Bacterial Vaginosis in Pregnancy: Current Findings and Future Directions

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Abbreviation: BV, bacterial vaginosis.

INTRODUCTION

Bacterial vaginosis (BV) is an extremely prevalent vaginal condition and the number one cause of vaginitis among both pregnant and nonpregnant women (1). Although it is not a reportable disease, current studies have found the prevalence of BV among nonpregnant women to range from 15 percent to 30 percent; up to 50 percent of pregnant women have been found to have BV (2–5). However, the majority of cases of BV are asymptomatic and remain unreported and untreated (3, 6). Previously considered a benign condition, BV has been related to many gynecologic conditions and complications of pregnancy including pelvic inflammatory disease, posthysterectomy vaginal cuff cellulitis, endometritis, amniotic fluid infection, preterm delivery, preterm labor, premature rupture of the membranes, and, possibly, spontaneous abortion (7–12). The role of asymptomatic, compared with symptomatic, BV in both gynecologic and pregnancy-related conditions has been less studied, although research emphasis is shifting toward determining these independent relations. In laboratory and clinical studies, BV has been shown to ascend to the endometrium and invade the placenta, but the complete impact of this migration in terms of initial and sustained placental development and early fetal development is unclear (13). The purposes of this article is to review the background, diagnosis, and treatment of BV in pregnancy; discuss the epidemiology and consequences of BV in pregnancy; and outline current research findings and future research directions focusing exclusively on the consequences of BV in pregnancy.

BACKGROUND

BV is a polymicrobial, superficial vaginal infection involving a reduction in the amount of hydrogen-peroxide-producing Lactobacillus and an overgrowth of anaerobic and Gram-negative or Gram-variable bacteria (14, 15). The reduced number of Lactobacillus promote overgrowth of anaerobic bacteria, including Mycoplasma hominis, Bacteroides species, Mobiluncus species, and Gardnerella vaginalis (14, 15). Although most of these organisms are present in small numbers in the normal vagina, Mobiluncus is rarely found and is a sensitive marker for the diagnosis of BV (16). On the other hand, Gardnerella has been reported in up to 50 percent of women with no signs or symptoms of BV; therefore, the finding of Gardnerella is not a definitive diagnostic of BV (17, 18). In fact, it seems that the decrease in Lactobacillus, as opposed to the increase in other organisms, influences the vaginal flora and may be the most important predictor in subsequent BV development (19).

Studies among nonpregnant women collecting serial samples of vaginal flora have concluded that some events (either behavioral, hormonal, or environmental) occur that promote a change in the normal flora of the vagina. A recent study incorporating repeat measures of vaginal flora concentrations among women throughout the menstrual cycle reported a high rate of BV presentation during the follicular phase of the menstrual cycle and a spontaneous resolution of BV during the luteal phase. These results suggest that endogenous sex hormones may support and assist in sustaining high levels of Lactobacillus and illustrate the potential for sex hormones to influence the organisms present in the vagina (6, 20, 21).

Currently, we know of no studies that have been conducted among pregnant women to describe the changes in vaginal flora or BV prevalence during gestation. Of interest would be the assessment of BV prevalence by gestational age and the correlation between increasing sex hormone levels and BV presentation. In addition, it is
currently unknown whether the proportion of symptomatic and asymptomatic cases varies by gestational age. The presence of BV at a particular gestational age may be a factor in the subsequent development of pregnancy complications, and the risk for disease may change based on BV positivity during different stages of gestation. For example, the risk of preterm delivery due to BV in the first trimester, during early fetal and placental development, may be different compared with the risk of preterm delivery in the second and third trimesters, during profuse placental functioning. These relations currently are unknown.

