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Journal of Pediatrics & Neonatal Care

Review Article

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Non-pharmacological management in a neonatal intensive care unit- a systematic review

Abstract

Introduction: For many years it was thought that newborn babies could not feel pain due to their incomplete nervous system. Since 1980, there has been a revolution in the understanding of neonatal pain and more concern about this issue. Newborns (NBs) hospitalized in the Intensive Care Unit are commonly exposed to numerous stressful and painful events capable of causing physiological and behavioral disorganization. The reduction and prevention of these stimuli through non-pharmacological measures are essential to avoid harmful effects in the short and long term. Many studies address non-pharmacological management in the neonatal ICU; however, there is still doubt about the effectiveness of these methods. The objective of this study is evaluating the effectiveness of non-pharmacological methods used in the NICU to manage newborns.

Methodology: Systematic review of the literature based on the SciELO, PubMed , BIREME and Cochrane databases between 1998 and 2018, guided by the DeCS descriptors "*Neonatal Intensive Care Units*", "*Pain Management*" and MeSH descriptors "*Neonatal intensive Care*" , "*Neonatal*", "*Nonpharmacological Management*" , "*Complementary Therapies*" . An exploratory reading of the titles was carried out, followed by an analytical reading of the relevant studies. Three validated pain scales were considered: The NFCS Coding System, Newborn and Infant Pain Scale (NIPS) and Premature Infant Pain (PIPP). The level of evidence of the selected articles was assessed using the Oxford scale.

Results: A total of twelve studies involving around eight thousand newborns were included, including one Meta-Analysis, seven Systematic Reviews and four Randomized Clinical Trials, whose levels of evidence ranged from 1A to 1B on the Oxford scale. The findings indicated an improvement in crying time and pain scales with breastfeeding, music therapy and the Kangaroo method. A conclusion cannot be reached regarding the other techniques included in the study.

Conclusion: Despite the heterogeneity of studies, the benefits of using breastfeeding, music therapy and Kangaroo Care in pain management are evident. Larger studies must be carried out with greater methodological rigor to confirm the benefits in addition to exploring the best approach to dealing with different types of pain.

Keywords: neonatology, pain management, neonatal intensive care units, revision

Volume 13 Issue 3 - 2023

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Received: October 24, 2023 | **Published:** November 7, 2023

Introduction

For many years, the prevailing assumption in medicine was that newborns did not have the ability to feel pain due to the incomplete development of their nervous system. However, the 1980s witnessed a revolution in the understanding of neonatal pain, with a series of studies highlighting the presence of pain in neonates and its consequences.[1]

Newborns hospitalized in the Neonatal Intensive Care Unit (NICU) are commonly exposed to numerous stressful and painful events, including excess light, noise, manipulation and recurrent venipuncture. In a NICU setting, newborns are subjected to an average of 50 to 134 painful procedures per day, often performed without the effective adoption of analgesic protocols.[2] This leads to physiological and behavioral disorganization in newborns, using energy reserves that would be directed towards growth and development.[3] Furthermore, the immature nervous system predisposes to important physiological and psychological sequelae of inadequately treated pain.[3]

Studies indicate that, contrary to previous assumptions, newborns, especially premature babies, demonstrate greater sensitivity to pain, presenting prolonged hyperalgesia after acute painful stimuli.[4] This is related to an increase in the excitability of nocioceptive neurons in the spinal cord, known as the windup phenomenon.[5,6] This prolonged excitability triggers the activation of pain pathways, including in response to non-painful tactile stimuli, such as manipulation, resulting in physiological responses to stress for extended periods after the initial pain experience.[7–9]

Physiological responses to painful stimuli translate into an immediate increase in heart rate (HR), blood pressure (BP), HR variability, intracranial pressure and a decrease in oxygen saturation ($SpaO_2$).[9,10] The most commonly used scales for pain assessment are: the Neonatal Facial Activity Coding System (NFCS) and the Newborn and Infant Pain Scale (NIPS). The Premature Pain Profile Scale (PIPP) is the most recommended for PMTs as it takes into account the changes specific to this group of patients.[11]

Measures used in the NICU routine can be divided into two large groups - pharmacological and non-pharmacological. Pharmacological treatment consists of administering medications with the aim of reducing the discomfort experienced by the newborn. While non-pharmacological treatment is understood as the adoption of behavioral and environmental measures that can reduce such suffering.[12] Non-pharmacological therapies include: Kangaroo method, control of light exposure, control of sound exposure, music therapy, breastfeeding, octopus method and restraint method.

