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Breastfeeding combined with cryotherapy using Buzzy® for pain management during infant vaccination: a clinical trial

Amamentação associada com Buzzy® para manejo da dor durante vacinação infantil: ensaio clínico

Lactancia materna associada a crioterapia com Buzzy® para el dolor durante la vacunación infantil: ensayo clínico

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ABSTRACT

Objective: to evaluate the effect of breastfeeding combined with cryotherapy using the Buzzy® vibratory device on reducing pain in infants during pentavalent vaccine administration.

Method: randomized clinical trial conducted in the vaccination sector of a municipality in Minas Gerais, between May and November 2023. Sixty-two infants, aged between 2 and 12 months, participated, randomly and equally allocated into two groups: control (institutional routine) and experimental (breastfeeding combined with cryotherapy using Buzzy®). During vaccine administration, pain was assessed using the Neonatal Infant Pain Scale and by crying time. Data were subjected to descriptive and inferential analysis.
Results: in the control group, all infants obtained a pain score ≥4, with an average of 6.5 points on the scale, characterizing the presence of moderate to intense pain, and 29.1% of infants cried for more than 46 seconds. In the experimental group, 57.6% obtained a score ≥4, with an average of 3.7, and 90.9% cried for less than 30 seconds, showing a significant reduction in pain ($p < 0.001$).
Conclusion: breastfeeding associated with cryotherapy with Buzzy® proved effective in pain management, and may contribute to a less painful childhood vaccination practice. There is a need for training for professionals and active participation from the mother/family.
Descriptors: Nursing; Vaccination; Pain Management; Cryotherapy; Breast Feeding.

RESUMO
Objetivo: avaliar o efeito da amamentação associada à crioterapia com o dispositivo vibratório Buzzy® na redução da dor de lactentes durante a aplicação da vacina pentavalente.
Método: ensaio clínico randomizado realizado em setor de vacinação de um município de Minas Gerais, Brasil, entre maio e novembro de 2023. Participaram 62 lactentes, com idades entre 2 e 12 meses, alocados aleatória e igualitariamente em dois grupos: controle (rotina institucional) e experimental (amamentação associada à crioterapia com Buzzy®). Durante a aplicação da vacina, avaliou-se a dor pela *Neonatal Infant Pain Scale* e tempo de choro. Submeteram-se os dados à análise descritiva e inferencial.
Resultados: no grupo controle, todos os lactentes apresentaram escore de dor ≥4, com média de 6,5 pontos na escala, caracterizando presença de dor moderada a intensa e 29,1% dos lactentes choraram por mais de 46 segundos. No grupo experimental, 57,6% obtiveram escore ≥4, com média de 3,7, e 90,9% choraram por menos de 30 segundos, evidenciando redução significativa da dor ($p < 0,001$).
Conclusão: a amamentação associada à crioterapia com Buzzy® se mostrou eficaz no manejo da dor, podendo contribuir para uma prática de vacinação infantil menos dolorosa. Há necessidade de capacitação dos profissionais e participação ativa da mãe/família.
Descritores: Enfermagem; Vacinação; Manejo da Dor; Crioterapia; Aleitamento Materno.

RESUMEN
Objetivo: evaluar el efecto de la lactancia materna combinada con crioterapia mediante el dispositivo vibratorio Buzzy® en la reducción del dolor en lactantes durante la administración de la vacuna pentavalente.
Método: ensayo clínico aleatorizado realizado en el sector de vacunación de un municipio de Minas Gerais, entre mayo y noviembre de 2023. Participaron 62 lactantes de entre 2 y 12 meses de edad, asignados aleatoriamente y en partes iguales a dos grupos: control (rutina institucional) y experimental (lactancia materna combinada con crioterapia mediante Buzzy®). Durante la administración de la vacuna, se evaluó el dolor mediante la Escala de Dolor Neonatal y el tiempo de llanto. Los datos se sometieron a análisis descriptivo e inferencial.
Resultados: en el grupo control, todos los lactantes obtuvieron una puntuación de dolor ≥4, con una media de 6,5 puntos en la escala, lo que caracteriza la presencia de dolor moderado a intenso; el 29,1 % de los lactantes lloró durante más de 46 segundos. En el grupo experimental, el 57,6 % obtuvo una puntuación ≥4, con una media de 3,7, y el 90,9 % lloró

