Plenary 1: Laparoscopy

MODERATOR
Masoud Azodi, MD

CO-MODERATORS
Yves Leroy M., MD & Richard M. Soderstrom, MD

Jay M. Berman, MD  Kiley A. Bernhard, MD  Arturo Garza-Cavazos, MD
Richard S. Guido, MD  Kelly N. Wright, MD
Professional Education Information

Target Audience
Educational activities are developed to meet the needs of surgical gynecologists in practice and in training, as well as, other allied healthcare professionals in the field of gynecology.

Accreditation
AAGL is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The AAGL designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS
As a provider accredited by the Accreditation Council for Continuing Medical Education, AAGL must ensure balance, independence, and objectivity in all CME activities to promote improvements in health care and not proprietary interests of a commercial interest. The provider controls all decisions related to identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the activity. Course chairs, planning committee members, presenters, authors, moderators, panel members, and others in a position to control the content of this activity are required to disclose relevant financial relationships with commercial interests related to the subject matter of this educational activity. Learners are able to assess the potential for commercial bias in information when complete disclosure, resolution of conflicts of interest, and acknowledgment of commercial support are provided prior to the activity. Informed learners are the final safeguards in assuring that a CME activity is independent from commercial support. We believe this mechanism contributes to the transparency and accountability of CME.
Table of Contents

Course Description ........................................................................................................................................ 1

Disclosure ...................................................................................................................................................... 2

Reduction in Uterine and Fibroid Volumes in 135 Consecutive Subjects Following Laparoscopic and Ultrasound-Guided Radiofrequency Ablation of Fibroids: 12-Month Follow-Up
R.S. Guido ...................................................................................................................................................... 4

Prospective 12-Month Follow-Up of Menstrual Blood Loss Reduction Following 135 Consecutive Cases of Radiofrequency Volumetric Thermal Ablation of Symptomatic Fibroids
J.M. Berman .................................................................................................................................................. 7

Location of Epigastric Vessels Stratified by BMI
A. Garza-Cavazos ......................................................................................................................................... 10

The Impact of Robot Acquisition on Method of Hysterectomy at a Single Institution
K.N. Wright ................................................................................................................................................. 13

Hysterectomy Complications among Overweight and Obese Women: Role of 95% Confidence Intervals
K.A. Bernhard .............................................................................................................................................. 16

Cultural and Linguistics Competency ........................................................................................................ 19
Plenary 1: Laparoscopy

Moderator: Masoud Azodi
Co-Moderators: Yves Leroy M., Richard M. Soderstrom

Faculty: Jay M. Berman, Kiley A. Bernhard, Arturo Garza-Cavazos, Richard S. Guido, Kelly N. Wright

Course Description

This session provides an array of topics concerning laparoscopic surgery. These topics that will be presented at the session will include change in fibroid volume and amount of blood loss following radiofrequency ablation (RFVTA), mapping of epigastric vessels stratified by BMI, impact of robot acquisition on method of hysterectomy and role of 95% CI in reporting hysterectomy complications among obese women.

Course Objectives

At the conclusion of this session, the participant will be able to: 1) Evaluate the effect of radiofrequency volumetric thermal ablation (RFVTA) on fibroid volume and blood loss in patients with moderate-to-severe menorrhagia; 2) Review alternate location of epigastric vessels with varying BMI; and 3) review the implication of introducing the robot for different routes of hysterectomy.

Course Outline

11:00 Reduction in Uterine and Fibroid Volumes in 135 Consecutive Subjects Following Laparoscopic and Ultrasound-Guided Radiofrequency Ablation of Fibroids: 12-Month Follow-Up
R.S. Guido

11:10 Prospective 12-Month Follow-Up of Menstrual Blood Loss Reduction Following 135 Consecutive Cases of Radiofrequency Volumetric Thermal Ablation of Symptomatic Fibroids
J.M. Berman

11:20 Location of Epigastric Vessels Stratified by BMI
A. Garza-Cavazos

11:30 The Impact of Robot Acquisition on Method of Hysterectomy at a Single Institution
K.N. Wright

11:40 Hysterectomy Complications among Overweight and Obese Women: Role of 95% Confidence Intervals
K.A. Bernhard

11:50 Discussion

12:00 Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
Art Arellano, Professional Education Manager, AAGL*
Viviane F. Connor
Consultant: Conceptus Incorporated
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
Jonathan Solnik
Other: Lecturer - Olympus, Lecturer - Karl Storz Endoscopy-America

