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ORIGINAL ARTICLE

Defecatory dysfunction and other clinical variables are predictors of pessary discontinuation

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Abstract

Introduction and hypothesis Pessaries provide first-line therapy for women with pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The primary hypothesis was that defecatory dysfunction was associated with pessary discontinuation.

Methods This was a retrospective cohort study of all women undergoing first pessary placement at one academic center from April 2014 to January 2017. Defecatory dysfunction was defined as the presence of constipation, rectal straining, rectal splinting, and/or incomplete defecation. Pessary discontinuation was defined as <1 year of pessary use and not using one at the most recent visit. Descriptive statistics; Person's chi-square, Fisher's exact, and Student's *t* test, and multivariate logistic regression analysis were used where appropriate.

Results Charts of 1092 women were reviewed and 1071 were included. Mean age was 62 ± 15 years, mean body mass index (BMI) 28 ± 6 kg/m^2, and mean parity 2 ± 1; 68% were Caucasian, 73% were menopausal, and 41% were sexually active. Reason for pessary use included POP (46%), SUI (24%), or both (30%). Overall pessary discontinuation rate was 77%; overall rate of defecatory dysfunction was 45%. In a logistic regression model, defecatory dysfunction in the form of incomplete defecation remained significantly associated with pessary discontinuation [odds ratio (OR) 3.29, 95% confidence interval (CI) 1.43–7.52]. Absence of bulge symptoms (OR 2.18, 95% CI 1.22–3.90), and younger age (OR 1.02, 95% CI 1.02–1.05) also remained significantly associated with pessary discontinuation.

Conclusions Pessary discontinuation was common, and defecatory dysfunction in the form of incomplete defecation had the strongest association with discontinuation. Understanding predictive factors of pessary discontinuation may help guide clinicians and patients when choosing treatment options for pelvic floor dysfunction.

Keywords Defecatory dysfunction · Pessary · Pessary discontinuation · Predictors

Introduction

A pessary is a commonly used treatment option for pelvic organ prolapse (POP) and stress urinary incontinence (SUI) [1]. Because of its noninvasive nature and opportunity for immediate symptom relief, the pessary is offered as first-line therapy by up to 77% of urogynecologists, regardless of whether the patient is a candidate for surgery [2]. Among women using a pessary for treating POP, up to 70–90% of women report relief of bulging sensation and 29–49% report relief of pressure [3]. The same study found that among women using a pessary for SUI treatment, 59% were continent or mostly continent at 11 months, and pessary satisfaction has been associated with improved sexual function and body image [4]. All of these characteristics make the pessary a viable first-line option for treating both POP and SUI.

This research was presented as a poster presentation at the Society of Gynecologic Surgeons 44th annual scientific meeting from 11–14 March 2018 in Orlando, FL, USA and an oral presentation at the International Urogynecology Association 43rd annual scientific meeting 27–20 June 2018 in Vienna, Austria.

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However, pessary use has the potential for complications, including bleeding, erosion, or odor [5]. Although satisfaction remains high even with these symptoms [3, 6], some women opt for pessary removal, with the most common reason being involuntary expulsion [7, 8]. It has been suggested that pessary expulsion rates may be increased with pelvic pressure due to cough, obesity, or constipation [7]. Several studies have reported constipation as a result of pessary use, but none have investigated the impact of baseline constipation on pessary use [9, 10]. There is a lack of published literature directly examining the effects of defecatory dysfunction on pessary discontinuation.

Given the potential impact of defecatory dysfunction on pessary use, the primary aim of this study was to determine whether defecatory dysfunction is a risk factor for pessary discontinuation. We hypothesized that women experiencing defecatory dysfunction at baseline prior to pessary placement would have a higher rate of pessary discontinuation than women who did not have baseline defecatory dysfunction. Secondary aims were to assess other baseline factors as predictors of pessary discontinuation.

Materials and methods

This was a retrospective chart review of women undergoing first pessary placement at the University of North Carolina at Chapel Hill (UNC) in the Division of Female Pelvic Medicine and Reconstructive Surgery (FPMRS) between April 2014 and January 2017. Study inclusion criteria were women ageed ≥18 years undergoing first pessary placement for the indication of POP and/or SUI with a successful pessary fitting. Institutional Review Board (IRB) approval was obtained from the UNC IRB. Women were identified based on Current Procedural Terminology (CPT) code for pessary fitting (57160) in a query of the electronic medical record (EMR). Electronic chart review was performed to obtain demographic and clinical information. All new FPMRS patients completed a standardized symptom intake form that includeed the Pelvic Floor Distress Inventory Short Form (PFDI-20) [11]. This intake form includes a detailed description of urinary, POP, and defecatory symptoms. Patients also underwent a standardized physical exam that included the Pelvic Organ Prolapse Quantification (POP-Q) system [12].

