Endometrial Ablation for Perimenopausal Menorrhagia

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Menorrhagia and polymenorrhea are common complaints of perimenopausal women. Safe, effective, and minimally invasive endometrial ablation can be offered as a permanent non-hormonal treatment option. This article provides information on the basic diagnostic work-up of perimenopausal abnormal uterine bleeding. It also discusses the screening and counseling of patients and treatment outcomes for endometrial ablation using second-generation ablation devices.

Introduction

One of the most common gynecologic complaints of perimenopausal women is irregular uterine bleeding, which accounts for more than two-thirds of office visits. Patients present with intermenstrual spotting or heavy periods (menorrhagia), or frequent, irregular periods (polymenorrhea), due to inadequate luteal phase support and variations in progesterone production.

Classically, menorrhagia is defined as blood loss of greater than 80 mL per cycle. In practice, menorrhagia is frequently diagnosed subjectively based on the patient's perception of her own bleeding (which poorly correlates with objective measurements).[1] Compelling complaints include loss of time from work, leisure, or personal intimacy; fear of "accidents" in public; embarrassment; hassles with frequent feminine product changes; and lack of control over one's personal hygiene.

In a random phone survey of women over 40 who had completed childbearing, more than half preferred to never have another period.[2] The same survey of 1,300 women found that over 80% preferred some reduction in their menstrual bleeding, including amenorrhea. A computerized questionnaire of 234 Dutch women aged 45-65 years found that nearly all participants, including current hormone therapy users, "regarded the absence of menstruation as a relief."[3] Similar research is under way in the United States to determine the menstrual preferences of women who have completed childbearing. At any rate, practicing gynecologists are well aware of the adverse effect that heavy, lengthy, or untimely uterine bleeding can have on mid-life women.

Evaluation and Screening of Abnormal Bleeding

The cause of so-called "abnormal uterine bleeding" can be divided into four categories: organic, systemic, iatrogenic, and idiopathic. Organic causes include leiomyomata, polyps, pregnancy, malignancy, and infection. Systemic problems include intrinsic coagulation disorders, as well as thyroid, liver, and renal disease. Iatrogenic influences, such as use of anticoagulants, tamoxifen, glucocorticoids, and steroid hormones, as well as copper-containing intrauterine devices and certain herbal remedies, must be ruled out. If no obvious cause is identified, the disorder is considered idiopathic and termed dysfunctional uterine bleeding (DUB). DUB is thought to be caused by the unpredictable and erratic response of the endometrium to alterations in hormone function. DUB often is the result of anovulatory cycles and inadequate progesterone support leading to destabilized endometrial glands and stroma.

Gynecologists often have only one or two visits to see and plan therapy with these patients. However, the necessary preoperative work-up and therapy can be accomplished within this restraint. During the initial visit, a careful history and physical often will narrow the cause of bleeding. With a detailed menstrual history, including length of flow, number of pads/tampons used per day, and the degree of pad saturation, the impact of bleeding on the patient's life can be qualified during a visit. Necessary laboratory and imaging studies can be performed and ordered at the same time. Full counseling regarding the medical and surgical options can be discussed and a general plan also can be adopted then.

Laboratory studies that may be ordered at the first visit include a urine pregnancy test, complete blood count (CBC) with differential and platelet count, protime (PT) and partial thromboplastin time (PTT), a highly sensitive thyroid-stimulating hormone (TSH) level, and a prolactin level. The CBC with differential can determine the presence of anemia, suggest infection, and

rule out thrombocytopenia. Coagulation studies will be abnormal in patients with liver or renal diseases and in patients with intrinsic coagulation defects.

If thyroid disease is suspected from the evaluation, an abnormal TSH can confirm the diagnosis; and a full thyroid panel may be ordered. In patients with abnormal cycles, a prolactin level is indicated to rule out pituitary adenoma. Serum follicle-stimulating hormone (FSH) levels and luteinizing hormone (LH) levels are not reliable measures of ovulatory function in the perimenopause. Although elevated levels of both FSH (>20 IU/L) and LH (>30 IU/L) imply ovarian failure in a menstruating perimenopausal woman, fluctuations are known to occur; and sporadic ovulation may result in unintended pregnancy.

If an endometrial biopsy (EMB) has not been done within the last six months, it should be performed prior to treatment and can be done at the time of the initial consult. Conservative therapy requires the absence of endometrial malignancies or premalignant conditions such as hyperplasia with atypia. It is not usually necessary to give prophylactic antibiotics for an EMB, but a cervical prep with a sterilizing solution should be performed.