durante menos de 30 segundos, lo que demuestra una reducción significativa del dolor (p < 0,001).
Conclusión: la lactancia materna combinada con crioterapia con Buzzy® resultó eficaz para el control del dolor y puede contribuir a una vacunación infantil menos dolorosa. Es necesario capacitar a los profesionales y contar con la participación activa de la madre/familia.
Descriptores: Enfermería; Vacunación; Manejo del Dolor; Crioterapia; Lactancia Materna.

INTRODUCTION

Vaccination is a highly cost-effective and priority public health policy strategy in the country, standing out for its undeniable effectiveness in preventing, eliminating, and/or eradicating vaccine-preventable diseases and their complications. However, it is a complex activity that requires reliability, connection, updated standards and procedures based on scientific advances for a humanized, welcoming, safe and effective practice[1].

Despite highlighting all the benefits and potential of vaccination, especially childhood vaccination, this procedure, when injectable, is considered painful and a source of stress for children, parents and health professionals, representing a direct cause of vaccine hesitancy with a consequent impact on vaccination coverage[2]. Immediate adverse reactions are also observed, such as fear, intense crying and resistance to the procedure, directly related to previous traumatic experiences lived by the child and their caregivers, with persistent trauma in adult life and negative repercussions on child growth and development[3].

Given this, pain management is considered an effective strategy, a good vaccination practice, and a fundamental human right. Its implementation in practice is the responsibility of health professionals as an essential strategy to reduce trauma, improve vaccination adherence, promote comfort, relaxation, reduce agitation, provide safety, satisfaction, and decrease and better cope with pain in children[1,4-6].

Thus, some measures are recommended to reduce pain during vaccination, such as the professional's calm and well-informed posture, proper positioning according to age, and avoiding aspiration before injecting the immunobiological agent during intramuscular vaccine administration[1]. Scientific evidence also demonstrates that non-pharmacological interventions are effective in reducing pain during infant vaccination, such as breastfeeding and vibration associated with cryotherapy[7,8].

Breastfeeding, as a natural and accessible practice with numerous benefits for maternal and child health, has been recommended by the World Health Organization since 2015 and the importance of its implementation in practice was reaffirmed through the publication of

Technical Note No. 39/2021 by the Ministry of Health, for pain reduction and adherence to vaccination[9].

Their recommendation is based on the analgesic effect of breastfeeding due to the release of endorphins, in addition to the presence of tryptophan in breast milk, essential for melatonin production and related to serotonin synthesis, responsible for feelings of pleasure and reduced anxiety. Furthermore, sucking, smell, sound and skin-to-skin contact activate the parasympathetic system and promote sensory distraction, relaxation, decreased heart rate, crying and other clinical markers of pain[10].

However, this practice is not yet consolidated among nursing professionals, mainly due to deficient knowledge, with reports of fear of bronchoaspiration; therefore, there is a need for training. Consequently, there is low maternal adherence, which requires qualified and safe assistance through evidence-based interventions, encouragement, guidance and continuous support[11].

Buzzy®, in turn, a device that uses vibration and cryotherapy to reduce pain in painful procedures, works according to the Gate Control Theory, stimulating sensory receptors that provide partial blockage of the physiological transmission of pain signals along the nerve pathway to the spinal cord, providing effective and safe analgesia[12].

Although there are proven effective non-pharmacological strategies for pain control, such as breastfeeding and Buzzy®, their implementation is still infrequent in the practice of nursing professionals, and is commonly neglected in health services[13]. Furthermore, there are no studies in the literature that evaluate the effectiveness of combining breastfeeding and the use of the Buzzy® device during childhood vaccination, however, research that combined strategies for pain management showed potentiation of the analgesic effect with lower pain scores, better recovery with greater physiological stability after the procedure than with interventions alone[14].

