

**Contact: Diane Shnitzler 703-460-5582**  
**Emily Oehler Murdoch 703-460-5572**  
**From 3/26-4/1 Call 801-534-4753**

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**Multi-Center Study Shows Successful Pregnancies  
Following Uterine Fibroid Embolization Treatment for Fibroids**

***Promising Fertility Results for Minimally-Invasive Interventional Radiology  
Treatment***

Salt Lake City, Utah (March 31, 2003) -- Early study results show several successful pregnancies following uterine fibroid embolization (UFE) in a large cohort of women participating in a prospective multi-center trial comparing UFE to hysterectomy, according to new data presented today at the 28<sup>th</sup> Annual Scientific Meeting of the Society of Interventional Radiology. Despite the fact that UFE was not being used as a treatment for infertility caused by fibroids, initial patient follow-up is showing a surprising number of successful pregnancies in women who took part in this study. The study has already shown that UFE is a safe and effective treatment for fibroid symptoms.

Uterine fibroid embolization, also referred to as uterine artery embolization, is a minimally invasive interventional radiology treatment that cuts off the blood supply to the fibroids, causing them to shrink. Uterine fibroids, benign growths in the uterus, are a highly prevalent condition that often interfere with fertility and frequently cause miscarriages.

At study follow-up, nineteen pregnancies have been reported by 17 women, with two reporting two pregnancies. There were 14 live births and three miscarriages in the study. The women ranged in age from 27 to 42, and the average age was 34. All of the women had sizeable fibroids and many had previous miscarriages. Sixteen of the seventeen women were under 40 and twelve did not have children prior to uterine fibroid embolization. Of these twelve, eight went on to have a healthy baby. Most women were previously advised to have a hysterectomy.

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Of the seventeen women, 10 were white, 4 were black and 3 were Asian. These fertility results are from an ongoing longitudinal study known as the Ontario Uterine Fibroid Embolization trial, a large prospective multi-center trial of 555 women.<sup>1,2</sup>

“Miscarriage is a particularly traumatic event for women with fibroids. One of the women who had a healthy baby after UFE, had had nine prior miscarriages, says Gaylene Pron, PhD, epidemiologist and primary author of the study. These are particularly good results for these women, who were older women with a history of fibroids and infertility.”

“These UFE study results are really encouraging for women. Although we need a study designed to look at fertility and pregnancy outcomes, this study does show that successful pregnancies can occur after uterine fibroid embolization. More research is needed, but the initial data is very good. Prospective pregnancy data following uterine fibroid embolization will give women and their doctors more information, and hopefully, a better treatment option for women,” says Pron.

These study results are relevant because current treatments have well known limitations and risks and are not always options for women. Surgical removal of the fibroids, or myomectomy, has been the main treatment available. Even the conservative approach of not treating fibroids can result in problems. Untreated fibroids can cause repeat miscarriages and painful pregnancies. Prior to UFE, one of the women who became pregnant with untreated fibroids was hospitalized for several months during her pregnancy.

“There really is an urgent need to prospectively answer the fertility question for both myomectomy and uterine fibroid embolization,” says Pron. With women having babies at a later age, this is becoming a more prevalent medical issue for which the medical community has been unable to give women good answers.

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### **Currently available treatments for symptomatic fibroids**

The most common treatment for symptomatic uterine fibroids has been hysterectomy, or if the woman wanted to preserve future fertility, myomectomy, the surgical removal of the fibroids, was performed, if possible. Uterine fibroid embolization (UFE) is a newer treatment option that has been widely available in the United States in the past five years. Because it is minimally-invasive, has a much quicker recovery time than open surgery, and preserves the uterus, this newer treatment has become increasingly popular among women.

Myomectomy is a surgical procedure performed by a gynecologist that removes visible fibroids from the uterus. Myomectomy, like UFE, leaves the uterus in place and may, therefore, preserve the woman's ability to have children. Depending on the size and placement of the fibroids, a myomectomy can be an outpatient surgery or require a several day hospital stay. Recovery time varies, on average from four to six weeks. While myomectomy is frequently successful in controlling fibroid symptoms, the more fibroids the patient has, generally, the less successful the surgery. In addition, the fibroids may grow back several years later.

Uterine fibroid embolization is performed by interventional radiologists, physicians who are 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.

Because uterine fibroid embolization does not require open surgery or general anesthesia, the risks are less than with open hysterectomy or myomectomy. There is about a one percent chance of injury to the uterus or infection, potentially leading to hysterectomy. These complication rates are lower than those of hysterectomy and myomectomy. Fibroid embolization usually requires a hospital stay of one night. Many women resume light activities in a few days and the majority of women are able to return to normal activities within seven to ten days.

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### **About Uterine Fibroids**

Uterine fibroids are one of the most common medical conditions experienced by women ages 35 – 50. These benign tumors can cause prolonged, heavy menstrual bleeding that can lead to anemia, disabling pelvic pain and pressure, urinary frequency, pain during intercourse, and an abnormally large uterus resembling pregnancy. Twenty to 40 percent of American women 35 and older, and nearly 50 percent of African-American women, have uterine fibroids of a significant size. They are the most frequent indication for hysterectomy in premenopausal women and, therefore, a major public health issue. Of the 600,000 hysterectomies performed annually in the United States, and of the 50,000 performed annually in Canada, one-third of these are due to fibroids.

### **About the Society of Interventional Radiology**

An estimated 5,000 people are attending the Society of Interventional Radiology 28<sup>th</sup> Annual Scientific Meeting in Salt Lake City. The Society represents interventional radiologists — physicians who specialize in minimally invasive, targeted treatments performed using guided imaging. Interventional radiology procedures are a major advance in medicine that do not require large incisions — only a nick in the skin about the size of a pencil tip — and offer less risk, less pain and shorter recovery times compared to surgery. Interventional radiologists pioneered modern medicine with the invention of angioplasty, the first catheter-delivered stent and the coronary angiography technique most used worldwide -- state of the art treatments that are commonplace in medicine today. More information can be found at [www.SIRweb.org](http://www.SIRweb.org).

Interviews are available by contacting the press office on site at 801-534-4753.

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1. Pron, G, Cohen, M, Soucie, J, et al. The Ontario Uterine Fibroid Embolization Trial, Part 1 Baseline patient characteristics, fibroid burden and impact on life. Fertility and Sterility, January 2003
2. 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, January 2003