



Original article

Effect of recorded maternal voice, breast milk odor, and incubator cover on pain and comfort during peripheral cannulation in preterm infants



Dilek Küçük Alemdar, PhD*

Giresun University, Faculty of Health Sciences, Department of Midwifery, Giresun, Turkey

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ABSTRACT

Purpose: This study was conducted to assess the effect of recorded maternal voice, breast milk odor, and incubator cover on the pain and comfort of preterm infants during peripheral cannulation.

Methods: This study was a randomized controlled trial. The sample of the study included 136 preterm infants who met the case selection criteria. The infants were randomly assigned to different groups.

Data collection tool: In the study, a recorded maternal voice was played to the maternal voice group. The breast milk odor group was exposed to the odor of breast milk. The incubator cover group was covered by using an incubator cover before, during, and after the peripheral cannulation procedure on the infants in the experimental group.

Result: While no difference was observed between the groups before the peripheral cannulation procedure in terms of the total Premature Infant Pain Profile (PIPP) scores, a significant difference existed between the PIPP scores during and after the procedure. This difference was due to the incubator cover group.

Conclusion: Breast milk odor, recorded maternal voice, and incubator cover in preterm infants are recommended as simple, safe, and supportive stimuli that facilitate positive effects during painful procedures.

1. Introduction

Preterm infants in a modern neonatal intensive care unit (NICU) are frequently exposed to stress in the form of painful procedures and high levels of ambient light and noise. The vulnerability of these infants is being increasingly recognized. Consequently, different attempts are being made to reduce the negative effect of potentially harmful stimuli. Developmental care (DC) is the general term that signifies the efforts to reduce stressful exposure. DC includes a range of different interventions such as reduction of sound and light, clustering of care activities, positioning and swaddling of the infant, kangaroo care, and non-nutritive sucking (Sizun & Westrup, 2004; Symington & Pinelli, 2006).

Preterm infants are exposed to unfamiliar stimuli in the NICU and are also deprived of the intrauterine sensory experience (Ramachandran & Dutta, 2013; Reid & Freer, 2010; Vandenberg, 2007). Although mortality is decreased, neurodevelopmental problems, permanent learning and behavior disorders, decreased motor skills, and an increase in other developmental disorders have been observed in these infants (Özdemir & Tüfekci, 2014; Vandenberg, 2007). This situation indicates a need for developmental support approaches. DC involves arrangements for supporting the development of preterm infants during and after an intensive care procedure in an NICU setting. These

arrangements include reduction of stressful stimuli and increasing the stimuli that support development based on observations with regard to an infant's physiological responses and behaviors to various stimuli (Eras, Atay, Şakrucu, Bingöler, & Dilmen, 2013; Reid & Freer, 2010).

Various studies have applied the stimulation of the olfactory system in term and preterm infants. The odors that induce positive responses are that of the breast milk of the infant's own mother, (Bingham, Churchill, & Ashikaga, 2007; Raimbault, Saliba, & Porter, 2007; Yıldız, Arıkan, Gözümlü, Taştekin, & Budancamanak, 2011), that of the breast milk of other mothers, that of the mother's belongings, that of amniotic fluids among maternal odors, and that of infant formula and vanilla (Goubet, Strasbaugh, & Chesney, 2007; Marlier, Schaal, Gaugler, & Messer, 2001; Nishitani et al., 2009; Rattaz, Goubet, & Bullinger, 2005). Some of the results that have been observed are faster weight gain due to calmness and reduced energy expenditure, less pain, decreased apnea frequency and severity, earlier start on oral feeding, and decreased length of hospital stay (Sullivan & Toubas, 1998; Varendi, Christensson, Porter, & Winberg, 1998).

Ambient light has a direct effect on the infant's visual ability, physiological stability, and organization of the central nervous system. The visual environment in NICUs reportedly reduces visual activity, causes problems with visual processing, and changes visual attention-

* Corresponding author at: Giresun University, Health Science Faculty, Department of Midwifery, Yenimahalle, 28340 Piraziz, Giresun, Turkey.
E-mail address: dilekkucuk@atauni.edu.tr.

