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Disclosures

Dr. Levie reports that he is a medical advisory board member and consultant for Conceptus, Inc. **Dr. Ling** reports that he has no financial relationships to disclose. **Dr. Brill** reports that he is a consultant for Conceptus, Inc and Ethicon, Inc. **Dr. Chudnoff** reports that he has no financial relationships to disclose. **Dr. Rackow** reports that she has no financial relationships to disclose. **Dr. Mattson** reports that she has no financial relationships to disclose. **Dr. Bartz** reports that she has no financial relationships to disclose.

BEST PRACTICES FOR FEMALE STERILIZATION IN 2012 AND BEYOND

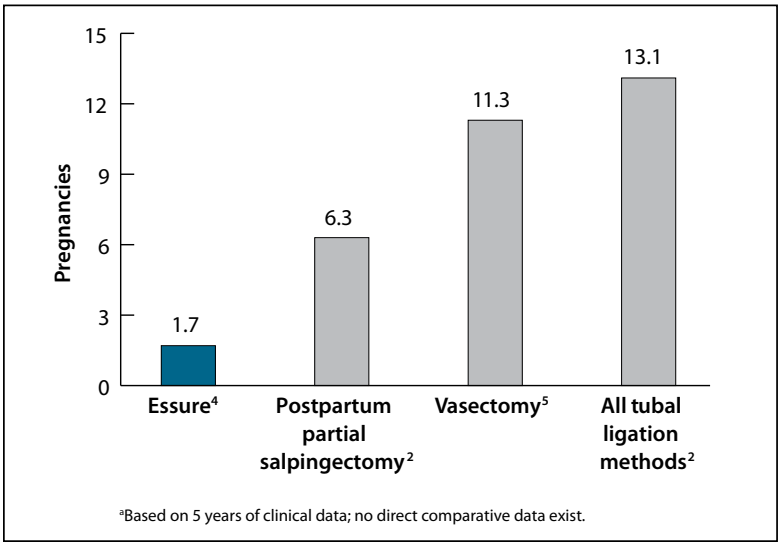
HISTORICAL PERSPECTIVE

Female sterilization remains the leading contraceptive choice for women in the United States who do not plan future childbearing, with over 40% choosing this option.[1] While different techniques for obtaining tubal occlusion have been developed over the years, including using monopolar or bipolar electrosurgery, rings, or clips, these procedures all require entry into the peritoneal cavity using a transabdominal approach. Data from the US Collaborative Review of Sterilization, also known as the CREST study have examined both the failure and complication rates related to various sterilization techniques. Surprisingly, the cumulative 5-year failure rate for all techniques was much higher than previously reported (1.31%), and with the most popular technique, using bipolar current, the failure rate was 1.65%. These rates were found to increase over time, with the 10-year failure rate for laparoscopic bipolar tubal sterilization approaching 2.5%.[2] A subgroup of patients from the CREST study,

To view a video introduction to this supplement on hysteroscopic sterilization by noted experts, please choose from one of the following options:

- scan the QR code (left)
- text "Essure" to 25827
- visit www.obgmobile.com/essure

FIGURE Failure rates per 1000 women at 5 years[a]



[a]Based on 5 years of clinical data; no direct comparative data exist.

who had undergone interval laparoscopic tubal ligation, had an overall complication rate of 1.6%. Of note, 0.9% of those scheduled to undergo a laparoscopic approach required conversion to laparotomy. The reasons identified for conversion to laparotomy included true laparoscopic complications, difficulty with the fallopian tube, failed entry, and detection of incidental disease.[3] The **FIGURE** examines failure rates for different methods of sterilization based on clinical data.[2,4,5]

Transcervical hysteroscopic sterilization

Over the past 10 years the transcervical hysteroscopic approach to tubal occlusion has proven to be an excellent option for women seeking permanent contraception. This technique takes advantage of recent innovations, such as miniaturization of endoscopes, continuous flow systems, and advanced cardiovascular technology, to facilitate access and improve the ability to accurately catheterize the fallopian tubes. The greatest advantage of the transcervical hysteroscopic approach is that it avoids entry into the peritoneal cavity and the associated complications. These procedures can be performed without general anesthesia and often in an office setting with minimal analgesia.

