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Research paper

The effect of foot reflexology on procedural pain before heel lancing in neonates

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ABSTRACT

Objective: This study was designed to investigate the effect of foot reflexology on alleviating term neonates' invasive pain caused by heel lance.
Methods: In this quasi-experimental study, 60 healthy neonates were recruited and divided into a reflexology group ($n = 30$) and a control ($n = 30$) group. The study design was quasi-experimental since the randomisation method was not used in the assignment of newborns to the groups. While the reflexology group received foot reflexology for an average of 20 min before heel lance, the control group received no intervention. The elicited data were analysed using descriptive statistics and independent *t*-test.
Results: The reflexology and the control groups were similar in terms of age, gestational week, Apgar score, weight, height, and sex ($P > 0.05$). The Neonatal infant pain scale (NIPS) scores of the newborns in the reflexology group after the heel lance procedure were found to be significantly lower than those in the control group ($P < 0.05$). It was also found that reflexology had a significant effect on the neonates' heart rate before heel lance ($P < 0.05$) and a borderline effect during heel lance. Moreover, it was observed that the application of foot reflexology shortened the experimental-group neonates' crying periods after the procedural pain ($P < 0.05$). However, reflexology had no statistically significant effect on the duration of heel lance in both groups ($P > 0.05$).
Conclusion: The application of foot reflexology before invasive procedures, such as heel lance in newborns, is an effective non-pharmacological method for reducing invasive pain. Thus, reflexology could be used to reduce neonates' pain and soothe them during painful procedures such as heel lance.

1. Introduction

In Turkey, newborns are exposed to many repetitive painful procedures in the period from their birth to discharge from the hospital as a result of routine care such as vitamin K, hepatitis B application, and heel lance to detect some diseases such as phenylketonuria, hypothyroidism, and biotinidase deficiency [1,2].

Repeated painful and stressful procedures affect the pain threshold, pain perception, and pain tolerance of infants and may lower the pain threshold, resulting in increased physiological and behavioural responses against painful conditions [3]. Therefore, accurate evaluation and control of pain symptoms are very important.

The most effective approaches to control pain in the newborn are to raise awareness of the presence of pain in the newborn, reduce invasive interventions in infants as much as possible, and minimise pain using pharmacological and non-pharmacological methods in cases when the pain is inevitable [4]. Pharmacological treatment methods commonly used for pain relief are effective methods in reducing pain. However, it is also recommended to use non-pharmacological pain relief methods, especially in newborns/infants and children due to the side effects of drugs. Non-pharmacological methods are valuable alternatives for pain management in minimally invasive procedures applied to the newborn [5]. By strengthening the newborn's coping ability, non-pharmacological methods used for pain management help make the pain tolerable, lead to perceiving pain less, and reduce anxiety [6]. The non-pharmacological methods frequently used for reducing the effects of invasive procedures on newborns include practices, such as music therapy [7], white noise [8], sucrose [7,9] and pacifiers [9]. In addition, physical methods such as positioning [10], massaging [11], and acupressure [12–14] may be effective in pain management.

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One of the physical methods considered as a non-pharmacological method and showing benefit in relieving pain is the application of reflexology. Reflexology is a safe technique applied to the reflex areas in hands, feet, and ears with gentle pressure and massage to stimulate the nerves in the body and to relax the body in order to accelerate the body's self-healing process. Reflexology enables endorphin and encephalin release by stimulating the pituitary gland through the pressure and massage performed on reflex points on hands and feet. It resolves problems in organs and body parts that correspond to these points, reduces pain, and alleviates discomfort [15]. Since the points reflecting the organs in the body have larger areas in the feet, these reflex points are more evident compared with those in the hands and ears. Therefore, the most widely preferred technique in reflexology is foot reflexology [15]. There are a limited number of studies in the literature conducted on the efficacy of reflexology in the newborn; most studies focus on other pediatric age groups. The studies investigating the effect of reflexology on pediatric age groups have examined topics such as functional constipation in children [16]; sleep, constipation, motor functions, quality of life, and family interaction in children with cerebral palsy [17]; spasticity and functions [18]; vital signs and anxiety after blood transfusion in children with thalassemia and leukemia [19]; and infantile colic pain in newborns [20]. A limited number of studies have been found on the effect of reflexology massage on procedural pain [12,13] and meconium transmission [21] in term infants; of these, only one study investigated the effect of reflexology massage on interventional pain in term infants.

