# Adapting to Challenging Circumstances: Pessary Care in a Racially Diverse Urban Population Within a U.S. Epicenter of the COVID-19 Pandemic

Priyanka Kadam Halani, MD,\* Eden Gelman, BS,\* Yvette Duchein, NP,† Nicole Roselli, MD, MBA,\* and Ava Leegant, MD\*

**Objectives:** The aim of the study was to describe time intervals between pessary maintenance visits in racially diverse women receiving care in a U.S. epicenter of the COVID-19 pandemic. We secondarily aimed to determine whether time interval between pessary changes is associated with adverse outcomes and to identify factors associated with adverse pessary outcomes. **Methods:** We performed a retrospective study of women undergoing pessary care after the COVID-19 pandemic began. Time between the most recent visit before the pandemic and first visit after the pandemic began was recorded. Pessary care data were collected from the latter visit, including vaginal bleeding, vaginal discharge, and erosion. Patient-reported symptoms and demographics were also recorded. The relationship between time interval between pessary visits and adverse outcomes as well as between adverse outcomes and demographic data was assessed.

**Results:** We identified 104 women undergoing pessary care, of which 35.6% were Hispanic and 32.7% were Black and  $26.2\% \pm 10.5\%$  lived in poverty. The median time to in-person visit was 4.5 months (interquartile range, 3.7–5.3 months). Seven women (8.7%) had vaginal bleeding, 15 (14.6%) had vaginal discharge, and 7 (6.8%) had erosions. There was no significant association between time interval between pessary visits and adverse outcomes or between adverse outcomes and patient characteristics (all P > 0.05).

**Conclusions:** Longer duration of time between pessary maintenance visits is not associated with increased adverse outcomes in this group of racially diverse women. Extended intervals between pessary visits can be considered to minimize risk and maintain patient safety during challenging circumstances, such as the COVID-19 pandemic.

Key Words: pessary care, racially diverse, pelvic organ prolapse treatment, COVID-19 pandemic

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**P** elvic organ prolapse (POP) and stress urinary incontinence (SUI) are common pelvic floor disorders affecting 3–50% of women depending on criteria used.<sup>1–3</sup> Vaginal pessary is a nonsurgical treatment option for women with POP and SUI often used for those who do not desire surgery, those who are medically unfit for surgery, or for symptom relief before surgery.<sup>4,5</sup> Pessaries are effective in reducing severity of POP symptoms, such as sensation of vaginal bulge, pressure, and splinting to urinate or defecate.<sup>6</sup> They can also improve urinary and bowel function, sexual function, and overall quality of life and are associated with high patient satisfaction.<sup>6–12</sup>

Practice patterns for pessary maintenance vary widely. While U.S. practitioners commonly use a 3-month interval between

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pessary checks based on limited data, reported times range from weekly to yearly.<sup>4,13–16</sup> In providing pessary maintenance care, practitioners conduct surveillance for adverse events related to pessary use, such as vaginal discharge, vaginal bleeding, and vaginal erosion. Such sequelae affect approximately 10–60% of pessary users, most commonly vaginal discharge.<sup>17–19</sup> Monitoring for adverse events is important because they can negatively affect quality of life and lead to poor patient satisfaction as well as cessation of pessary use.<sup>20</sup> Loss to follow-up among pessary users can also result in severe complications, such as vesicovaginal and rectovaginal fistulae.<sup>17</sup>

The optimal duration between pessary maintenance visits to minimize risk of adverse events is unknown.<sup>17,21–23</sup> The lack of consensus on pessary care posed a unique challenge in March 2020 when the coronavirus disease 2019 (COVID-19) pandemic unexpectedly mandated changes in standard clinical practice. New York City was declared the U.S. epicenter of the pandemic in March 2020.<sup>24,25</sup> Our health system cares for patients in the Bronx, a borough of New York City, which comprises approximately 90% Black and Hispanic residents with 27% of the population living in poverty.<sup>26</sup> In accordance with the New York State and Centers for Disease Control guidelines, nonemergent office visits were suspended and telemedicine was rapidly adopted to continue to provide clinical care.<sup>24,27–29</sup> There are limited data on practice patterns and rates of adverse events in racially diverse populations undergoing pessary care, particularly during the COVID-19 pandemic.

