

Uterine Fibroid Embolization

Image is courtesy of BioSphere Medical, In

Uterine Fibroid Embolization (UFE) is a proven, non-surgical alternative to hysterectomy and myomectomy (for the treatment of fibroids). A UFE procedure takes about one hour to complete, provides symptom control comparable to surgery, and has a significantly shorter recovery time as little as one week.

Many women are unaware of less invasive fibroid treatment options, such as UFE, and continue to accept hysterectomy as the treatment of choice. Hysterectomy involves surgical removal of the uterus, and many times the ovaries, and can have a profound impact on a woman's life.

Procedure

Uterine fibroid embolization, also known as uterine artery embolization, is clinically proven to reduce the major symptoms of all types of fibroids, including pain, excessive and prolonged bleeding, and frequent urination. It is often performed as an out-patient procedure that lasts about an hour, plus some time to recover from sedation. Compared to a larger surgical incision, the access for UFE is a small incision into a blood vessel on the top of the patient's leg.

UFE is performed by an interventional radiologist (IR), a doctor who uses X-rays and other imaging techniques to see inside the body and treat conditions without surgery.

During UFE, a patient is given a mild sedative to make her feel relaxed, but conscious. The IR inserts a catheter (thin tube) into the artery at the top of the leg, then uses X-ray imaging to guide the tube to the uterine artery.

Tiny round particles called Embosphere® Microspheres are delivered through a catheter and into the blood vessels that lead to the fibroids. Delivered to the fibroids, Embosphere Microspheres block the blood flow, causing the fibroids to shrink.

Proven Clinical History

Images courtesy of BioSphere Medical, Inc

UFE was first performed in 1994 and has an extensive clinical history. To date, more than 100,000 women worldwide have been treated with the procedure. Embosphere® Microspheres were the first embolic material to receive clearance from the FDA for use in UFE procedures on November 22, 2002.

Clinical studies have shown that UFE provides substantial improvement in major symptoms, including pain, pelvic discomfort and urinary problems. One-year data from the Fibroid Registry Outcomes Data (FIBROID), the largest registry on any procedure for benign uterine fibroids, indicates that more than 85 percent of women experience significant improvement in symptoms after undergoing UFE.

A five-year study shows that UFE provides long-term symptom improvement in more than 70 percent of women treated. The study also shows that patients are able to achieve excellent clinical improvement in symptoms like excessive bleeding and pelvic pain while requiring only about a one to two week recovery time. More invasive methods, such as hysterectomy or myomectomy, require six-to-eight weeks of recovery.

Deciding on UFE

UFE may be a good option for women who need treatment for fibroid symptoms, but want to avoid surgery. Patients who are ideal for UFE include women who:

- Have symptomatic fibroids
- Want to keep their uterus
- Do not want surgery
- Want to minimize in-hospital recovery time
- May not be good candidates for surgery
- Do not intend to get pregnant in the future

UFE and Fertility

Image is courtesy of BioSphere Medical, Inc.

It is currently advised that women who want to maintain fertility should not have UFE. However, a 2005 study of 555 women between the ages of 27 and 42 showed that the majority of women actively trying to become pregnant were able to achieve pregnancy after UFE. Most resulted in term deliveries and newborns of typical size. **(i)**

Risks Associated with Hysterectomy

Hysterectomy has been associated with numerous long-term physical and physiological effects including incontinence, loss of sexual pleasure and depression. The most common complications associated with hysterectomy are vaginitis, drug reactions, and urinary tract infections, with some more serious complications reported after 30 days including pneumonia, bowel injury, vaginal cuff herniation, and recurrent bleeding from the vaginal stump. **(ii)**

Risks Associated with UFE

UFE is a proven, safe procedure for treating symptomatic fibroids with minimal risk. Infrequent complications have been reported following UFE. Complications associated with UFE include, but are not limited to the following: short-term allergic reaction/rash, fibroid passage, recurrent/prolonged pain and groin hematoma. **(iii)**

1. Pregnancy After Uterine Artery Embolization for Leiomyomata: The Ontario Multicenter Trial; Pron G et al; Obstetrics & Gynecology; 1 January 2005; Vol. 105, No. 1
2. Complications After Uterine Artery Embolization for Leiomyomas; Spies JB et al; Obstetrics & Gynecology, Vol. 100, No. 5, Part 1
3. Ibid.

