

Hysteroscopic sterilisation with Essure®: a promising new alternative to tubal ligation?

Haritha Sagili, Mike Divers

Introduction

The Essure® (Conceptus Inc., San Carlos, CA, USA) contraceptive device consists of a nitinol (nickel/titanium alloy) coiled spring containing polyethylene fibres. It is a dynamic expanding microinsert, placed under hysteroscopic visualisation in the proximal section of the Fallopian tube. The microinsert acts by inducing a tissue reaction that permanently blocks the tube within 3 months. It is recommended that an additional form of contraception be used until correct placement of the device is confirmed by an imaging procedure 3 months after the operation. Intrauterine devices (IUDs) cannot be used during this time period. Essure is becoming increasingly popular as a non-incisional, permanent, birth control device and has been licensed for use in the European Union since 2001. Approximately 50 000 procedures have been performed worldwide, of which 14 000 have been carried out in Europe. National Institute for Health and Clinical Excellence (NICE) guidance¹ concluded that current evidence on safety appeared adequate, although evidence of the long-term efficacy did not appear adequate for the procedure to be used without special arrangements for consent and for audit or research.

Literature search

MEDLINE and PubMed literature searches for the period November 2001 to June 2007 were carried out with the following terms in the title or abstract: 'Essure,' 'hysteroscopic sterilisation' and 'permanent birth control device'. A total of 46 citations were identified. A search of the Cochrane Database revealed no directly relevant systematic reviews. The following presentations and reports were also reviewed: American Association of Gynecologic Laparoscopists (AAGL) Confirmation and Development of Essure's Potential,² Conceptus Inc. press releases and NICE Guidance on *Hysteroscopic Sterilisation by Tubal Cannulation and Placement of Intrafallopian Implants*.¹

Procedure

The Essure procedure is performed in the outpatient hysteroscopy department, typically with non-steroidal analgesic premedication, although local anaesthesia may be necessary in some cases. The uterine cavity and tubal ostia are viewed using a rigid hysteroscope with a 12–30° oblique objective lens and a 5 French gauge operating channel through which the device is placed. Normal saline under pressure is used to maintain uterine distension. Ideally the timing of the procedure should be such that it is performed in the early proliferative phase when visualisation and cannulation of the tubal ostia is technically easiest.

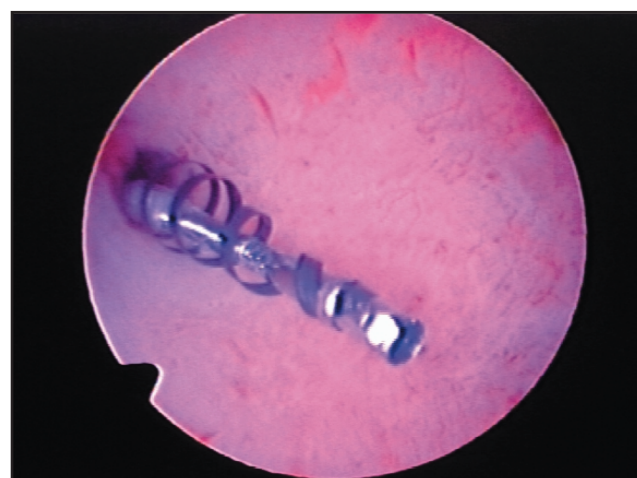


Figure 1 Hysteroscopic image showing ideal Essure® device placement with three to eight coils within the uterine cavity. © Conceptus Inc. Figure reproduced with the kind permission of the copyright owner

Data from the largest single series of 682 patients² suggests that bilateral placement of the device is possible in around 94% of cases (Figure 1), although reported success rates vary between 81% and 98%.^{3–8} Two procedures may be required in a minority of cases. Success rates have generally improved over time from 85%⁹ to 98%⁴ particularly after a new delivery catheter design replaced a braided mesh system with the nitinol coil device. The UK pilot study by Rogerson *et al.*¹⁰ achieved successful bilateral placement in 12/14 cases, with successful placement for the remaining two patients who initially had unilateral placement. UK multicentre experience⁶ with 59 patients resulted in a surprisingly low bilateral placement rate of 81%. The authors conceded that this was “most likely due to the relative inexperience of three of the four investigators who participated in this study”.

