Plenary 1 – Laparoscopy

MODERATORS
M.eir Jonathon Solnik, MD & David I. Eisenstein, MD

Sara Y. Brucker, MD  Erica C. Dun, MD  Lena El Hachem, MD
Lenore C. Ellett, MD  Simone Ferrero, MD, PhD  Richard S. Guido, MD
Professional Education Information

Target Audience
This educational activity is developed to meet the needs of residents, fellows and new minimally invasive specialists 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

Office Visceral Slide Test in Predicting Periumbilical Adhesions: A Pilot Study
E.C. Dun........................................................................................................................................................ 3

Long-Term Efficacy of Radiofrequency Volumetric Thermal Ablation (RFVTA) of Symptomatic Uterine Fibroids
R.S. Guido.................................................................................................................................................... 6

Intraoperative Blood Loss and Discharge Times after Laparoscopic Global Fibroid Ablation and Laparoscopic Myomectomy: A Blinded Randomized Controlled Trial
S.Y. Brucker ................................................................................................................................................... 9

Preoperative Treatment with Aromatase Inhibitor in Patients Undergoing Laparoscopic Myomectomy of Large Uterine Myomas
S. Ferrero ................................................................................................................................................... 12

The Effect of Patient Body Mass Index on Surgical Difficulty in Gynaecological Laparoscopy.
A Prospective Observational Study
L.C. Ellett .................................................................................................................................................... 15

A Randomized Blinded Trial of Transversus Abdominis Plane (TAP) Block Versus Trocar Site Infiltration for Postoperative Pain Control in Gynecologic Laparoscopy
L. El Hachem............................................................................................................................................... 20

Cultural and Linguistics Competency ........................................................................................................ 24
Plenary 1 – Laparoscopy

Moderators: David Eisenstein, M. Jonathon Solnik
Faculty: Sara Y. Brucker, Erica C. Dun, Lena El Hachem, Lenore C. Ellett, Simone Ferrero, Richard S. Guido,

This session provides a range of studies on topics of daily clinical importance to safe and effective laparoscopic practice. It also presents the latest data in the laparoscopic approaches to treatment of fibroids including new technology and preoperative medical therapies.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) Assess techniques for safe laparoscopic entry; 2) distinguish alternative laparoscopic technologies for treatment of uterine fibroids; and 3) compare approaches to pre-emptive analgesia.

Course Outline

11:00 Office Visceral Slide Test in Predicting Periumbilical Adhesions: A Pilot Study E.C. Dun
11:10 Long-Term Efficacy of Radiofrequency Volumetric Thermal Ablation (RFVTA) of Symptomatic Uterine Fibroids R.S. Guido
11:20 Intraoperative Blood Loss and Discharge Times after Laparoscopic Global Fibroid Ablation and Laparoscopic Myomectomy: A Blinded Randomized Controlled Trial S.Y. Brucker
11:30 Preoperative Treatment with Aromatase Inhibitor in Patients Undergoing Laparoscopic Myomectomy of Large Uterine Myomas S. Ferrero
11:40 The Effect of Patient Body Mass Index on Surgical Difficulty in Gynaecological Laparoscopy. A Prospective Observational Study L.C. Ellett
11:50 A Randomized Blinded Trial of Transversus Abdominis Plane (TAP) Block Versus Trocar Site Infiltration for Postoperative Pain Control in Gynecologic Laparoscopy L. El Hachem
12:00 Closing Remarks/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
Kimberly A. Kho*
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
M. Jonathan Solnik*
Johnny Yi*

SCIENTIFIC PROGRAM COMMITTEE
Ceana H. Nezhat
Consultant: Ethicon Endo-Surgery, Lumenis, Karl Storz
Other: Medical Advisor: Plasma Surgical
Other: Scientific Advisory Board: SurgiQuest
Arnold P. Advincula
Consultant: Blue Endo, CooperSurgical, Covidien, Intuitive Surgical, SurgiQuest
Other: Royalties: CooperSurgical
Linda D. Bradley*
Victor Gomel*
Keith B. Isaacson*
Grace M. Janik
Grants/Research Support: Hologic
Consultant: Karl Storz
C.Y. Liu*
Javier F. Magrina*
Andrew I. Sokol*

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).
Sara Y. Brucker*
Erica C. Dun
Consultant: Plasma Surgical
Lena El Hachem*
Lenore C. Ellett*
David I. Eisenstein*
Simone Ferrero*
Richard S. Guido
Training Consultant: Halt Medical
Meir Jonathon Solnik*

Asterisk (*) denotes no financial relationships to disclose.
Office Visceral Slide Test in Predicting Periumbilical Adhesions: a Pilot Study

Erica C. Dun, MD, MPH
Adi Katz, MD, and Ceana H. Nezhat, MD
Atlanta Center for Special Minimally Invasive Surgery and Reproductive Medicine

Objective

- To compare the Office Visceral Slide Test with two other preoperative tests to detect obliterating periumbilical adhesions within the abdomen.

