Uterine Morcellation
Risk, Benefits and Alternatives
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Conflict of Interest Disclosure

None to Disclose
Women's Health Alert: Deadly Cancers of the Uterus Spread by Gynecologists. Stop Morcellating the Uterus in Minimally Invasive and Robot Assisted Hysterectomy and Myomectomy
When a hysterectomy can be a death sentence

"This is hurting a lot of people, and they don't even know it," says Amy Reed, who says the procedure spread her cancer.

In a surgical advance that benefits tens of thousands of women a year, doctors can now remove a woman's uterus through an incision in her belly button, reducing recovery time for a hysterectomy from four to six weeks to three to five days.

But this advance comes at a terrible price for some.

A small number of women – the precise number is unknown – are effectively sentenced to death by a version of this procedure that can spread cancer cells as the uterus and any growths on it are pulverized to fit through the tiny incision, a process called morcellation.

Amy Reed, 40, is one of those women. The Boston doctor has six children under 13, a husband who's a surgeon, and a thriving medical practice. She treated Boston Marathon bombing victims last spring, as well as Dzhokhar Tsarnaev, who is charged in the attack.

The Boston surgeon and his wife, an anesthesiologist, are pushing to stop a widespread surgical technique used on thousands of women during hysterectomies, which they say caused her undetected cancer to dangerously spread.

Dr. Hoorn Noorhashem, a cardiothoracic surgeon at Brigham and Women's Hospital, has started an online petition and written dozens of letters to medical journals and media organizations charging that the technique, called "morcellation," is endangering women and creating a public health crisis. He has adamantly demanded that his own hospital—where his wife's operation was performed—stop using the procedure, and called on other hospitals and doctors nationwide to do likewise. It is typically employed during laparoscopic hysterectomies, a type of minimally invasive surgery.

"This is a very ethically black and white issue," Noorhashem said. "One of your own got it. Stop doing it at the Brigham at least, and encourage others to stop doing it."
Two hospitals adjust hysterectomy surgery

MGH, Brigham cite cancer fear

By Liz Kowalczyk | GLOBE STAFF MARCH 28, 2014

Brigham and Women’s and Massachusetts General hospitals are largely abandoning a common surgical technique used nationwide for years to perform many hysterectomies, prompted by two recent cases where the procedure dangerously spread undetected cancer.

Evaluating the Risks of Electric Uterine Morcellation

Kimberly A. Kho, MD, MPH; Cesna H. Nezhat, MD

March 5, 2014, Vol 311, No. 9

Gynecologic surgeons, like many other surgical specialists, have embraced laparoscopic surgical techniques because they offer quicker recovery, less postoperative pain, and fewer wound complications than open procedures. The removal of large pieces of tissue through the small incisions of laparoscopy is difficult. However, this problem can be overcome by tissue morcellation, a technique of fragmenting tissue into smaller pieces that often prevents the need to enlarge established incisions. Surgeons have long used manual morcellation with a scalpel or scissors to remove masses abdominally and vaginally, but use of the technique has increased with wide adoption of laparoscopic approaches and with the introduction of laparoscopic electric morcellators in 1993.
Morcellation Cancer Lawsuit Filed By Pennsylvania Widower Alleges Wife’s Death From Myelosarcoma Was The Result Of Uterine Morcellation, Alonso Krangle LLP Reports

Posted on March 28, 2014 by Editor

Complaint Alleges Defendants Failed To Warn The Decedent That The Use Of Morcellator During Her Hysterectomy Could Result In Seeding Of Undiagnosed Sarcoma Through The Peritoneal Cavity

The widow of a Pennsylvania woman who died from metastatic myelosarcoma has filed a morcellation cancer lawsuit alleging that her death was the result of uterine morcellation.

