EDITORIALS

# Bacterial Vaginosis — Time to Treat Male Partners

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Bacterial vaginosis, the most common cause of vaginal discharge in reproductive-age women,[1] is associated with multiple consequential adverse outcomes, including an increased risk of adverse birth outcomes, acquisition of human immunodeficiency virus and other sexually transmitted infections (STIs), pelvic inflammatory disease, and a high incidence of symptomatic recurrence.[2] Bacterial vaginosis is characterized as a polymicrobial vaginal dysbiosis due to a decrease in protective lactobacillus species and an increase in facultative and strictly anaerobic bacteria.[3] The incidence of symptomatic recurrence after treatment can be as high as 60% at 12 months.[4]

Despite substantial data supporting the role of sexual transmission of bacterial vaginosis associated bacteria,[2,5] bacterial vaginosis is still unfortunately not accepted as an STI by practitioners. This situation is primarily attributable to a lack of agreement regarding the inciting agent or agents (although hypothetical models have been proposed[6]), the absence of a disease counterpart in men, and the erroneous belief that a first episode of bacterial vaginosis can occur in women without a history of sexual activity.[7] This prevailing perspective has been sustained by the failure of virtually all previous trials of male-partner treatment to show that such treatment prevents recurrence of bacterial vaginosis in women.[8,9] Critical gaps in knowledge of the pathogenesis of bacterial vaginosis have impeded advances in treatment and prevention, to the frustration of clinicians and patients.

In this context, Vodstrcil et al.[10] report in this issue of the *Journal* the results of a multicenter, randomized trial of combination oral metronidazole and topical clindamycin antimicrobial therapy for regular (monogamous) male partners at the time their female partner was treated for bacterial vaginosis, as compared with treatment of the woman alone, in an attempt to reduce recurrence of bacterial vaginosis. At 12 weeks, recurrence was documented in 24 of 69 women (35%) in the partner-treatment group (recurrence rate, 1.6 per person-year; 95% confidence interval [CI], 1.1 to 2.4) and in 43 of 68 women (63%) in the control group (recurrence rate, 4.2 per person-year; 95% CI, 3.2 to 5.7). These findings corresponded to an absolute risk difference of −2.6 recurrences per person-year (95% CI, −4.0 to −1.2). The trial design differed from that of previous failed trials of male-partner treatment[8,9] (which used oral antimicrobial therapies only) by using a combination of oral and topical antimicrobial therapy for male partners in an attempt to clear cutaneous penile and urethral carriage of bacterial vaginosis associated bacteria.

The results of this trial are timely and important. They provide substantial evidence supporting the role of sexual transmission of bacterial vaginosis associated bacteria, particularly within regular sexual partnerships. They also signify a need for a major change to the treatment approach of women with bacterial vaginosis with respect to how women should be counseled regarding the origin of their infection and to the need to engage their male partners in sharing responsibility for transmission and treatment.

To date, there have been no effective strategies to prevent sexual transmission of bacterial vaginosis associated bacteria, apart from consistent use of condoms.[2]

The major paradigm shift that this trial represents will require clinicians to educate their patients on the role of sexual transmission of bacterial vaginosis associated bacteria when the pathogenesis of bacterial vaginosis is incompletely understood and the precise etiologic agent of this polymicrobial infection is not yet identified. It will also require a willingness of male partners to commit to taking both oral and topical medications, once notified by their female partner that she has bacterial vaginosis and that it is probably sexually transmitted. In the trial by Vodstrcil et al., 14% of the men in the intervention group reported taking less than 70% of their prescribed doses of medication, an early signal that male partner buy-in could be challenging in some situations. Nevertheless, adverse events related to topical clindamycin were uncommon among the men, and systemic side effects of oral metronidazole were similar to those in women and were no more common.

Some limitations of the trial affecting generalizability warrant mention. The trial, which was conducted in Australia, included a majority of persons of Western Pacific and European ethnic background. Substantial racial and ethnic disparities in the prevalence of bacterial vaginosis have been documented, with prevalence among Black women in North America being particularly high.[1] In addition, a majority of the male partners in both groups (80%) were uncircumcised and more than a quarter of women were using an intrauterine device (28% in the intervention group and 33% in the control group); both factors confer a predisposition to carriage of bacterial vaginosis associated bacteria and an increased risk of relapse.[2] Reassuringly, the results appeared to be similar in subgroup analyses with stratification according to these factors, although the trial was not powered for these subgroups or to explore the association between these factors and recurrence of bacterial vaginosis. The trial overall was relatively small, but it was stopped early for efficacy. Finally, results apply specifically to women with regular male partners. Similar trials are needed in diverse populations to confirm and extend these findings.

Despite these limitations, this trial provides data critical to educating clinicians and patients about the role of sexual transmission of bacterial vaginosis associated bacteria and the benefit of male-partner treatment. It is time to start the conversation.

Disclosure forms provided by the authors are available with the full text of this editorial at NEJM.org.

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