The Effect of Swaddling in Physiological Changes and Severity of Pain Caused by Blood Sampling in Preterm Infants: Randomized Clinical Trial

Ali Akbar Karimi[1*], Faezeh Jahanpour[2], Kamran Mirzaei[3], Sharafat Akeberian[4]

[1]Master Student of Nursing, Bushehr University of Medical Sciences, Bushehr, Iran.
[2]Ph.D. in Nursing, Associate Professor in Faculty of Nursing and Midwifery, Bushehr University of Medical Sciences, Bushehr, Iran.
[3]Epidemiologist, Faculty of Medicine, Bushehr University of Medical Sciences, Bushehr, Iran.
[4]Faculty member, Associate Professor of Faculty of Nursing and Midwifery, Bushehr University of Medical Sciences, Bushehr, Iran.

ABSTRACT

Background: Preterm infants admitted to hospitals are often exposed to many painful interventions, including venous blood sampling. Studies have shown that pain affects neural development and affects the subsequent responses to painful stimuli and behavioural responses. **Method**: The present study is a randomized controlled clinical trial conducted on 34 preterm infants admitted to the Neonatal Intensive Care Unit of the Persian Gulf Hospital in Bushehr. The infants were randomly assigned into control and swaddling groups using block randomized allocation method. Infants of swaddling group were swaddled by bed sheet 10 minutes before blood sampling until two minutes after it. In both groups, heart rate and arterial blood oxygen saturation were measured and recorded at time intervals of 30 seconds before, during, and 30, 60, 90, and 120 second after blood sampling. From the onset of blood sampling until 2 minutes after it, the infants' faces were videotaped and the videos were observed by a researcher who was not aware of the intervention type and the infants' pain measurement tool (pipp) was completed for 30-second time intervals**. Results:** The results revealed that pain in the swaddling group was significantly reduced compared to that in the control group. In addition, the results revealed that changes in heart rate were less and more stable and returned to the baseline level faster in the swaddling group, while in the control group, the changes were more and did not return to baseline level even after 120 seconds. **Conclusion**: based on the results of this study, swaddling can reduce the risk of blood sampling in preterm infants and keep their vital signs in a better status. Thus, it is recommended that nurses to use it as an effective intervention in the neonatal intensive care unit during performing painful procedures such as blood sampling.

Key Words: Swaddling, Preterm Infant, Infant Pain, Venous Blood Sampling, Nursing.

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INTRODUCTION

According to the World Health Organization (WHO), 15 million preterm infants are born around the world every year [1]. The infants born before the 37th week of pregnancy are necessarily spending first days of their life in the neonatal intensive care unit. Infants in this environment are affected by a large number of diagnostic and therapeutic interventions in order to maintain and improve their lives and 16 painful procedures are reported per day. In addition, 31% of these interventions are repeated, as they are not successful for the first time [2]. Despite recent developments in neurobiology, 79.2% of these procedures are still performed without any pharmacological or non-pharmacological pain reliving method [3, 4]. The most common type of these interventions is blood sampling [5]. Uncontrolled pain

Corresponding author: Ali Akbar Karimi
Address: Master Student of Nursing, Bushehr University of Medical Sciences, Bushehr, Iran.
E-mail: ✉ a.karimi@bpums.ac.ir
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leads to immediate, short-term and long-term side effects. Severe or prolonged pain in preterm infants may cause brain damage by increasing intracranial pressure. In addition, reducing the saturation of oxygen caused by pain may also result in the release of free radicals, which can disrupt the rapid growth of the brain tissue [6, 7].

Thus, reducing the pain of preterm infants is very important. The most effective strategy is to reduce the pain of the infants, to limit the number of painful practices, and to use pharmacological and non-pharmacological pain relieving methods [8]. Studies have shown that non-pharmacological methods have a greater effect on reduction of pain due to therapeutic interventions [9]. Non-pharmacological pain relieving methods include the use of sweet oral solutions such as sucrose, breast feeding, music, shaking, hugging, changing the position, skin to skin contact with mother and infant and swaddling [2]. One of the ways forgotten for many years and is being re-used is swaddling [10]. This method has now become popular in industrialized countries such as America, UK, and the Netherlands [11, 12]. It can be stated that the main reason for re-use of swaddling is its favorable and beneficial effects on the infant behavior, especially the crying of the infant [10]. However, few studies have been conducted on its pain reducing aspect. A systematic review study conducted by Van Slowan et al in 2007 on swaddling in USA showed that out of the 78 articles studied; only 4 articles measured the effect of swaddling on the pain control [10]. Thus, the objective of this study was to evaluate the effect of swaddling on reducing the pain associated with venous blood sampling in preterm infants.

