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The Effect of Warm Compression Applied before Heel Lance on Pain Level, Comfort Level and Procedure Time in Healthy Term Newborns: A Randomized Clinical Trial

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ABSTRACT

Background & aim: Warm compression is an effective method preferred in relieving pain. It enables procedures to be completed in a shorter time, and with less pain due to increasing blood flow in the area. This study aimed to investigate the effects of warm compress applied before heel lance on the procedure time, level of pain, and comfort level of healthy term newborns.

Methods: This randomized controlled clinical was conducted on 80 neonates who were randomly divided into experimental and control groups. The data were collected using demographic questionnaire, observation checklist for procedure, Neonatal Infant Pain Scale (NIPS), and The Comfort Behaviour Scale (TCBS). The experimental group was subjected to local dry mild-warm compression to the heel before the heel lance procedure. The control group received routine heel lance procedure. Body temperature, peak heart rate, and oxygen saturation levels before, during, and after the procedure were recorded in both groups. Data were analyzed in SPSS software (version 16) using the Chi-square test and Mann-Whitney U test.

Results: The results of the study showed shorter procedure time in the experimental group compared to the control group ($P<0.05$). Moreover, the mean NIPS and TCBS total scores were lower in the experimental group compared to control group, and this was found to be statistically significant ($P<0.05$).

Conclusion: It was found that warm compression applied before heel lance decrease the length of the procedure and is effective in decreasing pain and providing comfort in newborns.

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Introduction

It is known that healthy newborns are exposed to routine painful procedures following birth. In Turkey, before healthy neonates are discharged from the hospital, they are exposed to different invasive procedures, such as Hepatitis B vaccination, vitamin K injection, and blood bilirubin follow-up. All these painful procedures experienced by the neonate can influence his/her pain behaviors, adaptation to the outer world, and family-infant interaction negatively. In addition, while this situation can cause negative changes in the development of the brain and senses, it has even been reported that it can have an adverse effect on growth (1-3).

The pain management strategy aims to minimize the pain felt by neonates who are exposed to painful procedures from the first moments of life and help the neonates deal with pain (4, 5). Since newborns can remember the early and repeated stimulants, the best pain-relieving methods should be considered in procedures applied for the first time in the hospital (6). Nurses use family-centered and individualized procedural care, as well as pharmacological and non-pharmacological methods to relieve pain. Pharmacological methods are employed commonly to relieve pain; moreover, opioid and/or non-opioid

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analgesics, sedatives, and local anesthetics are used for this purpose (7, 8).

However, pharmacological methods are reported to have some adverse effects, such as respiratory depression, apnea, bradycardia, hypotension, desaturation, partial airway obstruction, and hypersalivation (1, 2, 9). On the other hand, non- pharmacological methods are also emphasized as much as pharmacological methods in decreasing the perception of pain. Non- pharmacological methods are valuable techniques for pain control, especially in small and short-term invasive procedures (10-12). Studies have found that non-pharmacological methods, such as frequently repeated heel lance and aspiration, applied during invasive procedures to neonates are effective in decreasing pain (13, 14).

Peripheral techniques, which are utilized in non-pharmacological methods, include skin stimulation procedures to decrease pain. Warm compression, which is included in this procedure group, is an effective method preferred in relieving pain. This technique decreases or relieves pain by activating gate control mechanism, stimulating touch receptors, decreasing vasodilatation and ischemic pain, removing metabolic waste, increasing the oscillation of endorphins, stopping muscle spasm, decreasing the effects of pressure, tension, and hypoxia on nerve endings as a result of the change in the viscoelastic characteristics of tissues, sedation, and creating relaxation in the patient (7-9).

Warm compression also enables procedures, such as heel lance to be completed in a shorter time, thereby decreasing the time the infant is exposed to the painful procedure by increasing the blood flow to that area (12, 15-17). The methods that have been used in the studies conducted on decreasing the pain during heel lance procedure include breastfeeding during the procedure, making the infant listen to music, applying massage, giving sucrose, positioning of the newborn, bundling, and giving kangaroo care (5, 18-20). There are several studies in the literature employing different methods to reduce the pain which occurs during heel lancing procedure; however, there is no study on the utilization of hot application to warm up the site of the heel.

Materials and Methods

This randomized controlled study aimed to investigate the effects of local dry warm compress applied before heel lance on the procedure time, level of pain, and comfort level of healthy term newborns. The study population consists of neonates born at a state hospital in the north of Turkey. The sample size was calculated over experimental studies, and the neonates of families who met the inclusion criteria and were willing to participate in the study were included for sampling.

According to the literature, it is indicated that in experimental studies and parametric measurements, the sample size should be regarded as at least 40 cases in experimental and control groups. Considering this issue, the sample size was determined at 40 (21), and the study was conducted with a total of 80 neonates in both groups.

