



Statement by the
Society of Interventional Radiology
To the
Senate Health, Labor, and Pension Committee's
Hearing on Women's Health
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The Society of Interventional Radiology (SIR), formerly the Society of Cardiovascular & Interventional Radiology (SCVIR), represents more than 4,000 physicians who specialize in the use of imaging guidance to perform minimally-invasive procedures to diagnosis and treat disease. SIR commends the Committee for its interest in and for the forum we have here today to discuss the important issues with respect to women's health. Additionally, SIR applauds the recent introduction of S. 2122, the Uterine Fibroid Research and Education Act of 2002, by Senators Carnahan, Mikulski, and Jeffords. S. 2122 holds the promise of substantially improving the lives of women with uterine fibroids and SIR urges other members of the Committee to support and enact this important piece of legislation.

Uterine Fibroids

Uterine fibroids are a major public health issue and the most frequent indication for hysterectomy in premenopausal women. Of the 600,000 hysterectomies performed annually in the United States, at least one-third of these are due to fibroids. Twenty to 40 percent of women ages 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 non-cancerous (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.

Depending on the size, location and number of fibroids, they may cause:

- Heavy, prolonged menstrual periods and unusual monthly bleeding, sometimes with passage of 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

Treatment of Uterine Fibroids

Hysterectomy and myomectomy are the traditional treatments for women with symptomatic uterine fibroids that fail medical therapy. Hysterectomy is the most common current therapy for women who have fibroids. It is typically performed in women who have completed their childbearing years or who understand that after the procedure, they cannot again conceive. Annual charges for inpatient care for fibroids (primarily surgical) exceeded \$2 billion in 1997.

In a hysterectomy, the uterus is removed in an open surgical procedure. This operation is considered major surgery and is performed while the patient is under general anesthesia. It requires three to four days of hospitalization and the average recovery period is about six weeks.

Myomectomy is a surgical procedure that removes visible fibroids from the uterine wall while allowing the uterus to remain in place. While myomectomy is frequently successful in controlling symptoms, the more fibroids there are in a patient's uterus, generally, the less successful the surgery. A myomectomy patient may be hospitalized one to two days following the procedure and can resume normal activity within a couple of weeks. In addition, fibroids may grow back several years after myomectomy.

Six years ago, an important advancement in the treatment of uterine fibroids was introduced in the United States. The procedure, called uterine fibroid embolization (also uterine artery embolization), involves directing a catheter under X-ray (fluoroscopic) guidance from a small nick in the leg to the uterine artery that supply blood to the fibroid(s). When the catheter reaches the uterine artery, the interventional radiologist slowly releases tiny plastic particles the size of grains of sand into the vessels. The particles flow to the fibroids first and wedge into the vessels and cannot travel to other parts of the body. This blocks blood flow to the fibroid, causing it to shrink. The process may be repeated on the other side of the uterus depending on the number of fibroids.

The clinical data demonstrate that embolization controls the symptoms attributed to uterine fibroids with a low rate of complications and with high patient satisfaction. Menorrhagia (abnormal bleeding) is successfully controlled in 81% to 94% of patients. Symptoms caused by large fibroid size (pelvic pain and pressure; back, leg, and flank pain or pressure; and urinary bladder compression) are controlled in 64% to 96% of patients. Further, at follow-up imaging three to six months post-procedure, marked reduction in fibroid volume and uterine volume has been documented. Complications have occurred in less than 5% of patients leading to hysterectomy in less than 1% of patients. Most patients have been treated during an overnight hospital stay. Data from several investigators indicate that patients have

resumed normal activities, including work, after 7-10 days of convalescence. This means uterine fibroid embolization can help a patient return to normal life in as much as five weeks (83%) faster than more invasive and more commonly prescribed procedures – while also affording a woman her opportunity to continue to conceive.

Need for Public Awareness and Research

Many women with symptomatic uterine fibroids, who fail medical therapy, assume that hysterectomy is their only recourse – despite the general availability of uterus-sparing procedures as myomectomy and embolization. This is particularly true for African-American women who have a higher hysterectomy rate. Women, for whom childbearing remains an option, need to be made aware of options other than hysterectomy.

Moreover, researchers at the Duke University Evidence-based Practice Center, in a recent report for the Agency for Healthcare Research and Quality, found that *"In general, there was a remarkable lack of high quality evidence supporting the effectiveness of most interventions for symptomatic fibroids."* Their report recommends more research, and underscores the real opportunity and promise of less-invasive treatments like uterine artery embolization.

Leading the way in uterine fibroid research, the Cardiovascular and Interventional Radiology Research and Education Foundation, SIR, and the Duke Clinical Research Institute have established the Uterine Artery Embolization (UAE) Fibroid Registry for Outcomes Data (FIBROID). The registry brings together a tremendous array of scientific and technical resources through the collaborative efforts and

support of a professional medical society, academic research organization, the U.S. Food and Drug Administration (FDA), industry and patients. The purpose of the FIBROID Registry is to assess UAE's durability, impact on fertility and quality-of-life, and to obtain data which will allow researchers to compare UAE to other fibroid therapies.

Why Passage of S.2122 is Important

The Uterine Fibroid Research and Education Act of 2002 (S. 2122) would authorize \$10 million for each of four consecutive years through the NIH for research into uterine fibroids. In addition, it would direct the Secretary of Health and Human Services (HHS) to carry out a public awareness campaign to educate women on the incidence, prevalence, and precautionary steps they should take regarding uterine fibroids. It will include information on the increased risks minority women face.

In closing, SIR, as a leader in innovative treatment options, again commends the Committee for its interest in the health of the American women. In addition, we applaud the leadership shown by Senators Carnahan, Mikulski, and Jeffords to address the issues of women with uterine fibroids through the introduction of S. 2122. We urge the Committee to make passage of S. 2122 a priority.

If you have any questions or would like to learn more about interventional radiology, interventional radiologists, uterine fibroid embolization (or other applications of interventional radiology in women's health), please contact Michael R. Mabry SIR's Director of Health Policy and Economics at (703) 691-1805, ext. 201 or mabry@scvir.org.