4th Annual
Texas Two Step Conference: Medicolegal Issues in Ob/Gyn

Friday and Saturday, February 28 – March 1, 2014
This activity is approved for 15.25 AMA PRA Category 1 Credits™
AGENDA • FRIDAY, FEBRUARY 28, 2014

* Please note that updates have been made to Friday's agenda

7:50 – 8 A.M. Welcome and Introductions
Sean Blackwell, M.D.

8 – 8:45 a.m. Preventable Adverse Outcomes Related to Maternal Hypertensive Disease
Baha Sibai, M.D.

8:45 – 9:30 a.m. How to Avoid Surgical Complications in Vaginal Surgery
Mickey Karram, M.D.

9:30 – 10 a.m. Understanding the Value of Nonverbal Communication During Crucial Conversations:
Keys to Presenting Difficult Information in a Positive Manner
Jan Hargrave

10 – 10:15 a.m. BREAK

10:15 – 11 a.m. Risk Management: A Primer of Issues for OB/GYNs
Aashish Shah, M.D., J.D.

11 – 11:45 a.m. Preventable Maternal and Fetal Complications Related to Operative and Routine
Vaginal Delivery
Alfredo Gei, M.D.

11:45 – 12:30 p.m. Most Common Medical Errors in Infertility
Mazen Abdallah, M.D.

12:30 – 1:15 p.m. LUNCH

1:15 – 2:30 p.m. Medicolegal Issues Related to Vaginal Mesh
Mickey Karram, M.D.

2:30 – 3:15 p.m. The Role of Hospitalists in Labor and Delivery in Reducing Medicolegal Liability
John Barton, M.D.

3:15 – 3:30 p.m. BREAK

3:30 – 4:15 p.m. Medicolegal Issues in Ultrasound and Prenatal Diagnosis
Anthony Johnson, D.O.

4:15 – 5 p.m. What Would You Do? GYN Case Studies
Allan Katz, M.D.

5 p.m. CONCLUSION
Course Description

Obstetrics and Gynecology is one of the highest at-risk specialties for legal litigation, as there remains a high acuity and case complexity rate for women (pregnant and non-pregnant). Although rates are improving, there remain multiple areas of opportunity to reduce the frequency of near misses and medical errors, therefore preventing unnecessary harm.

The two-day conference will include experts in Obstetrics and Gynecology providing current perspectives, guidelines and best practices for significant healthcare liability concerns in OB/GYN.

Target Audience

Physicians, nurses and other healthcare providers, as well as lawyer, risk managers and paralegals interested in medical malpractice in OB/GYN.

Continuing Education Hours for Nurses

Memorial Hermann-Texas Medical Center is an approved provider for continuing nursing education by the Texas Nurses Association, an accredited approved by the American Nurses Credentialing Center Commission on Accreditation.

This activity is approved for 15 total contact hours.

Continuing Education Hours for Physicians

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Texas Medical Association (TMA) through the joint sponsorship of Memorial Hermann Health System and the University of Texas Health Science Center at Houston. Memorial Hermann Health System is accredited by TMA to provide continuing medical education for physicians.

Memorial Hermann Health System designates this live activity for a maximum of 15.25 AMA PRA Category 1 Credits™. Participants should only claim credit commensurate with the extent of their participation in the activity.
Preventable Adverse Outcomes Related to Maternal Hypertensive Disease

Baha Sibai, M.D.
Preventable Adverse Outcomes Related to Maternal Hypertensive Disease

Baha M. Sibai, M.D.

Professor, MFM Division
Principal Investigator, Eunice Kennedy Shriver NICHD Maternal-Fetal Medicine Network
Director, Maternal-Fetal Medicine Fellowship Program

Diganosis of GHTN-Preeclampsia

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>GHTN</th>
<th>Preeclampsia</th>
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<tbody>
<tr>
<td>HTN &gt; 20 wks</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Previously normotensive</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>SBP: 140-159 mmHg</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>DBP: 90-109 mmHg</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Persistent for 4 hrs</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Presence of sx's</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Normal blood tests</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Proteinuria: ≥ 300mg/24h</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>P: C ratio ≥ 0.3</td>
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<td>Dip stick : ≥ 1+</td>
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Preeclampsia with Severe Features
preeclampsia plus any one of the following

- SBP > 160 or DBP > 110 mmHg
  - Two BP values 4 hrs apart while on bed rest
  - Once if anti-hypertensives are used
- Persistent Cerebral / Visual disturbances
- Pulmonary edema
- Severe persistent RUQ/epigastric pain unresponsive to RX
- Low platelets <100,000
- Elevated liver enzymes (>2x normal)
- Serum creatinine >1.1 mg/dl

Preeclampsia is a dynamic disorder

- Different clinical presentation
  - Maternal syndrome alone
  - Fetal syndrome alone
  - Both maternal & fetal
- Gestational age at onset (wk)
  - < 24
  - 24-27
  - 28-33
  - > 34 or > 37
- Onset in relation to delivery
  - Before labor
  - Intrapartum
  - Postpartum (< 48 & ≥ 48 h)

Maternal Manifestations
Symptoms suggestive of Severe HTN-preeclampsia

**Headaches**
- Occipital
- Frontal
- Temporal

**Visual Changes**
- Blurred vision
- Retinal ischemia
- Occipital edema

**Respiratory**
- Chest tightness
- SOB
- Orthopnea
- Dyspnea
- Tachypnea

**Liver Changes**
- Hepatic
- RUQ pain
- Back pain
- Heart burn
- Shoulder/neck pain
- Retrosternal burning

**Hematologic**
- Bleeding from gums
- Ecchymosis
- Petechiae
- Hematuria
- Vaginal

HELLP Syndrome?

- LP
- HEL
- EL
- ELLP

HELLP Syndrome?

- HTN
- ECLAMPSIA
- STROKE

- Heart failure
- Pulm. edema
- HELLP
- Liver Hemorrhage
- Abruptio
Acute Onset Maternal Syndrome

- 34 year old G3P2
- Same partner
- Active labor at 39 wks
  - Elevated BP, (-) protein, epigastric pain
- Vaginal delivery
- Postpartum BTL
  - Severe RUQ pain & N/V
  - Acute hypotension
  - HELLP + DIC
  - Liver hematoma
Hypertension in Pregnancy

- Incidence 2-5%
- Antepartum onset
  - CHTN, cardiac or renal disease
- Postpartum onset
  - Preeclampsia
  - Severe GHTN
- Association with organ dysfunction
  - HELLP/DIC
  - Renal dysfunction
  - Aspiration, sepsis

Pathophysiology of Pulmonary Edema

- Abnormal pump (heart)
- Increased after load: Severe HTN
- Increased preload: Excessive fluid
  - Prehydration for epidural
  - Fluid bolus for decreased urine
  - IV fluids in labor, delivery, PP
  - Fluid mobilization after delivery
- Capillary leak: low COP

Pathophysiology of Pulmonary Edema

- Abnormal pump: Heart
  - Systolic or diastolic dysfunction
- Increased after load
  - Severe HTN
- Increased preload
  - Fluids for epidural
  - Fluids in labor
  - Postpartum mobilization
- Capillary leak
  - Low COP
  - Endothelial damage
Hypertensive Left Ventricular Failure

- Control BP: decreases work load
- Sodium nitroprusside drug of choice
  - Reduces preload: venous return
  - Reduces afterload: impedance to ejection
- Furosemide 40-80 mg IV
  - Reduces preload
- Nitroglycerine IV: venodilator
Abruptio Placentae

Maternal & Fetal Syndrome
- 36 year old G1 with infertility
- Pregnancy after IVF
- Mild GHT, (-) Protein, normal UA at 25 wk
- Severe HTN, Sxs at 26 wk
- HELLP syndrome with bleeding
- ICH with hemiplegia
- C/S → 560 g, FGR infant
- Mother & infant survive
  - No residual deficit
Acute Onset of Eclampsia at term

- 19 yr G1, normal PNC up to 38 wks
- Mild GHTN, no proteinuria, normal UA
- No instructions about SXS, RTC in 1 wk
- Headaches, visual changes x 2 d
- Convulsions, HTN, proteinuria at 39 wk
- Massive cerebral edema, coma x 3 d
- DIC, ARF, Liver failure, Pulmonary edema
- ICP monitor, mannitol, Lasix, MgSO4
- ICU management, full recovery in 1 week

Steps in Managing an Eclamptic Seizure

Step 1: Prevent hypoxia: Support maternal respiratory & cardiovascular functions
Step 2: Prevent maternal injury / aspiration
Step 3: Do not try to arrest the first seizure
Treatment of seizures: Basic Principles

- Most seizures are self-limited
  - Do not give anticonvulsants: Mgso4, valium, phenytoin
- Prevent maternal injury
  - Protect from fall off bed
  - Protect airway
  - Cushion extremities
  - Suction oral secretions

Management of Hypoxemia

- Suction secretions
- Check for aspiration/pulm. edema
- Supplemental O2 by face mask
  - 8-10 L/min
- Monitor with pulse oximetry
- Obtain arterial blood gases
- Sodium bicarbonate if severe acidemia

Steps in Managing an Eclamptic Seizure

- Step 1: Prevent hypoxia: Support maternal respiratory cardiovascular functions
- Step 2: Prevent maternal injury & aspiration
- Step 3: Do not try to arrest the first seizure
- Step 4: Prevent convulsions from recurring (chiefly with magnesium sulfate)
Prevention of recurrent Convulsions

- **Magnesium sulfate**
  - Loading dose: 6 g IV over 20 min
  - Maintenance: 2 g IV per hour
- **If convulsions persist**
  - 2 g dose of magnesium sulfate
  - Ativan IV
  - Intubation if recurrent seizures

Steps in Managing an Eclamptic Seizure

- **Step 5**: Control severe hypertension to prevent cerebrovascular injury
- **Step 6**: Manage complications: DIC, pulmonary edema, aspiration, stroke
- **Step 7**: Begin induction/delivery within 24h

Control of Severe Hypertension

**SBP > 160 or DBP >110 mmHg after 15-60 min**

- **IV bolus hydralazine**
  - Initial dose of 5 mg
  - 10 mg, 10 mg at 20-30 min later
- **IV labetalol**
  - Initial dose of 20 mg
  - 40, 80, 80 mg every 10 min
  - Continuous IV infusion
- **Oral nifedipine**
  - 10, 20, 20 mg every 20 min
Anesthesia / mode of delivery in eclampsia

- Induction if indicated
  - Fetal presentation/status
  - Gestational age
  - Cervical Bishop score
- Continuous FHR monitoring
- Epidural/spinal
- Delivery within 24 hrs
  - Vaginal delivery
  - C/S if indicated

Fetal Manifestations in Preeclampsia

- Vascular
- Stillbirth
- FGR
- Abruption
- Abnormal UA
  - Doppler
- Oligohydramnios
- Oligohydramnios

Abruption

Abnormal UA

Doppler

Oligohydramnios
Syndrome of Postpartum Hypertension - Preeclampsia

Persistence of Preexisting HTN
Denovo HTN
Secondary HTN

- GHTN
- Preeclampsia
- Hypertension
- Renal disease
- Medications
- Hyperthyroidism
- Adrenal tumors
- TTP/HUS/SLE
- CVT/Stroke
- Cerebral angioptathy
- HELLP

Onset of HELLP in Relation to Delivery (n=700)

- ≤ 2 days (80%)
- 3-6 days (20%)

70% Antepartum, 6% Developed denovo, 24% Preecl before delivery

10 days Postpartum eclampsia
PRES
Postpartum HTN-Preeclampsia

All women with hypertensive disorders
- BP check at 3 days (hospital, office or home)
- BP again at 5-7 days
- educate for daily Sxs of preeclampsia
- No nonsteroidal anti-inflammatory agents

All women
- Education about signs / symptoms
- Sxs. to report
- Office and L&D phone #

Pitfalls in DX/Rx of HDP
Sibai's Pearls to remember

- Proteinuria
- Elevated UA
- Hypertension
- WL. gain is more important than total gain
- Preeclampsia
- HELLP
- Anytime in pregnancy up to 6 wks PP
- Headaches/visual changes to migraine/sinusitis
- Abd. pain to Gall bladder, appendicitis, Pyelonephritis

- vitals signs, Sxs, I-D, CBC, LFT, Cr only
- DIC tests only if abnormal LFT, Plat., or abruptio
Pitfalls in DX / Rx of HDP
Sibai’s Pearls to remember

Steroids for FLM result in:
- Transient changes in:
  - AST/ALT
  - platelets
  - Rebound deterioration in 2-4 days

No repeat treatment for:
- Headaches (oral or IV narcotics)
- Epigastric/RUQ pain
- Nausea/vomiting (Zofran, phenergan)
- Heart burn (oral maalox, lidocaine)
- Retrosternal chest pain (IV pepcid, narcotics)
- Reduced urine output (IV lasix, fluid boluses)

Consider pulmonary edema:
- Tachycardia
- Tachypnea
- Dyspnea
- Shortness of breath
- Low O2 saturation

The End
How to Avoid Surgical Complications in Vaginal Surgery

Mickey Karram, M.D.
HOW TO AVOID SURGICAL COMPLICATIONS DURING VAGINAL SURGERY

Mickey Karram, M.D.
Director of Urogynecology
The Christ Hospital
Professor of Ob/Gyn
University of Cincinnati

Financial Disclosures

- Consultant & Speakers Bureau
  AMS, Medtronic, Astellas, Ethicon

Objectives

- Review how best to position patients and avoid nerve injury during vaginal surgery
- Discuss techniques to avoid lower urinary tract injury and avoid complications of midurethral slings
- Discuss how to avoid complications during vaginal hysterectomy
- Review how best to avoid complications during prolapse repairs
- Discuss how best to avoid vaginal constriction and iatrogenic dyspareunia
Avoiding Nerve Injury During Vaginal surgery

- Appropriate positioning of patient
- Anatomic understanding of NERVES at RISK; including Ilioinguinal Nerve; Obturator Neurovascular Bundle; & Pudendal Nerve

Proper Positioning for Vaginal Surgery

- Buttocks should be at edge of table
- Slight extension and lateral rotation of thigh
- Avoid compression of lateral knee
- Type of stirrups
CURRENTLY AVAILABLE SYNTHETIC SLINGS

- RETROPUBIC: below to above vs above to below
- PREPUBIC
- TRANSOBТURATOR: outside in vs inside out
- MINI-SLING: urogenital diaphragm vs obturator internus
- HOMEMADE SYNTHETIC SLINGS
Intraoperative Complications

- Bleeding
- Injury to Bladder
- Injury to Urethra
- Injury to Nerves
- Injury to Bowel

ANATOMY OF THE ANTERIOR VAGINAL WALL

- Relationship of anterior vagina to posterior urethra
- Distinguishing mid from distal urethra
- Understanding lateral attachments of urethra and bladder
ANATOMY OF RETROPUBIC SPACE

- Anatomy of Bladder and Urethra
- Vascular Anatomy
- Potential for Bowel Injury
- Anatomy of Anterior Vaginal Wall

Synthetic Sling Placement

- Use of Hydrodistention
- Plane of Dissection between Posterior Urethra and Anterior Vaginal Wall
- Incision should be of sufficient size
- Utilize catheter guide for retropubic slings
- Utilize anatomic landmarks
Ischiopubic Ramus
Pubic symphysis
Obturator Canal
Obturator Foramen
Ilium
Ischium

Mesh Position
Transobturator Landmarks

Adductor longus

Urethra

Obturator canal

SAFE ENTRY ZONE of NEEDLE
Minimize Risk of Bladder Entry During TVH
NO!

GOAL OF RECONSTRUCTIVE PELVIC SURGERY

1. Restore Anatomy Correction vs. Overcorrection
2. Restore Or Maintain Functional Or Visceral Dysfunction
3. Restore Or Maintain Sexual Dysfunction
Specific Surgical Goals: Maintain or Create a Well Supported Functional Vagina

- What is normal vaginal length?
- What is normal vaginal caliber?
- What is normal relationship between perineum? and posterior vaginal wall?
- What is normal vaginal axis?
- What is the most important aspect of your repair?
- How do you determine who needs an augmented repair?

Anterior and Posterior Vaginal Wall Prolapse

- Extent of Dissection for Cystocele Repair (lateral to inferior pubic ramus and dissection of bladder base off of vaginal cuff)
- Extent of Dissection for Rectocele Repair (lateral to rectal gutter and proximally to preperitoneal space of cul-de-sac)
Anatomy of Sacrospinous & Uterosacral ligament

Intraperitoneal & Extraperitoneal Approaches to Apical Prolapse
Vaginal Estrogen Preparations

- Estradiol (Estrace Cream) .1 mg/gm
- Premarin Cream .625mg/gm
- Estropipate (Ogen) 1.5 mg/gm
- Estradiol Vaginal tablets (vagifem) 25 ug
- Estradiol vaginal ring (Estring) 2mg
Causes of Dysparaunia or Aparaunia after Pelvic Floor Surgery

- Vagina to tight
- Vagina to short
- Painful vagina
- Foreign body in vagina

Techniques to Prevent Vaginal Constriction

- Intra-operative assessment of vaginal length and caliber
- Vaginal exam in the first two weeks post-op
- Early initiation of local estrogen
- Aggressive use of vaginal dilators

PERINEAL PAIN AND DYSPAREUNIA

- INFECTION
- HEMATOMA
- SCAR TISSUE
- PERINEAL "SKIN BRIDGE"
- SEVERE ATROPHY
Perineal Surgery for a Tight Introitus

- REVERSE PERINEOPLASTY WITH VAGINAL ADVANCEMENT
- TAKEDOWN OF PERINEAL SKIN WITH COMPLETE RECONSTRUCTION OF PERINEAL BODY

Treatment of Symptomatic Posterior Ridges and Scars

- Daily vaginal estrogen
- Daily use of vaginal dilators
- Surgical incision of the vaginal ridges, usually at four and eight o’clock
Baseline Rate of Dyspareunia

- About 60% of women with prolapse are sexually active, and one-third of them have sexual discomfort
- Dyspareunia can result from the prolapse, from the prolapse repair, or from concurrent atrophy
- The actual shape (caliber and depth) of the vagina correlates poorly with sexual satisfaction

Tips to Avoid Dyspareunia

- Optimize vaginal estrogenization both pre- and post-operatively
- Avoid aggressive narrowing of the vaginal tube
- Treat mesh and suture erosions promptly
- The most common sites of dyspareunia are scar ridges in the posterior mid-vagina and posterior fourchette
Conclusions

- Many new surgical techniques and instruments are constantly introduced to the vaginal surgeon
- Some are promising, others not
- Need for long term data on cure and complications
- Proper patient selection and adherence to strict surgical principles is still the key
- Perform procedure that works best in your hands and follow your patients carefully
Understanding the Value of Nonverbal Communication during Crucial Conversations: Keys to Presenting Difficult Information in a Positive Manner

Jan Hargrave
Understanding Nonverbal Communication
Jan Hargrave

Shaking Hands
- A firm handshake indicates confidence.
- A limp handshake indicates a person who is ill at ease.
- Downward facing palms indicate control; upward facing palms show submissiveness.
- A double clasp (using both hands) indicates sincere feelings for another.

