Section: Pediatrics

Original Research Article

TO STUDY THE ANALGESIC EFFECT OF NON NUTRITIVE SUCKING IN NEONATES (>32 WEEKS) DURING PROCEDURAL PAIN USING THE NIPS SCALE

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Abstract

Background: Neonates frequently undergo painful procedures during their hospital stay, necessitating effective pain management strategies. Non-nutritive sucking (NNS) using a pacifier is a simple, non-pharmacological method that may alleviate procedural pain in neonates. This study aimed to evaluate the analgesic effect of NNS during heel prick procedures in neonates born after 32 weeks of gestation using the Neonatal Infant Pain Scale (NIPS).

Objective: The primary objective was to assess the impact of NNS on neonatal pain responses during heel pricks. The secondary objective was to analyze changes in heart rate (HR) and oxygen saturation (SpO_2) associated with NNS use. **Methods:** A cross-sectional observational study was conducted at Army Hospital (R&R), New Delhi, from November 2020 to March 2022. Thirty-five neonates were included based on predefined inclusion criteria. Each neonate underwent a heel prick without a pacifier, followed by another with a pacifier, and responses were recorded at 30 seconds and 2 minutes post-procedure. Pain responses were assessed using NIPS, and physiological parameters (HR, SpO_2) were analyzed. Statistical analysis was performed using SPSS version 28.0, with $p<0.05$ considered significant. **Results:** The pacifier group demonstrated significantly reduced facial grimacing, crying, and irregular breathing at 2 minutes post-heel prick compared to the non-pacifier group ($p<0.001$). NIPS scores were significantly lower in the pacifier group, indicating reduced pain perception. Heart rates normalized faster in the pacifier group, while SpO_2 remained comparable between groups. **Conclusion:** Non-nutritive sucking is an effective and safe non-pharmacological intervention for procedural pain relief in neonates. The study supports its routine use in neonatal care to enhance comfort and reduce distress during painful procedures.

INTRODUCTION

Newborns admitted to neonatal intensive care units (NICUs) undergo numerous painful procedures during their stay, ranging from diagnostic to interventional. Although these infants cannot verbalize their pain, they express it through physiological changes and specific behaviors. Historically, it was believed that infants' immature brain development meant they did not feel pain, leading to poor pain management. However, research has shown that both full-term and preterm neonates experience pain, prompting the Canadian Pediatric Society and the American Academy of Pediatrics to call for improved neonatal pain care.[1]

Pain, defined by the International Association for the Study of Pain (IASP) as an unpleasant sensory and emotional experience related to actual or potential tissue damage, is common among all newborns, including healthy ones. They undergo routine invasive procedures in the first few days of life, such as vitamin injections, vaccinations, and blood tests. Scientific studies suggest that infants may feel pain more intensely than older children and adults, and their early pain experiences can have long-term effects, even persisting into preschool age and beyond.[2]

To assess pain in neonates, surrogate markers are used, as they exhibit physiological, biochemical, behavioral, and psychological changes during painful experiences. Immediate effects of pain in

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neonates include irritability, fear, disrupted sleep, and increased oxygen consumption, which can lead to short-term consequences like delayed healing and impaired emotional bonding. Long-term effects can include developmental delays and altered responses to future painful experiences. It is essential to improve pain prevention, assessment, and management to minimize these adverse effects.[3]

Both pharmacological and non-pharmacological methods are used to manage neonatal pain. Among non-pharmacological techniques, non-nutritive sucking (NNS), where a pacifier stimulates the sucking reflex, is safe and effective. This method activates the analgesic pathway and tactile sensitivity, providing relief from acute pain caused by procedures like heel punctures and immunizations. Despite its effectiveness, NNS has not been widely studied using certain pain scales, such as the Neonatal Infant Pain Scale (NIPS), which is known for its reliability.[4]

Randomized controlled trials (RCTs) have explored NNS for pain relief during routine procedures, though variations in study methods and pain assessment scales exist. NNS has been found to reduce the discomfort associated with procedures like heel pricks, but more research is needed to standardize its use.[5]

Each year, millions of preterm babies are born globally, and despite advances in neonatal care, preterm infants are still at risk for long-term impairments such as cerebral palsy and respiratory issues. Preterm infants in NICUs often undergo multiple painful procedures daily. Their nociceptors and nervous systems are still developing, making them more vulnerable to pain than older children. Pain can lead to serious complications such as brain injury due to increased intracranial pressure or oxygen desaturation, both of which can result in cognitive and behavioral problems.[6]

Assessing pain in newborns can be done using unidimensional or multidimensional approaches. In NICUs, multidimensional tools like the Premature Infant Pain Profile (PIPP) and the Neonatal Infant Pain Scale (NIPS) assess physiological and behavioral responses. These tools are useful for detecting acute pain, but none specifically address chronic pain.