The present study was conducted to determine the effect of reflexology applied to relieve procedural pain associated with the heel lance procedure in term newborns.

2. Patients and methods

2.1. Study design

This single-centre study was conducted as a quasi-experimental research between November 6, 2017 and February 6, 2018 at a maternity and children's hospital affiliated with a university hospital located in southeastern Turkey. It is quasi-experimental because the first 30 babies were assigned to the reflexology group and the next 30 were assigned to the control group. Thus, the infants were not assigned to the reflexology or control groups randomly from an available sample of 60 infants [22,23].

2.2. Participants

The study population comprised infants who met the inclusion criteria and were born in the gynecology and obstetrics clinic during the study period. The infants who had a birth weight of 2500–4000 g, with 38–40 gestational weeks, an APGAR score of ≥ 8 in the 5th min, were breastfed at least 30 min before the procedure, remained calm during the procedure, had no health problems, were not exposed to any invasive interventions except for the routine vaccinations, from whom blood was drawn at the first attempt, and whose mothers agreed to participate in the study were included in the study. Gpower 3.1.9.2 version was used for the power analysis conducted to determine the sample size of the study. According to the study by Tutag Lehr et al. (2015), with the expectation of finding that an effect size (difference) of 1.5 ± 2 units between the experimental and control groups in terms of Neonatal infant pain scale (NIPS) scores is statistically significant (difference), the minimum number of subjects required was determined to be 29 term infants (Type 1 error = 0.05, test

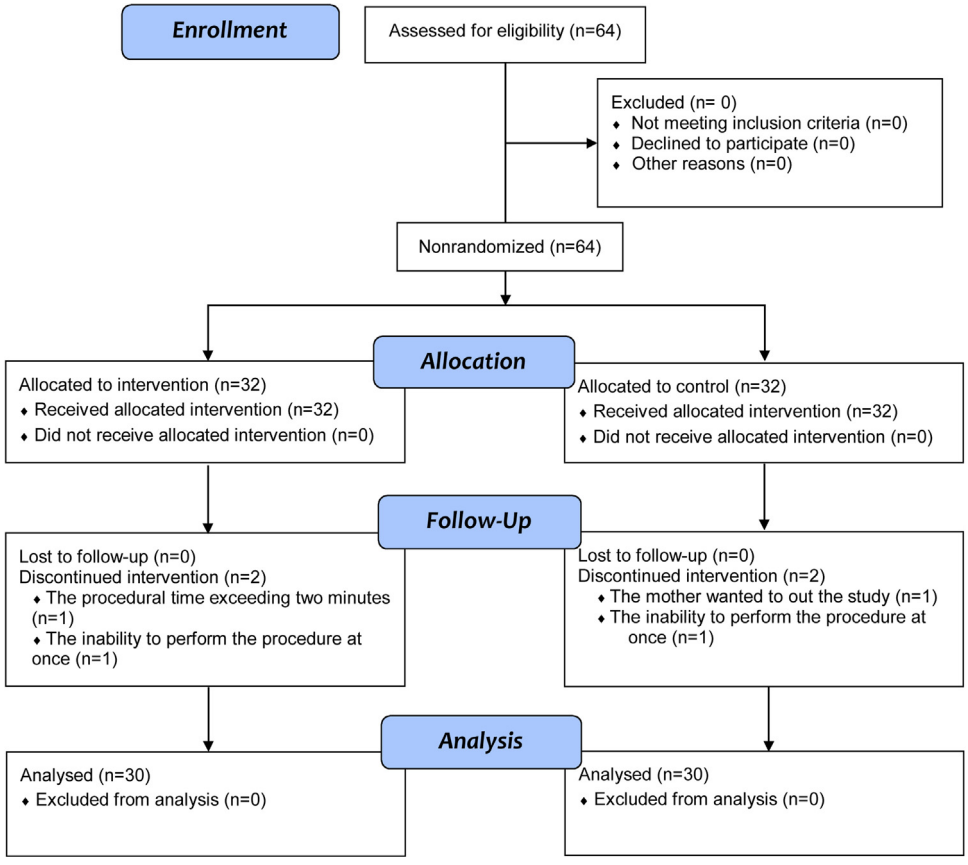

Fig. 1. Transparent reporting of evaluations with non-randomised designs (TREND) flow chart for trial profile.

power = 0.80) [24]. By considering that there would be drop-outs in the study, three infants were added into each group ($n = 64$). However, at the end of the study, four newborns were exluded from the research despite meeting the inclusion criteria of the study. This was because the procedural duration for a newborn in the reflexology group was more than 2 min; the procedure could not be performed at once on another newborn in the reflexology group; the mother of a newborn in the control group wanted to withdraw from the study since her infant was restless and crying; and the procedure could not be performed on another newborn in the control group. The study was completed with 60 newborns including 30 in the reflexology group and 30 in the control group. The study flow chart is illustrated in Fig. 1.

