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ORIGINAL PAPER

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The effect of foot reflexology applied to neonates before oro/nasopharyngeal suctioning on procedural pain and comfort in the neonatal intensive care unit

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ABSTRACT

Introduction and aim. This study was performed to examine the effect of foot reflexology applied to the neonates on the level of pain and discomfort developed due to suctioning procedure.

Material and methods. The study was conducted experimentally by taking pretest and repeated measurements on reflexology and control groups determined by simple randomization. The study was carried out with 66 neonates (reflexology applied: 33 and control group: 33). Neonatal Information Form, Neonatal Infant Pain Scale (NIPS) and Newborn Comfort Behavior Scale (NCBS) were used as the data collection tools.

Results. The during ($p<0.001$) and after suctioning ($p<0.001$), the NIPS scores of the neonates in the intervention group was statistically lower than the control group. The NCBS scores of the neonates in the intervention group during ($p<0.001$), and after suctioning ($p<0.001$), were statistically significantly lower than the control group.

Conclusion. It was concluded that foot reflexology applied to neonates was effective both in reducing pain during and after the suctioning and in increasing comfort during and after the suctioning.

Keywords. comfort, foot reflexology, neonates, procedural pain, suctioning procedure

Introduction

Many painful procedures are performed every day for neonates admitted to hospitals and this situation is repeated in intensive care units.[1] Neonates requiring intensive care undergo on average between 7.5 to 17.3 painful procedures per day during their hospital stay, with the most common procedures being heel lancing, venipuncture and suctioning.[2]

Pain management among infants at neonatal intensive care units (NICUs) has received increased attention over the last years, and it is well known that inadequate pain management is linked to negative shortand long-term consequences for the infant.[3] Besides, exposure to untreated procedural pain has been linked to adverse effects on neonatal outcomes, most notably brain development, neurodevelopment, immune system, regulation of stress systems, and, later, pain perception and sensitivity.[1,2,4] Procedures performed on neonates can cause pain as well as impairment the comfort of neonates.[5–7]

In addition to pharmacological methods, non-pharmacological methods can also be used in reducing pain and increasing comfort during invasive procedures in neonates.[6,7] Pharmacological methods are generally not recommended for use in neonates due to serious side effects such as apnea and respiratory depression.[8] Non-pharmacological methods are generally preferred

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for the most common repeated painful procedures as a results of their apparently superior efficacy and favorable safety profile.[2] Also, evidence suggests that neonate, could benefice of non-pharmacological interventions to relive mild to moderate pain and discomfort from minör invasive procedures.[9,10] Massage, therapeutic touch, acupressure, acupuncture and reflexology, which are among the non-pharmacological methods applied to neonates and infants[9,11,12], are also defined as Complementary and Alternative Medicine (CAM) Methods or Complementary Health Approaches (CHAs).[13-15]

Reflexology enables endorphin and encephalin release by stimulating the pituitary gland through the pressure and massage performed on reflex points on hands, feet and ears. It resolves problems in organs and body parts that correspond to these points, reduces pain, and relieves discomfort.[16,17] Foot reflexology is among the most popular forms of reflexology. It's an easy, safe, and non-invasive method which can be utilized without the need for special equipment.[18]

There are studies examining the effects of foot reflexology applied to the neonates on meconium passage, neonatal jaundice, neonatal abstinence syndrome, colic symptoms, and physiological index.[15,18-21] However, while a limited number of studies exists examining the effect of foot reflexology on neonatal pain[17,21,22], no studies examining its effect on comfort were found. Whereas, nurses are consistent caregivers for neonates, and their assessment of pain and pain practice is invaluable.[23] In addition, in recent years, nursing practices in NICUs have attracted attention with the aspect of increasing the comfort of neonates.[5]

Foot reflexology, which we used in this study, is one of the methods nurses use to manage symptoms in neonates.[15,17,22] Non-pharmacological methods such as reflexology generally advocate considering the individual as a body, soul, and mind. In the Watson model regarding postmodern nursing, it is recommended to use touch consciously (practices such as therapeutic massage, and reflexology). Therefore, CHAs that contribute to nursing are important for providing holistic care.[7] Also, nurses frequently exhibit a positive attitude toward the use of CAM because its philosophy complies with a holistic nursing care approach.[13] The fact that the foot reflexology used in this study was performed with an invasive procedure such as suctioning, which has not been studied before, is thought to make an important contribution to the literature.

