RESEARCH

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Validating a pain assessment tool in heterogeneous ICU patients: Is it possible?

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Abstract

Background: Non-communicative adult ICU patients are vulnerable to inadequate pain management with potentially severe consequences. In German-speaking countries, there is limited availability of a validated pain assessment tool for this population.

Aim: The aim of this observational study was to test the German version of the Critical-Care Pain Observation Tool (CPOT) in a heterogeneous adult ICU population.

Methods: The CPOT's feasibility for clinical use was evaluated via a questionnaire. For validity and reliability testing, the CPOT was compared with the Behavioural Pain Scale (BPS) and patient's self-report in 60 patients during 480 observations simultaneously performed by two raters.

Results: The feasibility evaluation demonstrated high satisfaction with clinical usability (85% of responses 4 or 5 on a 5-point Likert scale). The CPOT revealed excellent criterion validity [agreement between CPOT and BPS 94.0%, correlation of CPOT and BPS sum scores $r = 0.91$ ($P < .05$), agreement of CPOT with patient self-report 81.4%], good discriminant validity [mean difference of CPOT scores between at rest and non-painful stimulus 0.33 ($P < .029$), mean difference of CPOT scores between at rest, and painful stimulus 2.19 ($P < .001$)], for a CPOT cut-off score of >2 a high sensitivity and specificity (93% and 84%), high positive predictive value (85%), and a high negative predictive value (93%). The CPOT showed acceptable internal consistency (Cronbach's α 0.79) and high inter-rater reliability [90% agreement, no differences in CPOT sum scores in 64.2% of observations, and correlation for CPOT sum scores $r = 0.72$ ($P < .05$)]. Self-report obtained in patients with delirium did not correlate with the CPOT rating in 62% of patients.

Conclusion: This is the first validation study of the CPOT evaluating all of the described validity dimensions, including feasibility, at once. The results are congruent with previous validations of the CPOT with homogeneous samples and show that it is possible to validate a tool with a heterogeneous sample. Further research should be done to improve pain assessment and treatment in ICU patients with delirium.

1 | BACKGROUND

Critically ill adult patients are likely to experience pain, which is often iatrogenic in nature. The causes of pain range from surgery, trauma, and procedures (eg, arterial line placement, chest tube removal).[1] Pain is often also associated with nursing interventions such as tracheal suctioning, positioning, and wound care.[2] Many patients also have a history of chronic pain, which complicates assessment and treatment.[3] Critically ill adults experience moderate-to-severe pain during standard care procedures and at rest.[4] Many ICU patients cannot communicate their pain because of an altered level of consciousness, sedation, and/or mechanical ventilation.[5] Incomplete assessment and treatment of pain is associated with longer mechanical ventilation, prolonged ICU stay, and increased mortality.[6] Unrelieved pain in the ICU can also increase the risk of developing post-traumatic stress disorder, which is associated with a lower quality of life.[7] Although pain management in the ICU has improved within the last decade, still in the year 2016, it was said that "pain remains undetected, underestimated and poorly managed, particularly in critically ill intubated patients".[8] It is strongly recommended that ICU clinicians use validated behavioural pain scales when patients are unable to self-report pain.[4] The American Society for Pain Management Nursing proposes a four-step approach: (a) Always attempt to obtain the patient self-report of pain. (b) Use a validated behavioural pain scale or look for behavioural changes. (c) Ask the family about the patient's pain behaviours. (d) Attempt an analgesic trial when pain is suspected and reassess for pain.[9] A variety of pain assessment tools have been developed for non-communicative critically ill adults. Originally developed by Gélinas et al, the Critical-Care Pain Observation Tool (CPOT) has the strongest evidence with regard to validity and reliability for pain assessment in ICU patients who are unable to communicate verbally, mechanically ventilated or not.[8,10] It was tested in different ICU patient groups (surgical, medical, neurological and trauma)[5] and has recently been validated for critically ill patients with delirium.[11] Translated CPOT versions are available in Finnish,[12] Swedish,[13] Dutch,[14] Danish,[15] Persian,[16] Chinese,[17] Spanish,[18] Italian,[19] and Turkish.[20]

In German-speaking countries, there is limited availability of a validated pain assessment tool for non-communicative ICU patients. The widely accepted German S3 guideline "Analgesia, Sedation and Delirium management in Intensive Care" recommends the CPOT and provides a simply translated version. However, instructions for the clinical use are lacking.[21] In 2016, our study group applied a systematic, multistage process for translating the CPOT into German including detailed instructions for clinical use[22] (Appendix 1).

