Hysteroscopic permanent tubal sterilization using a nitinol-dacron intratubal device without anaesthesia in the outpatient setting: procedure feasibility and effectiveness

P.Litta1, E.Cosmi1,3, G.Sacco1, C.Saccardi1, A.Ciavattini2 and G.Ambrosini1

1Department of Gynecological Science and Human Reproduction, University of Padua School of Medicine, Via Giustinianini No. 3, 35128 Padua, Italy, 2Department of Obstetrics and Gynaecology, University Politecnico Belle Marche, Ancona, Italy
3To whom correspondence should be addressed. E-mail: ecosmi@hotmail.com

BACKGROUND: Hysteroscopic permanent tubal sterilization has recently been introduced, resulting in a non-invasive, safe and effective technique. The aim of this study was to assess the feasibility of outpatient hysteroscopic tubal sterilization using a nitinol-dacron intratubal device without anaesthesia and to assess patient procedure compliance.

MATERIALS AND METHODS: We undertook a prospective study of 36 consecutive cases of outpatient hysteroscopic tubal sterilization using a nitinol-dacron intratubal device without anaesthesia. Tubal sterilization was performed by placing the device with the aid of a 5.2-mm continuous-flow operative hysteroscope. At the end of the procedure women were asked to rate the pain experienced on a visual analogue scale (VAS) (0, no discomfort to 100, severe discomfort). Successful device placement was assessed after 3 months by hysterosalpingography and diagnostic hysteroscopy. RESULTS: Successful bilateral placement was obtained in 32 patients (88.9%); in one (2.8%) the placement was monolateral; and in three (8.3%) the procedure failed. Mean operating time was 8.6 ± 5.3 min. A mean VAS of 36.1 ± 23.9 was recorded. CONCLUSIONS: The nitinol-dacron intratubal device is safe, appears to be effective long-term, is non-invasive and can be used in the outpatient setting without anaesthesia. Low-level discomfort was experienced by the patients. Limitations of its use include that it is not effective immediately, it is irreversible, it requires special equipment and training, and it is difficult to use in cases of uterine anomalies. We conclude that this method may be offered to all woman asking for permanent tubal sterilization, particularly those who refuse or have contraindications for anaesthesia.

Key words: intratubal device/outpatient hysteroscopy/tubal sterilization

Introduction
Tubal sterilization has become the most widely used method for permanent contraception in the United States. The number of procedures increased during the 1970s, from 201 000 in 1970 to 702 000 by 1977 (Westhoff and Davis, 2000). From 1994 to 1996 almost 684 000 women underwent the tubal sterilization procedure each year, approximately half (45.5%) of all sterilizations were performed post partum and the remaining (55.5%) were interval procedures, which were performed by mini-laparatomy or laparoscopy, the latter being the most frequently used approach (Ross, 1992).

Laparoscopic tubal sterilization is safe and effective, albeit invasive, and has potential surgical and anaesthesiological risks and complications such as unintended major surgery, re-hospitalization, febrile morbidity, transfusion and life-threatening events may occur, with an incidence of 0.9% (Jameson et al., 2000). Moreover, fatal complications have been reported to occur in four to 11 patients per 100 000 procedures performed (Hulka et al., 1995; Intaraprasert et al., 1997). Furthermore, it has been shown that there is a time-related risk of contraception failure. In fact, it has been reported that after 10 years the pregnancy rate varied from 7.5 to 36.5 per 1000 procedures (Peterson et al., 1996; 1999; 2001).

Since 1970 several investigators have aimed to obtain permanent tubal sterilization by the transcervical approach, although the attempts were not safe and had low effectiveness (Sciarr and Keith, 1995).

Recently, a new micro-device namely the Essure (Essure permanent birth control system; Conceptus Inc., San Carlos, CA, USA) has been developed, which leads to the formation within 3 months of an intratubal fibrosis created by the proliferation of connective tissue (Valle et al., 2001). The Essure device is inserted by hysteroscopy in to the proximal section of the Fallopian tube. The advantage of this technique is the non-invasive approach, the effectiveness and the ability to use it in an outpatient setting.