Defensiveness
- Arms crossed on chest, scowl on face; also a sign of disagreement
- Closed fists; also a sign of nervousness
- Sitting with a leg over the arm of a chair; also a sign of indifference
- Crossed legs; moving of the crossed leg in a slight kicking motion signifies boredom or impatience

Openness
- Open hands with palms facing upward
- A man, who is open or friendly and feels agreement is near will unbutton his coat and then take it off.
- Arms and legs not crossed

Evaluation
- Hand-to-cheek gestures; an interested person will lean his body forward and slightly tilt his head.
- A critical evaluation is given when the hand is brought to the face, the chin is in the palm, the index finger is extended along the cheek, and the remaining fingers are positioned below the mouth.
- A head tilt is a definite sign of interest.
- Back and forth stroking of the chin signals a person who is deep in thought or seriously evaluating a situation.
- Direct eye contact indicates interest and a positive awareness of the speaker.

Suspicion and Secretiveness
- Left-hand gestures are typically associated with dishonesty.
- A person who avoids eye contact while speaking is likely concealing information.
- Touching or rubbing the nose, usually with the left index finger, is a sign of doubt or non-truth on the part of the speaker.
- Rubbing behind or beside the left ear with the left index finger when weighing an answer, indicates doubt.
- Tugging at the left eye with the left index finger says, “Do not see very clearly what I’m saying, because I’m lying to you.”
- Fake cough or yawn; increased swallowing, increased face touching, mouth shrugs; all indicate unpleasant truths.
- Watch for an increase in emblems (gestures used in place of words); a decrease in illustrators (gestures used to illustrate speech) and an increase in manipulators (unnecessary gestures).

Honesty/Trustworthiness
- Right hand over heart
- Palms-up gestures, uncrossed arms
- Direct eye contact
- Anchoring gestures
- Feet flat on floor or pointed toward target

Frustration
- Short breaths; a person who is angry will take short breaths and expel air through his nostrils
- “Tsk”; the sound usually made to communicate disgust
- Tightly clenched hands
- Wringing of the hands
- Kicking the ground or an imaginary object while walking

Confidence
- Steepling (hands or arms brought together to seemingly form a church steeple)
- Hands joined together at waist behind back
- Feet placed up on desk
- Erect posture, direct eye contact, genuine smile, no self touching
Boredom
- Drumming on table
- Tapping with feet
- Head in hand
- Doodling

Nervousness
- Clearing throat
- “Whew” sound
- Whistling
- Smoking cigarettes
- Fidgeting in a chair
- Tugging at pants while sitting
- Jingling money in pockets
- Tugging at ear
- Clenching fists
- Wringing of the hands
- Playing with pencils, notebooks, or placing eyeglasses in mouth
- Frequent self touching while speaking
- Avoiding eye contact or looking down
- Rocking, slouching, twisting hair

Become a Skillful Communicator
- Perfect your handshake; always extend your hand first.
- Provide nonverbal feedback (nod, smile, mirror, vary vocal pitch) based on your meeting partner's preferred learning style (visual, auditory, or action).
- Redirect questions if your meeting partner signals doubt—ask open questions, restate definites, and continue to display positive, supportive gestures.
- Create clear symmetry in your face and body; shoulders straight, weight balanced equally on both feet, arms to the sides.
- Use gestures to punctuate specific points; try to keep hands within an imaginary box that stretches from hipline to chin and shoulder to shoulder.

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Risk Management: A Primer of Issues for Ob/Gyns

Aashish Shah, M.D., J.D.
Objectives

- Understand what is risk
- Discuss how risk and quality are related
- List the common causes of OB/GYN liability
- Describe strategies to prevent and/or reduce OB/GYN risk

What is Risk?

- Essentially a “bad outcome”
- Traditional notions of risk are rooted in legal liability

   **HOWEVER**

- Risk is really two-fold
  - Quality of Care (licensure, privileging, credentialing, and reimbursement)
  - Medical Malpractice (legal liability)
Risk: Quality

- The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

- Six aims
  1. Safe
  2. Effective
  3. Patient-centered
  4. Timely
  5. Efficient
  6. Equitable

Risk: Medical Malpractice

- Medical malpractice is professional negligence.
- Act or omission by a health care provider in which care provided deviates from accepted standards of practice in the medical community and causes injury or death to the patient.
  - Duty
  - Breach
  - Causation
  - Damages

Risk: Outcomes

Bad outcomes are based on bad processes.
Risk: Outcomes

Outcomes on a continuum that include:
- Malpractice
- Standard of Care
- Compliance
- Clinical Outcomes
- Reimbursement
  - Pay for Performance
  - Justifying Cost
- Reporting
  - Joint Commission
  - State and Federal
  - Health Plan

Medical Malpractice: Top Causes

1. Failure to Obtain Informed Consent
2. Failure to Diagnose, Delay in Diagnosis or Misdiagnosis
3. Medical and Surgical Errors
4. Wrong Diagnosis and Negligent Misdiagnosis of Fracture or Trauma
5. Failure to Consult in a Timely Manner
6. Maintaining Illegible or Incomplete Documentation
7. Birth Injury Malpractice or Negligent Maternity Care Practice
8. Failure to Communicate Adequately

ACOG Professional Liability Survey

- 2/3 Obstetric (63.2%)
  - Neurologically impaired infant claims (28.8%)
  - Stillbirth or neonatal death (14.4%)
- 1/3 Gynecologic (36.8%)
  - “Patient injury major” (29.1%)
  - “Delay in or failure to diagnose” (22.1%)
  - Cancer diagnosis (41.8%)
    - Breast
    - Uterine
    - Ovarian
    - Cervical
  - “Patient injury minor” (20.7%)
Informed Consent

Informed Consent: Overview

- Physician must first obtain the consent of the patient before treating or operating on the patient
  - Gravois v. Physicians and Surgeons Hospital of Alice, 427 S.W.2d 310 (Tex. 1968).
- Physician has a duty to make a reasonable disclosure to the patient of the risks incident to the treatment
- Patient's right to receive information must be adequate to exercise an informed decision to accept or refuse the treatment

Informed Consent: General Requirements

- A physician must obtain express or implied permission prior to performing a medical treatment or surgical procedure after advising the patient of the inherent risks
  - The procedure (and any additional procedures) to be performed
  - Risks associated with the procedure(s)
  - Benefits
  - Alternatives
  - Consequences
- Express consent when assent orally or in writing
Informed Consent: General Requirements

- Consent may be implied in certain circumstances
  - Unconscious and life threatening illness/injury
  - Court ordered
  - Minor suffering from life-threatening illness/injury
- Special requirements for: minors; incapacitated adults; committed mentally retarded or ill

Informed Consent: Statutory Requirements

- Standard
  - In Texas, the statute governing medical liability mandates that the risks that must be disclosed are those risks that would influence a reasonable person
  - Objective standard
- Texas Medical Disclosure Panel
  - Creates two lists
    - List A: procedures and treatments for which informed consent must be obtained and specified risks that must be disclosed
    - List B: those treatments and procedures for which no particular disclosure is required
- Statutory Consent Forms

Informed Consent

- Statutory Form of Consent
  a. In writing
  b. Signed by the patient or person authorized to give consent
  c. Signed by a competent witness
  d. Written consent specifically states risks and hazards to the degree required
- Effect of Consent
  - Consent creates rebuttable presumption that physician was not negligent
  - Failure to disclose required risks and hazards creates rebuttable presumption that physician or health care provider was negligent
Informed Consent

- Medicare Conditions of Participation require properly executed informed consent form in the patient’s chart before surgery
  - 42 CFR § 482.51(b)(2)
- Similar requirements to that of Texas
- Responsible practitioner must disclose information necessary for patient to evaluate proposed medical or surgical procedure
- Informed consent means that the patient or representative is given the information in a language or means of communication understandable

Informed Consent

- The duty for obtaining consent for those procedures addressed by the Texas Medical Disclosure Panel is on the physician or the health care provider
- Referring physician has no duty but an assisting surgeon or anesthesiologist may have additional burdens
- No such duty is imposed on a hospital
  - Boney v. Mother Frances Hosp., 880 S.W.2d 140 (Tex. App.—Tyler 1994, writ denied).

Informed Consent

- Circumstances when consent may be implied or not necessary
  - Emergency treatment
  - Texas Health & Safety Code § 773.008
  - Breath or blood specimens for the presence of alcohol and/or controlled substances
  - General prohibition from taking samples if a person refuses
  - Specific instances notwithstanding refusal
  - Unconscious person deemed not to have withdrawn consent
  - Examination of minor for child abuse or neglect
Informed Consent

- Negligence is the only theory on which recovery may be obtained (as opposed to assault and battery)
  - Risk complained of is an inherent and could influence a reasonable person
  - Provider failed to disclose the risk
  - Failure was negligent
  - Would not have consented if risks known
  - Proximate cause
  - Damages

Informed Consent: Language Barrier

- The hysterectomy and abortion consents must be in English and Spanish
- Keep the translation objective
- Use hospital translator services
- Avoid using family members
- Conversational language not the same as technical language

Medical Errors
Medical Errors

- Bad things happen to good physicians
- Medical negligence doesn’t mean that you are a bad doctor
- Most of time means a mistake was made in retrospect
- This is a difficult issue and is a balancing test between reasonable and unreasonable

Medical Errors

- The IOM’s seminal report, To Err is Human
- Concluded that medical errors responsible for as many as 98,000 deaths annually, at costs of up to $29 billion
- Quality initiatives ensued followed by public sector payment policies
- Payment policies codified into commercial payors
- Policies have now been established as standards of care

Medical Errors

- Two terms incorrectly used interchangeably
  - Adverse Event: Harm to a patient as a result of medical care.
  - Never Event: An Adverse Event that “should never occur in a health care setting.”
- Contrast with Hospital Acquired Condition
Medical Errors

- Surgical Events
- Product or Device Events
- Patient Protection Events
- Care Management Events
- Environmental Events
- Criminal Events

NQF Never Events

Hospital Acquired Conditions

- Foreign Object Retained After Surgery
- Air Embolism
- Blood Incompatibility
- Stage III & IV Decubitus Ulcer
- Falls and Trauma
- Manifestations of poor glycemic control
- Catheter Associated Urinary Tract Infection
- Vascular/Catheter Associated Infection
- Surgical Site Infection (Ortho/Obstetric)
- Deep Vein thrombosis/Pulmonary Embolism

Medical Errors

Payment Policy

Investigation

Quality of Care Concern

Action

Medical Errors

Medical Staff

Health Plan

Actions

Medical Board

Malpractice

4th Annual Texas Two-Step Conference
February 28 - March 1, 2014
Medical Errors

- Improved Quality Reduces All Cost
- RAND study in California examined safety data from hospitals from 2001 – 2005
- Researchers found a strong correlation between risky incidents and malpractice claims.
- When risky incidents increased so did the number of malpractice claims

A decrease in 10 adverse events yields 3.7 less malpractice claims per year

In increase in 10 adverse events yields 3.7 more malpractice claims per year

Nearly three fourths of the variation in annual malpractice claims can be accounted for by changes in patient safety outcomes

Documentation
While we often think about documentation from a litigation perspective, it is really a matter of lost revenue.

Good documentation is not about being defensive or perfunctory.

A good medical record is evidence of the clinical rationale for others.

Medical records governed by Board Rule 165.1

"Each licensed physician of the board shall maintain an adequate medical record for each patient that is complete, contemporaneous and legible."

"Adequate Medical Record"

- Plan of Care
- "Billing codes, including CPT and ICD-9-CM codes, reported on health insurance claim forms or billing statements should be supported by the documentation in the medical record."

Poor documentation alone does not generally create liability.

BUT

Poor documentation makes defense difficult.

AND

Poor documentation drives settlement.
Documentation

- Weak Medical Records are an invitation to litigation
- Complete, timely records afford a physician a strong defense

1. Write legibly
2. Sign or initial all chart entries
3. Use prenatal forms with adequate space for data
4. Document prenatal risk evaluation
5. Document informed consent discussions carefully
6. Document informed refusal discussions
7. Document significant phone conversations
8. Dispense drug education and document the details
9. Review and sign all lab, x-ray and consultant reports
10. Avoid criticism of other professional in the chart notes

Elective Interventions
Elective Interventions

- 2008 National Institute of Child Health and Human Development Working Group
- March 2009 Agency for Health Care Research and Quality released “Maternal and Neonatal Outcomes of Elective Induction of Labor”
  - Induction of labor rate increased from 9.5% to 22.1% from 1990 to 2004.
  - Overall rate of induction of labor is rising faster than the rate of pregnancy complications
- National guidelines from the ACOG have long discouraged elective deliveries before the 39th week of pregnancy

Elective Interventions

- It is estimated that nationwide, 10% of all deliveries are elective inductions
- Driven by both physician and patient preferences
- ACOG revised its 2003 guidelines for induction of labor. The ACOG Practice Bulletin, Number 107
  - Unceremoniously includes “psychosocial indications”

Elective Interventions

- Women’s Perceptions Regarding the Safety of Births at Various Gestational Ages
- 24% of women surveyed considered a baby of 34-36 weeks gestation full term
- “What is the earliest point in pregnancy that is safe to deliver?”
  - 51.7% chose 34-36 weeks
  - 40.7% chose 37-38 weeks
Elective Interventions

- State requires reporting: U1, U2, U3 modifiers
- Joint Commission and others require hospitals to report all elective deliveries and the gestational age to its public database
- Process improvement has helped reduce risk
  - Quality bundles used as metrics
  - Development of standardized criteria

Technology

- Disadvantages are primarily in two areas:
  1. Medical Malpractice Liability
  2. HIPAA
Technology: EFM

- Allows a doctor greater access to the information for which he is already liable.
- Has the primary benefit of increasing physician access when the demands of their practice require them to be outside the hospital.
- Increases the hospital’s ability to conform with the standard of care thereby increasing patient safety.
- With the technology available, active management of the strip is always available.
  - Active management – Doctor calls the and asks the nurse to confirm by physical exam what he is seeing on his PDA
  - Passive management – Nurse calls the doctor and ask them to confirm what the nurse is reading by accessing the fetal monitor via PDA

Technology: EFM

- By reading the fetal strip on a smartphone, the physician is no longer:
  1. Dependent on a nurse to read a difficult strip
  2. Handcuffed by poor communication
- The technology provides a secondary benefit by providing a defense to an allegation of failing to monitor the patient

Technology: EFM

- The only limitation is the physician’s knowledge of EFM terminology
- Cannot claim he was unaware
Technology: Email

- Emerging role in the provision of care to patients
- Generally doctors have resisted this technology
- Can create a fair amount of inefficiency and confusion
- Timely response is critical

Technology: Email

- Key features:
  1. Security and Confidentiality
  2. Receipt Confirmation
  3. Word Limitation
  4. Email Delivery

Communication
Communication

Three Broad Areas:
1. Physician and Patient and/or family
2. Physician and Consultants
3. Physician and Staff (peer review)

Communication: Patient

- Basic interpersonal skills are just as important as clinical skills
- Economic and time constraints make simple courtesies rare
- Remember: Office staff are extensions of you when it comes to communication

Communication: Patient

- Make eye contact
- Listen actively
- Avoid perceived inaccessibility
  - Long wait times
  - Unreturned phone calls
  - Inappropriate scheduling
  - Not spending time with patient’s family
Communication: Consultant

- Treating the patient by phone
- Do not let convenience override common sense
- Inappropriate reliance on the ED physician or resident
- Lack of communication between emergency physicians or residents and specialists such as radiologists
- Document advice given

Communication: Hospital Staff

- Medical staff bylaws have a provision known as the Disruptive Physician clause
- The term disruptive physician is general, vague, subjective (subject to broad application)
  - Political
  - Economic
  - Concern for Quality Care
  - Personality
  - Competence

Communication: Hospital Staff

- The “Disruptive Physician”
  - Repeated acts of uncontrolled anger yelling or other verbal abuse towards patients, visitors, hospital personnel, other physicians
  - Any one act of physical abuse toward any person
- The American Medical Association, in its Code of Medical Ethics, states that “personal conduct, whether verbal or physical, that negatively affects or that potentially may negatively affect patient care constitutes disruptive (physician) behavior.”
Communication: Hospital Staff

- 95.7% physician executives reported regularly encountering disruptive physician behavior
- 70.3% said disruptive behaviors nearly always involved the same physician(s)
- Inability to get along with others is a cause for deteriorating patient care
- Disruptive physicians undermine morale, diminish productivity and quality of patient care, and cause work environment distress
- Leads to heightened employee turnover

Conclusion

1. Perception is reality
2. Risk is no longer about malpractice
3. Reducing risk generates revenue

RISK MANAGEMENT: A PRIMER OF ISSUES FOR OBGYN'S

Aashish Khan Shah, M.D., J.D.
Vice President & Medical Director
Community Health Choice, Inc.
Preventable Maternal and Fetal Complications Related to Operative and Routine Vaginal Delivery

Alfredo Gei, M.D.
Medico-legal Aspects of Operative Vaginal Deliveries

Alfredo F. Gei MD
Associate Professor, Division of Maternal-Fetal Medicine
UTHHealth Medical School

4th Annual Texas Two-Step Conference
February 28 - March 1, 2014

Medico-legal Aspects of Operative Vaginal Deliveries

Not all this material will be presented at the lecture

Disclaimer:

- No conflicts of interest to disclose
- Physician's perspective; not a lawyer
- Opinions expressed here at not necessarily those of ACOG or SMFM
Disclaimers:

- Perform and supervise vacuum and forceps deliveries including rotational procedures
- Coordinator of an annual Workshop on AVD’s for Junior Fellows at TAOG / ACOG District XI
- Have defended pro-bono physicians whose privileges for forceps have been questioned

Abbreviations used:

- AVD: Assisted vaginal delivery
- CD: Cesarean delivery
- FAD: Forceps-assisted delivery
- FCD: Fist cesarean delivery
- IVD: Instrumental vaginal delivery
- VAD: Vacuum-assisted delivery
- OVD: Operative vaginal delivery
- AVD = OVD = IVD (for purposes of this talk)
- TADR: Total assisted delivery rates

Objectives - I:

✓ Frame the use of Operative Vaginal Delivery (OVD) in the current environment of obstetrical practice in developed countries
✓ Outline the clinical role of Operative Vaginal Delivery in modern Obstetrics
✓ Describe the most common maternal and fetal / neonatal morbidities associated to the use of instruments during delivery
Objectives - II:

✓ Outline the most common causes of litigation related to Obstetric practice in developed countries
✓ Mention the most common claims associated with the use of instrumental delivery
✓ Review the importance of a systematic approach to the consideration of operative vaginal deliveries

Objectives - III:

✓ List key procedural factors leading to a safe approach to operative vaginal deliveries
✓ Propose measures to improve the standing and acceptability to the various methods of assistance of vaginal delivery

Specific questions:

✓ What is the perception of assisted vaginal delivery?
✓ What is role of OVD’s in modern Obstetrics?
✓ Does fear of litigation affect practice of Obstetrics?
✓ Can OVD’s prevent the first cesarean delivery?
✓ What would be required to modify the trends of OVD versus C/S in II stage of labor?
✓ What would be the tradeoffs if FCD was prevented by
Objectives:

× **Will not address:**
  × Technical aspects of the use of FAD or VAD’s
  × Economical aspects of OVD versus CD
  × Shoulder dystocia and brachial plexus injuries

**Fundamentally, a Clinical Problem**

**OPERATIVE VAGINAL DELIVERIES**
Medico-Legal Aspects

**Typical problem (real case):**

24 yo; AF; G2 P1;
Twins near term;
Cephalic / cephalic
II stage: 4.5 hours
OT at +2 station

**What to do ??**

OVD? ← ---- → FCD?
OBJECTIVES: To determine differences in maternal and neonatal morbidity between women who, due to anticipated difficulty, have trial of instrumental vaginal delivery in theatre and those who have immediate caesarean section for failure to progress in the second stage.