Data extracted from the EMR included age at pessary fitting, race, body mass index (BMI), parity, number of vaginal and Cesarean deliveries, menopause status (self-report), sexual activity status, surgical history (including prior pelvic surgery), presence/treatment of vaginal atrophy, reason for pessary fitting, presence of baseline defecatory symptoms, including diarrhea, constipation, splinting, or straining with defecation, number of bowel movements per day, and physical exam features, including presence and size of rectocele. Rectocele is defined in our practice as a weakness of the rectovaginal septum on rectal exam. Rectocele size was a subjective determination by the physician and is standardized on our EMR template as small, moderate, or large.

To assess pelvic floor symptoms, specific responses to the PFDI-20 were compared with the symptom intake form for corroboration. Responses to the Colorectal–Anal Distress Inventory (CRADI-8) subscale were used to assess straining with bowel movements (question 1), incomplete rectal emptying (question 2), fecal incontinence (FI) (question 3). Responses to the Urogenital Distress Inventory (UDI-6) subscale were used to assess SUI (question 3) and urge (UUI) incontinence (question 2).Total PFDI scores were not collected. If answers differed between PFDI responses and the physician's note, the response recorded in the physician's note was used, as this was felt to be more accurate, being based on the patient's oral response to direct questions and corroborated on the patient's intake form, which directly screens for specific pelvic floor symptoms and includes those listed above. FI was defined as unintended loss of formed stool.

Pessary use information was also extracted for all subsequent office visits, including whether the patient had a failed pessary fitting (defined as not leaving the office with a fitted pessary), was managing the pessary herself, the type and size of pessary placed at the initial fitting, the time between pessary placement and first pessary follow-up visit, length of use of the first pessary, pessary expulsion, whether the patient was refitted with a different pessary at follow-up, reason for the new pessary, and length of use of the second pessary (if applicable). Lastly, the total length of any pessary use, and whether or not the patient was still using a pessary at the most recent follow-up visit was recorded.

Defecatory dysfunction was defined as the presence of constipation, defecatory straining, defecatory splinting, and/or feeling of incomplete defecation, as documented at the new patient visit in the standardized intake form and the PFDI-20. Pessary discontinuation was defined as <1 year of pessary use and not using a pessary at the most recent follow-up visit, as documented in the EMR. Total length of pessary use was calculated as the time in weeks from first pessary placement to the most recent note, documenting continued pessary use. If the patient was using a pessary at the most recent visit but had stopped using it at any point between initial placement and the most recent visit, that time (in weeks) was subtracted.

Data were analyzed using SPSS 24 (IBM, Armonk, NY, USA). Descriptive statistics were used to assess demographic and clinic characteristics. Person's chi-square, Fisher's exact, and Student's*t* tests were used to determine differences between groups for categorical and continuous variables, respectively. A multivariate logistic regression model was constructed to measure the association between defecatory dysfunction and pessary discontinuation while adjusting for statistically significant variables on bivariate analysis. A p value <0.05 was considered statistically significant.

Results

The EMR of 1092 women were reviewed. Women who failed initial pessary fitting were excluded, with 1071 women ultimately included. Overall, mean age was 62 ± 15 years, mean BMI was 28 ± 6 kg/m^2, and mean parity was 2 ± 1, with 68% Caucasian, 73% menopausal, and 41% sexually active at the time of pessary fitting. We divided the study population into two cohorts: (1) women with successful pessary use (defined as at least 1 year of pessary use and still using at most recent follow-up visit) and (2) women with pessary discontinuation (those not meeting these criteria). Mean follow-up time from pessary fitting to most recent recorded follow-up visit for all participants was 50.3 ± 91.6 weeks (20.0 ± 14.6 weeks for pessary discontinuation vs 153.2 ± 124.5 weeks for pessary success). Mean time from pessary fitting to first follow-up visit for all participants was 10.2 ± 22.7 weeks (8.5 ± 10.6 for discontinuation vs 14.2 ± 34.5 weeks for success). The overall pessary discontinuation rate was 77% based on the above criteria. The primary reasons for pessary discontinuation were uncomfortable (29.6%), pessary fell out/would not stay in (23.7%), worsening of urinary leakage (14.0%), bulge comes past the pessary (11.3%), pessary shifting (10.3%), abrasions (5.8%), patient unable to place pessary (2.9%), and bleeding with pessary removal (2.4%).

