Pain Assessment in the Critically Ill Ventilated Adult: Validation of the Critical-Care Pain Observation Tool and Physiologic Indicators

Céline Gélinas, RN, PhD and Céleste Johnston, RN, DEd

Objectives: Use of a valid behavioral measure for pain is highly recommended for critically ill, uncommunicative adults. The aim of this study was to validate the English version of the Critical-Care Pain Observation Tool (CPOT) and physiologic indicators [mean arterial pressure, heart rate, respiratory rate, and transcutaneous oxygen saturation (SpO_2)] in critically ill ventilated adults.

Methods: A total of 30 conscious and 25 unconscious patients in the intensive care unit participated in the study. Patients were assessed by staff nurses and research team members before, during, and 20 minutes after the 2 following procedures: (1) nociceptive procedure: turning, and (2) non-nociceptive procedure: taking noninvasive blood pressure (NIBP). Conscious ventilated patients provided self-report level of pain.

Results: Interrater reliability of the CPOT was supported with high intraclass correlation coefficients (0.80 to 0.93). Discriminant validity was supported with increases of the CPOT and physiologic indicators, and a decrease in SpO_2 during turning, but remaining stable during NIBP. Conscious patients had higher CPOT scores during turning compared with unconscious patients. For criterion validity, the CPOT scores were correlated to the patients' self-reports of pain, whereas physiologic measures were not. Using a CPOT cutoff score of > 3 yielded a sensitivity of 66.7% and a specificity of 83.3%.

Discussion: The CPOT is a reliable and valid tool to assess pain in critically ill adults. Behavioral indicators represent more valid information in pain assessment than physiologic indicators. Further research is needed to explore how specific critically ill populations (eg, head injury) react to a painful procedure.

Received for publication February 5, 2007; revised March 30, 2007; accepted April 7, 2007.

From the School of Nursing, McGill University, Montreal, Quebec, Canada.

Supported by a Postdoctoral Fellowship Award (C.G.) from the "Fonds de la recherche en santé du Québec" (FRSQ) and the "Fondation de recherche en sciences infirmières du Québec" (FRESIQ), and a Postdoctoral Research Grant from the "Groupe de recherche interuniversitaire en sciences infirmières de Montréal" (GRISIM) and the Canadian Nurses Foundation (CNF).

Reprints: Céline Gélinas, RN, PhD, School of Nursing, McGill University, 3506, University Street, Room 420, Wilson Hall, Montréal, Qc, Canada, H3A 2A7 (e-mail: celine.gelinas@mcgill.ca).

Key Words: pain assessment, behaviors, physiologic indicators, critically ill, uncommunicative

(*Clin J Pain* 2007;23:497–505)

Critically ill patients experience moderate to severe pain in the intensive care unit (ICU).[1] Although critical care clinicians strive to obtain the patient's self-report of pain, many factors including the use of sedative agents, mechanical ventilation, and change in patient level of consciousness compromise the patient's ability to communicate verbally.[2] Pain assessment methods often need to be adapted to conform to the communication capabilities of the patient. In nonverbal patients who are unable to self-report, observable behavioral and physiologic indicators represent important indices for the assessment of pain.[3–6]

The development of instruments that measure behavioral and physiologic indicators of acute pain has recently been achieved in critical care.[7–9] Use of these instruments in critical care practice is a challenge due to limitations of those studies: (1) small sample sizes (< 40),[7–9] (2) absence of validation with ventilated patients, (3) use of a subjective scale (eg, absent, slight, moderate, and severe intensity of the behavior),[7] and (4) confusion in the definition of behaviors.[8]

To overcome those limitations, a newly tool the Critical-Care Pain Observation Tool (CPOT), was initially developed in French and forward-backward translated into English. It includes 4 behavioral categories: (1) facial expression, (2) body movements, (3) muscle tension, and (4) compliance with the ventilator for ventilated patients.[10] Items in each category are scored from 0 to 2 with a possible total score ranging from 0 to 8. Selection and operational definitions of the CPOT items were derived from the existing pain assessment instruments,[7–9] a chart review of 52 critically ill patients' medical files[11] and consultation with 48 critical care nurses and 12 physicians.[12]

The French version of the CPOT was first validated in 105 cardiac surgery ICU patients.[10] Results demonstrated acceptable reliability and validity of the CPOT. Interrater coefficients were moderate to high with weighted κ (0.52 to 0.88).[13] Discriminant validity was supported with significant results (paired t tests, $P \leq 0.001$) comparing CPOT scores at rest and during

turning (nociceptive procedure) with significantly higher CPOT scores during turning. For criterion validity, the patients' self-reports of pain were compared with the CPOT scores [analyses of variance (ANOVAs), $P \leq 0.001$ with the presence or absence of pain, and Spearman correlations from 0.40 to 0.59, $P \leq 0.001$ with the patients' self-report of pain intensity using a descriptive scale]. Also, the CPOT showed a sensitivity of 86% and a specificity of 78% with a cutoff score > 2 during turning.[14]

Although the CPOT seems to be a useful tool for assessing pain in critically ill adults, further steps in the tool validation are needed. Indeed, the initial study was conducted in a homogenous sample of cardiac surgery patients and to generalize the validity results, testing the CPOT with different ICU patient populations is necessary. Also, patients' assessments with the CPOT were completed by the principal investigator and only one critical care nurse. More staff could be trained to use the CPOT and considered in testing interrater reliability. Moreover, the CPOT was first validated in its French version and validation of its English version is essential.

