Brief Methodological Report

Pain Assessment Using the Critical-Care Pain Observation Tool in Chinese Critically Ill Ventilated Adults

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Abstract

Context. The psychometric properties of the Critical-Care Pain Observation Tool (CPOT) need to be tested in general intensive care unit patient populations in China.

Objectives. To further evaluate the psychometric properties of the CPOT and provide a pain assessment method for Chinese critically ill ventilated adults by validating a translation of the CPOT.

Methods. A total of 63 conscious ventilated Chinese adults were repeatedly assessed by two independent raters using the CPOT at rest as well as before and during the two procedures: 1) nociceptive procedure (turning) and 2) non-nociceptive procedure (taking noninvasive blood pressure). A total of 12 assessments were included.

Results. The principal component factor analysis revealed that the domain structure of the CPOT was acceptable. Cronbach's α coefficient as a measure for the internal consistency ranged from 0.57 to 0.86; intraclass correlation coefficients as a measure for inter-rater reliability ranged from 0.80 to 0.91; Spearman nonparametric coefficients as a measure for test-retest reliability ranged from 0.81 to 0.93. The CPOT total score was significantly higher during the nociceptive procedure, indicating that its discriminant validity was good. Self-reported pain was obtained as the gold standard; the receiver operating characteristic curve analysis determined the best cutoff value of the CPOT (>2) with the specificity (73.3–81.8%) and sensitivity (80.8–89.4%) as well as the area under the curve (range 0.849–0.902).

Conclusion. The CPOT has good psychometric properties and can be used as a reliable and valid instrument for pain assessment in Chinese critically ill ventilated adults. J Pain Symptom Manage 2014;48:975–982. © *2014 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

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Key Words
Pain assessment, ventilation, intensive care unit, critical care, psychometrics

Introduction

Critically ill patients frequently experience a variety of pain in the intensive care unit (ICU). Unrelieved pain gives rise to negative physiological and psychological events that can be detrimental to the prognosis of critically ill patients.[1–4] Appropriate pain-relieving interventions occur only where reliable and valid assessment has been achieved.[5,6] It is generally accepted that a patient's self-report is the most reliable indicator of the existence and severity of pain.[7] However, a substantial number of critically ill patients may not be able to report their pain because of mechanical ventilation.[4,7] Nurses' estimates of these patients' pain levels often understate actual levels.[8] Thus far, pain assessment in nonverbal ventilated ICU patients remains challenging for critical care nurses and clinicians.

Recently, a pain assessment tool, the Critical-Care Pain Observation Tool (CPOT), has been developed for a standardized assessment of pain in nonverbal ventilated patients.[9,10] In 2013, the new clinical practice guideline about pain recommended using the CPOT for ICU patients who are unable to self-report pain.[4] However, the guideline also pointed out that the CPOT should be translated into foreign languages other than English and French as well as further tested in other general ICU patient populations.[4]

Because the CPOT was not available in Chinese, we adapted the English version of the CPOT to Chinese and then performed a validation study of this tool in mechanically ventilated ICU patients. As the domain structure and test-retest reliability of the CPOT were never evaluated, this study also aimed to further evaluate the psychometric properties of the CPOT in these patient populations.[4,5]

Methods

Translation and Back Translation of the CPOT

The original published version of the CPOT in English was translated into simplified Chinese characters after obtaining written permission from the author (Céline Gélinas). A systematic approach to translation and adaptation was conducted as recommended by the World Health Organization,[11] which includes four steps: expert panel forward translation, backward translation, a pretest, and cognitive interviewing and a consensus on the final version.

Study Sample

The study was conducted over an eight-month period in a 19-bed general ICU at a tertiary referral academic teaching hospital. The sample size required for validating the CPOT was established using the precision of intraclass correlation coefficient (ICC). Thus, with a precision of ICC of 0.85 ± 0.10 as an objective, and for a scale with four subscales, 55 to 65 patients were required for the study.[5,12] All consecutive patients 18 years of age or older in the ICU were eligible if they were undergoing mechanical ventilation with endotracheal tubes for more than 48 hours, able to listen and understand Mandarin Chinese, in stable condition (without any extra invasive procedure for at least 24 hours), and had a Glasgow Coma Scale score of 8 or greater. Exclusion criteria were paralysis, cerebral injury, facial injury, arm injuries, those receiving muscular blocking agents, or those with muscular dysfunction. This study was approved by the ethics committee of our hospital, and informed consent was obtained.

