



Effect of Breast-Feeding and Maternal Holding in Relieving Painful Responses in Full-Term Neonates

A Randomized Clinical Trial

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ABSTRACT

This randomized clinical trial was conducted to determine the efficacy of breast-feeding with maternal holding as compared with maternal holding without breast-feeding in relieving painful responses during heel lance blood drawing in full-term neonates. A convenience sample of 128 full-term newborn infants, in their fourth to sixth days of life, undergoing heel lance blood drawing for screening of hypothyroidism were included in the study. The neonates were randomly assigned into 2 equivalent groups. During heel lance blood drawing for infants, they either breast-fed with maternal holding (group I) or were held in their mother's lap without breast-feeding (group II). The painful responses were assessed simultaneously by 2 neonatal nurses blinded to the purpose of the study. Outcome measures for painful responses of the full-term neonates were evaluated with the Premature Infant Pain Profile scale. Independent *t* test showed significant differences in Premature Infant Pain Profile scale scores among the 2 groups ($t = -8.447$, $P = .000$). Pain scores were significantly lower among infants who were breast-fed in addition to maternal holding.

Evidence from this study indicates that the combination of breast-feeding with maternal holding reduces painful responses of full-term infants during heel lance blood drawing.

Key Words: breast-feeding, heel lance, pain

Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage.”^{1(p454)} All full-term neonates have the ability to feel pain. Neonates respond to pain through various physiologic and behavioral responses; within their developmental abilities, neonates have sufficient abilities to meet the requirements and demands of any painful situation.² Normally, neonates undergo various minor painful procedures during their routine daily care. Several studies have shown that neonates have sufficient anatomic, functional, and neurochemical structures for feeling pain.^{3,4} Previous data suggest that untreated pain early in life may cause deleterious effects on the developing central nervous system.^{4–7} Pain can lead to decreased oxygenation, hemodynamic instability, increased intracranial pressure, emotional problems, hyperactivity-attention disorders, and defects in social skills.⁸ In response to this, both the International Evidence-Based Group for Neonatal Pain⁹ and the American Academy of Pediatrics¹ have made it a priority to reduce pain in infants and recommended the use of nonpharmacologic interventions as the first choice in uncompromised infants.¹⁰ Accordingly, the number of painful stimuli needs to be kept to minimum and every effort should be made to render them less painful. Clinical studies have shown reduction in changes in

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physiologic parameters and pain score measurements following preemptive nonpharmacologic measures in situations where the neonate is experiencing pain or stress.¹¹

The knowledge that even short-term pain can have lasting negative effects has led many neonatal nurses to develop strategies to alleviate pain caused by diagnostic and therapeutic procedures undergone by newborns. As a result, the efficacy of numerous nonpharmacologic interventions for common painful procedures in neonates, such as heel lance and venipuncture, has been well established.¹² Behavioral strategies such as containment, nesting, swaddling, maintaining flexed position, postural support, touch, massage, rocking, facilitated tucking, music, intrauterine sounds, skin-to-skin contact, and nonnutritive sucking are all effective nonpharmacologic strategies for pain relief and comfort enhancement.^{13–17}

For neonates who receive intensive care, it is accepted that analgesics are administered intravenously to relieve pain. Neonates who are less sick or who are not in neonatal intensive care units, however, usually do not receive any analgesics for painful procedures. Obviously, analgesics cannot be used for occasional blood sampling performed in newborns who do not need intensive care; it is therefore essential for neonatal nurses to find simple and well-tolerated methods to reduce pain in these neonates.

Within the Jordanian context, breast-feeding is culturally encouraged and can be a readily acceptable intervention for blood sampling. The Jordan Population Family Health Survey¹⁸ collected data on infant feeding for all children born in the 5 years preceding the survey. The results of survey showed that 23% of mothers exclusively breast-feed their children during the first 6 months of life. Among infants 0 to 5 months old, 13% are not breast-feeding, 9% are given water along with breast milk, and 55% are breast-fed with consuming other food sources such as nonmilk liquid, bottle milk, and solid food contents. A cross-sectional study in the north of Jordan showed that 88.1% have ever breast-fed their babies. Of those who breast-fed their babies, 40.7% have breast-fed their babies for the first 3 months of life, 21% continued breast-feeding for 6 months, and 17.5% continued breast-feeding for the first 12 months of life.¹⁹

During breast-feeding and maternal holding, the newborn will experience sensory inputs that may enhance the analgesic effects. A multisensorial approach, in which the neonate combines taste and sucking of the mother's milk while being held by the mother, provides tactile, auditory, visual, and olfactory inputs that can lead to sensory saturation that relieves pain for the full-term infant.¹⁷ The analgesic effect of breast-feeding dur-

ing heel lance procedures was studied using validated pain scales in 2 randomized clinical trials (RCTs),^{20,21} and the results indicate that breast-feeding provided superior analgesia when compared with oral sucrose or maternal holding.

