The Morcellation Controversy

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Department of Gynecologic Oncology

ACOG
August 14, 2015
This speaker has no conflicts of interest to disclose relative to the contents of this presentation

AAGL Spokesperson for Morcellation
The priority is the patient’s welfare
Objectives

At the end of this presentation, participants should be able to:

• Discuss the controversy regarding morcellation

• Recite the timeline of recent events

• Analyze and synthesize published data

• Review the FDA recommendation

• Consider future potential options
Why is morcellation important?

- 600,000 hysterectomies performed annually in the US
- 63% through an MIS approach (up from 30%)
- 77% show fibroids
- Without power morcellation, 50 - 150K cases/year may be converted to open procedures
- Concerns raised regarding undetected malignancy and dissemination

-Keshavarz, MMWR 2002; Merrill RM Med Sci Monit 2008; Wright JD, JAMA 2013; FDA 2014
The History of Uterine Morcellation

1949: Allen publishes “Vaginal removal of the uterus by morcellation” in the Gray Journal

The History of Uterine Morcellation

1993: Steiner publishes “Electrical Cutting Device for laparoscopic removal of tissue from the abdominal cavity” in the Green Journal

1995: The FDA clears the first uterine morcellator under the 510(K) process as an intermediate risk device
The History of Uterine Morcellation

1997: Time and Cost Analysis of power vs. manual morcellation shows benefit (Carter et al, JRM)

1997: First report of undetected adenocarcinoma in morcellated uterus - preop curettage recommended (Schneider, AJOG)
The History of Uterine Morcellation

1997-2013: 136 articles published referencing “uterine morcellation”

2013 (October) - Boston based anesthesiologist undergoes a laparoscopic hysterectomy for fibroids which is later determined to be a LMS
The History of Uterine Morcellation

2013 (December) - The Wall Street Journal and several other major newspapers publish stories on uterine morcellation

-Cite worse outcomes due to dissemination of undetected cancer
How Many People Have To Die To Show A New Surgery Technique Isn't Worth It?

Doctor. Mother of six. Stage 4 cancer patient. Amy Reed may not have much time to live, but she's making sure her death won't be in vain.

By Harriet Brown  Photograph by Jamie Young

Fibroid Surgery Puts Doctor Fighting Cancer Diagnosis in Spotlight

During Routine Procedure Doctors Find Rare Cancer, Which Procedure May Have Spread

F.D.A. Discourages Procedure in Uterine Surgery

By DENISE GRADY  APRIL 17, 2014

Doctors should stop using a procedure performed on tens of thousands of
"We as an organization certainly think this is absolutely worthwhile to look into" in hopes of advancing patient safety, said Jubilee Brown, an AAGL board member and a faculty member in MD Anderson Cancer Center's ob-gyn department. However, she added that "at this point we believe morcellation remains a valuable approach" (Kamp/Levitz, Wall Street Journal, 2/20; McCullough, Philadelphia Inquirer, 2/21; Weintraub, USA Today, 2/18).
"We as an organization certainly think this is absolutely worthwhile to look into" in hopes of advancing patient safety, said Jubilee Brown, an AAGL board member and a faculty member in MD Anderson Cancer Center's ob-gyn department. However, she added that "at this point we believe morcellation remains a valuable approach" (Kamp/Levitz, Wall Street Journal, 2/20; McCullough, Philadelphia Inquirer, 2/21; Weintraub, USA Today, 2/18).

Debate: Should Morcellation for Hysterectomy and Myomectomy Be Banned?

Four physicians weigh in on the controversy

Larry R. Kaiser, MD, Hooman Noorchashm, MD, PhD, Antonio R. Pizarro, MD, Joseph Ramieri, MD | August 01, 2014

Morcellation, a surgical technique that fragments tissue to facilitate removal through a small incision, has been done routinely by gynecologic surgeons since the US Food and Drug Administration (FDA) approved the first power morcellators in the 1990s. The procedure came under scrutiny in October 2013 when Boston-based cardiothoracic surgeon Hooman Noorchashm, MD, PhD, launched a campaign calling for a ban on morcellation after his wife had an unsuspected uterine leiomyosarcoma morcellated during what was supposed to be a routine hysterectomy. The procedure caused the leiomyosarcoma to progress to stage IV uterine cancer.
"We as an organization certainly think this is absolutely worthwhile to look into" in hopes of advancing patient safety, said Jubilee Brown, an AAGL board member and a faculty member in MD Anderson Cancer Center's ob-gyn department. However, she added that "at this point we believe morcellation remains a valuable approach" (Kamp/Levitz, Wall Street Journal, 2/20; McCullough, Philadelphia Inquirer, 2/21; Weintraub, USA Today, 2/18).

www.advisory.com/daily-briefing

Advisory Board Daily Briefing
February 24, 2014

Medscape Ob/Gyn

Is There a Future for Morcellation in Gynecologic Surgery?

