Didactic:
Evaluation and Management of Complex Pelvic Floor Disorders

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URO-605: Didactic:
Evaluation and Management of Complex Pelvic Floor Disorders

Presented in cooperation with the AAGL Special Interest Group on Urogynecology

Dobie L. Giles, Chair
Faculty: Heidi W. Brown, Patrick J. Culligan, Heather van Raalte, Anthony G. Visco, Johnny Yi

This course provides a detailed overview of the evaluation and management options for complex pelvic floor disorders. We will discuss the workup for defecatory dysfunction including fecal incontinence (accidental bowel leakage). Surgical options for the defecatory disorders, including fistula management, will be reviewed. Treatment options for Overactive Bladder (OAB) patients who have failed medical management will be discussed. Current surgical options for Stress Urinary Incontinence will include a discussion of synthetic slings, mini-slings, pubo-vaginal slings and Burch/MMK. The repair of utero-vaginal prolapse with and without mesh will be discussed and the course will conclude with tips on the management of mesh complications.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) Discuss treatment options for defecatory dysfunction including fecal incontinence; 2) compare different surgical treatment methods for Stress Urinary Incontinence; 3) discuss treatment options for refractory Overactive Bladder; and 4) describe treatment options for complications associated with mesh.

Course Outline

7:00 Welcome, Introductions and Course Overview D.L. Giles
7:05 Evaluation and Management of Defecatory Dysfunction – Testing, Imaging, and Diet H.W. Brown
7:30 Evaluation and Management of GI/GU Fistula H. van Raalte
8:20 Refractory Overactive Bladder Treatment D.L. Giles
8:45 Questions & Answers All Faculty
8:55 Break
9:10 Surgery for Stress Urinary Incontinence A.G. Visco
9:35 When to Use Mesh in Prolapse Repairs P.J. Culligan
10:00 Surgical Treatment of Prolapse Without Mesh J. Yi
10:25 Tips for Management of Mesh Complications H. van Raalte
10:50 Questions & Answers All Faculty
11:00 Adjourn
PLANNER DISCLOSURE
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Defecatory Dysfunction: Evaluation & Management

Heidi Brown, MD, MAS
University of Wisconsin - Madison
November 14, 2016

URO-605
Evaluation and Management of Complex PFDs
AAGL 45th Global Congress
Orlando, FL

Objectives

In the next 25 minutes, to:

1. Use the learning process to better understand relevant terminology
2. Describe components of initial evaluation
3. Identify indications for referral
4. Describe potential additional testing
5. Describe initial management from the gynecologist’s perspective

Relevant Terminology

Functional Constipation (Rome IV)

1. > 2 symptoms with > 25% of defecations in last 3 mo*
   - Straining
   - Lumpy or hard stools
   - Sensation of incomplete evacuation
   - Sensation of anorectal obstruction / blockage
   - Manual maneuvering required (vaginal / rectal)
   - Fewer than 3 defecations / week
2. Loose stools rarely present without use of laxatives
3. Insufficient criteria for irritable bowel syndrome
   * Symptom onset ≥ 6 months ago

Disclosures

I have no financial relationships to disclose.
International Consultation on Incontinence

- **Straining to defecate**: need to make intensive effort (by abdominal straining or Valsalva) to initiate, maintain, or improve defecation
- **Splinting**: need to digitally replace vaginal prolapse / apply manual pressure to vagina / perineum
- **Manual evacuation**: placement of fingers in the rectum to evacuate stool
- **Feeling of incomplete evacuation**: rectum does not feel empty after defecation
- **Diminished rectal sensation**: decreased / absent sensation of contents in the rectum


**Initial Evaluation**

- **Initial Evaluation: History**
  - Is it really constipation?
    - Nature and duration of symptoms
    - Two-week bowel diary (nutrition/dietitian)
  - Careful medication history
  - Other systemic symptoms?
  - Alarm symptoms?

**Bristol Stool Chart**

I CAN’T POOP!

- Cation-containing
- Analgesic
- Anticholinergic
- Neuromuscular

**History: Medications**

- Neurologic Disorders
  - Multiple Sclerosis
  - Parkinson Disease
  - Spinal cord lesion
  - Autonomic neuropathy
  - Chagas Disease

- Endocrine Disorders
  - Diabetes mellitus
  - Hypothyroidism
  - Pan hypopituitarism

- Miscellaneous
  - Hypokalemia
  - Anorexia nervosa
  - Pregnancy
  - Systemic sclerosis
  - Myotonic dystrophy

- Obstruction
  - Malignancy
  - Hirschsprung disease
  - Dyssynergic defecation

**History: Systemic Symptoms**
History: Alarm Symptoms

- Hematochezia or + FOBT
- Unexplained anemia
- Weight loss (≥10 pounds)
- FH colon cancer / IBD
- Acute onset in older adult
- Sudden changes to stool caliber / obstructive symptoms

Initial Evaluation: Physical Exam

- External evaluation
  - Hemorrhoids
  - Fissures
- Digital Rectal Exam
  - Tone with valsalva, at rest, with squeeze
  - Stool presence & consistency
  - Rectal prolapse?
- Pelvic exam

Prolapse and defecatory dysfunction

Posterior or apical vaginal support defects can cause defecatory dysfunction.

Rectocele

Enterocele

Indications for Referral

1. Alarm signs → GI
2. Concern for systemic cause of constipation → PCP or GI
3. If planning surgery and not up to date on colorectal cancer screening → PCP or GI
4. Failure to respond to conservative management options → GI

Additional Testing?

1. Labs?
   - CBC, glucose, Cr, calcium, TSH
2. Imaging / functional testing?
   - Endoscopy
   - Radiography
   - ARM / BET
   - Colonic transit studies
   - Defecography
Before going any further…

AGA medical position statement on constipation, January 2013
https://www.guideline.gov/summaries/summary/43610

Strong Recommendations with varying evidence quality

AGA Strong Recommendations

- Only a CBC is necessary (Low)
- No metabolic tests unless clinical features suggest otherwise (Moderate)
- No colonoscopy unless alarm sx or overdue for CRC screening (Moderate)
- ARM/BET if laxatives no help (Moderate)
- No defecography before ARM/BET (Low)

Endoscopy

- > 50 years old without prior colorectal cancer (CRC) screening
  - Family history of CRC / IBD
  - Alarm features
  - Planning surgery for constipation

Initial Treatment Recommendations

1. Stop medications that may be contributing
2. Patient education re: dietary changes
3. Fiber supplementation (with adequate fluid intake) to goal of 25-35 g daily
4. Consider therapeutic trial of osmotic or stimulant laxatives
5. Anorectal testing if no response

Radiography

- Mass lesions
- Strictures
- Megacolon
- Megarectum

http://www.nature.com/ajg/journal/v95/n10/full/ajg20001462f1.html
**AGA Recommended Evaluation Algorithm**

**Balloon Expulsion Test**

**Anorectal manometry**
- Rectal sensation and compliance
- Reflexive relaxation of IAS (RAIR)
- Manometric patterns with attempted sensor expulsion (pseudodefecation)
- Can predict response to biofeedback

**Abnormal ARM**

http://www.chijil75.co.kr/sub02/d-09-02.php

**Colonic Transit Study**

Day 0: Swallow 1 capsule (24 Sitz markers)
Day 5: Plain film abdominal X-ray

http://www.ucl.ac.uk/medicalschool/current-students/learning-resources/Virtual-consulting-room/medicine/gastroenterology/pic_protocols/protocols/colonic_transit/colonic_transit.htm
AGA Recommended Evaluation Algorithm

Defecography

Prior to defecation  During defecation

Before closing...

AGA Strong Recommendations

1. Stop constipating medicines and try fiber with or without laxatives (Moderate)
2. Long-term laxative use is safe for normal and slow transit constipation (Moderate)
3. Pelvic floor retraining by biofeedback therapy recommended over laxatives for defecatory disorders (High)
4. Re-evaluate anorectal tests and colonic transit if symptoms persist after adequate biofeedback therapy trial (Low)
AGA Weak Recommendations

1. Consider newer agents if laxatives fail for normal/slow transit (Moderate)
2. Consider subtotal colectomy over chronic laxatives for slow transit without defecatory disorder (Moderate)
3. Consider colonic intraluminal testing (manometry, barostat) to document colonic motor dysfunction before colectomy (Moderate)
4. Consider suppositories or enemas in addition to oral laxatives for patients with refractory pelvic floor dysfunction (Low)

AGA medical position statement on constipation, January 2013
https://www.guideline.gov/summaries/summary/43610

AGA Recommended Treatment Algorithm

The Gynecologist’s Management: FPMRS

Fiber & fluid – 25-35 g/day, dietetics referral
Patient education
Medications (laxatives – polyethylene glycol)
Referrals (pelvic floor physical therapy, GI, health psych, nutrition/dietetics)
Surgical correction (if appropriate candidate)

Surgical repair

1. Offered if symptoms persist after other treatments fail.
2. Posterior compartment prolapse with native tissue vaginal posterior repair has success rates for anatomic restoration of 76–98% for traditional posterior colporrhaphy and 56–100% for site-specific repairs.
3. No role for biological or synthetic grafts in the posterior compartment.


Post-op: avoid constipation / straining

http://www.evidentlycochrane.net/feet-up-constipation/

References Consulted

- Mugie SM. Chapter 4: The value of fluoroscopic defecography in the diagnostic and therapeutic management of defecation disorders in children, in: Unraveling childhood constipation: Pathophysiology, diagnostics and treatment, 2014 (Downloaded from UvA-DARE, the institutional repository of the University of Amsterdam (UvA), http://hdl.handle.net/11245/2.137981, File ID uvapub:137981
- Rome IV Criteria: http://theromefoundation.org
- Wald A. Etiology and evaluation of chronic constipation in adults. Up To Date (www.utdol.com) May 12, 2016 (lit review current as of Sep 2016).
Evaluation and Management of the Gentiourinary or Gastrointestinal Fistula

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Disclosure

I have no financial relationships to disclose.

Learning Objectives

• Define the types of fistulas and associated symptoms encountered affecting the pelvic floor.
• Describe the risk factors for developing a GI or GU fistula.
• Describe the pre-operative evaluation and surgical principles and techniques for repair.

