Controversies and Complications in Pelvic Reconstructive Surgery (Didactic)

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Controversies and Complications in Pelvic Reconstructive Surgery (Didactic)

Andrew I. Sokol, Chair
Faculty: Cheryl B. Iglesia, Charles R. Rardin

Course Description

FDA advisories, mesh lawsuits, media coverage, oh my! This course reviews "hot button" issues facing pelvic reconstructive and minimally invasive surgeons today: credentialing for new procedures, the FDA mesh advisory, management of mesh complications, hysterectomy versus hysteropexy, apical support during hysterectomy, and the use of biologics in prolapse repair surgery. These issues will be debated by the panel and data will be presented supporting each side. Practical tips will be given for navigating the consent process, managing mesh complications, and performing uterine sparing apical support procedures. The state of evidence for the use of native tissues and biologics will also be reviewed.

Course Objectives

At the conclusion of this course, the participant will be able to: 1) Summarize the FDA mesh advisory; 2) implement an effective surgical consent process; 3) use what was learned to support the vault at the time of benign hysterectomy; 4) identify appropriate hysteropexy patients; 5) apply skills learned to identify and manage mesh complications; and 6) summarize current literature about the use of biologics in prolapse repair.

Course Outline

8:00 Welcome, Introductions and Course Overview
A.I. Sokol

8:05 What Does the FDA Advisory Mean for Me and My Practice?
C.B. Iglesia

8:30 Pelvic "Deconstructive" Surgery – How to Manage the Complications of Prolapse Repair Surgery
C.R. Rardin

8:55 Credentialing for New Technologies – What is the Best Way Forward?
C.B. Iglesia

9:20 Is Hysterectomy Necessary in Pelvic Floor Repair?
C.R. Rardin

9:45 Questions & Answers
All Faculty

9:55 Break

10:10 Biologics in Prolapse Repair – Just a Bunch of Hocus-Pocus?
C.B. Iglesia

10:35 Back to the Future – Native Tissue Repairs for Apical Prolapse
A.I. Sokol

11:00 What Is the (F)utility of Urodynamics?
C.R. Rardin
11:25 Managing Sling Complications  A.I. Sokol
11:50 Questions & Answers  All Faculty
12:00 Course Evaluation
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Viviane F. Connor
Consultant: Conceptus Incorporated
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
Jonathan Solnik
Other: Lecturer - Olympus, Lecturer - Karl Storz Endoscopy-America

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Rosanne M. Kho
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Grants/Research Support: Ethicon Women’s Health & Urology
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Stock Shareholder: TransEnterix
Speaker’s Bureau: Covidien, Abbott Laboratories
Other: Proctor - Intuitve Surgical

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The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
Andrew I. Sokol*
Cheryl B. Iglesia*
Charles R. Rardin*

Asterisk (*) denotes no financial relationships to disclose.
What does the FDA Advisory Mean for My Practice and Me?

Cheryl B. Iglesia, MD
Director, FPMRS
MedStar Washington Hospital Center
Associate Professor, ObGyn and Urology
Georgetown University School of Medicine

Disclosure

I have no financial relationships to disclose.

Objectives

At the end of the presentation, the participant should be able to
1) Summarize outcomes and complications associated with vaginal mesh for prolapse
2) List potential indications and alternatives for synthetic vaginal mesh for prolapse

Evolution in Pelvic Reconstructive Surgery

Abdominal Sacrocolpopexy
Colporraphy
Trocared Vaginal Mesh
Laparoscopic-Robotic SCOP
Trocared Mini Mesh Systems
Uterosacral/Bowel Fixation

Why all the fuss?

• Was marketing ahead of science?
• Does a vaginal incision matter?
• Are mesh attachment points important?
• What are the training/learning curve issues?
• Why is sacrocolpopexy unscrutinized?

What a Difference A Year Makes
Industry developments

- Some trocared mesh kits no longer available (Prolift EWHU and Avaulta Bard)
- Smaller profile trocar-free mesh kits
- Sales down from nearly 79,500 kits sold in 2010
Elevate Anterior

California Jury Awards $5.5M

Multidistrict Litigation (MDL) pending

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh

- FDA has received over 1,000 reports* from 9 surgical mesh manufacturers on complications
  - Erosion
  - Infection
  - Pain / dyspareunia
  - Urinary problems
  - Recurrent prolapse
  - Bowel, bladder, blood vessel perforation

*Included slings for SUI and mesh for POP

www.fda.gov/cdrh/safety/102008-surgicalmesh.html

FDA UPDATE Notification

- Vaginal repair with mesh is main concern
  - serious AEs are not rare
  - effectiveness not superior to traditional repair (possible exception for anterior repair)
  - little known about long term implications
  - safety and effectiveness in question

July 2011

FDA Advisory 2011

- Obtain specialized training...
- Be vigilant for potential adverse events — especially erosion and infection
- Watch for complications...esp. bowel, bladder and blood vessel perforations
- Inform patients that implantation of surgical mesh is permanent...
- Inform patients about the potential for serious complications...including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair using surgical mesh.
- Provide patients with a copy of the patient labeling from the manufacturer...

FDA Informed Consent

- Recognize that in most cases, POP can be treated successfully without mesh...
- Consider before placing surgical mesh:
  - permanent implant
  - at risk for requiring additional surgery
  - removal of mesh may involve multiple surgeries
  - mesh placed abdominally may result in lower rates of mesh complications
522 Orders

- In January 2012, the FDA imposed a Section 522 Order on 40 manufacturers of transvaginal mesh.
- Mandate required companies to provide up to 3 years of post-market data on the safety and effectiveness of their devices.

