New Developments in Urogynecology

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Presentation Overview

- Urogynecology
  - Background and New Treatment Options:
    - Overactive Bladder
    - Stress Urinary Incontinence
    - Pelvic Organ Prolapse
Overactive Bladder (OAB)

- Urinary urgency, frequency, nocturia
  - Dry: No incontinence
  - Wet: Urge incontinence

- Treatment Options:
  - Behavioral-bladder training, diet
  - Physical Therapy/Biofeedback
  - Medications
Pharmacologic Therapy

- Ditropan (oxybutinin)
- Detrol (tolteradine)
- Ditropan XL
- Detrol LA
- Oxytrol patch
- Vesicare (solefenacin)
- Enablex (darefenacin)
- Sanctura (trospium)
- Sanctura XR
Botox®

- Botulinum Toxin Type A
- MOA: blocks release of acetylcholine at the neuromuscular junction which results in temporary paralysis of the muscle (chemodenervation)
**Botox®**

- 100-300U injected into detrusor
- 2 RCTs in IDO (idiopathic detrusor overactivity)
  - Significant improvement in urgency, frequency and incontinence vs. placebo (50-60% with Botox)
  - Onset 2d-4weeks
  - Duration 1) mean 373d  2)complete sx resolution 44% 4w, 25% 24w
- Risks

1Brubaker J Urol 2008, 2Sahai J Urol 2007
Urgent PC
PTNS

- Percutaneous Posterior Tibial Nerve Stimulation
- 60% positive response (van Balken)
InterStim®

- Sacral Nerve Stimulation

- INDICATIONS:
  - urge incontinence
  - urgency-frequency
  - urinary retention
Stress Incontinence (SUI)

- Involuntary loss of urine with increased abdominal pressure in the absence of detrusor contraction

- Treatment Options:
  - PME +/- PT, Biofeedback, E-stim
  - Pessary, Femsoft
  - Surgery
Operations for Urinary Incontinence

- **Suburethral Slings:**
  - Traditional (1907)
  - Mid-urethral:
    - Retropubic (1995)
    - Transobturator (2001)
    - “Mini Slings” (2006)

- **Colposuspension** (1949/1968)
Burch Colposuspension
Rectus Fascia Sling
The Tension-free Vaginal Tape System

PROLENE mesh protected by a plastic sheath (removed at end of procedure) attached to 2 needles

Mesh identical in composition to that used in PROLENE* polypropylene suture

Stainless steel rigid catheter guide

Stainless steel introducer

TVT Tension-free Vaginal Tape System
Product Codes:
10041 TVT Device
10051 TVT Introducer (reusable)
10061 TVT Rigid Catheter Guide (reusable)

For more information or to order product, contact your Gynecare sales representative.
RCT of Burch vs. TVT

- 14 centers in UK
- 175 TVT, 169 Burch
- **Objective** cure rate at 2 years:
  - Burch 51%
  - TVT 63%
  - ~20% in each group lost to f/u: considered failures
  - OR = 1.7 (95% CI: 1.1-2.6)

RCT of Burch vs. TVT

- Only 20-25% of each group reported no incontinence under any circumstance

- @ 2 years:
  - More cystocele in TVT group (63 vs. 39%)
  - More cervical / apical prolapse in Burch group (60 vs. 29%)

RCT of Burch vs. TVT: results by center

RCT of Burch vs. TVT: results by surgical volume of center

TVT Complications

- Vascular injury ~1: 10k
- Bowel injury ~1: 17k
- Urethral erosion ~1: 25k
- Hematoma ~1: 25k
- Nerve injury ~1: 125k

<table>
<thead>
<tr>
<th>Complication</th>
<th>%</th>
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<tbody>
<tr>
<td>Minor voiding difficulty</td>
<td>7.6</td>
</tr>
<tr>
<td>UTI</td>
<td>4.1</td>
</tr>
<tr>
<td>Bladder perforation</td>
<td>3.8</td>
</tr>
<tr>
<td>Post-op urinary retention</td>
<td>2.3</td>
</tr>
<tr>
<td>Retropubic hematoma</td>
<td>2.4</td>
</tr>
<tr>
<td>Wound infection</td>
<td>0.8</td>
</tr>
<tr>
<td>Mesh exposure</td>
<td>0.7</td>
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</tbody>
</table>

Transobturator Tape (TOT)
TOT Complications (MAUDE)

- 1/04-7/05: 173 complications in 140 reports
- Erosions (60%) - 1 urethral
- Infections (15%)
  - 2 ischiorectal fossa
  - 2 adductor muscle
- Neuropathy (2%)
- Excess bleeding (3%)
- Urethral & Bladder Injury (4%)

Review

- 13 RCTs through Sept. 2008
- 972 TVT, 931 TOT
- “cure rate” – various time points and definitions:
  - TVT 896/972 = 92.2% (95% CI=90.3-93.7)
  - TOT 832/931 = 89.4% (95% CI= 87.2-91.1)
- OR = 1.40 (95% CI= 1.03-1.92)
TOT: in women with poor urethral function

