Give Failed Bacterial Vaginosis Agents a Second Try

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BOSTON — Women with bacterial vaginosis who fail initial treatment with either metronidazole or clindamycin may respond favorably to subsequent treatment with the same medication, results of a small study have shown.

Using data from 119 nonpregnant women with bacterial vaginosis who participated in a randomized controlled trial comparing topical metronidazole with topical clindamycin for the treatment of bacterial vaginosis, Dr. Katherine E. Bunge of the University of Pittsburgh Magee-Womens Research Institute and her colleagues conducted a nested cohort investigation to compare retreatment cure rates in women who failed initial treatment with either of these drugs. For the purposes of this study, bacterial vaginosis was defined clinically as the presence of at least three of the four Amsel's criteria.

Participants were randomized to receive metronidazole for 5 days or clindamycin for 3 days and were asked to return for follow-up visits at 7-12 days post treatment, 35-45 days post treatment, and 70-90 days post treatment. "At each [follow-up visit], the women were assessed for clinical cure of bacterial vaginosis, defined as less than two Amsel's criteria," Dr. Bunge said at the annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology.

Study protocol dictated that women with early treatment failure, defined as clinical evidence of bacterial vaginosis at either the second or third follow-up visit, should be prescribed a second course of the medication to which they were initially randomized.

Of the initial 119 patients enrolled in the larger randomized controlled trial study, 104 had adequate clinical data for inclusion in the subgroup analysis. Of these women, 51 had evidence of failed initial treatment at follow-up visit two or three and 33 were retreated with the same medication they were initially randomized to receive, said Dr. Bunge. "These 33 women make up the cohort in this study," she said, noting that 19 of the women had been randomized initially to metronidazole treatment and 14 to clindamycin treatment. The mean age of the predominantly nonwhite cohort was 27 years.

Overall, 21 of the 33 women with a single early clinical failure responded successfully to retreatment, "giving a cure rate of 64%," Dr. Bunge reported. Retreatment resulted in 11 cures in the metronidazole arm and 10 in the clindamycin arm. There was no statistical significance in the difference between the respective cure rates of 58% and 71%, she said.

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While the study was not powered to detect differences between women in whom retreatment was and was not successful, said Dr. Bunge, "there were no obvious differences between the two groups in terms of therapy, smoking, age, race, or bacterial vaginosis history."

Of the 12 women who experienced a second treatment failure, only 2 received a third course of the same medication to which they were initially randomized and neither had clinical evidence of cure at the subsequent follow-up. The remaining 10 women with two treatment failures were retreated with a different medication, "but only 2 experienced cure at follow-up," said Dr. Bunge. "This suggests that women who experience repetitive early treatment failures are unlikely to respond favorably to retreatment."

The study is limited by its small size, Dr. Bunge noted. "Unfortunately, only 65% of the early treatment failures were retreated with the same medication, as had been our intention." In addition, she said, "long-term follow-up data were not available."

Despite the limitations, the findings do lead to the conclusion that for women who experience a single early treatment failure, "retreatment with the same medication is a reasonable approach," said Dr. Bunge. This is important, she added, "because early treatment failure of bacterial vaginosis is a common problem, and there is [a scarcity of] data that remotely touch on the best management course." ■

Pages 30a—30b