SCIENTIFIC PROGRAM COMMITTEE
Arnold P. Advincula
Consultant: CooperSurgical, Ethicon Women's Health & Urology, Intuitive Surgical
Other: Royalties - CooperSurgical
Linda Bradley
Grants/Research Support: Elsevier
Consultant: Bayer Healthcare Corp., Conceptus Incorporated, Ferring Pharmaceuticals
Speaker's Bureau: Bayer Healthcare Corp., Conceptus Incorporated, Ferring Pharm
Keith Isaacson
Consultant: Karl Storz Endoscopy
Rosanne M. Kho
Other: Honorarium - Ethicon Endo-Surgery
C.Y. Liu*
Javier Magrina*
Ceana H. Nezhat
Consultant: Intuitive Surgical, Lumenis, Karl Storz Endoscopy-America
Speaker's Bureau: Conceptus Incorporated, Ethicon Women's Health & Urology
William H. Parker
Grants/Research Support: Ethicon Women's Health & Urology
Consultant: Ethicon Women's Health & Urology
Craig J. Sobolewski
Consultant: Covidien, CareFusion, TransEnterix
Stock Shareholder: TransEnterix
Speaker’s Bureau: Covidien, Abbott Laboratories
Other: Proctor - Intuitive Surgical

FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
Richard S. Guido
Grants/Research Support: Halt Medical, ikonosys
Consultant: Halt Medical
Jay M. Berman
Grants/Research: Boston Scientific Corp. Inc., Halt Medical, Minerva Surgical, Thermablate-EAS
Consultant: Aegea Medical, Boston Scientific Corp. Inc.
Speakers Bureau: Boston Scientific Corp. Inc., Merck Serono
Arturo Garza-Cavazos*
Kelly N. Wright
Other: Resident Instructor for pig lab - Ethicon Endo-Surgery
Kiley A. Bernhard*
Masoud Azodi
Grants/Research Support: Intuitive Surgical
Richard M. Soderstrom*
Yves Leroy M.*

Asterisk (*) denotes no financial relationships to disclose.
Reduction in Uterine and Fibroid Volumes in 135 Consecutive Subjects Following Laparoscopic and Ultrasound-guided Radiofrequency Ablation of Fibroids: 12-Month Follow Up

Richard S. Guido, MD
University of Pittsburgh, Magee-Women’s Hospital of the UPMC Health System, Pittsburgh, PA
David J. Levine, MD
St. John’s Mercy Medical Center, St. Louis, MO
Donald I. Galen, MD
Reproductive Science Center of the Bay Area, San Ramon, CA
James A. Meier, MD
Pasadena Premier Women's Health, Pasadena, CA
Janice L. Falls, MD
Albert Einstein College of Medicine, Bronx, NY
Ian B. Tilley, MD
University of Southern California Medical Center, Los Angeles, CA
Scott G. Chudnoff, MD MS
Albert Einstein College of Medicine, Bronx, NY
Representing The Halt Study Group

Disclosures

• Grants/Research Support: Halt Medical, Ikonosys
• Consultant: Halt Medical

Objective

To assess outpatient radiofrequency volumetric thermal ablation (RFVTA) in women with symptomatic fibroids and moderate-to-severe heavy menstrual bleeding in terms of:

• Uterine volume reduction
• Fibroid volume reduction
• Incidence of surgical re-intervention within 12 months post treatment

Radiofrequency Volumetric Thermal Ablation of Fibroids
A Gynecologic Procedure

Combines three basic gynecologic skills:

• Laparoscopy: two trocars, no special suturing skills
• Ultrasound: laparoscopic ultrasound probe scans and manipulates
• Tip/needle array placement under ultrasound guidance

The Radiofrequency Handpiece

The RF Generator and Handpiece
Phase III Study – Design and Setting

- Prospective, multicenter, single-arm, international clinical trial; subjects serve as their own controls
- Study participants (N = 135) diagnosed with symptomatic fibroids; moderate-to-severe heavy menstrual bleeding confirmed by alkaline hematin testing
- Eleven (11) study centers; 13 investigators

Primary Method for Uterine and Fibroid Volume Measurement

- Magnetic Resonance Imaging
- Pre-contrast Imaging
  - T1/T2 axial, sagittal and transverse MRI
- Post-contrast Imaging
  - T1 axial and sagittal contrast-enhanced MRI

Inclusion / Exclusion Criteria

Inclusion Criteria:
- Asymptomatic, premenopausal, ≥ 25 yr old, and desires uterine conservation
- No more than 6 fibroids, no one fibroid larger than 7 cm in diameter, no more than 300 cm3 total fibroid volume
- Uterine gestational size ≤ 14 weeks
- Menstrual Bleed Loss ≥ 160 to ≤ 500 mL/cycle (one or two cycles)
- Normal Pap, normal or correctable coagulation profile
- Completed childbearing and practicing stable contraception
- Able to provide informed consent

