



# Understanding Menorrhagia

## TREATMENT WITH OFFICE-BASED ABLATIONS

LaDonna Miller, CST, CFA

Menorrhagia is a condition that many women silently suffer from. Deriving from the Latin word *men + rhegnyai*, meaning to "burst forth," menorrhagia is the condition of prolonged or excessive menstruation.<sup>3</sup> Women who lose 80 ml or more of blood during their menstrual cycle, which normally should consist of a 35–45 ml blood loss, experience menorrhagia.<sup>1</sup> Approximately 10 million women in the United States are affected by excessive menstrual flow. In the last few years, however, menorrhagia has become easily manageable.<sup>5</sup>

**T**he first step in resolving menstrual abnormalities is recognizing the problem. Some women have suffered from menorrhagia all their life and do not recognize this as abnormal. Others have a fear of discussing this problem with anyone, including their doctor. These reasons, factored in with the hustle and bustle of everyday life, has left women living in submission to menorrhagia. Women no longer have to be embarrassed by or concede to heavy periods. It is a real condition, not just an inconvenience, with a real name, and real treatment options.

### TREATMENT OPTIONS

There are a few different treatment options when it comes to helping relieve the symptoms of menorrhagia. Hormonal methods are the most conservative, and often the first step that most women will try. These include hormone replacement therapy, oral contraceptive pills, and other hormonal contraceptive devices such as the patch or ring. These, in combination with other medical therapies, such as non-steroidal anti-inflammatory drugs (NSAIDs), for some women, will greatly reduce the amount of

### LEARNING OBJECTIVES

- ▲ Examine the various treatment options for menorrhagia
- ▲ Compare and contrast the different in-office procedures
- ▲ Assess the challenges that face physicians who offer in-office procedures
- ▲ Explain the process of global endometrial ablation (GEA)

menstrual flow each month. For others, these therapies are not enough to improve their daily life.<sup>1</sup>

For women who no longer wish to preserve fertility, global endometrial ablation (GEA) is considered a conservative and effective treatment of menorrhagia. However, it should be noted that GEA is not a sterilization procedure and pregnancy following GEA is contraindicated. GEA is intended to denude the endometrial lining of the uterus and significantly reduce the amount of blood lost during a menstrual cycle. GEA is a less-invasive surgical treatment that requires minimal hospital time and recovery period for the patient.

It provides an alternative for women when medical therapies have failed and the definitive treatment for menorrhagia, hysterectomy, is not conducive to the patient's life at the current time.<sup>2,4</sup>

Hysterectomy is the most absolute option for the treatment of menorrhagia. By removing the uterus, menorrhagia is cured. However, hysterectomy is not the answer for every woman. Hysterectomy comes with all the risks of major surgery, including higher morbidity, and requires several weeks of recovery. Hysterectomy often requires an



*This is the complete operative field and office setup. The imaging equipment, bed, IV pole and sterile field are in view.*

care is changing. Once these women have completed their families and are ready to give up their fertility, they no longer need to live with menorrhagia. Hysterectomy is the right option for some women, but for most, GEA offers a less invasive approach with optimal results.

Historically, endometrial ablation was a much more complicated procedure. The older techniques, using a Nd:YAG laser and the electrosurgical rollerball, took more than three times longer to perform compared to GEA and were more

dangerous to the patient. Not only was the surgical time increased, but with that came the increase in the amount and type of fluids that were used during hysteroscopy. These factors combined together often led to hyponatremia and fluid overload. These risks, along with several others, paved the path to great advancement in endometrial ablation. The FDA's 1997 approval

of GEA gave patients and physicians a safer option for an alternative to hysterectomy.<sup>2,4</sup>

ThermaChoice®, a water-filled balloon device, was the first FDA-approved global endometrial ablation device. This was first approved in 1997, and many improvements have helped the product evolve into its current state.

ThermaChoice® uses D5W in the balloon to reach an ideal pressure of 160-170 mmHg. This pressure, combined with the 87 degrees Celsius temperature that the D5W

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invasive abdominal incision, when the GEA can be performed transvaginally. Also, depending upon whether the ovaries need to be removed or not, a woman may need hormone replacement therapy.

