HYSTERECTOMY: CURRENT CONTROVERSIES

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Disclosure

I have received grant support from Boston Scientific, American Medical Systems, Pelvalon, and Intuitive Surgical. None of these grants pertain to the CME topic discussed today.

My content will include reference to commercial products; however, generic and alternative products will be discussed whenever possible.

I do not intend to discuss any unapproved or investigative use of commercial products or devices.

CURRENT CONTROVERSIES?

49 yo G2P2 AAF with worsening menorrhagia and dysmenorrhea. She has failed management with NSAIDS. Hx/o DVT with OCPs
FH: Breast cancer in mother at age 55
PE: BMI 45  BP 160/90
  14 week mobile fibroid uterus
  Benign secretory endometrium
  Hgb 10.2

What is her “optimal” management?

Mode of hysterectomy?
  TAH?
  TVH?
  TLH with or without robotic-assistance?
  SCH?
How should the uterine tissue be extracted?
  Power morcellation?
  Vaginal morcellation?
  Laparotomy?
What should be done about the tubes and ovaries?

Objectives

Discuss the following controversies surrounding hysterectomy:
1. Optimal route of surgery
   a. Overall morbidity
   b. Morcellation
   c. Vaginal cuff dehiscence
   d. Cost
2. Cervix preservation versus removal?
3. Fallopian tube preservation versus removal?
4. Ovarian preservation versus removal?

Controversy # 1: Mode of hysterectomy
“Minimally invasive’ is an impact, not an incision.”

Ted Anderson, MD PhD, Vanderbilt University

Which mode of hysterectomy has lowest morbidity?
Vaginal > Laparoscopic > Abdominal

34 trials, N=4495

Surgical approach to hysterectomy for benign gynaecological disease (Review)

Nielson TJ, Johnson N, Lehto A, Tervander E, Carr E, Gavan R, van Voorst S, Mol BWJ, Khidere KB

Route of Hysterectomy Rates
Wright JD, et al. JAMA 2013

Robot Total costs $2189 (95% CI, $2030-$2349)

Why are rates of TVH so low?

Perceived as "difficult"
Requires specialized skill
Requires directed training

Overuse

TVH

Underuse
Increased training needed

**Costs?**

**Surgical costs**

**Hospital stay**

**Money may drive TVH training**

**Increased training needed**

**Research**

**General Gynecology**

**Hospital costs of total vaginal hysterectomy compared with other minimally invasive hysterectomy**

Sandeep Thirunavukarasu, MD; Ina Goldberg, MD, MSCP; Christin Harrington, MD

Benjamin E. Lundy, PhD; Jason M. McNiel, MBA

**OBJECTIVE:** The objective of the study was to determine total hospital costs and net hospital income for different types of minimally invasive hysterectomies and financial impact it has on patients underwent total vaginal hysterectomy (TVH) instead of their selected procedure.

**STUDY DESIGN:** A retrospective chart review was performed of patients who underwent hysterectomy for benign disease by TVH laparoscopic-assisted vaginal hysterectomy (LAVH), total laparoscopic hysterectomy (TLH), laparoscopic-assisted vaginal hysterectomy (LAVH/TA), and abdominal hysterectomy (AH) between January 2007 and April 30, 2011, at Thomas Jefferson University Hospital. The hospital revenue protection database was used to calculate net hospital income. A subset of patients with at least 1 prior vaginal delivery, no more than 1 laparotomy, and a similar gestational age than 14 weeks who had undergone BPH, TUR, or LVR was identified as potential TAH candidates. The financial impact of performing TVH from the selected hysterectomy was calculated.

**RESULTS:** Three hundred thirty-four cases of minimally invasive hysterectomy were identified. Fifty-five percent were TVH, 35% LAVH, 3% TLH, and 2% AH. Mean total hospital costs for TAH were $5,396, $12,959 for LAVH, $11,528 for TLH, and $13,439 for AH (P < .0001). Net hospital income was $1,736 for TAH. The hospital incurred losses of $3,066 for LAVH, $6,486 for TLH, and $8,426 for AH (P < .03). Our criteria to determine the mode of hysterectomy increased TVH from 23% to 36% of all minimally invasive hysterectomy.

