BRIEF REPORTS

Clinically Important Change in the Visual Analog Scale after Adequate Pain Control

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Abstract

Objectives: To define the minimum clinically important difference (MCID) for the visual analog scale (VAS) of pain severity by measuring the change in VAS associated with adequate pain control. **Methods:** The authors conducted a prospective, observational study. Adult emergency department (ED) patients with acute pain (<72 hours) were eligible. Patients rated their pain severity on a 100-mm VAS on presentation and at discharge. Patients were asked if they would accept any analgesic, then if they would accept a parenteral analgesic before treatment. At discharge, they were asked whether they had received adequate pain control. **Results:** The authors enrolled 143 patients (mean age, 36 years; 54% female). The mean decrease in VAS was −30.0 mm (95% confidence interval [CI] = −36.4 to −23.6) for the 116 of 143 (81%) patients with adequate pain control at discharge vs. −5.7 (95% CI = −11.2 to −0.3) for the 27 with inadequate pain control ($p < 0.001$). At discharge, the mean VAS was 31.3 mm for those with adequate pain control vs. 55.1 for those without. Mean VAS for the 114 of 143 patients who would accept any analgesics initially was 64.7 vs. 47.1 for the 29 reporting no analgesic need. Initially, 77 patients would accept parenteral analgesics (mean VAS = 72.5 mm). **Conclusions:** A mean reduction in VAS of 30.0 mm represents a clinically important difference in pain severity that corresponds to patients' perception of adequate pain control. Defining MCID based on adequate analgesic control rather than minimal detectable change may be more appropriate for future analgesic trials, when effective treatments for acute pain exist. **Key words:** pain measurement; analgesia; visual analog scale; minimum clinically important difference; clinical trials. ACADEMIC EMERGENCY MEDICINE 2003; 10:1128–1130.

Deficiencies in acute pain treatment are gaining recognition. Physician underestimation of pain severity is a contributing factor.[1,2] Variability in patients' expression and physicians' interpretation may contribute to disagreement on pain severity.[3] No method exists to objectively measure the complex internal process of pain perception. Thus, patient self-reports remain the ''gold standard.''[4]

The visual analog scale (VAS) is the most common research tool used to measure pain. Being a continuous measure, small changes in the VAS may have statistical significance, without clinical meaning.[5] Previous studies have defined the minimum clinically important difference (MCID) by correlating changes in the VAS with descriptive categories (e.g., ''a little less pain'').[6–9] A recent methodologic conference recommended that future research focus on defining ''major'' clinical improvement.[10] We propose that the point at which a patient perceives that his or her pain has been adequately controlled represents a natural alternative standard to define the MCID.

The primary objective of this study was to define the MCID by measuring the mean change in VAS associated with the patients' perception of adequate pain control. Secondary objectives were to estimate the mean value of the VAS that corresponds to the patients' perception of: 1) any analgesic need on arrival to the emergency department (ED), and 2) parenteral analgesic need on arrival to the ED.

METHODS

Study Design. We conducted a prospective, observational, cohort study. The study was approved by our institutional Research Ethics Board. Verbal informed consent was obtained from all patients.

Study Setting and Population. The study was conducted in the ED of a Canadian University teaching hospital (annual census, 55,000) between June and September 1999. We included patients presenting with acute pain (onset within 72 hours). We excluded patients who were: hemodynamically unstable (heart rate > 120, blood pressure < 90 sys-

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tolic or 60 diastolic, oxygen (O_2) saturation < 90%), pregnant, younger than 16 years of age, unable to provide informed consent, had a Glasgow Coma Scale Score (GCS) ≤ 14, had a history of chronic pain, or had previously enrolled in the study.

Study Protocol. We randomly selected 32 eight-hour shifts. All consecutive eligible patients presenting during these study hours were approached by a research assistant (RA) for consent. Interviews were conducted before assessment by the emergency physician (EP) and again at discharge. Ongoing analgesic treatment was left to the EP, blinded to the patient's questionnaire responses.

Measurements. The RA asked patients to rate their pain on a horizontal, 100-mm line bounded by ''no pain'' on the left and ''worst pain possible'' on the right. The RA asked patients: ''Would you accept any analgesic?'' and then ''Would you accept an injection for your pain?'' initially and at discharge. The VAS was repeated at discharge, and patients were asked whether their pain was adequately treated. The primary outcome measure was the mean change in VAS among patients who stated they had adequate pain control.

Data Analysis. The unpaired t-test was used to compare change in pain scores between groups with and without adequate analgesia. Confidence intervals (CIs) were calculated for point estimates of proportions using the score method with continuity correction. The sample size was determined according to the desired precision of the primary outcome, VAS at discharge. We calculated that a sample of 139 patients would allow estimation of the primary outcome with a 95% CI width of <10 mm, assuming a standard deviation of 30 mm.

RESULTS

Of 245 consecutive patients who were screened, 98 were excluded as a result of: chronic pain (36), communication barrier (16), altered mental status (14), no consent (14), younger than 16 years old (12), previous enrollment (3), hemodynamic instability (2), and pregnancy (1). Two patients had received analgesics before assessment by the RA. Two patients were discharged with incomplete data, leaving 143 enrolled patients. The mean age was 36.4 years, and 77 were female (54%). The presenting complaint was: abdominal pain (49), extremity pain (44), back pain (22), renal colic (13), migraine (8), and shoulder dislocation (7). Fourteen patients were admitted (10%).

