The Brief Pain Inventory: Meaningful Changes in Pain Interference

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Pain Assessment

The investigator who would study pain is at the mercy of the patient, upon whose ability and willingness to communicate he is dependent.

– Lasagna, 1960

Objectives

- **Introduction to the Brief Pain Inventory**
- **What are the Interference items?**
- **What do clinical trial data suggest about the performance of the Interference items?**
- **How best to summarize Interference scores?**
- **What are meaningful clinically significant differences in Interference scores?**

Derivation of the Brief Pain Inventory

Goals:

- **A quickly administered scale for cancer patients with pain**
- **Very simple stems for patient understanding and ease of translation**
- **Sample both pain severity and the impact of pain on the patient (pain interference)**

Development of the BPI

- **Items based on 50 in-depth interviews with patients who had pain due to cancer**
- **First version: Wisconsin Brief Pain Questionnaire (Daut and Cleeland, 1982; Daut et al, 1983)**
- **Current version: Brief Pain Inventory (Cleeland, 1989; Cleeland et al, 1994)**
- **Examination of the Interference items cross-culturally (Serlin et al 1995; Cleeland et al, 1996)**

STUDY ID #: _____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #: _____

Brief Pain Inventory (Short Form)

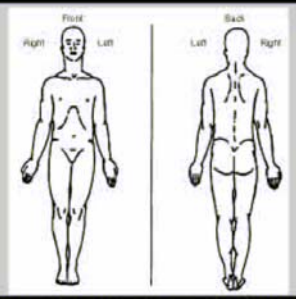
Date: ____/____/____ Time: _____

Name: _____ _____ _____
Last First Middle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

STUDY ID #: _____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #: _____

Date: ____/____/____ Time: _____

Name: _____ _____ _____
Last First Middle Initial

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

Brief Pain Inventory (Severity)

2. Please rate your pain by circling the one number that best describes your pain at its WORST in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

Brief Pain Inventory (Interference)

7. Circle the number that describes how, during the past 24 hours, pain has interfered with your:

A. General activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

BPI Interference Items

- **General activity**
- **Work (including housework)**
- **Ability to walk**
- **Mood**
- **Ability to relate to others**
- **Enjoyment of life**
- **Sleep**

Activities Impaired by Increasing Pain

3	4	5	6	7	8
					relate
				walk	walk
		sleep	sleep	sleep	sleep
		active	active	active	active
		mood	mood	mood	mood
	work	work	work	work	work
enjoy	enjoy	enjoy	enjoy	enjoy	enjoy

> > > > worst pain rating > > > >

N=186, Multi-institutional study

Mild, Moderate, and Severe Pain
Four-Country Sample

MILD	**1 - 4**
MODERATE	**5 - 6**
SEVERE	**7 - 10**

Serlin et al, 1995

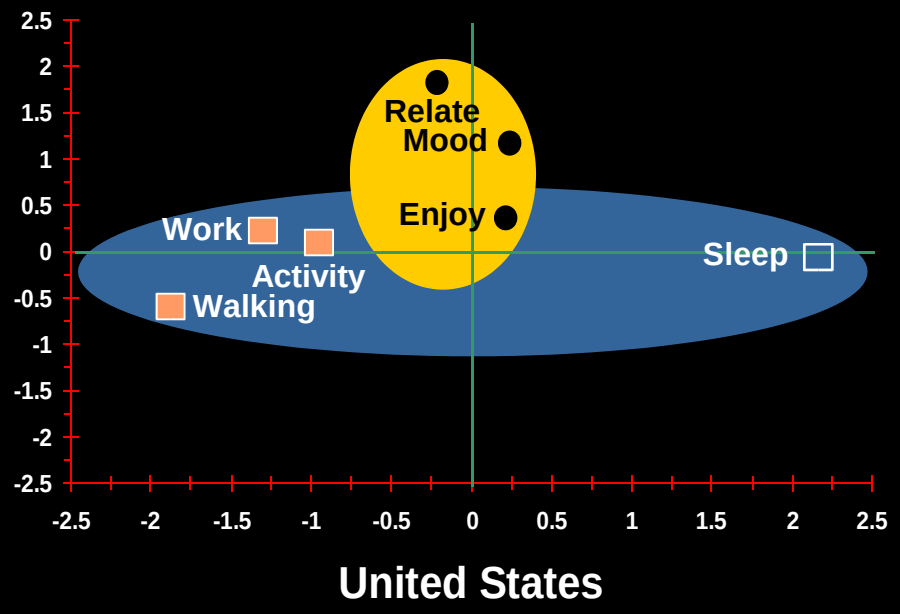
Correlations of BPI with Other Measures: Osteoarthritis (N=74)

