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ORIGINAL ARTICLE

Adverse events associated with pessary use over one year among women attending a pessary care clinic

Arshia Kakkar[1] · Adi Reuveni-Salzman[2] · Jouhayna Bentaleb[2] · Eric Belzile[3] · Lisa Merovitz[2] · Maryse Larouche[2,3]

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Abstract

Introduction and hypothesis The primary objective was to determine the adverse event rate associated with pessary use. Secondary objectives were to determine discontinuation, patient satisfaction, and factors associated with adverse events.

Methods A retrospective observational study included patients attending a nurse-led pessary clinic with ≥ 1 year follow-up. Patients were fitted with a pessary by a urogynecologist and pessary care by a nurse was performed every 3–4 months. Demographic characteristics, pessary fitting, adverse events, their management and discontinuation were recorded. Pearson Chi-square and Fisher exact tests assessed the association between predetermined risk factors and pessary complications or discontinuation. Relative risk and 95% confidence intervals were computed.

Results 215 women were followed for a mean (standard deviation) of 4.4 (1.9) years. Mean age was 73.8 (8.7) years. Adverse event rate was 83.7%; most commonly vaginal discharge, vaginal bleeding and erosions. Women with cardiovascular risk factors were less likely to develop pessary-related adverse events (79.7% vs. 91.9%, $p = 0.03$). Gellhorn and donut pessaries were more commonly associated with pessary erosions than ring with support pessaries or incontinence rings (RR 2.37 [1.67; 3.38]). Thirty-five (16.3%) women discontinued pessary use at a mean of 3.3 (1.7) years after initial fitting. Having a pessary erosion was not associated with discontinuation ($p = 0.698$), but recurrent erosions were ($p = 0.012$).

Conclusion Adverse events were common among women continuing to use pessaries past 1 year, but adherence and satisfaction rates remained high after 4.4 years. Pessary type and absence of cardiovascular factors were associated with pessary-related adverse events.

Keywords Pelvic organ prolapse · Pessary · Pessary-related complications · Long-term

Introduction

Pessaries have been used to manage pelvic organ prolapse (POP) since 400 B.C., but have evolved in material and shapes over time [1, 2]. Such intra-vaginal devices are typically made of medical-grade silicone, which allows for malleability, and prevents the development of odor [3]. These may also be thoroughly sterilized through boiling and adequate washing. Furthermore, pessaries vary in shape and size in order to fit the patient's needs.

The American College of Obstetricians and Gynecologists (ACOG) as well as the American Urogynecology Society (AUGS) recommend all women with POP be offered a pessary as an alternative to surgery [4]. They are also recommended as a non-invasive management option for stress urinary incontinence. Most women who opt for a pessary, rather than pelvic reconstructive surgery, are older, may have comorbidities, and are less likely to be sexually active [3, 5]. Up to 92% of women can be adequately fitted with a pessary, but factors such as short vagina, history of previous pelvic floor surgery including hysterectomy, younger age, higher body mass index, posterior pelvic organ prolapse, and wide introitus can contribute to treatment failure[3, 6]. Although pessary treatment is widely used and is deemed the leading non-surgical treatment of POP, it can be associated with numerous adverse events or complications such as erosions,

✉ Maryse Larouche
ml.larouche@mcgill.ca

1 Faculty of Medicine and Health Sciences, McGill University, Montreal, QC, Canada

2 Division of Urogynecology, Department of Obstetrics and Gynecology, McGill University, Montreal, QC, Canada

3 St. Mary's Research Centre, 4Th Floor Hayes Pavilion, 3830 Lacombe, Montreal, QC H3T 1M5, Canada

ulcers, vaginal bleeding, vaginal discharge, discomfort, pelvic pain, severe constipation, and, usually if neglected, vesicovaginal or rectovaginal fistula [7, 8].

One study showed that 86% continued pessary use at 5 years if successfully fitted [9]. However, very few studies have looked at long term pessary use and pessary-related adverse events [9–11]. The primary objective of this study was to determine long term adverse events rate among women followed in a specialized pessary care clinic for at least 1 year. Secondary objectives were to identify risk factors related to pessary-related adverse events and their management. Our hypothesis was that the adverse event rate is relatively high and associated with patient comorbidities.