Exclusion Criteria:
- Active pelvic infection or history of PID, malignancy, pelvic radiation, DUB, or chronic pelvic pain
- Prior pelvic surgery (except C-section, tubal, or diagnostic laparoscopy) or uterine-preserving technique for reduction of menstrual bleeding (with the exception of hysteroscopic myomectomy ≥ 1 year ago)
- Previous history of Type 1 fibroids, cervical myoma, significant adhesions, suspected endometriosis or adenomyosis
- Contraindications to laparoscopic surgery including anemia (Hb < 10 or Hct < 30)
- BMI > 35 kg
- Any Grade against the last 3 months
- Implanted fallopian tube devices

Baseline Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Statistic/Response (N = 137)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>42.4 ± 4.7</td>
</tr>
<tr>
<td>Gravida</td>
<td>3.2 ± 2.1</td>
</tr>
<tr>
<td>Para</td>
<td>2.3 ± 1.3</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White or Caucasian</td>
<td>62 (45.3%)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>46 (33.6%)</td>
</tr>
<tr>
<td>Hispanic, Hispanic indigenous, Caribbean</td>
<td>27 (19.7%)</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td>Smoking History</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>29 (29.2%)</td>
</tr>
<tr>
<td>Past</td>
<td>23 (16.8%)</td>
</tr>
<tr>
<td>Never</td>
<td>85 (62.0%)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>162.6 ± 8.1</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>81.0 ± 10.1</td>
</tr>
</tbody>
</table>

Laparoscopic Ultrasound: Number and Location of Treated Fibroids

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N = 135</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of fibroids per subject</td>
<td>6.3 ± 4.9</td>
</tr>
<tr>
<td>Median</td>
<td>4.0 (range, 1 – 29)</td>
</tr>
<tr>
<td>Total number of fibroids</td>
<td>818</td>
</tr>
</tbody>
</table>

Location

- Fundal                  | 163 (20.3%) |
- Mid uterus              | 43 (5.3%)   |
- Lower uterus            | 127 (15.8%) |
- Anterior                | 283 (35.2%) |
- Posterior               | 273 (34.5%) |
- Left                    | 173 (21.5%) |
- Right                   | 195 (24.3%) |
- Broad Ligament          | 2 (0.2%)    |
- Not specified           | 14         |

Laparoscopic Ultrasound: Types of Treated Fibroids

<table>
<thead>
<tr>
<th>Type</th>
<th>N = 135</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subserosal</td>
<td>212 (26.6%)</td>
</tr>
<tr>
<td>Intramural</td>
<td>462 (58.0%)</td>
</tr>
<tr>
<td>Transmural</td>
<td>39 (4.9%)</td>
</tr>
<tr>
<td>Submucosal</td>
<td>173 (21.7%)</td>
</tr>
<tr>
<td>Not specified</td>
<td>22</td>
</tr>
</tbody>
</table>

1 A fibroid could have been more than one type. Percentages were based on the number of fibroids with nonmissing data.
Operative and 12-Month Results

- Mean duration of procedure: $2.1 \pm 1.0$ hours
- Total blood loss: $39.2 \pm 26.8$ mL
- Treated on outpatient basis: 96.2%
- 5 Device-related AEs: 3.6%
  - SAEs: Pelvic abscess in posterior cul de sac, sigmoid serosal tear caused by ultrasound probe
  - AEs: severe lower abdominal pain, superficial uterine serosal burn, post procedure vaginal hemorrhage
- Time to normal activity: 7–10 days
- Re-intervention rate: 0.7%

Significant Reduction in Mean Uterine Volume, cm³ [$p < .001$]

Significant Reduction in Mean Total Fibroid Volume, cm³ [$p < .001$]

Percentage of Change in Uterine and Fibroid Volume From Baseline

Conclusions

- RFVTA significantly reduces fibroid and uterine volume
- RFVTA is associated with a low rate of perioperative complications
- RFVTA is associated with a low re-intervention rate
- RFVTA provides an effective outpatient procedure for women with fibroids and heavy-to-severe menstrual blood loss
Prospective 12-Month Follow Up of Menstrual Blood Loss Reduction Following 135 Consecutive Cases of Radiofrequency Volumetric Thermal Ablation of Symptomatic Fibroids

