

# ACOG PRACTICE BULLETIN

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This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins—Gynecology with the assistance of Malcolm G. Munro, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

*Reaffirmed 2018*



## Endometrial Ablation

*Endometrial ablation refers to a number of minimally invasive surgical procedures designed to treat abnormal uterine bleeding in selected women who have no desire for future fertility. In this document, standard resectoscopic endometrial ablation will be compared with the newer nonresectoscopic endometrial ablation devices and techniques. Evidence comparing endometrial ablation with other techniques for treating abnormal uterine bleeding also will be reviewed. The purpose of this document is to review the efficacy, safety, indications, and limitations of techniques for endometrial ablation.*

### Background

#### *History*

The technique of targeted endometrial destruction, using a radiofrequency electrosurgical probe passed through the cervical canal into the endometrial cavity without endoscopic guidance, was originally developed in 1937. Another blind technique, called cryoendometrial ablation, using a probe that supercooled the endometrial lining, was introduced in 1967 (1). Despite these early introductions, endometrial ablation did not become more widely adopted until the advent of hysteroscopically directed techniques. The first of these was laser endometrial ablation, introduced in 1981, using the neodymium:yttrium–aluminum–garnet (Nd:YAG) laser through the instrument channel of an operating hysteroscope (2). Subsequently, a number of investigators described case series using a urological resectoscope to resect (3), electrodesiccate (4), or vaporize (5) the endometrium. For most gynecologic surgeons, these techniques replaced the generally more cumbersome and expensive laser-based approach to endometrial destruction.

The rediscovery of nonresectoscopic endometrial ablation techniques led to the development of a number of systems that use different energy sources to achieve destruction of the endometrium, including tissue freezing, radiofrequency electricity, microwaves, and heated fluid, either freely circulating in the

endometrial cavity or contained within a balloon. The first of these devices was approved by the U.S. Food and Drug Administration (FDA) in 1997, and others were released over the next few years. Currently, five systems are now approved for use in the United States.

### **Indications**

Endometrial ablation is indicated for the treatment of menorrhagia or patient-perceived heavy menstrual bleeding in premenopausal women with normal endometrial cavities who have no desire for future fertility. In general, such patients will have experienced failure of or will be intolerant of medical therapy. When menorrhagia or excessive menstrual bleeding occurs in the context of submucosal myomata, endometrial ablation may be effective, depending on the location and diameter of the myomata as well as the system used for performing endometrial ablation. Patients who choose endometrial ablation should be willing to accept normalization of menstrual flow, not necessarily amenorrhea, as an outcome. The presence of anemia or failure or intolerance of medical therapy are important considerations but should not be construed as prerequisites for the procedure. The use of endometrial ablation in postmenopausal women or in women with disorders of hemostasis has not been rigorously evaluated.

The process of informed consent for endometrial ablation should include device- or system-appropriate information regarding risk and a realistic discussion of the potential outcomes of surgery because amenorrhea is not achieved in a substantial number of cases. Furthermore, given the persistence of endometrial tissue, premenopausal patients undergoing endometrial ablation should be counseled to use appropriate contraception.

### **Preoperative Evaluation**

The structure and histology of the endometrial cavity should be thoroughly evaluated, both to assess for malignancy or endometrial hyperplasia and to ensure that the length and configuration is suitable for endometrial ablation. These parameters will vary depending on the technique or system used. Endometrial sampling, typically with an outpatient technique, can be used to evaluate all women for hyperplasia or malignancy, and results should be reviewed before ablation is scheduled. Women with endometrial hyperplasia or uterine cancer should not undergo endometrial ablation. Sounding and the use of transvaginal ultrasonography, saline infusion sonohysterography, hysteroscopy, or a combination of these procedures should be performed to measure the length of the cavity and to evaluate the internal architecture for structural anomalies and, in particular, for intracavitary or sub-

mucosal myomata. If such myomata are identified, it is important to characterize them by quantifying their diameter and determining the proportion of the lesion(s) that extend into the endometrial cavity.

## **Devices and Mechanisms of Action**

### **Laser and Resectoscopic Endometrial Ablation**

The modified urological resectoscope that uses radio-frequency-alternating current has become the most commonly used instrument, initially described using a resection technique by way of a loop electrode (6) and subsequently the combination of electrosurgical tissue desiccation and coagulation with a ball or barrel-shaped electrode (4). Another modification was introduced using grooved or spiked electrodes and higher wattage that allowed the surgeon to electrosurgically vaporize the endometrium (5, 7). This technique results in an endomyometrial furrow similar to that made by a loop electrode, without the creation of tissue “chips,” and a slightly greater degree of coagulation in the adjacent tissue, a feature that has been shown, in the context of a comparative trial, to be associated with markedly reduced systemic absorption of distention media (8).

### **Nonresectoscopic Systems**

Nonresectoscopic endometrial ablation refers to destruction of the endometrium using any of a number of techniques or devices, placed within the endometrial cavity, that do not require a uterine resectoscope. These systems appear to require less training and experience than for resectoscopic endometrial ablation, and they seem to result in clinical outcomes similar to those achieved by experienced resectoscopic surgeons. Performance of endometrial ablation with each of these systems comprises manual positioning of a device through the cervical canal to the endometrial cavity. The device controller unit is then activated and energy is applied, usually with microprocessor-based monitoring that aids in the determination of the treatment endpoint or that actually terminates the process when that endpoint is reached.

