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ORIGINAL RESEARCH

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The effect of breastfeeding, breast milk odour and mother's heartbeat sound on pain level in newborns: A randomized trial

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Abstract

Aim: This study aimed to compare the effects of breastfeeding, breast milk odour and mother's heartbeat sounds on perceived pain during heel lance procedures in term newborns.

Design: This was a randomized three-group experimental study.

Methods: The sample of the study consisted of 90 newborns. The data were collected using pulse oximeter, fetal hand doppler, voice recorder, loudspeaker, a data collection form and the ALPS-Neo Pain and Stress Assessment Scale for Newborn Infants.

Results: During the procedure, newborns in the breast milk odour group had high levels of pain and stress, those in the mother's heartbeat sounds group had mild pain and stress, and those in the breastfeeding group had no pain and stress. Additionally, a statistically significant difference was found between their crying times. This difference was the highest for newborns in the breast milk odour group, followed by the mother's heartbeat sounds and breastfeeding groups, respectively.

Conclusion: Breastfeeding and mother's heartbeat sounds, which are non-pharmacological pain relief methods, are effective in neonatal pain management. However, breast milk odour is not effective for pain control in newborns. Further studies should examine the efficacy combinations of these methods.

KEYWORDS
breast milk odour, breastfeeding, mother's heartbeat, newborn, pain

Summary statement

What is already known about this topic?

- The presence of pain is a major stress factor for newborns.
- The American Academy of Pediatrics (AAP) recommends the use of non-pharmacological pain control methods to relieve the pain caused by routine medical procedures in newborns.

What this paper adds?

- This randomized controlled experimental study showed breastfeeding is a very effective method for pain control in newborns during heel lance procedures.
- The sound of the mother's heartbeat was found to be moderately effective.
- Breast milk odour was not effective for pain control in newborns.

The implications of this paper:

- The use of non-pharmacological pain management methods such as maternal heart sounds in combination with methods with high evidence level (breast milk, breastfeeding, etc.) may increase the effectiveness of pain management in newborns.
- In order to determine the effect of sense of smell on pain management in newborns, new studies should be planned comparing newborns of different postnatal ages.

1 | INTRODUCTION

Pain is a multidimensional biopsychosocial phenomenon that includes sensory, emotional, cognitive, developmental, behavioural, spiritual and cultural components (Manworren & Stinson, 2016). Pain is transmitted by A-delta (fast-conducting myelinated) and C (slowly conducting unmyelinated) fibres in peripheral nerves. Pain is transmitted in newborns by non-myelinated C fibres, causing slower and uncontrolled pain transmission and making them feel the pain more severely (Raju et al., 2017).

The presence of pain is a major stress factor for newborns, and some painful interventions (heel lance, venous intervention, etc.) are applied to newborns in the first days of their lives. When evidence-based pain control methods are not used in newborns, they can develop neurodevelopmental problems in the short and long term (Bucsea & Riddell, 2019; Ranger et al., 2013). Therefore, the American Academy of Pediatrics (AAP) recommends the use of non-pharmacological pain control methods to relieve the pain caused by routine medical procedures in newborns (Keels et al., 2016).

The number of studies comparing various non-pharmacological methods for pain management in newborns has significantly increased in recent years (Bucsea & Riddell, 2019; Mangat et al., 2018; Rossi et al., 2021). However, there are a limited number of studies comparing different senses such as touch, hearing, smell and taste with maternal interaction in newborns. This randomized controlled experimental study was conducted to compare the effects of breastfeeding, breast milk odour and mother's heartbeat sounds on perceived pain and stress during heel lance procedures in term newborns.

2 | METHOD

2.1 | Design

This was a randomized three-group experimental study.

2.2 | Research hypotheses

H1: Newborns who are breastfed during the procedure have lower pain than those who receive breast milk odour and those who listen to the mother's heartbeat sounds.

H2: Newborns who listen to the mother's heartbeat sounds during the procedure have lower pain than those who receive breast milk odour and those who are breastfed.

H3: Newborns who receive breast milk odour during the procedure have lower pain than those who listen to the mother's heartbeat sounds and those who are breastfed.

2.3 | Population and sample calculation

The population of the study included all newborns born in Muş State Hospital, and the sample consisted of a total of 90 newborns who were born alive in this hospital between 15 February 2019 and 15 July 2019 and met the sampling criteria.