Erika Banks, MD
Micah Harris, MD
José Garza Leal, MD
Rodolfo Robles Pemueller, MD
Scott G. Chudnoff, MD, MS
Karen R. Abbott, MD
Jay M. Berman, MD
For the Halt Study Group

Albert Einstein College of Medicine, Bronx, NY
Women’s Health Research, Phoenix, AZ
Hospital Universitario Nuevo Leon, Monterrey, Mexico
Hospital Universitario Esperanza, Guatemala
Wayne State University School of Medicine, Detroit, MI

Disclosures

Jay M. Berman
Grants/Research: Boston Scientific Corp. Inc., Halt Medical, Minerva Surgical, Thermablate-EAS
Consultant: Aega Medical, Boston Scientific Corp. Inc.
Speakers Bureau: Boston Scientific Corp. Inc., Merck

Objectives

To assess the efficacy and safety of radiofrequency volumetric thermal ablation (RFVTA) in women with symptomatic myomas and moderate-to-severe heavy menstrual bleeding (≥ 160 to ≤ 500 mL), in terms of:

- Mean Menstrual Blood Loss
- Incidence of Device-Related Adverse Events
- Surgical Re-interventions

Radiofrequency Volumetric Thermal Ablation of Myomas
A Gynecologic Procedure

Combines three fundamental gynecologic skills:

- Laparoscopy using 2 trocars and requiring no special suturing skills
- Ultrasound using a laparoscopic ultrasound probe to scan and manipulate
- Tip/array placement under laparoscopic ultrasound guidance

Phase III Study Design and Setting

- Prospective, multicenter, single-arm, international clinical trial
- Study participants (N = 135) serve as their own controls
- All enrolled subjects diagnosed with:
  - Symptomatic myomas
  - Moderate-to-severe heavy menstrual bleeding (≥ 160 to ≤ 500 mL)
- Menstrual bleeding confirmed by alkaline hematin testing
- Eleven (11) study centers and 13 investigators
Inclusion and Exclusion Criteria

**Inclusion Criteria**

- Symptomatic, premenopausal, ≥ 25 yrs old, and desires uterine conservation
- No more than 6 myomas, no one myoma > 7 cm in diameter, total myoma volume not to exceed 300 cm³
- Menstrual Blood Loss ≥ 160 to ≤ 500 mL/cycle (one or two cycles)
- Normal Pap; normal or correctable coagulation profile
- Childbearing completed and practicing stable contraception
- Able to provide informed consent

**Exclusion Criteria**

- Active pelvic infection or history of PID, malignancy, pelvic radiation, DUB, or chronic pelvic pain
- Prior pelvic surgery (except C-section, tubal or diagnostic laparoscopy) or uterine-preserving technique for reduction of menstrual bleeding (except hysteroscopic myomectomy ≥ 1 year prior)
- Menstrual Blood Loss ≥ 160 to ≤ 500 mL/cycle
- Any surgical re-intervention for heavy menstrual bleeding was reported at 3, 6, and 12 months post treatment

Menstrual Blood Loss Outcomes

**Methods of Measurement**

- Bleeding outcomes measured by alkaline hematin (AH) analysis
- AH assessment of returned sanitary products (pads / tampons) quantified MBL at baseline and at 3, 6, and 12 months post treatment
- Each subject’s used catamenial products processed at a central laboratory (KCAS, Shawnee, KS)
- Subjects meeting all inclusion criteria underwent LUS-guided radiofrequency volumetric thermal ablation of their symptomatic myomas
- Any surgical re-intervention for heavy menstrual bleeding was reported at 3, 6, and 12 months post treatment

Baseline Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=137</th>
<th>Statistic/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>Mean</td>
<td>42.4 ± 4.7</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>43 (range, 30–55)</td>
</tr>
<tr>
<td>Gravida</td>
<td>Mean</td>
<td>3.2 ± 2.1</td>
</tr>
<tr>
<td>Pairs</td>
<td>Mean</td>
<td>2.3 ± 1.3</td>
</tr>
<tr>
<td>Height, cm</td>
<td>Mean</td>
<td>162.6 ± 8.1</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>Mean</td>
<td>81.0 ± 19.1</td>
</tr>
<tr>
<td>Race</td>
<td>White or Caucasian</td>
<td>62 (45.3%)</td>
</tr>
<tr>
<td></td>
<td>Black or African-American</td>
<td>46 (33.6%)</td>
</tr>
<tr>
<td></td>
<td>Hispanic, Hispanic indigenous, Caribbean</td>
<td>27 (19.7%)</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td>Baseline AH, mL [Per Protocol Set, N = 124]</td>
<td>Mean</td>
<td>271.3 ± 79.7</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>248 (range, 160–486)</td>
</tr>
</tbody>
</table>