#### **GLOBAL ENDOMETRIAL ABLATION (GEA)**

There are more than 600,000 hysterectomies performed annually in the United States, 90 percent of them result from benign causes.<sup>4,6</sup> For that 90 percent, the standard of



reaches in the balloon, allows the destruction of the endometrial lining up to 5mm in depth. The procedure takes an ablation time of eight minutes. Safety mechanisms, including the machine shutting off if there is a sudden drop in pressure or if the temperature deviates out of normal range, are in place to make sure ThermaChoice® offers a safe procedure.<sup>2,4</sup>

NovaSure® has been another form of GEA since its FDA approval in 2001. It is the first bipolar radiofrequency device approved for GEA. NovaSure® is made up of a fan structure layered with copper mesh. First, the bipolar electrode conforms to the contours of the uterine cavity, making sure the proper settings for the cavity length and width are noted. The system then insufflates the uterine cavity with CO<sub>2</sub> to perform the cavity integrity assessment to ensure that no uterine perforation has occurred. The bipolar radiofrequency procedure produces an ionized saline layer that disrupts molecular bonds without using heat. As the energy is transferred to the tissue, ionic dissociation occurs, causing removal of tissue with a thermal effect of 45-85 degrees Celsius. This procedure usually takes about two minutes or less.<sup>2,4</sup>

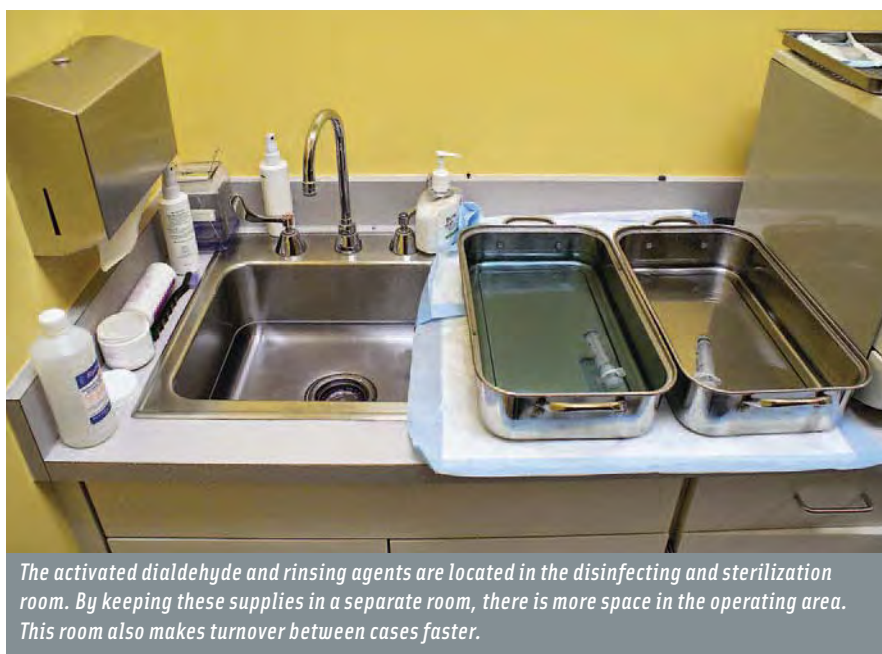
Hydrothermal ablation, or HTA, became the first balloonless hot water system to gain approval by the FDA in 2001. HTA is the only GEA method that allows hysteroscopic visualization as the procedure is performed. The saline is heated externally and reaches a temperature of 90 degrees Celsius. It then is circulated in the uterine cavity, abating the endometrium to about 3-4 mm. This procedure takes around 11 minutes, including the one-minute cool down phase. To maintain safety with this device, the pressure is kept to 55 mmHg to avoid fluid flow through the fallopian tubes. The machine is also able to detect significant fluid loss, which indicates the loss of a cavity seal.<sup>2,4</sup>

A completely different method of GEA is called Her Option®, a cryosurgical endometrial ablation. Her Option® was the first GEA device that was marketed as an in-office procedure. The use of Her Option® began in 1997, and gained FDA approval in 2001.<sup>7</sup> The procedure is performed with ultrasound guidance, so visualization is present during the whole procedure. A cryoprobe is cooled by pressurized gas to

