Anaesthesist 2019 · 68:836–842

<https://doi.org/10.1007/s00101-019-00694-5>

Received: 8 June 2019

Revised: 2 September 2019

Accepted: 16 October 2019

Published online: 20 November 2019

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The German version of the Critical-Care Pain Observation Tool for critically ill adults

A prospective validation study

Electronic supplementary material

The online version of this article (<https://doi.org/10.1007/s00101-019-00694-5>) contains the translated COPT version. Article and supplementary material can be found at www.springermedizin.de. Please enter the article title in the search option; the supplementary material can be found under "Additional Contents"

Introduction

Critically ill patients frequently experience pain for a variety of reasons including traumatic injuries, infections, immobility and procedures. Approximately 50% of patients indicated moderate to severe pain in interviews, both at rest and during routine procedures [5, 22]. Rates may be even higher in patients unable to communicate. However, pain assessment rates remain below 40% in mechanically ventilated patients [21]. Poor pain management has been associated with a number of adverse outcomes including thromboembolic events, pulmonary complications, increased length of intensive care unit (ICU) stay, chronic pain

and posttraumatic stress disorder [8]. Improved pain management has been shown to reduce morbidity and improve long-term outcomes, as well as increase patient comfort [4], e.g. regular pain assessments in nonverbal patients in the ICU have been associated with reduced duration of mechanical ventilation, reduced length of ICU stay and decreased rates of nosocomial infections [21, 29].

Reliable pain assessment methods are required as an inevitable fundament of pain management. Self-reporting is considered as the most valid measure of pain [3, 23]. In the absence of patients' ability for self-reporting, the assessment methods must be adapted to the communication capabilities of the patient. Observational pain scales that rely on behavioral responses to pain are valuable proxies for self-reporting and should be used in nonverbal patients [1, 3].

The Behavioral Pain Scale (BPS) and the Critical-Care Pain Observation Tool (CPOT) are recommended as the most valid and reliable behavioral pain scales for monitoring pain in adult ICU patients. Results of recent studies highlighted the advantages of CPOT [3] in particular for discrimination validity of a nociceptive versus a non-nociceptive stimulus [11, 25]. Furthermore, the implementation of CPOT in ICUs has been associated

with more frequent pain assessments, a reduced number of complications and an improved adapted administration of analgesics and sedatives [9].

The CPOT was developed and validated by the Canadian nurse Celine Gelin and her team [10] in English and French. The use of CPOT in other ICU patient populations and translation into foreign languages requires further validation testing [3]. The CPOT has now been validated in many other languages, e.g. Swedish [20], Danish [7], Chinese [18], Italian [27], Spanish [30], Korean [17] and Polish [16]. This is the first validation of the German version of CPOT in adults in a prospective study. The aim of this study was to validate the German version of CPOT in a population of adult cardiac surgery ICU patients with the objectives to analyze interrater reliability, discriminant validity, criterion validity and further receiver operating characteristic (ROC) curve analysis of diagnostic accuracy of CPOT.

Methods

Study design

The study was performed as a prospective observational validation study. A convenience sample of 292 cardiac surgery

G. Schneider and S. Pilge contributed equally to this work.

patients in the ICUs of 2 German university hospitals (Helios Clinic Wuppertal, University Witten/Herdecke and LMU Munich) were recruited for the study. Inclusion criteria were patients admitted to the ICU after cardiac surgery, informed consent to take part in the study, age ≥ 18 years, sufficient understanding of German and intact hearing and vision. Exclusion criteria were patients after heart transplantation or thoracic aortic aneurysmal repair, an ejection fraction less than 0.25 (25%), pre-existing psychiatric or neurological disorders, dependence on alcohol or drugs, treatment for chronic pain, neuromuscular relaxation after cardiac surgery or development of complications after surgery (such as hemorrhage, delirium or death). A sample size calculation of 200 patients was determined for the planned analysis of interrater reliability, discriminant validity and criterion validity. Based on 200 cases predictions of frequency distributions of CPOT scores can be made with an accuracy of $\pm 4\text{--}7\%$ (95% confidence interval). Variations in pain intensity were analyzed with paired t-tests (alpha 0.5, power 80%) to detect differences with 0.2 standard deviation (SD). Patients were recruited during the preoperative preparation process according to the inclusion and exclusion criteria. If during the perioperative or postoperative process new exclusion criteria arose, the collection of data was stopped at this moment.

