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No. 371-Morcellation During Gynaecologic Surgery: Its Uses, Complications, and Risks of Unsuspected Malignancy

This Clinical Practice Guideline has been prepared by the authors and reviewed by the Gynaecology Guideline Management and Oversight Committees and the Executive of the Society of Gynecologic Oncology of Canada (GOC) and approved by the Board of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

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KEY MESSAGES

1. Risk of unsuspected uterine sarcoma at the time of fibroid surgery is very low.
2. When considering morcellation, patients should be counselled about the risks (malignant and non-malignant), benefits and alternatives.
3. Techniques for morcellation of a uterine specimen vary, and physicians should consider employing techniques that minimize specimen disruption and intra-abdominal spread.

All people have the right and responsibility to make informed decisions about their care in partnership with their health care providers. In order to facilitate informed choice, patients should be provided with information and support that is evidence-based, culturally appropriate and tailored to their needs.

This guideline was written using language that places women at the centre of care. That said, the SOGC is committed to respecting the rights of all people - including transgender, gender non-binary, and intersex people - for whom the guideline may apply. We encourage healthcare providers to engage in respectful conversation with patients regarding their gender identity as a critical part of providing safe and appropriate care. The values, beliefs and individual needs of each patient and their family should be sought and the final decision about the care and treatment options chosen by the patient should be respected.

CHANGES IN PRACTICE

1. Gynecologists will be better able to counsel patients about the risk of malignancy at fibroid surgery.
2. Improve knowledge about tissue morcellation techniques.
3. Develop a strategy for preoperative counselling around morcellation.

ABSTRACT

Objective: This guideline provides guidance to gynaecologists regarding the use of tissue morcellation in gynaecologic surgery.

Outcomes: Morcellation may be used in gynaecologic surgery to allow removal of large uterine specimens, thus providing women with a minimally invasive surgical option. Adverse oncologic outcomes of tissue morcellation should be mitigated through improved patient selection, preoperative investigations, and novel techniques that minimize tissue dispersion.

Evidence: Published literature was retrieved through searches of PubMed and Medline in the spring of 2014 using appropriate controlled vocabulary (leiomyosarcoma, uterine neoplasm, uterine myomectomy, hysterectomy) and key words (leiomyoma, endometrial cancer, uterine sarcoma, leiomyosarcoma, and morcellation). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. There were no date limits, but results were limited to English or French language materials. Searches were updated on a regular basis and incorporated in the guideline to July 2017. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology assessment-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Values: The quality of evidence in this document was rated using the criteria described in the report of the Canadian Task Force on Preventive Health Care.

Benefits, harms, and costs: Gynaecologists offer women minimally invasive surgery, and this may involve tissue morcellation and the use of a power morcellator for specimen retrieval. Women should be counselled that in the case of unexpected uterine (sarcoma, endometrial), cervical, and/or tubo-ovarian cancer, the use of a morcellator is associated with increased risk of tumour dissemination. Tissue morcellation should be performed only after complete investigation, appropriate patient selection, and informed consent and by surgeons with appropriate training in the safe practices of tissue morcellation.

Summary Statements:

1. Uterine sarcoma is rare, and as such it is difficult to characterize the absolute risk of occult sarcoma at the time of fibroid surgery. Risk estimates range from 1 in 350 to 1 in 2000. Patient counselling regarding risks should be tailored based on age and other risk factors (II-2).
2. Morcellation of any type is contraindicated in women with established cancer, pre-cancerous lesions, or suspected cancer (III).
3. When considering morcellation, patients should be counselled about the risks (malignant and non-malignant), benefits, and alternatives as part of the informed consent, especially in women over 50 (III).
4. Alternatives to uncontained electromechanical morcellation can be used during fibroid surgery for tissue extraction depending on surgical route, specimen size, surgeon skill/training, and patient preference. If the specimen cannot be removed intact, then no method of tissue extraction can eliminate the risk of iatrogenic tissue dissemination (II-2).
5. The benefits of in-bag contained morcellation, including survival rates and ability to prevent dissemination of malignant cells/tissue, have not been established (II-2).
6. An unexpected uterine sarcoma treated by primary surgery involving tumour disruption, including morcellation of the tumour, has the potential for intra-abdominal tumour spread and a worse prognosis (II-2).
7. Clinicians should be aware of the general complications associated with morcellation beyond the spread of malignant tissue (II-3).

