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Evaluation of Breastfeeding as an Analgesic Intervention in Neonates Undergoing Heel Prick: A Randomized Controlled Stud

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ABSTRACT

Background: Heel pricks in neonates cause significant pain and stress, with potential adverse outcomes. Pharmacological analgesics are limited, so non-pharmacological methods are vital. Breastfeeding offers safe analgesia through maternal contact, suckling, and sweet taste. Pain can be assessed using the Premature Infant Pain Profile (PIPP).

Objective: To assess the analgesic effectiveness of breastfeeding during painful procedures in neonates using the Premature Infant Pain Profile (PIPP) scoring system.

Methods: A randomized controlled trial was conducted at JK Lon Mother and Child Hospital, KOTA, from January 2022 to December 2022. One hundred neonates (51 males, 49 females) with gestational age ≥34 weeks requiring heel prick for blood sugar monitoring were randomized into two equal groups: Group A (without breastfeeding, n=50) and Group B (with breastfeeding, n=50). Pain assessment was performed using PIPP scoring system before, during, and after the procedure.

Results: The study demonstrated significant differences in pain perception between groups. In the breastfeeding group, 74% of neonates experienced no pain compared to only 20% in the non-breastfeeding group. Severe pain was observed in 14% of neonates without breastfeeding, while none in the breastfeeding group experienced severe pain. The relative risk was 0.351 (95% CI: 0.203-0.607, $p<0.0001$), and odds ratio was 0.087 (95% CI: 0.034-0.223, $p<0.0001$).

Conclusion: Breastfeeding serves as an effective non-pharmacological analgesic intervention during painful procedures in neonates, significantly reducing pain perception as measured by PIPP scoring.

Keywords: *Breastfeeding, Neonates, PIPP scoring, Analgesia, Pain management, Heel prick.*

1. INTRODUCTION

Neonatal pain management has become a fundamental focus in modern neonatal care, with evidence confirming that newborns not only perceive pain but may experience heightened sensitivity compared to older populations [1]. Pain in neonates is expressed through autonomic, motor, and behavioural responses, making recognition and management challenging [2]. Indicators include changes in heart rate, oxygen saturation, facial expressions, motor activity, and crying patterns [3]. Anatomical and physiological factors contribute to this sensitivity; neonates have densely innervated skin and mucous membranes, and their immature neurological pathways amplify pain perception while making responses harder to interpret [4,5].

Untreated pain in neonates has both immediate and long-term consequences. Repeated exposure to painful stimuli activates oxidative stress and inflammatory cascades, disrupts pre-myelinating neural development, and interferes with cortical growth [6]. Longitudinal studies have linked repetitive procedures, such as skin punctures, with reduced cortical gray matter thickness and adverse neurodevelopmental outcomes [7]. These include impaired cognition, delayed motor function, and

maladaptive behavioural patterns later in life [8]. Heel puncture for blood sampling remains one of the most frequent painful procedures in neonatal intensive care units, subjecting neonates to repeated noxious stimuli, often without adequate analgesia [9].

Non-pharmacological pain management has emerged as the preferred first-line approach due to safety, low cost, ease of application, and avoidance of side effects associated with pharmacological drugs [10,11]. Among these strategies, breastfeeding stands out as particularly effective. It provides multimodal analgesia: suckling diverts infant attention from pain, breast milk sweetness triggers endogenous opioid release through μ-receptors, and maternal skin-to-skin contact stabilizes physiology while reducing stress responses [12–15]. This combination makes breastfeeding a natural, safe, and practical intervention for procedural pain relief.

To objectively measure neonatal pain, validated tools are essential. The Premature Infant Pain Profile (PIPP) is widely used and incorporates physiological parameters such as heart rate and oxygen saturation, contextual variables like gestational age and behavioural state, and behavioural indicators including brow bulge, eye squeeze, and nasolabial furrow [16]. Its multidimensional design allows reliable assessment of both baseline distress and the effectiveness of interventions.

