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Severity of Bacterial Vaginosis and the Risk of Sexually Transmitted Infection

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Abstract

Objective—To determine whether the association between bacterial vaginosis (BV) and incident sexually transmitted infection (STI) varies with more extreme bacterial vaginosis scores.

Study Design—We analyzed the data from 535 women enrolled in a randomized trial to promote dual method contraceptive use. Incident STI was defined as any case of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* or pelvic inflammatory disease. BV was defined based on Gram stain (Nugent score). STI risk was estimated using proportional hazards regression.

Results—Binary (0–6 vs. 7–10) and 3-level (negative 0–3, intermediate 4–6 or BV 7–10) categorizations were not associated with time to STI; however, women with the highest Nugent scores (9–10) had a 2.7 fold increased risk of STI (95% CI 1.38–5.17) compared to women with normal flora.

Conclusion—Nugent score >8 is associated with incident STI. More accurate classification of BV will allow clinicians to identify those at greatest risk of STI.

Keywords

Bacterial vaginosis; epidemiology; sexually transmitted disease

Introduction

Bacterial vaginosis (BV) is a form of vaginitis, characterized by a shift in vaginal bacterial flora and altered pH, which is common among reproductive aged women. Estimates from the National Health and Nutrition Examination Survey (NHANES) indicate that 29% of US women between the ages of 14 and 49 have BV.[1] Rates of BV are even higher among women at high risk for sexually transmitted infection (STI). Over half of African American, 37% of those living below the federal poverty level and 39% of women with two or more sexual partners in the past month had BV at the time of their NHANES assessment.

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BV has been found to be associated with the prevalence and incidence of multiple STIs including: chlamydia, gonorrhea, herpes, HIV and trichomoniasis and is also implicated in the development of pelvic inflammatory disease (PID).[2–10] In prospective studies, BV has been shown to increase the odds of HIV acquisition [11]–[12] as well as herpes simplex virus (type 2).[13] As these prospective studies highlight, there are multiple common approaches for defining the presence of BV. In the clinical literature, BV is most often defined using two approaches: 1) Amsel's criteria (>20% clue cells, whiff test, pH, or characteristic discharge) or 2) gram stain of vaginal smears scored using Nugent's criteria reflecting the presence of three categories of bacterial morphotypes.[14] Most studies estimate STI risk using 2 (BV yes or no) or 3 level categorizations (normal, intermediate, or BV) of BV, but few take into consideration the extent of abnormal flora and the impact of alternative diagnostic thresholds for the definition of BV. In this prospective study, we seek to determine whether severity of BV - specifically, measures of extreme cases of anaerobic overgrowth (Gram stain score – 9 or 10)- is associated with incident STI. More accurate classification of BV will allow clinicians to better identify those at greatest risk of STI.

Materials and Methods

The current study was a secondary analysis of collected by Project Protect, a randomized clinical trial funded by the National Institute of Child Health and Human Development (NICHD). The methods of this study have been described in detail elsewhere.[15] Briefly, Project Protect evaluated the extent to which a computer-based individualized intervention could improve dual contraceptive method use compared to a computer-based enhanced standard care counseling approach.

Enrollment began in October 1999 and continued through October 2003. Women eligible for Project Protect included English-speaking women between the ages of 13 and 35 who were able and willing to give informed consent. Parental permission and minor assent were obtained for all participants less than 18 years of age. Women had to be sexually active with a male partner in the past 6 months and desire to avoid pregnancy for 24 months after randomization. High-risk women were recruited from two specific age groups: 1) all sexually active women age 13 – 24; and 2) high-risk sexually active women age 25 - 35 years. Women over 24 years of age were determined to be at high-risk if their history included *any* of the following: unplanned pregnancy; history of an STI; inconsistent use of contraception; or other factors that placed a patient at above average risk for unplanned pregnancy or STI (e.g., more than one sexual partner in the past six months or drug or alcohol abuse). To be eligible for participation in this study, women tested negative for all STIs or, if infected, to accept directly observed therapy with a repeat negative test of cure.