WHAT IS KNOWN ABOUT THIS TOPIC

- The Critical-Care Pain Observation Tool has strong evidence for pain assessment in ICU patients who are unable to communicate verbally.
- It was tested in various homogeneous patient populations and is used in ICUs worldwide.
- In German-speaking countries, there is limited availability of a validated pain assessment tool for non-communicative ICU patients.
- There is still a lack of evidence for pain assessment in delirious ICU patients.

WHAT THIS PAPER ADDS

- This is the first validation study of the CPOT to comprehensively assess multiple validity dimensions including feasibility at once in a heterogeneous ICU patient population.
- The previously translated German CPOT version is valid and can be recommended for implementation in ICUs in German-speaking countries.
- Differentiating between symptoms of pain and symptoms of stress/anxiety could be an approach for a more targeted use of neuroleptic or sedative agents and pain medication in ICU patients with delirium.

The aim of this study was to test the German CPOT's feasibility in clinical practice as well as to test its psychometric properties: validity of the tool through criterion validity, discriminant validity, sensitivity and specificity, and reliability of the tool through inter-rater reliability and internal consistency.

2 | METHODS

2.1 | Design, setting, and sample

This observational study, applying a repeated-measures design, was carried out in a 24-bed surgical and a 20-bed medical ICU at the University Hospital Basel in Switzerland. Adult ICU patients with heterogeneous diagnoses became eligible when they were unable to position themselves without the help of a nurse and if at least one

rating with the CPOT was documented in the 24 hours before inclusion. Delirium was not an exclusion criterion: patients with delirium were assessed with the Intensive Care Delirium Screening Checklist (ICDSC) and evaluated in a subgroup analysis.[23]

The exclusion criteria were defined as follows: current muscle relaxation medication, critical illness myopathy and status epilepticus (because of aberrant motor activity), traumatic brain injury (because of aberrant grimacing patterns), end-of-life patients (for ethical reasons), and patients with a Glasgow Coma Scale of 15 (the CPOT is not relevant if patients are conscious, fully oriented, and able to communicate verbally).[24] Clinical ICU nurses, which were part of the study team, recruited the study participants if they met the inclusion criteria and if two trained raters were available.

2.2 | Ethics approval

Because the CPOT and all other assessment scales had already been implemented in the study setting, the study procedures did not comprise in new interventions or burden for the patients. Written consent was obtained either from the patient's next of kin or retrospectively from the patients when they were awake and able to give consent. All data from patients who were not able to give consent themselves or for which consent could not be obtained from the next of kin were excluded from analysis. The responsible ethics committee "Ethikkommission Nordwest- und Zentralschweiz" approved the study (BASEC Reference number: 2017-00925).

2.3 | Variables and measurements

2.3.1 | Clinical and demographic variables

Demographic variables were retrieved from the electronic health record directly before the bedside observations and included gender, age, main diagnosis, respiratory condition, pain medication, ICU length of stay, sedation and agitation ratings (Sedation and Agitation Scale, Richmond Agitation and Sedation Scale), delirium rating (ICDSC), and the Glasgow Coma Scale rating.[25,26]

2.3.2 | Critical-Care Pain Observation Tool

The CPOT includes four behaviours considered to be indicators for pain: facial expressions, body movements, muscle tension, and compliance with the ventilator for intubated patients or vocalization for non-intubated patients. Each behaviour is rated from 0 to 2 resulting in a possible total score ranging from 0 to 8 (with 0 probably representing no pain and 8 probably representing the most severe pain).

2.3.3 | Behavioural pain scale

For criterion validation, the BPS was assessed simultaneously. The BPS consists of three behavioural items (facial expression, movements of the upper limbs, and compliance with ventilation) scored from 1 to 4 giving a total score ranging from 3 to 12 (with 3 probably

representing no pain and 12 probably representing the most severe pain).[27] For patients who were not mechanically ventilated, the behavioural pain scale-non-intubated (BPS-NI) that uses the item vocalization instead of compliance with ventilation was used.[28]

2.3.4 | Self-report of pain

Self-report is regarded as the gold standard for pain measurement and should be combined with pain observations whenever possible. In our study, we assessed the self-reported presence of pain dichotomously (yes/no). If possible, it was assessed by asking for a nod or shake of the head if pain was present or absent in patients who were awake but not able to verbalize. Patients who were able to verbalize were asked for answering yes/no for the presence and absence of pain. No rating scale was used to assess self-report.