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>T/U (incl)</th>
<th>Mesh Type</th>
<th>Non-mesh Cure</th>
<th>P</th>
<th>Blinded</th>
<th>COMPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nguyen 2008</td>
<td>75</td>
<td>12</td>
<td>87% ant</td>
<td>55%</td>
<td>&lt;.05</td>
<td>Single</td>
<td>5%</td>
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<tr>
<td>Carey 2009</td>
<td>139</td>
<td>12</td>
<td>81% ant</td>
<td>65.6%</td>
<td>NS</td>
<td>Non</td>
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<tr>
<td>Fawes et al. 2010</td>
<td>202</td>
<td>36</td>
<td>87% ant</td>
<td>59%</td>
<td>&lt;.001</td>
<td>Non</td>
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<td>Iglesia 2010</td>
<td>65</td>
<td>9.7</td>
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<td>29.6%</td>
<td>NS</td>
<td>Double</td>
<td>15.6%</td>
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<td>Ullman 2011</td>
<td>194</td>
<td>12</td>
<td>50.4% all</td>
<td>54.8%</td>
<td>&lt;.001</td>
<td>Non</td>
<td>16.9%</td>
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<tr>
<td>Altman 2011</td>
<td>389</td>
<td>12</td>
<td>82% ant</td>
<td>47.5%</td>
<td>.008</td>
<td>Non</td>
<td>2.2%</td>
</tr>
</tbody>
</table>

IUGA recommends surveillance on first 1000 cases

**Altman Trial - Effectiveness**

**Anterior**
- Study success POPQ<Stage 2
  - 60.8% mesh vs. 34.5% non-mesh (p<0.001)
- No bulge symptoms
  - 75.4% mesh vs. 62.1% non-mesh (p=0.008)
- No difference in prolapse QoL outcomes

**Altman Trial - AEs**

**Anterior**
- Peri-operative complications with mesh: longer operative time, greater mean blood loss, more bladder perforations
- More de novo SUI with mesh (12% vs. 6%)
- Total erosion rate not reported
Altman Trial: Re-surgery at 1-yr

<table>
<thead>
<tr>
<th></th>
<th>Non-Mesh (n=182)</th>
<th>Mesh (n=186)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat anterior repair or SUI surgery</td>
<td>0.6%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Surgery for complication</td>
<td>0%</td>
<td>3.2%*</td>
</tr>
<tr>
<td>Total</td>
<td>0.6%</td>
<td>5.9% (p &lt;0.05)</td>
</tr>
</tbody>
</table>

*for mesh erosion

Graft Complications (Abed 2011)

- 110 studies reported on erosion 10.3%
- Range was 0 – 29.7%
- No difference in rate btw synthetic & biologic
- 7.8% wound granulation (16 studies)
- Dyspareunia 9.2% (70 studies)
- Range 0 – 67%
- No difference in rate btw synthetic & biologic

Effectiveness: Outcome Measures

Most use study endpoint:
- "ideal pelvic support" = POP-Q stage 0 - 1 (prolapse > 1 cm above hymen)

However......
- not correlated with POP symptoms or patient assessment of improvement*
- central anterior wall: interobserver variability 68% agreement (kappa 0.35)†

*Barber Obst Gyn 2009  †Whiteside AJOG 2004

Composite Outcome Measures: New standard

- Absence of prolapse beyond hymen
  - average number of symptoms increases when prolapse beyond hymen*
- Improvement in prolapse Quality of Life (QoL)
- Re-surgery for recurrence
- Absence of bulge symptoms
  - most associated with patient assessment of improvement and greatest difference in prolapse QoL measures compared to other measures†

†Barrow AJOG 2003  †Barber Obst Gyn 2009

Studies since UPDATE

- Three arm RCT (n=99) of native tissue vs biologic vs synthetic graft after two years of f/up*
  - Anatomic failure: native tissue 58%, biologic 46% graft, mesh 18% (P=.002)
  - Composite failure: native tissue 13%, biologic 12% graft, mesh 4% (P=. 28)
  - No difference in sexual fxn
  - 14% mesh & 4% porcine erosions

Menefee et al. Obstet Gynecol Dec 2011

- 3 year f/up of surgical intervention after 600 Prolift repairs 2005-2009*
  - 87% f/up median f/up 38 months (range 15-63)
  - Re-op rate 31.6% 6.3% for SUI, 3.6% mesh-related complications, 3% recurrent POP.
- Sokol 1 year f/up of 65 pts higher re-op rate for mesh*
  - Symptomatic prolapse 2/26 (3.8%) of mesh and 3/33 (9.1%) of no mesh (P=.63)

*Sokol et al AJOG Jan 2012  †Landsheere et al AJOG Jan 2012
DEBATE

MESH EXPOSURE VS PROLAPSE RECURRENCE

Serious Mesh Complications

- Pain/Dyspareunia
- Visceral erosion/injury

Where do we go from here?

CONSIDER MESH USE:

- Recurrent Prolapse, especially anterior
- Advanced Stage
- Certain Situations:
  - Collagen deficiency
  - Contraindications to abdominal surgery
- ***BE CAREFUL: pelvic pain

<table>
<thead>
<tr>
<th>Potential benefits of graft use for POP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>------------------------------------</td>
</tr>
<tr>
<td>1. Age</td>
</tr>
<tr>
<td>a. 50 patients &lt; 50</td>
</tr>
<tr>
<td>b. 50 patients &gt; 50</td>
</tr>
<tr>
<td>2. Recurrence (new or old)</td>
</tr>
<tr>
<td>3. Cystocele and Compartments</td>
</tr>
<tr>
<td>a. 0-1</td>
</tr>
<tr>
<td>b. 2-4</td>
</tr>
<tr>
<td>4. Parastomal Fallopian</td>
</tr>
<tr>
<td>5. Empyema</td>
</tr>
<tr>
<td>6. Collagen deficiency</td>
</tr>
<tr>
<td>7. Chronic cough</td>
</tr>
<tr>
<td>9. Pelvic or abdominal</td>
</tr>
<tr>
<td>10. Possible of pregnancy</td>
</tr>
<tr>
<td>S = synthetic mesh</td>
</tr>
<tr>
<td>B = biologic grafts</td>
</tr>
<tr>
<td>E = evidence</td>
</tr>
<tr>
<td>O = expert opinion</td>
</tr>
</tbody>
</table>
Mesh tips

- Pre and postop estrogen use in menopausal women
- Hydrodissection with thick dissection plane
- Minimize size of incisions
- Avoiding over-trimming epithelium and T incisions
- Avoid over-tensioning of graft arms
- Cystoscopy/rectal exam mandatory

Final Words

- Learn/Master/Offer Native Tissue Repairs
- If you are doing Mesh Repairs
  – Track Outcomes: Objective, Subjective, QoL, resurgery for complications and recurrence
  – Enroll in National Mesh Registry once available

References

Iglesia CB. Synthetic vaginal mesh for pelvic organ prolapse. Curr Opin Obstet Gynecol 23; 362-365
FDA.gov website
Pelvic Deconstructive Surgery
Managing Iatrogenic Pelvic Floor Dysfunction

Charles R. Rardin, MD
Associate Professor
Alpert Medical School of Brown University
Division of Urogynecology
Women and Infants’ Hospital
Providence, RI

I have no financial relationships to disclose.

