ISSN: 1607-8322, e-ISSN: 2220-5799 **Anaesthesia, Pain & Intensive Care**
Vol 27(2); April 2023 DOI: 10.35975/apic.v27i2.2183

ORIGINAL RESEARCH **PAIN MANAGEMENT**

The effect of vibration on pain intensity during neonatal heel-blood sampling

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ABSTRACT

Background: Mechanical vibration is an effective analgesic technique for controlling pain, during painful procedures among children and adults. Nevertheless, little information exists about its efficacy and proper application in neonates. We investigated the effect of mechanical vibration on pain during heel-blood sampling in term neonates hospitalized in the neonatal intensive care unit (NICU).

Methodology: In this clinical trial, we used sequential sampling and randomly allocated the participants into intervention group (n = 47) and control group (n = 47). The pain was measured three times; before, during, and after heel lancing. In the intervention group, the vibrator was placed in the middle of the knee cuff at the back of the leg, consistent with the afferent nerve fibers behind the neonate's leg, and vibration was induced for 30 sec. Immediately after the intervention, the heel lancing sampling was performed. The premature infant pain profile (PIPP) was used to measure pain in these neonates.

Results: The mean pain score in the intervention group during blood sampling was significantly lower compared to the control group (5.44 ± 1.76 vs. 7.12 ± 1.88; P < 0.05). Moreover, a statistically significant difference was observed in the mean pain score between the intervention and control groups (2.72 ± 1.22 vs. 3.48 ± 1.76; P = 0.017) two min after blood sampling.

Conclusion: According to the findings, mechanical vibration positively reduces pain during heel lancing in term neonates hospitalized in the NICU. Hence, this method can be used as one of the beneficial non-pharmacological interventions.

Key words: Infants; Lancet Puncture; Neonatal nursing; Pain; Vibration, Mechanical

Citation: Shoghi M, Dehghan A, Bozorgzad P. The effect of vibration on pain intensity during neonatal heel-blood sampling. Anaesth. pain intensive care 2023;27(2):191−197; **DOI:** 10.35975/apic.v27i2.2183

Received: Jan 08, 2023; **Reviewed:** Jan 08, 2023; **Accepted:** Feb 10, 2023

1. INTRODUCTION

Although pain control is essential in all age groups, it is more critical in infants. Adequate pain relief goes beyond providing comfort to them.[1] Pain increases heart rate and oxygen demand of the body with decrease in SpO_2 and puts the neonate at risk for intra-ventricular hemorrhage by increasing intracranial pressure.[2]

Moreover, pain and stress weaken the infants' immune systems and increase their susceptibility to infection. Some authors argue that painful experiences are associated with impaired brain development and poor response to pain in the future. In addition, the frequent experience of pain in infants affects the evolution of organs.[3,4]

According to reports, premature infants born at 24−42 weeks of gestational age, experience an average of 98 painful procedures in the first 14 days of life. Most procedures are performed without pharmacological or non-pharmacological interventions to reduce pain.[5] Evidence shows that healthcare providers consider only 20% of painful procedures in infants,[6] and more than half of the painful procedures are performed without any intervention to manage the infant's pain.[7]

Non-pharmacological interventions can control and manage pain in infants, and are often used because of the side effects of analgesic drugs. Studies have shown that these interventions have soothing effects, relieve pain, and modulate physiological behavior and cognitive responses.[8,9] Non-pharmacological interventions reduce the infants' pain diversely and can be categorized into maternal-related interventions, e.g., maternal odor and voice and Kangaroo care, sensory stimulation, e.g., vibration and non-nutritional sucking, and nutritional interventions, e.g., sucking sweet liquids.[10,11] Despite controversies, different degrees of effectiveness of non-pharmacological interventions have been reported.

