

Laparoscopic Morcellation Update

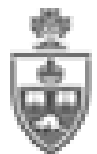
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Disclosure

- I have received a grant(s) or an honorarium from the following commercial organizations:
 - AbbVie
 - Actavis
 - Bayer
 - Hologic



Learning Objectives

- Discuss the risks of intra-corporeal morcellation
- Evaluate the available evidence related to electromechanical morcellation
- Identify risk reduction strategies and alternatives for laparoscopic electromechanical morcellation





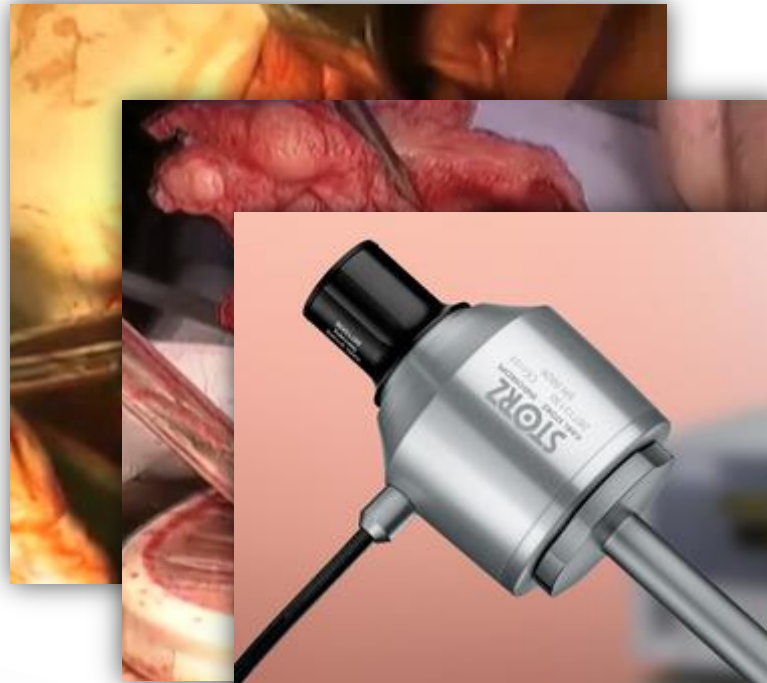
MORCELLATION

mor-cel-la-tion (mōr'sĕ-lā'shŭn)

Division into and removal of small pieces, as of a tumor.

[Fr. *morceler*, to subdivide]

Types of Morcellation





Chicago Tribune

Cancer risk drives debate over hysterectomy tool

By Julie R

HEALTH

F.D.A. Discovers

By DENISE GRADY

The New York Times

When a hysterectomy can be a death sentence

11:33 PM

Karen Weintraub, Special for USA TODAY 11:33 p.m. EST February 18, 2014

HEALTH

Uterine Surgical Technique Is Linked to Abnormal Growths and Cancer Spread

By DENISE GRADY FEB. 6, 2014

The New York Times

Uterine Surgery

Uterine Surgical Technique Is Linked to Abnormal Growths and Cancer

Amy Reed

- 40 yo
- Gyne Onc
- Biopsy
- USS
- MRI

**What is the risk of
encountering occult sarcoma at
the time of fibroid surgery?**

- A) Between 1/300 – 1/500
- B) Between 1/500 – 1/1000
- C) Less than 1/1000

RESULTS

- A) Between $1/300$ – $1/500$ **18%**
- B) Between $1/500$ – $1/1000$ **31%**
- C) Less than $1/1000$ **52%**

FDA Statement April 2014



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- Risk 1:350
- Significantly worsening the patient's likelihood of long-term survival
- **Discourages** the use of laparoscopic morcellation during hysterectomy or myomectomy for uterine fibroids

Health Canada May 2014



Government
of Canada

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du Canada

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Healthy Canadians



Canada

- Recognize prevalence of sarcoma
- Inform patients
- Consider alternatives

Chronology ...

