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Comparing the Analgesic Effects of 4 Nonpharmacologic Interventions on Term Newborns Undergoing Heel Lance

A Randomized Controlled Trial

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ABSTRACT

This randomized trial compared the analgesic effect of 4 nonpharmacologic interventions (breastfeeding, oral sucrose, nonnutritive sucking, and skin-to-skin contact) on term newborns between 24 and 48 hours of age who underwent a heel lance. The Neonatal Pain, Agitation, and Sedation Scale was used to evaluate pain. The newborns ($N = 226$) were assigned to one of 4 intervention groups ($n = 176$) or a control group without pain intervention ($n = 50$). The results indicate that all intervention groups showed decreased pain levels when compared with the control group ($P < .01$). The oral sucrose group experienced a superior analgesic effect when compared with the skin-to-skin contact group ($P < .01$), but no difference was observed when compared with the breastfeeding group ($P > .05$) or the nonnutritive sucking group ($P > .05$). All intervention groups showed a shortened crying time ($P < .01$) and reduced procedural duration ($P < .01$) compared with the control group. All of these interventions are clinically applicable and acceptable when caring for a newborn during a minor painful procedure.

Key Words: newborns, nonpharmacologic intervention, pain control

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Neonatal pain management in the clinical setting is a burgeoning field of research. Implementing pain interventions for newborns who undergo minor procedures has become increasingly common.[1] Multiple studies have shown that the newborn nervous system is mature enough to perceive pain; this puts newborns at risk of experiencing short- and long-term negative effects.[2,3] In the hospital, newborns are frequently subjected to invasive diagnostic and therapeutic procedures that are painful. During their hospital stay, every healthy term newborn is required to have a blood sample drawn by heel lance as a newborn screening test. Pharmacologic interventions are not standard therapy for neonates who undergo minor painful procedures because analgesic medications raise concerns about associated adverse effects.[4] These common, minor, painful procedures are usually accompanied by inadequate pain management.[5]

Several nonpharmacologic modalities have been reported to have analgesic effects on newborns who undergo minor procedures; these include breastfeeding, oral sucrose, nonnutritive sucking, skin-to-skin contact, music, swaddling, warmth, and tucking.[1,6–10] Of these, breastfeeding, oral sucrose, nonnutritive sucking, and skin-to-skin contact have been the most commonly studied. However, analgesic efficacies of these

nonpharmacologic modalities have been inconsistent, even contradictory.[1] No studies have yet been published that compare the outcomes of nonpharmacologic pain interventions with the goal of identifying the most effective, safe, reliable, and feasible interventions for neonates.[9,11,12]

The primary aim of this study was to compare the analgesic effect of 4 nonpharmacologic interventions (ie, breastfeeding, oral sucrose, nonnutritive sucking, and skin-to-skin contact) on healthy term newborns between 24 and 48 hours of age who underwent a heel lance. The secondary aim was to assess the effect that these interventions had on the duration of crying and time required to perform the procedure. To the best of our knowledge, ours is the first study to compare the analgesic effects of 4 nonpharmacologic interventions (breastfeeding, oral sucrose, nonnutritive sucking, and skin-to-skin contact) on healthy term newborns.

METHODS

Design

This study was designed to investigate the analgesic benefits of 4 nonpharmacologic treatments of infants who were to undergo the heel lance procedure. The study nurses were trained postpartum nurses. Infants undergoing this procedure were initially identified by medical record review; thereafter, the study obtained inform consent from a legal guardian. A control group of infants who fit the inclusion criteria were selected prior to the randomization into the 4 intervention groups. A random number generator was used that ensured appropriate randomization to each of the 4 intervention groups. This study was not blinded; parents of the newborns and nurses were aware of the treatment group assignment. Privacy was ensured by using curtains in semiprivate rooms or closed doors for infants in private rooms.

