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Research Article

The Effects of Kangaroo Mother Care and Swaddling on Venipuncture Pain in Premature Neonates: A Randomized Clinical Trial

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Abstract

Background: Hospitalized premature babies often undergo various painful procedures. Kangaroo mother care (KMC) and swaddling are two pain reduction methods.

Objectives: This study was undertaken to compare the effects of swaddling and KMC on pain during venous sampling in premature neonates.

Patients and Methods: This study was performed as a randomized clinical trial on 90 premature neonates. The neonates were divided into three groups using a random allocation block. The three groups were group A (swaddling), group B (KMC), and group C (control). In all three groups, the heart rate and arterial oxygen saturation were measured and recorded in time intervals of 30 seconds before, during, and 30, 60, 90, and 120 seconds after blood sampling. The neonate's face was video recorded and assessed using the premature infant pain profile (PIPP) at time intervals of 30 seconds. The data was analyzed using the t-test, chi-square test, Repeated Measure analysis of variance (ANOVA), Kruskal-Wallis, Post-hoc, and Bonferroni test.

Results: The findings revealed that pain was reduced to a great extent in the swaddling and KMC methods compared to the control group. However, there was no significant difference between KMC and swaddling ($P \ge 0.05$).

Conclusions: The results of this study indicate that there is no meaningful difference between swaddling and KMC on physiological indexes and pain in neonates. Therefore, the swaddling method may be a good substitute for KMC.

Keywords: Infant, Premature, Neonate, Pain, Venipuncture, Kangaroo Mother Care

1. Background

According to the international association of pain study, pain is an unpleasant feeling and an emotional experience following actual or potential tissue damage (1), which is created by a harmful stimulus, and its goal is essentially to defend and protect (2). Presently, it is accepted that neurons are formed during the embryonic period and anatomically and functionally have the necessary efficiency to conduct painful stimuli (3). Premature neonates are able to identify and react automatically to pain as early as 20 weeks of age (4). In addition, premature neonates are less able to reduce or inhibit painful stimuli because of descent neuron lines, which make them more sensitive to pain (3, 5). According to the world health organization (WHO), 15 million premature neonates are born globally each year, which is more than 0.1 of total neonate births (6). Premature neonates undergo many diagnostic and therapeutic procedures in the neonatal intensive care unit (NICU), which is reported to be more than 10 to 16

interventions per day (7-9). Unfortunately, 40 to 90 percent of neonates do not receive any preventative or therapeutic actions to reduce the pain of these painful interventions (7, 8, 10). The most common intervention is blood sampling, or heel stick, to prepare laboratory samples (11). Continuous pain impulses by afferent nerves to specific areas of the brain cause atrophy of that part of the brain. The repeated pain of procedures leads to ventricular bleeding in premature neonates, increases in brain plasticity of neonates, and reduction of subcortical white and gray matter, with subsequent increases in fluctuations inside the skull (12). Therefore, controlling the pain of harmful procedures, such as blood sampling, is of great importance, especially in premature babies, as it is proposed that the neonatal pain threshold is 30 to 50 percent less than in adults (3, 5). Moreover, uncontrolled pain can increase the risk of infection, the hospitalization period, and the death rate of neonates (13). Pain relief, which is among nursing interventions, can be done with or without medicine (14). Although the use of powerful medications for neonatal

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surgeries is an accepted practice, using such medications in painful interventions such as blood sampling is not appropriate (15). Fortunately, it has been proven that nonmedical interventions have greater impact on reducing pain caused by procedure (14). Swaddling and Kangaroo mother care (KMC) are two of the non-medical methods. KMC was innovated in 1979 in Colombia (16) and its pain controlling function can be justified with the neuromatrix theory of pain (17). The effect of KMC on neonate pain was first examined in 2000 with term neonates (18), then in 2003, in preterm neonates (19), and after that, by many researchers, with its effectiveness being established. Another pain controlling method for neonates is swaddling, which has advantages including improving sleep (20) improving neuromuscular growth, reducing pain and crying (21), and reducing the risk of sudden infant death syndrome (SIDS) (21, 22).

2. Objectives

Since diagnostic and therapeutic procedures are performed throughout the day and night, and since the presence of the mother is not possible in the closed environment of the NICU, if swaddling is as effective as KMC, then it can be used as a substitute for KMC. Thus, this clinical trial study was undertaken for the first time in Iran in order to compare the effects of swaddling and KMC on venipuncture pain in premature neonates.