2.3. Data collection tools

The following tools were used to collect data: an introductory information form, the Neonatal infant pain scale (NIPS), a newborn infant follow-up form (intervention follow-up form), a pulse oximeter (Covidien Nellcor), a chronometer, and iPad Mini 4 tablet cameras.

2.3.1. Introductory information form

The information form prepared by the researcher in accordance with the literature [25] included the descriptive characteristics of the infants such as age, sex, APGAR score, birth weight, and birth height.

2.3.2. Neonatal infant pain scale

The scale was developed by Lawrence et al. (1993) to evaluate the behavioural pain response of premature and term newborns during needle interventions by recording a video for 2 min before the procedure, 2 min during the procedure, and 3 min after the procedure. The reliability coefficient of the scale was between 0.92 and 0.97. One physiological and five behavioural parameters against pain are evaluated in this scale. While facial expression, breathing pattern, arm movements, leg movements, and state of arousal are rated as 0 or 1 point, crying is rated as 0, 1, or 2 points. The highest total score is 7 points and a high pain score signifies more severe pain [26]. The Turkish adaptation of the scale was conducted by Akdovan and Yıldırım in 1999 and Cronbach's alpha internal consistency coefficient was between 0.83 and 0.86. In this study, Cronbach's alpha internal consistency coefficient of the scale was 0.90 [27].

2.3.3. Newborn infant follow-up form (intervention follow-up form)

This form was prepared to record the physiological parameters (heart rate, oxygen saturation) of the infant before, during, and after the procedure as well as the procedure duration and crying time.

2.3.4. Pulse oximeter

A console/patient-bedside-type calibrated pulse oximeter (Covidien Nellcor) was used to the measure oxygen saturation and pulse rate of infants in both groups before, during, and after the heel lance procedure.

2.3.5. Chronometre

The duration of the heel lance procedure and infant crying in both groups was measured using the chronometer of a Samsung mobile telephone (SM-N910CQ) during and after the procedure.

2.3.6. Digital camera (iPad 4 mini)

The video recordings of the newborns in the reflexology and control groups were made with the iPad 4 mini tablet camera (128 GB storage, 8 MP camera, 326 pixels per inch, 2048 × 1536 resolution) before, during, and after the heel blood collection process and these image recordings were then used by two observers who were experts in the field for processing time, crying time, and NIPS scores.

2.4. Data collection

During the data collection stage, the researcher informed the parents about the purpose of the study and written informed consent was obtained from those who agreed to participated in the study. The data in the introductory information form were collected from the parents via a face-to-face interview. The researcher filled out the data collection form. The heel lance procedure was performed in the blood collection room of the department. The environmental factors (ambient temperature, quiet environment, etc.) appropriate for the comfort of the infants were adjusted for the study environment. No pharmacological or non-pharmacological pain relief procedure was applied to the infants in both groups, except for the application of reflexology to the experimental group before the painful procedure. In addition, the infants' mothers waited outside the blood collection room while the heel blood was drawn.

2.5. Nursing intervention

2.5.1. Control group

The infants were taken to the intervention room for the heel lance procedure. By placing the saturation probe on the right wrist of the infants, they were monitored and their pulse rates and oxygen saturation were evaluated before, during, and after the procedure. This group who received no intervention before the procedure was recorded with the video camera for 2 min before the procedure, for the duration of the procedure (maximum 2 min), and for 3 min after the procedure. For reliability of the study results, the heel lance procedure was performed by the same nurse working in the clinic.

