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CHANGES IN THE VAGINAL MICROENVIRONMENT AS RELATED TO FREQUENCY OF PESSARY REMOVAL

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Structured Abstract

Objectives—To describe the effect of frequency of pessary removal on the vaginal microenvironment.

Methods—We performed a secondary analysis of a multicenter randomized trial of hydroxyquinoline gel in women presenting for pessary fitting. Patients had vaginal secretions analyzed at baseline, 2 weeks and 3 months. Patients were stratified by frequency of pessary removal: at least once daily, at least once weekly, and less often than once weekly. These groups were compared for prevalence of *Lactobacillus* predominance (primary outcome), anaerobic predominance, *Mobiluncus* prominence, vaginal symptoms, and bacterial vaginosis (BV) by Nugent's criteria, and correction for confounding variables was performed.

Results—137 women were included in this analysis: 34 (25%) removed the pessary daily, 54 (39%) at least weekly, and 49 (36%) less often than once weekly. Women who removed the pessary less often than weekly were older ($p<0.01$), using more hormone therapy ($p=0.03$), and more likely to have BV at baseline ($p<0.01$). At 2 weeks, the predominance of *Lactobacillus* in the group removing pessary daily was higher (41% daily vs 24% weekly vs 9% longer, $p=0.03$) and this persisted after confounder correction ($p<0.01$). Women who removed their pessary less than weekly were more likely to have anaerobic predominance at 3 months ($p=0.04$).

Conclusions—Women who remove their pessaries less often than once weekly have an increased prevalence of anaerobes at 3 months, but no difference in vaginal symptoms or pessary satisfaction.

Keywords

Pessary; vaginal microenvironment; pessary removal; pessary management

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Response to Reviewers

The authors have responded to the reviewers' comments and made the necessary changes to the manuscript.

Introduction

Pelvic organ prolapse (POP) and urinary incontinence (UI) are prevalent and debilitating conditions that affect hundreds of thousands of women worldwide.^{1,2} Although many women choose to undergo surgical treatment for POP or UI, others may choose more conservative management with a pessary; a silicone device worn in the vagina to provide vaginal support for the treatment of pelvic organ prolapse and stress urinary incontinence.

Pessary use has been shown to improve quality of life, sexual function, and body image as well as POP and UI symptoms, but they are also associated with bothersome side effects, which lead to a high rate of discontinuation.^{3–8} Women using pessaries commonly report increased vaginal discharge, and up to 30% of women with a pessary experience bacterial vaginosis (BV), a shift in the ecologic balance of the vagina leading to malodorous vaginal discharge, as compared to the 10% incidence of BV in the general population.^{3,9,10}

There is considerable variability among pessary users in the frequency with which they remove and clean their pessaries. Some women perform this task daily while others may only remove and clean their pessaries weekly, monthly, or even less often. Providers offer a wide variety of counseling about how often women should remove or clean their pessaries, and there are few published trials on pessary care after fitting and no guidelines on the topic.^{3,9} Little is known about how the frequency of pessary removal and cleaning impacts shifts in vaginal microenvironment.

The aim of this study was to utilize Nugent scores from Gram staining of vaginal secretions in new pessary users participating in a randomized, controlled trial to investigate the vaginal microenvironment compared between different frequencies of pessary removal. We hypothesized that women with pessary removal less often than once a week would have a lower prevalence of *Lactobacilli* predominance when compared to women removing their pessaries more frequently.

Materials and methods

This is a planned secondary analysis of a multi-center randomized controlled trial (ClinicalTrials.gov NCT01471457) conducted at two tertiary care centers from 2010 to 2014. Each clinical site provided institutional review board approval, and all participants gave written informed consent prior to study participation.

The details of the primary clinical trial have been published.¹⁰ The parent trial was designed to determine if hydroxyquinoline gel decreases the prevalence of bacterial vaginosis (BV) or bothersome vaginal symptoms during the first three months of pessary use, and the use of the hydroxyquinolone gel had no effect on development of BV or symptoms during the first three months of pessary use in the parent trial. Women who were >18 years of age, suitable for follow up, and undergoing a pessary fitting for any indication were eligible for study participation, and potential participants were excluded from the parent trial if they had a known allergic or suspected adverse reaction to hydroxyquinoline gel or any of its components, had an inability to use a pessary or hydroxyquinoline gel as indicated, had used

a prior pessary within the last 12 months, had a history of frequent or chronic BV (>2 episodes per year or symptoms >6 months out of the last 12 months), had active vaginal ulcerative disease (active ulcers from atrophy, herpes, or mesh erosion with >2 episodes of ulcers per year or last ulcer with >2 episodes of ulcers per year or last ulcer <1 month ago), were using long-term antibiotics for indications not listed above, were unable to speak English, or were unable to provide informed consent due to other medical comorbidities. If patients were randomized at the time of initial pessary fitting but unable to retain the pessary or be successfully fitted before leaving the office, they were offered a second attempt at fitting. If they failed or declined a second attempt at pessary fitting, they were excluded after randomization.