Number and Types of Myomas Detected With Laparoscopic Ultrasound

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=135</th>
<th>Statistic/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of myomas per subject</td>
<td>Mean</td>
<td>6.1 ± 4.9</td>
</tr>
<tr>
<td>Total number of myomas</td>
<td>Mean</td>
<td>81.8</td>
</tr>
<tr>
<td>Type à</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subserosal</td>
<td>212 (26.6%)</td>
<td></td>
</tr>
<tr>
<td>Intramural</td>
<td>462 (58.0%)</td>
<td></td>
</tr>
<tr>
<td>Transmural</td>
<td>39 (4.9%)</td>
<td></td>
</tr>
<tr>
<td>Submucosal</td>
<td>173 (21.7%)</td>
<td></td>
</tr>
<tr>
<td>Not specified</td>
<td>22</td>
<td></td>
</tr>
</tbody>
</table>

Operative and Perioperative Results

- Total procedural blood loss: 39.2 ± 26.8 mL
- Mean duration of procedure: 2.1 ± 1.0 h
- Treated as outpatients: 96.2%
- Device-related AEs/SAEs
  - 3 AEs: superficial uterine serosal burn, post-procedure vaginal hemorrhage, severe lower abdominal pain
  - 2 SAEs: pelvic abscess in posterior cul de sac, sigmoid serosal tear caused by ultrasound probe
- Time to normal activities: 7–10 days

MBL Outcomes

- 11 subjects (11/135) did not submit catamenial products for evaluation at 12 months
  - Amenorrhea (n = 4), pregnancy (n = 3), voluntary withdrawal (n = 2), lost to follow up (n = 1)
  - 1 subject (1/135) did not collect per protocol requirements
- Remaining 124 subjects demonstrated statistically and clinically significant mean menstrual blood loss reduction from their baseline levels:
  - 88 ± 133 mL at 3 months (–33%) p < .001
  - 113 ± 103 mL at 6 months (–41%) p < .001
  - 103 ± 115 mL at 12 months (–38%) p < .001
Re-intervention

- Re-intervention rate: 0.7% (1/135)
  - One subject, who was lost to follow-up at 6-months post treatment, later pursued treatment by UAE

Discussion

- Recommendations in the literature for the use of subjective, patient-centered measures in the clinical management of heavy menstrual bleeding [1–3]
- Lukes et al identified the minimum change in MBL that would be meaningful to patients at 6 months as assessed by the Menorrhagia Impact Questionnaire [1,4]
  - 36 mL/cycle
  - 22% reduction
- In comparison, at the same time point, RFVTA provided MBL reduction of:
  - 113 mL per cycle
  - 41% mean decrease in bleeding

Conclusions

- RFVTA is effective in reducing MBL by statistically and clinically significant margins in women with myomas and moderate-to-severe heavy menstrual bleeding
- This outpatient procedure provides a viable new modality of symptomatic myoma management

References

Location of Epigastric Vessels Stratified by BMI
A. Garza-Cavazos, S. Lay, J. Buedefeldt-Pollard, K. Groesch, R. Robbs, J. Becker, S. Siddique

Arturo Garza-Cavazos, M.D.
MIGS Fellow
AAGL Nov 5-9, 2012

Objectives

• Review previously established safety zones in normal weight patients.

• Identify safety zones for trocar entry in obese patients.

Background

Laparoscopy: > 2 million cases/year (1)
Abdominal wall vessel injury occurs 0.2 – 2% in laparoscopic surgeries (1)

Previous studies have mapped safe zones for entry at > 8 cm from midline. (2)

1. Fuller et al., Zahi et al., Aharoni et al., Spitzer et al.
2. Saber et al., Hunt et al., Sinprasad et al., Epstein et al.

Study Objective

• Determine if the course of the epigastric vessels varies in obese patients

• Establish safe points in obese patients to avoid injury during port placement.

Design

Consecutive selected CT images
Mapped at fixed points
Patients were divided according to BMI values divided by WHO criteria

Disclosure

I have no financial relationships to disclose.
**Design**

Inclusion criteria:
Patients 18 years of age and older

Exclusion criteria:
< 18 yrs of age, and any condition that may alter the location of the epigastric vessels

Reviewed 310 CT scans. Included 252.

