Female Urinary Incontinence

Courtenay Moore, MD
Associate Professor - Clinical
Department of Urology
The Ohio State University Wexner Medical Center

MedNet21
Center for Continuing Medical Education

The Ohio State University
Wexner Medical Center

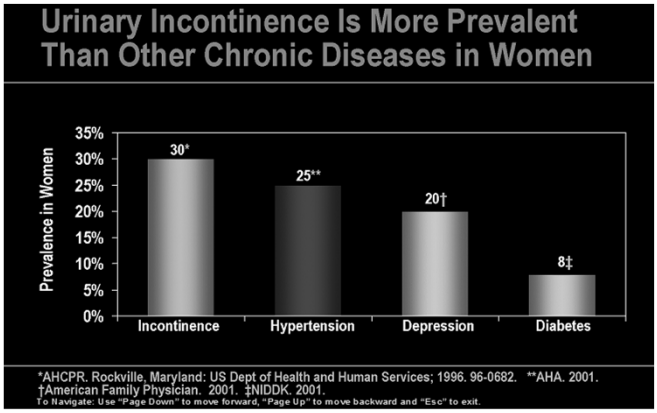
Objectives

- Differentiate the types of female urinary incontinence
- Evaluate, diagnose and treat female urinary incontinence

Female Urinary Incontinence (UI)

- Any involuntary leakage of urine
- Stress urinary incontinence (SUI)
  - Involuntary loss of urine associated with provocative maneuvers- coughing, laughing, sneezing, listing, exercise
- Urinary urgency incontinence (UUI)
  - Involuntary loss of urine associated with urgency
- Mixed urinary incontinence (MUI)
  - Both SUI & UUI

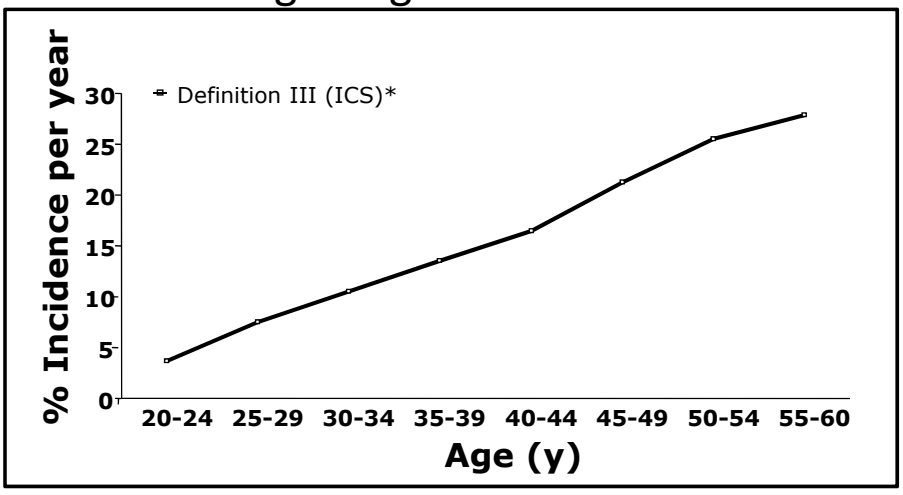
- Female UI is a highly prevalent condition affecting 50% of women
- Only 25% seek care and <50% of those that do receive treatment



- Population-based studies have reported that UI is more common in women than men
- Prevalence increases with increasing age
- Older women with UI are 1.5-2.3 times more likely to experience falls leading to increased mortality, morbidity and health care dollars

Lucacz et al. Jama 2017;318:1592-1604.

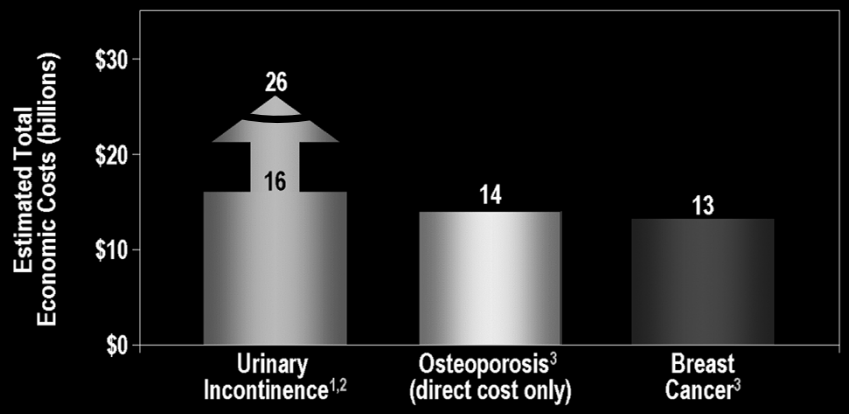
Cumulative Incidence of Incontinence in Women According to Age and Definition of UI



Per International Continence Society; requires objective demonstrability and presence of hygienic or social problem for uncontrolled loss of urine to be acknowledged as UI.

Elving LB et al. *Scand J Urol Nephrol.* 1989;125(suppl):37-43.

Urinary Incontinence Expenditures Are Greater Than Other Women's Health Conditions

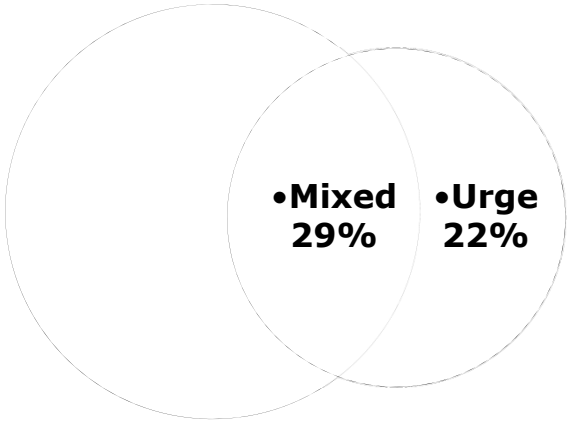


1.Wilson L, et al. *Obstet Gynecol.* 2001;98(3):398-406.
2.Wagner TH, Hu TW. *Urology.* 1998;51(3):355-361.
3.NIH. Electronic citation; 2000.

To Navigate: Use "Page Down" to move forward, "Page Up" to move backward and "Esc" to exit.

- According the U.S. National Health and Nutrition Examination Survey (NHANES) 49.6% of **women reported any UI with:**
  - 49.8% reporting pure SUI
  - 34.4% reporting mixed UI (MUI)
  - 15.9% reporting pure urgency UI (UUI

Stress Urinary Incontinence Is the Most Common Type in Women



•Adapted from: Hampel C et al. *Urology.* 1997;50(suppl 6A):4-14.