Aim

This study was performed to examine the effect of foot reflexology applied to the neonates on the level of pain and discomfort developed due to suctioning procedure. Hypotheses of the study; foot reflexology applied to neonatal;

- Is effective in reducing pain that develops during suctioning procedure.
- Is effective in reducing pain that continues after suctioning procedure.
- Is effective in increasing the comfort of the neonatal during suctioning procedure
- Is effective in increasing the comfort of the neonatal after suctioning procedure.

Material and methods

Design, setting and sample size

The study was conducted experimentally by taking pretest and repeated measurements on reflexology and control groups determined by simple randomization. The universe of this study consisted of 154 neonates admitted to the NICU at a university hospital in Ankara, Turkey between 1 July to 30 September 2017. A power analysis was performed using the G*Power 3.1 program to determine the size of research sample with two study groups. The results of research were used conducted on infants and neonates that determine the effect of foot reflexology before vaccination on acute pain; the effect of foot reflexology on meconium passage; the effect of foot massage on pain responses to heel stick.[17,19,24] The sample size was determined to include a total 52 neonates, 26 in each group, at a power of 80%, a significance level of 5%, and an effect size of 0.80 (t=2.009; Effect size d=0.80). Due to possible data loss, the sample consisted of 66 neonates (intervention group: 33 and control group: 33) who met the study inclusion criteria.

Data collection tools

Neonatal information form (NIF)

In this form prepared by the researchers; there are a total of 10 questions, 8 of which are open-ended, questioning descriptive features such as sex, gestational age, postnatal age, anthropometric measurements, medical diagnosis and medicines used.

Neonatal infant pain scale (NIPS)

Developed by Lawrence et al., and adapted to Turkish by Akdovan.[25,26] This scale is used to evaluate the pain associated with the procedures applied in term and premature neonates. It includes 6 behavioral parts that include facial expression, cry, breathing patterns, state of arousal, arm and leg movements. The total score ranges from 0-7. The high score indicates that the severity of pain increased. Lawrence et al., determined the cronbach alpha value of the scale is between .92-.97. and Akdovan as .83-.86.[25,26] In this study, it was found to be .91.

Newborn comfort behavior scale (NCBS)

"Comfort Scale", Ambuel et al. evaluates the distress of pediatric patients who were followed up in the NICU with mechanical ventilator support.[27] Van Dijk et al.

revised this scale as "COMFORTneo scale" for neonates and Kahraman et al. adapted to Turkish.[28,29] This scale is composed of 7 behavioral dimensions. These are alertness, calmness/agitation, facial tension, muscle tone, body movement, respiratory response (only in mechanically ventilated neonates) and crying (only in spontaneously breathing neonates). In this study, the dimension of "crying" was evaluated because neonates had spontaneous breathing and 6 dimensions in total were rated. As responses are on a 1 to 5 Likert scale, total scores range from 6 to 30. Scoring 13 points and below on the scale indicates that the neonate is comfortable, and scoring between 14-30 indicate that the neonate has pain or distress. Kahraman et al., found the scale's cronbach alpha value as .85 before medical care.[29] In this study, it was found as .85. In addition, a positive and high level relationship was found between NIPS and NCBS medians during and after suctioning (Table 1).