The Kangaroo method involves early skin-to-skin contact between the mother and the low birth weight and/or preterm baby in a gradual and increasing manner, safer and more pleasant for both, presenting three distinct stages.[13] The method is conducted in accordance with the figure provided in the Appendix 1.[14]

Figure 1 Mother and father with their LBW newborns in kangaroo position (Source: World Health Organization. Kangaroo Mother Care: A Practical Guide, 2004)

Controlling sensory light exposure consists of promoting cyclical brightness in the NICU. This is allowed by using an almost opaque blanket in the incubator for a period between 19 am and 7 am, being removed afterwards and adjusting the ambient lighting to standard lighting levels (300 lumens/m²).[15]

Sound exposure control consists of using a noise dampener as an individual, safe and comfortable device to protect newborns against high-intensity noise in the NICU.[16] The electrical activity of the central nervous system changes in response to acoustic stimulation in the range between 36 dB and 90 dB. Excessive sound may influence the neuroendocrine system and may have and indirect effect on immunity.[17]

Music therapy consists of the application of different forms of musical performance such as recorded or live music produced by one or more instruments and the female voice of the therapist or mother.[18] Music is beneficial to coordinate cortical functions of infantile brain, reducing the crying episodes and improving physiological functions.[19]

Breastfeeding consists of offering milk directly from the mother's breast or through a nasogastric tube (NGT), allowing pain relief in addition to providing nutritional and immunological benefits.[20]

The octopus method consists of using octopuses with crocheted tentacles similar to umbilical cords to simulate the intrauterine environment for premature newborns. It emerged as a project called "Octo Project" (Octopus Project) in Denmark in February 2013.[21] On Appendix 2, there is the image of the crocheted tentacles.[22]

Gentle restraint method consists of flexing the lower and upper extremities with alignment in the midline of the upper limbs, positioning the hand close to the mouth. Blanket swaddling can be used in newborns as long as they are adequately monitored and clinically stable.[23] In Appendix 3, there is a representative image illustrating how to perform facilitated containment.[24]

Figure 2 Tentacles for Tinies (Source: The Many Arms of the Crocheted Octopus. Irish medical journal, 2018).

Figure 3 Gentle restraint step by step (Source: Pediatric Nursing Procedure Manual, 2014).

The importance of these methods is to improve the care of newborns during hospitalization in the NICU, ensuring qualified and humanized neonatal care, in addition to avoiding possible damage due to exposure to stress.[23] Many studies address non-pharmacological management in the neonatal ICU; however, there is still doubt about the effectiveness of these methods.

The objective of this study is to carry out a systematic review of the literature on the effectiveness of non-pharmacological methods used in the neonatal ICU to manage pain in newborns.

Methodology

Design: systematic literature review study of non-pharmacological methods used in ICU for pain in newborns.

Bibliographic research methodology: The bibliographic research was carried out in online virtual libraries PubMed , VHL , SciELO and Cochrane using the descriptors (DeCS) used in the search: "Neonatal Intensive Care Units", "Pain Management" MeSH descriptors "Neonatal Intensive Care", "Neonatal", "Nonpharmacological Management", "Complementary Therapies" with filters for period (1998 to 2018), language (English, Spanish and Portuguese), types of studies (Clinical Trial, Meta-Analysis and Systematic Reviews). Only articles with Systematic Review, Meta-Analysis and Clinical Trials methodology were selected. No cohort or case-control studies were found.

