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Validation of the Critical-Care Pain Observation Tool in brain-injured critically ill adults

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ABSTRACT

Objective: Pain is a common symptom in the intensive care unit (ICU). Brain-injured patients are often unable to reliably self-report their pain, calling forth the need to use behavioral scales such as the Critical-Care Pain Observation Tool (CPOT). This study aimed to test the reliability and validity of the CPOT use with brain-injured ICU adults.
Materials and methods: Eight trained staff nurses and a medical student scored the CPOT before and during a nonpainful (ie, gentle touch) and at least 1 painful (eg, turning) procedure. Then, communicative patients self-reported their pain using yes/no and, when possible, on a 0 to 10 Faces Pain Thermometer.
Results: A total of 79 brain-injured ICU patients participated. The intraclass correlation coefficient between trained raters was 0.73 (95% confidence interval, 0.57-0.83) during turning. CPOT scores were significantly higher during turning compared with gentle touch ($P < .001$) and correlated significantly with self-reports of pain intensity during turning (0.64, $P < .01$). The receiver operating characteristics curve indicated a cutoff of 2 with a sensitivity of 0.90 and specificity of 0.67.
Conclusions: Overall, the CPOT use was found to be reliable and valid in this patient group and is new evidence fulfilling an important gap highlighted in the Society of Critical Care Medicine practice guidelines.

1. Introduction

Patients admitted to the intensive care unit (ICU) frequently experience pain and discomfort due to traumatic injury or illness, and standard care procedures (eg, tube/drain removal, turning, endotracheal suctioning) [1–3]. Lack or incomplete pain assessments can lead to unrecognized and undertreated pain which may result in multiple adverse physiologic consequences including adverse events (eg, fluctuations in vital signs, nosocomial infection) and increased ICU length of stay and mechanical ventilation duration [4–7]. Untreated pain has also been linked to increased intracranial pressure in traumatic brain injury patients [8], which can have severe clinical consequences such as brain herniation, hydrocephalus, and ischemia [9].

In addition, ICU patients with brain injury are often unable to reliably self-report the presence of pain either verbally or through body language (ie, nodding yes or shaking no) [10]. Because the patient's self-report remains the criterion standard of pain [11], observing pain behaviors may address this key challenge associated with assessing pain in brain-injured ICU adults.

A total of 8 observational assessment tools were developed for ICU adults unable to self-report [12], and 2 of them, namely, the Behavioral Pain Scale [13] and the Critical-Care Pain Observation Tool (CPOT) [14], were recommended for clinical use in medical, surgical, and non–brain trauma ICU patients [15]. Studies are still required to validate their use in brain-injured ICU patients. This study specifically aimed to test the reliability and validity of the CPOT use in brain-injured ICU adults. More specifically, the objectives were to examine:

1. Interrater reliability of CPOT scores between a medical student and trained ICU nurses;
2. Discriminant validation of CPOT scores during painful vs nonpainful procedures;
3. Criterion validation between patients' self-reports of pain and CPOT scores.

2. Materials and methods

2.1. Design, setting, and sample

This prospective cohort study used a repeated-measures within-subject design, as multiple data were collected for each participant across

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different conditions. The study took place in the Neuroscience Intensive Care Unit of the Harborview Medical Center in Seattle, WA. Because this study was designed as an observational and noninterventional quality initiative related to patient safety that maintained the anonymity of participants, the University Human Subjects Division determined it to not be considered as "human subjects research" under federal regulation 45 CFR 46.102(f). Thus, informed consent was not required.

Patients were eligible to be included in the study if they (*a*) were adults (18 years of age and older); (*b*) were admitted to the neurosciences ICU for a brain injury including stroke, aneurysm, and traumatic brain injury of greater than 2 days but less than 4 weeks in duration; and (*c*) had a Glasgow Coma Score greater than 4 [16]. Exclusion criteria included any condition that may confound or present a barrier for behavioral assessment: (*a*) isolated injury to the spinal cord, brainstem, or cerebellum; (*b*) peripheral nerve injuries; (*c*) administration of paralytic medications; (*d*) unarousable (ie, Richmond Agitation Sedation Scale score −5) [17]; or (*e*) if the patient was unable to be turned in bed. Convenience sampling was used to enroll eligible patients in this study.

2.2. Procedures

2.2.1. Sociodemographic and medical data

Demographic information (ie, sex and age) was collected from each patient. In addition, clinical information was collected including the diagnosis, category of the brain injury, surgical procedure, Glasgow Coma Scale score, Richmond Agitation Sedation Scale score, and administration of analgesics or sedatives (ie, intravenous infusions or bolus) within 4 hours prior to data collection.