Measures

The instrument tested in this study was the CPOT. Physiological indicators, including mean artery pressure (MAP), heart rate (HR), and respiration rate (RR), also were observed because they may be a cue of pain. The physiological indicators were examined using the present ICU monitoring equipment (Hewlett Packard, Palo Alto, CA). Other demographic data documented were age, gender, primary ICU diagnosis, administration of analgesia and sedation, and Acute Physiology and Chronic Health Evaluation score.

ICU nurses who volunteered to participate in the study were trained to use the CPOT. The

one-hour training session included 1) description of the Chinese version of the CPOT and the method of rating, 2) the method of completing the data collection sheet, 3) the method for obtaining self-reports of pain, 4) watching CPOT rating examples on the video clips that were provided by Gélinas. After making sure that every nurse recruited in the study could use the CPOT expertly, the formal study began. Forty-one ICU nurses were recruited as raters in the study.

For every patient recruited, two raters were randomly selected to assess them, using the CPOT independently to evaluate the inter-rater reliability. Patients were assessed during two procedures: one non-nociceptive procedure (NNP) (taking noninvasive blood pressure) and the other a nociceptive procedure (NP) (turning), which have been reported previously and can be used as strategies for determining discriminant validity.[10,13,14]

A repeated-measures design was used for discriminant validation of the CPOT. The assessments were performed at rest (without any medical procedure at least for half an hour), preprocedure (one to five minutes before performing the NNP and NP), and during the procedure. To evaluate the test-retest reliability, the assessments were repeatedly performed within 24 hours. The total number of assessment occasions for every study sample was 24 (2 raters × 12 assessments) (Fig. 1). All the aforementioned procedures were routine nursing procedures in the ICU. The patient's self-reported pain was obtained as the gold standard for criterion validation. After every assessment, each patient was asked "Do you have pain?" Ventilated conscious patients could nod or shake their head, blink their eyes, or squeeze the nurse's hand to indicate yes or no. Pain or no pain was identified only when both of the two independent raters simultaneously identified it.

Statistical Analysis

To determine if the subscales of the CPOT were suitable for the principal component factor analysis, two statistical tests were used: the Bartlett's test of sphericity and the Kaiser-Meyer-Olkin criterion. Then, the total observations were used to perform the principal component factor analysis to determine the contribution of each subscale of the CPOT.

Reliability analyses were performed by calculating Cronbach's α coefficient for the internal consistency of the CPOT, ICC between the two independent raters for inter-rater reliability, and Spearman nonparametric coefficients between the two symmetrical data collection periods of the CPOT for test-retest reliability.

For testing discriminant validity of the CPOT, a two-way repeated-measures analysis of variance (two procedures [NNP, NP] × three occasions [rest, preprocedure, during procedure]) was performed on the CPOT scores and physiological indicators as dependent variables. If Mauchly's test of sphericity was significant, the degrees of freedom method based on Greenhouse-Geisser was used for repeated-measures multivariate analysis of variance. The significant findings from repeated-measures analysis of variance were followed up using univariate and *post hoc* pairwise comparisons.

For testing criterion validity of the CPOT, receiver operating characteristic curve analysis was performed to derive the cutoff value that maximizes both the sensitivity and the specificity simultaneously. The area under the curve (AUC) also was calculated to evaluate the diagnostic efficiency of the CPOT for pain.

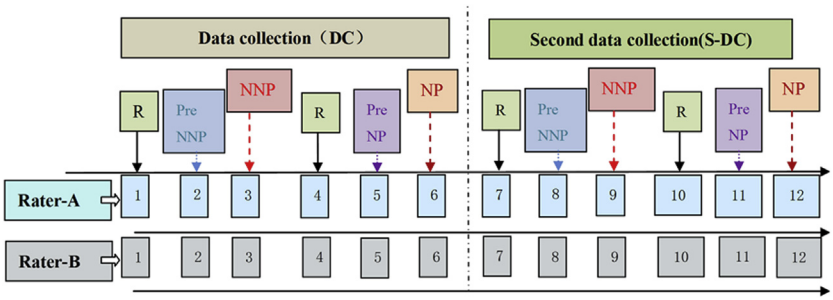

Fig. 1. Illustration of the course of assessments. R = rest; pre-NNP = pre-non-nociceptive procedure; NNP = non-nociceptive procedure; pre-NP = prenociceptive procedure; NP = nociceptive procedure.

