Effects of Non-Pharmacological Methods on the Pain Level Occurs Due to Heel Blood Collection: Randomized Controlled Trial*

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Abstract

Aim: Studies indicate that non-pharmacological methods applied during invasive procedures in newborns assist in managing pain and agitation. This randomized controlled trial aimed to determine the effect of non-pharmacological methods on pain associated with heel stick procedures in healthy newborns.

Method: This study conducted in the neonatal unit of a private hospital included a total of 100 newborns aged 24-48 hours and divided them into experimental and control groups. While no non-pharmacological intervention was applied to the control group during the heel stick procedure, the experimental group received interventions such as providing a pacifier, administering oral sucrose, swaddling the baby in a flexion position, and warming the heel under a radiant warmer. Data were collected using the Procedure Follow-up Chart and the Neonatal Infant Pain Scale (NIPS) and analyzed using the SPSS 21.0 program.

Results: There is a statistically significant difference between the mean score of the NIPS of the babies in the experimental group and the babies in the control group (p=0.000). It was determined that the control group had higher mean pain scores compared to the experimental group.

Conclusion: This study revealed a significant difference in NIPS pain scores between the experimental and control groups and demonstrated that non-pharmacological methods effectively reduced pain levels.

Keywords: Newborn, pain, non-pharmacological methods.

Topuk Kanı Alınmasıyla Oluşan Ağrı Düzeyine Farmakolojik Olmayan Yöntemlerin Etkisi: Randomize Kontrollü Çalışma

Öz

Amaç: Çalışmalar, yenidoğanlarda invaziv işlemler sırasında uygulanan non-farmakolojik yöntemlerin ağrı ve ajitasyon yönetimine yardımcı olduğunu göstermektedir. Bu deneysel çalışma, sağlıklı yenidoğanlarda topuk kan alma işlemi ile ilişkili ağrı üzerinde non-farmakolojik yöntemlerin etkisini belirlemeyi amaçlamıştır.

Yöntem: Özel bir hastanenin yenidoğan ünitesinde gerçekleştirilen çalışmaya, kronolojik yaşı 24-48 saat arasında olan toplam 100 yenidoğan dahil edilmiş ve deney ile kontrol grubuna ayrılmıştır. Kontrol grubuna topuk kanı alma işlemi sırasında herhangi bir non-farmakolojik müdahale uygulanmazken, deney grubuna emzik verilmesi, oral sukroz uygulanması, bebeğin fleksiyon pozisyonunda sarılması ve topuğun ısıtıcı

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altında ısıtılması gibi müdahaleler yapılmıştır. Veriler, İşlem Takip Çizegesi ve Yenidoğan Bebek Ağrı Ölçeği (NIPS) kullanılarak toplanmış ve sonuçlar SPSS 21.0 programıyla analiz edilmiştir.

Bulgular: Deney grubundaki bebekler ile kontrol grubundaki bebeklerin NIPS puanı ortalaması arasında istatistiksel olarak ileri düzeyde anlamlı fark bulunmaktadır (p=0,000). Kontrol grubunun ağrı puan ortalaması, deney grubuna kıyasla daha yüksek olduğu belirlenmiştir.

Sonuç: Bu çalışma, deney ve kontrol grupları arasında NIPS ağrı skorları açısından anlamlı bir farklılık olduğunu ve non-farmakolojik yöntemlerin ağrı seviyelerini etkili bir şekilde azalttığını ortaya koymuştur.

Anahtar Sözcükler: Yenidoğan, ağrı, non-farmakolojik yöntemler.

Introduction

Many procedures are performed on newborns for diagnosis and treatment purposes, causing pain and stress[1]. One of the procedural interventions applied is the Guthrie Scan[1,2]. In the early 1960s, a screening test was developed and newborns were evaluated for phenylketonuria (PKU). The screening program was expanded after a pilot study conducted in Ankara in 1983 in a pilot study in Türkiye[1-4]. As a result of the Guthrie Screening performed by taking blood from a heel prick, congenital diseases of many newborns can be diagnosed and the mortality and morbidity rate decrease with early treatment[1,2,4]. The guide published by the Turkish Neonatology Association (TND, 2021) on neonatal pain and management states that heel blood collection is among the most common painful procedures encountered by newborns treated in the neonatal intensive care unit. Taking blood from the newborn's heel, where nerve conduction is intense, increases the newborn's pain and stress levels[5,6].

