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Pain measurement in mechanically ventilated critically ill patients: Behavioral Pain Scale versus Critical-Care Pain Observation Tool☆

S. Rijkenberg, RN, MSc [a,*], W. Stilma, RN, MSc [a], H. Endeman, MD, PhD [a], R.J. Bosman, MD [a], H.M. Oudemans-van Straaten, MD, PhD [b]

[a] Department of Intensive Care Medicine, Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands
[b] Department of Intensive Care Medicine, Free University Medical Centre, Amsterdam, the Netherlands

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ABSTRACT

Purpose: The Behavioral Pain Scale (BPS) and Critical-Care Pain Observation Tool (CPOT) are behavioral pain assessment tools for uncommunicative and sedated intensive care unit (ICU) patients. This study compares the discriminant validation and reliability of the CPOT and the BPS, simultaneously, in mechanically ventilated patients on a mixed-adult ICU.
Materials and methods: This is a prospective observational cohort study in 68 mechanically ventilated medical ICU patients who were unable to report pain.
Results: The BPS and CPOT scores showed a significant increase of 2 points between rest and the painful procedure (turning). The median BPS scores between rest and the nonpainful procedure (oral care) showed a significant increase of 1 point, whereas the median CPOT score remained unchanged. The interrater reliability of the BPS and CPOT scores showed a fair to good agreement (0.74 and 0.75, respectively).
Conclusions: This study showed that the BPS and the CPOT are reliable and valid for use in a daily clinical setting. Although both scores increased with a presumed painful stimulus, the discriminant validation of the BPS use was less supported because it increased during a nonpainful stimulus. The CPOT appears preferable in this particular group of patients, especially with regard to its discriminant validation.
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1. Introduction

Critically ill patients frequently experience pain and discomfort during intensive care unit (ICU) stay. Approximately 50% of the patients reported moderate to severe pain, both at rest and during routine procedures [1–5]. Untreated acute pain in adult ICU patients has short- and long-term physiological and psychological consequences such as postoperative myocardial infarction, insufficient sleep, and the risk of developing a posttraumatic stress disorder. The consequences of inadequate control of pain are significant, but excessive use of analgesics and sedation can lead to unwanted side effects such as hypoventilation, gastrointestinal hypomotility, gastric bleeding, and renal dysfunction. A systematic assessment of pain is associated with a decreased incidence of pain, use of analgesics, duration of mechanical ventilation, and length of stay (LOS) on the ICU [6–9].

As a result of these findings, the Society of Intensive Care Medicine recommends that pain should be routinely monitored in all adult ICU patients [10]. A patient's self-report of pain is considered as the gold standard in the assessment of pain [11]. However, critically ill patients are often unable to communicate effectively due to severe illness, mechanical ventilation, administration of sedatives and analgesics or a decreased level of consciousness. Vital signs appear to be less valid for pain assessment in ICU patients due to underlying disease and treatment with inotropes and vasopressors [12]. Consequently, pain assessment in patients who are unable to self-report their pain is difficult [13–15]. Therefore, the Society of Intensive Care Medicine advises the use of pain assessment tools that focus mainly on behavioral indicators of pain. The Behavioral Pain Scale (BPS) [15] and Critical-Care Pain Observation Tool (CPOT) [16] are behavioral pain assessment tools for uncommunicative and sedated ICU patients. The content validation, criterion validation, discriminant validation, and interrater reliability of the BPS and CPOT have been tested in previous studies [7,13,15,17,18]. To date, there are no studies available comparing these pain assessment tools simultaneously. The aim of this study was to compare the discriminant validation and reliability of the CPOT and the BPS in mechanically ventilated patients with the purpose to find the most useful clinical pain assessment tool for patients in a mixed-adult ICU.

2. Material and methods

We performed a prospective observational cohort study with a repeated measurement design in a 20-bed mixed closed-format ICU in a teaching hospital in Amsterdam, the Netherlands. The hospital has

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* Corresponding author. Onze Lieve Vrouwe Gasthuis, Oosterpark 9 PO-box 95500 1090 HM, Amsterdam, the Netherlands. Tel.: +31 205 993 007.
E-mail address: saskia_rijkenberg@hotmail.com (S. Rijkenberg).

