A Practical Guide for Hysteroscopy in the Office (Didactic)

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

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This course provides the practical guidance necessary to perform hysteroscopic procedures safely and efficiently in the office setting. Designed for the gynecologist who wants to overcome common barriers, this course offers essential instruction, tools and information needed to begin or enhance a comprehensive in-office hysteroscopy practice. The course addresses billing and coding issues including RVU with CPT codes for hysteroscopic procedures and use of modifiers for reimbursement. Patient counseling, informed consent and documentation of procedures. Patient safety and regulatory guidelines, procedure checklists and personnel requirements guide the participant. Equipment acquisition, set-up and maintenance for both rigid and flexible hysteroscopes are presented. Office use of local anesthesia and oral medication for hysteroscopic procedures is examined in detail. Video based didactics address specific office operative hysteroscopic procedures in depth including tips, tricks and troubleshooting techniques as well as identification and management of office hysteroscopic complications.

Course Objectives

At the conclusion of this course, the participant will be able to: 1) Implement patient safety regulations and safety protocols for in-office procedures; 2) use correct coding and billing to maximize reimbursement for office hysteroscopic procedures; 3) appropriately counsel patients regarding in-office hysteroscopic procedures, obtain informed consent and document procedures correctly; 4) acquire, set-up and maintain equipment and supplies needed for office hysteroscopic procedures; 5) use cervical anesthesia, oral and injectable medication effectively for patient comfort with office hysteroscopic procedures; 6) utilize hysteroscopy for in office procedures such as biopsy, polypectomy, myomectomy, metroplasty, sterilization and IUD removal; 7) discern new technologies for hysteroscopic morcellation of polyps and myomas in the office; and 8) identify and address common complications encountered with office hysteroscopic procedures.

Course Outline

8:00 Welcome, Introductions and Course Overview A.L. Garcia  
8:05 Getting Started with Hysteroscopic Procedures in Your Office: Patient Safety, Regulation and Financial Considerations M. Harris  
8:30 Local Anesthesia, Oral and Injectable Medication for Office Procedures I.C. Green  
8:55 Diagnostic Hysteroscopy: Evaluation of the Uterine Cavity and Preoperative Decision Making A.L. Garcia
9:20  Office Operative Hysteroscopic Procedures: Directed Biopsy, Polypectomy, Metroplasty and IUD Retrieval  A.L. Garcia

9:45  Questions & Answers  All Faculty

9:55  Break

10:10  Hysteroscopic Sterilization: The Essure Procedure in the Office  I.C. Green

10:35  Hysteroscopic Morcellators: What’s on the Horizon for Hysteroscopic Polypectomy and Myomectomy in the Office?  A.I. Brill

11:00  Identifying and Managing Hysteroscopic Complications in the Office  M. Harris

11:25  Equipment Maintenance: The Rigid and Flexible Hysteroscope  E.C. Young

11:50  Questions & Answers  All Faculty

12:00  Course Evaluation
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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Linda Michels, Executive Director, AAGL*
Jonathan Solnik
Other: Lecturer - Olympus, Lecturer - Karl Storz Endoscopy-America

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Other: Proctor - Intuitive Surgical

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Other: Employee - Olympus  
Gary N. Frishman*  

Asterisk (*) denotes no financial relationships to disclose.
Office Based Hysterectomy: Safety and Regulation

MICAH HARRIS M.D.
OB/GYN CONSULTANTS AND WOMEN’S HEALTH RESEARCH
PHOENIX, AZ

Safety and Regulation

Grants/Research Support: Halt Medical

So Many New Procedures...

At the conclusion of this activity, the participant will be able to:
- List patient co-morbidities that are contraindications to office surgery.
- List qualities of surgical procedures that make them appropriate for the office setting.
- List the Levels of Office-Based Surgery
- List important features of an office-based surgical practice to promote patient safety.
- Describe the types of documentation necessary to maintain an office-based surgical practice.
- List the various agencies and associations that have published guidelines concerning office-based surgery.

Gynecologic Surgery in the Office: Overview

- Gynecology is a procedure-based specialty
  - Range from very minor (e.g., Pap smear) to very major (e.g., hysterectomy and pelvic support)
- Majority of income is from procedures
  - Better income per hour spent of actual effort
  - Income potential diluted by associated activities
    - Paperwork
    - Travel between office and surgery centers or hospitals
    - Peri-operative care – non-operative time with patient
- Traditional procedure model keeps us out of the office
  - Hospitals or surgery centers
  - Time out of office is not reimbursed
- Must become more efficient
  - Integrate procedures into office when possible
  - Allows greater productivity
  - Work smarter, not longer!
**Gynecologic Surgery in the Office:**

**General Considerations**
- Must be the correct surgeon
- Must be the correct patient
- Must be the correct procedure
- Patient safety a priority!

**Patient Selection**
- Patient Selection (ASA class I or II)
- Avoid Co-morbid conditions
  - Anxiety
  - Asthma
  - Obesity
  - Heart disease
  - Psychosocial issues
  - Prior experience with office procedures
  - Realistic patient expectations

**Procedure Choice**
- Appropriate for performing in office
  - Brief and focused
  - Not overly complicated
  - Basic technological requirements
- Anticipation of patient comfort
  - How long will patient be immobilized?
  - Comfortable table / bed for patient
  - Adequate room / time for recovery
  - Anticipation of analgesia
- Reasonable anticipation of patient safety

**Office Surgery Patient Safety Issues**
- Increasing number of office procedures
- Less oversight and scrutiny
- ACOG Presidential Task Force on Office Surgery
  - “Patients have a right to expect the same level of safety regardless of where they seek treatment.”

**Safety and Regulatory Considerations**
- Patient safety must remain primary
  - Desire for convenience should NOT increase risk
  - Desire for convenience should NOT trump safety
  - Accreditation requirements by certain states
Consider outpatient surgery guidelines of:
- ACOG monograph on ambulatory procedures
- American College of Surgeons (ACS) - www.facs.org
- American Association of Anesthesiologists (ASA) - www.asahq.org
- Professional liability insurers
- State (governmental) regulatory agencies

Office Surgery Patient Safety Issues

Florida Board of Medicine 4/2000 to 4/2002
- Adverse incidents:
  - Office 66 per 100,000 procedures
  - ASC 5.3 per 100,000 procedures
  - Relative risk: Office vs ASC 12.4 (95% confidence interval, 9.5-16.2)
- Death rate:
  - Office 9.2 per 100,000 procedures
  - ASC 0.78 per 100,000 procedures
  - Relative risk: Office vs ASC 11.8 (95% confidence interval, 5.8-24.1), respectively

ACOG: Quality and Safety in Women’s Health Care

GUIDELINES FOR OFFICE-BASED ANESTHESIA
(Approved by ASA House of Delegates on October 13, 1999, and last affirmed on October 27, 2004)
Levels of Anesthesia

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Local anesthetic with minimal preoperative oral anxiolytic</td>
</tr>
<tr>
<td>II</td>
<td>Moderate sedation</td>
</tr>
<tr>
<td>III</td>
<td>Deep sedation or General anesthesia</td>
</tr>
</tbody>
</table>

Levels of Office Based Surgery

- Level I - local anesthetic with minimal preoperative oral anxiolytic
- Level II - Moderate sedation
- Level III - Deep sedation or General anesthesia

Getting Started

- Identify a Medical Director
- Create Checklists
- Initiate Drills
- Maintain a Log

Getting Started: Checklists

- Create and use checklists for each case
- Promotes consistent behaviour
- Provides documentation for ongoing quality monitoring or external reviewers

Checklists for Office Based Surgery

- Preoperative
  - Informed consent, Patient Rights
  - History/Physical, work-up and results
  - Current medications, past reactions
  - Confirmation NPO status
  - Airway assessment
Checklists for Office Based Surgery

- **Intraoperative**
  - Surgical Time Out
  - Record of medications administered
  - Vital signs at 5 minute intervals
    - Blood pressure
    - Pulse
    - Oxygen saturation
    - End Tidal CO2 (optional)

- **Postoperative**
  - Return of vital signs to within 20% of baseline
  - Other signs: Bleeding, swelling
  - Discharge instructions
  - Driver for procedures having required any sedation
  - Follow up phone call within 48 hours

Mock Drills

- Performed quarterly
- Involve specifically identified individuals in the office (e.g. in the event of an emergency Tim will call 911.)
- Physically rehearsed for particular scenarios

Recommended Scenarios

- Vasovagal Reaction
- Local anesthetic toxicity
- Allergic reaction
- Hemorrhage
- Respiratory arrest/excessive sedation