In the preliminary part of the study, the English original version of CPOT was translated into German (see supplemental data in the online version of the article) according to the principles of good practice for translation and cultural adaptation process for patient-reported outcome measures of the ISPOR task force [31].

Instruments

Evaluation of pain

Pain was evaluated with the CPOT, BPS and NRS in awake patients. The CPOT is a tool developed and validated in clinical settings to observe and detect pain in critically ill and also mechanically ventilated or intubated patients [10]. It includes the four behavioral categories facial ex-

pression, body movements, compliance with ventilator for ventilated patients or vocalization for extubated patients and muscle tension. For each item, the observer scores 0–2 points with a possible total score range from 0 to 8. The BPS is another pain score developed specifically to measure the severity of pain in sedated, mechanically ventilated, unresponsive patients [21]. It is based on a sum score of the three items facial expression, upper limbs and compliance with ventilation. For each item the observer scores 1–4 points with a possible total score range from 3 to 12. The NRS and verbal rating scales (VRS) are commonly used one-dimensional scales to evaluate pain in a simple and effective way. They were developed for self-assessment of pain by the patient and therefore show high validity and reliability [14]. The German national guidelines for management of analgesia, sedation and delirium in intensive care recommends the use of NRS and VRS to monitor pain in awake, cooperative ICU patients [19]. In the present study an 11-step NRS (0–10) and a 6-step descriptive VRS (no pain to most severe imaginable pain) were used.

Evaluation of sedation and delirium

To evaluate the level of sedation patients were scored by a 5-step consciousness scale, the Glasgow coma scale (GCS) and the Richmond agitation-sedation scale (RASS). The confusion assessment method for the ICU (CAM-ICU) was used to assess delirium.

Clinical protocol/procedure

In the course of the patients postoperative stay on the ICU, three assessments were performed at each of three testing periods (T1–T3) leading to an overall number of nine assessments (M1–M9) according to the original CPOT validation protocol [10]. The first three assessments (T1: M1–M3) were conducted when the patients were admitted to the ICU and were still sedated and intubated. M1 was done approximately 2 h after the end of surgery with the patient at rest, M2 some minutes after M1 during positioning (for postop-

erative x-ray) and M3 was done at recovery 20 min after positioning. The second testing period (T2) was conducted when the patient was awake and conscious but still intubated: these three assessments (T2: M4–M6) were also performed before, during and after positioning (and endotracheal suctioning for extubation). The third testing period (T3: M7–M9) was performed after the patients were extubated, also before, during and after positioning (for mobilization).

Data for CPOT, BPS, RASS and level of consciousness were evaluated at all nine assessments (M1–M9). For M4–M9 pain was also scored by the NRS. At T2 and T3 patients were evaluated for the presence of delirium by using the CAM-ICU. At all assessments physiological parameters (heart rate, respiratory frequency, blood pressure, tears yes/no and perspiration yes/no) were documented. The following standardized drug regimen was applied to all patients: sedation with propofol at T1, analgesia with bolus administration of piritramide at all testing periods tailored to the patient needs. In both ICUs the whole team was trained in the use of the instruments (in Wuppertal up to 6 physicians and 15 nurses and in Munich up to 5 physicians and 17 nurses). Training material consisted of a presentation with background information of pain, the study procedures and explanation of the scores (CPOT/BPS/NRS/RAAS/CAM-ICU), the paper versions of the scores and training posters. In addition, an instruction card was available in every patient room. A trial run was performed to minimize the possible bias of a learning curve and to provide bedside teaching of the study procedures. Each assessment was performed by one physician and one nurse independently at the same time.