SEARCH STRATEGY: We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (May 2008).

SELECTION CRITERIA: Randomised controlled trials comparing trial of instrumental vaginal delivery (vacuum extraction or forceps) in operating theatre to immediate caesarean section for women with failure to progress in the second stage (active second stage more than 60 minutes in primigravidae).

DATA COLLECTION AND ANALYSIS: We identified no studies meeting our inclusion criteria.

MAIN RESULTS: No studies were included.

AUTHORS' CONCLUSIONS: There is no current evidence from randomized trials to influence practice.
Three important findings:

1. We do more CD's than other countries

2. We do less OVD's than other countries

Births delivered by forceps or vacuum
But, we do less total procedures to assist delivery than other countries.

Women need to be aware that there is over a 1/3 odds of requiring some form of assistance for delivery (V, F or CS)

Educational opportunity for professionals

Women need to be aware that there is over a 1/3 odds of requiring some form of assistance for delivery (V, F or CS)

Educational opportunity for professionals

The difference between AVD’s and CD’s is not a tradeoff...

We are managing labor differently!!
The perception on OVD’s...

"We should not use forceps or vacuums”
"Because they are dangerous”
"Instead, we should do a cesarean section”

Not true
We should!!
"Because they are dangerous”
Not true
They need to be used properly
"Instead, we should do a cesarean section”
Not true
Not faster or safer
Not outlawed in any state nor DC.

Operative Vaginal Deliveries
Medico-Legal Aspects

Obstetrics and Malpractice Claims

Proportion of physicians facing a malpractice claim annually, according to Specialty

Obstetricians are in a high risk group regarding malpractice claims

BY AGE 65, 99% OF PHYSICIANS IN THE HIGH RISK GROUP WILL FACE A MALPRACTICE CLAIM

Amount of malpractice payments according to specialty; 2008 dollars


OVD Safety Aspects

The Obstetrician’s Ecology

Expecting obstetrical outcomes may have different meanings to different people

Wall Street Journal 2003

Physicians avoid high-risk specialties and procedures that are the frequent target of lawsuit abuse

Troy M. Tippett, M.D. before U.S. House of Representatives April 6, 2011

OVD Safety Aspects

The Obstetrician’s Ecology
Does Fear of Litigation Influence Obstetric Practice?

**Operative Vaginal Deliveries**

Medico-Legal Aspects

- Obstetrics is one of the most sued subspecialties in the U.S.
- Study aimed to examine clinicians' medical/legal experience and its association with recommending CS.
- Survey included common obstetric clinical vignettes + 27 questions regarding clinicians' practice environment (analyzed using chi-square test and multivariable logistic regression models).
- Outcome of interest: Likelihood of recommending CD.

There were 1,486 clinicians who completed the survey. Categorized based on answers to clinical vignettes.

- Having had lawsuits and daily worry of suits were associated with higher likelihood of recommending cesarean, compared to those without lawsuits (17.2% versus 11.3%, respectively; p=0.008) as was frequent worry of lawsuits (every day, 20.3%; every week/month, 12.3%; few times a year/never, 11.4%, p<0.001).

Obstetric malpractice lawsuit and frequent worry about lawsuit are associated with higher propensity of recommending cesarean delivery in common obstetric settings.

**Litigation in Obstetrics:**

Does defensive medicine contribute to increase in cesarean delivery?

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Obstetric malpractice lawsuit and frequent worry about lawsuit are associated with higher propensity of recommending cesarean delivery in common obstetric settings.

**Effect of Fear of Litigation on Obstetric Care:**

A Nationwide Analysis on Obstetric Practice

- Retrospective cross-sectional population-based study using patient-level data obtained from the Healthcare Cost and Utilization Project-Nationwide Inpatient Sample on all deliveries in 2006.
- Mode of delivery was compared with the average state medical liability insurance premium paid by obstetricians (Medical Liability Monitor and the National Association of Insurance Commissioners) using a generalized estimating equation to calculate crude and adjusted odds ratios.
- 890,266 women delivered across 37 states in 2006.
- Average state malpractice premium of over $100,000 was associated with:
  - Higher incidence of total CD's (odds ratio [OR] 1.17, 95% confidence interval [CI]: 1.02, 1.35);
  - Lower incidence of VBAC (OR 0.60, 95% CI: 0.37, 0.98); and
  - Lower rate of instrumental deliveries (OR 0.72, 95% CI: 0.63, 0.83).

Compared with when the average state malpractice premium was less than $50,000.

Fear of litigation appears to have a marked effect on obstetric practice, particularly total CD, VBAC, and IVD, when malpractice premiums rise above $100,000/year.


5 malpractice insurance companies in 4 US regions (NE, MA, SW and West)
- Covered 63 acute care hospitals (35 academic, 26 non-academic), 428 outpatient facilities and ~ 33,000 physicians
- Approved by ethics RB’s ‘at the investigators’ institutions and at each review site
- Claims in the sample cost
  - >$449 million, with
  - Total indemnity costs > $376 million and
  - Defense costs of ~ $73 million

Claim: written demand for compensation for medical injury
- Anticipated claims or queries that fell short of actual demands did not qualify.
- We focused on 4 categories:
  - Obstetrics, surgery, missed or delayed diagnosis, and medication
  - These are key clinical areas of concern in research on patient safety; they are also areas of paramount importance to risk managers and liability insurers,
    - 80% of all claims in the US
    - even larger proportion of total indemnity costs

61% of plaintiffs were female
- Median age of the plaintiffs was 38 years
- 29% were newborns, and 12% were >=65 years of age
- Ob/Gyn were the most frequently sued physicians in the sample (19%),
- General surgeons (27%) and
- Primary care physicians: 16%
- Average length of time between injury and closure of the claim was 5 years

9 (<1%) contained only allegations of breaches of informed consent
37 of the claims (3%), no adverse outcome from medical care was evident
52 claims (4%) involved psychological or emotional injury,
1,406 claims (97%) involved injury
- Significant disability (39%)
- Major disability (15%)
- Death (26%)


### Claims, Errors, and Compensation Payments in Medical Malpractice Litigation

- Claims
  - Physical injuries
  - Psychological or emotional injuries
  - No adverse outcome
  - Breaches on informed consent


### Compensation in medical malpractice litigation:

- 69% of injuries were judged to be the result of error
  - 653 of 984 claims (66%) received compensation
- Most claims that did not involve errors (139 of 515 [72.9%]) or injuries (31 of 37 [84%]) did not receive compensation
- 73% (1,264 of 1,719) of all claims for which determinations of merit were made had outcomes concordant with their merit
- Discordant outcomes in the remaining 27 percent of claims consisted of three types:
  - Payment in the absence of documented injury (0.4% of all claims),
  - Payment in the absence of error (1.9%), and
  - No payment in the presence of error (16%)

The Alternative to OVD’s

OPERATIVE VAGINAL DELIVERIES
Medico-Legal Aspects

Cesarean delivery rates
USA / 1970-2009

Scott et al. Obstet Gynecol 2011;118:342-50

A multifactorial problem...

The perception:
“Vaginal deliveries can be bad”
“Cesarean sections are safe”

1- Patients requesting C/S's...
**Attitude Toward Elective CS:**

Urogynecologist (80%) vs MFM (55%)

<table>
<thead>
<tr>
<th>Total “Yes” Responses</th>
<th>MIS “Yes” Responses</th>
<th>MFM “Yes” Responses</th>
<th>$P^1$</th>
</tr>
</thead>
<tbody>
<tr>
<td>376 (74.4)</td>
<td>263 (84.6)</td>
<td>313 (74.5)</td>
<td>.001</td>
</tr>
<tr>
<td>5. Do you believe that a woman has the right to have an elective secondary cesarean delivery in the absence of any medical or obstetrical indication?</td>
<td></td>
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</tr>
</tbody>
</table>

Consultant’s response to maternal request:

- Agree for C/S: 3 - 31%
- Recommend vaginal but agree for C/S: 62 - 78%
- Recommend vaginal and refer: 7 - 24%

**The National Sentinel C/S Audit:**


www.rcog.uk.org

**And more importantly...**

3- Limited information to counsel...
OBJECTIVES:
To assess, from randomised trials, the effects on perinatal and maternal morbidity and mortality, and on maternal psychological morbidity, of planned caesarean delivery versus planned vaginal birth in women with no clear clinical indication for caesarean section.

SELECTION CRITERIA:
All comparisons of intention to perform caesarean section and intention for women to give birth vaginally; random allocation to treatment and control groups; adequate allocation concealment; women at term with single fetuses with cephalic presentations and no clear medical indication for caesarean section.

DATA COLLECTION AND ANALYSIS:
We identified no studies that met the inclusion criteria.

MAIN RESULTS:
There were no included trials.

AUTHORS’ CONCLUSIONS:
There is no evidence from randomised controlled trials, upon which to base any practice recommendations regarding planned C/S for non-medical reasons at term.

In the absence of trial data, there is an urgent need for a systematic review of observational studies and a synthesis of qualitative data to better assess the short- and long-term effects of caesarean section and vaginal birth.

Current use of Instrumental Delivery:

- **Prophylaxis:**
  (maternal / fetal indications)

- **Therapeutic:**
  
  - Correction of abnormalities of fetal head attitude:
    - Flexion
    - Position
    - Synclitism
  
  - Addition to the extracting vector:
    - lack of pushing effort
    - non-reassuring fetal condition
    - arrested delivery in II Stage

Gei AF; Pacheco LD. Current Women Health Reviews Feb 2008

Efficient use of OVD’s:

- The safe and successful use of instruments in Obstetrics rests mainly on three issues:
  
  I. Understanding their role and the problem they are attempting to address
  
  II. Systematic approach to their use
  
  III. Adherence to specific procedural key points

Timing of delivery interventions:

1. AVD’s can only impact the proportion of CD’s performed during the II stage

2. Comparison of outcomes to CD’s performed during the II stage
Both forceps assisted (FAD) and vacuum assisted (VAD) deliveries are obstetrical interventions (i.e. operations).

As such they have indications, contraindications, conditions, a sequential technique and proper documentation.

In certain clinical settings, one type of instrument is better suited for use (indications), but operator experience and established skill play an important role in the instrument chosen.

The successful and safe use of instruments in Obstetrics rests mainly on three issues:

- Understanding their role and the problem they are attempting to address
- Systematic approach to their use
- Adherence to specific procedural key points

**Individual more than Team performance**
I- Understanding the role of instruments

Mechanical model of delivery:

- Uterus
- Fetus
- Birth canal
- Expelling force
- Resistance vector
- Arrested delivery
**Bio-mechanisms of action of instrumental delivery:**

- Kristeller & variants
- Expelling force
  - Vacuum
  - Forceps

- Forceps
- Vacuum
- Head Perimeter
- Resistance vector
- Birth Canal
- Episiotomy
- Forceps
- Symphysiotomy

**Current use of Instrumental Delivery:**

- **Prophylaxis:** (maternal / fetal indications)
- **Therapeutic:**
  - Correction of abnormalities of fetal head attitude:
    - Flexion
    - Position
    - Synclitism
  - Addition to the extracting vector:
    - Lack of pushing effort
    - Non-reassuring fetal condition
    - Arrested delivery in II Stage

_Gei A / Pacheco L. Current Women Health Reviews Feb 2008_
II- The use of a systematic approach to OVD

A systematic approach to operative vaginal delivery:

Gei AF, Pacheco LD. Operative Vaginal Deliveries. Practical Aspects
Obstet Gynecol Clin N Am 2011;38

Contraindications for the use of instruments:

- Ruptured membranes
- Preterm labour
- Fetal distress
- Non-reassuring fetal heart rate
- Fetal macrosomia
- Fetal malpresentation
- Fetal anomalies
- Maternal indications

Box 3
Contraindications for the use of forceps:
- Premature rupture of membranes
- Prolonged rupture of membranes
- Maternal or fetal distress
- Fetal macrosomia
- Fetal malpresentation
- Fetal anomalies
- Maternal indications

Note: Contraindications for OVD using forceps should be used because of the increased risk of shoulder dystocia in this situation.
III- OVD Procedural key points:

Key-points for a safe and successful operative vaginal delivery:

1. Proper case selection
2. Patient preferences / Consent of the patient
3. Absolute knowledge of the fetal position
4. Proper instrument (cup) selection
5. Proper instrument placement
6. Proper instrument handling
7. Proper traction
8. Proper recognition of limitations
9. Proper communication (debriefing)
10. Proper documentation

1- Case selection
1- Proper case selection

POOR CANDIDATES:
- Protraction disorders in second stage
- Narrow subpubic arch
- Uncertain position of fetal head
- Deflexion or asynclitism
- Anticipated large-for-gestational-age infant
- Poor maternal compliance

Higher failure rates
Higher complication rates

Proceed at your own risk... better yet, DO NOT PROCEED.

VAD should be avoided in the following cases:
- Incomplete cervical dilation: Beware of the anterior lip of the cervix; do not attempt VAD before the cervix is completely dilated.
- Inconclusive fetal position: Where scalp is not visible at introitus.
- Delivery of severely compromised fetus as a "rescue procedure". Such an infant may be depressed at birth, and the VAD operator may be blamed.
- Maternal exhaustion: Do not increase traction force to compensate for reduced expulsive power.
- Excessive fetal head molding: Traction force increases the risk of intracranial injury in such cases.
- Suspected cephalopelvic disproportion: Brow, face, or breech presentation; gestation <34 weeks; or high fetal head station (above ischial spines).


2- Patient preferences and consent

OPERATIVE VAGINAL DELIVERY
2- Patient preferences / Informed consent

Informed consent is required for any surgical procedure, including an instrumental delivery. Informed consent is a process and not simply a signed form. Consent for a surgical procedure requires an explanation of the need for the operation, a discussion of risks and benefits, and a presentation of alternative modes of treatment. The patient (family) must also be given the opportunity to ask questions.

2- Verbal assent:

- A bedside consent process must be abbreviated in acute emergencies such as non-reassuring fetal monitoring tracings.
- Usually sufficient time is available to briefly describe the proposed operation to the mother and family, review the indications for the proposed procedure, and state the limits of effort intended.
- Hopefully, the patient was explained some options of assistance of delivery during her prenatal care.

RCOG: Consent advice for OVD

Operative Vaginal Delivery

Presentation information on risk

<table>
<thead>
<tr>
<th>Severity of Risk</th>
<th>Likely Outcome</th>
<th>Likely Aetiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>0% to 1%</td>
<td>Poorly described</td>
</tr>
<tr>
<td>Common</td>
<td>2% to 3%</td>
<td>Poorly common</td>
</tr>
<tr>
<td>Increased</td>
<td>4% to 5%</td>
<td>Commonly common</td>
</tr>
<tr>
<td>Rare</td>
<td>6% to 7%</td>
<td>Rarely common</td>
</tr>
<tr>
<td>Very rare</td>
<td>&gt;8% to 10%</td>
<td>Extremely rare</td>
</tr>
</tbody>
</table>

The above description are based on the RCOG Clinical Guidelines. Adverse Presentation Information on Jilt? They are used throughout this document.
Vacuum versus forceps: 
- generalities -

<table>
<thead>
<tr>
<th>Vacuum</th>
<th>Forceps:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Easier to apply</td>
<td>More difficult to apply</td>
</tr>
<tr>
<td>Slower delivery</td>
<td>Faster delivery</td>
</tr>
<tr>
<td>More likely to result in scalp trauma (neonatal)</td>
<td>Increased maternal soft tissue trauma (maternal)</td>
</tr>
<tr>
<td>Associated with increased rates of intracranial trauma</td>
<td>More prone to potential injury</td>
</tr>
<tr>
<td>Higher likelihood of failure</td>
<td>Requires better analgesia</td>
</tr>
<tr>
<td>Not recommended under 34 weeks</td>
<td>May be used at any gestational age</td>
</tr>
</tbody>
</table>

Gei AF, Pacheco LD. Operative Vaginal Deliveries, Practical Aspects Obstet Gynecol Clin N Am 2011

3- Fetal position

OPERATIVE VAGINAL DELIVERY

3- Fetal position (3D):

OPERATIVE VAGINAL DELIVERIES

We need to describe the fetal head based on all its axes in the space:
- Rotation: Fetal position
- Flexion: Modality of presentation
- Lateral rotation: Synclitism

This knowledge is going to define which procedure we do, with what instrument; which corrections to implement and even where the delivery should take place.
The head is a tridimensional structure:

Plane of position:

Plane of attitude (or flexion):
**Plane of synclitism:**

Our goal should always be to decrease the head perimeter:

Lower resistance
Lower force to exert delivery
Lower likelihood for maternal / fetal trauma

**4 Instrument selection**
Anterior cups (stemmed cups) are best used for deliveries:

- Station is low or outlet
- Fetal position is OA and rotated less than 45°

The pulling devices attached to soft (silicone or plastic) and rigid (plastic or metal) anterior extractor cups are semirigid, limiting maneuverability within the birth canal and presenting a handicap whenever the flexion point is not readily accessible.