Create a Procedure Log

- Documentation in addition to that in patient chart
- Essential for ongoing review, quality assessment
- Documentation of compliance and safety in one separate location
- Necessary should accreditation be sought

Accreditation

- Worthwhile if all recommendations followed and documented
- Process may assist in setting up protocols
- Many agencies available
- Not required in all instances
  - State Board of Medicine
  - Malpractice Insurer
  - Third Party Payors
Principles of Office Based Gynecologic Surgery

Gynecologic Surgery in the Office:

- General Considerations
  - Strict adherence to indications / contraindications
  - Thorough evaluation in advance
    - Imaging and other testing
  - No surprises in procedure room
  - Not the time or place for “atypical patient”

- More than just a change in location
  - Start with full sedation in operating room
  - Become totally comfortable with technique
  - Slowly lessen level of anesthesia
  - Achieve minimum needed anesthesia level
    - Balance between comfort and alertness
  - Mimic office conditions in OR before move
    - Use only instruments you have in office

- Know indications / contraindications
  - Complete comfort with procedure
  - Review IFU completely
  - Have written protocols in place
  - Have emergency contingency plan
  - Not the time or place for “atypical” procedure

Patient Analgesia

- Learn from our oral surgeon colleagues
  - Comfort, convenience and safety NOT mutually exclusive

ASA Physical Status Classification System
ASA Status and Mortality

- Only ASA Status 1 or 2 in office
- Prescreening
  - Adverse reaction to local anesthesia (personal or FH)
  - Previous failure with local anesthesia or low pain threshold
  - An acute respiratory process
  - Failure to comply with preoperative dietary restrictions
  - Substance abuse
  - High-risk airway assessment
  - Abnormal blood sugars
  - Pregnancy (unless procedure is pregnancy related)

Mallampati Airway Classification

- Ability to Rescue Patients
  - Level I
    - BLS training
    - Emergency equipment for cardiorespiratory support and treatment of anaphylaxis
  - Level II
    - Min of 2 staff members
    - Physician/surgeon
    - Health care professional with ACLS training
  - Time-Outs

Office Procedure Examples

- Hysteroscopic sterilization
- Endometrial ablation

Local Anesthetic Toxicity

<table>
<thead>
<tr>
<th>Agent</th>
<th>Duration</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1% Lidocaine</td>
<td>30-60 min</td>
<td>4.5 mg/kg</td>
</tr>
<tr>
<td>1% Lidocaine with Epinephrine</td>
<td>120-360 min</td>
<td>7 mg/kg</td>
</tr>
<tr>
<td>0.25% Marcaine</td>
<td>120-240 min</td>
<td>2.5 mg/kg</td>
</tr>
<tr>
<td>0.25% Maracne with Epinephrine</td>
<td>180-420 min</td>
<td>Do not exceed 225 mg</td>
</tr>
</tbody>
</table>
### Gynecologic Surgery in the Office: Patient Analgesia

- Dedicated patient monitoring
  - Surgeon should focus on procedure, not patient
  - Must have dedicated person to monitor patient
- Emergency measures
  - ACLS certification
  - Resuscitation / stabilization equipment

### Endometrial Ablation in the Office: Medicare Fee Schedule

### Procedure Billing

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Place of Service Code</th>
<th>Professional Fee (facility)</th>
<th>Professional Fee (non-facility)</th>
</tr>
</thead>
<tbody>
<tr>
<td>99243</td>
<td>Office Consult</td>
<td>1.72</td>
<td>0.13</td>
</tr>
<tr>
<td>99244</td>
<td>Office Consult</td>
<td>1.38</td>
<td>0.13</td>
</tr>
<tr>
<td>99245</td>
<td>Office Consult</td>
<td>1.38</td>
<td>0.13</td>
</tr>
</tbody>
</table>

**Fee for service:**
- Fee for providing equipment, room, staff, etc to you
- Fee for service goes to you

### CPT Codes

<table>
<thead>
<tr>
<th>Procedure</th>
<th>RVU's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office HSC Sterilization</td>
<td>53.93</td>
</tr>
<tr>
<td>Hospital HSC Sterilization</td>
<td>11.61</td>
</tr>
<tr>
<td>Office HSC Ablation</td>
<td>58.28</td>
</tr>
<tr>
<td>Office Her Option</td>
<td>64</td>
</tr>
<tr>
<td>Hospital HSC Ablation</td>
<td>9.48</td>
</tr>
<tr>
<td>Office HSC with biopsy</td>
<td>7.83</td>
</tr>
<tr>
<td>Endometrial biopsy</td>
<td>2.98</td>
</tr>
<tr>
<td>Office Cystoscopy</td>
<td>5.77</td>
</tr>
<tr>
<td>Saline infusion sonogram</td>
<td>4</td>
</tr>
<tr>
<td>Laparoscopic Tubal</td>
<td>9.7</td>
</tr>
<tr>
<td>Vaginal Hysterectomy</td>
<td>22</td>
</tr>
<tr>
<td>Global Obstetrical fee</td>
<td>47.4</td>
</tr>
</tbody>
</table>

### Procedures in the Office: Evaluation and Management

- Consult? New patient? Established patient?
- Endometrial Biopsy
  - Ultrasound
  - SIS + guidance + infusion
  - Hysteroscopy
- At time of consult? Unique visit? Modification?
- Type? Where?
- Follow-up

### Procedures in the Office: Reimbursement for Evaluation

<table>
<thead>
<tr>
<th>Code</th>
<th>Procedure</th>
<th>RVU's</th>
<th>Non-Facility</th>
<th>Facility</th>
<th>Conversion</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>99243</td>
<td>Office Consult</td>
<td>0.172</td>
<td>0.13</td>
<td>0.13</td>
<td>2.34</td>
<td>37.897</td>
</tr>
<tr>
<td>99244</td>
<td>Office Consult</td>
<td>0.172</td>
<td>0.13</td>
<td>0.13</td>
<td>2.34</td>
<td>37.897</td>
</tr>
<tr>
<td>99245</td>
<td>Office Consult</td>
<td>0.172</td>
<td>0.13</td>
<td>0.13</td>
<td>2.34</td>
<td>37.897</td>
</tr>
</tbody>
</table>

**Total reimbursement:** up to $759.47
Procedures in the Office: Reimbursement for Procedure

<table>
<thead>
<tr>
<th>Code</th>
<th>Procedure</th>
<th>Work RVU</th>
<th>Facility PE RVU</th>
<th>MP RVU</th>
<th>Facility Total</th>
<th>Conversion</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>58563</td>
<td>Hysteroscopy/endometrial ablation</td>
<td>6.16</td>
<td>2.75</td>
<td>6.74</td>
<td>9.85</td>
<td>37.897</td>
<td>$355.71</td>
</tr>
</tbody>
</table>

Place of Service: inpatient hospital (21); outpatient hospital (22); ambulatory surgery center (24)

Procedures in the Office: Effective Reimbursement in Office

<table>
<thead>
<tr>
<th>Procedure Reimbursement</th>
<th>$3000.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device (approximate cost)</td>
<td>-$1300.00</td>
</tr>
<tr>
<td>Disposables (drapes / drugs)</td>
<td>-$100.00</td>
</tr>
<tr>
<td>CRNA*</td>
<td>-$250.00</td>
</tr>
<tr>
<td>Effective Reimbursement</td>
<td>$1350.00</td>
</tr>
</tbody>
</table>

* CRNA may be able to bill independently

Procedures in the Office: Follow-up Visits

Global Interval
- Hysterectomy – 90 days
- Ablation – 0 days

Procedures in the Office: Summary

- Can be performed easily in office
  - Adequate preparation / training
  - Logical progression from OR to office
- Can be performed safely in office
  - Adherence to indications / contraindications
  - Adherence to published guidelines
- Is well accepted by (selected) patients
  - does not need to be uncomfortable
  - More comfortable for some
  - Perceived as more “confidential”

- Increases practice diversity
  - Can offer procedures in hospital or in office
- Ease of scheduling
- Reduces time spent out of office
- Optimize office space and personnel

Office Hysteroscopy
Office-Based Surgery
Thank you

References

1. Wortman M. Instituting an Office Based Surgery Program in the Gynecology Office. JIMG 2010; 17, 673-683.
2. ACOG Guidelines for Initiating an Office Based Surgical Practice. http://www.acog.org/

4. ASA Physical Status Classification System
http://www.asahq.org/clinical/physicalstatus.htm
5. Accreditation Handbook for Office Based Surgery
http://www.jointcommission.org/NR/rdonlyres/
Patient Comfort for Office Procedures

Isabel Green, MD
Johns Hopkins University
AAGL 2012

Disclosures
• I have no financial relationships to disclose.