Considering the established risks of untreated pain, the frequent need for heel pricks in clinical care, and the advantages of breastfeeding, there is strong rationale to study breastfeeding as a non-pharmacological analgesic strategy. Using validated assessment methods like PIPP, this study evaluates its clinical effectiveness during routine painful procedures in neonates.

2. MATERIALS AND METHODS

This investigation employed a randomized controlled trial design conducted within the postnatal care units of JK Lon Mother and Child Hospital, KOTA, during the period from January 2022 through December 2022.

Inclusion criteria encompassed neonates demonstrating physiological stability with gestational ages of 34 weeks or greater who required heel puncture for routine glucose monitoring and were receiving either exclusive or partial breastfeeding nutrition. Exclusion criteria eliminated neonates presenting with critical illness requiring intensive support, those with documented perinatal asphyxia histories, presence of congenital anomalies, neurological abnormalities, physiologically unstable vital signs, or requirements for supplemental oxygen therapy. Additional exclusions included neonates with feeding intolerance, absent bowel sounds, major congenital malformations such as cleft lip or palate, oesophageal atresia, tracheoesophageal fistula, or those receiving sedation or other analgesic medications.

The study protocol received approval from the institutional ethics review board, and written informed consent was obtained from parents or legal guardians prior to participant enrolment. The study population consisted of 100 neonates requiring routine heel puncture for blood glucose monitoring purposes. Participants were allocated through web-based randomization software into two equal groups of 50 neonates each: Group A serving as the control group without breastfeeding intervention, and Group B representing the experimental group receiving breastfeeding during the procedure.

The experimental protocol involved distinct intervention approaches for each group. Control group participants underwent heel puncture procedures without breastfeeding intervention, receiving standard comfort measures including maternal holding during the procedure. Experimental group participants were positioned for breastfeeding initiation two minutes prior to the heel puncture procedure, with breastfeeding continuing throughout the intervention and for two minutes following completion. During breastfeeding procedures, pain assessment evaluations were conducted using the visible portion of the infant's face, with the assumption of bilateral facial expression symmetry in neurologically normal neonates.

Pain evaluation utilized the Premature Infant Pain Profile scoring methodology, which incorporates seven distinct parameters including two physiological indicators measuring heart rate and oxygen saturation changes from baseline values, two contextual factors accounting for gestational age and pre-procedural behavioural state, and three behavioural indicators assessing brow bulge, eye squeeze, and nasolabial furrow expressions. Each parameter receives scoring on a scale from 0 to 3 points, with total possible scores ranging from 0 to 21 points, where higher numerical values indicate greater pain intensity. [16] Trained research personnel performed all assessments, recording baseline measurements and conducting post-procedural evaluations at standardized time intervals.

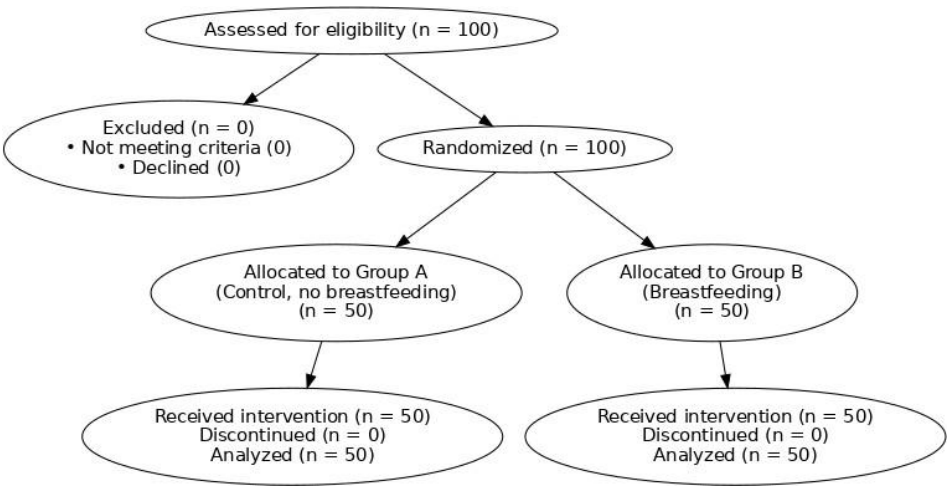
All enrolled participants had received feeding within one hour prior to the scheduled procedure to ensure appropriate nutritional status while avoiding immediate post-feeding timing that might interfere with assessment accuracy. Heel puncture procedures were performed using standardized technique with infants positioned in maternal laps to maintain consistent comfort measures across both study groups. Mothers were permitted to provide comfort through holding, verbal communication, or gentle rocking motions during procedures in both experimental conditions. Video documentation was employed to ensure accurate assessment and provide opportunity for secondary evaluation of pain indicators by independent observers blinded to group allocation.