AAGL

ACOG

SGO

The Washington Post

Economy

**Johnson & Johnson pulls power morcellator;
surgical device had sparked controversy**

SOGC SURVEY

43% of reported using power morcellator prior

14% had stopped

11% institution restrictions

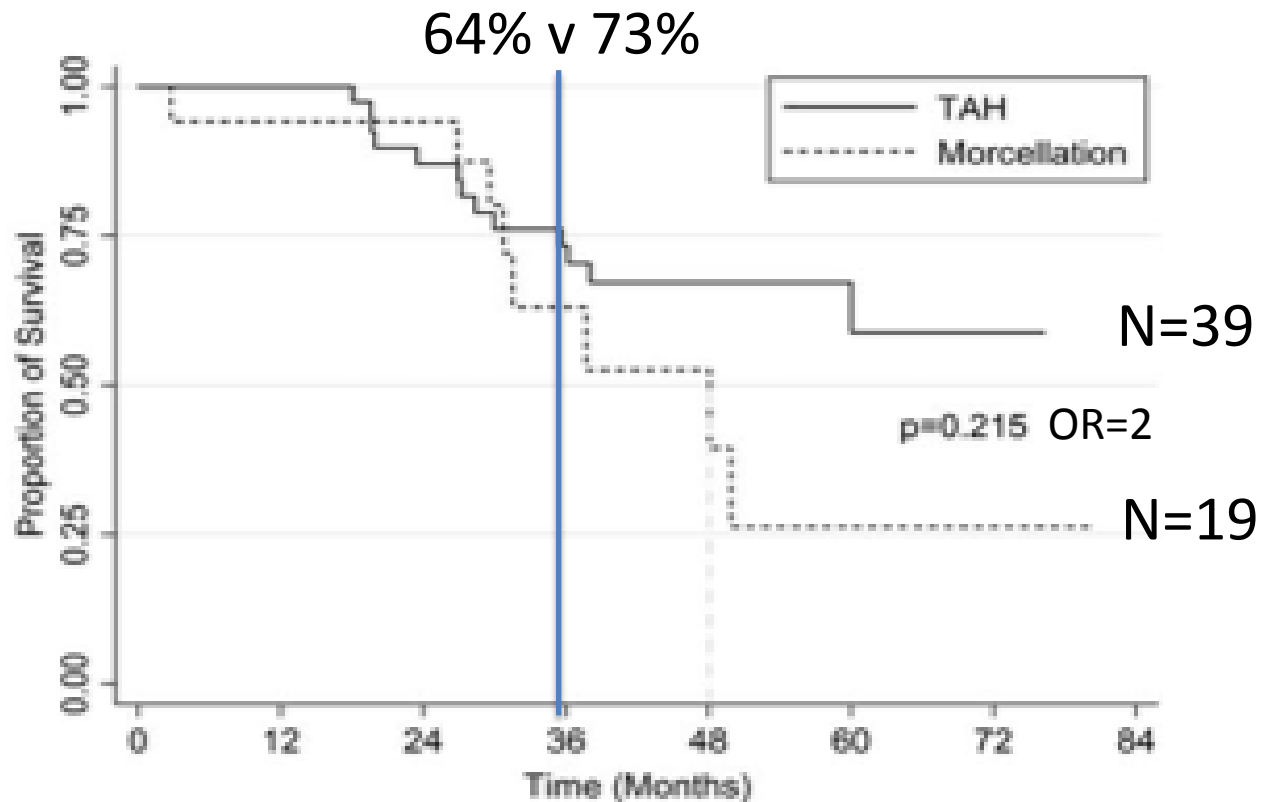
Leiomyosarcoma

Stage	Overall Survival (95% CI)¹	5-Yr Survival (SEER 2004-10)²
I Local	45.2 (31.9–58.5)	63%
II Pelvis	28.1 (18.7–37.5)	36%
III Abdo	37.6 (12.4–62.8)	
IV Distant	34.3 (15.8–52.8)	14%

¹Lim et al. 2013

²American Cancer Society May 2014

Outcomes with Sarcoma Morcellation



Number at risk								
TAH	39	39	32	25	14	8	4	0
Morcellation	18	16	14	7	4	2	1	0

Figure 2. Overall survival is illustrated from the date of initial resection according to type of surgery. TAH indicates total abdominal hysterectomy.

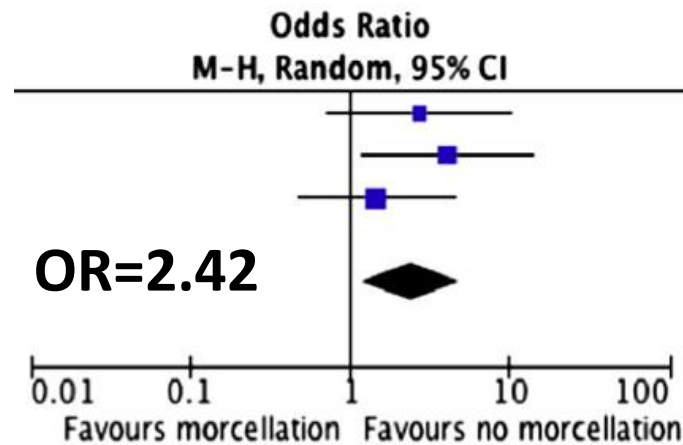
Outcomes with Sarcoma

Morcellation: Meta-analysis

- 3 Studies
- 149 patients
- F/U: 6 mo to 6 years

Overall Survival

48% Non-Morcel vs 29% Morcel



Who is at risk?

