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ORIGINAL ARTICLE

Hysteroscopic sterilization with Essure® device in situ: a challenge?

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Abstract Hysteroscopic sterilization through the Essure® method is preferably performed in the outpatient department without any form of anesthesia. This approach requires the hysteroscopic skills of the gynecologist to use the vaginoscopic route. Initially, the manufacturer advised to remove any type of intrauterine device (IUD), 1 month before the procedure, to prevent difficult procedures and also to increase the success rate of placement. This observational prospective study analyzed the outcome in women in where the IUD was left in the uterus during the sterilization. During a period of 2 years, all women have been included consecutively in seven public hospitals located in France and the Netherlands. During this procedure, 32 out of 239 IUDs had to be removed to finish the sterilization successfully. The placement success rate was 97%. Placement failures were not related to the IUD being present at the time of the procedure. At confirmation tests 3 months after insertion of the Essure®, only five tubes were still patent. No complications were registered. Pain was recorded, and women responded well on oral nonsteroidal anti-inflammatory drug medication. The IUD did not need to be removed before the start of the hysteroscopic sterilization; only in case the procedure could not be completed, the IUD had to be removed during the sterilization itself. Placement rate was 97.1%.

Keywords Essure · IUD · Sterilization

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Introduction

Female sterilization by the hysteroscopic route has been pioneered for many decades. The first commercially available method (Ovabloc®) was introduced in Europe in 1988, but never outside Europe. Since the introduction of the micro-insert "Essure"®, the hysteroscopic sterilization became a real option for women [1] worldwide. Sterilization by this device Essure® is meant to be performed in the outpatient department without spinal or general anesthesia.

The hysteroscopic approach is done preferably according to the vaginoscopic approach as has been promoted by Stefano Bettocchi [2]. After the placement of the device in both tubal ostia, the presence of the nitinol spring and its inner coil of polyethylene terephthalate fibers provokes a

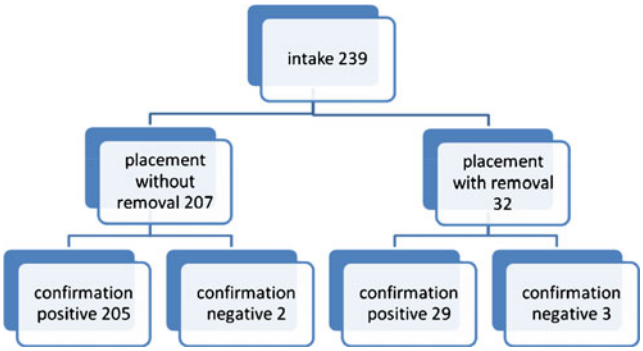

Fig. 1 Study design

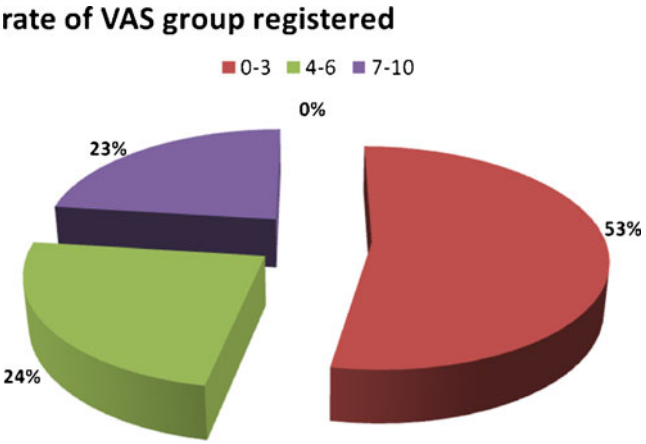

Fig. 2 Outcome of the pain score list (visual analogue score)

tissue reaction. Fibrotic tissue is formed in the proximal tube. This chronic fibrotic reaction will be completed in all patients after 3 months after the placement of the device and will block both tubes in all patients: 96.5% at 3 months and 100% at 6 months [3].