Recommendations:

1. Each patient presenting with uterine leiomyoma should be assessed for the possible presence of malignancy, based on her risk factors and preoperative imaging, although the predictive value of preoperative assessment is limited (III-C).
2. If there is a high index of suspicion of a uterine sarcoma prior to surgery, attempts should be made to remove the uterus intact. Myomectomy in perimenopausal and postmenopausal women should be discouraged (III-C).
3. Preoperative endometrial biopsy and cervical assessment is recommended in order to avoid morcellation of potentially detectable malignant and pre-malignant conditions of the endometrium and cervix (II-2A).
4. Uterine morcellation should be avoided in hereditary cancer syndromes that increase the risk of uterine malignancy (III-C).
5. Techniques for morcellation of a uterine specimen vary, and physicians should consider employing techniques that minimize specimen disruption and intra-abdominal spread (III-C).
6. Uterine morcellation is contraindicated in women with established or suspected uterine neoplasia (II-2A).

Table 1. Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of evidence assessment[a]	Classification of recommendations[b]
I: Evidence obtained from at least 1 properly randomized controlled trial	A. There is good evidence to recommend the clinical preventive action.
II-1: Evidence from well-designed controlled trials without randomization	B. There is fair evidence to recommend the clinical preventive action.
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than 1 centre or research group	C. The existing evidence is conflicting and does not allow one to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision making.
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in the category	D. There is fair evidence to recommend against the clinical preventive action.
	E. There is good evidence to recommend against the clinical preventive action.
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	I. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision making.

[a] The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described by the Canadian Task Force on Preventive Health Care.

[b] Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described by the Canadian Task Force on Preventive Health Care.

INTRODUCTION

Tissue morcellation during gynaecologic surgery has been widely practised to facilitate removal of large uteri or uterine myomas through less invasive incisions than those used in a traditional laparotomy[1]. The first electronic morcellator was introduced in 1993[2], and morcellation of uterine specimens through the vaginal route or by mini-laparotomy has been a longstanding practice in gynaecology. Statements by the U.S. FDA (April 2014) and Health Canada (May 2014) have discouraged the use of power morcellators in gynaecology because of the risk of disseminating an unsuspected uterine malignancy[3,4].

In Canada, 70% of hysterectomies are performed for heavy menstrual bleeding and uterine fibroids.[5] Uterine fibroids are a common benign gynaecologic condition, found in >80% of black women and ~70% of white women over the age of 50[6]. For women wishing to preserve or enhance their fertility, myomectomy is a therapeutic alternative.

Advantages of a Minimally Invasive Approach

The benefits of vaginal or laparoscopic MIS have been clearly established.[1] A vaginal or laparoscopic approach for hysterectomy offers patients faster recovery, reduced intraoperative blood loss, reduced perioperative complications, and a shorter hospital stay than laparotomy[1,7–9]. In certain cases, vaginal and laparoscopic hysterectomy may be performed safely on an outpatient basis. Although the literature on the surgical approach for myomectomy is not as robust as it is for hysterectomy, it has been suggested that a minimally invasive approach has similar advantages[10].

This guideline reviews the use of tissue morcellation in gynaecologic surgery for hysterectomy and myomectomy. The quality of evidence in this document was rated using the criteria described in the report of the Canadian Task Force on Preventive Health Care (Table 1).

