VALIDATION OF THE CRITICAL-CARE PAIN OBSERVATION TOOL IN ADULT PATIENTS

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BACKGROUND Little research has been conducted to validate pain assessment tools in critical care, especially for patients who cannot communicate verbally.

OBJECTIVE To validate the Critical-Care Pain Observation Tool.

METHODS A total of 105 cardiac surgery patients in the intensive care unit, recruited in a cardiology health center in Quebec, Canada, participated in the study. Following surgery, 33 of the 105 were evaluated while unconscious and intubated and 99 while conscious and intubated; all 105 were evaluated after extubation. For each of the 3 testing periods, patients were evaluated by using the Critical-Care Pain Observation Tool at rest, during a nociceptive procedure (positioning), and 20 minutes after the procedure, for a total of 9 assessments. Each patient’s self-report of pain was obtained while the patient was conscious and intubated and after extubation.

RESULTS The reliability and validity of the Critical-Care Pain Observation Tool were acceptable. Interrater reliability was supported by moderate to high weighted \( \kappa \) coefficients. For criterion validity, significant associations were found between the patients’ self-reports of pain and the scores on the Critical-Care Pain Observation Tool. Discriminant validity was supported by higher scores during positioning (a nociceptive procedure) versus at rest.

CONCLUSIONS The Critical-Care Pain Observation Tool showed that no matter their level of consciousness, critically ill adult patients react to a noxious stimulus by expressing different behaviors that may be associated with pain. Therefore, the tool could be used to assess the effect of various measures for the management of pain. (American Journal of Critical Care. 2006;15:420-427)

Pain is an important stressor for many patients in critical care, and it is not unusual for the intensity of the pain to be described as moderate to severe. Pain assessment is the first step in proper pain relief, an important goal in patients’ care. Although critical care clinicians strive to obtain each patient’s self-report of pain, many factors compromise patients’ ability to communicate verbally, including the use of sedative agents, mechanical ventilation, and changes in the level of consciousness. Several pain scales have been used to document self-reporting of pain in intubated patients. In the absence of a patient’s self-report, observable behavioral and physiological indicators become important indices for the assessment of pain.

Preliminary research has been conducted to validate instruments that include behavioral and/or physiological indicators. Use of these instruments in critical care practice is restricted because of the limitations of the studies. Limitations include small sample sizes (<40 patients), lack of validation in intubated...
patients, use of a subjective scale (eg, absence, slight, moderate, and extreme intensity of behaviors), confusion in the definition of behaviors (eg, body movements and muscle rigidity), and use of dependent observations (ie, statistical analysis of the observations rather than of the sample of patients). The aim of our study was to examine the reliability and validity of a newly developed instrument for pain assessment: the Critical-Care Pain Observation Tool (CPOT).

**Method**

**Design, Sample, and Ethics**

A repeated measures design was chosen for this quantitative study. A convenience sample of 105 cardiac surgery patients in the intensive care unit (ICU) at a cardiology health center in Quebec, Canada, was recruited for the study. Patients were considered for inclusion if they were 18 years or older, had been admitted for cardiac surgery, understood French, were in the ICU after surgery, and were able to hear and to see. Patients were excluded if they had been admitted for a heart transplant or thoracic aortal aneurysm repair, received medical treatment for chronic pain, had an ejection fraction less than 0.25, had preexisting psychiatric or neurological problems, had a dependence on alcohol or drugs, received neuromuscular blockers following surgery, or had complications after surgery (eg, hemorrhage, delirium, death).

This study was approved by the human research committee of the health center. Recruitment was done the day before the surgery; the study was explained to eligible patients, and informed consent was obtained. At this time, patients were taught how to use the pain intensity descriptive scale.