Maneuverability of rigid posterior cups is not restricted; the suction tube on these devices can be in the same plane as the cup body.

Posterior cups can be used for:

- Deliveries in the OP and OT positions and
- Deliveries in the oblique OA position when the fetal scalp is not visible.

Selection of Forceps - I:

<table>
<thead>
<tr>
<th>Forceps</th>
<th>Clinical criteria for the selection of forceps instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Gilstrap</td>
<td>A principle, choose an instrument that will accomplish all the functions required for that case/behavior of multiple interventions</td>
</tr>
<tr>
<td>- Other criteria</td>
<td></td>
</tr>
<tr>
<td>- Gilstrap</td>
<td>Consider a forceps with overlapping materials to minimize vector deviation</td>
</tr>
<tr>
<td>- Gilstrap</td>
<td>Upper-lower, lower-upper, or upper-lower</td>
</tr>
<tr>
<td>- Gilstrap</td>
<td>Vaginal forceps</td>
</tr>
<tr>
<td>- Gilstrap</td>
<td>Naegele forceps</td>
</tr>
</tbody>
</table>

Selection of Forceps - Prophylactic:

- Indications:
  - Prophylactic
  - Rounded head (e.g., normal orients hawser or forceps with greater cephalic curvature)
  - Yudkin-McKenna forceps
  - Basic forceps
  - Modified head (shallower vacuum cups or forceps with lesser cephalic curvature)
  - Singhon forceps
  - Ellis forceps

Selection of Forceps - Therapeutic:

- Indications:
  - Perinatal anephalic
  - Leffkowicz
  - Left hand
  - Correction of intrapartum forceps (sphincter, large, lateral, speculum)
  - Correction of malposition of the head
  - Facial forceps
  - Locking forceps
  - Halti forceps
  - Divicenzo forceps
  - Distal forceps

5. Instrument Placement

OPERATIVE VAGINAL DELIVERY
**5- Vacuum Cup Placement**

**OPERATIVE VAGINAL DELIVERIES**

*The single most critical step in vacuum extraction is the proper placement of the cup.*

It should be applied at the point of maximum fetal cranial flexion, which is ~3 cm proximal to the leading edge of the posterior fontanel.

---

**5- Correct and Incorrect Cup Placements:**

**Flexing median application**

- Symmetric (or "ideal") or asymmetric grip
- Safest grip of the fetal head
- Unsafe
- Asymmetric grip

---

**Different Fetal Applications or Grips**

- Biparieto - Malar
  - Symmetric (or "ideal") or asymmetric grip
  - Safest grip of the fetal head
- Fronto - mastoid:
  - Unsafe
  - Asymmetric grip
  - Suboptimal grip
Double facial marking by fenestrated forceps
(Courtesy of: Dr. G. Cabrera-Meza; Houston; TX)

Periorbital hematoma and frontal pressure marks

Left eye avulsion + right facial palsy after forceps placement
J Comm Eye Health 1997;10 (24):56
Nasal trauma after forceps placement; 6 days of life

Courtesy of Dr OO Adegbehingbe; Nigeria

Applications: Example - I

ANTERIOR

RIGHT

POSTERIOR

LEFT

RA

RT

RP

LA

LT

LP

4th Annual Texas Two-Step Conference
February 28 - March 1, 2014
Placement in the sagittal plane:

- Plane of the shanks ~ 2.5 cm (one inch) cephalad (anterior) to the edge of the posterior fontanel
- Promotes flexion
- Decreases traction force
- Facilitates delivery
- Decrease potential trauma

Forceps marks:

- Suggests placement above lambda and asynclitism

Fronto-mastoid grip:
Left facial palsy after forceps placement

(Courtesy of: Dr. G. Cabrera-Meza; Houston, TX)

**Placement in the coronal plane:**

- Plane of the shanks Perpendicular to the edge of the posterior fontanel
- Promotes synclitism
- Decreases traction force
- Facilitates delivery
- Decrease potential trauma

**6- Instrument Handling**

OPERATIVE VAGINAL DELIVERY
**6- Vacuum Cup Handling**

OPERATIVE VAGINAL DELIVERIES

- While suction is applied the cup should be explored continuously to prevent maternal tissues being pulled within the suction cup.
- One hand provides traction and direction while the other monitors progress and prevents cup detachment.
- The crossbar of the pull device should be held in the fingertips to limit traction force.


**Actions of forceps:**

1. Correction of asynclitism
2. Rotation
3. Correction of flexion
4. Traction

**7- Instrument Traction**

OPERATIVE VAGINAL DELIVERY
7- Vacuum Cup Traction
OPERATIVE VAGINAL DELIVERIES

• Traction is meant to be an adjunct to the mother’s expulsive efforts, not the primary force to overcome resistance to descent.

• Gentle traction with the cup extractor is begun as soon as a contraction starts and the mother pushes (with modern plastic cups waiting an arbitrary period of time for a chignon to form is not necessary).

• Between contractions, the vacuum may be either maintained or decreased, depending on operator preference (there is no evidence that maintaining the vacuum is harmful or that decreasing it is beneficial).

• Once the surgeon has verified cup placement, full vacuum is applied (450-600 mm Hg) and traction follows, parallel to the uterine contractions.

7- Cup traction / Direction:

• If application of the device is incorrect, or traction is applied in the wrong direction, excessive traction, or traction in the presence of disproportion, or an incomplete seal exists the cup will slip or pop off, and vacuum delivery will fail, with the potential for traumatic fetal injury.

• Sudden cup detachment is not a built-in safety feature of VAD devices.

• Scalp abrasion (most often caused by sudden “pop-off”) or underlying blood vessel damage may result if “pop-off” occurs during strong traction.

7- Cup traction / Duration:

• When extraction is initiated before fetal caput is visible, expect the head to descend to the introitus within 3 pulls.

• Allow 3 additional pulls to complete delivery of the head over the perineum.
Head rotation during rotational VAD occurs automatically as a passive event similar to the internal rotation that is an integral part of normal labor.

Autorotation of the malpositioned head occurs in about 90% of cases, provided the cup is positioned correctly and traction is directed along the axis of the pelvis.

The method of rotational VAD is identical to the standard technique.

On no account should the clinician attempt to rotate the head by physically manipulating the cup.

8- Recognition of Limitations

- If the vacuum can be properly applied, the first application of traction is crucial.
- Expect some progress with each pull (feedback to the patient and personnel).
- Proceed if significant descent of the fetal head (not the scalp) is achieved.
- If no descent occurs reevaluate cup placement and direction of pull.
- If significant descent has not occurred in 3 pulls, stop the procedure and deliver by cesarean section.
- If the cup detaches twice and the fetal head has not yet descended to the outlet, stop the VAD and complete the delivery by cesarean section.

When to Abandon the Procedure?

- There are no trials looking at this issue
- ACOG
- CNGOF
When to abandon the procedure?

- RCOG proposes to abandon a FAD when:
  - Forceps' blades cannot be applied easily,
  - Handles do not easily approximate,
  - A rotation is not easily effected with gentle torque, or
  - There is no evidence of progressive descent with each pull or
  - Delivery is not imminent following 3 pulls of a correctly applied instrument by an experienced operator

- SGOC proposes to consider abandonment of OVD when:
  - It fails to achieve delivery of the fetus in a reasonable time
    (no operational criteria provided)

Gei AF, Pacheco LD. Obstet Gynecol Clin N Am 2011

9- Debriefing

9- Proper communication (debriefing)

- Results of the inspection, including accuracy of cup placement in relation to the flexion point, should be recorded for educational and auditing purposes
- If the scalp was injured, arrangements for appropriate follow up should be made
- On the day of delivery, the clinician should examine the baby in the mother's presence, answer her questions, and relieve any concerns (proactively not reactively)!
9- Proper communication (debriefing) 

OPERATIVE VAGINAL DELIVERIES

• Immediately after VAD, the infant’s head should be carefully examined and then reexamined at regular intervals to exclude bleeding into the scalp.

• If a warming bonnet has been placed on the baby’s head, neonatal attendants should remove it periodically to inspect the scalp.

10- Documentation

OPERATIVE VAGINAL DELIVERY

“"The chart is the most important witness" (Gimovsky)"

• Include a dictated operative note as well as notation in the chart itself.
• Notes should be legible and properly timed and dated.
• Document the indications and processes completely, preferably on a standardized form.

Modified from: Gimovsky ML, and Han JS. Reducing the medicolegal risk of vacuum extraction. OBG Management June 2007.
**Documentation:**

1: Pregnant patient  
2: Fetus  
3: Instrument used  
4: Delivery  
5: Parturient  
6: Newborn

---

**10- Documentation:**

- Document well what you did well
- Document better what you did not do so well
- Always do well...

---

**Operative Vaginal Deliveries**

Operational examples of morbidities associated with OVD’s:
### Comparison of Maternal and Neonatal Morbidity in Relation to Completed IVD, CD After Failed Attempt at IVD and Immediate CD: (Values as n (%) and OR (95% CI))

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Total (n)</th>
<th>Failed Instrumental delivery (n = 494)</th>
<th>Failed Instrumental delivery (n = 275)</th>
<th>Failed Instrumental delivery to Immediate Caesarean Section (n = 219)</th>
<th>Completed Instrumental delivery (n = 494)</th>
<th>Failed Instrumental delivery (n = 275)</th>
<th>Failed Instrumental delivery to Immediate Caesarean Section (n = 219)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal morbidity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perineal laceration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III-IV degree</td>
<td>10 (8.0%)</td>
<td>7 (14.3%)</td>
<td>3 (11.1%)</td>
<td>0.34 (0.11, 1.09)</td>
<td>0.38 (0.13, 1.10)</td>
<td>0.30 (0.11, 0.88)</td>
<td>0.37 (0.12, 1.13)</td>
</tr>
<tr>
<td>PP hemorrhage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PP fever of 38.0°C or higher</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 minute Apgar score &lt; 7</td>
<td>11 (8.4%)</td>
<td>5 (5.1%)</td>
<td>6 (5.3%)</td>
<td>1.19 (0.62, 2.29)</td>
<td>1.15 (0.63, 2.10)</td>
<td>0.93 (0.50, 1.75)</td>
<td>1.09 (0.68, 1.76)</td>
</tr>
<tr>
<td>Cord pH &lt; 7.15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Admission to NICU</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Maternal Outcomes of Attempted Rotational Forceps Delivery:

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<tbody>
<tr>
<td>Total</td>
<td>1067</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kielland</td>
<td>94 (8.8%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRV</td>
<td>85 (8.9%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vacuum</td>
<td>517 (53.4%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forceps</td>
<td>249 (25.7%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequential</td>
<td>322 (34.4%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry</td>
<td>OVD: 94.2%</td>
<td>OVD: 76.3%</td>
<td>OVD: 99.2%</td>
<td>OVD: 90.2%</td>
<td>0.003</td>
<td>0.008</td>
<td>0.008</td>
</tr>
</tbody>
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### Neonatal Outcomes of Attempted Rotational Forceps Delivery:

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<td>0.003</td>
<td>0.008</td>
<td>0.008</td>
</tr>
</tbody>
</table>

### Adverse Maternal Outcome:
- III-IV degree perineal laceration
- PP hemorrhage
- PP fever of 38.0°C or higher

### Adverse Neonatal Outcomes:
- 5 minute Apgar score < 7
- Cord pH < 7.15
- Admission to NICU

*All p-values are adjusted for maternal age, gestational age, birthweight, previous cesarean section, and maternal diabetes or hypertension with 95% confidence intervals.

**References:**
- Murphy et al. *BJOG 2003, Vol. 110, pp. 610–615*
Neonatal outcomes of attempted rotational forceps delivery:

- Kielland: 94 (8.8%)
- Rotational vacuum: 84 (8%)
- Vacuum: 547 (55.4%)
- Forceps: 449 (43.3%)
- Sequential: 352 (34.4%)

OVD: 94.2%
OVD: 94.2%
OVD: 94.2%
OVD: 94.2%
OVD: 94.2%

Rotational forceps in expert hands can result in lower morbidity rates than less complicated procedures performed by less experienced operators. These levels of performance are achievable: procedures can be taught and learned.

OPERATIVE VAGINAL DELIVERY AND PREVENTION OF THE FIRST CESAREAN DELIVERY

Long-term impact of AVD or CD: (two aspects):

Fertility and pregnancy outcome at three years in relation to mode of delivery at index pregnancy: (n / %)

Bahl R et al; BMJ 2004;328:311
RESULTS:

- 140 women (49%) achieved a further pregnancy at three years.
- 91/283 (32%) women wished to avoid a further pregnancy.
- Women who had an OVD (vs CD) were more likely to:
  - Aim for VD (89% (47/54) v 33% (18/54)) OR: 5.55 (95% CI 1.94 to 16.04) and
  - Have a VD (98% (42/43) v 31% (11/35)) OR: 9.50 (95% CI 2.08 to 20.97)
- There was a high rate of VBAC among women who attempted vaginal delivery 17/18 (94%).

CONCLUSION:

- Instrumental vaginal delivery offers advantages over caesarean section for future delivery outcomes.
- The psychological impact of operative delivery requires urgent attention.

Outcomes of deliveries in II Stage:

- Registry of AVD and C/S in II stage (standardized and systematic collection of variables) are reasonable to try to identify groups that would benefit from one intervention or the other and the timing of the intervention.
- The variables included would depend on the length (analytic horizon) and depth of analysis desired.
  - Maternal and neonatal
  - Major and minor variables
  - Physical outcomes
  - Psychological outcomes
- We need to engage women in dialogue.

Maternal morbidities:
Maternal morbidities:

<table>
<thead>
<tr>
<th>Advance Outcomes</th>
<th>Vacuum vs. Tocolytic</th>
<th>Forceps vs. Tocolytic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>3.9 3.6 4.1</td>
<td>3.4 6.8 7.1</td>
</tr>
</tbody>
</table>


Neonatal morbidities:

<table>
<thead>
<tr>
<th>Advance Outcomes</th>
<th>Vacuum vs. Tocolytic</th>
<th>Forceps vs. Tocolytic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal hematuria</td>
<td>4.1 5.0 5.6</td>
<td>5.0 5.5 7.1</td>
</tr>
<tr>
<td>Episiotomy</td>
<td>9.9 8.4 18.5</td>
<td>5.9 5.5 9.1</td>
</tr>
<tr>
<td>Episiotomy</td>
<td>9.9 8.4 18.5</td>
<td>5.9 5.5 9.1</td>
</tr>
<tr>
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<td>9.9 8.4 18.5</td>
<td>5.9 5.5 9.1</td>
</tr>
<tr>
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<td>9.9 8.4 18.5</td>
<td>5.9 5.5 9.1</td>
</tr>
<tr>
<td>Episiotomy</td>
<td>9.9 8.4 18.5</td>
<td>5.9 5.5 9.1</td>
</tr>
</tbody>
</table>


Neonatal morbidity and AVD's:

<table>
<thead>
<tr>
<th>Neonatal morbidity</th>
<th>Vacuum vs. Tocolytic</th>
<th>Forceps vs. Tocolytic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrapartum anemia</td>
<td>0.9 1.9 24 589 6.0 19 11 6 4 2.1</td>
<td></td>
</tr>
<tr>
<td>Prolonged labor</td>
<td>0.3 1.0 0.0 1.0 0.0 1.0 1.0 1.0 1.0</td>
<td></td>
</tr>
<tr>
<td>Shoulder dystocia</td>
<td>1.5 2.7 22 11 1.0 12 28 12 92</td>
<td></td>
</tr>
<tr>
<td>Sympathy</td>
<td>0.1</td>
<td>0.0 1.5 3.5 0.3 4.5 5.5 6.5 7.5</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>10.9</td>
<td>8.9 14 3.5 10.4 0.4 0.4 0.4 0.4</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>10.9</td>
<td>8.9 14 3.5 10.4 0.4 0.4 0.4 0.4</td>
</tr>
<tr>
<td>Face length</td>
<td>0.5</td>
<td>0.3 0.0 0.0 0.0 0.0 0.0 0.0 0.0</td>
</tr>
<tr>
<td>Forehead - Angle</td>
<td>0.5</td>
<td>0.3 0.0 0.0 0.0 0.0 0.0 0.0 0.0</td>
</tr>
</tbody>
</table>

* This incidence is expressed as the number of cases per 1000 births. 
* Adjusted for birth weight and parity.
Neonatal morbidities and AVD's:

Table 8: Neonatal morbidity associated with spontaneous vaginal and assisted vaginal deliveries: Benacerraf et al.

