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Original scientific paper

Adaptation of the Croatian Version of the Neonatal Infant Pain Scale (NIPS)

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Abstract

Aim. The aim of this study was to adapt the NIPS scale for use in Croatia and to evaluate the content validity and internal consistency of its Croatian version in neonatal care.

Methods. The study was conducted from October 2024 to January 2025 at the University Hospital Rijeka on a sample of 94 healthy newborns, born vaginally or by cesarean section, between 37 and 41 + 6/7 weeks of gestation, and assessed as healthy during first initial clinical examination. Pain was assessed during routine blood sampling for phenylketonuria screening, and assessments were performed by trained nurses. Statistical analysis used descriptive and inferential methods (Wilcoxon test, Friedman's ANOVA, Cochran's Q test) and Cronbach's alpha coefficient.

Results. The Croatian NIPS version showed high internal consistency (Cronbach's $\alpha = 0.846$). Significant physiological and behavioral responses were recorded before (mean 1.51), during (mean 6.66) and after (mean 2.02) the painful procedure ($p < 0.001$).

Conclusions. The Croatian NIPS scale proved internal consistency and content validity for neonatal pain assessment. Its implementation could ensure timely recognition and management of pain, thereby reducing potential long-term consequences. The introduction of this tool as a nursing standard for neonatal care would enable timely recognition and relief of pain, reduce the number of painful procedures, and prevent long-term negative consequences of pain.

Introduction

The most common methods of pain assessment in pediatrics are self-assessment (not applicable in the neonatal period), behavioral assessment, and measurement of physiological parameters (1). Behavioral indicators include irritability, tremors, crying, grimacing, body movements, but also pathological calmness, lethargy, sleep disturbances, and loss of appetite. Physiological parameters encompass changes in skin color, variations in heart rate, respiratory rate, blood pressure, and neuroendocrine responses (e.g., cortisol and growth hormone levels) (2). The most reliable assessment is based on a combination of behavioral and physiological indicators, although in practice it is challenging to balance reliability with the time required for assessment (3). Despite its importance, standardized pain assessment scales for newborns are still not used in neonatal care in Croatia.

A review of the available neonatal pain assessment scales identified the NIPS (4) as a particularly valid and reliable instrument, a finding supported by numerous international adaptations and validation studies. Examination of the evidence confirms that the Neonatal Infant Pain Scale is a multidimensional tool with robust psychometric properties, including excellent inter-rater reliability, concurrent validity, construct validity, and predictive validity—features that are essential for accurate pain assessment and for guiding appropriate clinical interventions, especially in comparison with other pain assessment instruments. Furthermore, multiple studies demonstrate the successful implementation of NIPS and highlight its ease of use in routine clinical practice (5-7).

Therefore, as part of the scientific project uniri-iskusni-biomed-23-76, the implementation of systematic procedures for pain assessment and relief is planned as a standard in neonatal care. Special emphasis is placed on introducing the Neonatal Infant Pain Scale (NIPS), which assesses facial expression, crying, breathing patterns, arm and leg movements, and state of arousal (8). In combination with monitoring vital parameters, this scale will enable reliable assessment of pain intensity during medical procedures. This will create the prerequisites for the systematic introduction of all procedures for the prevention, relief, and treatment of pain in newborns in the Republic of Croatia.

Aim

The aim of this study is to adapt Neonatal Infant Pain Scale (NIPS) instrument for pain assessment in newborns, in order to evaluate its content validity and reliability, with the goal to introduce and apply the scale in neonatal care in Croatia.

Methods

Data were collected at the Clinical Hospital Centre Rijeka between October 2024 and January 2025. A total of 94 healthy newborns, delivered either vaginally or by cesarean section, participated in the study. Before the pain assessment procedure, both parents read and signed informed consent and voluntarily agreed to the participation of their newborn in the study. During the study period at the Clinical Hospital Centre Rijeka, a total of 534 healthy newborns were delivered, which represents an 18% response rate.

After the back-translated NIPS had been approved by the author of the original instrument, a panel of expert judges assessed the cross-cultural equivalence between the original and the adapted versions. All modifications made during the translation process resulted in a preliminary version of the NIPS. The expert panel consisted of a professor with expertise in cross-cultural adaptation, a pain management specialist, and a language professional. Each expert received the original instrument, the synthesized forward and back-translated versions, as well as all comments provided by the translators and researchers throughout the adaptation process.

