Surgical Tutorial 1:
Tissue Extraction and Retrieval

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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
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Surgical Tutorial 1: Tissue Extraction and Retrieval

Kimberly A. Kho, Chair

Faculty: Christopher S. Awtrey, Sarah L. Cohen

This session features subject matter experts who will review the most recent data on this important and timely topic. Speakers will use surgical videos to present their thoughts and illustrate techniques on Safe Tissue Extraction and Retrieval. Minimally invasive options for uterine, myoma, and adnexal mass removal will be discussed. Each video will be no more than 15 minutes to allow for a 15-minute question and answer segment at the end of the session, taking questions from the audience.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) Review the risks and benefits of various methods of tissue extraction; and 2) describe methods for tissue extraction in minimally invasive gynecology.

Course Outline

11:00 Welcome, Introductions and Course Overview
11:05 The Morcellation Issue and Minimally Invasive Approaches to Safe Tissue Extraction
11:20 Contained Power Morcellation: What Do We Know, What's New and What's on the Horizon?
11:35 A Gynecologic Oncologist's Perspective on Safe Tissue Extraction
11:50 Questions & Answers
12:00 Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Amber Bradshaw
Speakers Bureau: Myriad Genetics Lab
Other: Proctor: Intuitive Surgical
Erica Dun*
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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).
Christopher Awtrey*
Sarah L. Cohen*
Kimberly A. Kho
Contracted/Research: Applied Medical
Pivotal Protocol Advisor: Actamax

Asterisk (*) denotes no financial relationships to disclose.
The Morcellation Issue and Minimally Invasive Approaches to Safe Tissue Extraction

Kimberly Kho, MD, MPH
Gynecology Director, Southwestern Center for Minimally Invasive Surgery
University of Texas Southwestern Medical Center
Dallas, TX

Disclosures
• Contracted/Research: Applied Medical
• Other: Pivotal Protocol Advisor: Actamax

Objectives
• Describe methods for preoperative risk assessment to mitigate morcellation of occult malignancies
• Discuss techniques for minimally invasive tissue extraction
  – Transvaginally
  – Mini-lap
  – Enclosed power morcellation

Concerns about intracorporeal EMM
• Tissue dissemination
  – Benign tissue (parasitic myomas, disseminated leiomyomatosis, endometriosis, adenomyosis, splenosis)
  – Occult malignancy (sarcomas, endometrial, cervical, ovarian pathology)
    • Histopathologic challenges
    • Potential warrrning of prognosis and need for re-intervention
• Organ injury
  – FDA MAUDE review (’03-’13 55 complications, 6 deaths)
  – Associated with user inexperience

Risk estimates for occult malignancy
• FDA: 1:352 risk of sarcoma in women undergoing myomectomy/hysterectomy for suspected fibroids
• 1:458 risk of occult LMS
• Wright: 0.27% incidence of uterine malignancy in women undergoing morcellation during MIS
• 1.01% incidence of endometrial hyperplasia
• Manhert: 2.7% unexpected malignancy in hysterectomy pts; 0.22% incidence of occult sarcoma
• Kho: 9 sarcomas: 10,119 benign hysterectomy (0.09%)
• 5 LMS (0.05%)

No methods have been proven to reduce the risk of cellular dispersion
Preoperative considerations

- Informed consent process
- Preoperative evaluation
  - Thorough history and physical, including family hx
  - Endometrial evaluation —
    • Longitudinal review of imaging
  - Up to date cervical cancer screening
  - Consideration of risk factors for sarcoma
    • Tamoxifen use, pelvic XRT, HLRCC Sx
  - New symptoms or growth in postmenopausal woman
- Tissue extraction techniques
  - Enclosed vs non-enclosed
  - Intra-corporeal vs extra-corporeal

Utilization of cutting edge MRI modalities

- Diffusion weighed imaging (DWI) measures random movement of water in tissue
  - Increased intensity due to restricted water movement in highly cellular areas
  - Calculate ADC — quantitative assessment of cellularity
- Dynamic contrast enhancement (DCE) — for quantification of tissue perfusion & permeability
  - Rapid accumulation and washout may suggest malignancy

How do we safely remove large tissue masses while still performing MIS?

