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What decline in pain intensity is meaningful to patients with acute pain?☆

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Abstract

Despite widespread use of the 0–10 numeric rating scale (NRS) of pain intensity, relatively little is known about the meaning of decreases in pain intensity assessed by means of this scale to patients. We aimed to establish the meaning to patients of declines in pain intensity and percent pain reduction. Upon arrival to the postanesthesia care unit, postsurgical patients rated their baseline pain intensity on both a 0–10 NRS and on a 4-point verbal scale. Patients whose NRS was higher than 4/10 received intravenous opioids until their pain intensity declined to 4/10 or lower. During opioid titration, patients were asked every 10 min to rate pain intensity on a NRS and to indicate the degree of pain improvement on a 5-point Likert scale from 'no improvement' to 'complete pain relief'. Seven hundred adult patients were enrolled. For patients with moderate pain, a decrease of 1.3 units (20% reduction) corresponded to 'minimal' improvement, a decrease of 2.4 (35% reduction) to 'much' improvement, a decrease of 3.5 units (45% reduction) corresponded to 'very much' improvement. For patients with severe pain, the decrease in NRS pain score and the percentage of pain relief had to be larger to obtain similar degrees of pain relief. The change in pain intensity that is meaningful to patients increases as the severity of their baseline pain increases. The present findings are applicable in the clinical setting and research arena to assess treatment efficacy.

Keywords: Pain assessment; Gender differences; Age differences; Patient oriented research

1. Introduction

The most frequently evaluated dimension of the experience of pain is its intensity (Carr et al., 2002). The 0–10 numeric rating pain scale (NRS) and the 0–10 visual analog scale of pain intensity (VAS) are commonly used for this purpose. However, little is known about the significance from the patient's point of view of declines in the NRS or VAS.

To establish the clinical significance of any change in a symptom scale score, it is necessary to compare it with a change in a global measure of improvement. This approach was initially used to evaluate the clinical meaning of a change in a dyspnea score (Jaeschke et al., 1989). In pain studies, a key global measure of improvement is the degree of pain relief reported by the patient. In order to determine the meaning of a change in the pain intensity, we must ask the patient to report simultaneously the change in the pain score and the degree of pain relief (Max and Laska, 1991).

Efforts have been made to determine the clinical meaning of a decrease in the NRS or VAS, in children (Powell et al., 2001) and adults with cancer (Farrar et al., 2000) and chronic non-cancer pain (Farrar et al., 2001). However, the studies that evaluated adult subjects were retrospective analyses of randomized controlled trials that had not been designed for the purpose of determining the clinical meaning of a decrease in pain intensity, and are susceptible to measurement error. In the study of cancer pain relief, 'adequate relief' was defined not by asking patients what degree of relief they perceived as acceptable, but by their no longer requiring additional opioid doses as rescue medication (Farrar et al., 2000). In the study of chronic non-cancer pain, although global pain relief was used to

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determine the clinical meaning of a change in pain intensity score, that information was collected 5–12 weeks after the beginning of the study. Therefore, patients at the end of the study had to recall the intensity of their pain at the time the trial had commenced and compare it to their present pain intensity. In addition, there are no studies that evaluate the meaning of change in NRS in an adult population with acute pain. The clinical meaning of changes in the NRS in patients with cancer or chronic non-cancer pain may differ from that in patients with acute pain because cancer pain affects coping abilities and mood (Jacox et al., 1994), factors that could influence the meaning of a change in NRS pain score.

The proportion of subjects with a specific percentage reduction in pain intensity is increasingly used in the literature to evaluate treatment efficacy. A cutoff of 50% to dichotomize pain intensity outcomes is commonly used to calculate number-needed-to-treat (NNT) (Moore et al., 1996, 1997a,b). Although a 50% decline in pain intensity correlates well with other measures of pain intensity and pain relief (Moore et al., 1996, 1997a,b), the clinical meaning to patients of specific percentage reductions in pain intensity in patients with acute pain is unknown.