Fistula Locations in the Pelvis

GU Fistulas
• Vesicovaginal Fistula
• Ureterovaginal Fistula
• Urethrovaginal Fistula
• Vesiocutaneous Fistula
• Peritoneal Fistula to the Vagina

GI Fisultas
• Enterovaginal/ Colovaginal Fistula
• Rectovaginal Fistula
• Colovesicular Fistula

History:

• 2050 BC: Earliest documented fistula: Egyptian mummy, Queen Henhenit
• 1676: Roonhuyse- first documented attempt at repair
• 1852: Sims- improved technique with position and use of silver suture
• 1890: Trendelenberg- first transvesical approach
• 1914: Latzko- partial colpocleisis after TAH

1. Bladder Cavity
2. Infected bladder mucosa
3. Vesicovaginal fistula
4. Arm

The pelvis of Queen Henhenit. From Zacharon M. Obstetric Fistula
Etiology:

- Obstetrical Complication
- Gynecologic Surgery Complication
- Radiation Therapy
- Pelvic Trauma
- Foreign Body (neglected pessary, bladder stone, implanted material, tumor)
- Inflammatory Conditions (UC, Crohn's Dz)

Obstetrical complications

- Estimated to affect 2-3 million worldwide
- Highest prevalence in Africa, Asia, and South America
  - Complicates 2-5/1000 deliveries in sub-Saharan Africa

Obstetric Fistula Prevalence

* Reported by UN 1991

Top 5:
- UN Report Nov 27, 2007

Bottom 5:

Fig. 1. Relationships between the fetal head and maternal pelvis in higher primates: Pongo (orangutan), Pan (chimpanzee), Gorilla (gorilla), and humans. Redrawn from Schultz (1963) and Lautenberger (1965). Copyright Worldwide Fistula Fund, used by permission.
Maternal Mortality

VVF Prevalence

• The WHO estimates that 585,000 women die in childbirth per year. Of these, 219,000 are in sub-Saharan Africa.
  • The risk of dying in pregnancy or labour in Scandinavia is 1 in 30,000. For a woman in Africa, the risk is 1 in 12.
  • For each one that dies, it is estimated another 30 women sustain injury or infection.

• There is an estimated 1.5 and 2 million women in Africa alone who suffer from this condition.
• WHO estimates an additional 50,000 to 100,000 new cases/year.

Contributing Factors

• Marriage and conception at a young age (10 to 15 years of age), often before the pelvis has reached full size.
  • 50-80% percent of women in Africa with VVF are under 20 years old

• Immature pelvic size from chronic malnutrition and the young ages of these women, increases the risk of cephalopelvic disproportion and malpresentation.

• Few women have qualified health care providers or have access to medical facilities during childbirth

Diagrams:

- VVF Prevalence
- Contributing Factors
- Diagrams showing the relationship between low socio-economic status, malnutrition, limited social roles, lack of education/literacy, early marriage, childbirth before pelvic growth is complete, relatively large fetus/malpresentation, cephalopelvic disproportion, and lack of emergency obstetrical services leading to obstructed labor.
- Diagrams showing the relationship between obstructed labor, urinary incontinence, fistula formation, complex urologic injury, vaginal scarring and stenosis, secondary infertility, musculoskeletal injury, foot drop, chronic skin irritation, urine odor, stigma, isolation and loss of support, divorce or separation, worsened poverty, suffering, illness, premature death, and fecal incontinence.
Pathophysiology:

- Ischemia
- Tissue compression
- Necrosis
- Fistula

VVF Symptoms:

- Continued leakage of urine without urge or frequency, throughout day and night.
- Gross hematuria >48 hours after surgery or delivery
- Abdominal pain, distention, paralytic ileus
- Rarely present with vaginal/bladder pain

Evaluation:

- Physical Exam
  - Visualize defect if possible/"Dimple" - Dye test
  - Tampon test
- Cystourethroscopy
- Intravenous Pyelogram
- Additional imaging if needed

Pelvic cross section depicting a high vesicovaginal fistula
Fistula not identified on speculum exam

Fill bladder with methylene blue dye under speculum exam to attempt to visualize a leak point.

If still cannot see, proceed with tampon test filling the bladder with a methylene blue solution.

Consider using pyridium to evaluate for ureterovaginal fistula. Orange dye will confirm ureterovaginal fistula.

VVF Locations

Urethra

Small Juxta-urethral VVF
Vesicovaginal Fistula Repair:

[Images of medical procedures and anatomical sites with annotations]
Principles of Surgical Repair

- Adequate urinary diversion
- Maintenance of Infection-free Environment
- Adequate Drainage
- Adequate Exposure
- No tension on Suture Lines
- Graft Use when appropriate
  - Graft vascular tissue to the site of repair if needed
  - Graft of biologic tissue (ex: SIS or MatriStem)
- Non-apposition of suture lines
- Minimize bleeding and risk for PO hematoma

Flaps/ Grafts:

- Peritoneal Flap
- Omental graft
- Labial fat pad graft (with or without bulbocavernous muscle)
- Island bulbocavernosus musculocutaneous flap
- Rectus or gracilis muscle flap
- Medial thigh, gluteal, abdominal wall flap
- Commercially available "Regenerative" Graft
  - Cook (SIS) or Acell (MatriStem)

Martius/ Labial Fat Pad Transposition:

- Can be used for vesicovaginal and rectovaginal fistulas
- Cosmetically acceptable
- Fat pad is mobilized bilaterally
- Blood supply ligated anteriorly, inferior supply maintained
- Subcutaneous tunnel created from the base of the fat pad (posterior aspect) into the vaginal dissection
- Fat pad fixed with delayed absorbable sutures

Martius/ Labial Fat Pad Transposition:

- Brandes SB, Urethral Reconstructive Surgery, 2008
Martius/Labial Fat Pad Transposition:

Martius/Labial Fat Pad Transposition:

Martius/Labial Fat Pad Transposition:

Martius/Labial Fat Pad Transposition:

VVF Fistula Post-operative management

- Maintain foley catheter for 2-6 weeks
  - Dependant on size and location of fistula
  - Dependant on medical comorbidities
  - Dependant on complications of the surgical repair.
- Medication for bladder spasm
- Bladder analgesic prn
- Adequate nutrition and hydration
- Cystoscopy at time of catheter removal and 1-2 months after or as needed

Fistula Abdominal Repair

Indications:
- High, inaccessible VVF or RVF
- Multiple fistulas
- Involvement of the uterus or small bowel
- Need for ureteral reimplantation

- Surgical preference or expertise to perform through minimally invasive L/S or Robotic approach.
Peritoneal Vaginal Fistula
- Rare complication of a hysterectomy
- Case reports only in the literature
- Symptoms:
  - Ongoing vaginal drainage of straw to clear colored fluid
  - Rarely associated with peritonitis or pain
- Evaluation:
  - Unchanged in color with oral dye testing (pyridium or methenamine) or dye instilled in the bladder on tampon testing.
  - Negative cystoscopy, negative urogram/fistulogram
  - Can be difficult to clinically visualize tract in the office if at the site of the cuff (irregular surface). In the OR may place sterile probe or pediatric catheter for identification.
- Treatment:
  - If not resolution through initial suture healing, will likely need surgical treatment.

Vesicouterine Fistula
- Result of OB trauma, such as bladder injury at C/S
- Cyclic hematuria (Youusel’s Syndrome)
- Can diagnosis through MRI or hysterosalpingogram
- Surgical repair is abdominal
- Cystotomy at the dome of the bladder to identify the fistula site, dissect the bladder off the uterus and repair the fistula
- Interposition of omentum between uterus and bladder

Recurrent Fistulas
- Published success rates with wide variation from 12-100%
- Evaluate for recurrence or additional site
- Review prior approaches for repair
- Can repeat vaginal approach if indicated, however must use an alternative technique (such as a vascular graft use)
- An abdominal approach may be warranted
- Last option is diversion: Either temporary for extensive reconstruction procedures (colostomy with option for reversal) or long-term treatment (urinary conduit, such as the Miami pouch)
Fistula Prevention

- Backfill bladder if needed to demarkate borders of bladder
- Minimize electrosurgery use next to the bladder/ureters or bowel.
- Minimize potential for crush injury or devascularization
- Nutrition
  - If cystostomy at “at risk site” maintain foley catheter to 7-10 days for small defects (<0.5-1cm). Leave in longer (4-6 weeks) for complicated patients, medical comorbidities, larger defects.
    - Control for dietary irritants and consider anticholinergic medication/bladder analgesic.

Once you have found the fistula… you need to keep looking.

Multiple fistulas occur in up to 15% of cases

IVP/ CT Urogram or Fistulagram:

- Evaluate for ureteral involvement.
- Ureteric injury is associated with 10-15% of VVF’s.
- Ureteral injury occurs in up to 10% of post-op fistulas

Ureterovaginal Fistula

- Initial treatment with stent placement. The earlier the intervention, the more likely stent placement is possible.
  - 82% stent placement if <1 month
  - 33% stent placement if older
- May need retrograde and antegrade techniques
- Stents x 6-8 weeks
- If stent not possible, percutaneous nephrostomy placed ➔ Ureteroneocystotomy
  
  Seltzman et al, 1995

Rectovaginal/Enterovaginal Fistulas

Etiology

- Obstetric Complication
- Colorectal or Gynecologic Surgery
- Prior Radiation Therapy
- Trauma
- Foreign Body
  - (Retained Pessary, Implanted Material, Tumor, etc)
- Inflammatory Disease
  - Crohn’s Disease (0.2% to 2.1% incidence with flares)
  - Ulcerative Colitis
- Diverticular Disease (Entervaginal Fistula)
Rectovaginal Fistula


Principles of Surgical Repair

- Maintenance of Infection-free Environment
- Adequate Drainage
- Adequate Exposure
- No tension on Suture Lines
- Graft Use when appropriate
  - Graft vascular tissue to the site of repair if needed
  - Graft of biologic tissue (ex: SIS or MatriStem)
- Non-apposition of suture lines
- Reapproximate the layers of the rectum, internal and external sphincter.
- Possible fecal diversion pre-operatively

Recurrence of Rectovaginal Fistulas

- Wide variation in published success rates from 29-100%
  - Differences in technique
  - Differences in patients conditions
- For recurrent RVF, need to assess prior repair and evaluate whether an alternative approach could be attempted versus diversion preceding repair

Evaluation

- Physical Examination
  - Gel with Dye
  - Oral Charcoal
  - Tampon test
  - Air Test
- Colonoscopy
- Imaging with MRI, Ultrasound, CT Fistulogram, Rectal Contrast Defogram

References:

1. Zacharin RF, Obstetric Fistula
2. Source: OBG MANAGEMENT. August 2003
5. Gillenwater, Adult and Pediatric Urology, Urinary Fistula, 1272-1287, 2002

Conclusion

- Fistulas affecting the GU or GI systems into the vagina are rare, but potentially devastating complications of obstetrical and gynecologic interventions
- Early diagnosis and treatment can be critical for minimizing comorbidities
- Applying the principles of surgical repair are critical for success, including:
  - Tension-free repair, with full-thickness, multi-layer closures
  - Non-apposition of suture lines
  - Low threshold for graft use to augment the surgical repair
Disclosures

I have no financial relationships to disclose.

