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The effect of swaddling method applied to preterm infants during the aspiration procedure on pain

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ABSTRACT

Purpose: The study was carried out to determine the effect of the swaddling method on pain in preterm infants (between 27 and 36 weeks) hospitalized in the Neonatal Intensive Care Unit during the aspiration procedure. Preterm infants were recruited by convenience sampling from level III neonatal intensive care units in a city in Turkey.

Method: The study was conducted in a randomized controlled trial manner. The study consisted of preterm infants ($n = 70$) receiving care or treatment at a neonatal intensive care unit. While swaddling was applied to the infants in the experimental group before the aspiration process. The pain was assessed before, during, and after the nasal aspiration using the Premature Infant Pain Profile.

Results: No significant difference was found in terms of pre-procedural pain scores whereas a statistically significant difference was detected in terms of pain scores during and after the procedure between the groups.

Conclusion: It was determined in the study that the swaddling method reduced the pain of the preterm infants during the aspiration procedure.

Implications for practice: This study emphasized that swaddling had pain-reducing during the aspiration procedure in the neonatal intensive care unit in preterm infants. It is recommended that future studies be conducted using different invasive procedures in preterm infants born earlier.

Introduction

The World Health Organization (WHO) reports that nearly 15 million infants are born prematurely before the completion of the 37th week of gestation every year (WHO, 2018). Almost all of these infants need special care and they receive treatment in the neonatal intensive care unit (NICU) until they breathe regularly without clinical assistance. Preterm infants are exposed to an average of 5–15 invasive procedures per day in the NICU (Carter & Brunkhorst, 2017). The most frequently invasive procedures performed on preterm infants are heel blood collection (Guo et al., 2020; Ho et al., 2016), aspiration (Kundak et al., 2020; Rodrigues et al., 2017) venous blood collection, and peripheral venous catheter insertion (Cruz et al., 2016).

Aspiration is among the most common invasive procedures performed on preterm infants in neonatal intensive care units (Cruz et al., 2016; Kundak et al., 2020; Rodrigues et al., 2017). Pain has short- and long-term effects on preterm infants (Alinejad-Naeini et al., 2014; Kundak et al., 2020). Tachycardia, hypertension, decreased oxygen saturation, rapid respiration, hypoxia, metabolic acidosis, hypoglycemia, and changes in body temperature are among the short-term effects led by the pain (Akcan & Polat, 2017). Painful interventions may cause an increase in cortisol secretion and protein degradation, deterioration in blood glucose, growth development, and brain development disorders (Akcan & Polat, 2017; Eckstein Grunau, 2013; Hsieh et al., 2018). Preterm infants also experience long-term effects, including negative effects on neurologic and behavioral development (Anand et al., 2006). It can cause anxiety, hyperesthesia, hyperactivity, attention deficit, and stress disorders in children's later developmental periods (Çağlayan & Balcı, 2014).

Pain management of premature babies during NICU procedures is of great importance in their neurodevelopment (Peng et al., 2018). Nurses are in charge of conducting pain assessments in newborns and performing interventions to minimize the amount of pain experienced by them. Pharmacological and non-pharmacological therapies can be practiced to

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alleviate the pain. If a proper and right pain management technique is adopted, acute pain in newborns can be reduced (Witt et al., 2016). Correct assessment of pain is required to apply accurate and complete pain management. The main goal of pain assessment is to identify an infant's potentially painful condition, quantify the pain level, and predict the need for an intervention. Assessing pain is difficult for caregivers of this non-verbal population and requires adequate tools. Therefore, a comprehensive observation is necessary to accurately assess pain in infants. For the correct evaluation of the response to pain, it should be measured with appropriate measurement tools and these measurement tools should be multidimensional (behavioral, physiological, hormonal, etc.) (Table 1) (Mathew & Mathew, 2003; Melo et al., 2014; Törüner & Büyükgönenç, 2015; Walter-Nicolet et al., 2010).

