Kelly clamp, or dental floss/dental tape, to help gain traction on the pessary during removal.[12,37,54,70] Use of lubricant alone is also helpful.

In the Delphi survey, 75% (6 participants) strongly agreed and 12.5% (1 participant) weakly agreed, whereas 12.5% (1 participant) weakly disagreed with this statement. The writing group agreed that there is a potential benefit and low risk of harm with these techniques.

Complications

Q17. There are 4 levels of effects of the pessary on vaginal tissue, and vaginal epithelial changes from pessaries can be classified as either (1) erythema, (2) abrasion, (3) erosion/ulceration, or (4) fistula.

It is well understood that pessaries have the potential to cause vaginal injury. There is currently no standardized system for naming or grading these injuries. The Clavien-Dindo system, which was developed for use in surgical research, has been used to rank the severity of pessary-related complications.[14] Terms that have been used to describe vaginal injuries include mucosal pressure injury and medical device-related pressure injury.[37] However, these terms do not provide the specificity needed to describe injuries of the vaginal epithelium. We recommend the use of 4 terms to classify vaginal epithelial changes from pessaries: (1) erythema, (2) abrasion, (3) erosion/ulceration, or (4) fistula.

The National Pressure Injury Advisory Panel uses a staging system for pressure injury to the skin[44,71]: superficial, partial thickness, full thickness, and injury to an adjacent organ. These 4 stages are similar to the terms used to describe the vaginal epithelial changes seen with pessary use, and consideration was given to using these terms. However, the writing group does not agree with the concept of "staging" these injuries because it is difficult to measure the size and depth of these vaginal lesions.

The writing group aimed to develop a set of terms that could be used to describe pessary-related vaginal epithelial changes. These changes can be difficult to describe in terms of depth and location. We recommend use of the following terms: erythema, abrasion, erosion/ulceration, and fistula. Erythema describes the appearance of redness, without visible breakdown of the vaginal epithelium. Abrasion describes a superficial injury with visible, scant vaginal bleeding, without further treatment needed. Erosion/ulceration describes a deeper injury to the vaginal epithelium, with bleeding that usually requires a chemical cauterizing agent, such as silver nitrate or Monsel's solution, to achieve hemostasis. Fistula is a connection between the vagina and adjacent organ (bladder or rectum) that has developed as a result of pessary use.

We originally developed the following statement: "There are 4 levels of effects of the pessary on vaginal tissue, and vaginal epithelial changes from pessaries should be classified as either erythema (superficial), abrasion (partial thickness), erosion/ulceration (full thickness), and fistula (injury to adjacent organ)." In the first Delphi survey, 62.5% (5 participants) strongly agreed and 37.5% (3 participants) weakly agreed with this statement. However, there was concern that the original statement was too strongly worded. After discussion and revision of the statement (changing it from "should be classified" to "can be classified"), a second Delphi survey was completed, in which 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with the statement.

The writing group does agree that the terms *erythema* (superficial), *abrasion* (partial thickness), *erosion/ulceration* (full thickness), and *fistula* (injury to adjacent organ) are descriptive of the vaginal mucosal injuries seen with pessary use and recommend using these terms. Although the final topic statement regarding terminology to describe vaginal injury reached consensus in the first Delphi, the statement was revised in a second Delphi round from vaginal epithelial changes "*should* be classified…" to "*can* be classified…" because this is the writing group's recommendation and not agreed upon in the literature.[14,15,37]

Q18. If erythema or an abrasion is identified during the pelvic examination, it is appropriate to reinsert the pessary. However, if an erosion/ulceration is identified, then the pessary should usually be removed and not reinserted, and the patient should be seen again for a pelvic examination in 4–6 weeks. If a fistula is identified, then the pessary should be removed, and arrangements made to care for the fistula.

There are no clinical trials or guidelines of best practices for care of pessary-related vaginal epithelial injuries. The writing group developed recommendations based on their collective expertise and experience.