When comparing demographics of the two cohorts, women in the discontinuation group were younger, more likely to be sexually active, and less likely to be menopausal (all $p < 0.05$) (Table 1). There were also minor differences in racial diversity, with more Hispanic women in the discontinuation group. There were no differences in parity or BMI.

For primary outcome, we assessed the association between defecatory dysfunction (defined as the presence of constipation, straining with defecation, splinting with defecation and/or a feeling of incomplete defecation) and pessary discontinuation. The overall rate of any baseline defecatory dysfunction was 45%. The presence of baseline defecatory dysfunction was associated with pessary discontinuation (Table 2). Specifically, baselines for incomplete defecation, splinting with defecation, diarrhea, and FI were associated with pessary discontinuation (all $p < 0.05$), while defecatory factors not associated with pessary discontinuation included constipation, straining, and rectocele size. We also measured baseline pelvic floor symptom bother based on PFDI scores for individual questions. Pessary discontinuation was associated with higher baseline SUI bother (2.1 ± 1.0 vs 1.7 ± 1.1, $p = 0.02$) and lower incomplete bladder-emptying bother (1.6 ± 1.0 vs 2.0 ± 1.0, =0.02); there was no difference in bother scores for UUI (1.9 ± 1.0 vs 1.9 ± 0.8, $p = 0.94$) or FI (0.9 ± 0.8 vs 1.0 ± 0.8, $p =$ 0.68).

We also assessed the association between the following clinical variables and pessary discontinuation: less severe prolapse based on the Pelvic Organ Prolapse Quantification (POP-Q) system, bulge symptoms, vaginal atrophy, SUI as reason for pessary use, and initial pessary type (all $p < 0.05$), while prior pelvic surgery and hysterectomy were not associated with pessary discontinuation (Table 3).

In a logistic regression model controlling for age, race, sexual status, menopausal status, reason for pessary use, and all defecatory variables that were significant on bivariate anaylsis (constipation, diarrhea, FI, splinting, and incomplete defecation), incomplete defecation remained significantly associated with pessary discontinuation [odds ratio (OR) 3.29, 95%

Table 1 Demographics and pessary outcome

Demographic	All women ($n = 1071$)	Pessary success ($n = 243$)	Pessary discontinuation ($n = 828$)	*P* value
Age at first visit (years)	62.4 ± 14.9	68.23 ± 12.8	60.66 ± 15.0	<.001*
Parity	2.5 ± 1.4	2.39 ± 1.3	2.48 ± 1.5	.394*
BMI (kg/m^2)	27.7 ± 5.8	27.12 ± 5.0	27.82 ± 6.0	.089*
Race				
White ($n = 730$)	730 (79.9)	178 (80.2)	552 (79.5)	.001*
Black ($n = 95$)	95 (10.4)	33 (14.8)	62 (8.9)	
Hispanic ($n = 52$)	52 (5.7)	2 (0.9)	50 (7.2)	
Asian ($n = 9$)	9 (1.0)	3 (1.4)	6 (0.9)	
Other ($n = 30$)	30 (3.3)	6 (2.7)	24 (3.5)	
Sexually active	436 (44.8)	62 (31.0)	374 (48.3)	<.001**
Menopausal	782 (76.9)	208 (89.7)	574 (73.1)	<.001***

Data presented as *n* (%) or *n* ± standard deviation. Data on race and sexual and menopausal status were not available for all participants

BMI body mass index

*Student's *t* test , **Pearson's chi-square test, ***Fisher's exact test

Table 2 Bowel function and pessary outcome

Symptom	Pessary success ($n = 243$)	Pessary discontinuation ($n = 828$)	*P* value
Any defecatory dysfunction[a]	105 (43.2)	482 (58.2)	<.001*
Constipation	65 (30.7)	276 (36.0)	.058**
Straining	43 (25.4)	190 (29.8)	.294*
Incomplete defecation	12 (8.1)	170 (26.7)	<.001*
Splinting	23 (10.85)	161 (20.8)	.001*
Rectocele	101 (48.8)	394 (57.4)	.031*
Rectocele size			
Small	56 (60.2)	206 (51.5)	.261*
Moderate	28 (30.1)	157 (39.3)	
Large	9 (9.7)	37 (9.3)	
Fecal incontinence	14 (7.0)	107 (15.5)	.002*
Diarrhea	25 (11.8)	136 (17.7)	.046*