ABBREVIATIONS

EMM	electromechanical morcellation
ESS	endometrial stromal sarcoma
FDA	Food and Drug Administration
LDH	lactate dehydrogenase
LMS	Vaginose bactérienne
MIS	minimally invasive surgery
MRI	magnetic resonance imagery

DIAGNOSIS OF UTERINE MALIGNANCY

Endometrial cancer is the most common gynaecologic malignancy. The majority of women with endometrial cancer present with abnormal uterine bleeding. Endometrial biopsy is highly sensitive and should be performed in this

setting in accordance with clinical practice guidelines. The 5-year survival rates for endometrial cancer are 78% to 91% and 20% to 26% for stage I and IV disease, respectively[11,12]. In 1 retrospective series, the most common tumour type inadvertently morcellated was endometrial cancer[13]. This finding highlights the importance of appropriate patient selection and preoperative evaluation, including endometrial biopsy.

Risk factors for endometrial cancer must be identified preoperatively and endometrial biopsies performed as appropriate. Hereditary cancer syndromes that predispose women to endometrial cancer include Lynch syndrome (hereditary nonpolyposis colorectal cancer [HNPCC]) and Cowden syndrome (multiple noncancerous tumours [hamartomas] and certain cancers), which increase the risk of endometrial cancer to 22% to 50% and 13% to 19%, respectively. *BRCA* breast cancer mutation carriers may also be at risk for endometrial cancer; however, this remains controversial[14,15]. Because patients with hereditary cancer syndromes may have occult malignancy, even with negative endometrial biopsy, uncontained morcellation should be avoided in this scenario.

Uterine sarcomas represent approximately 3% to 6% of all uterine malignancies but 30% of deaths from uterine cancer[16,17]. Of the subtypes of uterine sarcoma, ESS and LMS are among the most difficult to diagnose preoperatively. Low-grade ESSs usually grow slowly, with 50% to 76% diagnosed only after surgery. The majority of ESSs are diagnosed at an early stage, and hysterectomy alone is often curative.

LMS is notoriously difficult to diagnose preoperatively and is often diagnosed on pathologic review of the surgical specimen[17]. The average age of diagnosis is 52[18]. If there is a high index of suspicion of a uterine sarcoma prior to surgery, a gynaecologic oncology opinion should be considered, and attempts should be made to remove the uterus intact[16]. In such cases, uterine-preserving therapies such as myomectomy, uterine artery embolization, myolysis (by radiofrequency or high-intensity focused ultrasound energy), and medical therapies should be avoided.

Risk of Occult Uterine Sarcoma at Fibroid Surgery

The risk of occult sarcoma during hysterectomy and myomectomy for uterine fibroids is not well appreciated. In fact, a survey of Canadian health care providers showed significant inconsistency in the risk quoted to patients of encountering occult sarcoma at the time of fibroid surgery[19]. A total of 52% of Canadian gynaecologists who responded quoted an occult sarcoma risk of <1 in 1000, 30% quoted a risk between 1 in 300 and 1 in 500, and 18% quoted a risk >1 in 300.

The FDA reported that 1 in 350 women who undergo hysterectomy or myomectomy for the treatment of fibroids will have an unsuspected sarcoma[3]. The FDA risk estimate of 1 in 350 (and 1 in 500 for LMS) is based on 9 studies, each of which was a retrospective, single-centre cohort study.[3] These studies had a range of 104 to 1429 patients and included postmenopausal women and those with preoperatively diagnosed sarcoma (who otherwise would not have qualified for MIS). Since the FDA safety communication, many studies have attempted to provide risk estimates for occult uterine sarcoma.

Pritts et al. in 2015 performed a meta-analysis of 133 prospective and retrospective studies on myomectomy/hysterectomy for fibroids[20]. Included studies were required to have histopathology reporting, regardless of whether cancer was found. Aggregate analysis showed a risk of approximately 1 occult LMS for every 2000 procedures. Since this meta-analysis, other studies have been published evaluating an additional 318 006 procedures, which show a weighted average risk of 0.17% (or 1 LMS per 588 procedures)[21]. The Agency for Healthcare Research and Quality summarized that an unexpected LMS will be identified in less than 1 and up to 13 in 10 000 surgeries performed for symptomatic fibroids[22]. These risk estimates must be tailored to patient characteristics, with age being the most important. Three studies stratified LMS risk by age[23–25] and reported a risk estimate of 0.11% to 0.13% for women <50 years old and 0.37% to 0.81% for women >50 years old. Other risk factors for uterine sarcoma include race (black women at higher risk), tamoxifen use, previous pelvic radiation, history of hereditary retinoblastoma, hereditary leiomyomatosis, and renal cell carcinoma[26].