Side effects of pain in newborns include decreased pain thresholds and hypersensitivity to pain. Immediate harmful effects include increased heart rate and blood pressure, reduced heart rate variability, and an increased incidence of serious complications such as desaturation and tachypnea[7]. The primary problem in pain management in newborn babies is the difficulty in assessing the pain response due to their inability to express their pain. Newborns' painful experiences vary depending on issues such as vital signs. These differences can be interpreted and the degree of pain and response to treatment can be evaluated. The essential approaches to pain in newborns are; raising awareness about this issue, educating healthcare professionals well on this issue, performing minimally invasive interventions on babies, and using appropriate methods to relieve pain when there is pain. Developing appropriate pain control methods is also a medical and ethical responsibility[8,9]. It is recommended to use non-pharmacological methods during painful procedures in newborns. It is known that different sensory stimulations such as kangaroo care, massage, music, touch, mother's voice, smelling milk, sucking, oral administration of sucrose, glucose, or other sweet liquids, acupuncture, reiki, aromatherapy, nesting, and fetal position are effective in reducing pain in newborns[10-13]. It was designed to determine whether the use of four methods together contributes to the reduction of pain during heel prick blood collection and to maintain evidence-based practices.

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Material and Methods

Research design

The research was planned in a randomized, controlled experimental design to determine the effect of four different non-pharmacological methods (oral sucrose, giving a pacifier, supporting the baby in a flexion position, and warming the baby's heel on a heating bed) on pain of newborn heel blood collection.

Dependent-independent variables

Independent Variables: Oral sucrose, giving a pacifier, supporting the newborn in a flexion position, warming the newborn's heel on the heating bed.

Dependent Variables: NIPS score

Control Variables: Chronological age of the newborn, gestational age, weight, health status, type of nutrition, mode of birth

Hypothesis

H_0: The combination of giving a pacifier, oral sucrose, wrapping the baby in a flexion position, and warming the heel during heel blood collection does not affect the level of pain.

H_1: The combination of giving a pacifier, oral sucrose, wrapping the baby in a flexion position, and warming the heel during heel blood collection reduces the level of pain.

Population and sample of the research

According to the annual records of the newborn baby unit, the number of babies between 38 and 42 weeks and weighing between 2500 and 4000 grams was 510. This number was taken as the population of the research. In determining the sample size, it was planned to study with a total of 100 babies, 50 in each group, considering that groups in experimental research should consist of at least 30 participants[14]. A non-probability random sampling method was used, and 100 healthy newborns were determined as the sample group, considering the study's selection criteria and control variables. 50 newborns were placed in the experimental group and 50 in the control group. Placement into the experimental and control groups was determined by birth order.

Sample selection criteria

Based on the relevant literature, age, weight, and week of gestation were criteria for sample selection because they are effective in response to pain[15].

-Gestational age range between 38 and 42 weeks

-Its weight must be between 2500 and 4000 grams

-The chronological age range is between 24-48 hours,

-No physical, metabolic or genetic diseases

-The fasting period of newborns should not exceed three hours

-Parents must give written permission

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Measures

Data Collection Form

The researcher prepared the data collection form with the support of the literature to help determine the variables that will affect the pain levels of newborns. The form consisted of 12 questions divided into two sections. The first section included six questions about the mother's age, educational status, chronic disease presence, and medication use due to chronic diseases. The second section included six questions about the newborn's gestational age, chronological age, weight, mode of birth, gender, and type of nutrition.

Transaction Tracking Chart: To facilitate transaction tracking, a chart was prepared in which the newborn's identity information, procedure time, physiological findings (heart rate, respiratory rate, and oxygen saturation), and the applied procedures were recorded.

Neonatal Infant Pain Scale (NIPS): The NIPS was developed by Lawrence J. and his colleagues in 1993 to evaluate the behavioral pain responses of newborn babies before, during, and after the invasive intervention. The reliability coefficient of the scale ranges from 92 to 97[16].

The data analysis was conducted using SPSS 21.0 software with a confidence level of 95%. A significance level of $p<0.05$ was adopted for all statistical analyses. The decision to select the appropriate test for the analysis was made based on the results of the normality analysis. In the research, which is an experimental study, the Shapiro-Wilk Test was used when the variable values between the control and experimental groups showed normal distribution. Since the Shapiro-Wilk normality test indicated that variables including the average NIPS total score, pre- and post-procedure heart rate, respiration, and saturation did not follow a normal distribution, non-parametric tests such as the Mann-Whitney U Test for independent groups were utilized for analysis.