Disclaimer

- Much of this talk is opinion, anecdote, or food for thought
- Speed of technological innovation is accelerating
  - Efficacy and safety data lag further behind
  - Collective evidence about management of complications is that much further behind

It’s a new day
and we have some new issues...

- Olsen 1997
  - 11% prolapse repair
  - 29% recurrent repair
- New devices and materials
  - FDA revising its 510(k) process
- New procedures
  - Mesh implant
  - More new procedures
    - Mesh excision
  - New Terminology
    - “mesh cripple”

Scenario 1

- Post-midurethral sling voiding dysfunction

Complication: Urinary Retention

- Voiding Dysfunction immediately post-op
  - r/o hematoma
  - d/c with Foley 24-72 hr
- If patient still unable to void at 3-10 days:
  - consider reopening site under local, place right-angle under mesh, and pull down slightly 5-10 mm
- Urethral dilation, downward retraction is to be avoided
Complication: Urinary Retention

- If beyond ~10 days
  - consider cutting mesh under local in midline after 2-4 weeks of catheterization
  - All cases of impaired emptying were completely resolved
  - Irritative symptoms were resolved (30%) or improved (70%)
  - 61% patients remained continent
  - 26% were improved over baseline
  - 13% had recurrence of stress incontinence

Scenario

- Mesh sling penetration or erosion into the bladder

Scenario

- Mesh Erosion
  - Non-healing at an incision
  - Vaginal bleeding or drainage
  - Bristles, pain or dyspareunia
  - Sinus tract or abscess
  - Vigilance!
    - Mesh precautions
    - Education
Know your materials

- Multifilaments, woven, non-macroporous materials (e.g., Mersilene) become chronically infected
- Partial excision likely to result in recurrent problems
- Changes in materials change their behaviors

Have an algorithm

- If minimally symptomatic, soon after surgery, and not extruding through the plane of the epithelium, try conservative:
  - Topical estrogen
  - Topical antibiotics
  - “pelvic rest”
- Otherwise, or if persistent, “trim” once
- If not resolved – to OR for more assertive management

Surgical Management: Erosion

- If non-Amid Type I: plan full excision
  - Combined vaginal and laparoscopic if retropubic component
- If Type I – excise until normal tissue ingrowth
  - Cannot see or feel the distinction between mesh and tissue
  - Then keep going a bit
- Hydrodissection (dilute marcaine/epi)
  - Delineates sinus tracts
  - Makes tissue-mesh distinction easier
  - Decreases bleeding

Surgical Management: Erosion, continued

- Anticipate difficulty delineating the mesh
  - Folds and kinks contribute to the erosion
  - Previous trimming make it difficult to find everything
  - Cystoscopy!!!
- Leave vaginal incision open to drain

Surgical Management: Pain or retraction

- Points of mesh fixation are usually to blame (especially when levators are used)
- Establish the goal (usually release of tension)
- Consider alternative routes
  - Paramedian vaginal incision, closer to the affected area
  - Laparoscopic retropubic dissection may afford excellent access to the affected area, without the need to traverse scarred fields
Scenario

- TVH (only) for prolapse
- Posthysterectomy vault prolapse
- Receives anterior repair
- Prolapse recurs; subsequent anterior repair
- Eventually, winds up with TVL of 3.5cm (but Aa and Ba are 0)
Credentialing for new technologies: What is the best way forward?
Cheryl B. Iglesia, MD
Director, FPMRS
MedStar Washington Hospital Center
Associate Professor, ObGyn & Urology
Georgetown University School of Medicine

Objectives
• Identify best practice guidelines for credentialing
• List common issues associated with proctoring

Why learn new procedures?
• “I want to provide the best care for my patients.”
• “I want to remain competitive.”
• “I feel pressure from my hospital system.”
• “My patients are asking for this.”
• “Using the ROBOT/Single port/etc is Cool!”

Disclosures
• I have no financial relationships to disclose.

Definition
• Credentials – a medical school diploma, certificate of attendance at a postgraduate course, specialty board certificate, or preceptor certification. Credentialing is the process of confirming applicant’s credentials.
• Surgical Competence – Competence is the minimum acceptable level of skill required to perform a surgical procedure.
• Surgical privileging is the evaluation process conducted by the credentialing committee for granting applicant’s privileges. Proctoring is one component of this evaluation process.
What are the potential problems with new technology?

- Patients may be placed at undue risk
- Surgeons may have increased liability
- A learning curve exists
- External regulatory bodies and the US Government may get involved

How are surgeons learning new technologies now?

- See one, do one, teach one?
- Weekend courses?
- Requisite knowledge, surgical skills and experience—volume matters
- Simulation

So how can we do this safely?

1. Assess the new procedure using evidence based information—efficacy, safety and need
2. Offer education for surgeons to acquire the requisite knowledge and skills
3. Monitor outcomes
4. Credential and privilege surgeons / teams
5. Educate patients

AUGS Guideline for Vaginal Mesh

[Instructions or guidelines related to the use of vaginal mesh, likely related to the American Urogynecologic Society (AUGS) guidelines for the use of vaginal mesh in pelvic organ prolapse.]

Conundrum

My older partners can teach me a lot.

She can teach us the latest things.
ACOG/AUGS Statement
1) undergo training specific to each device
2) have experience with reconstructive surgical procedures
3) understand pelvic anatomy
Reserve transvaginal mesh use for:
- recurrent prolapse (particularly of the anterior compartment)
- medical comorbidities that preclude more invasive procedures

AUGS Guidelines for Vaginal Mesh
- Demonstrate understanding of relevant pelvic anatomy
- Read the manufacturer’s instructions for use (IFU)
- Observe steps involved in procedure via animation, video, or live surgery
- Undergo hands on experience... using simulated models, animal or cadaveric models or other
- Consider specific intraoperative/postoperative complications that may be unique to the or device and the steps necessary to manage those complications
- Be familiar with the requirements for adequate informed consent

Surgeons
General knowledge documented by:
- completing a fellowship training program in Urogynecology, Female Pelvic Medicine and Reconstructive Surgery, or Female Urology or by completing adequate CME in pelvic anatomy and reconstructive pelvic surgery

Specific knowledge obtained by:
- Surgeons who do not have documentation of prior training with transvaginal mesh prolapse procedure should be proctored on no fewer than 5 procedures or as many as is necessary to demonstrate that they can independently perform the specific procedure.