Management of FI/ABL – Surgery, Neuromodulation, Injections and Inserts
Heidi Brown, MD, MAS
University of Wisconsin - Madison
November 14, 2016

URO-605
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Objectives

In the next 25 minutes, to:

1. Use the learning process to better understand anal continence mechanism and pathophysiology of fecal incontinence
2. Identify at least three current strategies for treatment of fecal incontinence
3. Identify most appropriate therapies for common symptom presentations

Fecal Incontinence:
the involuntary loss of liquid or solid stool that is a social or hygienic problem

- anal incontinence - flatus
- fecal urgency - inability to defer defecation for 15 min


Not just a female problem!

8.9% of US women have monthly FI
7.7% of US men have monthly FI

Prevalence increases with age


1 in 6 older women has ABL.


Preferred Terminology

Accidental Bowel Leakage (n=667)


Anal Continence Mechanism

Sampling Process

Prerequisites for continence

- Intact Muscles
- Intact Nerves
- Normal rectal compliance
- Normal stool consistency
- Normal cognitive function
### Risk factors for incontinence

- Intact Muscles – injury, surgery, trauma, obstetrics, congenital
- Intact Nerves – spina bifida, SCI, pudendal injury, diabetes, stroke, MS
- Normal rectal compliance – radiation, proctocolitis, cancer, impaction
- Normal stool consistency – diarrhea, constipation, bowel disorders
- Normal cognitive function – dementia, delirium

### Management Strategies

#### First Line Management: Conservative

Goals: Optimize stool consistency and rate of delivery
- Dietary modifications
- Fiber supplementation
- Avoidance of triggers
- Medications?
  - Laxatives
  - Antibiotics
  - Antacids
  - NSAIDS
  - Oral hypoglycemic agents

### Severity Distribution

#### Fiber Supplementation: Why?

- SCFA's
  - Colonic water absorption, cell metabolism
- Insoluble
  - Stool bulking, water-holding, gelling

More rectal distension → sensory awareness
- Reduced liquidity of stools
- More complete rectal evacuation

Best evidence supports psyllium

- Double-blind, placebo-controlled RCT of psyllium, gum arabic, and carboxymethylcellulose
- 16g total fiber/day x 32 days; N = 189


![Pie chart showing episodes per week for placebo, psyllium, gum arabic, and CMC. Only psyllium shows gel effect.]

Medications

- Loperamide:
  - More effective for urgency
  - No different from psyllium in FIRM RCT
  - More side effects

- Polyethylene glycol:
  - Superior to lactulose (stools per week, stool form, abdominal pain, gas)


Pelvic Floor Muscle Exercises & Biofeedback

- Strengthen external anal sphincter and puborectalis muscles
- Improve rectal sensation
- No RCTs
- If patient perceives improvement, why not?

Pelvic floor exercises image


Biofeedback

- Enema: 60% reduction in sensations; improvement in quality of life
- Rectal evacuation: 5% ENEM stimulation
- Biofeedback: 70% improvement


Management

- Optimization of stool consistency
- Modification of stool delivery
- Optimization of muscle strength
- Minimally invasive therapies
- Surgical options to
  - Optimize function
  - Restore anatomy

Minimally Invasive Therapies

- Image of biopsies and therapies
Renew rectal insert

• N = 85 subjects
• 6 episodes / week → 1 episode per week (3 months)
• No device-related serious adverse events
• Mild irritation and urgency


Eclipse™ vaginal bowel control system

• N = 61 subjects fitted / 110 enrolled
• 6 episodes / week → 1 episode per week (1 month)
• No device-related serious adverse events
• Pelvic cramping and discomfort (esp during fitting)


Eclipse™ vaginal bowel control system

Anal bulking injection: NASHA Dx

Surgical Therapies

Normal anal sphincter

Disrupted external anal sphincter

Overlapping sphincteroplasty

Sphincteroplasty Success

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Year of publication</th>
<th>Mean follow-up time (months)</th>
<th>Success rate (percentage of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kardos et al.</td>
<td>2001</td>
<td>40</td>
<td>18%</td>
</tr>
<tr>
<td>Ishihara et al.</td>
<td>2002</td>
<td>24</td>
<td>40%</td>
</tr>
<tr>
<td>Darouiche et al.</td>
<td>2004</td>
<td>120</td>
<td>42%</td>
</tr>
<tr>
<td>D'Amore et al.</td>
<td>2006</td>
<td>60</td>
<td>43%</td>
</tr>
<tr>
<td>D'Amore et al.</td>
<td>2007</td>
<td>84</td>
<td>43%</td>
</tr>
<tr>
<td>D'Amore et al.</td>
<td>2008</td>
<td>125</td>
<td>14%</td>
</tr>
<tr>
<td>D'Amore et al.</td>
<td>2009</td>
<td>63</td>
<td>14%</td>
</tr>
</tbody>
</table>

*Success variable defined in studies. Good, excellent or complete continence included as success.


Sphincteroplasty

- Addresses isolated anatomic defect
- Better results after acute sphincter disruption
- Low long-term success rates
- Risks of infection, wound separation, persistent / worse fecal incontinence

Replacing the Sphincter

Magnetic Anal Sphincter: Fenix

- Implanted around anal canal to maintain closure
- Expands to allow stool passage, then reapproximates

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The sphincter is almost never the only problem.
References

Refractory Overactive Bladder Treatment

Dobie Giles, MD, MS
University of Wisconsin - Madison
November 14, 2016

URO-605
Evaluation and Management of Complex PFDs
AAGL 45th Global Congress
Orlando, FL

Objectives

1. Review Overactive Bladder
2. Review AUA Guidelines for treatment of OAB
3. Discuss two Neuromodulation techniques
4. Discuss Botulinum toxin

What is Overactive Bladder?

Urinary urgency, usually accompanied by frequency and nocturia, with or without urge urinary incontinence

— International Continence Society

Affects > 38 million Americans (1 in 3 elderly adults)

Medications

- Several medications are available
  - Oxybutynin
  - Tolterodine
  - Solifenacin
  - Fesoterodine
  - Darifenacin
  - Trospium
- There are 5 subtypes of muscarinic receptors
  - Stimulation of M2 receptors will inhibit the sympathetic pathways to the bladder (thereby inhibiting relaxation of the detrusor muscle).
  - Stimulation of M3 receptors promote detrusor contractions.
- Contraindicated with narrow-angle glaucoma and those at risk for urinary retention (Bladder Outlet Obstruction).
- Side effects of dry mouth, dry eyes and constipation.
  - Less with extended release versions.
  - 18% of patients continue with antimuscarinic medications after 6 months.
Medications

- Something other than an Antimuscarinic B3-adrenergic agonist
  - acts on the B3-adrenoceptors in the wall of the bladder
  - Relaxation during the filling and storage phases of micturition.
- Contraindicated in uncontrolled hypertension.
- Side effects include hypertension, UTI, nasopharyngitis and headaches.
- Mirabegron

Sacral Neuromodulation

- In 1997 InterStim® received FDA approval for the treatment of urinary urgency incontinence.
  - This is the only available system.
- Efficacy due to the complex intrapelvic, intraspinal and supraspinal neural networks which control bladder (and bowel).
- Thought to act by activation of afferent sacral nerve fibers that inhibit parasympathetic motor neurons, thereby preventing detrusor contractions.
- Despite several neuro-imaging studies the true mechanism of action is not fully elucidated but clearly involves multiple neural pathways.


Sacral Neuromodulation

- Analysis at 2 years after implantation
  - Number of voids per day was significantly reduced (17.7 to 10.6; p<0.01)
  - 56% of patients showing 50% or greater reduction in the average voids per day
    - Including 32% who returned to a normal range of 4 to 7 voids per day.
  - Eventual reoperation for end of battery life is a reality for all patients.
  - Patients with currently available devices are unable to have axial MRI’s due to concerns about heating of the lead and potential nerve damage.


Sacral Neuromodulation

- Insite Trial (5 years)
  - RCT of Sacral Neuromodulation and Medical Management
    - 83% efficacy with SNM
  - Most frequent adverse events
    - undesirable change in stimulation (49/272, 18%)
    - implant site pain (34/272, 13%)
    - lack of efficacy (16/272, 6%)
    - Lead migrations were reported in 4% of subjects (12/272)
    - Implant site infections were reported in 4% of implanted subjects (10/272).
  - SGS Systematic Review
    - Superior to antimuscarinic at 6 months in one RCT. Must be weighed against discomfort, pain and infection.


Sacral Neuromodulation

- It is a two-step process
  - First step is to test to see if patient will respond
    - Office based Peripheral Nerve Evaluation (PNE) - office
    - Intraoperative placement of a lead wire - Operating Room
  - Second step in the operating room
  - Success is a 50% improvement in the symptoms
Sacral Neuromodulation

- PNE (Peripheral Nerve Evaluation)
  - Patients do not receive perioperative antibiotics
  - Can be performed with or without Fluoroscopy
  - Place temporary bilateral test leads to allow the patient to switch sides in the case of lead migration or decreasing sensation on one wire.
  - Disadvantages include a shorter test phase for the patient (3 to 7 day trial) without any ability to modify programs due to the use of bilateral unipolar leads.
  - Higher rate of false positives with a lower success rate.
  - Advantage – if successful can go to OR for full implant and save a surgical procedure.