Analysis of data

In this study, two trained raters (a physician and a critical care nurse) assessed the patients' pain with the German CPOT independently. A weighted Cohen's kappa was calculated to quantify the degree with which physician and care nurse agreed (interrater reliability). Cronbach's alpha was used to quantify the degree to which

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The German version of the Critical-Care Pain Observation Tool for critically ill adults. A prospective validation study

Abstract

Background. The implementation of the Critical-Care Pain Observation tool (CPOT) in intensive care units (ICU) has been associated with more frequent pain assessments, a reduced number of complications, and improved administration of analgesics and sedatives. So far no German translation exists. Translating this tool into foreign languages requires further validation testing.

Objective. The aim of this prospective observational validation study was to translate the original version of the CPOT according to scientific principles for translation and to establish the validity and reliability of the German translation of CPOT for critically ill adult patients.

Material and methods. A total of 292 cardiac surgery patients from 2 ICUs of 2 German

university teaching hospitals were included (114 patients at center 1 and 178 patients at center 2). Of the included patients 22.6% were female and 76.4% were male with a mean age of 68.5 years $\pm$ 9.3 SD. Pain was evaluated with the CPOT, the Behavioral Pain Scale (BPS) and with the Numeric Rating scale (NRS) at three time points (1. intubated + sedated, 2. intubated + awake, 3. extubated + awake) at rest and during nociceptive stimulus (positioning). Assessments were made separately by trained physicians and nursing staff.

Results. Good results for interrater reliability and internal consistency could be demonstrated (weighted Cohen's kappa of 0.73, Cronbach's coefficient alpha of 0.8). Spearman correlation between CPOT and NRS

was moderate but significant. The receiver operating characteristic (ROC) analysis to obtain optimal thresholds of CPOT to detect pain revealed different results during rest and stimulus and in intubated and extubated patients.

Conclusion. The validated German CPOT translation is a reliable tool for pain assessment in cardiac ICU patients in the absence of patients' ability for self-reporting. The use of this German version of CPOT now allows a better international comparability of corresponding data in future studies.

Keywords

Pain score · Pain measurement · Behavioral rating scale · Intensive care unit · Validation study

Die Deutsche Version des Critical-Care-Pain-Observation-Tools. Eine prospektive Validierungsstudie

Zusammenfassung

Hintergrund. Das Critical-Care-Pain-Observation-Tool (CPOT) wird von internationalen Leitlinien und der nationalen deutschen Leitlinie zur Erkennung von Schmerzen bei Intensivpatienten empfohlen. Studien zeigen, dass seine Verwendung mit häufigeren Schmerzmessungen, geringeren Komplikationsraten und einer verbesserten Steuerung der Gabe von Analgetika und Sedativa assoziiert ist. Eine offizielle deutschsprachige Übersetzung existierte bisher nicht. Für die Übersetzung des Tools in andere Sprachen benötigt es weitere Validierungstests.

Ziel. Ziel der Studie war es, die Validität und Reliabilität des deutschen CPOT nachzuweisen.

Material und Methoden. Es wurden 292 erwachsene herzchirurgische Intensivpatienten (Durchschnittsalter 68,5 Jahre $\pm$ 9,3 [SD]) von zwei deutschen Universitätskliniken eingeschlossen. Davon waren 22,6 % weiblich und 76,4 % männlich. Schmerzen wurden

anhand des CPOT, der Behavioral Pain Scale (BPS) und der Numeric Rating Scale (NRS) zu drei Zeitpunkten jeweils in Ruhe und während eines Stimulus erhoben: 1. intubiert + sediert, 2. intubiert + wach, 3. wach + extubiert. Alle Messungen wurden jeweils unabhängig voneinander von geschultem Arzt- und Pflegepersonal durchgeführt.

