

# The Utility and Validity of the Modified Brief Pain Inventory in a Multiple-Dose Postoperative Analgesic Trial

Tito R. Mendoza, PhD,\* Connie Chen, PharmD,† Andrew Brugger, MD,† Richard Hubbard, MD,† Michael Snabes, MD, PhD,† Stephen N. Palmer, PhD,\* Qiang Zhang, MD, MPH,\* and Charles S. Cleeland, PhD\*

**Objectives:** Patients undergoing major surgery often require several days of postoperative analgesia. However, few data exist on the longitudinal course of postoperative pain and the psychometric properties of pain assessment tools used in this setting. Our objective was to validate use of the modified Brief Pain Inventory through reanalysis of pain data from a multiple-dose, placebo-controlled, randomized trial of analgesia after coronary artery bypass graft surgery.

**Methods:** Four hundred sixty-two patients who underwent coronary artery bypass graft surgery via median sternotomy were administered a shortened form of the original Brief Pain Inventory that contained 3 severity and 5 interference items. Additionally, patients were presented with a single-item measure of procedure-specific pain. Daily pain and interference ratings were available from days 4 to 14 postoperatively. We performed factor analysis to evaluate the consistency with which the modified Brief Pain Inventory items loaded on 2 separate factors corresponding to the original Brief Pain Inventory's pain severity and pain interference subscales. We calculated 2 reliability measures, internal consistency and test-retest reliability, for each subscale.

**Results:** The modified Brief Pain Inventory consistently measured 2 underlying constructs, severity and interference, with Cronbach alphas of 0.85 or greater for the 2 Brief Pain Inventory scales, and test-retest stability coefficients ranging from 0.58 to 0.95 for each pair of consecutive assessment periods. The procedure-specific pain question showed substantial overlap with a general measure of pain severity, suggesting concurrent validity.

**Discussion:** The modified Brief Pain Inventory was stable and valid over the assessment period, suggesting that it can be used during the subacute postoperative period to assess postoperative pain among patients with coronary artery bypass graft surgery.

**Key Words:** pain assessment, longitudinal studies, postoperative pain, coronary artery bypass

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Postoperative pain often requires aggressive analgesia, especially following such highly invasive procedures as abdominal surgery, major orthopedic surgery, and thoracotomy, in which the physical insult from the procedure can produce severe pain. Although many thoracotomy patients, for example, experience wound healing and a relatively rapid resolution of pain in the days following surgery, those patients who experience acute postoperative pain are more likely to develop chronic post-thoracotomy pain,<sup>1,2</sup> thus requiring postoperative analgesia for days, weeks, or even months after their surgeries.<sup>3,4</sup> Although the pain is usually mild or moderate, a small percentage of patients have pain severe enough to be disabling.

Most published studies of post-thoracotomy symptoms have either been short-term studies in which pain was measured for a brief period (usually 1 day after surgery), or long-term studies that assessed pain for 1 or more months after surgery.<sup>5–7</sup> This is the only medium-duration (subacute) study in which postoperative pain was assessed daily for 1 to 2 weeks after surgery.

The choice of appropriate postoperative pain-assessment measures depends on the amount of time that has elapsed since surgery. During the first 72 hours following surgery, assessment is limited by the patient's restricted activity. Ratings of pain severity and pain relief can be supplemented only by ratings of how much pain interferes with a few basic functional areas, such as movement and coughing. As the patient recovers and gradually becomes more active, however, pain interferes with an increasing number of functions, such as those assessed by the Brief Pain Inventory (BPI)<sup>8</sup> or modified versions thereof.<sup>9</sup>

Although the BPI has been used longitudinally in several descriptive studies and clinical trials,<sup>10–16</sup> no study has systematically examined the psychometric properties of the BPI in this type of longitudinal study design. Consequently, the

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From the \*Pain Research Group, Department of Symptom Research, University of Texas M. D. Anderson Cancer Center, Houston, TX; and †Global Health Outcomes & Clinical Development, Pharmacia Corporation, Skokie, IL.

