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SCIENTIFIC ARTICLE

Validation of the Brazilian version of Behavioral Pain Scale in adult sedated and mechanically ventilated patients

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Abstract
Background and objectives: The Behavioral Pain Scale is a pain assessment tool for uncommunicative and sedated Intensive Care Unit patients. The lack of a Brazilian scale for pain assessment in adults mechanically ventilated justifies the relevance of this study that aimed to validate the Brazilian version of Behavioral Pain Scale as well as to correlate its scores with the records of physiological parameters, sedation level and severity of disease.
Methods: Twenty-five Intensive Care Unit adult patients were included in this study. The Brazilian Behavioral Pain Scale version (previously translated and culturally adapted) and the recording of physiological parameters were performed by two investigators simultaneously during rest, during eye cleaning (non-painful stimulus) and during endotracheal suctioning (painful stimulus).
Results: High values of responsiveness coefficient (coefficient = 3.22) were observed. The Cronbach's alpha of total Behavioral Pain Scale score at eye cleaning and endotracheal suctioning was 0.8. The intraclass correlation coefficient of total Behavioral Pain Scale score was $\geq$0.8 at eye cleaning and endotracheal suctioning. There was a significant highest Behavioral Pain Scale score during application of painful procedure when compared with rest period ($p \leq 0.0001$). However, no correlations were observed between pain and hemodynamic parameters, sedation level, and severity of disease.

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Conclusions: This pioneer validation study of Brazilian Behavioral Pain Scale exhibits satisfactory index of internal consistency, interrater reliability, responsiveness and validity. Therefore, the Brazilian Behavioral Pain Scale version was considered a valid instrument for being used in adult sedated and mechanically ventilated patients in Brazil.

PALAVRAS-CHAVE
Estudos de validação (tipos de publicação);
Mensuração da dor;
Unidades de terapia intensiva;
Escala de Dor Comportamental;
EDC brasileira

Validação da versão brasileira da Escala Comportamental de Dor (Behavioral Pain Scale) em adultos sedados e sob ventilação mecânica

Resumo
Justificativa e objetivos: A Escala Comportamental de Dor (*Behavioral Pain Scale*) é uma ferramenta de avaliação da dor para pacientes não-comunicativos e sedados em unidade de tratamento intensivo (UTI). A falta de uma escala brasileira para a avaliação da dor em adultos sob ventilação mecânica justifica a relevância deste estudo que teve por objetivo validar a versão brasileira da Escala Comportamental de Dor (ECD), bem como correlacionar seus escores com os registros de parâmetros fisiológicos, nível de sedação e gravidade da doença.
Métodos: Vinte e cinco pacientes adultos internados em UTI foram incluídos neste estudo. A versão brasileira da ECD (previamente traduzida e adaptada culturalmente) e os registros dos parâmetros fisiológicos foram realizados simultaneamente por dois avaliadores durante o repouso, durante a limpeza dos olhos (estímulo não doloroso) e durante a aspiração endotraqueal (estímulo doloroso).
Resultados: Valores elevados do coeficiente de coeficiente de responsividade (coeficiente = 3,22) foram observados. O coeficiente alfa de Cronbach do escore total da ECD durante a limpeza dos olhos e aspiração endotraqueal foi de 0,8. O coeficiente de correlação intraclasse do escore total da ECD foi $\geq$ 0,8 durante a limpeza dos olhos e aspiração endotraqueal. Houve um escore significativamente mais alto na ECD durante a aplicação do estímulo doloroso em comparação com o período de descanso ($p \leq 0{,}0001$). No entanto, não foram observadas correlações entre dor e parâmetros hemodinâmicos, nível de sedação e gravidade da doença.
Conclusões: Este estudo pioneiro de validação da ECD brasileira apresenta índices satisfatórios de consistência interna, confiabilidade entre avaliadores, Responsividade e validade. Portanto, a versão da ECD brasileira foi considerada um instrumento válido para ser usado em pacientes adultos sedados e ventilados mecanicamente no Brasil.