Vaginal erythema and granulation tissue are common findings in women who wear a pessary and are not always accurate predictors of more serious future complications.[72] The writing group recommends watching these findings over time and instructing women to call if vaginal bleeding develops.

Women with erosions/ulcerations require closer follow-up, which usually includes removing the pessary temporarily to allow the area to heal. For some women, it might be reasonable to cauterize the erosion/ulcer and replace the pessary.

For most women with vaginal erosions/ulceration, the writing group recommends removing the pessary, for 4 weeks. In women with a pessary-related fistula, the writing group agreed that the pessary should be removed, and the fistula treated. The decision to use a pessary after fistula treatment should carefully consider the risks of recurrence.

In the Delphi survey, 37.5% (3 participants) strongly agreed and 50% (4 participants) weakly agreed with this statement, whereas 12.5% (1 participant) weakly disagreed.

Q19. Granulation tissue can form as a result of pessary use with each of these epithelial changes.

Vaginal granulation tissue can develop in some pessary users. It is unclear who is at risk of vaginal granulation tissue, or whether there are clear guidelines on its management (see below for management recommendations). One study described pessary-associated vaginal granulation tissue and recommended the term *hypergranulation.* This term describes the abnormal buildup of mucosal granulation tissue due to chronic friction, such as pessary use in the vagina, in a process that impedes normal healing.[37]

In the Delphi survey, 75% (6 participants) strongly agreed and 25% (2 participants) weakly agreed with the statement. The writing group recommends documenting the location, size, and nature of the affected area.

Q20. Anticoagulant and antiplatelet medications (ie, warfarin, clopidogrel) may increase the risk of bleeding with pessaries but are not contraindicated with pessary use.

There are no clinical trials or guidelines examining the potential risk of anticoagulant or antiplatelet medications in women who wear pessaries. The risk of vaginal bleeding related to pessary use in women who take anticoagulants or antiplatelet medications may be higher than average; however, there are no data to suggest that antiplatelet medications are contraindicated with pessary use.[15,73]

Consensus was reached in the Delphi survey, 62.5% (5 participants) strongly agreed, 25% (2 participants) weakly agreed, and 12.5% (1 participant) was neutral with the statement. The writing group recommends that clinicians discuss the risks, benefits, and alternatives of

using pessaries with patients who are using anticoagulant medications and consider more frequent follow-up when there is bleeding.

Q21. For vaginal epithelial changes (erythema, abrasion, erosion/ulceration, fistula) and granulation tissue related to pessary use, there are no definitive guidelines for management.

Many studies show that vaginal epithelial changes occur during pessary use.[14] However, there are limited data to provide definitive guidelines for management (see below for our recommendations). Several studies suggest that decreased blood flow from the pessary leads to these injuries of the vaginal epithelium. Necrosis by continuous pressure may form a vesicovaginal or rectovaginal fistula.[74]

Consensus was reached in the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with this statement.

The writing group recommends that clinicians assess the vaginal epithelium for changes during pessary care office visits. Some vaginal epithelial changes, such as erosion/ulceration and granulation tissue, require treatment by removing the pessary for a few weeks, and possibly using vaginal estrogen if not contraindicated; if these vaginal lesions fail to improve, then a biopsy may be necessary, as noted below in consensus statement Q27. A pessary may be used again after the vagina has healed. Patients should be informed when pessaries are placed that follow-up is necessary to reduce the risk of severe complications. If the patient is unable to follow up, then clinicians should consider an alternate treatment option.

Q22. If a patient has a superficial epithelial abrasion from the pessary, no changes to care are required. Chemical cautery/silver nitrate may be helpful if there is bleeding.

There are no clinical trials or guidelines regarding best practices for managing superficial epithelial abrasions related to pessary use. The writing group developed recommendations based on collective expertise and experience.

Consensus was reached in the Delphi survey, 62.5% (5 participants) strongly agreed and 37.5% (3 participants) weakly agreed with the statement.