**Instruments**

*Critical-Care Pain Observation Tool.* The CPOT, developed in French, has 4 sections, each with different behavioral categories: facial expression, body movements, muscle tension, and compliance with the ventilator for intubated patients or vocalization for extubated patients (Table 1). Items in each section are

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial expression</td>
<td>No muscular tension observed</td>
<td>Relaxed, neutral 0</td>
</tr>
<tr>
<td>Presence of frowning, brow lowering, orbit tightening, and levator contraction</td>
<td>Tense 1</td>
<td></td>
</tr>
<tr>
<td>All of the above facial movements plus eyelid tightly closed</td>
<td>Grimacing 2</td>
<td></td>
</tr>
<tr>
<td>Body movements</td>
<td>Does not move at all (does not necessarily mean absence of pain)</td>
<td>Absence of movements 0</td>
</tr>
<tr>
<td>Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements</td>
<td>Protection 1</td>
<td></td>
</tr>
<tr>
<td>Pulling tube, attempting to sit up, moving limbs’ thrashing, not following commands, striking at staff, trying to climb out of bed</td>
<td>Restlessness 2</td>
<td></td>
</tr>
<tr>
<td>Muscle tension</td>
<td>No resistance to passive movements</td>
<td>Relaxed 0</td>
</tr>
<tr>
<td>Evaluation by passive flexion and extension of upper extremities</td>
<td>Tense, rigid 1</td>
<td></td>
</tr>
<tr>
<td>Strong resistance to passive movements, inability to complete them</td>
<td>Very tense or rigid 2</td>
<td></td>
</tr>
<tr>
<td>Compliance with the ventilator (intubated patients)</td>
<td>Alarms not activated, easy ventilation</td>
<td>Tolerating ventilator or movement 0</td>
</tr>
<tr>
<td>Alarms stop spontaneously</td>
<td>Coughing but tolerating 1</td>
<td></td>
</tr>
<tr>
<td>Asynchrony: blocking ventilation, alarms frequently activated</td>
<td>Fighting ventilator 2</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>Talking in normal tone or no sound</td>
<td>Talking in normal tone or no sound 0</td>
</tr>
<tr>
<td>Vocalization (extubated patients)</td>
<td>Sighing, moaning 1</td>
<td></td>
</tr>
<tr>
<td>Crying out, sobbing</td>
<td>Crying out, sobbing 2</td>
<td></td>
</tr>
</tbody>
</table>

Total, range 0-8

**Behavioral and physiological indicators are important indices for assessment of pain in patients unable to self-report.**
scored from 0 to 2, with a possible total score ranging from 0 to 8. The CPOT was developed as follows. Some items and their operational definitions were derived from previously described instruments for pain assessment.18-21 In addition, pain indicators were described by using findings from a chart review of the medical files of 52 critically ill patients22 and from 9 focus groups with 48 critical care nurses and interviews of 12 physicians.23

Content validity of the CPOT was established with 4 physicians and 13 critical care nurses. The physicians and nurses completed a questionnaire on the relevance of the inclusion of these indicators in the CPOT by using a Likert scale (1 = not at all, 2 = a little, 3 = moderately, and 4 = very much). Content validity indices, which are the proportion of participants who answered 3 or 4 on the Likert scale, were calculated. All indicators had indices of 0.88 to 1.00. Content validity indices greater than 0.80 were sufficiently satisfactory24 to consider including all these indicators in the CPOT.

Pain Intensity Descriptive Scale. A previously validated pain intensity descriptive scale (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = unbearable) was used. This scale has been used in previous studies18,25 in acute and critical care.

Confusion Assessment Method for the Intensive Care Unit. The Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) was used to assess delirium. The instrument has good sensitivity and specificity for assessing delirium in critically ill patients.26,27 Two modifications were made in the CAM-ICU to adapt it to the sedation scale used in our study and to facilitate assessment of patients’ inattention. First, the Ramsay Scale28 was used to assess the level of sedation. Second, patients’ inattention was verified by assessing their capacity to concentrate on the pain intensity descriptive scale used in our study.

