New studies quantify morcellation's link to uterine cancer

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The dangers of a power tool used in gynecological surgery have been debated for more than a year, with experts offering varying estimates of the chance that an undetected uterine cancer would be spread - and likely worsened - by the tissue-slicing device.

Now, two new studies have waded into the controversy.

Using a nationwide insurance claims database, Columbia University researchers looked at women treated for uterine growths called fibroids. Uterine cancer was discovered in one out of every 1,073 who underwent power morcellation, and one out of 528 without morcellation.

In the second study, University of Michigan researchers used a statewide hospital group database and found that among women undergoing hyterectomy for presumed benign conditions, 1 in 454 had uterine cancer. The study could not tell whether electric morcellators were used.

Both studies characterized the risk of discovering unexpected cancer as small.

For Hooman Noorchashm, the physician who set off the debate after the worst-case scenario befell his wife, trying to quantify the harm of power morcellation misses the point.

The new studies are "adding to a collage of estimates that are trying to sugarcoat this practice" said Noorchashm, a cardiac surgeon at Thomas

Jefferson University Hospital in Philadelphia. "If you put your patients in harm's way for an avoidable hazard, that is unforgiveable."

Noorchashm and his wife, anesthesiologist Amy Reed, began pushing for a ban on power morcellators after her October 2013 diagnosis with stage-four leiomyosarcoma, a rare, aggressive uterine cancer. Brigham and Women's Hospital in Boston, where she had the hystectomy with morcellation, has acknowledged that the procedure likely worsened her prognosis.

Power morcellators were introduced in 1993 and have been defended by gynecological specialty groups because dissecting tissue with the motorized blades enables it to be removed through tiny abdominal incisions. Alternative surgical approaches that require large incisions increase pain, recovery time, and the risk of infection, bleeding and blood clots.

Many factors complicate this risk-benefit tradeoff. Preoperative tests and scans can't reliably distinguish benign fibroids, which can cause bleeding and pain, from cancerous ones. No surgical methods - not even ones that remove tissue largely intact - are guaranteed to prevent the spread of an unsuspected cancer. Enclosing a power morcellator in a bag to prevent tissue from spewing in the body cavity also has limits and downsides.

Until Noorchashm raised the alarm, gynecologists downplayed the chance of power-morcellating a hidden uterine sarcoma, citing the risk as 1 in 10,000.

Recent studies have calculated that between 1 in 1,000 and 1 in 350 women who undergo power mocellation for presumed benign problems will have uterine cancer.

The worse estimate is from the U.S. Food and Drug Administration. In November, it stopped short of a ban, instead issuing tougher warning labels that say the devices "may spread cancer and decrease the long-term survival of patients." The agency also said the devices are rarely the most prudent surgical option.

Before the safety debate, about 600,000 hysterectomies were done each year, and 50,000 of them involved power morcellation, the FDA said.

Now, most hospitals have stopped using power morcellators. Johnson & Johnson's Ethicon division withdrew its top-selling version of the device from the market last July.

Sawsan As-Sanie, director of minimally invasive gynecological surgery at the University of Michigan Medical School and senior author of the new study in this month's Obstetrics and Gynecology, said she uses the device "in a very limited scenario."

"My primary goal is to help my patients relieve symptoms using the least invasive and least risky methods possible," she said. "The vast majority of patients [with bothersome fibroids] don't necessarily need surgery."

Both new studies looked at the prevalence of unexpected cancers other than just uterine sarcoma.

The Columbia study, published in this week's *JAMA Oncology*, found that among 41,777 women who had "myomectomy" - surgery to remove fibroids but leave the uterus - cancerous or precancerous abnormalities were diagnosed in 802 women, or 1.9 percent.

The Michigan study found an even higher rate. Among 6,360 women who had hysterectomies for benign indications, 2.7 percent were found to have malignancies including ovarian, fallopian tube, and cervical

cancers.

"Comprehensive patient counseling should address the usual risks of surgery, the risk of unexpected malignancy, and the possibility of poor prognosis should an unidentified malignancy be morcellated," As-Sanie's team concluded