According to the complaint, the use of a morcellator, a device used to remove tissue during hysterectomies and other gynecological procedures, caused the seeding of undiagnosed sarcoma throughout the Decedent’s peritoneal cavity. The Morcellator Cancer Lawsuit, which was filed on March 14, 2014 in the U.S. District Court, Eastern District of Pennsylvania, names Ethicon Inc., Blue Endo, and Lina Medical, among others, as Defendants. (Case No. 14 5557)
Uterine and Myoma Morcellation

• Manual morcellation by vaginal or abdominal route
• Robotic or laparoscopic sectioning of the uterus or myomata for delivery through the vagina or a mini-laparotomy
• Mechanical morcellation
Robotic Morcellation
Mechanical Morcellation
Case # 1

• 43 year old Puerto Rican female, G1P1 referred by REI.

• Long standing history of secondary infertility with myomectomy performed in Puerto Rico at age 34 and 37 for uterine fibroids.

• Laparoscopy one month ago demonstrated multiple masses with biopsy showing a spindle cell neoplasm.

• Robotic hysterectomy, BSO, resection of multiple intra-abdominal and abdominal wall masses on 9/21/2010.

• Final pathology endometrial stromal sarcoma. ER/PR (+) in >95% of cells.
Endometrial Stromal Sarcoma
Case # 2

- 42 year old female, G3 P2 AB1 referred by REI.
- Long standing history of menorrhagia and blood loss anemia. Initially declined Lupron, uterine artery embolization and surgery as she was unsure about further pregnancies.
- Seven months later evaluation by REI resulted in myomectomy 6/2007.
- Final pathology disclosed a leiomyosarcoma with 20 mitoses/10 HPF.
- 9/2007 CT evidence of large volume pelvic and pulmonary metastases.
Case # 3

• 40 year old female, G3 P3 referred by hepatobiliary surgeon.
• Evaluation of RUQ abdominal pain, resulted in findings of a mass with subsequent partial R hepatectomy, partial colectomy and resection of perinephric fat.
• Pathology is suspicious for a low grade leiomyosarcoma (low mitotic count)
• Past history is positive for laparoscopic myomectomy with morcellation two years and four years earlier.
Perspective
Hysterectomy Background Information

• 500,000 hysterectomies performed annually
• 35-58% of hysterectomies are performed due to leiomyomata
• 34% of hysterectomies are performed by vaginal, laparoscopic or robotic approach (MIS Minimally Invasive Surgery)
• By my rough estimation, 68,000 women could undergo some type of uterine morcellation. (5000,000 x 0.4 x 0.34)
• This does not include myomectomy as a distinct procedure.

National Hospital Discharge Survey 2010

Nationwide trends in the performance of inpatient hysterectomy in the United States.
Wright JD et al.
Leiomyosarcoma Background Information

• 52,630 new cases of uterine cancer are predicted for 2014.
• The American Cancer Society predicts that 1,600 of the 52,630 will be uterine sarcomas.
• Leiomyosarcoma = 2%, Endometrial Stromal Sarcoma = 1%, Undifferentiated sarcoma = 1% of uterine malignancies.
• Carcinosarcoma/Malignant Mixed Mullerian tumors are to be considered epithelial.

Leiomyosarcoma Background Continued

• 47-60% of patients are diagnosed at FIGO Stage I
  
  Gynecol Oncol 2003, 89;460-469. Giuntoli et al.

• Survival
  • Stage I  30%
    • Gynecol Oncol 2003, 89:460-469. Giuntoli et al.
  • Stage I-II  20%
    • Gynecol Oncol 2013, 131;629-633. Ricci et al.
  • Stage I  51%
    • Histopathology 2009;54:355-64. Abeler et al.

• Accurate Screening and Preoperative Diagnostic Studies
  • None
Leiomyosarcomas identified in women undergoing hysterectomy for leiomyomas.

