

A Study to Evaluate the Effectiveness of Cold Application for Reducing the Level of Pain during Intramuscular Vaccination among Infants in Selected PHC at Urban Community, Guwahati, Assam

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Abstract: *Background: Immunization, also known as vaccination, help protect you from getting an infection disease. When you get vaccinated, you help protect other as well. It is, therefore, very important to provide comprehensive healthcare to children right from conception to childhood to promote their health. The pain of immunization may induce the fear of needle sticks. So to prevent the infants from these suffering we can use cold application to reduce the level of pain during intramuscular vaccination. Objective: To evaluate the effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants. Material and Method: Quantitative research approaches with A True-Experimental post-test only control design. Sampl-68 infants were selected using simple random sampling technique and who fulfil the inclusion criteria of the study. Data was collected using demographic variable, Neonatal Infant Pain Scale for pain assessment, followed by selected nursing interventions such as cold application. Data was analyzed using descriptive and inferential statistic. RESULTS: The present study reveals that in experimental group mean score on the level of pain was 1.41 (SD=1.258) and in control group mean score on the level of pain score was 5.79 (SD=0.538) with mean difference of 4.38. Mean score was compared and tested using unpaired 't' test with calculated value ($t=18.67$, $df=66$, $p=0.001$) indicates statistically highly significant at $p<0.05$. Hence, there was a significant difference between the mean score on the level of pain during intramuscular vaccination among infants in experimental and control groups. So, the research hypothesis (H1) was accepted and null hypothesis (H01) was rejected. CONCLUSION: From the results of the study it concluded that nursing interventions (applying of cold application) were effective on reducing level of pain during intramuscular vaccination.*

Keywords: Effectiveness, Cold application, Pain, Infant, Intramuscular vaccination

“There is always one moment in childhood, when the door opens and lets the future inn.....”

Graham Green

The Power and The Glory

1. Introduction

Children of to-day is the citizen of tomorrow who frame the strongest pillar of a nation. Hence it is quite logical to consider that every child born is a potential asset to the community. This concept has led to the organization and implementation of various programmes to protect and promote the health of an individual from “womb to tomb”.¹

Children are not the people of tomorrow, but people of today. They are entitled to be taken seriously. They have a right to be treated by adults with tenderness and respect, as equals. They should be allowed to grow into whoever they were meant to be the unknown person inside each of them is the hope for future.²

Child health refers to a state of complete physical, mental and social well-being of the children in the age group of 0-5 years and not merely the absence of disease or infirmity. Presently, the concept of child health is widened; it also includes the health of the foetus. It implies the health care of the foetus during antenatal period which refers to antenatal paediatrics, health care of neonates from birth to 28 days, care of infants up to 1 year, care of the toddler from 1 years up to 2 years, care of the pre-school child from 2-5 years of age. The children in this age-group are vulnerable and are liable to get various diseases and disabilities which may lead to high mortality in this age-group. It is, therefore, very important to provide comprehensive healthcare to children right from conception to childhood to promote their health.³

There are a few different types of vaccines. They include:

- **Attenuated (weakened)** live viruses are used in some vaccines such as in the measles, mumps, and rubella (MMR) vaccine.⁴
- **Killed (inactivated)** viruses or bacteria are used in some vaccines, such as in IPV.⁴
- **Toxoid vaccines** contain an inactivated toxin produced by the bacterium. For example, the diphtheria and tetanus vaccines are toxoid vaccines.⁴
- **Conjugate vaccines** (such as Hib) contain parts of bacteria combined with proteins.⁴

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The American Academy of Paediatrics (AAP) recommends that kids get combination vaccines (rather than single vaccines) whenever possible. Many vaccines are offered in combination to help reduce the number of shots a child receives.⁴

1.1 Background of the Study

India, on its part, launched its first vaccine exactly 50 years back: BCG in 1962.^[1] as a part of National Tuberculosis Program. EPI was launched in India in 1978. Initially, it included BCG, DPT (3 doses) and typhoid vaccine; OVP was added the next year. In addition to 3 primary doses of DTP and OPV, 2 boosters at 1.5 years and 5 years were also given to cover up to 5 years of age. Achieving self-sufficiency in production of vaccines was also a part of program. In 1985, the program was converted into Universal Immunization Program (UIP) with a lofty goal to cover 'all' eligible children in the country, immunization of 'all' pregnant women with TT and to improve quality of services. Although the first booster of DPT was retained in UIP, the second booster at 5 years was reduced to DT (pertussis component was omitted). In the same year, measles vaccine was added at 9 months of age, but typhoid vaccine was dropped from the program. In the next 2 decades, there were lots of administrative changes in UIP: it was given status of National Technology Mission in 1986 to give a sense of urgency and commitment in achieving the goals; then it was made part of child survival and save motherhood (CSSM) Programme in 1992 and Reproductive and Child Health (RCH) Programme in 1997. However, the focus remained on 4 vaccines (BDG, DPT, OPV and Measles) and 6 diseases only. It was only after 2006 that new vaccines were introduced. Hepatitis B vaccine was initially introduced in 10 states and then extended to whole country.⁹

1.2 Need for the Study

The taxonomy committee of International Association for the Study of Pain (IASP) defines sensory and emotional experience associated with actual or potential tissue individual learns the application of the word pain through experiences related to injury in early life. Painful medical procedures for children begin with like injections at birth and continue throughout childhood. Children receive immunization injections multiple times throughout childhood and adolescence.¹¹

The Centre for Disease Control and Prevention schedule (2012) recommends immunizations based on ACIP's against 14 diseases, which translate in to 14 to 20 separate injections before the age of 2 years, depending on the number of combination vaccines available. Therefore, immunizations are the most frequently occurring painful procedures performed in paediatric settings. Vaccination help protect us from getting an infection. Vaccination is very safe and it is much safer to get the vaccine than an infectious disease.¹²

National Institute of Health (2011) reports that 77.2% of rural and 80 % of urban children are immunized with vaccines annually. However, the children vaccinated will experience severe to moderate pain. Hence there are many non- pharmacological measures to reduce the level of pain,

one of which is cold application at the injection site prior to injection.¹³

1.3 Problem Statement

A study to evaluate the effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants in selected PHC at urban community, Guwahati, Assam.