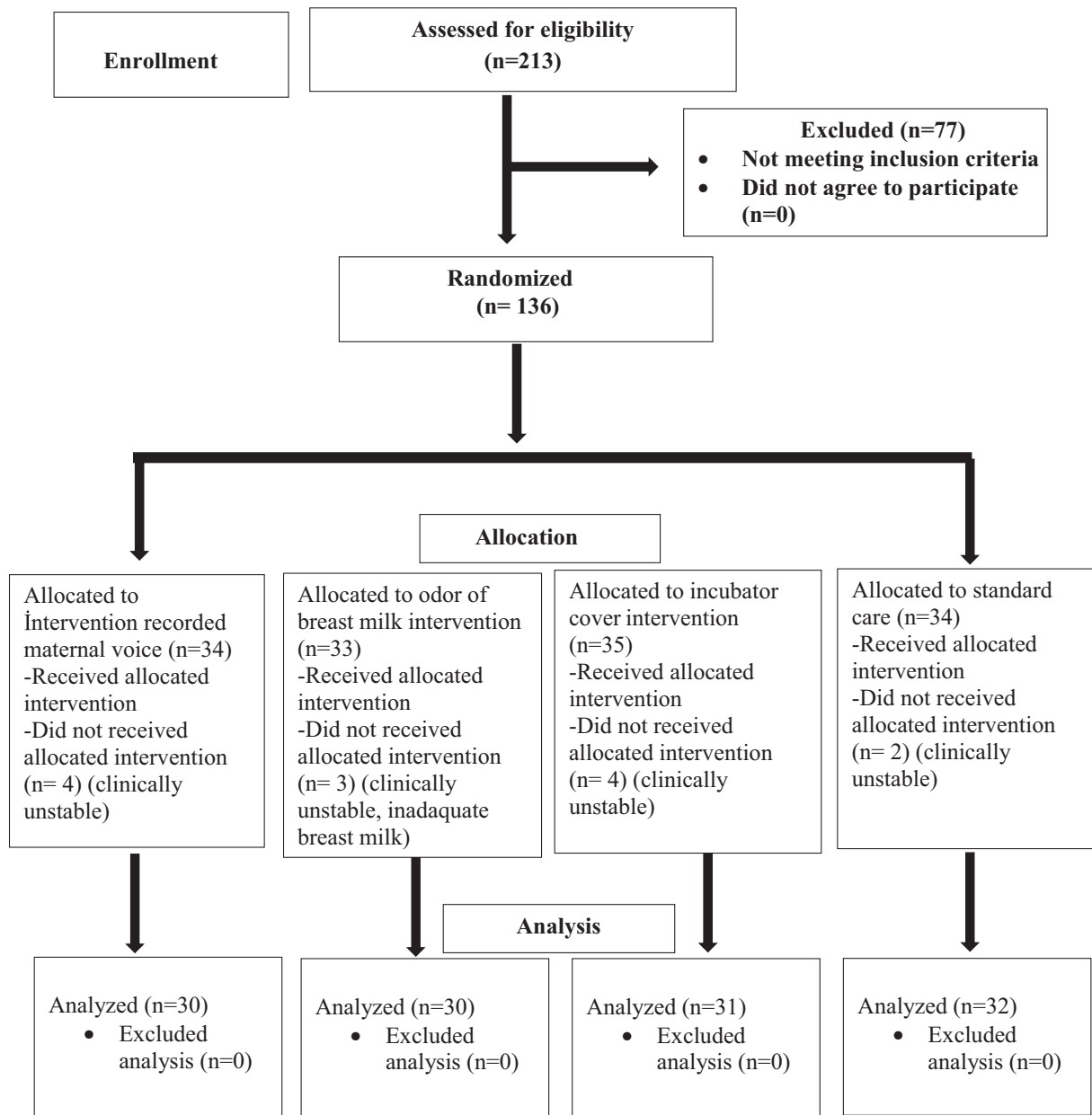


Fig. 1. Diagram showing the flow of participants.

