Bacterial vaginosis: review of treatment options and potential clinical indications for therapy

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Authors' objectives
To review the data on the treatment of bacterial vaginosis (BV) published from 1989 to 1992.

Searching
MEDLINE was searched from 1989 to 1992, using the search terms 'bacterial vaginosis', 'non-specific vaginosis', 'clindamycin', 'metronidazole'. Searches of books on sexually transmitted diseases (STDs), abstracts of meetings were gathered, and information from drug manufacturers sought. Other recent reviews were investigated.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), controlled trials or case studies, total n=25.

Specific interventions included in the review
Treatment of bacterial vaginosis.
Systemic formulations: Metronidazole (single dose vs 7 day), Clindamycin.
Topical formulations: Metronidazole pessaries. Metronidazole sponge (1 day vs 3 day).
Participants included in the review
Females presenting with BV as symptom, pregnant women with BV, sexual partners of women with BV; asymptomatic patients in surgical settings.
Outcomes assessed in the review
Cure rates were assessed.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
For each article, the authors discussed the study design (e.g. RCT or case study), the study population, their treatments, the outcome measures, the reported findings and the biases in the study design and analysis. The authors do not state how the papers were assessed for validity, or how many of the authors performed the validity assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
Studies were combined in a narrative review with one summary table for systemic metronidazole regimens. The studies identified are combined with the a previous review by Lossick (1990). They also appear to re-analyse studies from a meta-analysis by Lugo-Miro et al (1992) but do not present these data clearly.
How were differences between studies investigated?
The authors do not state how differences between the studies were investigated.

Results of the review
The number of studies included is unclear as studies were combined with those included in an earlier review (Lossick 1990).

Narrative summary of 5 studies of systemic formulations, 8 studies of topical formulations, 3 studies of treatment of sex partners, 1 study of treatment during pregnancy, 1 study of treatment for asymptomatic patients during surgery.

Systemic formulations: cure rates for the systemic metronidazole treatment range from 70% to 100% for individual studies, with a 'cumulative' cure rate of 92% (295 out of 322 patients treated) for the 7-day treatment regimen and 87% (369 out of 426) for the single dose regimen. The relapse rate for the individual studies ranged from 13%-44% for the 7-day regimen and 0-53% for the single dose.

Topical formulations: evidence of the efficacy of metronidazole sponges suggests 3-day sponge to be more efficacious than the 1-day sponge. The high dose (1000mg) 3-day sponge was found to have a better cure rate than the lower dose (250mg ) 3-day sponge (88% vs 56%). The efficacy of metronidazole pessaries is less clear. The only RCT evaluating this treatment found a high cure rate at one week (41 out of 41) but the study suffered from a high drop-out rate and 7 out of 41 women experienced local side-effects (itching, burning or increased vaginal discharge).

Treatment of sexual partners: one study reported a significantly different cure rate between women whose steady partners were treated with metronidazole compared to a placebo. The remaining studies found no effect. The authors conclude that the 'best' data show no benefit.

Treatment during pregnancy: as metronidazole is contraindicated during the first trimester of pregnancy, clindamycin is the preferred treatment during pregnancy. The one study evaluating the effects of clindamycin therapy found the treatment to be safe and well-tolerated.

Treatment before surgical abortion: one RCT found a threefold reduction in the incidence of post-abortion pelvic inflammatory disease (PID) in women with BV treated with metronidazole.

Treatment of asymptomatic patients during surgery: only one RCT was identified which suggests that treatment of asymptomatic patients with BV be considered before performing surgical abortion procedures to prevent PID.

Authors' conclusions
The review suggests that oral metronidazole (500mg twice daily for 7 days) is the preferred treatment for bacterial vaginosis. Other effective (but alternative) treatment regimens include single-dose metronidazole (2g orally), 2% clindamycin vaginal cream (once daily for 7 days), 0.75% metronidazole vaginal gel (twice daily for 5 days) and oral clindamycin (300 mg twice daily for 7 days).

Data do not support the practice of routine treatment of male sexual partners of infected females. Treatment of bacterial vaginosis during pregnancy should focus on the elimination of symptoms; data on adverse pregnancy outcomes for women with bacterial vaginosis remain insufficient to recommend treatment of asymptomatic patients. Before performing surgical abortion, treatment of bacterial vaginosis should be considered to prevent PID.

CRD commentary
This review is not methodologically rigorous. There are a number of inconsistencies in the presentation of the review; the authors claim to look at studies after 1989 but include pre-1989 studies in Table 1. This table also summarises studies included in Lossick's review yet there is no evidence that the Lossick review was systematic.

The search strategy for this review is very limited, thus open to potential bias. It relies heavily on the Lossick review for pre-1989 studies, possibly introducing bias into the review. The authors state they have inclusion criteria (i.e. some
attempt to assess quality) but do not develop them. It is unclear how the authors reach their conclusions as the studies do not appear to have been synthesised in any way.

Bibliographic details

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Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Administration, Topical; Female; Humans; Male; Metronidazole /therapeutic use; Pregnancy; Pregnancy Complications, Infectious /drug therapy; Sexual Partners; Surgical Procedures, Operative; Vaginosis, Bacterial /diagnosis /drug therapy /prevention & control

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.