



FDA Approves Ultrasound Fibroid Therapy

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THE US FOOD AND DRUG ADMINISTRATION has approved the first noninvasive, potentially ablative therapy for uterine fibroids. While hysterectomy remains the only definitive therapy for these benign tumors, the combination magnetic resonance imaging (MRI) and ultrasound technology, called the ExAblate 2000 System, could offer selected patients a less invasive alternative to surgery.

Uterine fibroids are found in approximately 20% to 40% of women over the age of 35 years, with an estimated incidence as high as 75% in certain high-risk populations. While many such tumors are asymptomatic, some are associated with significant and disabling symptoms, ranging from prolonged menstrual periods to urinary frequency and lower back and pelvic pain.

Hysterectomy may require a hospital stay as long as 4 days plus a 6-week recovery period. Options such as laparoscopic and hysteroscopic myomectomy and uterine artery embolization are less invasive but also require a hospital stay, are associated with morbidity and missed days from work, and have demonstrated mixed results. Hormonal therapies, although noninvasive, generally provide only temporary relief from symptoms and are not a long-term treatment option.

The ExAblate 2000 System, manufactured by InSightec, Ltd (Haifa, Israel), uses an MRI scanner to allow the operators to visualize and monitor the temperature of the treatment area while high-intensity sound waves are focused on the tumor to heat it and induce coagulation necrosis. Both gynecologists and radiologists will require special training with this system, which is currently available at 7 sites in the United States.

Researchers at 7 centers in the United States, Europe, and Israel found that nearly 71% of 109 women treated with this technology reported a decrease in their fibroid-related symptoms at

6-month follow-up. However, within 12 months of the initial intervention, 21% of patients required an additional, invasive treatment for their fibroids. One patient experienced a major adverse



Technology combining magnetic resonance imaging with high-intensity focused ultrasound was recently approved by the FDA for use in treating uterine fibroids.

event, sacral nerve damage secondary to heating of the nerve, which resolved spontaneously by 12 months after the treatment. Minor adverse events included superficial skin burns.

The treatment's main advantage is that it is an outpatient procedure with a shorter recovery time. On average, study participants treated with focused ultrasound missed 1.4 days of work compared to 18 days of missed work for the control group of women, who underwent hysterectomy.

However, while the approach's short-term benefits are clear, the long-term efficacy has not yet been determined, noted Kenneth Noller, MD, of Tufts-New England Medical Center in Boston. "Because we know that many fibroids tend to regrow, there are not enough data from this study to determine the long-term efficacy of this sys-

tem," said Noller, who served as chair of the FDA panel that evaluated the device. Longer-term follow-up is therefore necessary to determine how the recurrence rates of ultrasound-ablated fibroids will compare to those associated with other treatments.

Longer-term follow-up and additional studies will also be required to identify the women who will benefit the most from this treatment, said Elizabeth Stewart, MD, of Brigham and Women's Hospital in Boston, who headed the largest study of the technique. "We don't yet know who is the optimal candidate," she said.

The new technique mainly benefits women who report symptoms associated with fibroid bulk, especially back and bladder pressure. It is not currently indicated for the treatment of submucosal fibroids, which are associated with bleeding. The procedure currently may be performed only on women who are not planning additional childbearing, as its effects on the uterine wall and the patient's future fertility and ability to carry a fetus to term are not yet known. This technique also cannot be used on fibroids located near the bladder or bowel walls, on fibroids outside of the imaging area, or on heavily calcified fibroids.

While further studies will help identify women most likely to benefit from this particular treatment, cost benefits are not clear. Although it may decrease costs by reducing inpatient stays, the associated equipment and personnel costs are likely to be significant.

Additional studies are under way. One international trial has enrolled 250 women who will be treated and followed up for 3 years. The FDA specifically requested the inclusion of a significant number of African American women in this study; this population was underrepresented in the initial study and appears to have a higher incidence of fibroids and more severe disease and may have a different tumor response to treatment. □