Medical Xpress

FDA weighs cancer risk of fibroid removal devices

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Federal health advisers say there is little to no evidence that a popular technique for removing fibroids can be performed without the risk of spreading undetected cancers to other parts of the body.

The panel of Food and Drug Administration experts also said Friday that women who do undergo the procedure should sign a written consent form stating they understand the serious risks of laparoscopic power morcellation, in which electronic tools are used to grind tissue and remove it through a small incision in the abdomen.

Surgeons developed the technique as an alternative to traditional surgery, which requires a larger incision that often results in more bleeding and longer hospital stays. But the FDA convened a two-day meeting this week after concluding that the risk of accidentally spreading undetected cancer to other organs may be far more common than previously thought.

The agency asked its panel of obstetrics and gynecology experts to weigh in on potential methods for minimizing the risk, including using plastic specimen bags to catch bits of shredded tissue. Some surgeons already use that technique, but panelists said it is based on "intuition."

"There's no evidence that the bags or any containment devices prevent the outcome we are trying to prevent," said Dr. Craig Shriver of the Walter Reed Medical Center.

The panel also discussed the difficulties of screening women for a rare form of uterine cancer, called leiomyosarcoma, ahead of the procedure. Imaging techniques are often unable to distinguish between the cancers and normal fibroids. And while there are some common risk factors—based on women's age, race and family history—panelists said they are not reliable.

"It doesn't sound like anyone has confidence that those will be able to predict the vast majority of leiomyosarcomas," said Dr. Michael Diamond, of Georgia Regents University.

The FDA takes the opinions of its panelists into consideration when it makes regulatory decisions on medical devices and other treatments. The agency has not set a timeline for taking action on power morcellators.

Doctors have long acknowledged the risk of accidentally spreading undetected cancer with such electronic shredding tools. But in April the FDA said doctors should halt use of the devices for fibroid treatments after agency scientists calculated that the risk of cancer spread was greater than previously thought. The agency estimated as many as 1 in 350 women may have undetected uterine cancer that can be ruptured by the technique. Previous estimates put the rate closer to 1 in 7,000

Earlier in the day cancer patients and family members of deceased patients urged the FDA to ban the use of electronic surgical tools for fibroid removal.

"Would you permit your wife or sister to undergo a procedure that has a one in 351 chance of spreading cancer throughout the body?" Colleen Daley asked the FDA panel. Daley's sister, Patricia Marie Daley, died in 2011 of leiomyosarcoma that spread to her lungs after undergoing treatment via power morcellation.

The FDA approved the first electronic morcellators in 1995 and about two dozen have been approved in U.S. since then. The devices were cleared through an abbreviated review process because they were deemed similar to manual surgical devices long on the market.

Fibroids are non-cancerous growths in the uterus that can cause severe pain, heavy bleeding, and bladder and bowel dysfunction, mostly among women in their late 30s and 40s. It's unclear what causes the tumor-like growths—which can grow as large as cantaloupes—but they account for an estimated 240,000 of the 600,000 annual hysterectomies in the U.S. At least 50,000 U.S. women undergo hysterectomy using the power morcellation technique.

Hysterectomy is a key treatment because it is the only way to ensure that fibroids do not return. Myomectomy, surgery that removes fibroids while leaving the uterus intact, is recommended for women who still want to become pregnant.

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