T-test, one-way ANOVA (Tukey)

---

**Results**

<table>
<thead>
<tr>
<th></th>
<th>Normal (66)</th>
<th>Overweight (51)</th>
<th>Obese I (51)</th>
<th>Obese II (32)</th>
<th>Obese III (32)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid1 – R</td>
<td>4.4 (1.0)</td>
<td>5.4 (1.2)</td>
<td>5.8 (1.4)</td>
<td>6.3 (1.6)</td>
<td>7.4 (1.5)</td>
<td>.0001</td>
</tr>
<tr>
<td>Mid1 – L</td>
<td>4.9 (1.2)</td>
<td>5.4 (1.1)</td>
<td>6.3 (1.5)</td>
<td>6.7 (1.6)</td>
<td>8.0 (1.8)</td>
<td>.0001</td>
</tr>
<tr>
<td>ASIS R</td>
<td>4.6 (1.1)</td>
<td>4.9 (1.0)</td>
<td>5.4 (1.0)</td>
<td>6.0 (1.6)</td>
<td>6.8 (1.3)</td>
<td>.0001</td>
</tr>
<tr>
<td>ASIS L</td>
<td>4.7 (1.2)</td>
<td>5.0 (1.0)</td>
<td>5.4 (1.1)</td>
<td>6.1 (1.5)</td>
<td>6.7 (1.6)</td>
<td>.0006</td>
</tr>
<tr>
<td>Mid2 – R</td>
<td>5.1 (1.1)</td>
<td>5.3 (0.9)</td>
<td>5.6 (0.9)</td>
<td>6.2 (1.4)</td>
<td>6.5 (1.2)</td>
<td>.0026</td>
</tr>
<tr>
<td>M2 - L</td>
<td>5.1 (1.1)</td>
<td>5.2 (0.8)</td>
<td>5.4 (0.8)</td>
<td>6.0 (0.8)</td>
<td>6.4 (1.3)</td>
<td>.0079</td>
</tr>
</tbody>
</table>

---

Results, Tukey’s

Normal BMI compared to:

- Overweight
- Obese I
- Obese II
- Obese III

<table>
<thead>
<tr>
<th></th>
<th>OW</th>
<th>Obese I</th>
<th>Obese II</th>
<th>Obese III</th>
</tr>
</thead>
<tbody>
<tr>
<td>X – R</td>
<td>2.5 (0.7)</td>
<td>2.7 (1.0)</td>
<td>2.8 (0.6)</td>
<td>3.1 (1.0)</td>
</tr>
<tr>
<td>X – L</td>
<td>2.3 (0.8)</td>
<td>2.7 (1.0)</td>
<td>2.8 (0.8)</td>
<td>3.2 (1.1)</td>
</tr>
<tr>
<td>M1 – R</td>
<td>5.4 (1.2)</td>
<td>5.8 (1.4)</td>
<td>6.3 (1.6)</td>
<td>7.4 (1.5)</td>
</tr>
<tr>
<td>M1 – L</td>
<td>5.4 (1.1)</td>
<td>6.3 (1.5)</td>
<td>6.7 (1.6)</td>
<td>8.0 (1.8)</td>
</tr>
<tr>
<td>ASIS R</td>
<td>4.9 (1.0)</td>
<td>5.4 (1.0)</td>
<td>6.0 (1.6)</td>
<td>6.8 (1.3)</td>
</tr>
<tr>
<td>ASIS L</td>
<td>5.0 (1.0)</td>
<td>5.4 (1.1)</td>
<td>6.1 (1.5)</td>
<td>6.7 (1.6)</td>
</tr>
<tr>
<td>M2 – R</td>
<td>5.3 (0.9)</td>
<td>5.6 (0.9)</td>
<td>6.2 (1.4)</td>
<td>6.5 (1.2)</td>
</tr>
<tr>
<td>M2 - L</td>
<td>5.2 (0.8)</td>
<td>5.4 (0.8)</td>
<td>6.0 (0.8)</td>
<td>6.4 (1.3)</td>
</tr>
<tr>
<td>PS – R</td>
<td>5.8 (0.7)</td>
<td>6.0 (0.8)</td>
<td>6.2 (0.9)</td>
<td>6.5 (1.0)</td>
</tr>
<tr>
<td>PS – L</td>
<td>5.4 (0.7)</td>
<td>5.5 (0.7)</td>
<td>6.0 (0.8)</td>
<td>6.1 (1.2)</td>
</tr>
</tbody>
</table>

= significant
Conclusions

The average distance from midline to the epigastrics increases with increasing BMI.

Previously described safe zones for lateral laparoscopic port placement remain the same in patients with BMI's < 35.