Prevalence of UI in Women

Stress

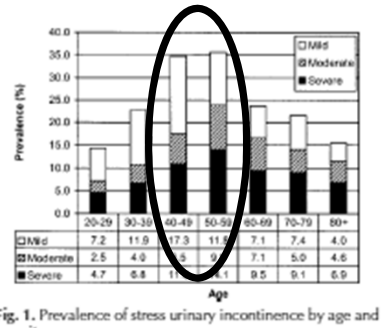


Fig. 1. Prevalence of stress urinary incontinence by age and severity.

Minassian. Urinary Incontinence In Women. Obstet Gynecol 2008.

Urge

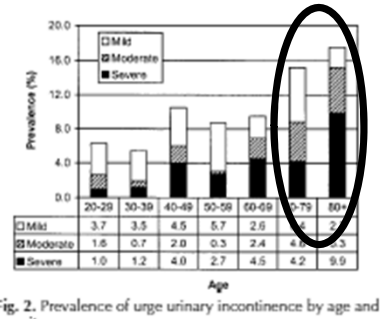


Fig. 2. Prevalence of urge urinary incontinence by age and severity.

Minassian. Urinary Incontinence in Women. Obstet Gynecol 2008.

Differential Diagnosis: Overactive Bladder, Stress Incontinence, and Mixed Symptoms

Medical History and Physical Examination

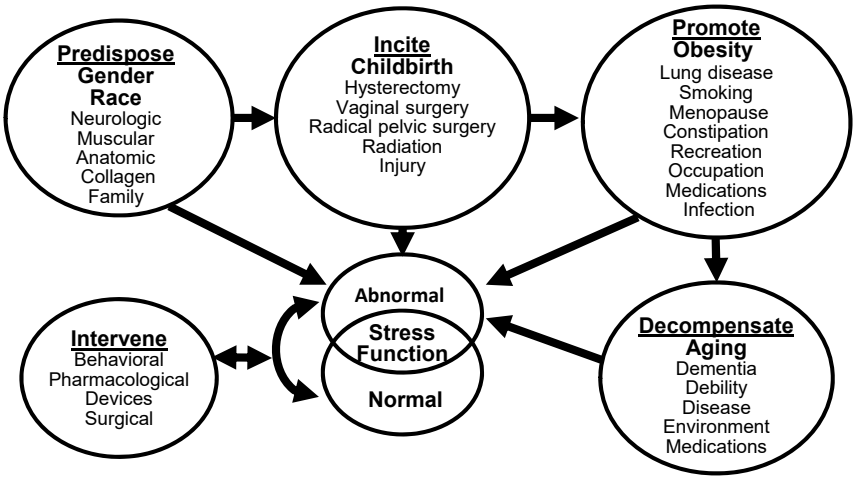
⇩

Symptom Assessment

Symptoms	Overactive bladder	Stress incontinence	Mixed symptoms
Urgency (strong, sudden desire to void)	Yes	No	Yes
Frequency with urgency (>8 times/24 h)	Yes	No	Yes
Leaking during physical activity, eg, coughing, sneezing, lifting, etc.	No	Yes	Yes
Amount of urinary leakage with each episode of incontinence	Large (if present)	Small	Variable
Ability to reach the toilet in time following an urge to void	Often no	Yes	Variable
Waking to pass urine at night	Usually	Seldom	Maybe

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

Risk Factors for SUI



Bump RC and Norton PA. *Obstet Gynecol Clin North Am.* 1998;25(4):723-746.

SUI

- Peak incidence 45-49 years
- Risk Factors
  - White race
  - Obesity
    - BMI >30 have twice the risk, independent of age and parity
  - Pregnancy
  - Childbirth
  - Parity

Evaluation

- History
  - Focused History
    - Elicit symptoms
    - Duration of symptoms
    - Severity- does it require pads, diapers
    - Associated factors- hematuria, dysuria, pain, straining, post void dribbling, UTIs
    - Past Medical History
      - Neurological conditions- MS, DM, CVA, Parkinson's, SCI
      - GU trauma
      - Previous or current XRT
    - Past OBGYN history
      - Gravity, parity
      - Estrogen status- pre, peri, post-menopausal
    - Past Surgical History
      - Previous anti-incontinence or POP surgery
      - Previous GU surgeries
      - APR, radical hysterectomy
    - Medications

PE

– *Focused PE*

- GU examination
  - » Estrogen status
  - » Pelvic Organ Prolapse
    - Pelvic Organ Quantification System

– Urethra

- » Supine cough stress test- involuntary leakage from the urethra with valsalva or cough

Testing

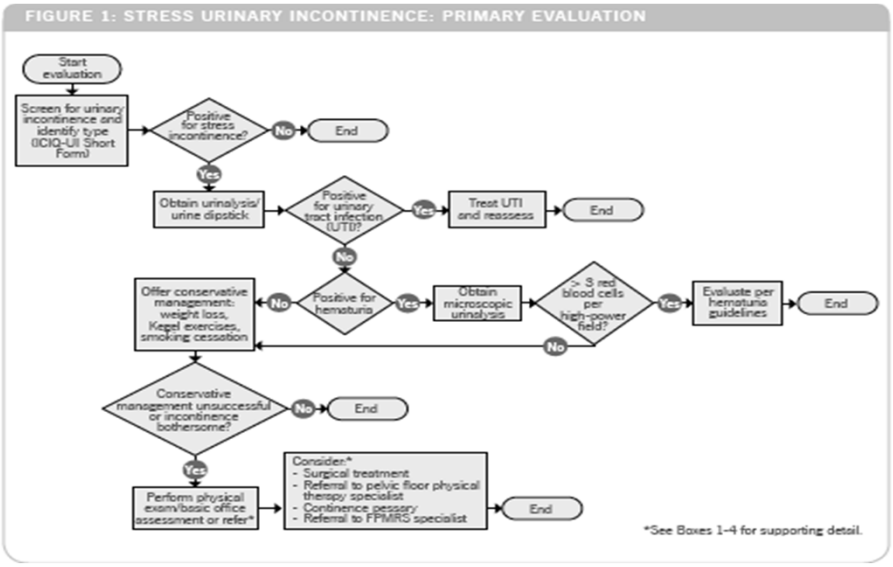
- **UA**
- **PVR**

Per AUA guidelines a PVR is not indicated in uncomplicated patients. It is recommended in patients with obstructive symptoms, history of previous incontinence or prostatic surgery, neurological diagnoses and in patients with SUI that may are considering invasive therapy

Testing

- UDS
  - VALUE Trial
    - For women with uncomplicated, demonstrable stress urinary incontinence, preoperative office evaluation alone was not inferior to evaluation with urodynamic testing for outcomes at 1 year.

