

Research Article

# Comparison of Effect of Various non-pharmacologic Methods on Pain in Infants during Vaccination

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## I N F O

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## A B S T R A C T

**Objective:** To compare the effect of various non pharmacologic methods on pain in infants during vaccination as assessed by Neonatal Infant Pain Scale (NIPS).

**Design:** Prospective randomized controlled trial.

**Sample:** 120 infants for pentavalent vaccination (30 in each group G1, G2 G3 and G4).

**Methods:** The enrolled infants were randomized into three intervention groups (Breast feeding G1, buzzy device group G2, Helper technique group G3 and control group G4). During vaccination procedure was videographed and pain score assessed by independent blinded observer.

**Result:** The mean pain score of four groups (G1, G2, G3 & G4) were 3.77, 3.80, 4.50 and 4.83. Breast feeding effectively reduces pain score than mechanical stimulation by buzzy device. Comparison of pain score of different group by F value is not significant at 0.05 level of significance.

**Keywords:** Pain, Infant, Intramuscular Injection, Vaccination, Neonatal Infant Pain Scale, Breast feeding, Buzzy device, Helper Skin Tap Technique

## Introduction

Pain is a multidimensional phenomenon with physiological, sensory, cognitive and behavioural alterations that can be recorded and to some extent can be quantified. Every child has his or her own perception of pain.<sup>1</sup>

The World Health Organization estimates that 12 billion injections are given annually and that approximately 5% are childhood vaccinations. Vaccine injections are the most common reason for iatrogenic pain in childhood.<sup>2</sup>

A basic tenet of dependable medical care is not "do not hurt," but "do no harm;" since pain causes harmful to children, the caregivers are dedicated to preventing harm to their patients. Research studies show that immunization is a stressful experience for children as well as parents. The

inability of infants to verbalize the pain underestimates its severity and intensity. Pain can be difficult to assess and thereby pain assessment tools/ scores for paediatric age group developed.<sup>3</sup>

Vaccines are substances which contains harmless microbes which otherwise can cause specific disease and is given to humans either to prevent acquiring disease or to produce immunity in the body against the pathogen.<sup>4</sup>

According to World Health Organization intramuscular injection is a common technique used to deliver medication deep into the large muscles of the body for prophylactic or curative purposes. Medication administration via intramuscular injection absorbed faster than other subcutaneous route due to increase vascularity to the muscle.<sup>5</sup>

Pentavalent vaccine provides immunity against five killer diseases such as Diphtheria, Pertusis, Tetanus, Hepatitis B and Haemophilus Influenza Type B infections. 0.5 ml of pentavalent vaccine is given intramuscular at vastus lateralis muscle. This causes pain and there may be redness and swelling where the injection is given.<sup>6</sup>

Pain experienced in childhood can have a negative and psychologically harmful effect in the life of an individual. There are several factors associated with poor immunization coverage and the fear of pain associated with vaccination is one of the factors that contribute to poor compliance with the immunization schedule. There is plethora of non-pharmacologic interventions to reduce pain, but it is unclear which intervention is most beneficial.<sup>7</sup>

Helper skin tap technique offers a painless injection experience. It provides a mechanical stimulation and distraction during intramuscular injection and thus helps to decrease pain as described in gate control theory. In Helper skin tap technique rhythmic tapping before injection over the skin at the site of injection keeps the muscle relaxed and stimulates large diameter fibers.<sup>8</sup>

The health care professionals have the responsibility to adopt measures to reduce pain. However there is plethora of non pharmacologic measures to reduce pain and it is unclear which intervention is most beneficial.

During the clinical experience, the investigator found that vaccine and other intramuscular administration causes iatrogenic pain in children. In this study the investigator is sought to compare the effects of various non pharmacologic methods on reducing pain during vaccination in infants.

### Problem Statement

“Experimental study to compare the effects of various non-pharmacologic methods on pain in infants during vaccination.”

### Objectives

- To assess the pain level of infants during vaccination in the experimental groups and control group.
- To compare the pain level of infants in the experimental groups and control group.

### Operational Definitions

**Breast Feed:** Breast feeding for 5 mts by the lactating mother immediately before vaccination

**Buzzy Device:** It causes thermo mechanical stimulation at the injection site with combination of thermal energy (cold) and mechanical energy (vibration).

**Helper Skin Tap Technique:** It is a technique in which the investigator is tapping over the intramuscular injection site with the palmer aspect of fingers 16 times before insertion and 3 counts during the procedure.

### Hypothesis

H0(1): There is no difference in the pain level between breast feeding, thermo mechanical stimulation by buzzy device, Helper skin tap technique, and usual standard technique during vaccination among infants at 0.05 level of significance.

### Review of Literature

The literature review for the present study on the pain experience of infants undergoing vaccination and non pharmacologic management of pain in children.

