

## Effect of Positioning on the Pain Response of Infants Vaccinated with Inactivated Polio and Pentavalent (dTwP-hepatitis B-hemophilus Influenza B) Vaccines

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### Abstract

**Objective** – To compare the acute pain response to sequential vaccination in two different positions: holding the baby on the parent's lap during vaccination injections (cuddle position) and making infants lie supine on the bed during vaccination procedure (bed position) after administration of IPV and pentavalent vaccines. **Material and Methods** – A total of 68 infants 34 each in cuddle and bed positions were included in the study. The procedure of injection was video recorded and later analysed by two resident interns for the pain response before and after the procedure using the neonatal infant pain scale (NIPS). **Results** – The baseline NIPS scores, median (IQR) was 0 (0-1) in the cuddle position and 0 (0-2) in the bed position. The pain response in both cuddle and bed positions was similar with a final NIPS score, median (IQR), of 7 (7-7). **Conclusion** – The parent held 'cuddle position' did not benefit the infants in terms of reducing acute pain response to vaccine injections compared to the supine (bed) position on the table.

**Key Words:** Immunization ■ Intervention during Vaccination ■ Pain ■ Modifying Position ■ Infants.

### Introduction

Vaccines are an important and easy way of preventing and eradicating a disease. However, globally there has been a rising trend of vaccine refusal and vaccine hesitancy (1). One of the important reasons for vaccine hesitancy among parents is the pain inflicted on the baby by the needle and the associated parental distress (2). Hence, efforts to reduce vaccination-related pain are very valuable. Several procedural and physical interventions that alleviate pain during vaccinations have been studied (3, 4). Vaccination pain responses in infants have also been found to change depending on the position of the child during vaccination. Few studies found that lying supine during vaccine injection results in more

pain than being held by a parent (3, 5). However, in another study was done by Ipp M et al. (6) there was no significant difference in pain responses of infants during vaccination when two different positions- supine position and held by a parent- were compared. The National Immunization Schedule (NIS) of India recommends the intramuscular pentavalent (DTwP-Hepatitis B-Hemophilus Influenza B) vaccine at 6, 10, and 14 weeks and intradermal fractional dose IPV (Inactivated Poliomyelitis Trivalent Vaccine) at 6 and 14 weeks (7).

The objective of this study was to compare the acute pain response in infants during sequential administration of IPV and pentavalent vaccines in two different positions: conventional supine position in

bed (bed position) versus being held on parent's lap (cuddle position) throughout the procedure.

## Methods

This controlled before-after study was conducted at the Government district hospital, (Regional Advanced Pediatrics Care Centre), Mangalore a tertiary care teaching hospital attached to KMC Mangalore, between February 2019 and April 2019. Ethical clearance was obtained from the institutional ethics committee of Kasturba Medical College Mangalore with a reference number for communication of decision IEC KMC MLR 02-19/66. Informed consent was obtained from the parents before video recording the process of vaccination of the infants. Infants aged 0-6 months, attending the outpatient of a district government hospital, Mangalore for primary doses of vaccination as per the National Immunization Schedule were included. Infants born with premature gestational age, parents who refused to consent to the study, infants whose parents were unavailable, those infants with major congenital anomalies, and infants who came for the second dose of vaccination that included pentavalent vaccine alone without injectable polio vaccine (IPV) were excluded. In order to get a difference of 2 in Neonatal Infant Pain Scale (NIPS) scores relating to the two vaccination positions; assuming a standard deviation of 2.5, for a power of 90% and  $\alpha$  5% a sample size of 34 infants in each group was calculated (8).

In the study center, the parents of infants were given a choice of either holding the baby on their lap during vaccination injections (cuddle position) or making the baby lie supine on the bed during vaccination procedure (bed position). All the infants received IPV intradermally at the right upper arm followed by pentavalent vaccine intramuscularly at left/right anterolateral mid-thigh sequentially (less painful first) in the same order in one of the two positions. The vaccine was administered by the same staff nurse in succession within 2-3 min of each other in the same order. The procedure was video recorded from 15 seconds before