Sacral Neuromodulation

- The staged approach is performed in the OR
  - Light sedation and local anesthesia.
  - First generation cephalosporin (AUA Guidelines)
  - Post operative 5-day course of antibiotics to cover for skin flora
  - Using fluoroscopy the permanent tined quadrivalent lead is placed through the S3 foramen
    - A longer two-week test phase is feasible without risk for lead migration or decreasing stimulation over that time.
    - The advantage of using the quadrivalent lead and multiple programs, as well as fluoroscopic placement leads to a higher conversion rate to full implant.
    - The patient wears a temporary stimulator box attached through a percutaneous lead extension wire.
  - Stage 2 (or Full Implant if PNE)
    - The Implantable Pulse Generator (IPG) is implanted.


Optimally placed lead has a characteristic appearance on an AP and lateral sacral film the lead occupies the most superior and medial position within the foramen and the contact points have a characteristic spacial orientation in each projection.

An ideally placed lead yields similar motor responses (bellow of the perineum first, Great toe flexion second) at thresholds under 2 volts or less on each contact.

The radiographic and motor response pattern predicts if the patient will sense stimulation comfortably in the genital region.

Optimizing the lead placement is likely to result in longer battery life of the device, less frequent reprogramming overall and greater chance of resolving problems with reprogramming instead of surgical revision.

Curved stylet improves ability to achieve a positive motor response at low thresholds in all four electrodes.


http://dx.doi.org/10.1016/j.urology.2016.06.004
PTNS first described by Stoller in 1990s.
- Mech of action is unknown – likely to exert both motor and sensory neuromodulatory effects, such as increasing inhibitory tone, decreasing awareness of abnormal stimuli.
- Approved FDA in 2005 for the treatment of refractory OAB.
- Urgent PC® (Uroplasty, Minnetonka, MN, USA).

A 34 G needle electrode is inserted into the skin 5 cm (3 fingerbreadths) cephalad to the medial malleolus and 2 cm (1 fingerbreadth) posterior to the tibia at a 60 degree angle. A surface electrode is attached to the skin near the medial aspect of the calcaneous bone.

Posterior Tibial Nerve Stimulation

- Burton (2012 Meta-analysis)
  - PTNS were 7 times more likely to have successful treatment compared to placebo.
- Peters (2010 Sham procedure) showed improvement in 54.5% vs 20.9%.
- Gaziev (2013 systematic review) success rates between 54 – 79%.

Side effects – pain, bruising and cramping.


Posterior Tibial Nerve Stimulation

- Treatment is accomplished through a retrograde stimulation from the posterior tibial nerve to the afferent nerves of the sacral plexus.
- Treatment response can be seen as early as the first session, but may take up to six sessions.
- Complete all twelve sessions before reevaluating.
- Contraindications:
  - Pacemakers or implantable defibrillators
  - Excessive bleeding
  - Nerve damage that can affect tibial nerve or pelvic floor function
  - Pregnant or planning to become pregnant.


**Botulinum Toxin**

- Botulinum neurotoxin (BoNT) is formed by Gram + anaerobic spore forming Clostridium botulinum. Used in chronic migraines, chronic pain, head and neck dystonias, strabismus, hyperhidrosis, and anal fissures.
- It is the most potent known neurotoxin.
- Acts a a muscle paralytic by inhibiting the presynaptic release of acetylcholine from the motor neurons, thereby inhibiting muscle contraction.


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**Botulinum Toxin**

- The active 150 kDa polypeptide has 3 separate domains.
  - 1-the C terminus which binds pre-synaptic membranes
  - 2-the N-terminus (L-chain)
  - 3-the middle domain which facilitates translocation of the L-chain into the cytosol
- Translocation of the toxin is correlated with synaptic activity and thus the most active nerves are preferentially affected.
- There are 7 subtypes of the L-chain (A-G). BoNT-A is used most commonly for therapeutic applications.


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**Botulinum Toxin**

- BoNT-A cleaves synapotsomal-associated protein (SNAP-25), which is necessary for fusion of synaptic vesicles at the cellular membrane, thus specifically preventing the SNARE-mediated release of neurotransmitters into the synaptic cleft.
- BoNT-A prevents the release of several NTs (acetylcholine, adenosine triphosphate
  [ATP], substance P)
- EMBARK trial (RCT of Botox A vs placebo) showed a decrease in UI episodes (-2.65 vs -0.87) and complete continence in 22.9% vs 6.5%.
- ABC Trial (RCT of anticholinergic vs botox). Showed similar reductions in number of UI episodes daily. Both improved QOL. Anticholinergics had greater rates of dry mouth while Botox had greater rates of voiding dysfunction (need for catheter and UTI).
- Most common side effects are UTIs (2-32%) and Urinary retention requiring self-catheterization (19% with 200 units and 5% with 100 units).


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**Botulinum Toxin**

- NDO – 2 double bind, placebo-controlled, phase three studies (691 patients) with MS or SCI.
  - Received 30 x 1 ml trigone sparing injection of 200 u, 300 u or placebo.
  - Reduction in number of voids and increase in QOL
  - No difference in efficacy between 200 u and 300 u
  - OAB trials (50, 100, 150, 200 and 300 U versus placebo)
    - Received 20 x 0.5 ml trigone sparing injections
    - Doses 150 U and greater was no better than 100 U.
    - Dose-depandent urinary retention the more units used.
    - Pts started on ISC if PVR >200 and symptoms or >350 regardless of symptoms.


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**Botulinum Toxin**

- SGS Systematic Review
  - No data of botos A vs other interventions.
  - Botox A vs antimusc – similar efficacy at 6 months.
  - Recommends self-cath if PVR >200 and symptoms or >350 regardless of symptoms.
  - The length of effect is patient-dependent and dose-dependent
  - Can not repeat before 12 weeks.
  - Patients should be contacted 3-7 days post procedure to assess the effectiveness of the injection and the bladder emptying.

Olivera CK, Meriwether K et al. Nonantimuscarinic treatment for overactive bladder: a systematic review. AJOG July 2016, 34-D
ACOG Committee Opinion 604 June 2014 (joint with AUGS).
There is no clinical dose conversion studies between the available preparations.

It is highly specific for peripheral nerves and does not spread from its site of local injection in significant quantities to cause systemic symptoms. Serious side effects are rare and usually associated with higher dose or underlying disease. See impaired vision, extremity weakness, dry mouth, dysphagia and constipation.

Absolute contraindication is active UTI or hypersensitivity to the toxin. Relative contraindications are pregnancy, motor neuropathies and concomitant use of drugs that affect the neuromuscular junction (aminoglycosides).

There is no universally accepted protocol for number or location of injections.

In clinic – 10-30 minutes before instill 30 mg of 2% lidocaine. Drain and flush bladder before injection.

100 units of onaBoNT-A diluted into preservative-free saline (or 200 if NDO).

Inject 0.5 to 1.0 cc per site.

Patients who completed a 3-year extension

100 U as needed to control overactive bladder symptoms.

Rate of de novo catheterization after the first treatment was 4.0% and it ranged from 0.6% to 1.7% after subsequent treatments.

Conclusions: Long-term onaBotulinum toxin A treatment consistently decreased overactive bladder symptoms and improved quality of life with no new safety signals.

Intravesical instillation of liposomal encapsulated BoNT-A

Significant improvement of daytime freq and urge severity. But no significant improvement of urgency and UI.

Cost-effectiveness of PTNS, SNS (both PNE and tined lead), BoTN-A and optimal medical therapy (OMT) in a 5 year and 10 year time frame in the UK using a Markov model. QALYs (Quality Adjusted Life Years) were calculated.

At 5 yrs, SNS and BoTN-A were more effective and less costly than PTNS.

At 10 yrs, SNS compared to OMT was more costly and more effective

At 10 yrs, SNS/TLE was more costly and more effective than BoTN-A.

Conclusion – SNS is either cost saving and more effective compared to OMT, PTNS and BoTN-A for OAB wet.

Which is better?

Combination therapy?

Adding mirabegron 50mg to solifenacin 5 mg was significantly superior to solifenacin 5 mg alone.

Improvements in daily incontinence, daily number of micturition, and incontinence noted in a 3-d diary.

Addition of mirabegron will further improve OAB symptoms compared to solifenacin 5 or 10 mg.

Back to the Beginning
References


15. Visco AG et al. Anticholinergic therapy vs. onabotulinumtoxina for urgency urinary incontinence. NEJM 2012. 367, 1803-1813
Surgery for Stress Incontinence

AAGL November 14, 2016

Anthony G. Visco, M.D.
Professor, Dept of Obstetrics and Gynecology
Division Chief: Urogynecology and Reconstructive Pelvic Surgery

Disclosures

• Stock Ownership: Ninomed

Objectives

1. Describe common surgeries for stress incontinence
2. List common associated complications
3. Review longterm success rates

Common surgeries for UI

Clinical Case:

• 42 year old G3P3 female with stress incontinence
  – Coughing, laughing, exercise
  – Bothersome symptoms, limiting her QOL
• BMI 32
• Normal pelvic organ support
• Completed child bearing
• Eager to have this “fixed”

First Things First:

✓ Correct diagnosis (SUI vs UUI vs MUI)
✓ Appropriate bother
✓ Offered conservative management
✓ Acceptable surgical candidate
✓ ? No desire for future fertility?
**Burch Urethropexy for SUI**
- Burch urethropexy
- Stitches placed abdominally to elevate anterior vaginal wall
- Stitches attached to Cooper’s ligament

**5 Year F/U Prospective RCT**

<table>
<thead>
<tr>
<th></th>
<th>1 Yr Cure</th>
<th></th>
<th>5 Yr Cure</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Burch</td>
<td>38</td>
<td>89%</td>
<td>33</td>
<td>82%</td>
</tr>
<tr>
<td>Mod Pereyra Needle</td>
<td>34</td>
<td>65%</td>
<td>30</td>
<td>43%</td>
</tr>
<tr>
<td>Anterior Repair</td>
<td>35</td>
<td>63%</td>
<td>30</td>
<td>37%</td>
</tr>
</tbody>
</table>


**Bladder Neck Slings for SUI**
- Rectus fascia, cadaveric fascia, or fascia lata
- Placed under urethra at bladder neck

**What are the data?**
- Fascial Sling superior (66%) over Burch (49%) \( p<0.001 \)
- Higher rates of voiding dysfunction, UUI, UTI
- Serious adverse effects similar
- Treatment satisfaction higher with Sling (86 vs 78%) \( p=0.02 \)

