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Clinically significant differences in acute pain measured on self-report pain scales in children

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Abstract

Objectives—The objective was to determine the minimum and ideal clinically significant differences (MCSD, ICSD) of the Faces Pain Scale–Revised (FPS-R) and the Color Analog Scale (CAS) in children and to identify any differences in these estimates based on patient characteristics.

Methods—This was a prospective study of children aged 4 to 17 years with acute pain presenting to two urban pediatric emergency departments. Participants self-reported their pain severity using the FPS-R and CAS and qualitatively described their changes in pain. Changes in pain score reported using the FPS-R and CAS that were associated with “a little less” and “much less” pain (MCSD and ICSD, respectively) were identified using a receiver operating characteristic–based method and expressed as raw change score and percent reductions. Estimates of MCSD and ICSD were determined for each category of initial pain severity (mild, moderate, and severe) and patient characteristics (age, sex, and ethnicity). Post hoc exploratory analyses evaluated categories of race, primary language, and etiology of pain.

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Supporting Information:

The following supporting information is available in the online version of this paper:

Data Supplement S1. MCSD and ICSD for the FPS-R and CAS based on initial pain severity.

Data Supplement S2. Raw change scores and percent reductions associated with MCSD and ICSD for FPS-R in subgroups of patient characteristics.

Data Supplement S3. Raw change scores and percent reductions associated with MCSD and ICSD for CAS in subgroups of patient characteristics.

The documents are in PDF format.

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Results—A total of 314 children with acute pain were enrolled; mean ($\pm$ SD) age was 9.8 ($\pm$ 3.8) years. The FPS-R raw change score and percent reduction MCSD estimates were 2/10 and 25%, with ICSD estimates of 3/10 and 60%. For the CAS, raw change score and percent reduction MCSD estimates were 1/10 and 15%, with ICSD estimates of 2.75/10 and 52%. For both scales, raw change score and percent reduction estimates of the MCSD remained unchanged in children with either moderate or severe pain. For both scales, estimates of ICSD were not stable across categories of initial pain severity. There was no difference in MCSD or ICSD based on age, sex, ethnicity, race, primary language, or etiology of pain.

Conclusions—The MCSD estimates can be expressed as raw change score and percent reductions for the FPS-R and CAS. These estimates appear stable for children with moderate to severe pain, irrespective of age, sex, and ethnicity. Estimates of ICSD were not stable across different categories of initial pain severity, therefore limiting their potential generalizability.

Researchers and clinicians frequently use self-report measures to identify the severity of pain a child is experiencing and to evaluate the child's response to a pain-reducing intervention.^{1–4} Identifying changes in pain score that are clinically meaningful is useful for researchers, allows them to design clinical trials based on clinically meaningful outcomes, and may be helpful for clinicians to determine whether their analgesic interventions had an effect that was important to the patient. These changes have been described as the minimum and ideal clinically significant differences (MCSD and ICSD, respectively) and represent changes in pain scores that are considered “a little less” and “much less” by the subject.^{5–9}

The Faces Pain Scale–Revised (FPS-R)¹⁰ and the Color Analog Scale (CAS)¹¹ are two commonly used measures of pain self-report in children in research and clinical settings.^{1,12–15} The FPS-R, in particular, is one of the self-report measures recommended for clinical trials in children.¹ However, the clinically significant differences in pain severity have not been previously determined for the FPS-R and have only been determined in a limited population for the CAS.⁶

Clinically meaningful differences in pain severity, however, can vary from child to child. The change in pain score required to experience a meaningful improvement in pain has been shown to differ based on a patient's initial pain severity.^{8,16} In addition, clinically meaningful differences may also vary based on a child's individual characteristics. Children's age, sex, and ethnicity are related to their ability to describe and quantify pain, as well as their perception of and sensitivity to pain.^{17–22} Therefore, it is important to determine whether the clinically significant difference of pain scales varies in children based on these factors, so that changes in pain score can be appropriately interpreted.

