The Female Pelvic Floor: Patient-centered care

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Disclosures

- Faculty for surgical education, Medtronic*

*All honorarium donated to Virginia Mason

Objectives

- Review prevalence and impact of female pelvic floor issues
- Review evaluation and management of female pelvic floor problems
- Discuss patient-centered approach to counseling patients on pelvic floor issues and concerns

Virginia Mason Urology Pelvic Floor Team

Three Types of PFDs

1 BLADDER CONTROL PROBLEMS

Urinary incontinence (UI) or accidental urine leak is most common

16 % of women

2 PELVIC ORGAN PROLAPSE

- Common on exam, not all women are symptomatic
- 3% of women

3 BOWEL CONTROL PROBLEMS

- Accidental bowel leakage, fecal incontinence, anal incontinence
- 9% of women

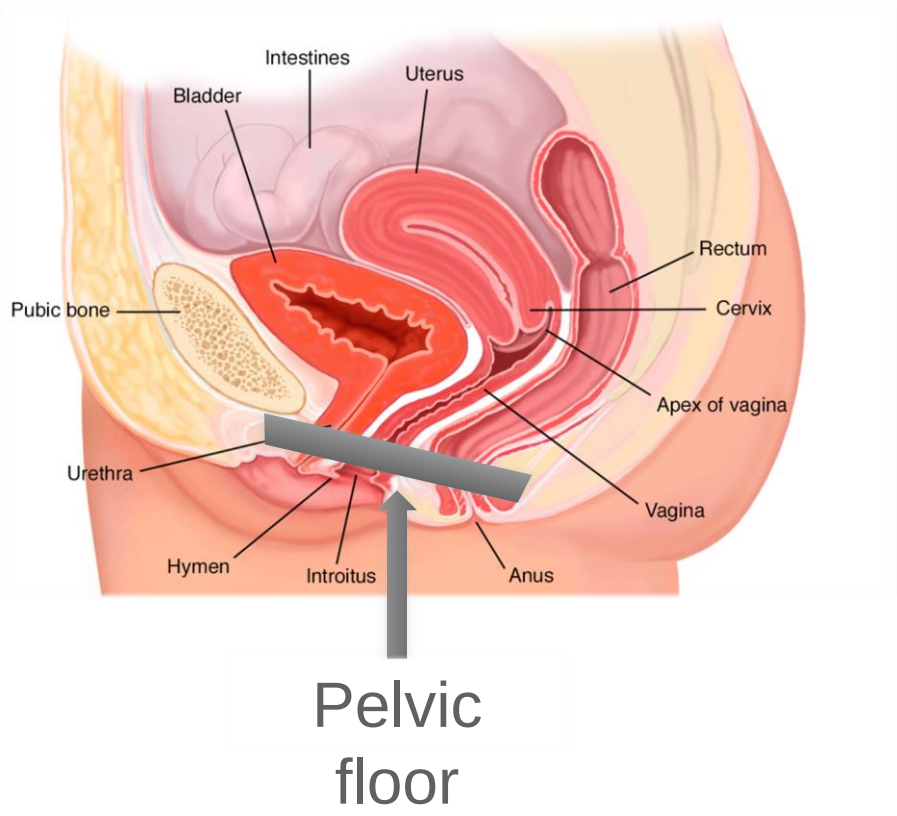
Source: Nygaard I, Barber MD, Burgio, KL, et al. Prevalence of Symptomatic Pelvic Floor Disorders in US Women. JAMA 2008;300(11):1311-1316

Who takes care of PFDs?

- **Female Pelvic Medicine and Reconstructive Surgery (FPMRS)**
  - Board Certification for urologists and gynecologists (2012)
  - ACGME approved Fellowships
  - Urogynecologists/Pelvic floor specialists
  - Urologists
  - Gynecologists
  - Colorectal surgeons
  - Gastroenterologists
  - Physical therapists
  - Primary care/Women's health providers

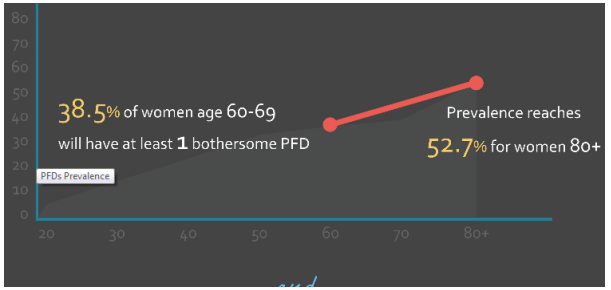
What is the Pelvic Floor?

- Set of muscles, ligaments and connective tissue in the lowest part of the pelvis
- Supports internal organs:
  - Bladder
  - Uterus
  - Rectum
  - Vagina
- Helps control pelvic organ functioning



Female Pelvic Floor Disorders (FPFDs)

- Extremely prevalent
  - 30% of women by age 80 will undergo FPFD surgery
- Expensive to treat
  - At least $12 billion (healthcare) a year
- Associated with poor long-term outcomes
  - Up to 30% of women require reoperation
- Affect quality of life
  - Greater negative impact than diabetes and arthritis



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Wu J et al, 2013, Wu J et al, 2014, Wu J et al, 2014
Chong et al, 2011
Olsen et al, 1997
Hawkins et al, 2011

A hidden condition

- Many patients self-manage and develop coping behaviors
- Nearly half of patients are symptomatic for >3 years before seeking treatment
- 60% of patients do not seek help because of lack of understanding of the disease and they do not know treatments are available
- Most do not mention the problem to their doctor or friends
- Many think it is part of normal aging

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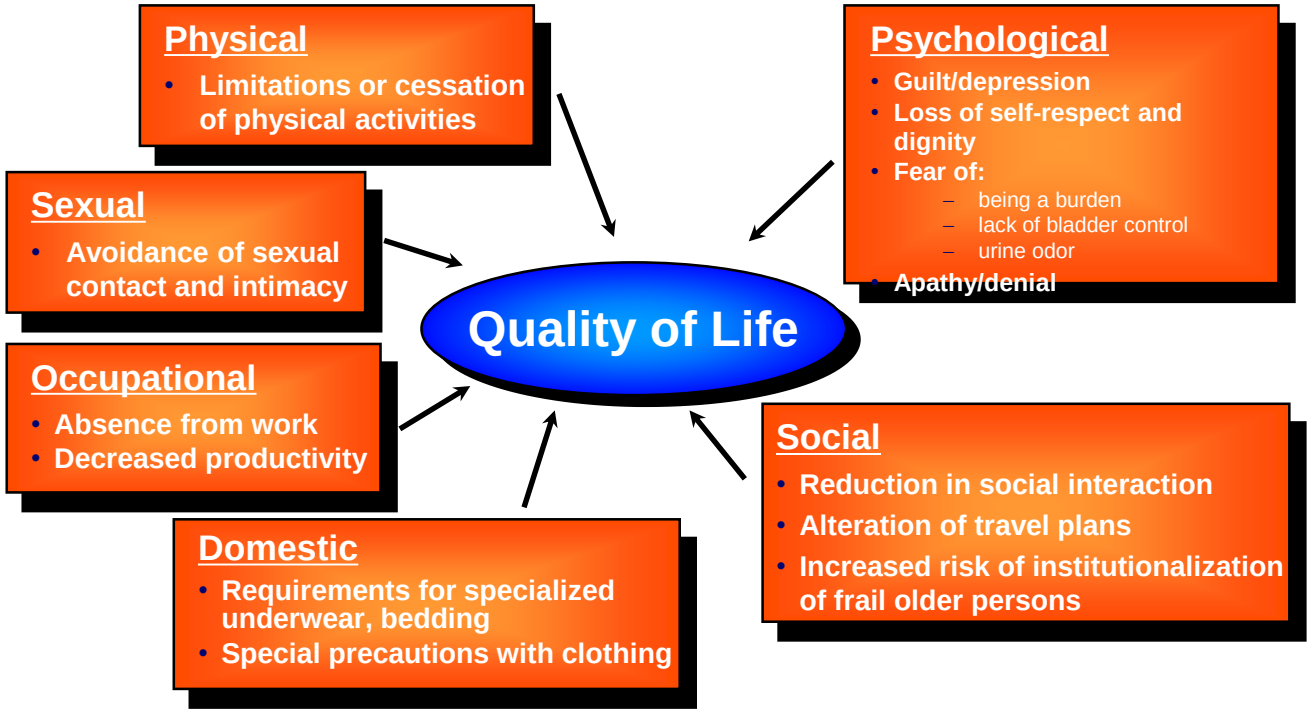
Milsom I et al. *BJU Int*. 2001;87:760-766.

Multidimensional impact on quality of life



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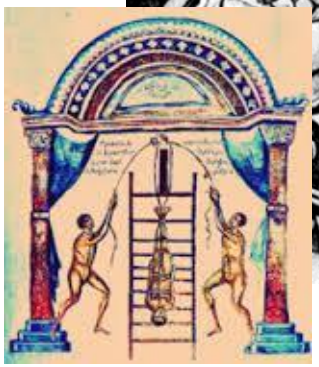
Ancient History of Urinary Incontinence and Pelvic Prolapse

- Ancient reports of female urinary incontinence are rare, mainly addressing fistula due to childbirth injury
  - *1826 T. Brown:* devised a self-retaining ivory female urethral device with a removable stopper
- References to pelvic organ prolapse appear in Egyptian hieroglyphics, Medieval woodcuts, and the Bible.
  - *Ebers Papyrus 1150 BC*: earth oil (petroleum), manure, and honey applied
  - *Hippocrates c. 460 BC*: uterus as an animal, treated with fumigation
  - *Polybus*: astringent with vinegar soaked sponge or half pomegranate or succession (tying women upside down)
  - *1st century C.E. Soranus*: bathe the prolapsed part of the uterus with lukewarm olive oil, and make a woolen tampon corresponding in shape and diameter to the vagina and wrap it in very thin clean linen, apply it to the uterus
  - *1603 Roderigo de Castro:* the prolapsed uterus, "be attacked with a red-hot iron as if to burn, whereupon fright will force the prolapsed part to recede into the vagina



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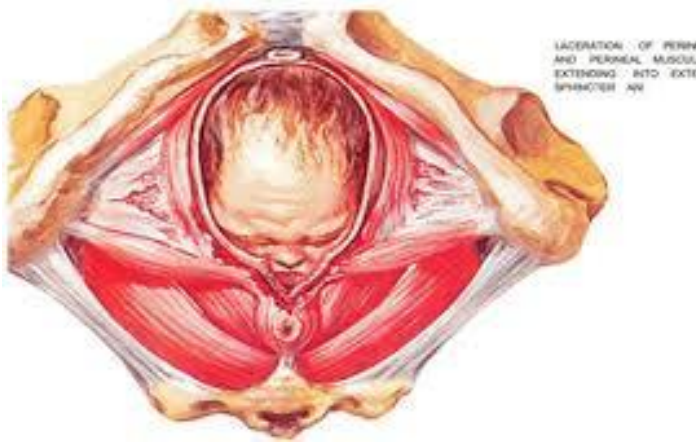
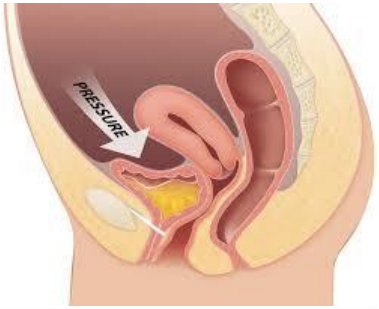
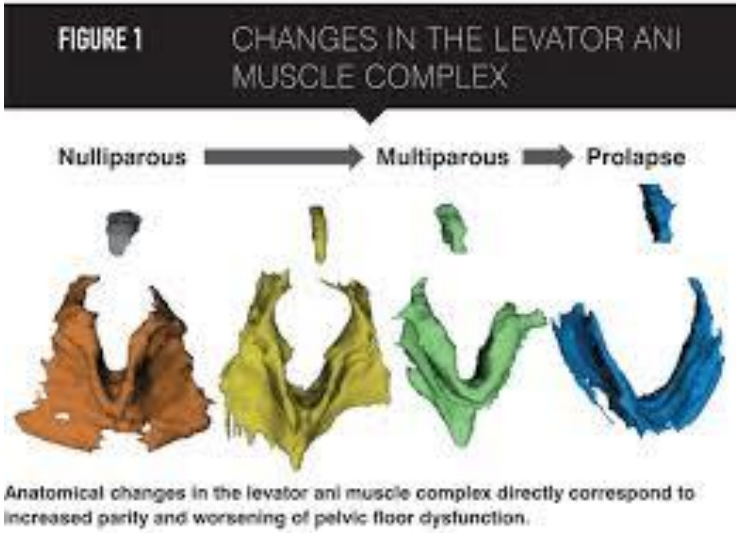
Current understanding



- Female stress urinary incontinence, pelvic floor prolapse, and fecal incontinence have multifactorial etiologies
- Childbirth injury is the common risk factor
- Additionally
  - Denervation of the pelvic floor
  - Aging/hormonal changes
  - Conditions with increased intraabdominal pressures (obesity, COPD/asthma)
  - Connective tissue disorders





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PFD Risk Factors

IN YOUR CONTROL

- Life *style:*
  - Don't smoke
  - Maintain normal weight
  - Be physically active
  - Be cautious with extreme sports
  - Limit caffeine and excessive intake of fluids
  - Avoid constipation

- Maintaining good health:
  - Keep pelvic floor healthy
  - Control blood sugar

LESS CONTROLLABLE

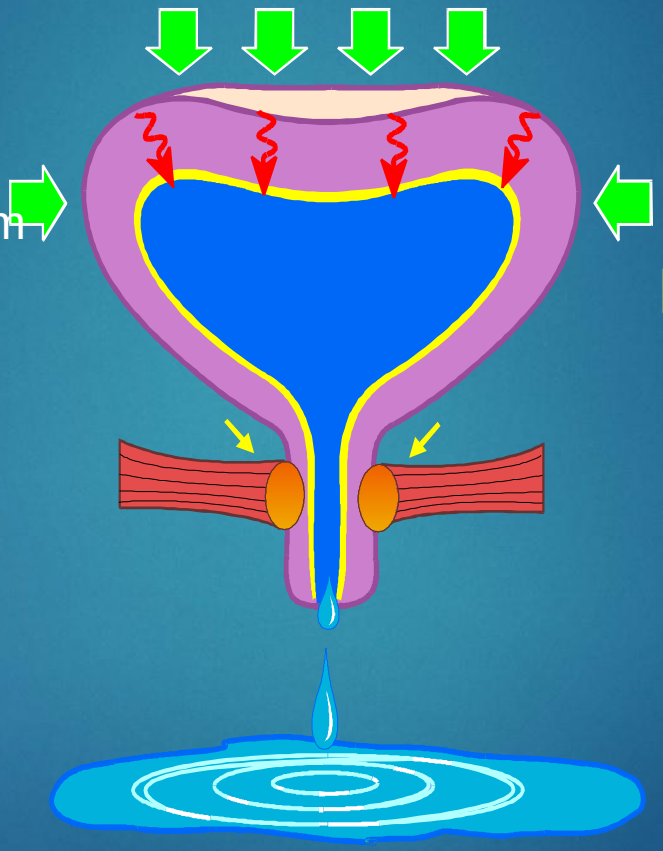
- Life *stage*:
  - Risk increases with age
  - Pregnancy and childbirth

- Health conditions:
  - Pelvic injury, pelvic surgery
  - Chronic lung disease
  - Neurological problems

1. Urinary Incontinence

Types of Urinary Incontinence

- Urge
  - urine loss accompanied by urgency resulting from abnormal bladder contractions
- Stress
  - urine loss resulting from sudden increased intra-abdominal pressure (eg, laugh, cough, sneeze)



- Mixed symptoms
  - combination of stress and urge incontinence

Types of Urinary Incontinence[1]

OVERACTIVE BLADDER (OAB) SYNDROME

- Urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection or other obvious pathology

STRESS URINARY INCONTINENCE

- Complaint of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing

OTHER TYPES

- Mixed (stress and urgency incontinence)
- Functional incontinence

1. Haylen, BT et al., Neurourol Urodyn. 2010; 29:4-20

Treatment Options for Urinary Incontinence

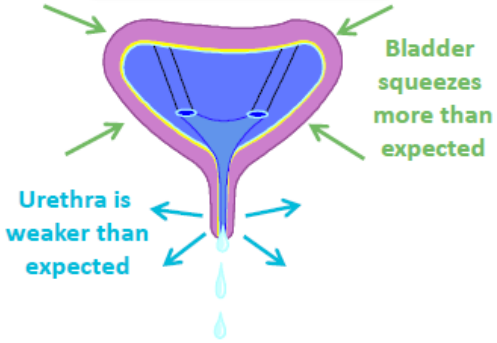
Stress Incontinence
Leakage with laughing, coughing, physical activity

Non-Surgical
- Pelvic floor muscle training
- Pelvic floor physical therapy
- Incontinence pessary
- Urethral inserts

Surgical
- Urethral bulking
- Sling
  - Autologous fascia (your own tissue)
  - Mesh (retropubic or transobturator approach)
- Retropubic suspension (Burch)

Clinical Trials

Mixed Incontinence



Reduce Risk Factors
- Patient education
- Weight loss
- Stopping smoking

Overactive Bladder
Urinary frequency, urgency, and/or incontinence associated with urgency

1st line: Behavioral Therapy
- Bladder control strategies & bladder training
- Fluid management & avoidance of bladder irritants
- Pelvic floor physical therapy

2nd line: Non-Surgical
- Overactive bladder medications
- Vaginal estrogen

3rd line: Minor Procedure or Surgical
- Botox® injections into the bladder
- Peripheral tibial nerve stimulation
- Sacral neuromodulation (Interstim®)

Clinical Trials

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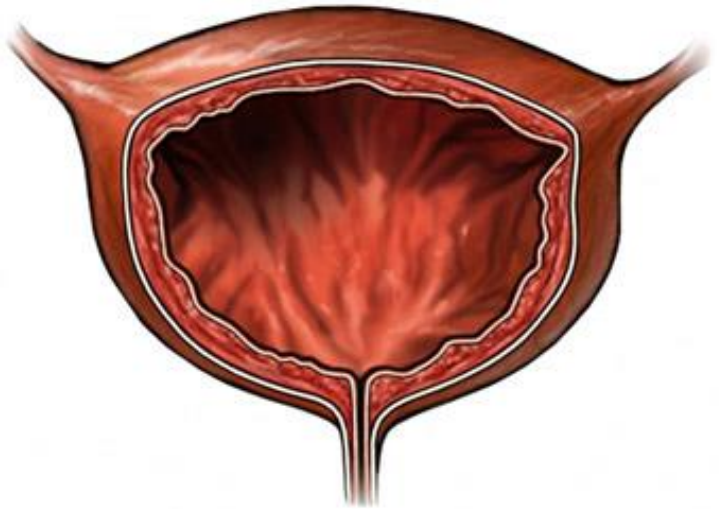
904012 (10/14)

*If you are not improving and still experiencing bothersome symptoms, please call your physician and schedule a follow up appointment