**Cryotherapy.** The FDA-approved cryotherapy system, Her Option, comprises a disposable 4.5-mm outside-diameter (OD) probe attached to a handle and cable that is connected to a dedicated controller unit. The cervix is exposed, and cervical dilation, if necessary, is performed. The device is passed into the endometrial cavity and then directed to one cornual area where a progressively expanding elliptical freeze zone, involving the surrounding endomyometrium, is created. This is repeated on the contralateral cornu. In some instances, an additional

application may be made lower in the endometrial cavity. The typical treatment time is approximately 10 minutes.

**Heated Free Fluid.** The Hydro ThermAblator heated free fluid system also is FDA approved and achieves endometrial ablation with heated normal saline. It is the only system with integrated hysteroscopic monitoring. The device comprises a single use 7.8-mm OD sheath that adapts to any of a number of 2.7–3-mm OD hysteroscopes. The controller unit automates the processes of distending the uterus, creating a closed circuit, heating fluid, and monitoring of temperature and circuit volume. The distending media is normal saline drawn from a bag mounted on an attached, modified intravenous fluid pole. The process takes approximately 3 minutes to heat the fluid to 90°C, 10 minutes to maintain that temperature to ablate the endometrium, and approximately 1 minute for the fluid to cool down, allowing the device to be removed. If there is egress of more than 10 mL of distending media, either via the cervix or fallopian tubes, the system shuts off automatically. The depth of necrosis attained is 3–4 mm (9).

**Microwave.** Microwaves occupy the part of the electromagnetic spectrum between radio and infrared waves and exert their effect both directly and, in adjacent deeper layers, by thermal propagation. There currently are two FDA-approved versions of the microwave endometrial ablation device, one reusable and one disposable, each of which comprises an 8-mm OD probe attached by a reusable cable to a dedicated control module. The probe also contains an integrated thermal coupling device that transmits information about adjacent tissue temperature back to the control module for display on a screen. The surgeon controls activation and manipulation of the device.

The microwave probe is inserted to the uterine fundus and, when the measured temperature of the tissue around the probe reaches 30°C, the machine is activated. The operator moves the probe across the entire endometrial surface from the fundus down as the device gradually is withdrawn. Treatment time depends, in part, on cavity size but is usually 2–4 minutes.

**Radiofrequency Electricity.** The NovaSure system is an FDA-approved nonresectoscopic endometrial ablation device that uses radiofrequency electricity to perform automated endometrial ablation. The system is based around a dedicated microprocessor-based control unit and a single-use 7.2-mm OD probe with a bipolar gold mesh electrode array located at the distal end. To detect inadvertent perforation of the myometrium, the probe contains a system for determining the integrity of the endometrial cavity based on injection of a fixed volume of CO<sub>2</sub>.

The electrode assembly is inserted transcervically and the mesh electrode is deployed by retraction of the outer sleeve. The unit is used to apply radiofrequency energy to the bipolar mesh while simultaneously applying suction, thereby evacuating steam and carbonized debris. This process allows for electrosurgical vaporization and underlying desiccation in a relatively rapid fashion (approximately 80–90 seconds).

**Thermal Balloon.** A balloon-tipped catheter probe is positioned in the endometrial cavity and then distended with fluid that is subsequently heated to a temperature that is high enough to destroy the endometrium. Although there are a number of such devices available worldwide, the ThermaChoice system currently is the only one approved by the FDA.

This system comprises a single-use balloon catheter, a connecting cable, and a dedicated controller unit. The OD of the catheter is 5.5 mm, and the heating element is contained within the balloon itself. The microprocessor-determined duration of treatment is 8 minutes (10).

After exposure of the cervix and any required dilation, the balloon tipped catheter is passed through the cervical canal into the endometrial cavity. The surgeon uses a syringe to inflate the balloon with 5% dextrose and water to a predetermined pressure of 160–180 mm Hg. The dedicated controller unit is then activated, thereby heating the element and the fluid. The microprocessor in the controller then monitors the parameters of balloon pressure and fluid temperature and automates treatment duration.

## Clinical Considerations and Recommendations

### ► *How do endometrial ablation outcomes compare with medical therapy?*

Oral medical therapy has been compared with endometrial ablation in a high-quality randomized trial (11). By 5 years, only 10% of those patients randomized to medical therapy continued receiving medical treatment, whereas 77% had undergone surgery. Of the group allocated to resectoscopic endometrial ablation, 27% had further surgery, including 18% with hysterectomy. Patients randomized to oral medical therapy were significantly less likely to be satisfied than those undergoing resectoscopic endometrial ablation.

A different picture emerges when intrauterine medical therapy is compared with endometrial ablation. The Cochrane meta-analyses showed that quality of life and satisfaction measures were similar for patients undergo-

ing endometrial ablation and receiving the intrauterine levonorgestrel-releasing system at 1 year (12, 13). In addition, whereas endometrial ablation was more effective at controlling uterine bleeding at 1 year, by years 2 and 3 there was no difference between the interventions.

► *Is pretreatment needed with these devices?*

### **Resectoscopic Endometrial Ablation**

Mechanically thinning the endometrium with curettage or by direct suppression or inhibition of ovarian steroidogenesis has been used a presurgical adjuvant to resectoscopic endometrial ablation. A meta-analysis demonstrated that either preoperative danazol or gonadotropin-releasing hormone (Gn-RH) agonists result in shorter procedures, greater ease of surgery, a lower rate of postoperative dysmenorrhea, and a higher rate of post-surgical amenorrhea (14). Whether the short-term increase in amenorrhea rates associated with adjuvant medical suppression is sustained for multiple years is not known.

At this time, there are no high-quality data that allow for objective evaluation of similar outcomes associated with other preoperative approaches such as systemic progestins or mechanical preparation of the endometrium with curettage.

