

4 global ablation devices: Efficacy, indications, and technique

Newer endometrial ablation technologies are easy to learn, and high efficacy rates match earlier techniques.

Endometrial tissues have amazing regenerative properties, with a controlled growth rate exceeding that of all known tumors. Within days of onset of menses, under appropriate estrogen stimulation, the endometrial surface “repairs” and “rebuilds”—from the basalis layer on up—rapidly achieving a thickness of 8 to 10 mm.

Thus, attempts to destroy it and achieve amenorrhea have met with limited success.

Hysterectomy is still the definitive treatment for excessive uterine bleeding, but a more conservative treatment, ablation, uses surgical or chemical means to obliterate the endometrial surface. Newer devices (FDA approved since 1997) allow office-based or same-day surgery; recovery time is shorter, and complication rates are lower than for hysterectomy.

This approach has gained popularity as instrumentation has improved; yet, because the endometrial surface is so resilient, success rates fall well shy of 100%. This article summarizes the data on efficacy, and describes the indications, preoperative evaluation, and technique for 4 ablation options:

- thermal balloon ablation

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- thermal fluid ablation
- cryotherapy
- impedance-controlled ablation

Other modalities include microwave, laser, and a progestin-releasing intrauterine contraception system.

Each uses a different energy-transfer technique to destroy the endometrium (TABLE).

Indications

The typical candidate for endometrial ablation has heavy menses requiring excessive sanitary protection (eg, tampon and pad simultaneously); her daily activity frequently is limited. The patient may have tried such management as nonsteroidal anti-inflammatory agents, oral contraceptives, or surgical dilation and curettage (D&C) without success.

Excessive or abnormal uterine bleeding is

KEY POINTS

- These techniques are easy to learn and use, and offer results comparable to rollerball procedures. Selected patients can be treated successfully in the office setting.
- It is vital that the patient have a reliable and permanent form of contraception, such as tubal ligation or vasectomy.
- Long-term complications, though rare, include endometrial hyperplasia and occult endometrial carcinoma.

defined as blood loss exceeding 80 mL per menses or a menstrual flow longer than 7 days. Abnormal uterine bleeding affects 22% of women of reproductive age.¹ Each year in the United States, approximately 180,000 women undergo hysterectomy for this indication.²

The optimal patient for endometrial ablation has a history of regular menses without excessive dysmenorrhea, which could suggest an underlying diagnosis of adenomyosis. (Findings suggestive of this difficult-to-diagnose condition include a tender, soft, boggy uterus at the time of menses.) Many women with adenomyosis fail to achieve adequate pain relief with endometrial ablation alone and eventually require a hysterectomy.

The patient should have completed child-bearing and have a permanent method of contraception in place—endometrial ablation only reduces fertility, it does not eliminate it.

Preoperative evaluation

Laboratory studies include a complete blood count and urine human chorionic gonadotropin level, as well as screening for bleeding disorders when indicated.

A bleeding diary helps quantify symptoms. Its use should be encouraged.

Other tests and examinations. Also recommended are endometrial biopsy, a Pap test, and assessment of the endometrial cavity via hysteroscopy or sonohysterography.

Biopsy should reflect histologically normal tissue. The patient should have:

- regular menstrual cycles lasting 25 to 34 days
- no uterine anomaly or potential myometrial wall defect from a previous classical cesarean or transmural myomectomy

Preparing the endometrium. After careful patient selection and appropriate counseling for the procedure, preoperative preparation of the endometrium may be required, depending on the technique chosen. For example, thermal fluid ablation requires pretreatment with a gonadotropin-releasing hormone (GnRH) agonist or suction curettage. The

most widely used preparation methods are hormonal treatment with GnRH agonists over 2 menstrual cycles, and suction D&C.

Contraindications

Anovulatory patients may not be good candidates because islands of endometrial tissue can remain after ablation. These tissue “nests” may spontaneously change to hyperplasia or endometrial carcinoma (due to unopposed estrogen). Further, uterine bleeding may not always occur when hyperplasia is present after endometrial ablation, delaying this serious diagnosis.

Relative contraindications include intramural or submucosal uterine myomas.

Earlier techniques:

Hysteroscopic ablation

Techniques developed earlier require expert operative hysteroscopic skills and should be performed by experienced gynecologic surgeons to minimize complications.