Table 1. Correlation between NIPS and NCBS*

		NCBS			
		Control group		Intervention group	
NIPS	During suctioning	r_s 0.728*	p<0.001	r_s 0.775*	p<0.001
	After suctioning	r_s 0.728*	p<0.001	r_s 0.834*	p<0.001

*Both scales showed a correlation above .70

Intervention phases

Pre-intervention

NIF, NIPS and NCBS were applied to 154 neonates hospitalized in NICU. Neonates, who got 0 points from NIPS (that shows they had no pain) and under 13 points from NCBS (that shows they were comfortable), included in the study. Other inclusion criteria were as follows: being born between the 37 and 42 weeks, not receiving analgesic and sedative medicine treatment, not being diagnosed with neurological or congenital heart disease in the prenatal and postnatal period, being on noninvasive respiratory support (Noninvasive Continuous Positive Airway Pressure "NCPAP"), and no skin problem that would prevent the application of reflexology. Eighty-eight neonates, who did not meet these inclusion criteria, were found to have pain according to NIPS and were found to be uncomfortable by NCBS, were excluded from the study. 66 neonates who met the inclusion criteria constituted the sample of the study. Randomization was performed to determine the intervention and control groups in the study. The method of randomization was based on patient admission order. A protocol number (ie, 1 through 66) was assigned and recorded to each neonate in order of admission to the NICU. Odd numbers were assigned to the intervention group and even numbers to the control group.

Intervention

Foot reflexology was applied to the neonates in the intervention group. No intervention was made to the control group. One of the researchers (N.E.O.) applied foot reflexology to neonates. N.E.O. is working as a nurse at NICU where the study is conducted, and also received a reflexology practitioner training certificate after three months of training. N.E.O. applied foot reflexology in the NICU. None of the parents of the neonates were present at the time of reflexology. Neonates lying naked in their incubators with only their diapers were placed in open beds in the NICU so that reflexology could be applied comfortably. While the neonates were lying in the infant incubator or reflexology was applied to the neonates in open beds, the neonates were connected to the bed warmer by means of a prop. Thus, instantaneous body temperature of neonates was seen and body temperature was followed. There was no risk of hypothermia in any of the neonates. Neonates were in the supine position during reflexology. Foot reflexology was performed to both feet with clean and non-cold bare hands for neonates. Reflexology time (minutes): The recommended reflexology session for infants is (10-15 min for each foot) 20-30 min total for both feet.[15,17,18,22,30] In this study, it was applied to both feet for a total of 30 min, 15 min to one foot of each neonates (Fig. 1).

Post-intervention

Reflexology applied neonates were taken from their open beds where reflexology was applied and placed in their incubators. The neonates in the control group, on the other hand, were never placed in an open bed because reflexology was not applied to them, they were in their incubators.

Before suctioning: Preparations and arrangements were made in both groups for situations that may affect the pain and comfort levels of neonates. These are; diaper replacement of the neonatal, feeding at least one hour before, keeping away from stimulating sounds such as ventilator, monitor and giving supine position to the neonatal. NIPS and NCBS were applied to neonates in both groups just before the suctioning. It was determined that all neonates in the intervention and control group did not have pain by getting "0" points from NIPS and were comfortable by getting under "13" points from NCBS. The vital signs of neonates were measured before the suctioning procedure. There was no statistically significant difference between the intervention and control groups in terms of median fever value (p=0.375); mean pulse value (p=0.483); median oxygen saturation value (p=0.151); and median blood pressure value (p=0.832). In addition, there was no obstacle to suctioning procedure in terms of vital signs.