We aimed to establish in patients with acute pain, the clinical meaning of a decrement in the NRS and a percentage reduction in pain intensity. We defined a 'meaningful' decrease in pain intensity as that associated with patient-reported pain relief characterized as 'much' or 'very much' improvement. In addition, we wanted to determine the impact of age and gender on the meaning of a change in the NRS pain score and percentage pain reduction.

2. Methods

This study was approved by the Institutional Review Board of San Ignacio Hospital. From February to December 2001, we recruited hospitalized or ambulatory patients with postoperative pain of intensity higher than 4/10 on the NRS. We asked patients undergoing routine care to rate their baseline pain on a 0–10 NRS (0, no pain; 10, worst pain imaginable) and to describe their pain intensity on a 4-point verbal scale (VRS) as none, mild, moderate, or severe. After their initial pain assessment, all patients received intravenous opioids. To titrate ongoing analgesic administration, we asked patients to rate their pain intensity on the NRS every 10 min, and to indicate the degree of pain improvement on a 5-point Likert scale (PILS) (no improvement, minimal improvement, much improvement, very much improvement, or complete pain relief). All patients received analgesics until their pain intensity was 4 or less at rest, according to the standard of care of the hospital. Study research nurses evaluated and recorded the information.

The opioids that were administered were morphine, hydromorphone, or fentanyl. For patients younger than 65 years, the loading dose for morphine was 2.5 mg, hydromorphone 0.5 mg, and fentanyl 25 μg. For patients 65 years or older, the loading dose for morphine was 1.5 mg, hydromorphone 0.3 mg, and fentanyl 15 μg.

2.1. Statistical methods

For the analysis of continuous variables, we estimated means and standard deviations. For discrete variables, we calculated percentages. We used box plots to present the distribution of the changes in NRS pain scores and the percent pain reduction, according to pain relief category. To evaluate the impact of baseline pain intensity, gender, and age on the meaning of a change in NRS and on percentage of pain reduction, we plotted the change in NRS and the percent pain reduction in subgroups according to these factors. For the exploratory analyses, we categorized age into three groups: 15–40 years, 41–60 years, and >60 years.

To determine the change in the NRS corresponding to each increment of pain relief, we used a linear regression model. For this purpose, we estimated the difference in the pain intensity score from the baseline value at each time of evaluation. Because visual inspection of the data suggested that the meaning of changes in pain intensity depended upon baseline pain intensity, we included in the model the baseline VRS (moderate or severe pain), and the interaction between VRS and the three categories of the PILS (minimal, much, and very much pain improvement). We did not include the 'complete' pain relief category of the PILS in our statistical model because only 24 patients had complete pain relief, but information from these patients was included in the corresponding category for times when they reported less than complete pain relief. To determine if the meaning of changes in the NRS depended upon American Society of Anesthesiologists (ASA) physical status, age, or gender, we included in the regression model ASA physical status, age as a continuous variable, and gender, and evaluated the interactions between pain relief and age, and pain relief and gender in the model. In the regression model, the dependent variable was the difference in the pain intensity and the independent variables were the categories of the pain relief scale, categories of the verbal scale, ASA physical status, and the interaction terms. To determine what variables or interactions were statistically significant, we used Wald statistics, in which each parameter estimate is divided by its standard error (Kleinbaum et al., 1998).

Because each patient had multiple pain evaluations (until the NRS was 4/10 or less) and these measures were not independent, we employed an analysis of repeated measures using generalized estimating equations (GEE) that takes this lack of independence into consideration by adjusting the standard errors (White, 1982; Zeger et al., 1988).

To determine the meaning of a percentage pain reduction and the impact of baseline pain, age, gender, and ASA physical status on the meaning of a percentage pain reduction, we followed a similar procedure as described

above. We calculated the percentage of reduction in pain intensity as 100 × ((baseline pain intensity − subsequent pain intensity)/baseline pain intensity).