In experimental studies, the sample should consist of at least 15 individuals for each group. However, it is recommended to have a sample size of at least 30 to minimize the error variance and increase the power of the sample for representing the population (Fraenkel et al., 2012). Therefore, a total of 90 newborns, 30 for each group, were included in the study. The sample distribution is shown in the CONSORT diagram (Figure 1).

At the end of the study, the effect size (eta squared) was found to be 0.431, based on the mean score of the scale during the procedure. Post hoc power analysis was performed with the GPower3.1 program. When the effect size is 0.431 and the alpha error is 0.05, the power of the sample was found to be 0.90.

2.4 | Sampling and randomization

Three experimental groups with independent control (parallel group) were formed. Randomization was performed using the lottery method. The lottery bag was prepared by the researcher. The drawing of lots was provided by the midwife who performed the heel blood draw.

The hospital registration protocol numbers of the infants whose heel blood was planned to be collected were written on pieces of paper and collected in a bag. Then, protocol numbers were respectively drawn from the bag for each of the breastfeeding, maternal heart sounds and breast milk scent application groups. In accordance with the experimental groups, heartbeat sounds recordings or breast milk samples were taken from the mothers.

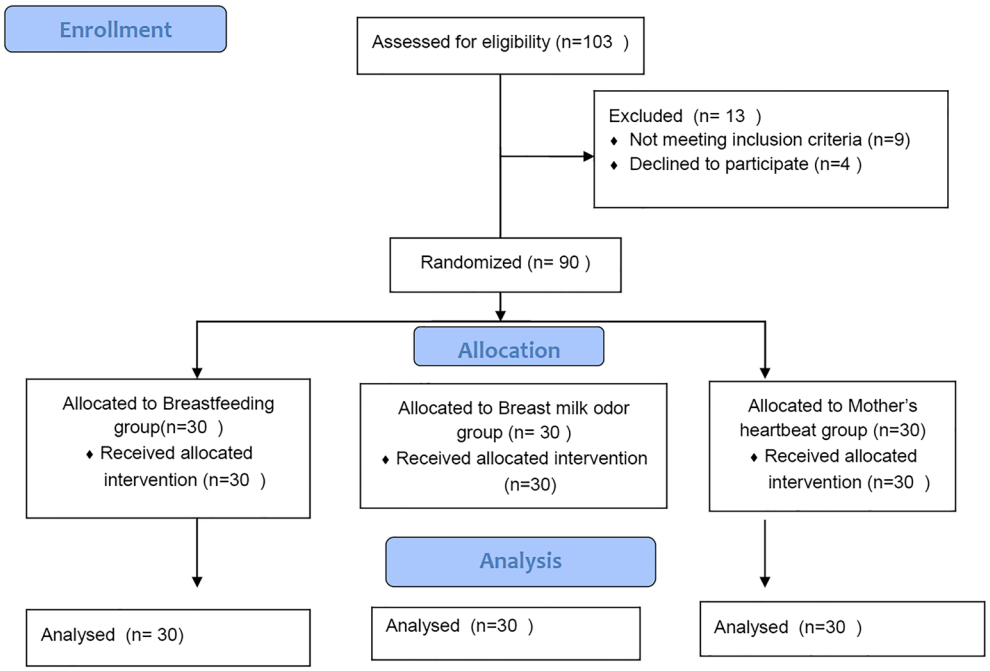

FIGURE 1 CONSORT flow diagram

2.5 | Study inclusion and exclusion criteria

Mothers who agreed to participate in the study and their babies at 38–42 weeks of gestational age, 2500–4000 g of birth weight, stable general health condition and no congenital anomaly were included in the study. Newborns who previously received any pharmacological or non-pharmacological therapy for pain management and mothers who did not want to continue the study were excluded from the study.

2.6 | Data collection tools

The data were collected using pulse oximeter, fetal hand doppler, voice recorder, loudspeaker, a data collection form and the ALPS-Neo Pain and Stress Assessment Scale for Newborn Infants (ALPS-Neo).

2.6.1 | ALPS-Neo pain and stress assessment scale for newborn infants

The scale was developed multidimensionally by Lundqvist et al. (2014) to assess pain and stress in premature and term newborns. It is a 3-point Likert-type scale consisting of five items: facial expression, breathing pattern, arm/leg muscle tone, hand/foot activity and level of activity. Measurements were made by observation. A higher scale score refers to a greater stress and pain, where 0–2 = *no pain and stress*, 3–5 = *mild pain and stress*, and >5 = *high pain and stress*. The total internal reliability score of the scale was reported as 0.91 and the internal consistency alpha coefficient as 0.95 (Lundqvist et al., 2014). The Turkish validity and reliability study of the scale was performed by Ceylan and Bolışık (2017), and their permission to use the scale in this study was obtained. The newborns' ALPS-Neo scores were recorded before, during and after the heel lance procedure.

