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Validation of the Italian version of Behavioral Pain Scale in sedated, intubated, and mechanically ventilated pediatric patients

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Abstract. *Background and aim of the work:* Pain assessment in pediatric intensive care unit (PICU) is a demanding challenge. The Behavioral Pain Scale (BPS) is considered the gold standard for pain assessment in deeply sedated, mechanically ventilated adult patients. The BPS has been validated in Italian, requires a short observation time and does not increase workloads. A first evaluation of BPS was made in PICU with good results regarding face validity and content validity. However further studies are requested given the small sample on which it was tested. The aim of this study was the validation of the BPS in sedated, intubated, and mechanically ventilated pediatric patients. *Methods:* A descriptive, comparative design was used. A convenience sample of 84 non-verbal, sedated and mechanically ventilated critical care pediatric patients was included. Patient pain was assessed concurrently with three observational scales (BPS, COMFORT-B, NRS) before, during and after routine procedures that are considered painful and non-painful. *Results:* Internal consistency was $\alpha = .86$. Correlations between BPS and the other instruments were high, demonstrating a good concurrent validity of the BPS. T test and assessment of ROC curves demonstrated also a good discriminant validity of the BPS. *Conclusions*: The BPS proved to be valid and reliable for the assessment of pain also in the use with pediatric patients. (www.actabiomedica.it)

Key words: Behavioral Pain Scale, pain assessment, Pediatric Intensive Care Unit, pediatric patients

Background

Pain assessment in Pediatric Intensive Care Unit (PICU) is a challenge due to the criticality of the patients, to the different levels of cognitive development, to the possible alteration of the state of consciousness, and to the presence of mechanical ventilation and the sedation (1–5).

Children admitted to PICUs commonly experience pain caused by disease, trauma, medical care procedures, and invasive devices (2), Pain is reported as the most frequent preventable adverse event in PICUs in the United States (3) and incorrect management can cause short and long-term physical and psychological repercussions (3,5,6). Some studies revealed that pain is often not optimally managed (5). Research carried out in the PICUs of two hospitals in northern Italy also reports a poor assessment of pain by the staff (7).

In order to manage pain, the recommendations encourage the use of algometric scales that are validated and diversified according to the age of the child (1,6,8). Currently, the gold standard is represented by

self-assessment scales (9), but self-assessment is often impossible or unreliable for PICU patients (7).

The literature indicates the absence of an effective and simple method for assessing pain in intubated and ventilated children (10). The COMFORT-Behavior scale (COMFORT-B) (11,12) is available in Italian (13) and recognized as the gold standard in these patients. However, the use of this tool in PICUs is controversial: some studies have shown insufficient correlation between physiological and behavioral items and the fact that, for a correct use, the tool requires long periods of observation has been found to be problematic (7). COMFORT-B requires 2 minutes of observation, but it has been shown that nurses, probably due to workload, tend to reduce observation time thus increasing the risk of underestimating pain and placing a limit on the use of the scale in PICUs' patients (14).

The Behavioral Pain Scale (BPS) (15) is the hetero-assessment scale considered the gold standard for pain assessment in deeply sedated and mechanically ventilated adults (16). BPS has been shown to be better than other scales in assessing the pain of sedated, non-quadriplegic and non-curarised patients and can also be used in patients with partial motor disabilities of neurological origin (hemiplegia or paraplegia) (16).

The BPS has been validated in Italian, requires a short observation time and does not increase workloads (16).

A first evaluation of BPS was made in the pediatric field with good results regarding face validity and content validity, however suggesting further studies given the small sample on which it was tested (7).

Therefore, the researchers decided to test the BPS in the PICU in order to evaluate the effectiveness of BPS in detecting the pain of children admitted to PICU.

Aim

The objective of this study is to verify the validity of the BPS for the assessment of pain in sedated, intubated and mechanically ventilated pediatric patient within the PICU.

Methods

Study design and characteristics of the participants

A comparative observational study was chosen and it was conducted on a convenience sample.
The sample is represented by children hospitalized in the PICUs of Parma University Hospital and Gaslini Institute, the inclusion and exclusion criteria are shown in Table 1.

Sample size

The sample size was 84 patients. The number was obtained from an a priori power analysis, using the G * Power software. Expected power = 0.80, alpha = 0.05, and moderate effect size (δ = 0.3) was set.

Instruments

- The BPS (15,16) is a behavior rating scale that evaluates three behavioral domains (i.e., facial expression, movements of upper limbs, and compliance with ventilator). Each domain contains four descriptors that are rated on a 1-4 scale. A total BPS value can range from 3 (no pain) to 12 (maximum possible pain).

