POWER MORCELLATION AND THE RISK OF UTERINE SARCOMA DISSEMINATION

An estimated 50,000 women a year in the United States undergo a hysterectomy (removal of the uterus) or myomectomy (removal of uterine fibroids) with the use of a medical device known as a power morcellator. Power morcellators typically use a rapidly rotating blade to cut (or "morcellate") fibroids and other tissue into small pieces (approximately 1 cm diameter) that can be removed through small incision sites in a minimally invasive procedure known as laparoscopic surgery.

The high speed of the morcellator blade spreads bits of tissue to other parts of the abdomen and pelvis. If an undetected cancer is present, morcellation can spread malignant tissue, particularly uterine sarcoma, beyond the uterus. This can significantly worsen a woman's prognosis for long-term survival.

Uterine Fibroids

Uterine fibroids are noncancerous growths that develop from the muscular tissue of the uterus. Most women develop uterine fibroids (known as leiomyomas) during their lifetime, although most cause no symptoms. In some cases, however, fibroids cause symptoms, including heavy or prolonged menstrual bleeding, pelvic pressure or pain, or frequent urination. In these instances, a hysterectomy or myomectomy may be necessary to remove the fibroids.

Uterine Sarcomas

Based on information compiled by the Food and Drug Administration (FDA), 1 in 352 women undergoing fibroid removal (hysterectomy or myomectomy) have an unsuspected uterine sarcoma. In those cases where an unsuspected sarcoma is morcellated, an analysis by the FDA indicates that 25% to 64% of the cases result in abdominal cavity dissemination and/or cancer upstaging to Stage III or IV. Women with unsuspected sarcoma who undergo morcellation may have worse disease-free survival and overall survival than women who do not undergo morcellation.

Uterine leiomyosarcomas are the most common uterine sarcomas, accounting for about 25% to 36% of all uterine sarcomas. Leiomyosarcomas are notorious for their aggressive nature and poor prognosis, and become more dangerous when morcellation spreads the malignancy beyond the uterus. Based on the medical literature, 1 in 498 women undergoing fibroid removal have an unsuspected leiomyosarcoma.

It is difficult to distinguish benign growths from malignant leiomyosarcomas or other uterine sarcomas. There are several reasons for this including 1) the absence of symptoms specific to leiomyosarcomas, 2) the similarity in symptoms between benign leiomyomas and malignant leiomyosarcomas and 3) the location of the malignancy below the surface of the endometrial tissue.

Most leiomyosarcomas are discovered only incidentally after surgery when uterine tissue removed during a hysterectomy or myomectomy is examined by a pathologist. Even an MRI done before surgery does not always give a doctor the ability to distinguish between fibroids and sarcoma.

FDA Warns About Sarcoma Dissemination with Power Morcellation

In April 2014, the FDA issued a safety communication about the risk of spreading unsuspected uterine sarcoma within the abdomen and pelvis when a power morcellator is used for fibroid removal. For this reason, and since there is no reliable method for predicting whether a woman with uterine fibroids may have a uterine sarcoma, the FDA discouraged the use of a power morcellator during hysterectomy or myomectomy.

In July 2014, the FDA convened a two-day meeting of its Obstetrics and Gynecology Devices Advisory Panel to address the safety of power morcellation. Panel members were concerned about the lack of data on the prevalence of uterine sarcoma among women undergoing fibroid removal. Despite the lack of studies, the panel agreed that the magnitude of the risk is too large to be ignored.

Panel members recommended adding much stronger product warnings, known as "black box" warnings, to advise of the sarcoma risk, as well as heightened informed consent requirements to ensure women are fully informed of the serious risks. The FDA is also considering reclassifying the devices into a more restrictive category—a class III medical device. Several speakers at the hearing called for a ban on the devices.

Following this hearing, Johnson & Johnson announced a "worldwide voluntary market withdrawal" of three power morcellators, and requested that health care providers return the devices. Johnson & Johnson stated that "the risk-benefit assessment associated with the use of these devices in hysterectomy and myomectomy procedures for removing fibroids remains uncertain." Other manufacturers continue to market power morcellation devices.

Some well-respected medical centers in the Boston area have banned power morcellation devices after the FDA warning in April. These include Brigham and Women's Hospital, Boston Medical Center, Tufts Medical Center and Massachusetts General Hospital.

Conclusion

Power morcellators carry a very real risk of spreading unsuspected uterine sarcoma. This risk can lead to stirring up and upstaging aggressive cancers, along with a poor prognosis for survival. Power morcellator manufacturers appear to have known of these serious risks for some time, but have elected to play up the benefits of morcellation, while ignoring the dangers. One wonders why a company would promote a medical device knowing its risk-benefit assessment "remains uncertain."

Women with cancer that spread following power morcellation have begun filing lawsuits based on the manufacturer's failure to adequately warn of this serious, indeed life-threatening, risk. Device manufacturers should be accountable for the harm caused by these dangerous devices.

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