Introduction

Critically ill patients frequently experience pain and discomfort during Intensive Care Unit (ICU) stay. ICUs are specialized centers where subjects are exposed to different factors which causes acute pain including routine procedures,[1–5] such as endotracheal suctioning, turning, peripheral and central intravenous puncturing.[6] Thus, pain assessment and treatment in mechanically ventilated ICU patients have been considered important and studied in last two decades.[7]

The Society of Intensive Care Medicine recommends that pain should be routinely monitored in all adult ICU patients.[8] Patient's self-reports of pain, physiological parameters and scales based on typical behaviors constitute available methods in the assessment of pain. However, critically ill patients are often unable to effectively communicate due to severe illness, mechanical ventilation, administration of sedatives and analgesics or a decreased level of consciousness.[4,9,10] On the other hand, patients may be evaluated by physiological parameters and through the use of scales based on typical behaviors. However, physiological parameters, such as blood pressure, heart rate, peripheral oxygen saturation and respiratory rate appear to be less valid for pain assessment in ICU patients due to underlying disease and treatment with inotropes and vasopressor medicines.[11–13] Therefore, the Society of Intensive Care Medicine advises the use of pain assessment tools that focus mainly on behavioral indicators of pain.[8]

In this context, in order to quantify pain in mechanically ventilated patients, Behavioral Pain Scale (BPS) was firstly validated in English.[6] The BPS was translated in four languages[6,14–16] and validated just in two of them.[6,15] Several studies have shown that BPS is reliable and responsive.[10,17–25] Despite the importance of pain assessment in ICU nonverbalizing patients, there is a lack of Brazilian studies on

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this topic. This occurs because the nonexistence of validated scales in Brazilian Portuguese to measure pain in ICU patients. In Brazil, the BPS was firstly translated to Brazilian Portuguese in a preliminary study recently published by our group.[26] It was applied in mechanically ventilated patients showing to be very promising as a tool for measuring pain in Brazilian ICU patients. Thus, the importance of pain measurement in non-verbal patients hospitalized in ICUs and the absence of a validated Brazilian scale for this purpose highlights the relevance of this study. Taking into account the potential of the BPS to measure pain in mechanically ventilated patients,[26] this study aimed to analyze the reliability, responsiveness and validity of the translated BPS to Brazilian Portuguese.

Methods

Sample

We performed a cross-sectional study with a repeated measurement design in 25 sedated and mechanically ventilated subjects admitted at a cardiac ICU of a public hospital. Sample size was estimated based on a precision of Cronbach α as 0.90 ± 0.05 for a scale with 3 subscales as BPS. Thus, a minimum of 25 subjects should be assessed in this study.[18] All subjects were legally represented by their conservators, who have signed the term of consent, once they were unconscious or in use of sedative medicines. The Federal University of Sergipe and hospital ethical committees approved the study protocol.

Patients who were sedated and unconscious, in use of mechanical ventilation and in the postoperative period (immediate or delayed) of Coronary Artery Bypass Graft (CABG) or Valve Surgery (VS) were included in our sample. Exclusion criteria considered those with age less than 18 years old and/or with one of these conditions that could change behavioral expressions: quadriplegia, peripheral neuropathy, stiffness due to decortication or decerebration or in use of neuromuscular blockers during the assessment.

Validation methodological procedures

The Brazilian version of BPS was developed after validation process based on pre-established procedures[27,28] as shown in Fig. 1.

The first five procedures (from authorization to pretesting) were performed in the preliminary study published by our group.[26] Due to the occurrence of doubts and discrepancy among investigators regarding the adequacy of the meanings of each item to clinical practice during pretesting, a second expert committee review was done. After this review and consensus, the ''Brazilian BPS application guide'' was created with explications and practice adequacy of the sub-items (See Supplemental Digital Content, which is a text document with Brazilian BPS guide).

Training of the ICU staff

For final version test phase, four professionals from the ICU staff (three physical therapists and one nurse) were recruited and trained to participate as investigators in this study. They individually read Brazilian BPS application guide before data collection to standardize the assessment. Explanations for any doubts were done to avoid bias on items interpretation.

Each of these health professionals had specific activities during the evaluation. The physical therapists were responsible for pain assessment (register of BPS scores simultaneously by two of them) and physiological parameters recording (multimodal monitor observation), while the nurse performed the routine procedures (painful and non-painful). For reliability measurement, they could not keep any kind of communication between them during this process.

