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Acupressure Vs Cold Application: Impact on Pentavalent Vaccination Pain and Physiological Parameters in Infants

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KEYWORDS

Pain;Physiological parameters; Acupressure;Cold application; Pentavalent vaccination.

ABSTRACT:

Introduction:Childhood immunization represents one of the most significant achievements in modern medicine and public health, saving millions of lives each year from vaccine-preventable diseases. However, vaccination procedures often cause pain and distress in infants, which can lead to fear and anxiety during subsequent medical encounters. Pain management, therefore, plays a crucial role not only in reducing immediate discomfort but also in enhancing the overall quality of life.

Objectives: The study aimed to compare the effectiveness of acupressure and cold application on pain and physiological parameters among infants .

Methods: A crossover research design was adopted for the study. Sixty infants were randomly allocated into two groups. Group I received acupressure, while Group II received cold application. After a four-week washout period, the interventions were interchanged. Pain intensity was assessed using the Neonatal Infant Pain Scale (NIPS), and physiological parameters such as heart rate and oxygen saturation were measured using a pulse oximeter.

Results: The mean age of infants in Group I and II was 1.97 ± 0.51 and 1.77 ± 0.45 months. During vaccination, the mean heart rate increased, and oxygen saturation decreased significantly in both groups, indicating a physiological response to pain. No significant crossover effect was observed, suggesting that the order of interventions did not influence the infants' pain perception or physiological responses.

Conclusions: The findings of the study indicate that both acupressure and cold application are effective in alleviating pain associated with pentavalent vaccination among infants. These interventions are simple, safe, low-cost, and easy to administer, with a rapid onset of action.

1. Introduction

Pentavalent vaccine offers immunity to a child against five deadly illnesses that are Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib. Current immunization in India already includes DPT (Diptheria+ Pertussis+ Tetanus), Hep B, Hib vaccine is a new one. The combination is referred to as Pentavalent. Hib vaccine is able to prevent severe conditions caused by Haemophilus influenzae type b such as pneumonia, meningitis, bacteraemia, epiglottitis, septic arthritis etc. Pentavalent vaccine is able to give protection against all the five conditions and also results into a reduced number of pricks on the child. It has been estimated that, with Universal Immunization Programme (UIP) 2.7 crore children will be eligible to receive vaccines in our country [1]. Vaccines are currently saving 3 million lives annually in the world and they are among the most affordable health interventions that are available. Paediatric immunization schedules have been provided with combination vaccines that have led to reduction in the number of clinic visits, logistical issues, cost of

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operations and injections and an increase in parental consent, respectively [2-3]. Even though modern and new vaccines applied across the nation are claimed to be safe, the effect of any vaccine is not without adverse reactions. Every vaccine has its side effects which may manifest after using them[4]. Pain as a side effect of vaccination has received more attention recently [5-6]

The pain associated with vaccination procedures disturbs everyone involved children, their parents, and the physicians administering the injections. Untreated vaccination pain, may result in subsequent pre-procedural anxiety, needle phobias, and health care avoidance behaviors, such as failing to follow recommended immunization regimens[7].

Recently, significant steps have been made in the management of pain, including the use of numerous medical techniques (pharmacological) [8] medications include narcotics (morphine), sedatives (acetaminophen), and local analgesics (lidocaine) are utilized in medical procedures [9].Cryotherapy, acupressure, diversion, and music therapy are a few successful non-medical (Non pharmacological) methods to manage pain. While non-medical pain relief techniques have many benefits, such as no side effects and no interference with vaccinations, they also have a pleasant effect on infants. Medical pain relief techniques are rarely employed in infancy due to their negative effects, such as skin rashes and irritations [10].