Several non-pharmacological methods, such as Kangaroo Care (skin-to-skin contact) and massage therapy, have shown promise in reducing neonatal pain. Kangaroo Care has been particularly effective in reducing crying and improving pain scores during procedures like heel sticks. Massage therapy, involving gentle manipulation of the skin, has also been found to reduce pain scores and promote weight gain in preterm infants. Acupuncture, though less studied, is another non-pharmacological method that may stimulate the endorphin system to alleviate pain.[7]

Non-nutritive sucking, especially when combined with sweeteners like sucrose or glucose, enhances the pain-relieving effects of these methods. Sucrose, in particular, has been effective in reducing pain during minor procedures such as heel sticks, though repeated use raises concerns about potential long-term effects.[8]

Non-pharmacological treatments like NNS are safe and effective for managing neonatal pain. These methods not only reduce acute pain but also offer benefits for growth and long-term neurodevelopment. Although the mechanisms behind NNS are not fully understood, its ability to stimulate analgesia makes it a valuable tool for alleviating neonatal discomfort.[9,10]

The aim of the study is to evaluate the analgesic effect of non-nutritive sucking (oral pacifier) in neonates born after 32 weeks of gestation during procedural pain. The secondary objective is to assess the impact of non-nutritive sucking on heart rate (HR) and oxygen saturation (SpO2) fluctuations during these procedures.

MATERIALS AND METHODS

This Cross-sectional observation study was conducted at the Department of Pediatrics, Army Hospital (R & R), New Delhi from Nov 2020 to Mar 2022. Ethical approval has been obtained from the Ethical Approval Committee of Department of Paediatrics, Army Hospital (R & R), New Delhi. Neonates who met the inclusion criteria were selected over a period of 18 months and underwent first heel prick without pacifier and later the subsequent heel prick with pacifier and NIPS scores were recorded. Neonates were videotaped within the first 14 days after birth. Only heel prick was videotaped on each neonate. The videotaping was done when infants were free of analgesia for at least 3 hours (in the unlikely event they had been medicated) and for heel prick with one attempt only using a 24 G Hypodermic needle. The neonates were allowed to stabilize and calm prior to beginning of videotaping. A mobile video camera (VIVO V7 with 14 MP camera) held at a fixed distance of one meter from the head of the infant was used to record the procedure, starting 30 seconds before until 2 minutes after the heel prick. The recorded videos were later analysed using the Neonate Infant Pain Scale (NIPS) scale once at 30 seconds and at 2 minutes by one independent assessor, who was Nursing Officer on duty and was trained in analysing the NIPS scale.

Study Population: The study included neonates born at ≥32 weeks of gestation admitted to the NICU and postnatal ward. Informed consent was obtained from parents before enrollment. Inclusion criteria: neonates born at the study center requiring heel prick. Exclusion criteria: neonates on respiratory support, with neonatal depression, congenital anomalies, dysmorphic facies, or CNS disorders.

Data Analysis: Data analysis was conducted using SPSS version 28.0. Continuous variables were presented as mean ± SD, median (IQR), and range,

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while categorical variables were shown as absolute numbers and percentages. Normality was assessed before analysis. Normally distributed variables were compared using the unpaired t-test, non-normal variables with the Mann-Whitney U test, and categorical variables with the chi-square or Fisher's exact test. A p-value <0.05 indicated statistical significance.

RESULTS

In the study of 35 neonates, 57.1% were female (20) and 42.9% were male (15). Regarding the mode of delivery, 62.9% (22) were delivered through normal vaginal delivery (NVD), while 37.1% (13) were born via lower segment cesarean section (LSCS). The birth weight analysis showed that 31.4% (11) of the neonates weighed less than 2500 grams, and 68.6% (24) had a birth weight exceeding 2500 grams. The average birth weight was 2753.43 ± 546.05 grams, with a range between 1005 and 4050 grams. Concerning gestational age, 14.3% (5) of the neonates were born before 37 weeks, while the majority, 85.7% (30), were born at or after 37 weeks. In terms of conception, 74.3% (26) were conceived spontaneously, and 25.7% (9) were conceived through in vitro fertilization (IVF). Additionally, most of the neonates were singletons, accounting for 88.6% (31), while twins represented 11.4% (4). Lastly, resuscitation at birth was required for only one neonate (2.9%), while the remaining 97.1% (34) did not need any resuscitation.