According to physiologic indicators, they have received little attention. They were included in one critical care pain assessment tool (PAIN[9]) and their evaluation in that scale is based on the nurses' judgment. Objective values of physiologic indicators, that is, those derived from continuous monitoring, in the context of pain in critically ill adults have not been widely documented. In the study by Payen and colleagues,[8] significant increases of mean arterial pressure (MAP) and heart rate (HR) were found in critically ill ventilated and unconscious patients in response to a nociceptive procedure. Although little research supports the validity of physiologic indicators for pain assessment, vital signs are considered to be relevant cues in association with pain by the critical care nurses and other clinicians.[12] Also, they are easily available by continuous monitoring in the ICU.

STUDY AIM AND OBJECTIVES

The aim of this study was to examine the reliability and validity of the English version of the CPOT and physiologic indicators [MAP, HR, respiratory rate (RR), and transcutaneous oxygen saturation (SpO_2)] in critically ill ventilated adults. More specifically, the objectives were to:

1. determine interrater reliability of the CPOT;
2. determine discriminant validity of the CPOT and physiologic indicators during a nociceptive procedure versus a non-nociceptive procedure;
3. determine criterion validity of the CPOT and physiologic indicators with the "gold standard" measure of pain: self-report of pain of conscious ventilated patients.

METHOD

Design and Participants

A cross-over observational design was chosen to achieve the objectives of this study. A sample of 30 conscious and 25 unconscious ventilated ICU adults were recruited in a university hospital in the Montreal area. The patients recruited met the following inclusion criteria: (1) age 18 years and older, (2) admitted at the ICU, (3) ventilated, and (4) conscious or unconscious (Glasgow coma scale ≤ 8). Quadriplegic patients, those receiving neuromuscular blocking agents, or being investigated for brain death were excluded.

Ethics approval was provided by the Hospital Research Ethics Board. Patients or representatives were initially approached by staff to agree to meet with research team who explained study and obtained consent. Whenever possible, consent was obtained from the patient (n = 4). In the case where patients were not able to give their own consent, the consent form was given to the decision maker (next-of-kin) to complete on their behalf. Conscious patients were taught how to use the Faces Pain Thermometer (FPT) (see section The Patient's Self-report of Pain). A consent form was signed and a copy was given to the participant.

Measures

Besides the CPOT,[10] the main indicator of this study, other measures were documented: (1) physiologic indicators, and (2) the patient's self-report of pain.

Physiologic Indicators

Physiologic indicators such as MAP, HR, RR, and SpO_2 were examined with the monitoring equipment available at the ICU. Only 6 patients were monitored for intracranial pressure (ICP), and this indicator was also explored.

The Patient's Self-report of Pain

Ventilated patients able to self-report were asked to rate their level of pain immediately after the nurses had assessed them using the CPOT. This method was specified so that nurses were not biased by the patient's self-report of pain when they scored pain with the CPOT.

Self-report of pain was obtained in the following manner as recommended by Kwekkeboom and Herr[6]:

1. The patient was asked to answer "yes or no" by head nodding to the question: "Do you have pain?" or "Does it hurt?"
2. If the patient was able to concentrate on a scale, he or she pointed his or her pain intensity on the FPT.

The FPT was developed for critically ill adults.[15] It consists of a thermometer graded from 0 to 10, including 6 faces adapted from the work of Prkachin[16] and other existing tools. The FPT was also validated with 105 postoperative ICU patients. The scale demonstrated good convergent ($r = 0.80$ to 0.86, $P < 0.001$ with a pain intensity descriptive scale) and discriminant validity ($t = -5.10$, $P < 0.001$ comparing patients' pain intensity at rest and during turning) supporting a higher pain intensity score during turning. Content validity was also examined and patients positively evaluated its content and use.

Procedure

Patients participating in the study were assessed by ICU nurses, previously trained to use the CPOT, and members of the research team during 2 procedures: (1) nociceptive procedure: turning,[1] (2) non-nociceptive procedure: taking noninvasive blood pressure (NIBP). Assessments were completed at rest preprocedure, during the procedure (nociceptive and non-nociceptive) and 20 minutes postprocedure for a total of 6 assessments. Twenty minutes was selected as a postprocedure rest assessment because that amount of time is required for the liberation, the reaction and the elimination of stress hormones (epinephrine and norepinephrine), response activated by a stressor (turning). The epinephrine and norepinephrine half-life is short, 1 to 3 minutes, and these hormones are completely eliminated after 15 to 20 minutes.[17]

To complete the CPOT, patients were observed during 1 minute at rest preprocedure and postprocedure. During the nociceptive and the non-nociceptive procedures, patients were observed for the duration of the procedures, which could be a few minutes to detect any behavior of the patient. To examine interrater reliability, patients were assessed by 2 ICU nurses and a member of the research team (principal investigator or research assistant) at rest before the nociceptive procedure and during turning, simultaneously. For the other assessments, patients were evaluated by 2 raters, the nurse responsible for the patient and a member of the research team.

Sixty-two ICU nurses were trained to use the CPOT. The 1-hour training session, provided by the principal investigator, included the following: (1) objectives, sample criteria, and procedure of the study; (2) description of the CPOT indicators and the scoring; (3) completion of data collection sheet.