Objectives
• Describe the innervations of the uterus and cervix, and apply knowledge of anatomy to consider sources of discomfort during hysteroscopy
• Describe the analgesic options for office hysteroscopy, including mechanism of action, risks and dosages of each class of medication.
• Apply current data on analgesic options to establish a safe analgesia protocol for the office

CHALLENGE
Pain is the most frequently cited reason for failed office hysteroscopy, it is the most important determinant of procedure acceptability

“Once a patient is invited into the office setting, they have the right to expect the same level of patient safety that occurs in a more regulated hospital setting”

Innervation of the Uterus

Superior hypogastric plexus – uterovaginal plexus
Plexus courses lateral to attachment of uterosacral ligaments
Fibers travel in the parametrial tissue

Nerves course with uterine branches and IP ligaments
Myometrium
Basal layer of endometrium
Submucosal layer of the cervix
Sources of Discomfort
Consider anatomy
- Speculum
- Cervix
- Dilation
- Manipulation
- Uterine distension
- Endometrium
- Fallopian tube

PROCEDURE SPECIFIC PATIENT FACTORS
- Menopause
- Cervical Stenosis
- Obesity
- Anxiety

Analgesia Options
- NSAIDS
- NARCOTICS
- ANXIOLYTIC
- LOCAL

NSAIDS
Examples | Mechanism of Action | Onset/Duration
---|---|---
Ibuprofen | Cyclooxygenase inhibition | 30 – 60 min Duration 4-6 hrs
Ketorolac | Inhibits PG synthesis | Long acting: Duration 12 hrs
Meloxicam | Anti-inflammatory | C Wiley
Nabumetone | | C Wiley
Naproxen | | C Wiley
Celecoxib | | C Wiley

RISKS:
- GI toxicity
- Acute renal failure
- Drug interactions
- Allergies

NSAIDS - Data
Double-blind placebo trial demonstrates significant reduction in POST procedure pain, NO significant benefit in discomfort during procedure

May reduce pain post procedure
May reduce need for rescue analgesia

Narcotics
Examples | Mechanism of Action | Onset/Duration
---|---|---
Oxydode | CNS: opioid receptors | ORAL
Tramadol | Serotonin | 15-60 min/4 hour
Fentanyl | Norepinephrine | IV
Buprenorphine | | <10 min/30-60 min

RISKS:
- Somnolence
- Respiratory Depression
- Hypotension
- Nausea/vomiting
- Pruritus
- Allergic reaction

Narcotics - Data
IV Tramadol 30 min prior resulted in significant decrease in VAS during and immediately following procedure when compared to placebo.

May result in decreased pain score at placement of 2nd Essure device
Limited isolated RCT
Anxiolytic

<table>
<thead>
<tr>
<th>Examples</th>
<th>Mechanism of action</th>
<th>Onset/Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lorazepam (2mg)</td>
<td>Bind to GABA receptor</td>
<td>IV 2-5 min/30-60 min</td>
</tr>
<tr>
<td>Alprazolam (0.5mg)</td>
<td>Anxiolysis</td>
<td>PO 30 min/60-120 min</td>
</tr>
<tr>
<td>Diazepam (10mg)</td>
<td>No analgesic properties</td>
<td></td>
</tr>
</tbody>
</table>

**RISKS**
- CNS depression
- Respiratory depression
- Unclear dose dependence

Coadministration with opioid may potentiate sedation

Counsel patient for recovery

Anxiolytics - Data

- Clinical case studies support use for procedure anxiety
- Hysteroscopy: Isolated studies are missing
  - anxiolytic, not analgesic
- In combination, may improve pain VAS
- Weigh benefit and risk of sedation

Local Dosing

<table>
<thead>
<tr>
<th>Agent</th>
<th>Duration (min)</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1% Lidocaine</td>
<td>30-60</td>
<td>4.5 mg/kg</td>
</tr>
<tr>
<td>1% Lidocaine w/ Epi</td>
<td>120-360</td>
<td>7 mg/kg</td>
</tr>
<tr>
<td>0.25% Maraine</td>
<td>120-240</td>
<td>2.5 mg/kg</td>
</tr>
<tr>
<td>0.25% Maraine w/ Epi</td>
<td>180-420</td>
<td>Do not exceed 225 mg</td>
</tr>
</tbody>
</table>

EPINEPHRINE
Vasoconstrictor – slows absorption, increase duration
Additional risks – BP variations, dysrhythmias, or catecholamine sensitivity

Local - Data

- **Topical:**
  - Spray, gel, instillation
    - Not demonstrated to be effective in limited, poor quality studies
- **Blocks:**
  - Paracervical
    - Reduced pain during parts of office procedures
  - Intracervical
    - Reduced pain, less pronounced than paracervical

Local - Data

- **Topical:**
  - Spray, gel, instillation
    - Not demonstrated to be effective in limited, poor quality studies
- **Blocks:**
  - Paracervical
    - Reduced pain during parts of office procedures
  - Intracervical
    - Reduced pain, less pronounced than paracervical

Risks

- Medication absorption – toxicity
  - Intravascular injection, dose is exceeded, or idiosyncratic response
- Vasovagal episodes
  - Data to support use in high risk patients
  - Data to support possible increase risk of episodes
- Bleeding at injection site
- Pain from administration
Complications
Local anesthetic toxicity
NEURO
— Ringing in ears, tingling, metallic taste, agitation, seizures
— Stop infiltration, airway support, serial vitals,
— Consider/prepare benzodiazepine for seizures
CARDIO
— Bradycardia, vasodilation, AV block, ventricular arrhythmias
— Stop infiltration, airway, cardiac monitor, call for help
— ACLS
— Consider fat emulsion

Complications
Allergic Reaction/Anaphylaxis
— Urticaria, flushing, pruritus, respiratory distress
— Stop, position, airway, oxygen, call for help
— 1st step: epinephrine (1mg/mL): 0.3-0.5 mg IM, repeat q 5-15 min
— IV fluid boluses
Over sedation/Respiratory Depression
— Decrease responsiveness to stimuli, desaturation
— Stop meds, engage the patient, position, airway, oxygen, call for help
— Reverse w/ meds: naloxone or flumazenil

Minimize Need for Analgesia
Flexible hysteroscope
Smallest diameter
Vaginoscopy technique
Balance patient comfort and no analgesia

Put it all together: example protocols

<table>
<thead>
<tr>
<th>Diagnostic Hysteroscopy &amp; Endometrial biopsy</th>
<th>Hysteroscopic Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen 800 mg at 10pm prior</td>
<td>Ibuprofen 800 mg q 8hr day prior</td>
</tr>
<tr>
<td>Ibuprofen 800mg 1 hour prior</td>
<td>Toradol 30 mg IM 30 min-60 min prior</td>
</tr>
<tr>
<td>Paracervical block 1% lidocaine, 10cc total</td>
<td>Paracervical block 1% lidocaine, 10cc total, 10 min prior</td>
</tr>
<tr>
<td>10 min prior</td>
<td>Optional: Oxycodone 5mg PO 30 min prior</td>
</tr>
</tbody>
</table>

Analgesia Levels
Level I: Local anesthesia with limited preoperative oral anxiolytic
Level II: Moderate sedation
Level III: Deep sedation

Definitions
Analgesia: relief of pain without intentionally producing a sedated state. Altered mental status may occur as a secondary effect of medications administered for analgesia
Definitions

• Minimal sedation: patient responds normally to verbal commands. Cognitive function and coordination may be impaired, but ventilatory

• No mention of types of medications, dosages, or route of administration

• Right patient, Right procedure, Right Surgeon, Right Place

What to do in your office?

Beyond ACOG guidelines:
State regulation and accreditation requirements
Hospital regulations and protocols

“The decision regarding type of anesthesia should NOT be altered based on limitations of equipment or personnel ... Such limitations might necessitate performing the procedure in a more acute care facility.”