Until recently there were 2 options for performing hysteroscopic sterilization: the Essure device (Conceptus, Inc) and the Adiana device (Hologic, Inc). (NOTE: In May 2012, Hologic, Inc withdrew the Adiana device from the market.) The Essure device has been approved by the US Food and Drug Administration (FDA) since November 2002; the Adiana method was approved by the FDA in July 2009. The Essure insert traverses the uterotubal junction and is anchored in place using a nitinol coil.[6] Within this outer nitinol coil is an inner coil with polyethylene fibers. There is a 3-fold explanation for the Essure device's mechanism of action: first, the expandable outer coil is responsible for acute device anchoring; second, the device provides both space filling and mechanical blockage of the tubal lumen; and finally, occlusion is achieved as a result of a tissue in-growth from the tubal mucosa into and around the insert. Complete occlusion is currently confirmed with a hysterosalpingogram (HSG) 12 weeks after the procedure. The devices are radiopaque, which make them easily identifiable. Correct placement is established based on appropriate position of the inserts as well as tubal occlusion. Data from a pivotal trial show no pregnancies being reported from that cohort for the past 5 years.[6] Product labeling calculates the effectiveness of this technique to be 99.83% at 5-year follow-up. Bilateral placement rates in large cohort studies range from 92% to 99%.[7,8] In a recent publication examining the currently-marketed purple handle 305 Essure device, the average placement rate among 76 physicians, involving 576 patients, was 97%.[9] In comparison with the 5-year CREST data, which include nonhysteroscopic approaches, Essure appears to be the most effective form of sterilization. Unlike the techniques evaluated in the CREST study, there does not appear to be any significant drop off in effectiveness for Essure going out to 10 years.

The Adiana procedure worked by causing an electrosurgical insult to the intimal portion of the proximal fallopian tube using bipolar energy. A silicone matrix was placed in the area of the thermal injury. Data from the pivotal trial for the Adiana technique in 2008 showed similar bilateral placement rates to the Essure procedure.[9,10] The Adiana labeling gave an effectiveness rate of 98.41% at 4 years.

Advantages of hysteroscopic sterilization

The major advantage of hysteroscopic sterilization is the avoidance of entry into the peritoneal cavity, which has its inherent risks and morbidity. In addition, the lack of an incision, quick recovery, and ability to be performed

in an office setting make this an excellent option for most patients. Hysteroscopy has a lower complication rate when compared to laparoscopy and even when a complication does occur it is most often not major.

The hysteroscopic approach to sterilization also yields many tangible and intangible advantages to patients, physicians, and the larger health care system. Women are afforded the benefits of an effective procedure that can be executed in an office setting, with minimal or no anesthesia. The placement rates are not affected by the site of performance (ie, office, ambulatory surgery center, or hospital), with multiple studies showing extremely high satisfaction rates for this procedure.[8,11] In fact, most cases can be performed in an office setting with just a nonsteroidal anti-inflammatory drug prior to starting. Many procedures are now performed vaginoscopically, avoiding the discomfort of placement of a speculum (see videos of the Essure procedure at www.obgmanagement.com/Essure/Essure1.html and www.obgmanagement.com/Essure/Essure2.html). Given the lack of an incision and anesthesia, as well as the rapidity with which this procedure can be executed (typically 10 minutes of hysteroscopy time), patients are able to return to normal activity almost immediately without any major loss of time from work or family life.

