Minimally Invasive Approach to Pelvic Organ Prolapse (Didactic)

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Professional Education Information

Target Audience
This educational activity is developed to meet the needs of residents, fellows and new minimally invasive specialists in the field of gynecology.

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Minimally Invasive Approach to Pelvic Organ Prolapse (Didactic)

C.Y. Liu, Chair
Linda Brubaker, Co-Chair
Faculty: Robert S. Furr, Joseph Nassif

Recent FDA warnings against the use of synthetic mesh in Pelvic Organ Prolapse (POP) surgery and the alarming increase of the number of mesh-related lawsuits in the United States have prompted renewed interest in non-synthetic-mesh use in POP surgery. This course will use real case illustrations to provide participants with an opportunity to learn the step-by-step surgical techniques for the minimally invasive surgical repair of various compartmental defects from the world’s renowned experts. Beginning with the current understanding of the anatomy and functional dynamics of the female pelvic floor, this course then continues with demonstration of laparoscopic surgery for enterocele repair, apical suspension, posterior compartmental defects repair, anterior paravaginal and transverse defects repair, followed immediately by critique and demonstration of vaginal approach by world renowned vaginal surgeons. Topics addressed also will include the appropriate use of synthetic mesh in POP surgery, laparoscopic and robotic sacrocolpopexy, as well as total laparoscopic repair for recurrent severe prolapses, and procidentia with mesh. The final focus will be the recognition and management of complications of laparoscopic POP surgery. Participants are also encouraged to bring their own clinical cases for discussion during the Q & A session.

Course Objectives: At the conclusion of this course, the clinician will be able to: 1) Appraise the current concepts of the functional dynamics and anatomy of female pelvic floor; 2) identify a systematic and logical approach to various compartmental defects in minimally invasive POP surgery; 3) define enterocele and review a step-by-step laparoscopic repair of the defect; 4) review a step-by-step laparoscopic repair of apical prolapse, anterior, and posterior compartmental defects; 5) review the use of synthetic mesh in repairing recurrent severe prolapse; and 6) diagnose, appraise, and manage the complications of minimally invasive surgery for POP.

Course Outline

8:00 Welcome, Introductions and Course Overview C.Y. Liu
8:05 Laparoscopic View of Female Pelvic Floor C.Y. Liu
8:45 Principles of Laparoscopic Surgery for POP C.Y. Liu
9:00 Laparoscopic Enterocele Repair and Apical Suspension – Step by Step C.Y. Liu
9:25 Critique and Comment of Laparoscopic Enterocele Repair and Uterosacral Ligaments Suspension L. Brubaker
9:45 Break
10:00 Laparoscopic Repair for Severe POP: Sacrocolpopexy with Synthetic Mesh J. Nassif
10:20 Robotic Sacrocolpopexy R.S. Furr
10:40 Laparoscopic Paravaginal Repair and Burch C.Y. Liu
10:55 Concomitant POP and SUI Surgery: Combining Sacrocolpopexy and Continence Procedures L. Brubaker
11:20 Use of Synthetic Mesh in POP Surgery L. Brubaker
11:40 Prevention, Recognition and Management of Complications of POP Surgery J. Nassif
11:40 Questions & Answers Faculty
12:00 Course Evaluation/Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Asterisk (*) denotes no financial relationships to disclose.
Laparoscopic View of Female Pelvic Floor

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Professor,
University of Tennessee, School of Medicine
Director Emeritus
Fellowship Program in Minimally Invasive Gynecology

Disclosure
I have no financial relationships to disclose.

Retropubic Space and Anatomy

Rectovaginal Space
Vesico-cervical and Vesico-vaginal Space
Pre-lumbar and Presacral Space

Pararectal Uterosacral Ligament and Pelvic Ureter
Principles of Laparoscopic Surgery for POP

C.Y. Liu, M.D.

Disclosure

I have no financial relationships to disclose.
POP Surgery

200,000 POP surgery annually (2009 U.S. National Hosp Discharge Survey)—Prevalence is increasing
Precise causes unknown, most likely multifactorial
Defective pelvic support against Normal intra-abd. Pressure
Normal pelvic support subject Chronically to high intra-abd. Pressure.
Pelvic support:Bony pelvis, endopelvic fasc. pelvic diaphragm.

Female Genital Prolapse

- The functional dynamics of female pelvic floor is extremely complex. In addition to supporting the abdominal and pelvic organs and maintaining continence of urine and feces, pelvic floor must also permit sexual intercourse, parturition, and storage and evacuation of excretory products

Female Genital Prolapse

- The precise pathophysiology and functional anatomy of the condition are poorly understood.

Clinical Observation of Prolapse

a) Female organs do not drop out by themselves; they are being pushed out by patient.
b) Prolapse does not bother patient when she is lying down, prolapse only bother patient when she is in an upright position.
c) Many women with prolapse also have overt or occult urinary/fecal incontinence. Some also have sexual problems.
Female Organ Prolapse

- Female organ prolapse is the end result of fascial (endopelvic fascia) break. It’s pathophysiology is a condition of hernia.
- Prolapse very rarely causes evisceration, incarceration or strangulation of bowel.

