Incontinence and Overactive Bladder for Primary Care Physicians

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Case

- 51 yo female presents to you for follow-up of her HTN, Asthma, Chol. At the end of the visit, she complains of urinary incontinence and needing to wear pads.
- You are the first person she has told about this and she is very embarrassed about it.

Case

- She reports frequent “episodes” of needing to urinate suddenly and rushes to bathroom
- Sometimes she leaks before she can get there or as soon as she stands up to rush there
- She is urinating more frequently than usual and awakes at night to urinate

Question

- The next best step in management is:
  - A. Initial trial of an oral antimuscarinic
  - B. Moderate fluid intake and avoid caffeine and alcohol
  - C. Obtain additional history and evaluation
  - D. Kegel exercises
  - E. Tell her she should use pads and stop whining because the condition is not life threatening

Answer

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  - D. Kegel exercises
  - E. Tell her she should use pads and stop whining because the condition is not life threatening

Case

- You question her further:
- She reports leakage every time she coughs or sneezes. This is frequent due to her asthma and seasonal allergies
- Also leaks during P 90X workouts (after seeing the infomercial)
- 4-5 large pads per day, soaked.

Question

- What symptoms does the patient report?
  - A. Urge incontinence and stress incontinence
  - B. Nocturia, urgency, urge incontinence, stress incontinence
  - C. Frequency, urgency, stress incontinence
  - D. Frequency, urgency, nocturia, urge incontinence, stress incontinence
  - E. None of the above

Answer

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Definitions and Evaluation

Definition/Types of Incontinence

- The involuntary loss of urine
- First Step: establish pattern of incontinence
  - Urge Incontinence / (Overactive Bladder)
  - Stress Incontinence
  - Mixed Incontinence
  - Overflow Incontinence

Definition: “Overactive Bladder”

ICS Definition of Overactive Bladder, 2010:

“Urgency with or without urge incontinence, usually with frequency and nocturia, in the absence of urinary tract infection or other obvious pathology”

Abrams et al, 2002

Evaluation/Diagnosis of OAB

- Minimum evaluation of uncomplicated patient includes:
  - Careful history
  - Physical Exam
  - Urinalysis
- Additional assessment
  - Ucx, PVR, bladder diary, symptom questionnaires
- NOT recommended for initial evaluation
  - Cystoscopy, urodynamics, renal/bladder sonogram

AUA/SUFU Guideline, 2012

Stress Incontinence

- The complaint of involuntary leakage on effort or exertion, or on sneezing or coughing
- Minimum Evaluation:
  - History and physical exam
  - Objective demonstration of SUI
    - Cough or Valsalva leak test (supine or standing)
  - Assessment of PVR
  - Urinalysis/Ucx, if indicated

AUA Guideline on SUI, 2009
Abrams et al., 2002

Mixed and Overflow Incontinence

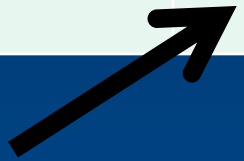
- Mixed Urinary Incontinence
  - Presence of both stress and urge incontinence
  - Involuntary leakage associated with both urgency and exertion, effort, sneezing, coughing

Abrams et al, 2002

- Overflow Incontinence
  - Continuous incontinence due to a full bladder
  - Can present similar to stress incontinence
  - Elevated PVR, often painful

Urinary Incontinence: Symptoms

Symptoms	Stress	Urge	Mixed	Overflow
Leak with cough, sneeze, exercise	+	-	+	-
Leak with urgency	-	+	+	-
Frequent urination, nocturia	-	+	+	-
Continuous leakage	-	-	-	+



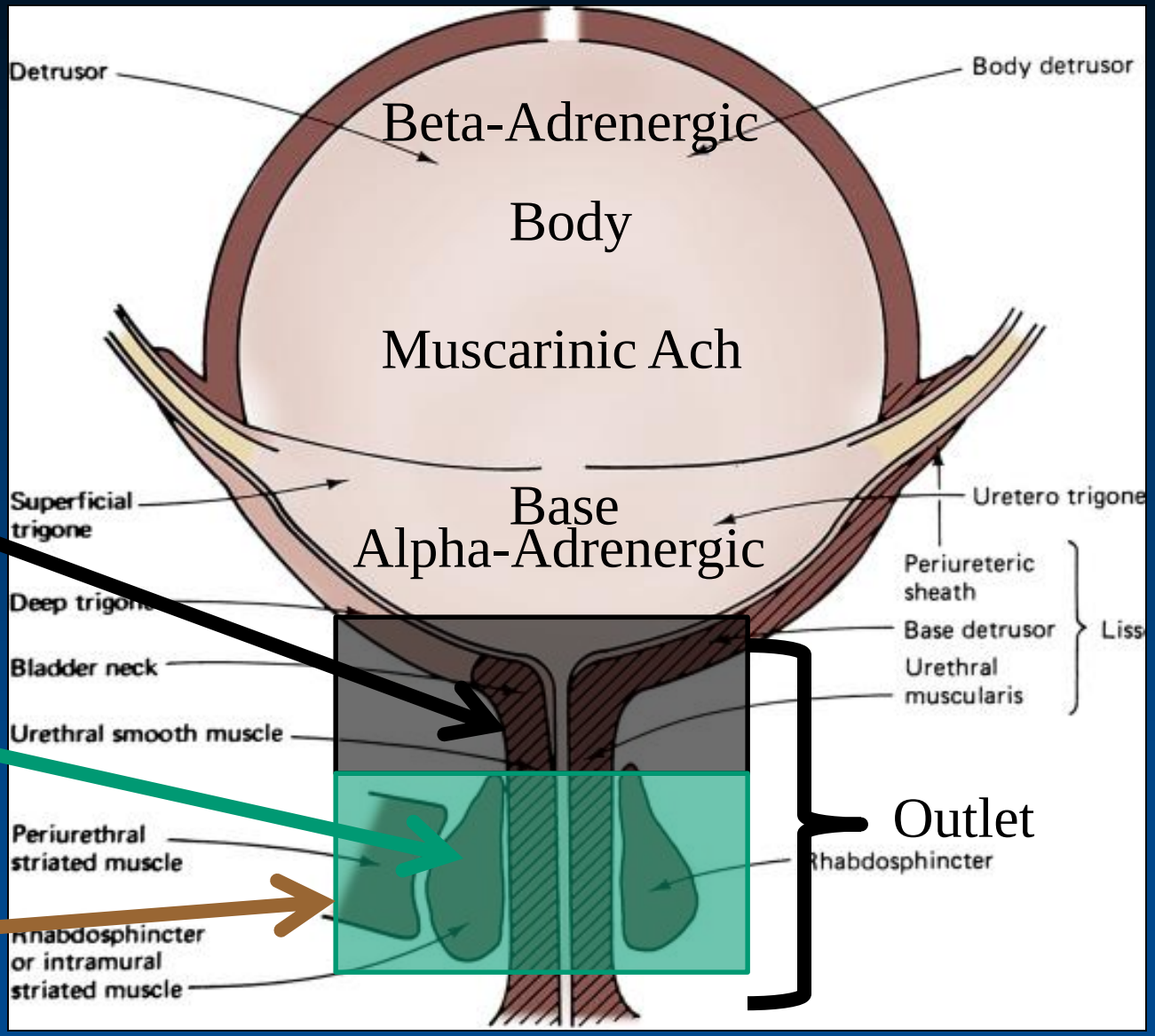
Clinical Pearl: Severe, total gravitational stress incontinence (“incontinence of non-resistance”) will also report continuous leakage and so will urinary fistula

Bladder Functional Anatomy

"Smooth Sphincter" (BN/ Prox Urethra)

"Striated" Sphincter"

Pelvic Floor



Case

- What is the minimum required workup on this patient?
  - A. History and physical
  - B. History, physical, U/A
  - C. History, physical, U/A, PVR
  - D. History, physical, U/A, PVR, Renal sonogram
  - E. History alone

Case Answer

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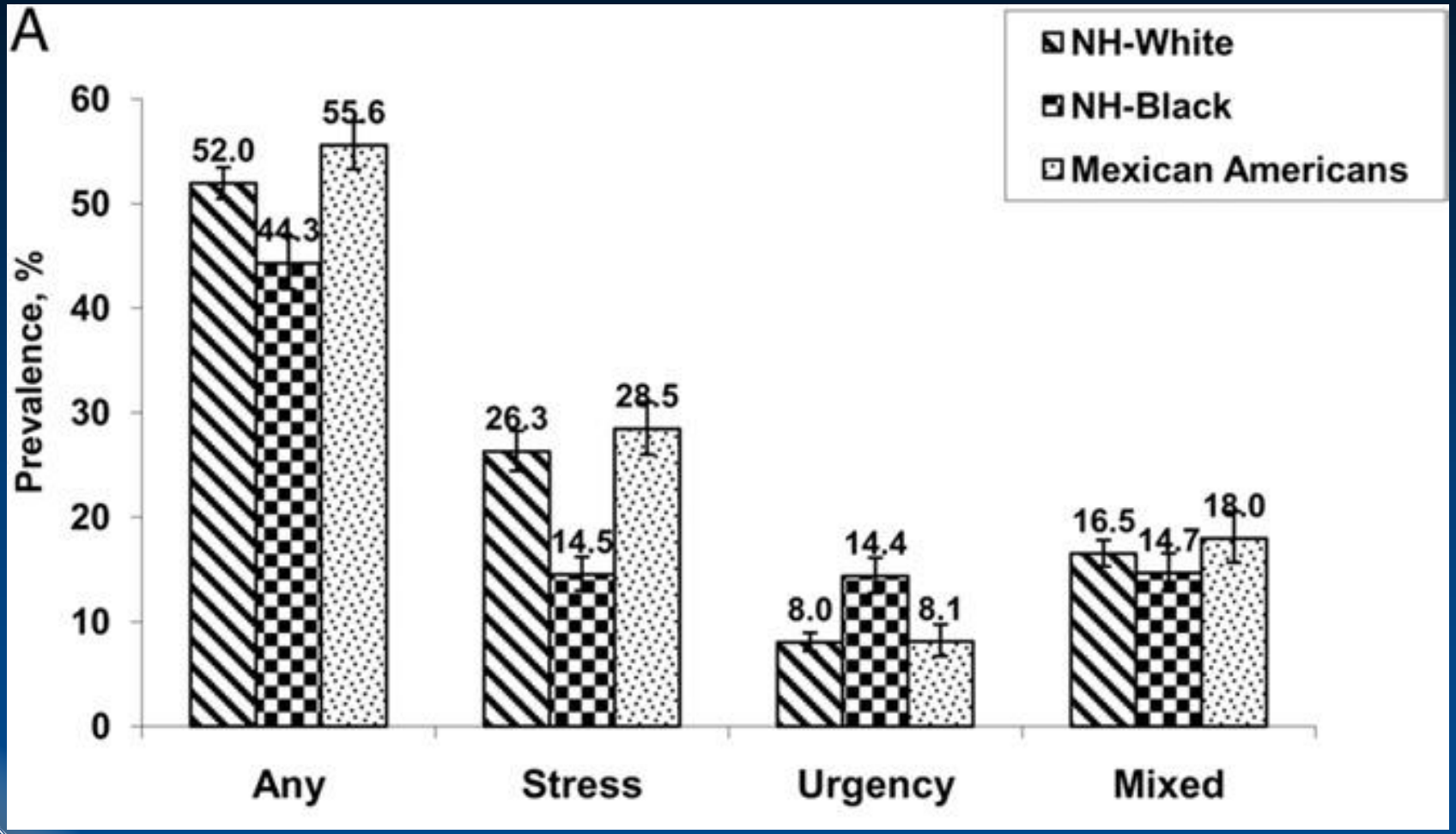
Scope of the Problem

