Twelve-year retrospective review of unintended pregnancies after Essure sterilization in the Netherlands

Emilie Hitzerd, M.D.,[a] Henk W. R. Schreuder, M.D., Ph.D.,[b] Michel P. H. Vleugels, M.D., Ph.D.,[c] and Sebastiaan Veersema, M.D., Ph.D.[a]

[a] Department of Gynecology and Obstetrics, St. Antonius Hospital, Nieuwegein; [b] Division of Women and Baby, Department of Reproductive Medicine and Gynecology, University Medical Center, Utrecht; and [c] Department of Gynecology and Obstetrics, Rivierenland Hospital, Tiel, the Netherlands

Objective: To identify factors contributing to the occurrence of unintended pregnancies after Essure sterilization in the Netherlands. Even though Essure is a permanent method of contraception, unintended pregnancies have been reported.
Design: Retrospective case series analysis.
Setting: Not applicable.
Patient(s): Thirty-five pregnancies were reported in the Netherlands after Essure sterilization from 2002 through 2014 out of 27,346 placements.
Intervention(s): Data regarding Essure placement procedure, confirmation tests, and pregnancy outcome of the reported cases were obtained and analyzed to identify a possible cause of failure.
Main Outcome Measure(s): Four causes of failure were identified: perforation (n = 10), expulsion (n = 7), unilateral placement (n = 7), and luteal pregnancy (n = 2).
Result(s): The occurrence of most pregnancies was related to physician noncompliance (n = 14). The other cases were associated with patient noncompliance (n = 5) or misinterpretation of the confirmation test (n = 9). Most pregnancies occurred within the first 24 months after the 3-month confirmation test (n = 23).
Conclusion(s): The results of this study show that the incidence of pregnancies after Essure sterilization is low. Most pregnancies were related to incorrect positioning of a device or unilateral placement, and seem therefore preventable. Unilateral placement without prior history of salpingectomy should always be considered as unsuccessful sterilization. Furthermore, interpretation of the confirmation tests should be done by trained physicians, and with caution. We want to emphasize the importance of strictly adhering to placement and follow-up protocols. (Fertil Steril® 2016;105:932–7. ©2016 by American Society for Reproductive Medicine.)
Key Words: Essure, failure, pregnancy, sterilization, unintended

Discuss: You can discuss this article with its authors and with other ASRM members at http://fertstertforum.com/hitzerde-unintended-pregnancies-essure/

Use your smartphone to scan this QR code and connect to the discussion forum for this article now.*

* Download a free QR code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

Female sterilization as a method of permanent contraception has become increasingly popular (1). The Essure system (Conceptus) was the first hysteroscopic sterilization method approved for use by the US Food and Drug Association in 2002 (2–4). Because of the hysteroscopic placement, Essure sterilization is a minimally invasive procedure that does not require anesthesia or abdominal wall incisions and can be performed in an office setting. Therefore, it provides a favorable alternative to laparoscopic sterilization (5–7).

Since the introduction of Essure sterilization in 2002 more than 27,346 procedures have been performed in the Netherlands (Bayer, personal communication, May 2015). The two micro-inserts are made out of a stainless steel inner coil, with polyethylene terephthalate fibers surrounding the inner coil and a nickel–titanium alloy (nitinol) outer coil (5, 8). After release into the fallopian tubes, the outer coil of the device expands and anchors the micro-insert inside the tube. According to the instruction for use, three to eight coils should be visible in the uterine cavity after placement to prevent migration (3, 9). A local inflammatory response is then caused by the polyethylene terephthalate fibers, resulting in the growth of fibrotic tissue, and thus luminal occlusion of

Received September 22, 2015; revised December 21, 2015; accepted December 22, 2015; published online January 11, 2016.
E.H. has nothing to disclose. H.W.R.S. has nothing to disclose. M.P.H.V. is a trainer with Bayer for Essure sterilization. S.V. reports personal fees from Bayer; is on the advisory boards of Hologic, Johnson & Johnson, and Gedeon Richter; is a consultant and trainer with Bayer; and has an Olympus patent pending for a hysteroscopic shaft.
Reprint requests: Emilie Hitzerd, M.D., Department of Gynecology and Obstetrics, St. Antonius Hospital, Nieuwegein, the Netherlands (E-mail: ehitzerd@gmail.com).

Fertility and Sterility® Vol. 105, No. 4, April 2016 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2015.12.129

the fallopian tubes (10, 11). Tubal occlusion should be complete within 3 months. It is advised to use additional contraceptives until a confirmation test is done 3 months after the procedure. The confirmation test is meant to prove correct micro-insert position, and additionally tubal occlusion can be evaluated (6, 10).

The Essure system has proven to be an effective method of permanent contraception when properly placed (12, 13). However, unintended pregnancies afterward have been reported.

Determining and evaluating causes of failure of sterilization with the Essure system should help to optimize protocols and prevent adverse events.

The aim of this study was to identify factors that contribute to the occurrence of unintended pregnancies after hysteroscopic sterilization with Essure in the Netherlands.