1.4 Objectives

1.4.1 General Objectives

To evaluate the effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants.

1.4.2 Specific Objectives

- To assess the level of pain during intramuscular vaccination among infants in experimental group.
- To assess the level of pain during intramuscular vaccination among infants in control group.
- To evaluate the effectiveness of cold application on level of pain during intramuscular vaccination among infants in experimental group.

1.5 Operational Definition

Evaluate

It refers to the determination of level of pain associated with the administration of intramuscular immunization.

Effectiveness

It refers to the cold application that helps in reducing pain and is evidenced by significant difference in the pain score of infants in the experimental and control groups.

Cold Application

It refers to application of small pack filled with crushed ice was covered with a zip-lock polythene packed and after that it is wrapped in a gauze pieces' measures 4x4 and applied it at the injection site for 30 seconds just prior to intramuscular injection.

Injection Site

- It refers to the vastus laterals site.
- To the thigh injection site an imaginary box on the upper leg. Find the groin. One hands width below the groin become the upper border of the box.
- Find the top of knee. One hands width above the knee become the lower border of the box.

Pain

It refers to the level of discomfort among infants associated with intramuscular immunization a measured by Standardized Neonatal Infant Pain Scale.

Infant

It refers to babies between the age group of 1^{1/2} month to 4^{1/2} months.

Intramuscular Vaccination

- It refers to the administration of Pentavalent vaccine through intramuscular route in vastus lateral's muscle of anterior thigh of infants.
- A pentavalent vaccine or 5-in-1 vaccine, is a combination vaccine with five individual vaccines conjugated into one, intended to actively protect people from multiple diseases. (combination of DTP vaccine, hepatitis B vaccine and Heamophilus vaccine.)

1.7 Assumptions

The Study assumes that

- Children will experience pain during administration of injection.
- Every child is unique and responds in a unique way to pain.
- Application of ice will reduce pain.

1.8 Hypothesis

(Hypothesis is tested at 0.05 level of significance)

- H₁: There is a significant difference between the mean score on the level of pain during intramuscular

vaccination among infants in experimental and control groups.

1.9 Delimitation

The study will be delimited to

- The infant who are receiving pentavalent vaccination.

2. Research Methodology

Research methodology refers to investigation the ways of obtaining, organizing and analyzing data.²⁴

The chapter dealt with methodology used for the study.

2.1 Research Approach

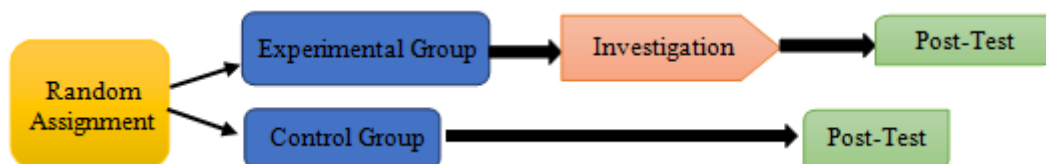
The research approach used for this study was quantitative approach to evaluate the effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants.

2.2 Research Design

The research design is the master plan specifying the method and procedure for collecting and analysis the needed information in a research study.²⁸

A True-Experimental post-test only control design was used for the study.

The diagrammatic representation of the research design is given as follow:



Key Points:

Intervention: Application of ice pack filled with crushed ice which is wrapped in a zip locked polythene bag and the again wrapped with standard size gauge pieces at the injection site for 30 seconds just prior to intramuscular

vaccination.

Post-test: Post-test assessment on level of pain during intramuscular vaccination among infants in experimental and control group respectively.

