"A STUDY TO ASSESS THE EFFECTIVENESS OF COLD NEEDLE IN PAINREDUCTION AFTER INTRAMUSCULAR VACCINATION AMONG NEONATES DELIVERED IN SMVMCH AT PUDUCHERRY"

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ABSTRACT

One of the most dramatic advances in pediatrics has been the decline of infectious diseases during the twentieth century because of the widespread use of immunization for preventable diseases. The aim of present study is to assess the effectiveness of cold needle in pain reduction after intramuscular vaccination among neonates. A quantitative research approach and true experimental post-test only control group research design was used for this study the 30 samples in the study group and 30 samples in the control group were selected with the simple random sampling technique. Sample consists of neonates. In study group received the cold needle vaccination which was cooled at the range of 0-2 degree Celsius in the chiller chamber of refrigerator for 1-2 hours and control group received the routine vaccination after that level of pain was assessed by the neonatal infant pain scale. The result was conducted using descriptive and inferential statistics. In study group, (18) 60% neonates had mild pain, (9) 30% of neonates had moderate pain and (3) 10% of neonates had no pain. In control group, (21) 70% of neonates had moderate pain, (6) 20% of neonates had severe pain and (3) 10% of neonates had mild pain. The calculated independent 't' test value of t = 5.787 showed the statistically significant difference in the effectiveness of cold needle in pain reduction after intramuscular vaccination among neonates in the study group. Therefore, the study findings concluded that cold needle vaccination was found to be very effective in pain reduction among neonates.

Key words: Cold needle, vaccination, neonates

INTRODUCTION

The birth of an infant is one of the most awe-inspiring and emotional events that can occur in one's lifetime. One of the most dramatic advances in pediatrics has been the decline of infectious diseases during the twentieth century because of the widespread use of immunization for preventable diseases. Widespread use of immunization has brought the most dramatic advances in pediatrics by its important part of health promotion and disease prevention. The vaccines are prepared from microorganisms or genetically engineered antigens. These vaccines when introduced into the body evoke an immune response.

NEED FOR THE STUDY
Internationally, 18.2 million infants did not receive their first dose of DTP vaccine, indicating a lack of access to immunization and other health services, and another 6.8 million were only partially vaccinated. More than 60% of the 25 million children are found in ten countries: Angola, Brazil, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Myanmar, Nigeria, Pakistan, and the Philippines. Sub-national data monitoring is critical for assisting countries in prioritizing and tailoring vaccination strategies and operational plans to address immunization gaps and reach every person with life-saving vaccines.

The Universal Immunization Programme (UIP) is one of the largest public health programs, with an annual target population of 2.67 crore newborns and 2.9 crore pregnant women. It is one of the most cost-effective public health interventions, and it is largely responsible for the decrease in vaccine-preventable under-5 mortality.

Immunization is provided free of charge under UIP against 12 vaccine-preventable diseases: Diphtheria, pertussis, tetanus, polio, measles, rubella, severe childhood tuberculosis, hepatitis B, and meningitis and pneumonia caused by Hemophilus influenza type B are all being fought on a national scale.(National Health Mission)

STATEMENT OF THE PROBLEM
"A study to assess the effectiveness of cold needle in pain reduction after intramuscular vaccination among neonates delivered in SMVMCH at Puducherry."

OBJECTIVES
1. To assess the level of pain after intramuscular vaccination among neonates in the study group and control group.
2. To compare the level of pain after intramuscular vaccination among neonates between the study group and control group.
3. To evaluate the effectiveness of cold needle in pain reduction after intramuscular vaccination among neonates in the study group.
4. To associate the pain reduction after intramuscular vaccination among neonates between study and control group with their selected demographic variables.

REVIEW OF LITERATURE
The literature directs the researcher in designing the study and interpreting the outcomes. The primary purpose is to gain broad background or understanding of the information that is available related to the problem. This helps the investigator to gain in-depth knowledge that is needed to make changes in practice and problem. The review of literature is organized and presented under the following headings.
Section A: Review related to intramuscular vaccination of Neonates
Section B: Review related to effectiveness Cold needle on Intramuscular injection pain.