The inclusion criteria were: 1) stable health status, 2) no congenital anomalies, 3) no analgesics or oxygen treatment, 4) vitamin K injection, and 5) hepatitis B vaccination in the delivery room. On the other hand, the neonates who had no heel lance and were born between 38 and 42 weeks with a birth weight of 2,500-4,400 grams and postnatal age of<1 week, as well as those who have been fed within an hour before the procedure with a body temperature of 36.5-37.5 ºc were excluded from the study.

Demographic characteristics form, which was designed by the researcher in line with the study objectives, included multiple-choice and 8 open-ended questions about gender, birth date, gestational age, postnatal age, type of birth, birth weight, length, and head circumferences of the newborns.

Observation Form (Patient procedure observation form): This form includes the name of the procedure, the last feeding time before the procedure, total procedure time, (before, during, and after the procedure), body temperature, peak heart rate, saturation values, Neonatal Infant Pain Scale score (NIPS), and the Comfort Behaviour Scale score (TCBS).

The NIPS (Neonatal Infant Pain Scale) was developed by Lawrence et al. in 1993 and translated into Turkish by Akdovan in 1999 to assess pain. This scale consists of five behavioral indicators including facial expression, leg

movement, arm movement, crying and wakefulness, and one physiological indicator of respiratory rhythm. Total scores range from 0 to 7. Higher scores show that the intensity of pain is higher. The internal consistency of NIPS was reported to be 0.95 before the transaction, 0.87 during the transaction, and 0.88 after the transaction. According to a study conducted by Akdovan et al. in 1999, the internal consistency coefficient of this scale using Cronbach's alpha was found to be between 0.83 and 0.86 (22).

The Comfort Behaviour Scale: This scale is a Likert type scale that was developed to use sedation and comfort requirements in the pain and distress assessment of neonates followed by intensive care. Van Dijk et al. revised the scale and studied the scale in terms of reliability and validity as COMFORT neo (Neonates Comfort Behaviour Scale, (NCBS)) to assess only behavior without physiological parameters in neonates (23). The reliability and validity assessments of this scale were conducted by Kahraman et al. (2014). The NCBS consists of six parameters, such as awakeness, calmness/agitation, respiratory response, crying, body movements, facial tension, and muscle tonus. The NCBS is a numerical assessment scale enabling the researcher to assess the neonate's pain and distress in addition to finding out comfort.

It has been stated that the lowest and highest scores in NCBS are 6 and 30, respectively. Higher scores show that the infant is not comfortable and needs comforting interventions. In addition, the scores within the range of 4-6 from this numerical assessment scale show moderate pain and distress, whereas the scores between 7 and 10 indicate severe pain and distress (24). Before statistical analysis, the reliability of NIPS and NCBS scores were assessed and Cronbach's alpha values of NIPS and NCBS were obtained at 0.75 and 0.88, respectively.

A BMTNexTemp Thermometer (BMTNexTemp model) was used to measure the infant's body temperature before heel lance; moreover, a multiparameter bed-side monitor (Nelcor make Plus Oximeter) was employed to assess oxygen saturation and peak heart rate before, during, and after saturation. Furthermore, the warmth of the water in the thermophore was measured using a thermometer (Weewellhigro Thermometer). A chronometer was utilized to measure the period of the procedure (Samsung Galaxy Grand 2 model), and a green injector nozzle was also used in this study. Lance procedure period and body temperature were measured as second and degree Celsius (° C), respectively.

In total, 80 neonates who met the inclusion criteria were selected using a computer-assisted randomized method and divided into two groups of experimental (n=40) and control (n=40). Care was taken for the baby to be fed at least one hour before the procedure and to have normal body temperature. In addition, at the beginning of the procedure, it was ensured that the infant was quiet and was held in the correct position. It should be noted that all procedures were conducted by the same nurse. During the data collection process, parents could observe their newborns either in the experimental or control groups. The infants were monitored in both groups before, during, and after the procedure; moreover, body temperature, heart rate, and oxygen saturation levels of the infants were recorded in the procedure observation form.

Before the heel lance procedure, the newborns in the experimental group were subjected to a local dry mildly warm compress for five min using a thermophore. The warmth of the water in the thermophore was kept between 34-37 ˚C. To prevent the thermophore from contacting the sole of the infant's foot, it was wrapped in a cloth and placed on the sole from which heel lance would be taken. During the period until the procedure was completed, the total procedure period, number of pricks, NIPS, and TCBS were assessed and recorded in the patient procedure observation form.