An expert interview with Jubilee Brown, MD, member of the board of trustees for AAGL - Advancing Minimally Invasive Gynecology Worldwide

Stephanie Cajigal, Jubilee B. Brown, MD | Disclosures
April 25, 2014
The History of Uterine Morcellation

2014 (March) - Senator Elizabeth Warren queries FDA commissioner Margaret Hamburg

2014 (April): Margaret Hamburg organizes FDA review of data and organization of expert panel
The History of Uterine Morcellation

2014 (April) - FDA releases initial report on prevalence and discourages use of morcellation
- Risk of sarcoma is about 1:350
- Risk of LMS is 1:500
- Many hospitals limit or ban morcellation

*F.D.A. Discourages Procedure in Uterine Surgery*

By DENISE GRADY  APRIL 17, 2014

Doctors should stop using a procedure performed on tens of thousands of
The History of Uterine Morcellation

2014 (May) - AAGL convenes Task Force on Tissue Extraction
The History of Uterine Morcellation

2014 (July) - The FDA convenes an expert panel to review options of status quo, black box warning, or complete ban of this practice

FDA Advisors Debate Ban, Black Box And Status Quo of Power Morcellators

In a heated two-day hearing, several members of an FDA advisory panel on medical devices expressed low confidence in power morcellation as a treatment for uterine fibroids, and focused on alternative methods for performing hysterectomies and fibroid removal.

There was no formal consensus on either an outright ban on power morcellators or issuance of a “black box” warning label.

*Photo: Families harmed by power morcellation pose on FDA’s White Oak campus July 11, following a two-day hearing on the controversial surgical procedure*

*The Numbers*

**GYN Group: Open Surgery Would Cost More Lives than Morcellation**

More women would die from open surgery each year if the FDA decides to ban power morcellation, said Jubilee Brown, an associate professor at MD Anderson Cancer Center and a spokesperson of the American Association of Gynecologic Laparoscopists.
The History of Uterine Morcellation

2014 (July) - AAGL presents at FDA and publishes Statement to the FDA
The History of Uterine Morcellation

J&J discontinues their morcellator (> 70% market share)

J&J Withdraws Power Morcellators, Citing Risk of Disseminating Cancer

Ethicon, the Johnson & Johnson subsidiary that manufactures nearly three-quarters of laparoscopic power morcellators on the market, has requested a withdrawal of the controversial devices.

“Immediatley review inventory to determine if you have any Ethicon Morcellation Devices which are the subject of this market withdrawal,” the company wrote in a letter to hospitals worldwide.

“If you have provided Ethicon Morcellation Devices to any hospital within your system, you are responsible for notifying the appropriate parties immediately,” said the letter dated July 31.
The History of Uterine Morcellation

November 24, 2014
FDA Issues Statement

UPDATED Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication
• Are outcomes of MIS better, even when considering the low but present risk of undetected cancer?

• What is the risk of undetected cancer/sarcoma?

• Is the prognosis worse for a patient with morcellated sarcoma compared with a patient with a sarcoma removed intact?
Comparative Risk: 2 studies

- Weighing the Benefits of Minimally Invasive Surgery against Rare Adverse Oncology Outcomes with Leiomyosarcoma: A Decision Analysis

- Utilized a conservative estimate of LMS risk of 1:585

- Risk of local spread from PM = 15-35%

- Model: TreeAge Pro 11.0

-Naumann RW, Herzog TJ, Coleman RC, Brown J (submitted)
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Comparative Risk

• Mortality from AH: 0.085%

• Mortality from LH with PM: 0.077%

• Difference of 0.008% in favor of LH with PM

• Combined mortality from LH and potential dissemination of LMS from uterine power morcellation would be less than AH.