- 2008:
  - Overactive Bladder: 10.7% of population
  - Urinary Incontinence: 8.2% of population
- 2018 Estimate:
  - Overactive Bladder: 20.1% of population
  - Urinary Incontinence: 21.6% of population
- Highly prevalent diseases
  - Will double over next decade
  - Over 1 billion people afflicted worldwide

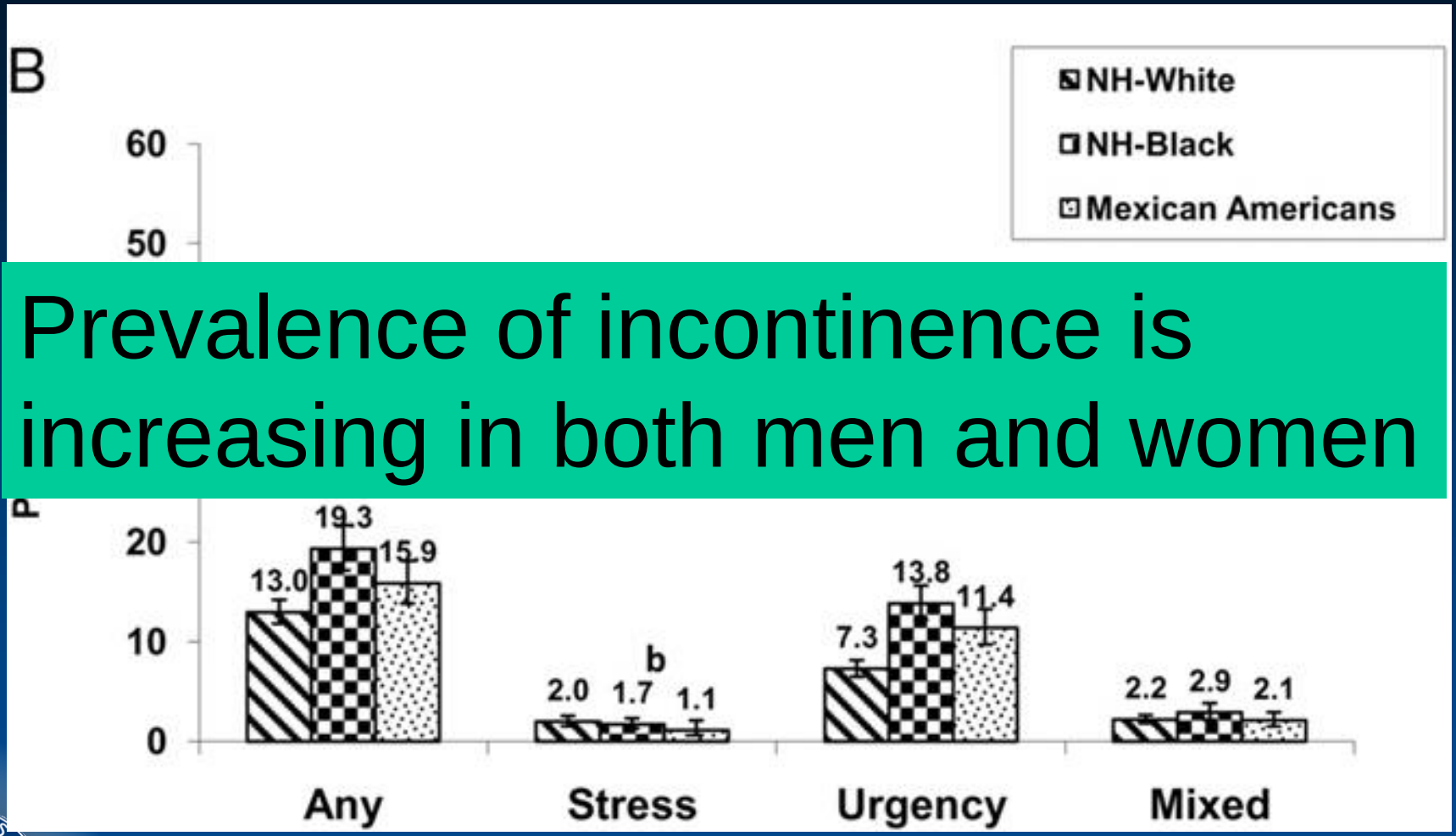
Irwin et al., 2011

Prevalence in U.S. Women



Markland et al., 2011

Prevalence in U.S. Men



Prevalence of incontinence is increasing in both men and women

Markland et al., 2011

Overactive Bladder / Urge Incontinence

Economic Burden

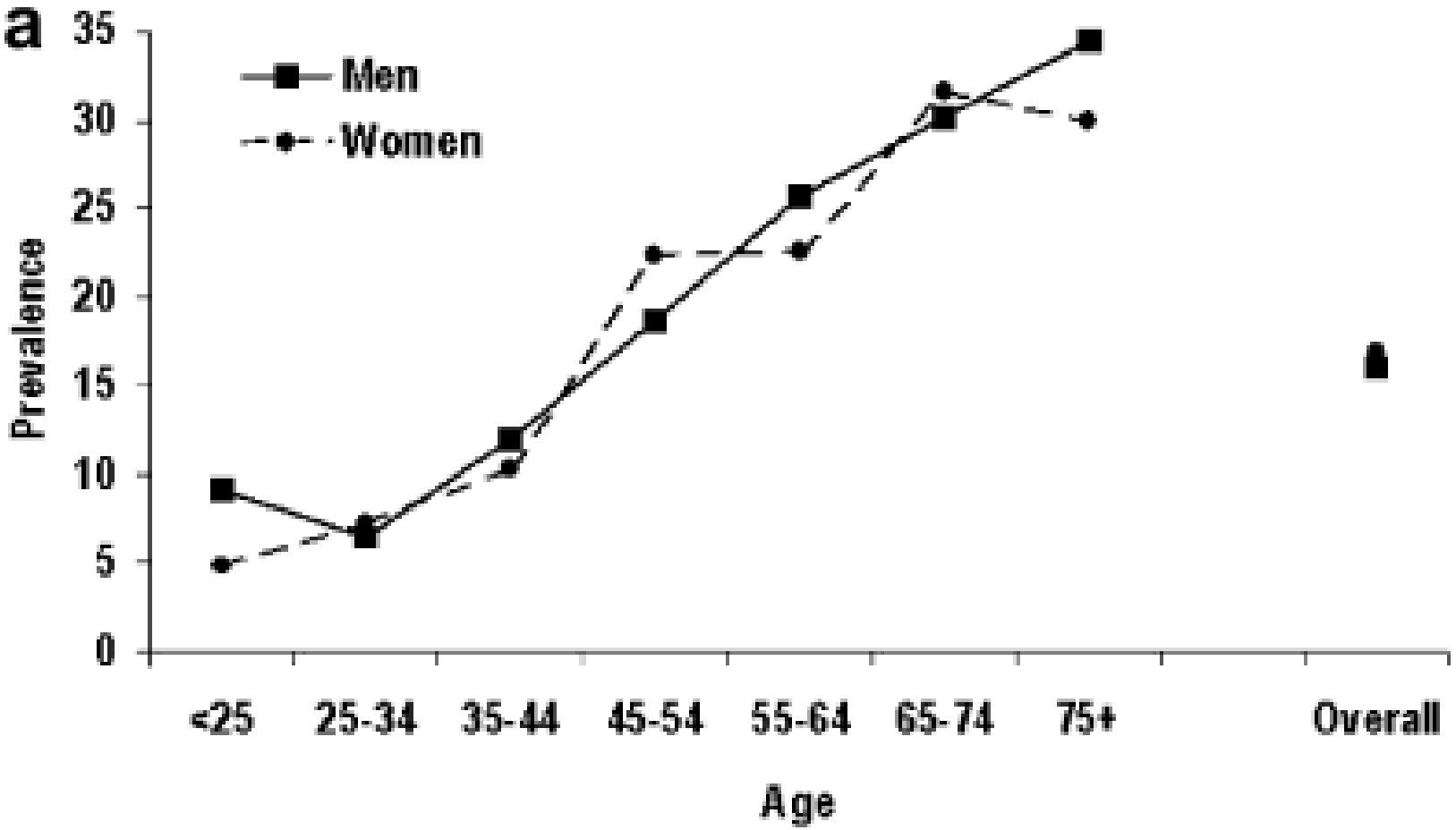
- U.S. National cost of OAB with incontinence
  - 2007: $65.9 billion
  - 2015: $76.2 billion
  - 2020: $82.6 billion
- Perspective:
  - Osteoporosis 2008: $22 billion
  - Breast Cancer 2010: $16.5 billion
  - Colon Cancer 2010: 14.1 billion
  - Lung Cancer 2010: 12.1 billion

