Treating Urinary Incontinence: An overview of Innovative Options

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Trends in Treatment of Urinary Incontinence (UI)

- Fewer visits, more homecare
- Reimbursement (need for pre-authorizations)
- Cost driven
- Time considerations

Working with your Patients

- Begin with proper:
  - History
  - Physical exam
  - DIAGNOSIS!
- Develop realistic goals
  - Decrease UI/No UI
  - Increase quality of life
  - Containment
- Focus on prevention
  - Good bladder health
  - Future considerations
- Educate patient
  - Treatment costs
  - Pros and cons

Making Lifestyle Changes

- Weight Management: weight gain has been associated with development of UI
- Fluid management: increase fluid load
- Decrease caffeine: diuretic affect, bladder irritant
- Smoking cessation: cough causes chronic increase in pelvic floor pressure
- Constipation: pressure on bladder
- Physical activity/physical forces

Imamura M, Williams K, Wells M, McGrother C (2015) Lifestyle interventions for the treatment of urinary incontinence in adults (Review) *Cochrane Library* pp 1-69.

Pelvic Health Fitness

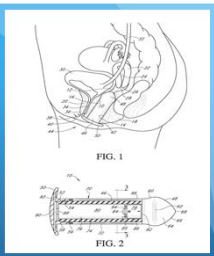
- Total Control (Women's Health Foundation, Chicago, Il)
  - Evidence-based, award winning fitness program with emphasis on the pelvic pyramid.
  - Improved Bladder Control
  - Better core, strength, balance and posture
  - Chronic pelvic pain: learn awareness and relaxation techniques
  - Improved sexual health
  - Women only (all ages)
- Yoga (Tenfeld, 2014)
  - ↓stress perception
  - ↓mood disturbance
  - Improved sympatho-vagal balance resulting in decreased inflammation
- Urinary incontinence:
  - ↓ severity of symptoms
  - ↓ distress r/t UI symptoms
  - ↓ impact of UI symptoms on quality of life

UI Treatment Options

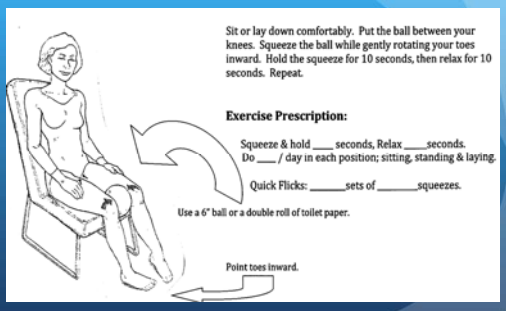
- Pelvic floor therapy: Options for use with stress, urge, mixed UI and dysfunctional voiding
  - Kegel exercises
  - Biofeedback therapy
  - Pelvic floor stimulation
  - Home stimulators/devices

Kegel Exercises

- Introduced by Dr. Kegel in 1948
- Use of Perineometer



Kegels using 6" ball



Hulme, Janet MA, PT (1999)

Biofeedback Therapy

- Patient must be cognitively intact
- Use of visual or auditory feedback based on contraction of pelvic floor
- Use of vaginal/rectal probe or external electrodes and computer and monitor
- Treatments generally 15-30 minutes ~2weeks to one month apart
- Patient is given "immediate" feedback based on strength, endurance, relaxation and technique of pelvic floor movement
- Positive results in 8-12 weeks with regular daily Kegel exercises and follow up
- Best results when patient is motivated and wants to be actively involved in treatment (Newman, 2014)
- Reduction in UI episodes ~78% from baseline with 50% of subjects showing 90% improvement (Newman, 2014)
- Post prostatectomy: Pelvic floor muscle training:
  - 3 sets of 10 repetitions/day improve short and long term post prostatectomy UI (Fernandez, 2015)

Pelvic Floor Stimulation

- Stimulation by vaginal or rectal probe or external electrodes. Used to strengthen or increase activation of your pelvic floor muscles.
- The probe/electrode is used to deliver an electric current that causes the pelvic muscles to contract.
- The current can be set at different strengths and time intervals.
- Electrical stimulation therapy can be done with at-home devices or in a clinician's office.
- Used in the treatment of urinary incontinence, urgency, pelvic floor dysfunction or pelvic floor spasm