To evaluate the opioid dose that patients received, we converted the doses of the different opioids to equipotent doses of morphine. We considered 1 mg of parenteral morphine equivalent to 0.2 mg of parenteral hydromorphone and 0.01 mg of parenteral fentanyl (Carr et al., 1992; Janssen, 1984; Woodhouse et al., 1999).

P values less than 0.05 were considered significant. Ninety-five percent confidence intervals were also estimated. All statistical calculations were performed with STATA® statistical software, version 7.0 SE.

3. Results

We included 700 patients. There were no patients who were lost to follow-up. Female patients predominated in the sample. The ASA physical status of our patients, the total intraoperative fentanyl dose received, the type of operation, and other characteristics of the patients are listed in Table 1.

More than 55% of the patients complained of severe pain and more than 90% of the patients received morphine as their postoperative analgesic. All patients reached the target pain level of 4/10 or less. The analgesics employed and the doses required are shown in Table 2. Forty-one percent of the patients achieved 'very much' improvement (Table 2).

In terms of the correspondence of pain intensity evaluated with the NRS and VRS, we found that a median value of 6 on the NRS corresponded to moderate pain on the VRS and a median value of 8 corresponded to severe pain.

Table 1
Characteristics of the subjects included in the study and type of surgical procedures

Number of patients	700
Mean number of observations per patient	5
Age	
Mean (years ± s.d.)	40.9 ± 15.1
Range (years)	16–88
Percentage of women	62.2
Weight (kg ± s.d.)	65.2 ± 11.8
Mean intraoperative dose of fentanyl (μg ± s.d.)	129.1 ± 69.4
ASA physical status (%)	
ASA I	67.7
ASA II	26.0
ASA III	5.9
ASA IV	0.4
Type of surgery (%)	
Head and neck	14.6
Thoracic	7.7
Abdominal	47.6
Orthopedic	26.7
Spinal	3.4

Table 2
Pain intensity at postanesthesia care unit (PACU) arrival, type and dose of analgesics administered, and pain relief obtained

Pain intensity at PACU arrival	
Mean numerical rating scale score (0–10)	7.9 ± 1.7
Median numerical rating scale score (range)	8 (5–10)
Patients with moderate pain (%)	43.7
Patients with severe pain (%)	56.3
Type of analgesics administered (%)	
Morphine	93.4
Hydromorphone	6.2
Fentanyl	0.4
Opioid dose received (as morphine equivalents)	
Mean (mg ± s.d.)	5.1 ± 3.1
Range (mg)	1.5–17.5
Median NRS after final loading dose (range)	3 (0–4)
Pain relief obtained (%)	
'Much' improvement	55.7
'Very much' improvement	40.8
'Complete' relief	3.5

3.1. Meaning of a change in the NRS score

3.1.1. Exploratory analyses

The box plot shows that larger changes in the NRS correspond to greater degrees of pain relief (Fig. 1). The meaning of a decline in the NRS varies with the intensity of the baseline pain. When the baseline pain intensity is severe, larger changes in the NRS appear necessary to obtain a similar degree of pain relief than when the pain intensity is moderate, particularly to achieve 'much' or 'very much' improvement. The meaning of a decline in NRS is similar in