2.6.2 | Data collection form

The form included demographic data of both mothers and newborns (gestational week, postnatal age, birth weight, APGAR score, etc.) and newborns' heartbeat, SPO2 and crying time before, during and after the procedure.

Pulse oximetry: A pulse oximeter (numbered 8691231635844 and manufactured by Medtronic Medikal Teknoloji Ticaret Ltd. Sti.) was used to measure newborns' oxygen saturation and heart rate.

Fetal hand doppler: A rechargeable fetal hand doppler (Endostall EN-FD-E5) with colour screen and recording was used in the study.

Voice recorder: A stereo voice recorder (Olympus WS-852 4GB) was used in the study.

Loudspeaker: A preo loudspeaker (myMusic 2018042103172) was used in the study.

2.7 | Data collection

2.7.1 | Stage 1

The data were collected by the researcher in the Obstetrics and Gynecology Services of state hospital between 15 February and

15 July 2019. Before the heel lance procedure, parents were informed about the metabolic scans of their newborns and explained the purpose of the study. The data were collected from parents, whose written and verbal consents were obtained, and their infants. The parents' characteristics were obtained via face-to-face interviews and those of newborns from their medical files. Before the procedure, the heel was warmed in the palm, and the heel skin was cleaned with alcohol. The procedure was applied to the left heel for all newborns using a lancet. The heel blood collection procedures of all newborns were applied by only one (the same person) midwife and lasted around 2 min.

2.7.2 | Stage 2

Because the use of no method in pain management was not considered ethically appropriate, the control group was not formed, but three experimental groups were formed in the study. Randomization: The hospital registration protocol numbers of newborns who were planned to receive heel lance procedure were written on a piece of paper and included in a bag. Then, a total of 30 protocol numbers were drawn from the bag for each group, including breastfeeding, mother's heartbeat sound and breast milk odour, respectively. In accordance with the groups formed, heartbeat sound recordings or breast milk samples were taken from the mothers. All newborns in the sample groups, whose heel blood was planned to be collected, were breastfed 30 min before the procedure.

2.7.3 | Stage 3

ALPS-Neo scale score, heart rate, oxygen saturation and crying time were evaluated for each newborn by the researcher and recorded 3 min before, during and 3 min after the heel lance procedure. The data were evaluated by two observers. The observers were a researcher and a newborns midwife. The second evaluator midwife had 15 years of experience in the newborn nursery.

2.8 | Experimental groups

Breastfeeding group: Newborns in this group were breastfed starting from 3 min before to 3 min after the procedure. The right breast was preferred so that the newborn would not be affected by the mother's heartbeat.

Mother's heartbeat sounds group: Before the procedure, the maternal heartbeat sounds of each newborn was recorded from their mothers by means of a fetal hand doppler. The mother's heartbeat sound was listened to the newborn starting from 3 min before to 3 min after the procedure (max. sound level: 60 dB).

Breast milk odour group: A total of 5 ml of breast milk sample was extracted from each baby's own mother before the procedure and poured onto a sterile odourless cloth. Then, the cloth was placed 3 cm from the newborn's nose and remained there starting from 3 min before to 3 min after the procedure.

2.9 | Ethical considerations

An ethical approval (dated: 01.02.2019 and coded: 09.2019.170) was obtained from the Clinical Research Ethics Committee of Marmara University Faculty of Medicine. An institutional permission (numbered: 614144002-605.01 and dated: 27.02.2019) was obtained from the Provincial Health Directorate. Both oral and written consents were obtained from the mothers of the newborns who were planned to include in the study.

2.10 | Data analysis

The Shapiro–Wilk test was used to check whether the data were normally distributed, and the data did not have normal distribution ($P < 0.01$). Therefore, non-parametric tests were used for group comparisons.

Cohen's kappa values were examined to evaluate the inter-observer agreement. It was found to be 0.941 before the procedure, 0.823 during the procedure and 0.894 after the procedure. A Cohen's kappa value of 0.81 and above indicates a very good fit level. The data reported by the second observer were used for statistical evaluations in the study.

Cronbach's alpha values of the scale were found to be 0.836 before the procedure, 0.819 during the procedure and 0.837 after the procedure. A Cronbach' alpha value of 0.70 and above indicates that the scale is reliable.