A randomized control trial conducted by Esfahani MS et al. to compare vaccination pain in 6-12 month old infants in Isfahan. 96 infants were studied. Experimental group is given breast feeding, massage therapy and in control group intramuscular injection is given with standard technique. The study result shows mean pain score in the breast feeding group was found to be significantly less than in the massage therapy and control group.<sup>9</sup>

Randomized controlled was study conducted on the effectiveness of manual pressure on pain severity in Iran 2012. The study concluded that manual pressure in IM injection site leads to pain relief and we can apply this technique for reducing pain severity and promote comfort.<sup>10</sup>

A prospective randomized controlled trial was conducted by Redfern et al. to investigate the effect of thermo mechanical stimulation on reducing the pain and anxiety experienced by children during vaccination. The study result showed that the experimental group showed significantly lower pain and anxiety levels than the control group.<sup>11</sup>

Randomized controlled study conducted by P Meera et al. on the effectiveness of Helper Skin Tap Technique during Immunization in Infants in Ambala, Haryana. The objectives of the study was to assess and compare level of pain in infants with and without Helper skin tap technique during immunization and find out relationship between level of pain and duration of cry. One hundred infants were selected through purposive sampling technique, who were attending immunization clinic. The mean level of pain (6.7) of infants in control group was higher than mean level of pain (5.3) of infants in experimental group. The mean duration of cry (28.9) of infants in control group was higher than mean duration of cry (37.4) of infants in experimental group. There is a correlation between pain and duration of cry. Cry increases with pain.<sup>12</sup>

A true experimental research study conducted by Sivapriya et al. to assess the effectiveness of Helper technique on pain associated with intramuscular injection among neonates. The study result showed that there is significant difference in the pain score during intramuscular injection with Helper technique.<sup>13</sup>

## Methodology

**Research Approach:** Quantitative Research Approach.

### Research Design

True experimental post-test only design composed of four randomly assigned groups. Four groups consist of:

- G1: Infants given breast feed for 5 minutes just before vaccination
- G2: Infants given mechanical stimulation for 5 minutes by buzzy device before vaccination
- G3: Infants given tactile stimulation with Helfer skin tapping before vaccination
- G4: Control group infants given pentavalent vaccination with standard technique

**Research Setting:** Immunization clinic of a tertiary hospital Pune. Maharashtra.

### Sampling Technique

Purposive sampling to select study subjects who fulfils the inclusion criteria. Simple random sampling technique (Lottery method) was used to allocate the infants into experimental G1 G2 G3 and control group (G4).

**Sample Size:** Sample size estimated based on the study:<sup>14</sup> 120 (30 each in experimental groups G1, G2, G3 and control group (G4).

### Inclusion Criteria

- Infants from 6 wks-4 months were taken for the study.
- Infants available for sampling during data collection period.

### Exclusion Criteria

- Infants who had high fever, respiratory infection and skin problems in vastas lateralis area.

### Variables under Study

**Independent variable:** In this study, breast feeding, mechanical stimulation by buzzy device and tactile stimulation with Helfer skin tap technique before administration of pentavalent vaccination.

**Dependent Variable:** The dependent variables in this study are pain level during pentavalent vaccine.

### Tool Used for Data Collection

The Neonatal Infant Pain Scale (NIPS) is used for assessing the pain after vaccination.

Maximum Score: 7      Minimum Score: 0

No Pain 0-2, Moderate Pain 3-4, Severe Pain >4

### Ethical Consideration

Permission has been obtained from the ethical committee of the institution (Reg no IEC S No IEC/2018/30) and the

written consent has been obtained from the participants.

### Procedure for Data Collection

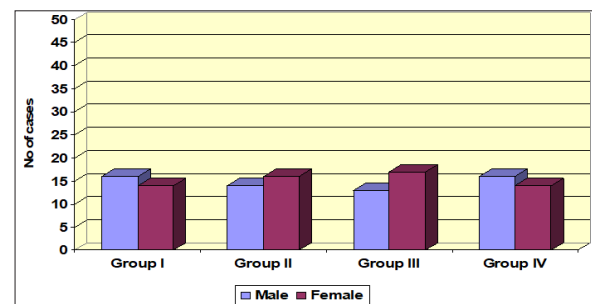
- Formal permission was obtained from the administration
- Infants were identified as per inclusion criteria
- Collected baseline data

The intervention was done as per the groups. The procedure was video recorded. Pain assessment was done by using NIP scale by the researcher for all the groups.

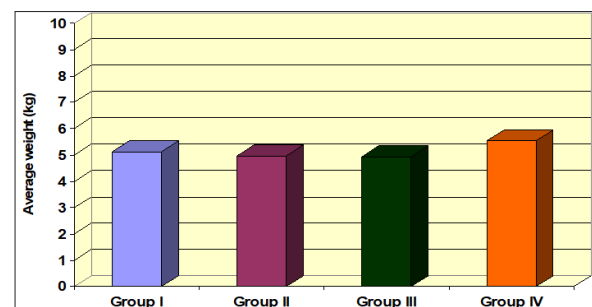
### Result and Analysis of Data

A total of 120 infants were randomly allocated to the four groups. Breastfeed Group I (G1): 30, Buzzy device (G2): 30, Helfer technique (G3): 30 and Control Group (G4): 30. The four groups were similar in terms of demographic characteristics.