Ergebnisse. Für die Interrater-Reliabilität sowie die interne Konsistenz konnten gute Ergebnisse demonstriert werden (gewichtetes Cohens κ = 0,73, Cronbach's α = 0,8). Hinsichtlich der Diskriminations-Validität konnte das CPOT signifikante Unterschiede zwischen Ruhe und Stimulation zeigen. Die Korrelation zwischen CPOT und NRS nach Spearman war moderat aber signifikant (p = 0,48 für Ärzte und 0,54 für Pflegekräfte). Die Analyse der Receiver-Operating-Characteristic(ROC)-Kurven zeigte unterschiedliche Ergebnisse in Ruhe und während des Stimulus sowie für intubierte und extubierte Patienten.

Schlussfolgerung. Die vorliegende, für die deutsche Sprache validierte Version des CPOT ist ein verlässliches und valides Instrument zur Messung von Schmerzen bei herzchirurgischen Intensivpatienten, die ihr Schmerzniveau nicht selbst kommunizieren können. Diese Version des CPOT kann nun offiziell entsprechend der Leitlinien im klinischen Alltag verwendet werden und gewährleistet in der Zukunft eine bessere internationale Vergleichbarkeit wissenschaftlicher Daten. Analog zum Originalinstrument sollten einzelne Unterpunkte, wie die Ermittlung von Grenzwerten als therapeutische Interventionsschwelle, in zukünftigen Studien noch weiter untersucht werden.

Schlüsselwörter

Schmerzmessung · Intensivpatienten · Schmerz-Score · Fremdbeurteilung · Validierung

a set of items of the German CPOT measure the same general construct (internal consistency). Interrater reliability and internal consistency were calculated separately for each of the nine assessments (M1–M9). Spearman correlation coefficient between the CPOT and the gold

standard measure of pain, i.e. patient self-reporting of pain intensity (NRS), was calculated as a measure of criterion validity. In the present study patients were sedated for M1–M3, therefore self-reporting pain was available at M4–M9

and the correlation coefficient was calculated for these assessments only.

This study examined the ability of the German CPOT to discriminate between different assessment conditions (discriminant validity), i.e. the ability to discriminate between pain during positioning

	Testing period	Assessment (M1–M9)	n	Mean	SD	Range	p* vs. (1)	p* vs. (2)
Physician	T1 (sedated intubated)	M1	279	0.13	0.53	0–4	–	–
		M2		0.73	1.74	0–8	<0.001	–
		M3		0.14	0.70	0–8	0.816	<0.001
	T2 (awake intubated)	M4	261	1.08	1.73	0–8	–	–
		M5		2.05	2.17	0–8	<0.001	–
		M6		0.36	0.89	0–7	<0.001	<0.001
	T3 (awake extubated)	M7	258	0.31	0.84	0–8	–	–
		M8		0.62	0.70	0–8	<0.001	–
		M9		0.27	0.71	0–7	0.211	<0.001
Nurse	T1 (sedated intubated)	M1	273	0.21	0.84	0–8	–	–
		M2		0.78	1.65	0–8	<0.001	–
		M3		0.21	0.81	0–8	0.940	<0.001
	T2 (awake intubated)	M4	256	1.14	1.68	0–8	–	–
		M5		1.88	2.10	0–8	<0.001	–
		M6		0.39	1.01	0–7	<0.001	<0.001
	T3 (awake extubated)	M7	250	0.34	0.78	0–7	–	–
		M8		0.70	1.31	0–8	<0.001	–
		M9		0.27	0.68	0–5	0.060	<0.001

SD standard deviation, n number of patients

*Comparison of CPOT values at different assessment time points with paired t-tests, e.g., vs. (1): M2 vs. M1, M3 vs M1, M5 vs M4, M6 vs M4; vs. (2): M3 vs M2, M6 vs M5

Table 2 Internal consistency of the German CPOT (Cronbach's alpha) at M1–M9 for physicians and nurses

