Reliability and internal consistency in the assessment of neonatal pain in preterm infants during tracheal aspiration: prospective study

Confiabilidade e consistência interna na avaliação da dor neonatal de prematuros durante o procedimento de aspiração traqueal: estudo prospectivo

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ABSTRACT

BACKGROUND AND OBJECTIVES: Inadequate pain assessment in preterm infants (PI) is a persistent problem. Currently, a precise pain assessment is one of the main challenges for health professionals in the intensive care units (NICU). The objective of this study was to verify the correlation between the Neonatal Infant Pain Scale (NIPS) and Premature Infant Pain Prole - Revised (PIPP-R), internal consistency, and inter-evaluator reliability on pain assessment during aspiration in PI.
METHODS: Prospective observational study with low birth weight PI (< 2500 g), hemodynamically stable, minimal or no sedation, under mechanical ventilation, continuous positive airway pressure, nasal cannula oxygen, or ambient air, and needing aspiration during hospitalization in the neonatal intensive care unit in the period from 2019 to 2020.. PI were evaluated during three different aspiration procedures: without intervention (1), using gentle touch (2), and using sucrose (3). NIPS and PIPP-R instruments were applied, while internal consistency was determined using Cronbach's alpha, reliability using the intraclass correlation coefficient, and concurrent validity using Spearman's correlation coefficient.
RESULTS: Fifty PIs requiring tracheal aspiration were evaluated. NIPS and PIPP-R showed high (Cronbach α: 0.824) and moderate (Cronbach α: 0.655) internal consistency. Inter-evaluation reliability was excellent in all aspiration procedures for NIPS (1: 0.991, 2: 0.987, and 3: 0.993) and PIPP-R (1: 0.997, 2: 0.986, and 3: 0.977). Concurrent validity was observed only for aspiration without intervention.
CONCLUSION: Although NIPS may have better clinical utility than PIPP-R, both instruments presented good internal consistency and inter-evaluator reliability and may be used for assessing pain during aspiration in PI.
Keywords: Pain, Pain Measurement, Preterm Infant.

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HIGHLIGHTS
• Reliability measures between two scales to assess pain in preterm infants.
• NIPS and PIPP-R scales were sensitive in identifying pain.
• High reliability on the NIPS scale and moderate reliability on the PIPP-R scale.

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RESUMO

JUSTIFICATIVA E OBJETIVOS: A avaliação inadequada da dor em recém-nascidos prematuros (RNPT) é um problema persistente. A avaliação precisa da dor é um dos principais desafios para profissionais de saúde nas Unidades de Terapia Intensiva Neonatais (UTIN). O objetivo deste estudo foi verificar a associação entre a Escala de Dor Neonatal (*Neonatal Infant Pain Scale* - NIPS) e o Perfil da Dor do Bebê Prematuro - Revisado (*Premature Infant Pain Profile Revised* - PIPP-R), assim como a consistência interna e a confiabilidade inter-avaliadores na aferição da dor durante a aspiração do RNPT.
MÉTODOS: Estudo transversal prospectivo com RNPT de baixo peso ao nascer (<2500 g), hemodinamicamente estáveis, com mínima ou nenhuma sedação, sob ventilação mecânica, apresentando pressão positiva contínua nas vias aéreas, oxigênio na cânula nasal ou ar ambiente, e precisando de aspiração durante a internação na UTIN no período de 2019 a 2020. Os RNPT foram avaliados durante três diferentes procedimentos de aspiração: sem intervenção (1), toque gentil (2) e administração de sacarose (3). Os instrumentos NIPS e PIPP-R foram aplicados durante a avaliação. A consistência interna foi determinada pelo alfa de Cronbach, a confiabilidade pelo coeficiente de associação intraclasse e a validade concorrente pelo teste de associação de Spearman.
RESULTADOS: Foram avaliados 50 RNPT que necessitaram de aspiração traqueal. A NIPS e a PIPP-R mostraram consistência interna alta (Cronbach α: 0,824) e moderada (Cronbach α: 0,655), respectivamente. A confiabilidade inter-avaliadores foi excelente em todos os procedimentos de aspiração para NIPS (1: 0,991, 2: 0,987 e 3: 0,993) e PIPP-R (1: 0,997, 2: 0,986, e 3: 0,977). A validade concorrente foi observada apenas para aspiração sem intervenção.