SECTION A: REVIEW RELATED TO INTRAMUSCULAR VACCINATION OF NEONATES
Sefika Dilek Guvenet al., (2023) was conducted a randomized controlled trial study on the effect of Helfer skin tap technique on hepatitis B vaccine intramuscular injection pain in neonates. The study aim was to determine the effect of Helfer skin tap technique (HSTT) on hepatitis B vaccine intramuscular (IM) injection pain in neonetes. This study was conducted total 60 neonates including 30 in the HSTT group and 30 in the Routine Technique (RT) group. Data were collected using a questionnaire form and the Neonatal Infant Pain Scale (NIPS). The difference between the groups arising in the comparison of means of the total pain scores obtained during and after injection in HSTT and RT groups was determined to be statistically significant (p <0.05).they concluded that HSTT was proven to be effective in reducing hepatitis B vaccine intramuscular (IM) injection pain in neonates. This study demonstrates that HSTT is associated with reduced pain in newborns during hepatitis B vaccine IM injections.

Yashodha Ediriweeraet al., (2022) was conducted a study on a randomised controlled trial of ice to reduce the pain of immunization. They investigated the effects of applying an ice pack on vaccine-related pain in adults. Medical students receiving the flu vaccination were randomised to receive an ice pack (intervention) or placebo cold pack (control) at the injection site for 30 s prior to needle insertion. Immediate post-vaccination pain (VAS) and adverse reactions in the proceeding 24 h were recorded. Pain scores between the intervention (n = 19) and control groups (n = 16) were not statistically significant (intervention: median pain VAS = 7.00, IQR = 18; control: median pain VAS = 11, IQR = 14 (p = 0.26). There were no significant differences in the number

of adverse events between the two groups (site pain p = 0.18; localized swelling (p = 0.67); bruising p = 0.09; erythema p = 0.46).They concluded that use of ice packs to reduce injection-related pain in adults.

SECTION B: REVIEW RELATED TO EFFECTIVENESS COLD NEEDLE ON INTRAMUSCULAR INJECTION PAIN

Ajithet al., (2020) was conducted a study on Effect of Cold Needle on Pain of Infant after Intramuscular Vaccine in Selected Hospitals. A quasi experimental posttest only design was used.60 samples were taken using probability sampling technique-systematic random from selected hospitals, of which 30 were using normal room temperature needle and 30 were using cold needle. The data was collected using self-structured demographic data, FLACC pain assessment scale and observation checklist. On observation, Majority of infant 63% experience moderate level of pain during intramuscular injection with cold needle, 23% of the infants had mild pain and least percentage of 13% of the infant had severe pain in experimental group. In control group most of the samples had severe pain i.e. 70% and 30% had moderate level of pain during intramuscular injection. Corresponding p- value was 0.00001 which is significant less than p<0.05 level. They concluded that Cold needle was effective in reducing pain during intramuscular immunization in infants.

Jancy (2019) was conducted a study, the main aim of the study was to determine the effect of cold needle on perception of pain during intramuscular (IM) injection among adults in a selected hospital, Kerala. A quasi experimental one group pre-test post-test design was used in this study. The study was conducted among adults (21-60 years) those who received IM injection of Diclofenac sodium. Using non probability purposive sampling technique 50 adults were selected. Each adult received IM injection (2 doses) with needle at room temperature and cold needle (0-2 degree Celsius) alternatively. Study findings revealed that the mean pain score 5.32 with needle at room temperature was found significantly higher than the mean pain score (2.00) with cold needle. There was a significant association found between the level of pain perception and previous experience to IM injection with cold needle. She was concluded that cold needle (0-2 degree Celsius) is effective in reducing the perception of pain during IM injection.

