

NEW TECHNOLOGY UPDATE

Office-based treatment of abnormal uterine bleeding

Opportunities for improved patient care and better practice management

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Recent advances in endometrial ablation

Until recently, effective surgical control of uterine bleeding depended on hospital-based procedures (most notably, hysterectomy or hysteroscopic endometrial ablation) that required extensive physician training and time for patient recovery. New global endometrial ablation technologies have expanded access to minimally invasive procedures that permit selected patients to be treated successfully in the office setting.

Office-based procedures to control abnormal uterine bleeding offer significant benefits to physicians and their patients. Clinicians do not need

extensive training. Nor is it necessary to waste time traveling from the office to the hospital or worrying about operating room scheduling; thus, Ob/Gyns can enhance the efficiency of their practice. These procedures offer clinicians opportunity to “grow” their practices by offering more services—and more choices—to patients, which contributes to patient confidence. In addition, insurance reimbursement adds to the productivity of the practice.

For patients, office-based procedures offer concrete benefits in the form of minimal discomfort and a rapid return to normal activities. Typically, patients experience a higher level of comfort and satisfaction with minimally invasive office-based

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Dr. Levy reports that she serves on the medical advisory board for American Medical Systems. Dr. Isaacson reports that he serves as a lecturer for American Medical Systems and Karl Storz Endoscopy.



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TABLE 1

Currently available endometrial ablation products

PRODUCT	KEY FACTS
Her Option <i>Endometrial cryoablation</i> AMS Gynecology • 94% 2-year success rate • 5-mm diameter probe	<ul style="list-style-type: none"> • Cryoanesthesia results in little pain for patient; IV sedation not required • Treatment time: 12 to 18 minutes • Depth of ablation: 9 to 12 mm • Ultrasound guidance provides individualized treatment and control of the depth of tissue destruction • Large uteri can be treated
ThermaChoice <i>Hot water balloon</i> Gynecare • 89% 2-year success rate • 5.5-mm diameter probe	<ul style="list-style-type: none"> • Pain from heat and intrauterine pressure • Treatment time: 8 minutes • Depth of ablation: 3 to 4 mm • Requires normal size and shape of uterus • Less likely to offer complete coverage of the endometrium
Hydro Thermablator <i>Free-flow hot water</i> Boston Scientific • 91% 2-year success rate • 8-mm diameter probe	<ul style="list-style-type: none"> • Dilation and heat necessitate anesthesia; not appropriate for office use • Treatment time: 10 minutes heat; 17 minutes total • Depth of ablation: 2 to 4 mm • Hysteroscopically guided • Reports of free-flow hot water resulting in vaginal burns • Large uteri can be treated
NovaSure <i>Bipolar mesh</i> NovaCept • 91% 1-year success rate • 8-mm diameter probe	<ul style="list-style-type: none"> • Dilation, heat, and suction require anesthesia for patient tolerance • Treatment time: 90 seconds energy time; 10 minutes total • Depth of ablation: 2 to 9 mm • No pretreatment recommended • Requires normal shape and size of uterus
MEA <i>Microwave wand</i> Microsulis • 83% overall satisfaction rate at 3 years • 9-mm diameter probe	<ul style="list-style-type: none"> • Dilation requires anesthesia • Treatment time: 5 to 7 minutes • Currently pending FDA approval • Most studied of these therapies (>2,000 cases reported in European studies)

procedures versus those that require a hospital setting.