CONCLUSÃO: Embora a NIPS possa ter melhor utilidade clínica do que o PIPP-R, ambos os instrumentos apresentaram boa consistência interna e confiabilidade inter-avaliadores, e podem ser usados para avaliar a dor durante a aspiração em RNPT.

Descritores: Dor, Medição da Dor, Prematuro, Recém-Nascido.

INTRODUCTION

According to the International Association for the Study of Pain, pain is an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage. In addition, repeated exposure to pain can cause permanent damage in the short and long term (e.g. irritability, sleep disturbances, hypersensitivity to painful stimuli, and cognitive problems)[1,2].

Preterm infants (PI) often require invasive care and procedures in Neonatal Intensive Care Units (NICU), which can cause pain and stress[4-6]. One study[7] noted that 50 PI experienced 643 acute painful procedures during their NICU stay (i.e., 23 painful procedures per day). Furthermore, healthcare professionals consider airway aspiration to be the most frequent and painful procedure for infants[7-10].

Among the procedures that cause pain in respiratory physiotherapy, aspiration is the most common procedure and the one that causes most pain to the newborn (NB) (72.7%)[10]. Among the painful and invasive procedures performed during hospitalization, observed in a study, there was an average of 6.6 procedures per day of RN hospitalization, with an average of 27.9 per hospitalization. The most frequent procedures are heel punctures (36.1%), airway aspiration (26.3%) and venipuncture for test collection (9%)[7].

Pain assessment is a challenge when dealing with infants, since it is commonly expressed through verbalization. Since infants cannot verbalize yet, pain is assessed by observing physiological, hormonal, and behavioral responses[1]. Moreover, a gold standard instrument to accurately assess pain in infants has not yet been identified in clinical practice[4]. The American Academy of Pediatrics recommends the use of reliable instruments to adequately classify and control pain in infants[11].

However, choosing a valid, reliable method that is a feasible and practical instrument for pain assessment has been a challenge[11]. Although more than 40 instruments are available for pain assessment in infants, few are regularly used in NICUs, such as the Premature Infant Pain Profile (PIPP) and Neonatal Infant Pain Scale (NIPS)[3, 12].

A study[5] compared four validated instruments for pain assessment in PIs and suggested that the PIPP and NIPS had good clinical utility and were the best choice to assess pain in Pis submitted to blood collection by heel puncture. Furthermore, no studies were found that investigated the comparison of these instruments applicability during the aspiration procedure in NBs[4]. Therefore, the objective of this study was to verify the association between NIPS and PIPP-Revised (PIPP-R), the internal consistency and reliability and inter-evaluators agreement during aspiration in Pis. The belief is that the results will help health professionals choose and use appropriate instruments to assess pain in NB.

METHODS

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement was used to properly report all important information in this manuscript[13].

This is a prospective cross-sectional study that included low birth weight PIs of both genders, admitted to the NICU of a public and maternity hospital in the city of Goiânia, and data collection occurred in the period from March 2019 to June 2020. This hospital and maternity ward was renovated and reopened in 2012, since then it is a reference in labor and birth care of low and medium complexity, with 10 NICU beds, 10 ICU beds (Intermediate Care Unit) and 5 Kangaroo care beds. The NB profile was mostly premature.

The following inclusion criteria were adopted: PI (gestational age [GA] between 26 and 36 weeks and 5 days); low birth weight (< 2500 g); hemodynamic stability; minimal sedation (< 0.3 µg/kg fentanyl) or no sedation; under mechanical ventilation; continuous positive airway pressure (CPAP); oxygen from nasal cannula or room air; cardiac and respiratory monitoring; no respiratory distress or oxygen desaturation; and need for aspiration during NICU admission. Infants with genetic syndromes, major malformations, or congenital infections were excluded.

