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Assessing the Minimal Clinically Important Difference and Patient-Accepted Symptom State Using Visual Analog Scales and Numerical Rating Scales in Postoperative Patients: a Prospective Descriptive Study

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Abstract

Introduction: Visual analog scale (VAS) and numerical rating scale (NRS) are widely used in measuring pain scores and guide treatment. In using these tools, the minimal clinically important difference (MCID) and patient acceptable symptom state (PASS) are crucial for guiding treatment. However, they vary in different situations and populations. The aim of the present study was to determine MCID and PASS for acute pain in elective surgical patients.

Materials and methods: Pain assessment was done by first measuring VAS and NRS in the immediate postoperative period. Then 24 hours later, participants were asked to rate their pain score, perception of pain change, and state of recovery. The mean changes in pain scores among patients who reported "a little change" were used to calculate MCID. The 75th percentile of pain score rated by participants who considered themselves as having recovered well from surgery was defined as PASS.

Results: Data from 79 of 104 participants, after excluding illogical data, showed that the MCID was 16 mm for VAS and 1.8 for NRS. While PASS for VAS and NRS were 38 mm and 5, respectively.

Conclusion: MCID and PASS in our setting were similar to other population.

Keywords: acute pain, minimal clinically important difference, patient acceptable symptom state, postoperative pain

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Introduction

Adequate pain control is crucial in post-operative care. Inadequate postoperative pain control leads to morbidity, quality of life impairment, and higher healthcare costs.[1] The most reliable method of measuring pain is self-reporting, as multiple biological and psychosocial factors make each individual's perception of pain unique.[2-4] Visual analog scale (VAS) and numerical rating scale (NRS) are widely used self-reporting tools to measure pain scores and guide treatment.[5,6] In using these tools, it is vital that the minimal clinically important difference (MCID) and the patient acceptable symptom state (PASS) are known, as it is possible for a pain score to improve or worsen while the patient does not perceive any clinically meaningful difference.

MCID is defined as the smallest difference in pain score which provides a clinically meaningful change in a patient's perception of pain.[7] MCID can guide treatment decisions. If some conditions are difficult to manage, having only the MCID is not enough. The PASS should also be known, defined as the highest level of pain in which a patient considers himself or herself well.[8,9] While MCID is used to detect the effects of treatment from the patient's perspective, PASS is used to explore the patient's satisfaction with the state of symptoms.

Delineating the MCID in acute postoperative pain settings would be beneficial for the management of pain, which strongly affects patient outcomes. As pain is affected by biological and psychosocial factors, MCID and PASS may differ greatly between different populations and may be best studied separately for groups with different cultures, traditions, and beliefs.[10-16] Previous studies have shown MCID to vary between 8-40 mm of VAS or 13-85% reduction for VAS.[10,17-19] In our setting, the population is different from previous studies, thus MCID and PASS in this population cannot be inferred from previous studies. The aim of the present study was to study the MCID and PASS for acute post-operative pain patients at Srinagarind Hospital, Khon Kaen University, Khon Kaen, Thailand.

Methods

The present study was a prospective descriptive study. It was approved by the Institutional Review Board of Khon Kaen University, approval code HE631563. Thai Clinical Trials Registry (TCTR) registration number was TCTR20201206001. We excluded patients who denied participating, were unable to communicate, were pregnant, had drug or alcohol dependence, had a psychiatric disorder, had an intellectual impairment, had concurrent chronic pain, or had vision impairment. Moreover, patients who were expected to be admitted to an ICU or were expected to remain intubated were excluded due to difficulties in assessing pain.

Each evening during the data collection period, a simple random sampling by computer generated randomization was done to select five patients from all eligible patients that would be operated on the day after. This was because the research team could only handle data collection on five patients per day. These patients were

approached for possible inclusion to the study. This process was repeated every weekday for three months.