We aimed to determine the MCSD and ICSD in pain for the FPS-R and CAS in children aged 4 to 17 years with acute pain. We also aimed to determine whether there were any differences in MCSD and ICSD based on initial pain severity and patient characteristics including age, sex, and ethnicity.

METHODS

Study Design

We conducted a prospective, observational study. The institutional review boards at both sites approved this study.

Study Setting and Population

The study was carried out in two urban pediatric emergency departments (PEDs) with a combined annual census of approximately 110,000 visits. This investigation was part of a larger pain scale validation study that included children with both painful and nonpainful conditions; the present study analyzed only the children with painful conditions.¹⁵ The population in this study was a convenience sample of patients based on availability of the investigators and research coordinators. We enrolled English- and Spanish-speaking children between 4 and 17 years of age, inclusive. We excluded children for any of the following: clinical instability or illness necessitating admission to the intensive care unit; developmental delay or neurologic impairment; intoxication; altered mental status; underlying chronic pain conditions, such as sickle cell disease; or a medical history of multiple painful experiences, such as malignancies. We did not collect details on children who were eligible but not enrolled.

Study Protocol

We performed all assessments in each child's primary language. Using standardized scripts, children with painful conditions were asked to indicate their severity of pain first on the FPS-R and then on the CAS. For both scripts, the word "hurt" or "pain" was used interchangeably, depending on what seemed most understandable for each child.

All children received analgesics at the attending physicians' discretion and were reassessed at least 30 minutes later, at which time they were asked, "Is your pain: much less, a little less, about the same, a little worse, or much worse compared to before you got your medicine?" Their pain was then assessed using the FPS-R and CAS in the same manner as the initial assessment.

Measurements

The FPS-R consists of six faces that are scored 0–2–4–6–8–10. Each face represents an increasing degree of pain moving from left to right. Each child was shown the FPS-R and read standard instructions in English or Spanish (both versions from www.iasp-pain.org/FPSR). The CAS is a plastic instrument consisting of a wedge-shaped color-gradated figure on one side, a numerical scale on the other, and a moveable slider. The child was shown the side with the wedge-shaped color-gradated figure with the slider positioned in the middle and read a standard script: "Move the slider to the place that shows how much pain you have. This end means you have no pain [*slider moved to the bottom*], this end means you have the worst pain [*slider moved to top*]." A researcher moved the slider back to the middle of the scale before the child used the scale. Once the child finished moving the slider, we recorded the corresponding numerical score from the reverse side of the instrument (scored from 0 to 10 in 0.25 units).

Data Analysis

We used a method based on the receiver operating characteristic (ROC) curve to define the MCSD and ICSD. We chose to use the ROC-based method instead of another commonly used approach, a distribution-based method, because the ROC-based method recognizes that the MCSD and ICSD have diagnostic utility, with their performance describable in terms of sensitivity and specificity.^{23,24} This ROC-based method allows estimates of MCSD and ICSD to be selected based on the desired test characteristics. In contrast, the distribution-based method only identifies an estimate that is a measure of central tendency most frequently associated with the MCSD and ICSD and commits the user to the test characteristics associated with those estimates. The ROC-based method is a standard methodology used to identify clinically meaningful changes in pain severity in patients with chronic pain, but has not been previously used for this purpose in patients with acute pain in the ED.^{23,24}

The ROC-based method determines the MCSD by comparing the changes in pain scores reported by those children whose pain had become “a little less,” to those whose pain was either “about the same,” “a little worse,” or “much worse.” For the ICSD ROC-based method determination, we compared children with “much less” pain to all those with no change or any other degree of change. Using the ROC-based method, all possible changes in pain score reported by patients in the study were evaluated as potential cut points using “a little less” and “much less” as the criterion against which the sensitivity and specificity of the changes in pain scores were computed. Each cut point was inspected, and the one with the smallest absolute difference between sensitivity and specificity, and highest values for sensitivity and specificity, was selected to represent the change in pain score that had the best balance of test characteristics.²³ We present the ROC-based MCSD and ICSD estimates, and the results based on the distribution-based methods are available on request.

