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Original Article

Confirmation Testing of Essure Microinserts in Unintended Pregnancies Using a 10-Year Retrospective Database

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ABSTRACT **Study Objectives:** To examine the imaging modality used in cases of Essure failures and determine the cause of the unintended pregnancies (noncompliance to follow-up recommendations, misinterpretation of the imaging test, or device failure).
Design: Retrospective, single-center interventional cohort (Canadian Task Force classification II-2).
Setting: Tertiary level hospital.
Patients: Women who have had Essure placement and subsequent pregnancy.
Interventions: Coding data from the Regina General Hospital was examined for any pregnancy occurring after an Essure procedure. The hospital charts were then reviewed for data collection. A separate imaging database established over the same time frame was then reviewed to determine the imaging modality used in each case (transvaginal ultrasound [TVU], hysterosalpingogram [HSG], or none). Results of the imaging study were reviewed and the cause of the failure determined.
Measurements and Main Results: Twenty-four pregnancies in 25 women were identified after Essure procedures from January 1, 2003 to March 31, 2013. There were 4 in vitro fertilization pregnancies and 4 pregnancies where the woman had been instructed not to rely on the devices because of incomplete placement noted at time of the procedure. Therefore, 17 unintended pregnancies occurred of a total 2080 procedures performed. Examination of the imaging studies revealed that 11 were due to patient noncompliance (either early cessation of backup contraception or failure to go for confirmatory imaging), 5 due to misinterpretation of the imaging tests (3 HSG, 2 TVU), and 1 device failure. This reveals a cumulative failure rate of 6 of 2080 or .29% over 10 years with only .04% (1/2080) being device related.
Conclusion: Essure sterilization is an effective means of permanent contraception with a device failure rate of only .04%. Most unintended pregnancies after the Essure procedure result from a failure to comply with follow-up recommendations, and strategies to improve compliance should be emphasized. Journal of Minimally Invasive Gynecology (2016) 23, 944–948 © 2016 AAGL. All rights reserved.

Keywords: Contraception; Essure; Hysteroscopic sterilization; Permanent birth control

The Essure permanent birth control system for tubal sterilization (Bayer Healthcare, Whippany, NJ) was introduced in 2001, and by 2010 approximately 500 000 Essure kits had been distributed worldwide, with the number increasing to 750 000 in 2016 [1,2]. The Essure microinsert induces a benign fibrosis in the fallopian tube that occludes the tubal lumen within the corneal portion of the tube. Because this fibrosis can take up to 3 months to occur, patients are required to continue using an alternate form of contraception for 3 months after the procedure, when a confirmatory radiologic imaging study is necessary to verify proper microinsert positioning within the fallopian tube and/or tubal occlusion. The standard follow-up examination has been the hysterosalpingogram (HSG); however, in Canada, Holland, and Australia transvaginal ultrasound (TVU) is used as the first-line modality to confirm Essure microinsert location within the fallopian tube [3–6].

The estimated pregnancy rate in the United States between 2001 and 2010 was .15% [1]. Veersema et al [3] reported a failure rate of .16% in women with Essure over a 6-year period. Two studies from France have reported pregnancy rates of .10% over 7 years [7] and .36% over a 4 years [8].

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The 5-year follow-up results from a phase III trial reported no pregnancies, although the authors did exclude 4 pregnancies that occurred before completion of the HSG [9]. These rates are very similar despite differences in the confirmation tests used, although a criticism of the studies that report on pregnancy rates is that they are looking at "perfect use" rather than "real world use." The results all compare favorably with the overall failure rate of laparoscopic tubal sterilization of 1.8% noted in the Collaborative Review of Sterilization (CREST) trial [10].

The purpose of the current study was to determine the pregnancy rate and etiology of reported failures (noncompliance to follow-up recommendations, misinterpretation of the imaging test, or device failure) in a single real world center using TVU (2- and 3-dimensional [2D and 3D]) as the primary confirmation test.