- The COMFORT-B scale (11-13) asks observers to consider intensity of six behavioral manifestations: alertness, calm/agitation, respiratory response (for ventilated children) or crying (for spontaneously breathing children), body movements, facial tension and muscle tone. For each of these items, 5 descriptors

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
- age < 18 years old	- Patients on therapy with neuromuscular blocking drugs
- Sedated, intubated and mechanically ventilated patients	- Patients on continuous therapy with direct muscle relaxants
- Expression of informed consent by parents or guardians	- Patients with previous tetraplegia or post-trauma or surgery
	- Patients with drug-resistant epilepsy

are provided, rated from 1 to 5, which reflect the increasing intensity of the behavior in question. By adding together the six evaluations, a total score ranging from 6 to 30 (7) is obtained. Scores between 23 and 30 indicate inadequate sedation (13).

- The Numerical Rating Scale (NRS) (17) is a self-report tool that asks the patient to evaluate the intensity of pain by assigning a number between 0 (no pain) and 10 (maximum pain possible) The NRS is a pain clinic measure commonly used based on the age of the child (8). In patients who cannot express a degree of pain, because they are sedated or intubated, the NRS rating expresses the expert opinion of the nurse taking into account the environmental characteristics of the patient (7).

Data analysis

The following characteristics were analyzed: (i) internal consistency assessed by calculating the Cronbach α index (18); (ii) inter-rater reliability evaluated with Cohen's k index (19); (iii) concurrent validity calculated with Pearson's "r" coefficient (20) between BPS and both COMFORT-B and NRS scales; (iv) discriminant validity evaluated through a t-test for independent measures (20) on the total score in the different measurements and estimated by the amplitude of the area below the ROC (Receiver Operator Characteristic) curve (21).

Procedure

The data was collected in the PICUs of Parma University Hospital and Gaslini Institute of Genoa (Italy) between 1st August 2019 and 28th February 2020.

Each patient was evaluated through BPS (16), COMFORT-B (13) and NRS (17) scales before (T0), during (T1) and after (T2) the care procedures of mobilization, endotracheal aspiration, administration of nutrition through Gastric Tube, hematic withdrawal of Central Venous Catheter (CVC) and CVC medication. The procedures were chosen on the basis of the indications found in the literature (7).

In order to test the reliability and objectivity of the BPS, the assessments were made simultaneously and independently by two nurses within the researchers group trained in the use of the instruments. The nurses viewed patient videos available for free online and made observations using the tools in question; observers only entered PICU after achieving at least 80% agreement in two consecutive video observation sessions. The procedures performed at the time when the researchers were present in the PICUs were observed and the data were collected in data collection sheets also containing patients' socio-demographic characteristics.

Ethical considerations

The study was approved by the Ethics Committee of the Area Vasta Emilia Nord (AVEN) [North area of Emilia Romagna region] on January 11th of 2018 with an amendment resolution of the General Manager on January 31st of 2019, and by the Management of the University Hospital of Parma and the Giannina Gaslini Institute of Genoa. The study was conducted following the principles of the Declaration of Helsinki and Good Clinical Practices.

The informed consent of the parents/guardians for the children's participation in the study and data processing was obtained. Each patient was assigned an alphanumeric code in order to guarantee the pseudonymisation of the data.

Results

84 observations were conducted on intubated pediatric patients aged between 0 and 15 years. 27 measurements (32.1%) were carried out in the PICU of Parma University Hospital and 57 (67.9%) at the PICU of Genoa.

The characteristics of the sample are described in table 2. 57.1% (N = 48) are male. Entry pathologies are mainly concentrated for 37% (N = 31) in cardiological diseases, for 19% (N = 16) in respiratory diseases, in 17% (N = 14) in gastroenterological problems and in 11% (N = 9) in neurological pathologies. Palliative treatment was non-pharmacological for 53% (N = 89) of the sample (Table 2).

Table 2. Characteristics of Sample (N=84)

Gender	Male	48 (57.1%);
	Female	36 (42.9%);
Entrance Diagnosis	Cardiological Pathologies	31 (37%)
	Abdominal Pathologies	6 (7%)
	Respiratory Pathologies	16 (19%)
	Neurologic Pathologies	9 (11%)
	Perinatal Suffering	3 (4%)
	Muscoloskeletal Pathologies	2 (2%)
	Fetal Hydrops	1 (1%)
	Sepsis	1 (1%)
	Gastroenterological Pathologies	14 (17%)
	Liver Pathologies	1 (1%)
Palliative Treatment	Pharmacological	79 (47%)
	Non-pharmacological	89 (53%)

The T1 BPS scores ranged from 3 to 11 (M = 5.53; s.d. = 2.31). Cronbach's α index for the analysis of internal consistency was 0.86.

