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A comparison of gradual sedation levels using the Comfort-B scale and bispectral index in children on mechanical ventilation in the pediatric intensive care unit

Comparação dos níveis de sedação graduados pela escala Comfort-B e pelo índice biespectral de crianças em ventilação mecânica na unidade de terapia intensiva pediátrica

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ABSTRACT

Objective: Compare the scores resulting from the Comfort-B scale with the bispectral index in children in an intensive care unit.

Methods: Eleven children between the ages of 1 month and 16 years requiring mechanical ventilation and sedation were simultaneously classified based on the bispectral index and the Comfort-B scale. Their behavior was recorded using digital photography, and the record was later evaluated by three independent evaluators. Agreement tests (Bland-Altman and Kappa) were then performed. The correlation between the two methods (Pearson correlation) was tested.

Results: In total, 35 observations were performed on 11 patients. Based

on the Kappa coefficient, the agreement among evaluators ranged from 0.56 to 0.75 ($p < 0.001$). There was a positive and consistent association between the bispectral index and the Comfort-B scale [$r = 0.424$ ($p = 0.011$) to $r = 0.498$ ($p = 0.002$)].

Conclusion: Due to the strong correlation between the independent evaluators and the consistent correlation between the two methods, the results suggest that the Comfort-B scale is reproducible and useful in classifying the level of sedation in children requiring mechanical ventilation.

Keywords: Respiration, artificial/methods; Monitoring, physiologic/instrumentation; Conscious sedation; Electroencephalography/instrumentation; Child; Intensive care units, pediatric

INTRODUCTION

The management of critically ill children admitted to pediatric intensive care units (ICUs) is usually invasive and aggressive, including numerous traumatic and painful procedures that, in addition to causing pain, result in agitation, anxiety, and stress for the child.⁽¹⁾

Sedation and analgesia are therefore needed to treat these patients. Sedation seeks to reduce the anxiety and agitation affecting the child, who is faced with a hostile environment and intense manipulation, whereas analgesia aims to reduce or even eliminate the pain caused by invasive techniques or by the disease itself.⁽²⁾

In patients requiring mechanical ventilation (MV), the combined use of analgesics and sedatives also results in better adaptation to the ventilation due to its depressant effects on breathing and cough reflexes and its hypnotic effect.⁽²⁾

Conflicts of interest: None.

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Defining the best strategy for controlling pain and anxiety depends on an accurate evaluation of the needs of each patient. Thus, frequent evaluations are essential in ascertaining the level of sedation of patients.^(3,4)

Inaccurate evaluations of the level of sedation can lead to excessive or insufficient sedation. Excess sedation can result in hemodynamic instability, delayed ventilation weaning and increased morbidity and mortality, whereas insufficient sedation can lead to self-extubation, asynchrony between the patient and ventilator, and the unwanted or accidental loss of the devices used for patient monitoring and adjuvants in their treatment.⁽⁵⁾

The use of protocols to assist in selecting and administering sedatives and analgesics and careful patient monitoring can improve the quality of sedation and analgesia while helping to prevent their adverse side-effects.⁽²⁾

One of the most commonly used tools in assessing the level of sedation in pediatric patients is the Comfort scale,⁽⁶⁾ which consists of eight factors, six of which are behavioral and two physiological (baseline heart rate and blood pressure). Studies^(7,8) have reported that the physiological factors may be affected by the patient's hemodynamic condition or medications used in his/her treatment, and thus, they may not reflect the patient's true level of sedation, comfort or discomfort. It has therefore been recommended that only the six behavioral factors be used, giving rise to the Comfort Behavioral or Comfort-B scale, as it is now known. Amoretti et al.⁽⁹⁾ validated the Comfort B-scale for the Portuguese language.

In addition to the clinical scales, we currently rely on monitoring the level of consciousness using the bispectral index (BIS), which is an objective indicator determined using a monitor that turns electrical EEG signals into a numeric value. This index has been used during the perioperative period, but it has also been suggested for use in the ICU, as it determines the patient's level of consciousness and their real sedation needs.⁽¹⁰⁾

Previous studies have compared the Comfort scale and BIS scores and have reported a correlation ranging from fair to strong between the two methods.⁽¹⁰⁻¹³⁾ This study was performed to compare the ability of the Comfort-B scale and the BIS scores in evaluating the level of sedation of children hospitalized in a pediatric ICU who require MV and the use of sedative medication.