Pharmacological analgesia therapy used for pain management in infants provides both benefits and risks. Respiratory depression, apnea leading to bradycardia and desaturation, partial airway obstruction, and hypersalivation are the most important side effects of analgesic drugs (Lago et al., 2009). In addition, it is stated that an adequate analgesic effect cannot be achieved even when an intravenous (IV) morphine loading dose is given continuously while invasive intervention is applied to preterm newborns (Anand et al., 2004). In contrast to pharmacological pain management, non-pharmacological pain management may have lower risk. The administration of oral sucrose or glucose (Beken et al., 2014), skin-to-skin care in the kangaroo method (Kostandy et al., 2008), non-nutritive sucking (Losacco et al., 2011), breastfeeding (Gabriel et al., 2013) massage (Jain et al., 2006), positioning and swaddling (Apaydin Cirik & Efe, 2020; Erkut & Yildiz, 2017), facilitated tucking, music and sensory saturation (Witt et al., 2016) are among the non-pharmacological therapies.

Table 1
Pain symptoms in newborns.

Physiological changes
Increases
Heart rate
Blood pressure
Oxygen consumption
Intracranial pressure
Respiratory rate and carbon dioxide
Muscle strain
Decreases
Breathing depth
Oxygenation
Paleness/redness
Hormonal changes
Increases
Plasma renin activity
Catecholamine levels
Cortisol levels
Growth hormone
Antidiuretic hormone
Aldosterone and glucagon release
Decreases
Insulin secretion
Behavioral changes
Vocalizations
Crying
Moaning
Facial expressions
Grimace
Wrinkles on eyebrows and forehead
Eye wrinkles
Situations
Changed sleep and wake times/alertness.
Difficulty relaxing, calming and stillness
Changes in tone
Increase in tone/stretch/pressure
Decreased/relaxed tone
Anti-touch responses
Body movements
Convulsive general body movement
Pulling in arms and legs
Strong beats

One of the non-pharmacological methods used to control the effects of invasive interventions is safe swaddling (wrapping), which is performed by keeping the legs flexed close to the body following the anatomical position of the newborn (Erkut & Yıldız, 2017; Meek & Huertas, 2012; Mosiman & Pile, 2013). Safe swaddling facilitates the infant's adaptation to the extrauterine environment, makes him/her feel safe, reduces the physiological and behavioral stress he/she experiences, shortens the time it takes him/her to fall asleep, ensures uninterrupted sleep, prevents spontaneous awakening between naps, and shortens the crying time (Erkut & Yıldız, 2017; Meyer, 2009; Mosiman & Pile, 2013).

Reducing pain during invasive procedures regulates heart rate and oxygen saturation, and also positively affects neuromuscular and motor development (Ramachandran & Dutta, 2013).In the literature review, studies have been found that used swaddling for the control of pain during invasive procedures such as orogastric tube insertion and heel blood collection in infants (Apaydin Cirik & Efe, 2020; Erkut & Yildiz, 2017). However, no study has been found on the control of pain during the aspiration procedure. For this purpose, this study was carried out to determine the effect of the swaddling method on the pain that occurred during the aspiration procedure in preterm infants hospitalized in the NICU and who needed aspiration. In this study, the suggested hypothesis is as follows: Swaddling decreases the pain in preterm infants when during the aspiration procedure.

Materials and methods

Design

This study was conducted in a paired randomized controlled trial manner on preterm infants hospitalized in the NICU of a university hospital from March 2021 to July 2021.

Sample

Preterm infants were recruited by convenience sampling from level III neonatal intensive care units in a city in Turkey. The inclusion criteria were: (1) gestational age between 28 and 37 weeks at delivery; (2) postnatal age between 2 and more days; (3) enteral nutrition; (4) no use of sedatives, muscle relaxants, or analgesics 24 h before a study session; (5) noninvasive mechanical ventilation (NIMV) (with mask), (6) birth weight 1500–3200 g, (7) no congenital or known genetic abnormalities; (8) no history of surgical procedures; (9) stable condition.

