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First Large Multi-Center Study Shows High Efficacy Rate for Minimally Invasive Treatment of Uterine Fibroids

New Canadian Results Parallel Findings of Large American and British Single-Center Studies

Study Shows Women Endure Uterine Fibroid Symptoms for Years Rather Than Undergo Hysterectomy; Interventional Radiology Treatment Offers Patients Effective, Non-Surgical Option

Fairfax, VA (January 13, 2003) -- Results of the largest multi-center prospective uterine fibroid embolization study of 555 Canadian women shows a high clinical success rate with a low complication rate, and rapid recovery as reported in the January 2003 issue of *Fertility and Sterility*, the journal of the American Society for Reproductive Medicine.[1,2] Uterine fibroid embolization (UFE), 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. The study showed a high degree of symptom improvement, 83 percent, a high degree of patient satisfaction, 91 percent, and a low rate of major complication, less than two percent. These results are similar to and confirm the results of several earlier, large, single-center studies in Britain and the United States.[3,4,5]

"This multi-center study involving eight Canadian Ontario university and community hospitals confirms that uterine fibroid embolization is a safe and effective treatment for fibroids. It is significant because of its size and because it shows a high rate of efficacy for a relatively new procedure, even when performed widely in multiple hospitals by a variety of interventional radiologists," says Gaylene Pron, PhD, epidemiologist and primary author of the Canadian study known as the Ontario UFE Trial.

"The study showed that uterine fibroid embolization was effective for multiple fibroids, large fibroids, and for women with an enlarged uterus," says Pron. "Significant improvements in heavy menstrual bleeding occurred in most women, even those with large uteri and minimal initial volume reductions."

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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.

Uterine fibroids can have a significant impact on quality of life. Many of the women in the Ontario study experienced pain and excessive bleeding that forced them to be housebound and to miss work for several days a month. For some women, they caused pain during intercourse and limited their ability to exercise. Those with an enlarged uterus, similar in size to a four-month pregnancy or greater, were embarrassed by looking pregnant.

"Despite experiencing severe symptoms that had a heavy impact on their lives, women with uterine fibroids continued to seek alternatives to hysterectomy over extended periods of time. In general, women would prefer to have a benign disease such as uterine fibroids treated as conservatively as possible. Uterine fibroid embolization is giving women a non-surgical choice that preserves their uterus," says Pron.

Most of these women work and the recovery time for open hysterectomy, on average six weeks, would be burdensome for them. These women experienced symptoms for an average of five years while continuing to seek alternatives to hysterectomy. They consulted with many physicians including, on average, three different gynecologists. The recovery time for uterine fibroid embolization varies from one to two weeks. The average time back to work in this study was 13 days.

"These women were highly educated, 68 percent of them had university or college education. Our findings are consistent with other reports in the literature that suggest that women with less education are at greater risk of having a hysterectomy."[6] Not only were most of the women in the Ontario study highly educated, most also had access to the Internet. The use of additional sources of health information now available may reflect the desire of women to become more informed and actively participate in decisions regarding their health care. This is further evidenced by the high self-referral rate of 18 percent (99 women) in this trial.

The study also showed significant differences in disease onset and treatments for black women. Because black women are more prone to this disease and experience it at a younger, childbearing age, they were more likely to have had a myomectomy, surgical

removal of the fibroids, than white women (24 percent versus nine percent). In the Ontario study, the black women were younger and had experienced symptoms longer. They were also more likely to report pain and bleeding and were more likely than white women to have multiple fibroids, suggesting a greater genetic predisposition for fibroids.

The Ontario cohort consisting of 66 percent white, 23 percent black, and 11 percent other races, mostly Asian, had an average age of 43. Eighty percent reported heavy menstrual bleeding; 73 percent urinary urgency/frequency; 41 percent pain during intercourse; and 40 percent work absences. They had high (greater than 7 out of 10) overall life-impact scores, representing the interference of symptoms with everyday or usual activities.

The main outcome measures were uterine fibroid volume reduction, symptom improvement, improvement in quality of life, and satisfaction with the treatment. At three months follow-up, median fibroid volume reduction was 42 percent. Significant improvements were reported for menorrhagia, or heavy menstrual bleeding, (83 percent), dysmenorrhea, or painful periods, (77 percent), and urinary frequency/urgency (86 percent). Before UFE, 30 percent had reported menstrual durations of longer than 7 days, and 9 percent after UFE.

The overall life-impact scores, representing the interference of symptoms with everyday or usual activities, were markedly improved after uterine fibroid embolization. Before UFE, 72 percent of the women reported high impact scores (7-10 on a 10-point scale) and three months after UFE, only 11 percent did. Median impact scores dropped from eight to three.

About Uterine Fibroid Embolization

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, less than a ¼ 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 a grain of sand, into the uterine arteries that supply blood to the fibroid tumor. This blocks the blood flow and causes the fibroid tumor 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.

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About the Society of Interventional Radiology

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 – 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.

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