### **Nonresectoscopic Endometrial Ablation**

Because single-layer thickness of the endometrium is typically up to 6 mm in the luteal phase (even thicker for women who are anovulatory) and most of the nonresectoscopic endometrial ablation systems typically treat to a depth of 4–6 mm, preoperative endometrial thinning seems to be logical. Endometrial thinning may not be necessary with the NovaSure system, which appears to vaporize and remove tissue, thereby, at least theoretically, increasing the thickness of endometrium that could be treated. With the exception of the NovaSure system (15), most of the randomized trials involving nonresectoscopic endometrial ablation devices have been performed on women who have had pretreatment to thin the endometrium. The ThermaChoice balloon ablation system was evaluated after suction curettage (16). For other devices, medical therapy, usually with Gn-RH agonists, was used (17–19).

► *What is the efficacy of resectoscope endometrial ablation?*

There are six randomized controlled trials (RCT) comparing endometrial ablation (almost exclusively resectoscopic endometrial ablation) with hysterectomy; four are from the United Kingdom (20–23), one is from Italy (24), and one is from North America (25, 26). Each of these tri-

als has resulted in a number of important additional publications comparing hysterectomy with endometrial ablation, including the Cochrane meta-analyses (27, 28).

These studies conclude that total hysterectomy is superior in attaining amenorrhea and, although satisfaction with resectoscopic endometrial ablation is high, there usually are somewhat greater patient satisfaction rates when the uterus is removed (21–23). Women who received resectoscopic endometrial ablation had shorter hospital stays and fewer postoperative complications, and they resumed activities earlier than those undergoing hysterectomy (20–23).

In clinical trials with long follow-up intervals, reoperation rates for women assigned to endometrial ablation increased steadily over time. Up to 36% of women at 4 years had either repeat ablation or hysterectomy, and treatment with hysterectomy was at least 24% (26, 29).

There is a relative paucity of randomized trials comparing the different techniques of resectoscopic endometrial ablation; those that are available are reviewed in the Cochrane systematic review (28). In the RCT conducted by the Aberdeen group, patients assigned to endometrial ablation were subsequently randomized to either laser ablation or endometrial resection (30). Whereas both procedures were associated with similar patient satisfaction and clinical outcomes at 12 months, laser ablation was associated with longer procedure time. Compared with loop resection, resectoscopic endometrial ablation with a vaporizing electrode was associated with significantly reduced systemic absorption of distending media during surgery and similar 1-year clinical outcomes (8). Resectoscopic endometrial ablation with rollerball electrodesiccation was compared with loop resection in an RCT in which 120 patients were recruited, with a 5-year follow-up involving 94% of the original sample. There were no differences in complications, bleeding outcomes, or the incidence of repeat surgery, which included a hysterectomy rate of 15% (31).

► *What is the efficacy of nonresectoscopic endometrial ablation therapy?*

Table 1 summarizes amenorrhea rates and patient satisfaction rates based on pivotal RCTs for nonresectoscopic endometrial ablation devices.

### **Thermal Balloon**

The original ThermaChoice system underwent a multicenter RCT comparing it to resectoscopic endometrial ablation with rollerball electrosurgical coagulation and desiccation. Primary outcomes were reported at 1 year (16) with subsequent reports at 2 (32), 3 (33), and 5 years (34). Patient satisfaction with the therapeutic results was

**Table 1. Patient Satisfaction and Amenorrhea Rates Associated With Nonresectoscope Endometrial Ablation Compared With Resectoscopic Ablation at 12 Months\***

Device	Nonresectoscopic/Resectoscopic Ablation (%)		
	Satisfaction Rate	Amenorrhea Rate <sup>†</sup>	Diary Success (Score: 75 or Less)
ThermaChoice (thermal balloon)	96/99 <sup>‡</sup>	13.2/27.2	80.2/84.3
Hydro ThermAblator (heated free fluid)	— <sup>§</sup>	35.3/47.1	68.4/76.4
Her Option (cryotherapy)	86/88 <sup>¶</sup>	22.2/46.5	67.4/73.3
NovaSure (radiofrequency electricity)	92/93 <sup>‡</sup>	36/32.2	77.7/74.4
Microwave Endometrial Ablation System (microwave energy)	92/93 <sup>‡</sup>	55.3/45.8	87/83.2

\*Based on U.S. Food and Drug Administration pivotal trials.

<sup>†</sup>Based on intent to treat.

<sup>‡</sup>Patients reported being satisfied or very satisfied.

<sup>§</sup>Quality-of-life scores compared with baseline only.

<sup>¶</sup>Patients reported being very or extremely satisfied.

Adapted from Sharp HT. Assessment of new technology in the treatment of idiopathic menorrhagia and uterine leiomyomata. *Obstet Gynecol* 2006;108:990–1003.

equal at 1 year (balloon ablation 95.9%, resectoscopic endometrial ablation 99.1%) and the success rates defined by the FDA (Pictorial Blood Loss Assessment Chart score less than 75) were equivalent. At 5 years, 122 (48%) of the original 255 patients treated were available for evaluation, an equal number from each group. By this time, 21 of the women available for evaluation in each of the groups had undergone hysterectomy; three and two underwent repeat ablation, respectively. However, with a high attrition rate and reporting based on the patients available for evaluation, it is possible that repeat surgery rates could be higher in the subset of women not available for evaluation.

Another single-institution RCT from the Netherlands also compared the original ThermaChoice balloon ablation system with resectoscopic endometrial ablation in 137 patients (35, 36). Perioperatively, complications with resectoscopic endometrial ablation included uterine perforation and electrolyte imbalance related to excess absorption of distention media; no such complications were seen in the balloon ablation group. At 24 months, the reduction in bleeding (measured by the same Pictorial Blood Loss Assessment Chart system used in the U.S. trial) was greater with balloon ablation, but success rates (Pictorial Blood Loss Assessment Chart score less than 185) and satisfaction rates (resectoscopic endometrial ablation 75%, ThermaChoice balloon ablation system 80%) were equivalent.

