

Original Research Article

Efficacy of breast milk olfactory and gustatory interventions on preterm neonates behaviour responses to pain during heel prick procedures: a hospital-based study

Wichamjailiu Ringkangmai¹, Neeta Singh¹, Bharati Saikia^{2*}, Deeksha Thakur³,
Seema⁴, Rachna Khanna³

¹Department of Child Health Nursing, Government Institute of Medical Science (GIMS), Greater Noida, Uttar Pradesh, India

²Department of Community Health Nursing, Sharda University, Knowledge Park 3, Greater Noida, Uttar Pradesh, India

³Department of Child Health Nursing, KINPMS, Knowledge Park 3, Greater Noida, Uttar Pradesh, India

⁴Department of Child Health Nursing, Sharda University, Knowledge Park 3, Greater Noida, Uttar Pradesh, India, India

Received: 16 December 2024

Revised: 15 January 2025

Accepted: 05 April 2025

*Correspondence:

Dr. Bharati Saikia,

E-mail: bharatijipmer2021@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Premature infants are particularly vulnerable to stress and pain due to the multiple procedures they undergo in the NICU during a critical phase of brain development. Their heightened sensitivity to tactile stimuli increases the risk of negative effects from frequent medical interventions. Acute pain can have both immediate and long-term neurodevelopmental consequences. This study aimed to assess the impact of breast milk feeding on pain levels during the heel stick procedure in late preterm neonates in selected hospitals of Greater Noida.

Methods: A randomized clinical trial compared pain levels in late preterm neonates undergoing a heel stick, with one group receiving breast milk feeding prior to the procedure (n=64) and the other group not (n=64). Pain was assessed using the premature infant pain profile (PIPP) at baseline, 5 minutes and 15 minutes after the procedure.

Results: Among 64 late preterm neonates who did not receive breast milk, 79.7% experienced no to minimal pain and 20.3% had minimal to moderate pain, with none experiencing severe pain. In the breast milk feeding group, all 64 neonates reported no to minimal pain during the procedure. 15 minutes post-procedure, the control group reported higher pain (2) than the experimental group (2), with a significant difference ($p < 0.001$).

Conclusions: Breast milk feeding is effective in reducing pain during the heel stick procedure in late preterm neonates. This method is a cost-effective and non-pharmacological approach that can be readily adopted to alleviate procedural pain in this vulnerable population.

Keywords: Breast milk, Olfactory and gustatory interventions, Preterm neonates, Pain, Behavioral response, Heel prick

INTRODUCTION

"Babies are like little suns that, in a magical way, bring warmth, happiness and light into our lives." Kartini Diapari Oengider. The international association for the

study of pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.¹ Premature and ill infants often endure numerous painful procedures during their hospital stay. In

neonatal intensive care units (NICUs), neonates frequently face pain and discomfort due to various iatrogenic procedures, such as blood draws, bilirubin tests, venepuncture and vitamin K injections.² Hospitalized neonates typically experience between 10 to 14 painful procedures per day, with as many as 53 procedures recorded in the first two weeks of life. Preterm infants are particularly sensitive to pain and stress from these procedures, which can lead to negative outcomes, including poor neurological development and abnormal pain responses later in life. Research increasingly shows that pain and stress during this critical developmental period can impact the immature brain, potentially affecting neurodevelopment and stress-related behaviors.³⁻⁵

Neonates in intensive care units typically undergo an average of 16 painful procedures per day, with 79% of these procedures performed without specific analgesia. These infants exhibit physiological, hormonal, metabolic and behavioral responses to invasive procedures that are more intense than those observed in adults. Inadequately managed pain during early life can have both immediate and long-term detrimental effects on neonates.⁶⁻¹⁰

Heels stick procedures are common for obtaining blood samples for tests such as random blood sugar and bilirubin levels. However, it is impractical to administer potent medicinal analgesia for routine therapeutic and diagnostic procedures. Therefore, it is crucial to explore non-pharmacological methods to alleviate procedural pain in neonates. Techniques such as kangaroo mother care, breastfeeding, soft music, skin-to-skin contact and cuddling can help reduce stress during painful procedures. Among these, breastfeeding stands out as a convenient, cost-effective and time-efficient method that requires minimal skill.¹¹⁻¹²

