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What’s New in Pelvic Floor Disorders?

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No Disclosures
What are Pelvic Floor Disorders?

• Urinary Control Problems
  – Incontinence or leakage of urine

• Prolapse of pelvic organs
  – Vagina, bladder, rectum

• Bowel Control Problems
  – Fecal Incontinence
What is the Pelvic Floor?

• Muscles, ligaments and connective tissue in the lowest part of the pelvis
• Supports internal organs:
  - Bladder
  - Uterus
  - Rectum
  - Vagina
Facts

• Very common
  – Urinary control problems affect millions US women
    • >60% of post-menopausal women
    • >30% young women

• 1 in 3 women will experience a PFD in her lifetime
Prevalence of Urinary Incontinence

4. NIDDK. Electronic citation.
Facts

• 1 in 5 with urinary control problem also report bowel control problem

• 30% lifetime risk of having surgery for pelvic floor disorder

• “Don’t ask, don’t tell”
Myths

• It is ‘normal’ ….
  – To lose control of bladder or bowel with aging

• Surgery is the only option

• Surgery doesn’t work

• Long recovery and lifestyle (lifting restrictions)
Risk Factors for PFD

- Aging
- Obesity
- Childbirth
- Smoking
- Constipation
When do women seek help?

- 41% seek help within 1 year
- 33% wait 1 to 5 years
- 26% of women wait > 5-years

Who Treats Pelvic Floor Disorders?
Women’s Integrated Pelvic Health Program

**Multidisciplinary approach to pelvic floor disorders**

- Female Pelvic Medicine & Reconstructive Surgery
  - Urogynecology
  - Urology
- Colon & Rectal Surgery
- Physical Therapy
What is new?

• Level I Evidence
  – Midurethral Slings
  – Physical therapy
  – Pessary
  – Botox
  – NO Urodynamics
  – Laparoscopic & robotic prolapse repair
NIH Treatment Networks

Urinary Incontinence Treatment Network

- NIH-NIDDK
  - National Institute of Diabetes & Digestive & Kidney Diseases
- 9 clinical sites across US
- 3 large comparative effectiveness trials in NEJM

Pelvic Floor Disorders Network

- NIH-NICHD
  - National Institute of Child Health & Human Development
- 7 clinical sites across US
- 6 large comparative effectiveness trials
  - 3 NEJM; 2 JAMA
Stress Urinary Incontinence

Bladder

Urethra

Urethral Sphincter (Knot)
**Stress Incontinence Surgical Treatment Efficacy**

- 655 women randomized in OR day of surgery
  - 329 Burch colposuspension
  - 326 Rectus fascial sling
- 520 (79%) completed **24 month** follow-up

**Superiority Trial**
- Designed to show one treatment better than the other
SISTEr

• Success rates & satisfaction higher for sling than Burch
  – Overall success (47% v 38%, p=0.01)
  – Stress specific success (66% v 49%, p<0.001)
  – Satisfaction 86% v 78%

• Higher success rates in sling at cost of MORE
  – UTI (48% v 32%)
  – Voiding dysfunction (14% v 2%)
  – Treatment for urgency incontinence (27% v 20%)
E-SISTEr: 5-Year Follow-Up

- Continence rates decreased over 5-years
- Satisfaction remained high
- Satisfaction higher
  - Sling arm despite voiding dysfunction

Incontinent patients more likely to enroll (86% vs 52%)

Log-rank test Chi-square = 9.63, p = 0.002
Mid-Urethral Slings

- 1st line surgical treatment for SUI
- 27% surgical management of SUI
  - 2000-2007
- Synthetic polypropylene mesh
- Best studied gynecologic operation
- Level 1 efficacy studies
- Adverse events well understood
Minimally Invasive Midurethral Slings

Retropubic

Transobturator
Trial Of Mid-Urethral Slings (TOMUS)

• Randomized *equivalence* trial
  – Confirm absence of meaningful difference between treatments
  – Clinically relevant difference or equivalence margin pre-determined
    • (±12%)

• Retropubic vs transobturator midurethral slings
Trial Of Midurethral Slings
597 women randomized to retropubic or transobturator sling

• 1-year primary outcome
  – Satisfaction
    • 93% (retropubic) vs 92% (transobturator)

• 5-year outcomes
  – Satisfaction HIGH but declining
    • Retropubic 79%
    • Transobturator 85%

• Mesh erosion rates remain low
Physical Therapy vs Sling

RCT 460 Women with Stress Incontinence

• 49% in PT crossed over to MUS
• 11% in MUS crossed over to PT
• Subjective Improvement (IIT)
  – 91% MUS
  – 64% PT

• Women who crossed over to MUS similar outcomes to those who had MUS
  – both superior to PT

• Initial MUS as compared to PT
  – Higher rates of subjective improvement
  – Higher rates subjective and objective cure

The NEW ENGLAND JOURNAL of MEDICINE
2013
ATLAS
RCT comparing conservative treatments for Stress Incontinence

- Pessary
- Pelvic Floor Muscle Training (Kegels)
- Combination
ATLAS

1-year Satisfaction Rates

• Physical therapy – 54%
• Pessary – 50%
• Combined – 54%

- SIGNIFICANTLY improved women’s quality of life and bother from urinary incontinence

- BOTH effective NON-SURGICAL TREATMENTS for certain types of incontinence
Urgency Urinary Incontinence

Overactive Bladder

“Gotta Go, Gotta Go Go”
Botox

Overactive bladder

• Office procedure
  – Women with incontinence not responsive to other treatment

• First line treatment
• Botox vs Bladder Medications
  • 27% vs 13% completely dry at 6 months
• Lasts up to 6-9 months