Materials and Methods

A single-center retrospective case series was conducted at a specialized pessary clinic of a university-affiliated hospital. The research protocol was approved by the local ethics committee (SMHC 20–07). We included all adult women who attended the pessary clinic for POP or incontinence pessary care, identified through the electronic appointment system between 2015 to 2019. (With those patient visits spanning the 2012–2020 period). Women were excluded if no baseline information was available and if they were followed for less than 1 year. The pessary clinic is a nurse-led clinic where patients present for pessary care every 3 to 4 months. Patients managing their pessaries through self-care do not attend this clinic and were excluded from the study. These patients are usually autonomous and do not require regular nursing interventions. Pessary fitting and re-fitting was performed by a urogynecologist. Trained nurses were responsible for pessary clinic visits which included pessary removal, cleaning and reinsertion, as well as speculum exam as needed based on women's symptoms.

Through chart review, we collected baseline demographic data, comorbidities, pelvic floor symptoms, prolapse stage (as determined by POP-Q score) [12], and previous gynecological surgeries. We documented type and size of pessary fitted, number of pessaries tried, and pessary refitting. Finally, a predetermined list of outcomes of interest included presence and type of adverse events such as pessary erosions/ulcerations (including recurrence rate), vaginal discharge, vaginal bleeding, odor, discomfort, pain, vaginitis, urinary tract infections, fistula formation, pessary discontinuation, and complication management. As an adverse event, bacterial vaginosis was diagnosed clinically based on bothersome abundant malodorous yellow vaginal discharge, that was treated with metronidazole. Culture confirmation for diagnosis was not required as it is not performed in every case at our center, due to the prevalence of this condition among pessary users. Indeed, it was found that over 30% of women using pessaries develop bacterial vaginosis [13]. The variable "any pessary-related adverse events" was defined as one or more of: pessary erosions/ulcerations, vaginal discharge, vaginal bleeding, odor, discomfort, pain, vaginitis, urinary tract infections, or fistula formation. Patient subjective satisfaction, and if discontinuation, reason for discontinuation and alternative management chosen were recorded. Satisfaction was determined by the absence of complaints or the mention in the chart of "happy" or "satisfied" with pessary.

We reported descriptively demographic and baseline pelvic floor characteristics of the population. Data is presented as mean (SD) or median (interquartile range; IQR). We determined the rate of adverse events occurring among women using pessaries for over 1 year. We then conducted tests of association between 2 categorical variables (univariate analysis) with Pearson Chi-square and Fisher exact tests. Specifically, we assessed effect of age, type of pessary, cardiovascular risk factors (including diabetes, hypertension, heart disease, and cholesterol), previous hysterectomy, and number of pessaries tried on adverse events, pessary erosions, recurrent erosions, and discontinuation. We also assessed the association between pessary erosion as well as recurrent erosions on discontinuation. Odds ratios (OR) and 95% confidence intervals were computed from the estimates obtained from logistic regression [14]. Odds ratios were converted in relative risk (RR) by following the approach suggested by Zhang 1998 [15]. Pessary types were grouped as 1. Ring with support pessary or incontinence ring vs. 2. Gellhorn or donut pessaries for the logistic regression. We separated pessaries in these two groups to simplify the analysis, because adverse events and erosion rates were similar within group and different between groupings. For the variable "any pessary-related adverse events", the RR was adjusted for age and cardiovascular risk factors. Missing data were excluded from the analysis. Statistical analysis was performed with SAS version 9.4.

Results

Initially, 263 patients were identified from the appointment data but 48 were excluded from the analyses due to unavailable baseline data or follow-up less than 1 year. Finally, 215 women were included in the study analysis and were followed for a mean of 4.4 (1.9) years.

Demographic data and baseline characteristics are presented in Table 1. Mean age of study participants was 73.8 (8.7) years. Hypertension and hypercholesterolemia were the two most common comorbidities in our study population. Fifty-one (32.5%) women reported stress urinary incontinence (missing 58), and 44 (30.6%) reported urge urinary incontinence (missing 71) at baseline. Most presented with stage 2–3 POP. Overall, 102 (87.2%) women had anterior prolapse, 55 (47.0%) had apical prolapse and 48 (41.0%) had posterior prolapse (98 missing information on prolapsed compartment). The most commonly fitted pessaries were Gellhorn (48.8%) and ring with support (37.7%). 188

