Fellowship in MIGS Postgraduate Course

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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 7.5 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.
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Histological Characterization of Vaginal Cuff Tissue Using Different Energy Sources During Robotic Hysterectomy: A Randomized Trial
This full day course will provide current, graduating and recently graduated (2011-2013 only) FMIGS fellows with the professional development skills to succeed in either an academic or community-based practice. An emphasis on life-long learning and knowledge acquisition in the field of minimally invasive gynecologic surgery will be made. A morning session will concentrate on career-building strategies, followed by an afternoon scientific program designed to showcase research projects completed by current and graduating FMIGS fellows. An invited keynote speaker will address the summit during a sponsored luncheon. The evening graduation ceremony will highlight the achievements of fellows and the role of the AAGL in ongoing practice.

AAGL encourages fellows outside the FMIGS program to participate for a nominal fee.

**Learning Objectives:** At the conclusion of this course, the clinician will be able to: 1) Identify and evaluate key aspects of academic and community medicine relevant to his/her personal and professional goals; 2) articulate the critical components of contracting and negotiating a professional path forward; and 3) formulate strategies to answer scientific questions and incorporate research into clinical practice.

**AM Course Outline**

*Develop Career Strategies*

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<td>The Path Forward: Academic vs. Community-Based Practice</td>
<td>K. Huang</td>
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<td>7:55</td>
<td>The Devil’s in the Details: Negotiating Your Contract</td>
<td>S. Mansuria</td>
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<td>8:20</td>
<td>Navigating the Hurdles of Being a Junior Attending</td>
<td>K. Patzkowsky</td>
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<td>8:55</td>
<td>Questions and Answers</td>
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<td>9:15</td>
<td>Break</td>
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<td>A Conversation with Past FMIGS Fellows:</td>
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<td>Lessons Learned...</td>
<td>M.W. Dassel, M.R. Hoffman</td>
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<td>11:00</td>
<td>Adjourn</td>
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<tr>
<td>11:15</td>
<td>Lunch with Dr. Rosanne Kho: Balancing Work and Life: Can It Be Done?</td>
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<tr>
<td>Time</td>
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<tr>
<td>12:30</td>
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<td>Developing a Research Idea and Writing a Scientific Abstract</td>
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<td>12:55</td>
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<td>1:15</td>
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<td>Jay M. Cooper: Unexpected Uterine Sarcoma and Other Gynecologic Malignancies</td>
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<td>2:30</td>
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<td>2:45</td>
<td>Robotic Simulators: A Case for the Return on Investment</td>
<td>K.M. Simpson, K. Huang</td>
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<td>3:10</td>
<td>Paracervical Block of Bupivacaine with Epinephrine Prior to Robotic-Assisted</td>
<td>R.L. Barr, K. Patzkowsky</td>
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<tr>
<td>3:35</td>
<td>Histological Characterization of Vaginal Cuff Tissue Using Different Energy Sources</td>
<td>M. Billow, K. Patzkowsky</td>
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<tr>
<td>4:00</td>
<td>Questions and Answers</td>
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<td>4:30</td>
<td>Adjourn</td>
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<tr>
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<td>FMIGS Graduation Ceremony</td>
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<td>Reception</td>
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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*
Kimberly A. Kho*
Frank D. Loffer, Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
M. Jonathon Solnik*
Johnny Yi*

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Other: Royalties: CooperSurgical
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Other: Scientific Advisory Board: SurgiQuest
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Other: Stock Ownership: Titan Medical
Robert K. Zurawin
Consultant: Bayer Healthcare Corp., CONMED Corporation, Ethicon Endo-Surgery, Hologic, 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).
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Megan Billow*
Mark W. Dassel*
Stuart R. Hart
Consultant: Boston Scientific Corp. Inc., CooperSurgical, Covidien, Stryker Endoscopy
Grants/Research: Boston Scientific Corp. Inc., CooperSurgical, Covidien, Stryker Endoscopy
Speakers Bureau: Boston Scientific Corp. Inc., Covidien
Mark R. Hoffman*
Jian Qun (Kathy) Huang*
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Rosanne M. Kho*
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Gretchen E.H. Makai*
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Consultant: Stryker Endoscopy
Nima R. Patel*
Kristin E. Patzkowsky*
Khara M. Simpson*
Karen C. Wang*

Asterisk (*) denotes no financial relationships to disclose.
ACADEMIC OR COMMUNITY MEDICINE

KATHY HUANG, M.D.
DIRECTOR, GYN ROBOTICS SURGERY
NYU LANGONE MEDICAL CENTER
ASSISTANT PROFESSOR, NYU SCHOOL OF MEDICINE

DISCLOSURE
I have no financial relationships to disclose.

DECISIONS, DECISIONS, DECISIONS...

Location
Teaching
Income
Research
Family
Privat
Academic
Lifestyle

“THE MATCH” WAS SO MUCH EASIER!

DON’T DESPAIR....

You WILL find a job.
(Albeit somewhat stressful)
This is what you’ve been working towards.
Enjoy the ride!

WHAT KIND OF JOB ARE YOU LOOKING FOR?
WHAT KIND OF JOB ARE YOU LOOKING FOR?

- University / Academic
  - Clinical tract
  - Educational tract
- Private practice
- Hybrid
  - Academic affiliate
  - Hospital employed

ACADEMIC “PROS”

- Standardized contracts
- Guaranteed salary *
- Education is part of routine activities
- Collegiate support / shared coverage
- Opportunities for collaboration
- Resources to participate in clinical research
- Environment that encourages innovation
- Better malpractice environment
- Greater potential to be “MIS” and/or “gyn only”

ACADEMIC “CONS”

- Standardized contract & little negotiation
- Balancing clinical volume/administrative work/research/education
- Pressure to obtain grants & publish
- Promotion process difficult & lengthy
- Productivity requires significant collection
- Bureaucracy; less control over practice environment
- Business mechanisms are not as efficient
- Lower income

PRIVATE PRACTICE “CONS”

- Lawyer recommended for contract negotiation
- Malpractice
- Restrictive covenant
- Challenging to stay involved in departmental / educational meetings
- Management of practice / staff
- More difficult to establish yourself as “MIS”
- Obstetrics likely

PRIVATE PRACTICE “PROS”

- Contract negotiation
- Flexibility in building practice
- Partner opportunity
- Good potential for financial growth
- Higher salary
- Productivity feasible & rewarded
- Patient population
- Efficient office

HYBRID MODELS

- Hospital based employment
- Standardized contracts
- Moderate amount of negotiation possible
- Typically offer a base salary with production-based incentives
- Minimal responsibility for business aspect
- Hospital malpractice coverage
POSSIBLE BARRIERS

• Location, location, location
• Market Saturation
• Sub specialists
• Depressed market

GETTING STARTED

SOMETIMES WHAT YOU THINK YOU WANT ISN'T WHAT YOU WANT AT ALL!
BE OPEN MINDED!

THE JOB SEARCH

• National / regional meetings
• Networking
  • Department chair/faculty
  • Fellowship director/co-fellows
  • Personal contacts
  • "Socializing"
  • Journals
• Professional recruiter

TIMELINE

• Never too early to start looking
• Takes several months to find a position, negotiate a contract, obtain a license, join insurance plans
• Start the job search at least 9-12 months prior to your projected start date

GETTING STARTED

• Organize and update your CV
• Write a cover letter
• Obtain professional references
THE COVER LETTER

- Your introduction
- What you have to offer:
  - Surgical skills / experience
  - Professional accomplishments
  - Unique things you bring to the department/practice
  - Marketing advantage; robotics, single incision, chronic pain

THE COVER LETTER

- What you are looking for:
  - Specify for what position
  - Plans for future / practice growth
  - Any special circumstances
  - Give your future employer a sense of commitment

THE COVER LETTER

This is the time to sell yourself, don’t be shy!

THE INTERVIEW

- Do your homework
- Dress the part
- Informal dinner
- Formal interviews (a long day)
- Intro to facility
- Meet partners/colleagues
- You = Grand Rounds

GET HIRED!

- Be confident
- Take initiative
- Patience and determination
- Best foot forward

YOU GOT THE JOB, NOW WHAT?

- Get a lawyer.
**CONTRACT NEGOTIATION**

- Salary
- Benefits
- Delineation of responsibilities
- Non-compete clause
- Malpractice coverage

**SALARY**

- $150-250K
- Varies depending on location, need & cost of living
- Know your value
- Know the market
- Loan repayment
- Signing bonus
- Moving costs
- Productivity Clause

**BENEFITS**

- Medical, dental, disability & life insurance
- Retirement package
- Vacation, conference & CME time
- Cross coverage
- Maternity/paternity leave
- License/DEA fees
- Society membership, journal subscription

**DELINEATION OF RESPONSIBILITIES**

- Office sessions per week (appt slots, hours, # of patients)
- OR time
- Call coverage
- Administrative time
- Research responsibilities
- Teaching responsibilities
- Committee meetings

**NON-COMPETE CLAUSE**

- .... physician agrees that for a period of "x" years after expiration or termination of this agreement... physician will not establish a medical practice within "y" mile radius of any practice site the institution currently or in the future maintains.

**MALPRACTICE INSURANCE**

- Institutional
- Occurrence based

- Claims made (tail coverage)
COVER YOUR TAIL!

