



New Trends in Thermal Balloon Ablation

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The ThermaChoice uterine balloon system is the only FDA-approved balloon system and was the first of the modern second-generation devices approved to perform global endometrial ablation.¹ It is the only global endometrial ablation system with long-term clinical efficacy and patient satisfaction data published at 1, 3, and 5 years.

In a recent clinical evaluation of the ThermaChoice III UBT system, it was shown that ThermaChoice III had greater efficacy compared to its predecessor, ThermaChoice I.

Thermal balloon ablation can be used in the office to provide a safe, cost-effective, and efficacious treatment. The catheter, controller, and umbilical cable are designed as a system.² No incisions, hormones, or hospital stay are required. This very thin device (< 4 mm outside diameter) requires no cervical dilation in most cases. Additionally the device is flexible, unlike comparable devices.

The thermal balloon system thus usually allows for access to the anteflexed or retroflexed uterus.

This system has undergone a number of randomized clinical trials that established its safety and efficacy. In a 3-year comparison of uterine balloon therapy (UBT) and hysteroscopic rollerball endometrial ablation (REA), 14 sites randomized 255 women to one of these procedures.³ The women were followed for 3 years, and results showed that patient satisfaction remained similar.

Another trial looked at 5 years of follow-up, and of 255 women treated under the original protocol 147 were available to be interviewed.⁴ Of these, 25 patients reported undergoing hysterec-

tomy, repeat ablation, or dilatation and curettage between years 3 and 5, leaving 122 patients eligible for analysis (61 UBT, 61 REA). Of these, 58 (95%) having UBT and 59 (97%) having REA reported normal or less bleeding. Similarly 93% and 100%, respectively, were satisfied with the procedure. In addition, a multinational cohort study found that of 188 patients available for 5 years of follow-up after thermal balloon ablation, 75% had avoided subsequent hysterectomy surgery.⁵

LATEST STUDY RESULTS

In a recent clinical evaluation of the ThermaChoice III UBT system it was shown that ThermaChoice III had greater efficacy compared to its predecessor, ThermaChoice I.⁶ In the intent-to-treat analysis set of 250 patients treated with ThermaChoice III, the rate of amenorrhea 12 months after treatment with ThermaChoice III was 31.7%. Furthermore, when matched to patients in the original ThermaChoice I clinical study the rate of amenorrhea 12 months after treatment was 32.6%. This success rate is significantly greater (32.6% versus 13.7%, $P=.0025$) than the success rate in the patient-matched controls in an earlier study using the first marketed ThermaChoice system (ThermaChoice I). More than 90% of women reported that they “returned to normal bleeding

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or less” after ThermaChoice III treatment, compared to 75.4% of patients treated with ThermaChoice I for the modified intent-to-treat analysis set. Quality of life and patient satisfaction end-points also showed favorable results for women treated with ThermaChoice III. A reduction in menstrual pain and cramping was experienced by 89% of patients. Approximately 96% of patients were satisfied with their outcome and 99% would recommend the procedure.⁷ Thus, these data show that the ThermaChoice III offers improved treatment efficacy versus the prior balloon system.

Benefits of In-office Endometrial Ablation

Once the decision is made to treat, the question is whether to perform the treatment in the office or in the hospital. There are many arguments supporting the in-office decision, including the fact that the physician, patient, and payer all benefit from in-office treatment. Physicians benefit because in-office procedures maximize the high demand on their services, expertise, and time by providing more control than in the hospital. Thus, the ability to take a procedure from the hospital into the office saves precious time for the physician as well as provides a new avenue for patient care.

For example, in the hospital an 8:00 am appointment may mean 9:00, 9:30, or 10:00 am depending on anesthesia, break times, or emergencies that may arise. Medication reconciliation sheets and the lack of standing orders for preoperation medications add to physician frustration. In the office, however, an 8:00 am appointment usually means the physician enters the examining room at 8:00 am and the patient is

in the stir-ups, prepped and draped, and the case is ready to commence. Additionally, standing orders in the office for preoperation medications are allowed.