Heel lancing is a painful procedure often performed for various purposes, such as screening tests, taking blood samples for diagnostic tests, and in emergencies. Repeated lancing on the baby's foot may have persistent adverse effects on infants' pain processing and response to stress.[12] Using vibration within safe level with a vibrator is used to relieve pain in the adults and pediatric populations, but its use has been less studied in infants. Melzack and Wall first proposed the gate control theory in 1965, expressing the analgesic effect of vibration on perceived pain. According to this theory, vibration stimuli compete with the transmission of pain impulses in the spinal cord-thalamic pathway, hypothesizing that infants are less likely to perceive pain.[13]

Providing comfort and maintaining the patient's safety and health are the nurses' primary professional and ethical responsibilities, and the infant patients are all the more important. However, reducing the pain experienced in neonates admitted to NICU is challenging for nurses.[14,15] Non-pharmacological approaches are a priority among pain management strategies particularly for this population.[16]

We aimed to investigate the effectiveness of the mechanical vibration on pain during heel blood sampling in neonates.

2. METHODOLOGY

This clinical trial was performed at our institutional neonatal intensive care unit (NICU) under ethical code: IR.IUMS.REC.1397.119 and RCT code: IRCT20160119026104N10.

Sequential sampling was used, and the participants were randomly divided into control and intervention groups with 4-block sampling. The inclusion criteria were; the birthweight of 2.5−4.0 Kg, taking no analgesic, sedative, or anticonvulsant medication 12 h before blood sampling, and absence of heart problems and severe respiratory, neurological, anatomical, and chromosomal abnormalities. The exclusion criteria were inadequate blood collection, repeated use of a lancet for blood sampling, and redness and swelling at the vibration site.

Considering a 95% confidence interval, test power of 80%, and assuming that the heel pain intensity in the intervention group was 1.5 points higher than that of the control group, the sample size was determined to be 43 neonates in each group. However, 47 neonates were recruited in each group due to the 10% probability of sample attrition.

The mini vibration device, previously used for neonatal chest physiotherapy in the NICU, could induce 94 Hz vibration. According to studies, this device can be used safely for infants.[13,17]

2.1. Data collection tool

The demographic information was recorded about the infant's gestational age, cause of hospitalization, and gender, and the Premature Infant Pain Profile (PIPP) to measure neonatal pain. The Persian translation of the original PIPP with seven indicators measures three behavioral (facial actions: brow bulge, eye squeeze, and nasolabial furrow), two physiological (heart rate and oxygen saturation), and two contextual indicators (gestational age and behavioral state). A score of up to four points (0, 1, 2, and 3) is used for each of the seven indicators, with a total score ranging from 18 to 21, depending on the neonate's gestational age.[18] On this scale, scores between 0−6 indicate the infant has minimal/no pain, 7−12 show slight to moderate pain, and higher than 12 confirms severe pain. This scale can estimate pain in neonates at 28−42 weeks of gestational age. A researcher simultaneously scored the PIPP on a separate sheet for each child. A psychometric analysis of PIPP has been done in Iran. Ayazi et al. calculated the inter-rater reliability of this tool using the Spearman correlation coefficient and found R = 89%.[19] Similarly, Jebreili et al. reported a coefficient of agreement of 0.9 between two observers on 10 neonates in their study using Cohen's Kappa coefficient.[20]

2.2. Intervention

We obtained written consent from the parents of the neonates recruited in the study. Participants were randomly assigned to the intervention and control groups using 4 block method. The screening tests were performed by taking blood samples on the third day of neonatal hospitalization in the two groups.

