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Validation of the Dutch version of the critical-care pain observation tool

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ABSTRACT

Background: Systematic assessment of pain is necessary for adequate treatment of pain. Patient self-reported pain is a superior assessment but is of limited use for intubated patients in the intensive care unit. For these patients, the critical-care pain observation tool (CPOT) has been developed.

Aim: To perform a validation of the Dutch CPOT.

Study design: Cross-sectional observational study.

Methods: The Dutch translation of the CPOT was used. Clinimetric characteristics were analysed in a cross-sectional design. Internal consistency (Cronbach's alpha) was tested by collecting CPOT scores in patients at rest and during turning. Inter-rater reliability was tested by collecting CPOT scores simultaneously by two different nurses who were blinded to each other's scores. Criterion validity (area under the curve, sensitivity and specificity) of the Dutch CPOT (index test) was analysed using patient self-reported pain (reference test).

Results: Cronbach's alpha was 0.56. During rest, the inter-rater reliability was 0.38 (95% confidence interval (CI): 0.20–0.53). During turning, the inter-rater reliability was 0.56 (95% CI: 0.42–0.68; area under the curve = 0.65 [95% CI 0.57–0.73]). At a threshold CPOT score of 2, the sensitivity and specificity were 39% and 85%, respectively.

Conclusion: The Dutch CPOT is available for pain assessment in intubated patients unable to self-report. Inter-rater reliability is moderate. At the threshold, a CPOT score of 2, the sensitivity was 39% and the specificity of 85%.

Relevance to clinical practice: The CPOT is easy to use for systematic assessment of pain. Additional information about the threshold is valuable for use in daily practice.

Key words: Pain assessment • Validation study • Intensive care • Adult • CPOT

BACKGROUND

Pain assessment in intensive care patients is a challenge. Pain is reported in nearly 50% of intubated adult intensive care patients, and nurses underestimate patient pain in 35–55% of the cases (Sessler and Wilhelm, 2008; Payen *et al.*, 2009; Puntillo *et al.*, 2009). Systematic assessment of pain is necessary for adequate treatment and is associated with decreased pain and complications, such as inadequate sleep, disorientation and prolonged sedation (Fraser and Riker, 2001; Chanques *et al.*, 2006; Sessler and Wilhelm, 2008). Patient self-reported pain is a superior method of assessment, but this method is of limited use for most intensive care patients because they are intubated, severely ill or have a decreased level of consciousness (Kwekkeboom and Heerr, 2001; Breivik *et al.*, 2008).

Different pain assessment tools have been created for these patients (Li *et al.*, 2008; Pudas-Tahka *et al.*, 2009). Five scales include facial expressions and behavioural aspects, and three scales include physiological indicators as well (Puntillo *et al.*, 2001). Physiological indicators have been found to be unreliable for pain assessment in intensive care patients due to illness, medication and the tendency to adapt to the presence of pain (Pudas-Tahka *et al.*, 2009). Consequently, guidelines advise the use of the critical-care pain

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observation tool (CPOT) or the behavioural pain scale (BPS) for intubated intensive care patients (Spijkstra J.J. *et al.,* 2013; Barr *et al.,* 2013). We selected the CPOT because it has demonstrated high inter-rater reliability (Gelinas *et al.,* 2009a, 2009b). Additionally, the CPOT is an easy-to-use tool that provides uniform pain assessment in intensive care patients unable to self-report (Gelinas, 2010). Thus far, the CPOT is available in English, French, Spanish, Swedish and Korean (Gelinas *et al.,* 2006; Gelinas and Johnston, 2007; Gelinas *et al.,* 2009a, 2009b; Vazquez *et al.,* 2009; Nurnberg *et al.,* 2011; Kwak and Oh, 2012) but has not been officially translated into Dutch or validated in a Dutch population.

In addition to the value of this study to Dutch critical care, it is also of relevance internationally as the concept of using CPOT as a pain assessment tool is increasingly being adopted both within and outside Europe as is evidenced by the number of languages into which it has been translated.

METHODS

Aim

The aim of this study is to perform a cross-cultural validation of the Dutch version of the CPOT in intubated adult intensive care patients.

Design

To perform a cross-cultural validation of the Dutch version of the CPOT, we used a cross-sectional design. This design makes is possible to compare the CPOT and the reference standard simultaneously, which is essential for pain assessment in a dynamic environment like the intensive care unit (ICU).