All newborn participants received a pulse probe, which was attached to their right foot to monitor heart rate. A heel lance was performed by a hospital phlebotomist who followed standard hospital protocol. Two study nurses scored infant discomfort on the Neonatal Pain, Agitation, and Sedation Scale (NPASS) before and immediately after the heel lance and throughout the blood sampling procedure. Procedure duration was measured from the moment the heal lance poked the infant to the completion of the blood collection. NPASS scores of 3 or less are considered effective pain control.[13] Each group received the following interventions:

Breastfeeding group: Breastfeeding was initiated before the heel lance and maintained throughout the procedure. A study nurse ensured that infants were firmly latched (infants mouth is wide open and against the mother breast with rhythmic sucking) onto their mother's breast and actively breastfeeding before proceeding with the procedure.

Oral sucrose group: Infants received 5 drops (0.33 mL) of sucrose orally by the study nurse through a plastic vial of oral 24% sucrose TootSweet (TootSweet; Natus Medical, San Carlos, California) before the heel lance and again during the procedure if more cues of pain were displayed, up to 15 drops (1 mL).

Nonnutritive sucking group: Infants received pacifiers before and during the procedure.

Skin-to-skin contact group: Newborns wore only diapers and were positioned on their mother's bare chest immediately before the procedure.

*Control grou*p: The control group was recruited prior to the randomization of the 4 intervention groups based on the existing inclusion criteria. Newborns were placed in a crib in supine position and covered with blankets.

Setting

This randomized controlled clinical study was conducted in a California tertiary-level hospital maternity unit (42 mother-baby beds) from September 2013 to September 2015. A Letter of Determination was received from the institutional review board (IRB) on January 11, 2013, stating that this project did not meet the federal definition of research; however, after beginning the study, it was determined that a full IRB approval was necessary and this study did meet the federal definition of research. The IRB granted approval for this study on September 30, 2014, by the University Office of Human Subjects.

Sample

Newborns were eligible to participate in either the control or intervention groups if they (1) were 38 to 40 weeks' gestational age, (2) weighed 2.5 to 4.0 kg, (3) were 24 to 48 hours old, (4) were more than 24 hours old when receiving the heel lance procedure as a newborn screen test, (5) had an Apgar score of more than 7 at 1 minute of birth, and (6) had an NPASS score of less than 3 before the heel lance procedure. Newborns were excluded from participation if they (1) had a prior heel lance procedure; (2) had birth trauma including but not limited to cephalohematoma, lacerations, and fractures; (3) had a forceps or vacuum delivery; and (4) were delivered of a mother who used drugs during pregnancy. Two hundred thirty-six healthy term newborns were identified. Because 10 of the newborns did not

meet the inclusion criteria, 226 infants were ultimately enrolled and completed the study (see Figure 1).

Procedure

A fully automated heel incision device, the Tenderfoot (TF50I; Accriva Diagnostics, Bedford, Massachusetts), was used to perform the heel lance procedure in this study population. All heel lances were performed on the outside surface of the infants' left heel after the heel had been warmed. Oxygen saturation and heart rate were recorded by a Masimo SET machine (model no. 3293900; Masimo, Irvine, California). For infants in the oral sucrose group, a 1-mL plastic vial of oral 24% sucrose TootSweet was used; no additional pacifier was provided.

Measurement

The NPASS was used to evaluate neonatal pain because it provides usable, consistent, and age-appropriate assessment for infant pain and is a reliable and valid assessment tool.[13] The NPASS measures the behavioral and physiological components of pain in newborns by evaluating crying/irritability, behavioral status, facial expression, extremity tone, and vital signs. This scale ranges from 0 (*no pain*) to 10 (*extreme pain*). Higher scores indicate greater pain.

Data collection

NPASS scores for the intervention groups and the control group were collected by 2 study nurses. The study nurses' scores were averaged and, if the difference between them was more than 2, the data were eliminated from the study to achieve consensus. Duration of the procedure was calculated from the point of lancet puncture until blood collection was completed. NPASS scores were collected at these same procedure points.