Ports should be placed > 10 cm from midline in patients with BMI's 35 to minimize vessel injury.

References

The impact of robot acquisition on method of hysterectomy

Kelly N. Wright, MD
Lahey Clinic Medical Center
Burlington, MA

Hysterectomy

- 600,000 hysterectomies per year
- Second most common surgical procedure women undergo
- Hysterectomy accounts for over $5 billion health care dollars per year
  [AHRQ.gov]
- Analysis of U.S. surgical data in 2005 showed the following rates of hysterectomy:
  - Abdominal (66%), vaginal (22%), and laparoscopic (12%)
  [Wu, et al]

Changing trends

- Despite recommendations by professional organizations and evidence of superior health and economic outcomes, most hysterectomies continue to be performed via a laparotomy
- Robotic surgery has been proposed as a way to overcome the difficulties encountered with traditional laparoscopic techniques for hysterectomy
  [Advincula, Wang]

Objectives

- To observe the impact of the acquisition of a surgical robotic system on method of hysterectomy performed in a single gynecology department.

Study Design

- Retrospective cohort analysis
- Medium-sized academic community hospital in an urban location
- All gynecological cases performed at Mt Auburn Hospital from January 1, 2006 to April 30, 2012 were obtained from operating room case records
- 1111 women were identified as undergoing hysterectomy
  - --- different gynecologic surgeons
  - --- sub-specialists, --- generalists

DISCLOSURE

Consultant:
- Ethicon – Resident suturing lab instructor
Results

- From 2006 to 2010 (pre-robot):
  - Abdominal hysterectomy decreased from 26% to 8% (p<.001)
  - Laparoscopic hysterectomy increased from 59% to 82% (p<.001)

- From 2011 to 2012 (post-robot):
  - Abdominal hysterectomy stayed stable at 8-10%
  - Laparoscopic hysterectomy decreased from 82% to 46% (p<.001)

Committee guidelines

*ACOG and the AAGL have issued guidelines in support of minimally invasive procedures, vaginal hysterectomy in particular, when choosing the method of hysterectomy*

- We should aim to reduce abdominal hysterectomy when feasible

Findings

- At our institution, the acquisition of a robot decreased laparoscopic hysterectomy by 44% while abdominal hysterectomy rates remained unchanged
- Similar findings by Brenot and Goyert
  - Compared with the 18 months prior to robot acquisition:
    - Laparoscopic hysterectomy decreased by 62% in the 18 months after robot acquisition
    - Abdominal hysterectomy decreased by 18%

How can we increase minimally invasive hysterectomy?

The costs

- Barbash and Glied found that, on average, the additional cost of using a robot was $1600 - $3200 per procedure [NEJM]
- If the 600,000 hysterectomies performed in the United States each year were all done robotically:
  - $960 million to $1.6 billion increase in health care costs
Conclusions

- In an institution where a minimally invasive gynecologic surgery program already exists, the robot decreased laparoscopic hysterectomy.
- This study should be replicated at an institution where a laparoscopy program has not been established.
- Further institutional, regional, and national data are needed to truly determine trends in rates of hysterectomy.

References

Gynecologic Surgeons: Profiling At A Glance

Kiley A. Bernhard, MPH¹
Hannah Louks, BS²
Danish S. Siddiqui, MD³
Suneet P. Chauhan, MD⁴

¹Center for Urban Population Health, Milwaukee, WI;
²University of Wisconsin School of Medicine and Public Health;
³Department of Obstetrics and Gynecology, Aurora Sinai Medical Center;
⁴Eastern Virginia Medical School, Norfolk, Virginia

Disclosures

• I have no financial relationships to disclose.

Learning Objectives

• Identify the strengths and limitations of surgeon report cards and surgeon profiling
• Compare two different mechanisms of reporting surgeon complication rates
  1. Rank ordering by means
  2. Overlapping 95% confidence intervals
• Illustrate the benefits of examining the overlap between confidence intervals for comparison
• Discuss study limitations and future directions

Introduction

• Surgeon report cards have become a popular approach to surgery quality improvement
• Must take careful consideration when presenting data on surgeon performance to prevent consumers from drawing incorrect conclusions
• The majority of the research on surgeon profiling has occurred in cardiac surgery
• Paucity in studies within the specialty of gynecology

Literature Review

Relevant peer-reviewed publications were identified through searching PubMed using combinations of MeSH and keywords with surgical specialties.

Searches yielded considerably more publications within cardiac surgery than gynecological surgery.

