Global Endometrial Ablation in the Presence of Essure® Microinserts

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Abnormal uterine bleeding (AUB) affects 30% of women at some time during their reproductive years and is one of the most common reasons a woman sees a gynecologist. Many women are turning to endometrial ablation to manage their AUB. This article reviews the data relating to the available endometrial ablation techniques performed with hysteroscopic sterilization, and focuses on data from patients who had Essure® (Conceptus, San Carlos, CA) coils placed prior to performance of endometrial ablation. Reviewed specifically are data regarding safety and efficacy of these two procedures when combined. Data submitted to the US Food and Drug Administration for the three devices currently approved are reviewed, as well as all published case series. Articles included were selected based on a PubMed search for *endometrial ablation* (also using the brand names of the different techniques currently available), *hysteroscopic sterilization*, and *Essure.*

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KEY WORDS

Abnormal uterine bleeding • Endometrial ablation • Hysteroscopic sterilization

Abnormal uterine bleeding (AUB) affects 30% of women at some time during their reproductive years and is one of the most common reasons a woman sees a gynecologist.[1] AUB tends to occur more frequently as patients get older, and women typically present between the ages of 30 and 55 years with this problem. After appropriate evaluation, medical management is often the first line of treatment. However, many women are turning to endometrial ablation to manage their AUB. Patients are counseled to avoid pregnancy after endometrial ablation due to the increased risks for pregnancy after ablation. Problems such as premature rupture of membranes, preterm labor, intrauterine growth restriction, abnormal placentation, and higher cesarean delivery rates are reported.[2] Practitioners

must offer a reliable contraceptive method after endometrial ablation has been performed.[2]

There is a higher prevalence of women choosing permanent sterilization for their contraception as they age. According to the 2006-2008 National Survey of Family Growth, 28.2% of women aged 35 to 39 years and 39.1% of women aged 40 to 44 years use female sterilization as their choice of birth control.[3] Ideally, women requiring endometrial ablation could benefit from concomitant procedures providing relief of their menorrhagia as well as permanent birth control. The transcervical approach of endometrial ablation and hysteroscopic sterilization makes the two methods well suited to be performed simultaneously, providing both menorrhagia relief and permanent sterilization. Furthermore, the second-generation endometrial ablation methods and hysteroscopic sterilization can both be performed in an office setting with local anesthetics and minimal anesthesia.

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Currently the NovaSure® (Hologic, Bedford, MA), hydrothermal ablation (HTA), and Gynecare ThermaChoice® (Ethicon, Somerville, NJ) are third-generation methods of global endometrial ablation (GEA) that are approved by the US Food and Drug Administration (FDA) for use with Essure® (Conceptus, San Carlos, CA) coils in situ. In consideration of performing a concomitant endometrial ablation with Essure coils in situ, several concerns regarding safety and efficacy need to be addressed.

Hysteroscopic sterilization requires placement of a microinsert that spans the uterotubal junction. This coil is made up of stainless steel, nitinol, and polyethyl terpathalate material. Proper placement of the Essure coils requires 3 to 8 coils to be in the endometrial cavity,[4] which puts the microinsert in direct or indirect contact with the ablation device. Some concerns that need to be evaluated include

1. Thermal and/or Electrical Conductivity
   - Given that the coils used in hysteroscopic sterilization are made out of metal, does the microinsert transmit the heat or conduct energy that is generated during endometrial ablation distally to the tube or outside the uterus?
   - What is the extent of damage that may occur due to this increase in temperature or energy transmission?
   - Most importantly, is the ability of the microinsert to yield tubal occlusion affected by its exposure to these conditions?
2. Tubal Occlusion Confirmation Testing
   - A confirmation of tubal occlusion prior to proceeding with endometrial ablation is currently recommended by the FDA.[4] Although concomitant use of Gynecare ThermaChoice with Essure coils was granted by the FDA in 2006, this was rescinded after several patients had inadequate hysterosalpingogram (HSG) procedures due to Asherman syndrome. Therefore, how does ablation affect the ability to perform the confirmation test?
   - If the ability to perform HSG is compromised, are there alternatives to this confirmatory test that are acceptable?