The aim of the present study was to assess the feasibility, effectiveness and patient procedure compliance of permanent tubal sterilization using the micro-device system in an outpatient setting without anaesthesia.
Materials and methods

The present prospective study was conducted from June 2003 to July 2004 in the Department of Gynecological Science and Human Reproduction of the University of Padua.

Use of the Essure, a nitinol dacron intratubal device, was suggested to each women asking for tubal sterilization after they were informed about the technique, benefits, failure rate, irreversibility and procedure complications, and the necessity to verify tubal occlusion by the devices after 3 months by hysterosalpingography and to use contraception for the first 3 months after the procedure. After acceptance women were asked to sign an informed consent form.

Exclusion criteria were women with a positive pregnancy test, unsure about their desire to end their fertility, uterine, cervical or adnexal pathologies, uterine or cervical neoplasia, abnormal uterine bleeding, chronic pelvic pain, pelvic inflammatory disease, previous tubal surgery, and monolateral tubal occlusion.

The study group underwent ultrasonography and diagnostic hysteroscopy to exclude anatomic or dysfunctional uterine and adnexal disorders.

All the women received 0.6 ml of atropine and 0.6 ml of diazepam intramuscularly 15 min before hysteroscopic tubal sterilization. The procedure was performed during the proliferative phase of the cycle without anaesthesia using a continuous flow hystroscope 30° lens (Karl Storz®, Tuttingen, Germany), with an operative channel of 1.8 mm. Uterine distension was obtained using pumped saline solution.

The procedure was performed by introducing the hysteroscope without the use of vaginal speculum in to the uterine cavity with the Essure devices inserted in the hysteroscope operative channel. After visualization of the proximal tubal ostia the operator placed the Essure devices in the intramural part of the tube. Optimal placement of the Essure device was obtained at the moment the black stop ring of the device wire reached the level of uterine tubal ostia, at which point the wire was removed.

After the procedure, the operating time required for the procedure was recorded and the discomfort experienced by the patient recorded using a visual analogue scale (VAS) using the following rating scale: 0, no discomfort; 100, severe discomfort (Valle et al., 2001). Each woman was familiarized with the scale before the procedure.

Pelvic pain was classified as mild when pain was rated from 0 to 40, moderate from 41 to 70 and severe from 71 to 100. The occurrence of moderate or severe pain were considered limits of the procedure in office setting.

At the end of the procedure, an assistant monitored each patient for at least 1 h and recorded the pain score provided by the patient and the presence of any side-effects.

Three months after the procedure, all patients underwent a hysterosalpingography to evaluate tubal occlusion and diagnostic hysteroscopy to assess the number of coils in the uterine cavity and detect the migration of the micro-device from the intramural portion of the tube.

The effectiveness of pregnancy prevention, complications and patients satisfaction (assessed by asking each woman whether they would undergo the same procedure if they had the chance to choose again) were recorded by a telephone interview. Statistical analyses has been performed using the Chi-Square analyses. A P < .05 has been considered statistically significant.

Results

Thirty-six women underwent tubal sterilization using the Essure device. Mean age of the study group was 39.1 ± 3.4 years (range 30–46). There were three (8.3%) nulliparous and 33 (91.7%) pluriparous women. Mean height was 165 ± 4.6 cm (range 155–174) and mean weight was 65.6 ± 10.2 kg (range 51–88) (Table I).

Bilateral micro-insert placement was successfully performed in 32 patients (88.9%), 31 (96.9%) of whom were obtained in a single session; in one (3.1%) two procedures were performed. One patient (2.8%) with monolateral insertion of the device asked for laparoscopic approach, refusing to proceed with further hysteroscopy. In three (8.3%) women (two nulliparous and one pluriparous) the procedure was not successful and women refused further approaches.

Mean operating time was 8.6 ± 5.3 min (range 4–20). Mean VAS was 36.1 ± 23.9 (range 0–85). Twenty-three (64%) patients experienced a VAS <40; 11 (30.5%) a VAS of 41–70; and two (5.5%) a VAS of 71–100.