Table 1 Demographics and Baseline Characteristics ($n=215$)*

Variables	Value	Missing Data (n)
Age, years	73.8 (8.7)	
Medical History		
Hypertension	119 (58.6)	12
Diabetes	35 (17.1)	10
Cholesterol	51 (24.9)	10
Heart disease	26 (12.7)	10
Any of these 4 cardiovascular factors	143 (69.8)	10
Previous Hysterectomy	29 (16.1)	35
Prolapse stage		62
Stage 1	8 (5.2)	
Stage 2	79 (51.6)	
Stage 3	44 (28.8)	
Stage 4	22 (14.4)	
Number of pessaries tried at pessary fitting		30
1	153 (82.7)	
2	21 (11.4)	
3 or more	11 (5.9)	
Type of pessary fitted		0
Ring with support	81 (37.7)	
Incontinence ring ± support	21 (8.8)	
Gellhorn	105 (48.8)	
Donut	8 (6.0)	
Required pessary refitting during follow-up	100 (46.5%)	0

*Data presented as N (%), or mean (standard deviation)

(87.4%) patients used vaginal lubricant or vaginal estrogen at some point during follow-up, either as a preventive measure or to treat adverse events. Thirty-nine women (18.1%) used both lubricant and vaginal estrogens, 11 (5.2%) used only lubricant, and 138 (64.2%) used only estrogens. Vaginal estrogens used included estradiol tablets, topical conjugated estrogen, and topical estrone.

Adverse events are presented in Table 2. During follow up, 180 (83.7%) patients reported at least one adverse event with the most common being vaginal discharge, vaginal bleeding and erosions. Erosions were found on examination in 98 (45.6%), with 61 (64.9%) of those developing recurrent erosions. Mean time to first erosion was 2.4 (1.7) years. Ten patients had unhealed erosions at their last visit. Gellhorn and donut pessaries were more commonly associated with erosions (61.9% and 75% respectively) than ring with support pessaries or incontinence rings ($p<0.001$). RR of erosion with a Gellhorn or donut vs. Ring/incontinence ring pessaries was 2.37 [1.67; 3.38]. Management of pessary erosions was handled individually. Most commonly, the pessary was removed for a period of approximately 4 weeks and vaginal estrogens were either started or increased in dose. Treatment of concomitant bacterial vaginosis was also undertaken when clinically indicated.

Table 2 Pessary-Related Adverse Effects ($n=215$)*

Variable	Value	Missing data (n)
Total adverse effects	180 (83.7)	0
Vaginal Discharge	73 (34.0)	0
Pain	39 (18.1)	0
Odor	49 (22.8)	0
Vaginal bleeding	72 (33.5)	0
Discomfort	49 (22.8)	0
Constipation	18 (8.4)	0
Irritation	59 (27.4)	0
UTIs	1 (0.5)	0
Bacterial Vaginosis	15 (7.0)	0
Erosions		
At least one erosion during follow-up	98 (45.6)	0
Recurrence of erosions	61 (64.9)	4
1 recurrence	19 (22.2)	
2 or more recurrence	42 (44.7)	
Fistula formation	0 (0)	0

*Data presented as N (%)

At the end of follow-up, 164 (76.3%) patients appeared satisfied with the use of pessary to manage their pelvic floor condition, while 51 (23.7%) patients reported to be unsatisfied with pessary usage. Most common reasons for dissatisfaction included symptomatic POP despite the use of pessary [15 (29.4%)], pessary erosions [11 (21.6%)], and bothersome discharge [4 (7.8%)]. Overall, 35 (16.3%) women discontinued pessary use, with the most common reason for discontinuation was discomfort or inability to fit properly (Table 3). Discontinuation occurred at a mean of 3.3 (1.7) years after

Table 3 Discontinuation of pessary ($n=215$)

Variable	Value	Missing data (n)
Total discontinued	35 (16.3)	0
Reason for pessary discontinuation		1
Discomfort or inability to fit properly	22 (64.7)	
Incontinence	2 (5.9)	
Recurrent erosions	3 (8.8)	
Other reasons	7 (20.6)	
Alternative to pessary		3
Opted for surgery	18 (56.3)	
Opted for expectant management	14 (43.7)	

*Data presented as N (%)

initial fitting. Having a pessary erosion was not associated with discontinuation ($p=0.698$), but recurrent erosions were ($p=0.012$). No correlation was found between having multiple different adverse events and pessary discontinuation.