Although not randomized, a large multicenter, multinational cohort study described results of ThermaChoice balloon ablation for 260 women with dysfunctional uterine bleeding (37). Of the 260 original patients, 188 (72%) were available for 5 years of follow-up. Of these, 75% had avoided subsequent surgery altogether, whereas 21 had repeat ablation and 25 had undergone hysterectomy.

### Cryotherapy

Published data regarding the FDA-approved Her Option cryotherapy system has been limited to endometrial cavities without submucosal myomata and that sound to 10 cm or less. The clinical outcomes from the pivotal trial designed for the FDA approval process have been published at 12 months (17) and 24 months (38). The total enrollment was 279 participants with a 2:1 randomization ratio (193 patients assigned to cryotherapy system and 86 assigned to resectoscopic endometrial electrodesiccation). At 12 months, 156 of the patients assigned to the cryotherapy system were available for evaluation, whereas 94 took part in the 24-month follow-up. For the resectoscopic ablation group at 12 months and 24 months, 72 and 43 patients were available for evaluation, respectively. Success rates, defined by reduction of the Pictorial Blood Loss Assessment Chart scores to less than 75, were equivalent in the two groups at 12 months (cryotherapy system 84.6%, resectoscopic endometrial ablation 88.9%). Amenorrhea rates are not

reported at 2 years postablation. However, the investigators report that 7% of the patients assigned to the cryotherapy system and 8.1% of the patients assigned to resectoscopic endometrial ablation underwent hysterectomy in the follow-up period, whereas repeat ablations were performed on 8.1% and 1.2% of the patients, respectively (38). These 2-year outcomes also must be considered in the context of a relatively high attrition rate, with less than 50% of the original cohort available for follow-up at 2 years.

## Heated Free Fluid

The only published clinical trial for the heated free fluid system was a comparison of 276 patients with dysfunctional uterine bleeding or heavy menstrual bleeding (no intracavitary or submucosal leiomyomata or endometrial polyps) treated with either the Hydro ThermAblator or with resectoscopic rollerball ablation in a 2:1 randomization scheme (18). A report in which the 3-year results were described also has been published (39). Of the 177 patients treated with the Hydro ThermAblator according to protocol, 167 were available for evaluation at 12 months and 135 were available for data collection at 3 years. At 1 year, bleeding was reduced to normal or less in 127 (94%) of these patients, with 72 (53%) experiencing amenorrhea. Each of these results was similar to those for resectoscopic electrodesiccation and coagulation (91% and 46%, respectively). At 3 years, satisfaction was high for the patients in both groups (98% for those treated with the Hydro ThermAblator, 97% for those treated with resectoscopic endometrial electrodesiccation), and hysterectomy was performed in 16 (9%) of the group treated with the Hydro ThermAblator and five (6%) of the patients treated with resectoscopic endometrial ablation. There were three repeat ablations in each group—2% of the patients treated with the Hydro ThermAblator and 4% of the patients treated with resectoscopic endometrial ablation.

Two retrospective studies have indicated that women with intracavitary myomata may have outcomes similar to women with normal cavities (40, 41), but prospective trials will be necessary to confirm such an impression.

## Microwave

The Microwave Endometrial Ablation System has been the subject of a number of high-quality randomized trials. The first published RCT involved 263 women and compared the Microwave Endometrial Ablation System with resectoscopic endometrial ablation by expert surgeons, with outcomes published at 1 (42), 2 (43), and 5 years (44). Surgical time was shorter for those treated with the Microwave Endometrial Ablation System. At 1 year of

follow-up, 116 (90%) of the 129 assigned to the Microwave Endometrial Ablation System and 124 (93%) of the 134 assigned to resectoscopic endometrial ablation were available for evaluation, with three fourths of each group satisfied with their outcome at 12 months following treatment. At 5 years, 236 (90%) of the original 263 women were available for follow-up. Bleeding and pain scores both were significantly reduced, and amenorrhea rates were similar (65% for those treated with the Microwave Endometrial Ablation System, 69% for those treated with resectoscopic endometrial ablation); however, those assigned to the Microwave Endometrial Ablation System were more likely to be satisfied with therapy than those who underwent resectoscopic endometrial ablation (86% compared with 74%).

Another RCT compared the Microwave Endometrial Ablation System to resectoscopic endometrial ablation performed by expert surgeons using rollerball electro-surgical desiccation and coagulation (19). In this trial, 322 participants were randomized to either the Microwave Endometrial Ablation System or resectoscopic endometrial ablation in a 2:1 allocation scheme. Of the 215 patients allocated to the Microwave Endometrial Ablation System, 209 were treated with the Microwave Endometrial Ablation System, with 194 available for evaluation at 1 year; of the 107 designated for resectoscopic endometrial ablation, 106 were treated, with 96 available for evaluation at 12 months. The Microwave Endometrial Ablation System treatment time was 3.45 minutes, whereas that for rollerball electrodesiccation was 20.22 minutes. At 12 months, and using intention-to-treat analysis, 87% of the patients treated with the Microwave Endometrial Ablation System and 83.2% of the patients treated with resectoscopic endometrial ablation had successful outcomes (Pictorial Blood Loss Assessment Chart scores less than 75). If only cases available for evaluation were considered (ie, only those treated according to assignment and available for evaluation at 12 months), the rate increased to 96.4% and 92.7%, respectively. The rate of amenorrhea in patients available for evaluation was 61.3% for those treated with the Microwave Endometrial Ablation System and 51% for those treated with resectoscopic endometrial ablation. At 1 year, 98.5% of the women undergoing treatment with the Microwave Endometrial Ablation System and 99% of those treated with resectoscopic endometrial ablation were either satisfied or highly satisfied with their treatment.