Scale	BPI Severity	Interference
Chronic Pain Grade		
Intensity	**0.77**	**0.74**
Disability	**0.54**	**0.80**
Grade	**0.54**	**0.75**
SF-36		
Physical	**-0.59**	**-0.65**
Role Physical	**-0.59**	**-0.72**
General Health	**-0.52**	**-0.62**
Vitality	**-0.35**	**-0.55**
Social Function	**-0.67**	**-0.83**
Role Emotion	**-0.41**	**-0.55**

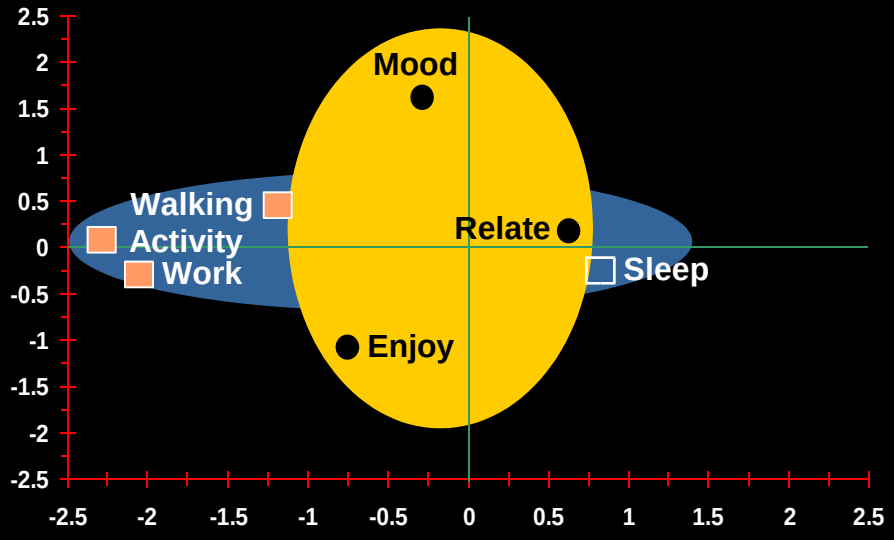
Correlations of BPI with Other Measures: Cancer (N=207)

Scale	BPI Severity	BPI Interference	BPI REM	BPI WAW
SF-36 component				
Physical	**-0.59**	**-0.67**	**-0.61**	**-0.69**
Mental	**-0.45**	**-0.53**	**-0.52**	**-0.51**
SF-36				
Physical	**-0.50**	**-0.58**	**-0.51**	**-0.61**
Role Physical	**-0.27**	**-0.38**	**-0.37**	**-0.39**
General Health	**-0.44**	**-0.51**	**-0.51**	**-0.48**
Vitality	**-0.45**	**-0.53**	**-0.49**	**-0.54**
Social Function	**-0.38**	**-0.46**	**-0.43**	**-0.47**
Role Emotion	**-0.42**	**-0.47**	**-0.45**	**-0.46**

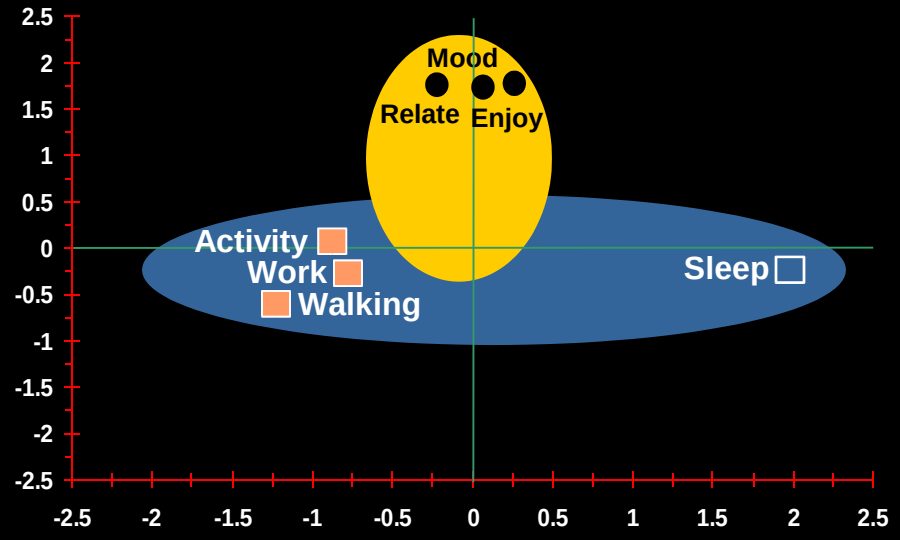
MDS Solutions for Three Countries



United States



Philippines



France

Clinical Trial Data: BPI Interference

- **Disease variability**
- **Sensitivity**
- **Effect sizes**
- **What is a minimally clinically significant difference?**