Early experiences with pain can lead to altered pain responses later in infancy, making accurate assessment and effective pain management essential. Healthcare professionals are responsible for implementing these pain management strategies in hospital settings. Despite this, there is a limited body of research on the effectiveness of breastfeeding in reducing pain perception among preterm neonates. This highlights the need for further studies on pain management in late preterm infants, prompting the researcher to undertake this study.¹³⁻¹⁴

To assess the effect of breast milk feeding on pain during heel stick procedure among late preterm neonates. To identify the association of the pain with socio-demographic factors in late preterm neonates.

METHODS

Research approach

For the current study, quantitative approach had been adopted

Research design

The research design adopted for the present study was randomized clinical trial.

R= Randomization, E= Experiment group, C= Control group, X= Provision of breast milk feeding before heel stick procedure, O= Assessment of pain score with premature infant pain profile

Research setting

The study was conducted in postnatal ward & NICU of Hospitals of Greater Noida.

Study population

The study population was all late preterm neonates who were admitted in postnatal ward & NICU, Hospitals of Greater Noida.

Sample

The sample consisted of 128 preterm neonates.¹⁹

Sampling technique

Sampling method for the study is random sampling.

Sample size calculation

The sample of this study n= 64 in each group. The sample size estimated with an expected mean difference in the level of pain between the study groups as 2 and standard deviation of 4 at 5% level of significance and 80% power.

Inclusion criteria

Preterm neonates admitted in NICU and post-natal ward, Hospitals of Greater Noida. Preterm neonates of 34-36 weeks of gestational age.

Exclusion criteria

Preterm neonates who were sick. Preterm neonates with major congenital malformation.

Description of data collection instrument

The data collection instrument consisted of two sections.

Section A: clinical characteristics

Dealt with clinical characteristics of late preterm neonates. It included five variables age, gender of the baby, gestational age, birth weight, Apgar score of the baby at 5 min.²⁰

Section B: premature infant pain profile

The premature infant pain profile was developed by Stevens B, Johnston C, Petryshen P, Taddio A in 1996. The indicators were gestational age, behavioural state, heart rate, oxygen saturation and facial actions. The indicator, facial actions had three component such as brow bulge, eye squeeze and naso labial furrow.

Scoring and interpretation of instrument

Section A

No scoring for clinical characteristics.

Section B

In premature infant pain profile, there were 7 indicators. Each indicator is scored from 0-3. Total minimum score of PIPP is 0. Total maximum score of PIPP is 21 premature infant pain profile interpretation is as, score 0-6, minimal or no pain, score 7-12, slight to moderate pain, score >12, severe pain

Validity

The tool (Premature Infant Pain Profile) used in the study was a standardized tool. Content validity of the tool was established from subject experts in the medical and nursing field.²¹

Reliability

The reliability of the tool was established by inter rater reliability. The tool was found to be reliable ($r=0.85$).

Description of intervention

Late preterm neonates were assigned to experimental group and control group randomly. Clinical characteristics such as age, gender, gestational age, birth weight and APGAR score were collected from the patient case sheet for both control and interventional groups. For the neonates in the control group, PIPP assessment had done 15 minutes before heel stick and repeated 5 and 15 minutes after the procedure. For the neonates in the experimental group, baseline pain assessment had done 15 minutes before heel stick procedure. Direct breast milk feeding or Paladai feed of 5 ml expressed breast milk of own mother provided 5 minutes before heel stick procedure. Pain score assessed 5 minutes and 15 minutes after the heel stick procedure using Premature Infant Pain Profile (PIPP).

Ethical consideration

Ethical clearance was obtained from the Institute Ethical Committee and human studies of Sharda University. Consent obtained from the parents prior to the data collection by the investigator. Assurance was given to the

parents regarding the confidentiality and anonymity of study subjects.

