The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Power Morcellation and Occult Malignancy in Gynecologic Surgery

*A Special Report**

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Executive Summary

Power morcellation in gynecologic surgery has come under recent scrutiny because of concern about the risk of intraperitoneal dissemination of malignant tissue, particularly uterine sarcoma. Of note, the U.S. Food and Drug Administration (FDA) recently released a safety communication regarding uterine power morcellation in hysterectomy and myomectomy. ACOG has reviewed and analyzed the available scientific evidence on power morcellation and occult malignancy in gynecologic surgery.

In gynecologic surgery, power morcellation is sometimes used during hysterectomy and myomectomy to facilitate removal of the uterus or leiomyomas (fibroids). It is well established that minimally invasive surgical techniques for hysterectomy and myomectomy reduce the risk of intraoperative and postoperative morbidity and mortality. Without power morcellation, some patients may be ineligible for minimally invasive gynecologic surgery (e.g., supracervical hysterectomy).

Morbidity associated with abdominal hysterectomy includes serious complications such as infections, bleeding, deep vein thrombosis, nerve injury, and genitourinary and gastrointestinal tract injury. Patients who undergo abdominal hysterectomy have three times the risk of mortality than those who have laparoscopic hysterectomy.

Obstetricians and gynecologists continually focus on providing the best medical care at the lowest risk. Nonetheless, it is important to recognize that all medical procedures carry risk. Although the risks can often be quantified and compared, they cannot be eliminated. Various sources cite estimates of occult uterine sarcoma, ranging from 2:1000 to 1:350. While these incidence numbers are within the same statistical range, they have questionable applicability because of the rarity of the disease, the small sample size, age variability, and lack of age stratification. In addition, it is important to note that none of these estimates take into consideration the number of uterine sarcomas that were morcellated.

Minimally invasive surgery, including with power morcellation, continues to be an option for some patients when performing hysterectomy and myomectomy. At the same time, it is critical to minimize the risks for patients undergoing these surgeries who may have an occult gynecologic cancer.

As with all surgical procedures, it is important to conduct a thorough patient evaluation before choosing the type and route of operation. This evaluation includes appropriate measures to diagnose a malignancy before surgery. Preoperative evaluation before hysterectomy or myomectomy with morcellation should include current cervical cytology, and may include pelvic imaging and endometrial assessment depending on the features of the clinical presentation. Other preoperative considerations before surgery with power morcellation include increasing age, menopausal status, uterine size, rapid uterine growth, or

* This Special Report was developed by a group of ACOG Fellows who are experts in areas such as laparoscopic surgery, gynecologic oncology, and urogynecology. Recognizing the urgency of the issue of power morcellation in gynecologic surgery, ACOG used an expedited process to conduct a thorough review and analysis of the scientific literature and conducted multiple statistical evaluations.

The information contained in this report is intended to aid practitioners in making independent treatment decisions about appropriate gynecologic care for their patients. This report should not be construed as dictating an exclusive course of treatment. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

certain treatments or hereditary conditions. However, although preoperative evaluation may improve the detection of cancer, it has limitations and does not eliminate the possibility of an occult malignancy, particularly for uterine sarcomas. In women with strongly suspected or known malignancy, power morcellation should not be used.

For each woman who is considering a minimally invasive hysterectomy or myomectomy that involves power morcellation, alternative treatment options as well as the risks and benefits should be discussed. Alternative treatment options to morcellation may include removal of intact tissue through mini-laparotomy, laparotomy, or colpotomy incisions, or by total abdominal hysterectomy, vaginal hysterectomy, or laparoscopic vaginal hysterectomy. Specifically, it must also be recognized and discussed that, if an occult cancer is present and morcellation is used during surgery, there is a risk that the cancer may spread and worsen the patient's outcome.

There is a continuing need to develop technology, devices, and techniques to further improve patient safety in gynecologic surgery. The inability to preoperatively identify leiomyosarcomas with certainty illustrates and confirms the need for further research to develop reliable diagnostic tools. It is important to develop more effective and safer methods to reduce the risk of disseminating tissue associated with gynecologic power morcellation (e.g., intraperitoneal bags that are specifically designed for use with power morcellation). Appropriate training and credentialing are also important considerations.