Research Process

Pre-Application

Ten newborns received non-pharmacological applications. Methods such as supporting the baby in a flexion position, giving oral sucrose, giving a pacifier, and heating the heel were used. No changes were made to the data collection form after the pre-application. A Transaction Tracking Chart was prepared with the thought that it would facilitate the tracking and recording of the application.

Application

All research applications were carried out by the researcher between 08:00 and 18:00. Babies born by normal spontaneous birth are discharged in the 24th hour, and newborns born by cesarean section are discharged with their mothers in the 48th hour. The parents of babies who met the sampling criteria were interviewed, and the purpose of the research and the implementation method were explained. Families who agreed to have their babies included in the sample signed an Informed Consent Form.

In the application for the experimental group of babies: The newborn was placed in the flexion position by supporting the rolled blanket. His heel was heated under

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the bed warmer at a rate of 30% for five minutes. For two minutes, the newborn's behaviors were measured according to the NIPS scale. 24% oral sucrose was administered with a pacifier just before the heel puncture. Heel blood collection was performed on all newborns by pricking with the same brand automatic lancet of the same sharpness. This process took an average of 5 minutes. After the procedure, the patient was monitored for three minutes and evaluated according to the NIPS and the data was recorded.

For the babies in the control group: The newborn's behavior was monitored for two minutes. No non-pharmacological methods were applied to the newborns in the control group before and during the procedure. All newborns were treated with the experimental group. Heel blood samples were taken using the same brand of automatic lancet with the same cutter and hole. This process took approximately 5 minutes. The newborn's pain and post-procedure behaviors were monitored for three minutes according to the NIPS, and data were recorded.

Ethical Issues

Permission was received from the Istanbul Medipol University Ethics Committee on 18.07.2014. (Decision number:164). Informed Consent Forms were signed by the families who agreed to include their infants in the study sample.

Results

When examining the descriptive characteristics of the newborns, it was observed that the demographic characteristics, including gestational weeks, chronological age, mode of birth, weight, and feeding style, were similar between the two groups (Table 1).

Table 1. Descriptive characteristics of newborns (n=100)

Newborn		**Experiment**		**Control**	
		n	**%**	**n**	**%**
Gestation Age	**38 and 39 weeks**	25	50.0	25	50.0
	39 and 40 weeks	17	34.0	18	36.0
	40 weeks and above	8	16.0	7	14.0
Chronological Age	**24 hours**	13	26.0	16	32.0
	48 hours	37	74.0	34	68.0
Gender	**Female**	25	50.0	16	32.0
	Male	25	50.0	34	68.0
Birth Type	**Cesarean section**	36	72.0	32	64.0
	Normal spontaneous birth	14	28.0	18	36.0
Weight	**2500 and 3000 grams**	9	18.0	10	20.0
	3001 and 3500 grams	29	58,0	25	50,0
	Over 3501 grams	12	24.0	15	30.0
Nutrition	**Breast milk**	34	68	40	80
	Breast milk +Formula	16	32	10	20

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When the gestational and chronological ages of the newborns are examined in Table 1, it was observed that 50% of both the experimental and control groups were in the 38–39-week gestational age range. Additionally, 74% of the experimental group and 68% of the control group were at the 48th hour of chronological age. When the characteristics of the newborns were examined, information about their gender, birth style, weight, and nutrition was as follows: 50% were girls, 50% were boys in the experimental group, 32% were girls, and 68% were boys in the control group. 72% of the experimental group and 64% of the control group were born by cesarean section, 58% of the experimental group and 50% of the control group weighed between 3001 and 3500 grams, and 68% of those who gave birth, 68% of the experimental group, and 80% of the control group were breastfed.

When the mothers' ages were analyzed (Table 2), 48% of the experimental group and 44% of the control group were between the ages of 30 and 34. Regarding the educational status of the mothers, 84% of the experimental group and 86% of the control group had undergraduate or graduate-level education. When examining whether mothers have chronic diseases, it was observed that 74% of the experimental group did not have any disease, and 86% of the control group did not have any chronic disease. When the chronic disease of mothers was examined, it was observed that 69.2% of the experimental group had an endocrine system disease, and 76% of them did not use medication, while 42.9% of the control group had an endocrine system disease and 90% did not use medication.