Data analysis

Demographic data were collected for newborns in all 5 groups. Data were entered into software (Research Electronic Data Capture [REDCap]) and analyzed using the χ^2 test (categorical variables >5) or Fisher's exact test (categorical variables ≤5).

Continuous variables were analyzed with one-way analysis of variance for results with normal distribution or the Kruskal-Wallis test for those with nonparametric distributions. To analyze whether the characteristics were associated with NPASS scores, a *t* test was used for 2 independent samples with normal distribution or the Wilcoxon-Mann-Whitney test was used for nonparametric distribution data. Spearman's rank correlation coefficient was used to analyze the correlation of newborns' crying time and the duration of procedure with NPASS scores. A *P* value of .05 was considered a statistically significant difference.

RESULTS

Of the 236 neonates who were considered for this study, 226 met the inclusion criteria (see Figure 1). They were assigned to interventions as follows: the nonnutritive sucking group ($n = 51$), the breastfeeding group ($n = 45$), the oral sucrose group ($n = 42$), and the skin-to-skin contact group ($n = 38$). Fifty newborns were

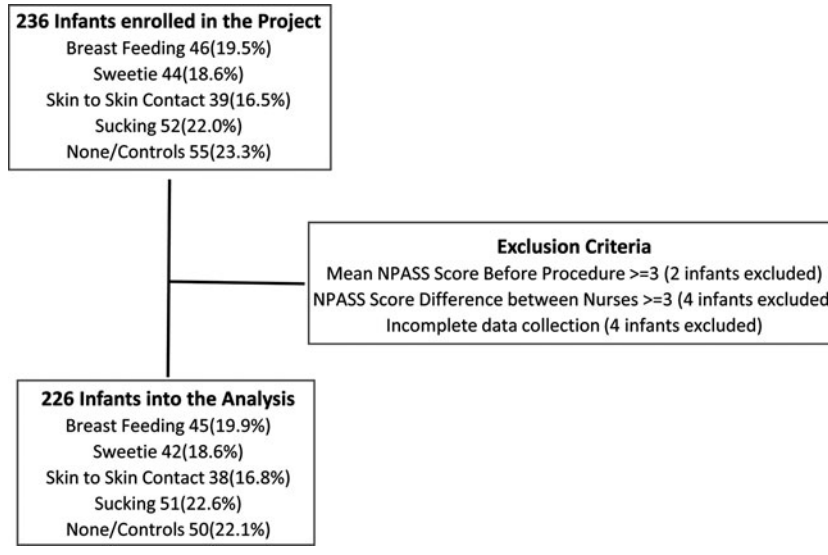

Figure 1. Participation flow diagram.

assigned to a control group. No statistical difference between the treatment groups and the control group was observed in baseline demographics: gestational age, birth weight, sex, Apgar score, maternal age, parity, and mode of delivery. The mean NPASS score for heel lance in the control group was 5.14; a score of more than 3 generally indicates that a pain control intervention should be implemented.[13] The mean NPASS scores for the breastfeeding group, the oral sucrose group, the nonnutritive sucking group, and the skin-to-skin contact group were 1.88, 1.01, 1.84, and 3.21, respectively. This demonstrates a significant decrease compared with the control group ($P < .01$; see Figure 2). Among the 4 intervention groups, a paired group comparison of mean NPASS scores was performed and analyzed. The results showed that the analgesic effect of oral sucrose is statistically superior to skin-to-skin contact ($P < .01$). No significant difference was observed in NPASS scores between the other intervention groups (see Table 1).

Compared with the control group, the odds ratios of infants' feeling pain (NPASS >3) in the intervention groups were as follows: 0.03 in the oral sucrose group, 0.09 in the breastfeeding group, 0.10 in the nonnutritive sucking group, and 0.25 in the skin-to-skin contact group. The odds ratio of effective pain control between the intervention groups and the control group was significant ($P < .01$; see Table 2).