All statistical analyses were performed using SPSS 19.0 (SPSS, Inc./IBM, Chicago, IL) software.

Results

Descriptive Statistics

A total of 71 patients or representatives agreed to participate in the study. During the study period, eight patients were excluded because mechanical ventilation was discontinued before the end of data collection (three patients) or a sudden change of condition ensued that needed extra invasive treatment (five patients). Eventually, 63 patients were recruited. Demographic data of the study sample are displayed in Table 1.

Principal Component Factor Analysis

The value of Kaiser-Meyer-Olkin was 0.61, and the Bartlett's test of sphericity was significant ($\chi^2 = 16.011$, $P = 0.014$). The principal component factor analysis revealed a main component, accounting for 65.59% of the variance in the component of pain, with coefficients of 0.806 for facial expression, 0.744 for body movements, 0.737 for muscle tension, and 0.674 for compliance with the ventilator.

Reliability Analysis

Cronbach's α coefficients as a measure for the internal consistency of the CPOT at the 24 assessments are displayed in Table 2. Cronbach's α ranged from 0.57 to 0.86, indicating moderate to good internal consistency. The inter-rater reliability of the CPOT was assessed by calculating the two-way random ICC for absolute agreement between the two independent raters for all the 12 assessments. As can be seen in Table 2, the ICC ranged from 0.80 to 0.91, indicating an overall good inter-rater reliability. The Spearman nonparametric coefficients for test-retest reliability between the two repeated data collection periods of the CPOT also are displayed in Table 2 and ranged from 0.81 to 0.93, indicating overall good test-retest reliability.

Table 1
Descriptive Statistics of the Study Sample ($n = 63$)

Variable	Value
Age in yrs	
Mean (SD)	61 (8)
Sex (*n*)	
Male	39
Female	24
Diagnostic groups (*n*)	
Surgical (thoracic, abdominal, and others)	16
Medical (sepsis, pulmonary problems, and others)	47
Analgesia (*n*)	
Morphine	5
Fentanyl	29
Sedation (*n*)	
Midazolam	26
Propofol	4
Acute Physiology and Chronic Health Evaluation II	
Mean (SD)	21.8 (6.7)

Discriminant Validity

During the first data collection period, as far as some dependent variables (CPOT, MAP, RR) were concerned, significant effects for procedure and assessment occasions as well as for an interaction (procedure × occasion) were found (Table 3). Examination of *post hoc* pairwise contrasts revealed significantly higher values of dependent variables (CPOT, MAP, RR) during NP than during NNP (Table 3). However, the difference between the occasion of rest and the preprocedure was not significant (Table 3).

During the second data collection period, all dependent variables (CPOT, MAP, RR, HR) displayed significant effects for procedure and assessment occasions as well as for an interaction (procedure × occasion) (Table 3). Examination of *post hoc* pairwise contrasts revealed significantly higher values of all dependent variables for NP than for NNP (Table 3). The difference between the occasion of rest and the preprocedure was not significant (Table 3).

Criterion Validity

The total number of pain or no pain reports was 494. Self-reports of pain from mechanically ventilated patients (yes or no) at rest, preprocedure, and during NNP and NP are displayed in Table 4. The receiver operating characteristic curve, cutoff value, sensitivity, and specificity at rest, preprocedure, and during NNP and NP are displayed in Figures 2–5. At all these assessments, the cutoff value associated with maximization of the sums of sensitivity and specificity was found to be a score greater than 2 on the CPOT. Accordingly, the AUC ranged from 0.849 to 0.902, indicating good

Table 2
Cronbach's α, ICC, and Spearman Coefficients for the 12 Assessments With the CPOT (n = 63)

Assessment		Cronbach's α		ICC (Rater A/Rater B)	Spearman Coefficients (DC vs. R-DC)
		Rater A	Rater B		
DC					
R	1	0.76	0.69	0.81[a]	0.81[a] (1 vs. 7)
Pre-NNP	2	0.59	0.64	0.86[a]	0.86[a] (2 vs. 8)
NNP	3	0.79	0.82	0.84[a]	0.82[a] (3 vs. 9)
R	4	0.71	0.80	0.80[a]	0.91[a] (4 vs. 10)
Pre-NP	5	0.78	0.77	0.91[a]	0.85[a] (5 vs. 11)
NP	6	0.64	0.67	0.81[a]	0.93[a] (6 vs. 12)
R-DC					
R	7	0.74	0.73	0.90[a]	
Pre-NNP	8	0.69	0.81	0.81[a]	
NNP	9	0.81	0.86	0.86[a]	
R	10	0.61	0.57	0.83[a]	
Pre-NP	11	0.59	0.66	0.87[a]	
NP	12	0.71	0.76	0.88[a]	

