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Original Article

Hysteroscopic Sterilization: 10-Year Retrospective Analysis of Worldwide Pregnancy Reports

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ABSTRACT **Study Objective:** To identify factors that might contribute to pregnancies reported after hysteroscopic sterilization worldwide.

Design: Retrospective review of commercial data compiled from the MAUDE database, medical literature, and manufacturer reports received during commercial distribution of hysteroscopic sterilization micro-inserts from 2001 through 2010 (Canadian Taskforce classification III descriptive study).

Measurements and Main Results: From 2001 through 2010, 497 305 hysteroscopic sterilization kits were distributed worldwide, and 748 pregnancies were reported, i.e., 0.15% of the estimated user population based on the number of distributed kits. The data were sufficient to enable analysis of 508 pregnancies for potential contributing factors and showed most to be associated with patient or physician noncompliance (n = 264) or misinterpreted confirmation tests (n = 212). Conceptions deemed to have occurred within 2 weeks of the procedure and therefore too early for detection were identified in 32 cases.

Conclusion: Although there are limitations to the dataset and the study design is retrospective, it represents the largest body of cumulative hysteroscopic sterilization data available to date. Of the 748 pregnancies reported, it is apparent that some might have been prevented with greater patient and clinician attention to interim contraceptive use and counseling and with more rigorous evaluation and informed interpretation of the procedure confirmation tests. Although the estimated pregnancy rate based on such a dataset is likely an underestimation, it does suggest that the evaluable field performance of hysteroscopic sterilization micro-inserts is consistent with the labeled age-adjusted effectiveness of 99.74% at 5 years. Journal of Minimally Invasive Gynecology (2014) 21, 245–251 © 2014 AAGL. All rights reserved.

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

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Background and Rationale

Essure (Conceptus, Inc., San Carlo, CA), the first hysteroscopic sterilization method approved for use, has been distributed worldwide for >10 years and has been supported as an effective permanent minimally invasive female sterilization technique by the American College of Obstetricians and Gynecologists [1]. The system is composed of 2 micro-inserts, one for each oviduct, for intraluminal occlusion that are positioned using a disposable delivery system. Each micro-insert consists of a stainless steel inner coil, a nickel–titanium (nitinol) expanding outer coil, and polyethylene terephthalate fibers wound in and around the inner coil. When released from the delivery system, the outer coil expands to a diameter of 1.5 to 2.0 mm to anchor the micro-insert in the varied diameters and shapes of the proximal fallopian tube. The currently-available insert (ESS305) was modified slightly so that the proximal portion of the

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outer coil was reduced to a half band from the full band found in the earlier model (ESS205) (Fig. 1). Each model has some unique design features that result in a slight difference in appearance on radiographs or hysterosalpingograms (HSGs) (Fig. 1).

Using hysteroscopic guidance, the micro-inserts are placed across the uterotubal junction to occupy the proximal portion of the fallopian tube. The polyethylene terephthalate fibers elicit a local fibrotic tissue response designed to result in luminal occlusion, which typically is complete within 3 months. As a result, patients must use an alternative form of contraception until a confirmation test is performed at 3 months after the procedure. The confirmation test is designed to evaluate micro-insert location and, in either selected instances (outside of the United States) or in all instances (within the United States), to demonstrate proximal tubal occlusion. The types of imaging vary with the region and regulatory environment in which hysteroscopic sterilization is approved for use. In the United States, the approved hysteroscopic sterilization confirmation test is the modified HSG, which enables confirmation of satisfactory location of both radiopaque micro-inserts and bilateral tubal occlusion (Fig. 2). Flat-plate radiography was the standard first-line confirmation test in Europe; however, transvaginal ultrasound has recently been approved as an alternate confirmation method in Europe, Canada, South Africa, and Australia and is used primarily to identify satisfactory location of the micro-inserts. If there is reason to suspect unsatisfactory location on transvaginal ultrasound or flat-plate radiography, the patient is referred for HSG. From independent studies in the literature, the requirement for HSG for further confirmation occurs in approximately 15% of cases [2–7].

Evidence demonstrates that the hysteroscopic sterilization approach is highly effective when used either as an in-office procedure or in the outpatient operating room [8–12]. Effectiveness in the commercial setting was previously evaluated in the 2007 summary of 64 reported pregnancies in an estimated 50 000 Essure hysteroscopic sterilization procedures [13]. That analysis also revealed that most pregnancies were the result of noncompliance and misread confirmation tests and thus were preventable. The present analysis was designed to similarly evaluate all available data from the reported post-Essure pregnancies that have been received from initial release through December 2010. The primary goal was to identify factors that might have affected the effectiveness of the procedure in this population. A secondary goal of this assessment of the 10-year commercial experience was to estimate the pregnancies reported during 10 years of worldwide hysteroscopic sterilization as a percentage of distributed kits.

Methods

Design

This was a retrospective identification and review of pregnancies that occurred after use of the Essure system and was designed to identify potential factors that contributed to the pregnancies. In addition, confirmation test image review was performed by an expert panel and compared with the written report provided by the local radiologist. The number of pregnancies identified was compared with the number of Essure kits distributed worldwide during the study period.

Subject Identification

Pregnancy data were gathered via retrospective review of commercial pregnancies compiled from the medical literature, the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database, and voluntary reports directly received by the manufacturer from 2001 through 2010. The MAUDE data comprises voluntary reports from manufacturers and users including clinicians and hospitals or other facilities. The nature of such data dictates that it not be used either to evaluate the rates of adverse events (AEs) or to compare AE occurrence rates across devices. Additional voluntary reports received by the manufacturer were from a number of sources

Fig. 1

Essure micro-inserts EES205 (**top**) and EES305 (**bottom**). **Inset:** Radiographic appearance of an EES305 micro-insert. Radiographic markers are delineated with **arrows** and numbered accordingly: 1, distal end of inner coil; 2, distal end of outer coil where attached to inner coil; 3, proximal marker of inner coil (proximal marker moved 0.5 mm from proximal end of inner coil on ESS305), and 4, proximal end of outer coil, which is not fixed to inner coil.