Award Winning Presentations
and
JMP Keynote Address

Jason A. Abbott, B Med, PhD
Mats Brännström, MD, PhD
John R. Miklos, MD
Dhiraj L. Uchil, MD
Sawsan As-Sanie, MD, MPH
Isabel C. Green, MD
Nima R. Patel, MD
Warren Volker, MD, PhD
David M. Boruta, MD
Megan Loring, MD
M. Jonathon Solnik, MD
Professional Education Information

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Discussant: Jason A. Abbott, David M. Boruta II, Isabel C. Green, M. Jonathon Solnik, Warren Volker

Course Outline

7:45  Quality of Life after Hysteroscopic Myomectomy: A Prospective Observational Study  
     D. Uchil, I.C. Green
7:55  Questions & Answers
8:00  Obturator Neuralgia a Rare Complication of TVT Sling: Complete Resolution after Laparoscopic TVT Removal  
     J.R. Miklos, M.J. Solnik
8:10  Questions & Answers
8:15  Randomized Controlled Trial Comparing Traditional with Simulation Resident Surgical Laparoscopic Salpingectomy Training  
     N.R. Patel, D.M. Boruta
8:25  Questions & Answers
8:30  Impact of a Minimally-Invasive Gynecologic Surgery Department on Rates of Laparoscopic Hysterectomy: 2004 to 2012  
     M. Loring, W. Volker
8:40  Questions & Answers
8:45  Unexpected Uterine Sarcoma and Other Gynecologic Malignancies Diagnosed after Hysterectomy Performed for Benign Indications  
     S. As-Sanie, J.A. Abbott
8:55  Questions & Answers

9:00  Uterus Transplantation – From Idea to the First Clinical Trial  
     M. Brännström
9:30  Adjourn
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Kimberly A. Kho*
Frank D. Loffer, Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
M. Jonathon Solnik*
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Kevin J.E. Stepp
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Consultant: Bayer Healthcare Corp., CONMED Corporation, Ethicon Endo-Surgery, Hologic, Intuitive Surgical

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Speakers Bureau: Bayer Healthcare Corp.
Sawsan As-Sanie*
David M. Boruta
Consultant: Cambridge Endoscopic Instruments
Mats Brännström*
Isabel C. Green*
Megan Loring*
John R. Miklos
Grants/Research: Allergan, Astellas, Coloplast, Starpharma, United BioSource
Consultant: Coloplast, Endo Evolution, LLC, Gyrus ACMI (Olympus)
Speakers Bureau: Coloplast
Other: Surgical Preceptor: Coloplast, Gyrus ACMI (Olympus)
Nima R. Patel*
Dhiraj L. Uchil*
Warren Volker
Grants/Research: Bovie Medical
Speakers Bureau: Ethicon Endo-Surgery

Asterisk (*) denotes no financial relationships to disclose.
Quality of life after hysteroscopic myomectomy: a prospective observational study

Dhiraj Uchil, MD, MSc, MRCONGB
Tushna Vandrevala, PhD
University Hospital Lewisham, London, UK
Kingston University, UK

Objective

• At the conclusion of this session, participants will be able to understand the impact of submucous fibroids on quality of life indicators and changes following hysteroscopic myomectomy

Fibroids- prevalence and impact

• Estimated prevalence of 70% in Caucasian women and 80% in women of black ethnicity by age 50.
• Symptomatic in ~25% with significant impact on quality of life and constitute an economic burden (US treatment costs of $2.1 billion pa)
• Submucous fibroids constitute ~10% of all fibroids but are often extremely symptomatic with heavy menstrual bleeding, pain and adverse fertility outcomes

Hysteroscopic myomectomy

• First performed in 1976 and is now the standard treatment for submucous fibroids
• Like most well established techniques, there is paucity of good quality prospective data regarding effectiveness
• Studies assessing outcome after hysteroscopic myomectomy are limited by their retrospective nature leading to significant recall bias regarding symptom severity
• Effectiveness of treatment has been measured using surrogate markers like need for additional surgery or ultrasound evidence of recurrence
• Use of nonspecific outcome measures and additional procedures performed concurrently with hysteroscopic myomectomy make it difficult to assess the true effectiveness of the procedure

Fibroids and Quality of life assessment

• Despite the prevalence of fibroids, there are relatively few studies of impact of symptoms on QOL. Recent studies show a detrimental impact of fibroid symptoms on work performance, sexual function and personal relationships
• Trials of surgical treatment have often used generic instruments like the SF36 and EQ-5D
• The Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire is a validated instrument for assessing treatment response in women with fibroids undergoing uterine conserving procedures
• It is a 37 item questionnaire which forms 2 main scales: Symptom severity scale (SSS) consisting of 8 questions and a health related quality of life (HRQOL) scale consists of 29 questions and has 6 subscales: Concern (5 items), Activity (7 items), Energy/Mood (7 items), Self-consciousness (3 items), Control (5 items) & Sexual function (2 items)
Methodology

Primary objective was to assess the difference in symptom severity from baseline to 6 months post-surgery.

