Effect of Vibratory Therapy in Decreasing the Vaccination-induced Pain in Infants: Randomized Controlled Study

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ABSTRACT

Background: Different non-medical therapies such as Non-nutritive sucking (NNS), oral sucrose with or without NNS (non-nutritive sucking), wrapping with thin blanket or cloth, kangaroo mother care (KMC), songs as well as multi-sensory stimulation are beneficial in pain reduction among neonates and infants. According to the gate control theory, vibrations applied sat a site on the body block the nociceptive signals via the Aδ and C fibers reducing the pain perception. When used along with many other nonpharmacological methods, This technique has been shown to minimize discomfort in pain-inducing treatments such as Intravenous cannulation, vaccines, heel prick, etc. The primary purpose of this study is to analyze vibrational therapy effects on infant’s pain perception, thereby, providing evidence for a better pain management strategy in vaccination centers.

Objective: To determine the efficacy of vibration therapy on pain perception by infants during vaccine administration.

Authors’ contributions

This work was carried out in collaboration among all authors. Authors AT and RM designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors SD and PZJ managed the analyses of the study. Authors SC, AP, AJ and RR managed the literature searches. All authors read and approved the final manuscript.

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Material and Methods: Out of total 90 eligible healthy infants who come for routinely immunization will be given either vibrational therapy (interventional group) or breastfeeding(control therapy) after doing randomization in this randomized controlled trial. The baseline vitals include cardiac rate (HR), respiratory rate (RR), and oxygen (SpO2) will be recorded before, during, and after vaccination during this treatment. Similarly, we will report Visual analog scales (VAS), Neonatal Infant Pain Scale (NIPS), and Wong-Baker FACES Pain Rating Scale, Modified Behavioral Pain Scale (MBPS) after giving the vaccine to the infant.

Results: After completion of the study we will come to know the effect of vibratory therapy on pain control. The pain intensity with the help of the NIPS score will get less in the vibratory group than in the control group. The level of distress by using the Color Analogue Scale, MBPS scale, and FLACC scale, during the vaccine-related procedure will get a lower score in the infants who has taken vibratory therapy than the control group.

Conclusion: study will probably give us information about vibration therapy, which will be an effective method for managing the pain after vaccination in infants.

Keywords: Infant; vibration; NIPS; pain; breastfeeding.

1. INTRODUCTION

An indispensable segment of the health care delivery system is the routine vaccination of infants. Vaccination remains to be one of the most influential interventions in the health sector which have hugely reduced the morbidity and mortality of various vaccine-preventable infectious diseases. A majority of these vaccines are administered in injectable form which is painful, and almost always leads to a certain amount of anxiety among the infants and their parents [1-2]. Although, vaccination is considered as an outpatient procedure by health care providers (HCPs), a considerable percentage of infants experience intense fear resulting in irregularity on the recommended vaccination schedule. Trypanophobia is the term coined for fear of needles and injections, commonly encountered in infants and adolescents which continues into adult life in about 25% of the population. Recent studies support the fact that pain experienced by neonates/infants may contribute to various psychological sequelae up to or beyond the school years. Such sequelae could have physiological and behavioral effects in infants which could be direct, short-term, long-term effects [3-4]. A previous school of thought that human newborns did not experience pain does not hold true as newer research has shown a greater nociceptor nerve ending density along with a shorter interneuron and neuromuscular distance in neonates. Also, the age of the infants, temperament and previous painful experience has been found to have an impact on pain perception while the gender and position of the infants have no such impact [5]. Different non-medical therapies such as (NNS), oral sucrose with or without NNS (non-nutritive sucking), wrapping infants, kangaroo mother care (KMC), songs as well as multi-sensory stimulation are beneficial in pain reduction among neonates and infants. Breastfeeding is a realistic technique that can be used effectively to reduce discomfort during processes such as vaccines and blood samples from the standpoint of the health workers and the parents [6-9].

There are no sufficient evidence that compare the impact of simultaneous implementation of different pain control measures in comparison to the individual effect on pain. This study is planned with the prime objective to assess the effect of vibratory therapy on pain intensity perception by infants. Also, bring forth evidence for effective pain management caused by vaccination in infants.

1.1 Research Question

Does Vibratory Therapy decrease vaccination-induced pain after intramuscular vaccination in Infants?

1.2 Aims and Objectives

Aims: To assess the effect of vibration treatment on pain experiences in infants upon administration of pentavalent vaccines.

1.3 Objective

- Comparing the individual effectiveness and the add on effects of pain control or pain-reducing interventions in an infant after vaccination
To compare the crying duration in the interventional and control population group.
Comparison of intervention and control classes with color analog scales, MBPS scales, and FLACC scales.

