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Original Research Article

# COMPARISON OF VARIOUS HOLDING POSITIONS IN REDUCING VACCINATION PAIN AMONG INFANTS: A RANDOMISED CONTROLLED TRIAL

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## ABSTRACT

**Background:** Vaccination is one of the most common painful procedures experienced during infancy. Due to immature pain modulation mechanisms, infants exhibit significant behavioral responses to immunization-related pain, which may contribute to parental anxiety and vaccine hesitancy. Simple, non-pharmacological interventions that are feasible in routine clinical settings are therefore essential to minimize infant distress. The aim is to evaluate and compare the impact of different holding positions on reducing pain responses during routine immunization among infants. **Materials and Methods:** A single-blinded randomized controlled trial was conducted at the Immunisation Clinic, Aarupadai Veedu Medical College and Hospital, Puducherry, from August 2023 to February 2025. Four hundred infants aged 6, 10, and 14 weeks were enrolled after obtaining written informed consent. Infants were randomly allocated into two groups: Group A (supine position, n=200) and Group B (cuddling position, n=200). Pain responses were assessed using the Infant Pain Scale (IPS) by a blinded observer before, during, and after vaccination. Data were analyzed using descriptive statistics, and a chi-square test was used to assess the association between crying, irritability, and facial expression in groups A and B using SPSS version 26.0. An independent-samples t-test was used to analyze gestational age, birth weight, and the duration between groups A and B. $P < 0.05$ is considered significant. **Results:** Baseline characteristics were comparable between groups. Infants in the cuddling group demonstrated significantly fewer pain behaviors than those in the supine group. Vigorous crying, severe irritability, and distress-related facial expressions were markedly higher in the supine group, whereas none of the infants in the cuddling group exhibited severe pain responses. Significant associations were observed between holding position and crying ($p=0.001$), irritability ($p=0.02$), and facial expression ($p=0.02$). **Conclusion:** The cuddling position is a simple, safe, and effective non-pharmacological intervention that significantly reduces vaccination-related pain in infants and can be easily integrated into routine immunization practices.

## INTRODUCTION

Infants require immunization against multiple infectious diseases, and vaccination programs are implemented universally as a cornerstone of child health care. Infants are particularly vulnerable to vaccination-related pain due to the immaturity of their neurophysiological pain modulation mechanisms and their limited ability to self-regulate stress. The effectiveness of vaccines in preventing serious illnesses is well established.[1] Despite this, parental concern and hesitancy persist, largely due to apprehension about potential adverse effects of vaccination, leading to a growing body of research in this area.[2] When parents perceive the vaccination experience as distressing or traumatic for their child, they may delay or avoid subsequent immunization visits, including scheduled booster doses. Over the past decade, growing attention has been directed toward non-pharmacological strategies for pain reduction, as they are simple, safe, cost-effective, and easily implementable in routine immunization settings.

Vaccination is among the most frequently performed painful medical procedures in early life. Exposure to pain during infancy has been shown to influence later


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physiological and behavioral responses. Behavioral responses such as crying, facial grimacing, and motor agitation are commonly observed and are widely used as indicators of pain severity in this age group.[3] To address this issue, numerous strategies—ranging from pharmacological to psychological and physical interventions—have been investigated for their effectiveness in alleviating vaccination-related pain in infants.[4,5] Sweet-tasting solutions such as sucrose or glucose have demonstrated efficacy in reducing acute injection pain, and breastfeeding has also been recognized for its analgesic properties during immunization.[6-8] Although both approaches are widely recommended for pain reduction during vaccination, their routine use may be constrained by practical limitations.[9] Administering sweet solutions can be time-consuming in busy clinical environments, while breastfeeding may not always be feasible due to cultural norms or situational constraints.

In contrast, physical comfort measures are inexpensive, simple to implement, and require minimal resources when compared with pharmacological or psychological methods. In settings where sweet solutions or breastfeeding are not feasible, physical interventions provide a practical alternative for pain relief during vaccination. Among these strategies, physical comfort measures provided by caregivers or healthcare professionals play a crucial role. Holding positions during vaccination may influence an infant's perception of pain by promoting a sense of security, facilitating containment, and reducing fear-related stress responses. Techniques such as close body contact, upright posture, swaddling, gentle shushing, rocking, non-nutritive sucking, and specific holding or positioning methods are commonly employed to soothe infants during injections.[10] However, there is limited research systematically evaluating the effectiveness of these physical strategies in young infants, and existing evidence remains inconsistent.

