REVISTA DA ESCOLA DE ENFERMAGEM DA USP
JOURNAL OF SCHOOL OF NURSING · UNIVERSITY OF SÃO PAULO

ORIGINAL ARTICLE

DOI: http://dx.doi.org/10.1590/S1980-220X2017008603285

Validation of the *Échelle Douleur Inconfort Nouveau-Né* for Brazilian culture*

Validação da *Échelle Douleur Inconfort Nouveau-Né* para a cultura brasileira

Validación de la *Échelle Douleur Inconfort Nouveau-Né* para la cultura brasileña

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How to cite this article:
Dias FSB, Gasparino RC, Carmona EV, Marba STM. Validation of the *Échelle Douleur Inconfort Nouveau-Né* for Brazilian culture. Rev Esc Enferm USP. 2017:e03285. DOI: http://dx.doi.org/10.1590/S1980-220X2017008603285

* Extracted from the dissertation "Tradução, adaptação cultural e validação da "EDIN – Échelle Douleur Inconfort Nouveau-Né" para a língua portuguesa do Brasil", Faculdade de Ciências Médicas, Universidade Estadual de Campinas, 2012.

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ABSTRACT

Objective: To evaluate the reliability and validity of the Brazilian version of the *Échelle Douleur Inconfort Nouveau-Né*, which measures prolonged pain in neonates. **Method:** A methodological study carried out with 96 neonates. The Brazilian versions of the *Échelle Douleur Inconfort Nouveau-Né* and the *Children's and Infants' Postoperative Pain Scale* were used for data collection. For reliability, equivalence measured by intraobserver agreement and homogeneity were considered. To evaluate the validity, the convergent construct approach was considered correlating the Brazilian versions of the *Échelle Douleur Inconfort Nouveau-Né* and the *Children's and Infants' Postoperative Pain Scale*. **Results:** In assessing reliability, the coefficient of agreement between observers varied between 0.64 and 0.85 for the items that make up the instrument, and 0.96 for the total score. Cronbach's alpha was 0.82. Regarding the convergent validity evaluation, Spearman correlation coefficient between the values found for both scales was 0.79 ($p< 0.0001$). **Conclusion:** The Brazilian version of the *Échelle Douleur Inconfort Nouveau-Né* is a reliable and valid instrument for assessing prolonged pain in neonates.

DESCRIPTORS

Pain; Pain Measurement; Infant, Newborn; Validation Studies; Neonatal Nursing.

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Received: 02/23/2017
Approved: 08/29/2017

INTRODUCTION

In the past, it was believed that neonates did not feel pain since central nervous system immaturity contributed to an absence of experienced pain or pain memory. However, after conducting neurobiological studies, it is known that the neurochemical elements necessary for transmitting pain are evidenced from as early as the 20th week of gestation. In addition, the presence of sufficient nerve pathways to process painful sensations in the brainstem can be observed as early as the 24th week[1].

With regards to pain memory, the literature indicates that children who were repeatedly submitted to painful stimuli during the neonatal period presented alterations in pain threshold, demonstrating that even though the painful experience is not accessible to the conscious memory, it is active in the procedural pain memory[2].

Preterm neonates admitted to the Neonatal Intensive Care Unit (NICU) due to clinical characteristics that compromise their adaptability to extrauterine life are subjected to numerous stressful and painful stimuli, which are often inherent to the diagnostic and care process[3].

Researchers have accompanied neonates undergoing knowingly painful procedures with the aim of developing scales which are capable of assessing pain in order to better manage it. The possibility of assigning a numerical score to an abstract concept allows for establishing effective communication language between the observer and the observed, guiding the interventions[4].

The *Échelle Douleur Inconfort Nouveau-Né* (*EDIN*) was the first scale developed for assessing prolonged pain in preterm neonates[5]. Few studies have been developed with the purpose of increasing knowledge about prolonged neonatal pain, and there is still no consensus on definitions for prolonged, continuous and chronic pain for these patients. The definitions for chronic pain in neonates can be based on different aspects of this experience, whether in the duration of pain, on the repeated exposure to acute painful procedures or in adopting the same criteria adopted for chronic pain in adults and older children. Despite the lack of consensus, there is no doubt that the suffering of neonates admitted to NICU goes beyond acute pain[6].

