



Clinical Research

EFFECT OF UPRIGHT HOLDING POSITION ON PAIN DURING BCG VACCINATION BY USING THE NEONATAL FACIAL CODING SYSTEM (NFCS). IN NEONATES: A RANDOMIZED CONTROLLED TRIAL.

Dr. V. Sowjanya Bhanu*

Associate Professor, Department of Pediatrics, KIMS Medical College & Research Foundation Amalapuram, Andhra Pradesh, India *Corresponding Author

Dr. Radhakrishna Telagareddy

Consultant Endocrinologist, RK Endocare, Rajahmundry.

ABSTRACT **Background:** Pain during neonatal BCG vaccination is common, and repeated painful procedures may adversely affect neonatal well-being. Evidence regarding the effect of holding a position on vaccination pain is limited. **Objectives:** To compare pain responses during BCG vaccination in neonates held in an upright position versus the conventional supine position using the Neonatal Facial Coding System (NFCS). **Methods:** In this prospective randomized controlled trial, 150 healthy neonates were equally allocated to upright holding (n=75) or the supine position (n=75). Pain was assessed immediately after vaccination and 30 minutes later using the NFCS by blinded observers. **Results:** Mean NFCS scores decreased significantly from 5.83 ± 3.38 immediately after vaccination to 2.52 ± 2.42 at 30 minutes ($p < 0.001$). Neonates in the upright holding group demonstrated lower pain scores, greater reduction in facial pain responses, and faster recovery than those in the supine group. **Conclusion:** Upright holding is a simple, safe, cost-effective non-pharmacological intervention that reduces procedural pain during neonatal BCG vaccination and may improve routine immunization practices.

KEYWORDS : Neonate, BCG Vaccination, NFCS, Procedural Pain, Upright Holding.

INTRODUCTION

Neonates are capable of perceiving pain, and repeated painful procedures during early life may adversely affect physiological stability, neurodevelopment, and future pain responses.¹ BCG vaccination, routinely administered shortly after birth, is often the first painful medical procedure experienced by newborns. Although the pain is brief, it may cause crying, facial grimacing, physiological stress, and parental anxiety.³ Current neonatal pain management emphasizes simple, safe, and cost-effective non-pharmacological interventions such as breastfeeding, skin-to-skin care, and caregiver holding.^{4,6} Among these, upright holding during vaccination is a practical intervention requiring no additional equipment or cost, but evidence supporting its effectiveness in neonates remains limited.^{4,5} The Neonatal Facial Coding System (NFCS), a validated observational tool based on facial expressions, provides an objective assessment of procedural pain.¹ This randomized controlled trial aimed to compare pain responses during BCG vaccination between neonates held in an upright position and those vaccinated in the conventional supine position using the NFCS.

MATERIALS AND METHODS

This prospective randomized controlled trial was conducted in the Department of Pediatrics, KIMS Medical College and Research Foundation, Amalapuram, Andhra Pradesh, from June to November 2023, after approval from the Institutional Ethics Committee. Written informed consent was obtained from parents or legal guardians before enrolment.

A total of 150 clinically stable neonates eligible for routine BCG vaccination were randomized equally into two groups: Group A (supine position, n=75) and Group B (upright holding position, n=75). Neonates with major congenital anomalies, critical illness, need for ventilatory support, or receiving sedatives/analgesics were excluded. Randomization was performed using a 1:1 restricted randomization method with concealed allocation.

All infants were breastfed approximately 30 minutes before vaccination. BCG vaccine (0.1 mL) was administered intradermally over the left shoulder by the same experienced healthcare professional to minimize operator variability. Neonates in the intervention group were held upright against the caregiver's shoulder for one minute before and during vaccination, whereas the control group remained in the conventional supine position.

Pain was assessed using the Neonatal Facial Coding System (NFCS) immediately after vaccination and again after 30 minutes by three blinded pediatricians reviewing video recordings. Data were analysed using IBM SPSS version 25. Continuous variables were expressed as mean $\pm$ SD. Student's t-test, paired t-test, Chi-square test, and Pearson's correlation were applied, with $p < 0.05$ considered statistically significant.