**DIAGNOSIS**

Two diagnostic tests are commonly used for BV. Amsel criteria, the test most commonly used in the clinical setting, involves assessing four clinical conditions, with the existence of three or more conditions corresponding to a diagnosis of BV (figure 1). These conditions include an elevated vaginal pH (>4.5), an amine or fishy odor when vaginal fluid is prepared with 10 percent potassium hydroxide solution (called the “whiff test”), the presence of clue cells on wet mount, and a homogeneous vaginal discharge. In brief, clue cells are vaginal epithelial cells coated with bacteria that look speckled rather than translucent and have serrated or unclear borders because of the adherent bacteria (22). The updated Amsel criteria specify that at least 20 percent of epithelial cells should be clue cells, although these amended criteria may reduce the sensitivity of the test (7). In the past, the Amsel criteria was the most common method of identifying BV; however, there are inherent difficulties with each of the individual parameters. Assessment of vaginal pH lacks specificity because an increase in vaginal pH may be a consequence of many other lower genital tract conditions, conduct of the whiff test is subjective for each individual clinician and lacks sensitivity, and identification of clue cells may vary according to the skill and interpretation of the microscopist and the quality of sample collection (11).

The second, more commonly used diagnostic test involves a Gram stain of vaginal fluid and use of Nugent criteria to identify a case of BV (figure 1). This method has been shown to have a high sensitivity and specificity compared with Amsel criteria (89 percent and 83 percent, respectively) (23, 24). A vaginal swab is obtained, spread on a glass slide, air dried, and later Gram stained. The amount of three morphotypes is quantified and scored: *Lactobacillus*, *Mobiluncus*, and *Gardnerella*. For *Lactobacillus*, scores range from 0 to 4; 0 indicates that 30 or more organisms were found, and 4 indicates that no organisms were found in the sample. In contrast, for *Gardnerella*, a score of 0 indicates that no organisms were found and the highest score, 4, indicates that 30 or more organisms were found. For *Mobiluncus*, scores range from 0 to 2, with a score of 2 indicating that five or more organisms were identified in the sample. A summary BV score is computed ranging from 0 to 10; this score is dichotomized, with values of 7 and over indicating a case of BV (25).

The validity of BV diagnosis given the method of swab collection (either self-collected or provider collected) has been examined (26). Using self-collected vaginal swabs may be particularly attractive for epidemiologic studies because this method does not require recruiting study participants from clinical settings, and it facilitates repeat sampling for studies designed to measure BV status at multiple points in time. Two studies of nonpregnant women assessing the validity of self-compared to provider-collected swabs to detect BV found excellent validity when the two methods were compared (26).

The Nugent criteria is the test most often used in epidemiologic studies such as the large-scale ones conducted by the Maternal-Fetal Medicine Network Units of the National Institute of Child Health and Human Development (27, 28). This method has several advantages that include 1) creating a permanent record that can be subsequently reviewed to confirm the diagnosis of BV and assess the reliability of the reading; 2) reporting intermediate stages of BV, which is
particularly useful in longitudinal studies examining serial vaginal fluid samples for changes in BV status; and 3) quantifying the amount of the three individual organisms, enabling assessment of the organism-specific risk of disease.

More recently, BV is beginning to be considered a condition with a spectrum of positivity. Currently, a case of BV is classified as either positive or negative without an organism-specific definition or an assessment of organism-specific risk for disease. In addition, to our knowledge the relation between BV and risk of disease has not been assessed recognizing that the summary BV score itself, ranging from 0 to 7, indicates a continuous degree of BV positivity. In the future, studies should relate a dose-response disease risk to individual BV scores as well as examine the affect of the separate organisms on disease occurrence. Thus, we are in the early stages of both identifying and diagnosing BV as well as determining the relation between BV and adverse pregnancy outcomes.

**TREATMENT**

What is meant by “cure”? Typically, a cure for BV refers to resolution of symptoms and perhaps a repeat BV-negative screen. We know from clinical studies that BV has both a spontaneous resolution and recurrence, but the factors contributing to this resolution or recurrence are unknown (29). In addition, the behavioral, hormonal, or environmental factors predisposing a woman to multiple, recurrent cases of BV are also unclear. This section reviews current therapies to treat BV during pregnancy. It is important to recognize that the diagnostic tests we describe, which are used to detect BV, collect fluid samples from the vagina; however, we know that BV ascends to the upper genital tract. Therefore, identifying factors that predict BV ascension and the efficacy of treatment therapies to resolve lower and upper genital tract infection are important. The efficacy studies described refer to the cure rate for the initial case of BV and do not attempt to follow the patient for recurrence. As many as 30 percent of women relapse within 1 month of treatment, with spontaneous relapse occurring more commonly among women treated with topical compared with systemic antibiotics (29).

