International Urogynecology Journal (2024) 35:333–339
https://doi.org/10.1007/s00192-023-05648-5

ORIGINAL ARTICLE

Pessaries for pelvic organ prolapse: evaluation of vaginal discharge and pain during pessary cleaning in an outpatient setting

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Received: 9 May 2023 / Accepted: 29 August 2023 / Published online: 5 October 2023

Abstract

Introduction and hypothesis Pessary treatment for pelvic organ prolapse (POP) is effective and safe, but long-term continuation is low. Pain and vaginal discharge may play a role. This study was aimed at evaluating vaginal discharge and pain during pessary cleaning in an outpatient setting and in continuous pessary use.

Methods Women with POP who attended the outpatient clinic for pessary cleaning between January and October 2021 were included. Primary outcome was pain during removal and reinsertion of the pessary, measured by an 11-point numeric rating scale (NRS). Secondary outcome was vaginal discharge, measured by the NRS and Patient Global Impression of Change scale (PGI-C). Multiple linear regression analysis was used to identify associated variables for pain and discharge.

Results A total of 150 women were included. Mean NRS during pessary removal was 4.3 (±2.7), with 25% of women scoring a 7 or higher. Mean NRS during reinsertion was 1.8 (±2.0). A smaller genital hiatus and presence of vaginal atrophy or vulvar skin disease were associated with pain during pessary removal. Mean NRS for vaginal discharge was 2.5 (±2.3). Twenty-five percent of women reported that their vaginal discharge was "(very) much worse" than before they used a pessary. Presence of vaginal erosions was associated with vaginal discharge in this study population.

Conclusions Removing a pessary in an outpatient setting is a painful procedure for many women who use a pessary continuously. Moreover, 25% of these women experience an increase in vaginal discharge while using a pessary. Future research should focus on reducing these disadvantages.

Keywords Pelvic organ prolapse · Pain · Vaginal discharge · Vaginal pessary

Introduction

Around 5–15% of middle-aged women experience prolapse symptoms [1–3]. Treatment options include pelvic floor muscle training, a vaginal pessary and reconstructive surgery. Pessary use is an effective conservative treatment option, that is also inexpensive, well tolerated, and safe [4, 5]. Successful pessary fitting is achieved in around 70% of women [6–10]. After successful fitting, patient satisfaction is high and has been reported to be over 90% [11–13]. In a Dutch study, the continuation rate after successful fitting was 63% at 12-month follow-up [14]. However, the longer-term continuation rate of pessary use is lower. Another Dutch study in a primary care setting, with a median follow-up of 9 years, reported continued pessary use in 44% of patients [15]. Sarma et al. found a continuation rate of only 14% after a median follow-up of 7 years in a tertiary urogynecology unit in Australia [16]. Frequently cited reasons for discontinuing pessary treatment are discomfort and pain [13, 16–20]. Additionally, vaginal discharge is common in women using a pessary [17, 21–23]. Surprisingly, little evidence is available about pain experienced during pessary removal and reinsertion, which is done on a regular basis by a physician, nurse, or by women themselves.

We hypothesized that pain during pessary cleaning in an outpatient setting is substantial. In addition, we aimed to evaluate vaginal discharge in pessary use and to identify

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associated factors for pain during pessary cleaning and for vaginal discharge.

Materials and methods

A prospective observational study was performed in a tertiary urogynecology unit in the Netherlands. The local medical ethics committee of the hospital approved the study protocol prior to inclusion (no. 2020–145). In our outpatient clinic, we see both women who have failed pessary treatment at their general practitioner or another gynecologist and women who have not yet tried a pessary. All women with POP are offered pessary treatment and surgery. When women opt for a pessary and the fitting test is successful, we see them again after 6–8 weeks. If pessary treatment is satisfactory, women generally return to primary care for further periodic cleaning, or they switch to self-management. For some women, pessary-cleaning visits are continued in the hospital. Often, this is at their own request, sometimes this is because they have another gynecological condition that requires further monitoring (e.g., an ovarian cyst or lichen sclerosus). If women do not want to try a pessary, if the fitting test is not successful, or if pessary treatment is not satisfactory, surgery is suggested. This is easily accessible to all women in our hospital.

