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## FIRST DIRECT COMPARISON SUGGESTS UTERINE FIBROID EMBOLIZATION BETTER THAN MYOMECTOMY IN LESSENING BLEEDING

### AT A GLANCE

- ✍ Uterine fibroid embolization (UFE) is better than myomectomy in alleviating bleeding, a major symptom of fibroids, in the first head-to-head comparison of the two alternatives to hysterectomy.
- ✍ The Stanford study found UFE and myomectomy equivalent in alleviating pain and pressure, two other major symptoms.
- ✍ The study also found women who had UFE spent less time in the hospital, took pain killers for fewer days, lost less blood and returned to normal activity far more quickly than those who had myomectomy.

Fairfax, VA, February 19, 2001 — Minimally invasive uterine fibroid embolization (UFE) appears to be superior to myomectomy in alleviating excessive menstrual bleeding, a major symptom of uterine fibroids, according to the first head to head comparison of the two main uterus-sparing treatments for the common problem.

Bleeding decreased significantly in more than 90 percent of women who had UFE, vs. 61 percent of those who had myomectomy, according to a Stanford University study being presented at the 26<sup>th</sup> Annual Scientific Meeting of the Society of Cardiovascular & Interventional Radiology (SCVIR). Early

results show no statistical difference between the two therapies in alleviating pain and pressure, the two other major symptoms.

“Myomectomy typically is a surgical procedure, while UFE is not,” said Mahmood K. Razavi, M.D., associate professor of interventional radiology, division of cardiovascular and interventional radiology, Stanford University Medical Center, Stanford, Calif. “Recovery after UFE is typically five times faster and much less painful, and procedural blood loss is negligible as compared with myomectomy.”

Both UFE and myomectomy are alternatives to hysterectomy, or removal of the uterus. More than a third of the more than 600,000 hysterectomies performed each year are due to fibroids.

UFE (also called uterine artery embolization, or UAE) is a nonsurgical procedure that treats all fibroids in the uterus and typically is performed while the patient is lightly sedated. Myomectomy is most often a surgical procedure performed under general anesthesia and removes only some fibroids, depending on their location in the uterus. Typically, the more fibroids a patient has, the less successful myomectomy is. Additionally, fibroids grow back several years after myomectomy in 10 percent to 30 percent of cases. Nearly 9,000 UFE procedures have been performed in the United States since 1996 and so far, regrowth has not been a documented problem.

In the Stanford study, 36 women had myomectomies and 76 women had UFE. After an average of 9 months: 91 percent of UFE patients and 61 percent of myomectomy patients reported the heavy periods they had experienced due to fibroids had significantly improved; 69 percent of UFE patients and 48 percent of myomectomy patients reported their pain significantly improved; and 73 percent of UFE patients and 95 percent of myomectomy patients reported pressure symptoms significantly improved. The differences between the two therapies in treating pain and pressure are not considered statistically significant, Dr. Razavi said.

According to the study, none of the UFE patients were hospitalized (all were done as outpatient procedures), while myomectomy patients were hospitalized an average of 3 days. While UFE patients required narcotics for an average of 3 days to treat post-procedure pain, myomectomy patients required narcotics for an average of 6 days. UFE patients returned to normal activity after an average of 6 days, vs. 35 days for myomectomy patients. While blood loss related to the treatment was minimal

with UFE, it averaged 380 ccs for myomectomy patients, or more than three-fourths of a pint of blood.

Three women (8 percent) who had myomectomy required transfusions due to excessive blood loss.

“After several years of offering UFE as an alternative to myomectomy, it’s gratifying to finally be able to show that for many women, it is a more appropriate therapy,” said Dr. Razavi.

UFE is a nonsurgical procedure in which an interventional radiologist makes a small nick (less than ¼ inch) in the skin of the groin to reach the femoral artery, inserts a catheter (a tiny tube) and guides it to the uterus while watching the progress of the procedure via a moving X-ray (fluoroscopy). The interventional radiologist then injects small plastic and/or gelatin sponge particles into the vessels supplying blood to the fibroid to cut off the blood flow, or embolize it. The right and left uterine arteries generally are embolized during the procedure.

Myomectomy involves surgical removal of the fibroids and can be performed several ways, most often as an open surgical procedure or laparoscopically, in which the physician makes small incisions in the abdomen and uses a probe with a tiny camera and small surgical instruments to remove the tumor.

In the last four years, 8,600 UFE procedures have been performed in the United States. Approximately 35,000 myomectomies are performed per year in this country.

#### **UFE and Fibroid Facts:**

- ✍ Fibroids are benign (noncancerous) growths in the uterus that can enlarge and cause pain, heavy bleeding and pressure in the abdomen. Fibroids range in size from very tiny to the size of a cantaloupe or larger and can be located in various parts of the uterus.
- ✍ From 20 percent to 40 percent of women age 35 and older — and as many as 50 percent of African-American women — have uterine fibroids of a significant size.
- ✍ More than 10,500 UFE procedures have been performed worldwide, 8,600 of them in the United States.

- ✍ In clinical UFE studies, as many as 90 percent of patients have experienced improvements in symptoms following the procedure, with very few side effects.
- ✍ Early research suggests UFE may not adversely affect fertility in women younger than 45, although a small percentage of women 45 or older stop menstruating after the procedure. A number of women who have had the procedure have become pregnant. Long-term studies on the pregnancy rate after UFE have not been completed, however, and myomectomy is the standard-of-care for women desiring to become pregnant after fibroid treatment.
- ✍ The Fibroid Registry for Outcomes Data (FIBROID) has been established to collect information on the safety and effectiveness of UFE. The registry is open to all women having UFE, and the goal is to collect information from approximately 4,000 patients per year, with long-term follow up on a quarter of them. The registry will assess the procedure's impact on fertility and quality of life, as well as long-term results. The goal of the registry is to provide ongoing information to physicians and the public.

Co-authors of this paper are: G.L. Hwang, B.S; and B.H. Chen, M.D.

An estimated 5,000 people are attending the SCVIR Annual Scientific Meeting. The Society, based in Fairfax, Va., is the professional association for physicians who specialize in minimally invasive interventional radiology procedures.

An interventional radiologist is a physician who has special training to diagnose and treat conditions using miniature tools and imaging guidance. Typically, the interventional radiologist performs procedures through a very small nick in the skin, about the size of a pencil tip. Interventional radiology treatments are generally easier for the patient than surgery because most involve no surgical incisions, less pain and shorter hospital stays.

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Editor's note: Study numbers are current as of February 19, and may change upon presentation at the SCVIR annual meeting.

General consumer information on interventional radiology is available online at [www.scvir.org](http://www.scvir.org).