

Start	End	Topic	Speakers
14:00	14:05	Introduction and welcome	Doreen McClurg
14:05	14:20	Lifestyle Management	Margaret Sherburn
14:20	14:35	Evidence for PFMT or other treatments e.g hypopressive techniques	Chantale Dumoulin
14:35	14:50	Vestibulodynia - evidence for physiotherapy	Melanie Morin
14:50	15:00	Tibial nerve stimulation for women with UI	Doreen McClurg
15:00	15:15	Discussion	Doreen McClurg Chantale Dumoulin Margaret Sherburn Melanie Morin
15:15	15:30	Questions	All

Aims of Workshop

The evidence for conservative management of female UI and pelvic pain was synthesised and updated in the 6th International Consultation on Incontinence book published in 2017 (Abrams et al). It is important that clinicians are made aware of such updates (and any new robust evidence published since) and what they mean to clinical practice but this is often difficult especially for those early career professionals. This workshop aims to highlight significant changes identified and then discuss these using a series of interactive case studies with an opportunity for attendees to bring their own case scenarios to be discussed in the final session.

Learning Objectives

To update clinicians on the evidence for conservative interventions for female UI and pelvic pain.
To highlight changes such evidence may mean for clinical practice.
To stimulate discussions on how these can be implemented in practice.

Learning Outcomes

To be fully converse with the latest evidence on the conservative management of women with UI or pelvic pain.
To be able to apply such evidence when treating patients through a raised awareness of treatment options, patient preferences and goals.

Target Audience

This is the annual free basic physiotherapy workshop. Due to the anticipated audience having greater knowledge than those in some venues the course has been re-vamped and aims at updating levels of evidence with interactive case study scenarios.

Advanced/Basic

Basic

Conditions for Learning

Interactive with some group discussions and case scenarios. Anticipate breakout sessions of 10-12 participants facilitated by one of the presenters.

Suggested Learning before Workshop Attendance

Abrams P, Cardozo, Wagg A, Wein A. Incontinence Ch 12 Adult Conservative Management 6th Edition 2017 ISBN: 978-0-956907-3-3

Suggested Reading

FitzGerald MP, Anderson RU, Potts J, Payne CK, Peters KM, Clemens JQ, et al. Randomized multicenter feasibility trial of myofascial physical therapy for the treatment of urological chronic pelvic pain syndromes. J Urol 2009, Jun 15.
Phelan S, Kanaya AM, Subak LL, Hogan PE, Espeland MA, Wing RR, et al. Weight Loss Prevents Urinary Incontinence in Women With Type 2 Diabetes: Results From the Look AHEAD Trial. Journal of Urology. 2012;187(3):939-44. 8.
Pinto AM, Subak LL, Nakagawa S, Vittinghoff E, Wing RR, Kusek JW, et al. The effect of weight loss on changes in health-related quality of life among overweight and obese women with urinary incontinence. Quality of Life Research. 2012;21(10):1685-94. 10.
Nygaard IE, Shaw JM, Bardsley T, Egger MJ. Lifetime physical activity and female stress urinary incontinence. American Journal of Obstetrics and Gynecology. 2015;213(1). 14.

Wyman J, Allen A, Hertzgaard L, Overson E, Allen S, Hatsukami D. Effect of Smoking Cessation on Overactive Bladder Symptoms in Adults: A Pilot Study. *Neurourology and urodynamics*. 2014;33(6):866-7.

Barakat R, Pelaez M, Montejó R, Luaces M, Zakythinaki M. Exercise during pregnancy improves maternal health perception: A randomized controlled trial. *American journal of obstetrics and gynecology*. 2011;204(5):402.

Kocaoz S, Eroglu K, Sivaslioglu AA. Role of pelvic floor muscle exercises in the prevention of stress urinary incontinence during pregnancy and the postpartum period. *Gynecologic & Obstetric Investigation*. 2013;75(1):34-40.

R. Pelvic floor muscle training included in a pregnancy exercise program is effective in primary prevention of urinary incontinence: a randomized controlled trial. *Neurourology & Urodynamics*. 2014;33(1):67-71. 39

Konstantinidou E, Kalaitzi M, Mytilekas K, Mikos T, Ioannides E, Hatzichristou D. Is there a role for training of the transversus abdominis muscles in the physiotherapy schemes applied in the treatment of female urinary incontinence? . Proceedings of the 43rd Annual Meeting of the International Continence Society (ICS). 2013.

Donahoe-Fillmore B, Chomy W, Braehler CJ, Ingley A, Kennedy J, Osterfeld V. A comparison of two pelvic floor muscle training programs in females with stress urinary incontinence: A pilot study. *The Journal of Applied Research*. 2011;11(2):73-83.

Souto SC, Reis LO, Palma T, Palma P, Denardi F. Prospective and randomized comparison of electrical stimulation of the posterior tibial nerve versus oxybutynin versus their combination for treatment of women with overactive bladder syndrome. *World Journal of Urology*. 2014;32(1):179-84.

M. Morin, M-S. Carroll, S. Bergeron. Systematic review of the effectiveness of physical therapy modalities in women with provoked vestibulodynia. *Sex Med Rev*, 2017.

A. Morin, G. Léonard, V. Gougeon, M-P. Cyr, G. Waddell, Y-A. Bureau, I. Girard, M. Morin. Efficacy of transcranial direct current stimulation in women with provoked vestibulodynia. *American Journal of Obstetrics and Gynecology*, 2017; 216(6): 584.e1-584.e11.

Lifestyle Management

Margaret Sherburn

Lifestyle advice is a part of a complete package of interventions a clinician might use for the resolution or prevention of incontinence and prolapse in women and men. Lifestyle modifications are defined as the application of interventions in management of lifestyle-related health conditions. Many of the lifestyle changes we advise our patients might be considered 'logical' or 'sensible'. They are low cost, non-invasive changes to lifestyle and include weight loss, dietary advice, fluid intake modification, reduction of caffeinated, carbonated and alcoholic beverages, avoidance of constipation, smoking cessation, alteration of physical activity, and reduction in lifting and coughing.

But do we have evidence for this advice? Specifically, which lifestyle advice is evidence based and what is not? Evidence for lifestyle advice for both incontinence and prolapse, and for both prevention and treatment, is lacking, particularly high level evidence from RCT's. Weight loss and dietary factors have been examined and there are some prospective and observational studies for dietary advice, smoking cessation, and avoiding constipation. Other advice commonly given has little or no evidence.

This presentation will explore lifestyle advice and what is the most up to date evidence we have for lifestyle advice as preventions and treatment for incontinence and prolapse. Specifically, we will address the following:

- Are lifestyle modification interventions effective in the prevention of UI and prolapse?
- Are lifestyle modification interventions better than not treatment, placebo, or control in the treatment of UI and prolapse?
- Is one lifestyle modification intervention better than another?

Dumoulin C, Adewuyi T, Booth J, Bradley C, Burgio K, Hagen S, Hunter KF, Imamura M, Morin M, Morkved S, Thakar R, Williams K. (2017) *Adult Conservative Management*. In Abrams PH, Cardoza L, Khoury AE and Wein A, eds.: 6th Ed. *International Consultation on Urinary Incontinence*, Plymbridge United Kingdom: Health Publication Ltd. Volume 2, pages 1443-1628.

Evidence for other pelvic floor treatments

Chantal Dumoulin

Pelvic floor muscle training is defined as exercises to improve pelvic floor muscle strength, endurance, power, relaxation or a combination of these parameters. Pelvic floor muscle training remains a key factor in the treatment of urinary incontinence. Because pelvic floor muscle integrity appears to play an important role in the continence mechanism, there is a biological rationale to support the use of pelvic floor muscle training in preventing and treating stress urinary incontinence in women.

The role of pelvic floor muscle training in the treatment of urge urinary incontinence implies that pelvic floor muscle contractions can also be used to occlude the urethra to prevent leakage during detrusor contraction, as well as inhibit and suppress detrusor contraction.

Pelvic floor muscle training is an intervention that involves the understanding of pelvic floor muscle activation and the pursuit of a repeated exercise programme over time. A number of factors can influence the outcome of a Pelvic floor muscle training program such as the way it is taught and/or supervised, the parameters of the actual exercises, adherence to the training regimen and even the addition of other treatment (ie: biofeedback or cones). Finally, in the past decades, new interventions emerged as alternatives to pelvic floor muscle training in the treatment of urinary incontinence (hyporessive, yoga, pilate).