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no neurosurgical facility. The local medical ethical committee approved the study and waived the requirement for written informed consent because this study did not require any deviation from the routine standard care on the ICU.

The ICU nurses screened all patients at bedside after admission. Inclusion criteria were as follows: critically ill patients with (1) age ≥18 years, (2) an expected LOS on the ICU of ≥12 hours, (3) mechanical ventilation, and (4) an inability to self-report pain. We excluded patients who were able to self-report pain and who were admitted for elective surgery, who were quadriplegic or paralyzed due to their current condition and/or treatment, who were unable to be repositioned, or who participated in the study during a previous admission.

2.1. Assessments of pain, agitation/sedation, and delirium

The BPS has been previously tested in mechanically ventilated ICU patients, of which the most were unconscious and therefore unable to self-report pain. This scale is based on a sum of 3 behavioral domains: facial expression, movements of the upper limbs, and compliance with ventilation. Each domain is scored from 1 (no response) to 4 (full response). The score ranges from 3 (no pain) to 12 (maximum pain) [15] (see Appendix 1).

The CPOT has been developed for the assessment of pain in critically ill adult patients unable to self-report pain. This scale consists of 4 behavioral domains: facial expression, body movements, muscle tension, and compliance with the ventilation for intubated patients or vocalization for patients without endotracheal tube. Each domain is scored between 0 and 2, and the total score ranges from 0 (no pain) to 8 (maximum pain) [16]. See Appendix 1. An extensive analysis and comparison of the psychometric properties of both tools are given in a recent review of Gelinas et al [19].

The level of agitation and sedation was assessed with the Richmond Agitation and Sedation Scale (RASS) 6 times daily. This system assigns a score between 4 (combative) and −5 (unresponsive). A score of 0 indicates an alert and calm state [20,21]. The presence of delirium was routinely assessed by the nurses and attending physician using the Confusion Assessment Method for the ICU (CAM-ICU) [22].

2.2. Data collection

We extracted demographic and clinical characteristics from the patient clinical information system (CIS) (iMD-Soft: Metavison, Tel Aviv, Israel), including the Acute Physiology and Chronic Health Evaluation IV predicted mortality (APACHE IV PM) score [23], the Sequential Organ Failure Assessment score [24], and the administration of analgesics and sedatives 1 and 4 hours before the pain assessments.

2.3. Pain medication in the ICU

The intensive care physician prescribed analgesics and/or sedatives, titrated to the patient's requirements. Depending on the degree of agitation and pain, patients received either morphine as a continuous infusion (in combination with midazolam for sedation) or piritramide 2.5 to 5 mg intravenously. Piritramide is a synthetic opioid analgesic with a strength of approximately 0.7 times that of morphine [25].

Epidural levobupicaine/sufentanyl was continued in the ICU if an epidural catheter was inserted perioperatively. Intravenous fentanyl was used for short surgical interventions in the ICU. Intravenous ketamine was used for the treatment of status asthmaticus or pain that was unresponsive to the previously mentioned interventions. Levels of pain were not systematically assessed and recorded until the start of the training for this study.

2.4. Study procedures

The bedside nurse screened and included patients on the day of admission and performed, together with a second nurse, the assessments. The BPS and CPOT were performed simultaneously but independently of each other in 4 conditions: at rest just before a nonpainful procedure, during the nonpainful procedure, at rest just before a painful procedure, and during the painful procedure. The first assessment recorded was always the BPS. We chose turning of the patient (turning) as a painful procedure and oral care as a nonpainful procedure [26]. The procedures were chosen after a literature review and during an expert group meeting with ICU nurses, an intensivist/anesthesiologist, and a clinical epidemiologist. The pairs of assessing nurses were not randomized but assigned by convenience and varied across the 4 procedures; however, the nurse in charge of the patient was always one of them. The assessors were asked to wait for at least 20 minutes after turning, or other painful procedures, before performing the assessments of the second procedure. The timing of the procedures was adjusted to the patient's day schedule. The nurses performed all assessments on the same day between 4:00 AM and 10:00 AM, and recorded the scores in custom-made study forms in the CIS.