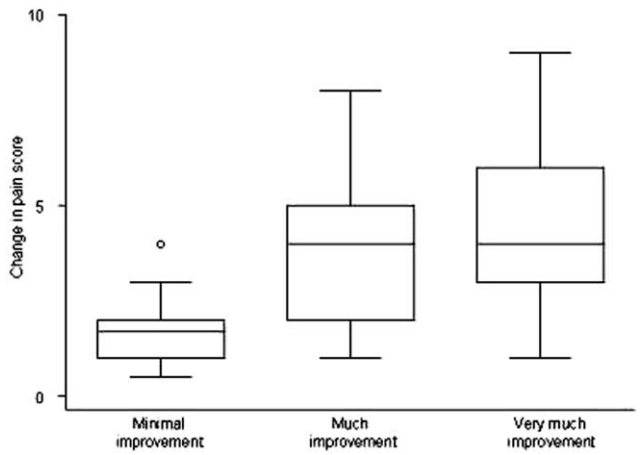

Fig. 1. Box plots of the change in the NRS by pain relief category. The box plots illustrate the distribution of the change in the NRS pain score by pain relief category. Larger changes in the NRS pain score occur as the degree of pain relief increases. Each patient could contribute responses to more than one pain relief category. For example, a patient might report 'minimal' improvement initially, but after subsequent opioid doses could report 'very much' improvement. We have plotted only the pain relief categories included in the regression model. The line in the middle of the box represents the median. Each 'box' extends from the 25th percentile to the 75th percentile. The vertical lines extending outwards from each box represent observations beyond these percentiles, and the circles represent observations that are considered to be outliers.

both genders (Fig. 2). The meaning of a decline in the NRS is similar in all three age groups (Fig. 3).

3.1.2. Statistical analysis

Linear regression analysis confirms the findings of the exploratory analysis. When baseline pain is severe, larger changes in the NRS are necessary ($P = 0.001$) to achieve similar degrees of pain relief than when baseline pain is moderate. The interactions between pain relief and baseline pain intensity were statistically significant ($P = 0.001$ for both), which indicates that if the baseline pain is severe, even larger decreases in the NRS are necessary to obtain 'much' or 'very much' improvement than those necessary to obtain 'minimal' improvement. The meaning of change in the NRS according to baseline pain intensity can be seen in Table 3.

The interactions between pain relief and age ($P = 0.3$), and pain relief and gender ($P = 0.6$) were not statistically significant, indicating that the meaning of a change in pain intensity was similar in all ages and in men and women. The ASA physical status did not affect the meaning of a decline in pain intensity ($P = 0.1$).

3.2. Meaning of a percentage change

3.2.1. Exploratory analyses

The box plot shows that larger percentage reductions in pain intensity occur as the magnitude of patient-reported pain relief increases (Fig. 4).

The percentage pain reduction for 'minimal' improvement is similar for baseline pain of moderate or severe intensity. Larger percentage pain reductions, however, are necessary to achieve 'much' or 'very much' improvement when the baseline pain intensity is severe than when the baseline pain intensity is moderate (Fig. 5). The meaning of percentage changes is similar in both genders (Fig. 5).

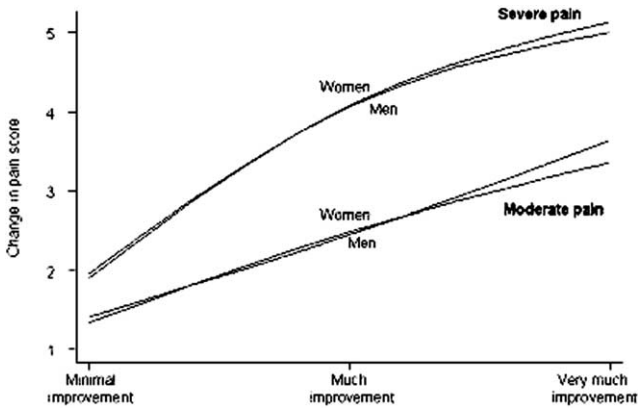

Fig. 2. Change in the NRS by pain relief category, severity of pain, and gender. The meaning of a change in the NRS pain score varied with the intensity of the pain. When the baseline pain intensity is severe, larger changes in the NRS pain score are necessary to obtain a similar relief of pain than when the pain intensity is moderate, particularly to achieve much or very much improvement. The meaning of a change in NRS pain score is similar in both genders.

