Predictive factors of Essure® implant placement failure: prospective, multicenter study of 495 patients

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Objective: To assess a new hysteroscopic method of tubal sterilization; specifically, to examine the factors associated with placement failure of Essure® implants.

Design: Observational, multicenter, 6-month study.

Setting: Seven gynecology clinics, including five public hospitals and two private clinics, in France.

Patient(s): A total of 495 women who provided informed consent.

Intervention(s): All procedures were done by a vaginoscopic approach with a 5-mm operating hysteroscope.

Main Outcome Measure(s): Data collected were age, parity, type of anesthesia, premedication, endometrial aspect, ostia visualization, duration of the procedure, pain during the procedure, and associated procedures. Unilateral and bilateral placement rates were assessed. Adverse events at 3 months (expulsion, migration, perforation) were also recorded.

Result(s): Mean parity was 2.45; 20 women were nulliparous. In 56.3% of cases (n = 277), none or local anesthesia was used for the placement procedure. Overall, 86% of the women (n = 423) had nonsteroidal anti-inflammatory drug (NSAID) premedication, and 8.1% (n = 40) had another intrauterine surgical procedure performed at the same time. In 24 cases, at least one of the tubal ostia could not be visualized well during hysteroscopy.

Conclusion(s): The failure rate for Essure® micro-insert placement was 6% at first attempt and 3.3% after two attempts. Success rate was not significantly associated with parity, mode of analgesia, NSAID premedication, or combination with another procedure. The only factor significantly associated with the failure rate was poor visualization of the tubal ostia. (Fertil Steril 2010;93:29–34. ©2010 by American Society for Reproductive Medicine.)

Key Words: Tubal sterilization, Essure®, failure of placement, hysteroscopy, parity, anesthesia, NSAID, concomitant procedure

Tubal sterilization is the most commonly used contraceptive method in the world. In 2005, the United Nations reported that 20.5% of women of childbearing age living with a partner had been sterilized (0–45.8%, depending on the country), compared with 3.4% of men (0–18.7%, again depending on the country) (1). The various methods of tubal sterilization all prevent patency of the tubes. The laparoscopic techniques include tubal ligation (with Yoon’s ring or Filshie or Hulka clips) or laser ablation or even salpingectomy (2). These techniques are sometimes accompanied by incidents associated with general anesthesia or, more often, a gastrointestinal or vascular wound. The failure rates for laparoscopic tubal sterilization range from 0.18% to 5.43%, depending on the technique and the patient’s age (3, 4). More recent development of the hysteroscopic pathway has made it possible to propose irreversible tubal occlusion, with no scar and even without anesthesia. In 1999, sterilization with Essure® implants (Conceptus France, Versailles, France) began in Australia. These micro-inserts are placed hysteroscopically in the proximal fallopian tube, where they induce a fibrotic reaction that causes complete tubal occlusion in 3 months (5, 6). Verification is essential at the end of that period that the inserts are in the correct position and the tubes blocked.

Several studies have shown the contraceptive effectiveness of these Essure® inserts for tubal sterilization (7). The success rate for their placement exceeds 95% (6–9). The aim of the present study was to determine the factors that predict its placement failure.

MATERIALS AND METHODS

We conducted a prospective multicenter study in France from January through June 2006 to assess the factors associated with failure in the placement of Essure® micro-inserts. Gynecology departments of seven hospitals participated in this study: Pontoise Public Hospital, Ambroise Paré Private Hospital in Toulouse, Nantes University Hospital, Bichat Claude Bernard University Hospital in Paris, Atlantic Private Hospital at St. Herblain, Versailles Public Hospital, and Dunkerque Public Hospital. All patients requesting tubal sterilization received clear information about the different methods of contraceptives and their consequences and about the different procedures for female and male sterilization, with details...
about the differences between laparoscopic and hysteroscopic tubal sterilization. Each patient signed an informed consent form; according to the French law on human sterilization, the procedure was performed 4 months later, at the end of the legal waiting period.

The Essure® device had to be placed during the first half of the menstrual cycle, in the absence of bleeding, as recommended by the manufacturer. Each center determined its own protocol, including the site and hospitalization conditions (traditional hospitalization, day hospitalization, outpatient hospitalization, in the operating room, or in a hysteroscopy room), and each physician and patient together chose the level of analgesia (none, local, regional, general, or simple intravenous sedation), in part on the basis of whether another hysteroscopic surgical procedure was also planned. In the latter case, the implants were placed during the first part of surgery, except when an intrauterine device was removed first.