to 30 seconds after the sequential injections to assess pain response in infants. A group of 34 infants (bed position group) were vaccinated in the supine position and the parents were allowed to carry the infant comfortably anytime following the vaccination injections. Another 34 infants (cuddle position group) were vaccinated after the parents held the child on their lap in a semi-recumbent position throughout the procedure. 0.1 ml of IPV vaccine (ShanIPV™) was given intradermally at the convex aspect of the right shoulder using a 0.1mL syringe with 0.45×10 mm (26×3/8) needle. Pentavalent vaccine (ComBEfive™), 0.5 ml was given intramuscularly at the anterolateral aspect of the left/right thigh using 0.5 mL syringe with 0.60×25 mm (23×1) needle. The newborns were soled during, before, and after the injections. The newborns were restrained only during the procedure to warrant that the pain responses could be seen.

Acute pain response in neonates, the primary outcome measure of the study was assessed using NIPS (Table 1), a tool found to be valid, reliable, and practical in assessing neonatal pain (9). It evaluates six behavioral indicators in response to painful procedures in preterm newborns and full-term newborns. It is a non-invasive assessment that includes parameters like facial expression, cry, breathing patterns, motor activity (arms and legs),

Table 1. Neonatal Infant Pain Scale

Pain Assessment	Score	
Facial expression	Relaxed	0
	Grimace	1
Cry	No cry	0
	Whimper	1
	Vigorous crying	2
Breathing pattern	Relaxed	0
	Change in breathing	1
Arms	Relaxed	0
	Flexed/extended	1
Legs	Relaxed	0
	Flexed/extended	1
State of Arousal	Sleeping/ Awake	0
	Fussy	1

and state of arousal. Two pre-trained pediatric resident doctors watched the video recordings of the injection process and rated the infant's pain using NIPS. The baseline rating was between 15 seconds to just before injection whereas the post-procedure pain rating was with the end of vaccination to up to 30 seconds. The maximum response was scored and both agreed upon the final scores.

### Statistical Analyses

The groups were compared using the Mann-Whitney U test for continuous variables and the Chi-square test for categorical variables. The data was analyzed using the software SPSS for Windows, version 15.0.  $P \leq 0.05$  was considered statistically significant.

### Results

A total of 68 infants were included of which 34 infants received the vaccine in 'Cuddle position' and 34 in 'Bed position'. The baseline parameters of the two groups are given in Table 2. There were no significant differences in the baseline characteristics between the two groups.

The median (IQR) values of baseline and final NIPS scores in both groups were similar without

any significant difference, Table 3. The difference between pre-vaccination (baseline) and post-vaccination (final) pain scores was almost similar in both the groups and it was not significantly different statistically.

### Discussion

Our findings suggest that there is no significant difference in the acute pain response of infants in the two different positions during the primary dose vaccinations of Pentavalent and IPV. The final NIPS scores, median (IQR), of 7 (7-7) in both the positions 'Cuddle position' with the infant on the lap of parent and 'bed position' lying supine on the bed were similar with no statistically significant difference between the two. According to Module 5 of the practical guide for health staff dealing with managing an immunization session by WHO, both these positions have their own advantages and disadvantages (10). The disadvantage in 'cuddle position' is that the parents are responsible for restraint and secure restraint may not occur. However, in the 'bed position', the vaccinator ensures restraint. According to the WHO Position Paper on reducing pain at the time of vaccination (September 2015), it has been recommended that infants and young children should be held by caregivers (11).

Table 2. Comparison of the Baseline Characteristics of the Infants in the Groups

Parameter	Cuddle position group, N=34	Bed position group, N=34	P
Age, months, Median (IQR)	3.5 (1.5-3.5)	3 (1.5-3.5)	0.383*
Weight, kilograms, Median (IQR)	5.75 (4.58-6.62)	5.52 (4.26-6.32)	0.167*
Sex, male, N (%)	15 (44.1)	19 (55.9)	0.332†
Dose of Pentavalent vaccine, 1st N (%)‡	15 (44.1)	18 (52.9)	0.467†

\*Mann-Whitney U test; †Chi-square test; ‡Children included received either the 1<sup>st</sup> or the 3<sup>rd</sup> primary dose of pentavalent vaccine.