3 | RESULTS

Table 1 compares demographic characteristics of the newborns by study groups. There was no statistically significant difference between the groups in terms of all demographic characteristics, including gender, type of delivery, nutritional status, gestational age, postnatal age and birth weight ($P > 0.05$).

Table 2 compares the groups' ALPS-Neo mean scores, where no statistically significant difference was found before the procedure ($P = 0.203$). However, statistically significant results were found between their ALPS-Neo scores during and after the procedure ($P < 0.001$). A further analysis using the Mann–Whitney U test was made for group pairs to determine the group order by difference, and the order was determined as Group 2 > 3 > 1. The breast milk odour group had the highest ALPS-Neo mean score during and after the procedure.

Table 3 compares the groups' CAB, SPO2 and crying times measured before, during and after the procedure. A statistically significant difference was found between their crying times during and after the

TABLE 1 Comparison of demographic characteristics of newborns

	Experimental groups							
	Breastfeeding		Breast milk odour		Mother's heartbeat			
Characteristics	*M* ± *SD*	Min–Max	*M* ± *SD*	Min–Max	*M* ± *SD*	Min–Max	*F*/*P*	
Gestational age	39.26 ± 1.01	38.00–41.00	39.26 ± 1.08	38.00–41.00	39.33 ± 0.95	38.00–41.00	0.043	0.958
Postnatal age	1.70 ± 0.46	1.00–2.00	1.76 ± 0.43	1.00–2.00	1.76 ± 0.43	1.00–2.00	0.227	0.797
Birth weight	3191.16 ± 352.16	2,375–3,800	3218.83 ± 447.74	2,550–4,450	3258.66 ± 401.99	2,560–4,170	0.213	0.808
Birth height	50.60 ± 1.40	48.00–55.00	50.60 ± 1.16	48.00–53.00	50.53 ± 1.41	49.00–53.00	0.030	0.970
Head circumference	33.70 ± 1.82	30.00–36.00	33.36 ± 1.06	31.00–35.00	33.96 ± 1.09	31.00–36.00	1.436	0.243
APGAR1	8.96 ± 0.55	8.00–10.00	8.96 ± 0.55	8.00–10.00	8.86 ± 0.50	8.00–10.00	0.343	0.711
APGAR5	10.00 ± 0.00	10.00–10.00	10.00 ± 0.00	10.00–10.00	10.00 ± 0.00	10.00–10.00		
	n	%	*n*	%	*n*	%	χ^2	*P*
Gender								
• Girl	14	46.66	12	40.00	11	36.66	0.725	0.643
• Boy	16	53.34	18	60.00	19	63.34		
Type of birth								
• Vaginal birth	22	73.33	18	60.00	15	50.00	3.46	0.177
• C section	8	26.67	12	40.00	15	50.00		

Note: *F*: ANOVA. χ^2: chi square.

TABLE 2 Comparison of ALPS-Neo scale total scores by groups

	Experimental groups										
	Breastfeeding (1)			Breast milk odour (2)			Mother's heartbeat (3)				
ALPS-Neo scores	*M* ± *SD*	Median	Min–Max	*M* ± *SD*	Median	Min–Max	*M* ± *SD*	Median	Min–Max	*χ2/*P**	
Before the procedure	0.10 ± 0.54	0.00	0.- 3.00	1.10 ± 2.86	0.00	0–1.00	0.40 ± 1.24	0.00	0–5.00	3.187	0.203
During the procedure	1.13 ± 2.63	0.00	0–10.00	7.56 ± 3.08	10.00	2.00–10.00	4.13 ± 3.44	5.00	0.00–10.00	41.486	<0.001* 2 > 3 > 1
After the procedure	0.30 ± 1.05	0.00	0–5.00	4.13 ± 3.44	5.00	0–10.00	1.90 ± 2.77	0.00	0–9.00	25.290	<0.001* 2 > 3 > 1

Abbreviations: ALPS-Neo, ALPS-Neo Pain and Stress Assessment Scale for Newborn Infants.
*χ^2: Kruskal–Wallis Test.

procedure ($P < 0.001$). A further analysis using the Mann–Whitney U test was made for group pairs to determine the group order by difference, and the order was determined as Group 2 > 3 > 1. The breast milk odour group had the highest crying time during and after the procedure.