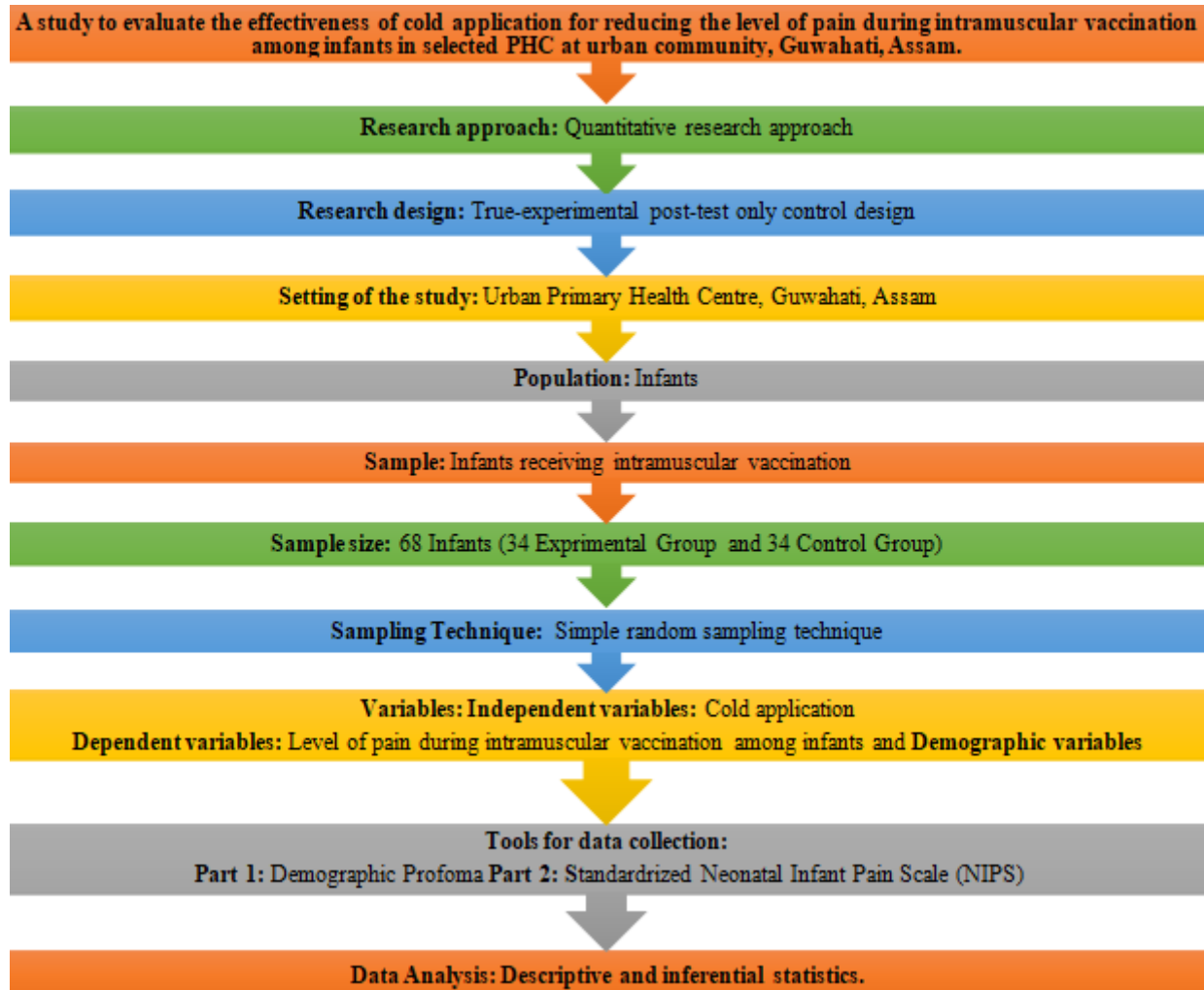


Figure 2: Schematic Representation of Research Study

2.3 Setting of the Study

The study was conducted in Urban Primary Health Centre (UPHC), Basistha which comes under the Capital State Dispensary at Urban Community, Guwahati, Assam. It has different Out-Patient department and emergency care facility. It provides day care services.

The District Immunization Officer (D.I.O) is Mr. B. Das. Every Wednesday is the immunization day it covers 38 sub-centres and 4 UPHC under it.

2.4 Population

Target population: In this study, the target population are the Infants receiving intramuscular vaccination.

Accessible population: In this study, the accessible population are the Infants receiving intramuscular vaccination at Urban Primary Health Centre (UPHC) Basistha, Guwahati, Assam.

2.5 Sample

In this study, the sample are the infants receiving intramuscular vaccination at Urban Primary Health Centre (UPHC) Basistha, Guwahati, Assam.

2.6 Sample Size

The sample size consisted of 68 infants (34 experimental group and 34 control group) who have fulfilled the inclusion criteria.

2.7 Sampling Technique

The sample of the study was selected by adopting Simple Random sampling technique.

2.8 Criteria for Sample Selection

Inclusion Criteria

- Healthy infants who are receiving their routine intramuscular vaccination.
- Infant's parents/caregiver who are willing to participate.
- Infants receiving pentavalent vaccination.

Exclusion Criteria

- Infants who are ill.
- Infants who are receiving any injections other than vaccination

2.9 Variables

The present study consists of dependent, independent and demographic variable.

Dependent Variable

The dependent variable was the level of pain during intramuscular vaccination among infants.

Independent Variable

The independent variable was cold application.

Demographic variable

In this study, demographic variables were Age in month, Gender, Weight, Order of vaccination, Position of child during vaccination, Previous experience of cold application, Previous experience of intramuscular vaccination and History of allergic reaction due to intramuscular vaccination

2.10 Development of the Tool

The tool was developed after an extensive literature review and guidance from the experts. Based on the objectives of the study, a demographic Performa was developed to collect the background information. As the study, aimed to evaluate the effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants Standardized Neonatal Infant Pain Scale (NIPS) was used.

2.11 Description of the Tool

The tool consists of two parts: -

Part 1: Demographic Variable

Part 2: Standardized Neonatal Infant Pain Scale (NIPS).

Part 1: Demographic Variable:

- Age in month
- Gender
- Weight
- Order of vaccination
- Position of child during vaccination
- Previous experience of cold application
- Previous experience of intramuscular vaccination
- History of allergic reaction due to intramuscular vaccination.

Part 2: Standardized Neonatal Infant Pain Scale:

Standardised neonatal infant pain scale was used to assess the level of immunization pain in infants. The Neonatal Infant Pain Scale (NIPS) is a behavioural assessment tool for measurement of pain in preterm and full-term neonates, birth to 1 year. This can be used to monitor a neonate before, during and after a painful procedure such as intramuscular vaccination or vein-puncture. It was developed at the Children's Hospital of Eastern Ontario and adapted from CHEOPS scale. This tool includes six categories of pain behaviours including facial expression, cry, breathing pattern, arms, legs and state of arousal. The possible scoring is done as 0,1 and 2. The infant should be observed for 1

minute in order to fulfil the assessment. The total pain score range is from 0-7.

Scoring Procedure

- Regarding pain score, the maximum score is 7 and minimum score is 0.
- The score is divided into the following categories:
 - 0-1: No pain
 - 2-3: Mild pain
 - 4- 5: Moderate pain
 - 6-7: Severe pain

National Infant Pain Scale		
Parameter	Finding	Points
Facial Expression	Relaxed	0
	Grimace	1
Cry	No Cry	0
	Whimper	1
	Vigorous Crying	2
Breathing Patterns	Relaxed	0
	Change in Breathing	1
Arms	Restrained	0
	Relaxed	0
	Flexed	1
	Extended	1
Legs	Restrained	0
	Relaxed	0
	Flexed	1
	Extended	1
State of Arousal	Sleeping	0
	Awake	0
	Fussy	1

2.12 Content Validity of the Tool

Validity of an instrument is the determination of the extent to which the instrument reflects the abstract construct.¹⁷

Four experts in nursing and one medical experts in the field of community health nursing and child health department evaluated the content validity of the tool. Suggestion and recommendation given by the experts were accepted and necessary corrections were made for modifying the tool.

2.13 Reliability

In this study, Standardized Neonatal Infant Pain Scale (NIPS) was used to assess level of pain during intramuscular vaccination, was a reliable tool.

