Pelvic floor muscle pain: Outcome Measures, Tues 4th Sep 2012

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Study / treatment end-points (Turk et al 2006)
- Chronic pain: most measures of treatment response involve patient-reported outcomes (PROs), for which the patient is the most important judge of whether changes are important or meaningful
- PROs: unmodified patient responses
  o Esp important for conditions which involve symptoms such as pain / fatigue, where objective measures of patient perception are not available.
  o Should include assessment of pain, physical functioning, emotional functioning, participant / patient rating of improvement, satisfaction with treatment
- CROs (clinician-reported outcomes):
  o Include outcomes either observed by a provider or requiring interpretation
  o Also includes scales completed by a health care provider about the patient
- Laboratory, behavioural and device measurements include objective and usually quantitative behavioural or physiological measures often performed by devices or raters

PRO (1) Pain
- Numerical rating scale (NRS): 0 – 10
- Visual Analogue Scale (VAS)

Pain scaling: addresses sensory-discriminative intensity, but not motivational-affective nor cognitive-evaluative aspects.
The symptom: pain in the PFM: On PFM palpation at rest, contraction, relaxation.

How to measure PFM pain: Digital methods
Digital pressure to elicit tenderness / pain: commonly reported: “light”; “moderate”; “firm”
- Kavvadias et al (2012):
  o $\kappa = 0.86$ combined, for levator ani, obturator internus, piriformis muscle, measured on 0-10 VAS with cut-off at 3
  o ICC=0.27 – 0.69 for levator ani
- Montenegro et al (2010): pelvic muscle tenderness scale
  o Reliability: $\kappa = 0.91$ for tenderness (levator ani x)
  o Intra-rater reliability: $\kappa_w = 0.79$; inter-rater reliability as $\kappa_w = 0.85$
- Tu et al (2008): muscle hyperalgesia scale
  o poor to fair reliability, $\kappa$ values ranging from 0.02-0.35
  o formal reliability training was not conducted

How to measure PFM pain: instrumented methods
  o applied to PFM sites and anterior and posterior vaginal raphe
  o high correlations between pressure applied and pain perceived ($r=0.99$)
Short-term reliability of this test was good (ICC=0.63 – 0.75), however longer-term reliability was less so (r<0.40)
pressure-pain thresholds in women with and without chronic pelvic pain: found significant differences between groups (p<0.001)
PFM and vaginal site pain detection thresholds demonstrated moderate – strong correlations with each other (r = 0.62– 0.91) associated with enhanced pelvic floor and vaginal pressure-pain sensitivity
- vulvalgesiometer (Pukall et al 2009)

PRO (2) Physical Functioning
The Interference Scale of the Multidimensional Pain Inventory (MPI) (Kerns et al 1985)
The MPI consists of 12 empirically derived scales that are grouped into 3 sections:
1. pain and its impact; 2. responses by significant others; 3. activities
The Interference Scale is included in the section on pain and its impact and consists of 9 questions (eg, “In general, how much does your pain interfere with your day-to-day activities?”; “How much has your pain changed your ability to take part in recreational and other social activities?”), which are rated on 7-point scales ranging from 0 (“no interference/change”) to 6 (“extreme interference/change”)

The Interference Scale of the Brief Pain Inventory (BPI) (Cleeland & Ryan 1994)
7-item self-report measure, designed to assess the extent to which pain interferes with various components of functioning, including physical and emotional functioning and sleep
The items in this scale can be grouped into those that assess:
- physical functioning (general activity; walking ability; normal work, including both work outside the home and housework)
- those that assess emotional functioning (mood; relations with people; enjoyment of life)
- and a single item that assess the extent to which pain interferes with sleep.

PRO (3) Emotional functioning
Beck Depression Inventory (BDI) (Beck et al 1961)
excellent psychometric properties and its extensive use in pain clinical research and responsiveness to change in pain clinical trials. The BDI consists of 21 groups of 4 statements designed to assess severity of current symptoms of depressive disorders, with total scores on the measure ranging from 0 to 63.
The Profile of Mood States (POMS)
is a 65-item adjective checklist that provides a total mood disturbance score and 6 subscale scores: Tension, depression, anger, vigor, fatigue, and confusion (McNair et al 1992)
Hospital Anxiety & Depression Scale (HADS) (Zigmond 1983, Bjelland 2002)

