



Effectiveness of pessary and pelvic floor physiotherapy alone and in combination for management of stress and mixed urinary incontinence: a literature review

Maria Giroux, Corrine Jabs, Susan McLellan, Leslie P. Beck, Amanda Scollan, Nadeane Nelson, Erwin Karreman, Caitlyn Howe, Jihane Henni

Department of Obstetrics and Gynecology, University of Saskatchewan, Regina, Saskatchewan, Canada

Contributions: (I) Conception and design: M Giroux, C Jabs, E Karreman; (II) Administrative support: None; (III) Provision of study materials or patients: None; (IV) Collection and assembly of data: M Giroux, S McLellan, LP Beck, A Scollan, N Nelson, C Howe, J Henni; (V) Data analysis and interpretation: M Giroux; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Maria Giroux, BSc, MD. Department of Obstetrics and Gynecology, University of Saskatchewan, Regina, Saskatchewan, Canada. Email: mag640@mail.usask.ca.

Abstract: Stress urinary incontinence (SUI) affects 29–75% of women and can have a significant impact on quality of life. Pessaries are low-cost interventions that have been used since the 5th century BC. Pessaries can be used to conservatively manage SUI alone or in combination with other evidence-based conservative treatments, such as pelvic floor physiotherapy. Unfortunately, pessaries have been underutilized and the value of pessaries in the treatment of SUI remains uncertain. Pessary is an effective short-term management option for SUI. Improvement in SUI was noted in 36–66% of patients. Combination of pessary and behavioural therapy is more effective than pessary alone. Behavioural therapy includes pelvic floor physiotherapy and instructions for use of pelvic floor muscles to prevent SUI. For long-term pessary use, results are conflicting. The current evidence is limited by considerable discontinuation and dropout rates. There is a gap in knowledge regarding the effects of long-term pessary and pelvic floor physiotherapy use alone and in combination for treatment of SUI with more frequent clinician contact. Future research would guide clinicians in the value of pessary use and assist in managing patient expectations.

Keywords: Stress urinary incontinence (SUI); mixed urinary incontinence; pessary; pelvic floor physiotherapy

Received: 07 January 2020; Accepted: 21 February 2020; Published: 25 March 2020.

doi: 10.21037/gpm.2020.02.02

View this article at: <http://dx.doi.org/10.21037/gpm.2020.02.02>

Introduction

Stress urinary incontinence (SUI) affects 29–75% of women (1) and impacts patients' quality of life (2). The 2010 International Urogynecological Association (IUGA) and International Continence Society (ICS) Joint Report defined SUI as involuntary loss of urine with increased intra-abdominal pressure with sneezing, coughing, laughing, or physical exertion (3). SUI can be treated conservatively with an incontinence pessary. Pessaries have been used since the 5th century BC (4) and can be successfully fitted in 64–75% of patients (5). Pessaries can be used for patients who are awaiting surgery, who are poor

surgical candidates, who wish to avoid or defer surgery, or who have not finished childbearing years (6). Pessaries have several advantages including ease of use, reversibility, and low complication rate (7). The Society of Obstetricians and Gynaecologists of Canada (SOGC) recommends for pessaries to be considered the first line of treatment for all women presenting with urinary incontinence at any age group (8). Pessaries are a low-cost intervention that can be used alone or in combination with other evidence-based conservative treatments, such as pelvic floor physiotherapy (9,10). Unfortunately, the value of pessaries in the treatment of SUI remains uncertain (11). Pessaries have been

underutilized (5) and the use of pessaries is not supported in the 2013 National Institute for Health and Care Excellence Guidelines due to limited high-quality evidence (12).

Current evidence

The current evidence for the effectiveness of pessaries derives from one three-arm randomized control trial, the 2010 Ambulatory Treatments for Leakage Associated with Stress Incontinence (ATLAS) trial (10), three randomized cross-over trials (3,13,14), ten prospective studies (3,5,7,14–20), and one retrospective chart review (21). These studies examined adult females with SUI (5,10,14,15,17,18,20–22), stress-predominant mixed urinary incontinence (2,7,10,13), and mixed urinary incontinence (10,15–17,19,21,22). Nine studies compared the effectiveness of pessary to no treatment (7,14–21). The ATLAS trial was the only study to compare the effectiveness of pessary, pelvic floor physiotherapy and bladder control strategies, and a combination of pessary and behavioural therapy (10).

