Plenary 1: Laparoscopy

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D. Alan Johns, MD
Dan C. Martin, MD

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Mallory A. Stuparich, MD
Jamie Stanhiser, 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.

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Plenary 1: Laparoscopy

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Discussants: Shan Biscette, Olav Istre, Ted T.M. Lee, Claire Templeman, Ming Tsai

Faculty: Kenneth I. Barron, Anna Lyapis, Wolfgang Nugent, Shailesh P. Puntambekar, Jamie Stanhiser, Mallory A. Stuparich

This session will explore the effects of the FDA recommendations on power morcellation on practice patterns as well as less controversial topics in laparoscopic surgery.

Learning Objectives: At the conclusion of this course, the participant will be able to: 1) Discuss the power morcellation controversy and its effects on our surgical practice. Surgical techniques, anatomy, and pain issues will also be discussed.

Course Outline

11:00 Trends Over Time and Surgical Outcomes of Abdominal, Mini-Laparotomy, and Traditional and Robotic-Assisted Laparoscopy With and Without Tandem Mini-Laparotomy: A Comparison of Myomectomy Techniques J. Stanhiser
11:06 Discussant O. Istre
11:10 Does the Difference in Fascial Closure Surgical Technique Affect Post-Operative Pain? A. Lyapis
11:16 Discussant M. Tsai
11:20 Rates of Minimally Invasive Hysterectomy and Myomectomy Decrease After the FDA Warning on Power Morcellation K.I. Barron
11:26 Discussant C. Templeman
11:30 Laparoscopic Supravaginal Hysterectomy or Myomectomy With Power Morcellation: Risk of Uterine Leiomyosarcomas. A Retrospective Trial Including 35,161 Women in Germany W. Nugent
11:36 Discussant T.T.M. Lee
11:40 Video: Fascial Anatomy and Its Relevance in Safe Laparoscopic Hysterectomy S.P. Puntambekar
11:46 Discussant T.T.M. Lee
11:50 Video: Lysis of Anterior Abdominal Wall Adhesions: A Systematic Approach M.A. Stuparich
11:56 Discussant S. Biscette
12:00 Adjourn
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Speakers Bureau: Myriad Genetics Lab
Other: Proctor: Intuitive Surgical
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Shan Bisette*
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Anna Lyapis*
Dan C. Martin
Consultant: AbbVie
Wolfgang Nugent*
Shailesh P. Puntambekar*
Jamie Stanhiser*
Mallory A. Stuparich*
Claire Templeman
Spouse: Other: Advisory Board Membership: Astellas, Bayer Healthcare Corp., Johnson & Johnson, Merck Serono, Pfizer, Roche
Ming Tsai*

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Trends Over Time and Surgical Outcomes of Abdominal, Mini-Laparotomy, and Traditional and Robotic-Assisted Laparoscopy with and without Tandem Mini-Laparotomy: A Comparison of Myomectomy Techniques

Jamie Stanhiser, M.D.
Cleveland Clinic

Objective
• Comparison of the trends over time and surgical outcomes of myomectomy by abdominal, mini-laparotomy, and traditional and robotic-assisted laparoscopy with and without tandem mini-laparotomy techniques

Introduction
• April 17, 2014 FDA Warning
  Because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation for uterine fibroids.

• Previously minimally invasive myomectomies are necessitating larger incisions for leiomyoma extraction

Design and Methods
• Retrospective cohort study
• Population:
  – Patients undergoing myomectomy January 1995 to February 2015 in a tertiary care center
• Surgical Technique Trends by Year and Surgical Outcomes assessed by:
  – Operative Time
  – Estimated Blood Loss (EBL)
  – Myoma Weight (g)
  – Length of Stay (LOS)
  – Complications and Blood Transfusions

I have no financial relationships to disclose.
Methods

• Data:
  – Medians [Interquartile Ranges]
  – Means ± Standard Deviation

• Statistical Analysis:
  – Student’s t-test and Wilcoxon rank sum test
  – p < 0.01

