Tissue Extraction using Morcellation

CON: It is not safe

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Gynecologic Oncology
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MORCELLATION & FDA

• FDA Statement; 17 April 2014;
• For use in sarcomas; upstaging
• Confusion..
• Released opinion almost all of scientific institutions.
• Conclusions;
  – inform the patient..
  – If there is suspicion of sarcoma;

"DO NOT USE MORCELLATION!!"

‘Upstaging’
Uterine Leiomyosarcoma

<table>
<thead>
<tr>
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<th>n</th>
<th>yaş</th>
<th>Takip/ay</th>
<th>(%)5y DFS</th>
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<tbody>
<tr>
<td><strong>LGESS</strong></td>
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<tr>
<td>Morc(-)</td>
<td>27</td>
<td>45</td>
<td>64</td>
<td>84</td>
</tr>
<tr>
<td>Morc(+)</td>
<td>23</td>
<td>43</td>
<td>66</td>
<td>55</td>
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<tr>
<td><strong>LMS</strong></td>
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<tr>
<td>Morc(-)</td>
<td>31</td>
<td>47</td>
<td>52</td>
<td>65</td>
</tr>
<tr>
<td>Morc(+)</td>
<td>25</td>
<td>46</td>
<td>27</td>
<td>40</td>
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</tbody>
</table>

MORCELLATION & QUESTIONS

- What is the risk of sarcoma in patients with a presumed fibroid
- How to diagnose a uterine sarcoma and distinguish it from a fibroid
- What are the complications of morcellation
- How to prevent morcellation complications
- Recommendations on clinical management in patients with fibroids
Risk for sarcoma?

- FDA meta-analysis of 18 studies:
  - Sarcoma risk for fibrioid thought to 0.28%
    - LMS incidence: 0.64 / 100,000
- Literature:
  - 0.49 % (1/204) --- 0.056 % (1/1788)
- European meta-analysis: 0.14%
  - In myomectomy 0.08% (1/1306).
  - In hysterectomy to 0.15% (1/650).

Laparoscopic surgery

• The advantages of laparoscopic surgery
  – Include small incisions,
  – Less postoperative pain,
  – Short hospital stay,
  – Earlier recovery and improved quality of life during the postoperative period.

• One of the challenges of laparoscopic surgery
  – To retrieve the specimen after excision without or with minimal spillage.

Medeiros LR, Cochrane Database Syst Rev. 2009
Methods of removal for specimens excised laparoscopically:

- Posterior Colpototomy
- Minilaparatomy (suprapubic, transumbilical, ancillary port-site)
- Posterior colpotomy + endoscopic bag
- Trocar port + endoscopic bag
- Safety compartment technic
FDA, April 2014,

84% of gynecologist has changed procedure

- 58% Mini LT
- 25% TAH
- 39% suprareccival Hyst.

Gue et al, 2015
Trends in Mode of Hysterectomy After the FDA Power Morcellation Advisory

Route of hysterectomy among patients with leiomyomas by year (n, %). A. 2013 (n=268). B. 2014 (n=195). C. 2015 (n=176).

Type of hysterectomy among patients with leiomyomas by year (n, %). A. 2013. B. 2014. C. 2015.

Brigham and Women's Hospital, Boston

Ottarsdottir H, Obstet Gynecol. 2017
Impact of Surgery on the Evolution of Uterine Sarcomas.

• Median DFS
  – 6.3 months in morcellation cases,
  – 11.9 months in vaginal fragmentation cases,
  – 149.9 months in nonmorcellated cases (p < .002).

• No statistically significant differences in prognosis were related to myomectomy versus hysterectomy.

• There were significant differences between morcellation and nonmorcellation cases.

Cusido M, J Minim Invasive Gynecol. 2015
Open or L/S
57 uterine sarcoma: 25 leiomyosarcoma, 19 carcinosarcoma, 9 endometrioid stroma sarcoma, 3 adenosarcoma

Ebner F, J Turk Ger Gynecol Assoc. 2018
Survival Associated With Morcellation

n: 111
No morcellation
76 (68%)
Power morcellation
8 (7.2%)
Nonpower morcellation
27 (24%)

Bennett TR: OBSTETRICS & GYNECOLOGY, 2016
A retrospective MITO group study (n: 125)

- 24.8%: power morcellation (L/S)
- 21(16.8%): non power morcellation during open surgery
- 73(58.4%): non morcellation during open procedures
- Morcellation or power morcellation experienced 3-fold increase risk of death in comparison to patients who had not morcellation (p=0.02)

Raspagliesi F, Gynecol Oncol. 2017
Morcellation
( Power vs Non power)

- Re-exploration → Stage III
- 33% : Power morcellation
- 7% : Nonpower morcellation.
  – Total recurrence (58% and 55.5%)
  – Abd recurrence (100% and 29%).

