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ORIGINAL ARTICLE / ARAŞTIRMA YAZISI

Primary Health Care / Birinci Basamak Sağlık Hizmetleri

Effect of Heel Warming with a Thermofor at Two Different Temperatures Before Heel Stick Sampling in Healthy Term Neonates on Total Crying and Procedure Durations: A Randomized Controlled Trial

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ABSTRACT

Purpose: The purpose of this research is to determine the effect of heel warming with a thermofor at two different temperatures before heel stick sampling in healthy term neonates on total crying and procedure durations.

Methods: This study was a randomized controlled trial. The sample for the research comprised 120 healthy term neonates with heel stick sampling performed by the same nurse. Neonates were randomized into control (n = 40), heel warming with a thermofor containing warm water (n = 40) and heel warming with a thermofor containing hot water (n = 40) three groups. In the study, to determine the efficacy of the heel warming intervention, neonates were recorded for six minutes before heel stick sampling and five minutes after heel puncture with a video camera.

Results: In the study, both the total procedure duration and total crying duration were statistically significantly shorter in the group with heel warming with hot water compared to the control group (KW = 6.088, p = 0.016; KW = 7.611, p = 0.006, respectively). However, in the group with heel warming with warm water, there was no significant difference in terms of total crying and procedure durations compared to both the control group and the group with heel warming using hot water (p> 0.05).

Conclusion: Before heel stick sampling in healthy term neonates, warming the heel with a thermofor containing hot water is effective in shortening the total crying and procedure durations.

Keywords: Atraumatic Care, Heel Warming, Heelstick Sampling, Thermotherapy, Neonate Care

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Sağlıklı Term Yenidoğanlarda Topuk Kanı Örneklemesi Öncesinde İki Farklı Sıcaklıkta Termofor İle Topuk Isıtmanın Toplam Ağlama ve İşlem Süreleri Üzerindeki Etkisi: Randomize Kontrollü Çalışma

ÖZET

Amaç: Bu çalışmanın amacı, sağlıklı term yenidoğanlarda topuk kanı örneklemesi öncesinde iki farklı sıcaklıkta termofor ile topuk ısıtmanın toplam ağlama ve işlem süreleri üzerindeki etkisini belirlemektir.

Yöntem: Çalışma, randomize kontrollü bir araştırmadır. Araştırmanın örneklemini aynı hemşire tarafından topuk kanı örneklemesi alınan 120 sağlıklı term yenidoğan oluşturdu. Yenidoğanlar, kontrol (n = 40), içinde ılık su olan termofor ile topuk ısıtma (n = 40) ve içinde sıcak su olan termofor ile topuk ısıtma (n = 40) olmak üzere üç gruba randomize edildi. Çalışmada, yenidoğanlar topuk kanı örneklemesi öncesinde altı dakika ve topuk delindikten sonra beş dakika bir video kamera ile kaydedildi ve böylece topuk ısıtma müdahalesinin etkinliği belirlendi.

Bulgular: Çalışmada, içinde sıcak su olan termofor ile topuk ısıtma yapılan grupta, hem toplam işlem süresi hem de toplam ağlama süresi, kontrol grubuna göre istatistiksel olarak anlamlı derecede kısaydı (KW = 6.088, p = 0.016; KW = 7.611, p = 0.006, sırasıyla). Ancak, içinde ılık su olan termofor ile topuk ısıtma yapılan grupta hem kontrol grubuna hem de içinde sıcak su olan termofor ile topuk ısıtma yapılan girişim grubuna göre toplam ağlama ve işlem süreleri açısından anlamlı fark yoktu (p>0.05).

Sonuç: Sağlıklı term yenidoğanlarda topuk kanı örneklemesi öncesinde topuğun içinde sıcak su olan bir termofor ile ısıtılması, toplam ağlama ve işlem sürelerini kısaltmada etkilidir.