The EDIN was developed based on studies with expert panels that grouped the signals expressed by neonates into different indicators after 2 consecutive years of observing them in potentially painful situations: Facial activity, Body movements, Quality of sleep, Quality of contact and Consolability[5,7]. These exclusively behavioral parameters have been described considering that they are more sensitive and specific for measuring prolonged pain, since physiological alterations may not be present in this type of pain since they are not maintained for long periods[6].

In order to establish the measurement properties of the instrument, reliability was assessed by homogeneity (0.92) and equivalence (0.59-0.74), while the construct validity was evaluated in two ways: 1) in 40 preterm neonates with respiratory distress syndrome, in which the mean EDIN score before analgesia of 9.2 (SD=1.7) was correlated with the mean of the total instrument score after fentanyl infusion for eight hours 4.7 (2.1) ($p < 0.0001$); and 2) in 36 neonates admitted to an Intermediate Care Unit (IMCU), where the instrument was applied on the day of admission 4.5 (SD=3.7) and one day before discharge 1.5 (1.5) ($p=0.0009$). These differences suggest that EDIN is a valid and reliable scale that is able to distinguish situations of pain and absence of pain in preterm neonates[5].

The instrument's authors do not determine a minimum recommended period of observation for assessing pain, but the EDIN should be applied after several hours of contact with the neonates and not in a timely manner[5] in order to allow a more consistent evaluation of parameters such as sleep and consolability. Another interesting point of the scale is that for the items related to facial expression and body movement, there is an option for a response of "no expression or body movement", which may reflect an energy conservation mechanism and not necessarily the absence of pain[6]; an important consideration, especially regarding preterm neonates.

Considering the following: a) the routine use of instruments that evaluate prolonged pain can reveal suffering that often goes unnoticed in the eyes of professionals, and thus promote better treatment as a way to qualify care to neonates; b) a lack of validated instruments in Brazilian culture that measure prolonged pain in neonates; c) that the development of a new instrument for evaluating a particular construct is generally a complex and time-consuming process, and for this reason the adaptation and validation of an instrument with consistent psychometric properties[5] for a new culture is much more advantageous; and finally, d) that EDIN has already been adapted for Brazilian culture[7], thus the objective of the present study was to validate the Brazilian version of the *Échelle Douleur Inconfort Nouveau-Né*.

METHOD

This is a methodological study characterized by the process of testing instruments carried out in two public teaching hospitals in partnership with the Universidade Estadual de (UNICAMP), SP, Brazil. Hospital A has a neonatal unit with 15 neonatal intensive care beds and 15 intermediate care beds, while hospital B has 10 beds for neonatal intensive care and 12 intermediate care beds.

The sample size was calculated according to the objective of evaluating the convergent construct validity of the Brazilian version EDIN, with an estimate of 0.30 for the Pearson correlation coefficient, 5% significance and 80% test power. The calculation resulted in a minimum sample of 84 subjects. G*Power® 3.1.9.2 software was used to perform the sample calculations.

The following inclusion criteria were established: neonates admitted to the NICU or IMCU; Apgar equal or greater than five in the fifth minute; and being without a diagnosis of neurological alterations. All neonates included in the study were selected by convenience, and were followed up for a period of 15 days after data collection so that the researchers could make sure that the neonates would not

present these alterations as diagnosed by transfontanelar ultrasound. If the condition was confirmed in this period, the neonate was excluded from the sample.

A form for sample characterization, the Brazilian version EDIN and the Brazilian version of the *Children's and Infants' Postoperative Pain Scale* (CHIPPS) were used for data collection. To characterize the sample, the following variables were considered: gender, gestational age (verified by the Capurro method, New Ballard or amenorrhea), birth weight, hospitalization diagnosis, presence of invasive and non-invasive devices, as well as the number of manipulation episodes and punctures performed during the observation period.

The EDIN was adapted to the Brazilian culture[7] and it consists of five indicators that evaluate a neonate's facial activity, body movements, quality of sleep, quality of contact and consolability. Each indicator is rated by a four-point Likert scale ranging from 0 to 3. The sum of each indicator determines the instrument's total score, which can range from 0 to 15 points. Scores equal to or greater than 7 indicate a strong presence of pain. The authors who developed the scale suggest that it should be applied once or twice a day by professionals who have several hours of contact with the evaluated neonates in order to properly diagnose pain[5].