1. Increasing Age

- Mean age = 60
- Highest incidence age > 65

2. Menopausal status

3. Uterine Size / Rapid growth

4. Patient factors

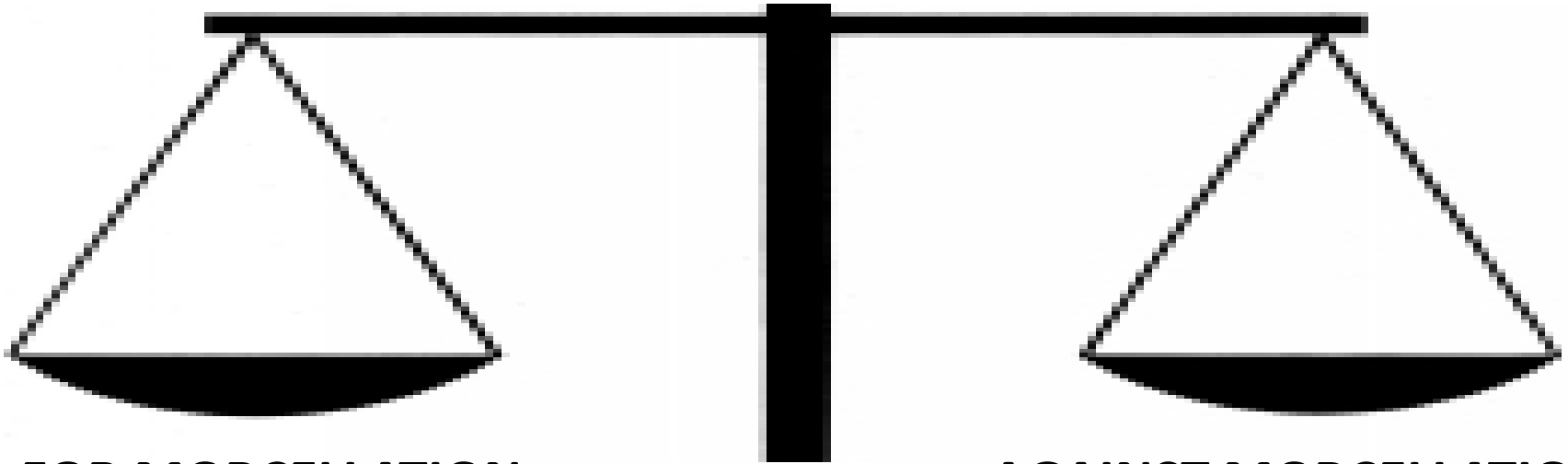
- Black (2x)
- Tamoxifen
- Previous pelvic radiation
- Hereditary Conditions (Lynch)

Pre-operative Suspicion

- 1. Cervical Cancer Screening**
- 2. Endometrial biopsy**
 - 30-84% detection rate
- 3. Ultrasound**
 - Echogenic areas: central necrosis
 - Irregular vessels
 - Low impedance / high PSV
- 4. MRI**
 - Central necrosis
 - Ill-defined margins

**There is no reliable method
for predicting or testing
whether a woman with
fibroids may have a uterine
sarcoma.**

Balancing Risks



FOR MORCELLATION

Level I evidence
Decreased morbidity,
perhaps mortality

AGAINST MORCELLATION

1/350-500 risk of occult
sarcoma
Worsens survival

Decision Analysis

Converting all hysterectomies currently using power morcellation to open surgery: increase of 17 more women dying from surgery each year and a substantial increase in morbidity

FDA Statement Nov 24 2014



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Laparoscopic Power Morcellation is

Contraindicated:

- Peri- or Post- Menopausal women
- Tissue is known or suspected to contain malignancy

Box Warning Nov 24 2014



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- Uterine tissue may contain unsuspected cancer. Use of power morcellators at fibroid surgery may spread cancer, and decrease long-term survival.
- Inform the small group of patients for whom power morcellation may be an acceptable therapeutic option that their fibroid(s) may contain unexpected cancerous tissue and that power morcellation may spread the cancer, significantly worsening their prognosis