All patients were able to return to normal activity within 24 h of the procedure.

The hysterosalpingography performed 3 months after the procedure confirmed tubal occlusion in all 32 women. Diagnostic hysteroscopy performed after 3 months in 32 patients with bilateral mini-device positioning showed a mean upward migration of 3.9 ± 2.2 coils in the right [95% confidence interval (CI) 3.1–4.8] and of 3.3 ± 2.1 coils in the left tube (95% CI 2–4.1) (Table II).

The reduction in the number of coils was statistically significant for both tubal ostia. In four cases in the right and in six cases in the left tube a complete migration of the micro-device was observed. In all cases the number of coils left in the uterine cavity during the procedure was less than six.

Six (16.6%) women required non-steroidal anti-inflammatory drugs (30 mg ivanously) because of severe localized pelvic pain after the procedure (Table III).

There were neither short- nor long-term severe complications in the study group.

All the women with successful bilateral placement were contacted by means of a telephone interview after a mean follow-up of 11.5 months, and none of the women had had a pregnancy. A total of 31 women (96.8%) answered that they would opt for the same procedure again if they had the chance to choose again.

Table 1. Demographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>Patients with successful bilateral placement</th>
<th>Patients with failed placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients [n (%)]</td>
<td>32 (88.9)</td>
<td>4 (11.1)</td>
</tr>
<tr>
<td>Age [years ± SD (range)]</td>
<td>39.6 ± 3.2 (33–46)</td>
<td>36 ± 4.1 (30–39)</td>
</tr>
<tr>
<td>Height [cm ± SD (range)]</td>
<td>164.4 ± 4.4 (155–174)</td>
<td>166.5 ± 3.9 (162–171)</td>
</tr>
<tr>
<td>Weight [kg ± SD (range)]</td>
<td>66.2 ± 10.5 (51–88)</td>
<td>64 ± 5.2 (58–70)</td>
</tr>
<tr>
<td>Parity [n (%)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2 (6.2)</td>
<td>1 (25)</td>
</tr>
<tr>
<td>1</td>
<td>11 (34.5)</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>8 (25)</td>
<td>3 (75)</td>
</tr>
<tr>
<td>3</td>
<td>9 (28.1)</td>
<td>0</td>
</tr>
<tr>
<td>&gt;3</td>
<td>2 (6.2)</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 2. Coils in the uterine cavity

<table>
<thead>
<tr>
<th></th>
<th>Placement</th>
<th>After 3 months</th>
<th>Mean reduction</th>
<th>95% CI reduction</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coils right</td>
<td>6.5 ± 3.5</td>
<td>2.6 ± 2.9</td>
<td>3.9 ± 2.2</td>
<td>3.1–4.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Coils left</td>
<td>5.6 ± 3</td>
<td>2.5 ± 2.5</td>
<td>3.4 ± 2.1</td>
<td>2–4.1</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
Surgical characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral placement</td>
<td>32 (88.9)</td>
</tr>
<tr>
<td>One step placement</td>
<td>31 (96.9)</td>
</tr>
<tr>
<td>Two step placement</td>
<td>1 (3.1)</td>
</tr>
<tr>
<td>Unilateral placement(^a)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Failed placement</td>
<td>3 (8.3)</td>
</tr>
<tr>
<td>Procedure time [min ± SD (range)]</td>
<td>8.6 ± 5.3 (4–20)</td>
</tr>
<tr>
<td>VAS [± SD (range)]</td>
<td>36.1 ± 23.9 (0–85)</td>
</tr>
<tr>
<td>Post-procedure analgesia [n (%)]</td>
<td>6 (16.6)</td>
</tr>
</tbody>
</table>

\(^a\)Patient asked for laparoscopic sterilization.

Discussion

Permanent tubal sterilization may be performed using several approaches. Transcervical tubal sterilization may be performed by the injection of sclerosing agents in to the tubes, tissue adhesives, electrocoagulation or cryosurgery, all of which are associated with side-effects related to tissue destruction, such as abnormal uterine bleeding, discharge, infection and chronic pelvic pain. Moreover, the above techniques have failed to gain widespread acceptance because of their tendency towards expulsion and an associated unacceptable pregnancy rate (Sciarr and Keith, 1995).

