

Adoption of Robotic and New Technology in Gynecologic Oncology

Jason D. Wright, M.D.

Division of Gynecologic Oncology

Columbia University College of Physicians and
Surgeons

Overview

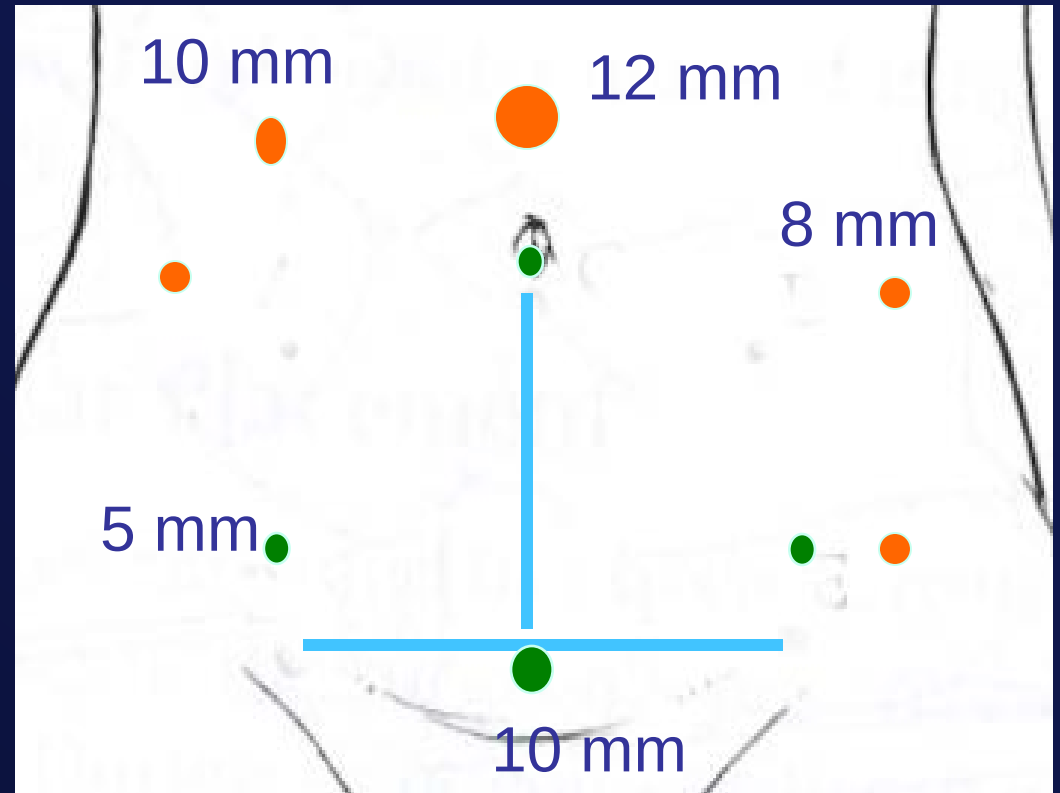
- Robotic-assisted gynecologic surgery
- Electric power morcellation in gynecology

Hysterectomy

- Hysterectomy
 - 600,000 procedures annually
 - 1 in 9 women in the US
 - Oncology (10%)
 - Benign indications (90%)

Robotic Surgery in Gynecology

- Abdominal |
- Vaginal
- Laparoscopic •
- Robotic •



Robotic Platform



Benefits of Robotic Surgery

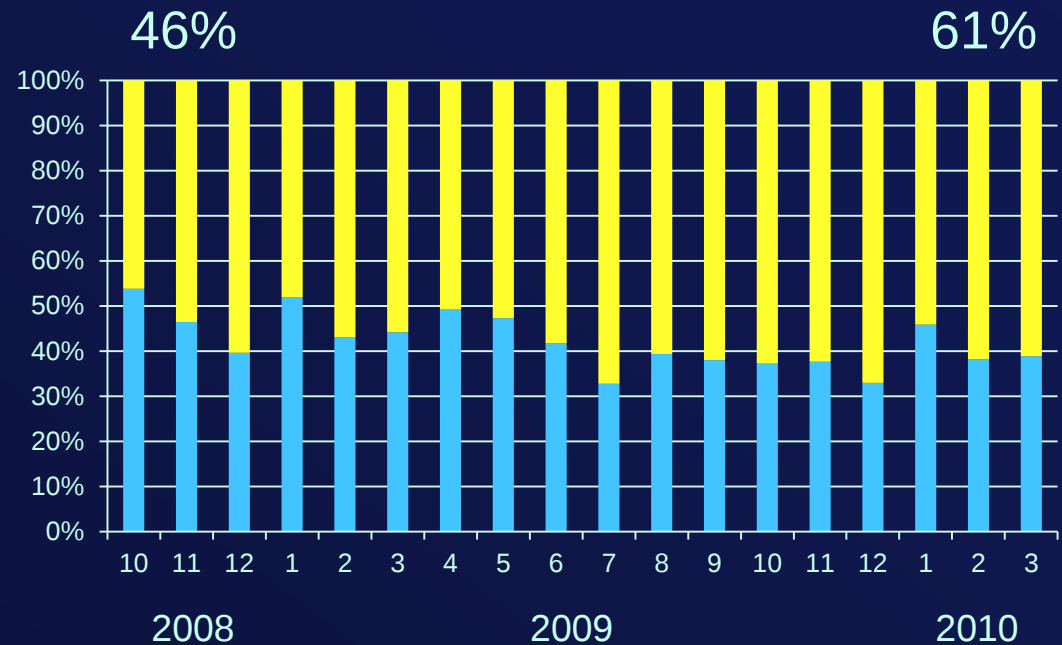
- 3-D visualization
- Increased range of motion
- Enhanced surgeon ergonomics
- *May* allow for completion of more technically challenging cases via a minimally invasive approach

Endometrial Cancer

- Meta-analysis of 8 observational studies (589 robotic, 396 LSC, 606 laparotomy)
- Robotic vs. laparotomy
 - Robotic: lower EBL, shorter LOS, longer operative time (207 vs. 130 min), fewer wound complications
- Robotic vs. laparoscopic
 - Robotic: lower EBL (92 vs. 182 ml)
- No difference in lymph node yield

Utilization of Robotic Hysterectomy

- 2008-2010
- 2464 patients identified
- Laparoscopic
 - N=1027 (41.7%)
- Robotic hysterectomy
 - N=1437 (58.3%)



Morbidity

	Laparoscopic	Robotic	<i>P-value</i>
Any morbidity	9.8%	8.1%	
Intraoperative complications	4.0%	3.0%	NS
Surgical site complications	1.8%	2.9%	NS
Medical complications	4.9%	2.9%	0.01
Transfusion	3.2%	2.2%	NS
Prolonged length of stay	11.4%	9.9%	NS
Readmission	0%	0.1%	NS
Non-routine discharge	1.9%	1.5%	NS
Death	0.2%	0.1%	NS