SUI Care Pathway



Treatment of Stress Incontinence

- Observation
- Pelvic Floor Exercises
- Incontinence devices
- Injectable Therapy – Bulking Agents
- Retropubic procedures
- Slings

Pelvic Floor Muscle Training

- Perception of cure is more common in women who perform pelvic floor exercises than in those who do not
- Efficacy has been shown with 30-50 daily contractions
- Not all women can perform Kegels correctly with oral instruction alone

Surgery versus Physiotherapy for Stress Urinary Incontinence

- 460 women randomized to PT or MUS
- 49.0% PT and 11.2% of women in the surgery group crossed over
- Subjective cure rates 85.2% in MUS & and 53.4% PT
- Objective cure were 76.5% in MUS and 58.8%, PT

N Engl J Med 2013; 369:1124-1133

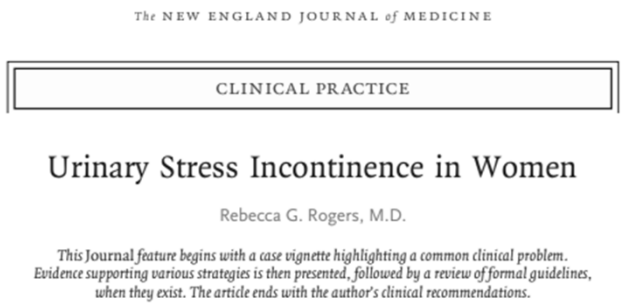
Conclusion

- For women with stress urinary incontinence, initial midurethral-sling surgery, as compared with initial physiotherapy, results in higher rates of subjective improvement and subjective and objective cure at 1 year.

Medications

- No FDA approved medications

Devices-Pessary


The NEW ENGLAND JOURNAL of MEDICINE

CLINICAL PRACTICE

Urinary Stress Incontinence in Women

Rebecca G. Rogers, M.D.

This Journal *feature begins with a case vignette highlighting a common clinical problem. Evidence supporting various strategies is then presented, followed by a review of formal guidelines, when they exist. The article ends with the author's clinical recommendations.*

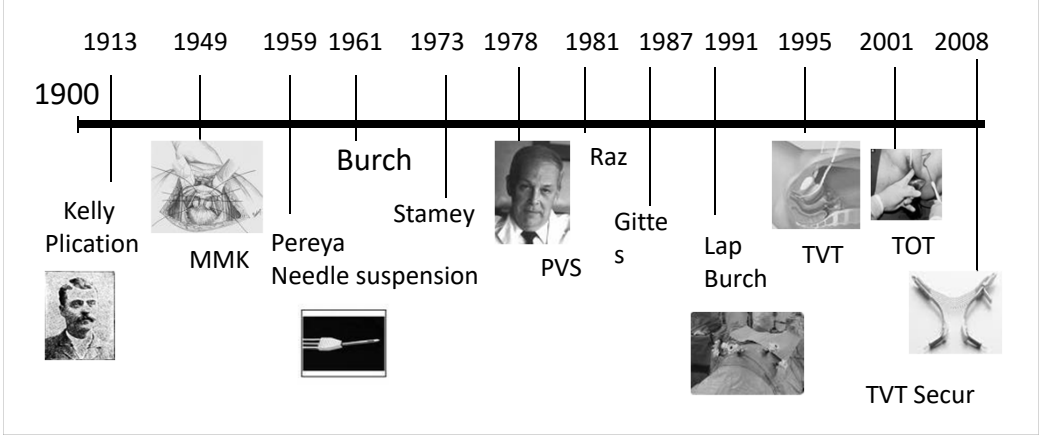
See Figure 2. Pessaries for Treating Stress Incontinence.

N Engl J Med 2008; 358:1029-1036 - DOI: 10.1056/NEJMcp0707023

Devices

- Approximately ½ of women successfully fitted with a pessary use it for the next 1-2 years
  - Clemons et al, Am J Obstet Gynecol 2004: 191: 159-64
- A randomized controlled trial comparing use of super tampon and pessary to no device in women with incontinence only with exercise found that the tampon and pessary were equally effective
  - Nygaard. J Reprod Med 1995: 40: 89-94

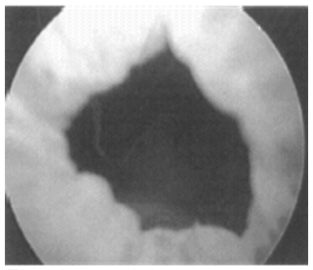
History of Surgery for Female Stress Urinary Incontinence



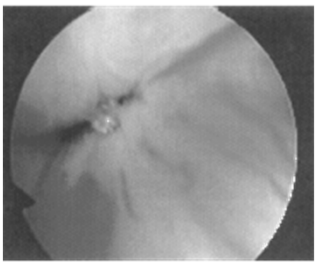
Surgical Treatment of SUI

- Bulking Agents
- Retropubic Suspensions
  - Burch
- Slings
  - Autologous fascia
  - Mid-urethral
    - Retropubic
    - Transobturator
    - Mini-sling

Urethral Bulking Agents



Bladder neck Incompetence

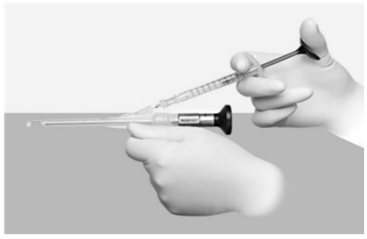


Bladder neck after
Macroplastique injection

Bulking Agents—Results

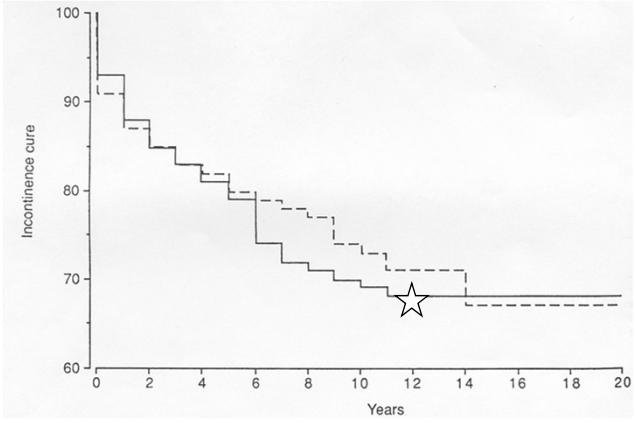
- In office under local or in the OR under MAC
- 12 month cure rates 24- 36%

- Bulkamid (polyacrylamide hydrogel)
  - 70% cure rate at 60 months



Riemsma et al. BMC Med. 2017 (15) 1:63.
Pai et al. Cent European J Urol. 2015; 68(4): 428.