One day prior to surgery, participants were asked for informed consent. Demographic data, such as gender, age, weight, height, religion, place of origin, blue-collar workers, depression, prior surgery, American Society of Anesthesiologists (ASA) physical status, and decision of surgery, were also collected at the same time. Data on operational durations and anesthetic techniques were reviewed from the anesthetic records. All participants received standard post-operative pain control. Pain scores, VAS, and NRS were collected at two time points: immediate post-operative at postanesthetic care unit (PACU) within 1 hour, and delayed postoperative at ward within 24 hours, both times by a nurse anesthetist.

For immediate postoperative, participants were asked to rate their pain score and this score was used as a baseline. For delayed postoperative, participants were asked to rate their pain score and rate their feeling of pain, compared to baseline, on a 7-point Likert scale: much better, moderately better, a little better, about the same, a little worse, moderately worse and much worse. In addition, participants were also asked to rate whether they felt they had recovered well from the operation by choosing from three options of yes, unsure, and no. The answer "yes" was taken as representing a good recovery, while the answers "unsure" and "no" represented a poor recovery.

MCID (Minimal Clinically Important Difference)

To define the smallest difference in pain score which corresponded to a clinically meaningful change in a patient's perception, we performed the anchor-based approach. This method was used to interpret the data in patient-reported outcomes[20] compared with external indicators. In this study, we used the change in the postoperative pain scores from patients who rated their feeling of pain change as "a little better" or "a little worse" to calculate MCID.

PASS (Patient Acceptable Symptom State)

To determine the clinical relevance of the treatment effect, the delayed postoperative pain scores of the participants who considered themselves to have a good recovery were collected. The 75th percentile of this data was used for calculating PASS as a minimal clinically important improvement (MCII).[8]

Statistical methods

Categorical data were reported as frequency and percentage. Continuous data were reported as mean (SD) or median (IQR) depending on data distribution, which was determined by the Kolmogorov-Smirnov Test. MCID and the changes in VAS and NRS between the two time points, Immediate postoperative and delayed post-operative, were presented as median differences with a 95% confidence interval (CI). A P-value of less than 0.05 was considered statistically significant. We used a simple linear regression model, backward stepwise, and multiple linear regression model to analyze the

factors that correlated with pain scores. We used STATA version 10.0 for analysis. The sample size was calculated using the formula for test of difference between paired means[21] as shown in Figure 1.

$$n = \frac{\sigma^2 \left(Z_{\alpha/2} + Z_{\beta} \right)^2}{\left(\mu_{before} - \mu_{after} \right)^2}$$

Figure 1 Sample size formula for test of difference between paired means

Using parameters from a previous study[10], the SD was 15, the mean before was 26, and the mean after was 20. The level of confidence was 95% and the power of the test was 90%. The resulting sample size was at least 66.

Results

One hundred and four participants were enrolled in the study. The demographic characteristics (Table 1) showed that 65.4% of the participants were females, and the median age was 50 years. Over 95% of the participants were born in Northeast Thailand, and more than 90% had an ASA physical status of I or II. The anesthetic techniques were general anesthesia (67.3%), combined general and regional anesthesia (11.5%), and spinal anesthesia (19.2%). Most participants (n=102) reported that they had had a good recovery on postoperative day 1 at the ward. The distribution of pain scores was not normal. Changes in pain scores over time in different levels of severity are shown in Figure 2 and 3.

