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Original Article

Adaptation and Initial Validation of the Premature Infant Pain Profile–Revised (PIPP-R) in Brazil

Mariana Bueno, RN, PhD [*], Mily Constanza Moreno-Ramos, PhD(c), MSc, WOCN, RN [†], Evelyn Forni, RN [‡], Amelia Fumiko Kimura, RN, PhD [†]

[*] Child Health Evaluative Sciences, Hospital for Sick Children, Toronto, Ontario, Canada
[†] Department of Mother and Child and Psychiatric Nursing, School of Nursing of the University of São Paulo, São Paulo, Brazil
[‡] Paulista Nursing School of the Federal University of São Paulo, São Paulo, Brazil

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ABSTRACT

Background: The use of reliable pain assessment measures is essential for scoring and managing pain in infants. The Premature Infant Pain Profile (PIPP) is reliable and valid and has been recently revised. To adapt and validate the PIPP-R into Portuguese and to evaluate its psychometric properties are required to ensure maintenance of meaning and content.
Aims: The aim of this study was to culturally adapt to Brazilian Portuguese and explore content validity and construct validity of the Premature Infant Pain Profile–Revised.
Design: This is a methodological study.
Participants/Settings: Two existing data sets of randomized clinical trials previously conducted were used to examine initial construct validity of the prefinal version of the Premature Infant Pain Profile–Revised.
Methods: Cross-cultural adaptation and validation occurred in four steps. Independent versions of the Premature Infant Pain Profile–Revised were produced, followed by the preparation of a synthetic version. Two back-translated versions were realized by professional translators. An expert committee evaluated idiomatic and semantic equivalence and clarity and relevance of the items. A content validity index was calculated. Finally, a consolidated prefinal version in Portuguese was then produced.
Results: No difficulties in producing the material were reported. Semantic and idiomatic aspects were considered adequate, and content validity index was 1.0. Premature Infant Pain Profile and Premature Infant Pain Profile–Revised scores were highly correlated for pain after heel lancing and venipuncture ($R^2 = 0.986$, $p < .001$) and for pain associated with analgesic strategies ($R^2 = 0.966$-1.00, $p < .001$).
Conclusions: The Premature Infant Pain Profile–Revised was culturally adapted into Brazilian Portuguese. Appropriate content validity index was determined. Evidence of construct validity was also found. Future studies are warranted to explore the feasibility and other psychometric properties of using the Premature Infant Pain Profile–Revised translated and adapted into Brazilian Portuguese in the clinical setting.

Pain is a complex multidimensional phenomenon experienced throughout the human life cycle. Our first painful experiences occur in very early, within hours or days of life for neonatal immunization and blood sampling. However, infant pain prevention and management are poorly implemented worldwide (Courtois, Cimerman, Dubuche, Goiset, Orfèvre, et al., 2016a; Courtois, Droutman, Magny, Merch aoui, Durrmeyer, et al., 2016b; Cruz, Fernandes, & Oliveira, 2016).

The use of reliable pain assessment measures is essential for scoring and managing pain in infants. However, clinicians and researchers need to rely on indirect indicators to evaluate infant pain because of the lack of self-report as well as lack of objective ways of assessing pain in this population. Pain indicators include behavioral, physiologic, hormonal, and cortical changes, although there is an absence of convergence of these responses (Benoit, Martin-Misener, Latimer, & Campbell-Yeo, 2017; Harrison, Beggs, & Stevens, 2012). In addition, although several pain indicators have been explored to date, aspects of validity, reliability, and specificity are not well established yet (Harrison, Bueno, & Reszel, 2015).

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Address correspondence to Mariana Bueno, RN, PhD, Peter Gilgan Centre for Research and Learning (PGCRL), The Hospital for Sick Children, 686 Bay Street, 6th floor, 06.9717 Admin Area, W10-West, Toronto, Ontario M5G 0A4, Canada.
E-mail address: mariana.bueno@sickkids.ca (M. Bueno).

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A plethora of infant pain measures have proliferated over the past decade; however, none is considered ideal to date. Composite measures such as the Premature Infant Pain Profile (PIPP) (Stevens, Johnston, Petryshen, & Taddio, 1996), which includes both behavioral and physiologic indicators as well as contextual factors, may offer more breadth for pain assessment, whereas multidimensional behavioral measures may provide greater depth in a particular dimension of a pain indicator (e.g., facial activity) (Stevens, Johnston, Taddio, Gibbins, & Yamada, 2010).

