



UPDATE:

Options in Endometrial Ablation

- Introduction: Nonresectoscopic endometrial ablation devices

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- Hydro ThermAblator® (HTA) System: Requires no uterine manipulation, provides direct visualization

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- Gynecare ThermoChoice® Uterine Balloon Therapy System: Minimal dilation and technical changes for enhanced coverage

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- NovaSure® System Bipolar Radio Frequency Technology: Impedance-based ablation technology

Padmavathy Tummula, MD

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Disclosures

Dr Sanfilippo reports that he is a consultant to Bayer HealthCare.

Dr Glasser reports that he is a consultant to and is on the speakers bureau of Boston Scientific.

Dr Munro is or has been a consultant to AMAG, Inc., Bayer HealthCare, Boston Scientific Inc, Covidien PLC, Ethicon Women's Health & Urology, Gynesonics, Inc, Hologic, Inc., Impres Medical, and Karl Storz Endoscopy-America, Inc.

Dr Tummula has previously served as a paid consultant to Hologic, Inc.

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INTRODUCTION

Nonresectoscopic endometrial ablation devices

Joseph S. Sanfilippo, MD, MBA, Editor

Professor
Department of Obstetrics
and Gynecology
University of Pittsburgh
Vice Chairman of Reproductive
Sciences
Magee-Womens Hospital
Pittsburgh, Pennsylvania

Disclosure

Dr Sanfilippo reports that he is
a consultant to Bayer HealthCare.

This monograph serves as an update to the 2005 publication, “Options in endometrial ablation,” which provided brief overviews of nonresectoscopic technologies that accomplish endometrial ablation (EA) by tissue freezing, radio frequency electricity, microwaves, and heated fluid.

EA represents a viable option for women who experience menorrhagia and have completed childbearing or who plan not to become pregnant. It provides an alternative to hysterectomy, which is associated with significant rates of major and minor postoperative complications and lengthy recovery.

This update describes new data and details the experience of individual gynecologic surgeons regarding the use of 3 EA technologies: the HydroThermAblator® (HTA) System, the Gynecare ThermoChoice® Uterine Balloon Therapy System, and NovaSure® System Bipolar Radio Frequency Technology. Gynecologic surgeons describe the current evidence on the safety and effectiveness related to these commonly used EA technologies, with an emphasis on in-office use. They also review reports in the medical literature concerning:

- Desired outcomes (eg, normal menstrual bleeding, amenorrhea, or reduced pain)
- Complication rates and patient satisfaction
- Benefits of performing EA as an office procedure
- Procedure coding
- Practice pearls, with tips to enhance procedure success, ease of use for the physician, and comfort for the patient

Important options for gynecologists and their patients

Given the long-term clinical experience with these devices, the continued improvements made by manufacturers, and the relative ease in learning these techniques compared with earlier methods (eg, laser treatment, resectoscopic procedures, and transcervical resection), nonresectoscopic systems give gynecologists a means of offering patients an effective treatment for EA in the office, while requiring minimal intervention for pain control and avoiding complications often associated with earlier procedures.¹

When patients are carefully selected, these interventions also produce high rates of patient satisfaction (TABLE).

Patient selection

When dire causes of excessive uterine bleeding and contraindications to EA have been ruled out, clinicians should understand patients' desired outcomes and counsel them accordingly on the appropriateness of undergoing EA. Although candidates for these procedures have decided to forgo further childbearing, not every woman wants cessation of menses. For such individuals,

TABLE

Patient satisfaction rate, amenorrhea rate, and percentage with reduced dysmenorrhea associated with nonresectoscopic endometrial ablation at 12 months

Device	Satisfaction rate (%)	Amenorrhea rate (%)	Diary success (score ≤ 75) (% patients)	Reduced dysmenorrhea (% patients)
Her Option ¹	86	22	67	76
Hydro ThermAblator ²	—	35.3	68.4	—
Microwave Endometrial Ablation System ³	99	55.3	87	63
NovaSure ⁴	93	36	77.7	63
ThermaChoice III ⁵	96	37	81	89

1. Her Option. Instructions for use. Minnetonka, MN: American Medical Systems, Inc; 2006.

2. Hydro ThermAblator System (HTA). Instructions for use. Natick, MA: Boston Scientific Corporation; 2005.

3. Microwave Endometrial Ablation System. Instructions for use. Hampshire, UK: Microsulis; 2002.

4. NovaSure. Instructions for use. Marlborough, MA: Hologic, Inc.; 2008.

5. Gynecare ThermaChoice III. Instructions for use. Somerville, NJ: ETHICON, Inc., a Johnson & Johnson Company; 2008.

EA could be an appropriate choice. If, however, a woman's goal is amenorrhea, hysterectomy is the only reliable option. Although amenorrhea rates with EA techniques range roughly between 20% and 50%, it is difficult to predict with certainty which women will achieve amenorrhea.

Careful assessment of the size and configuration of the uterus is also important. Each device is designed for use in women with specific uterine anatomies. As a prerequisite to ablation, a complete history and physical examination, including pelvic examination, should be done. The surgeon should review Papanicolaou smear results, conduct ultrasound examination of the uterus, and evaluate endometrial sampling to rule out hyperplasia or malignancy, as indicated.²

The procedure is typically performed with use of paracervical block and conscious (moderate) sedation. The US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database review¹ of complications indicates that serious complications associated with these devices, although rare, are usually associated with use in patients for whom a specific product is contraindicated. Clinicians must carefully evaluate each patient and consider the specifications of each device on a patient-by-patient basis. Additionally, in some women with a previous cesarean delivery, the incision site may be thin

and could increase the risk for complications. Prophylactic antibiotics also may be useful but are not mandatory.

Long-term results indicate that with use of EA, hysterectomy is avoided in 86% of women. Uterine position plays a role, with the retroverted uterus having the lowest success rate, at 61%, and anteversion having the highest success rate, at 80%.³

Physician training

Surgeons interested in learning EA procedures should have experience in gynecologic ultrasound and basic procedures, such as endometrial biopsy or cervical loop electrosurgical excision. Hysteroscopic visualization is required for several ablative procedures. Office personnel should be trained in airway management, with advanced cardiac life-support certification. They should be able to manage the rare vasovagal reaction to cervical manipulation.

Conclusions

I hope that you will find the material presented in this publication of interest and that it will provide you with useful information to enhance patient care with advanced technologies. Significantly, EA represents an opportunity to expand physician management alternatives and provide better outcomes for patients.

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Hydro ThermAblator® (HTA) System: Requires no uterine manipulation, provides direct visualization

Mark H. Glasser, MD

Chief Emeritus
Department of Obstetrics
& Gynecology
Kaiser Permanente
Medical Center
San Rafael, California

Disclosure

Dr Glasser reports that he is a consultant to and is on the speakers bureau of Boston Scientific.

The Hydro ThermAblator (HTA) System, approved by the US Food and Drug Administration (FDA) in 2001, is the only nonresectoscopic ablation device that allows the procedure to be performed under direct hysteroscopic control. Using a rigid 3-mm hysteroscope inserted in a sterilized disposable 8-mm sheath, the operator fills the uterus with a 0.9% saline solution (**FIGURE 1**). The solution circulates by gravity at a low pressure of 50 to 55 mm Hg, thus avoiding leakage into the fallopian tubes, which have an opening pressure of 70 mm Hg. The physiologic saline solution is heated to 90°C and circulates for a total of 10 minutes to achieve its ablative effects. The system is microprocessor-controlled and automatically stops the procedure when it detects a 10 mL fluid loss. The system cannot be manually overridden, making it impossible to continue the procedure in the event of a uterine perforation.

PRACTICE PEARL: Clinicians may wish to keep in mind that pain fibers and baroreceptors in the myometrium respond to stretching of the uterus as a result of distention and to contact with the uterine walls—but they are only minimally responsive to electrical stimulation, heat, or cold. The absence of uterine manipulation or high-pressure distension associated with this device optimizes patient comfort during the procedure and makes it suitable for in-office use as well.

Significant impact on bleeding rates

The pivotal study submitted to the FDA in 2001 compared results of endometrial ablation conducted with HTA on 187 women and with rollerball (RBA) on 89 women. Patients kept diaries and self-reported on decreased menstrual bleeding at 2 weeks and at 3, 6, and 12 months following the procedures.¹ Treatment success, defined as menstrual diary scores of 75 or less, was achieved in 77% of the HTA group and in 82% of the RBA group. At 12 months, the amenorrhea rate was 40% for HTA and 51% for RBA. These patients were interviewed again at 24 and 36 months.² At 36 months, rates among the HTA group for amenorrhea and reduction of bleeding to normal levels or less were 53% and 94%, respectively. Among the RBA group, the rates for these same outcomes were 46% and 91% (**FIGURE 2**).