Table 1: Demographic characteristics of the infants in the intervention and control groups. Data presented as N (%)

Parameter		Control (n = 47)	Intervention (n = 47)	Analysis
Gender	Boy	24 (51.1)	26 (55.3)	**χ^2 = 0.171**
	Girl	23 (49.6)	21 (43.7)	***P* = 0.679**
Apgar at 5 min after delivery	5−6	0 (0)	2 (4.4)	**Fisher's exact test = 0.108**
	7−8	10 (21.8)	9 (20.0)	
	9−10	36 (78.3)	34 (75.6)	
Cause of hospitalization	Feeding problems	31 (65.2)	22 (44.7)	**Fisher's exact test = 0.982**
	IUGR, Sepsis	16 (34.8)	15 (39.1)	
Gestational age	38−39	33 (70.2)	41(82.7)	**T = 1.82, P = 0.072**
	40−41	14 (28.9	6 (12.8)	
	Mean ± SD	38.78 ± 1.08	38.42 ± 0.82	
Birthweight	<2799	3 (6.4)	5 (10.6)	**T = 0.044, P = 0.966**
	2800−3199	14 (29.8)	12 (25.5)	
	3200−3799	26 (55.3)	25 (52.2)	
	>3800	4 (8.5)	5 (10.6)	
	Mean ± SD	3328.4 ± 354.51	3318.36 ± 403.86	
Height	< 50 cm	19 (40.4)	15 (32.6)	**T = 0.044, P = 0.965**
	> 50 cm	28 (59.6)	31 (67.4)	
	Mean ± SD	50 ± 2.38	50.2 ± 2.41	

Table 2: The frequency and mean of neonatal pain scores in the control and intervention groups before, during, and after heel−blood sampling.

Pain		Intervention (N = 47)	Control (N = 47)	T−Test
Before heel lancing	Mild	47 (100)	47 (100)	**t = 1.68**
	Moderate	0	0	**df = 92**
	Severe	0	0	**P = 0.096**
	Mean ± SD	0.93 ± 1.85	1.25 ± 2.23	
During heel lancing	Mild	35 (74.5)	18 (38.3)	**t = 4.462**
	Moderate	12 (25.5)	28 (59.6)	**df = 92**
	Severe	0 (0)	1 (2.1)	**P < 0.001**
	Mean ± SD	1.76 ± 5.44	1.88 ± 7.12	
2 min after heel lancing	Mild	47 (100)	44 (93.6)	**t = 2.439**
	Moderate	0 (0)	3 (6.4)	**df = 92**
	Severe	0 (0)	0 (0)	*** P = 0.017**
	Mean ± SD	2.72 ± 1/22	3.48 ± 1.76	

First, we assessed and recorded the physiological parameters including heart rate and oxygen saturation of the neonates half an hour before the intervention. Two minutes before vibration with a mechanical vibrator, the PIPP tool was completed for the infants in the intervention group. Then, the researcher placed the vibrator device in the middle corner of the knee cuff, consistent with the afferents neural fibers behind the infant's leg and the vibration was performed for 30 sec. Subsequently, the vibrator was disconnected, and the heel lancing was performed (the foot's outer side). The PIPP tool was completed again at the heel lancing and during blood collection. After taking the blood sample and placing the cotton ball on the site, the researcher calculated the time and completed the PIPP after 2 min. Pain measurement was performed in the control group, similar to the intervention group; the pain was measured using the neonatal PIPP tool half an hour before any intervention to obtain baseline physiological information, at the time of lancing during blood collection, and 2 min after the procedure. In this study, all blood sampling was performed at 8:30 AM.

A similar lancet (Green Medlance®Plus lancet) was used for blood sampling in both groups. The PIPP tool was completed by a single person (a research assistant with a bachelor's degree in nursing) in both groups. One research assistant recorded the physiological parameters on a checklist. During the procedure, the child was carefully observed for any side effects. In the case of apnea, bradycardia, or a significant decrease in oxygen saturation, the vibrator was immediately removed, and supportive measures were applied.

2.3. Data analysis

Independent t-test, ANOVA, and repeated measure tests were utilized to analyze the data.