METHODS

This was a descriptive, observational, cross-sectional study in which children hospitalized in the pediatric ICU of the *Hospital de Clínicas de Porto Alegre* (HCPA) were included. The patients were between 1 month and 16 years of age and required MV and sedative therapy. Patients who had any physical or mechanical condition that would prevent the placement of electrodes to determine the BIS, who had a history of hypoxic-ischemic injury during their current hospitalization, or who were administered continuous ketamine were excluded. Data collection was suspended for 4 and 6 hours for those patients who, as part of the sample, received bolus doses of ketamine or neuromuscular blockers.

In the validation study of the Comfort-B scale for the Portuguese language, Amoretti et al.⁽⁹⁾ used two examiners and performed reproducibility and internal consistency tests. In this study, working with the previously validated scale, we chose to test the agreement among four independent evaluators in terms of the sedation classification they gave. None of the evaluators participated in any training or standardization procedure on the Comfort-B scale. No evaluator was considered a control, although the first evaluator performed the scale testing directly with the patients, whereas the other evaluators watched videos of the patients. For the scale item that refers to "muscle tone", the first evaluator was able to test it, and the other evaluators were asked to use his/her evaluation of this item for their classification and were only able to observe the test being performed on video and the stance taken by the patient at the time the patient was filmed. All patients received only one Comfort-B evaluation in each of the videos analyzed.

Data were collected from September 2008 to September 2009.

Comfort-B scale

The Comfort-B scale used in this study is a behavioral clinical scale that consists of six factors: alertness, calmness/agitation, respiratory response (or crying, used in patients with no MV), physical movement, muscle tone, and facial tension.⁽⁹⁾ Each factor can be scored with values ranging between 1 and 5, generating scores between 6 and 30 points. Scores between 6 and 10 indicate oversedation; scores between 11 and 23 indicate a moderately sedated patient; and scores between 24 and 30 indicate little sedation.⁽¹⁴⁾

Bispectral index

BIS measurements were performed using a BIS monitor, A2000XP model from Aspect® (manufactured by Covidiem, USA). The electric waves from the EEG are captured using a sensor with four electrodes attached to the front of the patient and connected to the monitor via a cable. The monitor processes the information and uses a computer algorithm to convert the information into data that are continuously updated on a screen. The BIS provides an absolute number that reflects the patient's state of consciousness. BIS values range from zero to 100, where zero corresponds to the complete suppression of the EEG and 100 to a fully awake patient.⁽¹⁵⁾ Indexes above 80 indicate mild sedation; indexes between 60 and 80 indicate moderate sedation; indexes between 40 and 60 indicate deep sedation; and indexes below 40 indicate very deep sedation.⁽¹⁰⁾

The HCPA Research Ethics Committee approved this study, and the hospitalized patients were selected and included in the study after their legal guardians signed an informed consent form. By signing the document, the legal guardians authorized the patients' participation in the study and the use of their images filmed during the data collection and evaluation period.

After inclusion in the study and skin preparations (cleansing with 70% alcohol), the participants were monitored with the BIS sensor. The signal was captured using a monitor and analyzed for its impedance and quality. If the monitor detected a signal level less than 50%, the sensor was repositioned.

The BIS monitoring tracked the patient while the child was videotaped for subsequent classification of the sedation level using the Comfort-B scale, according to behavior. Filming lasted 2-3 minutes at a minimum of 1-hour intervals, at which time the BIS index monitoring results were also collected. Each participant was filmed several times, depending on clinical stability and their need for the withdrawal of sedation and/or MV.

To assess the reproducibility and reliability of the Comfort-B scale, four experts, including two doctors and two nurses, simultaneously and independently applied the scale, observing the child's behavior and classifying the level of sedation. One observer applied the scale at the time of filming, and the 3 other evaluators used the film reproduction. The first observer collected the BIS index values and set up the data collection instrument. The last three observers were blinded to the

BIS index of the patient, as well as the Comfort-B scale evaluations from the other evaluators. Subsequently, the sedation levels reported by the four evaluators were compared to each other and to the BIS index values recorded during the filming. Using a minimum correlation of 0.5 between the methods and an 80% power and 5% alpha, a calculated 29 examinations would be needed to concurrently compare the BIS index and Comfort-B scale.

The reproducibility of the scale was evaluated by simultaneously and independently testing the agreement among the four evaluators. The Kappa coefficient was used to test the agreement according to the range of sedation reported by the four evaluators. In evaluating the correlation between the Comfort-B scale and the BIS, the Pearson's coefficient correlation was used.