2.5. Training of the nursing staff

All ICU nurses were trained to use the BPS and CPOT for 2 hours during the annual ICU training. Training material consisted of a presentation with background information of pain, the study procedures and explanation of the pain scores, the paper versions of the BPS and CPOT, training posters, and an instruction video [18,27]. This was followed by a 30-minute weekly training sessions on the ICU, provided by members of the study group (expert team). We also posted an explanation of the study procedures and the use of BPS and CPOT on the ICU intranet. In addition, an instruction card was available in every patient room. We performed a trial run of 1 month, in which we evaluated 66 test patients to minimize the possible bias of a learning curve and to provide bedside teaching of the study procedures.

2.6. Data analysis

Data were analyzed with SPSS version 18.0 (SPSS, Inc, Chicago, Ill) according to a prospectively defined protocol. Interrater reliability of the BPS and CPOT was tested by the calculation of intraclass correlation coefficients (ICC) for all assessments (two-way random absolute) [28]. Internal consistency was assessed with Cronbach's coefficient α using the scores during turning, when the patient was most likely to be experiencing pain. Values between 0.70 and 0.80 are considered as acceptable, and values >0.8 as good [19,29]. The discriminant validation was examined by calculating within-patient differences in scores between the assessments using the Friedman test. This is the nonparametric alternative to the one-way analysis of variance with repeated measures. To determine which pairs of differences between mean ranks were significant and thus the likely source of a significant Friedman test, we performed a post hoc analysis with a nonparametric related-sample test; the Wilcoxon signed rank test. This test is suitable for ordinal or nonnormally distributed continuous data [30]. The pain scores were not normally distributed, and therefore, we used nonparametric statistical tests. Only patients with complete scores were suitable for analysis. We hypothesized that the score should increase during the painful procedure and remain the same during the nonpainful procedure.

3. Results

During the 4-month study period, 277 medical and surgical ICU patients and patients after major surgery were admitted, 245 patients were screened, and 123 patients met the inclusion criteria. The data of 68 patients (55% of the patients meeting the inclusion criteria) were

complete and suitable for further analysis (see Fig. 1). Reasons for incomplete assessments were as follows: transfer to the ward or another hospital, deteriorating illness, death, extubation, or excessive workload of the nurses. Patients with a complete data set had a significantly higher APACHE IV PM (0.23 [0.07-0.59] vs 0.48 [0.24-0.77], $P = .01$), were older (66.79 ± 12.5 vs 63.0 ± 17.8; $P = .005$), and had a longer ICU stay (82 [27.0-120.0] vs 169 [87.5-365.0]; $P = .00$), compared to patients with incomplete data.

Baseline characteristics are presented in Table 1. The first assessments were performed 33.0 (20.25-59.75) hours after admission. All assessments were performed within 1.39 (00.51-04.31) hours. The median Glasgow Coma Scale (GCS) and RASS did not significantly differ between the painful and nonpainful procedures (turning and oral care). The median RASS was −2.0 (−3.0 to 0.0) during all assessments. The median GCS was 9.0 (4.8-15.0) during rest I and oral care, and 9.5 (5.5-15.0) during rest II and turning. Approximately 30% of the patients received analgesics and/or sedatives, of which midazolam and morphine were given to most of these patients. Three patients received piritramide, ketamine, fentanyl, or epidural levobupicaine/sufentanyl.