MATERIALS AND METHODS

A quantitative research approach and True experimental research design was used for this study, the 30 samples in study group and 30 samples were in control groups selected with the use of simple random sampling technique. Sample consists neonates delivered in Sri Manakula Vinayagar Medical College and Hospital who fulfill the inclusion criteria. In that study group received the cold needle vaccination and control group received the routine vaccination. Standardized Neonatal Infant Pain Scale was used to assess the level of immunization pain in neonates. The result was conducted using descriptive and inferential statistics.

DATA COLLECTION TOOL
DEVELOPMENT OF DATA COLLECTION INSTRUMENTS
Section A: Demographic variables
Section B: Neonatal infant pain scale (NIPS) to assess the level of pain.
DESCRIPTION OF DATA COLLECTION INSTRUMENTS
Section A: This section consists of 7 Demographic variables such as Weight of the baby, Gender, Nature of delivery, Gestational age, Birth order of the new born, Types of marriage, Family monthly income.
Section B: The Standardized Neonatal Infant Pain Scale was used to assess neonatal immunization pain. The Neonatal Infant Pain Scale (NIPS) is a behavioral assessment tool used to assess pain in preterm and full-term neonates aged birth to one year. This can be used to track a Neonate before, during, and after a painful procedure like venipuncture. This tool includes six pain behavior categories: facial expression, cry, breathing pattern, arms, legs, and state of arousal.

Each behavioral indicator is scored with 0 or 1 except "cry" which has three possible descriptors therefore, being scored with 0-1 or 2. Infants should be observed for 1 minute in order to fully assess each indicator. Total pain scores range from 0-7.

Neonatal infant pain scale (NIPS)

S. No	Parameters	0 Points	1 Points	2 Points
	Facial expression	Relaxed	Grimace	-
	Cry	No cry	Whimper	Vigorous crying
	Breathing pattern	Relaxed	Change in breathing	-
	Arms	Relaxed	Flexed/extended	-
	Legs	Relaxed	Flexed/extended	-
	State of arousal	Sleeping/awake	Fussy	-

SCORING INTERPRETATION

Regarding pain score, the maximum score is 7 and minimum score is 0. The score was divided into the following categories.

S.NO	LEVEL OF PAIN	SCORING	PERCENTAGE
	No pain	0 -1	(0 – 14) %
	Mild pain	2-3	(28 – 43) %
	Moderate pain	4-5	(57 – 71) %
	Severe pain	6-7	(85 – 100) %

STATISTICAL ANALYSIS

The data obtained was analyzed in terms of objectives of the study using descriptive and inferential statistics. The plan of data analysis was as follows:

Descriptive statistics: Frequency, percentage distribution, mean, mean percentage and standard deviation.

Inferential statistics: Independent "t" test. Chi square test, in the form of tables and figures.

DATA ANALYSIS	METHODS	REMARKS
Descriptive statistics	Frequency, Percentage, Mean, Standard Deviation	To describe the demographic variables among neonates delivered in SMVMCH at Puducherry.
Inferential statistics	Independent 't' test, chi square	Comparison of study and control group and find the association between the study and control groups and their selected demographic variables.

RESULTS AND DISCUSSION

The study finding reveals that in study group, (18) 60% of neonates had mild pain, (9) 30% of neonates had moderate pain and (3) 10% of neonates had no pain. In control group, (21) 70% of neonates had moderate pain, (6) 20% of neonates had severe pain and (3) 10% of neonates had mild pain.

Comparisons of pain score experimental and control group. Study group have mean score of 3.07 with SD 1.015 and control group have mean score of 4.50 with SD 0.937. There is significant difference between study and control group. On an average, study group are having 3.07 mean score whereas in control group are having 4.50 mean score, so the difference is 20.47%. This difference shows the effectiveness of cold needle.The finding reveals that there is significance association between the nature of delivery (p=0.009) and level of pain among neonates with intramuscular injection in study group with selected demographic variables.