There was a significant variation among study designs. The ATLAS trial was the largest multicenter randomized clinical trial consisting of 446 patients and was the only study to assess effectiveness of pessary alone, behavioural therapy alone, and the combination of pessary and behavioural therapy for management of SUI. Behavioural therapy included pelvic floor physiotherapy and instructions for use of pelvic floor muscles to prevent SUI (10). Three studies had moderate sample sizes of 95 (5) and 100 patients (15,21). Other studies had small sample sizes of 6–57 patients (3,7,13,14,16–18,20). Studies used different types of pessary: ring pessary (7,10,13,21), dish pessary (5,10,16,21), Hodge pessary (3,14), cube pessary, Gellhorn pessary (21), elastic vaginal pessary (17), vaginal sponge (18), and the Uresta device (19). Outcome measures included: self-reported symptoms (10,13,16,17,19), comfort with pessary (13,14), validated questionnaire regarding symptom severity and/or quality of life (7,10,13,15,19), patient satisfaction (10,15), the number of incontinence episodes in 7 days (7,10,13), pad weighing test (7,14,17–19,21), urodynamic parameters (5,13,17,20), and the Q-tip angle (5,20). Duration of follow-up also varied. Short-term follow-up included same day (5,14,18,20), 1 month (13), 2 months (15), and 3 months (10,17). Only five studies examined long-term effects of pessaries (7,10,16,19,21) with follow-up of 6 months (21), 11 months (16,19,21), and 1 year (7,10). The ATLAS trial was the only study that assessed both short and long-term effectiveness (10).

Pessary is an effective short-term management option

for SUI (3,14,15,17–19). Improvement in SUI was noted in 36–66% of patients (3,14,15,17–19). Complete immediate resolution of incontinence was achieved in 20–83% (5,13,17,20) of patients on urodynamics. Pessary was found to improve pad weight test scores (14,17,18) and Q-tip straining angle (5,20). The ATLAS trial found greater improvements in the physiotherapy group (49%) than the pessary group (33%). Combination of treatments was more effective than pessary alone (10). The ATLAS trial recommended that clinicians use physiotherapy alone or the combination of pessary with behavioural therapy (10).

For long-term pessary use, results are conflicting. The ATLAS trial found no statistically significant differences at 12 months in any of the outcomes. The trial concluded that combination therapy was not superior to a single-modality therapy. In clinical practice, the ATLAS trial recommended clinicians use a single-modality therapy for long-term conservative management of SUI (10). Furthermore, one study found pessary to have low success rate of 24% (7). In contrast, another study reported moderate to great improvement in urinary symptoms in 71% of patients (16). Another study found that the Uresta pessary significantly reduced incontinence questionnaire scores, quality-of-life measures, pad weights, and the number of incontinence episodes (19).

Strengths of current literature

The ATLAS trial was the first randomized control trial to compare the effectiveness of single-modality therapy to combination therapy for treatment of SUI (10). It was also the largest trial, thus minimizing confidence intervals around estimated differences. The strength of current literature is that it presents evidence for a variety of pessary types and outcomes measures. Patients may need to be fitted with several pessary types before a successful fit is achieved. Furthermore, some clinicians may use urodynamic parameters, while others may use self-reported symptoms, validated questionnaires, number of incontinence episodes, or patient satisfaction to determine success in their clinical practice (11).

Weaknesses of current literature

There are several weaknesses in the current literature. The major weakness of nine studies is the small sample size (3,7,13,14,16–20), which produces wide confidence intervals around the estimated differences (11). Furthermore, several studies had considerable discontinuation and dropout rates. In the ATLAS trial, 26%, 15%, and 12% of

participants in the pessary, behavioural, and combination groups respectively dropped out. The overall continuation of pessary use at 1 year varied from 16–57% (7,10). In the ATLAS trial, 45% of patients in the pessary group and 57% of patients in the behavioural group continued to use the treatment modality at 1 year (10). This rate is lower than other studies, where 50–66% and 54% of patients continued to use pessary at 12 months (19,21) and 3 years (23) respectively. The major weakness of the ATLAS trial was that patients in the combined treatment group could continue the trial while using only one of the therapies after the 8-week treatment period (10) and no data were provided regarding the number of patients in the combined group that discontinued one element of the therapy. This makes the data obtained at 12 months a less accurate reflection of the intervention. The third weakness of the ATLAS trial is the limited amount of clinician contact. The behavioural group had only four clinic visits during eight weeks (11).