Patients completed baseline questionnaires on their medical history and health, vaginal symptoms and hormone therapy (HT) use. Hormone therapy use in any form prior to or during trial participation (any HT) was defined as the use of systemic (oral, transdermal) or vaginal HT. Within those women using any HT, vaginal hormone therapy use (vaginal HT) was defined as any hormone therapy given via a vaginal route (cream, ring, etc.), and this included women already using vaginal HT upon entry in to the study and women who initiated vaginal HT at the time of pessary initiation.

Prior to pessary fitting, the study patients underwent enzyme-based, color-changing BV testing (OSOM® Rapid Tests, Sekisui Diagnostics)¹¹ and microscopic slide collection. This air-dried slide of the patient's mid-vaginal secretions underwent Gram stain and was analyzed for BV by Nugent's criteria, including three subscores for *Lactobacillus*, anaerobes, and *Mobiluncus* according to Nugent's protocol (Table 1).¹² Gram staining and analysis were performed by laboratory assessors who were unaware of treatment allocation. If the patient was found positive for BV by OSOM BV BLUE® at the baseline visit, independent of the slide analysis, she was treated with oral metronidazole or clindamycin therapy prior to continuing in the trial.

Following the completion of vaginal specimen collection and questionnaires, patients were fitted with a pessary that was comfortable and allowed them to adequately void. After pessary fitting, women were randomized to either proceed with standard pessary hygiene plus use of hydroxyquinoline gel (half applicator of gel vaginally twice a week) or to standard pessary care without use of the gel. The randomization scheme was a blocked randomization sequence with randomly alternating block size (block size ranging from 5–10) with a 1:1 ratio of hydroxyquinoline gel to no hydroxyquinoline gel, stratified by women who intended to remove their pessary at least daily and women who intended to remove their pessary less often than daily based on their preference stated to the provider at pessary fitting. Frequency of pessary removal for the initial months was not suggested to the patients; this was left to patient convenience and comfort. Women returned 2 weeks and 3 months later for repeat slide collection for Nugent's analysis, BV® BLUE testing, and completion of questionnaires on vaginal symptoms of discharge, itching, pain, and sores since pessary fitting, desire to continue the pessary, and pessary satisfaction. Women were asked at 2 week and 3 month follow up how often they removed their pessary (daily or more often, less often than daily but at least once per week, less often than once per week), and how often they wore their pessary (never wear, wear 1–7 days per month, >7 days per

month, daily). “Pessary satisfaction” was defined as a reply to the question “How much do you want to keep wearing your pessary in the future?” of “Quite a bit” or “Moderately”. “Excellent pessary satisfaction” was defined as a reply of “Quite a bit” to this question.

In this analysis, we included all women from the parent trial who followed up at least once during the study (at 2 weeks or 3 months) and who reported their frequency of pessary removal. We excluded women who followed up and replied to the question about pessary removal frequency with a response that they were not using the pessary for any amount of time. We divided the women included in this analysis into three cohorts: those who reported removing their pessary at least daily, those removing the pessary less often than once a day but at least once a week, and those removing the pessary less often than once a week.

All outcomes for this study were compared between the three cohorts of pessary removal frequency. The primary outcome for this secondary analysis was the predominance of *Lactobacilli* (*Lactobacillus* Nugent subscore 0 or 1). Secondary outcomes were vaginal predominance of anaerobic organisms (*Gardnerella* Nugent subscore 3 or 4), vaginal predominance of *Mobiluncus* (score 2 or 3), BV by Nugent’s criteria (total Nugent score 7), the presence of vaginal symptoms (discharge, itching, pain, ulcers), and pessary satisfaction (“very likely” or “likely” to continue pessary use on Likert scale).

The original study was powered to a different primary outcome (BV by Nugent’s total score at 3 months), but we performed a *post hoc* analysis to determine our power to detect clinically important difference in *Lactobacilli* predominance. Given that the mean age of the study population is predominantly menopausal, this population would have a baseline prevalence of the primary outcome (*Lactobacilli* predominance, or Nugent subscore 0–1) of only 40%¹³ at baseline, and the group removing the pessary less often than once a week would have a prevalence of the primary outcome as low as 15%. With our sample size of 137, the *post hoc* power calculation indicated that we had 80% power to detect this difference ($\alpha=0.05$), or detect a risk ratio of 0.33 of the primary outcome in the group removing the pessary less often.