2.3.5 | Patients with delirium

All patients were screened for delirium with the ICDSC. In patients who had delirium at study enrolment, the study nurses indicated if they also observed any kind of stress/anxiety. The study nurses judged based on their clinical expertise, individual patient characteristics, and observations of the symptoms (eg, eyes wide open accompanied by stressful awakening or a panic reaction was more likely to be a sign of stress/anxiety). Self-report from patients with delirium (if available) was assessed to test correlation with the CPOT. However, because of possible cognitive dysfunction, these self-reports were not included in the final analysis for testing criterion validity.

2.4 | Data collection

2.4.1 | Phase 1: Feasibility evaluation by nurses

For testing the CPOT's feasibility, a questionnaire was distributed to 27 ICU nurses who had been working with the German CPOT version for 3 years. The questionnaire was developed by two ICU Clinical Nurse Specialists based on face validity. The aim was to evaluate the suitability of the CPOT for clinical use in relation to six feasibility dimensions: brevity (tool can be used in a short time), simplicity (tool is clearly structured and includes simple user instructions), relevance (users acknowledge the meaning and relevance of the tool), availability (tool is disposable and visible), value (benefits of the tool are higher than the costs or the effort), and acceptability (overall acceptance of the tool by users).[29] Each dimension was rated on a 5-point Likert scale: 1 = *strongly disagree*, 2 = *disagree*, 3 = *neither agree nor disagree*, 4 = *agree*, and 5 = *strongly agree*.

2.4.2 | Phase 2: Pain evaluation in patients

Data were collected from September to December 2017 for testing criterion validity, discriminant validity, sensitivity, specificity, inter-rater reliability, and internal consistency of the CPOT. The study team consisted of 25 ICU nurses who routinely worked in the two ICUs where the study was carried out. These 25 nurses received a 1-hour

instruction programme about the study procedure by the first author. Each assessment of the CPOT, BPS, and self-report was simultaneously performed by two raters who were blinded to the other's scoring. The observations were done at four different time points on each patient: at rest (T1), immediately after a non-painful stimulus (a gentle touch of the arm) (T2), during a possibly painful stimulus from routine care (turning procedure) (T3), and 20 minutes after turning (T4). The different assessment time points helped to discriminate between different conditions (non-painful vs painful stimulus) as well as to give enough time to the patients to recover from possible physiological stress caused by pain before performing T4.

2.4.3 | Statistical analysis

Because the initial observations were recorded by hand, the data transcription to an electronic form was tested for quality control. A total of 20% of the cases were randomly selected and crosschecked for errors. Analyses were performed using the SPSS 25.0 software (IBM Corp., Armonk, New York). Frequency distributions were calculated from all 27 feasibility questionnaires. For criterion validity, the CPOT was tested against the established BPS. We correlated both rater's sum scores and calculated the percentage agreement for which they were above or below the predefined cut-off scores (CPOT > 2 and BPS > 5). Concordance between CPOT and self-report was calculated as percentage of agreement. Discriminant validity was examined using a repeated-measures general linear model by comparing CPOT scores obtained during non-painful and painful stimuli. It was hypothesized that CPOT scores would be statistically significantly different between the non-painful stimuli (T1, T2, and T4) and the painful stimulus (T3), but not between adjacent non-painful stimuli (T1 and T2). The time point T3 was used to find the optimal cut-off score. We used receiver-operating characteristic (ROC) curve analysis comparing the performance of the CPOT to that of the BPS to maximize sensitivity and specificity.

Inter-rater reliability was quantified, firstly, by calculating a Spearman's ρ coefficient between the two rater's CPOT sum scores and, secondly, by calculating their percentage of agreement in scoring the patient using the predefined cut-off score of the CPOT (>2). To test the internal consistency of the translated CPOT version, Cronbach's α was calculated for each observation point separately using both raters' values. For the subgroup of patients with delirium and agitation during the observations, the experts' judgements (agitation due to pain or stress/anxiety?) were compared with each CPOT score. Furthermore, the obtained self-reports of some patients with delirium were checked for correlation with the CPOT.