In the calculation of the sample size, G-Power 3.1 analysis program was used. The required minimum sample size was determined to be 64. The power analysis was at a confidence level of 95% (1st type margin of error = 0.05) and 90% power (2nd type margin of error = 0.10). Seventy (70) newborns were included in the sample considering that there could be case losses and cases that could disrupt the homogeneity of the groups in terms of variables affecting pain management.

During the study period, 183 preterm infants were hospitalized. However, a sample size of 70 preterm infants who met the inclusion criteria were included in the study. The preterm infants were randomly divided into two groups (experimental group and control group). Numbers from 1 to70 were assigned in two groups using a program on a computer without recurrence of the numbers at randomization. The CONSORT flow diagram for the study procedure is shown in Fig. 1 (Schulz et al., 2010).

Instruments

Parent-premature newborn assessment form: The form prepared by the researchers consists of 12 sociodemographic questions about

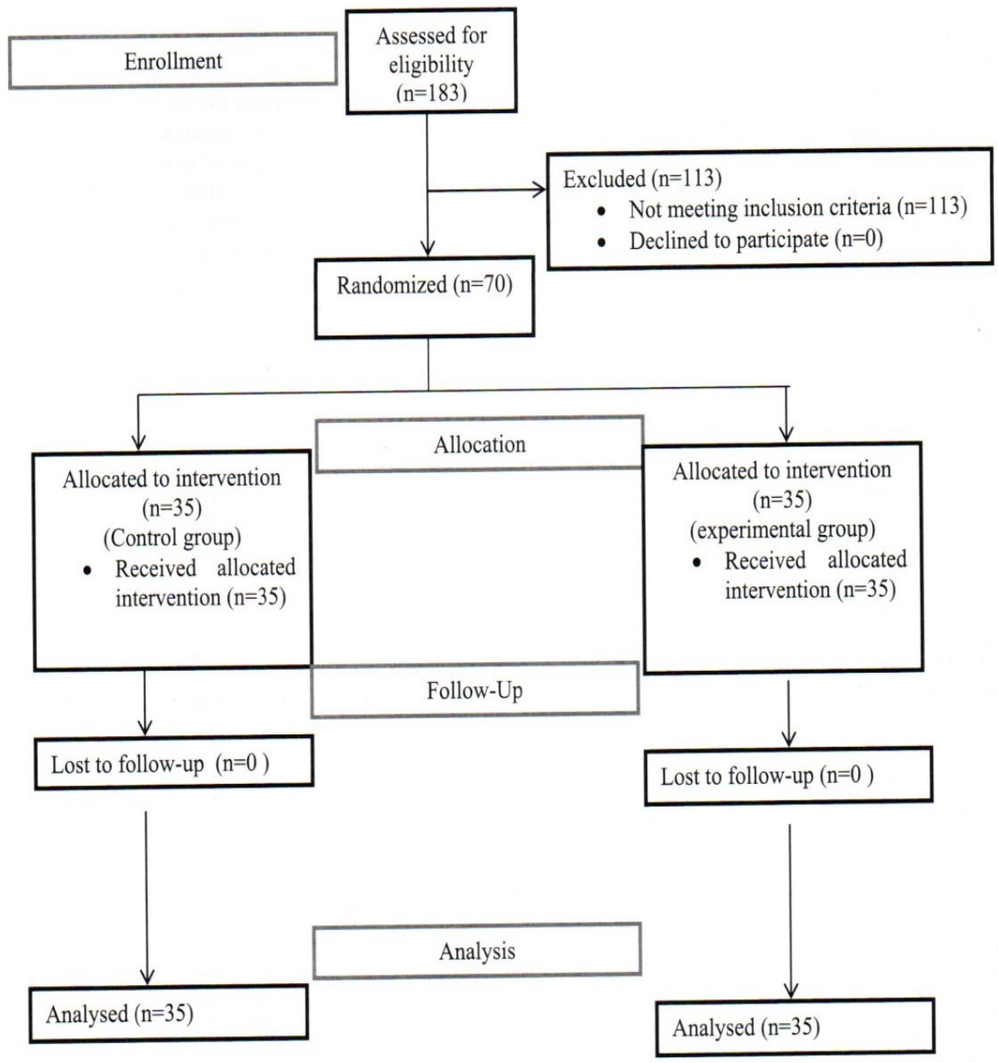

Fig. 1. CONSORT diagram of this.

parents (age, education, number of children, etc.) and infant (birth weight, birth length, week of birth, mode of birth, nutritional status, etc.).