This trial was unique in that it included participants with submucosal myomata of up to 3 cm in diameter, provided that the myomata did not interfere with the positioning of the probe; such patients were available for subgroup evaluation. This is a similar diameter and configuration to those reported in the study on Thermo-

Choice balloon ablation (45). In the subgroup analysis of the patients treated by the Microwave Endometrial Ablation System, success, amenorrhea, and patient satisfaction rates for women with submucosal myomata did not differ from those of women with normally configured endometrial cavities without submucosal leiomyomata.

### Radiofrequency Electricity

In the RCT performed in North America (15), 265 participants were enrolled at nine clinical centers in a 2:1 randomization scheme. The resectoscopic endometrial ablation procedure was different from all of the other U.S. nonresectoscopic endometrial ablation trials to date because resection was used with subsequent electro-surgical desiccation with a rollerball electrode. At 1 year, success (Pictorial Blood Assessment Chart scores less than or equal to 75) was experienced by 88.3% of the patients treated with the NovaSure system and 81.7% of those treated with endometrial resection and ablation. The amenorrhea rates at 1 year were 41% for patients treated with the NovaSure system and 35% for those treated with resectoscopic endometrial ablation. In the first year, there were three hysterectomies in the group treated with the NovaSure system (1.3%) and two in the resectoscopic endometrial ablation cohort (2.2%). The 1-year patient satisfaction rates also were similar, with 92.8% of the patients treated with the NovaSure system and 93.9% of the patients treated with resectoscopic endometrial ablation reporting that they were satisfied or very satisfied with the outcome. Trials comparing the NovaSure system with other nonresectoscopic endometrial ablation methods will be discussed later.

The NovaSure system also has been subjected to prospective observational studies with follow-up data up to 3 (46) or 4 (47) years. Data from these studies suggest that repeat surgery rates may stay low and satisfaction rates high beyond the 12-month follow-up interval reported in the single North American RCT.

In the North American RCT, participants with polyps or submucosal leiomyomata smaller than 2 cm in diameter were allowed, but there was no subgroup analysis of patients with such lesions (15). Consequently, the efficacy of the NovaSure system in the presence of submucosal myomata, even smaller than 2 cm in diameter, remains unknown.

#### ► *How do clinical outcomes of nonresectoscopic endometrial ablation devices compare with each other?*

Although there are abundant trials comparing resectoscopic endometrial ablation with nonresectoscopic endometrial ablation techniques, there has been a rela-

tive paucity of comparative studies involving two or more nonresectoscopic endometrial ablation devices. In a review of the literature via MEDLINE and the Cochrane Database, no comparative trials were found involving the Hydro ThermAblator device or the cryotherapy system called Her Option. However, there have been trials involving the Microwave Endometrial Ablation System, the NovaSure system, and the ThermaChoice balloon ablation system.

Two double-blinded RCTs have been published comparing the radiofrequency electrosurgical endometrial ablation system, NovaSure, with thermal balloon ablation systems; however, one involved the Cavaterm system, which is not currently available in the United States (48). The RCT comparing the NovaSure system with the original ThermaChoice system (49) followed a 2:1 randomization scheme, with 83 of the 126 participants assigned to the NovaSure system and 43 to the thermal balloon ablation system. Patients assigned to the ThermaChoice system underwent preprocedural mechanical thinning of the endometrium with suction curettage. There also was a generator problem encountered with the NovaSure system controller unit that was not discovered until 44 participants had been treated. The generator was replaced and enrollment into the trial continued with clinical outcomes reported by considering both the entire treatment cohort (intent to treat analysis) and including only the patients who were randomized following replacement of the generator. The patients were monitored to 12 months postprocedure using a validated semiquantitative Pictorial Blood Loss Assessment Chart as the primary outcome. The rate of amenorrhea in the entire cohort in the group assigned to the NovaSure system was 43% (34:83) and 8% (3:43) for those assigned to the ThermaChoice system. When the patients who were treated before changing the generator were excluded, 56% of those treated with the NovaSure system experienced amenorrhea, a proportion that is consistent with the results obtained in other RCTs. For both treatment groups, therapy was generally successful, as the mean Pictorial Blood Loss Assessment Chart scores decreased to the normal range, but the magnitude of the decrease was significantly greater for the group assigned to the NovaSure system. There were four hysterectomies in each group in the 12-month follow-up interval.

#### ► *What are the reported complications associated with ablation devices?*

Both resectoscopic endometrial ablation and nonresectoscopic endometrial ablation have been associated with a number of adverse events (Table 2). Unique to resectoscopic endometrial ablation are complications related to

**Table 2.** Percentages of Postoperative Adverse Events Occurring Within Two Weeks of Nonresectoscopic Endometrial Ablation Surgery\*

Complication	ThermaChoice (Thermal Balloon)	Hydro ThermAblator (Heated Free Fluid)	Her Option (Cryotherapy)	NovaSure (Radiofrequency Electricity)	Microwave Ablation System (Microwave Energy)
Urinary tract infection	0.8	2	3	0.6	0.5
Vaginal infection	0.8	0	1	0.6	2.3
Fever	0	0	0	0	1.4
Endometritis	2.1	1	0	0	2.8
Thermal injury <sup>†</sup>	0	1	0	0	0
Abdominal pain	0	2	4	0.6	3.2
Hematometra	0	0	0	0.6	0
Bacteremia	0	0	0	0	0.5

\*Reported During U.S. Food and Drug Administration pivotal trials.

