PART 2D

Bacterial vaginosis

F Keane, C A Ison, H Noble, C Estcourt

Sex Transm Infect 2006;**82**(Suppl IV):iv16–iv18. doi: 10.1136/sti.2006.023119

WHY TEST FOR BACTERIAL VAGINOSIS?

Bacterial vaginosis (BV) is a very common condition causing distressing vaginal symptoms, primarily a malodorous discharge. A high proportion of women with BV are asymptomatic.¹ The aetiology is unknown but BV is associated with a change in vaginal ecology, resulting in overgrowth of certain bacteria such as *Gardnerella vaginalis*, and anaerobes, replacing the lactobacillus dominated flora of the normal vagina. The true prevalence is unknown, being reported as 10–20% in sexually active women² and higher in women attending specialised clinics for sexually transmitted infections (STI) or for termination of pregnancy.³ The bacteria associated with BV can be treated but recurrence is common.⁴ BV has been associated with serious health problems including adverse pregnancy outcomes such as preterm delivery and low birthweight babies,^{5–6} as well as an increased risk of pelvic inflammatory disease (PID)^{7–8} and post-abortion sepsis.⁹ BV has also been linked to increased rates of HIV acquisition.¹⁰ Although early trials of antibiotic therapy of BV in pregnancy gave variable results,^{11–14} more recent studies have shown a positive effect of treatment.^{15–16} However, there are no follow up data available on the effect of treating BV and the subsequent risk of developing PID. There are limited data available on the benefits of treating BV in women undergoing first trimester abortions.^{17–18}

RECOMMENDED TESTS

A variety of tests, which reflect the changes in vaginal ecology, have been used to diagnose BV. Isolation of the bacteria associated with this condition, such as *G vaginalis*, has a poor specificity (these bacteria being present in a proportion of normal women, albeit in smaller numbers) and is discouraged. Other tests that detect the biochemical changes associated with BV are more useful for studies on pathogenesis rather than for clinical diagnosis and include the detection of sialidase and proline aminopeptidase. Two diagnostic methods for BV have been used extensively in genitourinary medicine clinics and remain the tests of choice.

Both require interpretation within the given clinical scenario.

Amsel's criteria

The use of composite criteria was proposed by Amsel *et al*¹⁹ in 1984 and reflected the clinical entity as first described by Gardner and Dukes²⁰ in 1955. The presence of three or more of the criteria is considered consistent with BV and this has been used as the gold standard for many years.

- Typical appearance of discharge at vaginal examination
- Vaginal discharge pH >4.5
- Positive "whiff test" following the addition of potassium hydroxide to a sample of discharge
- Clue cells on dark ground microscopy of a saline wet mount preparation.

The criteria are simple to perform, particularly in a clinic setting and require minimal material with the exception of a

microscope. However, the disadvantages are that the patient must undergo a vaginal examination and the recognition of the vaginal discharge and the fishy "smell" has a subjective end point. In the majority of UK clinics the whiff test is no longer performed because of the caustic nature of the potassium hydroxide. Thus, the method is invalidated because it is dependent on measurement of all four criteria to achieve a high sensitivity for the diagnosis of BV.²¹

Appearance of Gram stained vaginal smear

The grading or scoring of Gram stained smears offers an alternative to use of the composite criteria; it has the advantage of a more objective end point, and allows for a common approach that can be audited. A microscope is required. The original method, as described by Spiegel,²² divided patients into two groups, with BV or without BV (normal vaginal flora), but subsequent methods have included an intermediate category, believed to be a transition between normal vaginal flora and BV. The disadvantage is that multiple methods have been described and are in use, resulting in a lack of consistency in diagnosis and reporting. The method described by Nugent *et al*,²³ which is widely used particularly for research studies, requires counting of bacteria; this is time consuming and not feasible in a busy genitourinary medicine (GUM) clinic. A number of simplified schemes have been described^{24–25} but the grading of vaginal flora described by Ison and Hay²⁶ allows a method of assessment that gives a good correlation with Amsel's criteria for the diagnosis of BV and correlates well with other scoring methods.²⁷ This latter method has been endorsed by the Bacterial Special Interest Group of BASHH.

RECOMMENDED DIAGNOSTIC TEST: APPEARANCE OF GRAM STAINED SMEAR ACCORDING TO MODIFIED ISON-HAY SCORING SYSTEM

The modified Ison-Hay scoring system suggests five grades of flora

- Grade 0, epithelial cells with no bacteria
- Grade 1, normal vaginal flora (lactobacillus morphotypes alone)
- Grade II, reduced numbers of lactobacillus morphotypes with a mixed bacterial flora
- Grade III, mixed bacterial flora only, few or absent lactobacillus morphotypes
- Grade IV, Gram positive cocci only.

Grades 0, I, and IV are found in women without BV.

Grade II is intermediate and not found in women with BV as defined by Amsel's criteria.

Grade III is consistent with BV as diagnosed by Amsel's criteria.