On the other hand, the control group received routine heel lance procedure, and the total procedure period, number of pricks, NIPS, and TCBS were assessed and recorded in the patient procedure observation form. It should be noted that no comforting or relaxation interventions were used during the heel lance procedure, and these newborns were immediately comforted after the procedure.

Data were analyzed in SPSS software (version 16) through the Chi-square test and Mann Whitney U test. Initially, the Shapiro-Wilk test was used to determine the normal distribution of the data. Moreover, number, percentage, mean, standard deviation, and median were

obtained using descriptive statistics. Since the data set was not normally distributed in the comparison of two variables in scale score analyses, Mann-Whitney U test, which is an alternative for parametric tests, was employed in this study. A p-value less than 0.05 was considered statistically significant.

The study protocol was approved by the Local Ethical Committee of Ondokuz Mayis University, Samsun, Turkey (B.30.2.ODM.0.20.08.739). Moreover, institutional permission was taken from the Ministry of Health, Union of Public Hospitals, Samsun Maternity and Children's Hospital. The legal guardians of the newborns who were included in the study were informed of the aim, type, and implementation procedure of the study, as well as how and where the data would be used. In addition, written informed consent was obtained from the parents before the study, and the required permissions were taken from the related authors to use the scales in this study.

Results

According to the data obtained from the demographic characteristic form, 50% of the control group were male; moreover, 65% and 75% of the control and experimental groups were born in weeks 40-41, respectively. Regarding weight, 87.5% of the newborns in the control group and 75% of them in the experimental group were between 3000-3500 gr in the postnatal first day. Furthermore, 82.5% of the neonates in both groups were breastfed alone. It is worth mentioning that 92.5% and 80% of the neonates in the control and experimental groups were born through vaginal birth (Table1).

Table 1. Demographic characteristics of the newborns (N=80)

Variable	Control Group (n=40)	Experimental Group (n=40)	P-Value
	N (%)	N (%)	
Gender			
Female	20 (50.0)	18 (45.0)	0.659
Male	20 (50.0)	22 (55.0)	
Gestational Age			
38 week	5 (12.5)	2 (5.0)	
39 week	9 (22.5)	8 (20.0)	0.503
40-41 weeks	26 (65.0)	30 (75.0)	
Postnatal Age			
First day	35 (87.5)	31 (77.5)	0.432
Second day	5 (12.5)	9 (22.5)	
Delivery Method			
Vaginal birth	37 (92.5)	32 (80.0)	0.107
Cesarean	3 (7.5)	8 (20.0)	
Birth Weight			
2500-3000gr	8 (20.0)	4 (10.0)	
3001-3500gr	17 (42.5)	22 (55.0)	0.886
3501-4000gr	15 (37.5)	14 (35.0)	
Feeding Methods			
Human milk	33 (82.5)	33 (82.5)	
Human milk + formula milk	7 (17.5)	7 (17.5)	0.844

Number of Pricks on the Heels and Procedure Period

Table 2 shows the frequency distribution of pricks on the heels of newborns during the heel lance procedure. It was found that the neonates in the control and experimental groups had at least one prick (80% and 92.5% in the control and experimental groups, respectively).

The frequency of two or more pricks in the control group was estimated at 20%, and this corresponding value was determined at 7.5% in the experimental group. However, there was no statistically significant difference between the

groups in this regard (P=0.193) (Table 2).
On the other hand, a statistically significant difference was observed between the control and experimental groups in terms of the total procedure period (P=.020).

Table 2. Frequency of the pricks during heel lance procedure by groups

Variable	Control Group (n=40)	Experimental Group (n=40)	Test statistics	P-Value
	N (%)	N (%)		
Number of Pricks on the Heels				
One prick	32(80.0)	37 (92.5)	$\chi 2=2.635$*	0.193
Two or more pricks	8 (20.0)	3(7.5)		

* Chi-square Test, Fisher's Exact Test

It was found that the heel lance procedure period was shorter in the experimental group, compared to the control group. According to the results, there was a statistically significant difference between the control and experimental groups regarding the newborn pain scale (P<0.001) (Table 3). It can be said that the procedure of heel lance causes less pain with the method applied to the experimental group, compared to the control group. On the other hand, a statistically significant difference was observed between the groups in terms of newborn comfort scale (P=0.000). According to this result, the experimental group obtained lower comfort scale scores (Table 3).