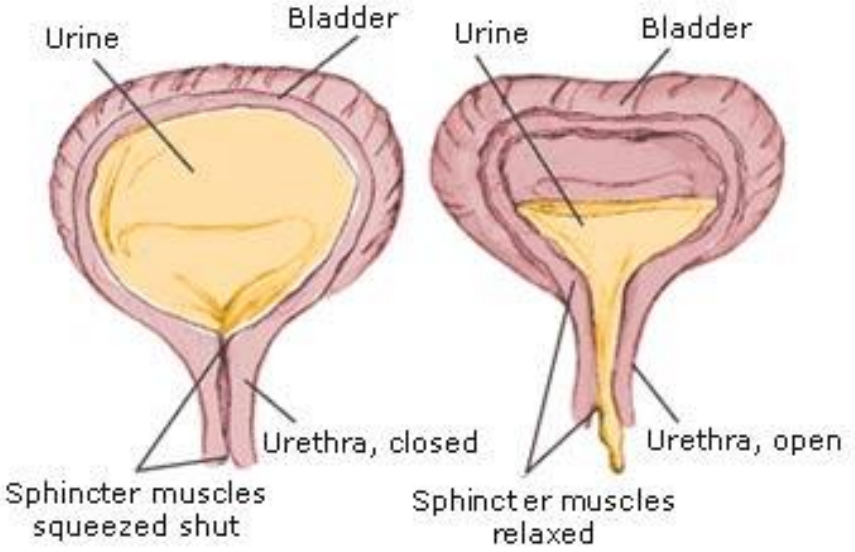
The Bladder

- Urine storage at low pressure
- Urine evacuation
- In overactive bladder…
  - Signals of urgency are aberrant/strong
  - Contraction without your permission



Urinary Sphincter (outlet)

- Prevent urine leakage when closed.
- Allow evacuation of urine when open.
- In stress incontinence- the urethral sphincter is weakened



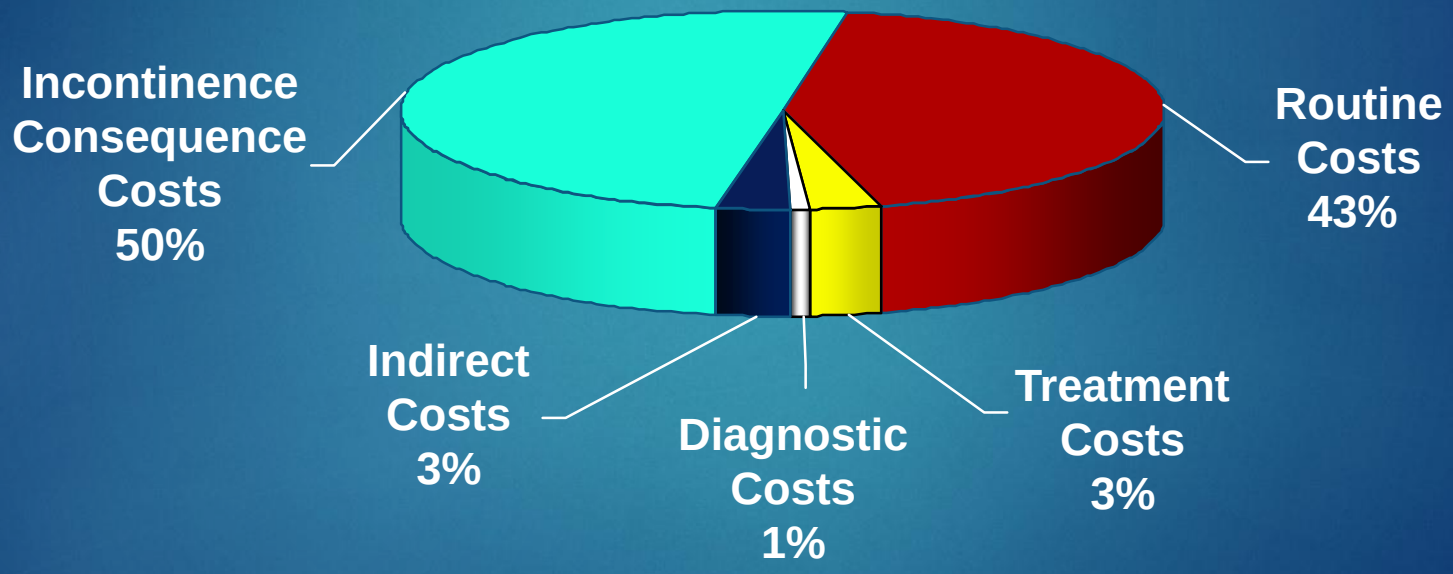
How common is it?

In the US, 18 million women have urinary incontinence

Society's economic burden as a result of Urinary Incontinence

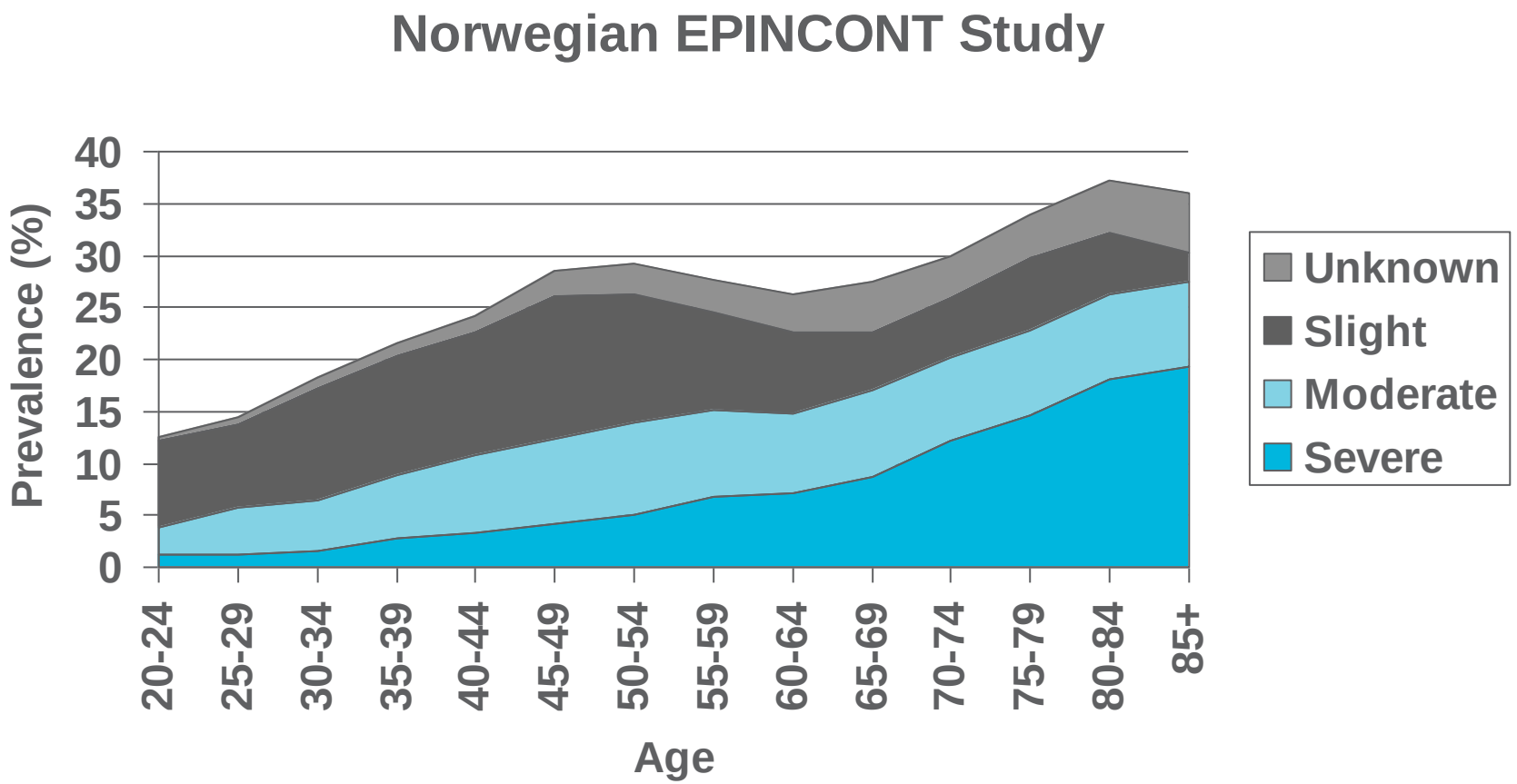
Total Costs in 1995 > US $26 Billion

$3,600 Annually Per Person Aged ≥ 65 Years



Wagner TH, Hu T-W. *Urology.* 1998;51:355-361.
Hampel C, et al. *Urology*. 1997;50(suppl 6A):4-14.

Does age matter?

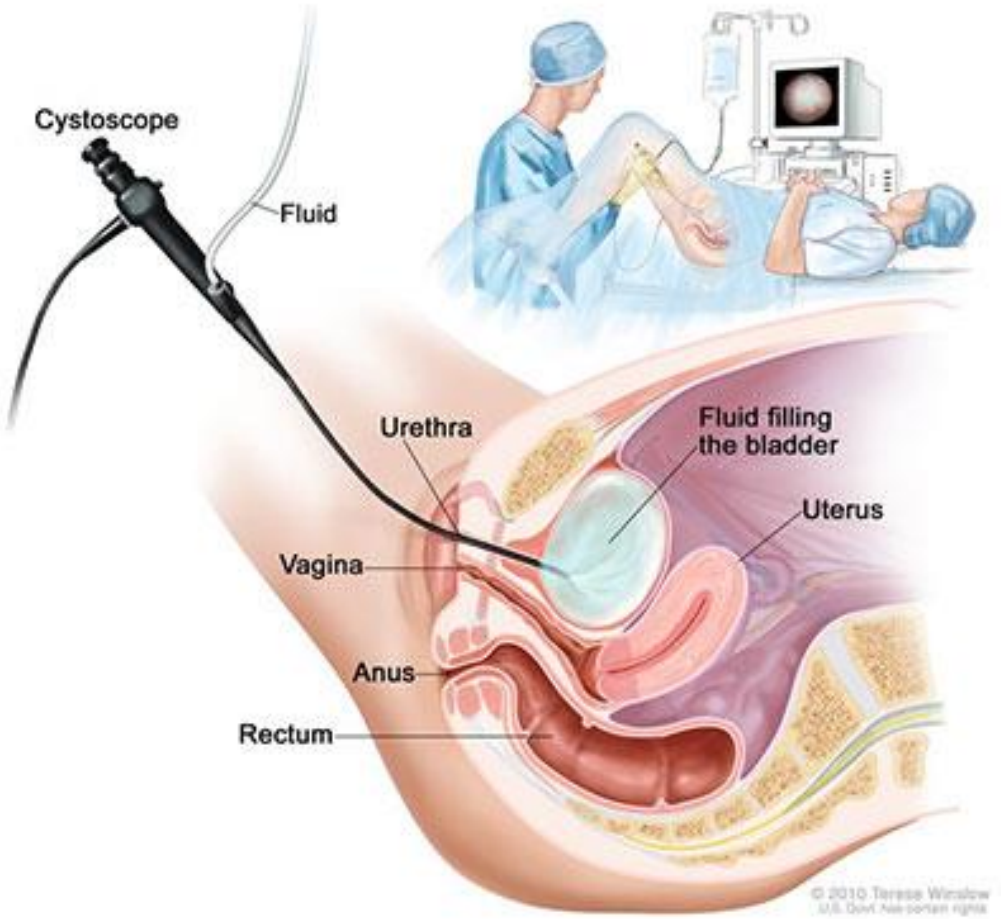


STRESS URINARY INCONTINENCE

How do we evaluate?

- Office visit
  - History
    - Parity
    - Duration of symptoms
    - Type of incontinence
    - Bother
  - Exam
    - Positive cough stress test
  - UA/PVR

Tests: Cystoscopy



Tests: Urodynamics

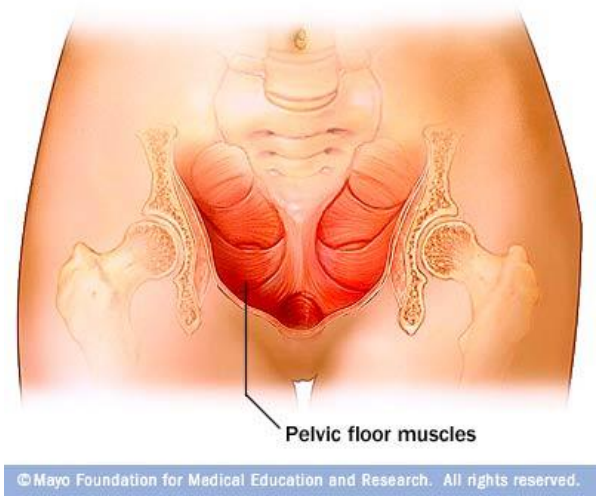
Lifestyle Interventions for SUI

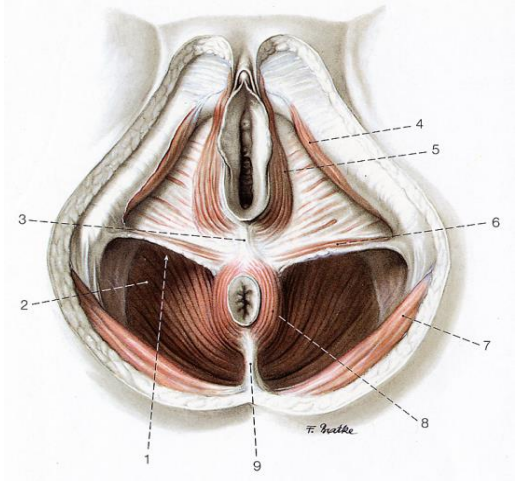
- Weight loss (1)
- Smoking cessation (2)
- Cough prevention (3)
- Avoiding constipation
- Modifications of activities (chronic straining, heavy lifting) (4)

1. Bump RC et al Am J ObstrGyne 1992;167: 392-9
2. Diokndo AC et al Urology 1990; 36: 129-38
3. Lubowski DZ et al BJS, 1988;75: 1095-7
4. Davis G et al Military Med 1999; 164: 182-7

Pelvic Floor Training: Kegels!

- Identify muscles
- Contract: 5-8 seconds then relax 10 seconds.
- Start with one set of 10 repetitions then progress to 3-4 sets a days.
- For at least 3 months



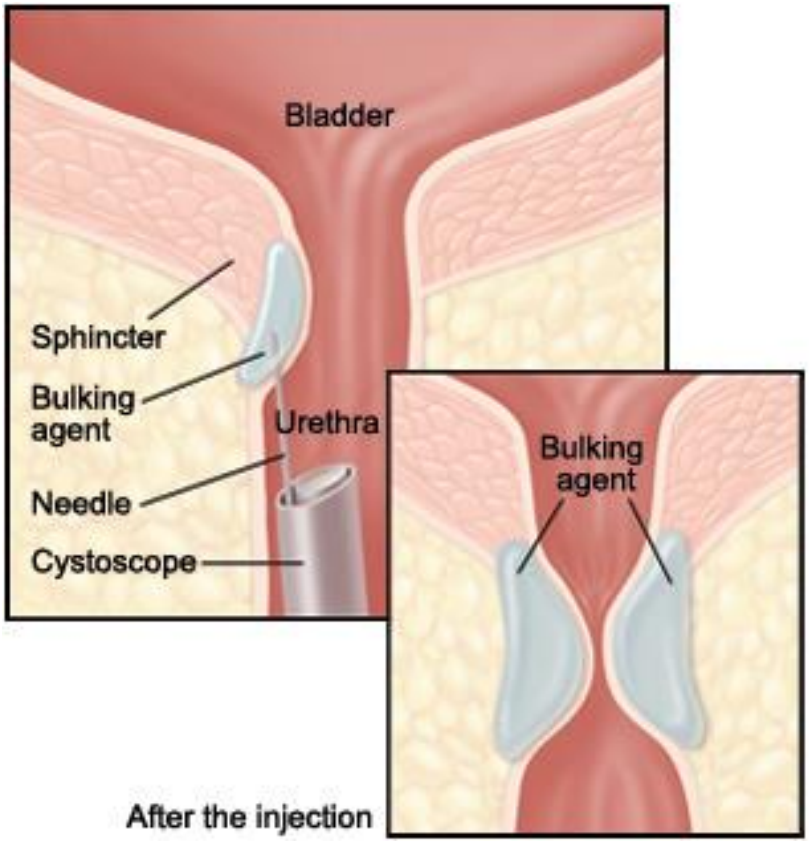


Continence Vaginal Pessaries

- Ring with/without support
- With/without knob

Urethral Bulking

- Outpatient, can be done in the office or OR
- Quick recovery
- Helps in 60% of patients
- Last ~1 year



Sling surgery

- Targets stress urinary incontinence
- Can be of polypropylene mesh or autologous fascia
- Mesh slings: 3 main types
  - retropubic/TVT
  - TOT/transobturator
  - mini-sling/single incision sling
- Autologous fascial sling
  - Strip of fascia harvested from lower abdomen or leg

LONG-TERM DURABILITY OF MIDURETHRAL SLINGS: A TIME TO EVENT ANALYSIS IN A TERTIARY REFERRAL SETTING

Kevin Gioia, Erika Wolff, Dena Moskowitz, Alvaro Lucioni, Kathleen Kobashi, Una Lee

UT Table | **Sling outcomes at 1, 5, and 9 years**

	Virginia Mason success rate*	Completely dry rate
1 year	97%	47%
5 years	81%	29%
9 years	70%	31%

*Patient perception of being at least 70% improved or having no more than 1 incontinent episode/week

