6 Unintended pregnancies after Essure sterilization in the Netherlands

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Abstract

**Objective** To analyze the data of cases of unintended pregnancies after Essure sterilization.

**Design** Retrospective case series analysis.

**Setting** National multicenter.

**Patient(s)** Ten cases of unintended pregnancies after Essure sterilization in the Netherlands were reported from August 2002 through May 2008.

**Intervention(s)** Data on the hysteroscopic Essure sterilization procedures and post-procedure confirmation tests of the reported cases were reviewed and analyzed by two authors. The causes of the unintended pregnancies were determined in agreement with the physicians who performed the sterilizations.

**Main Outcome Measure(s)** Most pregnancies occurred in patients with only one device placement and bilateral occlusion on hysterosalpingography (HSG). Other cases included misinterpretation of HSG, undetected abnormal device position by ultrasound, one undetected pre-procedure pregnancy, and two patient failures to follow up with the physician advice.

**Conclusion(s)** The risk of pregnancy after hysteroscopic sterilization may be reduced by strictly following the follow-up protocol, performing a urinary pregnancy test on the day of the procedure, and instructing the patient to return for the follow-up visit. A procedure with only a single device placement in a patient without a history of salpingectomy of the heterolateral tube should be considered unsuccessful.

**Key Words** Essure sterilization, Confirmation test, Unintended pregnancy, Hysterosalpingography, Ultrasound
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 200,000 women have been sterilized with this method. In combination with the vaginoscopic no-touch technique of hysteroscopy, it is a patient-friendly procedure that does not require general or regional anesthesia or surgical incisions (1,2). In the Netherlands, around 9,000 women are sterilized each year (3). In May 2008, Essure sterilization was first offered to patients who requested permanent contraception in 45 out of 100 Dutch hospitals. Since its introduction in 2002, more than 6000 procedures have been performed. All gynecologists performing the Essure method are appropriately trained gynecologists with experience in office hysteroscopy who have been trained by a precept in the procedure. During office hysteroscopy, the uterine cavity is inspected and the tubal openings are identified. The introduction device is inserted into the fallopian tube, after which the device is allowed to expand while the Essure microinsert remains in position. After insertion and expansion of the microinsert, ideally three to eight coils of the insert are visible outside the tubal opening (2). The Essure microinsert consists of a stainless steel inner coil, a nickel titanium alloy outer coil, and polyethylene terephterate (PET) fibres covering the inner coil (1,4). The PET fibres induce a tissue response, which causes fibrous tissue to grow and hence tubal occlusion (4,5). Patients have to use additional contraception until correct placement of the inserts and/or tubal obstruction is proven at 3-month follow-up. Transvaginal ultrasound examination has proven to be an adequate method to confirm the microinsert position at follow-up (6-9). When ultrasound examination is inconclusive or an abnormal location of a microinsert is suspected, a hysterosalpingography (HSG) is indicated.

The inability to place the inserts bilaterally, perforation, and/or expulsion are known undesirable events of the Essure placement procedure. Most of these events described in previous studies have been detected during the procedure itself and were either attributed to a design problem of the material that was subsequently improved or to incorrect placement procedures (4,5). Malformations or abnormalities of the uterine cavity and the fallopian tubes are associated with placement failure (1,2,10,11). Other factors, such as tubal spasms, are also suspected to have a negative influence on Essure placement procedures (1,11,12).