RESULTS

Pilot study

A pilot study was conducted among 7 late preterm neonates each in 22 experimental and control groups, in Neonatal Intensive Care Unit, Hospitals of Greater Noida. The feasibility of the intervention ensured through the pilot study. Investigator found that the tool was reliable. No modifications were however required after the pilot study.

Data collection procedure

The investigator introduced themselves to the mothers of late preterm neonates. Brief description of the study was given to them. It was assured that all data will be strictly confidential and will be used only for the study purpose and consent was taken. Late preterm neonates of 34-36 weeks of gestation were assigned to experimental group and control group randomly. Clinical characteristics such as age, gender, gestational age, birth weight and APGAR score were collected from the patient case sheet for both control and experimental groups. The heel prick was performed by a person not involved in the study with the use of 26-gauge needle.

For the neonates in the control group, PIPP assessment had done 15 minutes before heel stick and repeated 5 and 15 minutes after the procedure. For the neonates in the experimental group, baseline pain assessment had done 15 minutes before heel stick procedure. Direct breast milk feeding or Paladai feed of 5 ml expressed breast milk of own mother provided 5 minutes before heel stick procedure. Pain score assessed using Premature Infant Pain Profile (PIPP) 5 minutes and 15 minutes after the heel stick procedure.²³

Plan for data analysis

Both descriptive and inferential statistics were used to analyze the data. The distribution of categorical variables such as gestational age, Apgar score, birth weight, age and gender had been expressed in terms of frequency and percentage. The distribution of discrete or continues variables such as pain had been expressed in terms of mediana with interquartile range.

The effect of intervention on pain had been interpreted out by using Mann Whitney u test. The association of level of pain with categorical variables mentioned above had been carried out using Pearson chi-square test. Data analysis was performed in SPSS version 20. All the statistical analysis had been carried out at 5% level of significance.²⁴

Analysis and findings

Data was collected from 128 late preterm neonates who have admitted in postnatal ward and neonatal intensive care unit, regarding the “Effect of breast milk feeding on pain during heel stick procedure among late preterm neonates”. All statistical analysis were carried out at 5% level of significance.

Organization of study findings

The findings are arranged in the following sections.

Section I

Demographic characteristics of late preterm neonates

The Table 1 illustrates the demographic characteristics of the late preterm neonates. Among the 128 study participants, 73 (57%) were males and 55 (43%) were females. Majority of the late preterm neonates 48 (37.5%), 46 (35.5%) were born in a gestational age of 34 weeks+6 days and 35 weeks+6 days respectively.

Section II

Effect of breast milk feeding on pain during heel stick procedure.

The given Tables represent that 64 (100%) late pre term neonates had no pain to minimal pain 15 minutes before the procedure. 5 minutes after heel stick procedure 51 (79.7%) experienced no pain to minimal pain, whereas 13

(20.3%) had minimal to moderate pain. 100% of the late preterm neonates experienced no pain to minimal pain 15 minutes after the procedure.

The above Table delineates that 15 minute before the heel stick procedure and 5 minutes and 15 minutes after the procedure, 64 (100%) of the late preterm neonates experienced only no pain to minimal pain. No single subject experienced minimal to moderate pain.

The Table 4 represented the comparison of median pain scores between control group and experimental group, 15 minutes before and 5 minutes and 15 minutes after heel stick procedure showed that 15 minutes before heel stick procedure median pain score in control group and experimental group were 1 (1, 1) and 1 (0.5, 1) respectively with a statistical significance of 0.864.

5 minutes after heel stick procedure in control group median pain score was 6 (5, 6), whereas in experimental group median pain score was 3 (2, 4) with a statistical significance of <0.001.

15 minutes after heel stick procedure in control group and experimental group median pain scores were 2 (2, 3) and 2 (1, 2) respectively with a statistical significance of <0.001.

Section III

The Table 5 depicted that there was no significant association between the level of pain and clinical characteristics.