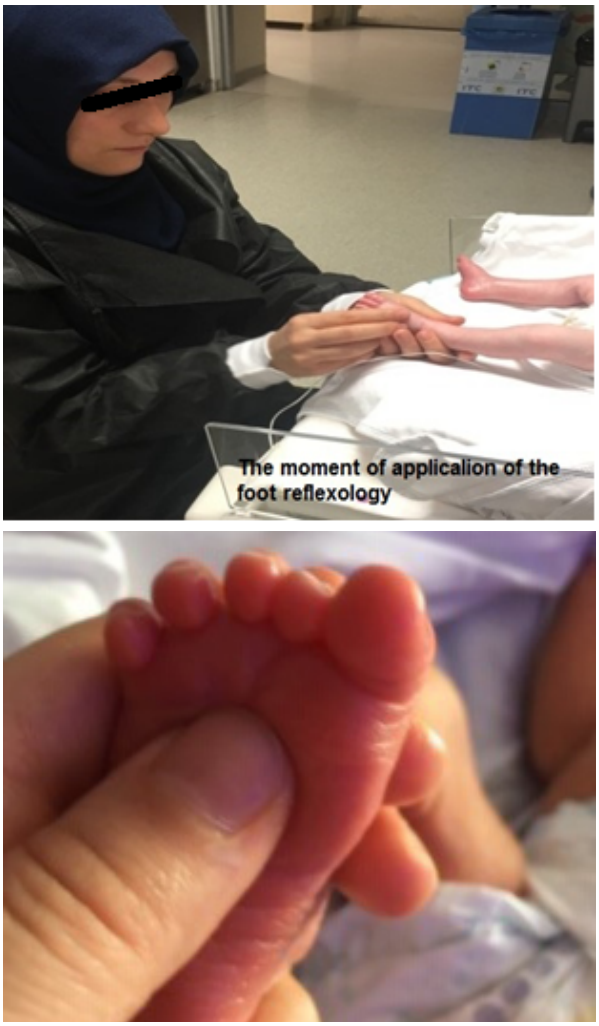

Fig. 1. The moment of application of the foot reflexology and the foot reflexology pressure points

During suctioning: Suctioning procedure for all neonates was done by N.E.O. The mean time of suctioning was 16.29±2.665 (min-max 8-22) seconds. The same brand 8 Fr disposable suctioning probe was used for each neonatal. The suctioning was performed with a pressure in the range of 80-100 mmHg, first being the oropharyngeal and then the nasopharyngeal. While performing the suctioning, NIPS and NCBS were applied to the neonates. The vital signs of neonates were measured during the suctioning procedure. There was no statistically significant difference between the intervention and control groups in terms of median fever value (p=0.989); mean pulse value (p=0.431); median oxygen saturation value (p=0.110); and median blood pressure value (p=0.390). In addition, there was no situation requiring early termination of the suctioning.

After suctioning: NIPS and NCBS were not administered to the neonates immediately after suctioning. Because neonates cry after suctioning, the crying time of neonates was measured. The mean time of crying was 12.50±12.953 (min-max 0-55) seconds. During crying, neonates in both groups were not held during crying. Each neonates was in his own incubator. After measuring the crying times of the neonates, their vital signs were measured. There was no statistically significant difference between the intervention and control groups in terms of median fever value (p=0.439); median oxygen saturation value (p=0.462); and median blood pressure value (p=0.059). However, while the mean pulse value of the intervention group was 138.67±14.59, it was 162.03±15.615 in the control group, and there was a statistically significant difference between the two groups (p<0.001). A 10-minute period was defined for completion of neonates crying times and vital signs measurements and, the nurse other than the researcher, to be ready to administer the scales. NIPS and NCBS were applied to all neonates in the intervention and control groups 10 minutes after the suctioning (Fig. 2).