InTone

Pelvic floor stimulation

-Treats incontinence, weak pelvic floor muscles and over-active detrusor muscle

-Combo biofeedback, electrical stimulation

-Voice guided program

-Visual biofeedback

-Inflatable probe

-Sessions 12 minutes, 6/week

-Symptom improvement 12-26 weeks

-Cost: $199-$799

-Intensity, Apex, ApexM, Apex MV

PeriCoach

- Biofeedback system
- Used stress UI, pelvic muscle dysfunction, pelvic prolapse, fecal incontinence
- Kegel app. Need smart phone to use
- Tracks progress, provides guidance for Kegel exercises
- Recommended 3 month use 4-7/week for best results
- Cost: $249

Pessaries

Supportive devices:

-Stress UI

-Pelvic Organ Prolapse

-Type/size dependent on vaginal length, width and severity of problem

Vaginal Devices

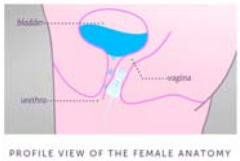
- Cones, weights, balls

Limited research available, poor study designs, no insurance coverage, cost ~$25-90. Results apparently seen in 12 weeks of daily use.

Vaginal Devices: Urethral Plugs

- Temporary, short term
- UTI common
- One time use
- Needs to be sized
- Works for specific activities related to stress UI

Vaginal Devices: Impressa

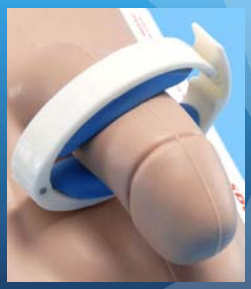


PROFILE VIEW OF THE FEMALE ANATOMY

Used for stress UI. Cost ~$1.20/each. Sizing kit: 3sizes. Can stay in for up to 12 hrs
85% women say device is comfortable. No data on effectiveness.

Male Incontinent Devices

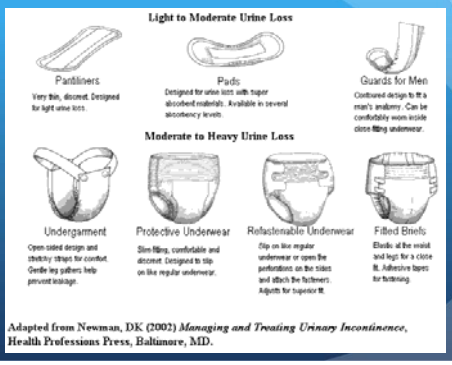
- Penile clamp
  - Temporary use only
  - Can cause lack of blood supply if left on too long
  - Can be uncomfortable
  - Available in plastic or metal



Collection Devices: Stress, Urge & Mixed

Condom Catheters
-Better for temporary use
-Great for nighttime use
-Easy on, easy off
-Use in male Parkinson's patients*

Collection Devices: Undergarments



Adapted from Newman, DK (2002) *Managing and Treating Urinary Incontinence*, Health Professions Press, Baltimore, MD.

Functional Incontinence

- Issues to consider:
  - Cognition
  - Mobility
  - Co-morbidities
  - Sensory deficits
- Application of general behavioral management, medications and 3rd line therapy
  - **Caregiver support**

OAB Medication Comparisons

Medication	Adverse Events (>5%)	Drug/drug Interactions	Half Life	Comments
Detrol LA (Tolteridine)	Dry mouth 23% Headache 6% Constipation 6%	NONE	8 hrs	Oral meds cannot be crushed
Ditropan IR Ditropan XL (Oxybutynin)	Dry mouth 29% Diarrhea 7% Headache 6%	Studies not conducted	12 hrs	Likely to cross blood brain barrier (Kay, 2005) Not recommended for elderly (Beers list, 2005)
Gelnique 10% (Oxybutynin)	Dry mouth 7%	Studies not conducted		
Enablex (Darifenacin)	Constipation 21% Dry mouth 19% Headache 7%	Digoxin, ketoconazole, clarithromycin, etc	13-19 hrs	Highest % of constipation of all drugs in the class
Oxytrol Patch (Oxybutynin)	Site pruritis 21% Site erythema 8%	Studies not conducted	7-8 hrs	More convenient form of delivery. Fewer GI side effects. Available over the counter
Sanctura (XR) (Trospium)	Dry mouth 20% Constipation 10%	NONE	20 hrs.	Needs to be taken on an empty stomach. Best for pts with dementia
Toviaz (fesoterodine)	Dry mouth 19% Constipation 5%	Other anti-muscarinics and anti-cholinergics	7 hrs	Hot environment caution
Vesicare (Solifenacin	Dry mouth 10.2% Constipation 5% Blurred vision 4.1%	NONE	51 hrs	Head to head study with Detrol LA. Lowest % of side effects in the class.

