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Review

Essure® permanent birth control effectiveness: a seven-year survey

S. Jost [a,*], C. Huchon [b], G. Legendre [c], A. Letohic [a], H. Fernandez [c], P. Panel [a]

[a] Department of Obstetrics and Gynecology, Centre Hospitalier de Versailles, 177 rue de Versailles, 78150 Le Chesnay, France
[b] Department of Obstetrics and Gynecology, Centre Hospitalier Inter-Communal de Poissy, Poissy, France
[c] Department of Obstetrics and Gynecology, Hôpital Bicêtre, Assistance Publique Hôpitaux de Paris (APHP), Le Kremlin-Bicêtre, France

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ABSTRACT

Essure appears to be a safe reliable contraception. The aim of this study is to report French pregnancies after Essure hysteroscopic sterilization.

This study is a retrospective national survey between January 2003 and September 2010. Data were collected in two ways:

- a mail-in questionnaire addressed to all surgeons performing Essure procedures in France
- pregnancies reported directly to the manufacturer.

The surgeons contacted in our study were responsible for 63.4% of all Essure procedures in France. Fifty-eight cases of unintended pregnancies after Essure sterilization in France were reported during the study period. Factors associated to unintended pregnancies were patient' non compliance with follow-up (22 pregnancies, 38% of cases) and misinterpretation at the 3rd-month confirmation test (19 cases, 33%). Other causes were physician's deviation from protocol (10 cases) and undetected pre-procedure pregnancy (3 cases). Three pregnancies happened before the 3-months confirmation test. Based on the number of kits sold during the period, the estimated pregnancy rate was between 1.07 and 1.09/1000 procedure.

The pregnancy risk after hysteroscopic sterilization may be reduced by improving patient education and physician knowledge concerning the 3rd month confirmation test.

Contents

1. Introduction

Tubal ligation is a birth-control method used throughout the world by 17% of women of child-bearing age [1]. Seven hundred thousand sterilizations are conducted every year in the United States, and between 30,000 and 75,000 in France [2–4]. More than 450,000 Essure procedures have been done worldwide and more than 70,000 in France (Conceptus SAS data December 2010).

Essure hysteroscopic sterilization is non-surgical and non-hormonal and provides physicians and patients a favorable alternative to tubal ligation. The technique of tubal sterilization by the Essure procedure is increasingly chosen over traditional laparoscopic tubal sterilization. This method has indeed many advantages: no incision, high successful bilateral placement rates [4], non-mandatory use of anesthesia [5], in office procedures, a low level of pain, and low-risk surgery [6]. Recently, the French Authority for Health (HAS) recommended that the Essure procedure should be offered as a first line alternative for women

* Corresponding author at: Centre Hospitalier de Versailles, Le Chesnay, 177 rue de Versailles, 78157 Le Chesnay cedex, France. Tel.: +33 6 84 94 76 36; fax: +33 1 39 63 97 32.
E-mail address: jost.stephanie@hotmail.fr (S. Jost).

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over 40 years who request permanent birth control [7,8]. A recent study on Essure procedures in France found a placement success rate of 97%, with 93% of patients satisfied or very satisfied [9].

Despite the large number of international publications on Essure, few are aimed at measuring the rate of pregnancy following Essure sterilization [10–14]. According to Conceptus SAS, France is the world's second-largest consumer of Essure devices. We therefore decided to conduct a national survey of pregnancies following Essure sterilization in France.

2. Materials and methods

In this retrospective review we assessed pregnancies that occurred between January 1, 2003 and September 30, 2010. The data were collected in two different ways: (1) data directly reported by practitioners or patients to the Conceptus™ Company and (2) by means of a mail-in questionnaire addressed by name to all surgeons performing Essure procedures. According to HAS all surgeons are required to complete at least five supervised cases before performing Essure procedures. Conceptus SAS France organized surgeon training sessions prior to the sale of the micro-inserts to each institution, to ensure procedure accuracy. All surgeons were asked to report known pregnancies that occurred after an Essure procedure. If they were aware of such cases, they were asked to specify the time lapsed between the procedure and the pregnancy, the type of confirmation test used (3 months post-procedure), the supposed cause for the sterilization failure and the pregnancy outcome. Practitioners were given the possibility of replying either by post or by email. The data were cross-checked in order to avoid double-counting.

