

Lesley-Ann M. Hanson · Jane A. Schulz
Catherine G. Flood · Bonita Cooley · Florence Tam

Vaginal pessaries in managing women with pelvic organ prolapse and urinary incontinence: patient characteristics and factors contributing to success

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Abstract *Objective:* An aging population has resulted in higher prevalence of urinary incontinence (UI) and pelvic organ prolapse (POP). This study examines a nurse-run clinic and analyzes the factors contributing to successful pessary use. *Study design:* A retrospective chart review of 1,216 patients was completed. History, pelvic examination and pessary fitting was done. Data was analyzed utilizing a categorical model of maximum-likelihood estimation to investigate relationships. *Results:* Median patient age was 63 years. Median number of pessaries tried was two. Eighty-five percent of post-menopausal women were on hormone replacement therapy (HRT) prior to fitting. Highest success rate of 78% was in the group on both systemic and local HRT. Success rates ranged from 58% for urge incontinence to 83% for uterine prolapse. Prior vaginal surgery was a factor impacting success. In our series highest success rates for fitting were obtained with ring pessaries, ring with support, and gellhorns. *Conclusions:* This model is a viable, option for the conservative management of UI and POP. Local HRT plays an important role in successful pessary fitting. Complications are rare.

post-menopausal women [1]. Pessaries are currently experiencing a rebirth in both design and indications for use. Most pessaries currently available are of medical grade silicone thereby providing the advantage of longer shelf life, lack of odor absorption, ability to be boiled or autoclaved and non-allergenic nature. A wide range of styles and sizes are available (Fig. 1). Pessaries are now viewed as an excellent conservative management option for anyone with POP and UI. Not only are pessaries used for the treatment of stress, urge, and mixed urinary incontinence, they are also used as a diagnostic tool to predict outcomes for prolapse and incontinence surgeries [2–4]. Pessaries can be used to facilitate preoperative healing of vaginal and cervical ulcers as well as to improve mucosal hypertrophy, which is a common occurrence in cases of genital prolapse [5]. The strategy of using pessaries has not been shown to jeopardize future therapies.

It is time consuming for physicians to fit and care for pessaries as well as costly to stock the large number of different styles and sizes required for the physician to offer patients an appropriate trial. We present a description of a nurse-run pessary clinic for managing patients with POP and UI and an analysis of the patient characteristics and factors contributing to the successful use of vaginal pessaries in this patient population.

Introduction

Pessaries were developed centuries ago to manage troublesome genital prolapse in an era when surgical management was not an option. The world's population is aging and by 2033 there will be an estimated 1.2 billion

Methods

A retrospective chart review was conducted of 1,216 patients referred to the Nurse Continence Advisor (NCA) pessary clinic at the Royal Alexandra Hospital in Edmonton, Alberta, Canada between August 1997 and August 2001. Ethics approval was obtained through our Health Research Ethics Board. The patient referral base was from urogynecology, gynecology, urology, family physicians, urotherapists and NCA's. Patients were assessed and fit by a trained NCA. A standard visit began with a focused history, pelvic floor examination and assessment of pelvic floor strength. Patients were

L.-A. M. Hanson (✉) · J. A. Schulz · C. G. Flood · B. Cooley
F. Tam
Department of Obstetrics and Gynecology,
Urogynecology Clinic, Royal Alexandra Hospital,
Women's Health Clinics, University of Alberta,
10240, Kingsway Ave, Edmonton, Alberta, Canada, T5H 3V9
E-mail: lhanson@cha.ab.ca
Tel.: +780-7354868
Fax: +780-7355896



Fig. 1 A wide range of pessaries can be used. Reproduced with permission from Mileyx Products Inc

educated regarding conservative management options and treatment was initiated by the NCA. Symptoms were reported by the patient's referring physician and confirmed by history and physical completed by our nurse continence advisors at the initial visit with the patient. Our nurse continence advisors were using the modified Baden and Walker system for prolapse grading at the time of review.