Ice therapy (cryotherapy) is one of the most widely used treatment modalities used for acute pain. The Some of the possible mechanisms include: follow Reduces edema by decreasing bleeding at the injured site through constricting the vas, reduces transmission of nerve signals in pain fibers, Free nerve ending activity is decreased by the cold, Cold sensations predominate over pain [11]. The use of cold compresses in the treatment of pain has been proven to be effective in many studies [12-14]. Application of manual pressure is a practically effective approach to pain management in infants [15]. Acupressure is a complementary medicine that applies fingers and hands to stimulate acupoints which helps maintain the balance of energy [16].Acupressure site, also known as Hegu, is located between the thumb base and the index finger. Acupressing this point to relieve pain.[17-18].

In actual practice, the technique that is less expensive and gives anesthesia or pain relief quickly is regarded as the best technique. Pain management, which requires to be carried out by a multidisciplinary strategy.

2. Objectives

The main purpose is to compare the outcome of acupressure and cold application in and between groups and the secondary purposes is to establish the behavioral responses to pain and physiological parameters among infants. Despite the various interventions that have been researched upon, not many studies have compared them in order to find out whether one of them could be superior to the other. Then, further research is needed to ascertain whether one of them would be superior to the other intervention. Consequently, the current research problem centered on the outcomes of the LI.4 acupressure Vs cold application to physiological parameters and behavioral reaction to pain in infants that were vaccinated with pentavalent.

3. Methods

A true experimental crossover research design was adopted. The study was conducted in the well-baby clinics of AJ Hospital and Research Centre, Mangalore in Karnataka. Ethical clearance was obtained from institutional ethics committee (AJEC/REV/02/2023). The Study was registered in Clinical Trial Registry of India (CTRI/2023/11/060179). The study protocol was published in International Journal of Clinical Trial , Parents/care takers were approached to conduct the study after taking permission from the hospital authorities. Sixty infants (30 infants in group I (acupressure first then cold application) and 30 in group II (Cold application first then acupressure) receiving Pentavalent vaccination were included (This is a pilot study). Data were collected from March to June 2025.

The purpose of the study was explained to the parents/care givers and they were assured of anonymity and confidentiality to their responses. Informed written consent to participate in the study was sought from the parents/care givers of the infants. Written consent for video recording of the infant behavioral responses to pain during and after

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intramuscular injection was also obtained from parents/ care takers. Infants who met the inclusion criteria were enrolled.

An enrolled infants were randomly allocated into group I and II using SNOSE (Sequentially numbered opaque sealed envelope) method. Each envelope was labelled with a serial number I or II, the investigator asked the parents/caregivers to pick an envelope and assigned the sample according to the number they selected. During the immunization procedure the infants along with caregiver was taken to the immunization room. The care givers were allowed to calm their babies by touching and talking to them. Parents/care givers of infants were interviewed for baseline data. A pulse oximeter was connected before injection and obtain the heartrate and oxygen saturation of an infants.

Infants in group I received acupressure at the LI.4 Acupoint ,before pentavalent vaccination once for 30 seconds and Infants in group II received ice application i.e ice cubes covered in double layered gauze and applied to the vastus lateralis intramuscular injection site before pentavalent vaccination once for 30 seconds.

Following the administration of the injection, the investigator documented the intervention on the immunization card . Group I was indicated by the letter GIA, whereas Group 2 was indicated by the letter G2C. Two days before the scheduled date for the child's next dose of the pentavalent vaccine, the investigator contacted and reminded the parents about the upcoming immunization.

After a washout period of 4 weeks , Infants in group I received cold application and in group II received acupressure. After completing the interventions, the investigator marked the corresponding letters specified on the immunization card with a cross to indicate completion. To assess the behavioral responses to pain the research assistant performed a video recording during the procedure. subsequently, the assessor evaluated pain using the NIPS (Neonatal Infant Pain Scale) by observing the recorded videos. The assessor was blinded to the treatment allocation.