<table>
<thead>
<tr>
<th>Neonatal Morbidity</th>
<th>Unassisted (n = 381, 379)</th>
<th>Forceps (n = 26, 487)</th>
<th>Vacuum (n = 9, 109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cephalohematoma</td>
<td>548 (14.0)</td>
<td>689 (36.5)</td>
<td>211 (18.6)</td>
</tr>
<tr>
<td>Fracture of arm</td>
<td>76 (2.1)</td>
<td>98 (5.7)</td>
<td>19 (2.1)</td>
</tr>
<tr>
<td>Intrapartum hemorrhage</td>
<td>122 (3.1)</td>
<td>49 (2.7)</td>
<td>32 (2.7)</td>
</tr>
<tr>
<td>Adjacent vessels (%)</td>
<td>0.35 (0.30-0.41)</td>
<td>1.00</td>
<td>0.34 (0.26-0.43)</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>788 (21.9)</td>
<td>29 (2%)</td>
<td>77 (6.8)</td>
</tr>
<tr>
<td>Retained placenta</td>
<td>587 (15.6)</td>
<td>53 (3.0)</td>
<td>30 (2.7)</td>
</tr>
<tr>
<td>Adjacent vessels (%)</td>
<td>0.67 (0.50-0.93)</td>
<td>1.00</td>
<td>0.70 (0.50-1.29)</td>
</tr>
</tbody>
</table>

* Adjusted for birth weight, gestational age, deep transverse arrest, persistent occipitoposterior position, oligohydramnios, fetal distress, neonatal depression, and newborn bleeding.


[Gei AF, Pacheco LD. Obstet Gynecol Clin N Am 2011]

Typical problem:

24 yo; AF; G2 P1;
Twins near term;
Cephalic / cephalic
II stage: 4.5 hours
OT at +2 station

What to do ??
OVD ? ← FCD ?

What happened to the twins ??
Trial of forceps offered and explained
Couple assented
Kielland-Luikart 90\degree rotation in OR
(fellow under Faculty supervision)
Forceps removed and infant delivered

Il degree median laceration

Severe variables after 10 minutes
Membranes ruptured / LOT at 0 station
Kielland-Luikart 90 rotation and delivery
True knot of the cord
Il degree median laceration repaired

Uneventful maternal and neonatal course
Couple happy with outcome

In summary:
SUMMARY - I:

- Forceps and vacuum are instruments designed to assist delivery (not to harm mothers or children)
- Assisted vaginal deliveries continue to play an important role in modern Obstetrics
- The potential benefit of AVD’s is limited to the II stage of labor (and contingent upon a management of labor allowing women to reach the IInd stage)
- Indications for FAD and VAD might be slightly different
- Conditions for application of forceps and vacuum are the same

SUMMARY - II:

- Key-points to the success of an operative vaginal delivery are proper:
  1. Adequate case selection
  2. Informed consent of the patient
  3. Knowledge of the fetal position
  4. Suitable instrumental selection
  5. Adequate placement of the instrument
  6. Appropriate handling
  7. Traction
  8. Recognition of limitations
  9. Appropriate communication (debriefing)
  10. Documentation of procedure

SUMMARY - III:

- Maternal and fetal injuries may occur in all form of delivery (spontaneous / assisted vaginal / cesarean)
- The likelihood of injuries increases with the number, duration and magnitude of assistance (interventions)
- The use of instruments to assist delivery needs to outweigh the potential for injury
- The societal framework needs to be modified to impact the epidemic of cesarean section and the unpopularity of vaginal (and assisted) delivery
Factors that might contribute to a reverse of recent trends in OVD’s versus CD’s include:
- Professional and organizational endorsement for the use of OVD’s
- Formal incorporation into Residency curricula
- Funding support for research and education
- Maintenance and analysis of registries (II Stage or labor and OVD’s)
- Containment of medico-legal threat
- Improved reimbursement

Both children were delivered with forceps:

- The best defense against malpractice is good practice
Operative Vaginal Delivery
Medico-Legal aspects

THANK YOU

What would be required to modify the trends of OVD versus C/S in II stage of labor?

OPERATIVE VAGINAL DELIVERY
Medico-Legal Aspects

The contextual use of OVD’s:

- Safety
- Validation
- Technology
- Society
- Awareness
- Education
- Training
- Proficiency
- Physicians
- Knowledge
- Patients
- Willingness
Towards a rational management of the II Stage - I:

- Patients (couples/families) willing to consider an AVD (societal perception: "AVD more than OVD")
  - Agents of change: ACOG / SMFM / NIH

- Physicians (hospitals) able to offer the option of an OVD (Training and proficiency)
  - Agents of change: CREOG / ACOG / ABOG

- Physicians (hospitals) willing to offer the option (Professional endorsement / Perception of threat climate)
  - Agents of change: NIH / ACOG / Congress

Towards a rational management of the II Stage - II:

- Practice within the context of improved labor management (practice guidelines)
  - Agents of change: NIH / ACOG / SMFM

- Appropriate reimbursement (relative to CD):
  - Agents of change: ACOG / SMFM / Medicaid / Private payors

- Investments in research and development (Registries/Better instruments/Simulation):  
  - Agents of change: NIH / ACOG / SMFM / AHQR
EVALUATION OF CESAREAN DELIVERY / ACOG-2000

CONCLUSIONS
- Reform of medical liability laws and legal procedures may reduce the cesarean delivery rate.
- Education of physicians, nurses, attorneys, and the public regarding the causation of perinatal brain damage may assist in reducing unwarranted litigation.

RECOMMENDATIONS
- The obstetric community should seek reform of medical liability laws and legal procedures, which may result in reducing the cesarean delivery rate.

Freeman R et al. Task Force on Cesarean Delivery Rates. ACOG 2000

STRATEGIES
- Hospitals with a high cesarean delivery rate should consider introducing training during and after residency in the appropriate use of forceps and the vacuum in the management of second-stage arrest.
- Institutions may consider making the assistance of obstetricians experienced in operative vaginal deliveries available to obstetric practitioners desiring their expertise.

Freeman R et al. Task Force on Cesarean Delivery Rates. ACOG 2000
This trend toward a declining operative vaginal delivery rate might be reversed, however, with improved understanding of the conduct of normal labor, particularly in the second stage.

Freeman R et al. Task Force on Cesarean Delivery Rates. ACOG 2000

The importance of professional endorsement:

Example: NIH State-of-the-Science Conference (March 27-29, 2006)

3 references to forceps (*):

1/ “There is evidence that the risk of SUI may be increased when forceps are used to assist vaginal delivery.” (page 10)

2/ “…the frequency of obstetric trauma, such as third and fourth degree perineal lacerations, can be reduced by labor management practices such as reducing the use of midline episiotomy and limiting the use of forceps delivery whenever possible.” (page 10)

3/ “Use of midline episiotomy and use of forceps are associated with sphincter disruption. Limiting these practices can reduce the frequency of this injury.” (page 11)

(*) None to Obstetric vacuum
### Instrumental birth and delayed II\textsuperscript{nd} stage / NICE: Sep 2007:

- Instrumental birth should be considered if there is concern about fetal wellbeing, or for prolonged second stage.
- On rare occasions, the woman’s need for help in the second stage may be an indication to assist by offering instrumental birth when supportive care has not helped.
- The choice of instrument depends on a balance of clinical circumstance and practitioner experience.
- Instrumental birth is an operative procedure that should be undertaken with tested effective anaesthesia.
- If a woman declines anaesthesia, a pudendal block combined with local anaesthetic to the perineum can be used during instrumental birth.
- Where there is concern about fetal compromise, either tested effective anaesthesia or, if time does not allow this, a pudendal block combined with local anaesthetic to the perineum can be used during instrumental birth.
- Caesarean section should be advised if vaginal birth is not possible.

### Example: Position on rotational forceps:

- The Royal College of Obstetricians and Gynaecologists (RCOG): The options available for rotational delivery include Kelly’s forceps, manual rotation followed by direct traction forceps or rotational vacuum extraction 
  (Guideline 26 Oct 2005)

- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG): Reviews of Kelly’s forceps have consistently found a place for their use 
  (Statement C-Ob 13 Rotational forceps Nov 2006)

- The American College of Obstetricians and Gynaecologists (ACOG): There appears to be a role for midforceps rotational deliveries in current practice 
  (ACOG Practice Bulletin 17 June 2006)
Most Common Medical Errors in Infertility

Mazen Abdallah, M.D.
Common Medical Errors in Infertility

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Disclosure Statement

- I do not have relevant financial relationships with commercial interests related to the content of this presentation.

Learning Objectives

- 1) List common medical errors involving infertility therapy
- 2) Identify strategies to decrease medical errors in infertility treatment
“Infertility is a disease, defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse.”

Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years.

Infertility affects one out of eight couples attempting to conceive

Work up of infertility reveals:
- Male factor in 40%
- Female factor in 40-45%
- Unexplained 15-20%
- More than one factor in 25%

Evaluation of the infertile couple

History and physical exam

Ovulatory function
- The most common reason for a woman not to conceive is related to ovulation
- 95% of women with regular cycles ovulate regularly
Methods to document ovulation

- Basal Body temperature (BBT)
  - It cannot reliably define the time of ovulation
  - It is no longer considered the best method for evaluating ovulatory function

Methods to document ovulation

- Serum progesterone
  - is a reliable measure of ovulation
  - should be measured 1 week before the expected onset of the next menses
  - Level > 3 ng/mL provides evidence of recent ovulation
  - it is not reliable to measure the quality of luteal function because corpus luteum P4 secretion is pulsatile and levels may vary up to 7-fold within an interval of a few hours

Methods to document ovulation

- Ovulation Predictor Kits (OPK)
  - identify midcycle LH surge that precedes ovulation by 1-2 days
  - provides indirect evidence of ovulation
  - 98% sensitive
  - defines the interval of greatest fertility, the day of the LH surge and the following two days
Methods to document ovulation

- Endometrial biopsy (EMB)
  - histology can demonstrate secretory endometrial
  - “Dating” the endometrium using traditional histologic criteria is not accurate
    Murray MJ et al. Fertil Steril 2004
  - EMB cannot distinguish fertile from infertile women
    Coutifaris C et al. Fertil Steril 2004
  - EMB is no longer recommended for the evaluation of ovulatory or luteal function in infertile women
    Committee Opinion
    Fertil Steril 2012

- TSH and Prolactin should be measured
  - In women with amenorrhea, FSH / E2 measurements can distinguish women with ovarian failure from those with hypothalamic amenorrhea

- Age alone has an impact on fertility
Ovarian reserve

- Ovarian reserve evaluation:
  - Day 3 FSH and Estradiol
  - Clomiphene Citrate Challenge Test
  - Antral Follicular Count
  - Anti-Mullarian Hormone

Day 3 FSH
- High FSH is associated with both poor ovarian stimulation and the failure to conceive
  
  Broekmans FJ et al Hum Reprod Update 2006

- FSH should always be checked with E2 level
CCCT
- FSH is measured before and after treatment with clomiphene citrate (100 mg daily, cycle days 5–9)
- Elevated FSH after clomiphene stimulation suggests DOR

Hendricks DJ et al Fertil Steril 2006

Antral Follicular Count
- Antral follicle measuring 2–10 mm are counted in the early follicular phase using transvaginal u/s
- A low AFC (< 6) is associated with poor response to stimulation and failure to conceive

Hendricks DJ et al Fertil Steril 2005

Antimullerian Hormone (AMH)
- AMH is produced by granulosa cells in the preantral and antral follicles
- AMH production is independent of FSH stimulation
- AMH can be checked at any day of the cycle
Lower AMH level (<1 ng/mL) is associated mainly with poor response to ovarian stimulation and, to a lesser extent, poor pregnancy outcomes

Silberstein T et al Hum Reprod 2006
Mandrichna L et al BJOG 2005

Tubal Patency
- Tubal disease is the second most common cause of infertility in women
- HSG is the traditional and standard method for evaluating tubal patency
- HSG may suggest the presence of fimbrial phimosis or peritubular adhesions
- HSG has a low PPV (38%) but high NPV (94%)

Coppus SF et al. Hum Reprod 2007
- Proximal tubal obstruction can result from transient tubal/myometrial contractions

Saline infusion sonography (SIS) demonstrates tubal patency if fluid is seen in the cul de sac, but it does not differentiate between unilateral or bilateral patency.

Laparoscopy and chromotubation

Fluoroscopic/hysteroscopic selective tubal cannulation
- will confirm or exclude any proximal tubal occlusion suggested by HSG and provides the means for possible correction via recanalization
- Uterine abnormalities
  - relatively uncommon causes of infertility in women
  - HSG can reveal developmental or acquired abnormalities
  - HSG has low sensitivity (50%) and PPV (30%) for diagnosing polyps and submucous fibroids
  - Ultrasound is good for detecting uterine fibroids
  
  *Source SR et al. Fertil Steril 2000*

- SIS better defines the size and shape of the uterine cavity and has high PPV (>90%) and NPV (>90%) for detection of intrauterine pathology (endometrial polyps, submucous fibroids, synechiae)

  *Source SR et al. Fertil Steril 2000*

  - Hysteroscopy is the definitive method for the diagnosis and treatment of intrauterine pathology

- Cervical factors
  - Abnormalities of cervical mucus production or sperm/mucus interaction rarely are the sole or principal cause of infertility
  - PCT is no longer recommended for the evaluation of the infertile female because it is subjective, has poor reproducibility, is inconvenient to the patient, rarely changes clinical management, and does not predict inability to conceive

  *Oei SG et al. BMJ 1998*
Male partner evaluation

Semen Analysis

- Obtained after 2-5 days of abstinence

Committee Opinion
Fertil Steril 2012

Case 1

25 yo G0P0 has been attempting to conceive for 6 months. She has history of irregular cycles, used OCP to regulate cycles. LMP was more than a year ago. Husband has a normal semen analysis. HSG is normal. BMI 20 kg/m². She used progestins twice and did not have withdrawal bleeding.

Case 1

What is the best treatment for conception?

A) Metformin
B) Clomiphene citrate
C) Letrozole (Femara)
D) Gonadotropins (FSH)
E) needs further evaluation
The patient has anovulation and did not respond to a progestin challenge.

There are three different classes of anovulation and each require a different approach for fertility treatment.

- TSH, Progesterone, FSH / E2 levels are needed.

WHO Classification of Anovulation

- WHO class 1
  - Hypogonadotropic hypogonadal anovulation (hypothalamic amenorrhea)
    - 5 to 10% of anovulatory women
    - Eating disorders, stress or exercise amenorrhea
    - This class does not respond to anti-estrogen therapy (Clomid) because the estrogen level is low
    - Patients will respond only to gonadotropin (FSH/LH) OI

- WHO class 2
  - Normogonadotropic normoestrogenic anovulation
    - 60 to 85% of anovulatory women
    - PCOS, hyperprolactinemia, hypothyroidism
    - Ovulation could be established by correcting the underlying cause or use of anti-estrogen agents like Clomid or Letrozole
WHO class 3
- Hypergonadotropic hypoestrogenic anovulation
- 10% of cases of anovulation
- Ovarian failure
- Patients do not respond to any form of OI and the best fertility treatment is Donor egg IVF

Case 2
27 yo G0P0 with irregular cycles since menarche. She used OCP on and off to regulate cycles and control acne. She has been trying to conceive for 6 months. LMP 2 months ago.
BMI 28 kg/m², she has hirsutism
Work up:
- FSH / LH: 4.1 / 8.9
- E2: 98
- Testosterone: 67

U/S
PCOS affects 7-8% of women and is a common cause of infertility.

PCOS is diagnosed according to Rotterdam criteria:
- Oligomenorrhea
- Hyperandrogenism
- Polycystic ovaries

The cause of infertility in PCOS is anovulation.

The goal of fertility treatment is to achieve monofollicular ovulation when possible.

Case 2
What is the first-line therapy to induce ovulation in PCOS?

A) Metformin
B) Clomiphene citrate
C) Metformin and clomiphene citrate
D) Letrozole (Femara)
E) Gonadotropins
626 infertile women with PCOS were randomized to one of three study groups:
- Metrofemin 2000 mg daily
- CC 50 mg for 5 days beginning cycle day 3
- Metformin and CC

Live birth rate was significantly lower in the metformin group (7.2%) than in the CC group (22.5%) and the combination-therapy group (26.8%) (P < 0.001)
CC is superior to metformin in achievement of live births in PCOS. There is no added benefit of combination therapy.

The authors recommend using CC as the first-line therapy for infertility in women with PCOS.

The goal is to determine which method of first-line ovulation induction, CC or letrozole, is more likely to result in live birth in infertile women with PCOS.

750 women were randomized to:
- CC 50 mg every day for 5 days (days 3–7 of cycle)
- letrozole 2.5 mg every day for 5 days (days 3–7 of cycle)
Letrozole had more Live birth (27.5%) compared to CC (19.5%), \( P=0.007 \)

RR of live birth: \( 1.44, 95\% CI (1.10-1.87) \)

Authors’ conclusion:
- Letrozole is preferable to CC as first line therapy in PCOS

Case 2

This same patient used clomid 50 mg day 3-7 of her cycle for 2 months. She ovulated but did not conceive. She had HSG that was normal. Husband’s SA is normal

What would you do next?

A) since she is ovulating, continue clomid use until she conceives
B) increase clomid dose every month until conception
C) continue clomid at the same dose for 4 more cycles
D) consider other treatments like Gonadotropin OI or IVF
Clomiphene Citrate Use

- CC is used daily for 5 days starting on D 2-5
- Ovulation rates, conception rates, and pregnancy outcome are similar regardless of day of start
  Wu CH et al. Fertil Steril 1989
- The standard effective dose ranges from 50 mg/d to 250 mg/d
  Gysler M et al. Fertil Steril 1982
- 52% ovulate with 50 mg, 22% with 100mg, 12% with 150mg, 7% with 200mg, and 5% with 250mg
- In anovulatory women the cumulative conception rates for 50, 100 or 150 mg/d at 3 months are 50%, 45%, and 33%
  ESHRE/ASRM PCOS Consensus Workshop Group
  Fertil Steril 2008
- Cumulative conception rates at 6 months are 62%, 66%, and 38%
- Once ovulation occurs, there is no benefit from increasing the dose in a subsequent cycle
  Fertil Steril 2013;100:341–8
- Higher doses may be required with increased BMI
  Al-Azemi M et al. Arch Gynecol Obstet 2004
- Pregnancy is most likely to occur in the first 3 to 6 cycles of CC
- Therapy beyond 6 cycles is not recommended
  Committee Opinion
  Fertil Steril 2013
Increasing age, duration of infertility and obesity are associated with treatment failure.

Subjects with a BMI < 30 had a significantly higher rate of live births than those with BMI > 30 independent of the treatment, P<0.001.