Sexually Transmitted Infections

At the time of the initial baseline visit, a member of the research team completed a gynecological and contraceptive history, performed a pelvic examination and performed tests for bacterial vaginosis and STIs. Strand-based testing (Amplified DNA Assay, Becton-Dickenson, Sparks, MD) was completed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Patients were examined for signs of pelvic inflammatory disease and genital HSV infection. Acute PID was diagnosed if patients presented with signs and symptoms consistent with the minimal criteria as outlined by the Centers for Disease Control and Prevention (STD Treatment Guidelines, 2003), and no other cause could be identified. Serologic testing was performed for syphilis and HIV. In order to determine whether a genital herpes simplex virus (HSV) infection was a primary outbreak or a recurrent infection, we collected serum to be tested for type-specific IgG and IgM. This testing was repeated at 12 and 24 months. Participants were also encouraged to contact the study team between visits if they experienced any gynecologic changes or problems.

Women with a positive test at the time of initial evaluation were treated and had a test of cure before enrolling, therefore, any positive test after baseline was considered an incident STI. The outcome of interest was defined as time from baseline to the first positive STI result. If a participant did not have an STI during the follow-up time, their observation time was censored at their last study visit. Censoring allows patients who have not experienced an event (STI) to contribute person-time to the survival analysis.

Bacterial Vaginosis

Bacterial vaginosis evaluation included both a Gram stain and Amsel's clinical criteria.[14, 16] Amsel's criteria included four clinical symptoms: 1) positive whiff test, 2) presence of thin, homogenous white/gray discharge; 3) pH > 4.5; or 4) more than 20% clue cells. Nugent's criteria estimates relative prevalence of bacterial morphotypes (lactobacilli, *Gardnerella vaginalis*/*Bacteroides*, and *Mobiluncus*). The Nugent score is calculated by assessing the presence of large gram-positive rods (Lactobacillus morphotypes; scored from 4 to 0), small gram-variable rods (G. vaginalis morphotypes; scored from 0 to 4), and curved gram-variable rods (Mobiluncus spp. morphotypes; scored from 0 to 2). Scores range from 0 to 10 with scores from 7 to 10 typically considered evidence of BV. Nugent scores were completed by the laboratory of Dr. Sharon Hillier at the University of Pittsburgh.

We investigated a number of different categorizations of BV. BV was defined first based on Amsel's clinical criteria (1: total number of criteria; 2: 2 or more criteria vs. 0–1; and 3: 3 or more criteria vs. < 3 criteria and 4: all 4 criteria) and then by gram stain Nugent score (1: continuous (0–10); 2: dichotomous score less than 7 vs. 7–10; 3 groups: 0–3 (negative), 4–6 (intermediate) vs. 7–10 (BV); 4 categories: score 0–3, 4–6, 7–8 vs. 9–10; and 5 (3 groups based on Gram stain): score 0–4, 4–8 vs. 9–10).

Confounders

All participants completed a self-administered questionnaire and a more extensive computer-based survey that collected demographic, reproductive, and sexual history data at the time of randomization. Patients self-identified their race/ethnicity as Hispanic versus non-Hispanic, African-American (Black), Caucasian (White), or other. Factors potentially associated with incident STIs were evaluated as potential confounders. These included: age, education, annual income, current cigarette smoking, pregnancy history (nulligravid or nulliparous), history of STI, history of having exchanged sex for drugs or money, reported using condoms every time they had sex at baseline, and lifetime and last month sexual partners.

Statistical Analysis

The data were analyzed using SAS (v.9.1, SAS Institute, Cary, NC). We described the sample in terms of reproductive health history and demographics and assessed the distribution of the exposure (incident BV) in our study sample. Categorical variables were compared with either a chi-square or Fisher's exact test, as appropriate. Survival curves were estimated using the Kaplan-Meier method and compared using the log-rank test. Univariable and multivariable comparisons were conducted using Cox proportional hazards regression. As a secondary analysis, the sample size was limited to the 535 women in Project Protect. However, for our primary analyses examining the comparison of Nugent scores of 9 or 10 compared to an expanded intermediate (4–8) and negative (0–3) our power was 84%. This study was approved by the Women and Infants' Hospital and the University of Rhode Island Institutional Review Boards.

Results

All 535 women enrolled in Project Protect were at high-risk for STI as determined by age or high-risk sexual behavior. Three quarters of women were 24 years of age or younger, half were white, and one quarter were black. Half had a prior unintended pregnancy or STI and one in five reported consistent condom use at the time of enrollment. Fifty two percent (95% CI 48–57) of women had 6 or more lifetime sexual partners and 15% (95% CI 12–18) had 2 or more sexual partners in the past month. BV positivity was significantly associated with increasing age, self-reported Black race, prior live birth, prior STI, number of sexual partners in the past month, sex after drinking or drug use (see Table 1). Although not statistically significant, BV positivity was lower among consistent condom users and women with fewer lifetime sexual partners.