This procedure has been shown to be cost-effective, especially when performed in an office setting.[12,13] These savings are multifold and include the pure savings of moving a procedure out of the operating room (OR), an expensive and limited commodity that is better used for high-acuity procedures. This move also allows many women to pay just a small copay for an office visit rather than a higher sum until their deductible is met. Lastly, the physician benefits by being able to remain in the office, where several of these procedures could be performed, while seeing other patients. In the office, the physician and staff are responsible for the equipment and take pride and care to make sure that things run efficiently. Furthermore, having a hysteroscope in the office opens the possibilities of in-office diagnostic and operative hysteroscopy for abnormal uterine bleeding, polypectomy, retained intrauterine device (IUD) removal, and selective endometrial sampling, all of which are beneficial to patients.

Confirmatory hysterosalpingogram

Currently in the United States, patients are counseled to have a 3-month postoperative HSG in order to confirm location and tubal occlusion after placement of the Essure device. When patients have bilateral placement with proper positioning and bilateral occlusion demonstrated on HSG, the risk of pregnancy is negligible. In commercial use, as can be expected, there have been pregnancies.[14] As of 2010 there have been approximately 500,000 Essure kits sold with 748 pregnancies reported to the company. This number is far less than the 0.26% failure rate expected by the initial data for Essure and is very reassuring. Outside of the United States (in Europe and Australia), HSG is no longer used as the standard confirmatory test; it has been replaced with either flat plate x-ray or transvaginal ultrasound localization. A study is now ongoing within the United States to evaluate whether transvaginal ultrasound is an adequate technique to confirm device positioning.

Patient counseling and choices

Counseling patients prior to any permanent sterilization procedure is essential. Data from the CREST study show that most women express no regret after tubal sterilization; however, women aged 30 years or younger at the time of sterilization have an increased probability of expressing regret.[15] Therefore, consideration of all other reversible options must be discussed with patients prior to deciding on a permanent technique. Long-acting reversible contraception (LARC) is the most effective reversible form of contraception, as its effectiveness is not user dependent.

While LARC may be an excellent option for women who desire, or are not sure of their desire for, future fertility, data from the LARC Guideline Development Group show that female sterilization is overall more effective than all LARC methods.[16] Female sterilization was also found to be more cost-effective for patients seeking contraception that lasted longer than 6 years. Furthermore, LARC method use is associated with side effects, predominantly menstrual disturbances, which are among the major causes of discontinuation. Up to 43% of women discontinue IUD use at 4 years, with close to one-third stopping due to method-related reasons.[17]

Summary

Whereas sterilization has been available to women for more than 200 years, our oath to minimize risk and maximize outcomes and reliability should shift the paradigm from laparoscopic and laparotomic toward hysteroscopic sterilization. The benefits to society as a whole are convincing. The applicability for almost all women seeking sterilization, the high effectiveness rates, and the overall satisfaction make this approach very appealing to patients and their physicians. Hysteroscopic sterilization should be considered a best practice for physicians and their patients as we care for women in the 21st Century.

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PEARLS TO BUILD YOUR PRACTICE: INCORPORATING HYSTEROSCOPIC STERILIZATION

Hysteroscopic sterilization has been established as an effective option for patients choosing permanent contraception. The advantages to patients and health care providers have been well documented. This transcervical approach can be performed in an office setting with minimal analgesia/anesthesia, avoids any incisions, and allows patients to return to normal activity almost immediately. The advantages to the physician include the ability to offer a safe, minimally invasive procedure in the office while avoiding the inefficiencies of the operating room (OR). Currently, reimbursement to physicians for this procedure is very favorable when performed in the office. Lastly, society benefits from a procedure that is cost-effective and enables women to quickly return to work and normal function. Given these facts, it would seem that physicians would be enthusiastic supporters of this technique for their patients; however, the adoption of hysteroscopic sterilization has been slow. In fact, only 15% to 20% of gynecologists use in-office hysteroscopy, compared to 100% utilization of in-office cystoscopy by urologists.[1] The underutilization of in-office hysteroscopic sterilization may be related to several different factors, which are universal to all physicians. Below we will attempt to address some of the issues and concerns that physicians may have.