A normal pap smear within the last year also is important. However, pathology studies suggest fewer than 10% of perimenopausal patients have endometrial hyperplasia or endometrial cancer; and approximately 20% of patients with endometrial carcinoma will have classic risk factors, including obesity, hypertension, diabetes mellitus, and chronic anovulation.[4]

The presence of leiomyomata, and intracavitary polyps can be evaluated with transvaginal sonography (TVS) or saline infusion sonography (SIS).[5] A triage study published in 1997 by Goldstein et al concluded that unenhanced TVS with a homogeneous, bilayer endometrium (≤5 mm early in the proliferative phase) is highly correlated with lack of significant uterine pathology. If TVS suggests a lesion or the lining is >5 mm, or poorly visualized, SIS should be performed. Approximately 40% of patients triaged this way have no abnormality on SIS. If an abnormality is found, the lesions are most often polyps, followed by submucosal fibroids, proliferative thickened endometrium, and hyperplasia.[6] Offices equipped for hysteroscopy can directly evaluate the endometrial cavity for lesions and perform directed biopsy. Adequate imaging of the uterine cavity is important in choosing therapy. If a lesion is found, it may require hysteroscopic removal prior to endometrial ablation. Small intramural (<4 cm) or subserosal fibroids are unlikely to effect the performance of endometrial ablation. Due to an increased risk for malignancy, polypoid lesions should be directly biopsied prior to an ablation.[7]

Therapy for Dysfunctional Uterine Bleeding

Therapy for dysfunctional uterine bleeding is either medical or surgical. Because the physiology of DUB is usually hormone-based, traditional teaching has been to exhaust medical therapies prior to surgery. However, many perimenopausal women are either intolerant of progestin or combination estrogen and progestin therapy (EPT), have contraindications to their use, or refuse to take daily hormone medication due to forgetfulness, fear of hormone preparations, or inconvenience. Most patients actually prefer hormone options that can significantly reduce or eliminate the bleeding. Some such options include continuous low-dose (20 mcg or less of ethinyl estradiol) oral contraceptives, the patch (Ortho Evra), the vaginal ring (NuvaRing), or the progestin releasing IUD (Mirena). The clinical experience of many gynecologists is that patients' disdain for daily hormone therapy grows as they complete their childbearing and undergo tubal sterilization. For these patients, highly effective, low-risk, relatively inexpensive endometrial ablation therapies offer new alternatives for treatment. However, women who are not candidates for endometrial ablation, and in whom medical therapy is not a possibility, should be offered hysterectomy.

Patient Considerations

Women who elect to have endometrial ablation must have an accessible uterine cavity, documented benign endometrial and cervical evaluation, (preferably within 3-6 months), and no future childbearing plans. Sterilization of the patient or her partner is preferred, but other methods of contraception are acceptable if used reliably. Patients with cavity-distorting uterine fibroids were not included in any of the pivotal trials of the endometrial ablation devices on the U.S. market. Reports of success with some devices in patients with submucosal fibroids and polyps abound, but patients with these lesions should be advised that outcome data are lacking in these circumstances. Patients also must understand that complete amenorrhea is the exception, not the rule, for the ablation devices on the market. Setting realistic expectations for treatment outcome will help to improve patient satisfaction.

Device Options

Currently, four endometrial ablation devices are available in the United States (Table 1). Because they have been offered as an alternative to roller-ball and transcervical resection of the endometrium (TCRE), they have been classified as "second-generation" endometrial ablation technologies. The choice of ablation method depends on several factors. Familiarity with the device should not be a major issue since all of the devices are simple to operate and can be performed with minimal instruction. Availability of a device in one's office or preferred surgical site will narrow the options further. Device characteristics are presented in Table 2.

Endometrial ablation usually is performed in an outpatient surgical site.

Table 1.
FDA-Approved Endometrial Ablation Devices

- ThermaChoice , Uterine Balloon Therapy System, GyneCare, Inc. Ethicon, Inc. A Johnson & Johnson Company, Menlo Park, CA
- Hydro ThermAblator Endometrial Ablation System, BEI Medical Systems, Inc., Boston Scientific, Teterboro, NJ
- Her Option Uterine Cryoblation Therapy System, CryoGen, Inc., American Medical Systems, San Diego, CA
- NovaSure Impedance Controlled Endometrial Ablation System, Novacept, Inc., Palo Alto, CA

Endometrial ablation devices have been used in the office setting and can offer convenience for surgeon and patient alike. Physicians who are comfortable with operative hysteroscopy may elect to complete the ablation with roller-ball or TCRE, especially if these instruments had been required for the resection of a cavity-distorting lesion, rather than combining the procedure with a disposable ablation device.