• If all women were converted to open hysterectomy, 17 more US women each year would die of open hysterectomy than power morcellation

-Naumann RW, Brown J, Herzog TJ, Coleman RC (submitted)
Comparative Risk: Siedhoff study

- Decision tree analysis with QOL utility estimates

- Predicted fewer deaths with LH vs. AH (98 vs. 103 per 100,000 women)

- More deaths from LMS after LH (86 vs. 71 /100,000)

- More hysterectomy related deaths with AH (32 vs. 12/100,000 women)

- More QALY in LH group (499,171 vs. 490,711/5y)

Is morcellation advantageous over laparotomy?

• Are outcomes of MIS better, even when considering the low but present risk of undetected cancer?

• What is the risk of undetected cancer/sarcoma?

• Is the prognosis worse for a patient with morcellated sarcoma compared with a patient with a sarcoma removed intact?
## Summary of Morcellated Endometrial Cancer

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Single site/registry data - all consistent
“Low risk” but not “No risk” procedure

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**Objective:** To establish the risk of unidentified neoplasia and subsequent adverse outcomes in patients undergoing laparoscopic supracervical hysterectomy (SCH) with morcellation

**Retrospective review, all consecutive women who had laparoscopic SCH over a 5 year period with 5 year F/U**

- 808 women were identified with planned laparoscopic SCH with morcellation
  - Median age was 44.1 years (23.4 - 79.8y)
  - Most common indications for surgery were menorrhagia (58.4%) and leiomyomata (49.5%)

-Brown J et al, JMIG 22, 2015
• 30 women were converted to an open procedure prior to morcellation
  - 1 had a leiomyosarcoma - NOT MORCELLATED; DOD 54 m

• 778 patients completed LSCH with morcellation
  - 16 (2.0%) had endometrial hyperplasia - all NED (FU 108m)
  - 3 (0.4%) had cancer on final pathology
    2 adenocarcinomas NED 81 and 93m ; 1 ESS NED 90 m

-Brown J et al, JMIG 22, 2015
• Prevalence LMS: 0/778

• Essential to evaluate preoperatively: cervical and endometrial screening

• Patients with LMS may do poorly if uterus removed intact - underscores that this is an aggressive malignancy

• Patients with morcellated hyperplasia or adenocarcinoma: NO adverse outcomes with over 5 year FU

-Brown J et al, JMIG 22, 2015
- 232,882 women who underwent MI hyst 2006-2012

- Morcellation performed in 36,470 (15.7%)

- Uterine cancer: 27/10,000

- Endometrial hyperplasia: 101/10,000

- Increasing age was significant

-Wright et al, JAMA 2014
• 232,882 women who underwent MI hyst 2006-2012

• Morcellation performed in 36,470 (15.7%)

• Uterine cancer: 27/10,000..ALL CANCERS - Not LMS

• Endometrial hyperplasia: 101/10,000

• Increasing age was significant

-Wright et al, JAMA 2014
• 232,882 women who underwent MI hyst 2006-2012

• Morcellation performed in 36,470 (15.7%)

• Uterine cancer: 27/10,000

• Endometrial hyperplasia: 101/10,000... No information on preoperative endometrial biopsy and we know there are no adverse outcomes in these patients - so meticulous preoperative assessment and patient selection

• Increasing age was significant

-Wright et al, JAMA 2014
• 232,882 women who underwent MI hyst 2006-2012

• Morcellation performed in 36,470 (15.7%)

• Uterine cancer: 27/10,000

• Endometrial hyperplasia: 101/10,000

• Increasing age was significant... So careful patient selection - not in postmenopausal patients

-Wright et al, JAMA 2014
Original Research

Unexpected Gynecologic Malignancy Diagnosed After Hysterectomy Performed for Benign Indications

Nichole Mahnert, MD, Daniel Morgan, MD, Darrell Campbell, MD, Carolyn Johnston, MD, and Sawsan As-Sanie, MD, MPH

-Mahnert et al, Obstet Gynecol 2015
Original Research

Unexpected Gynecologic Malignancy Diagnosed After Hysterectomy Performed for Benign Indications

Nichole Mahnert, MD, Daniel Morgan, MD, Darrell Campbell, MD, Carolyn Johnston, MD, and Sawsan As-Sanie, MD, MPH

FEBRUARY 19, 2015

Risk of unexpected sarcoma being discovered after hysterectomy appears fairly low

Uterine sarcoma diagnosed in 0.22 % of women after hysterectomy for benign conditions; study may shed new light on power morcellation debate

ANN ARBOR, Mich. — Uterine sarcoma – a potentially aggressive type of cancer that forms in tissues in the uterus – was found in 0.22 % of women following a hysterectomy for benign conditions, a new large-scale study by the University of Michigan departments of Obstetrics and Gynecology, and Surgery finds.
Can we identify uterine malignancy in the preoperative setting?