• Tail coverage is purchased to protect you from future claims that occurred while your "claims-made" policy was in effect
• Be sure you know who covers your tail
  • You
  • Your practice
  • May be prohibitively expensive

OTHER CONSIDERATIONS

• Non-clinical office
• Nurse/MA/Staffing
• Admin support
• Office procedures
• Billing
• Equipment
• Protected time
• Marketing
• OR block time
• Surgical assist
• Equipment
• In-house call
• ER call
• OB call
• GYN Rounder

CONTRACTS

IF YOU DON’T ASK, YOU WON’T GET IT.

GROWING PAINS

• Adjust to a new medical system & to new:
  • Home
  • Partners & Colleagues
  • Medical records
  • OR staff
  • OR equipment

BE REALISTIC

EXPECTATIONS ≠ REALITY

• 1-2 years to get comfortable in practice
• 2-3 years to build patient and surgical volume
• Research takes longer than you think

Take advantage of the initial downtime, it won’t be around for long!
GOOD LUCK!

IT’S BEEN A LONG TRIP, NOW YOU CAN ENJOY LIFE! YOU DESERVE IT!

Trust me. I’m a doctor.
The Devils in the Details: Negotiating Your Contract

Suketu Mansuria, M.D.
Associate Professor
Assistant Director of Gynecologic Minimally Invasive Surgery
University of Pittsburgh Medical Center

First Things First

- EVERYTHING is negotiable (almost)
- What is your dream job?
  - What aspects of the job are most important to you?
    - Location
    - Research/Teaching time
    - Case load/Variety
    - Lifestyle
    - Compensation
- What are you willing to compromise on for the first few years?
- What is non-negotiable long term?
- Determine what the needs of your employer are—the more you fill a void the better your negotiating position is

Disclosures

Consultant: Stryker Endoscopy

Headhunters

- May be of limited value given our specialty (not a lot of places specifically looking for an MIS; though they all need one!!)
- If they are familiar with the institution:
  - Can help with negotiations
  - They know what other physicians were offered
- They don’t come cheap
  - $20,000-$30,000 – to be paid by employer
  - Can make you less attractive

What can you negotiate?

- OB
- Research/Teaching time
- Compensation

What can you negotiate

- Miscellaneous
  - Moving expenses
  - House hunting visits
  - Parking
  - Cell phone
  - Computer
  - Housing assistance/Mortgage assistance
  - Loan forgiveness
  - Signing bonus
  - Make sure you understand the tax implications
- Maybe: non-compete language, vacation time, benefits package, marketing (more likely from a recruiting hospital), physician extenders
**General Words of Wisdom**

- Discuss your contract with a senior person who has experience dealing with these issues.
  - Lawyer
    - Non-academic-YES
    - Academic-May not be necessary
- Do your research—know what is reasonable for that position in that area
  - Look into other department members’ job descriptions/responsibilities/expectations
- Don’t be afraid to ask for something…this is a negotiation!
  - Just don’t look like a fool!

**OB**

- Do you want to do OB?
  - Yes—then you are set!
  - No
    - Never?
    - Maybe for a short period of time?
- Benefits of doing OB
  - Built in practice base
  - Immediate productivity—less financial pressure
  - Collect board cases
  - Build a loyal patient following
  - Post call day off?!?

**OB**

- Doing OB for the short term—what can you negotiate
  - Length of time (1-3 years)
  - Number of calls/month
    - Declining with subsequent years (ie. 3/month for the first year, 2/month year 2, 1/month year 3)
  - No OB patients in the office
    - L&D coverage provides productivity
    - Allows you to develop an office Gyn practice

**Research**

- Very institution dependent
  - Some may have research requirements as part of their contract
- Look into the promotion process of the institution
  - Is promotion necessary to retain your position?
  - What is required for promotion?
    - Research/Publications
    - Teaching
    - Clinical productivity
    - Program development
    - Other “academic” pursuits

**Research**

- Protected time usually reserved for those expecting to get NIH funds
  - Non-funded research likely will have to be completed during non-clinical time
  - Rare for a “surgeon” to get more than 20% protected time without an outside source of funding
- If research is to be a big part of your career
  - Larger institutions may “float” you for up to three years while you secure external funding
  - Negotiate research essentials into your recruitment package
    - Lab space
    - Lab techs
  - They will likely look at your productivity as a resident/fellow to determine if investing in your research career is worthwhile

**Teaching**

- Teaching has many forms
  - Medical Students
  - Residents
  - Fellows
  - Other faculty/staff
    - This may be part of the reason you are being hired
  - Are you training the competition?
    - How will you be protected?
    - How will these efforts be valued/compensated?
    - Is this something you are ready to undertake?
- Rare to get protected time for teaching
Most contracts will have a 1-3 year guarantee for new hires. After your guarantee is “up” then salaries are usually determined by:

TOTAL COMPENSATION = BASE + INCENTIVE/BONUS

- It is reasonable to ask what the structure of your contract will be once your initial “guarantee” period is up
- Rarely will a commitment be made.

Initial contracts/"Guarantee"—what to ask

- Protected time—usually ½ day per week
- Use this time to build towards your long term goals
- Volume—where will it come from?
- Responsibilities
  - Teaching: Medical Students/Residents/Fellows/Faculty
  - Research/Publications
  - Administrative
- HOW WILL YOU BE EVALUATED?

Starting Salaries

- Ask your peers
- May be dependent upon whether you do OBI
- Also dependent upon your Clinical/Research/Teaching/Administrative efforts

Moonlighting/Paid call

Benchmarks

- Your institution may already have benchmarks set based on other MIS surgeons
- If there are no other MIS surgeons, usually benchmarks set for UroGyn and GynOnc used
- Very much dependent upon local market

Starting Salaries

- Good resources:
  - Association of American Medical Colleges
    - Salary by region/academic level/25th/50th/75th percentiles
  - MGMA Physician Compensation and Productivity Survey
    - Not just for Academic Physicians
    - Salary by percentiles/collections/Compensation to collection ratios
    - wRVU percentiles

Long term your salary will be based on:

BASE+INCENTIVE/BONUS=TOTAL COMPENSATION

- Base—once your guarantee is up how will your base be determined?
  - Stable
  - Go up every year by a set amount
- What percent of your salary will be base vs incentive?
  - Try to maximize base
    - Protects you from changes in:
      - Patient volume
      - Changes in healthcare
      - Competition

Incentive

- Can be departmental/divisional
- Your incentive is based on the productivity/success of the department/division as a whole
- Usually a fixed/non-negotiable formula
- Pros: less pressure to be highly productive, protects you from fluctuations in your productivity, better lifestyle, allows you to focus on other academic pursuits (i.e., research, teaching, administration)
- Cons: if you are highly productive you have to share your profits with others, if the department as a whole does poorly…so do you
- Can be individualized
  - More pressure on you to be productive, less incentive to “help” the competition, can be more financially rewarding (if you are willing to do the work)
- Make-up of this type of plan is highly individualized and negotiable
Compensation

- Incentive
  - Can be based on “academic” productivity
  - Publications (e.g., original research, case reports, chapters)
  - Authorship (first, second, senior)
  - Impact factor of journal
  - Presentations at meetings
  - Mentorship to students/residents/fellows
  - Research projects
  - Teaching awards

Compensation

- Incentive
  - Can be based on individual productivity
  - Can be based on:
    - RVU’s
    - Collections/Profits
  - Rarely will you be paid more than you collect
  - Always ask for a Profits/Loss statement
  - Profits
    - Collections
  - Losses
  - Salary
  - Benefits
  - Overhead: Nursing staff/Office space/Administrative costs/Physician extenders
  - “Taxes”

Compensation

- Incentive
  - Healthcare is moving towards incentivizing “quality” over “quantity”
  - Measures are still being developed and are “moving targets”
    - Deviation from Standard of Care
    - Completion of OR reports
    - Meeting SCIP criteria for OR cases
    - Completion of outpatient documentation
    - Patient satisfaction
    - Best outcomes at the lowest cost

Thank You

Questions?
Navigating Politics in Medicine
Kristin Patzkowsky, MD
Montefiore Medical Center
Bronx, NY
AAGL Fellows Course 2014
Vancouver, BC

I have no financial relationships to disclose

MEDIA
Times Ousts Jill Abramson as Executive Editor, Elevating Dean Baquet
By DAVID CARR and RAVI SOMAIYA MAY 14, 2014

Course Objectives
- To formulate preparative strategies for workplace conflict
- To identify potential social barriers relevant to the attainment of his/her professional goals

Course Outline
- Navigating Workplace Politics
- Workplace Equality?
- Gender Biases
1. Navigating Workplace Politics

Tips to Avoid Office Politics
- Work in an environment which is in keeping with your personality and system of beliefs

Tools to Navigate Workplace Politics:
- Build a broad coalition of support
- Avoid smear campaigns
- Stay true to your values
- Connect with your coworkers
- Play by the rules

Positive tactics to deal with Negative vibes:
- Don’t participate in the email & telephone game
- Get to know the people who practice bad politics
- Watch what you say “in confidence”
- Want to give someone a piece of your mind?... Keep it to yourself.
- When all else fails, keep documentation
“The savviest professionals practice workplace diplomacy”

2. Workplace Equality?


Discrimination or Favoritism?

