Australian STI Management Guidelines for Use in Primary Care

Bacterial vaginosis

Overview

Bacterial vaginosis (BV) affects one in four people with a vagina of reproductive age globally, with considerable variation in prevalence between countries and subpopulations.

Cause

A polymicrobial vaginal dysbiosis characterised by a change from a *Lactobacillus* dominant state to one with high diversity and quantities of anaerobic bacteria including *Gardnerella vaginalis*, *Fannyhessea vaginae*, *Mobiluncus spp*, *Prevotella spp*, and other BV-associated bacteria. Studies have identified a polymicrobial biofilm adherent to vaginal epithelial cells of people with bacterial vaginosis.

BV has the epidemiological profile of a sexually transmissible infection. There is a strong association between acquisition of BV and young age of first sex, increased numbers of sex partners, exposure to new sex partners and lack of condom use for penile-vaginal sex. While post-treatment recurrence is associated with exposure to an ongoing sex partner and lack of condom use for penile-vaginal sex, implicating reinfection.

BV-associated bacteria are present in the urethra and penile skin in partners of people with bacterial vaginosis, with high concordance of BV-associated bacteria in the genitals of couples where one partner has a penis and the other a vagina. Couples with vaginas show very high concordance for bacterial vaginosis and BV-associated bacteria.

A recent randomised controlled trial, published in the New England Journal of Medicine, has shown that treating an ongoing/ regular sexual partner with a penis with a combination oral and topical antibiotics, at the same time a person with a vagina is receiving first line antibiotic therapy for BV, improves BV cure over 12

weeks. This trial provides evidence that reinfection is a very significant driver of BV recurrence, and that BV is sexually transmissible. The intervention involved the partner with penis taking 7 days of oral metronidazole twice daily in combination with the application of 2% clindamycin cream to the penile skin twice daily. Partner treatment was effective in people with vaginal BV with and without IUDs, and with circumcised and uncircumcised partners, and is described below.

Clinical presentation

Symptoms

- Malodorous vaginal discharge
- Thin white or greyish homogenous vaginal discharge
 - Commonly asymptomatic

Complications

Increased risk of:

- spontaneous abortion
 - premature labour
 - chorioamnionitis
- · postpartum endometritis
- <u>pelvic inflammatory disease</u> (including after surgical termination of pregnancy, intra-uterine device (IUD) insertion or other gynaecological instrumentation)
 - acquisition of chlamydia, gonorrhoea, herpes simplex type 2
 - acquisition and transmission of human immunodeficiency virus (HIV) infection.

Diagnosis

Clinical diagnosis is made using Amsel criteria (see below); if 3 or 4 of the following criteria are present, presumptive treatment can be offered.

- 1. Thin white/grey homogenous discharge on speculum examination
- 2. Elevated vaginal pH (pH > 4.5)
- 3. Whiff test: malodour with addition of potassium hydroxide to vaginal secretions, or if not available, genital malodour on examination
- 4. Clue cells on microscopy of Gram stain of high vaginal swab.

Specimen collection:

Clinician collection ensures visualisation of secretions and measurement of vaginal pH; microscopy can be performed on self-collected pH strips or clinician collected

swabs smeared on a slide.

Special considerations

Isolation of *Gardnerella vaginalis* (by NAAT) is reported by some laboratories but cannot be used to diagnose bacterial vaginosis as this organism can also be isolated in people with an optimal vaginal microbiota and no bacterial vaginosis. If your laboratory uses NAAT testing, speak to your pathology provider about its comparative performance. Scoring of the vaginal Gram stain (i.e. Nugent score, Ison-Hay method), are increasingly only used in specialised services.

Clinical Indications for testing

Symptoms of bacterial vaginosis: abnormal vaginal discharge and/or malodour

Management

Principal treatment option		
Situation	Recommended	Alternative
Symptomatic bacterial vaginosis	Metronidazole 400 mg PO, BD with food for 7 days. OR Metronidazole 0.75% gel 5 g, intravaginally nocte for 5 nights (not on PBS). OR Clindamycin 2% vaginal cream 5 g, one applicator intravaginally nocte for 7 days (not on PBS). For people with vaginal BV who have an ongoing or regular partner with a penis, concurrent partner treatment is recommended (and outlined below).	Clindamycin 300 mg PO, BD fo 7 days. OR Metronidazole 2 g PO, stat.

BD: twice a day

Nocte: every night

PO: orally

Stat.: immediately

Treatment advice

- Treatment is aimed at alleviating symptoms in people with BV or offered to asymptomatic people with BV requesting treatment.
- Stat. dose and short-duration regimens are associated with higher rates of recurrence.
- Treatment of ongoing/regular partners with a penis has been shown to improve BV cure when administered at the same time the index is receiving first line therapy for BV, and unprotected sex during treatment is avoided.
- Patients and their partners should refrain from vaginal penetrative sexual practices or use condoms for penile-vaginal sex consistently during treatment.
- Douching and intravaginal cleaning practices should be avoided.

