Complications of Female Anti-incontinence Surgery

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SUI Epidemiology

• Estim. prevalence of female incontinence
  – 20-30% of young adults
  – 30-40% of middle aged
  – Up to 50% of elderly

• Type of incontinence
  – SUI 50%
  – Mixed 30%
  – UUI 20%
SUI Pathophysiology

- Intact neural and anatomic mechanisms
- Continence requirements
  - Bladder
    - Compliant
    - Absence of instability
    - Normal sensation
  - Outlet
    - Closed at rest
    - Remains closed during rises in intra-abdominal pressure

SUI Pathophysiology

- Bladder
  - Compliant
  - Absence of instability
  - Normal sensation

- Outlet
  - Closed at rest
  - Closed during rises in IAP

- Bladder
  - Hypocompliance
  - DO
  - Sensory UI

- Outlet
  - ISD
  - Hypermobility
Female Sphincter Mechanism

• Urethral Support
  – Muscle (levators)
  – Fascia (endopelvic, pubocervical, ATFP)
  – Ligaments (pubourethral, urethropelvic)

Pelvic Floor Musculature
Fascial Supports

• **SANDWICH**
  – Levators covered by fascia on both sides
    • Superior (internal) side: endopelvic
    • Inferior (external) side: periurethral/perivesical

  – Condense laterally to form “ligaments”
    attached to arcus or bony pelvis
    • Classified by organ they support

Urethral ligaments

• **Pubourethral Ligaments**
  – Anchors mid-urethra to symphisy

• **Urethropelvic Ligaments**
  – Endopelvic fascia + periurethral fascia
  – Attach to arcus laterally
  – Supports proximal urethra and bladder neck
    to lateral pelvic sidewall
Hypermobility vs ISD

**Definition**
- Coexist in most incontinent women
- All patients with sphincteric incontinence have some degree of ISD

**Clinical Parameter**
- Subjective physical finding
  - Q tip test
- Anatomic support defects
- Retropubic suspension

**Pathophysiology**
- Objective
  - ALPP < 60
  - Neurologic, injury
  - Sling/tape, bulking

**Repair**

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Hypermobility vs ISD

- Definitions controversial
- Use in guiding therapy controversial
SUI Risk Factors

• Age
• Menopause
• Parity
• Obesity
• Smoking/COPD
• Surgery

SUI Evaluation

• Basic Evaluation
  – Focused History
    • Questionnaires
    • Voiding diary
  – Physical Examination
    • Demonstrate incontinence
  – Urinalysis
  – PVR
SUI Evaluation

• Goals of basic evaluation
  – Confirm presence of incontinence
  – Identify reversible factors
  – Treat uncomplicated cases
  – Identify those that require further evaluation

Indications for Further Evaluation

• Diagnosis unclear
• Failure of initial treatment
• Plan for surgery
• Previous failed surgery
• Comorbid conditions
  – Neurogenic bladder
  – Suspected obstruction
  – Recurrent UTIs
  – Prolapse
Further Evaluation

- Urodynamics
  - Uroflow
  - CMG
  - LPPs
  - PFS
- Pad testing
- Radiology
  - Pelvic US
  - Pelvic MRI
  - VCUG
- Cystoscopy

SUI Conservative Management

- Behavior modification
  - Dietary changes
  - Timed voiding
  - Smoking cessation
  - Weight loss
    - Pelvic floor muscle training
      - Kegels, biofeedback, E-stim
- Pharmacologic
  - A-agonists, Imipramine, Duloxetine
  - Estrogen not helpful
SUI Conservative Management

“proper to counsel women who might appropriately choose surgery that, although surgery is the single most effective treatment for SUI there is a 40% to 50% chance that they can avoid an operation and be satisfied with the outcome by going through PFMT.”

CWU 9, p2142

Patients Who Benefit From Prompt Surgical Management

- Associated significant prolapse
- Severe SUI
- Already have good pelvic floor muscle tone and function
- Motivated to be completely dry
Indications for SUI Surgery

- Diagnosis confirmed
- Failure of conservative management
- Bothersome symptoms

Selection of Surgical Procedure

- Choices
  - Retropubic suspension
  - Pubovaginal sling
  - Trans-vaginal needle suspension
  - Trans-vaginal tape
  - Urethral injection
CUA Guidelines 2005

- Retropubic suspensions and PV slings are gold standard
- PV slings best for significant ISD or failed retropubic repair
- Tapes show good intermediate-term results
- Vaginal needle suspensions and colporrhaphy are less effective
- Urethral bulking is a good first option

SOGC Guidelines 2005

- Retropubic suspension has best durable cure (I-A)
- Tapes effective but long-term data lacking (I-A)
- Anterior repair or needle suspensions are inferior for isolated SUI (I-A)
- Urethral bulking associated with high failure rates (III-C)
What is Long-Term?  
What is Success?