Premature Infant Pain Scale (PIPP): The scale developed by Stevens et al. (1996) to evaluate the pain of infants between 28 and 36 weeks consists of seven items such as gestational age, behavioral status, highest heart rate value, lowest oxygen saturation value, forehead wrinkling, squinting eyes, and enlargement of the nose wings. Each item is scored as 0, 1, 2, and 3, from best to worst (Table 2). According to the PIPP, the pain of the infant is evaluated over the total score. The scale ranges from 0 to 21, with a score 6 or lower, no pain or minimal, moderate pain between 7 and 12 points, and a score of 13–21 points considered severe pain (Stevens et al., 1996). Akcan and Yiğit adapted the Premature Infant Pain Scale to Turkish and tested its validity and reliability (Akcan & Yiğit, 2015).

Table 2
Premature infant pain profile.

Indicator	Score 0	1	2	3
Gestational age	≥36 weeks	32 weeks–35 weeks +6 diaries	28 weeks–31 weeks +6 diaries	<28 weeks
Behavioural state	Active/awake eyes open, facial movements crying with eyes open/closed	Quiet/awake, eyes open, no facial, movements	Active/sleeping, eyes closed, facial movements	Quiet/sleeping, eyes closed, no facial movements
Maximum heart pulse rate	0–4 beats per minute increase	5–14 beats per minute increase	15–24 beats per minute increase	25 and more pulse increase
Minimum oxygen Saturation (%)	0–2.4 decrease	2.5–4.9 decrease	5–7.4 decrease	≥7.5 decrease
Brow bulge	None 0%–9% of time (<3 s)	Minumum 10%–39% of time (≥3 to <12 s)	Moderate 40%–69% of time (≥12 to <21 s)	Maximum 70% of time or more (≥21 to s or more)
Eye squeeze	None 0%–9% of time (<3 s)	Minumum 10%–39% of time (≥3 to <12 s)	Moderate 40%–69% of time (≥12 to <21 s)	Maximum 70% of time or more (≥21 to s or more)
Nazolabial furrow	None 0%–9% of time (<3 s)	Minumum 10%–39% of time (≥3 to <12 s)	Moderate 40%–69% of time (≥12 to <21 s)	Maximum 70% of time or more (≥21 to s or more)

The intra class correlation coefficient (ICC) indicating the correlation between the PIPP scores obtained before, during, and after the aspiration procedures were calculated by two independent observers, under the same circumstances, to detect the inter-rate reliability of PIPP. The ICC was found to be 0.96 before sampling, 0.98 during sampling, and 0.99 after sampling. Score indicating a coherence of 0.75 is considered to be an acceptable level of coherence between the raters more than one (Kanık & Erdogan, 2004).

Implementation of the study

A 10–15 min interview was held with the families of the preterm infants who were included in the study. The purpose and plan of the study were explained to the parents, and written consent was obtained from the parents who agreed to participate in the study.

Some of the information in the "Parent-premature newborn assessment form", which included the sociodemographic data of the parents and preterm newborns meeting the sampling criteria, was filled in line with the information received from the patient files and parents by the researchers.

It was ensured that the diapers of all infants in the study group were clean before the procedure. Enterally fed infants were fed at least one hour before the procedure and no painful intervention was practiced on these infants for one hour before the procedure. All infants were monitored in the incubator and the lid of the incubator was only opened during the procedure to conserve heat. An intern doctor assessed the need for preterm neonates to do suctioning in a noninvasive mechanical ventilation as per unit. The procedure of suctioning was performed only when the neonate was needed and no procedure was performed only for the study. A nasal aspiration procedure was applied to all infants in the study group in the supine position.