Data Analysis

Descriptive statistics were calculated for all variables. Intraclass correlation coefficients (ICC) were calculated with the CPOT to examine interrater reliability. ICC ≥ 0.70 were expected. Discriminant validity of the CPOT and physiologic indicators was determined by comparing a nociceptive procedure and a non-nociceptive procedure.[8] Increases in the CPOT scores, MAP, HR, RR, and a decrease in SpO_2 were predicted during the nociceptive procedure (turning). Repeated measures (RM)-multivariate analyses of variance (MANOVAs) (profile analysis) were performed to determine the results across the 2 procedures. Criterion validity was also examined by measuring the relationship between the CPOT and physiologic indicators, and the patients' self-reports of pain.[18] Logistic regression was performed to examine the prediction of the CPOT scores and physiologic indicators with the ventilated patients' self-reports of pain (yes or no). Receiver operating characteristic curve analysis was also performed to evaluate the ability of the CPOT to detect pain of ventilated patients during turning and to derive the threshold that maximized both the sensitivity and specificity simultaneously.[19] Finally, Pearson correlation coefficients were calculated between the patients' self-reports of pain intensity (0 to 10 FPT), the CPOT scores, and physiologic indicators. A moderate correlation with the CPOT was expected. As complementary analyses, ANOVAs between the 2 groups (conscious and unconscious patients) and types of medication (sedative and analgesic agents) were performed. Most statistical analyses were completed using SPSS 14.0 except for RM-MANOVA and the receiver operating characteristic curve which were completed using SAS 9.1. Satterthwaite-based degrees of freedom method was used for RM-MANOVA. The correlation of the repeated measures within each patient was modeled with the use of an unstructured covariance matrix. The appropriate covariance matrix was chosen based on the likelihood ratio test and Akaike's information criterion.

RESULTS

Sample

A total of 84 patients or representatives were approached for consent, and 56 (66.7%) agreed to participate in the study. During the course of the study, 1 patient was excluded because mechanical ventilation was stopped before the end of data collection. The final sample size was 55 patients enrolled over a 4 and a half month time period (Table 1 for patient demographics). Both males and females were represented but males were dominant in the unconscious group. Patients in the conscious group were admitted in the ICU mainly for a medical problem whereas patients in the unconscious group were mainly trauma victims with a head injury. According to age, patients in the unconscious group were younger compared with conscious patients. In terms of the revised Acute Physiology And Chronic Health Evaluation (APACHE II), a severity of disease classification system, both patient groups had similar scores. Unconscious patients obtained a slightly higher APACHE score as they had a lower level of consciousness (Glasgow Coma Scale ≤ 8). Regarding medications, patients were clustered into 4 regimen groups: (1) no drips (analgesics or sedatives), (2) analgesia only, (3) sedation only, and (4) analgesia and sedation (Table 1). Unconscious patients were slightly more heavily sedated with propofol infusions compared with conscious patients. Moreover, only a few conscious ($n = 4/30$) and unconscious ($n = 5/25$) ventilated patients received an intravenous bolus of either a sedative or an analgesic agent before turning.

Descriptive Statistics for the CPOT and Physiologic Indicators

Descriptive statistics for the CPOT and physiologic indicators in separate groups (conscious and unconscious patients) and all patients ($n = 55$) are presented in Table 2. For the CPOT, conscious patients showed a higher score during turning (P2) compared with unconscious patients. However, results were similar in both

TABLE 1. Descriptive Statistics of the Conscious and the Unconscious Groups

Variable	Conscious Patients	Unconscious Patients	Total
Sex (n)			
Male	15	17	32
Female	15	8	23
Diagnostic group (n)			
Trauma (with head injury)	5	14	19
Other trauma	3	2	5
Neurology (eg, subdural hemorrhage, hydrocephaly, brain infarct)	1	2	3
Surgical (thoracic, abdominal)	4	1	5
Medical (eg, pulmonary or cardiac problem, hemorrhage, sepsis)	17	6	23
Age			
Mean (standard deviation)	63.07 (16.29)	54.96 (23.03)	59.38 (19.87)
APACHE			
Mean (standard deviation)	19.60 (5.56)	21.44 (4.23)	20.44 (5.04)
Type of regimen (n)			
No drips	11	6	17
Analgesia only	7	1	8
Fentanyl drip (μg/h)	58.64 (64.30)	25.00 (–)	54.44 (60.71)
Sedation only	5	9	14
Propofol drip (μg/kg/h) or	22.50 (5.00)	25.00 (9.05)	24.23 (7.89)
Midazolam drip (mg/h)	1.00 (–)	4.00 (–)	2.50 (2.12)
Sedation and analgesia	7	9	16
Propofol drip (μg/kg/h) or	25.42 (13.82)	37.14 (25.14)	31.73 (20.80)
Midazolam drip (mg/h)	6.00 (–)	3.00 (2.82)	4.00 (2.65)
Fentanyl drip (μg/h)	86.43 (79.57)	64.44 (72.06)	74.06 (73.67)

groups for most of the physiologic indicators. During turning MAP, HR, and RR increased, whereas during NIBP monitoring, values remained stable. SpO_2 levels decreased more during turning in the conscious group (a decrease of 3.10%). Six patients with a head injury had continuous monitoring of ICP. It was observed that mean ICP increased from 14.7 mm Hg (SD = 5.2) at rest preprocedure to 20.3 mm Hg (SD = 4.4) during turning whereas it remained stable at 11.0 mm Hg (SD = 3.5) preprocedure and 10.7 mm Hg (SD = 2.7) during NIBP.