Because hysteroscopic sterilization is a rather new method, it is important that all pregnancies are reported and that the cases are reviewed to determine the cause of the unintended pregnancy. Some of the causes might be preventable. Understanding these causes can be helpful to improve the follow-up protocols and reduce the number of failures in the future.
Materials and methods

This study is a retrospective multicenter case series in the Netherlands. An estimated 6,000 hysteroscopic sterilizations were performed in 45 hospitals in the Netherlands from August 2002 to May 2008 as estimated from the data from the Dutch distributor. All procedures were performed by appropriately trained gynecologists with experience in office hysteroscopy who participated in a training course for hysteroscopic sterilization with Essure. The procedures were 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 on the evening before and 1 hour before placement of the Essure microinserts. The majority of procedures were performed by a vaginoscopic approach hysteroscopy, using a 4.2 to 5.5 mm continuous-flow rigid hysteroscope without the use of local or general anesthesia. Uterine distension was obtained using saline that was introduced through a fluid management system or by gravity. From the beginning, all patients underwent a HSG after 3 months of follow-up. Since the introduction of the Dutch protocol for the follow-up of Essure sterilization in 2005, vaginal ultrasound has been used for confirmation of tubal-cornual location of the

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Table 1
Overview of 10 cases of unintended pregnancies after Essure sterilization.

<table>
<thead>
<tr>
<th>Case</th>
<th>Age</th>
<th>Parity</th>
<th>Year</th>
<th>Confirmation test</th>
<th>Interval*, months</th>
<th>Cause of failure</th>
<th>Conclusion a</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>36</td>
<td>0</td>
<td>2004</td>
<td>US, HSG</td>
<td>8</td>
<td>Perforation</td>
<td>Misread</td>
</tr>
<tr>
<td>B</td>
<td>31</td>
<td>4</td>
<td>2005</td>
<td>US</td>
<td>3</td>
<td>Expulsion</td>
<td>NC</td>
</tr>
<tr>
<td>C</td>
<td>41</td>
<td>2</td>
<td>2005</td>
<td>HSG</td>
<td>24</td>
<td>Unilateral placement</td>
<td>NA</td>
</tr>
<tr>
<td>D</td>
<td>38</td>
<td>3</td>
<td>2006</td>
<td>US</td>
<td>10</td>
<td>Expulsion</td>
<td>Misread?</td>
</tr>
<tr>
<td>E</td>
<td>36</td>
<td>1</td>
<td>2006</td>
<td>US</td>
<td>11</td>
<td>Unknown</td>
<td>NA</td>
</tr>
<tr>
<td>F</td>
<td>40</td>
<td>2</td>
<td>2006</td>
<td>US</td>
<td>7</td>
<td>Perforation</td>
<td>NA</td>
</tr>
<tr>
<td>G</td>
<td>39</td>
<td>5</td>
<td>2007</td>
<td>—</td>
<td>6</td>
<td>Partial expulsion</td>
<td>NC</td>
</tr>
<tr>
<td>H</td>
<td>41</td>
<td>2</td>
<td>2007</td>
<td>HSG</td>
<td>6</td>
<td>Unilateral placement</td>
<td>NA</td>
</tr>
<tr>
<td>I</td>
<td>41</td>
<td>1</td>
<td>2007</td>
<td>HSG</td>
<td>4</td>
<td>Unilateral placement</td>
<td>NA</td>
</tr>
<tr>
<td>J</td>
<td>24</td>
<td>3</td>
<td>2007</td>
<td>—</td>
<td>0</td>
<td>Luteal pregnancy</td>
<td>NA &amp; NC</td>
</tr>
</tbody>
</table>

* Interval between Essure placement and pregnancy. US = ultrasound.

b NA = nonadherence to protocol; NC = patient noncompliance.
microinserts after an uncomplicated successful bilateral placement. In all other cases, an HSG is still indicated (6). Patients were instructed to continue alternative contraception until the follow-up visit at 3 months.

The reported cases were reviewed by one of two authors who participated in the faculty of the physician training courses and who supervised as preceptors all first three to five procedures of beginning gynecologists of Essure sterilization in The Netherlands.