3.1. Discriminant validation

The median BPS and CPOT scores of all 68 patients increased by 2 points from rest to the painful procedure: BPS 3.0 (3.0-3.0) to 5.0 (4.0-6.0), $P = .000$, and CPOT 0.0 (0.0-0.0) to 2.0 (0.0-3.0), $P = .000$. The median BPS scores between rest and the nonpainful procedure showed a significant increase of 1 point, whereas the median CPOT score remained unchanged: BPS 3.0 (3.0-4.0) to 4.0 (3.0-4.0), $P = .002$, and CPOT 0.0 (0.0-0) to 0.0 (0.0-2.0), $P = .002$ (see Fig. 2). The highest BPS and CPOT scores were 11 and 7, respectively, during rest. This was in a patient not receiving any analgesic or sedative.

3.2. Reliability

The interrater reliability of the BPS and CPOT was recorded for all analyzed patients, with a total of 1088 assessments (68 patients × 2 raters × 4 different times × 2 scales). The ICC of the BPS scores and the ICC of the CPOT scores for all assessments showed a fair to good agreement. The ICC of the BPS (544 measurements) was 0.74 (95% confidence interval [CI], 0.68-0.79), $P = .001$. The ICC of the CPOT (544 measurements) was 0.75 (95% CI, 0.69-0.79), $P = .001$ (see Table 2).

Cronbach's α values indicated that the BPS and CPOT had an acceptable internal consistency during the painful procedure (turning) of 0.70 and 0.71 respectively.

3.3. Complementary analysis

After the primary analysis, the sample of 68 patients was divided into 3 subgroups according to their RASS scores. In a subgroup of 28 sedated patients (RASS −5, −4, and −3), the median BPS and CPOT scores did not increase from rest to the nonpainful procedure. However, the median BPS and CPOT scores in this subgroup increased by 2 points from rest to the painful procedure: BPS 3.0 (3.0-3.0) to 5.0 (4.0-6.8), $P = .000$, and CPOT 0.0 (0.0-0.0) to 2.0 (0.3-4.0), $P = .000$. In a subgroup of 33 calm patients (RASS −2, −1, and 0), the median BPS scores between rest and the nonpainful procedure increased by 1 point: BPS 3.0 (3.0-3.5) to 4.0 (3.0-4.5), $P = .003$. The median CPOT scores remained similar: CPOT 0.0 (0.0-0.0) to 0.0 (0.0-1.5), $P = .006$. A subgroup of 7 agitated patients (RASS +1) showed nonsignificant increases between rest and the procedures (see Fig. 2).

4. Discussion

This is the first prospective controlled study that has simultaneously assessed and compared discriminant validation and the reliability of 2 pain assessment scores, the BPS [15] and the CPOT [16], in critically ill, mechanically ventilated patients who were unable to self-report pain [19,31]. Discriminant validation of the BPS and CPOT was demonstrated by a significant increase in scores during a painful procedure (turning). However, the CPOT score remained unchanged when comparing a nonpainful procedure (oral care) with rest, whereas the BPS score significantly increased during a nonpainful procedure. Both tools showed a fair to good interrater reliability. Internal consistency of the BPS and the CPOT was acceptable.

This study shows that both the BPS and the CPOT were able to discriminate between a nonpainful procedure/rest and a painful procedure in patients who are unable to self-report pain, which is consistent with previous studies. However, contrary to previous studies, the BPS score in our study also increased significantly during the presumed nonpainful procedure, whereas the CPOT did not [15,17,32]. Most of the increase in BPS score during oral care was the result of changes in facial expression and movements of the upper limbs. This increase might have been due to a reflex to touch rather than to pain. This finding is partially supported by the results of Young et al [32], who assessed 44

