Interpretation of Visual Analog Scale Ratings and Change Scores: A Reanalysis of Two Clinical Trials of Postoperative Pain

Mark P. Jensen,*,† Connie Chen,‡ and Andrew M. Brugger‡

Abstract: The visual analog scale (VAS) is one of the most commonly used measures of pain intensity in pain research. However, there remain important unanswered questions concerning interpretation of specific VAS ratings and change scores. To address these questions, we performed a reanalysis of data from 2 randomized controlled trials of postoperative pain (N = 123 and N = 125) to determine the meaning of VAS pain intensity ratings and change scores. The findings suggested that 100-mm VAS ratings of 0 to 4 mm can be considered no pain; 5 to 44 mm, mild pain; 45 to 74 mm, moderate pain; and 75 to 100 mm, severe pain. As predicted, in assessment of the amount of change corresponding to differing levels of pain relief, percentage change in a patient's VAS score was less biased by pretreatment pain than was absolute change score. The findings also suggested that a 33% decrease in pain represents a reasonable standard for determining that a change in pain is meaningful from the patient's perspective.

Key words: *Pain assessment, treatment outcome, meaningful change.*

The visual analog scale (VAS) of pain intensity consists of a line, most often 100 mm long, with 2 descriptors representing extremes of pain intensity (eg, no pain and extreme pain) at each end. Patients rate their pain intensity by making a mark somewhere on the line that represents their pain intensity, and the VAS is scored by measuring the distance from the "no pain" end of the line.

VASs are among the most commonly used measures of pain intensity in clinical trials. Moreover, a great deal of evidence supports the validity of VASs for assessment of pain intensity.[7] However, 2 important issues concerning interpretation of VAS ratings and change scores have not yet received adequate empirical attention: (1) interpretation of specific VAS ratings and (2) the clinical significance of VAS change scores. Each of these issues has important implications for clinical decision making and for interpretation and analysis of clinical trials.

The first issue relates to how clinicians and researchers should interpret and use specific VAS scores. For example, it has been recommended that pain severity ratings be used to classify pain intensity into specific categories for guiding treatment decisions.[6,16,17] The 3 categories of pain intensity most often used for such classifications are mild, moderate, and severe. However, there has yet to be consensus on the point at which pain intensity turns from mild to moderate or from moderate to severe. Serlin and colleagues[15] demonstrated one method of answering this question by use of a series of analyses of variance (ANOVAs) to determine which cutoffs (based on 0-10 ratings of worst pain intensity) best distinguished cancer patients as a function of the impact of pain on patient functioning. The investigators found that a system that classified a score of 1 to 4 (on a 0-10 scale) as mild pain, 5 to 6 as moderate pain, and 7 to 10 as severe pain provided the optimal classification across samples from 4 different countries.[15] However, similar cutoffs for VAS ratings have not been empirically identified.

The second issue that has not received adequate empirical examination concerns the clinical significance of VAS change scores. How much of a decrease is necessary before it is noticed by patients? How much is necessary for such a change to be deemed significant and meaningful by patients? Unfortunately, relatively little research has examined the question of clinical meaningfulness of changes in pain ratings. (A percent change [decrease] of 50% is commonly used in clinical trials,[2,3,10,11] but this cutoff is arbitrary and may be too conservative.) It is possible that a decrease of less than 50% would be meaningful to some patients. Because of the importance of the cutoff selected and its potentially profound effect on the decision whether a treatment is effective, it would be useful to identify a cutoff by use of a reasonable empirical, not arbitrary, approach.[14]

Two recent studies addressed the question of clinical meaningfulness of pain rating change scores in 2 ways. In one study, Farrar and colleagues[4] determined the pain intensity change score cutoffs that best differentiated subjects who asked for a rescue dose and those who did not. The investigators found the best balance between sensitivity and specificity for a 33% decrease in pain in-

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From the *Department of Rehabilitation Medicine, University of Washington School of Medicine, and †Multidisciplinary Pain Center, University of Washington Medical Center, Seattle, WA; and ‡Pfizer, Skokie, IL.
Address reprint requests to Mark P. Jensen, Department of Rehabilitation Medicine, Box 356490, University of Washington School of Medicine, Seattle, WA 98195-6490. E-mail: mjensen@u.washington.edu