For example, the first treatment of menorrhagia using a hysteroscopic approach with a Nd:YAG laser power source, reported in 1981 by Goldrath et al,³ utilized 55 watts of power with a 600-micron fiber dragged across the endometrium. Later, other surgeons used a rollerball unipolar electrode that coagulated the surface with continuous contact.^{4,5}

Modifications of this technique included a loop electrode that used monopolar electrical energy to “shave” the thicker portions of endometrium. In some reports, the rollerball electrode was used to reach the uterine cornu and endocoagulate the lower uterine segments. The most successful reports of this approach used a loop electrode to shave the endometrium followed by rollerball coagulation of the shaved areas. Amenorrhea rates with these techniques approached 60%.

Thermal balloon ablation

ThermaChoice (*Gynecare, Somerville, NJ*), the first global-ablation device to be mar-

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TABLE

4 global ablation devices at a glance

	THERMAL BALLOON (THERMACHOICE)	THERMAL FLUID (HYDROTHERM-ABLATOR)	CRYOTHERAPY (HER OPTION)	IMPEDANCE-CONTROLLED (NOVASURE)
Pretreatment	Yes	Yes	Yes	No
Time of energy delivery	8 minutes	10 minutes	10–12 minutes	90–120 seconds
Cornual ablation	No	Yes	User-dependent	Yes
Principle	Balloon filled with fluid (5% dextrose in water) at 87°C	Hydrothermal circulation of saline at 90°C	Probe with transfer media creates ice ball at –100 to –120°C	Bipolar, radiofrequency ablation at 100°C
Direct visualization	None	Hysteroscopy	Ultrasound guidance	None
Safety features	Pressure and temperature-sensing cutoffs	Fluid loss detection system	Ultrasound guidance	Uterine cavity integrity assessment system

keted, was FDA-approved in 1997.^{6,7} It is a single-use balloon that is filled with fluid (5% dextrose and water) and inflated to a pressure of 180 mm Hg.

Technique. After general or regional anesthesia and prior to balloon insertion, remove the superficial endometrium by suction curettage.

The balloon contains a central heating element that warms the fluid to 87°C for 8 minutes via electronic control. Pressure within the balloon must be stabilized within the uterine cavity.

Safety features include a pressure shut-off device that activates at 210 mm Hg or higher and 45 mm Hg or below. The procedure is terminated if the temperature exceeds 95°C or falls below 75°C.

Caveats. The device may not function optimally if the cavity is irregular. In addition, it may not destroy residual and endometrial tissue in cornual regions of the uterus.

Postoperative response. Patients have reported increased uterine pain secondary to release of prostaglandins and other tissue factors that may increase uterine contractility.

What the data show. In a series of 296 patients followed for 1 year, 88% reported

decreased flow and 14% achieved amenorrhea.⁶ Meyer et al⁷ compared thermal balloon ablation with the rollerball technique and found an amenorrhea rate of 27% with rollerball and 15% with the balloon. Patient satisfaction remained high in both groups: 87% for rollerball versus 86% with the balloon.

More recently, 5- and 7-year follow-up studies have been published. At 5-year follow-up, Loffer and Grainger⁸ concluded that thermal balloon ablation therapy was an effective treatment of menorrhagia in premenopausal women, with clinical outcomes similar to rollerball ablation. Patient satisfaction was noted in 93% of women treated with thermal balloon ablation and 100% of those treated with rollerball ablation. A 7-year multicenter follow-up study of thermal balloon therapy defined avoidance of hysterectomy as the primary outcome.⁹ Overall, the probability of avoiding any surgery was 75% at 6.5 or 7 years.

Thermal fluid ablation

The HydroThermAblator (*Boston Scientific, Natick, Mass*) is similar to the balloon. It delivers heated saline at 90°C directly to the uterine cavity under hysteroscopic guidance.¹⁰ CONTINUED

This solution is circulated at gravity pressure so that it remains in the uterine cavity and does not flow out the fallopian tubes into the peritoneal cavity. Approximately 10 minutes is required for the procedure.

Preparation is via GnRH-agonist hormonal suppression or a suction D&C.

Technique. Following regional or general anesthesia, the uterus is sounded and the endocervical canal dilated sufficiently to insert the operative hysteroscope. After inspection of the uterine cavity by direct visualization via the hysteroscope/TV monitor, the tubing that delivers the heated saline is connected to the operative hysteroscope to perform the ablation. The procedure takes place under direct visualization.

Safety features include automatic shutdown if there is a 10-mL fluid loss or an increase in fluid accumulation in excess of 20 mL.