RESULTS

In total, 35 examinations (films) were studied, which were performed in 11 patients between the ages of 1 month and 16 years. The patient characteristics are presented in table 1.

Table 1 - Patient sample characteristics of the children requiring mechanical ventilation and sedation

Characteristics	Results
Age (months)	7 (4-36)
Gender	
Male	7 (64)
Female	4 (36)
Basic diagnosis	
Bronchiolitis	3 (27)
PO tracheoplasty	3 (27)
PO surgery (several)	1 (9.2)
BCP + liver failure	1 (9.2)
Septic shock	1 (9.2)
Heart disease	1 (9.2)
Chemical intoxication	1 (9.2)
PIM2	2.85 (1.0-7.0)

PO - post-operative; BCP - bronchopneumonia; PIM2 - Pediatric Index of Mortality. Results expressed as number (%) or median (interquartile range 25-75).

One to six evaluations were performed per child, averaging 3.7 evaluations per patient. All participants required MV, which was set on the synchronized intermittent mandatory ventilation (SIMV) mode. The

most common continuous infusion medications used in the sedation regimen offered to the patients were midazolam and fentanyl, which were administered to 88.6% and 62.9% of the patients, respectively.

The measurements of the sedation level in children by the four evaluators using the Comfort-B scale placed 37.1% to 57.1% of the measurements performed in the oversedation range, 37.2% to 54.3% in the moderate sedation range, and only 5.7% to 11.5% of measurements in the little sedation range. The evaluation of the state of consciousness using BIS measurements classified 28.6% of the measurements as very deep sedation, 31.4% as deep, 25.7% as moderate, and 14.3% of the measurements as mild sedation.

When comparing the results reported by the four evaluators in terms of the sedation range indicated by the Comfort-B scale (oversedation, moderate sedation, or little sedation) using the Kappa coefficient, only one of the comparisons among the blinded evaluators showed a moderate agreement (Kappa 0.56). All the remaining comparisons showed good agreement, with Kappa values between 0.61 and 0.75 (Table 2).

Table 2 - Comparison among independent evaluators in applying the Comfort-B scale (Kappa coefficient)

Comparisons	Kappa	95%CI	p value
Evaluator 1* versus Evaluator 2	0.71	0.49-0.92	<0.001
Evaluator 1 versus Evaluator 3	0.75	0.55-0.95	<0.001
Evaluator 1 versus Evaluator 4	0.65	0.41-0.89	<0.001
Evaluator 2 versus Evaluator 3	0.56	0.33-0.80	<0.001
Evaluator 2 versus Evaluator 4	0.75	0.55-0.96	<0.001
Evaluator 3 versus Evaluator 4	0.61	0.38-0.84	<0.001

95%CI - 95% confidence interval. * Evaluator 1 was not blinded to the bispectral index.

In the comparison between Comfort-B and BIS, there was a statistically significant, positive, and consistent association between the scale and the index (Figure 1).

DISCUSSION

In our results, the agreement within the different ranges of sedation indicated in the application of the scale (oversedation, moderate sedation and little sedation) was tested using the Kappa coefficient, which showed moderate to good agreement (Table 2).

Four previous studies⁽¹⁰⁻¹³⁾ have compared the Comfort scale with eight factors to the BIS. In this study, we compared the Comfort-B scale with six

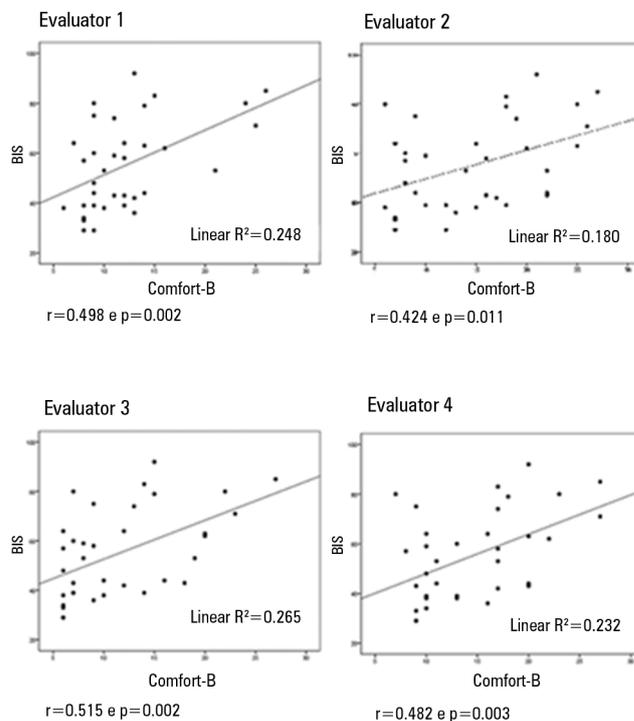


Figure 1 - Correlation between the Comfort-B scale and the bispectral index.

factors to the BIS, and we would like to emphasize the following points.