*No statistically significant differences in any category in multivariate models

Cost

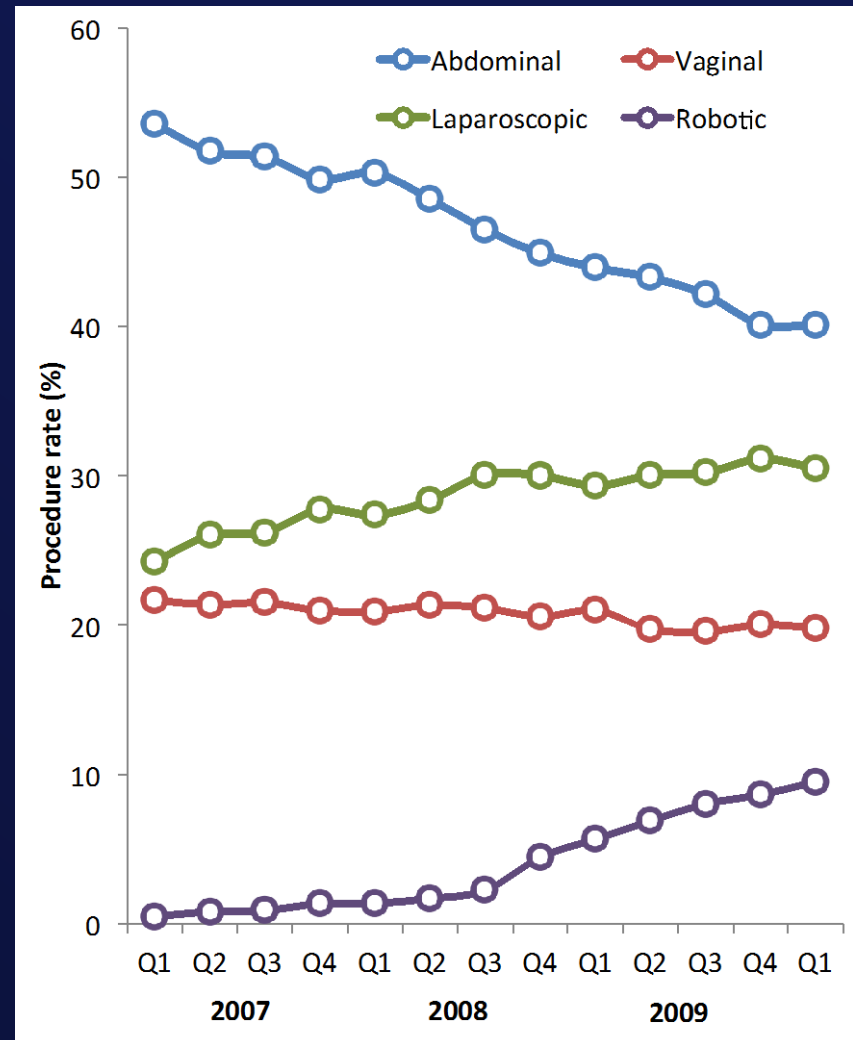
- Mean cost
 - \$8996 laparoscopic
 - \$10,618 robotic + \$1622
- Adjusted model
 - \$1291 (95% CI, \$985-\$1597) greater for robotic surgery
- Cost higher for low compared to high volume surgeons for both procedures

Robotic Hysterectomy for Benign Indications

- Cochrane review
 - 2 prospective trials, 158 patients
 - Robotic surgery not associated with improved effectiveness or safety
- Meta-analysis of observational data
 - 6 studies
 - Outcomes equivalent to laparoscopy
 - Operative times and cost higher for robotic

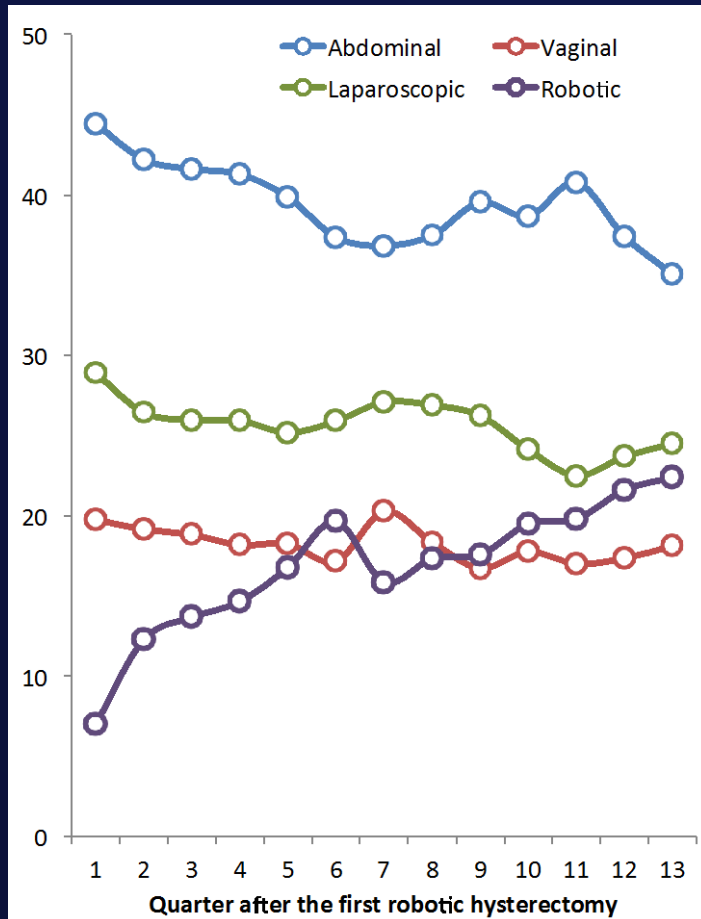
Robotic Hysterectomy for Benign Indications