• 5 yrs or more  
  – Late failures  
  – Delayed complications
• No standard definition
  – Subjective cure, QoL  
  – Objective cure
• Difficult to compare studies…

Reporting of Complications

• Lack of standardized definitions
• Differences in reporting
• Difficult to compare and summarize studies…
• Knowledge of potential complications important for INFORMED CONSENT
Retropubic Suspensions

• Indications
  – Surgeon preference
  – Significant hypermobility
  – Limited transvaginal access
  – Undergoing laparotomy for something else
    • Abdominal colposacropexy
Retropubic Suspension

• Contraindications
  – Lack of hypermobility, ie. Pure ISD
  – Inadequate vaginal length or mobility
  – Significant prolapse (need to address prolapse as well)

Abdominal Sacrocolpopexy with Burch Colposuspension to Reduce Urinary Stress Incontinence

• 322 women with no SUI and apical prolapse
• Grade 2-4 apical prolapse
• Randomized to Burch or no Burch
3 month follow-up

- 25% subjective SUI if no Burch
- 6% subjective SUI with Burch
  - Maintained effect when pre-op SUI excluded
- Also a significant reduction in urge/UI
- No difference in adverse events
Procedures

• Open
  – MMK
    • Paraurethral tissue anchored to pubic periosteum
  – Burch
    • Anchored to Cooper’s ligament
  – Paravaginal repairs
    • Anchored to ATFP

• Laparoscopic
Complications

• Early
  – Bleeding (<5% transfusion)
  – Organ injury (<2%)
  – Wound complications
  – Osteitis Pubis - MMK (1-3%)
• Late
  – OAB
  – Voiding dysfunction/Retention
  – Prolapse

Leach 1997

OAB

• Urgency or DO present in up to 30% pre-op
• Most resolve after repair
• 36% persistent urgency
• 11% de novo urgency
• May be associated with obstruction
Voiding Dysfunction

• Retention lasting > 4 wks (5%)
• Permanent retention (<5%)
• Require CIC or revision

• Risk factors:
  – pre-operative voiding dysfunction/retention
  – re-do surgeries

Prolapse

• Lateral vaginal wall tension may aggravate posterior weakness → enterocele
• 10-38% incidence
• most are asymptomatic
• < 5% require surgery
Pubovaginal Sling

• Indications
  – Loss of proximal urethral closure (ISD)
    • Neurogenic
    • Iatrogenic
      – Surgery
      – Radiation
    • Trauma
  – Proximal urethral defects/loss requiring surgery
    • Fistula
    • Diverticulum
    • Chronic catheterization

• Contraindications
  – Hypocompliant detrusor
Sling Materials

- Autologous fascia (Rectus/Fascia lata)
- Allografts (cadaveric)
- Xenografts
- Synthetics

Pros
- Erosion rare
- Strong
- Avoid harvest
- Abundant

Cons
- Harvest morbidity
- Processing weakens
- Infection
- Erosions

Specific Complications

- Retention relatively common
- Harvest site pain
- Erosion very rare (autologous sling)
- Sling failure
Retention

- Reported incidence varies widely
  - Groen & Bosch, 2004:
    - 42% require CIC at 3 months
    - 18% at 6 months
  - Leach et al. 2007:
    - 8% beyond 4 wks

- Predictors of??

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**ORIGINAl Article**

*Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence*

Sling too tight...

- **Presentation variable (Webster, 2003)**
  - Obstructive LUTS, CIC dependence
  - Urge, urge incontinence (most common)
  - Recurrent UTIs

- **Evaluation**
  - Hx, Px, Voiding diary, cysto, VUDS
  - Only 33% had urodynamic evidence of obstruction
  - Thus, clinical diagnosis in most

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**Table 2. Adverse Events.**