Burch Long Term Results



De Novo Detrusor Instability = 14.7%
Long Term Complaints of Voiding Difficulty = 22%
Recurrent UTI = 4.6%
After 12 years, long term cure rate plateaus at 69%

Alcalay et.al. Br J Ob Gyn 1995

Autologous Fascial Sling/ Pubovaginal Sling

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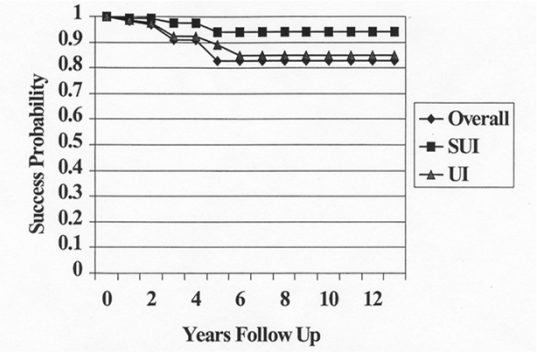
See Figure 3 - Surgical Procedures for Treating Stress Incontinence.

N Engl J Med 2008; 358:1029-1036 - DOI: 10.1056/NEJMcp0707023

Autologous Fascia—Long Term Results

- 15 x 2 cm autologous rectus fascia
- N = 251
- Minimum of 1 year follow up
- Median follow up 3 years
- 92% cure of SUI
- 95% cure of SUI in 20 patients with 10 yr fu



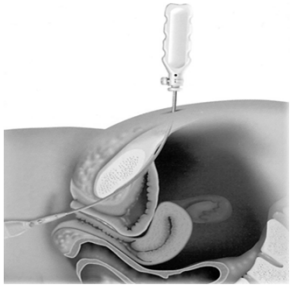
Chaikin & Blaivas, J Urol, 1998

Autologous Fascia – Long Term Results

- Multiple authors report 75-85% cure with > 5 year f/u
- No dyspareunia (without bone anchors)
- 5-15% voiding dysfunction
- Gold standard sling

Midurethral Sling

- TVT
  - Introduced in 1995
  - Rapidly became the most widely-performed procedure for SUI
- TOT
  - Introduced in 2001
  - Created to avoid common complications associated with TVT



Retropubic Midurethral Sling Outcomes

Author	*Success Rate*	*Follow up*
Ulmsten et al	**86%**	**36 months**
Olsson et al	**90%**	**36 months**
Wang et al	**83-87%**	**24 months**
Moran	**80%**	**24 months**

TVT Complications

- Multicenter retrospective review of 241 patients who underwent TVT (22 patients had a secondary procedure)
- Mean Follow-up 6 months
  - Sling Lysis for BOO 4.1%
  - De Novo Urgency 15%
  - Intravaginal Tape Erosion 0.4%

Abouassaly et al, BJU, 2004:94, 110-13

Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors

Michele Jonsson Funk, PhD; Nazema Y. Siddiqui, MD, MHSc; Virginia Pate, MS; Cindy L. Amundsen, MD; Jennifer M. Wu, MD, MPH

- 188,454 sling performed

FIGURE
Cumulative 1 year risk of sling revision for any indication, retention, or mesh erosion, stratified by year of index sling

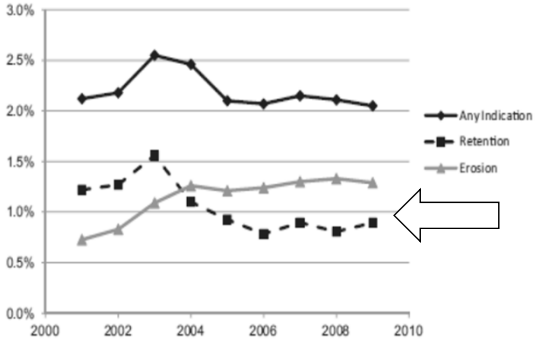


TABLE 2
Cumulative risk of sling revision/removal by indication reported by follow-up time after the index sling

Follow-up after index sling, y	Cumulative risk of revision/removal for urinary retention
0.25	0.6 (0.5, 0.6)
0.5	0.8 (0.7, 0.8)
1	0.9 (0.9, 1.0)
2	1.1 (1.0, 1.1)
3	1.2 (1.1, 1.2)
4	1.2 (1.1, 1.3)
5	1.2 (1.2, 1.3)
6	1.3 (1.2, 1.4)
7	1.3 (1.2, 1.4)
8	1.3 (1.2, 1.4)
9	1.3 (1.2, 1.4)

JANUARY 2013 American Journal of Obstetrics & Gynecology 73.e1

Current Surgical Treatments

- Bulking agents
  - Pros: Minimally invasive, can do in the office or under MAC, no post-operative restrictions
  - Cons: 50% efficacy
- Midurethral slings:
  - Pros: High success rate 85%
  - Cons: 4 week recovery, mesh complications, urinary retention
- Fascial slings
  - Pros: High success rate 87%
  - Cons: Voiding dysfunction 10%, SSI 5%, 6 week recovery, foley X 1 week post-op

UUI Epidemiology

- Affects 33 million Americans
  - 500 million worldwide
- Prevalence
  - 11-19% men and women
- OAB sx prevalence and severity increase with age

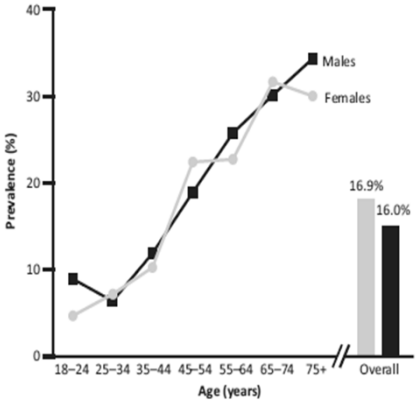


Fig. 1. Prevalence of OAB, according to age and gender (reproduced with permission from Ref. 7).