This presentation will update the evidence for the use of pelvic floor muscle training in the prevention and treatment of urinary incontinence in women. Questions addressed are:

- Is Pelvic floor muscle training effective in the prevention of urinary incontinence?
- Is Pelvic floor muscle training better than no treatment, placebo or control treatments in the treatment of urinary incontinence?
- Is one type of Pelvic floor muscle training programme better than another in the treatment of urinary incontinence?
- Is Pelvic floor muscle training better than other interventions in the treatment of urinary incontinence?

Dumoulin C, Adewuyi T, Booth J, Bradley C, Burgio K, Hagen S, Hunter KF, Imamura M, Morin M, Morkved S, Thakar R, Williams K. (2017) *Adult Conservative Management*. In Abrams PH, Cardoza L, Khoury AE and Wein A, eds.: 6th Ed. *International Consultation on Urinary Incontinence*, Plymbridge United Kingdom: Health Publication Ltd. Volume 2, pages 1443-1628.

Vestibulodynia – Evidence for Physiotherapy

Mélanie Morin

Chronic vulvar pain is a highly prevalent condition affecting up to 7-16% of women. Provoked vestibulodynia (PVD), characterized as a sharp pain or burning sensation at the entry of the vagina when pressure is applied or vaginal penetration is attempted, is recognized as the leading cause of vulvar pain and dyspareunia. Pelvic floor physiotherapy treatment is recommended as a first line intervention for PVD and is judged by experts as the most effective intervention. Physiotherapy treatment encompasses several modalities used combined or separately. The most commonly used modalities include PFM exercises with or without biofeedback, manual therapy (e.g. stretching, myofascial trigger point release, connective tissue mobilization, desensitization, etc.), education (e.g. removal of irritant, chronic pain physiology, sexual function, relaxation), electrotherapy and dilators/insertion techniques. New emerging modalities are also available including low level laser therapy, transcranial direct-current stimulation and dry needling. It should be underlined that combination of modalities more closely represents current practice in physiotherapy for women with PVD.

This presentation will provide an update of the evidence supporting the effectiveness of physiotherapy modalities for treating PVD. The specific objectives are:

- Present and discuss the effectiveness of various isolated physiotherapy modalities in women with PVD;
- Present and discuss the effectiveness of combined physiotherapy modalities in women with PVD. Findings from a large randomized clinical study on the efficacy of multimodal physiotherapy in women with provoked vestibulodynia will be discussed;
- Discuss these modalities with a clinical perspective to facilitate their integration in clinical practice.

M. Morin, M-S. Carroll, S. Bergeron. Systematic review of the effectiveness of physical therapy modalities in women with provoked vestibulodynia. *Sex Med Rev*, 2017.

A. Morin, G. Léonard, V. Gougeon, M-P. Cyr, G. Waddell, Y-A. Bureau, I. Girard, **M. Morin.** Efficacy of transcranial direct current stimulation in women with provoked vestibulodynia. *American Journal of Obstetrics and Gynecology*, 2017; 216(6): 584.e1-584.e11.

M. Morin, C. Dumoulin, S. Bergeron, M.H. Mayrand, S. Khalifé, G. Waddell, M.F. Dubois. Provoked vestibulodynia (PVD) Study Group. Randomized clinical trial of multimodal physiotherapy treatment compared to overnight lidocaine ointment in women with provoked vestibulodynia: Design and methods. *Contemp Clin Trials*. 2016 Jan;46:52-9.

Posterior tibial nerve stimulation

Doreen McClurg

Posterior tibial nerve stimulation (PTNS) is a form of peripheral neurostimulation targeted towards symptom relief of OAB and UUI. Indirect access to the sacral plexus is achieved by intermittent, electrical stimulation of the PTN which lies behind the medial malleolus. PTNS may be minimally invasive, involving the insertion of a fine needle close to the nerve (Percutaneous TNS) or non-invasive, using skin surface electrodes applied to the medial malleolar area (Transcutaneous TNS).


Although the full mechanism of action of treatment effect for PTNS is not yet understood it is thought the observed effects may be related to neuroplastic reorganisation of sacral spinal reflexes and cortical excitability.

This presentation will update the application of and evidence for

- Percutaneous tibial nerve stimulation for the treatment of UI;
- Transcutaneous tibial nerve stimulation for the treatment of UI;

Comparisons will include no active treatment, another treatment, percutaneous versus transcutaneous. Specific populations e.g. neurological will be included as will other factors that may affect outcome tolerability, adverse effects,

Dumoulin C, Adewuyi T, Booth J, Bradley C, Burgio K, Hagen S, Hunter KF, Imamura M, Morin M, Morkved S, Thakar R, Williams K. (2017) *Adult Conservative Management*. In Abrams PH, Cardoza L, Khoury AE and Wein A, eds.: 6th Ed. *International Consultation on Urinary Incontinence*, Plymouth United Kingdom: Health Publication Ltd. Volume 2, pages 1512-1521.

Margaret Sherburn 

Affiliations to disclose*:

Nil

* All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

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Institution (non-industry) funded

Sponsored by:



Introduction - Lifestyle interventions 

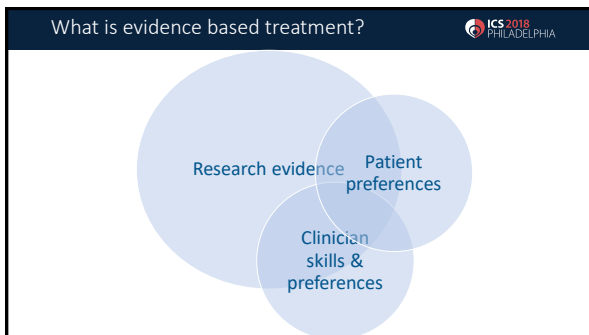
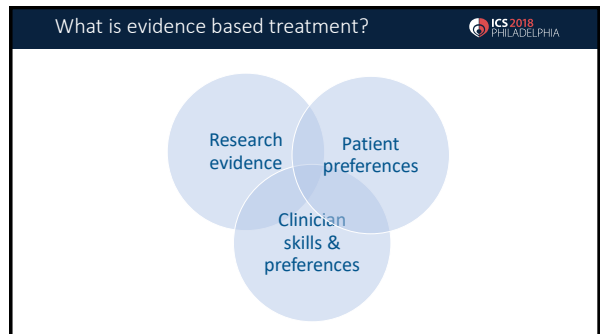
Drum roll


This is THE text:

Dumoulin C, Adewuyi T, Booth J, Bradley C, Burgio K, Hagen S, Hunter KF, Imamura M, Morin M, Morkved S, Thakar R, Williams K. (2017) *Adult Conservative Management*. Committee 12.

In Abrams PH, Cardoza L, Khoury AE and Wein A, eds.: 6th Ed. *International Consultation on Urinary Incontinence*, Plymbridge United Kingdom: Health Publication Ltd. Volume 2, pages 1443-1628.

Evidence presented today gathered from articles published July 2011 to Sept 2015



What do levels of evidence actually mean? 

Level 1 involves **meta-analysis** of trials (RCTs) or a **good quality RCT**, or 'all or none' studies in which no treatment is not an option,

Level 2 includes "**low**" quality RCT (e.g. < 80% follow up) or meta-analysis (with homogeneity) of good quality **prospective 'cohort studies'**, including parallel cohorts, where those with the condition in the first group are compared with those in the second group.

Level 3 **good quality retrospective 'case-control studies'** where a group of patients who have a condition are matched appropriately (e.g. for age, sex etc) with control individuals who do not have the condition.

good quality 'case series' where a complete group of patients all, with the same condition/disease/therapeutic intervention, are described, without a comparison control group.

Level 4 **expert opinion** were opinion is based not on evidence but on 'first principles' (e.g. physiological or anatomical) or bench research. The Delphi process can be used to give 'expert opinion' greater authority

Grades of recommendation



Grade A depends on consistent level 1 evidence and often means that the recommendation is effectively mandatory and placed within a clinical care pathway.

Grade B depends on consistent level 2 and or 3 studies, or 'majority evidence' from RCT's.

Grade C depends on level 4 studies or 'majority evidence' from level 2/3 studies or Delphi processed expert opinion.

Grade D "No recommendation possible" would be used where the evidence is inadequate or conflicting

What are lifestyle interventions?



They are:

- interventions in management of **lifestyle-related health conditions**
- low cost, non-invasive changes to lifestyle, such as:
 - weight loss
 - dietary advice
 - fluid intake modification
 - reduction of caffeinated, carbonated and alcoholic beverages
 - avoidance of constipation
 - smoking cessation
 - alteration of physical activity
 - reduction in lifting and coughing

Do you use any other interventions not in the list above?

