Hysterectomy in 2007: Do Route and Extent Matter?

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Disclosure Slide

I have none of the following to disclose:
1. Financial ownership or significant stock position in any company whose products will be mentioned
2. Honorarium or Speakers Bureau relationship with any companies
3. Any discussion involving FDA off-label indications for drugs or devices.

Educational Objectives

Learners attending this talk will be able to:
• Understand the evidence comparing laparoscopic, abdominal and vaginal hysterectomy.
• Answer the question, “Is one technique of hysterectomy superior to the others?”
• Identify important unanswered questions that should guide future research.

In the beginning . . .


• Conrad Johan Martin Langenbeck (1776-1851) from Göttingen, Germany
• First planned, successful vaginal hysterectomy (1813)
• 50yo, ulcerated possibly cancerous cervix
• No anesthesia or assistance
• No entry into peritoneal cavity, part of corpus retained
• Patient lived to age 76
...and then came abdominal...

- "We consider the extirpation of a uterus not previously protruded or inverted, one of the most cruel and unfeasible operations that ever was projected or executed by the head or hand of man."
  - Editor of the London Medico-Chirurgical Review, 1825

- Charles Clay (1801-1893)
- Manchester, England
- Ovariotomy pioneer
- Incidental subtotal hyst (1843)
- SCH, BSO (1844), waxed Indian hemp
- Fell from bed, died 2 days later

...the rest of the story...

- 1853: First planned SCH: Burnham (Lowell)
- 1853: First SCH for fibroids: Kimball (Lowell)
- Mid-1800s: high mortality (>70% for abdominal)
- 1868: First caesarean hyst (SCH): Storer (Boston)
- 1878: Standard TAH technique: Freund (Germ.)
- 1898: Radical abdominal hyst: Wertheim (Vienna)
- Late-1800s: anesthesia, antiseptics, clamps
  - Mortality in London: VH 5.3%, AH (SCH) 3.4-22%

...until laparoscopic hyst...

- 1980s: Semm extends laparoscopy to advanced operations (previously diagnostic and TL)
- 1988: Reich completes first total laparoscopic hyst
- 1990s: Success in highly elite centers but wider dissemination associated with urinary tract injury
- 1993: Semm introduced technique of laparoscopic SCH, with reduction in ureteral injury

U.S. National Data

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</thead>
<tbody>
<tr>
<td>Abdominal hysterectomy</td>
<td>73.6</td>
<td>72.3</td>
<td>67.2</td>
<td>63.3</td>
<td>62.8</td>
<td>62.5</td>
<td>63.2</td>
<td>63.0</td>
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<tr>
<td>Vaginal hysterectomy</td>
<td>24.4</td>
<td>25.8</td>
<td>27.3</td>
<td>27.8</td>
<td>28.8</td>
<td>26.9</td>
<td>23.3</td>
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<tr>
<td>Subtotal hysterectomy</td>
<td>0.7</td>
<td>0.7</td>
<td>1.1</td>
<td>1.4</td>
<td>1.3</td>
<td>1.7</td>
<td>2.0</td>
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<tr>
<td>Laparoscopic Hysterectomy</td>
<td>0.3</td>
<td>1.3</td>
<td>4.9</td>
<td>6.6</td>
<td>6.2</td>
<td>5.8</td>
<td>6.6</td>
<td>9.9</td>
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<tr>
<td>Radical hysterectomy</td>
<td>1.0</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
<td>1.3</td>
<td>1.5</td>
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</tbody>
</table>

V.A. National Data

• Quality improvement database
• 6 years: 1991 - 1997
• 2,947 procedures in 97 VA hospitals
• Type of hysterectomy
  • 74% abdominal
  • 22% vaginal
  • 4% LAVH

Kaiser of Northern California

Small uterus, good descent

• 44 year-old para 3 with anovulatory bleeding refractory to medical management
• Declines LNG-IUS, endometrial ablation
• Desires an end to her bleeding
• BMI = 32, Type II DM on metformin
• Exam and sonogram show uterus 10x6x4cm with no adnexal abnormalities
• Cervix descends to mid-vagina with Valsalva
• EMB dysynchronous, no hyperplasia/cancer

Larger uterus, no descent

• 41 year-old para 1 with bulky fibroids, menorrhagia refractory to meds
• Prior abdominal myomectomy
• Hct 32%, desires an end to her bleeding
• Declines embolization, repeat myomectomy
• Exam and sonogram show corpus 14x8x6cm and an exophytic subserosal myoma 3x5cm
• Uterus well-suspended on exam
• EMB secretory, no hyperplasia/cancer
Is There a Rank Order?