Disclosures

- Consultant: Plasma Surgical

Trocar insertion accounts for 40% of laparoscopic complications & most of the fatalities


Entry Complications

- Abdominal wall
- Vascular
- Gastrointestinal

Preoperative Tests for Predicting Adhesions

- Office Visceral Slide Test
- Preoperative Examination with Visceral Slide
- Periumbilical Ultrasound-Guided Saline Infusion (PUGSI)
Study Design

- **Design**: Comparison of an office ultrasound diagnostic technique with an operating room ultrasound diagnostic test and PUGSI test with the gold standard – laparoscopy

- **Patients**: 82 women (12 Control, 70 Study) undergoing benign gynecologic surgery; Study Group included women with previous abdominal/pelvic surgery

- **Interventions**: Three screening tests: 1) Office Visceral Slide Test, 2) Preoperative Examination with Visceral Slide Test, and 3) PUGSI Test

- **Measurements**: The presence of obliterating umbilical lesions in the high-risk patients and the ability of the Office Visceral Slide Test to detect them
Conclusion

- Office Visceral Slide Test (OVST) is a simple and reliable test for detecting obliterating periumbilical adhesions.
- OVST is comparable to other validated tests.
- OVST may have value for preoperative surgical assessment and planning laparoscopic abdominal entry.
- Implementing the OVST may decrease injuries, allow surgeons to be better prepared for complications, and increase the number of patients benefiting from minimally surgery.

References


Patients with prior surgery, n=70

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>PPV (95% CI)</th>
<th>NPV (95% CI)</th>
<th>Accuracy (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Visceral Slide Test</td>
<td>83.3% (43.6, 96.9)</td>
<td>100% (94.3, 100)</td>
<td>100%</td>
<td>98.4% (91.8, 99.7)</td>
<td>98.6% (92.3, 99.8)</td>
</tr>
<tr>
<td>OR Visceral Slide Test</td>
<td>83.3% (43.6, 96.9)</td>
<td>96.8% (89.3, 99.1)</td>
<td>71.4% (35.9, 91.8)</td>
<td>98.4% (91.5, 99.7)</td>
<td>95.7% (88.1, 98.5)</td>
</tr>
<tr>
<td>PUGSI Test</td>
<td>66.7% (30.0, 90.3)</td>
<td>98.4% (91.7, 99.7)</td>
<td>80.0% (37.5, 96.4)</td>
<td>96.9% (89.5, 99.2)</td>
<td>95.7% (88.1, 98.5)</td>
</tr>
</tbody>
</table>

Extended McNemar Test: χ² = 2, df = 1, significance < 0.05, 0.20 < p < 0.10

Conclusion: no significant difference in the sensitivity and specificity among the 3 Tests.
Long-term Efficacy of Radiofrequency Volumetric Thermal Ablation (RFVTA) of Symptomatic Fibroids

Richard S. Guido, MD  University of Pittsburgh Medical Center, Pittsburgh, PA

Objective

- At the end of this lecture, the clinician will be able to describe the clinical significance of radiofrequency volumetric thermal ablation (RFVTA) at two years' follow up in terms of
  - Subject responses to validated questionnaires
    - Uterine Fibroid Symptom and Quality of Life (UFS-QOL)\(^1\)
    - Mean Health State Scores (EQ-5D)\(^2\)
  - Adverse events
  - Surgical re-intervention for fibroid-related bleeding

Design and Setting

- Prospective follow up of patients through 24 months posttreatment in a multicenter, international trial of outpatient, laparoscopic ultrasound-guided RFVTA of symptomatic uterine fibroids\(^3,4\)
- Continuous and categorical variables summarized based on t-test, paired t-test, signed-rank test, and chi-square test
  - p-values < 0.05 were significant
- 11 University hospitals and private surgery centers

Flow of Subjects Through Study

Study Participants Entering Year 2

- 124 Premenopausal women
  - Mean age: 42.4 ± 4.4 years
  - Mean BMI: 30.5 ± 6.2
  - Having symptomatic uterine fibroids (as measured by transvaginal ultrasound [TVUS] and magnetic resonance imaging [MRI])
  - Objectively confirmed (alkaline hematin testing) heavy menstrual bleeding (≥ 160 to ≤ 500 mL) at baseline

Disclosures

- Consultant: OmniGuide
Intervention: laparoscopic ultrasound-guided RFVTA [ACESSATM]

Results:
UFS-QOL Mean Transformed Scores

Results:
UFS-QOL Subscale Scores

Results:
Mean Health State Scores (EQ-5D)

Serious Adverse Event: possibly related to procedure
- Excessive blood loss at full-term delivery
  - Subject delivered a healthy, full-term baby by C-section
  - During C-section, subject lost 1400–1500 mL blood
  - 2 Days later, she experienced abdominal pain, additional blood loss and tissue expulsion
  - Pathology showed degenerative fibroid tissue
  - Patient received 6 units of blood
  - She was discharged with oral iron therapy for her anemia

Surgical re-interventions for fibroid-related bleeding
- 4 Hysterectomies
- 2 Hysteroscopic myomectomies
- Follow-up pathology was available for 5 of the 6 patients
  - Multiple small fibroids and adenomyosis (n = 4)
  - Possible polyp (n = 1)
- Re-intervention Rate
  - 0 to 12 months: 0.8% (1/127)
  - 12 to 24 months: 4.8% (6/124)
  - 0 to 24 months: 5.7% (7/124)
Discussion