Mean Interference by Mild, Moderate, and Severe Pain Across Disease

	Mild	Moderate	Severe
CABG	0.88 (1.41) (n=152)	1.77 (2.24) (n=63)	3.18 (2.74) (n=49)
Cancer	2.78 (2.16) (n=323)	4.51 (2.32) (n=301)	6.35 (2.41) (n=473)
OA of the hip	2.23 (1.42) (n=35)	3.63 (1.75) (n=80)	6.33 (1.88) (n=347)
OA of the knee	2.6 (1.80) (n=75)	4.02 (1.81) (n=175)	5.85 (2.04) (n=714)

Mean Interference by Mild, Moderate, and Severe Pain Across Disease

	Mild		Moderate		Severe
CABG	0.88 (1.41) (n=152)	0.53	1.77 (2.24) (n=63)	0.57	3.18 (2.74) (n=49)
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OA of the hip	2.23 (1.42) (n=35)	0.85	3.63 (1.75) (n=80)	1.45	6.33 (1.88) (n=347)
OA of the knee	2.6 (1.80) (n=75)	0.78	4.02 (1.81) (n=175)	0.92	5.85 (2.04) (n=714)

Numbers in green boxes represent the effect size between the adjoining cells.

Reliability of the Interference Subscale:

OA of the Knee (N=753 1019?)

Day	Cronbach alpha	Test-retest (two adjoining assessments)
0 (baseline)	0.92	0.72 (0 &1)
1	0.94	0.87 (1 & 2)
2	0.95	0.91 (2 & 3)
3	0.96	0.90 (3 & 4)
4	0.96	0.92 (4& 5)
5	0.96	0.93 (5&6)
6	0.96	0.91 (6& 7)
7	0.96	

Reliability of the Interference Subscale:

OA of the Hip (N=328 467?)

Day	Cronbach alpha	Test-retest (two adjoining assessments)
0 (baseline)	0.93	0.77 (0 &1)
1	0.95	0.86 (1 & 2)
2	0.96	0.90 (2 & 3)
3	0.96	0.93 (3 & 4)
4	0.96	0.92 (4& 5)
5	0.96	0.92 (5&6)
6	0.96	0.92 (6& 7)
7	0.96	

Stability and Test-Retest Reliability

Day	Alpha	Test-retest (day)
Osteoarthritis of the hip N=467		
0	.93	.77 (0 and 1)
1	.95	.86 (1 and 2)
2	.96	.90 (2 and 3)
3	.96	.93 (3 and 4)
4	.96	.92 (4 and 5)
5	.96	.92 (5 and 6)
6	.96	.92 (6 and 7)
Osteoarthritis of the knee N=1019		
0	.92	.72 (0 and 1)
1	.94	.87 (1 and 2)
2	.95	.91 (2 and 3)
3	.96	.90 (3 and 4)
4	.96	.92 (4 and 5)
5	.96	.93 (5 and 6)
6	.96	.91 (6 and 7)

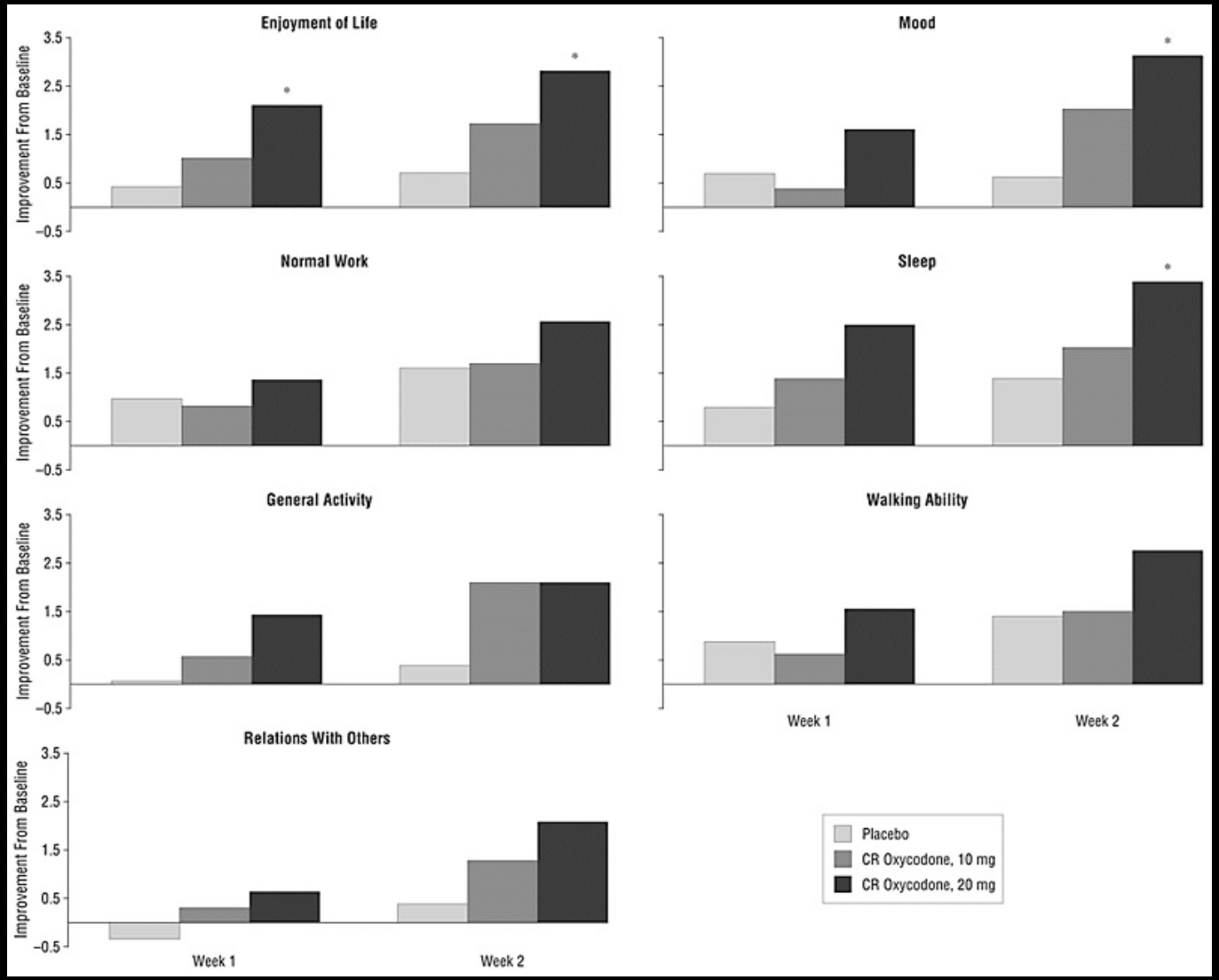
Reliability of the Interference Subscale:

CABG (N=220)

Day	Cronbach alpha	Test-retest (two adjoining assessments)
4	0.91	0.58 (4 & 5)
5	0.90	0.76 (5 & 6)
6	0.91	0.72 (6 & 7)
7	0.92	0.74 (7 & 8)
8	0.91	0.77 (8 & 9)
9	0.91	0.86 (9 & 10)
10	0.92	0.87 (10 & 11)
11	0.92	0.90 (11 & 12)
12	0.91	0.89 (12 & 13)
13	0.91	0.90 (13 & 14)
14	0.92	

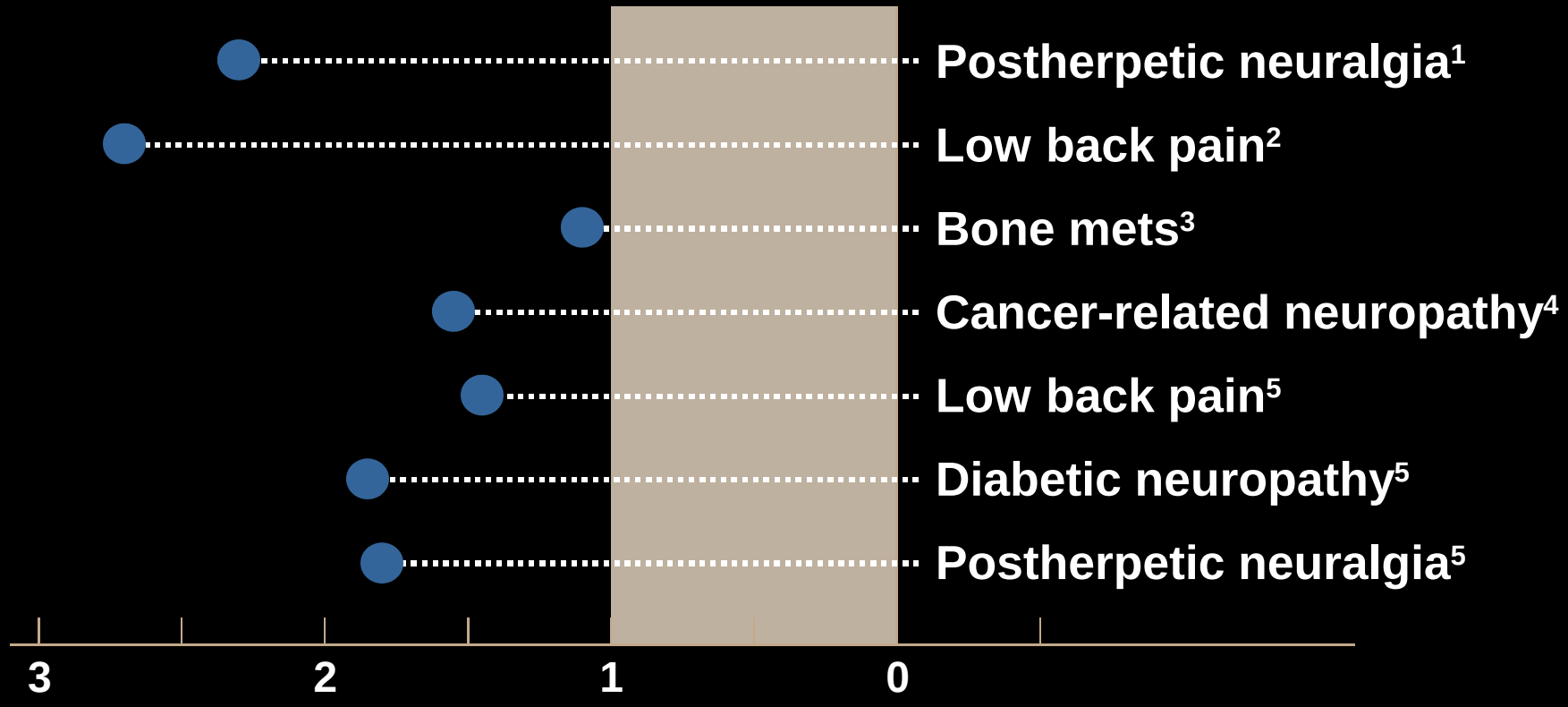
What Do the Scores Mean? Distribution-Based Outcomes