Reprints: Tito R. Mendoza, PhD, Department of Symptom Research, Box 221, University of Texas M. D. Anderson Cancer Center, 1515 Holcombe Boulevard, Houston, TX 77030 (e-mail: tmendoza@mdanderson.org).

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present study examines the psychometric characteristics (internal consistency, reliability, and construct validity) of patients' responses to a modified version of the BPI over several days following coronary artery bypass graft surgery (CABG). Because the sternotomy incision site is the primary locus of pain following CABG, we also examined patients' responses to a separate, single-item measure of sternotomy pain for comparison with the data from the modified BPI.

## MATERIALS AND METHODS

The data for this analysis were obtained from a multicenter, multiple-dose, double-blind, placebo-controlled, randomized, parallel group study designed to compare the safety and efficacy of an analgesic drug following CABG. All patients received supplemental patient-controlled analgesia (morphine) as needed during post-surgery hospitalization. This was supplemented by codeine 30 mg/acetaminophen 300 mg (Tylenol #3) as soon as patients could tolerate oral medications. Patients also received regular doses of either the study medications or placebos. The primary results of this study will be reported elsewhere.

This reanalysis of the study data examined assessments made over a 10-day period that began when patients were switched from intravenous to oral analgesic therapy, about 72 hours after CABG. A single sternotomy pain item was presented to patients once per day on days 1, 2, and 3; beginning on the fourth postsurgical day, the modified BPI<sup>17</sup> was also used. Most of the patients were discharged from the hospital on day 7; the final assessment was made on the patient's last clinic visit, between days 14 and 17. Accordingly, from day 4 through at least day 14, pain severity, pain interference, and sternotomy incision pain were assessed daily.

## Subjects

Four hundred sixty-two CABG patients enrolled in the study. Of these, 338 patients used the English versions of the assessment instruments, whereas 124 patients were administered the German versions. Sample size varied among the various study measures, as patients did not respond to all items with equal frequency. The maximum numbers of patients responding to the various items were as follows: 336 for the BPI pain severity items, 266 for the BPI pain interference items, and 336 for the sternotomy pain item. The maximum number of patients responding to the sternotomy pain question on days 1, 2, and 3 were 445, 434, and 412, respectively. The majority of patients were white (93%) and male (87%), with an average age of 59.9 (SD = 8.1).

## Measures

The BPI asks patients to rate their "pain at its worst," "pain at its least," and "pain on the average" over the previous 24 hours, as well as "how much pain you have right now," on four 0-to-10 numerical rating scales.<sup>8</sup> Each scale is presented

as a row of equidistant numbers where 0 = "no pain" and 10 = "pain as bad as you can imagine." Patients are also asked to rate separately how their pain interferes with "enjoyment of life," "general activity," "walking ability," "mood," "sleep," "normal work," and "relations with other people." These scales are bounded by 0 = "does not interfere" and 10 = "interferes completely."

A modified version of the BPI<sup>9</sup> was used in this study. Unlike the original BPI, the modified BPI contains 3 severity items and 5 interference items. The 3 pain severity items are "worst pain," "pain on the average," and "pain right now," and the 5 interference items are "walking ability," "mood," "sleep," "relations with others," and "ability to concentrate." We eliminated the interference items querying "enjoyment of life," "activity," and "work," because we did not view them as relevant to the immediate postoperative period. Additional research may determine whether these deletions, especially "enjoyment of life" and "activity," were appropriate.

In addition to the modified BPI, patients were presented with a single-item measure of procedure-specific pain. On day 1 of the study, patients were asked to rate "my maximum amount of sternotomy pain since first dose of study medication," with possible responses of "none," "mild," "moderate," and "severe." On days 2 through 14, patients were presented with the item "my maximum amount of sternotomy pain since this time yesterday." The response choices were the same as on day 1.

