CASE REPORT

Incorrect position of Essure microinserts 3 months after successful bilateral placement

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Objective: To describe incorrect positions of Essure microinserts detected at 3 months' follow-up.
Design: Case report.
Setting: Outpatient department of obstetrics and gynecology in a Dutch teaching hospital.
Patient(s): Initial series of 100 patients who underwent hysteroscopic sterilization using Essure between December 2003 and June 2004.
Intervention(s): Hysteroscopic placement of the Essure System, follow-up at 3 months with transvaginal ultrasound (TVU), and hysterosalpingography.
Main Outcome Measure(s): Bilateral placement rate, tubal obstruction, and detection of incorrect Essure microinsert localization at follow-up after apparent successful bilateral placement.
Result(s): Bilateral placement of Essure microinserts in one session was successful in 93 women (93%). In 90 of these women (96.8%), tubal obstruction was proven at follow-up 3 months later. Three incorrect positions of an Essure insert were seen: two expulsions and one perforation into the abdominal cavity.
Conclusion(s): Incorrect position of Essure microinserts was seen only when the initial placement procedure was difficult. When a placement procedure was difficult or other suboptimal conditions are present during the procedure, we advise performing a TVU or pelvic X-ray in these women 4 weeks after the procedure or after the first vaginal bleeding, instead of waiting for follow-up after 3 months. (Fertil Steril® 2009;91:930.e1–e5. ©2009 by American Society for Reproductive Medicine.)

Key Words: Essure, hysteroscopic sterilization, transcervical sterilization, perforation, expulsion

Transcervical sterilization using the Essure System (Conceptus, Mountain View, CA) is becoming increasingly popular as a means of permanent birth control. Worldwide, more than 100,000 women have been sterilized with this method. It is a patient-friendly procedure that does not require general anesthesia and surgical incisions (1, 2).

During office hysteroscopy the uterine cavity is inspected and the tubal openings identified. The introduction device is inserted in the fallopian tube, after which the device can be deployed and the Essure microinsert remains in position (2). After insertion and deployment, ideally 3–8 coils of the insert are visible outside the tubal opening (2).

An Essure microinsert consists of a stainless steel inner coil, a nickel titanium alloy outer coil, and polyethylene terephthalate (PET) fibers covering the inner coil (1, 3). The PET fibers induce a tissue response, which causes fibrous tissue ingrowth and thus tubal occlusion (3, 4). Patients have to use additional contraception until at 3 months' follow-up correct placement of the inserts and/or tubal obstruction is proven.

Transvaginal ultrasound (TVU) examination has proved to be an adequate method to confirm the microinsert position at follow-up (5–8). When ultrasound examination is inconclusive or an undesirable position of an insert is suspected, a hysterosalpingography (HSG) can be performed (8).

Bilateral placement rate in one session ranges from 86% to 91.3% (2, 6, 11, 12). Perforation, expulsion, and inability to place the inserts bilaterally are known undesirable events of the Essure placement procedure. Most of these events described in earlier studies have been detected during the procedure itself and were attributed either to a design problem of the material that was subsequently improved or to incorrect placement procedures (3, 4). Malformations or abnormalities of the uterine cavity and the fallopian tubes are associated with placement failure (1, 2, 9, 10). Other factors, such as tubal spasms, are also suspected to have a negative influence on

Received March 17, 2008; revised July 22, 2008; accepted August 7, 2008.
M.B.E.G. has nothing to disclose. S.V. is a consultant for Conceptus SAS, and a member of the Advisory Board of Hologic. A.T. has nothing to disclose. H.A.M.B. has nothing to disclose.
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0015-0282/09/$36.00

doi:10.1016/j.fertnstert.2008.08.013

TABLE 1

Patients' characteristics.

	Mean	Median	Range
Age (yrs)	38	38	29–47
Parity	2	2	0–6
Operating time (min)	10	8	4–34

Gerritse. Incorrect position of Essure inserts. Fertil Steril 2009.

Essure placement procedures (1, 10, 12). More recently, a case has been described in which there was no tissue ingrowth with a correctly positioned device 3 months postpartum (13).