- 2007-2010
- 264,758 patients

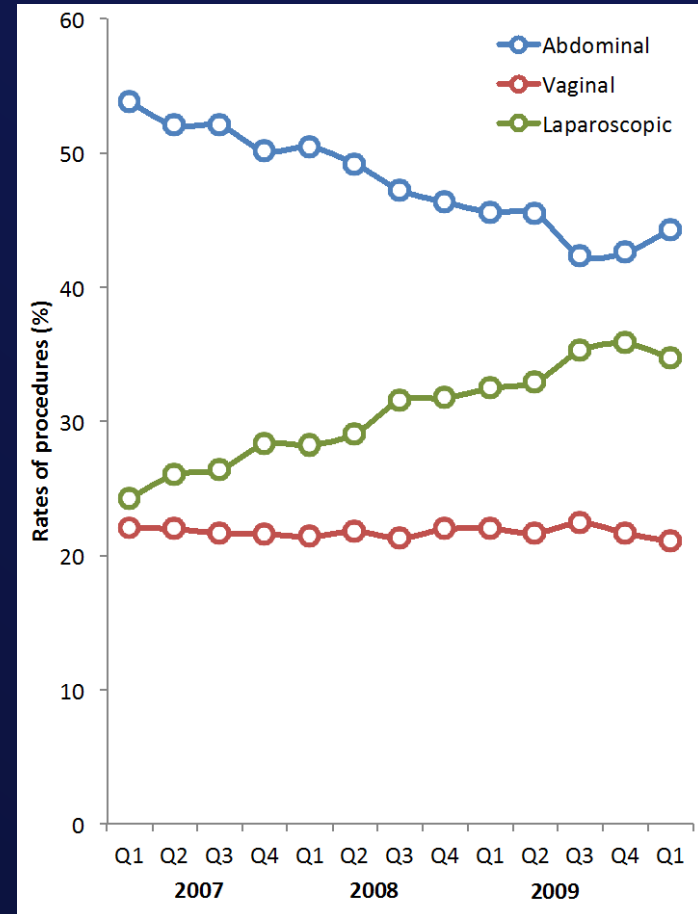


Robotic Hysterectomy for Benign Indications

Hospitals that performed robotic hysterectomy



Hospitals that did *NOT* perform robotic hysterectomy



Outcomes

- Morbidity
 - Robotic superior to laparotomy
 - *No* difference robotic and laparoscopy
- Cost
 - Robotic vs. abdominal +\$2317 (95% CI, \$2168-2465)
 - Robotic vs. laparoscopic +\$2189 (95% CI, \$2073-2377)

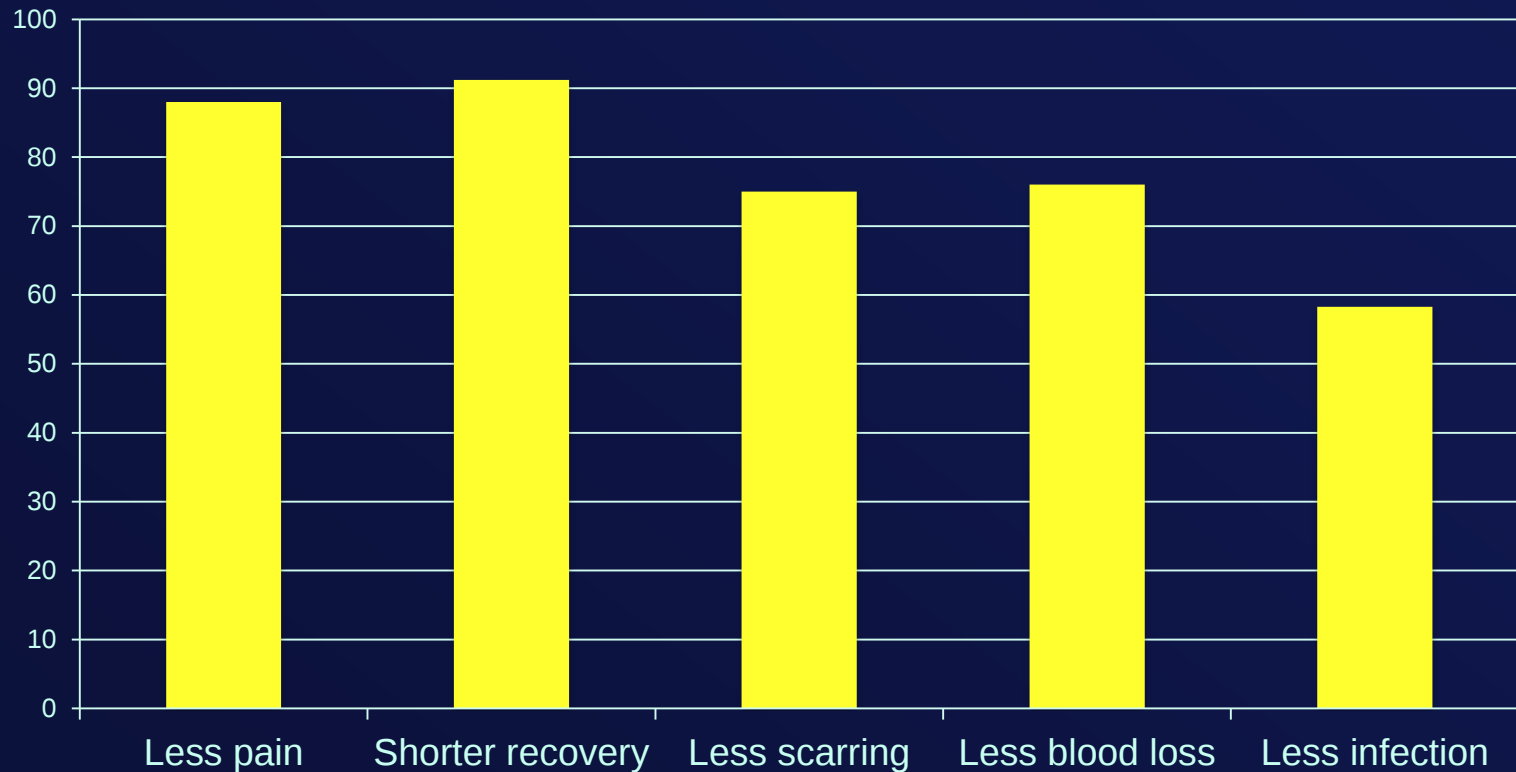
Cost

- Fixed costs
 - Laparoscopic \$3040
 - Robotic \$4002
 - Adjusted +\$962 (95% CI, \$878-1047)
- Variable costs
 - Laparoscopic \$3493
 - Robotic \$4700
 - Adjusted +\$1207 (95% CI, \$1110-1304)