Initially, low-birth-weight PIs admitted to the NICU were identified through an active search of medical records. Then, parents or guardians were contacted within the unit for an interview. Due to the complexity of the study, many parents or guardians requested to read the informed consent form together, which was signed after all doubts were clarified. Quantitative variables regarding the main characteristics of PIs (for example: type of delivery, birth weight, Apgar score at first and fifth minutes and health complications after birth) were collected using a standardized form. The study followed the guidelines and regulatory standards for research involving human subjects (resolution 466/12 of the National Health Council) and was approved by the research ethics committee of the *Hospital e Maternidade Dona Iris* (Dona Iris Hospital and Maternity Ward) - CAAE: 2.894.555.

NBs who met eligibility criteria underwent three procedures at least 48 hours apart: one without intervention and two with interventions (gentle touch and sucrose). Interventions were not allowed less than five minutes before aspiration, and recordings with adequate quality were made 30 seconds before the procedures to observe infants' expression and limb movements. The aspiration procedure lasted 60 to 90 seconds, while the recovery time after aspiration lasted 30 seconds, according to the NICU protocol. A person with no technical knowledge in the health field edited all the voices before data analysis to eliminate bias.

For the pain relief interventions, the gentle touch was performed, chosen for being a very effective non-pharmacological method used to relieve pain and calm the baby. It is an easily applied method, which consists of placing one hand on the head and the other hand on the abdomen of the newborn. Sucrose 25%

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was chosen because it is an effective intervention for the relief of acute pain in PIs[14-16]. Based on a study[16], the solution was manipulated and administered 0.5mL of 25% sucrose per kg of the PI weight using a syringe devoid of a needle.

Two validated scales, the NIPS and the PIPP-R, were used as pain assessment instruments. The scales were scored by two independent evaluators. The evaluators had clinical experience in Neonatal Intensive Care for approximately 10 years and Master degree.

NIPS was developed based on the Eastern Ontario Children's Hospital Pain Scale for infants >24 weeks and without neurological impairment. It is a multidimensional, easy-to-understand, and clinically applicable instrument to assess pain in NB and full-term infants. NIPS assesses six variables referring to acute painful procedures behavioral response: facial expression, crying, breathing patterns, arms, legs, and arousal state. In each variable there are two items that should be scored from 0 to 1 (except the crying variable, which has three items and should be scored from 0 to 2). The instrument was adapted and translated into Portuguese[17-19].

PIPP-R is a multidimensional instrument that assesses acute pain in NB and full-term infants, and is one of the few scales that has metric adjustments for premature children, using gestational age as the score. PIPP-R analyzes seven indicators related to behavior (facial actions: eyebrow protrusion, eye contraction, and nasolabial sulcus), physiological (heart rate and oxygen saturation), and contextual factors (GA and baseline behavioral status). In addition, it classifies pain intensity according to a score of mild, moderate, or severe. A study translated and adapted this instrument into Portuguese in 2013[20,21].

Physiological and behavioral items are scored on a four-point scale (0 to 3), affecting changes in each item from baseline values. In contrast, contextual factors are scored at the beginning of the pain assessment (before touching the NB). Different behavioral and physiological factors are scored in ascending order according to 6 changes from baseline; contextual factors are scored in descending order to explain physiological differences related to prematurity. Therefore, the maximum score is 21 points for preterm (28 weeks GA) and 18 for term infants[20,21].

The original version of the PIPP-R was recently revised and translated into Portuguese to simplify its use[18]. Although the items have been maintained, the scoring of the PIPP-R was changed: contextual items are scored only if changes are observed in the other item. The total score also ranges from 0 to 21 points, and pain is classified as "no" or "mild" (from 0 to 6), "mild to moderate" (from 6 to 12 points) and "moderate to severe" (> 12)[21].