- UFS-QOL and EQ-5D scales have been validated\(^1,2,5\)
- Results from these validated scales show continued benefits out to 24 months of follow up
- The 3-month outcomes appear to predict long-term results
- Re-intervention rate at 2-3 years for other uterine-conserving procedures can be as high as 26%\(^6,7\)
- Important to follow patients beyond 12 months to confirm durability of treatment

Conclusions:
RFVTA results indicate

- Procedure is safe and efficacious
- Durable and significantly improved quality of life and decreased symptom severity out to 2 years
- Low re-intervention rate
- Results are positive outcomes for patients’ wellbeing through 2 years of follow up

References

Intraoperative Blood Loss and Discharge Times after Laparoscopic Global Fibroid Ablation and Laparoscopic Myomectomy: a Blinded Randomized Controlled Trial

Sara Y. Brucker, MD University of Tübingen, Tübingen, Germany

Disclosures

- I have no financial relationships to disclose.

Objectives

- At the end of this lecture, the clinician will be able to assess mean hospital discharge times and perioperative outcomes for laparoscopic global fibroid ablation (radiofrequency volumetric thermal ablation of fibroids [RFVTA—Acessa™]) and laparoscopic myomectomy (LM).

Study Design

- Single site and randomized: compares two minimally invasive, uterine-sparing treatments for symptomatic uterine fibroids
  - Laparoscopic Ultrasound-Guided RFVTA using Acessa™
  - Laparoscopic Myomectomy

Primary endpoint
- Hospitalization time—number of hours from induction of anesthesia to discharge from the hospital

Secondary endpoints
- Intraoperative blood loss
- Postprocedure use of pain medication
- Days to return to normal activities of daily living

Major Inclusion/Exclusion Criteria

- Women ≥ 18 years old, menstruating, desiring uterine conservation, and w/normal pap
- Symptomatic fibroids of <10 cm, uterus <16 wks
- No contraindications for laparoscopic surgery
- No significant intra-abdominal adhesions
- No major concomitant procedures
- No implanted intrauterine or fallopian device
- No suspected endometriosis or adenomyosis
- R/O intracavitary submucous fibroids that are better treated by hysteroscopic resection

Operative Procedures and Randomization

- Hysteroscopy performed on all subjects
  - Rule out Type 0 or 1 intracavitary fibroids
- Following laparoscope insertion
  - Subject assessed for continued suitability for either procedure; if not suitable for both, subject excluded
- Ultrasound mapping using a laparoscopic ultrasound probe
  - Located and measured fibroids
  - Recorded time of mapping
- Randomization – Call made to central location and envelope opened
  - 1:1 randomization
Laparoscopic Ultrasound Mapping and RFVTA

Discharge Assessment

- Protocol for assessment at 4 hours post treatment
  - No concerns regarding post op bleeding?
  - No adhesiolysis performed at surgery?
  - Is the patient awake enough to function?
  - Is patient able to ambulate without assistance?
  - Is the patient able to use the bathroom and urinate?
  - Is the pain level tolerable?
  - Is the patient able to take oral pain meds?
  - No intraoperative or post op complications?
  - If "Yes" to all of the above, patient is discharged.

Results: Demographics

50 enrolled and treated subjects met all criteria (25 RFVTA and 25 LM)

- RFVTA patients were about 5.6 years older than the LM patients (40.0 years vs 34.4 years)
- Height and weight were similar between groups
- In both groups, heavy menstrual bleeding was the primary complaint (84% RFVTA, 72% LM)
- Next most common complaints
  - urinary frequency (52% RFVTA, 36% LM) and
  - pelvic pain and discomfort (40% RFVTA, 44% LM)

Results: Types of Treated and Excised Fibroids

<table>
<thead>
<tr>
<th>Variable</th>
<th>RFVTA</th>
<th>Laparoscopic Myomectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibroid type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submucosal</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Transmural</td>
<td>0 (0%)</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>Intramural</td>
<td>33 (46.5%)</td>
<td>18 (36.7%)</td>
</tr>
<tr>
<td>Intramural abutting the endometrium</td>
<td>2 (2.8%)</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>Subserosal</td>
<td>36 (50.7%)</td>
<td>33 (67.3%)</td>
</tr>
<tr>
<td>Pedunculated subserosal</td>
<td>0 (0%)</td>
<td>2 (4.1%)</td>
</tr>
<tr>
<td>Total fibroids treated/excised</td>
<td>71</td>
<td>49</td>
</tr>
<tr>
<td>Fibroids treated/excised as a percentage of those imaged on LUS</td>
<td>98.6% (71/72)</td>
<td>80.3% (49/61)</td>
</tr>
</tbody>
</table>

Results - Primary Endpoint

- Mean total hospitalization time (start of anesthesia to discharge readiness) significantly shorter for RFVTA subjects (p < .0001)
  - RFVTA 9 h 59 min (range 4 h 12 min–25 h 30 min)
  - LM 29 h 56 min (range 16 h 6 min–68 h 6 min)

Reasons for Overnight Hospitalization

- LM (25)– Standard of Care in Germany
  - Concern for bleeding from uterine incisions
  - Inability to ambulate without help or dizziness
  - Unable to urinate
  - Pain requiring narcotics
  - Lack of alertness
- RFVTA (5)
  - 1 patient elected to stay
  - 1 w/ fatigue and vomiting
  - 2 w/dizziness
  - 1 w/pain following adhesiolysis
Results - Secondary Endpoints