Placebo-Controlled Trial Oxycodone SR



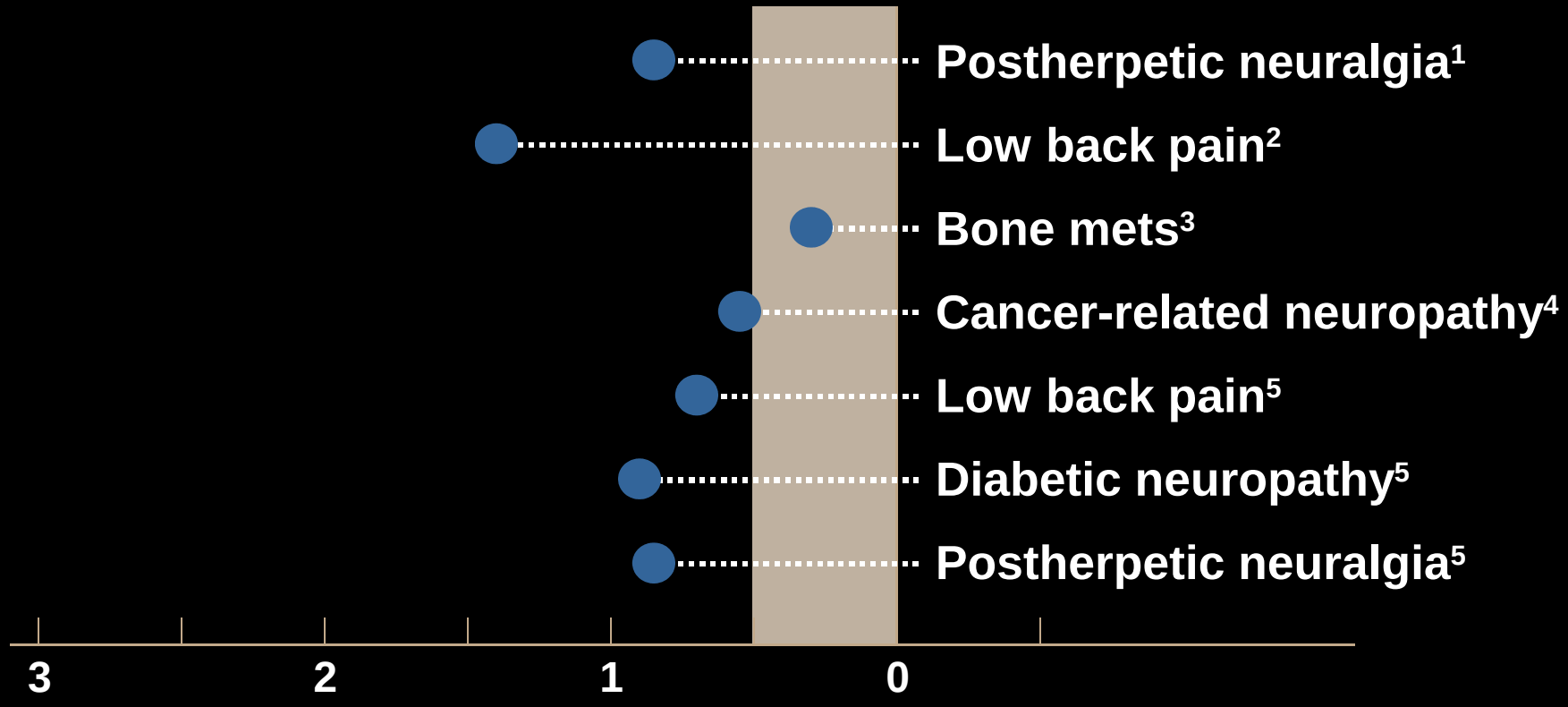
(Roth et al, *Arch Intern Med* 160: 853-860, 2000)

Reduction in Mean Interference: Phase II Trials



[1] Katz et al, *Pain Med* 3: 324-332, 2002.
[2] Gammaitoni et al, *Pain Med* 4: 21-30, 2003.
[3] Goetz et al, *J Clin Oncol* 22: 300-306, 2004.
[4] Hardy et al, *J Pain Symptom Manage* 21: 204-209, 2001.
[5] White et al, *Pain Med* 4: 321-330, 2003.