**Mesh Midurethral Slings for SUI**
- Synthetic mesh
- Placed under mid-portion of urethra

**Mid urethral Slings**
Midurethral Slings

**Patient Benefits**

1. Minimally invasive
2. Choices of Anesthesia
   - (epidural, spinal, general)
3. Normally, same day discharge
4. Normally, no post-op urinary catheterization

**Ward and Hilton:**

**Open Burch vs TVT**

- 344 patients randomized in the UK (14 centers)
- No significant differences in 6 month cure rates
  - TVT - 66%
  - Burch - 57%
- TVT:
  - Bladder injuries more common
- Burch:
  - Longer time to voiding, longer recovery time

**Complications TVT vs Burch**

<table>
<thead>
<tr>
<th>Complications</th>
<th>Vaginal tape group (n=179)</th>
<th>Colposuspension group (n=148)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder injury (perforation or evidence of trauma)</td>
<td>15 (8)</td>
<td>3 (2)</td>
<td>0.0155</td>
</tr>
<tr>
<td>Vaginal perforation</td>
<td>2 (1)</td>
<td>0</td>
<td>0.057</td>
</tr>
<tr>
<td>Wound infection</td>
<td>4 (2)</td>
<td>10 (7)</td>
<td>0.069</td>
</tr>
<tr>
<td>Fevers**</td>
<td>1 (1)</td>
<td>7 (5)</td>
<td>0.0275</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>3 (2)</td>
<td>3 (2)</td>
<td>0.196</td>
</tr>
<tr>
<td>Inserted hernia</td>
<td>Not applicable</td>
<td>3 (2)</td>
<td></td>
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<tr>
<td>Retropubic hematoma</td>
<td>3 (1)</td>
<td>0</td>
<td>0.259</td>
</tr>
<tr>
<td>Vascular injury</td>
<td>1 (1)</td>
<td>0</td>
<td>0.05</td>
</tr>
<tr>
<td>Tape erosion</td>
<td>1 (1)</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection (in six weeks after surgery)</td>
<td>38 (22)</td>
<td>46 (23)</td>
<td>0.0746</td>
</tr>
<tr>
<td>Total complications (excluding fever)**</td>
<td>67 (36)</td>
<td>66 (44.5)</td>
<td>0.385</td>
</tr>
</tbody>
</table>

**Long Term Results of the TVT Procedure for Surgical Treatment of Female SUI**

- Prospective, study of 90 consecutive patients
- Three study sites
- Median follow-up: 56 months (48-70 months)
- Patients with ISD excluded
- 84.7% (72/85) cured
  - Negative stress test, negative 24hr pad, improved QOL ≥ 90%
- 10.6% (9/85) significantly improved
  - > 50% or < 15g/24hr, QOL ≥ 75%

TVT Complications in 1455 Patients
(38 Hospitals, Finland, through 1999)

- Voiding difficulties: 7.6%
- UTI: 4.1%
- Bladder perforation: 3.8%
- Retention: 2.3%
- Retropubic hematoma: 1.9%
- Major vessel injury: 0.07%
- Need for postop laparotomy for a complication: 0.34%


Most Common Problems:

PUBOVAGINAL SLING
- Short-term Complications:
  - Bleeding/wound seroma/hematoma
  - Injury to bladder
  - Injury bowel: rare
  - Voiding difficulty
- Long-term Complications:
  - Voiding dysfunction
  - Erosion from synthetic material

Rare But Significant Problems:

- Midurethral Sling

- Based on 500,000 cases:
- Bowel perforations: 28
- Vaginal mesh erosion: 60
- Urethral erosion: 20
- Nerve injury: 4
- Urinary retention: 93
- Hematoma: 20

TVT Complications – First 500,000

- 7 deaths:
  - 5 undiagnosed bowel perforations,
  - 1 uncontrolled bleeding retropubic space in undiag bleeding disorder
  - 1 bowel perforation no info
- Vascular injuries 44/500,000:
  - Prevent avoiding hip flexion ≥60º
  - Avoid candy cane stirrups
  - Needle medial
- Control venous direct pressure
  - Moderate bleeding with Foley with 50cc
- Retropubic hematomas self-limiting
Management of Complications

- Bladder perforations:
  - 2-4%; Foley catheter for 1-2 days
- Urinary retention:
  - 2-5% persistent requiring release
- UTI: 7-8% in 2 months postop
- Urgency:
  - usually resolves 6 weeks
  - 10-12% may persist

Trans-Obturator Slings:

- A variation of midurethral sling

Transobturator vs. Retropubic Midurethral Slings:

- Ideally not passing in Retropubic Space avoids:
  - major complications
  - retroperitoneal vascular, bowel, and bladder injuries
- Risk of injury to:
  - obturator vessels and nerves
  - long term pain syndromes
  - higher risk of mesh erosion
- Postop voiding dysfunction lower
- No evidence they are superior to retropubic slings

TVT vs TOT:

Retropubic vs Transobturator Sling; TOMAS RCT

<table>
<thead>
<tr>
<th></th>
<th>Retropubic (n=299)</th>
<th>Transobturator (n=322)</th>
<th>Statistically Equivalent?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective Cure</td>
<td>80.8%</td>
<td>77.7%</td>
<td>Yes</td>
</tr>
<tr>
<td>Subjective Cure</td>
<td>62.2%</td>
<td>55.8%</td>
<td>No</td>
</tr>
<tr>
<td>Voiding Dysfunction Requiring Surgery:</td>
<td>2.7%</td>
<td>0</td>
<td>P=0.004</td>
</tr>
<tr>
<td>Neurologic Symptoms (Weakness/Numbness):</td>
<td>4%</td>
<td>9.4%</td>
<td>P=0.01</td>
</tr>
<tr>
<td>Pain &gt; 6 weeks</td>
<td>2.3%</td>
<td>2.0%</td>
<td>0.79</td>
</tr>
<tr>
<td>Mesh exposure</td>
<td>1.3%</td>
<td>1.0%</td>
<td>ns</td>
</tr>
</tbody>
</table>

No difference in postop urge incontinence, satisfaction or QOL
What are the data?

- Good long term results with low rate of complications

What are the data?

- TVT sling is similar to Burch but less invasive

What are the data?

- Mid-urethral sling becomes the new "gold-standard" procedure for SUI

Retropubic MUS

Transobturator MUS

"Mini-sling" MUS
“Mini-sling” MUS

Mesh Slings for SUI

• Have become the “gold standard” treatment for SUI
• Best data comes from retropubic TVT
• TOT also well-studied
• Mini-slings – newer; not as well studied

Complications of Mesh Slings

• Can include:
  – Urinary retention/voiding dysfunction (4%)
  – Urgency/frequency (worsening of UUI)
  – Mesh erosion (4%)
  – Dyspareunia
  – Groin pain/neurologic (9% TOT, ? Mini-slings?)

Slings for SUI

• Underlying principle is to provide support under urethra
• Can be a highly effective treatment option for SUI
• Expect 85% improvement over long-term

Clinical Case:

• 42 year old G3P3 female with stress incontinence
  – Coughing, laughing, exercise
  – Bothersome symptoms, limiting her QOL
• BMI 32
• Normal pelvic organ support
• Completed child bearing
• Eager to have this ‘fixed’

Thank you
When to use mesh in prolapse repairs

Patrick Culligan, M.D., FACOG, FACS
Director of Urogynecology & The Center for Female Pelvic Health
Professor of Ob-Gyn and Urology
Department of Urology
Weill Cornell Medical College
New York-Presbyterian Hospital
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Better Question:
When should we NOT use mesh in prolapse repairs?

Answer:
1) Isolated anterior defects
2) Most posterior compartment vaginal cases
3) When patient declines after full informed consent
4) When radiation may be in her future

300,000 Prolapse Operations in US per Year: Breakdown of cases – 2011

Source: 2011 FDA UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication
Results of ‘Native Tissue’
Anterior Colporrhaphy

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>N</th>
<th>Follow-Up Interval</th>
<th>Success Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macer</td>
<td>1978</td>
<td>54</td>
<td>5 - 20 years</td>
<td>80</td>
</tr>
<tr>
<td>Stanton</td>
<td>1982</td>
<td>109</td>
<td>Up to 2 years</td>
<td>85</td>
</tr>
<tr>
<td>Walter</td>
<td>1982</td>
<td>78</td>
<td>1.2 years</td>
<td>100</td>
</tr>
<tr>
<td>Porges</td>
<td>1994</td>
<td>388</td>
<td>2.6 years</td>
<td>97</td>
</tr>
<tr>
<td>Colombo</td>
<td>2000</td>
<td>33</td>
<td>8 - 17 years</td>
<td>97</td>
</tr>
<tr>
<td>Sand</td>
<td>2001</td>
<td>70</td>
<td>1 year</td>
<td>57</td>
</tr>
<tr>
<td>Weber</td>
<td>2001</td>
<td>57</td>
<td>23 months</td>
<td>42</td>
</tr>
</tbody>
</table>

Uterosacral Ligament Suspension

- May be performed vaginally, abdominally or laparoscopically (either with or without hysterectomy)
- Main Pitfalls:
  - Inadequate bites
  - Overzealous bites
  - Kink sutures (up to 11% of cases)
  - Sural nerve root pain

How are we Doing with our Native Tissue Procedures in General?

- 29-40% of reconstructive procedures require surgical re-intervention for failure within 3 years
- 60% of recurrences are at the same site
- 32.5% occur at a different site due to unmasking of an occult support defect
- Reoperation is the “tip of the iceberg”

“vaginal mesh” is not a brand new concept...

- Synthetic Mesh for abdominal hernias became the “gold standard” in 2000
- Julian et al published the first RCT involving mesh in anterior prolapse repair in 1996 (AJOG)
  - Tradeoffs - BETTER “OBJECTIVE” success at the cost of MORE COMPLICATIONS
  - Erosion
  - Mesh-Related pain

Traditional non-mesh repairs work in “most cases”....

