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Intracorporeal Electromechanical Tissue Morcellation:

A Critical Review and Recommendations for Clinical Practice

Kimberly A. Kho, MD, MPH, Ted L. Anderson, MD, PhD, and Ceana H. Nezhat, MD

Departments of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas, Texas, and Vanderbilt University School of Medicine, Nashville, Tennessee; and the Atlanta Center for Minimally Invasive Surgery & Reproductive Medicine, Atlanta, Georgia

Abstract

Electromechanical morcellators have come under scrutiny with concerns about complications involving iatrogenic dissemination of both benign and malignant tissues. Although the rapidly rotating blade has resulted in morcellator-related vascular and visceral injuries, equally concerning are the multiple reports in the literature demonstrating seeding of the abdominal cavity with tissue fragmented such as leiomyomas, endometriosis, adenomyosis, splenic and ovarian tissues, and occult cancers of the ovaries and uterus. Alternatives to intra-corporeal electric morcellation for tissue extirpation through the vagina and through minilaparotomy are feasible, safe, and have been shown to have comparable, if not superior, outcomes without an increased need for laparotomy. Intracorporeal morcellation within a containment bag is another option to minimize the risk of iatrogenic tissue seeding. Patient safety is a priority with balanced goals of maximizing benefits and minimizing harm. When intracorporeal electromechanical morcellation is planned, physicians should discuss the risks and consequences with their patients. Although data are being collected to quantify and understand these risks more clearly, a minimally invasive alternative to unenclosed intracorporeal morcellation is favored when available. It is incumbent on surgeons to communicate the risks of practices and devices and to advocate for continued improvement in surgical instrumentation and techniques.

The benefits of laparoscopy over laparotomy are well documented and include shortened recovery times, less postoperative pain, and fewer infectious and wound complications. There are also advantages to surgeons including improved visualization of, and access to, the operative field. This has led to increased adoption of laparoscopy over the past 30 years.

Small laparoscopic incisions make tissue extraction a challenge. Morcellating tissue to facilitate removal was described by Semm in 1991,¹ but the 1993 introduction of

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Corresponding author: Ceana H. Nezhat, MD, 5555 Peachtree Dunwoody Road, Suite #276, Atlanta, GA 30342; ceana@nezhat.com.

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electromechanical (power) morcellators, which use a spinning blade to remove strips of tissue through laparoscopic ports, improved the process.^{2,3} They are used by general surgeons, urologists, and gynecologists during a variety of procedures, including thousands of the laparoscopic and robotic-assisted total and supracervical hysterectomies and myomectomies performed annually.⁴

RISKS ASSOCIATED WITH INTRACORPOREAL MORCELLATION

Electromechanical morcellators have come under scrutiny regarding iatrogenic dissemination of benign and malignant tissue^{5,6} with fragments being inadvertently scattered during intracorporeal morcellation of leiomyomas, endometriosis, adenomyosis, splenic and ovarian tissues as well as occult uterine malignancies such as adenocarcinomas and sarcomas.^{7–15} In response, the U.S. Food and Drug Administration recently released a safety communication regarding their use¹⁶ and the largest manufacturer suspended device sales.¹⁷

The inadvertent spread of unrecognized malignant tissue is particularly concerning. Although preoperative tests for symptomatic patients are available for endometrial adenocarcinoma, there are no pathognomonic symptoms or accurate preoperative diagnostic tests available for uterine sarcomas.¹⁸ Unfortunately, they are usually discovered postoperatively. Leiomyosarcoma carries a poor prognosis regardless of stage with only 66% survival at 5 years.¹⁹

The incidence of occult uterine sarcomas is poorly appreciated. Women undergoing a uterine procedure in the United States have a risk of undiagnosed uterine sarcoma estimated to be as high as 0.49%.^{20–26} The U.S. Food and Drug Administration quoted a risk of one in 352 for unanticipated sarcoma. However, this estimate was based on pooled data from retrospective single-site and small network studies seeking to define the risk of diverse occult uterine malignancy including sarcomas, adenocarcinomas, atypical leiomyomata, and stromal tumors of uncertain malignant potential.²⁷ Pooling such data for a single risk estimate is complex and error-prone, does not stratify risk based on age or other factors, and does not account for over- or underreporting. Without prospective mandatory reporting to capture adverse events accurately, risk estimates for specific uterine pathologies remain difficult to ascertain.

