Critical Appraisal reviews important articles in the literature relevant to family physicians. Reviews are by family physicians, not experts on the topics. They assess not only the strength of the studies but the “bottom line” clinical importance for family practice. We invite you to comment on the reviews, suggest articles for review, or become a reviewer. Contact Coordinator Michael Evans by e-mail michael.evans@utoronto.ca or by fax (416) 603-5821.

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routine prenatal care with no vaginal symptoms (ie, odour, discharge, itch).

A total of 21 965 women met the initial study criteria and had vaginal swabs taken. The swabs were used to determine vaginal pH, to provide culture for bacterial growth, and to determine the Gram stain score (developed and validated by Nugent et al’). Women were identified as BV-positive if they had a Gram stain score of ≥7 and a vaginal pH of >4.4.

The 6540 women identified as BV-positive on vaginal swab screening were subjected to further inclusion or exclusion criteria. Only women between 16 and 24 weeks’ gestation were included. Women were excluded if they had a vaginal pH of <4.4; could not arrange for follow up; had used antibiotics since the initial screening; had been screened more than 8 weeks previously; had evidence of infection with trichomoniasis, syphilis, gonorrhea, or chlamydia; or met any of the initial exclusion criteria.

At the time of randomization, women were examined by ultrasound for gestational age if they had not already had that examination. A second swab was taken for pH, Gram staining, and T vaginalis cultures. Results of these tests were concealed. Subjects remaining in the study were then randomized to either treatment with 2 g of metronidazole by mouth (n = 966) or to placebo (n = 987). At 24 to 30 weeks, vaginal swabs were taken again and a second course of the same treatment was undertaken.

Results

Most subjects (98.3%) were followed up after delivery. There were no significant differences between the two groups in primary outcomes (prematurity and low birth weight). All 95% confidence intervals (CI) crossed 1.0. With respect to secondary outcomes, there were no significant differences for any of the proposed risk factors (previous preterm delivery, gestational age at randomization, race, low prepregnancy weight, or trichomoniasis co-infection at randomization).

Adverse effects were significantly more frequent in the treatment group (21.9% versus 9.1%, P.10). Gastrointestinal symptoms affected 19.7% of women in the treatment group but only 7.5% in the placebo group. Complaints of vomiting were the most frequent: 9.7% in the treatment group and 2.8% in the placebo group.

Analysis of methodology

This randomized, double-blind, placebo-controlled study had strict exclusion and inclusion criteria. Intention-to-treat analysis was carried out, and follow up was excellent. Treatment and placebo groups were similar in their characteristics.

Because the study population is similar to that in most of our communities and the patients similar to those family physicians see, this paper can inform us in triaging and treating our pregnant patients appropriately. The treatment protocol used in the study is similar to that used routinely by family physicians, which furthers its applicability.

Application to clinical practice

According to this well designed prospective study, treating pregnant women with clinically asymptomatic BV does not reduce rates of preterm delivery or decrease numbers of low-birth-weight babies. Results of subgroup analysis also suggest there is no benefit in treating high-risk pregnant women with asymptomatic BV. Although common practice would be to treat these high-risk women, this practice is not supported by results reported in this paper.

Currently, BV is identified through vaginal swabs that, surprisingly, are only 50% specific! In 1983, Amsel and colleagues’ provided clinicians with criteria for making an objective diagnosis of BV (three of the following four criteria had to be met: homogeneous white or gray discharge that adheres to vaginal walls, pH > 4.5, clue cells in >20% of a wet mount, and positive results from a potassium hydroxide whiff test). Kits for rapid diagnosis (similar to a urine dip stick) that incorporate the Amsel criteria will be available soon. This testing method will be more sensitive and specific for screening appropriate patients for BV.

If patients have symptoms, they should of course be treated appropriately according to the 1997 Society of Obstetricians and Gynecologists of Canada’s guideline on BV. Current medical treatments include metronidazole (500 mg twice daily for 7 days or 2 g in a single dose) and clindamycin (300 mg twice daily for 7 days). Topical preparations have similar efficacy but are more likely to cause vaginal candidiasis. A meta-analysis recently found no increased risk of teratogenicity in fetuses exposed to metronidazole during the first trimester. Routine screening and treatment of male partners is not indicated.

Bottom line

• Regardless of their risk level, this paper does not support treating asymptomatic women with positive cultures for G vaginalis. Treatment does not prevent preterm delivery or low-birth-weight infants.
• When assessing pregnant women with vaginal discharge, physicians should consider using stringent diagnostic criteria, such as the Amsel criteria, for diagnosing BV.
Points saillants
• Quel que soit leur degré de risque, le présent article ne préconise pas le traitement des femmes asymptomatiques dont les résultats de cultures indiquent positivement la présence de *G vaginalis*. Le traitement ne prévient pas l’accouchement prématuré ni le faible poids chez le nouveau-né.
• Lorsqu’ils procèdent à l’évaluation de femmes enceintes présentant des écoulements vaginaux, les médecins devraient envisager le recours à des critères diagnostiques stricts, comme les critères Amsel, pour le diagnostic de la vaginose bactérienne.

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References