**CONCLUSION:** Hospital costs were greater with LAVH, TLH, and AH than for TAH. The hospital incurred financial losses with LAVH, TLH, and AH. TVH was the only minimally invasive modality of hysterectomy that generated net hospital income. Our conservative criteria to determine the mode of hysterectomy would increase the number of TVHs by more than 30%.

**Key words:** cost, robotic hysterectomy, vaginal hysterectomy

**Robotic Technology Resulted in Substantially More Costs**

Despite increased and laparoscopic hysterectomy being the most cost-effective method, the use of robotic technology resulted in substantially more costs.

**Robotic Assisted vs Laparoscopic Hysterectomy Among Women With Benign Gynecologic Disease**

Jesse D. Wright, MD

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Maya S. Lewis, MD

William R. White, MD

Tom M. Pham, MD

Thomas J. Harvey, MD

Diana J. Hannah, MD

**H**ysterectomy is one of the most common gynecologic operations performed across the United States. The procedure is performed laparoscopically by minimal invasive surgery techniques. However, robotic hysterectomy has been performed extensively because of the added benefit of minimally invasive surgery. This study compares robotic hysterectomy with laparoscopic hysterectomy and reports outcomes and complications of robotic hysterectomy. It is a randomized clinical trial comparing robotic hysterectomy and laparoscopic hysterectomy. The study's primary end point was incidence of complications and secondary end point was impact on quality of life and cost outcomes. The study showed that robotic hysterectomy is a safe and effective treatment option for women with benign gynecologic disease.
Impact of robotic technology on route of hysterectomy

Retrospective medical record review of 461 hysterectomies performed from July 2007 to June 2008 (period 1) and July 2008 to June 2009 (period 2) at VCU Medical Center.

Rates of complications and routes of hysterectomy by time period were compared using fisher’s exact test and chi-square statistic, respectively.

Analyses by intention to treat

Complications
Matthews et al. AJOG, 2010

What hurts cost?

Is when a more expensive minimally-invasive route is substituted for the less expensive minimally-invasive route ie robotic instead of laparoscopic hysterectomy

OR, when any route substitutes vaginal hysterectomy

Robotic technology needs to be used sparingly in benign hysterectomy

“Its not complicated”
Controversy # 2: How should tissue be extracted?

What we know

Minimally invasive approach to hysterectomy or myomectomy results in:

- Lower EBL
- Shorter hospital stay
- Reduced pain
- Reduced incidence of VTE
- Reduced incidence of wound complications
- Shorter convalescence
- Better cosmesis

Morcellation creates a diagnostic and therapeutic challenge with occult LMS

What we know about leiomyosarcoma

It is a disease with poor prognosis

<table>
<thead>
<tr>
<th>Stage</th>
<th>Spread</th>
<th>5-year survival</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>Confined to uterus</td>
<td>60%</td>
</tr>
<tr>
<td>II</td>
<td>Confined to pelvis</td>
<td>35%</td>
</tr>
<tr>
<td>III</td>
<td>Abdominal spread, local nodes</td>
<td>28%</td>
</tr>
<tr>
<td>IV</td>
<td>Bladder / rectum or distant mets</td>
<td>15%</td>
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</tbody>
</table>
Emerging evidence

Morcellation worsens prognosis of patients with LMS
George S et al. Retrospective cohort study evaluating the impact of intrauterine morcellation on outcomes of localized uterine leiomyosarcoma. Cancer. 2014
Retrospective review of all patients w LMS 2007-2012 at Dana-Farber and BWH n=58; 19 morcellation (power and scalpel); 39 TAH

<table>
<thead>
<tr>
<th>TAH (n=39)</th>
<th>Morcellation (n=19)</th>
<th>P-value</th>
</tr>
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<tbody>
<tr>
<td>Age 56</td>
<td>49</td>
<td>0.01</td>
</tr>
<tr>
<td>Stage I 87%</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Recurrence 51%</td>
<td>74%</td>
<td>0.002</td>
</tr>
<tr>
<td>Recurrence Abd / pelvis 20%</td>
<td>86%</td>
<td>0.001</td>
</tr>
<tr>
<td>Overall survival 67%</td>
<td>58%</td>
<td>0.22</td>
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Challenges

Preoperative identification
Imaging – difficult to distinguish from benign disease
Dynamic MRI + LDH + LDH isoenzyme-3 (degenerating myomas vs. LMS)
Diffusion-weighted-imaging (DWI), apparent diffusion coefficient (ADC)
Endometrial biopsy – rarely positive
Uterine biopsy – may miss disease or seed cells
Clinical factors
“Rapid” growth
Age
African-American women twice as likely to get LMS
Pelvic radiation
Retinoblastoma gene

ACOG on Consent

Incidence of occult sarcoma, including LMS, is unknown. However, the risk estimate of approximately 2:1000 women who undergo hysterectomy or myomectomy should be discussed.