Morcellated surgical specimens can be more difficult for pathologists to interpret than an intact specimen.²⁸ With disruption of architecture, a tumor's original size and invasion may not be accurately determined and staging may be incorrect; focal areas of malignancy may be missed altogether.²⁹ Iatrogenic dissemination of malignant cells by morcellation has been shown to worsen the prognosis of patients with unsuspected sarcomas, increasing odds of tumor recurrence and death.³⁰ Additionally, patients may require surgical reexploration or chemotherapy that may have been unnecessary if tissue had been removed en bloc.^{30,31}

Iatrogenic complications from dissemination of benign tissue fragments implanting on parts of the abdominal cavity have resulted in peritonitis, intra-abdominal abscesses, and intestinal obstruction.³² Case reports have described iatrogenic myomas on the appendix, bladder, and retroperitoneally⁷; scattered leiomyomatosis throughout the pelvis has been reported.³³

Uterine or ovarian tissue can retain hormonal responsiveness, resulting in de novo endometriosis and ovarian remnant syndrome. Ovarian malignancy has been reported after morcellation of a presumed benign teratoma.^{12,34}

The rate at which new technologies diffuse into practice has outpaced our ability to monitor their benefit and harm, let alone regulate them. Prospective data collection with defined outcomes is the most precise way to obtain such information so that timely data-driven clinical recommendations can be made.

ALTERNATIVES TO ELECTROMECHANICAL MORCELLATION

Extirpation of uterine tissue through the vagina or minilaparotomy, even with the aid of manual morcellation, may limit tissue-scattering effects and has been shown to be safe with outcomes comparable to electromechanical morcellation in avoiding the need for laparotomy.^{35–38} Laparoscopic morcellation within an endoscopic bag is an emerging option. Although each of these techniques has inherent risks and benefits that should minimize iatrogenic tissue dissemination, it should be noted that occult malignancies have been reported after all types of tissue morcellation, including vaginal and abdominal.³⁰ No technique is a perfect substitute for en bloc extirpation through a laparotomy incision with regard to tissue disruption. However, the search for safe alternatives is critical to avoid the well-described, more commonly occurring risks of traditional laparotomy with increased morbidity and mortality.^{39,40}

The vagina can accommodate removal of bulky tissue after hysterectomy or through a posterior colpotomy, providing a single, concealed incision. This technique is safe with outcomes comparable or superior to traditional extirpation methods.^{41–44} Nonetheless, it is common for surgeons to use intracorporeal electromechanical morcellation of the uterus because of technical challenges associated with large uteri or to avoid the more demanding vaginal approach.

A large uterus with a narrow pelvic arch makes transvaginal tissue removal challenging, but several maneuvers may be used by skilled gynecologic surgeons to facilitate this process, especially in obese patients. A vaginal retractor with long instruments can provide appropriate exposure.³⁵ For large specimens tissue morcellation techniques, including bivalving, coring, and wedge resection, have been utilized for the past century, and newer techniques such as the “paper roll” method have been described.^{36,37} A randomized trial comparing transumbilical with transvaginal specimen removal after adnexectomy demonstrated less pain in those removed transvaginally with no difference in dyspareunia or infectious or wound complications.⁴³

Although laparotomy loses benefits of a minimally invasive procedure, it allows a mass to be removed en bloc, minimizes risks of tissue seeding, and provides pathologists with an intact specimen. Reports of mini-laparotomy incisions as small as 4 cm have demonstrated feasibility for the safe management of adnexal masses, myomectomy, benign hysterectomy, and endometrial cancer.^{38,45–48} We have had success extracting uteri up to 2,800 g using a circumferential wound retractor. A video demonstration is available online at <http://links.lww.com/AOG/A547> (Video 1). With this hybrid approach, most of the procedure is