perception, visual memory, and visual identification (Eras et al., 2013; Reid & Freer, 2010). Overall, the aim is to preserve life and provide proper medical care in a uterus-like environment, thus continuing the experience that was interrupted at an early stage as much as possible. Some NICU environments are constantly bright and noisy, which is in stark contrast to the dark intrauterine environment, where perceptible ambient sounds consist of the maternal heart and voice filtered through amniotic fluid (Küçük, 2015; Mirmiran & Ariagno, 2000). To prevent preterm infants' exposure to excess light, the American Academy of Pediatrics (1997), the American College of Obstetricians and Gynecologists (2007) suggested that the ambient light level at each infant bedside should be adjustable from 10 lx to 600 lx.

Even though 646 lx is the maximum light intensity recommended for NICUs, the light intensity in the intensive care units easily reaches 600 lx to 900 lx (Küçük, 2015). Various methods can be used to reduce the negative effects of light intensity in NICU. Intermittent lighting reportedly reduces infants' heart rate and activities, strengthens the biological rhythm, and increases restful sleep, nutrition, weight gain,

and attention of the infant toward its surrounding (Küçük, 2015; Ramachandran & Dutta, 2013; Reid & Freer, 2010). Other suggested ways to address this issue is to prevent direct light from shining on the baby, covering lighted equipment, and reducing the intensity of light by using various options such as veils for incubators and pads for closing eyes (Eras et al., 2013; Sizun & Westrup, 2004; Vandenberg, 2007).

Reducing pain and stress in preterm infants is an important issue in the NICU (Symington & Pinelli, 2006). Numerous pharmacological and non-pharmacological interventions are used to reduce pain during invasive methods. Audio stimulation effectively distracts a baby and provides a pain control and cognitive strategy to suppress the pain response (Hartling et al., 2009; Kemper & Danhauer, 2005; Kisilevsky et al., 2009; Reid & Freer, 2010; Standley, 2001). However, infants mostly hear maternal heart sounds in the intrauterine period. Therefore, infants will remember their secure environment as soon as they hear these familiar sounds that they heard while they were in the womb, thereby creating a sense of relief in these infants (Panagiotidis & Lahav, 2010). Previous studies found that soothing music (Hartling

Table 1
Comparison of descriptive characteristics of the control and intervention groups (N = 123).

Groups										
Characteristics	Odor of breast milk (n = 30)		Maternal voice (n = 30)		Incubator cover (n = 31)		Control (n = 32)		X ²	p
	n	%	n	%	n	%	n	%		
Gender										
Girl	15	50.0	13	43.3	16	51.6	17	53.1	0.683	0.87
Boy	15	50.0	17	56.7	15	48.4	15	46.9		
	Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD		F	p
Gestational ages	30.26 ± 0.69		30.06 ± 0.63		30.22 ± 0.66		30.25. ± 0.50		0.644	0.25
Birth weight (g)	1430.70 ± 146.00		1460.50 ± 133.36		1404.80 ± 99.23		1503.80 ± 194.86		2.643	0.30
Birth height (g)	41.00 ± 1.01		40.53 ± 1.00		40.54 ± 1.17		40.54 ± 1.43		1.141	0.33
Birth head circumference (cm)	29.70 ± 0.53		29.46 ± 0.81		29.29 ± 0.78		29.28 ± 0.85		2.005	0.11
Apgar score 1	6.40 ± 0.49		6.40 ± 0.49		6.58 ± 0.67		6.25 ± 0.43		2.017	0.11
Apgar score 5	7.53 ± 0.62		7.55 ± 0.77		7.70 ± 0.69		7.37 ± 0.55		1.325	0.26

Table 2
Comparison of the average PIPP scores between the control and intervention groups.