The most common oral treatment for BV in both pregnant and nonpregnant women is metronidazole (30). The individual cure rate given a 7-day, twice-daily course of 500 mg of metronidazole ranges from 84 percent to 96 percent, and the cure rate given a 2-g single dose of metronidazole is 54–62 percent (31). Previously, there was concern regarding use of metronidazole during the first trimester of pregnancy before the completion of organogenesis (32, 33). However, a small study examining children exposed in utero to metronidazole suggested no evidence of long-term teratogenic effects (34). Although it was long considered an effective treatment for the resolution of symptoms related to BV, an interesting article recently reported that high concentrations of metronidazole, greater than 5,000 µg/ml, completely suppressed the growth of Lactobacillus and that concentrations of 1,000–4,000 µ/ml significantly inhibited the growth of Lactobacillus (35). Therefore, the dose of metronidazole may be important in determining both the cure and the recurrence rate.

The second systemic treatment for BV is oral clindamycin. The one known clinical trial conducted describing the efficacy of oral clindamycin reported that a 300-mg, twice-daily course of clindamycin for 7 days resulted in a 94 percent cure rate (31). Of note, all of the efficacy studies have been conducted among nonpregnant women, with the assumption that the cure rate for BV among pregnant woman is similar.

The two topical treatments for BV include metronidazole 0.75 percent vaginal gel and clindamycin 2 percent vaginal cream. A twice-daily, 5-day therapy of vaginal metronidazole had a reported cure rate of 75–81 percent, while treatment with clindamycin cream was reported to resolve 82–96 percent of cases of BV (36). The efficacy of the 3-day treatment and the 7-day treatment of clindamycin cream has been found to be equally effective and well tolerated in treating BV (37). Again, these topical treatments result in the resolution of lower genital tract infection but do not treat BV occurring in the upper genital tract. What is the correlation between lower genital tract resolution and upper genital tract resolution? Currently, the answer is unknown.

**EPIDEMIOLOGY: RISK FACTORS**

Much information is known regarding the microbiology and identification of BV; however, limited information exists concerning the factors or behaviors that increase a woman’s risk for BV during pregnancy. The current predictors of BV have been limited to race, sexual activity, socioeconomic status, and perhaps vaginal douching. Most of the epidemiologic studies conducted to date to determine risk factors for BV have concentrated on symptomatic cases and included results from women seeking care in sexually transmitted disease clinics or inner-city obstetric offices. Generalizability of the current literature is unclear since asymptomatic cases have not been examined fully and the current data represent only a subset of women of reproductive age. Nonetheless, the reported prevalence of BV among pregnant women ranges from 10 percent to 35 percent, with higher rates occurring among African-American women, low-income women, or women with prior sexually transmitted diseases (10, 38, 39). The Vaginal Infections and Prematurity Study, which measured BV among pregnant women between 23 and 26 weeks of gestation, found a 2.0- to 2.5-fold increased risk of BV among African-American compared with White pregnant women (10). Numerous studies have confirmed at least a twofold increased risk of BV among African-American women presumably due to environmental/behavioral exposures or stressors (40, 41).

Women of lower socioeconomic status and women self-reporting higher levels of psychosocial stress also have increased rates of BV. In recent studies among obstetrics populations, the reported prevalence of BV ranged from a low of 10 percent among private patients to a high of 35 percent among women reporting low monthly incomes and low educational levels, although these studies did not adjust for race (42, 43). Culhane et al. assessed the role of chronic maternal stress, as measured by the Cohen perceived stress scale, and found that independent of sociodemographic and
behavioral factors, chronic maternal stress remained a significant predictor of BV among pregnant women (44).