The panel systematically compared all versions of the instrument and evaluated idiomatic, experiential, conceptual, and semantic equivalence. Semantic equivalence was assessed by classifying each item as having "exactly the same meaning," "nearly the same meaning," or "a different meaning" compared with the corresponding item in the original scale. Following this evaluation and consensus discussion, a preliminary final version of the Croatian NIPS was established.

In the second phase of the study, the reliability, and clinical application of the instrument were assessed. Data were collected with the help of three nurses employed at the Clinical Hospital Centre Rijeka, who were asked to apply the scale to a sample of newborns. Prior to using the scale, two researchers trained the nurses on how to apply the scale, assess parameters, and record data in the questionnaire. The sample consisted of newborns undergoing routine blood sampling as part of the National Newborn Screening Program of the Newborn Screening Committee of the Ministry of Health of the Republic of Croatia. Screening is conducted as an organized system of testing for certain congenital diseases in all newborns of a defined population, with the aim of identifying them before they cause adverse health outcomes. As in most countries, newborn screening is a mandatory health protection measure in Croatia. Blood samples for screening are collected between the third and fifth day of life, and no later than the eighth day. Blood is most often drawn from the newborn's heel while still in the maternity ward (9). The inclusion criteria for newborns in the study were: gestational age from 37 + 0/7 weeks to 41 + 6/7 weeks; newborns classified as healthy according to their first clinical examination; Apgar scores of ≥7 at one and five minutes, as lower scores may be associated with alterations in central nervous system pain-processing mechanisms (10). Both vaginally and caesarean-delivered newborns were included, as the study aimed to assess whether there is a difference in pain perception between these two modes of delivery. In addition, the following exclusion criteria were applied: maternal use of opioids, as these substances may cross the placental barrier and cause changes in neonatal nociceptive pathways; maternal use of alcohol or drugs; mother under 18 years of age without a legal guardian present; mother with vertically transmittable infectious diseases such as syphilis, toxoplasmosis, cytomegalovirus infection, mumps, herpes, hepatitis B, and HIV/AIDS; and newborns with visible congenital malformations (9).

Instrument

The Neonatal Infant Pain Scale (NIPS) (4) is a behavioral scale used for pain assessment. It is designed to evaluate procedural pain in newborns. This scale takes into account pain assessment during and after a painful procedure and considers several behavioral indicators for assessing pain in both preterm and full-term newborns. The scale can be used to monitor a newborn before, during, and after a painful procedure, such as venipuncture. The instrument was developed at the Children's Hospital of Eastern Ontario.

The assessment parameters include:

- Facial expression (Q1): relaxed muscles, neutral calm face, grimaces (tense facial muscles, furrowed brows, chin/jaw).
- Crying (Q2): none, whimpering (mild intermittent moaning), and vigorous cry (loud screaming).
- Breathing patterns (Q3): relaxed breathing, changes in breathing.
- Arm and leg movements (Q4 and Q5): relaxed/restrained (no muscle stiffness, occasional random limb movements), flexion/extension (tense, straight, rigid, and/or rapid extension or flexion).
- State of arousal (Q6): sleep/awake (quiet, calm sleep or alert and calm), restless/nervous (awake, restless).

Each parameter is scored from 0 to 2 points, with a total score of 0–2 indicating no pain, 3–4 indicating moderate pain, and a score greater than 4 indicating severe pain (4).

Ethics

The study protocol was approved by the Ethics Committee of the Clinical Hospital Center Rijeka and the Ethics Committee for Biomedical Research of the Faculty of Health Studies, University of Rijeka (Class: 003-05/20-1/08, Reg. No.: 2170-29-02/1-20-02). Written informed consent for participation was obtained from the parents of all children after they had received both oral and written information regarding the study objectives, voluntary participation, ethical considerations, and data protection. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistics

Statistical analyses were performed using Statistica, version 14.1.0.8 (Cloud Software Inc.). Statistical significance was set at $p \leq 0.05$, with 95% confidence intervals. The sample size was determined based on the rule of thumb recommending 10 cases per item. Since the instrument contained six items, a minimum sample size of approximately 60 participants was required. A power/precision calculation with 80%

power and a 5% margin of error indicated a required sample size of 89 participants. Descriptive statistics were used to summarize the data, including mean and standard deviation. For nominal variables, frequencies and percentages were reported. The Kolmogorov-Smirnov test was applied to assess the normality of the data distribution. Since the data were not normally distributed, non-parametric tests were used. The Wilcoxon matched-pairs test was applied for two dependent samples, and Friedman ANOVA for three groups.