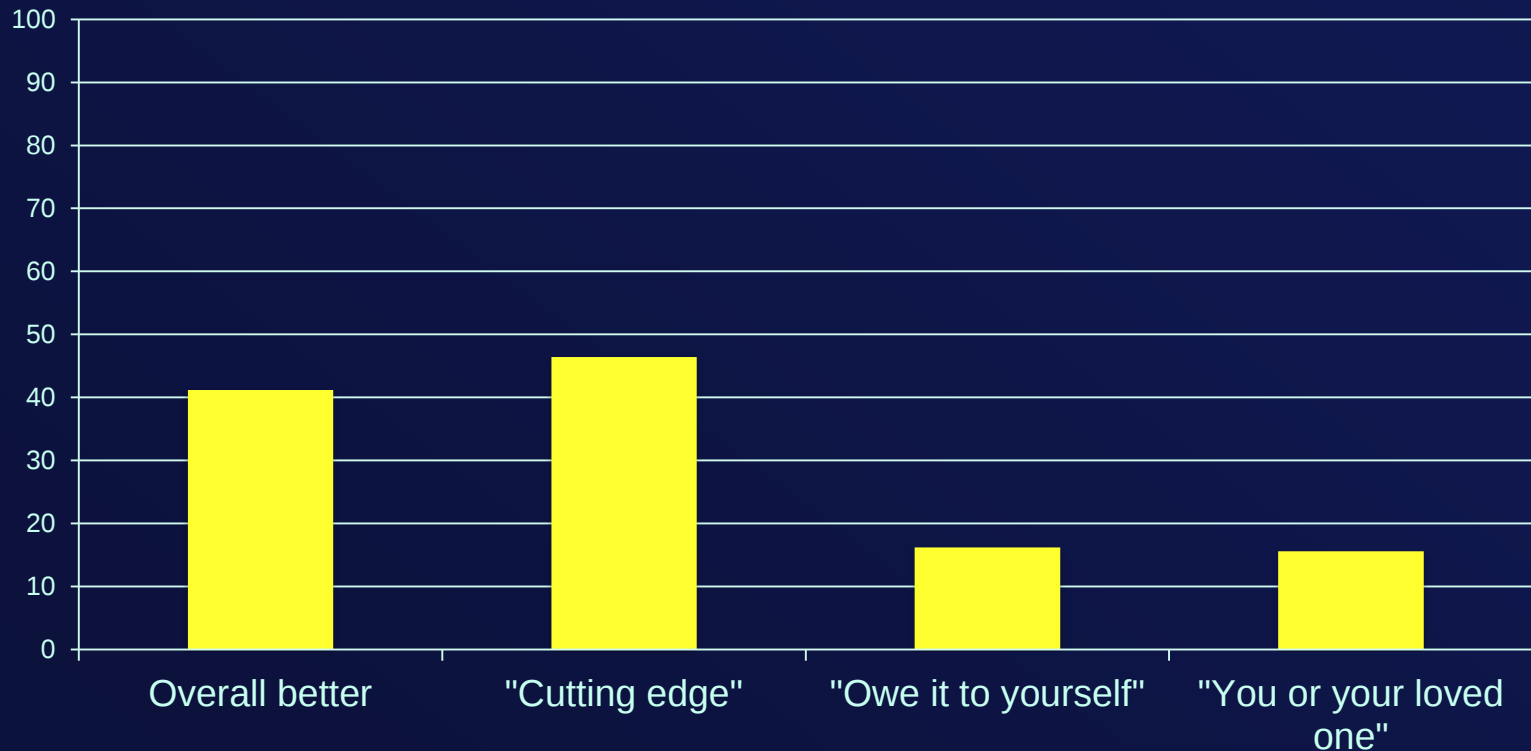
Drivers of Robotic Gynecologic Surgery

- Traditional methods of data collection
- Reimbursement policy
- Regulation
- Marketing

Marketing of Robotic Gynecologic Surgery



Marketing of Robotic Gynecologic Surgery



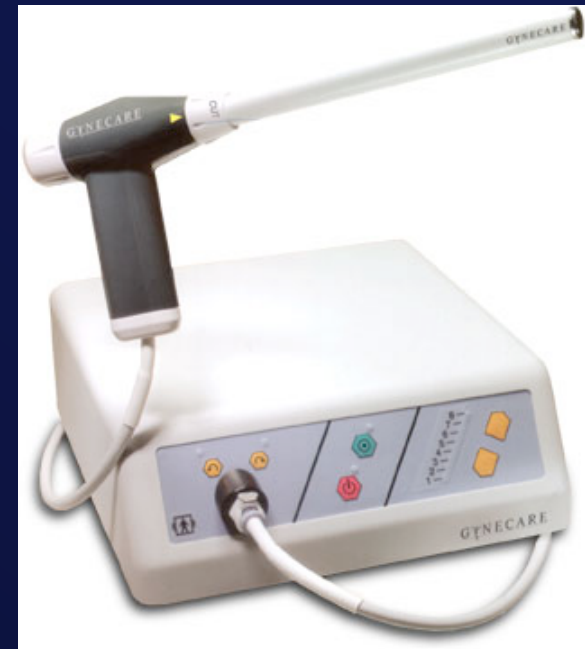
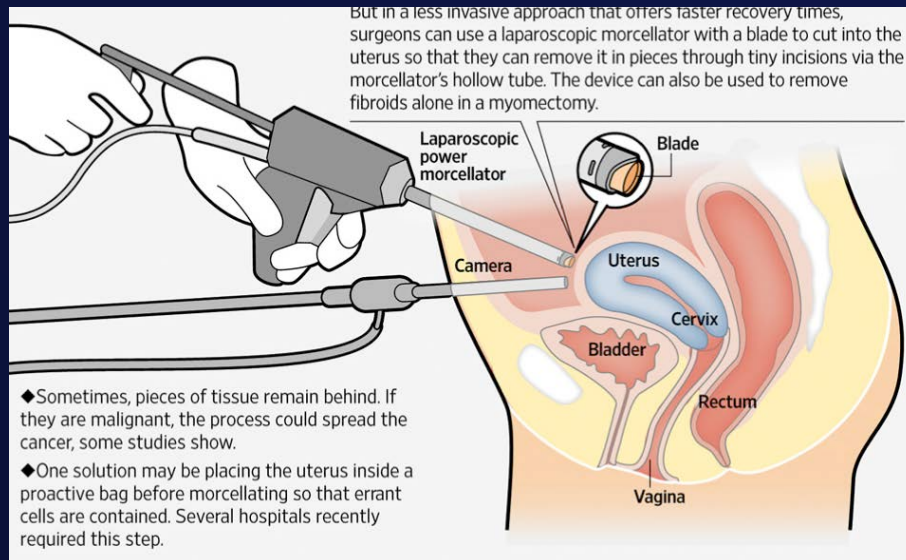
Electric Power Morcellation

Removal of the Uterus

- Challenge of removal of parenchymal organ
- Vaginal removal of the uterus
- Morcellation
 - Vaginal morcellation
 - Scalpel through colpotomy
 - Minilaparotomy
 - Laparoendoscopic single site (LESS)
 - Electric power morcellation

Electric Power Morcellation

- First described in 1993
- Variety of morcellators are approved by the FDA
- Passed through a 12-20 mm incision



Controversy Surrounding Morcellation

THE WALL STREET JOURNAL. U.S.