Data analyzed for each patient included age, parity, previous contraception, premedication with a nonsteroidal inflammatory drug (NSAID), endometrial thickness, any intrauterine disorders, ability to visualize the tubal orifices, the placement of one or both implants, and the performance of another hysteroscopic procedure during the same surgery. For each placement, the duration of the surgical procedure was measured (from introduction to final withdrawal of the hysteroscope), and the surgeon assessed the difficulty of placement on a scale from 1 (very easy) to 5 (very difficult). Pain associated with the procedure was assessed with a visual analogue scale, and the prescription of analgesic treatment and patient satisfaction were both recorded.

The success of placement was defined by tubal catheterization, with bilateral placement of the Essure® device or unilateral placements in the following circumstances: previous salpingectomy or adnexectomy; on a second attempt after another unilateral placement; or when contralateral tubal occlusion was confirmed by hysterosalpingography (HSG). All other situations were considered failures; that is, when one or both tubes were left patent or when a method other than Essure® was used for final tubal sterilization.

Statistical analysis used Fisher’s exact test and Student’s t-test to compare means. Probability (P) values of ≤ .05 were considered statistically significant.

RESULTS

This survey included 495 patients who had undergone tubal sterilization with Essure® implants. At least one item of data was missing from 2.74% of the files. Three patients (0.6%) were excluded because of intrauterine disorders at hysteroscopic examination that led to others therapeutic options.

The success rate for bilateral placement at first attempt was 89.4% (n = 440). Six patients had no implant placed at first attempt: two had bilateral tubal occlusion confirmed on HSG and were thus classified as placement failures but sterilization successes, one had a laparoscopic tubal ligation the same day, and three were awaiting HSG findings. Thus the bilateral placement failure rate was 1.2% (n = 6).

The rate of unilateral placement at first attempt was 9.3% (n = 46), including 19 for past history of salpingectomy and 4 for tubal occlusion on HSG; these 23 cases were classified as successes. The other 23 patients received appointments for a second attempt; 15 were performed, 13 of them successfully. The total number of successes at first or second attempt was thus 476 (96.7%).

There were no significant differences for success rates between different centers. Intraoperative difficulties at first attempt prevented uni- or bilateral placement for 33 women. Six times, these difficulties were associated with uni- or bilateral tubal occlusion subsequently confirmed by HSG; 27 times, because of poor visualization of the tubal ostium or spasm or stenosis.

Figure 1 summarizes the outcome of the various attempts of Essure® implant placement.

The patients’ mean age was 42 years (range, 28–54 years), mean parity was 2.45, and 20 women (4%) were nulliparous. Hormonal contraceptives were used by 73.1%, mechanical contraceptives by 12.7%, and none by 14.2%.

Assessment of endometrium during hysteroscopy found it to be normal in 52% of patients, atrophic in 31%, and hypertrophic in 10%. The uterine cavity was adenomyotic in 1% of cases, with polyps or myomas in 6%.

Preprocedure medication with an NSAID was taken by 423 patients (86%).

All additional procedures were performed under general or regional anesthesia, except two: one for surgical ablation of a polyp removed through the cervix and one for an endometrial biopsy. Figure 2 reports the various types of analgesia used. In 8.1% of cases (n = 40), another intrauterine surgical procedure was performed concomitantly. These other procedures included total endometrial ablation (n = 24), ablation of polyp or fibroma (n = 11), curettage (n = 4), and treatment of an unexpected uterine synechia that was resected to perform the procedure (n = 1). Extraterine interventions were combined with Essure® placement in nine cases.

In 24 cases, at least one tubal ostium was not clearly visible during implant placement. Placement was nonetheless successful in 13 of these cases.

Placement was considered difficult in 6% of cases (n = 30) and very difficult in 4% (n = 20); in 6 of these cases (12%), one or both inserts could not be placed. Placement was considered more difficult in cases in which placement failed, but this difference was not statistically significant (P = .15).

