The effect of hydroxyquinoline-based gel on pessary-associated bacterial vaginosis: a multicenter randomized controlled trial

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OBJECTIVE: Pessaries are important options for women with pelvic floor disorders, but many pessary users experience bacterial vaginosis (BV). The aim of this study was to evaluate the effect of TrimoSan gel (Milex Pessaries, Cooper Surgical, Trumbull, CT) on BV prevalence among pessary users.

STUDY DESIGN: Women presenting for a pessary fitting completed questionnaires on vaginal symptoms and hormone therapy use and underwent a BV BLUE test and slide collection for BV analysis by Nugent's criteria. Following pessary fitting, women were randomized to either standard pessary care with the use of TrimoSan placed vaginally twice weekly or to standard pessary care without TrimoSan gel. Women returned 2 weeks and 3 months later for a repeat slide collection for Gram stain, BV BLUE testing, and completion of questionnaires on vaginal symptoms and desire to continue the pessary.

RESULTS: There were 184 women randomized after successful fitting (92 to the TrimoSan group), and 147 (79%) presented for 3-month follow up. Mean age was 56 ± 16 years; patients were mostly white (57%) or Hispanic (23%), and 36% were using hormone therapy. The groups did not differ in the prevalence of BV by Nugent's criteria at 2 weeks (20% TrimoSan vs 26% no gel, $P = .46$) or 3 months (24% TrimoSan vs 23% no gel, $P = .82$), nor did they differ in BV by BV BLUE testing at 2 weeks (0% TrimoSan vs 4% no gel, $P = .12$) or 3 months (3% TrimoSan vs 0% no gel, $P = .15$). The prevalence of at least one vaginal symptom did not differ between groups at 2 weeks (44% TrimoSan vs 45% no gel, $P = .98$) or 3 months (42% TrimoSan vs 32% no gel, $P = .30$). The TrimoSan group was equally likely to want to continue their pessary use compared with the standard care group at 2 weeks (90% vs 86%, $P = .64$) and 3 months (63% vs 60%, $P = .76$).

CONCLUSION: TrimoSan gel in the first 3 months of pessary use does not decrease the prevalence of BV or vaginal symptoms and does not alter the likelihood of a woman desiring to continue pessary use.

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Background and Objective

Many women can be successfully fitted with a pessary for the treatment of pelvic organ prolapse or stress urinary incontinence. Bacterial vaginosis (BV) is common among pessary users and may negatively affect their experience with a pessary. A mildly acidic, hydroxyquinoline-based gel dispensed with some pessaries, may lower the pH of the vagina and keep the vaginal ecosystem in balance during pessary use, but no clinical trial has examined its effect on BV or on other outcomes.

We conducted a randomized controlled trial to determine whether use of hydroxyquinoline gel decreases the prevalence of BV or bothersome vaginal symptoms during the first 3 months of pessary use.

Materials and Methods

This was a multicenter randomized single-blind controlled trial of patients who were fitted for a pessary for any indication at 2 tertiary care centers: one from July 1, 2010, through Dec. 31, 2011, and the other from July 1, 2012, through May 5, 2014. The primary outcome was the determination of BV by Nugent's criteria on Gram stain 3 months after pessary fitting.

Potential patients were identified prior to or at the time of a pessary fitting visit. Enrolled patients completed baseline questionnaires on their medical history and health, use of hormone therapy orally and/or vaginally, any products or medications being used in the vagina, and vaginal symptoms, including discharge, fishy odor, clear or gray discharge, excessive discharge, discharge interfering with sex, itching, pain, pain interfering with sex, and sores.

BV testing was performed via swab. If the test was positive, the patient was instructed to take 500 mg of oral metronidazole twice daily for 7 days.