PRO (4) Participant ratings of improvement and satisfaction with treatment
The Patient Global Impression of Change scale (PGIC) (Guy 1976)
7-point scale
PGI-I (improvement) (UI: Yalcin & Bump 2003; Sx for POP: Srikrishna et al 2010)
Patient’s Overall Rating of Symptom Index (PORIS scale)
patients globally assess their symptoms as either worse or improved by 0, 25, 50, 75 or 100% (Nickel et al 2005, Parsons et al 1993)

**Interpreting Changes in Chronic Pain Clinical Trial Outcome Measures** (Dworkin et al 2008)

<table>
<thead>
<tr>
<th>Outcome Domain and Measure</th>
<th>Type of improvement</th>
<th>Change</th>
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<tbody>
<tr>
<td>(1) Pain intensity:</td>
<td>Minimally important</td>
<td>10–20% ↓</td>
</tr>
<tr>
<td>- 0–10 numerical rating scale</td>
<td>Moderately important</td>
<td>≥ 30% ↓</td>
</tr>
<tr>
<td></td>
<td>Substantial</td>
<td>≥ 50% ↓</td>
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<td>(2) Physical functioning:</td>
<td>Clinically important</td>
<td>≥ 0.6 point ↓</td>
</tr>
<tr>
<td>- Multidimensional Pain Inventory Interference Scale</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Brief Pain Inventory Interference Scale</td>
<td>Minimally important</td>
<td>1 point ↓</td>
</tr>
<tr>
<td>(3) Emotional functioning:</td>
<td>Clinically important</td>
<td>≥ 5 point ↓</td>
</tr>
<tr>
<td>- Beck Depression Inventory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Profile of Mood States:</td>
<td>Clinically important</td>
<td>≥ 10–15 point ↓</td>
</tr>
<tr>
<td>- Total Mood Disturbance</td>
<td>Clinically important</td>
<td>≥ 2–12 point Δ</td>
</tr>
<tr>
<td>- Specific subscales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(4) Global rating of improvement:</td>
<td>Minimally important</td>
<td>Minimally improved</td>
</tr>
<tr>
<td>Patient Global Impression of Change</td>
<td>Moderately important</td>
<td>Much improved</td>
</tr>
<tr>
<td></td>
<td>Substantial</td>
<td>Very much improved</td>
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**Clinician reported outcomes**

The sign: altered tension. Commonly measured on palpation at rest, contraction, relaxation. “tone of the pelvic floor muscles is difficult to define and cannot be measured” (Messelink et al 2005, p376).

Is it ‘Tone’ or ‘Tension’?

- Muscle tone is the resting tension in the muscle and is clinically determined as resistance to passive movement or deformation (Mense & Simons 2001)
- Muscle tightness: an equivalent meaning to tension?
- high-tone / hypertonia and spasticity: have specific meanings in the neurophysiological sense related to upper motor neuron lesions
- should be avoided when there is no indication of such a neurological condition

**How to measure PFM tone / tension: Digital methods**

- Several scales proposed, not tested for reliability (Carrico & Peters 2011, Devreeese et al 2004, Lukban & Whitmore 2002)
- Kavvadias et al (2012): ICC=0.10 – 0.13 (non-significant), scale?
- Dietz & Shek (2008):
  - 6, 11 and 21-point resting tone scale analogous to the Modified Oxford Scale
  - validated against translabial ultrasound to detect levator hiatal dimensions and pelvic organ prolapse (POP)
  - tested for inter-rater reliability: moderate agreement (κ=0.42 – 0.55)
  - resting tone can be measured digitally using the methodology reported
  - Limitations of this scale
- tone scale tested for reliability was undertaken in a cohort of patients with multiple sclerosis (de Ridder et al 1998)
  - Therefore this scale was a measure of true spasticity
  - may not be appropriately applied to a non-neurogenic PFM
- Confounder: presence of myofascial trigger points

**How to measure PFM tone / tension: Instrumented methods**
- Real-time ultrasound: Davis et al (2011)
- Electromyographic activity: potentially a useful surrogate measure for muscle tension, as the degree of activation of the contractile apparatus of the muscle is a specific component of the definition of muscle tone. There are no widely accepted values for ‘normal’ resting sEMG of the PFM
  - Tu et al (2008): ≤ 2µV
  - Voorham-van der Zalm et al (2007): ≤2µV for women and ≤2 – 3µV for men

**References**


Srirksrithna et al (2010) Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse Int Urogynecol J 21:523–528