Anahtar Kelimeler: Atramatik Bakım, Topuk Isıtma, Topuk Kanı Örneklemesi, Termoterapi, Yenidoğan Bakımı

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Heel stick sampling is an important protective and preventive health service implemented around the world (1,2). However, it causes distress, pain and stress in neonates (3,4), and disrupts comfort (5). Invasive interventions disrupting comfort may negatively impact the biopsychosocial development of neonates (3,4). As a result, there is a need for support and protection of neonates during invasive interventions like heel stick sampling (6–10). During invasive interventions, a way to support and protect neonates is to implement atraumatic care during the procedure (4,11,12).

Atraumatic care is a therapeutic care philosophy developed by Donna Wong that reduces or eliminates physical and psychological stress experienced by children and families through interventions applied by health care professionals during therapeutic or health-developing behavior in health care systems (4,11,12). Scientific evidence shows that atraumatic care implementation during heel stick sampling may have positive effects like less procedural pain and stress experienced in neonates (3–5), shortening the duration of crying (13,14), preventing bruised or swollen heels (7), shortening the procedure duration (14), and preventing repetition of the procedure (7). Additionally, atraumatic care implementations in this process may reduce parental concern (2), and may increase the quality of the blood taken (7). However, some current studies revealed that though nurses have information related to how to prepare heel stick samples, they frequently do not implement atraumatic care during the stages of sampling (2,6). Erdim et al. (2023) found that 56.7% of nurses did not use any intervention to soothe the neonate before heel stick sampling, 38.2% did not pay attention to the temperature of the heel and 56.2% continued the intervention by squeezing the heel if blood did not flow (2). Furthermore, since beginning spinal muscular atrophy (SMA) screening in 2022, Guthrie papers in Turkey contain five circles. Considering the increased need for blood, the importance of nurses implementing atraumatic care in this process is revealed once again.

A variety of non-pharmacological atraumatic care implementations (breastfeeding, oral breast milk, non-nutritive sucking, oral sucrose, facilitated tucking, swaddling, kangaroo care, automatic lancet use, white noise, holding) can be used alone or combined during the heel stick sampling process (1,3,4,15,16). One of these interventions is to pay attention to the temperature of the heel before taking the blood sample (5,7,13,14,17). Current available evidence shows positive effects of warming the heel with an additional intervention before taking heel blood like increasing blood flow (18), reducing acute symptoms like pain (5,13,19), preserving comfort (5), and reducing total procedure duration and total crying time (13,14). Heel warming was stated to reduce pressure applied to the heel and may prevent injury to the heel (5,7). Additionally, in the literature there are studies reporting that the temperature of the heel is adequate and there is no need to heat the heel with an additional tool (16,20–22). When studies are investigated, it appears there is no consensus between researchers about heel warming. When the literature is further examined, studies reporting advantages of heel warming appear to have been completed with tools providing heel warming with warm (34-37 ºC) or hot (38-40 ºC) temperatures before heel stick sampling (5,14,17,23). In the literature, there is no study comparing the effect of heel warming with a thermofor using warm (34-37 ºC) and hot (38-40 ºC) temperatures on total crying and procedure durations. Before heel stick sampling, warming the heel with a thermofor is a method without high cost that can be easily applied in clinic. The findings of this study may guide clinical applicators with the aim of ensuring standardization in practice. It may create a database to guide future studies. As a result, this study is needed. This article presents findings of a study to research the effect of heel warming with a thermofor with warm and hot temperatures before heel stick sampling in healthy term neonates on total crying and total procedure durations.

Methods

Study Design

This study was a randomized controlled, experimental, single-center study. It was registered at ClinicalTrials.gov with identifier NCT05228366.

Study Settings, and Participants

The research was completed from May-October 2022 with participation of healthy term neonates with capillary blood samples taken from the heel for the metabolic and endocrine screening program in the obstetrics III ward of a hospital in the Mediterranean region of Turkey.

G*Power package version 3.1.9.2 was used to determine the sample size. The study took total procedure duration points from a similar study as reference and for 0.78 effect size, 5% error, and 95% power, each group would be adequate with 36 participants (14). Considering missing data, the decision was made to include 40 participants in each group. The study ended after inclusion of a total of 120 healthy term neonates (Table 2).

