Evidence-Based Critically Appraised Topic:

Probiotics for Bacterial Vaginosis Prevention and Treatment

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Clinical Scenario
A 34-year-old female patient presents to the clinic complaining of a white vaginal discharge. She denies vaginal itching and burning with urination. No foul vaginal odor noted. CBC is within normal limits. Laboratory results confirm bacterial vaginosis.

Clinical Question
Does probiotic therapy aid adult female patients in the prevention and/or treatment of bacterial vaginosis?

Articles


Summary and Appraisal of Key Evidence
Study 1: Ya, Reifer, and Miller (2010) completed a single-center, triple-blinded, randomized, placebo-controlled trial in January 2009 in Shanghai, China (Grade A level of evidence 1b) to evaluate the effectiveness of vaginal probiotic capsules for recurrent bacterial vaginosis (BV) prevention. 120 eligible subjects were assigned randomly to bacterial vaginosis prophylaxis (test group) with a proprietary vaginal probiotic capsule or a placebo capsule (control group) containing only lactose. Subjects were instructed to administer the capsules for 7 days on, 7 days off, and 7 days on. The women were contacted by telephone post treatment intervention to either confirm or deny the presence of BV symptoms, diagnosis of BV or G vaginalis, and adverse effects over the course of the trial.

Lower rates of BV and G vaginalis were experienced by the test group during the 2-month follow-up period. Probiotic prophylaxis was effective in reducing discharge, lowering vaginal pH, and reducing clue cell presence. However, malodor was hardly affected. A similar beneficial effect of probiotics was observed at the 11-month follow-up period for both BV and G vaginalis. Symptoms of vaginal discharge and malodor were 3-fold higher in the control group over the same duration of time.

Probiotic prophylaxis was well tolerated and produced dramatic reductions in BV recurrence as well as G vaginalis risk through 11 months post treatment in women with a
history of recurrent BV. The prospective, randomized, placebo-controlled, triple-blinded design and rigorous data monitoring, entry, and analysis standards were strengths of this clinical study. Multiple sexual partners and moderate or heavy smoking are both known risk factors for recurrent BV, but no subjects reported either of these significant risk factors and therefore their history did not influence BV and G vaginalis risk. Limitations included only telephone follow-up interview contact with subjects for 11-month outcomes. Also, frequency of BV and G vaginalis may have been underreported. Another drawback to the trial was its conduction in women of only Asian descent.

Study 2:Senok, Verstraelen, Temmerman, and Botta (2009) conducted a systematic review to investigate the efficacy of probiotics in treating BV (Grade A level of evidence 1a). Four randomized controlled trials met the inclusion criteria for this review. Anukam 2006a evaluated the usefulness of oral metronidazole with oral probiotics in the treatment of BV. In contrast, Anukam 2006b assessed the efficacy of intravaginal probiotic capsules with metronidazole gel for the treatment of BV. Eriksson (2005) studied the use of clindamycin ovules and either placebo or probiotic impregnated tampons for the treatment of BV. Parent (1996) looked at the use of combined probiotic/estriol vaginal tablets for both pregnant and non-pregnant women.

A systematic review of various research studies and a high level of evidence form strengths of this resource. However, the main weakness of the analysis included a lack of inclusion material for the meta-analysis due to significant differences in the use of probiotic types and methodologies. A major hindrance was the variation of trial methodologies. Two studies (Eriksson, 2005 & Parent, 1996) lacked adequate methodological quality. Parent (1996) failed to describe study blinding. Also, considerable possible attrition bias may have developed due to lost patient follow-up resulting in too small of sample size groups.

Opportunities for both studies involve new education for the health care provider that may result in a practice change. Current guidelines do promote a diet including Lactobacillus acidophilus supplements to help prevent vaginitis, but there are no current guidelines recommending probiotics alone for the treatment of BV (Epocrates, 2012). Threats to the studies involve patient expectations of antibiotic treatment and a potential practice change in the future. The validity of the research for both studies was compromised with small population sizes and poor methodologies. Further research is needed to truly evaluate the effectiveness of probiotics for the prevention and/or treatment of BV.

Clinical Bottom Line
Study 1: The individual study “represents the first report of vaginal probiotic capsules solely for recurrent BV prevention” and “is likely beneficial across all racial backgrounds” (Ya, et al., 2010, p. 120.e4). Promising outcomes of this study promote well-designed, randomized, controlled trials comparing probiotics to the standard of care (metronidazole) to further determine efficacy of probiotics for not only the prevention, but also the treatment of BV (Ya, et al., 2010 & Vaginitis, 2012).
Study 2: Analyses of the results suggest a beneficial outcome, however, there is insufficient evidence either for or against treating BV with probiotics alone. Probiotic combination treatment regimens appear promising, but “well-designed randomized controlled trials with standardized methodologies and larger patient size are needed” (Senok, et al., 2009, p. 2).

As health care providers, we are striving for disease prevention and probiotics lead us to believe they will aid in this medical effort. The relevance to clinical practice is quite evident as probiotics assist in maintaining and possibly restoring the normal vaginal flora. They continue to prove valuable in clinical practice for the prevention of BV, but ongoing research is required to provide strong evidence of probiotic use either alone or in combination with antibiotic therapy in the treatment of BV.

References

