Uterine balloon therapy

Background

Approximately 22% of all menstruating women suffer from excessive bleeding known as menorrhagia, with almost 200,000 American women undergoing hysterectomies each year to correct the condition. A hysterectomy, which involves complete removal of the uterus, is the second most performed female surgical procedure in the nation and the most common surgical treatment for menorrhagia. However, the procedure requires a hospital stay of several days, a three- to six-week recovery period, and may also cause physical and psychological side effects. Other treatments for menorrhagia include drug therapy, dilatation and curettage, and endometrial ablation using a laser or electrosurgical probe.

The ThermaChoice uterine balloon therapy (UBT) system developed by Gynecare, Inc. offers an alternative approach to the treatment of menorrhagia, due to benign causes, in premenopausal women who have completed childbearing. UBT is attractive because it is considered to be a simpler procedure requiring less surgical skill and less expensive equipment.

UBT reduces or eliminates menstrual flow by removing the inner surface of the uterus through a process known as thermal ablation. The device consists of two components: a balloon catheter containing heating and sensing elements, and a controller connected to a catheter that monitors and controls pressure, time, and temperature during the treatment, according to Gynecare, Inc. Once the patient has undergone either local or general anesthesia, the balloon catheter is inserted vaginally through the cervix and into the uterus. The balloon is then inflated with sterile fluid and conformed to fit the shape of the uterus.

During UBT, the temperature inside the balloon is raised to 87 degrees Celsius (188 degrees Fahrenheit) and maintained for eight minutes. The extreme heat destroys the endometrial lining of the uterus without affecting other parts of the uterus or other pelvic organs. When the treatment cycle is complete, the balloon is deflated and the catheter is withdrawn and discarded. The entire surgical procedure usually takes 30 minutes and most women are able to resume normal activity within 24 hours.

International clinical trials of the procedure began in 1994 and United States clinical trials began in 1996. One-year follow-up results from the United States clinical trials indicated that UBT was successful in 81% of the 125 patients who were treated. During the trials there were no intra-operative complications reported and only 2.1% of patients experienced effects such as endometritis or urinary tract infection. The
most common post-procedural effect usually reported by women who undergo UBT is mild to moderate abdominal pain during the first day, according to Gynecare, Inc.

Contraindications for UBT include women who have fibroids in the uterine lining, those with latex allergies, and those who are pregnant or wish to become pregnant in the future.

### Involved specialists
Gynecologists and obstetrician/gynecologists.

### Positions of societies and academies
The American College of Obstetricians and Gynecologists (ACOG) has no published position concerning the delineation of privileges for UBT. However, UBT is currently recognized as an “experimental procedure,” according to Mary Mitchell, associate director of clinical practice for the ACOG.

### Positions of other interested parties
The Food and Drug Administration (FDA) has granted a pre-market approval (PMA) status to the ThermaChoice UBT system, for the treatment of excessive menstrual bleeding, according to Dan Schultz, MD, chief medical officer for the office of device evaluations.

Until recently, women suffering from menorrhagia have had limited choices for treatment, he says. Hysterectomies have been the primary form of treatment for the condition, yet with recent concerns about the high numbers of hysterectomies performed in the country each year, physicians have begun to look at alternative therapies.

“ThermaChoice and a number of others have been investigating whether destroying the endometrium lining by using a heating or cooling process would achieve the same effect as other applications,” explains Schultz. “ThermaChoice is actually the one that’s been studied, gone through the PMA process, and is consequently being marketed.”

Schultz is optimistic about the overall success of the UBT system. “We think this is a major step forward in terms of treating a significant number of women who have these problems and in a less invasive manner.”

### Institute for Endocrinology and Reproductive Medicine
Assuming a physician is an experienced hysteroscopic surgeon and has been granted full gynecological privileges at his or her institution, privileging for UBT should be a very simple process.
process, says Andrew B. Dott, MD, an OB/GYN at the Institute for Endocrinology and Reproductive Medicine in Atlanta, GA. He recommends that a physician wishing to become competent in UBT either attend a specific course for the procedure or watch the instructional videotape put out by ThermaChoice and be mentored on one procedure by someone who has experience in the area and thus has already been granted those privileges.

“UBT is a very simple procedure to do from a surgical standpoint because of the low technology,” he says. “The most important thing is to make sure that before someone is permitted to perform the procedure, they are familiar with the equipment.” Since the procedure is so new, it has not even been specifically added to the privilege delineation form at his facility, Dott notes.

According to Dott, UBT is a favorable alternative to a hysterectomy for the right patient. “The advantage of the balloon ablation therapy is that it’s much simpler to do and it does not require someone who is highly skilled. The total cost of the procedure is $3,000 to $3,500, which is much cheaper than a hysterectomy.”

In comparison to endometrial ablation, UBT has a similar outcome; however, it appears to come up short in other aspects. The balloon, which can only be used once, costs $650 and is likely to be marked up by hospitals for profit. In his experience, Dott says patients also appear to have more postoperative pain with UBT as compared to endometrial ablation.

