

## An open letter to the FDA on morcellation for presumed uterine fibroids

On December 8, 2015, 46 minimally invasive surgeons, gynecologic oncologists, and other experts spoke out in unison when they sent an open letter to the US Food and Drug Administration (FDA). They called into question the FDA's estimate of the likelihood of occult leiomyosarcoma (LMS) and recommended continued use of power morcellation in appropriate cases.

An excerpt from this letter is published here. The letter in its entirety and the names of the signees can be found at [obgmanagement.com](http://obgmanagement.com). Access this url <http://bit.ly/1I0yVpH> or use this QR code\* to gain access on your smartphone.



\*Free QR readers are available at the iPhone App Store, Android Market, and BlackBerry App World.

### Letter excerpt:

#### If abdominal hysterectomy is recommended to women with fibroids, will women be better off?

By focusing exclusively on the risk of LMS, the FDA failed to take into account other risks associated with surgery. Laparoscopic surgery uses small incisions, is performed as an outpatient procedure (or overnight stay), has a faster recovery (2 weeks vs 4–6 weeks for open surgery), and is associated with lower mortality and fewer complications. These benefits of minimally invasive surgery are now well established in gynecologic and general surgery.

Using published best-evidence data, a recent decision analysis<sup>1</sup> showed that, comparing 100,000 women undergoing laparoscopic hysterectomy with 100,000 undergoing open



DECEMBER 2015

hysterectomy, the group undergoing laparoscopic surgery would experience 20 fewer perioperative deaths, 150 fewer pulmonary or venous embolus, and 4,800 fewer wound infections. Importantly, women having open surgery would have 8,000 fewer quality-of-life years.

A recently published study<sup>2</sup> found that, in the 8 months following the FDA safety communication, utilization of laparoscopic hysterectomies decreased by 4.1% ( $P = .005$ ), and abdominal and vaginal hysterectomies increased by 1.7% ( $P = .112$ ) and 2.4% ( $P = .012$ ), respectively. Major surgical complications (not including blood transfusions) increased from 2.2% to 2.8% ( $P = .015$ ), and the rate of hospital readmission within 30 days also increased from 3.4% to 4.2% ( $P = .025$ ). These observations merit consideration as women weigh the pros and cons of minimally invasive surgery with morcellation versus open surgery.

#### Clinical recommendations

Recent attention to surgical options for women with uterine leiomyomas

and the risk of an occult LMS are positive developments in that the gynecologic community is reexamining relevant issues. We respectfully suggest that the following clinical recommendations be considered:

- The risk of LMS is higher in older postmenopausal women; greater caution should be exercised prior to recommending morcellation procedures for these women.
- Preoperative consideration of LMS is important. Women aged 35 years and older with irregular uterine bleeding and presumed fibroids should have an endometrial biopsy, which occasionally may detect LMS prior to surgery. Women should have normal results of cervical cancer screening.
- Ultrasound or MRI findings of a large irregular vascular mass, often with irregular anechoic (cystic) areas reflecting necrosis, may cause suspicion of LMS.
- Women wishing minimally invasive procedures with morcellation, including scalpel morcellation via the vagina or mini-laparotomy, or power morcellation using laparoscopic guidance, should understand the potential risk of decreased survival should LMS be present. Open procedures should be offered to all women who are considering minimally invasive procedures for "fibroids."
- Following morcellation, careful inspection for tissue fragments should be undertaken and copious irrigation of the pelvic and abdominal cavities should be performed to minimize the risk of retained tissue.
- Further investigations of a means to identify LMS preoperatively should be supported. Likewise, investigation into the biology of LMS should be funded to better

CONTINUED ON PAGE 14

CONTINUED FROM PAGE 11

understand the propensity of tissue fragments or cells to implant and grow. With that knowledge, minimally invasive procedures could be avoided for women with LMS and women choosing minimally invasive surgery could be reassured that they do not have LMS.

Respecting women who suffer from LMS, we conclude that the FDA directive was based on a misleading analysis. Consequently, more accurate estimates regarding the prevalence of LMS among women having surgery for fibroids should be issued. Women have a right to self determination. Modification of the FDA's current restrictive guidance regarding power morcellation would empower each woman to consider the pertinent issues and have the freedom to undertake shared decision making with her surgeon in order to select the procedure that is most appropriate for her.

#### References

1. Siedhoff MT, Wheeler SB, Rutstein SE, et al. Laparoscopic hysterectomy with morcellation vs abdominal hysterectomy for presumed fibroid tumors in premenopausal women: a decision analysis. *Am J Obstet Gynecol.* 2015;212(5):591.e1-e8.
2. Harris JA, Swenson CW, Uppal S, et al. Practice patterns and postoperative complications before and after Food and Drug Administration Safety Communication on power morcellation [published online ahead of print August 24, 2015]. *Am J Obstet Gynecol.* doi:10.1016/j.ajog.2015.08.047.