If the patient's vaginal tissues were atrophic, they were sent back to their referring physician for a prescription for local estrogen therapy or if that was not medically feasible, then they were treated with a vaginal lubricant prior to fitting [6]. Pessary fitting was carried out based on the specific needs of the individual patient [7]. A pessary fitting was attempted on all patients; if their vagina was narrowed or scarred, or if they had a lax introitus, it was often impossible to fit the patient with a pessary. The pessary used was chosen based on patient symptoms and diagnosis, physical examination, patient's expectations and nurse experience. After fitting, the patients were asked to try to recreate in the clinic their normal exercise patterns. For some that meant running on the spot and doing jumping jacks, for others it meant bending over and/or straining. Assessment was done for comfort, fit and relief of symptoms. The patient's voiding pattern was assessed with

uroflowmetry and their post-void residual was checked with a bladder scanner. After the pessary was fitted, the patients were sent home with instructions to call or return immediately if problems such as pain, bleeding, difficulty voiding or defecating occurred. An initial follow up visit was arranged within one to two weeks to re-assess the patient's status.

At the first follow-up visit, the patient was questioned regarding comfort with the pessary, relief of symptoms, bladder and bowel function as well as any sexual health issues. They were also asked if they were willing to continue with the pessary for treatment. Vaginal speculum exam was done to assess tissues for irritation or erosion. Once fit was established, the patient was reassessed at the pessary clinic at 1 month and at 3 months. Depending on the level of independence achieved by the patient, follow up visits were organized either at the clinic or with the patient's family doctor, according to Wu and Farrell's suggested schedule of every 3–6 months [8]. All patients were encouraged to learn to remove and reinsert the pessary weekly in order to clean the pessary and to maintain their independence. Clinical observation and patient report measured success. If the patients had relief of symptoms, were comfortable, and chose to continue to wear the pessary for more than 1 month they were considered a success. Patients were classified as "unable to fit" if they did not leave the clinic with a pessary to trial.

An independent research student reviewed charts, entered demographic data and documented results into a specially designed database. Cases in which patients were unable to be fitted ($n=173$), were excluded from the analysis. Data was statistically analyzed utilizing a categorical model using maximum-likelihood estimation to investigate relationships. Statistical significance was achieved with $P < 0.05$.

Results

One thousand two hundred and sixteen women were assessed in the pessary clinic. The median patient age was 63 years (range 22–95). Of the 967 (80%) post-menopausal women 12% were not on any form of HRT. Pre-menopausal women numbered 249 (20%). The median number of visits required for fitting was 2 (range 1–7) and the median number of pessaries tried was 2 (range 1–7). 1043 women (86% of the referred population) could be fit with pessaries, and of these, 744 or 71% were able to wear the pessaries successfully.

Of the study population 661 (54%) presented with various degrees and types of POP, 368 (30%) with stress urinary incontinence (SUI), 115 (9%) with mixed urinary incontinence (MUI), and 72 (6%) with urge urinary incontinence (UII).

Successful fit was achieved in 64% of the SUI patients, 67% of the MUI patients and 64% of the UII patients (Fig. 2).

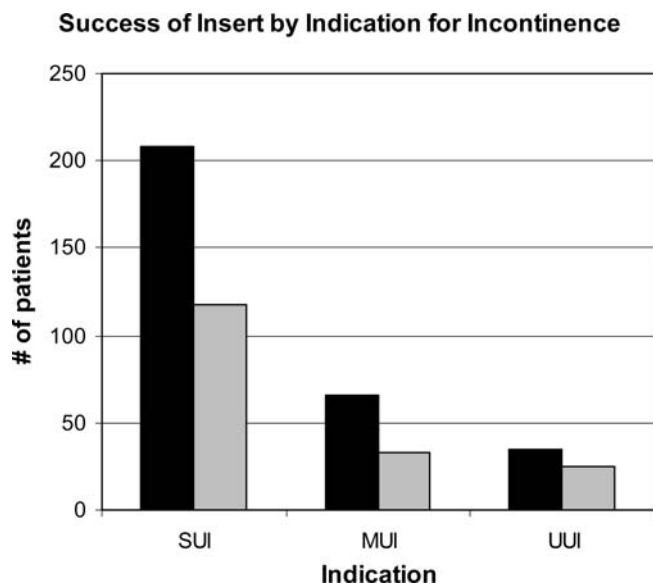


Fig. 2 Success of insert by indication for incontinence (black—# patients successful, grey—# patients unsuccessful); (SUI stress urinary incontinence, MUI mixed urinary incontinence, UUI urge urinary incontinence)

Pelvic organ prolapse was assessed into the following categories: uterine prolapse, cystocele, vault prolapse/enterocele, and cystocele/rectocele. Successful fit was achieved in 83% of the patients with uterine prolapse, 82% of the patients with cystocele, 69% of the patients with vault prolapse/enterocele and 66% of the patients with cystocele/rectocele (Fig. 3).