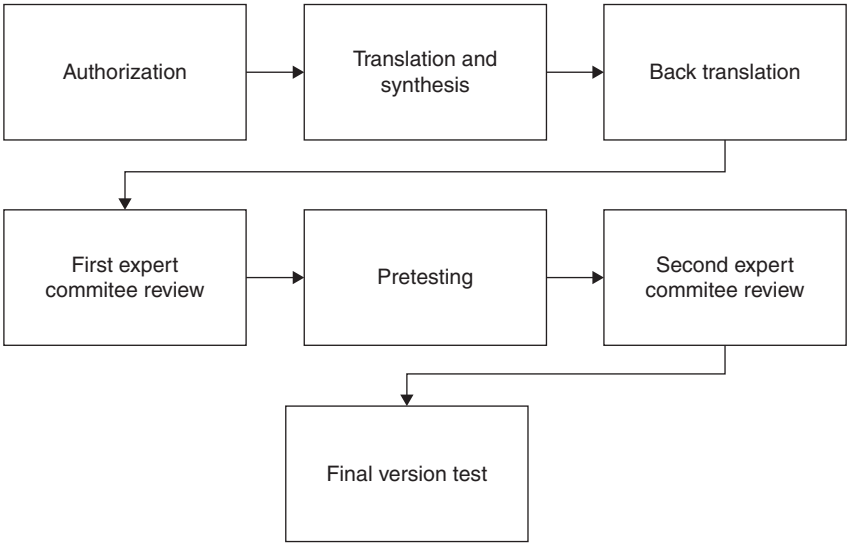

Figure 1 Validation methodological procedures for Brazilian Behavioral Pain Scale.

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Data collection

Before pain assessment, baseline data as age, sex, clinical diagnoses, use of sedative and/or analgesics and severity of disease (APACHE II score)[29] was recorded based on medical record information. Patient's sedation level was assessed by using both Ramsay and RASS scales.[30–32] These tools were chosen to establish the inability of subjects to verbalize caused by sedative drugs effects.

Study procedures

Pain assessment with Brazilian BPS occurred in three different moments: at rest (stable subject in bed), during Eye Cleaning (EC) with cotton soaked in saline 0.9% (non-painful procedure)[24] and during Endotracheal Suctioning (ETS) with the catheter insertion on the airway (painful procedure)[24,26,33–35] In addition to pain scores, hemodynamic parameters were recorded during the three phases of evaluation. Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Blood Pressure (MBP), HR and SpO_2 were measured through non-invasive methods.

Table 1 Demographic data ($n = 25$ subjects).

Variable	Specification
Age (years)	60 ± 2.1[a]
Sex	
Male	10
Female	15
Surgery type	
VS	12
CABG	13
Postoperative period	
Immediate	16
Delayed	9
RAMSAY	4.9 ± 0.21
RASS	-3.8 ± 0.24
APACHE II	19.12 ± 0.89[a]

VS, valve surgery; CABG, coronary artery bypass graft; Immediate, 1 h after surgery; Delayed, 24 h after surgery.
[a] Data is represented as mean ± standard error of mean or absolute frequency, when relevant.

Statistical analysis

Data were analyzed with SPSS Statistics version 22.0 (SPSS, Inc., Chicago, IL) and Graph Pad Prism 5 (GraphPad Software, Inc., La Jolla, CA). Baseline data were represented as mean ± standard error of mean. *t*-Test and Fisher exact test compared the type of surgery and postoperative period data.

Reliability, responsiveness and validity were the psychometric properties analyzed on Brazilian BPS version. Interrater reliability of the BPS was tested by the calculation of Intraclass Correlation Coefficients (ICC) and internal consistency was assessed with Cronbach's coefficient α. These were calculated for Brazilian BPS total scores and for each sub-item during EC and TS. Values between 0.70 and 0.80 were considered as acceptable, and values >0.8 as good.[36,37]

Responsiveness is the capacity to detect significant changes over time. This coefficient was obtained by dividing the difference between the mean scores of the Brazilian BPS at rest and during painful procedures by the Standard Deviation (SD) of the mean scores at rest. A coefficient value higher than 0.8 was considered satisfactory.[38]

The ability of a scale to measure what it intends characterizes the instrument validity. It was established in three ways: construct, criterion and content. Pain scores were not normally distributed, and therefore, nonparametric statistical tests were applied. Spearman correlation was calculated to compare Brazilian BPS scores during ETS with physiological parameters, Ramsay, RASS and APACHE II scores (construct validity), while Friedman's test followed by Dunn post hoc test was used to analyze pain score differences over the assessment moments (criterion validity). Semantic, idiomatic, conceptual and practical review of Brazilian BPS items by an expert committee at pre-test phase and final version test consisted on content validity analysis.[28]

Hemodynamic data were normally distributed, thus to determine changes on physiological parameters over time (at rest, during EC and ETS) one way ANOVA for repeated measures was performed. Only subjects with complete evaluation recordings were suitable for analysis. Significance for all statistical tests was set at $p \leq 0.05$.

