## Longer BV Treatment Helps in the Short Term

BY SHERRY BOSCHERT

San Francisco Bureau

MONTEREY, CALIF. — Four strategies that have been proposed to improve treatment of bacterial vaginosis produced mixed results, with only an extended course of metronidazole improving cure rates, and that only in the short term, Dr. Jane R. Schwebke reported.

A double-blind study randomized 568 women with bacterial vaginosis (BV) to

one of four treatment arms: daily metronidazole for 7 days; metronidazole for 14 days; metronidazole for 7 days plus 1 g azithromycin on days 1 and 3, or metronidazole for 14 days plus azithromycin on days 1 and 3. The metronidazole was given in 750-mg extended-release form.

At a first follow-up visit 7 days after completion of treatment, BV was cured in 63% of patients who took metronidazole for 14 days, compared with 45% of patients who took metronidazole for 7 days. By a second follow-up 21 days after completing treatment, however, there was no significant difference in cure rates among any groups. Azithromycin therapy did not seem to make a difference at either time point, Dr. Schwebke and her associates reported in a poster presentation at the annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology.

Any benefit from the longer course of metronidazole in the short term was lost in the long term. "We don't know if that's because of relapse or reinfection," she said in an interview at the meeting.

Some physicians have advocated using 10-14 days of metronidazole to treat recurrent BV, though they lacked supportive data. Others have suggested the relatively low cure rates of 50%-80% seen when treating BV with metronidazole or clindamycin may be due to resistant organisms that are susceptible to macrolide antibiotics, such as mycoplasmas and Mobiluncus curtisii, noted Dr. Schwebke, professor of medicine at the University of Alabama, Birmingham, and her associates.

Patients with a Nugent score at baseline of 5-8 (less complicated flora) were more likely to be cured than were those scores of 9-10, the intent-to-treat analysis found. ■

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COMTRAINDICATIONS: Oral contraceptives should not be used in women who currently have the following conditions: \* Thrombophlebitis or thromboembolic disorders \* Cerebrovascular or coronary artery disease (current or history) \* Valvular heard disease with thrombogenic complications \* Uncontrolled hypertension \* Diabetes with vascular involvement \* Headaches with focal neurological symptoms \* Major surgery with prolonged immobilization \* Known or suspected carcinoma of the breast or personal history of breast cancer \* Carcinoma of the endomethrum or other known or suspected estrogen dependent neoptasia \* Undiagnosed abnormal genital tedebers.

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Cholestatic jaundice of pregnancy or jaundice with prior pill use
 Hepatic adenomas or carcinomas, or active liver disease
 Known or suspected pregnancy
 Hypersensitivity to any component of this product

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

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The use of oral contraceptives is associated with increased risk of several serious conditions including venous and arterial thrombotic and thromboembolic events (such as myocardial infarction, thromboembolics, and stroke), hepatic neopless, galibladder disease, and hypertension. The risk of serious morbidity or mortality is yety small in healty women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as certain interited thrombopolities, hypertension, hypertipidemias, obestly and diabetes.

Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks. The information contained in this brief summary is principally based on studies carried out in patients who used oral contraceptives with lower doses of both estrogens and progestogens than those in common use today. The effect of long-term use of the oral contraceptives with lower doses of both estrogens and progestogens remains to be determined. Throughout this belief up, epidemiological studies reported are or for two types retrospective or case control studies and prospective or control studies. Case control studies and prospective or control studies, and prospective or control studies. The relative risk dose not provide information on the actual clinical occurrence of a disease, among oral contraceptive users to that among nonusers. The relative risk dose not provide information on the actual clinical occurrence of a disease mong and contraceptive users to that among nonusers. The attributable risk dose provide information about the actual courrence of a disease in the population. For further information, the reader is reterred to a text on epidemiological methods.

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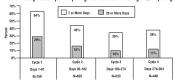
findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogens and progestogens.

8. Carbolydrate and Lipid Metabolic Effects: Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users. Oral contraceptives noral risk oral resistance of estrogens cause less glucose intolerance.
Progestogens increase insulin secretion and create insulin resistance, this effect varying with different progestational agents. However, in the nonclabelic woman, oral contraceptives appear to have no effect on tasting blood glucose. Because of these demonstrated effects, prediabelic and diabetic womens should be carefully observed while taking and contraceptives. A small proportion of women will have persistent hypertrigh-greatedma while on the pill. As discussed earlier (see WARNINGS. 1.a. and 10.), changes in serum triglycentices and lippororbic invels have been reported in oral contraceptive users.

9. Eveated Blood Pressure: Women with significant hypertrisons should not be started on hormonal contraceptive users.

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As in any case of bleeding irregularities, conhormonal causes should always be considered and adequate diagnostic measures taken to rule out malignancy or pregnancy. In the event of amenorhea, pregnancy should be ruled out. Some women may encounter post-pill amenorhea or digomenorhea (possibly with anoustion), especially when such a condition was preexistent.

PRECAUTIONS

1. Sexually Transmitted Diseases: Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

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**OVERDOSAGE:** Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea, and withdrawal bleeding may occur in females.

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## Thrombophilia Screening Is Questioned

LISBON — There is absolutely no reason today to universally screen pregnant women for inherited thrombophilias, Dr. Ian A. Greer said at the 15th World Congress of the International Society for the Study of Hypertension in Pregnancy.

Although easy and accurate tests for inherited thrombophilias are available, the best management of women who have these disorders remains unclear. A systematic review of the literature turned up results from just one randomized, controlled trial showing that pregnant women with a thrombophilia—in this case, antiphospholipid syndrome—had a modest benefit from treatment with aspirin and heparin, said Dr. Greer, professor of obstetrics and gynecology at the University of Glasgow, Scotland. But antiphospholipid syndrome is an acquired, not inherited, thrombophilia and no other results from randomized, controlled trials in women with a thrombophilia have been reported, he said.

Although aspirin, unfractionated heparin, and low-molecular-weight heparin are all treatment options, alone or in combination, not enough evidence currently exists to recommend any specific regimen over the

Dr. Greer and his associates have run a cost-effectiveness analysis of thrombophilia screening and treatment, using a hypothetical, representative population of 10,000 pregnant women. They assumed that treatment with low-molecular-weight heparin would have an 80% efficacy for preventing adverse maternal and fetal outcomes, including intrauterine growth restriction, miscarriage, and preeclampsia.

In this analysis, the cost for preventing a single adverse event through universal screening would be about \$90,000. The cost to prevent a single adverse event would be about \$80,000 using selective screening of women with a personal or family history of thrombophilia or a history of venous thromboembolism, Dr. Greer said.

-Mitchel L. Zoler

Reference: 1. Data on file. Duramed Pharmaceuticals Inc., Pomona, NY.