
RSNA Press Release

Noninvasive Ultrasound Treatment Shrinks Fibroids

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Media Contacts:

RSNA Media Relations: (630) 590-7762

Maureen Morley
(630) 590-7754
mmorley@rsna.org

Heather Babiar
(630) 590-7738
hbabiar@rsna.org

CHICAGO - A totally noninvasive procedure using high-intensity ultrasound waves to heat and destroy uterine fibroid tissue significantly relieves fibroid-related symptoms in women, according to the results of a multicenter clinical trial. Magnetic resonance-guided, focused ultrasound surgery (MRgFUS) allows radiologists to precisely target fibroids without harming healthy surrounding tissue. The study was presented today at the annual meeting of the Radiological Society of North America (RSNA).

"This treatment immediately stops blood flow in the fibroid tissue, which results in a significant, sustained decrease in symptoms for up to 12 months," said the study's lead author, Fiona M. Fennessy, M.D., Ph.D., instructor of radiology at Harvard Medical School and staff radiologist at Brigham and Women's Hospital in Boston.

Uterine fibroids are benign growths of the muscle inside the uterus. According to the National Institutes of Health, at least 25 percent of women in the United States age 25 to 50 suffer from uterine fibroids, and as many as 50 percent of African American women have uterine fibroids.

Symptoms can include excessive menstrual bleeding, enlarged uterine size, frequent urination, pelvic pressure or pain and infertility. The absolute treatment for symptomatic fibroids is hysterectomy, which is the complete removal of the uterus. According to the National Women's Health Information Center, fibroids are the primary reason for hysterectomy, accounting for 175,000, or approximately one-third, of hysterectomies performed annually in the United States.

"Hysterectomy is currently the gold standard of therapy for uterine fibroids," Dr. Fennessy said. "However, women are increasingly seeking minimally invasive or noninvasive

At A Glance

- Magnetic resonance-guided focused ultrasound surgery (MRgFUS) safely and effectively treats fibroids in women.
- MRgFUS significantly relieves uterine fibroid symptoms and reduces fibroid volume.
- Fibroids affect approximately 25 percent of women in their reproductive years and account for one-third of the hysterectomies performed annually in the United States.

alternatives to hysterectomy."

Dr. Fennessy and colleagues studied 160 women with symptomatic fibroids treated as part of a clinical trial at five medical centers. The women received pre-treatment MR imaging to identify and define the target fibroids for MRgFUS. Radiologists then used focused ultrasound to deliver heat to the targeted fibroid volume. Temperature-sensitive MR guidance allowed the team to monitor the location of the ultrasound beam and to track temperature changes in tissue during the procedure.

One hundred eleven patients were treated under the original study protocol (A), and 51 patients were treated under an optimized protocol (B). Protocol A allowed a maximum treatment time of 120 minutes or a maximum treatment volume of 100ccs (roughly six centimeters (cm) in diameter), or up to 33 percent of total fibroid volume. Protocol B allowed a maximum treatment time of 180 minutes and maximum treatment volume of 150ccs (about 7 cm in diameter), or up to 33 percent of total volume in subserosal fibroids (those on the outer wall of the uterus) and 50 percent of volume in non-subserosal fibroids.

Treatment outcomes were assessed by Uterine Fibroids Symptoms and Quality of Life (UFSQOL) scores obtained at baseline, three, six and 12 months post-treatment. The findings showed significant symptom relief at three and six months and sustained relief at one year. Women treated with the optimized protocol reported greater symptom relief and quality of life improvement than those treated with the original protocol. No serious adverse effects were reported. Initial findings in follow-up of patients 24 and 36 months after treatment suggest that symptom relief is maintained.

"We have shown that treating fibroids with an optimized, less restrictive protocol allows for treatment of a greater fibroid volume, which results in even greater symptomatic relief at clinical follow-up," Dr. Fennessy said.

Co-authors are Clare M. Tempany, M.D., Kelly H. Zou, Ph.D., Minna J. So, M.D., Elizabeth A. Stewart, M.D., Frank J. Rybicki, M.D., Ph.D., Nathan J. McDannold, Ph.D., Kullervo Hynynen, Ph.D., Gina K. Hesley, M.D., and Ferenc A. Jolesz, M.D.

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