2.5.2. Reflexology group

Before the heel lance procedure of the infants in the reflexolgy group, a foot massage was performed for 15–20 min in accordance with the literature. Before reflexology application, hands were washed and warmed up to body temperature. In order for the infants to feel safer and relaxed, the practice was performed when the infants were in their mother's arms. The practice started with the right foot and then continued on the left foot. After the reflexology procedure was completed, the infants were taken to the intervention room for the heel lance procedure. The saturation probe was placed on the right wrist of the infants, they were monitored, and the pulse rates and oxygen saturation were evaluated before, during, and after the procedure. Video recordings of the infants in the reflexology group were made for 2 min before the heel lance procedure, for the duration of the procedure (maximum 2 min), and for 3 min after the procedure. For reliability of the study results, the heel lance procedure was carried out by the same nurse working in the clinic.

2.6. Evaluation of pain scores

The video recordings made during the study were evaluated separately and independently through the use of NIPS by two observers who are experts in the field of pediatric nursing. The experts evaluated the video images without knowing whether or not they were reflexology and control groups. Interrater reliability analysis was performed to determine whether or not there was

agreement between NIPS scores given by the two independent experts. While the overall intraclass correlation coefficient was 0.94, the intraclass correlation coefficient results before, during, and after the procedure were 0.96, 0.92 and 0.89, respectively. These results show a strong agreement between the two experts [28]. Therefore, the NIPS pain scores of the infants after reflexology were evaluated by obtaining the means of the scores given by the two experts.

2.7. Data analysis

The statistical package SPSS 19 was used to analyse the data obtained in the study. In the data analysis, percentage distributions, means, and standard deviations were examined using the independent-samples *t*-test or the Mann–Whitney U test, which is the non-parametric equivalent of the former test, and the Chi^2 test for independence. The study results were evaluated at a confidence interval of 95% and a significance level of $P < 0.05$.

2.8. Ethical principles of the study

Approval from the ethics committee was obtained (university code 2011-KAEK-27/2017-E.84731) to conduct the study and written permission was obtained from the hospital where the data were collected. After being informed about the purpose of the study and confidentiality of the data obtained, the infants' parents filled out and signed an informed consent form, as well as an image–voice record permission form. The reflexology researcher obtained a practitioner reflexologist certificate and gained competence in this field through a 120-h theoretical and applied courses given by the International Reflexology Institute between June 5 and July 5, 2017 in Istanbul.

3. Results

The newborns in the reflexology and control groups were similar in terms of age, gestational week, APGAR score, birth weight, birth height, and sex ($P > 0.05$, Table 1).

To examine the pain scores of the newborns in the refloxology and control groups, their NIPS scores during and after the heel lance procedure were compared. The NIPS mean score of the infants in the reflexology group during the procedure (6.65 ± 1.11) was similar to that of the newborns in the control group during the procedure (6.93 ± 0.21), with no statistically significant difference ($P > 0.05$). It was also found that the NIPS mean score of the infants after the procedure was 1.80 ± 2.53 in the reflexology group and 2.96 ± 2.68 in the control group, with a statistically significant difference in favor of the reflexology group ($P < 0.05$, Table 2).

In Table 3, the mean heart rate of the infants in the reflexology and control groups before, during, and after the procedure is presented. The mean heart rate of the newborns in the reflexology group before the procedure was 131.40 ± 16.81, while that of the newborns in the control group was 139.63 ± 14.83. The mean heart rate of the infants in the reflexology group during the procedure was 157.77 ± 12.64, whereas that of the infants in the control group was 164.46 ± 13.29. The mean heart rates of the infants in the reflexology group before and during the procedure were lower than those of the control group and the difference between them was statistically significant ($P < 0.05$). When the mean heart rates of the infants after the procedure were compared, it was found that the reflexology group (147.30 ± 15.73) had a lower mean heart rate than the control group (153.93 ± 15.32), but the difference was not statistically significant ($P > 0.05$). It was also determined that the oxygen saturation of the newborns was similar between the groups before, during, and after the procedure and this did not have any statistically significance ($P > 0.05$).

When the crying duration of the newborns in the reflexology and control groups was examined, the mean crying duration of the procedure was found to be 88.26 ± 26.88 seconds in the reflexology group and 90.10 ± 24.83 seconds in the control group. The mean crying duration of the infants in the reflexology group during the procedure was found to be similar to that of the infants in the control group ($P > 0.05$, Table 4). The mean crying duration after the procedure was 37.26 ± 48.18 seconds in the reflexology group and 67.83 ± 58.59 seconds in the control group. The mean crying duration of the infants in the reflexology group after the procedure was significantly shorter than the mean crying duration of the infants in the control group, and this was statistically significant in favour of the reflexology group ($P < 0.05$, Table 4).