Oral sucrose was the most effective intervention in shortening the newborns' crying time ($P < .01$). Nonnutritive sucking was superior to skin-to-skin contact in reducing newborns' crying time ($P < .05$). However, no difference was found when breastfeeding was compared with skin-to-skin contact or nonnutritive sucking (see Figure 3). The duration of crying time was strongly correlated with the NPASS score ($r = 0.81$).

Although the intervention groups demonstrated a shorter duration for the heel lance procedure ($P < .01$), no significant difference was noticed among the 4 intervention groups ($P > .05$) when compared with each other (see Table 3). The duration of procedure was not highly correlated with the NPASS score ($r = 0.38$; see Figure 4). Crying time was not correlated with the length of procedure ($r = 0.39$).

DISCUSSION

This study shows that healthy term newborns who underwent a routine heel lance as a newborn screen test experienced moderate-to-severe pain with a mean

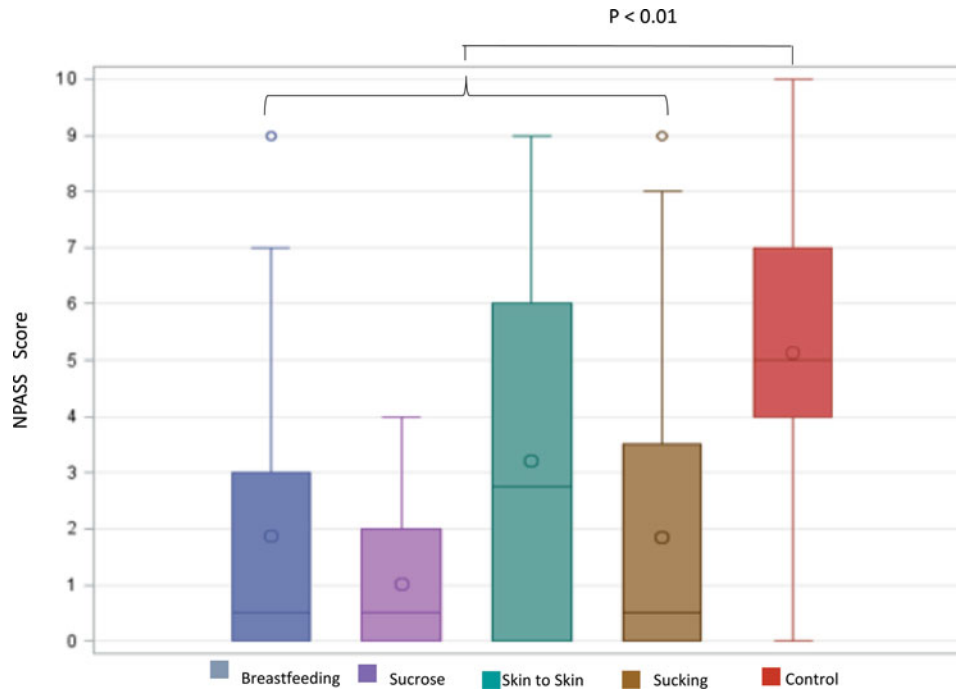

Figure 2. Mean (standard deviation) of NPASS score: breastfeeding 1.88 (2.49), oral sucrose 1.01 (1.25), skin-to-skin contact 3.21 (3.17), nonnutritive sucking 1.84 (2.49), and control 5.14 (2.50). Since NPASS score is not normal distributed, the Kruskal-Wallis test is used, which is $P < .01$. NPASS indicates Neonatal Pain, Agitation, and Sedation Scale. This figure is available in color online (www.jpnnjournal.com).