Statistical analysis employed appropriate methodological approaches with categorical variables analysed using chi-square testing procedures, while continuous variables were compared using parametric or non-parametric tests as indicated by data distribution characteristics. Relative risk calculations and odds ratio determinations were performed with 95% confidence

interval estimations. Statistical significance was established at p-values less than 0.05, with analysis conducted using statistical software packages by personnel not directly involved in data collection procedures.

3. RESULTS

Figure 1: Trial Flowchart



Demographic Characteristics

The study enrolled 100 neonates with balanced demographic characteristics between groups, ensuring adequate baseline comparability. Mean gestational age was 37.3 ± 1.7 weeks with mean birth weight of 2.67 ± 0.41 kg across the total study population.

Table 1: Demographic Profile in Both Groups

Parameter	Group A (Without Breastfeeding) n=50	Group B (With Breastfeeding) n=50	P-value
Gestational Age (weeks)			
34-36 weeks	8 (16.0%)	7 (14.0%)	0.779
>36 weeks	42 (84.0%)	43 (86.0%)	
Mean ± SD	37.2 ± 1.8	37.4 ± 1.6	0.567
Sex			
Male	26 (52.0%)	25 (50.0%)	0.841
Female	24 (48.0%)	25 (50.0%)	
Weight (kg)			
<2.5 kg	15 (30.0%)	13 (26.0%)	0.754
2.5-3.5 kg	32 (64.0%)	34 (68.0%)	
>3.5 kg	3 (6.0%)	3 (6.0%)	
Mean ± SD	2.65 ± 0.43	2.69 ± 0.39	0.623
Mode of Delivery			
Normal Vaginal Delivery	29 (58.0%)	31 (62.0%)	0.689
Caesarean Section	21 (42.0%)	19 (38.0%)	

***Chi Square test**

Pain Assessment Results

Substantial differences in pain perception were documented between the two study groups, with the breastfeeding group demonstrating markedly reduced pain scores across all measured parameters of the PIPP assessment scale.

Table 2: PIPP Score in Both Groups After Prick

Parameter	Group A (Without Breastfeeding) n=50	Group B (With Breastfeeding) n=50	P-value
Total Mean PIPP Score	8.9 ± 2.6	4.1 ± 1.9	<0.0001#
Pain Categories			
No Pain (PIPP 0-6)	10 (20.0%)	37 (74.0%)	<0.0001
Moderate Pain (PIPP 7-12)	33 (66.0%)	13 (26.0%)	<0.0001
Severe Pain (PIPP >12)	7 (14.0%)	0 (0%)	<0.01
Statistical Measures			
Relative Risk	0.351 (95% CI: 0.203-0.607)		<0.0001
Odds Ratio	0.087 (95% CI: 0.034-0.223)		<0.0001