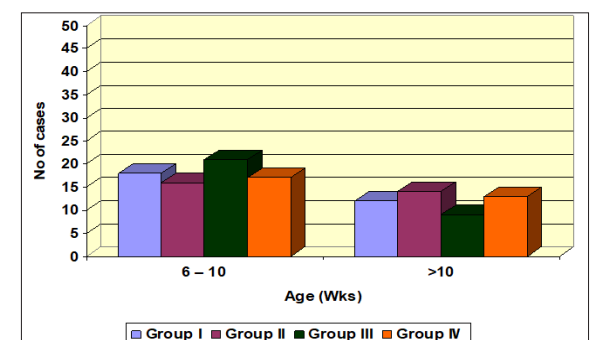
Data analysis is described in Figures 1 to 5 and Table 1.



**Figure 1.** Bar diagram showing sex wise distribution of cases in G1, G2, G3 and G4



**Figure 2.** Bar diagram showing comparison of weight in G1, G2, G3 and G4



**Figure 3.** Bar diagram showing age wise Distribution of cases in G1, G2, G3 and G4

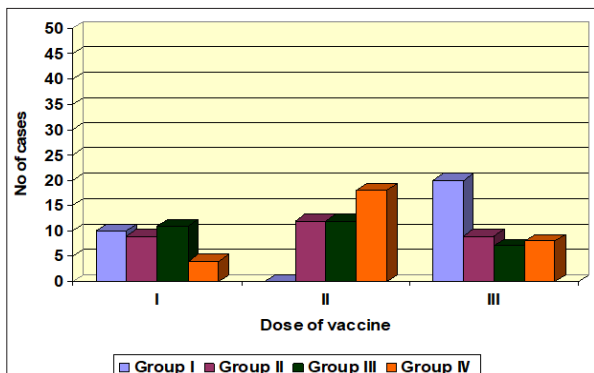


Figure 4. Bar diagram showing dose of vaccine wise distribution of cases G1, G2, G3 and G4

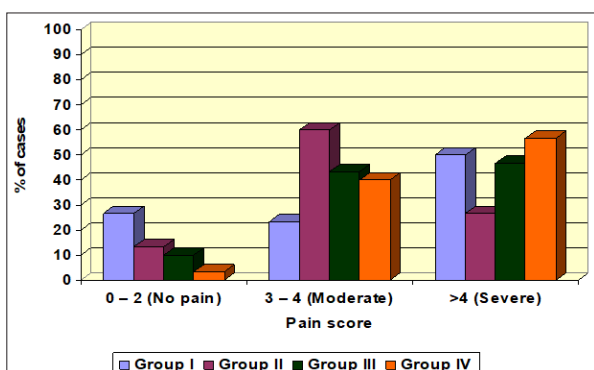


Figure 5. Bar diagram showing pain level of Infants during vaccination in G1, G2, G3 and G4

Table I. Comparison of Neonatal Infant Pain Scale (NIPS) score in G1, G2, G3 and G4

Group	n	Neonatal Infant Pain score		f-value	p-value
		Mean	SD		
G1	30	3.77	1.736	4.08	0.009
G2	30	3.80	1.297		
G3	30	4.50	1.383		
G4	30	4.83	1.262		

**Discussion**

Immunization is one of the preventive measures to develop immunity in children. It is also of concern as vaccine has become the inseparable part of the health care services But it is a distressing experience for them. This was confirmed by the present study. Thus, the present randomized control trial was conducted to compare the effect of various non-pharmacological methods to relieve pain during vaccination among infants attending immunization clinic.

Sixty % of infants in G2, 43% of infants in G3 and 40% of infants in control group had moderate pain. Fifty six % of infants in G4 and 50% of infants in G1 had severe pain during immunization. Twenty seven % of infants in G1 had no pain where as only 1% of neonates in G4 had no pain.

Similar findings were also reported by Sivapriya.<sup>13,9,11</sup> The study emphasizes that vaccination is a painful stimulant for the infant with 50%-60% in severe to moderate pain during vaccination.

The mean pain score is lowest in G1 (Breast feeding Group). The finding from this study was very similar to the findings from other study.<sup>15</sup> Breast feeding group has the lowest mean pain score. There was no statistically significant within-group difference in mean pain score.

It is observed that breast feeding group (G1) and buzzy device group (G2) had reduced mean pain score during vaccination. However, f-value depicts the comparison of mean pain score in the three interventional groups and control group is not statistically significant at 0.05 level of significance.

**Conclusion**

Vaccination causes pain in infants and pain during vaccination should be recognized and treated. The study concludes that breast feeding and effect of mechanical stimulation by buzzy device cause effective reduction in pain response in infants during vaccination but better response with breast feeding. Breast feeding is easily available and useful in alleviating pain. Further studies should be done for other non-pharmacological methods for more concrete evidence.

**Conflicts of Interest:** None

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