Bipolar Radiofrequency Ablation

Bipolar radiofrequency ablation (NovaSure) uses a bipolar mesh array that delivers radiofrequency electrical current to the endometrial surface until an impedance of 50 Ω of resistance is obtained.[5] In February 2012, the FDA changed the Essure package labeling to read "NovaSure Impedance Controlled Endometrial Ablation System can be safely performed with the Essure micro-insert in place."[6] This was based on bench and clinical studies that are outlined below.

Hysterectomy Studies

Coad and colleagues[7] looked at women previously scheduled for hysterectomy for benign conditions who underwent unilateral Essure microinsert placement immediately followed by NovaSure ablation (n = 13), with the contralateral tube serving as a control. Thermal imaging was used to monitor surface temperatures during the ablation portion of the procedure. The uteri were stained for thermal fallopian tube injury and endomyometrial injury immediately following hysterectomy. Placement of the microinserts with subsequent ablation was accomplished without clinical difficulty. The mean serosal temperature during the ablation portion was < 44°C and was similar between the microinsert and control tubes. The mean thermal ablation depths were not altered by the microinserts. No control tubes showed thermal injury. Four microinsert tubes showed thermal injury within the interstitia (n = 3) and interstitial/isthmic (n = 1) segments with a mean depth of 0.4 mm. This tubal injury had a decreasing proximal to distal injury gradient. No serosal injury was identified.[7]

Garza-Leal and associates[8] studied 13 women undergoing

abdominal hysterectomy for AUB. Patients underwent proximal microinsert placement in one fallopian tube and the contralateral tube served as a control. During NovaSure ablation, thermal imaging monitored serosal temperatures. The specimens were stained for thermal injury to the tubes and intrauterine cavity. During the NovaSure procedure, the mean serosal temperature was $< 40°C$ and was similar between the microinsert and control tubes. The microinsert did not significantly alter the mean cornua maximum thermal injury depths (implanted 6.3 ± 1.7 mm and nonimplanted 6.3 ± 1.1 mm; $P = .989$). The minimum cornua thermal injury to uterine serosal distance was similar for the implanted and nonimplanted cornua (15.0 ± 7.7 mm vs 15.2 ± 7.9 mm; $P = .382$). Three implanted fallopian tubes showed thermal injury within the interstitial. One tube showed thermal injury within the interstitial/isthmic (n = 1) segments. This thermal injury was confined to the myometrium and had a mean depth of 1.1 mm and focally extended within 0.7 mm of the serosa. The degree of thermal injury was noted to have a decreasing proximal to distal gradient. No primary serosal thermal injury arising from the microinserts was noted. No thermal injury was identified in the control tubes.[8]

In another study by Coad and colleagues[9], six patients underwent bilateral Essure placement, a confirmatory test by HSG at 90 days, and endometrial ablation with NovaSure, followed by hysterectomy 5 days later. The uteri were stained for viability to evaluate the extent of NovaSure ablation. The uteri showed complete or eccentric partial cornual ablation. Maximum viability-negative endomyometrial ablation was 6.3 ± 1.6 mm. The closest serosal distance from NovaSure ablation was 10.1 ± 4.3 mm with the minimum being 3.6 mm; 10 microinserts showed hyperthermic tissue thermal necrosis within the cornual, tubal os, and/or proximal interstitial fallopian tube (regional overlap with NovaSure ablation). None of 10 microinserts showed in-growth necrosis in the distal interstitial and/or isthmic tubal regions; two microinserts showed no thermal in-growth necrosis at any location.

Case Series

In a retrospective cohort study by Basinski and Price,[10] 117 patients underwent Essure placement followed by NovaSure in two separate office settings; 83 patients (71%) returned for a 3-month HSG. Satisfactory placement of Essure coils and tubal occlusion on the HSG was noted in 95% of patients. There were no reported adverse effects. Patients were evaluated for satisfaction of procedure through a questionnaire that they filled out at the time of HSG; 74% reported amenorrhea and/or vaginal spotting, 23% reported only decrease in menstrual flow, and 3% reported ablation failure. The authors concluded that subsequent NovaSure after Essure did not decrease the effectiveness of either procedure.