	M	n	Alpha
Physician	M1	282	0.73
	M2	284	0.94
	M3	283	0.87
	M4	278	0.89
	M5	268	0.90
	M6	270	0.72
	M7	265	0.70
	M8	263	0.79
	M9	259	0.67
Nurse	M1	280	0.85
	M2	279	0.92
	M3	281	0.83
	M4	273	0.86
	M5	265	0.90
	M6	263	0.80
	M7	262	0.64
	M8	261	0.83
	M9	256	0.59

n number of patients

(M2, M5, M8) and lack of pain at rest and recovering (M1, M4, M7, M3, M6, M9). The paired t-test was used for the comparison of the different assessment time points. The ROC curve analysis was used to evaluate the diagnostic accuracy of the German CPOT: the ability of the German CPOT to detect pain. In addition, ROC curve analysis was used to choose optimal thresholds of CPOT to detect pain. The CPOT value with maximal Youden index was chosen as threshold. This index combines sensitivity and specificity, it equals 1 when the diagnostic test discriminates perfectly between patients who report having pain and those who report not having pain.

All statistical analyses were performed separately for physicians and nursing staff in order to allow the comparison of the results of the two groups and to avoid dependencies between data of physicians and nursing staff. Statistical analyses were completed by using Stata/IC 13.1 for Windows. All statistical tests were two-sided at a significance level of 0.05.

Ethics

Ethical approval for this study was provided by the Ethics Committee of the University of Witten/Herdecke, Germany, (chairperson Prof. P.W. Gaidzik) on 19 December 2011 (registration number 132/2011), and by the Ethics Committee of the University of Munich, Germany (chairperson Prof. Dr. W. Eisenmenger) on 3 September 2013, registration number 394-13. Recruitment was done by a physician during the preoperative preparation process. The study was explained to eligible patients orally and in written information and informed consent was obtained. All data were observational, collected and stored pseudonymously.

Results

A convenience sample of 292 patients was recruited: 114 patients at the LMU Munich and 178 patients at the Helios clinic Wuppertal, University Witten/Herdecke. Data were collected between January 2014 and April 2015. The mean age was 68.5 years $\pm$ 9.3 SD, 22.6% of the

included patients were female and 76.4% were male (1% missing data). A total sum of 2394 CPOT measurements were obtained by physicians and 2337 by nurses. **Table 1** gives a detailed description of the respective number of CPOT measurements at the nine assessments.

CPOT

The range of CPOT scores was from 0 to 8 as assessed by physicians and nurses. Mean CPOT values at assessments M1–M9 are shown in **Table 1** for physicians and nurses. Scores were higher during positioning (M2, M5, M8) than during rest or recovering. During the second testing period (T2), patients had the highest CPOT scores.

Internal consistency

Internal consistency was good with an average of 0.8 (Cronbach's alpha) for both physicians and nursing staff. By trend, internal consistency achieved best results at M2 and declined with subsequent assessments M6–M9 (**Table 2**).

Fig. 1 ▲ **a** Mean CPOT scores for physicians. **b** Mean CPOT scores for nurses

Detailed analysis included item-test-correlation (correlation of each of the four items of the German CPOT with full test CPOT scale). Overall, all four German items of CPOT showed a good item-test correlation and internal consistency decreased when a single item was omitted.

Discriminant validity

Results from paired t-tests showed that mean German CPOT values significantly differed during positioning (M2, M5, M8) and at rest/recovering (■ Fig. 1).

Interrater reliability

Interrater reliability (agreement between physician and nurse) of the German CPOT was good with a weighted Cohen's kappa of 0.73 (■ Table 3) representing a high degree of agreement between the two groups of raters.

Criterion validity

Patients self-reporting of pain was measured by NRS at M4–9. Correlations between NRS and CPOT is shown in ■ Table 4. Due to medication and illness not all patients were able to describe their pain level on all six assessments which explains the variation in numbers of patients.

The highest Spearman correlation coefficient rho (correlation CPOT and NRS) was calculated during the positioning

procedure at M8: with a rho of 0.48 for physicians and 0.54 for nurses, indicating a moderate correlation between CPOT and NRS. For the assessments M4–M6, M7 and M9, the correlation coefficient rho was considerably lower.