Table 1. **Paired-group comparison of means of NPASS score**

Compared Characteristics	Comparison Groups	Breastfeeding ($n = 45$)	Oral sucrose ($n = 42$)	Skin to skin ($n = 38$)	Sucking ($n = 51$)	Control ($n = 50$)	*P* (Wilcoxon)
Mean NPASS score (STD)	Breastfeeding vs Sucrose	1.88 (2.49)	1.01 (1.25)				.24
Mean NPASS score (STD)	Breastfeeding vs Skin to skin	1.88 (2.49)		3.21 (3.17)			.1
Mean NPASS score (STD)	Breastfeeding vs Sucking	1.88 (2.49)			1.84 (2.49)		.74
Mean NPASS score (STD)	Breastfeeding vs Control	1.88 (2.49)				5.14 (2.50)	<.01[a]
Mean NPASS score (STD)	Oral sucrose vs Skin to skin		1.01 (1.25)	3.21 (3.17)			<.01[a]
Mean NPASS score (STD)	Oral sucrose vs Sucking		1.01 (1.25)		1.84 (2.49)		.37
Mean NPASS score (STD)	Oral sucrose vs Control		1.01 (1.25)			5.14 (2.50)	<.01[a]
Mean NPASS score (STD)	Skin to skin vs Sucking			3.21 (3.17)	1.84 (2.49)		.06
Mean NPASS score (STD)	Skin to skin vs Control			3.21 (3.17)		5.14 (2.50)	<.01[a]
Mean NPASS score (STD)	Sucking vs Control				1.84 (2.49)	5.14 (2.50)	<.01[a]

Abbreviation: NPASS, Neonatal Pain, Agitation, and Sedation Scale.
[a]Wilcoxon signed-rank test, $P < .01$, significant difference of means between two compared groups.

NPASS score as 5.14. This finding requires further attention because the literature reports that pain management should be considered in newborns when they have an NPASS score of more than 3.[13] In the discussion that follows, each nonpharmacologic intervention in this study is reviewed in the light of the literature.

Breastfeeding

In this study, breastfeeding infants demonstrated an odds ratio of 0.09 to experiencing pain (NPASS >3), which can be interpreted as having 91% (odds ratio = 1-0.09) of scoring a 3 or less on the NPASS. Our results support the findings of other studies that breastfeeding is an effective analgesic intervention for full-term infants.[9,12,14,15] It is a natural behavior with universal applicability for nursing mothers. Breastfeeding is a convenient, viable option for healthy term newborns, but it can be difficult for infants who are sick or preterm. In addition, heel lance procedures for the newborn screen test are generally performed between 24 and 48 hours after birth, which can coincide with an infant's breastfeeding period. Ideally, the heel lance procedure can be performed without interrupting infants who are breastfeeding. Breastfeeding allows mothers to engage in other bonding activities such as skin-to-skin contact, distraction, and nutritive sucking. Breastfeeding revealed no side effects in our study, which is consistent with the literature. Considering breastfeeding's natural features, it may be the most convenient first line of nonpharmacologic pain control for term newborns. In clinical settings, nurses should assist and support mothers' breastfeeding while their newborn undergoes minor procedures.

Table 2. **Efficacy of pain management in intervention groups versus the control group**

Categorical variables	NPASS ≤3 ($n = 141$)	NPASS >3 ($n = 85$)	% (NPASS ≤3/total)	OR (95% CI)	*P*
Breastfeeding	34	11	75.6	0.09 (0.04-0.24)	<.01
Oral sucrose	38	4	90.5	0.03 (0.01-0.10)	<.01
Skin-to-skin contact	20	18	52.6	0.25 (0.10-0.64)	<.01
Sucking	38	13	74.5	0.10 (0.04-0.24)	<.01
Control	11	39	22.0	ref	ref

Abbreviations: CI, confidence interval; NPASS, Neonatal Pain, Agitation, and Sedation Scale; OR, odds ratio.