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tensity and an absolute decrease of 2 on a 0 to 10 numeric rating scale (NRS). In a second study, Farrar and colleagues[5] defined a clinically meaningful change in pain as patients' rating overall status after treatment with pregabalin as being very much improved or much improved versus minimally improved, no change, or 1 of 3 levels of being worse. Among patients with various chronic pain diagnoses, an absolute decrease of 1.74 points on the 0 to 10 scale and a percentage decrease of 27.9% were best associated with patient ratings of very much or much improved. Moreover, Farrar and colleagues found that the pretreatment pain intensity had a biasing effect on the absolute change needed to represent a decrease that was meaningful. Patients with higher levels of pretreatment pain needed greater absolute decreases in pain than did patients with lower pretreatment pain to judge those decreases as reflecting improvement. However, this biasing effect of pretreatment pain intensity was not observed for percentage change scores.

Taken together, the studies by Farrar and colleagues provide important advances in our knowledge about the clinical importance of changes in pain intensity ratings. The 2 studies, which assessed different types of pain (chronic versus acute) and different patient populations, provided results that were remarkably similar. These findings provide potential guidelines that may be used to assess whether a change in pain (a decrease in pain of approximately 30%-33%) is clinically meaningful. Such guidelines may be useful in clinical trials to help determine the numbers of patients who benefit from specific treatments, thereby expanding the information derived from analyses of average changes in pain across all patients.

As Farrar and colleagues[5] pointed out, however, their findings may not generalize to all pain syndromes. There is a need to replicate the findings in additional samples of patients and with other commonly used rating scales such as the VAS. The current study was performed to address the meanings of VAS ratings and change scores on the basis of the issues discussed earlier. In this study, we used data from 2 randomized controlled trials involving patients with acute postoperative pain that assessed treatment outcome with 3 scales: a VAS, a 0 to 3 verbal rating scale (VRS) (0, no pain; 1, mild pain; 2, moderate pain; 4, severe pain), and a 0 to 4 pain relief rating. In both studies, groups of patients who had undergone either unilateral total knee replacement surgery[13] or abdominal hysterectomy or myomectomy by laparotomy[1] were randomly assigned to receive different study medications, including 30 mg ketorolac, 4 mg morphine, or placebo on the first postoperative day. Preintervention assessment of pain intensity was made with the VAS and a 4-point VRS. Postintervention measurements were made with these 2 measures plus a 5-point VRS pain relief rating at 16 time points up to 24 hours after treatment (assessment was discontinued if a rescue dose of analgesic was given). Including 2 studies in which the same procedures, treatments, and measures but 2 different clinical populations were used provided us the opportunity to determine the replicability of the findings in 2 different postoperative populations.

The primary research questions for this study were as follows: (1) What VAS scale scores represent no pain, mild pain, moderate pain, and severe pain according to the patients involved in these trials? (2) What are the absolute and percentage changes in a 100-mm VAS associated with no, a little, some, a lot, and complete relief ratings by patients? (3) Do the amounts of absolute and percentage change in a 100-mm VAS associated with each level of relief rating vary as a function of pretreatment pain? Although we did not have specific hypotheses concerning the answers to questions 1 and 2, we did predict, on the basis of the findings of Farrar and colleagues,[3] that larger absolute change scores would be needed to rate a change as providing relief when pretreatment pain intensity is relatively high than when pretreatment pain is relatively low. We also expected the biasing effect of pretreatment pain on the amount of change needed for the change to be rated as providing relief to be less for percentage change scores compared with absolute change scores.

Methods

Subjects

A detailed description of the subjects in each of the 2 randomized, multicenter, double-blind studies can be found in the primary reports of these studies.[1,13] In brief, 123 subjects in the knee surgery study received placebo (n = 39), morphine (n = 42), or ketorolac (n = 42). The average age was 64.85 years (SD, 9.97 years), and 65.9% of the subjects were women. One hundred twenty-three women in the laparotomy study received placebo (n = 42), morphine (n = 42), or ketorolac (n = 41). Participants in the laparotomy study had an average age of 40.85 years (SD, 7.59).

Measures

The outcome measures included a VAS and a VRS of pain intensity and a VRS of pain relief.

