Analysis of agreement in the evaluation of pain in newborns during hepatitis B vaccination

Análise de concordância na avaliação da dor de recém-nascidos durante a vacinação contra hepatite B

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ABSTRACT

BACKGROUND AND OBJECTIVES: Healthy newborns inevitably undergo painful procedures from the first hours of life and pain assessment is essential for choosing the right treatment. The objective of this study was to evaluate the agreement between evaluators of the Neonatal Facial Coding System (NFCS) pain scale in healthy newborns before, during and after hepatitis B vaccination performed in the first 48 hours of life.
METHODS: This is an analysis of agreement between two evaluators, carried out as part of a quasi-experimental intervention study, developed in a maternity hospital in Belo Horizonte. Two researchers carried out an independent evaluation based on filming 2 minutes before, during and 2 minutes after the procedure.
RESULTS: The study included 129 newborns between August and December 2022, 60 (46.51%) in the control group (facilitated restraint) and 69 (53.49%) in the intervention group (breastfeeding). There was substantial agreement between the researchers before (0.69) and after (0.70) vaccination. When the agreement between the groups was analyzed, it was substantial for the evaluations of newborns submitted to facilitated restraint before and after the procedure. In the breastfeeding group, agreement was almost perfect before and substantial after the procedure.
CONCLUSION: There was substantial agreement between the researchers who used the NFCS scale before, during and after vaccination. This data validates the use of the scales when assessing the pain of newborns undergoing easy restraint and breastfeeding, even though it is an indirect method of assessment. It is important to highlight the importance of periodic staff training programs for the use of pain assessment scales at bedside.
Keywords: Newborn, Nursing, Pain assessment, Vaccination.

RESUMO

JUSTIFICATIVA E OBJETIVOS: Recém-nascidos saudáveis são submetidos a procedimentos dolorosos desde as primeiras horas de vida e a avaliação da dor é essencial para escolha do tratamento adequado. O objetivo deste estudo foi avaliar a concordância entre pesquisadores da escala *Neonatal Facial Coding System* (NFCS) antes, durante e após a vacinação contra hepatite B nas primeiras 48 horas de vida de recém-nascidos saudáveis.
MÉTODOS: Trata-se de uma análise de concordância entre pesquisadores, realizada como um estudo de intervenção quase-experimental, desenvolvido em uma maternidade pública de Belo Horizonte. Dois pesquisadores procederam a avaliação independente a partir de filmagens 2 minutos antes, durante e 2 minutos após o procedimento.
RESULTADOS: Foram incluídos 129 recém-nascidos entre agosto e dezembro de 2022, sendo 60 (46,51%) no grupo controle (contenção facilitada) e 69 (53,49%) no grupo intervenção (amamentação). Observou-se concordância substancial entre os pesquisadores antes (0,69) e após (0,70) a vacinação. Quando analisada concordância entre os grupos, ela foi substancial para as avaliações de recém-nascidos submetidos à contenção facilitada antes e após o procedimento. No grupo submetido à amamentação, a concordância foi quase perfeita antes e substancial depois do procedimento.
CONCLUSÃO: Há concordância substancial entre os pesquisadores que utilizaram a escala NFCS antes, durante e após a vacinação. Este dado valida a utilização das escalas durante a avaliação da dor de recém-nascidos submetidos à contenção facilitada e amamentação, mesmo tratando-se de um método indireto

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HIGHLIGHTS
- Assessment of neonatal pain by the nurse;
- Applicability of the NCFS Neonatal Pain Assessment Scale during vaccination;
- Use of methods to minimize neonatal pain.

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de avaliação. É importante destacar a importância de programas periódicos de capacitação da equipe para utilização de escalas de avaliação da dor à beira leito.
Descritores: Enfermagem, Medição da dor, Recém-nascido, Vacinação.