Results

Twenty-five patients were included in this sample study. Baseline data (age, sex, surgery type, postoperative period, APACHE II score) are presented in Table 1.

There was no significant difference between subjects undergone to VS or CABG in the immediate or delayed postoperative period ($p \geq 1.0$). Similarly, it was not verified influence of surgery type and postoperative period on sedative and severity of disease parameters ($p \geq 0.05$). Thus, the surgery type and postoperative period did not influence the results.

All patients were sedated in continuous infusion (midazolam and fentanyl) at the evaluation moment, one hour (immediate period) or more than forty-eight hours (delayed period, 5 ± 1.2 days) after surgery procedure. Neuromuscular blockers and analgesic drugs were not administered at the 8 hours previously to the assessment, to not interfere with the data collected.

Reliability

Considering the satisfactory established values for Cronbach α,[36] a high relation between the scales items (internal consistency) occurred in EC and ETS procedures (Cronbach $\alpha = 0.8$, each).

At the same way, high values of ICC were obtained for Brazilian BPS total scores during EC (ICC = 0.8) and ETS (ICC = 0.9). For sub-items scores, the analysis resulted in higher concordance and reliability between

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Table 2 Physiological variables at the three assessment moments with Brazilian Behavioral Pain Scale.

Variable	Rest	Eye cleaning	Endotracheal suctioning	*p*-Value[a]
SBP (mmHg)	122.4 ± 3.6	119.4 ± 3.8	123.4 ± 4.2	0.5
DBP (mmHg)	71.5 ± 2.8	69.7 ± 3.9	73.1 ± 3.9	0.4
MBP (mmHg)	82.4 ± 3.1	81.3 ± 3.8	82.8 ± 4.0	0.8
HR (bpm)	82.7 ± 4.0	85.8 ± 4.7	84.7 ± 4.2	0.4
SpO_2	97.4 ± 0.3	96.3 ± 0.8	97.2 ± 0.3	0.2

SBP, systolic blood pressure; DBP, diastolic blood pressure; MBP, mean blood pressure; HR, heart rate; SpO_2, peripheral oxygen saturation.
[a] $p \geq 0.05$ (one way ANOVA for repeated measures).
Data were represented as mean ± standard error of mean.

the investigators for facial expression items during these moments (ICC ≥ 0.8).

Responsiveness

The coefficient calculated resulted in a good capacity to detect pain intensity changes over time. The value obtained was 3.22, considered a high effect for a scale.[38]

Validity

Change in physiological variables is shown in Table 2. There was not a significant increase in all physiological variables when these values were compared at rest, EC and ETS. Construct validity was evaluated by correlations between pain scores and physiological parameters, sedation and severity of disease levels. These correlations were non-significant (Table 3).

For criterion validity, the comparison of pain scores over time was done. Fig. 2 shows that Brazilian BPS final score was significantly higher during painful procedure (TS) than at rest ($p \leq 0.0001$).

Table 3 Correlation between Behavioral Pain Scale scores during painful procedures and physiological parameters, sedation and severity of disease levels.

	Tracheal suctioning	
	BPS score	
	CC	*p*-Value
SBP	0.35	0.86
DBP	−0.83	0.69
MBP	−0.17	0.93
HR	−0.30	0.89
SpO_2	0.11	0.61
RAMSAY	−0.34	0.10
RASS	0.32	0.12
APACHE II	−0.03	0.89

CC, Spearman correlation coefficient; SPB, systolic blood pressure; DBP, diastolic blood pressure; MBP, mean blood pressure; HR, heart rate; SpO_2, peripheral oxygen saturation; RASS, Richmond Sedation-Agitation Scale; APACHE, Acute Physiology Health Chronic Evaluation.

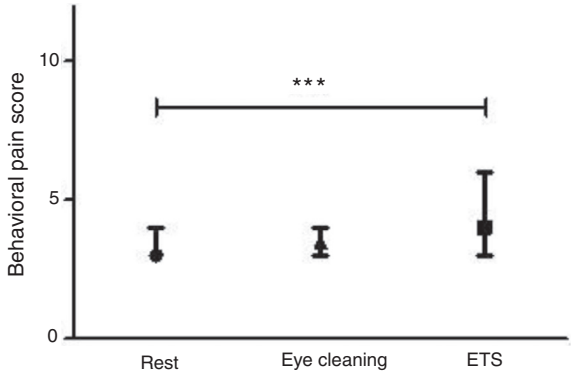

Figure 2 Behavioral Pain Scale score changes over time: at rest, during eye cleaning and during endotracheal suctioning. Values were represented as median, 25th and 75th percentile. *$p \leq 0.0001$ between rest and endotracheal suctioning (Friedman's test and Dunn post hoc test). ETS, endotracheal suctioning.