-100 to -200 degrees Celsius. This allows for a tissue destruction depth of about 9-12mm. The freezing of the tissue makes the procedure less painful for the patient. This method of producing local anesthesia by localized application of cold is called cryoanesthesia, or refrigeration anesthesia. The entire procedure takes around 10-20 minutes to perform.<sup>2,4</sup>

## IN - OFFICE PROCEDURES

One of the greatest advantages of global endometrial ablation is the ability to perform it in an office setting. Many patients, properly selected, can alleviate their problems with menorrhagia without the complications of general anesthesia. Patients receive anxiolytics, NSAIDs and a



*The activated dialdehyde and rinsing agents are located in the disinfesting and sterilization room. By keeping these supplies in a separate room, there is more space in the operating area. This room also makes turnover between cases faster.*

paracervical block based on physician's preference, prior to the procedure. This, along with the less-stressful atmosphere of the office, is a perfect combination for an effective, comfortable experience.

Patient selection for office procedures includes criteria such as patient medical history and insurance coverage. The patient must be able to tolerate a mild amount of discomfort. It is also important to make sure to review the patient's history of gynecological procedures to confirm that there will not be any problems that would increase the operative time. Because office-based procedures are reimbursed by insurance companies at a different rate than hospital-based procedures, it is important to confirm that the patient's insurance carrier will reimburse for office-

based procedures. This allows for the equipment and supplies in the office to be adequately covered. Proper history screening and thorough counseling will aid in correct patient selection.

### Starting Up

When a physician is contemplating starting to perform office-based ablation procedures, there are many different considerations. He or she must select which GEA device

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will be used, hysteroscope brand and equipment, and what personnel will be helping to get the business started. Many supply companies offer incentives for choosing their product and they may aid in the equipment and device selection. (See the sidebar at the end of this article for more details.) One vital component in making the process a success is having a competent, well-trained, patient-friendly staff. It is also important for the doctor to have a surgical technologist who understands the importance of sterility and has knowledge of scope care. This will prevent the physician from having to worry about proper sterilization and any unnecessary equipment repairs.

### Preoperatively

For an office-based surgical technologist, the main role in in-office procedures is to ensure all the necessary equipment and supplies are available, cleaned, and sterilized correctly. Prior to the procedure, the tower containing the monitor, light and camera box needs to be turned on and pretested to make sure it is functioning without a glitch. The camera and light cord need to be disinfected and plugged into the tower. After it is determined that the

equipment is in working order, the scope and its accessories need to be taken to the designated disinfecting station and prepared for sterilization.

The best method of sterilization for scopes in office is activated dialdehyde, which allows a quick and effective sterilization method with the least amount of damage to your scope. The hysteroscope is a big investment, and is very vulnerable to damage if handled improperly. Therefore, it is in the best interest of the physician to have it

handled by someone with knowledge of its parts and handling care. Once the scope is in the activated dialdehyde (between 12–20 minutes, depending on the type—be sure to consult the manufacturer's instructions), a nonsterile working surface containing an open-sided speculum, single-tooth tenaculum, betadine swabs, and anesthetic of choice, will

be placed in an accessible location for the surgical technologist and surgeon. Once the nonsterile field is established, a sterile area needs to be created. A Mayo stand covered with a sterile impervious drape and towels is ideal. The Mayo stand will hold the scope, white balanced and ready to go, and cervical dilators. Right before the patient comes to the room, a pre-warmed bag of normal saline needs to be hung on an IV pole in a pressure bag and hooked up to the irrigating system.



*This is the nonsterile working table. This is the portion of the procedure where the physician injects the local anesthetic.*

Once the patient comes to the room, it is the surgical technologist's job to make sure the surgeon has exactly what he or she needs, when it is needed, but also, and more importantly, help provide a stress-free, comfortable procedure for the patient. Having everything ready and available and not having to interrupt the continuity of care is important to the patient's trust in the procedure.

First, the prepping and paracervical block will be performed. The paracervical block consists of a series of injections with a local anesthetic chosen by the physician. Once the block is given, it needs time to set up. During this time, the patient's comfort is most important. Starting conversation about family or work and answering any additional questions the patient has about the procedure is a great way to help pass time and allow the block to become effective. The block is performed as a clean procedure and does not require sterile technique.