4. Results

The data were analysed using SPSS Version 23. The Kolmogorov–Smirnov test was initially performed to assess the normality of the data distribution and conduct data analysis. The chi square test and fisher exact test were used to evaluate the homogeneity of the sample. To test cross over effect Mannwhitney U test for pain scores and 't' test was applied for physiological parameters. The Friedman test was used to determine the effectiveness of the intervention.

Out of 60 infants the majority of the infants in both Group I (53.3%) and Group II (73.3%) belonged to the age group of 1.5 months. With regard to gender, most infants in both groups were males. In terms of gestational age, the majority of infants in both groups were between 8 and 9 months (37-40 wks) considering the birth order, most infants in Group I (53.3%) were first born, whereas in Group II (46.7%) the majority were second born. With respect to current weight, half of the infants (50%) in Group I and 56.7% in Group II weighed between 4.1–5 kg, while 26.7% in both groups weighed more than 5 kg. Regarding birth weight, the majority of infants in both groups had a birth weight of more than 2.5 kg (76.7%) in Group I and 66.7% in (Group II). In terms of past history of intramuscular injection or vaccination, 43.3% of infants in Group I and 73.3% in Group II had no previous exposure to invasive procedures.

Cross over effect of intervention on pain among infants

In Group I, who first received acupressure followed by cold application, the mean pain score increased from 6.67 ± 0.92 to 6.93 ± 0.36 ($Z = -1.40$, $p = 0.16$), Similarly, in Group II, who first received cold application followed by acupressure, the mean pain score decreased from 6.37 ± 0.99 to 5.97 ± 1.18 ($Z = -1.32$, $p = 0.18$), Thus, the results suggest no significant crossover effect, implying that the order of interventions did not influence the infants' pain perception.

Cross over effect of intervention on physiological parameter among infants

In Group I, who initially received acupressure, the mean heart rate increased from 127.47 ± 22.15 to

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128.67±19.30 (t =−0.224, df =58, p = 0.82), Similarly, in Group II, who initially received cold application, the mean heart rate decreased from 126.10 ± 21.51to 126.57 ±17.53 (t = −0.092, p = 0.92). In Group 1, which initially received acupressure, the mean oxygen saturation increased from 98.03 ± 1.00 to 98.60 ± 0.67 (t =-1.552, df =58, p=0.06) . In Group 2, which initially received cold application, the mean oxygen saturation slightly decreased from 98.53 ± 0.78 to 98.36 ± 0.68 (t=-1.221, df=58, P=0.22). These findings suggest that there was no significant crossover effect, and the order of interventions did not influence the heart rate and oxygen saturation of infants.

Range, Mean and standard deviation of physiological parameters (Heart rate and oxygen saturation) among infants

In Group 1, the mean heart rate increased markedly from 128.07 ± 20.60 before injection to 137.20 ± 22.03 during injection, and further to 139.95 ± 23.89 one minute after injection, suggesting an acute physiological response to pain . By five minutes after injection, the mean heart rate decreased to 131.07 ± 21.17, approaching the baseline value. In Group 2, a similar pattern was observed, though the magnitude of increase was smaller. The mean heart rate rose from 126.33 ± 19.45 before injection to 131.85 ± 19.43 during injection and 133.32 ± 21.05 one minute after injection, followed by a return to near-baseline levels 126.83 ± 19.43

In Group 1, the mean oxygen saturation decreased from 98.32 ± 0.89 before injection to 94.58 ± 1.06 during injection and 94.17 ± 1.23 one minute after injection, indicating a short-term reduction likely due to pain or distress during the procedure. By five minutes after injection, oxygen saturation improved to 97.03 ± 1.55, approaching the pre-injection level. In Group 2, a similar pattern was observed. The mean oxygen saturation dropped from 98.42 ± 0.74 before injection to 95.33 ± 0.93 during injection and 95.07 ± 0.98 one minute after injection, then increased to 97.58 ± 1.16 at five minutes post-injection.