For 12 weeks after the placement of the device, an alternative form of contraception is necessary. Women are advised to continue their usual method of contraception. In case the woman is using an intrauterine device (IUD), it is advised by the marketing company to remove the IUD preferably one cycle before the placement of the device. The reason for the removal of the IUD is the fear that it can hamper a quick hysteroscopic procedure and might interfere with proper placement of the device in the tubes.

The disadvantage of this advice is the need to rely on an alternative contraception for the duration of 3 months. This increases the risk of an unreliable contraception.

In this multicenter prospective observational study, the surgeons left all the IUDs in place and tried to insert the devices. Once they succeeded, this IUD was removed after the confirmation test at 3 months. Patients' characteristics and procedures were recorded; the outcome measurements were the placement rate of the devices, the number of IUDs which had to be removed during the procedure, and the outcome of the confirmation test at 3 months.

Materials and methods

This prospective observational study has been performed by seven study centers spread out over France and the Netherlands. The study setup is shown in Fig. 1. All gynecologists used this sterilization method for more than 1 year. In all patients, the vaginoscopic approach according to Bettocchi was used.

The procedures were performed ambulatory, either on the outpatient department or in the clinical theater. All gynecologists advised their patients the use of nonsteroidal anti-inflammatory drug (NSAID) premedication before the start of the procedure.

The endpoints were defined as the placement rates of Essure devices in those women who had an IUD in place at the moment of the hysteroscopy. The acceptance of the patients measured by pain scores during the procedure, their voluntary use of NSAID medication, and the complication rate were recorded. Sedation, local, or general anesthesia was only given in specific situations at the decision of the surgeon and on request of the patients. In case of local anesthesia, cervical clockwise injections were given.

From November 2006 till January 2009, all 239 consecutive women who requested sterilization through this method of Essure and who were using an IUD have been included.

Three months after the sterilization, the confirmation was done according to the protocol chosen by the

Table 1 Type of analgesia

General anesthesia	15
Intravenous sedation	45
Oral sedation	6
Local anesthesia	3
No anesthesia	170

Table 2 Visual analogue score (VAS) pain registration related to the use of nonsteroidal anti-inflammatory drug (NSAID)

VAS score	NSAID premedication	No premedication
0–3	72 (57%)	40 (47%)
4–6	27 (21.5%)	24 (28%)
7–10	27 (21.5%)	21 (25%)
	126	85

p value=0.206; Mann–Whitney U test

Table 3 Problems encountered

1 breakage of device; replacement
1 none expenditure; replacement
2 lost in cavity to shallow placements replaced
1 migration, i.e., perforation into the abdominal cavity
2 incorrect placement without any further information

gynecologist, either the protocol based on the plain X-ray of the abdomen or the transvaginal ultrasound. A hysterosalpingogram was done on the judgment of the gynecologist to exclude patent tubes.

Results

The majority of the procedures, 136 of 239 (57%), were done on a day care unit, while a smaller group of 103 of 239 (43%) was performed in the outpatient department.

All surgeons used the vaginoscopic hysteroscopic approach, so called Bettocchi hysteroscopy: no use of disinfectants, speculum, or tenaculum. Overall, there was no use of anesthesia; only in a few exceptional cases, sedation, local, or general anesthesia was given (Table 1).

Pain has been scored during the procedure using the visual analogue score (VAS) listed in 211 of 239 patients; the procedure was very well accepted (Fig. 2).

Most patients used the prescribed premedication of NSAID drugs, which is suppose to influence the pain, although the comparison of the VAS scores for premedication versus no premedication did not show a significant difference (p value=0.206 Mann–Whitney U test; Table 2).

The devices could be placed in 232 of 239 (97%) of all women; the presence of the IUD was not registered by the surgeons as the cause of failure. In all these patients, the IUD was left in place.