#### *Intraoperatively*

The procedure is now ready to begin with a quick look into the uterus with a hysteroscope to make sure there are not any anatomical anomalies that would prevent the procedure from being performed. Most of the time, the cervix does not need to be dilated with instruments, but can be hydrodilated with the hysteroscope. Hydrodilation reduces the amount of discomfort for the patient if it is possible, but sometimes due to prior procedures on the cervix or lack of vaginal births, cervical dilators are necessary. Once the cavity is inspected, the GEA device can be opened onto the field and the ablation can proceed. The amount of time it takes, once again, is dependent on the device. Most patients will experience some mild cramping during the procedure, but it will subside the moment the ablation is stopped and the device removed.

When the GEA is finished, the patient will be cleaned up and allowed time to make sure they feel well enough to leave and given proper home instructions. Recovery time for each patient will vary according to how they tolerate the procedure and how the preoperative medications affect them. Most patients will go home and sleep for a couple of hours and wake up to experiencing some mild menstrual-like cramps. The physician instructions should include a medication protocol along with other methods, such as a heating pad, to help alleviate the patient's discomfort. The next day, most patients resume normal activities, excluding any vaginal activity such as tub baths or intercourse. The patient can expect a few weeks of vaginal discharge.



A patient's results can range from complete elimination of menstruation to no change at all. The size of the patient's uterine cavity, depth of the endometrial lining and accuracy in the performing of the procedure all affect the outcome. Most patients will experience a significant reduction in their menstrual cycle and this is the primary goal with global endometrial ablation.

#### **CONCLUSION**

The FDA approval of global endometrial ablation in 2001, brought a new light to women's health. Women no longer have to live with the embarrassment and hassle of menorrhagia or the fear of having major surgery. GEA is a minimally-invasive procedure with great results for most women. Not only can women alleviate or reduce their menstrual flow, but they can do it in the comfort of their doctor's office.



As GEA opened the door for better treatments in women's health, it also opened a door to more career choices for surgical technologists. The office-based procedure provides a different route of employment for surgically-trained personnel. It allows a less stressful job setting with the addition of awake-patient care. It enhances

#### ABOUT THE AUTHOR

LaDonna Miller, CST, CFA, is employed by OB/GYN of Paducah, in Paducah, Kentucky, as a surgical assistant. OB/GYN of Paducah specializes in da Vinci robotic hyster-



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ectomies, pelvic prolapse procedures, office-based uterine ablations and office-based hysteroscopic tubal sterilization. Mrs Miller has been a surgical technologist for nearly 10 years and a certified first assistant since September 2007. She is a member of AST and ASA, and resides in Paducah, Kentucky with her husband and three children.

one's ability to prioritize and effectively communicate with co-workers and patients. GEA and office-based procedures can be a great supplementary income and addition to current employment, or it can be a pathway to a part-time job opportunity. Whatever the case may be, the flow of health care changes everyday and surgical technologists must be prepared to go with it. By increasing the depth of knowledge and adding to the list of job skills, the surgical technologist becomes more marketable to the medical community.

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## UNDERSTANDING MENORRHAGIA:

# A Physician's Perspective

When a physician decides to begin in office procedures, whether it is global endometrial ablation or hysteroscopic tubal sterilization, several considerations must be made. First, one must decide what type of ablation technique he or she wants to use. All have advantages and disadvantages, so it really comes down to the physician's preference. Being comfortable with the procedure avoids the cumbersome nature of learning a new technique while the patient is aware of her surroundings. Most companies have programs available where there is minimal capital investment in terms of purchase of the generator. Some generators are given to the physician after the purchase of a minimal number of disposable devices; whereas others have programs where one commits to a monthly minimal purchase for a year and the generator is provided at no extra cost.