Repeated-measures ANOVA was performed for the vital parameters because the data are quantitative, and the Kolmogorov–Smirnov test indicated that they follow a normal distribution. The NIPS questionnaire, on the other hand, yields ordinal data; therefore, a nonparametric ANOVA was used to examine differences in the total score of the six behavioral indicators before, during, and after the painful procedure.

For categorical data with three groups, Cochran's Q test was employed. The reliability of the questionnaires was assessed using Cronbach's alpha coefficients, as well as by calculating the change in Cronbach's alpha if individual items were removed from the respective scale.

Results

The study included a total of 94 healthy newborns delivered via vaginal or cesarean section. General characteristics for the participants are summarized in Table 1. A total of 79.8% of the infants were born at 37+0/7 weeks of gestation, 4.2% at 37 weeks, and 16% after 38 weeks. Apgar scores were recorded at two intervals, with the second measurement being significantly higher than the first ($p < 0.001$).

Vital parameters

To compare heart rate and oxygen saturation before, during, and after the painful procedure, repeated measures ANOVA (RM ANOVA) with Bonferroni post-hoc testing was applied. The results are presented in Table 2.

Table 2. **Heart rate and oxygen saturation before, during, and after the painful procedure**

	Mean	95% CI	*p*
Pulse before	124.18	121.34–127.02	< 0.001
Pulse during	144.15	140.10–148.20	
Puls after	148.02	143.58–152.45	
oxygenation before	98.79	98.59–99.01	< 0.001
oxygenation during	97.55	97.18–97.92	
oxygenation after	97.83	97.48–98.17	

Note: 95% CI- confidence interval, *p* - statistical significance

Heart rate and oxygen saturation differed significantly between the pre- and intra-procedure measurements, as well as between the pre- and post-procedure measurements ($p < 0.001$). Changes in respiratory rate were significantly more frequent during the painful procedure ($p < 0.01$).

Behavioral responses

Facial expression (Q1) revealed that 22.4% of newborns grimaced before the procedure, compared to 24.5% after the procedure. During the painful procedure, all newborns exhibited grimacing. Crying (Q2)

Table 1. **General characteristics (N = 94)**

N = 94	Mean	Min	Max	SD	Z*	*p*
Apgar 1	9.78	7	10	0.59	3.3	0.001
Apgar 2	9.98	9	10	0.14		
Mass /g	3476.92	2240	4330	481.88		
Body length/cm	50.07	43	55	2.36		

Note: N- number SD- standard deviation *Wilcoxon matched-pairs test *p* - statistical significance

showed significant differences across all time points: 27.7% of newborns cried before the procedure, compared to 51.1% after.

Significant differences were observed across all behavioral assessment parameters (Q1–Q6) when comparing responses before, during, and after the painful procedure (Table 3.)

Figure 1. shows the total score of the six behavioral indicators before, during, and after the painful procedure.

The Friedman ANOVA revealed a significant overall difference ($p < 0.001$). Post-hoc analyses indicated significant differences between the pre-procedure and during-procedure measurements, as well as between the during-procedure and post-procedure measurements. No significant difference was observed between the pre- and post-procedure measurements ($p = 0.068$).

Discussion

The aim of this study was to adapt the Neonatal Infant Pain Scale (NIPS) for the Croatian-speaking area and to evaluate its reliability. The results demonstrate high internal consistency of the scale (α = 0.768–0.891), which is consistent with previous studies by Lawrence et al. (4) and Hudson-Barr (11). Although the inter-rater agreement (ICC 0.516–0.759) was moderate and somewhat lower compared to the excellent results reported by Sarhangi et al. (6), the findings confirm that the scale is a stable instrument for application within the local clinical context.

The interpretation of the results indicates a significant sensitivity of the NIPS scale to behavioral changes. The statistically significant increase in facial grimacing and changes in respiratory patterns during the painful procedure ($p < 0.001$) confirms the validity of the behavioral indicators measured by the scale. Furthermore, the correlation between the scale scores and physiological deviations (heart rate and oxygen saturation) supports the multidimensional nature of the neonatal pain response, aligning with international findings (10 – 12). The observation that a smaller proportion of newborns cried in the presence of parents suggests that situational factors may influence the intensity of the response captured by the scale, further emphasizing the importance of standardized assessment conditions.

The decision to validate the NIPS scale in Croatia (Bošković and Ličen (1)) is based on its successful cultural adaptation in numerous countries (5). The findings of this research provide an empirical basis for its integration into neonatal care standards in Croatia.

Study limitations

The primary limitation of this study is the relatively small sample size, which restricts the generalizability of the results to the broader national population and various gestational ages. Additionally, the research focused primarily on reliability and internal consistency, while aspects such as concurrent validity in relation to other behavioral scales within the Croatian context remain less explored.