References

"First of all, relax."
Diagnostic Hysteroscopy

evaluation of the Uterine Cavity and Pre-Operative Decision Making

Amy Garcia, MD
AAGL/SRS Fellowship-Trained in MIG
Director, Center for Women’s Surgery
Clinical Assistant Professor, University of New Mexico
Department of Obstetrics and Gynecology
Division of Urogynecology
Albuquerque, New Mexico

Objectives

- Acquire, set-up and utilize supplies and equipment necessary for diagnostic hysteroscopy in the office
- Utilize a hysteroscope (rigid and/or flexible) for diagnostic procedures in the office
- Discern diagnostic hysteroscopy techniques for in-office procedures

Indications for Hysteroscopy

- Evaluation of AUB
  - Heavy menstrual bleeding
  - Menopausal bleeding
- Abnormal Ultrasound Findings
  - Enlarged endometrial stripe
  - Suspected intra-cavitary pathology
- Infertility
- IUD

Hysteroscopy vs. TV US
Menopausal Women

- Marello, et al.
  - Menopausal women with EMS < 5 mm
  - 3% of symptomatic women
    - polyps
    - 10% of asymptomatic women
    - 16 polyps
    - 3 myomas

Hysteroscopy (HS) & Saline Infusion Sonography (SIS) vs. TV US

- Diagnosis of Intracavitary Pathology
  - TV US vs. HS Breitkopf et al.
    - 1 of 6 women had intracavitary lesions missed by TV US
    - 74% sensitivity
  - HS and SIS vs. TV US Jansen et al.
    - HS and SIS equal in diagnosis of intracavitary pathology
    - Significantly greater sensitivity/specificity vs. TV US

Disclosure

- Grants/Research Support: Hologic
- Consultant: Conceptus Incorporated, Ethicon Endo-Surgery, Ethicon Women’s Health & Urology, IOGYN, Minerva Surgical
- Speaker’s Bureau: Conceptus Inc.
19 studies from 1980 through July 2001

TVUS higher false negative vs. SH and HS for diagnosis of intrauterine pathology

SH and HS excellent diagnostic accuracy for hyperplasia and submucosal myomas

Hysteroscopy was the best for diagnosis of submucosal myomas

89 patients – premenopausal TVUS, SIS, HS

HS and SIS superior diagnostic accuracy to TVUS

HS best diagnostic accuracy

Especially for endometrial polyps

A prospective comparison of transvaginal ultrasound, saline infusion sonohysterography, and diagnostic hysteroscopy in the evaluation of endometrial pathology

2004 to 2006

38 patients TVUS, SIS and DH

DH the most accurate diagnostic technique for:

Diagnosis of any endometrial pathology

Diagnosis of endometrial diseases – hyperplasia or cancer

Intracavitary mass – polyp or myoma

Structural abnormalities

Hysteroscopy and SIS are BETTER than TV US at evaluating the uterine cavity.

Advantages of Hysteroscopy

Direct visualization

Opportunity for directed biopsy

Histopathology

<table>
<thead>
<tr>
<th>Blind Biopsy</th>
<th>Polyps</th>
<th>Myomas</th>
<th>Hyperplasia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity %</td>
<td>11</td>
<td>13</td>
<td>25</td>
</tr>
<tr>
<td>Specificity %</td>
<td>93</td>
<td>100</td>
<td>92</td>
</tr>
<tr>
<td>Accuracy %</td>
<td>59</td>
<td>98</td>
<td>80</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hysteroscopy</th>
<th>Polyps</th>
<th>Myomas</th>
<th>Hyperplasia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity %</td>
<td>89</td>
<td>100</td>
<td>74</td>
</tr>
<tr>
<td>Specificity %</td>
<td>93</td>
<td>99</td>
<td>93</td>
</tr>
<tr>
<td>Accuracy %</td>
<td>91</td>
<td>99</td>
<td>90</td>
</tr>
</tbody>
</table>
HS with Directed Biopsy vs. D & C
Evaluation of AUB

- Loffer 1989
- Evaluation of AUB
- HS with Directed Biopsy vs. D & C
  - 100% specificity for both
  - 98% sensitivity for HS vs. 65% for D & C
  - HS with directed biopsy missed 1 endometritis

Overcoming Barriers to In-Office Hysteroscopy
- Surgeon Skill
- Staff
  - Procedure awareness
  - Procedure assistance
  - Equipment maintenance
- Patient Expectations
  - Patient comfort
  - Ease of evaluation
  - Less overall risk
  - Immediate visual feedback
- Capitol Expenditure

Evaluation Technique
- Cervical evaluation
- Identify cornu
- Evaluation of cavity
  - Size, contour, septum, polyps, myomata, scaring
- Evaluation of endometrium
- Better cervical evaluation

Endometrial Adenocarcinoma
- 3401 resectoscopic procedures
- 16 occult, 3 known cancers
- Standard treatment with hysterectomy
- 5-14 year follow-up
- No change in 5 year survival or long-term follow-up
Submucosal Fibroids
Preoperative Evaluation ESGE

* Percent Intramural Extension
  - Type 0 None
  - Type I < 50%
  - Type II > 50%


Anesthesia

* 3 mm Flexible/Rigid
  - Usually not needed
* 5.5 mm Rigid w/o Dilation
  - Parous usually not needed
  - Tenaculum site local
  - 1% Lidocaine
* 5.5 mm Rigid with Dilation
  - Tenaculum site local
  - Paracervical block
  - 1% Lidocaine

No Cervical Preparation

* See and Treat
  - Cervical dilation usually not needed
  - 3 mm flexible hysteroscope
* Misoprostil
  - Cramping and bleeding
  - Give narcotic pain medication
  - Not useful for menopausal women

Misoprostol

* Oral/Vaginal 400 μg 6-8 hr prior
* Sublingual 400 μg 2-4 hr prior

In-Office Essentials

* Patient is awake
  - Keep fluid pressure low
  - Remove speculum
  - Minimize movement
* Scope-light cord relationship
  - 30° lens
* Communicate with patient
  - Position Monitor

Hysteroscopy Essentials
Procedure Steps

* Lithotomy with boot stirrups
* Manual exam of uterus
* Speculum
  - Pederson
  - Open-sided
* Clean cervix
* Place hysteroscope
**Vaginoscopic Hysteroscopy**

**Procedure**
- Consideration for misoprostol
- No speculum needed
- Betadine vagina
- No anesthesia
- Fill posterior fornix with saline

**Equipment**
- Monitor
- Camera
  - Camera head
  - Processor
  - Light source
- Tower
- Recording Device

**Flexible Hysteroscope**
- Fiber-optic or digital
- Single channel
- 3 – 4 mm diameter
- 0° lens with 240° range of visual field
- Saline as distention medium
- IV tubing/cystoscopy tubing or 60 cc syringe

**Office Set-Up**

**Retroverted Uterus**
- Anteverted Uterus
  - Posterior Fornix
  - Mucous/Blood

Recreated from the work of Dr. Martin Farrugia
Office Set-Up
Procedure Room

Supplies and Instruments

Supplies and Instruments

Supplies and Instruments

Supplies and Instruments

Supplies and Instruments

Documentation

Reimbursement

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
<th>Medicare</th>
<th>125% Medicare</th>
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<tbody>
<tr>
<td>58555</td>
<td>Diagnostic Hysteroscopy</td>
<td>CF 34.037</td>
<td>CF 42.55</td>
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<td>5.67</td>
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<td>$192.99</td>
<td>$241.24</td>
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No Global

In-Patient (21), Out-Patient (22), ASC (24)

Non-Facility/Office (11)

With E/M Visit
Modifier 25
Document HS Separately
Reimbursement

**In-Patient (21), Out-Patient (22), ASC (24)**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medicare CF</th>
<th>125% CF</th>
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<tr>
<td>Hysteroscopy with Polypectomy, Biopsy, D &amp; C</td>
<td>$271.28</td>
<td>$339.10</td>
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**2012 RVU**

<table>
<thead>
<tr>
<th>Facility/Office</th>
<th>Medicare CF</th>
<th>125% CF</th>
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</thead>
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<tr>
<td>In-Patient</td>
<td>$7.97</td>
<td>$9.96</td>
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<tr>
<td>Non-Facility/Office</td>
<td>$11.27</td>
<td>$14.16</td>
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</table>

**With E/M Visit**

**Modifier 25**

Document HS Separately

In-Office Hysteroscopy -- Why

- Patient Comfort
- Patient Financial Burden Lessened
  - Office co-pay vs. outpatient co-pay
  - Co-insurance, self-pay
- Reduced Risk
  - No general anesthesia
  - EMB vs. D & C
  - See and treat
- Immediate Visual Affirmation
- Patient Convenience
- Physician Convenience

Flexible HS $6,000/192.00 = 31.2 procedures
Operative Hysteroscopy

Amy Garcia, MD

AAGL/SRS Fellowship-Trained in MIG
Director, Center for Women’s Surgery
Clinical Assistant Professor, University of New Mexico
Department of Obstetrics and Gynecology
Division of Urogynecology
Albuquerque, New Mexico

Objectives

* Acquire, set-up and utilize supplies and equipment necessary for procedures in the office
* Utilize an operative hysteroscope and operative instruments in the office
* Discern operative hysteroscopy techniques for in-office procedures

Operative Office Hysteroscopy

* Myomectomy
* Uterine Septum
* Polypectomy
  * Mechanical
  * Scissors
  * Morcellator
  * Bipolar energy