3. Patients and Methods

This is a parallel-group controlled trial. A total of 82 premature neonates admitted to the NICU of Shohadaye-Khalije-Fars hospital in 2014 were included in the study. It is a general-governmental referral and teaching hospital in Bushehr-Iran affiliated with the Bushehr University of Medical Sciences, with 200 beds and 13 hospital sections. The inclusion criteria were as follows: born at less than 37 weeks of pregnancy; less than 2500 grams in weight; Apgar score higher than 6 in the first 5 minutes after delivery; being alive at least 24 hours after birth; and being awake and calm. The sampling was the first blood sample performed on a neonate on the same day as the delivery. Neonates who were fed within 30 minutes prior to the intervention, those who received any sedatives during the 24 hours prior to the study, and those who received vasodilators during their hospital stay, were excluded from the study. Other exclusion criteria were as follows: presence of congenital, genetic or neurological anomalies; intraventricular hemorrhage; seizures; undergoing any surgery; and any skin lesions in areas of skin contact in the mother or neonate.

The neonates who met the eligibility criteria were assigned into one of three intervention groups using a permuted block randomization method. Blocks of six were used for this purpose.

3.1. Data Collection

Venous blood sampling was done under swaddling in group 1, KMC in group 2, and routine care in group 3 (control group). Blood sampling was a part of the diagnostic and therapeutic procedures of all neonates and no invasive intervention was added. The blue scalp vein set (number 23) was used for all neonates.

In the swaddling method, the bare neonate was wrapped in a thin sheet with a clean diaper by the researcher, and using a stopwatch, 10 minutes after the swaddling began (23), the neonate's hand was taken from the swaddle and blood sampling was performed by the same skilled nurse. After a dressing was placed on the blood sampling site, the neonate's hand was placed back in the swaddle and the condition was kept for 2 minutes after blood sampling. Before blood sampling each neonate, the initial part of the tool was completed by the researcher, and this part included demographic and physiological information of the neonate (heart rate and arterial oxygen saturation). Physiologic information was obtained with a Saadat co. Arya brand monitoring machine that was calibrated by the medical equipment engineer in the hospital. In addition, the neonate's face was video recorded with a Canon camera for 2 minutes following the moment of blood sampling. In KMC, the neonate had only a clean diaper and socks and was placed in direct skin contact with the mother's chest, with the head at a 60 degree angle. In order to avoid lowering the neonate's body temperature, the neonate's back was covered with a thin blanket and the mother was asked to wrap her hands around the neonate's back, limit the neonate's movement, and avoid any additional actions, such as talking, caressing, moving, and feeding the neonate. After 10 minutes (18) of KMC, blood sampling was done on the neonate's hand and KMC was maintained for a further 2 minutes. The neonate's face was video recorded from the time of blood sampling until 2 minutes after. The videos were then coded and a single observer (an experienced research assistant that was unaware of the type of intervention) was asked to complete the premature infant pain profile (PIPP) tool for each video. In order to measure physiological parameters, a pulse oximeter attached to the neonate's hand was used to measure the heart rate and arterial oxygen saturation. These parameters were measured and recorded before, during, and after blood sampling.

The PIPP tool was used to evaluate acute pain in the neonates. The validity and reliability of this tool have been

shown in many studies, and it has desirable validity and reliability of 0.93 - 0.96 (24, 25); in a domestic study, the reliability was reported as 0.88 (26). The PIPP includes seven indexes as follows: three behavioral indexes, including brow bulge, eye squeeze, and nasolabial furrow; two physiological indexes, including heart rate and arterial oxygen saturation; and two indicators of age and behavioral state. Each of these indicators has a degree from zero to 3, which in total results in a value from 0 to 21. Values under 6 indicate lack of pain, values between 7 and 12 indicate mild to average pain, and values above 12 indicate severe pain.

This trial was approved by the research ethical committee of Bushehr University of Medical Sciences on (DATE) 2014, with the reference number (B-93-16-1), and registered in the Iranian registry of clinical trials (IRCT: 2014042212830N3R1). The study began after a written informed consent letter was obtained from each mother.

