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Investigating the effect of vibration on the reduction of blood sampling pain from heel (lance) in preterm neonates: a clinical trial study

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Keypoints

There is positive effect of vibration on the reduction of pain caused by blood-sampling from the heel in neonates.

Abstract

Introduction

Preterm neonates are exposed to very painful procedures during hospitalization, which non-pharmacological and pharmacological methods are used to reduce pain. Vibration stimulations is performed using a vibrator to relieve pain in adults and children, but little research has been done on the sedative effect of vibration in neonates. This study was aimed to investigate the effect of vibration on pain reduction caused by blood-sampling from heel (lance) in preterm neonates hospitalized to the neonatal intensive care unit.

Material and Methods

This study is a randomized controlled clinical trial study in which 70 neonates with fetal age[1] of 30-36 weeks were hospitalized in Ali Ibn Abi Talib Hospital (Zahedan in 1398) and blood sampling from the heel was carried out for them. The samples were selected by random blocks method and placed in two groups of intervention and control. In the intervention group used from vibration by Norco Mini Vibrator massage device (North Coast Medical Inc, NC70209, Gilroy, California), which was placed on the middle muscle and next to the leg below knee 30 seconds before the blood sampling from the heel and the test was performed for 30 seconds.. The data collection tools included a demographic information questionnaire and a pain intensity tool of term and preterm neonates (NIPS). Data was analyzed using descriptive and inferential statistics methods and SPSS 20 software.

Results

Of the 70 neonates who participated in this study, 62.9% were male (44) and 37.1% were female (26) and 69.4% of them had fetal age of 32-35 weeks. The mean pain

score was 2.48 in the intervention group and 4.37 in the control group. There was a statistically significant difference between the mean score of pain intensity in the control and intervention groups (p = 001).

Conclusion

The use of vibration is an effective technique in reducing neonatal pain, which should be considered by nurses and health centers staff compared to routine cares (non-nutritive sucking, oral sucrose, hug care) when performing invasive procedures on neonates.

Keywords

Vibration, pain, preterm neonates, blood sampling from the heel, pain measurement, procedure

Introduction

Neonates who are hospitalized in the neonatal intensive care unit are exposed to many painful daily procedures. Preterm neonates do not have the ability to control pain compared to adults. Since their hospitalization lasts for days and months, they experience 100 types of painful procedures during hospitalization, which if these procedures are not controlled, can cause brain damage and impaired brain development (1). Blood sampling from the heel is less dangerous and more common than other sampling methods, but it is also associated with a high risk. The risk of nerve damage, bone damage, osteomyelitis, infection, and remaining Oscar of sampling are among known complications of blood sampling from the heel (2).Pain in neonates cause to immediate, short-term, and long-term detrimental complications. Immediate complications become painful as fear, irritability, sleep disturbances, and decreased nutrition; Short-term complications as delayed wound healing, altered immune system activity, and damage to emotional relationships, and finally long-term complications as delayed development and a different response to stimulation (3). Epidemiological research carried out on neonates hospitalized in the NICU in the first 14 days indicate that 16 stressful procedures are performed daily on these neonates (4). Pain management is a fundamental and important component for neonates who are unable to utter and express their pain. This traditional view that neonates are incapable of perceiving pain is completely rejected, and it has recently been found that neonates perceive pain (5). Pain treatment includes pharmacological and non-pharmacological methods. Non-pharmacological methods include: muscle relaxation, touch-therapy[2], electrical stimulations, etc. Today, non-pharmacological methods of pain relief have attracted nursing systems. In addition, these types of interventions are useful, simple, and safe, and do not require special time or equipment and also, non-pharmacological pain relief methods have no drug complications (6).Pharmacological methods to reduce pain is usually not used to blood-sampling from the heel because there are many unwanted complications due to taking painkillers such as: suppression of the respiratory system and the possibility of poisoning. Research has shown that topical painkillers such as Emla ointment and acetaminophen are not effective in reducing the pain caused by blood-sampling from the heel (7, 8). The results of a study by Manju et al (2014) on touch-therapy models and obtaining results on preterm neonates showed that all touch-therapy methods had positive results on pre-term neonates and touch-therapy should be considered as a non-invasive method to improve the growth and development of preterm neonates (9). Pretti Parashar (2016) found that touch-therapy is effective in pain management in neonates and calming them, improving sleep, and reducing their stress level (10).