How do I learn hysteroscopic sterilization?

Teaching of basic operative hysteroscopic skills is a requirement of all obstetrics and gynecology residencies. To facilitate this, the AAGL has recently developed a course to help educate residents in this technique. For physicians already in practice an effective way to learn this procedure is to be mentored by a fellow physician who currently performs this procedure. The physician-to-physician mentoring process offers a comprehensive clinical and technical interchange between the mentor and novice. However, this is certainly not mandatory, and supervision by a nonphysician trainer for some cases is a reasonable training option.

While hysteroscopy in the OR is familiar to all practicing OB/GYNs, office hysteroscopy does require some additional skills. As the patient is awake and alert, special attention to avoiding pain-

FIGURE 1 The Essure procedure

- Radiopaque inserts are placed in the proximal portions of each fallopian tube
- Tissue ingrowth occurs through the insert
- Immediate visualization of the Essure coils documents placement
- Essure confirmation test (hysterosalpingogram) at 3 months verifies both tubal occlusion and proper device location

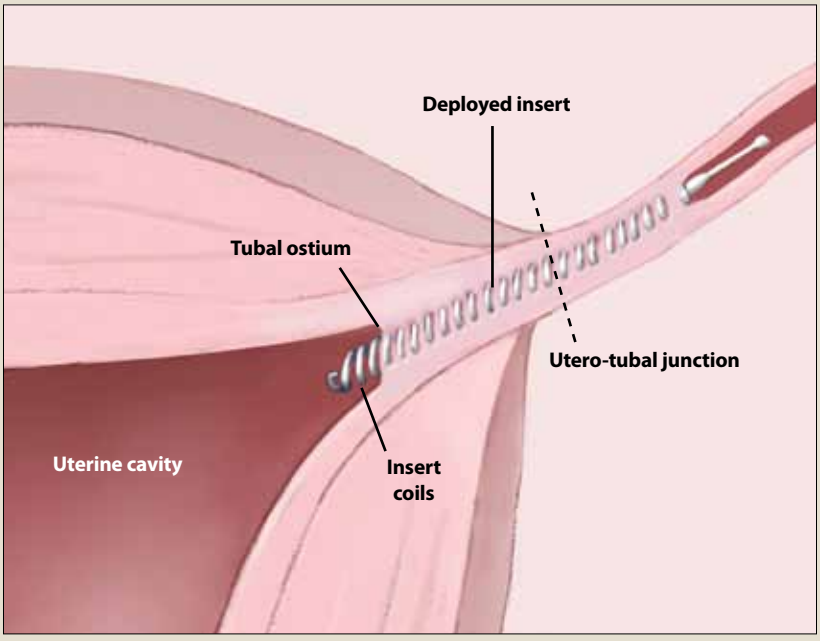

Image courtesy of Conceptus Inc.

ful stimuli is very important; non-contact hysteroscopy is a useful technique to minimize patient discomfort. VirtaMed and Conceptus have developed an excellent simulator (EssureSim™) with various hysteroscopic sterilization case scenarios to help residents in training and physicians prior to performing in vivo cases. **FIGURE 1** details a brief visualization of the Essure procedure.

How many procedures will it take me to become proficient?

Several studies have shown that there is a steep learning curve for performing hysteroscopic sterilization. In the recently published ESS305 postapproval trial, providers were divided into novice and experienced users.[2] Novice users had never performed hysteroscopic sterilization and had only performed 3 to 5 proctored cases. Both groups had high bilateral placement rates (novice users, 96.1%; experienced users, 98%; $P = .4$), and experienced physicians were able to complete the procedure slightly faster than novice users (8 minutes vs 11 minutes). What is reassuring is that the bilateral placement rates were excellent even in novice users.

Which patients are good candidates?