Table 3. Differences in total procedure period (sec), Neonatal Infant Pain Scale, and Neonates Comfort Behavior Scale Scores by groups

Variable	Median (min-max)	Test Statistic*	P-Value
Total Procedure Period(sec)			
Control group	3(1-4)	558.500	0.020
Experimental group	2(1-3)		
Neonatal Infant Pain Scale			
Control group	8(2-10)	397.500	<.0001
Experimental group	7(3-10)		
Neonates Comfort Behavior Scale			
Control group	16(14-30)	383.500	<.0001
Experimental group	11(13-24)		

*Mann- Whitney U test

Mean Body Temperature, Peak Heart Rate, and Oxygen Saturation Scores

According to the results, there was no statistically significant difference between the groups in terms of mean body temperatures and peak heart rates before, during, and after taking blood samples (P=0.144). However, a significant difference was observed between the groups regarding the mean oxygen saturation values before, during, and after taking blood samples.
The values were found to be higher in the experimental group (during blood sampling: P<0.0001, after blood sampling: P=0.047) (Table 4).

Table 4. Mean body temperature, peak heart rate, and oxygen saturation before, during, and after heel lance procedure

Variable	Body Temperature	*MWU P-Value	Peak Hear Rate	*MWU P-Value	Oxygen Saturation	*MWU P-Value
	Median (min-max)		Median (min-max)		Median (min-max)	
Before Heel lance Procedure						
Control group	36.81(36.10-37.50)	-1.621	139.27(104.00-171.00)	-1.699	96(90-100)	-1.462
Experimental group	36.94(36.10-37.50)	.105	133.27(118.00-220.00)	.089	96(88-100)	.144
During Heel Lance Procedure						
Control group	36.83(36.20-37.50)	-1.522	167.00(118.00-220.00)	-,188	84(64-100)	-3.826
Experimental group	36.93 (36.10-36.50)	.128	165.95(136.00-199.00)	.851	92(76-100)	.000
After Heel Lance Procedure						
Control group	36.80(36.20-37.50)	-1.575	148.72(116.00-180.00)	-.323	93(85-100)	-1.991
Experimental group	36.90(36.00-37.50)	.115	150.65(126.00-176.00)	.747	95(90-100)	.047

*MWU: Mann-Whitney U test

Discussion

This study revealed that the heel lance procedure lasted longer in the control group with two or more pricks, compared to the experimental group; however, the mean oxygen saturation values were higher in the experimental group during and after the procedure (Tables 2, 4). Furthermore, the total mean scores of NIPS and NCBS were higher in the control group, compared to the experimental group (Table3). Limited numbers of studies have been found in the literature investigating the effects of applying warm compress before heel lance procedure on newborn pain. Therefore, other studies using different non-pharmacological methods have also been addressed in this study.

An experimental study was conducted using a warm compress method and compared the groups in terms of swaddling and local warm compress before the heel lance procedure. According to the results, warm compress decreased the pain level and heart rate of the warm compress group, compared to the other groups. Moreover, oxygen saturations were found to be more decreased in the swaddled group, compared to the warm compress group (16). Another study revealed that local warm compress before VitK injection decreased the pain scores of newborns, and mean pain scores decreased with increasing the time of warm compression (25). Similarly, according to the results of a study, crying and grimacing periods of neonates who were given sucrose with warm compression before vaccination were shorter and the heart rates were lower only in the group which was given sucrose (17). In their study, they found that the method of warming under radiant heater caused shorter periods of crying and grimacing after vaccination, compared to the methods of giving pacifier and sucrose. However, a study indicated that the heart rate was not affected using this method (15).

In the same vein, an experimental study analyzed the effect of warm compression before heel lance on the procedure time, and it revealed longer total procedure time, compared to that in the experimental group (3.36±2.45 and 2.33±1.31 sec in the control and experimental groups, respectively) (26). The result of the aforementioned study is consistent with the findings of the present study in terms of total procedure time. Regarding other non-pharmacological pain approaches in the heel lance procedure, an experimental study indicated that the newborns swaddled before heel lance procedure cried less than those in the control group, and their pain levels were also

lower, compared to the control group (2).

Furthermore, in a study, sucrose and mechanic vibration method used for pain control in the heel lance procedure, and it was determined more effective than only sucrose method, and the mean pain scores after the procedure were found to be statistically significantly higher than those during the procedure (27). Additionally, another study utilized breast milk, sucrose, and pacifier methods in heel lance procedure and found pacifier as the most effective method in crying time followed by sucrose (28).

Limitations of the study was that the neonate selection was according to the inclusion criteria, and the necessity of the same staff presence made it difficult to reach the number of cases in this study.

Implications for Clinical Practice of this practice include: 1) a non-invasive method, 2) lack of requiring the use of any medication, 3) inexpensiveness of the materials used, and 4) the possibility for nurses to use their time efficiently by shortening the procedure time. Warm compression technique can also be used in invasive procedures, such as heel lance, which is a procedure applied to all newborns.

Conclusion

It was found in this study that warm compression applied before heel lance procedure was effective in shortening the time of the procedure, decreasing pain in newborns, and providing comfort.

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Conflicts of interest

Authors declared no conflicts of interest.

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