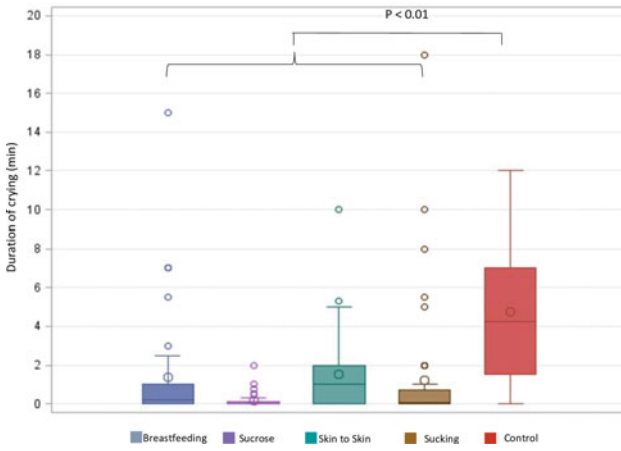

Figure 3. Mean (standard deviation) of infants' crying (minute): breastfeeding 1.35 (2.83), oral sucrose 0.16 (0.38), skin-to-skin contact 1.50 (2.02), nonnutritive sucking 1.22 (3.13), and control 4.74 (3.50). Since variable is not normal distributed, the Kruskal-Wallis test is used, which is $P <$ .01. This figure is available in color online (www.jpnnjournal.com).

Oral sucrose

The effective analgesic capabilities of oral sucrose in neonates have been reported for the past 2 decades. It is the most common modality for managing neonatal procedural pain, especially for preterm or compromised infants who need multiple invasive procedures. Although how oral sucrose works is still not completely understood, researchers have shown that the activation of an infant's endogenous opioid system through the taste receptors may impact its pain response.[1–13,16]

The analgesic effect of sucrose with different concentrations and dosing has also been investigated.[17–19] In this study, we used 24% sucrose with a maximum dose of 1 mL because it was the most commercially available agent with the most clinical data and it is recommended by the American Academy of Pediatrics.[9,16–18]

Our findings show that oral sucrose significantly decreased the NPASS score in comparison with the control group. The infants who received oral sucrose while heel lance have 97% (odds ratio = 1-0.03) decreased risk of pain (NPASS ≤3). In addition, the oral sucrose group had on average the shortest procedure time. A recent study has reported that oral sucrose has an immediate analgesic effect, which results in decreased agitation and cessation of crying.[20] This is consistent with our findings. Although sucrose is considered to be the criterion standard in nonpharmacologic pain relief,[11] concerns of tolerance, safety of long-term use, and the efficacy of repeat use have been reported and are still under investigation.[11,14] The American Academy of Pediatrics considers oral sucrose to be a medication.[14]

Nonnutritive sucking

We found that the analgesic effect of nonnutritive sucking in reducing newborn pain was similar to that of breastfeeding and oral sucrose. The advantage of nonnutritive sucking is that it is easy to implement, can be

Table 3. **Impacts of pain intervention on the duration of procedure**

Duration of procedure	Comparison groups	Breastfeeding ($n = 45$)	sucrose ($n = 42$)	Skin to skin ($n = 38$)	Sucking ($n = 51$)	Control ($n = 50$)	*P* (Wilcoxon)
Mean of minutes (STD)	Breastfeeding vs Sucrose	4.98 (3.38)	5.28 (2.86)				.19
Mean of minutes (STD)	Breastfeeding vs Skin to skin	4.98 (3.38)		5.25 (3.54)			.33
Mean of minutes (STD)	Breastfeeding vs Sucking	4.98 (3.38)			5.18 (3.56)		.43
Mean of minutes (STD)	Breastfeeding vs Control	4.98 (3.38)				6.45 (2.79)	<.01[a]
Mean of minutes (STD)	Sucrose vs Skin to skin		5.28 (2.86)	5.25 (3.54)			.78
Mean of minutes (STD)	Sucrose vs Sucking		5.28 (2.86)		5.18 (3.56)		.43
Mean of minutes (STD)	Sucrose vs Control		5.28 (2.86)			6.45 (2.79)	<.01[a]
Mean of minutes (STD)	Skin to skin vs Sucking			5.25 (3.54)	5.18 (3.56)		.62
Mean of minutes (STD)	Skin to skin vs Control			5.25 (3.54)		6.45 (2.79)	<.01[a]
Mean of minutes (STD)	Sucking vs Control				5.18 (3.56)	6.45 (2.79)	<.01[a]

[a]Wilcoxon signed-rank test, $P < .01$, significant difference of means between two compared groups.