Because there are inadequate data on preoperatively undiagnosed uterine sarcoma, a national prospective morcellation surgery registry is needed. The FDA is encouraged to call for the establishment of a registry, which would offer a national, integrated data infrastructure for morcellator product safety and surveillance.

ACOG looks forward to partnering with medical peer organizations and the FDA on this important topic as we continually strive to advance high quality women's health care and enhance patient safety.

Introduction

Power morcellation in gynecologic surgery has come under recent scrutiny because of concern about the risk of intraperitoneal dissemination of malignant tissue, particularly uterine sarcoma. Of note, the U.S. Food and Drug Administration (FDA) recently released a safety communication regarding uterine power morcellation in hysterectomy and myomectomy (1).

The appropriate use of power morcellation as well as its risks and benefits are of significant concern to obstetricians and gynecologists who continually strive to provide safe, high-quality care to all women. ACOG has reviewed and analyzed the available scientific evidence on power morcellation and occult malignancy in gynecologic surgery.

Background

Manual tissue morcellation has been practiced for decades, during both vaginal and open abdominal (laparotomy) surgery, for hysterectomy and myomectomy. Morcellation of tissue using electromechanical devices was introduced in 1993, and involves the use of a power morcellator to shave or cut tissue during the process of extraction (2).

Power morcellators typically use a rapidly rotating cylindrical blade within a tube, through which tissue is extracted. During this process, small fragments of morcellated tissue may be disseminated. There are some power morcellators that rely on electrical current rather than a rotating blade to shave tissue, and there are no studies on whether this mitigates the possibility of tissue dissemination.

In gynecologic surgery, power morcellation is sometimes used during hysterectomy or myomectomy to facilitate removal of the uterus or leiomyomas (fibroids) in pieces.

Morcellation also enables the performance of subtotal hysterectomy or other supracervical procedures that may not be otherwise accomplished in some patients; because the cervix is left intact, it may not be possible to deliver the uterus through the vagina. Although power morcellation is most often used in gynecologic surgery, it is also used in other surgical specialties such as urology (for the performance of nephrectomies and prostatectomies) and general surgery (for the performance of splenectomies).

Risk Analysis

There are approximately 600,000 hysterectomies performed in the U.S. each year. Among women younger than 40 years, approximately 30% of hysterectomies are performed laparoscopically through minimally invasive surgery, almost 44% of hysterectomies in women aged 40 to 49 years are performed laparoscopically, and roughly 16% of hysterectomies in women aged 50 to 59 years are performed laparoscopically (3). The most common indication for hysterectomy is uterine leiomyomas, accounting for an estimated 40% of hysterectomies (4).

When indicated, minimally invasive gynecologic surgical procedures, such as vaginal or laparoscopic hysterectomy, are preferred because they reduce a patient's overall operative risk. Minimally invasive surgery is associated with smaller incisions and generally results in fewer complications, less postoperative pain, and shorter hospital stays (5).

Without power morcellation, some patients may be ineligible for minimally invasive surgery for hysterectomy (e.g., supracervical hysterectomy).

Abdominal hysterectomy has an increased risk of morbidity and mortality over minimally invasive surgery. Morbidity associated with abdominal hysterectomy includes serious complications such as infections, bleeding, deep vein thrombosis, nerve injury, and genitourinary and gastrointestinal tract injury (6). Patients who undergo abdominal hysterectomy have three times the risk of mortality than those who have laparoscopic hysterectomy (7).

It is well established that minimally invasive techniques spare thousands of women each year from the increased morbidity and mortality associated with open or abdominal gynecologic surgery.

Power morcellation inherently involves the risk of spreading tissue. There is no conclusive evidence that manual morcellation, performed either vaginally or abdominally, eliminates this risk. Morcellation also may lead to the dissemination of benign tissue that can potentially become implanted and may result in ectopic leiomyoma, endometriosis, adenomyosis, ovarian tissue, and fragments of spleen or kidney. Intervention may be required if ectopic tissue implantation occurs (8).