Irwin D et al. BJU Int 2011;108:1132
Haab F et al. Neuro Urol 2014;33: S2
Stewart WF et al. World J Urol 2003;20:237

Impact on Psychosocial Functioning and Quality of Life

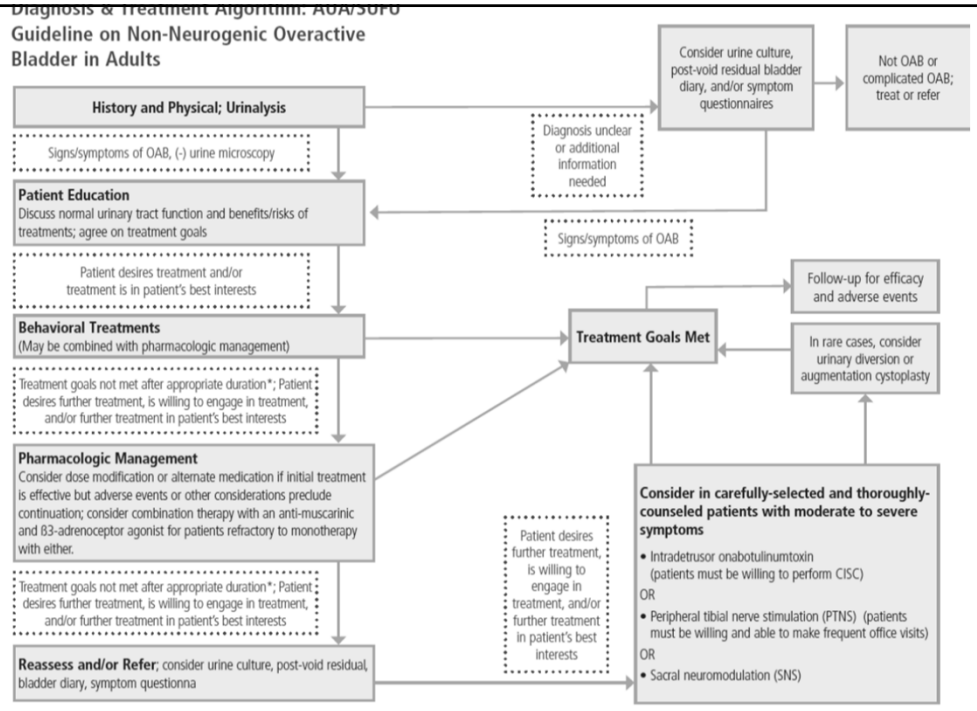
- Negatively affects sleep, mental health, work productivity, overall QOL
- UUI independently associated with increased risk of falls and non-spine non-traumatic fractures in older woman

Coyne et al. BJU 2008; 101:1388
Brown et. al. Am J Man Care 2000;6:S574-9

Concerning Statistics

- Nearly 2/3 of patients are symptomatic for 2 years before seeking treatment
- 76% of diagnosed pts remain untreated
- 50% pts on current treatment regimens say treatment is not helping their symptoms
- 73.5% stop medications within 1 yr due to SE or lack of efficacy

Abrams P et al. *Am J Managed Care*. 2000;6:S580
D'Souza et al J Manag Care Care Pharm 2008;14:291



AUA Guidelines

Guideline Statement 1

- The clinician should engage in a diagnostic process to document symptoms and signs that characterize OAB and exclude other disorders that could be the cause of the patient's symptoms
  - UTI, IC/PBS, Diabetes insipidous, Polydipsia
- **The minimum requirements for this process are a careful history, physical exam and urinalysis.**

History

- Duration of symptoms
- Severity of incontinence
- Inciting events (post-op, neurological symptoms)
- Obstructive voiding symptoms
- Fluid intake habits
  - Caffeine and alcohol intake
- Medications
- Surgeries/radiation/chemo
- Does it BOTHER the pt enough to warrant treatment?

Co-Morbid Conditions: DIAPPERS

- Diabetes Mellitus
- Infection
- Atrophy
- Psychological
- Pharmacologic
- Excessive urine production
- Restricted mobility
- Stool impactions

Physical Exam

- Vital signs: BP
- Cognitive function- dementia?
- Mobility/gait/ dexterity
- Abdominal exam
  - Scars
  - Suprapubic distention
- Pelvic exam
  - Atrophic vaginitis
  - Pelvic organ prolapse
  - Levator spasm
  - Perineal skin – rash/breakdown
  - Lower extremities – edema

Urinalysis

- UA
  - Rule out UTI
  - Rule out hematuria
  - Microscopic hematuria ≥ 3 or more RBC on **1** properly collected specimen in absence of obvious benign cause*
- Urine Culture – **NOT** indicated unless there are signs of infection on UA
- PVR: Is it indicated?

AUA Guidelines 2012

Post-Void Residual

"Measurement of the post-void residual (PVR) is not necessary for patients who are receiving first-line behavioral interventions or for uncomplicated patients (i.e., patients without a history of or risk factors for urinary retention) receiving anti-muscarinic medications"

PVR should be assessed in patients with:

- obstructive symptoms
- history of incontinence surgery
- neurologic diagnoses
- when PVR deemed necessary to optimize care and minimize potential risks

- Useful … not familia
- Useful … tment assess
- Compl
  - # vo
  - Voi
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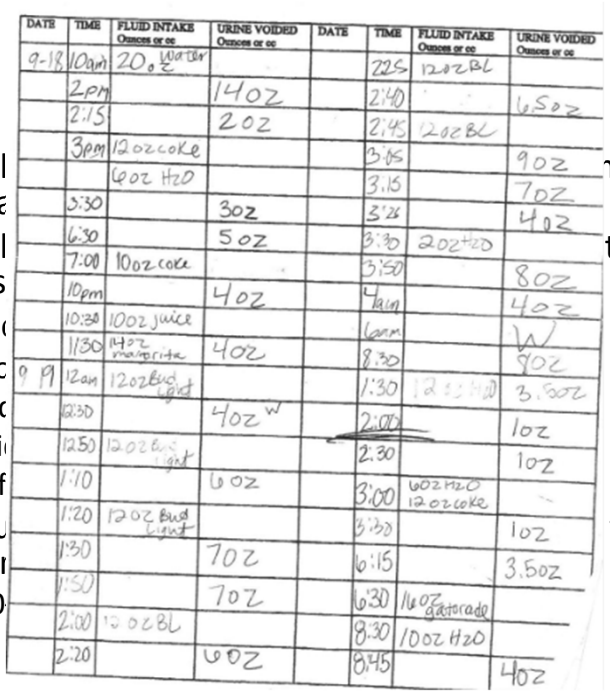
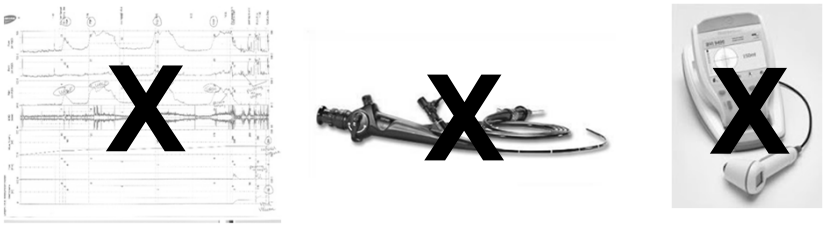
- Helpfu … to noctur
  - >20