Reduction in Mean Interference by Effect Size: Phase II Trials



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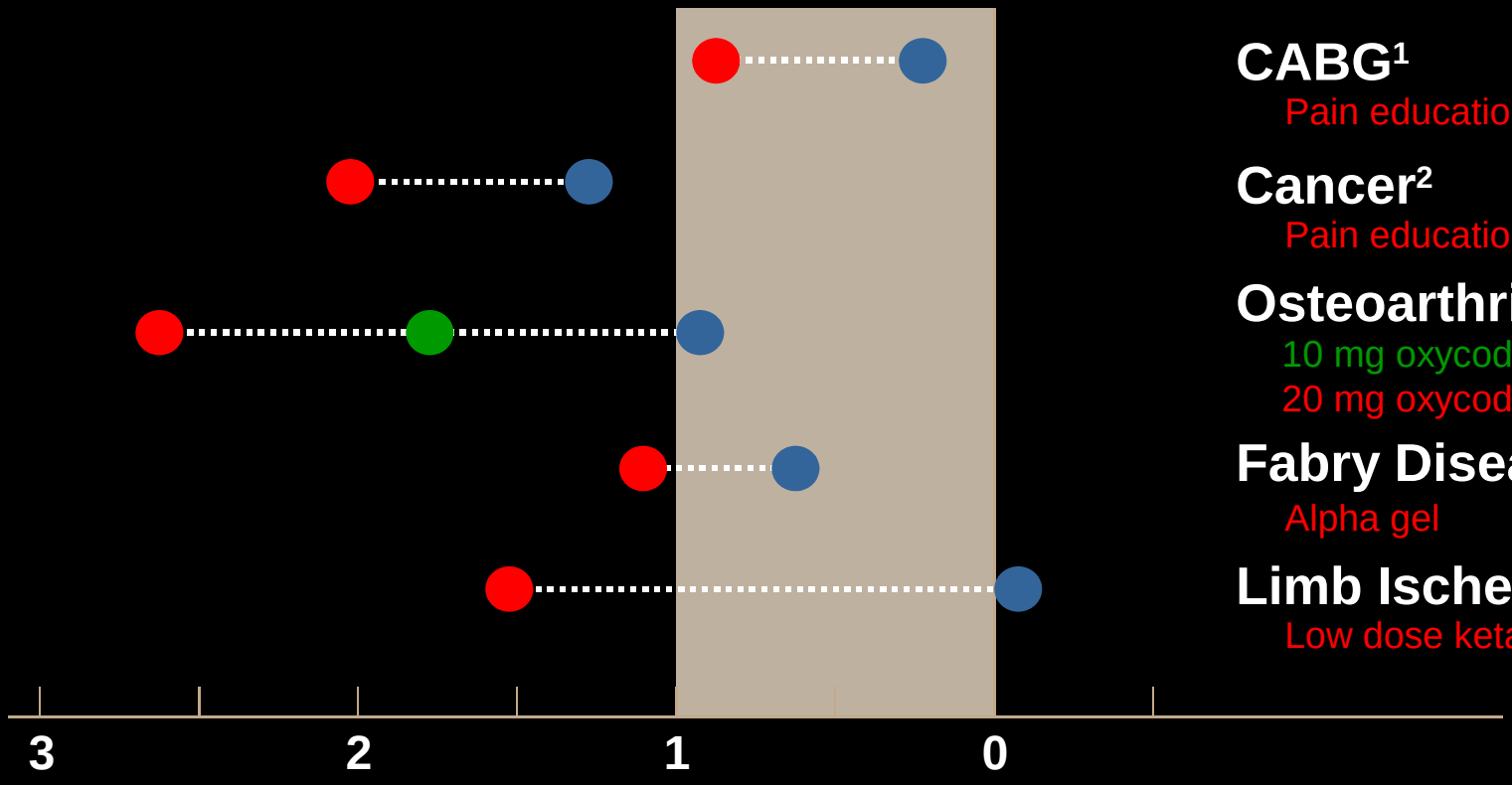
Reduction in Mean Interference: RC Trials