The finding reveals that there is significance association between the gestational age (p=0.015) and level of pain among neonates with intramuscular injection in control group with selected demographic variables.

Section A: Distribution of Demographic Variable of neonates in study group and control group

Table I: Frequency and Percentage-Wise Distribution of Demographic Variable of neonates in study group and control group.   N=30+30

S. No	Demographic variables	Study group N=30		Control group N=30	
		N	%	N	%
1.	**Weight of the baby**				
	Below 2 kg	1	3.3%	0	0%
	>2 to 3 kg	25	83.3%	18	60%
	>3 to 4 kg	4	13.3%	12	40%
	Above 4 kg	0	0%	0	0%
2.	**Gender**				
	Male child	13	43.3%	17	56.7%
	Female child	17	56.7%	13	43.3%
3.	**Nature of delivery**				
	Normal vaginal delivery	12	40%	16	53.3%
	Lower segment caesarean section	18	60%	14	46.7%

The finding reveals that majority 25 (83.3%) of the neonates weight were between of > 2 to 3 kg in the study group and 18 (60%) of the neonates weight were between of > 2 to 3 kg in the control group. Majority 17 (56.7%) of the neonates were male in the study group and 17(56.7%) were male in the control group. Considering the nature of delivery, most of the neonates 16 (53.3%) were by lower segment caesarean section in study group and 18 (60%) were by natural vaginal delivery in control group.
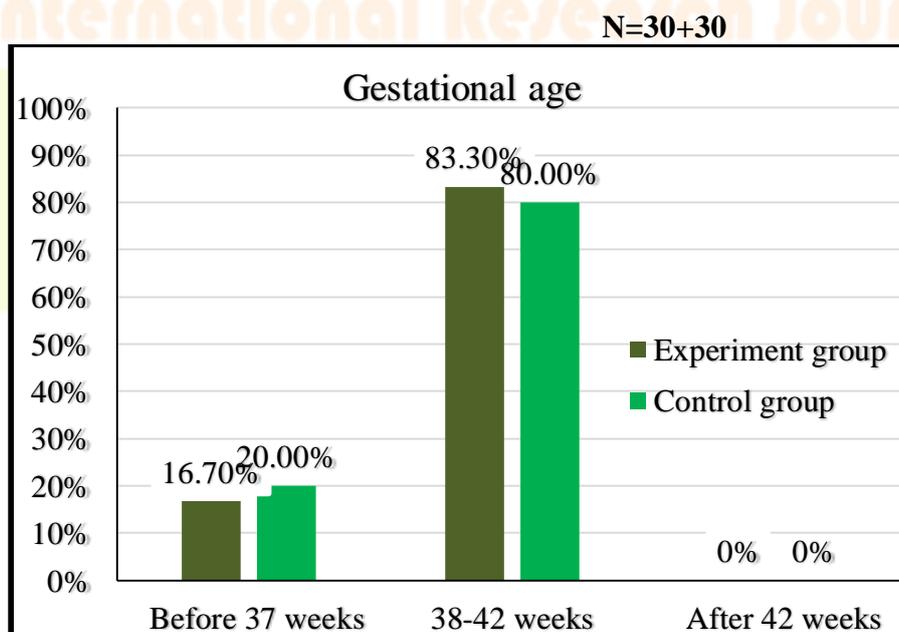
N=30+30

Figure 1: Shows gestational age distribution among neonates in both experimental group and control group