Privileging recommendations
- surgery for pelvic floor disorders represents >50% of their surgical practice including a minimum of 30 surgical cases for pelvic organ prolapse annually
- Demonstrate experience and privileges in non-mesh vaginal repair of prolapse including anterior colporrhaphy, posterior colporrhaphy, and vaginal colpopexy (eg, uterosacral or sacrospinous ligament fixation), and experience and privileges to perform intraoperative cystoscopy to evaluate for bladder and ureteral integrity.
- Annual internal audits should be performed. [REGISTRY pending]

Experienced Vaginal Mesh Surgeons
- Continuing medical education in female pelvic reconstructive surgery
- A minimum of 30 surgical cases for pelvic organ prolapse (any route, with or without transvaginal mesh)
- Demonstrate experience and privileges in non-mesh vaginal repair of prolapse, and experience and privileges to perform intraoperative cystoscopy
Experienced Surgeons (cont)

- Annual internal audits should be performed
- Prior to adoption of a new transvaginal mesh technology or device, should be proctored on no fewer than 5 procedures or as many as is necessary to demonstrate that they can independently perform the newly adopted procedure.

Proctoring

- Impartially monitor, regulate, or oversee, surgical privileging for its medical staff
- The surgical proctor does not establish a patient/physician relationship
- Teleproctoring may be the most cost effective
- The surgical proctor is under no obligation to intervene
- The length/number of procedures governed by institutional bylaws
- A confidential written report submission to the institution's credentialing

REGISTRY

- BSUG British Society of Urogynecology
- US Pelvic Floor Disorders Registry (TBD)

References

- Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. Female Pelvic Medicine & Reconstructive Surgery & Volume 18, Number 4, July/August 2012

References (cont)

- Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. American Urogynecologic Society’s Guidelines Development Committee (www.fpmrs.net) Female Pelvic Medicine & Reconstructive Surgery & Volume 18, Number 4, July/August 2012
Hysterectomy – Evolution of Terminology

- Total Hysterectomy
  - Used to mean TAH/BSO
  - Now refers to uterus and cervix
- Supracervical Hysterectomy
- LAVH, LASH, TLH, TRH
- Prophylactic salpingectomy (but not BSO)
- Uterine preservation

Hysterectomy for Prolapse?

- Hysterectomy (on its own) does not treat prolapse
- Hysterectomy is a risk factor for prolapse
  - TAH: 50% increased risk
  - Supracervical: 100% increased risk
  - TVH: 400% increased risk
- Traditional approach
  - Allows access to target tissues
  - Weight of uterus contributes to prolapse

Treatment Options for Uterovaginal Prolapse

- Cohort of Stage III and IV uterovaginal prolapse
- 3 groups:
  - TAH with ASC
  - Abdominal sacrohysterectomy
  - TAH with Uterosacral suspension
- No difference in failures between TAH/ASC and Sacrohysterectomy
- TAH with non-mesh repairs had 6x increase in failure

Pros
- Traditional approach
- Eliminates certain future risks (bleeding, endometrial cancer, cervical cancer if total hysterectomy)

Cons
- Eliminates a portion of the procedure (with some of the highest risks)
- Reduces surgical impact
- Allows retention of nondiseased organs
- Psychosocial considerations
- Reduces complications associated with mesh
Treatment Options for Uterovaginal Prolapse

- Cohort of Grade 2-3 Uterovaginal Prolapse
- TVH with sacrospinous vault fixation, vs vaginal sacrospinous hysteropexy
- No significant differences in objective or subjective failures in any compartment (followup at least 26 months)
- Favored Hysteropexy (p < .01):
  - Blood loss (198 v 402 cc)
  - Operative Time (59 v 91 min)

Maher CE, Int Urogyn J 2001

Treatment Options for Uterovaginal Prolapse

- Randomized trial of 66 women with Stage II-IV uterovaginal prolapse
  - TVH with uterosacral suspension
  - Vaginal Sacrospinous hysteropexy
  - (repairs, slings as indicated)
- Hysteropexy was favored for:
  - Hospitalization
  - Return to work activities
- No difference in QOL or functional outcomes
- Higher rates of recurrence for hysteropexy if starting with Stage IV

Draz V, Int Urogyn J 2010

Variations on the Theme:
Hysteropexy with anterior and posterior mesh

Conclusion

- Prolapse is an important issue that impacts quality of life in a burgeoning patient population
- Failure rates are significant
- New technologies offer reductions in failures, but introduce new issues
- Patients and providers need to go through all these options (Hyst? Mesh? What Approach?), and understand the patient’s values
- Stay tuned for prospective research!
BIOLOGICS in prolapse repair: just a bunch of hocus-pocus?

Cheryl B. Iglesia, MD
Section Director, FPMRS
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Associate Professor, ObGyn and Urology
Georgetown University School of Medicine

Disclosure

- I have no financial relationships to disclose.

Objectives

- Describe options for biologics grafts
- List outcome data from biologic repairs

Clinical Implications for POP

The concept of graft use makes sense
1. Connective tissue deficiencies
2. Prolapse may represent “vaginal hernias”
3. Level I data that use of mesh reduces the risk of recurrence of groin hernias between 50% and 75%

The ideal surgical material (Cumberland and Scales 1950)

- Chemically and physically inert
- Non-carcinogenic
- Ability to resist mechanical stress
- Easily attainable
- Sterilizable
- Affordable

****NO SUCH MATERIAL EXISTS!

Choice of graft materials

- Permanent
- Exposure
- Contraction
- Encapsulation
- Breakdown

Synthetic

Biologic
Types of Materials

- Autologous: rectus fascia and fascia lata
- Allografts: cadaveric fascia lata and dermis, chemically processed fascia lata (Tutoplast)
- Xenografts: porcine dermis, small intestine submucosa, bovine pericardium
- Synthetics: absorbable (polyglactin), non-absorbable (polypropylene PPM), most common now: Type 1, pore size >75μm

Currently available biologics

Cross-linked biologic grafts

- Initially well tolerated
- Rare exposure
- May harden and shrink (encapsulate)
- May distort anatomy
- Modifications: meshing/making holes in it may make it softer; however limited data