INTRODUCTION

Pain is defined as an ''an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"[1]. The recognition of pain as a health problem has been gaining prominence in recent decades, highlighting the need to implement assessment and treatment strategies according to the specificities of each age group. In addition to all the difficulties related to its identification and treatment, the neonatal period brings other challenges.

Until the 1980s, misconceptions related to pain processing in newborns (NB) led to its undertreatment[2]. The immaturity of the central nervous system, the presence of demyelinated nerve fibres and the risk of drug dependence were aspects that contributed to the fact that, in clinical practice, the treatment of pain was not understood as a health priority for many years[2,3].

However, current scientific evidence shows that NB have sufficient anatomical, physiological and neurochemical development to be able to perceive and react to painful stimuli[2,3]. By the 24th week of intrauterine life, some thalamic cortical connections that are essential for pain perception are present and are already organized[4]. Therefore, NB, even if premature, have neurotransmitters and neural pathways similar to adults and are more exposed to painful experiences due to the immaturity of the inhibitory efferent pathway[5].

Untreated pain can have a negative impact on the development of NB, which can be identified immediately through difficulties in physiological and behavioral recovery after painful stimuli[5]. Later effects, such as internalizing behavior, a tendency towards depression, drug addiction and alcoholism in adulthood are also described in the literature[6].

So that pain treatment can be implemented, and the goal of prevention and control can be achieved, health professionals must be able to recognize NB pain, since there is an interdependence between assessment and treatment. Observation of physiological, behavioral and contextual changes is used to assess the NB's pain experience[8]. Various scales have been used in different contexts depending on the age of the target population, the nature of the procedures, the clinical situation and the easiness and experience of use[7-9].

No specific scale for this assessment has shown superiority so far. Because this is necessarily an indirect measurement, health professionals can be influenced by their own experience, participation in training and research and personal experiences[8]. In this way, the variability between researchers in assessing NB pain can compromise the results of the evaluation and, consequently, the implementation of appropriate treatment, increasing exposure to pain[10].

The present study consists of one of the stages of a quasi-experimental study which verified the influence of breastfeeding on pain control in healthy NB during application of vaccines against hepatitis B in the first 48 hours of life. In this stage, the primary objective of the study was to evaluate the agreement between researchers who used the Neonatal Facial Coding System (NFCS) scale to assess the pain of healthy NB before, during and after vaccination against hepatitis B in the first 4 hours of life. A secondary objective was to assess the applicability of using the NFCS during pain assessment of breastfed NB who were submitted to facilitated restraint.

METHODS

This is an analysis of agreement between researchers, carried out as part of a quasi-experimental intervention study carried out in a philanthropic public maternity hospital in Belo Horizonte. Two independent researchers used the NFCS pain scale. Evaluator 1 carried out the assessment synchronously, during the administration of the vaccine, and evaluator 2, asynchronously, by filming the NB' faces.

Patients were randomly assigned into two groups: A (control group), made up of NB who were unable to breastfeed due to clinical contraindications, family disapproval or the mother's absence at the time of vaccination. In this group of patients, the measure of facilitated restraint was adopted, a resource used in the unit's routine.

Group B (intervention) was made up of NB who were breastfed. The study included late preterm or healthy term NB (34 to 41 weeks of gestational age), admitted to the rooming-in unit, who had a clinical indication for Hepatitis B vaccination. To be included in group B, the mother had to be present at the time of the procedure. The exclusion criterion was the presence of clinical alterations during the procedure that made it impossible to continue with the pain control measure instituted (facilitated restraint or breastfeeding).

Procedure

Facilitated restraint was carried out by the vaccine room nursing technician five minutes before the procedure using a blanket that wrapped around the baby's upper and lower limbs, promoting body contouring. In the breastfeeding group, the mothers were instructed to keep the baby's belly in contact with their own body, so that their arms would stabilize the NB's upper and lower limbs, which were positioned on the mother's breast 5 minutes before the vaccine was administered or until they established a regular sucking rhythm.