VAS Pain Intensity Rating

The VAS intensity rating consisted of a 100-mm line with the end points no pain and worst pain. Study participants were asked to make a mark on the line that represented their current pain intensity, and the VAS pain intensity level was scored by measurement in millimeters of the distance from the no pain end of the line. The difference between each posttreatment VAS score and the pretreatment score was calculated and represented each participant's VAS difference score.

VRS Pain Intensity Rating

A 4-point VRS pain intensity rating (0, none; 1, mild; 2, moderate; 3, severe) was administered to participants at each assessment time point.

VRS Pain Relief Rating

The VRS relief rating consisted of a list of 5 words or phrases describing different levels of pain relief: 0, none; 1, a little; 2, some; 3, a lot; 4, complete. Study participants were asked to pick the single word or phrase that best described the amount of relief they had experienced compared with starting (pretreatment) pain. The VRS relief rating score was the number associated with the word or phrase the participant chose.

Procedures

Data were taken from 2 completed multicenter, double-blind, placebo-controlled studies. The procedures used in the 2 studies were essentially the same. After knee surgery[13] or laparotomy,[1] all study participants received patient-controlled analgesia (PCA). PCA consisted of 0.5 to 2 mg/dose morphine sulfate or 10 to 30 mg/dose meperidine hydrochloride with a 10-minute lockout between doses. On the morning of the first postoperative day, PCA was discontinued. Patients who had at least a moderate level of pain (45 mm or greater on the VAS intensity ratings and either moderate or severe on the VRS intensity rating) within 6 hours of discontinuation of PCA were randomized to receive one of several study medications, including 30 mg ketorolac (Toradol; Roche Pharmaceuticals, Nutley, NJ), 4 mg morphine, or placebo. Rescue medication was permitted at any time and was administered according to the standard practice of the study site. All participants were blinded to treatment until all study data had been collected and entered into a database.

Pain assessment was conducted after elicited incisional pain before treatment (VAS and VRS intensity ratings) and 0.25, 0.50, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 7, 8, 10, 12, 16, and 24 hours after administration of the study medication until (and if) a rescue dose of a medication was required. Both studies were approved by the institutional review boards associated with each study site, and informed consent was obtained from each study participant.

Data Analysis

All analyses for addressing the 3 questions of the study were performed separately for each sample of patients to help determine ability to generalize findings across samples.

Study Question 1

To address the first study question concerning the VAS intensity rating scores that represent pain described as none, mild, moderate, and severe, we computed an average of the VAS intensity scores associated with each posttreatment VRS descriptor separately for each subject. This process resulted in no more than 1 average VAS score for each subject per VRS rating. If the subject never used a particular VRS rating, an average VAS score for that rating could not be computed for that subject. We then examined the mean, standard deviation, minimum, and maximum of these average VAS scores separately for each VRS descriptor. Because it is possible that these average VAS scores might have varied somewhat as a function of the drug the patients received, we performed a series of ANOVAs to compare average VAS scores across the drug conditions for each descriptor and for each study. In a secondary analysis, we grouped each VAS rating at each assessment point into 1 of 20 possible categories (0-4, 5-9, 10-14, . . . , 95-100) and examined the distributions of VAS score categories associated with each pain intensity descriptor (none, mild, moderate, severe).

Study Question 2

To address study question 2, that is, the amounts of absolute and percentage change in a 0 to 100 VAS that are associated with no, a little, some, a lot, and complete relief, we computed separately for each subject the average absolute and percentage change score associated with each relief rating (no relief, a little relief, some relief, a lot of relief, and complete relief). We averaged these individual patient averages across the study participants for each study separately. To determine ability to generalize the mean absolute and percentage change scores across both samples, we tested for significant differences in these change scores between the knee surgery and the laparotomy subjects.

Study Question 3

To test the hypothesis that the amount of absolute change in pain intensity associated with each rating of pain relief varies as a function of pretreatment pain, we computed separately for each study the correlation between pretreatment pain and absolute and percentage change in pain associated with each VRS rating of pain relief. The prediction that the amount of change needed to rate a change as providing relief varies as a function of pretreatment pain level would be supported if significant associations were found between pretreatment pain intensity and the change scores associated with each relief rating.