Table 1: Comparison of pain scores at baseline among infants receiving intramuscular injection in group I and Group II n=30+30

Pain	mild to no pain	moderate	severe
Group I			
During	0.0	1.7	98.3
After I min	15.0	13.3	71.7
After 5 min	93.3	3.3	3.3
Group II			
During	0.0	68.3	98.3
After I min	3.3	8.3	1.7
After 5 min	96.7	23.3	0.0

Data in table 1 showed that the majority of infants in both acupressure group and cold application group experienced severe pain during pentavalent vaccination. At one minute after-injection, most infants in acupressure group continued to experience severe pain, whereas the majority in cold application group reported mild to no pain. By five minutes after-injection, infants in both groups predominantly demonstrated mild to no pain.

Table 2: Compare the effect of intervention on pain between group I and II n=30+30

NIPS/Group	Fr	df	P value
Group I	105.77	2	0.0001*
Group II	107.70	2	0.0001*

Fr-friedman test, ** - Highly significant.

Data presented in table 2 revealed the analysis of friedman test to test the effectiveness of interventions within the group I (Fr= 105.77, df=2, p =0.00) and Group II (Fr= 107.70, df=2, p =0.00) showing a higher statistical significance within group I and II.

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Table 03: Effect of intervention on physiological parameters within and between group I and group II

Comparison	Heart rate		Oxygen saturation	
	F	P	F	P
Within the				
Groups	165.33	0.00**	498.83	0.00 **
Between the				
Groups	16.344	0.00**	1.42	0.23

**- highly Significant.

The two factor repeated measures of ANOVA showed a highly significant difference in heart rate within the groups ($F = 165.331$, $df = 3,354$, $p = 0.000$, $\eta^2 = 0.584$). Between-group comparisons also revealed a significant difference in heart rate ($F = 16.344$, $df = 1,118$, $p = 0.000$, $\eta^2 = 0.122$). For oxygen saturation, a significant difference was observed within groups ($F = 498.834$, $df = 3,354$, $p = 0.000$, $\eta^2 = 0.236$). However, between-group comparisons were not statistically significant $F = 1.421$, $df = 1,118$, $p = 0.236$ (Table 03)

5. Discussion

According to the current study, most infants who were administered acupressure and cold application suffered excruciating pain during pentavalent vaccination. Most of the infants who were in acupressure group were still complaining of extreme pain one minute after-injection as compared to most of the infants who were in cold application group who complained of mild pain to none at all. The outcome is aligned with the results of Mathew et al., who have found that both acupressure and the breastfeeding group experienced severe pain [19]. Likewise, the current research results were also corroborated with those of Horo Abha et al., who reported that over 55 percent of the sample in ice pack application group reported to feel mild pain. Although a greater percentage of severe pain was proved in the manual pressure group [20]. Moreover, Thomas S et al, stated that most of the children (83.3) in ice application group report mild behavioural reaction to pain and children (73.3) in acupressure group report moderate behavioural reaction to pain[15].

The Present study demonstrated a highly statistical significance in both acupressure group and cold application group (p=0.0001). Similar findings were reported by Karale et al., who observed that applying ice wrapped in gauze for three minutes prior to venipuncture resulted in significantly lower pain intensity compared to those who did not receive any intervention.[21] Das and colleagues found that applying ice for 30 seconds at the intramuscular injection site significantly decreased immunization pain. In addition, [22] Bilgic et al. reported comparable results, noting no significant difference between the effects of manual pressure and local cold application, thereby concluding that both methods are effective in reducing injection-related discomfort.[23] Further support comes from the study by Unesi et al., which demonstrated that combining vibration with external cold therapy significantly reduced vaccination-related pain among six-month-old infants when compared to the control group. [24] The alignment of these results with the present study reinforces the effectiveness of cold application and acupressure as non-pharmacological interventions for minimizing procedural pain in infants. Erkut and colleagues also observed lower pain scores among infants who received cold application prior to venipuncture, further strengthening evidence that cryotherapy is an effective non-pharmacological pain-relieving method. In addition, manual pressure applied before injection has been shown to attenuate pain responses.[25]