PIPP scores	Groups				F	p
	Odor of breast milk (n = 32)	Maternal voice (n = 30)	Incubator cover (n = 31)	Control (n = 32)		
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD		
Before peripheral cannulation	4.40 ± 1.06	4.80 ± 1.65	3.90 ± 1.42	4.45 ± 1.02	3.41	0.49
During peripheral cannulation	11.04 ± 3.33	12.30 ± 2.89	9.63 ± 3.22*	12.41 ± 2.91	7.27	0.00
After peripheral cannulation	6.66 ± 1.18	8.10 ± 3.39	5.47 ± 1.70*	8.16 ± 2.64	6.80	0.00

* Advanced analysis result (Bonferoni tests).

Table 3
Comparison of the average PICS scores between the control and intervention groups.

PICS scores	Groups				F	p
	Odor of breast milk (n = 32)	Maternal voice (n = 30)	Incubator cover (n = 31)	Control (n = 32)		
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD		
Before peripheral cannulation	18.96 ± 6.80	17.90 ± 7.45	16.90 ± 6.92	18.70 ± 6.94	0.53	0.66
During peripheral cannulation	23.60 ± 5.05	21.93 ± 5.37	21.40 ± 4.95	23.54 ± 4.97	1.47	0.22
After peripheral cannulation	18.96 ± 6.80	17.90 ± 7.45	16.90 ± 6.92	18.70 ± 6.84	0.53	0.66

et al., 2009; Standley, 2001) and maternal sounds (Cevasco, 2008; Krueger, Parker, Chiu, & Theriaque, 2010; Panagiotidis & Lahav, 2010) are beneficial in NICU incubators. The AAP (1997) and the Committee to Establish Recommended Standards for Newborn ICU Design (2012) also recommended that noise levels should not exceed an average of 45 dB.

This study was conducted to assess the effect of recorded maternal voice, breast milk odor, and incubator cover on pain and comfort during peripheral cannulation in preterm infants.

1.1. Study hypotheses

Hypothesis 1. The interventions of recorded maternal voice, breast milk odor, and incubator cover reduce pain severity before, during, and after peripheral cannulation in preterm infants.

Hypothesis 2. The interventions of recorded maternal voice, breast milk odor, and incubator cover provide comfort before, during, and after peripheral cannulation in preterm infants.

2. Methods

2.1. Study design and sample

This study was a randomized controlled trial. The population of the study consisted of the preterm infants at the NICU of a hospital. The sample of the study consisted of 136 preterm infants who met the case selection criteria, and the infants were randomly assigned to different groups. After excluding some infants, the total number of the infants in all the groups was 123 (30 infants in the maternal voice group, 30 infants in the breast milk odor group, 31 infants in the incubator cover group, and 32 infants in the control group) (Fig. 1). Randomization was performed by using a computer program. Power analysis determined that the power was 0.90 with the risk of $\beta = 0.20$ and $\alpha = 0.05$ at a significance level of 0.05 for 123 preterm infants. All the infants were included in the study during second peripheral cannulation. The following criteria were used for inclusion in this study: born after the 30th or before the 34th week of gestation, birth weight > 1000 g, mean of

Apgar scores > 6, medically stable during the first 24 h after birth (heart rate, blood pressure, age-appropriate respiratory rate, and oxygen saturation), had no congenital malformation that could have caused asphyxia or otherwise affected respiration and had spontaneous respiration at birth, and no cranial bleeding or hyperbilirubinemia that could have led to blood abnormalities. Exclusion criteria (similar to those used in previous studies) were necrotizing enterocolitis, chromosomal anomalies, craniofacial malformation, respiratory distress syndrome, bronchopulmonary dysplasia, other chronic lung disease, need for mechanical ventilation, neonatal seizures, intracranial hemorrhage, periventricular leukomalacia, or culture-positive sepsis or meningitis at study screening.