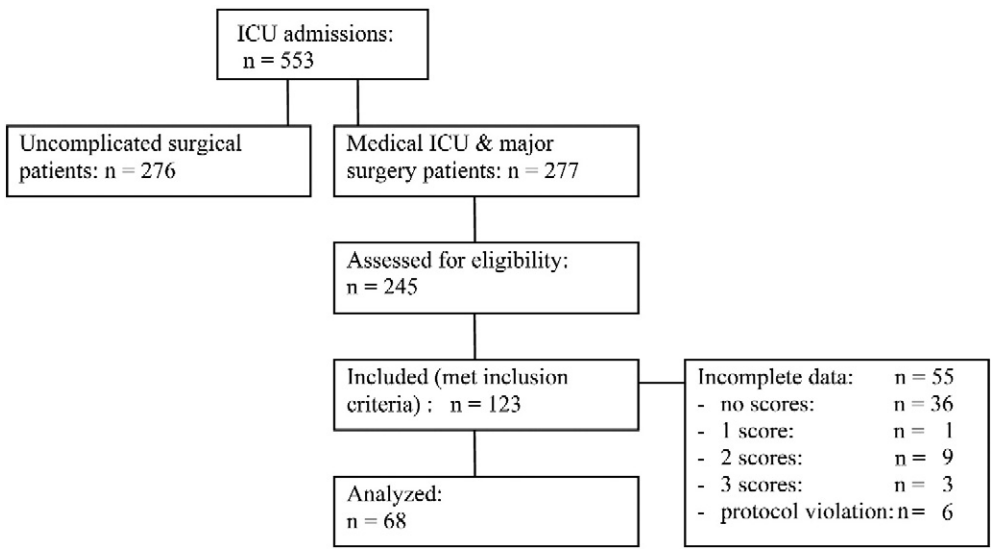

Fig. 1. Flow chart of participants.

Table 1
Baseline characteristics ($N = 68$)

Age, y		66.79 ± 12.5
Sex (male)	No./total no. (%)	41 (60.3)
APACHE IV PM		0.48 [0.238 to 0.757]
SOFA[a] at moment assessments		7.0 [6.0 to 10.75]
Admission type	No./total no. (%)	
Medical		48 (70.6)
Surgical		20 (23.5
Admission	No./total no. (%)	
Nonelective		65 (95.6)
Elective		3 (4.4)
CPR[b]		12 (17.6)
BMI[c]		26.03 [23.09 to 31.80]
LOS, h		169.0 [87.5 to 365.0]
GCS		
Rest I		9.0 [4.8 to 15.0]
Oral care		9.0 [4.8 to 15.0]
Rest II		9.5 [5.5 to 15.0]
Turning		9.5 [5.5 to 15.0]
CAM-ICU	No./total no. (%)	
Negative		16 (23.5)
Positive		5 (7.4)
Not feasible		39 (57.4)
RASS		−2.0 [−3.0 to 0.0]
Oral care	No./total no. (%)	
≤−3		28 (41.2)
−2 to 0		30 (48.5)
≥1		7 (10.3)
Turning		
≤−3		27 (39.7)
−2 to 0		38 (55.9)
≥1		6 (8.8)
Medication regimen[d]	No./total no. (%)	
1 h before assessments		
Rest I		24 (35.3)
Oral care		24 (35.3)
Rest II		22 (32.4)
Turning		21 (30.9)
4 h before assessments		
Rest I		23 (33.8)
Oral care		24 (35.3)
Rest II		23 (33.8)
Turning		23 (33.8)
Morphine[e]		
1 h before assessments		
Rest I	n = 25	3.0 [2.0 to 5.0]
Oral care	n = 25	3.0 [2.0 to 5.0]
Rest II	n = 22	3.0 [2.0 to 6.0]
Turning	n = 2	3.0 [2.0 to 6.0]
Midazolam[e]		
1 h before assessments		
Rest I	n = 23	1.8 [1.2 to 3.5]
Oral care	n = 23	1.8 [1.2 to 3.6]
Rest II	n = 20	1.8 [1.2 to 3.6]
Turning	n = 20	1.8 [1.2 to 3.3]

Plus-minus values are means ± SDs; other values are medians and interquartile range [IQR].
[a] Sequential Organ Failure Assessment scores can range from 0 to 24, with higher scores indicating more severe organ dysfunction.
[b] Patients admitted after cardiopulmonary resuscitation.
[c] Body mass index (kg/m^2).
[d] Sedatives and/or analgesics. Sedatives included oxazepam, midazolam, haloperidol, ketamine, and propofol. Analgesics included morphine, fentanyl piritramide, and levobupivacaine. Medication was administered enterally, intravenously, or via an epidural catheter.
[e] Milligrams per hour continuously.

