Pelvic Floor Disorders and the Geriatric Patient

Cassandra L. Carberry, MD, MS, FACOG
Assistant Professor (Clinical), Ob/Gyn
Alpert Medical School of Brown University
Director of Clinical Services
Division of Urogynecology and Female Pelvic Reconstructive Surgery
Women and Infants Hospital of Rhode Island
Objectives

• Why you should care about pelvic floor disorders
  – What are pelvic floor disorders?
  – Who is affected?

• What can be done for your patients with pelvic floor disorders?
  – Non-surgical and surgical treatment options
  – Team approach
    • Rhode Island Center for Pelvic Floor Disorders
    • Your input!
  – Research protocols
    • NIH Pelvic Floor Disorders Network
Pelvic Floor Disorders – What are they?

- Urinary incontinence
- Pelvic organ prolapse
- Fecal incontinence
- Voiding dysfunction
- Defecatory dysfunction
- Chronic pain syndromes involving pelvic organs
Prevalence of pelvic floor disorders

• 2005-6 NHANES data: 24% of women have sx of at least 1 disorder
  • 39% for women 60-79 yo
  • 50% for women >80 yo

• Urinary incontinence (UI)
  – 15.7-49.6%

• Pelvic Organ Prolapse (POP)
  – 41.1% based on exam only
  – 2.9-5.7% symptoms

• Fecal Incontinence (FI)
  – 11-24%
This concerns you...

- Population is aging – in US:
  - 2008: >65 yo: 38.6 million
  - 2050: 88.5 million
- Aging women outnumber men
- Prevalence of pelvic floor disorders increase with AGE!
- Projected increases 2010 to 2050
  - Urinary incontinence: 18.3 to 28.4 million women
  - POP: 3.3 to 4.9 million women
  - Fecal incontinence: 10.6 to 16.8 million women
This concerns …many of us

• Treatment …more on this later
  – Anyone taking care of female patients
  – Rhode Island Center for Pelvic Floor Disorders
    • Urogynecologists
    • Gastroenterologists
    • Colorectal Surgeons
    • Urologists
    • Radiologists
    • Physical therapists
  – NIH Pelvic Floor Disorders Network
    • SUPER – uterine prolapse (recruiting)
    • ESTEEM – mixed incontinence (recruiting)
    • CAPABLe – fecal incontinence (recruiting)
Urinary Incontinence

- **Stress**
  - Leakage with increased intra-abdominal pressure in the absence of a detrusor contraction
- **Urge**
  - Leakage associated with an urge to void
- **Mixed**
  - stress + urge
- **Overflow**
  - Incontinence w/o urge
  - Associated with neurogenic bladder or bladder outlet obstruction
- **Continuous**
  - Fistula
  - Intrinsic Sphincter Deficiency
- **Functional Incontinence**
Urinary Incontinence

• Testing
  – UA/C&S
  – Urodynamics
  – Cystoscopy
Treatment of Urinary Incontinence

- Stress (SUI)
  - Kegel exercises*
  - Weight loss*
  - Pelvic floor physical therapy*
  - Pessary
  - Surgery
- Urge (UUI)
  - Behavioral modification*
  - Pelvic floor physical therapy*
  - Medication*
  - Sacroneuromodulation
  - ROSETTA trial
- Mixed: stress + urge
  - Combination of approaches – determine where to start with the patient
  - Expectation management*
- Overflow
  - Timed voids*
  - Intermittent self-catheterization
Failures of Continence Mechanisms
Pessaries
Surgery for SUI

• Midurethral slings: TVT, TVT-O, Monarc
  – GETA, spinal or local

• Burch colposuspension:
  Open vs laparoscopic
  – GETA

• Fascial sling
  – GETA

• Urethral bulking
  – Local + sedation
This concerns you again

• Team approach
  – Includes meaningful input from primary care providers
    • Perioperative evaluation and recommendations
    • Co-management of medications
Midurethral Slings
Risks and benefits: MUS

**Efficacy**

- Nilsson et al found\(^3,4\)
  - 85% cured at median follow-up of 56mo
  - Additional 10.6% improved
  - 4.4% failed
  - 17 yr follow-up – 87% cured or improved
- Other trials 70-85%

**Complications**

- Bladder perforation 3-6%\(^5\)
- Minor voiding difficulties 8%
- Retention 2.5%
- Retropubic hematoma 2%
- Major vessel injury 0.07%
- Mesh erosion <1%
Burch Procedure
Urethral injections

- Urethral injections
- Long history since 1938
  - Coaptite ®
    • calcium hydroxyl apatite
  - Macroplastique ®
    • Silicone microparticles
  - GAX Collagen ®
    • glutaraldehyde cross linked
SUI Treatment

Systematic Review Group of the Society of Gynecologic Surgeons (SGS) 2014 Review:

- Midurethral sling (MUS) vs fascial sling
- Favored MUS for subjective cure
- Midurethral sling vs Burch
  - No difference in objective or subjective cure rate
  - Burch is more invasive
- Fascial sling vs Burch colposuspension
  - Favored sling for objective and subjective cure
FDA Public Health Notification