<table>
<thead>
<tr>
<th>Event</th>
<th>Burch Procedure (N=329)</th>
<th>Sling Procedure (N=326)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious adverse events;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with event</td>
<td>32 (10)</td>
<td>42 (13)</td>
<td>0.20</td>
</tr>
<tr>
<td>Total events</td>
<td>39</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Genitourinary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary injury</td>
<td>2</td>
<td>0</td>
<td>0.12</td>
</tr>
<tr>
<td>Ureterovaginal fistula</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Incidental vaginotomy</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Incidental cystotomy</td>
<td>10</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Erosion of suture into bladder</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Recurrent cystitis, leading to diagnostic cystoscopy</td>
<td>5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Pyelonephritis</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Catheter complication</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Voiding dysfunction leading to surgical revision</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>0</td>
<td>2</td>
<td>0.25</td>
</tr>
<tr>
<td>Bleeding</td>
<td>3</td>
<td>1</td>
<td>0.62</td>
</tr>
<tr>
<td>Wound complication requiring surgical intervention</td>
<td>13</td>
<td>11</td>
<td>0.83</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>1</td>
<td>1</td>
<td>1.00</td>
</tr>
<tr>
<td>Respiratory distress requiring intubation</td>
<td>0</td>
<td>1</td>
<td>0.50</td>
</tr>
<tr>
<td>Laryngospasm requiring reintubation</td>
<td>0</td>
<td>1</td>
<td>0.50</td>
</tr>
</tbody>
</table>
Sling too tight…

• Most recommend urethrolysis if urethra appears hypersuspended

• Most recommend intervening if retention lasts > 5-6 wks

CWU 9, p 2245

Method of Urethrolysis

• Webster 2003
  – Anterior vaginal wall approach
  – Localize sling and incise in midline
  – Dissect sling laterally into retropubic space as needed

  – Fill bladder and perform Crede manœuvre
  – Endpoint is good urinary stream
Urethrolysis Results

  - 93% re-established efficient voiding
  - 67% improved urge
  - 10% recurrent SUI

Persistent Incontinence

FIGURE 3. Diagnostic algorithm for persistent or recurrent incontinence after PVS. UDS = urodynamie studies; VUS = voiding leak point pressure; DO = detrusor overactivity; PFS = pressure-flow study; VCUG = voiding cystourethrogram (lateral views).

Poon & Zimmern, 2004
Tension-Free Tapes
Rise of the Tape

- TVT first introduced in 1996 (Ulmsten)
- Despite lack of long-term data, tapes have gained popularity
  - “minimally invasive”
  - Day surgery
  - Excellent short-term results
- Over 1,000,000 tape procedures worldwide (Raz, 2007)

Rise of the Tape

- In Europe (de Tayrac, 2005)
  - 84% of all incontinence procedures
  - 2/3 TVT, 1/3 TOT
- In North America, Canada, B.C.?
Trans-Vaginal Tape Procedures

• Principles
  – Mid-urethra placement
  – Monofilament polypropylene mesh
  – Tension-free
  – General or Spinal anesthetic
  – Day surgery

Approaches

• Retropubic
  – Ascending (TVT)
  – Descending (SPARC)
• Trans-obturator (TOT)
  – In-out
  – Out-in
## Large TVT Series

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>N</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nilsson (2004)</td>
<td>90</td>
<td>7yr</td>
</tr>
<tr>
<td>Kuuva (2002)</td>
<td>1455</td>
<td>-</td>
</tr>
<tr>
<td>Ward (2002)</td>
<td>344</td>
<td>2 yr</td>
</tr>
<tr>
<td>Aboussaly</td>
<td>241</td>
<td>-</td>
</tr>
<tr>
<td>Tamussino (2001)</td>
<td>2795</td>
<td>-</td>
</tr>
<tr>
<td>Schrafford (2005)</td>
<td>809</td>
<td>2 yr</td>
</tr>
</tbody>
</table>

### Complication Frequency

<table>
<thead>
<tr>
<th>Complication</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peri-operative</strong></td>
<td></td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>0.6-2.5%</td>
</tr>
<tr>
<td>Bladder injury</td>
<td>2.7-13.8%</td>
</tr>
<tr>
<td>Urethral injury</td>
<td>0-0.1%</td>
</tr>
<tr>
<td>Vascular injury (Iliac)</td>
<td>0.1-0.6%</td>
</tr>
<tr>
<td><strong>Post-operative</strong></td>
<td></td>
</tr>
<tr>
<td>Pelvic hematoma</td>
<td>0.7-3.4%</td>
</tr>
<tr>
<td>Urinary retention</td>
<td>2.3-19.7%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>0.7-22.3%</td>
</tr>
<tr>
<td>De novo urgency</td>
<td>0.2-15%</td>
</tr>
<tr>
<td>Vaginal erosion</td>
<td>0.5-1.3%</td>
</tr>
<tr>
<td>Bladder/Urethral erosion</td>
<td>0.02%</td>
</tr>
</tbody>
</table>
Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-reported?

