Determining the Minimum Clinically Significant Difference in Visual Analog Pain Score for Children

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Study objective: We sought to determine the minimum clinically significant difference in visual analog scale (VAS) pain score for children.

Methods: We performed a prospective, single-group, repeated-measures study of children between 8 and 15 years presenting to an urban pediatric emergency department with acute pain. On presentation to the ED, patients marked the level of their pain on a 100-mm nonhatched VAS scale. At 20-minute intervals thereafter, they were asked to give a verbal categoric rating of their pain as "heaps better," "a bit better," "much the same," "a bit worse," or "heaps worse" and to mark the level of pain on a VAS scale of the same type as used previously. A maximum of 3 comparisons was recorded for each child. The minimum clinically significant difference in VAS pain score was defined as the mean difference between current and preceding scores when the subject reported "a bit worse" or "a bit better" pain.

Results: Seventy-three children were enrolled in the study, yielding 103 evaluable comparisons in which pain was rated as "a bit better" or "a bit worse." The minimum clinically significant difference in VAS score was 10 mm (95% confidence interval 7 to 12 mm).

Conclusion: This study found the minimum clinically significant difference in VAS pain score for children aged 8 to 15 years (on a 100-mm VAS scale) to be 10 mm (95% confidence interval 7 to 12 mm). In studies of populations, differences of less than this amount, even if statistically significant, are unlikely to be of clinical significance.

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INTRODUCTION

"Health care is both a technical and an ethical enterprise. The ethical obligation to manage pain and relieve the patient's suffering is at the core of a health care professional's commitment."[1]

Managing pain is one of the key goals of health care workers. However, to assess the quality of pain-management efforts and to evaluate new pain-management techniques, pain must be measured, the results must be analyzed, and differences must be assessed for significance.

In pain research, the method commonly used for the quantification of pain severity and relief is the visual analog scale (VAS).[2] The VAS is easy to use, the results are reproducible, and it can be applied in a variety of practice settings.[2] It is sensitive to treatment effects, and the data derived can usually be analyzed by using parametric statistical techniques.[3,4] It has been validated for use with adults and children as young as 5 years[5,6]; however, research suggests that children younger than 8 years may be unable to meaningfully separate pain intensity from affective distress.[7]

Despite the strengths of VAS as a measurement and research tool, relying on statistically significant differences may overestimate the clinical importance of small differences in scores. Although statistical significance is an essential requirement for judging one treatment to be superior to another, it is not necessarily the same as clinical significance. For pain research, one of the challenges is to determine the minimum clinically significant difference (MCSD) in pain experience.

Previous research in adults has found the MCSD in VAS pain scores to be of the order of 10 mm.[8,9] Additionally, it has been shown that the MCSD in the VAS score did not differ in adults with age, sex, or cause of pain.[9]

Pain experience is a complex interplay of physiologic, psychologic, cultural, and situational factors.[10] Children differ from adults in many of these ways,[7,10] and thus it is possible that the MCSD in the VAS pain score for children is quite different from that for adults. To date, no studies investigating the MCSD in the VAS pain score in children have been published.

The aim of this study was to determine the MCSD in VAS pain score for children.

MATERIALS AND METHODS

This prospective, single-group, repeated-measures study of children between 8 and 15 years was conducted in the emergency department of Sunshine Hospital, a 200-bed community teaching hospital with a pediatric ED. The project was approved by the Research and Ethics Committee of the North Western Healthcare Network.

This observational study was conducted on a convenience sample of children between 8 and 15 years (inclusive) presenting to the ED with acute pain of either traumatic or nontraumatic cause. Exclusion criteria were inability to understand the questions in English, unwillingness or inability of the parent and child to give informed consent, inability to mark a VAS, and altered level of consciousness. Patient entry into the study was dependent on the availability of a trained nurse–research officer for data collection. In effect, this limited enrollment to the 8 AM to midnight period but introduced no other systematic bias.