DATE	TIME	FLUID INTAKE Ounces or cc	URINE VOIDED Ounces or cc	DATE	TIME	FLUID INTAKE Ounces or cc	URINE VOIDED Ounces or cc
9-18	10am	20oz Water			225	12oz BL	
	2pm		14oz		2:40		6.5oz
	2:15		2oz		2:45	12oz BL	
	3pm	12oz coke			3:05		9oz
		6oz H2O			3:15		7oz
	5:30		3oz		3:26		4oz
	6:30		5oz		3:30	20oz H2O	
	7:00	10oz coke			3:50		8oz
	10pm		4oz		4am		4oz
	10:30	10oz juice			6am		W
	11:30	14oz margarita	4oz		8:30		9oz
9-19	12am	12oz Bud Light			1:30	12oz H2O	3.5oz
	12:30		4oz W		2:00		1oz
	12:50	12oz Bud Light			2:30		1oz
	1:10		6oz		3:00	60z H2O 12oz coke	
	1:20	12oz Bud Light			3:30		1oz
	1:30		7oz		6:15		3.5oz
	1:50		7oz		6:30	16oz gatorade	
	2:00	12oz BL			8:30	10oz H2O	
	2:20		6oz		8:45		4oz

Guideline Statement 3

- Urodynamics, cystoscopy and diagnostic renal and bladder ultrasound should not be used in the initial workup of the uncomplicated patient



Treatment

- First-line treatment with behavioral therapy presents essentially no risks and should be offered to all

Behavioral Treatment

- Education
  - Normal and abnormal bladder function
  - "Normal" fluid intake
- Modifying voiding habits
  - Bladder training
  - Delayed voiding
- Pelvic floor muscle training
  - Biofeedback
  - Vaginal weights
  - Manual training
- Weight loss

Fluid Management

- 25% reduction in fluid intake reduced urinary frequency and urgency
  - daytime frequency ⇩ 23%
  - urgency ⇩ 34%
  - nocturia ⇩ 7%
- Reducing caffeine decreases urgency & frequency by 37%

Hashim H et al. BJU Intl 2008; **102**: 62.
Bryant et al. Br J Nurs 2002; **11**: 560.

Pelvic Floor Muscle Training

- PFMT via biofeedback, verbal feedback or self-administered via pamphlet
  - Similar outcomes for incontinence reduction (60%) and increased bladder capacity (40-60cc)
  - Pts in both feedback groups reported higher patient satisfaction

Burgio KL et al. JAMA 2002; **288**: 2293.

Weight Loss

- 6 mo weight loss program vs education program
- 8% weight loss in obese women
- Reduced urgency incontinence episodes:
  - 47% in weight loss group
  - 28% in control group

Subak L et al. NEJM 2009; 360: 481.

2nd Line: Pharmacologic Treatment

- Choice of oral anti-muscarinics as second-line therapy reflects the fact that these medications reduce symptoms but also can commonly have non-life-threatening side effects
  - Antimuscarinics
  - Tricyclic antidepressants
  - Beta-3 agonists

Anti-muscarinics

- Oxybutynin IR
- Oxybutynin ER
- Tolterodine ER
- Trospium
- Solifenacin (vesicare)

Available as generics

- Darifenacin (enablex)
- Fesoterodine (toviaz)

- Oxytrol
- Gelnique

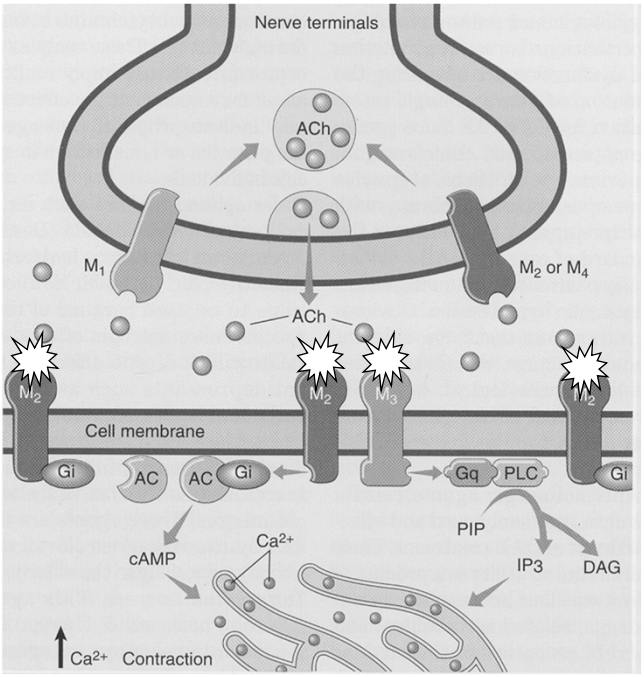
Over the counter

TABLE 1 Characteristics of pharmacologic agents for treatment of overactive bladder[7,27-33]

Drug	Dose range	Dosage form	Metabolism	Receptor affinity	Other notes
Darifenacin (Enablex)	7.5–15 mg once daily	Tablet, ER	Hepatic by CYP450 isoforms	M3	Low rate of CNS side effects; high rate of constipation (14.8% to 21.3%)
Fesoterodine (Toviaz)	4–8 mg once daily	Tablet, ER	Hepatic by CYP450 isoforms	M1, M2, M3, M5	Low CNS penetration; possibly fewer CNS side effects
Oxybutynin IR (Ditropan) ER (Ditropan XL)	 5 mg 2-3 times/ day, max 4 times/ day (IR) 5-30 mg once daily (ER)	Tablet Tablet, ER	Hepatic by CYP450 isoforms	M1, M2, M3, M4	IR is limited by high rates of dry mouth; ER associated with cognitive impairment
Oxybutynin transdermal patch (Oxytrol) Oxybutynin transdermal gel (Gelnique) 3% and 10%	1 patch applied twice weekly Applied once daily	Transdermal patch Transdermal gel	Hepatic by CYP450 isoforms; second pass	M1, M2, M3, M4	Transdermal patch and gel associated with lower rates of dry mouth; transdermal patch associated with significant rate of skin reaction (lower with gel)
Solifenacin (VESIcare)	5–10 mg once daily	Tablet	Hepatic by CYP450 isoforms	M3	High rate of dry mouth at 10 mg dose (27.6% vs 10.9% at 5 mg)
Tolterodine LA (Detrol LA)	2–4 mg once daily	Capsule, ER	Hepatic by CYP450 isoforms	M1, M2, M3, M5	Constipation
Trospium (Sanctura; Sanctura XR)	20 mg twice daily (non-XR) 60 mg in the morning (XR)	Tablet	Active renal tubular secretion; no CYP450 involvement	M1, M2, M3, M4, M5	Low penetration across blood-brain barrier (quaternary amine); XR formulation should be taken in the morning

Ellsworth et al. J Fam Prac 2014;S63:38.