Coyne et al., 2014
Blume and Curtis, 2011
NCI: www.cancer.gov

Epidemiology

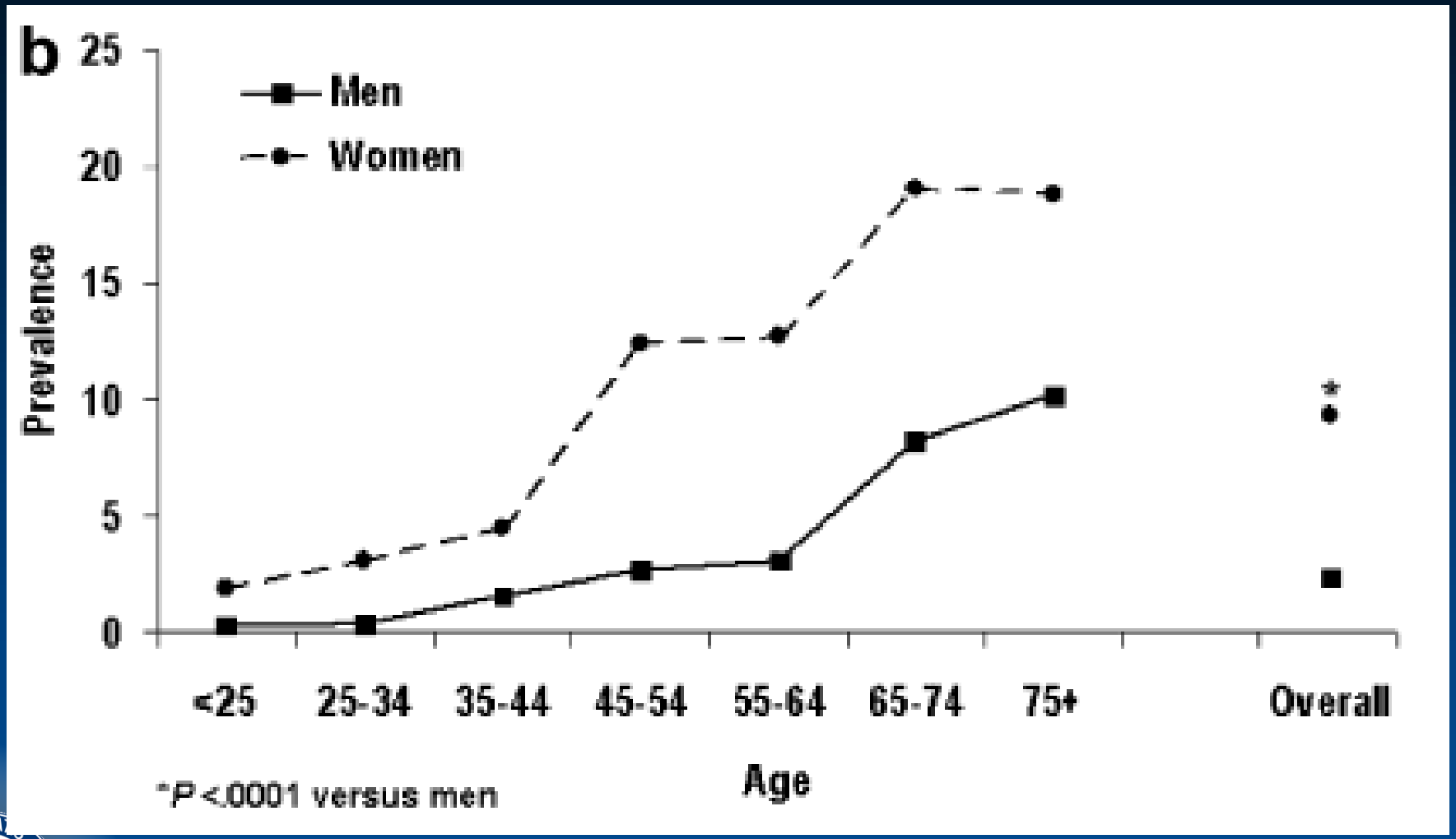
- Age specific OAB prevalence similar in men and women
  - 16% men vs. 16.9% women — Stewart et al, 2003 (NOBLE Study)
  - 11% men vs. 13% women — Irwin et al, 2006 (EPIC Study)
- Prevalence increases with age