ICC = intraclass correlation coefficient; CPOT = Critical-Care Pain Observation Tool; DC = data collection; R-DC = repeated data collection; R = rest; Pre-NNP = pre-non-nociceptive procedure; NNP = non-nociceptive procedure; Pre-NP = prenociceptive procedure; NP = nociceptive procedure.
[a]$P < 0.05$.

discriminative properties and diagnostic efficiency of the CPOT for pain.

Discussion

Pain assessment is challenging in adult ICU patients who are unable to self-report. In such situations, relying on observational assessment tools is an alternative strategy (i.e., CPOT).[6] Because of the lack of a pain scale for ventilated patients in China, there is an urgent need for a valid pain instrument in this patient population. The results of the present study supplement the findings reported for the English versions of the CPOT.[9,10,15]

The principal factor analysis revealed that a large component was dominant and that the four subscales were strongly related to this component. Furthermore, the positive significant correlation found among the four subscales demonstrates that they evaluate the same concept, which is associated with pain. These results imply that the domain structure of the CPOT is acceptable.

Measurement of the internal consistency of an instrument determines whether all its subscales measure the same characteristic.[15,16] In this study, Cronbach's α coefficient ranged from 0.57 to 0.86, suggesting moderate to good internal consistency. As no measures of internal consistency were reported for the English versions of the CPOT, a comparison between the Chinese version and English version is not possible. However, the Swedish version revealed a substantial spread (0.31–0.81) in the range of Cronbach's α coefficient.[17] This may suggest that under certain conditions, for example, in the absence of pain, the individual items in the CPOT are not necessarily rated consistently. With regard to our study, as all the patients were suffering from tracheal intubation, which is a source of pain, this may ensure the internal consistency to a certain degree.

Measurements of inter-rater reliability and test-retest reliability of an instrument determines whether the tool yields the same results when used by different assessors and at different times.[5,16] Generally, a value of ICC or Spearman nonparametric coefficients larger than 0.8 is desired.[5,16] Our findings on the inter-rater reliability and test-retest reliability are good overall. The ICC reported for the English versions of the CPOT ranged from 0.80 to 0.92. These results are very similar to ours and the Swedish version. Because it is essential that pain in ICU patients be assessed routinely and repetitively,[4] the test-retest reliability of the CPOT needed to be tested. We evaluated the test-retest reliability of the CPOT, and the results revealed good agreement.

The discriminant validity of the CPOT means that it was indeed measuring pain.[5] In this study, the CPOT total score was significantly higher during the NP procedures, even if it was measured repeatedly. This change in CPOT score testifies to its capacity to discriminate

Table 3
RM-ANOVA (Two Procedures [NNP, NP] × Three Occasions [R, Pre-P, Dur-P]) During DC and Second DC (Greenhouse-Geisser-Based df) (n = 126)

	F (df)	Significant *Post Hoc* Comparisons at $P < 0.05$
DC		
CPOT		
P	$F_{(1,250)} = 11.01^a$	NP > NNP[b]
O	$F_{(1.74,435.26)} = 10.81^a$	Dur-P > R and pre-P[b]
P × O	$F_{(1.74,435.26)} = 13.09^a$	Dur-P NP > all other assessments[b]
MAP		
P	$F_{(1,250)} = 16.33^a$	NP > NNP[b]
O	$F_{(1.83,459.68)} = 28.07^a$	Dur-P > R and pre-P
P × O	$F_{(1.83,459.68)} = 10.52^b$	Dur-P NP > all other assessments[b]
RR		
P	$F_{(1,250)} = 24.54^a$	NP > NNP[b]
O	$F_{(1.71,428.47)} = 39.78^a$	Dur-P > R and pre-P[a]
P × O	$F_{(1.71,428.47)} = 20.24^b$	Dur-P NP > all other assessments[b]
HR		
P	$F_{(1,250)} = 1.54$	
O	$F_{(2,500)} = 2.34$	
P × O	$F_{(2,500)} = 1.22$	
Second DC		
CPOT		
P	$F_{(1,250)} = 10.07^b$	NP > NNP[a]
O	$F_{(1.87,268.32)} = 12.49^a$	Dur-P > R and pre-P[b]
P × O	$F_{(1.87,268.32)} = 12.25^a$	Dur-P NP > all other assessments[b]
MAP		
P	$F_{(1,250)} = 24.47^a$	NP > NNP[b]
O	$F_{(1.91,477.46)} = 33.53^a$	Dur-P > R and pre-P[b]
P × O	$F_{(1.91,477.46)} = 8.24^a$	Dur-P NP > all other assessments[b]
RR		
P	$F_{(1,250)} = 18.76^a$	NP > NNP[a]
O	$F_{(1.91,477.46)} = 51.48^a$	Dur-P > R and pre-P[b]
P × O	$F_{(1.91,477.46)} = 7.46^a$	Dur-P NP > all other assessments[a]
HR		
P	$F_{(1,250)} = 7.13^b$	NP > NNP[b]
O	$F_{(2,500)} = 13.81^a$	Dur-P > R and pre-P[b]
P × O	$F_{(2,500)} = 7.20^b$	Dur-P NP > all other assessments[b]