***Chi Square test, # Unpaired t test**

Physiological and Behavioural Parameters

Heart rate modifications differed significantly between groups, with the breastfeeding cohort demonstrating minimal cardiac acceleration (mean increase: 7.8 ± 6.1 beats per minute) compared to the control group (mean increase: 25.2 ± 13.1 beats per minute, $p<0.001$). Oxygen saturation measurements revealed less pronounced decreases in the breastfeeding group (mean reduction: 1.1 ± 2.0%) versus controls (mean reduction: 4.9 ± 3.8%, $p<0.001$). Behavioural indicator assessments showed marked reductions in facial expression changes, with brow bulging present in 34.0% of control participants compared to 10.0% in the breastfeeding group ($p<0.01$), eye squeezing observed in 38.0% of controls versus 4.0% of breastfeeding participants ($p<0.001$), and similar patterns for nasolabial furrow expressions.

4. DISCUSSION

The findings of this investigation provide robust evidence supporting the analgesic efficacy of breastfeeding during neonatal procedural pain management. The substantial reduction in PIPP scores observed in the breastfeeding group, with 74% of participants experiencing no pain compared to merely 20% in the control group, demonstrates clinically significant therapeutic benefit. The complete absence of severe pain in breastfed neonates, contrasted with 14% of control participants experiencing severe pain, further emphasizes the protective effects of this intervention [5-6].

The physiological mechanisms underlying breastfeeding's analgesic properties involve multiple synergistic pathways that collectively contribute to pain reduction. The mechanical stimulation of oropharyngeal receptors during suckling creates a focal point for infant attention, effectively reducing awareness of concurrent painful stimuli through attention-modulation mechanisms [2]. Concurrently, the natural sweetness inherent in breast milk composition triggers endogenous opioid release within midbrain structures, with these neurochemical compounds exerting analgesic effects through μ-receptor pathway activation [7]. This mechanism has been consistently demonstrated in studies evaluating sweet solution administration for procedural pain management.

The skin-to-skin contact component of breastfeeding provides additional therapeutic benefits through multiple physiological stabilization pathways. Research has demonstrated that maternal-infant skin contact promotes regulation of autonomic nervous system function, contributing to stabilized cardiovascular parameters, improved thermoregulation, and reduced stress hormone secretion [5-6]. These effects likely contributed to the reduced heart rate variability and improved oxygen saturation stability observed in our breastfeeding group participants. Furthermore, the intimate maternal-infant interaction inherent in breastfeeding may stimulate oxytocin release, contributing to enhanced comfort and stress reduction through neuroendocrine pathways [11].

Our findings demonstrate consistency with previous research investigating breastfeeding's analgesic properties. Goswami and colleagues conducted a comparable investigation involving 120 infants receiving DPT vaccination, reporting significantly reduced crying duration in directly breastfed participants (33.5 seconds) compared to control subjects (80.5 seconds) [17]. Their study additionally documented significantly lower Modified Facial Coding Scores in breastfed infants,

supporting our PIPP score observations. The consistency of findings across different painful procedures and assessment methodologies strengthens the evidence base for breastfeeding's analgesic effectiveness.

Comparative studies have demonstrated breastfeeding's superiority over alternative non-pharmacological interventions. Upadhyay et al. conducted a randomized, placebo-controlled, double-blind trial examining the analgesic effect of expressed breast milk in procedural pain in term neonates, demonstrating significant pain reduction compared to placebo interventions [9]. Similarly, investigations by Uyan and colleagues evaluated the effect of foremilk and hindmilk on simple procedural pain in newborns, finding substantial analgesic benefits [10]. These findings suggest that breastfeeding may provide superior analgesia compared to sweet solutions alone, potentially due to the additional benefits of maternal contact, thermal regulation, and the multisensory experience inherent in breastfeeding.