Vibration stimulation is performed using a vibrator to relieve pain in adults and children and in dentistry, but little research has been done on the sedative effect of vibration in neonates. The sedative effect of vibration has been identified in Gate's pain control theory, which first was developed by Melzack and Wall in 1965. Stimulation by vibration device when performing painful procedures can slow or stop pain nerve impulses. Despite little research

carried out for the use of vibration devices, neonates are usually confronted to mechanical vibrations. Vibration is used in hospitals and homes to silence neonates, which has beneficial effects on improving neonatal colic. The use of manual vibration devices is one of the methods used in NICU for chest physiotherapy.In 2016, MCGinns et al used a vibrator in blood-sampling from heel to reduce neonates' pain, which the use of vibrator had an effect on reducing neonates' pain, and another study was carried out by Lisa in 2010 under the same title on pain relief of blood sampling from the heel, which in both studies, using vibrator caused to reduce neonates' pain. . Carried out research has shown that relieving the pain caused by blood sampling from the heel in neonates can have positive effects on the growth and development of neonates, as well as reducing the misbehavior effects in the future (1, 2).

Choosing an appropriate method that is most effective in reducing the pain caused by blood sampling from the heel and also improving behavioral responses are among the main concerns of the treatment team; Therefore, with regard to clinical experiences and lack of studies in this field, the researchers decided to carry out this study with the aim of investigating the effect of vibration on the pain reduction of blood-sampling from the heel in preterm neonates hospitalized in the NICU.

Material and Methods

This study is a randomized controlled clinical trial and the sampling method was as random blocks. In the first group, intervention (vibration) was used and no intervention was performed for the control group and the effect of independent variable (vibration) on the dependent variable (pain intensity) caused by blood-sampling from the heel was examined and compared. The sample volume was estimated using the study data of Mc Ginnis et al (2016) and considering $k = 1$, $\alpha = 0.05$, $\beta = 0.05$, $\varepsilon = 5$. Sample volume was estimated equal to 35 neonates for each group.

Then, seventy neonates were selected according to the inclination criteria to the study and were randomly divided into two groups. Inclination criteria include preterm neonates with fetal age of 30 to 36 weeks, weight over 1,500 grams, vital signs in the normal range, no severe respiratory distress, no congenital defects and anomalies, written parental consent to participate in the study, and no maternal addiction during pregnancy to drugs ; and exclusion criteria include neonates death, discharge by doctor's order or personal consent of the parents before completing the intervention , intubation of neonate, hemodynamic disturbances during the study (heart rate more than 180 or less than 100 beats per minute, respiration more than 60 or less than 30 beats per minute, a decrease in the percentage of oxygen saturation of arterial blood less than 85%) during the intervention and the failure to take blood-sample from the heel in the first turn. The data collection tool included two parts: contextual variable and NIPS scale. The questionnaire related to contextual variables includes personal information and information related to the neonate (including: fetal age, gender, birth weight, weight at the time of blood-sampling) which were extracted from the study. In this study, NIPS scale was used to measure pain, which is used to assess pain in term and preterm neonates before, during and after painful interventions such as blood sampling, vein sampling, vaccination and blood sampling from the heel and it is a standard tool which was used in many studies inside and outside the country to measure pain and it has been approved and has the necessary credibility that its content and structural validity has been documented with validity and reliability tests.The validity of this tool has been confirmed by 10 experts with PhD nursing of the School of Nursing and Midwifery in Mashhad University of Medical Sciences. The reliability of this test is also well confirmed by the coherence of the content (11).