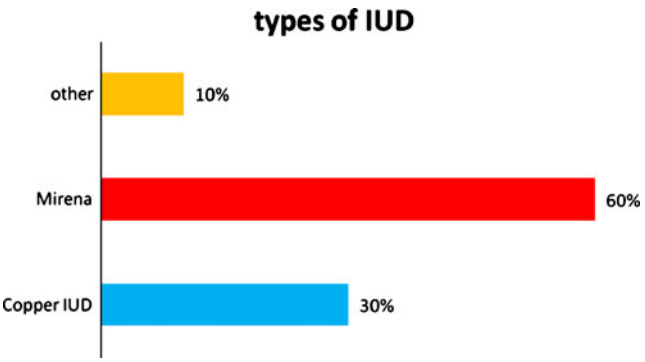

Fig. 3 Types of intrauterine device used in this group

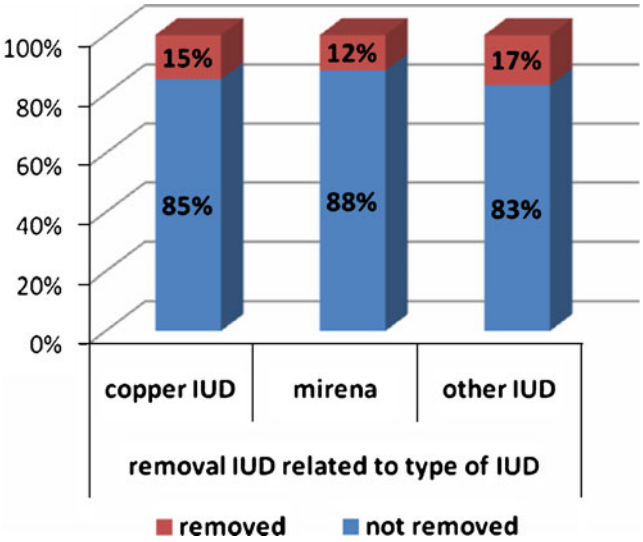

Fig. 4 Rates of removal of intrauterine device type

An overview of the different causes of placement failure is given in Table 3. Except for one perforation, all other problems were resolved.

Mirena IUD was used in 60% (144/239), a copper IUD in 30% (71/239), and other types of IUD in 10% of patients (24/239; Fig. 3).

During the procedure, 32 IUDs had to be removed to successfully insert Essure®; in these women, no placement failure occurred. There was no relation between the type of IUD and the rate of removal during the sterilization: p value=0.6267 (Fig. 4). For the comparison of the removal rate by type of IUD, we used the Chi-square test.

An overview of placement failure rates and removals of IUD in order to succeed the procedure related to the different gynecologists is given in Table 4.

The confirmation test at 3 months after placement of the devices was done by transvaginal ultrasound, plain X-ray, or hysterosalpingogram (Fig. 5).

Table 4 Removal of intrauterine device during placement and placement failure rate (divided by gynecologist)

	Total/removal	Placement failure
Panel	22 (7; 31.8%)	1 (4.5%)
Fernandez	36 (4; 11%)	3 (8.3%)
Engrand	95 (11; 11.6%)	3 (3.2%)
Heckel	27 (2; 7.4%)	0 (0%)
Villefranque	15 (0; 0%)	0 (0%)
Vleugels	22 (1; 4.5%)	0 (0%)
Veersema	22 (7; 31.8%)	0 (0%)
Total	239 (32; 13.4%)	7 (2.9%)