patients and also found an increase in BPS during a nonpainful procedure (eye care), although this increase was not significant. Secondly, the difference in discriminant validation of the CPOT and BPS during the nonpainful stimulus could also be the result of the different number of options in each domain. For the BPS, nurses have to choose between 4 options compared to the 3 options of the CPOT. It is possible that the 4 options of the BPS could be less clearly distinguished than the 3 options of the CPOT and could therefore lead to incorrect assessment of a nonpainful stimulus. Finally, Gelinas et al described and analyzed the psychometric proportions of several pain assessment tools for use in nonverbal critically ill adults. According to their study, one of the limitations of the BPS is that operational description of some items may be interpreted differently by users [19].

Table 2
Interrater reliability

Assessment	BPS ICC[a]	CPOT ICC[a]
Overall	0.74 95% CI (0.68-0.79)	0.75 95% CI (0.69-0.79)
Rest I	0.69 95% CI (0.55-0.80)	0.73 95% CI (0.59-0.82)
Oral care	0.71 95% CI (0.57-0.81)	0.71 95% CI (0.57-0.81)
Rest II	0.81 95% CI (0.71-0.88)	0.79 95% CI (0.67-0.86)
Turning	0.60 95% CI (0.55-0.79)	0.61 95% CI (0.44-0.74)

[a] Intraclass correlation coefficient.

This study also found that in a subgroup of sedated patients (RASS −5, −4, and −3), neither of the 2 pain scores increased during oral care, whereas in calm patients (RASS −2, −1, and 0), the BPS increased by 1 point. This could be explained by the fact that both the BPS and CPOT are developed for patients who cannot self-report their pain, mainly being deeply sedated patients [15,16,19]. Nurses have to decide in daily practice whether a patient is able to self-report pain or whether a behavioral pain assessment tool is appropriate for that individual patient. It is possible that they use an inappropriate method of assessing pain due to an incorrect assessment of a patient's abilities. An additional explanation could be that less sedated patients exhibited more behaviors than sedated patients, which might have led to errors in the pain assessment during a nonpainful stimulus with the BPS due to the 4 options in each domain.

The median BPS and CPOT scores in the small subgroup of agitated patients (RASS +1) were generally higher and increased during all procedures. Discriminating between behaviors as a result of agitation or pain might be difficult. This important issue requires further research.

The BPS and CPOT in our study showed a fair to good interrater reliability, 0.74 and 0.75, respectively. Previous studies generally found a higher interrater reliability, consistently being better during rest than during the painful procedure [13,15–17,19,33–36]. However, 2 studies analyzing the BPS found a lower interrater reliability during painful procedures [32,37]. Our interrater reliability could be lower because the nurses had to assess the BPS and CPOT simultaneously, which is more demanding. An additional reason may be the large number (105) of nurses on our ICU, resulting in less experience with the assessments. The number of assessors in prior studies was generally lower [15–17,34,36]. Furthermore, pairs of nurses differed in our study, and only the bedside nurse was constant. In several previous studies, either one of the investigators or the physicians participated in the assessments [13,16,17,34]. Pain assessment by a large group of nurses is, however, a reflection of real-life intensive care. Furthermore, the bedside nurse potentially understand the patient's reactions better because of a longer contact time. The interrater reliability during the painful procedure was lower than during the nonpainful procedure (0.60 and 0.61, respectively). This could be due to the hypothesis that turning is a painful procedure for all ICU patients, whereas it may only be uncomfortable or stressful in medical patients without wounds [26]. Behavioral changes in these patients might have been more difficult to interpret. Another explanation is that patients could have exhibited more behaviors during turning, and some of these might have been missed by the nurses during the assessments.

The internal consistency as measured with the Cronbach's alpha was acceptable for the BPS and the CPOT, and similar to other studies investigating the internal consistency of the BPS and CPOT [17,32,34,36–38].