The PIPP has been widely used in research and is considered a reliable and valid measure for infant pain assessment, although scarce studies have explored its clinical utility; moreover the PIPP is an effective outcome measure in intervention studies in pain in infants (Stevens et al., 2010). The PIPP is consistently recommended by international consensus and guidelines as being a reliable measure that has been subjected to rigorous psychometric testing (American Academy of Pediatrics, 2016; Howard et al., 2012; Registered Nurses' Association of Ontario, 2013; Stapelkamp, Carter, Gordon, & Watts, 2011).

In an attempt to facilitate the use of the measure by clinicians, the original version of the PIPP scale was recently revised (Premature Infant Pain Profile—Revised [PIPP-R]), and despite the maintenance of the indicators, the scoring method was modified for oxygen saturation, facial activity, baseline behavioral state, and gestational age (Stevens et al., 2014). Preliminary studies have shown found construct validity, convergent validity, high correlation between PIPP-R and PIPP scores, and feasibility (Stevens et al., 2014).

Although the PIPP measure was recently translated and adapted to Brazilian Portuguese (Bueno, Costa, de Oliveira, Cardoso, & Fumiko, 2013), adaptation and validation of its new version and evaluation of psychometric properties of the adapted version are required to ensure maintenance of meaning and content. Thus this study aimed to culturally adapt and to explore content validity and construct validity of the PIPP-R for the Portuguese language spoken in Brazil.

Methods

Cross-Cultural Adaptation and Validation

Cross-cultural adaptation and validation occurred in four steps (Beaton, Bombardier, Guillemin, & Bosi Ferraz, 2000; Beaton, Bombardier, Guillemin, & Ferraz, 2007). Three independent versions of the PIPP-R were produced from the original language (English) to the target language (Brazilian Portuguese). Two nurses experienced in neonatal pain and familiar with the measure and a biologist who was not familiar with neonatal pain research or the measure created the three translated versions of the tool (T1, T2, T3). Produced versions were analyzed by the researchers to identify discrepant terms and consensually establish a synthetic version (S1). Two professional translators who have English as their native language, have no medical background, and were blind to the original measure independently produced two back-translated versions (BT1, BT2) of the synthetic version.

An expert committee composed of three experienced researchers in the field of interest reviewed produced material (S1, BT1, BT2) and the original measure. The committee was requested to examine idiomatic and semantic equivalence. Based on the recommendations of the committee, researchers produced a consolidated prefinal version of the PIPP-R in Portuguese.

Content Validity

Content validity refers to the degree to which elements of an assessment measure are relevant to and representative of the targeted construct for a particular assessment purpose (Haynes, Richard, & Kubany, 1995). The Content Validity Index (CVI) is a quantitative measure that relies on knowledge of experts with the construct being measured (Alexandre & Coluci, 2011). Thus the same committee assessed the prefinal version for relevancy and clarity of the items, and CVI was calculated.

Construct Validity

Construct validity refers to the degree to which a measure consistently relates to other similar measures derived from the same theory and/or concepts (Martins, 2006) Therefore two existing data sets of randomized clinical trials that measured procedural neonatal pain by using the PIPP as the main outcome were used to examine initial construct validity of the prefinal version of the PIPP-R.

In the first study (Bueno et al., 2012), late preterm infants were randomly assigned to receive 25% glucose or expressed breast milk before heel lancing. Records of 56 neonates were considered for pain assessment at 30 seconds after the procedure, and data from 47 neonates were used for pain occurrence at 60 seconds after puncture. Neonates were predominantly male (60.7%), mean birth weight was 2,291.6 grams (±471.5), and mean corrected gestational age was 35.4 weeks (±0.7).

The second data set (Camargo, 2013) involved term and preterm neonates randomly assigned to receive 25% glucose or glucose 25% plus non-nutritive sucking during peripherally inserted central catheter installation. Records related to venipuncture of 84 neonates were considered. Neonates were male (54.8%), mean birth weight of 2,424.6 grams (±805.1), and mean corrected gestational age 36.7 weeks (±2.1).