## Data Analysis

The BPI has been shown to be a valid and reliable measure for the assessment of several types of clinical pain.<sup>8,11,18,19</sup> Zalon used the BPI to assess postsurgical pain in particular.<sup>14</sup> However, the present study differed from previous validation studies of the BPI in that: 1) a modified form of the instrument was used; and 2) the BPI was presented repeatedly over an extended period. Consequently, we wished to examine the psychometric properties of the instrument under these circumstances. This was done for each of the 2 subscales of the modified BPI: Pain Severity, which is the mean of the patient's "worst pain," "average pain," and "pain now" ratings; and Pain Interference, which is the mean of the patient's ratings on the 5 interference items. As a step in demonstrating the validity of these subscales, we performed factor analysis (principal axis factoring with oblimin rotation) to evaluate the consistency with which the items of the modified BPI loaded on 2 separate factors corresponding to the original BPI's Pain Severity and Pain Interference subscales. This was done for each assessment day to ensure the stability of the factor structure across the entire study period. Because the solutions showed 2 factors, we also calculated 2 measures of reliability—internal consistency and test-retest reliability—for each subscale. We computed Cronbach alphas for each assessment day to measure internal consistency and correlation coefficients to deter-

mine subscale test–retest reliabilities for several combinations of assessment days.

For the sternotomy pain item, we examined its test–retest reliability by calculating a correlation coefficient for patients’ responses to this item within each pair of consecutive assessments. We also described the proportion of patients reporting moderate or severe pain using this item over the 11 assessment days. To provide a measure of criterion validity, we calculated the correlation coefficients between the modified BPI Severity subscale and the sternotomy pain item for each of the 11 assessment days.

The analyses described above were performed on both the sample as a whole and on the 2 language subgroups. This was done to test for any differences between the English and German versions of the shortened BPI in terms of reliability and validity.

Finally, we were concerned that pain severity would be underestimated over time because patients with higher levels of pain would drop out of the study at a higher rate than patients with less pain. We therefore compared the magnitude of pain severity in the observed data to pain severity estimated using the method of last observation carried forward (LOCF) across time.

### RESULTS

The subgroup analysis showed no substantial differences between the English and German versions of the modified BPI. Factor analyses performed on each group produced the same 2-factor structure associated with severity and interference. The severity and interference subscales are equally reliable in the 2 versions. Therefore, we combined the data from both groups for all of our analyses.

No statistically significant differences were found between the magnitude of “worst pain” using the observed data

and that estimated using LOCF. Similar analysis did not find significant differences using the 2 methods on a composite score based on pain interference. Thus, we focused on using the observed data in subsequent analysis.

### Psychometric Properties of the Measures Used

To establish the validity of the modified BPI for CABG patients, we examined whether the modified BPI measures the same 2 factors—pain severity and pain interference—that the original BPI was designed to measure. On each of the 11 days of the study, we found that the pain interference items “relations with other people,” “concentrate,” “mood,” “walking ability,” and “sleep” showed higher loadings with the interference factor than the severity factor. Conversely, the items “average pain,” “worst pain,” and “pain now” showed higher loadings with the severity factor than the interference factor. Table 1 illustrates this finding, showing the factor loadings of the items from the modified BPI for days 4, 5, 13, and 14; the same 2-factor structure was observed for days 6, 7, 8, 9, 10, 11, and 12.

Table 2 shows the Cronbach coefficient alphas and test–retest reliability coefficients for the Severity and Interference subscales. The internal consistency reliability coefficients range from 0.85 to 0.91 for the Severity scores and from 0.90 to 0.92 for the Interference scores. Also, the test–retest reliability coefficients range from 0.72 to 0.95, placing them within or above the moderate range, with the exception of the test–retest reliability coefficient for Interference on days 4 and 5, which was 0.58. The correlations between the Severity and Interference scores ranged from 0.54 to 0.68, suggesting moderate overlap between the 2 scales.

The test–retest reliabilities of the sternotomy pain item, according to Nunnally’s standard,<sup>20</sup> are adequate on day 4 and continue to improve over time (Table 3).