<sup>†</sup>Involving an extremity.

Sharp HT. Assessment of new technology in the treatment of idiopathic menorrhagia and uterine leiomyomata. *Obstet Gynecol* 2006;108:990-1003.

fluid overload and electrolyte disturbances, but both approaches have been associated with bleeding, injury of the cervix and vagina, and uterine perforation with potential damage to surrounding structures. Postprocedural infection as well as pregnancy, malignancy, and a painful syndrome associated with prior or concomitant tubal ligation have all been described.

### **Distention Media Fluid Overload**

Distention media are required for hysteroscopic and resectoscopic surgery and, on occasion, substantial volumes of such media can be absorbed into the systemic circulation. Such complications do not occur in association with nonresectoscopic endometrial ablation.

Standard radiofrequency electrosurgical operative hysteroscopy or resectoscopy with monopolar instrumentation requires the use of electrolyte-free, low-viscosity solutions, such as 3% sorbitol, 1.5% glycine, 5% mannitol, and combined solutions of sorbitol and mannitol, each of which, if sufficiently absorbed into the systemic circulation, will result in dilutional hyponatremia and, with the possible exception of mannitol, hypoosmolality (50, 51). These electrolyte-free fluids can result in hyponatremia, hyposmolality, subsequent brain edema, and, in some instances, permanent neurologic damage or death. Such outcomes may be more common in premenopausal women because of the inhibitory impact of estrogen and progesterone on the brain's sodium pump, making such women more vulnerable to cerebral edema (52). As a result, appropriate fluid management is critical to the safety of resectoscopic and operative hysteroscopic surgery. The development of hysteroscopic electrosurgical systems that can operate in electrolyte-rich media, such as normal saline, has provided an

opportunity to eliminate the risk of hyponatremia (53, 54), but risks of fluid overload remain.

The volume of systemically absorbed distention media may be reduced with the preoperative use of GnRH analogues (52, 55) or the immediate preoperative administration of dilute intracervical vasopressin (56) or both. There are a number of other measures that should reduce the extent of systemic intravasation, including operating at the lowest effective intrauterine pressure and avoidance of preoperative overhydration. Early detection of intravasation is enhanced by adherence to a strict fluid measurement and management protocol that is recommended to include an automated system that measures fluid inflow and captures fluid from three sources: 1) the resectoscope, 2) the perineal collection drape, and 3) the floor. Such systems allow for real-time measurement of systemic intravasation of distention media. The management of intraoperatively recognized excessive intravasation varies according to the patient's baseline medical condition, her intraoperative assessment, the status of the procedure, and the amount of measured fluid intravasation.

### **Uterine Trauma**

The uterus may be injured at the time of endometrial ablation, either with lacerations of the cervix or secondary to perforation of the corpus, an event that may be associated with damage to surrounding structures, such as blood vessels or viscera. The largest published evaluation of resectoscopic complications reflects the experience in the United Kingdom and suggests that techniques involving endometrial resection are most often associated with serious complications secondary to hemorrhage or perforation (57). This study also docu-



ments that experience is an important variable because these complications were most commonly encountered in the first 100 cases of a given surgeon.

The Cochrane systematic review showed that both cervical lacerations and perforation of the corpus were more commonly associated with resectoscopic endometrial ablation when compared with the various published nonresectoscopic endometrial ablation systems, despite the fact that, in most instances, those performing resectoscopic endometrial ablation in these trials were highly experienced. Given this information, the reported incidence of complications found in the literature from series and trials may not reflect the risk in the population at large because of the expertise and the experience of most published investigators.

The risk of cervical laceration can be reduced with the preoperative use of mechanical dilators, such as laminaria, or the use of vaginal misoprostol to soften the cervix (58). Alternatively, the injection of a low volume of a diluted vasopressin solution has been demonstrated to reduce the force required for dilation (59).

Although it is not possible to completely avoid the complication of perforation of the uterine corpus, serious complications should be minimized if the surgeon avoids advancing an activated electrode at all times. Should perforation with an activated electrode occur or if the activation status of the electrode at perforation is unknown, exploration of the peritoneal cavity is mandatory. Although laparotomy generally is the best method for evaluation of the bowel, laparoscopy may be selected in certain instances, provided there is adequate training and expertise of the surgeon.

### **Lower Tract Thermal Injury**

A number of instances of burns to the vagina and vulva associated with the use of monopolar instrumentation for resectoscopic endometrial ablation have been reported (60). These lesions appear to be the result of shorting or capacitative coupling of current to the external sheath of the resectoscope (61–64). Careful attention to technique or the use of bipolar resectoscopes should minimize the incidence of these uncommon complications (64).

### **Postablation Tubal Ligation Syndrome**

Shortly after the introduction of resectoscopic endometrial ablation, postablation tubal ligation syndrome was first described as a complication of endometrial ablation performed in women with previous tubal occlusion for purposes of contraception (65). Patients experienced cyclical pelvic pain presumably related to residual and trapped endometrium in one or both cornua. Women undergoing endometrial ablation with previous or con-

comitant laparoscopic sterilization are at low risk for the development of cyclic or intermittent pelvic pain subsequent to the procedure. The incidence of this syndrome is unclear but has been reported to be as high as 10% (66). Hysteroscopic decompression and laparoscopic salpingectomy are frequently not effective, and hysterectomy has been described as the most effective treatment (66).