Given the above, this investigation was justified by the need to highlight, disseminate, and implement safe, accessible, and effective interventions to mitigate pain during childhood vaccination among professionals and the general population, as a fundamental human right.

This is also essential due to the lack of research demonstrating the effectiveness of interventions such as combining breastfeeding with the use of Buzzy® for pain management during childhood vaccination, and the positive public health impact of pain management during immunization.

The hypothesis was that administering the pentavalent vaccine to infants in conjunction with breastfeeding and cryotherapy using the Buzzy® device results in a lower

pain score compared to administering the vaccine without any analgesic intervention. Therefore, the present study aimed to evaluate the effect of breastfeeding combined with cryotherapy using the Buzzy® device on reducing pain in infants during pentavalent vaccine administration by nursing professionals.

METHOD

Type of research

Research of the randomized, parallel, blinded clinical trial type, reported according to the Statement: updated guidelines for reporting parallel group randomized trials (CONSORT)[15].

Research location

The research was conducted in the municipality of Juiz de Fora, Minas Gerais, in a children's vaccination sector of a secondary health institution, between May and November 2023.

Population and sample

To estimate the sample size, scientific literature was considered, and the sample size calculation was performed using G*Power 3.1.9.2 software, considering a test power (1-β) of 0.90 and a standard error (α) of 0.05, with 60 participants expected to be divided into two groups. The sampling in this investigation was considered random, being randomized in a factorial block design. Therefore, participants had the same probability of being allocated to both groups.

The eligibility criteria were: being an infant and attending the vaccination sector surveyed to be vaccinated with the pentavalent vaccine, accompanied by their caregivers, at the time of data collection.

Inclusion criteria were: 1) infants accompanied by a legal representative, over 18 years of age, who provided consent to the infant's participation in the investigation by signing the Informed Consent Form; 2) infants aged 2 to 12 months; and 3) breastfed infants. Exclusion criteria were: 1) infants who did not receive the pentavalent vaccine for any reason; and 2) infants with a history of prophylactic analgesic treatment within eight hours before vaccine administration.

The legal guardians (mothers) of the infants eligible to participate in the research were individually invited by the principal investigator to express their authorization by signing the Informed Consent Form. They were informed about what the infants' participation would entail and about the interventions that could occur. Furthermore, it was explained to them that, through a random selection process, the infants would be allocated to the group receiving breastfeeding combined with cryotherapy using the Buzzy® device or to the group following the institutional routine. The guardians of the infants could thus accept or decline the invitation for their children to participate in the research. There were no refusals.

Infants were considered blinded participants because, due to their age range (2 to 10 months) and stage of cognitive development, they lack the capacity to perceive or understand changes in the vaccine application technique or the introduction of interventions for pain management during the vaccination procedure.

Participants were allocated by a researcher external to the research team, using the website www.randomization.com. and the sequence was made available by this in an opaque and sealed envelope, numbered in the order of allocation to be followed and accessed by the principal investigator at the time of vaccine administration, and thus the participant was allocated to the experimental or control group. The randomization adopted was of the block type, characterized by a random sequence of participants grouped together, instead of being allocated individually. In this research, the 62 participants eligible for the investigation were distributed into two blocks of previously defined sizes, with 31 participants in each group – experimental group (EG) and control group (CG). This strategy aimed to ensure balance between the investigated groups and mitigate possible biases resulting from refusals or losses of participants[16].

Infants eligible for the study were randomized into two groups: an experimental group, in which breastfeeding was combined with cryotherapy using the Buzzy® device. (GE), and a control group, in which the vaccine was administered as part of the institutional routine (GC).

Intervention protocol

In the experimental group (EG), the non-pharmacological intervention used was breastfeeding combined with cryotherapy using the Buzzy® device to assess pain reduction in infants undergoing pentavalent vaccine administration. In the control group, the

pentavalent vaccine was administered following institutional routine (CG), and pain due to vaccination was also evaluated.