Swaddling was performed on the infantsin the intervention group ten minutes before the nasal aspiration. Swaddling was carried out with a 90 cm^2 cloth in the neonatal supine position. Following the anatomical posture of the newborn, the legs were wrapped in flexion and abduction position, without causing movement restriction. The body of the newborn was completely wrapped. In order not to limit the movements of all extremities of the newborn, it was ensured that the swaddle was comfortable and not too tight. The newborn's head was not wrapped and he/she was able to his/her head move freely. Swaddling process was completed approximately in a minute (Apaydin Cirik & Efe, 2020; Fallah et al., 2017). Nasal aspiration was performed in a sterile manner 10 min after the swaddling process.

The aspiration procedure was applied to both groups by the same nurse with the number seven aspiration catheter. Aspiration was performed by a nurse who had five years of experience in neonatal intensive care, by entering the intubation tube once, at a pressure of 80 mmHg, using the aspiration method in an aseptic way. The process took an average of 10–15 s. Thirty seconds before the aspiration procedure, the oxygen concentration of all newborns in the control and intervention groups was increased to 100% and fixed to its original value. The PIPP scores of the groups (15 s before the aspiration procedure, during the procedure, and 30 s after the procedure) were evaluated by two independent observers.

The ethical aspect of research

Written approval for the study to be carried out was obtained from the hospital management and University Non-invasive clinical trials with the number 2021/04. Written informed consent was obtained from the nurse who agreed to participate in the study and from the parents of the preterm infants who met the inclusion criteria.

Evaluation of data

SPSS 16.0 package program was used in the evaluation of the data. The distribution of the data was analyzed with the Shapiro Wilk test. Descriptive statistics of the data were given as mean ± standard deviation, minimum-maximum and median values. Descriptive statistics of categorical variables were given as a number (n) and percentage (%). Differences between the groups in categorical variables were examined with Pearson Chi-Square Test. The independent samples *t*-test was used for paired comparisons of normally distributed parameters, and the Mann Whitney *U* test was used for two-group comparisons of parameters that did not show a normal distribution. Friedman Test was used for within-group comparisons of parameters that did not show a normal distribution. Wilcoxon Signed Ranks Test was used to evaluate paired comparisons. Intraclass Correlation Coefficient (ICC) was used to evaluate the harmony among observers. The results were evaluated at a 95% interval and a significance level of 0.05.

Results

Preterm infants in the intervention ($n = 35$) and control ($n = 35$) groups were examined in terms of sociodemographic characteristics (age, weight, height, type of delivery, and duration of the procedure) and it was determined that there was no statistical difference between them ($p \geq 0.05$) (Table 3). All of the infants in the intervention and control groups were delivered by cesarean section and were followed up with the diagnosis of respiratory distress syndrome.

No significant difference was found between the sociodemographic characteristics of the parents, maternal age, maternal and paternal education level, planned/unplanned pregnancy status, and the distribution of the number of children of the infants in the intervention and control groups ($p > 0.05$) (Table 4).

When the mean PIPP scores of the preterm infants who were included in the study and who constituted the intervention and control groups were evaluated, there was no significant difference between the intervention and control groups in terms of pre-procedural PIPP pain levels ($p > 0.05$); however, a statistically significant difference was found between the intervention and control groups in terms of PIPP pain levels during and after the procedure ($p = 0.001$, $p < 0.05$). The PIPP scale means a score of the preterm infants in the intervention group ($6.63 + 3.38$) during the procedure was found to be lower than the mean scores of those in the control group ($10.32 + 3.58$). The post-procedural PIPP scale means the score of the preterm infants in the intervention group ($1.12 + 1.13$) was lower than the mean score of the preterm infants in the control group ($3.44 + 2.20$) (Table 5).