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Under-Reporting?

- Literature review:
  - 14 studies met criteria (TVT, SPARC, TVTO, TOT)
  - 11,806 patients
  - 86 major complications (0.7%)
- FDA MAUDE database (voluntary reporting of device complications)
  - 161 major complications, 10 deaths
  - No denominator (ie. No national registry)
Bleeding (0.6-2.5%)

- Most define as >200-500mL blood loss
- Few require intervention
- Laceration of named arteries rare (0.1%)

- Post-op pelvic hematoma more common than intra-op hemorrhage
- Rarely requires intervention/transfusion

**TABLE IV. Comparison of the Distribution of Major Complications (Major/Total Complications) of Retropubic and Transobturator Approach in Published Literature versus FDA MAUDE Database**

<table>
<thead>
<tr>
<th></th>
<th>Literature</th>
<th>FDA database</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVT/SPARC</td>
<td>78/1497 (5.2%)</td>
<td>154/766 (20%) → 8 deaths</td>
</tr>
<tr>
<td>TO</td>
<td>8/233 (3.4%)</td>
<td>7/162 (4%) → 2 deaths</td>
</tr>
<tr>
<td>Total</td>
<td>86/1730 (4.6%)</td>
<td>161/928 (17%)</td>
</tr>
</tbody>
</table>

FDA, food and drug administration; MAUDE, manufacturer and user facility device experience.
Bladder Perforation (2.7-13.8%)

• More common early in the learning curve
• Higher risk if previous incontinence surgery
• Conflicting evidence for other risk factors:
  – Previous hysterectomy
  – Obesity
  – Prolapse
  – Type of anesthesia

Value of Cystoscopy

• Duckett, 2007:
  – 5 bladder perforations picked up in 100 consecutive patients with routine cystoscopy

• LeSala, 2006:
  – No difference in subjective cure rates in patients with bladder perforation recognized at surgery
Voiding Dysfunction (2.3-19.7%)

- Most define as prolonged need for catheterization
- May also present with
  - Urgency
  - Recurrent UTIs
- Risk factors not well delineated
- Optimal evaluation and management not defined

Post-TVT Voiding Patterns

- Cohort studies have shown urodynamic changes consistent with obstruction
  - Gateau et al. 2003.
    - 112 patients. 86% cured. 99% improved.
    - Compared pre and post-TVT UDS
      - Decreased Qmax
      - Increased PdetQmax
      - PVR > 100 cc in 10%
Post-TVT Voiding Patterns

- **Gateau et al. cont’d**
- Of interest:
  - 12% de novo urgency
  - No de novo detrusor overactivity
  - 24% had urodynamic obstruction pre-op

Urethrolysis

- Several studies showing effectiveness in restoring efficient voiding
  - Klutke, 2001: 17/600 patients in retention
    - All 17 urethrolysis at mean 64 days post-op
    - All had obstruction relieved, only 1 recurrent SUI
- No established predictors of who will benefit
- No optimal timing established
Vaginal Erosion (0.5-1.3%)

- Most present b/w 3wk and 3mo
  - Vaginal discharge
  - Dysparunea
  - Palpable mesh
  - LUTS
- Optimal management controversial
  - Conservative (Kobashi and Govier, 2003)
  - Vaginal flap reapproximation
  - Tape excision

Vaginal Erosion

- 10 erosions identified.
- 3 managed conservatively.
- 6 re-operated.
- All resolved and continence maintained.
Vaginal Erosion

• Conservative management plausible in asymptomatic small erosions
• Good results with reapproximation of vaginal mucosa for small erosions
• Tape excision reserved for severe symptoms or failure of above
• Continence usually maintained after tape excision

Urethral Erosion

• Rare
• Conservative therapy not an option
• Typically require tape excision and urethral reconstruction
• Martius flap may be used to bolster repair
• Autologous fascial sling placement has been described
Other

- Chronic Pelvic Pain
- Dysparunea
- Leg Pain
- Obturator hematoma
- Obturator abcess

Conclusion

- Each procedure has a unique side effect profile
- Important in gaining informed consent
- Minimally invasive procedures not to be taken lightly
- Complication reporting is not standardized