Operative Hysteroscope

* Rigid Lens
  * 2.8 – 3.2 mm diameter
* Continuous Flow Sheath
  * 5.5 mm diameter
* Operative Channel
  * 3 Fr or 5 Fr
* 0°, 12°, 25°, 30°

Disclosure

* Grants/Research Support: Hologic
* Consultant: Conceptus Incorporated, Ethicon Endo-Surgery, Ethicon Women’s Health & Urology, IOGYN, Minerva Surgical
* Speaker’s Bureau: Conceptus Inc

Operative Hysteroscope
Continuous Flow Sheath

- Operative hysteroscopes and resectoscopes
- Inflow through inner channel—low resistance
- Outflow through outer sheath—high resistance
- Creates a clear visual field
- Helps to maintains uterine distention

Supplies and Instruments

- Semi-rigid Instruments
- 5 Fr Diameter
- 34 and 40 cm Length
  - Scissors
  - Alligator forceps
  - Biopsy forceps
  - Tenaculum
Risk Factors for Polyps

- Age
- Menopause
- HTN
- Obesity

Only AGE keeps statistical significance in univariable analysis

Endometrial Polyps and Hyperplasia

Increased risk of atypical hyperplasia in random directed biopsies

Reimbursement

<table>
<thead>
<tr>
<th>Procedure</th>
<th>In-Patient (21), Out-Patient (22), ASC (24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>58558 Hysteroscopy with Polypectomy, Biopsy, D &amp; C</td>
<td>Medicare CF 34.037, 125% CF42.55</td>
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<tr>
<td>2012 RVU</td>
<td>7.97</td>
</tr>
<tr>
<td>Non-Facility/Office (11)</td>
<td>11.27</td>
</tr>
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</table>

Medicare | CF 34.037, 125% CF42.55 |

8.62 | $294.77 | $368.46 |

Non-Facility/Office (11) | 11.72 | $398.92 | $498.65 |

With E/M Visit Modifier 25 Document HS Separately
In-Office Hysteroscopy—Why

* Patient Comfort
* Patient Financial Burden Lessened
  * Office co-pay vs. outpatient co-pay
  * Co-insurance, self-pay
* Reduced Risk
  * No general anesthesia
  * EMB vs. D & C
  * See and treat
* Immediate Visual Affirmation
* Patient Convenience
* Physician Convenience
Hysteroscopic Sterilization: Changing the Paradigm of Permanent Contraception

Isabel Green, MD
Johns Hopkins University

Disclosures

- I have no financial relationships to disclose.

Objectives

- Anticipate needed equipment and supplies for successful implementation of office sterilization
- Demonstrate proper patient selection & counseling for office hysteroscopic sterilization
- Demonstrate proper technique of the Essure procedure and confirmation test
- Establish protocols for office sterilization

Hysteroscopic Sterilization: Essure

- Hysteroscopic placement of radiopaque inserts in the proximal portion of the fallopian tube
- Tissue ingrowth occurs through the insert creating natural barrier

The Essure insert Design

- Device Length: ~3.85 cm
- PET Fiber Length: ~1.75 cm
- Expanded Outer Diameter: 1.5 – 2.0 mm
- Inserts are visible by X-Ray, Ultrasound, MRI and CT Scan

Permanent Contraception

re-li-able adj \ri-ˈli-a-bal\ː suitable or fit to be relied on: dependable

SAFE
&
CONVENIENT
Essure Tubal Occlusion Results*

<table>
<thead>
<tr>
<th>% occluded at three months</th>
<th>96.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>% occluded at six months</td>
<td>100%**</td>
</tr>
</tbody>
</table>

*Essure Instructions for Use, CONCEPTUS

Tubal patency was demonstrated in 16 women at the 3-month HSG, but all 16 women were shown to have tubal occlusion at a repeat HSG performed 6-7 months after Essure placement.

Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Phase II Trial ESS-005</th>
<th>Pivotal Trial ESS-005</th>
<th>2009 Commercial Setting Reported Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforations</td>
<td>3.4%</td>
<td>1.1%</td>
<td>0.177%</td>
</tr>
<tr>
<td>Expulsions</td>
<td>0.5%</td>
<td>2.9%</td>
<td>0.043%</td>
</tr>
<tr>
<td>Initial tubal patency</td>
<td>3.5%</td>
<td>3.5%</td>
<td>0.097%</td>
</tr>
<tr>
<td>Other unsatisfactory location</td>
<td>0.5%</td>
<td>0.0%</td>
<td>NA</td>
</tr>
</tbody>
</table>

COMPLICATIONS

Vasovagal episodes 2-5%

Why transition to the office?

The case of Mrs. Jones....

39 year old, multiparous, has completed her family, and after counseling desires hysteroscopic tubal occlusion.

Mrs. Jones in the office....

- Patients:
  - Familiar setting for patients
  - Avoids hospital hassle
  - Can watch procedure if desired
  - “have a procedure,” not a surgery

- Surgeon:
  - Time-saving
  - Consistent staffing
  - Higher reimbursement

Essure in the Office

Of 209 women...

70% experienced pain less than or equal to menses

Of 1603 women.....

97% would recommend the procedure to others

52% state the most valuable aspect was avoidance of the operating room

Equipment

HIGH COST

- Hysteroscope
  - Operative
- Camera
- Light source
- Monitor
- Mobile cart
- Printer
- Recorder
- Disinfection station
Equipment
Low cost:
- Speculum
- Stirrups
- Tenaculum
- Paracervical block
- Dilators
- Distending medium
- Tubing
- Pressure bag
- Outflow pouch
- Channel seal

Priceless: reliable well-trained staff

Equipment Cost as a Barrier
- Multiple indications
- Shared equipment
- Equipment programs & trials
- Reimbursement

ICD-9
V25.2
Interruption of fallopian tubes or vas deferens
CPT
58565
Bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants

Reimbursement

<table>
<thead>
<tr>
<th>In-Patient (21), Out-Patient (22), ASC (24)</th>
<th>Hysteroscopic Sterilization</th>
<th>58565</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012 RVU</td>
<td>Medicare CF 34.037</td>
<td>125% CF 42.55</td>
</tr>
<tr>
<td>12.96</td>
<td>$ 441.13</td>
<td>$ 551.41</td>
</tr>
<tr>
<td>Non-Facility/Office (11)</td>
<td>$ 1,934.02</td>
<td>$ 2,417.53</td>
</tr>
</tbody>
</table>

Essure Candidates for the Office
Woman who....
- Qualifies for permanent sterilization
- Has no contraindications to hysteroscopic sterilization
- Good candidate for an office procedure
- Understands follow up after Essure procedure

Contraindications*
- Uncertain about her desire to end her fertility
- Can have only 1 insert placed
- Has previously undergone a tubal ligation
- Pregnant or suspected pregnancy
- Delivery or termination less than 6 weeks prior
- Active or recent upper or lower pelvic infection
- Known allergy to contrast media**
- Should not be used concomitantly with ablation procedures
- Discouraged in women undergoing immunosuppressive therapy

Analgesia Example Agents
- LOCAL
  - Paracervical Block
  - Intrauterine lidocaine
- NSAIDS
  - Motrin, Toradol, Mefenamic Acid
- Narcotic
  - IV tramadol, Oxycodone
- Anxiolytic

Chudnoff et al. Obstet Gynecol 2010
Reducing pain in the office

**Paracervical Block Efficacy in Office Hysteroscopic Sterilization**
*A Randomized Controlled Trial*
Sarah Chudnoff et al Obstet Gynecol 2010

**RCT 1% Lidocaine vs Saline for PCB**
Significant Lower Pain Scores
- Tenaculum placement
- Traversing external cervical os
- Traversing internal cervical os
No Difference for Device Placement

Chudnoff et al Obstet Gynecol 2010
Courtesy Amy Garcia, MD

---

**Example Protocol**

**Preprocedure:**
NSAIDS
Motrin 600 mg day prior

**IDEAL PROTOCOL HAS YET TO BE DETERMINED**

Literature doesn’t support single protocol

Xanax 0.5 mg po 30 min prior as needed
Paracervical block
1% lidocaine, 10cc total, wait time 10 min

**Postprocedure:** NSAIDS

---

**Ess305 System**

Ess305 System consists of
(1) Delivery System; (2) Insert; and (3) DryFlow Introducer

1. 
2. 
3. Special thanks: Conceptus Inc

---

**Procedure Steps**

1. Insert catheter to black marker - stabilize Essure handle to hysteroscope - wheel button toward you to hard stop
2. Confirm position = gold band at ostium + green catheter in view!
3. Deploy device = push button, wheel back button toward you to hard stop again while maintaining stabilization