It was found in the study that there was a significant difference between the PIPP scale mean scores of the infants in the intervention and control groups in terms of the procedure time ($p < 0.05$). In further analysis, which was carried out to determine the source of the difference, the mean of the pre-procedural PIPP scale score values of the infants in both intervention and control groups was found to be lower than during and after the procedures. It was determined that the mean of the PIPP scale score values after the procedure was lower than during the procedure (Table 5).

Further analysis was carried out to determine the source of the difference, and it was found to be because the mean PIPP scale score values of the infants in both groups before the procedure were lower than the values during and after the procedures. The mean of the PIPP scale score values after the procedure was also found to be lower than the values during the procedure (Table 5).

Table 3
Sociodemographic characteristics of preterm infants (n = 70).

Özellikler		Experimental Group (n = 35)		Control Group (n = 35)		Test and p value
		Ort ± Ss	Min–Max. (Medyan)	Ort ± Ss	Min–Max. (Medyan)	
Birth weight		2233.18 ± 570.73	1130–3350	1970.85 ± 577.59	1040–3450	t = 1.869 p = 0.07
Birth length		45.27 ± 4.01	38–56	44.11 ± 3.80	31–50	t = 1.209 p = 0.231[a]
Gestational week		34.27 ± 1.84	30.0–37.0	33.5 ± 2.10	29–37	t = 1.596 p = 0.115[a]
The duration of aspiration (sn)		56.15 ± 10.09	35–70	50.0 ± 9.17	35–80	t = −1.044 p = 0.299
			n	%	n	%	
Gender	Boy		17	48.5	18	41.7	$\chi^2 = 0.014$ p = 0.907[b]
	Girl		18	51.5	17	52.9	

[a] Independent samples *t* test.
[b] Pearson ki kare testi.

Discussion

To improve the physiologic conditions of the infants hospitalized in NICU, various procedures are performed on the infants especially those treated with mechanical ventilation (Anand et al., 2001; Ball et al., 2010). Suctioning is one of these procedures performed for the mechanical removal of lung secretions from the patient (Akça Ay, 2011). Safe swaddling is used to control the effects of invasive procedures in newborns. It has been reported that the safe swaddling technique in preterm and term newborns reduces the pain experienced by the infant during medical interventions. This study was conducted to determine the effect of the swaddling method practiced on the infants during the aspiration procedure on the pain.

When the mean PIPP scores of the preterm infants in the intervention and control groups were evaluated, no significant difference was found between the intervention and control groups in terms of pre-procedure PIPP pain levels; however, a statistically significant difference was found between the intervention and control groups in terms of PIPP pain levels during and after the procedure. With this result, the hypothesis of the research "Swaddling decreases the pain in preterm infants when during the aspiration procedure" was confirmed.

Pain is one of the most important complications of aspiration. Sönmez Düzkaya and Kuğuoğlu (2015) reported in their study that children between ages 1 and 12 months, experienced pain during the aspiration process and recommended the use of standard aspiration guides in units (Sönmez Düzkaya & Kuğuoğlu, 2015).

No study has been found in the literature evaluating the effect of the swaddling method on the level of pain during aspiration. However, studies have been found on other non-pharmacological methods used to reduce pain during the aspiration procedure in newborns and children. When the studies on other non-pharmacological methods used to reduce pain during the aspiration procedure were examined, it was observed in a study by Demir (2019) that the application of parental voice and musical sound during the aspiration procedure to the children under mechanical ventilation in the pediatric intensive care unit reduced the pain associated with the aspiration procedure and improved vital signs (Demir, 2019). Küçük Alemdar and Güdücü Tüfekçi (2017) carried out a study in which they had premature babies listen to the mother's heart sound during the aspiration procedure and evaluated the effect of this sound on pain, comfort, and physiological parameters. They found in their study that the mother's heart sound had a positive effect on the level of pain and comfort (Küçük Alemdar & Güdücü Tüfekci, 2017). In addition, Taplak and Bayat (2021) stated that the fetal position, breast milk smell, and white noise applied to preterm infants in reducing the pain during the endotracheal aspiration procedure were effective (Taplak & Bayat, 2021).

