Original Article

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Effect of Ear Protector on Heart Rate and Pain Due to Intravenous Sampling in Premature Infants

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ABSTRACT

BACKGROUND AND OBJECTIVE: Noise is the most common environmental stressor source for premature infants admitted to the neonatal intensive care unit. Venous sampling is one of the most painful-causing actions in newborns. The aim of this study was to determine the effect of voice loss using ear protector on pain caused by intravenous sampling and heart rate of premature infants.

METHODS: This randomized clinical trial study was performed on 112 premature infants aged between 28-36 weeks who were randomly divided into two groups of intervention (56 subjects) and control (n=56). The ear protector was used for the intervention group when the baby was subjected to intravenous sampling. Neonatal pain was measured by PIPP instrument (premature infant pain measuring instrument) in five steps (2 minutes before the needle penetration), (moment of needle penetration), (pump time), (moment of needle withdrawal) and (5 minutes after needle withdrawal). Heart rate was measured with a pulse oximeter (8 times every 30 minutes during 4 hours after using the ear protector) and compared. (IRCT: 2015210828925N1).

FINDINGS: The mean changes in PIPP score were in the intervention and control groups (1.6±5.6 and 4.6±1.6), second (12.1±3.3, and 12.6±2.8), third (13.5±2.7 and 13.4±2.9), fourth (6.4±2.6 and 8.5±2.8), and fifth (5.1±4.2) and 1.6±6.2) respectively. Scores in all states except for the second and third stages were statistically significant in both groups ($p<0.05$). In addition, the mean of heart rate in the fifth stage in the intervention group (145.8±16.6) was significantly higher than the control group (138.1±21.1) ($p=0.03$).

CONCLUSION: The results of the study showed that the ear protector used for premature infants is effective in reducing pain during venipuncture.

KEY WORDS: *Premature Infant, Heart Rate, Pain, Ear Protector.*

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Introduction

Premature and persistent exposure to a painful stimulant before weeks 38 to 40 in preterm infants leads to permanent behavioral changes, increased intracranial pressure, suppressed immune system and cardiac arrhythmia (1,2). Venous sampling is one of the most painful actions in neonates (3), while venipuncture is known as a stressor for children and infants (2). The need to monitor several hours after drug discontinuation with opioid use, liver toxicity, and thrombocytopenia using non-opioid analgesia and methemoglobinemia with the use of lidocaine-perilocaine mixed ointment lead to non-pharmacological interventions toward the drug (3). Sohrabi showed that the first step in controlling pain in newborns is creating a quiet environment for the newborn, which improves their weight gain (4). Varvara et al. concluded that sound and light had an effect on neonatal EEG changes. Therefore, reduction of disturbing stimuli is recommended as an effective environmental strategy for reducing the response of neonatal to pain (5).

Van Rompuy et al. concluded that the use of ear protectors is effective in reducing Delirium (6). The volume of the inside of the incubator is reported to be at the highest level with 117 dB, in addition, the equipment and activities inside and around can add up to 40-10 dB, routine care interventions such as formula bottle placement on the table beside the bed, closing the drawer and opening the packed items, according to sound reports, make about 58-76 dB. Furthermore, infusion pump alarms and cardio-respiratory monitors have been measured about 57-66 dB (1).

The maximum sound from the infusion pump is more than 65 dB and the respiratory device is more than 80 dB (7). The neonatal intensive care unit is the first extra uterine physical environment for premature infants, which has been implanted for a long time (10-8). The baby's hearing system is also evolving, like the rest of the organs, which includes the middle ear, internal, snail, and auditory nerves (11). The American Environmental Protection Agency recommends 45 dB per day and 35 dB per night in the Neonatal Intensive Care Unit (16-12).

Exposure to loud noise in newborns, in addition to physiological changes in response to it, including decreased oxygen saturation and fluctuations in blood pressure and pulse, can reduce the pain tolerance in patients admitted to intensive care unit (8). Several methods have been proposed to reduce the exposure of infants admitted to neonatal intensive care unit with sound, including using incubators, improving unit design, modifying devices, reducing alarms, using music, using mother tone, change the behavior of employees and consider the silent hour in the department (17, 8).

Measuring the volume of voice in the neonatal intensive care unit in 2012, despite the use of these solutions, is an average of 65 dB (10, 9). The study by Zahedpasha et al. showed that the rate of observance of physical sound-related environmental factors in the neonate departments is weak (18). Due to the ineffectiveness of sound control programs and the cost of acoustic roofing, the use of hearing protection devices is essential (19, 11). The protector by controlling the sound from the source decreases the sound by 6 dB (12).