At the time of pessary fitting, patients were randomized to standard pessary

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TABLE
Comparison of outcomes between the TrimoSan gel and no TrimoSan gel groups (intent-to-treat analysis)

Variable	TrimoSan gel, n (%) or mean ± SD[a]	No TrimoSan gel, n (%) or mean ± SD[a]	*P* value
BV by Nugent's criteria			
2 wks (n = 106, 60 TrimoSan)	12 (20)	12 (26)	.46
3 mo (n = 133, 62 TrimoSan)	15 (24)	16 (23)	.82
Total Nugent's score			
2 wks (n = 106, 60 TrimoSan)[a]	4.5 ± 2.1	4.7 ± 2.3	.75
3 mo (n = 133, 62 TrimoSan)[a]	4.7 ± 2.3	4.6 ± 2.3	.83
BV by BV BLUE test			
2 wks (n = 116, 63 TrimoSan)	0 (0)	2 (4)	.12
3 mo (n = 137, 67 TrimoSan)	2 (3)	0 (0)	.15
Pessary satisfaction			
2 wks (n = 86, 49 TrimoSan)	44 (90)	32 (86)	.64
3 mo (n = 115, 57 TrimoSan)	36 (63)	35 (60)	.76
Excellent pessary satisfaction			
2 wks (n = 86, 49 TrimoSan)	26 (53)	21 (57)	.73
3 mo (n = 115, 57 TrimoSan)	23 (40)	27 (47)	.50
Vaginal symptoms			
2 wks			
At least 1 vaginal symptom reported (n = 110, 63 TrimoSan)	28 (44)	21 (45)	.98
Vaginal discharge (n = 110, 63 TrimoSan)	14 (22)	10 (21)	.91
Vaginal itching (n = 108, 60 TrimoSan)	11 (18)	8 (17)	.82
Vaginal pain (n = 109, 61 TrimoSan)	6 (10)	3 (6)	.50
Vaginal cuts/sores (n = 55, 33 TrimoSan)	4 (12)	1 (5)	.34
≥1 vaginal symptom reported as increased since pessary fitting (n = 63, 37 TrimoSan)	15 (41)	9 (35)	.83
3 mo			
≥1 vaginal symptom reported (n = 147, 72 TrimoSan)	30 (42)	24 (32)	.30
Vaginal discharge (n 147, 72 TrimoSan)	17 (24)	12 (16)	.25
Vaginal itching (n = 147, 71 TrimoSan)	8 (11)	12 (16)	.42
Vaginal pain (n = 144, 71 TrimoSan)	6 (8)	6 (8)	.96
Vaginal cuts/sores (n = 78, 41 TrimoSan)	4 (10)	3 (8)	.80
≥1 vaginal symptom reported as increased since pessary fitting (n = 81, 42 TrimoSan)	18 (43)	13 (33)	.41

TrimoSan; Milex Pessaries, Cooper Surgical, Trumbull, CT.

BV, bacterial vaginosis.

[a] Designates that the mean +/− standard deviation is reported for that value.

Meriwether. TrimoSan gel does not affect bacterial vaginosis in new pessary users. Am J Obstet Gynecol 2015.

hygiene alone or with the addition of hydroxyquinoline gel use (half applicator of gel vaginally twice a week). Subjects were seen at 2 weeks and then 3 months later for examination and to complete repeat questionnaires on pessary use, hygiene practices, and vaginal symptoms. Women were asked how often they removed their pessary and how often they wore it and to rank their desire to continue pessary use on a 5-point Likert scale. At each examination, a midvaginal secretion swab was done to perform the BV test in the clinic and to prepare the microscopy slide for Gram staining.

We performed intention-to-treat (primary) and per-protocol analyses. For the primary outcome of BV as detected by Gram stain 3 months after pessary fitting, the study sought to achieve a power of 88% at an α of 0.05 to detect a lowering of the prevalence of BV at 3 months in the gel-using group from 30% back to the baseline rate of 10%. This translated to a sample size of 62 in each group.

Results

Of 466 women screened for eligibility during the study period, 187 were randomized. Three were excluded after randomization for inability to be fitted with a pessary at their initial visit and declining to attempt another fitting. This left 184 active eligible participants, 92 randomized to hydroxyquinoline gel use, and 92 to no gel use. The mean age of the patients was 58.6 ± 16.4 years; mean body mass index was 28.3 ± 7.5 kg/m^2; and median parity was 3. The majority of women were white (57%), Hispanic (23%), or African American (10%). The prevalence of BV (by Nugent's criteria or BV testing) and total Nugent's score were similar between groups at baseline.