Results

Study Question 1

In the knee surgery study, 20, 84, 101, and 42 patients used the VRS intensity descriptor none, mild, moderate, or severe, respectively, at least once during the study. These descriptors were used by 15, 85, 100, and 50 patients at least once in the laparotomy study. The means, standard deviations, and minimum and maximum average VAS intensity scores associated with each VRS pain intensity descriptor for the knee surgery and the laparotomy study are presented in Table 1.These findings indicated that, on average, 100-mm VAS scores in the 0.0- to 1.4-mm range (SD approximately 3 mm) are very likely to be rated no pain by patients, VAS scores of approximately 27 to 28 mm (SD approximately 10 mm) are considered mild pain, VAS scores of approximately 56 to 58 mm (SD approximately 10 mm) are considered moderate pain, and VAS scores of approximately 83 to 87 mm (SD approximately 10 mm) are considered severe pain.

The results of ANOVA comparing average VAS scores associated with each VRS descriptor across drug conditions showed only 1 statistically significant difference between patients who received morphine and patients who received ketorolac for severe pain. However, across all 3 drug condition groups in both studies, the severe pain scores were approximately 79 mm or greater on average, indicating that average VAS scores at this level or higher are likely to be judged severe by all patients.

The results of the analyses examining the distributions of VAS score categories associated with each VRS intensity rating are shown in Fig 1. The results indicated that for both samples, any VAS pain rating less than 5 mm tended to be labeled *no pain.* VAS ratings between 5 mm and 44 mm on a 0 to 100-mm VAS scale were labeled mild most often by subjects in both studies. Pain ratings between 45 mm and 74 mm were labeled moderate by most of the subjects in both studies. Ratings in the 75- to 79-mm range were labeled severe most often (60%) by subjects in the laparotomy study and remained moderate for most of the subjects in the knee surgery study, although 40% of the subjects in the knee surgery study rated pain in the 75- to 79-mm range as severe. All pain intensities 80 mm or greater were considered severe by most subjects in both studies.

Study Question 2

The findings concerning study question 2 are presented in Table 2. When patients reported no relief, they reported an average, albeit small, increase in pain from pretreatment to each assessment point that was rated no relief. A little relief was associated with an average decrease of 13.3 mm and 9.4 mm on the 100-mm VAS for the knee surgery and laparotomy patients, respectively. Some relief was associated with average absolute decreases of 20.0 mm and 27.3 mm and a lot of relief with average absolute decreases of 43.7 mm and 44.4 mm. Complete relief was associated with average absolute decreases of 61.6 mm and 66.9 mm. The percentage change scores associated with each relief rating ranged 12% to 18%, 36% to 41%, 63% to 66%, and 99% to 100% for a little, some, a lot, and complete relief, respectively. In all cases, there were no statistically significant differences in absolute or percentage change scores associated with each relief rating between the knee surgery and laparotomy patients.

Table 1. Mean, Standard Deviation (SD) and Minimum, and Maximum Visual Analog Scale (VAS) Scores Associated With Each Pain Intensity Descriptor for the Knee Surgery and Laparotomy Study

Intensity Descriptor	*VAS Mean*	*VAS SD*	*VAS Minimum*	*VAS Maximum*	*No. of Subjects*
Knee surgery study					
None	1.4	2.6	0.0	28.0	20
Mild	27.8	10.4	2.0	60.0	84
Moderate	55.8	11.7	22.0	88.0	101
Severe	86.6	9.9	52.0	100.0	42
Laparotomy study					
None	0.0	0.0	0.0	0.0	15
Mild	26.8	9.4	2.0	60.0	85
Moderate	58.2	8.6	32.0	84.0	100
Severe	82.5	10.0	62.0	100.0	50

