# Pain Assessment

Mark P. Jensen, Ph.D.

April 11, 2003

# Overview

Strengths and weaknesses of measures of:

- Pain intensity
- Pain relief
- Temporal aspects of pain
- Pain quality (including pain affect)

Pain assessment recommendations

Issues in pain assessment

Research recommendations

# Pain intensity: Contenders

- Visual Analogue Scale
- Numerical Rating Scale
- Verbal Rating Scale

# Visual Analogue Scales

No pain

Pain as bad as
you can imagine

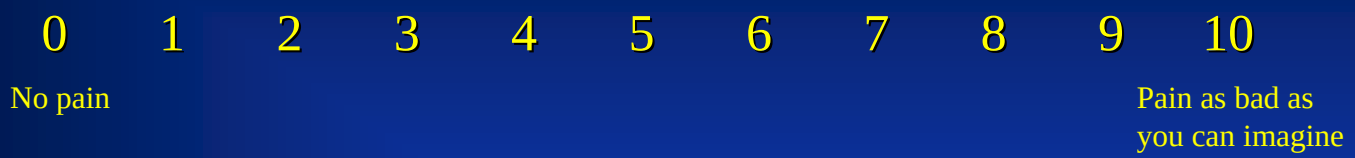
Strengths

- Many ("infinite") response categories.
- Average (group) scores can be treated as ratio data.
- Good evidence for validity.

Weaknesses

- Extra step in scoring the paper-and-pencil version can take more time and adds an additional source of error.
- Some people, especially older people, have difficulty using VASs (higher failure rates).
- Cannot administer by interview.
- Requires motor control.

# Numerical Rating Scales




Strengths

- Easy to administer.
- Adequate number of response categories (0 – 10, 0 – 100).
- Easy to score.
- Good evidence for validity.
- Compliance with measurement task is high (few failures).
- Can be administered via interview.

Weaknesses

- Average (group) scores cannot necessarily be treated as ratio data.

# Verbal Rating Scales

None Mild Moderate Severe

Strengths

- Easy to administer.
- Easy to score.
- Good evidence for validity.
- Compliance with measurement task is high (few failures).
- May approximate ratio scaling if CMM methods used.

Weaknesses

- Can be difficult for persons with limited vocabulary.
- Relatively few response categories compared to VAS or NRS.
- If scored with ranking method, scores do not have ratio qualities.
- People forced to choose one word, even if no word on the list adequately describes pain intensity.

# Pain Intensity: Recommendations

- In most trials, a measure of pain intensity is the appropriate primary outcome dimension.
- 0 – 10 NRS-I appears to have the most strengths and fewest weaknesses of pain intensity measures.
- VRS-4-I (none, mild, moderate, severe) may be a useful secondary measure.

# Pain Relief: Summary of findings

- Relatively little research has compared VAS, NRS, and VRS pain relief measures to each other.
- Pain relief measures are sensitive (sometimes more so than pain intensity measures) to the effects of pain treatments.
- Pain relief is not the same as change in pain intensity:
  - Pain relief is sometimes endorsed even when pain changes little or worsens.
  - Perceived pain relief is more strongly associated than change in pain intensity with treatment satisfaction.

# Pain Relief: Recommendations

- Should be strongly considered as a secondary outcome measure in pain clinical trials.
- No strong evidence to support one type of pain relief measures (VAS, NRS, VRS) over the others;

  although concerns raised about VAS-I may encourage investigators to select a NRS (e.g., 0 = none; 10 = complete) or VRS (e.g., none, a little, some, a lot, complete relief) over a VAS for this purpose.

# Temporal qualities: Summary of findings

- Dimensions: Variability, frequency, duration, pattern, "Breakthrough" pain, time to analgesia onset/time to meaningful pain relief.
- Temporal pain qualities are distinct from pain intensity.
- Temporal pain qualities may predict patient function over and above effects of pain intensity.
- Measures of temporal qualities are under-utilized in pain clinical trials.

# Temporal qualities: Recommendations

- Temporal aspects of pain should be strongly considered as a secondary outcome dimensions in pain clinical trials.
- Temporal dimension selected should be consistent with the expected effects of treatment:
  - -Time to analgesia onset/Time to meaningful pain relief for fast-acting analgesics is appropriate.
  - - Presence/absence, intensity, and frequency of breakthrough pain for BP treatments.
  - - Frequency of pain for treatment of intermittent pain problems (e.g., headache).

# Pain quality: Single-item measures of pain affect

## Visual Analogue Scale

Not bad at all

The most unpleasant Feeling possible for me

## Numerical Rating Scale

0 1 2 3 4 5 6 7 8 9 10

Not bad at all

The most unpleasant Feeling possible for me

## Verbal Rating Scale

Bearable Distracting Unpleasant Uncomfortable Distressing Oppressive Miserable Awful Frightful Dreadful Horrible Agonizing Unbearable Intolerable Excruciating

# Pain quality: MPQ and SF-MPQ

MPQ

- 78 pain descriptors in three major categories (sensory, affective, evaluative, one miscellaneous category) and 20 subcategories.
- For example: sharp, cutting, lacerating; tingling, itchy, smarting, stinging.
- Respondents pick one descriptor per sub category.
- Responses summed within categories (e.g., affective, sensory, and evaluative), and across categories (total score).