The goal of prolapse surgery is to restore the integrity of endopelvic fascia.

Female Organ Prolapse

- Prolapse is a dynamic condition; regression of prolapse occurs at the same or higher rate as incidence.


 Restore the normal vaginal

 Length

 Axis
Principles of Pelvic Floor Reconstruction

1. Restore the integrity of fibromuscular vaginal tube by repair the enterocele.
2. Resuspend the apex of vagina to the level of ischial spine—sacrospinous suspension, uterosacral ligament vaginal vault suspension, sacro-colpopexy.
3. Resuspend the mid vagina to the pelvic sidewalls by performing paravaginal suspension.
4. Perform anti-incontinent procedure.
5. Repair the rectocele and restore the perineal body if needed.

What is Enterocele?

(Your Definition ?)

Pericervical Ring

The crucial connection or continuation of the pubocervical fascia, rectovaginal septum, and uterosacral ligaments.

Normal Position of Pericervical Ring
At level of Ischial Spine

Definition of Enterocele

When pelvic peritoneum contacts directly with vaginal epithelium without intervening fascia.
Repair enterocele = Reconstruct and Restore Pericervial Ring

Reattachment of uterosaco-cardinal ligament, rectovaginal septum and pubocervical fascia to restore the Integrity of Vaginal fibromuscular tube.

Resuspend the apex of vagina to the level of ischial spine.
Repair enterocele = Reconstruct and Restore Pericervical Ring

Reattachment of uterosacral-cardinal ligament, rectovaginal septum and pubocervical fascia to restore the Integrity of Vaginal fibromuscular tube. Resuspend the apex of vagina to the level of ischial spine.

Principles of Pelvic Floor Reconstruction

• 1. Restore the integrity of fibromuscular vaginal tube by repair the enterocele.
• 2. Resuspend the apex of vagina to the level of ischial spine—sacrospinous suspension, uterosacral ligament vaginal vault suspension, sacro-colpopexy.
• 3. Resuspend the mid vagina to the pelvic sidewalls by performing paravaginal suspension.
• 4. Perform anti-incontinent procedure.
• 5. Repair the rectocele and restore the perineal body if needed.

Vaginal Vault/Uterovaginal Suspension

By suspend apex of vagina to the level of ischial spine.

- Sacrospinous suspension
- Sacrocolpopexy

Surgery for Pelvic Organ Prolapse

- Apex is the keystone for the pelvic organ support. Without good support of the vaginal apex the ventral and dorsal wall of vagina are exposed to intra-abd. force that drive these tissue toward introitus.
- The best surgical correction of the anterior and posterior walls is doomed to failure unless the apex is well supported.
Is Uterosacral Ligament Strong Enough for Use in Apical Support?
Uterosacral Ligament Suspension
(Originally described by Milton McCall in 1938)

Once access to the posterior cul-de-sac has been attained, the uterosacral ligament remnant can be found with the use of Allis clamps placed at the posterior medial aspect of the ischial spine. Up to three sutures are placed in each ligament and incorporated into the anterior and posterior fibromuscular layer of the vagina as well as vaginal epithelium.

Uterosacral Ligament Origin and Insertion Points
(MRI studies on 61 asymptomatic nulliparous women)

Three regions of origin:
- Cervix: 33%
- Cervix and Vagina: 63%
- Vagina: 4%

Four insertion points:
- Sacrospinous ligament/Coccygeus m: 82%
- Sacrum: 7%
- Piriformis m, ischial spine or Sciatic foramen: 11%

Uterosacral ligament suspension
(Vaginal route)
up to 11% ureteral injury. (usually kinking due to medial displacement or suture ligation that impedes urinary flow, rather than transection).

Pericervical Ring

- The narrowest diameter in the pelvis is in between the ischial spines.
- Maximum pelvic connective tissue strength is located within this most restricted area.
- The impact of childbirth.

Pericervical Ring is at Level of Ischial Spine!

(what is the normal position of cervix or apex of vagina?)

Where to put the sacrocolpopexy stitch?

MRI of the L5 spines of 73 patients:

- 53 (73%) the promontory was intervertebral disc
  - The distance between the promontory and the body of L5
    - 13 mm (9.4-26 mm)
  - 20 (27%) the promontory was at the superior aspect of S1
  - The medium distance between the promontory and the base of L5 disc is 1.29 mm (1.1-2.2 mm)

- The S1 vertebral body was located within 5 mm inferior to the promontory in 100% of the images reviewed.

Where to put the sacrocolpopexy stitch


Female Pelvic Med Reconstr Surg
Uterosacral ligament suspension – Mayo clinic experience

- 693 posthysterectomy vaginal vault prolapse.
- 31 patients underwent abdominal sacro-curopexy.
- 662 (95%) underwent McCall uterosacral ligament vaginal vault suspension.
  - 82% are satisfied with their repair.