Chemically Cross-linked e.g. PDA porcine dermis

- Pelvicol
  - Modifies collagen structure to inhibit degradation
  - Decreases cellular infiltration into graft
  - Foreign body reaction and encapsulation
  - Cross-linking makes graft stiffer

Non-cross linked grafts

(See small intestine submucosa)

- Composed of acellular ECM
- Permits cellular infiltration, replaced by patient-derived collagen
Non cross-linked grafts

7 months 14 months

Concern with Biologics

- Concerning tensile properties (SIS, CFL)
- Foreign body reactions (PDA)
- Documented autolysis
  - Freeze dried
  - Solvent dehydrated
  - HDA human dermal

Lessons learned from ASC

- Culligan et al 2005 AJOG
  - Polypropylene Mesh vs. Tutoplast
  - Cure rates: Mesh 91% Fascia 68%

- Deprest et al J Urol 2009
  - Polypropylene mesh vs SIS small intestine submucosa
  - Xenograft more apical failures and reoperations

2008 SGS Systematic Review

(Sung VW et al Obstet Gynecol 2008;112:1131)

Posterior Compartment 2 RCTs (1 biologic, 1 absorbable)
Anterior Compartment 5 RCTs (1 biologic, 1 absorbable, 1 synthetic)
Multiple Compartment No RCTs

2008 SGS Systematic Review

1950-2007

1) Native tissue repair is appropriate compared with biologics for anterior compartment
2) Use of biologic and synthetic absorbable mesh in the posterior compartment is not superior
3) Synthetic mesh may be beneficial for anterior compartment (apex posterior compartment have insufficient data)—but there are trade-offs
### Author Graft N Follow-up Outcome Failure Baseline Complications

<table>
<thead>
<tr>
<th>Author</th>
<th>Graft</th>
<th>N</th>
<th>Follow-up</th>
<th>Outcome Failure Baseline</th>
<th>Complications</th>
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<tbody>
<tr>
<td>Meschia 2007</td>
<td>RCT Anterior Pelvicol vs. No mesh</td>
<td>201</td>
<td>12 mos</td>
<td>7% graft 19% no graft</td>
<td>Extrusion &lt;1%</td>
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<tr>
<td>Natale 2009</td>
<td>RCT Ant. Gynemesh vs. Ant Pelvicol</td>
<td>190</td>
<td>24 mos</td>
<td>28% Gynemesh 43.6% Pelvicol</td>
<td>Erosion 6.3% Gynemesh</td>
</tr>
<tr>
<td>Menefee 2011</td>
<td>RCT Anterior repair vs. Mesh vs. Biologic</td>
<td>90</td>
<td>2 years</td>
<td>58% AR 18% Mesh 46% Pelvicol P=pig</td>
<td>14% mesh erosion 4% porcine erosion</td>
</tr>
</tbody>
</table>

### Current Status on Biologics

- Limited data on POP repair
- Early breakdown may affect success
- Fewer mesh-related complications compared with synthetics
- Modifications may improve tissue reactivity
- Outcomes depend on technique used for implantation

### Unanswered Questions

- Reproducible results?
- Primary vs recurrent prolapse?
- Dissection and implantation technique
- Effect on sexual function?
- Need more basic science:
  - Ideal biologic
  - Wound breakdown/metabolism
  - Combination synthetic/biologic

### References


Iglesia CB. Synthetic vaginal mesh for pelvic organ prolapse. Cur Opin Obstet Gynecol 23; 362-365


FDA.gov website
Back to the Future - Native Tissue Repairs for Apical Prolapse

Andrew I. Sokol, M.D.
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Section of FPMRS
MedStar Washington Hospital Center
Associate Professor of Ob/Gyn and Urology
Georgetown University School of Medicine

Objectives

1. Review anatomy of apical support
2. Summarize techniques/outcomes of vaginal repairs for apical prolapse:
   - McCall culdoplasty
   - Uterosacral ligament suspension
   - Sacrospinous ligament suspension
   - Iliococcygeus suspension

Prolapse - Background

- 16% of women in US have POP\(^1\)
- Lifetime prevalence 30-50%
  - 2% symptomatic\(^2\)
  - 7% lifetime risk of surgery for prolapse\(^3\)
- Vault prolapse occurs after 1/200 (0.5%) hysterectomies

\(^1\)Pannu et al, Radiographics 20(6):1567-82;2000
\(^2\)Samuelsson EC et al, AJOG 180:299-305;1999
\(^3\)Olsen et al, Obstet Gynecol 89:501;1997

Risk Factors

- Things that disrupt support of uterus and/or vagina
  - Pregnancy/childbirth (vaginal > C-section)*
  - Obesity
  - Family history
  - Chronic cough or heavy lifting
  - Prior hysterectomy (especially if top of vagina not supported)

Delancey’s levels

- Level I
  - McCall culdoplasty
  - Uterosacral suspension
  - Sacrospinous suspension

- Level II
  - Paravaginal repair
  - Anterior mesh procedures that use arcus only

Disclosures

- I have no financial relationships to disclose.
Goals of surgery for apical support – Level I

- Establish continuity of anterior and posterior muscularis at apex
- Suspend vagina and restore posterior axis
- Maintain vaginal length
- RESTORE FUNCTION AND IMPROVE QOL

There are currently NO data supporting the use of vaginal mesh or biologics for APICAL prolapse repair

Questions

1. Can this be prevented?
2. How can it be treated vaginally?
3. Given controversy surrounding mesh and biologic implants, what other options can we offer?

Prevention

McCall culdoplasty

- Surgical correction of enterocele and deep cul-de-sac during TVH
  - Uterosacral ligaments plicated in midline, incorporating cul-de-sac peritoneum and posterior vaginal cuff
  - Closes redundant cul-de-sac and enterocele
  - Provides apical support
  - Lengthens vagina
McCall culdoplasty

- Superior to uterosacral plication and simple peritoneal closure in prevention of post-hysterectomy enterocele

Complications: McCall’s culdeplasty

- Ureteral obstruction rate:
  - Up to 4.5% intraoperatively
  - Easily visualized as unilateral lack of indigo carmine dye on cysto

  PERFORM CYSTOSCOPY!

