Update on Power morcellation and Uterine Fibroids

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What is all the fuss?

- Background of LMS
- Power morcellation
- Recent events surround the case of Dr Amy Reed
- 12 months on...
- Into the future
Leiomyosarcoma (LMS)

- Smooth muscle cancer arising from uterus/fibroid
- Absolute risk 0.1-2 in 1000**

Clinical presentation
- Rapid growth in the premenopausal state – not absolute
- Growth in the post menopausal state

Staging
- I – confined to uterus, no nodes
- II – growing outside uterus but confined to pelvic organs, no nodes
- III – growing into tissues around pelvis and abdomen
- IV – growing into bladder and bowel
Leiomyosarcoma

- Prognosis 5yr survival
  - Localised (I): 63%
  - Regional (II and III) 36%
  - Distant (IV): 14%

Current Treatment strategy
- Surgical clearance
- Radiation and Chemotherapy??

Staging of invasion of disease; *not after morcellation*
Power morcellation

- **1995**: The FDA approves the first laparoscopic power morcellator
- Allows Minimally invasive surgery to progress
Case of Dr Amy Reed

- **2012:** Researchers review the medical records of 1091 women who underwent morcellation for uterine masses presumed to be fibroids at Brigham and Women's Hospital in Boston from 2005 to 2010. 9-fold higher than the 1 in 10,000 rate; <1 in 1000
- Concluded: sarcomas have a very poor prognosis even if they are removed intact.

- **October 2013:** Boston-based anesthesiologist Dr Amy Reed undergoes minimally invasive surgery with power morcellation at Brigham and Women’s Hospital. She later finds out that the mass is cancerous.

- Dr. Reed's husband, cardiothoracic surgeon Dr. Hooman Noorchashm, launches a campaign against morcellation.
How did it get so bad so quickly?

- Crusading Dr?
- Internet /facebook
- Friends in high places
- etc

- Don’t under estimate the fight of a wounded tiger
F.D.A. Discourages Procedure in Uterine Surgery

Doctors should stop using a procedure performed on tens of thousands of American women a year in the course of uterine surgery, because it poses a risk of spreading cancerous tissue, the Food and Drug Administration said Thursday.

The procedure, power morcellation, involves using a device to cut tissue into pieces that can be pulled out through the tiny incisions made during minimally invasive surgeries. The device, known as morcellators, were used to remove uteri and various other organs in procedures, including those for uterine fibroids.

Johnson & Johnson Praised for Taking Uterine Surgery Tools Off Market

By Katie Thomas, The New York Times
July 31, 2014

Johnson & Johnson, which has come under withering criticism for its response to problems with some of its medical devices, won cautious praise from critics on Thursday for its decision to withdraw three products used in uterine surgery because of a risk of spreading cancerous tissue, only months after the safety issue became widely known.

Some experts continued to debate the medical value of the devices. A handful of other, smaller companies sell similar products.
• **December 2013:** *The Wall Street Journal* publishes its first article about Dr. Reed's case, Dr. Reed's case and another in the past 14 months have prompted discussions at the hospital's top levels. It says the hospital issued a note to medical staff in early December warning that morcellation of an occult tumor may occur in 1 in 400 to 1 in 1000 women who have this procedure.
The FDA announces that, after reviewing the current literature, it concludes that the risk of morcellating an unsuspected uterine sarcoma is 1 in 352.

FDA then makes a recommendation to ‘discourage the use of power morcellation’.
How did it get so bad so quickly?

- Crusading Dr?
- Internet /facebook
- AAGL and ACOG
- Johnson & Johnson
  - 2.5 billion pay out to 8000 pxs; metal hips
  - Johnson & Johnson is also facing more than 30,000 lawsuits involving its pelvic mesh implants
- Storz
- Asia & Europe
- AGES
12 months on...

- Re-evaluate the risk of sarcoma in uterine fibroids
  - 1:1000?
  - 1:350?
- Wide range of reporting denominator?
- Uterine sarcoma in hysteroscopic resection of fibroids
  - remove all fibroids?
  - which fibroids?
  - Tests?
Reliability of pre operative tests

- Ca 125
- LDH
- USS
- MRI
- CT

- Few are reliable
- Overcall of results on MRI
- Degenerating fibroids
- Liquefaction of fibroids
Some facts
- 600,000 hysterectomies a year in the USA
- 30% in 2004 to 60% in 2014 done via MIS
- Up to 150,000 morcellated

‘When compared with hysterectomy through laparotomy, MIS results in a decrease of blood loss, transfusion, pulmonary complications, infection, thromboembolic events, hospital stay, and postoperative pain with an improvement in quality of life, body image, and return to baseline function (Level I evidence).’
AAGL replies…

- Estimates risk of uterine sarcoma to range from 1:360 to 1:7400. Thus, the risk of an undetected leiomyosarcoma is not zero, but is low.
- Risk of upstaging based on morcellation alone is unclear – very limited data.
- ‘leiomyosarcoma is an aggressive malignancy, and outcomes are suboptimal whether morcellation is used or not.’
- The key question is whether the proven benefits of MIS are outweighed by the low risk of disseminating a leiomyosarcoma through power morcellation.
AAGL replies...

- ‘the mortality from open hysterectomy was 0.085%, while the mortality from laparoscopic hysterectomy with power morcellation was 0.077%.’

- 150,000 needing morcellation a year

- ‘Converting all hysterectomies currently undergoing power morcellation to open surgery would result in an annual increase of 17 more women dying from surgery each year, and a substantial increase in morbidity from open surgery.’
Into the future... back to the future

- Clinical suspicion
- MRI
- Options... don’t hold onto your uterus but your dear life...

- INFORMED CONSENT

- Laparotomy
- Laparoscopy /robotic
- Hysterectomy vs myomectomy
Back to the future...

Offer morcellation in a bag
- Longer and more tedious operation
- Requires a 2.5cm umbilical incision
- Extra ports
- Much more technically challenging

- Informed Consent
- Patient decides

- 16 pxs suitable patients for laparoscopic Myomectomy since June
- 14 opted for the bag
- 2 declined the bag
Your future is whatever you make it. So make it a good one.
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