- Utilize techniques during
  - Hysterectomy (TLH, SCH)
  - Myomectomy
  - Cystectomy, Oophorectomy
- Routes for tissue extirpation
  - Mini-laparotomy
  - Vaginally through colpotomy
  - Laparoscopic power morcellation within containment bag

  Goal: To minimize risks while maximizing benefits

Retrieval Bags

- Endoscopic bags
  - Ethicon Endopouch: 4x6 in, 224 cc
  - Covidien EndoCatch: 10mm-6 cm d (220 cc), 15mm-12.7 cm d (1000 cc)
  - Applied Contained Extraction System: 17cm d (6500 cc)
- Isolation (Lahey) bags — transparent PVC
  - 3M, Isodrape — 50 x 50 cm
- Containment bag — rip stop nylon
  - Cook LapSac: 4x6, 5x8, 8x10 cm (1500cc)
  - BERT bags: 30 x 35 cm (3000 cc)
  - Eco Sac: 3100 cc

Mini-laparotomy Extraction

- Use a circumferential wound retractor
  - New systems combining containment bag with abdominal wound retractor
- 2-3 cm incision
  - Suprapubic vs Umbilical
- Lahey thyroid clamps
- 10 or 11 blade
- Peeling technique

Mini-laparotomy Extraction during Laparoscopic Myomectomy
Vaginal tissue extraction

- Naturally occurring, accommodating orifice
- Maintain existing port sites without extension
- Consider this a clean contaminated procedure
- Clinical trials compared to trans-abdominal extraction have not shown inferior outcomes:
  - Conversion
  - Postoperative pain
  - Dyspareunia
  - Infection
  - Adhesions

Transvaginal morcellation

- Coring
- Bi-valving
- Wedge resection
- Myomectomy
- Posterior retractor
- Tenaculums to maintain specimen orientation

Enclosed transvaginal morcellation after TLH

In bag manual morcellation through posterior colpotomy

- Creation of posterior colpotomy
  - Create colpotomy laparoscopically
    - Moist sponge stick for delineation
    - Monopolar hook, scissors, harmonic scalpel
  - Create colpotomy vaginally
- Introduce containment bag
- Vaginal extraction and enclosed morcellation
- Vaginal closure

Enclosed morcellation of 18 cm adnexal mass via posterior colpotomy
Multiport power morcellation in insufflated bag

- Technique not FDA-approved, currently being used in clinical trials
- Use large containment bag
- Insert bag via 15 mm umbilical incision
- Open bag in abdominal cavity and place specimen within bag
  - Use reverse Trendelenburg positioning
- Insufflate bag intra-abdominally
- Concerns regarding bag integrity and need for puncture of bag

On the horizon

- Innovation of instrumentation and techniques
- Prospective evaluation of safety and outcomes
- Systematic reporting of AE’s for accurate ascertainment of risks
- Development of preoperative diagnostic tools for risk stratification

References

Kho K, Nishimura T. Prospective histologic and clinical outcomes. 209. 2014.0 813 14.

Thank you!

Email: Kimberly.Kho@utsouthwestern.edu
Contained Power Morcellation: What Do We Know, What's New and What's on the Horizon?

Sarah L. Cohen MD MPH
Division of Minimally Invasive Gynecologic Surgery
Brigham and Women’s Hospital

OBJECTIVES

1. Analyze rationale behind contained tissue extraction
2. Review history, data, tips and tricks for contained power morcellation
3. Discuss future directions

Defining the problem

• FDA statement 11/2014
  - “Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or are candidates for en bloc tissue removal”
• Industry response
  - Johnson and Johnson: Gynecare (Morcellex TM) 80% market share of morcellation products, as of July 2014- recalls the Morcellex
• Insurance limitations
  - Aetna, United Healthcare require Peer to Peer review

Possible Solutions

Can we identify patients who are high risk for occult malignancy?
Should we avoid morcellation altogether?
Can we better minimize risks of morcellation via tissue containment?
  - Allow patients benefits of minimally invasive surgery
  - Minimize risk of tissue dissemination - both benign and malignant tissue
  - Has been reported in general surgery, urology and even gyn - even for malignancy

From innovation to possible solution

• KA ‘Tony’ Shibley MD
  - Video at AAGL in 2012 detailing tissue isolation and extraction within artificial pneumoperitoneum
  - Initially developed for use with single-site laparoscopic supracervical hysterectomy
Collaboration between BWH, MGH, JHH; KA Shibley

Jan 2013-April 2014: 73 patients, robotic and conventional LSC

- Hysterectomy: Multiport 26, single site 32
- Myomectomy: Multiport 11, single site 1

- 2/3 had prior abdominal surgery
- Median operative time 114 min (32-380 min)
- Median EBL 50 mL (10-500 mL)
- Median specimen weight 257 gm (53-1,481 gms)
- No conversions, readmissions, or reoperation; 78% discharged home same day

Limitations: lack objective measure bag integrity
- small observational study
- specialized high volume surgeons

- Compared OR time 3 months before and after implementing in bag power morcellation
- 36 IBM, 49 open morcellation; IBM added 26 minutes to OR time
Contained Power Morcellation Emerging Data