Codipietro et al²⁰ conducted an RCT to compare the efficacy of breast-feeding versus orally administered sucrose solution in reducing pain response during blood sampling through heel lance in 101 full-term neonates. Group I ($n = 51$) received breast-feeding while being held by their mothers and there was continuous active suction prior to heel lance. Group II ($n = 50$) were laid on a changing table and received 1 mL of 25% sucrose solution through a syringe into the mouth 2 minutes prior to heel lance. The primary outcome measured was the pain score measure by the Premature Infant Pain Profile (PIPP) scale, and the secondary outcome measures were increase in heart rate, decrease in oxygen saturation, duration of first cry, percentage of crying in the first 2 minutes after the procedure, and the number of heel lance procedures performed for each blood sampling. Median group differences were calculated for all outcome measures using the Wilcoxon-Mann-Whitney test. Results indicated that there were significant differences between the groups. Specifically, the median PIPP score was 3 for the breast-feeding group indicating minimal pain and 8.5 for the sucrose group indicating moderate pain. These researchers concluded that breast-feeding provides superior analgesia for heel lance compared with oral sucrose in full-term neonates.

Leite et al²¹ compared the effects of breast-feeding versus maternal holding in an RCT including 60 healthy term newborns undergoing heel lance for routine newborn screening. Infants in group I ($n = 31$) were held by the mother and were breast-feeding with effective sucking movements 5 minutes prior to the procedure, and those in group II ($n = 29$) were held by the mother for the same length of time. The outcomes measures were the Neonatal Facial Coding System and the change in heart rate. The Mann-Whitney U statistical test comparing Neonatal Facial Coding System scores among the 2 groups revealed significantly lower scores for the breast-feeding group during blood collection ($U = 116.5$, $P < .001$), compression ($U = 88.0$, $P < .001$), and recovery phases ($U = 184.0$, $P < .001$).

For the purpose of this study, the following assumptions were made. Heel lance is a painful procedure and it is considered a painful stimulus that elicits nociceptive pain. The experience of pain that would be observed in this study reflects the neonates' true ability to respond to pain. The purpose of this study was to examine the efficacy of breast-feeding with maternal holding in relieving painful responses during heel lance

blood drawing in full-term neonates as compared with maternal holding without breast-feeding. Specifically, the hypothesis “full-term neonates who are breast-fed while being held in their mothers’ arms will experience less pain than those who are just held in their mothers’ arms during a heel lance procedure” was tested.

MATERIALS AND METHODS

The study was conducted at the neonatal unit of a major teaching hospital in Amman, Jordan, between January and June 2013. The study protocol and informed consent forms were approved by the ethical committee of the Royal Medical Services of Jordan.

Study design

This prospective RCT was designed to compare 2 different interventions for decreasing pain associated with heel lance in full-term neonates. Accordingly, infants in the experimental group (group I) received breast-feeding combined with maternal holding and those in the control group (group II) received only maternal holding while blood was drawn by heel lance. The primary outcome measure was the difference in the mean pain scores following heel lance between the 2 groups as measured by the PIPP scale. To compare potential differences between the 2 groups prior to heel lance, infant demographic data, baseline pain score, heart rate, and oxygen saturation were obtained. Random assignment to 2 groups was done. Following assessment of eligibility and recruitment, a research assistant blindly drew a card for each subject from an envelope containing equal numbers of cards representing each group and assigned each newborn to either group I or group II.

Sample selection

The study involved a convenience sample of 128 healthy, full-term, breast-fed neonates who were scheduled to receive routine heel lance blood drawing for hypothyroidism screening. The inclusion criteria were as follows: full term neonates (38-42 weeks of gestation) who underwent heel lance blood drawing for routine hypothyroidism screening, aged 4 to 6 days, no feeding occurred in the previous 30 minutes, and Apgar score ranged from “7 to 10” at “1 and 5” minutes. Exclusion criteria were the presence of medical instability, artificial feeding, and neonates with a diagnosis of neurodevelopmental health problems with which their responses to painful stimuli may be altered. A sample size of 64 infants in each group was calculated using G*Power 3.1.7 software to achieve 80% power in detecting a difference in the mean of PIPP scores between group I

and group II at a significance level of .05 assuming a medium effect size (0.5).

