

Asymptomatic Bacterial Vaginosis: Should You Be Concerned?... (continued from p. 1)

Health care professionals can take a step further to help diagnose asymptomatic BV. Routine screening for BV is occurring more frequently in medical offices. According to preliminary results from a recent study presented at the annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology, fewer than 3 of the 4 Amsel criteria may need to be met for an accurate diagnosis of BV. Elevated pH tests predicted 80% of patients with BV and positive amine tests provided 97% accuracy. Together, the tests predicted BV to 99% accuracy.⁴

"Although Gram staining is the gold standard for diagnosing BV, it's rarely done outside of research settings," says Richard Sweet, MD, Professor and Chairman of the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of Pittsburgh School of Medicine and Magee-Womens Hospital in Pittsburgh, Pennsylvania. According to Dr. Sweet, "Routine screening for all patients can be simplified with these in-office tests, without sacrificing accuracy, and at a low cost to the patient."

Length of Therapy... (continued from p. 1)

National Vaginitis Association (NVA), "When it comes to treatments for vaginitis, patients think that 1 day is better than 3 days, which is better than 7 days. But since the introduction of shorter therapies, for BV in particular, we're starting to see a fall in cure rates and an increase in recurrent and challenging cases."

Recurrent BV is a particular challenge for the clinician. Studies have shown that in 30% of women with BV, the condition will recur within 3 months, and in 80% of women with BV, within 9 months.² Anecdotal evidence suggests that retreatment with a different regimen for at least 7 days produces results, although formal studies are needed. One pilot trial showed that twice-weekly maintenance therapy with metronidazole intravaginal gel for 3

months reduced symptomatic recurrence. Only 17% of patients in the treatment group experienced a recurrence versus 67% of women in the placebo group.²

If efficacy and patient compliance are important considerations when determining which treatment to prescribe, health care providers may need to think twice about giving patients a choice based on length of therapy. "In order to help prevent recurrences and particularly for complicated cases of vaginitis, health care providers should resist recommending shorter treatments," says Eschenbach, "and focus on educating patients about the importance of completing courses of therapy."

Although it is often considered a barrier to compliance, length of therapy may one day

be considered the important factor in curing vaginal infections, including BV. More research is still needed to examine the long-term efficacy of shorter treatments. For now, health care professionals should continue to encourage patients to use treatments correctly, discourage patients from interrupting the course of therapy based solely on resolution of symptoms, and conduct tests to ensure that the therapy resulted in a cure.

References:

1. Broumas AG. Potential patient preference for 3-day treatment of bacterial vaginosis. *Adv Ther.* 2000;17(3):159-166. 2. Sobel JD, Leaman D. Suppressive maintenance therapy of recurrent bacterial vaginosis utilizing 0.75% metronidazole vaginal gel. *Int J Gynaecol Obstet.* 1999;67(suppl 1):S41.

References:

1. Priestly CJ, Jones BM, Dhar J, Goodwin L. What is normal vaginal flora? *Genitourin Med.* 1997;73(1):23-28. 2. Eschenbach DA, Hillier S, Critchlow C, Stevens C, DeRouen T, Holmes KK. Diagnosis and clinical manifestations of bacterial vaginosis. *Am J Obstet Gynecol.* 1988;158:819-828. 3. 2001 National Study of Women Regarding Awareness and Treatment of Vaginal Infections. 3M Pharmaceuticals; March 2001. 4. Gutman RE. Simplify testing for bacterial vaginosis without sacrificing accuracy. Poster presented at: Annual Meeting of the Infectious Diseases Society for Obstetrics and Gynecology; August 2001; Quebec City, Canada.

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Asymptomatic Bacterial Vaginosis: Should You Be Concerned?