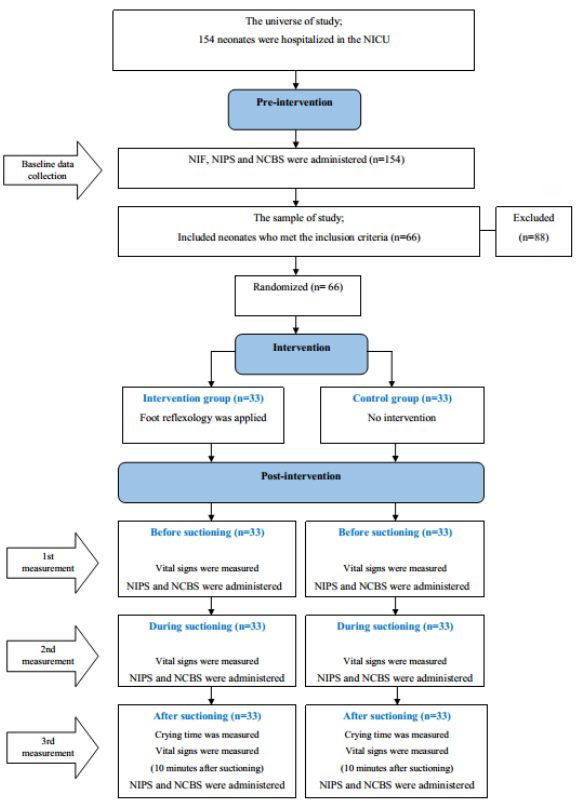

Fig. 2. Intervention phases diagram of the study

Data analysis

The IBM SPSS Statistics 23 (IBM Corp, Armonk, New York, USA) was used to evaluate the data. Kolmogorov-Smirnov test was used to determine whether the variables showed normal distribution. The difference between categorical variables with two groups; evaluated with independent t test (for normally distributed variables) and Mann Whitney U test (for non-normally distributed variables). Wilcoxon test was used to determine the difference in measurements made at two different times. Repeated measures analysis of variance (for normally distributed variables) was used to examine

the difference in measurements made at different three times, and the Friedman test (for non-normally distributed variables) to determine the difference in measurements made at different three times.

The Chi-square test was used to analyze the relationship between two categorical variables. In addition, the Sepearman Correlation coefficient was used to analyze the relationship between two numerical variables.

Results

The study was conducted with a total of 66 neonates. When neonates in the intervention and control groups are compared according to their descriptive characteristics; there was no significant difference between groups in terms of sex (p=0.805), mode of delivery (p=0.592), and medical diagnosis (p=1) (Table 2). Also, when age and physical characteristics of neonates are compared according to the groups; there was no statistically significant difference between groups in terms of gestational age (p=0.44), postnatal age (p=0.646), birth weight (p=0.837), length (p=0.157) and head circumference (p=0.577) (Table 3).

As a result of the applied Mann Whitney U test; during (p<0.001) and after suctioning (p<0.001), the median pain (NIPS) scores of the neonates in the intervention group were statistically lower than the control group. As a result of the Friedman test applied, there was a statistically significant difference between the times in terms of median level of pain in the intervention (p<0.001) and control groups (p<0.001). When time differences (significance between measurements) were examined; In the intervention group, the decrease occurred after suctioning according to the during suctioning was found to be statistically significant (p<0.001). However, in the control group, the decrease occured after suctioning according to the during suctioning was not statistically significant (p=0.419) (Table 4).

As a result of the applied Mann Whitney U test, there was no statistically significant difference between the intervention and control groups in terms of median NCBS scores before suctioning (p=0.429), while there was a statistically significant difference during (p<0.001) and after (p<0.001) suctioning. Accordingly, the NCBS score medians of the neonates in the intervention group during and after suctioning were statistically significantly lower than the control group. As a result of the Friedman test applied, there was a statistically significant difference the times in terms of median level of NCBS intervention (p<0.001) and control groups (p<0.001). When time differences (significance between measurements) were examined; In the intervention group, the increase in NCBS score medians during (p<0.001) and after suctioning (p=0.004) was found to be statistically significant according to before suctioning, while the decrease that occurred after suctioning was statistically significant according to during suctioning (p<0.001). In the control group, the increase in NCBS score medians during (p<0.001) and after suctioning (p<0.001) was found to be statistically significant according to before suctioning, while the decrease that occurred after suctioning was statistically significant according to during suctioning (p=0.003) (Table 5).