Twite et al.⁽¹³⁾ evaluated 75 children without neurological damage in 869 valid paired observations and reported a strong correlation between the methods ($r=0.61$, $p<0.0001$). In a similar study that also examined children without neurological damage, Triltsch et al.⁽²⁾ divided the patient sample into children older and younger than 6 months of age and reported a strong correlation in children under 6 months ($r=0.781$, $p<0.001$) and a consistent correlation in children older than 6 months age ($r=0.473$, $p=0.041$). Working with patients with neurological damage, Courtman et al.⁽¹⁰⁾ divided the patient sample into two groups according to their neurological status, with and without damage. These authors used only one scale evaluator and compared their results to the BIS. They reported values of $r=0.26$ and $p<0.007$ in patients with neurological damage, which indicates a weak correlation, and $r=0.51$ and $p<0.0001$ in patients without neurological damage, which are values that indicate a moderate correlation in this group. Twite et al.⁽¹³⁾ reproduced the findings reported by Courtman et al.,⁽¹⁰⁾ reporting values of $r=0.26$ and $p<0.007$ in the group with neurological damage and values of $r=0.51$ and $p=0.0001$ in the group without neurological damage.

Comparing the Comfort-B scale with BIS and working with only 11 patients without neurological damage, we chose not to divide the patients by age. We found that the correlation between methods varied among the four evaluators, from $r=0.515$ ($p=0.002$) to $r=0.424$ ($p=0.011$). All comparisons indicated a moderate correlation.

The subjectivity of the variables does not allow any observational scale to be considered a gold standard for this evaluation. In the Comfort scale, the evaluation of the patient's state of alertness, calmness, muscle tone and facial expression is subjective.⁽¹³⁾ In addition, a moderate correlation between the methods is not unexpected, as the correlation between "comfort" and "sedation" is highly individual.⁽²⁾ The BIS measures the level of hypnosis (sedation), whereas the Comfort-B scale was designed to measure overall comfort, including sedation, pain, and agitation.⁽¹³⁾

Twite et al.⁽¹³⁾ explained the above statement when they used the example of a patient who can lie awake with a high BIS value and still be comfortable, which would generate a relatively low score on the behavioral scale. Likewise, some stimulus might cause another patient to awaken, increasing the BIS without significantly changing the scale values.

In measuring the level of sedation using the Comfort-B scale, the oversedation and moderate sedation levels were the most frequently encountered. The evaluation of consciousness using the BIS showed values that were distributed in four ranges of sedation, predominantly in the moderate, deep, and very deep sedation ranges.

As in the current study and the previously mentioned studies,⁽¹⁰⁻¹³⁾ the reported levels of sedation

were concentrated in the moderate, deep, and very deep sedation ranges. Courtman et al.⁽¹⁰⁾ studied 43 children and reported Comfort values ranging from 8 to 34 (mean 14.5 ± 4.2), representing moderate to oversedation, and BIS values ranging from 1 to 97 (mean 48.1 ± 21.2), representing deep to very deep sedation. In the results reported by Triltsch et al.⁽²⁾ for the 40 patients analyzed in their study, 29 were deeply sedated and 11 were mildly sedated. Twite et al.⁽¹³⁾ reported finding an average of 11 points using the Comfort scale and 52 using the BIS, thus indicating moderate and deep sedation ranges, respectively.

The present study is limited in that it was conducted in only one ICU with a small number of patients and evaluators, and one of the four evaluators was not blinded to the BIS.

CONCLUSION

The Comfort-B scale is reproducible and useful in classifying the level of sedation in children requiring mechanical ventilation. Including this tool in routine assessments at the bedside could assist in appropriately administering sedatives and analgesics, thus preventing both the effects of insufficient sedation and the potentially dangerous effects of excessive sedation. Its use could contribute to early ventilation weaning, with a consequent reduction in injuries and infections related to mechanical ventilation and reductions in the length of stay in the pediatric intensive care units, costs, and morbidity and mortality rates.

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RESUMO

Objetivo: Comparar os escores resultantes da escala Comfort-B com o índice bispectral, em crianças de uma unidade de terapia intensiva.