How do you use each of these interventions?

Prevention



Are lifestyle modification interventions effective in the **prevention** of UI and prolapse?

No robust evidence, so no evidence based recommendations can be made

An area for future research

Lifestyle interventions for Treatment of UI & POP



Are lifestyle modification interventions better than no treatment, placebo, or control in the **treatment** of UI and prolapse?

Variable evidence so take each in turn.

For UI - Weight loss



Level of evidence: 1 **Grade of recommendation: A**

From 1 RCT (Phelan et al 2012)

Each Kg weight loss reduced odds of developing UI at one year by 3%

Cohort study (Auward et al 2008)

Weight loss of >5kg from initial weight in obese or overweight women reduces severity of UI & improves QoL

Systematic review (Vissers et al 2014) n = 6 studies

Weight loss should be considered standard practice for overweight (& obese) women with UI

For UI - Physical activity



Level of evidence: 3 **Grade of recommendation: C**

No robust RCT's

Moderate Exercise:


Low level evidence to suggest that moderate exercise decreases the incidence of UI

Vigorous Exercise:

No recommendations can be made. Need robust RCT's

Lifetime Physical activity:

Lifetime strenuous activity was not associated with SUI or odds of developing SUI (Nygaard et al 2015)


For UI - Smoking 

Level of evidence: 3 **Grade of recommendation: C**


No robust RCT's


1 pilot cohort study investigated the effect of smoking cessation on OAB symptoms – no significant outcomes


Data suggests that smoking increases the risk of more severe UI
(Wyman et al 2014)

For UI - Fluid intake and caffeine 

Level of evidence: 2 **Grade of recommendation: B**


Fluid intake: 
Fluid intake may play a minor role in the pathogenesis of UI

Caffeine: 
1 RCT, 1 Epidemiological study: Decreasing caffeine intake improves continence and related symptoms, urgency and frequency
(Davis et al 2013, Wells et al 2014)

For UI - Constipation 


Level of evidence: 3 **Grade of recommendation: none**

No new trials (since 5th ICI) on constipation were found, so evidence suggests that **chronic straining may be a risk factor** for development of UI

For UI & POP 


Is **one** lifestyle modification intervention **better than another?**

No robust evidence, so no evidence based recommendations can be made


Lifestyle interventions and POP 

Aims of conservative treatment in the management of POP:

- prevent the prolapse becoming worse
- decrease frequency or severity of symptoms caused by prolapse:
 - pelvic pressure,
 - vaginal bulging,
 - backache,
 - urinary, bowel and sexual dysfunction
- prevent or delay of the need for surgery.

What lifestyle interventions for POP? 

- Weight loss
- Reduce exacerbating activity:
 - lifting – exercise & occupation
 - high impact exercise
 - coughing
- Treat constipation

Lifestyle interventions and POP 


Are lifestyle modification interventions effective in the **prevention** of prolapse?
Level of Evidence: 3 **Grade of Recommendation: D**

Evidence linking **physical activity, occupation, body weight, smoking, low Vit D** with an increased risk for POP is weak and inconclusive.
(Nyggaard et al 2014, Elbiss et al 2015, Estanol et al 2015, Lonnee-Hoffman et al 2015)

Overall evidence is conflicting,
 due to different ways of defining prolapse?

Two new, low risk studies concluded that **constipation** was associated with prolapse symptoms and having prolapse surgery, contributing more evidence of an association.
(Bezerra et al 2014, Elbiss et al 2015)

Level of Evidence: 3 **Grade of Recommendation: C**
New recommendation; Majority evidence of an association


Lifestyle interventions and POP – Weight loss 

Are lifestyle modification interventions better than no treatment, placebo, or control in the **treatment** of POP?
Level of Evidence: 2 **Grade of Recommendation: D**

Evidence from secondary analysis of one robust trial regarding **weight loss** in the treatment of POP (PRIDE Trial).
(Myers et al 2012)

The trial was in overweight and obese women with UI, some of whom had POP. Weight loss in both groups led to an improvement in POP, however there was no relationship between degree of weight loss (intensive vs normal weight loss programme).


Conclusion: Any weight loss may improve POP in overweight or obese women with UI.

Future research directions 


Constipation: Trials of interventions for constipation are needed to assess their effectiveness in preventing/treating POP.

Occupation/heavy lifting, and bodyweight: These interventions need to be assessed rigorously:



- Use instruments with sound psychometric properties.
- Consider founding variables - to overcome recall bias in assessing lifetime occupational history, when comparing POP in women currently employed in heavy labour jobs versus others.
- Use valid, reliable and consistent outcome measures across studies
- **POP symptoms** should be the primary outcome in studies,
 - then **POP anatomical severity**


So it's over to you ... 

*Do you use any other interventions not discussed in this talk?
 How do you use each of those interventions?*



Consider a question/topic you'd like to discuss today
 &
 write it down now!

Chantale Dumoulin 

Affiliations to disclose*:

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Funding for speaker to attend:
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EVIDENCE FOR PFMT OR OTHER TREATMENTS FOR PELVIC FLOOR DYSFUNCTIONS IN WOMEN

Chantale Dumoulin, Ph.D., Physiotherapist
 Professor, School of rehabilitation, Faculty of Medicine, University of Montreal
 Canadian Research Chair in Urogynecological Health and Aging, Research Center
 Institut Universitaire de Gériatrie de Montréal




Content:

- Sources: International Consultation on Incontinence and Cochrane Reviews
- Method
- Is PFMT effective in the prevention and treatment of urinary incontinence (UI)?
- What is the most effective PFMT program?
- Are cones, ESstim and MStim effective in the treatment of UI?
- Is PFMT effective for prevention and treatment of POP?

3

Source: International Consultation on Incontinence Books


- Created in partnership with the International Consultation on Urological Diseases
- Updated every 4 years
- 2 volumes with 23 chapters on incontinence
- Includes over 200 contributors
- A key text to refer to in clinical practice or when planning future research.



4

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5

Method:

- **Literature search:** Cochrane Incontinence group (published abstracts and papers)
- **Trial assessment:** Consort Statement
- **Risk of bias assessment:** Cochrane Collaboration methodology



6

Levels of evidence

Level 1 evidence (incorporates Oxford 1a, 1b) : usually involves meta-analysis of trials (RCTs) or good-quality randomized controlled trial.

Level 2 evidence (incorporates Oxford 2a, 2b and 2c): includes "lower"-quality RCTs (e.g. < 80% follow-up) or meta-analysis (with heterogeneity) of good-quality prospective cohort studies".

Level 3 evidence (incorporates Oxford 3a, 3b and 4) includes good-quality retrospective case-control studies or good quality "case series".

Level 4 evidence (incorporates Oxford 4) includes: expert opinion where the opinion is based not on evidence but on "first principles" (e.g. physiological or anatomical) or bench research.

Grade of Recommendation

Grade A recommendation depends on consistent level 1 evidence and means that the recommendation is **effectively mandatory and placed within a clinical-care pathway**.

Grade B recommendation: depends on consistent level 2 and or 3 studies, or "majority evidence" from RCTs.

Grade C recommendation: depends on level 4 studies or "majority evidence" from level 2/3 studies or Dephi processed expert opinion.

Grade D: "No recommendation possible"

Are pelvic floor muscle training effective in the prevention or treatment of UI?



PFMT for Prevention



- **Prevention:** Evidence Level 2; GRADE C (New)
1 RCT in elderly women (N= 359 continent women 0-5 leakages per year)

Intervention: multi-component behavioral modification program, PFMT, Bladder Training, and other behavioral skills delivered in a 2-hour class followed 2-4 weeks later by an individualized session to test PFMT technique and reinforce adherence

Control: no intervention

- **Results:** After 12 months, continence status was the same or better in 56% of the prevention group compared to 41% of the control ($p=0.01$).
- Relatively high rate of non-completion : (97/238 in the treatment group and 65/242 in the control group).

PFMT for treatment



- **Treatment:** Evidence Level 1; GRADE A (Unchanged)

Intervention and control : 31 trials comparing PFMT to no treatment or sham

Results: PFMT cure or improve symptoms of stress and all other types of UI. It may reduce the number of leakage episodes and the quantity of leakage, while improving reported symptoms and quality of life (Dumoulin, Cacciari, Hay Smith, Cochrane review update, September 2018 New)

Benefits are shown across:

- age cohorts and in various cultural contexts
- UI type (UUI, MUI New)
- using several different training regimens (mobile technology New)
- assessed by multiple outcome measures (cost-effectiveness New)

What is the most effective PFMT program?

