

Morcellation use in gynecologic surgery: Current clinical recommendations and cautions

Here, evolving thought on preoperative evaluation and counseling, updated ACOG guidelines, and changes implemented at the authors' institution

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Morcellation of gynecologic surgical specimens became controversial after concerns arose about the potential for inadvertent spread of malignant cells throughout the abdomen and pelvis during tissue morcellation of suspected benign disease. In 2014, the US Food and Drug Administration (FDA) issued a warning

against the use of laparoscopic power morcellation specifically for myomectomy or hysterectomy in the treatment of leiomyomas (fibroids) because of the risk of spreading undiagnosed malignancy throughout the abdomen and pelvis.¹ This warning was issued after a high-profile case occurred in Boston in which an occult uterine sarcoma was morcellated during a supracervical robot-assisted hysterectomy for suspected benign fibroids.

Recently, the American College of Obstetricians and Gynecologists (ACOG) published a committee opinion with updated recommendations for practice detailing the risks associated with morcellation and suggestions for patient counseling regarding morcellation.²

In this review, we summarize the techniques and risks of morcellation, the epidemiology of undiagnosed uterine malignancies, practice changes noted at our institution, and clinical recommendations moving forward. A case scenario illustrates keys steps in preoperative evaluation and counseling.

Morcellation uses – and risks

Morcellation is the surgical process of dividing a large tissue specimen into smaller pieces to facilitate their removal through the small incisions made in minimally invasive

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surgery. Morcellation may be performed with a power instrument or manually.

In power morcellation, an electromechanical instrument is used to cut or shave the specimen; in manual morcellation, the surgeon uses a knife to carve the specimen. Power morcellation is performed through a laparoscopic incision, while the manual technique is performed through a minilaparotomy or vaginally after hysterectomy (TABLE). Unlike uncontained morcellation, contained morcellation involves the use of a laparoscopic bag to hold the specimen and therefore prevent tissue dissemination in the abdomen and pelvis.

Morcellation has greatly expanded our ability to perform minimally invasive surgery—for example, in patients with specimens that cannot be extracted en bloc through the vagina after hysterectomy or, in the case of myomectomy or supracervical hysterectomy without a colpotomy, through small laparoscopic ports. Minimally invasive surgery improves patient care, as it is associated with lower rates of infection, blood loss, venous thromboembolism, wound and bowel complications, postoperative pain, and shorter overall recovery time and hospital stay versus traditional open surgery.^{3,4} Furthermore, laparoscopic hysterectomy has a 3-fold lower risk of mortality compared with open hysterectomy.⁴ For these reasons, ACOG recommends choosing a minimally invasive approach for all benign hysterectomies whenever feasible.³

With abundant data supporting the use of a minimally invasive approach, laparoscopic morcellation allowed procedures

involving larger tissue specimens to be accomplished without the addition of a minilaparotomy for tissue extraction. However, disseminating potentially malignant tissue throughout the abdomen and pelvis during the morcellation process remains a risk. While tissue spread can occur with either power or manual morcellation, the case that drew media attention to the controversy used power morcellation, and thus intense scrutiny focused on this technique. Morcellation has additional risks, including direct injury to surrounding organs, disruption of the pathologic specimen, and distribution of benign tissue throughout the abdomen and pelvis, such as fibroid, endometriosis, and adenomyosis implants.⁵⁻⁷

The challenge of leiomyosarcoma

The primary controversy surrounding morcellation of fibroid tissue specimens is the potential for undiagnosed malignancy, namely uterine leiomyosarcoma or endometrial stromal sarcoma. While other gynecologic malignancies, including cervical and endometrial cancers, are more common and potentially could be disseminated by morcellation, these cancers are more reliably diagnosed preoperatively with cervical and endometrial biopsies, and they do not tend to mimic benign diseases.

Epidemiology and risk factors. Uterine leiomyosarcoma is rare, with an estimated incidence of 0.36 per 100,000 woman-years.⁸ However, leiomyosarcoma can mimic the appearance and clinical course of benign fibroids, making preoperative diagnosis difficult. Risk factors for leiomyosarcoma include postmenopausal status, with a median age of 54 years at diagnosis, tamoxifen use longer than 5 years, black race, history of pelvic radiation, and certain hereditary cancer syndromes, such as Lynch syndrome.⁹⁻¹¹ Because of these risk factors, preoperative evaluation is crucial to determine the most appropriate surgical method for removal of a large, fibroid uterus (see “Employ shared decision making” on page 32).

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TABLE Approaches to morcellation

Type of morcellation	Method
Power, contained	Laparoscopic incisions (umbilical or suprapubic)
Manual, uncontained	Vaginally
Manual, contained	Minilaparotomy or Vaginally

Estimated incidence at benign hysterectomy.