Summary Statement

1. Uterine sarcoma is rare, and as such it is difficult to characterize the absolute risk of occult sarcoma at the time of fibroid surgery. Risk estimates range from 1 in 350 to 1 in 2000. Patient counselling regarding risks should be tailored based on age and other risk factors (II-2).

PREOPERATIVE EVALUATION

Advances in MRI technology have improved the sensitivity of imaging for sarcoma detection, although cost and availability still limit its clinical utility[27–29]. Uterine masses growing in the postmenopausal period in the absence of

hormonal stimulation should be considered malignant until proven otherwise. Adult soft tissue sarcoma of any site, including uterine sarcoma, requires reliable and complete excision[30]. Morcellation of an unexpected malignancy prior to its removal, however, presents the potential for tumour seeding and spread.

There is significant concern about the possible negative impact on patients' prognosis for survival following inadvertent morcellation of a malignant tumour. Disease survival is dependent on stage and dissemination. In general, the 5-year survival is 60% and 90% for stage I (uterine contained) LMS and ESS and 15% and 37% for stage IV (disseminated) LMS and ESS, respectively[31].

High index of suspicion and better patient selection may reduce the risk of unsuspected cancer morcellation. A careful history and preoperative assessment may identify known risk factors for uterine cancer. The risk of malignancy increases significantly with age, especially after menopause. Tumour-disrupting procedures should be avoided in postmenopausal women with enlarging uterine fibroids in the absence of hormonal stimulation.

In 2008, Bansal et al. reviewed all uterine tumours identified at hysterectomy. Of 142 sarcomas identified, 51% had undergone endometrial sampling[32]. Preoperative biopsy suggested an invasive tumour in 86%. Endometrial biopsy must be performed for any abnormal uterine bleeding and any suspicion of a uterine malignancy. Endometrial biopsy should be considered prior to any procedure involving uncontained uterine morcellation or potential tumour disruption even in the absence of abnormal bleeding or risk factors.

Additional investigations have been explored to improve the detection of LMS preoperatively. Serum LDH tends to be elevated in LMS, and 1 study found a sensitivity of 100%; however, the specificity of the test ranged from 33% to 53% because LDH is elevated in many patients with uterine fibroids, and this limits its use as a screening tool[27]. MRI has also been evaluated as a tool to detect LMS preoperatively. In 1 study the positive predictive value ranged from 52.6% with MRI alone to 100% with the combined use of dynamic MRI and specific serum LDH isozymes[27]. Sato et al. studied the role of diffusion-weighted MRI and demonstrated 100% sensitivity but a positive predictive value of only 67% in a study of 81 patients[28].

Tamura et al. described a series of patients who underwent ultrasound guided biopsy when a screening MRI was suggestive of uterine LMS. Sensitivity, specificity, and the positive and negative predictive values of biopsy in the aforementioned study were 91.7%, 100%, 100%, and 96.2%, respectively, in the 38 patients who subsequently underwent definitive surgery[29].

Obvious limitations for a universal approach such as the aforementioned are the cost and invasive nature of these investigations for all women with uterine fibroids. There may be a role for LDH, MRI, and even biopsy for young women who wish to maintain fertility and who require a myomectomy or tumour-disrupting procedure. In these selected cases, the use of serum LDH, MRI, and biopsies may be considered as part of an individualized approach to patient care; however, more research is required.

Recommendations

1. Each patient presenting with uterine leiomyoma should be assessed for the possible presence of malignancy, based on her risk factors and preoperative imaging, although the predictive value of preoperative assessment is limited (III-C).
2. If there is a high index of suspicion of a uterine sarcoma prior to surgery, attempts should be made to remove the uterus intact. Myomectomy in perimenopausal and postmenopausal women should be discouraged (III-C).
3. Preoperative endometrial biopsy and cervical assessment is recommended in order to avoid morcellation of potentially detectable malignant and pre-malignant conditions of the endometrium and cervix (II-2A).
4. Uterine morcellation should be avoided in hereditary cancer syndromes that increase the risk of uterine malignancy (III-C).

