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Mayo Clinic Collaborative Study Finds Focused Ultrasound Treatment of Uterine Fibroid Tumors Provides Long Term Symptom Relief

ROCHESTER, Minn. -- A noninvasive, outpatient treatment for noncancerous uterine tumors provides sustained relief from symptoms, according to a new Mayo Clinic led collaborative study.

The study of this innovative treatment approach -- called magnetic resonance imaging guided focused ultrasound surgery (MRgFUS) -- also shows that the more completely tumors are destroyed by focused ultrasound, the more durable the symptom relief. In addition, the incidence of severe side effects is low. Combined, these results produce an overall improved quality of life. The report by Mayo and its collaborators, the Magnetic Resonance Imaging Guided Focused Ultrasound for Uterine Fibroid Group at Brigham and Women's Hospital and Harvard Medical School, appears in the Aug. 1 issue of *Obstetrics & Gynecology*.

Significance of the Mayo Clinic Collaboration

This new study examined more endpoints and follows women for a longer period after treatment than previous studies of the effects of focused ultrasound to treat uterine fibroid tumors. For example, the current study followed patients post-treatment for twice as long -- 24 months versus 12 months -- than earlier studies. It also followed a patient group that was more than twice as large -- 359 women versus 160 women. The results are therefore stronger than those from earlier studies, and more clinically relevant in their potential to:

- improve patient care by decreasing the need for repeat tumor-removal procedures.
- keep health care costs down, given that treating fibroid tumors constitutes a significant health care expenditure, particularly if it involves major surgery such as hysterectomy, or requires multiple, repeat procedures of the traditionally used noninvasive therapies that include abdominal and laparoscopic tumor removal, or uterine artery embolization.

Explains Mayo Clinic reproductive endocrinologist Elizabeth Stewart, M.D., the study's lead author: "Up to one-third of women who undergo alternatives to hysterectomy to treat fibroids experience recurrence of fibroids, so demonstrating the durability of focused ultrasound is important. Our study does this by examining rates of subsequent surgery for fibroid tumor symptoms and other key outcomes such as uterine shrinkage. Finally, our study demonstrates that the more completely you treat the fibroids, the better the outcomes are."

Evidence indicates that this novel technology, in the hands of experienced care-giving teams, is an effective, durable treatment for uterine fibroid tumors that safely produces sustained relief of symptoms, Dr. Stewart says.

About Focused Ultrasound

Magnetic resonance-guided focused ultrasound is a novel noninvasive technology for the outpatient treatment of fibroid uterine tumors. This treatment has been approved by the Food and Drug Administration (FDA) since 2004. Mayo Clinic was among the first in the U.S to offer the procedure.

Unlike other alternatives to hysterectomy, focused ultrasound does not depend on the insertion of devices, needles or catheters into the body. High-energy sound waves are directed precisely through the abdominal wall to targeted fibroid tissues. Thermal energy destroys the growths by coagulating the blood supply, while preserving healthy tissue. MRI images help physicians visualize the tissue volume and location and gauge the temperature of treated tissue.

About Uterine Fibroid Tumors

Uterine fibroid tumors -- also called leiomyomas -- are common noncancerous growths of the uterus. When symptomatic, they can cause severe abdominal and leg pain, excessive menstrual bleeding and abdominal bloating. In the past, they have been treated by surgical removal of the uterus via hysterectomy, or through noninvasive techniques such as abdominal and laparoscopic tumor removal, or uterine artery embolization. However, those approaches are associated with elevated rates of tumor regrowth, and need for repeated treatments.

About the Study

All 359 women in the study were typical uterine fibroid tumor patients with severe fibroid tumor symptoms as measured by a scientifically valid quality-of-life measurement tool. The mean patient age was mid-to-late 40s. Treatment at the various sites was guided by the same treatment protocol. Patients were scheduled for follow-up physical exams at six, 12 and 24 months after treatment.

Collaboration and Support

In addition to Dr. Stewart and Bobbie Gostout, M.D., of the Mayo Clinic, the key team members included Jaron Ravinovici, M.D., Sheba Medical Center, Tel-Hashomer, Israel; Kyun Kim, M.D., Johns Hopkins Hospital and School of Medicine, Baltimore, Md.; Lesley Regan, M.D., St. Marys Hospital and Imperial College of Medicine, London; and Clare Tempany, M.D., Brigham and Women's Hospital and Harvard Medical School in Boston. The group's work was funded by the Insightec, Ltd., Haifa, Israel.

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