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Pilot Study

Feasibility of Essure Placement in Intrauterine Device Users

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ABSTRACT We present a review of 28 cases of intrauterine device (IUD) users who asked for permanent contraception with Essure procedure and accepted concomitant use of IUD and Essure. We ultimately achieved correct bilateral placement in 26 women (92.8%). In 8 cases (28.6%), it was necessary to remove the IUD to try and place the device. Our results suggest hysteroscopic tubal sterilization with Essure microinserts in IUD users is feasible, safe, and reliable. Moreover, there is no need to instruct the patients to use another form of birth control until 3 months postprocedure. We think this application could be a good alternative approach for a high percentage of IUD users who request a permanent hysteroscopic sterilization. Journal of Minimally Invasive Gynecology (2008) 15, 485–490 © 2008 AAGL. All rights reserved.

Keywords: Hysteroscopy; Essure; Intrauterine device; Sterilization

The evolution of minimally invasive hysteroscopic procedures has advanced with the introduction of the Essure microinsert for female sterilization [1], approved by the Food and Drug Administration in 2002 [2]. The Essure device as hysteroscopic option for permanent contraception is becoming increasingly popular as an alternative to laparoscopic tubal ligation [3]. Maximizing physician and patient benefit, performance of this sterilization procedure is transitioning into the office setting. The procedure is well-tolerated and results in rapid recovery, high patient satisfaction, and effective permanent contraception [1,4].

The Essure microinsert is a dynamically expanding microcoil, hybrid metalic and fiber, designed to be placed through a hysteroscope into the proximal section of the fallopian tubes with the implant portion of the device spanning the uterotubal junction [4]. It comprises of a microinsert and a delivery catheter. Its inner fibers, made of polyethylene terephtalate, elicit a benign tissue ingrowth that blocks the fallopian tubes usually within 3 months, resulting in permanent tubal occlusion [1,4]. There are 26 coils in the device. The manufacturer's literature defines optimal placement as 3 to 8 microinsert coils visible in the uterine cavity at the conclusion of the placement procedure. Patients are advised to use an alternative form of contraception during the ensuing 3 months, when usually a pelvic radiograph and/or an office ultrasound confirm device location and demonstrates bilateral tubal occlusion [3,5,6].

An intrauterine device (IUD) is the most popular and highly effective nonpermanent method of contraception, used by nearly 160 million women in the world [2]. The considerable number of IUD users requesting the Essure method is expected to increase. For this reason, we consider the alternative of proposing the possibility of continuing use of an IUD as temporary alternative contraception for the first 3 months after microinsert placement and removing the IUD when proper microinsert location is confirmed, although the Essure leaflet does not advise so.

This report evaluates the feasibility of Essure procedure in IUD users and the use of the IUD as an alternative nondefinitive contraceptive method for 3 months postprocedure.

Methods

In all, 28 IUD users, aged from 26 to 44 years, were recruited from December 2004 through April 2007. The choice of the sample was made using a consecutive nonrandom

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system, drawing women IUD users who asked for the Essure procedure as an option for permanent contraception in a tertiary university hospital. Procedures were conducted at an office setting.

Successful placement was defined as women without IUD removal and Essure bilateral optimal placement or Essure unilateral optimal placement if a contralateral tubal occlusion was recently confirmed.

Inclusion criteria included IUD users requesting a definitive sterilization method and willing to use an IUD for 3 months after device placement. The type of IUD was not considered as a selection criteria. A first attempt without previous IUD removal was offered. Women were instructed to continue with the IUD as a temporary alternative contraception for the first 3 months postprocedure. The protocol followed in this study was reviewed and approved by the ethical committee of our center, and written informed consent was obtained from all participants.

Exclusion criteria included all conditions considered contraindications for the Essure procedure as defined in the instructions for use, except for use of an IUD for contraception after microinsert placement procedure.

All women received an oral nonsteroidal anti-inflammatory drug (ibuprofen, 600 mg) approximately 1 hour before the procedure, as commonly recommended because good evidence exists that it can reduce the likelihood of tubal spasm [1]. Mechanical dilation of the cervix and/or local anesthesia were not necessary in any case.