- Mean blood loss
  - RFVTA 16.2 mL
  - LM 50.6 mL
- Pain medication use in first week similar
  - 20% RFVTA subjects took no pain meds
  - 17.6% LM subjects took no pain meds
- No significant difference in return to normal activities between groups

Conclusions

- RFVTA with Acessa resulted in
  - Greater percentage of treated fibroids than at LM
  - Significantly shorter hospitalization time than with LM
  - Less intraoperative blood loss than at LM
  - Similar use of pain medication as LM subjects
  - Similar time to return to normal activities as LM subjects
  - No myometrial incisions

Perioperative Safety Results

Three perioperative complications were related to the procedure

- One RFVTA subject had vertigo due to anesthesia
- One LM subject had a hematoma at the trocar site
- One RFVTA subject had hypermenorrhea upon her first menses

Two serious adverse events not related to procedure or device

- RFVTA subject returned to hospital 17 days post op with a ruptured ovarian cyst
- LM subject became pregnant early in her post treatment period; scan showed anecephaly and pregnancy was terminated
Preoperative treatment with aromatase inhibitor in patients undergoing laparoscopic myomectomy of large uterine myomas

S. Ferrero, PhD

Department of Obstetrics and Gynaecology,
San Martino Hospital and National Institute for Cancer Research, University of Genoa

University of Genoa, Italy

Disclosure

I have no financial relationships to disclose.

Objective of the study

To assess the efficacy of preoperative treatment with AIs in premenopausal women undergoing laparoscopic myomectomy of large uterine myomas

After this lecture, the attendee should implement the preoperative hormonal treatment prior to laparoscopic excision of large uterine myomas

University of Genoa, Italy

Background

• The use of gonadotropin-releasing hormone analogues (GnRHa) in the 3-4 months before surgery is a consolidated strategy to decrease both uterine volume and fibroid size (Lethaby et al., 2001)
• In addition, the preoperative treatment with GnRHa has been demonstrated beneficial in the correction of pre-operative iron deficiency anaemia, if present, and reduce intra-operative blood loss (Lethaby et al., 2001; Chen et al., 2011)
• Similarly, aromatase inhibitors (AIs) block estrogen synthesis and have been used as medical management of uterine myomas (Shozu et al., 2003; Varelas et al., 2007; Gurates et al., 2008; Hilário et al., 2009; Parsanezhad et al., 2010)
• Continuous administration of AIs to premenopausal women may cause the development of functional ovarian cysts; therefore, hormonal therapies suppressing ovarian activity is required (Remorgida et al., 2007; Ferrero et al., 2010)

Materials and methods

Prospective open-label pilot study

Group A (n=26)
Treatment with oral letrozole* (2.5 mg/day) and norethindrone acetate (2.5 mg/day) plus elemental calcium (1000 mg/day) and vitamin D3 (800 IU/day) continuously in the three months prior to surgery

*Letrozole is not approved for the treatment of uterine myomas by the FDA and Italian Ministry of Health and therefore the use of these drugs should be considered experimental

Group B (n=26)
No treatment

University of Genoa, Italy
### Preoperative treatment with aromatase inhibitor in patients undergoing laparoscopic myomectomy of large uterine myomas

**University of Genoa, Italy**

### Characteristics of the myomas

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of myomas</th>
<th>Total number of myomas</th>
<th>Number of myomas according to number of myomas</th>
<th>Basal diameter of the largest myoma at baseline</th>
<th>Volume of the largest myoma at baseline</th>
<th>Decrease in the volume of each patient at surgery</th>
<th>Degree of difficulty in the cleavage of the myomas</th>
<th>Quality of suture in the cleavage of the myomas</th>
<th>Percentage change in the total myoma volume of each patient at surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>49 (38.5%)</td>
<td>136 (35.1%)</td>
<td>10 (38.5%)</td>
<td>13 (46.2%)</td>
<td>13 (46.2%)</td>
<td>12 (43.1%)</td>
<td>Very difficult</td>
<td>Good</td>
<td>0.125</td>
</tr>
<tr>
<td>Group B</td>
<td>71 (26.9%)</td>
<td>146 (40.6%)</td>
<td>14 (53.8%)</td>
<td>16 (61.5%)</td>
<td>16 (61.5%)</td>
<td>14 (53.8%)</td>
<td>Good</td>
<td>Good</td>
<td>0.125</td>
</tr>
</tbody>
</table>

### Results

**University of Genoa, Italy**

### Characteristics of the study population

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± SD, years)</td>
<td>35.1 ± 3.9</td>
<td>34.6 ± 3.6</td>
</tr>
<tr>
<td>BMI (m0n ± SD)</td>
<td>29.3 ± 7.7</td>
<td>22.9 ± 1.8</td>
</tr>
<tr>
<td>Parity with prior live births (n)</td>
<td>1 (3.9%)</td>
<td>1 (3.9%)</td>
</tr>
<tr>
<td>Feasibility (mean ± SD)</td>
<td>21.85 (5.25)</td>
<td>20.9 (5.15)</td>
</tr>
</tbody>
</table>