### **"CAN WE REDUCE THE USE OF ABDOMINAL HYSTERECTOMY AND INCREASE THE USE OF VAGINAL AND LAPAROSCOPIC APPROACHES?"**

ROBERT L. BARBIERI, MD  
(EDITORIAL; NOVEMBER 2015)

### **Choose the best approach for the patient**

I cannot decrease the number of abdominal hysterectomies I perform—all of them are indicated.

**Richard Hatch, MD**  
Augusta, Georgia

### **Supracervical hysterectomy: simplest is best**

Supracervical hysterectomy (SCH) via a Pfannenstiel incision in women with a body mass index less than 25 kg/m<sup>2</sup> is a great procedure for uterine pathology. SCH addresses only the uterine pathology and preserves the cervix, is a sterile procedure, requires no ancillary equipment, should take less than 30 minutes, preserves the full length of the vagina, requires only an overnight hospitalization, and has a short learning curve.

Removal of the cervix in any hysterectomy is the procedure that results in bladder and ureter injury and infection from contamination. Patients should be driving and back to nonphysical jobs in less than 1 week. As medical care becomes a truly transparent market-based business, patients will opt for SCH over higher priced alternatives. Sometimes the simplest procedures are still the best.

**Joe Walsh, MD**

Philadelphia, Pennsylvania

### **Continue to teach abdominal hysterectomy**

No one can disagree with the statistics of shorter recovery and less morbidity for laparoscopic and vaginal procedures. In fact, what separates a gynecologist from other surgeons is the ability to operate in and through the vagina. There is still a place for abdominal hysterectomy for benign disease in modern gynecology.

Most programs produce good laparoscopic surgeons but ill prepared abdominal and vaginal surgeons. No gynecologist should be operating in the pelvis unless he or she is comfortable going into the retroperitoneal space if necessary. Many of the total laparoscopic hysterectomies that are performed could be

done vaginally without abdominal incisions.

Now we have a generation of gynecologic surgeons who believe a robotic hysterectomy (at great extra expense) offers the patient an advantage, despite longer anesthesia and procedure times. We know morbidity has a direct correlation to operating and anesthesia time. Although I am impressed with what the next generation can do through a laparoscope, I would hate to let them continue without the experience or the ability to do an open abdominal procedure.

**Allan N. Boruszak, MD**

Washington, North Carolina

### **>> Dr. Barbieri's response**

*I appreciate the perspectives of Drs. Hatch, Walsh, and Boruszak on the important issue of improving hysterectomy outcomes. Dr. Hatch raises the important point that gynecologists routinely select the best surgical approach for the unique needs of their patients. Based on a given gynecologist's panel of patients and their unique medical issues, it may be difficult to change the distribution of surgical approaches to hysterectomy. Dr. Walsh advocates for a "minimally invasive" abdominal SCH, which is a valid approach to improving the outcomes of the abdominal approach. Dr. Boruszak rightly highlights the importance of teaching gynecologists to access the retroperitoneum, paravesical, and pararectal spaces in order to improve patient outcomes.*

### **"VAGINAL HYSTERECTOMY WITH BASIC INSTRUMENTATION"**

BARBARA S. LEVY, MD (OCTOBER, 2015)

### **Appreciates the instrument review**

Dr. Levy's article on vaginal hysterectomy using basic instruments is really

wonderful. The segment on uterine reduction strategies will be especially useful. I appreciate her preference to use the Ligasure vessel-sealing device over suturing pedicles. Before we take steps to debulk the uterus, it is always essential, and better, to ligate uterine vessels, as this minimizes blood loss and makes the surgical field clearer.

**R. Sasirekha**  
Puducherry, India

**Skill should be rewarded**

When I trained, vaginal hysterectomy was reserved for prolapse. After joining the Army, my eyes were opened by physicians who could morcellate a 16-week uterus or perform a 20-minute vaginal hysterectomy on

a nulliparous woman for sterilization (which, of course, is controversial).

Once in private practice, incorporating these new skills into my own techniques was challenging and rewarding. Imagine my disappointment when I found out that reimbursement was a disincentive. It is easy to be altruistic, but one has to consider the incentives, too. Skill should be rewarded.

**Mark B. Vizer, MD**  
Lansdale, Pennsylvania

**A long-time proponent of vaginal hysterectomy**

I appreciate the articles by Drs. Levy and Gebhart on vaginal surgical techniques. I have long been a proponent of vaginal hysterectomy as

the preferred route for removal of the uterus (and tubes and ovaries, if indicated). I do most of my hysterectomies vaginally, with salpingectomies and oophorectomies if indicated. As an older surgeon, I now refer patients with uteri larger than 16 weeks, endometriosis, or suspected cancer.

**Doug Tolley, MD**  
Yuba City, California

>> **SHARE YOUR THOUGHTS!**

Send your letter to the editor to:  
**rbarbieri@frontlinemedcom.com**

Please include your name and the city and state in which you practice.

This space has purposely been left blank.