ROC analysis

The CPOT values at rest (before and after positioning M4/M6 and M7/M9) were pooled with respect to clinical practicability: recommendation of CPOT thresholds at rest and during nociceptive stimuli. The calculation of bootstrap confidence intervals enabled repeated measurements. For patients at T2 (awake and intubated) at rest (M4/M6), a CPOT threshold value of ≥ 3 was calculated for data obtained from physicians (sensitivity 29.09, specificity 91.28, area under the curve, AUC 0.59) or of ≥ 2 for data obtained from nursing staff (sensitivity 32.61, specificity 82.24, AUC 0.55). For patients at T2 during positioning (M5), a CPOT threshold value of ≥ 4 was calculated for both data obtained from physicians and from nursing staff. Parameters of diagnostic accuracy were for physicians (nursing staff): sensitivity 45.45 (45.16), specificity 71.91 (74.79), AUC 0.58 (0.58). For all patients at T3 (awake and extubated), a CPOT threshold value ≥ 1 was calculated: at rest and during positioning, no differences in threshold values between data from physicians and from nursing staff. At T3 and rest (M7/M9), parameters

of diagnostic accuracy were for physicians (nursing staff): sensitivity 30.59 (32.53), specificity 82.92 (80.23), AUC 0.56 (0.56). At T3 and during positioning (M8), parameters of diagnostic accuracy were for physicians (nursing staff): sensitivity 46.30 (40.82), specificity 71.29 (69.81), AUC 0.58 (0.54).

Discussion

The present study validated the German version of the CPOT. Compared with results of previous studies that developed an adaption of CPOT for other languages, the presented German version showed good results for reliability and validity. Patient's self-reported pain measured by NRS as the gold standard of pain assessment, showed a moderate but significant correlation with CPOT scores (Spearman correlation coefficient at M8 was 0.48 for physicians and 0.54 for nurses). These moderate correlations and the finding that higher scores were obtained for the nociceptive procedure than at rest are in accordance with the findings of the original validation study of the English version of CPOT by Gelinas et al. (Spearman correlations of 0.49, 0.59, and 0.40 at M7 to M9, [10]) and also with other European studies for language validation [7, 20, 27].

The good results obtained for interrater reliability measures (weighted Cohen's kappa of 0.54–0.89) of the German CPOT was also comparable with those reported in previous studies: in the

Table 3 Interrater reliability of the German CPOT (agreement doctors and nurses) at M1–M9

M	n	Weighted Cohen's kappa
M1	276	0.54
M2	277	0.84
M3	279	0.58
M4	270	0.83
M5	259	0.89
M6	256	0.70
M7	258	0.69
M8	256	0.82
M9	248	0.67

n number of patients

Table 4 Spearman correlation coefficients (rho) for correlations between German CPOT and NRS for M4–M9

	M	n	Rho	p
Physician	M4	130	0.12	0.164
	M5	145	0.24	0.004
	M6	248	0.20	0.002
	M7	257	0.25	<0.001
	M8	254	0.48	<0.001
	M9	251	0.28	<0.001
Nurse	M4	131	0.07	0.418
	M5	144	0.22	0.007
	M6	219	0.22	0.001
	M7	247	0.26	<0.001
	M8	249	0.54	<0.001
	M9	245	0.23	<0.001

French version corresponding measures ranged between weighted kappa coefficients of 0.52–0.88 [12], the Japanese version showed kappa coefficients of 0.52–1 [15]. The good values for internal consistency for CPOT that were demonstrated by the Italian version (Cronbach's alpha 0.78 at T2 and 0.86 at T3 [27]), the Chinese version (Cronbach's alpha 0.57–0.86 [18]) or the Danish version (Cronbach's alpha with all scores >0.70, [7]) could also be supported by the present findings with an average of 0.8 (Cronbach's alpha, range 0.59–0.94) for both physicians and nursing staff.