2.14 Pilot Study

After securing written permission from the respective authority pilot study was conducted among 6 infants (3 experimental group and 3 control group) at Urban Primary Health Centre, Basistha, which again comes under Capital State Dispensary, Guwahati, Assam. The purpose was to find out the feasibility of the study.

After explaining the study, Informed consent was taken from the mother and caregiver, then ice pack was applied for 30 second prior to intramuscular vaccination. At the end of this period intramuscular vaccination is given during which pain

assessment is done among infants in experimental group for one minute using standardized neonatal infant pain scale. The pain assessment among control group is done without the intervention.

The result of pilot study showed that the study was feasible. Hence, Pilot study helped the investigator to confirm the feasibility of carry out the main study.

2.15 Data Collection Procedure

The study was conducted after obtaining permission from Institutional Ethical Committee of Army Institute of Nursing, C/O 151 Base Hospital and also from Office of The Joint Director of Health Service (DHS), Kamrup (Metro), Assam. The investigator obtained a written permission from the Joint Director and District Immunization Officer of DHS Kamrup (Metro), Assam prior to data collection. The data collection period was from 24 June 2020 to 8 July 2020. The investigator introduces herself and explained the purpose of the study to the infant's mother and caregiver who met the inclusion criteria. The investigator obtained written informed consent infants mother or caregivers who are receiving intramuscular vaccination. i.e. Pentavalent to participate in the study.

The investigator selected the participants by using simple random sampling technique. Total sample taken were 68 infants (experimental group was 34, control group was 34). The investigation was explained to participant's mother or caregiver in the Experimental Group. Ice pack applied for 30 seconds prior to intramuscular vaccination. At the end of the procedure, intramuscular vaccination was given during which pain assessment was done among infants in experimental group for one minute using standardized neonatal infant pain scale. The pain assessment among control group was done without the intervention.

2.16 Ethical Consideration

Ethical clearance was obtained from the Institutional Ethical Committee, Army Institute of Nursing c/o 151 Base Hospital, Basistha, Guwahati, Assam on 29. May. 2019.

Ethical clearance was obtained from The Office of The Joint Director Kamrup (Metro), Assam on 7-December-2019.

Formal permission was taken from District Immunisation Officer on 16-March-2020 to conduct the study from 11-April-2020 but due to COVID-19 Pandemic the date changed from 24-June-2020 to 8-July-2020.

Informed written consent was taken from the participants prior to data collection. Privacy was maintained during the data collection and thereafter.

Confidentiality and anonymity of the subjects were maintained throughout the study.

2.17 Plan for Data Analysis

The data was analyzed by using both descriptive and inferential statistics based on the objectives and hypothesis

of the study.

- The demographic variable was analyzed by using descriptive measures (frequency and percentage).
- The level of pain was analyzed by using descriptive statistics (frequency, percentage, mean, standard deviation and mean difference).
- Effectiveness of cold application for reduction the level of pain during intramuscular vaccination was analyzed by using unpaired 't' test.

3. Analysis and Interpretation

This chapter deals with the analysis and interpretation of data collection from 68 infants who receiving intramuscular vaccination in the Urban Primary Health Centre (UPHC), Guwahati, Assam. The present study aims to evaluate the effectiveness of cold application for reducing the level of pain among infants. The analysis and interpretation of data were done by using descriptive and inferential statics based on the objectives and hypothesis formulated for the purpose of the study.

3.1 Objectives

The analysis and interpretation of data was done by using descriptive and inferential statistics based on the following objectives:

- To assess the level of pain during intramuscular vaccination among infants in experimental group.
- To assess the level of pain during intramuscular vaccination among infants in control group.
- To evaluate the effectiveness of cold application on the level of pain during intramuscular vaccination among infants in experimental group.

3.2 Hypothesis (Hypothesis is tested at 0.05 level of significance):

H_1 : There is a significant difference between the mean score on the level of pain during intramuscular vaccination among infants in experimental and control groups.

3.3 Organization of the Findings

The analysis of the data was organized under the following sections:

Section I: Demographic variables of infants in Experimental and control groups.

Section II: Level of pain during intramuscular vaccination among infants in experimental and control groups.

Section III: Effectiveness of cold application on level of pain during intramuscular vaccination among infants in experimental group.

Section – I: Demographic variables of infants in Experimental and control groups

Table 1: Frequency and percentage distribution of age of infants in experimental and control group

N=68

Age in months	Experimental group(n=34)		Control group (n=34)	
	F	%	f	%
a. 1 ½ - 2 months	11	32.4	14	41.2
b. 2 ½ - 3 months	16	47.1	12	35.3
c. 3 ½ - 4 months	7	20.6	8	23.5

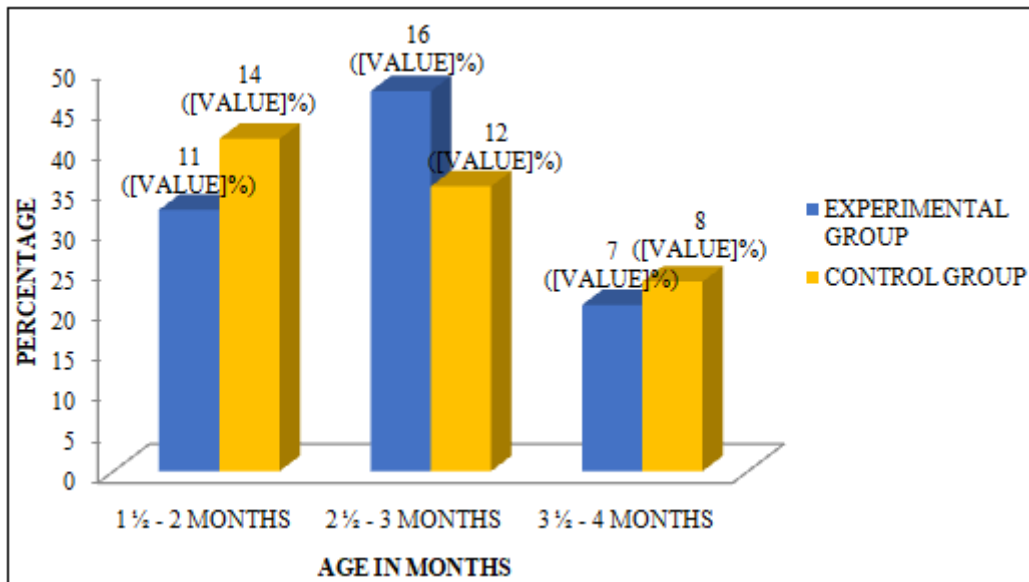


Figure 3: Percentage distribution of age of infants in experimental and control groups