<table>
<thead>
<tr>
<th></th>
<th># of Patients</th>
<th>Surgery Type</th>
<th># of LMS</th>
<th>Frequency of LMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parker et al, 1994</td>
<td>1332</td>
<td>Hysterectomy or myomectomy</td>
<td>1</td>
<td>0.08%</td>
</tr>
<tr>
<td>Leung et al, 2009</td>
<td>1297</td>
<td>Hysterectomy</td>
<td>3</td>
<td>0.23%</td>
</tr>
<tr>
<td>Leibsohn et al, 1990</td>
<td>1429</td>
<td>Hysterectomy</td>
<td>7</td>
<td>0.49%</td>
</tr>
</tbody>
</table>

Uterine/myoma morcellation

• For purposes of discussion, there is no literature to suggest that manual morcellation is less likely to disseminate cells/tissue than mechanical morcellation.
• Mechanical morcellation was described in 1993.
• Peritoneal leiomyomatosis and endometriosis attributable to mechanical morcellation at the time of supracervical hysterectomy has been reported.
• Bowel, bladder and vascular injuries have also been noted with the use of mechanical morcellation.
Unexpected malignancies identified following LASH (Laparoscopic-assisted supracervical hysterectomy)

<table>
<thead>
<tr>
<th># of Patients</th>
<th>Surgery Type</th>
<th># of Malignancies</th>
<th>Frequency of LMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theben et al, 2013</td>
<td>1,584</td>
<td>LASH</td>
<td>2 LMS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 Endomet. Cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 Total</td>
</tr>
</tbody>
</table>

87.8% of patients (1,391/1,584) underwent preop Pap testing and ultrasound evaluation.

LMS patients were aged 43 and 49 with Preop Dx of fibroids with normal Pap and unsuspicious sono. EC patients were aged 52 and 50 with Preop Dx of menorrhagia and rapidly enlarging fibroids. Normal sono in one and 12 mm endo. Stripe in the other.

Arch Gynecol Obstet 2013; 287:455-462
Impact of morcellation on prognosis for early stage uterine leiomyosarcoma.

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<th>Non-morcellation (n=31)</th>
<th>Morcellation (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known sarcoma Preop Dx</td>
<td>3 (9.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1 (3.2%)</td>
<td>6 (24%)</td>
</tr>
<tr>
<td>Adjuvant Therapy</td>
<td>18 (61.3%)</td>
<td>14 (56%)</td>
</tr>
<tr>
<td>5 Yr. Disease Free Survival</td>
<td>65%</td>
<td>40% <strong>p = 0.032</strong></td>
</tr>
</tbody>
</table>

Additional Literature Pertinent or Not

• 1091 cases of uterine morcellation from 2005-2010 at BWH.

• Identified 10 cases of cellular leiomyoma, atypical leiomyoma, smooth muscle tumor of uncertain malignant potential. One case each of leiomyosarcoma and endometrial stromal sarcoma. One case of disseminated peritoneal leiomyomatosis.

• The incidence of unexpected leiomyosarcoma was 0.09%

Additional Literature
Pertinent or Not

• Einstein et al. Int J Gynecol Cancer 2008;18:1065-1070. Management of uterine malignancy found incidentally after supracervical hysterectomy or uterine morcellation for presumed benign disease. Includes endometrial cancer, endometrial stromal sarcoma and LMS.

• Oduyebo et al. Gynecol Oncol 2014;132:360-365 The value of re-exploration in patients with inadvertently morcellated uterine sarcoma.
Factors reported to assist in identifying women with uterine leiomyosarcoma preoperatively.

• Rapidly enlarging uterus
• Menopausal bleeding
• Tamoxifen (carcinosarcoma)
• Pelvic radiation
• Hereditary leiomyomatosis and renal cell cancer (HLRCC)

NOTE: There is no reproducible evidence for items 1-4.
Usefulness of Gd-DTPA contrast enhanced MRI and serum LDH in the differentiation of leiomyosarcoma from degenerated leiomyoma of the uterus

• Prospective study from 1990-2000 enrolling 298 women.
• Dynamic MRI and LDH assessed preoperatively
• Study compared 130 degenerating leiomyoma to 10 leiomyosarcoma patients
• Specificity, PPV, NPV, Diagnostic accuracy was 100%, 100%, 100% and 100% with Dynamic MRI and LDH (total and isoenzymes)
• Note: No published confirmatory studies, and only comparing 10 LMS to degenerating leiomyoma.