- Social networking: getting an inside edge by using help from family & friends
- Social resources are concentrated among whites
  - White Americans tend to help other whites
  - If African Americans are not part of the same networks, they will have a harder time finding decent jobs
- Because we still live largely segregated lives, such networking fosters categorical inequality

Gender Pay Gap

- 2012: women made 81% of the median earning of male full time workers
  - vs 62% in 1979
- The narrowing of the pay gap has slowed over the last decade
Gender Pay Gap According to Race
The median women’s-to-men’s earnings ratio is:
- 81% White
- 73% Asian
- 90% Blacks
- 88% Hispanic/Latinos


The gender pay gap still consistently pervades every segment of society — by age, race, education level, occupation type and hours worked.

3. Gender Biases

“Women face a narrower band of acceptable behavior than men do. Women can be powerful. Women can be likeable. Being both is difficult to do.”

Heidi & Howard
Women vs Men

- 4.2% of CEOs at Fortune 500 companies are women
  - Biology; childbearing, maternity leave
  - Cognitive biases
  - Gender variation in work collaboration

References

THE DO'S AND DON'TS OF ESTABLISHING YOUR FIRST PRACTICE

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MY STORY

• Fellowship at University of Michigan 2008
• Director MIS Beth Israel Medical Center 2008-2010
• Associate Director MIGS BWH 2010-present
  • Fellowship Director MIGS BWH 2012-present

BETH ISRAEL

• PROS
  • Known entity from residency
  • Lack of MIGS faculty
  • Gyn Onc who supported MIGS
  • Diversity of cases

• CONS
  • No infrastructure
  • No administrative support
  • Starting from scratch
  • No marketing
  • Took time to build surgical volume

BRIGHAM AND WOMEN’S

• PROS
  • Well established busy surgical referral practice
  • Solid infrastructure
  • Administrative support
  • Great collaborative opportunities

• CONS
  • Unknown entity
  • Competition Neighboring hospitals Outside division

THREE PILLARS

AVAILABILITY

AFFABILITY

ABILITY
AVAILABILITY

• Be available and visible as much as possible
  - Other specialties
  - Other gyns
  - Residents
  - Patients
  - Phone calls
  - Last-minute scheduling
  - And even when they’re late…

AFFABILITY

• Catch more flies with honey…
  - Patient reviews matters
  - Colleagues
    - Nursing staff
    - Physicians
    - Residents
    - Administrative assistants

ABILITY

• Surgical volume breeds confidence, competence, and fewer complications
• Know your limitations
• Ask for help
  - Anticipated tough cases
  - Recruit your partner, colleague (gyn onc, gen surgeon, urologist, etc)

DO’S

• Say “yes” to everything
  - Take any case offered
  - Offer to help other surgeons
  - Cover resident cases

DO’S

• Network
  - Grand Rounds
  - Meet referring providers (PCP, REI, gyns, etc)
  - Always have business cards
  - Marketing, social networks
  - Meet and greet

DO’S

• Provide excellent care to your patients
  - Be attentive
  - Spend time with your patients
  - Word of mouth works wonders
  - Be accessible
**DON'TS**

- Don't expect patients to come to your practice without work
- Networking
- Marketing
  - Flyers, radio, meet and greet with providers and patients
  - Lectures

---

**PUBLIC PERCEPTION**

- Survey; 60% response rate

<table>
<thead>
<tr>
<th>Table 1: Importance of Factors in Selecting a Physician (N=2,230)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response to the question “When selecting a primary care doctor for yourself, how important is each of the following?”</td>
</tr>
<tr>
<td>Very Important</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Accepts my health insurance</td>
</tr>
<tr>
<td>Convenient office location</td>
</tr>
<tr>
<td>Physician’s years of experience</td>
</tr>
<tr>
<td>Part of a specialist group practice</td>
</tr>
<tr>
<td>Word of mouth (from family/friends)</td>
</tr>
<tr>
<td>Referral from another physician</td>
</tr>
<tr>
<td>Physician’s rating on websites</td>
</tr>
</tbody>
</table>

*All percentages are weighted to approximate the US population


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**DON'TS**

- Don't be arrogant or picky
- You can be confident without being egotistical
- Reserve being selective about cases based on ability rather than personal preference

---

**DON'TS**

- Don't get frustrated or disheartened
- Takes time to build practice and reputation

---

**THANK YOU**
Technology Innovation in MIGS: From Bench to Bedside

Stuart Hart, MD, MS, FACOG, FACS
Associate Professor
Division of Female Pelvic Medicine and Reconstructive Surgery
Department of Obstetrics and Gynecology
Director, USF Center for the Advancement of Minimally-Invasive Pelvic Surgery (CAMPS)
Director, Tampa Bay Research and Innovation Center (TBRIC)
USF Center for Advanced Medical Learning and Simulation (CAMLS)
University of South Florida Morsani College of Medicine

Objectives

• Understand difference between Innovation and Invention
• Discuss areas of potential innovation in MIGS
• Review case study in medical device innovation in MIGS

Innovation

Late 1980's
• NASA (National Air and Space Administration) Ames Research Center began working on a concept called telepresence surgery
• NASA-Ames team joined the Stanford Research Institute (SRI) to develop a telesurgical manipulator for hand surgery
• U.S. Army and the Defense Advanced Research Projects Administration (DARPA) also became interested in telesurgery, with the goal of decreasing soldier mortality by bringing the surgery to the soldier
• Army developed a system called MASH (Mobile Advanced Surgical Hospital), which was a mobile vehicle that allowed a wounded soldier to be operated on with robotic surgical equipment

Disclosures

• Consultant: Boston Scientific Corp. Inc., CooperSurgical, Covidien, Stryker Endoscopy
• Grants/Research: Boston Scientific Corp. Inc., CooperSurgical, Covidien, Stryker Endoscopy
• Speakers Bureau: Boston Scientific Corp. Inc., Covidien

Innovation

• iPod - 2001
• iPad - 2010
• iPhone - 2007

Innovation

• Rio - 1998
• Palm Pilot - 2002
• "Windows XP Tablet PC Edition" - 2001
Innovation

Early 1990's
• Prototype of a robotic surgical system incorporating innovative technology for MIS including stereoscopic imaging, ergonomic design and force feedback
• SRI struggled to develop the device for military applications
• Unsuccessfully attempted to shop the prototype around to various surgical companies and venture capitalists with the goal of using this technology to develop a commercial surgical system

What is Innovation?
• Is the implementation and use of a new or improved idea, product / device, process / method or technology
• Meaningful and transformative
• May integrate multiple inventions

Create value

How is this different from Invention?
• Is the creation of a new or improved idea, product / device, process / method or technology
• Creative
• Experimental
• Multidisciplinary teams

How Can I Innovate?

Innovation Process
Discover  Develop  Deliver

• Questioning
• Observing
• Experimenting
• Networking
• Associating

Creative Intelligence
Disruptive Innovation
Facilitate the Innovation Process.
Areas of Innovation in MIGS?

**Goal is to Create Value**

- Clinical Programs
- Process Flow
  - Patient Flow in Clinic
  - Surgical Flow in OR
- Surgical Procedures
- Procedural Training
- Research
- Medical Devices

Technology Innovation in MIGS: From Bench to Bedside

The Transvaginal Specimen Extraction Device

Innovation: From Bench to Bedside in MIGS

**Questioning**

How can surgical specimens larger than the laparoscopic port sites used to perform the surgery be removed without either enlarging the abdominal incision or using a morcellator?

Innovation: From Bench to Bedside in MIGS

**Observing and Associating**

1. Culdocentesis and Colpotomy are “Safe” access sites for abdominal entry
2. Posterior portion of the vagina directly communicates with the abdomen through only a few tissue layers, and when placed on stretch, is distant from vital anatomic structures.
3. Vaginal elasticity allows stretching to accommodate dimensions greater than size of the incision
4. Natural orifice transluminal endoscopic surgery

Innovation: From Bench to Bedside in MIGS

**Experimenting**

**Goal:** To develop a novel device used to extract specimens transvaginally during Minimally-Invasive Surgery

**Objective:** Removal of multi-centimeter surgical specimens efficiently and reproducibly through the vaginal natural orifice during Minimally-Invasive Surgery

Concept #1
**Concept #2**

**Experimenting**

**Goal:** To develop a fully functional transvaginal laparoscopic port with inner port diameter of 2.5 to 3.5 cm.

**Objective:** Utilize the vagina as a port site for removal of multi-centimeter sized specimens or introduction of instruments or materials (i.e. laparoscopic instruments, suture material, laparoscopic specimen retrieval bags, etc.)

---

**Concept #3**

**Experimenting**

**Goal:** Enhance safety of colpotomy entry by improving the location and angle of port opening in the posterior cul-de-sac.

**Objective:** Change device to bring inner port opening closer to device apex to reduce changes of rectosigmoid injury during entry, and increase ease of using laparoscopic instruments to assist in development of colpotomy incision.

---

**Prototypes and Cadaver Lab**

- **Observing**
- **Questioning**
- **Experimenting**

---

**Networking**
Concept #3

Concept #4

Add-on Laparoscopic Instruments

Questioning

Observing

Experimenting

Concept #5

Experimenting

Goal: Enable port to also be used as a vaginal stent for performance of a sacrocolpopexy procedure

Objective: Change shape to facilitate attachment of mesh to the vaginal wall
- Semi-flat front to facilitate suturing of mesh to anterior vaginal wall
- Curved back to facilitate dissection into the sometimes difficult to reach rectovaginal septum and enable suturing of mesh deep towards the perineal body

Design #5

Flat Front

Curved Back

Transvaginal Specimen Extraction Device

MIGS Innovation?