3. RESULTS

In this study, 94 full-term neonates with a mean age of 38.5 weeks were enrolled. Most participants in the two groups were boys, and most were hospitalized in the NICU due to jaundice and poor nutrition. Table 1 demonstrates the demographic characteristics of infants in both groups. The pain intensity in all neonates was mild in both groups before the intervention; no statistically significant difference was observed (P = 0.96). However, during heel-blood sampling, 59.6% of the control group had moderate to severe pain and 38.3% had mild pain, but in the intervention group, 74.5% had mild pain. The independent t-test showed that the mean pain score in the infants in the intervention group was significantly lower than in the control group (*P* <0.001). Finally, 2 min after heel blood sampling, 93.6% of the control group and the entire intervention group had mild pain, indicating a statistically significant difference (P = 0.017) (Table 2, Figure 1).

A two-way Bonferroni test showed that the mean pain score was significantly higher than before heel lancing in both control and intervention groups during blood sampling (P < 0.001) and 2 min later (P < 0.001). In addition, the pain was significantly higher 2 min after blood sampling (P < 0.001) compared to before sampling (Table3).

Table 3: Mean neonatal pain score before, during, and two minutes after heel blood sampling in the control and intervention groups. [Mean ± SD]

Pain	Intervention group	Control group
Before heel lancing	1.85 ± 0.93	1.25 ± 2.23
During heel lancing	5.44 ± 1.76	1.88 ± 7.12
Two min after heel lancing	2.72 ± 1.22	1.76 ± 1.22
ANOVA test	F = 131.14 *P* < 0.001	F = 152.29 *P* < 0.001

Table 4: Mean neonatal pain score changes in the control and intervention groups (Mean ± SD)

Time	Intervention	Control	T-Test
During−Before	3.59 ± 1.19	4.89 ± 1.98	**T = 3.227 *P = 0.002**
After−Before	0.87 ± 1.37	1.25 ± 1.83	**T = 1.144 P = 0.225**
After−During	2.72 ± 1.41	3.63 ± 2.16	**T = 2.431 *P = 0.017**

Pain changes were positive before and during heel sampling in both groups, implying increased pain during blood sampling, which was significantly higher in the control group than in the intervention group. Two minutes after blood sampling, there was an increase in pain in both groups, though it was not statistically

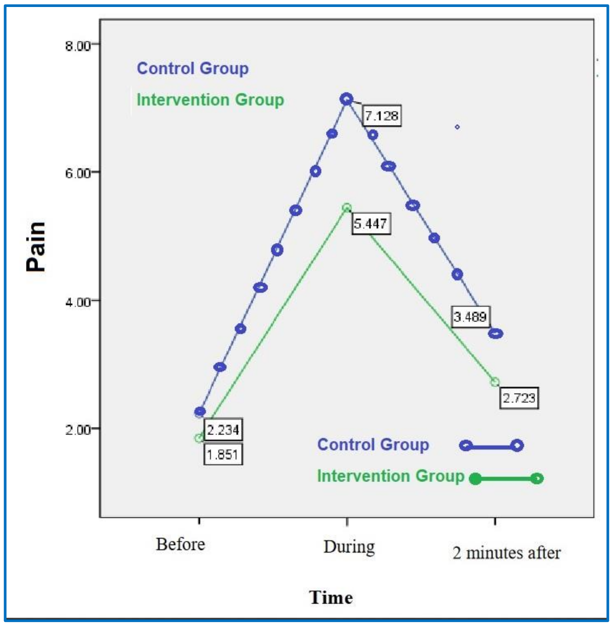

Figure 1: Neonatal pain before, during, and two minutes after heel sampling in the control and intervention groups

significant. Finally, 2 min after blood sampling, the pain reduced in both groups; it was significantly higher in the control group than during blood sampling (P = 0.017)(Table 4).

4. DISCUSSION

This randomized controlled trial investigated the effect of vibration on pain response to a heel lancet puncture among term infants. At heel lancet puncture (from heel lancing to finishing the intervention) and 2 min after the procedure, the neonates' pain score in the control group was higher than the intervention group. This difference was statistically significant between the two groups; the intervention group had a significantly lower mean pain score than the control group during heel lancing and 2 min after that. Two minutes after the intervention, mean pain scores in both groups decreased, and most newborns in the control group and all infants in the intervention group felt mild pain. However, the mean pain score in both groups did not return to the pre-intervention level.