1Cruikshank SH, Kovac SR. RCT of three surgical methods used at the time of vaginal hysterectomy to prevent posterior enterocele. AJOG 180:859-65, 1999.

Treatment

Uterosacral ligament suspension (USLS)

USLS: Goals
- Reestablish continuity of pubocervical and rectovaginal muscularis
- Elevate vault toward uterosacral ligaments

USLS: Helpful tips
- Pack with 2 or 3 laps
- Long weighted speculum
- Pull USL pedicle up (Kochers)
  - Long Allis clamps
  - Highest stitch 4cm above spine (most medial)
- 2-3 sutures per side

Uterosacral ligament suspension

Complications: USLS
- Ureteral obstruction rate:
  - 1 - 11% intraoperatively
  - 90% resolved intraoperatively
  - 0.9% ureteral injury rate requiring further intervention
  - PERFORM CYSTOSCOPY!

Patient Number | Follow-up | Cure Rate |
---|---|---|
Jenkins 1997 | 50 | 6-24 mos | 100% |
Webb 1998 | 683 | 11-22 mos | 82% |
Shull 2000 | 289 | 2-4 yrs | 87% |
Barber 2000 | 46 | 16 mos | 90% |
Karram 2001 | 292 | 22 mos | 95% |
Silva 2006 | 72 | 5 yrs | 85% |

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Webb 1998 683 11-22 mos 82%
Shull 2000 289 2-4 yrs 87%
Barber 2000 46 16 mos 90%
Karram 2001 292 22 mos 95%
Silva 2006 72 5 yrs 85%

**Sacrospinous ligament fixation**
- Enter R perirectal space
  - Anterior or posterior
- Visualize/palpate C-SSL
- Place 2 sutures >2cm medial to spine
- Pass through apex
- Tie sutures
  - Vagina directly opposed to C-SSL

**SSLF: Surgical Tips**
- Measure vagina
  - Must reach ligament
  - Mark apex
- Visualize ligament
  - Lighted suction/irrigator
  - Lighted retractor
- Sew full thickness vagina to ligament
  - Capio device
  - Can use pulley stitch

**SSLF: Complications**
- Complications:
  - Buttock pain
  - Nerve injury
  - Rectal injury
  - Vaginal stenosis
  - Stress incontinence
  - Hemorrhage

**Sacrospinous ligament fixation**
- Cure rates 80-94%
- Recurrence 6-35%
  - 20% anterior wall prolapse at 1 year
  - Posterior deviation of vaginal axis

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**RCT: Bilateral SSLF vs ASC**
- "Optimal" surgical result:
  - 29% of vaginal group
  - 58% of abdominal group
- Reoperation rate for recurrences:
  - 33% of vaginal group
  - 15% of abdominal group
- Relative risk of "optimal effectiveness" abdominal vs vaginal 2.03 (1.22 - 9.83)

**Comparison abdominal versus vaginal colpopexy**
- ASC vs unilateral SSF
- All USI received Burch
- Follow-up 2 yrs
- ASC longer OR time, higher cost, and slower return to ADL

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- Buttock pain
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- Rectal injury
- Vaginal stenosis
- Stress incontinence
- Hemorrhage
**Iliococcygeus vaginal vault suspension**

- Posterior incision
- Iliococcygeus exposed
- Biresky-Narrattil retractor
- Single delayed absorbable suture through levator muscle
  - 1-2 cm caudal and posterior to spine
- Both ends passed through posterior apex
- Procedure repeated on opposite side


**References**

4. Cookshank DH, Kovac SR. RCT of three surgical methods used at the time of vaginal hysterectomy to prevent posterior enterocele. AJOG 1999;180:859

**Recommendations**

- McCall/USLS for all TVH (prophylactic)
- Biresky-Narrattil retractors
- USLS for primary prolapse repair
- Sacrospinous fixation
- No enterocele or poor uterosacral ligaments
- Adhesions
- High posterior wall prolapse
- Iliococcygeus suspension
- Minimal apical prolapse
- PERFORM CYSTOSCOPY!
Urodynamic Testing in the Straightforward Patient: Utility or Futility?

Charles R. Rardin, MD
Associate Professor, OB/Gyn
Director, Fellowship in Female Pelvic Medicine and Reconstructive Surgery
Alpert Medical School of Brown University
Director, Minimally Invasive and Robotic Surgery
Women & Infants Hospital

Disclosure
- I have no financial relationships to disclose

Effects of Burch on Pressure-Transmission Ratio

Adapted from Hilton P, Stanton SL, Br J Obstet Gynaecol 1983

“The Low Pressure Urethra as a Factor in Failed Retropubic Urethropexy”

- 86 women with GSI
- multichannel urodynamic testing
- Burch colposuspension
- 54% failure rate if pre-op MUCP < 20
- 18% failure rate if pre-op MUCP > 20

**Intrinsic Sphincter Deficiency**

- history: continuous leakage
- cystoscopy: UVI open at rest
- UPP: MUCP < 20 cm H2O
- LPP: < 60 cm H2O
- Q-tip variable
- PTR variable

---

**Correlation of UCP and LPP**

- Statistically significant (but clinically weak) correlation, with coefficients of 0.5-0.6
  - Sultana 1995, Swift & Ostergard 1995
- No correlation
  - Bump 1995, McGuire 1995
- Empty Supine CST correlates with low LPP but not UCP
  - McLennan & Bent, 1998

---

**Do Urodynamic Indices predict Differences between TVT and TOT?**

- 60 patients with TVT (historical controls) compared with 85 with TOT (Monarc)
- No significant differences between groups
- A cut-off point of MUCP <42 cm H2O was identified as a predictor of failure in the overall group
- Among these patients, TOT failure rate was 6-fold higher than TVT

**TVT vs TOT: Randomized Noninferiority Trial**

- 170 women with Urodynamic SUI randomized to TVT or TOT, with concurrent repairs as indicated (stratified by presence of prolapse)
- Primary outcome: abnormal bladder function
  - Any subjective incontinence
  - Positive CST
  - Reoperation
  - Retention

**TVT vs TOT: Randomized Noninferiority Trial**

- Abnormal Bladder Function observed in 47% (TVT) and 43% (TOT)
  - Retention and reoperation appeared to favor TOT
- Noninferiority of TOT was confirmed