Urge UI Medications cont…

Mirbegron (Myrbetriq)

- Dosed at 25 and 50 mg, once daily
- Beta 3 agonist
- Effectiveness within 8 weeks, sooner with 50 mg.
- Side effects minimal
  - Hypertension, nasopharyngitis, UTI, headache
- No food effects
- No contraindications

Considerations with Mirbegron

- Drug interactions: CYP2D6 (metaprolol), digoxin
- Use with caution in bladder outlet obstruction
- Limited side effects (headaches) Monitor BP
- Not recommended with severe renal impairment or moderate hepatic impairment

Vaginal Estrogen

- Conjugated estrogen vaginal cream 0.5 gm 3/week up to 8 months
- Estradiol (0.1mg/gm) or Estriol (0.5mg/gm) compounded
- Estradiol vaginal insert/ring 2 mg (one ring); replace every 3 months
- Estradiol vaginal tablets, 10 mcg; insert one tablet nightly for 2 weeks then twice weekly
- Application can be with applicator or with finger
- NOT appropriate treatment for stress UI
- Helpful also with urethritis (peas size application to urethra 3/week
- Robinson, D., & Cardozo, L. (2011). Estrogens and the lower urinary tract. *Neurourology and Urodynamics*, *30*(5), 754-757.

Third Line Therapy for OAB

- OnobotulinumToxinB (BOTOX)
  - Safe therapy, minimal SE (~6% retention, UTI), 100 u/50% improvement, repeated q3-8 mo. (Harris, 2016) Considered superior to SNS (SUFU, 2017)
- Interstim Therapy
  - Implantable device, surgical procedure, SE pain, infection
- Percutaneous Tibial Nerve Stimulation (PTNS)
  - Future: implantable, home device, self adhesive conducting pads, etc.

SUMMARY

- Creativity in treating UI is critical
- Be considerate of patients time and money
- Hammer home behavioral management
- UI is a chronic disease: REINFORCE
  - Lifestyle changes
  - Behavioral interventions
  - Compliance
- Follow up, follow up, follow up

Percutaneous Tibial Nerve Stimulation: PTNS

Objectives

- Define PTNS
- State its usage within OAB
- Identify the right patient for PTNS
- Identify preparation process for procedure
- Demonstrate procedure
- Return demonstration of procedure
- Illustrate examples of documentation for PTNS
- State patient and staff resources

PTNS Defined

- Minimally invasive neuromodulation
- Neuromodulation: the physiological process to influence activity in one neural pathway through synapti interaction with another pathway
- Designed to treat OAB symptoms by modulating signals to and from the bladder
  - Via sacral plexus
  - By retrograde afferent stimulation

PTNS: Indications

- Refractory Overactive Bladder (OAB)
  - Urinary urgency, frequency and/or urge incontinence
- Identified as 3rd line therapy for OAB
  - An option after behavioral and medication management has failed
- In office therapy delivered by nurse, NP or PA under the direction of the physician
- Non-drug, non-surgical therapy

Choosing Patients for Urgent PC

- Medical necessity
  - Behavioral failure
  - Medication failure
  - Intolerance
  - Contraindications (internal defibrillator, pacemaker)
- Compliance
- Review of contraindications
- Insurance coverage
  - CPT code: 64566
  - Diagnosis: 788.31 (UUI), 788.41 (frequency), 788.63 (urge)
- Patient informed consent (hand-out)

Getting Started: Equipment

- Equipment
  - Lead packet
  - Gloves
  - Tape
  - Stimulator
  - Timer

Urgent PC Neuromodulation System

Preparing for PTNS

- Position patient comfortably
- 30 minute treatment
- Support treatment leg
- Make sure insertion site is easily accessible

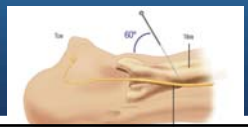
Urgent PC Neuromodulation System

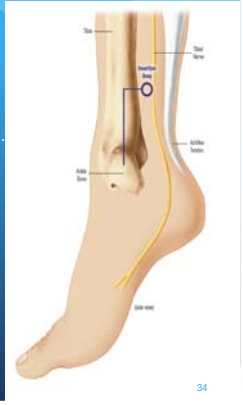
PTNS Insertion Location

- On the inner leg, use the width of 3 fingers to measure approximately 2 inches from center of ankle bone.
- Move the top finger back 3/4 - 1 inch. Your finger should be positioned just behind the tibia.

