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EXTENSIVELY STUDIED UTERINE FIBROID EMBOLIZATION EQUIVALENT TO STANDARD MORE INVASIVE TREATMENTS

AT A GLANCE

- ? Two Georgetown University studies show UFE for the treatment of uterine fibroids compares favorably to the more invasive surgical alternatives of hysterectomy and myomectomy.
- ? More than 50 UFE research papers have been published or presented at scientific meetings.
- ? One recent Georgetown study shows UFE is safe and effective, compared to hysterectomy, and another shows UFE may be less expensive than myomectomy.

BALTIMORE – As results from comparative studies are reported, uterine fibroid embolization (UFE), a non-surgical, uterine-sparing treatment for benign but troublesome uterine tumors, compares favorably with more invasive surgical alternatives for this common condition, according to research being presented here today at the 27th Annual Scientific Meeting of the Society of Cardiovascular & Interventional Radiology (SCVIR).

Uterine fibroid embolization is performed by interventional radiologists, physicians who specialize in targeted, image guided treatments. By blocking the blood flow to the fibroids and causing them to shrink, the treatment is approximately ninety percent successful in alleviating the heavy bleeding and painful periods caused by them. Since the introduction of uterine fibroid embolization (UFE) in the United States in 1996, more than 50 research papers have been

published or presented at scientific meetings analyzing performance of the procedure. Historically, symptomatic fibroids have been treated surgically, most commonly by hysterectomy (surgical removal of the entire uterus), or myomectomy (surgical removal of individual fibroids). About 20 percent to 40 percent of women 35 and older, and as many as half of African-American women have uterine fibroids of a significant size. In addition to prolonged bleeding which can lead to anemia, fibroids can cause pelvic pain and pressure and an abnormally large abdomen.

“We can best serve our patients by telling them about success rates, after-effects and long-term results for UFE, as well as how it compares to hysterectomy and myomectomy,” said James B. Spies, M.D., associate professor of radiology and vice chairman of the department of radiology, Georgetown University Medical Center, Washington, D.C. “There is a real need for this kind of research. There have been a limited number of studies done on myomectomy, and there are almost no studies comparing myomectomy and hysterectomy.”

Dr. Spies is presenting research on several studies, one showing that UFE is safe and effective compared to hysterectomy, and another comparing the cost of UFE versus myomectomy.

“Some gynecologists and family practitioners are unfamiliar with UFE and with the medical specialty of interventional radiology. They may even be skeptical, which is somewhat understandable – it’s not a procedure they perform, and although the very same procedure has been safely used in women to stop bleeding after childbirth since the 1970s, it’s been used for fibroids less than 10 years,” said Dr. Spies. “Comparative studies such as ours hopefully will provide the needed information and help doctors

become more comfortable with presenting UFE to their patients as an option to treat fibroids.” (See sidebar)

UFE vs. Hysterectomy

The UFE vs. hysterectomy study was designed to determine the safety and effectiveness of UFE compared to hysterectomy, and the results have been favorable to UFE. In the study, 102 patients treated with UFE were compared to 47 patients who had hysterectomies to treat uterine fibroids. A questionnaire to determine physical and mental quality of life before and after the procedures was administered to women in both groups. Scores of 50 or higher are considered normal. Scores of physical well-being increased from 45 before UFE to 52 after UFE and from 42 before hysterectomy to 51 after hysterectomy. Regarding mental well-being, scores increased from 45 to 52 in the UFE group, and from 41 to 50 in the hysterectomy group. Among patients having UFE, 94 percent were satisfied to some extent three months after treatment, compared to 95 percent for hysterectomy patients.

“Hysterectomy has been shown to be effective – it was the gold standard for treating uterine fibroids, which is why more than 200,000 hysterectomies are performed every year for that indication,” said Dr. Spies. “The data from this study suggests that UFE also is effective, without the patient having to have major surgery.”

In UFE, the interventional radiologist makes a tiny incision (less than one-eighth of an inch) in the groin and inserts a thin catheter into the artery, while the patient is conscious, but sedated. The catheter is guided through the artery to the uterus under X-ray imaging. The interventional radiologist then injects tiny particles the size of grains of sand into the artery that is supplying blood to the tumor to cut off the blood flow, or

embolize it. UFE usually requires a one-night hospital stay. Many women resume light activities in a few days and the majority of women are able to return to normal activities within one week.

Myomectomy can be performed several ways, including hysteroscopically via a scope inserted into the uterus through the vagina to remove the fibroids using special surgical tools; laparoscopically using three tiny incisions in the abdomen, through which a tiny camera and probe are advanced; and abdominally, with an open surgical incision. Abdominal myomectomy usually requires a two- or three-day hospital stay and several weeks recovery time.

Although there are less invasive methods of performing hysterectomy, including laparoscopically and hysteroscopically, when used to treat fibroids, most are performed with an open surgical incision, because the uterus with many fibroids tends to be quite large. Open hysterectomy typically includes three to four days in the hospital and a six-week recovery time.

UFE vs. Myomectomy: A Cost Comparison

In the UFE vs. abdominal myomectomy study, total costs – including hospital care, procedure room and professional fees – were estimated for 23 UFE procedures and 17 myomectomy procedures. Myomectomy costs averaged \$7,486 per procedure, vs. \$6,861 for UFE, suggesting a trend toward lower costs for UFE.

“The school of thought has been that UFE might have higher costs than myomectomy because patients have more extensive imaging exams before and after the procedure, but even with these tests, its overall costs are not higher and in fact show a

trend toward being lower,” said Dr. Spies. “There are clearly lower hospitalization costs with UFE due to lower operating room costs and the shorter length of stay.”

Co-authors of the study comparing UFE/hysterectomy comparison being presented at the meeting by Dr. Spies are: J.M. Cooper, R.L. Worthington-Kirsch, J.C. Lipman, J.F. Benenati and B. McLucas.

Co-authors of the UFE/myomectomy cost comparison study in addition to Dr. Spies are: C.M. Baker, C.A. Winkel and S. Subramanian.

About 15,000 to 20,000 UFE procedures have been performed worldwide, at least half of them in the United States, according to the SCVIR, which has established the Fibroid Registry for Outcomes Data (FIBROID), a registry for worldwide data about UFE. The Registry is currently tracking long term patient outcomes, including quality of life.

An estimated 5,200 people are attending the SCVIR Annual Scientific Meeting in Baltimore. SCVIR is the professional society of interventional radiologists – physicians who specialize in minimally invasive, targeted treatments performed using imaging guidance. Interventional radiology procedures are an advance in medicine that replace open surgical procedures. They are generally easier for the patient because they involve no large incisions, less risk, less pain and shorter recovery times. To find out more information about interventional radiology procedures or to find an interventional radiologist, visit the SCVIR Web site, www.scvir.org.

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