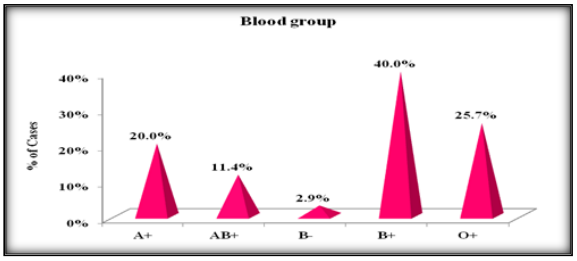

Figure 1: Distribution of neonates according to the Blood group

The chart above illustrates the distribution of neonates in the study by blood group. It was found that 20.0% of the neonates were A+, 11.4% were AB+, 2.9% were B-, 40.0% were B+, and 25.7% were O+.

The distribution of neonates according to comorbidities revealed that 17.1% had gestational diabetes mellitus (GDM), 12.9% had hypothyroidism, and 4.3% had gestational hypertension. Analyzing the day of life (DOL), 8.6% of neonates were 2 days old, 62.9% were 3 days old, 22.9% were 4 days old, while 2.9% were 5 and 8 days old, respectively. In terms of disease distribution, 1.4% had hydronephrosis, 4.3% had low birth weight (LBW), 35.7% had neonatal jaundice (NNJ), 2.9% were preterm, and another 1.4% had Rh isoimmunization.

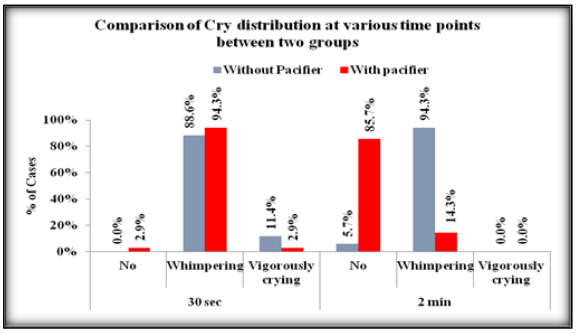

Figure 2: Comparison between the two groups according to the Cry at various time points

The comparison of facial expressions between the two study groups revealed that 100% of neonates in the Without Pacifier Group displayed a grimace at 30 seconds, decreasing to 40% at 2 minutes. In contrast, 88.6% and only 2.9% in the Pacifier Group exhibited similar expressions, with a significant difference noted at 2 minutes (p = 0.001).

The comparison of crying behavior between the two groups showed that in the Without Pacifier Group, 88.6% of neonates were whimpering at 30 seconds, with 11.4% crying vigorously. At 2 minutes, 94.3% were whimpering, and 5.7% did not cry. In the Pacifier Group, 94.3% of neonates were whimpering at 30 seconds, with 2.9% crying vigorously, and at 2 minutes, 85.7% did not cry while 14.3% were whimpering. There was no significant difference at 30 seconds (p = 0.239), but it was significant at 2 minutes (p = 0.001).

The comparison of breathing patterns showed that 88.6% of neonates in the Without Pacifier Group had irregular/fast breathing at 30 seconds, reducing to 48.6% at 2 minutes. In the Pacifier Group, 80% had irregular breathing at 30 seconds, dropping to 20% at 2 minutes. No significant difference was observed at 30 seconds (p = 0.513), but it was significant at 2 minutes (p = 0.012).

The comparison of arms pattern revealed that 57.1% of neonates in the Without Pacifier Group had flexed/extended arms at 30 seconds, reducing to 31.4% at 2 minutes. In the Pacifier Group, 40% had flexed/extended arms at 30 seconds, decreasing to 5.7% at 2 minutes. No significant difference was noted at 30 seconds (p = 0.151), but it was significant at 2 minutes (p = 0.012).