12 PFMT variation comparisons (20 new trials):

- **Health professional taught and supervised PFMT** is more effective than self-directed Evidence Level 1; GRADE A (Unchanged)
- **Individual vs group setting:** Data was unclear (small inadequate power trials). One large non-inferiority RCT [ClinicalTrials.gov: NCT02039830](https://clinicaltrials.gov/ct2/show/study/NCT02039830) is being analyzed (N= 362)
- **'Indirect' vs 'direct training' methods:** Based on limited evidence (6 previous RCTs and 2 new RCTs), 'indirect' methods of PFMT (the 'Paula method', 'Sapsford' approach, Hip rotators) are not better than direct PFMT. Evidence Level 2: GRADE B (Unchanged).

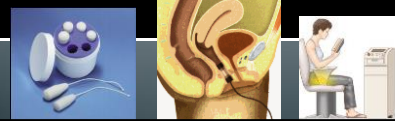
What is the most effective PFMT program?



- **Adding other modalities to PFMT:** No clear added benefit Evidence Level 2; GRADE B (New)
Addition of abdominal exercises : (1 new trial, limited information/abstract only)
Addition of hip muscle exercises (2 new trials)
- **Adding a resistive device (exerciser or spring load device) to PFMT :** No added benefit (2 new trials) Evidence Level 2; GRADE B (Unchanged)
- **PFMT + clinic (2 new trials) or home-based biofeedback (4 new trials) :** No clear benefit Evidence Level 1 and 2; GRADE B (Unchanged) to a PFMT program.

Clinicians should consider patient specificity in adding other modalities

Are cones, EStim and MStim effective in the treatment of urinary incontinence?



Vaginal cones (VC)



- Evidence Level 2; GRADE B (Unchanged)
- **VC vs no active treatment :** effective (5 trials) when used with supervision by a trained healthcare professional (HCP)
- **VC with HCP vs PFMT :** have similar effect (14 trials)
- **VC with HCP plus PFMT vs PFMT :** no added benefit over PFMT (2 studies)

VC treatment may be inappropriate in some cases due to inability to use or potential side effects

Electrical Stimulation (EStim)



- Evidence Level 2; GRADE B (Unchanged)
- All UI - EStim may be more effective than no treatment for improvement (not cure) (N=21)
- SUI/MUI - EStim + PFMT may be of no added benefit to PFMT
- UI/OAB - medical treatments appear to be no more effective than EStim with more side effects

Some women experienced discomfort with the treatment device.

Magnetic Stimulation (Mstim)



11 trials

Evidence Level 2; GRADE D (Unchanged)

- All UI: Unclear benefit of MStim over no treatment or other active treatment
- All UI: Unclear if one type of MStim is better than another

Evidence level 2; GRADE C (Unchanged)

- SUI: MStim + PFMT may not add benefit over PFMT alone

No strong recommendation is possible based on current conflicting evidence

Is PFMT effective to prevent or treat POP?



PFMT for Prevention of POP



Evidence Level 1

- **Postnatal group (13% stage II POP)** : PFMT does not appear to influence the development of POP at 6 months, if treatment is initiated immediately after giving birth
GRADE B (1 RCT, New)
- **Middle-aged women group (with 55% stage II or greater never treated)** : A PFMT intervention delivered 12 years+ after childbirth resulted in fewer prolapse symptoms at 2 years and less uptake of treatment. PFMT can prevent symptoms of POP which develop in the longer term
GRADE B (1 RCT, New)

PFMT for treatment of POP

PFMT vs no treatment or other control (7 new RCTS/13 trials, Unchanged)

- PFMT is effective in reducing pelvic floor symptoms in women with prolapse (Consistent Level of Evidence: 1, Grade of recommendation: A) and in alleviating specific prolapse symptoms (e.g. vaginal bulge) (Majority Level of Evidence: 1, Grade of recommendation: C).
- There is no evidence that PFMT is effective in reducing signs of prolapse based on POP-Q stage (Consistent Level of Evidence: 1, Grade of recommendation: B).

Peri-operative PFMT does not improve POP symptoms in women undergoing surgery for vault POP;
GRADE B (1 RCT, New)

Conclusion

- Overall, *increasing* evidence to support conservative management as first-line treatment for UI and for POP.
- Larger, well designed trials with long-term follow-up using high-quality outcomes (cost-effectiveness) are needed for prevention and treatment.

Acknowledgments


- Authors of the International Consultation on Incontinence Chapter 12
- Cochrane Incontinence Group






Thank you!

VESTIBULODYNIA – EVIDENCE FOR PHYSIOTHERAPY

Mélanie Morin, PT, Ph.D

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Affiliations to disclose¹:

None

* All financial ties (over the last year) that you may have with any business organization with respect to the subjects mentioned during your presentation.


Funding for speaker to attend:

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Objectives



- 1 Discuss the effectiveness of various **isolated** physiotherapy modalities in women with vestibulodynia
- 2 Discuss the effectiveness of **combined** physiotherapy modalities in women with PVD (including findings from a large randomized clinical study on the efficacy of multimodal physiotherapy in women vestibulodynie)
- 3 Discuss these modalities with a clinical perspective to facilitate their integration in clinical practice.

Case study




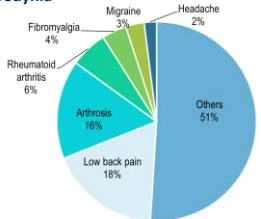
Florence

- 22 year old, nulliparous
- Vulvodynia

Context

Chronic vulvar pain or vulvodynia

Prevalence 8%¹ – 21%²

Increase in incidence⁴


1. Harlow (2014); 2. Arnold (2006); 3. Johannes (2010); 4. Danielsson (2003)

Context

Consensus Statement

2015 ISSVD, ISSWSH and IPPS Consensus Terminology and Classification of Persistent Vulvar Pain and Vulvodynia

Jacob Baranov, MD, MSc,¹ Andrew T. Goldstein, MD,² Colleen K. Stoddard, MD, MS,³ Sophie Bergeron, MD,⁴ Caroline Palard, MD,⁵ Dennis Zolotor, MD, MS,⁶ and Deborah Coady, MD, on behalf of the consensus vulvar pain terminology committee of the International Society for the Study of Vulvovaginal Disease (ISSVD), the International Society for the Study of Women's Sexual Health (ISSWSH), and the International Pelvic Pain Society (IPPS)



Florence

- Localized at the entry of the vagina.
- Pain 9/10 during intercourse (or tampon insertion, bike)
- Since her first intercourse (primary) at 16 y old

Vulvodynia

« Vulvar pain of at least 3 months' duration, without clear identifiable cause, which may have potential associated factors »

- > Generalized / localized pain or mixed
- > Provoked, unprovoked and mixed pain
- > Onset (primary/secondary)
- > Temporal pattern (intermittent, persistent, constant, immediate, delayed)


(Obstet Gynecol 2016;127:745-51)

EFFECTIVENESS OF PHYSIOTHERAPY MODALITIES



Which modalities will you most likely use with her?

1. Biofeedback
2. Manual therapy / MSK approaches
3. Dilators
4. Electrotherapy (electrical stimulation, laser, tDCS)
5. Education
6. Others



Physiotherapy modalities

SEXUAL MEDICINE REVIEWS REVIEW

Systematic Review of the Effectiveness of Physical Therapy Modalities in Women With Provoked Vestibulodynia 

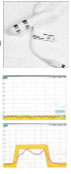
Mélanie Morin, PT, PhD,¹ Marie-Soleil Carroll, MA,² and Sophie Bergeron, PhD¹ Sex Med Rev 2017;5:205–322

- 43 eligible studies
 - 7 randomized controlled trials
 - 20 prospective studies / 5 retrospective studies
 - 6 case reports
 - 6 study protocols

Biofeedback / PFM exercises

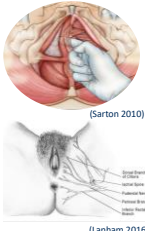
- **Glazer's protocol**
 - 8 sessions of 45-min, x12 w
 - 3x 5s rest
 - 6x 5s maximal contraction
 - 3x 5s rest
 - 5x 10s contraction /10s rest
 - 1x 60s contraction
- Home exercises with biofeedback **2x/day**
 - 60x 10s contraction /10s rest (20 min)

Long-term follow-up favored CBT and vestibulectomy over biofeedback



Manual therapy

- Stretching, massage, desensitization
- Myofascial trigger point release
- Scar mobilization
- Neural mobilization
- Connective tissue manipulation
- Neuromuscular re-education
- Joint mobilization
- Visceral manipulation