Uterosacral Ligament Vaginal Vault suspension

<table>
<thead>
<tr>
<th>Investigator</th>
<th>No of pts</th>
<th>Mean follow-ups (months)</th>
<th>Cure rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amundsen et al</td>
<td>33</td>
<td>28 (6-43)</td>
<td>27/33 (82%)</td>
</tr>
<tr>
<td>Karram et al</td>
<td>168</td>
<td>21.6 (6-36)</td>
<td>158/168 (94%)</td>
</tr>
<tr>
<td>Shull et al</td>
<td>289</td>
<td>Maximum 48</td>
<td>251/289 (87%)</td>
</tr>
<tr>
<td>Barber et al</td>
<td>46</td>
<td>15.5 (3-48)</td>
<td>90%</td>
</tr>
<tr>
<td>Jenkins</td>
<td>50</td>
<td>33 (6-48)</td>
<td>48/50 (96%)</td>
</tr>
<tr>
<td>Mikolas et al</td>
<td>17</td>
<td>6.3 (1-17)</td>
<td>88%</td>
</tr>
</tbody>
</table>
Laparoscopic Sacrocolpopexy with Synthetic Mesh

Joseph NASSIF, MD
Assistant Professor
Department of Ob/Gyn
American University of Beirut Medical Center

Disclosure
I have no financial relationships to disclose.

Objective(s)
• Describe a simplified technique of Laparoscopic Sacro Colpopexy (LSC)

Sacrocolpopexy
• Gold Standard: trt of genital prolapse
• Technically difficult (posterior compartment ++)
• Gained popularity again after many alerts

Prolapse Surgery

Twenty years of laparoscopic sacrocolpopexy: where are we now?
Boris Gabriel - Joseph Nassif - Soleda Barata - Arnaud Warnez

Abstract
Introduction and purpose Laparoscopic sacrocolpopexy (LSC) was first described about 20 years ago. This technique aims to provide the outcomes of the gold standard abdominal approach while offering the benefits of a naturally minimally invasive surgery. However, the widespread diffusion of LSC in the management of pelvic organ prolapse (POP) is

Prolapse Surgery

Évaluation des implants de renfort posés par voie vaginale dans le traitement des prolapsus genitaux

V. Conclusion
En l'état actuel des connaissances, et aimes des experts, les implants de renfort dans la chirurgie du prolapsus genital par voie vaginale relèvent donc de la morcellement clinique.
Mesh Specifications

Theoretical specifications of an ideal mesh:
- Rapid tissue ingrowth for an efficient support, ... without extensive fibrosis leading to discomfort, pain, and erosion.

A late or problematic tissue ingrowth can induce:
- Local complications: seroma, hematoma, erosion, sepsis
- Functional complications: pain, discomfort, recurrences

The exact requirements will obviously depend on the indication.

The mesh tissue ingrowth

Sequence of occurrences:
- 2 days: cellular appeal
- 4 days: cellular penetration

Objective: reduce intensity and time of inflammatory period

Achieved tissue differentiation within the mesh without fibrous encapsulation

The early phase largely determines the long term tolerance
Acceptance of vaginal placement of mesh

- The good results of TVT and TOT with a low rate of complications pushed the surgeons to go further with vaginal mesh placement.
- The new material such as polypropylene monofilament is well tolerated and presents less risk for infection.

Need for Standardization

The use of Standardization is to implement guidelines, a design, or measurements in order to obtain solutions to a disorganized system (to make things easier)

Laparoscopic Sacrocolpopexy standard technique:

“The 6 points technique”

1. Placement of trocars and exposure
2. Promontory dissection
3. Preparation of spaces
4. Hysterectomy?
5. Fixation of meshes: 6 points
6. Peritonization

1. Placement of trocars and exposure

 HOW?
- Suspension of bowel
- Uterine manipulator
- WHY?
- Keep a good vision
- Keep your assistant
- Retraction is restriction

2. Promontory dissection and preparation of mesh placement
3. Preparation of the spaces: rectovaginal and bladder dissections

- The dissection goes:
  - Towards the vagina
  - Stay as close as possible to the vaginal wall
  - The dissection continues until the identification of the puborectalis muscle
  - Traction on the rectum by the assistant
  - The rectum is lateralized to the left part and is larger in the lower part

Bladder dissection

- Bladder is dissected down to the upper part of the trigone
- Do not dissect to low: Risk of bladder inestability
- Lateral dissection stays limited to avoid ureteral injury

4. Hysterectomy?

- Not mandatory
- Allows a better distribution of the traction forces (orientation) to the anterior and posterior compartments
- **Subtotal hysterectomy** is preferred in order to avoid mesh erosion

5. Fixation of the meshes

- **Posterior mesh**
- **Anterior mesh**
“The 6 points technique”

- Posterior mesh fixation: 2 points on the pubo-rectalis. « BIG bite »
- Anterior mesh fixation: 1 point. « Small bite »
- Solidarisation of meshes: 2 points
- Fixation in the promontorium: 1 point. « BIG bite », Only one mesh!