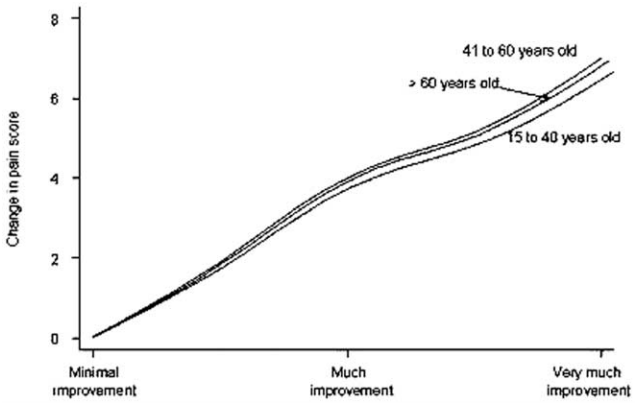

Fig. 3. Change in the NRS by pain relief category and age. The meaning of a change in the NRS pain score is similar in the three age groups. For our exploratory analyses, age was grouped in three categories: 15–40, 41–60, and >60 years.

The meaning of percent reductions in pain intensity appears similar in the three age groups (Fig. 6).

3.2.2. Statistical analyses

Linear regression analysis confirms the findings of the exploratory analyses. The percentage pain reduction necessary to obtain 'minimal' improvement is similar for baseline pain of moderate or severe intensity ($P = 0.5$). However, the interactions between pain relief and baseline pain were statistically significant ($P = 0001$ for both). In other words, when the baseline pain is severe, larger percentage pain reductions are necessary to obtain 'much' or 'very much' improvement than those necessary to obtain 'minimal' improvement. The meaning of percentage pain reduction stratified according to baseline pain intensity can be seen in Table 4.

The interactions between pain relief and age ($P = 0.2$) and pain relief and gender ($P = 0.8$) were not statistically significant, indicating that the meaning of a percentage pain

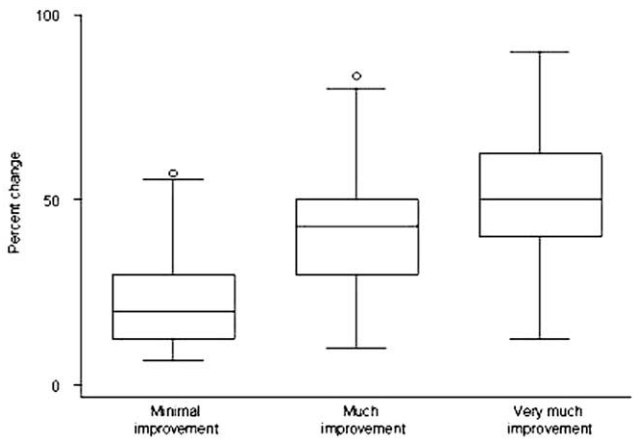

Fig. 4. Box plots of the percentage reduction in the NRS by pain relief category. The box plots illustrate the distribution of the percentage reductions in the NRS pain scores according to pain relief category. Larger percent reductions in NRS occur as the degree of pain relief increases (see Fig. 1 legend for explanation of box plots).

Table 3
Declines in the NRS pain score and their meaning to patients, according to baseline pain intensity

	Baseline pain moderate (95% confidence interval)	Baseline pain severe (95% confidence interval)
Minimal improvement	1.3 (1.2–1.4)	1.8 (1.7–1.9)
Much improvement	2.4 (2.2–2.6)	4.0 (3.9–4.1)
Very much improvement	3.5 (3.3–3.8)	5.2 (5–5.4)

reduction was similar in all ages and in men and women. The ASA physical status did not affect the meaning of a percentage pain reduction ($P = 0.1$).

4. Discussion

Pain evaluation is a crucial step to achieve adequate pain control (Carr et al., 1992; Carr and Goudas, 1999). The understanding of the meaning of changes in the NRS or percentage pain reduction is indispensable for interpretation of the effectiveness of pain treatment. We found that in patients with acute pain, both the meaning of changes in NRS and the meaning of percent pain reduction depend upon baseline pain intensity.