What the data show. At 12 months, 1 trial reported an amenorrhea rate of 50%, hypomenorrhea of 39%, and eumenorrhea of 5.5%.¹¹

Cryotherapy

The Her Option cryoablation system (*American Medical Systems, Minnetonka, Minn*) involves insertion of a cryoprobe into the uterine cavity, cooling it to -100 to -120°C to form an ice ball, and destroying adjacent endometrium.

Preparation is via preoperative hormonal suppression with a GnRH agonist.

Abdominal ultrasound monitoring is necessary for insertion of the cryoprobe and ice ball formation.

Technique. In some patients, multiple ice balls may be needed to thoroughly ablate the endometrial cavity, which can prolong the procedure.

What the data show. A multicenter randomized trial comparing durability of treatment effects after endometrial cryoablation versus rollerball electroablation for abnormal uterine bleeding found 94% of patients ($n = 94$) free of abnormal uterine bleeding at 24

months of follow-up, compared to 93% of rollerball electroablation patients ($n = 43$).¹²

Impedance-controlled endometrial ablation

The NovaSure device (*Novacept, Palo Alto, Calif*) consists of a hand-held, disposable, 3-dimensional ablation wand that functions as a bipolar electrode. It is constructed of gold-plated fabric mesh mounted on a metal wire frame.

Treatment time. The procedure can be completed in less than 120 seconds. Because it is so quick, this technique can be accomplished with paracervical blockade and conscious sedation in suitable patients.

Pretreatment is not necessary. The procedure can be performed any time during the menstrual cycle.

Technique. After measuring the uterine cavity with a sound, insert and deploy the wand. Because it is flexible, it will make contact with and conform to the shape of the uterine cavity. Ablation depth is controlled by tissue impedance (electrical resistance).

As the wand makes contact with the endometrial surface, tissue is vaporized, and vapors are evacuated from the uterine cavity by continuous suction—which also brings additional endometrial tissue layers into contact with the bipolar electrode. As the device reaches myometrial tissue, resistance increases to a preset threshold and the device automatically shuts down.

The ablation electrode is configured so that the ablation zone in the lower uterine segment and corneal region will not exceed 2 mm; in the miduterine cavity, meanwhile, it reaches a depth of 5 to 7 mm.

Safety features. If inadvertent perforation occurs before the treatment cycle begins, the device will not activate.

What the data show. In a large multicenter clinical trial of 265 patients followed for 12 months, 41% reported amenorrhea and 88% eumenorrhea or hypomenorrhea.¹³

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Other techniques

Microwave. Novel endometrial ablation techniques include use of microwave energies delivered to the uterine cavity via an 8-mm probe (*Microsoulis, Waterloo, UK*).¹⁴

Laser. A procedure known as endometrial laser intrauterine thermal therapy, or ELITT,¹⁵ delivers laser energy via a tri-fiber-shaped intrauterine device.

Progestin-releasing intrauterine system.

Recently, the medical treatment of excessive uterine bleeding has been advanced by the levonorgestrel-releasing intrauterine device, approved by the FDA in 2000 for intrauterine contraception. The Mirena device (*Berlex, Montville, NJ*) has a Pearl index of 0.11 and is more reliable than tubal ligation. It can induce endometrial thinning and reduce menstrual blood loss by as much as 90%. When Mirena was compared with rollerball endometrial ablation, it was more effective in reducing menstrual blood loss and had similar satisfaction rates.¹⁶ No doubt future trials will compare Mirena with the newer ablation devices.

Complications and long-term considerations

Short-term complications, which are rare, include uterine perforation, low-grade endometritis, cervical stenosis, hematometra, and pelvic infection. These problems can be minimized by giving preoperative antibiotics and reducing tissue destruction in the lower uterine segment and cervix.

Long-term complications. Development of occult endometrial carcinoma in islands of endometrial tissue is a remote possibility. The likelihood of this rare occurrence remains low if the patient is ovulatory. Once a woman transitions into menopause and desires hormone therapy, a progestin should be included in treatment to reduce the risk of endometrial hyperplasia.

Pregnancy after endometrial ablation has been reported even in the absence of significant amounts of normal endometrial tissue.¹⁷

Thus, it is vital that the patient have a reliable and permanent form of contraception, such as tubal ligation or vasectomy.

Failure rates. Long-term failure rates in women undergoing ablation are not known, but clinical trials exploring the issue are under way.¹⁸ ■

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