WORLD CUP 2014 » GOAL ALERTS SUI 2 vs 1 ECU FINAL FRA 3 vs 0 HON FINAL

U.S. NEWS

Doctors Eye Cancer Risk in Uterine Procedure

Popular Technique to Remove Growths Comes Under Question

Email Print 20 Comments f t + in A A

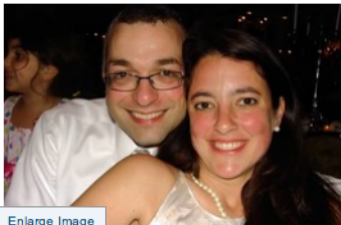
ARTICLE FREE PASS
Enjoy your free sample of exclusive subscriber content. \$2 A WEEK SUBSCRIBE NOW

By JENNIFER LEVITZ CONNECT

Updated Dec. 18, 2013 1:21 p.m. ET

An increasingly popular method of removing common uterine growths is coming under assault by some doctors worried about the risk of spreading a potentially deadly cancer.

Brigham and Women's Hospital, a prominent Boston medical center, said Tuesday it plans to impose new limits on the procedure, called morcellation. And Massachusetts General Hospital said it expects to change what it tells women about possible risks from the technique. The Harvard University-affiliated hospitals said they believe the dangers remain very small.



Enlarge Image

Amy Reed and her husband, Hooman Noorchashm, have launched a campaign against a procedure to remove uterine fibroids. *Hooman Noorchashm*

The changes come as four Boston-area doctors have submitted a draft article to the New England Journal of Medicine calling for a moratorium on the procedure, which involves using a power tool to grind up fibroids—growths in the uterus—or the uterus itself so the pieces can be removed through small incisions used in minimally invasive surgery.

The article says a much higher number of women than previously thought have

- October 2013 hysterectomy with electric power morcellation
- Disseminated LMS
- Petition to ban procedure begins
- December 18, 2013 WSJ article published

Potential Concerns with Electric Power Morcellation

- Intra-abdominal organ injury
- Dissemination of malignant disease
- Dissemination of benign disease

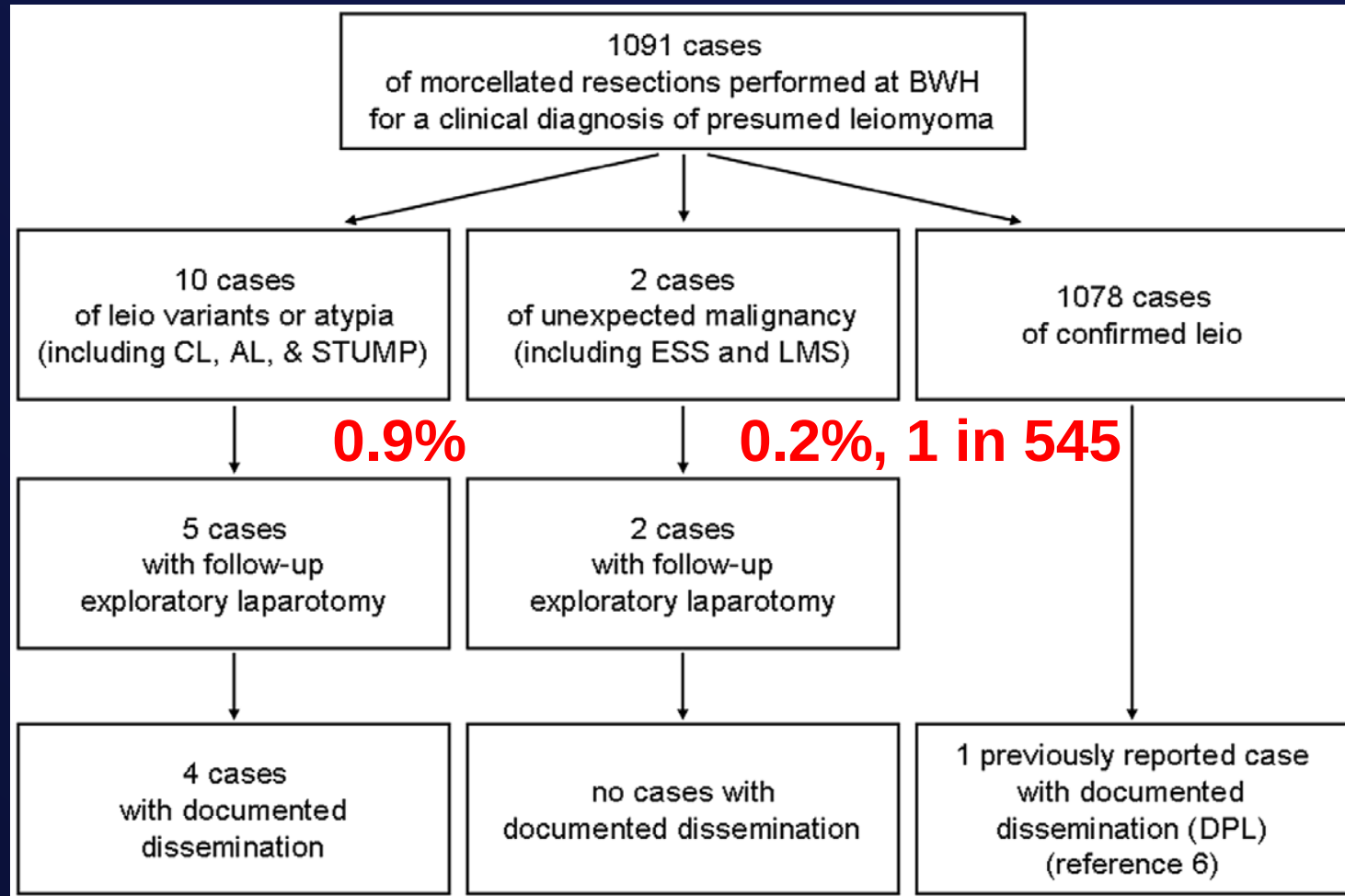
Intraabdominal Organ Injury

- Review of FDA device database (MAUDE) and published literature 1993-2013
- 55 complications
- 66% identified intraoperatively
- Substantial underreporting

Cancer Associated with Apparent Fibroids

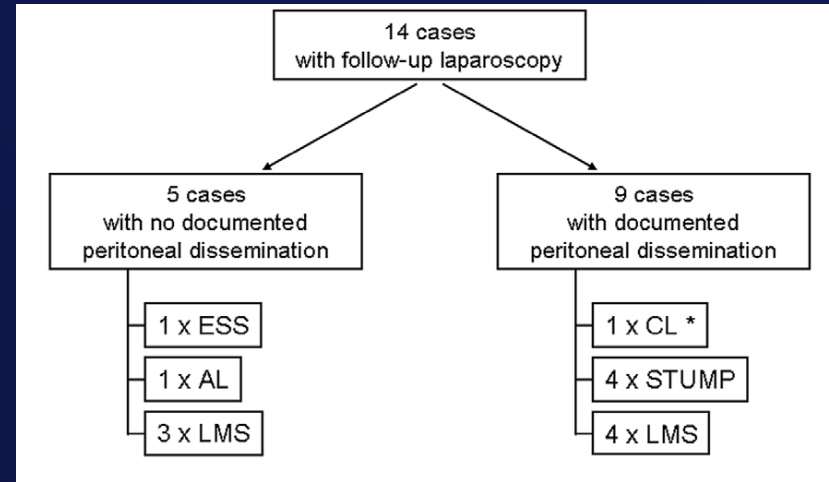
- Focus on leiomyosarcoma
- Series of 1432 women who underwent hysterectomy for presumed leiomyoma
 - LMS in 0.49%
- Incidence of LMS increased with age:
 - 40's (0.2%), 50's (0.9%), 60's (1.4%), 70's (1.9%)