The Procedure

A successful ablation is primarily the result of an informed and comfortable patient. Adequate patient preparation involves many factors and begins with an effective preoperative counseling session in which expectations are outlined. The physician should encourage the patient to talk with family and friends, investigate device Web sites and outcome data, and ask any questions prior to deciding to undergo the procedure. All of this information gives the patient confidence and control over her decision. Following the initial consult and recommendation for ablation, the patient can go home, make her therapy decision, and then schedule the ablation if she so chooses.

The physician's office can draft an informed consent form and give this to the patient during initial consultation. This document should detail the risks of the procedure, the normal and abnormal operative and postoperative symptoms, the expected outcomes, and long-term risk of post-ablation pregnancy.

Anesthesia for second-generation ablation procedures may be general, regional, or local, with or without sedation. The appropriate anesthetic choice will depend on patient and physician preferences, medical issues, and the type of procedure that is planned. For a simple diagnostic hysteroscopy followed by an ablation, we prefer local anesthesia with minor sedation. This can be accomplished in the operating room or the office with an oral or rectal preoperative non-steroidal anti-inflammatory drug (NSAID) such as ibuprofen 800 mg, a minor benzodiazepine (Ativan 0.5 mg or Valium 10 mg), and a generous paracervical block.

The ablation procedure begins by properly positioning the patient in the dorsal lithotomy position, (thigh stirrups are preferred), followed by bimanual examination that confirms the position of the uterus. Speculum placement allows visualization of the cervix. A sterile prep is then performed, followed by a paracervical block. We prefer

Table 2.
Device Characteristics

Approved Device	Technology	Probe Size	Treatment Time	Approximate Procedure Time
ThermaChoice[9]	Silicone balloon with circulating heated saline (87°C) at a pressure of 160 mm Hg	5.0 mm	8 minutes	20-30 minutes
Hydro ThermAblator[10]	Free heated saline (90°C) at pressure of 50 mm Hg with direct hysteroscopic visualization	7.8 mm	10 minutes	20-30 minutes
Her Option[11]	Metal tipped probe placed into each cornu; cools to -90°C and generates cytotoxic freeze zone	5.5 mm	10-15 minutes	15-30 minutes
NovaSure[12]	Bipolar thermal energy (90°C) delivered through inverted triangular fabric array, impedance controlled	8.0 mm	1- 2 minutes	10-15 minutes

2% lidocaine without epinephrine, approximately 3-5 cc injected in the anterior cervical lip and an additional 2.5 cc injected intracervically, while withdrawing the needle at 3 and 9 o'clock, approximately 7 mm deep to the endocervical glands. Athough a deviation from the standard lateral fornix technique to anesthesize the nerve in the uterosacral ligament, it is hypothesized that this technique targets the nerve endings directly—especially at the isthmus—and provides a superior block.

A single-tooth tenaculum then is placed on the anterior lip of the cervix and the uterus is sounded. Dilation is performed to accommodate the ablation device's disposable applicator. Device disposables range from 5-8 mm in diameter (Table 2). Manual or electric suction aspiration may be performed, if indicated, at this point. The procedure specific to the chosen device then is initiated for completion of the therapy.

All ablation devices have been used in an office setting, but the smaller-diameter disposables—and technology that minimizes the expansion or retraction of the uterine muscle—are more likely to be comfortable for the patient. A small, randomized, Novaceptsponsored comparison of intraoperative and postoperative pain scores between the NovaSure and ThermaChoice was published recently. All patients received similar anesthesia with preoperative NSAID suppository, a paracervical block, and fentanyl sedation for the ablation. The study found that those treated with NovaSure reported statistically significantly less intraoperative and postoperative pain than those treated with ThermaChoice.[8] If office ablation is available, outpatient surgery can be reserved for patients who need an operative hysteroscopy for directed biopsy or cavitary lesion removal.

Following the ablation, the patient is observed in the recovery room or office for 30-60 minutes and then discharged. Post-procedure pelvic cramping and pain are common, but usually limited to 24-48 hours. Most patients benefit from scheduled NSAIDs in the immediate post-procedure period. These individuals should expect bloody vaginal discharge immediately after the procedure. This discharge will become profuse and watery over time and can last up to six weeks for some patients.

Outcomes

Table 3 lists one-year results after ablation for each device.[9-12] All of the devices have similar outcomes for improvement of bleeding and amenorrhea. Patient satisfaction with therapy also is very high for all procedures. In the Hydro ThermAblator trial, an indicator of satisfaction was not measured, but quality of life measures showed marked improvement in ability to work outside the home and participate in leisure activities. All of the device trials report a significant improvement in dysmenorrhea.