---

**Essure Procedure**

Preprocedure checklist & HCG
Premedication
Moderate lithotomy
Bimanual exam
Speculum
Clean cervix
Single tooth tenaculum
Paracervical block – pause
Place hysteroscope - Maintainate
Dilate if needed
Diagnostic hysteroscopy - identify both ostia
Place devices
Photograph
Assess hemostasis at cervix
Document
Fluids
Anesthesia
# of coils
Pain scale

---

**Tips for Success in the Office**

- Contraception before and after
- Scheduling in early proliferative phase
  - Improve visualization
  - Decrease risk of pregnancy
  - Hormonal meds favorable
- Avoid unnecessary instrumentation
  - Decrease cost and clutter
  - Remove speculum for comfort
  - Vaginoscopy
- Maintain back up equipment/kits
- Know your learner and use visual imagery
Tips for Success in the Office
30 degree scope

Performing the Essure Confirmation Test
- Perform at 3 months
- Confirm satisfactory insert location
- Document bilateral tubal occlusion

If satisfactory position, but contrast seen past the outer coil – repeat in 3 months

Suspected Expulsion & Perforation

If unsatisfactory position, patient cannot rely on Essure for contraception and alternative should be sought and coils removed is possible

Example Follow-up Protocol
- Essure list with due date for HSG
- Phone call at due date
- Follow up phone call at 2 weeks
- Follow up phone call at 4 weeks with certified letter

RATES OF COMPLIANCE
Vary based on clinical setting
12-80%
Area of improvement for successful permanent contraception

Essure Typical Use

RATES OF COMPLIANCE
Vary based on clinical setting
12-80%
Area of improvement for successful permanent contraception

Comparing Effectiveness to CREST:
Five-Year Failure Rates per 1000 Women
Tips for Success in the Office

• Invest in your team
  – Vocal anesthesia
  – Set the atmosphere
  – Practice safety drills

• Involve the patient
  – Use the monitor

• Write a protocol, circulate and post it in the office

Thank you

References

• ACOG 2011 Women’s Health Stats & Facts
• Mirena Prescribing Information. Bayer Health Care Pharmaceuticals. July 2008
• Data on file Conceptus Inc
• IFU insert Essure

• Report of the Assessment Task Force on Outpatient Hysteroscopic Sterilization.
Hysteroscopic Morcellators: What’s on the horizon?
Andrew I. Brill MD
Director, Minimally Invasive Gynecology
California Pacific Medical Center
San Francisco, CA

Disclosure
- Consultant: Karl Storz Endoscopy-America, Ethicon Endo-Surgery, Conceptus Inc., CooperSurgical
- Speaker’s Bureau: Karl Storz Endoscopy-America, Ethicon Endo-Surgery, Conceptus Inc., CooperSurgical

Submucosal Fibroids

Clinical Indications for Hysteroscopic Myomectomy

Infertility
- Molecular Causal Relationship
  - Rackow BW, Taylor HS
    - Submucosal uterine leiomyomas have a global effect on molecular determinants of endometrial receptivity. Fertil Steril. 2010;93(6):2027-2034
- Improved Fertility After Myomectomy
  - Pritts EA, Parker WH, Olive DL

Improved Pregnancy Rates
- Shokeir T, et al.
  - Submucosal myomas and their implications in the pregnancy rates of patients with otherwise unexplained primary infertility undergoing hysteroscopic myomectomy: a randomized matched control study. Fertil Steril. 2010;93(2):259-269
- 215 women infertility longer than 12 months
- Fibroids classified by US with ESGE classification

Results
- Myomectomy patients twice as likely as control to become pregnant (RR = 2.1; 95% CI = 1.59-2.9)
- Women with type 0 and type 1 myomas removed had significantly higher pregnancy rates than control (p < .001)
- No statistically significant difference in the type II groups

Abnormal Uterine Bleeding
- Genetic - Molecular Level
  - Stewart EA, Nowak RA
  - Laughlin SK, Stewart EA
- Improved Bleeding after Myomectomy
  - Loffer FD
  - Emanuel NH
Pre-operative Assessment of Submucosal Myomas is Essential!

Submucosal Fibroids
Pre-Operative Decision Making

* Percent Intramural Extension
  - Type 0: None
  - Type I: < 50%
  - Type II: > 50%

Wamsteker K, et al.

Hysteroscopic Myomectomy

Wamsteker K, 1993

<table>
<thead>
<tr>
<th></th>
<th>Type 0</th>
<th>Type I</th>
<th>Type II</th>
<th>Total</th>
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<tbody>
<tr>
<td>No. Patients</td>
<td>73</td>
<td>97</td>
<td>108</td>
<td>278</td>
</tr>
<tr>
<td>No. Procedures</td>
<td>73</td>
<td>102</td>
<td>158</td>
<td>333</td>
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<tr>
<td>Complete Resection</td>
<td>N = 73</td>
<td>N = 95</td>
<td>N = 103</td>
<td>N = 271</td>
</tr>
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<td></td>
<td>100%</td>
<td>98%</td>
<td>95%</td>
<td>97%</td>
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<tr>
<td>Repeat Procedures</td>
<td>-</td>
<td>9%</td>
<td>40%</td>
<td>17%</td>
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<tr>
<td>Mean Fluid Intavasion (cc)</td>
<td>437</td>
<td>971</td>
<td>1642</td>
<td>1110</td>
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</table>

Type II Hysteroscopic Myomectomy

* Increased risk of:
  - Excessive fluid absorption
  - Electrolyte abnormalities with non-electrolyte media
  - Excessive bleeding
  - Incomplete resection
  - Need for additional procedure
  - Increased operative time

Even with expert hysteroscopic surgeons

Lasmar RB, et al.
**Submucosal Fibroids**

Preoperative Evaluation New Classification

Lasmar, 2005

- **STEPW**
  - 57 myomectomies compared to ESGE
  - STEPW more accurately predicted differences between groups I and II with respect to:
    - completed procedures
    - fluid deficit
    - operative time

**STEPW Better predicted incomplete resection of Fibroids (p < .001)**

- **STEPW**
  - 100% (95% CI 89.4%-100%)
  - 84.0% (95% CI 80.2%-87.3%)

**ESGE Classification of Fibroids**

0.4 cm Type 1
0 + 1 + 0 + 1 + 0 = 2

1.5 cm Type 0
0 + 1 + 0 + 0 + 1 = 2

2.5 cm Type 1
1 + 0 + 1 + 1 + 1 = 4

1.5 cm Type 2
0 + 0 + 0 + 2 + 1 = 3

Lasmar, 2005, 2011

**UTERINE FIBROIDS**

Fertil Steril. 2011;95:2073-2077


Feasibility of a new system of classification of submucous myomas: a multicenter study

- 465 myomas comparing STEPW and ESGE
- Complete removal in 432 (92.9%) incomplete in 33 (7.1%)
- All 320 myomas with score <4 removed (100%)
- 112/145 myomas with score >4 removed (77.2%)
- All 33 cases of incomplete removal had score >4 (100%)
- 85/86 Type 0 removed (98.3%)
- 278/298 Type 1 removed (93.3%)
- 69/81 Type 2 removed (85.2%)
**Clinical Indications for Hysteroscopic Polypectomy**

- **AUB**

- **Infertility**
  - Rackow et al.
  - Afifi et al.
TRUCLEAR 8.0 – Smith & Nephew
FDA Approved 2005

- Dedicated Fluid Management
- Tissue Removed with Suction
- Offset Lens Hysteroscope
- Outer Blade 4.0 mm OD
- Scope 8 mm, 0°
- Hysteroscopic Sheath 9 mm OD
- Continuous flow
- Tissue Trap
- Reusable Hand-piece

Images Courtesy of Smith and Nephew

TRUCLEAR 8.0 – Smith & Nephew

- Reusable Hand-Piece
- Rotary Morcellator
  - Polyps
  - Oscillates back and forth
  - Serrated
  - 7 mm cutting window at tip
- Reciprocating Morcellator
  - Myomas
  - Rotates and reciprocates
  - 357 bites per minute

Fluid Management

- Pressure Inflow Controlled
- Total Fluid Used
- Total Deficit
- Weight based
- Any Operative HS Procedure

Images Courtesy of Smith and Nephew

TRUCLEAR 5.0 – Smith & Nephew

- Offset Lens Hysteroscope
- Outer Blade ‘TRUCLEAR INCISOR PLUS’
  - 2.9 mm OD
- Rotary morcellator
- Polyps – especially fundal
- Scope 5.0 mm, 0°
- Hysteroscopic Sheath 5.6 mm OD
- Continuous Flow
- Ideal for office use

Images Courtesy of Smith and Nephew

The Intra Uterine Morcellator: A new hysteroscopic operating technique to remove intrauterine polyps and myomas

Mark Hans Emmanuel, MD, PhD, and Kees Wamsteker, MD, PhD

From the Department of Obstetrics and Gynecology, Academic Medical Center, the Netherlands (both authors, both surgeons).