On presentation to the ED and after informed consent was obtained from the parent and child, children were asked to mark, on a standardized data collection booklet, the level of their pain on a 100-mm nonhatched VAS scale marked at one end as "no pain" and at the other as "worst pain ever." At 20-minute intervals thereafter, they were asked to give a verbal categoric rating of their pain as "heaps better," "a bit better," "much the same," "a bit worse," or "heaps worse" and to mark the level of pain on a VAS scale of the same type as used previously. Children were not permitted to refer to previous VAS markings. A maximum of 3 comparisons was recorded for each child. Children were withdrawn from the study if they became pain free, on discharge, on transfer from the ED, or at their request. Measurements were made by nurses or research assistants.

Pain interventions (eg, splinting, ice, and pharmacologic therapy) were instituted according to clinical need, as assessed by the treating doctor. Pain management was not delayed or withheld by participation in this study.

The MCSD in the VAS pain score was defined as the mean difference between current and preceding scores when the subject reported a bit worse or a bit better pain.[4]

Descriptive statistics were used to determine the mean, median, SD, and 95% confidence intervals (CIs) of the sample as a whole, as was done in previous studies.[8,9] To determine whether there was any cluster effect caused by within-patient correlation, data were also analyzed, with the patient used as the fundamental unit of analysis. For each patient, the mean VAS change when he or she reported "a bit better" or "a bit worse" pain was calculated, from which a grand mean, SD, and 95% CI were determined.

RESULTS

A total of 73 children completed the study, with a mean age of 12 years (median, 12 years). Causes of pain were

limb trauma (n=36), abdominal pain (n=22), head/face trauma (n=6), medical (n=3), back trauma (n=2), abdominal trauma (n=2), and headache (n=2). No patients with sickle cell disease were enrolled.

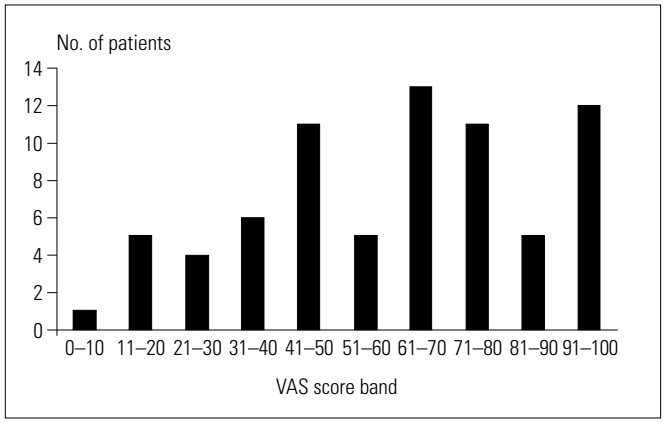
Sixty-three children completed 3 comparisons, 8 completed 2 comparisons, and 2 completed only 1 comparison. The average number of comparisons per subject was 2.8. Initial VAS scores covered the whole range of the scale, with a mean of 60 mm and a median of 64 mm (Figure). Fifteen children were excluded from analysis because of violations in study protocol.

Of the 208 comparisons, 83 categorized pain as "about the same." VAS score differences for this group were essentially zero (average 0.4 mm, median 0 mm; interquartile range [IQR] –3 to 4 mm).

In this study, the comparisons of particular interest were those in which pain was categorized as "a bit better" or "a bit worse." There were 56 comparisons in which pain was categorized as a "a bit better." The average VAS difference was 11 mm, with a median of 9 mm (IQR 15 to 19 mm). For the 47 comparisons categorized as "a bit worse," the average VAS difference was 8 mm, with a median of 8 mm (IQR 0 to –14 mm). Changes in VAS score for all verbal pain state categories are summarized in the Table.