Fixation of the mesh to the promontory

- Fix only one mesh to avoid dead spaces between two meshes
- We turn around the mesh with the suture to enhance the fixation in the promontorium

Anterior fixation of the mesh

6. Peritonization

video
To reduce post-operative morbidity remember to avoid:

- Total hysterectomy
- Very low vesico-vaginal dissection
- Transfixing sutures on the vaginal wall
- Traction on the mesh while fixing it over the promontorium
- Dead spaces (fixing only one mesh on the promontorium)

To conclude

Laparoscopic sacrocolpopexy is the “gold standard” procedure for POP repair and its standardization is a step towards its acceptance.

Laparoscopic Colpopexy

- video

References

- FDA warning on mesh use (2011)
- RCOG green top guideline (2007)
- French High Authority of Health warning on mesh use (2006)
- Gabriel et al. Twenty years of laparoscopic sacrocolpopexy: where are we now? Int Urogynecol J (2011) 22:1165-1169
LAPAROSCOPIC AND ROBOTIC APPROACHES TO CORRECTION OF PELVIC ORGAN PROLAPSE

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Assistant Director, AAGL Fellowship in Minimally Invasive Gynecologic Surgery
Clinical Instructor, Dept. of Obstetrics and Gynecology, UTCOM

OBJECTIVE:
To understand effective methods available for laparoscopic and robotic correction of pelvic prolapse

Introduction
- By 2050, nearly one-third of the adult female population in the US, will be affected by at least one symptomatic pelvic floor disorder. 1
- 200,000 inpatient surgical procedures for prolapse are performed annually in the United States. 2,3

- 11 to 19 percent of women will undergo surgery for prolapse or incontinence by age 80 to 85 years. 4
- 30 percent of these women will require an additional prolapse repair procedure. 4
- Women with symptomatic POP experience daily discomfort, as well as interference with sexual function and activities of daily living.

Introduction
- Only Symptomatic prolapse should be addressed:
  - Conservative (pessary) v. Surgical
- The choice of a primary surgical procedure depends upon a variety of considerations:
  - anatomic site of prolapse
  - presence of urinary or fecal incontinence
  - health status
  - patient preferences.
Surgical Management of Pelvic Prolapse

- Laparoscopic and robotic approaches may offer the improved vaginal support associated with open procedures and the shorter recovery of vaginal procedures.

Minimally Invasive Approach to Surgical Management of Pelvic Prolapse

- Procedure depends on:
  - Type and degree of defects that need to be repaired
  - Need for graft material (recurrent prolapse/poor native tissue)
  - Patient opinions regarding mesh
  - Surgeon experience
  - Patient health status and desire to maintain a functional vagina

Minimally Invasive Approach to Surgical Management of Pelvic Prolapse

- Our Philosophy:
  - Restore the integrity of the vaginal tube
    - Correct enterocele/cystocele
  - Support the apex
    - Uterosacral suspension
    - Sacrocolpopexy

MIS APPROACH TO SURGICAL MANAGEMENT OF PELVIC PROLAPSE

- Restoring the Integrity of the Vaginal Tube

MIS APPROACH TO SURGICAL MANAGEMENT OF PELVIC PROLAPSE

- Suspending the Apex
There is no justification for any restriction for mesh placed abdominally (i.e. mesh sacrocolpopexy, including laparoscopic and robotic approaches) for the treatment of prolapse.

-AUGS: Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders

Any restriction of mesh slings for the treatment of stress urinary incontinence is clearly not supported by any professional organization or the FDA.

-AUGS: Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders

Laparoscopic Paravaginal Repair & Burch Procedure

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Chattanooga, Tennessee.

Disclosure

I have no financial relationships to disclose.
Paravaginal Defects

- 1. F. Endopelvina detached from pelvic side wall. However ATFP is intact.
- 2. ATFP split in the middle.
- 3. ATFP is completely broken away from the pelvic sidewall.
Concomitant POP and SUI Surgery: Combining Sacrocolpopexy and Continence Procedures

Linda Brubaker, MD MS
Dean and Professor
Loyola University Chicago Stritch School of Medicine
Chicago, IL

Disclosures
I have no financial relationships to disclose.