2.2.2. Pain assessments

Pain assessments were coordinated by the medical student according to the availability of trained nursing staff and the patient's condition. Pain assessments were made in real time before and during painful procedures such as turning [18] and, when possible, during other common painful medical procedures (Table 1), as well as before and during gentle touch, a nonpainful procedure [19].

First, the medical student and responsible nurse independently observed the patient's face, body movements, and compliance with the ventilator or vocalization, and then assessed muscle tension by performing passive flexion and extension of the patient's arm and evaluating the resistance felt in response to the passive movement [14]. Then, the raters compiled the CPOT total score by adding scores to each item. This process took place once per patient with assessments before and during a painful and a nonpainful procedure. Once both raters scored the CPOT, patients who were conscious and able to communicate were asked to self-report the presence/absence of pain by indicating yes or no by means of verbal or physical cues (eg, head nodding) and to self-report the intensity of pain using the 0 to 10 Faces Pain Thermometer (FPT) [20].

Table 1
Frequencies of other nociceptive procedures

Procedure	Frequency
Endotracheal or tracheal suctioning	17
Blood draw	6
Trapezius squeeze	3
Injection	3
Central line insertion	3
Foley catheter insertion	3
Catheter removal	2
Spinal tap	2
Suturing	2
External ventricular drain removal	1
Feeding tube insertion	1

2.3. Instruments

2.3.1. The CPOT

The CPOT includes 4 behavioral domains: facial expression, body movements, muscle tension, and vocalization in nonintubated patients or compliance with the ventilator in intubated patients. Each item is rated on a 0 to 2 response scale, with a total score ranging from 0 to 8 [14]. It has been tested in more than 500 adult ICU patients able or not to self-report with various diagnoses including surgical, medical, and trauma (mainly non–brain injured) [12]. In these patient populations, the CPOT use has been shown to be reliable with intraclass correlation coefficients (ICCs) mainly varying between 0.50 and 0.96 between trained raters' CPOT scores [21–26]. The tool use has also been shown to be valid as evidenced by significantly higher CPOT scores during painful compared with nonpainful procedures [14,21–28] (ie, discriminant validation) and significant moderate positive correlations between CPOT scores and patient's self-report of pain intensity (r= 0.40-0.69, P< .05) [14,21,23–25] (ie, criterion validation).

2.3.2. Training for the use of CPOT

The raters (ie, medical student and 8 participating nurses) were trained on the CPOT use by the author of the tool using a 90-minute standardized training including CPOT scoring with patient videos [29]. The trained raters also completed bedside assessments with the author in real time to ensure complete understanding of the tool use. In addition, the first day of bedside assessments was completed by the raters as "practice runs." Scores were then discussed after the procedures to ensure agreement between raters within 1 score. These scores were discarded and are not included in the presented data set. A nurse rater had to be excluded from the sample because her scores were too discordant with all others.

2.3.3. Self-reports of pain

Patients were asked to indicate whether they were in pain or not by either verbal affirmation/negation (yes/no) or by head nodding. Patients were then asked to rate their pain intensity on the 0 to 10 FPT. This scale consists of a thermometer graded from 0 (no pain) to 10 (worst possible pain) and includes 6 faces adapted from the work of Prkachin [30]. When tested in cardiac surgery ICU adults, it demonstrated good convergent validation with a 4-point descriptive pain scale (r= 0.80-0.86, P< .001), discriminant validation between rest and turning (t= −5.10, df= 100, P< .001), and content validation [20]. The FPT was also successfully used in previous CPOT validation studies [18,21,24,26].

2.4. Data analysis

Data were entered in the SPSS version 22 software (SPSS Inc, Chicago, IL), which was also used for analysis. Descriptive statistics of sociodemographic and medical information, presence/absence of each behavioral indicator (eg, grimace, touching pain site, moaning, clenching fists) included in the CPOT, and clinician-recorded CPOT item scores were computed. Following the guidelines for the attribution of scores (ie, 0-2) for each item of the CPOT (ie, face, body, compliance with ventilation/vocalization, and muscle tension), the SPSS syntax was used to calculate the CPOT total scores.

The Shapiro-Wilk test was used to assess the normality of the distribution of self-report (FPT) and CPOT scores. Intraclass correlation coefficients (ICC) between raters' CPOT scores were obtained before and during each nonpainful and painful procedure to establish interrater reliability. For discriminant validation, Friedman 2-way analysis of variance and the related-sample Wilcoxon signed rank test were performed. Criterion validation of CPOT scores with patients' self-reports of the presence of pain was accomplished using Mann-Whitney tests, and Spearman correlation coefficient for self-reports of pain intensity. Receiver operating characteristic curve analysis was used to establish whether the CPOT was able to distinguish between patients with or without pain.