2. MATERIALS AND METHODS

a. Study place

This research will be performed at Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Research Hospital, Sawangi, Wardha, in the Pediatric Department.

b. Sources of Data

Study participants: All healthy infants attending Pediatrics OPD for immunization.

c. Inclusion & Exclusion Criteria

Inclusion criteria

- Age 2-6month
- Absence of any diseases
- Not on any medication
- Exclusive breastfeeding Infant
- Vaccination for Pentavalent (Route of administration: Intramuscular)

Exclusion Criteria

- Written informed consent given by the parents
- If the infant is crying and will not get calm

d. Study Design: Randomized Controlled trial

e. Time Frame / Duration: 6 month

f. Randomization

Randomization will be implemented using the WINPEPI software with the allotments being placed in sealed non-transparent envelopes. The pediatric residents involved in the study will register the participants, complete the baseline measurements and obtain parental consent. Pediatricians participating in this study will open the sealed envelopes. Within each envelope, a randomization number is enclosed along with the allotted intervention.

All participating infants who are registered are allocated automatically in equal proportion to an experimental or research group (vibrational group) or control group (breastfeeding). As the two interventions have differences in terms of application, it is not possible to blind the infants, their parents, and the pediatrician involved.
Healthy neonates come for vaccination

Vaccination (Intramuscular route)

Intervention group
(vibratory therapy)

Control group
(breast feeding)

Vital (HR, RR, SPO2)

Anthropometry

Vital
HR, RR, SPO2

NIPS score
CAS score
FLACC score

NIPS score
CAS score
FLACC score

ANALYSIS

Fig. 2. Flow chart of study design
g. Assessments & Examination

A Detailed information sheet will be given to the infant parents in which the methodology of vaccination will be explained in their local language. Demographic information will be collected for all infants (study cases), which include their age, gender, and weight. All study cases will be subjected to perinatal history (including maternal illness, mode of delivery, Apgar score, history of cyanosis or convulsions), and clinical examination (including anthropometry, vital signs, and systemic examination).

h. Intervention

Healthy infants who will come for the routine immunization will be included in the study group. Routine Indian academy of pediatrics (IAP) immunizations will be given to the infant. Infants will allocate to the experiment group or the control group (breastfeeding) randomly.

The study phases will be

i. Primary Phase

The baseline RR, heart rate (HR), and O2 saturation (SpO2) before intervention are recorded during this process.

ii. Interventional Phase

- Experimental Group (vibratory therapy): Participants in the experimental group will receive the Nebulizer Vibratory device (NVD) intervention. The NVD with three components: (1) body of the Nebulizer, (2) Tube, and (3) face mask. Breastfeeding will be given 10min before vaccination. As soon as the nurse is ready to administer the vaccine after disinfecting the local site with an alcohol swab, the pediatric resident will affix the NVD as close to the vaccination site as possible. The NVD will then be switched on transmitting vibrations to the local site. The NVD will be given for about 30-60 sec. before the insertion of the needle for vaccination and 60sec after the needle removal. The nebulizer vibratory device has to be kept in contact with the infant’s thigh throughout the procedure at least until the vaccination syringe needle is removed. After the completion of the procedure, the used facemask is decontaminated using a disinfectant cleaner as per the Infection Prevention and Control guidelines of the hospital.

Physiological basis of the NVD: The theoretical basis of the NV device is formulated on the gate control theory and the descending noxious inhibitory controls. As per the gate control theory, Aβ and C nociceptive fiber impulses are blocked due to the stimulation of Aβ non-nociceptive fibers because of the vibrations from the NVD.

- Control Group (Breastfeeding): Breastfeeding will be given 10 minutes before vaccination and no additional pain control intervention will be provided. Infants, then, will be swaddled following the completion of the video recording.

iii. Post interventional phase

I. Neonatal Infant Pain Scale (NIPS)

A blinded researcher (pediatrician/pediatric resident) will observe and note the following parameters: cry, breathing pattern, the expression on the face, movements of all four limbs, and state of arousal of NIPS scale to evaluate the level of pain at time intervals of 0, 3 and 5 minutes post-vaccination. NIPS is used in infants as they are unable to tell if the vaccination was painful or not. It uses body language to comprehend if the infants has pain or not. A score of 0 or 1 is given in each of the categories of NIPS based on their behavior. In these total scores is calculated score of more than 3 is an indication that the infants is having some amount of discomfort/pain.

II. We will also use a standardized tool - the modified behavioral pain scale - to measure the pain of the infants during vaccine injection (MBPS). The 10-point scale of the MBPS evaluates three elements of the action (facial, motion, and cry) as a measure of patient pain-distress experience.

III. Visual analog scales (VAS) have been used to measure pain. Parents will also measure pain with the VAS scale and will evaluate the presence of tears before the beginning of vaccination.