Age Specific OAB Prevalence



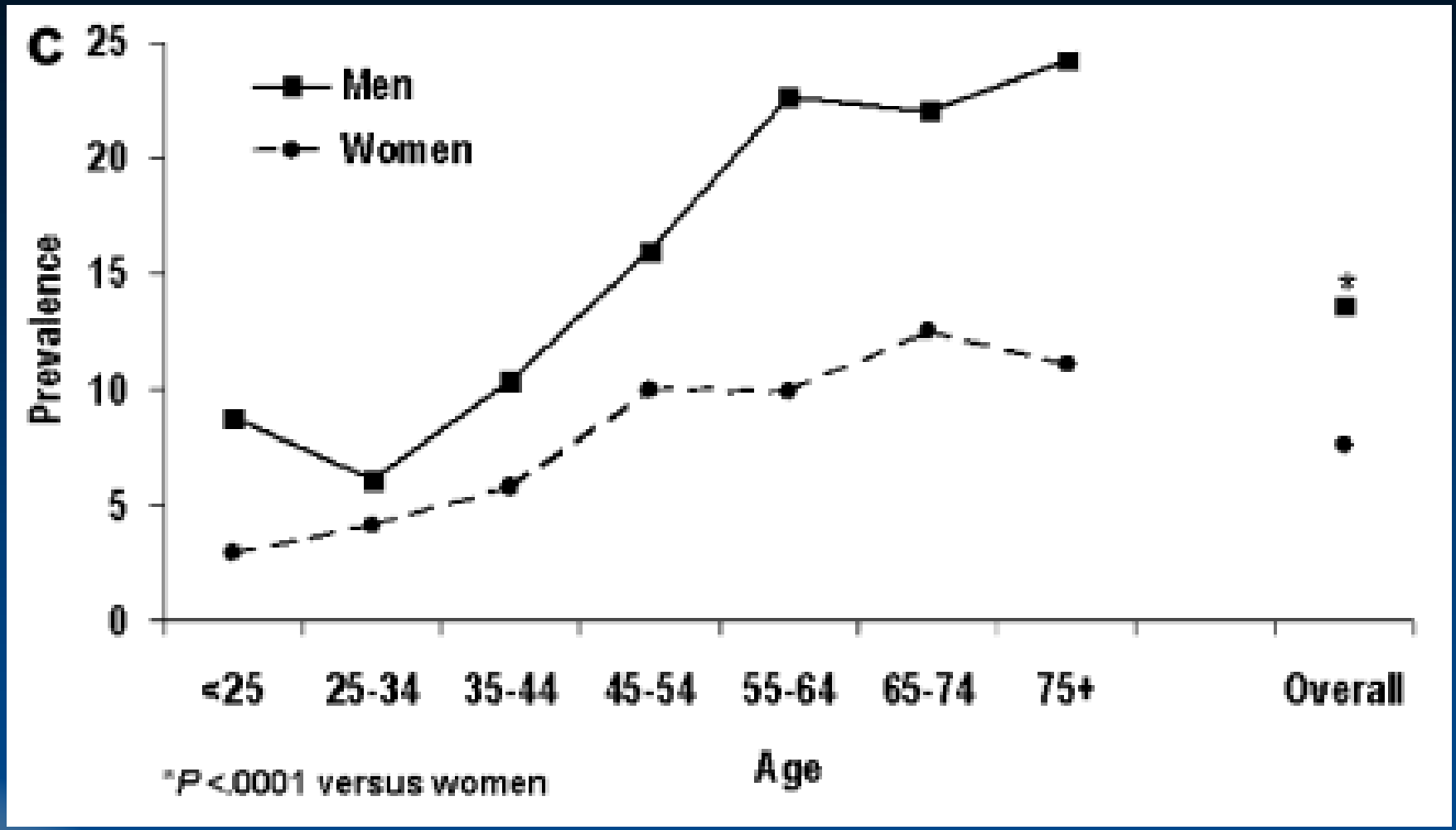
Stewart et al, 2003

Epidemiology: Urge Incontinence



Stewart et al, 2003

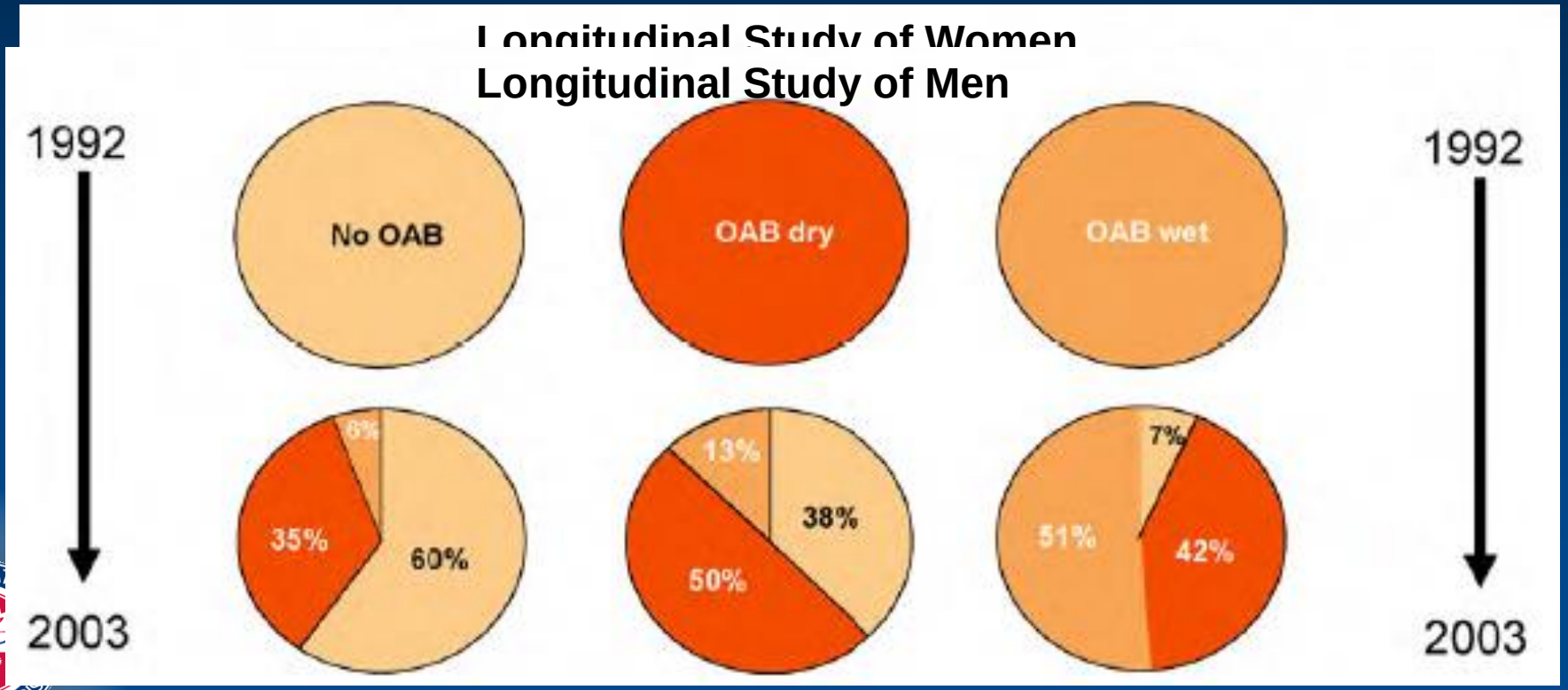
Epidemiology: Dry Urgency



Stewart et al, 2003

Natural History of OAB

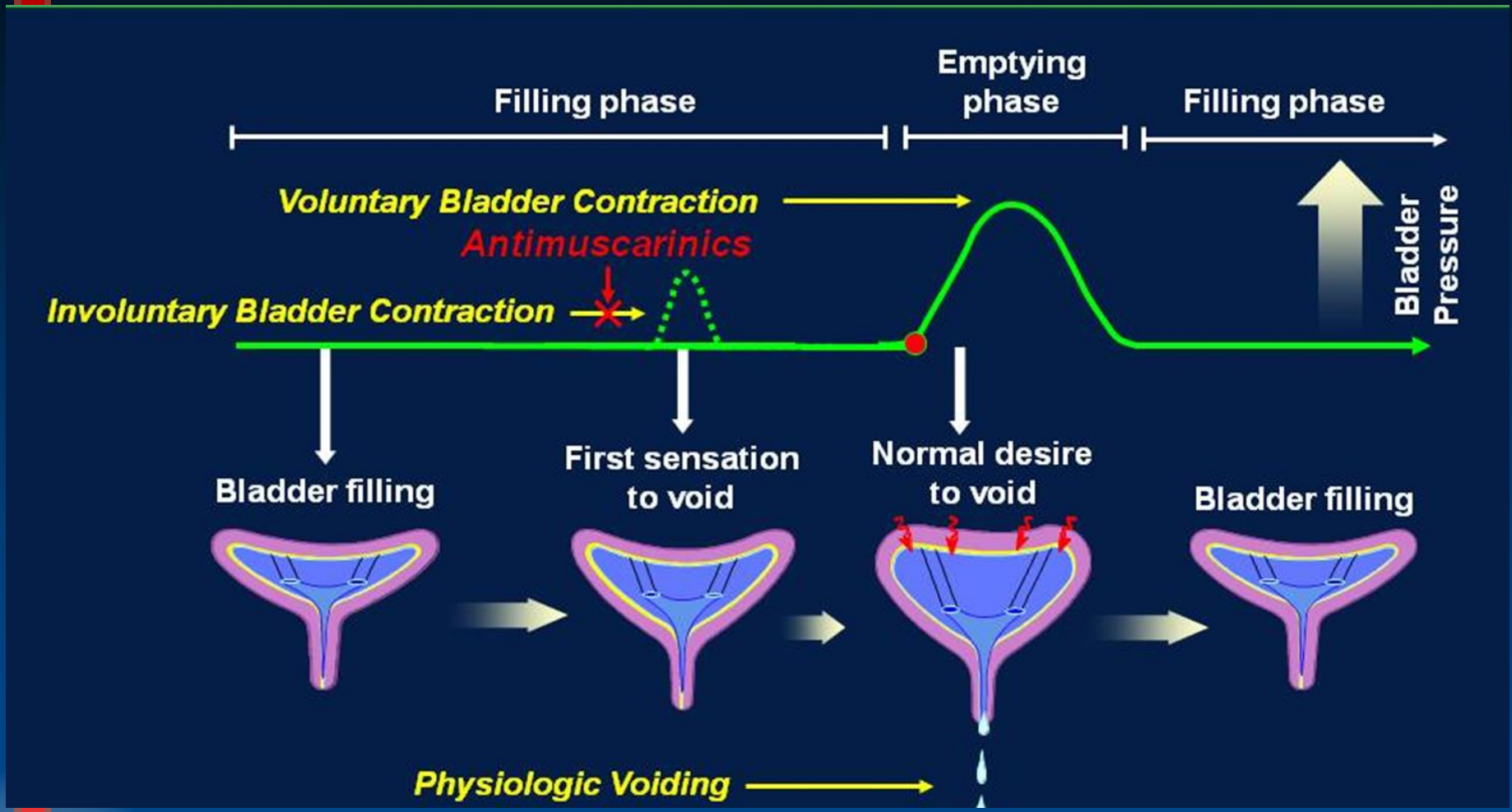
- Comprehensive review of longitudinal studies 1990-2009: Irwin et al, 2010
- OAB tends to be chronic, progressive disease



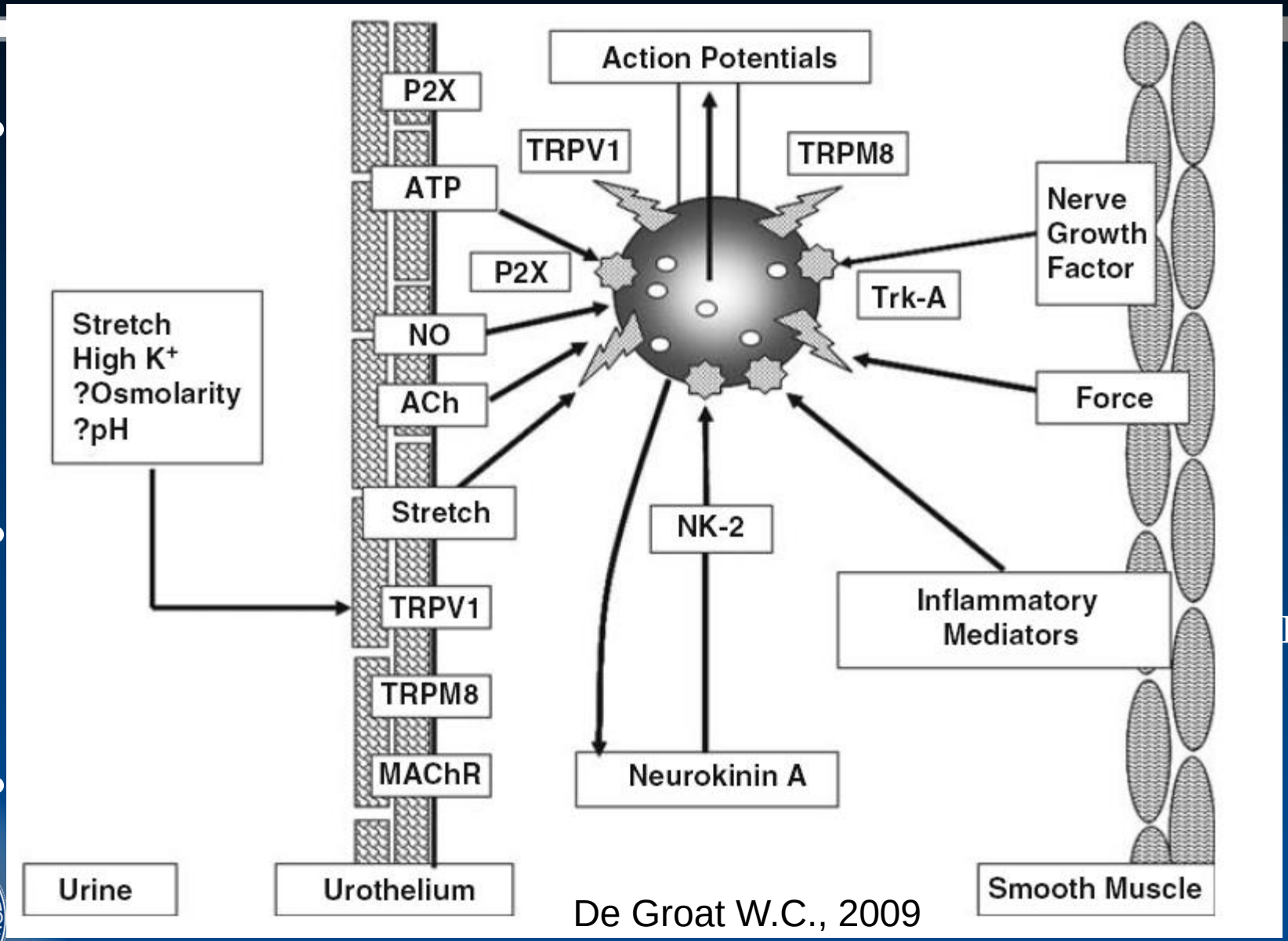
Etiology

- Precise mechanisms of OAB not fully understood
- Especially true for sensation of urgency
  - Subjective human experience
  - Modified by other disease states
  - Difficult to make animal model of “urgency”
- Neurogenic Overactive Bladder
  - Animal models exist

Classical Model of OAB



Urgency: Afferent Pathways



De Groat W.C., 2009

Hypotheses

- Neurogenic Hypothesis
  - Detrusor overactivity arises from generalized, nerve-mediated excitation of detrusor muscle
- Myogenic Hypothesis
  - Increased probability of spontaneous contraction and/or propogation of activity between muscle cells
- Not mutually exclusive

OAB Management

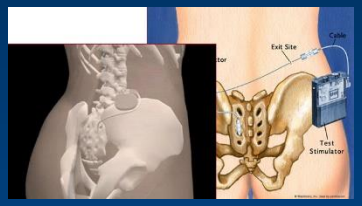
- AUA Guideline: Diagnosis and Treatment of Adult Overactive Bladder
- General guidelines for management of female incontinence
  - International Consultation on Incontinence (ICI)
  - National Institute for Health and Clinical Excellence (NICE), UK
- Helpful evidence-based approach to management

Urge Incontinence

- First Line
  - Behavior / lifestyle changes, kegels

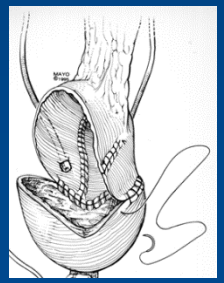
- Second Line
  - Antimuscarinics, Beta-3 agonsits

- Third Line
  - Neuromodulation



  - Intravesical Botox

- Fourth Line
  - Surgery: Augmentation cystoplasty



Management

- Bladder Diary / Frequency Volume Chart
- Principal objective means of evaluating frequency/urgency symptoms
  - Functional bladder capacity
  - Mean voided volumes
  - Voids per day / night
  - Accidents per day / night
- Foundation for starting therapy
- Means of tracking progress (or lack of it)

Conservative Management

- Lifestyle changes and behavior modifications
- Relative paucity of Level 1 evidence
- Considered first line treatment by all modern guidelines panels
- Minimal to no risk for patient with reasonable outcomes
- Grade A recommendation from ICI as first line treatment

Two Basic Types of Therapy

- Habit changes
  - Dietary modifications
  - Timed voiding routine
- Training Techniques
  - Urgency suppression
  - Bladder Training
  - Delayed Voiding
  - Pelvic Floor Muscle Training (PFMT)
    - With or without biofeedback
  - Multicomponent Behavioral Training

Dietary Modification

- Reduction/elimination of caffeine
  - Diuretic, promotes UDC's in vitro
  - Increases urinary frequency / urgency sx's
  - Little Level 1 evidence that improves continence

- Smoking cessation
  - Higher risk of OAB/LUTS in smokers
  - Little data demonstrating cessation improves continence

Payne, 2007
Wyman et al, 2009

Lifestyle Changes

- Weight Reduction
  - BMI positively correlates with SUI and OAB sx
  - BMI > 30 independent risk factor OAB in women
  - Weight loss improves female urge and stress incontinence