In routine clinical practice, caregivers often instinctively hold their infants during vaccination to provide comfort and reassurance.[9] Physical holding has been shown to attenuate pain responses during minor medical procedures and to calm and distract infants.[11] The World Health Organization (WHO) recommends that infants and young children be held by caregivers during immunization.[9] Nevertheless, there is no clear consensus regarding the optimal holding position. While upright holding is more effective in reducing injection-related pain in older children, the most suitable position for younger infants has not been clearly established.[12] The present study was designed to evaluate and compare the impact of different holding positions on pain responses during routine immunization.

## MATERIALS AND METHODS

A randomized controlled trial was conducted at the Immunisation Clinic, Outpatient Department, Aarupadai Veedu Medical College and Hospital, Puducherry. The objective of this study was to compare the various holding positions (supine, cuddling) on the mother's lap during vaccination and to assess pain using the infant pain scale. The duration of study was conducted for a period of 18 months from August 2023 to February 2025. Ethical approval was obtained from the Institutional Human Ethics Committee (IHEC No: AV/IHEC/01/2024/085), and the trial was registered with the Clinical Trials Registry of India (CTRI/2025/10/096594). The study included 400 infants aged 6, 10, and 14 weeks presenting for routine pentavalent intramuscular immunization. Eligible infants were enrolled after written informed consent was obtained from parents or guardians. Infants weighing less than 2000 g, with gestational age below 34 weeks, or having any acute illness requiring neonatal intensive care admission were excluded. The sample size of 400 was calculated based on a similar study by Yin et al in the year 2017, using comparison of means with a significance level of 5% and a power of 90%.[13] Participants were randomly allocated into two equal groups of 200 each using a computer-generated simple randomization sequence with allocation concealment ensured through sequentially numbered, opaque, sealed envelopes. Group A infants were held in the supine position during vaccination, while Group B infants were held in the cuddle position. The randomization sequence was generated by an independent investigator, and outcome assessment was performed by a blinded observer, making the study single-blinded. Vaccinations were administered by trained healthcare personnel following standard immunization protocols. Demographic and relevant clinical details were recorded using a structured proforma. Pain response was assessed using the Infant Pain Scale (IPS) at predefined time points before, during, and after injection, and findings were systematically documented.

**Ethical Approval and Registration**

Ethical approval was obtained from the Institutional Human Ethics Committee (IHEC No: AV/IHEC/01/2024/085), and the trial was registered with the Clinical Trials Registry of India (CTRI/2025/10/096594).

**Randomization and Grouping:**

**Randomization:** Participants were randomly assigned in a 1:1 ratio to either the supine position group (Group A) or the cuddling position group (Group B). A computer-generated simple randomization sequence was created by an independent investigator who was not involved in participant recruitment, intervention delivery, or outcome assessment.


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**Allocation Concealment:** Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope contained the group assignment according to the pre-generated randomization sequence. After obtaining informed consent and confirming eligibility, the next envelope in sequence was opened to reveal the allocation. This procedure prevented foreknowledge of treatment assignment and minimized selection bias.

**Blinding:** The study employed a single-blind design. Due to the nature of the intervention, blinding of caregivers and vaccination personnel was not feasible. However, outcome assessment was performed by an independent observer who was unaware of group allocation. Pain responses were assessed using the Infant Pain Scale (IPS) before, during, and after vaccination.

**Statistical Analysis**

To analyze the data, SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019) is used. The results of the Normality tests, Kolmogorov-Smirnov and Shapiro-Wilks, revealed that the data follows a normal distribution. Therefore, to analyze the data, a parametric test was applied. Descriptive statistics determined the variables frequency, percentage, mean, and SD. Independent sample t-test was used to analyze gestational age, birth weight, and duration between groups A and B. The Chi-square test was used to find the association of crying, irritability and facial expression between groups A and B. The significance level is fixed at 5% ($\alpha = 0.05$). P-value <0.05 is considered to be statistically significant.

