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Study Shows Minimally Invasive Uterine Fibroid Embolization Treatment Offers Much Quicker Recovery, Shorter Hospital Stays, and is Safer With Lower Adverse Event Rates than Myomectomy Surgery

Phoenix, Arizona (March 26, 2004) -- The first large, multi-center, comparative trial shows that uterine fibroid embolization -- a minimally invasive interventional radiology treatment that blocks the blood supply to the fibroid tumors, causing them to shrink -- offers a much quicker recovery and a lower adverse event rate compared to myomectomy, the surgical removal of uterine fibroids. The study, which was presented today at the 29th Annual Scientific Meeting of the Society of Interventional Radiology, found that the uterine fibroid embolization (UFE) patients were back to work in 10 days versus 37 days for the myomectomy group, and the UFE patients returned fully to normal activities in 15 days versus 44 days for the myomectomy group. The average hospital stay for UFE patients was one day, versus 2.5 days for myomectomy patients.

"This study is significant because it is the first trial to compare the two primary uterus-sparing treatments widely available to treat fibroids. The problem with myomectomy is that it's a local treatment for a global problem. Most women have multiple fibroids, and usually they can't all be removed with myomectomy surgery. Uterine fibroid embolization is a global solution and it's effective for multiple fibroids," says John Lipman, M.D., interventional radiologist and study investigator.

Previous studies have already shown UFE, also referred to as uterine artery embolization (UAE), to be a safe and effective treatment compared to hysterectomy, still the most common treatment for uterine fibroids, but UFE has had less complications than either surgery. In this study, the proportion of patients with the occurrence of at least one adverse event was higher for the myomectomy cohort and the difference was statistically significant.

"Uterine fibroid embolization offers many advantages for patients. In addition to a much quicker recovery time, the procedural blood loss is negligible with UFE. Myomectomy surgery can entail significant blood loss and, in about 2-3 percent of cases, an emergency hysterectomy is required because of it. A woman who chooses myomectomy as a treatment because she doesn't want to lose her uterus, may wake up without one," says Lipman. Embolization of fibroids was first used as an adjunct prior to myomectomy to help decrease blood loss. Embolization is a well-established interventional radiology technique that is often used to decrease blood loss in major surgeries, to treat trauma

victims with massive bleeding, and to control hemorrhage after childbirth. It has been used for over 20 years.

About Uterine Fibroids

Uterine fibroids, benign tumors in the uterus, are a highly prevalent condition that can cause a variety of symptoms including prolonged, heavy menstrual bleeding that can lead to anemia, disabling pelvic pain and pressure, urinary frequency, pain during intercourse, miscarriage, interference with fertility, and an abnormally large uterus resembling pregnancy. Twenty to 40 percent of American women 35 and older have uterine fibroids, and nearly 50 percent of pre-menopausal African American women have fibroids of a significant size.

Uterine fibroids are the most frequent indication for hysterectomy in pre-menopausal women. Of the 600,000 hysterectomies performed annually in the United States, one-third of these are due to fibroids.

About Uterine Fibroid Embolization and Myomectomy Surgery

Uterine fibroid embolization is performed by interventional radiologists. These physicians are board certified and fellowship trained to perform this and other types of embolization and minimally invasive targeted treatments. The interventional radiologist makes a tiny nick in the skin, about the size of a pencil tip, and inserts a catheter into the femoral artery. Using real-time imaging, the physician guides the catheter through the artery and then releases tiny particles, the size of a grain of sand, into the blood vessels feeding the fibroid, cutting off its blood flow and causing it to shrink and symptoms to subside.

Myomectomy is usually major surgery that involves cutting out the biggest fibroid or collection of fibroids and then stitching the uterus back together. Most women have multiple fibroids, and it is not physically possible to remove all the fibroids because it would remove too much of the uterus. While myomectomy is frequently successful in controlling symptoms, the more fibroids the patient has, generally, the less successful the surgery. In addition, fibroids may grow back. Because of this, myomectomy surgery often needs to be repeated.

