Current Issues in Urogynecology

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Urinary Incontinence

- Common
  - 25% reproductive age women
  - 40% postmenopausal women
- Chronic - social seclusion
  - Profound effect of QOL
  - 3x Nursing home admits, falls & fractures
- Costly
  - $26 billion annually
  - More than all cancer care for women

Incontinence Definitions

- Overactive Bladder (OAB)
  - urgency, frequency, nocturia, urge UI
- Urge UI - loss with urgency, feeling need to empty but cannot get to the toilet fast enough
- Stress - coughing, sneezing, straining, exercise
- Mixed - both urge and stress
- Other - neurologic, obstruction
Stress vs. Urge Incontinence

<table>
<thead>
<tr>
<th></th>
<th>Stress UI</th>
<th>Urge UI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precipitant activity</td>
<td>immediate</td>
<td>urge</td>
</tr>
<tr>
<td>Timing</td>
<td>immediate</td>
<td>delayed</td>
</tr>
<tr>
<td>Amount</td>
<td>small-mod</td>
<td>large</td>
</tr>
<tr>
<td>Frequency, Nocturia</td>
<td>rare</td>
<td>common</td>
</tr>
<tr>
<td>Remissions</td>
<td>rare</td>
<td>common</td>
</tr>
</tbody>
</table>

UI: Who is at Risk?

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>↑ Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral estrogen</td>
<td>90%</td>
</tr>
<tr>
<td>Stroke</td>
<td>90%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>70%</td>
</tr>
<tr>
<td>BMI (per 5 units)</td>
<td>60%</td>
</tr>
<tr>
<td>Poor overall health</td>
<td>60%</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>40%</td>
</tr>
<tr>
<td>COPD</td>
<td>40%</td>
</tr>
<tr>
<td>Age (per 5 years)</td>
<td>30%</td>
</tr>
<tr>
<td>Live birth</td>
<td>30%</td>
</tr>
</tbody>
</table>

Brown (SOF) 1996

Evidence-Based Guidelines

1996 AHRQ Clinical Practice Guidelines:
- Primary Care diagnosis & treatment
- History, neurologic & pelvic exam, PVR, U/A

10 years later, where are we?
Barriers for Primary Care:
- Work up too time consuming & complex
- No pelvic exam tables
- PVR not possible
Prior Literature

- Early 1990’s: Urodynamics
- Late 1990’s: Questionnaires
- Neither feasible in Primary Care
- Depression: 2 Questions as good as many

Jensen 1994; Diokno 1999; Klovning 1996; Whooley 1997

European Primary Care

- 96-98% of UI diagnosed by PCP
- As few as two questions are as sensitive
- Is less better?
  - specificity acceptable when the risk of a missed diagnosis or incorrect treatment are very low
  - May even be preferred if cost and discomfort

Largo-Janssen 1991; Sandvik 1995; Kloving 1996; Shaw 2001

Diagnostic Aspects of Incontinence Study (DAISy)

- Multi-center, cross-sectional study (N = 301)
- 3 Incontinence Questions (3 IQ) vs. Extended Evaluation
  - US, UK, WHO Clinical Practice Guidelines
  - H & P, Neuro & pelvic exam, PVR, Cough Stress Test, UA, 3-Day Diary

Brown Annals 2006
3 Incontinence Questions (3IQ)

1. During the last 3 months, have you leaked urine, even a small amount? If yes:

2. Stress UI: physical activity, coughing, sneezing, lifting, or exercise
   Urge UI: urge, feeling need to empty but could not get to the toilet fast enough
   Other

3. Type of UI most often: Stress, Urge, Mixed, Other

Primary Care UI Patients

Inclusion criteria:
Incontinent women appropriate for Primary Care
- Community dwelling, ambulatory, weekly UI
- Bothersome enough to seek treatment

Exclusion criteria:
Complex UI: Incontinent women for referral
- Failed surgery, failed UI treatment
- Fistula, CNS etiology: MS, spinal cord injury

Accuracy of 3 IQ Compared to Extended Evaluation

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>LR+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urge UI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3IQ</td>
<td>0.75</td>
<td>0.77</td>
<td>0.79</td>
<td>3.26</td>
</tr>
<tr>
<td>Stress UI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3IQ</td>
<td>0.86</td>
<td>0.60</td>
<td>0.74</td>
<td>2.13</td>
</tr>
</tbody>
</table>
3 IQ in Action

Ms. I. Gotta-Go is a 60 yo teacher G0P0:
“I have a hard time waiting until the end a class to go to the bathroom and usually have to run to get there. Almost every day I leak on the way to the bathroom. When I have a severe cough, I may leak also but that occurs rarely.”

And the diagnosis is?

1. Stress UI
2. Urge UI
3. Mixed UI
4. Other UI

3 IQ in Action

Ms. Stressed is a 54 yo Techie G2P2:
“Ever since my first birth, when I am physically active - I leak urine. Recently, almost every day I leak with a cough or when I lift something heavy. Sometimes when I wait too long, I leak on the way to the bathroom but that occurs rarely.”
And the diagnosis is?

