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Original Article

Incidence and Risk Factors for Chronic Pelvic Pain After Hysteroscopic Sterilization

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ABSTRACT **Study Objective:** To investigate the incidence of and preoperative risk factors for developing pelvic pain after hysteroscopic sterilization using the Essure microinserts.

Design: Retrospective cohort study (Canadian Task Force classification II-2).

Setting: University medical center.

Patients: A total of 458 patients who underwent hysteroscopic sterilization using Essure between January 1, 2005, and June 30, 2012.

Intervention: Hysteroscopic sterilization using Essure.

Measurements and Main Results: The incidence of acute pelvic pain after hysteroscopic sterilization was 8.1%, and of persistent pain at 3 months after the procedure was 4.2%. The range of presence of pain was 1 to 469 days (mean, 56 days). Of patients who developed chronic pelvic pain after the procedure, 75% reported it within 130 days of the procedure. Patients with previous diagnoses of any chronic pain (chronic pelvic pain, chronic low back pain, chronic headache, and fibromyalgia) were more likely to report both acute pain (odds ratio, 6.81; 95% confidence interval, 2.95–15.73) and chronic pain (odds ratio, 6.15; 95% confidence interval, 2.10–18.10) after hysteroscopic sterilization.

Conclusions: Pelvic pain may develop after hysteroscopic sterilization. Patients with a diagnosis of preexisting chronic pain may be at increased risk of developing pelvic pain after the procedure. Fifty percent of new pelvic pain after Essure placement will resolve within 3 months. Journal of Minimally Invasive Gynecology (2015) 22, 390–394 © 2015 AAGL. All rights reserved.

Keywords: Chronic pelvic pain; Essure; Hysteroscopic sterilization

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Since approval by the US Food and Drug Administration in 2002, hysteroscopic sterilization using the Essure microinsert (Bayer Healthcare Pharmaceuticals, Whippany, NJ) has become a popular, safe, and reliable choice for women who desire a permanent form of contraception. It has gained favor in part because it can be completed without incisions, in the operating room or office setting. The rate of successful placement on initial attempt ranges from 92% to 96% [1,2]. When successfully placed, the pregnancy rate is approximately 0.2% [3]. Most women who undergo Essure placement are satisfied with their choice and report no long-term complications [4]. However, there have been case reports of chronic pelvic pain after Essure placement.

To date, there are limited long-term data regarding the incidence of new-onset pelvic pain after Essure placement. There are no data about preoperative risk factors for development of chronic pelvic pain after this procedure. Currently available information on Essure-related complications is limited to case reports, post-procedure questionnaires, premarket device development information, and patient or

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provider-initiated reporting. The MAUDE (Manufacturer and User Facility Device Experience) database contains voluntary reports of device complications by consumers and providers. Using the MAUDE database between January 2004 and January 2009, 1 report found 20 cases of pelvic pain after Essure placement [3]. The causes cited for pain included malposition of the device, cornual perforation, multiple microinserts placed in a single fallopian tube, and complications with concomitant ablation [3]. Additional case reports noted 3 patients with pain severe enough to require implant removal [5,6].

Given the widespread use of Essure as a method of contraception and the current lack of information about post-Essure complications, we chose to investigate this further in a large university-based practice. The objective of our study was to determine the incidence of post-Essure pelvic pain and any related risk factors.

Material and Methods

All patients who underwent a hysteroscopic sterilization procedure at Vanderbilt University Medical Center between January 1, 2005, and June 30, 2012, were identified using an institutional electronic medical record database (REDCap). A total of 509 patients were identified for retrospective review of medical records, and 458 patients met criteria for inclusion in the study. Patients were included if they had undergone bilateral hysteroscopic sterilization using Essure microinserts in the operating room or office setting. Patients were excluded if they and undergone hysteroscopic sterilization using a device other than Essure, placement of 1 or both Essure coils was unsuccessful, or the procedure was converted to laparoscopic sterilization.

Data were collected via review of medical records and included demographic data (age, race/ethnicity, and body mass index), medical history (metal allergy, multiple allergies, parity, number of vaginal deliveries, previous sexually transmitted infection, previous pelvic surgery, and previous chronic pain including chronic pelvic pain, chronic low back pain, chronic headache, and fibromyalgia), procedure characteristics (place where surgery was performed, experience of surgeon, and type of anesthesia), and follow-up information (confirmation of bilateral tubal occlusion at hysterosalpingography [HSG], report of pelvic pain, and timing of pelvic pain).

Acute pain after hysteroscopic sterilization was defined as new pelvic pain beginning after the procedure and lasting up to 3 months postoperatively. Chronic pain was defined as pain lasting >3 months after the procedure. Patient and operative characteristics were compared between those without pain vs those with acute pain, and those without pain vs those with chronic pain.

Statistical analysis was performed using the χ^2, Fisher exact, and independent *t*-tests, where appropriate. Multivariate analysis was completed to adjust for confounders. Variables with $p < .05$ were considered statistically significant. All statistical analyses were performed using commercially available software (STATA version 11; StatCorp, College Station, TX).

The Vanderbilt University Medical Center Institutional Review Board approved the study.

Results

A total of 458 patients met inclusion criteria for the present study. Demographic data, medical history, and follow-up via HSG are given in Table 1. Only 67.0% of patients underwent follow-up HSG, and in 93.5% of those patients bilateral occlusion of the fallopian tubes was confirmed. Most procedures were completed by a supervised resident in the operating room with the patient under general anesthesia (Fig. 1).

The incidence of acute pelvic pain after hysteroscopic sterilization was 8.1%, and of persistent pain at ≥3 months after hysteroscopic sterilization was 4.2%. The mean time from procedure to development of pain, in all patients with new pelvic pain, was 56 days (range, 1–469 days). Most patients with acute pain (75%) reported it within 32 days of the procedure. Of those with chronic pelvic pain after hysteroscopic sterilization, 75% reported it within 130 days of the procedure (Fig. 2).

Patients with a previous diagnosis of chronic pain (chronic pelvic pain, chronic low back pain, chronic headache, or fibromyalgia) were more likely to report both acute pain (odds ratio [OR], 6.81; 95% confidence interval [CI], 2.95–15.73) and chronic pain (OR, 6.15; 95% CI, 2.09–18.05) after hysteroscopic sterilization (Table 2). A previous

Table 1

Demographic data, medical history, and follow-up[a]

Variable	Value
Age, yr	32.4/32 (6.5)
Race/ethnicity	
White	45.0
Black	43.7
Hispanic	2.4
Asian	3.1
Other/unknown	5.0
Body mass index	30.5/32.3 (8.9)
Parity	2.9/3 (1.3)
No. of vaginal deliveries	2.1/2 (0.4)
Previous chronic pain condition	8.7
Previous pelvic surgery	28.0
Previous sexually transmitted infection	15.9
Metal allergy	0.9
Multiple allergies	2.2
Follow-up HSG	67.0
Confirmed bilateral occlusion at HSG	93.5

HSG = hysterosalpingography.
[a] Data are given as mean/median (SD) or as percent.