The vibration device used in the research was the Buzzy® Mini Healthcare Bee from PainCareLabs, manufactured by Buzzy Medical, Ireland. The device was acquired by the researcher responsible for the investigation for her own use and belongs to the research group to which she is affiliated.

For the application of the intervention, the pentavalent vaccine was chosen, composed of a combination of purified diphtheria and tetanus toxoids, inactivated Bordetella pertussis cell suspension (whole cells), hepatitis B surface antigen (recombinant) and conjugated Haemophilus influenzae type B oligosaccharides (conjugated). The immunobiological agent protects against diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type b[1]. The current schedule consists of three doses, administered at 2, 4 and 6 months of age, with an interval of 60 days between doses and a minimum of 30 days as established by the National Vaccination Calendar[17].

The choice was based on evidence that this immunobiological agent is associated with greater pain intensity, due to the presence of the aluminum phosphate adjuvant, resulting in frequent, more intense local and systemic manifestations during and after its administration, as demonstrated in the scientific literature and observed in clinical practice [1].

The intervention protocol in the experimental group consisted of positioning the infant lying on the mother's lap and initiating breastfeeding for three minutes before administering the vaccine, when it was being prepared by the nursing technician in the ward, while the Buzzy® device was positioned simultaneously in the middle third of the anterolateral aspect, in the midline of the infant's left thigh, the site where the vaccine was to be administered, for a period of 30 seconds, with vibration stimulation associated with cryotherapy, as recommended in the device's manual.

At the time of the infant's vaccination, breastfeeding was maintained, and the Buzzy® device was administered. It was moved from the middle third of the anterolateral aspect of the thigh, in the region of the *vastus lateralis* muscle of the left lower limb, to about 2.5 cm above the site of vaccine application in the infant, along the path of the nerves for physiological pain blocking, according to recommendations, that is, it functions as a distraction for the brain to alleviate pain[18]. After vaccination, sucking was maintained for another five minutes, and the Buzzy® device was then slid toward the needle insertion site for an additional 30 seconds.

The vaccine was administered by a nursing professional working in the service, while the application of the protocol and the evaluation of the pain score were carried out by the main investigator. A second researcher provided technical support, assisting in timing and conducting the protocol during the vaccination procedure.

To ensure data reliability and minimize potential biases arising from subjective observation, all pain score assessments were conducted by a single, previously trained researcher using standardized, scale-specific criteria.

Data collection strategy

For the assessment of pain in infants, the Neonatal Infant Pain Scale (NIPS) was used, which is recommended and validated for before, during and after procedures[19], and translated into Portuguese. The scale was applied immediately before vaccination and implementation of the intervention protocol, in order to exclude the previous presence of signs of pain and crying related to factors external to vaccination such as discomfort/pain, irritability, sleepiness or hunger and thus ensure the reliability of the data, and immediately after vaccination, through direct observation of the infant's signs and behaviors by the main researcher.

The NIPS considers six behavioral indicators, namely: facial expression, crying, breathing pattern, position and tone of the upper limbs, position and tone of the lower limbs, and state of consciousness. Each indicator can score from zero to two, resulting in a total score ranging from zero to seven points, with scores equal to or greater than four indicating significant pain[20].

Additionally, the crying time immediately after vaccination was measured. The crying time was categorized into the following ranges: a) less than 5 seconds; b) between 5 and 15 seconds; c) between 16 and 30 seconds; d) between 31 and 45 seconds; e) between 46 and 60 seconds; f) greater than 60 seconds; g) no crying.

Data collection was guided by a data collection instrument developed by the researchers, previously tested and adjusted through a pilot study with four infants, whose data were excluded from the main sample. Data recording was performed using the Open Data Kit (ODK®) electronic application, installed on a tablet, which allows data to be stored in the cloud, optimizing the process of recording and consolidating the information collected in the field.

Control procedures

To assess pain scores in infants immediately before and after immunization with the pentavalent vaccine in the GE and GC groups, specific criteria were adopted for each of the variables observed during the application of the NIPS scale in order to standardize the assessments and observations by the researcher.