If occult malignancy is present, power morcellation increases the likelihood of intraperitoneal dissemination. It may also worsen prognosis, make a definitive diagnosis and accurate staging difficult, and result in additional surgery, medical management, or both.

If fragments of benign tissue are disseminated through morcellation, there is the possibility of seeding viable ectopic tissue as a result (e.g., leiomyoma, endometriosis, adenomyosis, and ovarian remnants). This potentially may require additional intervention.

If power morcellation is to include the use of a specimen bag, potential concerns should be discussed, including insufficient bag size, disruption of the bag by the morcellator, and reduced visualization as a result of using the bag.

Alternatives to the use of power morcellation should be discussed, including removal of intact tissue through mini-laparotomy, laparotomy, or colpotomy incisions, or by total abdominal hysterectomy, vaginal hysterectomy, or laparoscopic vaginal hysterectomy.

Decision Analysis: LH + morcellation v AH
Siedhoff et al. AJOG in press
100,000 subject hypothetical cohort
5-year time horizon
Decision: Abdominal hysterectomy vs laparoscopic hysterectomy with morcellation
Outcomes:
Transfusion, wound infection, cuff dehiscence, VTE, hernia
Leiomyosarcoma
Death from leiomyosarcoma
Assumed occult LMS cases would be FIGO stage I-II (59% death 5-yr)
Assumed morcellation would escalate to FIGO stage III (72% death 5-yr)

Utilities
Value and duration determined from literature, 1-mo increments

Decision Analysis Conclusions

Model predicted lower mortality and higher quality of life with LH
Supports existing recommendations for a minimally invasive approach to hysterectomy when feasible (ACOG, AAGL)

Strengths
Decision analysis helpful when RCT not feasible
Considers procedure-related mortality, not just mortality associated with morcellation
Evaluates additional clinical outcomes, complications
Robust in sensitivity analyses

Results

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<tbody>
<tr>
<td>Leiomyosarcoma cases</td>
<td>120</td>
<td>120</td>
<td>n/a</td>
</tr>
<tr>
<td>Leiomyosarcoma deaths</td>
<td>86 [50-353]</td>
<td>71 [41-289]</td>
<td>15</td>
</tr>
<tr>
<td>Transfusion</td>
<td>2,400 [1,300-3,500]</td>
<td>4,700 [4,300-4,700]</td>
<td>-2,300</td>
</tr>
<tr>
<td>Vaginal cuff dehiscence</td>
<td>640 [200-890]</td>
<td>290 [150-600]</td>
<td>350</td>
</tr>
<tr>
<td>Abdominal wound infection</td>
<td>1,500 [55-1,500]</td>
<td>6,300 [6,300]</td>
<td>-4,800</td>
</tr>
<tr>
<td>Hernia</td>
<td>710 [140-900]</td>
<td>4,500 [4,500-9,800]</td>
<td>-8,090</td>
</tr>
<tr>
<td>Quality-adjusted life years</td>
<td>499,171 [499,062-499,280]</td>
<td>490,711 [482,733-486,270]</td>
<td>8,460 *</td>
</tr>
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* LH experience 0.85 additional QALYs (1.02 mos) over 5 years
Conclusions regarding morcellation

The issue appears confined to power morcellation
Vaginal morcellation has been done for years without controversy
Recommendation: Remove uterine tissue through the vagina or mini-lap

Controversy #3: How to close the vaginal cuff?

Original Research
Vaginal Cuff Dehiscence in a Series of 12,398 Hysterectomies: Effect of Different Types of Colpotomy and Vaginal Closure
[Further information]

Controversy #4: Take or leave the cervix?