In both groups, the right lower limb remained accessible for the procedure. The vaccination was carried out by the nursing technician in the vaccination room, who gently stabilized the NB's right lower limb and administered 0.5 mL of the Hepatitis B vaccine, using a 1 mL syringe with a 13x4.5 needle at a 90° angle.

The procedure was filmed by the researcher. Heart rate, oxygen saturation and the score on the NFCS scale were recorded 2 minutes before the start of the procedure, during the administration of the vaccine and 2 minutes after the end of the procedure. A Mindray MEC-1000 multiparameter monitor

with a pulse saturation sensor, positioned on the lower limb contralateral to the one where the vaccine was administered, was used to assess heart rate and oxygen saturation.

Pain assessment - Neonatal Facial Coding System

The NFCS is a behavioral scale that analyzes the NB's facial mimicry using 7 indicators (brow bulge, eye squeeze, deepening of the nasolabial furrow, open lips, stretched mouth, taut tongue and tongue protrusion)[9]. The score ranges from 0 to 7, and pain is considered to be present when the score is greater than or equal to 3. The assessments were carried out 2 minutes before the procedure, during the insertion of the needle into the NB's skin and 2 minutes after the end of the procedure.

In this stage of the agreement analysis, two independent observers were responsible for measuring the pain scale indicators, with evaluator 1 carrying out the assessment synchronously during the procedure and evaluator 2 filming it.

Before starting the study, an alignment training session was held at a workshop attended by the researchers involved in the data collection. At the workshop, in addition to the presentation of the scale and clarification of doubts, 5 clinical situations were presented, taken from videos available on the internet, from which the researchers carried out the evaluations using the NFCS and clarified their doubts with the main researcher.

Ethical considerations

This study was conducted in accordance with the ethical principles of CNS Resolution No. 466/2012 and approved by the UFMG Research Ethics Committee under CAAE number 46889120.0.3001.5132. The main benefits of this stage were ensuring the reliability of the data collected during the research and the training of the institution's professionals involved in the research. During the concordance assessment stage, the main risk was some kind of embarrassment for the researchers involved, which was mitigated by masking the name of the examiner identified through codes. All those responsible for the NB included in the study signed the Free and Informed Consent Term (FICT) and authorized the images' recordings.

Statistical analysis

Data was entered into an Excel spreadsheet and analyzed using the Stata software version 12.0, using the kappa statistical coefficient, which measures the agreement between two researchers by adjusting the agreement that would be expected for the case[11]. The method is based on a contingency matrix showing the number of cases in which both researchers agree on each response category. If one of the researchers opts for only one response category, this can lead to a contingency matrix with empty cells, which can affect the calculation of the Kappa coefficient.

The agreement of the overall score and between each of the instrument's items was established by considering the values: Kappa: 0 to 0.19 - poor agreement; 0.20-0.39 - relative agreement; 0.40-0.59 - moderate agreement; 0.60-0.79 - substantial agreement; 0.80-0.99 - almost perfect agreement and 1.00 - perfect agreement[11]. The variables analyzed were eye squeeze, brow bulge, deepening of the nasolabial furrow, stretched mouth, horizontally and vertically stretched mouth and taut tongue, before, during and after the hepatitis B vaccination procedure. NFCS scores greater than or equal to 3 were considered as indicators of pain. The researchers were identified as A and B, keeping their identity confidential during the statistical analysis. Fisher's exact test was used to test the homogeneity of the sample.

RESULTS

A total of 129 NB were included in the study between August and December 2022, being 60 (46.51%) in the control group (facilitated restraint) and 69 (53.49%) in the intervention group (breastfeeding). The groups were considered homogeneous. Each researcher carried out 387 assessments, 3 per NB. Considering the final NFCS score, there was substantial agreement between the researchers before and after vaccination. During the procedure, raw agreement was high (96.12%), but it was not possible to calculate the Kappa agreement index, as one of the researchers only recorded the presence of pain as a response category.