In assessing facial expression, it was considered “relaxed” (0 points) when the infant presented a calm face, with eyes gently open or naturally closed. The expression was classified as “contracted” (1 point) when there were signs such as furrowed brows, wrinkled forehead and closed eyes and/or lips[20].

Regarding the variable "crying," it was classified as "absent" (0 points) when there was no sound emission; as "grumble" (1 point) when the infant emitted weak sounds, of low volume, short duration (< 5 seconds) and that ceased easily; and as "vigorous crying" (2 points) when the sounds were inconsolable, of high intensity, high volume and prolonged (≥ 5 seconds).

The respiratory pattern was classified as normal (0 points) when the infant's breathing was calm, without the use of accessory muscles, and with baseline breathing values expected for the infant's age, and considered altered (1 point) when the use of accessory muscles and/or shallow and rapid breathing was observed.

The movement of the upper and lower limbs was assessed according to the tone and position of the limbs. When the arms and legs were relaxed, 0 points were assigned; when they were flexed or extended in a tense manner, the score was 1 point. The state of consciousness was classified as sleeping or calm (0 points) when the infant was calm and without signs of discomfort, and considered uncomfortable (1 point) when there was agitation, accompanied by abrupt and rapid body movements and signs of restlessness.

Data analysis

The data were double-entered into Microsoft Office Excel® version 2013 and analyzed using IBM Statistical Package for Social Science (SPSS®) version 23.0, with descriptive statistics (absolute and relative frequencies and means) and inferential statistics by a researcher external to the research team. The proportion of infants and their respective crying time was compared using Pearson's Chi-square test or Fisher's Exact test, in cases where the frequencies were less than 5; and the means of the NIPS scores immediately after vaccination were compared using Student's t-test for independent samples[21].

The percentage of infants and their respective crying time was compared using Pearson's Chi-square test or Fisher's Exact test, in cases where the frequencies were less than

5; and the means of the NIPS scores immediately after vaccination were compared using Student's t-test for independent samples[21].

Ethical aspects

This research was submitted to and approved by the Ethics Committee of Universidade Federal de Juiz de Fora (CEP/UFJF) under Protocol No. 5.794.125 and CAAE: 65027822.3.0000.5147, and the RCT was registered on April 28, 2025, in the Brazilian Registry of Clinical Trials- RBR-6khstfv available at https://ensaiosclinicos.gov.br/rg/RBR-6khstfv. The data collection process began after approval by CEP/UFJF, and all ethical requirements for research involving human subjects were met.

RESULTS

Sixty-two breastfed infants who received the pentavalent vaccine during the data collection period participated in the study. Most were male (62.5%), with ages ranging from 2 to 10 months, with a mean age of 4 months. They were randomly assigned to two groups of 31 participants each: a control group (CG) – institutional routine – and an experimental group (EG) – breastfeeding combined with cryotherapy using the Buzzy® device.

Immediately before the vaccine was administered, the infants showed no behavioral signs of pain according to the NIPS scale; that is, in both groups, all participants had a score < 2 (no pain classification), with a predominance of scores 0, 93.5% in the control group and 90.9% in the experimental group (breastfeeding associated with Buzzy®).

Regarding the assessment of pain in infants immediately after vaccine administration, using the NIPS scale, it was found that all infants in the control group (institutional routine) obtained a pain score greater than or equal to 4, with an average score of 6.5, indicating the presence of pain. In the experimental group (breastfeeding combined with cryotherapy using the Buzzy®) device, 57.6% of infants presented a pain score greater than or equal to 4, with an average pain score of 3.7, as shown in Table 1. Thus, it was observed that the association between breastfeeding and cryotherapy with the Buzzy® device resulted in a lower mean pain score on the NIPS scale in infants after administration of the pentavalent vaccine, with a significant effect (p-value < 0.001) between the groups. The predominance of NIPS scores between 6 and 7 in the control group deserves mention.

Table 1 – Results of pain score assessment according to the NIPS scale immediately after vaccination, according to absolute and relative frequency and mean. Juiz de Fora, Minas Gerais, Brazil, 2025.