The data presented in Table 1 and Figure 3 depicts that in the experimental group majority of the infants 16(47.1%) were in 2½ to 3 months, 11(32.4%) were in 1½ to 2 months and 7(20.6%) were in 3½ to 4 months whereas in the control group majority of the infants 14(41.2%) were in 1 ½ to 2 months, 12(35.3%) were in 2½ to 3 months and 8(23.5%) were in 3 ½ to 4 months.

Table 2: Frequency and percentage distribution of gender of infants in experimental and control group, N=68

Gender	Experimental group(n=34)		Control group (n=34)	
	F	%	f	%
a. Male	16	47.1	18	52.9
b. Female	18	52.9	16	47.1

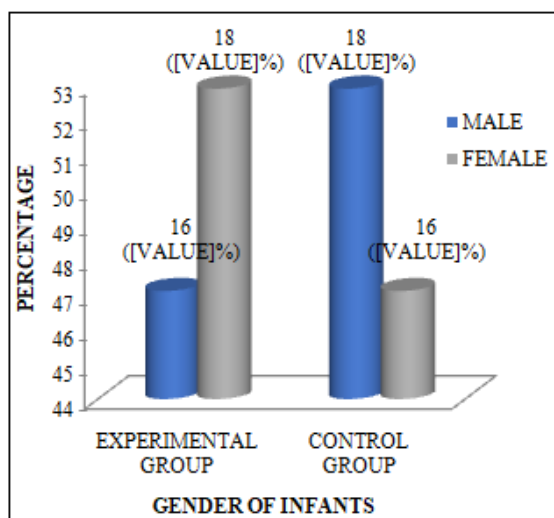


Figure 4: Percentage distribution of gender of infants in experimental and control group

The data presented in the on Table 2 and Figure 4 depicts that in experimental group majority of the infants 18(52.9%) were female and 16(47.1%) were male whereas in control group majority of infants 18(52.9%) were male and 16(47.1%) were female.

Table 3: Frequency and percentage distribution of weight of infants in experimental and control group, N=68

Weight	Experimental group(n=34)		Control group (n=34)	
	F	%	f	%
< 2 kg	7	20.6	6	17.6
2-4 kg	23	67.6	24	70.6
> 4 kg	4	11.8	4	11.8

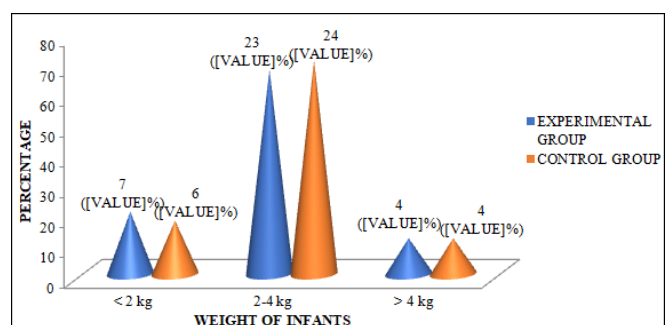


Figure 5: Percentage distribution of weight of infants in experimental and control group

The data presented in the Table 3 and Figure 5 depicts that in experimental group majority of the infants 23(67.6%) had 2-4 kg weight, 7(20.6%) had <2 kg weight and 4(11.8%) had >4kg weight whereas in control group majority of the infants 24(70.6%) had 2-4 kg weight, 6(17.6%) had <2 kg weight and 4(11.8%) had >4kg weight.

Table 4: Frequency and percentage distribution of order of vaccine of infants in experimental and control group, N=68

Order of vaccine	Experimental Group (n=34)		Control group (n=34)	
	F	%	f	%
a. Penta – 1	11	32.4	13	38.2
b. Penta – 2	16	47.1	12	35.3
c. Penta – 3	7	20.6	9	26.5

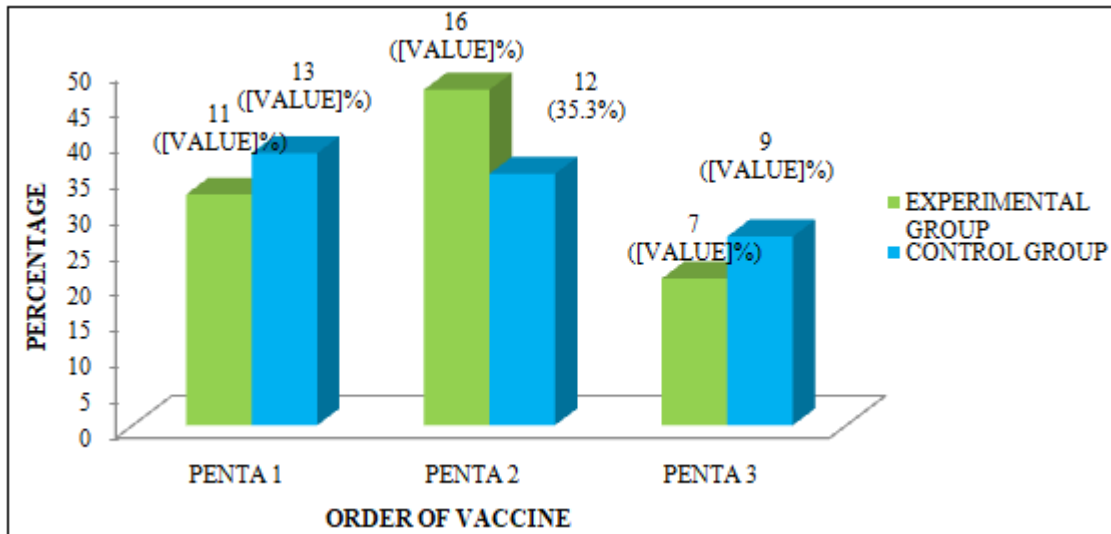


Figure 6: Percentage distribution of order of vaccine of infants in experimental and control groups

The data presented in the Table 4 and Figure 6 depicts that in experimental group majority of the infants 16(47.1%) had Penta-2 vaccine, 11(32.4%) had Penta-1 vaccine and 7(20.6%) had Penta-3 vaccine whereas in control group majority of the infants 13(38.2%) had Penta-1 vaccine, 12(35.3%) had Penta-2 vaccine and 9(26.5%) had Penta-3 vaccine.