Immerzeel and associates[11] conducted a study to evaluate ultrasound as confirmatory test after Essure sterilization followed by immediate NovaSure ablation. Fifteen patients were assigned to Essure sterilization followed by immediate NovaSure ablation if placement of Essure was considered uncomplicated. Twelve patients had uncomplicated Essure procedures followed by NovaSure ablation and ultrasound at 3 months to confirm proper placement. One case was complicated by accidental removal of a microinsert with removal of the NovaSure probe. The microinsert was replaced successfully. This patient underwent a successful HSG at 3 months, which confirmed proper coil placement. Three other patients required HSG due to the course of the procedure and all underwent successful ablation after the confirmatory test.

A retrospective chart review of 10 cases performed by Kulbersh[12] evaluated the placement of Essure followed by NovaSure ablation. Patients underwent bilateral Essure placement followed by NovaSure in the same surgical session. Bilateral microinsert placement was achieved in all of the patients. Microinsert placement was confirmed by ultrasound at 3 months.

Long-term Follow-up

In the study by Basinski and Price,[10] patients were followed for contraceptive and endometrial ablation effectiveness. Out of 117 patients, 97 completed a questionnaire on satisfaction of results and contraception. All patients were "satisfied" or "very satisfied" with the procedure. All patients were relying on Essure for contraception with no reported pregnancies. In the study by Kulbersh,[12] one patient underwent total abdominal hysterectomy with bilateral salpingo-oopherectomy 1 year postablation secondary to persistent bleeding and a large fibroid.

Thermal Balloon Ablation

In thermal ablation techniques (Gynecare ThermaChoice, Cavaterm™ [Pnn Medical SA, Morges, Switzerland], Thermablate EAS™ [Idoman Ltd, Dublin, Ireland]), a silicone balloon is inserted into the uterine cavity through a probe and is expanded with either 5% dextrose in water (Gynecare ThermaChoice, Cavaterm) or

glycerin (Thermablate EAS). The fluid reaches temperatures ranging from 78°C to 173°C.[13] Unlike the NovaSure, with which there is dual concern for electrical and thermal spread to the microinsert, with these techniques the only concern is thermal injury to adjacent structures. There is also a potential risk for balloon rupture by the tubal microinserts.

Hysterectomy Studies

Valle and coauthors[14] conducted a study of 40 patients. The study was divided into a feasibility arm and a safety arm. In the feasibility arm, 16 women underwent placement of Essure followed by immediate Gynecare ThermaChoice ablation. In the safety study, seven patients had temperature sensors placed under the tubal serosa to assess heat transmission from the intratubal insert devices to the surrounding organs during ablation. The feasibility arm of the study evaluated the completeness of endometrial ablation and possible device dislodgement. The safety study looked at temperature readings. Microinserts were not disturbed during the ablation. Ablation was noted to be complete visually and histologically, although small areas near the tubal ostia showed less endometrial destruction. Mean tubal temperatures ranged from 37.1°C to 37.5°C. No damage to the tubes was noted.[14]

Case Series

Donnadieu and colleagues[15] and Donnadieu and Fernandez[16] studied 23 women with AUB who desired permanent tubal sterilization. Patients were treated with combined Essure placement and endometrial ablation. Eleven patients underwent Essure placement followed by Gynecare ThermaChoice ablation. Patients were followed for 4 to 26 months with no reported pregnancies; 85% of patients reported satisfaction with the outcomes. In one study by Vilos and colleagues,[17] 80 patients underwent Essure placement prior to or after Thermablate EAS ablation. Of these, nine women underwent Essure placement followed by Thermablate EAS endometrial ablation. There were no complications noted. All microinserts were placed successfully and at 3 months one tube was patent. At 3 to 12 months follow-up, 30% of patients reported amenorrhea, 50% reported spotting or hypomenorrhea, 7% reported eumenorrhea, and 10% reported menorrhagia. The overall satisfaction rate was 85%.

Donnadieu and associates[18] conducted a retrospective study in which 12 women underwent Essure placement immediately before Gynecare ThermaChoice ablation. At 3 months, proper positioning of the microinserts was confirmed by contrast three-dimensional ultrasound in all women. No pregnancies were reported at 18-month follow-up.