Data analysis methodology: Initially, an exploratory reading of the titles and type of study was carried out in accordance with the objective of the research. Then, the relevant studies were selected, followed by an analytical reading and the full text of the selected articles was obtained. Initially, the methodology of each article was analyzed in an attempt to evaluate the homogeneity of variables for

the newborn population, intervention methods and results. As all non-pharmacological methods evaluate the pain response in newborns, three validated pain scales were considered: The NFCS Coding System[20,25] (Appendix 1), Newborn and Infant Pain Scale (NIPS) (Appendix 2)[26] and Premature Infant Pain Profile (PIPP) (Appendix 3).[27] The level of evidence adopted for the selected articles was the Oxford scale. It was initially planned to perform a meta-analysis but it was not feasible due to inconsistent reports or marked clinical heterogeneity in study populations, interventions and outcomes studied. Studies on the non- pharmacological methods mentioned above were researched. However, no article was identified that met the methodological criteria regarding the octopus method.

Inclusion criteria: Clinical Trial articles, preferably double-blind randomized, Systematic Review and Meta-Analyses, were included.

Exclusion criteria: articles whose methodology is not suitable for systematic review studies will be excluded.

Results

Figure 1 shows a flowchart of the results of the bibliographic search in electronic libraries using the descriptors mentioned above, initially obtaining 272 titles. Of these, 74 texts were identified, with titles and abstracts written and read, with subsequent exclusion of 62 articles as they did not meet the objectives of the study. Thus, 12 eligible articles were found that met the inclusion criteria and the objective of the study.

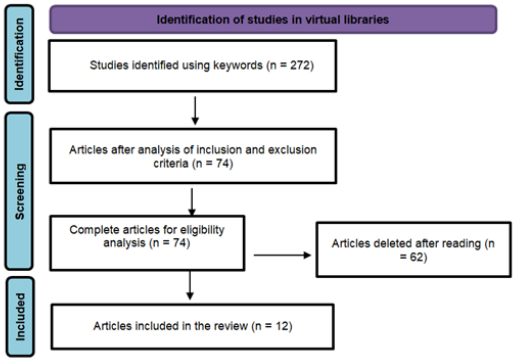

Figure 1 Flowchart of the selection of articles included in this study.

A total of twelve studies involving approximately eight thousand neonates were included. Nine studies evaluated premature newborns,[28] three at term and two included both. The studies were conducted in 8 different countries; United States (2), Canada (4), China (1), Finland (1), Spain (1), Italy (1), India (1) and Iran (1), as described in Table 1.

Shabani et al.,[29] conducted a study to evaluate the effect of music therapy on physiological and behavioral pain responses in PMTs during and after phlebotomy. This randomized clinical trial (RCT) involved 40 premature newborns between 29 and 36 weeks weighing less than 2,500 grams who underwent the technique 5 minutes before phlebotomy until 10 minutes after collection. The study demonstrated benefits in HR values, facial expression of pain (assessed by the NFCS scale) and sleep-wake pattern.

Standley et al.,[30] carried out a study to evaluate the benefits of using music therapy in premature newborns between 28 and 35 weeks and with low birth weight. Furthermore, the study aimed to establish best practice guidelines for the use of MT in the NICU. This analysis combined data from 10 randomized controlled trials (RCTs) with a total number of 1,243 neonates. The results revealed significant improvements in physiological parameters such as heart rate (HR), respiratory rate (RR), oxygen saturation ($SpaO_2$), blood pressure (BP), sucking/swallowing capacity, weight gain, behavior and length of stay. The benefits were greater in live music therapy and early onset in those with low birth weight and females.

Hartling et al.,[31] through a systematic review, they analyzed nine RCTs, which involved a total of 388 NBs. The review sought to evaluate the effectiveness of music as a therapy for full-term and premature newborns based on several measures, including physiological parameters (HR, RR, $SpaO_2$), behavior and pain (Riley Infant Pain Scales (RIPS), NFCS, NIPS and Movement Coding System (MCS), as well as facial expression using the maximally scale Discriminative Facial Movement Coding System (MAX).