Next, the physician must choose the hysteroscopic equipment. Most companies have similar products and competitive prices. This is usually the largest capital expense and it is important that the service of the equipment is researched prior to the purchase. In other words, one should "buy the company," not the equipment. Most major companies have representatives who are willing to come to the office and demo their equipment for a couple of days at no charge. With several companies vying for business, one can essentially do a significant number of cases, test drive several systems, and do so at no expense. Obviously, scope, light source, camera and monitor are recommended. A printer can be added for documentation purposes at the physician's discretion.

There are multiple advantages to performing in-office procedures. However, the physician must do some research prior to the implementation of this service. One must look at his/her payer mix and determine if there are enough opportunities for this to be financially feasible, as not all insurance companies will reimburse the amount needed to justify the expense of the procedure.

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If the payer mix can sustain the business, this is a service that one will be surprised at how many patients prefer the in-office atmosphere for treatment of menorrhagia or for sterilization procedures.

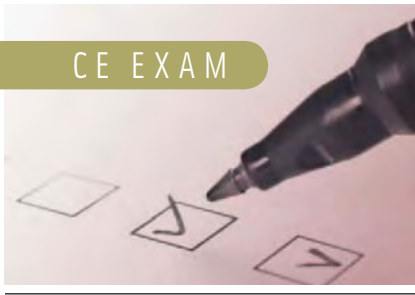
In the office, the staff must be able to put the patient at ease. After all, that is

what the office employees provide, from answering phone calls, to giving test results, or simply a shoulder to cry on. However, oftentimes, one does not have a staff member that is efficient and qualified to care for the costly investment when it comes to handling the hysteroscope. One of the advantages of having a Certified Surgical Technologist with operating room experience on staff is that he or she provides that extra comfort. He or she can efficiently perform all the duties that may exceed the expertise provided by other office staff members. These duties include maintenance of the equipment, careful handling of the equipment, "turning over" your procedure room efficiently, respect for the sterile field, and assistance in trouble shooting the optics or the ablation equipment.

In closing, office based procedures allow the gynecologist an opportunity to increase reimbursement in an environment that is welcomed by patients. In addition, one can avoid the risks of general anesthesia by safely performing the same procedure with minimal medications.



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# Office-Based Ablations

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1. \_\_\_\_\_ is **not** a conservative method of treating menorrhagia.
  - a. Hysterectomy
  - b. Hormone replacement therapy
  - c. Oral contraceptives
  - d. All are conservative methods
2. **Of the 600,000 hysterectomies performed in the United States, \_\_\_\_\_ percent are from benign causes.**
  - a. 75
  - b. 80
  - c. 85
  - d. 90
3. \_\_\_\_\_ is an FDA-approved alternative to hysterectomy.
  - a. ThermaChoice®
  - b. NovaSure®
  - c. Global Endometrial Ablation
  - d. All of the above
4. \_\_\_\_\_ is made up of a fan structure layered with copper mesh.
  - a. NovaSure®
  - b. ThermaChoice®
  - c. Her Option®
  - d. All of the above
5. **The only GEA method that allows hysteroscopic visualization during the procedure is \_\_\_\_\_.**
  - a. ThermaChoice®
  - b. Her Option®
  - c. Hydrothermal ablation
  - d. B & C
6. **Producing local anesthesia by localized application of cold is known as \_\_\_\_\_.**
  - a. Her Option®
  - b. Cryoanesthesia
  - c. Refrigeration anesthesia
  - d. B & C
7. **By keeping pressure to 55 mmHg, HTA avoids \_\_\_\_\_.**
  - a. Ionic dissociation
  - b. Fluid flow through the fallopian tubes
  - c. FDA sanctions
  - d. All of the above
8. **The best method for sterilizing scopes in the office is \_\_\_\_\_.**
  - a. Steam sterilization
  - b. Sterile wipes
  - c. Activated dialdehyde
  - d. Antimicrobial solution
9. **A/An \_\_\_\_\_ consists of a series of injections with a local anesthetic.**
  - a. Paracervical block
  - b. Ionic dissociation
  - c. Refrigeration anesthetic
  - d. None of the above
10. **Postoperatively, most patients can expect \_\_\_\_\_.**
  - a. Mild, menstrual-like cramps
  - b. A few weeks of vaginal discharge
  - c. significant reduction in menstrual cycle
  - d. All of the above

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Mark one box next to each number. Only one correct or best answer can be selected for each question.