Results

- Average age: 38.2 ± 6.2 years
- LOS (days): 2.9 ± 1.5 0.5 ± 0.7 0.5 ± 0.7 1.6 ± 1.5 1.0 ± 0.6 1.3 ± 1.5

Conclusion

• With recent limitations in available techniques for myoma extraction in MIS, the trend toward the use of laparotomy or an additional mini-laparotomy incision may not be benign
• Potential for greater operative time, EBL, LOS, and complications including blood transfusions
• This study supports the need for further investigation of minimally invasive myoma extraction techniques

REFERENCES


Thank You
Does the difference in fascial closure surgical technique affect post-operative pain?

A. Lyapis

Disclosures

• I have no financial relationships to disclose

Objectives

At the conclusion of this activity, the participant will be able to compare the
• Difference in the patients’ report of pain on POD 1
• Difference in the patients’ report of pain on POD 14
• Difference in the time taken to perform the closure

When using fascial closure device versus standard fascial closure to close a lateral 12mm port

Background

• Incisions > 10mm require closure of fascia to prevent hernia formation
• Traditional closure
• Fascial closure

Design

• Randomized controlled trial
• Two academic affiliated hospitals, 11/2012 – 10/2014
• Benign GYN surgery
• 12mm upper quadrant port required

Design

• Consented at preoperative visit
• Allocation via computer generated sequence
• Randomization immediately prior to closure
• Intraoperative trocar site instillation of 5ml 0.25% marcaine
• Patient and surgeon blinded preop
• Patient blinded post op
Outcomes measured

- Incisional pain
  - 10 point Likert analogue pain scale on POD 1
  - 10 point Likert analogue pain scale on POD 14
- Time to close

Results

<table>
<thead>
<tr>
<th></th>
<th>Fascial closure device</th>
<th>Traditional closure</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age</td>
<td>X</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>29.1</td>
<td>28.5</td>
<td>0.62</td>
</tr>
<tr>
<td>Pain, POD 1</td>
<td>3.41</td>
<td>2.06</td>
<td>0.024</td>
</tr>
<tr>
<td>Pain, POD 14</td>
<td>1.82</td>
<td>0.76</td>
<td>0.027</td>
</tr>
<tr>
<td>Time to close fascia (sec)</td>
<td>108</td>
<td>145</td>
<td>0.168</td>
</tr>
</tbody>
</table>

Conclusion

- Traditional fascial closure is associated with less post operative pain on POD 1 and 14
- Technique of closure does not impact time to close
- Trend for higher BMI associated with longer closure in the traditional fascial closure group

References

- Yamamoto M, Minikel L, Zarinsky E., Laparoscopic 5-mm Trocar Site Herniation and Literature Review. JSLS (2011)15:122–126
Rates of Minimally Invasive Hysterectomy and Myomectomy Decrease After the FDA Warning on Power Morcellation

Kenneth Barron, MD, FACOG
Fellow, MIGS
Advanced & Minimally Invasive Gynecology
Florida Hospital Orlando

I have no financial relationship to disclose.

At the conclusion of this activity, participants will be able to:

• Describe the effect of the U.S. FDA morcellation warning statement on surgical approach to hysterectomies and myomectomies.

Background

• Electromechanical (power morcellation) – Easier removal of large specimens without larger incisions or laparotomy

• April 17th, 2014: U.S. Food & Drug Administration (FDA) releases warning statement discouraging power morcellation for leiomyoma – risk of iatrogenic dissemination of malignant tissue

• Many hospitals, including Florida Hospital, banned power morcellators for myoma-related surgery after FDA announcement.

• Has there been a change in surgical practice immediately following the FDA announcement?