On univariate analysis we found a protective effect between hypertension ($p=0.007$), as well as any cardiovascular risk factor (including diabetes, hypertension, heart disease or cholesterol; $p=0.031$) and the risk of pessary-related adverse events. However, no association was seen between those factors and the risk of erosion (Table 4). After adjusting for age and type of pessary, the protective association between cardiovascular risk factors and pessary-related adverse events persisted (aRR = 0.81 [0.55; 0.97]). Gellhorn and donut pessaries were associated with a higher risk of adverse events than ring with support or incontinence ring pessaries ($p=0.039$, RR 1.18 [1.04; 1.34]). After adjusting for age and cardiovascular risk factors, this association between pessary type and adverse events also remained significant (aRR 1.19 [1.08; 1.25]). We found no association between the risk of having an adverse event and previous hysterectomy, number of pessaries tried at fitting, stress urinary incontinence or patient's age group.

Discussion

Pessaries are commonly used conservative treatment options for pelvic organ prolapse and stress urinary incontinence with low risk of complications [3]. However, long term follow-up data on pessary use, including associated adverse events is limited in the literature [11]. We reported 4.4-year follow-up among 215 women attending a nurse-led pessary clinic. We found a high pessary-related adverse events rate, but a low discontinuation rate. Gellhorn and donut pessaries were associated with an increased risk of pessary erosion.

Although menopausal status was not recorded, the mean age of our study population was 73.8 years, and only 2 women were younger than 50 years old. Most of our sample was at a high risk of experiencing genitourinary syndrome of menopause. The latter was previously found to be a risk factor for vaginal bleeding and erosion [11]. The age of our population is likely associated with our overall high adverse event rate. In addition, considering that many studies on pessary use have follow-up below 1 year [11], it is not surprising that we found a higher adverse event rate at a mean follow-up time of 4.4 (1.9) years. Furthermore, our study population did not include patients who perform pessary self-care. We typically find that these patients experience a lower erosion rate, as they usually clean their pessaries more frequently (usually daily to weekly). In our study, erosion rate was found to be higher with Gellhorn and donut pessaries compared with other types. The suction-type mechanism of the Gellhorn, and the space-filling property of a donut pessary could be prompt to erosions [16]. Fortunately, despite the high rate of pessary-related adverse events, none of our study population developed any serious adverse events such as fistulas, urosepsis and fecal impaction [9, 17]. Most of the adverse events resolved conservatively. Surprisingly, hypertension and cardiovascular factors were found to be protective for pessary adverse events, but not for pessary erosions specifically. We also looked at possible association explaining that finding. We controlled for age and type of pessary (aRR = 0.81 [0.55;0.97]) and the protective association between cardiovascular condition including hypertension and adverse events persisted. This association is difficult to explain clinically but could involve factors such as vaginal microbiota, patient's medications, or body mass index. Those parameters were not assessed in this study. A review of the literature did not reveal previous reports of this association. Future studies should explore this association.

Seventy nine percent of our study population was prescribed local vaginal estrogens. Precise data regarding duration, frequency of utilization, indication of local estrogen and the proportion of adverse events in the population using vaginal estrogen at baseline were missing due to the retrospective nature of the study. The literature is inconsistent regarding the effect of vaginal estrogen in patients treated with pessary for POP. There is recent evidence showing that vaginal microbiota is a factor that can change the erosion rate. Bouchard et al. found that women with vaginal erosions had significantly higher vaginal pH and more complex vaginal microbiota suggesting treatments focusing on lowering vaginal pH and/or re-establishing the vaginal microbiota should be considered [18]. On the other hand, Chiengthong et al. found no benefit of preventive intravaginal estrogen in reducing vaginal abrasions and vaginal bleeding in women using pessary in a one-year follow-up [19]. More long-term randomized controlled trials are needed to clarify the effect of vaginal estrogen for prevention of pessary adverse events. In addition, studies on the management of pessary erosions with estrogen or other modalities are lacking.

Another main finding of our study is the high continuation rate of pessary usage despite a significant adverse event rate. Eighty three percent of patients continued using the pessary at the end of our study follow-up. Our study excluded patients that discontinued pessary use within the first year. Clemons et al. found that every 10 year increase in age was associated with a 20% to 40% increase in continued pessary use [7]. Considering that our population is mainly composed of elderly women, our findings are consistent with the higher rates of adherence reported in literature and is found to be between 66% and 83.9% [20].