Data presented as *n* (%) or *n* ± standard deviation (SD)

[a] Constipation, defecatory straining, defecatory splinting, and/ or feeling of incomplete defecation

*Pearson's chi-square test, ** Fisher's exact test

Table 3 Clinical variables and pessary outcome

Predictor	Pessary success ($n = 243$)	Pessary discontinuation ($n = 828$)	*P* value
POP-Q			
GH	3.8 ± 1.4	3.6 ± 1.3	.086*
PB	3.0 ± 2.3	3.1 ± 0.9	.594*
TVL	8.2 ± 1.3	8.5 ± 3.4	.218*
Aa	0.8 ± 1.9	0.2 ± 2.0	<.001*
Ba	1.7 ± 2.8	0.6 ± 2.6	<.001*
Ap	−1.3 ± 1.9	−1.7 ± 1.7	.003*
Bp	−0.6 ± 3.0	−1.3 ± 2.3	.001*
C	−2.1 ± 4.8	−3.2 ± 4.5	.003*
D	−5.1 ± 4.0	−5.6 ± 3.9	.186*
Bulge symptoms	180 (81.4)	533 (67.3)	<.001**
Vaginal atrophy	173 (75.9)	416 (52.1)	<.001**
Reason for pessary			
POP	130 (54.4)	357 (43.9)	<.001**
SUI	30 (12.6)	220 (27.1)	
Both	79 (33.1)	236 (29.0)	
Prior pelvic surgery	85 (35.0)	330 (40.2)	.155**
Prior hysterectomy	71 (29.2)	257 (31.5)	.528**
Pessary type			
Ring with support	145 (63.0)	389 (52.8)	.003**
Incontinence ring with support	24 (10.4)	126 (17.1)	
Incontinence ring without support	24 (10.4)	124 (16.8)	
Gelhorn	37 (16.1)	98 (13.3)	

Data presented as *n* (%) or *n* ± standard deviation (SD)

*Student's *t* test, **Pearson's chi-square test

confidence interval (CI) 1.43–7.52]. Other factors that remained significantly associated with pessary discontinuation were younger age (OR 1.02, 95% CI 1.02–1.05) and absence of bulge symptoms (OR 2.18, 95% CI 1.22–3.90).

Discussion

The presence of defecatory dysfunction in the form of incomplete defecation was associated with pessary discontinuation. Other factors associated with pessary discontinuation included younger age and absence of bulge symptoms. This makes sense clinically, as pessary use does not typically alleviate incomplete defecation, and women that have this bothersome symptom may elect for surgical management rather than continuing pessary use. Women of younger age were also less likely to continue pessary use. While the OR for this variable was low (1.02), this corroborates other studies that show that younger women are more likely to ultimately opt for surgical management of pelvic floor symptoms rather than long-term pessary use, likely due to the fact that surgery offers a immediate treatment that does not require ongoing management [13]. Lastly, the absence of bulge symptoms was associated with pessary discontinuation. This may be explained by the fact that women who do not have bulge symptoms are seeking pessary treatment for SUI and may experience less immediate relief from a pessary compared with women with bothersome bulge symptoms. This theory is corroborated by our study, which found that SUI as the reason for pessary use was associated with higher rates of discontinuation.

While the long-term discontinuation rate of pessary use in our study was high, at 77%, the rate of initial successful pessary fitting was also high, at 98%. This high success rate is likely due to how we defined successful pessary fitting (leaving the office with a fitted pessary). It is rare in our practice for a patient to not leave with a pessary to try based on what was determined to be a good fit on exam. However, many patients find that the initial pessary falls out or becomes uncomfortable within the first hours to days of use, and it is discontinued. Thus, while the rate of pessary fitting is high, the rate of short-term successful pessary use is likely lower. We chose to use this more liberal definition of successful pessary fitting because it represents a more realistic approach to what happens when a pessary is fit in the office, even thought we cannot predict what may happen after that fitting. When assessing the rate of short-term pessary use, we found that 242 women had <1 week of pessary use. When excluding these women and rerunning all analyses, there were no differences in any outcome.

