

# Evidence for e-stim in adults with pelvic floor dysfunction

(this is a short presentation)



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# Conclusions



- ⌘ There is no added benefit of adding e-stim to pelvic floor muscle training

(Hay-Smith in Abrams et al ICI 2009, Berghmans in Bo et al 2007, Shamliyan et al 2008)

- ⌘ Weak evidence for OAB, few studies and protocols variable

(Hay-Smith in Abrams et al ICI 2009)

- ⌘ No evidence for pain relief

(Hanno in Abrams et al ICI 2009)

- ⌘ In neurological conditions, little research is done and extensive clinical evidence is lacking.

(van Rey & Heesakkers Urol Int 2008)

There may be little  
evidence...  
But we have come  
a long way



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# Evidence for e-stim to treat SUI



- ⌘ Lack of consistency in e-stim protocols
    - ☒ Lack of understanding of physiological principles
  - ⌘ Insufficient evidence to judge whether e-stim is better than no or placebo treatment
    - ☒ Difficult to recommend an optimal protocol
  - ⌘ Insufficient evidence to judge whether e-stim is better than vaginal oestrogen or cones
  - ⌘ PFMT seems to be better than e-stim though conclusive evidence is lacking
  - ⌘ No extra benefit in adding e-stim to PFMT
- (Berghmans in Bø et al 2007, Hay-Smith in Abrams et al 2009)

# E-stim for SUI



## ⌘ Rationale:

- ☑ Strengthen the PFM, using current parameters which cause least discomfort
  - ☒ Improving the resting and active closure of the urethra
  - ☒ Improving vascularity of urethra and bladder neck
- ☑ Biofeedback to learn a PFM contraction through duplication of the sensation to contract (no studies on this)

(van Rey & Heesakkers 2008)

# Parameters used in studies for SUI

(Berghmans in Bø et al 2007)

## ⌘ Pulse frequency:

- ☒ 20Hz to 100Hz, commonly combinations of low and higher Hz; eg. 10 & 35Hz, 12.5 & 50Hz

## ⌘ Pulse duration:

- ☒ 0.08msec to 0.4msec

## ⌘ Duty cycle:

- ☒ 1:1 to 1:3

## ⌘ Intensity: variable ...

- ☒ Max tolerable, to muscle contraction, low intensity, add a PFM contraction to e-stim

## ⌘ Electrode placement:

- ☒ Vaginal most common, perineal body & pubic symphysis, perineum & buttock

## ⌘ Duration & frequency of sessions:

- ☒ 10 – 18 in clinic, x1-3/week
- ☒ At home, daily for 8 weeks, to daily for 6 months

# Evidence for e-stim to treat OAB

## ⌘ Weak evidence for effectiveness

- ☑ Alone or with PFMT

- ☑ Trend in favour of e-stim over no or placebo treatment

- ☑ No evidence for e-stim over other treatments for OAB (drug, PFMT) or adding e-stim to PFMT

## ⌘ However, flawed studies due to unclear biological rationale

- ☑ ie. Aiming for a PFM contraction to inhibit detrusor, or just stimulation of pudendal nerve?

(Berghmans in Bø et al 2007)

# Unclear rationale for e-stim/neuromodulation for Detrusor inhibition

## ⌘ 3 hypotheses:

### 1. Stimulation of autonomic nerves to Detrusor:

- ⊞ Hypogastric efferents (sympathetic, postganglionic, unmyelinated, small)
- ⊞ Pelvic splanchnic efferents (parasympathetic, preganglionic, myelinated, similar size to  $A\delta$ )

## ⌘ IMPLICATIONS

- ⌘ Parasympathetics could be stimulated (ganglia in the vicinity of the target tissue)
- ⌘ Sympathetics, in practice, cannot (?) Only post-ganglionic nerve fibres in pelvis

### 2. Stimulate sensory afferents of pudendal n, via an intact sacral reflex arc

#### ⌘ Stimulate motor afferents to automatically inhibit detrusor?

- ⊞ Increased PFM voluntary strength provides more inhibition of detrusor?