Objectives
Following this presentation, the reconstructive pelvic surgeon should:
• Optimize continence at time of sacrocolpopexy
• Understand limitations of urinary tract testing

What You Think is Wrong Is What You Fix

The Mechanisms of SUI Surgery is Unknown
• Deliberately obstruct
• Alter (stabilize) UVJ to obstruct outflow
• Reduce the urethral caliber
• Optimize anatomy to optimize function
• Reposition the urethra under pubis
• Backstop for otherwise OK urethra

Sacrocolpopexy
• One of the oldest mesh-based procedures!
• Level 1 evidence supports superiority of polypropylene over
  • Fascia lata
  • Cadaveric fascia lata
  • Porcine dermis
**Sacralcolpopexy**
Level 1 evidence for superior outcomes compared to:
- Sacrospinous colpopexy
- Total vaginal mesh procedures

- Lower inpatient costs
- Comparison of open vs. laparoscopic (with/without robotic assistance)
  - Complications associated with open procedure decreased
  - Complications associated with laparoscopic route increased

**Concurrent SUI**
- Women with Stage II POP = 55%
- Women with Stage III POP = 33%
- In reality – difficult to find “NO SUI” patients

**Risk of New or De Novo SUI**
- CARE trial: Open Sacrocolpopexy
  - Randomized to Burch (157) v. no Burch (165)
  - Subjective SUI:
    - Burch 26% v. no Burch (41%)
  - Costantini (smaller RCT)
    - Burch (9/31 - 29%) v. no Burch (5/31 - 16%)
### Recommendation

**Grade A**

In continent women undergoing POP surgery with occult SUI, the addition of continence surgery reduces the rate of postoperative SUI.

### “Occult” SUI

- Depending on reduction method, much higher rates of SUI
- Urodynamic testing without reduction not useful (less than 3% new diagnosis).

### Advanced POP with UI

- Pure USI – Can poor sphincters be detected?
- Does your treatment choice matter?
  - Are measures of sphincteric integrity reliable
    - Leak Point Pressures
    - Closure Pressures

### Compare these women

#### Stage IV POP

- Healthy 68 y/o
- Mild SUI
- PVR 175
- Healthy 65 y/o
- Very athletic
- No SUI but history of SUI years ago before prolapse worsened
- PVR 5
- Healthy 65 y/o
- Very athletic
- No SUI but history of SUI years ago before prolapse worsened
- PVR 5
- Negative Reduction Testing

### CARE SUI Outcomes: Burch Advantage

<table>
<thead>
<tr>
<th></th>
<th>3 mo</th>
<th>24 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Burch</td>
<td>Control</td>
</tr>
<tr>
<td>PFDI (i)</td>
<td>19%</td>
<td>39.7%</td>
</tr>
<tr>
<td>Stress Test</td>
<td>4.7%</td>
<td>8.6%</td>
</tr>
<tr>
<td>SUI Rx</td>
<td>5.8%</td>
<td>11.0%</td>
</tr>
<tr>
<td>SUI Endpt (i)</td>
<td>22.4%</td>
<td>40.9%</td>
</tr>
<tr>
<td>Bothersome SUI (i)</td>
<td>5.9%</td>
<td>24.5%</td>
</tr>
</tbody>
</table>
Treat these women
• No change!
• Staged procedure (no concomitant continence procedure)
  • Her PVR should normalize, however.
• Consider change!
  • Counsel accordingly for potential staged procedure.
  • SCPXY and staged continence surgery

Compare these women
Stage IV POP
• Healthy 68 y/o
• Mild SUI
• PVR 175
• Positive Reduction Testing
• Healthy 65 y/o
• Very athletic
• No SUI but history of SUI years ago before prolapse worsened
  • PVR 5
  • Positive Reduction Testing

Treat these women
• Consider SUI vs. Voiding Dysfunction...
  • Discuss staged procedure (no concomitant continence procedure)
  • Her PVR should normalize, however.
• Concomitant SCPXY and continence surgery

Voiding Dysfx vs. Incontinence
• There is a delicate balance between voiding dysfunction and incontinence.
  • Better to error on incontinence side.
  • When both present, undertreat incontinence.

Substituting Midurethral Slings for Colposuspension
• As we have moved to minimally invasive procedures, more surgeons substitute a polypropylene suburethral sling instead of a Burch colposuspension.
  • This shifts the risks/benefit ratio and requires separate discussion.
  • In patients who have accepted a mesh-based procedure, use of a similar product is often accepted.

E=SISTEr Continence Rates
Kaplan-Meier Cumulative Continence Rate Curves are significantly different by the Log-rank test (Chi-square =9.63, p= 0.002).
Burch 43% Sling 52%
Burch 24% Sling 52%
Modern Continence Surgery

• Burch/MMK – rare procedures
• Midurethral sling – TVT, TOT
  
  o Evidence based procedures

PFDN: OPUS

• Registered RCT comparing the utility of TVT in stress-continent women at time of vaginal prolapse repair
• 327/337 (97%) completed follow-up at 1 year.
• At 3 months, the UI rate (or treatment) was 23.6% in the sling group and 49.4% in the sham group (P<0.001).
• At 12 months, UI (allowing for subsequent treatment of incontinence) in 27.3% and 43.0% of patients in the sling and sham groups, respectively (P=0.002).