Three-Year Registry Data from 1,278 Women Shows Long-Term Efficacy for Uterine Fibroid

Embolization (UFE).

Interventional Radiology Treatment Could Decrease the Hysterectomy Rate by As Much As One-Third

Image is courtesy of BioSphere Medical, Inc.

Fairfax, Virginia (January 2, 2008) ? Three-year data from the largest, multi-center, prospective voluntary registry on any procedure for benign uterine fibroids showed that 90 percent of the women participating avoided a hysterectomy and of these, 85 percent had a substantial improvement in symptoms and quality of life. The registry included three-year data on 1,278 patients from 26 sites who had this minimally invasive interventional radiology treatment for symptomatic fibroids, showing uterine fibroid embolization is a durable treatment for fibroids with sustained improvement in quality of life and symptom relief. Twenty to 40 percent of American women age 35 and older, and nearly 50 percent of pre-menopausal African American women, have uterine fibroids. Of the 600,000 hysterectomies performed annually in the United States, one-third of these are to relieve symptoms caused by fibroids. "This registry data is great news for women. With uterine fibroid embolization, we could significantly decrease the hysterectomy rate in the United States" says Scott Goodwin, MD, interventional radiologist and lead author.

Uterine fibroids are benign tumors that can cause prolonged, heavy menstrual bleeding that can be severe enough to cause anemia or require transfusion, disabling pelvic pain and pressure, urinary frequency, pain during intercourse, miscarriage, interference with fertility, and an abnormally large uterus resembling pregnancy. UFE is a minimally invasive interventional radiology treatment that blocks the blood supply to the fibroid tumors, causing them to shrink and die, and symptoms to subside.

The FIBROID Registry was designed to follow the "real world" outcomes for uterine fibroid embolization as it became a mainstream treatment widely available across the country. The purpose of the Registry was to assess the procedure's effectiveness in improving fibroid-related symptoms, to determine the durability of those improvements, and to assess the safety of the procedure in broad practice. The 1,278 women who completed the three-year follow-up had significant improvement in symptoms and in quality of life (QOL), moving them into the normal range on this validated survey instrument. The mean symptom scores before embolization were 58.61, and postprocedure at three years were 16.54. Mean QOL scores pre-embolization were 46.95 and at three years were 89.55. Eighty-five percent would

recommend the procedure to a family member or friend. The study also identified subgroups of patients that appeared to have a greater likelihood of improvement.

This data shows that the long-term clinical outcomes of UFE are consistent when the procedure is performed in any experienced community or academic interventional radiology practice. "The Registry's outcomes are important not only because of its size, but also because of the diversity of sites that participated. These results demonstrate that uterine fibroid embolization is safe and very effective beyond the academic or specialized centers." The Registry is one of the few efforts ever undertaken to study the efficacy of a procedure as it disseminates into broad practice, and this is the first such effort for a fibroid therapy by any specialty.

"It is important for women to know all of their treatment options in order to make an informed decision. Interventional radiologists can provide a second opinion and assess whether UFE is a treatment option. The vast majority of women are eligible for this treatment," says Goodwin. Interventional radiologists use MRI to delineate the location of each fibroid, determine if a tumor can be embolized, detect alternate causes for the symptoms, identify pathology that could prevent a women from having UFE, and avoid ineffective treatments. The number of women requiring retreatment after UFE in the registry is similar to the surgical reintervention rates, of approximately five percent per year, following myomectomy.

About Uterine Fibroid Embolization

Uterine fibroid embolization is performed by interventional radiologists, physicians who are fellowship trained in minimally invasive treatments. Embolization is a common interventional radiology treatment for benign and cancerous tumors. In uterine fibroid embolization, 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 up the artery and then releases tiny particles, the size of grains of sand, into the blood vessels feeding the fibroid, cutting off its blood supply, causing it to shrink and die, and symptoms to subside. Most women return home the next day and can resume normal activities, with an average full recovery time of seven to 10 days.

About the Society of Interventional Radiology Foundation

The SIR Foundation is a scientific foundation dedicated to fostering research and education in interventional radiology for the purposes of advancing scientific knowledge, increasing the number of

skilled investigators in interventional radiology, and developing innovative therapies that lead to improved patient care and quality of life. Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use X-rays, MRI and other imaging to advance a catheter in the body, usually in an artery, to treat at the source of the disease nonsurgically. As the inventors of angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease, interventional radiologists pioneered minimally invasive modern medicine.