

# Factors associated with treatment failure following male partner-treatment for bacterial vaginosis

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## Background:

Recurrence of bacterial vaginosis (BV) after recommended antimicrobials in women with an ongoing sexual partner approaches 80%. We have shown by randomised controlled trial (RCT) that the addition of male partner-treatment with combined antimicrobials reduces recurrence over 12-weeks (controls: 63% recurrence vs. partner-treatment group: 35% recurrence; hazard ratio=0.37, 95%CI:0.22-0.61,  $p<0.001$ ), demonstrating that reinfection is a significant driver of recurrence and amenable to intervention. We hypothesised that some women may experience post-treatment BV persistence and not experience the same benefit from partner-treatment. Data from participants in our RCT and pilot studies were combined to examine factors associated with BV at week 4.

## Methods:

Women received recommended therapy and males received combination therapy with oral metronidazole 400mg and topical 2% clindamycin (for penile application) twice daily for 7 days. Participants provided questionnaires at enrolment, day 8 and week 4. Females provided vaginal smears for Nugent scoring (NS: 0-3=no BV, 4-6=intermediate-BV, 7-10=BV). We used Cox regression to assess factors associated with week 4 BV.

## Results:

Across 165 treated couples, 35 (21%, 95%CI:15-28%) women had BV at week 4. At day 8, ten women (6%, 95%CI:3-11%) had a NS=7-10 and 58 (35%, 95%CI:28-43%) had a NS=4-10. Having a day 8 NS=4-10 was associated with a 4.5-fold increased risk of BV at week 4, relative to no BV (adjusted-HR=4.53, 95%CI:2.05-10.04). Women with an intrauterine device (IUD) vs no IUD had an elevated risk of BV at week 4 (AHR=2.15, 95%CI:0.98-4.73,  $p=0.056$ ) that was of borderline significance.

## Conclusion:

Male partner-treatment had a substantial impact on reinfection and recurrence, however, the association between non-optimal day 8 Nugent scores and week 4 BV, suggests persistence is occurring in a sub-group of women, which may be in part

mediated by IUD-use. Partner-treatment in combination with prolonged/alternative regimens for women to target persistent BV-organisms may further improve cure rates.

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