Thus, only grade III flora are indicative of BV. There is some evidence to suggest that grade II flora respond to oral,

Abbreviations: BV, bacterial vaginosis; GUM, genitourinary medicine; PID, pelvic inflammatory disease; STI, sexually transmitted infections

Table 1 Diagnostic methods for BV

	Amsel's criteria	Gram stain Ison/Hay
Convenient to perform	Yes	Yes
Microscope required	Yes	Yes
Caustic material required	Yes	No
Reproducible	No	Yes

but not vaginal, clindamycin in pregnant women.^{16–28} There is insufficient evidence on the clinical significance of grades 0, II, and IV in the non-pregnant population and their response to standard treatment regimens for BV.

Screening should take place in the following patient groups:

- Women presenting with vaginal discharge, an offensive odour, or any genital symptom (evidence level Ia, recommendation grade A).
- Women found to have a copious discharge at examination (recommendation grade A).
- Pregnant women with a history of previous preterm labour may be offered screening²⁹ (evidence level Ia, recommendation grade A).
- To date there is insufficient evidence to support routine screening of asymptomatic pregnant women²⁹ (evidence level Ia, recommendation grade A).
- There is some evidence to support screening and treating BV before termination of pregnancy to reduce subsequent endometritis and PID (evidence level Ib, recommendation grade B).
- There is a complete lack of evidence to inform any decision on screening asymptomatic non-pregnant women as regards PID outcomes (evidence level IV, recommendation grade C).

SITES FOR TESTING

- Vaginal wall smear following the insertion of a speculum is recommended.
- Prepubertal women and those declining speculum examination—posterior vaginal wall sample—blind.
- Pregnant women—vaginal wall smear.
- Sex workers—no different advice.
- Men—not applicable.

RECOMMENDATION FOR TEST OF CURE

There is no available evidence to support or refute need for a test of cure (evidence level IV, recommendation grade C).

AUDIT STANDARD

To compare the scoring of Gram stained vaginal smears by routine readers against a collection of smears prescored by an expert panel; 90% concordance would be an acceptable standard.

RIGOUR OF DEVELOPMENT

A Medline search was conducted from 1966 to January 2005 using the terms “bacterial vaginosis”, “diagnostics”, “pregnancy”, “screening”, and “treatment” as key words. A Medline search was also conducted 1988 to December 2004 using “bacterial vaginosis”, “pelvic inflammatory disease”, and “treatment”. The Cochrane database was also searched using the terms “bacterial vaginosis”, “diagnosis”, and

“pregnancy”. The Centres for Disease Control and Prevention guidelines for bacterial vaginosis and the draft revised guidelines for the management of bacterial vaginosis were also consulted.

RESOURCE REQUIREMENTS

Laboratory with staining facility and appropriate microscopes, staff training and updates, quality assurance programme for reading Gram stained slides.

Authors' affiliations

F Keane, Department of Genito-urinary Medicine, Royal Cornwall Hospital, Truro, UK

C A Ison, Health Protection Agency, Colindale, London, UK

H Noble, Ambrose King Centre, Barts and the London NHS Trust, London, UK

C Estcourt, Ambrose King Centre, Barts and the London NHS Trust, UK

Conflict of interest: none.

Correspondence to: Dr Frances Keane, Department of GU Medicine, Royal Cornwall Hospital, Treliske, Truro, Cornwall TR1 3LJ, UK; frances.keane@rcht.cornwall.nhs.uk