When the studies evaluating the effectiveness of the non-pharmacological swaddling method in reducing the pain in newborns

Table 4
The sociodemographic characteristics of the parents (n = 66).

		Experimental Group (n = 35)		Control Group (n = 35)		Test and p value
		Ort ± Ss	Min–Max. (Medyan)	Ort ± Ss	Min–Max. (Medyan)	
Maternal age		31 ± 4.28	19–43 (31)	30.12 ± 6.29	19–42 (30)	t = 0.861; p = 0.724[a]
		n	%	n	%	
Mother education status	Primary education	17	51.6	16	47.1	$\chi^2 = 6.420$ p = 0.212[b]
	Secondery education	9	24.2	11	32.4	
	High education	9	24.2	8	20.5	
Father education status	Primary education	16	48.5	13	38.2	$\chi^2 = 0.562$ p = 0.435[b]
	Secondery education	11	30.3	16	47.6	
	High education	8	21.2	6	14.2	
Pregnacy status	Planned	27	78.8	30	88.2	$\chi^2 = 8.678$ p = 0.123[c]
	Unplanned	8	21.2	5	11.2	
Number of children	1 child	7	18.2	13	35.3	$\chi^2 = 4.321$ p = 0.645[b]
	2 children	18	54.6	14	41.2	
	3 and over children	10	27.2	8	23.5	

[a] Bağımsız gruplar *t* testi.
[b] Pearson ki kare testi.
[c] Fisher exact testi.

Table 5
PIPP Pain scores before, during and after the aspiration by groups.

GROUPS		Before aspiration[a]	During aspiration[b]	After aspiration[c]	p	p^{a-b}	p^{a-c}	p^{b-c}
Experimental Control	PIPP scores	1.68 ± 1.06	6.63 ± 3.38	1.12 ± 1.13	**0.001**[d]	**0.001**[e]	**0.001**[e]	**0.003**[e]
		1.82 ± 1.27	10.32 ± 3.58	3.44 ± 2.20	**0.001**[d]	**0.001**[e]	**0.001**[e]	**0.001**[e]
	p	0.768[f]	**0.001**[f]	**0.001**[f]				

[a] Before aspiration.
[b] During aspiration.
[c] After aspiration.
[d] Friedman test.
[e] Wilcoxon signed ranks test.
[f] Mann Whitney U Test.

were examined, it was observed that the safe swaddling during the heel blood collection procedure alleviated the pain of the newborn (Huang et al., 2004; Morrow et al., 2010; Shu et al., 2014; Sinpru et al., 2009) regulated the newborn's heart rate (Huang et al., 2004; Sinpru et al., 2009)and oxygen saturation (Huang et al., 2004) and shortened crying time (Shu et al., 2014). Ho et al. (2016) and Apaydin Cirik and Efe (2020) stated that swaddling was an effective method of reducing the pain caused by the heel blood collection procedure and orogastric tube insertion in newborns, respectively (Apaydin Cirik & Efe, 2020).

Conclusion

In this study, it was determined that swaddling reduced pain during the aspiration procedure in 28–37 weeks-old preterm infants.

Limitations

The results of the study are limited to the effect of the swaddling method on pain preterm infants (between 27 and 36 weeks) hospitalized in the NICU during the aspiration procedure.

Implications for practice

This study emphasized that swaddling had pain-reducing, relaxing, and stress-relieving effects during the aspiration procedure in the NICU in preterm infants. It is recommended that future studies be conducted using different invasive procedures in preterm infants born earlier.

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Declaration of Competing Interest

There are no conflicts of interest to declare.

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All authors have met the authorship criteria.

1. Substantial contributions to conception and design of the study, or acquisition of data, or analysis and interpretation of data;

2. Drafting the article or advising it critically for important intellectual content.

3.Final approval of the version to be published.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pedn.2022.05.025.

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