Importantly, morcellation of an undiagnosed cancer may adversely affect a patient's prognosis. The potential risk of morcellating an undiagnosed uterine, endometrial, or cervical malignancy is currently very difficult to calculate.

Uterine Sarcoma

The American Cancer Society (ACS) estimates 1,600 cases of uterine sarcoma will be diagnosed in the U.S. during 2014. Uterine sarcoma is categorized as undifferentiated sarcoma, endometrial stromal sarcoma, and uterine leiomyosarcoma (9). Leiomyosarcoma accounts for about 2% of cancers that start in the uterus (9). However, these estimates do not specify the number of uterine sarcomas diagnosed pre-operatively versus post-operatively.

General estimates based on limited retrospective studies indicate the incidence of post-operatively diagnosed leiomyosarcoma and stromal sarcoma is approximately 2:1000 women undergoing hysterectomy or myomectomy (10–18).

The annual incidence of uterine leiomyosarcoma is approximately 0.64 per 100,000 women (19). Further, the FDA has recently estimated that 1:350 women undergoing hysterectomy or myomectomy for the treatment of fibroids will have an unsuspected uterine sarcoma (1).

None of these estimates identify the number of uterine sarcomas that were morcellated.

Epidemiologic/statistical evaluation of the incidence numbers in these studies are all within the same 95 percent confidence interval, placing them within the same statistical range. Therefore, while the incidence numbers may appear different, they are actually relatively consistent. However, the numbers have questionable applicability because of the rarity of uterine sarcoma, the small sample size, age variability, and lack of age stratification.

Endometrial Cancer and Cervical Cancer

Unlike uterine sarcomas, endometrial cancer and cervical cancer may be more easily diagnosed preoperatively (13, 20–22). Despite established cervical screening guidelines for asymptomatic women (23) and established diagnostic evaluation for abnormal uterine bleeding (24), some of these cancers remain undetectable. Further, there are no guidelines for screening asymptomatic women for endometrial cancer (25).

Preoperative Diagnosis and Evaluation

As with all surgical procedures, it is important to conduct a thorough patient evaluation before choosing the type and route of operation. This evaluation includes appropriate measures to diagnose a malignancy before surgery.

Preoperative evaluation before hysterectomy or myomectomy with morcellation should include current cervical cytology, and may include pelvic imaging and endometrial assessment depending on the features of the clinical presentation (6, 23, 24). It is noted, however, that there are no preoperative diagnostic tests—including ultrasonography, computed tomography, positron emission tomography, or magnetic resonance imaging—that reliably detect uterine sarcomas.

Other preoperative considerations before morcellation are as follows:

- Increasing age. The incidence of uterine cancers, particularly leiomyosarcoma, increases with age. Women younger than age 35 years seem to have the lowest incidence (26). The highest incidence of uterine sarcoma is in women over age 65 (26).
- Menopausal status. Women who are perimenopausal or postmenopausal, particularly postmenopausal women with symptomatic uterine fibroids, are at increased risk of an occult malignancy.
- Uterine size or rapid uterine growth. Rapid growth or large leiomyomas may increase concern for the pres-

ence of an occult malignancy, but have not been shown to be predictive of leiomyosarcoma (12, 27).

- Certain treatments or hereditary conditions. Women who have undergone certain treatments (e.g., tamoxifen or pelvic radiation) or have certain hereditary conditions (e.g., Lynch Syndrome or hereditary leiomyomatosis and renal cell cancer) are at increased risk of a uterine malignancy (28, 29). In these cases, power morcellation should not be used.

Although preoperative evaluation may improve the detection of cancer, it has limitations and does not eliminate the possibility of an occult malignancy, particularly for uterine sarcomas. In women with strongly suspected or known uterine cancer, power morcellation should not be used.

Alternative treatment options to morcellation may include removal of intact tissue through mini-laparotomy, laparotomy, or colpotomy incisions, or by total abdominal hysterectomy, vaginal hysterectomy, or laparoscopic vaginal hysterectomy. There is no evidence that catheter-based artery embolization and high-intensity focused ultrasound offer benefits to women with known or occult uterine sarcoma, and use of these procedures may lead to a delay in diagnosis.