Procedure

Three testing periods, each including 3 assessments for a total of 9 pain assessments (T1-T9) with the CPOT, were completed during each patient’s early postoperative course (Figure 1). For each patient, the first 3 assessments (T1-T3) were done while the patient was intubated and still unconscious (ie, with a sedation score of 5 or 6 on the Ramsay Scale). T1 was done with the patient at rest, approximately 2 hours after the end of surgery. T2 was completed a few minutes after T1 during positioning of the patient. Positioning represented a previously confirmed nociceptive procedure.9 On the basis of the patient’s needs, endotracheal suctioning often was performed at the same time as positioning. Finally, T3 was done at recovery, 20 minutes after the positioning procedure.

The second testing period (assessments T4-T6) was 3 hours after the first testing period. During this time, the patient was still intubated but conscious. Patients were considered conscious if they had a score of 2, 3, or 4 on the Ramsay Scale.

Finally, the third testing period (assessments T7-T9) was after the patient was extubated, approximately 5 hours after the second testing period. The positioning procedure at T8 sometimes occurred with ambulation and/or respiratory exercises, which were part of the postoperative care protocol.

For each of the 3 testing periods, patients were evaluated with the CPOT for 1 minute at rest both before and after positioning and for the duration of the positioning procedure. This standardization of procedures was based on the work of Puntillo et al.9 One of us (C.G.) and a critical care nurse (G.N.) evaluated the patients. Upon completion of the CPOT during the second testing period (ie, assessments T4-T6), intubated patients communicated the presence or absence of pain by nodding their heads (yes or no) to the

![Figure 1 Illustration of the time of consent and the 3 testing periods.](http://ajcc.aacnjournals.org)

Abbreviations: P, positioning procedure; R, rest; REC, recovery (20 minutes after the positioning procedure).
question, Do you have pain? This procedure was selected because many intubated patients during this phase of their recovery were unable to use the pain intensity descriptive scale. Before the third testing period, at T7, patients were evaluated by using the CAM-ICU to determine the presence of delirium. Three patients were excluded because of delirium. During the third testing period (ie, assessments T7-T9) after completion of the CPOT, the extubated patients used the pain intensity descriptive scale to grade their pain.

Data Analysis

Statistical analyses were completed by using version 11.5 of SPSS for Windows (SPSS Inc, Chicago, Ill). Descriptive statistics were computed for all variables. Interrater reliability was examined. Weighted κ coefficients were calculated for all assessments (T1-T9).29 To test validity of the CPOT, we determined criterion and discriminant validity (Table 2). Criterion validity was examined by measuring the relationship between the CPOT scores and the patients’ self-reports, the gold standard measure of pain. Analysis of variance was used to examine the differences between the intubated patients’ self-reports of pain (yes or no) and the CPOT scores (assessments T4-T6). Also, Spearman correlations31 were calculated between the extubated patients’ self-reports of pain intensity (ordinal descriptive scale) and the CPOT scores (assessments T7-T9). Finally, discriminant validity31 was examined by performing paired t tests between assessments with the CPOT taken at rest and during positioning (T1 with T2, T4 with T5, and T7 with T8).

Results

Characteristics of the Sample

A total of 131 patients were approached for consent the day before surgery, and 117 (89%) agreed to participate in the study. Reasons for refusal were as follows: anxious about the surgery (n = 9 patients), not interested (n = 3), undecided (n = 1), and bad experience with research (n = 1). During the course of the study, 8 patients were excluded because of postoperative complications (hemorrhage, delirium, death), 3 because their surgery was canceled, and 1 because of extubation right after surgery. The final sample size was 105 patients enrolled during a 3-month period. Table 3 gives the demographic characteristics of the patients.