Source: Kevin Gioia, MD

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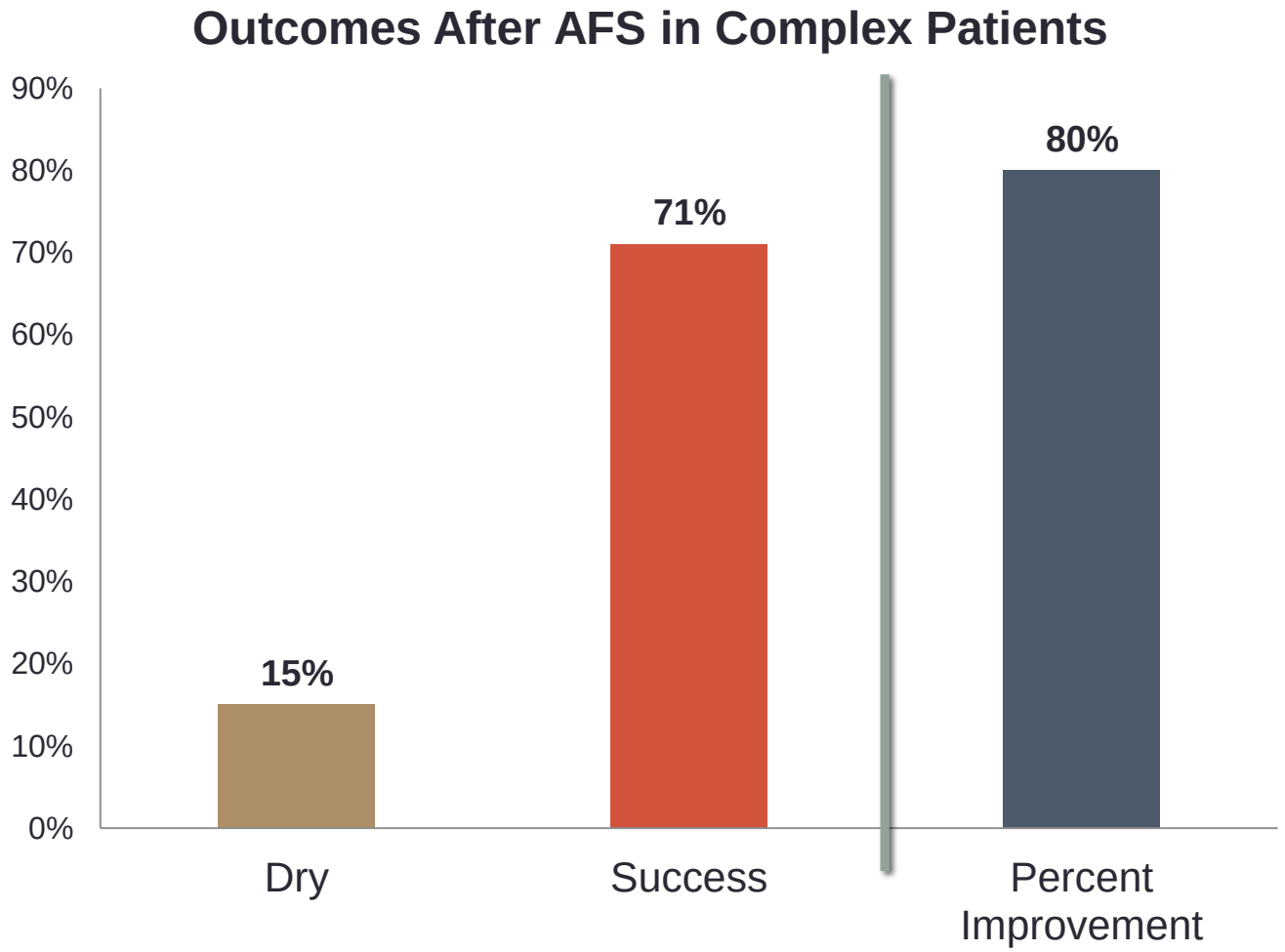
Autologous Fascial slings (n=77, mean f/u 6 yrs



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CURRENT STATE

Stress urinary incontinence (SUI)

- 38% of women
- $12 billion/year
- Impairs quality of life

- **Mid-urethral sling surgery is current gold standard with widely varying results**

THE PROBLEM

Mid urethral mesh slings

- Safe and effective
- 3 million slings; 6% complications
- >100,000 suffer complications, including long term disability
- Banned in UK and Australia
- Sweeping measures limit access to care

- **The presence of risks and serious complications unique to sling mesh use has not significantly changed the surgical management of SUI**

THE NEED

The gap is a lack of comprehensive understanding of patient's, spouse/partners', and surgeons' perspectives on sling surgery outcomes on women's health and quality of life.

- **Can be used to develop patient-centered shared decision making on sling surgery**
  - **Inform patients**
  - **Avoid unnecessary treatments**
  - **Decrease harm**
  - **Reduce health care costs**

What is a Clinical Trial?

A research study in which patients consent to participate in the study of health-related outcomes

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Where do clinical trials fit in?

Alongside well established treatment options,

we also offer clinical trials to patients on a voluntary basis

in order to study *innovative treatments* and investigate ways *to improve our current care*

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What is informed consent?

Patients should understand and agree before proceeding

- *Risks*
- *Benefits*
- *Alternatives*
- *Purpose of the study*

Ethical Principles of :
Autonomy, Justice, Beneficence, Non-maleficence

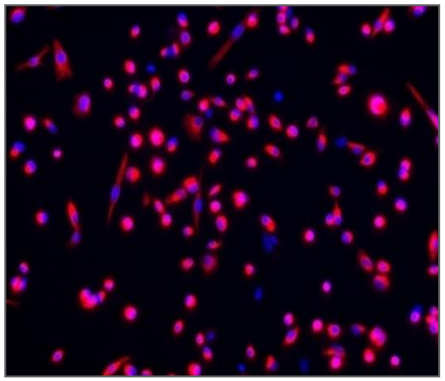
Current Studies in Incontinence and Prolapse

- Cell based study for treatment of stress incontinence
- Spinal cord injury bladder study
- Pelvic Floor database to study long term surgical outcomes
- Pioneer Study of pelvic floor tissue
- Bladder patient education research
- Optimizing pain control and reducing opioids in surgical patients
- Whole fruit cranberry and urinary PACs

Cook Myosite Clinical Trial

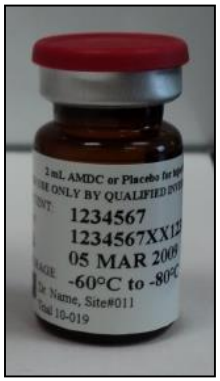
Women with Stress urinary incontinence

Processing



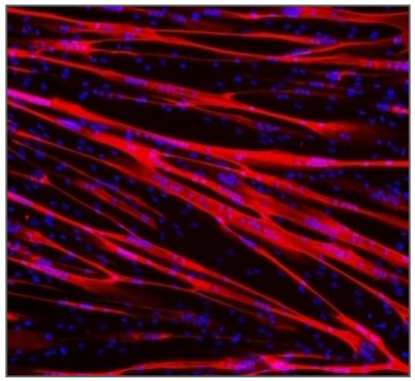
Muscle Progenitor Cells

Product Frozen



AMDC-USR

Thawed & Injected



Striated Myotube/Myofiber

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BRING IT ON.

OVERACTIVE BLADDER

What is overactive bladder?

- Urinary urgency
- Urinary frequency
- Urinary leakage associated with a sense of urgency (urgency incontinence)
- “Feeling” of incomplete bladder emptying
- Nighttime urinary frequency is also called nocturia

How common is overactive bladder?

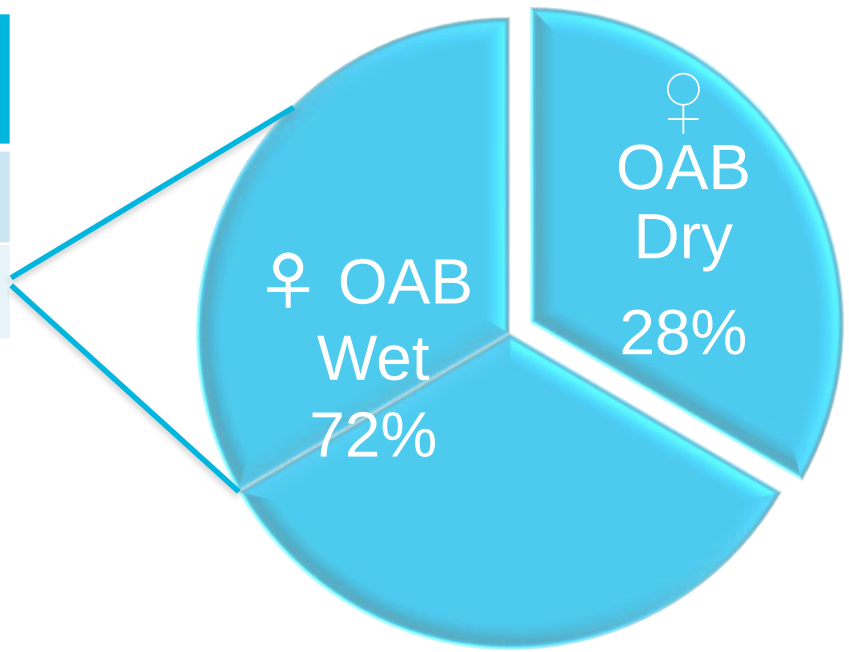
- 40.4% in men and 46.9% in women
- Significant impairments across all domains of patient-reported outcomes
  - general health related quality of life, ratings of anxiety and depression, and urinary condition-specific outcomes
- Rates of seeking treatment low

Sexton et al., Prevalence and effect on health-related quality of life of overactive bladder in older americans: results from the epidemiology of lower urinary tract symptoms study. J Am Geriatric Soc 2011

OAB Syndrome: Prevalence[1]

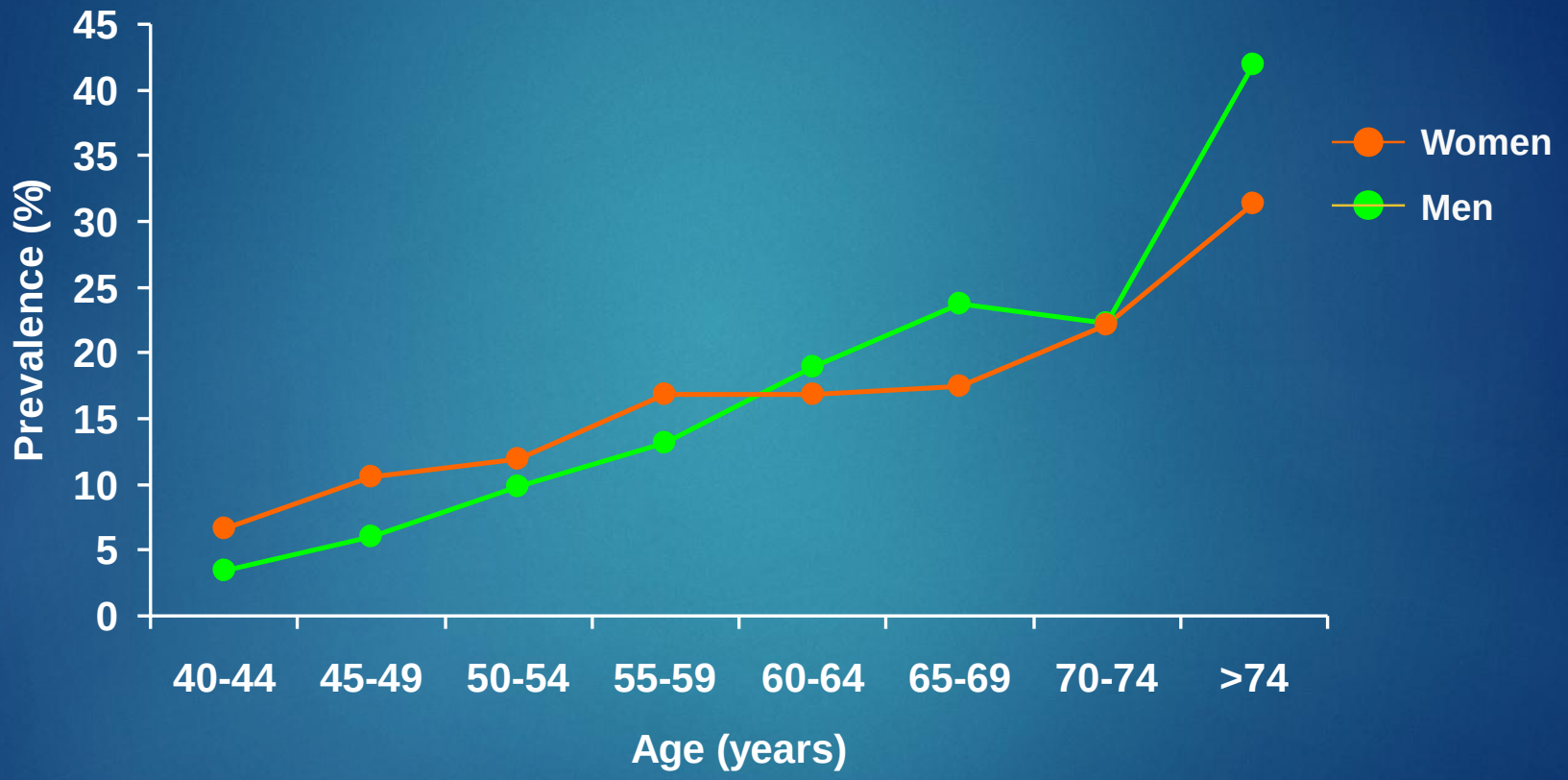
- EpiLUTS (2011)
  - Internet based cross-sectional study of 20,000 US adults ≥40 years
  - ~30 million with OAB symptoms
  - Prevalence of OAB symptoms

	Any OAB	"Often" OAB
♂	27%	16%
♀	43%	33%



1. Coyne KS, et al. Urology 2011; 77(5):1081-1087

Prevalence of urge incontinence by Age and Sex

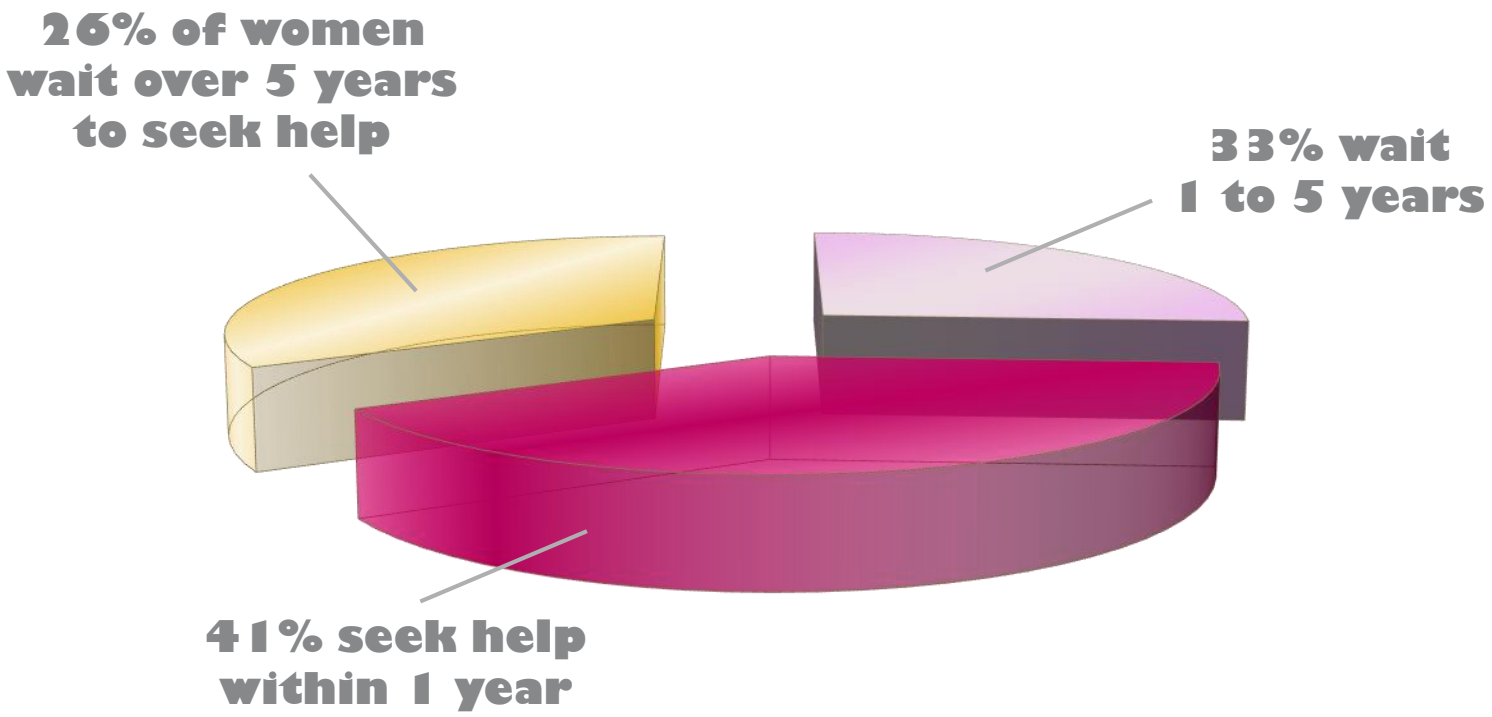


Milsom I et al. *Am J Managed Care.* 2000; 6 (suppl):S565-S573.

Why don’t people talk about it?

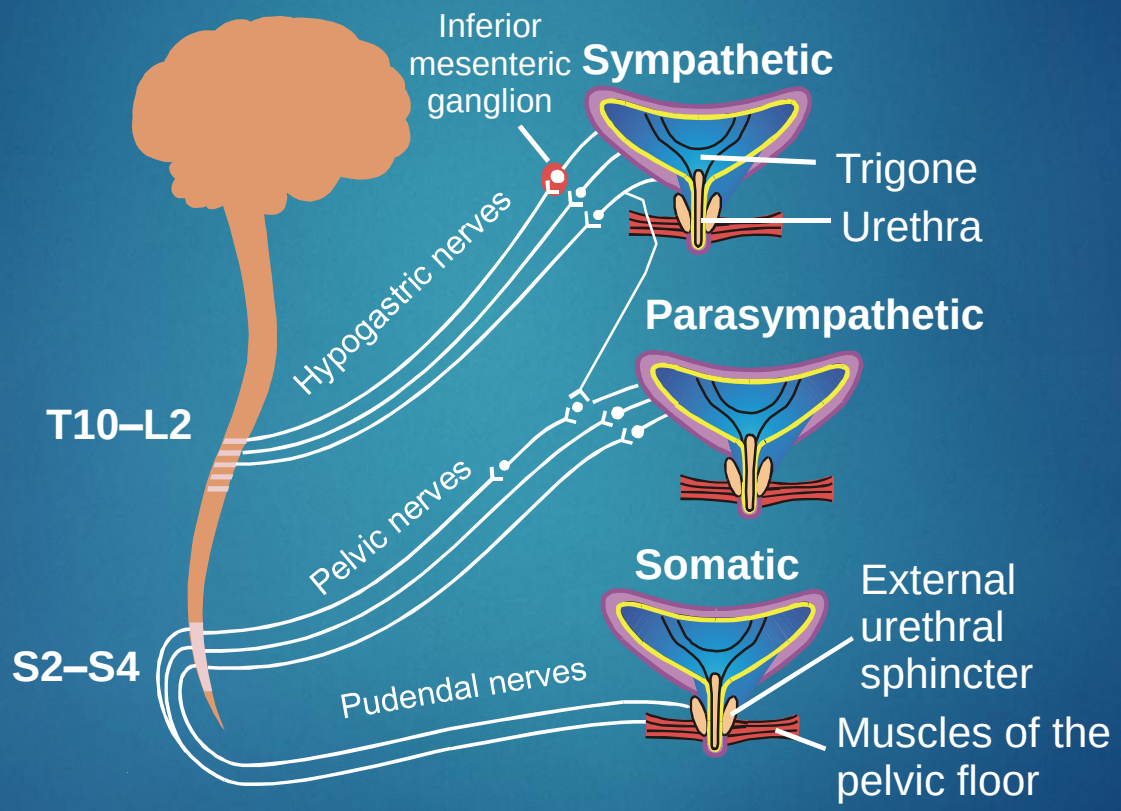
- Embarrassment
- Fear of being a burden
- Afraid of social stigma and consequences
  - Incontinence is the 2nd most common reason for nursing home placement
- Don’t believe anything can be done
- Normal part of aging/ not a “problem”

Delay in seeking care



Norton, P A et al. Distress and Delay Associated With Urinary Incontinence. BMJ, 297(5), November 1988.