Inclusion Criteria

Term newborns born between 38 and 42 gestational weeks, with birth weight 2500-4400 g, physiological parameters and general condition stable, vitamin K injection and hepatitis B vaccine administered in the delivery room, Apgar score ≥ 8 in the first and fifth minutes, with no complications during or after birth and during pregnancy, no congenital anomaly, not receiving oxygen therapy, not having undergone a surgical procedure, and without sepsis or suspected sepsis were included in the study.

Exclusion Criteria

Term newborns who received pharmacological or non-pharmacological pain management intervention before the procedure, and term newborns whose parents stated that they wanted to leave the study while the study continued were excluded from the study.

Randomization

Participants were randomly assigned to one of three groups using a simple randomization method. A total of 120 envelopes (40 for each group) were placed inside an opaque envelope, from which parents selected envelopes for their newborns who met the inclusion criteria.

Interventions

In the study, all groups received standard nursing care during heel stick sampling. In addition to standard care, Group A received ineffective heel warming with 28°C water, Group B received heel warming with warm water (34-37°C), and Group C received heel warming with hot water (38-40°C). The same nurse provided standard care and performed blood draws for both control and intervention groups. Researchers performed heel warming only and ineffective heel warming procedures.

In the study, water temperature in the thermofor was checked using a calibrated thermometer capable of measuring from -50 to 300 degrees Celsius. The thermofor was filled two-thirds with water, air was removed, and the lid was sealed. It was checked for leaks. To prevent contamination, each intervention used a separate plastic bag. Neonates remained in their clothing during heel warming or ineffective warming, with the thermofor not directly touching their skin. They were observed closely, lying supine, with their own blankets during the procedures.

- Standard nursing care: As routine in the hospital where the research was performed, each neonate had heel stick sampling performed 24-48 hours after beginning oral feeding before discharge. The procedure is performed in the patient's room. The temperature of the patient rooms is mean 25-26°C and mean humidity is 40%. The neonates are held in the arms of the mother or father during the heel prick and sampling procedure. To increase venous pressure, the legs of the neonate are held below heart level. Mothers or fathers are requested to talk to the neonate in a pleasant calm tone of voice during the heel stick and sampling process. During the procedure, the neonate is wrapped so only their foot is open. Before the heel stick, the skin is cleaned with 70% alcohol, then dried with a sterile gas compress. Heel blood is sampled from one of the medial or lateral external sides of the planar face of the heel. During the heel stick process, a single-use sterile manual lancet is used. During heel stick sampling, no pressure/compression is applied to the heel. In Turkey, metabolic and endocrine screening is performed for five diseases (phenylketonuria, biotinidase deficiency, congenital hypothyroidism, cystic fibrosis, congenital adrenal hyperplasia, and spinal muscular atrophy).

- Control group (Group A): To ensure blinding in the study for neonates in the control group, in addition to the standard nursing care applied routinely in the ward, ineffective heel warming was applied with a thermofor containing water at 28°C for 5 minutes before heel stick sampling.

- Heel warming group with a thermofor containing warm water (34-37°C) (Group B): Neonates included in Group B received standard nursing care applied routinely in the ward and the heel was heated with a thermofor containing water at 34-37°C for 5 minutes before heel stick sampling.

- Heel warming group with a thermofor containing hot water (38-40°C) (Group C): Neonates included in Group C received standard nursing care applied routinely in the ward in addition to warming of the heel for 5 minutes before heel stick sampling with a thermofor containing water at 38-40°C.

Data Collection Tools

Neonate Information Form

A neonate information form was used to determine the descriptive characteristics of neonates participating in the study. The neonate information form was prepared by the researchers in line with the literature. The form included 5 questions about the sex, type of birth, gestational week, mean body weight or mean body length of the neonates (13–15).