Failure of placement is commonly due to proximal tubal stenosis and tubal spasm, although poor visualisation can also limit placement.^{3,7} Technical failure, which is usually quoted to be 1 in 10, was more likely when the procedure was carried out in the secretory phase of the menstrual cycle or with a clinically enlarged uterus⁷ and prolonged use of an IUD.⁸ A mean hysteroscopic procedure time of 8 minutes has been reported⁴ although most studies^{3,5–8,10} suggest that 13 minutes is required, with an average time from admission to discharge of 80 to 188.7 minutes.^{3,6} Tolerance of device placement is ‘good to excellent’ in 82–99% of cases;^{2,3,6} 60% of women return to normal function within 1 day or less, 92% missing 1 day or less of work, and comfort was rated as good to excellent by 99% of women at all follow-up visits.³

Contraindications for Essure use are summarised in Table 1.¹¹

Follow-up methods to determine microinsert placement and tubal status

Initially, performing a hysterosalpingogram (HSG) was the only imaging method approved by the United States Food and Drug Administration (FDA) at 3 months to check the position of the Essure device (Figure 2). The current

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Department of Obstetrics and Gynaecology, Nobles Hospital, Isle of Man, UK

Haritha Sagili, MRCOG, MFSRH, Senior House Officer
Mike Divers, FRCOG, Consultant

Correspondence to: Mrs Haritha Sagili, Department of Obstetrics and Gynaecology, Nobles Hospital, Isle of Man, IM4 4RJ, UK. E-mail: harithas@hotmail.com

Table 1 Contraindications to Essure® use¹¹**Contraindications**

- Uncertain about desire to end fertility
- Pregnancy or suspected pregnancy
- <6 weeks after delivery/miscarriage/termination of pregnancy
- Active or recent pelvic infection
- Uterine abnormalities
- Known allergy to nickel confirmed by a skin test
- Unwilling to use another method of contraception for 3 months after the procedure
- Unwilling to undergo an imaging procedure to confirm placement
- Prior tubal ligation
- Current immunosuppressive therapy

recommendation is that it is appropriate to perform X-ray imaging alone following uncomplicated procedures, with a HSG being necessary only if placement has been difficult or painful.¹¹ However several recent studies^{12–14} have advocated ultrasound in preference to the other imaging modalities – this being a more convenient procedure for the patient – sufficient to confirm Essure placement in the majority of cases, and avoiding radiation exposure. One study¹² comparing the three imaging modalities in 150 patients with successful bilateral device placement showed that detection of both devices was satisfactory with transvaginal ultrasound and X-ray imaging in 141 and 149 patients, respectively. In only eight patients with satisfactory X-ray results was it not possible to confirm the satisfactory position of the device with ultrasound. A second study¹³ demonstrated that ultrasound findings correlated with pelvic radiograph and HSG assessments in all the 37 cases followed over a 2-year period and provided a simple, reliable and convenient method of assessing microinsert location.

Contrast infusion sonography, an adaptation of hysterosalpingo-contrast sonography (HyCoSy), performed in 10 women at 3–23 weeks following Essure placement, revealed that all microinserts were readily identified. Tubal status was assessed by the presence or absence of real-time contrast agent flow.¹⁴ This technique looks very promising and could present a convenient alternative to HSG.

Whatever imaging method is chosen, training of staff to identify appropriate device placement is essential.