3.2. Sample Size and Power

The sample size was calculated using G power 3.1 software. Based on the information drawn from a study by Akcan et al. (27), the mean PIPP score was considered 10 with a standard deviation of 2. Assuming the equality of variances of PIPP scores in the intervention groups, alpha error of 5%, and statistical power of 80%, the required sample size to detect a difference of two scores between the groups was estimated to be 24. In order to increase the statistical power, and considering sample attrition, it was decided to include 30 neonates in each group.

3.3. Statistical Analysis

Mean and standard deviation were used to describe quantitative variables and frequency and percentage were used to describe qualitative variables.

The normality of the distribution of data was examined using the Kolmogorov-Smirnov test. According to the results of this test, the distributions of PIPP scores in the studied groups were not far from normality. Therefore, the mean PIPP score in each time point (30, 60, 90, and 120 seconds), was compared by one-way analysis of variance (ANOVA) test. The Bonferroni correction was used to adjust for multiple comparison testing.

Since the variables of heart rate, arterial oxygen saturation, and face scale did not have normal distribution, the non-parametric Kruskal-Wallis test was used to compare these variables among groups at any point in time (0, 30, 60, 90, and 120 seconds) after the sample was drawn.

Repeated measure ANOVA was used to compare the effect of the interventions on PIPP score in repeated measurements at 30, 60, 90, and 120 seconds. Tests of betweensubjects effects were used to examine the overall effect of the interventions on the PIPP score. Post-hoc multiple comparison tests were used to compare pairwise comparisons between the groups.

All statistical tests were carried out using SPSS statistical software, version 20 and the graphs were drawn using STATA statistical software version 11. The significance level was considered 0.05 in all tests.

4. Results

A total of 90 neonates who met the eligibility criteria were randomized into three groups, from which 82 remained in the study and were analyzed. There were 28 neonates (34.1%) in the swaddling group, 25 neonates (30.5%) in the KMC group, and 29 neonates (35.4%) in the control group. Figure 1 shows the flowchart of recruitment and follow-up of neonates during the study.

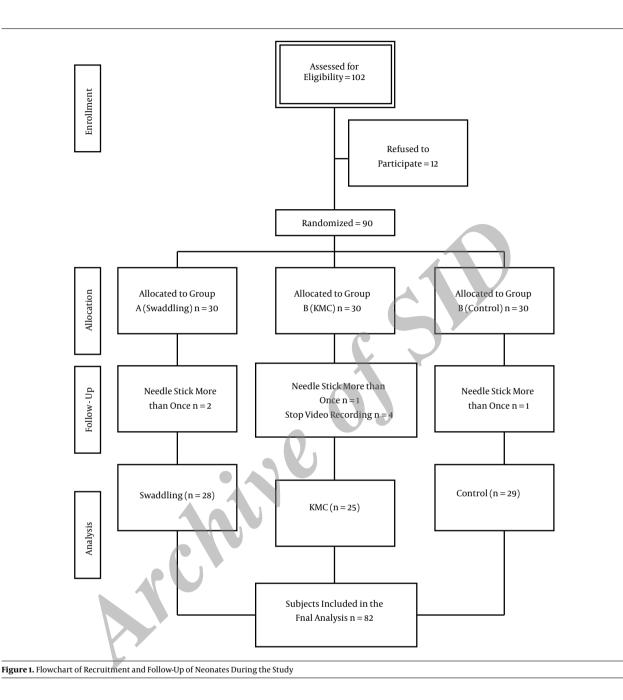
Table 1 displays the baseline and demographic characteristics of the neonates in the study.

Characteristics	Swaddling (n = 28)	Control (n = 29)	KMC (n = 25)
Gestational age	32.61 ± 2.48	33.21 ± 2.44	34.6 ± 1.55
Gender, male	16 (57.10)	14 (48.30)	17 (68)
Weight, g	1694.64 ± 512.788	1796.9 ± 571.202	2138.2 ± 336.783
APGAR score	9.07 ± 0.81	9.1 ± 0.86	9.64 ± 0.86
Delivery type			
Normal Vaginal Delivery	9 (32.10)	10 (34.50)	6 (24)
Cae- sarean Section	19 (67.90)	19 (65.50)	19 (76)
Duration of sampling, s	18.39 ± 9.818	22.14 ± 12.380	14.2 ± 7.024
Baseline heart rate, bpm	139.32 ± 17.053	142.55 ± 14.022	139.96±18.959
Baseline O2sat	96.89 ± 2.283	96.07 ± 2.463	98.26 ± 1.173

^aValues are expressed as mean \pm SD or No. (%).