Anesthesia was similar for all patients, and all were receiving continuous infusions of propofol after surgery (mean dose 85.4 mg/h, SD 39.7 mg/h). For each patient, this medication was tapered off and stopped 1 to 3 hours after the patient’s arrival in the ICU. Thus, all patients were receiving propofol during

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**Table 2** Description of reliability and validity methods examined in this study

<table>
<thead>
<tr>
<th>Psychometric property</th>
<th>Description</th>
<th>Coefficient or analysis</th>
<th>Level of acceptability*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interrater reliability</td>
<td>Interrater reliability is the consistency with which 2 raters agree on their measurement/observation (ie, the CPOT) of a phenomenon (ie, pain) Two raters assessed the patients in this study: the principal investigator and 1 critical care nurse</td>
<td>κ coefficient (proportion of responses in which the 2 raters agreed)</td>
<td>&lt;0 Poor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.21-0.40 Fair</td>
<td>0.41-0.60 Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.61-0.80 Substantial</td>
<td>0.81-1.00 Almost perfect</td>
</tr>
<tr>
<td>Criterion validity</td>
<td>Criterion validity refers to the relationship between the instrument (ie, the CPOT) and the gold standard measure of pain (ie, the patient’s self-report) In this study, yes/no and pain intensity were used as the gold standard self-report measures</td>
<td>Intubated patients (T4-T6): analysis of variance</td>
<td>P ≤ .01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Extubated patients (T7-T9): Spearman correlation</td>
<td></td>
</tr>
<tr>
<td>Discriminant validity</td>
<td>Discriminant validity refers to evidence that instruments measuring 2 different constructs should not correlate In this study, we examined whether the CPOT could be used to discriminate between pain during positioning and lack of pain at rest</td>
<td>Rest time compared with positioning for all three testing periods: paired t test</td>
<td>P ≤ .01</td>
</tr>
</tbody>
</table>

Abbreviation: CPOT, Critical-Care Pain Observation Tool.

* Levels of acceptability for interrater reliability scores from Landis and Koch.30
the first testing period (ie, assessments T1-T3). All patients also were receiving continuous infusions of fentanyl when they were admitted to the ICU from surgery. The mean dosage of fentanyl decreased from 73.7 µg/h (SD 21.8) at the first testing period to 50.7 µg/h (SD 31.1) at the third testing period. Rarely, patients (n = 4) received an intravenous bolus of fentanyl before positioning.

Sample at the 3 Testing Periods

First Testing Period. For assessments T1 to T3, data were collected on 33 of the 105 intubated patients who were unconscious, a criterion for testing during this period. CPOT scores were higher during the positioning procedure (T2) than during rest (T1) or recovery (T3; Figure 2).

Second Testing Period. For assessments T4 to T6, data were collected on 99 of the awake 105 intubated patients. The remaining 6 patients were extubated before the completion of this testing period. Again, CPOT scores were higher during the positioning procedure (T5) than during rest (T4) or recovery (T6). Moreover, in this testing period, patients had the highest scores on the CPOT (Figure 2).

Third Testing Period. Finally, for assessments T7 to T9, all 105 patients were assessed after they were extubated. The CPOT scores were similar to those of the 2 previous testing periods (Figure 2).

Interrater Reliability

Together, the principal investigator and the critical care nurse (C.G. and G.N.) completed the CPOT at all 9 assessments and were blinded to each other’s scores. The sample sizes for interrater reliability differed for each time, reflecting the times when both were present.

Table 3 Description of the study sample (n = 105)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>60 (8)</td>
</tr>
<tr>
<td>Sex, No. (%) of patients</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>83 (79)</td>
</tr>
<tr>
<td>Female</td>
<td>22 (21)</td>
</tr>
<tr>
<td>Type of cardiac surgery, No. of patients (%)</td>
<td></td>
</tr>
<tr>
<td>Coronary artery bypass graft</td>
<td>83 (79)</td>
</tr>
<tr>
<td>Valvular repair or replacement</td>
<td>11 (10)</td>
</tr>
<tr>
<td>Coronary artery bypass graft and valvular surgery</td>
<td>9 (9)</td>
</tr>
<tr>
<td>Interauricular/interventricular communication repair</td>
<td>2 (2)</td>
</tr>
</tbody>
</table>

*All patients had sternal incisions.

Figure 2 Mean scores and standard deviations of the Critical-Care Pain Observation Tool for the 3 testing periods (N = 105 patients). The scores can range from 0 to 8.

