FDA, Joint Commission cite safety concerns with power morcellation

Reports about problems associated with power morcellation in gynecologic surgery led to safety warnings in November 2014 by the Food and Drug Administration (FDA) and the Joint Commission.

The FDA on November 24 updated its Safety Communication on the use of laparoscopic power morcellation in hysterectomies and myomectomies. The previous Safety Communication was issued April 17, 2014.

In the update, the FDA says when laparoscopic power morcellation is used for hysterectomy or myomectomy in women with uterine fibroids, it poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas.

Based on an analysis of currently available data, the FDA estimates that approximately 1 in 350 women having a hysterectomy or myomectomy is found to have an unsuspected uterine sarcoma. Currently there is no reliable method to predict or test whether a woman with fibroids may have a uterine sarcoma.

The FDA also issued an Immediately in Effect (IIE) guidance that urges manufacturers of power morcellators to include a boxed warning and two contraindications in their product labeling.

The boxed warning states that “uterine tissue may contain unsuspected cancer” and that use of laparoscopic power morcellators may “spread cancer and decrease the long-term survival of patients.” The warning also recommends that healthcare providers share this information with patients when considering using these devices.

The two contraindications advise that:

• Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or postmenopausal or who are candidates for en bloc tissue removal through the vagina or a mini-laparotomy.
• Laparoscopic power morcellators are contraindicated for gynecologic surgery in which the tissue to be morcellated is known or suspected to contain cancer.

In a November 17 Quick Safety alert, the Joint Commission said its office of quality and patient safety had received a number of patient safety concerns regarding gynecologic surgery and power morcellation.

The Joint Commission notes that healthcare organizations have been quick to recognize the risk of procedures using power morcellation and to provide guidelines to physicians considering the use of power morcellation in a patient’s plan of care.

Included in the alert are seven safety actions healthcare organizations can take to support communication between physicians and patients, ensure safe and effective surgical procedures are performed, and inform patients fully about the benefits and risks of power morcellation.

—Judith M. Mathias, MA, RN

References