MORCELLATION TECHNIQUES

Large uterine or fibroid size may act as a barrier to offering patients a minimally invasive surgical approach. A variety of preoperative medical therapies and morcellation techniques can be employed to reduce the size of the fibroids and to facilitate a vaginal or laparoscopic surgical route. Vaginal retrieval of the uterine specimen has been long employed, with modifications of the technique for increased uterine size. For this procedure, the specimen is directly visualized and may, if necessary, be incised with a scalpel to assist with removal. The specimen removal may be achieved through colpotomy for vaginal or total laparoscopic hysterectomy[33] or culdotomy for laparoscopic supracervical hysterectomy or myomectomy[34].

There is one report of transvaginal bivalve morcellation with the uterus in a bag for women with endometrial cancer who

have bulky uteri, but larger studies are needed to determine the implications of this extraction method on histologic assessment[35]. The mini-laparotomy is another popular alternative to traditional abdominal hysterectomy/myomectomy, and many variations of this technique are available[36]. Single-incision laparoscopic surgery is currently being explored in gynaecologic surgery, but the literature is limited[37]. This is a technique that involves working with several endoscopic articulating instruments through 1 umbilical incision[37].

One option for laparoscopic hysterectomy or myomectomy is to perform electromechanical or "power" morcellation to facilitate specimen retrieval[38]. This morcellation device was first approved by the FDA in 1995. The laparoscopic morcellator device consists of a hollow cylinder that penetrates the abdominal wall and ends with a circular rotating blade, through which a grasper can be inserted to pull out an extractable specimen[38]. This device, although used, is not approved for transvaginal applications.

The risk of disseminating an unexpected uterine malignancy, particularly LMS, during power morcellation procedures has raised concerns in the media, health care providers and regulatory bodies, industry, hospitals, and medicolegal fields. Both the FDA and Health Canada have issued statements warning about the use of power morcellators because of the risk of inadvertently morcellating a uterine malignancy and the possible intra-abdominal dissemination that may result[3,4].

Recommendation

5. Techniques for morcellation of a uterine specimen vary, and physicians should consider employing techniques that minimize specimen disruption and intra-abdominal spread (III-C).

Tissue Extraction and Morcellation

Hysteroscopy

Fibroids can be removed transcervically using either electrosurgery or mechanically with the aid of hysteroscopic morcellators (tissue removal systems). Although this route of tissue removal occurs within the confines of the uterus, there is a possibility of peritoneal dissemination through patent fallopian tubes or hematogenous dissemination through cut vessels. Limited data exist describing long-term outcomes in cases of hysteroscopic resection of uterine sarcoma[39]. Hysteroscopic removal should remain the gold standard treatment of submucosal fibroids and for tissue diagnosis[40]. At this juncture, it is not possible to evaluate differences in outcomes at myomectomy because studies comparing hysteroscopic morcellators and electrosurgical resection usually combine intracavitary lesions (polyps and fibroids)[41]. The major advantages of the hysteroscopic morcellators are that they use isotonic and isonatremic fluid distension media (e.g., normal saline) and can often be used in outpatient settings with local/neuraxial anaesthesia. This is balanced by the costs of disposables and decreased versatility (the inability to coagulate bleeding and perform multiple procedures with same instrument, such as adhesiolysis, septoplasty, ablation, etc.).

Laparoscopic and vaginal surgery

When planning on removing a specimen (uterus/fibroid) during MIS, 3 aspects must be considered: containment, morcellation method, and route of extraction (Table 2). The risks of uncontained morcellation include dissemination of malignant cells/tissue and non-malignant sequelae (e.g., iatrogenic endometriosis, adenomyosis, parasitic myoma, disseminated peritoneal leiomyomatosis)[42,43]. Two Canadian retrospective series showed that uncontained EMM of uterine sarcoma is rare because only 2 cases were reported at 4 academic institutions over 13 years[44,45]. Uncontained abdominal morcellation occurred in 4 cases at laparotomy and 5 cases during vaginal surgery in these reports.