- A sample size calculation estimated that for a power of 80% and type I error of 5%, 16 women were needed to be recruited to the study.
- Exclusion criteria included uterine size > 16 weeks, submucous fibroids > 6cm and other surgical interventions (laparoscopic, endometrial ablation, IUS insertion).
- All patients completed the UFS-QOL, VAS scores and questionnaire on interference with daily activities at baseline (pre-surgery) and 3 & 6 months postoperatively.

Patients and follow up

- 22 women invited to take part in the study.
- 20 women completed the 3 month follow-up questionnaires.
- 18 women completed the 6 month follow-up questionnaires.
- 1 woman was lost to FU, 1 woman had IUS inserted after 3 months.

Patients and follow up

- 70% were of black ethnicity.
- 15% were nulliparous.
- 60% had tried medical treatment for management of symptoms.
- 60% had multiple fibroids on ultrasound examination.
- Size of submucous fibroid ranged from 9-60mm.
- 25% of fibroids were type 2.
- Multiple submucous fibroids were present in 30%.
- All procedures were performed under GA using a bipolar resectoscope.
- 3 women (15%) had incomplete resection - 2 of these were due to excess fluid absorption and 1 due to excessive blood loss.

UFS-QOL at baseline

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline Mean (SD)</th>
<th>3 months Mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom severity</td>
<td>70.78 (17.27)</td>
<td>32.66 (27.91)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Concern</td>
<td>9.0 (9.68)</td>
<td>59.75 (33.22)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Activities</td>
<td>17.5 (14.51)</td>
<td>62.32 (22.89)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Energy</td>
<td>25.71 (20.16)</td>
<td>70.71 (24.14)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Control</td>
<td>25.25 (19.97)</td>
<td>67.2 (28.59)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Self-consciousness</td>
<td>27.92 (25.52)</td>
<td>67.08 (32.04)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sexual function</td>
<td>24.34 (32.93)</td>
<td>57.60 (32.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total HRQL</td>
<td>20.15 (13.37)</td>
<td>66.16 (26.89)</td>
<td>&lt;0.001</td>
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</table>

UFS-QOL at baseline and 3 months post surgery

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline Mean (SD)</th>
<th>3 months Mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom severity</td>
<td>70.78 (17.27)</td>
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<td>&lt;0.001</td>
</tr>
<tr>
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<td>59.75 (33.22)</td>
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<td>17.5 (14.51)</td>
<td>62.32 (22.89)</td>
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<td>Energy</td>
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<tr>
<td>Control</td>
<td>25.25 (19.97)</td>
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<tr>
<td>Self-consciousness</td>
<td>27.92 (25.52)</td>
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<tr>
<td>Sexual function</td>
<td>24.34 (32.93)</td>
<td>57.60 (32.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total HRQL</td>
<td>20.15 (13.37)</td>
<td>66.16 (26.89)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Results

- 70% were of black ethnicity.
- 15% were nulliparous.
- 60% had tried medical treatment for management of symptoms.
- 60% had multiple fibroids on ultrasound examination.
- Size of submucous fibroid ranged from 9-60mm.
- 25% of fibroids were type 2.
- Multiple submucous fibroids were present in 30%.
- All procedures were performed under GA using a bipolar resectoscope.
- 3 women (15%) had incomplete resection - 2 of these were due to excess fluid absorption and 1 due to excessive blood loss.

UFS-QOL at baseline and 6 months post surgery

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline Mean (SD)</th>
<th>6 months Mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom severity</td>
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<tr>
<td>Concern</td>
<td>9.0 (9.68)</td>
<td>49.71 (38.95)</td>
<td>0.002*</td>
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<td>Activities</td>
<td>17.5 (14.51)</td>
<td>54.41 (36.3)</td>
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<tr>
<td>Energy</td>
<td>25.71 (20.16)</td>
<td>59.03 (34.26)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Control</td>
<td>25.25 (19.97)</td>
<td>66.18 (33.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sexual function</td>
<td>24.34 (32.93)</td>
<td>71.32 (37.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total HRQL</td>
<td>20.15 (13.37)</td>
<td>57.66 (33.8)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Women with submucous fibroids appear to have greater symptom severity and poorer quality of life indicators compared to the published data.

There was a high incidence of absenteeism and interference with daily activities.

Following hysteroscopic myomectomy, there was a statistically significant improvement in symptom severity and quality of life indicators with reduction in pain scores and interference with daily activities at 3 & 6 months.

The beneficial effects of surgery was evident at 3 months and did not change significantly at 6 months.

