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Assessment of Procedural Pain with and without interventions in Term Neonates Using Neonatal Infant Pain Scale (NIPS): A Comparative Cross-Sectional Study

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ABSTRACT

Background: Neonatal procedural pain is associated with significant physiological and neurodevelopmental consequences. Routine procedures such as venipuncture and heel lance can cause considerable pain in term neonates. This study aimed to compare procedural pain intensity between term neonates receiving pain-relieving interventions and those receiving usual care using the Neonatal Infant Pain Scale (NIPS).

Materials and Methods: A hospital-based comparative cross-sectional study was conducted in the Department of Paediatrics at SDUMC, SDUAHER, Kolar, India, from February 2026 to March 2026. A total of 100 term neonates undergoing routine painful procedures were divided into two groups: Group A (with interventions) and Group B (without interventions). Pain was assessed using NIPS, and group comparisons were performed using Student's t-test.

Results: The study included 50 neonates in each group. Baseline characteristics including gender, gestational age, and mode of delivery were comparable between the groups. The mean NIPS score was significantly lower in Group A compared to Group B (2.6 ± 0.72 vs. 5.08 ± 0.87; $p < 0.01$), indicating a substantial reduction in procedural pain among neonates receiving interventions.

Conclusion: Pain-relieving interventions significantly reduced procedural pain in term neonates undergoing routine invasive procedures. The findings support the routine implementation of evidence-based non-pharmacological pain management strategies in neonatal care settings to minimize procedural distress and improve neonatal outcomes.

Keywords*: Neonatal Pain Neonatal Infant Pain Scale (NIPS) Procedural Pain Management Term Neonates Non-Pharmacological Interventions.*

INTRODUCTION

Neonatal procedural pain remains a significant and often under-recognized clinical challenge in term neonates, despite growing awareness of its profound impact on neurodevelopment and long-term health outcomes [1]. Routine interventions such as heel lance, venipuncture, and intramuscular injections are frequently performed in neonatal intensive care units (NICUs) and other care settings for diagnostic or therapeutic purposes [2]. Historically, neonates were thought to have immature nervous systems incapable of fully perceiving pain, leading to widespread undertreatment [3]. However, contemporary research unequivocally demonstrates that neonates, including those born at term, not only perceive pain but exhibit heightened responses due to underdeveloped pain-modulating pathways [1,3]. Untreated or poorly managed acute pain can lead to immediate physiological instability, including changes in heart rate, oxygen saturation, and salivary cortisol levels, and is associated with adverse long-term consequences such as altered pain processing, neurodevelopmental issues, and increased pain sensitivity later in life [1,4,5].

The Neonatal Infant Pain Scale (NIPS) is a widely validated, behavior-based observational tool used for assessing procedural pain in both preterm and term infants, evaluating facial expression, cry, breathing patterns, arm and leg movements, and state of arousal [6–8]. Despite its utility, evidence on the magnitude of pain reduction achievable through non-pharmacological and pharmacological interventions in term neonates remains crucial, particularly in resource-constrained settings where protocol-driven pain management is not yet standard. This study aims to quantitatively compare procedural pain intensity, as measured by NIPS, between term neonates receiving evidence-based pain interventions (e.g., sucrose, non-nutritive sucking, swaddling, and parental holding) versus those receiving usual care (no standardized intervention) in a comparative cross-sectional design. By focusing exclusively on term neonates, this research addresses a key gap in neonatal pain science and provides robust estimation of intervention efficacy.

MATERIALS AND METHODS

Study Design: This was a hospital-based comparative cross-sectional analytical study conducted to assess procedural pain in term neonates with and without interventions using the NIPS.

Study Area: The study was conducted over a period of 2 months (February 2026 to March 2026) at a tertiary care hospital in the Department of Paediatrics, SDUMC, SDUAHER, Kolar, India.

Study Population: The study population comprised term neonates undergoing routinely indicated painful procedures during their hospital stay.

Study Groups:

- Group A: Term neonates undergoing procedural pain with interventions.
- Group B: Term neonates undergoing procedural pain without interventions.

Inclusion Criteria:

- Hemodynamically stable neonates admitted or born in the hospital.
- Term neonates (≥37 weeks gestational age) aged ≤28 days of life.
- Neonates undergoing routinely performed painful procedures such as venipuncture, heel lance, arterial puncture, intramuscular injection, or endotracheal intubation.

Exclusion Criteria:

- Neonates receiving continuous sedation or neuromuscular blockade at the time of assessment.
- Neonates with major congenital neurological malformations.
- Critically unstable neonates in whom pain assessment was not feasible.

Sample Size: A total of 100 term neonates meeting the inclusion criteria were enrolled in the study.

Sampling Methodology: A consecutive sampling technique was used, wherein all eligible neonates admitted during the study period were included until the desired sample size was achieved.