TABLE 2. Means and Standard Deviations of the CPOT and Physiologic Indicators at Rest Preprocedure, During Each Procedure and Postprocedure in the Conscious and the Unconscious Groups

Physiologic Indicator	Group	P1 At Rest Preprocedure	P2 During the Turning	P3 At Rest Postprocedure	BP1 At Rest Preprocedure	BP2 During Blood Pressure Taking	BP3 At Rest Postprocedure
CPOT	Conscious patients	0.50 (0.94)	3.70 (2.00)	0.33 (0.76)	0.27 (0.58)	0.67 (0.99)	0.30 (0.75)
	Unconscious patients	0.36 (0.57)	2.20 (1.32)	0.56 (0.92)	0.44 (0.71)	0.40 (0.65)	0.44 (0.87)
	Total	0.44 (0.79)	3.02 (1.87)	0.44 (0.83)	0.35 (0.65)	0.55 (0.86)	0.36 (0.80)
MAP	Conscious	82.16 (14.95)	94.47 (18.26)	83.67 (14.40)	82.40 (12.39)	86.74 (12.42)	81.84 (15.13)
	Unconscious	87.41 (14.70)	95.13 (13.80)	89.49 (13.36)	87.83 (14.44)	88.97 (12.59)	87.31 (12.50)
	Total	84.55 (14.93)	94.77 (16.25)	86.32 (14.12)	84.95 (13.54)	87.76 (12.43)	84.41 (14.09)
HR	Conscious	86.80 (15.34)	94.50 (16.11)	89.20 (15.56)	85.27 (13.91)	87.60 (15.18)	86.47 (14.11)
	Unconscious	87.92 (21.38)	93.72 (20.87)	90.20 (20.83)	89.52 (23.45)	89.84 (22.96)	89.56 (22.49)
	Total	87.31 (18.16)	94.15 (18.25)	89.65 (17.97)	87.20 (18.79)	88.62 (18.96)	87.87 (18.25)
RR	Conscious	19.27 (7.38)	26.27 (11.01)	19.07 (6.48)	18.20 (6.22)	19.53 (6.92)	18.57 (6.25)
	Unconscious	20.52 (6.40)	24.92 (8.96)	20.40 (6.05)	20.40 (6.67)	21.04 (6.11)	20.24 (6.51)
	Total	19.84 (6.92)	25.65 (10.06)	19.67 (6.26)	19.20 (6.46)	20.22 (6.55)	19.33 (6.36)
SpO_2	Conscious	97.10 (2.45)	94.00 (4.86)	97.17 (2.23)	97.40 (2.34)	97.20 (2.09)	96.80 (2.48)
	Unconscious	98.00 (1.53)	96.88 (2.62)	98.04 (1.51)	98.12 (1.88)	98.32 (1.77)	98.20 (1.92)
	Total	97.51 (2.12)	95.31 (4.22)	97.56 (1.97)	97.73 (2.16)	97.71 (2.02)	97.44 (2.33)

TABLE 3. ICC for the 6 Assessments With the CPOT

		Evaluators			
	n	Nurse Responsible for the Patient	Member of Research Team	Interrater Nurse	
P1	3	√	√	√	0.80**
P2	3	√	√	√	0.88**
P3	2	√	√	—	0.92**
BP1	2	√	√	—	0.84**
BP2	2	√	√	—	0.84**
BP3	2	√	√	—	0.93**

**$P \leq 0.001$.

Interrater Reliability

The number of raters varied between the 2 procedures. Three raters were present before and during turning (P1 and P2), and 2 raters were present for the other assessments. Raters completed the CPOT and were blinded to each other's scores. A total of 51 ICU nurses out of the 62 trained nurses used the CPOT during the study. High ICCs were obtained at all 6 assessments (Table 3).

Discriminant Validity

Discriminant validity of the CPOT and physiologic indicators was determined by comparing a nociceptive procedure (turning) and a non-nociceptive procedure (NIBP monitoring). Significant differences between the 2 procedures (interaction effects) were found for the CPOT scores and physiologic indicators (Table 4 for RM-MANOVA results). Results of the single effects showed that significant changes were found for all indicators during the turning procedure only (Table 5). Specifically, the CPOT scores, MAP, HR, and RR increased during turning (P2) whereas SpO_2 decreased. No statistical differences were found between rest assessments preprocedure and postprocedure (P1 and P3) except for HR which remained elevated postprocedure (P3).

TABLE 4. Repeated Measures MANOVA (Profile Analysis) of the CPOT Scores and the Physiologic Indicators (n = 55) for the 2 Procedures

Indicator	Effect	*df*	*F*
CPOT score	Procedure	(1, 63.3)	53.36**
	Time	(2, 73.3)	43.59**
	Procedure × time	(2, 86.5)	59.35**
MAP	Procedure	(1, 40.5)	2.41
	Time	(2, 54.3)	14.33**
	Procedure × time	(2, 87.7)	11.53**
HR	Procedure	(1, 41.5)	1.13
	Time	(2, 53.7)	8.70**
	Procedure × time	(2, 90.7)	8.34**
RR	Procedure	(1, 45.9)	4.30*
	Time	(2, 59.6)	16.01**
	Procedure × time	(2, 86.3)	14.03**
SpO_2	Procedure	(1, 48.3)	7.55*
	Time	(2, 60.4)	6.01*
	Procedure × time	(2, 85.7)	14.41**

*$P \leq 0.05$; **$P \leq 0.001$.