Epidemiologic studies have found that early sexual activity, a high number of lifetime sexual partners, women with a new sexual partner, and women with a prior sexually transmitted disease are also at increased risk of BV (45–47). BV is more prevalent among women with a prior or current sexually transmitted disease. However, the occurrence of BV may be the direct consequence of exposure to the infectious pathogen, not the sexual behavior. In fact, many pathogens have been shown to change vaginal flora by reducing the concentration of Lactobacillus and promoting anaerobic bacteria proliferation and subsequent BV development (29). Although sexually transmitted diseases and BV commonly coexist, particularly trichomoniasis and BV, BV is not considered a sexually transmitted disease (48–51). For example, a study among school-age girls found similar rates of BV among virgin girls and nonvirgin girls (12 percent and 15 percent, respectively) (49). Furthermore, although the anaerobic organisms in excess in cases of BV have been cultured from the male sexual partners of women with BV, treatment of male sexual partners is not a reliable way to reduce the recurrence of BV in these women (51). However, a small study of monogamous lesbian women concluded that the likelihood of one partner having BV was 20 times greater if the other partner was BV positive (odds ratio = 19.7, 95 percent confidence interval: 2.1, 588.0), supporting the early finding by Gardner and Dukes that BV is transmissible through direct inoculation of vaginal secretions (50, 52).

Some behaviors, such as vaginal douching, have been examined as potential risk factors for BV. Among nonpregnant women, self-reported vaginal douching has been reported to increase the risk of BV (53, 54). Holzman et al. found more than a twofold increased risk of BV among nonpregnant women who self-reported vaginal douching in the prior 2 months (4). No known studies have been published to date examining the role of douching and BV development among pregnant women. Vaginal douching may change the vaginal flora, reduce the amount of Lactobacillus, and create an environment promoting excessive anaerobic growth; on the other hand, the act of douching may be a consequence of the symptoms of BV (i.e., vaginal discharge and odor) or a current sexually transmitted disease (53, 54). Currently, prospective studies are under way to answer these questions.

**EPIDEMIOLOGY: ADVERSE PREGNANCY OUTCOMES**

BV is very prevalent among reproductive-age women, but, for a common condition, the subsequent risk of adverse pregnancy outcomes is marginal (11, 56). The finding of a relatively low risk for a variety of events may in fact be due to the imprecise definition of exposure. As discussed previously, BV is a syndrome with degrees of positivity. The current literature has examined the relation between BV positivity and health outcome, but currently we know of no studies that have examined the organism-specific risks for disease. In addition, it is unclear whether BV is the risk factor for disease or whether exposure to BV or the various microorganisms causes inflammatory changes that are the necessary event predicting adverse outcomes. We do know that BV diagnosed from the lower genital tract has been related to 1) an increased potential for other vaginal pathogens to gain access to the upper genital tract, 2) the presence of enzymes that reduce the ability of leukocytes to reduce infection, and 3) an increased level of endotoxins stimulating cytokine and prostanoid production (57–61). In fact, Imseis et al. reported higher vaginal levels of interleukin-1 beta, an inflammatory cytokine, among pregnant women with BV, and Spandorfer et al. found higher levels of both cervical interleukin-1 beta and interleukin-8 cytokine levels among nonpregnant women with BV (62, 63). Future BV research should attempt to define BV exposure and to outline the inflammatory consequences of BV exposure and risk of adverse pregnancy outcomes. The next section reviews the studies conducted to date examining the role of BV and pregnancy outcomes.

The vast majority of epidemiologic research designed to examine the role of BV and adverse pregnancy outcomes has focused on the risk of preterm delivery, although many of these studies incorrectly combined preterm labor and preterm, premature rupture of the membranes. In any case, these studies have consistently shown a twofold increased risk of preterm delivery among women diagnosed with BV, particularly BV diagnosed in the early second trimester (11, 55, 56). A recent meta-analysis reviewing studies examining the role of BV and the risk of preterm delivery reported a summary odds ratio of 1.6, indicating a 60 percent increased risk of preterm delivery among pregnant women with BV. A smaller number of studies have assessed the relation between BV and the outcomes of premature labor, low birth weight, and premature rupture of the membranes. One study examining several pregnancy outcomes related to BV diagnosed during the first trimester of pregnancy reported a 2.6-fold increased risk of preterm labor (95 percent confidence interval: 1.3, 4.9), a 6.9-fold increased risk of preterm delivery (95 percent confidence interval: 2.5, 18.8), and a 7.3-fold increased risk of preterm, premature rupture of the membranes (95 percent confidence interval: 1.8, 29.4) (11). Another study found that BV diagnosed in the second trimester was associated with an increased risk of preterm delivery and premature rupture of the membranes and that BV accounted for 83 percent of the attributable risk for preterm birth (64).