Bergomi et al.,[32] carried out an RCT with the purpose of investigating the effectiveness of music therapy in comparison with the use of sucrose or another standard procedure in newborns from 30 weeks of GA with at least 48 hours to live, without the use of medications to relieve pain. However, it did not detail the details of randomization, allocation and blinding of the study. The assessment covered physiological measures (HR and $SpaO_2$) as well as behavioral measures such as the PIPP pain scale and sleep-wake pattern. A reduction in pain associated with MT was observed with the reproduction of Mozart's "Sonata K.448".

Polkki et al.,[33] conducted a systematic review with the objective of evaluating the effectiveness of MT in the pain of premature infants admitted to NICUs. The review covered two RCTs with a total of 41 neonates, analyzing physiological (HR, RR, BP, $SpaO_2$), behavioral (facial expression, movement and sleep-wake pattern) and pain (NIPS and NFCS) measures.

Obeidat et al.,[34] undertook a systematic review to determine the effectiveness of gentle restraint as a non-pharmacological management during invasive procedures performed on PMTs admitted to NICUs. In this analysis, five RCTs were considered with a total of 132 premature babies. Assessment parameters included pain, measured by the NIPS scale, as well as physiological measures (HR and $SpaO_2$) and behavioral aspects (sleep-wake pattern). The results suggested a reduction in pain during procedures.

Singh et al.,[35] carried out an RCT to determine the analgesic effect of breastfeeding during heel puncture in healthy newborns. Assessment parameters included physiological measurements (HR, $SpaO_2$ and BP) and crying time. The results highlighted the benefits of breastfeeding as analgesia during painful procedures.

Benoit et al.,[36] carried out a systematic review to evaluate the effectiveness of breastfeeding and expression in reducing acute pain caused by the procedure in preterm and full-term newborns. In this study, data from 21 RCTs were examined, involving a total of 2,336 neonates. To evaluate the effectiveness of the technique, parameters such as HR, crying time and pain assessment were considered, using scales such as PIPP, NIPS, DAN and NFCS. They observed equal or greater benefits to sweetened solutions after procedures such as heel puncture, venipuncture and intramuscular injections.

Zhu et al.,[37] conducted an RCT with 250 healthy newborns to determine the effectiveness of breastfeeding in three different approaches in relieving pain caused by heel puncture: breastfeeding, music therapy and the combination of both techniques. Pain was assessed using the NIPS score and crying time and latency were measured. The results revealed that breastfeeding provided a superior benefit over MT, while combining MT with breastfeeding demonstrated no additional benefit in reducing pain.

Citation: Machado MEPF, Paiva TN, Paiva ISD. Non-pharmacological management in a neonatal intensive care unit- a systematic review. *J Pediatr Neonatal Care.* 2023;13(3):213–217. DOI: 10.15406/jpnc.2023.13.00519

Cordero et al.,[38] in a systematic review based on 21 RCTs with a total of 2,030 patients, to determine the effectiveness of kangaroo care, breastfeeding, non-nutritive sucking and gentle restraint in pain management. Multiple evaluation parameters were used, such as pain manifestation, measured by pain scales (NIP and PIPP), physiological indicators (HR and $SpaO_2$), in addition to electrocardiogram and cortisol. In relation to the kangaroo method, numerous advantages were described in addition to pain management, including increased mother-child bonding, encouragement of breastfeeding, greater competence and confidence of parents in handling their child, better thermal control and a shorter hospital stay.

Almadhoob et al.,[39] carried out a systematic review to determine the effects of reducing sound on the growth, neurological development and sleep pattern of newborns. Within this study, an RCT was included that com-pared the use of silicone tampons with a control group without use in 34 neonates with a gestational age of less than 32 weeks and birth weight of less than 1,500 grams. Several parameters were evaluated, including body measurements (weight, height and BMI), auditory function (AABR and EOA), sleep patterns (sleep time), mental development index (Bayley II), suction feeding time or nasogastric tube, time on mechanical ventilation, oxygen supplement, presence of comorbidities and length of hospital stay. The results revealed a significant difference in the Mental Development Index, favoring the group that used silicone tampons. However, no difference was observed in relation to psychomotor development, as assessed by the Bayley II scale.

