The tubal-occlusion microinsert for permanent contraception

Cooper JM, Carignan CS, Cher D, Kerin JF, for the Selective Tubal Occlusion Procedure 2000 Investigators Group. Microinsert nonincisional hysteroscopic sterilization. *Obstet Gynecol.* 2003;102:59-67.

OBJECTIVE To assess the efficacy, reliability, patient recovery, and patient satisfaction associated with a tubal-occlusion microinsert (Essure; *Conceptus, San Carlos, Calif*) for permanent contraception.

METHODS AND RESULTS A cohort of 518 fertile women participated in this phase III, international, multicenter trial. Microinsert placement was attempted in 507 of these women, with 464 (92%) ultimately undergoing successful bilateral insertion.

The average time to discharge was 80 minutes; 60% of women resumed normal function in 1 day or less. More than half of the women reported either mild or no pain with the procedure, and 88% described tolerance of the procedure as good to excellent. Three months after placement, correct bilateral placement and tubal occlusion were confirmed in 96% and 92% of cases, respectively. Ultimately, 449 of 518 women (87%) were able to rely on the device for permanent contraception.

WHO MAY BE AFFECTED BY THESE FINDINGS? Women who desire sterilization.

EXPERT COMMENTARY This pivotal trial demonstrates that permanent sterilization for women can now be accomplished without incisions, general anesthesia, use of an operating room, or a prolonged recovery period.

In the trial, all sterilization procedures were performed hysteroscopically, either in an office setting or ambulatory treatment center, and patient satisfaction was over 98%. Fifty-two percent of women required only paracervical block anesthesia, and just 12% of patients required postplacement narcotic analgesics. Ninety-two percent of women missed 1 day of work or less.

In contrast to conventional incisional sterilization (laparoscopic, abdominal, and vaginal), there were no serious procedure-related complications associated with microinsert placement. Further, as of January 3, 2003, no pregnancies were reported in 449 women and 9,620 woman-months, with a mean follow-up of 21.4 months.

Easy to learn and perform. Among the 20 clinical investigators in this study, hysteroscopic skill levels ranged from average to excellent, yet high device-placement rates were noted for all physicians. For the typical gynecologist who performs only diagnostic hysteroscopy, a short learning curve is required for efficient placement. Physicians also must take a half-day course sponsored by the manufacturer prior to beginning microinsert placement.

I have placed these devices in more than 30 women using only paracervical block anesthesia and found visualization and placement to be easy to moderate.

Steps to proficiency. For the clinician with average hysteroscopic skills, a number of steps can help simplify the first few cases of microinsert placement:

- Perform hysteroscopic procedures only during the first 10 days of the patient's cycle.
- Practice by inserting scissors or biopsy forceps through the small operating channel of the hysteroscope.
- Identify the proximal tubal ostia during hys-

teroscopy, and observe the ostia for peristaltic closing. Increase intrauterine fluid pressure and note improved visualization.

- Experiment with both 12° and 30° hysteroscopes. The latter are more difficult to learn, but provide better visualization for hysteroscopic sterilization procedures.
- Observe as an experienced hysteroscopist performs the procedure, then seek proctoring for the first 1 to 3 cases.

Sterilization is likely irreversible. What about the feasibility of pregnancy at a future date in women who have undergone this sterilization method? In contrast to conventional incisional sterilization, microsurgical tubal reversal is not an option because of the fibrous occlusion of the proximal and interstitial tubal segments. As for whether in vitro fertilization would be possible, it is unclear if the portion of the device that projects into the endometrial cavity has any impact on embryo implantation or creates an increased risk of first-trimester abortion. Further, no method has been developed for hysteroscopic resection of the metal "tail" that projects into the uterus.

BOTTOM LINE This hysteroscopic microinsert sterilization method is not only safe and reliable, but also offers a high level of patient satisfaction. In addition, cost savings should be realized since neither general anesthesia nor an operating or recovery room is necessary. ■

DONALD I. GALEN, MD
SURGICAL DIRECTOR,
REPRODUCTIVE SCIENCE CENTER
OF THE SAN FRANCISCO BAY AREA
ASSISTANT CLINICAL PROFESSOR
OF OBSTETRICS AND GYNECOLOGY
UNIVERSITY OF CALIFORNIA, DAVIS

Dr. Galen reports no financial relationship with any companies whose products are mentioned in this article.