To combine the comparisons, the positive or negative sign for pain score differences when the subject reported that pain had decreased was reversed. This is justified because the magnitude of the changes was similar. The MCSD in VAS score calculated from this data was 10 mm (IQR 3 to 19 mm, 95% CI 7 to 12 mm).

Figure.
Distribution of initial VAS scores.



With respect to the cluster analysis, there are 60 clusters. In other words, 60 patients reported pain as "a bit better" or "a bit worse" at one or more of the measurement intervals. The mean change in VAS score (when analyzed as described above) was 9 mm (median 9 mm, 95% CI 6 to 12 mm). This is not significantly different from results derived from the descriptive method.

DISCUSSION

To improve the quality of pain management and to evaluate new pain management techniques, pain must be measured, the results must be analyzed, and changes must be assessed for clinical significance. The determination of clinical significance poses the biggest challenge.

The method commonly used for measuring pain is the VAS. Despite its power as a measurement and research tool, it can be tempting to overestimate the clinical importance of small differences in scores because they reach statistical significance. For example, Kopscielniak-Nielson et al[11] compared the pain of spinal puncture between a group that was pretreated with eutectic mixture of local anesthetics (EMLA) and a group that received lignocaine infiltration and a placebo patch. The group treated with EMLA reported an average VAS score of 7.5 mm compared with an average VAS score of 17.5 mm reported by those that had lignocaine infiltration ($P<.0001$). Although statistically different, does this represent a clinically significant difference?

Research correlating changes in VAS pain scores with clinical changes in pain experienced by patients in the ED setting is sparse, with only 2 previous studies investigating this question. Kelly[9] found the MCSD in the VAS pain score to be 9 mm (95% CI 6 to 13 mm). This is very similar to the findings of Todd et al,[8] who, using similar methodology, found the minimum clinically significant

Table.
Pain score parameters for each verbal evaluation.

Category	No. of Comparisons	Mean (SD)	Median	IQR
Heaps worse	5	16	13	–11 to –13
A bit worse	47	8	8	0 to –14
About the same	83	0.4	0	–3 to 4
A bit better	56	11	9	15 to 19
Heaps better	17	20	13	7 to 26

difference in the VAS pain score to be 13 mm (95% CI 10 to 17 mm). However, these studies were conducted in adults, and their generalizability to children could be challenged on the basis of developmental and psychological differences in the subjects and differences in the injury and disease processes causing pain.

Of particular note, there is a high degree of similarity between the changes in VAS score for all categories between the group in this study and that previously reported by Kelly.[9] This suggests that although there is considerable variation in the VAS score changes for individuals in each category in these studies, there is considerable consistency in the median VAS score changes for the study groups. The implication of this finding is that although the VAS change that is clinically significant varies between individuals, in studies of populations, VAS changes of less than 10 mm are not of clinical significance for either adults or children.

This study has some limitations that should be considered in interpreting its merit. This study focuses on reported pain changes for acute pain and thus is not generalizable to chronic pain states. The assumption that the degrees of pain comparison categorized as "a bit worse" or "a bit better" are equivalent may not be valid. Patients may have perceived more room on the scale to decrease rather than increase their pain score. In addition, the sample is limited to a convenience sample of patients who were able to communicate in English and who presented to a community teaching hospital ED, and thus the generalizability of the findings may be questioned. The similarities with the findings of Todd et al[8] from the United States and the study of Kelly[9] suggest that this is not likely to be a major issue. Patients were not given access to their previous pain ratings. Although it is common practice to blind patients to previous ratings, it has been shown that patients may overestimate their pain if these are not available.[12] There may also be an effect attributable to interpersonal relations between the interviewer and the patient, particularly if there is a change of staff.[13]

In summary, this study found the minimum clinically significant difference in the VAS pain score for children 8 to 15 years (on a 100-mm VAS scale) to be 10 mm (95% CI 7 to 12 mm). In studies of populations, differences of less than this amount, even if statistically significant, are unlikely to be of clinical significance.

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