To mitigate the risk of tissue dissemination, various techniques of contained morcellation in endoscopic bag systems have been described. Contained EMM in a retrieval bag has been described[46]. This is a technically challenging procedure, provides limited visualization, and does not eliminate the risk of tissue dissemination due to interruption of bag integrity or inherent bag permeability. In fact, bag leaks have been reported using these techniques, where up to 9% of apparently intact bags demonstrated spillage of test dye[47]. Newer bags have been developed to help mitigate the risk of tissue dissemination and facilitate tissue extraction without the need of laparotomy. Large retrieval bags made of rip-stop nylon and providing 2 openings, 1 for the camera and 1 for the power morcellator, are presently undergoing clinical evaluation. Specimens larger than 2000 g can be removed without gross tissue spillage[48]. However, these containment bags are *not* impermeable to cellular dissemination[47].

Contained abdominal scalpel morcellation consists of introducing an endoscopic retrieval bag into the abdomen through the laparoscopic ports, incision sites, or colpotomy.

Table 2. Tissue removal considerations during MIS

Containment	Method	Route
Uncontained vs. contained	Scalpel vs. EMM	Abdominal vs. vaginal

Specimens are placed in the bag, which is then exteriorized either by extending the umbilical incision or creating an additional "mini-laparotomy" incision. In addition, a circumferential self-retaining retractor system can be inserted through the incision to facilitate visualization and provide additional protection of the bag from perforation (if placed inside retrieval bag)[46,49,50]. The specimen is then grasped with piercing instruments, elevated, and manually morcellated extracorporeally with a scalpel. A manual morcellation technique of creating a series of C-incisions is a reproducible and efficient method of removing large specimens[50].

Even with the use of contained systems, there is always a risk of inadvertent bag damage and subsequent peritoneal dissemination or possible damage to underlying viscera. Furthermore, the size and location of the mini-laparotomy incision for tissue extraction may be associated with different risks, including pain, infection, scar formation, hernia, and so forth. The benefits of contained morcellation including survival rates and ability to prevent dissemination of malignant cells/tissue have not been established.

Uncontained vaginal morcellation using techniques such as coring, bivalving, or removing wedges[50,51] is frequently performed at vaginal hysterectomy or total laparoscopic hysterectomy. For laparoscopic myomectomy, the specimen can be retrieved by making a posterior culdotomy. The vaginal route provides advantages of a concealed incision and less pain. Contained morcellation can also be performed by the vaginal route when the surgeon has laparoscopic access. In this case, a retrieval bag can be introduced either laparoscopically or vaginally. The bag is then manipulated laparoscopically, and the specimen is maneuvered into the bag and exteriorized through the vagina. Vaginal exposure can be optimized with the use of vaginal retractors, long instruments, or insertion of a flexible circumferential wound retractor system with 1 ring intraperitoneally placed and the other at the vulva[50]. Because of limited visibility with the vaginal route, surgeons should take care not to injure viscera and vaginal mucosa. Contained vaginal in-bag morcellation does not prevent dissemination; leaks have been found in bags used during vaginal morcellation[52]. Uncontained EMM by the vaginal route has been reported, but it carries the same risks described earlier[53].

Although varying morcellation techniques have been described, there is a paucity of data comparing outcomes. Each technique comes with its unique set of inherent risks, benefits, and surgical learning curve. Ultimately, the choice of tissue removal technique will be dependent upon the procedure being performed, size of specimen, and surgeon's experience, comfort, skill, and bias. Regardless of the morcellation technique, it is good practice to search for and remove any tissue fragments and copiously irrigate the abdomen and pelvis. Appropriate patient selection and informed patient consent are critical components of any decision-making algorithm.