Marsha Howerton, MD, an OB/GYN at Tulsa OB-GYN Associates, Inc. and chair of the OB/GYN department at St. John’s Medical Center in Tulsa, OK, agrees that UBT is a simple surgical procedure for the experienced gynecological surgeon. She recommends that physicians attend the manufacturer’s training program over those sponsored by individual hospitals. “I’m just concerned that when we teach people from doctor to doctor, we may not remember all of the points involved in performing the procedure,” she says.

In addition, she notes that patients who undergo hysteroscopic or endometrial ablations instead of UBT might see a better long-term result for the treatment of menorrhagia.
Howerton, who is in the midst of devising a privileging form for St. John’s Medical Center, is using the following criteria from neighboring Saint Francis Health System as a guide.

I. Threshold criteria
   A. The applicant must currently hold core privileges in gynecology at Saint Francis Health System.

II. Required previous experience
   A. Attendance and documentation of satisfactory completion of the manufacturer’s thermal balloon ablation training program, or
   B. Residency training in the use of thermal balloon ablation equipment and instrumentation. The training must be verified by the residency director at the time of application for initial privileges at Saint Francis Health System.

III. Oversight
   A. New procedures and technology are routinely reviewed by the quality improvement department for a period of one year or 25 cases, whichever occurs first.
   B. Additional proctoring of this procedure will be in accordance with the established proctoring system of the department of obstetrics and gynecology.

IV. Maintenance requirements
   A. Maintain core privileges in gynecology.
   B. Applicant must perform four documented thermal balloon ablation procedures with a satisfactory quality record during the previous 24-month period.

**CRC draft criteria**

- **Basic education**: MD or DO
- **Minimal formal training**: Successful completion of an approved residency training program in gynecology.
- **Required previous training**: The successful applicant must be able to demonstrate that he or she has performed at least 50 gynecological surgical procedures in the past 24 months. In addition, attendance and documentation of satisfactory completion of the manufacturer’s thermal balloon ablation training program or residency training in the use of thermal balloon ablation equipment and instrumentation is required. This training must be verified by the residency director at the time of application for initial privileges.

   *Note: A letter of reference must come from the residency director or*
A supplement to Briefings on Credentialing 781/639-1872 Criteria reviewed 2006

Uterine balloon therapy Procedure 95

Chief of obstetrics and gynecology from another hospital where the applicant has been affiliated for the last two years. Two others must come from an anesthesiologist and primary care physician who have known the applicant at least two years and are acquainted with the applicant’s current professional status, medical practice, and involvement in the field of gynecology.

Core privileges in gynecology

Privileges include admission, work up, consultation, diagnosis, and pre-, intra-, and postoperative care necessary to correct or treat female patients of all ages presenting with illnesses, injuries, and disorders of the gynecologic system and nonsurgical treatment of illnesses and injuries of the mammary glands and urinary tract.

Reappointment

Reappointment should be based on unbiased, objective results of care according to the hospital’s quality assurance mechanisms. In addition to maintaining privileges in gynecology, the applicant must perform four documented thermal balloon ablation procedures with a satisfactory quality record during the previous 24-month period.

For more information

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Washington, DC 20090-6920
Telephone: 202/638-5577
Fax: 202/484-5107

Food and Drug Administration
Office of Device Evaluations
9200 Corporate Boulevard
Rockville, MD 20850
Telephone: 301/594-5072
Fax: 301/480-4224

Gynecare, Inc.
235 Constitution Drive
Menlo Park, CA 94025
Telephone: 800/898-5711
Privilege Request Form
Uterine balloon therapy

In order to be eligible to request clinical privileges for uterine balloon therapy, a practitioner must meet the following minimum threshold criteria:

- **Education:** MD or DO

- **Minimal formal training:** Successful completion of an approved residency training program in gynecology.

- **Required previous experience:** The successful applicant must be able to demonstrate that he or she has performed at least 50 gynecological surgical procedures in the past 24 months. In addition, attendance and documentation of satisfactory completion of the manufacturer’s thermal balloon ablation training program or residency training in the use of thermal balloon ablation equipment and instrumentation is required. This training must be verified by the residency director at the time of application for initial privileges.

- **References:** A letter of reference must come from the residency director or chief of obstetrics and gynecology from another hospital where the applicant has been affiliated for the last two years. Two others must come from an anesthesiologist and primary care physician who have known the applicant at least two years and are acquainted with the applicant’s current professional status, medical practice, and involvement in the field of gynecology.

I hereby request core privileges as follows: Admission, work up, consultation, diagnosis, and pre-, intra-, and postoperative care necessary to correct or treat female patients of all ages presenting with illnesses, injuries, and disorders of the gynecologic system and nonsurgical treatment of illnesses and injuries of the mammary glands and urinary tract.

- **Reappointment:** Reappointment should be based on unbiased, objective results of care according to the hospital’s quality assurance mechanisms. In addition to maintaining privileges in gynecology, the applicant must perform four documented thermal balloon ablation procedures with a satisfactory quality record during the previous 24-month period.

I understand that by making this request I am bound by the applicable bylaws or policies of the hospital and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: __________________________________________________________

Typed or printed name: ________________________________________________________

Date: _________________________________________________________________________
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