Table 1: Clinical characteristics of late preterm neonates n=128.

Variables	Frequency (No.)	%
Gender		
Male	73	57.0
Female	55	43.0
Gestational age		
34 weeks+6 days	48	37.5
35 weeks+6 days	46	35.9
36 weeks+6 days	34	26.6
Age in days		
0	3	2.3
1	59	46.1
2	39	30.5
3	14	10.9
4 days or more	13	10.2
Birth weight		
1-2.499 kg	120	93.8
>=2.50 kg	8	6.3
APGAR		
Score 8	2	1.6
9	126	98.4

Table 2: Level of pain among late preterm neonates during heel stick procedure in control group n=64.

Categories	15 min (before)		5 min (after)		15 min (after)	
	Frequency (No)	(%)	Frequency (No)	(%)	Frequency (No)	(%)
No pain to minimal pain	64	100	51	79.7	64	100
Minimal to moderate pain	0	0	13	20.3	0	0
Severe pain	0	0	0	0	0	0

Table 3: Level of pain among late preterm neonates in experimental group.

Categories	15 min (before)		5 min (after)		15 min (after)	
	Frequency (No)	(%)	Frequency (No)	(%)	Frequency (No)	(%)
No pain to minimal pain	64	100	64	100	64	100
Minimal to moderate pain	0	0	0	0	0	0

Table 4: Comparison of median pain scores between control group and experimental group.

Parameter	Control group		Experimental group		P value
	Median	Interquartile range	Median	Interquartile range	
Pain score 15 minutes before heel stick	1	0.5, 1	1	1, 1	0.864
Pain score 5 minutes after heel stick	6	5, 6	3	2, 4	<0.001
Pain score 15 minutes after heel stick	2	2, 3	2	1, 2	<0.001

Table 5: Association between level of pain 5 minutes after heel stick procedure and clinical characteristics of late preterm neonates in control group N=64.

Variables	Level of pain				Statistical significance (P value)
	No pain to minimal pain		Minimal pain to moderate pain		
	Frequency (No)	(%)	Frequency (No)	(%)	
Gender					
Male	29	82.9	6	17	0.489
Female	22	75.9	7	24.1	
Gestational age					
34 weeks+6 days	23	76.7	7	23.3	0.086
35 weeks+ 6 days	14	70.0	6	30.0	
36 weeks+ 6 days	14	100.0	0	0.0	
Birth weight					
1-2.49	49	79.0	13	21.0	0.468
>=2.50	2	100.0	0	0.0	

DISCUSSION

A total of 128 late preterm neonates were included in the study (64 in each group). The study findings are as follows.

Among one hundred and twenty-eight late preterm neonates 73 (57%) were males, remaining 55 (43%) were females. 37.5% the late preterm neonates born at a gestational age of 34 weeks+6 days and 35.9% were at 35 weeks+6 days. 26.6% of the late preterm neonates were at 36 weeks+6 days. Out of the 128 study participants 120 (93.8%) had been categorized into a birth weight of 1-2.49 kg. Only 8 (6.3%) were above 2.50 kg. 46.1% late

preterm neonates belonged to the age category of 1 day, whereas only 2.3% were at an age of 0 day. Regarding Apgar score 126 (98.4%) of the participants had a score of 9. The first objective of the study was to assess the effect of breast milk feeding on pain during heel stick procedure among late preterm neonates.

Among 64 late preterm neonates during heel stick procedure without breast milk feeding 51 (79.7%) had no to minimal pain, 13 (20.3%) had minimal to moderate pain. none of the late preterm neonates had experienced severe pain. In the breast milk feeding group the total 64 (100%) of the study participants experienced only no to minimal pain which is similar to study done by Shah