performed laparoscopically followed by a 4-cm extended port-site incision to perform manual specimen removal. This also allows for hand-assisted dissection and suturing while retaining many benefits of a minimally invasive procedure.^{21,49,50} It should be noted that both vaginal and abdominal extirpation of a uterus have been associated with tissue dissemination if uncontained morcellation is performed.³⁰ Accordingly, using a tissue retrieval bag to isolate specimens during this type of morcellation has been suggested.⁵¹ The tissue is placed in a bag and brought to the anterior abdominal wall or vaginal orifice for manual morcellation with a scalpel or scissors within the bag. In experienced hands, this method appears to be an efficient method to remove even large specimens.^{51,52} Our experience with enclosed manual morcellation and vaginal removal has been successful with uteri up to 1,160 g. A video demonstration is available online at <http://links.lww.com/AOG/A548> (Video 2). Unenclosed intracorporeal morcellation could be obviated as vaginal tissue removal techniques are repopularized and devices for enclosed intracorporeal morcellation become widely available.

Intracorporeal electromechanical morcellator use within a laparoscopic bag has been offered as a method to reduce tissue seeding.^{53–55} With this technique, the specimen is placed in a bag intraperitoneally and morcellation occurs with an electromechanical device in the confines of the bag. This promising method should mitigate iatrogenic tissue dissemination. However, currently available commercial bags are not ideal for this activity. Milad⁶ described a case in which a morcellator “penetrated the bag” with injury to the aorta, vena cava, and bowel, ultimately resulting in the patient’s death. Endoscopic bags need to be developed that are large enough to contain bulky tissues and impervious to a morcellator blade while permitting simultaneous visualization of the specimen, morcellator, and surrounding organs. We must await demonstration of safety and effectiveness as instrumentation and techniques are refined by skilled surgeons.

It appears that unenclosed intracorporeal morcellation will be obviated as techniques for vaginal tissue removal are repopularized and devices that allow for safe, enclosed intracorporeal morcellation become available widely. Furthermore, clarification of the specific benefits of supracervical hysterectomy outside of the setting of pelvic reconstructive procedures will likely evolve as well.

It should be emphasized that no method of tissue extraction can eliminate the risk of iatrogenic cellular spreading. For these reasons, morcellation of any type should be examined critically, especially when risk factors for malignancy exist. Appropriate patient selection for cases with anticipated morcellation is critical.

AVOIDING PREVENTABLE COMPLICATIONS

Although adequate tools for preoperative diagnosis of uterine sarcomas are lacking, more common conditions such as neoplastic conditions of the endometrium can be detected preoperatively. Protocols to minimize surgical complications should be explored, including those using imaging, endometrial sampling, cytologic screening, and laboratory analyses. Systems should be developed to avoid complications that may be preventable (Box 1).

Just as patients undergoing hysterectomy are a heterogeneous group, and indications vary, we must acknowledge the role of risk stratification. Patients with symptomatic uterine bleeding carry a different risk profile than patients with pelvic organ prolapse. Although Pipelle endometrial sampling is considered 95% effective in cancer detection, this rate was established in symptomatic women with confirmed endometrial malignancies.^{56,57} In contrast, hysterectomies are frequently performed on patients with prolapse but no bleeding symptoms. Pipelle sampling is less sensitive²⁶ in this low-risk group, and occult endometrial hyperplasia or carcinoma has been reported in up to 3% of patients.^{25,58} Given higher false-negative rates of Pipelle sampling in this group, we recommend imaging to evaluate the endometrium and dilatation and curettage to rule out underlying pathology in patients with focal findings.⁵⁹ Indeed, to avoid dissemination of undiagnosed endometrial pathology, we believe it would be prudent to perform similar evaluation for all women before morcellation, even in the absence of abnormal bleeding or other risk factors. Should imaging suggest focal abnormality, hysteroscopy with endometrial sampling is recommended. Reliability of intraoperative frozen section for endometrial pathology has not been established and may correlate poorly with final pathology.⁶⁰ Thus, we recommend a separate procedure for sampling before hysterectomy with morcellation; patient safety is more critical than expediency. If suspicion for occult malignancy remains high after evaluation, alternatives to morcellation are recommended.

Because there is a risk for dissemination of cervical cancer cells during morcellation, we recommend cytologic or molecular screening of the cervix be accomplished per current American Society for Colposcopy and Cervical Pathology guidelines before morcellation. Intracorporeal electromechanical morcellation of the cervix in patients with known malignancy is not advised.