- AH
- VH
- TLH
- LAVH
- LH(a)

1. ??
2. ??
3. ??
4. ??
5. ??

What Outcomes Matter Most?

- Operating Time
- Complications: organ injury, bleeding, unintended laparotomy
- Short-term Outcomes: pain, consequences of bleeding, infection, thromboembolism, death
- Recovery: hospitalization, return to activities
- Long-term Outcomes: pain, urinary or bowel dysfunction, sexual dysfunction, satisfaction and QOL, pelvic organ prolapse, fistula
- Cost, resource use

Cochrane Review

- 33 published trials and 9 abstracts identified
- 27 included with 5 (4 abstracts + 1 untranslated Swedish trial) awaiting assessment
  - VH vs. AH: 2 trials
  - LH vs. AH vs. VH: 3 trials
  - LH vs. AH: 16 trials
  - LH vs. VH: 4 trials
  - LH vs. AH and LH vs. VH: 1 trial
  - LAVH vs. LH(a): 1 trial


Which LH Do You Do?

Richardson (1995)

Nezhat (1995)

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Richardson (1995)

Nezhat (1995)
Three Subcategories of LH

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LH(a)</td>
<td>Laporoscopic hysterectomy performed through an abdominal incision</td>
</tr>
<tr>
<td>TLH</td>
<td>Laparoscopic hysterectomy performed through a small incision</td>
</tr>
<tr>
<td>LAVH</td>
<td>Laparoscopic-assisted vaginal hysterectomy</td>
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</tbody>
</table>

Participants

- N = 3643
  - Garry (2004) LH vs. AH, LH vs. VH: total N=1380
- Age 41-50 with hysterectomy for benign indications
- No blinding, few to no drop-outs
- Attendings alone or with residents assisting
- General anesthesia and antibiotic prophylaxis specified in 18 trials
- Wide range of countries and settings

Operating Time

- AH < LH(a) by 30.6 (25.6-35.7) minutes
- AH < TLH by 16.3 (7.0-25.6) minutes
- LAVH < AH by 7.6 (3.0-22.2) minutes
- VH < LH by 41.5 (33.7-49.4) minutes

- AH Subgroups
  - SCH < TAH by 11.4 (6.6-16.3) minutes

Intraoperative Complications

- Urinary tract (bladder, ureter) injuries:
  - LH vs. AH, OR 2.61 (1.22-5.60)

- Bladder, ureter, bowel, vascular injuries individually:
  - No diffs VH, AH, LH
  - No diffs LH(a) vs. LAVH

- Mean blood loss:
  - No diffs VH, AH
  - LH < AH in EBL by 45 (18-73) mL
  - SCH < TAH in EBL by 85 (27-143) mL

- Unplanned laparotomy:
  - No diffs VH vs. LH
  - No diffs LH(a) vs. LAVH
### Fevers and Infections

- **VH vs. AH**
  - OR 0.42 (0.21-0.83) for febrile episodes or unspecified infections
- **LH vs. AH**
  - OR 0.32 (0.12-0.85) for wound or abdominal wall infections
  - OR 0.65 (0.49-0.87) for febrile episodes or unspecified infections
- **SCH vs. TAH**
  - OR 0.43 (0.25 to 0.75) for all febrile morbidity

- Chest infections and UTI: LH≈AH≈VH
- Vaginal cuff infection: LH≈AH≈VH, LH(a)≈LAVH
- Other febrile illness: LH≈VH, LH(a)=LAVH

### Other Short-term Outcomes

- **Pain and analgesic use**
  - LH < AH days 0-4
- **Blood transfusion**
  - LH≈AH≈VH, LH(a) = LAVH, SCH = TAH
- **Pelvic hematoma**
  - LH≈AH≈VH, LH(a) = LAVH, SCH = TAH
- **Thromboembolism**
  - LH≈AH≈VH

### Recovery Period

- **VH speedier than AH**
  - by 1.0 (0.7-1.2) days in hospital
  - by 9.5 (6.4-12.6) days until return to normal activities
- **LH speedier than AH**
  - by 2.0 (1.9-2.2) days in hospital
  - by 13.6 (11.8-15.4) days until return to normal activities
- VH = LH days in hospital & return to activities
- SCH = TAH days in hospital & return to activities
- LAVH = LH(a) days in hospital