"Up to half of the women who have myomectomy surgery will have a complete recurrence of their symptoms within five years, and up to one-third in three years, due to the localized nature of the surgery. [5,6] In the past, all we had was surgery for a treatment, but now with UFE, patients have an excellent, much less invasive treatment option," says Lipman.

About The Study

This study, sponsored by Boston Scientific, involved 209 patients at 16 U.S. sites and assessed the improvement in symptoms for uterine fibroid patients undergoing either UFE or myomectomy, as measured by quality of life endpoints, adverse event rates, time to

return to normal activities, fibroid and uterine size change and menstrual bleeding changes. The study used Contour® PVA particles as the embolic agent, which is cleared by the FDA for uterine artery embolization and other embolization procedures. Both treatments improved symptoms and quality of life (QOL), although some age-adjusted QOLs were better in the UFE group. Bleeding scores were reduced by 55.2 percent in the UFE cohort versus 46.1 percent in the myomectomy cohort, and 81.2 percent of UFE patients had significant improvement in their fibroid-related symptoms compared with 75 percent of myomectomy patients. Both groups had significant reductions in uterine size. UFE patients returned to normal activities in 15 days versus 44 days for the myomectomy group. The average hospital stay for UFE patients was one day, versus 2.5 days for myomectomy patients.

Also relevant, the UFE cohort of patients had more fibroid tumors and longer menses. This difference between the two groups was statistically significant. Because the UFE cohort was older, the QOL endpoints for the UFE and myomectomy arms were compared for the same age group, 36-40 year olds. The UFE group showed statistically significant better symptom relief, as measured by age-adjusted QOLs for improvement in sleep, less need to restrict usual activities due to fibroid symptoms, and improved mental health.

Treatment Availability

Uterine fibroid embolization has been widely available in the United States in the past six years as a treatment for fibroids and is widely covered by insurance carriers. There have already been multiple studies that showed uterine fibroid embolization to be an effective treatment with a quicker recovery time and less serious complications compared to hysterectomy, which is still the most common treatment in the U.S. for uterine fibroids.[1-4]

" Now we have trials comparing UFE to both surgical treatments, showing UFE to be a good treatment option. UFE is another example of the overall trend in medicine to treat disease in the least invasive way possible. As a doctor that specializes in minimally invasive medicine, I think that patients should be offered the least invasive treatment first. Eventually, the trend to offer surgery first will be reversed. It's important for women to ask questions, obtain consults with different types of physicians, and know all of their treatment options," says Lipman.

If the woman wishes to preserve future fertility, myomectomy, the surgical removal of the fibroids has been the only available treatment. Myomectomy, like UFE, leaves the uterus in place and may, therefore, preserve the woman's ability to have children. "Although there have been several reports of successful pregnancies following UFE, we need a comparative fertility trial with myomectomy. But we do know that only about 35-40% of women will be fertile after a myomectomy[7]," says Lipman.

About the Society of Interventional Radiology

An estimated 5,000 people are attending the Society of Interventional Radiology's 29th Annual Scientific Meeting in Phoenix, Arizona. Interventional radiology is the medical

specialty devoted to advancing patient care through the innovative integration of clinical and imaging-based diagnosis and minimally invasive therapy. Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments performed using imaging for guidance to treat disease non-surgically through the blood vessels or through the skin. Interventional radiologists pioneered modern medicine with the invention of angioplasty and the catheter-delivered stent, which were first used to treat peripheral arterial disease. Interventional radiology procedures are a major advance in medicine that do not require large incisions – only a nick in the skin – and offer less risk, less pain and shorter recovery times compared to open surgery. More information can be found at www.SIRweb.org.

Interview, broadcast quality footage, and medical illustrations are available by contacting the press office on site at 602-514-7890.

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