Case 3

31 yo G0P0 with infertility of 2 years duration. Regular cycles. She had positive OPK for past 6 months. Workup showed D3 FSH/E2 8.4/34, AMH 2.1, normal TSH and PRL. HSG was normal. SA sperm 2 million/ml, 30% motility, 1% morphology. Total motile sperm 1 million.
Case 3

What is the best fertility treatment for this couple?

A) Intrauterine insemination (IUI)
B) Clomiphene citrate with timed intercourse
C) Clomiphene citrate with IUI
D) IVF

Although IUI may work in severe male infertility, it is not efficient and has low success rate.
A systemic review of 55 studies showed that 5-10 million total motile sperm in the sample is needed for IUI to work.

Ombelet W et al. Reprod Biomed Online. 2013

Couples with men’s sperm count less than 5 million/ml would benefit for ART.

Men with severe oligospermia need evaluation
- Hormonal profile:
  - FSH / LH
  - Testosterone
  - Prolactin
- Karyotype
- Y chromosome microdeletions
Case 4

24 yo G1P0010 with history of PID. She had an ectopic pregnancy treated with Methotrexate. She has regular cycles. She has been trying to conceive for 2 years.

Workup:
- SA 38 million/ml, 45% motility, 4% morphology.
- AMH 6, D3 FSH/E2 7.4 / 26, AFC 26
- HSG

What is the best fertility treatment?
A) Clomiphene citrate OI with IUI
B) laparoscopy for tuboplasty
C) IVF
D) laparoscopic tubal ligation then IVF
This patient has tubal disease infertility.

- IVF is the best treatment option when the tubes are damaged beyond repair.

- A systemic review showed an increase in IVF success rate if the hydrosalpinx was removed (OR 2.31) or proximally occluded (OR 4.66) before IVF.

  Johnson N et al. Cochrane Database Syst Rev. 2010

Complications of IVF:

- Ovarian Hyperstimulation Syndrome (OHSS)
  - Affects <1% of women undergoing IVF
  - Mortality is 1:500,000
  - Risks: young age, increased AFC / AMH, history of OHSS

- Multiple gestation
  - In 2012 SART report the rate of twin delivery in women 35 years or younger was 29.5%
  - Higher order multiples 1.1%

Case 5

- 29 yo G3P0030 with history of 3 spontaneous first trimester losses. She had evaluation for recurrent pregnancy loss and had the following HSG
Case 5

A) This is a normal HSG  
B) This is a uterine septum  
C) This is a bicornuate uterus  
D) This is an abnormal HSG, could not tell the anomaly

Case 5

What do you do to differentiate uterine septum form bicornuate uterus?

A) Hysteroscopy  
B) Laparoscopy  
C) MRI  
D) 3D ultrasound
Uterine septum is the most common Mullarian anomaly – affects 3% of the general population
(Simon C et al. Fertil Steril. 1991)

10% of women with RPL have a septum
(Acién P Hum Reprod. 1997)

The septum is associated with:
- recurrent pregnancy loss
- preterm labor
- Malpresentation
- May cause infertility

Bicornuate uterus is less common than uterine septum

It is mostly asymptomatic

It is associated with
- Preterm birth
- Malpresentation
- Cervical insufficiency
- Renal anomalies
Case 6

- 34 yo G1P0010 with infertility for 2 years duration. She had an SAB 2 years ago. Her cycles are regular but heavy. Her partner has a normal semen analysis.
- Evaluation:
  - Day 3 FSH/E2 8.7/36
  - AFC 12
  - AMH 2
Case 6

What is the best fertility treatment option

A) Uterine artery embolization  
B) IVF  
C) Hysteroscopic myomectomy  
D) Abdominal myomectomy

Fibroids are rarely the sole cause of infertility (1-2.4%)  
Donnez J et al. Hum Reprod 2002

Fibroid location seems to be critical for fertility

In ART, the OR for conception is 0.3 with submucosal fibroids and 0.8 with intramural fibroids  
Somigliana E et al. Hum Reprod update 2007

Hysteroscopy is the method of choice for removal of submucosal fibroids

Success depends on fibroid position and surgical skills

Classification of submucosal fibroid:
- Type 0 – 100% in the cavity
- Type I – > 50% in the cavity
- Type II – <50 % in the cavity

Instruments available
- Monopolar resectoscope
- Bipolar resectoscope
- Hysteroscopic morcellator
How to avoid complications

- Be familiar with the instruments used
- Continuous fluid monitoring is necessary throughout the procedure to avoid excessive absorption of distending fluid
- If there is a rapid increase in the fluid deficit perforation should be suspected
- Terminate procedure when the fluid deficit is
  - 1000 ml with electrolyte poor distention media
  - 2500 ml with electrolyte rich distention media

If the patient has more than 1 submucosal fibroid avoid resecting fibroids on opposing walls of the uterus during the same procedure to avoid adhesion formation

- Always keep a speculum or heavy weight retractor in the vagina while using a monopolar resectoscope to avoid electric injury

Case 7

- 24 yo G1P0 has unexplained infertility. She underwent ovulation induction with clomid and IUI. She is pregnant at 5 weeks with vaginal spotting and mild abdominal pain.
- B hCG levels drawn 2 days apart over the past week:
  - 200 / 340 / 550 / 900 mIU/ml
Case 7

A) The B hCG is rising but not doubling, the patient has an ectopic pregnancy – Methotrexate Treatment

B) Perform a transvaginal u/s and if endometrial cavity is empty then the patient has an ectopic pregnancy – Methotrexate treatment

C) perform a dilation and curettage and if there are no chorionic villi then treat for ectopic pregnancy

D) continue observation and repeat B hCG

Differentiating normal for abnormal pregnancies by serial measurement of serum hCG concentrations has been long described.

Earlier studies reported the average doubling time for hCG in the first 2 weeks after missing the cycle was 2.3 days


The concept of “doubling hCG” every 2 days (48 hrs) in normal pregnancy was coined.

More recent studies have shown that the rise in hCG could be as slow as 53% in 2 days and the pregnancy could still turn out to be viable

Bambhat KT et al. Obstet Gynecol. 2004

These patients can be followed with Beta hCG and u/s performed when the hCG is above the discrimination level of 1500 – 2000 mIU/ml
Administering Methotrexate in pregnancies misdiagnosed as ectopic may cause severe fetal malformations or demise.

A report of 8 women with desired pregnancies, misdiagnosed with EP, who were given Methotrexate in the first trimester:
- 2 had severely malformed embryos (Methotrexate embryopathy)
- 3 had miscarriage shortly after
- 3 had their physicians advising surgical termination


Questions?
Medicolegal Issues Related to Vaginal Mesh

Mickey Karram, M.D.
MEDICOLEGAL ISSUES RELATED TO VAGINAL MESH

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UNIVERSITY OF CINCINNATI

OBJECTIVES
1. Review prevalence of mesh complications and discuss FDA warning and mandated 522 studies
2. Discuss ways to avoid mesh complications
3. Discuss various mesh complications and how best to manage them
4. Review some recently published data
5. Present a variety of cases of mesh complications with video demonstrations of their surgical management

What the FDA said
1. Between Jan 1, 2008 & Dec 31, 2010; the FDA received 2874 reports of complications associated with surgical mesh used to repair SUI and POP; with 1503 associated with POP.
2. The most frequent complications reported were erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems.
3. There were also reports of recurrent prolapse, neuromuscular problems, vaginal scarring or shrinkage, & emotional problems.
FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk. While the literature suggests an anatomic benefit to anterior repair with mesh augmentation, this anatomic benefit may not result in superior clinical outcomes, and the associated risk of adverse events should be considered.

FDA Regulatory Changes

• Change risk classification of prolapse meshes from Class II to Class III
• Manufacturers will need PMA
• Clinical studies to address risks and benefits of mesh for POP and SUI
• Expanded post-market monitoring of device performance

MESH COMPLICATIONS

• Vaginal Exposure
• Vaginal Pain & Dyspareunia
• Vaginal Scarring and Loss of Vaginal Tissue
• Visceral Injury
• Thigh Pain and Referred Pain
Mayo Data – Mesh Complications

Complications specific to synthetic material use continue to increase.
Multiple surgeries to address complications may be necessary, and may incompletely resolve symptoms.
Potential for underreporting – only 14% referred from original treating physicians.
Dyspareunia and recurrent prolapse are common reasons for referral.

Mesh Complications; How Common are They

The BIG QUESTION

Severe mesh complications are occurring; but are the majority of them TECHNICAL or WOULD THEY OCCUR IN THE BEST OF HANDS

Serious Delayed Complications with Mesh in RPS

Use of mesh, especially polypropylene, in the transvaginal repair of anterior and posterior vaginal wall prolapse results in vaginal erosion, with associated bleeding, drainage and dyspareunia, in 5% to 17% of cases. Some cases are asymptomatic and some only need trimming but re-operations can result. Vaginal pain however is a particular and new concern.
What about Complications with Meshes?

Outcomes for Pelvic Organ Prolapse

• Vaginal anatomy; bulge, pressure, mass
• Visceral symptoms: Urinary and bowel symptoms
• Sexual activity and expectations
• Future surgical procedures or medicines to manage failures or complications

Abdominal Sacrocolpopexy
Mesh Overlay Techniques

MESH KITS – TROCAR BASED SYSTEMS
1. Prolift (Gynecare)
2. Apogee & Perigee (AMS)
3. Avaulta (Bard)

MESH KITS; DIRECT ACCESS SYSTEMS
1. ELEVATE (AMS)
2. UPHOLD & PINNACLE (BSC)
3. PROSIMA (GYNECARE)
Evaluation and Management of Complications from Synthetic Mesh after Pelvic Reconstructive Surgery: a Multi-center Study

Materials and Methods

- 4 tertiary care centers enrolled
- Mesh placed between 2006-2010
- 347 patients with complications involving mesh for either incontinence or prolapse
- Demographic, index surgery, and management following referral investigated
- Complication rated by Expanded Accordion Classification

Mesh used in index surgery
Presenting Characteristics

<table>
<thead>
<tr>
<th>Complaint</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 1 complaint</td>
<td>70.3</td>
</tr>
<tr>
<td>Erosion</td>
<td>42.7</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>34.6</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>30</td>
</tr>
</tbody>
</table>

77% Accordion Grade 3 or 4 (severe)

TVM patients:
- more likely to have Grade 4 (return to OR)
- more erosion than sling alone
- more prevalent compared to sling alone:
  - Pelvic pain
  - Dyspareunia
  - Vaginal constriction
  - Vaginal bleeding
  - Obstructive defecation

After ASC, more likely to complain of vaginal discharge only
Sling only group had more voiding dysfunction

<table>
<thead>
<tr>
<th>Interventions</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median # of interventions</td>
<td>2</td>
</tr>
<tr>
<td>% of subjects with more than 2 interventions</td>
<td>60</td>
</tr>
<tr>
<td>% Surgical intervention initially</td>
<td>49.1</td>
</tr>
<tr>
<td>% conservative management initially</td>
<td>51.9</td>
</tr>
<tr>
<td>% Patients who eventually had surgical management</td>
<td>59.6</td>
</tr>
<tr>
<td>Average number of surgeries to correct</td>
<td>1</td>
</tr>
<tr>
<td>% of patients requiring &gt;1 surgery</td>
<td>7.8</td>
</tr>
</tbody>
</table>
Conclusions

The majority of women presenting to tertiary centers with mesh complications have a severe complication.

A significant number of women require more than one corrective surgery.

Patterns of presenting complaints depend on index surgery type.

Limitations of existing literature

Ideal anatomic results not necessary for symptom relief.

Many studies combine primary and repeat repairs.

Adverse events are inconsistently defined.

Many studies are not blinded.

Few long term studies past 2 years.

Indications for Vaginal Mesh Augmentation

Surgeon preference due to comfort level with technical aspects of the repair.

Recurrent prolapse.

High risk for failure of conventional repair.

Want to avoid abdominal cavity.

Potential to standardize repair.

Part of a research trial.
Conclusions

• Mesh placed for POP repair has significantly more morbidity when complication arises
• More extensive complaints
• More extensive surgery(ies)
• More office visits to resolve issues
• Further study should investigate prospectively to verify data

Case 1 - Mesh Complications

HISTORY
56 yr old sp. Anterior Prolift one year prior to presentation. Presents with c/o of vaginal discharge and vaginal pain. Had three prior attempts at excision of eroded vaginal mesh from anterior segment.

EXAM
Exposed mesh in anterior vaginal wall

CYSTOSCOPY
No mesh in urethra or bladder
Case 2-Mesh Complications

HISTORY
63 yr old s/p total Prolift 2yrs prior to presentation with complaint of recurrent prolapse and tissue protrusion as well as pain with intercourse

EXAM
Large apical enterocele that descends approximately 6 cm beyond introitus. Erosion of mesh into fornix/shortened anterior vaginal wall. Significant pain in posterior vaginal wall, with significant bunching of posterior mesh in rectovaginal space noted on rectal exam.

CYSTOSCOPY
No mesh in urethra or bladder
**Case 3 - Mesh Complications**

**HISTORY**
49 yr old presents with recurrent prolapse 1 yr s/p Perigee for recurrent symptomatic cystocele. Had vaginal hyst with anterior and posterior repair approximately 4 yrs ago. Also c/o of vaginal bleeding and pain when attempting intercourse.

**EXAM**
Recurrent prolapse of anterior segment and vaginal apex with large vaginal erosion.

**CYSTOSCOPY**
No mesh in urethra or bladder.

---

**Case 4 - Mesh Complications**

**HISTORY**
72 yr old who presents with constant urinary leakage since repair of a symptomatic cystocele 6 months ago. Repair was augmented with Pelvicol.

**EXAM**
Obvious vesicovaginal fistula with vaginal opening present in midportion of anterior vaginal wall.

**CYSTOSCOPY**
Fistula in midportion of trigone with large amount of pelvicol seen in submucosa extending very near the right ureteral orifice.
The Role of Hospitalists in Labor and Delivery in Reducing Medicolegal Liability

John Barton, M.D.
The Role of a Hospitalist in Labor and Delivery in Reducing Medicolegal Liability

John R. Barton, M.D.

Disclosure of Relevant Financial Relationships

Research support
• Alere, San Diego (BIOSITE)

Clinical advisory board
• NX PharmaGen Inc
• Pluristem Therapeutics

Learning Objectives

• Review the hospitalist’s role in L&D to prevent medical errors and adverse outcomes.
• Review the medical literature involving OB hospitalists and their effect on perinatal outcomes.
• Discuss the relationship OB hospitalists have with other perinatal care specialists.
The “ist” Explosion

- Hospitalist
- Laborist
- Intensivist
- Surgicalist
- Nocturnist
- Weekendist
- Specialty Hospitalists

Growth of Hospitalists in Medicine North America, 1997-2011

34x growth since 1997

Driving Forces- Physicians

- Increasing complexity of hospital practice
- Graduating physicians prefer employment (and increasingly, existing physicians)
- Divergent skill sets
- Deteriorating clinical revenues
- Those who do something repetitively do it better

Weinstein. AJDG 2003
Driving Forces- Hospitals

- Recruiting/retaining physicians
- ED coverage/ EMTALA compliance risks
- Decreasing physician participation in hospital affairs
- Integration for new financial reimbursement models
  - Accountable care organizations
  - Bundled payments

Laborist - Definition

- Board certified OB/GYN
- Typically an experienced provider with a variety of skills.
- Always physically present in hospital
  - primarily in L&D
- Typically provide ED GYN coverage
- Supported by ACOG and Society for MFM

(Holson & Andress, 2012)

History

- Laborist = pre 1990’s OB residents
  - Supervised by phone
- All resident activities in labor and delivery must be supervised by an attending physician who is physically present
  - Required by the ACGME and the RRC
Laborist Trends in America

- Generally programs begin with part-time coverage but move to 24 hr coverage.
- Urban hospitals performing > 1000 deliveries per year.
- Scope of practice and responsibilities vary:
  - Emergency OB care
  - Management of unassigned patients
  - Surgical assistance
  - Perinatology extender
  - Allow private OBs to sign out to cover nights, weekends or vacations.

(Olson & Andress, 2012)

Laborists – The Motivation

- Review of perinatal claims between 2000-2005 showed that 70% of claims involved substandard care.
- Payments in:
  - 85% of these cases involved fetal monitoring
  - 16% maternal injury
  - 80% involved VBAC
  - 54% of those that were shoulder dystocia cases were avoidable

(Clark, Belfort, Dildy & Meyers, 2008)

Laborists – The Motivation

More than half of hospital litigation costs might be avoided if physician practice included:
- Delivery in a facility with 24 hr. in-house obstetric coverage
- Adherence to published high-risk medication protocols
- A more conservative approach to VBAC
- Use of more comprehensive standardized procedure notes in cases of shoulder dystocia.
Metro Traffic Jam

Rural Traffic Jam

Laborists Prevent and Treat Emergencies

- Decrease the chance for precipitous deliveries when patient’s physician is in transit
- Rescue babies during emergent deliveries (e.g. abruption, uterine rupture, cord prolapse etc.)
- Act as a liaison between nurses and physicians when there is concern about a potential unsafe practice
- Emergency call coverage for patients without physicians

Veltman, J Healthcare Risk Mgmt. 2014
How many drinks did you have while on call?

Correlation Between Cognitive Performance With Sleep Deprivation and Ethanol Intoxication

<table>
<thead>
<tr>
<th>Sleep Deprivation (hr)</th>
<th>Functional Serum Ethanol Level (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 -19</td>
<td>0.05</td>
</tr>
<tr>
<td>19 - 21</td>
<td>0.08</td>
</tr>
<tr>
<td>24</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Clark S. Am J Obstet Gynecol 2009

Obstetrical Practice

- Larger OB groups
- Call is less frequent BUT
  - Cover more deliveries on call
  - More post op, post delivery patients
  - The inevitable “2 at once”
- Covering more than one hospital
### OB Group Size and Work Load

<table>
<thead>
<tr>
<th></th>
<th>OB Group n = 3</th>
<th>OB Group n = 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliveries/DB</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Per Year</td>
<td>150</td>
<td>150</td>
</tr>
<tr>
<td>Deliveries / Call</td>
<td>0.8</td>
<td>2.2</td>
</tr>
<tr>
<td></td>
<td>1.2</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>1.6</td>
<td>4.4</td>
</tr>
</tbody>
</table>

### Patients are getting bigger

Dr. Sibai Fan Club

### Even the thin ones are bigger
Obesity Trends*Among U.S. Adults

*BMI >30


In a 2013 report on obesity from the CDC, the overall current prevalence rate of obesity in the USA is 35%
http://www.cdc.gov/nchs/data/databriefs/db131.htm

Which Ob/Gyns Are More Overweight?