• July 2011

“The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are not rare. This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk.”
FDA Public Health Notification: 2011

- Incidence of reported complications
  - 2005-2007: 1000
  - 2008-2010: 2874 (1371 SUI repairs)
- Did not include review of literature for SUI

“The FDA continues to evaluate the literature for SUI surgeries using surgical mesh and will report on that usage at a later date.”
FDA Public Health Notification: 2011

- Transvaginal mesh for prolapse repair most problematic
- Some specific materials used in slings problematic
- Led to barrage of advertising/lawsuits
FDA Public Health Notification: 2013 Update

• Sept 2011 FDA convened a panel & conducted systematic review

“The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year. Longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up.”
FDA Public Health Notification: 2011
Recommendations for physicians

• Obtain specialized training for each mesh placement technique, and be aware of its risks.
• Be vigilant for potential adverse events from the mesh, especially erosion and infection.
• Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
• Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
• Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
• Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.
Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence

The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.
Not “that mesh”

• Important to educate patients that type of mesh, volume of mesh, and implementation of mesh critical to risk

• Complications associated with large pieces of transvaginal mesh for POP repair mostly what trigger FDA advisory
  – 10-20% erosion rates
Treatment of Urge Incontinence

- Pelvic floor physical therapy
- Behavior modification
- Medications
  - anticholinergics
    - Significant side-effects
      - Dry mouth and constipation most common
      - Dizziness, blurry vision, cognitive impairment
- contraindicated in narrow angle glaucoma
Urgency Incontinence

- Antimuscarinics
  - Act at M2/M3 receptors
  - Block contraction/inappropriate emptying
  - Better than placebo but modest improvement

- Oxybutynin IR/ER (Ditropan)
- Oxytrol (patch) now OTC
  - least constipation
  - ~15% site rxn
- Gelniq (gel)
- Tolterodine (Detrol)

- Solifenacin succinate (Vesicare)
- Trospium chloride (Sanctura)
- Darifenacin (Enablex)
- Fesoterodine fumarate (Toviaz)
UUI Treatment: Anticholinergics

• Side effects
  – Dry mouth
    • Dental caries
  – Constipation
  – Dry Eyes
  – Blurred vision
  – Dyspepsia
  – Sedation
  – Headache

• Contraindications
  – Narrow angle glaucoma
  – Urinary retention
  – Gastroparesis

• Use with caution
  – Myasthenia gravis
  – Prolonged QT (tolterodine, solifenacin)
Which anticholinergic?

- No medication is definitively superior
- Extended release formulations better tolerated
- Base on coverage
  - Oxybutynin most widely covered
- 4 week trials
- Dose titration?
- Trial and error
Which anticholinergic?

DIAGNOSIS AND TREATMENT OF OVERACTIVE BLADDER (Non-Neurogenic) IN ADULTS: AUA/SUFU GUIDELINE 2012¹⁰
### Which anticholinergic?

Based on side-effects

Dry mouth and constipation most consistently reported

<table>
<thead>
<tr>
<th>Dry mouth</th>
<th>Constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo 6.9%</td>
<td>Placebo 3.6%</td>
</tr>
<tr>
<td><strong>Oxybutynin 61%</strong></td>
<td><strong>Oxybutynin 12%</strong></td>
</tr>
<tr>
<td>Tolterodine 24%</td>
<td>Tolterodine 4.9%</td>
</tr>
<tr>
<td>Solifenacin,</td>
<td>Fesoterodine, Solifenacin, Trospium 7-9%</td>
</tr>
<tr>
<td>Fesoterodine,</td>
<td><strong>Darifenacin 17%</strong> (but does not cross BBB)</td>
</tr>
<tr>
<td>Darifenacin,</td>
<td></td>
</tr>
<tr>
<td><em>Tropium 20-40%</em></td>
<td></td>
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</tbody>
</table>
UUI Treatment: Anticholinergics

• Poor compliance
• Veenboer et al. J Urology 2014
• Systematic review of studies of adherence/persistence
  – 12-39.4% at 12mo
  – 8-15% at 18mo
  – 6-12% at 24mo
  – Risks for discontinuation
    • Younger age
    • Oxybutynin
    • Immediate release formulation
UUI Treatment: β3 Agonist

• Mirabegron (Myrbetriq)$^{14,15}$
  – β3 agonists
  – Receptors in urothelium and detrusor muscle
  – Promote relaxation and stability/ improve storage
    • Less risk of retention
  – Approved in US 2012
  – Doses 25 and 50mg
UUI Treatment: β3 agonists

- Two phase II and two large phase III trials\textsuperscript{16}
  - Demonstrate efficacy
    - 50, 100, 200 mg
    - 25 and 50mg clinically available
  - Rate AEs not different from placebo or tolterodine
  - 3 fold less constipation than tolterodine
  - Hypertension most common s/e \( \sim 7\% \)
  - Mean increased in pulse rate 1.6 to 4.1 bpm
  - Undetermined significance
UUI Treatment: Neuromodulation

- PTNS (posterior or percutaneous tibial nerve stimulation)