Summary Statements

2 Morcellation of any type is contraindicated in women with established cancer, pre-cancerous lesions, or suspected cancer (III).

3. When considering morcellation, patients should be counselled about the risks (malignant and non-malignant), benefits, and alternatives as part of the informed consent, especially in women over 50 (III).

4. Alternatives to uncontained electromechanical morcellation can be used during fibroid surgery for tissue extraction depending on surgical route, specimen size, surgeon skill/training, and patient preference. If the specimen cannot be removed intact, then no method of tissue extraction can eliminate the risk of iatrogenic tissue dissemination (II-2).

5. The benefits of in-bag contained morcellation, including survival rates and ability to prevent dissemination of malignant cells/tissue, have not been established (II-2).

PROGNOSIS FOLLOWING SURGERY FOR UTERINE MALIGNANCY

Preoperative diagnosis of uterine sarcoma is challenging; therefore, patients should be counselled that there is a small chance that apparent leiomyomas may be LMSs. There is evidence that the prognosis is worse for patients initially treated with myomectomy regardless of route or use of morcellation, instead of hysterectomy when the final pathologic diagnosis is LMS[54–56].

Several studies have attempted to ascertain whether morcellation of a malignant uterine specimen affects patient prognosis. Seidman et al. reviewed 1091 cases of uterine morcellation from 2005 to 2010[57]. They found unexpected leiomyoma variants or atypical and malignant smooth muscle tumours in 1.2% of cases using power morcellation, including 1 ESS and 1 LMS. They also examined follow-up laparoscopies, both from in-house and consultation cases, and found that disseminated disease was present in 64.3% of all tumours. Only disseminated LMS, however, was associated with subsequent death (75%; 95% CI 30.1%–98.7%), with an average postdiagnosis survival of 24.3 months (95% CI 8.4–40.3 months). The dissemination

and viability of noncancerous leiomyoma variants in this series also highlighted the potential alteration of their natural history with the use of electromechanical morcellation.

Park et al. retrospectively compared outcomes between patients with apparent early-stage low-grade ESS who did and did not undergo a type of morcellation procedure[58]. Indicative of the difficulty of preoperative diagnosis, tumour morcellation occurred in 46% of patients with low-grade ESS in this Korean study. Five-year disease-free survival was 84% in the group that did not undergo uterine morcellation and 55% in those who did ($P = 0.028$). The rates of abdominopelvic recurrence were 7.4% and 31.4% ($P = 0.035$), respectively, again in favour of the group that did not undergo a morcellation procedure[58].

Park et al. also assessed 56 consecutive patients with stage I and II uterine LMS, 25 with and 31 without tumour morcellation[59]. They found that tumour morcellation was significantly associated with worse overall 5-year survival (46% vs. 73%, $P = 0.04$). The percentage of patients with abdominopelvic dissemination (sarcomatosis or vaginal apex recurrence) was significantly greater in patients with tumour morcellation than in those without morcellation (44% vs. 12.9%, $P = 0.032$). Within the study period, 22.6% and 52% ($P = 0.022$), respectively, of patients in the nonmorcellated group and the morcellated group had a recurrence.

George et al. also published data evaluating intraperitoneal morcellation on outcomes of localized uterine LMS[60]. In this retrospective cohort study, a multivariate adjusted model demonstrated a risk of recurrence associated with morcellation of greater than 3 times that of total abdominal hysterectomy. The median recurrence-free survival was 10.8 months for those who underwent a morcellation procedure and 39.6 months for those who did not. There was a trend towards lower overall survival in the morcellation group at 36 months (64% vs. 73%); however, this did not reach statistical significance (Table 3)[58–61].

Re-exploration after morcellation of cancer has revealed a significant rate of dissemination of viable tissue. Oduyebo et al. reported that 28.5% of patients with LMS who had undergone tumour morcellation had disseminated peritoneal disease at a median of 33 days after original surgery[62].