### 3. A learning process through awareness of PFM contraction during a detrusor contraction?

(Berghmans in BØ et al 2007)

# To achieve inhibition of detrusor by e-stim - neuromodulation



⌘ Electrically stimulating **all** nerves

Hypothesis: electrical stimulation may normalise a disturbed balance in neurotransmission

# Parameters used in studies for OAB



- ⌘ Duration of treatment:
  - ☒ Single session to 4 months
- ⌘ Intensity:
  - ☒ 5mA to max tolerable intensity
- ⌘ Frequency of current:
  - ☒ 4Hz – 20Hz
- ⌘ Pulse duration:
  - ☒ 0.1msec to 1msec, 0.2msec most commonly
- ⌘ Duration of session:
  - ☒ 20 mins to several hours
- ⌘ Frequency of treatment:
  - ☒ Once to twice per day

(Berghmans in Bø et al 2007)

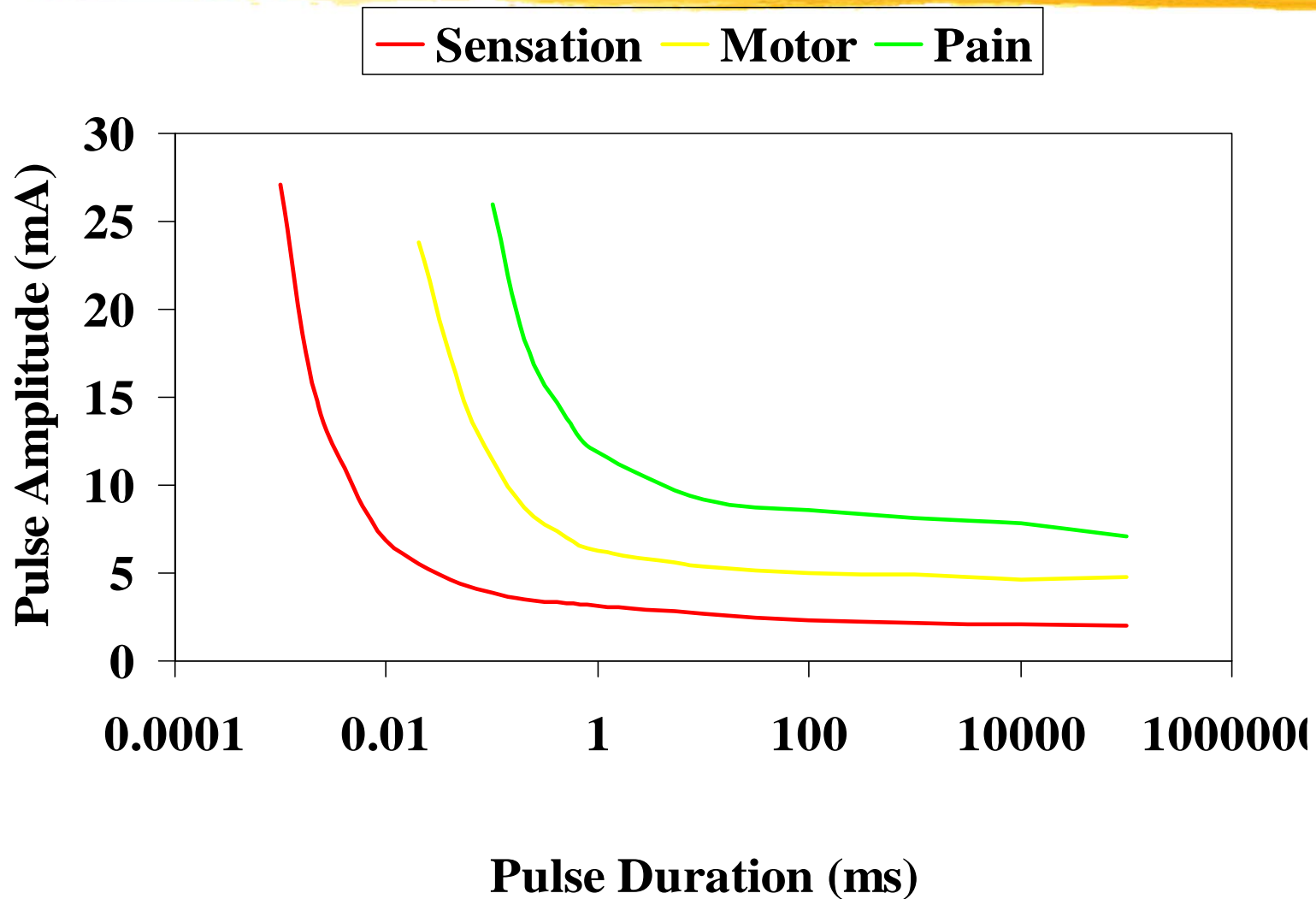
# E-stim for pain relief



Hypotheses:

- ⌘ Inhibition of nociceptors via selective stimulation of  $A\alpha$  and  $A\delta$  fibres (large, fast, mechanoreceptors)
  - ☒ “Gate theory”
- ⌘ Counter-irritant effect
- ⌘ Release of endogenous opioids

# Pulse widths and nerve stimulus



# Pain relief

- from basic science; little research available for best parameters

- ⌘ Frequency – >80Hz, commonly 100Hz
- ⌘ Pulse duration - 0.001-0.01ms