METHODOLOGY

The present research is a clinical trial conducted after obtaining license from the ethics committee of Bushehr University of Medical Sciences at Iran Clinical Trial Center with code of IRCT2017040433209N1. This study was conducted on preterm infants admitted to the neonatal intensive care unit of hospitals in Bushehr. The research inclusion criteria included: the birth age of less than 37 weeks and birth weight less than 2500 grams, Apgar score greater than 6 at the first five minutes of birth, passing at least 24 hours of birth, awake and calm infant, not feeding the infant 30 minutes before intervention and receiving no sedative drug 24 hours before the intervention and non-receiving vasodilators. The first blood sampling was performed on the same day and no blood sampling was performed before it. Exclusion criteria of study included congenital, chromosomal or neural anomalies, and intraventricular bleeding, seizure, epilepsy, and neonates undergoing surgery, as well as skin lesions in skin to skin contact areas of the mother or infant. Sample size was determined to be 17 people in each group based on the previous studies [13, 14].

First, the researcher attended in the research environment, and after obtaining the license and introducing himself to head of the unit, he identified and selected the qualified preterm infants and by taking written informed consent from the parents of the infant, he started his work. The neonates were assigned two groups of intervention and control by block randomization method using four blocks. Two subjects of each group were in each block. The order of the blocks was determined randomly, and then, the subjects were assigned into swaddling group or control group. Blood samplings were part of the diagnostic and therapeutic process of the infant, and no additional invasive intervention was performed. Blue Scalp Vein (No. 23, Shan Chuan) was used for all infants. In the swaddling method, the infant without clothe and only with a clean diaper was wrapped in a thin bed sheet by a researcher. The swaddling procedure was in this way that research folded the bed sheet in triangular form. Then, he placed the infant on it and one side of bed sheet was turned on infant. Then, the lower part of the bed sheet and finally other side of the bed sheet were turned on infant. This procedure is called Frog Flexible. In this technique, the infant is easily able to move the pelvic joints; the arms are bent and placed along the line below the chin, as infant's position in mother's womb.

Using chronometer, 10 minutes after completion of swaddling, the infant hand was taken out of the swaddle, and the blood sampling was performed by a nurse with adequate skill. After placing a small dressing on the blood sampling site, the infant hand was placed again in the swaddle and the swaddle position was kept = for 2 minutes after blood sampling. Before blood sampling from each infant, the first part of the tool was first completed by the researcher. This part includes the demographic and physiological information of the infant. Physiological factors included heart rate and arterial blood oxygen saturation. Then, the infant face was videotaped using the camera since the blood sampling moment up to 5 minutes after that. Then, the videos were encoded and an experienced researcher, who did not aware of type of videotaping intervention, was asked to complete the standard tool of acute pain measurement in preterm infants.

To measure the physiological parameters of heart rate and the arterial blood oxygen saturation, pulse oximeter attached to the sole of the infant was used. These parameters (heart rate and the level of arterial blood oxygen saturation, were measured and recorded by pulse oximeter device attached to the sole of infant during and

after blood sampling. Validity and reliability of this tool have been examined in many studies. Its validity has been reported at desirable level and its reliability has been reported 0.93-0.96 [15, 16]. In this study, the tool translated by Mohebi et al in the Midwifery Faculty of Mashhad University was used [17]. In addition, in order to reduce the severity of the disease as an interventional factor, the pipp score was evaluated at 30-second intervals. The pipp included 7 indicators. Each of these indicators ranged from zero to three, which total values between 0 and 21 were finally obtained.

Data analysis

In descriptive statistics, frequency, percentage, mean, standard deviation and range were used. In order to compare the demographic characteristics of the two groups of participants in the study (due to the non-compliance of the research data with normal distribution: Kolmogorov Smirnov Test: P value < 0.05), Chi-Square, Mann Whitney U, Kruskall Wallis H tests were used. To analyze the research data, Univariate GLM Test with Bonferroni Post Hoc Test (given the same regression axis of the variables of gender, age and birth weight p>0.05) was used at the significant level of 0.05 using SPSS Ver.19 software.

RESULTS

This research was conducted on 34 infants met the inclusion criteria. The results show that the majority of samples were male (Table 1).

Table 1: Comparison of the frequency of gender of infants separately for groups of study

Group	Subgroup	n	F (%)	P-*Value**
Control	male	9	52.9	/006
	female	8	47	
Swaddling	male	30	35	
	female	11	62	

The results of chi square (p >0.05) also revealed a significant difference between the two groups and a significant difference was seen between two groups in terms of type of delivery (p >0.05), so that 52.9% of the infants in the swaddling group were born by caesarean delivery and 88.2% of the infants were born by normal delivery method (Table 2).

Table 2: Comparison of the frequency of type of delivery of infants separately for the groups of study

Group	Subgroup	n	F (%)	P-Value*
Control	Normal delivery	2	11	/0020
	cesarean delivery	15	88	
Swaddling	Normal delivery	8	47	
	cesarean delivery	9	52	

Results revealed that two groups were not significantly different in terms of the variables of birth rank, Apgar score in the first 5 minutes of birth, birth weight and duration of blood sampling, while statistical analysis showed a significant difference between two groups in terms of mean fatal age of the infants participated in the study, so that the age of infants of the control group was lower (P = 0.002) (Table 3).