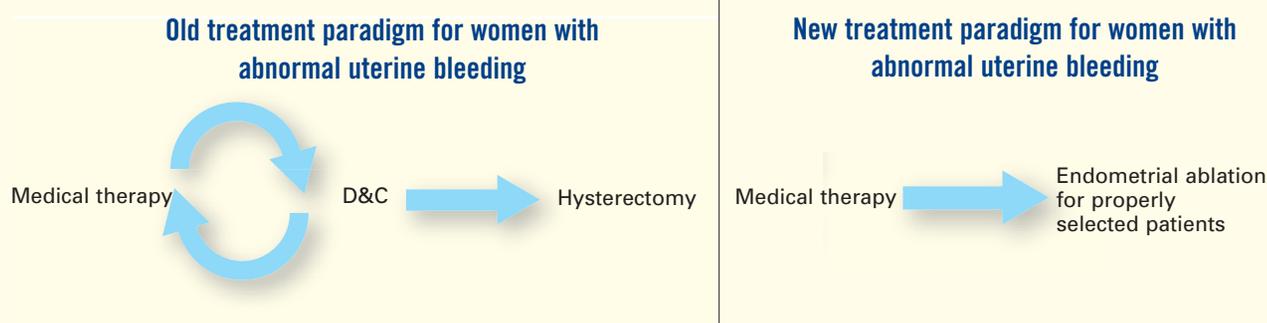
**From the hospital to the office:
A shifting paradigm
for optimal patient care**

The shift from hospital-based to office-based procedures to control abnormal uterine bleeding has taken several decades and is resulting in new paradigms for patient care (Figure 1). The move from hysterectomy to less invasive procedures began in the 1980s, with endometrial ablation using resection, the rollerball technique, and the Neodymium:YAG laser. New, so-called “global” ablation techniques have emerged over the past decade. These include the hot-water balloon, free-flow hot water, bipolar radiofrequency web, microwave, and endometrial cryoablation. These techniques are very easy to learn and to use, and they offer results comparable to endometrial resection and rollerball procedures (Table 1). Further, they provide alternatives to hysterectomy and increase options for patients who are prescribed hormonal therapy that often has little benefit. Because of the ease of use and low relative discomfort, endometrial cryoablation therapy represents the first modality appropriate for use in a standard gynecologic office setting.

**Cryoablation: The first
office-based modality
for endometrial ablation**

Approximately 100 physicians across the country perform endometrial cryoablation in the office setting. A critical factor that permits office-based endometrial ablation

FIGURE 1



is the anesthetic effect provided by cryoablation. A paracervical block provides sufficient pain control; intravenous sedation is not required (**Figure 2a**).

Surgeons interested in learning the procedure should be trained in gynecologic ultrasound and comfortable in office-based procedures (such as endometrial biopsy, loop electrosurgical excision procedure [LEEP], or hysteroscopy; or placing an intrauterine device [IUD]). The procedure itself is straightforward (**Figure 3**). One or 2 office personnel should be trained in airway management, with advanced cardiac life-support certification. An office emergency plan should be developed to manage the rare vasovagal reaction to cervical manipulation.

Cryoablation technology

Cryotherapy (Her Option, *American Medical Systems, Minnetonka, Minn*) at temperatures less than -20°C causes cell death through chemical damage or intracellular ice formation. This endometrial cryoablation technology uses the Joule-Thomson effect, in which gases under high pressure expanded through an orifice produce temperature reductions to 153°K (-120°C). The unique gas mixture produces low temperatures *and* low pressures (350 to 375 psi) to improve the safety and reliability of the system. The low-temperature gas cools the tip of the cryoprobe and transfers the refrigeration to an external object. Temperatures at the edge of the iceball (0° to -2°C) cause little to no cell destruction. Because the system is closed, high-pressure tanks are not required, and no gas is

Can the endometrium feel pain?

Sensory nerves travel to the pelvic plexus from S2, S3, and S4, entering the uterus through Frankenhauser's plexus within the uterosacral ligaments. Afferent fibers from the uterus accompany the sympathetic nerves and enter the spinal cord at T10 and T11.

Thermal injury to epithelial tissue causes a release of biologic response mediators (complement, prostaglandins, interferon, oxygen-free radicals, and histamines) from white blood cells. This acute reaction causes local pain production.

When nerves are lowered to a temperature of -20°C , nerve conduction decreases and there is a degeneration of nerve axons without destruction of the nerve architecture. The axons regrow several months later.

