Gynecol Surg (2005) 2: 155–158
DOI 10.1007/s10397-005-0118-4

ORIGINAL ARTICLE

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Hysteroscopic sterilisation in the outpatient department without anaesthesia

Published online: 21 May 2005

Abstract *Background*: Compared to laparoscopic sterilisation, the hysteroscopic approach obviates admission, general anaesthesia, surgical incisions and a complication rate of 5 per 1,000 procedures. The use of the new hysteroscopic sterilisation device Essure (Conceptus) for the first consecutive 175 patients, without the use of local or intravenous anaesthesia or any sedation, has been evaluated in the outpatient department (OPD). *Results*: Successful bilateral placement was achieved in 95% of all women. Pain during the procedure was assessed by a visual analogue score and appeared to be 2.5 on average. All women could be discharged within 1 h; only two women encountered a vasovagal collapse; no adverse events occurred. All women were satisfied with this method. After 1,200 woman-months, no pregnancy was found. *Conclusion*: Hysteroscopic sterilisation with Essure can be done safely in the OPD without anaesthesia.

Keywords Contraceptive devices · Hysteroscopic sterilisation · Local anaesthesia · Outpatient

Introduction

Tubal laparoscopic sterilisation is the most used method for permanent female contraception worldwide. Most of these sterilisations are performed under general anaesthesia and in a day care setting. Depending on the used method, a pregnancy rate of 5–7 per 1,000 well performed procedures has been reported [1].

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A complication rate of 5 per 1,000 procedures has been mentioned by Janssen et al. [2].

Male sterilisation is a good alternative to female laparoscopic sterilisation since severe complications are rarer. A waiting period of 12 weeks is accepted, after which, control of successful sterilisation is performed by semen analysis, providing a high success rate of this method.

Despite the high success and low complication rates of the laparoscopic approach, a lot of women will not choose to undertake laparoscopic sterilisation, fearing admission to a clinic, the need of general anaesthesia, risk of complications, the nausea and abdominal pain afterwards and the skin scars.

A hysteroscopic route offers an attractive alternative to the laparoscopic approach, especially since operative hysteroscopy can be performed nowadays in an outpatient setting using small-diameter, continuous-flow hysteroscopes with a 5-French working channel. Hence, the need for general anaesthesia can be avoided [3].

Since November 2002, the Essure system for hysteroscopic sterilisation has been approved by the FDA, the US Department of Food and Drug Administration. Hysteroscopic sterilisation by Essure results in a rapid patient recovery, high satisfaction rates and effective permanent contraception [4, 5].

The system is based on the hysteroscopic placement of a nitinol coil in both tubal ostia. The centre of this coil consists of polyethylene terephthalate (PET) fibres that induce a sterile inflammatory reaction over a period of 3 months, thereby, occluding the tubes [6]. Phase II and pivotal studies proved the safety of this method, with a high success rate of placement of between 88% and 90% [7]. After 9,620 woman-months of exposure to intercourse, no pregnancies have been recorded.

In our clinic, we accepted the challenge and designed a protocol by which patients were sterilised without the use of any anaesthesia, including even local anaesthesia. The first results are presented in this paper.

Methods

Patient selection

From August 2002, hysteroscopic sterilisation was offered as an alternative to laparoscopic sterilisation to all women visiting our clinic (Rivierenland Hospital, The Netherlands) and seeking permanent birth control. Patients gave written informed consent if they agreed to undertaking the hysteroscopic sterilisation procedure by Essure.

Women with a history of recent pelvic inflammatory disease (PID) or any abundant cervical discharge suspicious of cervical infection or sexual transmitted diseases were excluded.

Since the use of the Essure device precludes re-anastomosis, women younger than 25 years of age were excluded. In the case of nulliparity and/or women younger than 35 years old, they were strongly advised to choose an alternative, reversible method of contraception. They were asked to consider our advice and to return for another appointment later on after reconsidering their request.

Patients were planned for hysteroscopy before the tenth day of her cycle. Hysteroscopy was performed for visualisation of the uterine cavity and sterilisation in the same session, i.e. the patients were scheduled for hysteroscopy and, if deemed possible, sterilisation was performed in that same session.

Procedure

The hysteroscopic sterilisation by Essure is performed in the outpatient department. In an outpatient setting, it is important to create a calm and friendly atmosphere. Therefore, the patient is advised to bring an accompanying friend. Furthermore, two nurses are present: one to assist the gynaecologist and one to look after the patient's well being. An extra screen is available and the patient can watch her own procedure while an explanation is given.

Patients are scheduled in the morning hours and receive premedication, diclopenac 100 mg suppository, 2 h and 1 h prior to the procedure and 1,000 mg paracetamol 1 h orally, also prior to the operation.

We emphasise to have a good breakfast, preventing the patient having an empty stomach, since this is not necessary for an outpatient department (OPD) procedure without anaesthesia.