### Degree of difficulty in the cleavage of the myomas (5-point Likert scale)

- Very Easy
- Easy
- Normal
- Difficult
- Very Difficult

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Easy</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Easy</td>
<td>2 (46.2%)</td>
<td>2 (46.2%)</td>
</tr>
<tr>
<td>Normal</td>
<td>1 (3.9%)</td>
<td>1 (3.9%)</td>
</tr>
<tr>
<td>Difficult</td>
<td>17 (61.5%)</td>
<td>16 (61.5%)</td>
</tr>
<tr>
<td>Very Difficult</td>
<td>2 (46.2%)</td>
<td>2 (46.2%)</td>
</tr>
</tbody>
</table>

### Percentage change in the total myoma volume of each patient at surgery

**University of Genoa, Italy**

### Ultrasonographic evaluation of the quality of suture

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 week from surgery</td>
<td>22 (46.2%)</td>
<td>16 (33.7%)</td>
</tr>
<tr>
<td>3 months from surgery</td>
<td>25 (53.8%)</td>
<td>25 (53.8%)</td>
</tr>
</tbody>
</table>

### Degree of difficulty in the cleavage of the myomas (5-point Likert scale)

- Very Easy
- Easy
- Normal
- Difficult
- Very Difficult

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Easy</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Easy</td>
<td>5 (10.6%)</td>
<td>5 (10.6%)</td>
</tr>
<tr>
<td>Normal</td>
<td>5 (10.6%)</td>
<td>5 (10.6%)</td>
</tr>
<tr>
<td>Difficult</td>
<td>11 (22.9%)</td>
<td>11 (22.9%)</td>
</tr>
<tr>
<td>Very Difficult</td>
<td>3 (6.3%)</td>
<td>3 (6.3%)</td>
</tr>
</tbody>
</table>
Discussion

- This pilot study demonstrates that the preoperative administration of letrozole for 3 months decreases the time required to suture the hysterotomies and the intraoperative blood loss without decreasing the quality of the suture of the uterine wall detect.
- The major limitation of this study is that it was not randomized.
- Future randomized studies should compare the usefulness of preoperative administration of AIs and gonadotropin-releasing hormone analogues prior to laparoscopic myomectomy.

References

The effect of patient body mass index on surgical difficulty in gynaecological laparoscopy

Dr Lenore Ellett FRANZCOG, Mercy Hospital for Women, Melbourne, Australia

Declaration
I have no financial relationships to disclose.

Objectives
- At the conclusion of this activity participants will be able to list complication rates of laparoscopic surgery at different BMI categories.

Background
- Obesity has been well studied in obstetrics and we are well aware of problems to mother and baby including
  - Gestational hypertension/pre eclampsia
  - Gestational Diabetes
  - Congenital abnormalities
  - Increased risk of still birth
  - Increased caesarean section rate
  (Jarvie 2010, Rowlands 2010)

Obesity and laparoscopic surgery
- Not as well studied
- Available literature recommends laparoscopic approach superior to open in the obese due to
  - Reduction post operative stay
  - Reduced wound infection
  - Reduced post operative fever and ileus
Obesity and Laparoscopic Surgery

Can the planned surgery be completed in overweight and obese women undergoing gynaecological laparoscopy for benign pathology?
Do obese women face an increased risk of complications with a laparoscopic approach?
Is the conversion to laparotomy rate increased in the obese population?

Methods - Recruitment

Ethical Approval was obtained from the Human Research Ethics Committee Mercy Hospital for Women
Recruitment commenced Jan 2009 and ran until Oct 2012
Inclusion Criteria
- Woman aged over 18 attending Mercy Hospital for Women
- English speaking
- Booked for laparoscopy

Study Design

Baseline data was collected including:
- Age
- Previous surgery
- Reason for operation, intended operation
- Weight (kg)
- Height (m)
- Waist circumference (cm)
- Hip circumference (cm)

Intraoperative data was recorded on a standard data entry sheet and contained the following information:
- Operation indication
- Complexity of procedure
- Entry technique used and number of attempts
- Anatomical landmarks
  - Inferior epigastric artery right and left
  - Ureters right and left
  - Surgery performed
  - Was surgery completed as planned and why?

Other data recorded

- Who was the operator (consultant/fellow/registrar)
- Conversion to laparotomy and reason
- Difficulty of surgery
  - Simple operative eg ovarian cystectomy
  - Complex operative eg excision gr III endo
  - Advanced procedure eg TLH
- Degree of pelvic adhesions
- 6 week check:
  - Length of stay in hospital
  - Any complications
Other data recorded

- 6 week check:
  - Length of stay in hospital
  - Any complications

Clavien-Dindo classification of surgical complications

<table>
<thead>
<tr>
<th>GRADE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Any deviation from normal postoperative course without the need for pharmacological, surgical, endoscopic, radiological interventions. (Allowed therapeutic regimens are antiemetics, antipyretics, analgaesics, diuretics, electrolytes, physiotherapy)</td>
</tr>
<tr>
<td>II</td>
<td>Requiring pharmacological treatment with drugs other than such allowed for grade I. Blood transfusions and TPN are included</td>
</tr>
<tr>
<td>III</td>
<td>Requiring surgical, endoscopic or radiological intervention. a. Not under general anaesthetic b. Under general anaesthetic</td>
</tr>
<tr>
<td>IV</td>
<td>Life threatening complication (including CNS complications) requiring ICU management a. Single organ b. Multi organ</td>
</tr>
<tr>
<td>V</td>
<td>Death</td>
</tr>
</tbody>
</table>