Source: Rogers M, Tinker J, Covenlo B, Longnecker D. eds. *Principles and Practice of Anesthesiology*. Vol. 2. New York: Mosby Year Book, 1993:1897-1899.

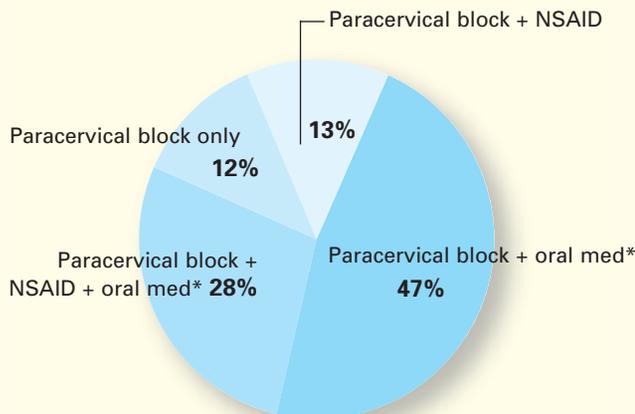
exhausted into the atmosphere. The gas mixture is nonflammable, nontoxic, noncorrosive, environmentally safe, and thus well suited for medical applications.

Outcomes with cryoablation

Cryoablation therapy requires treatment of the entire endometrium (**Figure 3**). High rates of safety and efficacy have been shown (**Table 2**). Some physicians have chosen to use alternate freeze patterns, different from those performed in clinical trials (1 4-minute freeze and 1 6-minute freeze). Most common is a 6-minute freeze in each

FIGURE 2A

Cryoablation anesthesia (n = 110 patients)⁵



*oral med = oral antidepressant/tranquilizer

FIGURE 2B

Patient tolerance of cryoablation⁵

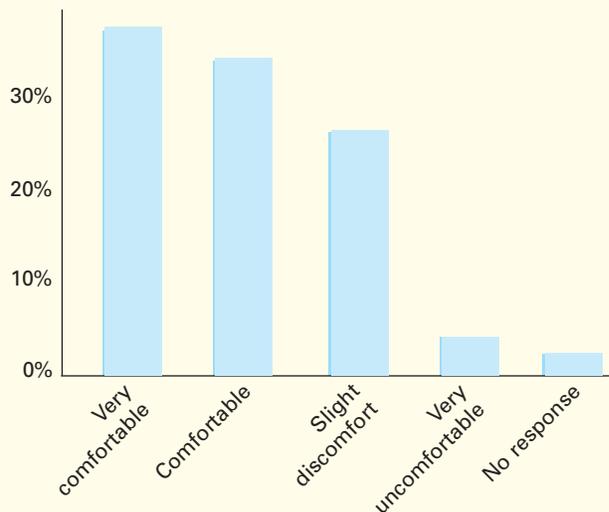


TABLE 2

Cryoablation: Key efficacy data

	24-month follow-up ¹	
	ENDOMETRIAL CRYOABLATION	ELECTROABLATION
	n = 94	n = 43
Free of AUB	94%	93%
Improved or eliminated menstrual pain	77%	81%
Very/extremely satisfied patients	91%	88%
Retreatment rate (30 month)	13%	14%

	12-month follow-up ^{2,3}	
	FULL COHORT	TOP 4 SITES
	n = 156	n = 91
Amenorrhea	28%	35%
Amenorrhea + spotting	44%	53%
Hypomenorrhea or less	85%	94%
Eumenorrhea or less	88%	94%
Menorrhagia	12%	7%

	Alternate freeze patterns ⁴		
	4X6 MIN FRZ	6X6 MIN FRZ	4X4X4 +6X6 DBL FRZ
Amenorrhea	35%	40%	45%
Amenorrhea + spotting	58%	66%	80%
Eumenorrhea or less	93%	94%	95%
Menorrhagia	7%	6%	5%

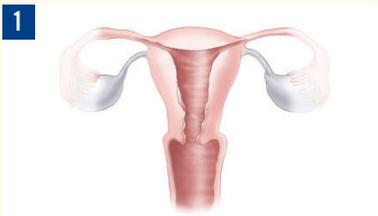
cornu. These appear to produce better results (Table 2). Uteri larger than 9 cm may be treated with additional freeze cycles in the mid fundus and lower uterine segment. Anecdotal evidence suggests good outcomes.