All women seeking permanent contraception can be considered candidates for Essure. Women with unexplained vaginal bleeding or an active infection should be evaluated and treated prior to proceeding. Patients immediately postpartum should wait for uterine involution to occur (6 weeks). While patients with nickel hypersensitivity were initially excluded from having the Essure inserts placed, this contraindication has been removed from the product labeling. Data from Zurawin et al[3] show that there is a minimal level of nickel leached into the system after placement of Essure inserts. Moreover, similar stents used in cardiovascular procedures do not have nickel hypersensitivity as a contraindication. Although women with comorbid medical conditions may be excellent candidates for this procedure, since it does not require the use of general anesthesia in an OR setting, they must be healthy enough for an in-office procedure. In most patients this procedure can be performed with analgesia alone or in combination with a local anesthetic.

Where should I be doing Essure?

The optimal place to perform hysteroscopic sterilization is in the office setting. Advantages of the office setting include: patient comfort and familiarity with the environment, efficient use of physicians' time, cost savings, and favorable reimbursement. Studies have confirmed that insert placement rates are not affected by the location where the procedure is performed, with similar placement rates in the OR, ambulatory surgery center, and the office.[2,4] Physicians who currently perform these procedures in the OR are often concerned

about the process of transitioning these procedures to the office; a common concern is pain management in the office setting. To gain confidence in their ability to perform these cases in the office, physicians can begin by conducting these cases in the OR, using just minimal or no sedation (ie, trying to mimic the office setting). As the physician gains confidence, the transition to the office will be much easier.

What are the problems my patients and I might encounter?

With the hysteroscopic approach there will be a small percentage of patients who will not be able to have the devices placed. Using the current data, patients should be counseled that placement rates are approximately 97%. However, the remaining 3% of patients will need to choose another method of permanent sterilization.[2] Common causes for inability to place a device include anatomic issues and primary tubal occlusion. If one is unable to place a device and the patient desires another attempt, a hysterosalpingogram (HSG) can be performed prior to the second procedure to confirm that insert placement is feasible and reasonable.

Patients who only have unilateral placement cannot rely on the device. Rarely, devices can abort into the uterine cavity; these patients can undergo removal of the aborted device and placement of a new device. Cases of perforation with the device should be handled on an individual basis. Removal of these devices has been reported in the literature using hysteroscopic and laparoscopic approaches.[5,6]

What about pain management; can I really do this in my office?

Several published studies examining the pain associated with hysteroscopic sterilization provide guidance in this area. In one study that reviewed 253 patients undergoing hysteroscopic sterilization, the average pain that patients felt on a 0 to 10 pain scale was 2.5. In comparison, the average menstrual pain score for these women was 3.5.[7] A double-blind, placebo-controlled trial reviewing the use of paracervical block versus placebo showed that paracervical block did decrease pain at the internal os, but there was no change in pain scores with device placement.[8] Of note, patients identified the injections for the paracervical block as the most painful part of the whole procedure. Currently, many providers are using an anti-inflammatory, such as ketorolac 30 mg intramuscular, approximately 30 to 60 minutes prior to the procedure, and using vaginoscopy to avoid having to place a speculum in the vagina. Each physician can tailor the anesthetic choice to their individual patient population and to what they feel comfortable administering in the office. If sedation is used, physicians should be cognizant of their local regulations about sedation for office procedures.

How do I get patients to follow up in three months?

Confirmation of proper placement of the Essure inserts and tubal occlusion is an important component of this procedure. If the devices are correctly placed and tubal occlusion is confirmed the failure rate is negligible. However, pregnancies have occurred in clinical use and often these failures could have been avoided. Tubal occlusion does not happen immediately. Currently, it is recommended that the postprocedure confirmation test is performed at 3 months. Patients must use alternative contraception for this interval. This counseling should be done prior to performing the procedure. The confirmation test performed after the Essure procedure is able to identify the small percentage of women with improper insert placement who would ultimately fail to achieve bilateral tubal occlusion. It should be emphasized that no sterilization procedure is 100% effective. Even with tubal ligation, the CREST data show that there is a cumulative 10-year failure rate of approximately 1.8% when considering all types of sterilization procedures.[9]