Medscape Ob/Gyn Lifestyle Report 2014

What if 3 a.m. and active labor?

Lean OB, Super Obese patient
How about a little help?

How about a little help?

Truisms 101

- Beauty is in the eyes of the beholder. (or 'Beer Holder')
- Good fences make good neighbors.
- The early bird gets the worm.
- The sequel is never the equal.
- All new grads go to nights.
New Grads on Night Shift

- Least experience
  - FHR tracing
  - Medications and dosing
  - Dysfunctional labor
  - OB emergencies
- The Dumping ground
  - The patient no one else wants
- Easily intimidated
  - “Don’t call until it’s ready to come out in 1 push”

“The is fetus asleep
or
maybe Category III”?

The Blessing
But they are not 39 weeks!

- 38 weeks s/p fall on ice
  - No FM
  - Positive KB prep
  - NST reactive
- 38 weeks G3 P2
  - 6-7cm/90%/-1 station
  - NST reactive
  - Irregular uterine activity

TOLAC

At 1601 the patient reports feeling a “big pain.”
To OR at 1605.

Good Samaritan in the Hospital?

The Parable of the Good Samaritan
by Jan Vermeer (1670)
Laborist Models

- Employed Laborist
- Contract with medical practices to provide laborist coverage
  - Part-time laborist
  - Teaching laborist
  - MFM extender
- Multiple companies that will provide and run a laborist program

Laborists and the Obstetric MSE

- EMTALA requires a Medical Screening Exam prior to discharge
- KY BN statute does not credential RNs to perform MSE
- Laborists are present to perform MSE and discharge patients
- Improves compliance
- Reduces wait time and overcrowding
- Improves patient satisfaction
- Improves nurse satisfaction

Perinatal Outcomes

Retrospective database evaluation of 3 types of practices
- No laborist
- 24 hour laborist coverage by community staff
- 24 hour coverage by full-time laborist team
- Primiparous patients ≥37 weeks
- Significant reduction in C/S seen with the full-time laborist team as compared to the no laborist and community laborist groups
  - 27.5% reduction
  - "Implementation of a full-time laborist program is associated with a substantial reduction in cesarean section rate."

Iriye et al. AJOG S 2013
BHLEX: 5 of 7 SAE’s from 2002-2009 occurred at night or on the weekends.

**The Risk Case**

- BHLEX average attorney fees and expenses for litigated birth injury cases that have resolved since 2002 is approximately $200,000 per case.
- BHLEX has paid $750,000 in indemnity for birth injury incidents occurring since 2002.
- The Kentucky average verdict for a birth injury case since 2002 is $5,860,243.
- Newborn brain injury verdicts have brought more than $20 million.
Benefits - BHLEX

- Continuous MD availability in L&D for:
  - Emergency management
    - Review FHR tracings, questionable patterns
    - Ultrasound exam for uncertain presentation
    - Able to initiate a stat C-Section while primary OB en route for cord prolapse, uterine rupture, etc.
  - Continuous/Dual coverage – TOLAC/VBAC
- BHLEX has achieved 100% benchmark of no elective inductions before 39 weeks
- Since the inception of the program, BHLEX has experienced a greater than 25% increase in patient referrals.

Choosing the Right Laborists

- Expert communicator
- Service oriented, able to quickly bond with new patients
- Able to collaborate, respond to needs of team
- Professional, diplomatic, tactful
- Experienced
- Decision-making skills
- Able to manage emergent situations
- Set example of best-care practices

(Chain & Andress, 2012)
Conclusion: The Laborists

- Cost-effective tool in reducing risk
- Providing quality services to patients
- Providing valuable support services to obstetrical providers
- Improving nursing quality
- Desirable in recruiting new obstetricians
References


References


References

References

- Society of OB/GYN Hospitalists (SOGH)  
  www.SocietyofOBGYNHospitalists.com
Medicolegal Issues in Ultrasound and Prenatal Diagnosis

Anthony Johnson, D.O.
Medicolegal Issues in Ultrasound and Prenatal Diagnosis

Anthony Johnson, D.O.
Visiting Professor
Departments of Obstetrics, Gynecology and Reproductive Sciences and Pediatric Surgery
Co-Director, Texas Fetal Center

Disclosure

• I do not have relevant financial relationships with commercial interests related to the content of this presentation

• I am an author for http://www.uptodate.com Pathogenesis and Management of TTTS

Learning Objectives

1. Describe the common medicolegal issues that arise with ultrasound including ultrasounds in obese patients and proper technique for patients with different characteristics;

2. List the most common missed prenatal diagnosis and the items that should be considered in making the diagnosis: history, lab results, ultrasounds, genetic test results.
Prenatal Diagnosis

- Offers parents the option of avoiding the physical and emotional trauma associated with birth of children with severely debilitating disease
- Alerts families and health care providers of the need to prepare for delivery of a compromised neonate
- In selective disorders, presents the option of in utero therapy to correct or improve the perinatal and long term outcome

Factors contributing to patient injury

<table>
<thead>
<tr>
<th>Factor</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problems with clinical judgment</td>
<td>38%</td>
</tr>
<tr>
<td>Technical skills</td>
<td>23%</td>
</tr>
<tr>
<td>Communication</td>
<td>22%</td>
</tr>
<tr>
<td>Patient behaviors</td>
<td>20%</td>
</tr>
<tr>
<td>System failures</td>
<td>14%</td>
</tr>
<tr>
<td>Documentation</td>
<td>13%</td>
</tr>
</tbody>
</table>

Prenatal Diagnosis Medical Legal Issues

Key areas of concern

- Informed consent
- Prenatal genetic counseling
- Negligent practice
- Genetic Discrimination
Maternal Fetal Medicine Referral
Comprehensive Ultrasounds Patient’s Perception

<table>
<thead>
<tr>
<th>Reason for study</th>
<th>N = 381</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sent for a specific indication</td>
<td>57%</td>
</tr>
<tr>
<td>“See if the baby is okay”</td>
<td>22%</td>
</tr>
<tr>
<td>“Doctor sent me”</td>
<td>14%</td>
</tr>
<tr>
<td>Unsure</td>
<td>4%</td>
</tr>
<tr>
<td>To determine fetal gender</td>
<td>3%</td>
</tr>
</tbody>
</table>

Just over half of the women knew the reason for the test
Informed Consent?

Indication for Genetic Counseling and Prenatal Diagnosis

- Risk of fetal aneuploidy (Down syndrome) ≥ 35 y/o
- Previous pregnancy affected with chromosome abnormality
- Recurrent pregnancy loss (≥ 3)
- Parental consanguinity
- Parental translocation carrier
- Maternal history +, IDDM, epilepsy, myotonic dystrophy
- Exposure to viral infection: CMV, parovirus, rubella
- Maternal teratogen exposure, medical or environmental
- Family history of Mendelian disorders:
- Fetal malformation

Informed Consent

Healthcare providers

- More often insufficient information rather than none
- Duty to offer general, in many cases patient-specific, prenatal counseling and screening or diagnostic testing
- Provide and document patient understanding essential information of testing order

- Risk of an affected fetus/neonate
- Probably course
- Risks/limitations of testing procedure
- Length of time to completion
- Cost of testing
- Patient’s reproductive options
- Potential therapies for condition in question

Failure to Provide open to allegations of lack of informed consent
Genetic Counseling

“Nondirective prenatal counseling”
- Patients have limited understanding and experience with complex technical topics
- Information with significant emotional connotations conveyed in limited time frame in circumstance where the patient is psychologically overwhelmed
- Patients request guidance from experienced trusted professionals
- Superior medical knowledge relieve to the patient, physicians may filter information delivered with encroachment of personal beliefs

Wrongful Life\(^1\) or Birth\(^2\)

Allegations
- Negligence
- Breach of Contract
- Liability lawsuit

Malpractice
- Laboratories: missed misdiagnosis with immunologic assay (rubella) or genetic studies (Tay Sachs, Down syndrome)
- Care Providers: failed to offer prenatal testing, diagnostic or screening or inaccurate counseling
- Ultrasound: missed malformation, inaccurate measurements or recalculation of EDD, suboptimal imaging or documentation

Lawsuit brought by (1) child or (2) parent

Prenatal Diagnosis Medicolegal Case

Wrongful Life

- Proband: neonatal death from infantile polycystic kidney disease (PKD).
- Obstetrician, informed patient that RR extremely slim; infantile PKD is not a hereditary disease.
- An autosomal recessive disease, recurrence risk (RR) ~ 25%
- Second child affected with infantile PKD and died at 2.5 y/o.
- Alleged Negligence: with accurate medically advice ~ no further pregnancies: relied on Ob/Gyn’s superior knowledge and medical expertise to guide them
- Ruling:
  - Physician failed to perform a pre-existing duty:
    - Asserted the right of a child to be born free of anomalies as a fundamental right
    - Established that the parents of a disabled or deformed, deceased child can sue for wrongful life that was directly caused by a doctor’s negligence.
    - The burden of informing the parents of possible genetic defects on the medical professional

Park v. Chessin (1977)
Blind Amniocentesis Leads Fetal Demise

- 21 y/o G1P0 unsure of LMP
- 3rd Trimester ultrasound ~ 36-37 weeks
- Admitted for labor following day
- Amniocentesis ordered for lung maturity testing
- Procedure performed blindly w/o ultrasound guidance; 1st 2 attempts failed to obtain sample, 3rd blood tinged AF
- 1 hour later ~ Fetal distress
- Emergency C-section
- Neonatal demise

* Allegation: Negligence failed to follow SOC by not using ultrasound guidance
Indefensible: Ultrasound is universally available Settled pretrial for undisclosed amount

Prenatal Diagnosis Medicolegal Case
Mishandled Prenatal Genetic Test

- Severely disabled cousin with unbalanced chromosome translocation
- Patient carrier of balanced translocation: 50:50 risk of an affected child.
- Preconception genetic counseling with prenatal testing recommendations.
- Prenatal genetic tests – fetus normal
- Neonate dysmorphic, profound mental and physical delay – unbalanced translocation
- Alleged wrongful birth:
  - Sampling facility failed to provide lab with the “indication” (translocation carrier)
  - Lab failed to follow up to obtain the information & missed the unbalanced translocation
  - Had the couple known the fetus was affected pregnancy would have been terminated
- Award: $50 million

**Most Common Missed Obstetrical Ultrasound Diagnoses Associated with alleged Malpractice**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ectopic pregnancy</td>
<td>25%</td>
</tr>
<tr>
<td>Fetal anomaly</td>
<td>46%</td>
</tr>
<tr>
<td>Placenta previa</td>
<td>8%</td>
</tr>
<tr>
<td>Multifetal pregnancies</td>
<td>13%</td>
</tr>
<tr>
<td>IUGR</td>
<td>3%</td>
</tr>
<tr>
<td>IUD</td>
<td>1%</td>
</tr>
<tr>
<td>Abruptio placenta</td>
<td>2%</td>
</tr>
<tr>
<td>Ovarian mass</td>
<td>3%</td>
</tr>
</tbody>
</table>


Scan: Intracranial Hemorrhage
Autopsy: Brain punctured 19 times by amniocentesis needle
Is it negligent to miss a significant fetal anomaly on routine ultrasound at 20 weeks gestation?

- Modern equipment significant improvement in quality and accuracy of imaging, but not still number of limitations;
  - Fetal position,
  - Maternal body habitus,
  - Operator skill and knowledge of evolving fetal anatomy
- Informed consent: Ultrasound is not 100% diagnostic, rather a screening test with false negatives and false positives results; realistic expectations
- Report the limitations of study in completing the anatomic survey requires

Routine ultrasound screening for second trimester fetal malformations

<table>
<thead>
<tr>
<th>Birth Defect</th>
<th>N (99,753)</th>
<th>Detection rate &lt; 23 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNS</td>
<td>81</td>
<td>75%</td>
</tr>
<tr>
<td>Face &amp; Neck</td>
<td>52</td>
<td>15%</td>
</tr>
<tr>
<td>Cardiac</td>
<td>412</td>
<td>7%</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>19</td>
<td>89%</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>45</td>
<td>37%</td>
</tr>
<tr>
<td>Renal</td>
<td>149</td>
<td>5%</td>
</tr>
<tr>
<td>Total Isolated</td>
<td>1002</td>
<td>23%</td>
</tr>
</tbody>
</table>

Detection Rates of Isolated Birth Defects by Prenatal Ultrasound
Practice Guidelines

- Performance and recording of high-quality ultrasound examinations
- Minimum criteria for complete examination
- Not intended to establish a legal standard of care (SOC)
- Deviation from or exceeding guidelines will be needed in some cases

ACR – ACOG – AIUM Reston (V A), 2007;1025-1033
ACOG Practice Bulletin 101, 2009,
AIUM J Ultrasound Med 2010;29:157-166,
ISUOG Ultrasound Obstet Gynecol 2011;37:158-159

Standard Examination Essential Elements 1st trimester Scan

- Gestational sac
  - Location
  - Yolk sac / embryo
  - Amnionyonic – MGSD
- Crown rump length (CRL)
- Cardiac activity
  - TV ≥ 5 mm embryo
  - < 5 mm w/o FHR repeat
- Fetal number

- Multi-fetal
  - Chorionicity
  - Amnioncyt
- Uterus, adnexa & cul-de-sac
- Aneuploidy screening
  - Nuchal translucency
  - NTQR
  - Fetal Medicine Foundation

Embryonic/fetal anatomy
“Appropriate for 1st trimester assessment”?

First trimester ~ Anatomic Survey
Fetal Malformations

- Acrania
- Diaphragm Hernia
- Megacystis
- Holoprosencephaly
- Polydactyly
- Omphalocele

Syngelaki A et al Prenat Diagn 2011;31:90-102
**FIRST TRIMESTER* Detection Rate of Fetal Abnormalities**

<table>
<thead>
<tr>
<th>System</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Nervous System</td>
<td>75%</td>
</tr>
<tr>
<td>Neck Anomalies</td>
<td>100%</td>
</tr>
<tr>
<td>Neural Tube Defects</td>
<td>100%</td>
</tr>
<tr>
<td>Heart anomalies</td>
<td>25%</td>
</tr>
<tr>
<td>Limb defects</td>
<td>50%</td>
</tr>
<tr>
<td>Overall</td>
<td>70%</td>
</tr>
</tbody>
</table>

*D11-13 weeks*

---

**Standard Examination Essential Elements**

2nd*/3rd trimester ultrasound (76805)

- Fetal presentation
- Amniotic fluid volume
- Cardiac activity (FHR)
- Placental position
- Fetal biometry
- Fetal number
- Anatomic survey*
- Maternal cervix and adnexa

> 18 weeks

---

**Assessment of Gestational Age**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Gestational age, wks</th>
<th>Accuracy, days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean sac diameter</td>
<td>4.5 - 6</td>
<td>+/- 5-7</td>
</tr>
<tr>
<td>Crown rump length</td>
<td>7 – 10</td>
<td>+/- 3</td>
</tr>
<tr>
<td></td>
<td>10 – 14</td>
<td>+/- 5</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>+/- 8.4</td>
</tr>
<tr>
<td>BPD, HC, FL</td>
<td>14 – 20</td>
<td>+/- 7</td>
</tr>
<tr>
<td></td>
<td>21 – 30</td>
<td>+/- 14</td>
</tr>
<tr>
<td></td>
<td>&gt; 30</td>
<td>+/- 21-28</td>
</tr>
<tr>
<td>BPD, biparietal diameter</td>
<td>Assignment of EDD late in gestation fraught with risk and exposure</td>
<td></td>
</tr>
<tr>
<td>HC, head circumference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FL, femur length</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACOG Practice Bulletin #98; Obstet Gynecol 2008
Ultrasound for Fetal assessment

<table>
<thead>
<tr>
<th>Outcome</th>
<th>RR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to detect twins &lt; 24 wks</td>
<td>0.07</td>
<td>0.03-0.17</td>
</tr>
<tr>
<td>Induction of labor for postdates</td>
<td>0.59</td>
<td>0.42-0.83</td>
</tr>
</tbody>
</table>

Whitworth M et al, Cochrane Database Syst Rev 2010

“Surprise miracle”
Quads born to Mississippi woman

42 y/o G2P1
The identical quadruplets delivered at 28 weeks.
A. 2.1lbs; B. 2.3lbs; C. 2.5lbs, and D. 2.6lbs

http://www.sunherald.com/2014/02/17/5345539/surprise-miracle-quads-born-to.html#storylink=cpy

Standard Examination Essential Elements
2nd/3rd trimester fetal anatomic survey

- Head, face and Neck
  - Cerebellum / Cisterna magna
  - Choroid plexus
  - Lateral ventricles
  - Midline falx
  - Cavum septi pellicudii
  - Upper lip (nostrils)
- Chest-heart
  - A 4-chambered heart
  - Outflow tracts (attempt)
- Abdomen
  - Stomach
  - Kidneys
  - Umbilical cord insertion
  - Bladder & Umbilical cord vessels
- Spine
- Extremities
  - Legs
  - Arms
- Sex/Gender
  - Medically indicated only in low-risk pregnancies for multiples
Documentation and Image Capture from 2nd/3rd trimester fetal anatomic survey

- Adequate documentation is essential for high-quality patient care.
- Record of the ultrasound examination and its interpretation.
- Quality control careful record keeping of obstetric ultrasound examination results, archiving of reports and images, and clinical correlation with clinical outcomes.
- Active obstetric ultrasonography units should make every effort to correlate imaging results with clinical outcome.
- Suboptimal imaging should be documented with plan to resolve critical in defense with late onset disorders;
  - hypoplastic left heart syndrome.
  - achondroplasia.
  - diaphragm hernia.
  - duodenal atresia.