NNT (12 months) was 6.3

Surgical Counseling

• Prediction models being developed
  o Currently best function is for vaginal, not abdominal, POP repair
• Is patient prepared for surgery?
• Are her surgical goals realistic?
• What preferences relate to her adverse event tolerance?
  o Prefers “less surgery” – will take risk of SUI
  o Prefers “everything done”

OPUS

• A prophylactic midurethral sling inserted during vaginal prolapse surgery resulted in a lower rate of UI at 3 and 12 months but higher rates of adverse events:
  o bladder perforations, higher in the sling group than in the sham group [6.7% vs. 0%],
  o urinary tract infection [31.0% vs. 18.3%],
  o major bleeding complications [3.1% vs. 0%], and
  o incomplete bladder emptying 6 weeks after surgery [3.7% vs. 0%] (P<0.05 for all comparisons).

References

• Costantini et al. Burch colposuspension does not provide any additional benefit to pelvic organ prolapse repair in patients with urinary incontinence: a randomized trial. J. Urol. 180(3):1007-1012, 2008
Use of Synthetic Mesh in POP Surgery

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Objectives
Following this presentation, the reconstructive pelvic surgeon should:
• Describe indications and contraindications for synthetic mesh for POP surgery

Risks
• The use of mesh for POP surgery is associated with a risk of specific complications, whatever the surgical approach and whatever type of mesh.
• Preoperatively, patients must be informed of these risks and give their consent for the use of a mesh.

Adopting New Techniques
Too early
• Patients suffer needlessly
• Potential risks for surgeon

Just right
• Optimal surgical care

Too late
• Patients are denied benefits of new techniques

Current Status of Prolapse Surgery
• 11.1% lifetime risk of surgical intervention
• 29-40% of reconstructive procedures require surgical reintervention for failure
  • 43-56% reoperation for POP in academic referral
• 60% of recurrences are at the same site
• 32.5% occur at a different site due to unmasking of an occult support defect

Disclosures
I have no financial relationships to disclose.
Potential Etiology of Recurrence

- Tissue Factors (collagen content and structure)
- Underlying Medical Factors (COPD, constipation, asthma)
- Technical Factors
- Impaired healing and scarring

Synthetic Mesh

- General surgery
  - Mesh reduces inguinal hernia recurrence 50-75%

- Urogynecology
  - 58% recurrence ≥ Stage II following vaginal repair
  - Younger women and Stage III-IV increased risk
  - Mesh overlay may reduce recurrence after traditional anterior repair (RR 1.39, 95% CI 1.02-1.90)

Adoption of Mesh

Synthetic Mesh may have slightly higher success rates compared to biologics or absorbable but potential for complications is greater.

Success of newer retropubic tension-free synthetic mesh sling and transobturator slings increases comfort with type 1 polypropylene mesh use in the vagina

Full-Thickness Vaginal Incision

Available Biomaterials

- **Permanent Synthetics**: Material of choice in ASC and suburethral slings. Superiority supported by published prospective RCTs and case series
- **Absorbable Synthetics**: Conflicting data; fibrosis disappears
- **Autografts**: Good outcomes in SUI surgery, morbidity of 2nd surgical site
- **Allografts**: Poor outcomes in both sling & ASC
- **Xenografts**: Conflicting data; poor outcome in ASC

 Amid Classification of Synthetic Mesh

<table>
<thead>
<tr>
<th>Type</th>
<th>Pore size</th>
<th>Component</th>
<th>Fiber type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I</td>
<td>Macro (75um)</td>
<td>Polypropylene</td>
<td>Monofilament (Prolene, Marlex, Atrium, Vicryl)</td>
</tr>
<tr>
<td>Type II</td>
<td>Micro (&lt;10um)</td>
<td>Expanded PTFE</td>
<td>Multifilament (Gore-Tex)</td>
</tr>
<tr>
<td>Type III</td>
<td>Macro (&gt;75um)</td>
<td>Polypropylene</td>
<td>Multifilament (Dexon, Mersilene)</td>
</tr>
<tr>
<td>Type IV</td>
<td>Submicron (0um)</td>
<td>PTFE, Polypropylene, Polyglactin</td>
<td>Membranes</td>
</tr>
</tbody>
</table>

Features of Synthetics

- Weight
- Porosity
- Softness
- Elasticity
- Flexural Rigidity/Stiffness
- Inflammatory response
- Degree of contraction

Ideal Properties of Mesh

- Easily handled and implanted
- INERT: Histologically well tolerated
- Resist infection
- Resist mechanical stretch
- Not shrink or contract
- Recreate and maintain the physical characteristics of the supple and distensible vaginal wall
- Incorporate into surrounding tissue

ICI Recommendations

Grade A:
- Polypropylene – superior anatomical outcome (vs. Pelvicol), but with significantly higher mesh exposure rate.
- Polypropylene – superior anatomical outcomes for anterior repair, but without concomitant functional outcomes – offset by higher adverse events

Grade B:
- Polypropylene – superior anatomical outcome (vs. Pelvicol), but with significantly higher mesh exposure rate.
- Polypropylene – superior anatomical outcomes for anterior repair, but without concomitant functional outcomes – offset by higher adverse events
- Hysteropexy with mesh augmentation of the anterior compartment was as effective as hysterectomy and mesh augmentation with no significant difference in the rate of mesh exposure between groups.