PS12. The comparison of median pain scores between control group and experimental group, 15 minutes before and 5 minutes and 15 minutes after heel stick procedure showed that 15 minutes before heel stick procedure median pain score in control group and experimental group were 1 (1, 1) and 1 (0.5, 1) respectively with a statistical significance of 0.864. 5 minutes after heel stick procedure in control group median pain score was 6 (5, 6), whereas in experimental group median pain score was 3 (2, 4) with a statistical significance of <0.001 . 15 minutes after heel stick procedure in control group and experimental group median pain scores were 2 (2, 3) and 2 (1, 2) respectively with a statistical significance of <0.001 which is similar to study done by Lin CH, Liaw JJ.²⁵

Osinaike et al, conducted a prospective clinical trial in 2013 to evaluate the analgesic effect of breastfeeding during venipuncture. They found that the median pain score (interquartile range) of the neonates when breastfed was 1.50 (1-2) and 4.00 (2-6) when not breastfed. The statistical significance was <0.001 .²⁶

Codipietro et al, conducted a randomized control trial in 2008 to compare the efficacy of breastfeeding versus orally administered sucrose solution in reducing pain response during blood sampling through heel lance. Median premature infant pain profile scores were lower in the breastfeeding group (3.0) than in the sucrose-solution group (8.5) and the median group difference was -5.0. The median heart rate increase, oxygen saturation decreases and duration of first cry for the breastfeeding group were, respectively, 13.0, -1 and 3 and for sucrose group were 22, -3 and 21. Median pain score was significantly different between the groups ($p<0.01$).²⁶

The second objective was to identify the association of the pain with socio-demographic factors in late preterm neonates. The association between the level of pain and the clinical characteristics of late preterm neonates had found that there were no significant association between the clinical characteristics and pain score level in both breast milk feeding group and non- breast milk feeding group similar to study done by Bulut et al.²⁸

Generalizability is limited because of small sample size. Study is limited to only Greater Noida, Uttar Pradesh. Only late preterm neonates were enrolled in the study.

CONCLUSION

Breast milk feeding is an effective method of managing pain in late preterm neonates during heel stick procedure. Feeding with breast milk before heel stick procedure is a low-cost intervention that can be effectively used in children. The present randomized clinical trial was conducted among 128 late preterm neonates admitted in neonatal intensive care and postnatal ward of Hospitals of Greater Noida. The pain was assessed using Premature infant pain profile (PIPP) 15 minutes before the heel stick

procedure and 5 and 15 minutes after the heel stick procure. The result proved that the level of pain reduced with breast milk feeding with a statistical significance of $p<0.001$. The level of pain was not associated with the clinical characteristics.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Merskey H, Bugduk N. Classification of chronic pain, descriptions of chronic pain syndromes and definitions of pain terms. 2nd ed. 1994.
2. Krishnan L. Pain relief in neonates. J neonatal surg. 2013;2:19-20.
3. Yamada J, Stinson J, Lamba J, Dickson A, McGrath P, Stevens B. A review of systematic reviews on pain interventions in hospitalized infants. Pain Res Manag. 2008;13:413-20.
4. Kothari SY, Dogara AR, Nimbalkar SM, Phatak AG, Nimbalkar AS. Missed Opportunities for sedation and pain management at a Level III Neonatal Intensive Care Unit. Front Pediatr. 2016;4:7-8
5. Grunau re. Neonatal pain in very preterm infants: long term effects of brain, neuro development and pain reactivity. Rambam Maimonides. 2013;4:25.
6. Grunau RE, Holsti L, Peters JW. Long term consequences of pain in human neonates. Semin Fetal Neonatal Med. 2006;11:268-75.
7. Donia ASE, Tolba OA. Effect of early procedural pain experience on subsequent response among premature infants. Egyptian Pediatric Association Gazette. 2016;64:74-8.
8. Carbaial R, Rousset A, Danan C, Coquery S, Nolent P, Ducrocq S, et al. Epidemiology and treatment of painful procedures in neonates in Intensive Care Units. JAMA. 2008;300:60-70.
9. Gardner SL, Carter SB, Hines IM, Hernandez AJ. Handbook of neonatal intensive care. 7th ed. USA: Mosby. 2011.
10. Appleyard L. Breastfeeding reduces procedural pain in infants: A review of literature. NZJ Med Sci. 2014;68:88-9.
11. Holsti L, Grunau R E, Shany E. Assessing pain in preterm infants in the neonatal intensive care unit: moving to a brain oriented approach. Pain Manag. 2011;1:171-9.
12. Shah PS, Herbozo C, Aliwalas LL, Shah VS. Breastfeeding or breast milk for procedural pain in neonates. Cochrane Database Syst Rev. 2012;12:4950.
13. Hockenberry MJ, Wilson D. Wong's nursing care of infants and children. 8th edition. Missouri: Elsevier publication. 2009.