Complications

Some 65–80% of women experience mild pain^{3,7} and severe pain has been reported in 4–17% of cases either during or after the procedure.^{3,7,15} In the UK cohort study of Essure versus laparoscopic sterilisation, Duffy *et al.*⁶

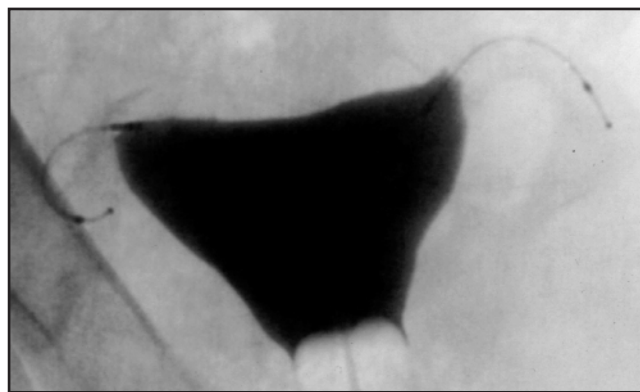


Figure 2 Hysterosalpingogram showing satisfactory location of Essure® device and resulting occlusion. © Conceptus Inc. Figure reproduced with the kind permission of the copyright owner

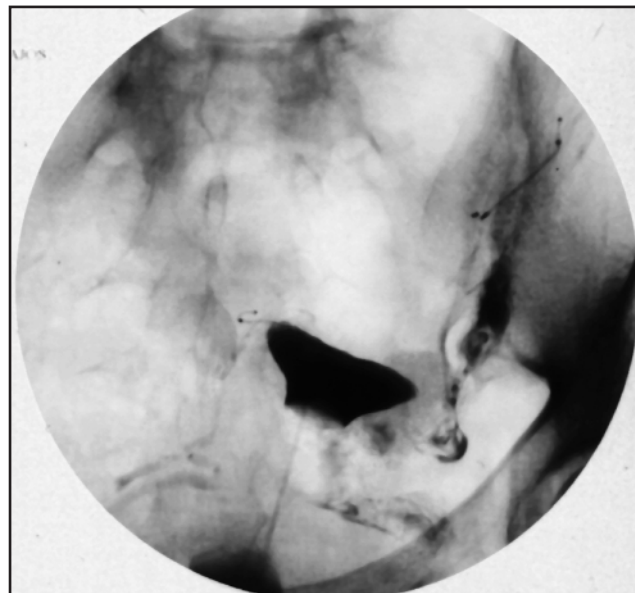


Figure 3 Hysterosalpingogram showing peritoneal location of Essure® device. © Conceptus Inc. Figure reproduced with the kind permission of the copyright owner

reported moderate to severe pain in 65% of cases during the Essure procedure, although in the recovery room this fell to 31% compared to 63% in the laparoscopic sterilisation group. The majority (82%) of the Essure patient group reported 'good to excellent' tolerance of the procedure compared with only 41% in the laparoscopic sterilisation group. Postoperatively, immediate and medium-term problems were lower with Essure (11%/21%) compared to the laparoscopy group (27%/50%). Minor symptoms including cramping (30%), nausea (9%) and light bleeding or spotting for up to 3–7 days (19–57%) may occur, although significant adverse events noted on the day of the procedure including vasovagal episodes (4%) and hypervolaemia due to absorption of the distension medium (3%) are uncommon. Tubal perforation (<1%) and expulsion (3%) are rare events (Figure 3) but may not be apparent until follow-up imaging.^{3,4,7} There was no significant morbidity in the 5-year follow up of 643 women.² Removal of the microinserts requires surgery. Successful removal of the device up to 6 weeks after placement has been reported in two patients.¹⁶ In one case the procedure was performed entirely by hysteroscopy as the device was completely visualised, whereas in the other case a laparoscopic approach was required as the device was completely within the Fallopian tube. Pain symptoms resolved within 2 weeks of removal in both patients. Further studies are needed to assess the safety/effectiveness of surgery and functionality of the tube after the procedure, as well as the feasibility of removal beyond 6 weeks.

Cost effectiveness

An American study¹⁷ found laparoscopic tubal ligation (\$3449) to be three times more expensive than office hysteroscopic Essure placement (\$1374), although a cost-analysis study in the UK prepared for the manufacturer in April 2003¹¹ showed the costs of laparoscopic sterilisation to be £100 less than the outpatient Essure device (£714.64 and £816.46, respectively). Another recent study¹⁸ comparing Essure and laparoscopic tubal coagulation in an operating room setting found that Essure had a significantly decreased cost compared with tubal coagulation. The decrease per patient in institutional cost

was \$180. Laparoscopy is associated with risks of general anaesthesia and procedure-related complications, which may increase costs. Robust studies comparing cost effectiveness, acceptability and long-term success rates of the two procedures are required.