Criterion Validity

Patients in the conscious group were asked to provide their self-report of pain. Many patients acknowledged having pain during turning (P2) compare with other assessments when only few patients mentioned having pain (Table 6). For patients who were able to use the FPT, pain was mild for most assessments except during turning where pain was moderate (Table 7). Only the CPOT scores could predict the presence or the absence of pain on the basis of the patient's self-report during turning (Table 8). The threshold associated with maximization of the sums of sensitivity and specificity was found to be a score > 3 on the CPOT (Fig. 1). Specificity was higher than sensitivity which led to a positive predictive value of 85.7%. In other words, 85.7% of the patients who were detected with a CPOT score > 3 reported having pain (yes). Finally, a high Pearson correlation coefficient of 0.71 ($P \leq 0.05$) was found between the patients' self-reports of pain intensity using the FPT with the CPOT scores during turning. No significant correlations ($P > 0.05$) were found between the FPT and the physiologic indicators.

Complementary Analyses

According to the 2 sample groups, conscious patients showed significantly higher CPOT scores during turning (P2) compare with unconscious patients (Fig. 2 and Table 9). A similar pattern was observed when comparing patients on the basis of the medications (4 regimen groups) they were receiving (Fig. 3 and Table 9). During turning, patients receiving an analgesic agent only (fentanyl) showed higher CPOT scores compared with patients with no analgesics or sedatives ($t = -2.27$, $df = 23$, $P = 0.033$) and those receiving a sedative agent only (propofol or midazolam) ($t = 3.13$, $df = 20$, $P = 0.005$) who had the lowest CPOT scores. No significant results were found for physiologic indicators with the 2 sample groups or the 4 regimen groups.

DISCUSSION

This study validated the English version of the CPOT and examined the validity of physiologic indicators in conscious and unconscious ventilated adults. Interrater reliability of the CPOT was high for all assessments. These results were similar to the previous

TABLE 5. Analyses of Single Effects of the Interaction Procedure × Time for CPOT Scores and the Physiologic Indicators

Indicator	Effect Procedure × Time	*df*	*F*	Single Effect	*df*	*t*
CPOT score	Turning procedure (P1-P3)	(2, 82.8)	67.90**	P1-P2	91.2	−11.28**
				P2-P3	95	11.20**
				P1-P3	73.9	0.00
	NIBP procedure (BP1-BP3)	(2, 63.3)	0.98†			
MAP	Turning procedure (P1-P3)	(2, 69.4)	20.28**	P1-P2	81.7	−6.40**
				P2-P3	80.3	5.04**
				P1-P3	59.1	−1.63
	NIBP procedure (BP1-BP3)	(2, 59.4)	2.74†			
HR	Turning procedure (P1-P3)	(2, 66.1)	17.09**	P1-P2	68.5	−5.87**
				P2-P3	67	3.92**
				P1-P3	65.5	−2.62*
	NIBP procedure (BP1-BP3)	(2, 67.1)	0.72†			
RR	Turning procedure (P1-P3)	(2, 75.1)	21.82**	P1-P2	91.4	−6.40**
				P2-P3	93.1	5.96**
				P1-P3	60.7	0.24
	NIBP procedure (BP1-BP3)	(2, 55.3)	1.33†			
SpO_2	Turning procedure (P1-P3)	(2, 77.3)	12.97**	P1-P2	86.9	4.99**
				P2-P3	88	−4.65**
				P1-P3	66.9	−0.18
	NIBP procedure (BP1-BP3)	(2, 51.3)	0.86†			

†Nonsignificant test; further tests for single effects not performed.
*$P \leq 0.05$; **$P \leq 0.001$.

validation study of the CPOT[10] in which moderate to high weighted κ coefficients were found between the principal investigator and one critical care nurse. Such results were consistent with those of Payen and colleagues[8] who obtained a weighted κ coefficient of 0.74 when comparing the Behavioral Pain Scale (BPS) scores between pairs of evaluators involving 46 nurses and nurse's aides, 1 physical therapist, and 1 physician. However, in a recent study and for this same tool (BPS), lower results were obtained for interrater reliability between a research nurse and ICU nurses with agreement ranging from 36% to 46% when assessing patients during turning.[20] In comparison with the BPS, the CPOT leads to better agreement between the raters when patients are exposed to a nociceptive procedure when they are more likely to feel increased level of pain.

In terms of discriminant validity, increases in CPOT scores, MAP, HR, and RR, and a decrease in SpO_2 were observed during the nociceptive procedure (turning) whereas these values remained stable during the non-nociceptive procedure (NIBP). ICP also increased during turning on the basis of the descriptive statistics, although the small sample size did not permit statistical analysis. Higher CPOT scores during turning were also obtained in postoperative ICU patients at different states of level of consciousness.[10] In previous studies,[8,20] higher behavioral scores, blood pressure, and HR during nociceptive procedures were found whereas no changes were observed

TABLE 6. Conscious Patients' Self-reports of Pain (Yes or No) and CPOT Scores

Patients' Self-Reports of Pain			CPOT Scores	
Pain Present or Absent	n	%	Mean	SD
P1*				
Yes	5	17.9	0.60	1.34
No	23	82.1	0.39	0.84
P2				
Yes	18	60.0	4.50	1.79
No	12	40.0	2.50	1.73
P3*				
Yes	7	25.0	0.29	0.76
No	21	75.0	0.38	0.81
BP1*				
Yes	3	10.7	0.33	0.58
No	25	89.3	0.28	0.61
BP2*				
Yes	3	12.0	1.00	1.00
No	22	88.0	0.77	1.07
BP3*				
Yes	4	15.4	0.50	0.58
No	22	84.6	0.23	0.75

*Some patients could not provide their self-report of pain because of intermittent drowsiness.