The demographic variables in the three groups of samples had no statistically significant differences except for mean weight between the KMC and swaddling groups (P = 0.00), and between the KMC and control groups (P = 0.03) (Table 1). The control and swaddling groups did not show a statistically significant difference (P = 1.00).

Tests of between-subjects effects of repeated measure ANOVA showed that mean PIPP scores were statistically

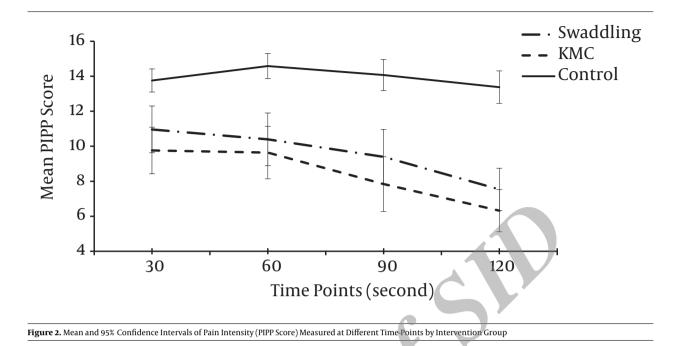


significantly different between the intervention groups F (2, 79) = 29.35, (P < 0.001). Post-hoc pairwise comparison tests determined that mean PIPP scores were not statistically significantly different between the KMC and swad-dling groups (P = 0.405). However, mean PIPP scores in both groups were statistically significantly lower than in

Mean PIPP scores were also statistically significantly different between the groups at seconds 30, 60, 90, and 120

the control group (Ps < 0.001).

[F(2, 81) = 13.289, F(2, 81) = 18.555, F(2, 81) = 25.465, F(2, 81) = 48.446, respectively, (all Ps < 0.001)]. Post-hoc pairwise comparisons determined that PIPP scores were not statistically significantly different between the KMC and swaddling groups at any time-point. However, mean PIPP scores in both groups were statistically significantly lower than in the control group at all time-points (all Ps < 0.01). Figure 2 illustrates mean PIPP scores and their confidence intervals at all time-points.



Non-parametric Kruskal-Wallis test results showed that heart rates were not statistically significantly different between the groups at the baseline, needling time, or 30 seconds after the needling (P = 0.850, P = 0.072, and P = 0.057, respectively). However, the differences were statistically significantly different at 60, 90, and 120 seconds after the needling (P = 0.004, P < 0.001, and P < 0.001, respectively). Pairwise comparisons showed that the significant differences were present between the heart rates of neonates in the swaddling or KMC group and the control group. There were no significant differences between the heart rates of neonates in the swaddling and KMC groups (all Ps < 0.05) (Figure 3 and Table 2).

The Kruskal-Wallis test results showed that oxygen saturation values differed significantly between the intervention groups at different time-points (Figure 4). Unlike heart rate, baseline oxygen saturation values were statistically, not clinically, significantly different between the groups. The differences were also statistically significant at all other time-points after the needling (all Ps < 0.01). Pairwise comparisons determined that oxygen saturation values differed significantly between the KMC and control groups (all Ps < 0.01) and also between the swaddling and control groups [all Ps < 0.05 except for baseline (P=0.254)]. Oxygen saturation values were also different significantly at the baseline (P = 0.022) and at the seconds 90 and 120 after the needling, (P = 0.039 and P = 0.005, respectively);however, the values were not significantly different at the needling time (P = 0.181) and at the seconds 30 and 60 after

the needling (P = 0.167 and P = 0.422, respectively) (Table 3).

Based on the Kruskal-Wallis test results, facial change scores were statistically significantly different between the KMC and control groups at 30, 60, 90, and 120 seconds after needling (P = 0.041, P = 0.006, P < 0.001, and P < 0.001, respectively). There were also significant differences between facial change scores in the swaddling and control groups at all time-points measured i.e. 30, 60, 90, and 120 seconds after the needling (all Ps < 0.001). However, there was no statistically significant difference between facial change scores in the KMC and swaddling groups at any time-point (Figure 5).