As for cardiac surgery patients Gelinass et al. suggested a threshold of CPOT >2 for therapeutic (analgesic) interventions [12]. The present study was only able to confirm the validity of these cut-off values when nursing personnel used the CPOT at T2 for patients at rest (M4/M6). At the same time, a CPOT threshold value of ≥ 3 was calculated for data obtained from physicians. Patients at T2 during positioning showed a CPOT threshold value of ≥ 4 and at T3 for all patients a CPOT threshold value ≥ 1 was calculated. The study conducted by Nürnberg Damström et al. also had problems to confirm the suggested threshold of >2 [20]; however, Stilma et al. agreed on a threshold of >2 but admitted that different sedation regimens could influence the threshold [26]. In a second study by Gelinass et al. thresholds were shown to be >3 in more critically ill unstable patients with

various diagnoses undergoing mechanical ventilation, leading to the conclusion that thresholds also may depend on the patient's condition [12]. According to this assumption, in a collective of brain surgery patients CPOT cut-off thresholds were found to be equal or higher than 2 [6]. Even if there is controversy about pain intensity-based cut-off points and their meaning in clinical routine as basis for therapeutic consequences [13], further studies should explore the different factors that influence intervention thresholds of the CPOT. Both the CPOT and the BPS can be considered as the most valid and reliable behavioral pain scales for monitoring pain in several collectives of adult ICU patients who are not able to self-report [24]. The clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the ICU published by the American Society of Critical Care Medicine [3] recommend the use of both scales but stress the superiority of the CPOT. Accordingly, guidelines for German speaking countries many years only recommended the BPS [19], but the newest version of the German guideline for the management of analgesia, sedation and delirium in intensive care [2] suggests both scores but leaves the decision open to the individual ICU. The present study contributes to a decision about this question in favor of the CPOT, as it presents the first validation for the German CPOT, which does not yet exist for the German BPS.

From the authors' point of view a regular clinical use of the German CPOT can now, also scientifically underpinned, be recommended and thus may lead to better pain management and improvement of clinical outcomes in ICU patients in German speaking countries. Compared to studies validating the CPOT in other languages, this study included a higher number of patients. The good data set enabled analysis of the data for the German CPOT for physicians and nurses separately with the objective of gaining more detailed information with respect to clinical applicability.

Limitations

Although these findings are comparable with those of other validation studies of the CPOT, some potential limitations of the study should be discussed.

The inclusion of cardiac surgery patients only may be considered as one major limitation of the study. Although Gelinass et al. in their first version also included only patients undergoing cardiac surgery [10], further studies are warranted to achieve generalizability of the German CPOT for other critically ill patient groups, such as for internal medicine, general surgery or brain injury or suffering from special conditions such as chronic pain. Also, the German CPOT was not compared with the medication regimen as performed by Gelinass in a later study [10]. Furthermore, as mentioned above this study cannot give clear recommendations concerning CPOT cut-off values for therapeutic intervention. In consequence, questions whether the implementation of the German CPOT can improve pain management, decrease postoperative complications and shorten durations of mechanical ventilation and ICU stay, requires further investigation.

Conclusion

The German version of the CPOT has good to acceptable psychometric properties and can be adopted to standardize pain assessment in patients who are unable to self-report. Data from the Netherlands showed that in this group of patients, standardized behavioral pain as-

assessment tools were used in only 19% (CPOT in 6%) [28]. Although there are no corresponding data, similar conditions are assumed for the German-speaking part of Europe. Pain monitoring is considered as highly relevant and specifically the use of CPOT is recommended in German ICU guidelines [2]. A validated German version of the CPOT can now be provided that seems to be eligible for daily routine as it is simple to use and that clinical staff can easily be trained in. This study may be considered as a basis for extensive implementation and further evaluation in German speaking ICUs.

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Acknowledgements. We would like to thank all patients for their contribution and all colleagues, physicians and nurses in Munich and in Wuppertal, for the work they did and the support they gave us to gather the data for the present study.

Funding. This study was funded from departmental sources and a grant from the Helios Clinic GmbH (grant ID 005477). The first author received a 1-year clinical sponsorship (support program for research and teaching by the medical faculty of the Ludwig Maximilians University Munich, FöFoLe Reg.-Nr. 855).

Compliance with ethical guidelines

Conflict of interest I. Kiesewetter, U. Bartels, A. Bauer, G. Schneider and S. Pilge declare that they have no competing interests.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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