Short-term use of silicone ear protectors was associated with better weight gain for neonates without evidence of phone complaints (13). Duran Ridvan's study found that the reduction of sound by using ear protectors is effective in the sleepiness of premature infants (7). However, studies also show that the ear protector could not properly reduce the sound of water flow inside the fan and opening and closing the incubator (13). Another study by Abujarir and colleagues found that the effect of reducing the sound volume was by reducing heart rate, increasing systolic blood pressure, reduced respiratory rate, increased oxygen saturation, and decreased days of oxygen demand in the ear protector group over a 72-hour period compared with those without ear protectors (3). Regarding the importance of sound reduction, this study aimed to determine the effect of ear protector on the amount of pain caused by intravenous sampling and heart rate of premature infants.

Methods

This clinical trial study after obtaining permission from the Ethics Committee of Mashhad University of Medical Sciences with IR.mums.REC.1392.204 and the clinical trial code of IRCT: 2015210828925N1, after presenting the referral from of university to Qa'im hospital and Um al-Benin hospital and permission of the authorities and staff of the neonatal intensive care unit in these hospitals was performed on 112 preterm infants with gestational age of 28-36 weeks in October 2015. To calculate sample size with 95% confidence level and 80% test power, the mean and standard deviation of all variables was used based on the results of previous studies (14,15); the sample size based on

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mean and standard deviation of heart rate and also pain intensity based on the PIPP (Premature Infant Pain Profile) tool were calculated 56 and 5, respectively, which was performed on 56 neonates in both intervention and control groups and a total of 112 infants. Neonates with gestational age of at least 28 and at most 36 weeks and 6 days, without congenital anomalies, clinical status stability; lack of pain (PIPP<7); non-intake of sedative and inotropic drugs within 24 hours and lack of mother addiction were entered into study. In the event of failure in intravenous sampling, one-time injection of needles, apnea, or infants' death during the neonatal sampling were excluded. To determine the validity of the tool, content validity was used.

The PIPP tool was used to determine the facial image of the baby. This instrument is a precautionary measure for assessing pain in premature infants, and according to fetal age, behavioral status, maximum cardiac output, minimum oxygen saturation and infant's face, the pain score is estimated at between 0-21(20) . The reliability of the tool was estimated by the reliability method of the evaluators with the spremem correlation coefficient (r = 89%).

Data included age, sex, weight, number of days of admission and duration of venipuncture were controlled by registration in the questionnaire. The infant was in the back rest position, and the pulse oximeter probe was fixed to the anterior part of the baby's right thigh. In the intervention group, the ear protector was placed on the ear of the baby and was fixed to prevent its exit with Sergi Fix. After calving the infant every half hour, the physiological variables were measured and recorded by the researcher, respectively: first, the heart rate for 30 seconds was observed on the cardiopulmonary monitoring system and recorded at a minimum and maximum range, and the average was calculated. In the control group, all measures were similar to the use of ear protectors except use of ear protector.

After 4 hours, the ear protector was removed from the ears of the newborns in the intervention group and simultaneously with the intravenous sampling, the ear protector was again restored by the neonate intensive care unit nurse and the neonate was filmed during the intravenous sampling by the researcher assistant. The neonate was resting on the vertebral column, and a pulse oximeter probe was fixed to the anterior posterior part of the infant's right thigh (6). The researcher recorded the pain score by using the PIPP tool 2 minutes before the needle penetration, moment of needle penetration, pump time, moment of needle withdrawal and 5 minutes after needle withdrawal. Then heart rate was recorded from a cardiopulmonary monitoring device. Since the sampling was carried out at various hours of the day, the environmental sound level before starting measurement of physiological variables was performed using sound level meter SYROS CR: 303 model in the UK was measured near the baby's ear for 30 seconds (the average of the maximum and minimum displayed voices in dB was considered as the environmental sound). In the infants admitted to the incubator, sound level meter was placed in incubator and in infants were placed on the recovery bed near the baby's ears. The used ear protector was Elox made in US, which reduced the sound to a maximum of 25 dB (6).

Venous sampling was done by a nursing expert (having at least one year of work experience in neonatal intensive care unit), with a one-time needle stick number 22, for simultaneous viewing of the baby's face, filming was done by researcher assistant, and It lasted up to 5 minutes after the needle withdrawal. Data were entered into the SPSS 16 software and the Kolmogorov-Smirnov test was used to examine the normal distribution of quantitative data. To compare two groups in terms of quantitative demographic variables according to the normal or abnormal distribution, independent t-test and Mann-Whitney (Z) tests were used and also to compare qualitative variables including gender and cause of admission from Chi-square test was used.

Independent t-test (for variables that were normal in both groups) and Mann-Whitney test (for variables that were not normal in one of the groups) were used for inter-group test of heart rate and PIPP score. In addition, for intragroup testing for normal variables repeated variance analysis (F) and paired t-test were used, Friedman test (x2) was used for abnormal variables and $p<0.05$ was considered significant.