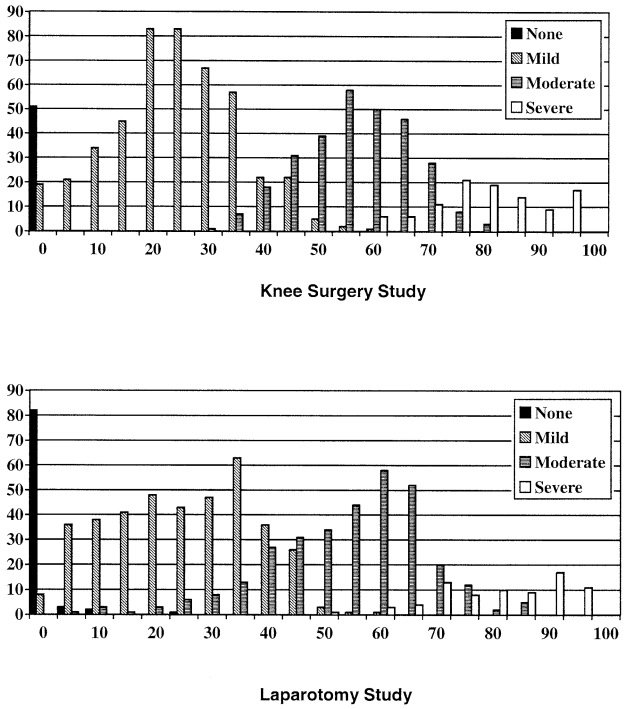

Figure 1. Distribution of visual analog scale scores associated with each level of pain intensity for each study.

Study Question 3

The correlations between pretreatment pain and average absolute and percentage change scores associated with each relief rating are presented in Table 3. As predicted, these coefficients are large and statistically significant across all pain relief ratings for both studies for absolute change scores. As predicted, and except when patients rated themselves as having no relief, the associations between pretreatment pain intensity and change in pain associated with each rating of pain relief were less for percentage change than for absolute change in pain. However, the associations between pretreatment pain and average percentage change were still statistically significant among change scores associated with no relief and a little relief for both studies and a lot of relief among the laparotomy patients.

Discussion

The results of this study shed light on the classification of VAS ratings into mild, moderate, and severe levels of pain intensity from the perspective of patients experiencing pain, the clinical significance of changes in pain as assessed with the 100-mm VAS, and the effect of pretreatment pain intensity on the meaning of change in

Table 2. Mean Visual Analog Scale Absolute and Percentage Change Scores Associated With Each Rating of Pain Relief for Each Study Separately

	Knee surgery study			Laparotomy			
Relief Rating	Mean	SD	n	Mean	SD	n	t
Absolute change score							
No relief	−6.8	10.9	56	−7.3	12.1	69	0.22
A little relief	13.3	14.8	80	9.4	12.4	82	1.79
Some relief	20.0	15.3	79	27.3	12.5	76	0.56
A lot of relief	43.7	16.0	67	44.4	15.6	65	0.23
Complete relief	61.6	14.8	20	66.9	13.2	15	1.10
Percentage change score							
No relief	−11.4%	17.9	56	−12.5%	20.1	69	0.33
A little relief	18.0%	19.5	80	12.5%	19.8	82	1.78
Some relief	36.4%	19.6	79	40.8%	16.1	76	1.52
A lot of relief	63.7%	17.5	67	66.0%	15.6	65	0.80
Complete relief	99.2%	1.7	20	100.0%	0.0	15	—

Note: None of the *t* values are statistically significant. A *t* value for the comparison of percentage change scores between the knee surgery and the laparotomy subjects who rated themselves as having complete relief could not be computed because there was no variance in this variable among the laparotomy subjects.

pain. The results can be used to make judgments about the importance of changes in pain found in clinical trials and have important implications for understanding the effects of analgesia in research and in clinical practice.

Classification of VAS Ratings of Pain Intensity

Current clinical guidelines base clinical decision making on classifications of discrete levels of pain intensity.[6,16,17] The current findings provide assistance for this effort by identifying cutoffs for transforming VAS scores into specific pain intensity classifications. Specifically, and in both of the samples studied, the results indicated that a 100-mm VAS score less than 5 mm may be labeled as no pain, 100-mm VAS scores from 5 to 44 mm may be labeled as mild pain, 100-mm VAS scores from 45 to 74 mm may be labeled as moderate pain, and 100-mm VAS scores 75 mm and greater may be labeled as severe pain.