Multiple studies have confirmed the effectiveness of breastfeeding during various painful procedures. Osinaike et al. demonstrated the effect of breastfeeding during venipuncture in neonates, showing significant pain reduction [11]. Singh and colleagues investigated the antinociceptive effect of exclusive breastfeeding in healthy term infants during vaccination procedures, finding substantial protective effects [12]. Uga et al. evaluated heel lance procedures in newborns during breastfeeding, confirming the analgesic properties of this intervention [13]. The consistency across these diverse investigations reinforces the robustness of breastfeeding's analgesic effects.

The clinical implications of these findings extend beyond immediate pain relief to broader considerations of neonatal care quality and developmental outcomes. Breastfeeding represents an ideal non-pharmacological intervention that is immediately available, cost-free, and associated with numerous additional health benefits including enhanced immune function, improved maternal-infant bonding, and optimal nutritional provision [14]. Unlike pharmacological pain management approaches, breastfeeding carries no risk of systemic adverse effects while actively promoting other aspects of neonatal health and development.

However, several methodological considerations warrant acknowledgment. The inherent nature of the breastfeeding intervention precluded complete investigator blinding, potentially introducing assessment bias despite standardized evaluation protocols. Additionally, breastfeeding feasibility may be limited in certain clinical scenarios, such as maternal unavailability, feeding restrictions, or critical illness requiring intensive support [18]. The assessment of facial expressions during breastfeeding was necessarily limited to the visible portion of the infant's face, though the assumption of bilateral facial symmetry in neurologically intact neonates appears physiologically reasonable.

The broader implications of enhanced neonatal pain management extend to long-term developmental considerations. Research evidence suggests that repeated painful experiences during the neonatal period may have lasting effects on pain sensitivity, stress response patterns, and neurodevelopmental outcomes [8]. By providing effective analgesia during routine procedures, breastfeeding may contribute to improved long-term developmental trajectories, though longitudinal investigations would be necessary to definitively establish these associations.

Future research directions should explore optimal timing and duration parameters for breastfeeding interventions to maximize analgesic effectiveness, investigate combination approaches with other non-pharmacological strategies, and evaluate effectiveness across diverse procedural types and clinical settings [7]. Additionally, studies examining the comparative effectiveness of expressed breast milk administration when direct breastfeeding is not feasible would provide valuable clinical guidance for broader implementation.

The integration of breastfeeding into standardized pain management protocols requires consideration of practical implementation factors including staff education and training programs, maternal education initiatives, and development of appropriate clinical guidelines for various scenarios [3]. Healthcare providers require education about the scientific evidence supporting breastfeeding for procedural analgesia and training in facilitating this intervention when clinically appropriate and feasible.

The strength of this randomized controlled trial lies in its robust design, adequate sample size, and use of a validated multidimensional tool (PIPP) for objective pain assessment, ensuring reliability of findings. The study also maintained balanced baseline characteristics between groups and standardized procedural protocols, enhancing internal validity. Furthermore, the intervention—direct breastfeeding—was safe, cost-effective, and clinically feasible, thereby increasing the applicability of results in routine neonatal care. However, certain limitations exist: complete blinding of observers was not possible due to the nature of the intervention, which could introduce some assessment bias. The evaluation of facial expressions during breastfeeding was restricted to the visible part of the face, assuming bilateral symmetry, which may slightly affect precision. Additionally, the study was conducted in a single-centre setting, limiting generalizability to broader populations, and excluded critically ill or non-breastfed neonates, restricting applicability to all neonatal subgroups. Despite these limitations, the trial provides strong evidence supporting breastfeeding as an effective non-pharmacological analgesic strategy during neonatal heel pricks.

5. CONCLUSION

This study shows that breastfeeding is a highly effective, safe, and practical non-pharmacological intervention for neonatal procedural pain, with most breastfed infants experiencing no pain and none experiencing severe pain during heel pricks. Its natural availability, cost-effectiveness, and added health benefits make it an ideal first-line strategy, and healthcare providers should incorporate it into routine neonatal pain management to ensure humane care and better developmental outcomes.

Conflict of interest: None

Acknwoldgement: None

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