Complications

In a case report by Jansen and colleagues[19] and Del Pozo and Gómez[20] from 2007, the authors describe a patient with Essure microinserts in situ who was treated by thermal balloon ablation 9 months after Essure placement for AUB. Three months after the ablation, the patient developed bilateral cornual abscesses. She was treated with doxycycline and metronidazole and underwent a laparotomy with bilateral salpingectomy and appendectomy. On laparotomy bilateral abscesses were noted in both intramural parts of the tubes, which extended to the cornua of the uterus and the tip of a normal-appearing appendix. Microinserts were located in the center of each abscess. Cultures were positive for *Haemophilus influenzae*. On histology there was chronic inflammation and fibrosis and the appendix was infected and contained a small intraluminal abscess. The patient recovered without further complications. The authors discuss the possibility of asymptomatic endometritis and consequent bilateral abscess formation at the site of foreign bodies after the endometrial ablation.

Hydrothermal Ablation

HTA is performed by placing a hysteroscope into the uterine cavity under direct visualization; heated isotonic saline is then circulated into the cavity using gravity.[21] The circulating fluid reaches temperatures of 90°C, which can potentially cause thermal injury to surrounding structures if there is leakage of fluid.

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Prehysterectomy Studies

Coad and colleagues[9] looked at seven women previously scheduled for hysterectomy for benign conditions who underwent unilateral Essure microinsert placement immediately followed by Hydro ThermAblator® (Boston Scientific, Natick, MA). The contralateral tubes served as controls. During endometrial ablation, thermal imaging monitored serosal temperatures. Following immediate hysterectomy, the uteri were stained for thermal fallopian tube injury and adjacent endomyometrial ablation. Mean serosal temperatures during endometrial ablation were < 44°C and were similar between

the microinsert and control tubes. In comparison with control tubes, the microinserts did not alter the mean thermal ablation depths. None of the tubes with microinserts showed thermal injury. Three control tubes showed thermal injury in the interstitial (n = 1), interstitial/isthmic (n = 1), or interstitial/isthmic/proximal ampullary (n = 1) segments with a mean depth of 0.4 mm. The tubal injury showed a decreasing gradient from proximal to distal. No serosal injury was identified. In a study by Dhainaut,[22] four patients had Essure placement followed by immediate HTA procedure. One patient who had planned for hysterectomy underwent the HTA procedure, after which a detailed histologic study was performed. On histology, the process of coagulation was limited to the mucous membrane without reaching the muscularis of the fallopian tube.

Hysterectomy Studies

Seven women undergoing abdominal hysterectomy for AUB underwent proximal microinsert placement in one fallopian tube; the contralateral tube served as a control. Thermal imaging monitored serosal temperatures during ablation. The uteri were stained for thermal injury to the tubes and the extent of endomyometrial ablation. Microinsert placement with subsequent HTA was accomplished without clinical difficulty. Mean serosal temperatures during ablation were all $< 44°C$. No leakage was noted from the fallopian tubes. The microinsert did not significantly alter the mean thermal ablation depths (implanted cornua 3.6 ± 1.1 mm; nonimplanted cornua 4.0 ± 2.2 mm; $P = .346$). The minimum cornua thermal injury to uterine serosal distance was similar between the implanted and nonimplanted cornua (15.6 ± 5.3 mm vs 15.7 ± 5.5 mm; $P = .866$). No implanted fallopian tubes showed thermal injury after ablation. Three control tubes showed proximal thermal injury with a maximum radial depth of 0.5 mm. There was no serosal injury noted. The thermal injury of one control tube extended to within 1.0 mm of the serosa.[23]

Microwave Ablation

During microwave ablation (Acculis MTA; Microsulis Medical, Denmead, England) the microwave probe is placed in the uterine cavity to generate temperatures of $> 60°C$ at a depth of 6 mm.[24] Prior to its approval in the United States, there were reported cases of thermal bowel injury; therefore, the FDA requires a minimum of 1 cm of myometrial thickness. This thermal injury can potentially happen with all endometrial ablation devices.