In children, a one-unit decrement in NRS has been reported to be the threshold for clinical significance (Powell et al., 2001). Our study supports this finding. We found that a change of 1.3 units was the threshold for minimal pain relief if the baseline pain intensity is moderate. However, the authors of the pediatric paper did not evaluate the effect of baseline pain intensity upon the meaning of changes in pain intensity. We found that for severe baseline pain, the minimum clinically significant decrease in the NRS is 1.8 units.

Although it is important to recognize the minimal change in the NRS that is discernible to patients, we believe that identification of this threshold is not sufficient to evaluate analgesic effectiveness. We found that a decline in the NRS has to be 2.4 units or greater to be identified as 'much' improvement by patients with acute pain of moderate intensity on the VRS. Other researchers have reported similar results in patients with cancer pain, but baseline pain was not considered in their analysis (Farrar et al., 2000). We found that if the baseline pain is severe, the change in the NRS pain score must be 4.0 units for patients to identify 'much' improvement. Farrar et al. (2001) in their study of patients with chronic non-cancer pain considered the effect of baseline pain intensity and found, as we did, that the meaning of a change in the NRS depends upon the intensity of the initial pain.

It is not surprising that the relation between declines in pain intensity and patient-described pain relief is a function of initial pain intensity. Lasagna (1962), in a classic paper, found that initial pain intensity was a predictor of pain relief after morphine administration. The more intense their initial pain, the less likely were patients to experience complete pain relief. In Lasagna's study, 92% of patients with mild acute pain obtained complete pain relief after 10 mg of morphine vs. 32% of patients who had very severe pain. Price et al. (1985, 1986) have also shown that the higher the pain intensity, the lower the percentage reduction in experimentally induced heat pain in response to intravenous doses of morphine or fentanyl.

In terms of the clinical meaning of percent pain reduction, we found that independently of the baseline pain severity, the minimal change in the NRS that is noticeable (i.e. identified with 'minimal' improvement) to

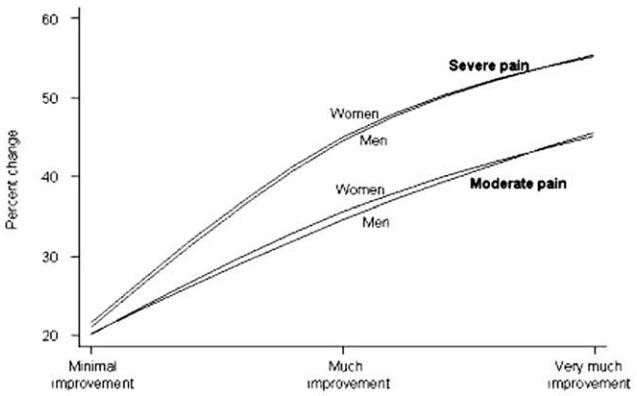

Fig. 5. Percentage pain reduction by pain relief category, severity of pain, and gender. The percentage pain reduction for minimal improvement is similar when baseline pain intensity is moderate or severe. Larger percentage pain reductions are necessary to achieve 'much' or 'very much' improvement when baseline pain intensity is severe than when the baseline pain intensity is moderate. The meaning of percentage change is similar in both genders.

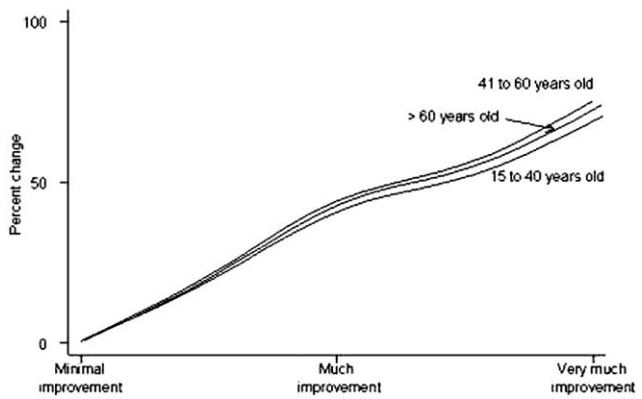

Fig. 6. Percent pain reduction by pain relief category and age. The meaning of a percentage reduction is similar in the three age groups. For our exploratory analyses, age was grouped in three categories: 15–40, 41–60, and >60 years.