Table 2. Descriptive characteristics of mothers (n=100)

Mother		**Experiment**		**Control**	
		n	**%**	**n**	**%**
Age	**29 years and younger**	11	22.0	12	24.0
	30-34 years	24	48.0	22	44.0
	35 years and older	15	30.0	16	32.0
Educational background	**High school**	8	16.0	7	14.0
	Undergraduate/Graduate	42	84.0	43	86.0
Chronic disease	**No**	37	74.0	43	86.0
	Yes	13	26.0	7	14.0
Chronic disease type	**Endocrine**	9	69.2	3	42.9
	Hematology	1	7.7	2	28.6
	Diabetes	2	15.4	1	14.3
	Other	1	7.7	1	14.3
Medication use status	**Not using**	38	76.0	45	90.0
	Using	12	24.0	5	10.0

The analysis comparing the babies in the experimental group and the control group using the Mann-Whitney U test indicated a statistically significant difference in the mean total NIPS score, as shown in Table 3 (p=0.000)

According to the results of the post-procedure respiratory analysis presented in Table 3, there is a statistically significant difference in the post-procedure respiratory values

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between the babies in the experimental group and the control group. Specifically, the respiratory values of the control group after the procedure were higher compared to those of the experimental group (p=0.016).

According to the analysis results in Table 3, there is no statistically significant difference between the babies in the experimental group and the control group in terms of post-procedure saturation value (p=0.336).

The analysis of post-procedure peak heart rates for babies in both the experimental and control groups, as detailed in Table 3, revealed a statistically significant difference. Specifically, the post-procedure peak heart rates of the control group exceed those of the experimental group (p=0.023).

Table 3. Comparison of the total score average and physiological parameters received by the experimental group and the control group from the NIPS

Group		**n**	**Order Average**	**U***		**P****
NIPS	Experiment	50	28.65	**157.500**		**. 000****
	Control	50	72.35			
*Mann-Whitney U Test **p<0.05 was considered significant						
Group		**n**	**Order Average**	**U***		**P****
Before breathing procedure	Experiment	50	48.97	**1173.500**		**.593**
	Control	50	52.03			
Post-respiratory procedure	Experiment	50	43.62	**906.000**		**.016****
	Control	50	57.38			
*Mann-Whitney U Test **p<0.05 was considered significant						
Group		**n**	**Order Average**	**U***		**P****
Saturation before operation	Experiment	50	51.88	**1181.000**		**.625**
	Control	50	49.12			
Saturation post-processing	Experiment	50	53.24	**1113.000**		**.336**
	Control	50	47.76			
*Mann-Whitney U Test **p<0.05 was considered significant						
Group		**n**	**Order Average**	**U***		**P*****
Heart rate peak before the procedure	Experiment	50	50.72	**1239.000**		**.939**
	Control	50	50.28			
		n	**Average**	**Ss**	**t****	**p*****
Peak heart rate after procedure	Experiment	50	133.72	10.25	**-2.318**	**.023*****
	Control	50	139.26	13.44		

*Mann-Whitney U Test **Independent Groups T Test ***p<0.05 was considered significant

Discussion

When examining the descriptive characteristics of the newborns in the study, the distribution of demographic characteristics of the babies in both groups, such as weeks of gestation, chronological age, birth type of the baby, weight, and feeding style, were similar (Table 1). In various experimental studies in the evaluation of pain in newborns,

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it is stated that the homogeneous distribution of the groups in terms of these characteristics is essential for comparing the two groups[12,17].

When the descriptive characteristics of their mothers were examined in the study, it was observed that mothers were similar in terms of demographic characteristics such as age, education levels, chronic disease, and whether they used medication related to chronic disease (Table 2). The education levels of mothers in the adult age group were high. It is thought that the high age and education levels of the mothers may influence their anxiety and stress related to the newborn's pain. In the study conducted by Dik et al., the knowledge of mothers who gave birth about baby care, nutrition, and hygiene was investigated. It was observed that the mother's age, number of children, and working status did not affect the level of knowledge on these subjects, but as the mother's education level increased, the scores obtained increased[18].