Grade C:
- Does not support use of polypropylene mesh for recurrent anterior vaginal prolapse

ICI Recommendations

Grade B:
- Apical or posterior prolapse was significantly more common after polypropylene mesh and mesh extrusion rate of 10.4% with 6.3% undergoing surgery.
- Hysterectomy at the time of sacrocolpopexy was associated with a 4x higher risk of mesh exposure.
- Compared to sacral hysteropexy, sacrocolpopexy with concomitant hysterectomy was assisted with 5x higher rate of mesh exposure.
No Benefit to Transvaginal Posterior Mesh

- Grade B:
  - No benefit to mesh overlay or augmentation of a suture repair of posterior vaginal wall prolapse.

Transvaginal vs. Transabdominal

Transvaginal mesh placement is associated with a higher re-operation rate than native tissue vaginal repairs.

Posterior Placement of Sacrocolpopexy Mesh

Recommend to place the mesh via the abdominal route, avoiding a vaginal insertion.

Selecting Mesh

- Recommend using a macroporous polypropylene monofilament mesh
- Not recommended: silicone-coated polyester polytetrafluoroethylene

Mesh erosion/extrusion

Oddly – No Evidence

No evidence whatsoever to recommend routine local or systemic estrogen therapy before or after prolapse surgery using mesh.
Mesh Complications

• Just google it...
• When problematic, generally plan to remove that portion of problematic mesh that can be safely excised and reasonably expected to resolve current symptoms

Eyes Wide Open

• Mesh – sometimes, it is the gift that keeps on giving
  • It doesn’t care what your intentions were
  • It doesn’t care what your surgical route/technique etc.

References

• Amid et al. Langenbecks Archiv fur Chirurgie 1994;379:168-171
• Clark et al. Am J Obstet and Gynecol 2003;189:1261-1267
• Maher C. Cochrane Database Syst Rev. 2004;(4):CD004014
• McCormack K. Cochrane Database Syst Rev. 2003;(1):CD001785
• Olsen et al. Obstet and Gynecol 1997;99:501-506
• Scott NW. Cochrane Database Syst Rev. 2002;(4):CD002197
• Whiteside JL et al AJOG 2004; 191:1533-8
Objective(s)

- Understand the incidence of complication in Laparoscopic Sacrocolpopexy
- Implement the measures to avoid these complications
- Treat these complication when they occur

Complications related to laparoscopy

- > 50% of all complications: pneumoperitoneum & trocars insertion

- Entry-related complications include:
  - vascular
  - intestinal
  - urinary tract injuries and
  - gas embolism, rare (0.001–0.59%)
    - mortality rate < 28.5%

Disclosure

I have no financial relationships to disclose.
Vascular injuries

- Incidence = 0.05%
- Incidence:
  - Initial phase = 76.5%
  - Surgical dissection = 23.5%
- Mortality rates = 8 - 17%
- No technique is absolutely safe !!!

  Chapron et al., J Am Coll Surg
  Roviaro et al., Surg Endosc

Bowel injuries

- 0.3–0.5% of operative laparoscopies
- < 50% are recognized intra op (remainder from 1-30 days after!)
- Delayed diagnosis: mortality rate up to 3.6% (peritonitis, septicaemia & MOF)
- Incidence:
  - Small bowel (58%)
  - Colon (32%)
  - Stomach (8%)

  J Am Assoc Gynecol Laparosc 2003

Open vs closed entry

- Average complication rate: Visceral: 31/1000,
  Vascular: 44/1000
- n = 411,262

  Jansen et al., AJOG 2004

Operative strategy

- Exposure
- Dissection of spaces
  - Sacral promontory
  - Lateral pelvic space
  - Recto-vaginal space
  - Vesico-vaginal space
- +/- Hysterectomy
- Mesh fixation
- Peritonisation

Bowel injuries

- 0.3–0.5% of operative laparoscopies
Dissection of the sacral promontory

- 3 Dangers !!!

- The adjacent vascular structures
  - Median sacral vessels (artery and vein)
  - Left common iliac vein (not always visible, low bifurcation, obese...)
  - Right ureter
  - Hypogastric plexus

- Palpation
- Lifting up

Dissection just below the peritoneum
Beware of the middle sacral artery
Free enough peritoneum: avoid right ureter and bowel when peritonizing

Rectovaginal dissection

- The peritoneum is incised away from the vagina
- Traction on the rectum (assistant)
- Then dissection
  - Towards the vagina
  - Stays as close as possible to the vaginal wall

Right lateral peritoneum

Pay attention
- To the pelvic vessels
- In particular the right internal iliac vein

Anatomy of the sacral promontory
**Vesicovaginal dissection**
- Can be very challenging especially in patients with previous hysterectomy
- Distending the vagina with a probe will facilitate dissection
  - Do not dissect too low (risk of bladder instability), the bladder is dissected down to the upper part of the trigone
- Ureters are at risk as dissection gets closer to the bladder trigone.

