Incorrect position of Essure microinserts 3 months after successful bilateral placement.
Abstract

Objective To describe incorrect positions of Essure microinserts detected at 3 months’ follow-up.

Design Case series 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 hysterosalpingograp (HSG).

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.

Key Words Essure, Hysteroscopic sterilization, Transcervical sterilization, Perforation, Expulsion
Introduction

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) fibres covering the inner coil (1,3). The PET fibres 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 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 System 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 non-steroidal anti-inflammatory 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 anaesthetics. 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 hours.
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 over won. 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

### Table 1

**Patients’ characteristics.**

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<th>Mean</th>
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<td>Operating time (min)</td>
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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. Perforation of the left device into the abdominal cavity was suspected, and a laparoscopy was performed. The Essure microinsert was detected in the omentum. No signs of inflammation or adhesions were seen. During laparoscopy, the insert was removed, and tubal ligation of the left tube was performed using a Filshie Clip.

Patient B was a 42-year-old multiparous woman. During hysteroscopy, a normal uterine cavity was seen with some small endometrial polyps. Insertion of both Essure microinserts was difficult. After insertion, one coil extended from the right tubal ostium. The number of coils extending from the left tubal opening was not clearly visible. At the time of the procedure, it was speculated that this was attributable to thickened endometrium. Procedure time was 17 min.

The TVU 3 months later detected only the right microinsert in a cornual position; no insert was seen on the left side. Pelvic X-ray showed one device present in the pelvis. On HSG, the right microinsert was seen with tubal occlusion, whereas the left tube was patent (Fig. 2). The patient had not noticed an expulsion. In a second procedure, another microinsert was placed in the left fallopian tube. After another 3 months, obstruction of both fallopian tubes was proved by HSG.

Patient C was a 43-year-old multiparous woman with a history of two caesarean sections. During the procedure, a levonorgestrel intrauterine device was removed.

**Figure 1**
The microinsert on the right side shows a normal configuration of the four markers. The left-side insert has an abnormal configuration and an abnormal position in the pelvis; on HSG the left tube is patent.
Intrauterine adhesions were seen in the left tubal corner. Insertion of the left device was very difficult but successful, although it took longer than usual. Owing to the formation of edema caused by the extended procedure time, the placement on the right side became unexpectedly difficult, too. Three coils were visible on the left side and two coils on the right side; total procedure time was 31 min.

On follow-up TVU, the left insert was visible in a correct position, but the insert on the right side could not be made clearly visible. On pelvic X-ray, the right device was seen in an abnormal position, proximal of the right tube. The HSG showed a patent right fallopian tube (Fig. 3). During hysteroscopy, the right microinsert was floating in the uterine cavity. After removal, another Essure microinsert was placed in the right tube with three coils visible. Control HSG after 3 months showed tubal obstruction on both sides.

Discussion

Perforation rate in our initial series of 100 patients was 1%, which is in accordance with the literature. Through the years, the perforation rate has decreased from 3.7% (2,4) to 1.2-2.6% (1,9). In 2% of our patients, we observed an expulsion after an initially apparent successful placement procedure. Expulsion from the fallopian tube is reported in 1.3-3.6% and is due to incorrect insertion of the microinsert, mostly concerning placement too proximal in the tube (1,2).

Figure 2
Only the right insert is visible, and the left tube is patent for contrast fluid.
Every procedure has its period of training, and the learning curve for this particular intervention has been shown in other studies to be short, about five completed procedures (1,2). When accustomed to performing a hysteroscopy, physicians rate the Essure placement procedure as simple or moderately simple (1). It is unlikely that the learning curve contributes much to misplacement rates. However, even in the hands of experts, placement procedures can result in an incorrect position of microinserts.

When we review our own cases, we see that in case A, in which the left insert perforated into the abdominal cavity, a resistance thought to be a tubal spasm was over won. In retrospect, this was probably the moment of perforation. The insert migrated to the abdominal cavity in the weeks after the procedure, causing the patient abdominal pain. Why the patient did not contact the hospital with this complaint is unknown. Patient education and staff education are very important to recognize symptoms associated with complications. Tubal spasms can occur during a hysteroscopic procedure, but perforation and thus making a false route with the Essure placement device can mimic a tubal spasm, as we have seen here. Tubal spasms have been reported to have an adverse effect on the Essure placement (1,10,12). A spasmolytic such as butylscopolamine can be administered before the procedure to prevent tubal spasms (12). Use of NSAIDs before the procedure is also associated with better placement rates (1).

**Figure 3**
The right device has an abnormal position in the pelvis on X-ray, and on HSG the right tube is not obstructed.
In case B, the complete expulsion, the uterine cavity contained some endometrial polyps, which could have blurred vision. The insertion was also more difficult than normal and procedure time was longer than usual. When the procedure was completed, the left insert, which would later be expelled, was not clearly visible. In this case, there were multiple suboptimal conditions that could have caused the insert misplacement. Failure to place the Essure microinserts bilaterally is more often seen in the presence of abnormalities of the uterine cavity or openings of the fallopian tubes (1,2,9,10).

In the case of expulsion into the uterine cavity, case C, the procedure time was significantly longer than average. This was due to removal of the intrauterine device in the beginning of the procedure and to the placement procedure that turned out to be difficult on both sides. The first device was placed on the side with adhesions, which was thought to be the most difficult side to place, but because of the prolonged procedure time, the other side turned out to be difficult to place as well. This last microinsert was later expelled into the uterine cavity. After placement, both sides showed a normal number of coils extending from the uterotubal corner. We think the prolonged procedure time caused a fluid collection to form under the endometrium and thus complicated the placement of the second insert. The second insert was probably placed under a layer of endometrium instead of in the opening of the tube, and a shedding of endometrium, such as in a menstrual bleeding, released the insert.

In conclusion, perforation into the abdominal cavity and expulsion from the fallopian tube can occur with or after placement of Essure microinserts, even in the hands of experienced physicians. It is important that patients are seen at follow-up with at least TVU to make sure that microinserts are in the correct position. Only after normal findings at followup examination should patients get the advice to stop contraception.

Complications can be detected during the procedure itself or at follow-up. When, during the procedure, there is doubt about the position of a microinsert, a TVU can be performed at that time. But one should realize that in case of perforation and expulsion, most incorrectly placed microinserts will migrate in the period after the procedure. A majority of cases will not be detected during or directly after the procedure.

We advise screening patients with apparent successful bilateral placement but with difficult placement procedures, other suboptimal conditions during the procedure, or abdominal pain earlier than 3 months after the procedure. Initially this can be done with TVU after the patient’s first period or withdrawal bleeding (approximately 4 weeks), and when in doubt, a pelvic X-ray can be performed. Perforation and expulsion do not seem to cause serious adverse events in patients. These women will have to undergo a laparoscopy to trace and remove the missing insert in case of perforation, and undergo a new Essure insertion procedure or choose a different form of birth control.
References