How does the bladder work?



Abrams P, Wein AJ. *The Overactive Bladder—A Widespread and Treatable Condition.* 1998.

Control of Lower Urinary Tract Function

Dual control mechanisms

- Autonomic nervous system control
  - parasympathetic and sympathetic innervation of the bladder
- Central nervous system/voluntary control
  - choosing when to void
- Both can be altered by aging and disease

Pathways are altered in Overactive bladder

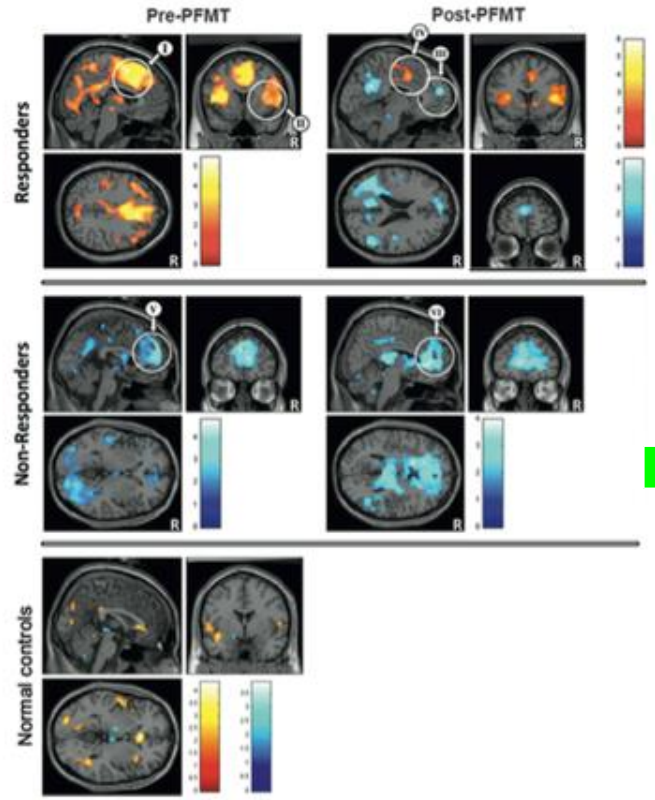
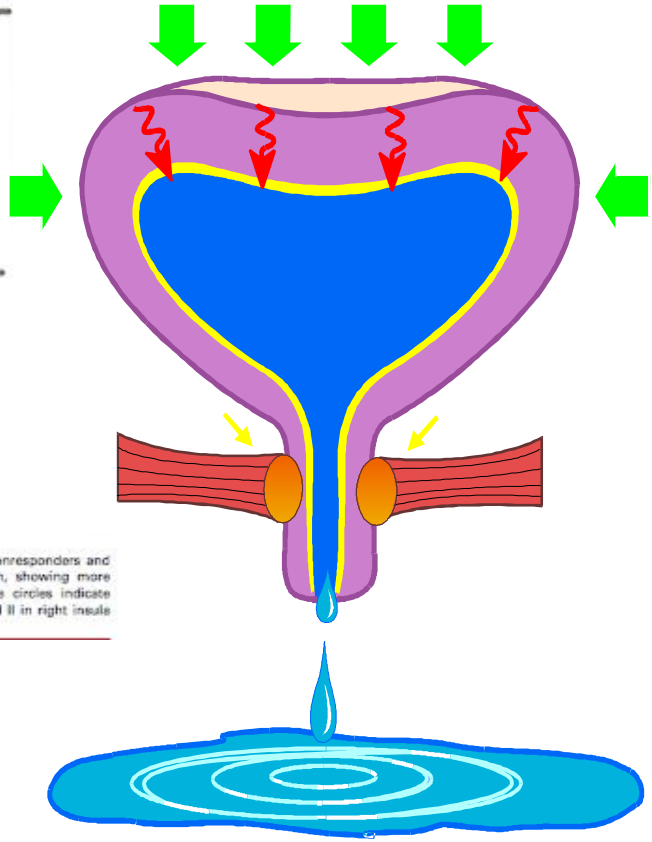


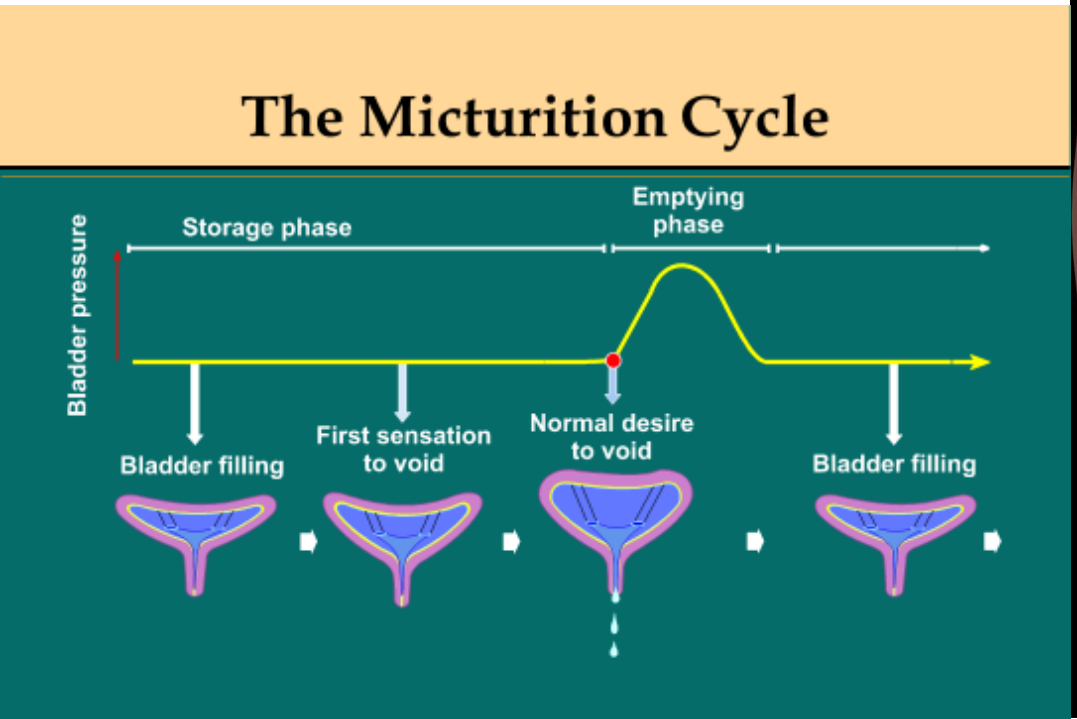
Figure 2. PrePFMT and post-PFMT activation (yellow/red areas) and deactivation (blue areas) in responders, nonresponders and normal controls with no PFMT. In responders activation and deactivation pattern changed after intervention, showing more deactivation. Nonresponders showed marked prePFMT deactivation, which changed little after PFMT. White circles indicate 3 predetermined spherical ROIs with 18 mm radius, including III, V and VI in mPFC, I and IV in dACC/SMA, and II in right insula (table 1). Color bars indicate Student t-test values.

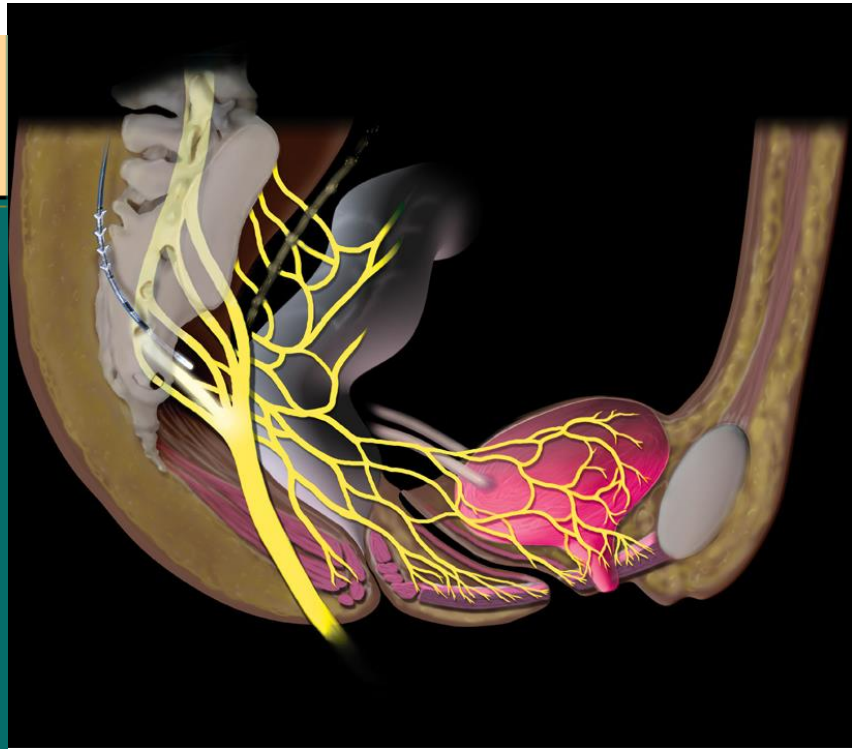
- Sensory
- Neurogenic
- Myogenic
- Integrative



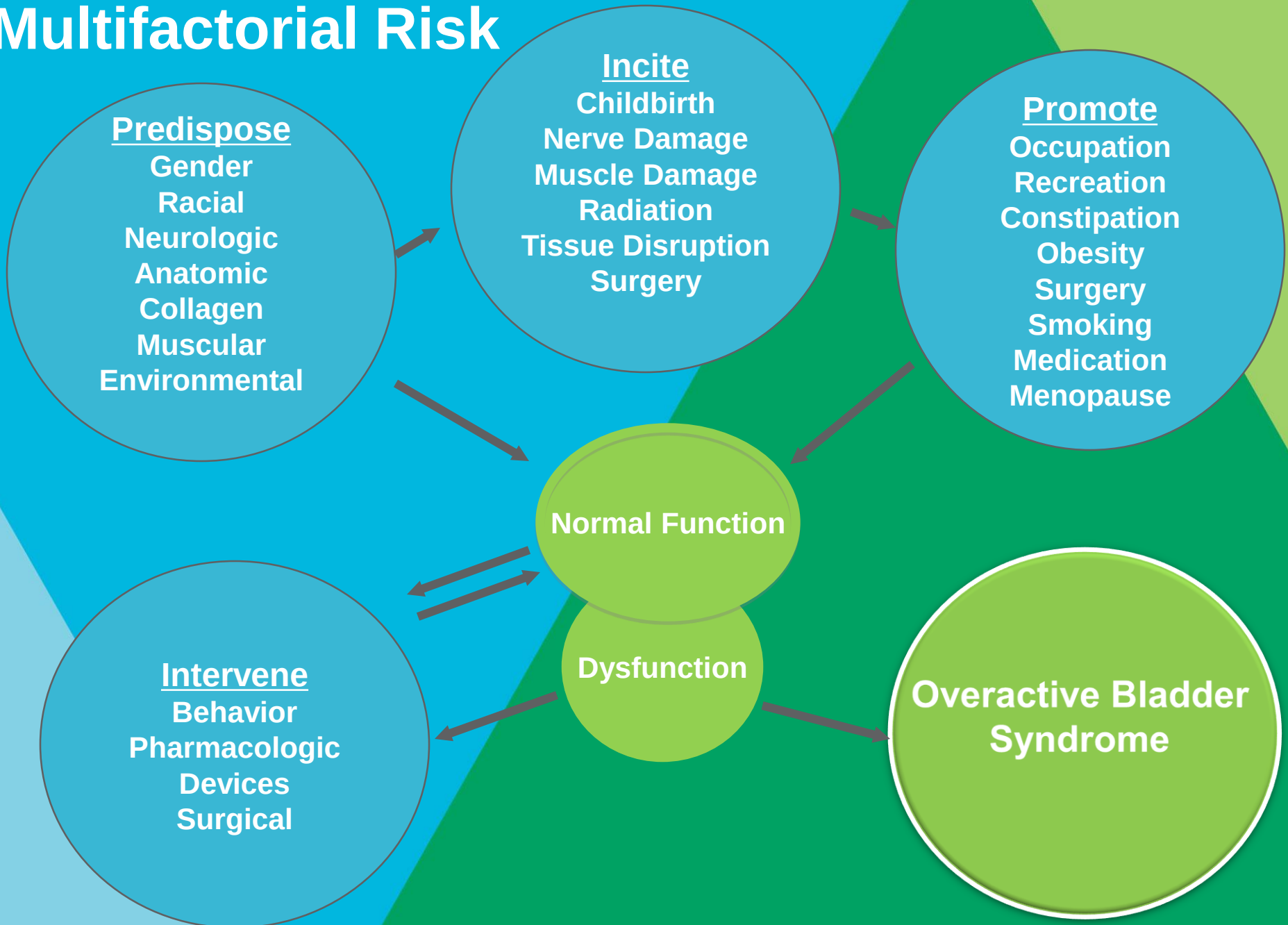
How can I keep my bladder healthy?

- Hydration
- Regular voiding
- Perineal hygiene
- Regular bowel function





Multifactorial Risk



Bump RC, Norton PA. Obstet Gynecol Clin North Am. 1998; 25(4):723-46.

Clinical evaluation

- AUA/SUFU Guideline for OAB (2014)
  - Document signs/symptoms that characterize OAB
  - Exclude other disorders
    - Malignancy
    - Neurologic disease
    - Systemic disease
  - Minimum requirements
    - Careful history
    - Physical exam
    - Urinalysis

How can I improve my bladder control?

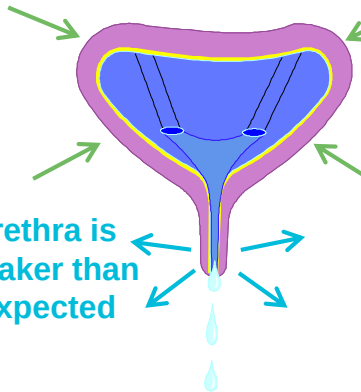
- Lifestyle interventions
  - Moderate Fluid intake
  - Eliminate dietary irritants (caffeine, alcohol)
  - Smoking cessation
  - Maintain a healthy weight
  - Elevation legs before bed/treat peripheral edema
  - Sleep hygiene

Treatment Options for Urinary Incontinence

Stress Incontinence
Leakage with laughing, coughing, physical activity

Mixed Incontinence

Overactive Bladder
Urinary frequency, urgency, and/or incontinence associated with urgency



Reduce Risk Factors

- Patient education
- Weight loss
- Stopping smoking

Non-Surgical

- Pelvic floor muscle training
- Pelvic floor physical therapy
- Incontinence pessary
- Urethral inserts

Surgical

- Urethral bulking
- Retropubic suspension (Burch)
- Sling
  - Autologous fascia (your own tissue)
  - Mesh (retropubic or transobturator approach)

Clinical Trials

1st line: Patient Education and Behavioral Therapy

- Bladder control strategies
- Bladder training
- Fluid management
- Avoid bladder irritants
- Pelvic floor muscle training
- Weight loss

2nd line: Non-Surgical

Medications
- Overactive bladder medications
- Vaginal estrogen

3rd line: Minor Procedure or Surgical

- Posterior tibial nerve stimulation
- Botox® injections into the bladder
- Sacral neuromodulation (Interstim®)

Virginia Mason

*If you are not improving and still experiencing bothersome symptoms, please call your physician and schedule a follow up appointment

What are treatment options?

1. Conservative management is a good option if minimally or not bothered
2. Behavioral/Fluid modifications
3. Pelvic floor physical therapy
4. Medical therapy
5. Procedural options

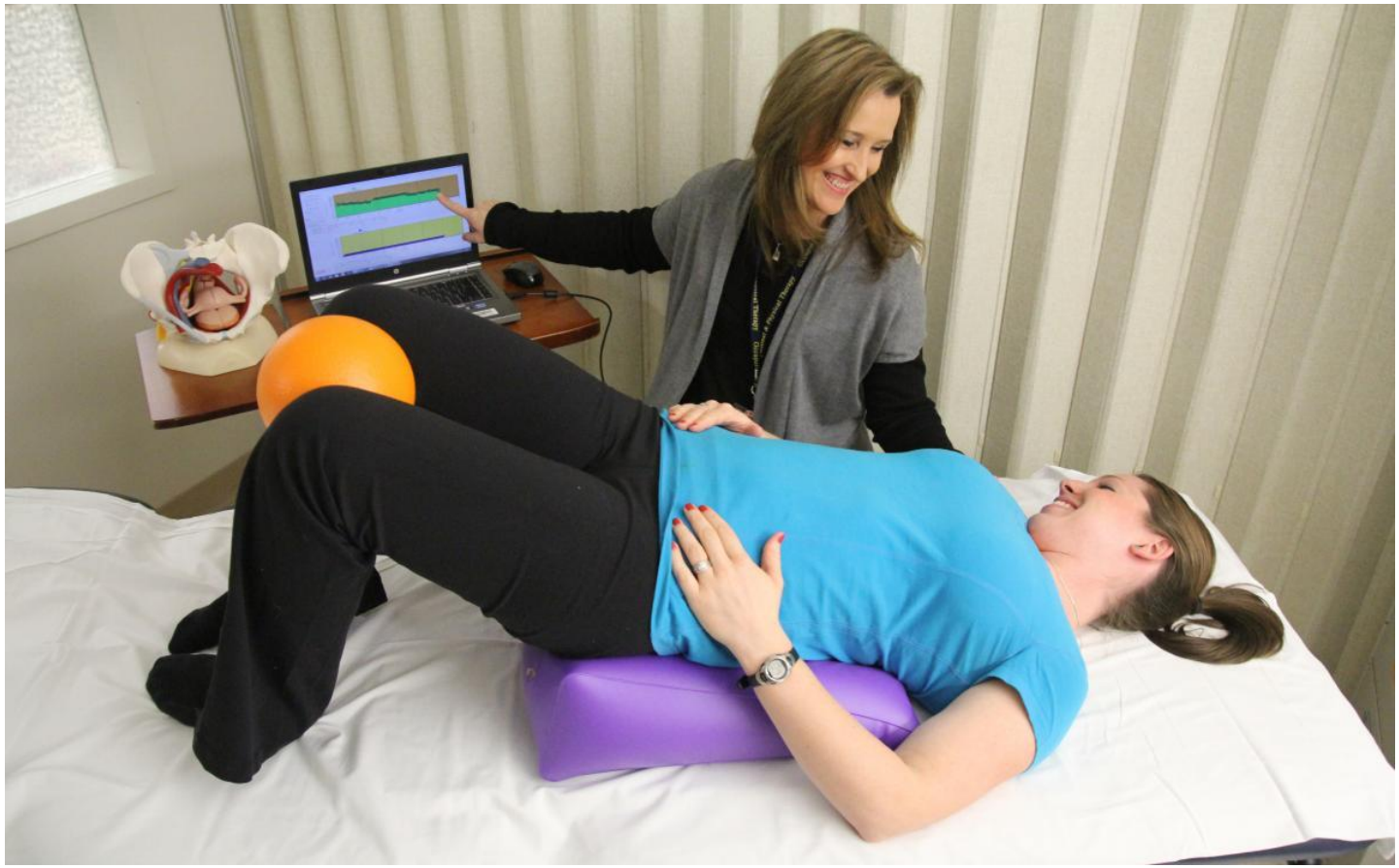
1st steps

- Urge suppression techniques
- Mindfulness
- Bladder retraining
- Modify fluids and bladder irritants
- Keep a voiding diary
- Timed voiding
- Pad use

