

Array of Contraceptives Safe for Patients With Lupus

BY MARTHA KERR
Contributing Writer

Women with stable systemic lupus erythematosus can use with relative safety any one of three forms of birth control—a combined oral contraceptive, a progestin-only contraceptive, or the copper intrauterine device—according to the findings of a study that showed each method had its own small degree of risk.

The safety of these forms of contraception was evaluated in a study of 162 women with mild, stable systemic lupus erythematosus (SLE), according to Dr. Jorge Sanchez-Guerrero of the Salvador Zubiran National Institute of Medical Science and Nutrition in Mexico City and his associates.

The women's mean SLE Disease Activity Index (SLEDAI) scores were 6.1 in women on combined OCs, 6.4 in women receiving progestin-only pills, and 5.0 in recipients of the copper IUD.

The primary outcome measure was global disease activity. Among the secondary outcomes were disease flares, me-

dian time to first flare, and adverse events. Disease activity was assessed at baseline and at months 1, 2, 3, 6, 9, and 12.

There were no significant differences in disease activity between the three groups (N. Engl. J. Med. 2005;353:2539-49).

Median time to disease flare was 3 months in each of the three groups. Two women in each group on hormonal contraception developed thrombosis, for a total of four cases. There were five cases of severe infection in the IUD group, two in

the OC group, and two in users of the progestin-only pill.

Although all three methods are relatively safe, women on hormonal contraceptives require close monitoring for risk of thrombosis, notes Dr. Sanchez-Guerrero and his associates.

In an accompanying editorial, Dr. Bonnie L. Bermas, of Brigham and Women's Hospital in Boston, noted that there are a number of reasons for prescribing oral contraceptives in women with stable SLE.

Among them are that pregnancies planned during remission result in better outcomes; these women are often on teratogenic medications and require a reliable form of birth control; and OCs may reduce bone loss in those on long-term glucocorticoid therapy (N. Engl. J. Med. 2005;353:2602-4).

Overall, she says the findings "support the use of combined oral contraceptives by those with inactive or moderately active, stable disease." ■

Early Clot Data Don't Absolve Ortho Evra Patch

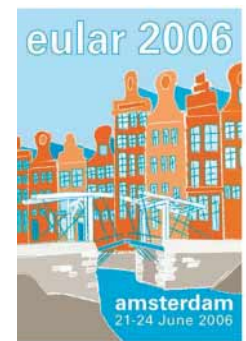
Preliminary results from two large ongoing epidemiologic studies evaluating the safety of the Ortho Evra contraceptive patch provided conflicting data on whether the risk of thrombotic events might be greater with the patch than with oral contraceptive pills.

Last month, the manufacturer, Ortho Women's Health and Urology, announced preliminary results of the two studies, which are comparing thrombotic event rates in women on Ortho Evra and women on an oral contraceptive pill containing norgestimate with 35 mcg of ethinyl estradiol. One study found the incidence of nonfatal thrombotic events was about the same among users of Ortho Evra and those on the comparator oral contraceptive. But in the second, the incidence of nonfatal thrombotic events was twice as high than among those on the comparator.

However, these data are preliminary and need to be evaluated further, and are not resulting in any changes to the label or any regulatory actions or specific recommendations on the use of the patch, Dr. Daniel Shames of the Food and Drug Administration emphasized in an FDA-sponsored teleconference, held the day after the manufacturer released these results.

The studies are using data from large medical claims insurance databases in the United States; these are the first results to become available. Dr. Shames, director of the division of reproductive and urologic drug products, in the FDA's Center for Drug Evaluation and Research, Rockville, Md., said that more precise information could be available by May.

—Elizabeth Mechatie



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