5. Discussion

According to the findings of this study, the swaddling method reduces the pain of arterial blood sampling in neonates to a similar extent as the KMC method. The physiological index differences in both groups of swaddling and KMC were more stable and less than the differences in the control group. The average pain comparison score in neonates with swaddling was less than in the control group. It is possible to justify the reduction of pain in swaddling using the Gate control theory of pain. According to this theory, stimulation of larger sensory fibers from touch receptors in areas of pain, or further ones, leads to pain signals weakening, therefore, it can be suggested that swaddling reduces pain by stimulating touch. One of the other effects of swaddling is warming the neonate. Heat

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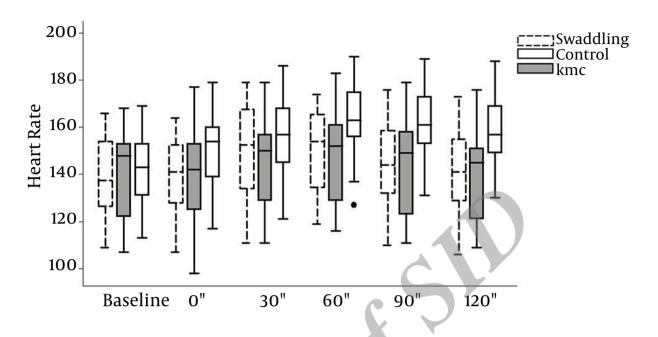


Figure 3. Box Plots of Heart Rate Values at Different Time-Points by Intervention Group

 Table 2. Comparison of Average Heart Rate in Premature Neonates in Each Group^a

Time		Groups		
	Swaddling	КМС	Control	
Needling time	140.71 ± 16.64	140.16 ± 19.90	150.28 ± 15.02	0.07
Second 30	148.75 ± 18.20	145.80 ± 19.18	157.62 ± 15.97	0.052
Second 60	150.36 ± 17.70	147.56 ± 20.35	163.83 ± 15.13	0.004
Second 90	144.86 \pm 17.46	143.28 ± 20.94	162.41 ± 14.91	0.00
Second 120	141.25 ± 16.87	139.36 ± 20.75	159.31 ± 14.57	0.00

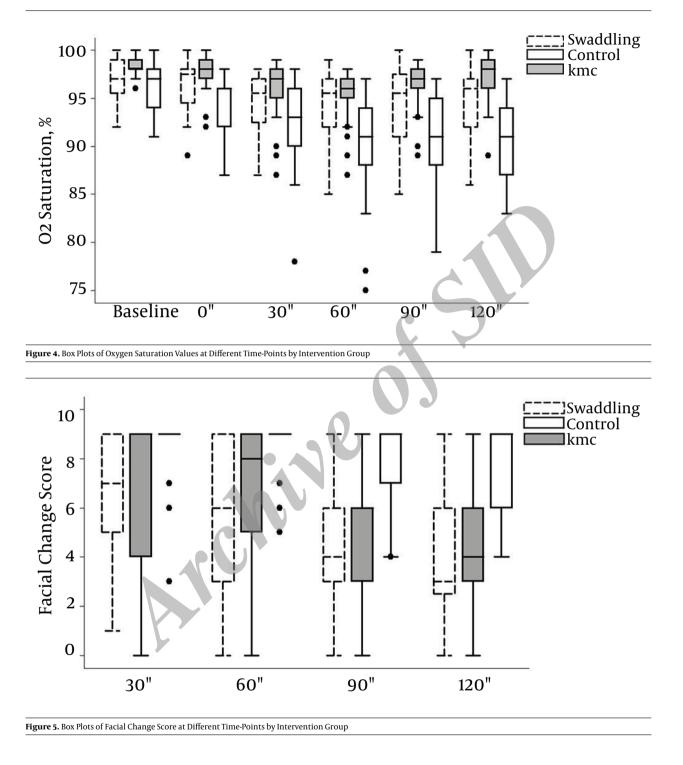
"Values are expressed as mean \pm SD.

Table 3. Comparison of the Average Arterial Blood Oxygen Saturation (O2 sat) in Premature Neonates in Each Group^a

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Time		Groups			P Value
		Swaddling	КМС	Control	
Needling time		96.54 ± 2.61	97.52 ± 1.98	94.48 ± 2.55	0.000
Second 30		94.64 ± 3.24	95.72 ± 3.06	92.41± 4.34	0.003
Second 60		94.21 ± 3.84	95.36 ± 2.78	90.0 ± 5.29	0.000
Second 90		94.04 ± 4.29	96.36 ± 2.66	90.76 ± 4.74	0.000
Second 120		94.61 ± 3.64	97.00 ± 2.50	91.00± 4.06	0.000

^aValues are expressed as mean \pm SD.

increases blood flow and may reduce pain through excretion of metabolic materials which cause pain. Another way to reduce pain is muscle relaxation, which means muscle slackness, and reduction of respiratory and heart rates.



