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Original Article

Essure Permanent Birth Control, Effectiveness and Safety: An Italian 11-Year Survey

Mario Franchini, MD*, Brunella Zizolfi, MD, Carmela Coppola, MD, Valentino Bergamini, MD, Cecilia Bonin, MD, Giovanni Borsellino, MD, Enrico Busato, MD, Stefania Calabrese, MD, Stefano Calzolari, MD, Gian Piero Fantin, MD, Giovanna Giarrè, MD, Piero Litta, MD, Massimo Luerti, MD, Francesco Paolo Mangino, MD, Gian Luigi Marchino, MD, Maria Antonietta Molinari, MD, Elisa Scatena, MD, Federica Scrimin, MD, Paolo Telloli, MD, and Attilio Di Spiezio Sardo, MD, PhD

From Department of Obstetrics and Gynecology, Tuscany Regional Health Agency, Florence (Dr. Franchini), Department of Obstetrics and Gynecology, University of Naples "Federico II", Naples (Drs. Zizolfi, Coppola, and Di Spiezio Sardo), Department of Obstetrics and Gynecology, University of Verona, Verona (Drs. Bergamini and Bonin), Department of Obstetrics and Gynecology, Saronno Hospital, Saronno (Drs. Borsellino and Molinari), Department of Obstetrics and Gynecology, Santa Maria di Ca' Foncello Hospital, Treviso (Dr. Busato), Department of Obstetrics and Gynecology, Lodi Public Hospital, Lodi (Dr. Calabrese), Department of Obstetrics and Gynecology, Palagi Freestanding Unit, Florence (Drs. Calzolari and Giarrè), Department of Obstetrics and Gynecology, Conegliano Hospital, Conegliano (Dr. Fantin), Department of Obstetrics and Gynecology, University of Padua, Padua (Dr. Litta), Istituto Clinico Cittá Studi, Milan (Dr. Luerti), Department of Obstetrics and Gynecology, Institute for Maternal and Child Health, Istituto di Ricovero e Cura a carattere Scientifico "Burlo Garofolo", Trieste (Drs. Mangino and Scrimin), Department of Obstetrics and Gynecology, Department of Surgical Sciences, A. Anna Hospital, University of Torino, Torino (Dr. Marchino), Department of Obstetrics and Gynecology, Prato Hospital, Florence (Dr. Scatena), and Lecco Hospital, Lecco (Dr. Telloli), Italy.

ABSTRACT **Study Objective:** To describe safety, tolerability, and effectiveness results through a minimum 2-year follow-up of patients who underwent permanent sterilization with the Essure insert.

Design: A retrospective multicenter study (Canadian Task Force classification II2).

Setting: Seven general hospitals and 4 clinical teaching centers in Italy.

Patients: A total of 1968 women, mean age 39.5 years (range, 23–48 years) who underwent office hysteroscopic sterilization using the Essure insert between April 1, 2003, and December 30, 2014.

Intervention: The women underwent office hysteroscopic bilateral Essure insert placement, with satisfactory device location and tube occlusion based on hysterosalpingography or hysterosalpingo-contrast sonography (HyCoSy).

Measurements and Main Results: Placement rate, successful bilateral tubal occlusion, perioperative adverse events, early postoperative (during the first 3 months of follow-up), and late complications were evaluated. Satisfactory insertion was accomplished in 97.2% of women and, in 4, perforation and 1 expulsion were detected during hysterosalpingography. Three unintended pregnancies occurred before the 3-month confirmation test. Two pregnancies were reported among women relying on the Essure inserts. Postprocedure pain was minimal and brief; in 9 women, pelvic pain became intractable, necessitating removal of the devices via laparoscopy. On telephone interviews, overall satisfaction was rated as "very satisfied" by the majority of women (97.6%), and no long-term adverse events were reported.

Conclusion: The findings from this extended Italian survey further support the effectiveness, tolerability, and satisfaction of Essure hysteroscopic sterilization when motivated women are selected and well informed of the potential risks of the device. Moreover, the results do not demonstrate an increased incidence of complications and pregnancies associated with long-term Essure use. Patients with a known hypersensitivity to nickel may be less suitable candidates for the Essure insert. Journal of Minimally Invasive Gynecology (2017) ■, ■–■ © 2017 AAGL. All rights reserved.

Keywords: Adverse events; Essure; Failure; Hysteroscopic sterilization

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Corresponding author: Mario Franchini, MD, Tuscany Regional Health Agency, Borgo Santa Croce 17, 50122, Florence, Italy.
E-mail: framagi@alice.it

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Since November 2002, when the Essure insert system was approved, hysteroscopic sterilization using the system has been performed on more than 750 000 women worldwide, based on the reported number of products sold [1]. Hysteroscopic sterilization is a multistep process and can be performed in an office setting, but unlike laparoscopic sterilization, it is not immediately effective. At 3 to 6 months after Essure placement, women undergo hysterosalpingography (HSG) or contrast infusion sonography (HyCoSy) to confirm device placement and tubal occlusion before discontinuing the use of other contraceptive methods [2–6].