A recently reported review of 710 women whose menorrhagia was treated with HTA over 7 years showed an overall success rate of primary ablations of 70% and a success rate of 50% for repeat ablations. Ten percent of the patients underwent hysterectomy for their abnormal bleeding, for a hysterectomy prevention rate of 90%.³

One surgeon's experience: series of 246 patients. I have performed several hundred in-office endometrial ablations and have recently reported on a series of 246 patients, done under minimal oral sedation and paracervical/intracervical block.⁴ Of the 231 patients in the analysis, 121 (53.4%) reported

amenorrhea, 62 (26.8%) reported light menses or spotting, 21 (9.1%) reported normal menses, 15 (6.5%) reported menorrhagia, and 12 (5.2%) had hysterectomy for bleeding.

The failure rate, defined as patients with menorrhagia or undergoing hysterectomy for bleeding, was 11.7% overall. All of the hysterectomy patients had multiple fibroids, and 9 of the 11 (81.8%) also had adenomyosis. Another 13 patients underwent repeat ablation, and 11 of those 13 has successful outcomes.⁴ Therefore, in the rare instance of an unsatisfactory outcome, HTA can be repeated successfully, since there are very few intrauterine synechiae formed after the initial procedure.

Patient satisfaction with HTA

In the study submitted to the FDA and its follow-up research report,^{1,2} the investigators also recorded quality-of-life (QOL) measurements before treatment and at 12 months after treatment as well as patient satisfaction at 12, 24, and 36 months. QOL scores for the HTA and rollerball groups before treatment were 53.5 and 51.2 respectively. These improved dramatically to 9.3 for both groups after treatment.¹ At 24 and 36 months following treatment, patient satisfaction was 98% and 97%, respectively.²

The Ruta score for health-related quality-of-life impact of uterine bleeding focused on hydrothermal ablation has proven that this method of ablation is effective for abnormal uterine bleeding with and without endometrial cavity pathology.⁵ Other patient benefits of HTA noted by the investigators were reduced need for anesthesia compared with RBA, shortened procedure time, the ability to successfully perform the procedure in the office setting, and complete elimination of the risk of excessive fluid absorption and subsequent dilutional hyponatremia.

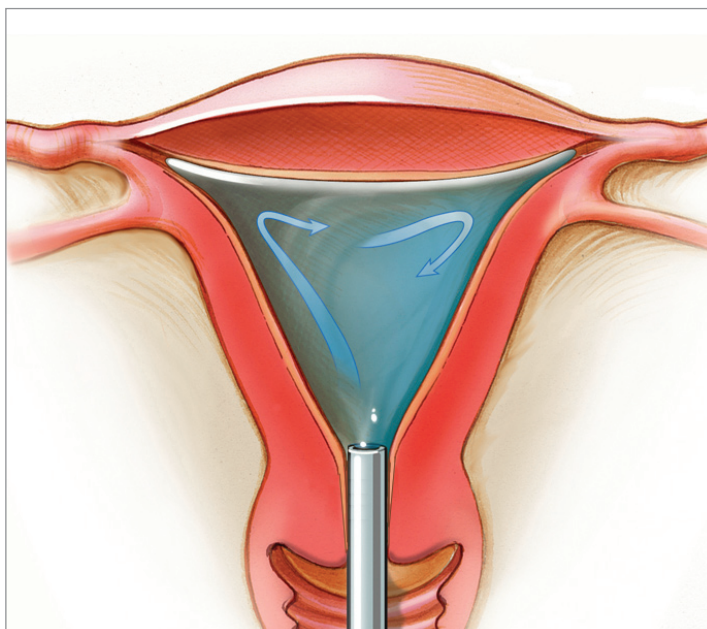
HTA well suited for in-office use

In my experience, nearly all women with excessive bleeding who do not desire continued fertility are candidates for HTA in the office setting, under local anesthesia with minimal oral sedation. Exceptions are those with excessively large cavities (>12 cm), with abnormal cervical cytology or endometrial hyperplasia, with intracavitary myomas or synechiae that completely obstruct the cavity, and those who don't tolerate a simple office diagnostic hysteroscopy or are allergic to local anesthetics.

Patient acceptance of in-office procedure

Patients tolerate the procedure well, given the low pressure of the infused heated physiologic saline and the

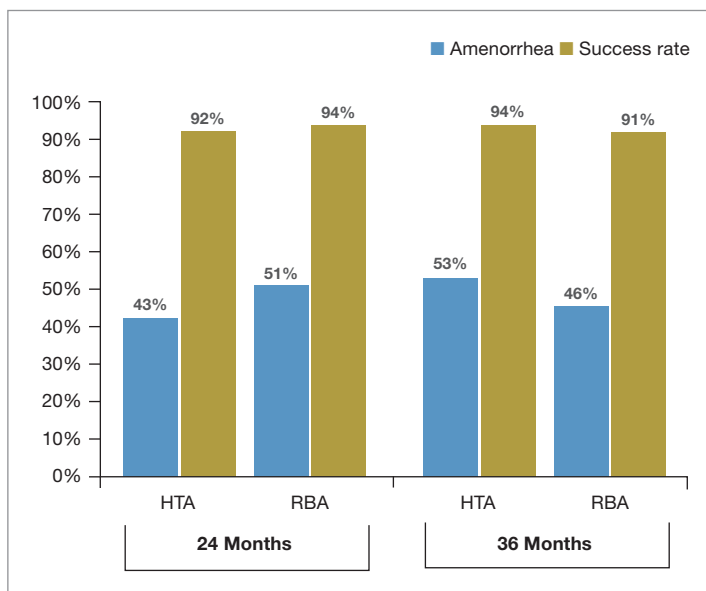
FIGURE 1
Endometrial ablation with HTA



HTA, Hydro ThermAblator.

With the HTA sheath tip positioned just inside the cervical os, a 0.9% saline solution kept to a pressure between 50 and 55 mm Hg circulates throughout the uterine cavity at a temperature of 90°C for 10 minutes.

FIGURE 2
HTA vs RBA: outcomes at 2 and 3 years



HTA, Hydro ThermAblator; RBA, rollerball ablation.

In the pivotal HTA study submitted to the FDA, 276 women with menorrhagia (22 of whom also had myomas up to 4 cm in diameter) underwent endometrial ablation with either HTA or rollerball. At 2 years' and 3 years' follow-up, outcomes with HTA were equivalent to those achieved with RBA.

Goldrath MH. J Am Assoc Gynecol Laparosc. 2003;10:505-511.

lack of mechanical manipulation. Direct visualization provided by hysteroscopy enhances patient safety by confirming placement of the device within the uterine cavity rather than in a false passage and ruling out uterine perforation. Also, the chances of detecting myomas or other abnormalities are markedly increased. Moreover, patients usually prefer an in-office procedure to one performed in the hospital or a surgicenter. Their financial burden is often much less, since office copayments are markedly lower. The savings are also greater for those who have deductibles or who self pay. Office procedures are less intimidating, general anesthesia is unnecessary, a family member can be in the room for support, and dialogue with the physician throughout the procedure is reassuring and allows the physician and staff to assess how well the patient is tolerating the procedure.

In-office sedation protocols

In our study discussed above, all procedures were performed in the office procedure room, with minimal oral sedation taken at home 1 hour prior to the procedure (diazepam 10 mg, hydrocodone/acetaminophen 5 mg/500 mg, 2 tabs, and ibuprofen 800 mg) and a paracervical/intracervical block given 10 to 15 minutes before initiation of cervical dilation.⁴

In a study specifically assessing pain tolerance of 100 patients with menorrhagia undergoing HTA in freestanding medical offices in Glendale, AZ, and Milwaukee, WI, Phillips used a similar protocol of oral premedication and paracervical/intracervical block.⁶ Patients were surveyed postprocedure. Using a 1-to-10 pain scale, the average procedure pain score was 3.6. The average pain score the day after surgery was 1.0. The patients' use of pain medication was documented, and the average office recovery time was less than 30 minutes. Satisfaction was excellent. Phillips concluded that HTA can be performed in the freestanding office setting without hospital support.⁶

In another study that assessed the feasibility and patient acceptance of HTA in an outpatient setting under local anesthesia, 40 of 44 women (91%) were treated successfully—defined as a completed HTA cycle.⁷ There were no serious complications, and 88% of the women found the procedure acceptable. The investigators concluded that HTA is feasible for selected outpatients treated under local anesthesia.

In-office procedures: Benefits to physicians

The in-office procedure precludes the need to schedule OR time at another facility and thus also eliminates related logistical concerns (eg, travel time, parking, changing into scrubs, the possibility of getting “bumped” for emergencies).

Ensuring patient safety. HTA is readily performed with local anesthesia (eg, 1% mepivacaine) administered by paracervical/intracervical block, and oral premedication (eg,

diazepam), and is therefore defined as level-I surgery. In many states, level-II surgery—use of “intravenous, intramuscular, or rectal sedation/anesthesia” or a “drug or drugs that produce depression of consciousness”—requires that physicians and office staff obtain special certification, follow various regulations ensuring patient safety, and use complex postprocedure recovery protocols. The physician must also obtain and maintain accreditation of the office setting by an approved accreditation agency such as the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), the Accreditation Association for Ambulatory Health Care (AAAHC), the Joint Commission, or the Healthcare Facilities Accreditation Program (HFAP), a division of the American Osteopathic Association.