We compared the primary outcome (predominance of *Lactobacilli*) and secondary outcomes by frequency of pessary removal using the chi-squared test at three time points (baseline, 2 weeks, and 3 months). Differences in baseline demographic variables and outcomes by removal frequency were tested using chi-square for categorical/binary variables and ANOVA for continuous variables. Logistic regression models for the primary and secondary outcomes were performed integrating the suspected confounding variables (age, any HT, vaginal HT, randomization to hydroxyquinoline gel, and baseline values for the corresponding outcome being analyzed at 2 weeks and 3 months). Women needing a pessary for either POP or stress urinary incontinence (SUI) or both were included the study. All statistical analysis was performed in the R statistical software, version 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 187 women were originally randomized, of which three women were excluded, leaving 184 active eligible women after successful pessary fitting. Ninety-two were randomized to hydroxyquinoline gel use and 92 were randomized to no gel use. From a total of 184 active participants in the initial study, 160 followed up at either 2 weeks or 3 months, and of these 156 gave responses on pessary removal frequency. Nineteen more women indicated they were not using the pessary at follow up, so removal frequency was not relevant. Any participant who responded with frequency of pessary removal and had at least 1 vaginal swab at any time point were included in the analysis. This left 137 women who constituted the cohort in this study (Figure 1). As reported in a prior publication on these data, the majority of the patients in this study used a ring pessary or an incontinence ring.¹⁴ Baseline clinical and demographic characteristics and primary results of the pessary study have been previously described.¹⁰

Of the 137 eligible women were included in this analysis, of which 34 (25%), 54 (39%), and 49 (36%) removed the pessary at least daily, less often than daily but at least weekly and less often than once a week, respectively. Patient characteristics are presented in Table 2. Women who removed the pessary less than once a week were older (69 ± 14 years for daily group vs 54 ± 12 years for weekly group vs 53 ± 15 years for longer group, $p < 0.01$) and more likely to be using any HT [18/49 (37%) daily vs 8/54 (15%) weekly vs 7/34 (21%) longer, $p = 0.03$] or vaginal HT [16/49 (33%) vs 6/54 (11%) vs 5/34 (15%), $p = 0.02$]. HT use was not stratified by those who had previously been on HT and those who started it at the time pessary fitting. There was no significant difference between the removal cohorts in randomization to hydroxyquinoline gel use. None of the measured vaginal symptoms were different between the cohorts at baseline (all $p > 0.05$, Table 3).

Outcomes at 2 weeks and 3 months as compared between the different cohorts of frequency of pessary removal are reported in Table 3. At baseline, both *Lactobacilli* predominance and BV by Nugent's criteria were more prevalent in the group that went on to remove their pessary less often than once weekly. This difference, however, was no longer significant once corrected for confounding variables. At 2 weeks after pessary fitting, the group removing the pessary at least once daily had a higher prevalence of *Lactobacilli* predominance (41% daily vs 24% weekly vs 9% longer, $p = 0.03$) which remained significant after correction for covariates (corrected $p < 0.01$). However, at 3 months, there was no longer a significant difference in *Lactobacilli* predominance (38% daily vs 18% weekly vs 29% longer, $p = 0.19$).

The prevalence of anaerobic predominance was not different amongst the cohorts at 2 weeks, but women who removed their pessaries less often than once weekly were more likely to have a predominance of anaerobic organisms at 3 months after pessary fitting [32/42 (76%) vs 38/73 (52%), $p = 0.04$], and this persisted with correction for covariates ($p = 0.04$). There was no significant difference in pessary satisfaction or vaginal symptoms amongst the cohorts at either time point.

Discussion

This secondary analysis of a randomized controlled trial among new pessary users found that women who removed their pessaries most frequently (at least daily) had more *Lactobacilli* predominance within their vaginal microenvironment two weeks after pessary fitting when compared with those who removed less often, and less anaerobic predominance by 3 months. However, these differences in microenvironment did not translate into a significant difference in patient satisfaction or vaginal symptoms, so women do not seem to have an altered pessary use experience with different removal frequencies.

