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Top gynecologists oppose FDA ruling on minimally invasive procedures for uterine fibroids

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Two UNC physicians have joined other leading experts in gynecology and related specialties across the country in asking the Food and Drug Administration to rescind or revise a warning it issued severely restricting use of a device commonly employed in minimally invasive procedures to treat uterine fibroids.

Dr. Daniel Clarke-Pearson, chair of UNC's Department of Obstetrics and Gynecology at UNC's School of Medicine, and Dr. Matthew Siedhoff, director of the department's minimally invasive gynecologic surgery division, are among a group of 48 gynecologists, gynecologic oncologists, surgical oncologists, department chairs and women's health advocates who sent an open letter to the FDA yesterday (Dec. 7) saying they believe the agency's decision, although well-intentioned to protect against the spread of a very rare form of uterine cancer, was based on incorrect data.

In addition to its Dec. 7 plea to the FDA, the Leiomyoma Morcellation Study Group published a related article online Dec. 8, 2015 in *Obstetrics & Gynecology*, the journal of the American College of Obstetricians and Gynecologists. That paper presented statistics that support the group's objections and offered suggestions for clinical recommendations.

"Our research finds that morcellation can be a safe, effective, minimally invasive treatment option for fibroids," said Dr. Clarke-Pearson. "We

believe the FDA failed to identify important information that has led to inaccurate conclusions that would negatively impact the health of many women across the country."

"If the use of the device were restricted, it could require tens of thousands of women with benign fibroids to undergo major surgery with large abdominal incisions each year," Dr. Clarke-Pearson said. The doctors point out that the more invasive operations have higher risks and require longer hospital stays and many more weeks for recovery than less invasive procedures.

The letter aligns with two articles published by Dr. Clarke-Pearson and Dr. Siedhoff, along with other faculty in the department and UNC's top-ranked Gillings School of Global Public Health. These papers argue that, even when accounting for potential device complications, minimally invasive surgery for fibroids is more cost-effective, safer, and results in fewer procedure-related deaths.

Benign fibroids, also called leiomyomas, can be found in about 75 percent of all women at some point in their lives, resulting in an estimated 210,000 hysterectomies and 50,000 myomectomies - surgical fibroid removals - each year in the United States. Many of these operations are done laparoscopically and a small, electrical device called a power-morcellator is used to cut or break down the fibroids into tiny pieces that can be removed through the small incisions.

The FDA's concern is that if a presumed benign fibroid is later found to be a highly aggressive malignancy called a leiomyosarcoma, fragments of the cancer will be scattered by the power-morcellator, increasing the risk of spread.

Leiomyosarcoma, or LMS, is a rare form of uterine cancer only diagnosed in about 1,600 women in the U.S. each year and is difficult to

identify preoperatively. When LMS is suspected prior to surgery, surgeons typically opt for open surgery using a large abdominal incision and try to remove the tumor intact. Even in its early stages and without morcellation, LMS often advances quickly and is difficult to treat because its cells readily travel in the bloodstream and attach and grow elsewhere in the body.

But gynecology experts in the study group said the FDA's warning against power-morcellation was based on a flawed medical literature review and assumptions based on inconclusive evidence.

"There are serious gaps in the studies used to estimate the frequency of finding unexpected LMS where the device might be used," said Dr. Siedhoff. "Our research suggests that, rather than abandon the clear benefits minimally invasive surgery affords women, future research efforts ought to focus on better preoperative identification and new techniques, such as placing specimens in bags before removing them."

A recent and more rigorous analysis of 133 studies determined that the risk of finding a leiomyosarcoma among women having surgery for presumed fibroids was 1 in 1,960, or 0.051 percent. Another recently published large population-based study found 2 leiomyosarcomas among 8,720 women having surgery for fibroids, which equates to 1 in 4,360 or 0.023 percent.

The authors said they believe that restriction of any type of morcellation - whether by powered device or by hand using a scalpel - would severely restrict women's access to most procedures other than traditional abdominal surgery, which has more risks and complications.

Dr. Clarke-Pearson and his study group colleagues said that although it is difficult to distinguish between benign fibroids and LMS in preoperative exams, images and tests, there are some clues that can help doctors and

patients make treatment decisions. For example, benign fibroids are more likely to cause symptoms in younger women, primarily those in their 40s, but LMS typically affects a more senior population; prevalence is 10 times higher in women older than 60 than in those younger than 50.

All doctors signing the article and letter to the FDA affirm that they have no conflicts of interest.

More information: *Obstetrics & Gynecology*, "The FDA's Guidance Regarding Morcellation of Leiomyomata - Well Intentioned, but is it Harmful for Women?" (2015)

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