Strengths of our study were the long 4-year follow-up and the large sample size compared to other reports. With these numbers, our analysis revealed important factors associated with pessary adverse events. We also reported results obtained

Table 4 Univariate analysis: association between preselected variables and discontinuation, adverse events, and erosions

Variables	N	Discontinuation		Adverse events		Erosion			Recurrent erosion	
		%	Chi-square *p*-value	%	Chi-square *p*-value	%	Chi-square *p*-value	N	%	Chi-square *p*-value
Overall rate	**215**	**16.3**		**83.7**		**45.6**		**94**	**64.9**	
Age groups			0.985		0.585		0.413			0.936
40–68	53	17.0		79.3		37.7		19	63.2	
69–79	105	16.2		84.8		48.6		48	66.7	
80+	57	15.8		86.0		47.4		27	63.0	
Number of pessaries tried			0.588		0.478		0.553			0.297
1	153	14.4		82.4		41.2		60	65.0	
2–5	32	18.8		87.5		46.9		14	50.0	
Missing	30	23.3		86.7		66.7		20	75.0	
Type of pessary fitted			0.249		**0.039**		**< 0.001**			0.307
Ring with support pessary	81	13.6		75.3		24.7		20	60.0	
Incontinence ring	21	28.6		81.0		33.3		7	71.4	
Gellhorn pessary	105	17.1		89.5		61.9		61	62.3	
Donut pessary	8	0.0		100.0		75.0		6	100.0	
Cardiovascular comorbidities										
Any cardiovascular comorbidity			0.908		**0.031**		0.196			0.492
Yes	143	16.8		79.7		46.9		64	67.2	
No	62	16.1		91.9		37.1		22	59.1	
Missing	10	10.0		90.0		80.0		8	62.5	
Hypertension			0.979		**0.007**		0.599			0.146
Yes	119	16.8		77.3		45.4		53	71.7	
No	84	16.7		91.7		41.7		32	56.3	
Missing	12	8.3		91.2		75.0		9	55.6	
Diabetes			0.922		0.551		0.325			0.877
Yes	35	17.1		80.0		51.4		18	66.7	
No	170	16.5		84.1		42.4		68	64.7	
Missing	10	10.0		90.0		80.0		8	62.5	
Cholesterol			0.503		0.842		0.899			0.839
Yes	51	19.6		84.3		43.1		19	63.2	
No	154	15.6		83.1		44.2		67	65.7	
Missing	10	10.0		90.0		80.0		8	62.5	
Heart disease			0.264		0.582		0.053			0.462
Yes	26	7.7		88.5		61.5		15	73.3	
No	179	17.9		82.7		41.3		71	63.4	
Missing	10	10.0		90.0		80.0		8	62.5	
Previous hysterectomy			1.000		0.407		0.717			0.484
Yes	29	13.8		79.3		41.4		10	50.0	
No	151	16.6		85.4		45.0		66	65.2	
Missing	35	17.1		80.0		50.0		18	72.2	
Stress urinary incontinence			0.382		0.602		0.281			0.860
Yes	51	19.6		86.3		35.3		16	62.5	
No	106	14.2		83.0		44.3		45	60.0	
Missing	58	17.2		82.8		56.9		33	72.7	

Significant *p*-values are bolded

Missing data excluded from the analysis

at a nurse-led pessary clinic. Limitations of this study derive from well-known characteristics intrinsic to retrospective studies. Indeed, missing data in patient's electronic medical records affected our findings. Pre-existing cardiovascular disease, baseline POP-Q, surgical history and erosion recurrence were occasionally missing. Missing data was mostly noted in patients attending the clinic in 2012 and 2013, which was a transition period from paper to electronic medical records at our center.

Conclusion

Despite common mild adverse events, continuation rates were high with pessary use past the first year. Gellhorn and donut pessaries were associated with a higher erosion rate, whereas cardiovascular comorbidities were associated with a reduced risk of adverse events. Pessary use should continue to be highly recommended, especially in elderly women or those with comorbidities. Comparative long-term studies on pessary adverse events, their management and risk factors are needed.

Declarations

Conflicts of interest A Kakkar received the McGill Faculty of Medicine Harold and Rhea Pugash Research Bursary 2020 for her work on this project. M Larouche receives research stipend from the St. Mary's Research Centre. L Merovitz is a consultant for the Royal College of Surgeons and Physicians of Canada. Other authors have no conflict of interest to declare.

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