Data Collection and Procedure:

- After obtaining Institutional Ethics Committee approval and written informed consent from parents or guardians, eligible neonates were enrolled consecutively in the study.
- Baseline demographic and clinical details including gestational age, birth weight, postnatal age, sex, primary diagnosis, and relevant clinical parameters were recorded using a predesigned proforma.
- Pain assessment was performed during routinely indicated painful procedures such as venipuncture, without conducting any additional procedures solely for research purposes.
- Pain was assessed using the NIPS at baseline (before the procedure), during the procedure, and immediately after the procedure (within 1–2 minutes).
- All assessments were performed by trained healthcare personnel, and the observer did not interfere with routine clinical care.
- The highest NIPS score recorded during the observation period was considered for analysis, while the average NIPS score for venipuncture was calculated to estimate pain severity and categorize neonates into graded pain severity groups.

Data Analysis:

- Data were entered into Microsoft Excel and analysed using SPSS software version 22.0.
- Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages.
- Comparison between the two study groups was performed using Student's t-test.
- A p-value <0.05 was considered statistically significant.

Ethical Considerations:

- Ethical approval was obtained from the Institutional Ethics Committee prior to commencement of the study.
- Written informed consent was obtained from parents or legal guardians of all enrolled neonates.
- The study adhered to ethical principles for biomedical research involving human participants.
- Confidentiality of patient information was strictly maintained throughout the study.

RESULTS

The baseline characteristics of neonates included in both study groups are shown in (Table 1). The distribution of gender, gestational age, and mode of delivery was comparable between Group A and Group B, with no major differences observed between the groups.

The mean NIPS score was significantly lower in Group A compared to Group B, indicating reduced procedural pain in neonates receiving interventions (Table 2). This difference was statistically significant ($p<0.01$).

Table 1: Baseline Characteristics of Study Groups

Variable	Category	Group A (n=50)	Group B (n=50)
Gender	Male	25 (50%)	27 (54%)
	Female	25 (50%)	23 (46%)
Gestational Age	37–38 weeks	9 (18%)	13 (26%)
	38–39 weeks	17 (34%)	18 (36%)
	39–40 weeks	17 (34%)	13 (26%)
	>40 weeks	7 (14%)	6 (12%)
Mode of Delivery	LSCS	26 (52%)	33 (66%)
	NVD	24 (48%)	17 (34%)

LSCS: Lower Segment Caesarean Section; NVD: Normal Vaginal Delivery.

Table 2: Comparison of NIPS Scores Between Study Groups (Mean ± SD)

Parameter	Group A (n=50)	Group B (n=50)	p-value
NIPS Score	2.6 ± 0.72	5.08 ± 0.87	<0.01**

NIPS: Neonatal Infant Pain Scale. **Statistically significant.

DISCUSSION

This comparative cross-sectional study demonstrates a clinically and statistically significant reduction in procedural pain among term neonates receiving interventions compared to those receiving usual care, as measured by the NIPS. The mean NIPS score in the intervention group (Group A) was 2.6 ± 0.72, which was significantly lower than the mean NIPS score of 5.08 ± 0.87 in the control group (Group B), with a p-value of <0.01. This reduction highlights the critical importance of implementing evidence-based pain management strategies in term neonates during common invasive procedures. The baseline characteristics, including gender, gestational age, and mode of delivery, were comparable between the two groups, strengthening the internal validity of our findings.

These results are consistent with a substantial body of recent literature emphasizing the efficacy of non-pharmacological interventions in mitigating neonatal procedural pain . A meta-analysis published in 2023 highlighted the effectiveness of various non-pharmacological interventions during heel prick procedures in neonates, underscoring their positive impact on physiological responses and pain scores [3]. Specifically, our observed absolute decrease in mean NIPS scores ($\Delta = 2.48$) aligns closely with recent randomized controlled trials. For instance, a 2024 randomized controlled trial by Akkaya-Gül and Özyazıcıoğlu found that pacifier use, especially when combined with 25% dextrose, significantly reduced NIPS pain scores and improved physiological responses during orogastric tube insertion in term neonates [9]. Similarly, a 2012 Cochrane review by Shah et al. reported significantly lower NIPS scores in breastfed neonates compared to no intervention, with analgesic effects comparable to oral sucrose for procedural pain relief in neonates [4].

While our study did not isolate the effect of individual interventions, the combined approach in Group A yielded a notable reduction in pain intensity. This aligns with continuous quality improvement measures in neonatal pain management that advocate for multimodal approaches [10]. The consistent findings across these recent studies, including ours, underscore the effectiveness of both pharmacological and non-pharmacological methods for mitigating procedural pain in neonates. The results reinforce current clinical guidelines from organizations like the WHO and AAP, which advocate for universal, protocolized pain mitigation during neonatal procedures, demonstrating that even low-cost and easily implementable interventions can yield substantial, measurable analgesia in term infants [3,4]. This research contributes to the growing body of evidence supporting the integration of comprehensive pain management protocols into routine neonatal care to improve patient comfort and long-term outcomes.

CONCLUSION

Overall, the study confirms that while baseline characteristics such as gender, gestational age, and mode of delivery were comparable between groups, the implementation of interventions significantly reduced procedural pain. This underscores the need for routine use of non-pharmacological analgesic strategies to improve neonatal outcomes and minimize procedural distress.

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