Measurement of total crying, and procedure durations

In the study, the efficacy of the heel warming interventions was determined by investigating data from video camera recordings. The healthy term newborns were recorded with a video camera for 6 min before the procedure, during the procedure and for five minutes after. The average recording time was 15 min (Figure 2).

Video recordings were investigated by an independent evaluator who did not know the purpose of the study and hence total crying and procedure durations were identified. The digital camera focused on the heel from the 0 second when the heel was punctured until the second when the 5th circle on the filter paper was filled. Apart from this the focus was on the face of the neonate and high quality image and sound recording was obtained.

Characteristics of the thermophore

In the study, a thermophore (hot water bag) was used to warm the heel. The thermophore was a durable and reusable device with a 2-liter capacity, measuring 20x35 cm, and featuring a plush cover and rubber properties. It had been reported in previous research as suitable for heel warming (5,7,13), which is why it was used in this study.

Blinding

Participants were randomly selected by simple random selection method and had no knowledge of the interventions. Information about which group the participant was assigned to was not given to the nurse sampling heel blood or the parent. Total crying and procedure durations in the research were identified by an independent evaluator who did not know the purpose of the study by observing video recording data. Hence, the health professional assessing the study data was blinded. The database for the research was created with Group A, Group B and Group C, by a health professional with no knowledge of intervention-control groups. Statistics for the research were assessed by a statistical expert blind to the study.

Ethical Considerations

Study data were collected in accordance with the standards of the Helsinki Declaration after receiving approval from Suleyman Demirel University Clinical Research Ethics Committee (Approval number: 23/358, Date of approval: 23.12.2021) and from the hospital where the study would be performed. During registration, parents of potential participants were given information about being able to freely choose or reject participation. Then parents of participants who met the inclusion criteria provided written consent.