Hysteroscopy is performed using a 4.9-mm or 4.2-mm continuous-flow hysteroscope with a 5-French working channel (Storz). The hysteroscope is introduced with a vaginoscopic approach without the use of speculum, tenaculum or local anaesthetics [3]. Distension is achieved by saline 0.9% at body temperature; pressure inflow is regulated by gravidity [8]; outflow is regulated by active suction. We believe that, by using this minimally invasive method of hysteroscopy, the release of prostaglandins can be minimised, thereby, preventing uterine cramping and tubal spasms.

After localisation of both tubal ostia, the Essure device is unpacked, introduced through the working channel and placed in the ostium that might be the more difficult of the two. By using this policy, we try to prevent the spoiling of the devices in case the first ostium is the easiest to access, after which, it could happen that the second can not penetrated at all.

After the first placement of the Essure device, the other device has to be introduced very rapidly into the working channel in order to be placed into the second tubal ostium. We try to be ahead of any spasm of the tube after the placement of the first device, which will definitely raise the prostaglandin levels.

The time between the introduction and removal of the hysteroscope is registered. After the procedure, the patients dress immediately, have a small drink and go home or to their work.

Pain sensations are scored by the patients themselves with the visual analogue score (VAS) at the end of the procedure [9].

After this sterilisation method, 3 months of anticonceptive alternatives have to be taken care of. After 3 months, the position of the device is controlled by transvaginal ultrasound and tubal patency is tested by hysterosalpingography.

Results

From August 2002 to August 2004, 175 patients underwent a hysteroscopic procedure for sterilisation by Essure.

Patients characteristics show an average age of 37.4 years (range 25–47), parity 2.0 (range 0–6).

The procedure time ranged between 3 min and 56 min, with mean 18 (SD: 8.1; median of 10 min). The first procedure took 56 min, the last 3 min, as shown in the learning curve (Fig. 1).

The vaginoscopic approach was used in all 173 women. In two patients, local anaesthesia was used on request.

The mean pain score was 2.5 (SD: 2.5; median 2.0; range 0–8).

All women could be discharged within 1/2 h; except two women, who got experienced vasovagal collapse and had to be observed for the next 2 h.

The success rate of bilateral placement in all patients without exclusion was 92% (161/175). After the exclusion of all patients with partially occluded uterine cavity—partial Asherman syndrome—in which patients where a real sterilisation attempt could never be done, the true failure rate was 95% (161/170) (Table 1).

Out of these 161 patients, 10× two sessions were needed, due to spasm, pain or concomitant adhesiolysis, of which, one counted also for spasm/pain.

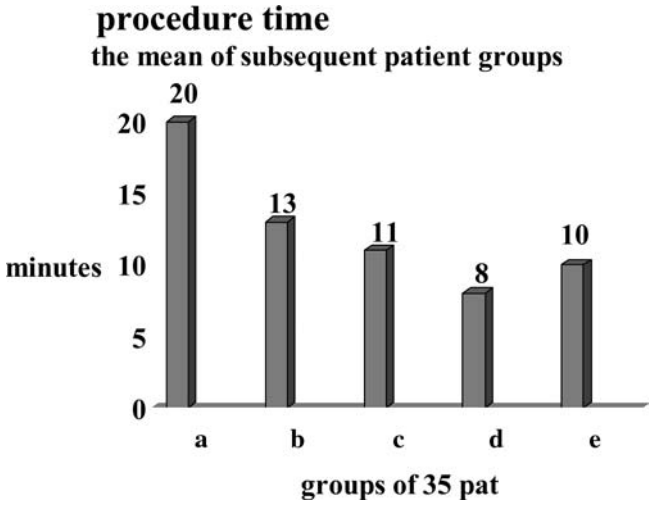

Fig. 1 Learning curve

Table 1 Success rates of placement

Bilateral placement overall[a]		161/175 (92%)
True bilateral placement[b]		161/170 (95%)
One session	151	
Two sessions	10	

[a]The intention was to treat 175 patients
[b]After the exclusion of Asherman syndrome, no sterilisation attempt was made

After partial adhesiolysis of two of these patients, the anatomic position of the tubal ostia was disturbed; the ostia were so widened that one device felt out of the ostium at the end of the procedure. A second placement later on was successful.

The failure rates of placement, 14/175 (8%), were caused by a partial Asherman syndrome (classification according Wamsteker III), therapy-resistant spasm of the tubes, one device failure or by an unknown cause. In two other patients, only one tube could be catheterised by the device. In both cases, one tube appeared to be blocked on the control hysterogram. One patient had a history of PID in the past and another had a feverish period after a caesarean section (Table 2). All patients received laparoscopic sterilisation without any adverse events occurring.