IV. The Wong-Baker FACES Pain Rating Scale employs a range of faces from 0 to 10 pain with a smiley face to extreme pain. Crossroads uses the scale of FLACC from 0=no pain to 10=serious pain. The scale of FLACC evaluates pain sensations, like the face, lower legs, movement, cries, and if the patient is consolable.
2.1 Method of Vaccination

The process of vaccination will be performed by the same pediatric nurse to minimize the variability of the stimulus. A 0.5ml capacity syringe with a 24G needle will be used to administer the pentavalent vaccine into the right thigh region via the intramuscular route. During the process of administration, the needle will have to be inserted with steady pressure at an angle of 90° into the anterolateral aspect of the right thigh. There is no aspiration and the vaccine is administered quickly within 1 to 2 seconds and the needle is quickly withdrawn.

2.2 Video Recording

A video of the infant’s facial expression and body language with pulse-oximetry will be recorded, 5 minutes before and after the vaccination, to calculate the NIPS score. NIPS scoring is to be performed at 30 seconds post-vaccine administration. Two residents posted in neonatology, trained in measuring NIPS scoring, will independently analyze the videos to calculate the final NIPS score. If the difference is more than 2 points on the total NIPS score, the average of the NIPS scores will be considered. A secondary outcome of the research is that the cry is observed from the onset of the cry to 5 minutes. A total of 5 minutes is observed to assess each indicator correctly. Data will be collected at different points in the study: before randomization (T0), 5 minutes before administering the vaccine (T1), during the process of vaccination (T2), and promptly post-vaccination (T3).

2.3 Statistical Test

STATA 12 software will be used to analyze data. The graphs will be done using Microsoft Excel 2007. Numerical data will be summarized using means and standard deviations. The baseline/post-vaccination measures will be compared using the paired-samples, two-sided t-test. NIPS scores across groups will be compared using the analysis of variance (ANOVA) test. Scheffe’s test will be used for post-hoc comparison to find out the presence of any significant differences between groups. P values <0.05 will be considered significant. ‘Cry’ time of the babies post-vaccination will be analyzed using an independent sample test. Comparison of respiratory rate, heart rate, and SpO2 would be performed using repeated-measures ANOVA.

2.4 Sample Size Calculation

We have calculated the sample size by OPENEPi software. The sample size required for this analysis was based on the theory and data from a related earlier study [10]. Given the primary result, 10% of non-inferiority is identified (NIPS score at 30 seconds post-vaccination). Due to the margin of non-inferiority, 80 neonates (40 in each group) are expected, a=5 and b=90 percent. To reflect the risk of data loss, the sample size was expanded by 15%, so 90 infants will be included in the analysis.

Sample scale required = 90. Required

2.5 Outcome Measures

- The main result is the pain tolerance measurement, based on the NIPS score. Pain ratings vary from 0-7 and 0-2 with no pain or minimal pain, from 3-4 with mild to moderate pain, and more than 4 is severe pain [111].
- Secondary outcomes measured will be the mean difference in the level of distress during the process of vaccination between the two groups. This assessment will be done immediately post-vaccine administration using the Color Analogue Scale (CAS). MBPS and FLACC scales will be used to assess the mean differences between groups on distress scores during the vaccination process. An infant monitoring system will record the physiological as well as the behavioral/facial indicators of discomfort or pain intensity throughout the intervention. Will be noticed the rate of cry, the percentage of time spent crying during and for three minutes after immunization, and negative symptoms, including nausea, vomiting, regurgitation, choke, reduction in SpO2, tachycardia, and bradycardia. The reliability of an intra-class correlation coefficient is tested on ten percent of coded images.

3. EXPECTED RESULTS

We will learn the effects of vibration therapy on pain control once the study has been completed. In the vibratory group, the intensity of the pain will be lower than the control group using the NIPS score. The vaccine-related distress level is less marked in the vibration group than the
control group, using the color analog scale, the MBPS scale, and the FLACC scale. In the intervention group, the incidence of crying and weeping after vaccination will be less time than in the control group. In the intervention group, there will be no significant change in cardiac rate and oxygen saturation than the control team.