Statistical Analysis

In the descriptive analysis, the mean and median standard deviation (SD), and minimum-maximum values, were calculated for continuous variables; the absolute-relative frequencies were calculated for discrete variables.

Data were analyzed in SPSS software (IBM Corp, USA, version 23.0), and statistical significance was set at 5% (p < 0.05). The intraclass association coefficient (ICC) assessed the inter-evaluators reliability of pain perception scores using NIPS and PIPP-R

instruments. The ICC was calculated for individual and mean scores, and Cronbach's alpha assessed the internal consistency of the instruments. ICC scores were considered excellent (>0.90), good (0.90 to 0.75), moderate (0.50 to 0.75), or low (< 0.50)[19]. The Kolmogorov-Smirnov test verified the normality of the data. Nonparametric tests used since the pain assessment results showed a non-normal distribution. Spearman's association test was used to assess the association between the NIPS and PIPP-R instruments.

RESULTS

Fifty PIs (26 female PIs) with a mean GA of 28 weeks (24.42 to 35.41) and a mean birth weight of 1050 g (595 to 2225 g). Of these, 41% were on invasive mechanical ventilation, 37% on nasal Continuous Positive Airway Pressure (CPAP), and 22% on oxygen therapy (Table 1). A total of 150 recordings were evaluated, and each RNPT was recorded in three situations (aspiration without intervention, aspiration with the gentle touch, and aspiration with sucrose). The median scores during the aspiration procedures in the NIPS scale were 4.27 (3.49 to 5.09) when aspiration was performed without intervention, 3.14 (2.47 to 3.81) with gentle touch and 2.19 (1.57 to 2.81) with sucrose, respectively. While on the PIPP-R scale the scores were 10.04 (8.92 to 11.16) without intervention, 8.53 (7.74 to 9.32) with gentle touch, and 7 (6 to 8) with sucrose. The inter-evaluators reliability for NIPS was 0.983 (no intervention), 0.975 (gentle touch), and 0.985 (sucrose). Reliability for A PIPP-R was 0.995 (no intervention), 0.973 (gentle touch) and 0.955 (sucrose) (Figure 1).
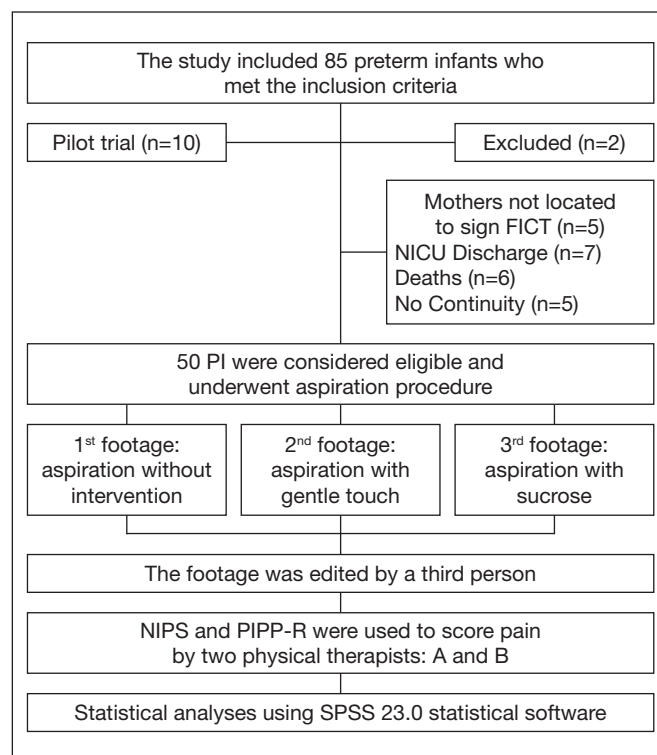

Figure 1. Research design flowchart. Goiânia, Goiás, 2020.