Use of a Bag During Morcellation in Gynecologic Surgery

Some investigators have suggested that the use of an intraperitoneal bag during manual or power morcellation may be helpful in reducing intraperitoneal tissue dissemination (8, 30). However, power morcellation performed within a bag is not well studied and has several limitations that potentially increase the risk of the procedure. For example, currently available bags were not designed specifically for use in conjunction with power morcellation. The bags often have size limitations and have not been adequately constructed to prevent tearing by the morcellator. Further, the use of bags limits simultaneous visualization of the tissue being morcellated and the surrounding tissue that must be protected from the sharp morcellator blade.

Patient Counseling and Informed Consent

For any therapeutic intervention, it is important for the patient and physician to balance patient safety and patient autonomy. Patient–physician communication facilitates a patient's ability to make an informed and voluntary decision about accepting or declining medical care, including surgery (31). In the case of uterine leiomyomas for which minimally invasive surgical techniques are being considered, this includes a discussion about the risks, benefits, and alternatives to power morcellation if there is a possibility that it may be used. The following information should be included as part of the informed consent process when the use of power morcellation is being considered:

- There is a potential risk of undiagnosed gynecologic cancers. The precise incidence of all undiagnosed uterine sarcomas—including leiomyosarcoma—in women undergoing hysterectomy for fibroids is unknown. However, the risk estimate of approximately 2:1000 women who undergo hysterectomy or myomectomy should be discussed.
- If an occult malignancy is present, the use of power morcellation will increase the likelihood of intraperitoneal dissemination. It also may worsen the patient's prognosis, make a definitive diagnosis (histologic interpretation) and accurate staging of an underlying malignancy more difficult, and result in the need for additional surgery, medical management, or both.
- If fragments of benign tissue are disseminated through morcellation, there is the possibility of seeding viable ectopic tissue as a result (e.g., leiomyoma, endometriosis, adenomyosis, and ovarian remnants). This potentially may require additional intervention.
- If power morcellation is to include the use of an intraperitoneal bag, potential concerns should be discussed, including insufficient bag size, disruption of the bag by the morcellator, and reduced visualization as a result of using the bag.
- Alternatives to the use of power morcellation should be discussed, including removal of intact tissue through mini-laparotomy, laparotomy, or colpotomy incisions, or by total abdominal hysterectomy, vaginal hysterectomy, or laparoscopic vaginal hysterectomy.

Development of Technology and Training

The inability to preoperatively identify leiomyosarcomas with certainty illustrates and confirms the need for further research to develop reliable tools for preoperative diagnosis of uterine malignancies. For example, one study, with a very small sample size, used lactate dehydrogenase isoenzyme-3 (LDH3) and magnetic resonance imaging in an effort to distinguish leiomyosarcoma from other leiomyomas (32). However, these data have neither been replicated nor integrated into clinical practice.

Another key area for potential advancement is the development of more effective and safer methods to reduce the risk of disseminating tissue in the peritoneal cavity. This may include the use of bags that are designed specifically

for use with power morcellators. The utilization of intraperitoneal bags needs further study to document their effectiveness in diminishing dissemination of intraperitoneal uterine tissue as well as increased intraoperative risk associated with an obstructed visual field.

There should be a continual focus on training, including techniques for morcellation, inspection for tissue fragments after morcellation is performed, and on determination of when morcellation is considered an appropriate therapeutic option. Credentialing for the performance of minimally invasive surgery, including the use of morcellation techniques within and across specialties, should be based on training, experience, and documented current competency (33, 34).

In addition, there are no sufficiently large population-based series to provide an accurate rate of preoperatively undiagnosed uterine sarcoma in patients undergoing hysterectomy. Given the relative rarity of uterine sarcomas in this context, it would take a considerably large cohort (approximately 100,000) to have much narrower confidence intervals and, therefore, a more precise risk estimate. As a result, a national prospective morcellation surgery registry is needed to acquire an adequate volume of consistent and reliable data. ACOG encourages the FDA to call for the establishment of such a registry.

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