When the agreement of the pain assessment between the groups was analyzed, the agreement result was substantial before and after the procedure in the group submitted to facilitated restraint (control group). In the breastfeeding group (intervention), before the procedure the agreement was almost perfect and substantial after it (Table 1).

Table 2 shows the proportion of agreement between the researchers according to the variables analyzed by the NFCS. All the variables showed substantial or almost perfect agreement, except for the variable "taut tongue" during and after the procedure, which showed poor agreement.

When the inter-researcher reliability for each variable in the intervention and control groups was analyzed separately, the raw agreement values before the procedure were above 95% and the Kappa coefficient was substantial to almost perfect for all the variables in the scale. During the procedure, raw agreement was below 50% between the variables "mouth stretched", "mouth

Table 1. Raw agreement values and Kappa agreement index of the total score of the Neonatal Facial Coding System scale before, during and after application of the hepatitis B vaccine (n = 129).

Time of assessment	Raw agreement (%)/Kappa Facilitated restraint group	Raw agreement (%)/Kappa Breastfeeding group	Raw agreement (%)/Kappa General
NFCS before procedure	95/0.64	98.55/0.80	96.9/0.69
NFCS during procedure	96.67/*	95.65/*	96.12/*
NFCS after the end of the procedure	82.14/0.64	93.94/0.74	88.52/0.70

*One of the researchers recorded only one response category, making it impossible to calculate the Kappa coefficient.

Table 2. Raw agreement values and Kappa agreement index between researchers for each variable of the Neonatal Facial Coding System scale before, during and after application of vaccine on healthy newborns against hepatitis B in the first 48 hours of life.

Moment of assessment	Variables	Raw agreement (%)	Kappa
NFCS before procedure	Brow bulge	96.90 %	0.73
	Eye squeeze	98.45%	0.85
	Deepening of the nasolabial furrow	96.90%	0.73
	Stretched mouth	98.45%	0.87
	Stretched vertical mouth	96.90%	0.70
	Stretched horizontal mouth	96.90%	0.70
	Taut tongue	96.90%	0.70
NFCS during procedure	Brow bulge	96.90%	*
	Eye squeeze	97.67%	*
	Deepening of the nasolabial furrow	97.67%	*
	Stretched mouth	96.12%	*
	Stretched vertical mouth	93.80%	*
	Stretched horizontal mouth	91.47%	*
	Taut tongue	90.70%	0.10
NFCS after procedure	Brow bulge	87.60%	0.67
	Eye squeeze	83.72%	0.61
	Deepening of the nasolabial furrow	86.82%	0.68
	Stretched mouth	86.05%	0.67
	Vertically stretched mouth	88.37%	0.71
	Horizontally stretched mouth	86.05%	0.65
	Taut tongue	81.40%	0.1887

*One of the researchers recorded only one response category, making it impossible to calculate the Kappa coefficient.

stretched horizontally", "mouth stretched vertically" and "taut tongue", with Kappa values showing a poor association.

After the procedure, the raw agreement in the control group (facilitated restraint) ranged from 61.17% to 81.33% between the variables on the scale, with a Kappa coefficient of substantial to almost perfect (Kappa of 0.60 to 0.75). In the intervention group (breastfeeding), raw agreement after the procedure was above 88.41% for all the variables and the Kappa coefficient ranged from relative to moderate agreement (0.28 to 0.57).

DISCUSSION

Agreement between examiners reduces deviations related to the study's criteria and procedures, increasing its accuracy. In order for examiner error not to affect the accuracy of the data and fulfill the role for which it is intended, especially in studies whose primary objective is to obtain results from evaluation processes, in order for the data to be reliable and reproducible, methodological rigor is necessary.