The figure shows the findings that, the gestational age, majority of neonates 25 (83.30%) were 38-42 weeks in study group and 24 (80%) were 38-42 weeks in control group. 5(16.70%) of neonates were before 37 weeks in study group and 6(20%) were in control group. none of them comes under the after 42 weeks of gestation.
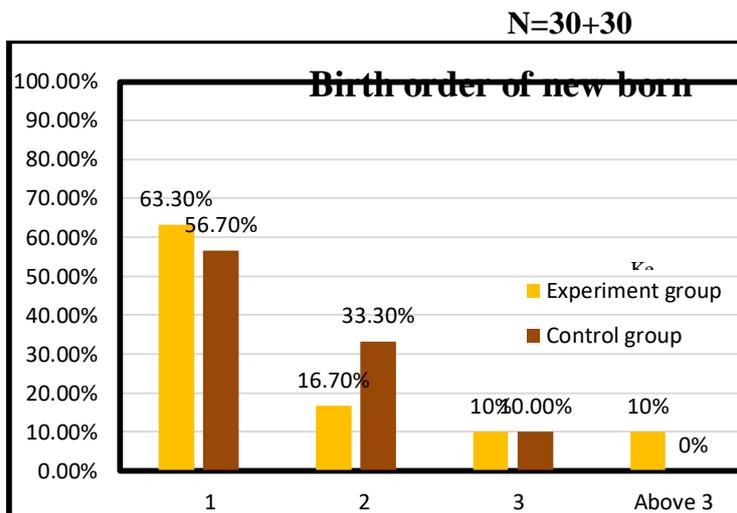
N=30+30

Figure 2: Shows birth order of newborn distribution among neonates in both experimental group and control group

The figure reveals that considering the birth order of the newborn majority of neonates 19 (63.30%) were first birth order in study group and 17 (56.70%) were first birth order in Control group. 5(16.70%) of neonates were second birth order in study group and neonates 10 (33.30%) were second birth order in control group. neonates 3 (10%) were third birth order in study group and neonates 3 (10%) were third birth order in control group and neonates 3 (10%) were above fourth birth order in study group and none of them in control group.

Section B: Assessment of level of pain after intramuscular vaccination among neonates in the study group and control group

Table II: Frequency and percentage wise distribution of level of pain after intramuscular vaccination among neonates in the study group and control group

S.NO	LEVEL OF PAIN	EXPERIMENTAL GROUP (N =30)		CONTROL GROUP (N=30)	
		N	%	N	%
1.	No pain	3	10%	0	0%
2.	Mild pain	18	60%	3	10%
3.	Moderate pain	9	30 %	21	70%
4.	Severe pain	0	0%	6	20%
	TOTAL	**30**	**100%**	**30**	**100%**

The findings show that frequency and percentage wise distribution of level of pain after intramuscular vaccination among neonates in the study group and control group. In study group, 18 (60%) of neonates had mild pain, 9 (30%) of neonates had moderate pain and 3 (10) of neonates had no pain. In control group, 21(70%) of neonates had moderate pain, 6 (20%)   of neonates had severe pain and 3(10%) of neonates had mild pain.
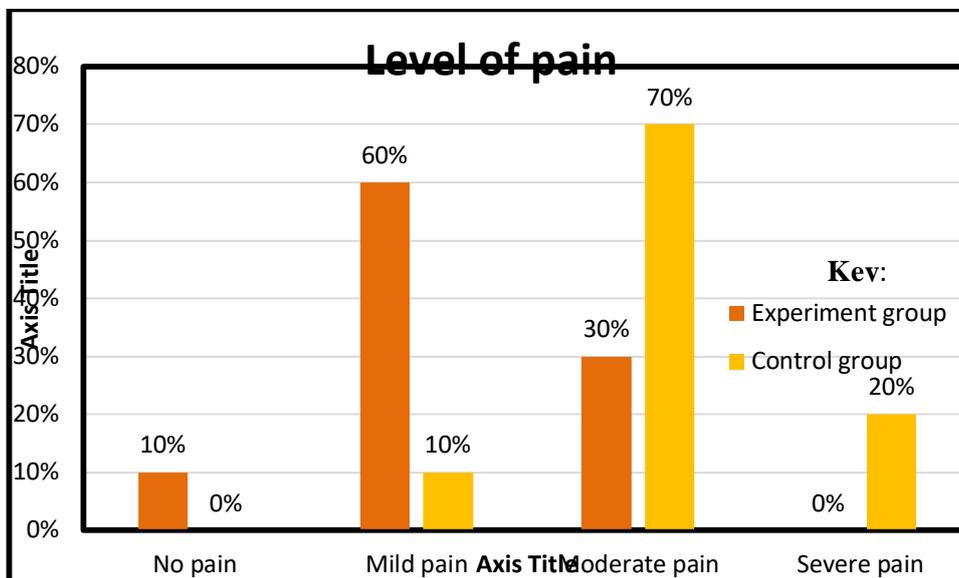
N=30+30