Issues of reimbursement. Reimbursement under Medicare has declined recently for hysteroscopically guided endometrial ablation performed in the physician's office—Current Procedural Terminology (CPT) code 58563—although it is still 63% higher than that allowed for nonhysteroscopic ablation techniques (CPT code 58353). In 2009, the average payment for HTA in the office setting is \$1,747.07. Physician reimbursement for HTA in the operating room is just \$332.17. Private payers generally follow Medicare's lead on reimbursement and usually exceed it. The most up-to-date information on physician fee schedules can be obtained from the Centers for Medicare & Medicaid Services (CMS) website at: <http://www.cms.hhs.gov/pfslookup/02/PFS-search.asp>. Insurance companies are now adopting these differential reimbursement rates rather than reimbursing the physician the same amount for a procedure, regardless of the setting. This now makes it economically advantageous to perform procedures in the office setting, especially diagnostic hysteroscopy, endometrial ablation using the second-generation devices, and hysteroscopic sterilization.

Certainly, reimbursement rates vary greatly throughout the country and even vary tremendously among insurance carriers in the same community. It makes good business sense for the physician to know the reimbursement rates for each insurance carrier the practice accepts. For prepaid integrated health care systems such as Kaiser Permanente, moving procedures from the operating room to the medical office is extremely cost-effective.

PRACTICE PEARL: To avoid the possibility of a fluid leak, and to keep patient discomfort to a minimum, carefully dilate the cervix to no more than the 8 mm necessary for inserting the sheath. Position the sheath tip just inside the internal cervical os to a point where you can no longer see the “tunnel” of the endocervical canal. Try to hold the sheath steady in this position, and especially try to avoid excess lateral movement, which will stretch the cervix (FIGURE 1).

Economic considerations. The economic impact of in-office endometrial ablation with the HTA system is significant for individual physicians and for our health care system. Typically, a physician performing one endometrial ablation a week could expect to break even on his or her capital outlay for hysteroscopy equipment at 14 months, and the increase in procedures will grow the practice. Adding diagnostic hysteroscopy and hysteroscopic sterilization will pay for the equipment in much less time. There are also companies that will bring the equipment to your office on a per case basis. A shift away from hospital operating rooms to private offices would also help control medical costs at the national level (TABLE 1). Moreover, opting for endometrial ablation instead of hysterectomy, when appropriate, would generate considerable cost savings (TABLE 2).

PRACTICE PEARL: Diagnostic hysteroscopy during the work-up for excessive uterine bleeding will identify those who can tolerate HTA well and also detect intrauterine pathology. Hysteroscopic guidance during the HTA procedure also minimizes the possibility of injury and can detect false passage and perforation. Another potential complication with HTA is vaginal burn due to leakage of heated saline or accidental withdrawal of the sheath from the cervix during the ablation. The HTA system features not only a tenaculum stabilizer but a newly designed sheath with a built-in cervical-sealing mechanism consisting of consecutive soft baffles to prevent leakage (FIGURE 3).

Endometrial ablation and risk factors for hysterectomy: Results of a recent study

A recently published study demonstrated that age at the time of ablation is an important predictor of which patients are likely to undergo subsequent hysterectomy.⁸ Data were collected retrospectively on women 25 to 60 years of age who underwent endometrial ablation between 1999 and 2004 at Kaiser Permanente Northern California facilities by both rollerball and the second-generation techniques, including HTA, ThermoChoice, and NovaSure. Variables the researchers assessed included age, presence of leiomyomas, inpatient or outpatient procedure, and type of procedure (RBA, radio frequency, hydrothermal, or thermal balloon). Of 3681 women in this retrospective analysis, 774 (21%) subsequently had a hysterectomy. Overall, the type of procedure, the procedure setting, and the presence of leiomyomas were not predictors of hysterectomy. However, women younger than 45 years were 2.1 times more likely to have a hysterectomy following ablation than were older women. Moreover, the younger the patient, the greater was her risk of having a hysterectomy—among women 40 years or younger, the risk exceeded 40%.

TABLE 1
Estimated cost savings with office HTA vs endometrial ablation in the OR

Kaiser Northern California, cost analysis (1 year)	
OR: 510 endometrial ablations at \$2,483/case (includes \$410/case for disposables)	\$1,266,330
If 75% of endometrial ablations now performed in the OR at Kaiser N Cal were converted to office HTA	
Office HTA: 382 endometrial ablations at \$1,200/case (\$1,000 procedure kit + \$125/hr for MD + MA time, including pre-op diagnostic hysteroscopy)	\$ 458,400
Cost savings	\$ 807,930

HTA, Hydro ThermAblator; OR, operating room.

TABLE 2
Estimated cost savings with office HTA vs hysterectomy for AUB in the OR

Kaiser Northern California, cost analysis (1 year)	
OR: Hysterectomies for AUB (700 cases)	\$8,277/case
Office HTA: Endometrial ablations (\$1,000 procedure kit + \$125/hr for MD + MA time, including pre-op diagnostic hysteroscopy)	\$1,200/case
Cost savings	\$7,027/case
If 50% of hysterectomies now performed for AUB in the OR at Kaiser N Cal were converted to office HTA	
700 hysterectomies at an average cost of \$8,277/case; 350 cases @ \$7,027/case	
Total cost savings	\$2,459,450

AUB, abnormal uterine bleeding; HTA, Hydro ThermAblator; OR, operating room.

Importantly, risk for these patients increased through 8 years of follow-up.

Study weaknesses. This study's main weakness is that it did not account for the wide variation in the historical hysterectomy rates for benign disease between facilities within Kaiser Northern California. These rates range from a low of 196/100,000 at Kaiser San Rafael to a high of 714/100,000 at a facility where most of the ablations reported in the study were performed.⁹ The presence of fibroids was a significant risk factor for hysterectomy in our study, yet age was not.⁴ When those hysterectomies performed for bulk symptoms alone are added to the number performed for bleeding, the rate rises from 11.6% to 17.3%, vs 0.7% in those patients with normal cavities. The hysterectomy rate of >1% at Kaiser

FIGURE 3
HTA ProCerva sheath for cervical seal



HTA, Hydro ThermAblator.

The new ProCerva sheath has a tenaculum stabilizer, which prevents inadvertent removal of the sheath before cooling, and a new cervical seal assist to prevent transcervical leakage.

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San Rafael in our patients with normal cavities is consistent with the fact that we have the lowest hysterectomy rate in the Kaiser Permanente Northern California region. This is due, in a large part, to patient preference and demographics as well as physician practice. We found that of those patients with fibroids who opted for office HTA to treat their bleeding, 88.4% avoided hysterectomy related to their fibroids. Admittedly, we were quite aggressive in treating some of the patients with larger uteri. But since we were offering them an office procedure done under local anesthesia with minimal sedation, a failure rate as high as 50% was worth avoiding the risks, disability, and cost of a hysterectomy. Our results were much better than this. I feel strongly that when the failure rate—or success rate—of an endometrial ablation technology is measured and reported by whether or not the patient has a hysterectomy, the hysterectomy practice of that particular facility or region should be considered by the reader. Unfortunately, it is not uncommon to see a patient with normal menses have a hysterectomy for a “failed” ablation because she’s been counseled unrealistically to expect amenorrhea.

Conclusions

Endometrial ablation using the HTA system, performed in the medical office under local anesthesia with minimal sedation, is a safe, effective, and economically advantageous alternative to hysterectomy, electrosurgical endometrial ablation, or fibroid resection for the treatment of abnormal uterine bleeding. As the eyes of our nation and legislators are now keenly focused on the rising costs of health care, physicians have a unique opportunity to take cost out of the system by performing procedures in the office which will ultimately benefit our patients as well.

Gynecare ThermaChoice® Uterine Balloon Therapy System: Minimal dilation and technical changes for enhanced coverage

Malcolm G. Munro, MD, FRCS(c), FACOG

Professor
Department of Obstetrics
& Gynecology
David Geffen School of Medicine
at UCLA
Director of Gynecologic Services
Los Angeles Medical Center
Kaiser Permanente Southern
California
Los Angeles, California

Disclosure

Dr Munro is or has been a consultant to AMAG, Inc., Bayer HealthCare, Boston Scientific Inc, Covidien PLC, Ethicon Women's Health & Urology, Gynesonics, Inc, Hologic, Inc., Impres Medical, and Karl Storz Endoscopy-America, Inc.