In the past, bacterial vaginosis (BV) was considered a nuisance condition that was treated to eliminate annoying symptoms. More recently, studies have associated BV with potentially serious conditions, including upper genital tract infections, pregnancy complications, and an increased risk of acquiring HIV and other sexually transmitted diseases. Even with greater importance placed on BV, it can be difficult to cure and goes undetected in many women. Some studies show that symptoms of BV can be intermittent and as many as 35% of women with BV are asymptomatic.^{1,2}

Many women are unaware of the symptoms associated with BV. In a recent survey of 300 women, 21% of those polled had never heard of BV and nearly 50% of women could not identify its symptoms. Interestingly, when asked about normal vaginal health, nearly one third of the women polled thought it was normal to have vaginal odor, and 1 in 4 women thought it was normal to have itching. One in 3 women thought it was abnormal to have discharge.³

Because there are so many misconceptions about vaginal health, health care professionals need to take an active role in educating their patients and helping them identify symptoms of infection. This can often be accomplished during the patient's history. Following are several tips to help establish open communication when obtaining a complete history:

- Ask questions and encourage conversation. If patients feel comfortable discussing their vaginal health, they'll be more likely to offer information that may lead the health care professional to diagnosing an infection.
- Discuss what is "normal." Often patients believe they are asymptomatic when in fact they are not, or believe symptoms such as a foul or "fishy" odor is normal for them.
- Discuss symptoms of infection. If a patient presents with an infection, ask about the duration of symptoms and when the patient first noticed symptoms.
- Discuss potential risk factors for vaginal infections, including sexual history and chronic gynecological conditions.
- Let women know the potential consequences of ignoring a vaginal infection.
- Discourage the use of douches and perfumed sanitary products.
- Dissuade the use of over-the-counter antifungal treatments or home remedies to treat a suspected infection. Encourage women to alert their health care provider about any unusual symptoms for proper diagnosis and treatment.
- If a woman presents with symptoms, test for infection and proceed with the appropriate treatment.
- Inform asymptomatic patients if they have a diagnosis of BV, and recommend an appropriate treatment.

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Length of Therapy:

Are shorter regimens really the best choice?

Over the past few years, shorter courses of therapy have gained popularity among patients and health care providers. When suffering from vaginal infections, most women would opt for the easiest and shortest course of therapy to relieve their symptoms. In fact, results from a recent patient preference survey suggest that women would more likely

comply with treatment guidelines if they were prescribed a shorter course of therapy.¹

The problem, however, may be that a "quick fix" solution doesn't always provide the most effective therapy. According to Dr. David Eschenbach, Professor of Obstetrics and Gynecology at the University of Washington in Seattle and member of the

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NVA NEWS

The National Vaginitis Association (NVA) has actively participated in a national education campaign for bacterial vaginosis sponsored by 3M Pharmaceuticals. Television journalist Deborah Norville, the host of *Inside Edition*, is the celebrity spokesperson for this campaign to educate women on vaginal infections.

In June 2001, Norville hosted a press event in New York City and was joined by several NVA members, including Sharon Hillier, PhD, Professor and Director of Reproductive Infectious Disease Research at Magee-Womens Hospital in Pittsburgh, PA; David Soper, MD, Professor of Obstetrics and Gynecology at the Medical University of South Carolina in Charleston; and EJ Mayeaux, MD, Professor of Family Medicine at Louisiana State University Health Sciences Center in Shreveport, Louisiana. Each played an integral role in educating women about BV through the national media.

In September, Norville made an appearance at the Women's Expo in Orlando, Florida, with NVA member Cynthia Selleck, ARNP, DSN, professor at the College of Medicine at University of South Florida in Tampa. Capacity crowds were on hand to hear the latest about preventing vaginal infections and maintaining good vaginal health. The BV awareness campaign with Deborah Norville will continue through 2002.

For more information about the NVA, click on to the NVA's official website, www.vaginalinfections.com. The website provides vaginal health resources for health care practitioners and consumers, including the consumer brochure "Women's Guide to Vaginal Infections."

FREE BROCHURES

Free Consumer Brochures Now Available

TV journalist Deborah Norville, host of *Inside Edition*, is featured in a new consumer brochure entitled, "Straight Talk About Vaginal Health with Deborah Norville." The new brochure discusses the symptoms, causes and treatments of vaginal infections, including bacterial vaginosis, the most common vaginal infection, and yeast infections. Health care professionals can order quantities of the brochure from 3M Pharmaceuticals for women in their practices.

To order brochures and other educational materials on vaginal health, please call 1-800-4BV-NEWS or for more information visit the website, www.vaginalinfections.com.