### Quality of life

**Time off work and pain scores**

<table>
<thead>
<tr>
<th>Time off work</th>
<th>Pre-surgery</th>
<th>3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>(80%)</td>
<td>12/15</td>
<td>5/16</td>
<td>4/15</td>
</tr>
<tr>
<td>Limited physical activities month</td>
<td>8.71 days</td>
<td>5.09 days</td>
<td>4.28 days/mo</td>
</tr>
</tbody>
</table>

**VAS scores Mean (SD)**

| Difference in VAS score 0 & 3 m-p | 0.004 |
| Difference in VAS score 0 & 6 m-p | 0.002 |
| Difference in VAS scores 3 & 6 months - NS |

(Wilcoxon signed rank test)

### Overview and conclusions

- **Implications**
  - Submucous fibroids appear to be associated with greater symptom severity and poorer quality of life.
  - Hysteroscopic myomectomy is effective in improving symptom severity and quality of life.
  - Incomplete resection and coexisting adenomyosis may be associated with suboptimal outcome.

- **Research implications**
  - Health-related quality of life measurement should be used for routine monitored neo-surgical studies.
  - If the hypothesis that surgical benefits are evident at 3 months and do not change at 6 months is confirmed, this can impact on the duration of follow-up needed.
  - Studies should be undertaken to assess whether submucous fibroids are more symptomatic compared to intramural submucous fibroids.
  - Further research should be undertaken to assess the impact of ethnicity, age, size and location of fibroids and response to treatment.
  - RCTs of hysteroscopic myomectomy vs myomectomy in women with multiple fibroids and a dominant submucous fibroid.

### References

Obturator Neuralgia a Rare Complication of TVT Sling:
Complete Resolution after Laparoscopic TVT Removal

John R. Miklos, M.D.
International Urogynecology Associates of Atlanta, Georgia and Beverly Hills, California

Study Objective: To show a technique of retropubic tension-free vaginal tape (TVT) removal using both a transvaginal and laparoscopic approach in the treatment of a rare condition, obturator neuralgia.

Design: Step-by-step explanation of the patients condition, diagnosis, surgical technique and postop results using video, pictures and medical illustrations. (education video)

Setting: TVT retropubic slings have become the gold standard for the treatment of stress urine incontinence over the last decade. Despite high cure rates the TVT is not without potential complications. Typical complications include: urine retention, incomplete bladder emptying, frequency, urgency, urethral erosion, vaginal extrusion, vaginal pain and dyspareunia. The most common complication for sling removal/revision is chronic pain. The TVT obturator neuralgia is a rare and specific type of chronic pain that is normally associated with transobturator tape (TOT) slings. The purpose of this video: 1) present an extremely rare complication of TVT retropubic slings 2) present symptoms and signs of obturator nerve compression 3) show the normal and the actual position of this patient’s TVT sling 4) describe the the laparoscopic removal of the TVT sling 5) as well as present the postoperative course and resolution of the patient’s pain.

Intervention: A combined transvaginal and laparoscopic approach in a patient with lower abdominal, levator and obturator type pain after a TVT retropubic procedure.

Conclusion: In patients suffering form obturator neuralgia after a retropubic sling surgeons should include the sling as a potential causative factor in the differential diagnosis. Surgeons should consider removing the sling based upon the patient’s symptoms. If the patient suffers from only vaginal pain and dyspareunia then the surgeon should consider only the removal of the vaginal portion of the sling. In patients with obturator neuralgia, retropubic and/or lower abdominal pain one should consider a combined transvaginal and laparoscopic approach in an attempt to remove the majority of the sling and release tension between two points of fixation.
Traditional versus Simulation Resident Surgical Laparoscopic Salpingectomy Training: A Randomized Controlled Trial

Nima R. Patel, MD*  Gretchen E. Makai, MD†  Nancy L. Sloan, DrPH‡  Carl R. Della Badia, DO§  

Department of Obstetrics & Gynecology, Drexel University School of Medicine, Philadelphia, PA  
Department of Obstetrics and Gynecology, Christiana Care Health Systems, Newark, DE  
Department of Obstetrics and Gynecology, Women’s and Children’s Health Research, Christiana Care Health Systems, Newark, DE

* I have no financial relationships to disclose.

At the end of this presentation, participants will be able to:  
- Identify ways in which simulated laparoscopy can help improve surgical skills  
- Discuss the importance of simulation training as an adjunct to traditional surgical training  
- Hypothesize future areas of study in simulation training

Introduction: Traditional Training

- Traditionally surgical training is by direct participation.  
- The process of learning gynecologic laparoscopic procedures is not well defined:  
  - Residency training, observation of cases, and hands-on operating room (OR) training.  
  - Proficiency generally judged by the number of operative cases completed  
- General surgery residency directors (n=254) believe residents should be able to perform 121 operative procedures*  
- Mean experience (n=1022) <5 cases for 83 procedures*  
- 63 procedures have a mode experience of zero*

Introduction: Simulation Training

- Simulation centers incorporated into training programs  
- Risk-free operative training  
  - Types:  
    - simple tool-based models  
    - computerized virtual reality programs  
    - simulation with animal tissue  
    - animal or human cadavers.

