



Risks related to power morcellation in gynecologic surgery

Issue:

The Joint Commission's Office of Quality and Patient Safety has received a number of patient safety concerns regarding gynecologic surgery and power morcellation – the use of an electromechanical device to shave or cut tissue during the process of extraction. In addition, the U.S. Food and Drug Administration (FDA) released a safety communication regarding uterine power morcellation in hysterectomy and myomectomy¹, and the American College of Obstetricians and Gynecologists (ACOG) conducted a review.² It was determined that power morcellation should not be used in gynecologic surgery of women with strongly suspected or known malignancy. (While power morcellation is used in other types of surgery, this publication focuses on its use in gynecologic surgery.)

When indicated, minimally invasive gynecologic surgical procedures (for example, vaginal or laparoscopic hysterectomy) are preferred because they reduce a patient's overall operative risk. However, power morcellation inherently involves the risk of spreading tissue. (In addition, there is no conclusive evidence that manual morcellation, performed either vaginally or abdominally, eliminates this risk.) Health care organizations have been quick to recognize the risk of procedures using power morcellation, and to provide guidelines to physicians considering power morcellation in a patient's plan of care.

Safety Actions to Consider:

Health care organizations can take the following actions to prepare for and support communication between physicians and patients so that safe and effective surgery is performed and patients are fully informed about the potential benefits as well as the risks of power morcellation in gynecologic surgery.

- Ensure appropriate training and credentialing for minimally invasive surgery, including use of the power morcellator. Privileges should be based on training, experience and documented competency. Physicians with these privileges should have ongoing professional practice evaluation (OPPE) and corresponding "triggers" where focused professional practice evaluation (FPPE) may be indicated for individual performance improvement.
- Consider evidence-based or consensus guidelines when evaluating patients to determine if they are appropriate candidates for power morcellation. Pre-procedure evaluation for possible malignancy can include, but not be limited to: current cervical cytology,³ pelvic imaging and endometrial assessment (depending on the clinical presentation). Other considerations include increasing age, menopausal status, uterine size, rapid uterine growth, or treatment (e.g., tamoxifen), or hereditary conditions (e.g., Lynch syndrome).
- Obtain current manufacturer's literature and operating instructions, so providers have an available reference if needed.
- Ensure that the health care organization's biomedical service conducts regular function checks of the power morcellation device, and that physicians and staff are kept current with any updates or issues which would compromise its safe operation.
- If the medical staff concludes that best practice should include the use of power morcellation in gynecologic surgery, the Obstetrics and Gynecology department should have documented education surrounding the consent process for morcellation and the pre-procedure evaluation.
- As part of the informed consent process, each woman who is considering minimally invasive hysterectomy or myomectomy where use of a power morcellator is being contemplated in a care plan should have an informed consent discussion with the provider about the alternative treatment options.
- Aggregate and analyze medical staff performance improvement data in gynecologic surgical cases with power morcellation. The data analyses should include preoperative and postoperative diagnosis

(Cont.)



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correlation, surgical pathology findings, and postoperative complications. This data analyses will allow physician leaders to affirm that medical staff performance is consistent with evidence-based guidelines. If undesirable patterns and trends suggest otherwise, physician leaders can determine steps to improve medical staff performance, as noted above.

Resources:

1. Food and Drug Administration: [Quantitative assessment of the prevalence of unsuspected uterine sarcoma in women undergoing treatment of uterine fibroids: summary and key findings](#). Silver Spring, Maryland: 2014 (accessed October 14, 2014)
2. The American College of Obstetricians and Gynecologists: Power morcellation and occult malignancy in gynecologic surgery. *A Special Report*, May 2014
3. The American College of Obstetricians and Gynecologists: Screening for Cervical Cancer. *Practice Bulletin* No. 131, November 2012

Note: This is not an all-inclusive list.



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