The national number of procedures was evaluated based on the number of kits sold between January 1, 2003 and December 31, 2009.

The Essure procedure includes a 3-month confirmation test, which in France takes the form of a pelvic X-ray. If the micro-insert placement appears to be unsatisfactory a second confirmation test by a hysterosalpingography (HSG) is recommended [15]. Until bilateral tubal occlusion and correct micro-insert placement are positively verified, the patient has to continue the use of her regular contraception method. X-ray criteria for proper positioning of the inserts are presented in Table 1.

Pregnancies following an Essure procedure were classified in five categories: misinterpretation of the 3-month X-ray, patient non-compliance (no follow-up or failure to continue using contraception until the confirmation test), luteal phase pregnancy, deviation from protocol, and other.

Table 1
X-ray's interpretation criteria.

Criteria of proper placement of the micro-inserts
– 2 inserts (if two inserts posed)
– 2 symmetrical inserts
– distance during the implants smaller or equal to 4 cm (length of the implant)
– 4 radio-opaque markers in line
AND data from the report
– uterine cavity
– number of expanded outer coils on each side (between 3 and 8)
– fallopian tubal ostia in view during the procedure
– difficulties to insert implants
– others difficulties
– length of the procedure (must be under 15 min)
– pain during procedure (if no anesthesia)

If one of the criteria is not respected, indication to proceed to hysterosalpingography.

3. Results

Thirty-four pregnancies were spontaneously reported to Conceptus SAS France. The mail-in questionnaire was sent to 1268 surgeons performing the Essure procedure, and 287 surgeons (22.5%) from 206 institutions replied either by post or by email. Most of them also reported data of procedures conducted by their colleagues working in the same institution. The surgeons contacted in our study were responsible for 63.4% of all Essure procedures in France. During the study period, an estimated 53,003 kits were sold by Conceptus SAS France, of which 33,611 (63.4%) were to institutions that answered the questionnaire.

After cross-checking, 58 pregnancies were reported in France between January 1, 2003 and September 30, 2010. Participating institutions reported 36 pregnancies, demonstrating a pregnancy rate of 1.07 pregnancies per 1000 Essure procedures. Considering all pregnancies (58), the total pregnancy rate in France was 1.09/1000.

The causes of pregnancies are detailed in Table 2. The primary cause identified was patient non-compliance with follow-up (22 patients): no confirmation test at 3 months (16 patients), no contraceptive use during the 3-month post-procedure period (5 patients) and one patient who did not undergo the HSG requested by the physician after the X-ray confirmation test.

The second cause of unintended pregnancies was misinterpretation of the 3-month confirmation test (18 pregnancies). Retrospective interpretation of the pelvic radiographs was possible in 10 cases: in 9 cases only one implant was found to be well-positioned, while the tenth showed that the two implants were implanted on the same side.

The third cause of unintended pregnancy was deviation from protocol (10 pregnancies). In four cases, the 3-month confirmation test was performed by ultrasound only. In four cases, HSG was not performed despite being required in cases of past salpingectomy, doubtful radiography, or difficulties during Essure procedure. In two cases, there was a lack of information about the necessity of for 3 months' contraception and a confirmation test.

Three cases of luteal pregnancy were reported.

No obvious cause was identified in the remaining five cases. One case was interpreted as "real failure" of Essure implants by the performing surgeon. Pregnancy occurred 18 months after the Essure procedure. The confirmation test (X-ray) was considered as correct. After a miscarriage, a bilateral salpingectomy revealed two well-positioned implants in the tubes (data from the performing surgeon). Two pregnancies were reported after a unilateral procedure in patients with a past history of a contralateral salpingectomy for ectopic pregnancy: in both cases, an HSG was performed before surgery proving the unilateral occlusion, but no operative reports of the performed salpingectomies were available. In the two last cases, no obvious cause was found but the confirmation test was not reviewed.

One case of ectopic pregnancy is reported (X-ray misinterpretation).

Table 2
Causes of reported pregnancies.

Reason pregnancy occurred	No.	% of total
Patient non-compliance	22	38
Misread X-ray	18	31
Deviation from protocol	10	17
Others	5	9
Pregnant at time of placement	3	5
Total	58	