Between December 2003 and June 2004 an initial series of one hundred women were sterilized with the Essure SystemTM in our teaching hospital. At three months follow-up three patients were diagnosed with an incorrect position of one of the inserts; we report those cases here.

MATERIALS AND METHODS

This was a prospective cohort study set in a university-affiliated teaching hospital with outpatient hysteroscopy facilities, where 500 outpatient hysteroscopic procedures are performed annually. Institutional Review Board approval was not necessary for this study. Placement of Essure devices started in December 2003, and the first 100 procedures were recorded. One gynecologist (S.V.) specialized in hysteroscopy performed all the procedures. The procedure was scheduled in the proliferative phase of the cycle or shortly after a withdrawal bleeding if patients were using oral contraceptives. Women were advised to take a nonsteroidal antiinflammatory drug (NSAID) the evening before and 1 h before the placement of the Essure microinserts.

The procedure was performed using a 5.5-mm continuous flow rigid hysteroscope with a 30° lens (Olympus; Winter and Ibe, Hamburg, Germany) and a 5-French working channel. Uterine distension was obtained using pumped saline solution with a pressure of 100 mm Hg. The hysteroscope was introduced using a vaginoscopic approach without speculum, tenaculum, or local anesthetics. If bilateral placement was unsuccessful in the first session, a second attempt was offered.

Patients' characteristics and procedure characteristics were recorded in a database. All procedures were recorded on VHS video.

After surgery, patients were instructed about possible complications and when they should contact the hospital. They were scheduled for a 3-month follow-up, which included TVU and HSG. After proven correct position of microinserts at follow-up, patients were given the advice to stop other methods of contraception.

Outcome was defined as successful bilateral placement and tubal obstruction. Incorrect localizations detected at 3 months' follow-up were analyzed. Findings at TVU and HSG were also recorded in the database.

RESULTS

From December 2003 to June 2004, 100 women underwent an Essure procedure. Mean operating time was 10 min (range 4–34 min). Patients were 29–47 years old with a mean age of 38 years, and parity ranged from zero to six with a median of two births (Table 1). Before the procedure, most women (47%) used oral contraception. All of the patients left the hospital within 2 h after the procedure and were able to return to normal activity within 24 h.

Bilateral microinsert placement in one session was successfully performed in 93 patients (93%); in seven patients (7%) the procedure failed. A second attempt was performed in three of these seven patients, and in all three cases the second procedure was also unsuccessful.

At 3 months' follow-up, correct cornual localization of both devices was confirmed by ultrasound in 84 (90.3%) of the 93 cases with successful bilateral placement. In 90 patients (96.8%), HSG showed bilateral occlusion of the fallopian tubes. In three patients an incorrect localization of one of the microinserts with patency of the ipsilateral fallopian tube was seen on HSG: one perforation, an expulsion into the uterine cavity, and one complete expulsion. The latter two patients were successfully sterilized in a second Essure placement procedure. We present here the three cases with failure of the Essure system detected at follow-up.

Case Descriptions

Patient A was a 42-year-old multiparous woman. No abnormalities were seen during hysteroscopy. During insertion of the microinsert in the left fallopian tube, a resistance occurred and was eventually overwon. This was thought to be a tubal spasm. When bilateral placement was completed, three coils were visible on the right side and six coils on the left side. Procedure time was 10 min.

At TVU follow-up after 3 months, both inserts were not clearly visible. On pelvic X-ray an abnormal configuration of the left microinsert was seen. In evaluating microinsert position with X-ray or HSG, it is very important to note the "markers" for the proximal and distal ends of the inner and outer coil.

The inner coil can be recognized very easily as a thin line structure with two landmarks: the distal end, most lateral (first marker), and the proximal end (third marker). The distal end of the outer coil (second marker) is next to the first marker, and the platinum band at the proximal end of the outer coil is visible as the fourth marker. In a normal configuration, the fourth marker is in line with the other three markers. In this case, the fourth marker was not in line with the other three markers and too close to the second marker. The HSG showed patency of the left tube (Fig. 1).

Retrospectively, the patient had experienced abdominal pain for several weeks after placement of the Essure System.