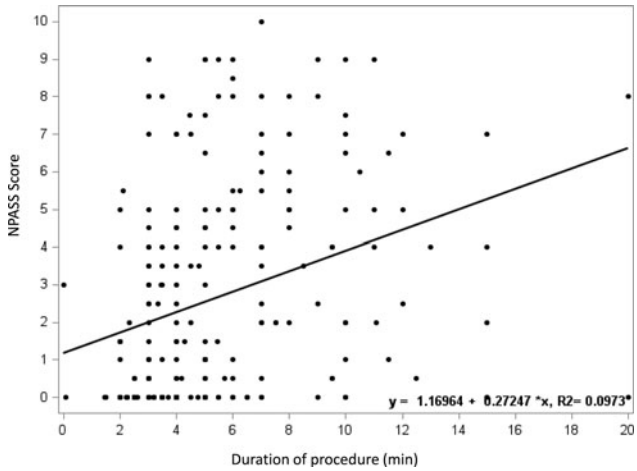

Figure 4. Since variable is not normally distributed, Spearman's rank correlation coefficients are used, $r = 0.38$, which indicates a weak uphill linear relationship. NPASS indicates Neonatal Pain, Agitation, and Sedation Scale.

used with most or all infants, and is especially appropriate for infants with latching difficulties or those who are unable to breastfeed. This nonpharmacologic intervention can be applied by a family member, allowing for a family-centered care environment. Using nonnutritive sucking for repeated procedural pain also been reported.[21,22]

Skin-to-Skin contact

Skin-to-skin contact is widely used in the clinical arena because it promotes breastfeeding and stabilizes newborns' body temperature and vital signs.[23] Studies have shown that skin-to-skin contact is an effective pain intervention comparable with oral sucrose.[23] However, most of those studies targeted the preterm population.[24–27] Our findings indicate that skin-to-skin contact has analgesic effects in term newborns, but its efficiency is less than that of oral sucrose ($P < .01$), which differs from research on preterm neonates.[23] More evidence is required to adequately analyze the correlation of analgesic effect with the duration of skin-to-skin contact before the procedure.[22,23] No side effects have been reported while using the skin-to-skin contact intervention.[23,28] It is simple to apply, allowing parents to be part of their newborn's pain management.

Our study shows that the duration of a procedure had a positive correlation with the NPASS score and the newborn's crying time. Decreased newborn agitation and struggle likely contributed to the length of the procedure. As with previous studies, our study suggests that optimal pain control for term newborns who undergo minor procedures requires that frontline medical providers must advocate, educate, and support patients by providing an appropriate pain relief intervention.[9,11]

Limitations

Our findings are tempered by some limitations. First, the control arm was not recruited or randomized at the same time as the other arms. When our study protocol was created, the standard of care in our unit was no pain intervention. We felt that randomization for no pain control while other newborns were receiving pain control would have created an unethical situation. Second, we encountered difficulty recruiting healthy term newborns. To have a fully powered study, a sample size of more than 400 would have been required. Because of constraints of budget and time, such a sample size was unobtainable. Finally, the lack of resources did not allow us to investigate the effects of confounding variables such as the presence of external triggers such as family interruptions, room lightening, sounds, and maternal state of mind.

CONCLUSION

Efficient pain management is necessary for term healthy newborns who undergo minor procedures. As indicated in this study, nonpharmacologic pain interventions (breastfeeding, oral sucrose, nonnutritive sucking, and skin-to-skin contact) have analgesic effects that can decrease the amount of pain that newborns experience. All of these interventions are clinically applicable and acceptable and have a minimal side effect profile. They shorten the length of procedures and reduce the newborn's crying time. To implement nonpharmacologic pain intervention, medical providers play a key role. They need to advocate, educate, assist, and supervise family involvement in applying appropriate techniques. The evidence provided by this study may influence and change clinical practice for the newborn population.

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