Decreased Operative Time

Polyps 2/3
Type 0 and Type 1 1/2

Instruments and Techniques:

Hysteroscopic Morcellator for Removal of Intrauterine Polyps and Myomas: A Randomized Controlled Pilot Study among Residents in Training

Results of the study revealed a significant difference in operating time between the Morcellator and the Traditional methods. The study also demonstrated a decrease in blood loss and an increase in patient satisfaction.

Operating time (minutes)

Volume of intrauterine lesion cm³
Clinical implementation of the hysteroscopic morcellator for removal of intrauterine myomas and polyps. A retrospective descriptive study

Retrospective Experience Report
- 315 women 2006 - 2009
  - Polyps: Rotary Blade S&N
    - Mean 7.3 minutes operative time
    - Mean diameter 2.4 cm, fluid deficit 40 mL (0-300)
  - Myomas Type I and II - Reciprocating Blade
    - Mean 18.2 minutes operative time
    - Total = 37 (Type 0 = 23, Type 1 = 11, Type 2 = 3)
    - Mean diameter 2 cm, fluid deficit 440 mL (100-890)

MyoSure - Hologic
FDA Approved 2009
- Standard Set-up Fluid/Suction
- Tissue Removed with Suction
- Offset Lens Hysteroscope
- Outer Blade 3 mm OD
  - 7 mm cutting window 7 mm from tip
  - Inner Rotating-Oscillating Blade 2 mm
- Hysteroscopic Sheath 6.25 mm OD
- Tissue Trap
  - Removes 1.5 gm/min of tissue
  - Single-Use Device

Myomectomy
Hologic MyoSure

Pending 510(K) FDA Approval
Fluid Management
Hologic Aquilex
- Use with MyoSure in-office
- Small footprint
- Pressure Inflow Controlled
- Total Fluid Used
- Deficit Meter
- Inflow roller wheel RPM based

Clinical Evaluation of a New Hysteroscopic Morcellator—Retrospective Case Review

- 11 Women
  - Polyps Mean Operating Time
    - 37 seconds (100%)
  - Myomas Mean Operating Time
    - Type 0: 2 minutes 19 seconds (100%)
    - Type 1: 9 minutes 10 seconds (100%)
    - Type 2: 11 minutes 49 seconds (50%)
In-Office Polypectomy
Hologic MyoSure

IOGYN Mistral
INVESTIGATIONAL
- Integrated Office System
- Rapid Tissue Removal
  - Bipolar RF initiated plasma energy
  - Hemostatic capabilities
- Offset Lens Hysteroscope
- Hysteroscopic Sheath OD 5.2 mm
- Continuous Flow
- Closed-Loop Fluid Management
  - Can eliminate fluid overload
  - Max deficit set at 2,500 cc
- Compatible with other RF Generators

Fluid Management
IOGYN Mistral

Polypectomy
IOGYN Mistral

Morcellated Myoma
IOGYN Mistral

Instrument Training
Truclear

Images Courtesy of IOGYN

Courtesy of IOGYN

Courtesy of IOGYN

Images Courtesy of IOGYN

Courtesy of Smith and Nephew

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**Hysteroscopic Morcellators**

**Advantages**

- Operate in Saline
- Decreased risk of fluid overload
- Mechanical
- No thermal injury
- Remove Tissue Pieces
- Clear visual field
- Decreases risks of multiple instrument placement
- Uterine perforation, false passageway and air embolus

**Disadvantages**

- No electrosurgery for hemostasis
- IOGYN Mistral has electrosurgery
- Type 2 myomas are difficult
- Fundal pathology is difficult
- Easier with TRUCLEAR blades and with Mistral
- Potential for significant fluid use
- Myosure
- Cost of fluid management system
- Mistral is incorporated into device
- Currently no reimbursement for office use

**Fluid Use**

- Emanuel -- TRUCLEAR
  - Total not recorded
  - 714 (0-3,000)
- Van Dongen -- TRUCLEAR
  - All Procedures
  - 3,433 (2,209-4,417)
  - Deficit 409 (229-589)
- Wibeke -- TRUCLEAR
  - Total not recorded
  - 400 (100 - 850)

**Operative Hysteroscopy**

- Emanuel -- TRUCLEAR
  - TRUCLEAR
  - Total not recorded
  - 714 (0-3,000)
- Van Dongen -- TRUCLEAR
  - TRUCLEAR
  - 3,433 (2,209-4,417)
  - Deficit 409 (229-589)
- Wibeke -- TRUCLEAR
  - TRUCLEAR
  - 400 (100 - 850)

**Reimbursement**

- **In-Patient (21)**, **Out-Patient (22)**, **ASC (24)**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medicare CF 34.01</th>
<th>125%</th>
<th>Medicare CF 42.5125</th>
<th>125%</th>
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<tbody>
<tr>
<td>5858 Hysteroscopy with Polypectomy, Biopsy, D &amp; C</td>
<td>$270.38</td>
<td>$337.97</td>
<td>$456.63</td>
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</tbody>
</table>

**In-Patient (21)**, **Out-Patient (22)**, **ASC (24)**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medicare CF 34.01</th>
<th>125%</th>
<th>Medicare CF 42.5125</th>
<th>125%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysteroscopy with Myomectomy</td>
<td>$555.38</td>
<td>$694.23</td>
<td>$456.63</td>
<td></td>
</tr>
</tbody>
</table>

**Non-Facility/Office (11)**

- **In-Patient (21)**
  - Medicare CF 34.01: $0
  - 125%: $0
- **Out-Patient (22)**
  - Medicare CF 34.01: $0
  - 125%: $0
- **ASC (24)**
  - Medicare CF 34.01: $0
  - 125%: $0
Hysteroscopic Morcellators

Summary

More women will have the opportunity for uterine preserving surgery with the removal of Type 0 and 1 myomas with safer instruments, that require less surgical skill.

Removal of polyps is easier and faster.

Learning Objectives

- Describe intracavitary myomas using a classification system
- Explain the different types of hysteroscopic morcellators
- Employ techniques to reduce risk during removal of intracavitary myomas
- Enumerate the fundamental differences between traditional resectoscopy and mechanical morcellation for removal of intracavitary lesions
- List the potential challenges and advantages of performing hysteroscopic removal of intracavitary lesions in the office setting
COMPLICATIONS OF OFFICE HYSTEROSCOPY
Micah Harris M.D.
Women’s Health Research
Phoenix, AZ

Disclosure
Grants/Research Support: Halt Medical

Objectives
- At the conclusion of this presentation the participant will be able to:
  1. List the common potential complications encountered during or after office hysteroscopy.
  2. Identify the correct management of uterine perforation dependant upon location.
  3. List the risk factors for uterine perforation.
  5. Identify office hysteroscopic procedures that have a higher risk of complication.

Potential Complications of Hysteroscopy
- Related to Entry/ Dilation of the cervix: 50%
  - Creation of a False Passage
  - Cervical Laceration/Hemorrhage
  - Uterine Perforation
- Related to Distention Medium
  - Fluid Overload, Hyponatremia
  - Air/Gas Embolism
- Related to Procedure- Adhesiolysis

Complications of Office Surgery
- Vaso-vagal Reaction
- Local Anesthetic Toxicity
- Inadequate Analgesia/Anesthesia
- Airway Management
  - Excessive Sedation
  - Allergic Reaction
Perforation... Happens

Signs and Symptoms of Uterine Perforation
- Loss of cavitary distention
- Change in the patient’s level of pain
  - Shoulder pain
  - Sudden fluid deficit
- Abdominal distention
- Ultrasound may show accumulation of pelvic ascites/hemoperitoneum

Uterine Perforation
- Incidence less than 1%, yet 50% of all hysteroscopic complications
- May result in:
  - Local bleeding
  - Visceral injury
  - Inability to complete the procedure
  - Laparoscopy/laparotomy
- Actual incidence may be higher than expected

Incidence of Uterine Perforation
- 6,408 women underwent first trimester abortions, 706 with concurrent laparoscopic tubal
  - 1.3/1000 rate of perforation
  - Although 2 perforations were suspected and confirmed with laparoscopy, twelve (15.6/1000) were unsuspected and only detected at laparoscopic sterilization following the termination.
  - Seven-fold difference between suspected vs. incidentally noted.