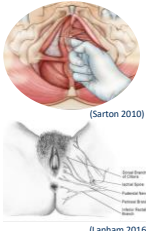


(Sarton 2010)
(Lanham 2016)

(Rosenbaum2008; Prendergast 2017; The overactive pelvic floor book, Padoa & Rosenbaum, 2016 chap 16-18)

Manual therapy

- **Interstitial cystitis and pelvic floor tenderness**
 - RCT n=81, myofascial treatment, 59% had improvement (global response scale) vs massage 26%. Pain non-sign btw groups (Fitzgerald 2012)
 - Prospective study n=42, myofascial treatment, 70% had improvement (Weiss 2001)
 - Prospective study n=21, massage/scar/connective tissue mobilization/dilator therapy, sign. reduction of pain (Oyama 2004)
- **Pelvic floor myalgia**
 - Pilot RCT n=29, 59% improvement in physio vs 58% TP injection steroid+anesthetic mixture (n.s) (Zoorob 2015)




(Sarton 2010)
(Lanham 2016)

Dilators/Insertion techniques

- Studies in the review
 - 3 prospective studies n=10-18 (Idama 2000; Smith 1998; Murina 2008)
 - 72% - 90% cure/improvement
 - Dilation twice daily - 3x/week (5-15 min)

Insertion (tx not well described), 3x8 movements (Murina 2008)

Additional stretching and hold relax not included



Syracuse Medical Devices, Inc.

Electrical stimulation

- Electrical stimulation can act on pain through the improvement of muscle proprioception (active component), the increase in local blood circulation, the decrease of nociceptive signal flows (ie, gate control theory), and the secretion of endorphins
- Studies in the review
 - 2 prospective studies (Vallinga 2015; Nappi 2003)
 - Sign. improvement in pain intensity
 - 1 RCT (Murina 2008) transcutaneous electrical nerve stimulation (TENS)
 - Sign. improvement in pain and sexual function.


Murina 2008
Transcutaneous electrical nerve stimulation (TENS)
20 sessions, 2x/w
Vaginal probe inserted at 20 mm
15 min, 10Hz, pulse 50 ms + 15 min, 50 Hz, pulse 100 µs.

Vallinga 2015 : 80 Hz, 50-180 µs
Nappi 2008 : 1-4 Hz, 0.1-0.3 ms

****Wide variation in parameters studied*****

Transcranial direct-current stimulation (tDCS)

- Meta-analysis supporting of transcranial direct-current stimulation for chronic pain (O'Connell 2011)
- Case report in woman with unprovoked vulvodynia (Cecilia 2008)
- Centralization of pain in women with PVD (Gougeon 2018; Pukall 2016)



Original Research ajog.org

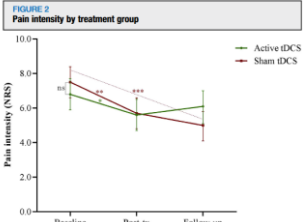
GYNECOLOGY

Efficacy of transcranial direct-current stimulation in women with provoked vestibulodynia

Azzie Morin, MSc; Guillaume Léonard, PT, PhD; Véronique Gougeon, MSc; Marie-Pierre Cyr, MPT; Guy Waddell, MD; Yves-André Bureau, MD; Isabelle Girard, MD; Marlene Morin, PT, PhD

Transcranial direct-current stimulation (tDCS)

A. Morin, G. Léonard, V. Gougeon, M-P. Cyr, G. Waddell, Y-A. Bureau, I. Girard, M. Morin. Efficacy of transcranial direct current stimulation in women with provoked vestibulodynia. AJOG, 2017; 216(6): 584.e1-584.e11.



Time Point	Active tDCS (Mean NRS)	Sham tDCS (Mean NRS)
Baseline	~7.5	~7.5
Post-tx	~5.5	~6.5
Follow-up	~5.0	~6.0

Low level laser therapy

- Pilot RCT in 34 women with provoked vestibulodynia (Lev-Sagie 2017)
 - 78% receiving laser reported improvement compared with 44% in the placebo
 - N.sign for other outcomes






August 5, 2018

ISSVD/ICS comments on the FDA communication on the use of energy-based devices to perform vaginal 'rejuvenation' or vaginal cosmetic procedures

Based on the available evidence, we recommend **against** the use of **LASER** and radiofrequency for the treatment of lichen sclerosus, **vulvodynia**, urinary incontinence, vulvovaginal atrophy, or for "rejuvenation" (a commercial not scientifically defined term) **out** of the setting of properly designed **clinical trials**.


Education

- Vulvar hygiene habits, avoidance of irritants, behavior modification, stress decreasing techniques, sexual function, pain pathophysiology and behavioral modifications to reduce fear/avoidance and catastrophization
 - Prospective study n=85 PVD Avoidance of irritants/dilators. 21% a complete response / 56% partial response (rowler 2000)
 - Prospective study n=25 PVD Educational seminar. Sign. effect on sexual function. No outcome on pain (Brotto 2010)

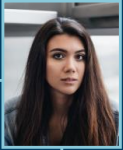
ISOLATED PHYSIOTHERAPY MODALITIES

Physiotherapy modalities including biofeedback, dilators, electrical stimulation and education were consistently effective across studies for decreasing pain.

Further studies are needed as the evidence is derived from only a handful of RCTs and mainly from prospective, retrospective, and case report studies with high risk of bias.




Which modalities will you most likely use with her?



1. Biofeedback
2. Manual therapy / MSK approaches
3. Dilators
4. Electrotherapy (Electrical stimulation, laser, tDCS)
5. Education
6. Others

Multimodal Physiotherapy

- **Multimodal physiotherapy**
 - Recommended as a first-line treatment (ACOG, 2006, Mandal, 2010; Stockdale 2014; Goldstein 2016)
 - Ranked by experts among the most effective treatments (Reed, 2008)
 - Its efficacy has only been evaluated through three small uncontrolled or pilot trials
 - Bergeron, 2002: Retrospective study in 35 women with PVD. Complete or great improvement for 51.4% of participants.
 - Goldfinger, 2009: Prospective study in 13 women with PVD. Complete or great improvement for 77% of participants.
 - Goldfinger 2016: Pilot RCT comparing physio (n=10) and cognitive behavioral therapy (CBT) (n=10). 80% physio vs 70% CBT had reduction of 30% (n.sign.)



There is a need to assess the efficacy of this promising treatment

Randomized controlled trial of multimodal physiotherapy treatment compared to overnight topical lidocaine in women suffering from provoked vestibulodynia

Principal Investigator: Mélanie Morin
 Co-investigators: Chantale Dumoulin, Sophie Bergeron, Marie-Hélène Mayrand, Samir Khalifé, Guy Waddell, Marie-France Dubois, PVD Study Group*

Clinical trials.gov NCT01455350
 Protocol published - *Contemporary Clinical Trials*, 2016, 46, 52-59



Objectives

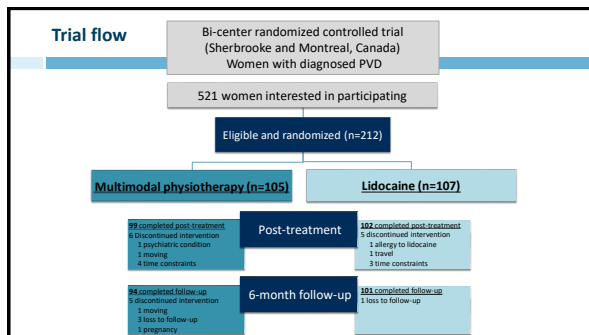
Primary objective

□ To evaluate and compare the efficacy of multimodal physiotherapy and overnight topical lidocaine in reducing pain intensity during intercourse in women with PVD

Secondary objectives

□ To compare the efficacy of both interventions for:

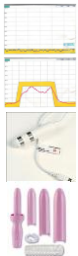
- Pain quality
- Sexual distress and sexual function
- Pain catastrophizing and fear of pain
- Patient's satisfaction and global impression of change