Finally, the relationship between pain scores and demographic characteristics was evaluated. The correlation between the groups' ALPS-Neo total scores by gestational age, postnatal age and birth weight was examined. No statistically significant negative or positive correlation was found between their scores ($P > 0.05$). In addition, there was no significant relationship between their ALPS-Neo total scores according to gender, type of delivery and nutritional status ($P > 0.05$).

4 | DISCUSSION

Newborns in the breastfeeding, breast milk odour and mother's heartbeat sounds groups were randomly selected for the study. No statistically significant difference was found between the groups in terms of gestational age, postnatal age, birth weight, height, head circumference, APGAR scores, gender and type of delivery. (Table 1). This indicates that all groups had a homogeneous distribution according to the specified characteristics.

In this study, the ALPS-Neo mean scores of all groups before the procedure were between 0 and 2, indicating that heel lance procedure was started in all groups under homogeneous conditions. During the procedure, a high level of pain was found for newborns in the breast milk odour group, a mild pain for those in the mother's heartbeat sounds group, and a very low pain for those in the breastfeeding group. These results are similar to those in the literature, where studies have reported lower pain scores for breastfeeding and breast milk odour compared to other methods (Nurbayanti, 2021; Peng et al., 2018; Wu et al., 2021).

A meta-analysis of 149 studies on non-pharmacological pain management methods reported the superiority of breastfeeding over other methods. Breastfeeding through skin-to-skin contact initiated 2 min before the procedure ranks first among non-pharmacological pain management methods for newborns. When breastfeeding is not possible, expressed breast milk, oral sucrose and non-nutritive sucking methods, respectively, are suggested. The non-pharmacological methods accepted as inclusion criteria in the systematic review were breastfeeding, expressed breast milk, oral sugar solutions, skin to skin care, non-nutritive sucking, swaddling and music (Wade et al., 2020).

In one study, higher first attempt blood sampling success and higher SPO2, shorter blood draw and bleeding times and lower pain scores were reported for term infants who were breastfed in the mother's lap during heel lance procedures (Wu et al., 2021). Cirik and Efe (2020) compared six groups in different combinations of non-pharmacological methods during orogastric (OG) tube insertion, and reported 'breast milk + swaddling' as the most effective method.

Regulation of environmental stimuli (sound, noise, smell, light, etc.) is recommended to control stress in newborns especially in

TABLE 3 Comparison of heart rate (HR), SPO2 and crying time by groups

	Experimental groups							
	Breastfeeding (1)		Breast milk odour (2)		Mother's heartbeat (3)			
Characteristics	Median	Min–Max	Median	Min–Max	Median	Min–Max	*χ^2/P	
HR/dk[1]	137.00	112-165	136.50	101–165	133.50	114–165	0.289	0.865
HR/dk[2]	140.00	110-185	150.00	117–175	142.50	116–170	1.985	0.371
HR/dk[3]	135.50	11-171	142.50	107–175	143.00	114–176	3.964	0.138
SPO2[1] (%)	95.00	90-100	97.00	92–100	96.00	87–100	4.084	0.130
SPO2[2] (%)	95.00	85-99	93.00	88–100	94.00	81–100	0.836	0.658
SPO2[3] (%)	94.00	90–100	94.00	90–99	95.00	80–99	1.028	0.598
Crying time[1] (sn)	0.00	0–15	0.00	0–10	0.00	0–10	3.024	0.220
Crying time[2] (sn)	0.00	0–120	45.00	0–120	10.00	00–120	30.306	<0.001* 2 > 3 > 1
Crying time[3] (sn)	0.00	0–30	7.50	0–120	0.00	0–50	20.934	<0.001* 2 > 3 > 1

[1]Before the procedure.
[2]During the procedure.
[3]After the procedure.
*χ^2: Kruskal–Wallis.

neonatal intensive care units (Als et al., 1996). According to the guideline for procedural pain in the newborn, breastfeeding, expressed breast milk and sucrose methods have been reported as level A evidence. In the same guideline olfactory stimulation and environmental care (light and noise), methods were described as level C and D evidence (Lago et al., 2009).

In parallel with the literature, the present study determined mild pain occurred for newborns in the mother's heartbeat sounds group. The sounds that the fetus can hear in the intrauterine period mostly include the physiological sounds of the mother such as breathing, heart and digestive sounds. However, the fetus can also hear external sounds and can form a sound memory at about 35 weeks of gestation. A positive auditory experience is recommended for early and healthy brain maturation (Als et al., 2005; McMahon et al., 2012). Therefore, the use of maternal sounds (mother's voice, heartbeat sound, etc.) in the neonatal period together with methods containing level A evidence (breast milk, breastfeeding, etc.) may increase the efficacy of pain relief in newborns.