Implications for future research

Future research should focus on validating the scale using a larger sample to achieve full national standardization. Comparative studies involving multiple pain assessment scales are recommended to identify the most sensitive instrument for specific types of stimuli (e.g., postoperative vs. procedural pain). Furthermore, it is necessary to investigate the impact of systematic NIPS implementation on long-term clinical outcomes and the effectiveness of pain management within neonatal intensive care units in Croatia.

Conclusion

The Croatian version of the NIPS scale demonstrated good reliability and high internal consistency (α = 0.846). Significant changes in vital parameters and behavioral indicators ($p < 0.001$) confirm the instrument's sensitivity in detecting neonatal pain. This study confirms the psychometric reliability of the scale for clinical use, while further research on a larger sample will enable its full standardization in accordance with national methodological guidelines.

Table 3. **Behavioral assessment parameters**

		0	1	2	*p*
Facial Expression	Before	73	21		< 0.001
	During	0	94		
	After	71	23		
Cry	Before	68	26	0	< 0.001
	During	0	27	67	
	After	46	48	0	
Breathing Patterns	Before	76	18		< 0.001
	During	1	93		
	After	72	22		
Arms	Before	69	25		< 0.001
	During	3	91		
	After	60	34		
Legs	Before	70	24		< 0.001
	During	1	93		
	After	66	28		
State of Arousal	Before	66	28		< 0.001
	During	0	94		
	After	59	35		

Note: *p* - statistical significance

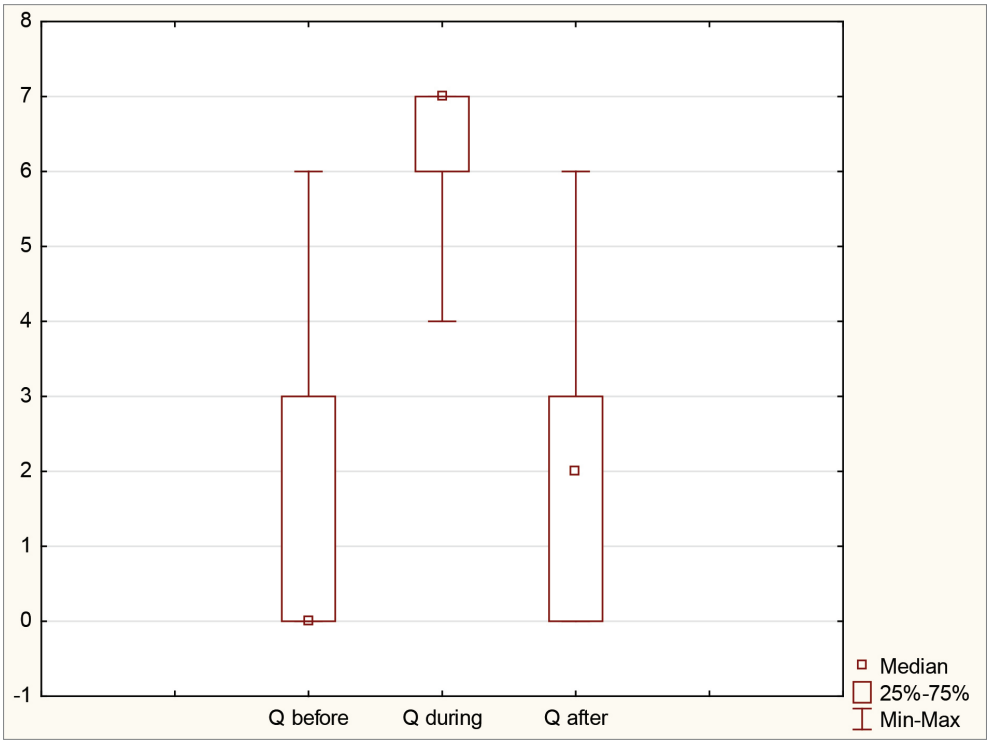

Figure 1. **Behavioral Responses**

Author contributions

Conceptualization and methodology (SB, MS, DŠ, IK, SŠ, AL); data curation and formal analysis (SB, MS, DŠ, IK, SŠ, AL); investigation and project administration (SB, MS, DŠ, IK., SŠ, AL); writing – original draft and review & editing (SB, MS, DŠ, IK, SŠ, AL). All authors have approved the final manuscript.

Conflict of interest

The authors declare no conflicts of interest.

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Use of Generative AI

During preparation, the author(s) used ChatGPT for language enhancement.

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