PERSPECTIVE

# Safety of Hysteroscopic Sterilization


Dr. Loffer

In recent months complications related to Essure hysteroscopic sterilization have gained media attention and online exposure via women's social networks. Al-Safi et al examined the Manufacturer and User Facility Device Experience (MAUDE) database for such events during the ten-year period 2002-2012 and reported their findings in the November/December 2013 issue of JMIG.[1]

There were 457 reported adverse events, including events that occurred during the procedure, symptoms the patient experienced afterward, and findings diagnosed later. The incidence and types of these events are summarized in Table 1.

**Table 1. Type and frequency of adverse events related to Essure in the MAUDE database**

| Description | Frequency (n. 457) |
|---|---|
| Pain | 47.5% |
| Delivery catheter malfunction | 26.4 |
| Perforation | 19.7 |
| Pregnancy | 13.3 |
| Abnormal bleeding | 9.6 |
| Micro-insert malposition | 7.2 |
| Allergic reaction | 4.4 |
| Other | 5.3 |

The MAUDE data are not intended to be used to establish rates of adverse events, but they are useful for clinicians because they cover infrequent complications that may not be published and/or those that may not come to light until substantial clinical experience with a device has accrued.

Standard follow-up after an Essure procedure is hysterosalpingography (HSG) at three months to document tubal occlusion. This test and/or patient symptoms prompted further evaluation and management for adverse events as summarized in Table 2. Notably, 30.6% of cases warranted additional imaging studies and 59.1% of cases required an additional surgical procedure, including 44 hysterectomies.

**Table 2. Evaluation and management of complications**

| Description | Frequency (%) |
|---|---|
| Imaging studies (n. 140)<br>-- ultrasound.....9.8%<br>-- CAT scan.....4.8<br>-- x-ray.....4.8<br>-- MRI.....0.7 | 30.6 |
| Surgical procedures (n. 270)<br>-- Laparoscopy.....28.6%<br>-- Hysteroscopy...10.3<br>-- Hysterectomy.... 9.6<br>-- Laparotemy..... 2.0<br>-- D&C..... 1.1<br>-- Unspecified..... 7.4 | 59.1 |

## Symptoms, conditions and lessons learned

Pain was the symptom most often reported (47.5%). Although some postoperative pain is normal, pain that persists after the procedure should alert the physician to the possibility of complications such as improper placement (7.0%) or perforation (24.9%). Proper placement of the microinserts may be affected by such factors as abnormalities of the uterine cavity or fallopian tubes, tubal spasm and fluid collection under the endometrium. Al-Safi et al note that even in the hands of experienced surgeons, misplacement, perforation and expulsion of Essure microinserts can occur, and therefore, HSG screening may be appropriate earlier than three months for patients who present placement challenges.

Twenty-nine of the 61 postoperative pregnancies were ectopic pregnancies, a fairly high occurrence that should alert physicians to consider this possibility in any woman who becomes pregnant following the Essure procedure. In 23 of the reported cases of pregnancy, tubal occlusion was documented by HSG. This suggests that the results of the test were misinterpreted and highlights the importance of physician experience in interpreting the HSG.

Pain may also signal an allergic reaction, including hypersensitivity to the nickel-titanium alloy used in the Essure micro-insert, although itching, nausea, rash and hives may be more common symptoms. Of the 20 reported cases of allergic reactions in the MAUDE database, only 4 had been confirmed by allergy testing. Patient allergies may be revealed during the preoperative screening process, and nickel hypersensitivity testing may be indicated for some patients.

There were 16 reports of concomitant use of Essure with endometrial ablation techniques. The most frequent symptom was pain, which in two cases was severe enough to warrant hysterectomy. The instructions for use of the Essure procedure state that it should not be performed concomitantly with any endometrial ablation technique.

This review of the MAUDE database helps not only to alert physicians of possible complications related to Essure, but also to place these events in perspective.

### References

1. Al-Safi ZA*, Shavell VI, Hobson DTG, Berman JM, Diamond MP. Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database. *J Minim Invasive Gynecol*. 2013; 20, 825-829.

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AMA NEWS

# AAGL Appoints Representative to the AMA's House of Delegates

The AAGL Board of Trustees recently appointed Michael Frumovitz, M.D., MPH as its representative to the American Medical Association's House of Delegates. Dr. Frumovitz is a gynecologic oncologist practicing at MD Anderson in Houston, Texas. He has been a member of the AAGL since 2006, and he was on the Executive Board of the AAGL's Oncology Special Interest Group from 2011 to 2013.

The AMA House of Delegates meets twice a year and is an advocate for medicine in the United States. While the AMA has no direct value to our many international members, it has a clear indirect value since it is a platform for the AAGL to present issues that affect our efforts to promote minimally invasive surgery.