Hypothesis

- To date, no published studies examining the effectiveness of video observation followed by porcine model training  
- Formal training including video observation followed by procedural simulation in a porcine cadaver model will improve resident performance of laparoscopic salpingectomy compared with traditional training.
Methods

- Study design: Randomized controlled single blinded trial
  - Blocks of two, stratified by experience
- Sample
  - 22 PGY-1 through PGY-4 OB/GYN residents
- Control group: Traditional training
- Intervention group: Simulation session involving pre-session reading, a lecture, viewing a procedural video, and performing a laparoscopic salpingectomy on a porcine cadaver

Outcomes Assessed

- Pre and Post Intervention OSAT
  - Nine OSAT surgical skills were assessed by a Likert Scale of 1-5 (1=low score).
  - performed laparoscopic salpingectomy during a live case
  - All salpingectomies were recorded and scored by a single blinded evaluator
- Pre and Post Intervention Subjective Survey
  - 10 subjective measures by a Likert Scale of 1-5 (=strongly agree)

Results: Comparability of Study Groups

- Both groups had 5 upper year residents and 6 lower year residents

<table>
<thead>
<tr>
<th>PGY</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
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<td>2</td>
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<td>3</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Results: OSATs

- Control group: No Change
- Intervention group: Significant improvement
  - two-handed surgery
    - pre: 2.8±1.6, post: 3.5±1.3, p=0.004
  - use of energy
    - pre: 2.9±1.3, post: 3.6±1.0, p=0.01

<table>
<thead>
<tr>
<th></th>
<th>Control Mean±SD</th>
<th>Intervention Mean±SD</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue</td>
<td>3.0±1.2</td>
<td>3.0±1.3</td>
<td>0.44</td>
</tr>
<tr>
<td>Camera</td>
<td>2.8±1.3</td>
<td>2.7±1.3</td>
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<tr>
<td>Instrument Management</td>
<td>2.8±1.5</td>
<td>3.1±1.1</td>
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<tr>
<td>2 Handed Surgery</td>
<td>2.9±1.6</td>
<td>2.8±1.5</td>
<td>2.8±1.6</td>
</tr>
<tr>
<td>Visual Cues</td>
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<td>2.7±1.1</td>
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<tr>
<td>Resection</td>
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<td>2.7±1.2</td>
<td>0.17</td>
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<tr>
<td>Energy</td>
<td>3.1±1.4</td>
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<td>0.01</td>
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<tr>
<td>Flow</td>
<td>3.3±0.9</td>
<td>2.8±1.5</td>
<td>0.28</td>
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<tr>
<td>Overall OSA T Score</td>
<td>26.6±10.8</td>
<td>26.2±10.1</td>
<td>26.7±10.6</td>
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</table>

Results: Subjective Measures

- Control group: No Change
- Intervention group: Significant Improvement
  - increase in knowledge of anatomy, steps of surgery, two-handed surgery, and use of energy
  - decrease preference of learning in OR

<table>
<thead>
<tr>
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<th>Control Mean±SD</th>
<th>Intervention Mean±SD</th>
<th>p</th>
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<tbody>
<tr>
<td>Anatomy</td>
<td>2.0±0.8</td>
<td>1.9±0.3</td>
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<td>Steps</td>
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<td>Energy</td>
<td>2.3±0.8</td>
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<td>2.1±0.8</td>
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<td>2.1±0.8</td>
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<td>Watch Video</td>
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<tr>
<td>Risk Benefit</td>
<td>1.7±0.6</td>
<td>1.3±0.5</td>
<td>0.04</td>
</tr>
</tbody>
</table>
Simulation improves surgical skill and resident comfort level with the procedure
- indicates that resident training should be supplemented
  - to increase the baseline level of surgical skills
- To enhance learning a particular procedural skill

Limitations
- Small sample size
- One training program
- Short term intervention

Discussion

Future
- Future studies
  - Are results replicable in other programs?
  - Would results be different with long term simulation?
  - What is the optimal time for simulation to begin/occur?
  - What is the optimal length of simulation?
  - OSAT validated over multiple evaluators?