Analysis indicates menopausal women using local with or without systemic HRT had higher success rates than those using only systemic HRT or not using any HRT (all $P < 0.05$, the power of the overall chi-square test was 94.6%). The use of local HRT alone was just as successful as using systemic and local HRT combined ($P = 0.71$) and the use of systemic HRT alone was no better than using no HRT ($P = 0.83$) (Fig. 4).

Fig. 4 Hormone replacement status and success of insert. (black—# patients successful, grey—# patients unsuccessful); HRT hormone replacement therapy (syst systemic, local topical/vaginal)

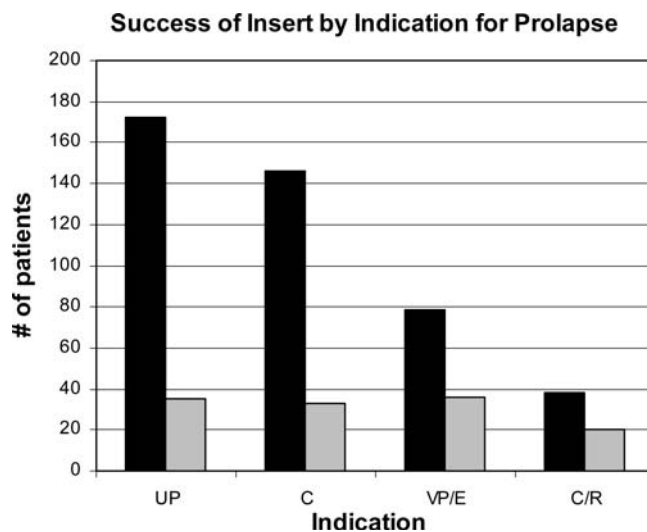


Fig. 3 Success of insert by indication for prolapse. UP uterine prolapse, C cystocele, R rectocele, VP vault prolapse, E enterocele (black—# patients successful, grey—# patients unsuccessful)

Previous genitourinary surgeries and success of pessary insert was also examined. 61% of patients had had at least 1 prior pelvic surgery; 6% had multiple prior pelvic floor surgeries. The analysis indicated that patients with previous genitourinary surgeries via the abdominal approach had a higher fitting success rate (71%, $n = 191$) than did patients with previous genitourinary surgeries via the vaginal approach (60%, $n = 184$) ($P = 0.027$).

In our study group, there was no significant difference between pre and postmenopausal women in terms of success rate of pessary fitting (71% vs. 72% respectively, $P = 0.69$).

Success rate for the different styles of pessaries was also analyzed. We found that the ring, ring with support and the gellhorn pessaries had higher success rates than the incontinence dish, incontinence ring and the shaatz style pessaries (all $P < 0.05$ with power of the overall chi-

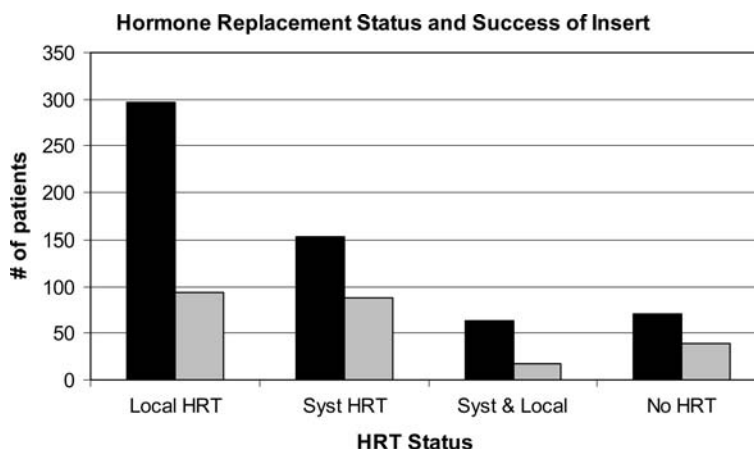


Table 1 Success rate of the most commonly used pessaries for prolapse and incontinence