Behavioral therapy

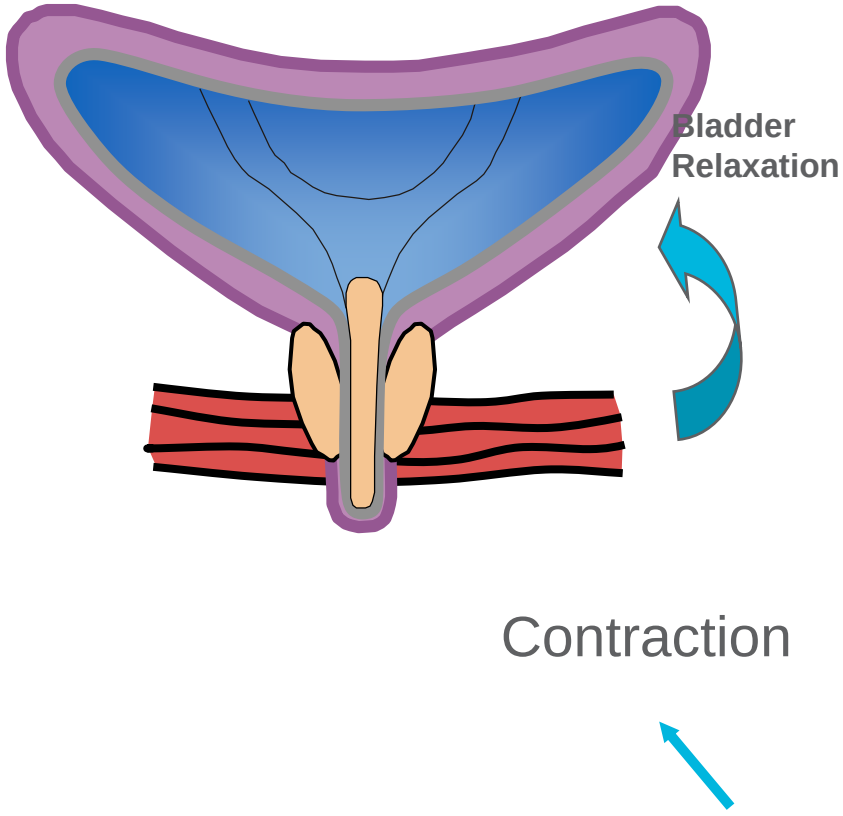
- **Modify symptoms through systematic changes in patient behavior or the environment**
- **Behavioral modification therapies:**
  - **dietary and fluid modification**
  - **bladder training**
  - **pelvic floor muscle exercises**
    - **adjunct therapies**
  - **scheduled/assisted voiding**
  - **Urge suppression**

Pelvic floor physical therapy



PELVIC FLOOR EXCERCISE

- **Kegels**
- **Help strengthen the muscles of the pelvic floor – improve bladder stability**
- **Help suppress the voiding reflex**
- **Sometimes difficult to isolate the muscle which needs to be contracted**
- **Biofeedback**



Bladder retraining

- Increased awareness of the lower urinary tract provides a cognitive control point over urinary urgency, urge incontinence

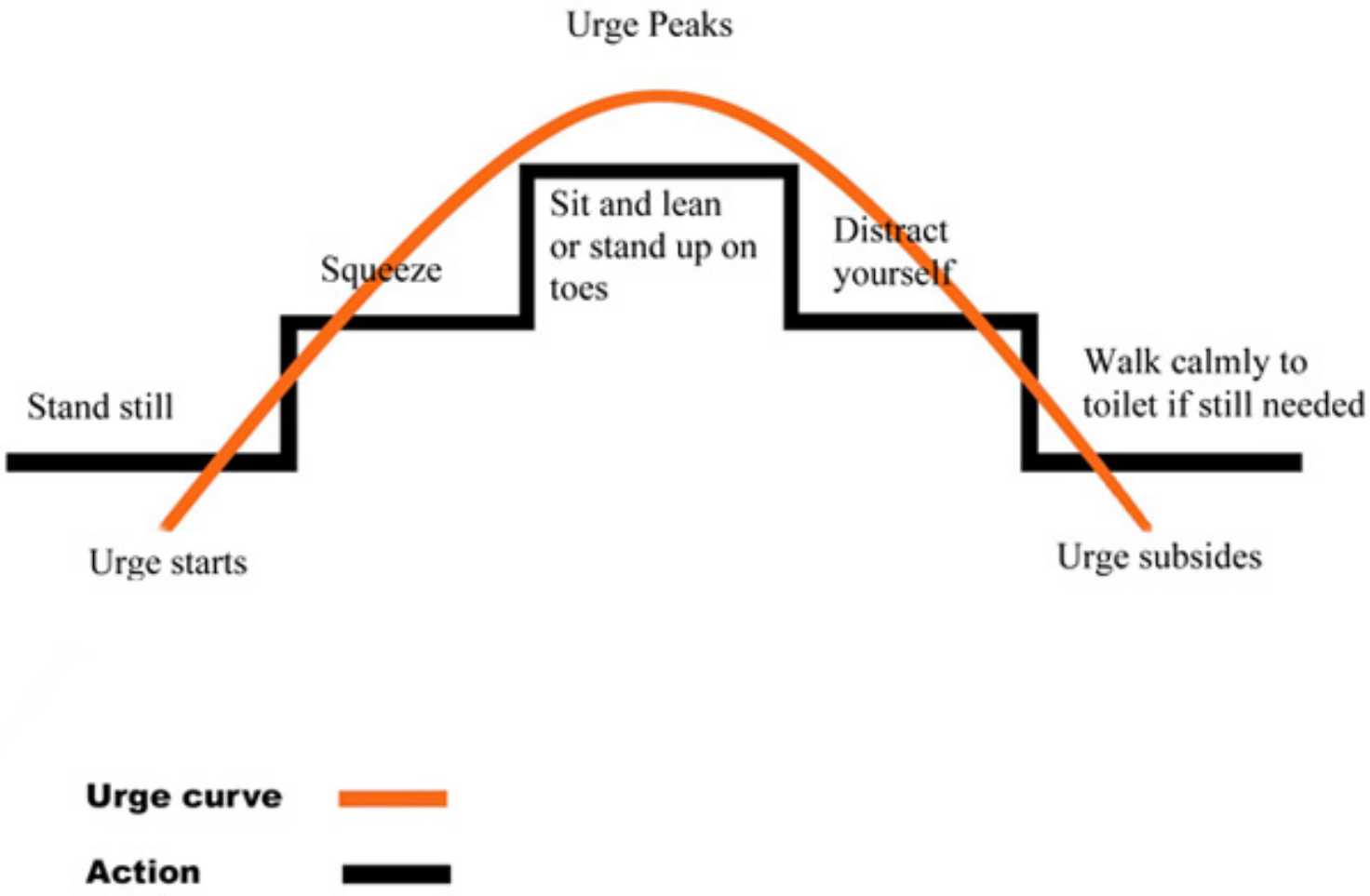
- 50% of a community dwelling individuals reported a 50%-75% reduction of symptoms
  - Lukban et al. Clin. Obst &Gyn Vol. 45 Nov. (273), 2002

Weight loss

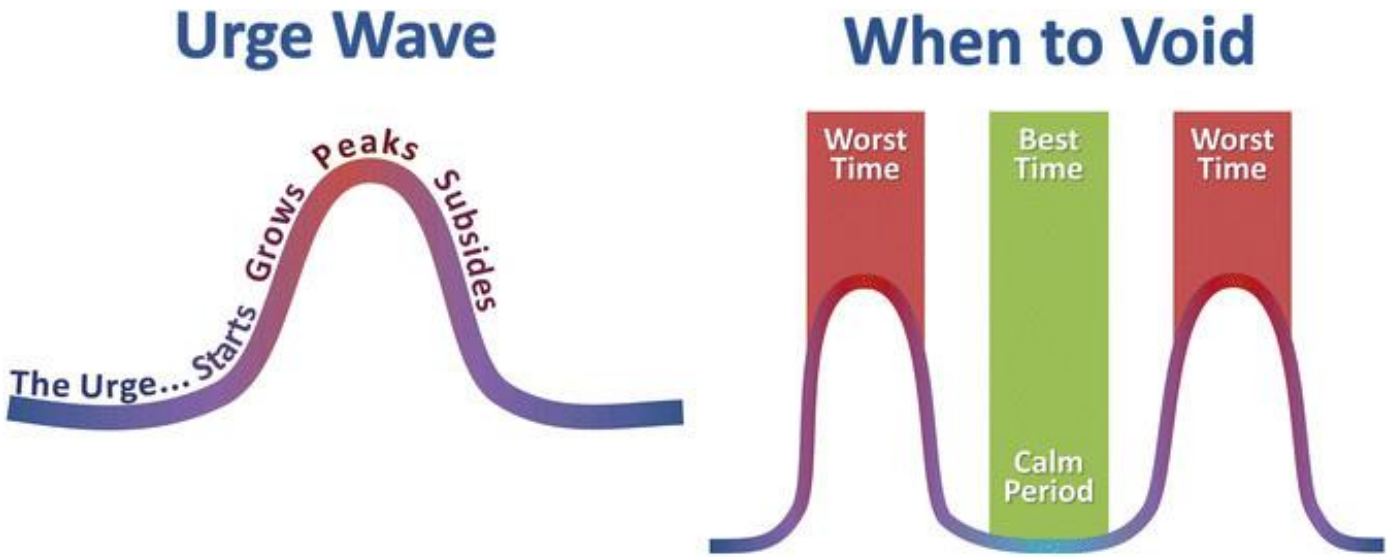
- NOBLE Study
  - In women the prevalence of OAB increased with increasing BMI
  - OAB in women with BMI > 30 was 2.2x higher than in women with BMI < 24

- Subak et al. 2005
  - **Weight loss of 5-10% reduces urge incontinence by 60%**

Urge suppression techniques



Urge suppression

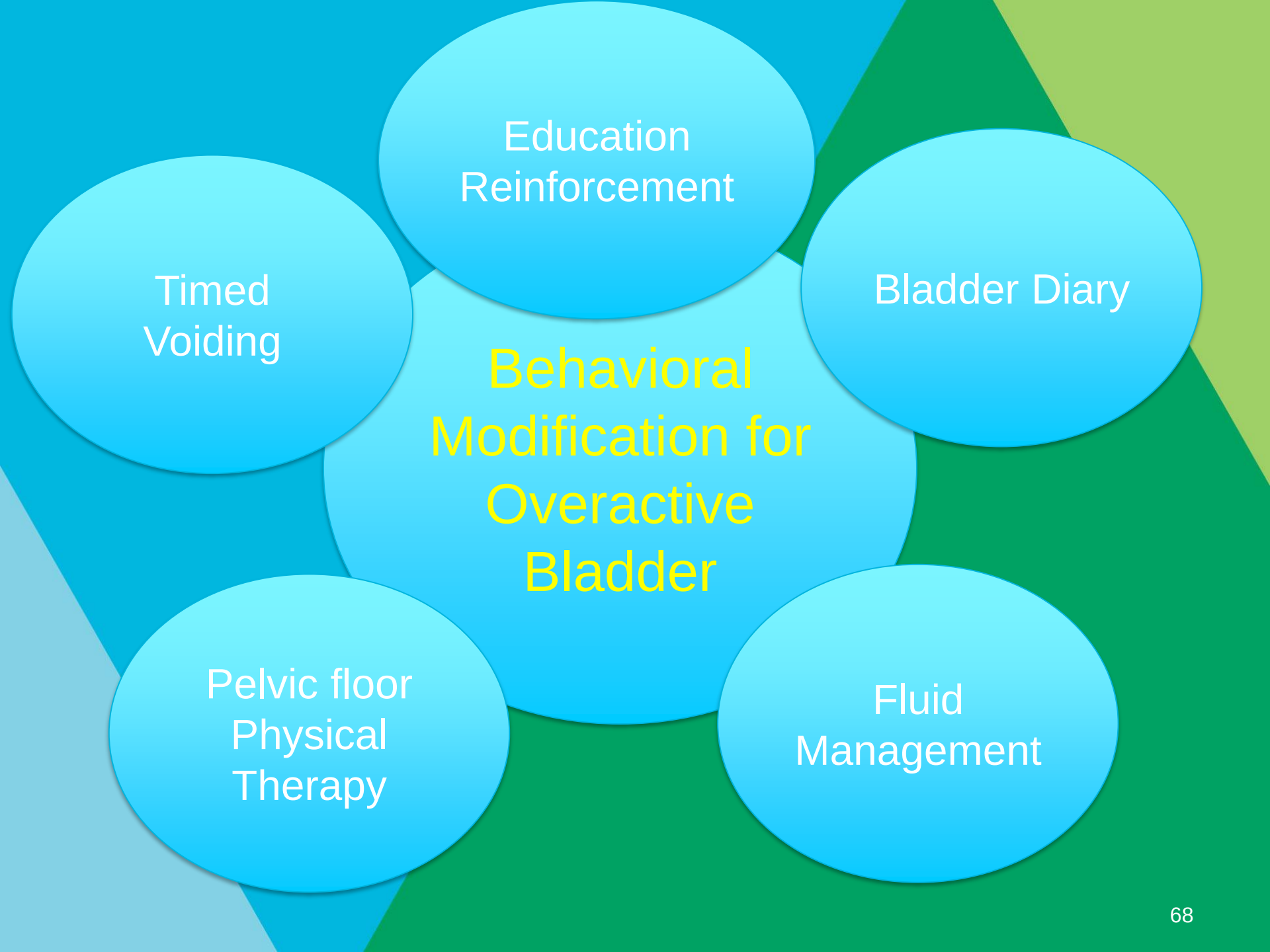


When the Urge Strikes...

- Stop and stay still. Sit down if you can.
- Squeeze your pelvic floor muscles quickly 3 to 5 times and repeat as needed – Don't relax muscles in between.
- Relax the rest of your body by taking several slow, deep breaths.
- Concentrate on suppressing the urgency and once it calms down, squeeze again as you stand up.
- Walk to the bathroom at a normal pace, do not rush or hurry.
- If the urge returns on the way to the bathroom, stop and squeeze away the urge again.

Diet Modification

- **Daily fluid intake < 4-6 glasses of 8 oz in 24 hours**
  - reduce nighttime fluids to manage nocturia
- **Eliminate bladder irritants such as:**
  - caffeine
  - alcohol
  - Nicotine
  - Sodas, diet sodas
- **Evaluate and modify bowel habits as appropriate**
  - add bulk fiber


Education
Reinforcement
Timed
Voiding
Bladder Diary
Behavioral
Modification for
Overactive
Bladder
Pelvic floor
Physical
Therapy
Fluid
Management

OAB pharmacologic therapy

- **Vaginal Estrogen**
- **Anticholinergics/antimuscarinics**
  - **oxybutynin chloride, tolterodine tartrate, trospium**
  - **Tablets, gels, patches**
- **Beta 3 agonists**
  - **Myrbetriq/mirebegron**
- **Antispasmodics**
  - **dicyclomine HCl/oxybutynin chloride**
- **Tricyclic antidepressants**
  - **imipramine, doxepin, desipramine, nortriptyline**

Medications

Anticholinergic and Dementia

- The most common anticholinergic drug classes used were tricyclic antidepressants, first generation antihistamines and bladder antimuscarinics.
- Mean follow-up of 7.3 years, 797 participants (23%) developed dementia (637 developed Alzheimer's).
- A 10-year cumulative dose-response relationship was observed for both dementia and Alzheimer's disease, compared to non-use. A similar pattern of results was noted for Alzheimer's disease. Results were robust to secondary, sensitivity and post-hoc analyses.
- Higher cumulative anticholinergic medication use is associated with an increased risk for dementia.

Shelly Gray, Cumulative use of Strong Anticholinergic Medication and Incident dementia JAMA Int Med March 2015

JAMA Internal Medicine | Original Investigation

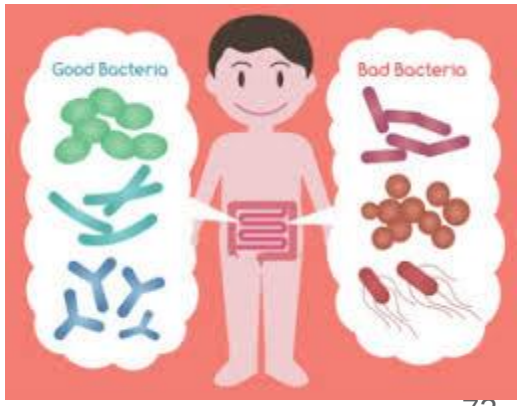
Anticholinergic Drug Exposure and the Risk of Dementia
A Nested Case-Control Study

Carol A. C. Coupland, PhD; Trevor Hill, MSc; Tom Dening, MD; Richard Morriss, MD; Michael Moore, MSc; Julia Hippisley-Cox, MD

- **Associations**
- Anticholinergic use 1-11 years before dementia diagnosis AOR
    1. 1.06 (95% CI, 1.03-1.09) w/ TSDD of 1-90
    2. 1.49 (95% CI, 1.44-1.54) for >1095 TSDDs