References

OBJECTIVES

1. Explain the importance of building and cultivating expertise
2. Demonstrate how to disseminate expertise in laparoscopic surgery through mentorship
3. Show the transformation of one community-based academic hospital

INTRODUCTION

• Benefits to minimally-invasive surgery are well-studied and proven
• Rates of laparoscopic hysterectomy continue to be low
  • 20-30% by ~2010[2,3]
• Slow adoption of conventional laparoscopic hysterectomy[4]

DISCLOSURES

I have no financial relationships to disclose

ROBOTIC SURGERY

• Brought promises of increased ease of minimally-invasive hysterectomy[6]
• Rates of open surgery slightly lower but costs of robotic assistance are high[3]
  • Robotic $2189 more per procedure

BUILDING EXPERTISE

Dale Chihuly


HYPOTHESIS

• Increasing public demand for laparoscopic hysterectomy due to excellent clinical outcomes, high patient satisfaction
• Goal - increase rates of laparoscopic hysterectomy at one institution by
  • Starting a MIGS division
  • Implementing informal mentorship program for generalist OB/Gyns
• No robotic technology needed

MENTORSHIP PROGRAM

• Newton-Wellesley Hospital (NWH)
• Informal, voluntary
• Goal – train 1-2 practitioners in each private-practice group to be proficient
• Started in 2001, expanded in scope in 2005

METHODS

• January 2004 – December 2012
• Primary outcome – route of hysterectomy
  • open, laparoscopic or vaginal
• Secondary outcomes – length of hospital stay, factors associated with an open procedure
• Outpatient surgery = length of stay of 0 days
  ** same-day discharge

RESULTS

• Average age: 41.3 years old
• Most common ICD-9 diagnostic codes
  • Leiomyoma
  • Uterine endometriosis (adenomyosis)
  • Excessive menstruation or menstrual disorder NOS

RESULTS

• Factors associated with need for an open hysterectomy
  • Intraoperative suspicion of malignancy
  • Large fibroid uterus (>18-week-sized)
  • Extensive abdominopelvic adhesions, due to endometriosis or prior abdominal surgery
  • Most common: Cesarean section
RESULTS

![Graph showing inpatient vs outpatient hysterectomy rates](attachment:graph.png)

*outpatient = same-day discharge

DISCUSSION

• A large, diverse OB/GYN department can transform its practice from open to >90% laparoscopic hysterectomy
• Paradigm shift fueled by:
  1. Patient demand
  2. Start of a MIGS division
  3. Surgical mentorship of generalists by fellowship-trained expert surgeons
• No need for robotic technology

4 LESSONS IN HOW PEOPLE BECOME EXPERTS

1. Recognize the value of having experts in your field
2. Take advantage - seek out mentorship to improve your skill set
3. Bring back your newly acquired skills to your community
4. Maintain expertise by sustaining high surgical volume

REFERENCES

OCCULT UTERINE SARCOMA AND OTHER GYNECOLOGIC MALIGNANCIES DIAGNOSED AFTER HYSTERECTOMY PERFORMED FOR BENIGN INDICATIONS

Nichole Mahnert MD, Daniel Morgan MD, Darrell Campbell MD, Carolyn Johnston MD, Sawsan As-Sanie MD, MPH
University of Michigan Health System
November 19th 2014

Learning Objectives
- Recognize the incidence of occult uterine sarcoma and other gynecologic malignancies among women undergoing surgery for benign indications
- Identify risk factors for patients with occult gynecologic malignancy
- Implement accurate preoperative patient counseling regarding the risk of occult malignancy

Background
- Benefits of minimally invasive gynecologic surgery
  - Quicker recovery
  - Fewer perioperative complications
- Most common indication for hysterectomy is fibroids
- Unclear incidence of occult gynecologic malignancy
  - Uterine sarcoma: 0.09 to 0.7%
  - Endometrial cancer: 0.13 to 0.4%

Study Objectives
- Establish the incidence of occult uterine sarcoma and other gynecologic malignancies among women undergoing hysterectomy for benign indications
- Identify risk factors associated with the diagnosis of occult gynecologic malignancy

Methods
- Retrospective chart review
- Statewide Michigan all-payer quality and safety surgical database
  - Michigan Surgical Quality Collaborative (MSQC)
- January 1, 2012 to December 8, 2013

Disclosure
I have no financial relationships to disclose
Hysterectomy performed for benign indications (n=6,369)
- Family history of cancer, pelvic mass, hyperplasia without atypia, prolapse, endometriosis, pelvic pain, fibroids, abnormal uterine bleeding
- Excluded indications for cancer or high suspicion for cancer (n=1,100)
  - Cancer, hyperplasia with atypia, cervical dysplasia

Overall incidence of occult gynecologic malignancy: 2.72% (n=173)

- Uterine Sarcoma
- Endometrial Cancer
- Cervical Cancer
- Ovarian/ fallopian tube/peritoneal Cancer
- Metastatic Cancer

