

Alterations in surgical technique after FDA statement on power morcellation

OBJECTIVE: Electromechanical morcellation (EMM), commonly known as “power morcellation,” often allows patients the benefits of minimally invasive surgical approaches that include decreased morbidity and mortality rates.¹ However, the role of EMM in myomectomy and hysterectomy recently has come under scrutiny due to concerns about heightened risks of intraperitoneal cancer dissemination in women with occult malignancies. In November 2014, the US Food and Drug Administration (FDA) issued a safety warning for using EMM to remove uterine fibroids.² Despite prevalent public debate, it is unclear whether and how gynecologic surgeons have changed their practice. The current study seeks to assess the influence of the FDA warning regarding EMM on management strategies in hysterectomies/myomectomies.

STUDY DESIGN: We conducted an online survey of American Association of Gynecologic Laparoscopists Minimally Invasive Gynecology Surgery Fellowship program faculty from December 2014 to February 2015 using the Qualtrics Survey Tool (Qualtrics, Provo, UT). Email addresses were obtained from the fellowship program’s website. Of the 201 faculty contacted, 40 messages were undeliverable, resulting in an effective target population of 161 faculty members. Survey questions were developed based on literature review and expert opinion and were pilot-tested on a convenience sample of gynecologic surgeons before final implementation.

RESULTS: Forty-six faculty members completed the survey (response rate, 29%). Of these respondents, 62% were men, 60% had >10 years of experience, 60% were in gynecology-

TABLE

Operative practices before and after the FDA safety warning regarding power morcellation^a

| Operative practice | n (%) |
|---|---------|
| PRACTICE IN 2013 (BEFORE FDA SAFETY WARNING) | |
| Types of preoperative evaluation performed before morcellation in 2013 | |
| None | 0 |
| Careful history taking for menopausal status, bleeding, estrogen exposure, irradiation, etc | 42 (98) |
| Endometrial sampling | 37 (86) |
| Magnetic resonance imaging | 19 (44) |
| Ultrasound scanning | 32 (74) |
| Other imaging ^b | 4 (9) |
| Other evaluation ^c | 4 (9) |
| Morcellation techniques used | |
| Vaginal morcellation without a bag and without culdotomy/colpotomy | 18 (42) |
| Vaginal morcellation with a scalpel through a culdotomy/colpotomy | 13 (30) |
| Minilaparotomy/laparoendoscopic single-site morcellation with a scalpel in a bag | 9 (21) |
| Laparoendoscopic single-site morcellation with a scalpel without a bag | 16 (37) |
| Uncontained power/electronic morcellation | 35 (81) |
| Electronic morcellation in a bag | 4 (9) |
| Other ^d | 4 (9) |
| CHANGE IN PRACTICE IN AFTER FDA SAFETY WARNING | |
| Change in preoperative evaluation | |
| Additional imaging | 8 (22) |
| Additional endometrial sampling | 2 (6) |
| Other ^e | 7 (19) |

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(continued)

TABLE

Operative practices before and after the FDA safety warning regarding power morcellation^a (continued)

| Operative practice | n (%) |
|--|---------|
| Change in surgical management | |
| Used additional ports | 2 (6) |
| Used electronic morcellation in a bag | 12 (33) |
| Used specimen retrieval pouches | 18 (50) |
| Used vaginal extraction without a bag | 8 (22) |
| Used vaginal extraction in a bag | 15 (42) |
| Used minilaparotomy to remove specimen | 21 (58) |
| Used hysteroscopic resection | 0 |
| Changed route of hysterectomy to total laparoscopic hysterectomy | 9 (25) |
| Changed route of hysterectomy to total abdominal hysterectomy | 9 (25) |
| Decreased use of laparoscopic supracervical hysterectomy | 14 (39) |
| Increased use of medical management (eg, uterine artery ablation and embolization) | 2 (6) |
| Increased use of intraoperative frozen specimen evaluation | 1 (3) |

FDA, Food and Drug Administration.

^a For removal of uterine fibroid tumors, among survey respondents who performed morcellation in hysterectomy or myomectomy in 2013 (n = 43). Percentages may add to more than 100% because the categories were not mutually exclusive; ^b Other imaging included magnetic resonance imaging selectively and computed tomography; ^c Other evaluations included endometrial biopsy as indicated and lactate dehydrogenase; ^d Checked "Other" but did not specify exact technique; ^e Other changes included altered or additional preoperative counseling and lactate dehydrogenase.

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only practices, and 67% performed >50 hysterectomies/myomectomies annually. Although 28 respondents (61%) said that they had never diagnosed leiomyosarcoma, 12 respondents (26%) encountered at least 1 patient in 2013 with occult malignancy during a benign procedure. Forty-three surgeons (93%) reported using morcellation during hysterectomies/myomectomies in 2013, with uncontained EMM being the most commonly used form (81%). The Table summarizes practice changes in these 43 surgeons. Thirty-six surgeons (84%) noted that they changed their surgical approach for hysterectomies/myomectomies after the FDA warning. Of them, 21 (58%) used minilaparotomy; 18 (50%) used specimen retrieval pouches, 15 (42%) used vaginal extraction in a bag; 14 (39%) reduced the use of laparoscopic supracervical hysterectomy, and 9 (25%) changed the route of hysterectomy to total laparoscopic hysterectomy and 9 (25%) changed to total abdominal hysterectomy.

CONCLUSION: Before the FDA warning, EMM was used commonly in hysterectomies/myomectomies. However, gynecologic surgeons have since adopted a variety of changes to their management strategies. Variations in preoperative evaluation demonstrates an inability to diagnose malignancy definitely preoperatively.⁵ The large proportion of respondents who now use larger incisions or open procedures raises concern about potentially higher patient morbidity. Safety, efficiency,

and long-term outcome data for the innovative surgical techniques that have been adopted (eg, various containment bags, vaginal incisions, and intraoperative biopsies) are needed urgently. Further research on the prevalence of occult uterine cancer in women who undergo hysterectomies/myomectomies for presumed benign indications and their prognosis after EMM will also facilitate discussion of optimal management approaches, because our current knowledge is based largely on studies with small sample sizes and nonrepresentative samples.^{3,4} Efforts to prevent cancer dissemination must be balanced against the lost benefits of minimally invasive surgery and the potential risk of newly adopted, yet understudied, surgical techniques. ■

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The authors report no conflict of interest.

➤ See related editorial, page 553

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