Setting and sample

The study was performed in a 22-bed mixed ICU in the Netherlands. Approximately 1500 patients are admitted to the ICU yearly, 40% of whom undergo cardio-thoracic surgery. The medical staff consists of senior and junior intensivists and intensive care nurses. Pain assessment is determined at the bedside based on a variety of observations by health care professionals, including patient behaviour and self-reports. The policy is to keep patients awake as much as possible unless this interferes with necessary mechanical ventilation or any other treatment. As the majority of the patients are awake, it is often possible to communicate with them, even if they are on mechanical ventilation.

All patients admitted to the ICU in the first 6 months of 2013 were eligible for inclusion in this study. Inclusion criteria were as follows: (a) minimum age of 18 years, (b) intubated for mechanical ventilation, (c) awake and able to answer simple YES/NO questions and (d) able to move their arms and locate pain. Exclusion criteria were as follows: (a) use of neuromuscular blocking agents, (b) being investigated for brain death, (c) impossibility of turning patient due to instability or treatment procedures, (d) presence of delirium and (e) Glasgow Coma Scale score below 9. We aimed to include 100 patients according to the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) manual (Terwee *et al.,* 2012).

Data collection tools and methods

CPOT

The CPOT has been developed for the assessment of pain in intubated adult intensive care patients. It was first validated in patients who had undergone cardio-thoracic surgery and later in a patient group with a medical diagnosis such as sepsis (Gelinas *et al.,* 2006; Gelinas and Johnston, 2007; Gelinas *et al.,* 2009a, 2009b). The scale includes four behavioural domains: (a) facial expression, (b) body movements, (c) muscle tension and (d) compliance with the ventilator for intubated patients or vocalization for non-intubated patients. All domains are scored by observing the patient, and muscle tension is examined by passive flexion of the patient's underarm (Gelinas *et al.,* 2006; Gelinas and Johnston, 2007; Gelinas *et al.,* 2009a, 2009b). Each domain is scored as 0, 1 or 2. The total score ranges from 0 (no pain) to 8 (maximum score). The CPOT only indicates the presence of pain, not its severity. Initially, the suggested threshold for the presence of pain was a CPOT score >3 (Gelinas and Johnston, 2007). Later, a threshold CPOT score >2 was adopted (Gelinas *et al.,* 2009a, 2009b). The validity of these thresholds could not be confirmed (Nurnberg *et al.,* 2011). The CPOT is presented in Appendix A.

Dutch translation

According to the COSMIN checklist, an official translation includes: (a) a double forward and backward translation, (b) establishment of face validity of the items and comprehensiveness in a multidisciplinary expert committee, (c) testing of the final translation in practice and (d) documentation of the process (Terwee *et al.,* 2012). To create a numerical method to compare the translations, translators were asked to rate the difficulty of translating the items of the CPOT. Rating scores were divided as follows: (a1) impossible to do, (b) extremely difficult, (c) moderately difficult, (d) a little bit difficult and (e) not at all difficult.

Training nurses

Before the start of the study, training was organized by four nurses who had read three articles explaining the

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CPOT (Gelinas *et al.*, 2006; Gelinas and Johnston, 2007; Gelinas *et al.*, 2009a, 2009b), watched a video instruction (CPOT, 2006) and had exercised assessments of the CPOT and discussed difficulties during a whole day. These expert nurses trained a team of 125 nurses in the Dutch CPOT through a 90-min training session. In addition, the expert nurses provided ongoing bedside support. The complete Dutch CPOT and instructions were available at the bedside and on the intranet.

Clinimetric characteristics

Three clinimetric characteristics of the CPOT were determined according to the COSMIN criteria (Terwee *et al.*, 2012). First, the internal consistency of the CPOT was analysed. We collected CPOT scores when the patient was at rest and while turning the patient, as turning has been proven to be a painful procedure (Puntillo *et al.*, 2004). Second, inter-rater reliability was calculated, for which the CPOT scores (again during rest and while turning) were collected simultaneously by two different nurses who were blinded to each other's scores. Finally, criterion validity of the index test, the Dutch CPOT, was analysed by using patient self-reports of pain as a reference test (Kwekkeboom & Herr, 2001; Breivik *et al.*, 2008; Chanques *et al.*, 2010). Self-reports were obtained by asking the question 'Do you have pain?', and the patient could answer by moving his/her head 'YES' or 'NO' (Kwekkeboom & Herr, 2001).