Although few studies have been published examining specific reasons for pessary discontinuation, our results are consistent with prior studies in the literature. Clemons et al. examined patient characteristics associated with pessary use vs surgery after 1 year [14]. Similar to our findings, they found pessary continuation was associated with older age. They also found that women opting for surgery were more likely to be sexually active and have SUI. These results are consistent with our findings that sexual activity and SUI as reason for pessary use were associated with pessary discontinuation in bivariate analysis, although sexual activity was not significant in the regression model. Clemons et al. also found that stage III–IV posterior vaginal wall prolapse was associated with pessary discontinuation, whereas our results found that pessary discontinuation was associated with less-severe anterior, posterior, and apical prolapse based on POP-Q points. This is consistent with our finding that bulge symptoms (i.e., more advanced prolapse) was associated with continued pessary use.

Interestingly, Geoffrion et al. found mixed results compared with ours [15]. Their retrospective chart review of 101 women found that younger age and lower POP-Q stage were associated with pessary discontinuation; they found no relationship with sexual activity. While we found an association between sexual activity and pessary discontinuation in bivariate analysis, this relationship did not remain significant in a regression model. Markle et al. completed a retrospective chart review of 158 patients who underwent pessary fitting for POP or SUI [16]. In contrast to our findings, they found that women with a prior hysterectomy and a TVL <8 cm were more likely to have an unsuccessful pessary fitting; we found that prior hysterectomy and TVL were not significantly associated with pessary discontinuation. Of note, they examined pessary fitting, whereas we examined continued use after 1 year, which may explain these differences in findings.

Sullivan et al. examined characteristics of women at a new FPMRS patient visit who chose conservative management of POP or SUI compared with those who opted for surgical management [13]. They found that among women who initially chose conservative management, at 1 year, 26.5% had opted to undergo surgery instead. The women who opted for surgery over pessary use were more likely to be younger and sexually active compared with women who continued with conservative therapy. These findings are similar to those in our study; however, we cannot comment on whether patients who discontinued pessary use in our study went on to surgery. Whereas we found pessary discontinuation was associated with less-severe prolapse and fewer bulge symptoms, Sullivan et al. found no differences in baseline prolapse or pelvic floor symptoms between those remaining with conservative therapy at 1 year vs those who initially chose conservative therapy but opted for surgical management by 1 year.

Brincat et al. performed a chart review of 136 women who underwent a pessary fitting for POP and/or SUI [17]. In contrast to our study, they found that sexual function and POP were associated with pessary use. This difference in findings may be due to the shorter overall follow-up period and the smaller number of participants. Other discrepancies were their

lack of association with pessary discontinuation and age or menopausal status, which may be due to lack of adequate power. Their study population had a similar age to ours, and they did not report racial breakdown. While there may be unknown factors related to each study population, it makes sense clinically that sexually active women may be less likely to be satisfied with a pessary, since most sexually active women opt to remove the pessary for intercourse, which can be disruptive. This is a common complaint among patients in our practice.

A limitation of this study is the retrospective design. However, all data were extracted from the EMR from actual visits. Furthermore, baseline pelvic floor dysfunction data were obtained objectively from the PFDI-20 at the office visit, and these definitions were used for the measured pelvic floor symptoms. These two factors decrease the risk of both recall and selection bias. An additional limitation of this study is failure to account for any concomitant treatment of defecatory dysfunction while using a pessary, such as physical therapy. More successful management of defecatory dysfunction could have affected long-term pessary use. Similarly, we could not account for vaginal discharge and any associated treatment; however, the rate of atrophy was higher in the pessary success group, which may limit the effect of vaginal discharge on pessary discontinuation. Furthermore, vaginal discharge was not noted as a primary reason for pessary discontinuation. Another limitation is the lack of follow-up for women who failed pessary management, although this was not an outcome of the study. Lastly, our study was performed at an academic center and may not reflect community populations.

A major strength of our study is the large sample size, which decreases the likelihood of a type I error. To assess for type II error, a post hoc power analysis was performed for the primary outcome of defecatory dysfunction, which—based on the reported rates of defecatory dysfunction in the two groups in Table 2, and an alpha of .05, demonstrated 97% power to detect a difference in this outcome between pessary discontinuation and success groups. Another strength is that it is one of few studies directly assessing the association between patient-reported defecatory dysfunction and pessary discontinuation. We additionally examined a variety of factors potentially contributing to pessary discontinuation, thus adding to the literature. Lastly, there was reasonable variation in age and race in our study population, which increases generalizability of study findings.

Defecatory dysfunction in the form of incomplete defecation was associated with pessary discontinuation. Younger age and lack of bulge symptoms were also associated with pessary discontinuation. Understanding the effect of baseline defecatory dysfunction and other clinical variables on long-term pessary outcomes will aid clinicians and patients when considering management options for POP and SUI.

Compliance with ethical standards

Conflicts of interest None.

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