TISSUE EXTRACTION USING MORCELLATION

PRO: It is safe.

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Morcellation

✓ Not new event
✓ Not suggested known malignity or a higher malignant suspected pathologies
✓ The main problem arise power- electromechanical morcellation.
✓ FDA approved power morcellation in 1995 and reported warnings 2014.
✓ Many societies report their statements.

Laparoscopic myomectomy
Laparoscopic supra-cervical hysterectomy
Laparoscopic hysterectomy
Vaginal hysterectomy
Society of Gynecologic Oncology – (December 2013)⁴¹

Power morcellator is generally contraindicated in the presence of documented or highly suspected malignancy, and may be inadvisable in premalignant conditions or risk-reducing surgery.
Currently there is no reliable method to differentiate benign from malignant (LMS or ESS) before they are removed. Furthermore, these diseases offer an extremely poor prognosis even when specimens are removed intact.

Patients and doctors should communicate about the risks, benefits, and alternatives of all procedures so that a patient is able to make an informed and voluntary decision about accepting or declining medical care.

American Association of Gynecologic Laparoscopists (April 2014)⁶⁴

Most women with uterine cancer can be diagnosed prior surgical intervention.
Between 1 in 400 and 1 in 1000 women who undergo hysterectomy for presumed benign uterine myomas will be diagnosed with LMS. The prognosis of patients with LMS is universally poor and may be worsened in the setting of power morcellation.

American College of Obstetricians and Gynecologists (May 2014)

Recommend comprehensive patient counselling and including the following points in consent:
There is a risk of inadvertent LMS diagnosis when a myomectomy/hysterectomy is being performed for a benign leiomyoma (2:1000). Morcellation will increase peritoneal dissemination if LMS is diagnosed and may worsen patients’ prognosis.
Minimally invasive surgical approach decreases perioperative risks to the patient.

Food and Drug Association (April 2014)³

1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine cancer. Laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus. FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

Health Canada (May 2014)⁴

Recommends the following considerations for physicians taking care of women with uterine fibroids:
Recognize the prevalence of unsuspected uterine sarcoma in patients under consideration for hysterectomy or myomectomy for the treatment of uterine fibroids.
Consider the treatment alternatives for women with symptomatic uterine fibroids and review these options with each prospective surgical patient. Apart from a laparoscopic approach, alternative surgical procedures exist that do not require power morcellation. Also, some surgeons and centers may recommend closed morcellation in a bag as a way to reduce the risk of inadvertent spread of uterine tissue.
Be aware and inform patients that laparoscopic power morcellation of unsuspected uterine sarcoma during hysterectomy or myomectomy may disseminate the disease and negatively impact prognosis.
“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 **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.)

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

Be aware of the following new boxed warning recommended by the FDA:

1. 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.”

ACOG Statement on Power Morcellation
November 24, 2014
Washington, DC — Hal C. Lawrence, MD, (ACOG),
“We are pleased that the FDA's action takes steps to enhance patient safety while allowing the appropriate use of power morcellation in gynecologic surgery for select women. “As we have said in the past, we continue to believe that power morcellation has a role in gynecologic surgery”

Not banned need preoperative proper evaluation of cases.
After FDA statement

✓ Reduction of L/S myomectomy (19%) and hysterectomy (8.7%)
✓ Increase abdominal surgery, morbidity and mortality.
✓ The overall death higher in the laparatomy group (98 vs 103 per 100,000)

A 4.1% decrease in L/S surgery, increase complication rate (2.2-2.8%, p 0.015) and increase readmission rate (3.4-4.2%, p 0.025) (Harris et al).
Main problem with
Unexpected endometrial cancer
Unexpected uterine sarcomas (Especially)

✓ Endometrial cancer can be diagnosed with preoperative endometrial sampling having higher detection rate.
✓ Unexpected endometrial cancer rate presumed leomyoma 0-0.53%.
✓ Most unexpected endometrial cancer are endometrioid type and have favorable prognosis.

