Nonsurgical Contraception

The Essure device may be a new advance in women's interventional radiology.

BY ROBERT L. WORTHINGTON-KIRSCH, MD

During the last several years, interventional radiologic procedures targeted primarily or exclusively toward women have grown increasingly more prominent.

The first of these procedures was fallopian tube recanalization, which many of us have been doing for years. Despite the impressive results consistently reported for this procedure, fallopian tube recanalization has remained somewhat of an orphan procedure. Most hysterosalpingograms are performed in the GI/fluoroscopy area of a busy radiology department, and there has historically been relatively limited interaction between interventional radiologists and gynecologists. In addition, many interventional radiologists have not been proactive about seeking referrals and building this area of practice.

Another women's health intervention that has been around for years but has been relatively underemphasized is managing ovarian vein insufficiency as a cause of chronic pelvic pain in women. A combination of factors has historically mitigated against the expansion of ovarian venography and embolization beyond a few centers staffed by interventional radiologists with a particular interest in this problem.

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This all changed in the late 1990s. With the introduction of uterine artery embolization (UAE) as a definitive therapy for fibroid disease, interest in the interventional radiology community in other women's health issues has increased. Although this interest has been tempered by resistance from many in the gynecology community and by the failure of many interventional radiologists to embrace the necessity of taking on full clinical responsibility for patient management, UAE has become one of the standard therapies for fibroid disease in the US and many other countries. Its popularity continues to

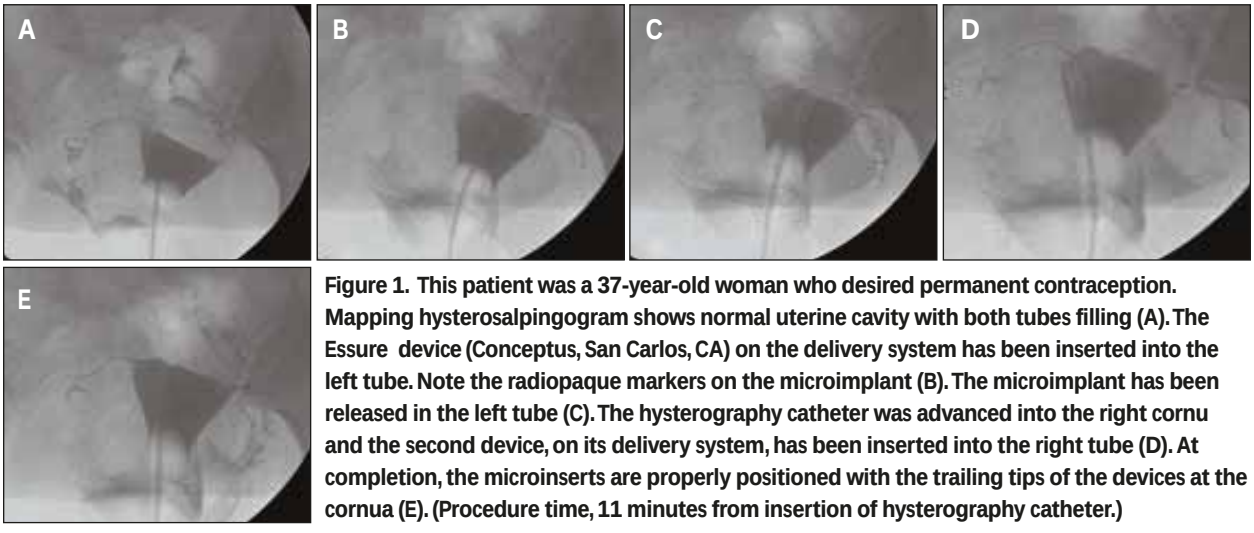

Figure 1. This patient was a 37-year-old woman who desired permanent contraception. Mapping hysterosalpingogram shows normal uterine cavity with both tubes filling (A). The Essure device (Conceptus, San Carlos, CA) on the delivery system has been inserted into the left tube. Note the radiopaque markers on the microimplant (B). The microimplant has been released in the left tube (C). The hysterography catheter was advanced into the right cornu and the second device, on its delivery system, has been inserted into the right tube (D). At completion, the microinserts are properly positioned with the trailing tips of the devices at the cornua (E). (Procedure time, 11 minutes from insertion of hysterography catheter.)

expand in many areas, especially as the literature supporting UAE has steadily improved in both quantity and quality.

Other procedures that have recently received significant interest in the interventional radiology community are the minimally invasive treatment of superficial vein insufficiency (varicose vein disease) and percutaneous vertebroplasty/kyphoplasty. Although these procedures are not limited to women, the majority of patients treated in both areas of practice are female.