- Innovate Patient Care
- Innovate Clinical Programs
- Innovate Surgical Training
- Innovate Process Flow
- Innovate Surgical Procedures
- Innovate Medical Devices
- Innovate Research
A Conversation with Past FMIGS Fellows: Lessons Learned...

Mark Dassel and Mark Hoffman
Assistant Professor
Department of OB/GYN
University of Utah

Assistant Professor
Department of OB/GYN
University of Kentucky

Disclosures
We have no financial relationships to disclose.

Learning Objectives
• To avoid pitfalls common to starting FMIGS graduates
• To build a plan for developing a practice right for you and your patients
• To identify resources to aid you in your first year in practice

Tips for building a practice
• Go to your strengths
• Know your demographics
• Bring your strength to your population
• Carve out your niche
• Make yourself known
• Start something
• Seek mentorship

Go to your strength

Know your patient population
Know your patient population

<table>
<thead>
<tr>
<th></th>
<th>KENTUCKY</th>
<th>UTAH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Size</td>
<td>2.45</td>
<td>3.10</td>
</tr>
<tr>
<td>Population growth</td>
<td>+1.3%</td>
<td>+5.0%</td>
</tr>
<tr>
<td>Obesity</td>
<td>33.2%</td>
<td>24.1%</td>
</tr>
<tr>
<td>African American Population</td>
<td>8.1%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>3.3%</td>
<td>13.4%</td>
</tr>
<tr>
<td>Below poverty level</td>
<td>18.6%</td>
<td>12.1%</td>
</tr>
<tr>
<td>Smokers</td>
<td>30.2%</td>
<td></td>
</tr>
</tbody>
</table>

Carve out your niche

Let people know

Further develop your expertise

Thank you.
Developing a Research Idea and Writing a Scientific Abstract/Publication

Georgine Lamvu, MD, MPH
Advanced Minimally Invasive Gynecology
Director and Fellowship Director
Associate Clinical Professor
University of Central Florida
Florida Hospital, Orlando

Objectives

• Study design
• Overview of publication guidelines

References

  – Overview of clinical research: the lay of the land
  – Descriptive studies: what they can and cannot do
  – Cohort studies: marching towards outcomes
  – Case-control studies: research in reverse
• Jonathan Koffel. Understanding Research Study Designs. University of Minnesota Medical Library:
  http://hsl.lib.umn.edu/biomed/help/understanding-research-study-designs
  • Overview of study designs. www.md.lib.pitt.edu/publications/publications/res_pdf
  • Introduction to Evidence-Based Practice. LibGuides at Duke University.
  http://guides.library.duke.edu/content.php?pid=412433&sid=3690451

What Do You Need To Be a Successful Researcher?

• A basic understanding of epidemiology and study design
• A well designed research question
• The ability to do a good literature search
• A basic understanding of the logistics of conducting research
• Resources for writing, publishing and data analysis
• Knowledge about funding sources

Common Problems

David F. Ransohoff 1999

• Wanting to do it all on your own
• Unwillingness to commit to a question
• Thinking you have to do something huge
• Not keeping it simple
• Being afraid to “imitate”
• Not using your mentor
• Not taking the time to learn the software that will make your life easy!!!
• Doing the project but not publishing

Disclosure

I have no financial relationships to disclose.
EDUCATE YOURSELF ON THE SUBJECT: THE BASIS OF A GOOD INTRODUCTION

- Epidemiology and burden of disease
- Critical gap in the literature
- How does your research question address the gap
- Put your research question in terms of
  - Stated overall research goals
  - Stated specific aims

How do you choose a study design?
Start with a focused / good research question

CHOOSE A STUDY DESIGN

- Study setting
- Participants
- IRB approval
- Study protocols
  - Exclusion and inclusion criteria
  - Exposure and outcome definitions
  - Statistical analysis to clearly state the comparators and confounders

Research question

- Is there a comparison group?
  - No: Observational
  - Yes: Experimental
    - Is the comparison group assigned?
      - Yes: Experimental
      - No: Observational

Descriptive Studies

- Types: Case report, Case-series, Cross-sectional Surveys, Surveillance, Ecological studies
- “...represent the first foray into a new disease or area of inquiry. A fundamental element of descriptive reporting is a clear, specific, and measurable definition of the condition in question. Good descriptive reporting answers the five basic W questions: who, what, why, when, where and sixth so what?”
  - They usually describe who has the disease (e.g. age and sex)
  - What is the disease being studied (e.g. ectopic pregnancy)
  - Offer clues as to why the disease may have developed
  - May be used for hypothesis generating
  - Where did the disease arise
  - The potential large scale effects

Descriptive Studies: Case Report or Case Series

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>May be quick and inexpensive</td>
<td>Only measures frequency</td>
</tr>
<tr>
<td>Unit of analysis: one individual or a series of individuals</td>
<td>There is no comparison group and no possible measure of association</td>
</tr>
<tr>
<td>Example case-report: reporting a rare case of hepatocellular carcinoma in a woman taking oral contraceptives</td>
<td>Literature is packed with case series, they have little ‘literary value’</td>
</tr>
<tr>
<td>Example case series: reporting a cluster of 12 homosexual men in Los Angeles with a similar clinical syndrome (eventually lead to the discovery of AIDS)</td>
<td>In most situations, an appropriately selected control group would provide more useful information</td>
</tr>
<tr>
<td>‘Easy’ publications for new trainees</td>
<td>Frequently data is based on chart review</td>
</tr>
<tr>
<td></td>
<td>Data is not standardized</td>
</tr>
<tr>
<td></td>
<td>Often much missing information</td>
</tr>
<tr>
<td></td>
<td>Observation often limited to one MD or one center</td>
</tr>
</tbody>
</table>
Uses of Descriptive Studies

- Primarily used for description of rare or ‘new’ disease
- Can be used for monitoring trends and planning larger studies
- Can be used for generating a hypothesis to be tested in future studies
- STUDIES WITHOUT A COMPARISON GROUP DO NOT ALLOW CONCLUSIONS ABOUT CAUSE OF DISEASE (DO NOT ALLOW INTERPRETATIONS TO OVERSTEP THE DATA)

Temporal direction of descriptive studies: Cohort, Case-Control, Cross-Sectional

- Determining the Temporal “Direction” of a Study
  - Cohort study: follows a group from exposure to outcome
  - Case-control: starts with an outcome (cases) and looks back to identify exposure
  - Cross-sectional: both exposure and outcome are ascertained at the same time within a population

Cohort studies

- Observational studies in which the starting point is the selection of a population or ‘cohort’
- Population divided into ‘exposed’ and comparison group ‘unexposed’
- Outcome is ascertained in each of the exposure groups
- Note: Exposure is not controlled by the investigator
  - Exposure occurs before the outcome (and this may have nothing to do with how the data is collected)
  - This type of observational study is the one that most clearly resembles intervention studies

Cohort Studies

- Retrospective Data Collection
  - Exposure: ART vs. No ART
  - Outcome: multiple births

- Prospective Data Collection
  - A cohort study tracks two or more groups forward from exposure to outcome.
  - HOWEVER, the data for a cohort study can be collected prospectively or retrospectively.
  - Thus a cohort study always moves in the same direction (i.e. from exposure to outcome) although data gathering may not

Cohort Studies

**Advantages**

- Best way to ascertain both the incidence and natural history of a disorder
- Best estimate of risk
- Temporal sequence between cause and outcome is usually clear
- Can reduce bias using statistics
- May assess several exposures within a population
- If retrospective can be quick and inexpensive

**Disadvantages**

- Inefficient for rare diseases
- Expensive and time consuming if prospective
- Loss of follow-up is a major problem
- Data quality not under control of investigator if retrospective

Important Features of a Cohort Study

**Study design**

- How much bias was present?
- What steps were taken to reduce bias?
- How complete was the follow-up in both groups?
- Were potential confounding factors evaluated and controlled for in the analysis?

**Strength of causal associations**

- How strong is the effect, measured as relative risk or odds ratios?
- Is there a dose-response relationship, i.e. does more exposure lead to more outcome?
- Does the association make sense biologically?
- Is the association consistent with available evidence, has this effect been seen by others?
- Has an RCT been done? (Prospective Cohort vs. RCT)
Case-control Studies

- Defines a group with outcome (e.g. ovarian cancer) and a group without cancer (the controls), then investigators try to ascertain the prevalence of exposure to a risk factor (e.g. oral contraceptives). If prevalence of exposure is higher among the cases than among controls, then exposure is associated with an increased risk of outcome.

Case-control studies

- THE MOST IMPORTANT POINT OF CASE-CONTROL STUDIES IS THAT THE CONTROLS SHOULD BE REPRESENTATIVE OF THE POPULATION FROM WHICH THE CASES ARE DERIVED
  - Answer the question: If this control subject would have become a case in this study, would they have been included in the case population?
  - The selection of controls determines what is estimated with the study, i.e. CONTROLS SHOULD BE SIMILAR TO CASES IN ALL IMPORTANT RESPECTS (MATCH) EXCEPT FOR NOT HAVING THE OUTCOME IN QUESTION
  - Inappropriate control groups will ruin a case control study

Case-control Studies

- The investigator determines the proportion of persons with the outcome
  - The investigator looks back to find out how many were exposed among cases vs. controls
  - Principal measure is the exposure
  - E.g. Outbreak of food-borne disease on a cruise ship: those with vomiting and diarrhea are asked about food exposures as are a sample of those not ill. If a higher proportion of those ill report having eaten potato salad than those who are not ill, potato salad becomes the suspect.