Results

The analysis was performed without any dropping of the research unit between 56 in the intervention group and 56 in the control group. In the intervention group, 28 (50%) were male and 28 (50%) were female and in control group, 31 (55.4%) were male and 25 (44.6%) were female. The mean age in the intervention group was 32.4±2 weeks and the control was 32.6±2.1

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weeks. Also, the mean weight in the intervention group was 1808.2±636.2 gr and in the control group was 1815.5±591.3 grams. The mean of voice in the intervention and control groups were 59±6.1 and 59.7±5, respectively.

The most common cause for admission was 56 (50%) due to RDS (Table 1). The mean PIPP score was first and foremost in the intervention and control groups (1.6±5.6 and 4.6±1.6), second (12.1±3.3 and 12.6±2.8), respectively, third (13.5±2.7 and 13.4±2.9), fourth (6.4±2.6 and 8.5±2.8) and fifth (5.1±4.2 and 6.1±2.6). Scores in all stages of measurement except for the second and third stages were statistically significant in both groups ($p<0.05$) (table 2).

The mean heart rate in the pre intervention stage was 153.9±14.4 and 143.5±20 per minute in the intervention and control groups, respectively that after intervention, reached to 141.8±18.9 and 153.9±14.4 per minute. Before the intervention, heart rate in the intervention group was significantly higher than the control group ($p=0.002$). After intervention, there was no significant difference between two groups in terms of heart rate. The difference in heart rate before intervention in the intervention group (9.9±53.8) was significantly higher than the control group (1.6±10) ($p<0.001$).

But in the control group, the heart rate in the post-interventional stage was not significantly different from the pre-intervention stage. The heart rate in the fifth stage of the measurement was significantly higher in the intervention group (145.8±16.6 per minute) than the control group (138.1±21.1 per minute) ($p=0.03$). In other stages, there was no significant difference between two groups in terms of heart rate (table 3).

Table 1. The mean of the studied quantitative demographic variables in two groups

Group / Quantitative variables	Intervention	Control	All samples	Test statistic	P-value
weight	1808.2±636.2	1815.5±591.3	1811.9±611.4	Z=-0.25	0.8
Gestational age	34.4±2	34.6±2.1	32.5±2.1	Z=-0.69	0.49
Chronological age	4.5±3.4	7±4.4	6.3±4	t_{103}=-1.7	0.09
Number of admission days	4.5±3.4	3.8±3.4	4.1±3.4	Z= -0.51	0.13
Duration of venipuncture	4.2±1.3	4.1±1.2	4.1±1.2	Z= -0.17	0.86
sound	59±6.1	59.7±5	59.3±5.6	t_{106}= -0.71	0.48
Qualitative variable	**Frequency (percent)**	**Frequency (percent)**	**Frequency (percent)**	**P-value and Test statistic**	
Cause of admission					
RDS	28(50)	28(50)	56(50)		χ^2_4=7.47
LBW	12(21.4)	8(14.3)	20(17.9)		P=0.11
ICTER	10(17.9)	14(25)	24(21.4)		
SEPSIS	4(7.1)	0(0)	4(3.6)		
other	2(3.6)	6(10.7)	8(7.1)		
total	56(100)	56(100)	112(100)		
Gender					
female	28(50)	25(44.6)	53(47.3)		$\chi^2_{1=0.32}$
male	28(50)	31(55.4)	59(52.7)		p=0.57
total	56(100)	56(100)	112(100)		

Table 2. Comparison of PIPP changes in different stages of measurement in two groups

Group / Measurement stages	Intervention (with ear protector) Mean±SD	control (without ear protector) Mean±SD	Test statistic[2]	P-value
First stage	5.6±1.6	4.6±1.6	Z= -3.55	[a]<0.001
Second stage	12.1±3.3	12.6±2.8	Z= -0.48	0.63
Third stage	13.5±2.7	13.4±2.9	Z= -0.04	0.97
Fourth stage	6.4±2.6	8.5±2.8	$t_{110.0}$= -4.24	[b]<0.001
Fifth stage	5.1±4.2	6.1±2.6	Z= -2.84	[c]0.005
Test statistic	χ^2_4=165.34	χ^2_4=174.78		
P-value	<0.001	<0.001		

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Table 3. Comparison of mean heart rate of infants in different stages of measurement in two groups