Variables	CG Routine	CG Routine	EG Breastfeeding + Buzzy®	EG Breastfeeding + Buzzy®	p-value*
	N	%	N	%	
NIPS After					
0	0	0	1	3.2	
1	0	0	0	0	
2	0	0	4	12.9	
3	0	0	7	22.6	
4	2	6.5	9	29.0	
5	0	0	6	19.4	
6	9	29	4	12.9	
7	20	64.5	0	0	
Mean ±sd	6.5 ±0.8		3.7 ±1.4		
Total	**31**	**100**	**31**	**100**	**<0.001**

Source: elaborated by the authors, 2025.
*Student's t-test for independent samples.
*GE = Experimental Group; GC = Control Group.
*NIPS= Neonatal Infant Pain Scale

In addition to the NIPS pain scale, the infants' crying time was also assessed. Analysis of the infants' crying time in the different groups showed that in the control group (institutional routine), 29.1% of infants presented a crying time greater than 46 seconds, while in the experimental group (breastfeeding associated with cryotherapy with Buzzy®), no infant presented a crying time greater than 45 seconds, with a predominance of crying times between 1 and 30 seconds (90.9%). Thus, it was found that the control group had a higher average crying time, with significant results (p-value < 0.001) , as shown in Table 2.

Table 2 - Results of participants' crying time immediately after vaccination, according to absolute and relative frequency and mean. Juiz de Fora, Minas Gerais, Brazil, 2025.

Variables	CG Routine	CG Routine	EG Breastfeeding+ Buzzy®	EG Breastfeeding + Buzzy®	p-value*
	N	%	N	%	
Duration off crying					
1-5 seconds.	0	0	6	19.4	
6-15 seconds	3	9.7	10	32.3	
16 -30 seconds	10	32.2	12	38.7	
31- 45 seconds	8	2.8	1	3.2	
46- 60 seconds	6	19.4	0	0	
> 60 seconds	3	9.7	0	0	
Did not cry	1	3.2	2	6.4	
Mean	31 a 45s		6 a 15 s		
Total	**31**	**100**	**31**	**100**	**< 0.001**

Source: elaborated by the authors, 2025.
*Pearson's Chi-square test or Fisher's exact test (for cases with a frequency of 5).
*EG = Experimental Group; CG = Control Group.

Thus, when analyzing the average final score on the NIPS scale and crying time, it was found that infants had lower average pain and crying time when vaccinated with the pentavalent vaccine while being breastfed, and cryotherapy with the Buzzy® device was used. Vaccine administration without pain management interventions resulted in twice the crying time in the evaluated infants and almost twice the NIPS score.

DISCUSSION

Regarding pain, it is known that health procedures are a significant cause of suffering in childhood, directly influencing the child's development and growth by triggering psychological, behavioral, physiological, and emotional changes. Negative experiences related to health care can generate fear, phobias, anxiety, and resistance to future procedures (4).

Vaccination is a routine procedure within health services; however, the undeniable benefits of this practice do not exclude the fact that administering injectable vaccines can be painful and stressful, especially for children, infants, and their families. Viable interventions based on scientific evidence allow for mitigating pain, but require that health professionals

are familiar with the strategies and that children and caregivers are educated on how to implement anticipatory and preventive pain interventions[22].

In this sense, despite the available evidence and recommendations from the Ministry of Health regarding non-pharmacological interventions for pain management during painful procedures, breastfeeding is still underutilized in clinical practice within healthcare institutions providing care to babies [9].

Furthermore, it is up to healthcare professionals, especially the nursing team, to train themselves in the use of non-pharmacological interventions and technologies in pain management, as well as to encourage mothers to offer breastfeeding during invasive procedures as a strategy to reduce pain. It is equally essential to guide caregivers regarding incorrect information related to this practice, in order to dispel fears and promote its adoption in a safe and informed manner[23]

The Neonatal Infant Pain Scale (NIPS) is widely used for assessing pain in infants during painful procedures, due to its ease of application and interpretation[24]. This instrument assesses behavioral and physiological variables associated with pain. A study that applied the NIPS scale to 27 different procedures found that 70.37% of them caused intense pain in the participants[25]. These findings are consistent with the results of this investigation, which observed a significant increase in NIPS scores in all groups, although this increase was minimized when pain management interventions were employed during vaccination.