Any type of morcellation of ovaries without a collection bag should be avoided.¹² Even in risk-reducing oophorectomy, there is a small risk of existing carcinoma.⁶¹

Radiologic techniques to differentiate benign leiomyomas from leiomyosarcoma are being investigated. A screening protocol involving dynamic gadopentetate dimeglumine-enhanced magnetic resonance imaging combined with serum analysis of lactic dehydrogenase isoenzymes is particularly compelling with reported high sensitivity and specificity.⁶² More recently, Sato et al⁶³ reported a novel technique using diffusion-weighted magnetic resonance imaging to differentiate leiomyosarcoma from benign fibroids preoperatively. Larger prospective studies and cost-effectiveness analyses examining these and other screening protocols are needed.

INFORMED CONSENT: A RISK-SHARING PROCESS

Informed consent involves sharing information so a patient can make informed decisions. The process requires the physician to contextualize risks and benefits so that a patient can understand them. Morcellator-related complications, including the potential for and consequences of dissemination of an undetected malignancy, should be discussed. Patients should be informed of the alternatives to electromechanical morcellation and surgeons should be able to offer these. The goal is to guide patients in the decision-making process by

allowing them autonomy to weigh risks and benefits from the perspective of their own individual values.

CONCLUSIONS

Increased scrutiny has presented an important opportunity to educate physicians and patients alike regarding the potential complications of intracorporeal electromechanical morcellation. Professional organizations including the American Association of Gynecologic Laparoscopists, American College of Obstetricians and Gynecologists, and Society of Gynecologic Oncologists released statements regarding morcellation.^{64–66}

Patient safety remains a priority and needs to balance maximizing benefits while minimizing harm. Gynecologic surgeons should actively discuss the risks of intracorporeal morcellation with their patients. While data are being collected to elucidate these risks more fully, we advocate using minimally invasive alternatives to unenclosed intracorporeal electromechanical morcellation when feasible. We also advocate comprehensive screening to rule out common malignant and premalignant conditions of the uterus and cervix. For rare cancers like uterine sarcomas, research should be established to determine the incidence and risks of the condition and to develop methods for preoperative diagnosis.

We propose stronger collaboration among surgeons, professional organizations, industry, and regulatory agencies to develop systems designed to mitigate unintentional harm to patients (Box 2). Data-driven action is needed as is a robust system for postmarket surgical device surveillance that requires mandatory reporting of adverse events for devices and procedures, including, but not limited to, electromechanical morcellators.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Box 1. Recommendations for Practice

- When possible, consider alternatives to intracorporeal electromechanical morcellation, including minilaparotomy or vaginal extirpation, and morcellation within a bag.
- When considering intracorporeal electromechanical morcellation, risks, benefits, and alternatives to this technique of tissue extraction should be discussed, including:
 - Potential for iatrogenic injury and tissue seeding of both benign and malignant tissue; and
 - Potential for exacerbating an occult malignancy and possible worsening of prognosis.
 - Potential for missing or mischaracterizing an occult malignancy.
- Rational patient selection should be used when considering the use of the electromechanical morcellator.
 - No type of intracorporeal morcellation should be used when malignancy is present or suspected; it is inadvisable when a premalignant condition of the uterus or cervix exists.
- Preoperative evaluation of the uterus for occult malignancy should be performed and documented in all women in whom morcellation is planned.
 - Normal cervical cytology as recommended per current guidelines.
 - Endometrial evaluation should be performed in all women and sampling performed when indicated.
 - Hysteroscopy dilatation and curettage should be performed in women in whom focal pathology is suspected or in whom endometrial biopsy or ultrasonography is inconclusive.

Box 2. Opportunities for Improvement

1. Mandatory system for adverse event reporting for surgical devices and instruments promoted by professional societies, device makers, and regulatory agencies.
2. A nationwide surgical database for the acquisition of consistent and reliable information and accurate quantification of outcomes data.
3. Funding and performance of studies to examine preoperative protocols to distinguish benign leiomyomas from leiomyosarcoma.
4. Partnership with surgical device manufacturers to develop instruments for enclosed morcellation and devices to facilitate vaginal removal of specimens.
5. A mechanism for early dissemination of hazards and “black box” warnings generated by regulatory agencies after consultation with appropriate professional societies.