

FDA, hospitals caution against laparoscopic power morcellation during hysterectomy and myomectomy

↘ The FDA's recent safety communication on the risks of laparoscopic power morcellation prompts Brigham and Women's and Massachusetts General hospitals to ban the procedure

Janelle Yates, Senior Editor

The use of power morcellation to remove the uterus or uterine tumors during hysterectomy and myomectomy may be riskier than many have thought. That's the conclusion reached by the US Food and Drug Administration (FDA) in a safety communication issued April 17, 2014. In its communication, the FDA "discouraged" use of power morcellation during hysterectomy and myomectomy. Shortly afterward, Brigham and Women's and Massachusetts General hospitals in Boston banned power morcellation in all hysterectomy and myomectomy procedures. The hospitals may resume power morcellation at some future date using a containment system, pending guidance from the Institutional Review Board.

Robert L. Barbieri, MD, who is chair of obstetrics and gynecology at Brigham and Women's Hospital, recently wrote about this concern for OBG MANAGEMENT in his capacity as editor in chief of the journal.

"When used to treat tumors presumed to be fibroids, open power morcellation [without a containment system] is associated with an increased risk of dispersing benign myoma tissue and occult malignant leiomyosarcoma tissue throughout the abdominal cavity," he wrote.¹ "Dispersion of benign myoma tissue may result in the growth of fibroids on the peritoneal surface, omentum, and bowel, causing abdominal and pelvic pain and necessitating reoperation. Dispersion of leiomyosarcoma

tissue throughout the abdominal cavity may result in a Stage I cancer being upstaged to a Stage IV malignancy, requiring additional surgery and chemotherapy. In cases in which open power morcellation causes the upstaging of a leiomyosarcoma, the death rate is increased."¹

The two Boston hospitals are not the only institutions reconsidering the use of power morcellation. Temple University Hospital in Philadelphia banned use of the procedure without a containment system in late February 2014.

And in December 2013, the Society of Gynecologic Oncology issued a position statement on the issue, which said, "power morcellation or other techniques that cut up the uterus in the abdomen have the potential to disseminate an otherwise contained malignancy throughout the abdominal cavity. For this reason, the Society of Gynecologic Oncology (SGO) asserts that it is generally contraindicated in the presence of documented or highly suspected malignancy, and may be inadvisable in premalignant conditions or risk-reducing surgery."²

For its part, at the time of this writing, the AAGL, previously known as the American Association of Gynecologic Laparoscopists, "is reviewing the scientific evidence and best practices reported by our members," stated an article in its *Association News*. "We recognize that, in rare cases, the use of power

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morcellators can lead to the dissemination of an occult malignancy of endometrial or myometrial origin, and also to dissemination of benign morcellated tissues. We encourage our members to fully research and understand the risks of power morcellation and to learn more about when alternative methods of tissue extraction may be appropriate.”³

FDA stops short of a ban

In laying out its concerns, the FDA stopped short of an outright ban on power morcellation. Instead, it stated that, “based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.”⁴

It also noted that approximately 1 in 350 women “undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma.”⁴

Among its recommendations for health-care providers:

- avoid laparoscopic uterine power morcellation in women with suspected or known uterine cancer
- carefully consider all available treatment options for women with symptomatic uterine fibroids
- thoroughly discuss the benefits and risks of all treatments with patients.⁴

The FDA also noted that “some clinicians and medical institutions now advocate using a specimen ‘bag’ during morcellation in an attempt to contain the uterine tissue and minimize the risk of spread in the abdomen and pelvis.”⁴

ACOG has yet to weigh in


At the time of this writing, the most recent committee opinion on choosing a hysterectomy route from the **American College of Obstetricians and Gynecologists** (ACOG) to touch on the issue states that, “the decision to perform a hysterectomy via [minimally invasive surgery] (with or without morcellation) is based on a patient

evaluation, including the patient’s history and general health, tests, and procedures, such as pre-surgery biopsies. The evaluation and diagnostic process also provides an opportunity to identify any cautions or contraindications, such as finding a gynecological cancer.”⁵

Filling the technology gap

Now that power morcellation appears to be receding as an option for minimally invasive gynecologic surgeons, what is the best approach?

In its position statement, the SGO recommends that, “Patients being considered for minimally invasive surgery performed by laparoscopic or robotic techniques who might require intracorporeal morcellation should be appropriately evaluated for the possibility of coexisting uterine or cervical malignancy. Other options to intracorporeal morcellation include removing the uterus through a mini-laparotomy or morcellating the uterus inside a laparoscopic bag.”²

K. Anthony Shibley, MD, a Minneapolis-area ObGyn, has developed a novel strategy to prevent tissue dissemination during open power morcellation, which is demonstrated in a video at obgmanagement.com. Similarly, Ceana Nezhat, MD, and Erica Dun, MD, demonstrate enclosed vaginal morcellation of a large uterus. These and other features on morcellation are available at <http://www.obgmanagement.com/topic-collections/morcellation/landing.html>. 

References

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