Hysteroscopic tubal sterilization has been developed to avoid the risks associated with the transabdominal approach.

The introduction of the Essure device resulted in a safe and effective procedure for permanent tubal sterilization, and bilateral insertion of the micro-device may achieved in 98% of cases by the use of the new coil catheter delivery system (Kerin et al., 2001; 2003; Cooper et al., 2003; Kerin et al., 2004; Menez and Lopes, 2004; Ubeda et al., 2004).

In the present study, successful bilateral insertion was obtained in 88.9% of women using the catheter delivery system. There was only one case of monolateral tubal insertion; the patient refused a second procedure and asked for laparoscopic approach, which was performed after 1 month.

In a phase II study, at second-look hysteroscopy following placement of the device between 4 and 18 months previously, Kerin et al. observed in seven patients that its proximal portion extending from the ostium into the uterine cavity underwent a gradual tissue encapsulation with a decrease in length from 6 to 1.3 mm (Kerin et al., 2003). In the present study, during hysteroscopic follow-up 3 months after insertion, complete migration of the micro-device (i.e. when the number of coils left in the uterine cavity during the procedure was less than six) was observed. According to our data, the optimal placement of the coils is to position the micro-device with at least six coils remaining in the uterine cavity.

The present study highlights that the placement of the Essure system may be performed in an outpatient setting without the need for anaesthesia. This is in agreement with the study performed by Ubeda et al. (2004); in phase I, II and III studies several investigators used sedation in 41–66% of cases and paracervical block in 32–52% of cases, whilst general anaesthesia has rarely been adopted (Kerin et al., 2001; 2003; Cooper et al., 2003). Kerin et al., in a study adopting a new coil catheter delivery system, performed paracervical block, using sedation in 19% of cases (Kerin et al., 2004). Menez and Lopes (2004) performed the procedure always using the paracervical block.

In the present study the procedure was found to be acceptable in terms of patient satisfaction rate, as the mean VAS was 36.1. However, being a small prospective study selection bias cannot be eliminated, which might have affected the VAS scores for the women recruited. Nevertheless, the procedure showed a great satisfaction rate as the VAS experienced was similar to that scored during diagnostic hysteroscopy usually performed with a 3.2 mm hysteroscope (Litta et al., 2003; Shankar et al., 2004).

Kerin and Ubeda reported good to excellent patient satisfaction rates in 96% of women (Kerin et al., 2003; Ubeda et al., 2004), with an increase to 99% in the phase III study (Cooper et al., 2003). In the present study, the satisfaction rate was obtained in 97% of patients after a mean follow-up of 11.5 months.

After 11.5 months of follow-up, none of the women was pregnant, which is in accordance with other studies (Cooper et al., 2003; Litta et al., 2003; Teoh et al., 2003; Kerin et al., 2004; Menez and Lopes, 2004; Rosen, 2004; Shankar et al., 2004; Ubeda et al., 2004), although long-term follow-up is needed.

Although there were no complications in the present study, which may be due to the small sample size, it should be stressed that several authors have reported a risk of malpositioning and expulsion of the devices, with an incidence ranging from 1.3% (Kerin et al., 2003) to 3.6%, and a risk of uterine perforation ranging from 0.9% to 2.6% (Cooper et al., 2003; Kerin et al., 2004). Kerin et al. (2004) described a perforation rate of 1%.

Our study, although limited by the small sample size, strengthens the evidence of the effectiveness and safety of the Essure device for permanent tubal sterilization.

In conclusion, permanent tubal sterilization using the Essure system is safe and effective, and may be performed in an outpatient setting without use of general anaesthesia. With a low risk and a high patient satisfaction rate, it is a valid alternative to the surgical approach, which has potential risks related to surgery and anaesthetics. It should be borne in mind that this procedure may be performed in women with high surgical and anaesthesiologic risk.

References


Submitted on March 25, 2005; resubmitted on June 7, 2005; accepted on July 4, 2005