THE FUTURE OF INTERVENTIONAL RADIOLOGY IN WOMEN'S HEALTH

What does the future hold for the involvement of interventional radiology in women's health? New procedures for fibroids are being evaluated. I believe that focal therapy for fibroids, whether by percutaneous radiofrequency ablation or MR-guided focused ultrasound therapy, will prove to be little more than niche applications when measured against good to excellent results of global fibroid therapy by UAE.

There have been a number of investigations for nonsurgical contraception (permanent or temporary) under fluoroscopic guidance. Transcervical embolotherapy of the fallopian tubes has been studied, at least in animals, using a variety of materials and devices, including collagen glues, cyanoacrylate glues, hydrogel or silicone plugs, and platinum microcoils.

THE ESSURE DEVICE

In 2002, Conceptus released a product called Essure. In the Essure procedure, a stainless steel/nitinol/Dacron microinsert is placed into the fallopian tube. This initially only partially obstructs the tube, but the Dacron fibers stimulate an inflammatory/fibrotic reaction (similar to the reaction incited by the Dacron cuff of a tunneled hemodialysis catheter). The reaction grows into the device, resulting in complete and irreversible occlusion of the tube in 10 to 12 weeks after placement.

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The original method for placement of the Essure device is under hysteroscopic visualization of the tubal ostia, with the device inserted through the working channel of a hysteroscope. Most of these procedures are done by gynecologists in the OR, with the patient under regional or (more commonly) general anesthesia. Although the anesthesia avoids the invasion of the peritoneal cavity that occurs with tubal ligation, many women still have concerns about being taken to the OR and undergoing general anesthesia. A few gynecologists perform Essure insertion as an office procedure, with good results.

Monitoring Caveats

There are potential problems with hysteroscopic monitoring. If the uterine cavity is distorted, as in a woman with significant fibroid disease, the ostia may not be easily identified and/or the rigid hysteroscope may be difficult to manipulate into a position adequate for microinsert placement. Also, as can be seen from hysterosalpingography, in many cases the tube has an acute angle, and there is a risk of perforation of the tube with the microinsert. In fact, this is one of the

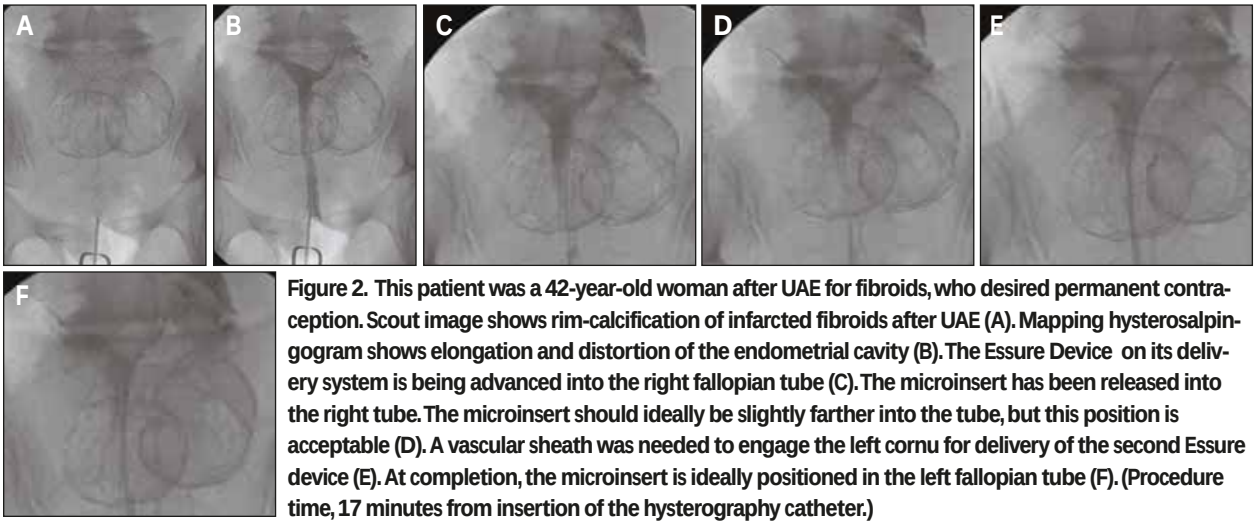

Figure 2. This patient was a 42-year-old woman after UAE for fibroids, who desired permanent contraception. Scout image shows rim-calcification of infarcted fibroids after UAE (A). Mapping hysterosalpingogram shows elongation and distortion of the endometrial cavity (B). The Essure Device on its delivery system is being advanced into the right fallopian tube (C). The microinsert has been released into the right tube. The microinsert should ideally be slightly farther into the tube, but this position is acceptable (D). A vascular sheath was needed to engage the left cornu for delivery of the second Essure device (E). At completion, the microinsert is ideally positioned in the left fallopian tube (F). (Procedure time, 17 minutes from insertion of the hysterography catheter.)