Methodology- Intervention

Multimodal PFM physiotherapy


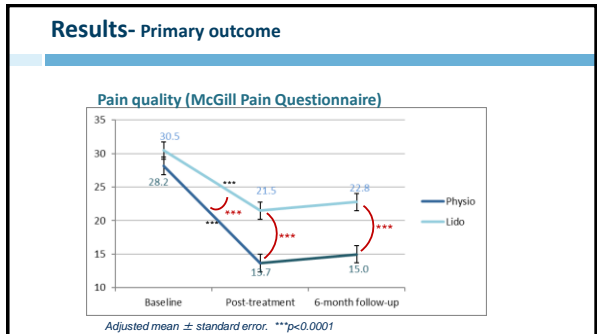
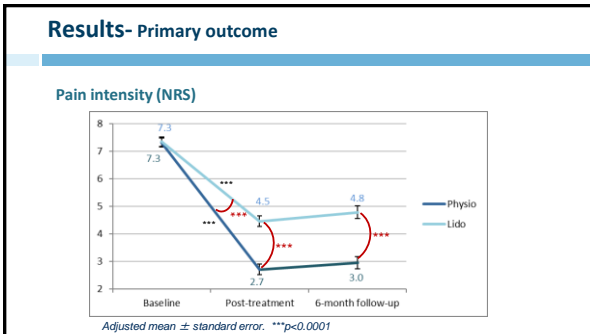
- 10 weekly sessions supervised by experienced physiotherapists
- Each session consisted of (According to Bergeron, 2002; Hartmann, 2007)
 - Education (e.g. pathophysiology, relaxation techniques, etc.)
 - Manual techniques
 - Biofeedback (relaxation, strength, endurance and coordination)
 - Insertion techniques
 - Home exercise program 5 days/week



Methodology- Intervention

Topical overnight lidocaine

- 5% lidocaine ointment (50mg/g, Lidocan®, Odan Lab, 35g) to the vestibule every night for 10 weeks according to Zolnoun et al. (2003)
- Weekly phone call and journal

Results- Secondary outcomes

	Physiotherapy			Lidocaine		
	Baseline	Post-tx	6-month	Baseline	Post-tx	6-month
Sexual distress	31.8 (1.1)	12.4 (1.1)	14.2 (1.2)	30.5 (1.1)	19.0 (1.1)	19.8 (1.2)
Sexual function	21.1 (0.8)	28.9 (0.4)	28.6 (0.4)	21.9 (0.7)	25.5 (0.6)	25.7 (0.6)

Over the clinical cut-off for sexual dysfunction (Wieger, 2005)

Sexual function: Female Sexual Function Index (Rosen, 2000)
 Sexual distress: Female Sexual Distress Scale (DeGrootis, 2002)

Adjusted mean ± standard error. ***p<0.0001

Results- Secondary outcomes

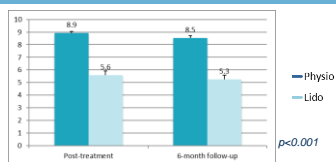
	Physiotherapy			Lidocaine		
	Pré-tx	Post-tx	6-mois	Pré-tx	Post-tx	6-mois
Pain catastrophizing	27.9 (0.9)	10.1 (1.0)	10.6 (1.1)	27.5 (0.9)	15.5 (1.0)	16.2 (1.0)
fear of pain	41.9 (1.5)	22.4 (1.6)	23.3 (1.7)	39.9 (1.5)	27.9 (1.6)	29.1 (1.6)

Pain catastrophizing: Pain Catastrophizing Scale (Silvan, 1995)
 Fear of Pain: Pain Anxiety Symptoms Scale (PASS-20) (McCracken, 2002)

Adjusted mean ± standard error. ***p<0.0001

Results- Secondary outcomes

Satisfaction



Patient's global impression of change

- Women reported being very much or much improved:
 - 77% of women in the physical therapy group compared to 38% in the lidocaine group ($p < 0.001$)

Conclusion

- Multimodal physiotherapy is effective in reducing pain, sexual distress, fear of pain and catastrophizing as well as improving sexual function in women with PVD.
- This information is important for clinicians and women in terms of management strategies.

Multimodal physiotherapy proved to be more effective than a frequently used first-line treatment - overnight lidocaine topical application.



More research are needed to determine the optimal combination of modalities

Acknowledgement

- Dr. Mélanie Morin is supported by a Junior 2 research award from the Fonds de la recherche en santé Québec – Santé
- Laboratory infrastructure and high technology equipment were funded by the Canada Foundation for Innovation
- The RCT was supported by a grant from the Canadian Institutes of Health Research



Thank you !

Merci ☺

Multidisciplinary treatment

Prospective study, Physio+Vestibulectomy n=111 (Goetsch 2007)

- 67% cure

Qualitative retrospective, Physio+Rx+Psycho n=29 (Munday 2007)

- 31 % cure / 93% improved

Retrospective study, Physio+Sexo+Vestibulectomy n=64 (Spoelstra 2011)

- 81% improved

Prospective study, Physio+Psycho+Education=64 (Brotto, 2015)

- 54% improved

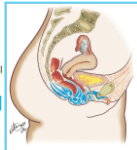
Conclusions

- The evidence regarding multidisciplinary treatment showed positive results. However, no study has thus far investigated the cost-effectiveness of these interventions.

Context

Table 4. 2015 Consensus Terminology and Classification of Persistent Vulvar Pain and Vulvodynia

- Appendix: potential factors associated with vulvodynia*
- Comorbidities and other pain syndromes (eg, painful bladder syndrome, fibromyalgia, irritable bowel syndrome, temporomandibular disorder; level of evidence 2)
 - Genetics (level of evidence 2)
 - Hormonal factors (eg, pharmacologically induced; level of evidence 2)
 - Inflammation (level of evidence 2)
 - **Local anatomical, eg, pelvic muscle overactivity; myofascial, biomechanical; level of evidence 2**
 - Neurologic mechanisms
 - Central (spine, brain; level of evidence 2)
 - Peripheral: neuroproliferation (level of evidence 2)
 - Psychosocial factors (eg, mood, interpersonal, coping, role, sexual function; level of evidence 2)
 - Structural defects (eg, perineal descent; level of evidence 3)



* The factors are ranked by alphabetical order.

(Obstet Gynecol 2016;127:745–51)

Methodology- Intervention

Education

- PFM anatomy and physiology
- Hygiene, lubricant, avoidance of irritants
- PVD: pathophysiology, treatment mechanisms
- Chronic pain / pain cycle
- Urogynecological health (infection vs normal secretion)
- Frequency of mictions, constipation, liquid ingestion
- Sexual function (desire, excitation and orgasm), importance of maintaining unpainful sexual activities, steps toward recovering intercourse
- Relaxation and breathing techniques

Methodology- Intervention

Manual therapy (15-20 min)

- Conjunctive tissue manipulation (if it reproduces patient's symptoms)
- Myofascial release (external)
- Myofascial release, stretching, hold-relax (PFMs and obturator, piriformis, gluteal, adductors muscles)
- Vestibule desensitization (sessions 7-8-9-10)



(Sarton 2010)

Methodology- Intervention

Biofeedback

- Relaxation 2x 30s
- Strength 2x 10 repetitions (ratio 6/12s to 10/20s)
- Coordination (podium or reversed podium) 2 repetitions
- Rapid contractions 45s**
- Endurance 1 min**
- Relaxation 2x 30s



Methodology- Intervention

- **Home exercises** (5 days / week)
 - Deep breathing
 - PFM exercises
 - PFM stretching (1 day/2)
 - Dilator insertion
 - Clock/hold-relax (with 1 finger or dilator)
 - Oscillations (10x 10 movements)
 - Desensitization (≥ session 7)
 - Stretching piriformis, adductors, gluteal muscles (≥ session 8)
- **Exercise journal**
 - Exercises completed (number of repetitions? pain?)
 - Sexual intercourse attempt? Pain?



Does stimulation of a nerve at the ankle really affect bladder function?

Prof Doreen McClurg PhD MCSP

Doreen.mcclurg@gcu.ac.uk

ICS 2018



Affiliations to disclose[†]:

None

† All financial ties (over the last year) that you may have with any business organization with respect to the subjects mentioned during your presentation

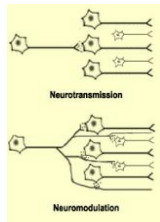
Funding for speaker to attend:

- Self-funded
- Institution (non-industry) funded
- Sponsored by:

Neuromodulator – what is it?



- Neuromodulation is a physiological process which influences the activity in one neural pathway and modulates the pre-existing activity in another synaptic interaction.



Neuromodulator – what does it?