A growing body of literature has begun to suggest an increased risk of spontaneous abortion among pregnant women with BV (12, 65, 66). Studies have reported a three- to fivefold increased risk of spontaneous abortion among pregnant women with BV in the first trimester, although these studies were hampered by small sample size (12, 65). Two additional studies among high-risk pregnant women also reported an increase in spontaneous abortion among women diagnosed with BV (66, 67). A study enrolling women undergoing infertility treatment found more than a twofold increased risk of spontaneous abortion among women with BV after adjustment for maternal age, prior livebirth, and self-reported cigarette smoking (relative risk = 2.67, 95 percent confidence interval: 1.26, 5.63) (66).

Numerous clinical trials have examined the efficacy of oral and topical BV treatment to reduce the risk of preterm
delivery and have found no reduced risk among pregnant women receiving topical treatments for BV (68, 69). Although controversial, the studies of oral therapies have suggested different therapeutic approaches for symptomatic, asymptomatic, and high-risk pregnant women. Symptomatic pregnant women with BV are treated to alleviate symptoms, with prevention of adverse events (i.e., preterm birth, preterm labor, premature rupture of the membranes) desirable but not well documented (31). The treatment of asymptomatic BV-positive pregnant women and the possible reduction in adverse pregnancy outcomes are also unclear. Three separate placebo-controlled randomized clinical trials indicated a reduction in the risk of preterm delivery following treatment with metronidazole; however, in two studies, the reduction was found in only the small subset of high-risk asymptomatic pregnant women (70–72). In fact, a meta-analysis of all randomized controlled trials of BV in pregnancy found no benefit to BV treatment in average-risk women for any pregnancy outcome (73). In addition, a recent clinical trial did not find a reduction in the occurrence of preterm delivery among either high-risk or low-risk asymptomatic pregnant women following treatment with oral metronidazole (28). In clinical practice, high-risk asymptomatic pregnant women are commonly screened in the early second trimester and are treated with oral metronidazole, but the benefit of this therapy in reducing the woman’s risk of preterm delivery remains unclear (74).

**CONCLUSION**

BV is an enormous public health problem, accounting for the majority of cases of vaginitis and vaginal discharge in the United States. Although symptomatic BV is an extremely prevalent vaginal condition among pregnant women, the true magnitude is not known because more than one half of BV cases are asymptomatic. Studies developed to quantify the prevalence of symptomatic and asymptomatic BV among pregnant women and to determine whether BV differs by gestational ages would be useful. Given the limited information regarding the factors and behaviors placing a woman at increased risk for BV in pregnancy, additional research in this area is also needed. It is essential to conduct large-scale epidemiologic studies to determine behavioral, hormonal, or environmental factors and/or comorbidities that increase a woman’s risk for BV in pregnancy and to explore the association of race, socioeconomic status, sexually transmitted diseases, and vaginal douching with BV presentation.

Current studies relating BV to adverse pregnancy outcomes have measured and categorized BV positivity from samples of the lower genital tract. These lower genital tract measurements of BV have been moderately related to the risk of adverse events, with the corresponding assumption being the eventual ascension of these organisms to the upper genital tract. The biologic or environmental events promoting the ascension of lower genital tract bacteria to the upper genital tract are of extreme interest but have not been adequately examined to date. In addition, the predictors of recurrent BV and spontaneous resolution of BV are important. Only when these microbiologic, epidemiologic, and sociologic determinants of BV are examined fully will we as a public health community begin to understand and prevent the occurrence of BV in pregnancy.

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