---

**TVT vs TOT: Does it matter which sling? Can UDE help select?**

- Low leak point pressures and mean leak point pressures were comparable
- Urethral closure pressures or bladder neck hypermobility not presented
- Presence of DO on urodynamics was an exclusion criterion
For women with uncomplicated, demonstrable stress urinary voiding phase dysfunction--

- Diagnosis of OAB and more likely to receive a diagnosis of
- Urodynamic testing for incontinence, preoperative office evaluation alone was not
- Inferior (11%) to evaluation with urodynamic testing

- Provider blinded to UDE (TOMUS)
- Provider blinded to UDE (TOMUS)

- Randomized to receive TVT or TOT (Monarc)
- at 6 months, Urodynamic SUI was observed in:
  - 21% of TVT
  - 45% of TOT
- 9 reoperations for SUI in TOT group (zero in TVT)
- Projection: 1 in 6 patients with TOT would request reoperation

- 523 women with “uncomplicated” SUI (Pure SUI or SUI--
- Randomized to office evaluation with Urodynamic testing
- 597 women randomized to TVT vs TOT
- Surgeons blinded to urodynamic results
  - Plan development
  - Sling placement and tensioning
- No significant differences in objective or subjective failure rates
  - TVT higher voiding dysfunction
  - TOT slightly higher neurologic symptoms

- 72.9% in the office evaluation only group (NS)
- 77.2% in the UDE group
- 78.9% in the office-evaluation only group (NS)

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- 46% surgical
- 27% medical

- 45% of TOT
- 21% of TVT

- 70% reduction in the UDI score:
  - Negative stress test rate, 300cc at 12 months:
  - 69.4% in the UDE group
  - 72.9% in the office-evaluation only group (NS)
  - 77.2% in the UDE group
  - 78.9% in the office-evaluation only group (NS)

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- 164 patients with ISD
  - MUCP < 20 cm H2O
  - Leak Point Pressure of <60 cm H2O

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CARE Trial and UDS

- Women who demonstrated preoperative USI during prolapse reduction were more likely to report postoperative stress incontinence, regardless of concomitant coposuspension (controls 58% vs. 38% (p = 0.04) and Burch 32% vs. 21% (p = 0.19)).

The OPUS Trial

- The vaginal equivalent of CARE Trial
- 322 of 337 randomized women (96%) completed 1-year FU.
- At 3 months, the rate of UI (or treatment) was 23.6% in the TVT group and 49.4% in the sham group (adjusted odds ratio (AOR) 3.22, 95%CI 1.99 to 5.22).

Conclusions

- Urodynamics may play a less important role than we thought as long as:
  - The patient has no OAB or DO, ISD, retention or prolapse
  - The surgeon is unlikely to change surgical plan anyway
- However, the value of testing in terms of plan development, patient counseling, and new technology assessment should not be discarded.
Managing sling complications

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Section of FPMRS
MedStar Washington Hospital Center
Associate Professor of Ob/Gyn and Urology
Georgetown University School of Medicine

Disclosures

- I have no financial relationships to disclose.

Objectives

1. Review mid-urethral sling complications
   - Minor
   - Major
2. Discuss strategies to decrease complication risk
3. Examine complication management strategies

Axioms

1. Mid-urethral slings gold standard
   - Advantages vs BN slings
2. Retropubic and transobturator slings have similar effectiveness
   - RP vs TOT trade-off
     - ↑ bladder injury and voiding dysfunction
     - ↓ groin pain
     - RP slings more effective for ISD1
3. Mini-sling data lacking
   - Postop incontinence worse if mini-sling fails2

Surgical Procedures for SUI (2010)

Non-Mesh
54,000 (21%)

Mid-urethral slings
206,000 (79%)

RP sling

<table>
<thead>
<tr>
<th>Non-Mesh</th>
<th>Mid-urethral slings</th>
</tr>
</thead>
<tbody>
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<td>206,000</td>
</tr>
</tbody>
</table>

Sling complications

“MINOR”
- Infection (UTI, wound)
- Bladder perforation
- Urinary retention
- De novo DO
- Hematoma

“MAJOR”
- Mesh erosion
- Bowel perforation
- Nerve injury
- Vascular injury
- Death

Top 10 sling complications reported to FDA

<table>
<thead>
<tr>
<th>Rank</th>
<th>Adverse Events</th>
<th># of MDRs</th>
<th>Percentile Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain</td>
<td>479</td>
<td>34.9%</td>
</tr>
<tr>
<td>2</td>
<td>Erosion</td>
<td>436</td>
<td>31.8%</td>
</tr>
<tr>
<td>3</td>
<td>Infection</td>
<td>260</td>
<td>19.5%</td>
</tr>
<tr>
<td>4</td>
<td>Urinary problems</td>
<td>220</td>
<td>16.0%</td>
</tr>
<tr>
<td>5</td>
<td>Organ perforation</td>
<td>110</td>
<td>8.3%</td>
</tr>
<tr>
<td>6</td>
<td>Recurrence, Incontinence</td>
<td>103</td>
<td>7.3%</td>
</tr>
<tr>
<td>7</td>
<td>Bleeding</td>
<td>103</td>
<td>7.5%</td>
</tr>
<tr>
<td>8</td>
<td>Dyspareunia</td>
<td>73</td>
<td>5.3%</td>
</tr>
<tr>
<td>9</td>
<td>Neuro-muscular problems</td>
<td>50</td>
<td>3.6%</td>
</tr>
<tr>
<td>10</td>
<td>Vaginal scarring</td>
<td>22</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

- Persistent FDA “signal” related to use of slings for SUI

Reported adverse events at follow-up (sum of literature)

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Range of Mean %</th>
<th>Follow-up (mos)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erosion</td>
<td>0.25 - 4.1</td>
<td>6 - 48</td>
</tr>
<tr>
<td>Reoperation</td>
<td>2.6 - 6.2</td>
<td>6 - 24</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>0.6 - 13.7</td>
<td>6 - 60</td>
</tr>
<tr>
<td>Pain</td>
<td>1.6 - 22.2</td>
<td>6 - 60</td>
</tr>
<tr>
<td>Urinary problems</td>
<td>7.9 - 16.2</td>
<td>6 - 60</td>
</tr>
<tr>
<td>Infection*</td>
<td>4.8 - 27.4</td>
<td>6 - 60</td>
</tr>
</tbody>
</table>

* includes UTI

“Minor complications”
Bladder injury

- 0-23% of cases
- Rates similar if TVT performed with hyst or reconstructive procedures
- Higher rate if prior incontinence surgery
  - 4.4% vs 2% \(^1\)
  
  \(^1\)Tamussino et al. Curr Opin Obstet Gynecol 2002;14:515-20

Tips to reduce cystotomy risk

- Slow, controlled placement
- Hold trocar handle level to floor
- Small proximal deviation causes large distal deviation
- Hug pubic bone
- Completely empty bladder before each pass
- Catheter guide and retropubic hydrodissection?
- ALWAYS CYSTO!!!