# Pain quality: MPQ and SF-MPQ

SF-MPQ

- 15 pain descriptors in two major categories (sensory, affective).
- For example: throbbing, shooting, sickening.
- Respondents rate severity of each descriptor on a 4-point Likert scale (none, mild, moderate, severe).
- Responses can be summed to form sensory, affective, and total scores.
- Scales strongly associated with MPQ scale scores.

# Pain quality: Summary of findings

- Measures of pain quality and affect are used relatively infrequently in pain clinical trials.
- Evidence supports the validity of the available measures for detecting treatment effects.
- Both the MPQ and SF-MPQ appear to be less sensitive than measures of pain intensity to changes in pain.
- Use of MPQ and SF-MPQ scale scores obscured the specific qualities of pain.

# Pain quality: Summary of findings (cont'd)

- MPQ is probably not practical is most clinical trials, but SF-MPQ appears to be.
- Single item measures of pain affect are distinct from measures of pain intensity under certain conditions.
- More research is needed to examine the psychometric qualities of the SF-MPQ and other possible pain quality measures.

# Pain quality: Recommendations

- Should be considered as secondary outcome measure(s) in pain clinical trials.
- SF-MPQ appears the most useful measure of pain qualities. SF-MPQ construct validity might be improved by adding descriptors, and by increasing response levels (e.g., from 4 11). The SF-MPQ's strongest asset (ability to detect changes in specific pain qualities) has been under-utilized in clinical trials.
- Single-item measures (VAS-A, NRS-A, VRS-A) may provide a useful summary measure of pain affect. VRS-A may be more effective that VAS-A or NRS-A for helping subjects distinguish between pain affect and intensity.

# Pain assessment issues in clinical trials

- How often and for how long should pain be measured?
- Multiple measures of current pain vs. recalled pain?
- Unsupervised diaries vs. supervised diaries (electronic, web-based, mail-in, interview).
- Single-item versus composite pain measures.
- Rescue dose requests as outcome measures.
- Multiple pain sites as a confounding variable.
- Time for standardized endpoints?

# How often and for how long should pain be measured?

- At a minimum, pain needs to be assessed both before and after the treatment conditions in a clinical trial.
- Ideally, more assessment points should be included, extended to beyond the point at which the experimental intervention is thought to be effective, to allow for comparisons between treatment conditions concerning the pattern of effects of the interventions on pain.
- A minimum of four assessments is needed to provide data concerning the pattern of effects of treatment.

# Multiple measures of current pain vs. recalled pain?

The evidence suggests that recall measures are not specifically accurate, but are valid (i.e., they reflect) measures of previous pain.

They can therefore be used as treatment outcome variables, eliminating the need for repeated (e.g., daily diary) measures in situations where “average” or “usual” pain is the primary outcome dimension (e.g., most chronic pain studies).

However, no studies have compared the relative sensitivity of single ratings of previous pain versus diary averages; it is possible that recall ratings may be less sensitive in some situations.

# Unsupervised diaries vs. supervised diaries

If diary data are needed, the veracity of unsupervised data collection can be called into question; the findings from such data should be considered preliminary and not conclusive.

All dairy data should be supervised (palm top computer, phone-in data, phone interview data, mail-in data, web-based assessment).

# Single-item versus composite pain measures

- The evidence indicates that single-item measures are adequately valid and reliable for most situations.
- Composite measures may increase the reliability and validity of pain assessment a little, on average, but perhaps not enough to warrant a requirement or recommendation that they always be used.
- Future research is needed to replicate this conclusion, which is based on a relatively few number of studies.

# Rescue dose requests as outcome measures

- The incidence of rescue dose requests should be strongly considered as one of the secondary outcome measures when appropriate.
- The use of such measures is probably appropriate in nearly all analgesic clinical trials.

# Multiple pain sites as a confounding variable

The extent to which subjects with multiple pain problems provide questionable responses to single-item pain measures, and the impact of this on the findings of clinical trials, is unclear.

This potential problem and confound needs to be examined further among pain populations with a high incidence of multiple pain problems.

In the meantime, investigators would do well to consider assessing pain in multiple sites at each assessment point at each assessment point.

# Time for standardized measures?

VAS: 100mm with demarcation lines; No pain/Pain as bad as you can imagine as endpoints.

NRS: 0 – 10; No pain/Pain as bad as you can imagine as endpoints.

VRS: None, mild, moderate, severe.

# Research needs: Pain intensity

- Individual versus composite measures.
- Relative sensitivity of actual usual pain versus recalled usual pain intensity.

# Research needs: Pain relief

- What contributes to a pain relief score in addition to change in pain?
  - Hope engendered by treatment?
  - Area under the curve (SPID)?
  - Change in pain qualities?
  - Other?

# Research needs: Temporal aspects

- Are recall measures of temporal aspects reliable and valid?
- Additional brief and psychometrically sound measures of temporal components should be developed

# Research needs: Qualitative aspects

- Are single-item measures adequate?
- Relative sensitivity of single-item versus multiple-item scales.
- Can SF-MPQ be improved?
  - More efficient – drop descriptors rarely used.
  - More content validity – add descriptors frequently used.
  - More sensitive – increase number of levels.