- ⌘ Constant current, modulated to reduce accommodation of nerves
- ⌘ Intensity – comfortable to max tolerable
- ⌘ Electrode placement
  - ⌘ suprapubic
  - ⌘ vaginal/anal
  - ⌘ sacral/tibial
- ⌘ Time – 1-2hrs x 2/day

# Basic research needed



- ⌘ To understand electrical parameters & effect on tissues
  - ☒ Autonomic and somatic nerves in pelvis
- ⌘ Parameters which can be defined in e-stim, & then altered for different effects:
  - ☒ wave form (*mono or biphasic*)
  - ☒ Pulse or burst duration (*msecs*)
  - ☒ Current intensity (*mA*)
  - ☒ Pulse frequency (*Hz*)
  - ☒ Treatment duration (*duty cycle & time*)
- ⌘ Clinical trials protocols will be difficult to ascertain best electrical parameters to use

# Basic research is ongoing



Some of this basic research is happening here in Melbourne, at La Trobe University

- ☒ Manipulating electrical parameters

- ☒ Comparing various currents

- ⌘ Using optimal burst duration, intensity and frequency, 'best' results can be obtained

(Ward et al 2006, 2007)

# Why hasn't this research translated into practice?

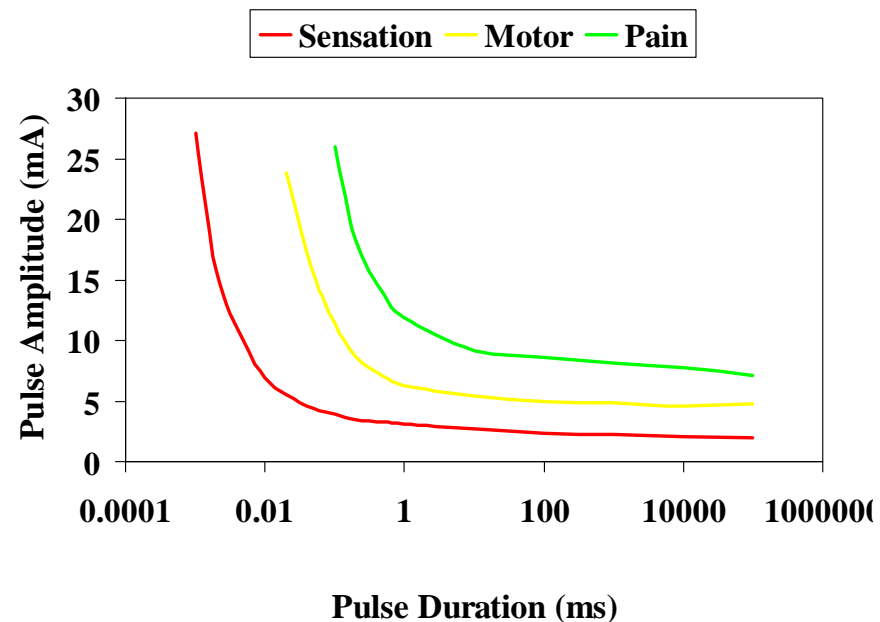
No TENS units available currently capable of producing the desired current