The CHIPPS is used to evaluate the convergent construct validity and has been satisfactorily adapted and validated for the Brazilian culture. It evaluates pain in children from 0 to 5 years of age. It also has five items that evaluate crying, facial expressions, posture of the trunk, posture of the legs and motor restlessness. The response is a Likert type scale ranging from 0 to 3 points. The sum of each item determines the total score, which can result in values ranging from 0 to 10 points. In CHIPPS, the higher the score, the greater the intensity of pain[8].

Data collection took place over a period of 4 months and was performed by two observers: observer A was one of the authors of the study, while observer B was a nurse or nursing technician responsible for neonate care during that shift. Similar to the original study, the nursing professional did not receive specific training regarding application of the scale. They were clarified about the objectives of the study and had the opportunity to have contact with the instrument and clarify any doubts before applying it. Considering that the study purpose was to validate the scale, the instruments were completed only once after an observation period of 3 hours. Observers simultaneously and independently applied the Brazilian version EDIN. In addition, the researcher also applied the CHIPPS.

Data were tabulated in the Excel – Windows/XP® program and analyzed by a statistician using the Statistical Analysis System® (SAS) version 9.4 program. Descriptive analysis of the categorical variables and central tendency measurements of continuous variables were used to describe the sample profile.

Equivalence and homogeneity were considered in order to evaluate the reliability of the Brazilian version EDIN. The following tests were used to evaluate the equivalence: Weighted Kappa coefficient to assess the agreement between the two observers for each EDIN indicator, in which values above 0.60 indicate substantial agreement; and the Intraclass Correlation Coefficient (ICC) to evaluate the agreement between the two observers regarding the total score of the instrument, in which values above 0.75 are indicative of good reliability. In addition, Cronbach's Alpha was considered for evaluating homogeneity, in which values higher than 0.70 indicate high internal consistency[9].

In order to evaluate the validity, the convergent construct approach was considered, correlating the results of applying the Brazilian version EDIN with those of the CHIPPS. The following hypothesis was considered for this evaluation: the greater the values resulting from application of the Brazilian version EDIN, the greater the values found by the CHIPPS. The Spearman coefficient was used to test this correlation with values higher than 0.5, thus indicating a strong correlation. The significance level adopted for all analyses was 5%.

The study received approval from the involved hospitals' directors and a favorable opinion from the Research Ethics Committee of the Faculty of Medical Sciences of UNICAMP (Opinion no. 995/2010 and CAAE 0775.0.146.000-10). All ethical guidelines for conducting research involving human beings were met.

RESULTS

The initial sample consisted of 107 neonates, 11 of which were excluded as a result of neurological alterations found by the transfontanelar ultrasound examination performed within 15 days after data collection.

Of the 96 neonates who composed the final sample, the majority were male (57.3%) and hospitalized due to a diagnosis of prematurity (70.8%). Birth weight varied between 720 and 4,005 grams, with a mean of 2,059 grams (SD=807). Gestational age ranged from 27 to 41 weeks, with a mean of 34.4 weeks (SD=3.3).

Regarding the presence of invasive devices, 80.2% had gastric tubes, 68.8% had venous access (of which the most prevalent was umbilical access), and 31.3% were receiving respiratory support (of which the endotracheal cannula was the most frequent), while 26.0% used phototherapy. During the observation period, the neonates were handled on average 1.7 times (SD=0.8), and 29.0% received some type of needle puncture.

Regarding the reliability assessment, the equivalence results as measured by the evaluation between the observers are represented in Table 1, as well as the means and standard deviations obtained by each observer. Regarding homogeneity, Cronbach's alpha was 0.82.

To evaluate the validity, the means found by observer A in applying the Brazilian version EDIN and CHIPPS were 4.1 (SD=2.5) and 3.7 (SD=2.4), respectively. The distribution of these scores can be found in Figure 1.