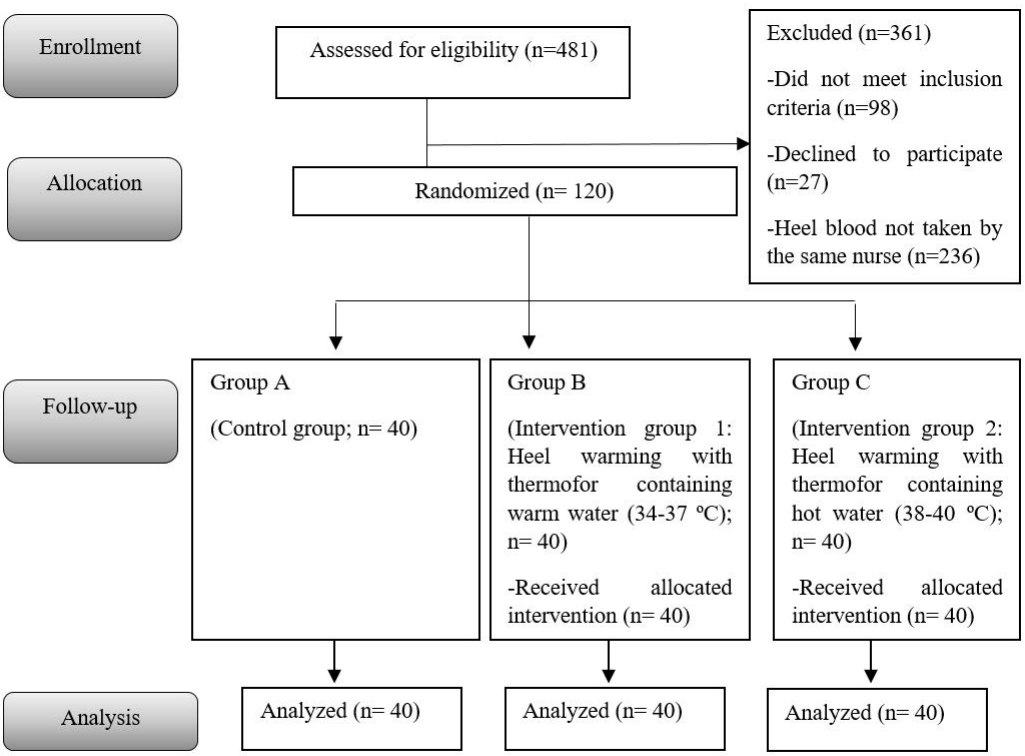

Figure 1. CONSORT flowchart for the research

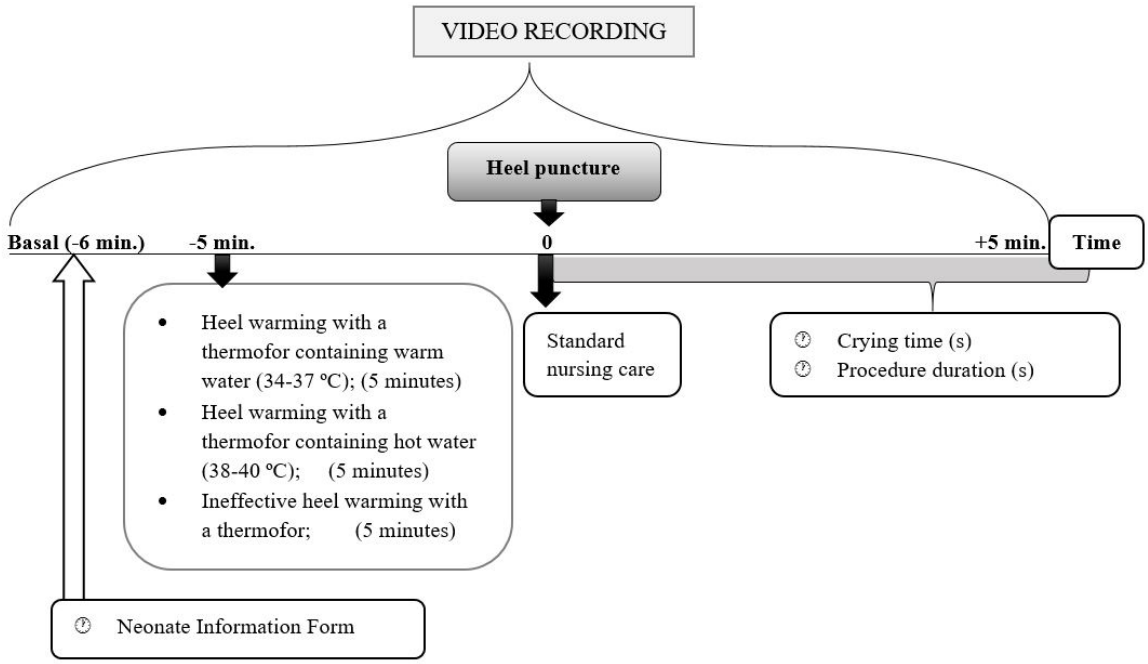

Figure 2. Study protocol

Data Analysis

Statistical analysis was carried out using a statistical package for the social sciences (SPSS) version 23.0 (IBM Corp., Armonk, NY), with statistical significance set at $p< 0.05$. Fit of data to normal distribution was assessed with the Kolmogorov-Smirnov test, skewness and kurtosis values and Q-Q plot. Descriptive statistical methods (mean, standard deviation, frequency, rate) were used to evaluate the study data. Pearson's chi-square test was used for the comparison of qualitative data. The one-way analysis of variance (ANOVA) test was used for the comparison of normally distributed data from the three groups. Intergroup comparisons of total procedure and crying durations used the Kruskal Wallis test. After the Kruskal Wallis test, Dunn's post hoc test was applied to determine the group(s) causing significance.

Results

Infant Characteristics

The study sample comprised 120 term infants with mean gestational age of 39.08±1.27 weeks. Among them, 49.2% were male and 50.8% were female. In addition, 57.5% of term newborns were born by vaginal delivery and 42.5% by cesarean section.

At baseline, infants in all groups did not differ significantly in terms of sex, delivery method, gestational age, mean body weight, or mean birth length ($p> 0.05$). These results indicate that the groups were similar in terms of variables (Table 1).