The procedure was completed within 89.93 ± 25.69 seconds in the reflexology group and 91.5 ± 23.83 seconds in the control group,

Table 1
Comparison of descriptive characteristics of newborns by group ($n = 60$).

Descriptive characteristics	Control group ($n = 30$)		Reflexology group ($n = 30$)		Test, *P*
	Mean ± SD[a]		Mean ± SD[a]		
Age (day)	1.00 ± 0.00		1.00 ± 0.00		$Z = 0.000$ $P = 1.00$
Gestational age (weeks)	38.10 ± 0.30		38.06 ± 0.25		$Z = -0.463$ $P = 0.643$
APGAR score in the 1st min	8.03 ± 0.24		8.63 ± 0.49		$Z = -0.580$ $P = 0.750$
APGAR score in the 5th mi	9.28 ± 0.55		9.63 ± 0.49		$Z = -0.498$ $P = 0.684$
Birth weight (g)	3046.00 ± 362.79		2965.00 ± 350.65		$Z = -0.890$ $P = 0.374$
Birth height (cm)	49.50 ± 1.61		49.53 ± 1.61		$Z = -0.031$ $P = 0.975$
	n	%	*n*	%	Test, *P*
Sex					
Female	16	53.3	19	63.3	$\chi^2 = 0.617$
Male	14	46.7	11	36.7	$P = 0.432$
Nutrition					
Breast milk only	25	83.3	26	86.7	$\chi^2 = 0.131$
Breast milk + formula milk	5	16.7	4	13.3	$P = 1.00$

Z = Mann–Whitney U test; χ^2 = chi-square test; $P > 0.05$; *n* = number; % = percentage.
[a] Mean ± standard deviation.

Table 2
Comparison of NIPS average points during and after intervention of newborns in control and reflexology groups ($n = 60$).

Intervention process	Control group ($n = 30$)	Reflexology group ($n = 30$)	Test, P
	Mean ± SD[a]	Mean ± SD[a]	
During intervention	6.93 ± 0.21	6.65 ± 1.11	$Z = -1.436$ $P = 0.151$
After intervention	2.96 ± 2.68	1.80 ± 2.53	$Z = -2.098$ $P = 0.036^*$

Z = Mann–Whitney U test; $^*P < 0.05$; NIPS: Neonatal Infant Pain Scale.
[a] Mean ± standard deviation.

Table 3
Comparison of physiological parameters before, during, and after intervention of newborns in control and reflexology groups ($n = 60$).

Physiological parameters	Control group ($n = 30$)	Reflexology group ($n = 30$)	Test, P
	Mean ± SD[a]	Mean ± SD[a]	
Before intervention			
Pulse (min)	139.63 ± 14.83	131.40 ± 16.81	$Z = -5.744$ $P = 0.022^*$
Oxygen saturation (%)	94.70 ± 3.15	95.87 ± 2.53	$Z = -1.304$ $P = 0.192$
During intervention			
Pulse (min)	164.46 ± 13.29	157.77 ± 12.64	$t = -2.001$ $P = 0.05$
Oxygen saturation (%)	91.37 ± 4.88	91.73 ± 4.90	$Z = -0.275$ $P = 0.784$
After intervention			
Pulse (min)	153.93 ± 15.32	147.30 ± 15.73	$t = -1.654$ $P = 0.103$
Oxygen saturation (%)	92.20 ± 4.10	92.90 ± 3.05	$Z = -0.312$ $P = 0.755$

t = independent-sample t-test; Z = Mann–Whitney U test; $^*P < 0.05$.
[a] Mean ± standard deviation.

Table 4
Comparison of crying times during and after intervention of newborns in control and reflexology groups ($n = 60$).

Intervention process	Control group ($n = 30$)	Reflexology group ($n = 30$)	Test, P
	Mean ± SD[a]	Mean ± SD[a]	
During intervention (s)	90.10 ± 24.83	88.26 ± 26.88	$Z = -0.119$ $P = 0.905$
After intervention (s)	67.83 ± 58.59	37.26 ± 48.18	$Z = -1.988$ $P = 0.047^*$

Z = Mann–Whitney U test; $^*P < 0.05$.
[a] Mean ± standard deviation.

with no statistically significant difference between the groups ($P > 0.05$).