There is a gap in knowledge regarding the effects of long-term pessary use for the treatment of SUI with more frequent clinician contact (11). The 2013 Cochrane Review (8) advises for the results of the ATLAS trial (11) to be interpreted with caution due to limited amount of clinician contact. Two studies suggested that high intensity supervised pelvic floor muscle training may improve results for SUI (24,25). The major drawback to unsupervised pelvic floor physiotherapy is variation in patient motivation to adhere to exercises (9).

Due to small sample sizes, the results should be considered with caution. The 24% success rate of pessary in Robert's (7) study was based on only six patients. Furthermore, quantitative synthesis of data from the studies was not possible since they used different definitions of SUI, types of pessaries, outcome measures, and definitions of success. SUI was diagnosed based on history (5,10,16), stress test (10,14,20), or urodynamic testing (14,19,20). There was a variation in definition of success, which included a decrease in pad tests (7,19), a decrease in number of incontinence episodes in 7 days (7,10,13,19,21), a decrease in mean scores on incontinence questionnaire (10,19), improvement in quality of life (10,19), patient satisfaction (10,15), subjective improvement in incontinence (15,16), normal stress test (20), changes on urodynamics and Q-tip test (5,20), and resolved incontinence (18,21). Therefore, success from one study may be considered a failure in another study (11). Patients who were not considered to be successful since they were not completely dry may feel satisfied with therapy (22). Furthermore, urodynamic testing is a static procedure and does not truly reflect real

life activity. Patients who may not be completely dry on urodynamics may have significant clinical improvement in their symptoms and may be satisfied with using a pessary (5). It is also important to critically appraise the possible reasons that there were no differences between groups at 12 months follow-up in the ATLAS trial. At 12 months, adherence to therapy was 31.8% and 22.8% in behavioural intervention and combined groups respectively and data regarding adherence was missing for 21.8% and 21.1% of patients in the behavioural intervention and combined groups respectively. Therefore, no difference in effectiveness could have been due to less than optimal adherence (26).

Conclusions

Both the Cochrane review and the SOGC concluded that there is insufficient evidence to determine whether pessaries are more effective at treating SUI than no treatment and other conservative treatments (8,11). Therefore, it is important for future research to assess the long-term effectiveness of pessary and high intensity physiotherapy alone and in combination with higher adherence to therapy than that in the ATLAS trial (3,7,11).

Future research would assist in guiding clinicians in the value of long-term pessary use alone and in combination with high intention physiotherapy. The results would assist in managing patient expectations of benefit and prognosis with pessaries and create more realistic goals.

Acknowledgments

Funding: None.

Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://gpm.amegroups.com/article/view/10.21037/gpm.2020.02.02/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Open Access Statement: This is an Open Access article distributed in accordance with the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International

License (CC BY-NC-ND 4.0), which permits the non-commercial replication and distribution of the article with the strict proviso that no changes or edits are made and the original work is properly cited (including links to both the formal publication through the relevant DOI and the license). See: <https://creativecommons.org/licenses/by-nc-nd/4.0/>.