Swaddling may reduce pain by reducing the respiratory and heart rates. In a study by Huang, it was found that the pain score in the swaddling group was lower than in the containment group (28). Also, in a review study by Meek in England, swaddling was identified as one of the effective nursing actions in reducing premature neonate pain (29). The findings of these two studies are consistent with the findings of the current research. In a review article

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in 2011 in Canada by Pilla Riddell et al. (30), it was suggested that swaddling can inhibit pain but may not be as effective as KMC, which is not consistent with the findings of this clinical trial. It is possible that this contrast is because of the guesses based on results of two studies, one by Johnston et al. (31) and another by Huang et al. (28), as no clinical study was done to compare these two methods. According to results of the current study, swaddling as a multi-dimensional intervention can reduce a neonate's pain to a considerable degree. This study found that physiological changes were less in the swaddling and KMC methods, and it was more stable compared to the control group. As was mentioned earlier, perhaps swaddling limits the neonate's movements and prohibits muscle stretch, causing muscle relaxation, and therefore improving respiration, increasing oxygen saturation, and decreasing heart rate. A study by Ho and Ho not only showed that the average pain from blood sampling in swaddling had a significant reduction compared to the control group (P = 0.001), but it also showed that heart rate and oxygen saturation indexes reached the baseline in 2 minutes, whereas in the control group, 6 to 8 minutes were needed for the indexes to return to baseline (32). The findings of this study are in line with the present study. However, a study by Khoddam et al. concluded that neonate and mother skin contact during intramuscular injection do not decrease physiological indexes of pain and only cause less neonate crying (16), which is in contrast with the findings of the current research. This contrast may be because the insufficiency of the sample in Khoddam's study, which was only 15 in the intervention group and 15 in the control group. It may be further explained by the short period of hugging time, as in Khoddam's study the neonate was hugged just at the moment of blood sampling, whereas in this study the neonate was hugged for 10 minutes before blood sampling. Considering the results of the current study, swaddling, like KMC, is an effective way to stabilize the physiological indexes of the neonate.

In the present study, it was shown that, in the two groups of swaddling and KMC, the physiological changes were similar to each other and less than in the control group. A systematic review which was done in 2007 on swaddling behavior stated that swaddling organizes the nervous behavior of the neonate well (21), which is in line with the findings of this study. Multiple studies refer to the effect of swaddling on neonate's sleep (33). It is possible that the improvement of neonate's sleep by swaddling is a reason which reduces the facial changes in response to pain. In the present research, it may be proposed that the neonates became sleepy when swaddled, and this reduced the changes in their face during the painful intervention. Fernandes stated that the appearance reaction can be a more practical observation than body movements and crying, and also can be more specific than physiological changes which are the total response to stressful stimuli (1). Assuming that this is true, nurses can understand the neonate's pain experience without using any specific tool and only by observing the neonate's face.

The average blood sampling time in the KMC group was 14.20 seconds, in swaddling it was 18.39 seconds, and in the control group it was 22.14 seconds. This difference was statistically significant (P = 0.020). The Bonferroni test revealed that there was no significant difference between the swaddling and KMC groups (P = 0.407) and also between the swaddling and control groups (P = 0.498), but there was a significant difference between the KMC group and control group (P = 0.016). It was observed that the blood sampling time was less in the KMC group than the other two groups. A possible explanation may be the vertical position and gravity, which improves blood flow and therefore allows sampling to be done faster. This issue has been mentioned in Johnston's study as well (31). Considering these findings, sampling can be done in a shorter period of time in the KMC method.

5.1. Strengths and Limitations

The present research was performed for the first time in Iran with a suitable design (randomized control clinical trial) and a strong performance. However, there are some limitations in this study. One of the major limitations of the study is the validity limitation of the utilized instrument (PIPP) to measure intensity of pain in neonates. Considering the limitation of sample volume, some differences are seen in the basic value of some demographic factors, such as birth weight, which is possibly the cause of random error.

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Footnotes

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draft review; Saeedeh Firouz Bakht: reviewer; Afshin Ostovar: statistical analysis.

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