Prevalence of Cancer



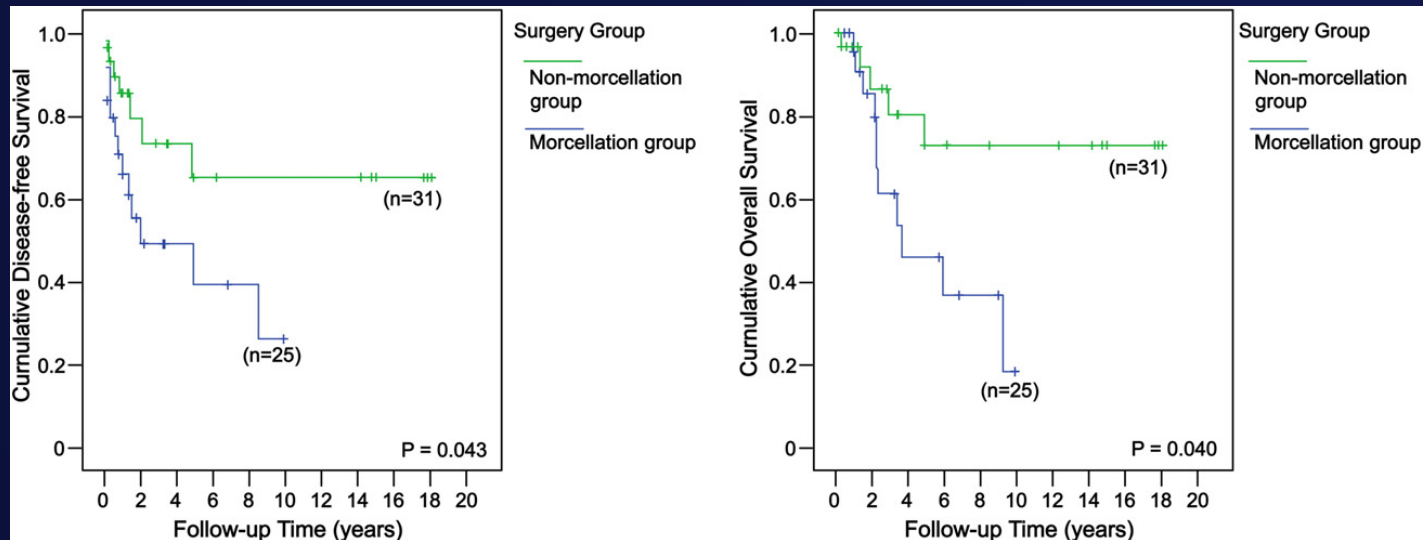
Dissemination of Sarcoma

- Morcellator-based dissemination: 64.3%
- Leiomyosarcoma and variants
- Death in 3 of 4 LMS patients with dissemination
- Median survival 24.3 months



Dissemination of Sarcoma

- 56 stage I/II LMS
- 31 morcellated
- Increased risk of death with morcellation, multivariable HR=3.11 (95% CI, 1.07-9.06)



Other Pathology

- Epithelial endometrial tumors
- Disseminated peritoneal leiomyomatosis
 - Series of 12 patients with parasitic myomas
 - 10 of 12 prior abdominal surgery
 - 8 prior morcellations
- Intraperitoneal adenomyosis (0.6%)
- Possible risk of endometriosis



FDA Advisory (1)



U.S. Department of Health and Human Services



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

[A to Z Index](#) | [Follow FDA](#) | [FDA Voice Blog](#)

Search FDA



[Home](#)

[Food](#)

[Drugs](#)

[Medical Devices](#)

[Radiation-Emitting Products](#)

[Vaccines, Blood & Biologics](#)

[Animal & Veterinary](#)

[Cosmetics](#)

[Tobacco Products](#)

Medical Devices



[Home](#) > [Medical Devices](#) > [Medical Device Safety](#) > [Safety Communications](#)

Medical Device Safety

[Safety Communications](#)

[Information About Heparin](#)

[Medical Device Safety Archive](#)

[Tubing and Luer Misconnections:
Preventing Dangerous Medical
Errors](#)

Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication

Date Issued: April 17, 2014

Audience:

- Health Care Providers
- Medical Professional Associations
- Cancer Advocacy Organizations
- Health Care Facilities/Hospitals
- Women with Symptomatic Uterine Fibroids who are Considering Surgical Options
- Manufacturers of Devices used for Minimally Invasive Surgeries

Medical Specialties: Pathology, Internal Medicine, Nursing, Obstetrics/Gynecology, Oncology