Theoretical underpinning of role of e-stim not accurately defined in clinical diagnoses



# Getting past skin resistance

- ⌘ Limiting factor for intensity in transcutaneous e-stim
  - ☑ Maximum torque production in muscle as a result of e-stim occurs at around 30-40% of an MVC
  - Limiting factor is **PAIN**
  - ☑ So treatment will always be sub-optimal



# Maximal intensity stimulation

⌘ 60 subjects with OAB

☑ Thoroughly informed about intense treatment  
– to 120 mA for vaginal e-stim; 60mA for anal e-stim

⌘ Short term effect, lost at 3 months

⌘ 6 subjects only could tolerate max current

☑ These subjects had longer lasting effects

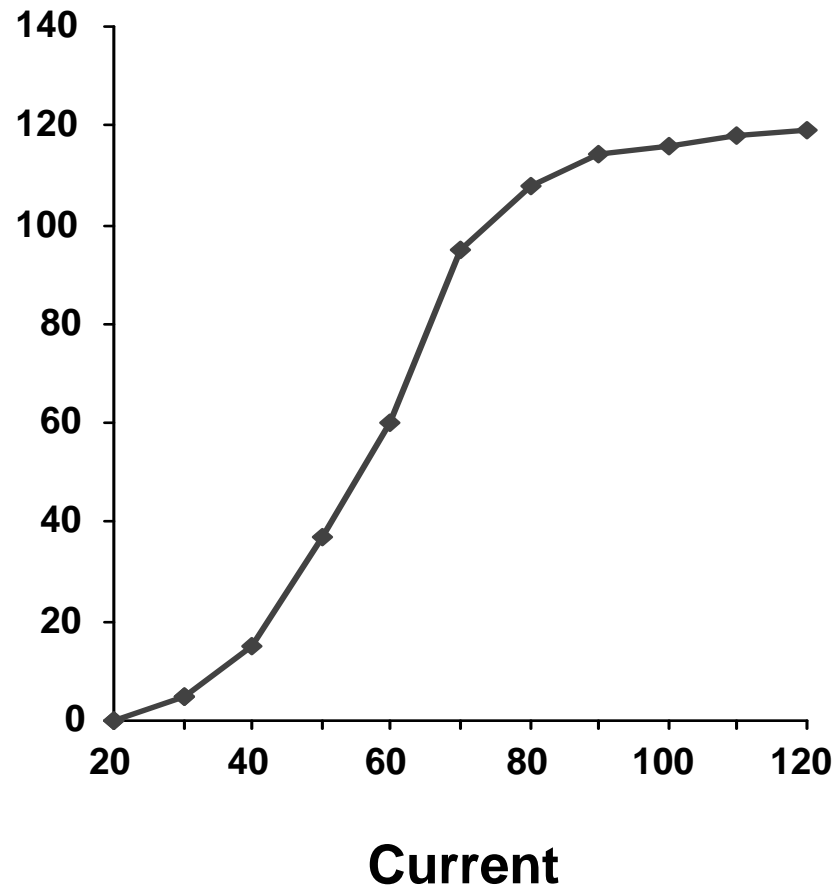
☑ Strict patient selection for RCT

(Fehrling et al Scand J Urol Neph 2007)

# Current

- ⌘ intensity (mA)
- ⌘ as  $I \uparrow$ , force  $\uparrow$
- ⌘ pins and needles
- ⌘ strong uncomfortable but not painful
- ⌘ patient control
- ⌘ Intensity stimulates more fibres ie. spreads the current, cannot stimulate each fibre more.