Cohen et al. JMG 2014

- Pilot study: Morcellation of 500g beef tongue in simulation lab
- Compared 3 techniques: Nylon bag multiport, Isolation bag multiport, Isolation bag single port
- Evaluated spill with indigo carmine and by cytology
  - Blue dye spilled in 1 of 12 trials (from seam of bag upon insufflation)- visible and on cytology

Contained Power Morcellation - Data

Submitted for publication:

- 76 cases successful
  - 3 specimen too large
  - 10 morcellation not necessary
- No bag tears during morcellation
- Avg morcellation time 30.2 minutes (+ 22.4)
- 1 patient with STUMP on final pathology
- 1 complication of large EBL

Contained Tissue Extraction: Future Directions

Espiner sleeved Ecosac prototype


Contained Power Morcellation - Variations

- Akdemir et al. Obstet Gynecol. 2015
  - Enclosed morcellation using insulated size 8.5 surgical glove

Contained Power Morcellation- Variations

- Review literature for any new developments/publications since summer 2015

Contained Power Morcellation Emerging Data

Submitted for publication:

- Prospective study across 7 sites in Boston
  - Multi-port approach, varying bags used
  - Primary outcome: leakage of tissue or blue dye
- Enrollment goal 400, early stop at 89 patients due to leakage events
  - 7 cases of dye or tissue leakage on post morcellation survey


A Gynecologic Oncologist's Perspective on Safe Tissue Extraction
Christopher S. Awtrey, M.D.

Director, Division of Gynecologic Oncology
Beth Israel Deaconess Medical Center

OBJECTIVES

1. Explain the potential oncologic concerns with electromechanical morcellation.
2. Review importance of conversation and consent with patients and their families.
3. Discuss the opportunity for advancement of our field.

The newspapers pick up a tragic story!

- Amy Reed, an anesthesiologist at BIDMC has 6 children and had been followed thru her last pregnancy for a fibroid uterus
- She underwent laparoscopic hysterectomy and electromechanical morcellation
- Discovered postoperatively that she had a LMS
- Went on to have re-exploration, Heated IP chemotherapy

Cancer Risks from Hysterectomy with Morcellation Lead Insurers to Drop Coverage

In response to continuing concerns about the risk of power morcellators used during hysterectomies spreading cancer, another health insurance company has announced that it will no longer cover the laparoscopic sterilization procedures.

In a press release issued on September 18, Capital BlueCross announced it will no longer pay for laparoscopic sterilization procedures.

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Mark Twain

- If you don’t read newspapers you are uninformed. If you read the newspaper, you’re mis-informed.
Uterine Pathology in Women Undergoing Minimally Invasive Hysterectomy Using Morcellation
(Wright et al. JAMA 2014)

- Database 232,882 patients underwent MIS surgery 2006-2012
- 36,470 (15.7%) Morcellation
  - 27/10,000 cancers in morcellated uteri (3/1000)
  - Increased with age
    - Prevalence ratio comp to younger than 40 years old
    - Greater than 65 prevalence ratio 35.97

Unexpected gynecologic malignancy discovered after hysterectomy performed for benign indications
Mahner et al Ob & Gyn 2015

- Aim: to determine frequency of unexpected malignancy in patients having a hysterectomy for benign indications
- Statewide Database data collected for 2013
  - 3,360 patients had a hysterectomy for benign indications
  - Unexpected path 172 pts (2.7%)
    - Ovary 1.08%
    - Endometrial 1.02
    - Uterine sarcoma 0.2%
    - Cervical 0.17%

So now what....?  
- Currently at BIDMC EMM is not utilized unless cleared by an expert review panel
- Alternative extraction methods are being developed and some are being dusted off
  - In-bag hand morcellation
  - Vaginal surgery
  - Mini-laparotomy
  - More laparotomies are likely being done

In Bag Morcellation

- Established technique in MIS removal of kidneys, ovaries and spleen
- Gynecologic specimens, uteri, fibroids may be large
  - Specialized bags
- It’s a challenge to hand carve the specimens
  - Specialized tools
- Still challenges for our pathologist due to fragmented specimen
AAGL Practice Report

- Collaboration with device makers to innovate new contained morcellation systems
- More rigorous system for mandatory adverse events reporting
- Stressed the importance of an informed consent process

The Future

- New technologic advances are needed
  - Contained morcellation systems
- Improvements in detection, dx Sarcoma
  - Serum Profile?
  - MRI?
- Nationally we need to improve in understanding how best to advocate for patients
- National registry, monitoring and discussion of adverse events
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.