When comparing the change in pain score and the change in perception of pain, we found that 79 participants reported them in the same direction (lower pain score and perceiving less

Table 1 Patient and surgical characteristics

Characteristics	n=104
Female, n (%)	68 (65.4)
Age (yr), median (IQR)	50.0 (40.0, 58.0)
Weight (kg), median (IQR)	61.5 (52.0, 73.0)
Height (cm), median (IQR)	160.0 (154.5, 167.0)
Religion, n (%)	
Buddhism	103 (99.0)
Christianity	1 (1.0)
Place of origin, n (%)	
Northeast	98 (94.2)
Others	6 (5.8)
Blue collar workers, n (%)	51 (49.0)
History of depression, n (%)	10 (9.6)
ASA physical status, n (%)	
I	56 (53.8)
II	41 (39.4)
III	7 (6.7)
Duration of surgery (min), median (IQR)	140.0 (95.0, 180.0)
Surgical division, n (%)	
General surgery	55 (52.9)
Gynecology	18 (17.3)
ENT	13 (12.5)
Others	33 (31.7)
Anesthetic technique, n (%)	
General anesthesia alone	70 (67.3)
General anesthesia with regional or nerve block	12 (11.5)
Spinal block	20 (19.2)

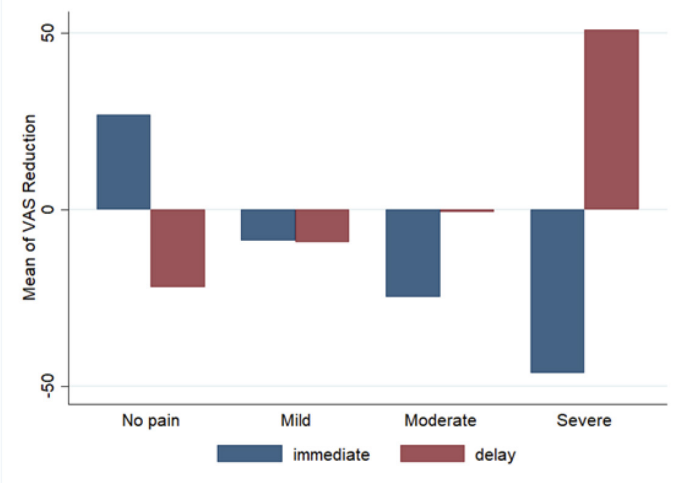


Figure 2 Changes in VAS pain score

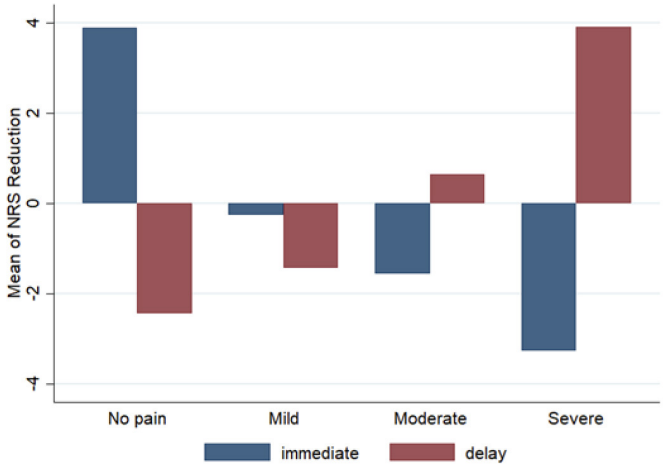


Figure 3 Changes in NRS pain scores

pain, or higher pain score and perceiving more pain). The data from these 79 patients were used to calculate MCID. While data from the other participants were considered illogical data, meaning the change in pain score and the change in perception of pain went in opposite directions, and thus were excluded.

Minimal Clinically Important Difference (MCID)

According to the Anchor based method, the median difference in pain score in patients reporting their pain change as "a little better" was reduced by 12 mm (IQR -12, -2) (95%CI -38, -2) for VAS and 0 (IQR 0, 0) (95%CI -3, 1) for NRS. The median difference between two pain scores in patients reporting their pain change as "a little worse" was increased by 14 mm (IQR10, 38) (95%CI 10, 38) for VAS and 4 (IQR 1, 5) (95% CI 1, 5) for NRS. The details on patients' pain reporting can be found in Table 2 and 3. By the definition of MCID, the changes in pain score from patients

Table 2 Changes in postoperative pain score as measured by VAS and participants' change in the perception of pain