MATERIALS AND METHODS

Design

This was a retrospective, multicenter case series analysis of unintended pregnancies after Essure sterilization in the Netherlands. The study is a sequel to an earlier published study (1).

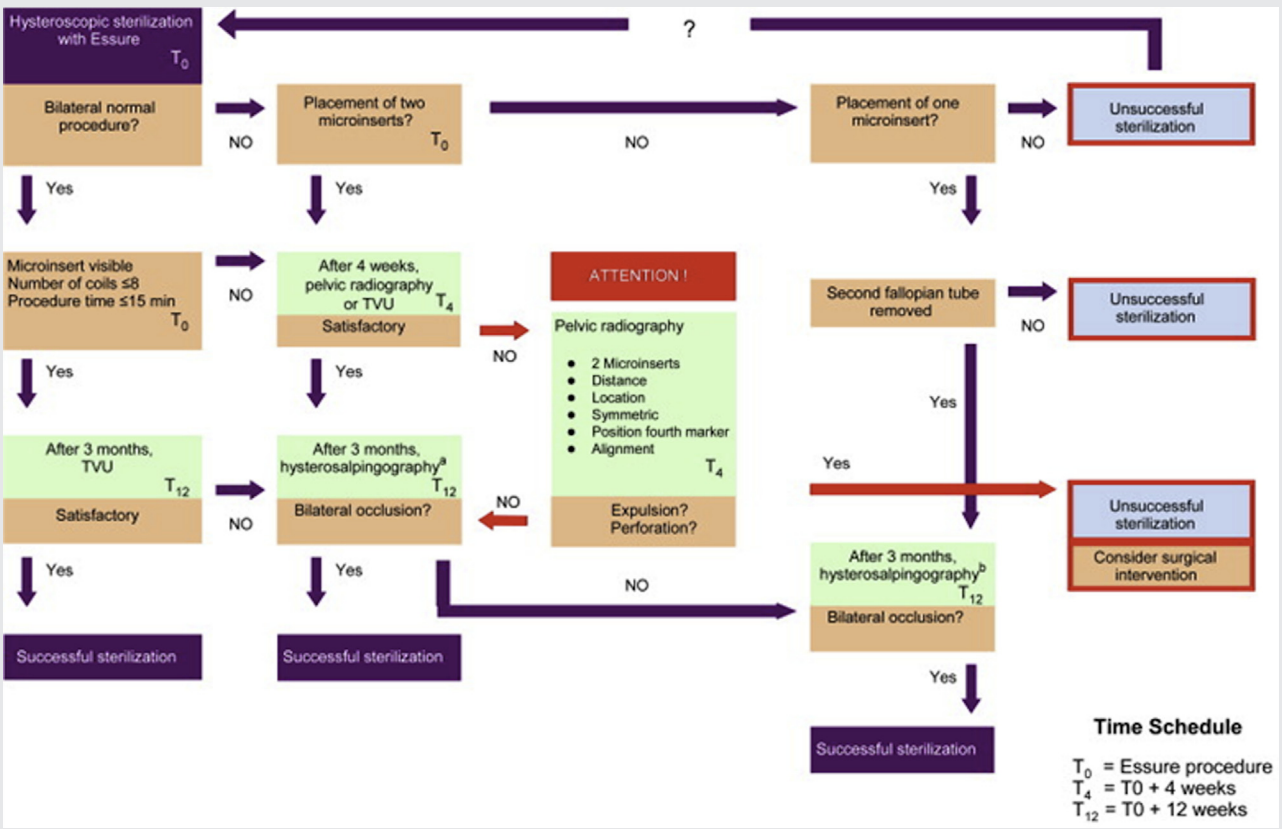
Essure Procedure and Follow-up

Placement procedure and follow-up protocol in the Netherlands were described previously by Veersema et al. in 2010 (1). Initially the follow-up was done with hysterosalpingography (HSG) in all patients. However, a new follow-up protocol was introduced in the Netherlands in 2005 (Fig. 1), introducing transvaginal ultrasound (TVU) as the first-line confirmation test after uncomplicated bilateral insertion (12). According to this protocol HSG is still indicated when placement is complicated or confirmation with ultrasound is unsatisfactory (e.g., when the device cannot be identified correctly, or the position is too proximal or too distal, or the device is curling). Unilateral placement without history of tubectomy is considered an unsuccessful sterilization. In case of a prior history of tubectomy, occlusion of the contralateral tube has to be confirmed with HSG. In the Netherlands the X-rays and/or HSGs are analyzed by a radiologist and the gynecologist who did the procedure.

Data Collection

Pregnancy data were gathered using voluntary reports, either to the distributor (Sigma Medical) or directly to the authors (S.V. and M.P.H.V.) from August 2002 through December

FIGURE 1



Dutch Essure follow-up protocol, implemented in 2005.

Hitzerd. Unintended pregnancies after Essure. Fertil Steril 2016.