  - RCT comparing mesh to no-mesh for anterior wall (n=202)
    - 42% vs 10% failure (17.3% exposure) 3 Year follow up
  - RCT comparing mesh to no-mesh for anterior wall (n=76)
  - 43% vs 13% failure (3% exposure) 1 Year follow up
  - RCT comparing mesh to no-mesh for anterior wall (n=90)
  - 28% vs 9% failure (6.9% exposure) 1 Year follow up
- Wiltfang et al. Obstet Gynecol 2011;117(2):242-250 (n=97)
  - 45% vs 9.6% failure (16.9% exposure) 1 Year follow up
Largest RCT on the subject..
- Altman et al. NEJM 2011;364:1826-1836 (n=389)
  - 52.5% vs. 17.7% failure 1 Year follow up
  - 3% re-operated for mesh exposure

SGS Systematic Review Group
- Graft and Mesh Use in Transvaginal Prolapse Repair
- Vaginal mesh in anterior compartment provides better anatomic outcomes AND bulge symptom relief than native tissue repair.
  - 42 comparative trials including 26 RCT’s

SGS Systematic Review Group
- Posterior Compartment – “No Benefit”
  - No new evidence
  - No RCT's
- Apical Compartment -
  - No relevant studies
- Multiple Compartments – benefit in anterior compartment. No benefit seen in others
  - 10 studies (7 RCT’s)

Enterocèle
Disrupted vaginal fibromuscular capsule with enterocèle sac under epithelium

...After multiple A & P repairs

Histology of the Vaginal Wall
- Non-Keratinized Squamous Epithelium
- Thin Lamina Propria
- Concentric layers of Smooth Muscle
- Vesicovaginal / Rectovaginal space
**Histology of the Vaginal Wall**

Colporrhaphy dissection

Split thickness: vaginal epithelium is separated from underlying muscularis/fascia creating an artificial surgical plane

Full thickness: vaginal epithelium is NOT separated from underlying muscularis/fascia: but rather the entire vaginal wall is incised to allow entry into true anatomical spaces (vesicovaginal and rectovaginal)

**Histology of the Vaginal Wall**

**Full Thickness Vaginal Dissection**

**Sacrospinous Ligament Suspension**

**OPEN Sacrocolpopexy results**

- Sacral Colpopexy first described by Lane in 1962
- “Modern Version” described and refined by Addison in the 1980s
- Dubbed the “main abdominal approach to prolapse surgery” in a systematic review article 2004
- Status solidified by a Cochrane review in 2005

**Open ASC compared to SSLS**

- OPEN ASC demonstrated lower rates of:
  - Recurrent
  - Dyspareunia
- Those benefits should be balanced against:
  - Longer operative times (21 min, 95% CI 12 to 30)
  - Longer time to return to full activities (8.3 days, 95% CI 3.9 to 12.7)
  - Increased cost of abdominal approach ($1,334, 95% CI $1,027-$1,641)
Long-term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse

- Maybe sacrocolpopexy isn’t “all that”
- By post-op year 7:
  - Overall POP success rate roughly 66%
  - Mesh exposure / complication 10.5%

Laparoscopic vs. Robotic Sacrocolpopexy
- 78 patients (38 laparoscopic; 40 robotic)
- Single-center, blinded, RCT of patients with post-hysterectomy POP stage II – IV
- Robotic arm showed:
  - Longer operative time by 67 min.
  - Higher pain levels reported
  - Longer use of NSAIDS
  - Higher cost ($1,936)

ASC Approaches-5th ICI
Barber and Maher. IUJ, 2013
- ASC has the lowest inpatient costs compared with laparoscopic sacral colpopexy (LSC) and robotic sacral colpopexy (RSC).
- LSC has lower inpatient costs than RSC (grade B).
- In small trials objective outcomes appear similar although postoperative pain was greater in RSC.
- LSC is as effective as ASC with reduced blood loss and admission time (grade C).
- The data relating to operating time are conflicting.

Main Confounding Factor….. Sacrocolpopexy Continues to Evolve
- 1962 (Lane) to 2016 (Various)
  - Single graft strip
  - Cone around vaginal apex
  - Y-mesh
  - Extension down to perineum
  - SCH rather than total hyst
  - Very lightweight Y-mesh
  - Extensive coverage from trigone to perineum

Y-mesh Products available for SCP

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Pore size (mm)</th>
<th>Density (g/m²)</th>
<th>Thickness (microns)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restorelle Y</td>
<td>1.8</td>
<td>15</td>
<td>305</td>
</tr>
<tr>
<td>ALTEC® Y-mesh</td>
<td>2.5</td>
<td>17</td>
<td>287</td>
</tr>
<tr>
<td>ALTEC® Y-mesh</td>
<td>2.5</td>
<td>34</td>
<td>574</td>
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<tr>
<td>Artion (Ethicon)</td>
<td>3.9</td>
<td>28</td>
<td>533</td>
</tr>
<tr>
<td>Izatan (Bios)</td>
<td>2.8</td>
<td>25</td>
<td>200</td>
</tr>
<tr>
<td>Vertessa (Caldera)</td>
<td>2.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

49
In my opinion, this is no longer a “true” Sacrocolpopexy

• If you’re just fixing the mesh to the vaginal apex, you’re not taking advantage of the possibilities of the sacrocolpopexy procedure.

• Worse yet – lightweight may be too light for this “minimalist” technique

Sacrocolpopexy **Key Elements**

When uterus present:
Supracervical Hysterectomy

– Anterior dissection to level of trigone
– Posterior dissection to perineum
– Vaginal sutures – CV4 GoreTex
  (6 to 10 per compartment)
– Sacral Sutures – Two CV4 GoreTex
– Re-peritonealization (zero Monocryl)

**Definitions of Surgical Cure**

• **Anatomic Cure** (i.e. POP-Q stage 0 or 1)

• **Clinical Cure**:
  – No need for POP treatment
  – Apex still “up”
  – No POP-Q points > 0
  – No POP symptoms (on PFDI-20)

Our Published Results

Our most recent published results

2 prospective studies: a total of 270 patients

- **Restorelle Y mesh**
  120 patients with 12-month follow up

- **Alyte Y mesh**
  150 patients with 12-months follow up

Mean operative time
148 min (range 75 – 250)
Mean EBL: 51 mL
(range 5 - 250)
combined “clinical cure”
94%
No mesh erosions

5 year follow-up (N = 316)

Mushonga et al, AUGS Oral Presentation 2015

N=320
316 eligible for our study
(4 Died)
80% Follow-up Rate
253 participated in the study
63 lost to follow up

5-Year Follow-up of Robotic Sacrocolpopexy

- 253 Study Participants
- 226 Successfully cured (89.3% success rate)
- 27 Failed treatment (10.7% failure rate)

NO APICAL FAILURES

16 Anterior Compartment
11 Posterior Compartment


Operative and Postoperative Characteristics: All Patients (N = 786)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median estimated blood loss, mL</td>
<td>50 (IQR 3–700)</td>
</tr>
<tr>
<td>Concomitant suburethral sling, n (%)</td>
<td>601 (76.4)</td>
</tr>
<tr>
<td>Intraoperative complications, n (%)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Bowel injury</td>
<td>0</td>
</tr>
<tr>
<td>Bladder injury</td>
<td>0</td>
</tr>
<tr>
<td>Ureteral injury</td>
<td>0</td>
</tr>
<tr>
<td>Postoperative complications, n (%)</td>
<td>3 (0.4)</td>
</tr>
<tr>
<td>DVT/PE</td>
<td>0</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>0</td>
</tr>
<tr>
<td>Postoperative ileus</td>
<td>0</td>
</tr>
<tr>
<td>Postoperative bowel obstruction</td>
<td>0</td>
</tr>
<tr>
<td>Pain</td>
<td>0</td>
</tr>
<tr>
<td>Mesh erosion</td>
<td>0</td>
</tr>
<tr>
<td>Postoperative fever</td>
<td>0</td>
</tr>
<tr>
<td>Operative site infection</td>
<td>0</td>
</tr>
<tr>
<td>Neurological injury to extremities</td>
<td>0</td>
</tr>
</tbody>
</table>

Recent Case:
Stage 4 Uterovaginal Prolapse
(supracervical hysterectomy & sacrocolpopexy) operative time 2 hours 35 minutes
Surgical Treatment of Prolapse without Mesh

Johnny Yi MD
Assistant Professor of Obstetrics and Gynecology
Mayo Clinic Arizona
11/14/2016

Disclosure
• I have no financial relationships to disclose.

Objective
At the conclusion of this lecture, the MIGS surgeon should be able to:
• Identify the different surgical approaches to native tissue prolapse surgery
• Compare the success rates of native tissue surgery with mesh augmented surgery

Background
• Uterosacral fixation described as early as 1927
• Published by Milton McCall[1]
• Multiple modifications since

Let’s talk about the APEX
• 50% of anterior descent can be explained by apical descent [3]
• Anterior and posterior vaginal defects are strongly correlated with apical prolapse [4]
  • Especially when leading edge >0
• 10 years after surgery, reoperation significantly reduced if concomitant apical suspension performed [5]
Uterosacral ligament suspension/McCall's culdeplasty

- Level 1 pelvic organ support
- Distal (cervical) - 5-20mm thick - 2-3cm length
- Intermediate - 1-2cm wide - 5cm length
- Proximal - Thin and diffuse - 5-6 cm length

Where does the USLS stitch go?