TABLE 7. Descriptive Statistics of Conscious Patients' Self-reports of Pain Intensity (0 to 10)

Assessment	N	Mean	SD	Minimum	Maximum
P1	10	2.85	2.77	0	9
P2	9	4.89	2.71	2	10
P3	8	1.69	1.58	0	4
BP1	9	2.39	2.78	0	9
BP2	8	1.50	1.69	0	5
BP3	9	2.50	2.57	0	8

Only few patients were able to use the 0 to 10 FPT. Most of them were too weak or drowsy to concentrate on a pain intensity scale.

TABLE 8. Pain (Presence or Absence) Logistic Regression Analysis During the Turning Procedure (P2)

Variable	R^2	B	Wald
CPOT score	0.24	0.66	5.94*
Constant	—	−1.88	3.65*
Variables not in the equation	—	—	—
MAP	—	—	0.11
HR	—	—	0.49
RR	—	—	1.06
SpO_2	—	—	1.40

*$P \leq 0.05$.

during non-nociceptive procedures in critically ill ventilated and unconscious patients. The results of the Thunder Project II[21] also showed that more behaviors were exhibited by patients with versus without procedural pain. Such results emphasize the fact that behavioral and physiologic indicators may be detected when the patient is exposed to nociceptive procedures known to be painful and this even if a patient cannot report pain.

Clinical recommendations and guidelines also support that observation of behavioral and physiologic indicators be considered for pain assessment in critically ill uncommunicative patients.[5,22] However, pain-related behaviors receive more support than physiologic indicators which may be related to other stressful conditions. Because limited evidence supports the use of physiologic indicators in pain assessment, they should not be used alone but rather considered as a cue for further assessment of pain.[5] Moreover, absence of increased vital signs does not mean an absence of pain.[12]

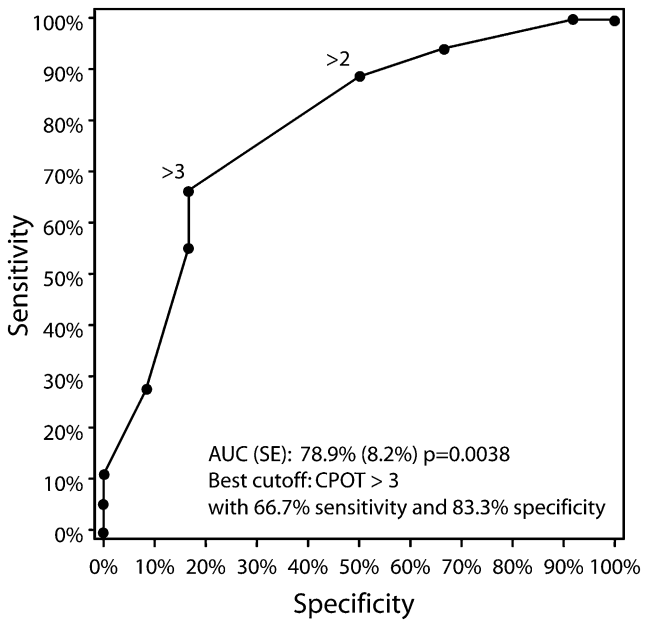

FIGURE 1. Receiver operating characteristic curve during turning (P2) in conscious ventilated patients.

TABLE 9. ANOVA of the CPOT Score and Changes in Physiologic Indicators During the Turning Procedure (P2) for the 2 Groups (Conscious and Unconscious Patients) and Types of Regimen

	ANOVA	
	df	*F*
CPOT score		
Group	(1,53)	10.27*
Type of regimen	(3,51)	2.85*
Increase in MAP		
Group	(1,53)	1.82
Type of regimen	(3,51)	2.14
Increase in HR		
Group	(1,53)	0.72
Type of regimen	(3, 51)	1.59
Increase in RR		
Group	(1,53)	1.48
Type of regimen	(3,51)	1.64
Decrease in SpO_2		
Group	(1,53)	3.87
Type of regimen	(3,51)	1.72

*$P \leq 0.05$.