Stimulus used to alter the neural control of the bladder

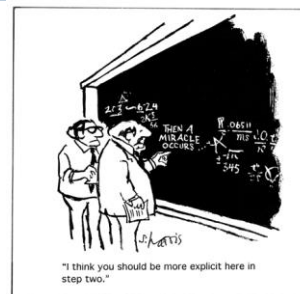
- Sacral neuromodulator (SNM)
- Peripheral or transcutaneous, intravaginal/anal, dorsal penile, TENS over the lumbar region
- Medication e.g. Noradrenaline, dopamine, serotonin
- **Percutaneous tibial nerve stimulation**
- **Transcutaneous tibial nerve stimulation**



- Recent literature suggests both sensory and motor neuromodulatory effects of PTNS. Changes in the **brain cortex** during PTNS similar to those reported by sacral nerve stimulation (SNS) have been described. Different brain effects during chronic and acute sacral neuromodulation in urge incontinent patients with implanted neurostimulators. (Sheldon 2005, Blok 2006)
- **Finazzi-Agro (2009)** and colleagues suggests **plastic reorganization** cortical signalling following PTNS in patients with OAB
- **Danisman and colleagues (2007)** found that PTNS **reduced mast cell** count in female rat bladders.
- **Choudhary and colleagues (2016)** found PTNS increases **bladder compliance** and, subsequently, pressures at which the voiding reflex is initiated in rats with overactive detrusors stimulated by acetic acid; increased bladder storage capacity was achieved via inhibition of afferent signalling
- Several very recent studies have also suggested a role of **certain neurotransmitter receptors** in the mechanism of action for PTNS (Matsua and colleagues 2013, Ferroni and colleagues 2015, Zhang and colleagues 2015)
- **Xiao and colleagues** found that PTNS ineffective in animals with **acute spinal cord transection**

Mechanism of Action -neuromodulation

Largely unknown mechanism of action



Neuromodulation – why use it?

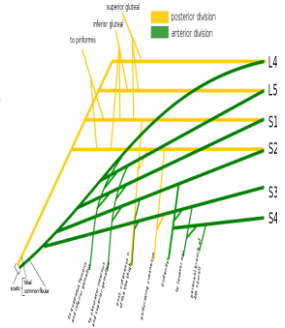


- Neuromodulation offers a minimally invasive, non-ablative, and reversible means to treat UI, voiding dysfunction (e.g Fowler’s syndrome) and potentially FI, cystitis, pelvic pain

Why Tibial Nerve?



- The tibial nerve is a mixed sensory-motor nerve that originates from anterior spinal roots L4 through S3, which also contribute directly to sensory and motor control of the urinary bladder and pelvic floor

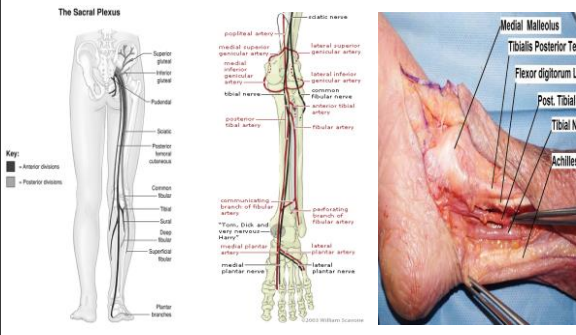


- Accessible

The tibial nerve (posterior) stems from L4, S1, S2 & 3



The Sacral Plexus



The History of Neuromodulation



Thursday 30th August 2018

SUFU Lecture

16:00 - 16:30

Hall C

Capacity: 250

Speakers

Kathleen C Kobashi

Development



- 1983 McGuire, et al. Evaluated 22 patients with varying pathologies using transcutaneous PTN stimulation and reported improvement in all but 2 patients
- 1997 - InterStim Therapy (Sacral Neuromodulation) FDA approval 1997

Sievert et al J. European Urol 2008.

Percutaneous Posterior Tibial Nerve - history



- The methodology was first invented by Dr. Marshall Stoller at UCSF Medical Center, San Francisco, and was first known as the SANS.
- In 2000, Dr. Stoller reported that 98 patients were treated with the SANS device with an approximate 80% success rate in treating urge incontinence syndrome, including urgency and frequency.
- In a corroborative multi-center study by Govier, et al., (2001) 71% of patients achieved success.
- Additionally, in a study by Shafik, et al., (2003) 78% of patients achieved a long-term improvement in faecal incontinence when treated with PTNS.

Percutaneous Posterior Tibial Nerve



- Since 2005 Uroplasty has marketed the Urgent PC Neuromodulation System



eCOIN
Medtronic NURO system

Trancutaneous Posterior Tibial Nerve Stimulation



The evidence in various populations – Women OAB/UII (11 protocols ICI 2017)



(P)TNS V No Active treatment in women

Summary:

The three included studies (2 percutaneous) were small (35-43 participants).¹⁻³

All were generally assessed as having a high risk of bias.

Data available from two studies on women with UII or OAB suggests PTNS may be more effective than no active treatment in improving symptoms and quality of life, although no data were available on cure (**Level of Evidence: 2**).

No serious adverse effects associated with either active or sham treatment (**Level of Evidence: 2**).

Recommendations:

For women with UII or OAB, (P)TNS may be more effective than no active treatment in symptom control (**Grade of Recommendation: C New**).

More studies with larger sample sizes and consistent and clear reporting of core outcomes would be beneficial in reaching a conclusion on the effectiveness of PTNS over no active treatment.



Is One Type of (P)TNS Better than Another in the Treatment of UI?

No study was found for this comparison.

Is (P)TNS Better than Other Treatments for Treatment of UI?

Summary:

The five included studies (4 percutaneous) were small (36-56 participants).⁴⁻⁸

All assessed as having a high risk of bias.

Recommendations:

There is no significant difference between percutaneous (P)TNS and tolterodine in terms of quality of life, (**Grade of Recommendation: B New**).

(P)TNS may be considered for women as it is associated with fewer and less bothersome adverse effects than those from drug treatment (**Grade of Recommendation: B New**).



Does the Addition of (P)TNS to Other Treatments Add any Benefit in the Treatment of UI?

Summary:

Three small studies (all percutaneous) were included (40-52 participants).⁹⁻¹¹

All high risk of bias.

Data from one study suggests that the addition of PTNS to PFMT and bladder training was more effective in improving symptoms and quality of life than PFMT and bladder training alone in women with UII (**Level of Evidence: 2**).

Data from two studies suggest that adding percutaneous (P)TNS to drug treatment resulted in a greater improvement in quality of life than the drug treatment alone in women with OAB, and this effect was sustained for a longer term (6 months) for the treatment with PTNS than the treatment without P(P)TNS (**Level of Evidence: 2**).

Adverse events appear uncommon for either group in the same study.

Recommendations:

P(P)TNS may be considered for symptom control when chosen in combination interventions by women with UII or OAB (**Grade of Recommendation: B New**).



Parkinson's

(P) Tibial nerve stimulation has been shown to be effective in short term management of OAB symptoms in patients with PD.¹²

Acute percutaneous TNS has been reported to increase functional bladder capacity in PD, and following chronic stimulation urinary frequency and urgency urinary incontinence reduced. However, long term outcomes in PD are lacking.¹³

Transcutaneous tibial nerve stimulation was found effective in the treatment of LUTS in 13 patients with PD, with benefits in urinary urgency and nocturia episodes, as well as urodynamic parameters.¹⁴

SCI and Parkinson patients with neurogenic DO have been treated with (P)TNS. (P)TN seems to increase cystometric bladder capacity and bladder volume at which DO and associated leakage occurs.¹⁵



Multiple sclerosis

Gobbit et al. looked at the effect in 21 MS patients. Eighty-nine percent of patients reported a treatment satisfaction of 70%. Significant improvement in QoL was seen in most domains of the King's Health QoL questionnaire.¹⁶

Kabay et al. looked at the clinical and urodynamic effects in MS and Parkinson's disease. They found significant clinical and urodynamic improvements, although it was impossible to completely suppress DO.¹⁷

De Seze et al. looked at transcutaneous (P)TNS in 70 MS patients. With daily stimulation sessions, they showed clinical improvement in urgency and frequency in more than 80% of patients at three months. They also observed an initial acute cystometric response in > 50% of the patients without correlation with clinical efficiency. There still is debate about the possibilities to really influence voiding behaviour via the posterior tibial nerve.¹⁸



Overview of effect on neurogenic bladder + Long term effect

A recent meta-analysis by Gaziev et al. (2013) (PercutaneousTNS) including MS and Parkinson's disease showed mixed findings on success rate ranging from approximately 40 % to 100 % for neurogenic overactive bladder or urinary retention.¹⁹

77% of participants with an initial positive response to 12 weekly percutaneous (P)TNS treatments safely sustained symptoms improvement to 3 years with an average of 1 treatment per month.²⁰

Percutaneous (P)TNS treatment also leads to improvement in open label uncontrolled studies patients with multiple sclerosis which was observed to persist for one year in one recent study.²¹

In 2015 Kabay et al. published the results of a retrospective case-controlled study with 34 MS patients enrolled to percutaneous (P)TNS treatment. 21 patients completed the one year P(P)TNS treatment with controls at 6, 9 and 12 months of therapy. After 12 weeks of therapy, P(P)TNS was applied at 14-day intervals for 3 months, then 21day intervals for 3 months, and in the end for another 3 months with 28-day intervals. The reported results demonstrate an excellent durability of PTNS over 12 months.²²



Nocturia

One study percutaneous (P) TNS demonstrated in 214 individuals a favourable outcome for nocturia reduction in the active treatment group (2.9 at baseline to 2.1 with treatment) that was statistically superior to the effect of sham (2.9 to 2.6, net benefit of active over placebo -0.4 reduction).