The primary aim of our study was to describe time intervals between pessary maintenance visits in a population of racially diverse women receiving care in the U.S. epicenter of the COVID-19 pandemic. Our secondary aims were to determine whether the time interval between pessary changes was associated with adverse pessary outcomes and to identify factors associated with adverse pessary outcomes.

# MATERIALS AND METHODS

After obtaining approval from the institutional review board at the Albert Einstein College of Medicine, we conducted a retrospective study of women presenting to the urogynecology department for pessary maintenance beginning in March 2020 when nonurgent in-person visits were suspended because of the COVID-19 pandemic. Scheduled in-person office visits were converted to telemedicine visits, and urgent in-person evaluation was offered per provider discretion. Routine in-person evaluation resumed once restrictions were lifted in summer 2020. We included women 18 years and older who had previously undergone successful pessary fitting for either POP or SUI before March 2020. We excluded women who presented for new pessary fitting and those who removed the pessary between office visits and thus presented for the first in-person visit without a pessary in situ.

From the \*Division of Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics & Gynecology and Women's Health; and †Department of Urology, Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY.

Correspondence to: Priyanka Kadam Halani, MD. E-mail: pkadamhalani@ gmail.com.

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Demographic and clinical information was collected from the medical record, such as age, body mass index (BMI), race and ethnicity, POP stage defined by the pelvic organ prolapse quantification (POP-Q) system,<sup>30</sup> indication for pessary, vaginal estrogen use, smoking status, pessary size and type, and total duration of pessary use. The dates of the most recent in-person pessary maintenance visit before the pandemic and of the first in-person pessary visit after the pandemic began were recorded. The difference between these 2 time points was calculated in months.

Data on pessary care were collected from the first in-person visit taking place after March 2020, including examination findings of vaginal bleeding, vaginal discharge, erosion, and pessary dislodgment as well as need for pessary holiday based on presence of erosion on examination. Patient-reported symptoms of pain, bleeding, discharge, and difficulty emptying the bladder or bowel were recorded. Practitioner type (nurse practitioner or physician) was noted. We defined adverse outcomes as any of the following: vaginal examination findings of blood, discharge, erosion, or pessary dislodgment, need for pessary holiday, and fistula formation. We defined erosion using a system proposed by Propst et al,<sup>23</sup> rating them from epithelial ery-thema to epithelial breaks or erosions. To compare patterns observed during the COVID-19 pandemic to those before the pandemic, we recorded these pessary outcomes from the same group of women 1 year prior in order to establish a baseline.

We categorized race/ethnicity into the following groups: non-Hispanic White, non-Hispanic Black, and Hispanic (regardless of racial group identification) in accordance with U.S. Census data.<sup>26</sup> Those who did not fall into these groups or did not specify this information were categorized as "other" or "declined," respectively. Zip codes were used to estimate socioeconomic status by recording the percentage of population living below the poverty line for each zip code from the 2018 U.S. Census data.<sup>31</sup>

Data were analyzed using Stata Version 15.1 Software (StataCorp, College Station, Tex). Descriptive data were described with mean and standard deviation or medians where appropriate. The Wilcoxon rank sum test was used to assess difference in time to first in-person visit between nurse practitioner and physician, and the Wilcoxon signed rank test was used to compare time between extended interval follow-up and at baseline. The McNemar test was used to compare baseline and extended interval pessary outcomes. The relationship between adverse outcomes and the time interval between pessary checks as well as adverse outcomes and demographic data was assessed with univariate logistic regression analysis.

### RESULTS

We identified 104 women undergoing pessary care during the COVID-19 pandemic (Table 1). Hispanic and Black women comprised 35.6% and 32.7% of the group, respectively, and  $26.2\% \pm 10.5\%$  of women lived in poverty based on zip code. Most women had Medicare insurance, with 37.5% of Medicare recipients getting secondary coverage from Medicaid plans, and 27.9% preferred non-English languages. Total lifetime use of pessary was 33.5 months (interquartile range [IQR], 13.0–56.3).