Power calculation and Statistics

- A pilot study of 60 patients was completed in 2009 and based on this it was estimated 299 patients would be needed to have sufficient power to show a difference in the ability to complete an operation based on BMI
- All data was analysed using the program SPSS 14

Participant flow diagram
Baseline Demographics *p<0.05

<table>
<thead>
<tr>
<th>BMI</th>
<th>&lt;25</th>
<th>25-29.9</th>
<th>30-34.9</th>
<th>≥35</th>
<th>Overall</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waist:Hip</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior Surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RESULTS

<table>
<thead>
<tr>
<th>BMI</th>
<th>&lt;25</th>
<th>25-29.9</th>
<th>30-34.9</th>
<th>≥35</th>
<th>Overall</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication rate</td>
<td>7.69%</td>
<td>8.9%</td>
<td>4.5%</td>
<td>10.3%</td>
<td>7.86%</td>
<td>p=0.7</td>
</tr>
<tr>
<td>Entry attempts &gt;1</td>
<td>10.48%</td>
<td>13.48%</td>
<td>13.63%</td>
<td>17.24%</td>
<td>12.45%</td>
<td>p=0.5</td>
</tr>
<tr>
<td>Veress needle Hasson</td>
<td>48.25%</td>
<td>50.30%</td>
<td>47.25%</td>
<td>51.63%</td>
<td>47.1%</td>
<td>p=0.006</td>
</tr>
<tr>
<td>Conversion to laparotomy</td>
<td>2/143</td>
<td>5/91</td>
<td>5/91</td>
<td>1/28</td>
<td>4/307</td>
<td>p=0.29</td>
</tr>
<tr>
<td>% surgery completed as planned</td>
<td>93.7%</td>
<td>93.26%</td>
<td>93.26%</td>
<td>93.10%</td>
<td>94.4%</td>
<td>p=0.2</td>
</tr>
</tbody>
</table>

Complications

- Overall complications 7.86% (laparotomy excluded)
- Minor complications 6.8% Clavien-Dindo I/II
- Major complications 0.098% Clavien Dindo III/IV
- Vesicovaginal fistula post TLH
- Ureteric burn TLH
- Asystole requiring CPR at insufflation (surgery cancelled)

Complications and mean BMI

<table>
<thead>
<tr>
<th>Complication</th>
<th>Mean BMI</th>
<th>Mean BMI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without complication</td>
<td>26.3</td>
<td>26.8</td>
<td>0.07 (t student test)</td>
</tr>
<tr>
<td>Including laparotomy</td>
<td>26.3</td>
<td>26.9</td>
<td>0.6 (t student test)</td>
</tr>
</tbody>
</table>

Results – Surgical landmarks

<table>
<thead>
<tr>
<th>BMI</th>
<th>&lt;25</th>
<th>25-29.9</th>
<th>30-35</th>
<th>p (&gt;35)</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>R epigastric artery % not visible</td>
<td>8</td>
<td>8.9%</td>
<td>20.4%</td>
<td>27.5%</td>
<td>Yes p&lt;0.001</td>
</tr>
<tr>
<td>L epigastric artery % not visible</td>
<td>0</td>
<td>7.8%</td>
<td>13.6%</td>
<td>34.4%</td>
<td>Yes p&lt;0.001</td>
</tr>
<tr>
<td>R ureter % not visible</td>
<td>6.2%</td>
<td>12.35%</td>
<td>9%</td>
<td>31%</td>
<td>Yes p&lt;0.06</td>
</tr>
<tr>
<td>L ureter % not visible</td>
<td>6.2%</td>
<td>14.6%</td>
<td>15.9%</td>
<td>41.3%</td>
<td>Yes p&lt;0.001</td>
</tr>
</tbody>
</table>
Discussion

- The strengths of this study were that it was a prospective trial that quantified the risks of surgery and looked at the role BMI played
- Our findings are in keeping with the literature on laparoscopic hysterectomy for endometrial cancer (O’Hanlan 2003, Obermair 2005)
- Laparoscopy is safe in overweight women – the group most likely to benefit from a laparoscopic approach
- Equipment is very important - we found the use of pedi ports to be essential

Conclusion

- Laparoscopic surgery can be offered to patients who are obese and overweight
- Be aware that anatomical landmarks may be obscured
- Majority of patients will be able to have surgery completed laparoscopically and in this trial conversion to laparotomy rates did not increase as BMI increased
- Complication rates did not significantly increase as BMI increased (max BMI in this study 49.7)
- It is anticipated that at the current rate of increase of overweight Australians, by 2020, 75% of the population will be overweight or obese and 65% of young Australians will be overweight or obese.

References

Introduction

- Known advantages of laparoscopy: better cosmetic results, decreased blood loss, decreased postoperative pain, shorter hospital stay, faster recovery time.

- Laparoscopic procedures are reported to cause intense pain during the immediate postoperative period (24h).