The Gynecare ThermaChoice Uterine Balloon Therapy System was the first nonresectoscopic endometrial ablation (NREA) device for heavy menstrual bleeding (HMB) approved by the US Food and Drug Administration (FDA), in 1997. Using a handheld catheter, the physician advances a single-use silicone balloon and then inflates it with 5% dextrose and water to a pressure of 180 mm Hg. Heated by a central element, the hot fluid circulates throughout the endometrial cavity, causing ablation of the adjacent endometrium. The initial device (ThermaChoice I, or T1) has been modified through 2 subsequent versions, with significant effects on 12-month amenorrhea rates, which were 15.2% with T1¹ and are 37.1% in the intention-to-treat (ITT) population with the current version, ThermaChoice III (T3).² It is worth mentioning that the ITT population considered to be failures all 30 (of the original 124) patients who didn't complete all postsurgical requirements (diary cards, all visits). If only the 94 patients who completed all protocol requirements are included ("evaluable" or "per protocol"), the amenorrhea rate was 44.7%.

As I will describe in more detail, the outside diameter of the catheter is 3.2 mm, but it expands to 4.5 mm at the site of the balloon. These dimensions mean that for most women, cervical dilation is unnecessary, thereby providing potential benefits for in-office use, including improved patient comfort and reduced likelihood of adverse events.

Design changes

T1

Dip-molded latex device filled with noncirculating saline solution

T2

Silicone balloon featured circulating mechanism, providing more even coverage of the endometrium

T3

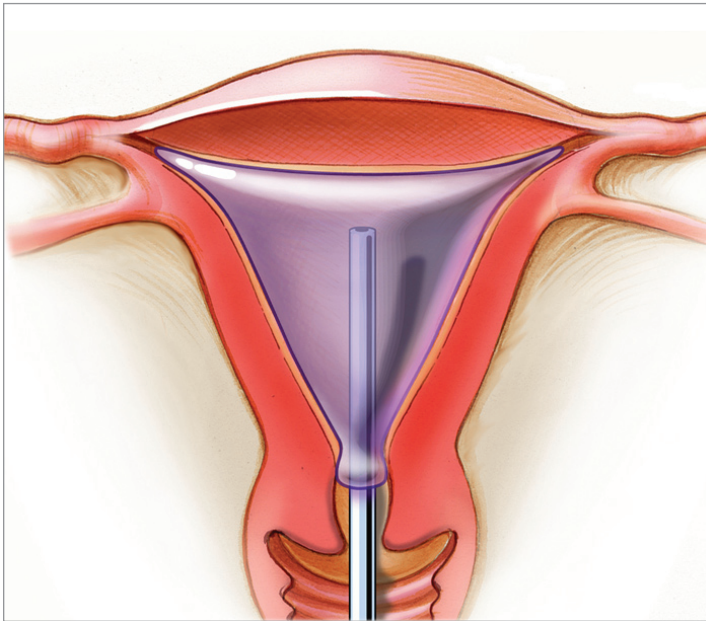
Stronger and more flexible silastic balloon, conforming better to the contours of the uterine cavity to improve cornual and lower uterine segment coverage

Result: T3 is appropriate for the most common uterine shapes and sizes.

The ThermaChoice Balloon—An evolution in design

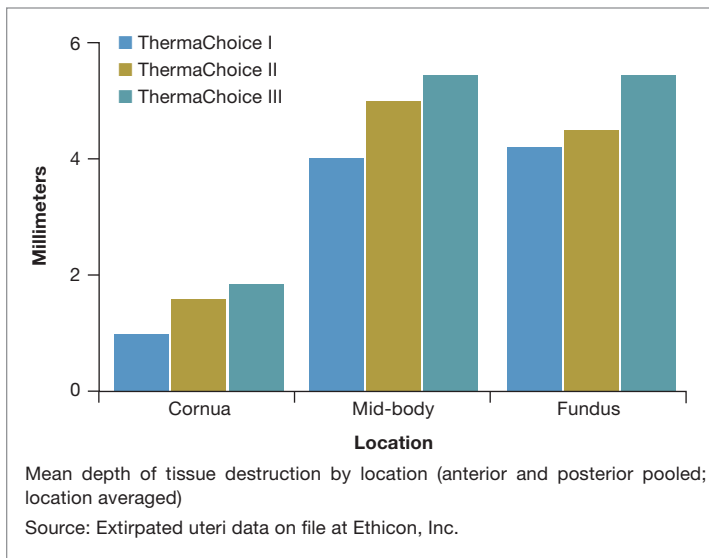
Since introducing the T1 design, the manufacturer has made a number of modifications that appear to have resulted in improved clinical outcomes. The T2, introduced in 1998, incorporated an impeller to circulate the distending fluid (5% dextrose in water) and achieve a more uniform temperature

FIGURE 1
Endometrial ablation with ThermoChoice III



ThermoChoice III features a double-dip construction that is both strong and flexible. As a result, it conforms better to the contours of the endometrial cavity. This provides better cornual and lower uterine segment coverage, reflected in improved rates of amenorrhea.

FIGURE 2
Advances in ThermoChoice technology



throughout the balloon. The resultant amenorrhea rate reached 26%.³ The currently available device, the T3, was introduced in 2003, and features a silicone balloon with increased flexibility, designed to provide better coverage of the cornual areas as well as the lower uterine segment (FIGURE 1). A study of extirpated uteri demonstrated that

depth of tissue destruction was also increased with the T3, as shown in FIGURE 2.⁴ On average, the first observed location of 1 mm depth of necrosis with the T3 was 3.5 mm from the tubal ostium, versus 4.8 mm and 6.3 mm for T2 and T1, respectively.

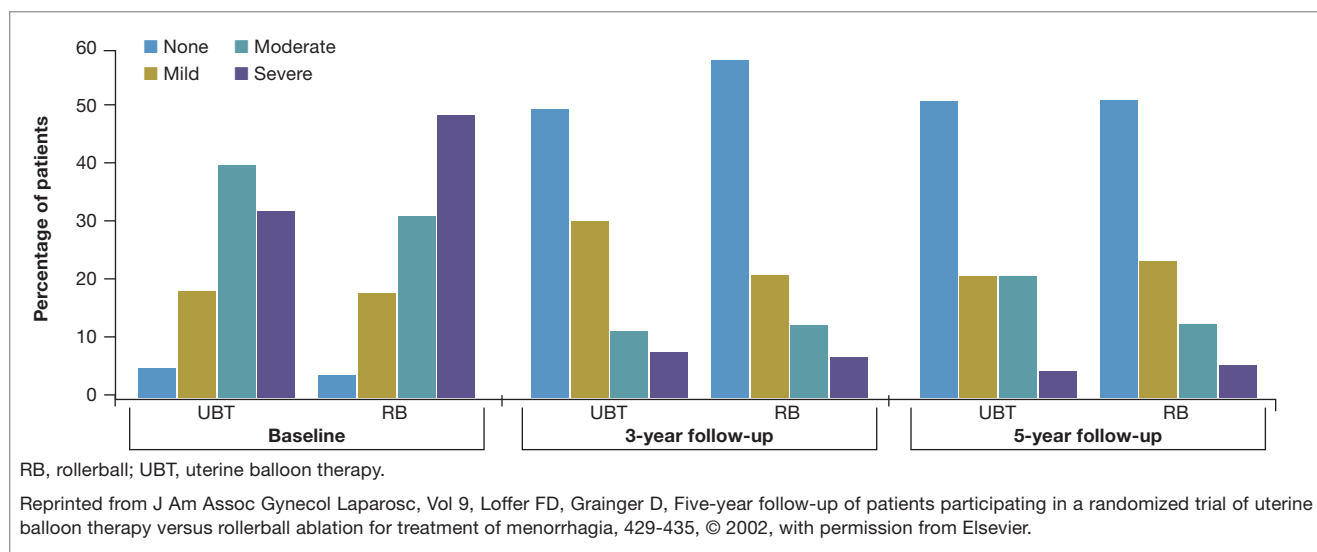
PRACTICE PEARL: ThermoChoice, like other NREA devices, is not designed to treat all women with HMB. Consequently, careful evaluation of the patient must be an integral component of the investigation prior to including EA in the menu of therapeutic options offered a given individual. Women with the symptom of HMB may have any of a number of causes of the excessive bleeding. These include disorders of ovulation, submucosal leiomyomas, systemic disorders of hemostasis (such as von Willebrand disease), and local disorders of hemostasis, usually related to excesses of vasodilating prostaglandins and/or plasminogen activator. The roles of endometrial polyps and adenomyosis in the genesis of HMB are still not clear. In addition, a number of women, particularly those with disorders of ovulation, may have endometrial hyperplasia or even endometrial cancer. As a result, the endometrial cavity should be evaluated with one or a combination of saline infusion sonography or hysteroscopy to be sure that the cavity length and configuration are suitable for balloon ablation (no significant Mullerian fusion defect, an absence of submucosal myomas, clinically significant endometrial polyps), and an endometrial sample should be obtained to evaluate for the presence of hyperplasia or carcinoma.

Unfortunately, although the clinical data associated with the T3 device are in press, findings have been presented at the 2006 Annual Meeting of the American Association of Gynecologic Laparoscopists and published in abstract form.² Because these data were not published in a peer-reviewed journal, they are not referenced in currently available guidelines for endometrial ablation (EA), including those published by the American College of Obstetricians and Gynecologists in 2007.⁵ Thus, guidelines still cite data from the early T1 trials, leaving many practitioners with the impression that T3 is less effective than other devices at achieving an acceptable amenorrhea rate.