1. Stress UI
2. Urge UI
3. Mixed UI
4. Other UI

Summary

3 IQ: Simple, inexpensive, feasible
- Accuracy for classification is acceptable

DAISy Take Home Message:
- 3 IQ is a good test for type of UI
- The risk of missed Dx and Rx low

PCP’s: 3IQ or 3-day diary to classify type of UI

We can remove barriers to care for women with UI!
Next: Simple treatments!

Initial Visit

- Clinical diagnosis - 3 IQ, UA
- Severity of leakage
  - Provocation
  - Protection
  - Problem

How bothersome is incontinence for your patient?
Initial Visit

- Patient information
- Urinary diary
- Bedside commode?
- Estrogens?
- Weight loss?
- Consider Rx

Information!

www.ucsf.edu/wcc

Urinary Diary

- Simple form for recording voids, incontinent episodes, fluid intake
- Excellent education & intervention!
- Very useful in planning therapy
  - fluid adjustment
  - timing and type of medications
Incontinence Treatment

- Initial Rx similar for stress & urge
- Behavioral Management
  - Fluids modification
  - Pelvic Floor Exercises
  - Bladder training
- Verbal and written instructions

Successful Pelvic Floor Exercises

- Strengthen levator ani and sphincter
- Finger in the vagina, one hand on the abdomen
- Two types: Rapid and Prolonged
- Individualized Program
- Biofeedback as needed
Bladder Training

- Re-establishing voluntary control
- Schedule voids q 30-60 minutes
- Diary, relaxation, urge suppression
- RCT demonstrated:
  - ≥ 50% improvement in 75% of participants
- Stress and Urge UI

Fantyl 1991

Behavioral Therapy

- 222 women with Urge UI: RCT

<table>
<thead>
<tr>
<th>Improvement</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Biofeedback</td>
<td>63%</td>
</tr>
<tr>
<td>Verbal/vaginal instruct</td>
<td>69%</td>
</tr>
<tr>
<td>Self-help booklet</td>
<td>59%</td>
</tr>
</tbody>
</table>

Not statistically different

Bottom line: Educate & Empower!

Burgio JAMA 2002

Additional Rx

- Stress UI
  - timed voids to prevent full bladder
  - pessary
  - surgery
- Urge UI
  - urge suppression / distraction
  - quick pelvic contractions
  - medication
OAB Medications

- Relax the bladder
- Symptom relief
- Balance:

IMPROVED OAB SIDE EFFECTS

OAB Medications

Side effects:
- dry mouth
- constipation
- drowsiness
- blurred vision
- dizziness

Contraindications:
- narrow angle glaucoma
- hepatic/renal disease

Cochrane Review
OAB Rx Effectiveness

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Drug</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective Cure/Improvement</td>
<td>60%</td>
<td>45%</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>32%</td>
<td>14%</td>
<td>NS</td>
</tr>
</tbody>
</table>

- 32 RCT's; 6800 participants
  Herbsin 2003
**Medication Prescribing Guideline**

**Appendix**

<table>
<thead>
<tr>
<th>Immediate Release</th>
<th>Extended release</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxybutynin (Ditropan)</td>
<td>Darifenacin (Enablex)</td>
</tr>
<tr>
<td>Tolterodine (Detrol)</td>
<td>Ditropan XL</td>
</tr>
<tr>
<td>Trospium (Santura)</td>
<td>Solifenacin (Vesicare)</td>
</tr>
<tr>
<td></td>
<td>Detrol LA</td>
</tr>
<tr>
<td></td>
<td>Oxybutynin transdermal (Oxytrol)</td>
</tr>
</tbody>
</table>

**Behavioral Rx vs. Medications**

- 197 women with Urge UI: RCT
  - Biofeedback/behavioral \(81\%^{* *}\)
  - Medication \(69\%^{*}\)
  - Placebo \(40\%\)
  - * \(P < 0.05\) vs. medication; + \(P < 0.05\) vs. control
  - Greater satisfaction in behavioral group

*Bottom line: Educate & Empower*

Burgio 1998

**Rx + Pt Info**

- Combo treatment: Makes sense
  - Behavioral to drug \(84\%\)
  - Drug to behavioral \(89\%\)

*Bottom line: Be creative!*

Burgio 2000
Weight Reduction & UI

- In women about 200 lbs:
  - Weight loss: > 5% or 30 lbs
  - > 50% Incontinence reduction
- Effective therapy for UI
- Unique motivator for weight loss
- Public Health Implications

Subak 2002; Subak 2006

PRIDE - Changes at 6 months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention</th>
<th>Control</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight UI / Week</td>
<td>- 8%</td>
<td>-2%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total</td>
<td>- 46%</td>
<td>-25%</td>
<td>0.04</td>
</tr>
<tr>
<td>Stress</td>
<td>- 57%</td>
<td>-33%</td>
<td>0.02</td>
</tr>
<tr>
<td>Urge</td>
<td>- 41%</td>
<td>-29%</td>
<td>0.23</td>
</tr>
</tbody>
</table>

Subak 2007

UI Treatment Effectiveness

- Placebo 20-40%
- Behavioral 40-80%
- Pharmacological 40-70%
  Side effects, discontinuation 50%
- Weight Loss 50-60%
- Surgery 80-100%
  Long-term cure 50-90%

Non-surgical treatments similar!
What treatments can you offer Ms. I. Gotta-Go?