Comparison of Procedure Duration

Table 2 shows the distribution of mean total procedure duration for the groups. Total procedure duration was determined to be shorter by a statistically significant difference in the group with heel warming with hot water (38-40°C) (Group C) compared to the control group (Group A) ($KW = 6.088$, post hoc test $p = 0.016$, $d = 0.61$).

Comparison of Total Crying Time

Table 2 shows the distribution of mean total crying duration for the groups. Total crying duration was shorter by a statistically significant difference in the group with heel warming using hot water (38-40°C) (Group C) compared to the control group (Group A) ($KW = 7.611$, post hoc test $p = 0.006$, $d = 0.67$).

Table 1. Characteristics of the participants in the groups

Variables	Total (n=120)	Group A Control group (n=40)	Group B Intervention group 1 (n=40)	Group C Intervention group 2 (n=40)		
	n (%)	n (%)	n (%)	n (%)	X^2	p
Sex						
Female	61 (50.8)	18 (15.0)	20 (16.7)	23 (19.2)	1.267	0.531
Male	59 (49.2)	22 (18.3)	20 (16.7)	17 (14.2)		
Delivery Method						
Vaginal birth	69 (57.5)	23 (19.2)	26 (21.7)	20 (16.7)	1.841	0.398
Cesarean	51 (42.5)	17 (14.2)	14 (11.7)	20 (16.7)		
	Mean±SD	**Mean±SD**	**Mean±SD**	**Mean±SD**	**F**	**p**
Gestational Age (week)	39.08±1.27	39.15±1.16	39.05±1.37	39.05±1.29	0.081	0.922
Body Weight (g)	3249.01±333.10	3246.55±356.10	3239.25±299.23	3261.25±349.23	0.045	0.956
Birth Length (cm)	49.85±0.78	49.95±0.90	49.65±0.53	49.95±0.84	1.980	0.143

Note. SD= Standard deviation; X^2= Pearson Chi-Square; F= One-Way ANOVA; Intervention group 1= Heel warming group with a thermofor containing warm water (34-37°C); Intervention group 2= Heel warming group with a thermofor containing hot water (38-40°C)

Table 2. Comparison of total procedure and crying durations of neonates by group

Variables	Group A Control group (n=40)	Group B Intervention group 1 (n=40)	Group C Intervention group 2 (n=40)				
	Mean±SD 95% CI (L;U)	Mean±SD 95% CI (L;U)	Mean±SD 95% CI (L;U)	*KW*	*p*	*Post Hoc Test p*	*Effect size d*
Total procedure time (s)	143.75±99.64 (111.88; 175.61)	113.57±56.47 (95.51; 131.63)	94.72±51.28 (78.32; 111.12)	6.088	**0.048**	c-b= 0.092 **c-a= 0.016** b-a= 0.473	**a to c= 0.61**
Total crying time (s)	165.82±135.18 (122.59; 209.05)	115.07±56.82 (96.90; 133.24)	96.45±50.77 (80.21; 112.68)	7.611	**0.022**	c-b= 0.106 **c-a= 0.006** b-a= 0.259	**a to c= 0.67**

Note. 95% CI (L;U)= 95% Confidence Interval (Lower; Upper); KW; Kruskal Wallis Test; Post Hoc Test p= Dunn's Post Hoc Test; Intervention group 1= Heel heating group with a thermofor containing warm water (34-37°C); Intervention group 2= Heel heating group with a thermofor containing hot water (38-40°C)

Discussion

There is no consensus in the literature about the need to perform an additional intervention like warming the heel before heel stick sampling (7,13,16,18,21,22). Furthermore, current studies appear to apply heel warming with hot or warm temperatures (5,13,14,18). There is no study comparing the effect of heel warming with hot water bottles at different temperatures on total crying and procedure durations in the literature. To the best of our knowledge, this study is the first study to research the effect of heel warming with hot water bottles containing warm and hot water before heel stick sampling on total crying and procedure durations in healthy term neonates with randomized, controlled, experimental research.