Tantitamtd T, Gynecol Minim Invasive Ther 2018
General Principles for specimen removal

- Curative surgery OR Palliative surgery
  - No seeding
  - No contamination
  - No fragmentation

- The surgeon must be adept at techniques that allow mass removal without intracorporeal rupture

Sisodia RM, Clin Obstet Gynecol. 2015
Forty-seven year old patient with peritoneal metastases of leiomyosarcoma during second-look laparoscopy 6 weeks after morcellation of a uterus with assumed leiomyoma.

Günthert AR, Am J Obstet Gynecol. 2015
Hysterectomy with morcellation had a better.....???

64 patients 15 underwent morcellation...

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Morcellation yes</th>
<th>Morcellation no</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median OS (years)</td>
<td>10.6</td>
<td>6.4</td>
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<tr>
<td>5Y-OS rate</td>
<td>76.0 %</td>
<td>54.8 %</td>
<td>0.115</td>
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<tr>
<td>Median RFS (years)</td>
<td>9.6</td>
<td>6.5</td>
<td></td>
</tr>
<tr>
<td>5Y- RFS rate</td>
<td>64 %</td>
<td>42.8 %</td>
<td>0.104</td>
</tr>
<tr>
<td>5Y Recurrence rate</td>
<td>23.0 %</td>
<td>43.2 %</td>
<td>0.204</td>
</tr>
<tr>
<td>5Y local Recurrence rate</td>
<td>6.7 %</td>
<td>11.7 %</td>
<td>0.579</td>
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<table>
<thead>
<tr>
<th></th>
<th>Morc(+)</th>
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<th>Moorc (-)</th>
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<td>FIGO</td>
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<td>I</td>
<td><strong>66.7</strong></td>
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<td>42.9</td>
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<td>II–IV</td>
<td>20.0</td>
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<td>55.1</td>
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<td>Na</td>
<td>13.3</td>
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<td>Grading</td>
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<td>1</td>
<td><strong>33.3</strong></td>
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<td>2</td>
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<td>18.4</td>
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<td>3</td>
<td>33.3</td>
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<td>40.8</td>
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<tr>
<td>X</td>
<td>6.7</td>
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<td>22.4</td>
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<td>Total residual</td>
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<td>tumor classification</td>
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<tr>
<td>R0</td>
<td><strong>26.7</strong></td>
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<td>42.9</td>
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<tr>
<td>R1</td>
<td>0.0</td>
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<td>8.2</td>
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<td>R2</td>
<td>6.7</td>
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<td>32.7</td>
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<td>Laparotomy</td>
<td><strong>20.0</strong></td>
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<td>81.6</td>
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<tr>
<td>Laparoscopic</td>
<td><strong>46.7</strong></td>
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<td>8.2</td>
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<td>Vaginal</td>
<td>26.7</td>
<td></td>
<td>4.1</td>
<td></td>
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<tr>
<td>Switch</td>
<td>6.7</td>
<td></td>
<td>6.1</td>
<td></td>
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</tbody>
</table>
Decision algorithm proposed by the ESGE

Patient having indication for fibroid morcellation

TVU: necrosis and high vascularity

TVU: no necrosis and high vascularity

≥ 40 years

< 40 years

Additional characteristics
- postmenopause
- US/MRI single fibroid
- US/MRI size largest fibroid ≥ 8 cm
- LDH elevated
- Abnormal uterine bleeding

Not reassuring

Counsel against morcellation

Reassuring

Counsel on minimal invasive management including morcellation

Brölmann H, Gynecol Surg, 2015
After a follow-up of at least 6 months, these women remained disease free (range, 6–36 months). The final case of leiomyosarcoma occurred in the preoperatively defined low-risk group.

