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Concomitant hysteroscopic endometrial ablation and Essure procedure: feasibility, efficacy and satisfaction

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ABSTRACT

Objective: Hysteroscopic endometrial destruction procedures for abnormal uterine bleeding are an alternative to hysterectomy. Such procedures are not contraceptive and are performed on fertile patients, requiring long-term contraception.

This is the first study evaluating long-term results of a combined procedure associating endometrial destruction and concomitant hysteroscopic tubal sterilization by Essure® micro-inserts.

Our goal is to evaluate efficacy of endometrial destruction as well as hysteroscopic sterilization and satisfaction after a combined procedure in the case of abnormal uterine bleeding in non-menopausal patients.

Study design: This is a retrospective study (Canadian task force II-2) that includes 131 patients operated with combined endometrial destruction and hysteroscopic tubal sterilization between 2002 and 2011 at our university hospital.

The patients were contacted to answer a questionnaire. Statistical analysis was performed with SAS© version 9.2. (SAS Institute Inc., Cary, NC).

Results: Ninety-three patients out of 131 could be reached. The mean follow-up was of 37.8 months (min = 8, max = 87, SD = 6.2). Thirty-eight patients (29%) were lost to follow-up.

Essure® micro-inserts introduction success rate (evaluated on 131 patients) was 95.8%, and their position was appropriate in 81.1% of the 106 patients with position control. Efficacy of the procedure on the haemorrhagic symptoms (evaluated on 93 patients) was 80.6%. Twelve patients (12.9%) underwent a hysterectomy, 7 of which (58.3%) were a direct consequence of treatment failure. No pregnancies were reported. Satisfaction rate was of 90.3%.

Conclusion: Inadequate position rates of the micro-inserts after 3 months seem somewhat above literature findings, though no pregnancy has been reported.

However, recurrent bleeding symptoms and hysterectomy rates are consistent with those observed after an endometrial destruction procedure alone.

Limitations are the limited number of patients, the bias inherent to retrospective studies (lost of follow-up, selection bias).

The concomitant endometrial destruction and tubal sterilization by micro-inserts is a safe and efficient procedure.

Introduction

Abnormal uterine bleeding (AUB) is a frequent medical complaint in non-menopausal patients. Their prevalence is estimated at 11–13% in general population, but can reach 24% of women between 36 and 40 years of age [1].

The aetiology is usually functional but uterine cavity pathologies can be associated (myomas, polyps, endometrial hyperplasia).

French and British guidelines recommend treating AUB medically as first line treatment (Levonorgestrel intra uterine device, tranexamic acid, oestroprogestative contraceptions, and NSAID), before proposing a conservative surgical approach (endometrial destruction or endometrial resection). Radical

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surgical management (hysterectomy) should be reserved in case of conservative treatment failure [1]. Surgical options must be proposed to patient with no further pregnancy desire.

First generation techniques for endometrial destruction include monopolar or bipolar hysteroscopic resection of the endometrium using a resection loop or a Rollerball®. Success rates are evaluated between 70% and 97%, with amenorrhea rates between 10% and 60% [2] and reintervention is needed in 10–31% of cases [3–5].

Second generation techniques include uterine balloon therapy (UBT), hydrothermablation, radiofrequency, micro-waves and cryotherapy. They are quicker and less associated with per-operative complications than first generation techniques. Satisfaction and reoperation rates are equivalent [6–9]. Among second generation techniques, a newer study has shown a better amenorrhea rate with microwaves and radiofrequency techniques than with UBT or hydrothermablation. Hydrothermablation had lower satisfaction rates as well [10].

Conservative surgical techniques, while responsible for synechiae, cannot be considered as a reliable contraception. The pregnancy rate after such procedures has been evaluated between 0.7% and 1.6% [11,12]. Pregnancies are at risk with high complication rates, including first trimester abortions, premature rupture of the membranes, premature delivery, caesarean-sections, placental complications, severe post-partum haemorrhage, high perinatal mortality [13,14]. It is therefore recommended that patients use long-term contraception after such a procedure [15,16].