Table 5: Frequency and percentage distribution of position of child during vaccination in experimental and control group N=68

Position of child during vaccination	Experimental group(n=34)		Control group (n=34)	
	F	%	f	%
a. Sitting	0	0	0	0
b. Lying	34	100	34	100

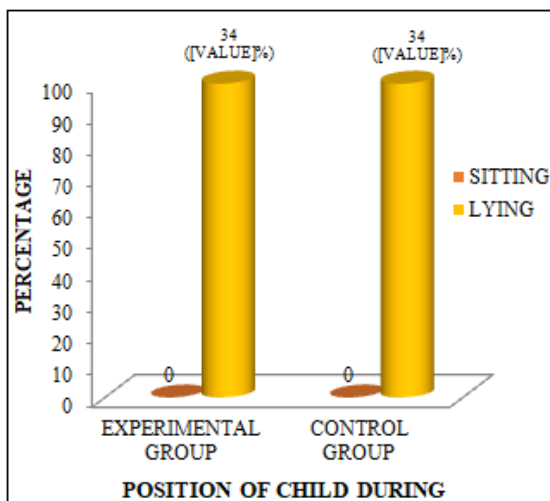


Figure 7: Percentage distribution of position of child during vaccination in experimental and control group

The data presented in the Table 5 and Figure 7 shows that all the infants i.e. 34(100%) in each experimental and control group were in lying position during vaccination.

Table 6: Frequency and percentage distribution of previous experience of cold application during intramuscular vaccination in experimental and control group, N=68

Previous experience of cold application during intramuscular vaccination	Experimental group (n=34)		Control group (n=34)	
	F	%	f	%
a. Yes	8	23.5	14	41.2
b.No	26	76.5	20	58.8

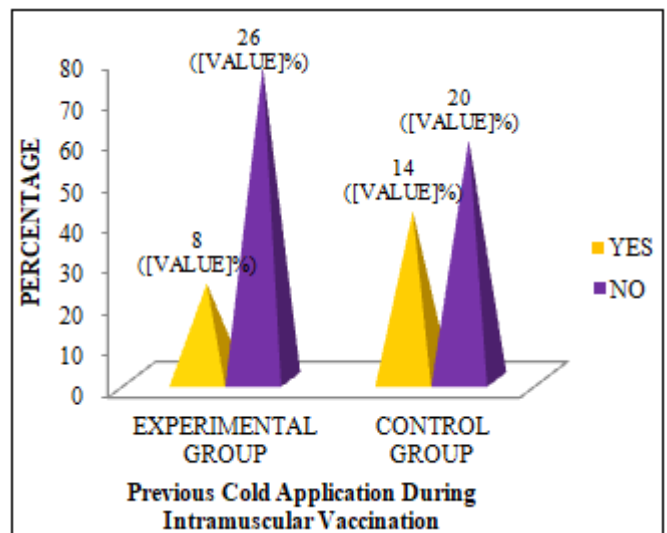


Figure 8: Percentage distribution of previous experience of cold application during intramuscular vaccination in experimental and control groups

The data presented in the Table 6 and Figure 8 depicts that in experimental group majority of infants 26(76.5%) had no

previous cold application and 8(23.5%) had previous cold application during intramuscular vaccination whereas in control group majority of the infants 20(58.8%) had no previous cold application and 14(41.2%) had previous cold application during intramuscular vaccination.

Table 7: Frequency and percentage distribution of previous experience of intramuscular vaccination in experimental and control group, N=68

Previous experience of intramuscular vaccination	Experimental group (n=34)		Control group (n=34)	
	F	%	F	%
a. Yes	20	58.8	15	44.1
b. No	14	41.2	19	55.9

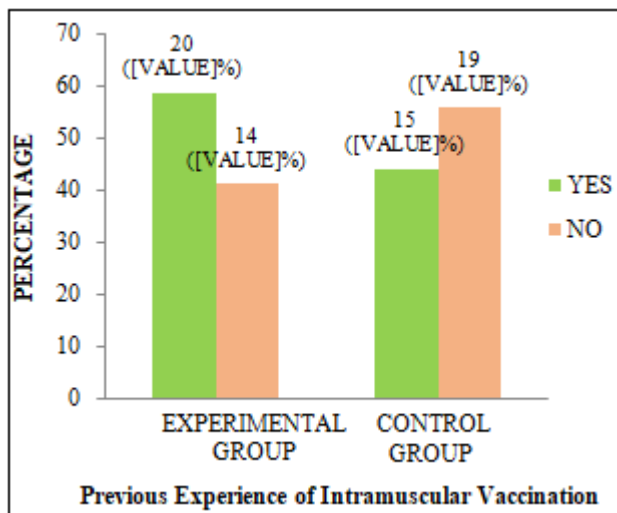


Figure 9: Percentage distribution of previous experience of intramuscular vaccination in experimental and control group

The data presented in the Table 7 and Figure 9 that in experimental group majority of the infants 20(58.8%) had previous experience of intramuscular vaccination and 14(41.2%) had no previous experience of intramuscular vaccination whereas in control group majority of the infants 19(55.9%) had no previous experience of intramuscular

Table 9: Frequency and percentage distribution of level of pain during intramuscular vaccination among infants in experimental and control groups, N=68

Level of pain	Experimental Group (n=34)		Control Group (n=34)	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
No pain (0-1)	24	70.6	0	0
Mild pain (2-3)	6	17.6	0	0
Moderate pain (4-5)	4	11.8	9	26.5
Severe pain (6-7)	0	0	25	73.5

vaccination and 15(44.1%) had previous experience of intramuscular vaccination.