Table 4 Weighted κ coefficients for each assessment from T1 to T9*

<table>
<thead>
<tr>
<th>Assessment</th>
<th>No. of patients</th>
<th>Weighted κ coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>12</td>
<td>0.83</td>
</tr>
<tr>
<td>T2</td>
<td>12</td>
<td>0.63</td>
</tr>
<tr>
<td>T3</td>
<td>14</td>
<td>0.85</td>
</tr>
<tr>
<td>T4</td>
<td>29</td>
<td>0.52</td>
</tr>
<tr>
<td>T5</td>
<td>33</td>
<td>0.85</td>
</tr>
<tr>
<td>T6</td>
<td>33</td>
<td>0.88</td>
</tr>
<tr>
<td>T7</td>
<td>34</td>
<td>0.62</td>
</tr>
<tr>
<td>T8</td>
<td>33</td>
<td>0.77</td>
</tr>
<tr>
<td>T9</td>
<td>34</td>
<td>0.71</td>
</tr>
</tbody>
</table>

*Assessments made by using the Critical-Care Pain Observation Tool were independently completed by the principal investigator and the critical care nurse when both were present.
Weighted κ coefficients were moderate to high at all assessments (Table 4).

**Criterion Validity**

Mean CPOT scores according to patients’ self-reports of the presence or absence of pain during the second testing period (ie, assessments T4-T6) and the analysis of variance are presented in Table 5. At each assessment in this testing period, CPOT scores were significantly higher for intubated patients reporting pain than for those who had no pain.

During the third testing period (ie, assessments T7-T9), mean pain intensity scores were significantly higher during the positioning procedure at T8 (2.01) than during rest at T7 (1.71) and recovery at T9 (1.40). Spearman correlations of 0.49, 0.59, and 0.40 \( (P \leq .001) \) at T7 to T9 showed that the patients’ self-reported pain intensity scores were moderately correlated with the CPOT scores.

**Discriminant Validity**

At the 3 testing periods, CPOT scores were significantly higher during positioning than during the rest periods. Table 6 gives the results of the paired t tests.

**Discussion**

Our findings validated the CPOT, which was developed specifically to assess pain in ICU patients. Interrater reliability was high for most assessments and moderate at T4. Payen et al\(^{19}\) obtained a weighted κ coefficient of 0.74 when they compared behavioral pain scores between pairs of evaluators. A total of 46 nurses and nurse’s aides, 1 physical therapist, and 1 physician participated in that study.\(^{19}\) In our study, only 2 evaluators used the instrument, which is a limitation to the examination of interrater reliability, and results cannot be generalized to other ICU nurses.

When patients were intubated during the second testing period, CPOT scores differed significantly between those who reported pain and those who did not. Moreover, when patients were extubated during the third testing period, the higher a patient’s self-report of pain was, the higher was the patient’s score on the CPOT. These results are consistent with those of previous studies\(^{30,32}\) in which self-reports of pain of patients in a postanesthesia care unit were moderately related to pain behaviors. Our results support the criterion validity of the CPOT because the indicators were tested against the most valid measurement of pain; that is, the patients’ self-reports.

**Discriminant validity was supported by the finding that CPOT scores were higher during positioning than at rest in the 3 testing periods. Payen et al\(^{19}\) also found higher behavioral scores during positioning than at rest in unconscious critically ill patients. Such results emphasize that pain behaviors are observable even if a patient cannot report pain.

Our study, however, is the first to document differences in pain behavior scores according to levels of activity during different states of consciousness and intubation: unconscious and intubated, conscious and intubated, and then awake and extubated. These results...
suggest that patients, whatever their levels of consciousness, may demonstrate pain behaviors in response to a nociceptive procedure. Whether a behavioral response to a noxious procedure is accompanied by perception of pain in an unconscious patient is unknown. Until there is evidence to the contrary, experts recommend that healthcare providers assume that unconscious patients may have pain, especially if behavioral responses to a known noxious stimulus occur. The experts recommend that these patients be treated the same way as conscious patients when the patients are exposed to sources of pain.