Patient satisfaction with ThermoChoice

In a study of 141 women who underwent EA with the T2 device, patient reports during interviews conducted 18 months following the procedure revealed marked reductions in days of menstrual bleeding per cycle and pads used per day. Overall, 96% of patients said they were satisfied or very satisfied with the procedure. No complications were reported.³

FIGURE 3
Dysmenorrhea at baseline and 3 and 5 years after ablation



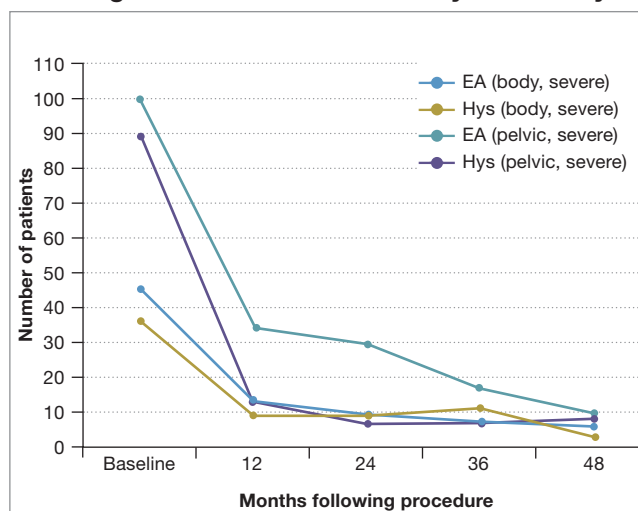
Long-term data: ThermaChoice vs hysterectomy

Amenorrhea is, however, only one element to consider; patients who select EA do not typically have a goal of amenorrhea but wish to reduce the volume of menstrual bleeding to normal levels or less. A study published by our group in 2007—the Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleeding (STOP-DUB)—was a multicenter randomized clinical trial (RCT) that compared the effectiveness of hysterectomy and EA in women with excessive bleeding.⁶ The investigators were allowed to select their EA method of choice, and, by chance (not by design), half of the ablation procedures were conducted with a resectoscope and half with the T1 device, thus providing some opportunity for post hoc comparison of T1 and hysterectomy and between T1 and resectoscopic endometrial ablation (REA).

For STOP-DUB, the primary outcome sought was a patient's report of "problem solved." The outcome achieved with EA was equivalent to that for hysterectomy, and in post hoc comparisons of T1 and REA, the outcomes also seemed similar, with an overall 31% 4-year reoperation rate for the EA group as a whole.⁷ The STOP-DUB clinical trial seems to confirm that women with HMB are typically satisfied with the ThermaChoice procedure, when compared with both hysterectomy and REA, a procedure that is associated with increased operative risk.

A 5-year analysis⁸ of evaluable patients from the earlier FDA pivotal RCT comparing T1 with "the gold standard" REA using rollerball electrocoagulation¹ showed that 95% and 97% of evaluable women, respectively, were satisfied with their treatment. Moreover, 70% of women who were treated with ThermaChoice and were available for evaluation required no further treatment. The shortcoming of these long-term data is

FIGURE 4
STOP-DUB trial: Rates of change in dysmenorrhea following endometrial ablation or hysterectomy



In the STOP-DUB Trial, women with heavy menstrual bleeding whose pain (body or pelvic) was severe, and who underwent endometrial ablation, experienced pain relief comparable to that achieved with hysterectomy, even out to 48 months postprocedure. Trends were equally impressive following ablation for those whose pain was categorized as mild or moderate.

Note: These data do not apply to T3, as it was not used in this trial, and they do not apply solely to T1, as these represent the aggregate of the REA and ThermaChoice I data.

Dickersin K, et al. Obstet Gynecol. 2007;110:1279-1289.

that only 147 of 255 of the women originally treated with either technique (61 REA, 62 ThermaChoice) were evaluable—with the additional 25 having undergone hysterectomy. However, other studies with higher proportions of evaluable patients

Administering local anesthesia: One surgeon's experience— Dr Munro's protocol

Unfortunately, the literature on uterine anesthesia is inconsistent, with some studies suggesting a benefit, while others—in fact, most—concluding that uterine anesthesia fails to reduce patient perceptions of pain. Clearly, as demonstrated by the Marsh et al study,¹⁶ many women undergo uterine procedures comfortably with little or no anesthesia, depending on a number of factors including parity, the procedure to be performed, and individual variations for pain threshold. However, in my experience, many patients cannot tolerate such procedures and, for them, local anesthetic techniques are usually highly effective as long as one considers the complex innervation of the uterus and the time required for various agents and techniques to achieve their maximum impact.

Many studies, including those that have an otherwise

credible design, fail to consider that the uterus is innervated by a number of sources, or they do not consider that up to 10 to 30 minutes may be needed for optimal anesthetic effect, depending on the type of anesthetic, its concentration, and the route of administration (injectable versus topical). Clearly, appropriately designed clinical trials addressing these considerations will be necessary to determine the optimal approach for uterine anesthesia using local agents. Although we are planning a number of studies, the technique described below has proven effective for virtually any uterine procedure I perform, including NREA.

The procedure room has a relaxed atmosphere. (Anything you can do to enhance the ambience of your facility—music, paintings, color selection—is probably worthwhile.) After the patient is positioned, I insert into the vagina an appropriately sized, heated metal speculum, coated with 2% lidocaine gel. Although there is no initial impact beyond lubrication, I suspect that many patients experience an anesthetic effect by 10 to 15 minutes into the procedure.

I use a dilute solution of 0.5% lidocaine with 1/200,000 epinephrine. This allows a larger volume of anesthetic to be

PRACTICE PEARL: The ThermoChoice device is simply inserted to the sound length of the uterine cavity and the balloon inflated. A control unit monitors uterine pressure, temperature, and treatment throughout the procedure. If pressure drops rapidly, suggesting a potential uterine wall defect, the cycle terminates automatically. Similarly, the procedure is discontinued if pressure reaches 210 mm Hg or if temperature varies outside of specific parameters. There are no user variables and no need for positioning or manipulation of the device while in the endometrial cavity.

have reported similar outcomes. For example, a large multicenter cohort study reported their analysis conducted 4 to 6 years following ablation with T1, with 72% of the 260 women responding. In this study, 86% had been able to avoid hysterectomy, and 88% had avoided reablation.⁹

Effective reduction of dysmenorrhea

The mechanisms of HMB-associated dysmenorrhea have not been well elucidated but, in a given individual, could be considered to include one or more of the following components: excessive endometrial levels of prostanoids such as prostaglandin $F_{2\alpha}$; concomitant symptomatic endometriosis; concomitant symptomatic adenomyosis; and mechanical factors such as the passage of clots.

An interesting outcome of the NREA trials is that EA seems to be associated with a general reduction in the prevalence and severity of dysmenorrhea. For example, in a study published in 2009 by Chapa and colleagues, ablation with T3 was performed on 148 women to gauge the effects of diminished

menstrual bleeding on dysmenorrhea as well as the impact on premenstrual mood symptoms.¹⁰ At 6 months following the procedure, 50% of the women were amenorrheic, 48% were hypomenorrheic, and dysmenorrhea as well as symptoms of agitation, irritability, and depression had all decreased.

Long-term data: Reduction of pelvic pain

Data from the earlier trials also showed that EA using ThermoChoice was associated with a reduction in both bodily and pelvic pain.* Nearly 75% of women reported pain reduction at 1 and 5 years following NREA with the ThermoChoice I device (FIGURE 3).^{1,8} At between 4 and 6 years, more than half of women said they experienced no pain with menses, and 28% said their pain was mild.⁹ Data from STOP-DUB demonstrated similar reductions (FIGURE 4).⁶

Use of ThermoChoice in the office environment

Given the narrow outside diameter of the ThermoChoice catheter (4.5 mm), minimal, if any, dilation will be required to position the device, a potential benefit for most patients and surgeons. Indeed, there is evidence that ThermoChoice NREA can be successfully performed in an office environment without the need for regional, parenteral, or general anesthesia and with preservation of acceptable clinical outcomes.

The pivotal trial submitted to the FDA for approval of T1 included a substantial number of procedures performed in-office using only local anesthesia.¹ In a subsequent

*Because of the nonspecific nature of the instruments, "bodily pain" is not well defined, but it is likely pain related to menses.

used in a given dose. Epinephrine also prolongs the anesthetic effect, reduces the amount of systemic absorption, and facilitates transfer of the anesthetic agent into the nerve fiber by increasing local pH. Epinephrine's effect is predictable, with a transient (40- to 60-second) period of palpitation that quickly disappears. For those patients for whom epinephrine is considered too risky, I'd suggest an alternative anesthesia or anesthetic environment.

I administer the agent via a 22-gauge spinal needle. I place the needle on the anterior exocervical epithelium and ask the patient to cough. This pushes the cervix against the needle, allowing it to penetrate to the point that the bevel is just below the epithelial surface. I inject 1 to 3 mL of the agent at about the 12 and 6 o'clock positions.