The median time to in-person visit after the COVID-19 pandemic began was 4.5 months (IQR, 3.7–5.3 months), significantly longer than 3.3 months (IQR, 3.0–3.9 months) at baseline (P < 0.001). There was 1 unscheduled urgent visit for discomfort; no abnormal examination findings were noted. Time to first in-person visit was significantly shorter for nurse practitioner versus physician (4.4 months; IQR, 3.7–5.1 vs 5.2 months; IQR, 4.7–6.1 months, respectively; P = 0.02).

We found that 7 women (6.8%) had blood on examination, 15 (14.6%) had vaginal discharge on examination, and 7 (6.8%) met criteria for erosion (Table 2). Seven women required pessary **TABLE 1.** Demographics and Clinical Characteristics of Study

 Population

Рориацоп	
Age	$77 \pm 8.5$
BMI	$28.0 \pm 5.5$
Parity	3 (2-4)
Race	- ( )
Hispanic	37 (35.6)
Black	34 (32.7)
White	7 (6.7)
Other	14 (13.5)
Declined	12 (11.5)
Preferred language	()
English	75 (72.1)
Non-English	29 (27.9)
Spanish	27 (26.0)
Bengali	1(1.0)
Portuguese	1(1.0)
Insurance type	1 (110)
Medicare	88 (84 6)
% of Medicare with secondary Medicaid coverage	33 (37.5)
Medicaid	5 (4 8)
Private	10 (9.6)
No insurance	1(1.0)
Living below poverty line %	$262 \pm 105$
History of POP or LII surgery	5(4.9)
History of hysterectomy	21(204)
Current smoker	4(3.9)
History of diabetes	46 (45 1)
Hemoglobin A1c	62 + 23
Aspirin use	45(437)
Anticoagulation use	15 (14.6)
Vaginal estrogen use	39 (37 5)
Hormone therapy	1(11)
Sexually active	19 (18.8)
History of erosion	14 (15.6)
Type of pessary	14 (15.0)
Ring with support	57 (54.8)
Gellhorn	35 (33 7)
Continence ring with support	10 (9.6)
Incontinence dish/continence ring	2(19)
Pessary size in	2(1.9) 27+03
Indication for nessary	$2.7 \pm 0.5$
POP	92 (88 5)
SUI	2(19)
Both POP and SUI	10 (9.6)
Total duration of pessary use mo	33.5
Total duration of pessary use, mo	(13.0–56.3)
Provider type	
Nurse practitioner	82 (78.8)
Physician	22 (21.2)
Prolapse stage	
1	2 (2.0)
2	23 (23.5)
3	49 (50.0)
4	24 (24.5)

Data are mean  $\pm$  SD, median (interquartile range), or n (%).

BMI, body mass index; POP, pelvic organ prolapse; SUI, stress urinary incontinence; UI, urinary incontinence.

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 TABLE 2.
 Adverse Pessary Outcomes at Baseline Pre-COVID-19

 Pandemic Versus Extended Interval During COVID-19
 Pandemic

Adverse Event	Baseline: Pre–COVID-19 Pandemic	Extended Interval: During COVID-19 Pandemic	Р
Time between pessary visits, median (IQR), mo	3.3 (3.0–3.9)	4.5 (3.7–5.3)	< 0.001
Vaginal bleeding	3 (2.9)	7 (6.7)	0.2
Vaginal discharge	30 (28.9)	15 (14.4)	0.003
Vaginal erosion	8 (7.7)	7 (6.7)	0.8
Dislodged pessary	3 (2.9)	3 (2.9)	1.0
Pessary holiday	5 (4.9)	7 (6.7)	0.5
Urinary tract infection	6 (5.6)	2 (1.9)	0.2
Fistula	0 (0)	0 (0)	1.0
Patient-reported symptoms:			
Pain/discomfort	4 (3.9)	5 (4.8)	0.7
Vaginal bleeding	9 (8.7)	5 (4.9)	0.3
Vaginal discharge	5 (4.8)	8 (7.7)	0.4
Urinary difficulty	2 (1.9)	1 (1.0)	0.6
Bowel difficulty	4 (3.9)	8 (7.7)	0.2

Data are n (%), unless otherwise specified.