Table 3: Comparison of mean birth rank and Apgar score in first 5 minutes of birth, infant birth weight and fatal age of infant participating in the study separately for types of intervention

Variable	subgroup	mean	SD	P-Value*
Birth rank	Control	1.70	0.77	0.407
	Swaddling	1.94	1.08	
Apgar score	Control	^8.8	0.85	0.633
	Swaddling	^8.8	0.48	
Weight	Control	1500.00	647.59	0.024
	Swaddling	2024.70	772.94	
age	Control	٣٥.٣٠	3.29	0.002
	Swaddling	34.00	2.97	

Given the normal distribution of pipp score data, Univariate GLM Test was used with Bonferroni post hoc test. The results revealed a significant difference between the two groups only in 120-second time (P = 0.038), so that the pain score in the infants of control group in 120-second time was more that in the swaddling group. In addition, the infants of swaddling group had the most pain at the moment of blood sampling, and their pain decreased after that time and at the 120-second time, it reached to pain level less than that of blood sampling time. However, in the control group, infant pain increased up to 60- second time and it was high still in the 120-second time and it decreased significantly compared to that in blood sampling time. The results of the Univariate GLM Test with Bonferroni post hoc test showed no significant difference between the two groups in terms of heart rate before blood sampling. However, comparison of heart rate at all times of blood sampling, except for 30 and 60-second time, showed statistically significant difference. Heart rate changes were more in the control group that in music group and increased up to 60 –second time in two groups, and then, it decreased in music group up to 90 –second time and reached to baseline level in

120-second time (p = 0.004). In the control group, after 60 seconds, heart rate slowly decreased, and it was still higher than that of baseline in 120- second time.

The Univariate GLM test with Bonferroni post hoc test showed no significant difference between the two groups in terms of arterial blood oxygen saturation level before blood sampling and no significant difference was found between the two groups at all stages of blood sampling. Arterial blood oxygen saturation changes were more in the control group than those in the swaddling group. After 60 seconds, this level increased significantly and reached to that of baseline in the control group, but in the swaddling group, it reached to baseline level with slower speed. In addition, the Univariate GLM Test with Bonferroni post hoc test showed that at all moments of blood sampling and afterwards, among all changes in facial expressions including lifting the eyebrows, closing the eyes and nasolabial groove, only a significant difference was observed in lifting eyebrow between two groups. The change in the facial expression in the form of lifting eyebrow in the swaddling infants was lower than that of the control group at all moments and decreased significantly up to 120 seconds, but in the control group, significant reduction was not seen in the general face expression since 30 seconds to 120 seconds.

DISCUSSION

The objective of this study was to evaluate the effect of swaddling on the pain caused by venous blood sampling in preterm infants. The results of this study showed that swaddling can greatly reduce the pain caused by blood sampling, which is consistent with the results of the research conducted by Shaohui (2014) [19] and Huang (2004) [18]. The results are consistent with those of research conducted by Hu (2012) [20]. Huang study (2004) also reported that although the heart rate and arterial blood oxygen saturation level after blood sampling from heel returns to baseline level faster in the swaddling group, this difference was not significant. The results of this study are consistent with those of the present study, while this relationship was significant in the present study [18]. One of the reasons for the more stability of heart rate in infants of intervention might be control of excessive movement of the infant by swaddling. By controlling the infant's movements, swaddling prevents excessive use of oxygen, leading to more oxygen storage [13]. Swaddling can also prevent excessive infant heart rate by reducing pain and reducing the movement of the infant. The results of present study showed that swaddling can reduce the pain associated with venous blood sampling in preterm infants (P = 0.038). The results of a study conducted by Seyed Rasouli under title of the effect of swaddling on the pain caused by nasogastric tube insertion showed that swaddling improves heart rate and arterial blood oxygen saturation in the infant during and after nasogastric tube insertion. Results also showed that the range of heart rate changes and arterial blood oxygen saturation in the swaddling method was lower than that of control group [21]. Thus, the results of these two studies are consistent. The results of this study showed that swaddling can keep the heart rate of the infants in a better status, which is in line with the results of the study conducted by Dejdar (2015). The results of the study conducted by Dejdar showed that swaddling can reduce the pain caused by blood sampling in preterm infants and keep their vital signs at better status, and there was a significant difference between the control swaddling and the control group at all times [22]. A study conducted by Shao (2014) showed that swaddling can reduce the pain caused by blood sampling from heel [19]. The results of this study showed that swaddling can reduce the pain caused by venous blood sampling in preterm infants, so the results of these two studies are consistent. Another effect of swaddling was reducing the face changes at the time of blood sampling and that in the swaddling group. As stated above, the swaddling reduced the infant pain and as a result of changes in the face of the infant by various methods.

Limitations

The present study is a randomized clinical trial study, conducted only on preterm infants. It is recommended that the effect of swaddling on term infants to be examined in the future studies.

CONCLUSION

The results of this study showed that the swaddling had a positive effect on heart rate control, arterial blood oxygen saturation, and infant face changes, which all of them are indicators for the diagnosis of infant pain. Thus, it reduced acute pain in the infants. As swaddling is a simple and inexpensive method, it can be easily used in performing most painful procedures. In addition, it can be used in infants who are unable in non-nutritious feeding (sucking) to relieve pain, due to having oral-stomach feeding tube or tracheal tube.

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