Measurements and study procedure

Demographic characteristics of the patients, administered analgesics and sedatives, type of admission, length of stay (LOS), severity of illness scores, Acute Physiology and Chronic Health Evaluation (APACHE II and IV) (Knaus *et al.*, 1985) and Sepsis-related Organ Failure Assessment (SOFA) (Vincent *et al.*, 1996) were extracted from the clinical information system (iMD-soft, 2013).

In order to measure the level of awareness, we used the Richmond Agitation-Sedation Scale (RASS) (Sessler *et al.*, 2002). Self-reports required a minimum RASS score of −2. When RASS scores were below −3, the neurological level of functioning was measured by the Glasgow Coma Scale (GCS) (Rowley & Fielding, 1991). The RASS score was measured six times a day. To rule out delirium, which could interfere with the reliability of the CPOT, the presence of delirium was tested at least twice a day using the Confusement Assessment Method (CAM-ICU) (van Eijk *et al.*, 2009; van Eijk *et al.*, 2011). Patients with a positive CAM-ICU result were excluded from the analysis. All measurements were part of daily care.

The order and instructions for study measurements appeared automatically in the clinical information system when the patient was eligible for the study according to the inclusion and exclusion criteria (iMD-soft, 2013). The timing of the measurements depended on care procedures and was planned by the nurse. When the patient had not experienced a painful procedure for 30 min, the CPOT was first scored simultaneously by two nurses blinded to each other's scores. Subsequently, the nurse who was taking care of the patient asked and registered the patient's self-report. In a direct sequence, the patient was turned. During turning, the CPOT scores were assessed and registered in the same way. Measurement procedures were only performed once per patient. All measurements were recorded bedside in the clinical information system.

Data analysis

Internal consistency was calculated by Cronbach's alpha of the CPOT scores at rest and during turning. The scores collected by the nurse who had taken care of the patient were used for this analysis. Reliability analysis was performed by the one-way random absolute agreement Inter-Class Correlations (ICC) because sample measurements were performed by a random set of the 125 ICU nurses (Shrout & Fleiss, 1979). We analysed the CPOT scores when the patient was at rest and during turning, separately. Criterion validity was analysed by calculating the sensitivity and specificity for the CPOT scores using self-reports as the reference standard. We determined the sensitivity and specificity for the threshold scores of 2 and 3. A receiver operating curve (ROC) was made for the CPOT scores, and 95% confidence interval (CI) was calculated.

Missing data were excluded from the analysis as were data that were not obtained in accordance with the instructions. All data were collected anonymously between November 2012 and August 2013 and analysed. All statistical analysis was performed using SPPS software (PAWS statistics version 18.0, Chicago, IL, USA).

Ethical considerations

The Medical Ethics Review Board of our hospital gave this study its approval (MEC nr WO 12.078) and waived the requirement for written informed consent because the study did not require any deviation from the routine standard care.

RESULTS

Dutch translation of the CPOT

With the permission of the original author, we translated the English CPOT into Dutch (email and contract

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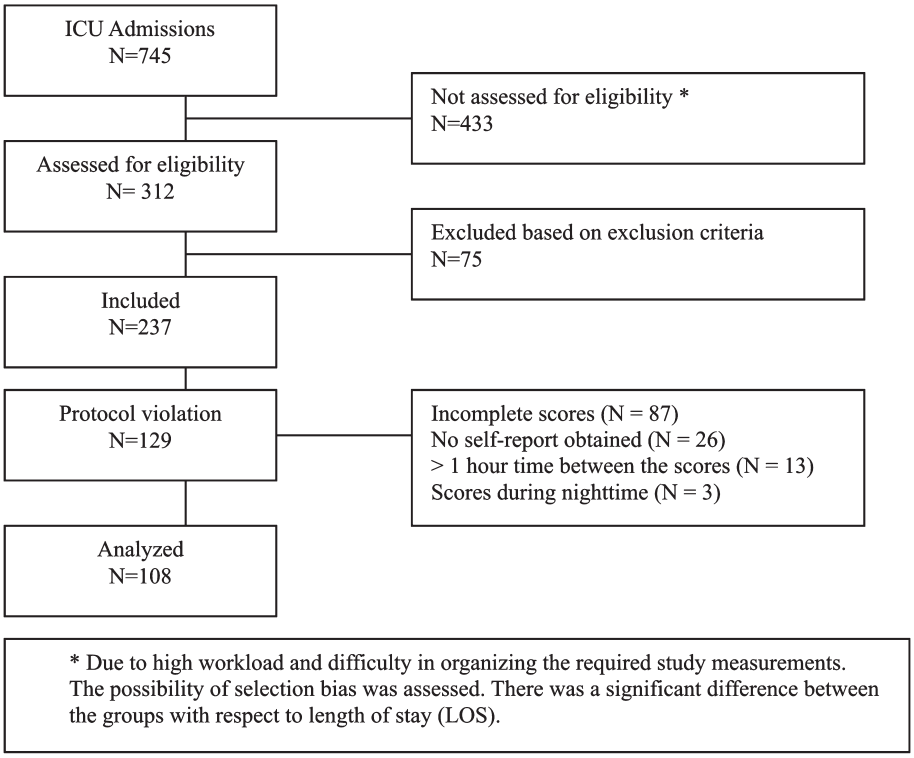