Osborn et al, 2013
Subak, 2005
Wyman et al, 2009

- Avoiding Constipation
  - Improves frequency and urgency in elderly

Charach, 2005
Wyman et al, 2009

Fluid Management

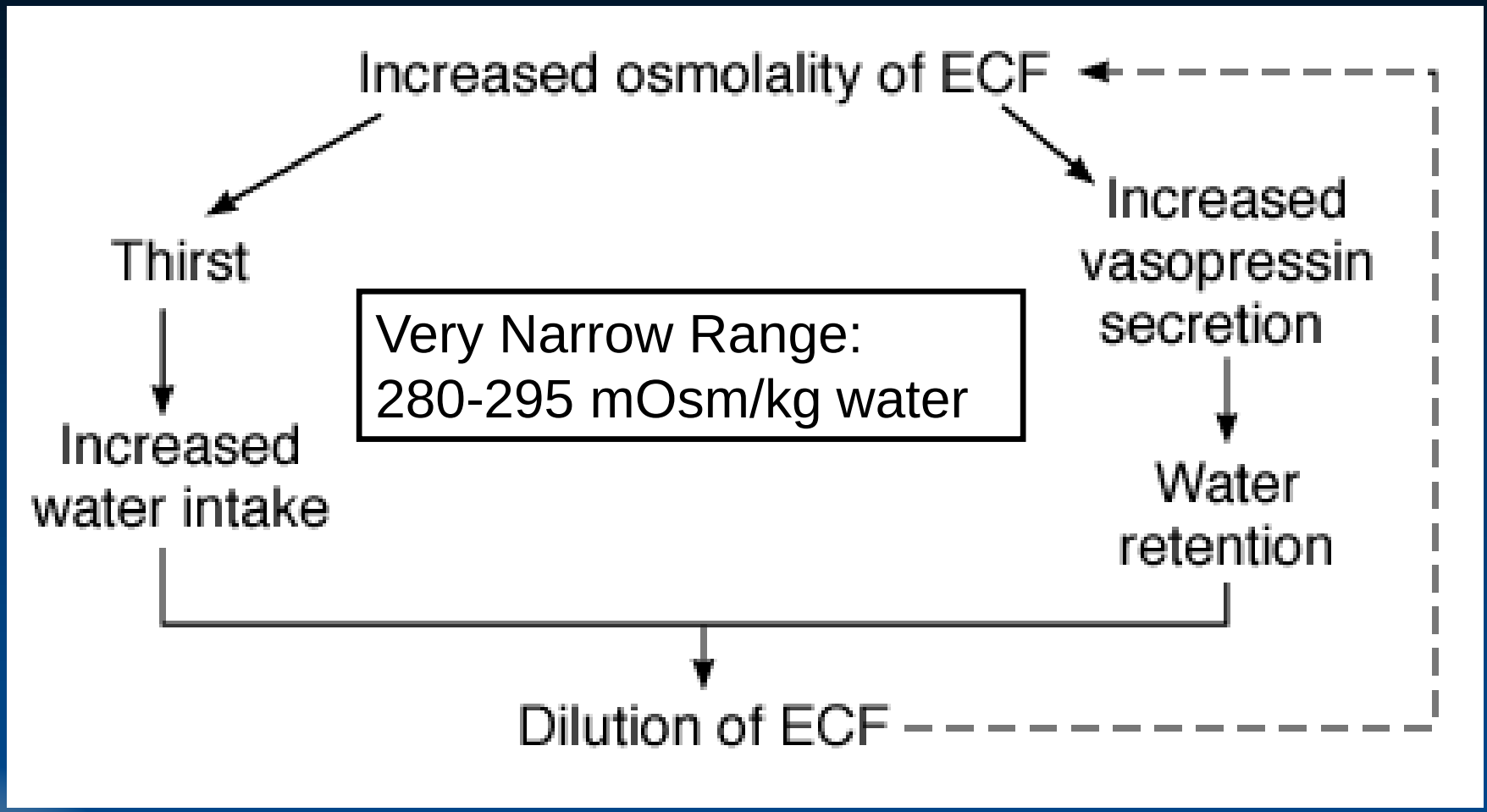
- Excessive fluid intake worsens frequency and urgency symptoms

"8 glasses per day" is a baseless convention, not supported by literature

- "Normal" intake recommended (ICI, NICE)
  - Required intake varies greatly depending upon environment and activity

Panel on Dietary Reference Intakes For Electrolytes and Water, IOM, 2005

Osmoregulation / Homeostasis



Technique	Description	Symptom			
		Frequency	Urgency	UUI	MUI
Habit changes (managing symptoms and promoting bladder health)					
Lifestyle modification	Diet, fluid, bowel and weight management; smoking cessation	X	X	X	X
Timed voiding*	Urination at a fixed interval that avoids the symptom (useful for urgency and UI not associated with frequency)		X	X	X
Training techniques (managing symptoms)					
Urgency control techniques	Deep breathing and using complex mental tasks (reciting poetry, counting backwards from 100 by 7 s etc.) to ignore urgency	X	X	X	X
Bladder training	Progressively increasing interval between voidings; utilises distraction and relaxation techniques to gradually increase the time between urinations	X	X	X	X
Multicomponent behavioural training*	Teaching to not rush to bathroom in response to urgency and use of PFM contractions to suppress bladder contraction and delay voiding, with use of pelvic floor muscle exercises	X	X	X	X
Pelvic floor muscle training	Daily regimen of pelvic floor muscle contractions to maintain or build strength and endurance			X	X
Delayed voiding*	Progressively increasing interval between onset of urgency and voiding	X	X	X	X

Wyman et al, 2009

Pelvic Floor Muscle Training

- PFM strength assessed and taught by provider
  - No consensus or proper protocol
- Weak or poor control of PFM candidates for biofeedback, physical therapy
- Cochrane Meta-analysis Data, 2010
  - Pelvic floor muscle training vs. no treatment
  - Best in 3 months, supervised PFMT
  - Recommended inclusion in first line treatment for stress, urge, or mixed incontinence

Adjunct to Oral Pharmacotherapy

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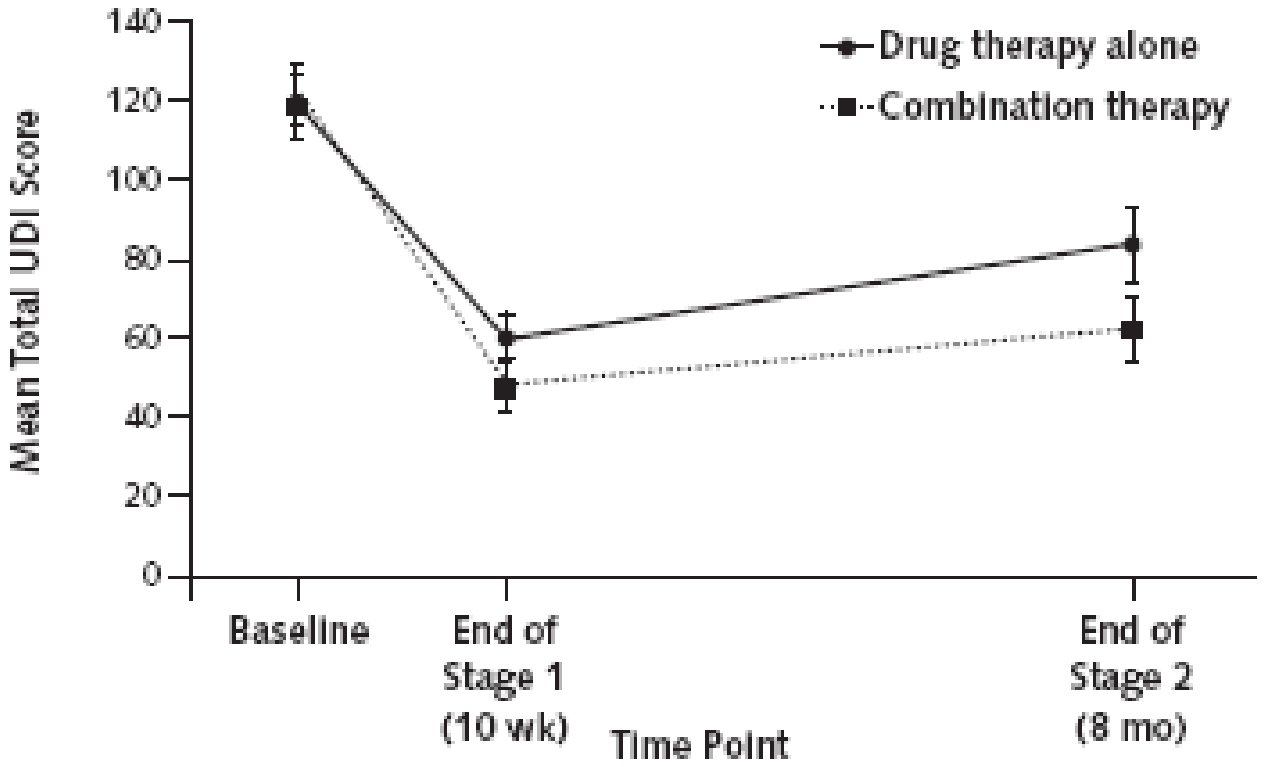
Figure 2. **Adjusted mean total Urogenital Distress Inventory (*UDI*) scores over time.**



Burgio KL et al. *Ann Intern Med.* 2008, 149: 161-9.

008, 149:

: 2599-2607.
006, 21:

2000, 48:

Mattiason et al., *BJU Int.* 2003, 91: 54- 60.

Drug Classes Used in OAB

- Antimuscarinics
- Membrane Channel Agents
- Antidepressants
- Alpha-Blockers
- Beta-3 Agonists
- PDE-5 Inhibitors
- COX Inhibitors
- Toxins
  - Botulinum Toxin
  - Vanilloids
- Hormones
  - Estrogen
  - Desmopressin

Antimuscarinics

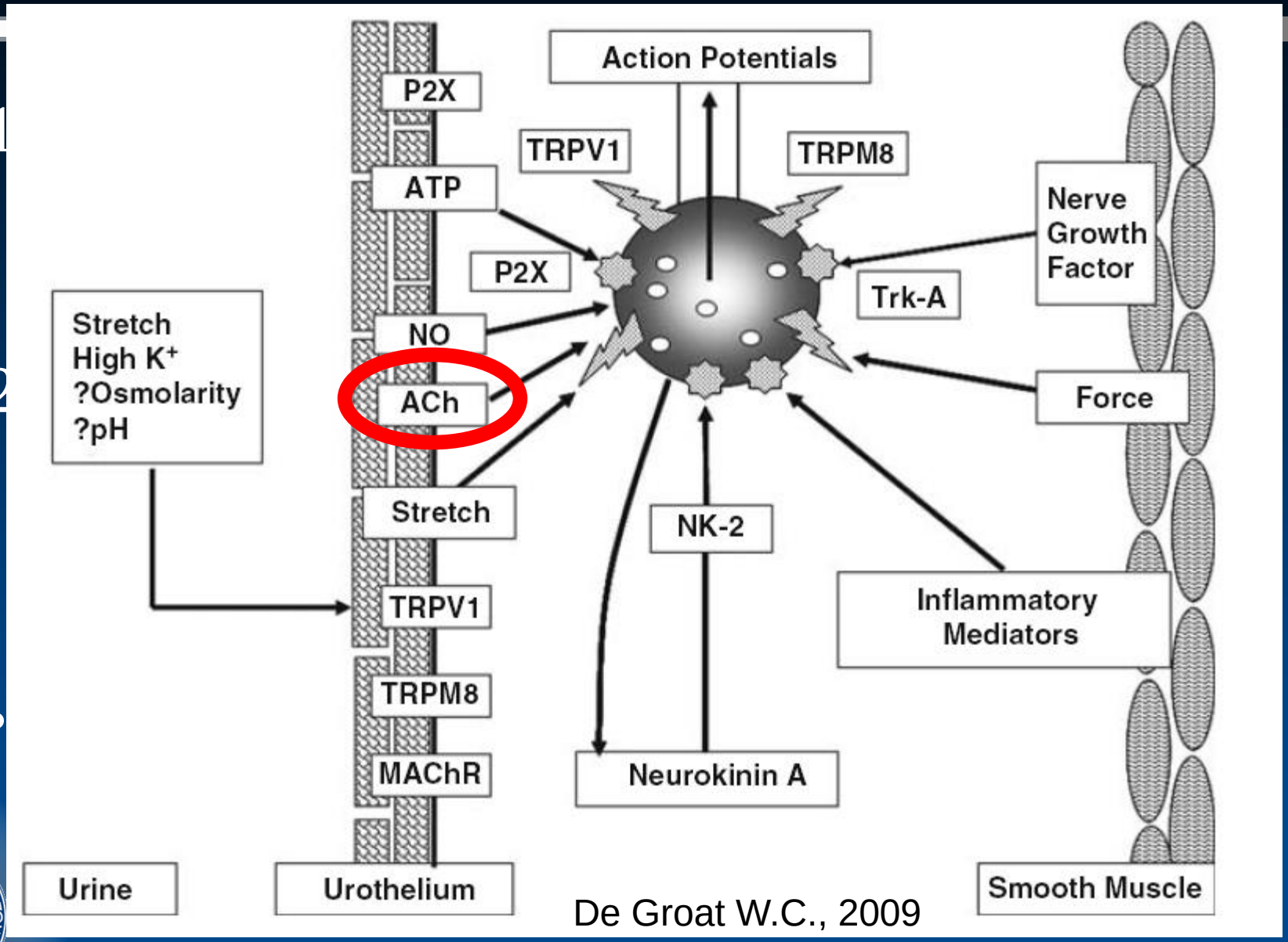
- Antimuscarinics mainstay of medical therapy, Grade A recommendation from ICI, 2008
- Compounds approved in U.S.:

Antimscarinic	Delivery	Dosing
Oxybutynin IR / ER	Oral	BID-TID / QD
Oxybutynin Patch	Transdermal	BIW
Oxybutynin Gel	Transdermal	QD
Tolterodine IR / ER	Oral	BID / QD
Fesoterodine	Oral	QD
Trospium IR / ER	Oral	BID / QD
Darafenacin	Oral	QD
Solafenacin	Oral	QD

Mechanism of Action

- *Competitive* antagonist of muscarinic acetylcholine receptor
- Reduce detrusor contractility during storage phase of micturition
  - Parasympathetic (voiding) nerves are quiescent
  - Massive release of Ach during voiding able to overcome competitive action drug (except at very high dosages)

Mechanism of Action



De Groat W.C., 2009

Muscarinic Receptors

- Bladder contains M1, M2, M3 receptors
  - M3 mediate detrusor contraction
  - M2 greatly outnumber M3 receptors
    - M2 likely also facilitate bladder contraction
- No evidence that M3 selectivity beneficial
  - Darifenacin most M3-selective

Properties

- Tertiary Amines
  - Oxybutynin, tolterodine, fesoterodine, solafenacin, darafenacin
  - Lipophilic: cross blood-brain barrier
  - Well absorbed from GI tract
- Quaternary Ammonium (Trospium)
  - Limited entry into CNS
  - Low CNS side effects
  - Not as well absorbed

Antimuscarinic Effects

- Compared to Placebo:
- Reduced daily urgency and UUI episodes
- Reduced voids per day
- Increased daily voided volumes
- Increased number of patients returning to total continence
- Improve patient-reported HRQoL

Chapple et al, 2008

Adverse Events Greater than Placebo

Event	Treatment %	Placebo %
Any Adverse Event	53.4	39.9
Any Dry Mouth	29.6	7.6
Pruritis	15.4	5.2
Constipation	7.7	3.9
Erythema	6.9	2.0
Headache	5.9	4.9
UTI	5.0	3.6
Dyspepsia	4.7	2.1
Blurred vision	3.8	2.6
Dizzyness	3.5	2.5
Somnolence	3.1	1.9
Sweating	1.8	0.0
Fatigue	1.6	0.6
Urinary Retention	1.1	0.2

Which Antimuscarinic to Use?

- No firm data demonstrating consistent superiority of one agent over another
- Other factors should guide therapy:
  - Side effects, cost, ease of administration
  - Individualized treatment
- NICE Guidelines, 1996:
  - First line: generic oxybutynin IR
  - Select alternative agent if side effects poorly tolerated

Which Antimuscarinic?

- Review of RCTs:
- Oxybutynin IR highest RR for withdrawal and adverse events
- ER formulations favored over IR
  - Fewer side effects, same or better efficiacy
- Oral vs. Transdermal (patch)
  - Transdermal = less dry mouth, constipation
  - Transdermal = skin site reactions, withdrawal

Chapple et al, 2008

Other AUA Recommendations

- Poor symptom control or side effects:
  - Modify dose
  - Alternative agent
    - Alternative antimuscarinic
    - Beta-3 agonist
- Manage constipation or dry mouth before abandoning antimuscarinic therapy

AUA/SUFU OAB Guideline, 2012

Other AUA Recommendations

- Antimuscarinic cautions:
  - Contraindicated in narrow-angle glaucoma
  - Other medications with anti-cholinergic properties
  - Frail, elderly patients
- Refer patients uncontrolled on medical / behavioral management for third line options.

AUA/SUFU OAB Guideline, 2012

Mirabegron: Beta-3 Agonist

- Binds bladder beta-3 receptors resulting in relaxation of detrusor
- Once daily dosing
  - 25mg and 50 mg doses approved in U.S.
- Multiple RCTs demonstrate vs. placebo
  - >50% reduction in incontinent episodes
  - Reduction in urinary frequency (8x/24h)
  - 12 week endpoints

Chapple et al, 2014

Mirabegron Adverse Events

- Pooled RCT data:
  - Dry mouth, constipation same a placebo
  - Most common reasons for discontinuation of antimuscarinics
- Most common AEs:
  - Hypertension (7.3%)
  - Nasopharyngitis (3.4%)
  - UTI (3.0%)

Chapple et al, 2014

Intravesical Botulinum Toxin (BTX)

- Neurotoxin protein produced by C. botulinum
  - Most potent neurotoxin known
- Blocks acetylcholine release at both somatic and autonomic nerve terminals
  - Prevents fusion of Ach-containing vesicles with neuronal cell membrane = blocks transmission

Mechanism: Botox-A

- Muscle is partially denervated until new innervation occurs (block efferents)
  - Long duration of action
- Mechanism probably more complex
  - Release of *urothelial* neurotransmitters blocked (acetylcholine, substance P, ATP)
  - Possibly blocks afferent pathways involved in OAB (peripheral afferent desensitization)

Urodynamic Effects of BTX-A

- Increased bladder capacity
- Increased bladder compliance
- Reduced maximum detrusor pressure during bladder contraction
- Reduced maximum urinary flow rate
- Increased PVR

Schurch et al, 2005
Sahai et al, 2009

Efficacy of Intravesical Botox

- RCT's idiopathic OAB:
- Significant reduction daily UI
- Significant reduction in voids per day
- Significant improvement in patient-reported QoL (UDI-6/UDI)
- RCT Objective outcomes:
  - Increased mean bladder capacity
  - Increased volume per void
  - (more robust to placebo effects)

Anger et al, 2010
Chapple, 2014

Urinary Retention Risk

	Idiopathic OAB (100U)	Neurogenic OAB (200U)
CIC (%)	6.5%	30.6%
Median duration (Days)	63 days	289 days

Must be willing/able to CIC to be considered for intravesical botox

Overall Adverse Events (100U)

Adverse Event	Percentage (N=552)
UTI	18%
Dysuria	9%
Urinary Retention	6%
Bacteriuria	4%
Elevated PVR	3%

Botox Pkg Ins

Botox Adverse Events

- Generalized Weakness (Rare)
  - Systemic dissemination (“flaccid paralysis”)
  - Swallowing, breathing problems reported
- Allergic Reaction (Rare)
  - Tachyphylaxis has been reported
- Resistance to treatment
  - 30% antibody-mediated
  - Use lowest dose, wait at least 3 months
- Caution in patients:
  - Dysfunction of neuromuscular junction

Leong et al, 2010

Long Term Follow-Up

- Need for repeated injection

Authors	Duration of Improvement	Interval Between Injections
Sahai et al	6 months	--
Brubaker et al	26 months	--
Kalsi et al	14 months	1.9 years
Khan et al		14 months
Schmid et al	9 months	13.5 months

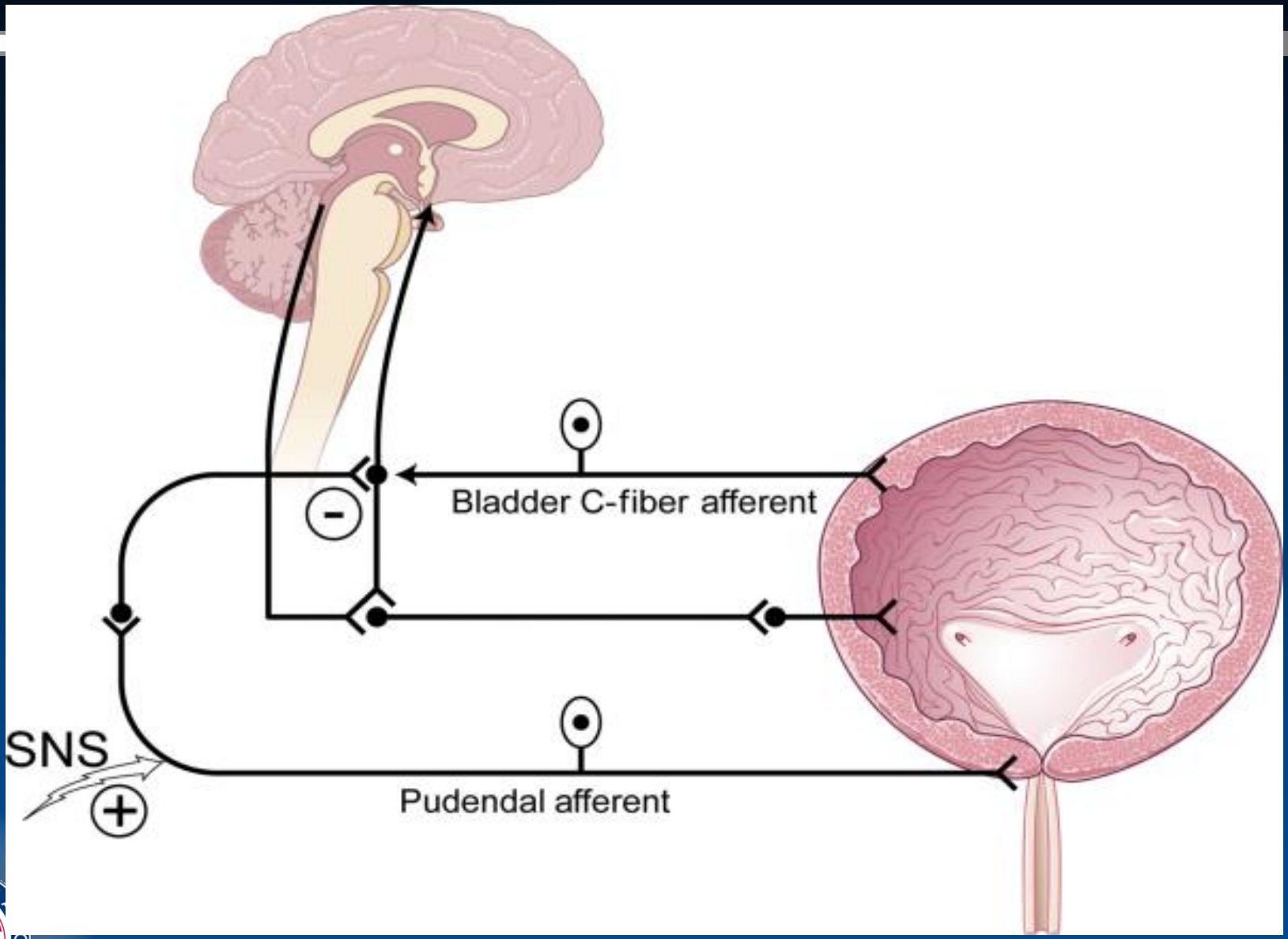
FDA Approved Urologic Uses

- Neurogenic detrusor overactivity
  - Dose 200U
- Idiopathic OAB
  - Dose 100U
- Long term efficacy and side effects
- Events associated with repeated administration