Table 3. Depiction of the NIPS Scores: at Baseline, Final after Immunization, and Difference between Baseline and Final Scores

Parameter	Cuddle position group, N=34	Bed position group, N=34	P*
Baseline NIPS score, Median (IQR)	0 (0-1)	0 (0-2)	0.609
Final NIPS score, Median (IQR)	7 (7-7)	7 (7-7)	0.438
Increase in score from baseline, Median (IQR)	6 (5-7)	6.5 (2-7)	0.340

NIPS=Neonatal Infant Pain Scale; \*Mann-Whitney U test.

Our findings are not in line with this as we found that the pain response of infants was no different in both the positions mentioned above.

Our findings were similar to a study that did not find any significant difference between supine positioning and parent-held positioning during infant vaccination injections (6). However, our findings are not in agreement with another study in Iran which found that mother's hugs reduced pain during immunization (12). The differences in the findings could be due to the variation in the interventions and the pain scales used.

### *Limitation of Study*

Our study had limitations because parents chose the position of vaccinations and it was not a randomized control trial. We did not include additional intervention like breastfeeding when held by the mother. Along with positioning alone additional interventions like these could provide pain relief and need to be studied further.

### **Conclusion**

We found that the parent held 'cuddle position' did not benefit the infants in terms of reducing pain response to vaccine injections compared to the supine position on the table. It may not be the position alone that reduces pain response in infants. Further studies with better design are needed to confirm our findings.

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**Conflict of Interest:** The authors declare that they have no conflict of interest.

### **References**

1. Gowda C, Dempsey AF. The rise (and fall?) of parental vaccine hesitancy. *Hum Vaccin Immunother.* 2013;9(8):1755-62.

2. Edwards KM, Hackell JM; Committee on the Infectious Diseases, The Committee on Practise and Ambulatory Medicine. Countering Vaccine Hesitancy. *Pediatrics.* 2016;138(3):2016-2146.
3. Taddio A, Appleton M, Bortolussi R, Chambers C, Dubey V, Halperin S, et al. Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline. *CMAJ.* 2010;182(18): E843-55.
4. Ravikiran SR, Kumar PMJ, Meundi AD. Pain response in newborns to the order of injecting BCG and hepatitis-B vaccines: A randomized trial. *Indian J Pediatr.* 2011;78(6):693-7.
5. Taddio A, Shah V, Mcmurtry CM, Macdonald NE, Ipp M, Ridell RP et al. Procedural and Physical Interventions for Vaccine Injections: Systematic Review of Randomized Controlled Trials and Quasi Randomized Controlled Trials. *Clin J pain.* 2015;31(10):S20-37.
6. Ipp M, Taddio A, Goldbach M, Ben David S, Stevens B, Koren G. Effects of age, gender and holding on pain response during infant immunization. *Can J Clin Pharmacol.* 2004;11(1):e2-7.
7. Ministry of Health and Family Welfare, Government of India. National Immunization Schedule (NIS) for Infants, Children and Pregnant Women. [Cited 2020 Oct 13]. Available from: <https://mohfw.gov.in>default>files>.
8. Im H, Kim E, Park E, Sung K, Oh W. Pain Reduction of Heel Stick in Neonates: Yakson Compared to Non-nutritive Sucking. *J Trop Pediatr.* 2008;54(1):31-5.
9. Suraseranivongse S, Kaosaard R, Intakong P, Pornsiritprasert S, Karnchana Y, Kaopinpruck J, et al. A comparison of postoperative pain scales in neonates. *Br J Anaesth.* 2006;97(4):540-4.
10. Immunization training resources [Internet]. World Health Organization. World Health Organization; 2020 [cited 2020 Oct 13]. Available from: <https://www.who.int/immunization/documents/training/en/>.
11. Reducing pain at time of vaccination position paper [Internet]. World Health Organization. World Health Organization; 2019 [cited 2020 Oct 13]. Available from: [https://www.who.int/immunization/policy/position\\_papers/reducing\\_pain\\_vaccination/en/](https://www.who.int/immunization/policy/position_papers/reducing_pain_vaccination/en/).
12. Taavoni S, Shah-Ali S, Neysani SL, Haghani H. Comparative study of the effect of being in mother's hug and routine clinical procedure on neonates' pain during immunization injection in health centers of West Tehran. *Iran J Nursing.* 2010;22:48-55.