A study by Unezi Z demonstrated that applying pressure for 10 seconds prior to injection significantly decreased pain, supporting our findings on the effectiveness of pressure-based intervention.[26] Further, evidence from another investigation revealed that stimulating the Hegu (LI4) acupressure point for three minutes prior to venipuncture resulted in significantly lower pain scores compared to control, which aligns with the positive impact of acupressure observed in the present study.[27] However, not all studies are consistent with our results. Thomas et al. reported that manual pressure was more effective than cold therapy [3]. These results suggest that the effectiveness of non-pharmacological pain relief

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methods may vary based on the population, interventional technique, duration and procedural context. These findings emphasize the importance of incorporating simple, cost-effective, and non-invasive pain management approaches in routine immunization practices. [28]

The present study demonstrated transient physiological changes in both the acupressure and cold application groups, with increased heart rate and decreased oxygen saturation during and one minute after injection, reflecting an acute pain response. By five minutes post-procedure, heart rate decreased and oxygen saturation returned to near-baseline values. Significant within-group differences were noted in both intervention groups, although oxygen saturation did not differ significantly between groups. These findings are consistent with earlier studies reporting improved physiological stability following acupressure, including reduced heart and respiratory rates and increased oxygen saturation compared to control groups [29]. Similarly, Joseph et al. observed a significant improvement in physiological responses among infants receiving acupressure, evidenced by lower heart rate and higher oxygen saturation post-intervention compared to controls [30]. Additional evidence also supports reduced heart and respiratory rates in infants who received acupressure or foot massage during heel-lancing procedures, indicating a significant physiological calming effect versus routine care [31]. Collectively, these results reinforce that acupressure and cold application can modulate physiological indicators of pain and promote faster return to baseline following painful procedures in infants.

Limitation of the study:

The study population was restricted to infants aged one to 6 months external validity is limited, and the results may not be applicable to all age groups. It was carried out in one centre only thus restricting the possibility to generalize the results on other settings, It is recommendable to carry out additional research with more participants in many health centres.

6.Conclusion

Based on the findings it is evident that both interventions significantly contributed to reducing the behavioural pain response, with observable stabilization of physiological parameters over time. These results support the use of non-pharmacological technique as safe, practical and cost-effective strategies for managing vaccination-related pain in infants and also it may enhance infant comfort, improve parental satisfaction, and promote positive vaccination experiences.

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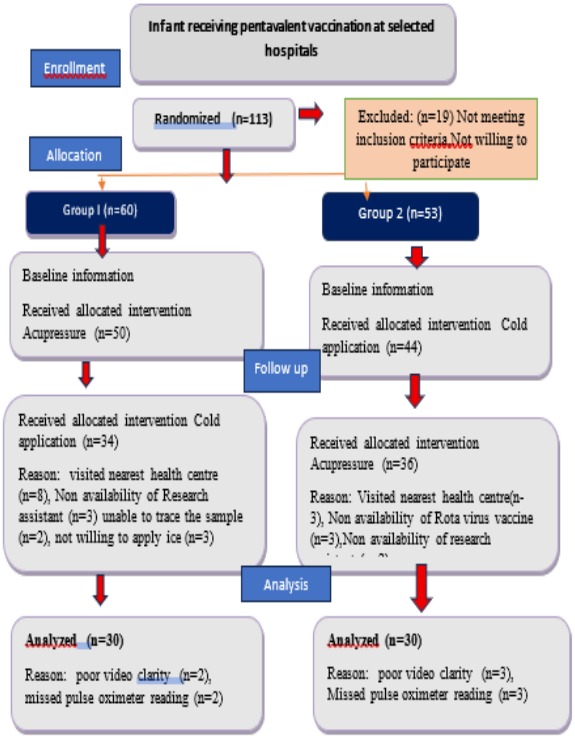

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