| Diagnosis | Type of pessary used | | | | | | | |
|------------------------------------|----------------------|-------------------|-------------------|-------------------|--------------------|-------------------|-------------------|--|
| | Gellhorn | Shaatz | Ring | Ring with support | Incontinence Dish | Incontinence Ring | Others | |
| Cystocele <i>n</i> = 178 | 84% <i>n</i> = 25 | 82% <i>n</i> = 49 | 94% <i>n</i> = 36 | 81% <i>n</i> = 36 | 67% <i>n</i> = 27 | 80% <i>n</i> = 5 | N/A | |
| Cystocele& Rectocele <i>n</i> = 58 | 75% <i>n</i> = 4 | 61% <i>n</i> = 18 | 67% <i>n</i> = 12 | 83% <i>n</i> = 12 | 20% <i>n</i> = 5 | 75% <i>n</i> = 4 | 67% <i>n</i> = 3 | |
| Uterine Prolapse <i>n</i> = 207 | 85% <i>n</i> = 55 | 82% <i>n</i> = 34 | 89% <i>n</i> = 44 | 88% <i>n</i> = 56 | 57% <i>n</i> = 14 | 0% <i>n</i> = 3 | 100% <i>n</i> = 1 | |
| Vault Prolapse <i>n</i> = 112 | 74% <i>n</i> = 23 | 69% <i>n</i> = 42 | 73% <i>n</i> = 15 | 81% <i>n</i> = 16 | 46% <i>n</i> = 11 | 67% <i>n</i> = 3 | 100% <i>n</i> = 2 | |
| SUI <i>n</i> = 322 | 67% <i>n</i> = 3 | 40% <i>n</i> = 20 | 63% <i>n</i> = 8 | 78% <i>n</i> = 18 | 65% <i>n</i> = 197 | 68% <i>n</i> = 75 | 100% <i>n</i> = 1 | |
| UUI <i>n</i> = 59 | 83% <i>n</i> = 6 | 40% <i>n</i> = 15 | 67% <i>n</i> = 6 | 86% <i>n</i> = 7 | 61% <i>n</i> = 18 | 50% <i>n</i> = 6 | 0% <i>n</i> = 1 | |
| MUI <i>n</i> = 96 | 100% <i>n</i> = 4 | 33% <i>n</i> = 3 | 100% <i>n</i> = 5 | 60% <i>n</i> = 10 | 62% <i>n</i> = 55 | 79% <i>n</i> = 19 | N/A | |

square at 100%). None of the other styles of pessaries differed significantly in terms of success rates.

Also analyzed was the kind of pessary most successful to treat prolapse and incontinence. The most frequently used pessaries for incontinence were the incontinence style pessaries. Table 1 outlines the results.

Data was also collected with regard to complications in this study population. 88.5% (*n* = 1092) of the patients did not have any complications reported. 8.9% (*n* = 93) of the patients developed erosions, 2.5% (*n* = 26) developed vaginal infections of various types and 0.1% (*n* = 5) stopped using their pessaries for unknown reasons.

Comments

In our NCA clinic over 70% of the patients, that could be fit with pessaries were relieved of their chief complaint. Complications were rare and localized estrogen replacement appeared to play a significant role in the success of fitting and possibly the low complication rate as well.

This data demonstrates that pessaries are an option for the treatment of UUI as well as MUI. It further demonstrates that pessaries are an option for the management of vaginal vault prolapse/enterocele.

Many health care professionals do not believe that pessaries should be offered as an option for young premenopausal women. However, Farrell and Nygaard have shown that a non-surgical management that works and allows this younger age group to be independent with their care is an appropriate option [9, 10]. Most pessaries are not contraindicated in sexually active women. If women are taught to be independent with the removal and reinsertion of their pessary then their sexual health need not be impacted. Many of our patients were able to remove and clean their own pessaries and this is something that we continue to study further. Gellhorn and cube pessaries are the most difficult to remove. However, a number of patients in this nurse-run clinic have been able to remove their own Gellhorn pessaries.

Nurses with increasing knowledge of and comfort with the use of the vaginal pessary can make a significant difference in the conservative treatment POP and UI

[11]. Advance practice nurses such as NCA's need to acquire the skills to assess POP and UI. They should also learn the indications for pessary use and how to properly fit and care for vaginal pessaries. This conservative management option should be readily available to women who are looking for an alternative to a surgical intervention [9, 12]. Pessaries have been available longer than any other treatment for prolapse and NCA's can be educated and trained to offer this valuable option to the appropriate patient population.

Research is still in its infancy regarding pessary use. A number of physicians and nurses have independently observed that after a few years of pessary use, prolapse may resolve and a pessary is no longer required. There are intriguing questions to be answered. Are the pessaries holding the vagina and uterus in place thereby decreasing the stretching and allowing connective tissue to remold? Can pessaries be used as a cure rather than as a temporary solution [13]? Should we encourage the younger woman with prolapse to wear a pessary as a prophylactic measure even if her symptoms are not troubling her [7]? Future research is required to address these and many other questions with regard to pessary use.

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