The incidence of leiomyosarcoma diagnosed at the time of benign hysterectomy or myomectomy has been studied extensively since the FDA's 2014 warning was released, with varying rates identified.^{11,12} The FDA's analysis cited a risk of 1 in 498 for unsuspected leiomyosarcoma and 1 in 352 for uterine sarcoma.¹ Notably, this analysis excluded studies of women undergoing surgery for presumed fibroids in which no leiomyosarcoma was found on pathology, likely inflating the quoted prevalence. The FDA and other entities subsequently performed further analyses, but a systematic literature review and meta-analysis by the Agency for Healthcare Research and Quality (AHRQ) in 2017 is probably the most accurate. That review included 160 studies and reported a prevalence of less than 1 in 10,000 to 1 in 770, lower than the FDA-cited rate.¹³

Prognosis. The overall prognosis for women with leiomyosarcoma is poor. Studies indicate a 5-year survival rate of only 55.4%, even in stage 1 disease that is apparently confined to the uterus.⁹ Although evidence is limited linking morcellation to increased recurrence of leiomyosarcoma, data from small, single-center, retrospective studies cite a worse prognosis, higher risk of recurrence, and shorter progression-free survival after sarcoma morcellation compared with patients who underwent en bloc resection.^{12,14} Of note, these studies evaluated patients who underwent uncontained morcellation of specimens with unsuspected leiomyosarcoma.

CASE Woman with enlarged, irregular uterus and heavy bleeding

A 40-year-old woman (G2P2) with a history of 2 uncomplicated vaginal deliveries presents for evaluation of heavy uterine bleeding. She has regular periods, every 28 days, and she bleeds for 7 days, saturating 6 pads per day. She is currently taking only oral iron therapy as recommended by her primary care physician. Over the last 1 to 2 years she has felt that her abdomen has been getting larger and that her pants do not fit as well. She is otherwise in excellent

health, exercises regularly, and has a full-time job. She has not been sexually active in several months.

The patient's vitals are within normal limits and her body mass index (BMI) is 35 kg/m². Pelvic examination reveals that she has an enlarged, irregular uterus with the fundus at the level of the umbilicus. The exam is otherwise unremarkable. On further questioning, the patient does not desire future fertility.

What next steps would you include in this patient's workup, including imaging studies or lab tests? What surgical options would you give her? How would your management differ if this patient were 70 years old (postmenopausal)?

Perform a thorough preoperative evaluation to optimize outcomes

Women like this case patient who present with symptoms that may lead to treatment with myomectomy or hysterectomy should undergo appropriate preoperative testing to evaluate for malignancy.

According to ACOG guidance, patients should undergo a preoperative endometrial biopsy if they¹⁵:

- are older than 45 years with abnormal uterine bleeding
- are younger than 45 years with unopposed estrogen exposure (including obesity or polycystic ovary syndrome)
- have persistent bleeding, or
- failed medical management.

Our case patient is younger than 45 but is obese (BMI, 35) and therefore is a candidate for endometrial biopsy. Additionally, all patients should have up-to-date cervical cancer screening. ACOG also recommends appropriate use of imaging with ultrasonography or magnetic resonance imaging (MRI), although imaging is not recommended solely to evaluate for malignancy, as it cannot rule out the diagnosis of many gynecologic malignancies, including leiomyosarcoma.²

Currently, no tests are available to completely exclude a preoperative diagnosis of leiomyosarcoma. While studies have

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evaluated the use of MRI combined with lactate dehydrogenase isoenzyme testing, the evidence is weak, and this method is not recommended. Sarcoma is detected by endometrial sampling only 30% to 60% of the time, but it should be performed if the patient meets criteria for sampling or if she has other risk factors for malignancy.¹⁶ There are no data to support biopsy of presumed benign fibroids prior to surgical intervention. Patients should be evaluated with a careful history and physical examination for other uterine sarcoma risk factors.

Employ shared decision making

Clinicians should use shared decision making with patients to facilitate decisions on morcellation use in gynecologic surgeries for suspected benign fibroids. Informed consent must be obtained after thorough discussion and counseling regarding the literature on morcellation.¹⁷ For all patients, including the case patient described, this discussion should include alternative treatment options, surgical approach with associated risks, the use of morcellation, the incidence of leiomyosarcoma with presumed benign fibroids, leiomyosarcoma prognosis, and the risk of disseminating benign or undiagnosed cancerous tissue throughout the abdomen and pelvis.