- Wieslander et al
- 14mm to ureters
- 43% at level of S1
- 33% at level of S2
- 22.9% at level of S3

Uterosacral/Cardinal Ligaments

Vaginal Cuff

Uterosacral ligament

Ureter

Sacrospinous ligament fixation[1]

- True ligament from Ischial spine to sacrum - 53-54mm long
- Covered by the coccygeus muscle
- Inferior to the S3 nerve root
- Extraperitoneal approach dissected through pararectal space

SSLF benefits

- Perform with TVH or for vaginal vault prolapse
- Need adequate vaginal length
- Allows excision of excess vaginal length
- Extraperitoneal approach
- Consistent anatomy
Compared to Mesh?
• ASC v USLS
  - Recurrence less with ASC
  - AP failure 34% v 5%
  - Apex failure 16% v 0%
  - Reoperation 18% v 5%
• ASC v SSLS
  - ASC lower rate of recurrent VVP
  - Less postop SUI
  - Less dyspareunia
  - ASC longer OR time, longer recovery
  - No difference
  - Objective failure, reoperation
• SSLS v vaginal mesh
  - Higher recurrence without mesh 39% v 17%
  - Mesh exposure 20% (total Prolift), 13% surgical correction
  - Low reoperation for prolapse, both groups

Long Term Outcomes
• 660 patients underwent McCall’s for VVP
• 36 required 2nd operation (5%)
• 392 patients underwent Michigan SSLS
• 8 year followup
• 76% completely or very satisfied
• G3-4 more likely to be highly satisfied than G2

Anterior compartment

PVDR vs Anterior colporrhaphy
Minassian et al. 2014- RCT Anterior repair with polyglactin mesh vs PVDR showed no difference between objective and subjective failure rates with high satisfaction.
• Vaginal Anterior repair is less invasive
• PVDR not a successful treatment for SUI.
Shippey et al. 2010- ASC ± PVDR
• No difference in Anterior wall objective outcomes (16% with PVDR, 27% without)
• Low reoperation rate both groups, <5%

Mesh vs no mesh AR
SGS Systematic Review 2016
• 20 studies looking at mesh augmented AR
• Significantly improved anatomic outcomes compared to native repair
• No difference in QOL, urinary, sexual function
• Erosion rates 1.4-19%, operative mesh revision 3-8%
• Cochrane 2013
• Overall reoperation higher with mesh 10% vs 5%, (mesh erosion 11.4%)
SFS systematic review 2016

- “Data on use of synthetic mesh in repair of isolated posterior vaginal prolapse remain sparse.”

- Paraiso et al. Biologic augmentation with SIS showed worse anatomic failure as compared to native tissue repair. (48% v 22%)

References


Questions?
Tips for Management of Mesh Complications

HEATHER VAN RAALTE MD
MEDICAL DIRECTOR, PRINCETON UROGYNECOLOGY
CHAIR OF OB/GYN, UNIVERSITY MEDICAL CENTER AT PRINCETON
CLINICAL FACULTY, UMDNJ

Disclosures
I have no financial relationships to disclose.

Learning Objectives
• Define the three critical surgical steps of transvaginal surgery, that when optimally executed minimize the known risks of the procedure.
• Describe the risk factors for mesh exposure after TVM surgery.
• Evaluate a patient who has developed post-operative dyspareunia or exposure after TVM surgery, and implement effective therapy to achieve resolution.

How to ‘best’ define success of RPS?
• No doubt both anatomical and functional
• Composite outcomes preferred
• Absence of all of the following:
  - Apical descent > 1/3 into vaginal canal
  - A or P wall descent beyond hymen
  - Bothersome vaginal bulge symptoms
  - Retreatment for POP by pessary or surgery

Success without mesh…??
• Comparison of 2 Transvaginal Surgical Approaches and Perioperative BPMT for apical Vaginal Prolapse (OPTIMAL RCT)
• MUS plus SSLF vs MUS plus USL then randomized to BPMT vs “usual care”
• 2yr follow up rate 84.5% of 374 women
• Surgery performed by urogyn experts from 2008-2013 at 9 US Med centers (Pelvic Floor Disorders Network)

Matthew D. Barber, MD, et al. JAMA 2014;Vol 311(10)

Success without mesh…??
• At 2yrs surgical success rates:
  SSLF = 60.5%
  ULS = 59.2%
• ....or... surgical failure rates at 2 yrs:
  SSLF = 39.5% !!!!
  ULS = 40.8% !!!!

... “neither ULS nor SSLF was significantly superior to the other...”

??????????
**Why is transvaginal mesh beneficial?**

- Mesh is clearly “needed” for long term success for repair of apical/anterior defects, most likely posterior as well….evidence evolving
- New lighter, more elastic monofilament meshes may offer even better post operative function
- Transvaginal delivery is minimally invasive, technically easier than laparoscopic, more cost effective than robotic and can be performed under regional anesthesia
- Data although not robust, is rapidly growing with several level I studies completed that when properly performed, transvaginal delivery of the mesh is safe and effective

**When can transvaginal mesh become a “mess”?**

- The mesh (post implant) has undesired biomechanical properties
- Patients are not properly and fully informed of the risk and benefits of the procedure
- There is suboptimal execution of the surgery
  * dissection = exposure
  * delivery/placement = pain and failure
  * setting/adjustment = pain

**Risk Factors for Mesh Extrusion After Prolapse Surgery: A Case-Control Study**

- Multicenter case-control study of patients who underwent ASC or VMP from 2006 to 2009 and had mesh exposure through vaginal epithelium at postoperative evaluation;
- 84 cases were identified (43 after ASC and 41 after VMP), and 252 patients were matched as controls
- Concomitant hysterectomy associated with mesh exposure ASC (adjusted odds ratio, 3.18; 95% confidence interval, 1.27–7.93; P = 0.01) and VMP (adjusted odds ratio, 3.72, 95% confidence interval, 1.20–11.54; P = 0.02)
- Age, race, type of vaginal incision, menopausal status, medical comorbidities, and smoking were NOT significantly associated with extrusion in either group

**CARE: Complications**

<table>
<thead>
<tr>
<th>Group</th>
<th>Burch (n=153)</th>
<th>No Burch (n=158)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All SAE</td>
<td>56/42 (36.6%)</td>
<td>64/49 (40.5%)</td>
<td>38.6%</td>
</tr>
<tr>
<td>Surgical SAE</td>
<td>13 (9.8%)</td>
<td>22 (13.9%)</td>
<td>11.9%</td>
</tr>
<tr>
<td>Blas</td>
<td>11 (7.2%)</td>
<td>10 (6.3%)</td>
<td>6.8%</td>
</tr>
<tr>
<td>Inc. Hernia</td>
<td>3 (2%)</td>
<td>4 (2.5%)</td>
<td>2.5%</td>
</tr>
<tr>
<td>Wound Complications</td>
<td>5 (3.3%)</td>
<td>6 (3.5%)</td>
<td>3.5%</td>
</tr>
<tr>
<td>Total Reop Rate</td>
<td></td>
<td></td>
<td>2.6%</td>
</tr>
<tr>
<td>Deas</td>
<td></td>
<td></td>
<td>1.3%</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td>1.3%</td>
</tr>
<tr>
<td>Mesh/suture Erosion</td>
<td>8 (5.2%)</td>
<td>12 (7.6%)</td>
<td>6.4%</td>
</tr>
<tr>
<td>Repeat surg. prolapse</td>
<td>2 (1.3%)</td>
<td>6 (3.8%)</td>
<td>2.5%</td>
</tr>
<tr>
<td>Surg to SUT</td>
<td>7 (4.6%)</td>
<td>13 (9.5%)</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

**Trocar-Guided Mesh Compared with Conventional Vaginal Repair in Recurrent Prolapse**

- 194 enrolled, 4 no surgery, 4 lost to follow-up
- 186 of 190 (98%) available for analysis at 1yr
- 93 TVM vs 97 conventional repair
- 1* Outcome: failure in treated compartments
- 2* Outcomes: QOL, ‘bother’, EQUD,LP,PGII
- RCT, type I error 5%, 80% power, 10% drop
- 22 surgeons at 13 centers

**Results:**

- Resoperation for symptomatic recurrence in the treated compartment in 12 months: 4 in the conventional group 0 in the transvaginal mesh group
- In the conventional group failures rates were higher in both the treated anterior AND posterior compartments compared to mesh (overall 45.2% vs. 9.6%)
Trocar-Guided Mesh Compared with Conventional Vaginal Repair in Recurrent Prolapse

RESULTS:
• Significant improvements in UDI and IIQ in both groups
• UDI domains of ‘pain’ and ‘incontinence’ scored significantly better in TVM group
• PGII showed no difference in improvement:
  80% in conventional group
  81% in transvaginal mesh group

Trocar-Guided Mesh Compared with Conventional Vaginal Repair in Recurrent Prolapse

CONCLUSIONS:
• Equal improvements in symptoms and function
• TVM was associated with a significantly lower anatomical failure rate in both anterior AND posterior compartments

“The Success Equation” *

Expertise:
‘you have a model, a structured process that you apply that accurately predicts an outcome in the future…’

Experience:
‘you have done a lot over time, but yet you have failed to create such a model…”

* Mike Macbousson (professional investor, author, professor)

Anterior Colporrhaphy vs. Transvaginal Mesh for Pelvic-Organ Prolapse

• Methods:
  • Multicenter, parallel-group RCT between 2007-2008
  • Trocar-guided polypropylene mesh repair vs. traditional native tissue plication for cystocele
  • Primary outcome:
    • A composite of the objective anatomical designation of stage 0 (no prolapse) or stage 1 (more than 1cm above the hymen) AND
    • The subjective absence of bulging 12 months after surgery (Question #16 on UDI)


Results in mesh group:
• Required longer OR time: 52.6min vs. 33.5min (P<0.001)
  • Although statistically significant, not clinically significant
• More blood loss >500mL in 4 patients, >1000mL in 1 patient (2.5%)
• IFPM has a database with nearly 4,000 who have undergone transvaginal mesh repair: only 4 (0.3%) patients with blood loss >500mL

Anterior Colporrhaphy vs. Transvaginal Mesh for Pelvic-Organ Prolapse

Results in mesh group
- Higher bladder injury rate: 3.5% vs. 0.5% \( (P=0.07) \)
- IFPM rate =1%
- Higher de novo SUI rate: 12.3% vs. 6.3% \( (P=0.05) \)
- Patients undergo careful preoperative evaluation for occult SUI and risk assessment for de novo SUI
- Concomitant pubovaginal slings are placed if patients are at high risk of developing de novo SUI

IFPM rate <1%


Surgeon Experience and Transvaginal Prolapse Mesh Complications

- 5488 women with transvaginal mesh surgery
- 368 surgeons
- Median follow-up of 5.4 years (IQR 2.9-8)
- Compared results of high-volume to low-volume surgeons
  - High volume defined as 13 procedures/year

Blayne Welk, Erin Kelly, Jennifer Winick-Ng, London, Canada. AUA May 2016.

Surgeon Experience and Transvaginal Prolapse Mesh Complications

- 218 women (4.0%) underwent mesh revision
  - Median of 1.17 (IQR 0.58-1.17) years post-op
- There was a higher probability of a surgical intervention for vaginal mesh complications with non-high volume surgeons adjusted HR of 1.70 (95% CI 1.16-2.50)
- Increased medical comorbidities (HR 1.30) and Intra/post-operative blood transfusion at the time of surgery (HR 3.70) were also significantly associated with vaginal mesh revision.