Not just for wrinkles!
Value of Urodynamic Evaluation

- Women with SUI planning surgery
  - Basic Office Evaluation (N=259)
    - Normal PVR (no retention)
    - Negative urine analysis
    - Positive Cough Stress Test (leak with cough)
  - Multichannel Urodynamics (N=264)

- 1-year: Treatment success
  - Office Evaluation 77%
  - Urodynamics 77%

- Office Evaluation NOT INFERIOR to UDS for SUI outcomes!
Pelvic Organ Prolapse

Nearly half of women ages 50-79 have Pelvic organ prolapse
Prolapse = Hernia
Normal Support

Loss of Support (Uterus)
Normal Vaginal Descent

½ of women presenting for GYN care have POP to or beyond hymen

POP-Q Staging: All women (n=497)

Normal?

½ of women presenting for GYN care POP to or beyond hymen
How evaluate POP outcomes?
History of POP Outcomes Assessment

Surgeon says “cured”

Patient says “cured”

OBJECTIVE

OBJECTIVE + SUBJECTIVE
(validated instruments, QOL)

Objective + Subjective + Global Assessment

Objective + Subjective + Global Assessment + Goal Oriented
NIH Recommendations: Objective

- "Optimal" = Stage 0 POP
- "Satisfactory" = Stage I POP
  - "Definitions picked arbitrarily"

Half of "normal" women don't meet definition!

(Weber A et al 2001)
CARE Trial Outcomes

322 women undergoing sacrocopopexy

• Anatomic Definitions
  - Stage 0, Stage 0/I, No descent > hymen

• Subjective Definitions
  - Absence of vaginal bulge symptoms
  - Global Impression of Improvement

• Treatment outcomes, “success” by definition

(Barber M 2009)
Success Varied With Definition
322 Women who underwent Prolapse Repair (CARE Trial)

Definition of Success

Stage 0
19%

Stage 0/I
58%

No POP > hymen
94%

No bulge symptoms
90%
What’s the Patient’s Perspective?

• Clinically relevant definition
  – differentiate between patients who consider treatment “success” and “failure”

• Rated treatment success from
  – Very successful (1) to Not at all successful (4)
Anatomic Criteria +
No Bulge

What matters to patient’s?
Bulge gone ≠ Patient satisfaction

- No bulge… now has
  - SUI
  - UUI
  - Dyspareunia
  - Complication
  - Mesh erosion ….

Pham T et al
Post-operative Satisfaction

• Correlates strongly with achievement of self-described, pre-operative goals
  
  (Hullfish K 2005, Elkadry E 2003)

• Dissatisfaction (3 mo & 1-year) correlates strongly with
  
  - Feeling “unprepared” for surgery
  - Perception of routine post-operative events as “complications”
  - Development of NEW symptoms, ie: OAB
  
  (Elkadry E 2003, Mahajan S 2006)
Can we help set realistic expectations?

- Women rated “preparedness” after surgical consent counseling & signing informed consent
- 42% still not completely prepared for surgery

“Prepared” vs. “Not Prepared”
- Higher PGI-I (greater improvement)
- Higher PFDI scores (symptoms improved)
- More satisfied
- No difference in anatomy

“Not Prepared”
- Complications – 44%
- Physician documentation – 8%
Patients want to:

• Optimize
  – Satisfaction
  – Outcomes
    • Anatomy
    • Functional
  – Quality of life

• Minimize
  – Complication
  – Recovery
Route Of Apical POP Repair?

Reconstructive

Open

Laparoscopic/Robotic

Vaginal

MESH

ASC

No MESH

• Uterosacral

NO MESH

• Uterosacral
• SSLS

NO Kit
• No Kit

Northwestern Medicine
• How should we select the best operation for POP repair?

❖ Know “normal”
❖ Know which outcomes meaningful to patient
❖ Know individual woman’s goals
❖ Know procedures
Sacrocolpopexy (ASC)

- Open
- Laparoscopic
- Robotic
- Mesh
  - Vagina to sacrum

- Level 1 Data
  - Anatomic superiority
  - Durability
  - Increased complications
When compared to vaginal approach
Minimally Invasive Prolapse Surgery

• Laparoscopic & Robotic
• Duplicate open technique
  • Improved durability
• Advantages
  • Decrease complications
  • Quicker recovery
Open versus Laparoscopic Sacrocolpopexy

LAS Trial

- 3 Centers in UK
- Equivalence trial

• Soft polypropylene mesh
  - Polydioxanone on vagina; Permanent suture to sacrum
  - Reperitonealized

• 1-year
  - Objective (point C) and PGI (‘much better’) equivalent

OPEN & LSC ASC EQUIVALENT
RCT LASC vs RASC

PARAISO 2011

- Primary outcome = OR time
  - ↑OR time & pain robot
- No DIFFERENCE
  - Anatomic, symptom, QOL outcomes
  - Complications
- Cost $1936 ↑with robot

KENTON, IN PRESS

- Primary outcome = COST
  - NO difference hospital costs
  - 12,586 vs 11,573, p=.160
  - NO difference RASC & LASC costs in first 6 weeks
  - 13,867 vs 12,170, p=.060
- No DIFFERENCE
  - Anatomic, symptom, QOL outcomes
  - Complications
Many new treatment options for treating PFD
- Surgical
- Non-surgical
- NOT one size fits all ....

Increasing high-quality data to guide treatment
- & more on the way

Balancing adverse outcomes & success
On behalf of ALL the women suffering with Pelvic Floor Disorders, THANK YOU for your attention!