CABG[1]
Pain education

Cancer[2]
Pain education

Osteoarthritis[3]
10 mg oxycodone
20 mg oxycodone

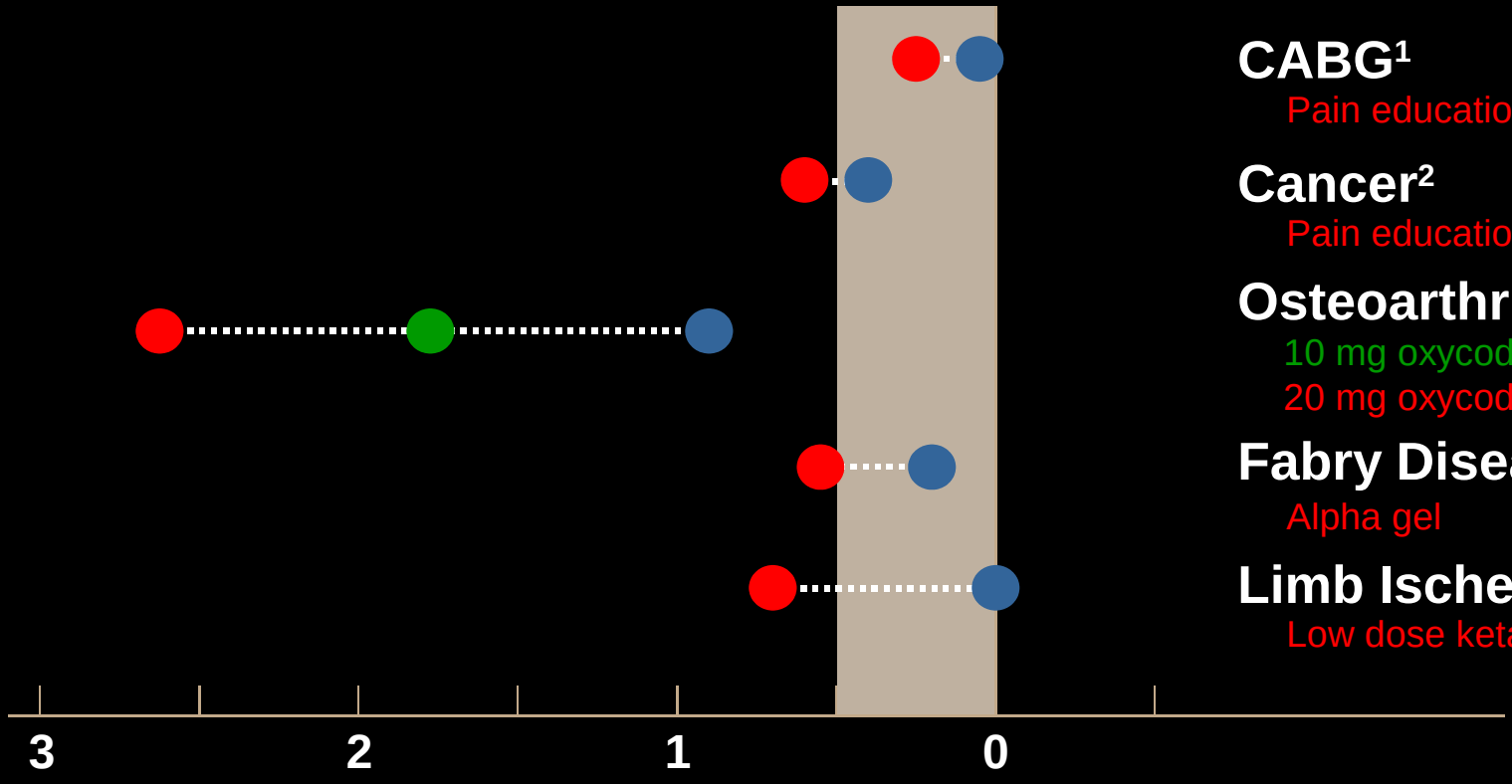
Fabry Disease[4]
Alpha gel

Limb Ischemia[5]
Low dose ketamine

- **Treatment as usual**
- **Intermediate intervention**
- **Full intervention**

[1] Watt-Watson et al, *Pain* 109: 73-85, 2004.
[2] Lai et al, *Support Care Cancer*, 2004.
[3] Roth et al, *Arch Intern Med* 160: 853-860, 2000.
[4] Schiffmann et al, *JAMA* 285: 2743-2749, 2001.
[5] Mitchell & Fallon, *Pain* 97: 275-281, 2002.