Management of Uterine Perforation
- Fundal
  - Without RF energy- Discontinue and observe
  - Laparoscopy to inspect for visceral injury
- Lateral
  - Ultrasound or laparoscopy to inspect for broad ligament hematoma
- Anterior
  - Assess for hematuria, consider cystoscopy
- Posterior
  - As with Fundal, depending on whether RF used.

Risk Factors for Uterine Perforation
- Nulliparity
- Menopause
- Use of GnRH agonists
- Cervical stenosis (Prior conization)
- Marked Retroversion
**Cervical Dilation 101 (Revisited)**
- Most office procedures involve small diameter scopes, and therefore little dilation is necessary.
- Over-dilation results in inadequate distention of the uterine cavity.
- The use of cervical dilators can result in potentially undetected uterine perforation.

**Cervical Dilation**
- Consider using the hysteroscope as the dilator.
  - Directly visualize the passage
  - Avoid creating a False Passage
  - Recognize perforation
  - Dilate only as much as necessary

**Cervical Ripening?**
- Misoprostil 400 mcg vaginally 6-12 hours pre-procedure
- Reduces the force necessary for dilation
- Reduces pain scores associated with dilation
- Concern for over-dilation


**Vasopressin**
- In dilute solutions (0.05-0.2 U/cc NS) promotes cervical dilation and myometrial hemostasis, as well as decreases fluid medium absorption.
- Toxicity is cardiac/vascular (Hypertensive Crisis, Arrhythmia)
- Cardiac effects may be treated with Nitroglycerin


**Type of Procedure and Risk of Complication**
- Prospective study of 13,600 subjects
  - Adhesiolysis 4.48%
  - Endometrial Resection 0.81%
  - Myomectomy 0.75%
  - Polypectomy 0.38%


**A word about tubal perforation...**
**Tubal Perforation**
- Rarely suspected at the time
- Associated with a sudden “give” in pressure during placement
- Associated with an abnormal deployment of the microinsert coil
- No reported acute complication such as hemorrhage
- Chronic problems include pain, lack of efficacy
- Connor VF Essure: A Review Six Years Later. JIMG 2009; 16 282-90

**Hemorrhage**
- Cervical/Vaginal
  - Inspect, suture as necessary.
  - Prevent cervical laceration with “solid” first tenaculum application
- Myometrial
  - Intrauterine balloon- carries some risk of uterine rupture if overinflated.
  - Remember Bimanual Compression- it works!!

**Distention Media- Gaseous**
- Carbon Dioxide- Primarily used for Diagnostic Procedures.
  - Visualization obscured by bleeding
  - Actually more water-soluable than Nitrogen-containing room air
  - The “Lethal Dose” of Room Air is 5X less than that of CO2
- Groenman FA et al, Embolism of Air and Gas in Hysteroscopic Procedures, JIMG 2008; 15 241-247

**Air Embolism**
- Signs and Symptoms: Related to bubbles creating disturbances in gas exchange or most severely, an Air-Lock in the Right Heart.
- Decreasing Oxygen Saturation
- Hypotension due to decreased venous return
- Decreased End-Tidal CO2

**Air or Gas Embolism: Risk Factors**
- Gaseous Distention Pressures > 100mmHg
- Trendelenburg Position
- More frequent insertions of the hysteroscope
- Procedures injuring myometrial vessels
  - Adhesiolyisis
  - Myometrial Resection

**Treatment of Air Embolus**
- Up to 50% Mortality
- Recognize Pulmonary symptoms early
- Administer 100% Oxygen
- Reverse Trendelenberg, Left Decubitus (Durant Manuever)
- Cardiovascular Resuscitation/ Support
Fluid Distention Media

- Non-ionic media
  - Glycine 1.5%
  - Sorbitol/Mannitol 3%/0.54%
  - Mannitol 5%

- Ionic Media
  - Normal Saline

Hysteroscopic Fluid Management

AAGL Guidelines 2000

- Deficit >750cc, electrolyte poor solution
  - Plan to terminate the procedure

- Deficit >1000cc electrolyte poor, >2500cc ionic
  - Terminate the procedure
  - Assess serum sodium
  - Lasix 10 mg IV

Ad Hoc Committee on Hysteroscopic Fluid Management. JAGL 2000 7(2) 167-168.

Other Complications

- Anesthetic Toxicity- Be aware of toxic doses of injectable anesthetics- Lidocaine, Marcaine
- Vasovagal reactions- Identify, support, administer Atropine 0.4-0.6mg SC/IM/IV
- HAVE A FULLY STOCKED CRASH-CART, AND STAFF WHO UNDERSTANDS HOW TO USE IT.

Delayed Complications

- Infectious- 0.01-1.4%
  - ACOG guidelines do not support prophylactic antibiotics for hysteroscopic surgery in the absence of a history of PID
  - Treat symptoms of pelvic pain, malodororous discharge, fever with extended spectrum penicillin or cephalosporin
  - Ultrasound if on pelvic exam an mass is felt

- Hematometrium 1-2%
  - Chronic or cyclic pain
  - Drainage with or without ultrasound guidance

In Summary

- Complications are fortunately rare (0.3%)
- Half are entry related, e.g. perforation
  - Avoid with entry under visualisation
  - Cervical ripening can be helpful
- Air embolism is more common than CO2 embolism
- Overabsorption of fluid media is preventable and easily treated.
- Know the contents of your crash cart and have knowledgable support staff.
Prevent complications and sleep at night!

References


Equipment Maintenance: The Rigid and Flexible Hysteroscope

Eileen Young, RN, BSN, CNOR

- Identify safe handling techniques for hysteroscopes.
- Describe proper reprocessing steps for hysteroscopes.

Advantages of Hysteroscope Types

- Rigid with rod lens optics
  - Clearest visualization
  - Easiest to insert
- Semi-rigid with fiberoptic/digital image
  - Large working channel and no additional telescopes
- Flexible
  - Patient comfort and no additional components

Rigid Hysteroscopes

- Telescope
  - 12 and/or 30°
- Sheath
  - Standard, intermittent flow (usually smaller diameter)
  - Continuous flow (may have inner and outer sheaths)
- Obturator
  - Visual, used for atraumatic insertion
- Bridge / Adaptor
  - Used with a seal to insert accessory devices
  - Biopsy forceps
  - Tubal sterilization

Sheaths

- Size dependent on patient anatomy and desired channel
- Continuous flow sheaths will likely provide better visualization
  - Small cavity size
  - Bleeding can obscure vision
  - Inflow and outflow pathways NOT interchangeable
Telescopes

- Angle of view
  - 30° wide angle provides best visualization of cavity and cornua
  - 12° is more direct, better for use with resection devices
- Lens is always opposite light post
- Field of view – amount of area seen through lens
- Characteristics
  - Most fragile and expensive component
  - Damaged telescope = no hysteroscope
  - Handle with eyepiece, protect lens

Semi-Rigid Hysteroscopes

- Hybrid device
  - Fiberoptic or digital image
  - May have a deflecting tip
  - Housed in a metal shaft
  - May be easier to insert / handle than flexible

Flexible Hysteroscopes

- Diagnostic
- Intermittent flow only
  - Accessory channel is same as irrigation channel
- Less discomfort for patient
- Require practice inserting and manipulating
- Repairs can be expensive

Buying Guide

- Determine patient population
  - Infertility and/or post-menopausal women – small diameter
  - Abnormal uterine bleeding – continuous flow
  - Patient comfort – flexible
  - Transcervical sterilization – channel size

Decontamination Supplies

- Enzymatic detergent
- Soft cloth, gauze and applicators
- Protective attire
- Syringes
- Leak tester for flexible and semi-rigid scopes
- Alcohol to clean glass surfaces

Decontamination Process

- Wipe and flush immediately after procedure
- Clean as soon as possible with properly mixed enzymatic detergent
- Flush and/or brush all lumens
- Dry exterior surface and push air through channel
- High-level disinfect or sterilize
  - If using a steam sterilizer, may wrap devices to maintain sterility
  - High-level disinfectants must be thoroughly rinsed and dried prior to storage or use
High-level Disinfection
- Considered semi-critical devices (not entering sterile cavity or bloodstream, moderate risk of infection)
- Minimum preparation is HLD, but can sterilize
- Glutaraldehyde-based HLD are most common
- OPA may be alternative
- Exposure time and temperature, rinsing
- Safety considerations
  - Venting
  - Gloves
  - Monitoring concentration

Sterilization
- Steam
  - High temperature and vacuum may not be compatible with device
  - Follow OEM recommendations for cycle type, time and temperature

Conclusion
- Hysteroscopes are an investment in your practice
- Require careful handling
- Require specific reprocessing
- Office procedures can enhance your practice
- Repairs can be minimized with proper care and handling

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.