The mean duration of the procedure was 11 minutes (range, 3–40 minutes). Placement of inserts took a mean of 9 minutes (range, 3–40 minutes) when performed alone and 12 minutes (range, 4–40 minutes) when another procedure was combined with it. The mean duration of the unsuccessful placements
was 18 minutes (range, 7–40 minutes). In 3 of the 13 cases of failure, another intrauterine procedure was associated with placement (two myomectomies and one curettage). Unsuccessful placements took significantly longer ($P=0.05$).

Table 1 summarizes the influence of parity, NSAID premedication, extent of anesthesia, and additional procedures on the placement success rate.

**DISCUSSION**

Hysteroscopic sterilization owes its great success to the absence of both a scar and any need for either general anesthesia or hospitalization. It is effective, and recovery is rapid (5, 7, 10). The success rate at first placement attempt ranges from 83% to 92% (2, 5, 6, 8, 9, 11). This technique is effective after 3 months, the time needed for fibrosis to develop around the central polyethylene terephthalate insert. Because the rate of secondary migration or expulsion can reach 5% (5), other contraception must be used until the 3-month verification visit.

The placement success rate in our series was 94.1% at first attempt and 96.7% at second. The placement success rate in the literature is not as high, ranging from 86.4% to 95% after two attempts (2, 5, 6, 8, 9). The studies by Cooper et al. (6), Rosen (9), and Menez and Lopez (11) reported mainly first placements, that is, the learning period. Their success rate for first placement attempts is thus lower. Nonetheless, in our study, we reclassified as successes unilateral placements for 19 patients (3.8%) with a history of salpingectomy and 4 patients (0.8%) with contralateral tubal occlusion on HSG verification. These data are rarely mentioned in the literature. Moreover, because laparoscopy for tubal sterilization is more frequent than a second attempt after a failure, any attempts at comparison are futile. In addition, modifications in the insertion catheter over the years have facilitated the procedure.
Finally, the operators’ increasing experience and the establishment of training organized by Conceptus has undoubtedly contributed to these high placements success rates. All the centers in our study have been placing Essure® implants for several years.

Hysteroscopy is the first procedure and conditions the success of placement. The cervix must be catheterizable. Parity does not limit this technique. Hysteroscopy did not fail in any case in this series, which included 20 nulliparous patients. The small diameter (5 Fr) of Bettocchi’s hysteroscope makes it possible to catheterize nearly every cervix without prerequisite dilatation, but sometimes countertraction or lidocaine injection of the cervix is required. In some cases the second sheath of the hysteroscope, which permits aspiration, can be withdrawn to reduce its diameter further. A longer hysteroscope is sometimes needed for obese women.

The good visibility of the tubal orifices during hysteroscopy determines the likelihood of success: the relative risk of failure is increased sevenfold when visibility is poor. The absence of bleeding and a thin endometrium during the first part of the cycle are essential. Rosen (9) reports that the mean placement time increases when the procedure is performed during the luteal phase (16.6 minutes vs. 9.3 minutes). In Rosen’s study, one of three patients with failure attributable to endometrial thickness had a successful second placement during the first part of the cycle. Moreover, performing the procedure during the second part of the cycle involves a risk of pregnancy.

In the procedure as described and taught by Conceptus, when the tubal orifice cannot be visualized, the implant should not be placed, and it thus remains sterile. In our study, we observed that despite these guidelines, catheterization was attempted 24 times when the tubal orifices could not be well viewed, with a success rate of 54%. A tubal spasm may hamper this visualization. It may cease during the procedure after several minutes or by reducing intrauterine pressure; in the best cases it can be avoided by performing the diagnostic hysteroscopy and implant placement as rapidly as possible. Difficulty in placement is correlated with the time required for the procedure. The tubal orifice may also be masked by a mucous flap. Visualization may also be more difficult because of anatomic conditions when the

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**TABLE 1**

**Influence of various factors on failure rates of Essure® implant placement.**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Failure (n)</th>
<th>Success (n)</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>1</td>
<td>19</td>
<td>1.8 (0.04–14.9)</td>
<td>.4229</td>
</tr>
<tr>
<td>Not nulliparous</td>
<td>13</td>
<td>457</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General, spinal or IV sedation</td>
<td>5</td>
<td>211</td>
<td>0.71 (0.2–2.8)</td>
<td>.7823</td>
</tr>
<tr>
<td>Local or no anesthesia</td>
<td>9</td>
<td>268</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premedication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSAIDs</td>
<td>13</td>
<td>410</td>
<td>1.71 (0.22–68.8)</td>
<td>1</td>
</tr>
<tr>
<td>Without NSAIDs</td>
<td>1</td>
<td>54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant procedure</td>
<td>3</td>
<td>37</td>
<td>3.2 (0.59–14.49)</td>
<td>.08284</td>
</tr>
<tr>
<td>No concomitant procedure</td>
<td>11</td>
<td>436</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visualization of ostia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>11</td>
<td>13</td>
<td>7.5 (7.23–41.21)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Good</td>
<td>3</td>
<td>464</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: OR = odds ratio; CI = confidence interval.