Recently published extended follow-up results of a phase III trial with the Essure system further support the system's safety, tolerability, satisfaction, and effectiveness at 5 years postinsertion [7]. However, a small percentage of women reported negative experiences with Essure (e.g., pelvic pain, heavy menstrual bleeding, headache, fatigue, weight fluctuations, hypersensitivity to nickel) and subsequently chose to have the tubal inserts removed. Device failure, complications (i.e., perforation, migration, and expulsion), and other problems became the subject of litigation in 2014 [8]. Thus, in September 2015, the Food and Drug Administration initiated a new study to compare outcomes in women receiving the Essure inserts and in women undergoing laparoscopic sterilization, to fully elucidate the safety and effectiveness of the Essure system [9]. In the present Italian retrospective multicenter study, we analyzed the safety, tolerability, and effectiveness of the Essure inserts during short- and long-term follow up.

Materials and Methods

In this retrospective multicenter study, we evaluated the charts of 1968 women (mean age, 39.5 years; range, 23–48 years) who underwent hysteroscopic sterilization using the Essure system (Bayer AG, Leverkusen, Germany) in 7 general hospitals and 4 clinical teaching centers in Italy between April 2003 and December 2014. Mean follow-up was of 7.5 years, with a range of 2 to 11 years.

Women with a history of pelvic inflammatory disease or autoimmune disease during steroid treatment, as well as those with a history of abnormal uterine bleeding or pelvic pain, were excluded from hysteroscopic sterilization. During appropriate counseling, other available contraception options were analyzed, including data on failure rates. The irreversible nature of the procedure, possible adverse effects and complications, and the possibility of failure to achieve sterilization during the hysteroscopic procedure were emphasized.

Because in 2002 nickel allergy was a contraindication to Essure placement, and then in 2011 this contraindication was removed by the Food and Drug Administration, we assessed the patients for previous reactions to metals and offered to refer them to a dermatologist or allergist for nickel patch testing [10]. In addition, we counseled patients with a positive patch test regarding the risk of eventual nickel allergy and the fact that the removal of Essure does not guarantee relief of symptoms.

Women were instructed to use oral contraceptives at least 1 month before the procedure, as well as after the procedure until HSG or HyCoSy was performed to confirm device placement and bilateral tubal occlusion.

The procedure was scheduled in the proliferative phase of the cycle or on any day in patients using oral contraceptives. Outpatient hysteroscopic sterilization was performed following a standard vaginoscopic protocol in all gynecologic units. General anesthesia and intravenous sedation or narcotic analgesia were used as needed. A 3.9- to 5.9-mm 30-degree rigid continuous-flow hysteroscope with a 5 Fr working channel (Karl Storz, Tuttlingen, Germany) was used. Experienced surgeons performed or supervised all procedures, and optimal positioning was ensured when 3 to 8 coils of the proximal end of the micro-insert were visible at the ostium.

All of the women were instructed to not fast and were medicated with an oral analgesic (diclofenac 50 mg) 1 hour before the procedure. On completion of the procedure, the women were discharged after a minimum stay of 30 minutes once they had achieved adequate pain control, with instructions to take analgesics (paracetamol 500/1000 mg 3 times daily) regularly for the first 24 hours. All women with a successfully completed procedure underwent a confirmation test at 3 to 5 months postprocedure, as recommended by the manufacturer. Device failure and complications (i.e., perforation, migration, and expulsion) were evaluated.

Between August and September 2016, a total of 1736 women with satisfactory device location and tubal occlusion and 177 women who were noncompliant with follow-up underwent a telephone interview to assess their level of satisfaction and document any adverse events. The interviews were centralized and performed by 3 operators (A.D.S.S., C.C., and B.Z.) at the same center with similar training and experience with hysteroscopic tubal sterilization by Essure.

The women were asked to assess their level of satisfaction (very satisfied, fairly satisfied, or not satisfied), and whether or not they would recommend the procedure to a friend. The interview also explored recently reported adverse events (e.g., pelvic pain, heavier menses/menstrual irregularities, headache, fatigue, weight fluctuations, hypersensitivity to nickel) with a systematic standardized questionnaire. Pain intensity was evaluated using a 10-point numeric pain rating scale. Baseline characteristics of menstrual flow were also documented, including the frequency of sanitary pad or tampon changes on the day of heaviest menses (considering "not normal" a frequency more often than hourly), use of more than sanitary pad at a time, number of days lost from work, and the impact of menses on various quality-of-life parameters. Any significant ($\pm$2 kg) weight gain or loss was documented. Finally, to evaluate hypersensitivity to nickel, all women were asked whether they underwent patch testing and whether they experienced any itching and/or skin rash or bumps after Essure placement.