✓ Preoperative diagnosis of uterine sarcomas difficult, but some clinical, imaging findings help us for malignancy.
✓ Main problem is LMS. ESS may be diagnosed with endometrial sampling and related with endometrium or endometrial mass. Also sonographic imaging may help as not to be myoma.
# Survival of unexpected leiomyosarcomas after hysterectomy and morcellation

<table>
<thead>
<tr>
<th></th>
<th>DFS(%)</th>
<th>OS(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cases</td>
<td>53</td>
<td>60</td>
</tr>
<tr>
<td>Nonmorcellation</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Morcellation</td>
<td>40</td>
<td>46</td>
</tr>
</tbody>
</table>

Retrospective data. Probably, morcellation worsens prognosis.

Other morcellation complications

✓ Iatrogenic endometriosis (1.4% the same with and without morcellation, problems with subtotal hysterectomy)
✓ Adenomyosis (0.56%)
✓ Disseminated peritoneal leiomyomatosis (0.12-0.95% after hysterectomy, 0.2-1.25% after myomectomy with morcellation).
✓ Parasitic leiomyoma
✓ Complications related to device
Uterine sarcomas

✓ Uterine sarcomas account for 2-7% of uterine malignancies.
✓ The two most common types LMS and ESS.
✓ LMS frequent 50th years of age, ESS mainly postmenopousal.
✓ Prognosis of LMS poor and tend to be systemic metastasis or distant metastasis.
✓ No clear benefit of chemotherapy or radiation therapy for overall survival.
✓ The surgery is main treatment as en-block resection.
Prognostic factors for LMS

✓ Age
✓ Stage
✓ Size
✓ Residual tumor
✓ Mitotic count
✓ Morcellation?
Unexpected LMS

✓ 0.15-0.7 % Incidence, different rate (1/352 FDA, 1/1960-1/8300 according to restricting prospective studies)
✓ LMS incidence increase with age.
✓ Black race
✓ Long term use of Tmx.
✓ Pelvic radiation
✓ Hereditary leomyomatosis and renal cell carcinoma syndrome (fumarate hydrotase germline mutation).
✓ History of childhood retinoblastoma
✓ Routine endometrial sampling and smear-HPV DNA testing.
✓ Biochemical markers (LDH-3 (sensitivity 90%, specificity 92.3%), Ca125)
✓ Imaging
Age important for LMS

The distribution of unexpected uterine sarcomas in patients’ age.

<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>
</tr>
<tr>
<td>51–60</td>
<td>375</td>
<td>10</td>
<td>2.60%</td>
</tr>
<tr>
<td>60</td>
<td>15</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Uterine sarcoma clinical risk criteria (adapted from ACOG and AAGL statements [30,31]).

### Symptoms
- Abnormal uterine bleeding (including irregular, heavy and/or prolonged menstrual bleeding)
- Dysmenorrhea
- Palpable abdominal mass
- Lower abdominal pain
- Lumbago
- Pressure symptoms (pollakisuria, dysuria, bowel symptoms)

### Risk factors

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black race</td>
<td>Two-fold higher LMS incidence rate comparing to the white race</td>
</tr>
<tr>
<td>Increasing age</td>
<td>Mean patient age at diagnosis: 60 years</td>
</tr>
<tr>
<td>Tamoxifen</td>
<td>Lowest risk in women &lt;35 years; highest risk in women &gt;65 years</td>
</tr>
<tr>
<td>Pelvic irradiation</td>
<td>Prolonged use (≥5 years)</td>
</tr>
<tr>
<td>HLRCC syndrome</td>
<td>Association especially strong for carcinosarcoma</td>
</tr>
<tr>
<td>Survivors of childhood RB</td>
<td>AD syndrome; sarcomas often found in younger women</td>
</tr>
<tr>
<td></td>
<td>Higher risk for uterine sarcomas and sarcomas in general</td>
</tr>
</tbody>
</table>

Note: Increased uterine size, large LM and rapid uterine/LM growth increase concern for the presence of an occult sarcoma, but have not been shown to be predictive of LMS [30,59,60].