At discharge, 116 of 143 patients reported adequate pain control (see Table 1). Their mean reduction in pain severity was −30.0 mm (95% CI = −36.3 to −23.6). Mean VAS reduction was −25.4 for all 143 patients. The mean discharge VAS for the 116 patients who reported adequate pain control was 31.3 vs. 55.1 mm for the 27 with inadequate pain control ($p < 0.001$).

TABLE 1. Initial, Discharge, Absolute Change, and Percentage Change in Pain Severity Visual Analog Scale (VAS) Score According to Patient Perception of Analgesic Need

	n (%)	Initial Mean VAS (mm)	Discharge Mean VAS (mm)	Mean Change, VAS	95% CI, Change in VAS	% Change, VAS
All patients	143 (100%)	61.2	35.8	−25.4	−30.9 to −19.9	−25.3%
Patients with adequate analgesia at discharge						
Yes	116 (81%)	61.3	38.6	−30.0	−36.4 to −23.6	−30.1%
No	27 (19%)	59.1	55.1	−5.7	−9.0 to 0.9	−5.2%
Patients who would accept any analgesia initially						
Yes	114 (80%)	64.7	37.7	−27.1	−33.3 to −20.8	−30.4%
No	29 (20%)	47.1	28.2	−18.9	−30.7 to −7.2	−5.6%
Patients who would accept IV/IM analgesia initially*						
Yes	77 (54%)	72.5	37.7	−34.8	−42.5 to −27.0	−40.1%
No	65 (45%)	47.9	33.0	−14.9	−22.1 to −7.6	−8.6%
Patients who would accept any analgesia at discharge						
Yes	63 (45%)	57.9	47.6	−10.3	−16.4 to −4.3	−1.9%
No	80 (56%)	63.7	26.5	−37.3	−45.0 to −29.5	−43.9%
Patients who would accept IV/IM analgesia at discharge						
Yes	29 (20%)	70.8	57.0	−13.9	−24.2 to −3.5	−1.8%
No	114 (80%)	58.7	30.4	−28.3	−34.7 to −22.0	−31.4%

*One subject could not be classified and is excluded from these subgroups. IV = intravenous; IM = intramuscular.

On presentation, 114 of 143 (80%) patients stated they would accept medication to relieve their pain. Their mean VAS was 64.7 vs. 47.1 for the 29 of 143 patients reporting no analgesic need. Initially, 77 of 143 (54%) patients stated that they would accept parenteral analgesics. Their mean VAS was 72.5 vs. 47.9 mm for those who would not accept parenteral analgesia.

DISCUSSION

This study is the first to our knowledge to define the MCID based on the change in VAS associated with adequate pain control. We found a larger change (30.0 mm) than the 13 to 19-mm values for MCID previously reported.[6–9] These previous authors defined the MCID by correlating mean change in VAS with descriptive categories such as ''a little less pain.'' But are such differences truly clinically meaningful? Our definition emphasizes a ''major'' clinically important difference, as recommended at a 2001 conference focused on methodologic issues concerning the MCID.[10] Detecting minimal improvement may be clinically relevant in pain syndromes refractory to treatment (i.e., chronic pain). Should the lowest threshold reliably detectable be the standard used in expensive, potentially risky clinical trials required to develop new analgesics for acute pain? We propose that a definition of the MCID based on adequate analgesic response may be more appropriate.

Complete pain relief is cited as the ultimate goal in pain management[4] but is not achieved in many cases. Dose-dependant side effects of analgesics, underlying pathology, or patient frustration with long delays in the ED may prevent complete relief.

The change in pain severity associated with the patients' perception of adequate pain control is a relevant alternative standard to define the MCID for the VAS of pain severity. Simply asking patients whether they require further analgesia seems a simple, logical alternative, making pain measurement and the definition of the MCID unnecessary. However, several studies have demonstrated that formal measurement improves pain management.[5] A patient's decision to refuse analgesia may be based on concerns other than pain severity. Understanding what changes in the values of VAS scores correlate with patients' perception of adequate pain control may allow physicians to better interpret patients' refusal of analgesia.

LIMITATIONS

It is possible that the study protocol introduced a Hawthorne effect. Patients may have been influenced to request analgesics because of study participation, or may have been more likely to report adequate pain control. Clinical use of the VAS may have similar effects, and control or measurement of such effects is difficult. We did not measure descriptive categories of pain relief as previous authors have done to minimize interview length, but this prevents direct comparison with previous studies. By design, we enrolled a heterogeneous patient population to improve the ability to generalize our results to an undifferentiated ED patient population; however, our findings may not apply to dissimilar patient populations. Subgroups were too small to allow for meaningful analysis.

CONCLUSIONS

A mean reduction in VAS of 30.0 mm represents a clinically important difference in pain severity that corresponds to patients' perception of adequate analgesic control. Defining MCID based on adequate analgesic control rather than minimal detectable change may be more appropriate for the design of future analgesic trials, given the availability of effective treatments for acute pain.

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