4. DISCUSSION

Non-pharmacologic interventions in pain management in infants is of major importance as it has been associated with high vulnerability to developmental injury because of repeated pain stimuli. Vu-Ngoc H et al [10] found that the mean Neonatal Pain Agitation and Sedation Scale (N-PASS) pain scores at the 30s, 60s, 90s, and 120s after a heel prick test were significantly lower in infants among the non-nutritive sucking group when compared to the control group [30s: 4.73 ± 2.78 vs. 7.90 ± 1.52 (p = 0.0002); 60s: 3.64 ± 3.06 vs. 5.55 ± 2.95 (p = 0.052); 90s: 2.59 ± 3.08 vs. 5.25 ± 3.51 (p = 0.011); 120s: 2.05 ± 2.94 vs. 4.90 ± 3.99 (p = 0.013)]. A strong, statistically significant (p-value <0.01) positive correlation was seen between the pain scores on the N-PASS and the other two scales-NFCS and NIPS. Also, Vu-Ngoc H et al. [12] suggested NNS be a secure and effective pain-relieving method in term neonates when performing heel-prick. In another similar study, there were no statistically significant differences in heart rate or SpO2 between the treatment group (TG) [oral 1 mL 24% sucrose] and the control group (CG) [oral 1 mL 10% glucose] before venipuncture. However, the heart rate was found to be signed on the lower side in the treatment group than the control group during and after venipuncture [13]. In addition to the heart rate, SpO2 was found to be significantly higher in the treatment group than in the control group [13]. Moreover, the NIPS scores were significantly lower in the treatment group (median 0) than the control group (median 6) throughout the procedure (P<0.05). The authors concluded that administering 24% oral sucrose along with NNS before and during a painful procedure reduces the response to pain in term neonates, reduces the NIPS score, and positively impacts the heart rate and SpO2. Pandita A et al. [14] compared the KMC to swaddling during vaccination in 61 infants who were ≤ 14weeks of postnatal age. They reported that in the KMC group, the NIPS scores at 1min and 5min after vaccination and duration of cry were significantly less. They concluded that in young infants, KMC is effective in minimizing pain caused by vaccination.

Another study [11] showed that N-PASS was inclusive of measuring acute and chronic neonatal pain. They mentioned that the N-PASS generated 98% of pain scores greater than the NIPS.

In another study carried out by Zargham-Boroujeni A et al. [15], evaluated the pain responses due to venipuncture in a total of 75 neonates. In the first group (n=25), the procedure was performed after 2 minutes of breastfeeding, the second group (n=25), it was done 2 minutes later after massaging with effleurage technique for about 3 minutes while the third group (n=25) was the control group. This study reported the lowest mean pain scores (0.92) in the second group (massage therapy) while it was 4.84 and 6.16 in the breastfeeding and control group respectively. Both the interventions, i.e breastfeeding and massage therapy helped by significantly lowering the pain scores. Breastfeeding and massage therapy is natural and cost-free interventions requiring no special facility, these interventions have been suggested before performing these painful procedures in infants.

A randomized controlled experimental study was conducted by Erkul M [16] to evaluate the impact of breastfeeding on pain perception by infants in the course of vaccine administration. They revealed that during the vaccine injections, the babies in the control group experienced extreme pain and the babies in the breastfeeding group felt moderate pain (p<0.05). Also, the NIPS score of the participants in the breastfeeding group was less than the control group during the vaccine injections. They also noted that the breastfeeding group had lower heart rates and elevated oxygen saturation values and spent less time crying during vaccine injections. Overall, as per the findings in their study, among the newborns, while the painful procedure was performed, breastfeeding reduced pain perception, hence, obviating an increase in heart rate, crying time, NIPS score, as well as SpO2 decline. In another study by Desjardins MP et al [17], no statistical difference in variation in NIPS (p=0.36) and FLACC (p=0.49) scores between the interventional group (oral sucrose) and control group according to the Mann-Whitney U test.

Also, they observed a statistically significant decrease in median crying time following cannulation [sucrose group (17s) vs control group (41s); p=0.04]. However, the mean change
in heart rate at 1-minute post cannulation was found to be similar in both the groups [sucrose group (16±4 beats/min) vs placebo group (18±4 beats/min); p=0.74]. In summary, their study did not show a statistically significant change in perception of pain after administering sucrose solution before cannulation, however, cry time was significantly reduced.

A number if studies related to infants development [18-22] and healthcare [23-25] were reviewed.

5. CONCLUSION

After completion of the study, we will come to know the effect of vibratory therapy on pain control after vaccination in the infant.

6. SCOPE OF THE STUDY

Vibratory therapy is extensively used for the treatment of neonatal pain control as it is non-invasive and easily applicable. Till now, there is not sufficient evidence to see that vibratory therapy may be used for infant pain control during vaccination in infants. Hence, this study will be used to evaluate the effectiveness of vibration application to avoid pain sensation during vaccination in infants.

7. LIMITATIONS

There will be an inability to blind the intervention group. When vibration therapy will be applied before and after the vaccination procedure, blinding would be very difficult.

CONSENT AND ETHICAL APPROVAL

Due to permission of the ethics committee of the institute will be taken before starting the study. The pediatric residents involved in the study will register the participants, complete the baseline measurements and obtain parental consent.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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