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## A New Treatment to Help Women Avoid Hysterectomy

By MELINDA BECK



Of all the pains and indignities the female body suffers, some of the most common are uterine fibroids—benign tissue growths in the womb. It's estimated that as many as 70% of women develop them at some point. Most are asymptomatic and women never know they're there. But in about one-third of cases—even more among African-American women—the fibroids become large enough to cause pain in the back, abdomen and pelvis, bloating and very heavy menstrual bleeding. Some grow to be as large as a grapefruit and can interfere with other organs.

The standard treatment is a hysterectomy, which permanently removes the uterus along with the fibroids. More than 200,000 hysterectomies are performed in the U.S. each year for fibroids; it's the second most common surgical procedure for women, after Cesarean sections.

But many women

who have fibroids aren't ready to surrender their uterus to get rid of them—so there's been intense interest in alternative treatments.

One of the newest is radiofrequency ablation, a minimally invasive procedure that involves inserting a needle-like device into the fibroid through the abdomen and heating it with low frequency electrical current.

Radiofrequency ablation is approved by the Food and Drug Administration for other purposes, including combating liver and lung tumors. But it's currently in phase-three clinical trials—the last phase needed to apply for approval—for uterine fibroids. Six medical centers in the U.S. are currently enrolling women for the trial, along with two in Mexico and one in Guatemala.

Dorothy Williams-Wallen was a prime candidate. "There were days when I didn't want to leave my house between the pain and the bleeding," says the 44-year-old mother from the Bronx, N.Y.. "At nights, I couldn't sleep, because my back was killing me. And the bloating was awful. I felt like I was seven months pregnant."

Even though she didn't want any more children, Mrs. Williams-Wallen was reluctant to have a hysterectomy. When doctors at Montefiore Medical Center in the Bronx told her about the trial, she jumped at the chance.

"It's an incredibly common problem, and it can be incapacitating for some women," says Erika Banks, director of the Fibroid Center at Montefiore and a principal investigator of the trial. Dr. Banks treated several of Mrs. Williams-Wallen's fibroids, one as big as a lemon, on Dec. 21.

Beyond radiofrequency ablation, alternatives to hysterectomy include:

**Managing symptoms:** Anti-inflammatory drugs can reduce pain, and birth-control pills or an intrauterine

device can reduce the bleeding. But neither will make the fibroids go away.

**Hormone blockers:** Drugs such as Lupron Depot shrink fibroids by preventing the ovaries from making estrogen, just as in menopause, when fibroids shrink naturally. Side effects include hot flashes and bone loss, so this is mostly used when menopause is near. Otherwise, the fibroids regrow when the drugs are stopped.

**Myomectomy:** Fibroids (also known as leiomyomata) can be surgically removed either with a major incision in the abdomen, a laproscopic procedure or with a hysteroscopy through the cervix, depending on their size and location. The fibroids must be dissected and the uterus must be repaired, but women can still become pregnant afterward.

**Uterine artery embolization:** The procedure, called UAE, involves threading a thin tube through an artery at the top of the leg and into a blood vessel that supplies the fibroid. Tiny plastic beads are injected to block the flow of blood, shrinking the fibroid. The embolization sometimes produces early menopause and is currently suggested mainly for women who don't want more children.

**High-frequency ultrasound:** This method, called HIFU, uses an MRI to locate the fibroids and shrinks them with highly focused sound waves. The patient lies in a scanner for several hours, and the sound waves penetrate without requiring an incision. Approved by the FDA in 2004, it is still not widely available and only treats small fibroids.

UAE and HIFU are generally performed by radiologists, not gynecologists, a source of some rivalry. "We came up with a device that gives control of the patient back to the gynecologists," says Jeffrey Cohen, co-founder and chief executive of Halt Medical Inc., which makes the radiofrequency ablation device.

The Halt procedure involves three small incisions. One is to insert the laproscopic camera so the surgeon can see inside the abdomen. A second is to insert an intra-abdominal ultrasound probe, which can determine the size and location of fibroids.

The third incision is for the Halt device, a needle electrode that penetrates the fibroid and burns the cells, which are eventually reabsorbed by the body. The device also cauterizes the incision to minimize bleeding.

The procedure, which requires general anesthesia, can take several hours depending on how many fibroids are found. But patients can go home the same day. Potential downsides are similar to other minimally invasive surgeries, says Dr. Banks, who has no financial ties to Halt. She notes that in early tests outside the U.S. with 70 women, 90% were satisfied with the results. The device has a CE mark for use in Europe, but the company has not yet been launched there.

In the current trial, investigators are ablating fibroids larger than one centimeter and only six at a time. They are studying whether the procedure reduces heavy menstrual bleeding and improves quality of life, not comparing it with other methods.

Treatment within the trial is free to qualifying women. Subjects must be over 25 years old and not interested in having more children, but Mr. Cohen hopes that future trials will show that it is safe for women who want to get pregnant as well.

"It certainly holds promise—the challenge will be to see what the long-term benefits are," says Howard Sharp, former chairman of the American College of Obstetrics and Gynecology's gynecologic practice committee. He notes that in 20% to 30% of cases with UAE and myomectomies, women eventually have hysterectomies because their fibroids recur.

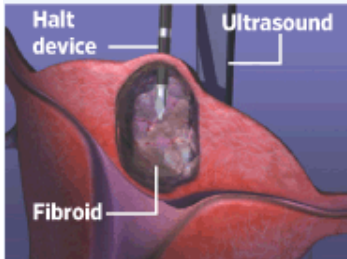
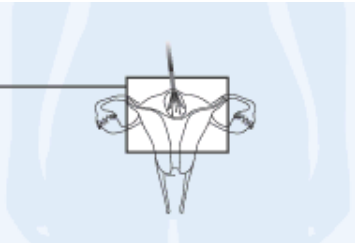
For now at least, Mrs. Williams-Wallen is very satisfied. "It's amazing how well I feel now," she says. "I feel like I have my life back."

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Melinda  
Beck at**

### Removing Fibroids

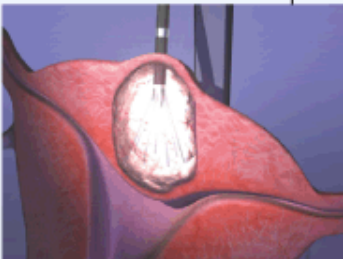
The radiofrequency ablation procedure requires three small incisions—for a laproscopic camera, an ultrasound probe and the Halt device, a needle with electrode arms that penetrates the fibroid and destroys the cells with heat.

Area of detail

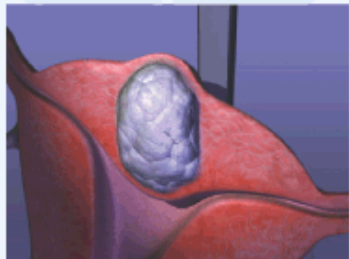


The ultrasound probe (behind) guides the Halt ablation device into the fibroid.

Source: Halt Medical



The device deploys electrodes which emit energy that destroys the fibroid using heat.



The dead cells are eventually reabsorbed into the surrounding tissue.

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