The prevalence of BV did not differ significantly between groups at 2 weeks or 3 months (Table). Pessary satisfaction was not different between groups at 2 weeks or 3 months. A high degree of pessary satisfaction was similar between groups at both time points ($P > .05$). Pessary satisfaction was substantially lower at 3 months than at 2 weeks in

both groups and overall (88% at 2 weeks vs 62% at 3 months; $P < .01$).

Individual and composite vaginal symptoms did not differ between groups at 2 weeks or 3 months, although the prevalence of at least one reported vaginal symptom was high (>30% in both groups at 2 weeks and >40% in both groups at 3 months). The prevalence of an increase in at least one vaginal symptom since pessary fitting was high (>30% in both groups at 2 weeks and 3 months) but did not differ between groups.

A per-protocol analysis comparing the experience of women compliant with hydroxyquinoline gel use once a week or more with that of women who used the gel less often or not at all did not substantially change results. The reported frequency of wearing or removing the pessary did not significantly affect any of the relationships between the randomization to hydroxyquinoline gel use and BV or vaginal symptoms at 2 weeks or 3 months (all $P > .05$).

Comment

In this multicenter randomized controlled trial, hydroxyquinoline gel use in the first 3 months after initiation of pessary use did not decrease the prevalence of BV or other outcomes such as bothersome vaginal symptoms or desire to continue pessary use. Our data indicate that the presence of at least one vaginal symptom is prevalent in pessary users (>30% just 2 weeks after pessary fitting and >40% at 3 months) but that hydroxyquinoline gel use does not decrease these symptoms.

CLINICAL IMPLICATIONS

- Use of a mildly acidic, hydroxyquinoline-based vaginal gel does not decrease the prevalence of bacterial vaginosis in the first 3 months of pessary use, regardless of the use of hormone therapy or the frequency of pessary removal.
- Use of hydroxyquinoline gel does not change the prevalence of bothersome vaginal symptoms or pessary satisfaction in the first 3 months of pessary use.
- Bothersome vaginal symptoms are prevalent in the first 3 months of pessary use. ■

Survey of male perceptions regarding the vulva

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OBJECTIVE: The purpose of this study was to characterize male preferences of vulvar appearance, their awareness of labiaplasty, and their knowledge of genital anatomy.

STUDY DESIGN: Men 18-80 years old were recruited via emails sent by an Internet provider to participate in a 27-question web-based survey. The questionnaire included images and queried demographics, men's familiarity with vulvar anatomy, preferences regarding labial appearance, and awareness of labiaplasty. Two deployments to >150,000 email addresses were sent. Demographic data were described using frequencies for categoric variables and mean measures of central tendency for continuous variables. Logistic regression models were used to analyze associations between demographics and responses.

RESULTS: Two thousand four hundred three men responded to the survey. After excluding incomplete and ineligible surveys, 1847 surveys were analyzed. The median age of respondents was 55 years. The majority was white (87%), married (68%), employed (69%), and had completed high school or beyond (97%). One-third of the respondents lived in the South, with the other regions nearly equally represented. A significant majority, 95%, reported having been sexually active with women, and 86% felt comfortable labeling the vulvar anatomy. With regard to preferences, more respondents considered smaller labia attractive compared to large labia; yet 36% of the men remained neutral. Men also showed a preference for partially or completely groomed genitals compared to natural hair pattern. Whereas 51% of participants believed the appearance of a woman's labia influenced their desire to engage in sexual activity, 60% denied it affected sexual pleasure. Only 42% of men were familiar with labiaplasty, and 75% of all respondents would not encourage a female partner to change her genital appearance. Multivariable analysis revealed younger age to be associated with preferences for small labia and complete genital hair removal, as well as familiarity with labiaplasty.

CONCLUSION: In this national survey, men demonstrated familiarity with the female anatomy, but many did not feel it impacted sexual desire or pleasure. Moreover, the majority lacked strong preferences for a specific vulvar appearance and would not encourage a female partner to alter her genital appearance surgically.

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