Reduction in Mean Interference by Effect Size: RC Trials



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What Do the Scores Mean?
Anchor-Based Outcomes

Painful Diabetic Neuropathy (N=230): Satisfaction Rating

How satisfied or dissatisfied are you with the relief you are experiencing from the prescription, non-prescription or other treatments you are taking for pain due to your diabetes?	n	Mean Interference (SD)
Extremely satisfied	11	4.61 (2.90)
Very satisfied	9	4.92 (3.46)
Somewhat satisfied	66	4.86 (2.37)
A little satisfied	30	6.65 (2.02)
Extremely dissatisfied	21	6.86 (2.35)

Zelman et al, presented at the 2004 meeting of the American Pain Society, Vancouver, BC

Osteoarthritis of the Hip (N=462): Global Assessment of Arthritis

Considering all the ways the osteoarthritis in your Index Hip affects you, how are you doing today?	n	Mean Interference (SD)
Very good/good	1	.17 (na)
Fair	2	1.92 (1.30)
Poor	401	5.41 (2.25)
Very poor	58	6.55 (2.15)

Mendoza et al, presented at the 2003 meeting of the American Pain Society, Chicago, IL

Osteoarthritis of the Knee (N=966): Global Assessment of Arthritis

Considering all the ways the osteoarthritis in your Index Knee affects you, how are you doing today?	n	Mean Interference (SD)
Very good/good	3	2.61 (2.11)
Fair	19	4.59 (2.50)
Poor	792	5.05 (2.17)
Very poor	152	6.48 (2.16)

Mendoza et al, presented at the 2003 meeting of the American Pain Society, Chicago, IL

Coronary Artery Bypass Graft (CABG) (N=220): Global Rating of Medication

How would you rate the study medication you received for pain?	n	Mean Interference (SD)
Poor/fair	27	2.45 (2.53)
Good	106	1.45 (2.02)
Excellent	87	1.04 (1.83)

Mendoza et al, *Pain*, in press.

OA of the Knee (N=753): Change in Global Rating (Baseline to Day 14)

	Interference	Mood-related	Activity-related
No change (n=107)	**0.38 (1.93)**	**0.41 (2.33)**	**0.36 (1.88)**
Got worse (n=10)	**0.23 (1.65)**	**0.67 (0.67)**	**0.45 (1.84)**
Improved (n=636)	**1.89 (2.08)**	**1.70 (2.35)**	**2.08 (2.18)**

Mendoza et al, presented at the 2003 meeting of the American Pain Society, Chicago, IL

OA of the Hip (N=328): Change in Global Rating (Baseline to Day 14)

	Interference	Mood-related	Activity-related
No change (n=39)	0.97 (2.38)	1.19 (2.65)	0.76 (2.36)
Got worse (n=3)	0.44 (0.84)	0.67 (0.67)	0.22 (1.02)
Improved (n=286)	2.26 (2.12)	2.21 (2.29)	2.32 (2.30)

Mendoza et al, presented at the 2003 meeting of the American Pain Society, Chicago, IL

CABG (N=176): Change in global rating (Day 4 to Day 7)

	Interference	Mood-related	Activity-related
No change (n=123)	0.10 (2.51)	0.08 (2.57)	0.04 (2.74)
Got worse (n=32)	0.41 (1.31)	0.31 (1.20)	0.94 (2.29)
Improved (n=21)	0.12 (1.92)	0.18 (1.89)	0.28 (2.30)

Mendoza et al, presented at the 2003 meeting of the American Pain Society, Chicago, IL

Factor-Loading Comparisons

	USA	China	Filipino	Cebuano
Sample size	**1106**	**147**	**267**	**110**
Pain worst	**.68**	**.69**	**.74**	**.38**
Pain least	**.87**	**.79**	**.83**	**.58**
Pain average	**.87**	**1.03**	**.75**	**.73**
Pain now	**.78**	**.77**	**.77**	**.80**
Interference items:				
General activity	**.80**	**.61**	**.72**	**.83**
Mood	**.79**	**.63**	**.71**	**.80**
Walking	**.71**	**.79**	**.72**	**.69**
Work	**.80**	**.91**	**.79**	**.84**
Relations with others	**.76**	**.94**	**.66**	**.81**
Sleep	**.68**	**.47**	**.60**	**.64**
Enjoyment of life	**.83**	**.72**	**.73**	**.78**

Conclusions

- **The Interference subscale is reliable internally and through test-retest across disease type**
- **The Interference subscale is more correlated than the severity subscale with other measures such as the SF36 and CPG**
- **An effect size of at least 0.53 differentiates the mean interference ratings between the mild, moderate, and severe categories of pain severity suggesting the feasibility of using such categorization in a responder analysis**
- **The Interference subscale can be decomposed into activity-related and mood-related subscales**

Conclusions

- **Published phase II studies have found reductions in mean interference rating anywhere from 1 to 3 points**
- **With the exception of bone metastases patients, the reduction in mean interference rating is at least half a standard deviation in Phase II trials**
- **With the exception of CABG patients, reduction in mean interference rating is also at least half a standard deviation in randomized controlled trials**

- **The Interference subscale is sensitive to dose treatment response, i.e, a larger effect is associated with a higher dose of drug**