Métodos: Onze crianças com idades entre 1 mês e 16 anos, submetidas a ventilação mecânica e sedação, foram classificadas pelo índice bispectral e pela escala Comfort-B, simultaneamente. Foi obtido registro de seus comportamentos por filmagem digital; posteriormente tal registro foi avaliado por três observadores independentes e foram aplicados testes de concordância (Bland-Altman e Kappa). Foi testada a correlação entre os dois métodos (correlação de Pearson).

Resultados: Foram realizadas 35 observações em 11 pacientes. A concordância entre os avaliadores, segundo o coeficiente de Kappa, variou de 0,56 a 0,75 ($p < 0,001$). Houve associação positiva e regular entre índice bispectral e Comfort-B, com $r=0,424$ ($p=0,011$) até $r=0,498$ ($p=0,002$).

Conclusão: Devido à alta concordância entre os avaliadores independentes e a correlação regular entre os dois métodos, conclui-se que a escala Comfort-B é reprodutível e útil na classificação do nível de sedação de crianças em ventilação mecânica.

Descritores: Respiração artificial/métodos; Monitorização fisiológica/instrumentação; Sedação consciente; Eletroencefalografia/instrumentação; Criança; Unidades de terapia intensiva pediátrica

REFERENCES

- Miyake RS, Reis AG, Grisi S. Sedação e analgesia em crianças. *Rev Assoc Med Bras.* 1998;44(1):56-64.
- Mencía SB, López-Herce JC, Freddi N. Analgesia and sedation in children: practical approach for the most frequent situations. *J Pediatr (Rio J).* 2007;83(2 Suppl):S71-82.
- Tobias JD. Monitoring the depth of sedation in the pediatric ICU patient: where are we, or more importantly, where are our patients? *Pediatr Crit Care Med.* 2005;6(6):715-8.
- Lago PM, Piva JP, Garcia PC, Sfoggia A, Knight G, Ramelet AS, et al. Analgesia e sedação em situações de emergência e unidades de tratamento intensivo pediátrico. *J Pediatr (Rio J).* 2003;79(2 Suppl):S223-30.
- Litalien C, Juvet P. Validation of a sedation scale for young mechanically ventilated children: a painful challenge? *Pediatr Crit Care Med.* 2006;7(2):183-4.
- Ambuel B, Hamlett KW, Marx CM, Blumer JL. Assessing distress in pediatric intensive care environments: the COMFORT scale. *J Pediatr Psychol.* 1992;17(1):95-109.
- van Dijk M, de Boer JB, Koot HM, Tibboel D, Passchier J, Duivenvoorden HJ. The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old infants. *Pain.* 2000;84(2-3):367-77.
- Carnevale FA, Razack S. An item analysis of the COMFORT scale in a pediatric intensive care unit. *Pediatr Crit Care Med.* 2002;3(2):177-80.
- Amoretti CF, Rodrigues GO, Carvalho PR, Trotta EA. Validação de escalas de sedação em crianças submetidas à ventilação mecânica internadas em uma unidade de terapia intensiva pediátrica terciária. *Rev Bras Ter Intensiva.* 2008;20(4):325-30.
- Courtman SP, Wardurgh A, Petros AJ. Comparison of the bispectral index monitor with the Comfort score in assessing level of sedation of critically ill children. *Intensive Care Med.* 2003;29(2):2239-46.
- Crain N, Slonim A, Pollack MM. Assessing sedation in the pediatric intensive care unit by using BIS and the COMFORT scale. *Pediatr Crit Care Med.* 2002;3(1):11-4.
- Trilttsch AE, Nestmann G, Orawa H, Moshirzadeh M, Sander M, Grosse J, et al. Bispectral index versus COMFORT score to determine the level of sedation in pediatric intensive care unit patients: a prospective study. *Crit Care.* 2005;9(1):R9-17. Erratum in: *Crit Care.* 2005;9(5):426.
- Twite MD, Zuk J, Gralla J, Friesen RH. Correlation of the Bispectral Index Monitor with the COMFORT scale in the pediatric intensive care unit. *Pediatr Crit Care Med.* 2005;6(6):648-53; quiz 654.
- Ista E, van Dijk M, Tibboel D, de Hoog M. Assessment of sedation levels in pediatric intensive care patients can be improved by using the COMFORT "behavior" scale. *Pediatr Crit Care Med.* 2005;6(1):58-63.
- Mandt MJ, Roback MG. Assessment and monitoring of pediatric procedural sedation. *Clin Pediatr Emerg Med.* 2007;8(4):223-31.