The comparison of leg patterns showed that 62.9% of neonates in the Without Pacifier Group had flexed/extended legs at 30 seconds, dropping to 31.4% at 2 minutes. In the Pacifier Group, 51.4% had flexed/extended legs at 30 seconds, reducing to 5.7% at 2 minutes. No significant difference was found at 30 seconds (p = 0.334), but it was significant at 2 minutes (p = 0.012).

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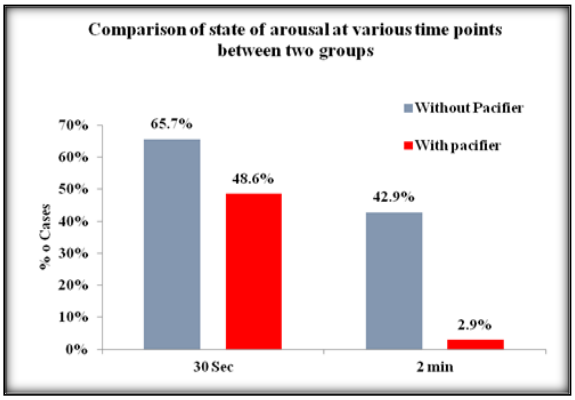

Figure 3: Comparison of State of arousal rate at various time points between the two groups

The comparison of state of arousal showed that in the Without Pacifier Group, 65.7% of neonates were fussy/restless at 30 seconds, decreasing to 42.9% at 2 minutes. In the Pacifier Group, 48.6% were fussy/restless at 30 seconds, dropping to 2.9% at 2 minutes. No significant difference was noted at 30 seconds ($p = 0.147$), but it was significant at 2 minutes ($p = 0.001$).

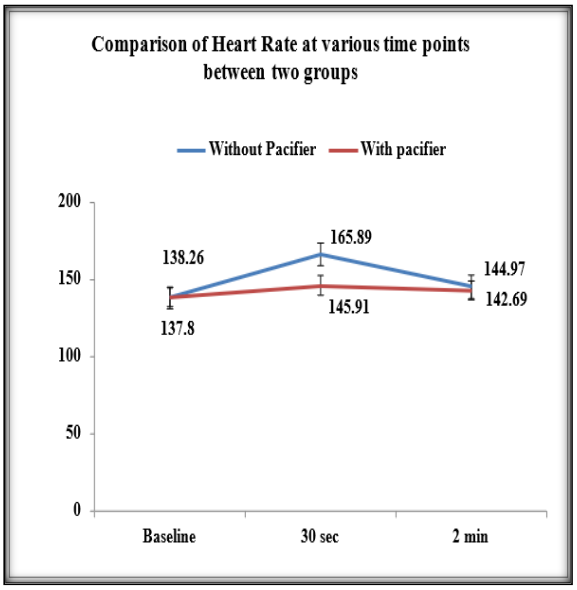

Figure 4: Comparison of Heart rate at various time points between two groups

The comparison of NIPS scores between the two groups showed that in the Without Pacifier Group, the mean score at 30 seconds was 4.85 ± 1.06, decreasing to 2.91 ± 1.22 at 2 minutes. In the Pacifier Group, the mean score was 4.28 ± 1.12 at 30 seconds, dropping to 0.51 ± 0.85 at 2 minutes. No significant difference was found at 30 seconds ($p = 0.106$), but it was significant at 2 minutes ($p < 0.001$).

The chart compares the mean heart rate (HR) between two groups at different time points. In the Without Pacifier Group, the mean HR increased from 137.8 at baseline to 165.89 at 30 seconds, then decreased to 144.97 at 2 minutes. In the Pacifier Group, the mean HR rose from 138.26 at baseline to 145.91 at 30 seconds, and then slightly dropped to 142.69 at 2 minutes. No significant difference was observed at baseline ($p = 0.770$) or 2 minutes ($p = 0.166$), but there was a significant difference at 30 seconds ($p = 0.001$).

The chart compares mean SPO2 between two groups at different time points. In the Without Pacifier Group, mean SPO2 decreased from 97.89 at baseline to 95.29 at 30 seconds, then rose to 96.74 at 2 minutes. In the Pacifier Group, mean SPO2 decreased from 98.14 to 96 at 30 seconds, then rose to 96.94 at 2 minutes. No significant differences were observed at baseline, 30 seconds, or 2 minutes ($p > 0.05$).

Table 1: Comparison of Facial Expression at various time points between two groups.