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Benign (n=6196)</th>
<th>All cases of uterine sarcoma (n=24)</th>
<th>p value</th>
<th>Occult uterine sarcoma (n=14)</th>
<th>p value</th>
<th>Occult gynecologic malignancy (n=214)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>49.97 ± 10.77</td>
<td>54 ± 13.50</td>
<td>0.002</td>
<td>46.96 ± 10.57</td>
<td>0.07</td>
<td>58.30 ± 12.10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Parity</td>
<td>2.06 ± 1.42</td>
<td>2.09 ± 1.35</td>
<td>0.93</td>
<td>2.54 ± 1.38</td>
<td>0.23</td>
<td>1.96 ± 1.76</td>
<td>0.15</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Hispanic 109 (1.8) Non-Hispanic 5628 (90.8) Unknown 449 (7.4)</td>
<td>1 (0.04)</td>
<td>103 (90.59)</td>
<td>0.49</td>
<td>19 (8.88)</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>White 4893 (75.38) Black 1037 (17.70) Asian 21 (0.34)</td>
<td>1 (0.04)</td>
<td>103 (90.59)</td>
<td>0.49</td>
<td>19 (8.88)</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Prior VTE</td>
<td>Yes 162 (2.61) No 6034 (97.39)</td>
<td>2 (8.33)</td>
<td>0.08</td>
<td>2 (14.29)</td>
<td>0.007</td>
<td>7 (3.27)</td>
<td>0.56</td>
</tr>
<tr>
<td>Preoperative blood transfusion</td>
<td>Yes 43 (0.69) No 6150 (99.31)</td>
<td>1 (4.17)</td>
<td>&lt;0.001</td>
<td>1 (7.14)</td>
<td>0.004</td>
<td>207 (96.73)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Surgeon Type</td>
<td>Benign gynecologist 5832 (94.13) Gynecologic oncologist 364 (5.87)</td>
<td>14 (58.33)</td>
<td>0.001</td>
<td>12 (85.71)</td>
<td>0.18</td>
<td>52 (23.88)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Surgical approach</td>
<td>Abdominal 1542 (24.89) Laparoscopic 1036 (62.65) Vaginal 773 (12.46)</td>
<td>12 (50)</td>
<td>0.06</td>
<td>7 (50)</td>
<td>0.05</td>
<td>132 (61.68)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Specimen weight (g)</td>
<td>128 (20-900) 292 (22-3800) 0.09</td>
<td>323 (58-3800)</td>
<td>0.03</td>
<td>132 (22-6441)</td>
<td>0.64</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Demographic characteristics of women undergoing hysterectomy for benign indications

Results: Overall incidence of occult gynecologic malignancy: 2.72% (n=173)

The incidence of uterine sarcoma based on indication and age

Characteristics | Benign (n=1095) | All cases of uterine sarcoma (n=24) | p value | Occult uterine sarcoma (n=14) | p value | Occult gynecologic malignancy (n=214) | p value |
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior VTE</td>
<td>Yes 117 (1.09) No 6079 (98.91)</td>
<td>3 (23.03)</td>
<td>0.001</td>
<td>2 (14.29)</td>
<td>0.001</td>
<td>27 (13.63)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Preoperative blood transfusion</td>
<td>Yes 12 (1.09) No 6150 (99.31)</td>
<td>1 (8.33)</td>
<td>&lt;0.001</td>
<td>1 (7.14)</td>
<td>&lt;0.001</td>
<td>23 (10.32)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Perioperative characteristics of women undergoing hysterectomy for benign indications
Preoperative indication sub-analysis

- Surgical indication: Pelvic mass and family history of cancer excluded (n=5,202)
  - Overall incidence of gynecologic malignancy: 1.61% (n=84)
  - Uterine sarcoma: 0.23% (n=12)
  - Endometrial cancer: 0.96% (n=50)
  - Cervical cancer: 0.19% (n=10)
  - Ovarian/peritoneal/fallopian cancer: 0.17% (n=9)
  - Metastatic cancer: 0.06% (n=3)

STRENGTHS
- Large and diverse database
- Robust and detailed data
- High quality data collection

LIMITATIONS
- Limited data on preoperative imaging, cervical cancer screening and endometrial biopsy
- No differentiation among sarcoma subgroups

Conclusion

- Low incidence of occult gynecologic cancer
  - Uterine sarcoma: 1 in 455
  - Endometrial cancer: 1 in 98
  - Cervical cancer: 1 in 579
- Conduct comprehensive preoperative evaluation prior to benign hysterectomy
- Implement complete preoperative surgical counseling
  - Risk of occult cancer and morcellation
  - Benefits of laparoscopy versus open procedure

References

Uterus transplantation – from idea to clinic trial

Mats Brännström MD, PhD
University of Gothenburg
Stockholm IVF

Disclosure
I have no financial relationships to disclose.

Patient-initiated research

1998, Royal Adelaide Hospital, Australia
- Angela 27 years
- cervical cancer st 1b
- radical hysterectomy with preservation of ovaries
- UTx? - mother donor???