Stages / Group	Intervention (with ear protector) Mean±SD	Control (without ear protector) Mean±SD	Test statistic[2]	P-value
Before intervention	153.9±14.4	143.5±20	$t_{100.1}$=3.17	0.002[(d)]
First time	146.4±15.9	144.4±23	Z=-0.03	0.97
Second time	143.6±17.6	141.2±18.2	t_{110}= 0.72	0.47
Third time	143.5±17.4	141.5±19.8	t_{110}= 0.56	0.57
Fourth time	141.5±18.4	139.7±20.7	t_{110}= 0.5	0.61
Fifth time	145.8±16.6	138.1±21.1	t_{110}= 2.14	0.03[(e)]
Sixth time	145.6±14.6	140.5±21.4	t_{97}= 1.47	0.14
Seventh time	142.5±14.9	144.3±23.7	$t_{92.7}$= -0.5	0.62
Eighth time	143.2±14.6	144.8±26.6	$t_{85.3}$= -0.4	0.69
Test statistic	$F_{4.0, 222.2}$=14.45	χ^2_8=15.82		
P-value	<0.001[(f)]	0.045[(g)]		
Average of steps	144±14.7	141.8±18.9	t_{110}=0.69	0.49
Difference after and before intervention	-9.9±3.8	-1.6±10	$t_{70.5}$= -5.8	<0.001[(h)]
Test statistic	t_{55}=19.63	t_{55}=1.24		
P-value	<0.001[(i)]	0.221		

Discussion

The results of the study showed that the use of ear protectors is effective in reducing the pain of neonates during venipuncture. PIPP scores were statistically significant in both groups except for the second and third stages. The second and third stages are the stage of entry of needle and blood pumping and depend on the skill of the nurse sampler, which was not the same in all nurses and this factor may affect the results as one of the research limitations.

The results of study of Atia et al. showed that sensory stimulation with the use of eye and ear protectors did not significantly affect pain response due to venipuncture in both control and intervention groups (8), which is not consistent with the results of our study. The reason for this difference can be the use of eye and ear protectors in the study of Atia et al and the creation of sensory deprivation with the simultaneous use of eye and eye protector, since sensory deprivation stress affects pain (14).

The results of study of Abujarir et al. indicated that ear protector did not affect the pain of neonates. In this study, neonates were not classified according to being term, premature and weight, and the CRIES scale was used to assess the pain (3), while the present study was performed only on preterm infants and the PIPP tool, which includes two moderators such as gestational age and behavioral status, was used to assess the pain. On the other hand, in the Abujarir's study, there was no stable clinical status for infants under ventilation. Also one of the factors influencing the results of the Abujarir study may be the loss of the behavioral patterns of the pain and the face of the baby during a painful process and withholding its physiological responses. The results indicated that the heart rate of premature infants before intervention and in the fifth stage of measurement was significantly higher in the intervention group than in the control group. In other stages, there was no significant difference between two groups in terms of heart rate.

Factors such as prematurity, previous exposure to noise, sleep and awakening, and the level and nature of sound, may be effective on the response of infants to sound before intervention but were not considered and are limitations of our study. In addition, heart rate in the intervention group after 4 hours had more reducing trend than the control group. This suggests that the effect of sound reduction on improvement of physiological variables is gradual, and the noise reduction intervention should be extended over a long period. Moreover, the reason for the difference between the results in response to the heart rate can be the volatility of the sound is only referred to the mean (4, 3). The study of Abujarir and colleagues is similar to the results of our study (3).

However, in this study, although the noise reduction intervention of 7 dB for 72 hours reduced the heart rate of the infants in the intervention group compared to the control group, there was no significant difference in mean heart rate between two groups in

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the first six hours of the study. The results of the study by Ridvan Duran showed that the noise reduction intervention had no effect on the neonatal heart rate variable (7). The results of this study are not consistent with the present study. The difference in the type of ear protector is probably cause of the inconsistency of this study with our study, because the ear protector of the above study was more effective at higher frequency sounds and the ear protector used in the present study was a small type that reduced the sound by 7-12 dB. Considering the length of stay of infants, the study of Ridvan Duran (7 days) compared to the present study (intervention group was 4.5±3.4 days and in the control group was 3.8±3.3 days) and the number of exposure days with loud noises of neonatal intensive care are the cause of the difference between two studies. Also, the mean gestational age in the study of Ridvan Duran was 29.9±2.1 weeks and in above study was 32.5±2.1 weeks, and greater maturity of neonates in our study might be the cause of difference between the results of two studies. The limitations of this study include: not registering the previous experience of pain, not being uniform the individual skills of venous sampling in all nurses, not being the same the threshold of pain in infants, and not generalizing the research for term neonates, that by random placement of samples in both intervention and control groups, the impact of these limitations was reduced to the extent possible. It is suggested that in future studies, the effect of sound reduction on weight gain, feeding tolerance of preterm infants and reduction of brain hemorrhage in premature infants. The results of this study showed that sound reduction intervention is a suitable method for reducing the pain score due to intravenous sampling.

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