Although previous research has indicated that direct transformation between NRSs and VASs are not necessarily accurate,[8,12] it is interesting to compare and contrast the classification cutoffs identified in this study with those identified for 0-to-10 NRSs in 2 previous studies in which a different approach was used for identifying cutoffs (based on ability to differentiate patients in terms of the effects of pain on function) in different pain populations (cancer-related pain,[15] amputation-related pain[9]). Across all 3 studies (the current and 2 previous), pain intensities greater than 0 but 40% or less of the total possible score (eg, 1-4 on the 0-10 NRS, 5-40 on the 0-100 VAS) were labeled mild pain. Scores 50% or greater and 60% or less of the total possible score (5-6 on the 0-10 scale, 50-60 on the 0-100 VAS) were generally classified as moderate pain, and scores 80% or greater of the total possible score were classified severe. These findings suggest a remarkable degree of consistency across measures and populations, such that ratings in these ranges could be classified into mild, moderate, and severe pain with a fair amount of confidence.

There is somewhat less consistency in the gray areas of the specific cutoffs across populations or even across pain sites within a single population,[9] especially for the

Table 3. Correlations Between Pretreatment Visual Analog Scale Pain Intensity Ratings and Absolute and Percentage Changes Scores Associated With Each Rating of Pain Relief

	No Relief	A Little Relief	Some Relief	A Lot of Relief	Complete Relief
Knee surgery study					
Absolute change	0.39**	0.52***	0.49***	0.67***	1.00***
Percentage change	0.45***	0.34**	0.17	0.07	−0.24
Laparotomy					
Absolute change	0.45***	0.48***	0.52***	0.80***	1.00***
Percentage change	0.51***	0.35**	0.13	0.34**	—

Note: A correlation coefficient between pretreatment pain and percentage change in pain intensity could not be computed for patients in the laparotomy study who rated themselves as obtaining complete relief because there was no variance in percentage change among these patients for these ratings. A positive correlation means that a larger absolute or percentage change in Visual analog scale score is needed for a patient to rate a change as providing relief when pretreatment pain is higher. The larger the correlation, the stronger is this biasing effect of pretreatment pain.
$^{**}P < .01$, $^{***}P < .001$

cutoff used to differentiate moderate from severe pain. For example, whereas the optimal cutoff for this switch for persons with acquired amputation rating back pain and pain in general was 7 (on a 0-10 scale) in 1 study,[9] the same as that found among patients with cancer pain,[15] it was 8 for persons with acquired amputation who were rating phantom limb pain.[9] In the current study, a single cutoff for identifying patients who reported moderate versus severe pain was not ascertained that was consistent across both samples. Although future research is needed to clarify the most appropriate cutoff for differentiating moderate and severe pain for VAS ratings, we would argue that a cutoff of 70% may make the most sense for postoperative patients, given that many participants in both samples rated pain in this range as severe.

Clinical Importance of Changes in VAS Ratings

The current findings provide, for the first time, specific guidelines concerning the clinical importance associated with different changes in VAS pain ratings. Absolute changes of approximately 10 mm on the 100-mm VAS (9.4 mm and 13.3 mm in the laparotomy and knee surgery studies, respectively) and percentage changes of approximately 15% (12.5% and 18.0% in the 2 studies) were rated as a little relief. Any average postoperative pain decreases less than these amounts could therefore be considered less than a little and probably have very little clinical meaning to patients, even if such changes are found statistically significant.

Absolute change between 20 mm and 30 mm on the 100-mm VAS and percentage change between approximately 35% and 40% were associated with some pain relief according to the patients in these studies. This amount of change is consistent with the percentage change (30% to 33%) in 0-to-10 NRSs identified by Farrar and colleagues as clinically meaningful in a reanalysis of clinical trial data among persons with acute pain[4] and chronic pain.[5] Moreover, the average percentage change ratings associated with some pain relief in the current samples were not biased by pretreatment pain intensity level.

The consistency with which change of approximately 33% emerges as clinically meaningful across studies, samples, and methods combined with evidence that the meaning of this change is not biased by pretreatment pain intensity provides strong support for a 33% decrease in pain as being a reasonable primary standard with which different treatments can be compared. Such a standard could be used to determine the frequency with which any particular treatment provides a meaningful decrease in pain. The establishment of such a standard also allows for greater comparability across studies and pain treatments.[5]

In addition to such a basic standard, however, it may be informative, perhaps as secondary analysis, to compare treatments with respect to the frequency with which they provide both noticeable (eg, an approximately 15% reduction in pain) and substantial (eg, an approximately 66% reduction in pain) decrease in pain. However, future research, with similar and different measures in additional samples of persons with pain is necessary to help determine the utility of these proposed secondary standards.