Study Design Guidelines

- CONSORT - Consolidated Standards of Reporting Trials (http://www.greenjournal.org/misc/consort.pdf)
- MOOSE – Guidelines for Meta-Analyses and Systematic Reviews of Observational Studies (http://www.greenjournal.org/misc/moose.pdf)
- QUOROM - Guidelines for Meta-Analyses and Systematic Reviews of RCTs (http://www.greenjournal.org/misc/quorom.pdf)
- PRISMA-Preferred Reporting Items for Systematic Reviews and Meta-Analyses (www.prisma_statement.org)
- STROBE- Strengthening the Reporting of Observational studies in epidemiology (www.strobe-statement.org)
- All interventional trials should be registered at clinicaltrials.gov
Your Research Needs to Be

• New / novel
• True
• Important and of interest ... to someone else besides you
• Readers take precedence over authors, so know your audience
• Consider whether the topic is better suited for an editorial, letter, review or expert opinion in clinical series
• Prevalence studies are boring unless it is a completely new subject

Before you Start

• Have multiple reviewers question / edit your work

RESULTS

• Demographics (describe your population)
• Describe comparison groups
• Text should tell the story, tables give the evidence
• Use confidence values rather than just p values
• Avoid starting the discussion, focus only on important results

Discussion

• Summary of findings
• How does it compare to other studies
• Limitations in relation to other studies in general
• Advantages
• Implications: why is what you found important and what does it mean?
• What are the next steps

Publication

• Check the journal specific guidelines, checklist and publishing costs
• Journal should be cited or web accessible
• Peer vs. non-peer reviewed
• Page numbers, name title on each page
• Double spaced with line numbers
• Pay attention to your formatting
• Pay attention to your tables
  — One table per page (separate document), each journal has a max
  — Avoid vertical lines
  — Format legends so that they are the same font size as text
  — Every journal has a listing of symbols you can use
  — Check your tables 2-3 times after the table is ‘finalized’
• Avoid colors on figures, they are expensive
• Endnote references

Common Errors

• Verbs/tense errors
• Quotes
• Lack of proofreading for spacing
• Typos and inconsistent fonts or formatting
  — Not using your spell checker
• Lengthy sentences
• Avoid the passive voice
• Do not ‘we we’ all over your paper
• Do not use unnecessary words “enourmously great”
• Avoid biased or personal opinions
Publication

• Before you submit have additional reviewers question/ edit your work
• It takes approx 2 months to get a decision and 6-12 months to actually get a citation / publish
• Expect revisions even with acceptance

“PPs”: Publication Problems

• Plagiarism: computer programs designed to find this
• Insufficient data to conclude what you want to conclude
• Misinterpretation of data
• Missing data and incomplete tables
• Authorship is not established prior to writing
• Know what you are publishing and KNOW the literature

Summary

• Focus on good study design and an interesting topic will increase chances for publication
• Avoid doing research without a purpose
• Use your resources and your colleagues
  – Thank you
  – Georginelamu@flhosp.org
Objective

- To inform novice researchers on how to access help (i.e. resources) to start a research project

*If you have already received national funding for research, please feel free to add to this discussion!

Disclosures

I have no financial relationships to disclose.

Research Framework

- Study Question/Idea
- Literature/Background Review
- Assess feasibility
  - Discussion with mentor/collaborator(s)
  - Power analysis
- IRB approval
- Obtain programmatic resources
  - Financial
  - Logistical
- Enact Research Project

Key Resources for Success

- Time
- Experience
- Knowledge
- Access to Data
- Support
- Money

Resource #1: TIME

- Allocate Dedicated Time
  - Paid or Unpaid
  - On/Off Duty Hours
  - Extenders: Research assistants
  - Department/Leadership support
Resource #2: Experience

- Mentor/Experienced Research Advisor*
- Departmental staff - OB/GYN
- Research Divisions
  - Dean of Education
  - Epidemiologist
- IRB staff
- Hospital-wide programs?

Examples: David Grimes Courses

Excellence in Clinical Research
- Six-day course
- Course in research methods and evidence-based medicine
- Target Audience: current OB/Gyn Fellows and OB/Gyn Junior Faculty
  (Residents are not eligible)

Course in Randomized Controlled Trials
- Three-Day Course
- Course in design and implementation of RCTs
- Faculty: Team of Drs. David Grimes and Kenneth Schulz
- Target audience: physicians and other health care providers interested in improving their skills in designing, conducting, publishing, or interpreting RCTs (any level of training eligible)

Sponsored by: The Foundation for Exxcellence in Women's Health Care

Resource #3: Knowledge

- What do you know about research?
- Internal educational opportunities
  - Residency/Fellowship Directors, Teachers
- Broader Educational Programs
  - University-level Epidemiology Courses
  - Other Private Programs

Another fellowship?

TECT Program
Training in Epidemiology and clinical trials

Goals
- To develop the skills needed to become a self-sustaining professional in women’s health research and
- To expand the number of researchers in obstetrics and gynecology in academia, international health organizations, public health agencies and industry

CREST Program
Clinical Research/Reproductive Scientist training

Goals
- Allow physicians in private or academic clinical practice to obtain formalized academic training in the quantitative and methodological principles of clinical research in reproductive medicine

Resource #4: Access to Data

- Librarian
  - Ovid, Pubmed, NLM, Cochrane Database
  - On-line journal access
  - http://www.acog.org/Resources-And-Publications
- IRB Staff
- Quality/Safety Teams
- Information Technology
- Residency Resources
- Public/Private Databases

Resource #5: Support

REEL IN STAKEHOLDERS
- Mentor interest
- Chairman/Leadership support
- Research teams
- Office/OR staff
- Simulation and Education specialists
- IRB staff
- Residents, Students
- Study enrollees
Resource #6: Money

Needs are determined by **Size and Scope** of Project

*Developing a Budget will require more help!*

- "Intangible" Funding – Internal
- Internal Hospital/Academic Funding
  - Program-specific Resources
- External Funding
  - Public
  - Private - Industry vs. Other

A Government Lesson:

- "Applicants may also find it helpful to seek advice from an experienced investigator and to contact the Institute or Center most likely to fund their application”*

Beyond Our Scope today

- **R-01**
  - The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator’s specific interest and competencies, based on the *mission of the NIH*.
  - $25K - $250K
- **R-03**
  - The R03 grant mechanism will support small research projects that can be carried out in a short period of time with limited resources. The NIH has standardized the Small Grant (R03) application characteristics, requirements, preparation, and review procedures in order to accommodate investigator-initiated (unsolicited) applications. Up to $25K/year for 2 years
- **K Grant**
  - Career development Awards (K Awards) for Individuals with a Health-Professional Doctorate

Public Funding

- [www.grants.gov](http://www.grants.gov)
  - National Institutes of Health (NIH)
  - NIH Office of Research on Women's Health (ORWH)
  - Centers for Disease Control (CDC)
  - Other national programs
  - International Sponsors

Private Sector Opportunities

- Professional Organizations
  - AAGL – Foundation of the AAGL
  - ACOG - Research Awards Program
    - Kathleen Kenny, researchgrants@acog.org
  - SGS, ASRM, ACS, OCRF, others
- Women's Heath research groups
  - www.scangrants.com
- Industry-Sponsored Research
  - Leadership access; Local representation

References

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3. [www.asrm.org](http://www.asrm.org)
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Traditional versus Simulation Resident Surgical Laparoscopic Salpingectomy Training: A Randomized Controlled Trial

Nima R. Patel, MD; Gretchen E. Makai, MD; Nancy L. Sloan, DrPH; Carl R. Della Badia, DO

1Department of Obstetrics & Gynecology, Drexel University School of Medicine, Philadelphia, PA
2Department of Minimally Invasive Gynecologic Surgery, Christiana Care Health Systems, Newark, DE
3Department of Obstetrics and Gynecology, University of Rochester School of Medicine, Rochester, NY

I have no financial relationships to disclose.