Sacral Neuromodulation

- FDA-Approved Therapy for
  - Urge Urinary Incontinence
  - Urgency-Frequency Syndrome
  - Non-obstructive Urinary Retention
- Reserved for patients refractory to behavior modification and medical therapy
  - Or unable to tolerate
- MRI contraindicated

Sacral Neuromodulation



Leng and Chancellor, 2005

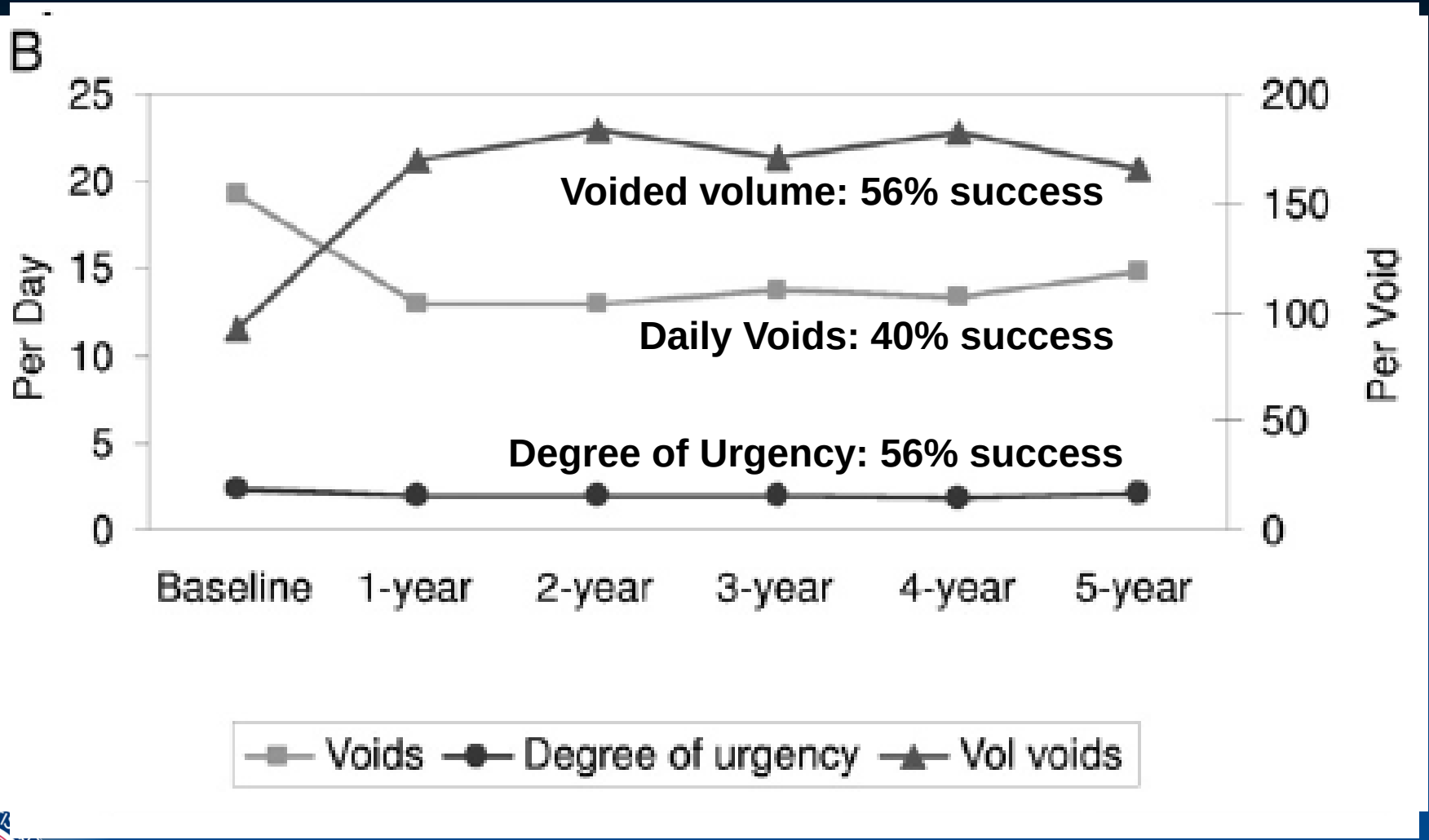
Clinical Efficacy

- Urge Incontinence (Schmidt et al, 1999):
- 73% reduction incontinence / 24h
- 82% reduction number pads / 24h
- Sustained effect at 18mo follow-up

Clinical Efficacy

- Urgency/Frequency (Hassouna et al, 2000):
  - 46% reduction in number voids / 24h
  - 92% increase in voided volumes
  - 27% reduction in degree of urgency
  - Sustained effect at 2 years post implant

Efficacy is Maintained Over Time



InSite Trial

- RCT Sacral Neuromodulation vs. Medication
  - 147 subjects randomized
  - All failed at least 1 medication, but not all
- Success = >50% reduction in symptoms

	Neuromodulation	Medical Treatment
Overall OAB Response	76%	49%
Urge Incontinence	71%	47%
Urinary Frequency	61%	37%

Seigel et al, 2014

InSite Trial

- Implication:
- Patients refractory to antimuscarinics may benefit more from neuromodulation than continued medical therapy

Problem: Adverse Events/Revisions

- Adverse events are common
- Significant differences in reporting

Problem	% Adverse Events
Pain at Implant Site	3-42%
Other Device-related Pain	3-43%
Lead Migration	1-21%
Bowel Dysfunction	4-7%
Infection	4-10%

Adapted from Leong et al, 2010

Revision

- At 1.5-3y follow-up (Seigel, 2000):
  - 33% of implanted devices required surgical revision to resolve adverse event
  - 10.5% explanted for lack of efficacy
- At 5y follow-up (van Kerrebroeck et al, 2007)
  - 39.5% revised to resolve adverse event
  - 6% explanted for lack of efficacy or adverse event

Tibial Nerve Stimulation

- Less invasive form of neuromodulation
  - Needle placed into SP6 accupuncture point
  - 12 weekly 30 minute sessions
  - Maintenance therapy for responders
- 60-81% positive response rate across all trials
- Only 1 sham-controlled RCT Peters et al, 2010
  - 54% improved vs. 21% sham control
- Objective outcome similar to tolterodine ER Peters et al, 2009
- Durability over 12mo in 1 study MacDiarmid et al, 2010

Augmentation Cystoplasty

- Poor compliance and refactory DO
  - Neurogenic vs. non-neurogenic
- Excellent outcomes
  - 93% dry rate in non-neurogenic patients
- CIC required in 39% non-neurogenic patients
  - Stoma vs. no stoma must be discussed preop

Reyblat and Ginsberg, 2010

Augmentation Cystoplasty: Complications

- Potential metabolic/electrolyte complications
  - Common source of exam questions
- Potential CRF
  - Assess baseline creatinine
- UTI: 4-46%
- Stones: 10-33%
- Perforation: 6-9%
- Carcinoma: very low risk

Reyblat and Ginsberg, 2010

Question

- 56 yo female on oxybutynin IR 5mg 3x per day. She reports resolution of incontinence, but is skipping doses due to constipation. Which intervention is *NOT* recommended:
  - A. Reduce dose of oxybutynin
  - B. Trial of neuromodulation
  - C. Administer a stool softener
  - D. Change to extended release oxybutynin
  - E. Try an alternative antimuscarinic

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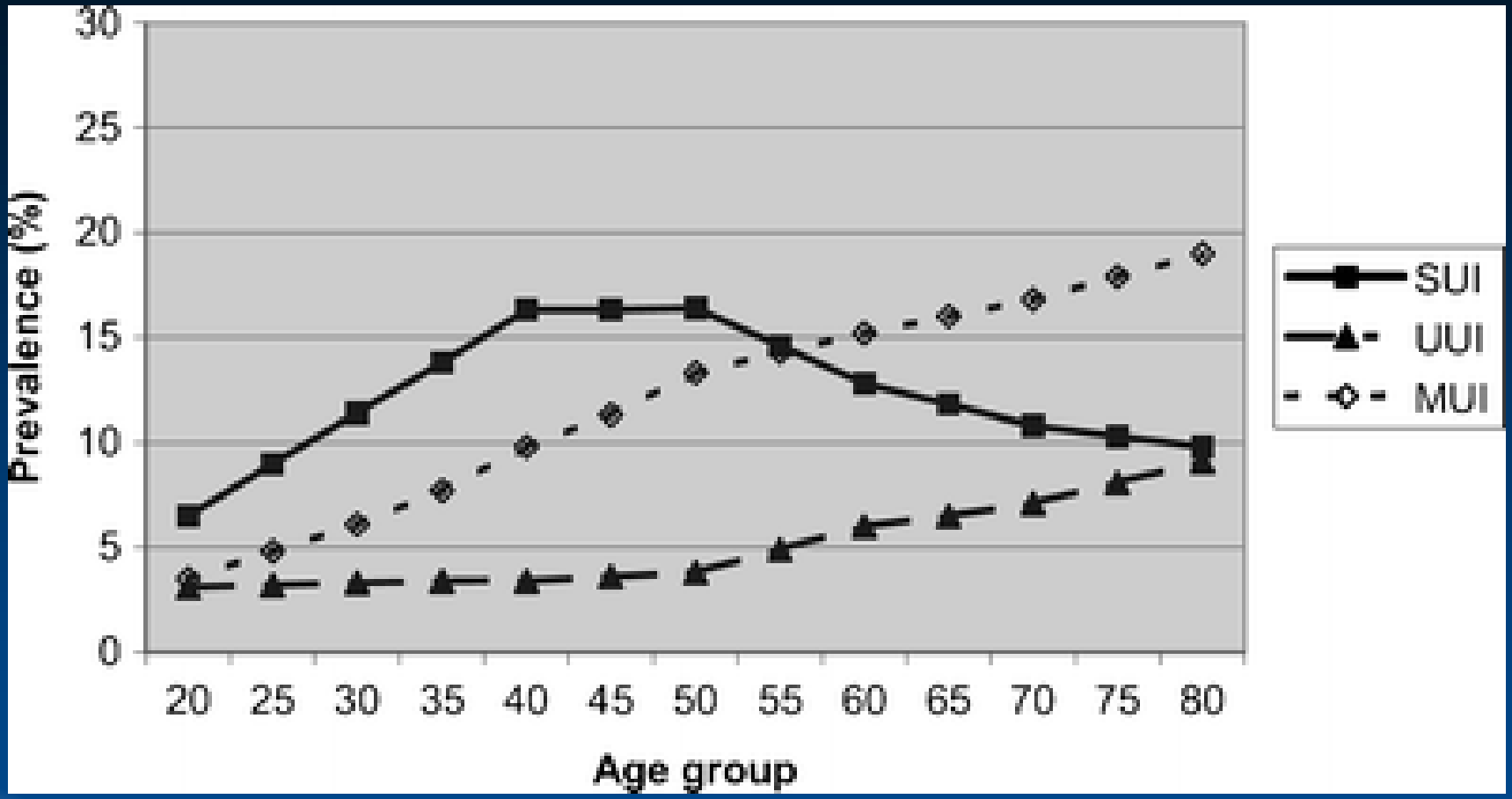
Stress Incontinence

