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Hysteroscopic tubal sterilization with Essure intratubal devices: A case-control prospective with inert local anesthesia or without anesthesia

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Abstract

Objective: The contraceptive efficacy of hysteroscopic sterilization is well documented. The objective of this study was to compare procedure success, patient tolerance, and procedure time of Essure micro-insert hysteroscopic sterilization with or without anesthesia.
Study design: Between February 2002 and May 2005, one operator performed 140 sterilization procedures in this prospective study: the first 70 were performed using local anesthesia and the following 70 began without administration of anesthesia. Analysis was based on intention-to-treat.
Results: The groups were comparable in their demographic characteristics. Successful bilateral micro-insert placement in the first 70 cases, utilizing paracervical block, was 82.8% and did not differ significantly from the next 70 cases, without anesthesia (91.4%). A similar number of patients in each group received additional anesthesia. Report of procedure pain did not differ significantly between the groups: 87.1% reported moderate or less pain with the paracervical block, compared with 91.4% in the group without anesthesia. Duration of surgery was significantly shorter without anesthesia: 11.2 ± 6.3 min vs. 25.0 ± 8.0 min ($p < 0.001$).
Conclusions: Administration of anesthesia does not appear to affect the procedure completion success rate or patient tolerance of this hysteroscopic sterilization procedure.

Keywords: Essure; Female sterilization; Hysteroscopy; Intratubal device; Permanent contraception

1. Introduction

Sterilization is the deliberate and permanent elimination of fecundity without damage to other sexual or endocrine functions. Women in industrialized countries ask for sterilization mainly as a matter of convenience or to improve their quality of life. The technique should be therefore sure, simple and noninvasive. Laparoscopic tubal ligation remains the reference technique today. Recent years, however, have seen the use of the Essure® system (Conceptus, Inc., Mountain View, USA), a hysteroscopic technique for female sterilization [1].

This method involves the placement of a micro-insert, or intratubal device (ITD), into the proximal portion of the fallopian tube. Polyethylene terephthalate (PET) fibers contained within the ITD induce progressive and complete fibrosis of the proximal portion of the tubal lumen, a stenotic process that requires approximately 3 months for total tubal occlusion. During this time the patient must continue using alternate contraception (condom, birth control pill) [2]. The Essure permanent birth control system was introduced in France in 2002 [3].

Most authors report placing these devices under general or local anesthesia, often lidocaine paracervical block. The aim of this work was to assess procedural success, patient tolerance, and procedure time between patients receiving local or no anesthesia.

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2. Materials and methods

This prospective before-and-after study took place in the Obstetric Gynecology Department of Nantes University Hospital Center between February 2002 and May 2005. The same operator placed all devices.

2.1. Inclusion criteria

The population included all patients who requested tubal sterilization, agreed to the conditions for this technique, and had no obvious contraindications. The indication for permanent sterilization was final and accepted by the patient. Patients complied with the manufacturer's initial protocol. Specific aspects of management (appointments, pre-medication, anesthesia) followed the department's usual practices. All the patients received explications about the sterilization systems (laparoscopy vs. hysteroscopy) and the others ways of contraception. If they agreed with the procedure, they had to sign a written consent. A 4-month delay of reflection had to be respected. No pregnancy tests pre-procedures were performed but all the cases were done in the first part of the cycle. All the patients received a pre-medication (Bi-Profenid 150 mg) 2 h before the procedure's start.

2.2. Exclusion criteria

Exclusion criteria were medical and physical contra-indications to the sterilization procedure or the decision not to use the Essure system.

2.3. Specific surgical technique

All Essure ITDs were placed by the same operator using a WOLF® (Knittlingen, Germany) hysteroscope with an angled three-way 5-mm catheter. Progressive distention of the uterine cavity was obtained with a bag of saline, compressed by a cuff to a mean pressure of 50 mm Hg. The first part of the procedure was to examine the uterus'cavity and check if the two ostia are accessible to the hysteroscope. Then, we usually begin to perform the easiest Essure ITDs, independently on the right or left side. All procedures for the first 70 patients took place after local anesthesia—lidocaine 1% paracevical bloc (5 mL by quadrant). They also received oral pre-medication (Bi-Profenid 150 mg) 2 h before the intervention. Hysteroscopic sterilization for the next 70 women was planned without any analgesic procedures except pre-medication. All procedures were performed in an outpatient surgery department: patients left immediately after their procedure.

ITD location 3 months post-insertion was verified by a plain pelvic radiograph, which can easily be replaced by ultrasound examination. In the United States, an FDA-mandated hysterosalpingography is performed at the 3-month follow-up appointment.

2.4. Assessment criteria

The following information was recorded for each patient: level of anesthesia, ITD placement data, perceived pain, and duration of surgery. The first 70 patients rated pain as none, slight, moderate, or strong. The following 70 rated their pain on a visual analog scale (VAS). To compare pain between the groups, VAS responses were operationalized as follows: none (0–1), slight (2–3), moderate (4–6), or strong (7–10). We noted the time of the following events: anesthesia injection, hysteroscope introduction, placement of the first and of the second micro-insert, and withdrawal of the hysteroscope. For the group with anesthesia, duration of surgery lasted from the administration of anesthesia to the withdrawal of the hysteroscope. For the group without anesthesia, it was calculated from the introduction to the withdrawal of the hysteroscope. To assess the feasibility of the procedure, we recorded every contraindication and every cause of every failure.

Statistical analyses were performed with R software Version 2.3.0 for Mac OS X (R Development Core Team, 2006). Differences were considered significant if the p value was less than 0.05. We used Student's t-tests to compare means (matched means if possible) for quantitative variables, and Fisher's exact test to compare proportions for the qualitative variables. For the ordinal variables, we used Wilcoxon's test.

3. Results

This study included 140 patients: the first 70 underwent the sterilization technique with anesthesia and the following 70 without planned anesthesia. Table 1 summarizes the characteristics of each group. There were no significant demographic differences between the groups.

Table 1
Patient demographic characteristics

	With local anesthesia ($n = 70$)	Without anesthesia ($n = 70$)	p value
Age (years)	41.1 (±3.2)	40.1 (±3.3)	n.s.
Parity (child)	2.6 (±0.8)	2.7(±1.0)	n.s.
Number of pregnancies	3.4 (±1.7)	3.1 (±1.3)	n.s.
Height (cm)	162 (±5.3)	163 (±6.3)	n.s.
Weight (kg)	66.1 (±11.8)	64.4 (±13.2)	n.s.

n.s.: Not significant.