Discussion

This pioneer validation study of Brazilian Behavioral Pain Scale exhibits satisfactory index of internal consistency, interrater reliability, responsiveness and validity. Furthermore, non-significant correlations between pain intensity and physiological parameters, sedation and severity of disease levels suggest that this pain assessment tool is a powerful instrument to detect pain in Brazilian ICU patients.

Validity of Brazilian BPS was demonstrated by a significant increase of the scores during painful procedure (ETS). It was evidenced higher pain intensity during ETS compared to rest, which proves the instrument capacity to discriminate pain.[18] These changes over the three assessment times is a parameter that indicates criterion validity and was used on previous studies of this scale in other languages.[10,14,15,17–25,39]

The ability to detect important changes on pain intensity over time corresponds to responsiveness. This psychometrical property was considered excellent for Brazilian BPS version with high and representative coefficient for this sample. In the same way, Aïssaoui et al.[18] evidenced high responsiveness coefficient and applicability of English BPS. In our study, during EC, Brazilian BPS score was 1 point higher than at rest, but was not significant. This variation on behavioral parameters can be justified by patient's reaction to the touch done by the investigator, which does not consist in a body response to pain. This result coincides with

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the observation of non-significant increases of pain scores measured with BPS during catheter dressing change,[6] body temperature measurement[15] and eye care[24,39] when compared to rest. Contrarily, Rijkenberg et al.[22] observed a significant increase of total score between rest and the non-painful procedure (oral care) as well as painful procedure (turning) in a critically ill subjects.[22]

The correlation of BPS scores with physiological data, sedation and severity of disease were not observed in the present study. Values of heart rate, blood pressure and saturation were not significantly higher during ETS as hypothesized. Oppositively, Payen et al.[6] and Aïssaoui et al.[18] indicated an increase on blood pressure and heart rate during painful procedure. Farther these authors found an inversely correlation between sedation level and pain scores recorded by the original BPS version. In this context, Young et al.[24] affirmed that in addition to sedative and analgesic drugs, tracheostomy and surgery procedure influenced on pain intensity measured by BPS.

It is recommended to record hemodynamic parameters only as a complement for pain assessment or when behavioral indicators are not present on the bedside.[11] The failure to prove criterion validity of these variables measured in ICUs sustains this recommendation.[12] Thus, in the current study was not observed a significant correlation between pain score and vital parameters probably due to the lower specificity of these variables.

Reliability results were considered satisfactory during EC and ETS as showed in other BPS validation studies.[6,15,18,20,24] Higher ICC values (interrater reliability) were observed on the sub-item ''Facial Expression''. The highest agreement between the investigators in this item may be linked to the familiarity for them to analyze facial changes (specific movements of the eyes, eyebrows, cheeks and lips), a common activity for human subjects who observe facial expressions daily.[40] Recently published evidence supports the findings of our study when affirms that facial expressions are accentuated during endotracheal suctioning.[19] Eyebrows raised, nose wrinkling and head turned right and up are movements that indicates pain in non-verbally patients.[19] This result encourages the facial expression analysis to quantify pain.

The relevance of this study for clinical practice consists on the applicability of a validated scale to measure pain in Brazilian ICUs. The ease of use, low cost and feasibility in Portuguese can contribute to the establishment of pain assessment and management protocols by ICU professionals from Brazil.

In summary, this study provides evidence that Brazilian BPS presents good interrater reliability, internal consistency, validity and responsiveness. Non-significant correlation between BPS scores and the other variables reinforces the no ability of the vital parameters to measure pain. Therefore, pain assessment and management in Brazilian ICUs is encouraged, by using valid scales, improving critically ill care and consequently promoting physical and social well-being.

Further studies involving different ICU samples are required to prove reproducibility of Brazilian BPS. Moreover, these studies can contribute to reinforce the importance of adequate assessment for a good management of pain by health care professionals responsible for critically ill adults in Brazil.

Summary

Brazilian BPS presents good interrater reliability, internal consistency, validity and responsiveness. It consists in the first validated instrument to assess pain in Brazilian ICUs.

Conflicts of interest

The authors declare no conflicts of interest.

Acknowledgments

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