Indeed, in a study by Lawrence, formerly unconscious patients revealed that they could hear, understand, and respond emotionally to what was being said while they were unconscious. In light of this finding, perhaps the CPOT can be used to assess pain in other populations of critical care patients. This hypothesis requires confirmation in future studies.

We also found that CPOT scores were similarly low for both unconscious and conscious extubated patients. This result may have occurred because the patients were highly sedated while unconscious and may have been experiencing the residual effects of anesthesia. Once extubated, they could have experienced less severe pain than they did when they were intubated.

Data collection in this study was completed in the 8 hours after surgery, a period when intermittent drowsiness can be expected. Previous studies in which intubated patients provided self-reports of pain were conducted in periods varying from 12 to 72 hours after the end of surgery. Those patients might have had more time to recuperate from the residual effects of anesthesia than our patients did. In the study by Ferguson et al, patients’ self-reports of pain after coronary artery bypass graft surgery were collected more than 8 hours after the end of surgery, and 9 (21%) of 43 patients were unable to communicate their self-report of pain because of drowsiness. The occurrence of the same inability to communicate in the patients in our study is not surprising.

Limitations
This study was not without limitations. First, data were collected by only 2 persons. More raters should be used in tests of interrater reliability in subsequent evaluations of the CPOT. Second, data could be collected for only 33 of the 105 patients while the patients were unconscious. Third, postoperative drowsiness led to missing data for some patients. Finally, cardiac surgery patients are a relatively healthy ICU group and may not represent most ICU patients, who are positioned during assessment T5, 18 of them who did not report pain had high CPOT scores (mean 2.11, SD 0.90). Perhaps for these patients the positioning was a distressful or an uncomfortable experience rather than a painful one. Also, the endotracheal tube may have caused coughing during the positioning procedure, leading to higher CPOT scores in the absence of reported pain. This finding suggests that behaviors observed by using the CPOT may be an indicator of more than pain. Further research is warranted to determine the sensitivity and specificity of the CPOT as a measure of pain.

Experts recommend we assume that unconscious patients have pain, especially if behavioral responses to noxious stimuli occur.

Behaviors observed by using the CPOT may indicate more than pain.

<table>
<thead>
<tr>
<th>Assessments</th>
<th>No. of patients</th>
<th>t</th>
<th>df</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-T2</td>
<td>33</td>
<td>-9.01*</td>
<td>32</td>
</tr>
<tr>
<td>T4-T5</td>
<td>99</td>
<td>-12.07*</td>
<td>98</td>
</tr>
<tr>
<td>T7-T8</td>
<td>105</td>
<td>-15.96*</td>
<td>104</td>
</tr>
</tbody>
</table>

*P < .001. Alpha is adjusted to 0.01 because 3 comparisons were made on the same subjects.

Table 6 Differences in scores on the Critical-Care Pain Observation Tool measured at rest before the procedure (T1, T4, and T7) and during the procedure (T2, T5, and T8)
much sicker. Future research on the effectiveness of the CPOT as a nonverbal measure of pain in other sicker ICU patients is warranted.

Despite these limitations, this study was innovative in several aspects. First, development of the CPOT was based on previous research of others as well as on descriptive data from 2 preliminary studies that led to selection of the behavioral indicators. Second, the relationship between intubated patients’ self-reports of pain and behavioral indicators was explored for the second time. Finally, data were obtained from patients at different levels of consciousness.

Future research should be conducted to determine if CPOT scores can be used to differentiate pain from other conditions. Also, receiver operating characteristic curve analysis could be performed to examine the specificity and the sensitivity of the CPOT as a measure of pain. This further testing could substantiate the CPOT as a valid, reliable, and useful tool for measuring pain in critically ill patients who are unable to self-report.

Conclusions

The CPOT had acceptable reliability and validity in this sample of cardiac surgery ICU patients. However, the tool needs to be further validated in different populations of critically ill patients. Appropriate pain assessment is an important part of quality care for critically ill patients, and use of validated measures of pain could aid in the evaluation of multidisciplinary pain management techniques for nonverbal critically ill patients.

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