

Power Morcellation Considerations for Physicians during the Informed Consent Process

Background

In a safety communication issued April 17, 2014, subsequently updated in December 2017, the FDA discouraged the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids. Several national professional organizations, including the American College of Obstetricians and Gynecologists (ACOG), the American Urogynecologic Society (AUGS) and the American Association of Gynecologic Laparoscopists (AAGL) have since issued communications stating that they do not discourage the use of power morcellation in all cases. Instead, these organizations emphasize the need for thorough preoperative patient evaluation and informed consent which entails a discussion regarding the risks, benefits, and alternatives to power morcellation. This communication provides considerations for obtaining informed consent if a surgeon wishes to proceed with using a laparoscopic power morcellator during hysterectomy or myomectomy for any indication.

Discussion of the following background information during the preoperative visit:

- Disclose that the surgeon proposes to use a power morcellator during surgery, due to either the size of the uterus, the size of the fibroid(s) or a plan to perform a supracervical hysterectomy
- Power morcellators are medical devices used to divide tissue into smaller fragments in order to facilitate tissue removal through small incisions
- Power morcellation allows for a minimally invasive approach, as opposed to an open/abdominal procedure
- On April 17, 2014 the FDA discouraged the use of power morcellation during hysterectomy or myomectomy for fibroids due to the risk of spreading unsuspected malignant tissue, but did not discourage the use of power morcellation for non-fibroid conditions such as pelvic organ prolapse

Discussion of the following benefits, risks, and alternatives to power morcellation:

Benefits

- Perform minimally invasive surgery which offers the patient the following associated benefits:
 - Lower risk of postoperative complications (e.g., infection, bleeding, venous thromboembolism, wound complications, and abdominal wall hernias)
 - Less postoperative pain
 - Shorter hospital stay
 - Quicker return to activities of daily living

Potential Risks

- Risk of undiagnosed or unsuspected gynecologic cancer that cannot always be detected preoperatively
 - If there is an undiagnosed malignancy, the use of power morcellation increases the risk of:
 - Intraperitoneal dissemination of malignant tissue which may significantly worsen the patient's prognosis
 - Inability to definitively diagnosis and/or accurately stage the underlying malignancy
- Need for additional treatments including surgery and/or medical management
- Dissemination of benign uterine tissue (e.g., leiomyoma, endometriosis, adenomyosis and ovarian remnants) may result in these tissues beyond its normal anatomical location
- Injury to adjacent organs when using the morcellator

Alternatives

- Removal of intact tissue through mini-laparotomy with manual morcellation, laparotomy or colpotomy incisions; total abdominal hysterectomy; vaginal hysterectomy; or laparoscopic hysterectomy with vaginal removal of the specimen
- An intraperitoneal bag can also be used to contain the specimen during power morcellation; however, potential disruption of the bag during morcellation and reduced visualization may limit its use and may increase the risk of injury to adjacent organs
- Not all of these may be an option for every patient

An understanding of the risks, benefits and alternatives, as well as the decision to proceed with surgery involving the option of either morcellation within a bag or traditional power morcellation techniques is part of the shared decision-making process. The informed consent process should be fully documented.

Additional Resources

US Food and Drug Administration (FDA) American College of Obstetricians and Gynecologists (ACOG) American Urogynecologic Society (AUGS) American Association of Gynecologic Laproscopists (AAGL) Society of Gynecologic Surgeons (SGS)

Disclaimer

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed, or as dictating the standard of care. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient. Physicians should also be aware of state specific laws on obtaining and documenting informed consent.

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