Confirmation of Essure® microinsert tubal coil placement with conventional and volume-contrast imaging three-dimensional ultrasound

John A. Thiel, M.D.,[a] *Ian B. Suchet, M.B.B.Ch.,*[b] *and Karine Lortie, M.D.*[c]

[a] Department of Obstetrics and Gynecology, Regina Qu'Appelle Health Region, Regina, Saskatchewan, Canada; and [b] Department of Medical Imaging and [c] Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Saskatchewan, Saskatoon, Saskatchewan, Canada

Objective: To determine the accuracy of ultrasound in the assessment of proximal fallopian tube positioning of the Essure® microinsert coil 3 months after postprocedure.
Design: Prospective cohort study (Canadian Task Force classification II-2).
Setting: Reproductive-age women in a tertiary care hospital.
Patient(s): Reproductive-age women presenting with a request for permanent contraception.
Intervention(s): Hysteroscopic sterilization with the Essure® microinsert coil and conventional or volume-contrast three-dimensional (3D) ultrasound imaging 3 months after the procedure.
Main Outcome Measure(s): Coil position on ultrasound.
Result(s): Forty-eight of the 50 patients had successful placement of the Essure® coils, and three patients required a second attempt on one tube. Conventional or volume-contrast (3D) ultrasound showed proper positioning of the coils within the proximal fallopian tube in 42 women (84%); five women (10%) required hysterosalpingogram to show appropriate positioning. Two patients (4%) required laparoscopic tubal sterilization, and one patient (2%) was lost to follow-up.
Conclusion(s): Transvaginal ultrasound is an acceptable method of confirming proper placement of the Essure® microinsert coil within the proximal fallopian tube 3 months after the procedure. (Fertil Steril® 2005;84:504–8. ©2005 by American Society for Reproductive Medicine.)

Key Words: Sterilization, hysteroscopy, contraceptive devices, ultrasonography, fallopian tubes, prospective study

Tubal sterilization remains the most common form of permanent sterilization, most often performed as a laparoscopic day surgery procedure (1, 2). The Essure® permanent birth control microinsert coil (Conceptus, San Carlos, CA) provides reliable permanent contraception without the risks of laparoscopic surgery (3), the need for general anesthesia, or the postoperative nausea and pain associated with this type of surgery (4, 5).

The Essure® hysteroscopic tubal sterilization is a well-tolerated ambulatory procedure that allows women access to permanent sterilization without the need for general anesthesia and risk of laparoscopic complications (4, 5). The Essure® microinsert coil is placed hysteroscopically into the proximal fallopian tube (Fig. 1) and induces a fibrotic reaction resulting in a physiologic obstruction (4, 5). Correct placement of the Essure® microinsert coil is essential to ensure retention of the device, an appropriate fibrotic response, and the subsequent tubal occlusion and desired sterility.

Received September 16, 2004; revised and accepted January 31, 2005.
Presented at the Global Congress of Gynecologic Endoscopy, San Francisco, California, November 10–13, 2004.
Reprint requests: John A. Thiel, M.D., 100-2631 28th Avenue, Regina, Saskatchewan, Canada S4S 6X3 (FAX: 306-586-3511; E-mail: drjthiel@aol.com).

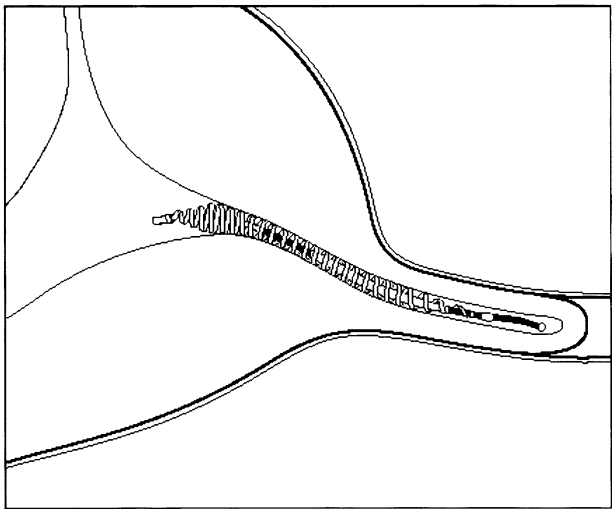
To ensure complete occlusion of the tubes, it is recommended that the Essure® coils be placed within the proximal portion of the fallopian tubes and that this position be imaged and confirmed at 3 months after the procedure (6). Initially, it was recommended that patients undergo hysterosalpingography to confirm tubal occlusion. However, the rate of cornual obstruction at 3 months is high enough that plain film pelvic radiography can be substituted for hysterosalpingography to determine whether the coils have been retained within the pelvic cavity in an appropriate position (7). The use of plain film pelvic radiography demonstrates coil retention, but because of the lack of soft tissue detail, there is no information available regarding the relationship of the coil to the uterine cornua. Furthermore, the use of either plain film pelvic radiography or hysterosalpingography results in exposure to ionizing radiation.