For each self-report measure, we report the MCSD and ICSD as a raw change score and a percent reduction. The raw change score is the value obtained that represents the difference between two pain scale scores obtained at two different points in time and is how clinically meaningful differences in pain severity have been traditionally reported for patients with acute pain in the ED.^{5–7,25–27} The percent reduction is the mean percent reduction in pain severity from the initial pain score associated with the MCSD and ICSD. This may be a more generalizable parameter because it recognizes that a clinically meaningful difference in pain severity may be dependent on a patient’s initial pain severity (i.e., the higher the initial pain severity, the greater the change in pain score required to experience a clinically meaningful difference in pain) and may remain consistent across all categories of initial pain severity.^{8,16,23} Using a percent reduction may also potentially address the limitation of the raw change score, in which a single estimate (e.g., 2/10) may represent both no change, as well as “very much improved” change in pain severity, in different patients and at different levels of initial pain severity.²³

To evaluate for differences in meaningful clinical change based on initial pain severity, we determined the MCSD and ICSD within each category of initial pain severity (i.e., mild, moderate, and severe) for both pain scales. We defined the categories of initial pain using conventionally accepted thresholds.^{28–31} To evaluate for any differences based on patient

characteristics, we determined and compared the MCSD and ICSD within subgroups based on age group (younger, 4 to 7 years; older, 8 to 17 years), sex (male and female), and ethnicity (Hispanic and non-Hispanic). The age groupings were selected to stratify younger patients into age groups that have been shown to demonstrate more variability in their accuracy and responses when describing pain.^{2,32} Post hoc exploratory analyses examined and compared the MCSD and ICSD within subgroups based on race (African American and white), primary language (English and Spanish), and etiology of pain (traumatic and nontraumatic). All categories of race, as defined by National Institutes of Health policy, were evaluated. Subgroups other than African American and white were not analyzed due to insufficient sample size.³³ We conducted statistical analyses using SPSS (version 20) and R (version 3.1).³⁴

RESULTS

From June 2011 to October 2012, we enrolled a total of 314 children with acute painful conditions (Figure 1); the mean ($\pm$ SD) age was 9.8 ($\pm$ 3.8) years. Table 1 presents the characteristics of the enrolled children. Most children received either ibuprofen or acetaminophen. There were 147 children who reported that their pain was “a little less” and 97 who reported that their pain was “much less,” after analgesic administration. The mean ($\pm$ SD) and median time to pain score reassessment were 38.2 ($\pm$ 17.7) and 32.2 (interquartile range = 30 to 40) minutes.

Table 2 presents the MCSD and ICSD as raw change score and percent reduction for the FPS-R and CAS. Figures 2 and 3 present the ROC curves of the FPS-R and CAS raw change score and percent reduction MCSDs and ICSDs, respectively. The areas under the curve for MCSD and ICSD ROC curves were similar between the FPS-R and CAS. Table 3 presents the test characteristics of the raw change score and percent reduction estimates for both scales. For the FPS-R, the MCSD raw change score of 2/10 (or one face) had moderate and balanced sensitivity and specificity of 80 and 77%, respectively. A raw change score of 1/10 had a slightly higher sensitivity but lower specificity. For both scales, no raw or percent reduction MCSD could achieve 90% sensitivity with at least 50% specificity.

Data Supplement S1 (available as supporting information in the online version of this paper) presents the MCSD and ICSD for both self-report pain measures based on the categories of initial pain severity. Raw change score and percent reduction estimates of MCSD were stable across initial pain severity categories of moderate and severe, meaning that the estimates were consistent and remained unchanged across these different categories. The ICSD percent reduction estimates were also stable across pain severity for the CAS, although somewhat less so for FPS-R. For both scales, raw change score estimates of ICSD increased with each higher category of initial pain severity.

There were no significant differences of the MCSD and ICSD for the FPS-R and CAS, when expressed as either raw change score or percent reduction, between subgroups based on age group, sex, or ethnicity (Data Supplements S2 and S3, available as supporting information in the online version of this paper). The post hoc analyses did not reveal any significant

differences between subgroups based on race, primary language, or etiology of pain (Data Supplement S2 and S3).