Of note, there were more individuals over 65 years of age (50%) compared to the sham group (41%) biasing against demonstrating benefit if it were true that older adults responded less well.^{23,24}



OAB/UII Males and females

The evidence on which to base recommendations for best practice in the use of (P)TNS to treat OAB/UII in men and women is sparse, for both percutaneous and transcutaneous PTNS.

Support the use of percutaneous PTNS when less intensive and invasive behavioral treatment options have failed (**Level of Evidence: 1**)

Suggestion that percutaneous (P)TNS may be as effective as some drug therapy, making it a viable alternative (**Level of Evidence: 2**).

Only two small trials investigated transcutaneous (P)TNS but the promising results indicate that further well-designed and reported trials would allow decisions to be made about the place of transcutaneous PTNS in the treatment algorithms for OAB/UII in men and women.

Health economic information is required to establish the cost effectiveness of the different forms of PTNS, particularly in comparison to pharmacotherapy.



Recommendations:

In adults with OAB/UII percutaneous (P)TNS is better for improving UII than no treatment or sham and should be offered to adults with UII/OAB who do not achieve satisfactory results from first-line lifestyle and behavioural interventions or drug therapy. (**Grade of Recommendation: B New**)

At least weekly percutaneous (P)TNS sessions should be offered during an active treatment program with regular top-ups provided to sustain benefits for up to three years. (**Grade of Recommendation: B New**)

Transcutaneous (P)TNS is a safe treatment option and may be offered to frail older adults with UI or urinary symptoms however definitive evidence of effectiveness is needed. (**Grade of Recommendation: C New**)

Percutaneous (P)TNS can be offered as an alternative to tolterodine for OAB/UII in adult men and women. (**Grade of Recommendation: B New**). Oxybutynin may be considered in addition to percutaneous PTNS in adults with DO. (**Grade of Recommendation: B New**)



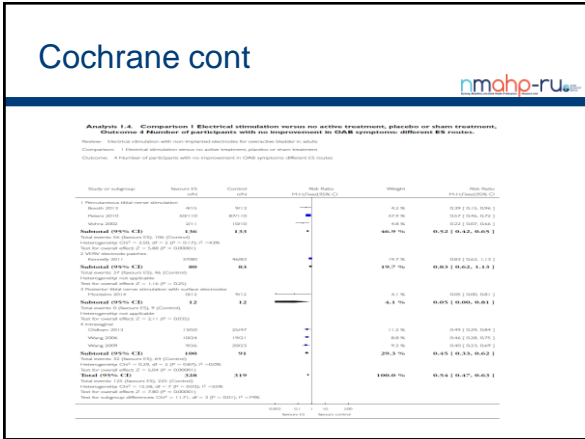
Cochrane

Stewart F, Gameiro OLF, El Dib R, Gameiro MO, Kapoor A, Amaro JL. Electrical stimulation with non-implanted electrodes for overactive bladder in adults. Cochrane Database of Systematic Reviews 2016, Issue 4. Art. No.: CD010098. DOI: 10.1002/14651858.CD010098.pub3.



A further subgroup analysis found the following routes of ES to be more effective than no active treatment, placebo or sham treatment (Analysis 1.4)

- Percutaneous tibial nerve stimulation (RR for no improvement 0.52, 95% CI 0.42, 0.65; n = 269, three studies)
- Posterior tibial nerve stimulation with surface electrodes (RR for no improvement 0.05 95% CI 0.00 to 0.81; n = 24, one study)
- Intravaginal (RR for no improvement 0.45, 95% CI 0.33 to 0.62; n = 191, three studies)
- However, one trial of ES delivered through surface electrode patches, compared to sham patches, found a difference which was not statistically significant (RR for no improvement 0.83, 95%CI 0.62 to 1.13; n = 163) (Kennelly 2011).



Transcutaneous Electrical Nerve Stimulation (TENS) for Lower Urinary Tract Disorders in Parkinson's Syndrome (UROPARKTENS)

- ClinicalTrials.gov Identifier: NCT02190851
- University Hospital Toulouse
- 20 minutes daily for 3 months – active or sham
- PD or MSA. 220 participants
- Main outcome Patient Global Impression of Improvement

ELECtric: ELECtric Tibial nerve stimulation to Reduce Incontinence in Care homes

- ClinicalTrials.gov Identifier: NCT03248362
- RCT comparing transcutaneous to sham tibial nerve stimulation
- 12 session programme, twice weekly for 30 mins for 6 weeks
- 500 care home residents
- UI weekly, may be cognitively impaired, uses toilet for some bladder evacuation

STARTUP Trial

- ISRCTN12437878.
- RCT comparing transcutaneous to sham tibial nerve stimulation
- 208 participants with PD and bladder problems
- Transcutaneous TNS for 6 weeks, twice weekly

ICS Neuro Nov 2014

- The eCoin™ implantable tibial nerve stimulation device for overactive bladder syndrome improves quality of life**
- Sand P¹, English S², Lucente V³, Clark M⁴, Kaaki B⁵, Gilling P⁶, Meffan P⁷, Sen S⁸, MacDiarmid S⁹
- Abstract 442

ICS 2018

- Abstract 143 Pilot study evaluating the effects of transcutaneous tibial nerve stimulation on urinary symptoms in female patients with multiple sclerosis reporting overactive bladder
- Abstract 431 A prospective, multicenter, international clinical trial to assess the efficacy and safety of a novel wireless implantable tibial nerve stimulator for the treatment of patients with refractory overactive bladder (OAB): 3-years results
- Abstract 442 The eCoin™ implantable tibial nerve stimulation device for overactive bladder syndrome improves quality of life
- SUFU lecture - History of Neuromodulation Kathleen Kobashi 30th Aug 2018 16.00-16.30 Hall C
- Abstract 745 Place of Posterior Tibial Nerve Stimulation in management of Lower Urinary Tract Symptoms in young men

- 1 Effectiveness of **Bilateral** PTNS Compared to **Unilateral** PTNS for the Treatment of Overactive Bladder/Urge Incontinence: Women & Infants Hospital of Rhode Island, USA
- 2 Home Neuromodulation of the Neurogenic Bladder in **Chronic Spinal Cord Injury** With Transcutaneous Tibial Nerve Stimulation. The University of Texas Health Science, USA
- 3 Effects of Transcutaneous Spinal Direct Current Stimulation in **Incomplete Spinal Cord Injury**. The University of Texas Health Science Center at Houston, Houston, Texas, USA
- 4 Percutaneous Tibial Nerve Stimulation **Maintenance**: Monthly Therapy or Per Patient Requested. Harbor UCLA Medical Center, Torrance, California, United States
- 5 **eCoin** Tibial Nerve Stimulation for OAB Active. The Clark Center for Urogynecology, Newport Beach, California, United States
- 6 A Study of **Transcutaneous Electrical Nerve Stimulation for Overactive Bladder**. University of Rochester Medical Center, Rochester, New York, United States
- 7 Transcutaneous Electric Nerve Stimulation (TENS) for the Treatment of **Nocturnal Enuresis in Children**. Albany Medical College, Albany, New York, United States
- 8 Overactive Bladder Treatment Using **StimRouter** Neuromodulation System: A Prospective Randomized Trial. Del Sol Research, Tucson, Arizona, United States
- 9 PTNS Versus Sham Efficacy in Treatment of **BPS**. New York University School of Medicine, New York, New York, United States
- 10 **CAN-Stim** Compared to SNS in Treatment of Urinary Urgency Incontinence With Wireless Neuromodulation Technology. University of California Irvine Medical Center, Orange, California, United States
- 11 A Trial of Transcutaneous Nerve Stimulation for **OAB**. St Josephs Health Care, London, Ontario, Canada

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