9 trials, N=1553
No benefit on urinary, bowel or sexual sx
Ongoing cyclic VB 16x higher
Total versus subtotal hysterectomy for benign gynaecological conditions (Review)
[Further information]
If you perform supracervical hysterectomy

You have to deal with tissue extraction....
And cyclic vaginal bleeding
And cervical cytology surveillance
For no evidence-based benefit

Controversy # 5: Take or leave the fallopian tubes?

Origin of ovarian cancer?

Paradigm Shift: The Tubal Hypothesis

Prophylactic Salpingectomy

Opportunity for Intervention

Potential decreased risk for ovarian cancer and other fallopian tube complications
Advocated by many during hysterectomy, sterilization, or other pelvic surgery
• 600,000 hysterectomies
• 700,000 tubal sterilizations
Proposed as a temporary measure for BRCA carriers wishing to avoid oophorectomy

Hysterectomy
Tubal Sterilization
• Interval
• Postpartum or Cesarean
Other Pelvic or Abdominal Surgery
### Risk: Benefit Ratio of Salpingectomy

**Benefits?**
- Potential reduction in ovarian cancer
- Reduction in re-operation for benign disease

**Risks?**
- Potential decrease in ovarian blood flow
- Operative complications

### Complications of Retained Fallopian Tubes

- Hydrosalpinx
- Retained Fallopian Tubes
- Hydatid Cyst
- Tubal Prolapse/Torsion
- Chronic PID/TOA

### Ovarian Blood Supply

### Tubal Sterilization Considerations

**Salpingectomy most effective tubal sterilization method**

*Women should routinely be offered salpingectomy*


### Controversy # 5: Take or leave the fallopian tubes?

This actually isn’t a controversy: Take the tubes!

### Controversy # 6: Take or leave the ovaries?
Ovarian Conservation at the Time of Hysterectomy for Benign Disease

William H. Parker, MD, Michael S. Broder, MD, WMH, Zhimei Liu, MD, Donna Shipp, MD, Cindy Forger, MD, and Jonathan S. Berel, MD, PhD

Variation in Ovarian Conservation in Women Undergoing Hysterectomy for Benign Indications

Ilana R. Press, MD, Candi Y. Jassal, MD, MS, Catherine A. Roberts, MD, David L. Neckel, MD, Sherry N. Landis, MD, Yvonne Chua, MD, Thomas J. Horwag, MD, Donna S. Handerman, MD, and Jason D. Wright, MD

OBJECTIVE: Emerging data suggest that oophorectomy at the time of hysterectomy for benign indications may increase long-term morbidity and mortality. We performed a population-based analysis to examine the rates of oophorectomy in women undergoing hysterectomy for benign indications.

Results: Among 16,345 participants with bilateral salpingo-oophorectomy (BSO) vs conservation (13,035), risks of cardiovascular disease (HR 1.19), and lung cancer (HR 1.26) were increased. Risks of breast, ovarian, and total cancer were decreased, but total cancer mortality increased (HR 1.17).

BSO at time of hysterectomy for benign disease was associated with an increased risk of all cause mortality:

- Over 35 years, 1 additional death would be expected for every 9 oophorectomies performed.

Cardiovascular disease


Nurse’s Health Study demonstrated that among participants with BSO (16,345) vs conservation (13,035), risks of CHD (HR 1.17) and lung cancer (HR 1.26) were increased.

Risks of breast, ovarian, and total cancer were decreased but total cancer mortality increased (HR 1.17).

BSO at time of hysterectomy for benign disease was associated with an increased risk of all cause mortality:

- Over 35 years, 1 additional death would be expected for every 9 oophorectomies performed.

Garbage in, garbage out?

Results based on a Markov model

Conclusions entirely drawn from use of a RR of 2.2 for women <45 who had BSO.

Not based on any observations of real patients

Summary: Women with BSO <55 have 8.58% excess mortality; BSO <59, 3.92% excess mortality
For pre-menopausal women

Leave ovaries behind unless there is a strong FHx of ovarian or breast cancer suggesting a germ line mutation

REMOVE TUBES

For women aged 52-65

No evidence for benefit on CHD
No evidence for benefit on hip fracture
Conflicting data on sexual function
Recommend BSO for ovarian cancer reduction
Remove tubes

For women > 65

Perform elective BSO
Remove entire specimen
For our case.....

Most reasonable to recommend:

Vaginal hysterectomy and bilateral salpingectomy

References