One way for physicians to explain the need for this confirmatory test is that it is a "graduation present" that confirms tubal blockage; if there is proper placement, the device is nearly 100% effective. It is important to develop a system within the practice to help assure that the confirmation test is performed. Scheduling an appointment at the time of the procedure and/or calling shortly before 3 months with a reminder may be helpful. By raising the level of importance of this follow-up, similar to that which is routinely done in following up abnormal Pap smear or mammogram results, helps everyone involved understand why the procedure needs to be done. If the confirmation HSG is being performed by another physician, the confirmation test protocol should be reviewed with them to ensure familiarity with the landmarks and images needed to confirm proper placement (**FIGURE 2**).

What should I know about the hysterosalpingogram?

Currently in the United States the Essure procedure requires an HSG at 12 weeks postprocedure. This confirmation test is performed differently than the HSG for fertility patients—it is a low-pressure confirmation to

FIGURE 2 Hysterosalpingogram image confirming proper placement of the Essure device

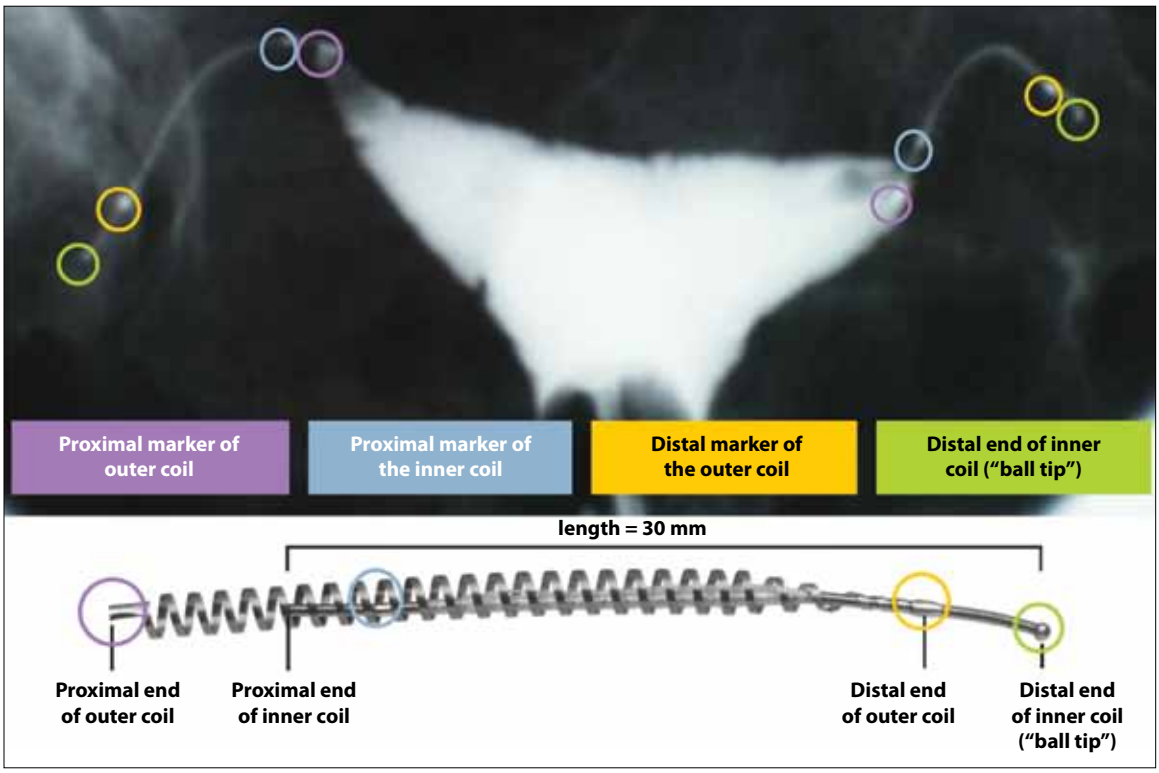

Image courtesy of Conceptus Inc.