Stress Incontinence

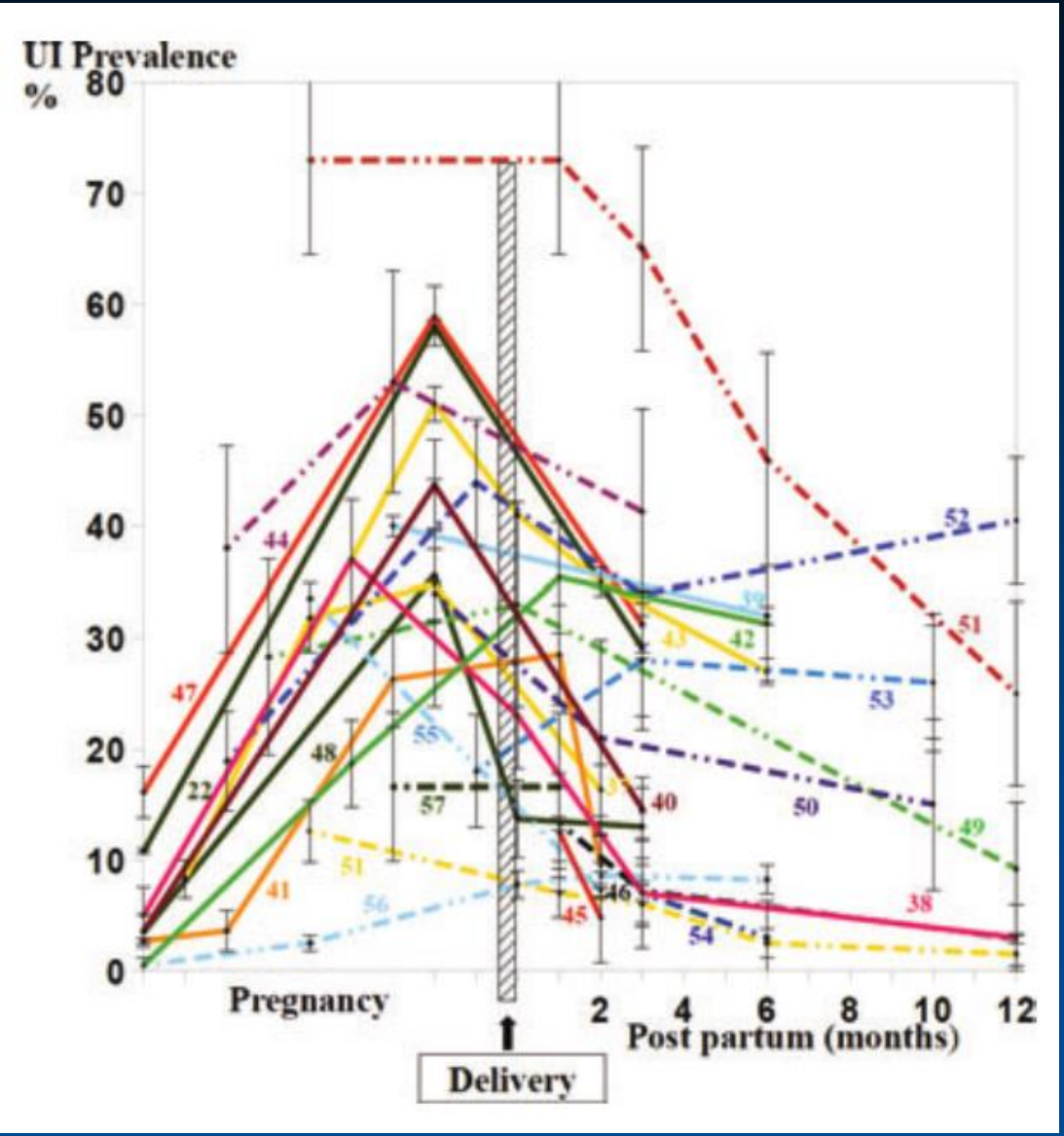
- Estimated total U.S. cost $13.2 billion
  - 70% routine care (MD visits, buying pads)
  - 14% nursing home admission
  - 9% treatment
  - 6% complications
  - 1% diagnosis

Chong et al., 2011

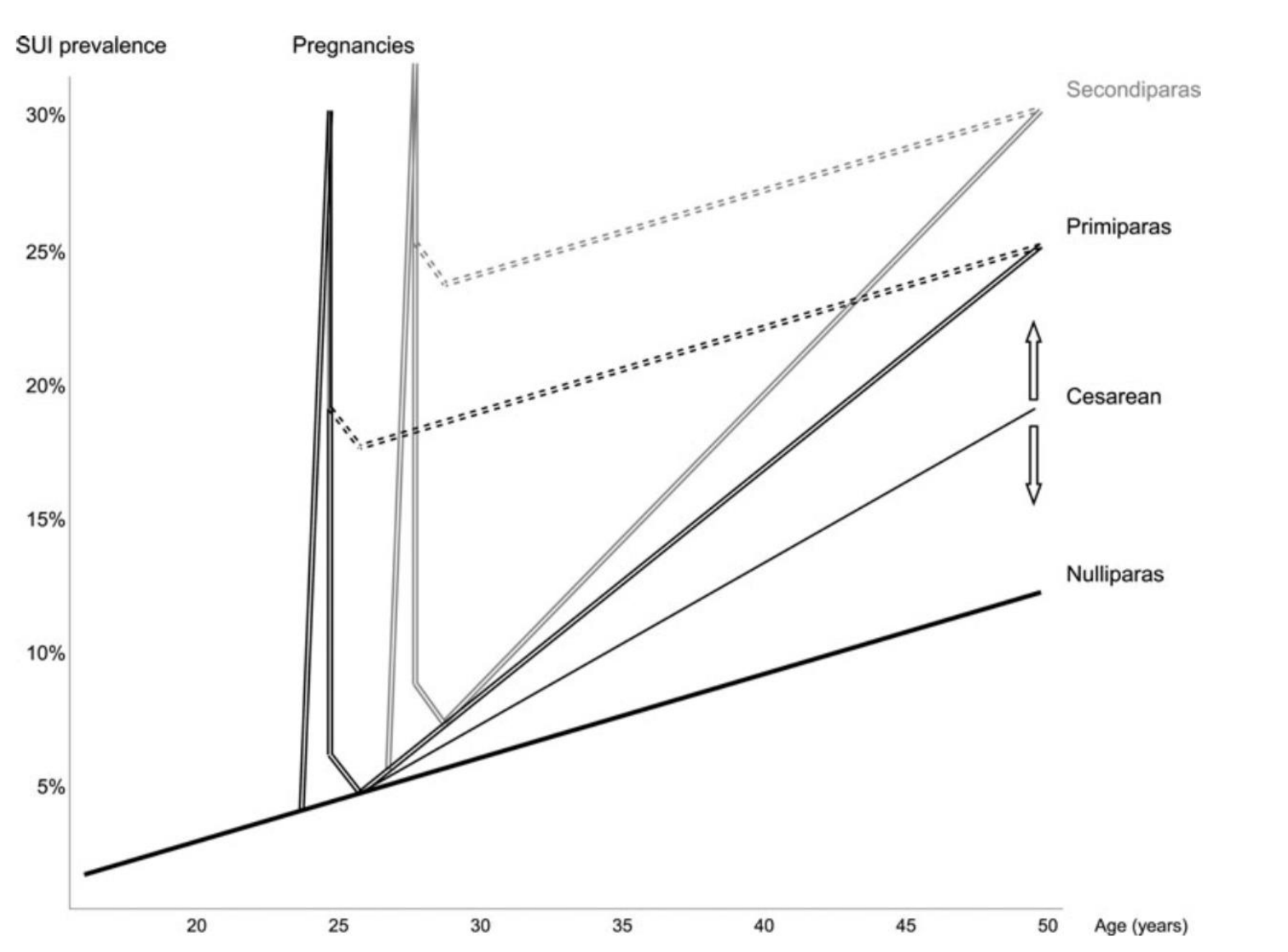
Epidemiology: Stress Incontinence



Prevalence Increases in Pregnancy



Conceptual Model



Etiology: Risk Factors

- Age
- Vaginal Delivery
- Parity
- Family History (i.e. genetics)
- Obesity / BMI
- Diabetes
- HRT
- Surgery / Hysterectomy

Etiology

- Primary zone of continence in men and women is urethral sphincter
  - Mid-urethra in females
  - Membranous urethra in males
- Stress incontinence caused by incompetence of the urethral sphincter
- Leakage across sphincter when bladder / abdominal pressure greater than pressure exerted by urethra.

Stress Incontinence Treatment

1. Behavior Modification
   - Pelvic Floor ("Kegel") Exercises
   - Increase tone of pelvic floor and external urethral sphincter
   - Non-invasive treatment for both male and female stress incontinence
   - Useful for all forms of urethral incontinence
- No FDA-approved medication
- Primarily surgical disease

Male and Female SUI Treatment

- First Line
  - Kegels
- Second Line

Female	Male
Urethral sling	Artificial Sphincter
Urethral bulking	Male Urethral Sling

Summary

- OAB and SUI highly prevalent diseases
- Significant healthcare cost
- Expected to increase over next decade
- Patients commonly do not seek care
  - PCP must screen
- Within scope of the PCPs
  - Guidelines in place

Summary

- Establish pattern of incontinence
  - Good H&P, +/- PVR, U/A if applicable
- Initial trial of therapy
  - Behavior / lifestyle
  - Kegels
- Add medical management (OAB)
  - Antimuscarinic, beta-3 agonist
- Refer failures to Female Pelvic Medicine and Reconstructive Surgery (FPMRS) specialist

Thank You!

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