Anti-muscarinic activity



Anti-muscarinics

- Class side effects
  - Dry mouth
  - Constipation
  - Dry/itchy eyes
  - Blurred vision
  - Dyspepsia
  - Impaired cognitive function

Choice of Anti-muscarinic

- An extensive review of the randomized trials that evaluated pharmacologic therapies for OAB revealed no compelling evidence for differential efficacy across medications
- Choice of medication should be based on:
  - Prior history of anti-muscarinic use
  - Side effect profiles
  - Delivery system
  - Comorbidities
  - Cost/Coverage

Guideline 9

- If an immediate release (IR) and an extended release (ER) formulation are available, ER formulations should preferentially be prescribed over IR formulations because of lower rates of dry mouth

Guideline Statement 11

- If a patient experiences inadequate symptom control and/or unacceptable adverse drug events with 1 anti-muscarinic medication, then a dose modification or a different anti-muscarinic medication or a β3-adrenoceptor agonist may be tried

Guideline Statement 12

- Clinicians should not use anti-muscarinics in patients with narrow angle glaucoma and should used with extreme caution in patients with impaired gastric emptying or a history of urinary retention.
  - Do not use in patients taking solid oral formulations of potassium chloride

Guideline Statement 14

- Clinicians must use caution in prescribing anti-muscarinics in patients who are using other medications with anti-cholinergic properties
  - Tricyclic antidepressants
  - Parkinsons drugs
  - Alzheimer's meds
  - Anti-nausea drugs with atropine like effects
  - Anti-cholinesterase inhibitors

Guideline Statement 15

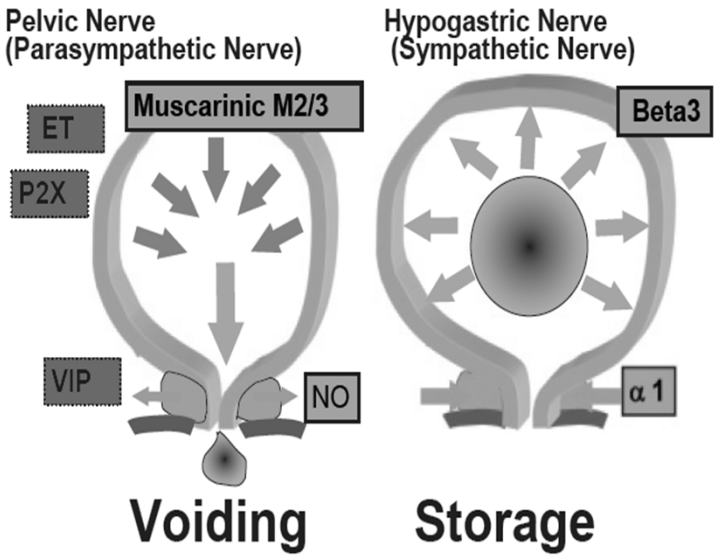
- Clinicians should use caution in prescribing anti-muscarinics or β3-adrenoceptor agonists in the frail OAB patient
  - Start with the lowest possible dose and increase slowly
  - Watch out for poly-pharmacy & cognitive changes

Mirabegron

Mirabegron (Myrbetriq)	25–50 mg once daily	Tablet, ER	Multiple hepatic pathways, including CYP450 iso-forms (specifically CYP2D6, though to a limited extent)	Beta-3 adrenergic receptor	Incidence of dry mouth, HTN similar to placebo; no significant CV, QT interval effects. Monitor BP, especially in HTN patients; avoid in patients with severe uncontrolled HTN. Monitor with concomitant digoxin or CYP2D6 substrates

- Beta-3 adrenergic agonist
- FDA approved in 2012
- β3 receptors in detrusor smooth muscle & urothelium
- Promotes storage by activating sympathetic nervous system (hypogastric nerve) via norepinephrine

Ellsworth et al. J Fam Prac 2014;S63:38



Takeda et al. J Pharm Sci 2010;2110:121

Mirabegron

- Pooled efficacy date 3 randomized, double blind, placebo controlled multi-center study- 151 sites
- N=3452
- Placebo, tolterodine 4mg, mirabegron25, 50,100 mg
- Significantly greater decreases in UI and freq than placebo
- "Efficacy" similar to anti-muscarinics
- AE- NO difference in dry mouth or HTN vs placebo

Niit et al. Int J Clin Pract

Medical Therapy Follow-up

- Telehealth visit 4-6 weeks after prescribe a medication
  - Assess SEs
  - Dose Escalation
  - If have tried & failed medications discuss 3rd line therapies
    - Botox after 1 med
    - PTNS & SNS most insurances make pts fail 2 meds

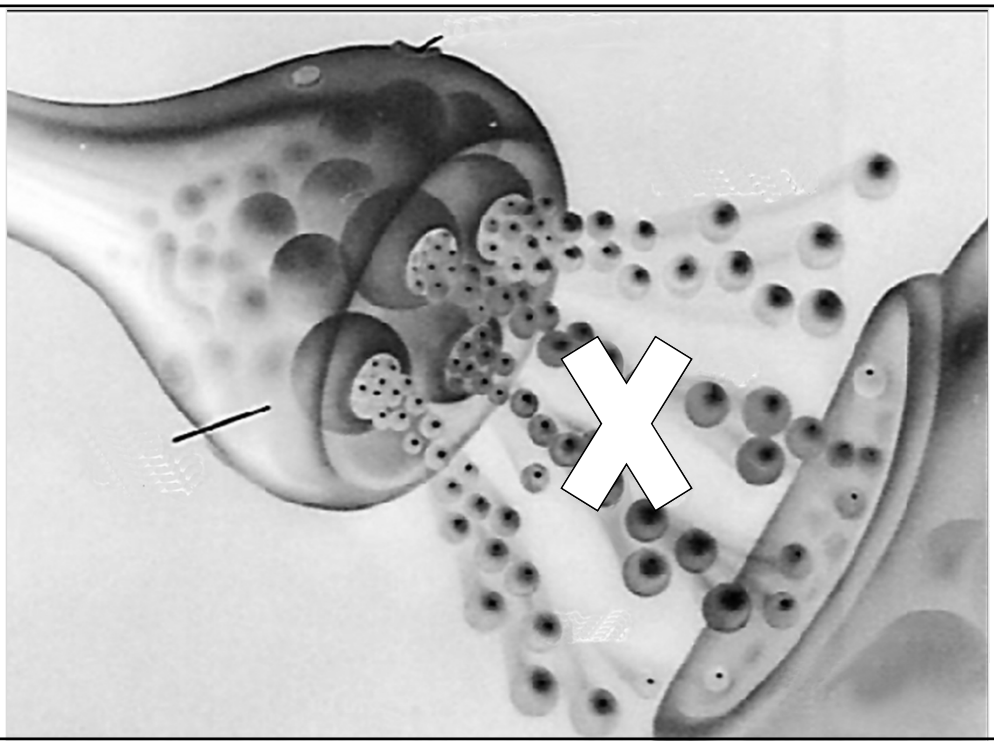
3rd Line Therapies: OnabotulinumtoxinA

Guideline Statement 17

- Clinicians may offer intradetrusor onabotulinumtoxinA (100U) as third-line treatment in the carefully-selected and thoroughly-counseled patient who has been refractory to first- and second-line OAB treatments. The patient must be able and willing to return for frequent post-void residual evaluation and able and willing to perform self-catheterization if necessary