Hysterectomy Studies

Ten women underwent unilateral Essure placement, with the contralateral fallopian tube serving as control. Thermal sensors were placed in the serosa of the fundus, uterine tubal junction, and isthmic portion of the fallopian tube via laparotomy. Microwave ablation was then performed followed by abdominal hysterectomy. The uteri were examined for microinsert placement and for ablated tissue around the uterine cornua. Essure placement and endometrial ablation were successful in all patients. No visual damage or movement of the Essure device was noted. Mean serosal temperatures ranged from 35°C to 36°C during microwave ablation. Fallopian tube cross sections from the uterine tubal junction, midtube, and distal tube locations were stained for regions of cellular devitalization. No significant increase in fallopian tube injury was noted. Only the expected degree of ablation was noted in the intrauterine cavity.[25]

Cryotherapy Ablation

The technique of cryotherapy ablation (Her Option®; Cooper Surgical, Trumbull, CT) consists of a cryoprobe that is placed in the uterine cavity and is cooled by liquid nitrogen. Using ultrasound, probe placement and depth of tissue destruction are monitored. No studies were found that describe the use of cryotherapy with hysteroscopic sterilization. An in vitro model in which cryoablation was performed with Essure in situ showed no change in temperature at the distal end of the microinsert in 22 tests.[26]

The technique of cryotherapy ablation consists of a cryoprobe that is placed in the uterine cavity and is cooled by liquid nitrogen.

Imaging to Confirm Device Location and Tubal Occlusion

The current confirmation test in the United States for proper placement of Essure microinsert coils and bilateral tubal occlusion is an HSG performed 3 months after Essure placement.[6] There is a risk of scarring or stenosis of the endometrial cavity after endometrial ablation that can interfere with the 3-month HSG. Some authors have evaluated the feasibility of performing a 3- or 6-month confirmatory HSG after endometrial ablation. Others have looked at performing ultrasound or radiography to confirm device location. The ability to perform

TABLE 1

Summary of Current Publications With Combined Endometrial Ablation After Essure® Procedure

Method	FDA Approval With Essure in situ	Cases (N)	Prehysterectomy Studies	Perihysterectomy Studies	Case Series
NovaSure® bipolar radiofrequency ablation	Yes	254	Coad JE et al[9]: 13 patients; 4 showed thermal injury at interstitial or interstitial/isthmic segment in average 0.4 mm in depth	Garza-Leal J et al[8]: 13 patients; 3 showed thermal injury at interstitial segment and 1 at interstitial/isthmic segment Coad JE et al: 6 patients; 10 tubes showed thermal necrosis within the cornua, tubal ostia, or interstitium; 2 tubes showed no necrosis at all	Basinski and Price[10]: 117 patients; 83 returned for HSG, 79 had bilateral occlusion, 80 had improvement of menorrhagia Immerzeel P et al[11]: 15 patients; 1 had microinsert removal at time of ablation, all had successful ablation after placement of microinserts Kulbersh DL[12]: 10 patients; at 3 mo all had bilateral occlusion Saunders DM[33]: 117 patients with Essure followed by Novasure with HSG as confirmatory test; no pregnancies at 2-y follow-up
Acculis MTA microwave ablation	No	10		Garza-Leal J et al: 10 patients; no significant increase in fallopian tube injury was identified	
Gynecare ThermaChoice thermal balloon	Yes	72	Valle RF et al[14]: 40 patients; no disturbance in intratubal devices, endometrial ablation was complete, with less destruction near the tubal ostia and no damage to the tubes was noted		Donnadieu and Fernandez[16]: 11 patients had ThermaChoice, at 3 months all showed bilateral occlusion Vilos GA et al[17]: 9 patients; at 3 mo 8 patients had bilateral occlusion, 1 had unilateral occlusion; at 3- 12-mo follow-up, 90% patients had decrease in menstrual flow and 85% patient satisfaction rate was noted Deffieux X[34]: 12 patients, all showed bilateral occlusion and no pregnancies at 18 mo
Hydro ThermAblator hydrothermablation	Yes	18	Coad JE et al: 7 patients; microinserts did not alter ablation depth, no microinsert tubes showed thermal injury Dhainaut C[22]: 4 patients had combined procedure, 1 had a hysterectomy with pathology showing coagulation limited to the mucosa	Garza-Leal J et al: 7 patients; microinserts did not alter ablation depth	
Her Option cryotherapy ablation	No	22 in vitro tests			Glasser MH[26]: 22 tests, no change in temperature at the distal end of the microinsert

Essure®, Conceptus (San Carlos, CA); NovaSure®, Hologic (Bedford, MA); Acculis MTA, Microsulis Medical (Denmead, England); Gynecare ThermaChoice®, Ethicon (Somerville, NJ); Hydro ThermAblator®, Boston Scientific (Natick, MA); Her Option®, Cooper Surgical (Trumbull, CT).