Instruments

Heart rate and oxygen saturation were measured using a pulse oximeter (Nellcor N-180; Nellcor Puritan Bennett, Hayward, CA). Pain was assessed using the PIPP scale. This scale is a 7-indicator pain measure that includes behavioral (time of brow bulge, eye squeeze, and nasolabial furrow), physiologic (changes in heart rate and oxygen saturation), and contextual indicators (gestational age and overall behavioral state). Scoring of up to 4 points (0, 1, 2, 3) is used for each of the 7 indicators of the PIPP scale for a possible total score of 18 for full-term neonates.²² A score of 6 or less generally indicates minimal or no pain, and a score of 7 to 11 indicates moderate pain. Scores of 12 or more indicate severe pain.²³

The PIPP scale is a reliable and valid measure of acute pain in infants as indicated by numerous studies.²⁴ It was derived from multiple data sets and has been shown to have face and content validity. Construct validity had been tested by multiple test data sets including infants of a variety of gestational ages and level of illness acuity.^{22,24} Findings from these studies indicated that PIPP scores between pain and nonpain situations are significantly different, with interrater reliability coefficients of 0.93 to 0.96. The intrarater reliability coefficients for individual events were 0.94 to 0.98, suggesting that the PIPP scale is accurately discriminating between pain and nonpain situations in this population. The internal consistency of the PIPP scale was evaluated using the Cronbach α . The α coefficient for the indicators ranged from .59 for behavioral state to .76 for the eye squeeze; these coefficients are in the moderate range.²²

Study procedure

Subject recruitment took place in the maternity ward. Mothers who had delivered a normal full-term neonate and had initiated breast-feeding were approached on the next day following delivery. They were informed of the study, and those who opted to participate (a total of 135 mothers were approached to reach the required sample size of 128 infants) signed an informed consent form during the discharge process from the maternity ward. The study was performed in the neonatal unit where the recruited neonates were given an appointment for routine screening of hypothyroidism on the fourth to sixth days following birth.

Neonates in group I ($n = 64$) who underwent heel lance blood sampling were breast-fed and held in their mothers’ lap while their mothers were seated reclining on a comfortable chair. Neonates in group II

($n = 64$) underwent sampling under the same conditions with the exception of breast-feeding. All neonates were awake at the time of the procedure. Breast-feeding neonates were observed for active sucking before heel lance. The mothers in group I were instructed to continue breast-feeding and cuddling if the infants started to cry during or after the heel lance blood drawing. The mothers in group II were instructed to continue cuddling if the infants started to cry during and after the heel lance blood drawing. Heel lance procedures were done with a Quikheel lancet (Becton, Dickinson and Company, Franklin Lakes, NJ), a 1-time use instrument with a standardized 1.00-mm incision depth. The same experienced skillful neonatal nurse performed all blood collections to reduce variability and human errors between the groups. The average time for blood drawing was 3 minutes for both groups. The heel was warmed up for around 2 minutes with a warm pad before the procedure. A pulse oximeter probe was placed on the big toe of the left or right foot to enable oxygen saturation and heart rate monitoring.

The painful responses of all neonates were measured using the PIPP scale simultaneously by 2 neonatal nurses who were blinded to the objectives of the study. PIPP scores were obtained on 2 occasions. Baseline scores were obtained immediately prior to heel lance while the neonates were held and breast-fed in their mother's arms or only held. The second set of scores was obtained immediately following heel lance. Interrater reliability analysis of individual event scores of the PIPP scale yielded reliability coefficients of 0.92 to 0.95.

Data analysis

Data were analyzed using SPSS (version 19) and included descriptive and inferential statistics. The level of significance set was .05. Mean and standard deviation (SD) were calculated for the subjects' demographics. Baseline heart rate, oxygen saturation, and PIPP scores

were obtained for each subject before the heel lance. The independent-samples t test was used to detect any differences in the baseline data between the 2 groups. PIPP scores obtained during the recovery period from heel lance at 3 minutes following the procedure were compared using a 2-tailed independent-samples t test to determine any significant differences between the experimental and control groups.