**Subtotal Hysterectomy**
- Preserving the integrity of the vaginal cuff led to a lower incidence of mesh exposure
- When hysterectomy is indicated, a supracervical technique should be strongly considered as the mesh exposure rate was significantly lower
- If removal of the cervix is indicated, the risk for mesh exposure remains low and should not preclude total hysterectomy

**Suturing**
- Needs training +++
- Accounts for a significant increase in operative time
- DO NOT suture or tack the sacrum if you don’t see the bone
- Use of absorbable sutures: ↓ erosions, ↑ relapses

**Fixation of the anterior mesh**
- One non transfixiant suture on the vagina
- Two lateral sutures placed on the cervix

**Fixation of the posterior mesh**
- Arcuate incision of the posterior mesh
- All the muscle should be involved in the suture allowing a partial myorrhaphy
- The mesh is sutured to the muscle and not to the vagina in order to minimize the risk of vaginal erosion

**Outcomes**
- n = 390
  - 1 ileus
  - 3 small bowel occlusion
  - 3 prolonged nausea/emacs
  - 3 small bowel and 2 rectal injuries for a bowel injury rate of 1.3%
  - reoperation rate for SBO or bowel injury was 0.8%
- **CONCLUSIONS:**
  - The rates of GI complications in laparoscopic sacrocolpopexy are low
  - Prior abdominal surgery was associated with an increased risk of functional GI complications, but not bowel injury

Bowel Occlusion

- video

Complications of the mesh

Graft material

- Large pores polypropelene mesh seems to be an excellent graft material with low risk for graft infection (1.4%) or erosion (1.7%). n = 74

- Overall vaginal mesh erosion/extrusion rate is 1.2% (95% CI 0.5%-2.7%). Overall infection rate 0.3%. n = 446
  

- Overall mesh erosion rate 0.8% n = 124 over 5-year FU
  

Mesh Infection

- video

Long-term complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>N patients (132)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal mesh erosions</td>
<td>5</td>
</tr>
<tr>
<td>Vesicovaginal fistula and bladder calculi</td>
<td>1</td>
</tr>
<tr>
<td>Incisional hernia on 10 mm trocar site</td>
<td>1</td>
</tr>
<tr>
<td>Recurrent acute cystitis</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
</tr>
</tbody>
</table>

- The median (IQR) follow-up 60 (48–71) months;
  
  Sabbagh R et al BJU Int. 2010

- Rare but serious complication: spondyloediscitis
  
  Bul C et al. Gynecol Obstet Fertil. 2010

Very rare complications

  - Transrectal mesh erosion remote from sacrocolpopexy

- Downing KT. J Minim Invasive Gynecol. 2008
  - Vertebral osteomyelitis and epidural abscess after laparoscopic uterus-preserving cervicosacropexy
Functional results

- Ano-rectal
  - Constipation
  - «False need»
- Urinary
  - Stress incontinence (13–46%)
  - Bladder instability
- Dyspareunia, Pain

Possible explanation

- High tension on mesh
- Inappropriate placement of the mesh
- Big mesh
- Retraction of mesh

Conclusion

- Laparoscopic sacrosolpopexy is associated with low incidence of complications
- Vaginal mesh erosion is a well recognized complication occurring in up to 5%
- Up to 1% the mesh has to be removed due to infectious complications
- Learning curve

Learning curve

<table>
<thead>
<tr>
<th>Mean Op time</th>
<th>Turning point</th>
<th>Cx</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mustafa et al 2012</td>
<td>196 ± 62</td>
<td>15</td>
<td>Cystotomy (2)</td>
</tr>
<tr>
<td>Akladios et al 2010</td>
<td>236.9 ± 48</td>
<td>18 - 24</td>
<td>Cystotomy (2)</td>
</tr>
</tbody>
</table>
Incidence

- measure of the risk of developing some new condition within a specified period of time

What is a complication?

- Recurrence = complications?

Methodology

- Rates of major intra- and postoperative complications vary widely, ranging from 0% to 13%
- Follow-up period is very different (usually few months)
- Dropouts are not included in the efficacy analysis

Conclusions

- All studies have statistics
- When we deal with one patient is 0% or 100%
- Also the same with the gynecological surgeon
- Almost all series come from experts and referral centers
  => RISK ALWAYS EXIST

RISK ALWAYS EXISTS!

Thank you for your attention!!
References

• FDA warning on mesh use (2011)
• RCOG green top guideline (2007)
• French High Authority of Health warning on mesh use (2006)
• Kaser DJ et al. Int Urogynecol J. 2012 Sep;23(9)
• Jansen et al., Entry related complications in laparoscopy. AOG 2004
• Gabriel et al., Twenty years of laparoscopic sacrocolpopexy: where are we now? Int Urogynecol J (2011) 22:1165-1169
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](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](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](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.

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