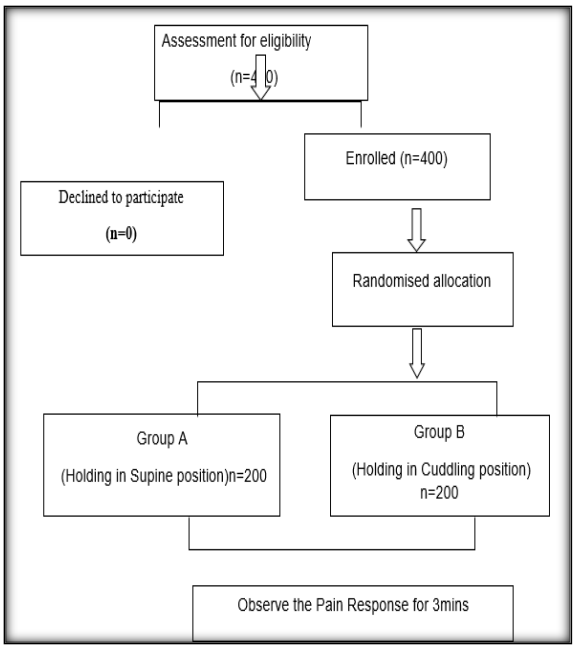


**Figure 1: Flowchart of participant recruitment, randomization and pain assessment**

[Figure 1] illustrates the participant flow throughout the study. A total of 400 infants were assessed for eligibility and enrolled after obtaining informed parental consent. No eligible participants declined participation. The enrolled infants were randomly allocated into two groups: the supine position group (n = 200) and the cuddling position group (n =200). Pain responses were assessed using the Infant Pain Scale (IPS) before, during, and after routine vaccination, and all participants were included in the final analysis.

## RESULTS

A total of 400 infants were included in the study, with 200 infants each in the supine and cuddling groups. The mean age of infants was identical in both groups (45.00 ± 0.00 days), ensuring complete age comparability. Gender distribution was nearly equal, with males constituting 46.5% in the supine group and 51.5% in the cuddling group. Baseline characteristics such as gestational age and birth weight were comparable between groups, with no statistically significant differences observed for mean gestational age (38.10 ± 1.41 weeks in the supine group vs 38.00 ± 1.40 weeks in the cuddling group; p = 0.568) or mean birth weight (3.51 ± 0.61 kg vs 3.51 ± 0.57 kg; p = 0.118). The mean duration of the vaccination-related procedure was also similar between the two groups (p = 0.967). Marked differences were observed in pain-related behavioral responses. In the supine group, vigorous crying was observed in 44.5% of infants, whereas no infant in the cuddling group exhibited vigorous crying, with the majority showing either no crying (54.5%) or only whimpering (45.5%). Similarly, severe irritability characterized by agitation with rigid limbs was present in 35.5% of infants in the supine group but was absent in the cuddling group, where over half of the infants remained at rest. Facial expression analysis showed that 35.0% of infants in the supine group demonstrated severe distress, while none in the cuddling group exhibited such responses. Statistical analysis revealed a significant association between holding position and crying (p = 0.001), irritability (p = 0.02), and facial expression (p = 0.02), indicating that the cuddling position was significantly more effective in reducing pain-related behavioral responses during immunization compared to the supine position.


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**Table 1: Descriptive variables between two groups among the study participants**

| Variables | Group | Mean | Standard Deviation | Standard error mean | P value |
|---|---|---|---|---|---|
| Gestational age (weeks) | Supine | 38.10 | 1.407 | 0.099 | 0.568 |
| | Cuddling | 38.00 | 1.396 | 0.099 | |
| Birth weight (Kg) | Supine | 3.507 | 0.606 | 0.042 | 0.118 |
| | Cuddling | 3.508 | 0.567 | 0.040 | |
| Duration (seconds) | Supine | 211.13 | 52.215 | 3.692 | 0.967 |
| | Cuddling | 206.85 | 51.933 | 3.672 | |

[Table 1] This table compares baseline characteristics including gestational age, birth weight, and procedure duration between the supine and cuddling groups. No statistically significant differences were observed, indicating comparable baseline characteristics.

**Table 2: Irritability distribution among the study participants**

| Irritability | Supine | | Cuddling | |
|---|---|---|---|---|
| | Frequency | Percentage | Frequency | Percentage |
| At rest | 56 | 28.0 | 107 | 53.5 |
| Irritation with flexed or extended limbs | 73 | 36.5 | 91 | 46.5 |
| Agitation with rigid limbs | 71 | 35.5 | 0 | 0.0 |

[Table 2] This table presents the distribution of irritability levels among infants in both groups during vaccination. Infants in the cuddling group showed lower irritability and no episodes of severe agitation compared to the supine group.