Several studies have reported that critically ill patients frequently experience pain and discomfort and that approximately 50% of the patients report moderate to severe pain [1–5]. The BPS and CPOT in our study generally demonstrated low pain scores during the painful procedure, which is similar to previous studies using the BPS and

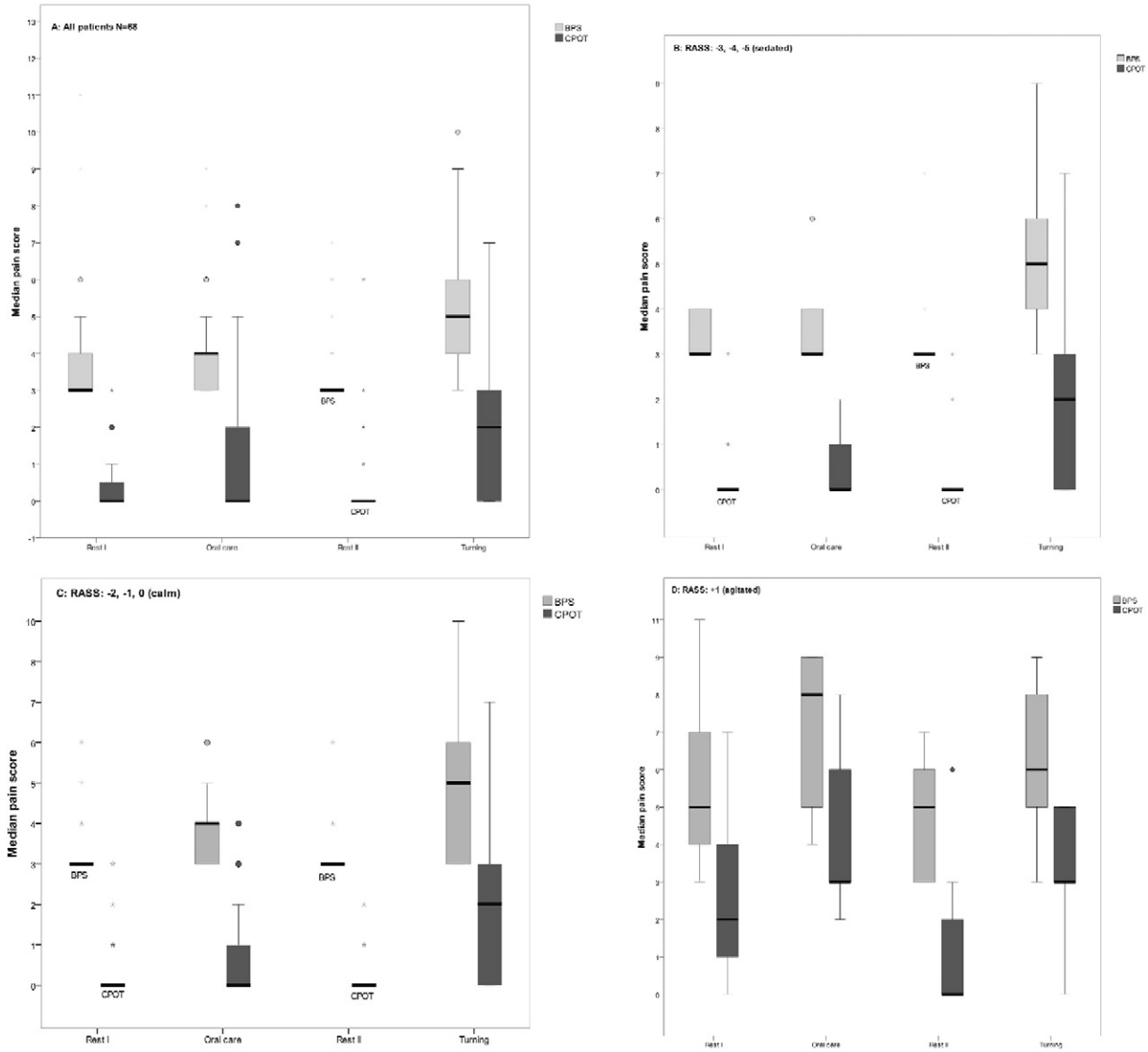

Fig. 2. Results discriminant validation.