Of the 274 children who reported that they felt less pain or more pain, nine (3.3%) had FPS-R scores and 22 (8%) had CAS scores that changed in the opposite direction from their verbal report. When comparing the younger to older groups, four of the 129 younger children (3.1%) and five of the 145 older children (3.4%) had FPS-R scores that changed in the opposite direction from the verbal report ($p=0.87$). However, 16 of the 129 younger children (12.4%) and six of the 145 older children had CAS scores that changed in opposite directions ($p = 0.006$).

DISCUSSION

In this present study, we have identified the MCSD and ICSD in children with acute pain for the FPS-R and CAS, expressed in two different ways (raw change score and percent reduction). The estimates for the MCSD for both pain scales were similar for patients with moderate and severe pain, suggesting that these estimates are generalizable and reasonable goals when treating pain in previously healthy children with this degree of acute pain. Similarly, the stability of these estimates across subgroups based on patient characteristics would support the generalizability of these estimates, irrespective of individualized factors such as age, sex, and ethnicity. Therefore, the stability of these MCSD estimates would make them reasonable choices for desired effect sizes when designing clinical trials to evaluate pain-relieving interventions. Although the estimates of ICSD were stable across subgroups based on patient characteristics, their instability across categories of pain severity makes them more difficult to use in both clinical and research contexts.

The MCSD and ICSD have not been previously determined for the FPS-R, despite its status as a recommended self-report scale for clinical use and clinical trials in children and its strong validity across the pediatric age range.^{1,15} The MCSD and ICSD have been determined to be one and two faces, respectively, for the predecessor of the FPS-R, the FPS.^{5,35} Although the FPS-R was derived from the FPS, the latter differs in that it consists of seven, rather than six, faces.^{10,12} Our estimates help resolve whether it is appropriate to use the clinically meaningful differences in pain determined for the FPS when using the FPS-R. Our findings suggest that it is reasonable to use one face for the MCSD for the FPS-R, but not to use two faces for the ICSD. A score of 3/10 can be used if the ICSD is chosen as the desired effect size when designing clinical trials. However, this score has limited clinical use, since each face of the FPS-R is associated with an even-numbered pain score.

Estimates of MCSD and ICSD for the CAS have been previously described and are higher than those determined in our study.^{5,6} Our lower estimates are likely the result of our use of the ROC-based rather than distribution-based methodologies. The clinical implications of using the higher distribution-based estimates would be that most patients who did not experience minimum clinically significant improvements in their pain would be appropriately identified. The cost would be that some patients who had experienced improvements would be incorrectly classified and potentially receive unnecessary additional analgesics. Using our estimates, which explicitly aim to balance sensitivity and specificity,

might result in slightly fewer patients receiving additional analgesia when necessary, but with the benefit of potentially minimizing the unnecessary administration of analgesics. For example, the previously identified raw change score MCSD for the CAS was 2.4 (95% confidence interval [CI] = 1.72 to 3.15).⁶ Based on our results, this estimate would have yielded a sensitivity and specificity of approximately 0.42 and 0.91, respectively. Compared to our estimate derived using a ROC-based methodology, this previously identified estimate may confer the benefits of a higher specificity, but at the cost of accepting a lower sensitivity.

The stability of the MCSD for both the FPS-R and the CAS scales in children who have moderate or severe pain suggests that these estimates are generalizable across the spectrum of pain for which most clinicians administer analgesics or other treatments. Previous determinations of clinically meaningful changes in pain for other self-report measures of pain have found that estimates varied depending on a patient's initial pain severity; i.e., the higher a patient's initial pain severity, the larger the value that represented a clinically meaningful change in pain for that patient.^{8,16} An estimate that varies based on a patient's initial pain severity has limited usefulness due to its inability to accommodate patients with different initial pain severities. Our study demonstrates, however, that an MCSD raw change score of 2/10 (one face) for the FPS-R and 1/10 for the CAS, and percent reduction estimates of 25% for the FPS-R and 15% for the CAS, are stable and generalizable to patients with moderate or severe acute pain. Our estimates of MCSD, however, may not be applicable to those children with mild pain. Our sample size of patients with mild pain was small (less than 30), with 50 patients generally required to provide valid and reliable MCSD estimates using the ROC-based method.³⁶