References

1. Wood LN, Anger JT. Urinary incontinence in women. *BMJ* 2014;349:g4531.
2. Kenton K, Barber M, Wang L, et al. Pelvic floor symptoms improve similarly after pessary and behavioral treatment for stress incontinence. *Female Pelvic Med Reconstr Surg* 2012;18:118-21.
3. Haylen BT, Ridder D, Freeman RM, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for the female pelvic floor dysfunction. *Neurourol Urodyn* 2010;29:4-20.
4. Jones KA, Harmanli O. Pessary use in pelvic organ prolapse and urinary incontinence. *Rev Obstet Gynecol* 2010;3:3-9.
5. Noblett KL, McKinney A, Lane FL. Effects of the incontinence dish pessary on urethral support and urodynamic parameters. *Am J Obstet Gynecol* 2008;198:592.e1-5.
6. Herbruck LF. Stress urinary incontinence: an overview of diagnosis and treatment options. *Urol Nurs* 2008;28:186-98.
7. Robert M, Mainprize TC. Long-term assessment of the incontinence ring pessary for the treatment of stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2002;13:326-9.
8. Robert M, Schulz JA, Harvey MA, et al. Technical update on pessary use. *J Obstet Gynaecol Can* 2013;35:664-74.
9. McIntosh L, Andersen E, Reekie M. Conservative treatment of stress urinary incontinence in women: A 10-year (2004-2013) scoping review of literature. *Urol Nurs* 2015;35:179-86.
10. Richter HE, Burgio K, Brubaker L, et al. A trial of continence pessary vs behavioral therapy vs combined therapy for stress incontinence. *Obstet Gynecol* 2010;115:609-17.
11. Lipp A, Shaw C, Glavind K. Mechanical devices for urinary incontinence in women. *Cochrane Database Syst Rev* 2014;(12):CD001756.
12. National Institute for Health and Care Excellence (NICE). Urinary incontinence in women: management. London, UK: NICE, 2013:49.
13. Harvey MA. The treatment of stress urinary incontinence using an incontinence ring: a randomized, cross-over trial treatment of stress urinary. *Neurourol Urodyn* 2009;28:817-8.
14. Nygaard I. Prevention of exercise incontinence with mechanical devices. *J Reprod Med* 1995;40:89-94.
15. Clemons JL, Aguilar VC, Tillinghast TA, et al. Patient satisfaction and changes in prolapse and urinary symptoms in women who were fitted successfully with a pessary for pelvic organ prolapse. *Am J Obstet Gynecol* 2004;190:1025-9.
16. Allahdin S, Oo N. Use of pessaries for urinary incontinence and pelvic organ prolapse- service development patient survey. *ICS, 2010:abstr 955*.
17. Kondo A, Yokoyama E, Koshiba K, et al. Bladder neck support prosthesis: a nonoperative treatment for stress or mixed urinary incontinence. *J Urol* 1997;157:824-7.
18. Glavind K. Use of a vaginal sponge during aerobic exercises in patients with stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1997;8:351-3.
19. Farrell SA, Baydock S, Amir B, et al. Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women. *Am J Obstet Gynecol* 2007;196:474.e1-8.
20. Bhatia NN, Bergman A, Gunning JE. Urodynamic effects of a vaginal pessary in women with stress urinary incontinence. *Am J Obstet Gynecol* 1983;147:876-84.
21. Farrell SA, Singh B, Aldakhil L. Continence pessaries in the management of urinary incontinence in women. *J Obstet Gynaecol Can* 2004;26:113-7.
22. Donnelly MJ, Powell-Morgan S, Olsen AL, et al. Vaginal pessaries for the management of stress and mixed urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2004;15:302-7.
23. Shamliyan T, Wyman J, Kane RL. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness [Internet]. In: AHRQ Comparative Effectiveness Reviews. Rockville (MD): Agency for Healthcare Research and Quality (US), 2012:97.
24. Bø K, Talseth T, Holm I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999;318:487-93.
25. Bø K, Hagen RH, Kvarstein B, et al. Pelvic floor muscle

exercise for the treatment of female stress urinary incontinence: effects of two different degrees of pelvic floor muscle exercises. *Neurol Urodyn* 1990;9:489-502.

26. Borello-France D, Burgio KL, Goode PS, et al. Adherence to behavioral interventions for stress incontinence: rates, barriers, and predictors. *Phys Ther* 2013;93:757-73.

doi: 10.21037/gpm.2020.02.02

Cite this article as: Giroux M, Jabs C, McLellan S, Beck LP, Scollan A, Nelson N, Karreman E, Howe C, Henni J. Effectiveness of pessary and pelvic floor physiotherapy alone and in combination for management of stress and mixed urinary incontinence: a literature review. *Gynecol Pelvic Med* 2020;3:3.