The objective of this study was to determine the effectiveness of ultrasound in localizing the Essure® coils within the fallopian tube 3 months after the procedure thus reducing the need for both plain film pelvic radiography and hysterosalpingography. We prospectively followed a cohort of women for 3 months after placing the Essure® microinsert coil, using transvaginal conventional (two-dimensional [2D]) and volume-contrast (three-dimensional [3D]) ultrasound to determine the position of the coils in relation to the uterine cornua and proximal fallopian tube.

0015-0282/05/$30.00
doi:10.1016/j.fertnstert.2005.01.135

FIGURE 1

Schematic diagram of proper Essure® microinsert coil placement within the uterine cornua extending into the proximal fallopian tube, with six coils remaining in the uterine cavity (used with permission).



Thiel. Ultrasound confirmation of Essure® coil position. Fertil Steril 2005.

MATERIALS AND METHODS

Fifty women presenting with a request for permanent sterilization between June 2003 and May 2004 were prospectively followed after undergoing the Essure® microinsert coil hysteroscopic tubal procedure. Placement of the Essure® microinsert coils was completed in an ambulatory setting using the technique as described by Kerin et al. (4). Patients received indomethacin 100 mg per rectum 1 hour before the procedure and were administered IV conscious sedation with fentanyl (Abbott Laboratories, Toronto, Canada) 2 μg/kg body weight and diazepam 2.5 mg (Pharmacia Canada, Mississauga, Canada).

Direct visualization of the tubal ostium was accomplished using a 2.7-mm 12-degree diagnostic telescope in a 5.5-mm single-channel operative hysteroscope (ACMI, Toronto, Ontario, Canada) with normal saline as the distending medium. The Essure® microinsert coils were placed into the tubes, and if one or both tubes could not be cannulated, a second procedure was booked within 1 month. If a second attempt was not successful, tubal patency was assessed with hysterosalpingography to determine whether the tubes were patent. If dye spill was noted on one or both sides on the hysterosalpingogram, the patient was offered laparoscopic tubal sterilization.

After the procedure, patients were instructed to continue using an alternative method of contraception until confirmation of coil placement was completed 3 months after the procedure.

Transvaginal ultrasound confirmation of coil placement was performed using the GE Voluson 730 ultrasound scanner (Kretztechnik; GE Medical Systems, Zipf, Austria). Initially, coil location was evaluated with a transverse image at the level of the uterine cornua using conventional 2D ultrasound. The coils were visualized as echogenic nonshadowing linear structures originating in the cornua or uterine cavity and following the expected location of the fallopian tubes toward the adnexa.

The last 34 cases in the series were also evaluated using volume-contrast (3D) imaging, which produced a 5-mm thick volume image in the C-plane (VCI-C) similar to that found at hysterosalpingogram. If either coil could not be demonstrated, a plain film pelvic radiograph was performed to exclude expulsion or extraluminal migration. If the coils were visualized to be within the tube, but were not in good proximal position, hysterosalpingography was completed using Conray 60 dye (Mallinkrodt, Point Claire, Quebec, Canada) to confirm tubal occlusion.

RESULTS

The mean age of the patients undergoing the Essure® procedure was 36 ± 5.8 (range, 24–44 years), the mean body mass index was 27 ± 6.3, and the mean gravidity and parity was 2.6 ± 1.4 and 2.2 ± 1.1, respectively.

Three of the 50 women (6%) undergoing the Essure® hysteroscopic sterilization procedure required a second attempt to cannulate one side. The second attempt was successful in two of these women. The third patient required laparoscopic tubal sterilization because of an inability to advance the coil into the proper position within the proximal fallopian tube. One other patient requested laparoscopic tubal sterilization after a failure of the initial attempt to pass the coils on either side.

Transvaginal ultrasound imaging was successful in demonstrating the adequate proximal placement of the Essure® coils in 42 women (84%). Figure 2 shows the echogenic coils in an ideal placement within the proximal fallopian tube when visualized with conventional (2D) ultrasound in the transverse plane. The use of volume-contrast (3D) imaging improved the visualization of the coils within the uterine cornua and proximal fallopian tube (Fig. 3). The 3D image produced provides excellent detail of the relationship of the coil to the uterine cavity and its position in the proximal tube.

Two patients (1%) had coils lying within the uterine cornua in an anterior plane, making it difficult to image either transvaginally or transabdominally. The coils were subsequently localized with a plain film pelvic radiograph. Although plain film pelvic radiography localized the coils in the pelvis, it was not possible to determine their relationship to the uterus or fallopian tubes (Fig. 4). Once the coils were determined to be within the pelvis, volume-contrast (3D)