**Table 3: Facial expression distribution among the study participants**

| Facial expression | Supine | | Cuddling | |
|---|---|---|---|---|
| | Frequency | Percentage | Frequency | Percentage |
| Relaxed or smiling | 74 | 37.0 | 101 | 50.5 |
| Grimace | 56 | 28.0 | 99 | 49.5 |
| Frown with trismus and chin shiver | 70 | 35.0 | 0 | 0.0 |

[Table 3] This table shows the distribution of facial expressions as indicators of pain response during vaccination. Infants in the cuddling group demonstrated fewer distress-related facial expressions and appeared more relaxed than those in the supine group.

**Table 4: Association between Supine and Cuddling position holding of Crying distribution among the study participants**

| Group A (Supine) | Group B (Cuddling ) | | | P value |
|---|---|---|---|---|
| | No crying | Whimpering | Vigorous crying | |
| No crying | 21 (13.5%) | 0 (0.0%) | **0 (0.0%)** | 0.001* |
| Whimpering | 69 (44.2%) | 11 (25.0%) | 0 (0.0%) | |
| Vigorous crying | 66 (42.3%) | 33 (75.0%) | 0 (0.0%) | |

Table 4 This table evaluates the association between holding position and crying response among infants during vaccination. A statistically significant reduction in crying severity was observed in the cuddling group compared to the supine group ($p = 0.001$).

**Table 5: Association between Supine and Cuddling position holding of Irritability distribution among the study participants**

| Group A (Supine) | Group B (Cuddling ) | | | P value |
|---|---|---|---|---|
| | At rest | Irritation with flexed or extended limbs | Agitation with rigid limbs | |
| At rest | 18 (12.8%) | 4 (6.8%) | 0 (0.0%) | 0.02* |
| Irritation with flexed or extended limbs | 68 (48.2%) | 20 (33.9%) | 0 (0.0%) | |
| Agitation with rigid limbs | 55 (39.0%) | 35 (59.3%) | 0 (0.0%) | |

[Table 5] This table assesses the relationship between holding position and irritability levels among infants. The cuddling position was significantly associated with lower irritability and absence of severe agitation during vaccination ($p = 0.02$).


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**Table 6: Association between Supine and Cuddling position holding of facial expression distribution among the study participants**

| Group A (Supine) | Group B (Cuddling ) | | | P value |
|---|---|---|---|---|
| | Relaxed or smiling | Grimace | Frown with trismus and chin shiver | |
| Relaxed or smiling | 46 (45.5%) | 28 (28.3%) | 0 (0.0%) | 0.02* |
| Grimace | 27 (26.7%) | 29 (29.3%) | 0 (0.0%) | |
| Frown with trismus and chin shiver | 28 (27.7%) | 42 (42.4%) | 0 (0.0%) | |

[Table 6] This table examines the association between holding position and facial expression responses during vaccination. Infants held in the cuddling position exhibited significantly fewer distress-related facial expressions than those in the supine position (p = 0.02).

## DISCUSSION

In the present study, the mean age of infants in both the supine and cuddling groups was 45.00 ± 0.00 days, indicating a homogeneous age distribution at baseline. No literature was found with the present study results compared with similar studies. In contrast, a study by Yin et al. in 2017 had a wider age range between groups, which may have influenced pain responses during vaccination.[13]

The gender distribution was also comparable, with 46.5% males and 53.5% females in the supine group and 51.5% males and 48.5% females in the cuddling group. A similar finding was reported by Yin et al. in 2017, in which the gender distribution between the intervention and control groups was balanced, minimizing bias in pain response assessment.[13] These findings are consistent with previous studies reporting balanced baseline characteristics in randomized controlled trials evaluating infant pain interventions. In contrast, a study by Shubhada Ponkshe et al. in 2022 had unequal gender proportions between groups, which may have affected behavioral responses to vaccination.[14]

The mean gestational age was 38.10 ± 1.41 weeks in the supine group and 38.00 ± 1.40 weeks in the cuddling group (p = 0.568), and the mean birth weight was 3.51 ± 0.61 kg versus 3.51 ± 0.57 kg, respectively (p = 0.118), showing no statistically significant differences. Similarly, the duration of the vaccination procedure was comparable between groups (211.13 ± 52.22 s vs. 206.85 ± 51.93 s, p = 0.967), confirming that both groups were equivalent in terms of procedural exposure. These findings indicate that any observed differences in pain responses are unlikely to be confounded by these baseline characteristics. A study by fieb et al. in 2025 similarly reported that controlling for demographic and procedural variables ensures that observed differences in pain behavior are attributable to the intervention itself.[15] A similar finding was reported by Taddio et al. in 2015, and Abdeyazdan et al in 2016 where the gender distribution between intervention and control groups was balanced, minimizing bias in pain response assessment.[4,16] No literature found to compare with contrast study.