2.2. Procedure

All peripheral cannulation procedures were performed by the same nurse who worked on the day shift and had six years' NICU experience. Any pharmacological or non-pharmacological pain relieving methods are not applied to infants under peripheral cannulation in the NICU where the study was conducted. All the factors that could affect the pain level of preterm infants in the intervention and the control groups during the practice were standardized. The procedure was administered while the preterm infant was not crying; if he/she was crying, then the nurse waited for 2 min before administering the procedure. Cephalic and basilic vein was used in all premature infants during the procedure. Before the procedure, the area was cleaned from the center to the periphery by using 70% alcohol as a skin antiseptic for all premature infants. The procedure was performed after waiting for at least 30 s. Yellow catheter no. 24 was used in the procedure. A cannula needle was inserted in the tissue with a 15°–20° angle. Thus, veins were accessed by penetrating the skin and the vein simultaneously. After ensuring that the needle was in the vein, catheters were fixed on the skin by using transparent plaster. The infants were recorded with a video camera by the researcher before, during, and after the procedure. Video recording was started 1 min before the procedure and lasted 15 min after the procedure for both groups.

2.3. Intervention

2.3.1. Breast milk odor group

Breast milk was taken from the mothers of each preterm infant in this group with the help of a milking machine when the status of the mother became stable. A total of 5 cm³ of the milk sample received was poured in a sterile sponge 15 min before the procedure and placed 5 cm away from the infant; at this point, the infant was assumed to be able to smell the breast milk. The infant continued to smell the milk during and 15 min after the procedure.

2.3.2. Maternal voice group

The mother of each preterm infant in this group was encouraged to express her thoughts and feelings and to say what she wanted to say to her baby. As she spoke, her words were recorded by using a voice recorder. Then, this recording was set to 45 dB and played for the infant inside an incubator for 15 min before the procedure. The recording was then played during and 15 min after the procedure.

2.3.3. Incubator cover group

The incubators of the preterm infants in this group were covered with a cover that was made with a special thick white fabric, and the front side was left open. The incubators were covered before, during, and after the procedure.

2.3.4. Control group

Peripheral cannulation was performed according to a clinical routine for preterm infants in the control group. Images of the baby before, during, and after the procedure were recorded by using a video

recorder.

2.4. Data collection tools

2.4.1. Personal information form

This form includes the newborn's age, gender, gestational age, birth weight, length, head circumference, Apgar score, nutritional status (breastfeeding and/or formula feeding), and diagnoses.

2.4.2. Premature Infant Pain Profile (PIPP)

This form was developed by Stevens, Johnston, Petryshen, and Taddio (1996) and its Turkish validity study was conducted by Akcan, Yiğit, and Atıcı (2009). In this form, the following seven indicators are scored to assess the infant's pain during the procedure: gestational age, behavioral state, maximum heart rate, minimum oxygen saturation, brow bulge, eye squeeze, and nasolabial furrow. Each item is scored between 0 and 3, from the least affected to the most affected by the procedure. Validity and reliability analysis was performed first in using the scale. According to the PIPP guidelines, the gestational age must be between ≥ 28 and ≤ 36 weeks, and the behavioral state must be scored depending on the criteria such as active–quiet, awake–sleep, eyes open–closed, and display of any facial movements. Furthermore, an increase in the heart rate must be scored in the range of 0–25 beats/min, and a decrease in oxygen saturation is assessed between 2.4% and 7.5% per minute. The final total score is determined with all the aforementioned parameters to obtain the infant's pain level score, the highest score being 21 and the lowest score being 0. The level of pain is considered mild if the total PIPP score is between 0 and 6 points, moderate if it is between 7 and 12 points, and severe if it is between 13 and 21 points (Akcan et al., 2009; Stevens et al., 1996).