### Long-term Outcomes

- **Fistula formation, urinary dysfunction**
  - LH=AH=VH
- **Sexual dysfunction**
  - LAVH=LH(a) at 1yr, SCH=TAH at 1-2 yrs
- **Patient satisfaction and QOL**
  - LH=AH at 1yr, SCH=TAH at 1-2 yrs
- **Incontinence, constipation**
  - SCH=TAH at 1-2 yrs
**Cost, Resource Use**

- LH≈AH in 5 trials
- SCH≈TAH in 1 trial
- VH < LH in 1 trial

**Issues Unique to SCH**

- Cyclic vaginal bleeding
- Prolapse of the stump
- Re-operation for trachelectomy
- Cervical cancer screening
- Are these issues any different for laparoscopic SCH (LSH)?

**Cyclic Vaginal Bleeding**

- 3 RCTs with 1-2 years of follow-up, N = 733
- Endocervical destruction by electrodessication
- 11.8% SCH vs. 0.8% TAH (intention to treat)
- Range for SCH: 6.8 to 19.9%
- OR = 11.31 (4.1-31.2)

**Cervical Cancer**

- How common is it after SCH?
  - Danish study of 1104 women 1978-88
  - 10-year incidence of cervical cancer 0.4%
  - Risk increased if age 50+ at time of hysterectomy
- Are patients not returning for Pap smears?
  - Marshfield (Wisconsin) study of 315 women s/p hysterectomy and 315 women with intact uteri
  - Same rate (1 per 2.5 yrs) after SCH as for women without hysterectomy


Trachelectomy after SCH

- Retrospective record review 1974 – 2003 at Mayo Clinics in Minnesota and Arizona
- 310 trachelectomies
- Average of 26 years after hysterectomy
- Most performed vaginally with 75% performed for cervical prolapse
- Less morbidity after vaginal vs. abdominal trachelectomy


Re-operation after LSH

- Retrospective series from Royal Surrey County Hospital
- 70 patients with mean follow-up 66 (52-84) months
- Re-operation at 14 (3-53) months
- Cervical stump symptoms in 17 women (24.3%)
  - Laparoscopically assisted trachelectomy (14)
  - Laparotomy with trachelectomy (2)
  - LSC LOA for bowel adhesions (1)
- Trachelectomy pathology
  - Normal cervix (6)
  - Endometriosis (4), residual endometrium (4)
  - Mild CIN, mucocele, chronic cervicitis (3)


TAH vs. SCH via Laparoscopy

- No RCT’s
- Case series and retrospective comparisons abound
- Review in 1997
  - 3 retrospective comparative studies in 1990s
  - 91 total and 90 supracervical hyst patients
  - Operating time 10-27 minutes shorter (NS)
  - Estimated blood loss 45-200cc less (NS)
  - Hospital stay 0.38 - 0.75 days shorter (p< .001 in 1 study)
  - No apparent differences in surgical complications
  - 1 small study: return to sexual intercourse 3.5 vs. 5.9 weeks
  - Postoperative cyclic bleeding in 10%


Summary: SCH vs. TAH

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Best Evidence</th>
<th>Results / Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCH preserves sexual functioning better than TAH.</td>
<td>UK RCT (n=279)</td>
<td>No evidence of better outcomes after SCH. Both groups benefit to a similar extent on multiple outcomes.</td>
</tr>
<tr>
<td>SCH causes less urinary symptoms including incontinence than TAH.</td>
<td>TOSH RCT (n=135)</td>
<td>No evidence of better outcomes after SCH. Both groups benefit to a similar extent on multiple outcomes.</td>
</tr>
<tr>
<td>SCH prevents surgical morbidity &amp; saves SS.</td>
<td>Danish RCT (n=319)</td>
<td>SCH does not decrease overall surgical morbidity or resource use.</td>
</tr>
<tr>
<td>Vaginal bleeding can persist after SCH.</td>
<td>Retrospective case series from Mayo (n=310)</td>
<td>Post hysterectomy cyclic bleeding in 7 – 20%!!</td>
</tr>
<tr>
<td>Cervical prolapse can occur after SCH.</td>
<td>Retrospective case series from Mayo (n=310)</td>
<td>No studies comparing suspension methods at time of SCH</td>
</tr>
</tbody>
</table>
SCH and LSH: Caution