Physicians should inform patients about expected outcomes for the device used. In general, about one-fourth of patients will achieve amenorrhea. Reduction to normal or below normal levels of bleeding occurs in the majority of patients. However, a failure rate of 10-15% is seen with the second-generation devices and is likely related to the presence of adenomyosis, undiagnosed organic or systemic pathology, or a sub-therapeutic ablation.

Procedure Risks

The risks of endometrial ablation are extremely low. However, fully informed consent should include a discussion of the potential risks, including cervical laceration, uterine perforation, and thermal injury to the surrounding structures (ie, bladder, bowel, cervix, and vagina). However, it is worth noting that fewer than 3% of patients will experience postoperative infection, hematometria, or severe pelvic cramping. Post-ablation hemorrhage is extremely rare. All of the ablation devices have safety measures to minimize the risk of device activation if a uterine perforation has occurred.

Longer-term risks include post-ablation pregnancy and a syndrome known as post-ablation tubal sterilization syndrome (PATSS). A review of all published post-ablation pregnancies (following roller-ball and TCRE) found an occurrence rate of 0.65% with a 50% major morbidity risk to either the mother or the fetus.[13] Physicians must strongly caution patients to use effective birth control if they are at risk for pregnancy. In fact, permanent sterilization for the patient or her partner is preferred.

PATSS is estimated to occur in 8–10% of patients who have had a tubal sterilization prior to an ablation.[14,15] Most of the data for PATSS are in patients who have had roller-ball or TCRE with incomplete resection of cornual endometrium. If the ablation results in distal scarring of the endometrium and blockage of the lower uterine segment, build-up of menstrual

Table 3.
Ablation Device Outcomes at One Year
(All data reflect evaluable patients only. All rates are rounded to whole numbers.)

Device	Hypomenorrhea or less (%) (success)	Amenorrhea	Satisfied or very satisfied (%)
ThermaChoice	80	13	96
Hydro ThermAblator	77	40	Not reported
Her Option	75	25	97
NovaSure	87	40	92

blood may lead to cyclic painful dilation of the cornua.[16] If this is suspected, an MRI can help confirm the diagnosis; and a hysterectomy or laparoscopic proximal resection of the tube and cornua will be curative. There are little data for this syndrome in second-generation ablation procedures. Post-hysteroscopic views of the uterine cavity after Her Option cryotherapy have demonstrated less endometrial scarring than that seen with ThermaChoice.[17]

A concern regarding occult post-ablation endometrial carcinoma has been raised in the literature.[18] However, only a handful of endometrial cancer cases have occurred after ablation; and the majority of those patients had abnormal bleeding as their presenting symptoms. Additionally, none of the patients were diagnosed late in their disease process, and all had known risk factors for endometrial carcinoma.[13] Proper selection of patients and documented benign endometrial histology is sufficient to prevent complications. If a patient has abnormal bleeding post-ablation, further work-up and therapy are required.

Costs and Coding

The cost of endometrial ablation depends on whether it is performed in an operating room or an office setting. For outpatient surgical cases, the usual CPT physician services codes are for a visualized (with hysteroscopy) procedure (CPT 58563, 6.17 RVUs) and non-visualized procedure (CPT 58353, 3.54 RVUs). Diagnostic hysteroscopy often is performed before the ablation procedure, permitting the 58563 code. The disposables are billed as miscellaneous supplies (CPT 99070) by the facility.

When this procedure is performed in the office, physicians must contract separately with each provider for reimbursement for the professional service, disposable cost, controller cost, personnel costs, and supplies. The average list prices for the disposable units are: $650.00 for the ThermaChoice and Hydro ThermAblator, $850.00 for the NovaSure, and $1,200.00 for the Her Option disposable. The non-disposable controllers range from approximately $10,000 to $30,000, depending on the device.

Some of the manufacturers, such as Cryogen, Inc. (subsidiary of American Medical Systems), have obtained a unique procedure code to make billing more accurate and financially practical for physicians and surgical centers. Each ablation manufacturer has its own program for physicians who would like to begin to offer ablation services either in the office or in an operating room.

Conclusions

Heavy and untimely menstrual cycles are a predominant complaint in the perimenopause.[19] After a thorough work-up, physicians can offer many patients with benign endometrium and minimal uterine cavity distortion treatment with endometrial ablation as a first-line alternative to medical therapy. Patients can anticipate minimal operative discomfort, quick recovery, a 75–87% chance of achieving hypomenorrhea, and a 13–40% chance of amenorrhea. Longer-term outcomes are emerging as the technologies develop some historical data. The Food and Drug Administration requires device manufacturers to collect clinical trial data for three years post-procedure. Importantly, the physician should discuss long-term risks of post-ablation pregnancy and PATSS with the patient and obtain extensive informed consent for this elective procedure. All of the approved devices offer similar outcome rates and costs associated with use. Choosing a device is based on personal preference and perceived patient tolerance in the office setting or operating room. ■

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References

1. Chimbira TH, Anderson AB, Turnbull A. Relation between measured menstrual blood loss and patient's subjective assessment of loss, duration of bleeding, number of sanitary towels used, uterine weight and endometrial surface area. *Br J Obstet Gynaecol.* 1980; 87(7):603-9.