**TABLE 1.** Factor Loadings and Eigenvalues of the 3 Severity Items and 5 Interference Items of the Modified BPI for the First 2 Time Points (Days 4 and 5) and Last 2 Time Points (Days 13 and 14)

	Day 4		Day 5		Day 13		Day 14	
	Interference	Severity	Interference	Severity	Interference	Severity	Interference	Severity
Relations	1.00	−0.13	0.97	−0.13	0.96	0.08	0.99	−0.09
Concentrate	0.91	−0.04	0.91	−0.03	0.92	0.02	0.92	−0.07
Mood	0.83	0.02	0.79	0.07	0.83	−0.04	0.82	0.07
Walk ability	0.70	0.13	0.70	0.10	0.83	−0.02	0.79	0.07
Sleep	0.58	0.18	0.59	0.10	0.65	−0.08	0.62	0.20
Average pain	−0.04	1.01	−0.09	1.04	0.01	−0.98	−0.07	1.03
Worst pain	0.08	0.75	0.12	0.75	−0.02	−0.93	0.14	0.79
Pain now	<0.01	0.67	0.06	0.71	0.03	−0.82	0.02	0.88
Eigenvalues	4.7, 1.4, 0.5		4.9, 1.2, 0.6		5.6, 0.9, 0.5		5.5, 1.1, 0.4	

BPI, Brief Pain Inventory.

**TABLE 2.** Cronbach Coefficient Alphas, Test–Retest Reliabilities, and Intercorrelations of the Pain Severity and Pain Interference Subscales Over Time

Day	Coefficient Alphas		Test–Retest Reliabilities (2 Adjoining Assessments)		Correlation of Severity With Interference
	Severity	Interference	Severity (Days)	Interference (Days)	
4	0.85	0.91	0.77 (4 & 5)	0.58 (4 & 5)	0.54
5	0.87	0.90	0.81 (5 & 6)	0.76 (5 & 6)	0.59
6	0.87	0.91	0.80 (6 & 7)	0.72 (6 & 7)	0.55
7	0.89	0.92	0.83 (7 & 8)	0.74 (7 & 8)	0.60
8	0.90	0.91	0.85 (8 & 9)	0.77 (8 & 9)	0.60
9	0.91	0.91	0.85 (9 & 10)	0.86 (9 & 10)	0.57
10	0.94	0.92	0.84 (10 & 11)	0.87 (10 & 11)	0.55
11	0.93	0.92	0.85 (11 & 12)	0.90 (11 & 12)	0.55
12	0.92	0.91	0.86 (12 & 13)	0.89 (12 & 13)	0.60
13	0.93	0.91	0.88 (13 & 14)	0.90 (13 & 14)	0.67
14	0.91	0.92	0.93 (14 & 15)	0.95 (14 & 15)	0.68

### Pain Severity, Pain Interference, and Procedure-Specific Pain Ratings Over Time

As expected, scores on the BPI Pain Severity subscale (composed of the items “worst pain,” “average pain,” and “pain now”) decreased over the 11 days of the study. Mean Pain Severity was approximately 2.3 (SD 1.8) at day 4, decreasing to about 1.1 (SD 1.5) by day 14. Table 4 shows that the means and standard deviations of the Pain Severity and Pain Interference subscales change from baseline to day 14. Because the Interference subscale was only moderately reliable for day 4 (alpha coefficients of 0.58 from Table 2), we used day 5 as baseline when comparing changes in pain interference. The data indicate that the changes in the BPI Severity subscale from day 4 to day 14 were all statistically significant.