Urinary tract infection prevention

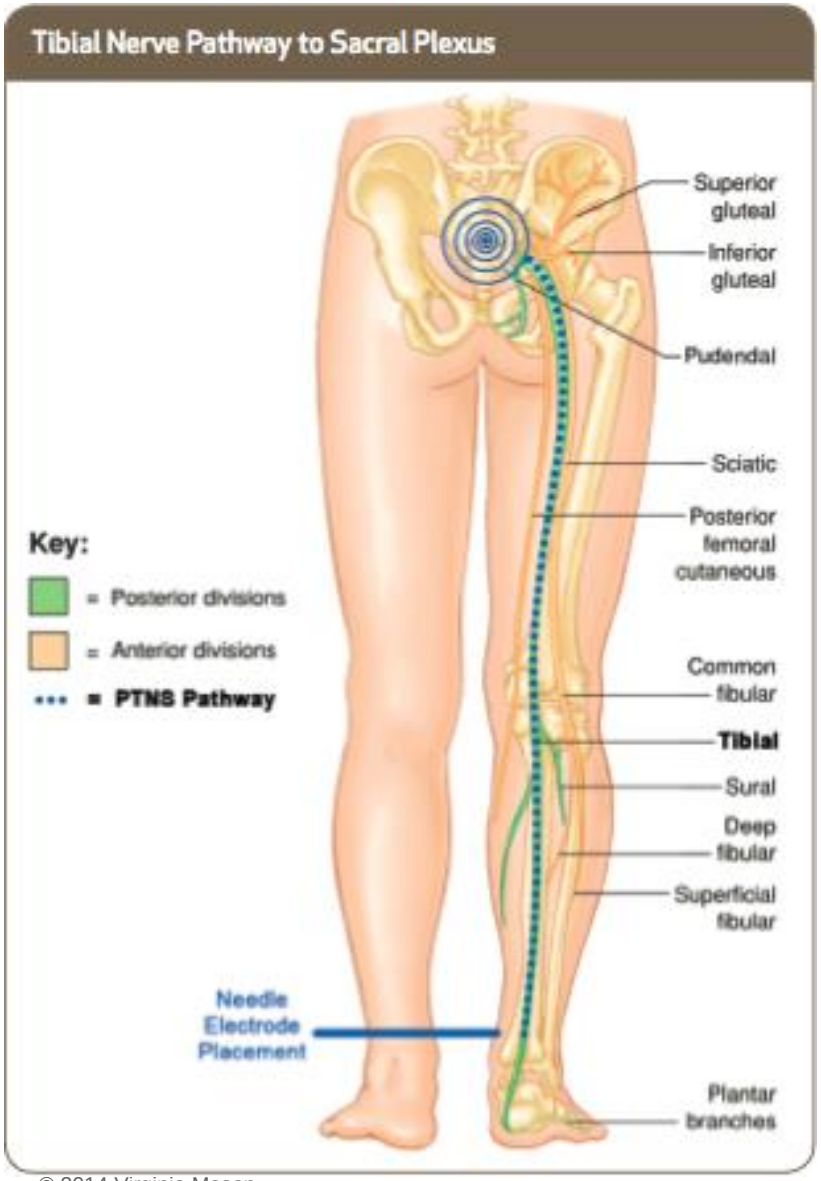
- Hydration
- Perineal hygiene
- Emptying bladder well
- Cranberry 36mg PACs
- Vaginal estrogen
- D-mannose
- Lactobacilus/probiotics
- Vitamin C



Procedures to improve OAB/urgency incontinence

- **Posterior Tibial nerve stimulation**
- **Cystoscopy with injection of botox**
- **Sacral neuromodulation with Interstim**

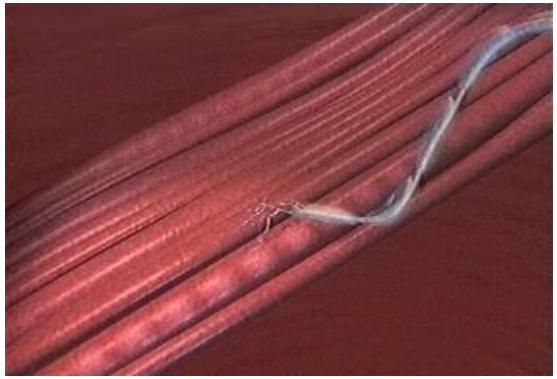
Peripheral tibial nerve stimulation



- Acupuncture needle with electrical stimulation
- Office based treatment once a week for 30 minutes for 12 weeks, then every 3-4 weeks
- Minimal side effects

Botulinum A Toxin (Botox)

- FDA approved for urgency, frequency, urgency incontinence, neurogenic bladder
- Works for up to 3-12 months, and can be repeated
- Office based cystoscopic procedure
  - Risk of UTI and retention
  - Increases bladder capacity (amount your bladder can hold)
  - Abolishes abnormal bladder spasms

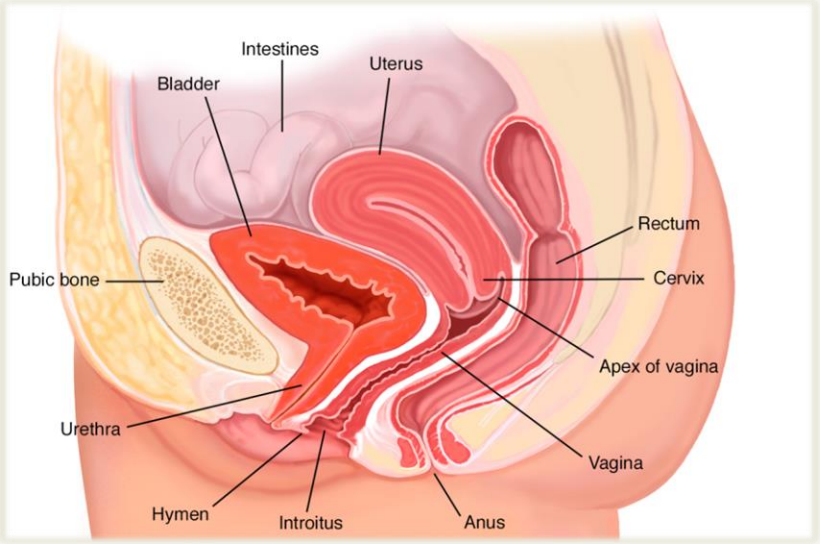


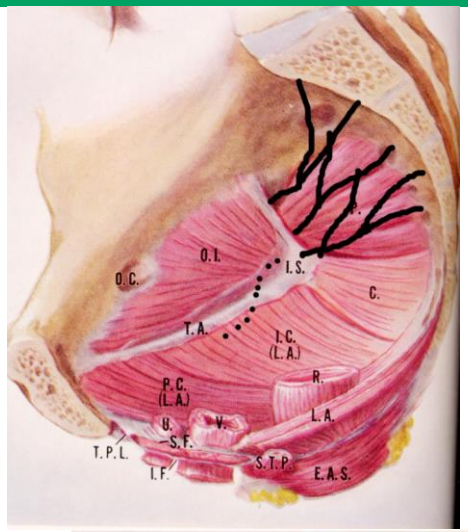
Sacral Neuromodulation "bladder pacemaker"

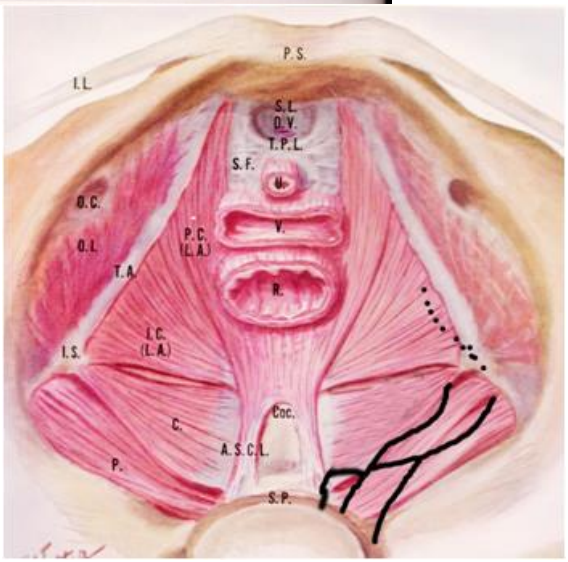
- Interstim FDA approved since 1997
- Treats urgency/frequency, urgency incontinence, retention, fecal incontinence
- Minimally invasive
- Thin pacemaker wire placed near S3
- 2 stage procedure
  - If symptoms improve by 50% or more, then battery placed
- Durable, safe, effective
- MRI head compatible

PELVIC ORGAN PROLAPSE

1. What is the pelvic floor and why it is important?







- Set of muscles, ligaments and connective tissue in the lowest part of the pelvis.
- Supports pelvic organs and urinary, bowel, sexual function

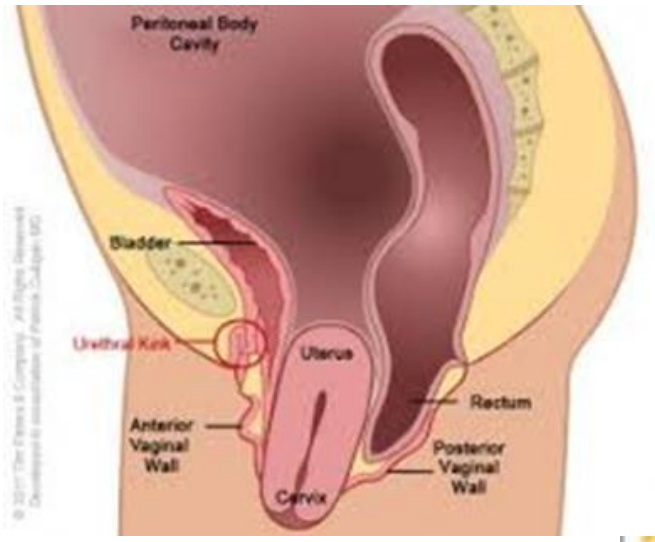
  -Bladder, Uterus, Rectum, Vagina.

2. What happens when the pelvic floor fails?

Pelvic organ prolapse

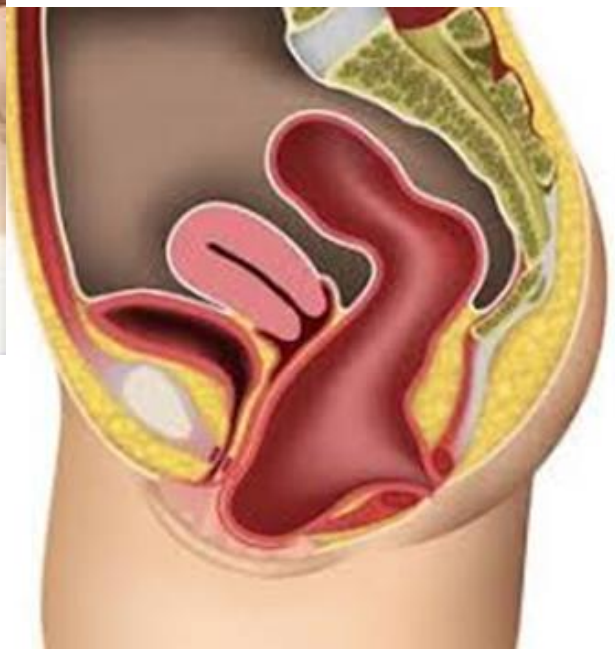
- "Hernia" of intimate functioning tissues
- Protrusion of the vaginal walls (bladder, uterus, rectum) through the opening of the vagina
- Symptoms: vaginal bulge, pressure, feeling of sitting on a "ball", splinting to have BMs, stool trapping, urinary problems
- Can also cause *no or minimal symptoms* and not cause problems

Types of prolapse



Uterine prolapse

Cystocele

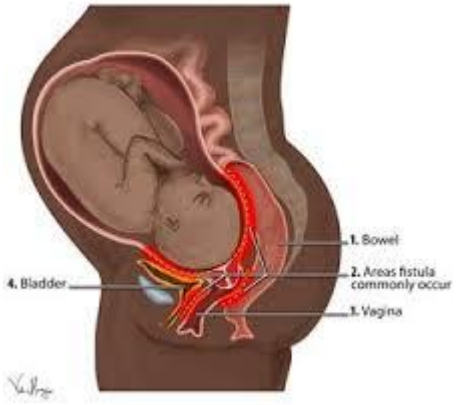


Rectocele

3. Why does prolapse happen?

Complex and multifactorial

- Aging
- Parity
- Vaginal delivery
- Prolonged 2nd stage/forceps delivery/large baby's head circumference
- Denervation or weakness of the pelvic floor
- Hysterectomy
- Menopause
- Chronically raised intraabdominal pressure
- Congenital or acquired connective tissue disorder



(Bump 1998; Gill 1998; MacLennan 2000).

4. Why do we care about prolapse?

Very common, but not talked about

- Up to 50% of parous women.
- 6 % of women will have had a surgical correction for prolapse by the age of 80.
- 10-20% of women will seek evaluation for prolapse
- Following hysterectomy 6-12 % will develop vaginal vault prolapse

[Marchionni 1999, Aigmueller 2009, Wu 2009] [Hendrix 2002, Handa 2004, Morley 1988].

4. Why do we care about prolapse?

- **Costly**
  - 300,000 Prolapse surgeries/year
  - Direct health care costs substantial

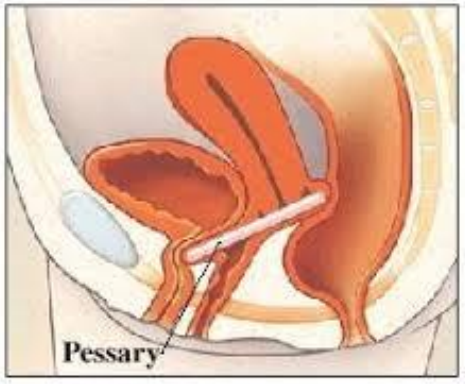
- **Negatively impacts quality of life**

- **Prevalence projected to increase**

[Marchionni 1999, Aigmueller 2009, Wu 2009] [Hendrix 2002, Handa 2004, Morley 1988].

5. What can be done?

- **Best treatment depends on how much symptoms bother you:**
  - Prolapse is not life-threatening
  - Treatments can help improve quality of life
- **Conservative approach:**
  - Watch and see how things go
  - Dietary changes
  - Pelvic floor muscle exercises
  - Pelvic floor physical therapy
- **Pessary:**
  - Support bladder, uterus and vagina



Wearing a pessary can help support any prolapsed organs.

Expectant management is ok

- 64 symptomatic women chose expectant management followed by sequential exams
  - 1.8% no change/ 19% progression >2cm/3% regression
  - 63% continued observation/38% pessary or surgery
- Natural history of women declining intervention is one of minimal change

Gilchrist et al, 2012

Pelvic floor PT

- A few studies have demonstrated
  - Objective and symptomatic improvements
- Best for stage 1 and 2 POP
- Low risk
- Requires motivated patient

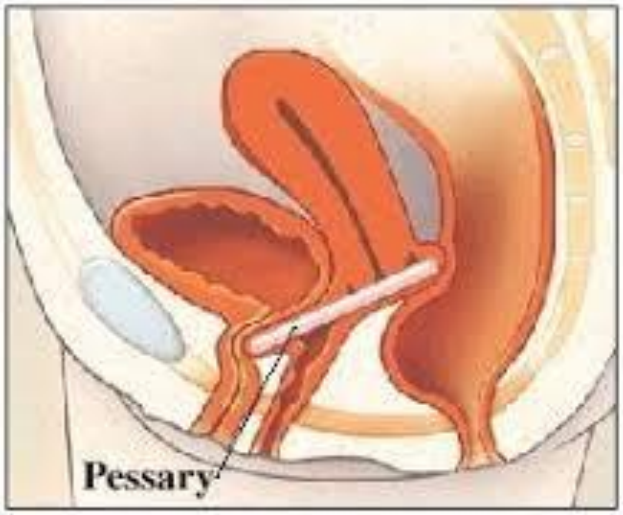
Stupp, 2011, Braekken, 2010; Hagan, 2011; Hagan, 2013

Pessary

- Support
  - ring, ring with support, incontinence ring
- Space filling
  - gelhorn, cube, donut

Factors affecting Pessary fitting

- Hysterectomy
- Prior pelvic reconstructive surgery (Mutone, 2005)
- Shorter vaginal length (<=6cm)
- Larger genital hiatus (4 fingerbreaths)
  - Predicted unsuccessful pessary fitting (Clemons et al. 2004)



Wearing a pessary can help support any prolapsed organs.

Common prolapse surgeries

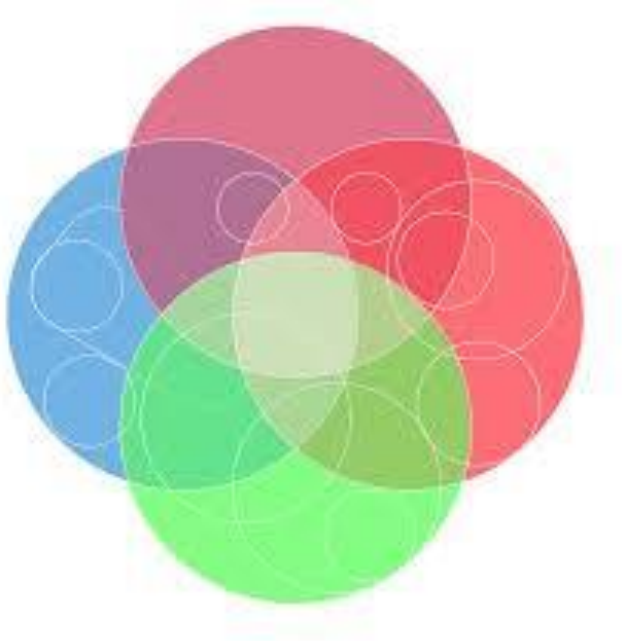
- Cystocele repair
- Rectocele repair
- Colpocleisis
- Vaginal hysterectomy with vault suspension
- Robotic-assisted laparoscopic sacrocolpopexy

Surgical approach

- Reconstructive vs Obliterative (Colpocleisis)
- Vaginal approach vs Abdominal approach
  - Abdominal approach (open, lap, robotic)
- Native tissue vs graft augmented
  - (biologic vs mesh)
- With or without hysterectomy

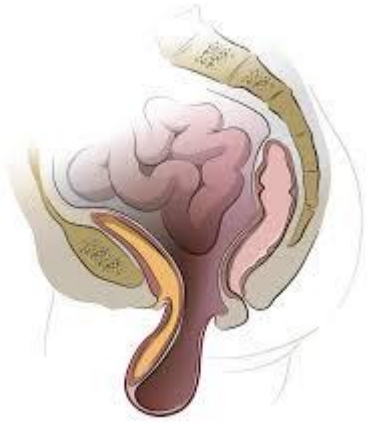
Goals of Prolapse treatment

- Relieve symptoms
- Restore anatomy and function
- Avoid complications
- Improve quality of life



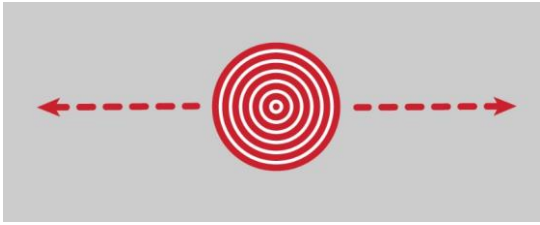
Surgical considerations

- Multi-compartment vs single compartment
- Importance of Apical support
- +/- anti-incontinence procedure
- Primary repair vs recurrent prolapse
- Patient factors (smoking, DM, obesity, pain, sexual activity, connective tissue disorders)
- Patient expectations



Defining success for incontinence and prolapse

- Outcomes are *variable* depending on defined measure of success
  - Objective outcomes
  - Subjective outcomes
  - Patient satisfaction
- Secondary analysis of the CARE trial described prolapse surgical success rates after sacrocolpopexy using 18 different definitions of treatment success
  - Treatment success varied widely depending upon definition used (19.2% to 97.2%).



(Barber et al, 2009)

Anatomic vs Symptomatic success

- Pelvic organ prolapse
  - multidimensional phenomenon
  - "success" of treatment is difficult to define
- Historically, most studies evaluating the treatment of pelvic organ prolapse have
  - focused exclusively on anatomic success
  - without considering other important areas such as symptoms, quality of life, or socioeconomic outcomes.
- For an individual patient, the most important outcome of a surgical procedure is
  - the relief of her symptoms and
  - improvement in her quality of life
  - yet until recently these areas have largely been ignored

[Barber 2009].