The NIPS tool consists of 6 options: crying (0-2), face mode (0-1), breathing pattern (0-1), hands movements (0-1), legs movements (0-1) and level of consciousness which its score is from 0 to 7. Data from this study were collected in one step and within 6 months. Sampling based on the inclination criteria of the target population,

i.e. preterm neonates with fetal age of 30 to 36 weeks and weight over 1500 g, who were hospitalized in the neonatal intensive care unit of Ali Ibn Abi Talib Hospital in Zahedan and were placed in two groups of vibration (group A) and control (group B). The researcher gave enough explanations about study to the mothers and obtained satisfaction from those who tended to participate in the study. In order to conduct corsorization[3] in this research, sampling and intervention were performed by the researcher.

All interventions were recorded by a video camera. First, the staffs of the department were given enough training and they were asked to do the scoring. In order to score and complete the form, the NIPS questionnaire of the film was checked and then the film questionnaire was reviewed by the researcher to confirm the accuracy of the information and the final score was given (through him). In group A: due to the placement of the neonate in this group, the researcher prepared the neonate to take a sample at 11:30, when the blood-sampling was taken from the heel to check the blood sugar routinely in the ward. Thirty seconds before the blood-sampling from the heel, the nurse placed the vibration device on the middle part and next to the leg just below the knee in the muscle path behind the leg for 30 seconds to test. During this time, the neonate was completely monitored for unwanted complications.

Neonates who suffered from bradycardia or change in arterial blood oxygen, the vibration device was quickly removed from the muscle and reactions were recorded. Also, the vibration device was removed from the muscle for neonates who had a heart rate changes of 20% higher than normal or long-term crying. Neonate who did not show any unwanted complications in the first 30 minutes, the researcher disinfected the blood-sampling site from their heel lance (which is the outer and lateral part close to the heel) with an alcohol pad and waited to dry. Blood sampling was performed by Lancet. The vibration continued during the blood-sampling and vibrator device was removed immediately just before sticking the wound adhesive on the blood-sampling site. In the control group (B): No intervention was performed to relieve the pain, and like the intervention group, to measure the pain caused by blood sampling from the heel, all the carried out actions were recorded by the video camera and all reactions were recorded and examined. After watching the film, the ward's nurse completed the NIPS pain tool. The researcher then re-examined the film to confirm the accuracy of the completed information, then the mean pain intensity score caused by the blood sampling from the heel was compared with the intervention group. The data were analyzed by spss-20 software after collection and coding. First, the frequency, percentage, mean, standard deviation, minimum and maximum were determined using descriptive statistics, and in continue, the independent t-test was used to compare the mean of the two groups of intervention and control, chi-square tests were used to compare the frequency of qualitative variables in the group and covariance analysis test was used to determine the pain intensity score by simultaneously controlling some distorting variables. The significance level in this study was 0.05.

Ethical considerations in this study include the approval of the plan by the ethics committee in the research of the school of Nursing and Midwifery of Zahedan University of Medical Sciences with the code (IR.ZAUMS.REC.1398.094) and the clinical trial code IRCT20190550043765N1 registered in the Clinical Trial Center of Iran, received a letter of introduction from the University's Vice Chancellor of Research, obtained a license from the hospital under study and obtained consent from the parents of neonates to participate voluntary to study and the confidentiality of collected data.

Results

In the present study, 70 neonates with a mean fetal age of 32/89 weeks participated in two intervention and control

groups with a standard deviation of 81.1. The lowest fetal age was 30 weeks and the highest was 36 weeks. The standard deviation for neonates' height was 63.3 cm, the standard deviation of weight at the time of sampling was 355.93 g, the birth weight was 351.27 g, the head-circumference was 20.6 cm, the respiration rate was 7.80 per minute, the hospital stay was 40.5 days, the heart rate was 15.32 beats per minute and the Apgar score was 0.57 (Table 1).