After the FDA Advisory

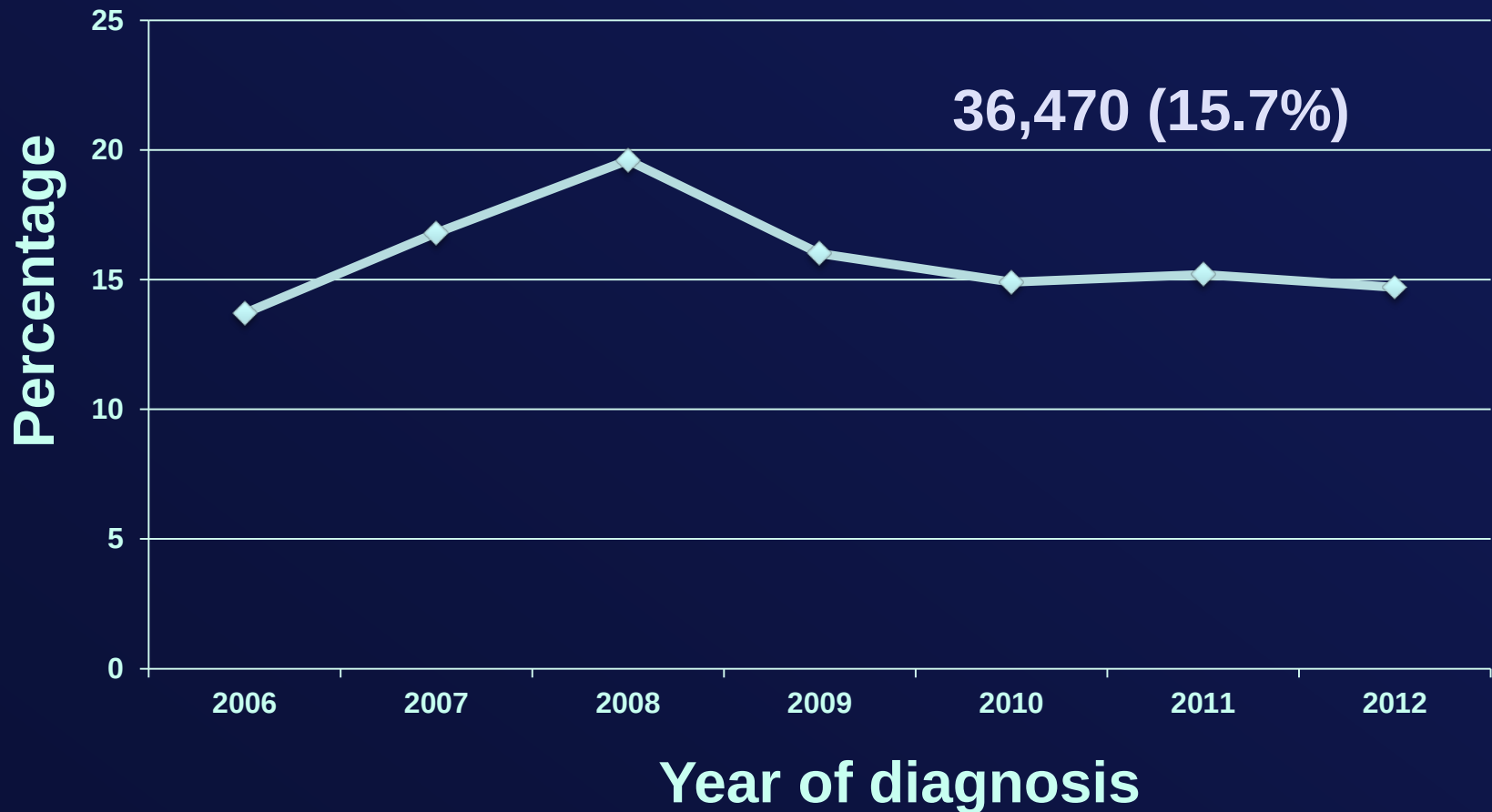
- Afternoon of April 17, 2014
 - Boston centers ban all morcellation
- April 28, 2014
 - Johnson and Johnson (Ethicon) remove their electric power morcellator from the market
- Institutional policies rapidly implemented and very diverse

FDA Medical Devices Advisory Committee (2)

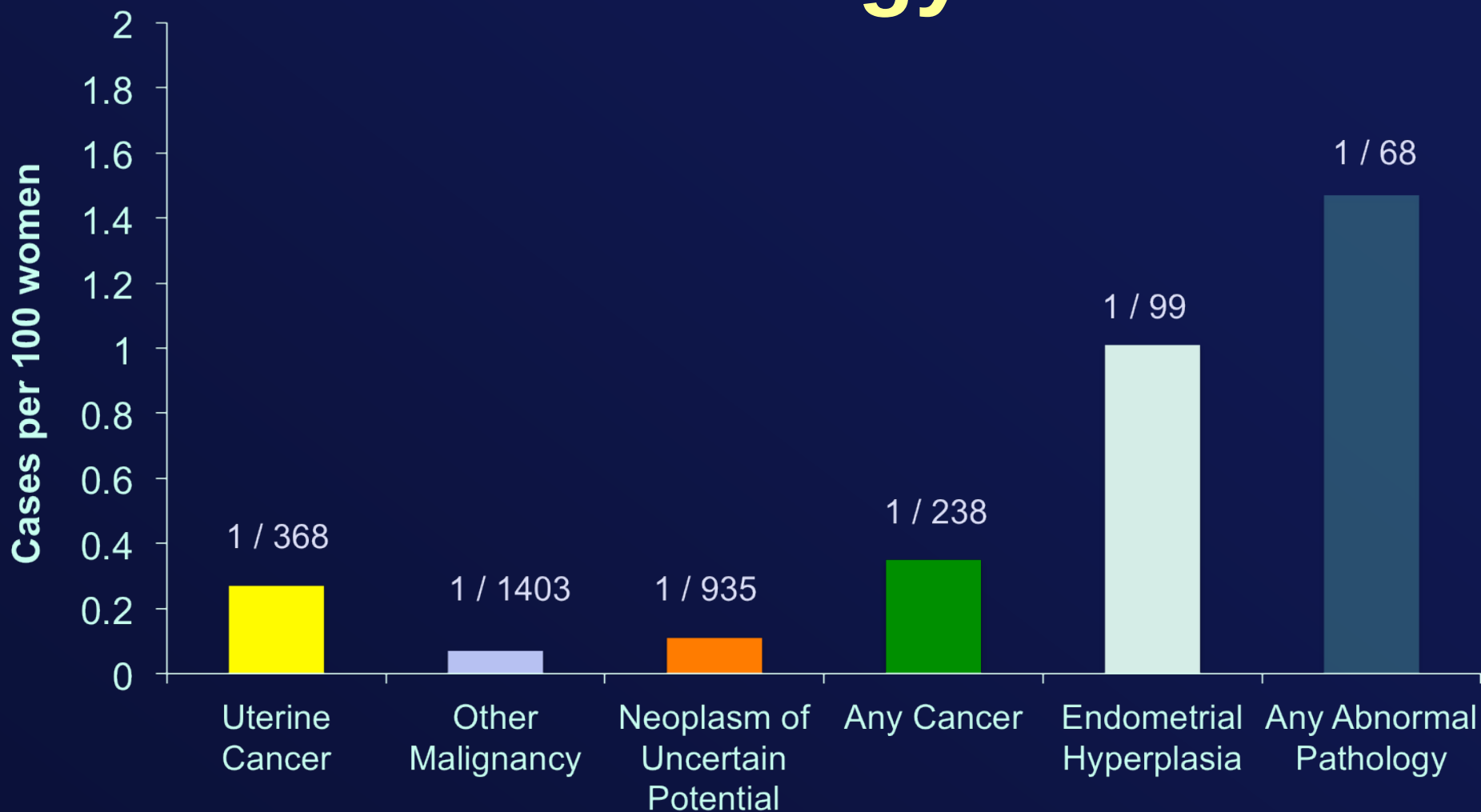
- July 11, 2014
- FDA literature review
 - 18 studies
 - Sarcoma 1 in 352 (LMS 1 in 498)
 - *Not* studies specific to morcellation
- AAGL
 - Sarcoma 1 in 7400

**What is the Prevalence of
Cancer in Women Who
Undergo Electric Power
Morcellation?**

Utilization of Morcellation



Pathology



Predictors of Uterine Cancer

	Cancer	Indeterminate smooth muscle neoplasms
<40 years	0.06%	0.02%
40-49 years	0.13%	0.12%
50-59 years	0.60%	0.20%
≥60 years	2.45%	0.08%