All women with POP attending the outpatient clinic for periodic pessary cleaning after previous successful pessary fitting were eligible. Women in this study used a pessary continuously and did not practice self-management. We included women with all pessary types and all prolapse stages who used a pessary for at least 6 weeks. Women using a vaginal pessary for stress urinary incontinence only and women who were unable to score experienced pain (e.g., because of cognitive disorders) were excluded.

All women were seen by one doctor from a team of three urogynecologists, one fellow in urogynecology and a registrar. Data were collected by the physician during one regular visit. At the start of the visit, women were asked consent to participate. For each woman, baseline characteristics such as age, menopausal state, parity, pessary type and size, number of earlier pessary cleanings, history of chronic pain syndromes, and history of hysterectomy or POP surgery were collected from the electronic medical record (EMR). During the visit women were asked about the use of pain medication and the use of estrogens. The pessary was removed, a vaginal examination was performed, and the pessary was rinsed and reinserted. All physicians used lubricants during pessary removal and reinsertion. The genital hiatus (GH), perineal body (PB), and total vaginal length (TVL) were measured using the POP-quantification system. The presence of vulvar skin disease (e.g., lichen sclerosis), vaginal atrophy, vaginal erosions, and skin cracks or abrasions caused by removal of the pessary were assessed by the physician and dichotomized as "present" or "not present." Anonymized data were stored according to local regulations.

The primary outcome was to evaluate the pain experienced during removal and reinsertion of the pessary. This was measured using the numeric rating scale (NRS), an 11-point scale ranging from 0 to 10 (0 representing no pain, 10 representing the worst pain imaginable) [24, 25]. Women were informed about the NRS before the start of the physical examination and asked to rate the pain immediately after pessary removal and reinsertion. In addition, experienced vaginal discharge was also measured with the NRS (0 representing no discharge, 10 representing the worst discharge imaginable) and the Patient Global Impression of Change scale (PGI-C). Women rated the change in vaginal discharge with the use of a pessary compared with the situation before using a pessary on a seven-point scale ranging from 0 to 7 (0 representing very much improved, 7 representing very much worse).

Descriptive statistics were used to analyze baseline characteristics and the NRS results for pain and discharge. Normally distributed continuous data are presented as mean and standard deviation, and categorical data are presented as counts and percentages. Given a margin of error (E) of 0.5, an estimated standard deviation (σ) of 3 on the NRS score, and using a confidence level (1-α) of 95% (Z-score = 1.96), we needed to include 139 women to estimate the mean NRS for pain during removal and reinsertion. To account for some loss of data, we decided to include 150 women.

To identify possible associated variables for pain and vaginal discharge, multiple linear regression models were used. Possible associated variables were selected in a consensus meeting before data collection and were based on literature and our own clinical experience. The selected possible associated variables for pain during pessary removal were type of pessary (open ring = 0; other = 1), genital hiatus (linear), presence of vulvar skin disease (no = 0), presence of vaginal atrophy (no = 0), and presence of vaginal erosions (no = 0). Selected possible associated variables for vaginal discharge were pessary type, pessary size (linear), history of POP surgery (no = 0), presence of vaginal atrophy, and presence of vaginal erosions. Variables that did not add significance ($p > 0.10$) were removed following backward stepwise selection. For the final model, the unstandardized coefficient (B) and standard error (SE) were calculated. A p value < 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS 25.0 (Chicago, IL, USA) for Windows.