I grasp the posterior cervix with a single-toothed tenaculum and retract it anteriorly, a technique that aids in identifying the attachment of the uterosacral ligaments. Repeating the cough technique, I inject a small amount of anesthetic agent into the vaginal epithelium at the junction with the cervix; then I advance the needle to a depth of 4 to 5 mm, aiming to position the tip on the medial aspect of the ligament

but not so deep that it is in the peritoneal cavity. Taking care to aspirate before injecting, I place approximately 5 to 8 mL of anesthetic solution in each side. I remove the tenaculum from the posterior cervix and reattach it at about the 12 o'clock position. Exerting a slight amount of traction, I inject about 4 to 6 mL of the lidocaine-epinephrine solution in each side of the cervix at about the 4 to 5 o'clock position on the patient's left side, and 7 to 8 o'clock on the right, to a depth of 3 to 5 cm, aiming to deposit the bulk of the solution in the region of the lower uterine segment and upper cervix. Care must be taken to aspirate to minimize the risk of inadvertent systemic administration.

After the anesthetic is injected, I push a conical-tipped syringe filled with 2% lidocaine gel against the exocervix and inject approximately 5 to 10 mL of the gel into the endometrial cavity. I remove the syringe and place 2 to 3 cotton-tipped applicators soaked in 4% liposomal lidocaine cream in the cervical canal, from the internal to the level of the external os. I then let the patient rest for 10 to 20 minutes before starting the procedure.

PRACTICE PEARL: Clinicians should note that if a patient experiences dysmenorrhea extending through or beyond the duration of her period, her HMB may stem, at least in part, from symptomatic adenomyosis. Although the contribution of adenomyosis to the genesis of any gynecologic complaint, including HMB or dysmenorrhea, remains controversial,¹¹ there is evidence that adenomyosis is present in the myometrium of a relatively high proportion of women who fail EA and undergo hysterectomy.¹² Consequently, women should be counseled that the presence of adenomyosis may limit the success of any ablation procedure. While MRI is largely perceived to be the most accurate imaging modality for the diagnosis of adenomyosis, transvaginal ultrasound imaging usually reveals features typical of the disorder.¹³

prospective observational study of 53 women with HMB unresponsive to medical treatment, 50 (94%) of the women successfully completed the procedure in an outpatient setting using only deep intracervical 3% prilocaine, in some instances with the same agent injected into the uterosacral ligaments.¹⁴ The clinical results were similar to those published elsewhere, with 39 of 49 (80%) participants who responded to a postprocedure questionnaire saying menstrual loss had decreased, and 33 (67%) saying they were satisfied with their outcome.

Two family practitioners trained to use the T1 device reported their performance of EA in an office environment on 89 women using only preprocedural rectal diclofenac, intracervical local anesthesia with 4% prilocaine, and postprocedural oral analgesics. The ablation was successfully completed in 87, and, at follow-up, more than 94% of these

women reported reductions in menstrual loss.¹⁵ Dysmenorrhea also decreased. At 2 years postprocedure, 94% said they were satisfied with their experience (see "Administering local anesthesia," above).

In another prospective cohort study published in 2005, 89% of women successfully underwent ablation with ThermaChoice in an outpatient setting, either without anesthesia and analgesia or with only ibuprofen administered preoperatively.¹⁶ These authors subsequently published an RCT in which women with HMB were randomized to receive either ThermaChoice III NREA in a hospital operating room setting with general anesthesia, or as "outpatients" in the same hospital in an outpatient setting with no anesthesia and only ibuprofen given as analgesia the evening before and then 1 hour before the ablation. The procedure was completed successfully in 87% of the "outpatients," and most (64%) required no "rescue analgesia."¹⁷

In the Chapa cohort study mentioned previously, the 148 women undergoing ablation with T3 received deep parametrial block with dilute mepivacaine and an oral anxiolytic.¹⁸ None asked that the procedure be stopped due to pain. Of 143 evaluable patients, 91% reported being "very satisfied" and 9% said they were "satisfied" with their outcomes.

PRACTICE PEARL: Titrating balloon pressure upward helps ensure patient comfort. Inflate the balloon, according to operating instructions, up to 180 mm Hg. As the uterus relaxes, the pressure in the balloon decreases slightly. Then increase the pressure gradually over the next 30 to 60 seconds until optimal pressure is reached.

ThermaChoice and submucosal leiomyomas

The T3 device is approved for use with normal uterine cavities no deeper than 10 cm, but a well-designed RCT has compared T1 to REA and demonstrated a reduction in menstrual blood flow at 12 months in women with submucosal myoma-associated HMB (Type II myomas ≤ 3 cm) similar to that achieved with the resectoscope.¹⁹ Those undergoing ThermaChoice received local anesthesia only and experienced no intraoperative complications, while those allocated to REA under general anesthesia experienced significantly more intraoperative complications. Consequently, although the pivotal trial and trials on the revised balloon designs (T2, T3) did not include women with submucosal myomas, it is apparent that well-selected patients could be counseled that they may achieve acceptable therapeutic results.

Reimbursement

Office reimbursement from Medicare in 2009 (which differs vastly from that associated with hospital or outpatient surgery centers) falls under 2 broad codes in Current

Procedural Terminology (CPT): 58563 (hysteroscopy, surgical; with endometrial ablation [any method]) has a National Medicare Average Payment of \$1,747.07; 58553 (endometrial ablation, thermal, without hysteroscopic guidance) has a National Medicare Average Payment of \$1,072.98. Either code is acceptable for TC, with the distinguishing feature being whether or not you perform a hysteroscopy at the same time.

Conclusions

ThermaChoice represents a safe and effective treatment option in both hospital and office settings for appropriately selected women with heavy menstrual bleeding. Data on the latest generation of the device, the ThermaChoice III, further validates the efficacy and effectiveness of thermal balloon ablation and where it fits within today's gynecologic practice. Endpoints for patient satisfaction, bleeding results, and other associated symptoms such as dysmenorrhea are encouraging. Additionally, as more procedures transition to the office setting, the small diameter of the catheter offers potential benefits for patient comfort and probably safety as well.

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NovaSure® System Bipolar Radio Frequency Technology: Impedance-based ablation technology

Padmavathy Tummula, MD

Private practice
Banner Thunderbird Medical Center
Glendale, Arizona

Disclosure

Dr Tummula has previously served as a paid consultant to Hologic, Inc.

The NovaSure System, approved by the US Food and Drug Administration (FDA) in 2001, uses radio frequency (RF) bipolar energy to gently remove endometrial tissue. To date, the system has been used to treat more than 1 million patients. The operator inserts a probe 7.5 mm in diameter through the cervical canal and deploys a 3-dimensional gold-plated bipolar mesh electrode, which conforms to the dimensions of the uterine cavity (**FIGURE 1**). The system verifies electrode deployment and uterine cavity integrity (absence of perforations, as small as an 18-gauge needle), and then determines the appropriate power level for the cavity dimensions measured. Up to 180 watts of bipolar energy is applied to the lining of the uterus. Varied electrode center-to-center distance tailors the depth of tissue ablation, ensuring a customized treatment independent of endometrial thickness, with a shallower ablation in the cornual area and a deeper ablation in the body. A proprietary vacuum system removes steam and moisture from the tissue as well as other ablation byproducts, such as prostaglandins. Once the tissue impedance reaches 50 ohms or the procedure time reaches 2 minutes, the procedure terminates automatically, and the operator retracts the electrode into the sheath before removal.

PRACTICE PEARL: The time required for ablation averages 90 seconds, and patients tolerate the procedure well in an office setting with analgesia and local anesthesia. Some patients, however, may prefer conscious sedation.

