The assessment of pain-related function in clinical trials

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Background: Measuring Pain-related Physical Function

- What domains to include?
  - Physical (dys)function – what does this include?
    - Social and recreational (dys)function
    - Overall activity level
- What to assess?
  - "Interference" with function
  - "Change" in function
  - "Disability"
- How to measure?
  - self-report
  - observation/performance-based measures

Challenges to measurement

1: Construct validity: most measures of pain-related physical (dys)function show a high correlation with measures of pain intensity

- Raises the issue of construct validity, specifically discriminant validity
  - Factor analyses generally support distinction between pain intensity and pain-related physical function
  - Some indication that specific domains of function (e.g., recreation) may show better discrimination than general domains (e.g., daily activities)

Challenges to measurement

2 Construct validity – The language used to determine function is likely quite important….

- "interference" (BPI; WHYMPI) vs. "disability" (PDI) vs. "change" (WHYMPI)
- one measure (WHYMPI) includes items assessing satisfaction

….but language has not been investigated

Challenges to measurement

3 Content validity of domains of (dys)function

- little work on content validity of domains or content validity of items measuring a domain
- some instruments (BPI) have been slightly modified by some investigators to broaden domains assessed
- specific domains may be differentially important across pain conditions, age groups, or settings

Challenges to measurement

4 Method of Measurement: Limitations of self-report - Appraisals/Judgments

- What influences people's appraisals or judgments of pain-related physical function
  - response biases such as social desirability
  - exaggeration or illness behavior in some settings
  - attribution that interference is due to pain, as compared to another correlated factors such as sleep disturbance or mood

Challenges to measurement

4 Method of Measurement: Limitations of self-report - Recall and Memory

- **How accurate are people at remembering specific activities?**
  - **e.g. "How often do you take a ride in a car or bus" as compared to "How often do you visit friends" or "How often do you mow the lawn"**
  - **rating scale: never to very often**
  - **time frame is not specified**

Challenges to measurement

4 Method of Measurement: Limitations of self-report - Recall and Memory

- **How accurate are people at comparing their present status to their past status?**
  - **"How much has your pain changed your ability to take part in recreational and other social activities?"**
  - **Similar to ratings of pain relief, this requires the person to compare present function to an unspecified and distant level of function**

Challenges to measurement

5: Scale construction – vague quantifiers when reporting on frequency of behavior

- Frequency ratings such as “Very often”
  - The same rating (i.e., “very often”) indicates different frequencies for different content domains
    - e.g., a rating of “very often” for ride in a car or bus reflects a different absolute frequency than “very often” for taking a trip or mowing the lawn

Schwarz, N. (1999) Self-Reports: How the questions shape the answers. American Psychologist, 54, 93-105.

Challenges to measurement

5: Scale Construction: Do the properties of a subscale change when it is removed from its larger scale?

- Survey researchers have nicely demonstrated that surrounding items influence responding to a targeted item
  - e.g., the correlation between marital satisfaction and general life satisfaction changes depending on the order of the questions

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Challenges to measurement

5 Scale Construction: Do the properties of a subscale change when it is removed from its larger scale?

- Two measures reviewed are subscales of a larger instrument
  - WHYMPI: the 11 interference items are embedded in a 28-item scale that includes questions about negative mood, life control and relationship support
  - BPI: the interference subscale follows the pain intensity subscale

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Brief Pain Inventory (BPI)

- ✓ **Strengths**
  - ✓ **Validated in a number of countries/languages and across a number of conditions (although most data pertain to cancer pain)**
  - ✓ **Strong psychometric properties**
  - ✓ **Language uses a single dimension: interference**
  - ✓ **Studies demonstrate its sensitivity to treatment effects**
    - ✓ **moderate evidence: mostly pharmacological treatments**

Brief Pain Inventory (BPI)

- ✓ **Weaknesses**
  - ✓ **Some investigators have expanded the domains measured to include “self-care” “social activities” and “recreational activities”**
  - ✓ **items include domains outside of physical function, including mood, enjoyment of life, relations with others**
    - ✓ **two-factor solution (affect and activity) not widely used, but this distinction does address this weakness**

Pain Disability Index (PDI)

- ✓ **Strengths**
  - ✓ **Used in patients with a variety of painful conditions**
  - ✓ **Strong psychometric properties**
  - ✓ **Language uses a single dimension: <u>disability</u>**

Pain Disability Index (PDI)

- ✓ **Weaknesses**
  - ✓ **Sleep is included in the "life-supporting activities" with eating and breathing**
    - ✓ **for pain, sleep might be better isolated from eating and breathing**
  - ✓ **Not clear whether the scale includes one or two factors and some recent analyses indicate the life-supporting activities item should be dropped, which will eliminate sleep**
  - ✓ **Very limited outcome data supporting its treatment sensitivity**

Sickness Impact Profile (SIP)

- ✓ **Strengths**
  - ✓ **Widely studied**
- ✓ **Weaknesses**
  - ✓ **Length and subject burden**
  - ✓ **Often total score rather than subscale scores have been used in outcome studies**
  - ✓ **Physical function scale does not include sleep/rest, household activities, work, or recreation**

West Haven-Yale Multidimensional Pain Inventory (MPI)

- ✓ **Strengths**
  - ✓ **Used in multiple countries with patients with a variety of painful conditions**
  - ✓ **Psychometric properties: strong for Interference scale; good for General Activity**
  - ✓ **Extensive validation work on these scales**
    - ✓ **includes comparisons to diary ratings and performance-based measures**

West Haven-Yale Multidimensional Pain Inventory (MPI)

- ✓ **Strengths**
  - ✓ **Interference domains include social/ recreational/family/friend activities and sleep**
    - ✓ **does not include ratings of interference with mood**
  - ✓ **Studies demonstrate sensitivity of Interference scale to treatment effects**
    - ✓ **strong evidence: mostly psychological treatments**

West Haven-Yale Multidimensional Pain Inventory (MPI)

- ✓ **Weaknesses**
  - ✓ Language within Interference scale includes multiple dimensions: interference, change, and satisfaction
  - ✓ Interference scale is embedded in other scales
  - ✓ Limited outcome data on General Activity scale suggest it may not be sensitive to treatment
    - ✓ diary studies suggest low concordance between diary ratings of activities and General Activity ratings

Rec #1: Studies should use at least 2 measures of pain-related physical function

- MPI Interference and General Activity
  - excellent validation work (both)
  - good treatment sensitivity (Interference)

- When possible, the 10-item modified BPI should also be included
  - single rating dimension
  - potential confounding of mood, life satisfaction

Rec #2:Assessment of Sleep

- **Sleep diary**
  - **single sleep quality or pain-related interference item (e.g., Rowbotham et al., 1998)**
  - **more complete diary that quantifies time to sleep, number of awakenings, and total sleep time (e.g., Haythornthwaite et al., 1991)**
- **Standardized summary measure – Pittsburgh Sleep Quality Index (Buysee et al., 1989)**

Future Research Directions

- Comparison of the sensitivity of different measures

- Studies of the language used to assess pain-related (dys)function
  - interference
  - change
  - disability

Future Research Directions

- Validation of domains assessed
  - areas of (dys)function
  - content validity of General Activity scale
- Development of performance-based measures