Re-operation rates lower than 29% often quoted

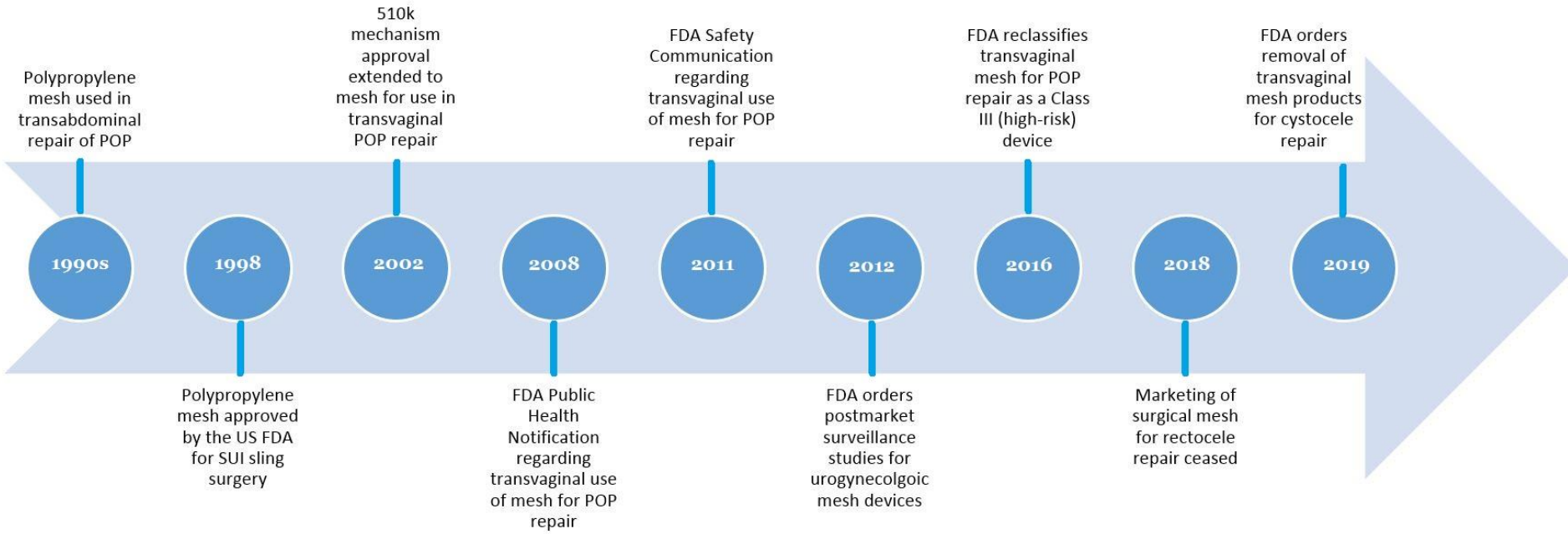
The rates of reoperation after POP surgery vary widely in the literature

Olsen et al using administrative data from a large U.S. healthcare system reported a lifetime reoperation rate of 29.2%.[Olsen 1997]

- Importantly, this study included both POP and stress incontinence surgery and did not distinguish between reoperation for incontinence or POP in their report
- Moreover, the authors did not distinguish between reoperation for POP in the same compartments originally operated versus the development of new POP in a new segment of the vagina ["de novo POP"].

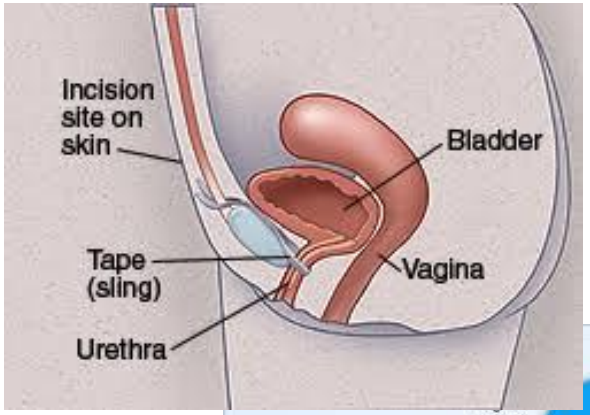
More recently several investigators have looked specifically at the issue of site-specific recurrence with re-operation rates ranging from 3.4%-9.7%.[Miedel 2008; Kapoor 2010]

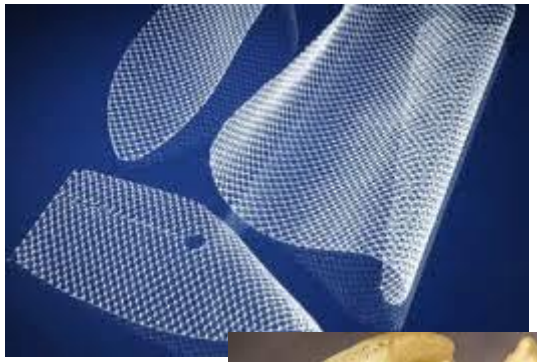
FDA notifications on transvaginal mesh

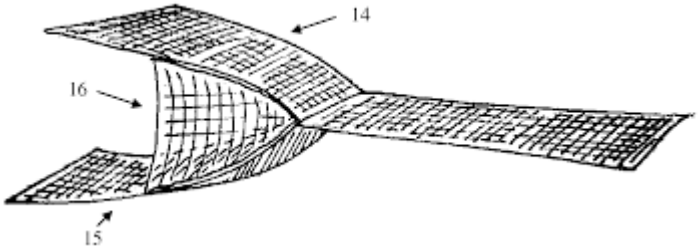


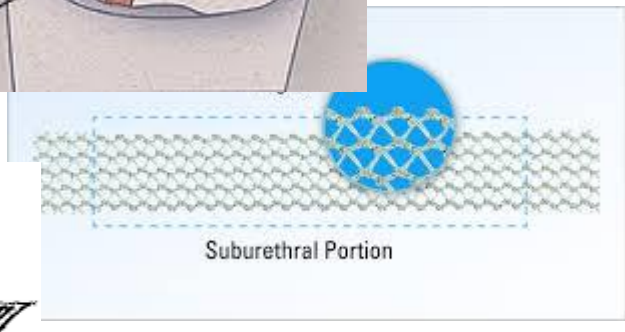
Mesh- size, location, skill matter

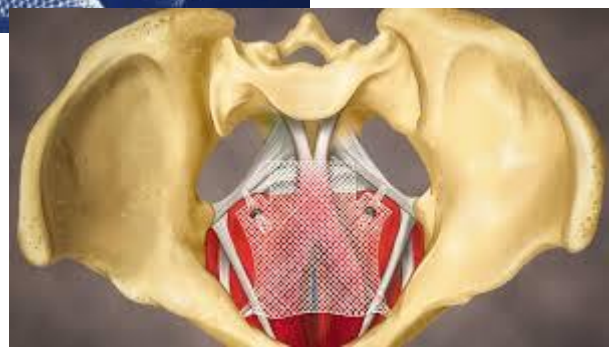
1) Mesh for slings
2) Transvaginal mesh
3) Abdominal mesh

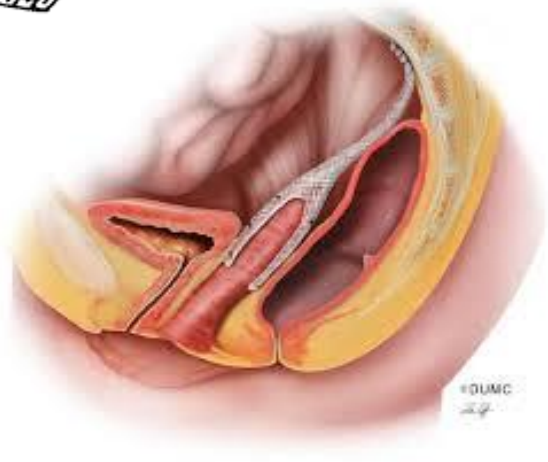








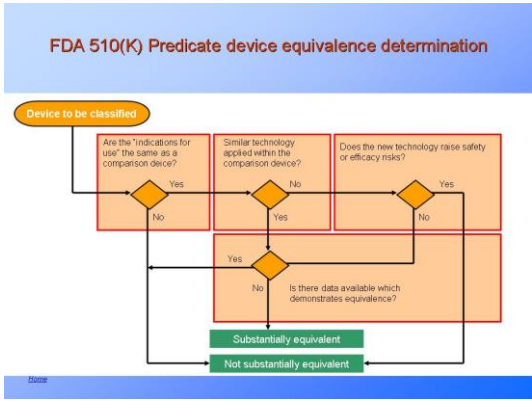




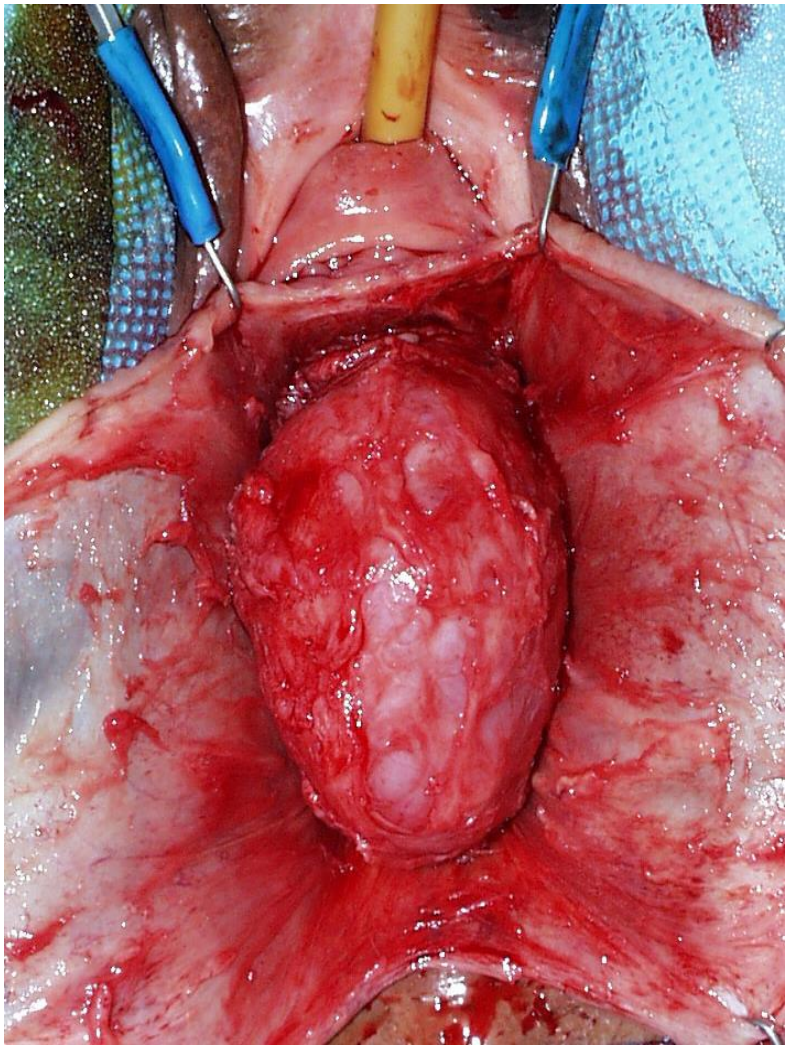
Informed consent

FDA notification on risks of transvaginal mesh has highlighted the need for:

- Informed consent
  - Discussion of Risks, Benefits, Alternatives, personnel
- Judicious use and testing of new technology in female pelvic floor problems



High grade Cystocele



Slide courtesy of S. Raz

Uterovaginal prolapse

Uterovaginal prolapse may be treated with or without concurrent hysterectomy

- Pelvic organ prolapse is the indication for 14% of hysterectomies performed in the U.S.

300,000 surgeries are perform annually for POP

- 80-90% performed vaginally
- 10-20% abdominally

Why Hysterectomy?

Indications

- Hysterectomy enables ACCESS for safe and durable apical prolapse repair

Route of hysterectomy determined by multiple factors, including choice of prolapse repair

- Vaginal
- Abdominal (lap/robotic/open)

Advantages of hysterectomy + prolapse repair

Excellent long term outcomes using clinically meaningful definitions[1,2]

- Bulge symptoms
- Durability/reoperation rates

Reliable anatomic outcomes

- Apical repair after hysterectomy better addresses severe anterior wall prolapse

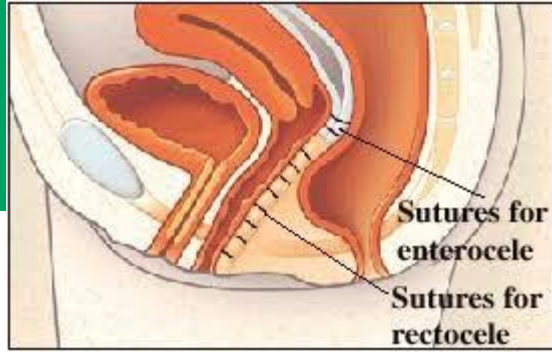
Prophylactic salpingectomy

- Decreases risk of ovarian cancer[3]

Avoidance of mesh complications specific to TVM

1. Roovers, 2004
2. Nygaard, 2013
3. Falconer, 2015

Rectocele repair

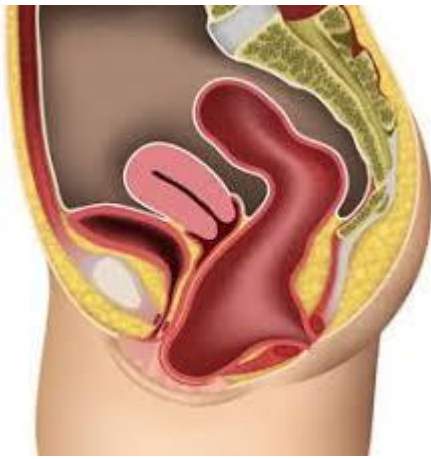


- Rectocele repair anatomic success rates ranges from 76-96%
- Mean post-operative dyspareunia rate of 18%(range 5-45%) and 26% splinting
- No study has shown clear benefit of biologic graft or mesh augmentation for posterior vaginal wall prolapse.
- Transvaginal approach
  - superior to trans-anal approach

[Nieminen, 2009]
[Maher, 2013]

Symptoms after Posterior Repair

- Bowel symptoms resolve or improve in 2/3
- 11% develop new symptoms
- 50% have 1 or more persistent symptoms
- Longer history of splinting assoc with persistent splinting post op
- Normal post op vaginal support assoc with reduced risk of incomplete bowel emptying



[Gustilo-ashby, 2007; Sung, 2012]

TEN-YEAR OUTCOMES OF POSTERIOR VAGINAL WALL PROLAPSE REPAIR IN A TERTIARY REFERRAL SETTING

Kevin Gioia[1], Erika M. Wolff[1], John D. Massman III[1], Alvaro Lucioni[1], Una J. Lee[1], Kathleen C. Kobashi[1]

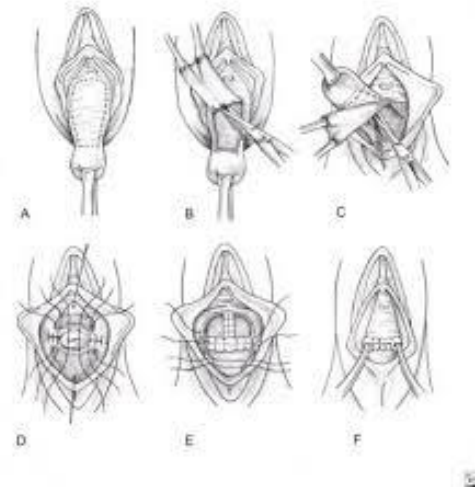
[1]Virginia Mason. Seattle, WA

- Retrospective review of 105 rectocele repairs

	Cadaveric Fascia	Native Tissue
Satisfaction: 1 year	88%	93%
Satisfaction: 10 years	59%	41%
Improvement: 1 year	71%	90%
Improvement: 10 years	55%	41%

- Durable success following rectocele repair with both native tissue and cadaveric fascia

Colpocleisis (or Le Fort Colpocleisis)

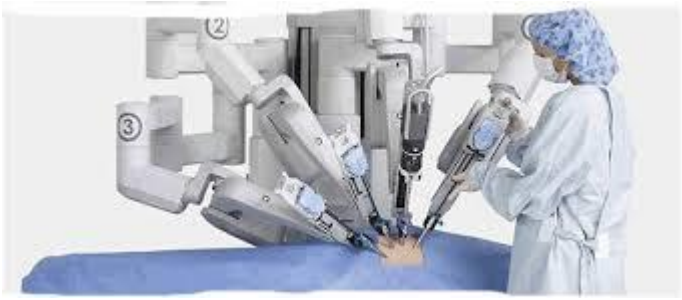


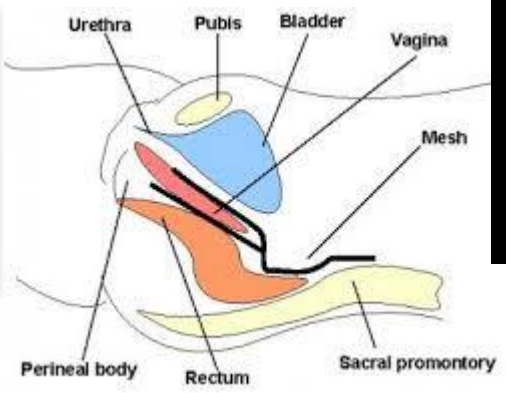
- Obliterative surgery
- Prolapse is reduced and vaginal canal is surgically closed
- Reserved for women who are elderly, medically compromised, and no longer sexually active
- Very high success rate
- High patient satisfaction and functional improvement
- Low rates of regret for loss of sexual function
- Low complication rate

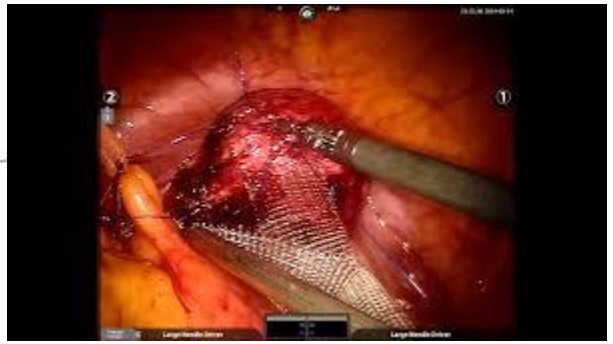
[Jelovsek 2007]

Robotic-asst laparoscopic sacrocolpopexy

- Intra-abdominal approach
- Lightweight mesh is placed around the vagina and suspended to the ligaments near the sacrum
- Durable and well tolerated







[Benson1996; Maher 2004; Lo 1998]

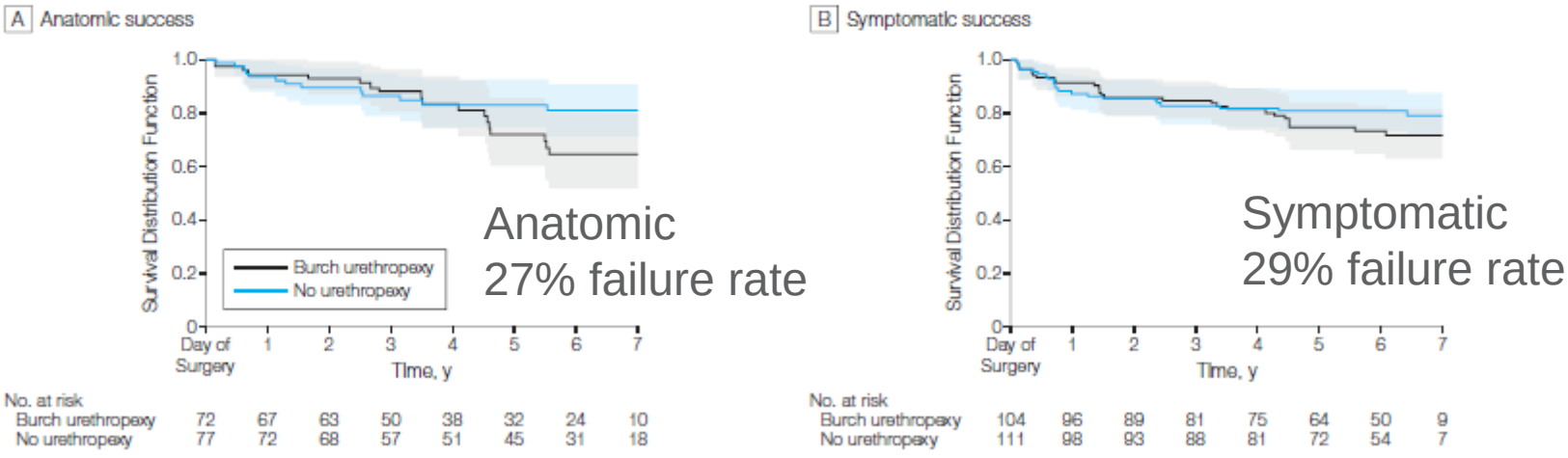
Long-term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse

Ingrid Nygaard, MD
Linda Brubaker, MD
Halina M. Zyczynski, MD
Geoffrey Cundiff, MD
Holly Richter, MD

Importance More than 225 000 surgeries are performed annually in the United States for pelvic organ prolapse (POP). Abdominal sacrocolpopexy is considered the most durable POP surgery, but little is known about safety and long-term effectiveness.