Methods

• Time-series analysis

• De-identified surgical case logs from OR documentation system

• All hysterectomies & myomectomies in Florida Hospital System Aug. 1, 2013-Dec. 31, 2014 – 8 months before FDA announcement vs. 8 months after – 6 hospitals, 98 surgeons

• Excluded hysteroscopic myomectomies

• Minimally invasive (vaginal, laparoscopic, or robotic-assisted) compared to laparotomy for each time period

• Bivariate analysis for significance was completed using chi-squared or z-tests

Patient Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Before (n = 1796)</th>
<th>After (n = 1777)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>49.22 ± 12.5</td>
<td>48.67 ± 12.1</td>
<td>.18*</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>.056†</td>
</tr>
<tr>
<td>White</td>
<td>1326 (73.8)</td>
<td>1253 (70.5)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>298 (16.6)</td>
<td>308 (17.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>124 (6.9)</td>
<td>165 (9.3)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>26 (1.4)</td>
<td>23 (1.3)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>22 (1.2)</td>
<td>28 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>29.87 ± 7.5</td>
<td>30.31 ± 7.6</td>
<td>.08*</td>
</tr>
<tr>
<td>Insurance Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>1223 (68.1)</td>
<td>1163 (65.5)</td>
<td>.001†</td>
</tr>
<tr>
<td>Public</td>
<td>434 (24.2)</td>
<td>384 (21.6)</td>
<td></td>
</tr>
<tr>
<td>Uninsured</td>
<td>139 (7.7)</td>
<td>230 (12.9)</td>
<td></td>
</tr>
</tbody>
</table>

* Determined by Student’s t-test.
† Determined by χ² test.
! P<.001 by 2 t-test
Hysterectomies 8 months before & after U.S. FDA safety warning on power morcellation

- 5.8% difference, \( P < .001 \)
- 8.7% difference, \( P < .001 \)

Hysterectomies by sub-specialty 8 months before & after U.S. FDA safety warning

- 6.8% difference, \( P < .001 \)
- 8.7% difference, \( P < .001 \)

Myomectomies 8 months before & after U.S. FDA safety warning on power morcellation

- 19% difference, \( P = .009 \)

Myomectomies by sub-specialty 8 months before & after U.S. FDA safety warning

- \( P < .05 \)

Rates of minimally invasive hysterectomy and myomectomy by surgeon volume

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Surgeon</th>
<th>Before</th>
<th>After</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysterectomy</td>
<td>High Volume*</td>
<td>1147 (86.4)</td>
<td>1132 (83.2)</td>
<td>.024</td>
</tr>
<tr>
<td></td>
<td>Low Volume</td>
<td>504 (83.1)</td>
<td>218 (66.1)</td>
<td>.001</td>
</tr>
<tr>
<td>Myomectomy</td>
<td>High Volume</td>
<td>50 (73.5)</td>
<td>27 (45)</td>
<td>.501</td>
</tr>
<tr>
<td></td>
<td>Low Volume</td>
<td>14 (41.2)</td>
<td>11 (39.3)</td>
<td>.880</td>
</tr>
</tbody>
</table>

Data are n (%). All data analyzed by \( \chi^2 \) test.

- \( \geq 30 \) hysterectomies/study period.
- \( \geq 9 \) myomectomies/study period.

Rates of surgery of uninsured patients

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Before</th>
<th>After</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysterectomy</td>
<td>32</td>
<td>103</td>
<td>54</td>
</tr>
<tr>
<td>Myomectomy</td>
<td>2</td>
<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

Conclusions

- Increase in laparotomies for benign hysterectomy (8.7%) and myomectomy (19%) during the 8 months after FDA warning statement.
- Largest decrease found in laparoscopic supracervical hysterectomies (60%).
- Practice changes were subspecialty dependent.
- If findings are reproducible in a national cohort, and with 433,000 hysterectomies in the U.S. each year, 21,700 to 39,000 additional women could be undergoing a laparotomy annually.
REFERENCES

Laparoscopic Supracervical Hysterectomy or Myomectomy With Power Morcellation: Risk of Uterine Leiomyosarcomas. A Retrospective Trial Including 35,161 Women in Germany

Wolfgang Nugent, MD
TAGESKLINIK ALTONAER STRASSE, Hamburg, Germany
Center of Gynecological Endoscopy

I have no financial relationships to disclose.