Objectives

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

Introduction: Traditional Training

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

Introduction: Simulation Training

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

Hypothesis

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

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

Results: Comparability of Study Groups

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

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

Outcomes Assessed

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

- Pre and Post Intervention Subjective Survey
  - 10 subjective measures by a Likert Scale of 1-5 (1=strongly agree)

Results: OSATs

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue</td>
<td>3.0±1.2</td>
<td>3.0±1.3</td>
<td>0.44</td>
</tr>
<tr>
<td>Camera</td>
<td>2.8±1.3</td>
<td>2.7±1.3</td>
<td>0.27</td>
</tr>
<tr>
<td>Instrument Management</td>
<td>2.8±1.5</td>
<td>3.1±1.1</td>
<td>0.10</td>
</tr>
<tr>
<td>2 Handed Surgery</td>
<td>2.9±1.6</td>
<td>2.8±1.5</td>
<td>0.004</td>
</tr>
<tr>
<td>Visual Cues</td>
<td>3.0±1.5</td>
<td>2.7±1.1</td>
<td>0.59</td>
</tr>
<tr>
<td>Anatomy</td>
<td>3.3±1.0</td>
<td>3.2±1.2</td>
<td>0.34</td>
</tr>
<tr>
<td>Resection</td>
<td>2.6±1.1</td>
<td>2.7±1.2</td>
<td>0.17</td>
</tr>
<tr>
<td>Energy</td>
<td>3.1±1.4</td>
<td>3.1±1.1</td>
<td>0.01</td>
</tr>
<tr>
<td>Flow</td>
<td>3.3±0.9</td>
<td>2.8±1.5</td>
<td>0.28</td>
</tr>
</tbody>
</table>

Results: Subjective Measures

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomy</td>
<td>2.0±0.8</td>
<td>1.9±0.3</td>
<td>0.016</td>
</tr>
<tr>
<td>Steps</td>
<td>1.9±0.5</td>
<td>1.3±0.5</td>
<td>0.004</td>
</tr>
<tr>
<td>Energy</td>
<td>2.3±0.8</td>
<td>1.6±0.5</td>
<td>0.002</td>
</tr>
<tr>
<td>2 Handed Surgery</td>
<td>2.1±0.8</td>
<td>2.1±0.5</td>
<td>0.04</td>
</tr>
<tr>
<td>Watch Video</td>
<td>2.0±0.6</td>
<td>1.1±0.3</td>
<td>0.01</td>
</tr>
<tr>
<td>Read</td>
<td>2.5±0.5</td>
<td>2.9±0.7</td>
<td>0.08</td>
</tr>
<tr>
<td>Practice Vest</td>
<td>1.7±0.5</td>
<td>1.5±0.5</td>
<td>0.19</td>
</tr>
<tr>
<td>Learn in OR</td>
<td>2.5±1.0</td>
<td>3.1±0.3</td>
<td>0.03</td>
</tr>
<tr>
<td>Learn in Vest</td>
<td>1.9±0.8</td>
<td>1.7±0.5</td>
<td>0.002</td>
</tr>
<tr>
<td>Risk Benefit</td>
<td>1.7±0.6</td>
<td>1.3±0.5</td>
<td>0.04</td>
</tr>
</tbody>
</table>

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

- Simulation improves surgical skill and resident comfort level with the procedure
  - Indicates that resident training should be supplemented
    - To increase the baseline level of surgical skills.
  - To enhance learning a particular procedural skill

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

References


Future

- Future studies
  - Are results replicable in other programs?
  - Would results be different with long term simulation?
  - What is the optimal time for simulation to begin/occur?
  - What is the optimal length of simulation?
  - OSAT validated over multiple evaluators?
OCCULT UTERINE SARCOMA AND OTHER GYNECOLOGIC MALIGNANCIES DIAGNOSED AFTER HYSTERECTOMY PERFORMED FOR BENIGN INDICATIONS

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

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

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

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

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

Disclosure
I have no financial relationships to disclose.
Participants

- Hysterectomy performed for benign indications (n=6,369)
  - Family history of cancer, pelvic mass, hyperplasia without atypia, prolapse, endometriosis, pelvic pain, fibroids, abnormal uterine bleeding
- Excluded indications for cancer or high suspicion for cancer (n=1,100)
  - Cancer, hyperplasia with atypia, cervical dysplasia

Results

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

<table>
<thead>
<tr>
<th>Uterine Sarcoma</th>
<th>Endometrial Cancer</th>
<th>Cervical Cancer</th>
<th>Ovarian/fallopian tube/peritoneal Cancer</th>
<th>Metastatic Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence n (%)</td>
<td>14 (0.22)</td>
<td>65 (1.02)</td>
<td>11 (0.17)</td>
<td>69 (1.08)</td>
</tr>
</tbody>
</table>

The incidence of uterine sarcoma based on indication and age

<table>
<thead>
<tr>
<th>Indication</th>
<th>Incidence n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All hystrectomies performed for benign indications</td>
<td>14 (0.22)</td>
</tr>
<tr>
<td>25-44 yr (n=2280)</td>
<td>1 (0.14)</td>
</tr>
<tr>
<td>45-64 yr (n=1911)</td>
<td>5 (0.26)</td>
</tr>
<tr>
<td>65 yr+ (n=673)</td>
<td>7 (0.29)</td>
</tr>
<tr>
<td>Preoperative indication of fibroids (n=2447)</td>
<td>7 (0.27)</td>
</tr>
</tbody>
</table>

Characteristics of women undergoing hysterectomy for benign indications

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Benign (n=6196)</th>
<th>All cases of uterine sarcoma (n=24)</th>
<th>p value</th>
<th>Occult uterine sarcoma (n=64)</th>
<th>p value</th>
<th>Occult gynecologic malignancy (n=173)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>49.67 ± 10.77</td>
<td>54 ± 15.60</td>
<td>0.002</td>
<td>46 ± 10.97</td>
<td>0.07</td>
<td>58 ± 15.42</td>
<td>0.001</td>
</tr>
<tr>
<td>Parity</td>
<td>2.06 ± 1.42</td>
<td>2.06 ± 1.35</td>
<td>0.83</td>
<td>2.04 ± 1.39</td>
<td>0.23</td>
<td>1.86 ± 1.76</td>
<td>0.19</td>
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<tr>
<td>Ethnicity</td>
<td>Hispanic</td>
<td>109 (1.8)</td>
<td>0</td>
<td>2 (0.22)</td>
<td>0.67</td>
<td>3 (0.23)</td>
<td>0.001</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>5628 (90.8)</td>
<td>25 (93.73)</td>
<td>0</td>
<td>14 (100)</td>
<td>0.49</td>
<td>15 (100)</td>
<td>0.49</td>
</tr>
<tr>
<td>Other</td>
<td>449 (7.4)</td>
<td>1 (17)</td>
<td>0</td>
<td>1 (17)</td>
<td>0</td>
<td>1 (17)</td>
<td>0</td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
<td>4893 (75.38)</td>
<td>15 (62.00)</td>
<td>9 (64.29)</td>
<td>0.07</td>
<td>18 (109.19)</td>
<td>0.07</td>
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<tr>
<td>Black</td>
<td>1037 (17.70)</td>
<td>17 (68.57)</td>
<td>4 (26.19)</td>
<td>4 (26.19)</td>
<td>0.05</td>
<td>4 (26.19)</td>
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</tr>
<tr>
<td>Asian</td>
<td>60 (1.07)</td>
<td>2 (33)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>349 (6.63)</td>
<td>2 (33)</td>
<td>1 (14)</td>
<td>10 (66.67)</td>
<td>0.67</td>
<td>10 (66.67)</td>
<td>0.67</td>
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<tr>
<td>BMI (kg/m2)</td>
<td>30.59 ± 7.50</td>
<td>29.2 (22-380)</td>
<td>0.009</td>
<td>30.35 ± 7.56</td>
<td>0.43</td>
<td>32.93 ± 9.47</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Demographic characteristics of women undergoing hysterectomy for benign indications

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Benign (n=6196)</th>
<th>All cases of uterine sarcoma (n=24)</th>
<th>p value</th>
<th>Occult uterine sarcoma (n=64)</th>
<th>p value</th>
<th>Occult gynecologic malignancy (n=173)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior VTE</td>
<td>Yes</td>
<td>162 (2.61)</td>
<td>2 (8.33)</td>
<td>0.08</td>
<td>2 (14.29)</td>
<td>0.002</td>
<td>7 (0.37)</td>
</tr>
<tr>
<td>No</td>
<td>6034 (97.39)</td>
<td>22 (81.67)</td>
<td>12 (65.71)</td>
<td>0.007</td>
<td>207 (96.73)</td>
<td>0.001</td>
<td>207 (96.73)</td>
</tr>
<tr>
<td>Preoperative biopsy</td>
<td>Yes</td>
<td>43 (6.89)</td>
<td>2 (8.33)</td>
<td>0.001</td>
<td>1 (7.14)</td>
<td>0.006</td>
<td>207 (96.73)</td>
</tr>
<tr>
<td>No</td>
<td>6152 (93.11)</td>
<td>22 (81.67)</td>
<td>13 (69.66)</td>
<td>0.018</td>
<td>7 (3.27)</td>
<td>0.02</td>
<td>207 (96.73)</td>
</tr>
<tr>
<td>Surgeon Type</td>
<td>Benign gynecologist</td>
<td>5032 (81.43)</td>
<td>14 (58.33)</td>
<td>0.001</td>
<td>12 (68.71)</td>
<td>0.18</td>
<td>52 (23.83)</td>
</tr>
<tr>
<td>Gynecologic oncologist</td>
<td>364 (5.97)</td>
<td>10 (41.67)</td>
<td>0.001</td>
<td>12 (68.71)</td>
<td>0.18</td>
<td>52 (23.83)</td>
<td>0.001</td>
</tr>
<tr>
<td>Surgical approach</td>
<td>Abdominal</td>
<td>1542 (24.89)</td>
<td>13 (52.17)</td>
<td>&lt;0.001</td>
<td>7 (3.81)</td>
<td>0.05</td>
<td>97 (45.33)</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>1880 (30.50)</td>
<td>12 (50)</td>
<td>&lt;0.001</td>
<td>7 (63.6)</td>
<td>0.05</td>
<td>97 (45.33)</td>
<td>0.001</td>
</tr>
<tr>
<td>Vaginal</td>
<td>773 (12.46)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Specimen weight (g)</td>
<td>128 (20-2000)</td>
<td>292 (22-3800)</td>
<td>0.009</td>
<td>303 (58-3800)</td>
<td>0.03</td>
<td>132 (22-6441)</td>
<td>0.64</td>
</tr>
<tr>
<td>Pathologic transfusion</td>
<td>Yes</td>
<td>117 (1.90)</td>
<td>3 (12.5)</td>
<td>&lt;0.001</td>
<td>2 (16.67)</td>
<td>0.059</td>
<td>27 (12.63)</td>
</tr>
<tr>
<td>No</td>
<td>6079 (98.11)</td>
<td>21 (87.50)</td>
<td>12 (68.71)</td>
<td>0.007</td>
<td>187 (87.36)</td>
<td>0.001</td>
<td>187 (87.36)</td>
</tr>
<tr>
<td>Perioperative VTE</td>
<td>Yes</td>
<td>12 (0.19)</td>
<td>1 (4.17)</td>
<td>&lt;0.001</td>
<td>1 (7.14)</td>
<td>0.002</td>
<td>2 (0.93)</td>
</tr>
<tr>
<td>No</td>
<td>6184 (99.81)</td>
<td>22 (85.83)</td>
<td>12 (68.71)</td>
<td>0.007</td>
<td>372 (99.07)</td>
<td>0.001</td>
<td>372 (99.07)</td>
</tr>
</tbody>
</table>
Preoperative indication sub-analysis

