

## FACT SHEET

Contact: Diane Shnitzler  
Emily Oehler  
703-691-1805

### **Uterine Fibroid Embolization, a Minimally Invasive Treatment for Uterine Fibroids**

#### ***Highly Effective, Widely Available Interventional Radiology Treatment Is Underutilized***

Uterine fibroids are very common noncancerous (benign) growths that develop in the muscular wall of the uterus. They can range in size from very tiny (a quarter of an inch) to larger than a cantaloupe. Occasionally, they can cause the uterus to grow to the size of a five-month pregnancy. In most cases, there is more than one fibroid in the uterus.

#### **Prevalence**

Twenty to 40 percent of women age 35 and older have uterine fibroids of a significant size. African American women are at a higher risk for fibroids: as many as 50 percent have fibroids of a significant size. Uterine fibroids are the most frequent indication for hysterectomy in premenopausal women and, therefore, are a major public health issue. Of the 600,000 hysterectomies performed annually in the United States, one-third of these are due to fibroids.<sup>10,13, 18, 21</sup>

#### **Symptoms**

Most fibroids don't cause symptoms—only 10 to 20 percent of women who have fibroids require treatment. Depending on size, location and number of fibroids, they may cause:

- Heavy, prolonged menstrual periods and unusual monthly bleeding, sometimes with clots. This can lead to anemia.
- Pelvic pain and pressure
- Pain in the back and legs
- Pain during sexual intercourse
- Bladder pressure leading to a frequent urge to urinate
- Pressure on the bowel, leading to constipation and bloating
- Abnormally enlarged abdomen

#### **About the Procedure**

Uterine fibroid embolization (UFE), also known as uterine artery embolization, is performed by an interventional radiologist, a physician who is trained to perform this and other types of embolization and minimally invasive procedures. It is performed while the patient is conscious, but sedated and feeling no pain. It does not require general anesthesia.

The interventional radiologist makes a tiny nick in the skin, less than one-fourth of an inch, in the groin 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 grains of sand, into the uterine arteries that supply blood to the fibroid tumor. This blocks the blood flow to the fibroid tumor and causes it to shrink.

### **Recovery Time**

Fibroid embolization usually requires a hospital stay of one night. Pain-killing medications and drugs that control swelling typically are prescribed following the procedure to treat cramping and pain. Many women resume light activities in a few days and the majority of women are able to return to normal activities within seven to 10 days.

### **Efficacy**

- On average, 85-90 percent of women who have had the procedure experience significant or total relief of heavy bleeding, pain and/or bulk-related symptoms.<sup>1,3,6,9,14</sup>
- The procedure is effective for multiple fibroids and large fibroids.<sup>3,6,9</sup>
- Recurrence of treated fibroids is very rare. Short and mid-term data show UFE to be very effective with a very low rate of recurrence.<sup>14,16,17</sup> Long-term (10-year) data are not yet available, but in one study in which patients were followed for six years, no fibroid that had been embolized regrew.<sup>10</sup>

### **Other UFE Facts**

- An estimated 13,000-14,000 UFE procedures are performed annually in the U.S. (as of 2004).<sup>24</sup>
- The embolic particles are approved by the FDA specifically for UFE, based on comparative trials showing similar efficacy with less serious complications compared to hysterectomy and myomectomy (the surgical removal of fibroids).
- Embolization of the uterine arteries is not new. While embolization to treat uterine fibroids has been performed since 1995, it has been used successfully by interventional radiologists for more than 20 years to treat heavy bleeding after childbirth.
- Embolization of fibroids was first used as an adjunct to help decrease blood loss during myomectomy. To the surprise of the initial users of this method, many patients had spontaneous resolution of their symptoms after only the embolization and no longer needed the surgery.
- UFE is covered by most major insurance companies and is widely available across the country.
- Most women with symptomatic fibroids are candidates for UFE and should obtain a consult with an interventional radiologist to determine whether UFE is a treatment option for them. An ultrasound or MRI diagnostic test will help the interventional radiologist to determine if the woman is a candidate for this treatment.
- Many women wonder about the safety of leaving particles in the body. The embolic particles most commonly used in UFE have been available with FDA approval for use in people for more than 20 years. During that time, they have been used in thousands of patients without long-term complications.

