

Advances in Fibroid Treatment Loom on Horizon

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TORONTO — Treating uterine fibroids may eventually be as simple as prescribing a pill, or zapping the benign growths with high-intensity focused ultrasound—two of several promising nonsurgical alternatives to the roughly 300,000 fibroid-related hysterectomies performed annually in the United States.

Hysterectomy “is the gold standard in fi-

broid treatment. ... The problem is that it's a big operation, and the patient loses her uterus. For some women, that just is not an acceptable solution,” Dr. R. Torrance Andrews said in an interview after his presentation at the annual meeting of the Society of Interventional Radiology.

Uterine fibroids, or leiomyomas, may cause infertility or premature delivery and in rare cases may become malignant. They affect about 30% of reproductive-age women, most commonly between the

ages of 35 and 45 years, and particularly African American women, whose incidence rate is up to nine times higher than that of white women.

Dr. Andrews, chief of vascular and interventional radiology at the University of Washington Medical Center, Seattle, discussed mainstream fibroid treatments such as hysterectomy, laparoscopic myomectomy, and uterine fibroid embolization (UFE), as well as emerging therapies like high-intensity focused ultrasound

(HIFU), asoprisnil, and other methods.

In terms of recommending one treatment over the other, Dr. Andrews was frank: “I think it's a big mistake for interventional radiologists to tell patients authoritatively that they should have an embolization, instead of [a surgical] treatment. Similarly, unless a gynecologist is really well versed in embolization and patient selection, they should not tell patients that they are not embolization candidates. I think it needs to be a collaborative effort.”

HIFU is a form of highly focused acoustic energy, delivered transcutaneously (without puncturing the skin) via an array of ultrasound transistors onto a single point within the body measuring 3 mm by 8 mm—about the size of a grain of rice.

In MR-guided HIFU procedures (granted FDA approval in 2004), the uterine region is scanned for fibroids and divided into planes at different depths. All visible fibroid cells at a given depth are individually ablated before moving onto the next plane, and the process is repeated until the entire volume is treated.

“The beauty of HIFU is that it's completely noninvasive. It's the ‘Star Trek’ of medical intervention ... and is going to have a very important role to play, not just for fibroids, but for all kinds of tumors,” Dr. Andrews said.

Despite its vaunted potential, Dr. Andrews said he knows of only a handful of U.S. centers offering HIFU treatment, and he attributes the scarcity to cost—about \$1.5 million per unit—and to poor results to date.

“The published data on HIFU are terrible. The success rates are bad, partly because a quarter or more of patients drop out before they complete their treatment” he said, noting that not all patients will want to go through three or more 3-hour sessions inside a noisy, cramped MRI machine.

He also argued that the FDA's strict restrictions during trials—that investigators could not treat any fibroid within a centimeter and a half of normal uterine tissue—was “a guarantee for failure,” and the main reason for the treatment's paltry 14% fibroid volume reduction.

His department at the University of Washington, which recently acquired an ultrasound-guided machine (“faster than MR, but not yet FDA-approved”) for clinical study, has chosen not to offer HIFU treatments until more data are available.

Dr. Andrews noted the buzz surrounding asoprisnil, a selective progesterone-receptor modulator that has been shown to significantly shrink fibroids and reduce their symptoms with minimal side effects during phase III trials. However, a new drug application, expected in late 2005, has not yet been filed with the FDA.

He also briefly discussed various thermal ablation techniques, developed mainly between 2000 and 2003. The basis of each is a transfer of energy—either laser, radiofrequency, microwave, or cryotherapy—through a percutaneous or transvaginal probe. They offer highly targeted delivery, but as with myomectomy, they only treat fibroids that can be seen. Interest in most of these techniques has largely faded away, Dr. Andrews said. ■

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