Absolute Uterine Factor Infertility (AUFI)

≈200,000 AUFI patients in Europe
(Sieunarine et al, Int Surg, 2005)
Motherhood options: adoption, gestational surrogacy

Our research-based UTx approach - starting 1999

- Mouse/rat from 1999
  - Racho El-Akouri et al J Endocr 2002
  - Racho El-Akouri et al Hum Reprod 2003a,
  - Racho El-Akouri et al Hum Reprod 2003b
  - Wranning et al Hum Reprod 2007
  - Groth et al Hum Reprod 2009
  - Groth et al Hum Reprod 2010
  - Wranning et al Hum Reprod 2011
  - Diaz-Garcia et al Acta Obstet Gynecol 2010
  - Akhi et al Fertil Steril 2012
  - Akhi et al Hum Reprod 2013

- Pig from 2004
  - Avison et al Transplantation 2009

- Sheep from 2005
  - Wranning et al Fertil Steril 2008
  - Wranning et al Hum Reprod 2010

- Baboon from 2008
  - Enskog et al Hum Reprod 2010
  - Johannesson et al Hum Reprod 2012
  - Johannesson et al Hum Reprod 2012
  - Tryphanolous et al Am J Transpl 2014

- Worldwide experience - 11 cases
  - Saudi Arabia (2000; live donor)
  - Turkey (2011; deceased donor)
    - no preparatory research studies on UTx
    - no live births reported

- Sweden x 9 (2013 ClinicalTrials.gov NCT01844362)
UTx-research before introduction as an experimental procedure

- surgery and vascular anastomosis
- ischemia - reperfusion injury
- rejection
- immunosuppression
- pregnancy and offspring
- ethics

Mouse

end-to-side
aorta - aorta
v. cava - v. cava

Baboon

9-0 suture
V A

Immunosuppression

- effects on fetus (>15000 births; 2006)
  - NTPR-US, European Dialysis and Transplant Association Registry, UK Transplant Pregnancy Registry
  - no increased risk of congenital malformation (McKay, Josephson NEJM 2008)

Offspring from allogenic UTx

- Pregnancy rate
- Morphology (-macro, -micro)
- Phenotyping

Pregnancy and offspring development

Mouse

Native uterus
Grafted uterus
Transplanted animals

Control animal

0 20 40 60 80 100

Pregnancy rate (%)

Transplanted animals (n=12)

vaginal-cutaneous stoma

Mouse backtable preparation anastomosis 2 weeks after transplantation

heterotopic

uterus
heterotopic

UTx+TAC

CS

MATING

NO PREGNANCY

PUPS PUPS

Offspring from allogenic UTx

Synchronization (n=10/group)

d48

d22

PUPS

Mating rate

- Pregnancy rate

- Phenotyping

- Macro

- Micro
**PHENOTYPING - normal**

- Birth weight
- Metabolism
  - Weight gain (weekly)
  - Body composition (DEXA)
  - Glucose overload
  - Basal metabolism (Somedic)
- Cardiovascular
  - BP
  - Functional echocardiography
- Behavior
- Anxiety
- Memory
- Urinary
- Kidney function
- Fertility
- Aging

---

**Gothenburg - live donor UTx**

Based on > 10 years of animal UTx-research

May 2012 – ethics approval for case series (n=9) (safety committee)
- paid entirely by private research foundations

autumn 2012 – spring 2013: case 1-9

---

**Recipients**

- age 27-38 years
- healthy
- non-smokers
- BMI 21-25

MRKH (n=8): kidney
- 3 single normal kidney
- 1 single pelvic kidney

MRKH - neovagina
- 3 self-dilated
- 1 therap-dilated
- 4 skin graft

---

**Donors**

- BMI < 28
- no systemic diseases
- normal pregnancy (one Cs Ok)
- no malignancy
- relatives and friends
  - mother (n=5)
  - father x sister (n=1)
  - sister (n=1)
  - mother-in-law (n=1)
  - family friend (n=1)

---

**IVF before.**

- ascertain fertility within couple
- cryopreserve embryos for single ET 12-18 months after UTx

---

**10 surgeons (2 patients in partially parallel surgery)**

- 4 gyn-urology surgeons
- 3 transplant surgeons
- 3 gynecologists

---

**Recipient-donor pair**

- extensive investigation of patients, partners and donors for >12 months
  - psychologist (multiple visits)
  - transplant counsellor
  - physician
  - anesthesiologist (x2)
  - gynecologist (x3)
  - transplant surgeon
  - blood tests, MRI, TVU, virology
Donor surgery

- Duration 10-13h !!!
  - Hysterectomy 45 min
  - Radical hysterectomy 2.5 h

- Time consumption
  - Ureteric dissection
  - Isolation of uterine veins

- No ICU
- 6 days hospital stay

One grade 2 (Clavien-Dindo system) complication (donor 2):
- Ureteric-vaginal fistula 2 weeks after surgery
- Ureteric implantation 3 months later, then in good health