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

Conclusion

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

STRENGTHS

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

LIMITATIONS

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

References

Background & Significance

- Endometriosis is a common benign gynecologic disease
- Abdominal Wall Endometriosis (AWE) is a rare variant with estimated rates from 0.004%-12%
- Most studies on AWE are case series, hence not much is known about risk factors and predictors

Study Objective

- To evaluate not only presentation and give detailed description of cases of AWE, but also describe risk factors for patients with AWE in a case control design

Methods

- 2,539 patients had surgery for endometriosis at Mayo Clinic, Rochester between 1999-2013
- 1.34% patients were noted to have AWE (34 out of 2,539)

Methods

- **Cases**
  - Women who had histopathologic diagnosis of endometriosis in the abdominal wall.
- **Controls**
  - Women with stage I-II (pathology proven) Endometriosis without any abdominal lesions.
- For each case two controls were used for comparison (1:2 matching)
- All clinical data was abstracted from the patients charts
Statistics

- t test or Wilcoxon rank sum test for continuous variables
- χ² test or Fischer exact test for comparison of categorical variables
- Logistic regression used for risk adjustments during multivariate analyses

Time to diagnosis & Location of AWE

Delayed diagnosis was very common, with mean of 53.4 ± 37.52 months before diagnosis was made.

Diagnosis of AWE

- Strong correlation between size of lesion on clinical exam and pathology specimen size (r² = 0.74)

Comparison of Cases & Controls

<table>
<thead>
<tr>
<th></th>
<th>Cases (n=34)</th>
<th>Controls (n=68)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>35.2±5.9</td>
<td>33.5±8.8</td>
<td>0.24</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 (0-5)</td>
<td>0 (0-3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Caucasian Race</td>
<td></td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>32 (94.1%)</td>
<td>64 (94.1%)</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>29.2±6.6</td>
<td>26.4±6.7</td>
<td>0.02</td>
</tr>
<tr>
<td>Current Smokers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 (17.7%)</td>
<td>10 (14.7%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Cyclical Abdominal Pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>34 (100%)</td>
<td>18 (26.5%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pelvic Pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 (14.7%)</td>
<td>16 (23.5%)</td>
<td>0.3</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 (11.8%)</td>
<td>27 (39.7%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Duration of symptoms (months)</td>
<td>30 (2-96)</td>
<td>12 (0.5-120)</td>
<td>0.029</td>
</tr>
<tr>
<td>Cyclic Abdominal pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>21 (61.7%)</td>
<td>18 (32.1%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Previous Laparotomy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>32 (94.1%)</td>
<td>10 (14.7%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous Laparoscopy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>16 (47.1%)</td>
<td>16 (23.5%)</td>
<td>0.016</td>
</tr>
<tr>
<td>Previous Cesarean Delivery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30 (88.2%)</td>
<td>7 (10.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Number of previous Cesarean Deliveries</td>
<td>1.74±0.96</td>
<td>1.29±0.49</td>
<td>0.08</td>
</tr>
<tr>
<td>Hysterectomy at presentation</td>
<td>74%</td>
<td>7%</td>
<td>0.003</td>
</tr>
<tr>
<td>Use of pain medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>13 (38.2%)</td>
<td>39 (57.4%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Use of Hormonal suppression</td>
<td></td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>9 (26.5%)</td>
<td>18 (26.5%)</td>
<td></td>
</tr>
</tbody>
</table>

Risk Factors/ Clinical Symptoms for AWE

- In the final multivariable logistic regression model the following were considered major risk factors for development of AWE

  **Cyclical Abdominal Pain**
  - Unadjusted HR = 3.41 (95% CI 1.40-8.31)
  - Adjusted HR = 10.6 (95% CI 1.85-104.4)

  **Absence of Dysmenorrhea**
  - Unadjusted HR = 4.94 (95% CI 1.56-15.62)
  - Adjusted HR = 12.4 (95% CI 1.64-147.1)

  **Previous Laparotomy**
  - Unadjusted HR = 92.8 (95% CI 19.15-449.84)
  - Adjusted HR = 70.1 (95% CI 14.8-597.7)

Recurrence of AWE

- After excision of AWE 2 patients (5.9%) needed repeat surgery.
- Time to recurrence was 50.5 ± 20.5 months
Conclusion

• AWE is a rare but unique subtype of endometriosis, that is commonly undiagnosed despite symptoms.
• Most lesions can be identified by clinical exam accurately.
• Cyclical abdominal pain with presence of dysmenorrhea and a history of previous laparotomy are independent risk factors with very high accuracy of diagnosis.
• A careful history and physical examination may therefore be key in timely diagnosis and treatment of this uncommon yet symptomatic disease entity.

References


Acknowledgement

• Sherif El Nashar MBBS
• Gaurang S. Daftary MD
• Abimbola O Famuyide MBBS
• Mathew R Hopkins MD

Thank you
Robotic Simulators: A Case for Investment

43rd AAGL Annual Congress on Minimally Invasive Gynecology

Presented By: Khara M. Simpson MD
Coauthor: Roger D. Smith PhD

Objective
• To identify key variables in the costs and benefits of robotic surgical simulators.
• To develop an interactive calculator to quantify the potential return on investment (ROI) with the purchase and implementation of robotic simulators.

Study Design
• Phase I - Literature review - ROI of surgical simulators and robotic surgery
• Phase II - Expert interviews at surgical simulation centers - academic, private, and military
• Phase III - Development of an interactive ROI calculator

Disclosures
I have no financial relationships to disclose.
Conclusion

- As in other industries, simulators have a number of practical uses, many of which accrue to financial improvements for the organizations that purchase and use them.
- In this report, we explore the potential advantages that can accrue from using the devices to improve skills through a structured training program, as well as provide a model to assist organizations in making the investment in these devices.
Paracervical Block of Bupivacaine with Epinephrine Prior to Robotic-Assisted Laparoscopic Myomectomy: A Randomized Placebo-Controlled Trial

Rachel L. Barr Grzesh, MD
Laurephile Desrosiers, DO
Salma Rahimi, MD
Suzanne S. Fenske, MD
Charles Ascher-Walsh, MD

Disclosures

- I have no financial relationships to disclose.

Learning Objectives

- At the conclusion of this activity, participants will be able to understand the benefit of the paracervical block in robotic-assisted laparoscopic myomectomy

Background

- Uterine leiomyomas (fibroids) are prevalent in up to 80% of women, almost a quarter with significant symptoms
- Many women with fibroids desire uterine-sparing treatment that allows future childbearing
- Robotic-assisted laparoscopic myomectomy (RALM) offers many benefits

Hypothesis/Objectives

- Hypothesis: Patients receiving a paracervical block before RALM will have lower admission rate to the hospital when compared to patients receiving placebo injections
- Primary outcome: Admission rate after surgery
  - Admission defined as at least one overnight stay in the hospital
- Secondary outcomes:
  - Pain medication use in post anesthesia care unit (PACU) and in first 14 days after surgery
  - Pain scores at postoperative hours 1, 2, and 4 and days 1 and 2
  - Estimated blood loss (EBL)
  - Complications

Background

- Preemptive analgesia
- Paracervical block
  - S2-S4 parasympathetic fibers supply the upper vagina, cervix and lower uterus
  - 1st trimester terminations
  - Vaginal hysterectomy

Hypothesis/Objectives

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- Secondary outcomes:
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  - Pain scores at postoperative hours 1, 2, and 4 and days 1 and 2
  - Estimated blood loss (EBL)
  - Complications
Methods

- **Study Design:** Double blind randomized controlled trial
- **Population:** 98 subjects scheduled to undergo an ambulatory RALM by a single surgeon at Mount Sinai Hospital in New York from 2011-2013
- **Inclusion criteria:** Patients ≥ 18 years old with presumed benign disease
- **Exclusion criteria:** Immunocompromised, malignant disease, not candidates for robotic surgery
- **IRB approved, registered with clinicaltrials.gov**

Subjects randomized to receive injection of 20 mL of 0.25% bupivacaine with 1:200,000 epinephrine (BE group) or normal saline (NS group)

Injected in equal parts at 2, 5, 7, and 10 o’clock around cervix

Randomization used computer-generated plan with random blocks in a 1:1 ratio

Patients and care providers other than circulating nurse were blinded

Standardized surgical technique

### Results – Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>BE Group (n=46)</th>
<th>NS Group (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>35 (15.7)</td>
<td>36 (14.8)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>24 (7.5)</td>
<td>24 (7.5)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>30 (65)</td>
<td>25 (49)</td>
</tr>
<tr>
<td>Black</td>
<td>9 (20)</td>
<td>13 (25)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2 (4)</td>
<td>7 (14)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (9)</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>40 (87)</td>
<td>42 (82)</td>
</tr>
<tr>
<td>1</td>
<td>3 (6.5)</td>
<td>5 (10)</td>
</tr>
<tr>
<td>2</td>
<td>3 (6.5)</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Uterine size (weeks)</td>
<td>13.4±3.2</td>
<td>13.8±3.4</td>
</tr>
<tr>
<td>Preoperative hematocrit (%)</td>
<td>37.1±3.3</td>
<td>37.8±3.9</td>
</tr>
<tr>
<td>Admission planned (%)</td>
<td>9 (0)</td>
<td>9 (0)</td>
</tr>
</tbody>
</table>

All data are mean ± standard deviation or n (%). *P*-value > .05 for all data.