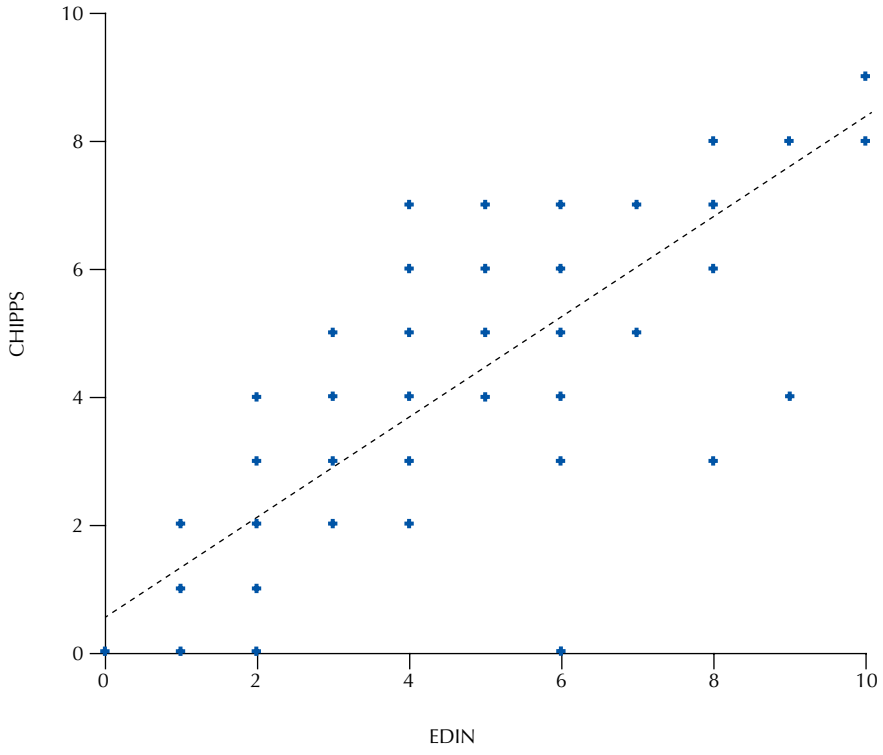
The coefficient obtained in evaluating the correlation between the Brazilian version EDIN and the CHIPPS scores was 0.79 ($p< 0.0001$).

Table 1 – Distribution of tendency measures of each observer and reliability between the observers for the Brazilian version EDIN – Campinas, São Paulo, Brazil, 2011.

	Mean/SD* Observer A	Mean/SD* Observer B	Agreement	95% Confidence Interval
Facial activity	0.9 (0.6)	0.8 (0.6)	0.67**	0.54 – 0.81
Body movements	0.9 (0.7)	1.1 (0.8)	0.67**	0.56 – 0.79
Quality of Sleep	0.4 (0.8)	0.4 (0.8)	0.85**	0.74 – 0.96
Quality of Contact	1.1 (0.6)	1.0 (0.5)	0.64**	0.48 – 0.80
Consolability	0.8 (0.6)	0.8 (0.6)	0.76**	0.64 – 0.87
Total	4.1 (2.5)	4.0 (2.5)	0.96***	0.93 – 0.97

*SD = Standard deviation; ** Weighted Kappa; *** ICC. Note: (n=96)

Source: Research Data.



Note: (n=96)

Source: Research Data.

Figure 1 – Score dispersion for the Brazilian versions EDIN and CHIPPS – Campinas, São Paulo, Brazil, 2011.

DISCUSSION

It was verified that the Brazilian version EDIN has satisfactory reliability and validity. Thus, the results of the present study indicate that EDIN is a safe instrument for assessing prolonged pain in neonates, and it should be used by professionals who work in the neonatology sector.

The reliability was measured in two ways: by equivalence and homogeneity. The agreement among the observers for the equivalence was considered great, and the coefficients obtained (Table 1) were higher than those from the original instrument, ranging from 0.59 to 0.74. In both versions of the instrument, sleep was the indicator that obtained the highest index of agreement. Regarding the instrument's total score, the Brazilian version again showed better performance, considering that the original version obtained a coefficient of 0.69. Regarding homogeneity, Cronbach's alpha for the five indicators was lower than the original version (α=0.92); however, the obtained value still indicates high internal consistency[9].

In comparing the validation results of the Brazilian version EDIN with another study that applied the same instrument in full-term neonates in France, it was possible to notice that agreement between the observers was similar,

as Kappa ranged from 0.62 to 0.86; with regard to homogeneity, the French study presented a lower Cronbach's alpha (0.62) than that found in the present study[10].

In the convergent validity evaluation, the tested hypothesis was confirmed since a strong positive correlation was achieved between the EDIN and the CHIPPS Brazilian versions, which indicates that the instrument under study is able to adequately measure the investigated construct.

Pain is very difficult to assess because it is a subjective phenomenon, especially in children who still cannot verbally communicate[11]. Studies published in Brazil show that professionals are not aware of scales for assessing pain in neonates and/or that they do not use them to support their decision making, demonstrating that recognizing the phenomenon in question occurs in an individualized rather than systematized way[12-13].