While these data demonstrated that the relationship between frequency of pessary removal and prevalence of *Lactobacilli* was no longer significant at 3 months after pessary fitting, there was still a trend toward a higher number of women with *Lactobacilli* predominance. It is known that *Lactobacilli* confer protection against potentially pathologic organisms and suppress the growth of anaerobes through the production of lactic acid, which results in a lower pH.^{15–17} We know from previous studies that pessaries alter the vaginal microenvironment and pessary users are at increased risk of bacterial vaginosis.^{9,10,18} It has been hypothesized that this change is attributable to the formation of some type of microfilm of bacteria that forms on the foreign object in the vagina and permits anaerobic growth to persist in this environment. Based on this understanding, it has been posited by clinicians in the past that more frequent removal or cleaning may prevent this microfilm and allow for a more “natural” microenvironment in the vagina despite the pessary’s presence. This study may suggest that women do preserve their *Lactobacilli* predominance if they remove their pessaries more frequently early in pessary use (2 weeks), even correcting for factors like age and hormonal use. In keeping with this, infrequent removal of the pessary resulted in higher predominance of anaerobic organisms. Surprisingly, we found that this improvement in the vaginal microenvironment with more frequent pessary removal had no significant clinical impact on women’s experience using a pessary in the initial months.

Women that use a pessary often require extensive counseling to understand pessary care and hygiene. Currently, there are no evidence-based clinical guidelines or recommendations to aid clinicians when counseling patients regarding pessary care. Our finding that pessary removal frequency may slightly change the microenvironment without affecting the pessary experience (vaginal symptoms or patient satisfaction), is useful data for clinicians to express to patients who are trying to decide the frequency of pessary removal and cleaning that works best for them. This is an important piece of knowledge in a medical environment that prioritizes patient individualization of care and the quality of experience for the patient. Patients can feel empowered to care for their pessary in a way they see fit without risk of self-harm.

Some limitations of the study deserve attention. In particular, many patients did not follow-up for 2 week (25%) or 3 month (11%) outcome collection and the original study was not powered to detect changes in outcomes based on frequency of pessary removal. The power of this study was also limited by the sample size and the inability to detect more subtle differences in the microenvironment than the post-hoc power analysis indicates. The microenvironment varies based on a multitude of factors, which was the reason for our

correction for confounders in this analysis, but the possibility of unknown or unmeasured confounders still exists. Also, the use of Gram staining in Nugent scoring may compromise the recognition of some *Lactobacillus* morphotypes.¹⁹ However, Nugent criteria is the preferred diagnostic tool for BV,^{20,21} and the Nugent score can integrate multiple components of the microenvironment.^{20,21} Finally, we did not collect any data past 3 months or on the stage of prolapse at time of pessary fitting, which could impact the patient's experience and the vaginal microenvironment. In spite of these limitations, there are no clear trends in this data that indicate a significant change in the vaginal microenvironment in the first 3 months of pessary use based on frequency of pessary removal.

The strengths of the study include the prospective and randomized nature of the parent study and standardized data collection across the centers. This standardization prevented the presence of BV or *Lactobacilli* predominance from modifying pessary management or decreasing the likelihood of detecting outcomes of interest. Also, as women and providers caring for the patient were not aware of their microenvironment by the Nugent scoring due to this being performed in a separate lab by uninvolved specialists, women did not have a chance to modify their behavior due to interval findings. Furthermore, we corrected for several clinically known confounders for the vaginal microenvironment, and that is vital when considering this very multifactorial microbial outcome. Lastly, this secondary analysis included adequate power in its larger sample size to detect a reasonable and clinically significant change in the predominance of certain organism groups in the vaginal microenvironment. As a result, the associations or lack thereof found on this analysis reflect real-life scenarios in pessary care without alteration in provider or patient behavior due to study findings.

In conclusion, women who remove their pessaries less often than once weekly have an increased prevalence of anaerobic predominance in their vaginal microenvironment and BV by Nugent's criteria at 3 months after fitting. However, this does not correlate to any notable difference in patient satisfaction or vaginal symptoms, which are the factors that our patients truly value. This is reassuring for both clinicians and patients, as patients can make autonomous decisions about how often they would like to remove their pessary. Further well-designed studies and consideration are needed to determine the effects of frequency of pessary removal on the vaginal microenvironment beyond three months and how the vaginal microenvironment changes based on the stage of prolapse may yield clinically important insights.

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Summary

Women who remove their pessaries less often than once weekly have an increased prevalence of anaerobic predominance and BV in their vaginal microenvironment at 3 months after fitting, but no difference in pessary satisfaction or vaginal symptoms.

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Figure 1.
Patient participant flow diagram

Table 1

Nugent's criteria

Score 1	Score 2	Score 3
<i>Lactobacillus</i> morphotypes: large, gram positive rods/HPF	Anaerobes: <i>Gardenerella</i> : small gram negative variable rods/HPF. Bacteroides: small gram variable rods/HPF	<i>Mobiluncus</i> : curved gram variable rods/HPF
0: >30	0: 0	0: 0
1: 5–30	1: <1	1: <5
2: 1–4	2: 1–4	2: 5+
3: <1	3: 5–30	
4: 0	4: >30	

Total score: 1+2+3. 0–3 negative for bacterial vaginosis (BV), 4–6: intermediate or equivocal, 7+: BV, HPF: high powered field.