For patients the office is usually much more pleasant and friendly than the hospital or outpatient setting. In the hospital the patient often has nothing to eat or drink past midnight, unfamiliar faces greet her, an intravenous therapy (IV) is put in place, and she is given general anesthesia. The patient having an in-office procedure has a light breakfast that morning, there are no IVs, and she is greeted by familiar faces who convey comfort and confidence. In addition, most patients also experience financial benefits since many payers require a copay for this procedure as opposed to a much larger deductible for an in-hospital or outpatient procedure.

The transferring of this technology from hospital to office potentially offers a reduction of 70% or more for payers. When all of these factors are taken into account the patient can experience the same procedure as in the hospital, with the same results, in a very safe office environment that is also very satisfying.

Logistics in the Office

Most physicians performing endometrial ablation in-office will use a regular examination room or procedure room. An examination room should be large enough to accommodate the table with stir-ups, a video tower, an IV pole, a table for instruments, phone/intercom, and a resuscitation cart. Staff can be either a highly trained clinical nurse practitioner, physician assistant, or a medical assistant. The staff must be friendly and patient-centered.

Training is mandatory for each member of the team to understand their role in the preoperative, intraoperative, and postoperative care of the patient. One training approach is for the gynecolo-

gist and nurse to observe an in-office case by a team who is already performing this procedure. Confidence is gained for the doctor by performing ablation procedures first in the hospital setting where a stronger safety infrastructure exists.

Procedure room items include a video tower, instrument table, IV pole, phone/intercom, and minimal drapes. Disposable packs are available that include drapes and antiseptic agents, syringes, needles, and any other disposables needed.

The equipment on the table includes 12, 25, or 30 degree hysteroscope with a 5 French operative channel. Also included is an open-sided speculum for the local anesthetic or the paracervical or intracervical block. Also needed are tenaculum forceps; either smooth tooth, Gimpelson, or Alice clamp; and Os finders and dilators. A 3 L bag of saline with pressure cuff is a must. A hysteroscopic grasper and scissors should also be included to remove incidental polyps or other simple space-occupying lesions of the uterine cavity.

Thermal balloon ablation uses a catheter, controller, and umbilical cable as a system (Table). A starting pressure of 160 to 180 mm Hg is recommended and typically requires 6 to 15 cc of fluid and may require as much as 35 cc.² Titration to achieve a stable pressure prior to activating the heating element is critical. Additional fluid should never be added during a therapy cycle. As with all endometrial ablation procedures uterine perforation can occur.

Effective Pain Management

The successful management of pain for in-office endometrial ablation requires appropriate protocols that deal with patient selection and preoperative, intraoperative, and postoperative pain management. Appropriate patient selection can be accomplished by discussing

TABLE. ThermaChoice At a Glance

The ThermaChoice Uterine Balloon Therapy System works by ablating the endometrial lining of the uterus in three phases: insertion and balloon inflation; heating, ablation, and monitoring; and deflation and removal.

Insertion and Inflation:

The balloon catheter is inserted vaginally through the cervix into the uterus. Inflation occurs when the catheter is filled with a sterile fluid solution until the pressure reaches 160 to 180 mm of mercury. The typical cavity holds 10 to 20 cc's of the fluid.

Ablation and Monitoring:

A heating element inside the balloon raises the temperature to approximately 87°C and maintains it for approximately 8 minutes. The controller continuously monitors and displays catheter pressure, regulates fluid temperature, and controls therapy time throughout the procedure. If any of the preset parameters are exceeded, the device is automatically deactivated and the procedure immediately terminated.

Deflation and Removal:

When the controller signals that treatment is complete, the balloon is deflated and the catheter is withdrawn and discarded.

the patient's experiences with previous procedures such as simple Papanicolaou tests and also more complicated procedures including endometrial biopsy, office hysteroscopy, transvaginal ultrasonography, and/or saline infusion sonography. The level of anxiety and difficulty that the patient experiences with these procedures should be considered when adding someone to the list for in-office ablation. Labor and delivery experiences, as well as the patient's expectations and perceived outcomes of in-office procedures, are additional critical determiners to the success of a patient. If a patient experiences cramping during menstruation, she may feel similar cramping during the procedure. Setting appropriate expectations for the patient beforehand is key.



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For the physician, experience with advanced pain management is essential.