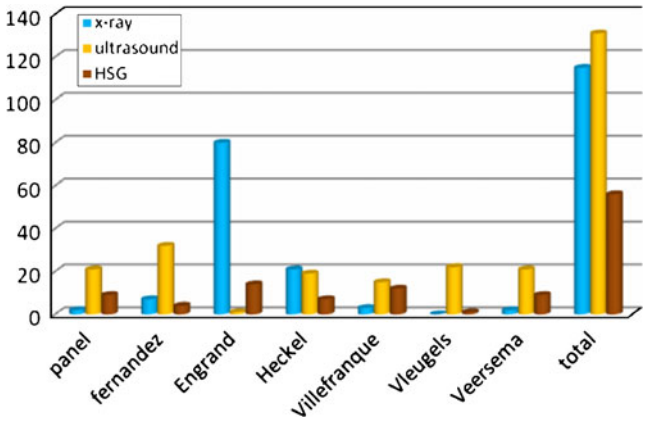

Fig. 5 Confirmation tests divided by surgeon

Almost all patients, 236 out of 239, turned up for their checkup at 3 months, including all patients from whom the IUD had to be removed during the procedure to succeed the placement. Ten patients received one device inserted on one side, since they had a registered tubectomy in the past.

The overall success rate of the sterilization procedure at 3 months was 98% (231/236; Table 5).

Discussion

Any IUD in the cavity of the uterus may hamper a good visualization of the whole cavity. Especially, the view on both tubal ostia is sometimes more difficult with an IUD with long arms like the Mirena®. Thereby, due to avascular fibrotic synechia, a clear view is often not possible, especially in case of atrophic endometrium due to the local progesterone release by the Mirena® IUD. These difficulties can prolong the hysteroscopic approach to the tubal area, and in combination with the inevitable manipulation of the IUD, spasm of the uterus and the tubes might be induced. The risk of placement failures increases.

In case the micro-inserts were placed correctly, some patients required a confirmation test by hysterosalpingogram instead of ultrasound or plain X-ray according to the Dutch confirmation protocol due to a difficult procedure that lasted longer than 15 min [4]. This protocol has been accepted by most European gynecologists. Due to all above-described difficulties, an increased risk of non-placement or displacement has been assumed. So, the product instruction for use advises to remove the IUD before the procedure.

In this study, we analyzed the outcome of all consequently performed sterilizations by seven surgeons who documented their experience with the IUD in place at the moment that they started the procedure.

The data are too small to analyze any relationship for each surgeon between the placement failure rate and removal of IUD during the procedure to succeed. The placement failure rate was very low in this group of patients.

Placement could be achieved in 97%, which is even higher than the overall success rates in the normal population [3, 5]. A few small retrospective feasibility studies elucidated the advantage to leave the IUD in place, but their outcomes were also less successful [6, 7].

Failure of placement was not related to the presence of the IUD. Eleven times (9.8%), the IUD had to be removed during the procedure since placement of the Essure® device might have been impossible. In all these women, the sterilization could be completed. Although the IUD may jeopardize a quick performance, the average procedure time did not exceeded 15 min. In spite of the preoccupation of more pain, the VAS did not show more pain compared to the literature; hence, most sterilizations were done without general or spinal anesthesia.

We concluded that every gynecologist who has experience with this hysteroscopic sterilization can perform this procedure without removal of the IUD beforehand. The outcome during sterilization, like the placement rate, pain,

Table 5 Patency of tubes at HSG=failure rate according protocol

Surgeon	Success		Failure		Control	Total treatments
	Bilateral	Unilateral	Bilateral	Unilateral		
Panel	21		1		22	22
Fernandez	31	3	1	1	36	36
Engrand	88	6	1		95	95
Heckel	24				24	27
Villefranque	15				15	15
Vleugels	22				22	22
Veersema	20	1	1		22	22
	221	10	4	1	236	239

Success=blocked tubes, 231=98%; Failure=open tubes, 5=2%

complications, and as well as the confirmation test at 3 months, does not differ from the normal population. Since we have the policy to leave the IUD in place, we know that it might be a little more painful and might create more discomfort in an individual case, but the consulting gynecologist has to counsel the patient about these items. The woman herself has to make the decision to leave the IUD in or not. The advantage is clear: a reliable contraception will be continued during the waiting period of 3 months.

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Conflict of interest Dr. Michel Vleugels is a member of the advisory medical board. He is a consultant. A group of gynecologists together is advising critical studies. The travel/accommodation expenses are covered or reimbursed in case the medical advisories organize a meeting abroad.

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