IQR, interquartile range.

holiday due to erosion. The incidence of urinary and bowel difficulty was low, and there were no fistulae. Patient-reported concerns were similarly uncommon. Significantly less vaginal discharge on examination was noted after extended interval compared with baseline; there were no differences in other outcomes.

We did not find a significant association between duration of time between pessary checks and any adverse pessary outcomes after the extended interval or at baseline (all P > 0.05). Similarly, we did not find a significant association between adverse pessary outcomes and patient characteristics, such as POP stage, pessary type or size, total duration of pessary use, medical comorbidities, age, BMI, preferred language, and race after extended interval between checks or at baseline (all P > 0.05).

#### DISCUSSION

In this population of racially diverse women undergoing pessary care at the peak of the COVID-19 pandemic in New York City, the median time to in-person office visit for pessary maintenance was 4.5 months, longer than both our baseline interval of 3.3 months and the most commonly used interval of every 3 months.<sup>4</sup> Reassuringly, we did not find this increased interval to be associated with increased adverse pessary outcomes. Moreover, we found the overall rate of adverse outcomes to be low. Our data suggest that a longer duration of time between in-person pessary maintenance visits could be offered to patients without compromising safety.

Despite a longer time to in-person pessary maintenance visit than usual, we did not note an association between increased duration of time and increased adverse outcomes. In addition, the rate of adverse outcomes, such as blood, discharge, and erosion on examination, was low and was not associated with specific patient characteristics. Data on rates of and risk factors for adverse pessary outcomes are limited in racially, ethnically, and socioeconomically diverse populations, particularly in the setting of long-term intervals. Our findings in a racially diverse cohort with

regard to erosion and bleeding are consistent with prior studies demonstrating low rates of complications with long-term continu-ous use of pessary, ranging from 1.7% to 12.2%.<sup>17,23,32–34</sup> Despite such findings, many practitioners choose 3-month intervals; factors affecting this decision are not well elucidated. Practitioner type could potentially play a role, as suggested by our findings. Overall, consensus on the optimal interval is lacking.<sup>17,21,22</sup> Based on our results, practitioners can consider extending follow-up periods for pessary cleanings beyond 3 months without incurring increased risk of adverse outcomes in racially/ethnically diverse women. An extended interval may increase pessary acceptance given the convenience of fewer in-person office visits, including decreased transportation costs, less time off work, and reduced need for caregiver or family accompaniment. This practice may also reduce strain on health care systems and offer an alternative under circumstances where more frequent in-person follow-up may not be feasible or safe, such as the COVID-19 pandemic. Further study on the impact of pessary practice patterns on both patient safety and satisfaction is needed to establish consensus on the optimal duration to minimize risk of adverse pessary outcomes.

We found that our rates of vaginal discharge noted on examination decreased with longer time between pessary visits compared with baseline, whereas there was no change in the patient-reported symptom of vaginal discharge. We found our baseline rates of vaginal discharge on examination and patient-reported discharge to be consistent with reported rates during short-interval follow-up.<sup>18,19,35</sup> However, although still low overall, our rate of discharge with extended interval between visits was higher than other studies of 6- to 24-month intervals (14.4% vs 5.8%).<sup>33</sup> Comparison of vaginal discharge rates among studies is challenging because of the heterogeneity in definitions used, including patientreported bother, examination findings, and vaginal cultures. Nonetheless, available data suggest that the presence of bothersome dis-charge is common among pessary users.<sup>17–19</sup> The etiology of vaginal discharge is not fully understood. Proposed theories include an infectious etiology, inflammatory reactive process, or pessary-induced change in vaginal flora.<sup>18,36</sup> Collins et al<sup>18</sup> reported that changes to the vaginal microenvironment occurred soon after initial pessary placement and did not find further alterations 3 and 6 months later. In another group of women newly fitted for pessary, less frequent pessary changes resulted in greater prevalence of anaerobes at 3 months and fewer Lactobacillus at 2 weeks.<sup>36</sup> Existing studies have not examined microenvironment changes in established pessary users between visits or in women continuously using pessaries for longer than 3 months. It is interesting to consider whether the vaginal microbiome resets each time the pessary and vagina are cleaned and the pessary is replaced, such that longer intervals between pessary visits could allow the environment to stabilize and subsequently generate less discharge than more frequent removal. Perhaps this could play a role in explaining our findings. Future studies could explore variations in the microenvironment in established and long-interval pessary users to determine whether they correlate with rates of discharge, symptom burden, and patient satisfaction.