Amenorrhea and spotting rates 12 months post-operatively at the top 4 sites participating in the pivotal Food and Drug Administration study were 53%, while those rates using alternate freeze patterns have been reported as high as 80%. Two-year data shows 94% of patients are free of AUB compared to electroablation's rate of 93% and retreatment rates of 13% for cryoablation and 14% for electroablation (Table 2). Patient tolerance of cryoablation in the office was excellent – only 4% of patients were uncomfortable during the procedure without IV sedation (Figure 2b).

Tips for easier visualization and probe placement

In a survey of physicians using this technology, 93% found the procedure easy to learn. Its safety and efficacy have been well documented (Table 2). A number of strategies can help ensure excellent technique:

- The patient should have a full bladder so that, under ultrasound, the bladder creates a black backdrop on the uterus.

FIGURE 3**Endometrial cryoablation: A 6-step procedure****1**

Perform a paracervical block. Dilate the cervix if needed. Perform transabdominal pelvic ultrasound. Sound the uterus.

**2**

Place cryoprobe at fundus. Angle it toward 1 cornu. Visualize probe placement on ultrasound.

**3**

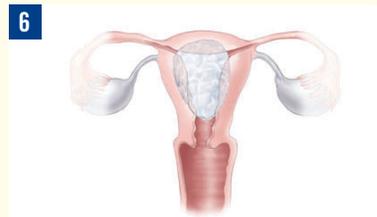
Press MINUS button to initiate freeze. Monitor CryoZone on ultrasound. Press PLUS to warm.

**4**

Remove probe to internal os and reposition toward contralateral side. Be patient to ensure probe reaches second cornu.

**5**

Press MINUS to initiate freeze. Monitor CryoZone on ultrasound. Press PLUS to warm probe.

**6**

The complete procedure should cover entire endometrium (6 min freeze = approximately 5 cm x 3 cm).

- Apply sufficient gel to ensure a good ultrasound image. Make sure that the ultrasound image lines up with the cryoprobe.
- Use ultrasound to guide probe placement and treatment progression. The longitudinal view can be used to ensure that the probe is at the appropriate depth. The sagittal view can be used to ensure proximity to the cornu.
- For obese patients, ultrasound visualization can be more difficult. Injection of saline can be used to verify probe placement by visualizing the saline flow.
- For patients with an anteverted or retroverted uterus, use gentle pressure on the tenaculum to straighten out the uterus until the ultrasound view is improved.
- When moving the probe for placement into the second cornu, patience is a virtue. If the first iceball blocks the path, it will take a minute or so for the cryoprobe to find its way through.

Remember that the heater on the tip of the probe will melt the ice and create a passage for the probe.

- To ensure good placement in the cornu, the probe should be gently touching the fundus and angled toward the patient's shoulder.
- Before starting the second freeze, always confirm placement of the cryoprobe to ensure that it has not reentered the original cryozone.

Patient selection

In selecting patients for cryoablation it is important for the clinician to first determine the cause of abnormal uterine bleeding, to rule out any contraindications, and to discuss with the patient the course of treatment most suitable for her.

■ Step 1: Take a good medical history

Ask about medications as well as over-the-counter

Questions to ask your patients about their periods

- How much are you bleeding on your heavy days?
- How long do your periods typically last?
- Is your cycle regular?
- Do your periods interrupt your daily life?
- Do you feel dirty because of your periods?
- How much time have you missed from work or social activities?
- How often are you soaking through a pad or tampon?
- Do you use double protection regularly?
- Do you have abnormal bleeding from other sites, such as gums?