localize position of the inserts. The inserts must span the utero tubal junction. The device is not considered properly located if greater than 50% is in the cavity or if it is further than 4 cm from the cornua. If the inserts are properly positioned but there is contrast noted beyond the distal portion of the insert, a repeat HSG at 6 months is warranted.[10]

What other advantages are there to bringing hysteroscopy into my office?

Retained/impacted IUDs and small endometrial polyps can be removed in the office using the same equipment as for in-office hysteroscopic sterilization. Patients with nondiagnostic imaging for irregular or postmenopausal bleeding can have uterine cavity evaluation and biopsies performed with a simple office hysteroscopy. See-and-treat algorithms for irregular bleeding have been shown to be cost-effective and avoid procedures using general anesthesia in approximately 30% of patients.[11]

Is hysteroscopic sterilization really cost effective?

A direct cost comparison of laparoscopic tubal ligation versus office hysteroscopic sterilization using actual institutional costs of the procedures identified a $2,075 difference between the procedures: $3,449 for laparoscopy versus $1,374 for office hysteroscopy.[12]

An economic decision tree analysis performed recently by Kraemer et al[13] found that Essure saves $1,178 (33%) compared with laparoscopic bilateral tubal ligation (BTL). See the **TABLE** for a cost comparison of Essure versus BTL.[12-15]

Physicians are often concerned about the cost that a new procedure in the office will incur to a practice. Start-up costs of purchasing the necessary equipment can be challenging; however, there are several leasing or financing options to help with the upfront costs of the equipment. The current environment is very favorable for reimbursement of in-office procedures. Bringing this equipment into the office will allow you to perform not only hysteroscopic sterilization but also a myriad of other diagnostic and therapeutic procedures. Scheduling procedures in the OR is time consuming for your staff, the patient, and yourself. Performing a tubal ligation in the OR requires you to travel to and from the OR and introduces the unpredictability of case start times and equipment issues inherent to any OR. Incorporating hysteroscopic procedures into the practice will allow

TABLE Cost comparison of Essure versus bilateral tubal ligation

Study	Cost per patient: Essure[a]	Cost per patient: BTL	Cost savings	*P* value
Levie et al[12] Essure in office	$1374	$3449	$2075	N/A
Thiel et al[14] Essure in ASC	$1287	$1398	$111	<.01
Hopkins et al[15] Essure in OR	$2700	$2880	$180	.038
Kraemer et al[13,b] Essure in office	$2367	$3545	$1178	N/A

ASC, ambulatory surgical center; BTL, bilateral tubal ligation; OR, operating room.
[a]Includes cost of hysterosalpingogram; [b]5-year cost to Medicaid system.

you to spend more time in the office, where productivity is greatest. Lastly, bringing minimally invasive procedures into your office will make your practice more attractive to patients. You will now be offering the least invasive diagnostic and therapeutic procedures to your patients in an environment where they are comfortable. The future of medicine seems to be heading toward increased cost-effectiveness and decreased hospitalization. Incorporating office hysteroscopy into your practice now will allow you to be on the leading edge of the curve rather than being left behind.

Hysteroscopic sterilization is an excellent option for those seeking permanent contraception. It has advantages to both patients and their physicians. Relocating procedures to the office by adding hysteroscopy to a practice's capabilities is a win-win situation for both patients and practice. The effectiveness of hysteroscopic sterilization, as well as the clear safety advantages it has over a laparoscopic approach, makes it clear that hysteroscopic sterilization is the best option for the majority of women seeking permanent sterilization. The cost-effectiveness and rapid patient recovery further bolster the argument that this should be considered the standard of care for sterilization.

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