- Varying study design
- VLPP<60 or MUCP <40-42
- Objective outcome (varies)
- Normal urethra: 224 “cured” / 250 total
  - 89.6% (95% CI= 85.8-93.4)
- Poor urethral function: 161/250
  - 64.4% (95% CI= 58.5-70.3)
- OR= 4.8 (95% CI= 2.9-7.7)
Ready or Not? TVT-Secur®
FDA Approval of Surgical Devices

- Devices unregulated until 1976
  - (drugs regulated in 1902)
- “Premarket Notification Process: 510k”
  - Device does not require premarket approval if “shown” to be substantially equivalent to an existing device
501 K for TVT-Secur®

- Application received by FDA: 11/17/2005
- Thanksgiving: 11/24/2005
- FDA approval given: 11/28/2005
Published Data for TVT-Secur®

- Nearly 3 years since FDA approval....
Published Data for TVT-Secur®
MiniArc®
POP-Q

Stage 0: no prolapse
Stage I: >1cm above level of hymen
**Stage II: <1cm above and < 1cm below hymen**
Stage III: >1cm below hymen but <TVL-2cm
Stage IV: complete protrusion
Anterior Repair: Synthetic Mesh

- **Hiltunen 2007**: randomized to traditional AR or AR with polypropylene graft (n=202)
  - Recurrence: 38.5% vs. 6% w/graft
  - Mesh exposure 17.3%
  - No difference in post-op symptoms

- **Nguyen 2008**: randomized to traditional AR or AR with polypropylene graft (n=75)
  - Recurrence: 45 vs 13% w/graft
  - Mesh exposure 5%
Non-absorbable Synthetic Mesh Complications

- Reported complications: infection, hemorrhage, dyspareunia, bladder injury, voiding dysfunction, ureteric obstruction, chronic pelvic pain, mesh erosion (bladder/urethra), mesh extrusion (vagina), VVF

- Overall mesh erosion/extrusion rate: 0-29%

- Altman 2007: 4.4% serious (10/11 visceral injury); 14.5% minor (UTI, retention, fever)
Mesh Complications

Case #1
59yo P2 TVH, BSO, APR
w/prolene mesh 10/06
- postop pain, SUI
- 12/06 TOT
- 2/07, 4/07 mesh removal
- multiple pain meds, trigger point injections
- 7/08 removal of small amt remaining prolene
- persistent pain, considering spinal implant

Case #2
78yo P4 2000-APR with mesh;
2001 mesh removed (infection)
- 3 surgeries for rectovaginal/perineal fistula;
persistent FI/purulent discharge
- 2007 colostomy, persistent anal discharge
- 2008 removal of mesh transrectal (obliterated vagina)
Sacrocolpopexy

vaginal vault Prolapse

Sacrocolpopexy with Mesh
Operating Room Configuration

- 4th arm on LEFT side to retract sigmoid laterally
- Assistant stands to RIGHT side of OR table
- Role of Assistant
  - Access and exchange of Vinci instruments
  - Use conventional laparoscopic instrument for retraction/countertraction, suction/irrigation, introducing suture and mesh, cutting
  - Uterine/vaginal manipulation
Intuitive Surgical da Vinci®
“Potential Benefits over Traditional Surgery”

- Less postoperative pain
- Less scarring
- Less blood loss
- Fewer transfusions
- Less risk of infection
- Faster recovery time
- Shorter hospital stay

http://www.intuitivesurgical.com
Robotic ASC

- 2 published studies (30, 15 total n=42)
- Short-term outcomes:
  - 3-6 months n=13: mean POP-Q stage 0 (C-8.28, Ba-2.29)
  - 12 months n=21: 19/20 (95%) successful apical repair at 24mos
- OR time, Learning curve
- Complications

Elliott 2006, Daneshgari 2007
Direct Hospital Based Costs

- Robotic: $24,161.48
- LSC: $19,308.94
- Open: $13,149.99

Patel 2008 AUGS Abstract
Robotic ASC: Short Term Outcomes

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<tr>
<th></th>
<th>Robotic</th>
<th>vs.</th>
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<tbody>
<tr>
<td>OR Time</td>
<td>328 min</td>
<td></td>
<td>225 min</td>
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<tr>
<td>Stay</td>
<td>1.3 days</td>
<td></td>
<td>2.7 days</td>
</tr>
<tr>
<td>Fever</td>
<td>4.1%</td>
<td></td>
<td>0%</td>
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<tr>
<td>EBL</td>
<td>103 ml</td>
<td></td>
<td>255 cc</td>
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</table>

- No clinical difference in POP-Q outcomes
- No difference in other secondary outcomes

Geller 2008 AUGS Abstract
Conclusions

- OAB: Botox® and neuromodulation are promising options in refractory cases
- Volume and site/surgeon are factors in surgical outcomes
- New devices/kits: minimal data on complications and long-term outcomes, some data for short-term success