Newer Bacterial Vaginosis Therapies Are Emerging

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CHICAGO — Oral tinidazole, single-dose clindamycin vaginal cream, and lactobacillus-containing products are among the newer therapies for the treatment of bacterial vaginosis, Dr. Paul Nyirjesy said at a conference on vulvovaginal diseases.

Many of the therapies have emerged since the Centers for Disease Control and Prevention's treatment guidelines for bacterial vaginosis (BV) were issued in 2006. Bacterial vaginosis is among the most common vaginal diseases, occurring in about 10% of American women of reproductive age.

Oral tinidazole was approved in the United States in May 2007 for the treatment of BV. A recently published randomized controlled study in 235 women with BV found no significant difference in cure rates when tinidazole was administered as 1 g daily for 5 days or 2 g daily for 2 days. (Obstet. Gynecol. 2007;110:302-9).

Using the Food and Drug Administration guidelines for cure, 32% of women using the 2-day regimen and 41% of those using the 5-day regimen were cured, compared with the 5.7% who received placebo, said Dr. Nyirjesy, an investigator for the study. Both tinidazole regimens were superior to placebo.

The CDC's recommended oral therapy for BV is metronidazole 500 mg, twice a day for 7 days, with clindamycin 300 mg, twice a day for 7 days listed as an alternative. Although metronidazole can cause GI complaints in up to 52% of patients, it remains the cheapest therapy for BV, said Dr. Nyirjesy, professor of obstetrics and gynecology and medicine at Drexel University College of Medicine, in Philadelphia. Oral metronidazole 2 g as a single dose was dropped as an alternative oral therapy in the 2006 guidelines because it is inadequate as a treatment for BV, he added.

Single-dose clindamycin 2% vaginal cream is a sustained-release preparation, said Dr. Nyirjesy, who has received support from Mission Pharmacal and KV Pharmaceuticals/Ther-RX, which respectively manufacture tinidazole and single-dose clindamycin cream. In a study of 251 women with BV, clinical cure rates were not significantly different between single-dose clindamycin (Clindesse) and clindamycin 7-day (Cleocin) vaginal creams (88% vs. 83%, respectively; Infect. Dis. Obstet. Gynecol. 2005;13:155-60).

Lactobacillus products would seem to have a role in BV because the goal of treatment is to reestablish naturally occurring lactobacillus flora in the vagina depleted by BV and to decrease the presence of other species, such as *Mobiluncus* and *G. vaginalis*. But study findings have been mixed, and Dr. Nyirjesy suggested individualizing BV therapy based on a range of variables including cost, convenience, compliance, efficacy, spectrum coverage, and patient preference. He noted that most of the lactobacillus products are not available in the U.S.

The debate about which antibiotic is better has been further complicated by emerging evidence that not all BV is the same. For example, research has shown that, compared with other pregnant women, women with BV who have *Mobiluncus* morphotypes on Gram stain are more likely to be symptomatic, have higher numbers of clue cells and positive "whiff" tests, and have vaginal immune and hydrolytic enzyme profiles, all of which are associated with a greater risk of preterm birth, Dr. Nyirjesy said.

A recent study led by Dr. Nyirjesy (Sex. Transm. Dis. 2007;34:197-202) found that significantly more patients on single-dose 2% clindamycin cream cleared *Mobiluncus* morphotypes than patients on multiple doses of 0.75 metronidazole gel (97.5% vs. 80%, respectively).

Among women with *Mobiluncus* at baseline, clinical cure rates were significantly higher in those who received clindamycin (57.5% vs. 27%), but were not significantly different between treatment groups in women with no *Mobiluncus* at baseline (61% vs. 53%). He stressed that this was a retrospective study from pooled data, and that marketing efforts not withstanding, it was a preliminary paper that calls for further investigation.

Some audience members asked whether they should identify species on wet mount for all their BV patients.

"Absolutely not," said Dr. Nyirjesy. "Not all bacterial vaginosis is the same, and there may be different responses to antibiotics in women with BV." ■

Pages 30a—30b