2.4.3. Premature Infant Comfort Scale (PICS)

This scale was developed by Monique Caljouw et al. (2007) to measure the pain and stress levels of preterm infants with a gestational age of ≥ 28 and ≤ 37 weeks. PICS was adapted to assess its Turkish reliability and validity (Alemdar & Tüfekçi, 2015). PICS is a multi-dimensional scale that is used to assess the behavioral and psychological comfort and pain. PICS assesses seven elements: alertness, calmness/agitation, respiratory status (only for mechanical ventilation support) or crying (we did not use this in our study because it was meant for children with spontaneous breathing), physical movements, muscle tone, facial movements, and mean heart rate. Each item is scored on a 5-point Likert-type scale from 1 (good) to 5 (bad). The final total score is determined with the aforementioned parameters to obtain the infants' PICS score, the highest score being 35 and the lowest score being 7. A total score of ≥ 17 points indicates that an intervention is required to relieve discomfort (Monique Caljouw et al., 2007).

2.5. Ethical considerations

To conduct this study, we obtained legal permission from the institution with the ethical consent form from the Ethics Committee. We explained the purpose of this study to the families of the premature infants who were included and answered their questions. Written informed consents were obtained from the parents of the infants. Parents were assured that the information they gave would be confidential and would not be used anywhere else. In this study, we have fulfilled the related ethical principles of informed consent, voluntariness, and privacy protection of the human subjects and upheld the protection of their individual rights.

2.6. Data analysis

The researcher viewed the video recordings after the procedures to evaluate the pain. Video recordings for both groups were viewed by two NICU nurses and the researcher after the procedure to evaluate the

pain, and the researcher's observations were used for data analysis because no statistically significant difference was observed according to the result of the inter-observer agreement test both for the pain (Kendall = 0.673, $p > 0.05$) and comfort (Kendall = 0.713, $p > 0.05$).

The data were analyzed with the Statistical Package for Social Sciences 18.0 software using appropriate statistical analysis. Percentage distribution, mean, standard deviation, chi-square test, Kendall's W, one-way ANOVA (between groups), and the post-hoc advanced analysis Bonferroni test in binary comparisons were used for the statistical analysis of the data.

3. Results

3.1. Sample characteristics

No statistically significant difference was found between the control and intervention groups in terms of gender, gestational age, birth weight, birth height, head circumference, and Apgar score at the fifth minute ($p > 0.05$; Table 1).

3.2. Comparison of the groups in terms of pain levels

While no significant difference existed between the PIPP scores of the control and intervention groups before the peripheral cannulation procedure ($p > 0.05$), a significant difference was observed between the PIPP scores during and after the procedure ($p < 0.05$, Table 2). Advanced analyses found that this difference was caused by the incubator cover group. In terms of difference, the infants in the incubator cover group were followed by infants in the breast milk odor, maternal voice, and control groups (Table 2).

3.3. Comparison of the groups in terms of comfort levels

Even though no significant difference was found in the comparison of PICS scores in the control and intervention groups before, during, and after peripheral cannulation, the best comfort score belonged to the infants in the incubator cover group, followed by the maternal voice, control, and breast milk odor groups ($p > 0.05$, Table 3).

4. Discussion

Previous studies report that DC interventions such as decreasing environmental light and noise, positioning, and grasping decrease preterm infants' heart rate and hypoxic events during nursing procedures (Catelin, Tordjman, Morin, Oger, & Sizun, 2005; Sizun & Westrup, 2004). However, pain response in these studies was measured during a diaper change and weighing, which are not painful procedures, and diaper change was used in other studies (Catelin et al., 2005; Gibbins et al., 2008; Holsti, Grunau, Oberlander, & Osiovich, 2008; Rodrigues & Guinsburg, 2013; Sizun & Westrup, 2004).

In this study, which evaluated the effect of maternal voice, breast milk odor, and incubator cover on pain and comfort in preterm infants during peripheral cannulation, pain was significantly lower in the preterm infants in the incubator cover group ($p < 0.05$). Reducing light in DC practices can be more effective than other environmental arrangements (odor, sound) because the infants are exposed to sound and odor in the intrauterine environment. However, such an environment is completely dark.