Sacral Neuromodulation (InterStim)
UUI Treatment: Neuromodulation

• PTNS for OAB– not UUI specifically\textsuperscript{15,16}
  – 37-82% success rate in men and women
  – 54-93% success rate in women
  – Significantly better than sham (RR 7.02
    95%CI 1.69-29.17)
  – Significantly better global improvement but not
    objective measures of OAB compared to
    anticholinergics
    • fewer side-effects
"There's nothing really wrong with you but I think a little surgery would make us both feel better."
Treatment of Urge Incontinence

- Sacroneuromodulation: InterStim
  - local + sedation
- Botox
  - local
  - office procedure
- ROSETTA
- RCT: InterStim vs Botox
UUI Treatment: Neuromodulation

• Sacral neuromodulation (InterStim®)
• 2009 Cochrane review\textsuperscript{17}
  – Case series:
    • 67% had $\geq 50\%$ improvement
    • 39% cured
    • Long-term benefit (3-5yrs)
  – Randomized trials
    • 50% cured or had 90\% improvement
    • 87% had $\geq 50\%$ improvement
UUI Treatment: Botox

- Onabotulinum toxin A
UUI Treatment: Botox®

- Anticholinergic vs Botulinum toxin Comparison (ABC) study by the Pelvic Floor Disorders Network (PFDN of NICHD)\textsuperscript{18}
  - 10 centers, double-blind, double-placebo –controlled randomized trial
  - Oral anticholinergic + intradetrusor saline vs intradetrusor Botox + oral placebo
    - Mean reduction of UUI not different
    - Significantly more cured in Botox group
    - Botox – less dry mouth
    - Anticholinergics – less catheter use, fewer UTIs
UUI Treatment: Botox

- FDA approved in January 2013
- Botox is injected into the detrusor cystoscopically
- Office procedure under local anesthesia
- Patients with incomplete bladder emptying or recurrent UTIs would NOT be good candidates

- Dose response
  - 100-200 units effective
  - Higher doses have increased s/e
  - ABC used 100 units
    - 27% dry
    - Lasts 3-12mo
    - UTI 33% vs 13% for meds (p<0.001)
    - Catheter use 5% vs 0% (p=0.01)
Pelvic Organ Prolapse

- Evaluate SYMPTOMS and exam
- Anterior compartment
  - Cystocele
- Posterior compartment
  - Rectocele
- Apical compartment
  - Uterine
  - Cervical
  - Enterocele
Anterior wall
Posterior wall
Uterine prolapse
Treatment Options for Prolapse

• Pelvic floor physical therapy
• Pessary
• Surgery
• Expectant management & reassurance
• Decision impacted by many factors: comorbidities, activity level, sexual activity
  – Age is one! …but not the only one
Pessaries
Surgery for Prolapse

- Various approaches
  - Vaginal
    - Obliterative
      - GETA, spinal, or local
    - Reconstructive
      - GETA or spinal
  - Abdominal
    - GETA
  - Laparoscopic/Robotic
    - GETA
- Common reconstructive procedures
  - cystocele repair, rectocele repair, enterocoele repair, sacrospinous ligament fixation, sacrocolpopexy, uterosacral vault suspension
Surgery for prolapse: Obliterative Procedures

• Lower risk of morbidity and mortality!
• Precludes vaginal intercourse
  – Le Fort Colpocleisis
  – Colpectomy
  – Partial closure of the introitus
    • With or without pessary
Lefort colpocleisis
LeFort (cont)
Urogynecologic Surgery in the Elderly

• Higher risk for morbidity and mortality but absolute risk is low
  – Independent of comorbidities in women >80yo
• Altered anatomy
  – Previous repairs- little vaginal access
  – Atrophy = poor tissue quality
• Special considerations
  – Preoperative evaluation - we need you!
    • Cardiac/ pulmonary
    • Diabetic control
    • Anti-coagulation
  – Fluid /volume status
  – Cognitive function
  – Type of anesthesia
  – VTE prophylaxis
  – Prophylactic antibiotics
Urogynecologic Surgery in the Elderly

• In the OR
  – Allen stirrups
  – Position awake
  – Limited dorsal lithotomy
• Postop confusion/ fall risk
• Consider post op rehab/ PT
• Home care issues
Fecal Incontinence

• Stool bulking is key!
  – Fiber! Fiber! Fiber!
  – If it’s loose – fiber!
    -diarrhea is #1 risk factor for FI
  – If it’s hard – fiber!

• Surgical repair
  – Testing: anal ultrasound, anal physiology
  – Sphincteroplasty
  – Gracilis or artificial sphincter
  – Colostomy

• Sacroneuromodulation
  – Recently FDA approved for this indication
Summary

• You **will** have patients with pelvic floor disorders!
• Reassure them that there are treatments
• Treatment does not = surgery
• BUT surgery may be an option and age alone, though significant, will not determine treatment
• Team approach: combined effort of patient’s providers and appropriate specialists
Division of Urogynecology & Reconstructive Pelvic Surgery

Deborah Myers, MD
Charles Rardin, MD
Vivian Sung, MD, MPH
Star Hampton, MD
Cassandra Carberry, MD, MS
Kyle Wohlrab, MD
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References