Several studies have examined the impact of tumour disruption during fibroid surgery when LMS is later diagnosed. Perri et al. published a series of 37 patients diagnosed with stage I LMS from 1969 to 2005[61]. Twenty-one patients were treated with total hysterectomy, and 18 patients initially underwent procedures involving tumour disruption (myomectomy, laparoscopic myomectomy with morcellation, hysteroscopic myomectomy, subtotal hysterectomy). They showed that survival was 2.8-fold better in the group initially treated with hysterectomy. Two of the patients included in this series initially underwent power morcellation[61].

Morice et al. similarly examined 123 patients diagnosed with uterine sarcomas[54]. In this series, 38 patients underwent surgery with some degree of tumour disruption—vaginal or laparoscopic morcellation (with morcellation described in the surgical procedure), myomectomy, tumour biopsy, or hysteroscopic myomectomy. They reported a trend of increased tumour recurrence at 3 months in the group that did not have total hysterectomy, but this trend was not statistically significant. Recurrence rate at 6 months and overall survival did not differ between the 2 groups.

Loizzi et al. concluded that myomectomy affected patients' prognosis in the treatment of LMS no more than hysterectomy or more comprehensive surgery. However, the sample size in this study was small, and only 5 of 28 patients underwent myomectomy[55].

Table 3. Oncologic consequences of uterine cancer morcellation

			5-year survival		Abdominopelvic recurrence	
Reference	Type of malignancy	Number of patients	Morcellation	No morcellation	Morcellation	No morcellation
Perri et al., 2009[61]	LMS	37	37 .5%[a]	62%[a]	—	—
Park et al.,. 2011[58]	Low-grade ESS	50	55%[b]	84%[b]	31 .4%	7 .4%
Park et al., 2011[59]	LMS	56	46%	73%	44%	12 .5%
George et al.,. 2014[60]	LMS	58	10 .8 months[c]	39 .6 months[c]	85 .7%	20%

Statistically significant unless otherwise stated

[a] 72-month study period.

[b] Statistically significant difference in disease-free survival (no statistically significant difference in overall survival detected in this series).

[c] Median recurrence-free survival.

If morcellation of an undiagnosed endometrial cancer occurs, pathologic assessment of the tumour can be limited, resulting in difficulty assigning patients to the appropriate adjuvant treatment, thereby affecting prognosis.

Non-malignant Complications With Uterine Morcellation

Case reports/series have described the progression of morcellation-related pelvic implants to atypical hyperplasia, iatrogenic endometriosis, peritoneal adenomyoma, and peritoneal leiomyomatosis[63–68]. Parasitic peritoneal leiomyomatosis, resulting from the implantation and growth of viable leiomyoma tissues disseminated throughout the peritoneal cavity, occurs in about 0.9% of patients with morcellated fibroids[65]. Although it is a benign disorder unlikely to affect overall survival, it requires many of these women to have a second surgery for symptoms such as pain or mass effect. Surgery may also be indicated by a suspicion of a new malignancy when imaging is highly suggestive and preoperative pathology difficult to interpret[67–69].

The true rate of complications with the power morcellator is difficult to ascertain because reporting of injuries is inconsistent and underreporting is expected. Milad and Milad completed a systematic review of morcellator related injuries in the United States from 1993 to 2013, including gynaecology, urology, and general surgery[69]. Most of the injuries they identified were from the FDA Medical Device Reporting and Manufacturer and User Facility Device Experience databases. There were 55 injuries noted and 6 deaths attributed to morcellator use. Injuries described were to the small and large bowel, vascular systems, kidney, ureter, bladder, and diaphragm. Surgeon inexperience was a notable finding in many of these cases. The authors suggested that increased surgeon experience and the implementation of safe practices might help to protect against such complications.

Summary Statements

6. An unexpected uterine sarcoma treated by primary surgery involving tumour disruption, including morcellation of the tumour, has the potential for intra-abdominal tumour spread and a worse prognosis (II-2).
7. Clinicians should be aware of the general complications associated with morcellation beyond the spread of malignant tissue (II-3).

Recommendation

6. Uterine morcellation is contraindicated in women with established or suspected uterine neoplasia (II-2A).

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