RESULTS

A total of 128 full-term neonates participated in the study. Table 1 summarizes the newborn characteristics. The mean gestational age was 38 weeks for both the experimental and control groups. The mean postnatal age was 5.7 (SD = 0.46) and 5.9 (SD = 0.52) days, and the birth weight was 3.34 (SD = 0.26) and 3.37 (SD = 0.28) kg, respectively. Male to female distribution and mode of delivery were mostly similar among both groups. There were no significant differences in the baseline heart rate, oxygen saturation, or PIPP scores before heel lance blood draws between group I and group II (see Table 2). These indicate that newborn infants in both groups, before heel lance procedures, were comparable, as there was no variability of the baseline data.

Comparison of PIPP scores obtained immediately after heel lance revealed that there were notable differences in the means of PIPP scores of the breast-feeding with maternal holding group ($M = 9.65$, $SD = 1.94$) as compared with the maternal holding-only group ($M = 13.32$, $SD = 2.75$). Two-tailed independent-samples t test was performed at 95% confidence interval ($t = -8.447$, $df = 105.6$) revealing significant differences between the PIPP scores ($P = .000$) of the 2 groups (see Table 3). Accordingly, the PIPP scores of the breast-feeding with maternal holding group were significantly lower and the research hypothesis "full-term neonates

Table 1. Demographic data and characteristics of neonates

	Group I: Breast-feeding with maternal holding ($n = 64$)	Group II: Maternal holding ($n = 64$)
Gestational age, mean (SD), wk	38 (0.80)	38 (0.89)
Postnatal age, mean (SD), d	5.70 (0.46)	5.9 (0.52)
Birth weight, mean (SD), kg	3.34 (0.26)	3.37 (0.28)
Apgar scores at 5 min, mean (SD)	7.82 (0.81)	7.83 (0.82)
Gender, n (%)		
Male	27 (42)	29 (45)
Female	37 (58)	35 (55)
Mode of delivery, n (%)		
Cesarean	35 (55)	31 (48)
Vaginal	29 (45)	33 (52)

Table 2. Mean, standard deviation, results for independent-samples *t* test of baseline variables prior to heel lance

Baseline variable	Group I: Breast-feeding with maternal holding (<i>n</i> = 64), mean (SD)	Group II: Maternal holding (<i>n</i> = 64), mean (SD)	<i>t</i>	<i>P</i>
Heart rate	142.5 (8.4)	142.4 (8.4)	1.8	.083
Oxygen saturation	93.9 (2.3)	93.7 (2.4)	1.9	.062
PIPP score	0.88 (0.8)	0.88 (0.8)	.000	1.000

Abbreviation: PIPP, Premature Infant Pain Profile.

who are breast-fed while being held in their mothers' arms will experience less pain than those who are just held in their mothers' arms during a heel lance procedure" was accepted on the basis of these results.

DISCUSSION

The sample of this study was representative of healthy full-term infants in the first week of their lives. The characteristics of the sample were demographically homogeneous. Subjects were randomized into the treatment and control groups. Baseline data, including heart rate, oxygen saturation, and PIPP scores prior to heel lance blood draws, indicated no significant differences between the treatment and control groups. Randomization and use of control group design increased the external validity, whereas the absence of significant differences in the baseline data between the 2 groups ensured the absence of selection bias and therefore increased the internal validity of the study.

The findings of this study indicated that full-term infants who were breast-fed and held by their mothers experienced less pain as than those who were held only by their mothers during heel lance blood drawing as evidenced by PIPP scores. There are 2 previous studies in the literature that assessed the effectiveness of breast-feeding among full-term neonates in reducing procedural pain during heel lance blood drawing. Our findings support the findings of both Leite et al and Codipietro et al. Leite et al²¹ reported significantly lower Neonatal Facial Coding System scores among breast-fed neonates

than those being held in their mothers arms. Codipietro et al²⁰ reported significantly lower PIPP scores among breast-feeding neonates than oral sucrose-fed neonates. However, Codipietro et al reported that breast-fed infants had a median PIPP score of 3, which indicates mild pain, whereas our findings indicated a mean PIPP score of 9.65 (SD = 1.94), which indicates moderate pain. This discrepancy cannot be explained because of comparison of medians and means because our data did not have outliers that could influence the mean PIPP score as demonstrated by the small SD. Furthermore, the PIPP scale has been shown to have high interrater reliability and therefore this difference in scores should not be due to differences among the raters in the 2 studies. One possible cause of this discrepancy is that heel pricks were conducted using different piercing devices. In our study, we used a Quikheel lancet with a standardized 1.00-mm incision depth whereas Codipietro et al used an Accu-Chek Softclix Pro (Roche Diagnostics, Burgess Hill, West Sussex, UK) set at level 3. These devices may have different piecing properties such as gauge, depth, and speed of skin prick. Future studies assessing pain intensity while comparing the use of different devices for heel prick may be enlightening.