3 | RESULTS

A total of 63 patients were recruited for the study, but three patients were excluded from data analysis because informed consent could not be obtained. A description of the sample characteristics is shown in Table 1.

3.1 | Feasibility

A total of 85% of the feasibility ratings returned "5" (*strongly agree*) or "4" (*agree*) responses. Only the acceptability of the CPOT was rated at "4" or "5" in <70% of responses.

3.2 | Criterion validity

The overall percentage of agreement between the CPOT and BPS was 94.0% (agreement in 451 of 480 observations). The total correlation coefficient for the CPOT and BPS sum scores of the two raters was $\rho = 0.91$ (P < .05). The CPOT showed an overall agreement of 81.4% with self-report, which was assessed in 86 of 480 observations. However, there was an agreement of only 59.1% with self-report at T3. The results are shown in Table 2.

3.3 | Discriminant validity

The measurements between the non-painful and painful stimuli as well as between the non-painful stimuli showed significant changes in mean CPOT scores. There was a statistically significant difference between T1 and T2, showing a difference of CPOT scores of 0.33 (P < .029). We also found statistically significant differences between T1 and T3 with a mean difference of CPOT scores of 2.19 (P < .001) and between T3 and T4 with a mean difference of CPOT scores of 2.38 (P < .001).

3.4 | Sensitivity and specificity

At T3, the CPOT had a sensitivity of 93%, a specificity of 84%, a positive predictive value of 85%, and a negative predictive value of 93%. The area under the ROC curve (AUC) was 0.97 [95% CI 0.93, 1.00] for rater 1 and 0.98 [95% CI 0.95, 1.00] for rater 2. The optimal CPOT cut-off score was >2.

3.5 | Inter-rater reliability

The overall agreement between the two raters was 90% (agreement in 216 of 240 pairwise observations). There was no difference in CPOT sum scores between the raters in 64.2% of observations, a difference of 1 in 22.9% of observations, a difference of 2 in 10% of observations, and a difference of 3 in 2.9% of observations. Correlation of the mean CPOT sum scores of all 240 observations between the two raters was $\rho = 0.72$ (P < .05).

3.6 | Internal consistency

The CPOT demonstrated an internal consistency with an overall Cronbach's α of 0.79. The Cronbach's α at each observation time varied from a minimum of 0.74 at T2 to a maximum of 0.84 at T3.

TABLE 1 Sample characteristics (N = 60)

	n (%)	Mean	SD	Range
Age (in years)		66.32	16.07	17-91
Male	42 (70.0)			
Female	18 (30.0)			
Main diagnosis: surgical	29 (48.3)			
Main diagnosis: medical	31 (51.7)			
Intravenous administration of opiates				
Continuously	18 (30.0)			
Single bolus within 60 min before study	11 (18.3)			
Single bolus during study assessments	6 (10.0)			
Glasgow Coma scale		9.3	3.62	3-14
Richmond Agitation and Sedation Scale[a]	28 (46.7)	−2.36	2.02	−5 to +1
Sedation and Agitation Scale[b]	32 (53.3)	3.63	1.24	1-6
Positive Delirium Screening (ICDSC ≥4)				
Not before and not during observations	32 (53.3)			
Before but not during observations	13 (21.7)			
Before and during observations	15 (25.0)			
Mode of ventilation				
Invasive mechanical ventilation	28 (46.7)			
Non-invasive mechanical ventilation	10 (16.7)			
No artificial airway	20 (33.3)			
Tracheostomy tube, not mechanically ventilated	2 (3.3)			
ICU LOS at assessment time (d)		4.28	3.65	0.1-13.6
Main diagnosis				
Sepsis	15 (25.0)			
Respiratory failure	10 (16.7)			
Post-cardiopulmonary resuscitation	5 (8.3)			
Subarachnoid/subdural haemorrhage	5 (8.3)			
Other infectious diseases	5 (8.3)			
Neurological diseases	5 (8.3)			
Post-cardiac surgery	3 (5.0)			
Intoxication	2 (3.3)			
Other	10 (16.7)			

Abbreviation: LOS, length of stay.
[a]Used in the medical ICU.
[b]Used in the surgical ICU.