**TABLE 3.** Test–Retest Reliabilities of the Sternotomy Pain Item Over Time

Days	Test–Retest Reliabilities (2 Adjoining Assessments)
4 & 5	0.71
5 & 6	0.70
6 & 7	0.70
7 & 8	0.72
8 & 9	0.70
9 & 10	0.76
10 & 11	0.74
11 & 12	0.76
12 & 13	0.81
13 & 14	0.81

The table also shows that the changes in the BPI Interference subscale were statistically significant, with the exception of changes between day 5 and day 7 and between day 5 and day 8, suggesting that the BPI Severity subscale is more sensitive than the BPI Interference subscale. Effect sizes associated with changes in pain severity ranged from moderate to large (0.11 to 0.72), whereas changes in pain interference ranged from small to moderate (0.09 to 0.36). Mean Pain Interference also generally decreased over time with the exception of day 4, when Interference scores were lower than they were for days 5 and 6. More patients had missing responses on the Interference items than on the Severity items over the course of the study, and the number of patients responding to any of the instruments declined significantly after day 14.

On the sternotomy pain item, 11% of patients in the sample reported severe sternotomy pain on day 1. This proportion decreased to about 5% on day 2 and 3% on day 3. Although the proportion of patients with severe pain on day 4 rose to 5%, the proportion reporting severe sternotomy pain between days 7 and 14 was approximately 2%.

### Criterion Validity: Relationships of “Worst Pain,” Pain Severity, and Pain Interference to the Sternotomy Pain Item

Table 5 shows the correlations on each of the assessment days between the sternotomy pain item and the “worst pain” item, the Pain Severity subscale, and the Pain Interference subscale. The “worst pain” item was highly correlated with the sternotomy pain item, with coefficients ranging from 0.71 to 0.82. Furthermore, the sternotomy pain item was highly correlated with the Pain Severity subscale, but only mildly correlated with the Pain Interference subscale.

**TABLE 4.** Means, Standard Deviations, and 95% Confidence Intervals Around Changes in Mean Pain Severity and Mean Pain Interference from Baseline (Day 4 or Day 5) to Day 14

	Mean Difference	SD of the Difference	95% CI Lower Limit†	95% CI Upper Limit†
<b>Severity</b>				
Day 4 and 5*	0.14	1.28	0.01	0.27
Day 4 and 6*	0.29	1.50	0.13	0.45
Day 4 and 7*	0.46	1.54	0.29	0.62
Day 4 and 8*	0.57	1.61	0.40	0.75
Day 4 and 9*	0.69	1.65	0.51	0.87
Day 4 and 10*	0.78	1.71	0.59	0.97
Day 4 and 11*	0.88	1.78	0.68	1.08
Day 4 and 12*	0.93	1.70	0.74	1.12
Day 4 and 13*	1.06	1.69	0.86	1.26
Day 4 and 14*	1.22	1.69	0.97	1.47
<b>Interference</b>				
Day 5 and 6*	0.19	1.32	0.03	0.35
Day 5 and 7	0.15	1.75	-0.06	0.36
Day 5 and 8	0.17	1.82	-0.06	0.40
Day 5 and 9*	0.40	1.98	0.15	0.65
Day 5 and 10*	0.46	1.72	0.24	0.69
Day 5 and 11*	0.50	1.85	0.26	0.74
Day 5 and 12*	0.60	1.80	0.36	0.85
Day 5 and 13*	0.58	1.78	0.33	0.83
Day 5 and 14*	0.54	1.48	0.27	0.81

\*If the interval does not include 0, the difference between assessments is statistically significant at  $P < 0.05$ .

†95% confidence interval around the mean difference between 2 assessments.

### DISCUSSION

The Severity and Interference subscales of the modified BPI demonstrated good test–retest reliability over time. The sternotomy pain item also showed acceptable reliability during the same time period. The sternotomy pain item was partly redundant with the BPI “worst pain” item.