Table 2. The descriptive characteristics of neonates*

Characteristics	Intervention group (n=33)		Control group (n=33)		Total (n=66)		x^2	P
	n	%	n	%	n	%		
Sex								
Female	15	45.5	16	48.5	31	47	0.061	0.805
Male	18	54.5	17	51.5	35	53		
Mode of delivery								
Caesarean	22	66.7	24	72.7	46	69.7	0.287	0.592
Normal	11	33.3	9	27.3	20	30.3		
Medical diagnosis								
Respiratory system diseases	28	84.8	28	84.8	56	84.8	<0.001	1
Other*	5	15.2	5	15.2	10	15.2		

*Intrauterine growth retardation (4), Meconium aspiration syndrome (6)

Table 3. Comparison of age and physical characteristics of neonates by groups*

Characteristics	Intervention group median (min-max)	Control group Median (min-max)	MW*	P
Gestational age	38.30 (37-40.2)	38.30 (37.0-40.2)	0.773	0.44
Postnatal age	1.00 (1-30)	1 (1-30)	0.459	0.646
Birth weight (g)	3.26 (1.54-4.3)	3.26 (1.54-4.3)	-0.205	0.837
Birt length (cm)	48 (36-53)	50 (36-54)	1.141	0.157
Birt head circumference (cm)	35 (30-38)	35(30-38)	0.557	0.577

*Mann Whitney-U test

Table 4. Examination of the NIPS score differences according to the group and time*

Groups	Before suctioning (1) median (min-max)	During suctioning (2) median (min-max)	After suctioning (3) median (min-max)	F**	p	Difference
Intervention group	0 (0-0)	4 (1-7)	2 (0-4)	61.443	<0.001	2 > 3
Control group	0 (0-0)	7 (3-7)	6 (0-7)	58.308	<0.001	
MW*	<0.001	4.845	6.725			
P	1	<0.001	<0.001			

*Mann Whitney-U test, **Friedman test

Table 5. Examination of the NCBS score differences according to the group and time*

Groups	Before suctioning (1) median (min-max)	During suctioning (2) median (min-max)	After suctioning (3) median (min-max)	F**	P	Difference
Intervention group	6 (6-10)	16 (10-28)	13 (6-19)	60.452	<0.001	1 < 2 > 3
Control group	6 (6-9)	23 (16-30)	19 (15-25)	61.477	<0.001	1 < 2 > 3
MW*	-0.79	5.371	6.483			
P	0.429	<0.001	<0.001			

* Mann Whitney-U test, **Friedman test

Discussion

Some factors are effective in sensing pain and creating a response to pain in neonates. These factors include sex, gestational age, birth weight, age, mode of delivery, neonatal illness severity, procedural pain exposure.[31–33] In this study, features such as sex, mode of delivery, medical diagnosis, gestational and postnatal age, birth weight, length and head circumference were homogeneous in the intervention and control groups. Therefore, while evaluating the effectiveness of applied foot reflexology on pain and comfort level, the possibility of being affected by these features was eliminated.

The hypotheses which are created in the planning stage of our study that "the foot reflexology applied to the neonatal is effective in reducing the pain that develops during the suctioning procedure and continues after the suctioning procedure" have been confirmed. When we look at the difference of pain scores over time; the median NIPS score decreased significantly over time only in the intervention group.

In this study, while evaluating the effectiveness of foot reflexology applied to neonates in reducing pain during and after the procedure; in the literature, the effects of reflexology on pain after the procedure have been examined. In these studies, they have been reported that foot reflexology applied to neonates and infants before procedure is effective in reducing acute pain after procedure.[17,21] In another study; while there was no statistically significant difference between the reflexology and control groups in terms of NIPS scores during the heel lance procedure, it has been reported that there was a statistically significant difference between the two groups in favor of the reflexology group in the NIPS scores after the heel lance procedure.[22] In our study, it was found that there was a statistically significant difference in favor of the intervention group (reflexology) between the two groups in terms of NIPS scores both during and after the suctioning procedure, and it was not consistent with this study. Reflexology based on touching skills is a form of massage that regulates body functions.[34] Foot massage and reflexology are some of the pain management procedures for neonates.[35] In studies evaluating the effectiveness of foot massage on pain, in accordance with our study, foot massage applied to neonates was found to be effective in reducing the pain of neonates.[24,36]