3.7 | Subgroup analysis in patients with delirium

A total of 15 patients had delirium (ICDSC ≥ 4) from at least 5 hours before the study observations to any time point between T1 and T4.

TABLE 2 Criterion validity

	CPOT vs BPS		CPOT vs self-report (if available)
	Rate of agreement[b]	Spearman's ρ correlation coefficient[c]	Rate of agreement[b]
T1[a]	96.7% (116/120)	r = 0.87	95.5% (21/22)
T2	94.2% (113/120)	r = 0.90	91.7% (22/24)
T3	88.3% (106/120)	r = 0.95	59.1% (13/22)
T4	96.6% (116/120)	r = 0.92	77.8% (14/18)
Total mean	94.0% (451/480)	r = 0.91	81.4% (70/86)

[a]T = time of observation.
[b]Agreement was calculated with sum score both below or both above predefined cut-off scores of CPOT (>2) and BPS (>5) or self-report.
[c]Correlation of CPOT and BPS sum scores $P < .05$.

This resulted in 120 CPOT observations in patients with delirium. When pain was present according to the CPOT, expert judgement was congruent with the CPOT in 50% of cases. If pain was not present according to the CPOT, expert judgement was congruent with the CPOT in 75% of cases. Self-report was obtained in 13 of 15 patients with delirium and did not correlate with the CPOT rating in 62% of these patients.

4 | DISCUSSION

In this observational study, we tested the German version of the CPOT in a surgical and medical ICU population. The results show excellent criterion validity, good discriminant validity, high sensitivity, and specificity, and that nurses were highly satisfied with the clinical usability. The German CPOT also showed acceptable internal consistency and a high inter-rater reliability. To our knowledge, this is the first validation study of the CPOT in any language to comprehensively assess multiple validity dimensions including feasibility at once.

Our feasibility evaluation of the CPOT demonstrated a high clinical usability. The only feasibility dimension that was not rated as high was acceptability. Participating nurses reported that the CPOT was initially not well accepted by the physicians, which may explain the low acceptability rating. The different requirements, experiences, and scope of practice in pain management between nurses and physicians have been well described.[30-32] A possible reason for the CPOT's more rapid integration into nursing protocol is that, as previously described by Erlenwein et al,[30] they are often more directly confronted with patients' pain. Therefore, the benefit of reporting pain based with the CPOT following adequate pain treatment might be more obvious to the nurses.

The CPOT revealed excellent criterion validity with a very high percentage of agreement between the CPOT and BPS, a strong correlation of the CPOT and BPS sum scores of the two raters as well as a good agreement of the CPOT with patient self-report. The CPOT and BPS are the best validated tools for non-communicative ICU patients

and have been tested together in recent research.[33] Using these two pain assessment tools simultaneously for criterion validation was possible. However, using them in combination to improve accuracy of pain assessment, as reported by Severgnini et al.,[34] does not seem feasible for routine care to our experience. Although self-report was often consistent with the CPOT assessments, we observed difficulties in assessing self-report in patients who were not awake enough due to sedation or illness. The low agreement of the CPOT with patient self-report at T3 could also be because a combination of both pain and stress/anxiety is present, limiting the patient's ability to give an adequate self-report. Assessing self-report in ICU patients was found to poorly correlate with various behavioural pain scales.[35] Therefore, if self-report is difficult to obtain, further steps in pain treatment should be guided by the CPOT score and can be complemented by an analgesic trial as supported by the American Society of Pain Management Nurses.[9]

With regard to discriminant validity, our results show a small but significant difference in mean CPOT scores between T1 and T2. A patient's reaction from being woken by a small stimulus after a longer period of rest may be falsely interpreted as pain and result in a slight but clinically irrelevant increase of the score. More important is the result of a highly significant difference between at rest and the painful stimulus as well as between the painful stimulus and the non-painful moment 20 minutes after turning. The original creators of the CPOT define turning/positioning as the painful stimulus, which is why this was integrated in our study. There are various CPOT validation studies using different painful stimuli, which also show significant discriminant validity results.[11,36-38]

Sensitivity and specificity of the CPOT was high in our study. The tool was effective for the assessment of pain. A cut-off score of >3 was reported by the original author of the CPOT.[39] More recent validation work showed that a cut-off score of >2 resulted in the best sensitivity and specificity, which is also supported by our findings.[40]