2. den Tonkelaar I, Oddens BJ. Preferred frequency and characteristics of menstrual bleeding in relation to reproductive status, oral contraceptive use, and hormone replacement therapy use. *Contraception.* 1999;59(6):357-62.

3. Barentsen R, Foekema HA, Bezemer W, van Stiphout FL. The view of women aged 45-65 and their partners on aspects of the climacteric phase of life. *Eur J Obstet Gynecol Reprod Biol.* 1994;57(2):95-101.

4. Sulak PJ. Endometrial cancer and hormone replacement therapy. Appropriate use of progestins to oppose endogenous and exogenous estrogen. *Endocrinol Metab Clin North Am.*1997;26(2):399-412.

5. Indman, PD. Abnormal uterine bleeding. Accuracy of vaginal probe ultrasound in predicting abnormal hysteroscopic findings. *J Reprod Med.*1995;40(8):545-48.

6. Goldstein SR, Schwartz, LB. Evaluation of abnormal vaginal bleeding in perimenopausal women with endovaginal ultrasound and saline infusion sonohysterography. *Ann NY Acad Sci.* 1997;828:208-12.

7. Anastasiadis PG, Koutlaki NG, Skaphida PG, et al. Endometrial polyps: prevalence, detection, and malignant potential in women with abnormal uterine bleeding. *Eur J Gynaecol Oncol.* 2000;21(2);180-83.

8. Laberge PY, Sabbah R, Fortin C, Gallinat A. Assessment and comparison of intraoperative and postoperative pain associated with NovaSure and ThermaChoice endometrial ablation systems. *J Am Assoc Gynecol Laparosc.* 2003;10(2):223-32.

9. Summary of Safety and Effectiveness Data: Thermachoice Uterine Balloon Therapy System. Gynecare, Inc. United States Food and Drug Administration Center of Devices and Radiologic Health; 1997. PMA P970021.

10. Summary of Safety and Effectiveness Data: Hydro ThermAblator Endometrial Ablation System. BEI Medical Systems Company, Inc. United States Food and Drug Administration Center of Devices and Radiologic Health; 2001. PMA P000040.

11. Summary of Safety and Effectiveness Data: Her Option Uterine Cryoablation Therapy System. Cryogen, Inc. United States Food and Drug Administration Center of Devices and Radiologic Health; 2001. PMA P000032b.

12. Summary of Safety and Effectiveness Data: NovaSure Impedance Controlled Endometrial Ablation System. Novacept, Inc. United States Food and Drug Administration Center for Devices and Radiologic Health; 2001. PMA P010013.

13. Roy, KH, Mattox, JH. Advances in Endometrial Ablation. *Obstet Gynecol Surv.* 2002; 57(12):789-802.

14. McCausland AM, McCausland, VM. Frequency of symptomatic cornual hematometra and postablation tubal sterilization syndrome after total rollerball endometrial ablation: a 10-year follow-up. *Am J Obstet Gynecol.* 2002;186(6):1274-80; discussion 1280-83.

15. Bae IH, Pagedas AC, Barr CA, et al. Postablation-tubal sterilization syndrome. *J Am Assoc Gynecol Laparosc.* 1996;3(3):435-38.

16. Townsend DE, McCausland V, McCausland A, et al. Post-ablation tubal sterilization syndrome. *Obstet Gynecol.* 1993;82(3):422-24.

17. Townsend, D. Post hysteroscopic evaluation of cryotherapy versus thermal balloon. Presented at: The 50th Annual Meeting of the American College of Obstetricians and Gynecologists; May 4-8, 2002; Los Angeles, CA.

18. Brooks Carter GN, Killackey MA, Neuwirth RS. Adenocarcinoma of the endometrium after endometrial ablation. *Obstet Gynecol.* 2000;96(5 Pt 2):836-37.

19. Cooper KG, Parkin DE, Garratt AM, Grant AM. A randomised comparison of medical and hysteroscopic management in women consulting a gynaecologist for treatment of heavy menstrual loss. *Br J Obstet Gynaecol* 1997;104(12):1360-66.