Biasing Impact of Pretreatment Pain

We had hypothesized, on the basis of the findings of Farrar and colleagues,[5] that pretreatment pain levels would be associated with the amounts of change, or decrease, in pain necessary for those changes to be judged as providing pain relief across each pain relief rating. This hypothesis was strongly supported across all measures of absolute change and was partially supported for the measures of percentage change. In practical terms, this finding means that the meaning of absolute change scores varies as a function of pretreatment pain. An absolute decrease in pain of 20 mm on a 100-mm VAS may be viewed as providing some relief for patients whose pretreatment pain is relatively low but only a little relief for patients whose pretreatment pain is relatively high.

Because of this biasing effect of pretreatment pain on the meaning of absolute change scores, the current findings do not support the use of a standard absolute change as a goal or guideline for pain treatment or as a way to compare treatments. Such a standard may result in a goal that is too high for patients whose pretreatment pain is relatively low, or too easy to achieve for patients whose pretreatment pain is relatively high.[5]

Although the percentage change scores were less biased by pretreatment pain, even those associated with a little relief in both studies and a lot of relief in the laparotomy study were associated with pretreatment pain. Thus caution should be used in interpretation of data that suggest a treatment provided either a little relief or a lot of relief and in interpretation of change scores substantially less than or greater than 33%. In interpretation of such findings, it would be important to take into account (and report on) the distribution of the pretreatment pain levels of the patients being evaluated.

Limitations of the Study

We studied only 2 samples of patients with 1 type of pain (acute postoperative). It is possible that different meanings of pain intensity and different change score cutoffs could be obtained in patients with different types of pain. For example, a 33% decrease in acute postoperative pain over the course of 1 day might be judged differently from the same decrease in chronic pain that occurs over the course of many weeks or months. In addition, we used patient self-report (descriptors of pain intensity levels and pain relief) as the criterion for labeling the meaning of pain and the meaning of change scores. Whereas patient self-reported improvement has been used as a standard by other investigators,[5] additional criteria may be used, such as behavioral indicants[4] or patient reports of functioning.[9,15] The analyses used

to examine specific VAS cutoffs associated with specific VRS intensity ratings were performed with all available observations. The number of observations available, however, varied from one subject to another, so that the results of these descriptive analyses are more heavily influenced by some subjects than others. However, the consistency of these findings across the 2 samples as well as with other research using other scales provides preliminary support for ability to generalize the results. Future research with other samples would provide additional important evidence concerning ability to generalize these cutoffs for classifying patients as having mild, moderate, or severe pain.

Another issue concerning this study, which might be considered both a strength and weakness, is that the participants rated their pain in 3 different drug conditions. It is possible that the different conditions might have influenced the meaning given to different intensity levels of pain or that the treatments, particularly morphine, might have produced sedative effects that would have made the pain ratings less accurate. However, few differences were found in how the VRS intensity and relief ratings were linked to VAS ratings and change scores. The only significant difference concerned the VAS scores associated with severe pain in the laparotomy subjects. Patients receiving morphine rated severe pain as significantly more intense (average VAS, 87.2 mm) than did patients given ketorolac (average VAS, 79.2 mm) or placebo (average VAS, 80.2 mm). However, these differences, although statistically significantly different from one another, were all above the 75-mm cutoff recommended for classifying a patient as experiencing severe pain.

There was a high percentage of female subjects in this study (66% of patients in study 1 and 100% of patients in study 2). It is possible that different findings might have occurred if the samples had included more male patients (although Farrar and colleagues did not find any effect of sex on the change scores associated with each rating of improvement[5]). Replication of the current findings is needed in additional (and different) samples and with additional criteria to determine ability to generalize the findings.

Finally, although the findings suggest overall that a decrease of approximately one third (33%) may be a reasonable standard for judging the efficacy of analgesia treatments, changes less then this value are clearly noticeable by patients and should probably also be reported in clinical trials. This factor is particularly important for treatments that may have minimal side effects, because it is likely that many patients would be interested in a treatment that produces a 20% or even a 15% decrease in pain that has few significant side effects. Therefore we are not proposing that a treatment that produces less than a 33% decrease in pain is not efficacious or should not be recommended for use.