Facial Expression	Without Pacifier		With Pacifier		p value
	Frequency	%	Frequency	%	
30 Sec after heel prick	35	100.0%	31	88.6%	0.114
2 min after heel prick	14	40.0%	1	2.9%	0.001*

**Significant p value<0.05*

Table 2: Comparison of Breathing pattern at various time points between two groups

Breathing	Without Pacifier (n=35)		With Pacifier (n=35)		p value
	Frequency	%	Frequency	%	
30 Sec	31	88.6%	28	80.0%	0.513
2 min	17	48.6%	7	20.0%	0.012*

**Signifies significant p value<0.05*

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Table 3: Comparison of Arms pattern at various time points between two groups

Arms	Without Pacifier		With Pacifier		p value
	Frequency	%	Frequency	%	
30 Sec	20	57.1%	14	40.0%	0.151
2 min	11	31.4%	2	5.7%	0.012*

**Signifies significant p value<0.05*

Table 4: Comparison of Legs pattern at various time points between two groups

Legs	Without Pacifier		With Pacifier		p value
	Frequency	%	Frequency	%	
30 Sec	22	62.9%	18	51.4%	0.334
2 min	11	31.4%	2	5.7%	0.012*

**Signifies significant p value<0.05*

Table 5: Comparison of NIPS score at 30 seconds and 2 minutes between two groups

NIPS score	Without Pacifier			With Pacifier			p value
	Mean ± SD	Min - Max	Median (IQR)	Mean ± SD	Min - Max	Median (IQR)	
30 sec	4.85 ± 1.06	3 - 7	5 (4 - 5)	4.28 ± 1.12	2 - 6	4 (3 - 5)	0.106
2 min	2.91 ± 1.22	1 - 5	3 (2 - 4)	0.51 ± 0.85	0 - 4	0 (0 - 1)	<0.001**

***Signifies highly significant p value<0.05*

Table 6: Comparison of SPO2 at various time points between two groups

SPO2	Without Pacifier	With Pacifier	p value
	Mean ± SD	Mean ± SD	
Baseline	97.89 ± 1.16	98.14 ± 1.4	0.405
30 secs	95.29 ± 1.36	96 ± 1.73	0.059
2 min	96.74 ± 1.22	96.94 ± 1.35	0.518

DISCUSSION

Several randomized controlled trials have investigated the efficacy of non-nutritive sucking (NNS) in alleviating pain during common neonatal procedures such as heel pricks, immunizations, and venipuncture. However, inconsistencies exist regarding the pain scales used, randomization techniques, and the duration of pacifier use necessary for an analgesic effect. Importantly, there is limited research examining the impact of NNS using the Neonatal Infant Pain Scale (NIPS).[11,12]

A cross-sectional observational study was conducted over 18 months to evaluate the analgesic effect of non-nutritive sucking (via oral pacifier) in neonates aged ≥32 weeks during procedural pain, using the NIPS scale. The study included neonates born at or after 32 weeks of gestation who were admitted to the Neonatal Intensive Care Unit and postnatal wards of Army Hospital in Delhi. Thirty-five neonates were enrolled based on specific inclusion and exclusion criteria, and their gender distribution revealed that 57.1% were female and 42.9% were male.[13,14]

The neonates were categorized by mode of delivery, with 62.9% born via normal vaginal delivery and 37.1% through lower segment cesarean section (LSCS). The birth weight distribution showed that 31.4% of neonates weighed less than 2,500 grams, while the majority, 68.6%, weighed more than 2,500 grams. The mean birth weight was 2753.43 grams, with a range from 1005 grams to 4050 grams.[15,16]

When categorized by the period of gestation (POG), 85.7% of the neonates were born after 37 weeks, while 14.3% were born before 37 weeks, indicating that the majority were full-term births. In terms of conception method, 74.3% of the neonates were conceived spontaneously, reflecting natural conception, while 25.7% were conceived through in vitro fertilization (IVF), highlighting the role of assisted reproductive technologies in a portion of the cases. Additionally, most of the neonates were singletons, comprising 88.6% of the births, while 11.4% were twin births. These patterns provide a clear understanding of the characteristics of the neonates based on their gestational age, conception method, and whether they were born as singletons or part of a multiple pregnancy. This data is important in assessing the overall health outcomes and developmental progress of the neonates, as gestational age, mode of conception, and birth plurality can all influence neonatal outcomes. Neonates born after 37 weeks are typically considered full-term and are expected to have more favorable health outcomes, while those born before 37 weeks may require additional care due to premature birth.[17-19]