Table 8: Frequency and percentage distribution of previous history of allergic reaction due to intramuscular vaccination in experimental and control group, N=68

Previous history of allergic reaction due to intramuscular vaccination	Experimental group (n=34)		Control group (n=34)	
	F	%	F	%
a. Yes	0	0	0	0
b. No	34	100	34	100

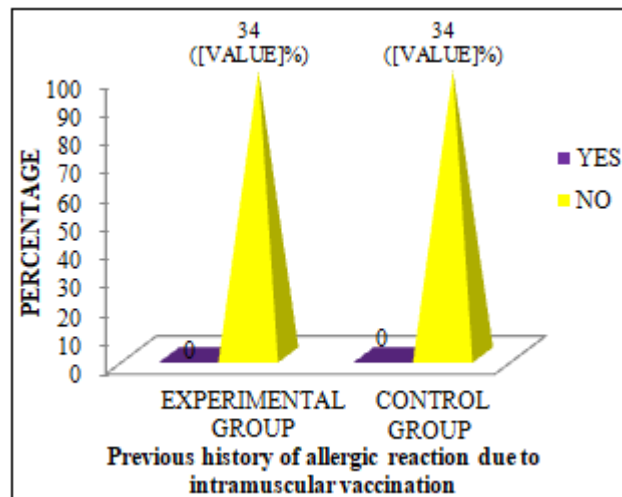


Figure 10: Percentage distribution of previous history of allergic reaction due to intramuscular vaccination in experimental and control group

The data presented in the Table 8 and Figure 10 shows that all the infants i.e. 34(100%) in each experimental and control group were no previous history of allergic reaction due to intramuscular vaccination.

Section II: Level of pain during intramuscular vaccination among infants in experimental and control groups.

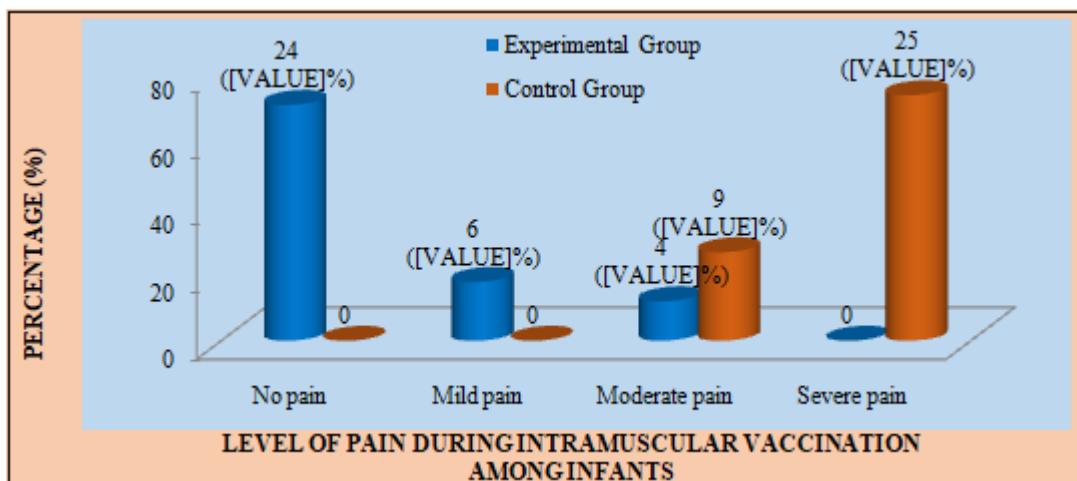


Figure 11: Frequency and Percentage distribution of participants by level of pain during intramuscular vaccination among infants in experimental and control groups

The data presented in the Table 9 and Figure 11 depicts that in experimental group majority of infants 24(70.6%) had no pain (0-1), 6(17.6%) had mild pain (2-3) and 4(11.8%) had

moderate pain (4-5) whereas in control group majority of infants 25(73.5%) had severe pain (6-7) and 9(26.5%) had moderate pain (4-5).

Table 10: Range, Mean, Standard Deviation (SD) and Mean Percentage on the level of pain scores in Experimental and Control Groups, N=68

Level of Pain	Range of Pain Score	Mean	SD	Mean Percentage
Experimental Group (n=34)	0 – 5	1.41	1.258	20.1%
Control Group (n=34)	5 – 7	5.79	0.538	82.7%

The data represented in Table 10 depicts that the mean score on the level of pain 1.41 (SD=1.258)of the experimental group was lower than the mean score on the level pain 5.79 (SD=0.538) of the control group.

In order to find out the significant difference between mean level of pain in experimental group Unpaired “t” test was computed and data is presented in table 11.

Section III: Effectiveness of cold application on the level of pain during intramuscular vaccination among infants in experimental group

To test the statistically significant the following null hypothesis was stated:

H₁: There is no significant difference between the mean score on the level of pain during intramuscular vaccination among infants in experimental group.

Table 11: Mean, Standard Deviation (SD), Mean Difference, ‘t’ value, Degree of freedom (df) and ‘p’ value on the level of pain in experimental and control groups, N=68

Level of Pain	Mean	SD	Mean Difference	‘t’ value	df	‘p’ value
Experimental Group (n=34)	1.41	1.258	4.38	18.67	66	0.001*
Control Group (n=34)	5.79	0.538				

*p<0.05 level of significance

The data presented in the Table 12 shows that in experimental group mean score on the level of pain was 1.41 (SD=1.258)and in control group mean score on the level of pain score was 5.79 (SD=0.538)with mean difference of 4.38. Mean score was compared and tested using unpaired ‘t’ test with calculated value (t=18.67, df=66, p=0.001) indicates statistically highly significant at p<0.05. Hence, there was a significant difference between the mean score on the level of pain during intramuscular vaccination among infants in experimental and control groups. So, the research hypothesis (H₁)was accepted and null hypothesis (H₀) was

rejected and concluded that effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants in experimental group.