The writing group recommends that if superficial epithelial changes occur from pessary use, no clinical changes are required. Some clinicians suggest the use of chemical cautery, but recognize that there are no data to recommend its use. The writing group suggests that practitioners use their best clinical judgment when determining the extent of the abrasion and consider removing the pessary as needed.

Q23. If a patient develops an erosion from a pessary, clinical management requires a risk/benefit discussion regarding continued use of the pessary.

There are multiple case reports that alert clinicians to the risk of vaginal erosions or fistula formation if pessaries are neglected.[35,75,76] Clinicians should emphasize the importance of regular follow-up to assess the integrity of the vaginal epithelium. There are limited data to predict who is at risk of vaginal erosions and, therefore, all patients should have a vaginal examination during their follow-up visits.[74,77]

Consensus was reached in the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with the statement.

The writing group recommends that clinicians discuss the risk and benefits of continuing pessary use in patients with a known history of vaginal erosions. Regarding the next step, 3 options are presented, in Q24 (use of vaginal estrogen), Q25 (temporary removal of the pessary), and Q26 (change to a smaller pessary or to a different pessary shape).

Q24. If a patient has an erosion from the pessary and is not currently using vaginal estrogen, then a therapeutic trial of vaginal estrogen therapy with continued pessary use is advised.

There are few data to support the use of vaginal estrogen to prevent vaginal epithelial injury.[8,15,57,58,67,68] In a retrospective cohort study of 69 women who developed pessary-related vaginal erosions, Handa and Jones[57] and Dessie et al[67] found no difference in those who used estrogen vaginal cream versus those who did not, but found a greater likelihood for pessary continuation among women who used vaginal estrogen. Also, the frequency and duration of vaginal estrogen therapy have not been determined.[60,77] Similarly, in women with significant vaginal atrophy that causes too much discomfort to fit a pessary, it is reasonable to use vaginal estrogen for 2 months and then try to fit a pessary.

Consensus was reached in the Delphi survey, 62.5% (5 participants) strongly agreed, 25.6% (2 participants) weakly agreed, and 12.5% (1 participant) were neutral with the statement.

The writing group recommends that clinicians discuss the risk and benefits of vaginal estrogen therapy with patients who have been diagnosed with a vaginal erosion. Patients should be informed of the risks and benefits of vaginal estrogen use in the setting of vaginal erosions due to pessary use. Clinicians should also determine the frequency and duration of estrogen use and ensure that patients are able to return for follow-up examinations.

Q25. If a patient has an erosion from the pessary that is enlarging or becoming deeper, the pessary should be removed for 4 weeks and the patient reexamined. Therapeutic vaginal estrogen is also recommended.

There are limited data from clinical trials regarding best practices in the management of the pessary-related erosions. Nonetheless, there are cohort studies that recommend temporary removal of a pessary and daily use of vaginal estrogen to manage enlarging vaginal erosions.[39,62,78] In addition, some authors discuss improvement in vaginal erosions after a "pessary holiday" and use of vaginal estrogen cream.[12,79]

Consensus was reached in the Delphi survey, 75% (6 participants) strongly agreed and 25% (2 participants) weakly agreed with this statement.

The writing group recommends that if a patient has an erosion from the pessary that is enlarging or becoming deeper, the pessary should be removed for 4 weeks and reexamined. Therapeutic vaginal estrogen is recommended.

Q26. If a pessary has been removed due to erosion, and improvement occurs, the pessary may be replaced. However, a different size or type of pessary may be necessary.

There are no clinical trials or guidelines regarding best practices for replacing a pessary after a "pessary holiday" related to vaginal erosion. However, based on the clinical experience and expertise of the writing group, it is reasonable to suggest that a change in size and type of pessary be considered. In this case, a smaller size or different type of pessary could reduce the pressure against the vaginal epithelium. Change to a different pessary may also be done as a first management option for an erosion, before use of vaginal estrogen, or instead of a "pessary holiday."

Consensus was reached in the Delphi survey, 75% (6 participants) strongly agreed and 25% (2 participants) weakly agreed with the statement.

Q27. If the vaginal erosion does not improve after the above management, then a vaginal biopsy should be considered.