Effect on concomitant/future procedures

Essure is magnetic resonance imaging (MRI)-compatible up to a magnetic field strength of 1.5 T. It has not been fully evaluated in the 3 T field and therefore the device represents a contraindication to MRI in these circumstances.¹⁹ Whilst the risk of electrical current transmission along the microinsert contraindicates the use of first-generation endometrial ablation methods, a small study in 49 women has shown that concomitant Thermachoice® endometrial ablation and Essure placement is effective and that the ablation procedure does not cause any disturbance of the devices or damage to the tubes.²⁰ Another recent study²¹ comparing Essure and different techniques of endometrial ablation (i.e. Thermachoice, NovaSure®, HydroThermAblator®)/resection (monopolar, bipolar) reported no adverse events and 85% of patients had a significant reduction in blood loss. At present there are no data regarding the use of Thermachoice or other second-generation endometrial ablation methods in women who already have the Essure device. These issues need to be addressed in future studies.

Efficacy

For women relying on Essure for contraception after successful placement of the device, an effectiveness rate of 99.74% after 5 years of follow-up has been accepted by the FDA.¹¹ A pregnancy rate of 1.2/1000 has been reported²² to the device manufacturer on an analysis of 64 pregnancies out of an estimated 50 000 procedures carried out from 1997 to December 2005. Most of these pregnancies occurred in patients without appropriate follow-up. Other causes included misread X-ray or HSG, undetected pre-procedure pregnancies, and failure to follow product-labelling guidelines. The observed pregnancy rate with Essure was lower than with any of the methods analysed in the US Collaborative Review of Sterilization (CREST Study).²³ NICE guidance on *Long-acting Reversible Contraception*²⁴ quotes failure rates of fewer than 2 in 100, 1 in 100, 0.4 in 100 and 0.1 in 100 women for the copper IUD, intrauterine system (IUS), progestogen-only injections and implants, respectively. The risk of pregnancy with hysteroscopic sterilisation may be reduced by educating patients about the necessity of follow-up, ensuring that patients use effective contraception before and after placement, following the instructions for use, and adhering to the HSG protocol.

Women's perspective

Reasons given by women for choosing Essure included desire to avoid general anaesthesia (72%), avoidance of surgical incision (59%), no need for hospital stay (50%) and convenience (33%).⁷ Satisfaction rates are generally high (i.e. 94–98%^{3,4,6,8,9}), and in the largest UK study to date⁷ 96% of women were satisfied with the overall experience of the procedure and radiological follow-up, with 88% reporting being 'very satisfied', and 91% would recommend it. Overall, 72% classed HSG as acceptable. Data analysis in a cohort of 96 women in the UK²⁵ showed that 77% would prefer laparoscopic sterilisation over the hysteroscopic procedure (23%), despite the advantages of an outpatient setting. Age, obstetric history, employment and marital status, access to transport and previous anaesthetic did not significantly influence the choice

made. This may partly have been due to lack of awareness of the procedure. At 90 days post-procedure patient satisfaction⁶ with their decision was high, with 94% of the Essure group being 'very' or 'somewhat' satisfied compared to 80% in the laparoscopic sterilisation group. All patients (100%) were 'very satisfied' with their speed of recovery with Essure compared to 80% in the laparoscopic group.

Conclusions

Outpatient hysteroscopic sterilisation with the Essure microinsert appears to be an effective method with decided advantages for the patient in terms of morbidity, recovery time and length of hospital stay. However, the device cannot be placed bilaterally in all cases, a minority of women do not tolerate the procedure, and although considered irreversible it should not be considered 100% effective. Additional contraception must be used for 3 months after the procedure. Whilst it is necessary to perform a HSG after difficult placements, recent evidence suggests that transvaginal ultrasonography may be a suitable alternative to pelvic X-ray imaging in straightforward cases. Further long-term data on Essure are awaited with interest.

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Competing interests None identified.

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