4. Discussion

The aim of the present study was undertaken to evaluate the effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants.

The findings of the study have been discussed under the following sections:

Section I: Demographic variables of infants in Experimental and control groups

Section II: Level of pain during intramuscular vaccination among infants in experimental and control groups.

Section III: Effectiveness of cold application on the level of pain during intramuscular vaccination among infants in experimental group.

4.1 Major findings of the study

Section I: Demographic variables of infants in Experimental and control groups

- In the experimental group, majority of the infants 16(47.1%) were in 2½ to 3 months whereas in the control group, majority of the infants 14(41.2%) were in 1 ½ to 2 months.
- In experimental group majority of the infants 18(52.9%) were female male whereas in control group majority of the infants 18(52.9%) were male.
- In experimental group majority of the infants 23(67.6%) had 2-4 kg weight whereas in control group majority of the infants 24(70.6%) had 2-4 kg weight.
- In experimental group majority of the infants 16(47.1%) had Penta-2 vaccine whereas in control group majority of the infants 13(38.2%) had Penta-1 vaccine.
- All the infants i.e. 34(100%) in each experimental and control group were in lying position during vaccination.
- In experimental group majority of infants 26(76.5%) had no previous cold application during intramuscular vaccination whereas in control group majority of the infants 20(58.8%) had no previous cold application during intramuscular vaccination.
- In experimental group majority of the infants 20(58.8%) had previous experience of intramuscular vaccination whereas in control group majority of the infants 19(55.9%) had no previous experience of intramuscular vaccination.
- All the infants i.e. 34(100%) in each experimental and control group were no previous history of allergic reaction due to intramuscular vaccination.

Section II: Level of pain during intramuscular vaccination among infants in experimental and control groups.

The present study reveals that in experimental group majority of infants 24(70.6%) had no pain (0-1), 6(17.6%) had mild pain (2-3) and 4(11.8%) had moderate pain (4-5) whereas in control group majority of infants 25(73.5%) had severe pain (6-7) and 9(26.5%) had moderate pain (4-5).

Section III: Effectiveness of cold application on the level of pain during intramuscular vaccination among infants in experimental group

The present study reveals that in experimental group mean score on the level of pain was 1.41 (SD=1.258) and in

control group mean score on the level of pain score was 5.79 (SD=0.538) with mean difference of 4.38. Mean score was compared and tested using unpaired 't' test with calculated value ($t=18.67$, $df=66$, $p=0.001$) indicates statistically highly significant at $p<0.05$. Hence, there was a significant difference between the mean score on the level of pain during intramuscular vaccination among infants in experimental and control groups. So, the research hypothesis (H_1) was accepted and null hypothesis (H_{01}) was rejected and concluded that effectiveness of cold application for reducing the level of pain during intramuscular vaccination among infants in experimental group.

5. Implication and Recommendation

This chapter deals with implication of the study in field of nursing education, nursing administration, nursing practices and nursing research. The limitation of the study has been stated and recommendations for future research in different aspect have also been presented in the chapter.

5.1 Implication

The finding of the study has implication in different branches of Nursing Profession I.e. Nursing Practices, Nursing Education, Nursing Administration and Nursing Research By assessing the effectiveness of cold application during intramuscular vaccination, we can get a clear picture regarding different steps to be taken in all fields, to improve the standards of Nursing Profession.

Nursing Practice

As it identified from the study findings that applying of cold application was an effective pain management during intramuscular vaccination. All institution and clinics should be supported and encouraged to facilitate this kind of non-pharmacological measures during vaccination.

Clinical nurse can also:

- Learn the techniques of cold application
- Learn the assessment of pain with use of Standardized Neonatal Infant Pain Scale.
- Understand the importance of cold application
- Use cold application as a complementary therapy to reduce pain before, during or after intramuscular vaccination among children's.

Nursing Education

The research suggests that cold application is a non-pharmacological measure to reduce pain. The findings suggest that cold application is simple, safe, cost-effective and easy to administer than any other pharmacological pain relief intervention. So, it must be incorporated in clinical setting as a pain intervention measures. The nursing students should be taught about the importance of various pain relief measure that can implemented in care of children.

Nursing Educator can motivate student to:

- Learn the effectiveness of cold application on reducing pain during intramuscular vaccination as an independent nursing intervention.
- Learn techniques and mechanism of cold application on reducing pain during intramuscular vaccination.

Nursing Administration

With technological advances and growing challenge of health care needs, the administration has a responsibility to provide nurse with substantive confined education opportunities. This will enable the nurses to update their knowledge on latest pain management strategies available to demonstrate high quality care.

Nurse administrator can:

- Organize conferences, in-service education and workshop to encourage staff nurse to learn about various alternative and complimentary therapies used as pain relief strategies including cold application intervention.
- Develop a written protocol on method of cold application implication.

Nursing Research

In India, evidence based clinical strategies are not sufficient. As there are fewer studies related to pain intervention during injection, there is need for extensive and intensive studies. Nurse researcher must focus on various aspects and develop appropriate tools for pain assessment in children during injection. Science cold application can be implemented to children who receive intramuscular vaccination and its effectiveness can be tested through research.

Nurse researcher can:

- Dissemination of findings of evidence based practice through conferences, seminar, publication in national and international nursing journals and internet media will benefit a wider community.
- Add to the research review about the importance of cold application.
- Expanding the scientific body of professional knowledge upon which further research can be conducted.
- Help in practice aspect to expand the role of nurses.

6. Recommendations

- Similar kind of study can be conducted on large group.
- Study can be conduct on different settings.
- A comparative study can be done between the effectiveness of various non-pharmacological measures for pain associated with intramuscular immunization.
- A descriptive study can be conducted on knowledge and attitude regarding cold application.

7. Conclusion

The intramuscular vaccination is stressful for infants. It is necessary to provide pharmacological or non-pharmacological intervention to reduce the pain and

discomfort in infants. The findings of the study indicated that the ice pack application is simple, safe, cost effective and easy to administer than any other pain intervention. So, it must be in corporate in clinical setting as a pain intervention measures.

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