There are several retrospective and review studies that recommend vaginal biopsy of a persistent erosion.[37,77,79] Although there are no data to suggest that pessaries can cause malignancy, vaginal epithelial injuries caused by a pessary could potentially obscure a precancerous or cancerous lesion.

Consensus was reached in the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participant) weakly agreed with the statement. The writing group recommends that if a patient has persistent erosion from the pessary that does not resolve after pessary removal and/or therapeutic vaginal estrogen, a biopsy should be considered.

Q28. If a pessary is unable to be removed in the office, then removal in the operating room may be required.

There are several case reports and review articles that discuss neglected incarcerated pessaries that required removal during an examination under anesthesia, or even surgical removal.[35,53,76] An incarcerated pessary occurs when the pessary becomes embedded in the vagina, typically in a patient who did not follow up after pessary placement. A trial of vaginal estrogen, use of lidocaine gel, and using the most experienced clinician may be successful in cases that are not emergent.[53,80] In this situation, shared decision-making can be helpful, as these removals can be difficult and painful, and the patient might prefer having sedation or general anesthesia. Surgical excision in the operating room may be necessary.[77,81]

Consensus was reached in the Delphi survey, with 62.5% (5 participants) strongly agreeing and 37.5% (3 participants) weakly agreeing with the statement. The writing group recommends removal of an incarcerated pessary under anesthesia in the operating room, possibly with surgical excision of the pessary, if the patient cannot tolerate removal in the office. However, most members of the writing group agree that nearly all pessaries can be removed in the office and that removal of a pessary under anesthesia is a rare event.

Q29. Women who use a pessary long term may later need to be refitted with a larger or smaller pessary, or refitted with a different pessary type (eg, change from ring to Gellhorn).

Although there are limited data to support refitting with a different type or size pessary, there is some evidence that "improved levator ani function secondary to recovery from passive stretch induced by pessary support of the pelvic organs may explain symptomatic improvement with pessary use."[57] As the pelvic muscles recover (shorten), there can be a decrease in the prolapse stage and/or the genital hiatus in some long-term pessary users,[82] and a smaller pessary may be adequate to treat the prolapse. (This may be the mechanism behind the concept that pessaries may prevent the progression of POP, as noted in Q12.) Clinically, this may be recognized when the health care provider notes increasing difficulty with pessary removal, and a trial with a smaller pessary may be considered. Conversely, with aging and continued muscle atrophy, the prolapse may enlarge, and a larger pessary may be needed.

Consensus was reached in the Delphi survey, 87.5% (7 participants) strongly agreed and 12.5% (1 participants) weakly agreed with the statement.

The writing group recommends that clinicians reassess the size and type of pessary periodically. Patients may benefit from a smaller, larger, or a different type of pessary to improve their QoL and limit adverse effects. Clinicians should consider a change in pessary type if the pessary unmasks occult urinary incontinence, causes pain or a vaginal erosion, or no longer adequately supports the prolapse.

Q30. Although many women have vaginal discharge when using pessaries, it usually is not due to a vaginal infection.

Approximately 30% of women using a pessary will report bothersome vaginal discharge.[83] The etiology of this discharge is thought to be from an inflammatory response to the foreign body.[21,84] Women who use pessaries, especially if postmenopausal, have a higher rate of bothersome vaginal discharge.[84] There are several cohort studies that suggest frequent self-replacement of the pessary decreases the rate of vaginal discharge.[43,66,85] It is unclear if vaginal estrogen or hydroxyquinoline-based gel prevents these symptoms.[66,84,85]

There is a growing body of literature regarding the vaginal microbiome of pessary users, with the recognition that increased vaginal discharge is common, yet often not due to vaginal infection.[7,14,63,74,84] Alperin[74] and Collins et al[84] found few objective differences between the vaginal microenvironments of women who wear pessaries and are bothered by discharge and those who wear pessaries and are not bothered. There also is little differ-

ence in the vaginal microbiome of women with self-care and provider care of their pessaries.[43,85,86]

Consensus was reached in the Delphi survey, with 87.5% (7 participants) strongly agreeing and 12.5% (1 participants) weakly agreeing with this statement. Clinicians should inform patients that pessaries may cause additional vaginal discharge, which is not typically infectious and does not require treatment. If patients are significantly bothered by vaginal discharge, the clinician may consider obtaining vaginal or cervical swabs to test for infection or consider increasing the frequency of pessary removal to reduce vaginal discharge.

