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Measuring acute postoperative pain using the visual analog scale: the minimal clinically important difference and patient acceptable symptom state

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Abstract

Background. The 100 mm visual analog scale (VAS) score is widely used to measure pain intensity after surgery. Despite this widespread use, it is unclear what constitutes the minimal clinically important difference (MCID); that is, what minimal change in score would indicate a meaningful change in a patient's pain status.

Methods. We enrolled a sequential, unselected cohort of patients recovering from surgery and used a VAS to quantify pain intensity. We compared changes in the VAS with a global rating-of-change questionnaire using an anchor-based method and three distribution-based methods (0.3 SD, standard error of the measurement, and 5% range). We then averaged the change estimates to determine the MCID for the pain VAS. The patient acceptable symptom state (PASS) was defined as the 25th centile of the VAS corresponding to a positive patient response to having made a good recovery from surgery.

Results. We enrolled 224 patients at the first postoperative visit, and 219 of these were available for a second interview. The VAS scores improved significantly between the first two interviews. Triangulation of distribution and anchor-based methods resulted in an MCID of 9.9 for the pain VAS, and a PASS of 33.

Conclusions. Analgesic interventions that provide a change of 10 for the 100 mm pain VAS signify a clinically important improvement or deterioration, and a VAS of 33 or less signifies acceptable pain control (i.e. a responder), after surgery.

Key words: analgesia; pain measurement; surgery

Pain scales are useful for the assessment of postoperative pain and for monitoring the effectiveness of treatment.[1] Most are based on self-reporting of a unidimensional scale aiming to represent subjective pain intensity.[2–6] The 100 mm visual analog scale (VAS) and the 11-point numerical rating scale (NRS) are the most commonly used. But a reduction in a pain score of itself may not equate to an improvement in the patient's experience.[5–9]

The VAS is frequently used as a measure of pain intensity, and authors and readers infer that a statistically significant difference in the VAS score equates to a clinically important reduction in pain. This is not necessarily correct.[9 10] Previous studies have indicated that reductions in pain scores of around 30–40% are needed in order to reflect clinically useful improvements in pain.[6 8 11–14] But it is unclear what is the minimal clinically

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Editor's key points

- The 100 mm visual analog scale (VAS) score is widely used to measure pain intensity after surgery, but the minimal clinically important difference in the VAS is not clear.
- A change of 10 for the 100 mm pain VAS would be the minimal clinically important difference, and the VAS of 33 or less signifies acceptable pain control after surgery.

important difference (MCID) of the pain VAS;[15 16] that is, what minimal change in a pain VAS score would indicate a real change in a patient's pain intensity.[16 17] Several studies have attempted to define the MCID or clinically useful effect in the postoperative setting,[18–20] but the methods used did not comply with existing standards nor did they include patient evaluation.[15]

The clinically important difference of the numerical rating scale (NRS) has been estimated for various chronic pain states,[13 15 21 22] as has the MCID of the VAS in chronic pain[23] and in the emergency department setting,[24 25] but it is unclear whether these results can be applied in the acute postsurgical pain setting. One study has determined the MCID of the pain VAS in patients after shoulder rotator cuff surgery.[26] The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recently reviewed and recommended specific methods that can be used for interpreting the clinical importance of treatment outcomes in chronic pain trials,[14] but there are currently no recommendations for acute postoperative pain.

The patient acceptable symptom state (PASS) is the value beyond which patients consider themselves well.[15 27 28] The PASS can therefore be used to define responders and non-responders to analgesic treatment in postoperative pain studies.[21] The PASS of the pain VAS score in this setting is often assumed, but has not been determined according to current recommendations.[15] The aim of this study was to determine the MCID and PASS for the pain VAS in patients recovering from surgery.

Methods

This prospective observational study evaluated adult patients recovering from surgery, using the 100 mm VAS to measure pain on two occasions, along with a generic Likert scale of overall recovery (see next subsection). Most patients (n=204) enrolled in this study participated in a concurrent study evaluating quality-of-recovery scales.[29] The study settings were the surgical wards at three hospitals in Australia (Alfred, Royal Women's, and Shepparton Hospitals) representing tertiary adult, tertiary obstetric/gynaecology, and rural/regional hospitals. Ethics approval was obtained from the institutional ethics committee at each hospital, and patient consent was obtained in all instances.

Patients were eligible to participate in the study if they were >18 yr of age and recovering from a surgical procedure requiring general or major neuraxial block anaesthesia. Patients were excluded if they had poor English comprehension, drug or alcohol dependence, psychiatric disorder, uncontrolled pain, or a concurrent serious medical disorder impairing completion of the VAS and questionnaire. Baseline patient characteristics and perioperative data were collected on a case report form and later de-identified and transcribed onto an electronic database.

Determination of the MCID for pain

There is currently no consensus on the optimal method for MCID estimation. As such, we chose to include a triangulation (average) of several methodologies,[15 16] as we have done previously when evaluating quality-of-recovery scales.[29] Previous methods used to determine MCID have included the SD/2 rule,[30] and 0.2 SD,[31] 0.3 SD,[32] and the standard error of measurement (SEM);[33] others have used 5–10% of the instrument range.[34] We chose to include three distribution-based measures: the 0.3 SD, SEM, and 5% range.[35] In addition, we used an anchor-based method with a global rating-of-change questionnaire.[36] This uses a 15-point Likert scale ranging from –7 (a very great deal worse) to +7 (a very great deal better).[15 16 36]

A 100 mm VAS, ranging from 0 (no pain) to 100 (very severe pain), was used to measure pain intensity throughout the previous 24 h on two occasions in the days after surgery. At the second visit, patients were asked to assess the following (adapted from Tubach and colleagues).[15] 'Think only about your pain you have felt over the past 24 hours. Compared with yesterday, is your pain': −7, a very great deal worse; −6, a great deal worse; −5, a good deal worse; −4, moderately worse; −3, somewhat worse; −2, a little worse; −1, almost the same, hardly any worse at all; 0, no change; 1, almost the same, hardly any better at all; 2, a little better; 3, somewhat better; 4, moderately better; 5, a good deal better; 6, great deal better; or 7, a very great deal better?

Patients whose score on the global rating-of-change questionnaire was 0, 1, or −1 were classified as unchanged.[36] Patients whose score was 2, 3, −2, or −3 were considered to have experienced a small change equivalent to the MCID; those with scores of 4, 5, −4, and −5 were considered to have experienced moderate change, and those with scores of 6, 7, −6, and −7 were considered to have experienced large change.[36] Absolute (i.e. we changed the sign of the scores for those who deteriorated) mean changes in pain VAS scores according to patient-rated change in postoperative recovery health status were then calculated. All four estimates (0.3 SD, SEM, 5% range, and global rating of change) were then averaged.

Patients' opinion of their improvement

The PASS was determined using the direct opinion-based approach,[15 37] in which patients were asked to define any improvement: 'In your opinion, have you made a good recovery from your operation?', with response options of yes, no, or unsure. Patients responding in the affirmative were classified as having made a good recovery, and those who responded negatively or were unsure were classified as having a poor recovery.

Statistical analysis

We could not reliably estimate a required sample size for this study. Given that previous relevant studies had enrolled 40–100 subjects,[20 36] we planned to enrol at least 150 subjects to provide an adequate number for subgroup testing.

Data are presented as mean (SD) or number (%) unless otherwise specified. Selected results are reported with a 95% confidence interval (CI), with the mean (95% CI) VAS score for minimal change calculated using 1000 bootstrap samples. The SEM was calculated as the SD multiplied by the square root of one minus the intraclass correlation coefficient.[33] Changes in pain