Policy Changes

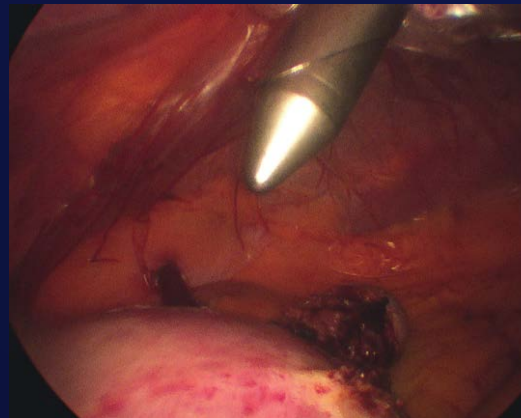
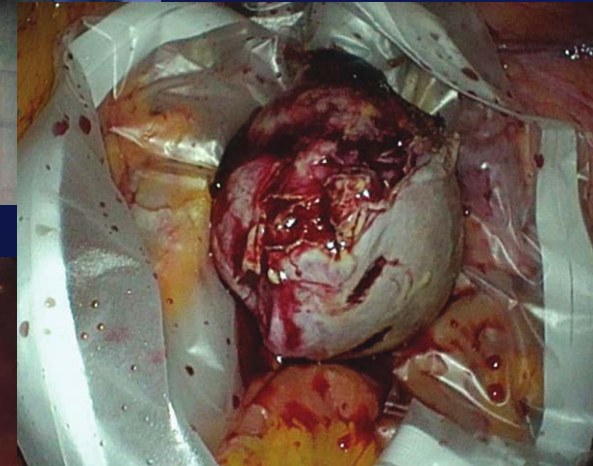
- Prevalence estimates (7/23/14)
- Worldwide market recall of most commonly used power morcellator (7/30/14)
- Changes in reimbursement policy (8/2/14)

Updated FDA Guidance (3)

- November 24, 2014
- Power morcellators contraindicated:
 - In which tissue is known or suspected to contain malignancy
 - For peri or postmenopausal women who are candidates for en bloc tissue removal

Morcellation Within an Isolation Bag

- Case series of 73 patients
- 50 x 50 cm isolation bag
- In bag power morcellation



Are There Any Women Who Benefit from Power Morcellation

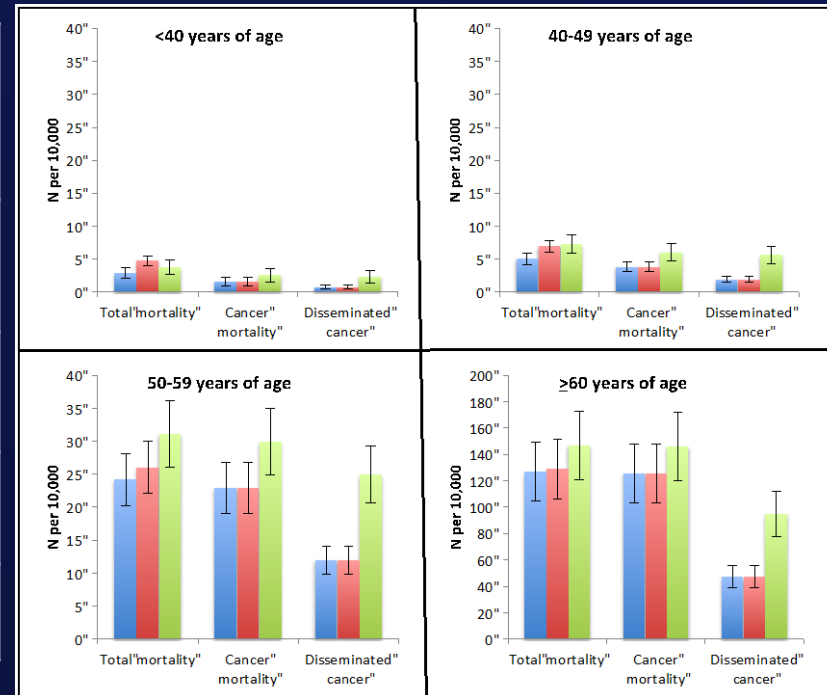
- Computer-simulation state-transition Markov model
- Compared 3 modalities of hysterectomy:
 - Abdominal
 - Laparoscopic (LAVH or TLH)
 - Laparoscopic with power morcellation

Risks and Benefits

Main simulation

Rates per 10,000 women (morcellation vs. TAH)

	Total Mortality	Cancer-Associated Mortality	Disseminated Cancer
<40 yo	-0.97	0.94	1.57
40-49 yo	0.30	2.21	3.75
50-59 yo	5.07	6.99	12.97
≥60 yo	18.14	20.05	47.54



THE WALL STREET JOURNAL.

U.S.

More Health Insurers Take Action to Curb Morcellator Use

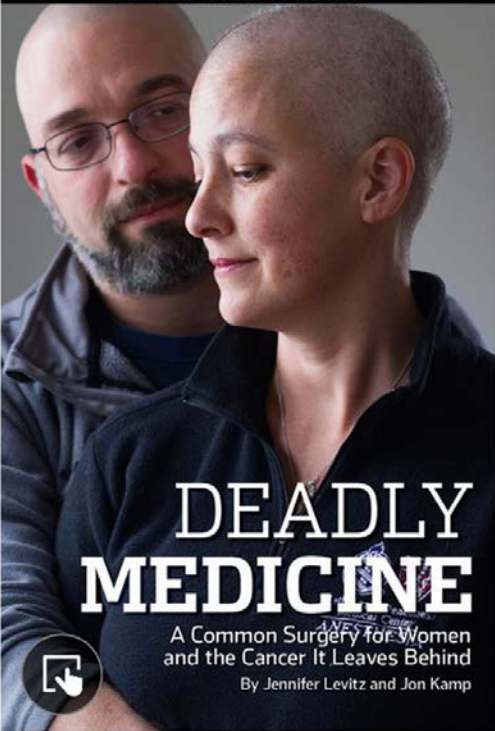
New policies further sideline once-popular medical device in wake of regulators' warnings

U.S.

FBI Is Investigating Hysterectomy Device Found to Spread Uterine Cancer

The morcellator surgical tool was found to spread uterine cancer, and the FBI is examining what the largest maker of it, Johnson & Johnson, knew about the hazards

THE WALL STREET JOURNAL.



DEADLY MEDICINE

A Common Surgery for Women and the Cancer It Leaves Behind

By Jennifer Levitz and Jon Kamp

The story of a common surgery for women and the cancer it leaves behind.

Conclusions

- Robotic gynecologic surgery and electric power morcellation demonstrate difficulty of surgical innovation
- Current debate demonstrates the power of public opinion and non-medical factors