For the physician, experience with advanced pain management is essential. If this is not currently the case, training and practice is required to transition from the hospital setting to the office. Many physicians currently performing in-office endometrial ablation recommend starting with analgesia at least 24 hours prior to the procedure.

Oral analgesics given before the procedure reduce pain and cramping substantially. Medications should be given with adequate time to achieve full effect before the procedure. In most cases this means giving the analgesics at least 1 hour before the procedure.

Some physicians may consider the use of an anxiolytic immediately preoperatively to facilitate relaxation. Nonsteroidal anti-inflammatory drugs are useful as well; one option is 800 mg of ibuprofen the night before and the morning of the procedure. An antiemetic is indicated if the patient develops nausea with pain. While most practitioners use a paracervical block, others provide no preoperative or intraoperative analgesia.

Another important intraoperative technique to reduce pain is conversational analgesia or the “vocal local.” This refers to engaging the patient in conversation throughout the procedure to reduce anxiety and to distract from cramping pain that she may experience. Some clinicians have a medical assistant or nurse who is specifically present to comfort the patient and to talk her through the procedure. This is a great example of the concept of the team approach to intraoperative pain management.

Listening to music that ideally the patient has chosen also has been shown to reduce intraoperative and postoperative pain in the office setting and has a calming effect during endometrial ablation. Placement of pictures for the patient to view on the ceiling above

the examining table is another distraction. Patients can also be encouraged to bring a supportive friend or family member on the day of procedure. Other nonpharmacologic management techniques that may reduce pain during endometrial ablation are positive suggestion, relaxation, guided imagery, and aromatherapy.

Some clinicians make rescue analgesia available, although many gynecologists using ThermaChoice in the office may not have these drugs available or may not have the monitoring or safety equipment needed to administer them. For this reason, some experts recommend doing the first few sedation-free surgeries in the surgery center. This would allow the use of rescue analgesia until the gynecologist perfects the deep paracervical block technique. With the proper technique rescue analgesia should rarely be needed.

Postoperative Management

Proactive, postoperative pain management is recommended by continuing ibuprofen, 800 mg, every 8 hours for three doses. This preemptive treatment works best if doses are taken as scheduled, not as needed. Patients may also be given prescriptions for non-narcotic pain relievers to use if ibuprofen does not control pain adequately. Potentially, a mild narcotic such as an opioid agonist may be used. Regardless of which endometrial ablation technology is utilized, patients should expect to encounter some degree of postoperative pain. Staying ahead of pain by following recommended dosing and scheduling should take care of this.

Patients should be called the evening of and the day after the ablation. Patients appreciate this follow-up because it shows that the health care provider is genuinely concerned with their well-being. Symptoms from the procedure will usually last 6 to 8 hours and then abate very quickly.

Conclusion

As more of these procedures are migrating to physician offices, thermal balloon ablation offers a safe and effective treatment option. The balloon's long-term safety record and low dilation profile make it appropriate for office use. In addition, the conforming balloon of the third-generation device has now been clinically proven to deliver good patient outcomes and high satisfaction rates.

REFERENCES

1. Endometrial Ablation. ACOG Practice Bulletin No 81. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007;109:1233-1248.
2. Product Insert. Gynecare ThermoChoice III Uterine Balloon Therapy With Fluid Circulation. 2003 Ethicon, Inc, Somerville, NJ.
3. Loffer FD. Three-year comparison of thermal balloon and rollerball ablation in treatment of menorrhagia. *J Am Assoc Gynecol Laparosc*. 2001;8(1):48-54.
4. Loffer FD, Grainger D. Five-year follow-up of patients participating in a randomized trial of uterine balloon therapy versus rollerball ablation for treatment of menorrhagia. *J Am Assoc Gynecol Laparosc*. 2002;9(4):429-435.
5. Amso NN, Fernandez H, Vilos G, et al. Uterine endometrial thermal balloon therapy for the treatment of menorrhagia: long-term multicentre follow-up study. *Hum Reprod*. 2003;18(5):1082-1087.
6. Leal JG, Pena A, Donovan A, Cash C, Jr. clinical evaluation of gynecare thermachoice III uterine balloon therapy system (thermchoice III) for menorrhagia. Abstract presented at: Global Congress of the Minimally Invasive Gynecology; November 6-9, 2006; Las Vegas, NE.
7. Data on file.