### **Effect on Fertility**

There have been numerous reports of pregnancies following uterine fibroid embolization, however prospective studies are needed to determine the effects of UFE on the ability of a woman to have children.<sup>4,10</sup> One study comparing the fertility of women who had UFE with those who had myomectomy showed similar numbers of successful pregnancies.<sup>11</sup> However, this study has not yet been confirmed by other investigators.

Less than 2 percent of patients have entered menopause as a result of UFE. This is more likely to occur if the woman is in her mid-forties or older and is already nearing menopause.<sup>15,16, 22, 23</sup>

### **Risks**

UFE is a very safe method and, like other minimally invasive procedures, has significant advantages over conventional open surgery. However, there are some associated risks, as there are with any medical procedure. A small number of patients have experienced infection, which usually can be controlled by antibiotics. There also is a less than one percent chance of injury to the uterus, potentially leading to a hysterectomy.<sup>15,16, 20</sup> These complication rates are lower than those of hysterectomy and myomectomy.<sup>25</sup>

### **Cost**

The cost of UFE is similar to the cost of performing hysterectomy and myomectomy and, in one study, the hospital charges for UFE were lower than those for hysterectomy.<sup>12</sup>

### **Other Treatments for Fibroids**

Gynecologists perform hysterectomy and myomectomy surgery. Hysterectomy is the removal of the uterus and is considered major abdominal surgery. It requires three to four days of hospitalization and the average recovery period is six weeks.

Depending on the size and placement of the fibroids, myomectomy can be an outpatient surgery or require two to three days in the hospital. However, 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 of them 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 several years later.

Myomectomy, like UFE, leaves the uterus in place and may, therefore, preserve the woman's ability to have children.

### **About Interventional Radiologists**

Interventional radiologists are doctors who specialize in minimally invasive, targeted treatments that have less risk, less pain and less recovery time compared to open surgery. They use their expertise in interpreting X-rays, ultrasound, MRI and other diagnostic imaging studies to understand, visualize and diagnose the full scope of the disease's pathology and to map out the procedure tailored to the individual patient. Then during the procedure, they image as they go to guide tiny instruments, such as catheters, through blood vessels or skin, to treat diseases at the site of the illness nonsurgically.

Interventional radiology is a recognized medical specialty by the American Board of Medical Specialties. Interventional radiologists are board-certified in diagnostic radiology and fellowship-trained in vascular and interventional radiology. The American Board of Radiology certifies their specialized training.

### **For Further Information**

For more information on UFE or interventional radiology, visit the SIR Web site at [www.SIRweb.org](http://www.SIRweb.org).