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A)
Correlation between the NIPS and PPIP-R instruments for evaluator A on the scale I

B)
Correlation between the NIPS and PPIP-R instruments for evaluator B on the scale I

B)
Correlation between the NIPS and PPIP-R instruments for evaluator A on the scale II

D
Correlation between the NIPS and PPIP-R instruments for evaluator B on the scale II

D
Correlation between the NIPS and PPIP-R instruments for evaluator A on the scale III

D
Correlation between the NIPS and PPIP-R instruments for evaluator B on the scale III
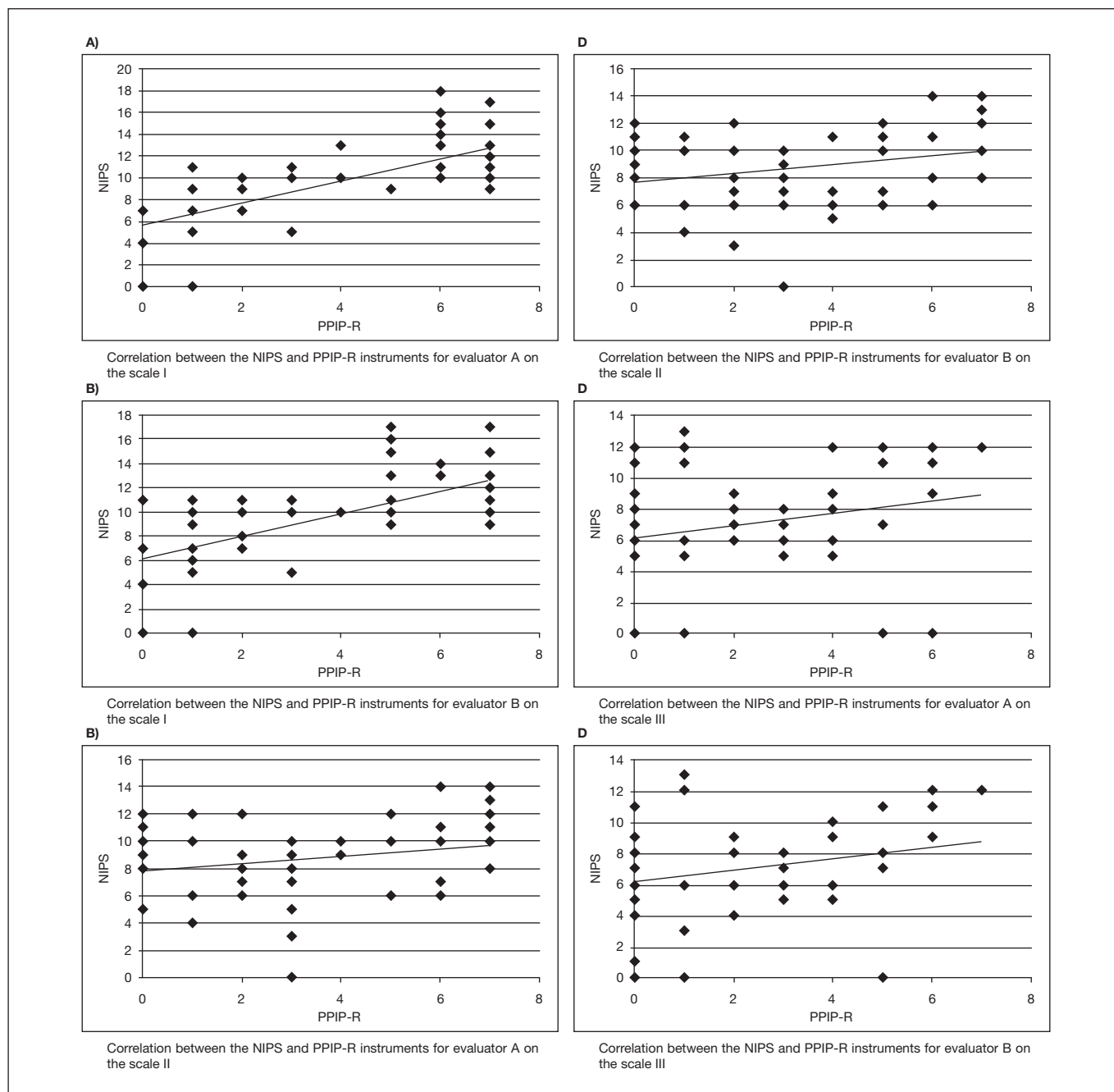
Figure 2. Evaluators Scale