Now what?.....

1. 
   - Replace trocar
   - Catheter x 3 days

2. Voiding dysfunction, retention, OAB
   - Rates depend on definition used
   - ~5% inadequate voiding by 6 wks
   - ~10% de novo OAB
   - If preop urgency, rule of thirds
     - 1/3 better, 1/3 same, 1/3 worse
   
   Sokol. AJOG 192(5):1537-43, 2005

Post-op urgency

- Set expectations
  - Up to 10% after sling
  - Avoid over-tightening
  - Rule out UTI, voiding dysfunction
  - Manage with behavioral modifications, PT and anticholinergics
  - Consider UDS/cysto if persistent despite therapy
    - Erosion
    - De novo DO
  - Sling division if cannot be managed

Options to manage urinary retention

- Prolonged catheterization/ISC
  - >70% voiding dysfunction resolved by 6 wks \(^1\)
- Urethral dilation
  - Probably not adequate
  - Only 1/7 (14%) improved after dilation \(^2\)
  
  \(^1\) Sokol. AJOG 2005;192:1537-43
  \(^2\) Rardin. AJOG 2002;100:898-202
## Tips for sling division

- If tight but no urethral erosion
  - Midline incision
  - Cut lateral to midline

## Erosions

- 0.3-23% for all slings
  - 0.5-1.7% vaginal erosions after TVT

## Management options

- Urethral erosions
  - Transurethral resection
  - Tape excision with repair of urethrotomy
  - Bladder erosions
  - Transurethral resection
  - Suprapubic endoscopic resection
  - Open cystotomy
  - Transvaginal resection
- Vaginal erosions
  - Observation / estrogen
  - Local excision
  - Over-sewing


## Major complications

## Tips for urethral erosion

- Recognize it!!!
  - High level of suspicion for urgency, frequency, or UTIs after sling
  - May be anterior if TOT
  - Dyed sling easier
  - Can inject dye for urethral localization

## Inverted U-flap

## Sling dissection
**Excision of mesh**

**Layered urethral closure**

**Urethral integrity testing**

**Closure of vaginal flap**

**Bowel Perforation**

**Vascular complications: TVT**

PREVENTION:
- Review prior operative notes
- Trendelenburg
- Direct needle along cephalad surface of pubic bone

INTERVENTION:
- Aggressively evaluate signs or symptoms of peritonitis
- Imaging &/or exploration

---

**Finnish review of 1455 patients**
- 27 cases of EBL >200cc
- 27 retropubic hematomas
- 7 hematomas “outside retropubic area”
- 1 (0.1%) major vessel injury (epigastric)

### Relationship of TVT to vasculature

<table>
<thead>
<tr>
<th>Vessel</th>
<th>Mean distance vessel to trocar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial epigastric</td>
<td>3.9cm</td>
</tr>
<tr>
<td>Inferior epigastric</td>
<td>3.9cm</td>
</tr>
<tr>
<td>External iliac</td>
<td>4.9cm</td>
</tr>
<tr>
<td>Obturator</td>
<td>3.2cm</td>
</tr>
</tbody>
</table>


### Reasons RP sling trocar deviation

- Inexperience
- Disorientation (drapes)
- Patient movement
- Lateral deviation to avoid bladder
- Curve of lateral pubic ramus in cephalad direction
  - lateral placement steers needle cephalad
- Lack of control while piercing perineal membrane
- Obesity
  - Trocar traverses labia majora in front of pubic bone


### Retropubic hematomas

- 10-12% have hematomas >5cm after TVT
  - If asymptomatic, manage expectantly
  - Have low threshold of suspicion if pain, ecchymosis, or anemia
  - Explore rapidly expanding hematomas for major vascular injury

### Vascular Injury

**INTERVENTION:**

- Minor venous bleeding
  - Electrocautery or direct pressure using finger or pack
- Moderate venous bleeding
  - 30 cc balloon Foley filled to 50 cc for tamponade
  - Foley placed on traction and taped to medial thigh for 12-24 hrs
- Major/arterial hemorrhage:
  - Initiate patient support
  - Consider open surgical intervention vs embolization

### Areas of concern for TOT

- ISD
- Neuropathic and muscular pain syndromes
- Mesh exposure
  - Vaginal perforation
  - Erosion
- Retropubic hematoma

### TOT traverses active medial thigh muscles

- Adductor longus
- Adductor brevis
- Adductor magnus
- Obturator internus and externus
- Gracilis
Pain syndrome – obturator neuralgia after TOT

- Incidence unclear
  - Up to 12% long-term with pain issues*
- Shooting or sharp pain of affected groin; radiation in variety of directions
- Often delayed onset
- Exacerbated by activity; relieved with rest
- May have vaginal and/or groin tenderness

Giberti, J Urol 2007

Obturator neuralgia

PREVENTION
- Consider retropubic approach in very active patients
- Trocar insertion (or exit) close to bone

MANAGEMENT
- PT
- Analgesics
- Trigger point injections
  - Steroid (40 mg triamcinolone in 10cc lidocaine)
- Sling excision

Penetrating the Sidewall

Erosion versus perforation?

Button-hole management

1. Recognize it
2. Remove and replace sling
3. Close puncture sites
4. Alternatively, open epithelium b/w puncture sites, and over-sew

Mini-slings

- Limited data
- Potential for office-based procedure
- Reports of:
  - Erosions
  - Bladder injury
  - Obturator muscle bleeding
  - Hematoma
  - Vaginal perforation
- FDA requesting post-market studies

Keys to complication management

1. Proper preop decision-making and consent
2. Prevention
  - Know anatomy and technique
  - Drain bladder
  - CYSTO ON ALL SLINGS
3. Recognize injury (high level of suspicion)
4. Be able to manage own complications!
References


Cultural and Linguistic Competency

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

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

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

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

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

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