All women filled in a questionnaire after the procedure. All stated, in their answers related to this subject, that they would advocate this method to other women. Even those women in whom failure of placement occurred remained enthusiastic.

Table 2 Causes of placement failure

Failure of placement		14 (8%)
Asherman syndrome	5	
Therapy-resistant spasms	2	
Device failure	1	
Unknown	4	
One-sided pre-existent occluded tubes	2	

At the hysterosalpingogram control after 12 weeks, two tubes still showed patency. The reason for this in the first case was inexperience, since the device was placed too deep into the intramural part of the tube, causing it to slip further into the tube. At the laparoscopic sterilisation later on, the device was located in the middle part of the tube. In the second patient, the hysterosalpingogram was performed 12 weeks after placement: a second hysterosalpingogram 12 months after the first did not show any patency. This patient refused to use any anticonceptive method after the first hysterosalpingogram, but she did not get pregnant.

Thus the total number of patent tubes after the successful procedures was 2 out of 322 tubes, or 2 out of all the 161 treated patients (Table 3).

No pregnancy was reported after 1,200 woman-months follow-up after the hysterosalpingogram.

Discussion

Diagnostic hysteroscopy nowadays is done preferentially in the outpatient department (OPD) with a high success rate [8]. Even minor hysteroscopic surgery can be performed without anaesthesia in the OPD [10]. The vaginal/approach, i.e. no use of specaculum and tenaculum, introduced by Bettocchi and Selvaggi [3], had made these procedures less painful and more acceptable for women to be performed without any anaesthesia at all.

Hysteroscopic sterilisation with the Essure device can be done with small hysteroscopes with a diameter of less than 5 mm and a working channel of 5-French. The use of these small hysteroscopes makes it possible to perform this sterilisation without dilatation of the cervix according the vaginal approach in the OPD.

In our clinic, we recreated and evaluated the conditions to perform these sterilisations in the most convenient way for the patient.

The data of 175 hysteroscopic sterilisations using the new device Essure proved that this procedure can be done safely in the OPD theatre without any kind of anaesthesia. No severe complications have been encountered; only two patients experienced a vaso-vagal collapse, requiring a period of 2 h observation.

To perform this procedure without local anaesthesia and without intravenous sedation, the optimal environment has to be created to comfort the patient.

Table 3 Control tubal patency at 12 weeks

Total number patients with successful placement	161
Patients with tubal patency	2/161 = 0.01%
Total number of treated tubes	320[a]
Tubal patency	1/320 = 0.006%

[a]Two tubes pre-existent occluded

The average pain score of 2.5 is even less than the pain score of 3 during a woman's period. Moreover, the period of pain is very short and ceases immediately after the procedure.

In the case of cervical stenosis, dilatation under direct vision can be done using a scissor or blunt dissection with biopsy forceps. Our experience is that the inconvenience or pain caused by this dilatation is well accepted by the patient, as long as she indicates her own limits, understanding and having a view of the ongoing procedure. A quiet atmosphere, calm background music and socially intelligent nurses and doctors may prevent the need for additional local anaesthesia. Once again, our experience is that the vaginal approach as promoted by Bettocchi and Selvaggi [3] is very essential to perform these hysteroscopic procedures without severe pain. In the case of multiparity, a 5.0-mm-diameter scope normally fits into the cervical channel. After cervical surgery, or in case of nulliparity, we strongly advise the use of a 4.5-mm scope, or even smaller, unless a 5-French working channel is present. Although we succeeded to perform the procedures without local anaesthesia in this group of 173 out of 175 women, in the case of cervical dilatation, the use of local anaesthesia might be necessary in some cases.

The outcome of the questionnaire data filled in by the patients after the procedure showed that women are very motivated to be sterilised by this route, since they prevent an admission of more one day, the use of general anaesthesia, occurrence of postoperative pains, nausea and incompetence one day after and they do not have small scars on the abdominal skin.

Compared to a recently published series [11], we had a slightly higher overall placement failure rate. Since we act as a referral hospital for hysteroscopic treatments, women with a suspicious history of intra-uterine infections hampering an uneventful sterilisation have been referred. After exclusion of these patients with a partially occluded uterine cavity in which an attempt to place the devices never was performed, the true placement failure rate was reduced to 5%, which is comparable with other series. Some patients first received an adhesiolysis and, later on, a successful hysteroscopic sterilisation. Even in this group of patients, an attempt to place Essure seems to be reasonable.

This sterilisation method has been developed to be used as an outpatient procedure.

Indeed, our experience proves that women can be sterilised without any anaesthesia using a safe and effective way made possible by this Essure device. However, patients have to be counselled very carefully, since this method is very definitive, regardless of the simplicity of the procedure.

The satisfaction of the patient, as well as the staff, is very high, although training is necessary to learn the techniques to perform hysteroscopy in a woman-friendly manner.

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