RM-ANOVA = repeated-measures analysis of variance; NNP = non-nociceptive procedure; NP = nociceptive procedure; R = rest; Pre-P = preprocedure; Dur-P = during procedure; DC = data collection; df = degrees of freedom; CPOT = Critical-Care Pain Observation Tool; MAP = mean artery pressure; RR = respiration rate; HR = heart rate.
[a]$P < 0.01$.
[b]$P < 0.05$.

pain. Meanwhile, MAP, HR, and RR increased during NP, whereas these values remained stable during NNP, and at preprocedure, and at rest. Such results emphasize the fact that the change of the CPOT and of physiological indicators may be detected when the patient is exposed to painful procedures. However as far as HR was concerned, the results between the first and second data collection periods were not consistent. The probable explanation is that these autonomous indicators may be affected by sepsis, volume status, and drug therapy, making these pain indicators unspecific in critically ill patients.[4,18] However, the vital signs may be used as a cue to begin further assessment of pain in these patients, just as the new clinical guidelines suggest.[4]

Table 4
Ventilated Patients' Self-Report of Pain

	Yes	No
Assessment	Presence of Pain (n)	Absence of Pain (n)
Rest	26	135
Preprocedure	25	141
NNP	17	69
NP	60	21
Overall	128	366

NNP = non-nociceptive procedure; NP = nociceptive procedure.

With regard to criterion validity of the CPOT, the best cutoff value was found to be greater than 2 whenever it was tested during NP or NNP, at rest, or at preprocedure. These results were a little different from Gélinas et al.[9,15] In the study by Gélinas et al., the sample was patients after cardiac surgery who were a relatively healthy ICU group and may not represent most ICU patients. The heterogeneity of the study sample may lead to the cutoff value drifting. As the best cutoff score of the

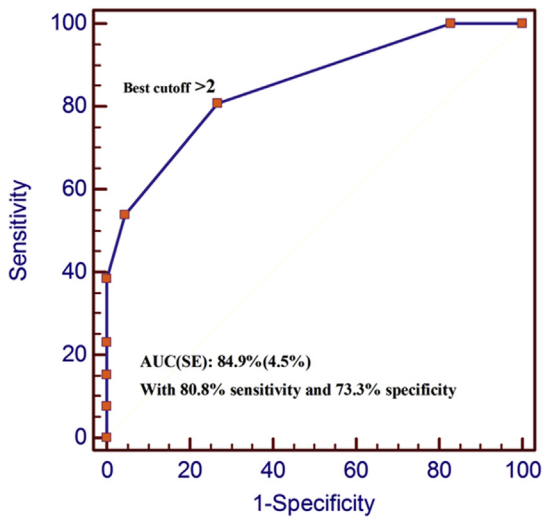

Fig. 2. Receiver operating characteristic curve at rest. AUC = area under the curve.