Even with the advantages of an estimate of MCSD for children with moderate to severe pain that is stable across age, sex, and ethnicity, there have been concerns with using pain scores, or changes in pain scores, in isolation to determine whether a child has truly experienced a clinically meaningful change in pain.⁴ One reason is the potential inability of pain scales to accurately reflect perceived changes in pain for children. One prior study described 27% of children 7 to 16 years old using the numeric rating scale reporting a perceived relief in pain that was in the opposite direction of the actual change in pain score (i.e., pain scores increased when the children said that they actually felt better).⁸ Our findings differ, potentially due to the different scales used, with a smaller proportion of divergent findings (3.3%) for the FPS-R. However, there were more divergent findings in the younger age group when using the CAS. This observation is consistent with the expectation that a higher level of cognitive skills is required by children for using visual analog scales, such as the CAS, and supports previous findings indicating that the FPS-R is preferable to the CAS for children 4 to 7 years of age.^{2,11} Although divergent findings do exist when using pain scales in children, this does not negate the utility of the MCSD as a useful metric in the clinical setting. Rather, clinicians should complement their use of such estimates with strategies such as quantitative observational measures of pain; personalized pain score goals or comfort function goals (i.e., self-identification of a pain score representing adequate pain relief or adequate comfort to carry out a particular function); and qualitative assessments, such as evaluating changes in the affective, evaluative, and sensory qualities of pain.^{8,37}

These considerations would allow for more comprehensive and representative evaluations of pain improvement in children.

LIMITATIONS

The limitations of our study include that the majority of our patients received nonopioid oral analgesics, which some may interpret as a sign that our population consisted mostly of children with mild pain. However, approximately 90% of children reported moderate or severe pain, and the observed analgesic prescribing practice may be attributable to the reported use of less potent medications for children compared to adults, rather than a reflection of a population with lower pain severity.^{38,39} We also enrolled a small number of patients with mild pain, which limited our ability to identify an accurate estimate of clinically meaningful change in this population. Finally, our population consisted only of children with acute pain. Future studies are necessary to determine the MCSD and ICSD in children with chronic and recurrent pain states, such as sickle cell disease, because they perceive pain differently and should have their self-reported changes on pain scales interpreted accordingly.^{40–42}

CONCLUSIONS

We identified the minimum and ideal clinically significant differences for both the Faces Pain Scale–Revised and the Color Analog Scale for children with acute pain between the ages of 4 and 17 years. Raw change score and percent reduction minimum clinically significant difference estimates for the Faces Pain Scale–Revised of 2/10 (one face) and 25%, respectively, and raw change score and percent reduction minimum clinically significant difference estimates for the Color Analog Scale of 1/10 and 15%, respectively, are stable and generalizable to previously healthy children with moderate to severe pain, irrespective of age, sex, and ethnicity. Estimates of ideal clinically significant difference, however, were not stable across different categories of initial pain severity, therefore limiting their generalizability.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. Patient flow diagram. CAS = Color Analog Scale; FPS-R = Faces Pain Scale–Revised.

Figure 2.

ROC curves of the raw change score and percent reduction estimates of the MCSD for the FPS-R and the CAS. AUC = area under the curve; CAS = Color Analog Scale; FPS-R = Faces Pain Scale–Revised; MCSD = minimum clinically significant difference; ROC = receiver operating characteristic.

Figure 3.

ROC curves of the raw change score and percent reduction estimates of the ICSD for the FPS-R and the CAS. AUC = area under the curve; CAS = Color Analog Scale; FPS-R = Faces Pain Scale–Revised; ICSD = ideal clinically significant difference; ROC = receiver operating characteristic.