<table>
<thead>
<tr>
<th>MeSH Term/Keyword</th>
<th>Total</th>
<th>English Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynecological Surgery</td>
<td>334</td>
<td>1616</td>
</tr>
<tr>
<td>Cardiac Surgery</td>
<td>348</td>
<td>1261</td>
</tr>
<tr>
<td>Benchmarking</td>
<td>67</td>
<td>77</td>
</tr>
<tr>
<td>Methods</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Confidence intervals</td>
<td>89</td>
<td>419</td>
</tr>
<tr>
<td>Database management</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Outcome assessment</td>
<td>86</td>
<td>9</td>
</tr>
<tr>
<td>Quality improvement</td>
<td>42</td>
<td>6</td>
</tr>
<tr>
<td>Quality of health care</td>
<td>212</td>
<td>684</td>
</tr>
<tr>
<td>Risk adjustment</td>
<td>2</td>
<td>137</td>
</tr>
<tr>
<td>Registries</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Prognostic models</td>
<td>35</td>
<td>0</td>
</tr>
<tr>
<td>Public reporting</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Quality performance measures</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Surgeon rating</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Surgical outcomes</td>
<td>36</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>348</td>
<td>1261</td>
</tr>
</tbody>
</table>

Overall conclusions:
1. Analysis of outcomes with appropriate feedback and education is a powerful tool for quality improvement
2. A national system studying the outcomes in gynecologic surgery using a risk-adjusted model would provide a meaningful mechanism in identifying areas in need of quality improvement

Publications were excluded if they did not study the assessment or describe the methods used to support the evaluation of surgeon performance: surgeon profiling, or surgical outcomes.

Specifically, the project team looked for articles that outlined the data collection methods and analysis techniques used to assess outcomes or articles that discussed the implementation of a quality improvement approach.
Methods

- **Subjects**: 25 surgeons in one tertiary center in an inner city hospital
- **Timeframe**: 7/9/2007 and 12/30/2011
- **Included procedures**: Women with BMI > 25 kg/m², who had hysterectomy for a benign indication
- **Excluded procedures**: Hysterectomy for malignant or obstetrical indications
- **Outcome variable**: Overall complication rate
  - Surgical complications: Urinary tract, bowel, vascular, or nerve injury, leak, or postoperative hemorrhage
  - Wound complications: Dehiscence, vaginal cuff cellulitis, wound infection, wound seroma, abscess, or hematoma
  - Medical complications: VTE, urinary complications, fecal incontinence, respiratory complication(s), renal failure, stroke, or retained sponge

Data Analysis

- Morbidity among surgeons was compared using 95% confidence intervals
- Non-overlapping 95% CI were considered significant
- This is a simple, conservative method for comparing two point-estimates.

Discussion

- The surgeon report card has been viewed with skepticism by numerous physicians.
- The utility of the report card has expanded beyond the hands of the actual physician and the hospital system and has been made publicly available to current and future patients.
- It is imperative that the methodology used to produce quality report cards be easily understood but as robust as possible.

Limitations

- Sample size restrictions – single hospital
- Did not use risk-adjusted outcomes
- Possible ambiguity with end points
- Surgeon volume – large CIs for few cases
Future Directions

• Development of a prognostic model for hysterectomies
• Utilization of risk adjusted rates which take into account higher risk patients (i.e. severity of illness)
• Feedback from administration and surgeons regarding interpretation of reporting mechanisms.

Table 1. Patient characteristics and comorbidities for non-overlapping surgeons

<table>
<thead>
<tr>
<th>Variable</th>
<th>All</th>
<th>S21</th>
<th>S10</th>
<th>S22</th>
<th>S5</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=538</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean/%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>35</th>
<th>40</th>
<th>45</th>
<th>50</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterine weight (g)</td>
<td>330</td>
<td>412</td>
<td>341</td>
<td>297</td>
<td>333</td>
</tr>
<tr>
<td>&gt;2 presence of Diabetes, CVD, and/or Pulmonary Disorder</td>
<td>12%</td>
<td>9%</td>
<td>7%</td>
<td>5%</td>
<td>23%</td>
</tr>
<tr>
<td>Previous abdominal surgery</td>
<td>40%</td>
<td>34%</td>
<td>45%</td>
<td>44%</td>
<td>40%</td>
</tr>
</tbody>
</table>

Conclusion

• Reporting 95% CI is a conservative method and can be used for single institutions
• Utilizing the 95% CI as a reporting method eliminates ranking of surgeons
• Surgeon report cards need to be simplified for the physician, administration, and the patient
• Hierarchical models with risk-adjusted outcomes are preferred esp. for comparing multiple hospitals

References

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).