Some would argue that the risks of laparotomy outweigh the possible risks associated with morcellation during a minimally invasive myomectomy or hysterectomy. However, this risk analysis is not uniform across all patients, and it is likely that in older women, because they have an a priori increased risk of malignancy in general, including leiomyosarcoma, the risks of power morcellation may outweigh the risks of open surgery.¹⁸ Younger women have a much lower risk of leiomyosarcoma, and thus discussion and consideration of the patient's age should be a part of counseling. If the case patient described was 70 years of age, power morcellation might not be recommended, but these decisions require an in-depth discussion with the patient to make an informed decision and ensure patient autonomy.

The contained morcellation approach

Many surgeons who perform minimally invasive procedures use contained morcellation. In this approach, specimens are placed in a containment bag and morcellated with either power instruments or manually to ensure no dissemination of tissue. Manual contained morcellation can be done through a minilaparotomy or the vagina, depending on the procedure performed, while power contained morcellation is performed through a 15-mm laparoscopic incision.

Currently, one containment bag has been FDA approved for use in laparoscopic contained power morcellation.¹⁹ Use of a containment bag increases operative time by approximately 20 minutes, due to the additional steps required to accomplish the procedure.²⁰ Its use, however, suggests a decrease in the risk of possible disease spread and it is feasible with appropriate surgeon training.

One study demonstrated the safety and feasibility of power morcellation within an insufflated containment bag, and subsequent follow-up revealed negative intraperitoneal washings.^{21,22} In another study evaluating tissue dissemination with contained morcellation of tissue stained with dye, the authors noted actual spillage of tissue fragments in only one case.²³ Although more information is needed to confirm prevention of tissue dissemination and the safety of contained tissue morcellation, these studies provide promising data supporting the use of tissue morcellation in appropriate cases in order to perform minimally invasive surgery with larger specimens.

CASE Next steps and treatment outcome

The patient has up-to-date and negative cervical cancer screening. The complete blood count is notable for a hemoglobin level of 11.0 g/dL (normal range, 12.1 to 15.1 g/dL). You perform an endometrial biopsy; results are negative for malignancy. You order pelvic ultrasonography to better characterize the location and size of the fibroids. It shows multiple leiomyomas throughout the myometrium, with the 2 largest fibroids (measuring 5 and 7 cm) located in

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Use shared decision making with patients to facilitate decisions on morcellator use in gynecologic surgery for suspected benign fibroids

the left anterior and right posterolateral aspects of the uterus, respectively. Several 3- to 4-cm fibroids appear to be disrupting the endometrial canal, and there is no evidence of an endometrial polyp. There do not appear to be any cervical or lower uterine segment fibroids, which may have further complicated the proposed surgery.

You discuss treatment options for abnormal uterine bleeding with the patient, including initiation of combined oral contraceptive pills, placement of a levonorgestrel-containing intrauterine device, endometrial ablation, uterine artery embolization, and hysterectomy. You discuss the risks and benefits of each approach, keeping in mind the fibroids that are disrupting the contour of the endometrial canal and causing her bulk symptoms.

The patient ultimately decides to undergo a hysterectomy and would like it to be performed with a minimally invasive procedure, if possible. Because of the size of her uterus, you discuss the use of contained power morcellation, including the risks and benefits. You have a thorough discussion about the risk of occult malignancy, although she is at lower risk because of her age,

and she consents.

The patient undergoes an uncomplicated total laparoscopic hysterectomy with bilateral salpingectomy. The specimen is removed using contained power morcellation through the umbilical port site. She has an unremarkable immediate postoperative course and is discharged on postoperative Day 1.

You see the patient in the clinic 2 weeks later. She reports minimal pain or discomfort and has no other complaints. Her abdominal incisions are healing well. You review the final pathology report with her, which showed no evidence of malignancy.

Society guidance on clinical applications

In current clinical practice, many surgeons have converted to exclusively performing contained morcellation in appropriate patients with a low risk of uterine leiomyosarcoma. At our institution, uncontained morcellation has not been performed since the FDA's 2014 warning.

ACOG and AAGL (formerly the American

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Association of Gynecologic Laparoscopists) recommend use of containment bags as a solution to continue minimally invasive surgery for large specimens without the risk of possible tissue dissemination, although more in-depth surgeon training is likely required for accurate technique.^{2,24} The Society of Gynecologic Oncology (SGO) states that power morcellation or any other techniques that divide the uterus in the abdomen are contraindicated in patients with documented or highly suspected malignancy.²⁵

With the presented data of risks associated with uncontained morcellation and

agreement of the ACOG, AAGL, and SGO professional societies, **we recommend that all morcellation be performed in a contained fashion to prevent the dissemination of benign or undiagnosed malignant tissue throughout the abdomen and pelvis.** Shared decision making and counseling on the risks, benefits, and alternatives are paramount for patients to make informed decisions about their medical care. Continued exploration of techniques and methods for safe tissue extraction is still needed to improve minimally invasive surgical options for all women. ●

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