More Than a Nuisance:

The Very Real

Health Threat of Bacterial Vaginosis

For many, BV is considered to be nothing more than an annoyance—a condition not worthy of screening and one whose treatment often focuses on symptom relief, not cure. Unfortunately, the reality is very different, and the health threat, very real.

Bacterial vaginosis poses serious gynecologic and obstetric risks. Gynecologically, BV is associated with morbidity ranging from pelvic inflammatory disease to postsurgical infection to increased likelihood of acquiring HIV and other sexually transmitted diseases. From an obstetric standpoint, the risks are even greater. They range from miscarriage to preterm labor and delivery to postpartum infection. All are very good reasons to take BV seriously—reasons to screen for it and treat it as the problematic condition that it is.

BV-Associated Gynecologic Morbidity

Numerous studies have investigated the etiology of gynecologic concerns such as post-abortion endometritis, pelvic inflammatory disease, posthysterectomy infections, pelvic cuff cellulitis, urinary tract infections, and cervical intraepithelial neoplasia.¹⁻³ While the causes of these conditions are many and varied, an etiologic component seen frequently in all is abnormal vaginal flora—namely, BV. Which is not to say that BV is always the culprit, but an association is clear.

BV's Role in Obstetric Complications

Bacterial vaginosis is a special concern in pregnant women. Women with BV are at greater risk for a host of obstetric complications: miscarriage, first trimester bleeding, chorioamnionitis, amniotic fluid infection, preterm premature rupture of membranes, preterm labor and delivery, and delivery of low birth weight babies.^{1,2,4} In addition, the organisms that cause BV are associated with postpartum and postcesarean endometritis.²

Given the prevalence of BV in pregnant women—approximately 20% in one study²—and the fact that women with BV are more than 3 times as likely as those without BV to experience preterm labor,⁵ it is essential that all pregnant women be evaluated for vaginal symptoms so that those with BV can be treated.

The HIV connection

The emergence of data linking BV infection to HIV acquisition further underscores the need for BV screening and treatment. At home and around the world, BV has been shown to be associated with an increased risk of HIV acquisition.^{6,7} It is theorized that the presence of hydrogen peroxide and lactic acid seen in women with healthy vaginal flora that includes lactobacilli reduces a woman's susceptibility to HIV infection. This theory is borne out in studies showing that women with abnormal vaginal flora that lacks adequate levels of lactobacilli have a greater risk of HIV acquisition and, if pregnant and already HIV-positive, a greater risk of fetal transmission.^{7,8} What's more, they also have a greater risk of acquiring trichomoniasis and gonorrhea.⁷

Dr. Sharon Hillier of the University of Pittsburgh goes so far as to posit that BV infection puts women at increased risk of HIV and gonorrhea acquisition.

Considering the evidence, it may well be that greater control of BV can reduce the incidence of HIV acquisition.

Just a nuisance? No.

The research is clear. Bacterial vaginosis is more than an annoyance, it is a significant health problem with potentially serious consequences. Knowing what we do, it is imperative that we screen our patients for BV and that those shown to have the infection be treated with therapy that spares protective lactobacilli.

BV-Associated Morbidity Gynecologic

- Pelvic inflammatory disease
- Postsurgical infection
- Pelvic cuff cellulitis
- Urinary tract infection
- Cervical intraepithelial neoplasia
- Increased risk of acquiring HIV and other STDs

Obstetric

- Miscarriage
- First-trimester bleeding
- Chorioamnionitis
- Amniotic fluid infection
- Preterm premature rupture of membranes
- Preterm labor and delivery
- Delivery of a low birth weight baby
- Postpartum endometritis
- Postcesarean endometritis

References:

1. Mayeaux EJ Jr. Work-up of bacterial vaginosis. *The Female Patient*. 2001;26:1-5.
2. Ament LA, Whalen E. Sexually transmitted diseases in pregnancy: diagnosis, impact, and intervention. *JOGNN*. 1996;25:657-666.
3. Gujjon F, Paraskevas M, R and F, Heywood E, Brunham R, McNicol P. Vaginal microbial flora as a cofactor in the pathogenesis of uterine cervical intraepithelial neoplasia. *Int J Gynaecol Obstet*. 1992;37:185-191.
4. French JL, McGregor JA, Draper D, Parker R, McFee J. Gestational bleeding, bacterial vaginosis, and common reproductive tract infections: risk for preterm birth and benefit of treatment. *Obstet Gynecol*. 1999;93:715-724.
5. Gravett MG, Hummel D, Eschenbach DA, Holmes KK. Preterm labor associated with subclinical amniotic fluid infection and with bacterial vaginosis. *Obstet Gynecol*. 1986;67:229-237.
6. Royce RA, Thorp J, Granados JL, Savitz DA. Bacterial vaginosis associated with HIV infection in pregnant women from North Carolina. *J Acquir Immune Defic Syndr Hum Retrovirol*. 1999;20:382-386.
7. Martin HL, Richardson BA, Nyange PM, et al. Vaginal lactobacilli, microbial flora, and risk of human immunodeficiency virus type 1 and sexually transmitted disease acquisition. *J Infect Dis*. 1999;180:1863-1868.
8. Gray RH, Wawer MJ, Taha T, et al. Depleted vaginal lactobacilli and BV increase HIV acquisition in studies in Uganda and Malawi. In: Program and abstracts of the IDSA 35th Annual Meeting; September 13-16, 1997; San Francisco, Calif. Abstract 763.

ON THE HORIZON

Several studies on BV published during 2001 shed new light on the association between BV and gynecological complications, including pelvic inflammatory disease and endometritis, and the negative effects of douching. In addition, the US Preventative Service Task Force met again to determine their guidelines for treatment and prevention of various conditions—including BV.

Douching and Endometritis

Results from the pelvic inflammatory disease (PID) evaluation and clinical health (PEACH) study appeared in the April 2001 issue of *Sexually Transmitted Diseases*. The goal of the study was to examine douching practices and the associated risk of PID among various race or ethnic groups. Researchers found that of the 654 women who participated in the multi-center trial, those with fewer than 13 years of education—especially the subgroup of African-American women with endometritis or upper genital tract infection—were more likely to have douched more than once a month or six days prior to enrolling in the study.¹

Prevention of Postcesarean Endometritis

The November 2001 edition of *Obstetrics and Gynecology* featured a study entitled “Adjunctive intravaginal metronidazole for

the prevention of postcesarean endometritis: a randomized controlled trial.” This placebo-controlled, randomized study from the University of Florida examined the benefit of preoperatively administering metronidazole intravaginal gel in women undergoing cesarean deliveries. Two hundred twenty-four women of at least 24 weeks' gestation, undergoing cesarean deliveries for different indications, were randomized into two groups receiving either 5 g of metronidazole intravaginal gel or a placebo. All patients underwent the same procedures, including abdominal cleansing and prophylactic antibiotics after cord clamping. Researchers found that the patients treated with metronidazole intravaginal gel had a significantly decreased incidence of postoperative endometritis compared to patients given the placebo.²

Douching and BV

The October 2001 issue of the *American Journal of Public Health* featured a study examining factors linked to BV, including race/ethnicity, years of education, sexual practices, methods of birth control, and hygiene practices. According to the cross-sectional study of 496 nonpregnant women, the two lifestyle factors that had the strongest association with BV were systemic contraceptives and douching.

Researchers found a reduction in BV in the subgroup of women using hormones but a statistically significant increase in the prevalence of BV among women who douched. Compared to women who had not douched in the past 2 months, women who reported douching were more than 3 times more likely to have BV.³

Task Force Guidelines

In 2001, the third US Preventative Service Task Force (USPSTF) released recommendations on BV. Despite research showing that pregnant women with BV have a higher risk of pre-term delivery, the USPSTF determined that there is no conclusive data that show treating pregnant women decreases that risk. However, for pregnant women with a history of pre-term delivery, routine screening and treatment is left to the discretion of the health care provider, according to the USPSTF.

References:

1. Ness RB, Soper DE, Holley RL, et al. Douching and endometritis: results from the PID evaluation and clinical health (PEACH) study. *Sex Transm Dis*. 2001;28:240-245.
2. Pitt C, Sanchez-Ramos L, Kaunitz AM. Adjunctive intravaginal metronidazole for the prevention of postcesarean endometritis: a randomized controlled trial. *Obstet Gynecol*. 2001;98(5 Pt 1):745-750.
3. Holzman C, Leventhal JM, Qiu H, Jones NM, Wang J and the BV Study Group. Factors linked to bacterial vaginosis in nonpregnant women. *Am J Pub Health*. 2001;91:1664-1670.