- Bothersome mixed urge incontinence
  1. Behavioral
  2. Medication
  3. Weight Loss
  4. Pessary
  5. Surgery

Falls & Fractures

- Weekly urge incontinence - ↑ Risk
  - Falls 26%
  - Fracture 34%

- Associated frequency & nocturia

- Early diagnosis and treatment

- Potential to prevent or ↓ falls & fx

Brown JAGS 2000

Estrogen Therapy for UI

- ↓ UI in observational studies
  - Receptors in urethra, bladder

- 7 RCTs oral CEE/MPA vs. placebo (N=15,593)
  - HERS & WHI

- For Stress, Urge, & Mixed UI:
  - Prevalent UI: ↑ frequency 40 - 50% (4 mo → 4 yrs)
  - Incident UI at 1 yr: ↑ 15% to 2 -fold

Bottom line: HT not for prevention or Rx of UI

Grady Ob Gyn 2001; Hendrix JAMA 2005
Summary

PCP, ObGyn can KISS

- Simple diagnosis: 3 IQ & UA
- Simple Treatments: Info ± Rx
- Ask patient what they want!
- Combine treatments, flexibility

*Educate & Empower!

Who for UI Surgery?

- Patient driven decision
- Failed conservative Rx
- Stress UI primarily (3 IQ!)
  - ↑ Severity: ↑ results
- Bladder neck mobility
- Understands risks & benefits

How does it work?

- ↓ Urethral mobility
- “Backstop” for the urethra
- Recreate “hammock”
- Obstruction
What do we know?

- 150 surgeries, 4 categories
- New and variations ongoing
- Data limited
- Published surgical literature: lowest level of evidence and limited quality
- Lack of controlled trials, selection and observation bias, short follow-up


What else?

- Overestimate success
- Underestimate complications
- First surgery: best surgery
- Burch or Sling best choices

Black 1996
Where?

- Vaginal: anterior repair, needle suspension
- Retropubic: MMK, Burch
- Slings: Autologous, synthetic
- **Minimally Invasive:**
  - Tension-free Vaginal Tape (TVT)
  - Transobturator Approach (TOT)
- Injections, artificial Sphincter

Urinary Incontinence Treatment Network (UITN)

- NIDDK supported; 9 centers
- Stress Incontinence Surgical Treatment Efficacy Trial: SISTEr
- RCT of Burch (N=329) vs Pubovaginal Sling (N=326)
- Randomized in OR; Surgeons, pts not blinded
- Procedures standardized
- N= 655; F/u 2 yrs N= 520 (79%)
  - Tennstedt 2005; Albo NEJM 2007

SISTEr Results

- **Overall success:** no self-report UI; no diary UI; neg stress test; no re-treatment

  *Overall success: Sling 47% vs Burch 38%  P=0.01*

- **SUI success:** no self report SUI, neg stress test, no re-treatment for SUI

  *SUI success: Sling 66% vs. Burch 49%  P<0.001*
  - Albo NEJM 2007
**SISTEr Results**

*Similar outcomes:*
- Blood loss (230 ml), Op time (138 minutes)
- No effect of prolapse surgery
- New onset Urge UI (3%)

*Voiding Dysfunction leading to Surgical Revision:*
- Sling N = 19 (6%) vs. Burch = 0
- Treatment Satisfaction (self-report: completely, mostly):
  Sling 86% vs Burch 78% P=0.02

Albo NEJM 2007

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**Tension Free Vaginal Tape (TVT)**

- Prolene tape needle suspension/sling
- Placed at the mid-urethra, unfixed
- Possible longitudinal deposition of collagen
- Local or light anesthesia
- Outcomes:
  - Short-term 85%; Long-term limited data

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**UK RCT: TVT vs. Burch**

- 14 UK Centers; Mix of centers and surgeons
- N= 344; 6 month f/u
- One of the first to adhere to CONSORT

*Bottom Line: No difference in effectiveness*
- TVT: More operative complications- bladder and vaginal injury
- Burch: ↑OR times, blood loss, catheterization
Limitations

• Inadequate sample size
• Blinding:
  When humans have to make observations there is always the possibility of bias
  - Patients not blinded;
  - Observer bias: post-op eval not blinded
• 2 yr f/u TVT 63% vs Burch 51%

Hilton 2005

CONCLUSIONS

• SUI surgery is not an emergency!
• First surgery most successful
• Sling or Burch reasonable
• TVT: RCT and long-term outcomes
• New surgeries: RCT to standard
• Long-term data coming....