Perception	n	VAS reduction	95%CI	*P*-value
Much worse	1	90	90	0.317
Moderate worse	2	27.5 (16.0, 39.0)	16, 39	0.180
Little worse	3	14 (10, 38)	10, 38	0.109
No change	5	0 (0, 0)	-2, 68	0.876
Moderate better	5	-12 (-12, -2)	-38, -2	0.041
Much better	29	-35 (-41, -14)	-39, -18.39	<0.001
Absolute change				
No change	5	0 (0, 2)	0, 68	
Minimal change	8	12 (6, 26)	2, 38	
Moderate change	36	16.5 (7.0, 39.5)	12, 32	
Large change	30	35.5 (14.0, 41.0)	19, 39	

Pain reduction is described as median (IQR). The unit is in millimeters. CI for large deterioration could not be calculated.

Table 3 Changes in postoperative pain score as measured by NRS and participants' changes in the perception of pain

Perception	n	NRS reduction	95%CI	*P*-value
Much worse	1	9	9	0.317
Moderate worse	2	4 (3, 5)	3, 5	0.180
Little worse	3	4 (1, 5)	1, 5	0.109
No change	5	1 (0, 2)	0, 7	0.090
Little better	5	0 (0, 0)	-3, 1	0.876
Moderate better	34	-2 (-3, 0)	-3, -1	<0.001
Much better	29	-2 (-3, -2)	-3, -2	<0.001
Absolute Change				
No change	5	1 (0, 2)	0, 7	
Minimal change	8	1 (0, 3.5)	0, 4.33	
Moderate change	36	2 (1, 3)	1, 3	
Large change	30	2 (2, 3)	2, 3	

Pain reduction is described as median (IQR). CI for large deterioration could not be calculated.

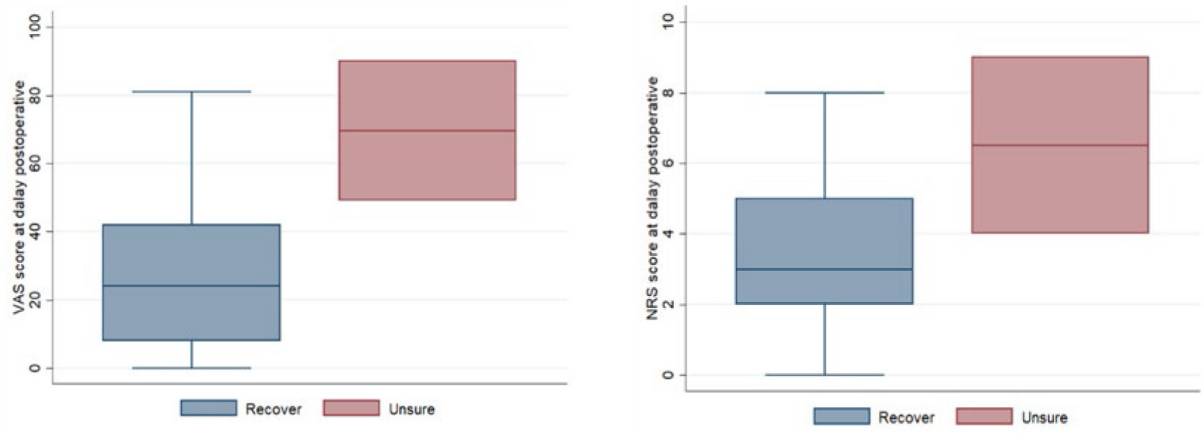


Figure 3 Changes in VAS pain score

who reported their pain as "a little better" combined with the changes in pain score from patients who reported their pain as "a little worse" were calculated without direction and the MCID values for VAS and NRS were found to be 12 mm (IQR 6, 26) (95%CI 2, 38) and 1.86 (IQR 0, 3.5) (95%CI 0, 4.33), respectively.