Painful and stressful interventions in the neonatal accompany the deterioration of the comfort of the neonatal.[37] In addition, physical structure, medical care and invasive procedures in NICU can cause loss of comfort in the neonatal.[29] In our study, the state of affecting comfort due to only the suctioning procedure performed on neonates was examined. The hypotheses which are created in the planning stage of our study that "the foot reflexology applied to the neonatal is effective in increasing the comfort of the neonatal during and after the suctioning procedure" have been confirmed. When we look at the difference of comfort scores over time, the comfort score medians decreased significantly after suctioning compared to during suctioning in both the intervention and control groups. The comfort level of neonates in the intervention group after suctioning is 13 points, and it can be said that these neonates are comfortable. However, the comfort level of neonates in the control group after suctioning is 19 points (14-30 points on the scale indicates that the neonate has pain and distress), and it can be said

that the distress of these neonates still continues even if the suctioning procedure is completed. Although there is no study in the literature examining the effect of reflexology directly on comfort; in one study, reflexology was reported to have positive effects in infantile colic, which is thought to negatively affect the comfort of infants.[34] In addition, the application of non-pharmacological methods other than reflexology has been reported to be effective in reducing the pain of the neonatal as well as increasing comfort, as seen in our study.[5,37,38]

Strengths and limitations

In order to fill the scales used objectively, the scales were administered by another nurse working at NICU, other than the researchers. While the nurse was administering the scales, it was ensured that the nurse did not know the neonates who underwent reflexology. The fact that the person evaluating the scales (the pain and comfort scores) is not one of the researchers, being a competent nurse working in this NICU and does not know which group the neonates are in (intervention or control?) is one of the strengths of the research. However, one of the weaknesses of the study is that the person evaluating the scales was the only person and the video recording could not be taken.

Conclusion

It was concluded that foot reflexology applied to neonates was effective in reducing pain that developed during the suctioning procedure and continued afterwards. It was concluded that the applied reflexology was effective both during and after the suctioning procedure in increasing the comforts that are directly related to the pain felt by neonates.

It was concluded that foot reflexology can be used in the management of procedural pain caused by suctioning in neonates. Based on this, nurses can use foot reflexology before the suctioning procedure for the pain sensation and comfort deterioration that may develop due to the suctioning in the neonates. In-service trainings on CHAs such as reflexology and massage, which can be used in the management of procedural pain in neonates, can be organized for nurses.

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Declarations

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Author contributions

Conceptualization, Ö.Ö.Ş. and N.E.O.; Methodology, Ö.Ö.Ş. and N.E.O; Software, N.E.O.; Validation, N.E.O.; Formal Analysis, Ö.Ö.Ş. and N.E.O. ; Investigation, N.E.O.; Resources, Ö.Ö.Ş and N.E.O.; Data Curation, Ö.Ö.Ş and N.E.O; Writing – Original Draft Preparation, N.E.O.; Writing – Review & Editing, Ö.Ö.Ş.; Visualization, Ö.Ö.Ş.; Supervision, Ö.Ö.Ş.

Conflicts of interest

The authors declare no conflict of interest.

Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval

The parents of all neonates were interviewed with information about the study. Verbal and written consent was obtained from the parents who agreed to participate in the study based on volunteering. The study was conducted in accordance with the ethical standards in the Helsinki Declaration of 1975, asrevised in 2008. Ethics approval for the study was taken from Republic of Turkey Ministry of Health Dr. Zekai Tahir Burak Women's Health Education and Research Hospital, the Clinical Research Ethics Committee (Date: 28/02/2017, Decision No. 35/2017), and an intitutional permission was obtained from the Ankara University Faculty of Medicine, Department of Child Health and Diseases (Number: 69545805-806.01.03-H.29765). Scale permissions for NIPS and NCBS uses used in the study were obtained via e-mail.

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