As a consequence, pain management is not completely effective. When investigating interventions in painful situations, the authors verified a divergence between the discourse and the practice of neonatologists, residents and medical students: although there has been an increase in awareness regarding the recognition and proper management of pain in neonates over the years, the performance of many procedures considered painful was not preceded by analgesia[3,14].

We emphasize the importance of the Brazilian version EDIN being incorporated by professionals who assist neonates, since accurate pain assessment is essential to guide treatment and pain management should be a priority in neonatal care in order to guarantee neonates a more humanized, safer and qualified care.

CONCLUSION

The Brazilian version of the *Échelle Douleur Inconfort Nouveau-Né* is a reliable and valid instrument for assessing prolonged pain in neonates, as reliability tests demonstrate that this scale has good equivalence and homogeneity, and also considering that good results in the evaluation between observers and in the evaluation of the internal consistency were obtained. With regard to validity, the instrument is able to measure pain which is the construct that it was proposed to measure, since the results reached almost perfect correlation when compared to another instrument that measures the same variable.

We emphasize the importance of implementing an institutional culture directed at pain management in neonates, since painful procedures are part of the neonatal care context. In this sense, incorporating EDIN has positive implications for the care practice in preventing physiological, behavioral and cognitive repercussions which can be developed as a result of repeated, prolonged and untreated pain.

RESUMO

Objetivo: Avaliar a confiabilidade e a validade da versão brasileira da *Échelle Douleur Inconfort Nouveau-Né*, que mensura a dor prolongada em recém-nascidos. **Método:** Estudo metodológico realizado junto com recém-nascidos. Para a coleta foram utilizadas as versões brasileiras da *Échelle Douleur Inconfort Nouveau-Né* e da *Children's and Infants' Postoperative Pain Scale*. Para a confiabilidade, foram consideradas a equivalência, mensurada pela concordância entre observadores, e a homogeneidade. Para avaliar a validade, foi considerada a abordagem de construto convergente correlacionando as versões brasileiras da *Échelle Douleur Inconfort Nouveau-Né* e da *Children's and Infants' Postoperative Pain Scale*. **Resultados:** Compuseram a amostra final 96 recém-nascidos. Na avaliação da confiabilidade, o coeficiente de concordância entre observadores variou entre 0,64 e 0,85 para os itens que compõem o instrumento e 0,96 para o escore total. O alfa de Cronbach foi de 0,82. Na avaliação da validade convergente, o coeficiente de correlação de Spearman entre os valores encontrados para as duas escalas foi de 0,79 (p< 0,0001). **Conclusão:** A versão brasileira da *Échelle Douleur Inconfort Nouveau-Né* é um instrumento confiável e válido para avaliar a dor prolongada em recém-nascidos.

DESCRITORES

Dor; Medição da Dor; Recém-Nascido; Estudos de Validação; Enfermagem Neonatal.

RESUMEN

Objetivo: Evaluar la confiabilidad y la validez de la versión brasileña de la *Échelle Douleur Inconfort Nouveau-Né*, que mide el dolor prolongado en recién nacidos. **Método:** Estudio metodológico realizado junto con recién nacidos. Para la recolección fueron utilizadas las versiones brasileñas de la *Échelle Douleur Inconfort Nouveau-Né* y la *Children's and Infants' Postoperative Pain Scale*. Para la confiabilidad, fueron consideradas la equivalencia, medida por la concordancia entre observadores y la homogeneidad. Para evaluar la validez, se consideró el abordaje de constructo convergente correlacionando las versiones brasileñas de la *Échelle Douleur Inconfort Nouveau-Né* y la *Children's and Infants' Postoperative Pain Scale*. **Resultados:** Compusieron la muestra final 96 recién nacidos. En la evaluación de la confiabilidad, el coeficiente de concordancia entre observadores varió entre 0,64 y 0,85 para los ítems que componen el instrumento y 0,96 para el puntaje total. El alfa de Cronbach fue de 0,82. En la evaluación de la validez convergente, el coeficiente de correlación de Spearman entre los valores encontrados para ambas escalas fue de 0,79 (p< 0,0001). **Conclusión:** La versión brasileña de la *Échelle Douleur Inconfort Nouveau-Né* es un instrumento confiable y válido para evaluar el dolor prolongado en recién nacidos.

DESCRIPTORES

Dolor; Dimensión del Dolor; Recién Nacido; Estudios de Validación; Enfermería Neonatal.

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