OBJECTIVES

• Discuss the benefit-to-harm balance of Laparoscopic Supracervical Hysterectomy or Myomectomy With Power Morcellation

Benefit-to-Harm Balance

Our low number of leiomyosarcoma (LMS) underlines the safety and beneficial technique of power morcellation in laparoscopic surgeries.

The incidence of occult LMS in women with symptomatic fibroids or abnormal uterine bleeding who undergo appropriate preoperative evaluation is 1.3 for 100,000 women

Design

A retrospective study (Canadian Task Force classification IIa)
10 years mean follow up

30,437 cases of VAAO (German multi-center group)
in comparison to the data of

FDA (Federal Drug Administration)
ESGE (European Society)
DGGG (German society)

Setting

7 free-standing gynecological day clinics in Germany - VAAO
1 Hospital of maximum care
~ 6800 laparoscopic surgeries / year
> 170,000 laparoscopic surgeries since 1990
LMS according to Type of Surgery

<table>
<thead>
<tr>
<th>7 Day clinics/1 Hospital</th>
<th>Period</th>
<th>Myomectomy</th>
<th>LMS</th>
<th>Hysterectomy</th>
<th>LMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamburg</td>
<td>2010-2014</td>
<td>5748</td>
<td>0</td>
<td>1863</td>
<td>0</td>
</tr>
<tr>
<td>Munich</td>
<td>2008-2014</td>
<td>2150</td>
<td>0</td>
<td>1784</td>
<td>4</td>
</tr>
<tr>
<td>Bonn</td>
<td>2004-2014</td>
<td>506</td>
<td>0</td>
<td>270</td>
<td>0</td>
</tr>
<tr>
<td>Munster</td>
<td>2005-2014</td>
<td>349</td>
<td>0</td>
<td>980</td>
<td>2</td>
</tr>
<tr>
<td>Velen</td>
<td>2008-2014</td>
<td>240</td>
<td>1</td>
<td>1010</td>
<td>1</td>
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<tr>
<td>Oldenburg</td>
<td>2006-2014</td>
<td>124</td>
<td>0</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>Mainz</td>
<td>2005-2014</td>
<td>122</td>
<td>0</td>
<td>831</td>
<td>1</td>
</tr>
<tr>
<td>Munster Hospital</td>
<td>1989-2014</td>
<td>6203</td>
<td>3</td>
<td>8021</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>38437</td>
<td>15622</td>
<td>4</td>
<td>14815</td>
<td>16</td>
</tr>
</tbody>
</table>

Measurements and main results

- **30,437** women, **20** leiomyosarcoma (LMS), incidence **1:1465 (0,056%)**
- **15,622** Laparoscopic myomectomy, LMS **1:3906** cases.
- **14,815** Laparoscopic supracervical hysterectomy, LMS **1:926** cases

All procedures included uterine power morcellation.

- FDA data incidence **1:350** = **0,29%**
- DGGG German society **1:416** = **0,24%**
- VAAO **1:1465** = **0,056%**
- ESGE European society **1:7400** = **0,014%**
- TKA (Hamburg) **1:7631** = **0,013%**

Statement

Laparoscopic surgery including uterine power morcellation has increased resulting in a decrease of morbidity and mortality

- Less postoperative pain
- Fewer wound complications
- Quicker recovery
- Cost savings

Conclusion I

The benchmark should be all the proven benefits of minimal invasive surgery (MIS) documented in retro- and prospective studies including significant improvements in morbidity and mortality in comparison to open surgery.

Conclusion II

There are currently existing neither preoperative examinations nor diagnostics capable of differentiating unambiguously between benign and malignant entities.

Dissemination of malignant tissue may worsen the patients prognosis. However the current data are not sufficient to arrive at a definitive conclusion which would allow to estimate the deterioration of prognosis.