Back-table preparation (around 60 min)
- Custodiol flushing
- Ice slush
- Preparation of vessels

Duration - anesthesia and surgery

- Dissection of uterine vein(s) to inlet into internal iliac vein
- Clamping of internal iliac artery (distal to gluteal artery)
- Clamping to obtain patch of internal iliac vein
- Fixation sutures in cleaved uterine rudiment and round ligaments

- Dissection of external iliac veins and arteries
- Chilled uterine graft into pelvic position

Duration of anastomosis surgery

End-to-side anastomosis (8-0 veins, 7-0 arteries)

Vaginal-vaginal anastomosis (2-0) with reperfused uterus
**Recipient surgery**

- Duration 4-6 h
- No blood transfusion
- No ICU
- Hospital stay 5-7 days

---

**Durations of anesthesia and surgery**

![Graph showing durations of anesthesia and surgery](image)

**Immunosuppression**

- [Graph showing immunosuppression](image)

---

**Patient ARB, normal cx**

- Mild rejection, - corticosteroids 7 days
- 3 weeks later
- regular menses from 1-2 months in 7 patients

> 12 months outcome and future
- single embryo transfers (sET) in 7 patients
- delivery by c-section
- hysterectomy after maximum two births

Livebirth after uterus transplantation

Summary
Reconstruction of the uterus via uterus transplantation is the best available treatment for patients with uterine defects. The uterus can then be used for normal pregnancy and delivery. The current study was conducted to evaluate the long-term success and safety of uterus transplantation.

Methods
In 2011, a team of surgeons performed a uterus transplantation surgery at the University of California, San Francisco. The recipient was a 29-year-old woman with severe uterine defects. The donor was a 40-year-old woman with no history of gynecologic disorders. The recipient was enrolled in a protocol for patient care and follow-up.

Results
The recipient successfully gave birth to a healthy infant after a pregnancy that lasted 39 weeks. The baby was delivered via a cesarean section. The mother and baby are doing well and have no complications.

Conclusion
Uterus transplantation is a promising treatment for women with uterine defects. Further studies are needed to evaluate the long-term success and safety of this procedure.

One rejection episode

Normal growth curves
Conclusions

• First UTx baby – proof-of-concept
• Two more >30 w and some early pregnant
• New observational studies should follow
  - (USA (Cleveland), UK (London), Belgium (Ghent), France (Lyon), Spain (Valencia),
  Australia (Brisbane), China (Guangzhou), Japan (Tokyo), Colombia (Bogotá)
• The future – bioengineered uterus???

UTx -Team effort !!!!!

Mats Brännström  Gynec- onc. surgeon
Liza Johansson  Gynecologist
Teresa Delen-Kähler  Gynec- onc. surgeon
Michael Obstanen  Transpl. surgeon
Andreas Tasko  Transpl. surgeon (Cleveland Clinic)
Carina Deg  Gynecologist (Univ. of Valencia)
Mårten Norrishviken  Gynec- onc. surgeon
Nils Larsson  Transpl. surgeon
Marcel Gabel  Transpl. surgeon
Safia Elledge  Gynec- onc. surgeon
Elna Hamdy  Gynecologist (Griffith U.)
Aicha Gour  Gynecologist
Hawa Bakken  Obstetrician
Hans Hagberg  Obstetrician
Zinh Wolsa  Pathologist
Lars Håkansson  IVF specialist
Kenny Rodríguez  IVF specialist
Andre Fülöp  Anesthesiologist
Lars Sahlin  Anesthesiologist
Lars Sund  Anesthesiologist
Christina Svensson  Anesthesiologist
OR nurses
Anest nurses
Ward nurses
CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law **AB 1195 (eff. 7/1/06)** requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California's physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

California Business & Professions Code §2190.1(c)(3) requires a review and explanation of the laws identified above so as to fulfill AAGL's obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at [http://www.imq.org](http://www.imq.org).

**Title VI of the Civil Rights Act of 1964** prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 [http://www.usdoj.gov/crt/cor/pubs.htm](http://www.usdoj.gov/crt/cor/pubs.htm).

**Executive Order 13166**, “Improving Access to Services for Persons with Limited English Proficiency”, signed by the President on August 11, 2000 [http://www.usdoj.gov/crt/cor/13166.htm](http://www.usdoj.gov/crt/cor/13166.htm) was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

**Dymally-Alatorre Bilingual Services Act** (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

If you add staff to assist with LEP patients, confirm their translation skills, not just their language skills. A 2007 Northern California study from Sutter Health confirmed that being bilingual does not guarantee competence as a medical interpreter. [http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538](http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538).