Accepted for publication 31 August 2006

REFERENCES

- 1 **Klebanoff MA**, Schwabke JR, Zhang J, *et al.* Vulvovaginal symptoms in women with bacterial vaginosis. *Obstet Gynecol* 2004;**104**:267–72.
- 2 **Hay PE**, Taylor-Robinson D, Lamont RF. Diagnosis of bacterial vaginosis in a gynaecology clinic. *Br J Obstet Gynaecol* 1992;**99**:63–6.
- 3 **Blackwell AL**, Thomas PD, *et al.* Health gains from screening for infections of the lower genital tract in women attending for termination of pregnancy. *Lancet* 1993;**342**:206–10.
- 4 **Hay PE**. Therapy of bacterial vaginosis. *J Antimicrob Chemother* 1998;**41**:6–9.
- 5 **Martius J**, Krohn MA, Hillier SL, *et al.* Relationships of vaginal Lactobacillus species, cervical Chlamydia trachomatis and bacterial vaginosis to pre-term birth. *Obstet Gynecol* 1998;**71**:89–95.
- 6 **Hillier SL**, Nugent RP, Eschenbach DA, *et al.* Association between bacterial vaginosis and preterm delivery of a low birth-weight infant. *N Engl J Med* 1995;**333**:1737–42.
- 7 **Sweet RL**, Draper DL, Schachter J, *et al.* Microbiology and pathogenesis of acute salpingitis as determined by laparoscopy: what is the appropriate site to sample? *Am J Obstet Gynecol* 1980;**138**:985–9.
- 8 **Soper DE**, Brockwell NJ, Dalton HP, *et al.* Observations concerning the microbial aetiology of acute salpingitis. *Am J Obstet Gynecol* 1994;**170**:1008–14.
- 9 **Larsson P-G**, Bergman B, Forsum U, *et al.* Mobiluncus and clue cells as predictors of PID after first trimester abortion. *Acta Obstet Gynecol Scand* 1989;**68**:217–20.
- 10 **Taha TE**, Hoover DR, Dallabetta GA, *et al.* Bacterial vaginosis and disturbances of vaginal flora: association with increased acquisition of HIV. *AIDS* 1998;**12**:1699–706.
- 11 **Morales WJ**, Schorr S, Albritton J. Effect of metronidazole in patients with preterm birth in preceding pregnancy and bacterial vaginosis: a placebo controlled, double blind study. *Am J Obstet Gynecol* 1994;**171**:345–49.
- 12 **Hauth JC**, Goldenberg RL, Andrews WW, *et al.* Reduced incidence of preterm delivery with metronidazole and erythromycin in women with bacterial vaginosis. *N Engl J Med* 1995;**333**:1732–36.
- 13 **McDonald HM**, O'Loughlin JA, Vigneswaran R, *et al.* Impact of metronidazole therapy on preterm birth in women with bacterial vaginosis flora (Gardnerella vaginalis): a randomised, placebo controlled trial. *Br J Obstet Gynaecol* 1997;**104**:1391–7.
- 14 **Carey JC**, Klebanoff MA, Hauth JC, *et al.* Metronidazole to prevent preterm delivery in pregnant women with asymptomatic bacterial vaginosis. *N Engl J Med* 2000;**342**:534–40.
- 15 **Lamont RF**, Jones BM, Mandal D, *et al.* The efficacy of vaginal clindamycin for the treatment of abnormal genital tract flora in pregnancy. *Infect Dis Obstet Gynecol* 2003;**11**:181–9.
- 16 **Ugwumadu A**, Manyonda I, Reid F, *et al.* Effect of early oral clindamycin on late miscarriage and preterm delivery in asymptomatic women with abnormal vaginal flora and bacterial vaginosis: a randomised controlled trial. *Lancet* 2003;**361**:983–8.
- 17 **Larsson PG**, Platz-Christensen JJ, Theiljs H, *et al.* Incidence of pelvic inflammatory disease in women with bacterial vaginosis after treatment with metronidazole: a double-blind, randomised study. *Am J Obstet Gynecol* 1992;**166**:100–3.
- 18 **Crowley T**, Low N, Turner A, *et al.* Antibiotic prophylaxis to prevent post-abortion upper genital tract infection in women with bacterial vaginosis: randomised controlled trial. *Br J Obstet Gynaecol* 2001;**108**:396–402.

- 19 **Amsel R**, Totten PA, Spiegel CA, *et al*. Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations. *Am J Med* 1983;**74**:14–22.
- 20 **Gardner HL**, Dukes CD. *Haemophilus vaginalis* vaginitis. A newly defined specific infection previously classified “non-specific” vaginitis. *Am J Obstet Gynecol* 1955;**69**:962–76.
- 21 **Keane FE**, Maw R, Pritchard C, *et al*. Methods employed by genitourinary medicine clinics in the United Kingdom to diagnose bacterial vaginosis. *Sex Transm Infect* 2005;**81**:155–7.
- 22 **Spiegel CA**, Amsel R, Holmes KK. Diagnosis of bacterial vaginosis by direct Gram stain of vaginal fluid. *J Clin Microbiol* 1983;**18**:170–1.
- 23 **Nugent RP**, Krohn MA, *et al*. Reliability of diagnosing bacterial vaginosis is improved by a standardised method of Gram stain. *J Clin Microbiol* 1991;**29**:297–301.
- 24 **Hay PE**, Lamont RF, *et al*. Abnormal bacterial colonisation of the lower genital tract and subsequent preterm delivery and late miscarriage. *BMJ* 1994;**308**:295–8.
- 25 **Thomason JL**, Gelbart SM, Anderson RJ, *et al*. Statistical evaluation of diagnostic criteria for bacterial vaginosis. *Am J Obstet Gynecol* 1990;**162**:155–60.
- 26 **Ison CA**, Hay PE. Validation of a simplified grading of Gram stained vaginal smears for use in genitourinary medicine clinics. *Sex Transm Infect* 2002;**78**:413–5.
- 27 **Forsum U**, Jakobsson T, *et al*. An international study of the interobserver variation between interpretations of vaginal smear criteria of bacterial vaginosis. *APIMS* 2002;**110**:811–8.
- 28 **Taylor-Robinson D**, Morgan DJ, Sheehan M, *et al*. Relation between Gram-stain and clinical criteria for diagnosing bacterial vaginosis with special reference to Gram grade II grade evaluation. *Int J STD AIDS* 2003;**14**:6–10.
- 29 **McDonald H**, Brocklehurst P, ParsonS J. Antibiotics for treating bacterial vaginosis in pregnancy. *The Cochrane Database of Systematic Reviews*, 2005, issue 1. Art No: CD000262, DOI:10.1002/14651858.CD000262.pub2.