Table 4
Percentage declines in the NRS pain score and their meaning to patients, according to baseline pain intensity

	Baseline pain moderate (95% confidence interval)	Baseline pain severe (95% confidence interval)
Minimal improvement	20.1 (18.1–22.2)	20.3 (19.0–21.6)
Much improvement	34.7 (32.7–36.8)	44.4 (43.2–45.6)
Very much improvement	45.0 (43.1–46.8)	56.1 (53.9–58.4)

patients is 20%. The American College of Rheumatologists (ACR) has defined improvement as a 20% decrease in pain; pain alleviation is one of five core parameters used by ACR to decide treatment effectiveness (Felson et al., 1995, 1998). In the present study to achieve higher degrees of pain relief, the percent reduction has to be 35% if baseline pain is of moderate intensity or 44% if baseline pain is severe. Therefore, we believe that the use of a cutoff of 50% to dichotomize pain intensity outcomes for calculation of NNT may be too stringent. Recent studies in patients with chronic and cancer pain that employed somewhat different methodologies (see above) found that a 30–33% decline in VAS was judged to be clinically important relief by patients (Farrar et al., 2000, 2001). One notable difference between the present study and that of patients with chronic pain is that the authors found that the meaning of a percent reduction did not vary with the intensity of the pain (Farrar et al., 2001). Indeed, they considered this lack of variation to be an advantage of using percentage pain reduction as an outcome measure. However, they employed only a graphical analysis of their results, and so it is possible that there may have been such a relation. We believe that a difference of 10%, as we found, could have been overlooked easily.

Gender differences in pain perception and in response to treatment are well described (Cepeda and Carr, 2003; Cepeda et al., 2002; Gear et al., 1996; Riley et al., 1999). We found, however, that the meaning of a change in the NRS or the percentage reduction did not depend upon the gender or age of the patients.

In terms of the relation between NRS and VRS, we found, as expected, that the mean value of the NRS increased as the adjectives that patients chose to describe their pain intensity became more extreme. Our results support previous findings that indicate values between 4 and 6 on the NRS correspond to moderate pain and those greater than 6 correspond to severe pain (Collins et al., 1997; Serlin et al., 1995). This division of the NRS has been validated in patients with cancer by grading pain severity according to its interference with function (Serlin et al., 1995), and in patients with acute pain by observing stepwise increases in analgesic consumption as patients moved from one pain intensity category to another (Bodian et al., 2001).

In the present study, we observed patients undergoing opioid titration as part of routine postoperative care, until their pain intensity was 4/10 or less. We could have continued administering loading opioid doses until patients reported ‘complete’ pain relief. However, pain treatment protocols of the San Ignacio Hospital indicate that when pain intensity is 4/10 or less, no more loading opioid doses are necessary. Instead, at that point patient-controlled analgesia (PCA) or another analgesic regimen ordered by the treating physician is started. This algorithm explains why only 41% of our patients achieved ‘very much’ improvement of their pain. However, this management strategy did not impair the precision of our results, as is evident from the width of the confidence intervals of our estimates.

In summary, the magnitude of acute reductions in NRS that patients identify with ‘much’ or ‘very much’ pain relief depended upon the severity of the initial pain. For moderate pain, a decrease of 2.4 units (35%) on the NRS is required for clinically meaningful pain relief. Patients in severe pain require larger decreases in the NRS and percentage pain reductions to obtain similar degrees of pain relief. The findings of this study support and extend other emerging research designed to help clinicians and researchers interpret patient-based estimates of pain treatment efficacy. However, because the present study relied only upon the NRS to evaluate pain intensity, we do not know if our findings are generalizable to other scales such as the VAS.

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