Sixteen percent of participants (N=87) were diagnosed with an STI within 24 months. There were 53 cases of chlamydia, 25 cases of gonorrhea, 22 cases of trichomoniasis and 12 cases of PID. No primary HSV infections were detected, nor were incident cases of HIV or syphilis detected. Sixty seven women had a single infection, while 20 had more than one diagnosis. The percentage of women with an incident STI varied by category of Nugent score; twelve percent (95% CI 8–16) of women with scores 0–3 were diagnosed with an STI compared with 18% (95% CI 11–26) for women 4–6 or 7–8 and 32% (95% CI 18–49) among women with scores of 9 or 10 ($p=0.01$). For Amsel criteria, however, there was no association between increasing score and increasing percent with incident STI: 0–1 criteria had an incidence of 13% (95% CI 10–17) compared with 24% (95% CI 11–40) for 2 criteria, 17% (95% CI 8–30) for 3 criteria and 26% (95% CI 17–37) for 4 criteria ($p = 0.06$).

We examined categorizations of BV based on both Nugent score and Amsel criteria and found that the association between BV and incident sexually transmitted infection was associated with the categorization of BV (Table 2). The two most common research definitions of Nugent score, a binary categorization (0–6 vs. 7–10) or 3 level (negative 0–3, intermediate 4–7 or BV 7–10) were not associated with time to incident STI after adjustment for age, race/ethnicity, sexual partners in the past month, history of STI, prior live birth, sex after drinking and randomization group.

However, we did find that women with the highest Nugent scores (9–10) had a 2.7 fold increased risk of STI (95% CI 1.38–5.17) compared to women with normal flora. Intermediate levels of abnormal flora (4–6) were associated with a modest, but insignificant, increase in risk (HR=1.61, 95% CI 0.92–2.81) of STI. This risk was similar to women with low levels of abnormal flora (7–8; HR=1.47, 95% CI 0.86–2.54). The continuous measure of Nugent score was also associated with STI risk (HR=1.08, 95% CI 1.01, 1.16).

An examination of Amsel criteria based definitions found a similar disparity. The most commonly used clinical definition - 3 or more Amsel criteria (HR=1.37, 95% CI 0.87, 2.14) - was not significantly associated with STI risk after adjustment for potential confounders, while alternative definitions (continuous number of criteria: HR=1.14, 95% CI 1.00, 1.30; 2 or more criteria: HR=1.55, 95% CI 1.01, 2.37) remained significantly associated. When categorizing Amsel's criteria into 4 levels (0/1, 2, 3 or 4 criteria) only the presence of all 4 criteria remained significantly associated with STI risk after adjustment for confounding (HR=1.75, 95% CI 1.03–2.95).

Comment

Common definitions of BV may underestimate the risk of STI. Our data supports that women with the highest abnormal Gram stain (Nugent) scores have the greatest risk, while women with intermediate and low abnormal scores may have more modest increases in risk

of infection. Since the Gram stain may not be routinely adapted in clinical practice, additional studies are necessary to identify markers and/or tests that can identify these women that are at greatest risk for STI.

Few studies have examined the potential impact of extreme scores for bacterial vaginosis on STI incidence. Sewankambo and colleagues studied the impact of varying levels of vaginal flora on HIV-1 infection rates and similar to our study, found that women with Nugent scores of 9 or 10 had the highest rates of acquisition.[17] Similarly, Taha and colleagues examined the association with an alternate categorization of Amsel's criteria and HIV seroconversion and found the highest risk among those with 2 criteria compared to 3 or more criteria in postpartum, but not pregnant women.[18] Among pregnant women increasing number of Amsel criteria was associated with increased risk of HIV acquisition. Our analysis found a similar association as the Taha postpartum cohort examining 2 or more criteria compared with 3 or more criteria; both studies did not find an increasing risk among women with the most severe BV category as defined by Amsel's criteria. It is possible this finding for Amsel criteria in our study is due to Type II error or misclassification of BV category given the lower sensitivity of Amsel's criteria.

Our study had a number of strengths and limitations. First, it included a diverse cohort of women at risk for sexually transmitted infection with 26% African American and 17% Hispanic women. It also included prospective objective assessment of both sexually transmitted infection and BV as well as two years of follow-up. Limitations included limited power for subgroup comparisons. More specifically, there was inadequate power for race specific analysis. Further, we had a single time point for the assessment of BV. As a prospective study, BV status was assessed at the enrollment visit and was not known at the precise time of infection. Prospective studies have found that BV is variable; a sizeable minority of women return to normal levels of vaginal flora without treatment.[19–21] Whether this is common among women with Nugent scores of 9 or 10 is not known.