• Among 72 women with sarcomas, preop sampling suggested an invasive tumor in 86% and predicted the correct histologic diagnosis in 64%.

• Rate of detection of an invasive cancer by preoperative sampling was not statistically different among sarcomas and epithelial tumors (86% vs. 84%, p=0.76).

• Preoperative sampling was significantly less reliable in predicting the correct histology for uterine sarcomas (64% vs. 81%, p<0.0001).

-Bansal et al, Gynecol Oncol, 2008
Can we identify uterine malignancy in the preoperative setting?

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Risk of “upstaging” of LMS

<table>
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<th>Author</th>
<th># upstaged</th>
<th>Total #</th>
<th>Interval</th>
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<td>21 d</td>
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<td>Sinha</td>
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<td>2</td>
<td>&lt;30 d</td>
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<td><strong>Total</strong></td>
<td><strong>10</strong></td>
<td><strong>20 (50%)</strong></td>
<td><strong>15-600 d</strong></td>
</tr>
</tbody>
</table>

*Includes patients with laparoscopic myomectomy
• 56 consecutive patients with presumed stage I-II LMS

• OR for recurrence = 2.59 (1.03-6.5)
  
  M: 13/25 (52%)  Intact: 7/31 (23%)

• OR for death = 3.07 (1.05-8.93)
  
  M: 11/25 (44%)  Intact: 5/31 (16%)

- Mode of morcellation not identified - ABD, vaginal, or laparoscopic morcellation

- Non-morcellation group has curiously good outcomes, which makes the OR significant

Park et al, Gynecol Oncol 2011
Risk of Upstaging?

• Perhaps these patients do worse

• However, we do not know that for certain

• The studies we have are biased

• These patients do poorly as they have LMS!

• Biggest question is whether the risk attributed to morcellating the rare patient with an undiagnosed LMS is GREATER than the risk posed to patients who undergo laparotomy
Updated FDA Safety Communication

Purpose:
When used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus. The FDA is warning against using laparoscopic power morcellators in the majority of women undergoing hysterectomy or myomectomy for uterine fibroids. Health care providers and patients should carefully consider available alternative treatment options for the removal of symptomatic uterine fibroids.

Based on an FDA analysis of currently available data, we estimate that approximately 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma. At this time, there is no reliable method for predicting or testing whether a woman with fibroids may have a uterine sarcoma.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm
Updated FDA Safety Communication
Recommendations:

- Be aware of the following new contraindications recommended by the FDA:

  1. Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or are candidates for en bloc tissue removal, for example through the vagina or mini-laparotomy incision. (Note: These groups of women represent the majority of women with fibroids who undergo hysterectomy and myomectomy.)

  2. Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

Specifies two contraindications: Peri- or postmenopausal women and patients in which the tissue is known or suspected to contain a malignancy
Updated FDA Safety Communication
Recommendations:

- Be aware of the following new boxed warning recommended by the FDA:
The FDA warns that uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

Underscores the importance of informed consent
Updated FDA Safety Communication

Actions:

• Issued an Immediately In Effect (IIE) guidance that asks manufacturers of new and existing laparoscopic power morcellators to include two contraindications and a boxed warning in their product labeling. This information warns against using laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterecomy and recommends doctors share this information with their patients.

• Published safety information related to these devices and alternative treatment options for the treatment of fibroids available on its website to help people better understand the risks of laparoscopic power morcellators.

• Even with the issues in analysis, the FDA did two things:
  
  • Issued a boxed warning
  
  • Published safety information for patients

• THE MORCELLULATOR IS NOT BANNED

• Prior to peri-menopause, power morcellation is still reasonable in low risk patients after informed consent.
Report: FBI investigating medical device that spread cancer in women

Johnson & Johnson's Ethicon division manufactured power morcellator devices which were withdrawn from the market after the FDA warned they could spread cancer. / AP PHOTO/MEL EVANS
...it is the AAGL’s position that we should improve but not abandon power morcellation, and that power morcellation with appropriate informed consent should remain available to appropriately screened, low risk women.
What does the future hold?

• Better patient screening/selection with registry
  • NOT MAUDE database (Naumann Brown JMIG 2015)

• Improved informed consent

• Improved tissue extraction techniques
  • Emphasis on vaginal removal

• Improved containment technology
What does the future hold?
What does the future hold?
Thank you!