### **References**

1. Spies JB, Cooper JM, Worthington-Kirsch R, Lipman JC, Mills BB, Benenati JF. Outcome of uterine embolization and hysterectomy for leiomyomas: Results of a multi-center study. *Am J Obstet Gynecol* 2004; 191:22-31.
2. Goodwin SC, Bradley L, Lipman JC, Stewart EA, Noshier JL, Yeko T, et. al. Uterine artery embolization vs. myomectomy: a prospective trial. *JVIR*; 2004; 15(suppl 2, part 2):S149.
3. Walker, WJ, Pelage P. Uterine artery embolization for symptomatic fibroids: clinical result in 400 women with imaging follow-up. *Br J Obstet Gynaecol*; 2002.
4. Pron G, Mocarski G, Vilos J, Bennett A, Comman L. Pregnancy after fibroid uterine artery embolization: the Ontario uterine fibroid embolization (UFE) trial. *JVIR*; 2003, 14 (suppl 2, part 2):S5.
5. Pron, G, Cohen, M, Soucie, J, et al. The Ontario uterine fibroid embolization trial, part 2. Baseline patient characteristics, fibroid burden and impact on life. *Fertility and Sterility* 2003.
6. Pron, G, Bennett, J, Common, A, et al. The Ontario uterine fibroid embolization trial, part 2. Uterine fibroid reduction and symptom relief after uterine artery embolization for fibroids. *Fertility and Sterility* 2003.
7. Spies JB, Cooper JM, Worthington-Kirsch R, Lipman JC, Benenati JF, McLucas B. Uterine artery embolization using embospheres: initial results of a phase II comparative study [vs. hysterectomy]. *JVIR* 2002; 13:S20.
8. Spies J, Coyne K, Guaou N, Boyle D, Skyrnarz-Murphy K, Gonzalves S. UFS-QOL, a new disease-specific symptom and health-related quality of life questionnaire for leiomyomata. *Obstet & Gynecol* 2002; 99:290-300.
9. Spies JB, Ascher SA, Roth AR, Kim J, Levy EB, Gomez-Jorge J. Uterine artery embolization for leiomyomata. *Obstet and Gynecol* 2001; 98:29-34.
10. Stavropoulos MD, Shlansky-Goldberg R. Embolization of uterine fibroids, patient selection and results of treatment. *Journal of Women's Imaging* 2001; 3:153-157.
11. McLucas B, Goodwin S, Adler L, Rappaport A, Reed R, Perrella R. Pregnancy following uterine fibroid embolization. *Int J Gynecol Obstet* 2001; 74:1-7.
12. Subramanian S, Spies JB: Uterine artery embolization for leiomyomata: resource use and cost estimation. *JVIR* 2001; 12:571-574.
13. Broder MS, Kanouse DE, Mittman BS, et al. The appropriateness of recommendations for hysterectomy. *Obstet Gynecol* 2000; 95:199-205.

14. Pelage J, LeDref O, Soyer P, Kardache M, Dahan H, Abitol M, et al. Fibroid-related menorrhagia: treatment with superselective embolization of the uterine arteries and midterm follow-up. *Radiology* 2000; 215:428-431.
15. Spies JB, Scalli AR, Jha RC, et al. Initial results from uterine fibroid embolization for symptomatic leiomyomata. *JVIR* 1999; 10:1149-1157.
16. Hutchins FL, Worthington-Kirsch R, Berkowitz RP. Selective uterine artery embolization as primary treatment for symptomatic leiomyomata uteri. *J Am Assoc Gynecol Laparosc* 1999; 6:279-284.
17. Goodwin S, McLucas B, Lee M, et al. Uterine artery embolization for the treatment of uterine leiomyomata: midterm results. *JVIR* 1999; 10:1159-65.
18. Vollenhoven B. Introduction: the epidemiology of uterine leiomyomas. *Baillieres Clin Obstet Gynaecol* 1998;12: 169-176.
19. Ravina J, Ciraru-Vigernon N, Aymard A, Ledreff O, Herbreteau D, Merland J. Arterial embolization of uterine myomata: results of 184 cases. Presentation at 10th Anniversary International Conference for the Society for Minimally Invasive Therapy; September 4, 1998: London, England. *MITAT* 1998; 7(suppl): 26-27 [abstract].
20. Ravina JH, Bouret JM, Ciraru-Vigernon N, et al. Recourse to particular arterial embolization in the treatment for some uterine leiomyom. *Bull Acad Natl Med* 1997; 181:233-236.
21. Greenberg MD, Kazamel TIG. Medical and socioeconomic impact of uterine fibroids. *Obstet Gynecol Clin North Am* 1995; 22:625-636.
22. Ravina JH, Herbreteau D, Ciraru-Vigernon N, et al. Arterial embolization to treat uterine myomata. *Lancet* 1995; 346:671-672.
23. Ravina JH, Bouret JH, Ciraru-Vigernon N, et al. Arterial embolization: a new treatment of menorrhagia in uterine fibroma [letter]. *Presse Med* 1995; 24:1754.
24. Based on sales and market data from Boston Scientific and Biosphere Medical, device companies with embolic agents approved by FDA for UFE.
25. Bernstein SJ, Fiske ME, McGlynn EA, Gifford DS. Hysterectomy, A Review of the Literature on Indications, Effectiveness, and Risks. *Rand Report*, 1997: ix-xi, 47-55. Prepared for the Agency for Health Care Policy and Research, U.S. Dept. Health and Human Services.