According to criterion validity, the best cutoff score of the CPOT was found to be > 3 during turning in this sample. In the previous study of Gélinas and colleagues (under review),[14] the CPOT cutoff score was > 2 with a higher sensitivity (86.1%) with 99 cardiac surgery ICU patients. Determining a cutoff score for this type of clinical tool may be difficult. Indeed, sensitivity and specificity results may vary from a sample to another as they depend on the data obtained. At this time, the CPOT cutoff score seems to be between 2 and 3 but further research with larger samples is needed. In the logistic regression, it was found that only the CPOT score could predict the patients' self-reports of the presence of pain. Also, the higher the patient's self-report of pain intensity, the higher was the score on the CPOT. These results

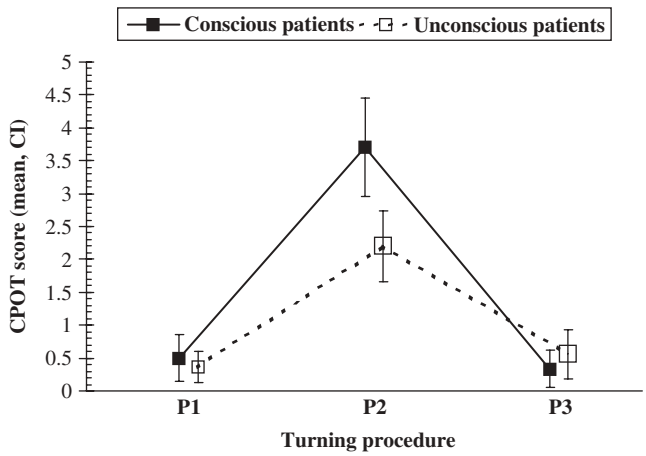

FIGURE 2. CPOT mean scores and confidence intervals (CI) of the turning procedure period testing in the conscious and unconscious patient groups.

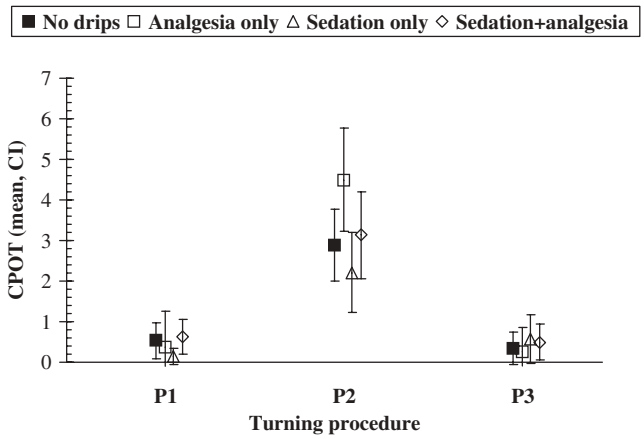

FIGURE 3. CPOT mean scores and confidence intervals (CI) of the turning procedure period testing in the 4 regimen groups.

are consistent with the first validation of the CPOT[10] and previous studies in which postanesthesia care unit patients' self-report of pain were moderately related to pain behaviors.[7,23] Regarding physiologic indicators, no significant relationship were found with the patients' self-reports of pain. Such results reinforce that physiologic indicators should not be considered as primary indicators for pain assessment in adults.

Few conscious ventilated patients were able to use the FPT to provide their self-report of pain intensity. On the other hand, answering yes or no by head nodding seemed to be easier to do for these patients. This observation suggest that the use of a pain intensity scale may be difficult for critically ill patients. In previous studies, many ventilated patients could use pain scales by pointing to them.[1,24,25] Patients who participated in those studies were mostly postoperative patients and their medical status was stable enough so that they could respond to questions. In the present study, patients may have been sicker and more unstable what would explain why so few patients were able to use the FPT.

Complementary analyses showed that conscious patients had higher CPOT scores during turning compared with unconscious patients. This result may be explained in 2 ways. First, both patients groups were different in terms of diagnoses. Unconscious patients were mainly trauma victims with head injury. These patients may react differently to noxious stimuli compared with other patients. This could be explored with more attention and discussed in a future manuscript. Second, unconscious patients were slightly more heavily sedated with propofol than conscious patients were. Such observation is consistent with results demonstrating that patients receiving sedative agents (propofol or midazolam) had the lowest CPOT scores. In previous studies, the higher the dosage of midazolam or patients receiving a midazolam bolus, the lower were the BPS scores.[8,20] Despite the fact that sedative agents do not have an analgesic effect, they seem to blur behavioral reactions to noxious stimuli. This finding reinforces the clinical recommendation of Herr et al[5] supporting that if a trauma, disease, injury, or procedure is known to be painful for most patients, it should also be considered painful for the uncommunicative patient as well even in the absence of observable evidence for the diagnosis of pain.

Interestingly, patients receiving an analgesic agent only (fentanyl) showed higher CPOT scores. It must be noted that fentanyl dosages in this study were moderate (mean = 54.44 μg/h) in this regimen group and only 2 of these patients also received a bolus before turning. Moreover, 5 out of 7 of the conscious ventilated patients in this regimen group reported having pain. It could be that pain in those patients was not adequately relieved which would explain why the CPOT scores were so high. However, more than half (6/11) of the patients with no sedatives or analgesics reported having no pain which could explain why CPOT scores were lower in this group.

This study was not without limitations. First of all, raters were aware of which procedures were performed. The nurses' raters may have perceived more behaviors during patient turning if they knew that the procedure is painful. Second, intermittent drowsiness and critical care conditions led to missing data for patients' self-reports of pain, especially when asked to use the FPT. Finally, the 2 patient groups, conscious and unconscious, recruited for this study were different in terms of their diagnoses so the conclusions regarding comparisons of behavioral responses between groups is limited. Further validation with the CPOT is being pursued so that more data will be available to explain behavioral reactions to a nociceptive procedure in specific critical care populations (eg, head injury patients).