Figure 1 Flow Chart

with Gelinas dated 9 October 2012). A double forward translation was performed by two professional translators, one of whom had a clinical background as an intensive care nurse. A synthesis of the translations was performed with the translators, according to common consensus, and documented. A backward translation was made by one professional translator unaware of the original CPOT and with mother tongue as English.

Translators did not find the translation difficult. Ratings varied between 3 (moderately difficult) and 5 (not at all difficult) with a slight difference in the mean scores: translator 1 (PR) 4.5, translator 2 (LvdW) 4.3 and translator 3 (DL) 4.5.

All the translations and face validity were discussed by an expert committee, resulting in a final translation. The expert committee consisted of health professionals, methodologists and language professionals. All discussions and changes were documented. The final translation and the documentation of the translation process were sent to the original author. The Dutch translation was pre-tested by 20 intensive care nurses on 20 patients to check the interpretation and ease of comprehension. No changes were necessary.

Study sample

One hundred eight patients were included in the study (Figure 1). Patients were admitted for medical (25%) or surgical (75%) reasons. The level of awareness (RASS scores) varied among patients: light sedation (24%), drowsy (36%), calm and alert (34%) and restless (7%). The median severity of illness as measured by the APACHE II score was 16 (range, 6–34), and the median SOFA score was 6 (range, 6–14). Before measurement procedures, 6% of the patients had received sedation and 12% had received analgesics. Baseline characteristics are presented in Table 1.

Clinimetric characteristics of the CPOT

Internal consistency, analysed by Cronbach's alpha, was 0.56 for the CPOT scores during rest and turning. The items 'facial expression', 'movement' and 'muscle tension' are correlated with the final CPOT score because deleting one of these items resulted in a lower Cronbach's alpha. The item 'compliance with the ventilator' is less correlated with the final score. The corrected item's total correlation was 0.15, and Cronbach's alpha increased to 0.60 when this item was deleted. The results of the internal consistency are presented in Table 2.

Reliability analysis was performed using the one-way random absolute ICC during rest and turning (Shrout and Fleiss, 1979). During rest, the ICC was 0.38 (95% CI: 0.20–0.53), indicating fair inter-rater reliability. During turning, the ICC was 0.56

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Table 1 Baseline characteristics (N = 108)

Age, median (range)	70 (24–91)
Male gender, n (%)	73 (68.2)
Type of admission	
Medical, n (%)	27 (25.2)
Surgery, n (%)	80 (74.8)
Apache IV PM, median (range)	0.4 (0–1)
Apache II PM, median (range)	16 (6–34)
SOFA, median (range)	6 (0–14)
LOS in hours, median (range)	34 (15–1162)
RASS	
Score 1 (restless), n (%)	7 (6.5)
Score 0 (calm and alert), n (%)	34 (31.8)
Score −1 (drowsy), n (%)	39 (36.4)
Score −2 (light sedation), n (%)	24 (22.4)
Analgesics administered 1 h before, n (%)	12 (11.1)
Sedatives administered 1 h before, n (%)	6 (5.6)

Apache IV or II PM, Acute Physiology and Chronic Health Evaluation; LOS, length of stay; SOFA, Sepsis-related Organ Failure Assessment; RASS, Richmond Agitation Sedation Scale.

(95% CI: 0.42–0.68), indicating moderate inter-rater reliability.