Botulinum Toxin

- Most potent neurotoxin known to man
- Seven immunologically distinct serotypes: A, B, C1, D, E, F, G
- Only A & B are available for use clinically
- Works by inhibiting acetylcholine release from presynaptic cholinergic junction leading to chemodenervation, reduced muscle contractility and likely reduce afferent input
- Reversible in 5-12 months
- FDA approved for NDO in 2011 & OAB 2013



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Botulinum Toxin Injection

ELSEVIER

European Urology
Volume 62, Issue 1, July 2012, Pages 148-157

Platinum Priority – Incontinence
Editorial by Ricarda M. Bauer and Christian Gratzke on pp. 158–159 of this issue

OnabotulinumtoxinA Improves Health-Related Quality of Life in Patients With Urinary Incontinence Due to Idiopathic Overactive Bladder: A 36-Week, Double-Blind, Placebo-Controlled, Randomized, Dose-Ranging Trial

See Figure 1. Injection-site pattern for the administration of onabotulinumtoxinA in the detrusor.

Fowler, C-J & Auerbach, Stephen & Ginsberg, David & Hale, Douglass & Radziszewski, Piotr & Rechberger, Tomasz & Patel, Vaishali & Zhou, Jihao & Thompson, Catherine & Kowalski, Jonathan. (2012). OnabotulinumtoxinA Improves Health-Related Quality of Life in Patients With Urinary Incontinence Due to Idiopathic Overactive Bladder: A 36-Week, Double-Blind, Placebo-Controlled, Randomized, Dose-Ranging Trial. European urology. 62. 148-57. 10.1016/j.eururo.2012.03.005.

Onabotulinum Toxin A injection

- 100 units (200 units for neurogenic bladder)
  - 20 injection sites 0.5cc/site
- In office or OR
- Flexible or rigid scope
- Negative UA
- 1% lidocaine instilled in bladder
- Discontinue antiplatelet therapy ≥3 days

Botulinum Toxin

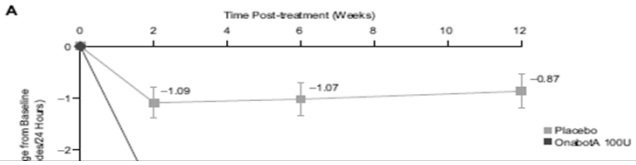
- Decreases OAB symptoms
- Increases bladder capacity

- Needs to be repeated roughly every 8-10 months
- Costly
- Up to 6% risk of need for temporary CIC w 100u
- Risk of UTI

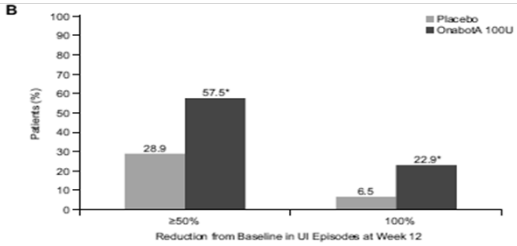
- There are other types of botulinum toxin
  - Dosages/strengths differ

Onabotulinum Toxin A Outcomes

Results: OnabotulinumtoxinA significantly decreased the daily frequency of urinary incontinence episodes vs placebo (–2.65 vs –0.87, p <0.001) and 22.9% vs 6.5% of patients became completely continent. A larger proportion of onabotuli-



UUI episodes decreased by 2.65 vs 0.87 for placebo (p<0.001)



Onabotulinum Toxin A Outcomes

Table 3. *Key safety parameters in first 12 weeks after treatment 1 and at any time during treatment cycle 1 in safety population*

	No. First 12 Wks (%)		No. Any Time (%)*	
	Placebo	OnabotulinumtoxinA 100 U	Placebo	OnabotulinumtoxinA 100 U
No. pts	272	278	272	278
AE with 5% or greater incidence:				
UTI†	16 (5.9)	43 (15.5)	25 (9.2)	68 (24.5)
Dysuria	26 (9.6)	34 (12.2)	27 (9.9)	40 (14.4)
Bacteriuria	5 (1.8)	14 (5.0)	10 (3.7)	23 (8.3)
Urinary retention‡	1 (0.4)	15 (5.4)	1 (0.4)	16 (5.8)
Serious AE	8 (2.9)	9 (3.2)	16 (5.9)	18 (6.5)
Death	0	0	1 (0.4)	0
PVR (ml):	0		0	
200 or Greater change from baseline		19 (6.8)		24 (8.7)§
200 or Greater		24 (9.6)		31 (11.2)

6.1% pts initiated CIC

PTNS: Percutaneous Tibial Nerve Stimulation

- Needle electrode inserted medial/above medial malleolus
- Impulses travel from the ankle along the tibial nerve to the sacral nerves
  - Tibial nerve has input from S 2, 3 and 4 roots
- Weekly x 12 weeks
- Maintenance Therapy – varies
  - 1/month

Interstim

- Must fail or be intolerant to 2 meds
- Now MRI compatible
- Two approaches:
  - PNE followed by combined
  - Stage 1 & 2

So which 3rd line therapy

- Botox
  - Contraindicated in pregnancy
  - Can't be used in Jehovah's' witnesses
  - Increases risk of UTIs
  - Should not be used in pts with incomplete emptying or elevated PVRS
  - Must be willing to cath
  - Must hold anti-coagulation 5-7 days before procedure

PTNS

- Time commitment – 12 weeks then maintenance therapy
- Cannot have lower extremity edema- will not stimulate PTN

Interstim

- Good for pts with dual incontince - UI & FI
- Now MRI compatible
- Does require reprogramming

Mixed Urinary Incontinence

- Treat the most bothersome symptom
- Caveat- if the pt has significant SUI surgical correction of SUI can improve OAB symptoms in 50-70% of patients

Conclusion

- Female urinary incontinence is a common, life altering condition affecting 50% of women
- It is important to differentiate the type of incontinence as the treatment algorithms are different