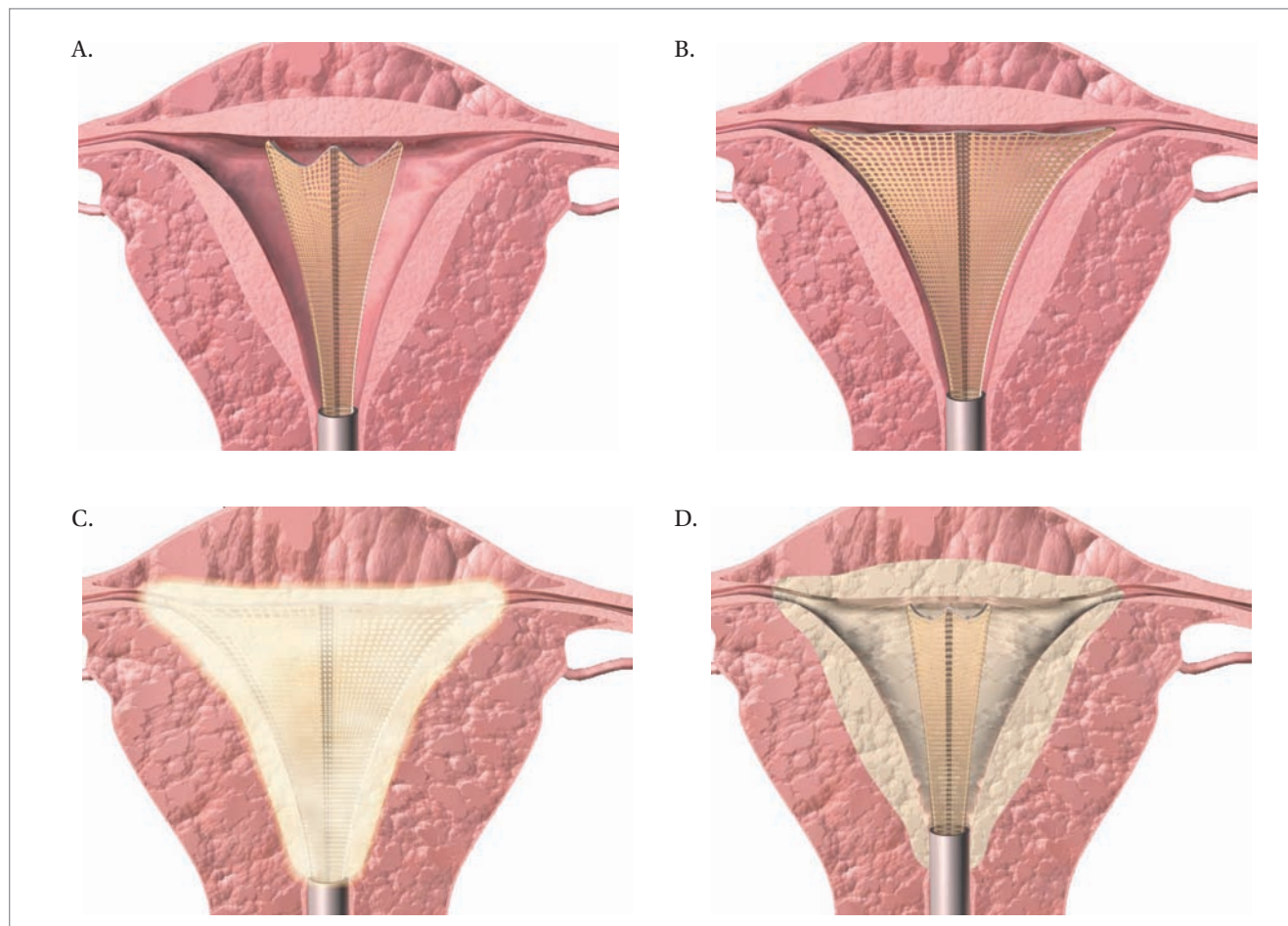
Treating menorrhagia

The clinical trial data submitted to the FDA for NovaSure approval compared this system's safety and effectiveness with that of hysteroscopic wire loop resection plus rollerball ablation in treating excessive uterine bleeding in 265 premenopausal women.¹ In patients available for follow-up, success—defined as a score of 75 or less on a pictorial blood loss–assessment chart (PBLAC)—was achieved in 88.3% of patients treated with NovaSure and 81.7% treated with rollerball. At 1 year posttreatment, evaluable data showed that 90.9% of NovaSure patients reported normal bleeding or less (PBLAC ≤ 100), compared with 87.8% for rollerball patients. A total of 41% and 35% patients, respectively, reported amenorrhea (PBLAC = 0). The rate of intraoperative complications with NovaSure was just 0.6%, compared with 6.7% for rollerball.

Long-term data: safety, efficacy, and outcomes

A 7-year follow-up study reported on the safety, efficacy, and long-term outcomes of endometrial ablation (EA) with NovaSure performed on 75 premenopausal women who had menorrhagia.² Treatment time averaged 92 seconds. Of the 73 evaluable patients, all experienced a successful reduction in bleeding (with 97.1% reporting amenorrhea). Of note, at 5 years' follow-up, half of the patients were age 50 years or older versus 16% at baseline.² Six of the

FIGURE 1
Endometrial ablation with NovaSure



The 3-dimensional gold-plated bipolar mesh electrode is inserted into the uterine cavity and advanced toward the fundus (A). Upon activation of the foot switch, the system insufflates the uterine cavity with carbon dioxide and begins a testing process to ensure that the cavity is intact (B). The system will not activate unless a tight seal is produced. If a uterine perforation is detected, the device will not activate. The dimensions of the uterine cavity are entered into the RF control unit, which automatically calculates the power level required for that specific uterine size. A second activation (C) of the foot switch produces up to 180 watts of bipolar power and starts a moisture transport vacuum that also draws the endometrium into contact with the mesh to enhance tissue vaporization and debris evacuation, ensuring that the bipolar energy continues to penetrate the wall of the uterine cavity. For this reason, the device may be used at any point in the menstrual cycle without any pretreatment. When an impedance level of 50 ohms is achieved, indicating destruction of the endometrial tissue and the superficial layer of the myometrium, the procedure automatically terminates. When the procedure is complete, the electrode is collapsed and retracted into the sheath before removal (D).

women underwent subsequent hysterectomy; all of the women had histologically confirmed adenomyosis. In all, 92% avoided additional surgery.

In a similar study, 107 premenopausal women with menorrhagia who underwent EA with NovaSure were evaluated 5 years following treatment.³ The PBLAC system was used to assess patients' posttreatment menstrual blood loss and bleeding patterns. Ninety-eight percent achieved successful reduction in bleeding (FIGURE 2), with 75% reporting amenorrhea. Just 2.9% of patients had a subsequent hysterectomy, and 3.8% required repeat ablation.

An independent systematic review by the Mayo Clinic

published earlier this year reported retrospectively on the outcomes experienced by 816 women with excessive uterine bleeding who underwent EA with either NovaSure or uterine balloon therapy from January 1998 to December 2005.⁴ This was the first population-based study of long-term outcomes for EA in treating excessive uterine bleeding. The primary goal of the study was to report amenorrhea and treatment failure after EA, and to develop a model for predicting treatment success and failure following EA in order to optimize preprocedural patient counseling.

Several key findings emerged from this review. Ablation was generally safe, and minor complications occurred in less

than 5% of patients. The failure rate with NovaSure at 1 year and 3 years was 0.59% and 1.3%, respectively; among the thermal balloon ablation group, these rates were 8.1% and 13%. Moreover, patients who underwent NovaSure were approximately 3 times more likely to achieve amenorrhea than were those who received thermal balloon ablation.

Of particular note was the identification of factors strongly associated with amenorrhea or potential for treatment failure (TABLES 1 AND 2).

The investigator concluded that NovaSure is more likely to achieve amenorrhea than the thermal balloon ablation utilized at the time of the study. Also, the 2 preoperative predictors of success with a P value $<.001$ were age 45 years or older and the use of NovaSure. Failure rates with NovaSure were significantly lower across both follow-up intervals, compared with thermal balloon ablation: “The use of impedance-based technology in radio-frequency ablation may optimize the delivery of treatment energy for more complete endometrial destruction.”

Effective reduction of excessive bleeding due to intracavitary disease

In a clinical study, NovaSure was used to treat 65 women whose menometrorrhagia was caused by hysteroscopically confirmed polyps or myomas up to 3 cm in diameter.⁵ No hormonal or mechanical treatments were used beforehand to thin the endometrial lining or to shrink the uterine pathologic condition. At 12 months postprocedure, 95% of patients reported a successful outcome (defined as a reduction in bleeding to at least normal levels), and 69% reported amenorrhea. The median time of energy application was 78 seconds. No adverse events were reported during or after surgery. Premenstrual symptoms and dysmenorrhea also decreased significantly.

Use in the office setting

The option of undergoing a procedure in a doctor’s office instead of the hospital is very appealing to many patients. Psychologically and emotionally it seems less of an ordeal, easier to manage logistically, and more comfortable. A critical deciding point, of course, is whether the procedure can be performed in the office safely and with adequate pain control.

PRACTICE PEARL: Diagnostic hysteroscopy can be done before or after the procedure; photographs can be taken for the record, if desired. Hysteroscopic visualization is not required.