Forty-four (participating) neonates (62.9%) were male and 26 neonates (37.1%) were female (Table 2-4). Twenty-nine neonates (41.4%) with RDS diagnosis, 11 neonates (15.7%) with Sepsis, and 26 neonates (37.1%) with prematurity and 4 neonates (5.7%) with Icter were present in this study (Table 2). Also, the results of χ^2 test showed that the two groups had a statistically significant difference in terms of diagnosis (χ^2 = 282/2, df = 3, P = 0.516).

Also, 2 neonates (2.9%) had a pain score of 1, 19 neonates (27.1%) had a pain score of 2, 18 neonates (25.7%) had a pain score of 3, 14 neonates (20%) had a pain score of 4, 11 neonates (15.7%) had a pain score of 5, and 6 neonates (8.6%) had a pain score of 6 (Table 3).

Comparison of gender between the two groups of test results χ^2 showed that the two groups had significant difference in terms of gender. (χ^2 = 6/119, df = 1, P = 0/013).

Table 1. Comparison of neonates' demographic characteristics in terms of qualitative variables

	Fetal age	height	weight at blood-sampling	weight at birth	head circumference	respiration rate	Hospital stay	Heart rate	Apgar score-10 minute
mean	32/89	44/75	1908/64	1914	32/12	44/55	5/38	142/01	9/40
medium	33	46	1880	1850	32	44	4	140/50	9
standard deviation	1/81	3.63	355.93	351/27	2.06	7/80	4/05	15/32	0/57
minimum	30	30	1500	1500	26	30	1	102	8
maximum	36	50	3200	3200	40	60	20	177	10

Table 2. Separation of neonates based on disease diagnosis

diagnosis	number	percent	cumulative frequency Percentage
RDS	29	41.4	41.4
SEPSIS	11	15.7	57.1
PREMATURITY	26	37.1	94.3
ICTER	4	5.7	100
Total	70	100	

Also, the results of χ^2 test showed that the two groups had a statistically significant difference in terms of diagnosis.

(χ^2= 2/282, df = 3, P = 0/516). (Table 3).

Table 3. Neonates based on disease diagnosis in two groups

			group		total
			vibration	control	
diagnosis	RDS	number	13	16	29
		percent	44.8%	55.2%	100%
	sepsis	number	7	6	11
		percent	63/6%	36.4%	100%
	Prematurity	number	12	14	26
		percent	46/2%	53/8%	100%
	Icter	number	3	1	4
		percent	75%	25%	100%
	Total	number	35	35	70
		percent	50%	50%	100%