Abbreviation: AD, autosomal dominant; HLRCC, hereditary leiomyomatosis and renal cell carcinoma; RB, retinoblastoma.
**Imaging and LMS**

- Ultrasound (rounded clear margin, vascular halo in pseudo-capsule, central hypoechoic area)
- MRI. Diffusion-weighted imaging, dynamic MRI, gaddolinum MRI (100% sensitivity and specificity).
- PET-CT may be useful for postmenopausal period.
- Postmenopausal new or growing lesions require evaluation.

**Table 1**

<table>
<thead>
<tr>
<th>Method</th>
<th>Sub-method</th>
<th>Sensitivity/specificity</th>
<th>N</th>
<th>Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endometrial sampling</td>
<td>D&amp;C, EMB</td>
<td>86%/67%</td>
<td>72</td>
<td>Bansal et al. [17]</td>
</tr>
<tr>
<td>MRI</td>
<td>EMB</td>
<td>52%/35%</td>
<td>68</td>
<td>Hinchcliff et al. [20]</td>
</tr>
<tr>
<td>MRI</td>
<td>Contrast-enhanced</td>
<td>94%/96%</td>
<td>8</td>
<td>Lin et al. [19]</td>
</tr>
<tr>
<td>MRI</td>
<td></td>
<td>100%/93%</td>
<td>10</td>
<td>Goto et al. [21]</td>
</tr>
<tr>
<td>PET</td>
<td></td>
<td>100%/NR</td>
<td>5</td>
<td>Umesaki et al. [22]</td>
</tr>
</tbody>
</table>

Legend: D&C = dilation and curettage; EMB = endometrial biopsy; MRI = magnetic resonance imaging; PET = positron emission tomography.

Ultrasound criteria to evaluate uterine sarcoma risk.

Level II: Ultrasound criteria

Echo pattern (homogeneous or inhomogeneous, with mixed echogenic and poor echogenic parts)
Necrotic, cystic, hemorrhagic changes
Single lesion
Presence or absence of central vascularization\(^a\)
Distribution of tumoral vascularization: a high vascularity score\(^b\)
Size (maximal diameter >8 cm)
Presence or absence of calcifications

\(^a\) Subjective color score: 1 – no color, 2 – minimal color, 3 – moderate color, 4 – abundant color.

\(^b\) The score for both central and peripheral region are combined (maximum vascular score: 8).

Sizi et al. Eur J Obs Gyn Reprod Biol 2018
Morcellation

Hand assisted
Electromechanical or Power morcellation

Open
Contained or in bag morcellation system

Laparoscopic/robotic
Minilaparatomy
Vaginal(Colpotomy, culdotomy)
Using an incidence for LMS of 0.24%, the cost to prevent one case of disseminated disease was $10,540,832 in 2013 US dollars. Even when the incidence of occult LMS was varied from 0.08 to 0.49%, a one-way sensitivity analysis was unable to demonstrate that an abdominal approach was cost-effective. We concluded that performing an abdominal hysterectomy for all patients, to eliminate use of power morcellation, was a costly policy from a societal perspective.

Clinicopathological features of unsuspected uterine cancers after laparoscopic surgery with morcellation.