PTNS Needle Angle

- Insert the Needle Electrode at a 60° angle (back view).





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Locate Needle Electrode Insertion Site

Approximately:

- 3 finger breadths above medial malleolus
- 1 finger breadth posterior to tibia

Prepare Needle Electrode Site

- Clean site with alcohol swab
- Place Needle Electrode/guide tube assembly over identified site
  -Create 60º angle

Insert Needle Electrode

- Remove stop plug in guide tube
- Tap Needle Electrode head to pierce skin

Advance Needle Electrode

- Remove guide tube
- Advance Needle Electrode with rotating motion
  - Advance parallel to tibia
  - Maintain 60° angle
- Insert ~ 2 cm, or ½ bottom portion

Attach Lead Wire

- Connect Lead Wire to Stimulator

Place Surface Electrode

- Remove adhesive backing from Surface Electrode
- Attach Surface Electrode near medial aspect of calcaneous

Attach Needle Electrode Clip

- Attach Needle Electrode Clip
  - Depress clip to expose connection hook
  - Place clip around Needle Electrode handle
  - Release Needle Electrode Clip

Enter Test Mode

- Enter Test Mode

  -Press and hold the yellow Test button for 2 seconds

Identify Treatment Level

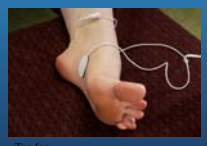
Adjust Current

- Slowly increase using the Current Adjustment button

Patient Response

- Patient response indicated by motor response or sensation in the ankle area
- Observe patient's foot for response (not all patients have a motor response)
- Ask patient if they feel any sensation

Toe flex



Toe fan

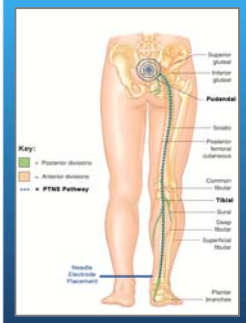
Conduct Therapy

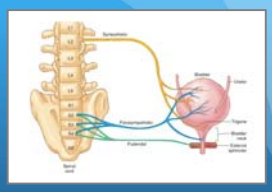
- Confirm patient response
- Enter Therapy Mode:
  1. Press red Stop button then press green Therapy button

     OR
  2. Press green Therapy button while Test mode is still active

Note: Pressing the Stop button after beginning Therapy Mode will end the treatment session and necessitate a new Lead Set.

PTNS – How does it work?





- Impulses travel along the tibial nerve to the sacral plexus
- Nerves in sacral plexus innervate the bladder and provide external sphincter control.

Assess Patient During Treatment

- Comfortable sitting position?
- Treatment leg supported?
- Tolerance of sensations?
- Ability to notify staff

Therapy Duration

- Therapy Mode will automatically end when 30 minutes have elapsed

When Therapy is Complete

- Turn off Stimulator
- Detach Needle Electrode Clip from Needle Electrode
- Remove Needle Electrode from leg
- Remove Surface Electrode
- Disconnect Lead Wire from Stimulator
- Discard Lead Set components appropriately

Turn On Stimulator

- Press and hold Power Button for at least 2 seconds

Touch Pad Controls

Power On / Off

Current Adjustment

Test Mode

GO

STOP

LCD Status Screen

- Operational status for
  - Battery level
  - Lead wire function
  - Current setting
  - Current

LCD Status Screen

- Treatment status for
  - Test mode
  - Therapy mode
    - Remaining time
  - Therapy completed

Documentation

- Quality of life survey (OABq)
- Informed consent
- Pre-authorization
- Voiding Diary
- Medical record documentation
- PTNS policy
- Patient education

Questions?

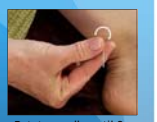
- Thank you for your attention
- For additional information refer to the Instructions for Use
- Visit **www.cogentixmedical.com**
- Blog site: **www.cogentixmedical.com/blogs**
- Contact Customer Service 866-258-2182
- Contact your local representative: Bill Gelbuda
- Pt ed : www.cogentixmedical.com/myptns-provider-overview

Treatment - Procedure Overview


3 fingers above ankle, 1 finger behind tibia


60° angle


Remove pink plug, tap needle, remove tube


Rotate needle until 2 cm (1/2 of bottom) is inserted


Enter Test Mode (hold yellow button for 2 seconds)


Adjust current


Patient response can be either motor (toe flex or fax) or sensory


Enter Therapy Mode (green button) - 30 minutes

References

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