Criterion validity analysis of the CPOT was based on patient self-reports. During 216 measurements, pain was reported in 65 cases. The Receiver Operating Characteristic (ROC) of the scores during rest and turning produced an Area under the curve (AUC) of 0.65 (95% CI: 0.57–0.73). We calculated a sensitivity of 39% and a specificity of 85% for a threshold CPOT score of 2. For a threshold CPOT score of 3, the sensitivity and specificity were 20% and 92%, respectively. We conclude that based on the ROC (Figure 2), a CPOT score of 2 could be chosen as the threshold.

DISCUSSION

The internal consistency presented as Cronbach's alpha was 0.56. This is congruent with previous research that reported an internal consistency of the CPOT with a Cronbach's alpha between 0.31 and 0.81 (Nurnberg *et al.,* 2011). Our results revealed a low correlation of the item 'compliance with the ventilator'. Although Streiner advises a minimum correlation of 0.20 for an item to be included (Streiner and Norman, 2008), we do not suggest the deletion of this item because it is part of the original scale. These results could not be compared with other studies because the correlation of the items with the final score has not been published previously (Gelinas *et al.,* 2009a, 2009b; Gelinas *et al.,* 2013).

We observed a fair to moderate ICC, which is lower than the results in other studies (Gelinas *et al.,* 2006; Gelinas and Johnston, 2007; Gelinas *et al.,* 2009a, 2009b; Nurnberg *et al.,* 2011). Some studies have used a fixed or limited set of raters, which might be an explanation for the higher ICCs. Our results can be explained by the fact that we analysed the CPOT scores for tests performed by various different nurses from a larger team of 125 nurses. Although the results of our study demonstrate lower reliability, they are more generalisable because the study settings reflect daily practice at an ICU. Another explanation for the lower ICCs might be the fact that most CPOT scores were 0. This lack of variance might have hampered the ability to determine higher ICCs. Also, ICCs might have been higher if we had assessed all the nurses before the study on their ability to score the CPOT. Differences in CPOT observations by nurses and self-reports could also be influenced by other aspects. For example, studies have mentioned that nurses underestimate their patients' pain (Aslan *et al.,* 2003; Prkachin *et al.,* 2007). On the other hand, high levels of vicarious exposure biases judgements of pain (Prkachin and Rocha, 2010). The influence of these aspects could not be excluded from this analysis.

Criterion validity of the CPOT at different thresholds was analysed. Because of the low incidence of pain, the sensitivity of the CPOT is 20% at a threshold score of 3 and 39% at a threshold score of 2. Gélinas *et al.* report a sensitivity of 66.7% at a threshold score of 3, which is higher than our results (Gelinas and Johnston, 2007). Another publication by the same author reported a sensitivity of 86.1% at a threshold score of 2 (Gelinas *et al.,* 2009a, 2009b). It is remarkable that we observed low sensitivity rates of the CPOT. This can be explained by the low incidence of pain registered by the self-reports of the patient. Other situations that could trigger an increase in the CPOT score include the side effects of turning (for example, coughing because of manipulation of the tube). For use in daily clinical practice, patient self-reports will be superior. The CPOT should only be used when patients are not able to self-report. Nurses must remain vigilant for other situations that could lead to higher CPOT scores.

Limitations

In the translation process, we used a double forward but a single backward translation, which might be considered a limitation. The value of a double backward translation has been discussed, and the quality of the translator is considered the most important component (Guillemin *et al.,* 1993; Acquadro *et al.,* 2008). Criteria for the quality of the translators are as follows: linguistically competent, fully briefed, experienced in the field and able to comment on their own version (Guillemin *et al.,* 1993; Acquadro *et al.,* 2008). We have fulfilled all these criteria.

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Table 2 Internal consistency

	Item-total correlation		
CPOT domains	Scale mean if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Face	0.54	0.411	0.417
Movement	0.61	0.343	0.483
Muscle tension	0.51	0.461	0.373
Compliance ventilator	0.70	0.151	0.599

	Inter-item correlation			
CPOT domains	Face	Movement	Muscle tension	Compliance ventilator
Face	1.00	0.230	0.414	0.177
Movement	0.230	1.00	0.361	0.091
Muscle tension	0.414	0.361	1.00	0.066
Compliance ventilator	0.177	0.091	0.066	1.00