FDA, US Food and Drug Administration; HDG, hysterosalpingogram.

the confirmation test should not be affected whether the Essure or the endometrial ablation was performed first. Given the paucity of data regarding confirmation testing after concomitant procedure, we included all data dealing with concomitant procedures independent of procedural order.

NovaSure

In a study involving 66 women, the feasibility of performing HSG following combined Essure and radiofrequency ablation procedures was analyzed. The inserts were successfully placed bilaterally in 65 of the 66 women. Of the 65 women, 50 (77%) women returned for the recommended HSG at 3 months. Two of the 50 were unable to proceed with the test due to cervical stenosis. In all 48 of the women who were able to undergo hysterosalpingogram, the study was adequate to assess device placement and tubal occlusion. Three (3/48, 6.2%) women had unilateral tubal patency at 3 months. All of these women returned at 6 months with documentation of total occlusion of both ostia. The authors concluded that the recommended use of HSG with the Essure procedure alone applies as well with the combined modalities.[27]

In the study by Basinski and Price,[10] 24 of 59 patients who underwent Essure followed by NovaSure had a 3-month HSG. Of these, 22 had bilateral tubal occlusion and two had unilateral occlusion.[10] Hopkins and colleagues[28] performed NovaSure followed by Essure followed by a 3-month HSG on 21 patients. At 3 months, 19 patients had bilateral occlusion and two had unilateral occlusion. At 6 months, the remaining two patients had bilateral occlusion. In another study, 10 patients underwent Essure placement followed by NovaSure ablation. At 3 months, ultrasound was used to confirm proper coil placement in all 10 patients.[12]

Mircea and colleagues[29] performed Essure immediately after NovaSure in 87 patients. At 3-month follow-up, 80 patients showed bilateral occlusion (HSG, 21 patients; three-dimensional sonography, 56 patients; radiograph, 3 patients). Six patients had unilateral occlusion and one patient had bilateral patency. Sabbah[30] conducted a study in which 14 patients underwent NovaSure followed by Essure, followed by HSG. At 3 months, 13 patients showed bilateral occlusion and the remaining patient showed bilateral occlusion at 6 months.

Gynecare ThermaChoice

In a prospective study to assess whether a concomitant Gynecare ThermaChoice endometrial ablation procedure caused intrauterine synechiae that could prevent or interfere with an effective HSG at 3 months, 10 of the 30 women had intrauterine synechiae. Of these 10, five women had scarring or synechiae that prevented the study physicians from assessing tubal occlusion by HSG. According to the instructions for use of the Essure System, these five women cannot rely on the Essure microinserts for permanent birth control because they failed to fully satisfy requirements of the FDA-approved HSG protocol. Thus, modifications to the Essure system labeling were made to reflect that Essure and Gynecare ThermaChoice should not be performed concomitantly due to the possible inability to complete the 3-month confirmatory HSG.[6]

Conclusions

Many women are seeking minimally invasive treatment alternatives such as GEA to manage their heavy menses. As the number of women choosing endometrial ablation increases, we must stress the need for adequate contraception as subsequent pregnancies can be potentially complicated and dangerous. Currently, a woman's only option for concomitant sterilization and endometrial ablation is to have a laparoscopic tubal ligation at the time of endometrial ablation. This has the drawbacks of requiring a general anesthetic, entry into the abdominal cavity with its inherent risks, as well as the recovery time associated with laparoscopy. This could be overcome by performing the two procedures transcervically and concomitantly.

These data, as summarized in Table 1, support the safety and efficacy of performing an endometrial ablation with Essure coils in situ. Perihysterectomy studies involving NovaSure, HTA, Gynecare ThermaChoice, Thermablate EAS, and microwave ablation show the depth of ablation was not altered by the presence of microinserts in the tubes. Only the expected degree of ablation was noted in these studies, and no thermal or electrical conduction extended to the serosa. Based on these studies, it is unlikely that Essure coils will transmit sufficient thermal heat or conduct significant electrical energy to the distal part of the tubes when properly placed.

