More Women Continued Ring Than Patch in Trial

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MINNEAPOLIS — Women who are content with combined oral contraceptives but are willing to try a nondaily method of birth control are more likely to be satisfied with the contraceptive ring than the patch, Dr. Mitchell D. Creinin said at the annual meeting of the Association of Reproductive Health Professionals.

This was the conclusion of a multicenter, open-label trial that enrolled 500 oral contraceptive (OC) users between June 2005 and September 2006, randomizing them to three menstrual cycles of either the ring or the patch.

The ring and the patch were introduced in the United States in 2002, but there has not been a trial comparing the two directly and there is no objective information on how to advise women who might be interested in switching from the pill to one of these newer methods, Dr. Creinin said.

In previous randomized trials, women found the ring and the patch superior or equal to the pill in terms of acceptability, but those trials typically randomized women to a pill or a new, otherwise unavailable method, he said.

To be eligible for the new study, women had to be satisfied current or recent users of the pill. A total of 84% were current users, and the remaining 16% had discontinued within the previous 3 months for reasons other than dissatisfaction with the OC.

The primary outcome measure was continuation rates after three cycles of the ring or patch, and the secondary outcome measure was intended use beyond the three cycles. The trial also compared side effects, adherence and retention problems, and overall acceptability, said Dr. Creinin, director of the division of gynecologic specialties, University of Pittsburgh. No daily diaries were used to record side effects or other daily concerns. "We felt that asking them to do something daily might have an impact on how they perceived the method," he said.

During the trial the Food and Drug Administration issued a warning about increased estrogen exposure with the patch. This information was given to all subjects who were enrolled then, and it was incorporated into the informed consent form for all subsequent enrollees.

A total of 479 women were evaluated; 3 never started using the products, 6 withdrew consent during the study, and 12 were lost to follow-up. Among the 241 women randomized to the ring, the mean age was 26; among the 238 randomized to the patch, the mean age was 25. Mean body mass index was 23 in both groups, and 8% of both groups were smokers.

The primary outcome measure of continuation through three cycles was achieved by 95% and 88% of the ring and patch users, respectively. Moreover, when asked if they planned to continue with the nondaily method, 71% of the ring users said they would, compared with only 27% of the patch users, Dr. Creinin said.

Patch users also reported significantly more systemic side effects than ring users. Women using the patch were more likely to complain of longer and more painful menstrual cycles. A total of 38% of patch users had longer periods, compared with 9% of ring users, while 29% of patch users reported dysmenorrhea, compared with 16% of ring users.

Nausea was reported by 8% and 1% of patch and ring users, respectively.

Approximately half of the women had the patch fall off or took it off at some point during the three cycles, while about 40% of ring users had it fall out or took it out at some point. This was significantly more patch detachment and ring expulsion than has been reported in the literature. "I think it's important to convey this to your patients, to let them know that these nondaily methods do require some daily attention to ensure the products are still there," he said.

"As far as overall acceptability, the bottom line was that women found the ring much more acceptable than the patch," Dr. Creinin said. They also were more likely to recommend it to their friends.

Dr. Creinin disclosed that the study was funded by Organon. "However," he said, "it was an investigator-initiated grant, meaning I wrote the proposal, wrote the protocol, picked the sites, supervised the sites, did the monitoring, did the data collection, and analyzed the data, with no requirements for approval from Organon."

He also disclosed that he does consulting for Organon and receives research funding from Bayer and Organon. ■

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