



TRENDS-in-MEDICINE

BULLETIN:

TREATMENT OF UTERINE FIBROIDS

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by Lynne Peterson

The Society of Interventional Radiology (SIR) denies it is in a turf war with OB-GYNs over the treatment of uterine fibroids (leiomyoma), but there is tension. SIR is upset because they believe OB-GYNs are not informing women with uterine fibroids about a treatment option they can get from interventional radiologists. SIR president Suresh Vedantham, MD, from Washington University School of Medicine, said uterine fibroid embolization (UFE) – a procedure interventional radiologists provide – is “vastly underutilized.”

SIR insists it would rather partner with OB-GYNs and primary care physicians as part of a “uterine fibroid care team.” But SIR is taking its message to the media and to the public: That women need to know the UFE option is available.

UFE is an outpatient, non-surgical, minimally-invasive procedure performed under local anesthesia in a hospital by interventional radiologists through a tiny incision in either the femoral or radial artery. Using real-time imaging, a catheter is guided into the uterine arteries and delivers small beads (about the size of a grain of sand) which block the blood flow to the fibroids, causing them to shrink or disappear. Fibroids can come back after UFE, but the procedure can be repeated.

UFE is not a new procedure; it has been around for >20 years, and several companies offer the devices used for the procedure, including Cook Medical, Boston Scientific, and Mentice.

According to SIR most women will develop uterine fibroids by the age of 50. Uterine fibroids are benign tumors in the uterus that can cause pelvic pain, heavy bleeding, and abdominal enlargement. It is a condition that women often are too embarrassed to discuss with their friends. The condition is more common in women who are age >40, overweight, hypertensive, have a family history of fibroids, have not borne children, or African American.

To find out why UFE is underutilized, SIR commissioned a survey of 1,176 American women age ≥ 18 by Harris Poll from June 23-27, 2017. In a webcast with reporters, SIR officials said the survey found an “alarming” lack of awareness by women of uterine fibroids:

- 28% of women had never even heard of uterine fibroids, including 70% of women age 18-34.
- 57% of women don’t think they are at risk.
- 37% didn’t know anyone who had been diagnosed with fibroids.
- 19% of women who have heard of fibroids falsely believe fibroids are cancerous, requiring a hysterectomy.

Among women who had been diagnosed with uterine fibroids, the survey found:

- 44% of women of all ages had never heard of UFE.
- 11% thought a hysterectomy was the only treatment option.

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The problem, as SIR sees it, is that OB-GYNs offer women other options that they supervise or perform, rather than referring the women to an interventional radiologist for UFE. SIR calls it a “disservice to women” for OB-GYNs not to tell women about the UFE option. The options OB-GYNs are offering women are:

- **Watchful waiting** – which SIR admits can be the right option in some cases, though it can require frequent checkups and scans.
- **Medication** – to treat the symptoms, not the cause. This does not eliminate fibroids. Repros Therapeutics’ Proellex (telapristone) is in development to treat fibroid symptoms, but the FDA put this oral drug on a partial hold that it indicated it won’t lift until it gets a “large” amount of safety information, which means a new and larger clinical trial.
- **Myomectomy** – surgical procedure, often performed laparoscopically, to physically remove the fibroids. Fibroids can come back after this procedure, and a repeat myomectomy is more difficult to do.
- **Hysterectomy** – surgical removal of the uterus. SIR says that ~600,000 hysterectomies are performed in the U.S. yearly. James Spies, MD, MPH, an interventional radiologist from Georgetown University Medical Center, estimated that ~10 times as many hysterectomies are performed in the U.S. as UFEs for women with symptomatic fibroids. He said, “Many healthcare providers still recommend hysterectomy as a patient’s best option for treatment. But 1 in 5 did not have evidence to support surgery in the record. A hysterectomy is necessary for many conditions, and many may choose it, but it is not needed in the majority of cases of fibroids.”
- **Radiofrequency ablation** – doesn’t have much data yet.

Most of the women getting UFE are self-referred. The survey found that only 27% of women had heard of UFE first from their OB-GYN. Instead, 32% heard about it from friends/family, 23% from advertising, and 9% from their own research. Janice Newsome, MD, an interventional radiologist from Emory University Hospital, who is in an academic practice, said, “[Even though] I have a combined clinic with an OB-GYN twice a month, more than 50% of patients are self-referred... They come from our ads or their own research, and only 23% of patients are referred from the GYN to our practice.”

Asked why her GYN colleague doesn’t refer more patients, Dr. Newsome said, “I wish I knew... I pulled the data last week, so we can have that discussion... More and more patients are asking for minimally-invasive ways of treating fibroids... But I think it will continue to be direct referral mostly.”

For the women in the survey, the five factors most important to them in choosing a uterine fibroid treatment are: proven effectiveness (46%), minimally invasive (45%), cost/insurance coverage (44%), minimal risk of complications (43%), and short recovery time (41%). And SIR points out that UFE offers symptom relief with a low complication rate, a less-invasive and less painful procedure, with a relatively quick (~1 week) recovery time. And the procedure is usually covered by insurance.

Other potential advantages to UFE that SIR cites include:

- Pregnancy is possible in up to 70% of women post-procedure.
- Follow-up treatment is usually not required.
- Menopause will not be triggered by the procedure.
- A women’s sex life may be improved by the reduction in pain and bleeding.
- It is more cost-effective than a hysterectomy.

Asked why OB-GYNs don’t recommend UFE, Dr. Spies said, “The medical profession is conservative, and new innovations sometimes take a while to permeate... but this has been around for 20 years.”

Asked what is the best procedure for women who want to conceive, Dr. Newsome said, “Many women retain the ability to conceive and have had successful pregnancies... but it is not guaranteed.” Dr. Spies added, “Our first recommendation [in that case] is consideration of myomectomy... but 60%-70% of women who want to get pregnant after UFE are successful. Which of the two is better [for women who want to conceive]? We are not sure. So, the conservative approach may be the better approach, but if a woman is a surgical risk or had a prior myomectomy, then UFE clearly has a role.”

Asked if UFE can be done for any size fibroid, Dr. Spies said, “Technically, yes, but this is a balanced decision between the patient’s goal, the size, and the location of the fibroid.”

Asked what the contraindications to UFE are, Dr. Spies said, “Early on, we were very conservative. There were certain types of fibroids and certain circumstances where we felt it shouldn’t be performed, but almost all of those have been debunked...So, we have broadened the indication. Now, there are only a few true contraindications.” He said there are no anatomic contraindications, and weight is not an issue, but there are reservations about recommending it for younger women with no prior therapies who might want to conceive. He said the contraindications are:

- Currently pregnant.
- Suspected uterine or pelvic malignancy.
- An active pelvic infection, which should be treated first.

Asked what percent of UFE patients later go on to have a hysterectomy, Dr. Spies said, “One randomized trial showed at 5 years <30% had a hysterectomy, either because their symptoms were not controlled or they had recurrent symptoms. All the other trials show a lower rate of recurrence...So, I tell patients there is a 20%-25% chance of recurrence requiring retreatment. Retreatment is 23% for myomectomy as well...Hysterectomy can be avoided in 80% of patients...UFE can be performed twice.”