According to a study by Doheny, Hurwitz, Insoft, Ringer, and Lahav (2012) which evaluated the effect of listening to maternal heart sound and maternal voice on the cardiorespiratory system of preterm infants, apnea and bradycardia were lower in the group who listened to maternal heart beat sounds. Johnston, Filion, and Nuyt (2007) reported significantly higher SO_2 values in preterm infants who listened to maternal voices during a heel lance procedure compared with the control

group. However, the effect on pain levels was insignificant. The results of our study are not consistent with these results.

Rattaz et al. (2005) determined that odors of breast milk and vanilla during heel lance decreased the grimaces of newborns, and only breast milk odor effectively decreased neonatal stress after the procedure. Goubet et al. (2007) stated that the newborns who were made to smell familiar scents during heel lance cried 32% less than those in the control group and the group that was made to smell the scent of vanilla. Studies on the heel lance procedure determined that the newborns who smelled their own mothers' breast milk felt significantly less pain and showed less uneasiness/agitation (Nishitani et al., 2009; Rattaz et al., 2005).

Evidence indicates that exposure to very bright light can harm the immature eye. High lighting levels have been associated with adverse clinical outcomes such as less weight gain, behavioral and sleep disturbances, and stress in very preterm or seriously ill patients (Peng et al., 2009; White, 2007). A sudden change in the amount of light also affects the newborn infant. Changes in ambient lighting include temporary effects; a reduced level of lighting results in an immediate and transient opening of the eyelids, followed by a significantly longer period when this dimmer illumination is maintained. Effects of light reduction in the NICU include better stability of the newborn infant, respiratory stability, decreased heart rate and respiratory rate, blood pressure and motor activity, and shorter time in ventilation and oxygen support (Morag & Ohlsson, 2011).

Aita, Goulet, Oberlander, Snider, and Johnston (2015) reported that covered eyes and earmuffs had no effect on physiological parameters during the heel lance procedure in preterm infants. Results of this study support the results of the present study. However, the pain levels of preterm infants were not evaluated in the study. Previous studies reported reduced heart rate and hypoxia during DC practices such as positioning and reducing environmental noise and light (Catelin et al., 2005; Sizun & Westrup, 2004). Reyhani, Aemmi, Sannadgol, and Boskabadi (2014) assessed the effect of using an incubator cover on the physiological parameters of infants and found a significant difference in oxygen saturation and respiratory rates between the control and the incubator cover groups.

The use of non-pharmacological and the pharmacological methods in the NICU is important to improve infants' comfort level. No study was found on the effect of maternal voice, incubator cover, and breast milk odor on infants' comfort level during the aspiration procedure, and studies that evaluate comfort in preterm infants are few. Corff, Seideman, Venkataraman, Lutes, and Yates (1995) found that the comfort levels of preterm infants positioned in a fetal position during the heel lance procedure were significantly higher than those of infants in the control group. Monique Caljouw et al. (2007) who examined the comfort levels of preterm infants during the heel lance procedure, determined a statistically significant difference between comfort scores recorded before and after the procedure.

5. Conclusions

Infants, especially preterm infants, are vulnerable beings who need considerable attention. The purpose of a health team is to provide comprehensive care with minimal complications for the infant's health and development. Thus, all factors, including environmental conditions that have an effect on growth and infant health need to be considered. The use of breast milk odor, recorded maternal voice, and incubator cover for preterm infants as simple, safe, and supportive stimuli is recommended for the formation of positive effects during painful procedures.

6. Limitations of study

The limitation of this study is that it is not blinded because pain evaluation should be performed by watching videos. A gauze sponge

placed near the noses of the infants to enable them to smell breast milk, an incubator cover, and recorded audios while watching videos enabled us to understand in which group they were involved.

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