A comparable finding was reported by Taddio et al. in 2015, where there was no significant difference in birth weight between intervention and control groups, ensuring comparability of baseline characteristics (4). In contrast, Anderson et al. in 2019 observed a slight but statistically significant difference in mean birth weights between groups, which could have influenced pain responses during vaccination.[17]

The present study demonstrated a significant reduction in pain-related behaviors among infants held in the cuddling position compared to the supine position. Crying responses were markedly lower in the cuddling group, with none exhibiting vigorous crying and 54.5% showing no crying, compared to 44.5% of infants in the supine group exhibiting vigorous crying (p = 0.001). A similar reduction in crying intensity with close physical contact was reported by Taddio et al. in 2015, who demonstrated that infants held in caregiver-supported positions during vaccination exhibited significantly less intense crying compared to those positioned supine on an examination table, supporting the calming effect of caregiver contact on procedural pain.[4] In contrast, a study by Kassab et al. 2018 found no significant difference in crying duration between the held and supine positions during immunization, suggesting that contextual factors such as caregiver anxiety and prior pain exposure may modify infant pain responses.[18]

Likewise, irritability levels were significantly lower in the cuddling group, with no infants displaying agitation with rigid limbs and over half (53.5%) being at rest (p = 0.02). A similar finding was reported by Harrison et al, in 2010 who observed that infants held in caregiver-assisted positions during immunization demonstrated significantly lower irritability scores, with fewer signs of motor agitation and greater periods of calm behavior compared to infants placed in the supine position.[19] In contrast, a study by Pillai Riddell et al. in 2018 reported that while holding reduced crying, it did not significantly reduce motor irritability in some infants, suggesting that behavioral pain responses may vary depending on infant temperament and contextual factors.[20]

Facial expression assessments showed that none of the infants in the cuddling group exhibited severe distress, such as a frown with trismus and chin shiver, while 50.5% appeared relaxed or smiling, compared to 35% severe distress in the supine group (p = 0.02). These findings indicate that the cuddling position is highly effective in reducing behavioral and emotional


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indicators of vaccination pain in infants. A similar observation was reported by Taddio et al. in 2015, who demonstrated that infants held in close physical contact with caregivers during immunization exhibited fewer pain-related facial expressions, such as brow bulge and eye squeeze, and were more likely to appear calm or relaxed compared to infants positioned supine.[4] In contrast, a study by Axelin et al. in 2006 found that while facilitated tucking and holding reduced crying duration, facial expression scores did not differ significantly between intervention and control groups, suggesting that facial indicators of pain may be less sensitive to positioning alone.[21]

The study findings align with previous research indicating the benefits of caregiver contact during painful procedures. Riddell et al. in 2018 and Blount et al. in 2006 reported that infants held closely by caregivers during vaccination or minor procedures exhibited lower crying intensity, reduced agitation, and calmer facial expressions.[20,22] In contrast, a study conducted by Stevens et al in 2013, examining supine or minimal-contact positions, reported higher levels of crying and irritability, suggesting that lack of tactile comfort may exacerbate procedural pain. Furthermore, the present study supports the concept that early physical comfort and emotional reassurance are key components in non-pharmacological pain management strategies for infants.[23]

## CONCLUSION

The present randomized controlled trial demonstrates that the cuddling holding position is significantly more effective than the conventional supine position in reducing vaccination-related pain among infants. While both groups were comparable with respect to baseline characteristics such as age, gender, gestational age, birth weight, and procedure duration, infants held in the cuddling position exhibited markedly lower pain responses, evidenced by reduced crying intensity, lower irritability, and calmer facial expressions. The absence of vigorous crying, severe agitation, and distress-related facial expressions in the cuddling group highlights the strong soothing effect of close caregiver contact during immunization. These findings are consistent with existing evidence supporting non-pharmacological, caregiver-assisted interventions for procedural pain relief in infancy. Overall, the study reinforces cuddling as a simple, safe, and cost-effective strategy that can be readily incorporated into routine immunization practices to improve infant comfort, reduce distress, and enhance the overall vaccination experience.

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