Morag et al.,[15] carried out a systematic review that covered nine RCTs with the participation of a total of 525 premature newborns who were between 3 and 6 months of chronological age and had low birth weight. The objective was to determine the effectiveness and safety of cyclic light on the growth of these newborns. Several parameters were analyzed, including physiological measures (HR, RR and $SpaO_2$), sleep patterns (active, silent, transition, awake), mental and psychomotor development (BSID), cortisol level, weight gain, length of stay and of MV, food tolerance and comorbidities. The results revealed that cyclical light exposure was associated with significant benefits, such as greater weight gain, a reduced incidence of retinopathy of prematurity, shorter hospital stays and mechanical ventilation, lower eating tolerance, and shorter crying times.

Discussion

In the last 15 years, there has been a significant increase in knowledge about pain in newborns, resulting in numerous studies on its management.[40] Despite the substantial number of studies carried out, we still do not have solid evidence regarding the effectiveness of non-pharmacological methods.

In relation to music therapy, a meta-analysis, a systematic review and three randomized clinical trials were evaluated. The systematic review by Hartling et al.,[31] incorporated RCTs with flaws in allocation techniques and lack of blinding, which resulted in a decrease in the quality of evidence. According to the results of the studies, MT is an effective method in pain management for full-term newborns and PMTs undergoing painful procedures. Therefore, the incorporation of music therapy into NICU protocols is recommended.

Regarding breastfeeding, a systematic review and two randomized clinical studies were evaluated with a total of 2,646 newborns.[35–37] In all studies, benefits of breastfeeding were demonstrated when performed during painful procedures. Therefore, breastfeeding should be considered a first-line analgesic intervention.

The evaluation of gentle restraint was based solely on a systematic review. However, due to the limited sample size and use of non-validated tools, it was not possible to evaluate its effectiveness based on this study.[34]

The Kangaroo method was evaluated in a systematic review that took into account 21 RCTs, with a total of 2,030 patients. This analysis highlighted a series of benefits beyond pain relief. As a recommendation, it is suggested to perform the Kangaroo Mother Care at least 30 minutes before painful procedures.

The influence of light exposure was investigated through an RCT involving 121 patients. Only some of the results reached statistical significance, and it is not possible to conclude their benefit based on this study alone.[15]

On one systematic review containing 34 participants.[39] This review suggests that a reduction in sound exposure may have the potential to reduce stress and allow for increased weight gain. However, due to the limited sample size, it is not possible to reach a definitive conclusion.

Pain in newborns is underdiagnosed by the nursing team and, therefore, undertreated.[41,42] However, it is crucial to recognize pain as the "fifth vital sign" and be assessed simultaneously with the measurement of other vital signs. Early diagnosis of pain and its control makes it possible to prevent possible adverse effects in the short and long term.

Conclusions

Despite the heterogeneity of the studies evaluated, the benefits of using breastfeeding, music therapy and Kangaroo Care are evident. Incorporating these practices into pain management protocols in NICUs would provide significant gains for the health and well-being of newborns. Effective implementation of these approaches would reduce babies' exposure to pain during their stay in the NICU, thus minimizing potential negative effects on their development. However, in relation to exposure to light and sound, no conclusion can be reached as to their ideal exposure levels, despite knowledge about the risks associated with excessive exposure. Additionally, the effectiveness of gentle restraint requires more solid evidence. Although there are growing signs of therapeutic benefits with these techniques, additional research is still needed to confirm the reported advantages. Future longitudinal research should be carried out to evaluate the benefit of each technique, considering the most ap-propriate approach for different types of pain in newborns. In the authors' opinion, every neonatal intensive care unit should implement a protocol for the identification and prevention of neonatal pain, in light of the risks mentioned above.

Acknowledgement

None

Ethics approval and consent to participate

Not applicable as all literature is published.

Publisher's note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Funding

None

Conflicts of interest

The authors declare that there are no conflicts of interest.

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Citation: Machado MEPF, Paiva TN, Paiva ISD. Non-pharmacological management in a neonatal intensive care unit- a systematic review. *J Pediatr Neonatal Care*. 2023;13(3):213–217. DOI: 10.15406/jpnc.2023.13.00519