Crying time is another relevant parameter, frequently used as an indirect indicator of pain intensity in infants, being directly associated with the pain score [26]. In the present investigation, infants vaccinated under the institutional routine had an exponential crying time compared to those who were vaccinated with the combination of interventions, breastfeeding and Buzzy® with cryotherapy, from 31 to 45 seconds to 6 to 15 seconds respectively.

A study that evaluated the effectiveness of breastfeeding in reducing pain in infants during painful procedures, using the Neonatal Infant Pain Scale (NIPS), proved that this strategy is effective in reducing pain. This effect occurs through multifactorial mechanisms, involving skin-to-skin contact, warmth, sucking, maternal smell and sound, as well as the release of endogenous substances present in breast milk[27]. These results converged with the evidence found in the present investigation, which found that infants who used breastfeeding associated with cryotherapy with Buzzy® obtained a reduction or absence of pain, with a final average score of 3.7 on the NIPS scale.

Different studies have investigated the effectiveness of Buzzy® in reducing pain during painful procedures in children and infants. The results demonstrate that the thermovibratory device associated with cryotherapy is effective in relieving pain and anxiety in invasive procedures such as vaccination, venipuncture, and blood collection. Its effectiveness is related to the mechanisms of vibration and cryotherapy, which block fibers receptive to painful stimuli and stimulate non-nociceptive fibers, activating inhibitory interneurons[28]. These findings converged with the findings of the present investigation, which demonstrated that infants in the EG (breastfeeding associated with Buzzy®) presented less pain, measured by the NIPS infant scale, when compared to infants in the CG (institutional routine).

The absence of adequate pain management during invasive procedures directly influences child development, potentially leading to psychological, physiological, cognitive, sensory, and motor consequences. According to the literature, infants are able to register the painful experience they have lived through, and these memories can trigger negative perceptions and behaviors in subsequent situations where they are again subjected to painful procedures[29]. Interventions for the prevention and reduction of pain during vaccination can and should be combined to improve the intended outcome of pain relief.

One limitation of this study is that it was conducted in a single setting. Thus, multicenter studies should be conducted to confirm and generalize the results. Another limitation concerns the restricted applicability of the intervention to breastfeeding infants, suggesting that investigations should be carried out to evaluate the effectiveness of combining the administration of 25% glucose solution with cryotherapy using the Buzzy® device when breastfeeding is not possible, as a way to avoid restricting the right to pain management.

Therefore, further studies are recommended to evaluate the effectiveness of other combinations of non-pharmacological interventions in pain management in children of different ages, in different contexts of painful procedures, as well as training for nursing professionals to apply interventions in clinical practice aimed at maximizing pain mitigation during vaccination and ways to include and encourage mothers and caregivers as partners in adherence to breastfeeding associated with the use of cryotherapy with Buzzy® in the vaccination room. Such investigations and awareness-raising can contribute to the consolidation of a more humanized, safe and evidence-based care practice, promoting comfort, well-being and safety for the pediatric population as a whole.

CONCLUSION

The results of this study demonstrated that infants who received the pentavalent vaccine, along with breastfeeding and cryotherapy using the Buzzy® device, experienced less pain, according to the NIPS scale assessment, compared to those who received the vaccine as part of routine institutional procedures. Thus, combining interventions is an effective strategy for highly painful vaccines.

Breastfeeding combined with cryotherapy using the Buzzy® device has been shown to reduce pain scores and crying time in infants after the procedure. Therefore, its implementation in nursing clinical practice allows for a decrease in pain and stress during childhood vaccination. The knowledge gained through this research points to a set of interventions capable of managing pain and providing scientific support for nursing professionals in their practice.

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AVAILABILITY OF DATA AND MATERIAL

Access to the dataset may be granted upon request to the corresponding author.

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