Figure 3: Shows level of pain among neonates in both experimental group and control group

The figure shows that frequency and percentage wise distribution of level of pain after intramuscular vaccination among neonates in the study group and control group. In study group, (18) 60% of neonates had mild pain, (9) 30% of neonates had moderate pain and (3) 10% of neonates had no pain. In control group, (21) 70% of neonates had moderate pain, (6) 20% of neonates had severe pain and (3) 10% of neonates had mild pain.

Section C:

Comparison of mean score of level of pain after intramuscular vaccination among neonates between study group and control group

Table III:

Comparison of mean score of level of pain after intramuscular vaccination among neonates between study group and control group.

S.NO	GROUP	Mean	SD	Independent 't' test	P value
1.	Study group	3.07	1.015	t = 5.787	p = 0.001* (S)
2.	Control group	4.50	0.937		

*p<0.05 - Significant; p<0.001 - Highly Significant

Table IV: The above table shows effectiveness of cold needle in pain reduction after intramuscular vaccination among neonates in the study group and control group by comparison of pain score study and control group. Study group neonates have mean score of 3.07 with SD 1.015 and control group have mean score of 4.50 with SD 0.937with the independent 't' test value = 5.787 and p value = 0.001*.There is significant difference between study and control group respectively.

CONCLUSION

The present study assessed the effectiveness of cold needle in pain reduction after intramuscular vaccination among neonates delivered in SMVMCH at Puducherry and cold needle vaccination was found to be very effective in pain reduction among neonates.

In conclusion it was evident that the neonatal infant pain scale tool was effectively measured the level of pain after intramuscular vaccination among neonates respectively.

NURSING IMPLICATIONS & PRACTICE

The findings of the study have implications for various areas of nursing practice, nursing education, nursing administration and nursing research.

• These findings will assist nurses in the clinical and public health sectors in implementing the use of a cold needle during intramuscular injection.

• Using a cold needle during an IM injection will help subjects overcome their fear of injection pain.

• The patient will be more comfortable with this method of intramuscular injection administration.

• This method will improve subjects' future health-seeking behavior.

• It contributes to the improvement of nursing care standards by implementing evidence-based practice.

NURSING EDUCATION& ADMINISTRATION
• Nurse educators should teach students about it and include it in the curriculum.
• The findings of this study will be useful in reforming the traditional method of teaching IM injection procedure to student nurses.
• It allows student nurses to learn about the collaboration of alternative therapies in nursing practice.
• The study findings assist nurse administrators in developing revised protocols and policies for IM injections.
• It allows nurse administrators to conduct inservice education on evidence-based nursing practice when administering IM injections.

NURSING RESEARCH & RECOMMENDATIONS
• The study will be useful reference material for future researchers.
• As intramuscular injection is the common nursing procedure carried out by all nurses worldwide, more studies regarding the practice should be encouraged.
• The study findings can be published in journals to spread the use of cold needles for intramuscular injection.
• The study's findings served as a foundation for nursing professionals and students to conduct additional injection technique research.
The following recommendations were made as a result of this study:
• In order to generalize the findings, a similar study in different settings must be conducted.
• A larger sample size could be used in a similar study to allow for more generalization of results.
• A longer intervention period can be studied for greater reliability and effectiveness.
• A comparative study could be conducted to compare the effectiveness of cold needle injections in intramuscular and intradermal injections.
• A comparative study could be conducted to assess the effectiveness of cold needle IM injection in adults based on physical build and pain perception.

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