Table 1

Patient Characteristics

Characteristic	Number (Total N = 314)	Percent
Female	158	50.3
Age group		
Younger (4 to 7 yr)	141	44.9
Older (8 to 17 yr)	173	55.1
Ethnicity		
Hispanic	180	57.3
Non-Hispanic	134	42.7
Race		
Black or African American	45	14.3
White	179	57
Primary language		
English	274	87.3
Spanish	40	12.7
Painful conditions		
Soft tissue injury	78	24.8
Abdominal pain	60	19.1
Headache	32	10.2
Ear or throat pain	23	7.3
Fracture, clinically obvious	18	5.7
Laceration	18	5.7
Chest pain	13	4.1
Back pain	9	2.9
Abscess	5	1.6
Other	49	15.6
Initial pain score reported: FPS-R		
0–0.9	3	1
1–3.9	26	8.3
4–6.9	155	49.3
7–10	130	41.4
Initial pain score reported: CAS		
0–0.9	3	1
1–3.9	27	8.6
4–6.9	157	50
7–10	127	40.4
Reported change in pain after analgesic administration		
Much less	97	30.9
A little less	147	46.8
About the same	40	12.7
A little more	20	6.4

Characteristic	Number (Total N = 314)	Percent
Much more	10	3.2
Analgesics administered		
Ibuprofen	128	40.8
Acetaminophen	46	14.6
Parenteral opioid*	42	13.4
Oral opioid-containing analgesic [†]	13	4.1
Ketorolac	12	3.8
Other	23	7.3
Missing data	50	15.9

* Morphine, hydromorphone, fentanyl.

[†] Codeine, oxycodone, hydrocodone, or any combination, analgesic with these components.

CAS = Color Analog Scale; FPS-R = Faces Pain Scale–Revised.

Table 2

MCSD and ICSD for the FPS-R and CAS

Self-report Pain Scale and Measurement	MCSD (95% CI) (<i>n</i> = 147 With MCSD, <i>n</i> = 70 With no MCSD) [*]	ICSD (95% CI) (<i>n</i> = 97 With ICSD, <i>n</i> = 217 With no ICSD) [†]
FPS-R		
Raw change score	2 (1–2)	3 (3–4)
Percent reduction	25 (10–33)	60 (50–67)
CAS		
Raw change score	1 (0.5–1.25)	2.75 (2.25–3.25)
Percent reduction	15 (10–20)	52 (50–58)

FPS-R = Faces Pain Scale–Revised; ICSD = ideal clinically significant difference; MCSD = minimum clinically significant difference; CAS = Color Analog Scale.

^{*} Patients with MCSD had pain that became “a little less”; patients with no MCSD had pain that was “about the same,” “a little worse,” or “much worse.”

[†] Patients with ICSD had pain that became “much less”; patients with no ICSD had pain that was “about the same,” or any other degree of change.

Table 3

Test Characteristics of Raw Change Score and Percent Reduction Estimates of MCSD and ICSD for the FPS-R and the CAS

Characteristic	MCSD		ICSD	
	Sensitivity	Specificity	Sensitivity	Specificity
FPS-R				
Decrease in raw change score				
3 [†]	0.32	0.91	0.70	0.76
2 [*]	0.80	0.77	0.91	0.38
Percent reduction				
60 [†]	0.29	0.93	0.73	0.78
25 [*]	0.76	0.80	0.91	0.42
CAS				
Decrease in raw change score				
2.75 [†]	0.37	0.94	0.73	0.73
1 [*]	0.76	0.74	0.89	0.41
Percent reduction				
52 [†]	0.33	0.94	0.72	0.75
15 [*]	0.78	0.79	0.91	0.40

CAS = Color Analog Scale; FPS-R = Faces Pain Scale–Revised; ICSD = ideal clinically significant difference; MCSD = minimum clinically significant difference.

* Estimate of MCSD with the smallest difference between sensitivity and specificity.

[†] Estimate of ICSD with the smallest difference between sensitivity and specificity.