

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...

A double-blind study randomized 568 women with bacterial vaginosis (BV) to one of four treatment arms...

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...

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...

By a second follow-up 21 days after completing treatment, however, there was no significant difference in cure rates among any groups.

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.

SEASONIQUE™

(levonorgestrel / ethinyl estradiol tablets) 0.15 mg / 0.03 mg and (ethinyl estradiol tablets) 0.01 mg Brief Summary. See full package brochure for complete information.

Patients should be counseled that this product does not protect against HIV-infection (AIDS) and other sexually transmitted diseases.

CONTRAINDICATIONS: Oral contraceptives should not be used in women who currently have the following conditions: • Thrombophlebitis or thromboembolic disorders • A past history of deep vein thrombophlebitis or thromboembolic disorders • Cerebrovascular or coronary artery disease (current or history) • Valvular heart disease with thrombotic complications • Uncontrolled hypertension • Diabetes with vascular involvement • Headaches with focal neurological symptoms...

Warnings: 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.

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, thromboembolism, and stroke), hepatic neoplasia, gallbladder disease, and hypertension.

1. Thromboembolic Disorders and Other Vascular Problems: Use of Seasonique™ provides women with more hormonal exposure on a yearly basis than conventional monthly oral contraceptives containing similar strength synthetic estrogens and progestins...

2. Estimates of Mortality from Contraceptive Use: Each method of contraception has its specific benefits and risks. One study concluded that with the exception of oral contraceptive users 35 and older who smoke and 40 and older who do not smoke...

3. Carcinoma of the Reproductive Organs and Breasts: Although the risk of having breast cancer diagnosed may be slightly increased among current and recent users of combined oral contraceptives (RR=1.24)...

4. Hepatic Neoplasia: Benign hepatic adenomas are associated with oral contraceptive use, although their occurrence is rare in the United States. Indirect calculations have estimated the attributable risk to be in the range of 3.3 cases/100,000 for users...

5. Ocular Lesions: There have been clinical case reports of retinal thrombosis associated with the use of oral contraceptives that may lead to partial or complete loss of vision.

6. Oral Contraceptive Use Before or During Early Pregnancy: Because women using Seasonique™ will likely have withdrawal bleeding only 4 times per year, pregnancy should be ruled out at the time of any missed menstrual period.

7. Gallbladder Disease: Earlier studies have reported an increased lifetime relative risk of gallbladder surgery in users of oral contraceptives and estrogens.

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

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

8. Carbohydrate and Lipid Metabolic Effects: Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users.

9. Elevated Blood Pressure: Women with significant hypertension should not be started on hormonal contraceptive. An increase in blood pressure has been reported in women taking oral contraceptives and this increase is more likely in older oral contraceptive users and with continued use.

10. Headache: The onset or exacerbation of migraine or development of headache with a new pattern that is recurrent, persistent, or severe requires discontinuation of oral contraceptives and evaluation of the cause.

11. Bleeding Irregularities: When prescribing Seasonique™ the convenience of fewer planned menses (4 per year instead of 13 per year) should be weighed against the inconvenience of increased intermenstrual bleeding and/or spotting.

12. Contact Lenses: Contact-lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

13. Pediatric Use: Safety and efficacy of Seasonique™ tablets have not been established in women of reproductive age. Safety and efficacy are expected to be the same in postpubertal adolescents under the age of 16 and users 16 and older.

14. Geriatric Use: Seasonique™ tablets have not been studied in women who have reached menopause.

ADVERSE REACTIONS: An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see WARNINGS): • Thrombophlebitis • Arterial thromboembolism • Pulmonary embolism • Myocardial infarction • Cerebral hemorrhage • Cerebral thrombosis • Hypertension • Gallbladder disease • Hepatic adenomas or benign liver tumors...

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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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.

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.

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 others.

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