Questions to ask your patients about whether they want a hysterectomy

- Is maintaining your uterus important to you?
- What are your views regarding hysterectomy?
- Do you want total elimination of bleeding or a return to a normal bleeding pattern?

Patient candidates

- Failed hormonal treatment with no desire for a hysterectomy or wants a less-invasive therapy
- In place of a D&C for a woman who has completed childbearing
- Poor surgical candidate for a hysterectomy
- Doesn't want to continue on hormones due to side effects or personal decision
- Has completed childbearing
- Willing to accept reduced bleeding rather than amenorrhea as a successful outcome
- Limited time for recovery from major surgery

products, including any oral vitamins or supplements and progesterone creams.

Evaluate whether the patient meets the clinical definition of excessive uterine bleeding:

- Cycle length less than or equal to 21 days
- Duration of flow of 7 days or more
- Blood loss per cycle greater than or equal to 80 mL of actual menstrual blood

The clinician should be aware that abnormal bleeding does not always require treatment. Normal women have abnormal bleeding in peri-

menopause. Stress and travel can contribute to abnormal bleeding.

Investigate iatrogenic causes of abnormal uterine bleeding

These can include:

- IUDs (copper and progesterone).
- Steroid contraceptives (Nor-plant, Depo-Provera, progestin-only contraceptive pills) can cause abnormal uterine bleeding and make it impossible to evaluate the patient accurately.
- Oral, transdermal, and transvaginal combined ethinyl estradiol/progesterone contraceptives.

Other agents can influence bleeding patterns. For example, phenytoin and other medications affect the body's ability to absorb and metabolize contraceptive agents. These drugs may lead to sub-therapeutic or abnormal levels, and the patient may have trouble with dysfunctional uterine bleeding.

It is important to rule out:

- Pregnancy
- Malignancy (via vaginal ultrasound and endometrial sampling)
- Infection
- Chronic endometritis
- Benign pelvic lesions (small polyps and fibroids in the endometrial cavity may be treatable by ablation)
- Systemic diseases, such as coagulopathies and hypothyroidism
- Drug interactions and effects
- Liver disease, which can affect bleeding

Step 2: Determine if bleeding is ovulatory or anovulatory

- Ovulatory bleeding is regular and associated with cyclic breast tenderness, cramping, and molimina.
- Anovulatory bleeding is irregular in timing and character.

Step 3: Evaluate reproductive tract

- Rule out cervical disease and infection for those at risk.

- Use pelvic ultrasound or office hysteroscopy to delineate uterine anatomy.

▪ **Step 4: Assess other factors specific to office procedures**

- Rule out patients who are obese or have difficult anatomy.
- Patients who have uncontrolled anxiety, pain sensitivity, or moderate systemic diseases (such as uncontrolled hypertension, arrhythmias, arteriosclerotic vascular disease, severe obstructive lung disease) are not appropriate candidates for an office-based procedure.

Preparing for an office-based endometrial ablation procedure

Equipment. Any gynecologist who does colposcopy and cervical or endometrial biopsies should have the proper equipment. This includes an emergency kit with atropine and the ability to check blood pressure and provide hemostasis for cervical lacerations.

Anesthetic control. Know your local anesthetic's maximum dose (eg, lidocaine = 4 mg/kg). (Epinephrine is not recommended because of toxicity.) To avoid the risk of overdose, draw out the maximum dosage. Know overdose symptoms: dizziness, lightheadedness, tinnitus, unconsciousness, seizure, arrhythmia, cardiac depression, and asystole. Ask about previous reactions to local anesthetics and be prepared to administer the following medications in case of a severe reaction:

- 0.5 mL adrenaline (1:1000) subcutaneously
- Clemastine 2 mg intravenously (antihistamine)
- Prednisolone sodium phosphate 25 mg intracervical
- Supportive measures

Managing complications

Various ablation techniques have shown small but varying rates of complications. As in any minor office-based procedure, certain precautions should

be taken to reduce risk. The following complications are possible in an office setting.