- Multifactorial pain:
  - Somatosensory
  - Visceral
  - Referred shoulder pain

- Decreased postoperative pain has been associated with improved outcome and patient satisfaction, a reduction in opioid consumption and fewer side effects.

  Wu et al., Region Anesth Pain Med, 2005

Background

- Traditional approaches include:
  - Perioperative narcotics and NSAIDS (IV or PO)
  - Local infiltration of anesthetics at trocar sites
  - Intraperitoneal instillation of anesthetics

- Tap block was shown to be efficacious in reducing postoperative pain after abdominal surgery as demonstrated in a meta-analysis of 18 RCT.
  Siddiqui et al., J Clin Anesth, 2011

- Conflicting data regarding gynecologic laparoscopy:

  - RCT of Tap block using 0.5% ropivacaine versus saline in laparoscopic hysterectomy (66 patients) showed significant decrease in pain.
    De Oliveira et al., Obstet & Gynecol, 2011

  - RCT of Tap block using 0.5% ropivacaine versus saline in TLH (58 patients) showed no significant decrease in pain scores or narcotic use.
    Kane et al., AJOG, 2012

Background - Tap Block

- Peripheral nerve blockade of the nerves supplying the anterior abdominal wall
  - Intercostal nerves (T7-T11)
  - Subcostal nerve (T12)
  - Ilioinguinal and iliohypogastric nerves (L1-L2)

- Local anesthetic is deposited through a single entry point between the internal oblique and transversus abdominis muscles

- Provides unilateral analgesia between the costal margin and the inguinal ligament

Disclosure

- I have no financial relationships to disclose.
Study Hypothesis and Objectives

- Null Hypothesis: TAP block does not reduce postoperative pain compared to traditional trocar site infiltration of bupivacaine in gynecologic laparoscopy

- Objective: To prospectively compare postoperative pain in patients receiving unilateral TAP block and contralateral local infiltration analgesia
  - Subjective measures:
    - Postoperative pain scores on Tap side versus contralateral side
    - Spontaneously and on palpation
  - Objective measures:
    - Postoperative narcotic use converted to morphine sulfate equivalents
    - Complications

Study Design

- Power analysis
  - Primary outcome: patient-reported pain score
  - A 2 point difference in pain scores was considered clinically significant
  - A sample size of 34 patients in each cohort is able to detect a difference of 2.0 points in pain score with a power of 80%, assuming a SD of 4 and a 2-sided alpha of 0.05

Methods: Interventions

**Experimental Arm**
- Total of 30 mL of 2.5% Bupivacaine with epinephrine (max 2.5 mg/kg)
- Mid-axillary line between the costal margin and the iliac crest

**Control Arm**
- Total of 30 mL of 2.5% Bupivacaine with epinephrine (max 2.5 mg/kg)
- Contralateral side lateral port 40% (3,3,3,3=12)
- Midline umbilical on contralateral side only 40% (6,6=12)
- Supra public sites on contralateral side only, 20% (3,3=6)

Study Design and Setting

- Prospective randomized blinded clinical trial using the patients as their own controls.
  - Treatment side randomized to right or left side of abdomen
  - Patients and postoperative assessments blinded to the laterality of treatment

- Set at White Plains Hospital.
  - IRB approved in January 2013, ongoing study
  - Single surgeon, two anesthesiologists

- Criteria of inclusion:
  - Patients aged >18 undergoing gynecologic laparoscopy using 4-port symmetrical technique.

- Criteria of exclusion:
  - Known allergy to anesthetic
  - Refusal to participate in the study or follow-up assessment
  - Any conversion to laparotomy, more or less than 4 ports

**Figure 1: Study Design**

- Standardized regimen for all patients:
  - Intraoperative IV Acetaminophen and Ketorolac
  - Postoperative analgesics upon request

- **Cohort 1**
  - Surgeon--administered laparoscopic-guided Tap block versus Trocar infiltration
  - Tap side via laparoscopy: 30 mL of 2.5% bupivacaine with epinephrine
  - Contralateral side: 30 mL of 25% bupivacaine with epinephrine in divided doses in the port sites

- **Cohort 2**
  - Anesthesiologist-administered ultrasound-guided Tap block versus trocar infiltration
  - Tap side via ultrasound: 30 mL of 2.5% bupivacaine with epinephrine
  - Contralateral side: 30 mL of 25% bupivacaine with epinephrine in divided doses in the port sites

Methods: Measurements

- Demographic and surgical data: age, race, BMI, ASA, diagnosis, procedure, surgical time, estimated blood loss

- Postoperative pain was assessed using the Numeric Rating Scale (NRS) [0-10] on the Tap side and contralateral side
  - At 1,2,4,6,8,12,18,24,48 hours postoperatively
  - Spontaneously and on palpation of the incisions

- Postoperative analgesic use (IV and PO) over 48 hours was converted to morphine sulfate equivalents (MSE) using equianalgesic tables

- Pain diary was collected at the 2-week postoperative visit

- Statistical analysis was conducted using SAS software Version 9.2 (SAS Institute, Inc., Cary, NC)
Results