<table>
<thead>
<tr>
<th>Cases</th>
<th>Age</th>
<th>Clinical Presentations*</th>
<th>First Surgery</th>
<th>Second Surgery</th>
<th>Tumor Size (cm)</th>
<th>Histopathological Diagnosis</th>
<th>FIGO Stage [15]</th>
<th>Adjuvant Treatment</th>
<th>Follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>47</td>
<td>Pelvic mass</td>
<td>LM</td>
<td>TAHBSO</td>
<td>5</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>ANED (40)</td>
</tr>
<tr>
<td>2</td>
<td>53</td>
<td>Pelvic mass</td>
<td>LASH</td>
<td>CE, BSO</td>
<td>9</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>ANED (20)</td>
</tr>
<tr>
<td>3</td>
<td>51</td>
<td>Abdomen mass</td>
<td>LM</td>
<td>TAHBSO</td>
<td>8</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>ANED (2)</td>
</tr>
<tr>
<td>4</td>
<td>37</td>
<td>AUB</td>
<td>LM</td>
<td>TAHBSO</td>
<td>5</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>Recurrence (12); AWD</td>
</tr>
<tr>
<td>5</td>
<td>53</td>
<td>Abdomen mass</td>
<td>LASH</td>
<td>CE, BSO</td>
<td>7</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>(41)</td>
</tr>
<tr>
<td>6</td>
<td>48</td>
<td>Pelvic mass</td>
<td>LASH</td>
<td>CE, BSO</td>
<td>4</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>ANED (19)</td>
</tr>
<tr>
<td>7</td>
<td>47</td>
<td>Abdomen mass</td>
<td>LASH</td>
<td>CE, BSO</td>
<td>7</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>ANED (8)</td>
</tr>
<tr>
<td>8</td>
<td>41</td>
<td>Pelvic mass</td>
<td>LM</td>
<td>TAHBSO</td>
<td>5</td>
<td>LGESS</td>
<td>I</td>
<td>N</td>
<td>Recurrence (3)</td>
</tr>
<tr>
<td>9</td>
<td>52</td>
<td>Postmenopausal bleeding</td>
<td>LASH</td>
<td>CE, BSO</td>
<td>8</td>
<td>LGESS</td>
<td>IA</td>
<td>N</td>
<td>(41)</td>
</tr>
<tr>
<td>10</td>
<td>35</td>
<td>Dysmenorrhea</td>
<td>LM</td>
<td>TAHBSO</td>
<td>4</td>
<td>LGESS</td>
<td>IA</td>
<td>N</td>
<td>ANED (40)</td>
</tr>
<tr>
<td>11</td>
<td>49</td>
<td>Pelvic mass</td>
<td>LASH</td>
<td>CE, BSO</td>
<td>4</td>
<td>LGESS</td>
<td>IA</td>
<td>N</td>
<td>ANED (19)</td>
</tr>
<tr>
<td>12</td>
<td>38</td>
<td>AUB</td>
<td>LM</td>
<td>TAHBSO</td>
<td>4</td>
<td>LGESS</td>
<td>IA</td>
<td>N</td>
<td>ANED (14)</td>
</tr>
<tr>
<td>13</td>
<td>52</td>
<td>Abdomen mass</td>
<td>LASH</td>
<td>Staging</td>
<td>5</td>
<td>HGESS</td>
<td>IA</td>
<td>N</td>
<td>ANED (8)</td>
</tr>
<tr>
<td>14</td>
<td>51</td>
<td>Postmenstrual bleeding</td>
<td>LASH</td>
<td>Staging</td>
<td>11</td>
<td>HGESS</td>
<td>IA</td>
<td>N</td>
<td>Recurrence (1); DOD (3)</td>
</tr>
<tr>
<td>15</td>
<td>48</td>
<td>Pelvic mass</td>
<td>LM</td>
<td>TAHBSO</td>
<td>8</td>
<td>LGESS</td>
<td>IA</td>
<td>N</td>
<td>ANED (5)</td>
</tr>
<tr>
<td>16</td>
<td>47</td>
<td>Pelvic mass</td>
<td>LM</td>
<td>TAHBSO</td>
<td>4</td>
<td>LGESS</td>
<td>IA</td>
<td>N</td>
<td>ANED (27)</td>
</tr>
<tr>
<td>17</td>
<td>39</td>
<td>Menostaxis</td>
<td>LM</td>
<td>TAHBSO</td>
<td>3</td>
<td>LGESS</td>
<td>IA</td>
<td>N</td>
<td>ANED (6)</td>
</tr>
</tbody>
</table>

Abbreviations: ANED, alive with no evidence of disease; AUB, abnormal uterine bleeding; AWD, alive with disease; BSO, bilateral salpingo-oophorectomy; CE, cervical extirpation; CT, chemotherapy; DOD, died of disease; ESS, endometrial stromal sarcoma; HGESS, high-grade endometrial stromal sarcoma; LASH, laparoscopic supracervical hysterectomy; LM, laparoscopic myomectomy; LGESS, low-grade endometrial stromal sarcoma; LMS, leiomyosarcoma; MMMT, malignant mixed mesodermal tumor; NED, no evidence of disease; RT, radiotherapy; TAHBSO, total abdominal hysterectomy with bilateral salpingectomy; TAHBSO, total abdominal hysterectomy with bilateral salpingo-oophorectomy.