The overall Cronbach's alpha indicates that the NIPS and PIPP-R instruments presented internal consistency of 0.824 and 0.655, respectively. Spearman's correlation coefficient between the NIPS and PIPP-R instruments was significant only for the first aspiration procedure (r = 0.668 for evaluator A and r = 0.660 for evaluator B; all p value < 0.001, Figure 2).

DISCUSSION

This study provided measures of reliability between two pain assessment instruments in PI during a painful procedure. The association between NIPS and PIPP-R, internal consistency,

and inter-rater reliability during PI aspiration procedures were evaluated. Both instruments were sensitive in identifying pain, which was evident during aspiration without intervention. Also, lower scores were presented when using sucrose and gentle touch than without intervention. The identification of reliable instruments will help health care professionals to improve pain management and quality of care for vulnerable infants. This study confirmed a research[21] that validated the Brazilian version of the PIPP-R and showed that scores responded to painful procedures and different relief strategies.

Another study[23] assessed pain using the PIPP in 109 NBs during heel blood sampling and noted a lower risk of moderate to severe

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pain in those who received combinations of aspiration, breast milk, and snuggling than in infants who received routine care. In the present study, pain was rated as moderate in all procedures, despite the low total PIPP-R score.

The results showed high reliability and internal consistency in the NIPS scale and moderate reliability and internal consistency in the PIPP-R scale. In an observational study[6], four scales (NFCS, DAN, NIPS, PIPP) were evaluated for validity when assessing pain during heel blood sampling in 111 preterm infants, and it was observed that the four scales had high reliability and internal consistency. No study that evaluated neonatal pain scales during the aspiration procedure was found.

A research[24], when evaluating 90 preterm and term NBs on invasive mechanical ventilation, obtained results similar to those of the present study, in which Cronbach's alpha of the three scales was an acceptable score, thus providing evidence for good reliability among the N-PASS, NIAPAS and PIPP-R scales for neonates on mechanical ventilation. However, the internal consistency of the N-PASS and NIAPAS scales was higher than the PIPP-R. The reason could be explained by small differences in the numbers and grading of the behavioral or physiological indicators, in addition to the contextual and gestational age factors, which affect the internal consistency in PIPP-R [21].

In a study[21] for adaptation and validation of the PIPP-R scale in Brazil, three nurses evaluated two data sets of randomized studies for pain assessment in infants using the PIPP scale. The nurses indicated that additional training was needed on PIPP-R scoring and the importance of establishing a baseline behavioral state before handling the infant, often a step that had been forgotten by them[21]. This finding was similar to other studies of psychometric properties, in that greater internal consistency of the PIPP-R was not demonstrated, especially when compared to the NIPS scale[9].

In an attempt to facilitate the use of the pain assessment instrument by professionals the original version of the PIPP scale was recently revised (PIPP-R) and despite maintaining the indicators, the scoring method was modified in the indicators oxygen saturation, facial activity (eyebrow arching, pinched eyes and nasolabial sulcus), baseline behavioral status and GA[21]. Studies have shown construct validity, convergent validity, and high association between PIPP-R and PIPP scale scores for different pain relief strategies (e.g. glucose, aspiration-associated glucose, and expressed breast milk), as well as for different procedures such as heel and venipuncture in term and preterm infants[22,25].

In PIPP-R the scores for the indicators behavioral state and GA were changed in order to minimize the effects of high scores based on baseline characteristics before the pain event[21]. Therefore, PIPP-R considers GA and behavioral state as modifying variables of pain response rather than infant-specific contextual variables. In the present study, the revised version was used in order to facilitate the understanding and assessment of pain during aspiration in NB.