Methods

A retrospective chart review (Canadian Task Force classification II-2) was conducted at the Regina General Hospital in the Regina Qu'Appelle Health Region from January 1, 2003 to March 31, 2013. Over this 10-year period, hospital coding data were examined for all pregnancies that occurred after an Essure procedure. The dates of the Essure procedures and pregnancies were recorded to ensure that the pregnancy did indeed take place after the sterilization.

The Essure procedures were completed in an ambulatory clinic in the Regina Qu'Appelle Health Region by physicians ranging in experience from first-year residents to consultants with more than 10 years of experience. The 2D ultrasound imaging for confirmation consisted of a midline sagittal view of the uterus, a coronal view including both inserts, and coned down images of both individual coils to demonstrate their relationship to the uterine cavity and appropriate shape. If the visualization was believed to be inadequate by the sonographer, 3D images were obtained to determine the relationship of the coil to the uterine cavity. The modified HSG was completed as outlined in the Essure instructions for use [2].

Complications noted at the time of Essure placement, imaging modality used, results of imaging study, type of pregnancy, and pregnancy outcome were also recorded. Patients identified during the chart review were assigned a study number and cross-referenced to an imaging database that had been created by one of the study authors (IS) over the study time frame (2003–2013). This database is a collection of all TVU images (2D and/or 3D) performed for Essure confirmation done in the health region. In cases where the TVU was nondiagnostic or suggested complications, the subsequent HSG results were also stored in this database. By using this database, any TVU done to confirm Essure placement could be captured (because they are done outside the hospital in a private radiology clinic and results are not available via chart review).

Once pregnancies after an Essure procedure were identified, the charts were reviewed and the etiology behind the Essure failure determined (noncompliance to follow-up recommendations, misinterpretation of the imaging test, or device failure). The total number of Essure procedures performed over the same time frame was acquired to calculate a rate of failure.

Descriptive results were reported with no comparisons made; therefore, no statistical calculations were required. This study was approved by the Regina Qu'Appelle Health Region Research Ethics Board. A waiver of informed consent was obtained.

Results

From January 1, 2003 to March 31, 2013, a total of 2080 Essure tubal occlusions was performed at the Regina General Hospital. Twenty-four pregnancies in 25 women were identified after the Essure procedure during these 10 years (Fig). All pregnancies were intrauterine, with 1 diagnosed as a molar pregnancy. Four pregnancies followed Essure placement for occlusion of hydrosalpinges before in vitro fertilization and thus were not considered failures. The "real world" pregnancy rate was .96% (20/2080).

Four pregnancies occurred after a procedure in which correct bilateral placement was not achieved, and the patients were immediately instructed not to rely on the devices for contraception. The mean time from placement to a positive pregnancy test in these patients was 14.0 ± 9.8 months (mean ± standard deviation [SD]) with a range of 1 to 24 months. Within the 17 remaining pregnancies, 11 were determined to be a result of failure to follow postprocedure recommendations (either not undergoing a confirmatory radiologic test or discontinuing backup contraception before having the test done). The mean time interval from placement to a positive pregnancy test was 14.9 ± 20.2 months (mean ± SD) with a range of 2 to 72 months. Six pregnancies occurred in women who were instructed to rely on the Essure microinsert as contraception. These pregnancies occurred 24.0 ± 27.9 months (mean ± SD) after the Essure placement (range, 6–72 months). These failures in patients with successful placement are referred to as "true failures," and the details of the imaging results are summarized in Table 1. Five pregnancies were a result of misinterpretation of imaging tests (3 HSG and 2 TVU). In all cases the initial diagnostic test suggested adequate placement or a lack of dye spill at HSG. Subsequent imaging after pregnancy or surgical intervention did reveal a previous complication that was not originally noted. In other words, the misinterpretation of these images led to a false-negative conclusion of proper microinsert positioning.

There was 1 true device failure with the TVU imaging showing optimal positioning of the inserts. This pregnancy occurred 48 months after the placement. At the patient's subsequent cesarean section there was no obvious perforation or Essure complication noted.