Vasovagal effects. Vasovagal effects are possible with any manipulation of the cervix. Treatment can include intravenous fluids and atropine 0.5 mg every 3 to 5 minutes (3 mg is total vagolytic dose). For lightheadedness a little ammonia (smelling salts) can be helpful.

Traumatic complications. Tenaculum laceration is treated by suture.

Uterine perforation. Signs are bleeding, pain, and extended length of insertion. With cryoablation, this complication is unlikely due to real-time ultrasound guidance. If it occurs, it will probably be fundal and immediately recognized. The patient will recover within 1 to 2 hours. Antibiotics are recommended.

Other complications have rarely been noted.

Patient comfort in the office setting

Patients are more comfortable if the clinician explains what will happen during and after the procedure. Knowing what to expect can alleviate much of the anxiety patients feel throughout the treatment and recovery periods. Physicians who perform office-based LEEPs or hysteroscopy will be familiar with many of these techniques:

- Provide the patient with diazepam or another relaxant and NSAIDs about 1 hour prior to the procedure.
- Provide a quiet, calm, home-like atmosphere.
- Provide a blanket and pillows to make the patient more comfortable.
- Provide soft music in the room or on headphones to calm her nerves.
- Encourage the patient to eat a light meal before the procedure so she isn't hungry.
- Encourage the patient not to void prior to the procedure so that her bladder is naturally full and a Foley is not required.
- Encourage the patient to move her legs around while the paracervical block is setting in.

Coding for endometrial cryoablation

As endometrial cryoablation challenges conventional care standards in women's health, it also poses challenges to conventional coding practices. Standard Current Procedural Terminology (CPT) codes do not adequately capture all the steps of performing Her Option, especially in the physician's office. Unlike other ablation technologies, Her Option uses cryogenics rather than thermal heat. In addition, endometrial cryoablation is the only technology that incorporates the safety of ultrasound guidance.

Pursuant to the American Medical Association's process for developing new CPT codes, Her Option was assigned 0009T. Gynecologists performing Her Option in the office setting submit a global fee. When performing an office-based procedure, 0009T should be submitted to the payer as a global fee. Initial claims require evidence of costs associated with the endometrial cryoablation procedure. A claim should specify the physician's fee, involvement of ancillary staff, ultrasound capital fee, cryogenics generator fee, disposable cryogenic hand probe unit price (invoice), and a miscellaneous office supplies charge. It is important to explain to the payer with the initial claim that a global fee is sought in order to establish the service differential in the payer's claims processing system.

With a body of compelling clinical evidence fueling continued market acceptance, the majority of payers regard endometrial cryoablation as medically necessary. As a result, Her Option is well-positioned for a Level I CPT code assignment in the very near future.

To meet the stringent standards of today's payer, American Medical Systems Gynecology Health Care Affairs department is prepared to help physicians obtain a reasonable reimbursement for Her Option in the office setting by proactively establishing its medical necessity, clinical efficacy, and cost-effectiveness with every

payer across the country. To take advantage of this service, providers are encouraged to call 866-For-Cryo (866-367-2796) for further information.

Outcomes with office-based cryoablation

Cryoablation of the endometrium for abnormal uterine bleeding brings a safe and effective treatment option into the gynecologic office setting. The unique analgesic properties of cryotherapy and the ease of use of the Her Option system enable its use in the comfortable, convenient office setting. This setting can be more efficient for the physician, saving both time and resources when compared to the hospital setting and can be a less traumatic experience for patients. Cryoablation in the office setting puts the control into the physician's hands without sacrificing outcomes.

Other innovations in operative cryotherapy for gynecologic applications are being explored as well; the most promising to date is in the treatment of uterine fibroids. Data presented at the annual meeting of the American College of Obstetricians and Gynecologists showed a mean reduction of volume of 57% at 6 months. Nearly all symptoms of the patients were eliminated at 2 weeks postoperatively. Patients' pain post-procedure was minimal, and all patients were discharged within 24 hours without narcotics.⁶

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