### **Pregnancy**

Pregnancy following endometrial ablation can occur and has been reported (67, 68). Although a limited number of women elect to carry the pregnancy, those that do so appear to experience high rates of malpresentation, prematurity, placenta accreta, and perinatal mortality. As a result, premenopausal women undergoing endometrial ablation should be counseled that pregnancy is possible and that an appropriate contraception method should be used.

### **Endometrial Malignancy**

An early concern about endometrial ablation was the potential for delaying the diagnosis of a subsequent endometrial carcinoma. However, it appears that in most instances, an intrauterine cavity remains, allowing egress of bleeding from retained endometrium. Consequently, delay in the diagnosis of endometrial carcinoma is unlikely because of the absence of uterine bleeding.

### **Infection Rates**

The incidence of infection following the performance of endometrial ablation is low. In the randomized trials comparing treatments of nonresectoscopic endometrial ablation and resectoscopic endometrial ablation performed in North America, endometritis was diagnosed in approximately 1% of the patients in each treatment group. Such patients seemed to respond to antibiotic therapy (15–19).

### **Nonresectoscopic Endometrial Ablation Complications**

High-quality evidence from the RCTs involving nonresectoscopic endometrial ablation devices suggest that there are fewer complications with these devices, particularly with respect to distention fluid overload, cervical lacerations, perforation of the corpus and postprocedural hematometra (28).

Nonetheless, as is the case for any surgical device, complications can occur with nonresectoscopic endometrial ablation systems, and the incidence may be greater

than that suggested by published clinical trials. In a review of the FDA's Manufacturer and User Facility Device Experience database, a number of complications were reported with the use of all nonresectoscopic endometrial ablation devices on the market at that time. These complications, not previously noted in the published literature, included uterine perforation, with at least one bowel injury in three of the four reports, and one death (69). This review was published shortly after introduction of three of the devices and before the introduction of one, and, consequently, underrepresents the incidence and extent of these complications. One example is the uncommon, but occasional, thermal injury to the vagina and vulva from spilled heated fluid while using the Hydro ThermAblator system. In addition, uterine perforation and thermal injury to the bowel have now been associated with all of five nonresectoscopic endometrial ablation devices approved by the FDA for distribution in the United States.

► ***What forms of anesthesia are indicated?***

To date, most trials describing the use of nonresectoscopic endometrial ablation devices with local anesthesia include the use of parenteral conscious sedation, which precludes these procedures in most office environments. The NovaSure and ThermaChoice devices have been compared in a prospective study that suggested less pain for a shorter duration in the group assigned to the NovaSure system (70). In an RCT, treatment with the Microwave Endometrial Ablation System was performed with local anesthesia and, frequently, parenteral conscious sedation or general anesthesia (71). There was no particular advantage to the local or intravenous sedation group. Some investigators have described the successful performance of treatment with the ThermaChoice system without anesthesia (10) or with only local paracervical anesthetics and a rectal suppository containing a nonsteroidal analgesic (72, 73). Use of the Hydro ThermAblator system has been reported to be feasible with similar analgesics and intracervical or paracervical block (74).

To date, ideal regimens for using local anesthetic agents have not been determined. The fact that the cervix is innervated via the sacral S-2–S-3 nerve roots, whereas the corpus receives its nerve supply from the thoracic T-8–T-10 nerves, should be considered when designing such regimens. Paracervical and intracervical anesthesia will address only the S-2–S-3 nerve region, whereas intracavitary anesthesia with topical agents may have to be considered to address pain from the corpus (75–77). Clinicians also should consider the time required for local anesthetics to reach maximum action before performing uterine manipulations in the office setting.

► ***Can nonresectoscopic endometrial ablation be performed in the presence of uterine leiomyomata?***

Data derived from RCTs involving the Microwave Endometrial Ablation System device (19, 42, 44) and one involving the ThermaChoice device (45) support the hypothesis that these systems can be used to treat women with abnormal uterine bleeding and selected submucosal leiomyomata up to 3 cm in diameter. With these devices, bleeding and satisfaction outcomes were similar to those achieved in women with normal endometrial cavities. Lesser quality evidence is available regarding the use of both the Hydro ThermAblator (40, 41) and NovaSure devices (78).

There is a relative paucity of information regarding the use of the ThermaChoice device in women with abnormal endometrial cavities, particularly those distorted by leiomyomata. However, a randomized trial involving 93 participants compared treatment results of the use of the ThermaChoice device (under local anesthesia with conscious sedation) with resectoscopic endometrial ablation in patients with type II myomata (with less than 50% of the diameter within the endometrial cavity) that were up to 3 cm in diameter. At 1 year, bleeding outcomes were significantly and equally reduced in the two treatment groups (45). At the time of this publication, there are no available studies or trials evaluating the currently distributed ThermaChoice III system.

► ***What are the relative and absolute contraindications to endometrial ablation?***

All of the currently available nonresectoscopic endometrial ablation devices have limitations with respect to the size of the endometrial cavity and the nature and extent of anatomic distortion of the endometrial surface. Consequently, they are not recommended for use in women with endometrial cavities that exceed device limitations. Similar circumstances apply for resectoscopic endometrial ablation as well, but the manual nature of the technique may allow it to be applied to a wider spectrum of endometrial cavity sizes and configurations. Indeed, there is evidence that, at least in experienced and able hands, success rates in uteri greater than 12 gestational weeks in size may be equivalent to that of women with smaller sized uteri (79).

Table 3 demonstrates parameters such as the current limitations in both minimum- and maximum-sounded length and for the type and diameter of submucosal leiomyomata for the nonresectoscopic endometrial ablation devices currently available in the United States.