Günthert AR, Am J Obstet Gynecol. 2015
Fig. 1. Preoperative diagnostic flowchart.
Women with sarcoma vs women with fibroids (n: 66)

- **Older** (62.1 ± 10.1 vs 46.5 ± 6.6; P < .0001),
- **Postmenopausal** (81.8% vs 9.2%; P < .0001),
- **Nonuterine malignancy** (16.7% vs 4.6%; P = .02).
- **Subserosal** (69.4% vs 34.8%; P < .0001),
- **Solitary vs multiple** (56.3% vs 18.5%; P < .0001).
- **Rapid growth** (16.7% vs 4.6%; P = .02).

Chen I, JSLS.2018
Tissue containment system

• “The PneumoLiner is intended to contain morcellated tissue in the very limited patient population for whom power morcellation may be an appropriate therapeutic option – and only if patients have been appropriately informed of the risks,”

• “This new device does not change our position on the risks associated with power morcellation. We are continuing to warn against the use of power morcellators for the vast majority of women undergoing removal of the uterus or uterine fibroids.”

• “We want to be clear that, although the device has been shown to successfully contain morcellated tissue, it has not been proven to reduce the risk of cancer spread during surgery.”

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements
• There are no imaging tests proven completely accurate or reliable laboratory markers to distinguish between uterine sarcomas and uterine fibroids. Pre-procedure or pre-operative tests, including endometrial biopsies (tissue sampling), cannot reliably predict the presence of a hidden uterine sarcoma.

• The containment system has not been proven to reduce the risk of spreading cancer during these procedures, and is intended to be used only in a limited patient population, including women without uterine fibroids undergoing hysterectomy and some pre-menopausal women with fibroids who want to maintain their fertility.
Thank You

Dont Forget !
Morcellation->Upstaging
Upstaging-> Poor Prognosis
Is open surgery the solution to avoid morcellation of uterine sarcomas? A systematic literature review on the effect of tumor morcellation and surgical techniques

• There is no reliable diagnostic tool to differentiate a fibroid from a uterine sarcoma preoperatively. The general incidence of sarcomas is generally low. Tumor morcellation occurs in various open and closed surgical techniques and is not limited to laparoscopic surgery only. There is an urgent need for a presurgical diagnostic parameter.
Spillage, Contamination, Dissemination,

• The risk of spillage of the cyst contents is associated with complications such as:
  – Pseudomyxoma peritonei (mucinous ),
  – Chemical peritonitis (dermoid cyst),
  – The potential dissemination of malignancy.
  – Trocar site metastasis
  – Unexpected Sarcoma

The spillage rates of dermoid cysts
- 15 and 100% laparoscopy; 4 to 13% laparotomy.

Chemical peritonitis
- 0.22 and 8% (pelvic adhesive disease, bowel obstruction, abdominal wall abscesses, fistulas, detrimental impact on fertility)

Shamshirsaz AA, JSLS 2011; Nezhat CR, JSLS 1999; Kondo W, BJOG 2010
Specimen extraction

• Tissue removal must be performed in an expeditious manner
• The route of retrieval must not compromise patient safety, either intra or postoperatively.
• How to get overcome ??
FDA News Release

FDA allows marketing of first-of-kind tissue containment system for use with certain laparoscopic power morcellators in select patients

Agency continues to warn against use of laparoscopic power morcellators for removal of uterus or uterine fibroids in the vast majority of women

For Immediate Release

April 7, 2016

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494650.htm
Günthert AR, Am J Obstet Gynecol. 2015
Vaginal morcellation: A new strategy for large gynecological malignant tumor extraction: A pilot study (n: 8)

The vaginal morcellation following oncologic principles is a feasible method that permits a rapid uterine extraction and may avoid a number of unnecessary laparotomies. Further studies are needed to confirm the oncological safety of the technique.

Favero G, Gynecologic Oncology, 2012
Vaginal extraction of large uteri with the Alexis retractor

Laparoscopic Single-Incision Supracervical Hysterectomy for an Extremely Large Uterus with Bag Tissue Extraction.

Guan X, J Minim Invasive Gynecol. 2017
Umbilical Zigzag Incision

VIDEOLAR
‘easy-to-make’ bags ‘homemade’

- Surgical glove fingers (powder-free),
- Condoms
- Plastic bags.
  - Inexpensive,
  - Simple to make
  - Available in a choice of sizes,
  - No quality control !!!

Yao CC, Surg Laparosc Endosc Percutan Tech 2000
General Principles for specimen removal

- Care must be taken to ensure that the integrity of the bag is not violated during these processes as a cut in the bag will allow dispersion of tissue into the abdomen and incision with potential spread of malignant tissues.