Evidence does not support routine screening for bacterial vaginosis in low risk pregnancies, before surgical termination of pregnancy or insertion of an IUD in asymptomatic people. Bacterial vaginosis diagnosed or suspected at the time of IUD insertion should be treated with no need to delay the procedure; for surgical abortion antibiotic prophylaxis refer to Electronic Therapeutic Guidelines (eTG) and local guidelines.

- Copper IUDs have been associated with increased risk of bacterial vaginosis acquisition and recurrence. If a patient using an IUD develops bacterial vaginosis, treat as recommended. Treatment of an ongoing partner with a penis has been shown to improve BV cure for people with an IUD. If the patient experiences recurrent bacterial vaginosis with a copper IUD consider switching to an alternative method.
- An association between hormonal IUD use and BV is unclear and more data are needed.
- Prior to evidence that treatment of ongoing partners with a penis improves
 BV cure, > 50% of people experience post-treatment recurrence within 3-12 months.
- There is currently insufficient evidence to recommend the use of intravaginal lactic acid or vaginal probiotics.

Sexual partners of people with BV

People with vaginas who have BV, and an ongoing/regular sexual partner, experience BV recurrence rates of 60-80% in the absence of partner treatment. Treatment of partners with a penis involves oral and topical antibiotics for 7 days at the same time the index partner is being treated for BV with recommended therapy. Partner treatmentis most effective in closed/monogamous relationships where all partners have been synchronously treated, due to the risk of introduction of BV-associated bacteria from concurrent untreated partners.

Treatment of partners with a penis involves:

Oral metronidazole: 400mg twice daily for 7 days in combination with **Topical 2% clindamycin cream** twice daily to the penile skin for 7 days. Instructions for the application of clindamycin cream are as follows:

- Patients need to squeeze a line of cream from the fingertip of their index finger to the first crease, as shown in this picture. (photo source: https://dermnetnz.org/topics/fingertip-unit])
- If they have foreskin, it should be retracted before applying the cream. Ask them to rub the cream gently over the skin of the head of the penis, covering the whole head from the tip of the penis to the groove, just below the head.
- Then squeeze a second line of cream from the fingertip of their index finger to the first crease and rub this second dose of cream down the shaft of the penis, starting at the groove under the head, and moving down the shaft to the base of the penis. They need to cover the front and the back of the shaft and make sure all of the cream is gently rubbed into the skin. They may not need the full two finger tips of cream.
- The process should be repeated twice daily for 7 days.
- They need to apply the cream immediately after showering and not before.
- Advise that 100% adherence to MPT and avoidance of unprotected sex during the treatment period.
- Clindamycin cream may potentially weaken latex if the cream has just

been applied.

<u>Partner treatment resources</u> are available to assist clinicians and consumers with discussion, prescribing and use of partner treatment for BV

Specific links include

- Clinician information
- Partner Treatment for BV Decision Making Tool
- Consumer information
- Partner Treatment Instructions
- Pharmacy letter to accompany partner treatment prescriptions

No trials of partner treatment for couples with vaginas have been conducted to inform clinical practice. However, high concordance for BV is consistently reported within couples with vaginas. Testing of partners with vaginas should be offered in order to detect and treat BV in the partner, which is likely to reduce reinfection of the index and BV recurrence. There are no published trials to determine whether empiric treatment without testing for BV in ongoing partners with vaginas improves BV cure for the index with vaginal BV.

Special treatment situations

Situation	Recommended
Breastfeeding	Consider intravaginal treatment. Metronidazole may affect taste of breast milk; avoid high doses in breastfeeding.
<u>Pregnancy</u>	Standard treatment is recommended if symptomatic. There is no clinical benefit of treatment for asymptomatic patients in low-risk pregnancies.
Recurrent infection	Intravaginal metronidazole 0.75% gel 5 g twice per week for 4 months reduces recurrence during treatment, although this benefit does not persist when discontinued. Intravaginal boric acid regimens (via compounding pharmacy) have also been used but have not shown sustained benefit on discontinuation. Seek specialist advice if required.

Allergy to principal treatment choice	If allergic to nitroimidazoles, use clindamycin.	
Intravaginal preparations	May affect condom integrity.	

Contact tracing

- Contact tracing is not indicated
- There are insufficient data to recommend treatment of casual/non-regular partners with a penis
- Assessment of partner(s) with a vagina is recommended as concordance is high (see women who have sex with women).

Follow-up

Unnecessary if symptoms resolve.

Test of cure

Not required

Retesting

If symptoms persist or recur it is recommended patients are reviewed, as it is important to confirm the diagnosis. Test for <u>STIs</u>, if not undertaken at first presentation as concurrent STIs are common.

Auditable outcomes

100% of symptomatic patients are treated.

Endorsement: These guidelines have been endorsed by the Blood Borne Viruses and Sexually Transmitted Infections Standing Committee (BBVSS).

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