Many studies evaluating the feasibility of a tubal sterilization using the Essure® system during the same operative time as the endometrial destruction have been conducted [17–21]. They all demonstrate the feasibility of this association, but none of them assessed the long-term results on both sterilization and bleeding symptoms.

This is the first study evaluating the results of this double concomitant procedure with a follow-up time of more than 3 years.

Materials and methods

Since 2002, we proposed the combined procedure (Essure® tubal sterilization and endometrial destruction) to patients with AUB (Higham score >150) seeking for conservative surgical management, as an alternative to the prescription of long-term contraception after the endometrial procedure. Whereas the combined procedure is not FDA approved in the US, it is not considered an off-label association in France.

We retrospectively consulted the paper medical records of these patients to gather data about the procedure technical details: surgical technique used, Essure® insertion, associated uterine cavity pathology (myoma, polyp). Follow-up modalities were noted: imaging for Essure® positioning, further operation or AUB complaints. We then contacted the patients by phone and a questionnaire was proposed.

In our department, three endometrial destruction techniques have been used: bipolar endometrial resection, uterine balloon therapy with Thermachoice® and radio-frequency destruction with Novasure®. They were performed according to the manufacturers' recommendations.

All Novasure® procedures were performed prior to the insertion of the Essure® device, while the order was variable for the other two techniques.

Procedures were performed as ambulatory surgery.

The primary outcome was efficiency of the endometrial destruction on bleeding symptoms. The secondary outcomes were the adequate position of the tubal micro-inserts, the rate of need for reoperation and patient satisfaction.

The patients were scheduled 3 months after the procedure for an imaging technique to assess the position of the tubal micro-inserts. This was done by either pelvic X-ray as proposed in Europe (reference examination in France), 3D pelvic ultrasound (3D pelvic US) or hysterosalpingography (HSG) as proposed in North America, or any combination of these three methods.

Imaging results have been interpreted by the radiologist in case of pelvic X-ray and HSG and by the ultrasonographist in case of 3D pelvic US.

The micro-inserts position was considered as adequate in the following cases:

- HSG showed bilateral tubal occlusion;
- 3D pelvic US showed a non-distal position of the implant (as described by Legendre et al. [22];
- pelvic X-ray showed adequate position for the implant with no other imaging concluding otherwise.

The tubal sterilization was considered as a failure in the following cases:

- HSG showed tubal patency;
- device expulsion; and
- pregnancy.

The micro-inserts position was considered uncertain in the following cases:

- uncertain pelvic X-ray position with no further 3D pelvic US or HSG;
- distal position on 3D pelvic US with no HSG control; and
- unilateral implant insertion (opposite ostium insertion failure) with no hysterosalpingographic control.

The phone questionnaire evaluated post-operatory complications (within 30 days of surgery), results on haemorrhagic symptoms (subjective assessment by patient), patient's satisfaction (0–10 satisfaction scale and recommendation to a friend), the need for a hormonal treatment, and the need for a new surgery related to bleeding symptoms. Treatment failure for the haemorrhagic symptoms was defined as persistent AUB (Higham score >150), the need for a hormonal treatment to deal with the AUB or the need for a delayed surgery for AUB.

Statistical analysis was performed with SAS© version 9.2. (SAS Institute Inc., Cary, NC). For qualitative variables, we used the Chi square test when the numbers were sufficient and the Fisher exact test when the numbers were less than five. For quantitative

Table 1
Patients characteristics.

	N = 131 All patients	*N* = 106 Patients followed up for Essure® position	*N* = 93 Patients followed up for AUB
Mean age	43 (min = 35, max = 50, SD = 0.6)	42.9 (min = 36, max = 50, SD = 0.6)	43.3 (min= 36, max = 50, SD = 0.7)
Number of pregnancies	2.9 (min = 0, max = 9, SD = 2.3)	2.8 (min = 0, max = 7, SD = 2.2)	2.6 (min = 0, max = 7, SD = 2.1)
Parity	2.3 (min = 0, max = 7, SD = 1.8)	2.3 (min = 0, max = 7, SD = 1.6)	2.2 (min = 0 max = 5, SD = 1.3)
Unilateral salpingectomies	2	–	2
Total number of ostiae	260		184