Data Analysis

For the CVI calculation, each member of the expert committee was asked to rank each item of the translated version in terms of clarity (1, unclear; 2, item requires major revision to be clear; 3, item requires minor revision to be clear; and 4, clear) and relevance (1, irrelevant; 2, item requires major revision to be relevant; 3, item requires minor revision to be relevant; 4, relevant). Revisions were required if items were ranked as 1 or 2. The sum of the items ranked as 3 or 4 by the experts was divided by the total responses for both clarity and relevance. We established an acceptable CVI of 1 (total agreement) according to literature recommendations when the instrument is evaluated by five or fewer specialists (Alexandre & Coluci, 2011).

For construct validity, the database was prepared by two research assistants who were not involved in translation and adaptation of the measure or in the original studies that generated the two data sets. A preset formula was used to calculate final pain scores for the PIPP and the PIPP-R using the results of the original studies. A random sample of 10% of the data was double entered to ensure data reliability. Data were analyzed according to the type of procedure (i.e., heel lancing, venipuncture), time points (i.e., 30 and 60 seconds after lancing), and analgesia (i.e., glucose, glucose plus sucking, and expressed breast milk). Values for PIPP and PIPP-R were presented as mean and standard deviation (SD). Pearson correlation test was used to verify correlation between the scores obtained with the PIPP tool and the PIPP-R (Mukaka, 2012).

Permissions and Ethics

We obtained prior permission from the authors of the PIPP-R (Stevens et al., 2014) as well as from *the Clinical Journal of Pain* and Wolters Kluwer Health Inc., copyright holder of the original article (license #380141089440), for translation and cross-cultural adaptation.

In addition, we obtained permission from the authors of the studies for using databases for construct validation. Finally, this study was approved by local Ethics Review Board (protocol #48171815.6.0000.5392).

Results

No difficulties were reported in producing the translated versions of the tool (T1, T2, T3), synthesis version (S1), and back translations (BT1, BT2). The expert committee considered the material as adequate in terms of semantic, idiomatic, and cultural aspects. All items were ranked as 3 or 4 by the committee. CVI attributed by the experts for both clarity and relevance was 1.0, which confirms content validity of the PIPP-R version translated into Brazilian Portuguese. Therefore a prefinal version of the PIPP-R was produced.

By using the previously translated PIPP and the prefinal version of the PIPP-R, preset formulas calculated the final pain scores in the data set. Mean (SD) score assessed at 30 seconds after heel lancing for the PIPP was 5.3 (3.6) and for the PIPP-R, 5.2 (3.8). At 60 seconds after lancing, mean scores were 3.6 (3.2) and 3.8 (3.4) for the PIPP and the PIPP-R, respectively. For pain assessed at 30 seconds after venipuncture, mean PIPP score was 7.4 (2.8) and mean PIPP-R score was 7.4 (2.8). PIPP and PIPP-R scores were highly correlated for pain assessment at 30 seconds and at 60 seconds after both heel lancing and venipuncture (Table 1).

Regarding pain scores according to analgesic interventions, mean (SD) PIPP and PIPP-R scores for infants receiving glucose for both heel lancing and venipuncture assessed at 30 and 60 seconds after the procedures were 7.2 (3.6) and 7.2 (3.7), respectively. For infants who received glucose plus sucking for venipuncture, mean scores were 6.6 (2.4) for both measures. Finally, for the ones who received expressed breast milk for heel lancing, mean scores were 3.3 (2.7) and 3.2 (2.8) for the PIPP and the PIPP-R, respectively. PIPP and PIPP-R scores were also highly correlated according to the different types of analgesic interventions implemented (Table 2).

Discussion

The aim of this study was to adapt the PIPP-R for the Brazilian Portuguese language and to explore its content and construct validity. Cultural adaptation is crucial in preserving validity and reliability of the measure across different cultures (Beaton et al., 2007; Pesce et al., 2005). In addition, adequate adaptation saves time and financial resources and allows the comparison of results of research conducted in different countries (Guillemin, Bombardier, & Beaton, 1993; Juniper, Guyat, & Jaeschke, 1995).

The initial version of the measure, the PIPP, has been translated into various languages such as Icelandic (Jonsdottir & Kristjansdottir, 2005), Norwegian (Vederhus, Eide, & Natvig, 2006), Portuguese (Bueno et al., 2013), and Greek (Dionysakopoulou et al., 2018). The measure may have been translated into many other languages although there is no evidence of its adaptation or validity. For example, studies conducted in France and Italy have reported the PIPP as their main outcome measure (Bellieni et al., 2001; Carbajal, 2003), but no research on translating the measure was published.