54 patients enrolled
- Exclusion of 1 patient converted to a laparotomy

Cohort 1 – 36 patients
Laparoscopic-guided Tap versus trocar infiltration

Cohort 2 (in progress)
Ultrasound-guided Tap versus trocar infiltration

18 Right sided Tap
18 Left sided Tap
9 Right sided Tap
8 Left sided Tap

Figure 2: Flow of enrolled subjects through the study

Table 1: Demographic Data

<table>
<thead>
<tr>
<th>Cohort 1 n=36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
</tr>
<tr>
<td>BMI, Kg/m2, mean (SD)</td>
</tr>
<tr>
<td>Race, n (%)</td>
</tr>
<tr>
<td>Caucasian</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>ASA, n (%)</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>Preoperative diagnosis, n (%)</td>
</tr>
<tr>
<td>Fibroid uterus</td>
</tr>
<tr>
<td>Adnexal mass</td>
</tr>
<tr>
<td>Malignant or Premalignant</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

Data shown as mean (SD) or n (%)

Table 2: Surgical Data

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cohort 1 n=36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating time, min, mean (SD)</td>
<td>79.3 (31.1)</td>
</tr>
<tr>
<td>Estimated blood loss, ml, mean (SD)</td>
<td>105.1 (75.7)</td>
</tr>
<tr>
<td>Procedures:</td>
<td></td>
</tr>
<tr>
<td>Adnexal only, n (%)</td>
<td>10 (28%)</td>
</tr>
<tr>
<td>Adnexal / BSO, n (%)</td>
<td>8 (22%)</td>
</tr>
<tr>
<td>TLH / BSO, n (%)</td>
<td>8 (22%)</td>
</tr>
<tr>
<td>TLH + staging, n (%)</td>
<td>10 (28%)</td>
</tr>
<tr>
<td>IP or Postoperative complications, n (%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Time to discharge from PACU, min, mean (SD)</td>
<td>113.9 (42.2)</td>
</tr>
<tr>
<td>Length of hospital stay in days, median (range)</td>
<td>5 [0-1]</td>
</tr>
</tbody>
</table>

Data shown as mean (SD), median [range] or n (%)

Table 3: Patient-reported pain scores, cohort 1

<table>
<thead>
<tr>
<th>Postoperative</th>
<th>Tap block side</th>
<th>Trocar infiltration side</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 hr</td>
<td>1.9 [0 - 8]</td>
<td>1.7 [0 - 10]</td>
<td>.75</td>
</tr>
<tr>
<td>2 hr</td>
<td>1.0 [0 - 6]</td>
<td>0.8 [0 - 4]</td>
<td>.77</td>
</tr>
<tr>
<td>4 hr</td>
<td>0.8 [0 - 5]</td>
<td>1.1 [0 - 9]</td>
<td>.34</td>
</tr>
<tr>
<td>6 hr</td>
<td>0.9 [0 - 6]</td>
<td>1.5 [0 - 9]</td>
<td>.30</td>
</tr>
<tr>
<td>8 hr</td>
<td>1.3 [0 - 6]</td>
<td>1.8 [0 - 9]</td>
<td>.37</td>
</tr>
<tr>
<td>10 hr</td>
<td>1.1 [0 - 6]</td>
<td>1.5 [0 - 7]</td>
<td>.34</td>
</tr>
<tr>
<td>12 hr</td>
<td>1.4 [0 - 6]</td>
<td>1.7 [0 - 8]</td>
<td>.55</td>
</tr>
<tr>
<td>14 hr</td>
<td>1.2 [0 - 6]</td>
<td>1.5 [0 - 9]</td>
<td>.94</td>
</tr>
<tr>
<td>18 hr</td>
<td>1.2 [0 - 6]</td>
<td>1.7 [0 - 6]</td>
<td>.31</td>
</tr>
</tbody>
</table>

There is no statistically significant difference in pain scores at any time point

Data shown as median (range), and analyzed using the Signed rank test

Narcotic Requirements

- The mean narcotic requirement at 24 hours is 8.2mg (SD 7.8mg)
- There is a significant difference between mean narcotic requirement in our study and the mean (15mg) recorded in the literature using placebo Tap block (p<0.0004) (De Oliveira et al)
- However no significant difference was found when compared to the mean (11.7mg) recorded in the literature using bupivacaine Tap block (p=0.06) (De Oliveira et al)

Figure 3: Narcotic doses in MSE

There is no significant difference in pain scores over time (Tobit model)
**Discussion**

- **Strengths:**
  - The design of the study: randomized, blinded study, using patients as their own controls.
  - Adequate sample size, and power.
  - Validated instruments (NRS) and objective measures (narcotic use converted to MSE) to assess pain.

- **Limitations:**
  - Low pain scores secondary to IOP analgesia or overall multimodal analgesia.
  - Need to compare laparoscopic guided tap block to ultrasound-guided tap block.

**References**


**Conclusion**

- Tap block offered no clinical benefit over local anesthetic port site infiltration in women undergoing gynecologic laparoscopy.
- Equal and large volumes of local anesthetic administration at trocar sites and tap block sites may have contributed to the equivalent pain relief.
- As part of this multimodal analgesic regimen, surgeon-administered tap block and trocar site bupivacaine infiltration were equally effective in terms of postoperative pain control.
- Further randomized studies are needed, and objective measures are particularly valuable because there is bias from anesthesiologists regarding this new technology.
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.

~