The present study's results followed the pain gate theory, showing that vibration effectively reduced pain during and after 2 min of infant heel lancing. Conclusively, this method can reduce the pain caused by heel blood sampling. Similarly, other studies have demonstrated that vibration reduces pain during heel lancing and venous blood sampling in infants.[13,17,21–25]

On the other hand, some studies have reported that vibration has no effect on pain relief during painful procedures such as heel lancing and venous sampling or during vaccination in infants and neonates.[17,26,27]

In the other studies, the location and the duration of vibration were different from our protocol, which may have affected the study outcome. Baba et al. applied a 5-sec vibration to the infants' heel before lancing.[17] Considering the similar method used to induce the vibration and the vibrator in this study and the one conducted by McGinnis et al., the similar results of these two studies can be explained. They confirm that applying the vibrator for 30 sec before heel lancing and placing it at the back of the child's leg effectively reduces pain during heel blood sampling in neonates. The results of this study are also in line with a review study investigating the effect of vibration on pain relief in neonates, which revealed the positive effect of vibration on pain relief during painful procedures in neonates. Although this review confirms the beneficial role of vibration in reducing pain despite different methods in terms of vibration duration, vibration frequency, the site, vibration interval to blood sampling procedure, and the vibrators used, they believe that this intervention still has many uncertainties in its practical application. However, according to the results of this study, using a mini mechanical vibrator and vibration can reduce pain due to heel blood sampling in neonates.[28]

According to the gate control theory of pain, the spinal cord's dorsal horns control the pain impulses entering the nerve pathways of pain. These valves facilitate or prevent the passage of pain messages to other body areas. This theory states that the brain performs its facilitation to the input upon the valve's opening and closing. This way, factors such as distraction, attention, thinking, precision, and emotion will stop or increase the pain-related messages. Stimulating large sensory fibers by tactile sensors, whether from the same region or farther away, will weaken the pain messages, which is an essential indicator of pain control. For this reason, performing a simple maneuver, such as rubbing the skin around the painful area or stimulating it in other ways, such as mechanical vibration applied in our study, will decrease the pain.[13,29–31]

One of the factors involved in the vibration-related pain reduction, (especially pain resulting from venipuncture or heel lancet) is sensitivity at the site of vibration. The tissue damage, tenderness, and redness are the significant complications of lancing and heel sampling.[8,32] In the existing studies, the vibration was often applied directly at the site of the heel in the foot sole.[17,21] In contrast in our study, the vibrator was placed at the back of the infant's knee. Providing safe vibration with appropriate vibrators is an easy, feasible, and beneficial intervention to relieve pain during heel lancing in infants.

5. LIMITATIONS

Similar to other studies, this study also had its limitation. The noisy and hectic environment could influence the change in the physiological and behavioral criteria in the infant. Although an attempt was made to keep the environment as stable as possible, the complete management of the environment was out of the control of the researchers.

6. CONCLUSION

The results of our study confirm the beneficial pain reducing function of mechanical vibration to relieve pain during heel lancing for blood sampling in infants. We recommend that the effect of vibration be compared with other non-pharmacological methods in reducing pain. Also, other researchers can investigate the application of vibration in other painful procedures.

7. Study Registration

The institutional ethics committee approved the protocol vide No. IR.IUMS.REC.1397.119 and the study was registered with RCT code: IRCT20160119026104N10.

8. Data availability

The numerical data generated in this study is available with the authors.

9. Conflict of interest

The authors declare no conflict of interest

10. Acknowledgment

The researchers would like to thank the Ethics and Research Committee of Iran University of Medical Sciences for supporting the project, Rasoul Akram Hospital Research Center for providing data collection facilities, and all the researchers who assisted us in conducting this project.

11. Authors' contribution

MS: Study Design, Drafting the manuscript

AD: Study Design, Data collection

PB: Drafting the manuscript

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