The reanalysis of the trial data here suggests several conclusions about the performance of pain measures in multidose postoperative analgesic trials. First, given that our data remain reliable across the 11 days of the study, it appears feasible to obtain modified BPI and sternotomy pain ratings on a daily basis for up to 2 weeks following surgery. Second, it is possible to obtain ratings of pain-related interference with several areas of function, such as those measured by instruments like the BPI, starting 72 hours after surgery. Third, the modified BPI performs in this postoperative setting much as the original BPI performs in clinical situations in which it has already been validated. Across each of the 11 days of the trial, the original factor

**TABLE 5.** Correlations Between the Study Measures to Show Criterion Validity

Days	“Worse Pain” With Sternotomy Pain	Pain Severity With Sternotomy Pain	Pain Interference With Sternotomy Pain
4	0.72	0.72	0.41
5	0.74	0.75	0.43
6	0.74	0.76	0.40
7	0.71	0.74	0.41
8	0.72	0.74	0.38
9	0.71	0.75	0.44
10	0.75	0.74	0.34
11	0.82	0.78	0.36
12	0.79	0.81	0.41
13	0.80	0.79	0.52
14	0.78	0.80	0.51

structure (severity and interference) of the BPI is replicated, the 2 subscales of the instrument demonstrate acceptable internal consistency, and test–retest reliability is high.

As expected, responses to the sternotomy pain item were highly correlated with the “worst pain” item, as well as the mean of the 3 BPI Severity items. These correlations ranged from 0.71 to 0.82, suggesting that the ratings are 50% to 67% redundant. (The BPI, which assesses pain in general rather than sternotomy pain specifically, may assess other types of pain as well, which might explain why the overlap between these 2 measures is not greater.) Sternotomy pain ratings, however, were only mildly correlated with BPI Interference scores. Furthermore, the correlations between the Severity and Interference subscales ranged from 0.54 to 0.68, suggesting 29% to 46% overlap. The sternotomy pain item and the Severity scale therefore appear to measure the same component of pain (severity), whereas the Interference scale measures a separate, though related, aspect of pain (pain-related interference with functioning). Because the procedure-specific pain item is more strongly associated with the BPI severity items but less strongly associated with the BPI interference items, the discriminant validity of the BPI scales becomes evident. If the situation requires that only 1 measurement tool be used, dropping the procedure-specific question might be considered, as the BPI obtains both severity and interference information in the same instrument.

The subgroup analysis comparing the English and German versions of the modified BPI showed the same 2-factor structure associated with severity and interference for each group. The severity and interference subscales were also equally reliable in the two versions. These findings were consistent with the results of the validation study of the German

BPI<sup>21</sup> and with studies using the English version of the BPI.<sup>22,23</sup>

This study has limitations. First, because the majority of patients who had CABG were white males, the psychometric properties of the modified BPI only apply to this group of patients. For applicability to a broader population, future studies should include patients who have undergone postoperative procedures other than CABG. Second, this study used a shortened version of the BPI. However, given that the underlying constructs—severity and interference—were observed using this shortened version (3 severity items and 5 interference items), it is very likely that the original BPI (4 severity items and 7 interference items) will demonstrate the same psychometric properties. Third, this study reanalyzes data from a clinical trial rather than from a validation study; the design of the original study did not provide for other assessment instruments to be administered as measures of either concurrent or predictive validity. Future studies, therefore, might examine how the BPI performs compared with other validated measures such as the postoperative quality of recovery score (QoR-40).<sup>24</sup>

In conclusion, these findings support the utility of the Brief Pain Inventory in multidose analgesic trials that extend beyond the immediate postoperative period. Starting at least 72 hours after surgery, the modified BPI can be used for 11 days or more to monitor pain severity and pain-related interference. With regard to the use of a sternotomy pain item versus the modified BPI, it is not clear that the two can be used interchangeably. However, the data suggest that the modified BPI is better because it provides information on two dimensions of pain: severity and interference. Finally, the majority of patients experience low levels of pain 6 days after surgery. Therefore, long-term clinical trials of postoperative pain control may be more efficient and cost-effective if they focus on the subset of patients with high levels of pain. The threshold for high levels of pain may need to be quantified in future studies.