**Results**

As of May 2008, 10 pregnancies were reported to the authors. Table 1 provides the causes of the pregnancies as determined by the reporting physicians in collaboration with the reviewers. In case A, there was a misinterpretation of the HSG at follow-up. The right device was in an unsatisfactory position (perforation), with patency of the right tube. This patient was also examined with ultrasound before the HSG, and an abnormal location of the microinsert or even perforation was not recognized. In two cases, the reported pregnancy was associated with a noncompliance of the patient. In case B, the physician suspected an abnormal location of one microinsert on ultrasound at the 3-month follow-up, but the patient did not return for HSG. One patient, patient G, failed to return for the 3-month follow-up. After delivery of a healthy child, ultrasound examination showed both devices to be in an apparently normal position, while on HSG there was an unsatisfactory device location, with kinking of the left device and patency of the left tube.

One patient, patient D, showed a complete expulsion of one device on X-ray after the delivery of a child. In this case, the ultrasound examination at her 3-month follow-up had probably been misinterpreted. A second patient, patient F, who had a misinterpretation of the ultrasound at 3 months of follow-up, had a complicated placement, with placement of a third device after a spontaneous expulsion of the first device. During laparoscopic sterilization after termination of pregnancy, one device was located intramurally under the serosa because of partial perforation, while the other one was in a proper position in the other tube (13).

One pregnancy occurred before the device placement was done (patient J). Taking the probable date of conception into account, it must have been a luteal-phase pregnancy due to a failure of contraception before the procedure. A urinary pregnancy test on the day of the procedure was not performed.

In three patients (C, H, and I) there was a unsuccessful attempt of device placement on one side, and only one device was placed. On HSG, the heterolateral tube seemed to be occluded.
One patient, patient E, delivered a healthy child by caesarean section. Tubal sterilization was performed during the procedure, but no information was obtained about the location of the device and patency of the tubes during surgery. At the 3-month follow-up after the initial uneventful procedure, both microinserts were in normal position on ultrasound.

**Discussion**

The Essure device has become an increasingly popular alternative for laparoscopic sterilization in the Netherlands and other Western countries because of its minimally invasive and well-tolerated placement without the need for general or local anesthesia. Since its introduction in the Netherlands in 2002, 10 unintended pregnancies have been reported. The majority of these pregnancies (cases B, C, F, G, H, I, and J) are associated with patient noncompliance or non-adherence to the Dutch follow-up protocol introduced in 2005.

It is apparent that Essure sterilization will not prevent pregnancy in all cases. It is impossible to prevent pregnancy in all cases with any contraceptive technique other than bilateral oophorectomy. There will always be product failures and human errors that result in pregnancy.

Until now, no pregnancies have been reported in patients from the phase II or pivotal trial, but recently Levy et al. reported about 64 pregnancies after Essure sterilization that were reported to the device company from countries all over the world up until December 2005 (14). The most important cause of reported pregnancies was patient or physician non-adherence to protocol (47%). The most common manifestation of non-adherence was the patient failure to return to the follow-up visit. The second most common finding was misinterpretation of X-ray films or HSG at the follow-up visit. Improperly read or interpreted results accounted for 18 (28%) of the reported unintended pregnancies. Contraceptive failure before device placement occurred in eight (12.5%) of the reported pregnancies; seven of these pregnancies were luteal-phase pregnancies.

Two more cases of pregnancy were reported (15). One patient cancelled the HSG due to financial concerns and was lost to follow-up. The second patient underwent a followup evaluation appropriately at 3 months. Her HSG appeared to indicate proper placement of the microinserts with subsequent bilateral tubal occlusion. Upon removal of the uterus by vaginal hysterectomy 6 months after termination of pregnancy, a microinsert was noted protruding through the upper myometrium at the left cornu of the uterus.
In this series of 10 cases of unintended pregnancies in the Netherlands, there were only two cases (B and G) of non-compliance of the patient (20%) Only one patient failed to return for the 3-month follow-up visit.