### Results – Admission Rate

<table>
<thead>
<tr>
<th></th>
<th>BE Group (n=46)</th>
<th>NS Group (n=51)</th>
<th><em>P</em></th>
<th>Relative Risk [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission Rate</td>
<td>15% (7)</td>
<td>20% (10)</td>
<td>.37</td>
<td>0.78 [0.32-1.87]</td>
</tr>
</tbody>
</table>

Two patients in each group had medically-induced admissions (p=1.0)

- BE group – both for vomiting
- NS group – one for extenomy with bowel resection, reanastomosis; one for blood loss of 2500ml with transfusion
## Results – Pain Medication

<table>
<thead>
<tr>
<th>Variable</th>
<th>BE Group (n=43)</th>
<th>NS Group (n=51)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACU fentanyl use</td>
<td>37 (80%)</td>
<td>45 (88%)</td>
<td>.86</td>
</tr>
<tr>
<td>PACU oxycodone use</td>
<td>31 (67%)</td>
<td>36 (71%)</td>
<td>.86</td>
</tr>
<tr>
<td>Postoperative narcotic rate (tablets/day)</td>
<td>0.71</td>
<td>1.01</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Postoperative OTC analgesics rate (tablets/day)</td>
<td>1.21</td>
<td>1.03</td>
<td>.003</td>
</tr>
<tr>
<td>Postoperative days on narcotics</td>
<td>3 (0-10)</td>
<td>4 (0-12)</td>
<td>.52</td>
</tr>
<tr>
<td>Postoperative days on OTC analgesics</td>
<td>3 (0-14)</td>
<td>4 (0-13)</td>
<td>.70</td>
</tr>
</tbody>
</table>

All data are n (%), or median [range] unless otherwise indicated.

## Results – Pain Scores

![Graph: Pain Scores Over Time Among Myomectomy Patients](image)

## Results – Perioperative Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>BE Group (n=46)</th>
<th>NS Group (n=51)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated blood loss (ml)</td>
<td>100 [50-100]</td>
<td>100 [100-200]</td>
<td>.01</td>
</tr>
<tr>
<td>Mass of specimen (g)</td>
<td>239 [66-395]</td>
<td>207 [140-388]</td>
<td>.72</td>
</tr>
<tr>
<td>Operating time (min)</td>
<td>116 [98-133]</td>
<td>114 [96-138]</td>
<td>.63</td>
</tr>
<tr>
<td>Complications/13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dindo Grade 1</td>
<td>8 (17%)</td>
<td>2 (4%)</td>
<td>.13</td>
</tr>
<tr>
<td>Dindo Grade 2</td>
<td>5 (11%)</td>
<td>4 (8%)</td>
<td></td>
</tr>
<tr>
<td>Dindo Grade 3b</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>12 (26%)</td>
<td>7 (14%)</td>
<td></td>
</tr>
</tbody>
</table>

All data are n (%) or median [q1-q3] unless otherwise indicated.

## Discussion

- **Strengths**
  - Randomized controlled trial, double blind
  - Large sample size
  - Single surgeon

- **Limitations**
  - Single surgeon
  - Did not control for additional procedures
  - No preoperative data on pain scores, pain medication use

## Conclusion

- Paracervical block of bupivacaine with epinephrine before robotic-assisted laparoscopic myomectomy associated with decreased consumption of postoperative narcotics and lower blood loss
- No difference in postoperative admission rate

## References

Histological Characterization of Vaginal Cuff Tissue Using Different Energy Sources During Robotic Hysterectomy: A Randomized Trial

Megan Billow DO, Meng-Ru Cheng MSPH, Tolgay Ocal MD, Longwen Chen MD, Jeffrey Cornella MD, Paul Magtibay MD, Rosanne Kho MD

Disclosure

- I have no financial relationships to disclose.

Objectives

• Diagnose a vaginal cuff dehiscence and identify patients who may be at increased risk for a vaginal cuff dehiscence.
• Demonstrate how different energy sources used to perform a colpotomy may impact vaginal cuff healing.
• Identify limitations of performing human studies on vaginal cuff healing.

Vaginal Cuff Dehiscence (VCD)

Risk Ratio of VCD – TLH vs. all other modes of hysterectomy

<table>
<thead>
<tr>
<th>Modes of Hysterectomy</th>
<th>Risk Ratio (2006-2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAH</td>
<td>2.0 (0.7-5.6)</td>
</tr>
<tr>
<td>TVH</td>
<td>6.9 (0.8-58.6)</td>
</tr>
<tr>
<td>LAVH</td>
<td>1.6 (0.3-8.3)</td>
</tr>
</tbody>
</table>

Hur et al. Vaginal Cuff Dehiscence After Different Modes of Hysterectomy. AJOG. Oct 2011

Incidence and Characteristics of Patients With Vaginal Cuff Dehiscence After Robotic Procedures

Suzanne M. Dir, MD, Mohamed N. Ali, MD, Jeffrey L. Cornella, DO, Paul M. Magtibay, MD, Mary Ellen Weckler, MD, and Justis T. Magrina, MD

OBJECTIVE: To describe the incidence and characteristics of robotic technology has been used successfully in patients with vaginal cuff dehiscence following robotic hysterectomy for benign gynecologic conditions. Incidence of robotic hysterectomy is increasing, and robotic surgery is associated with decreased blood loss and shorter hospital stays. To determine the incidence of VCD and describe the characteristics of patients with this complication following robotic hysterectomy.

METHODS: A retrospective review of the electronic medical records of patients who underwent robotic hysterectomy for benign gynecologic conditions from January 2008 to December 2010 was conducted. The incidence of VCD was calculated. Characteristics of patients with VCD and patients without VCD were compared. Results: A total of 198 robotic hysterectomies were performed during the study period. A total of 9 (4.5%) patients had VCD. The average age of patients with VCD was 51.6 years, compared to 47.1 years for patients without VCD. The majority of patients with VCD (77.8%) underwent a trachelectomy, compared to 49.1% of patients without VCD. The average length of stay for patients with VCD was 1.5 days, compared to 0.5 days for patients without VCD. Conclusion: Vaginal cuff dehiscence after robotic hysterectomy is a rare but serious complication. Further research is needed to determine the etiology of VCD and to develop strategies to prevent this complication.
VCD Etiology Unknown

- Suture material?
  - TLH VCD rate of 4.2% vs. 0.0% - braided vs. bidirectional barbed

- Use of electro-energy during colpotomy

![Image]

Study Objective

- To compare the degree of lateral thermal injury (LTI) effect resulting from the use of monopolar energy and CO2 laser at the time of colpotomy during robotic hysterectomy

Animal Studies

- Electro-energy had a 3-fold increased amount of tissue injury compared to CO2 laser.
  - Pilot Study. Orgill et al. Brigham and Women's Hospital.

Study Design

- Prospective
- Randomized
  - Monopolar cut (35 Watts) vs CO2 laser (Omniguide Inc, Cambridge, MA 14 W)
- Inclusion Criteria:
  - ≥ 18 yoa
  - robotic hysterectomy
  - benign indications
- Power calculation:
  - N = 10 in each group for 90% power

Methods

- Vaginal cuff tissue obtained from specimen side
- 12 and 6 o’clock positions
  - 5 micrometer sections
  - H&E staining: gross extent of LTI (µm)
  - Masson’s Trichrome: extent of coagulation and edema (µm)
- 4 blinded pathologists

Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>Electroenergy</th>
<th>CO2 Laser</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>51.0 ± 14.1</td>
<td>48.5 ± 8.4</td>
<td>0.6316</td>
</tr>
<tr>
<td>BMI</td>
<td>30.1 ± 6.1</td>
<td>28.8 ± 8.4</td>
<td>0.6990</td>
</tr>
<tr>
<td>Smoker</td>
<td>No 100%</td>
<td>Yes 90%</td>
<td>0.4762</td>
</tr>
<tr>
<td>Menopause</td>
<td>No 73%</td>
<td>Yes 60%</td>
<td>0.8994</td>
</tr>
</tbody>
</table>
Results

Clinical and Scientific Significance

- Compared to CO2 laser, use of monopolar cut during colpotomy showed:
  - 1.5 fold increase in LTI (698 +/- 705 µm vs 468 +/- 450 µm, p = 0.04)
  - There appears to be a greater coagulation and edema effect.

- Long term impact on vaginal cuff healing needs further evaluation.

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.

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.