Blayne Welk, Erin Kelly, Jennifer Winick-Ng, London, Canada. AUA May 2016.

Incidence of dyspareunia following vaginal prolapse repair with graft materials

Systematic review study of:
- Medline reports published between 1950 and 2010 on adverse events after vaginal prolapse repairs using graft materials
- Conclusion: erosions, wound granulation, and dyspareunia may occur after vaginal prolapse repair with graft materials, though rates vary widely across studies

\[ H. Abed et al, Int Uro J 2011 \]
The Importance of Consistent Placement of Mesh Material in Relationship to Full Thickness Vagina Wall

Mesh Exposure

• With ASC – 0.5 – 10.5%
• Vaginal Implantation – 0 - 29.7%
• Both utilizing macro-porous polypropylene mesh

WHY???

DISSECTION

• The most “difficult” step in transvaginal mesh delivery procedures
• The make or break point for achieving a low exposure rate
• Can be extremely challenging in patients with prior retro-pubic or para-vaginal dissection

Hydrodissection

• Arguably the most important aspect of transvaginal mesh augmentation
  Access to the correct anatomic spaces
  • minimizes bleeding
  • mobilizes/avoids hazards (ureters, bladder, blood vessels)
  • allows anatomically correct graft placement
  • potentially minimizes exposure risk

• Anterior Compartment
  • Literature review 80 articles anterior repair
  • "Dissection during anterior colpophaphy splits vaginal muscularis, and repair involves plication of the muscularis and adventitia (not vaginal "fascia")"

• Posterior compartment
  • Cadaveric dissection of the RV "septum"
  • "It is the splitting of the adventitial layer from the overlying vaginal wall that accounts for the "fascial layer" seen surgically"
Hydrodissection Guidance

- Set yourself up for success with manipulation of the vaginal wall and palpation of bladder through it.
- Place 2 allis clamps on the vaginal wall.
- Pinch back against the bladder to potentiate space.
- Use a 22g bevel or 18g Touhey needle.
- Use at least > 60cc per dissected compartment.
- Use 60cc marcaine w/epi diluted with 60cc injectable saline.
- Hold sagitally and displace bladder.
- Little resistance should be encountered.
- No "wheal" in epithelium (too superficial).
- Extend laterally using standard needle.

Hydrodissection Guidance

Midline Infiltration

Vaginal Wall Anatomy

Surgical placement of Mesh

Improper Mesh Placement

Dissection Technique:
Sharp Dissection

• Midline incision
  • Electrocautery or scalpel
  • Incise down to grey fluid bubble
  • Yellow fat – visual confirmation of correct space (plane)
    - Never grossly seen within bladder or vaginal wall

Vesicovaginal Space Abdominal View

Dissection Technique:
Sharp Dissection

• Midline incision
  • Lateral sharp dissection
  • Counter-traction on bubble (Atsons or gauze)
  • Use sharp dissection to separate bubble from vaginal wall
    • Tenotomy scissors: sharp Metzenbaum’s
    • Small nips – ‘Open and Spread’ technique
    • Keep scissor parallel to vaginal wall
    • Avoid “digging” into vaginal wall
    • YOU MUST SEE AND ‘FOLLOW’ THE FAT!!
Dissection Technique:
Sharp Dissection

• Lateral sharp dissection cont..

Blunt Dissection

GOAL: Blunt dissection with finger completes the dissection.

TIPS:
1. Use lateral pressure to avoid visceral injury, and gently slide the flat portion on the inside of the finger to dissect the tissue in a sweeping motion.
2. If using the tip of your finger to burrow into the tissue, always make sure you do so with a bony backstop to prevent visceral injury.
   - Backside of the pubic symphysis at midline
   - Directly over the ischial spine

A Retrospective Series of Over 1000 Patients Following Transvaginal Mesh Surgery for Pelvic Organ Prolapse

• Retrospective review of TVM
• Routine collection and electronic storage of pre- and post-op (4 & 12 month) validated questionnaires (short-forms of PFDI, PFQ, & PISQ and post-op SSQ) and POP-Q values begun in October 2006
• Chart review of all TVM patients from October 2006 – January 2010
• SPSS 15.0 database created from our EMR

IFPM Database, Allentown, PA

Results

• 1172 patients underwent TVM over 39 mo:
  • 1078 (92.0%) RTO for “Short-term” F/u (3.6 ± 1.6 mo)
  • 8–64 (73.7%) RTO for “One Year” F/u (12.0 ± 2.7 mo)
• 20 (1.7%) intra-op complications:
  • 12 (1%) cystotomies, 4 (0.3%) hemorrhages, 3 (0.3%) ureteral injuries, & 1 (0.1%) rectal injury
• 44 (3.8%) post-op complications (excluding UTI):
  • 34 (2.9%) mesh erosions (all vaginal)
  • 6 (0.5%) chronic pelvic pain (>6 weeks)
  • 2 (0.2%) vaginal cellulites
  • 1 (0.1%) DVT
  • 1 (0.1%) prolonged granulation tissue

Specific Outcomes Noted by FDA

• Vaginal (Mesh) Contraction:
  • Decrease in TVL >3cm = 2.2% (17/764) (avg 0.7cm)
• De novo Dyspareunia:
  • >1-unit negative change in item 5 of PISQ-12
  • (“Do you feel pain with sex?”) = 11.9% (22/185)
• Resolution of Pre-op Dyspareunia:
  • >1-unit positive change in item 5 = 13.5% (25/185)
• De novo Pelvic Pain:
  • >1-unit change in item 6 of UDI-6 (“Bothered by pain in…genital region?) = 1.8% (12/649)
Success of POP Repair at One Year

- **Subjective Success:** absence of any positive response to item 3 ("Bulge") of POPDI-6 = 92.8% (607/654)
- **Anatomic Success:** absence of any POPQ point beyond the remnants of the hymen = 98.2% (760/774)
- **Repeat Surgery for POP:** 1.6% (14/864)
- **Composite Success:** no surgery for POP and no symptomatic or anatomic failure = 93.2% (805/864)
- **Overall Satisfaction:** 88.2% (612/694)
- **Overall Dissatisfaction:** 4.3% (30/694)

Graft Complications

- **Vaginal Exposure**
  - Management based on symptoms, size, location
  - Local infiltrate with local with epi
  - Removal of ALL eroded material
  - Closure of vaginal mucosa not always necessary
  - Consider biologic graft in larger denuded area
  - Use of delayed absorbable monofilament suture preferred (PDS)

Eroded Graft

Sharp Resection

Dissected Mesh

Stay Sutures for Biologic Graft
Does a TVM system cause dyspareunia?

- TVM cases performed between 2005 and 2007 were evaluated (n=129)
- 2 attending surgeons at a tertiary referral center for female pelvic floor dysfunction in Indianapolis, IN.
- Of those sexually active (n=57), 21 (36.8) reported dyspareunia before the surgery, leaving 36 for evaluation. The rate of de novo dyspareunia was 16.7% (6/36)

94.7% answered “true” to the question, “Overall, the TVM surgery has improved my quality of life and I would have this surgery done again”

Dyspareunia

- Post-operative dyspareunia rates from vaginal and abdominal approaches range from 21-25%
- Certain risk factors may place a patient at additional risk for de novo dyspareunia when using transvaginal mesh grafts including:
  - Prior pelvic surgery with placement of permanent suture and/or graft
  - Prior pain condition (ie: interstitial cystitis, chronic lower back pain, sciatica, fibromyalgia, endometriosis)
  - Young age
- Graft properties... Weight (gm/m2 appears to be the most contributing factor)
- Proper graft “setting” or tensioning is a key surgical step
Pain/Dyspareunia Management

- To avoid pain, the procedure must be tension free
- Rectal pressure/discomfort may be felt and usually resolves within 6 to 8 weeks.
- Persistent rectal pain/defecatory dysfunction attributed to tight posterior straps
- Systemic agents for neuropathic pain (lyrica)
- Physical therapy, PFM myofascial release
- Valium suppositories for pelvic floor muscle spasm, consider Botox injection (60-80 units)
- Trial of local anesthesia/steroid injection
- Segmental mesh excision for tension release

Symptom Resolution After Operative Management of Complications from TVM

- Retrospective review of 90 pts 1/08 – 4/2012
- Most common was: pain 64%, exposure 62%, dyspareunia 48%
- After mesh removal: 51% had resolution of ALL symptoms
- Exposure treated successfully in 95%
- Pain treated successfully in 51%

Crosby et al, Obstet Gynecol 2014;123:134-9
Summary

• The most common complications of mesh use in reconstructive pelvic surgery are exposure and dyspareunia, both of which can be minimized by optimal surgical technique
• Regardless of delivery system or mesh type, dissection is the key step to minimize exposure
• Sizing, placement and setting are critical to minimize de novo pain
• Hydrodissection is critical to developing proper anatomical true spaces
• Surgeon should have the knowledge to readily identify complications and the skill set to properly manage most all of them

References

5. Mike Moshayee, The Success Equation, 2012
13. Cockeril et al, Symptoms Reduction After Operative Management of Complications From Transvaginal

Conclusion

• Recognize that trial lawyers have been more effective in shaping patient perceptions and opinions than physicians
• Develop robust education/communication tools (handouts, detailed consent, documentation of process)
• Careful patient selection, document risk factors for recurrent prolapse
• Recommit to becoming a true surgical expert in transvaginal mesh procedures
• Experience is not the same as expertise

Food for thought...

“...I think it is long overdue that we face the harsh reality that the biggest ‘messes’ that can arise from the attempt to safely adopt surgical innovation, is more often the result of our own ineffective processes for surgical skill set training and development beyond residency or fellowship, than it is the innovation itself.”
CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law AB 1195 (eff. 7/1/06) requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

California Business & Professions Code §2190.1(c)(3) requires a review and explanation of the laws identified above so as to fulfill AAGL’s obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at http://www.imq.org.

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 http://www.usdoj.gov/crt/cor/pubs.htm.

Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”, signed by the President on August 11, 2000 http://www.usdoj.gov/crt/cor/13166.htm was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

Dymally-Alatorre Bilingual Services Act (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

If you add staff to assist with LEP patients, confirm their translation skills, not just their language skills. A 2007 Northern California study from Sutter Health confirmed that being bilingual does not guarantee competence as a medical interpreter. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538.