- Open morcellation in the abdomen outside of a bag should be avoided if at all possible. When there is reasonable suspicion that a mass may be malignant, extension of an incision (mini-laparotomy) with intact removal is preferred.

Sisodia RM, Clin Obstet Gynecol. 2015
<table>
<thead>
<tr>
<th>Ref</th>
<th>Number</th>
<th>Recur, %</th>
<th>RFS (m)</th>
<th>Abd-pelvic recurr, %</th>
<th>Died of disease, %</th>
<th>Survival outcome</th>
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</thead>
<tbody>
<tr>
<td>Park</td>
<td>31 vs 25</td>
<td>22 vs 52</td>
<td>10 Vs 9</td>
<td>14 Vs 37</td>
<td>19 vs 44</td>
<td>5 yDFS: 65% versus 40%; P=0.04 OS: 73% versus 46%; P=0.04*</td>
</tr>
<tr>
<td>George</td>
<td>39 vs 19</td>
<td>51 vs 73</td>
<td>39 vs 10</td>
<td>20 vs 85</td>
<td>13 vs 42</td>
<td>3 y OS: 73% vs 64%</td>
</tr>
<tr>
<td>Bogani</td>
<td>127 vs 75</td>
<td>39 vs 62</td>
<td>9 vs 39</td>
<td>29 vs 48</td>
<td></td>
<td></td>
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<tr>
<td>Gao et</td>
<td>6 vs 11</td>
<td>50 vs 38</td>
<td>90 vs 60</td>
<td>71 vs 66</td>
<td></td>
<td>5 y RFS 43.5% vs 24% OS 43% vs 37.8%</td>
</tr>
<tr>
<td>Raine</td>
<td>76 vs 35</td>
<td>53 vs 62</td>
<td>41 vs 72</td>
<td>40 vs 37</td>
<td></td>
<td>5 yDFS: 54% vs 44%; OS: 64 versus 74%</td>
</tr>
</tbody>
</table>

Park JY, Gynecol Oncol. 2011; George S, Cancer. 2014; Bogani G, Gynecol Oncol. 2015
‘Upstaging’
Uterine Leiomyosarcoma

- Re-exploration in patients with morcellated uterine leiomyosarcoma (15-118 days)

Disseminated intraperitoneal disease 28.5%

Oduyebo T, Gynecol Oncol. 2014
### Unexpected uterine sarcomas/age

14 ESS (low-grade 12 and high-grade 2), 9 LMS, and 1 MMT

<table>
<thead>
<tr>
<th>Age</th>
<th>Total cases (n = 4454)</th>
<th>Unexpected sarcomas (n = 24)</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤30</td>
<td>255</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>31–40</td>
<td>1208</td>
<td>5</td>
<td>0.41%</td>
</tr>
<tr>
<td>41–50</td>
<td>2601</td>
<td>9</td>
<td>0.34%</td>
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<tr>
<td>51–60</td>
<td>375</td>
<td>10</td>
<td>2.60%</td>
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<tr>
<td>&gt;60</td>
<td>15</td>
<td>0</td>
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0.54%

Chen Q, Eur J Obstet Gynecol Reprod Biol, 2018
Unexpected uterine sarcomas/age

14 ESS (low-grade 12 and high-grade 2), 9 LMS, and 1 MMT

• Re-exploration including TAHBSO, staging surgery (mean 7 days)
  – 3 patients FIGO stage (IIIb-IVb)
  – 21 patients at stage I.

• 7 patients recurred within 1-25 (mean 6.29) months including
  – 5 leiomyosarcomas,
  – 1 high-grade
  – 1 low-grade ESS.

• 4 recurrent patients with leiomyosarcomas and 1 with high-grade ESS died of disease in 1-3 months.

Chen Q, Eur J Obstet Gynecol Reprod Biol, 2018
• 4,232 hyst → 16 sarcomas, of which 11 (69%) were suspected pre-operatively
• 5 (31%) were unexpected.
• The incidence of unexpected sarcoma surgeries for uterine fibroids was 0.35% (3/851) for premenopausal women and 0.57% (1/174)
• unexpected sarcoma incidence of 0.03% uterine weight <250 grams , 15.4% (2/13) with a uterine weight >=2,000 grams.

Multini F, Am J Obstet Gynecol. 2018
## Unexpected uterine sarcomas/age

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