Summary

The number of MIS has doubled in the last 10 years from 30% to 63% in gynecological surgeries (in the USA)

The benefit of the development of MIS with uterine power morcellation in the last 25 years can not be quit because of a rare event, imprecise data and an emotional discussion.


Kho KA, Nezhat CR. Evaluating the risks of electric uterine morcellation. JAMA. 2014;311(9):905-906


UPDATED Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy. FDA Safety Communication; Nov 24, 2014
Fascial Anatomy and Its Relevance in Safe Laparoscopic Hysterectomy
Shailesh P. Puntambekar, MD
Galaxy Care Laparoscopy Institute, Pune, India

Objective: To demonstrate importance of anatomy of endopelvic fascia as seen by laparoscopy to perform safe laparoscopic hysterectomies.

Design: Combination of surgical videos and design diagrams were used.

Setting: High definition surgical videos from Galaxy care Laparoscopy Institute, Pune, India were compiled. They clearly demonstrate anatomy of endopelvic fascia and describe tips to avoid damage to major structures including major vessels, ureter, bowel, bladder and endopelvic fascia. Laparoscopic view of anatomy with the current camera systems is an excellent tool to demonstrate and teach pelvic anatomy which can be applied to surgical principles in difficult benign and oncological cases.

Interventions: Total laparoscopic approach was used to demonstrate the fasciae that were seen during various types of hysterectomies. The video describes following:

1. Posterior leaf of broad ligament was opened till apex of uterosacral ligament.
2. Anterior leaf of broad ligament was opened till vesico-uterine peritoneal reflection.
3. Bladder dissection principles were described.
4. Pubocervico-vesical fascia and its relevance to bladder dissection.
5. Relevance of anatomy of uterine artery, vein and ureter with endopelvic fascia within the leaves of broad ligament.
6. Denonvillier’s fascia dissection technique for dissection of rectum away from vagina.
7. Vesicocervical ligaments anatomy forming ureteric tunnel were demonstrated.
8. Dissection principles of lateralising ureter in retrovesical region were explained.
9. Endopelvic fascia reflection continuing caudally covering pelvic floor was described.
10. Relevance of anatomy of endopelvic fascia and stress urinary incontinence treatment technique was described.

Conclusion: Understanding anatomy of fasciae of pelvis helps to create avascular planes and is crucial for performing safe hysterectomy.
Lysis of Anterior Abdominal Wall Adhesions: A Systematic Approach

Mallory A. Stuparich, MD
Magee-Womens Hospital of UPMC, Pittsburgh, Pennsylvania

Objective: To present a systematic approach and techniques for safe and efficient lysis of anterior abdominal wall adhesions.

Design: Stepwise demonstration of techniques with narrated video footage.

Setting: Prior abdominopelvic surgery is the most significant risk factor for the formation of anterior abdominal wall adhesions. These adhesions increase the risk of conversion to laparotomy as well as the risk of inadvertent trocar insertion injury. Adhesive disease may also distort the underlying anatomy during laparoscopy, necessitating modification of port placement or addition of upper abdominal ports. In this video, we show several scenarios of increasing complexity to review key principles and techniques for safe and efficient lysis of abdominal wall adhesions.

Interventions: The key principles for successful and safe lysis of anterior abdominal wall adhesions include:

- Gaining visibility superior to the pathology
- Choosing appropriate instruments for adhesiolysis
- Triangulating instruments to provide counter-traction
- Thinning and serially separating the adhesions

Conclusion: Techniques for safe and successful lysis of anterior abdominal wall adhesions include maintaining visibility, triangulating instruments to the pathology so that careful dissection can occur, and selecting an appropriate instrument for adhesiolysis. Additionally, to prevent abdominopelvic organ injury, the surgeon must avoid heat near bowel or uncertain adhesion contents and utilize cold cutting and gentle interrogative blunt dissection.
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

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.

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 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.