- An expectation that all bleeding will stop
- A history of (high grade) cervical dysplasia
- A history of (complex) endometrial hyperplasia
- Chronic pelvic pain, esp. central
- Lower segment / cervical fibroids
- Uterine prolapse

Summary of the Evidence

<table>
<thead>
<tr>
<th>Hysterectomy Technique</th>
<th>Shorter OR Time</th>
<th>Fewer Complications</th>
<th>Shorter Recovery</th>
<th>1-2 Year Outcomes</th>
<th>Lower Cost</th>
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<tbody>
<tr>
<td>VH</td>
<td>1</td>
<td></td>
<td>1</td>
<td>No Diff.</td>
<td>1</td>
</tr>
<tr>
<td>LH</td>
<td>2 (TLH, LH(a))</td>
<td>Mixed (injury vs. infection)</td>
<td>1</td>
<td>No Diff.</td>
<td>2</td>
</tr>
<tr>
<td>AH</td>
<td>2</td>
<td></td>
<td>2</td>
<td>No Diff.</td>
<td>2</td>
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<tr>
<td>AH Subgroups</td>
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</tr>
<tr>
<td>TAH v. SCH</td>
<td>SCH</td>
<td>SCH</td>
<td>No Diff.</td>
<td>Cyclic Bleeding</td>
<td>No Diff.</td>
</tr>
<tr>
<td>LH Subgroups</td>
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<tr>
<td>LAVH v. LH(a)</td>
<td>LAVH</td>
<td>No Diff.</td>
<td>No Diff.</td>
<td>No Diff.</td>
<td>??</td>
</tr>
<tr>
<td>TLH v. Others</td>
<td>??</td>
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Meaningful Differences

- Op Time:
  - VH 42 minutes shorter than LH
  - AH 31 minutes shorter than LH(a)
- Urinary tract injuries: LH > AH
- Post-op pain: AH > LH
- Febrile morbidities: AH > LH or VH
- Length of hospitalization
  - 1-2 days shorter for VH and LH than AH
- Return to usual activities
  - 10-14 days sooner for VH and LH than AH
- Cost: AH=LH > VH

NO meaningful Differences

- Most surgical complications
  - Transfusion, pelvic hematoma
  - Cuff cellulitis
  - Unplanned laparotomy
- 1-2 year outcomes
  - Sexual functioning
  - Satisfaction
  - Quality of life
  - Long-term complications
Small uterus, good descent

- 44 year-old para 3 with anovulatory bleeding refractory to medical management
- Declines LNG-IUS, ablation
- Desires an end to her bleeding
- BMI = 32, Type II DM
- Uterus 10x6x4cm with no adnexal abnormalities
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- Prior abdominal myomectomy
- Hct 32%, desires an end to bleeding
- Declines UFE, myomectomy
- Corpus 14x8x6cm and an exophytic subserosal myoma 3x5cm
- Uterus well-suspended on exam
- EMB secretory, no hyperplasia/cancer

Rank Order in 2007

1. VH
2. LAVH
3. TAH
4. SCH
5. TLH

The Evidence in Perspective
When is it time to try a new operation?

- There is no “old way”
- The old way has problems
  - Doesn’t work well
  - Morbidity, mortality
- The new way has potential benefits
  - Cost
  - Quality of life

What evidence is necessary before starting to use a new operation?

- None
- Case-series
- Cohort
- RCT
- Meaning of FDA approval
- Early vs. late adopters
**CONCLUSIONS**

- Vaginal hysterectomy is the procedure of choice by every measure.
- Laparoscopic hysterectomy costs the same as abdominal hysterectomy but gets patients back to their normal activities sooner. Trade-offs include greater urinary tract injuries vs. less post-operative pain and febrile morbidity.
- SCH offers no advantages to TAH and is associated with a 7-20% risk of cyclic bleeding.
- TLH has not been studied in RCT’s to document its superiority to other techniques of hysterectomy.

**Evidence Needed**

- SCH: can post-op cyclic bleeding be prevented?
  - Dessication vs. excision of endocervical tissue
- TLH is untested in RCT’s
  - vs. LSH: would we learn anything new?
  - vs. LAVH and LH(a)
  - vs. AH
  - “Every day” (vs. elite) outcomes
- SCH, TLH, LSH: prolapse and its prevention