Annotations: *The pelvic or abdominal mass was incidentally found by abdominal/pelvic sonography.

Morcellation not mandatory for every case.
AT LEAST 1 CLINICAL CRITERIA and/or US SCORE ≥18 and/or HIGH LEVELS OF LDH ISOENZYMES

Yes: HIGH RISK
No: LOW RISK

MRI
At least 3 conventional MRI criteria OR 1 malignant MRI criteria AND/OR
high b1,000-weighted signal with mean ADC at 1.23 x 10^{-3} mm²/s or less

Yes: HIGH RISK
No: LOW RISK

CLINICAL CRITERIA:
- Age: > 35 years
- Abnormal uterine bleeding (age > 35 years)
- Rapid fibroid/uterine growth (≥20% in 6 months)
- Certain treatment (tamoxifen or pelvic radiation)
- Hereditary conditions (HLRCC syndrome, RB, Lynch II)

US SCORE TO DIFFERENTIATE/DISTINGUISH LM FROM LMS:
- Peripheral Lesion Vascularity
  1 = no blood flow, 2 = minimal flow, 3 = moderate flow, 4 = marked flow
- Central Lesion Vascularity
  1 = no blood flow, 2 = minimal flow, 3 = moderate flow, 4 = marked flow
- Echotexture
  1 = homogenous, 2 = inhomogeneous 3 = strongly inhomogeneous,
- Solitary lesion
  1 = no, 2 = yes
- Cystic degeneration
  1 = absent, 2 = present
- Echogenicity compared with myometrium
  1 = hyperechoic, 2 = isoechoic, 3 = hypoechoic
- Reproductive status
  1 = fertile, 2 = perimenopausal, 3 = postmenopausal
- Lesion size
  1 = < 3 cm, 2 = 3 – 5 cm, 3 = 5 – 8 cm, 4 = > 8 cm

MRI CONVENTIONAL CRITERIA:
- irregular margins
- presence of intratumoral haemorrhage
- presence of intra-tumoral cystic alterations
- heterogeneous enhancement
- intermediate or high T2 signal intensity
- intermediate or high T1 signal intensity
- enhanced areas
- T2-weighted signal heterogeneity
- T1-weighted signal heterogeneity
- endometrial stripe: unidentifiable, thickened or with intracavitary process
- ascites

MRI MALIGNANT CRITERIA:
- lymphadenopathy
- invasion of the mass into the bladder, rectum, pelvic side walls or other structures
- peritoneal implants
Morcellation techniques and containment systems

✓ Open morcellation during endoscopic surgery may disseminate tissue.
✓ However, open vaginal morcellation can reduce this risk.
✓ Containment systems can reduce tissue dissemination.
✓ FDA approved system
✓ However some small studies reported tissue after containment system power morcellation, the rate of dissemination decrease. Also *tumoral tissue dissemination possible before morcellation*. 
To reduce risk of tumoral dissemination

✓ To evaluate risk of malignancy and morcellation. Meticulous case evaluation.
✓ Precise surgery
✓ Use contained system and vaginal morcellation
✓ Irrigate abdominal cavity
✓ Avoid unnecessary morcellation (uterine size until 12 weeks of pregnancy also sometimes larger size can be removed without morcellation).

Inform consent and inform cases for unexpected malignancy related to worse prognosis.
CONCLUSION

✓ Morcellation is safe for low risk patients underwent endoscopic myomectomy or hysterectomy.
✓ There is no evidence that universal elimination any type of morcellation serves the intended purpose of protecting patients.
✓ Physicians should modify patient selection and surgical technique to minimize established risks and optimize benefits of the procedure.
Thank you for your attention.