Despite these limitations, this study allowed validation of the English version of the CPOT so that both versions (French and English) of the tool present similar results in terms of reliability and validity. Many ICU nurses were trained to use the CPOT so that interrater reliability may be generalized. This study is one of the few in which physiologic indicators were explored, and RR, SpO2, and ICP were studied for the first time in the context of pain in critically ill ventilated adults.

In conclusion, the CPOT seems to be a reliable and a valid tool to assess pain in critically ill adults. Although physiologic indicators showed good discriminant validity, they were not related to the patients' self-reports of pain. This emphasizes that behavioral indicators represent more valid information in pain assessment than physiologic indicators. Further validation of the CPOT with head injury patients is required as those patients seem to react differently to a painful procedure which may be due to their cerebral injury. As it is recommended to establish a therapeutic plan of analgesia in all critically ill patients[22] and to initiate an analgesic trial if pain is suspected,[5] use of a valid measure for pain in uncommunicative patients is essential.

ACKNOWLEDGMENTS

Special thanks are given to the ICU team and nurses who supported and participated in this study. Thanks also

go to Andréanne Robitaille, the research nurse, who contributed to the recruitment and data collection. Finally, deep appreciation is given to all patients and families who participated in this study.

REFERENCES

1. Puntillo KA, White C, Morris AB, et al. Patients' perceptions and responses to procedural pain: results from thunder project II. *Am J Crit Care*. 2001;10:238–251.
2. Shannon K, Bucknall T. Pain assessment in critical care: what have we learnt from research. *Intensive Crit Care Nurs*. 2003;19:154–162.
3. Anand KJS, Craig KD. New perspectives on the definition of pain. *Pain*. 1996;67:3–6.
4. Hamill-Ruth RJ, Marohn L. Evaluation of pain in the critically ill patient. *Crit Care Clin*. 1999;15:35–54.
5. Herr K, Coyne PJ, Key T, et al. Pain assessment in the nonverbal patient: position statement with clinical practice recommendations. *Pain Manag Nurs*. 2006;7:44–52.
6. Kwekkeboom KL, Herr K. Assessment of pain in the critically ill. *Crit Care Nurs Clin North Am*. 2001;13:181–194.
7. Mateo OM, Krenzischek DA. A pilot study to assess the relationship between behavioral manifestations and self-report of pain in postanesthesia care unit patients. *J Post Anesth Nurs*. 1992;7:15–21.
8. Payen JF, Bru O, Bosson JL, et al. Assessing pain in the critically ill sedated patients by using a behavioral pain scale. *Crit Care Med*. 2001;29:2258–2263.
9. Puntillo KA, Miaskowski C, Kehrle K, et al. Relationship between behavioral and physiological indicators of pain, critical care self-reports of pain, and opioid administration. *Crit Care Med*. 1997;25: 1159–1166.
10. Gélinas C, Fillion L, Puntillo KA, et al. Validation of a Critical-Care Pain Observation Tool in adult patients. *Am J Crit Care*. 2006;15:420–427.
11. Gélinas C, Fortier M, Viens C, et al. Pain assessment and management in critically ill intubated patients: a retrospective study. *Am J Crit Care*. 2004;13:126–135.
12. Gélinas C, Viens C, Fortier M, et al. Les indicateurs de la douleur en soins critiques (Pain indicators in critical care). *Perspect Infirm*. 2005;2:12–22.
13. Landis RJ, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159–174.
14. Gélinas C, Harel F, Fillion L, et al. Sensitivity and specificity of the Critical-Care Pain Observation Tool for the detection of pain in intubated ICU adult patients. *J Pain Symptom Manage*. (under review).
15. Gélinas C. Le thermomètre d'intensité de douleur: un nouvel outil pour les patients adultes en phase critique (The Faces Pain Thermometer: a new tool for critically ill adults). *Perspect Infirm*. 2007;4:12–20.
16. Prkachin KM. The consistency of facial expressions of pain: a comparison across modalities. *Pain*. 1992;51:297–306.
17. Berne RM, Levy MN. *Physiology*. St Louis: Mosby, Inc; 1983.
18. Streiner DL, Norman GR. *Health Measurement Scales: A Practical Guide to Their Development and Use*. 3rd ed. New York: Oxford University Press, Inc; 2003.
19. Zweig MH, Campbell G. Receiver-operating characteristic (ROC) plots: a fundamental evaluation tool in clinical medicine. *Clin Chem*. 1993;39:561–577.
20. Young J, Siffleet J, Nikoletti S, et al. Use of a Behavioural Pain Scale to assess pain in ventilated, unconscious and/or sedated patients. *Intensive Crit Care Nurs*. 2006;22:32–39.
21. Puntillo KA, Morris AB, Thompson CL, et al. Pain behaviors observed during six common procedures: results from Thunder Project II. *Crit Care Med*. 2004;32:421–427.
22. Jacobi J, Fraser GL, Coursin DB, et al. Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. *Crit Care Med*. 2002;30:119–141.
23. Webb MR, Kennedy MG. Behavioral responses and self-reported pain in postoperative patients. *J Post Anesth Nurs*. 1994;9:91–95.
24. Puntillo KA. Dimensions of procedural pain and its analgesic management in critically ill surgical patients. *Am J Crit Care*. 1994;3:116–122.
25. Puntillo KA, Weiss SJ. Pain: its mediators and associated morbidity in critically ill cardiovascular surgical patients. *Nurs Res*. 1994;43: 31–36.