Q31. We recommend caution when considering pessary use in patients with vaginal mesh erosion, severe postirradiation scarring, nonhealing ulcers, undiagnosed vaginal bleeding, and severe vaginal infection.

There are limited data to guide clinicians regarding pessary use in women who have a history of vaginal mesh erosion, severe postirradiation scarring, nonhealing ulcers, undiagnosed vaginal bleeding, and severe vaginal infection.[27] The writing group suspects there is a higher rate of pessary complications in these women.

Consensus was reached in the Delphi survey, with 100% (8 participants) strongly agreeing there is likely a higher rate of pessary complications in women with these conditions. The writing group recommends that clinicians avoid using pessaries in women who have a history of vaginal mesh erosion, severe postirradiation scarring, nonhealing ulcers, undiagnosed vaginal bleeding, and severe vaginal infection. If a pessary is used in these patients, clinicians should inform patients of the risks, benefits, and alternatives to pessary use and consider more frequent follow-up. Patients with undiagnosed vaginal bleeding or vaginal infection should be evaluated before pessary fitting. If vaginal bleeding occurs after pessary placement, the clinician should evaluate all potential sources of the bleeding and may consider obtaining an endometrial biopsy or pelvic ultrasonography.[87]

Discussion

The purpose of this modified Delphi study was to develop consensus statements on pessary fitting and follow-up, along with complications of pessary use, in women who utilize pessaries in the treatment of POP. Development of expert consensus offers opportunities for improvement in the way clinicians fit pessaries, follow patients, prevent and manage complications, and use pessaries to improve patients' QoL. Experts in the fitting and management of pessaries achieved a high degree of consensus and identified 31 statements that are important for pessary providers to consider and apply in their everyday clinical care of the pessary patient. In addition, the writing group recognizes there is no statement regarding the potential positive benefits to body image with pessary use. However, it is likely because QoL is enhanced with pessary use. Data are limited but suggest that pessaries improve self-perception of body image.[2,65]

Research Needs

Although the writing group utilized the available literature to support the consensus statements, it is important to note that many statements are primarily based on expert opinion, and further research is needed.

Many questions regarding pessary fitting and management remain unanswered causing clinicians to continue to rely on expert opinion while treating patients using vaginal support pessaries. Some work has been done looking at best practices for clinician care follow-up protocols, self-care cleaning schedules, and office-follow-up, but RCTs and best practice guidelines are still needed. Should follow-up be different for different pessaries? Are different pessary shapes more likely to cause complications? Can patient time and financial burden be relieved by less frequent follow-up or use of telemedicine? More RCTs on fitting techniques and the selection of pessary shapes and sizes are needed. We continue to rely on pessary manufacturers for guidance in pessary cleaning and in the reuse and sterilization of pessaries used to fit patients in the office. Institutional practices vary based on their own infection prevention department guidance, but there are currently no standard protocols to guide clinician practice. Clinical trials examining optimal cleaning, disinfection, and sterilization practices would provide consistency in care and improve patient outcomes.