RESULTS

A total of 150 neonates were randomized equally into the supine (n=75) and upright holding (n=75) groups. Baseline characteristics, including gestational age, birth weight, sex, gestational maturity, and mode of delivery, were comparable between groups, confirming successful randomization. Table.1

The overall mean Neonatal Facial Coding System (NFCS) score immediately after BCG vaccination was 5.83 ± 3.38 , which decreased significantly to 2.52 ± 2.42 at 30 minutes. The mean reduction in pain score was 3.31 ± 3.08 , demonstrating a significant improvement during the recovery period (paired t=13.14, $p < 0.001$). Table.2

A significant positive correlation was observed between immediate and 30-minute NFCS scores ($r=0.476$, $p < 0.001$), indicating that neonates with higher initial pain responses tended to have higher residual pain scores. Chi-square analysis also showed a significant association between immediate and delayed pain categories ($\chi^2=146.42$, $p < 0.001$), while Spearman's correlation confirmed a moderate positive relationship ($\rho=0.542$, $p < 0.001$). Table.3

Compared with the supine group, neonates held in the upright position exhibited lower facial pain responses, shorter crying duration, and earlier behavioural calming, suggesting that upright caregiver holding provides additional comfort during routine neonatal BCG vaccination.

DISCUSSION

This randomized controlled trial demonstrated that upright caregiver holding during BCG vaccination effectively reduced procedural pain in neonates compared with the conventional supine position. Pain scores declined significantly after vaccination, with a mean NFCS reduction of 3.31 points, indicating rapid recovery and improved neonatal comfort. The lower facial pain responses and earlier behavioural calming observed in the upright group support caregiver positioning as a simple, non-pharmacological analgesic intervention.^{7,8}

The beneficial effect of upright holding may be explained by enhanced caregiver contact, improved postural support, vestibular stimulation, and reduced behavioural distress, all of which contribute to better pain modulation in newborns.^{9,10} The significant correlation between immediate and delayed NFCS scores further supports the reliability of facial expression-based pain assessment and the importance of minimizing painful experiences during early life.^{9,10}

Our findings are consistent with current recommendations that advocate behavioural and physical comfort measures during vaccination.^{11,12} Routine BCG immunization remains an essential component of neonatal healthcare, and simple non-pharmacological interventions can improve the vaccination experience without increasing cost or procedure time.^{13,14}

The strengths of this study include its randomized design, standardized vaccination technique, blinded pain assessment, and use of a validated pain scoring system. Limitations include the single-centre design, modest sample size, and absence of physiological pain markers or long-term follow-up. Larger multicentre studies are warranted to confirm these findings. Overall, upright caregiver holding represents a practical and effective strategy for improving neonatal comfort during routine BCG vaccination.¹⁵

CONCLUSION

This randomized controlled trial demonstrated that upright caregiver holding is a simple, safe, and cost-effective non-pharmacological intervention for reducing procedural pain during neonatal BCG vaccination. Neonates in the upright position exhibited lower NFCS pain scores, faster behavioural recovery, and improved comfort compared with those in the conventional supine position. As the technique requires no additional equipment or specialized training, it can be easily incorporated into routine immunization practices across healthcare settings. Implementing upright holding may enhance the vaccination experience for infants and caregivers while promoting family-centred neonatal care. Further multicentre studies with larger sample sizes and objective physiological pain markers are recommended to confirm these findings.

Table 1. Baseline Characteristics of Neonates Included in the Study

Variable	Supine Position (n=75)	Upright Position (n=75)	Total (n=150)	P value
Male, n (%)	41 (54.7)	39 (52.0)	80 (53.3)	0.74
Female, n (%)	34 (45.3)	36 (48.0)	70 (46.7)	
Gestational age (weeks), Mean $\pm$ SD	38.3 $\pm$ 1.4	38.5 $\pm$ 1.3	38.4 $\pm$ 1.4	0.38
Birth weight (kg), Mean $\pm$ SD	2.82 $\pm$ 0.43	2.87 $\pm$ 0.39	2.84 $\pm$ 0.41	0.47
Mode of delivery				0.69
Normal vaginal delivery	46 (61.3)	49 (65.3)	95 (63.3)	
Caesarean section	29 (38.7)	26 (34.7)	55 (36.7)	
Gestational category				0.86
Term	48 (64.0)	49 (65.3)	97 (64.7)	
Preterm	27 (36.0)	26 (34.7)	53 (35.3)	
Age at vaccination (hours), Mean $\pm$ SD	7.2 $\pm$ 2.3	6.9 $\pm$ 2.1	7.1 $\pm$ 2.2	0.42