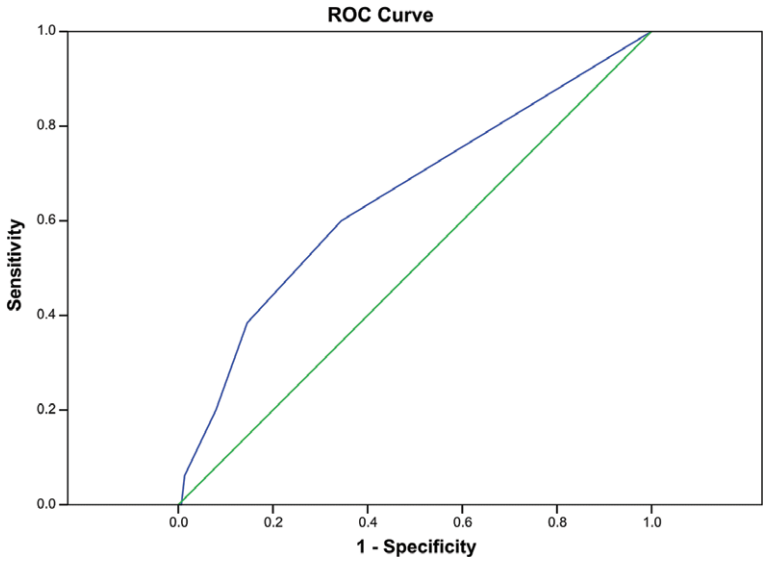

Figure 2 ROC Curve

A second limitation of this study might be the number of patients excluded because of protocol violations. Reasons for uncompleted or unperformed scores could be (a) the high workload during the study period, which might have hampered the organization of the study measurements, (b) an insufficiently short timeframe between the arrival at the ICU and the extubation of the patient and (c) study instructions that might have been too complicated for the team of 125 nurses, despite the availability of information and ongoing support given by the expert nurses. We did not experience any technical problems with the computerized data entry of the CPOT score during the study. We did analyse the possibility of selection bias by comparing baseline characteristics of the analysed patients with the excluded patients. Differences were observed only in the length of stay (LOS). Median LOS was 26 h in this group compared with a median 34 h in the included patient group (p-value = 0.009). This difference is consistent with the assumption that during the first 24 h, nurses were not able to complete the measurements for the study because of their workload and the short timeframe between the arrival of the patient and the extubation.

Implications and recommendations for practice

Further research is needed to study the inter-rater reliability and internal consistency of the CPOT. Additionally, further research on patients who are unable to self-report is needed. According to the original exclusion criteria, patients with a positive CAM-ICU or delirium were excluded. This limits the practical

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value of the CPOT because there is an incidence of delirium of up to 87% in ICU patients (van Eijk *et al.*, 2011). As the reliability of the CAM-ICU varies (van Eijk *et al.*, 2011), it is possible that some patients were missed in the diagnosis of delirium, which influenced the study results. We suggest that further research of the use of the CPOT is needed for this patient group.

In order to enhance pain assessment in the ICU, further development of education concerning pain and pain assessment in the ICU is necessary to maintain awareness among the staff. Additionally, the development of computer assistance in CPOT scores could support ongoing pain measurement during several shifts. Our results reflect an ICU where most patients are awake during mechanical ventilation. In an ICU where sedation is more common, the CPOT scores and the threshold could be different.

CONCLUSION

A Dutch version of the CPOT is available for daily clinical practice. We observed fair reliability in measurements when a patient was at rest and moderate reliability during turning. We observed a sensitivity of 39% and a specificity of 85% at a CPOT score threshold of 2. The low sensitivity scores in our study necessitate alertness to factors other than pain that might result in an increase in the CPOT score in patients who are able to self-report. We recommend further research to study the validity in patients with delirium or patients who are not able to self-report.

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WHAT IS KNOWN ABOUT THIS TOPIC

- The International Guideline (Barr *et al.*, 2013) advises the translation and use of the BPS and the CPOT in intensive care units to assess pain. Besides the information about the reliability and validity, information about the threshold is important for use in daily practice. Previous studies analysed threshold scores of 2 and 3. Nurnberg *et al.* (2011) could not confirm the threshold.

WHAT THIS PAPER ADDS

- This study translated the CPOT in Dutch and analysed the inter-item correlations, ICC and the threshold of the CPOT.
- This study adds information about the threshold and about validity of the use of the CPOT in practice.

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APPENDIX A

Critical Care Pain Observation Tool

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

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