In this current study, there was a statistically significant difference when newborns' respiration and heart rates in the experimental and control groups were examined after the procedure. There was no significant difference between the two groups in terms of oxygen saturation (Table 3). Similar studies combining wrapping the baby in a flexion position, giving a pacifier, warming the heel, and using oral sucrose were not found in the literature. However, studies have examined the effects of non-pharmacological methods on newborns' physiological parameters. Efendi[19] et al. investigated the peak heart rate and oxygen saturation in 30 preterm newborns in the experimental group, where wrapping was applied along with non-nutritive suction during heel prick blood collection, and in the control group, babies who received routine care. While there was a significant increase in peak heart rate in the control group, no significant increase was detected in the experimental group. There was no difference between the groups in terms of peak heart rate and oxygen saturation averages. Gao et al. examined the effects of non-nutritive sucking, sucrose, and their combination during the heel prick procedure in 86 preterm newborns. In the combined group where sucrose+non-nutritional suctioning was applied together, peak heart rate was found to be lower and oxygen saturation was higher than the non-nutritional suctioning and control group. No difference was detected between non-nutritive sucking alone and the control group. In line with the information obtained, there are studies in the literature that affect physiological parameters, as well as studies in which they have no effect. It is thought that non-pharmacological methods are not used together and post-procedure evaluations are made at different times. This study applied four non-pharmacological methods to the experimental group, while the control group did not receive any intervention. According to the total NIPS score averages of the newborns after the procedure (Table 3), the pain scores of the control group were significantly higher than those of the experimental group. In similar studies where non-pharmacological methods were applied, pain scores were found to be significantly lower[20]. For example, Mangat et al. reviewed 26 randomized controlled studies and examined the effect and safety of non-pharmacological strategies used in pain management in newborns. As a non-pharmacological method in experimental studies; skin-to-skin contact (n=3), wrapping (n=3), facilitated flexion (n=1), massage (n=4), music recital (n=5), breastfeeding (n=3), non-nutritive sucking (n=1), acupuncture (n=3) and oral sweet solution (n=3) interventions were applied.

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Randomized controlled studies included in the systematic review reported that skin-to-skin contact, wrapping, facilitated flexion, non-nutritive sucking, and oral sweet solution applications are safe and effective in reducing procedural pain in newborns[21]. In the study conducted by Shu et al., they divided 75 newborns between 31 and 41 weeks of gestation into three groups during the heel blood collection procedure. One group was wrapped with a blanket, a heat bag was applied to the heel of the other group until five minutes before the procedure, and the last group received no intervention. When the NIPS pain score averages of the groups were compared, the pain score averages of the newborns who were wrapped and whose heel was warmed were found to be lower than the control group[22]. Likewise, Gao et al. (2018)'s randomized controlled study examined the effect of non-nutritive suction and oral 20% sucrose on premature newborns (n=86) in reducing pain due to repetitive heel pricking. Intervention groups were divided into routine care (n=21), non-nutritive sucking (n=22), oral 20% sucrose (0.2 ml/kg; n=21), non-nutritive sucking and oral 20% sucrose (0.2 ml/kg; n=21). (0.2 ml/kg; n=22) has been reported to be applied. It has been stated that the combined application of oral 20% sucrose solution and non-nutritive suction is effective in reducing pain due to repeated heel pricking in premature newborns[20]. Chang et al. (2020)'s randomized controlled study; breastfeeding (n=45), oral sweet solution (n=42), skin-to-skin contact (n=38) applied to healthy newborns (n=226) with a gestational age of 38 weeks and above in a tertiary maternity hospital in the USA, while taking heel prick, the effects of non-nutritive sucking methods (n=51) and routine care (n=50) on pain and crying duration were examined. Reducing pain due to heel prick procedure in healthy term newborns; Breastfeeding, oral 24% sucrose, skin-to-skin contact and non-nutritive sucking have been reported to have an analgesic effect[23]. The quasi-experimental study by Avcin and Kucukoglu compared the effects of breastfeeding, kangaroo care and facilitated flexion methods applied to term newborns in a primary healthcare institution in Türkiye in reducing pain due to routine heel blood collection. Newborns in intervention groups: Breastfeeding (n=35), kangaroo care (n=35), facilitated flexion (n=35) and routine care (n=35) were reported to be applied. In terms of newborns, the severity of pain was evaluated with NIPS before, during and after the procedure. It has been reported that the most effective intervention in reducing pain due to routine heel blood collection in term newborns is facilitated flexion[24].

When the studies in the literature were examined, it was seen that the non-pharmacological methods used in the study were effective in reducing pain. No similar studies were found in which the four different non-pharmacological methods we used in our study were used together. When non-pharmacological methods are used together, their effectiveness in reducing pain increases. In line with the information obtained, the H1 hypothesis "During heel blood collection, giving a pacifier, oral sucrose, wrapping the baby in a flexion position, and applying heel warming methods together reduces the level of pain" was supported.

Conclusions

According to the NIPS scale scores, the lower total average scores of babies to whom non-pharmacological methods were applied show that the methods are beneficial in reducing

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pain. It is recommended that these practices be disseminated, necessary workload plans made, and training provided on the application of non-pharmacological methods.

Limitations

The research was conducted in a private hospital. For the results to be generalized to the province or country, the sample needs to be expanded. Due to the limited number of babies in the study and the limited number of hospitals where the researcher practiced, the difference between the methods could not be examined.

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