



Arthritis News

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RISKS FROM CONTRACEPTIVE METHODS PROVE EQUAL FOR LUPUS PATIENTS

SAN ANTONIO, TEXAS—The use of combined oral contraceptives, progestin-only oral contraceptives (minipill) and copper intrauterine devices (IUD) appear to produce the same level of risk for disease activity and flares in women with systemic lupus erythematosus, known as lupus, according to research presented this week at the American College of Rheumatology Annual Scientific Meeting in San Antonio, Texas.

The effect of contraceptive methods on disease activity and, therefore, the safety of their use by the many women who have the autoimmune disease lupus, has yet to be defined. Lupus, which causes inflammation in joints, tendons, and other connective tissues and organs, affects one million people in the U.S. and Europe, 90 percent of them women who are young and in their child-bearing years. To date, doctors have questioned prescribing oral contraceptives or estrogen replacement therapy for these women because of a widely held view that estrogens can make the disease worse.

To determine if other contraceptive methods offered lupus patients safer options, researchers conducted a single-blind, randomized clinical trial in which 162 women with lupus were divided in groups of 54 each and assigned one of three contraceptive methods. Combined oral contraceptives (ethinyl estradiol plus levonorgestrel) were given to one group, average age 27.4 years of age; progestin-only oral contraceptive given to a second group, average age 26.6 years of age; and an intrauterine device placed in patients in the third group, average 27.4 years of age. Other than the IUD participants' tendency to smoke less than the hormonal method users, the three groups were similar in demographic and disease characteristics.

All patients were monitored for disease activity at baseline, one, two, three, six, nine and 12 months by a rheumatologist who was unaware of the contraceptive method assigned. A gynecologist evaluated gynecological symptoms, adverse effects and medication compliance. Patients were also surveyed for hospitalization and other major events.

The disease activity as well as number of lupus flares proved to be similar across all three groups. Hormonal methods appeared to increase the risk of thrombotic events and IUD users showed a trend towards an increased risk of severe infections.

“Our results did not show a clinically relevant increase of disease activity by using estrogen containing contraceptive pills,” said F. Jorge Sanchez-Guerrero, MD, Immunology/Rheumatology, Instituto Nacional de Ciencias Medicas y Nutricion, Mexico City, Mexico, and an investigator in the study. “The choice of a contraceptive method in women with lupus must take into account the condition of the disease, the potential risks and benefits of the methods, and the expressed desires of the patients.”

The American College of Rheumatology is the professional organization for rheumatologists and health professionals who share a dedication to healing, preventing disability and curing arthritis and related rheumatic and musculoskeletal diseases. For more information on the ACR's annual meeting, see www.rheumatology.org/annual.

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Editor's Notes: Dr. Sanchez-Guerrero will present this research during a scientific session at the ACR Annual Scientific Meeting from 9:00–9:15 AM CT (10:00–10:15 AM ET) on Thursday, October 21, in Room 006 of the Henry B. González Convention Center. He will be available for media questions during a briefing at 1:30 PM CT (2:30 PM ET) on Monday, October 18 in the on-site Press Conference Room, Room 218.

Safety Of Use And Effect On Disease Activity Of Three Contraceptive Methods In Women With Systemic Lupus Erythematosus. A One Year Follow-Up Clinical Trial

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Background: The effect of contraceptive methods on disease activity and their safety of use are undefined.

Aim: To determine the effect on disease activity and the safety of use of three contraceptive methods in SLE women.

Design: Single blind, randomized, clinical trial. Patients and methods: 162 women with SLE (ACR criteria) were randomly assigned to use combined oral contraceptives (COC) (ethinyl estradiol: 30µg plus levonorgestrel: 150µg/day), progestin-only oral contraceptive (POC) (levonorgestrel: 0.3 mg/day) or an intrauterine device (IUD) (TCu 380). Patients were seen at baseline, 1, 2, 3, 6, 9 and 12 months. At each visit disease activity (SLEDAI), type and dose of medications were assessed by a rheumatologist, blinded to contraceptive method assigned. A gynecologist evaluated gynecological symptoms, registered adverse effects, assessed method adherence and reasons of discontinuation. Lupus flare was defined as an increase of >3 points in SLEDAI, and severe flare as an increase of >12 points, compared with the previous visit. In addition, during the study period, all patients were surveyed for hospitalizations and major events. Statistical analysis: Descriptive statistics, one-way ANOVA, chi-squared, areas under the curve (AUC), life-tables survival analysis, repeated measures analyses; $p < 0.05$ two-tailed.

Results: 54 patients were assigned to each method. For COC, POC and IUD, mean (SD) age of patients was 27.4 (5.3), 26.6 (5.3) and 27.4 (5.0) years ($p=0.65$); SLE duration 3.4 (4.2), 3.7 (4.2) and 4.0 (4.2) years ($p=0.77$); SLEDAI score at baseline 5.8 (5.5), 6.1 (4.6) and 4.6 (4.9) ($p=0.27$). IUD users tended to smoke less than hormonal methods users ($p=0.06$). Other demographic and SLE characteristics were not different among the three groups. 36, 37 and 37 flares occurred during 505, 441 and 540 person-months of follow-up. Cumulative net probabilities of SLE flares (SE) at 3 months were: 0.57 (0.08), 0.62 (0.07) and 0.56 (0.07); at 12 months: 0.92 (0.05), 0.90 (0.06) and 0.87 (0.06), for COC, POC and IUD respectively ($p=0.85$). No difference was seen in severe flares either. SLEDAI scores and AUC were not different among the three groups during the follow-up. Neither a difference was seen in type and dose of medications nor hospitalizations. POC users had a higher discontinuation rate ($p=0.01$). One patient died in the COC group. 2 thrombotic events occurred in each hormonal contraceptive group. Cumulative net probabilities of discontinuation (SE) for thrombosis were 0.04 (0.03) for COC and 0.05 (0.04) for POC. Two IUD users developed septic meningitis, discontinuation rate (SE) was 0.04 (0.03).

Conclusion: Global disease activity and lupus flares were similar among the three groups. COCs and POCs increased the risk of thrombotic events and IUD increased the risk of severe infections.

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