4. Discussion

Many factors are important in the perception of pain and the formation of pain response level in newborns, such as the infant's gestational week, sex, birth type, and nutritional status and type [29]. In this study, the infants in the reflexology group and those in the control group were similar in terms of descriptive characteristics. The fact that the descriptive characteristics of the infants in the reflexology and control groups were similar suggests that the newborns included in the study were equal in terms of factors affecting pain perception and response levels.

It is important to apply non-pharmacological methods to reduce invasive pain in newborns [30]. However, when the relevant literature was examined, it was found that studies using reflexology to reduce interventional pain in newborns are limited. In a study conducted to examine the effect of foot reflexology on pain and comfort level in newborns before the aspiration procedure, it was observed that reflexology reduced pain during and after the procedure [31]. Moreover, in two other studies examining the effects of foot reflexology and acupressure applied before heel lance in newborns, it was reported that both methods were equally effective in reducing pain [12,13]. In addition, a study investigating the effect of reflexology, which is a non-pharmacological pain relief method, on acute pain in pediatric age groups found that reflexology relieves pain before invasive procedures and reduces pain after invasive procedures [25]. In another study that examined the effect of reflexology on relieving colic pain in infants, the infantil colic scale mean scores of infants receiving reflexology were found to be low and thus significant when compared with those of the group not receiving reflexology [20]. In line with the results of the aforementioned studies, the findings of this study indicate that reflexology is one of the effective non-pharmacological methods used to reduce infants' pain and to calm them during painful interventions.

Infants show physiological changes, such as increased heart and respiratory rates, increased blood pressure, decreased oxygen saturation, sweaty palms, and differentiation on skin colour and

pupil sizes as a result of the activation of the sympathetic nervous system following painful stimuli [32]. Although physiological parameters can be objective indicators of pain response, they are not always specific to pain. Therefore, behavioural parameters should be evaluated along with physiological parameters [33]. One study observed that the pulse average after aspiration in the reflexology group was significantly lower than in the control group [31]. In a similar study, the mean pulse rate of preterm infants who received foot massage before the heel lance procedure was found to be lower than the control group [34]. In the same studies, it was found that reflexology significantly increased the oxygen saturation level [34]. Özkan et al. determined that the oxygen saturation levels of newborns who underwent reflexology before a painful intervention were significantly higher during and after the procedure when compared with the control group in their study [13]. According to the literature, foot massage, regardless of age group, alleviated pain by stimulating the nerve ends and decreased the heart rate by reducing pain [34]. Similarly, it was observed in the present study that reflexology applied to infants decreased both pain and heart rate. However, it was observed that foot reflexology has no effect on oxygen saturation level.

Crying is the most important communication method used by newborns who cannot express themselves verbally. This method is one of the most important indicators of pain in newborns. Crying, which is one of the behavioural expression methods, has an important place especially in evaluating the level and duration of pain [35]. In Deniz's study on newborns, it was observed that the crying time of the newborns in the control group was longer than those in the reflexology and acupressure groups, but the difference was not statistically significant [12]. In Koç and Gözen's study on infants, it was reported that reflexology massage conducted before the vaccination decreased the infants' crying duration significantly during and after the procedure [25]. In the study by Özkan et al., it was found that the application of reflexology before painful interventions in newborns reduces the time of crying [13]. Another study in the literature reported that different massage applications on acute interventional pain can shorten the crying duration [36]. In line with the related literature, the current study yielded similar results in that massage not only alleviated pain level [36], but also shortened the crying duration of infants [13,25].

Reflexology is an application that stimulates the release of serotonin in the body, which causes vasodilation through nitric oxide and increases vascular permeability. Therefore, reflexology is considered to be a method that can reduce the duration of painful interventions [14]. In a study conducted by Özkan et al., it was found that the application of reflexology significantly reduced the duration of heel lancing [13]. Contrary to the related literature, in our study, we observed that the application of reflexology did not have a significant effect on the duration of the procedure.

5. Conclusion

In this study, it was found that reflexology was an effective method in relieving pain after invasive interventions such as heel lance. Therefore, it is thought that reflexology can be used especially in painful procedures in the neonatal period, along with pharmacological methods, since its application is simple, inexpensive, and noninvasive. It is recommended to conduct randomised controlled studies with larger sample groups, in which the effect of reflexology can be compared with other non-pharmacological methods in the pain management of newborns.

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Disclosure of interest

The authors declare that they have no competing interest.

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