The calculated scores of observer 1 (M = 5.36; s.d. = 2.39) and the scores of observer 2 (M = 5.53; s.d. = 2.31) were not statistically different ($t_{[166]}$ = - 0.492; p = 0.623). Cohen's k for the evaluation of inter-rater reliability was 0.86.

COMFORT-B scores varied from a minimum of 6 to a maximum of 26 (M = 13.74; s.d. = 6.44). The variance in common between the BPS and COMFORT-B scores was very high: $r_{(166)}$ = 0.93; p <0.01.

The NRS scores ranged from 0 to 8 (M = 2.01; s.d. = 2.37). The correlation between BPS and NRS was 0.61 (p <.01). The correlation between COMFORT-B and NRS was 0.64 (p <.01).

There was a significant difference between the BPS scores at T0 (M = 3.32; s.d. = 0.75) and at T1 (T1: M = 5.54; s.d. = 2.31) ($t_{(83)}$ = -8.999; p <0.001). Furthermore, there was a significant difference between the scores at T1 and the scores at T2 (T2: M = 3.49; s.d. = 0.099) ($t_{(83)}$ = 8,079; p <0.001).

The discriminative capacity of the BPS was also estimated by the amplitude of the AUC of ROC curves, whose coordinates allowed to establish in a score between 2 and 3.5 the optimal cut-off in determining the best possible combination of sensitivity (1.00) and specificity (0.589).

The AUC of the BPS was found to be 0.968 (p <0.001; es = 0.016; 95% I.C. [0.937; 0.999]) (Figure 1).

Discussion

The purpose of the study was the validation of the Italian version of the BPS (16) within the PICU. Each pain measurement with BPS was compared with COMFORT-B (13) and NRS (17).

The independent measurements of the two observers did not give statistically significant differences and the Cohen's k values, between 0.75 and 1.00, demonstrate excellent agreement (19).

Analysing the AUC of the ROC with the criteria suggested by the literature (22), the scale was found to be valid in discriminating patients with controlled pain compared to patients with uncontrolled pain.

Observing the data obtained from the BPS surveys, statistically significant differences emerged between the scores obtained at T0 and T1 and between the scores obtained at T1 and T2, confirming what was detected by a previous study (7). This suggests, like what has been reported for adult patients (16), further evidence of the ability of the BPS to effectively measure the pain of pediatric patients in PICU.

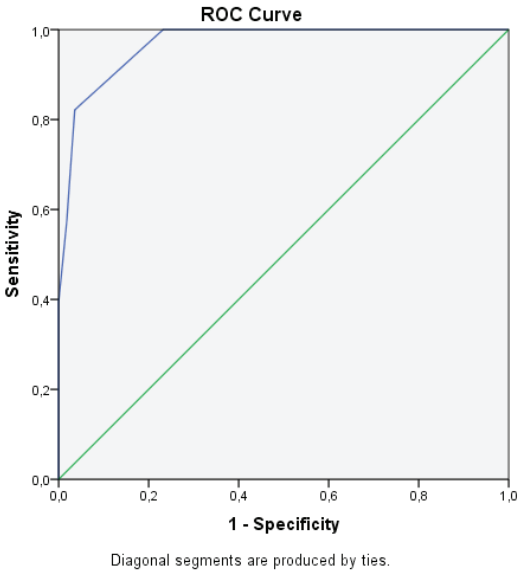

Figure 1. ROC curve of the BPS

Furthermore, by comparing the scores of the BPS and COMFORT-B scales, an optimal r value was obtained (23), confirming the validity of the scale in discriminating pain.

Conclusion

Following the results of the study, the BPS proved to be valid and reliable for the assessment of pain also in the use with pediatric patients.

Furthermore, thanks to a comparison with the other two pain assessment tools, it was possible to highlight how they can be correlated with each other.

The validation of the BPS in the pediatric field could represent a valid help for the detection of pain, a fundamental symptom in ICU/PICU patients' medical history.

We suggest the implementation of BPS in PICUs, in order to obtain an effective and efficient pain assessment and its optimal management.

The study inevitably has some limitations. The findings were made by the researchers and not by the nurses belonging to the PICUs under examination. This has probably increased adherence to the study, which could have been reduced by asking operators to increase their workload by using BPS, COMFORT-B and NRS simultaneously. This did not allow an evaluation of the use of the scale in a routine context.

Furthermore, the measurements were made only during the day and only during procedures performed in the presence of the researchers, diminishing the power of the results.

Finally, despite having recruited a satisfactory sample number, the data concentrated mainly on 4 pathologies. The lack of randomization on a larger population of cases does not allow complete generalization of the results.

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