The results of our study may be further explained within the context of pain relief by breast milk, breast-feeding, and maternal holding. The breast-feeding process itself leads to activation of endogenous opioids through orogustatory stimulation^{25,26}; furthermore, breast milk contains tryptophan,²⁷ which may have a nociceptive effect because it is a precursor of

Table 3. Results of 2-tailed independent-samples *t* test of PIPP scores following heel lance

Group	PIPP scores, mean (SD)	<i>t</i>	<i>P</i>
Group I: Breast-feeding with maternal holding (<i>n</i> = 64)	9.65 (1.94)	-8.447	.000
Group II: Maternal holding (<i>n</i> = 64)	13.32 (2.75)		

Abbreviation: PIPP, Premature Infant Pain Profile.

melatonin. Melatonin is known to increase the concentration of β -endorphin.²⁸ Evidence further indicates that neonates have some ability for olfactory processing of familiar odors such as those associated with mother's milk and that this memory recognition is associated with diminished pain responses during heel lance procedure.^{29–31} Moreover, the breast-feeding process where the neonate is exposed to direct contact with the mothers' chest may have an analgesic effect. Evidence indicates that skin-to-skin contact is a remarkably potent intervention against the pain experience during heel lance in newborns.³²

IMPLICATIONS FOR PRACTICE

The findings of this study support that breast-feeding can provide an analgesic effect in newborns. This result is clinically important, as it reveals that healthy full-term neonates can benefit from breast-feeding in addition to maternal holding to produce analgesic effect. Therefore, we recommend encouragement of breast-feeding to alleviate pain in neonates undergoing minimally invasive procedures such as heel lance. Encouraging breast-feeding during painful procedures may also alleviate the anxiety felt by the mother. Actively involving the mothers in their infant's care may be a comforting measure for mothers, as it may prevent feelings of helplessness and separation anxiety.

STUDY LIMITATIONS

A limitation in our study was that the 2 nurses who assessed the PIPP scores of infants were able to recognize the control and treatment groups. However, the possibility of bias was minimized by blinding the assessing nurses to the purpose of the study. The use of the PIPP scale for pain assessment may also be considered a limitation of the study. Although this scale has been validated and used on numerous studies, it assumes that a modification in physiologic and behavioral pain indicators reflects the real pain felt by neonates. Pain is a subjective phenomenon and therefore its assessment should be based on self-report. However, this is not possible in newborns; therefore, the use of a pain assessment scale is a necessity if any pain management is going to be achieved. Additional outcome measures such as changes in physiologic parameters, crying duration, or additional pain assessment scales were not used in this study. These measures could have provided data to better interpret the findings of the study.

CONCLUSION

Minor painful procedures such as blood sampling are common in full-term neonates. The use of nonphar-

macologic approaches for pain management should be encouraged because pharmacologic treatment may not be appropriate for acute, repetitive, and short-lasting procedures. Maternal holding with breast-feeding is a natural, noninvasive, accessible, and culturally appropriate intervention and should be readily adopted as an intervention to control and reduce pain during heel lance blood sampling by nurses who work with newborns. Updating practice guidelines for heel lance blood drawing in the neonatal unit to include maternal breast-feeding as an analgesic intervention in addition to other evidence-based strategies, such as nonnutritive sucking, positive touch and massage, skin-to-skin contact, and oral sucrose, will enable the delivery of evidence-based, high-quality care.

Future research needs to be undertaken to evaluate the analgesic effects of breast-feeding for painful procedures such as repeated heel lance. Current research, including our study, focuses on testing nonpharmacologic analgesic interventions, such as breast-feeding, mostly on healthy full-term neonates undergoing a 1-time painful procedure. In order for the results to be applicable, sampling should include sicker and smaller neonates who in reality are more likely to undergo repeated painful procedures. The results of this study indicated that breast-feeding was effective in eliciting a moderate pain response in the infants; however, clinicians should strive for interventions that elicit a minimal pain response. Further studies that combine breast-feeding with other pain-reduction strategies may reveal interventions that are more effective in pain management.

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