In three cases (A, D, and F), an abnormal position of one device was not recognized by the confirmation test (A: HSG + ultrasound; D and F: ultrasound) at the follow-up. The ultrasound images are not useful for reviewing because the final decision and results of the ultrasound examination are made by the physician performing a real-time ultrasound scan. The real-time images of ultrasound examination are not recorded and therefore not available for reviewing. This is one of the main disadvantages of ultrasound used as a diagnostic tool to confirm satisfactory device localization after Essure sterilization. Saved three-dimensional (3D) ultrasound volume data may serve that purpose in the future. Patient A, with the misinterpretation of the HSG (perforation of left device), was also examined by ultrasound during the 3-month follow-up visit. An abnormal position of one of the devices was not suspected. The procedure of case F was complicated by a spontaneous expulsion of the first device and placement of a third device. Only an ultrasound examination was done to confirm bilateral localization. According to the Dutch follow-up protocol, in this case an HSG was indicated. In addition, one patient who was lost to follow-up had a normal ultrasound after termination of pregnancy, while on HSG there was an abnormal positioning of one device with tubal patency. The explanation for these contradictions in the results of these different diagnostic tests could be that it is difficult to visualize the entire device on a single image plane. The full distal (tubal) extent of the device cannot always be followed.

The radio opaque markers at the ends of the coils are not visible on ultrasound images. The outer coil is always visible as two interrupted echogenic lines. The inner coil can be incidentally seen as a central linear echogenic line (16). In case of a partial perforation with the outer coil located intramurally or near the cornual-isthmic junction, the location of the microinsert could resemble a normal position on ultrasound. This means that if there is any suspicion of tubal or myometrial perforation (i.e., a sudden drop in resistance or difficult sounding of the tube) an HSG should be performed. It may be that 3D ultrasound with or without contrast infusion improves the diagnostic characteristic of two-dimensional imaging (8,17). Another pitfall of ultrasound could be that one device is recognized twice by turning the ultrasound probe from one site to the other. The same device will be seen at the opposite site of the uterus after turning the probe 180 degrees. According to the instructions to the physicians in the training courses, both devices have to be recognized at the same time in one single plane during ultrasound examination to be sure that two devices are examined. A print or recording of this view is recommended. Training should be initiated to guarantee the specific ultrasound
skills needed to recognize adequate placement of the microinserts in the patients undergoing Essure sterilization.

In the three patients with failed attempts on one side (C, H, and I), the delivery system could not be advanced to the ostia, and only one device was placed in a proper position. Subsequent HSGs showed occlusion of both tubes, which was thought to be caused by fibrosis of the tube. In an earlier report, such cases were omitted from the failures and considered to be successful (11). We advise that in case of a unilateral placement and an unsuccessful placement at the opposite site, without a history of tubectomy for this site, the procedure is considered to be unsuccessful and no HSG or other technique for evaluation should be performed. Even in instances in which the follow-up HSG shows occlusion of the tube, the occlusion could be caused by factors other than the device. Therefore, to rely on the device for contraception, it must be in a proper position and show occlusion on HSG.

Probably not all cases of pregnancy have been reported to the authors, although the estimated number of unreported cases is low. The number of pregnancies, 10 in 6,000, is similar to the number published earlier for global data, 64 in 50,000. The pregnancy rate is low, and it seems that the majority of the cases appear to be preventable. Misinterpretation of radiological as well as ultrasound imaging does occur.

The use of ultrasound imaging diminishes the need for radiological assessment, although the printed images are not useful for retrospective evaluation of abnormal localization of devices and other complications after microinsert placement. Procedures have to be performed by a gynecologist who has been properly trained in the technique as well as in the diagnostic tests during the follow-up visit. Patients have to be informed about the complication risks of hysteroscopic sterilization and the need for adequate contraception before the procedure and until the 3-month confirmation test has shown a satisfactory position of both devices.

**Conclusion**

This study illustrates that hysteroscopic sterilization with Essure is a popular and reliable alternative for laparoscopic sterilization in the Netherlands. The risk of pregnancy with hysteroscopic sterilization may be reduced by strictly following the protocol for follow-up, performing a urinary pregnancy test on the day of the procedure, and instructing the patient to return for the follow-up visit. A procedure with only a single device placement in a patient without a history of tubectomy of the heterolateral tube should be considered as unsuccessful.
References