Healthy NB are inevitably subjected to painful procedures from the first hours of life due to the need for routine care, such as administering vitamin K and vaccines, and are also vulnerable to the neurodevelopmental impacts of untreated pain[11]. Research into the repercussions of painful experiences in early life has shown that more intense pain responses (prolonged crying and higher pain scores) have been observed during routine application of vaccines at 4 and 6 months of age in circumcised NB when compared to uncircumcised ones[12].

Untreated pain in early life has been identified as an aspect that favors the development of chronic pain in children and adults[13,14]. There is a gap between the recommendations, the evidence produced by the scientific community and the adoption of practices with the objective of controlling pain in the neonatal period at bedside[17].

Assessment remains the main challenge for adequate pain control. More than 65 scales are available and validated for assessing pain in NB in different care settings[18]. These scales include physiological, behavioral and contextual variables, with the objective of qualifying and quantifying pain. The use of scales to assess pain experience is an indirect assessment method that necessarily requires the presence of a trained professional and articulated assessment and treatment protocols.

Health professionals play a key role in controlling NB pain, being responsible for diagnosis, as well as monitoring pain intervention and the effectiveness of treatment. Therefore, investing in training the multidisciplinary team to acquire specialized knowledge and develop skills is a fundamental aspect for ensuring accurate diagnosis and appropriate treatment, with a focus on pain control[19].

Although other assessment methods, such as the dosage of biomarkers and the identification of changes in cerebral blood flow using infrared spectroscopy (NIRS) are also being studied, the use of scales remains the most viable alternative at bedside, enabling immediate identification of pain and adoption of control methods[20].

The NFCS scale has been widely used to assess pain in the neonatal period because it includes behavioral variables related to facial mimicry. A randomized clinical trial with 55 NB compared kangaroo care and breastfeeding during hepatitis B vaccination and the results showed that the scale score was lower in the group that combined breastfeeding and skin-to-skin contact in all the periods evaluated. The mean heart rate values were higher in the skin-to-skin contact group. These results show that the combination of breastfeeding and contact enhances the analgesic effects during a painful intervention[19].

Another study compared the pain control of 131 healthy NB up to three days postnatal age during BCG vaccine applications. Patients were randomized into four groups: breastfed (n=33), wrapped a few minutes before injection (n=34), wrapped and breastfed (n=31), and the last group received no intervention (n=33). All the interventions resulted in lower pain intensity when compared to the control group, which received no intervention, and breastfeeding was more effective in controlling pain when compared to facilitated restraint[4].

The analgesia promoted by breastfeeding was also evaluated in a study that compared the use of breastfeeding and 25% dextrose in the pain control of 120 healthy NB, born at term and up to three months old, who were going to receive the DTP vaccine. The results showed that the breastfeeding group and the dextrose

group had a shorter crying time when compared to the control group. The score on the NFCS scale was also lower in the intervention groups when compared to the control group[21].

Despite the evidence showing the effectiveness of breastfeeding as a non-pharmacological method of pain control and a recommendation from the Brazilian Ministry of Health[21] for its use, in clinical practice there are still limitations and questions about the most appropriate assessment methods according to each context or procedure to be carried out. In the case of the NFCS, as it is a facial mimicry scale, comprehending the extent to which the adoption of breastfeeding compromises access to the assessment is an important issue that we sought to ensure through the application of agreement tests between researchers, an issue that has not been described in the studies investigated so far.

Some studies report differences in agreement between observers, which compromises the results and the replication of the data obtained. This may be due to their experience or lack of experience with the subject being researched, as mentioned in a study on breast cancer, in which researchers with more experience in the area agreed more with each other than those with less experience[22].

In another study, the authors presented several factors that can influence agreement between observers. Among them, the one that can most influence data recording by humans is the fact that behavior is transitory, i.e. it cannot be frozen and revisited. Filming is an excellent resource, although it can cause discomfort for participants[23].