Only 2.9% of neonates required resuscitation at birth, and the majority, 97.1%, did not. Blood group distribution showed that 40% of the neonates had blood group B positive, with smaller percentages for other blood types. Regarding maternal conditions, 17.1% of neonates were born to mothers with gestational diabetes mellitus (GDM), 12.9% had maternal hypothyroidism, and 4.3% had maternal gestational hypertension.[20-22]

The neonates were categorized based on the day of life (DOL) when the heel prick was performed. The highest proportion, 31.4%, underwent the prick on the third day of life. The study also looked at disease conditions, with 35.7% of neonates having neonatal

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jaundice (NNJ) and others having conditions such as low birth weight and preterm birth.[23,24]

In the study, neonates were subjected to a heel prick procedure first without a pacifier and then with a pacifier during a subsequent heel prick, with observations made at 30 seconds and 2 minutes post-prick. Facial expressions, such as brow bulge, eye squeeze, nasolabial furrow, and open mouth, were observed. The results showed that 100% of neonates in the without pacifier group exhibited a grimace at 30 seconds, decreasing to 40% at 2 minutes. In the pacifier group, 88.6% exhibited a grimace at 30 seconds, but only 2.9% at 2 minutes. There was no significant difference in facial expression at 30 seconds between the two groups, but a significant difference was observed at 2 minutes.[25,26]

Regarding crying patterns, in the without pacifier group, 65.7% of neonates were vigorously crying at 30 seconds, while 94.3% were crying at 2 minutes. In the pacifier group, 94.3% were whimpering at 30 seconds, and by 2 minutes, 85.7% showed no cry. There was no significant difference in crying patterns at 30 seconds, but a significant difference was found at 2 minutes.[27]

The breathing pattern, an important physiological indicator, was also monitored. At 30 seconds, 100% of neonates in the without pacifier group had irregular and fast breathing, which decreased to 48.6% at 2 minutes. In the pacifier group, 80% had irregular and fast breathing at 30 seconds, but this dropped to 20% at 2 minutes. A significant difference in breathing patterns was observed at 2 minutes between the two groups.[28,29]

Neonatal arm and leg positioning were monitored to detect muscle rigidity. In the without pacifier group, 57.1% had flexed/extended arms at 30 seconds, and 31.4% at 2 minutes. In contrast, in the pacifier group, 40% had flexed/extended arms at 30 seconds, and only 5.7% at 2 minutes. Leg patterns followed a similar trend, with a significant difference in the pacifier group at 2 minutes.[30]

State of arousal was measured as either fussy/restless or calm. In the without pacifier group, 65.7% were fussy at 30 seconds and 42.9% at 2 minutes. In the pacifier group, 48.6% were fussy at 30 seconds, dropping to 2.9% at 2 minutes. A significant difference was observed at 2 minutes in arousal states between the two groups.[31]

The NIPS scores were compared between the two groups, with the without pacifier group showing higher pain scores at both 30 seconds and 2 minutes. However, the pacifier group showed a significantly lower NIPS score at 2 minutes, indicating a greater reduction in pain.

Heart rate and oxygen saturation (SPO2) were also recorded. The without pacifier group exhibited a higher heart rate at 30 seconds, while both groups showed similar heart rates at baseline and 2 minutes. Oxygen saturation levels declined in both groups after the procedure but stabilized by 2 minutes, with no significant difference between the two groups.[32,33]

Non-nutritive sucking via pacifier showed a significant analgesic effect in neonates, particularly in reducing facial grimacing, crying, and pain scores as measured by NIPS, especially at 2 minutes after a painful procedure.[34]

CONCLUSION

The study demonstrated that non-nutritive sucking (NNS) using a pacifier significantly reduced pain responses in neonates during heel prick procedures. Neonates who used pacifiers showed a notable decrease in facial grimacing, crying, irregular breathing, and flexed limbs at 2 minutes post-procedure compared to those without pacifiers. Additionally, heart rates normalized more quickly in the pacifier group. The Neonatal Infant Pain Scale (NIPS) scores were significantly lower in the pacifier group, indicating a reduction in pain intensity. These findings highlight the effectiveness of NNS as a non-pharmacological pain management method in neonates.

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