Results

Between January and October 2021, a total of 150 women were included. Baseline characteristics are summarized in Table 1. The median age was 72 years (range 29 to 90). Of

Table 1 Patients' characteristics

Characteristic	% (*n*/*N*)
Age (years), median (range)	72 (29–90)
Multiparous	99 (148/150)
Previous POP surgery	12 (18/150)
Previous hysterectomy	10 (15/150)
Postmenopausal	95 (143/150)
POP stage	
≤2	58 (83/144)
≥3	42 (61/144))
Pessary type	
Open ring	31 (46/150)
Support ring	49 (73/150)
Urethral support ring	11 (17/150)
Shaatz	9 (14/150)
Earlier pessary cleaning appointments	
0–1	30 (45/150)
2–5	14 (21/150)
>5	56 (84/150)
History of chronic pain syndrome	1.3 (2/150)
Use of pain medication	4 (6/150)
Use of vaginal estrogens	10 (15/150)

Values are given as *n* (%) unless otherwise specified

all women, 95% were postmenopausal and 99% multiparous. The following silicone pessaries were used: open ring (31%), support ring (49%), urethral support ring (11%) and Shaatz (9%). Thirty percent of the women came for their first or second cleaning after a successful fitting test and 56% were experienced users who came for their sixth or more cleaning appointment.

Mean NRS results are shown in Table 2. The mean NRS for pain during removal of the pessary was 4.3 (± 2.7). Seventy-six women (51%) rated pain during pessary removal with an NRS of 5 or higher, and 38 women (25%) rated this pain with an NRS of 7 or higher. In 32 women (21%), pessary removal caused skin cracks or abrasions around the vaginal introitus. Eighty-one percent of women with skin lesions rated pain with an NRS of 5 or higher, compared with 42% of women without these lesions (RR 1.9; 95% CI 1.5–2.5). The results of the final multiple linear regression for pain NRS during pessary removal are shown in Table 3. Smaller genital hiatus, presence of vaginal atrophy and presence of vulvar skin disease were identified as associated variables ($p < 0.05$). The type of pessary (B = 0.23, $p = 0.63$) and the presence of vaginal erosions (B = 0.34, $p = 0.47$) were not associated with pain during pessary removal. See also Supplementary Table S1. The mean NRS for pain during reinsertion of the pessary was 1.8 (± 2.0). Associated variables for pain during reinsertion of the pessary were not investigated because of the low pain score.

Table 3 Multiple linear regression for pain during pessary removal

Variable	Unstandardized (B)	Standard error	*t*	Significance (*p*)
POP-Q gh	−0.45	0.24	−2.02	0.05
Atrophy	1.14	0.44	−2.60	0.01
Vulvar skin disease	1.35	0.66	2.05	0.04

POP-Q gh pelvic organ prolapse quantification genital hiatus

The mean NRS for vaginal discharge was 2.5 (± 2.3), with 33 women (22%) reporting an NRS of 5 or higher. Measured with the PGI-C, 37 women (25%) indicated that their vaginal discharge was "much worse" or "very much worse" than before they used a pessary. In the 45 women who had only recently started pessary treatment (zero or one previous cleaning session), this was 29%. The results of the final multiple linear regression model for the NRS of vaginal discharge are shown in Table 4. In this study population, the presence of vaginal erosions was identified as an associated variable for vaginal discharge in pessary use. The size (B = −0.05, $p = 0.08$) and type (B = −0.23, $p = 0.59$) of pessary, history of POP surgery (B = 0.29, $p = 0.62$), and presence of vaginal atrophy (B = 0.45, $p = 0.26$) were not associated with vaginal discharge in pessary treatment. See also supplementary Table S2.

Table 2 Numeric rating scale (NRS) reported during pessary cleaning ($n = 150$)

	Mean (SD)	Median (IQR)
Pain removal	4.3 (2.7)	5 (2–7)
Pain insertion	1.8 (2.0)	1 (0–2)
Vaginal discharge	2.5 (2.3)	2 (0–4)

Values are shown as mean ± standard deviation (SD) and as median with interquartile range (IQR)

Table 4 Multiple linear regression for vaginal discharge

Variable	Unstandardized (B)	Standard error	*t*	Significance (*p*)
Pessary size	−0.05	0.03	−1.74	0.08
Vaginal erosions	0.82	0.39	2.11	0.04

Discussion

In this prospective observational study, we found that removing a pessary in an outpatient setting is a painful procedure for many women who use a pessary continuously. The mean NRS was 4.3, and more than half (51%) of the women rated the pain during pessary removal with an NRS of 5 or higher, and 25% even reported a score of 7 or more. A smaller genital hiatus and the presence of vaginal atrophy and vulvar skin disease were associated with pain during pessary removal. Additionally, 25% of the women reported that vaginal discharge was much worse with a pessary than without. Presence of vaginal erosions was associated with vaginal discharge during pessary use.

