

Brief Methodological Report

Neonatal Infant Pain Scale: Cross-Cultural Adaptation and Validation in Brazil

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Abstract

Context. The Neonatal Infant Pain Scale (NIPS), initially developed in Canada, has been previously used but not adequately adapted and validated for use in Brazil.

Objectives. The goal of the present study was to perform a cross-cultural adaptation and clinical validation of the NIPS for use in the Brazilian population.

Methods. The instrument was adapted based on the method outlined by Beaton et al., including the production and combination of translated versions, back-translation, committee review, and pilot testing. The psychometric properties of the adapted instrument, including its validity, reliability, and internal consistency, were tested in a clinical validation study. The sample comprised 60 at-term newborns who were evaluated by six nurses as they experienced vaccination. Psychometric properties were evaluated using Student's *t*-tests, prevalence-adjusted and bias-adjusted kappa scores, the Bland-Altman method, and Cronbach's alpha coefficients.

Results. The Brazilian version of the NIPS (Escala de Dor no Recém-Nascido [NIPS-Brazil]) demonstrated excellent interobserver and intraobserver reliability. Total NIPS-Brazil scores yielded prevalence-adjusted and bias-adjusted kappa scores of 0.93, whereas the Bland-Altman method revealed interobserver and intraobserver reliability values of 95% and 90%, respectively. The NIPS-Brazil had adequate internal consistency, as evidenced by a Cronbach's alpha of 0.762.

Conclusion. The NIPS was successfully adapted for use in Brazil and is now available for use in the assessment of acute pain in at-term newborns in Brazil. *J Pain Symptom Manage* 2015;■:■-■. © 2015 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

Key Words

Pain, neonates, pain assessment, translation, validation studies

Introduction

The study of pain has advanced considerably in recent years, and its evaluation and treatment have become a growing concern among health care workers. The International Association for the Study of Pain¹ has defined the construct as a subjective “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of tissue damage,” which is modulated by life experiences. However, this definition does not entirely

apply to newborns, infants, and preverbal children, who are unable to verbally express pain and have no prior experience with painful sensations.² To account for this, the International Association for the Study of Pain also states that the “inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment.”¹

Neonates experience pain associated with immunizations and blood collection. Preterm or sick neonates

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are especially likely to undergo repeated or prolonged exposure to painful diagnostic, surgical, or treatment interventions.³ In fact, it is estimated that a neonate in a Neonatal Intensive Care Unit (NICU) experiences a mean of 12 painful procedures per day of hospitalization.⁴

Pain assessments can provide important information to guide the implementation of interventions that can alleviate or eliminate pain in newborns.² Such assessments should be performed at least once per shift on all neonates subjected to painful procedures.⁵ The absence of verbal expressions of pain poses a major challenge for the assessment of this construct in neonates. Therefore, reliable and easy instruments for the assessment of pain in this population are essential to ensure optimal patient care.

Several scales have been developed for this purpose and are often used before, during, and after neonatal exposure to painful stimuli. The most effective and widely used scales for the assessment of pain in neonates are multidimensional and assess both physiological and behavioral indicators of pain.⁶ However, such instruments are generally produced in English-speaking countries, so that translation and cross-cultural adaptation is often required to enable their use in other locations. The cross-cultural adaptation of assessment instruments is a complex process that, in addition to the translation and adaptation per se, involves the assessment of the psychometric properties of the adapted instrument, such as its experimental and clinical validity, as well as its reliability.⁷

The Neonatal Infant Pain Scale (NIPS),⁸ which was published in 1993, was developed based on the Children's Hospital of Eastern Ontario Pain Scale for the assessment of pain in children aged between one and seven years. The NIPS assesses five behavioral factors (facial expression, cry, arms, legs, and state of arousal) and one physiological factor (breathing patterns), each of which contains two items that are assigned scores of 0 or 1 (except for the crying factor, which comprises three items and is scored on a scale of 0 to 2). Each item also contains a brief operational definition. The scale yields a total score ranging from 0 to 7, where scores more than 3 are indicative of pain.⁸ The NIPS is easily understood and applied and is a useful tool for health professionals who work with neonates exposed to painful stimuli.

Although the NIPS is widely used in several countries, including Brazil, no studies have described its cross-cultural adaptation and clinical validity for use in Brazil. Using an adapted and validated scale ensures the reliability and effectiveness of pain assessment, which may not occur when a scale is freely translated. The utilization of a validated scale allows a reliable and systematic pain assessment, which is the first step in the process of managing newborn pain within a clinical protocol.

Therefore, the goal of the present study was to perform the cross-cultural adaptation of the NIPS for use in Brazil and to assess the clinical validity of the adapted instrument. The process included translation and adaptation of the instrument to the Portuguese spoken in Brazil and evaluation of the psychometric properties.

Methods

The present study comprised two stages: cross-cultural adaptation and clinical validation. The cross-cultural adaptation process followed the five main steps outlined by Beaton et al.:⁷ production and alignment of multiple translations, back-translation, committee review, and pretesting. These steps were performed to ensure that the content and validity of the original instrument were preserved in the adaptation process. After translation and adaptation, statistical analyses were performed to evaluate the psychometric properties of the translated instrument, with a focus on its clinical validity, that is, its ability to assess what it was designed to measure.^{7,9} The clinical validity of the instrument was evaluated through a cross-sectional study. All data collection was performed in a NICU in a university hospital in Southern Brazil, between September 2011 and January 2013.

The translation and validation of the NIPS for use in Brazil were authorized by the author of the original instrument, as well as by the Children's Hospital of Eastern Ontario, which currently holds the copyright for the scale. The present study also was approved by the Research Ethics Committee of the Clinical Hospital of Porto Alegre under protocol number 11-0343. All research subjects, including health care workers and the parents of the newborns, provided written consent for participation in the study.

The first stage of this study involved the translation and cultural adaptation of the NIPS for use in Brazil. The NIPS was translated from English to Brazilian Portuguese; this translation was performed by two bilingual translators with Brazilian Portuguese as their first language. Each translator worked independently and directed all observations and comments regarding the translation process to the researchers. The two translations were then compared and combined into a draft version in Brazilian Portuguese,⁷ which was then independently back-translated¹⁰ into English by two bilingual translators with English as their first language. Back-translation is a means to ensure the content equivalence between the original and adapted versions of an instrument and to identify semantic equivalence issues.⁷ Although the method proposed by Beaton does not involve the combination of multiple back-translations, the researchers felt that this procedure would make a significant contribution to the

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