The effect of race and ethnicity on the vaginal microenvironment in pessary users has not been evaluated. Such analysis is important given racial differences in the vaginal microenvironment exist, which could influence susceptibility to pathogens and symptom thresholds. Available studies were notably performed in primarily White women and *Lactobacillus* species subtypes were not reported, with the exception of a study of Asian women reporting mixed results.<sup>37–39</sup> Accordingly, existing data on microenvironment patterns in pessary users may not be applicable to women of other racial/ethnic backgrounds. For example, asymptomatic Black and Hispanic women are more likely to have non-*Lactobacillus*-

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dominated microenvironments than White women with resultant higher vaginal pH. Furthermore, even when *Lactobacillus* is the dominant organism, the species is not consistently the same as observed in White women.<sup>37,38</sup> This distinction is important given that susceptibility to pathogens, such as *Candida*, is dependent upon *Lactobacillus* subtype. Perhaps adaptions of the microenvironment unique to race/ethnicity occur that could lead to varying patterns of vaginal discharge over time, such as those seen in our study; this is a fascinating potential area of future study.

Our study is novel in presenting data on pessary care in women of diverse racial and ethnic backgrounds. Our population consisted of 68% Hispanic and Black women and approximately 26.2% of women living in poverty based on zip code, more than double the national rate of 11.8%.<sup>40</sup> We observed low rates of adverse pessary outcomes in this group. Moreover, we demonstrated that women of racially/ethnically diverse and lower socioeconomic backgrounds comply with recommended pessary follow-up as seen by our baseline time interval of 3.3 months consistent with nationally reported practice patterns. Prior studies on pessary care have focused on predominantly White women; the effect of race on pessary care outcomes is unknown. Reports of racial differences in pelvic floor disorders in general suggest discrepancies in the characteristics, symptom burden, and care-seeking patterns by race.41,43 Etiologies for these racial differences are unclear, but socioeconomic status and genetic predisposition have been proposed as contributing factors.<sup>44,45</sup> As such, generalizability of the results of studies that do not investigate these women could be affected and treatment outcomes may not be optimized, as suggested by an analysis of landmark urogynecology trials revealing underrepresentation of Black and Hispanic women and overrepresentation of White women.46 Although we did not note an association between race and pessary outcomes in our study, we provide unique data on adverse pessary outcomes in a population of underrepresented minority groups that could serve as useful information for future prospective studies.

Our study is unique in describing pessary maintenance at the peak of the COVID-19 pandemic in New York City as well as in reporting baseline pessary care patterns and rates of adverse pessary outcomes in a racially, ethnically, and socioeconomically diverse population. We are limited by the retrospective nature of our study, such that causality cannot be established. In addition, we could not assess patient satisfaction in this setting.

In conclusion, extended intervals between pessary maintenance visits longer than the commonly used 3-month period are not associated with increased rates of adverse pessary outcomes in a group of racially diverse women undergoing pessary maintenance during the COVID-19 pandemic. Practitioners can consider prolonging the interval between pessary visits to minimize risk and maintain patient safety during challenging circumstances. Future prospective studies on pessary care would benefit from inclusion of racially, ethnically, and socioeconomically diverse populations to further elucidate any potential impact of these factors on patient outcomes.

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