Conclusions

Despite the limitations of this study, the findings were remarkably similar across both samples and were generally consistent with the findings of previous investigators, who used very different samples, measures, approaches, and standards to define the cutoffs associated with specific levels of pain[9,15] and change scores that represent meaningful changes in pain.[4,5] As a group these studies indicate that pain intensities in the 0- to 4-mm range on a 100-mm VAS (0 on a 0-10 NRS) can be said to represent no pain, 5 to 44 mm (1-4 on a 0-10 NRS) to represent mild pain, 45 to 74 mm (5-6 on a 0-10 NRS) to represent moderate pain, and 75 to 100 mm (7-10 on a 0-10 NRS) to represent severe pain. To the extent that treatment decisions are based on classifications of pain intensity into these categories of pain intensity,[6,16,17] these cutoffs appear reasonable for this purpose. Because they indicated that percentage change is less biased by pretreatment pain than is absolute change, the current findings support the use of percentage change in pain as a primary outcome variable (over absolute change) in controlled trials. The findings also show that a 33% decrease in pain is a reasonable standard for a treatment to be deemed providing meaningful relief.

References

1. Barton SF, Langeland FF, Snabes MC, LeComte D, Kuss ME, Hubbard R, Dhadda SS, Talwalker S: Efficacy and safety of intravenous parecoxib sodium in relieving acute post-operative pain following laparotomy surgery. Anesthesiology 97:306-314, 2002

2. Ben Abraham R, Marouari N, Weinbroum AA: Dextromethorphan mitigates phantom pain in cancer patients. Ann Surg Oncol 10:268-274, 2003

3. Chrubasik S, Model A, Black A, Pollak S: A randomized double-blind pilot study comparing Doloteffin and Vioxx in the treatment of low back pain. Rheumatology 42:141-148, 2003

4. Farrar JT, Portenoy RK, Berlin JA, Kinman JL, Strom BL: Defining the clinically important difference in pain outcome measures. Pain 88:287-294, 2000

5. Farrar JT, Young JP, LaMoreaux L, Werth JL, Poole RM: Clinical importance of changes in chronic pain intensity measures on an 11-point numerical rating scale. Pain 94:149-158, 2001

6. Jacox A, Carr DB, Payne R. Management of Cancer Pain, Clinical Practice Guideline No. 9. AHCPR publication no. 94-0592, Agency for Health Care Policy and Research, US Department of Health and Human Services, Public Health Service, Rockville, MD, 1994.

7. Jensen MP, Karoly P: Self-report scales and procedures for assessing pain in adults, in Turk DC, Melzack R (eds): Handbook of Pain Assessment, 2nd ed, New York, Guilford Press, 2001, pp 15-34

8. Jensen MP, Miller L, Fisher L: Assessment of pain during medical procedures: A comparison of three scales. Clin J Pain 14:343-349, 1998

9. Jensen MP, Smith DG, Ehde DM, Robinson LR: Pain site and the effects of amputation pain: Further clarification of the meaning of mild, moderate, and severe pain. Pain 91: 317-322, 2001

10. McQuay H, Carroll D, Jadad AR, Wiffen P, Moore A: Anticonvulsant drugs for management of pain: A systematic review. Br Med J 311:1047-1052, 1995

11. Miner JR, Fish SJ, Smith SW, Biros MH: Droperidol vs. prochlorperazine for benign headaches in the emergency department. Acad Emerg Med 8:873-879, 2001

12. Price DD, Bush FM, Long S, Harkins SW: A comparison of pain measurement characteristics of mechanical visual analogue and simple numerical rating scales. Pain 56:217-226, 1994

13. Rasmussen GL, Steckner K, Hogue C, Torri S, Hubbard RC: Intravenous parecoxib sodium for acute pain after orthopedic knee surgery. Am J Orthop 31:336-343, 2002

14. Rowbotham MC: What is a "clinically meaningful" reduction in pain? Pain 94:131-132, 2001

15. Serlin RC, Mendoza TR, Nakamura Y, Edwards KR, Cleeland CS: When is cancer pain mild, moderate or severe? Grading pain severity by its interference with function. Pain 61:277-284, 1995

16. World Health Organization: Cancer Pain Relief, Geneva, World Health Organization, 1986

17. World Health Organization: Cancer Pain Relief and Palliative Care (World Health Organization Technical Report Series 804), Geneva, World Health Organization, 1990