Kanji et al[11] described the importance of inter-rater reliability in standardizing pain assessment in the ICU, where multiple clinicians must reliably assess pain in non-communicative patients. Clinicians often rely on a pain assessment tool and treat based on a defined cut-off score. Our results show small differences in CPOT sum scores between raters indicate that inter-rater reliability was high. Because the tool relies on special instruction, implementing the CPOT in a new setting should always be accompanied by a good training of the users.[41]

We describe acceptable internal consistency for all four items of the CPOT. Our overall Cronbach's α of 0.79 was similar to those obtained by other authors who reported values ranging from 0.71 to 0.81.[11,38,42,43]

Only 25% of participants had a positive delirium screening including agitation during at least one assessment time point. The expert judgement was often not congruent with the CPOT score, indicating how challenging it is to assess pain in patients with delirium. In delirious ICU patients, there is a potential for overestimating pain with the CPOT. Maybe the CPOT's sensitivity in delirious patients differs significantly compared with those without delirium. Besides the CPOT and BPS, there are no other validated pain assessment instruments that have been tested in critically ill patients with delirium.[11,28] Our findings show that the self-report, which was obtained in 13 of 15 patients with delirium, did not match with the CPOT scores in 62% of the patients. Delirium-specific neural dysfunctions including a reduced awareness of the environment is well described.[44] This explains why self-report from many ICU patients with delirium can be obtained but is regarded not to be valid. Differentiating between symptoms of pain and symptoms of stress/anxiety could be an approach for a more targeted use of neuroleptic or sedative agents and pain medication in ICU patients with delirium.

New trends in research (eg, translational research, pragmatic trials, and real-world evidence) tend to generate evidence in a pragmatic way based on existing clinical practice as well as to generate and share evidence that is directly relevant to clinical practice.[45-47] Our approach aimed at validating the German CPOT version in a routine care setting with a heterogeneous sample with the goal of making it available in German-speaking countries as soon as possible. We chose this approach because the CPOT has already been tested in various patient populations and is used in ICUs worldwide. Validating tools in various homogeneous samples takes more time and implies more effort for research. The generalizability of our results may be limited because of the sample size and heterogeneity. However, our results are congruent with previous validations of the CPOT with homogeneous samples and show that it is possible to validate the German CPOT version with a heterogeneous sample.

Further limitations to our study include, firstly, that although the distributions of most of the sample characteristics were ideal, in a sample of 60 patients, our results with delirious patients should be interpreted with caution and require further investigation with larger samples. Secondly, the last observation time point (T4) was brought forward in some cases when a clinical intervention was necessary. Thirdly, the generalizability of our findings is further limited because it was a monocentric study.

Our study is one of the few studies that addresses the topic of pain assessment in delirious ICU patients in a subgroup analysis. In this population, a comprehensive approach may improve pain assessment and management: considering a patient's individual history and previous behaviour as well as looking at specific symptoms, which can help to differentiate (as described above), can be performed to assess pain in addition to an assessment with the CPOT.

5 | CONCLUSION

Non-communicative adult ICU patients are vulnerable to inadequate pain management, which has been shown to have severe consequences. All ICU patients who cannot communicate should be assessed with a validated pain assessment tool. In German-speaking countries, no validated tool is currently available. This study shows that the previously translated German CPOT version is valid and our results are congruent with previous research with the CPOT. We believe that the German CPOT version can be recommended for implementation in ICUs in German-speaking countries. Further

research should be done to improve pain assessment and treatment in ICU patients with delirium.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest. The copyright for the original French CPOT version is owned by the author and developer of the tool: Dr Céline Gélinas. The copyright for the original English version is owned by the American Journal of Critical Care and the American Association of Critical Care Nurses (AACN). The published German version may be used to improve the pain treatment of intensive care patients with the permission of Dr Céline Gélinas and the AACN as long as no commercial interests are involved.

AUTHOR CONTRIBUTIONS

C.E. takes responsibility for the content of the manuscript and contributed to the previous translation process, study protocol, data analysis and interpretation, preparation, writing, and submission. U.B.S. contributed to the previous translation processes, data collection, and study protocol. K.D. contributed to the study protocol and data analysis. M.K. and F.G. contributed to the study protocol, data interpretation, and writing of the manuscript. I.A.F. contributed to the authorization of rights for the previous translation and to the writing of the manuscript. All authors discussed the results and contributed to the final manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.