Essure Approved With Two Ablation Techniques

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SAN FRANCISCO — The Essure sterilization procedure can be used in combination with two methods of endometrial ablation, according to studies presented at the annual meeting of the American Association of Gynecologic Laparoscopists.

The Essure procedure may be performed immediately before or immediately after using the ThermaChoice uterine balloon ablation system. It also can be done immediately after—but not immediately before—using the NovaSure radiofrequency ablation system, investigators reported.

The Food and Drug Administration approved the use of the Essure system with ThermaChoice ablation in July 2004. The agency has not approved the use of Essure with NovaSure, and a spokesperson for Conceptus Inc., which distributes Essure, told this newspaper that the company has no plans to apply for such approval. "The majority of women who undergo endometrial ablation are in their reproductive years, so many of them request Essure sterilization to control fertility after or during endometrial ablation," Rafael F. Valle, M.D., a consultant for Conceptus, reported.

"Because these two methods utilize the same approach, the transvaginal approach, they can be performed concomitantly," said Dr. Valle of Northwestern University, Chicago. In his study, 40 women who were about to undergo hysterectomy for benign uterine bleeding consented to ThermaChoice endometrial ablation before or after placement of the Essure microinserts. Their average age was 43 years.

The microinserts were placed before ablation in 24 of the women, and in 16 of these women the combined procedure was successful. In the other eight, gross uterine pathology prevented proper placement of the microinserts.

A total of 16 women underwent ablation before placement of the Essure microinserts, and placement was successful in eight of those cases. The failures were caused by unsuspected pathology and debris remaining in the cornual regions after the ablation, which made it difficult to visualize the tubal ostia.

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The combined procedure took an average of 25.7 minutes, including taking a second look by hysteroscopy.

The FDA requested a study on the temperature increase in the serosa during the combined procedure. Dr. Valle recruited nine additional women for this study: Seven underwent Essure insertion before ablation, and two underwent Essure insertion alone as controls. Each woman had eight thermocouples inserted via laparotomy before the procedure began.

The average maximum temperature in this subserosal space was 37.1° C, ranging from 34.7° C to 38.9° C. Tissue damage occurs only at temperatures above 45° C. Furthermore, no tissue damage could be seen either on gross or histologic examination.

Although the FDA required the investigators to perform the Essure procedure both before and after ThermaChoice ablation, in practice, "It doesn't make sense to do the endometrial ablation first," Dr. Valle said.

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Placing the Essure microinserts before ablation is not an option when NovaSure radiofrequency ablation is used, said Robert Sabbah, M.D., of Sacré-Couer Hospital in Montreal.

"We don't feel that using an electrical current with a metal tail in the cavity would be safe," he said. "Therefore, we think the only way to go about doing it if you want to combine both procedures is to start first with endometrial ablation and follow later by the installation of the Essure."

Dr. Sabbah stated that he had no relevant conflicts of interest. ■