AAGL Advisory Statement: Essure Hysteroscopic Sterilization

AAGL Advancing Minimally Invasive Gynecology Worldwide

The American Association of Gynecologic Laparoscopists (AAGL) publishes advisory statements on the state of minimally invasive gynecology to improve the overall quality of women’s gynecologic care. The AAGL follows a process to ensure that any conflicts of interest are disclosed and appropriately addressed and that relationships with manufacturers and other third parties do not influence the development process.

The Board of Directors of the AAGL formed a task force of leaders in the field of minimally invasive gynecology to provide the members of the society a document outlining the current status of hysteroscopic sterilization with the Essure device (Bayer, Whippany, NJ). The advisory statement has been developed by a group of individuals with experience and interest in the assessment of minimally invasive gynecologic surgery. The goal of this document is to present an unbiased view, informed by the available literature, of the critical aspects of the use of hysteroscopic sterilization.

Background

Permanent sterilization is 1 of the most common forms of birth control chosen by US women, accounting for almost one fourth of all contraceptive methods [1]. Before the introduction of hysteroscopic sterilization in 2001, tubal sterilization required surgical incisions. The rate of complications with laparoscopic sterilization is low at 1.6% [2]; however, compared with the hysteroscopic approach, it requires additional time off from work, a need for pain control, and the risks of general anesthesia. Hysteroscopic sterilization offers women many benefits that traditional sterilization does not, especially for women at increased surgical risk such as those with significant pelvic adhesions. The failure rate with hysteroscopic sterilization is 2.5% compared with 0.9% to 4% reported after laparoscopic sterilization [3–5]. Essure is currently the only product with Food and Drug Administration approval for hysteroscopic sterilization.

Current Concerns

Although the failure rates are similar between techniques, it is important to place hysteroscopic sterilization failures in the proper context. Hysteroscopic sterilization requires a unique technical skill set for ideal placement, a backup method of birth control until the device becomes effective through tubal occlusion, and reliance on the woman presenting for a follow-up hysterosalpingogram to confirm proper placement and tubal occlusion at 3 to 6 months. The failure rates with hysteroscopic sterilization are often given after ideal placement and follow-up. The rates may be higher with less experienced surgeons, an absence of backup birth control, and the loss of women to follow-up [6].

Recent published data, reports to the Manufacturer and User Facility Device Experience (MAUDE) database, and media reports have highlighted patient safety concerns with the Essure device and prompted a postmarket review by the Food and Drug Administration [7]. Those concerns include an increased risk of chronic pelvic pain, heavy menstrual bleeding, allergic reaction, fatigue, and weight gain.

It is estimated that approximately 750,000 women worldwide have undergone hysteroscopic sterilization based on the reported number of products sold [8]. The majority of data regarding problems after hysteroscopic sterilization are obtained through subjective voluntary patient and provider reports. A review of the MAUDE database in April 2016 reports 8046 complaints (1.07%) that might be related to the use of Essure as permanent contraception: 3353 reports of abdominal pain, 1408 heavy/irregular menses, 1383 headache, 966 fatigue, and 936 weight gain. Prospective and retrospective studies confirm findings from the MAUDE database and suggest that pelvic pain is the most commonly reported complaint after hysteroscopic sterilization. The risk of new-onset pelvic pain after the procedure ranges between 3.0% and 6.1% [9]. Four deaths from the MAUDE database...
are reported as Essure related: 1 infection related (group A streptococcus), 1 device perforation during placement, 1 air embolus during surgery for removal, and 1 from suicide.

In addressing possible removal of the device, the physician must counsel the woman adequately. An evaluation for other causes of pelvic pain and menstrual irregularities such as uterine leiomyomas, hormonal disturbances, and endometriosis, among other conditions, must be undertaken before proceeding with surgical removal of the Essure device. Physicians must also discuss the implications and different routes of removal with the woman, including hysteroscopic, laparoscopic, and open techniques. If the physician considers that he or she is unable to offer appropriate counseling or offer surgical removal options, he or she should refer women to clinicians capable of providing those services. The optimal route for device removal will depend on the location of the coils and the physician’s surgical experience. The risks and benefits of the procedure must be fully disclosed, including the possibility of retained coils. A preliminary study suggests surgical removal via salpingectomy and/or hysterectomy resulted in improvement in pelvic pain, sexual activities, daily activities, and quality of life [10].

Conclusion

Women must be fully informed of the risks, benefits, indications, and alternatives to hysteroscopic sterilization and be able to maintain their right to choose. With appropriate selection and a thorough preoperative workup, hysteroscopic sterilization offers women a less invasive alternative with clear advantages over traditional sterilization techniques including no incision or abdominal entry, no requirement for general anesthesia, and the ability to be performed in an office-based setting [11]. After hysteroscopic sterilization, women must be monitored closely and evaluated for possible complications related to the procedure. Removal of the coils is only indicated if other causes of pelvic pain and menstrual irregularities have been excluded. Women must be counseled on the risks of surgical removal of the Essure device, including the possibility of continued pelvic pain and other symptoms. The AAGL supports further research in the area of hysteroscopic sterilization and the continuing education of physicians as it relates to optimal patient selection, proper surgical placement, and the monitoring of possible complications and removal techniques when necessary.

Acknowledgments

Advisory statements are intended to be educational devices that provide information that may assist health care providers in caring for patients. This advisory statement is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Advisory statements are not intended to supplant the judgment of the health care provider with respect to particular patients or special clinical situations. Clinical decisions in any particular case involve a complex analysis of a patient’s condition and available courses of action, with the ultimate determination to be made by the health care provider in light of each individual patient’s circumstances. Therefore, clinical considerations may lead a health care provider to appropriately take a course of action that varies from this document.

The AAGL received no funding from any manufacturer to support the development of this advisory statement. The AAGL requested a review by the Practice Committee, and this advisory is approved by the AAGL Board of Directors for submission to the journal of the AAGL, The Journal of Minimally Invasive Gynecology.

There is currently only 1 manufacturer of the Essure hysteroscopic sterilization device, Bayer HealthCare ( Whippany, NJ). The 4 members of the Taskforce, the 13 members of the 2016 AAGL Board of Directors and the 6 members of the Practice Committee who reviewed and/or approved this advisory statement have completed disclosure statements, and 2 are on the Speaker’s Bureau for Bayer HealthCare.

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References