In this study, heel warming with a thermofor containing 38-40°C water before heel stick sampling in healthy term neonates was determined to be effective in shortening the total crying and procedure durations compared to a control group. This result of the study is similar to the results of some studies performing heel warming with devices at 38-40°C temperature. Shu et al. (2014) reported that heel warming with a thermofor containing 40°C

water was effective in reducing pain, and shortening total procedure and crying durations during heel blood sampling in neonates (7). Buyuk (2018) identified that heat application with a bottle containing maximum 38°C water before heel blood sampling shortened the time of crying in infants and total operation duration (13). Balcı et al. (2021) heated the hands of nurses to 40°C under a radiant heater, and then held the heels of the infants in the nurse's palms for 3 minutes before the procedures. Compared with the unheated manual lancet group, the total procedure and crying durations were significantly shortened (14). Mir et al. (2018) reported that warming the heel with a bottle containing 40°C water increased blood flow for easy blood sampling (18). Different to our study, Barker et al. (1996) reported no effect of heel warming with a hot gel pack at 40°C on procedure duration, collected blood volume, number of repeated procedures and behavioral responses of infants (20). Janes et al. (2002) reported that warming the heel with a chemical heel warmer pack for five minutes before the procedure was not effective on blood volume, total procedure duration, crying duration and number of repeated heel stick procedures (24). Hassan and Shah (2005) and Ray et al. (2011) stated that heel warming may cause negative unwanted effects like burns and they did not recommend the practice for this reason (21,22). Heel warming with a thermofor containing 38-40°C water before heel blood sampling is a method without high costs that can be easily applied. It is possible to implement it within routine care in the clinic. Minimum crying and stress experienced by neonates may support healthier growth and development.

In the study, heel warming with a thermofor containing warm water (34-37°C) before heel stick sampling did not cause a significant difference in total crying and procedure durations when compared to either the control group or the group with heel warming using a thermofor containing hot water (38-40°C). Different to our study, KarabıyıkOğurlu et al. (2019) reported that heel warming with a thermofor containing warm water (34-37°C) shortened the duration of heel blood sampling in neonates with heel warming (5). It is considered that heel warming with a thermofor containing warm water (34-37°C) does not adequately accelerate regional blood perfusion and hence did not create a significant difference compared to the control group.

Conclusion

The results of this study revealed that heel warming with a thermofor containing hot water (38-40°C) before heel stick sampling in healthy term neonates was an effective intervention to shorten total crying and procedure durations. Nurses may use the heel warming intervention with a thermofor containing hot water (38-40°C) before heel stick sampling as a part of standard care. In line with this, it is recommended to inform nurses about this intervention and to add it to guidelines. Additionally, future studies are recommended to test heel warming with a thermofor containing hot water (38-40°C) for preterm neonates undergoing heel stick sampling.

Implications for Practice

The heel warming intervention with a thermofor containing hot water (38-40°C) is a low cost, easy to apply, non-invasive, non-pharmacological atraumatic care method that can be applied before heel stick sampling. The heel warming intervention may support protection of infant health, healthier growth and development and effective time management for nurses by shortening total procedure and crying durations. Nurses may potentially contribute to increasing health care quality and care satisfaction by applying this intervention in clinic.

Limitations

This study has several strong aspects. The study is the first study to compare the effect of heel warming with hot water bottles containing water at different temperatures on total crying and procedure durations with randomized, controlled, experimental double-blind research. The study had adequate sample size. In spite of these strong aspects, the study has some limitations. This study is a single-center study. The sample only included participation of healthy term neonates with capillary blood samples taken from the heel for metabolic and endocrine screening program in the obstetrics III ward of a hospital located in the Mediterranean region of Turkey.

Declarations

Funding

The present study was not funded by any corporation.

Conflicts of Interest

The authors declare no conflict of interest.

Ethics Approval

All protocols for this study were approved by the Suleyman Demirel University Clinical Research Ethics Committee (Approval number: 23/358, Date of approval: 23.12.2021).

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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