Table 1
Correlation Between PIPP and PIPP-R Scores, According to Type of Procedures and Time Point Intervals for Pain Assessment

Procedure	N	R^2	95% CI	*p*
Heel lance (30 seconds)	56	0.990	0.982-0.994	<.001*
Heel lance (60 seconds)	47	0.954	0.919-0.975	<.001*
Venipuncture	84	1.000	1.000-1.000	<.001*
Total	187	0.986	0.981-0.989	<.001*

PIPP = Premature Infant Pain Profile; PIPP-R = Premature Infant Pain Profile–Revised; R = Pearson correlation coefficient; CI = confidence interval.
* Statistical significance $p < .05$.

Table 2
Correlation Between PIPP and PIPP-R Scores, According to Analgesic Interventions

Analgesic Intervention	N	R^2	CI 95%	*p*
Glucose	86	0.984	0.975-0.990	<.001*
Glucose plus sucking	43	1.000	1.000-1.000	<.001*
Breast milk	58	0.966	0.944-0.980	<.001*

PIPP = Premature Infant Pain Profile; PIPP-R = Premature Infant Pain Profile–Revised; R = Pearson correlation coefficient; CI = confidence interval.
* Statistical significance $p < .05$.

The major changes from the PIPP to the PIPP-R revolve around the scoring method for oxygen saturation and facial activity as well as the total score of the measure. Therefore conducting a new process of adapting and validating the measure into Brazilian Portuguese was considered crucial. Likewise, a collaborative attempt to translate and validate PIPP-R simultaneously into four Nordic languages has recently been carried out (Olsson et al., 2018). To date, no other translated versions of the PIPP-R have been published.

With regard to the psychometric properties of the measure, a high correlation between the PIPP and the PIPP-R scores was initially reported for infants across different gestational ages (25-41 weeks) who received sucrose, non-nutritive sucking plus sucrose, and facilitated sucking plus sucrose before heel lancing ($R^2 = .99$, $p < .001$) (Stevens et al., 2014). The authors of the measures acknowledges that scores were highly correlated because of the maintenance of the 7-item structure of the measure in the revised version (Stevens et al., 2014). Likewise, our findings identified high correlation between pain scores for PIPP and PIPP-R for different pain relief strategies (e.g., glucose, glucose and sucking, and expressed breast milk) as well as for types of procedures (e.g., heel lancing and venipuncture) in both term and preterm infants. These data indicate that PIPP-R scores were responsive not only to painful stimulus but also to the effectiveness of analgesic interventions.

In terms of feasibility, nurses who were familiar to the PIPP measure received training about the PIPP-R and reported they were clear on how to use the PIPP-R (3.5-3.9 out of 5) and considered the measure easy to score (mean 3.7-3.8 out of 5) and to use (mean 3.6-3.9 out of 5) and to require an appropriate length of time to complete (mean 3.6-3.9 out of 5) (Gibbins et al., 2014; Stevens et al., 2014). In the Brazilian context, there is no clarity on the use of the PIPP or the PIPP-R at the bedside. Recently published studies indicate insufficient knowledge and/or implementation of pain assessment measures for neonates and infants in clinical settings (Oliveira et al., 2016; Sposito et al., 2017).

Exploring the feasibility and clinical utility of infant pain measures is challenging, and the majority of the measures are not subjected to these evaluations. These studies may be a crucial component in determining the most appropriate measures to assess pain in infants at the bedside as well as in facilitating knowledge uptake into clinical practice, such as by developing training modules around scoring instructions and appropriate implementation of the measure by health care professionals (Stevens et al., 2014). In the future, the development of local protocols for pain management in neonates and infants, and consequently the adoption of practices in clinical settings, may be facilitated with a complete validation and feasibility evaluation of a variety of pain measures in the Brazilian context.

Conclusions

The PIPP-R was culturally adapted into Portuguese used in Brazil and appropriate content validity index was identified. Evidence of

construct validity was also determined by high correlation between PIPP and PIPP-R pain scores. Future studies are needed to better explore the feasibility of using the PIPP-R translated and adapted into Brazilian Portuguese in the clinical setting.

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