There are limitations in the Nugent scoring system. First, among healthy women of different race/ethnicity, there are significantly different proportions of domination by *Lactobacillus*. [22–23] For example, among white women 89.7% of bacterial communities are lactobacilli species compared with 80.2%, 61.9% and 59.6% among Asian, Hispanic and black women. [22] Thus, healthy women of ethnic and racial minorities often have higher Nugent scores than healthy white women. *Lactobacillus iners*, a common colonizer among healthy women, [24] is a short rod that on gram stain evaluation may not be scored as a lactobacillus resulting in a higher Nugent score. Finally, association is not causation. While the current analyses do adjust for recent sexual partners, it is possible that BV is a marker for high-risk sexual behavior.

We found that conventional definitions of BV were not associated with STI risk; yet, alternative definitions including continuous Nugent score and categorizations that isolate the highest Nugent scores (9–10) were significantly associated with incidence of STI. Current definitions of BV may underestimate the risk of STI for many women. BV may impact STI risk through alterations in vaginal pH,[25] differing levels of mucin-degrading enzymes [26–29] as well as through inflammatory mediators.[30–32] Investigators should also attempt to assess specific organisms in the more extreme Nugent score group that may be key pathogens in this association, and evaluate how women with more extreme Nugent scores differ in terms of bacterial colonization, bacterial metabolic products, and/or host immunologic response.

Our findings, if supported by additional studies, support the call for a more accurate assessment of anaerobic overgrowth. Gram stain scoring is unlikely to become widespread

due to logistical challenges in the clinical workflow. The Amsel criteria commonly used for BV diagnosis may be a crude representation of the degree of abnormal flora. Moreover, it may be acceptable for the assessment of vaginitis, but may not be specific for establishing the risk of adverse reproductive sequelae (e.g. incident STI, HIV acquisition, preterm birth, post-operative infection, etc). Additional studies are needed to identify the group of women with more extreme Gram stain (Nugent) scores who are at greatest risk. Finally, it is also necessary to determine whether this relationship extends to other adverse reproductive sequelae.

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Table 1
Overview of sociodemographic characteristics and reproductive and sexual history by Nugent score

	Nugent Score					p-value
	0 to 3	4 to 6	7 to 8	9 to 10		
All women	249 (46.5)	112 (20.9)	124 (23.2)	38 (7.1)		
Age						0.02
14–19	76 (50.0)	29 (19.1)	38 (25.0)	9 (5.9)		
20–24	138 (52.5)	52 (19.8)	52 (19.8)	21 (8.0)		
25 and older	35 (32.4)	31 (28.7)	34 (31.5)	8 (7.4)		
Race/Ethnicity						0.01
White	125 (50.2)	52 (46.4)	50 (40.3)	7 (18.4)		
Black	60 (24.1)	32 (28.6)	34 (27.4)	12 (31.6)		
Hispanic	41 (16.5)	18 (16.1)	18 (14.5)	9 (23.7)		
Other	23 (9.2)	10 (8.9)	22 (17.7)	10 (26.3)		
Education						0.06
< High school	50 (38.8)	28 (27.9)	36 (27.9)	11 (11.6)		
High school	88 (45.6)	45 (23.3)	46 (23.8)	14 (7.3)		
Some college	110 (55.0)	39 (19.5)	42 (21.0)	9 (4.5)		
Ever unintended pregnancy						0.14
No	136 (51.3)	58 (21.9)	57 (21.5)	14 (5.3)		
Yes	109 (43.4)	54 (21.5)	65 (25.9)	23 (9.2)		
Ever live birth						0.03
No	169 (52.3)	68 (21.1)	65 (20.1)	21 (6.5)		
Yes	80 (40.0)	44 (22.0)	59 (29.5)	17 (8.5)		
Ever STI						< 0.0001
No	161 (57.5)	47 (16.8)	53 (18.9)	19 (6.8)		
Yes	88 (36.2)	65 (26.8)	71 (29.2)	19 (7.8)		