Preoperative endometrial assessment in asymptomatic women undergoing hysterectomy for pelvic floor dysfunction


• Preop testing included; Endometrial biopsy in 18 %, pelvic sonography in 6%, EmBx & sonography in 3%. All at the discretion of the surgeon.

• 5/708 (0.7%) were found to have uterine malignancies, (4 EC, 1 LMS)

• Four of the five had normal EmBx, sonography or both

• The patient with the leiomyosarcoma was 55 years old with a 16x10x11 cm uterus.

Ramm et al, Int Urogynecol J. 2012;23:913-917
Unanticipated uterine pathology finding after morcellation during robotic-assisted supracervical hysterectomy and cervicosacropexy for uterine prolapse.

- Two of 63 (3.17%) were found to have grade 1 endometrial carcinoma. Neither patient was symptomatic (PMB), had risk factors for endometrial cancer or had a history of hormone therapy.
- 5/708 (0.7%) were found to have uterine malignancies, (4 EC, 1 LMS)
- Conclusion was that pre-operative endometrial assessment should be considered in all post-menopausal women undergoing uterine morcellation.

Hill et al. 2014;20(2);113-5.
How often does morcellation result in dissemination of tissue?

• Case Reports
• Case Series
• FDA MAUDE (Manufacturer and User Facility Device Experience)
  • Manufacturer reports to the FDA.
  • Facility reports to the manufacturer unless here is a death, then the FDA.

• There is no reliable way to assess how frequently tissue dissemination, malignant or benign occurs.
Event Date: 10/02/2009

Event Type: Injury

Patient Outcome: Hospitalization, Life Threatening, Disability

Event Description:
I had a hysterectomy laparoscopically with the da vinci robot 2009. My uterus was cut up with a morcellator to remove it due to fibroids. It left seeds in my abdomen which turned into tumors. In 2011, I went through 2 types of chemo, multiple blood transfusions, a 7.5 hour surgery to remove 7 tumors one weighing 25 pounds, with a total of 22 days in the hospital. I was treated and standford. My tumor's tissue has been tested at (b)(6), all confirm it is uterine in origin and smooth muscle tumor of unknown potential (a slight down grade from uterine leiomyosarcoma). I have to have an MRI every 3 months. Presently there are several things the oncologist is keeping an eye on my scans. I see the sarcoma specialist and surgeon every 3 months. I am lucky to be alive yet, i could still die from this terrible disease.
Known and proposed alternatives to uterine/myoma morcellation

- Abdominal hysterectomy, myomectomy (intact specimen)
- Vaginal morcellation of specimen (implied safety)
- Mini-laparotomy with manual morcellation within a bag
- Manual morcellation within a bag by vaginal approach
- Mechanical morcellation within an intraperitoneal bag (no evidence)
Final Thoughts and Observations.

- Elimination of morcellation as a tool could deprive a significant number of women the option of minimally invasive surgery.
- During the Informed Consent process a description of the potential to disseminate tissue secondary to morcellation should be clear, and a risk of 2/1,000 of disseminating a malignancy seems realistic.
- Alternatives to morcellation should be discussed.
- To date, there is no effective way to screen for uterine leiomyosarcoma.
Final Thoughts and Observations.

• Available reports lack sufficient power to define specific risk factors, BUT,
  • Age over 40
  • Women with perimenopausal or menopausal bleeding
  • Unexplained uterine enlargement in the perimenopausal or menopausal woman should be considered for further evaluation and perhaps an alternative to mechanical morcellation

• Reassess the role of supracervical hysterectomy outside of cervicosacropexy

• The patient makes the final decision.
Discussion