Table 2

Patient characteristics by frequency of pessary removal.

Demographics	Frequency of pessary removal			
	once daily n=34	Once per week n=54	Less often than once per week n=49	p-value *
Age (years)	53 ± 15	54 ± 12	69 ± 14	<0. 01
Any HT (n=33)	7 (21)	8 (15)	18 (37)	0.03
Vaginal HT (n=27)	5 (15)	6 (11)	16 (33)	0.02
Randomized to hydroxyquinoline gel (n=68)	16 (47)	32 (59)	20 (41)	0.27

HT, hormone therapy

Data are n (%) or mean ± standard deviation unless otherwise specified.

* ANOVA and chi-squared tests used.

Table 3

Comparison of outcomes by frequency of pessary removal.

Frequency of pessary removal								
	Total* n=137	N	once daily n (%) Total n=34	N	Once per week n (%) Total n=54	N	Less often than once per week n (%) Total n=49	‡ Uncorrected p-value
Lactobacilli (Nugent subscore 0–1)								
Baseline	129	33	5 (15)	54	11 (20)	42	17 (41)	0.02 Corrected p=0.21
2 weeks	96	22	9 (41)	42	10 (24)	32	3 (9)	0.03 Corrected p<0.01
3 months	115	24	9 (38)	49	9 (18)	42	12 (29)	0.19
Anaerobes (Nugent subscore 3–4)								
Baseline	129	33	17 (52)	54	33 (61)	42	31 (74)	0.13
2 weeks	96	22	12 (55)	42	24 (57)	32	22 (69)	0.49
3 months	115	24	13 (54)	49	25 (51)	42	32 (76)	0.04 Corrected p=0.04
Mobiluncus (Nugent subscore 2)								
Baseline	129	33	5 (15)	54	11 (20)	42	4 (10)	0.34
2 weeks	96	22	4 (18)	42	16 (38)	32	8 (25)	0.20
3 months	115	24	3 (13)	49	15 (31)	42	8 (19)	0.17
BV (Total Nugent score 7)								
Baseline	129	33	2 (6)	54	12 (22)	42	17 (40)	<0.01 Corrected p=0.08
2 weeks	96	22	7 (32)	42	9 (21)	32	7 (22)	0.62
3 months	115	24	7 (29)	49	8 (16)	42	14 (33)	0.16
Vaginal discharge								
Baseline	136	33	4 (12)	52	2 (4)	49	6 (12)	0.23
2 weeks	93	18	5 (28)	43	9 (21)	32	5 (16)	0.59
3 months	128	29	4 (14)	51	7 (14)	48	14 (29)	0.10
Vaginal itch								
Baseline	129	30	5 (17)	51	8 (16)	48	12 (25)	0.46

	Frequency of pessary removal					Less often than once per week n (%) Total n=49	N	Once per week n (%) Total n=54	N	once daily n (%) Total n=34	N	‡ Uncorrected p-value
	Total* n=137	N	once daily n (%)	Total n=34	N							
2 weeks	91	19	3 (16)	41	7 (17)	7 (23)	31 ^o	7 (17)	41	5 (17)	40	0.78
3 months	125	29	5 (17)	51	5 (10)	5 (11)	40	5 (10)	51	5 (11)	40	0.60
Vaginal pain/sores												
Baseline	128	29	1 (3)	51	2 (4)	7 (15)	41	2 (4)	51	7 (15)	41	0.09
2 weeks	92	19	0 (0)	42	5 (12)	3 (10)	31	5 (12)	42	3 (10)	31	0.30
3 months	124	28	2 (7)	50	5 (10)	2 (4)	46	5 (10)	50	2 (4)	46	0.57
Pessary satisfaction												
2 weeks	79	15	15 (100)	40	36 (90)	22 (92)	24	36 (90)	40	22 (92)	24	0.45
3 months	94	19	15 (79)	47	36 (77)	20 (71)	28	36 (77)	47	20 (71)	28	0.81

BV, bacterial vaginosis done by Nugent criteria; N, total number of patients by frequency of pessary removal.

Data are n (%) or mean ± standard deviation unless otherwise specified.

* Due to missing data at follow-up time points and for individual variables, sample size varies from comparison to comparison.

‡ Chi-squared test p-value is for uncorrected p-values unless otherwise specified.