Objectives To describe anatomic and symptomatic outcomes up to 7 years after abdominal sacrocolpopexy, and to determine whether these are affected by concomitant anti-incontinence surgery (Burch urethropexy).

Figure 3. Kaplan-Meier Survival Curves for Success of Abdominal Sacrocolpopexy in Treating Pelvic Organ Prolapse Through Year 7, Using Anatomic and Symptomatic Definitions of Success



The blue and gray shading indicate pointwise 95% confidence intervals.

Anatomic
27% failure rate

Symptomatic
29% failure rate

Mesh erosion rate 10.5%

Sacrocolpopexy vs vaginal native tissue repair

- Re-operation rates low for both
- Minimally invasive does not equal minimal risk
  - (cardio-pulm and bowel complications)
- Patient selection important
- Patient counseling very important
- Quality=right patient right procedure right time

Goals of prolapse treatment

Relieve symptoms

Restore anatomy and function

Avoid complications

Improve quality of life

Example questions to ask your surgeon

- What will my recovery be like?
- Do you offer all types of prolapse surgery? (vaginal, robotic)
- Will you be using mesh or other biologic grafts?
- Is this a large part of your surgical practice?
- What parts are prolapsed in my case and which areas are you going to repair?
- What are possible complications?
  - Informed consent: risks, benefits, alternatives, personnel
- If my prolapse comes back, what can we do?

5. How can you prevent prolapse?

- Maintain a healthy weight
- Stop smoking and avoid chronic coughing
- Pelvic floor muscle strengthening

FECAL INCONTINENCE

Accidental Bowel Leakage

Accidental leakage of any amount of fecal matter

- May be sensed (urgent) vs not sensed
  - Bathroom mapping
  - Social isolation
- Full fecal incontinence
- Fecal smearing
- Fecal soiling (itching, debris)

Accidental Bowel Leakage

Embarrassing and underreported

- 7-15% in women in the community
- <30% discuss with provider
- 71% prefer the term "accidental bowel leakage" vs "fecal incontinence"
  - Survey of 1100 women, 30% had heard of FI

Bharucha et al, Am J Gastro 2015;110:127-136

Accidental Bowel Leakage– Why?

Amount and consistency of stool

- Loose stool
- Transit time

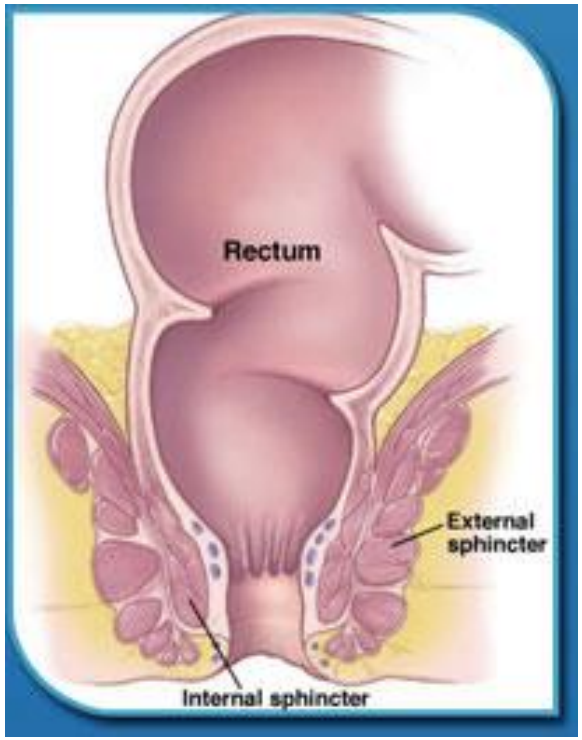
Brain and Nervous system

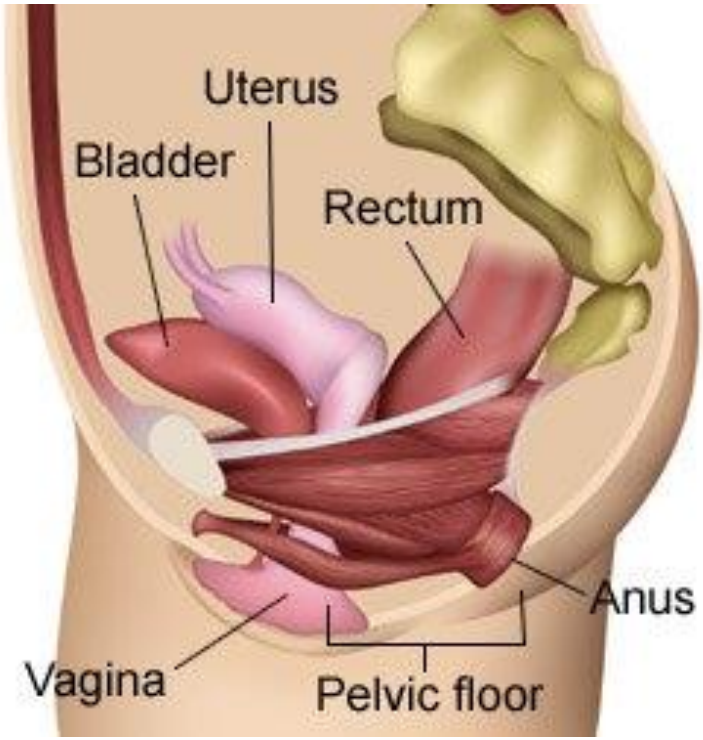
- Rectal nerve stretch receptors
- Senses solid stool better than liquid

Pelvic Floor problems

- Weakened muscle cannot hold stool that is too soft or loose

Accidental Bowel Leakage





Amount and Consistency of Stool

- **Medication side effects**
- **Diet**
  - Lactose Intolerance
  - Caffeine
- **Infection**
- **Colon polyps or tumor**
- **Inflammatory disease**
  - Crohn's, Ulcerative Colitis, Celiac Sprue, Microscopic Colitis
- **Irritable Bowel Syndrome (IBS)**
- **Small Bowel Bacterial Overgrowth**
- **Systemic disease**
  - Diabetes

Brain and Nervous System

- **Chronic constipation or diarrhea**
  - Over straining
  - Loss of sensation
- **Stroke**
- **Spinal Cord Injury**
- **Radiation Damage**

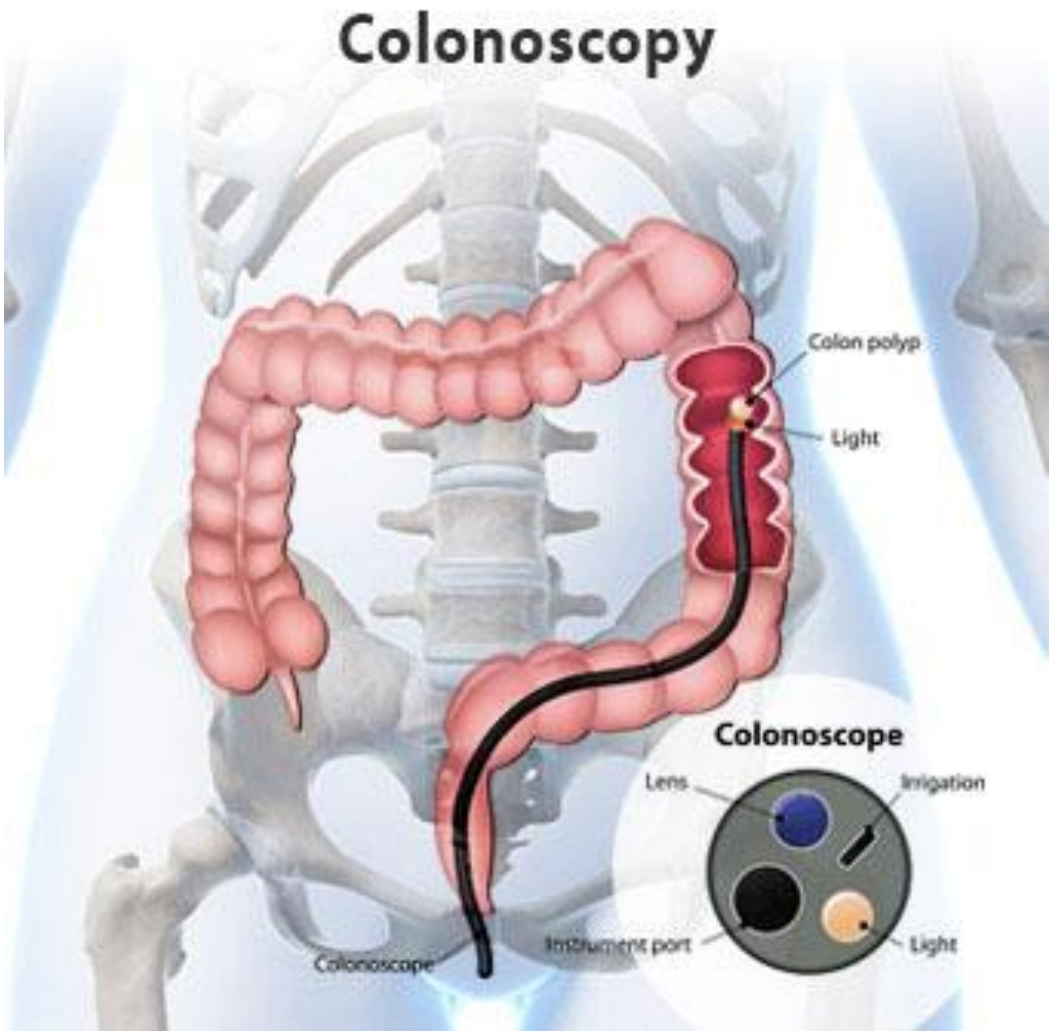
Pelvic Floor problems

- **Anal Sphincter Injury**
  - Child birth
  - Anal surgery or other injury
- **Pelvic Floor Weakness**
  - Pregnancy, delivery
  - Obesity
  - Age
  - Chronic over straining

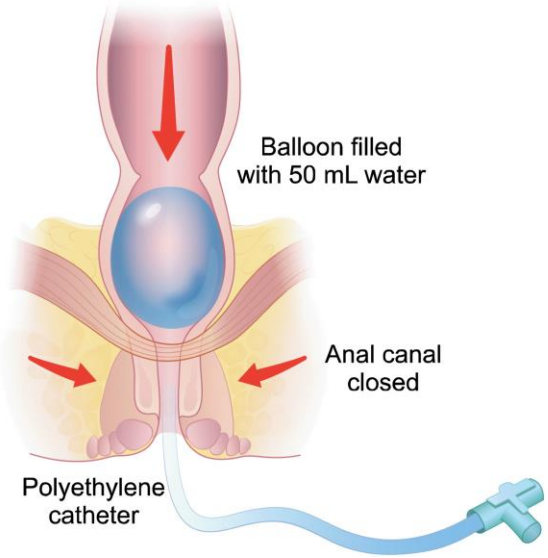
Diagnosis

- Labs, stool studies
- Colonoscopy with biopsies
- Anorectal Manometry
- Defecography

Colonoscopy



Anorectal Manometry



Defecography

Normalize Stool Consistency

- **Fiber supplement**
- **Elimination Diet**
  - Dairy
  - Caffeine
  - ETOH
  - Low FODMAP
- **Medications**
  - Lomotil or loperamide
  - Lotronex
  - Librax
  - Viberzi
  - Xifaxin

Treatment

Pelvic Floor PT

Treatment

Squatty Potty

Physical Therapy and Biofeedback

Clinical Trial: severe leakage (weekly)

- 108 patients failed medical therapy
- Biofeedback vs pelvic floor exercises
- 76% biofeedback vs 41% Kegel patients had adequate relief at 3 mo
- Improvement sustained x 12 months

Heymen et al, Dis Colon Rectum 2009;52:1730-7

Sacral Nerve Stimulation

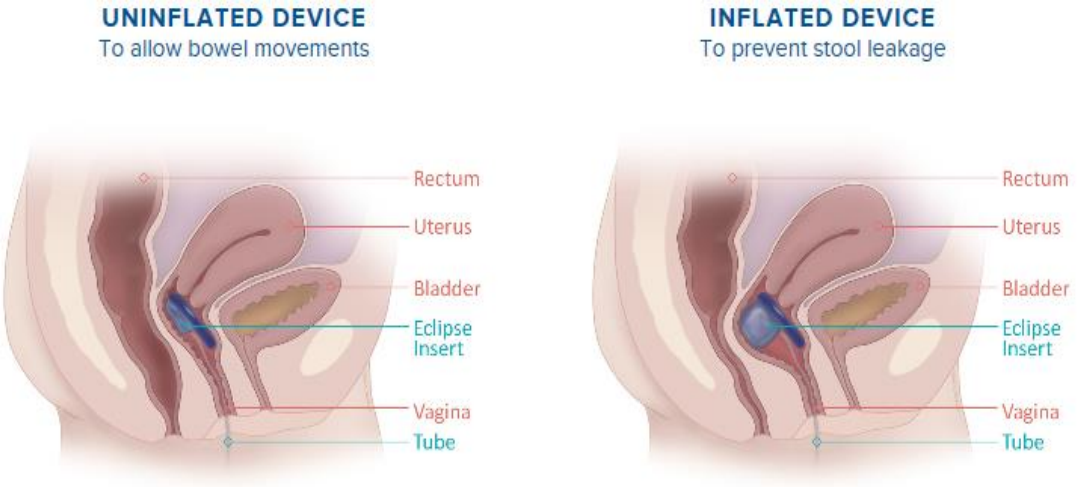
- Electrodes adjacent to sacral nerves
- Also for urge urinary incontinence
- At 5 years
  - 89% with 50% decrease in episodes/week
  - 36% with complete continence

Hull et al, Dis Colon Rectum 2013;56:234-45

Rectal and Vaginal Inserts

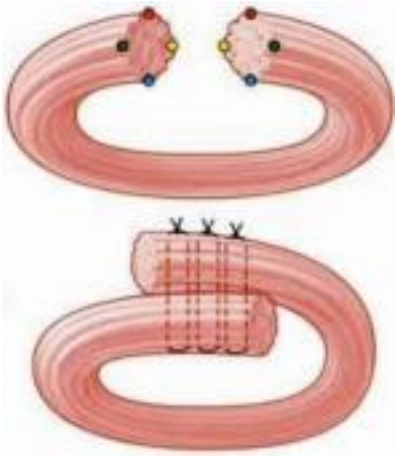
- Renew rectal inserts
  - Silicone inserts
  - Passes with BM
  - $3 each

- Eclipse vaginal insert

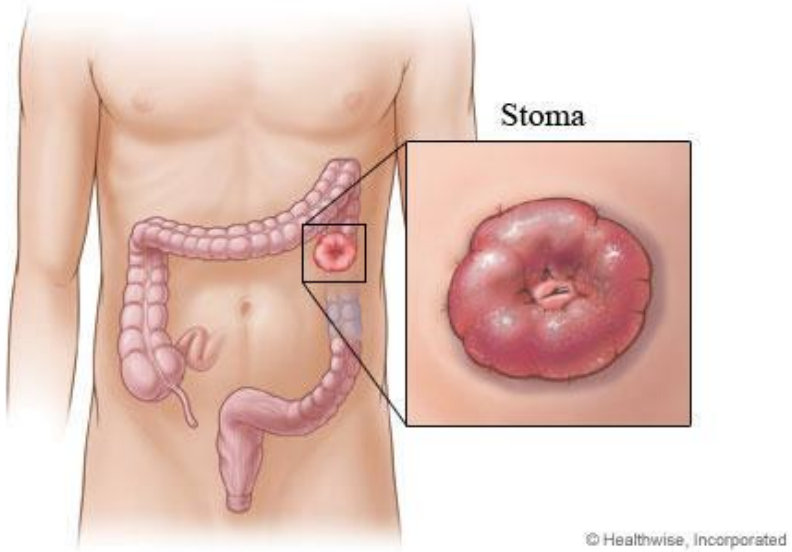


Surgical

- Sphincteroplasty



- Diversion



Patient-centered care

Five Things Worth Knowing About the Vagina

April 6, 2015 by Virginia Mason Team Member 3 Comments

By Una Lee, MD

Ever wish certain body parts came with an instruction manual? Particularly the parts that are less visible and tend to multi-task? Today we pull back the curtain on some interesting facts on a complex apparatus about half of us own: a vagina. Female pelvic medicine expert Una Lee, MD, shares five things worth knowing about the vagina. (You're welcome.)

While there's plenty more to talk about when it comes to a woman's vagina, and especially throughout the stages of life, consider this a little primer for vagina basics.

1) The vagina is surrounded by important structures. The vagina is just one part of the genital urinary tract, which includes the outer genitals, or vulva. The vulva consists of the inner and outer labia, and the clitoris. You could say the visible part of the clitoris is truly the tip of the iceberg, as several centimeters of the gland are below the surface,

What is needed to transform women's health care?

- Patient-centered counseling
  - Meeting patient needs
- Improving patient understanding of their condition
- Innovative prevention and treatments that are targeted toward the disease process
- Hope

Thank you

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