Unanswered questions

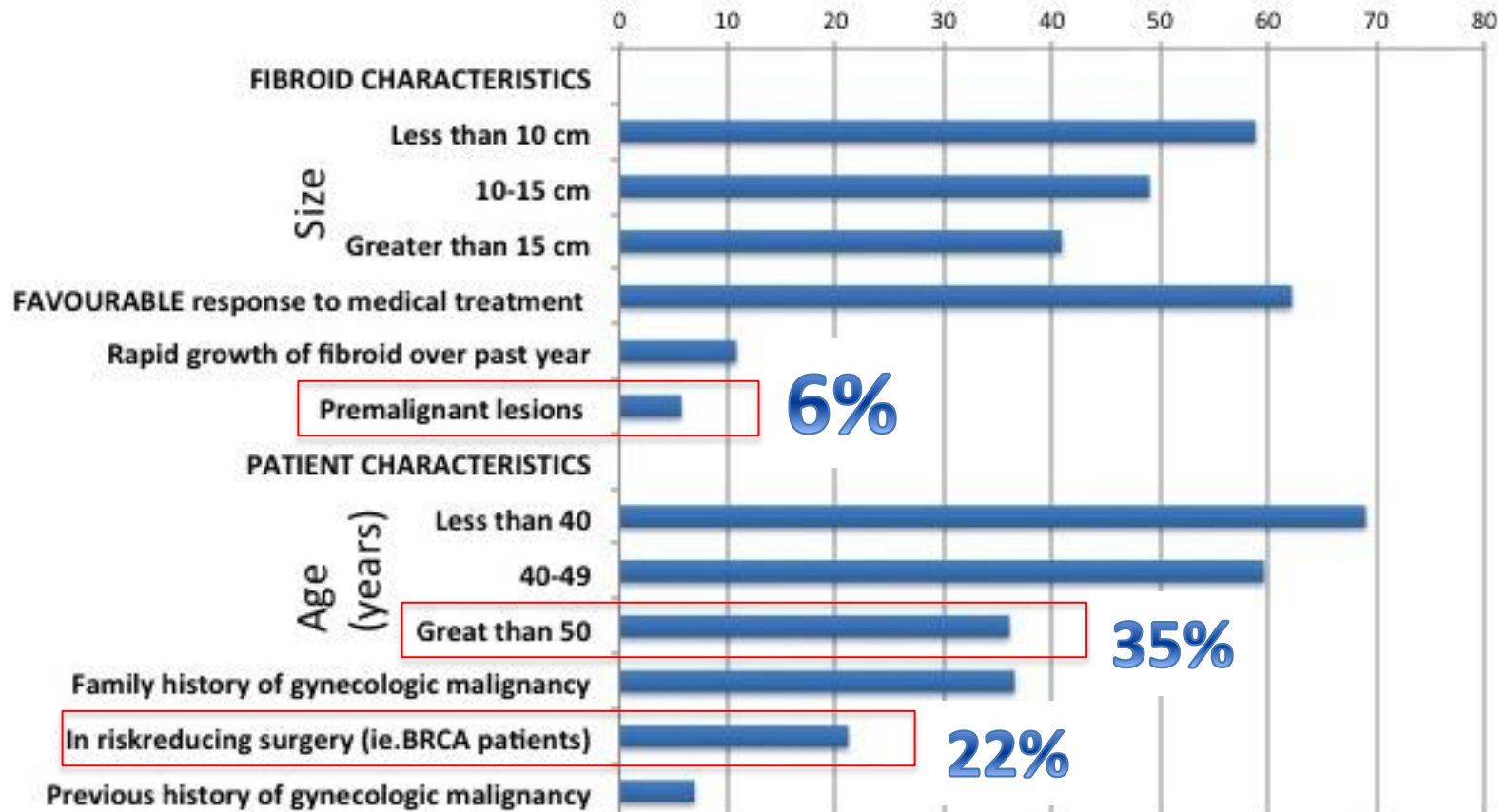
- Definition of peri-menopause
- Large group of women who undergo myomectomy for fertility-sparing surgery
- Non-fibroid indications: prolapse, horns, adenomyosis
- Non-power morcellation



- Assess all fibroids for possible malignancy
- Pre-op Ebx & Pap
- **Contraindication** to Morcellation:
 - Known or high index of malignancy suspicion
 - Hereditary cancer syndromes
- **Morcellation remains an acceptable option for specimen retrieval of benign uterine specimens BUT counsel your patients.**

Opportunity for education

Percent of respondents that would consider laparoscopic power morcellation



Implications for practice

- Choose your patient
- Appropriate work-up
- Counselling
 - risk of occult malignancy
 - risk of spread & impact on prognosis
 - injury
- Risk reduction strategies

Risk Reduction Strategies

- Power morcellation in a bag
- Mechanical morcellation in a bag
- Mini-laparotomy

Caution re: risks of other injuries

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