Help for recurrent bacterial vaginosis

Suggest that women who are plagued by recurrent episodes of BV try vaginal probiotic capsules.

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PRACTICE CHANGER

Recommend high-dose vaginal probiotic capsules to prevent recurrent bacterial vaginosis.[1]

STRENGTH OF RECOMMENDATION

B: Based on a single high-quality randomized controlled trial (RCT)

Ya W, Reifer C, Miller LE. Efficacy of vaginal probiotic capsules for recurrent bacterial vaginosis: a double-blind, randomized, placebo-controlled study. *Am J Obstet Gynecol*. 2010;203:120.e1-120.e6.

ILLUSTRATIVE CASE

A 26-year-old nonsmoking woman with a single sexual partner comes in with the second bout of bacterial vaginosis (BV) she's had this year. What can you give her to prevent a recurrence?

Bacterial vaginosis is the most common cause of vaginal discharge in women, responsible for 40% to 50% of clinical cases. Among American women ages 14 to 49, the general prevalence—including asymptomatic cases—is close to 30%.[2]

Recurrence rate, as well as prevalence, is high

BV is caused by a shift in vaginal flora from hydrogen peroxide-producing *Lactobacillus* species to anaerobes that raise the vaginal pH. Multiple species of anaerobic bacteria are implicated. The drug of choice for treatment of BV continues to be metronidazole, a drug prescribed for the past 45 years with minimal resistance.[3] However, there is growing resistance among *Bacteroides* species. Oral or intravaginal clindamycin is another option for treating BV.[4]

Even with the use of metronidazole, recurrence is common—with as many as 50% of symptomatic infections recurring within a year.[5] A randomized, double-blind placebo-controlled trial published in 2006 compared the results of 1 week of oral metronidazole (500 mg) twice daily plus 30 days of oral probiotics vs the same dose and duration of metronidazole plus 30 days of placebo.[6] The rate of recurrence at the end of 1 month was 12% in the antibiotic/probiotic group vs 60% in the antibiotic/placebo group.

The RCT reviewed here evaluated the effectiveness of a vaginal probiotic capsule in preventing recurrent BV.

STUDY SUMMARY

Probiotic use lowered recurrence rate

Ya et al enrolled 120 Chinese women with a history of recurrent BV in a double-blind RCT.[1] To be eligible, women had to be healthy, between the ages of 18 and 55, and free from BV (but have a history of ≥2 episodes in the previous year). They also could not have had any antibiotic treatment within a week of study participation, and had to be willing to refrain from using other intravaginal products during the course of the study.

The researchers excluded women who were found to have other causes of vulvovaginitis or urogenital infection within 21 days of participation, were pregnant or lactating, ate yogurt or fermented milk on a daily basis, were allergic to study product ingredients, or were immunosuppressed.

CONTINUED

Bacterial vaginosis was diagnosed in 15.8% of women in the probiotic group and 45% in the control group.

This intervention has not been tested outside of China, or in women with more than one sexual partner, so findings may not be generalizable.

Participants were assigned to either BV prophylaxis with the vaginal probiotic capsule Probaclac Vaginal (a lactose capsule containing 8 billion colony-forming units [CFUs] of *Lactobacillus rhamnosus, L acidophilus,* and *Streptococcus thermophilus)* (n=58) or a placebo capsule containing lactose alone (n=62). Both groups had similar baseline characteristics; most of the women were nonsmokers who had had either one sexual partner or no partners within the previous year.

After a baseline evaluation, the participants used the vaginal capsules daily for 7 days, skipped usage for 7 days, and then used them again for a final 7 days. The women then returned for follow-up visits at 30 and 60 days after treatment began for the collection of vaginal swabs, an assessment of vaginal flora, and a report of adverse events. Researchers also contacted them by phone roughly 11 months after treatment started to ask about BV symptoms or diagnosis after treatment.

The primary end point was the diagnosis in the first 2 months of BV using Amsel criteria: the presence of thin, grey-white homogenous discharge coating the vaginal walls; vaginal pH >4.5; a positive whiff-amine test (presence of "fish smell" with potassium hydroxide [KOH] or KOH prep); and the presence of clue cells on normal saline wet mount.[7]

This end point—based on the presence of 3 of the 4 criteria—was reached in 15.8% of women in the probiotic group and 45% in the control group (odds ratio [OR]=0.23; 95% confidence interval [CI], 0.10-0.55; *P*<.001), with a number needed to treat (NNT) of 3.4.

A secondary end point was the confirmed diagnosis of BV between 2 and 11 months; only 10.6% of women in the probiotic group and 27.7% of women in the control group had confirmed BV (OR=0.31, 95% CI, 0.11-0.93; *P*=.04), with an NNT of 5.8. No adverse advents were reported.

WHAT'S NEW

A new use for probiotics is established

This trial supports the use of probiotic vaginal capsules in the prevention of recurrent BV. We found the specific formulation (Probaclac Vaginal) that was tested in this RCT on an online natural health site (http://www.ladytobaby.com/show.php?item=219). This Web site sells Probaclac Vaginal at a cost of $28 for 10 capsules. A full course of a week's treatment, repeated once, would cost approximately $56.

CAVEATS

Will other formulations work?

This study was funded by the makers of Probaclac Vaginal, so we will be watching for independent replication of these findings in other populations. The vaginal probiotic tested had 80 times the current recommended concentration of lactobacilli required to restore and maintain normal vaginal flora, so we are unsure as to whether less concentrated formulations would be equally effective.

Probiotic formulations differ widely, although some are similar to the species/concentration used in Probaclac Vaginal, including LactoViden ID by Metagenics (http://www.metagenics.com/products/a-z-products-list/LactoViden-ID), with 15 billion CFUs, and Therbiotic by Klaire Labs (http://www.klaire.com/prod/proddetail.asp?id=V775-06-CN), with 25 billion CFUs.

Also, this intervention has not been tested in populations outside of China, in heavy smokers, or in women with more than one sexual partner, so there is a small risk that these findings may not be confirmed in subsequent RCTs or may not be generalizable to other populations. Nonetheless, we think the potential benefit outweighs any possible harm, and we will be watching for studies that confirm or challenge these findings.

CHALLENGES TO IMPLEMENTATION

Finding the right probiotic

The brand used in the study is available only on the Web, which may be difficult for some patients to access, and some patients will find the probiotic to be fairly expensive. In addition, other brands of probiotics may not be available as a vaginal capsule with applicator. It should be noted, though, that it is possible

to use an applicator to insert an oral probiotic capsule into the vagina. JFP

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