Torque



# Muscle re-education

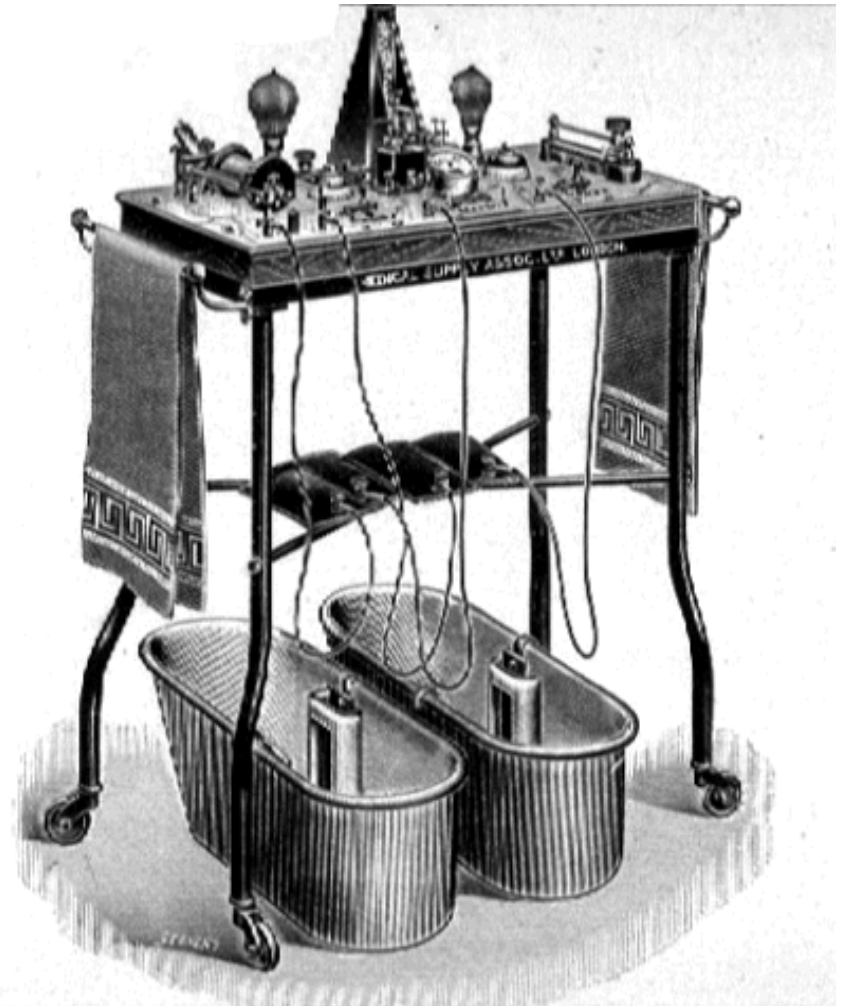
## Low Frequency Range...

- More closely resembles the natural firing rate of slow twitch fibers, preventing them from transforming into fast twitch fibers
- Limits fatigue in therapy
- Achieves sufficient force at 20 Hz (43% of maximum) and minimal acceleration to ensure a sufficiently smooth, functional contraction
- BUT stimulation time must be similar percent of day when slow twitch fibres are normally active.

(Ward & Oliver 07, Shanahan et al 06)

# Side effects of NMES

- ⌘ Vaginal irritation
- ⌘ Discomfort
  - ☑ Need to tolerate high intensities
- ⌘ Urinary tract infection???
  - ☑ Or inflammation?
- ⌘ Visceral symptoms
  - ☑ Nausea, pallor, sweating (Kitchen 2000)



# In Conclusion

- ⌘ PFMT is the mainstay of conservative treatment for stress & mixed incontinence
  - ☑ improves sphincteric action around the urethra
  - ☑ increases functional awareness and strengthens PFM
- ⌘ E-stim could assist this process
  - ☑ to the extent that patient selection is suitable for the electrical parameters chosen
  - ☑ particularly useful where there is patient motivation and adherence
- ⌘ High quality clinical trials are now needed