	Nugent Score				p-value
	0 to 3	4 to 6	7 to 8	9 to 10	
Consistent condom use					
No	184 (45.3)	91 (22.4)	96 (23.7)	35 (8.6)	0.06**
Yes	64 (55.7)	21 (18.3)	27 (23.5)	3 (2.6)	
Any condom use					
No	93 (46.5)	42 (21.0)	47 (21.0)	18 (9.0)	0.70
Yes	155 (48.3)	70 (21.8)	76 (23.7)	20 (6.2)	
Lifetime sexual partners					
1 to 2	41 (60.3)	9 (13.2)	14 (20.6)	5 (5.9)	0.07**
3 to 5	93 (51.7)	33 (18.3)	45 (25.0)	9 (5.0)	
6 to 10	50 (40.3)	28 (22.6)	33 (26.6)	13 (10.5)	
11 or more	64 (42.7)	42 (28.0)	32 (21.3)	12 (8.0)	
Last month sexual partners					
0	46 (65.7)	10 (14.3)	11 (15.7)	3 (4.3)	0.01**
1	170 (45.7)	85 (22.9)	94 (25.3)	23 (6.2)	
2 or more	32 (40.5)	17 (21.5)	18 (22.8)	12 (15.2)	
Current Smoking status					
Non-smoker	134 (50.0)	56 (20.9)	63 (23.5)	15 (5.6)	0.64
< 10 cigs/day	59 (44.4)	27 (20.3)	33 (24.8)	14 (10.5)	
10+ cigs/day	55 (45.5)	29 (24.0)	28 (23.1)	9 (7.4)	
Substance use - past year					
No	98 (43.3)	40 (19.7)	54 (26.6)	11 (5.4)	0.35
Yes	149 (47.2)	71 (22.5)	69 (21.8)	27 (8.5)	
Sex after drinking/drug use					
Never	131 (52.2)	46 (18.3)	63 (25.1)	11 (4.4)	0.01
1 to 2 times	73 (45.9)	33 (20.8)	41 (25.8)	12 (7.6)	

	Nugent Score					p-value
	0 to 3	4 to 6	7 to 8	9 to 10		
3 or more times	44 (39.3)	33 (29.5)	20 (17.9)	15 (13.4)		
Treatment Group						
Control	111 (42.5)	56 (21.5)	74 (28.4)	20 (7.8)	0.05	
Intervention	138 (52.7)	56 (21.4)	50 (19.1)	18 (6.9)		

* Percentages may not sum to 100 due to rounding error

** P-value estimated using Fisher's exact test

Table 2

Risk of sexually transmitted infection within 24 months for different categorizations of bacterial vaginosis

	Crude HRR (95% CI)	Adjusted* HRR (95% CI)
Nugent Score Based Definitions		
Continuous score	1.10 (1.03, 1.17)	1.08 (1.01, 1.16)
Binary		
0 to 6	Ref.	Ref.
7 to 10	1.22 (0.98, 1.51)	1.15 (0.92, 1.44)
3 level definition		
0 to 3	Ref.	Ref.
4 to 6	1.59 (0.91, 2.77)	1.38 (0.77, 2.47)
7 to 10	1.73 (1.07, 2.79)	1.49 (0.91, 2.46)
4 level definition		
0 to 3	Ref.	Ref.
4 to 6	1.59 (0.91, 2.77)	1.38 (0.77, 2.47)
7 to 8	1.45 (0.85, 2.49)	1.28 (0.73, 2.25)
9 to 10	2.65 (1.37, 5.13)	2.11 (1.05, 4.28)
Alternate 3 level		
0 to 3	Ref.	Ref.
4 to 8	1.51 (0.96, 2.39)	1.33 (0.78, 2.02)
9 to 10	2.65 (1.37, 5.13)	2.11 (1.05, 4.28)
Amsel Criteria Based Definitions		
Continuous number of criteria	1.18 (1.04, 1.34)	1.14 (1.00, 1.30)
3 or more criteria	1.56 (1.00, 2.44)	1.37 (0.87, 2.14)
2 or more criteria	1.78 (1.17, 2.72)	1.55 (1.01, 2.37)
4 level definition		
0–1 criteria	Ref.	Ref.
2 criteria	2.07 (1.02, 4.22)	1.93 (0.93, 3.99)
3 criteria	1.40 (0.69, 2.85)	1.0 (0.49, 2.16)
4 criteria	1.90 (1.13, 3.19)	1.75 (1.03, 2.95)

* Adjusted for age, race/ethnicity, sexual partners in the past month, history of STI at baseline, prior live birth, sex after drinking or drugs, and randomization group

HRR = Hazard rate ratio