Adoption of Robotic and New Technology in Gynecologic Oncology

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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

- Surgeon Console
- Patient Cart ("Robot")
- Video Cart
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

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

*No statistically significant differences in any category in multivariate models*
Cost

• Mean cost
  – $8996 laparoscopic
  – $10,618 robotic

• 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
    • Laparoendoscopy 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

- 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

1091 cases of morcellated resections performed at BWH for a clinical diagnosis of presumed leiomyoma

10 cases of leiomy variants or atypia (including CL, AL, & STUMP) - 0.9%

5 cases with follow-up exploratory laparotomy - 4 cases with documented dissemination

2 cases of unexpected malignancy (including ESS and LMS) - 0.2%, 1 in 545

2 cases with follow-up exploratory laparotomy - no cases with documented dissemination

1078 cases of confirmed leiomyoma

1 previously reported case with documented dissemination (DPL) (reference 6)
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

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

36,470 (15.7%

Wright JD, Tergas AI, Burke WM, et al. JAMA 2014;312(12):1253-5.
Pathology

- Uterine Cancer: 1/368
- Other Malignancy: 1/1403
- Neoplasm of Uncertain Potential: 1/935
- Any Cancer: 1/238
- Endometrial Hyperplasia: 1/99
- Any Abnormal Pathology: 1/68

Wright JD, Tergas AI, Burke WM, et al. JAMA 2014;312(12):1253-5.
# Predictors of Uterine Cancer

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Cancer Rate (%)</th>
<th>Indeterminate smooth muscle neoplasms Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40 years</td>
<td>0.06%</td>
<td>0.02%</td>
</tr>
<tr>
<td>40-49 years</td>
<td>0.13%</td>
<td>0.12%</td>
</tr>
<tr>
<td>50-59 years</td>
<td>0.60%</td>
<td>0.20%</td>
</tr>
<tr>
<td>≥60 years</td>
<td>2.45%</td>
<td>0.08%</td>
</tr>
</tbody>
</table>

Wright JD, Tergas AI, Burke WM, Cui RR, Ananth CV, Chen L, Hershman DL. *JAMA* 2014;312(12):1253-5.
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)
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

November 24, 2014

Updated FDA Guidance (3)
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)*

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Total Mortality</th>
<th>Cancer-Associated Mortality</th>
<th>Disseminated Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40 yo</td>
<td>-0.97</td>
<td>0.94</td>
<td>1.57</td>
</tr>
<tr>
<td>40-49 yo</td>
<td>0.30</td>
<td>2.21</td>
<td>3.75</td>
</tr>
<tr>
<td>50-59 yo</td>
<td>5.07</td>
<td>6.99</td>
<td>12.97</td>
</tr>
<tr>
<td>≥60 yo</td>
<td>18.14</td>
<td>20.05</td>
<td>47.54</td>
</tr>
</tbody>
</table>
More Health Insurers Take Action to Curb Morcellator Use
New policies further sideline once-popular medical device in wake of regulators’ warnings

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
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