## REFERENCES

- Katz J, Jackson M, Kavanagh BP, et al. Acute pain after thoracic surgery predicts long-term post-thoracotomy pain. *Clin J Pain*. 1996;12:50–55.
- Obata H, Saito S, Fujita N, et al. Epidural block with mepivacaine before surgery reduces long-term post-thoracotomy pain. *Can J Anaesth*. 1999;46:1127–1132.
- Mersky H. Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. *Pain*. 1986;(suppl 3):S1–S226.
- Rogers ML, Duffy JP. Surgical aspects of chronic post-thoracotomy pain. *Eur J Cardiothorac Surg*. 2000;18:711–716.
- Perttunen K, Tasmuth T, Kalso E. Chronic pain after thoracic surgery: a follow-up study. *Acta Anaesthesiol Scand*. 1999;43:563–567.
- Ochroch EA, Gottschalk A, Augustides J, et al. Long-term pain and activity during recovery from major thoracotomy using thoracic epidural analgesia. *Anesthesiology*. 2002;97:1234–1244.
- Senturk M, Ozcan PE, Talu GK, et al. The effects of three different analgesia techniques on long-term postthoracotomy pain. *Anesth Analg*. 2002;94:11–15.
- Cleeland CS. Research in cancer pain. What we know and what we need to know. *Cancer*. 1991;67(suppl 3):823–827.
- Ward SE, Gordon D. Application of the American Pain Society quality assurance standards. *Pain*. 1994;56:299–306.
- Lydick E, Epstein RS, Himmelberger D, et al. Area under the curve: a metric for patient subjective responses in episodic diseases. *Qual Life Res*. 1995;4:41–45.
- Breitbart W, McDonald MV, Rosenfeld B, et al. Pain in ambulatory AIDS patients. I: Pain characteristics and medical correlates. *Pain*. 1996;68:315–321.
- Du Pen SL, Du Pen AR, Polissar N, et al. Implementing guidelines for cancer pain management: results of a randomized controlled clinical trial. *J Clin Oncol*. 1999;17:361–370.
- Wang XS, Cleeland CS, Mendoza TR, et al. The effects of pain severity on health-related quality of life: A study with Chinese cancer patients. *Cancer*. 1999;86:1848–1855.
- Zalon ML. Comparison of pain measures in surgical patients. *J Nurs Meas*. 1999;7:135–152.
- Esnaola NF, Cantor SB, Johnson ML, et al. Pain and quality of life after treatment in patients with locally recurrent rectal cancer. *J Clin Oncol*. 2002;20:4361–4367.
- Tyler EJ, Jensen MP, Engel JM, et al. The reliability and validity of pain interference measures in persons with cerebral palsy. *Arch Phys Med Rehabil*. 2002;83:236–239.
- American Pain Society Quality of Care Committee. Quality improvement guidelines for the treatment of acute pain and cancer pain. *JAMA*. 1995;274:1874–1878.
- Thie NM, Prasad NG, Major PW. Evaluation of glucosamine sulfate compared to ibuprofen for the treatment of temporomandibular joint osteoarthritis: a randomized double blind controlled 3-month clinical trial. *J Rheumatol*. 2001;28:1347–1355.
- Schiffmann R, Kopp JB, Austin HA 3rd, et al. Enzyme replacement therapy in Fabry disease: a randomized controlled trial. *JAMA*. 2001;285:2743–2749.
- Nunnally JC, Bernstein IH. *Psychometric Theory*. New York, NY: McGraw-Hill; 1994.
- Radbruch L, Loick G, Kiencke P, et al. Validation of the German version of the Brief Pain Inventory. *J Pain Symptom Manage*. 1999;18:180–187.
- Serlin RC, Mendoza TR, Nakamura Y, et al. When is cancer pain mild, moderate or severe? Grading pain severity by its interference with function. *Pain*. 1995;61:277–284.
- Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med*. 1994;330:592–596.
- Myles PS, Weitkamp B, Jones K, et al. Validity and reliability of a postoperative quality of recovery score: the QoR-40. *Br J Anaesth*. 2000;84:1–2.