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ostium is lateral. Hysteroscopy must be performed prudently, minimizing bleeding by limiting any breakage of the endometrium by the hysteroscope or the distal part of the inserter.

For women with a past history of tubal surgery and in the absence of a reliable surgical report, HSG makes it possible to determine whether the tube is present or patent. On the other hand, the low failure rate of placement at first attempts (5.5% in our series) does not justify routine performance of HSG before the procedure. Finally, in the case of failure, this imaging makes it possible to document the obstruction and to select patients who might benefit from a second attempt with a high rate of secondary success (86.7% in our study).

The type of anesthesia used did not have a statistical effect on the success rate of placement. The choice of type of anesthesia depends on several criteria, including the anticipated performance of another uterine procedure during the intervention, the operator’s habits, and the patient’s wishes. Over time, the number of procedures performed under local or no anesthesia has increased, in correlation with operator experience. In a multicenter series, Nichols et al. (12) compared the placement success rate for procedures performed in an operating room (n = 252) with the rate for those performed in an examination room (n = 68) and observed no significant differences (88% vs. 91%), although 53.1% of the women in the operating room had general anesthesia or intravenous sedation, compared with only 23.9% in examination rooms (sedation only). Litta et al. (13), in a prospective series of 36 patients with implants placed without anesthesia, reported a mean pain level, evaluated by a graduated (1–100) visual analogue scale, of 36.1 ± 23.9.

On the other hand, when placement was combined with another surgical procedure, general or regional anesthetics were used most of the time.

Another intrauterine procedure can be combined with Essure® placement without compromising the success rate. In our experience, this surgical procedure takes place after implant placement, except when the former involves intrauterine device removal, which must be performed first. Two studies have examined Essure® placement during intrauterine surgery. Vallée et al. (14) assessed the feasibility of Thermachoice (Ethicon, Somerville, NJ) endometrial ablation in volunteer patients for whom hysterectomy was indicated; they placed implants, performed the thermoablation, and then hysterectomy. Tissues were analyzed subsequently. They concluded that Thermachoice was safe and would not cause thermal tubal lesions. Moreover, there were no cases in which the distal extremities of the implants perforated the Thermachoice balloon. In 2007, Donnadieu et al. (15) reported a retrospective series of 23 patients in whom the placement of Essure® inserts was combined with endometrial ablation or by thermal balloon system, radiofrequency, monopolar, or bipolar energy. Implant placement was possible in 20 of 23 cases. No complication was reported, and tubal occlusion was confirmed at 3 months for all 20 patients.

The role of NSAID premedication is controversial in the literature. Cooper et al. (6) found a significant increase in the rate of insert placement with NSAIDs, as did Chern and Siow (16); but the patients who did not receive NSAID premedication were also the first 30 patients (of 80) managed by the team and may thus have corresponded instead to their learning process. Nichols et al. (12) found in 2006 that NSAID premedication may have an effect in a series of 320 patients treated in the operating room, as opposed to a consultation room. They found a significant association between the risk of placement failure and the absence of premedication: 18% of successful placements did not receive an NSAID, compared with 33% of the failed placements.

Our study shows a high success rate for hysteroscopic tubal sterilization, even though bilateral placement was not always possible at first attempt. The failure rate for Essure® microinsert placement at first attempt was 5.9% and at second attempt was 3.3%. The success rate was not significantly associated with parity, mode of analgesia, NSAID premedication, or the performance of a concomitant intrauterine surgical procedure. The only factor significantly associated with the failure rate was the inability to visualize correctly the tubal ostia through the hysteroscope. In view of the cost of the implant and the risk of failure, surgeons should not attempt to place the micro-insert unless they can visualize the ostium well.

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