In addition, during the execution of the research, there may be protocols that involve the observation of several behaviors and/or individuals simultaneously. Sometimes these observations take place at very short intervals and without scheduled breaks for recording the data. Having to observe many phenomena simultaneously, without predetermined breaks, can result in recording errors. In addition, some researchers create recording sheets whose organization and formatting make it difficult to locate information about which behaviors should be recorded, where and in what sequence[23].

In the present study, substantial agreement was found between the two researchers for the total score of the NFCS scale before and after application of vaccines of the 129 investigated NB. It's important to note that the alignment workshop was an important stage in the method to ensure comprehension of the assessment tool to be used and to clarify any doubts.

During the procedure, as one of the researchers only recorded the presence of pain, it was not possible to calculate the Kappa coefficient. In the breastfed group, agreement between researchers before the procedure was almost perfect. When the agreement coefficient for each variable in the scale was analyzed, all showed substantial agreement before and after the procedure, except for the "taut tongue" variable, which showed poor agreement.

This study found that there was substantial to almost perfect agreement before, during and after the procedure for six variables on the NFCS scale. Only the "taut tongue" variable showed poor agreement, both in the control group (facilitated restraint) and in the breastfed group. When the kappa coefficient of the NFCS scale variables was analyzed separately between the groups, it was observed that the variables "stretched mouth", "horizontally stretched mouth", "vertically stretched mouth" and "taut tongue" showed a poor association, but a raw agreement of 96% between researchers, which is due to the fact that the NB was breastfeeding at the time of the evaluation, which hinder visualization.

This data points to the possibility of a limitation in applying this scale when the pain control method used is breastfeeding. The difficulty of assessing these parameters can compromise the total score and the identification of NB pain, despite the fact that several studies have used this assessment tool in the context of breastfeeding[18]. Considering that the scale has seven variables, which aim to identify the presence or absence of pain and that values equal to or greater than 3 indicate its presence, the difficulty of accessing these variables would not be enough to change the condition identified from absence of pain to presence of pain. Therefore, it is understood that this limitation does not compromise its identification, since the scale is not intended to describe pain intensity.

There were some limitations to the present study: the researchers recorded the data at different times, with the first researcher recording synchronously at the time of the procedure and the second researcher filming, which may have provided the second observer more elements and observation time. In addition, the study was carried out in a single center and the sample was not randomized or masked due to the nature of the research. It is also important to consider that the experience of the professional can influence the identification of pain signals, although an attempt was made to control such bias through alignment training.

Nevertheless, the present study provides unpublished data that can be used both locally and to generalize the findings to other institutions. It was possible to identify in which sub-items of the NFCS there is less agreement between researchers and even discuss the applicability of using the scale in situations where breastfeeding is used as a pain control measure.

Moreover, the study contributes to professional nursing practice, since nurses must have the knowledge to assess and recognize signs of neonatal pain. Thus, this scale can be applied in the context of vaccination, in order to institute measures to minimize neonatal pain during this routine procedure.

CONCLUSION

In general, agreement between the researchers when applying the NFCS scale was good before, during and after the procedure. However, of the 7 items that make up the score, four of them ("mouth stretched", "mouth stretched horizontally", "mouth stretched vertically" and "taut tongue") may be more difficult to identify when the pain control measure instituted is breastfeeding. As identified in this study, it is important to evaluate the clinical applicability of the scales since the identification of pain-related variables can vary according to the procedure or treatment. A compromised diagnosis can also compromise treatment, impacting on NB development in the short and long term.

AUTHORS' CONTRIBUTIONS

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Statistical analysis, Data Collection, Project Management, Writing - Preparation of the original, Writing - Review and Editing, Supervision
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Data Collection, Methodology, Writing - Review and Editing, Supervision
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Data Collection, Writing - Preparation of the original, Writing - Review and Editing
Juliana de Oliveira Marcatto
Resource Management, Project Management, Methodology, Writing - Review and Editing, Supervision, Visualization

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