Attempts were performed through defined vaginoscopic approach [7]. Following the Essure instructions for use, whenever possible, microinsert placement was performed during the early proliferative phase of the menstrual cycle to enhance visualization of uterine cavity and fallopian tubal ostia. Physiologic saline solution was used as uterine cavity distention medium to provide vision for safe introduction of the hysteroscope and ostia visualization. The endoscopic image of the uterine cavity and Essure placement was displayed on a video monitor that allowed the women to watch the entire procedure (Fig. 1). Adverse events, difficulties of device's insertion, and duration of the procedure were collected.

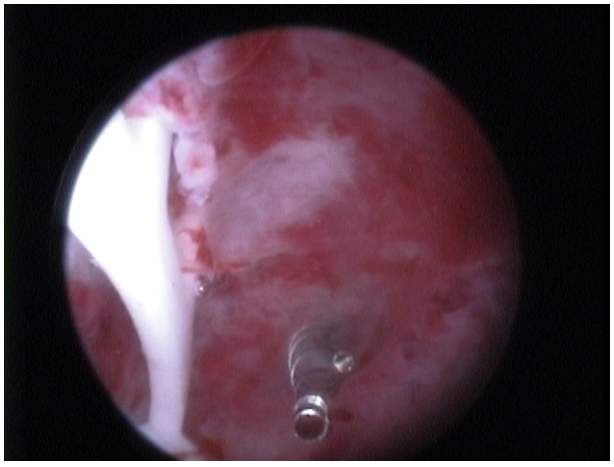

Fig. 1. Intraoperative image of Essure (Conceptus Inc., Mountain View, CA) placement in IUD user.

A pelvic radiograph was conducted 3 months after device placement to serve as a baseline evaluation of device location, accompanied by an office transvaginal ultrasound to identify the location and retention of the microinserts. As recommended by many authors [6], hysterosalpingography was required only after suspected unsatisfactory placements. Once correct placement was confirmed, the IUD was removed and patients were discharged being advised to rely on the microinserts for permanent contraception.

A retrospective study reviewed 28 cases of IUD users who accepted the Essure microinsert as definitive contraceptive method. Data analysis was recorded and conducted using Microsoft Excel 2003 software (Microsoft, Redmond, WA).

Results

In all, 28 women met the inclusion criteria. In this group, 71.4% of placements were achieved with the IUD in place. In all, 28.6% required IUD removal for placement. At 3 months, 92.8% correct bilateral placement was achieved (Fig. 2).

Only unilateral microinsert placement occurred in 2 (7.1%) women. In 1 case, this was a result of contralateral anatomic stenotic tubal ostium. Even after removing the IUD, it was not possible to insert Essure. The patient refused hysterosalpingography. In another case, a microinsert expulsion occurred, probably resulting from improper placement (11 trailing coils were left in the cavity) (pelvic radiograph) (Fig. 3). At 3 months, control hysterosalpingography informed us of a nonoccluded tube and a second attempt was performed without success as a result of stenotic tubal ostium. This suggests anatomic tubal defect was the cause of microinsert expulsion rather than an IUD-related cause. The woman was warned of the risk of pregnancy.

In 8 (28.6%) women, it was necessary to remove the IUD to try bilateral microinsert placement (Table 1). In 5 cases, the reason for failure was IUD related: in 2, the IUD obstructed the uterotubal junction, in 2, the IUD was descended in the uterine cavity, and in 1, it was necessary to remove the IUD because the ostium was not visible. Bilateral microinsert placement was completed after IUD removal. It was necessary to remove the IUD in 3 women after unilateral Essure placement. In the first case, this was due to impaired hysteroscopic visualization because of uterine bleeding, and in the other 2 cases stenotic unilateral ostia tube were seen. It was impossible to complete bilateral placement in 1 of them, even in a second attempt after IUD removal. Probably the failure was caused by a severe stenotic left tubal ostia. Correct bilateral placement was finally achieved in 2 of these women.