The difficulty in achieving consensus regarding use of vaginal estrogen with pessary users indicates a greater need for additional research not only for benefits of use, but also in the prevention and treatment of complications. Future studies addressing pessary-related vaginal lesions and the best frequency, duration, and form of vaginal estrogen (eg, creams, tablets, soft gels, rings) continue to be warranted. Further, what other vaginal products may be useful in the prevention of these lesions? Some work examining the changes of the vaginal microbiome of pessary users has been initiated. It is yet to be determined how estrogen and other vaginal products may affect the microbiome of pessary users. Are there newer formulations or products that could be developed to reduce the vaginal inflammatory response and vaginal discharge related to pessary use? There are a few case reports implicating the pessary as a cause of vaginal and cervical cancers.[88,89] If such a cancer risk exists, what patient or pessary factors might we need to explore? Of greater concern are patients who develop complications yet are not under a clinician's care (lost to follow-up). Can technology be used to track these patients to prevent this loss and the subsequent complications found in these patients?[11,90] How can we utilize telemedicine in supporting the care of the pessary patient? Can telehealth be utilized for some interval management to reduce costs among select patients who self-manage their pessaries or who have demonstrated minimal to no complications?

Considerable discussion among the writing group members revolved around how to classify mechanical vaginal epithelial injuries associated with pessary use. Interprofessional collaboration among groups who work

Simply Stated

A vaginal pessary is a silicone device that is commonly used to treat dropped pelvic organs (pelvic organ prolapse [POP]) when they become bothersome. Currently, there are many differences in how medical providers care for women who want to use a pessary for their symptoms. This clinical consensus statement (CCS) on vaginal pessary use for management of POP was put together by experts from both the American Urogynecologic Society and the Society of Urologic Nurses and Associates. The purpose of this CCS is to present information on pessary management that may allow for standardization of certain practices and improve patient care. The authors of this CCS sought to discuss the initial pessary fitting, when and how often to follow up women who are using pessaries, and how to best manage issues that arise from the utilization of pessaries. A total of 31 statements about pessary use for POP were agreed upon by the group. Although this CCS document will provide recommendations for medical providers and patients, future research can help better guide the use of pessaries for women with POP.

in defining and recommending treatment for skin conditions associated with device-related injuries may help further our knowledge in this area. The writing group reached consensus on terminology for 4 levels of vaginal tissue effects related to pessary use, but there is little evidence for the best treatment protocols for changes in the vaginal epithelium. Research is needed as to when to use vaginal estrogen, when to use a pessary "holiday" and duration of the pessary-free time, use of chemical cautery for bleeding lesions or granulation tissue, follow-up time frames, and whether there are benefits for pessary users of other vaginal dryness products such as ospemifene and prasterone. Additional research questions related to mechanical vaginal epithelial injuries include the following: When will patients benefit from changing the pessary and/or shape of the pessary when treating lesions? Are there newer pessary designs that will reduce the risk of pessary-related complications such as the 3-dimensional printing technology described by Barsky et al?[91] Are there patient factors such as medications, aging, or genetics that can be used to predict who is at risk of vaginal erosions?

Additional research questions relate to the idea of who should be providing pessary care and how those clinicians should be educated. There is evidence that registered nurses, advanced practice registered nurses, physician assistants, physicians, and physiotherapists/physical therapists manage pessaries,[11,92,93] yet there is no formal training program for pessary fitting and management. Best practices for formal education related to pessary care include standards for mentorship, audiovisual instruction, and improving clinical prolapse models.[10,11,37,92,94]

Summary

The vaginal pessary is a minimally invasive, cost-effective device that positively impacts the health of women worldwide. Once fitted correctly, a pessary enhances QoL, improves self-esteem, and restores the daily function of women suffering from POP. However, improved guidance in pessary care is needed. Although there are good data on quality-of-life improvement with pessary use, the data on pessary fitting and management are of low quality. The goal of this document is to provide guidance for health care providers in caring for women who choose a pessary to manage their prolapse symptoms. The writing group acknowledges that the risk of unintentional bias may exist in our recommendations, given the lack of quality pessary research from which to draw conclusions. Higher quality research will grow the base of knowledge and evidence providing clinicians a foundation to manage this care effectively and confidently. Increased knowledge may enable educators to develop concise educational protocols for future clinicians specializing in female pelvic medicine. This education may directly translate to improvements in patient care, starting with the initial fitting procedure, to surveillance, and, finally, management of complications. Achieving greater patient satisfaction and improved outcomes will advance the art and the science of the pessary.

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