A prospective, multicenter study compared intra- and postoperative pain associated with NovaSure and thermal balloon therapy as used in academic medical centers and in private offices.⁶ The researchers assessed pain using standard pain measurement instruments (visual analog and numeric rating scales). They also measured serum levels of prostaglandin- $F_{2\alpha}$ before the procedure and again at 5, 30, and 60 minutes after the procedure. Although prostaglandin- $F_{2\alpha}$ values did not

FIGURE 2
Long-term clinical results: Posttreatment menstrual blood loss and bleeding patterns with NovaSure

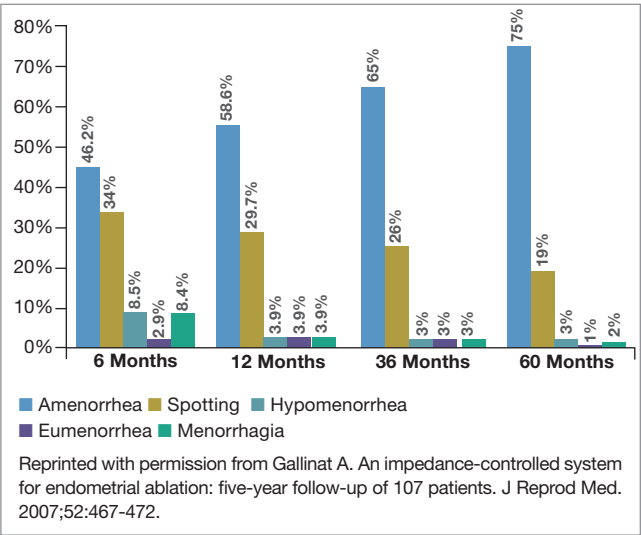


TABLE 1
Factors strongly associated with amenorrhea or treatment failure

Predictors of amenorrhea
• Patient age 45 years or older
• Uterine length less than 9 cm
• Endometrial thickness less than 4 mm
• Radiofrequency ablation instead of thermal balloon ablation
Predictors of treatment failure
• Patient age younger than 45 years
• Parity of 5 or greater
• Prior tubal ligation
• History of dysmenorrhea

El-Nashar SA, et al. Obstet Gynecol. 2009;113:97-106.

differ statistically between the 2 groups, women treated with NovaSure reported significantly lower levels of intra- and postoperative pain than did those treated with thermal balloon therapy. The study authors concluded that NovaSure could be performed in an office setting and is better tolerated in this setting than thermal balloon ablation.

Practical experience in the office environment

I brought the NovaSure system into my office 2 years ago and initially used local anesthesia. Soon thereafter, I enlisted the aid of an anesthesiologist to accommodate patients who have a low threshold for pain or who request a deeper level of anesthesia. The anesthesiologist can administer other forms of sedation for patients who specifically request it.

PRACTICE PEARL: Office personnel can also be readily trained to assist in the procedure, including preparedness with basic resuscitative techniques.

TABLE 2**Preoperative predictors of amenorrhea after global endometrial ablation**

Predictors	Unadjusted analyses		Adjusted analyses (final model) ^{a,b}	
	Univariable OR (95% CI)	P	Multivariable OR (95% CI)	P
Age 45 y or older	2.3 (1.4-3.6)	<.001	2.6 (1.6-4.3)	<.001
Parity of less than 2	1.3 (0.8-2.4)	.29		
Body mass index 30 kg/m ² or more	1.2 (0.8-2.0)	.38		
Previous cesarean delivery	0.8 (0.4-1.5)	.56		
Tubal ligation	1.0 (0.6-1.7)	.85		
Preoperative bleeding less than 7 d	1.0 (0.6-1.8)	.90		
Preoperative menstrual accidents	1.1 (0.7-1.8)	.70		
Regular bleeding	1.2 (0.8-1.9)	.39		
Preoperative dysmenorrhea	1.3 (0.5-3.5)	.56		
Uterine length less than 9 cm	1.6 (1.0-2.5)	.05	1.8 (1.1-3.1)	.02
Retroverted uterus	0.5 (0.1-1.6)	.21		
Hemoglobin 11.5 g/dL or more	2.1 (1.1-4.0)	.02		
Ultrasound suggestive of adenomyosis	1.7 (0.6-4.8)	.30		
Endometrial thickness less than 4 mm	2.7 (1.2-5.9)	.014	2.7 (1.2-6.3)	.02
Uterine cavity lesion (hysteroscopy)	1.3 (0.8-2.1)	.32		
Uterine polyp	1.5 (0.9-2.5)	.12		
Submucous leiomyoma	2.3 (1.1-4.6)	.02		
Nonsubmucous leiomyoma	1.3 (0.8-2.3)	.29		
NovaSure vs ThermoChoice	2.9 (1.8-4.9)	<.001	2.8 (1.7-4.9)	<.001

CI, confidence interval; OR, odds ratio.

^aThe c index of this model was 0.706.^bIf the variable had a *P* value <.20 in the unadjusted (univariable) analysis, it was considered in the final (multivariable model).Reprinted with permission from El-Nashar SA, Hopkins MR, Creedon DJ, et al. Prediction of treatment outcomes after global endometrial ablation. *Obstet Gynecol.* 2009;113:97-106.

NovaSure requires no pretreatment with dilation and curettage (D & C) or hormonal therapy. Besides sparing patients the extra expense and time of pretreatment procedures, NovaSure can be performed at any point during the menstrual cycle, even during active bleeding, thereby increasing flexibility for patients and physicians.

PRACTICE PEARL: I schedule all patients for the procedure on 1 day each month, which simplifies office logistics considerably.

For patients who will likely tolerate the procedure with minimal anesthesia, I prescribe ibuprofen 600 mg or naproxen 500 mg at bedtime the night before the procedure. One hour before the procedure, patients take diazepam 10 mg; hydrocodone-acetaminophen 5 mg/500 mg every 6 hours; and either ibuprofen 600 mg or naproxen 500 mg. I then administer a paracervical block with mepivacaine 1%, 20 cc total, with a divided dose at 4 to 5 injection sites on the cervix and posterior fornix. Twenty minutes following the paracervical block, I start the procedure. This protocol is one of many potential protocols for in-office NovaSure procedures.

PRACTICE PEARL: I prepare patients mentally to anticipate pain that may be equivalent to menstrual cramping, but that this will last only 60 to 90 seconds. Some of my patients do not feel any pain while others respond well to the analogy of the “heavy feeling” during dental block procedures.

Recovery takes 30 minutes. I recommend patients take naproxen 500 mg twice a day and hydrocodone-acetaminophen 5 mg/500 mg every 6 hours, as needed, for 24 hours. Most patients resume normal activities the day after the procedure. I receive very few calls from patients complaining about bleeding or pain following the NovaSure procedure.

Regulatory issues for clinicians

Regulations and requirements for office-based surgery vary by state, so clinicians will need to check with their state Department of Health Services to understand the steps that should be taken to be in compliance. Regulations can usually be obtained online (www.aaahcnewyork.org/lawsbystate.htm; www.auanet.org/content/practice-resources/office-based-surgery/office-based-surgery.cfm). If a physician does not want to complete the procedure room and staff certification requirements and have the necessary emergency equipment on hand to perform a level II procedure, that physician must choose an EA procedure best

suited for use with minimal sedation and local anesthesia and avoid the use of schedule 2 narcotic or hypnotic drugs given parenterally.⁷

Office economics

The in-office procedure benefits both patients and doctors considerably. For patients, most insurers require only a modest copayment, as opposed to paying a high deductible for the procedure performed in the outpatient facility or in the hospital. In addition, Medicare reimburses \$1,747⁸ in the office setting. A survey of more than 400 rates from offices across the country shows an average commercial payment of \$2,074⁹ for the office setting.

Conclusions

NovaSure's technology is unique due to a variety of factors:

- Impedance control leads to a customized ablation, independent of endometrial thickness.
- NovaSure can be performed at any point during the cycle.
- No pretreatment to thin the endometrial lining with medication or D & C is required.
- NovaSure is the only GEA system that assesses uterine cavity integrity.
- NovaSure is the only ablation procedure that allows multiple cases to be booked per hour.⁶
- NovaSure has an amenorrhea rate of over 40%.¹

References

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NovaSure® Endometrial Ablation System

The Only Impedance Controlled Ablation



Proactive Safety

CIA Test assesses uterine cavity integrity prior to procedure.

No Uterine Distention

Proprietary Moisture Transport System maintains contact between the uterus and the array while evacuating by-products of the procedure.

Customized Ablation

Designed to deliver optimal results based on patient's uterine cavity length and width.

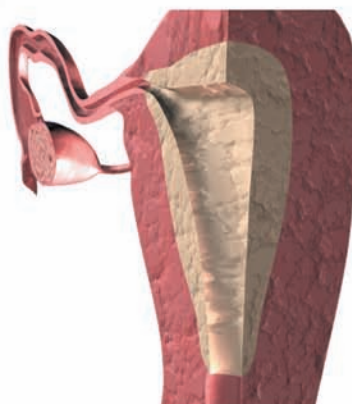
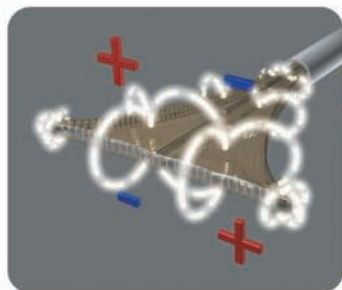
Automated Control

Controller constantly measures resistance during the procedure until tissue impedance reaches 50 ohms or procedure maximum of 2 minutes.



Controlled Depth of Ablation

Varied electrode center to center distance tailors the depth of tissue ablation ensuring a customized treatment independent of endometrial thickness, with a shallower ablation in the cornual area and a deeper ablation in the body.



SUPPLEMENT TO

OBG MANAGEMENT

December 2009



UPDATE:

Options in Endometrial Ablation