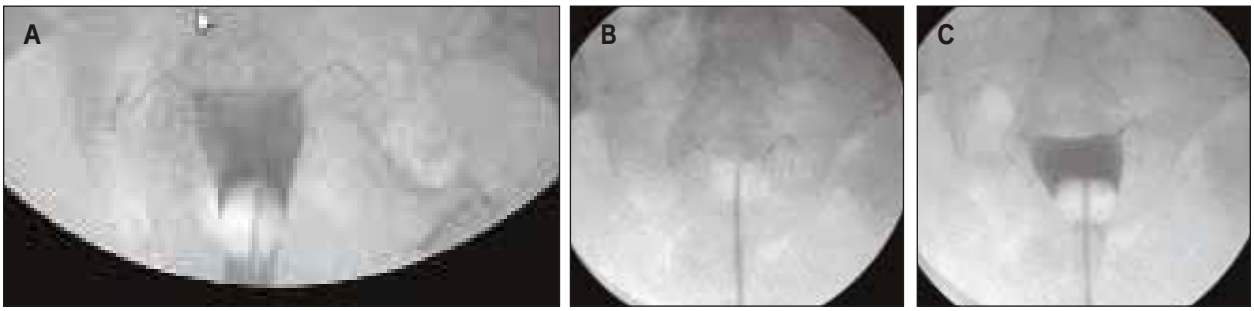

Figure 3. A 34-year-old woman who desired permanent contraception. Completion study from placement of Essure microinserts. Note that contrast continues to pass through the tubes and around/through the microinserts (A). A verification study 10 weeks after placement of the hysterography catheter fluoroscopy shows the implants in the pelvis. Note their position in relation to the air in the catheter balloon, which is in the endocervix (B). A hysterogram shows the implants ideally positioned in the tubes, unchanged in appearance from (A) except that there is now no flow into the tubes past the implants (C).

most common causes of failure of the tubes to be occluded at follow-up hysterography after Essure placement.

Placing the Device

Hugh McSwain, MD, an interventional radiologist practicing in San Diego, presented his early experience with placement of Essure microinserts under fluoroscopic control at the annual meeting of the Society of Interventional Radiology in 2005. His initial results were successful placement of the devices in seven of eight patients. At the time of his presentation, I had also begun to offer Essure placement under fluoroscopic control, both to my post-UAE patients who desired permanent birth control and to patients referred to me specifically for permanent birth control.

I perform this procedure on an outpatient walk-in basis. Before the procedure, I discuss it with the patient and obtain informed consent in the setting of an office consultation. For women who have had UAE, who have no desire for future fertility, and who do not already have permanent birth control (either by partner vasectomy or tubal ligation), I discuss Essure placement at the 3-month post-UAE follow-up appointment. Patients who opt for Essure placement are given a short course of antibiotic prophylaxis (similar to that used before hysterosalpingography) and are told to take a dose of an anti-inflammatory (typically 800 mg of ibuprofen) 2 hours before their appointments.

After registering as an outpatient, a serum pregnancy test verifies that the patient is not pregnant. In the angiography suite, the patient is positioned in the lithotomy stirrups and a vaginal speculum is inserted. After preparing the cervix and surrounding surfaces, I insert a 9-F hysterography catheter and perform a hysterosalpingogram, which demonstrates the uterine cavity and tubes. The microinserts are then inserted into the fallopian tubes and are released (Figure 1). Fluoroscopy allows the operator to ensure that the tubes are not perforated, and it is invaluable in patients whose uterine cavities are distorted by fibroid disease (Figure 2).

The procedure takes 5 to15 minutes. Most patients feel little more than some mild cramping during or afterward. After completion of the procedure, the patient leaves the interventional radiology suite and returns to her normal activities. An outpatient hysterogram is performed in 10 to 12 weeks to verify the location of the microinserts and to confirm tubal occlusion (Figure 3).

CONCLUSION

Essure microinserts appear to be a form of contraception that is at least as effective as tubal ligation, with the advantage of avoiding invasion of the peritoneal cavity. When done under fluoroscopic control, the procedure is performed on an outpatient basis without any systemic anesthesia. In addition, to date there is no report of anything like posttubal syndrome after Essure placement.

As interventional radiologists continue to expand their practices into this area of women's health, fluoroscopic transcervical fallopian tube occlusion may well become another basic procedure in this area. ■

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