Several studies have reported complications associated with pessary use [16, 19]. We are not aware of any previous research on pain during pessary removal and reinsertion. Pain during other gynecological procedures has been studied previously. Bakker et al. conducted a systematic review including six studies comparing speculum examination with or without lubrication [26]. The mean visual analogue scale (VAS) in the lubrication group ranged from 0 to 4 in these studies. Pain has also been examined during outpatient hysteroscopy, where two RCTs found a mean VAS of approximately 6 [27, 28]. Helder-Woolderink et al. found a median VAS of 5 during endometrial biopsy performed during an outpatient visit, which is comparable with the pain experienced during pessary removal in our study [29]. Although pessary removal is quick and the pain experienced is likely to be short-lived, this drawback needs attention and may affect a woman's choice to continue treatment.

Our study showed that women with a smaller genital hiatus, vaginal atrophy, and vulvar skin disease experienced more pain during pessary removal. This is likely because these women are at a higher risk of developing skin lesions during removal of the pessary. We found that 21% of the women had skin cracks or abrasions after pessary removal. Although never studied, women might benefit from treatment of their atrophy or underlying skin disease (e.g., lichen sclerosus). As lidocaine spray has been shown to be effective for pain relief in endometrial biopsy and outpatient hysteroscopy, applying analgesic cream before pessary removal might also be effective [30]. Besides, self-management may contribute to reducing pain during pessary removal. With self-management, a woman has more control, possibly resulting in less pain. Chien et al. found that fewer women with a Gellhorn pessary reported pain with self-management than with continuous use (24% vs 54%; RR 0.5; 95% CI 0.3–0.8) [31]. The development of a pessary that can be easily reduced in size during removal may also reduce pain and could possibly be easier to self-manage [32]. In addition, a lower frequency of pessary cleaning can help simply by reducing the number of pain episodes. Recent studies have shown that pessary cleaning intervals can be safely extended to every 6 months or even up to 4 years without, in general, increasing vaginal discharge and complications [33, 34]. To provide ongoing care and not lose sight of the patient, in our hospital, we plan an annual pessary check if self-management fails. Pain with pessary reinsertion was much lower than with removal. This is probably because the pessaries studied were easy to fold when reinserted but not when removed.

Twenty-two percent of the women in our study rated vaginal discharge with an NRS of 5 or higher, which we consider a significant burden. This is consistent with previous research reporting vaginal discharge in 17 to 34% of patients using a pessary [16, 20, 35, 36]. Of the women who had recently started pessary treatment, 29% reported a significant increase in vaginal discharge. When using the PGI-C, there may be some recall bias in those who have been using a pessary for a long time regarding vaginal discharge prior to using a pessary. Therefore, the NRS for vaginal discharge may be more reliable. In our model, only vaginal erosions were associated with vaginal discharge and not, for example, a history of POP surgery. For selecting variables, we hypothesized that women with a history of prolapse surgery are more likely to have decreased vaginal compliance (owing to decreased vascularization). We assumed that this could lead to an increased risk of erosions and vaginal discharge. The low number of women with a history of prolapse surgery ($n = 18$) may explain why this variable was not significant in the model. A substantial proportion of women with a history of prolapse surgery probably dropped out at an earlier stage owing to unsuccessful pessary fitting.

There are two common theories as to why women with a pessary experience more vaginal discharge: an infection-based theory and an inflammation-based theory. Several studies found a higher incidence of bacterial vaginosis in pessary users [22, 23]. This suggests that the presence of a foreign body reduces lactobacilli and increases the risk of anaerobic infection. Other studies found microscopic evidence of vaginal inflammation in women with a pessary, without a difference in the presence of microorganisms [21, 37, 38]. This suggests that vaginal discharge in pessary treatment may be due to an inflammatory reaction in the vagina, without necessarily causing an infection. Our finding of more vaginal erosions in women with vaginal discharge supports the inflammation theory. This theory is also supported by Ramaseshan et al., who found elevated levels of proinflammatory cytokines in pessary users with vaginal erosions [39]. Inflammation and infection can also coexist and vaginal discharge (as well as the development of vaginal

erosions) is probably related to a combination of many factors. For example, atrophy, degree and duration of pressure on the vaginal epithelium, volume of the foreign body, and degree of biofilm formation.