CPOT [13,15,17,32,36]. This could be explained by the fact that these studies included sedated patients who cannot self-report pain. Assessment of pain with behavioral pain scales could underestimate pain [39,40]. Gelinas et al [13] reported lower CPOT scores in their group of unconscious patients compared to the conscious patients. They found that a higher dose of sedation and/or analgesics resulted in lower pain scores. We excluded patients who were able to self-report, which might have resulted in lower pain scores. However, in former studies, between 75% and 100% of the patients received sedatives and/or analgesics, whereas only 34% of our patients received analgesics and/or sedatives [13,15,34,36,41,42]. This may be due to the higher proportion of medical patients in our study and the policy of aiming for the lowest acceptable dose of sedatives and analgesics. Finally, turning might not be painful for all critically ill patients, especially not for medical patients without wounds. This might explain the low increase in both scores comparing rest to turning. It is however unethical to provide an intentional painful stimulus to patients.

4.1. Limitations

Our study has potential limitations. First, the assessments were performed by bedside nurses and could therefore not be blinded. Consequently, the assessors were aware of which procedures were to be performed, and they may have perceived more behavioral changes during turning because they thought that this was a painful procedure. This could have led to higher scores during the painful procedure and an overestimation of the discriminant validation. Second, the BPS was always completed first, which could have affected the study data. Randomizing the order of the assessments could have strengthened the study design. Third, the number of patients included in the final analysis was relatively small, which might have led to an unrepresentative group of patients. We excluded patients who had incomplete data, and this could have caused selection bias. Therefore, we compared the baseline characteristics of the 68 analyzed patients with the 209 patients excluded from the study and final analysis. We also compared the baseline characteristics of the analyzed patients (68) with the patients with incomplete data (55) (see Fig. 1). The analyzed patients had a significantly higher APACHE IV predicted mortality, were older, and had a longer ICU stay, which conformed to the inclusion criteria. Other patient characteristics did not significantly differ. Therefore, we believe that our study sample reflects the group of patients for whom the BPS and CPOT are designed and that less severely ill patients were excluded.

The fourth limitation is that we initially trained the expert group and nurses in the English versions of the BPS and CPOT. During our study, the BPS and CPOT had not been translated and validated in Dutch. An expert group of ICU nurses, an intensivist/anesthesiologist, and a

qualified English language translator translated both tools (the short descriptions only) in Dutch in our CIS; thus, language misconceptions might have occurred. We did not perform a double forward and backward translation according to the requirements of an official translation. However, the descriptions in both tools are short, clear, and contain universally interpretable signs, and Dutch people generally have a high standard of English, so we believe that this factor has not likely affected our results.

Finally, the presence of a delirium could interfere with the behavioral pain scores and therefore be a confounding factor. Nurses at our ICU routinely assess twice daily the incidence of delirium with the CAM-ICU. A positive CAM-ICU was reported in 5 of 68 patients, but we cannot be sure that this reflects the true incidence of delirium, as the assessment of delirium in patients with decreased consciousness is extremely difficult. A valid and structured assessment of delirium performed by a psychiatrist should be taken account of during future research of behavioral pain scales.

5. Conclusion

This study in critically ill ventilated patients unable to self-report pain shows that the CPOT and BPS both had a fair to good interrater reliability. However, the CPOT was superior to the BPS in assessing pain, according to the discriminant validation. Although both scores increased with a presumed painful stimulus, the BPS had a reduced discriminative performance because it increased with a nonpainful stimulus as well. We therefore prefer using the CPOT for this particular group of patients. The use of a behavioral pain scale in daily intensive care practice could optimize pain treatment and use of analgesics and sedatives in critically ill patients. However, further research is needed on discrimination between discomfort, stress, and pain, on the effect of analgesics and/or sedatives on the CPOT, and on the assessment of pain in restless, agitated, or delirious patients.

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.jcrc.2014.09.007.

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