Basic Fetal Anatomic Survey

Head

- Satisfactory assessment
  - Fetal position dependent
  - Expertise & meticulous scanning
  - Complete evaluation from every projection not part of basic exam

Spine

- Transverse & sagittal views usually informative
- Most serve forms of spinal abnormalities have secondary intracranial findings
  - Spina bifida with cerebellar herniation
Basic Fetal Anatomic Survey
Head

Cerebellar Hemiation with "+ Banana Sign"
Spina Bifida till proven otherwise

Malpractice Issues in Prenatal Ultrasound

- Office based ultrasound contracted with outside mobile sonography unit
  - Experienced sonographer
  - Real-time images stored on videotape with thermal printed copies
  - Independent radiologist interprets study and provides report
- Case ~ 32 y/o G1P
  - 12 weeks US ~ single IUP “normal”
  - 22 weeks US: appropriate interval growth, normal anatomic study
  - 33 weeks US: hydrocephalus
  - Delivery: Liveborn neonate with hydrocephalus secondary to Arnold Chiari Malformation & meningomyelocele (MMC) @T4-L2
  - Postnatal repair with profound neurologic compromise

Malpractice Issues in Prenatal Ultrasound
Spina Bifida ~ Wrongful Life

- Lawsuit
  - Negligence: Radiologist missed MMC at 22 weeks – wrongful life
  - Defense:
    - “Simply Radiologist” not required to have expertise to dx MMC 22wks
    - Relyed on the sonographer who had more experience in fetal imaging
  - Negligence: Ob/Gyn failed to obtain MSAFP
- Expert review
  - MMC of this degree should be detectable at 22 weeks
  - Images were poor quality
  - 22 wk study failed to adequately define basic anatomy
  - Accompanying report failed to document study was technically inadequate
- Settlement: prior to trial on behalf of Radiologist
Physician ~ Sonographer Relationship
Agency Law

Sonographer
• Working under the supervision of the physician
• Any reasonable act performed within the scope of employment – liability for the physician

Physician
• Responsible for the quality of the study
• Basic anatomy depicted appropriately
• Measurements at accurate
• Acceptable study – Guidelines ACR/ACOG/AIUM*
• Rescanning patient: all or selectively with image review in all cases
• SOA calls for all reasonable skill and knowledge – dictated by code
• Liable for misdiagnosis or nondiagnosis


2nd Trimester detection rate & incidence of the more common fetal abnormalities

<table>
<thead>
<tr>
<th>System</th>
<th>DR%</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Nervous System</td>
<td>76%</td>
<td>1:1,600</td>
</tr>
<tr>
<td>Renal</td>
<td>67%</td>
<td>1:1,000</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>50%</td>
<td>Uncertain</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>42%</td>
<td>1.2,550 (omphalocele)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.4,300 (gastrochisis)</td>
</tr>
<tr>
<td>Skeletal</td>
<td>24%</td>
<td>1:500</td>
</tr>
<tr>
<td>Cardiac</td>
<td>17-40%</td>
<td>1:125</td>
</tr>
<tr>
<td>AVSD</td>
<td>29%</td>
<td></td>
</tr>
<tr>
<td>VSD</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>HLHS</td>
<td>55%</td>
<td></td>
</tr>
<tr>
<td>Outflow tract anomalies</td>
<td>21%</td>
<td></td>
</tr>
</tbody>
</table>

* Low risk population

Malpractice in Obstetrical Ultrasound Negligence: Incorrect diagnosis with delayed referral

32 y/o G3P2
1st trimester ultrasound
• SIUP with normal nuchal translucency 1.2 mm, negative FERST Screen
2nd Trimester Office Study
• 22 week anatomic survey, appropriate interval growth
• Amniotic fluid volume, w/ megacystis
• Referral to Fetal Treatment center
• Request indicated “Fetal Growth Study”

MFM/Treatment
• 23 3/7 weeks
• Anhydramnios, LUTO, poor candidate for in utero treatment

Outcome: Delivery Liveborn 32 weeks, ESRD with Dialysis; Infant Death 18 months

• Alleged: Negligence Incorrect documentation on referral form delayed MFM Evaluation and possible therapy


4th Annual Texas Two-Step Conference
February 28 - March 1, 2014
"There is NO diagnosis of twins. The only diagnosis is a monochorionic or dichorionic twin gestation. This should be written in capital red letters on the front of the chart at 8 - 10 weeks".

**Complicated Monochorionic Multifetal Pregnancies**

- sILGR
- TOPS
- 30% MC affected
- TAPS
- Unexplained Fetal Death

**Multifetal Pregnancies**

**Ultrasound Determination of Amnionicity & Chorionicity**

1st Trimester Ultrasound Examination:
- Amnionicity and chorionicity should be documented for all multiple gestations

2nd & 3rd Trimester Ultrasound Examination:
- Multiple gestations require the documentation of additional information: chorionicity, amnionicity, comparison of fetal sizes, estimation of amniotic fluid volume on each side of the membrane, and fetal genitalia (when visualized).

ACOG PRACTICE GUIDELINES, #101, Reaffirmed 2011
ACOG PRACTICE GUIDELINES, Oct 2007
Multifetal Pregnancies – Establish chorionicity
10 - 14 weeks

"T" sign
Monochorionic

Twin Peak (lambda)
Dichorionic

Accuracy of referral vs. tertiary diagnosis of amnionicity and chorionicity

<table>
<thead>
<tr>
<th></th>
<th>Center</th>
<th>DADC</th>
<th>DAMC</th>
<th>MOMO</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twins</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DADC</td>
<td>45%</td>
<td>83</td>
<td>98%</td>
<td>167</td>
<td></td>
</tr>
<tr>
<td>DAMC</td>
<td>49%</td>
<td>40</td>
<td>96%</td>
<td>72</td>
<td></td>
</tr>
<tr>
<td>MOMO</td>
<td>50%</td>
<td>8</td>
<td>83%</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Twins</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TADC</td>
<td>96%</td>
<td>25</td>
<td>96%</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>TAMC</td>
<td>92%</td>
<td>13</td>
<td>100%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Triplets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TADC</td>
<td>24%</td>
<td>4</td>
<td>24%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>TAMC</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Accurate diagnosis of A/C can be obtained by assessment of key sonographic findings
Emphasis on need to enhance diagnostic skills in the general community & referral if dx ambiguous

Wan JJ et al Prenat Diagn 2011

Prenatal Ultrasound Medicolegal Case
Complicated Monochorionic Twins

Suit
Alleged negligence – failed to monitor and treat evolving twin twin transfusion syndrome

Prenatal Imaging
- 10 week ultrasound revealed twin gestation
- Radiologist did not determine monochorionic
- 18 week scan noted discordant growth and AFV

Outcome
Single IUFD
Co-twin neurologic insult – presently 5 years of age

Award/Settlement – $2.3 Million Settlement
SMFM Algorithm for Screening for TTTS

First Trimester
- Confirm Chorionicity & Amnionicity
- Nuchal Translucency Measurements
  ~ 16 weeks
  - MVP in each sac
  - Presence of Fetal Bladder
  - Doppler: UA & MCA PSV

  MVP > 2 cm and < 8 cm in each sac
  - Yes
  - Continue q 2 wks scan
  - Alternate limited & growth
  - Doppler: UA & MCA PSV
  - Slaging

  MVP < 2 cm and > 8 cm in each sac
  - No
  - TTTS

SMFM: ACOG 2013;208:182-9

Percentage of Anomaly Scans Completed by Gestational Age

<table>
<thead>
<tr>
<th>Gestational weeks</th>
<th>18-19</th>
<th>20-21</th>
<th>22-23</th>
</tr>
</thead>
<tbody>
<tr>
<td>% scans completed</td>
<td>76%</td>
<td>90%</td>
<td>89%</td>
</tr>
<tr>
<td>(number)</td>
<td>(306)</td>
<td>(371)</td>
<td>(393)</td>
</tr>
</tbody>
</table>

Calls into question the ACOG Recommendation
For routine screening at 18-22 weeks


4th Annual Texas Two-Step Conference
February 28 - March 1, 2014
Maternal Obesity
Risk of Congenital Anomalies

<table>
<thead>
<tr>
<th>Anomaly</th>
<th>Odds Ratio 95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spina Bifida</td>
<td>2.24 (1.86-2.69)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>1.30 (1.12-1.51)</td>
</tr>
<tr>
<td>Cleft palate</td>
<td>1.23 (1.03-1.47)</td>
</tr>
<tr>
<td>Anorectal atresia</td>
<td>1.48 (1.12-1.97)</td>
</tr>
<tr>
<td>Hydrocephaly</td>
<td>1.68 (1.19-2.36)</td>
</tr>
<tr>
<td>Limb reduction</td>
<td>1.34 (1.03-1.73)</td>
</tr>
<tr>
<td>Gastroschisis</td>
<td>0.17 (0.10-0.30)</td>
</tr>
</tbody>
</table>

Maternal obesity is associated with an increased risk of structural anomalies. Absolute risk is likely to be small however, detection rate is inversely related to BMI.

Stothard KJ et al. JAMA. 2009;301:636-50

Overweight Pregnant Women Need More Ultrasounds To Complete Study

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Not Obese</th>
<th>Obese</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ultrasound time (min)</td>
<td>58.9</td>
<td>67.1</td>
<td>.01</td>
</tr>
<tr>
<td>Complete anatomy survey on initial attempt, n(%)</td>
<td>75 (75)</td>
<td>43 (69)</td>
<td>.02</td>
</tr>
<tr>
<td>Exams needed to complete anatomy survey, n(%)</td>
<td>1.2 (2.4)</td>
<td>1.4 (2.4)</td>
<td>.01</td>
</tr>
<tr>
<td>Satisfactory survey, n(%)</td>
<td>210 (96)</td>
<td>61 (91)</td>
<td>&lt;.00</td>
</tr>
<tr>
<td>All anatomy visualized, n(%)</td>
<td>98 (95)</td>
<td>86 (96)</td>
<td>.09</td>
</tr>
</tbody>
</table>

Ehsanipoor R et al. 2013 AIUM Annual Meeting

Effects of Maternal Obesity on Ultrasound Detection of Anomalous Fetuses

Dashe JS et al. Obstet Gynecol;2009;113:1001-7
Technical Tip on Scanning Obese Gravidae “Sims Position” & Periumbilical

Obese patient – 2nd Trimester

Sims Position

Ultrasound Accreditation

- Anthem Blue Cross and Blue Shield of VA adds Ultrasound to List of Modalities Requiring Accreditation – January 23, 2014
- Providers will have until March 2014 to fulfill this requirement.
- The requirement applies to ultrasound guided procedures as well.
- Medical practices will need to be accredited by the AIUM or the American College of Radiology:

http://aium.org/accreditation/accreditation.aspx

The Malpractice Crisis in Obstetrical Ultrasound

15 proven ways to meet plaintiff’s attorney

1. Missing the sonographic finding
2. Misinterpretation of the finding
3. Failure to compare findings to previous studies
4. Failure to communicate the report properly to referring physician or patient
5. Failure to examine the patient personally or take a proper history
6. Incorrect sonographic approach for a specific problem
7. Incomplete examination
8. Inadequate quality of films
9. Failure to obtain informed consent
10. Failure to order ultrasound
11. Failure to recommend additional imaging studies, ultrasound or MRI or prenatal diagnostic testing
12. Loss of films or reports, inadequate filling system
13. Abuse of patient (sexual, physical or mental) by sonologist or sonographer
14. Equipment complications (electrical shocks)
15. Complication of needle guided procedure under ultrasound control

Sanders RC. The effect of the malpractice crisis. 1993
Avoidance of patient injury and litigation

Risks that can be mitigated

- Faulty communication
- Lack of informed consent
- Failure to stay up-to-date on standards and training
- Inadequate follow-up of diagnostic tests and specialist referrals
- Variations in policies and procedures.
- Avoidance behavior

Torch of Obstetrical Lawsuits

Delivery Room  Fetal heart rate Monitoring  Fetal Ultrasound  Prenatal Diagnosis

Thank you for your attention
What Would You Do?

GYN Case Studies

Moderator: Allan Katz, M.D.
Robotic Hysterectomy
Case Presentation

Allan R. Katz, M.D.
Professor
Director, Generalist Division
Department Obstetrics, Gynecology & Reproductive Science

Case Presentation
42 year old Robotic Hysterectomy

- Menometrorrhagia
  - Uncomplicated surgery
  - Robotic Laporoscopic TAH
  - Discharged following day in the morning

- Post Op Check Up
  - No complaints
  - Unremarkable

Case Presentation
42 year old Robotic Hysterectomy

- Three weeks post op
  - Pelvic Pain
  - Bloody vaginal discharge

- Pelvic Exam
  - Serosanguinous Discharge-Apex of the cuff
  - Tender to Palpation
  - Small defect on the left
  - No masses palpable
Case Presentation
42 year old Robotic Hysterectomy

• What is your next step?
  a. Single dose broad spectrum antibiotic
  b. Outpatient observation
  c. Vaginal ultrasound
  d. Admit for IV Antibiotics
  e. Open the cuff
  f. More than one answer

Case Presentation
42 year old Robotic Hysterectomy

• One week later
  • Increasing abdominal pain
  • Fever & chills
  • Heavy Discharge
• Labs
  • UA-Neg
  • WBC - 18,000 Shift to the Left
• CT
  • 8cm mass at APEX of cuff

Case Presentation
42 year old Robotic Hysterectomy

• Your plan would be?
  a. Start IV Antibiotics and attempt to open cuff under sedation
  b. Exploratory Laparotomy
  c. I.R. to drain abscess
Case Presentation
42 year old Robotic Hysterectomy

- The cuff was opened in the examining room
- The patient recovered and was sent home
- Three months later
  - Pain with intercourse
  - Tenderness left side of cuff - no masses
  - MRI - Neg

Case Presentation
42 year old Robotic Hysterectomy

- Persistent dyspareunia
- Laparoscopic lysis of adhesions to the small bowel and vagina
- Long-term follow up. No complaints

Case Presentation
42 year old Robotic Hysterectomy

- Legal Issues
  - Consent documented and signed
  - Malocurrence - Yes
  - Standard of care - not breeched
  - Medical malpractice - None
Vesicovaginal Fistula Case Presentation

Case Presentation Abdominal Hysterectomy

- 45 year old with menorrhagia
- 2 previous C-Sections
  - 2 Small Fibroids
  - Requested abdominoplasty at time of hysterectomy

Case Presentation Abdominal Hysterectomy

- TAH
  - Bladder sharply dissected off of the cervix
  - Abdominoplasty- uncomplicated
  - Foley catheter removed within 48 hours
  - Clear fluid draining from vagina
Case Presentation
Abdominal Hysterectomy

• Plan of management
  a. Visual inspection of vagina- no fistula noted
     no further evaluation
  b. Instill methylene blue in bladder with a
     tampon in the vagina

Case Presentation
Abdominal Hysterectomy

• Urology consult-IVP
  • Single .7cm fistula anterior wall of vagina
  • Upper collecting system- negative no
    obstruction or leakage.

Case Presentation
Abdominal Hysterectomy

• What would you do next?
  a. Immediate vaginal repair
  b. Foley catheter drainage for two weeks
  c. Delayed closure in three months
  d. All of the above
Case Presentation
Abdominal Hysterectomy

- Repair successful
- Foley catheter drainage for two weeks
- Patient sued the hospital for costs.
  - Hospital settled
  - The physician was dropped from the case

Case Presentation
Abdominal Hysterectomy

- Legal Issue
  - Proper consent signed
  - Maloccurrence- Yes
  - Standard of care – not breeched
  - Medical malpractice - None

Polycystic Ovary Syndrome (PCOS)
Case Presentation
32 year old Nulliparous with PCOS

• 32 year old with Nulliparous
• Irregular periods for many years
• Wishes to start on oral contraceptives
• Physical Exam
  • Wt 310lbs
  • Acanthosis nigricans

Case Presentation
32 year old Nulliparous with PCOS

• What is your plan of management?
  a. Start on OCP’s
  b. Cycle with provera
  c. Endometrial biopsy

Case Presentation
32 year old Nulliparous with PCOS

• Started on OCP’s
• Referred to Endocrinologist
  • Labs – Hb A1C 7.4
    Fasting Blood Sugar 130
• Metformin
• Continues to have irregular bleeding
  referred back to the gynecologist
Case Presentation
32 year old Nulliparous with PCOS

- Two weeks later
  - Heavy Bleeding
  - Emergency room visit
  - Labs
    - Hb 7.0
    - UA- Neg
    - US- slightly enlarged irregular uterus
  - Gynecology consult in ER
    - Mass protruding from the cervix
    - Slightly enlarged uterus on physical exam

Case Presentation
32 year old Nulliparous with PCOS

- Biopsy Performed
  
- What was the path report?
  
  a. Endocervical polyp
  b. Prolapsed myoma
  c. Adenocarcinoma of the endometrium

Case Presentation
32 year old Nulliparous with PCOS

- Legal Issues
  
- Was the standard of care met?
- Was there medical malpractice?
Abnormal Uterine Bleeding
Case Presentation

24 year old Abnormal Uterine Bleeding

• 24 Year Old – Nulliparous
• Engaged- plan to be married
• Long term irregular bleeding
• Wants OCP’s – planning to become pregnant in 1 to 2 years

Case Presentation
24 year old Abnormal Uterine Bleeding

• Physical Exam

• Obese
• Mild Acne
• Acanthosis nigricans
• Normal pelvic exam
Case Presentation
24 year old Abnormal Uterine Bleeding

• Started on OCP’s

• Do you agree with management?
  a. Yes
  b. No

• Bleeding continues
• Endometrial biopsy
• Complex hyperplasia with atypia
Case Presentation
24 year old Abnormal Uterine Bleeding

- Trial of megace- Biopsy no regression
- Trial of clomid- Biopsy no regression
- Lost to follow up
- 1 year later-biopsy revealed advanced adenocarcinoma of the endometrium

---

Case Presentation
24 year old Abnormal Uterine Bleeding

- Ethical Principles
  - Autonomy- patients’ rights to bodily integrity and self determination
  - Freedom- the ability to choose or refuse treatment
  - Beneficence- duty to do good
  - Judgmental Decision- decision supported by literature or common use that is generally defensible, even if the decision results in a less than desirous outcome
THANK YOU

childrens.memorialhermann.org