**Table 3. Nonresectoscopic Endometrial Ablation Device Comparisons**

Method	Pretreatment	Outside Diameter (mm)	Approximate Treatment Time (min)	*Sounded Uterine Length (cm)		Treatment in the Presence of Submucosal Leiomyomata			
				Minimum	Maximum	Published Evidence	Type	Diameter (cm)	U.S. Food and Drug Administration Approval
ThermaChoice (thermal balloon)	Mechanical (suction aspiration)	5.5	8	4	10	Yes (Level I)	II	Smaller than or equal to 3	No
Her Option (cryotherapy)	Gonadotropin-releasing hormone agonist	4.5	10–18	Not specified	10	None	Not applicable	Not applicable	No
Hydro ThermAblator (heated free fluid)	Gonadotropin-releasing hormone agonist	7.8	14	4	10.5	Yes (Level II-3)	I†, II	Not specified	No
Microwave Endometrial Ablation System (microwave energy)	Gonadotropin-releasing hormone agonist	8.5	2.5–4.5	6	14	Yes (Level I)	I†, II	Smaller than or equal to 3†	Yes
NovaSure (radiofrequency electricity)	None	7.2	1–2	6	10	Yes (Level II-2)	I, II	Smaller than or equal to 3	No

\*From device activation to withdrawal

†Selected

Women who have abnormal uterine bleeding and a sounded cavity length or submucosal myomata outside the parameters of the devices available to the surgeon should consider either resectoscopic endometrial ablation or alternative approaches to the clinical problem. The impact of preoperative administration of Gn-RH agonists on the sounded length of the uterus or of submucosal myoma characteristics has not been specifically evaluated.

The presence of disorders of müllerian fusion or absorption also presents obstacles to the performance of endometrial ablation, and there are no data that specifically evaluate the performance of any system in the presence of such anomalies. The impact of müllerian fusion anomalies likely differs based in part on the anomaly itself and in part on the specific device or system. For example, it would seem that septate uteri may be successfully treated using heated free fluid or resectoscopic endometrial ablation, but other devices are less likely to be successful. Given that there are no existing data regarding this issue, clinicians are encouraged to individualize the therapy of such patients.

There are a number of circumstances in which endometrial ablation should probably be avoided. Certainly, the procedure should not be performed with

recent pregnancy or in the presence of active or recent uterine infection, endometrial malignancy, or hyperplasia. Selected disorders or distortions of uterine structure may unduly enhance the risks associated with the procedure or make success unlikely. For example, extreme uterine version or flexion may make it impossible to position a device safely within the endometrial cavity. Another concern exists when areas of the myometrium are extremely thin, which may be the case in the presence of previous uterine surgery, such as abdominal or laparoscopic myomectomy, cesarean delivery (in particular classic cesarean delivery), and even with previous endometrial ablation. In such instances, there may be an increased risk of transmural thermal injury that could involve the adjacent bowel or bladder. Preoperative ultrasound evaluation of myometrial thickness is a prerequisite for the Microwave Endometrial Ablation System, with patients excluded from the procedure if any part of the myometrium is less than 10 mm in thickness. However, there is no available evidence evaluating the ability of such ultrasound myometrial evaluation to identify a group of patients with previous transmural uterine surgery who are at low risk for the use of nonresectoscopic endometrial ablation techniques.

## Summary of Recommendations and Conclusions

*The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):*

- ▶ For women with normal endometrial cavities, resectoscopic endometrial ablation and nonresectoscopic endometrial ablation systems appear to be equivalent with respect to successful reduction in menstrual flow and patient satisfaction at 1 year following index surgery.
- ▶ Resectoscopic endometrial ablation is associated with a high degree of patient satisfaction but not as high as hysterectomy.

*The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):*

- ▶ Hysterectomy rates associated with both resectoscopic endometrial ablation and nonresectoscopic endometrial ablation are at least 24% within 4 years following the procedure.
- ▶ Women undergoing endometrial ablation with previous or concomitant laparoscopic sterilization are at low risk for the development of cyclic or intermittent pelvic pain subsequent to the procedure.
- ▶ Patient satisfaction and reduction in menstrual blood flow after endometrial ablation in women with normal endometrial cavities is similar to that experienced by women using the levonorgestrel-secreting intrauterine system.

*The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C):*

- ▶ Patients who choose endometrial ablation should be willing to accept normalization of menstrual flow, not necessarily amenorrhea, as an outcome.
- ▶ Premenopausal patients undergoing endometrial ablation should be counseled to use appropriate contraception.
- ▶ Nonresectoscope endometrial ablation is not recommended in women with endometrial cavities that exceed device limitations.

- ▶ The endometrium of all candidates for endometrial ablation should be sampled, and histopathologic results should be reviewed before the procedure.
- ▶ Women with endometrial hyperplasia or uterine cancer should not undergo endometrial ablation.
- ▶ Performance of nonresectoscopic endometrial ablation in patients with prior classic cesarean delivery or transmural myomectomy may increase the risk of damage to surrounding structures. If endometrial ablation is to be performed in such patients, it may be best to perform resectoscopic endometrial ablation with laparoscopic monitoring. Safety of nonresectoscopic endometrial ablation in women with low transverse cesarean delivery has not been adequately studied.
- ▶ For resectoscopic endometrial ablation, it is recommended that a fluid management and monitoring system that provides “real-time” output of fluid balance be used.

## Proposed Performance Measure

The percentage of patients who have endometrial sampling performed and results of histopathology reviewed before endometrial ablation

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79. Eskandar MA, Vilos GA, Aletabi FA, Tummon IS. Hysteroscopic endometrial ablation is an effective alternative to hysterectomy in women with menorrhagia and large uteri. *J Am Assoc Gynecol Laparosc* 2000;7: 339–45. (Level II-2)

The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and October 2006. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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