This study identified a high inter-evaluators reliability for NIPS and PIPP-R, with ICC higher than 0.90[22]. These findings corroborate the results found in a study[19] that performed a cross-cultural adaptation of NIPS in Brazil and showed excellent inter-evaluators reliability. In a prospective crossover study, 202 hospitalized infants divided into three gestational age groups (26-31, 32-36 and > 37 weeks) in three different NICUs were assessed at bedside by 195 nurses during painful procedures. A high degree of agreement was observed between PIPP-R expert evaluators and nurses in the assessment during painful (0.92) and non-painful (0.87) procedures, suggesting that the instrument is appropriate, reliable, and consistent with all infants older than 26 weeks gestational age during real-time assessment in the NICUs[25].

The Brazilian NIPS scale showed excellent inter-observer and intra-observer reliability, generating coefficients similar to the original scale version. The internal consistency of NIPS was satisfactory (Cronbach's alpha of 0.762) in the assessment of pain in 60 NB during vaccination[19]. A high internal consistency of the NIPS was found in the present study. The NIPS is a validated instrument with well-established psychometric results, high inter-evaluators reliability, internal consistency, and concurrent validity for pain assessment in infants. However, it may not be sensitive for assessing behavior in infants requiring intensive care. The concurrent validity between NIPS and NIAPAS (Neonatal Infant Acute Pain Assessment Scale) in the assessment of 34 NB undergoing 60 painful procedures showed the following results: heel blood sampling: 0.751; aspiration: 0.873, respectively[26]. In the present study, the psychometric findings were satisfactory for the NIPS instrument.

In a study that analyzed four scales (NFCS, DAN, NIPS, PIPP) in the pain assessment of PIs during blood draws, a difference was observed between the mean score of the four clinical utility scales. The mean clinical utility scores of PIPP were significantly higher than the scores of NFCS and DAN (p<0.05), but it was not higher than NIPS (p>0.05)[6]. In the present study, was observed that there was a significant association between the NIPS and PIPP-R scales only in the first condition, which may have occurred because in the first condition aspiration was performed without any non-pharmacological intervention, thus pain was more evident and more easily evaluated.

In another study[6], nurses considered the PIPP instrument easy to apply and accurate, while the NIPS was applied more quickly, probably because the items were easy to remember and evaluate. In NICU daily practices, physicians prefer a pain assessment tool that is easy to use and has good clinical feasibility[6]. In the present study the application time of the scales was not analyzed, however, both scales were considered by the evaluators as easy to understand and apply.

In this study, the NIPS scale seemed to have better feasibility and clinical applicability when compared to the PIPP-R scale, since its scores are easier to understand and more succinct, although the NIPS scale does not measure pain intensity.

The present study has strengths related to the research design, the fact that the evaluators were expert professionals with extensive experience in Neonatal Physiotherapy, in addition to having used two instruments validated and widely used in clinical practice. However, it presented the limitation of not having evaluated the inter-evaluators reliability, as well as the preference of the professionals who work at the NICU regarding the applicability of the instruments in practice. In addition, the study provided

evidence that will contribute to improve care at the NICU, since it helps health professionals in the choice and use of pain assessment scales, consequently in the appropriate management.

CONCLUSION

Therefore, choosing a valid, reliable, feasible and practical measure helps health professionals to do a better pain management, improving the quality of care to the patient, especially NBs, who are more vulnerable. The scales showed good reliability, internal consistency and inter-evaluators reliability, thus it is suggested that both PIPP-R and NIPS have good clinical validity and are a good choice to assess pain in preterm infants during the aspiration procedure.

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AUTHORS' CONTRIBUTIONS

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Data Collection, Conceptualization, Resource Management, Project Management, Research, Methodology, Writing - Preparation of the Original, Writing - Review and Editing
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