14. George JB. Nursing theories: The base for professional practice. 5th Ed. New Jersey: Prentice Hall. 2002.
15. Valeri BO, Holsti L, Linhares BM. Neonatal pain and developmental outcomes in children born preterm; a systematic review. *The Clin J of Pain*. 2015;31:355-62.
16. Brummelte S, Gurunau RE, Chau V, Poskitt KJ, Brant R, Vinall J, et al. Procedural pain and brain development in premature newborns. *Ann Neurol*. 2012;71:385-96.
17. Nair MKC, Jain. *The High Risk Newborn*. 1st ed. New Delhi: Jaypee Publications. 2008.
18. Field T. Preterm newborn pain research review. *Infant Behav Dev*. 2017;49:141-50.
19. Slater R, Cornelisen L, Fabrizi L, Patten D, Yoxen J, Worley A, et al. Oral sucrose as an analgesic drug for procedural pain in newborn infants: A randomised controlled trial. *The Lancet*. 2010;376:1225-32.
20. Castrat TC, Warnock F, Leite AM, Haas VJ, Scochi CGS. The effects of skin-to-skin contact during acute pain in preterm newborns. *European J of Pain*. 2008;12:464-71.
21. Kahalaf O, Clark L, Sivarajan E. Use of facilitated tucking for nonpharmacological pain management in preterm infants: a systematic review. *J Perinatal and Neonatal Nurs*. 2009;23:372-7.
22. Stevens B, Yamada J, Beyene J, Gibbins S, Petryshen P, Stinson J, et al. Consistent management of repeated procedural pain with sucrose in preterm neonates: Is it effective and safe for repeated use over time. *Clin J Pain*. 2005;21:543-8.
23. Sahebihag MH, Hosseinzadeh M, Mohammadpourasl A, Kosha A. the effect of breastfeeding infant's pain relief during vaccination. *Iran J Nurs Midwifery Res*. 2011;16:1-7.
24. Modarres M, Jazayeri A, Rahnama P, Montazeri A. Breastfeeding and pain relief in full-term neonates during immunization injections: a clinical randomized trial. *BMC Anesthesiol*. 2013;13:22.
25. Lin CH, Liaw JJ, Chen YT, Yin T, Yang L, Lan HY. Efficacy of breast milk olfactory and gustatory interventions on neonates' biobehavioral responses to pain during heel prick procedures. *Int J Environ Res Public Health*. 2022;22;19(3):1240.
26. Leite AM, Linhares MB, Lander J, Castrat TC, Santos CB, Silvan Scochi CG. Effects of breastfeeding on pain relief in full term newborns. *Clinical J of Pain*. 2009;25:827-32.
27. Codipietro L, Ceccarelli M, Ponzone A. Breastfeeding or oral sucrose solution in term neonates receiving heel lance: a randomized, controlled trial. *Pediatrics*. 2008;3:716.
28. Bulut O, Topaloglu SC, Bulut, N. Impact of breast milk on cortical pain response in newborns during the heel prick procedure: a randomized controlled trial. *J Perinatol*. 2024;44:1675-81.

Cite this article as: Ringkangmai W, Singh N, Saikia B, Thakur D, Seema, Khanna R. Efficacy of breast milk olfactory and gustatory interventions on preterm neonates behaviour responses to pain during heel prick procedures: a hospital-based study. *Int J Contemp Pediatr* 2025;12:741-7.