BV as an Emerging Infectious Disease: A Conversation With Ned Hook, MD

While some infectious diseases can obviously be considered “emerging,” medical experts continue to debate whether BV can be categorized in this way. In the following interview, infectious diseases expert Ned Hook, MD, Professor of Medicine/Epidemiology and Co-Director, Interdisciplinary Center for Social Medicine and STDs at the University of Alabama School of Medicine in Birmingham, discusses his views on the topic.

Q: What is an emerging infectious disease?

A: Generally speaking, an illness is considered emerging if it meets any one of 3 criteria: we didn't realize it existed before, we didn't realize how common or important it was, or it's been recognized but not appreciated for its importance. Traditionally it's a new illness and in most instances the pathogens are new. Legionnaires' Disease, AIDS, Lyme Disease, and genital warts are all examples of emerging illnesses.

Q: Do you consider BV emerging?

A: Clearly BV is emerging. It's a disease that has an important impact on health, it's common, and our knowledge and understanding has increased at a dramatic rate. Even today there are huge deficits in our knowledge about BV.

Q: What new issues regarding BV make it emerging?

A: There are several. For instance, the whole concept that this is a disease in which something happens to the organisms that normally protect the vagina has many implications, particularly in terms of therapy. There's also the question of recurrent BV. We now know that one quarter to one third of women with BV will have a second episode within 2 months. I think in the next few years we will have new strategies for preventing recurrent BV, and one of the most prominent approaches will be periodic prophylaxis, or periodic treatment on a regular or scheduled basis to avoid the vaginal ecosystem from getting out of kilter. For instance, we know that a healthy vaginal environment can be disrupted for a variety of reasons, including menses and a change in sexual partner. It may be that a dose of metronidazole gel prior to these events will help prevent recurrences, and researchers are currently investigating this approach.

Also, we've recently come to understand that as common as BV is in North America, it's even more common in developing countries.

For example, a study in Uganda by Sewankambo et al showed that as many as 50% of the women have BV and it seems to recur more and be more of a problem, including contributing to HIV acquisition. Emerging data regarding this syndrome as a contributor to HIV risk is a huge public health issue if you consider the proportion of women affected by BV.

Q: Some consider BV an incurable syndrome. What do you think?

A: I think that characterization doesn't really address the problem. Our cure rates are remarkably poor—we accept a cure rate for BV that we wouldn't accept for almost all diseases—but that doesn't put BV into the emerging category. We can clearly cure the disease in many women who have it.

Q: Why is BV still not recognized by many health care providers?

A: In terms of reproductive health, there's not a lot of attention paid to vaginal discharge syndromes. People aren't comfortable talking about it, it's not taught well in medical schools, and by and large, physicians are less well trained about it than other advanced practice clinicians. There's been a long tradition of misconception that BV is just a nuisance and doesn't pose a threat to women. Clearly, anyone who thinks it isn't important just hasn't been paying attention.

THE VAGINITIS REPORT is published by the 3M National Vaginitis Association and sponsored by 3M Pharmaceuticals. Editor: Richard L. Sweet, MD, Professor and Chairman, Department of OB/GYN and Reproductive Sciences, University of Pittsburgh School of Medicine.

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Published
2002 CDC
Treatment
Guidelines for
STDs

- New first-line BV treatment recommendations for nonpregnant women
 - metronidazole gel 0.75% intravaginally once a day for 5 days
 - metronidazole 500 mg orally twice a day for 7 days
 - clindamycin cream 2% intravaginally for 7 days

- Metronidazole gel deemed as effective as oral metronidazole

- Clindamycin cream appeared to be less efficacious than either metronidazole regimen

- Alternative BV treatment regimen recommendations: metronidazole 2 g orally in a single dose, clindamycin 300 mg orally twice a day for 7 days, and clindamycin ovules 100 g intravaginally once a day for 3 days

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