Patient Acceptable Symptom State (PASS)

The VAS and NRS scores among participants who rated their good recovery are shown (Figure 4.) and calculated for PASS by the 75th percentile technique. The VAS scores of 42 mm and NRS scores of 5 were considered Patient Acceptable Symptom State (PASS).

Discussion

The present study found that the MCID values were 12 mm for VAS and 1.86 for NRS. The PASS values were 42 mm for VAS and 5 for NRS. The present study included various surgical patients similar to a previous study[19], and the MCID for VAS of 12 mm from the present study was similar to the MCID for VAS of 10 mm from that study.[19] In chronic diseases such as knee osteoarthritis and ankylosing spondylitis, MCID has been found to be slightly higher at 15 mm for VAS.[9] Other studies of patients presenting to the emergency department have found the MCID for VAS to vary between 9 to 16.5 mm.[17,22] These results showed that the MCID value of our local population did not differ much from MCID in other people and settings. This could be coincidental, or it could be an indication that MCID would not differ much regardless of the differences in biological and cultural factors. Large-scale multi-center studies may be able to confirm this. At the moment, it seems prudent to study MCID in each population as even fine differences can still affect the quality of care.

Bernstein and coworkers found that PASS in lower-income patients undergoing foot and ankle surgery was lower compared to higher-income patients (39 mm vs 49 mm), possibly due to the latter group's higher expectations.[16] The PASS value found in the present study was 42 mm, consistent with the PASS value in lower-income patients from the study of Bernstein and

coworkers. As Thailand's average annual income is lower than those in European and North American countries, this finding may suggest that lower-income patients have similar expectations of pain after surgery regardless of their geographics. Similar to the case of MCID, large-scale multi-center studies may be able to confirm this. The PASS value in the present study was also consistent with a postoperative pain study[10] which found a PASS value of 33 mm, again suggesting that maybe PASS values might not differ much regardless of differences in biological and cultural factors. MCID and PASS or both values may vary only slightly between populations.

Our results showed that 79% of the participants reported their pain outcomes at the ward as moderately better or much better compared to the PACU. The median difference between the two pain scores in patients reporting their pain change as "moderately better" was 16.5 mm for VAS and 2 for NRS. The mean change of "much better" was 35 mm for VAS and 2 for NRS. Though these results were not part of the definition of MCID, we believe it is beneficial that practitioners are aware of them as they can guide acute postoperative pain management, denoting the changes in pain scores required for patients to perceive a significant improvement in their pain.

Even though all participants received standard pain control and postoperative care, some of them reported a perception opposite to the pain score, which was defined as illogical data. The illogical data in our study were excluded from the MCID analysis. This phenomenon might be associated with the anesthetic techniques used and environmental factors. Half of the illogical data came from patients who received spinal anesthesia. Seemingly, the dissatisfaction rate with spinal anesthesia was high (3.7%) due to paresthesia at puncture, postoperative nausea and vomiting, and postoperative backache.[23] Moreover, a previous study showed the main cause of the dissatisfaction was the immobility of lower limbs.[24] It was possible that discomfort after spinal anesthesia during their stay in the PACU caused the patients to report higher pain scores than their true pain would have suggested, thus resulting in illogical data. The differences in values of MCID and PASS between VAS and NRS warrant some attention. These differences might have resulted from the different natures of VAS and NRS, as choosing a point on a physical line is significantly different from sliding an imaginary scale in one's mind. This observation reminds us that the MCID and PASS values are specific to each tool.

Limitations of the study

Our sample size did not allow for robust subgroup analyses. As for the skewed gender ratio, we do not have a good explanation for this disparity considering the randomization method employed. Lastly, as pain is both a biological and psychosocial phenomenon, the results of the present study may not be fully generalizable to other populations.

Conclusion

MCID and PASS in our setting were similar to other populations and should be helpful in guiding the treatment of postoperative pain.

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