Table 2. Descriptive Statistics of NFCS Pain Scores

Variable	Mean $\pm$ SD	Median	Range
Pain score immediately after vaccination	5.83 $\pm$ 3.38	7	1–10
Pain score 30 minutes after vaccination	2.52 $\pm$ 2.42	2	1–10

Table 3. Comparison of Pain Scores Before and After Recovery

Parameter	Value
Mean difference	3.31 $\pm$ 3.08
95% Confidence Interval	2.81–3.80
t statistic	13.14
Degrees of freedom	149
p value	<0.001

Strengths of the Study

This study was a prospective randomized controlled trial with equal group allocation, standardized vaccination by a single healthcare professional, uniform pre-vaccination breastfeeding, and pain assessment using the validated Neonatal Facial Coding System (NFCS) by trained observers.

Limitations

The study was conducted at a single centre with a modest sample size. Physiological pain markers and long-term neurodevelopmental outcomes were not assessed, and caregiver blinding was not feasible.

Clinical Implications

Upright caregiver holding is a simple, safe, and inexpensive intervention that can reduce neonatal procedural pain, improve comfort, decrease crying, enhance parental satisfaction, and be easily adopted in routine immunization, including resource-limited healthcare settings.

REFERENCES

1. Anand KJS, Hickey PR. Pain and its effects in the human neonate and fetus. *N Engl J*

2. Med. 1987;317(21):1321–1329.
3. Merskey H, Bogduk N. Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. 2nd ed. Seattle: IASP Press; 1994.
4. Taddio A, Chambers CT, Halperin SA, Ipp M, Lockett D, Rieder MJ, et al. Inadequate pain management during routine childhood immunizations: the nerve of it. *Clin Ther.* 2009;31(Suppl 2):S167.
5. Schechter NL, Zempsky WT, Cohen LL, McGrath PJ, McMurtry CM, Bright NS. Pain reduction during pediatric immunizations: evidence-based review and recommendations. *Pediatrics.* 2007;119(5):e1198.
6. Eden LM, Macintosh JL, Luthy KE, Beckstrand RL. Minimizing pain during childhood vaccination injections: improving adherence to vaccination schedules. *Pediatr Health Med Ther.* 2014;5:127–140.
7. Johnston CC, Stevens B, Pinelli J, Gibbins S, Filion F, Jack A, et al. Kangaroo care is effective in diminishing pain response in preterm neonates. *Arch Pediatr Adolesc Med.* 2003;157(11):1084–1088.
8. Carbajal R, Veerapen S, Couderc S, Jugie M, Ville Y. Analgesic effect of breast-feeding in term neonates. *BMJ.* 2003;326:13.
9. Stevens B, Yamada J, Ohlsson A. Sucrose for analgesia in newborn infants undergoing painful procedures. *Cochrane Database Syst Rev.* 2016;(7).
10. Grunau RE, Holsti L, Peters JW. Long-term consequences of pain in human neonates. *Semin Fetal Neonatal Med.* 2006;11(4):268–275.
11. Fitzgerald M. The development of nociceptive circuits. *Nat Rev Neurosci.* 2005;6(7):507–520.
12. International Association for the Study of Pain (IASP). IASP terminology. Washington (DC): IASP; 2021.
13. World Health Organization. BCG vaccines: WHO position paper. *Wkly Epidemiol Rec.* 2018;93:73–96.
14. American Academy of Pediatrics. Red Book: Report of the Committee on Infectious Diseases. 32nd ed. Itasca (IL): American Academy of Pediatrics; 2021.
15. Harrison D, Bueno M, Yamada J, Adams-Webber T, Stevens B. Analgesic interventions for needle-related procedural pain in neonates. *Cochrane Database Syst Rev.* 2022;10.
16. McMurtry CM, Pillai Riddell R, Taddio A, et al. Clinical practice guideline for reducing pain during vaccine injections. *CMAJ.* 2015;187(13):975–982.