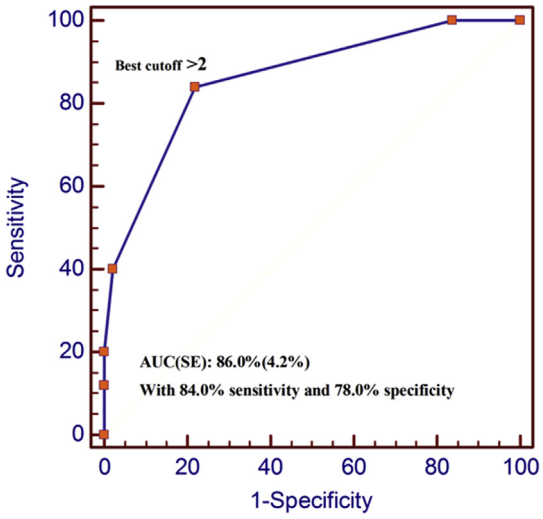

Fig. 3. Receiver operating characteristic curve at preprocedure. AUC = area under the curve.

CPOT in mechanically ventilated patients was never reported in a general ICU setting, our results require further study and comparison to confirm.

The specificity of the CPOT (range from 73.3% to 81.8%) was high enough for ventilated patients.[14,19,20] High specificity would help to "rule in" patients reporting pain.[14] Therefore, appropriate pain-relieving decisions can be made more accurately. As to sensitivity, it was also high enough (range from 80.8% to 89.4%). This implies that the CPOT

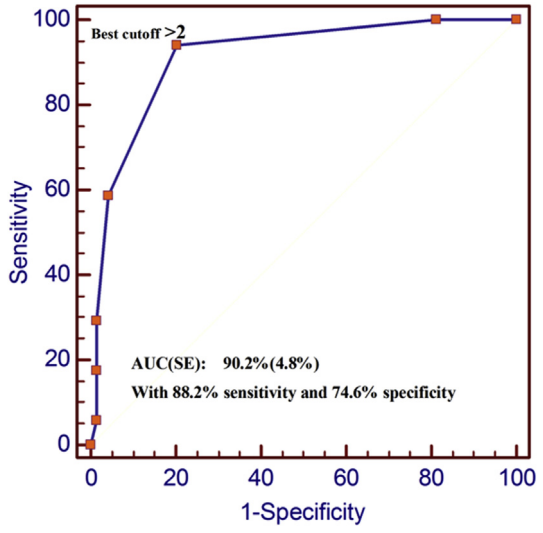

Fig. 4. Receiver operating characteristic curve during non-nociceptive procedure. AUC = area under the curve.

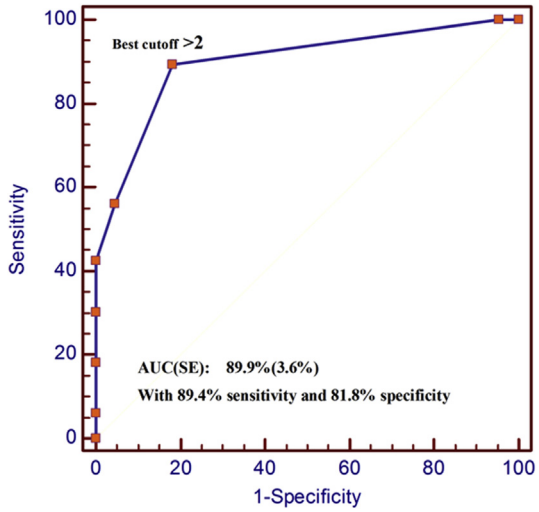

Fig. 5. Receiver operating characteristic curve during nociceptive procedure. AUC = area under the curve.

is sensitive in detecting pain when the pain is actually present.[15] In our study, the highest specificity and sensitivity were observed during the NP. When patients were exposed to the NP, it was not difficult to understand that the pain actually existed and became stronger, and of course the patients could not control their instinctive behaviors. The closer the AUC nears to 1, the better the CPOT possesses diagnostic efficiency.[15] In this study, the AUC ranged from 0.849 to 0.902, indicating good discriminative and diagnostic properties.

This study was not without limitations. First, many valuable pain intensity scales have not been validated in Chinese; therefore, the relationship between the patients' self-reports of pain intensity and the CPOT cutoff values is still unknown. Second, it should be noted that raters in our study were trained to use the CPOT before the formal test. This may impose a limitation on generalizability of the inter-rater and test-retest agreement. Third, whether the CPOT can be implemented to ICU pain management, including better use of analgesic agents and shorter durations of mechanical ventilation and ICU stay, requires further investigation.

Conclusions

This study focused on mechanically ventilated patients who comprised the great majority

of the ICU patient population. We concluded that the Chinese version of the CPOT has good psychometric properties and can be adopted to standardize pain assessment for ventilated patients who are unable to self-report.

Disclosures and Acknowledgments

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