Figure 1. neonates' pain score in two groups

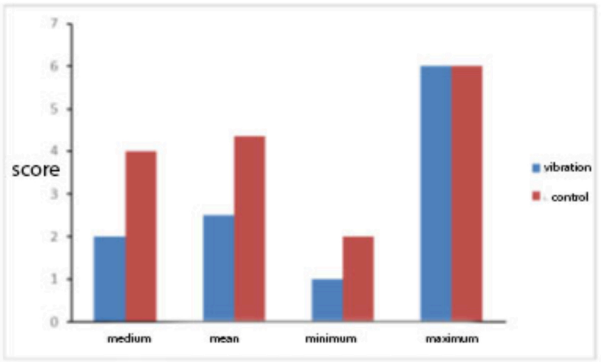

Table 4. Description of data by group Separation

	Group	M ± SD	Minimum	Maximum	Statistics	P
Fetal age	intervention	33/11± 2.07	30	36	1/06	0/293
	control	32/66± 1/49	30	35		
height	intervention	44/41± 3/67	30	50	0/77	0/44
	control	45/09± 3.62	35	49		
weight	intervention	1891/14± 390/22	1500	3200	0/40	0/68
	control	1926/14± 322.81	1500	2640		
weight at birth	intervention	1886± 387/14	1500	3200	0/664	0/50
	control	1942± 314/52	1500	2640		
head circumference	intervention	32/57± 2/02	28	40	1/82	0/07
	control	31/69± 2.03	26	36		
respiration rate	intervention	43.43± 7.59	30	58	1/21	0/22
	control	45/69± 7.95	31	60		
Hospital stay	intervention	6.26± 4/4	1	20	1/82	0/072
	control	4.51± 3.53	1	20		
Heart rate	intervention	144/69± 16.93	102	177	1/47	0/14
	control	139/34± 13/23	105	160		
Apgar score	intervention	9/43± 0/50	9	10	0/86	0/86
	control	9/37± 0/65	8	10		

T-test for two independent samples of Mann-Whitney nonparametric test, descriptive indicators for contextual and intervention variables along with comparisons between groups using t-tests for fetal age, height, weight, birth weight, head circumference, respiration rate , hospital stay and heart rate; and Mann-Whitney nonparametric test for the Apgar score are reported in the table 4. The results showed that the two groups of intervention and control in terms of fetal age, height, weight, birth weight, head circumference, respiration rate, hospital stay, heart rate and the Apgar score were the same and there was no significant difference between them.

Ranked Logistics Regression Model: Regarding to this matter that the distribution of gender variables in the two groups of intervention and control were different together ($p = 0.013$), and also with regard to being ranked[4] of the response variable (pain) to evaluate the effect of intervention on the pain score, a ranked logistic regression model was used in this study. The fit results of this model showed that by controlling the effect of gender, the intervention had a significant effect on reducing the amount of pain caused by blood sampling from the heel in preterm neonates hospitalized in the neonatal intensive care unit of Ali Ibn Abi Talib Hospital in Zahedan ($p < 0/001$).

Neonatal infant pain scal					
Vibration	medium	Minimum	Maximum	Amplitude	Changes domain
	2	1	6	5	1
control	medium	Minimum	Maximum	Amplitude	Changes domain
	4	2	6	4	1

Discussion

In response to the goal of No. 1 "Determining and Comparing the Mean Pain Score after Intervention in Two Control and Intervention Groups", the results showed a difference of pain score in the two control and intervention groups. In the study of Kate Mc Ginnis et al (2016) (1), the effect of vibration on pain reduction caused by blood sampling from the heel was consistent with the present study. In this study, the pain score caused by blood sampling from the heel decreased after vibration. Diagnostic and therapeutic measures in the neonatal intensive care unit cause pain in neonates. In the present study, the effect of vibration on the pain caused by blood sampling from the heel in preterm neonates was investigated. The results showed that using vibration can cause significantly to reduce the pain score when taking blood from the heel in neonates.

In a study by Lisa R. Baba et al (2010) who evaluated the impact of sedative effect of vibration on reduction pain caused by blood sampling from the heel on 20 neonates with fetal age of 35 weeks, showed that the use of vibration can cause to reduce pain caused by blood sampling from the heel in neonates ($p = 0.094$). This study was consistent with our study, with this difference that our study was performed on neonates with fetal age 30 to 36 weeks and the mentioned study was performed on neonates with fetal age of 35 weeks (2). Kate Mc Ginnis et al (2016), who tested the effect of vibration on the response to pain caused by blood sampling from the heel on 56 neonates hospitalized in the NICU, showed in a study that using vibration can lead to reduce the pain caused by blood sampling from the heel in neonates, and the pain score

before and after the intervention had statistically significant difference (p = 0.002) (1). This study was consistent with our study and showed that neonates, like adults, experience the pain and response to physiological and behavioral changes, and need intervention to reduce pain in order to perform painful procedures, with this difference that our study was carried out on preterm neonates and mentioned study was carried out on term neonates.

Conclusion

The results of the study showed a positive effect of vibration on the reduction of pain caused by blood-sampling from the heel in neonates, so the use of this method is recommended as a complementary method to reduce pain in neonates.

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