Lower pain scores and better vital signs were reported for term and preterm newborns who listened to maternal voice and heartbeat sounds compared with those to whom no non-pharmacological method was applied during invasive procedures (blood collection, aspiration, etc.) (Alemdar & Tüfekci, 2017; Chen et al., 2021; Chirico et al., 2017; Kucuk Alemdar & Guducu Tufekc, 2018; Sarhangi et al., 2021).

In the present study, the breast milk odour group had the highest pain mean score. Similar to this study, Taplak and Bayat compared the effect of breast milk odour, white noise and positioning methods on pain in infants during aspiration and reported the highest pain score for the breast milk odour group (Taplak & Bayat, 2021).

In studies involving non-pharmacological pain management for the sense of smell, stimuli such as aromatic fluids, mother's breast, breast milk and amniotic fluid odours have been used (Ezen & Acikgoz, 2018). It has been explained that the newborn's sense of smell develops in intrauterine 26th–28th weeks of gestation and starts to suck by turning to the mother's breast through the sense of smell (Ezen & Acikgoz, 2018; McGrath, 2004; Porter & Winberg, 1999).

Studies with a control group that did not use any non-pharmacological methods reported lower pain scores for newborns in the breast milk odour group than those in the control groups (Amiri Shadmehri et al., 2020; Sajjadi et al., 2017). One study compared the effects of own mother's breast milk odour and the odour of another mother's milk on pain in preterm infants with hepatitis B vaccine and reported a lower pain profile score (PIPP) for those who smelled their own mother's milk (Rad et al., 2021).

The results of the study differ from those in the literature. This may be because there was no control group in the study and the postnatal age of the newborns was a maximum of 48 h (2 days). For example, one study has reported that while 2-day-old babies react (turn their head) to amniotic fluid, 4-day-old babies react (turn their head) to breast milk (Ezen & Acikgoz, 2018; Marlier et al., 1998). Another study has reported that newborns can distinguish their mothers' scent on the fifth day of life (Ezen & Acikgoz, 2018; Nishitani et al., 2009). Therefore, new studies can be suggested to compare newborns at different postnatal ages in order to determine the effect of the sense of smell on pain management.

The present study found no statistically significant difference between the groups in terms of HR and SPO2 during and after the procedure. However, there was a significant difference between their crying times in parallel with their pain scores. The breast milk odour group had the highest crying time. Crying is one of the strongest behavioural responses of newborns (Als et al., 1996, 2005). Therefore, crying time is expected to increase as pain score increases. In different studies, crying times differed in similar-parallel groups according to pain scores (Kahraman et al., 2020).

Vital signs are included in the physiological parameters used to evaluate stress and pain (Als et al., 1996, 2005). However, studies of pain have found a significant difference in vital data such as heart rhythm and SPO2 (Chirico et al., 2017; Kahraman et al., 2020; Sajjadi et al., 2017; Sarhangi et al., 2021; Wu et al., 2021), but no significant difference in vital data was found in some studies (Alemdar & Tüfekci, 2017; Rad et al., 2021; Taplak & Bayat, 2021) Heart rate and SPO2 values can change according to the sampling criteria or material method of the study.

4.1 | Limitations

The evaluation of newborns' ALPS-Neo scores was planned to be recorded with a video camera. However, video recording could not be made because the mothers in the breastfeeding group, especially, were uncomfortable with being recorded. Therefore, the data were assessed by two independent observers.

5 | CONCLUSİON

In conclusion, breastfeeding is a very effective method for pain control in newborns during heel lance procedures and the mother's heartbeat sound was found to be moderately effective. Therefore, using maternal sounds (mother's voice, heartbeat sound, etc.) together with high-evidence methods (breast milk, breastfeeding, etc.) may increase the effectiveness of pain management in newborns. Breast milk odour is not effective for pain control in newborns. It is recommended to conduct new studies comparing newborns at different postnatal ages in order to determine the effect of the sense of smell on pain management in newborns.

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CONFLICT OF INTEREST

No conflict of interest all authors.

AUTHORSHIP STATEMENT

AK and MT designed the study; MT collected data, and AK analysed the data. AK and MT prepared the manuscript, and all authors approved the final version for submission.

The data of this manuscript were derived from the Masters thesis and presented as a verbal presentation at the 2nd International Congress of Multidisciplinary Studies in Medical Sciences at Ankara/Turkey (13–14 February 2021).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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