The treatment of vaginal discharge in pessary use is difficult. Meriwether et al. studied the treatment of bacterial vaginosis in pessary treatment with TrimoSan© gel (a hydroxyquinoline-based gel) [40] and found no difference in bacterial vaginosis or vaginal symptoms after 3 months. Based on the inflammation theory, treating inflammation should also help to reduce vaginal discharge. Estrogens can help to restore the vaginal wall. Two recent systematic reviews found a reduction in bacterial vaginosis in women who used topical estrogens during their pessary treatment [41, 42], but no difference in vaginal ulcers, bleeding or discharge was found. Self-management may also be beneficial in reducing inflammation and vaginal discharge. A recent small audit study showed fewer adverse events in women performing monthly self-management [43]. A similar result in daily self-management was found by Yoshimura et al. [44]. Less vaginal discharge with regular self-management can be especially effective when the pessary is not reinserted immediately, for example, by removing the pessary before going to sleep and reinserting it in the morning. This discontinued use may work because it improves epithelial repair or because it reduces bacterial biofilm formation.

The strengths of this study are the prospective study design and the use of validated instruments of measurement. Another strength is the relatively large group of women to reliably estimate pain during pessary removal and reinsertion. The limited number of pessary types used in this study resulted in robust information on these specific pessary types. At the same time, this is a limitation of this study. We cannot provide information about other pessaries, such as the Gellhorn or cube pessary. These may be more painful to remove and may cause more discharge than ring pessaries [20]. The homogeneity of our study population, being continuous pessary users in an outpatient setting, means that the results are not generalizable to all pessary users. Pain and vaginal discharge may be less in primary care or in women who practice self-management. In this study, we looked at the use of pain medication and history of chronic pain syndrome, but had no information on psychological or psychiatric conditions. These can also affect pain perception. Pain was reported by the patients themselves, resulting in self-reported bias. Additionally, patients were aware that they were being studied, possibly resulting in observation bias. Both forms of bias are hard to eliminate and are present in most pain studies. Atrophy emerged as an associated variable for pain during pessary removal. Problematically, atrophy is difficult to measure objectively, and there can be large observer variability. Other risk factors may also influence pain and vaginal discharge but were not included in our multiple linear regression analysis, e.g., pessary size, urinary incontinence, and POP stage. We did not collect data on BMI and sexual activity either. Finally, we studied pain and vaginal discharge during a single visit in 150 unique women, but did not examine whether these symptoms change over time in an individual woman.

Conclusion

Removing a pessary in an outpatient setting is a painful procedure for many women who use a pessary continuously. In addition, a relevant proportion of these women experience significant vaginal discharge. To improve the long-term continuation of this successful and inexpensive conservative treatment option, future research should focus on reducing these disadvantages. For instance, by developing easier-to-remove pessaries or extraction techniques or by exploring measures that can reduce pain and vaginal discharge (e.g., self-management, estrogen use, application of lidocaine before pessary removal).

Supplementary information The online version contains supplementary material available at https://doi.org/10.1007/s00192-023-05648-5

Authors' contributions Lara M. Kruyt: protocol development, data collection, data analysis, manuscript writing; J. Marinus van der Ploeg: protocol development, data collection, data analysis, manuscript writing; Karin Lammers: data collection, manuscript editing; Britt A. van Etten-Debruijn: data collection, manuscript editing; Anuschka S. Niemeijer: statistical analysis, manuscript editing; Robert A. Hakvoort: protocol development, data collection, data analysis, manuscript writing.

Data Availability The data that support the findings of this study are available from the corresponding author, Kruyt LM, upon request.

Declarations

Conflicts of interest None.

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