This has been confirmed in bench studies examining the thermal and electrical impact of endometrial ablation with in situ Essure coils. In these studies, there was no significant increase in coil temperature in response to thermal energy. However, the coil was conductive with direct application of monopolar cutting and coagulating current.[31]

Furthermore, the effectiveness of hysteroscopic sterilization with endometrial ablation was not

decreased by combining these procedures based on successful confirmatory testing and no unwanted pregnancies. Confirmatory testing was achieved using HSG or ultrasound as testing modalities and no pregnancies were reported. Most of the studies that used HSG testing for confirmation showed occlusion at 3 months, with only a few patients showing unilateral occlusion. HSG could be performed successfully in the large majority of patients to confirm microinsert placement. When the ablation causes Asherman syndrome, obstructing the endometrial cavity and thus interfering with HSG, ultrasound alone or in combination with radiography has been successfully used to confirm placement.

Assuming the pregnancy rate in ovulating women after GEA is 1.6%,[31] and the 5-year failure rate after Essure is 0.2%, the cumulative theoretical pregnancy rate after a combined procedure would be 0.2% of 1.6%, or .0032%. Furthermore, we have seen that outside the United States, device location rather than tubal occlusion is used as the endpoint for a confirmation test, with no higher pregnancy rates documented as a result. Taking these points into consideration, many physicians are comfortable performing Essure and GEA concomitantly, and are increasingly using ultrasound documentation of proper microinsert location as the confirmation test. Others choose to adhere to the FDA-recommended protocol of performing Essure with a 3-month HSG confirmation test, followed later by endometrial ablation.[32]

The safety associated with doing these procedures concomitantly is predicated on correct placement of the Essure microinserts. Although the coils are certainly a poor conductor of thermal energy, there is still a theoretic health hazard if the NovaSure procedure is performed in the presence of an electrically conductive Essure microinsert that is improperly positioned (eg, perforating the fallopian tube or the myometrium). If this occurs, energy may be drawn away from the intended treatment area toward other tissue and/or organs in contact with the conductive object, which may be sufficient to cause localized burns. There are no reported cases of such incidents in any of these case series. If placement of the Essure coils is difficult or anatomy is distorted, current opinion is that imaging should be performed to confirm proper placement prior to proceeding with ablation.

Currently, in the United States the FDA has mandated that HSG is the only acceptable confirmation test after hysteroscopic sterilization. A study is being carried out to assess whether two-dimensional ultrasound is adequate for confirmation of proper Essure placement. This is currently the standard of

MAIN POINTS

- Abnormal uterine bleeding affects 30% of women at some time during their reproductive years and is one of the most common reasons a woman sees a gynecologist. Many women seek minimally invasive treatment alternatives such as global endometrial ablation (GEA) to manage their heavy menses.
- Because patients are counseled to avoid pregnancy after endometrial ablation due to the increased risks for pregnancy after ablation, practitioners must offer a reliable contraceptive method after endometrial ablation has been performed. The transcervical approach of endometrial ablation and hysteroscopic sterilization makes the two methods well suited to be performed simultaneously, providing both menorrhagia relief and permanent sterilization. Furthermore, the second-generation endometrial ablation methods and hysteroscopic sterilization can both be performed in an office setting with local anesthetics and minimal anesthesia.
- Current techniques include bipolar radiofrequency ablation, thermal balloon ablation, hydrothermal ablation (HTA), cryotherapy, and microwave ablation. Currently the NovaSure, HTA, and Gynecare ThermaChoice are third-generation methods of GEA that are approved by the US Food and Drug Administration (FDA) for use with Essure coils in situ. The contraceptive effectiveness of hysteroscopic sterilization and the outcome of endometrial ablation do not seem to be altered when these procedures are performed sequentially.
- The current confirmation test in the United States for proper placement of Essure microinsert coils and bilateral tubal occlusion is a hysterosalpingogram (HSG) performed 3 months after placement. The FDA has mandated that HSG is the only acceptable confirmation test after hysteroscopic sterilization. A study is being carried out to assess whether two-dimensional ultrasound is adequate for confirmation of proper Essure placement.

care in many of the countries outside the United States and would remove the concern of not being able to confirm proper placement secondary to intrauterine synechiae. Furthermore, the FDA, since changing the packaging label in the NovaSure device to allow this procedure to be done with the Essure coils in place, has requested a postmarket approval study to confirm the safety profile of the two procedures together. ■

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