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Effect of Local Heat and Cold Application for Pentavalent Vaccine Injection Pain in Infants

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Abstract

Background: Associated vaccine injections pain is common in infants; pediatric nurses must employ pain management techniques in their practice. Non-pharmacological methods were reported to be **more** appropriate to reduce pain. **Aim:** The study was conducted to investigate the effect of local heat and cold application for Pentavalent vaccine injection pain in infants. **Design:** Quasi experimental study design was used in the present study. **Method:** A convenience sampling of 120 infants at El-Salam district family health center at Ismailia city throughout the period of data collection aged between 2-6 months from both sexes. Infant Information Form and FLACC Pain Scale were used to collect the data. **Results:** Revealed that, the mean Pain score was higher among infants who have 2 months of age, infants whose weight between 4 to less than 6 kilograms also have higher mean Pain scores in all groups. The current research demonstrates that in all groups, mean pain score were higher in female infants than in male infants. There were statistically significant variations between the mean Pain scores and the age, weight, and sex of the newborns in the three groups. **Conclusion:** The study concluded that there was statistically significant difference between the mean pain scores of the three studies' groups and there was statistically significant reduction in total scores of associated vaccine pain in cold application group. **Recommendations:** The study, emphasized on the importance of continuous training programs for pediatric nurses and parents regarding heat and cold application as method of non-pharmacological pain management.

Keywords: Cold application, Heat application, Pentavalent vaccine & Vaccine injection pain.

Introduction

Children are the foundation of a country. This implies that they will be able to act later. Being healthy from the start of life is important. The importance of vaccination administration must be emphasized in order to prevent children from contracting specific communicable diseases **(Das et al., 2020).** The prevalence of numerous infectious diseases has significantly decreased as a result of childhood immunization laws. Additionally, it shields children from diseases like measles, pertussis, diphtheria, polio, rubella, and tetanus that can be avoided with vaccination. A child's immunization significantly lowers the cost of disease treatment, ensures a healthy childhood, and alleviates poverty and suffering **(El-Hawy & Said, 2018).**

The immunization process is a common medical practice for children. The most economical and cheap preventative health measure is immunization, which has been shown to be successful. Under the age of one, a child should have received their full first immunization. Adverse events following immunization, which frequently happen after immunization due to vaccination reactions such as swelling, discomfort, redness at the injection site, and fever, are the side effects that manifest after immunization. **(Khalil et al., 2022).**

One of the frequent causes of pain children experience after receiving medical care is vaccination. Pain is defined as "an unpleasant sensory and emotional experience linked to actual or potential tissue damage". Immunization-related discomfort, worry, and anxiety may make it harder for patients to accept therapy. According to **Karimi et al., (2022)** the experience of pain has multiple dimensions, including physical, sensory, emotional, cognitive, and behavioral elements. Infants feel pain during the immunization period but are unable to verbally communicate it. The most significant contributing factor to behavioral abnormalities and distress in infants is the discomfort that comes along with this operation **(Das et al., 2020).**

The most significant issue that needs to be tracked by certain medical experts is pain. The most frequent and painful treatments during infancy are routine vaccine injections, which are typically performed without pain medication **(Redfern et al., 2018).** Since infants are unable to verbally convey their suffering, pain management is vital for them. Therefore, it's critical to create pain-relieving techniques for vaccinations. Pharmacological and non-pharmacological therapies

are the two main categories of treatments for children's vaccination-related pain **(Shiroshita et al., 2018).**

In recent years, the importance of non-pharmacological approaches has increased due to the potential side effects of pharmacological methods, such as respiratory depression, apnea, and bradycardia. As a result, nursing research has concentrated on these methods. While pain experienced by newborns after normal vaccination is not considered a symptom of disease, it has been suggested that non-pharmacological pain relief techniques are preferable. Non-pharmacological treatment options include things like using balloons to distract from pain, listening to music, massages, and therapeutic applications of heat and cold (**Güngör & Öztürk Şahin, 2021).**

The use of a cooling object to apply cold is known as cold application. Applying ice can either have a direct or indirect effect on pain relief. Peripheral nerves are directly impacted by cold, which reduces or eliminates pain transmission. It is believed that by producing vasoconstriction, the cold treatment raises the pain threshold. As the pain threshold rises, the gate control mechanism activates and closes the pain gates. As a result, the rate at which small-diameter non-myelinated nerve fibers transmit painful stimuli from the peripheral to the central nervous system is reduced, allowing for effective pain management. **(Binay et al., 2019)**.

The indirect impact of cold is shown in the reduction of discomfort caused by the resolution of edema, swelling, and muscle spasms. By activating the tactile receptors on the skin, vibration causes the pain to be localized in a small space. Vibration should be used frequently and repeatedly to relieve pain. Large-myelinated fibers near the neurologic pain gates in the periphery carry vibratory stimulations to the skin, activating the gate control mechanism and increasing beta endorphin levels. Secreted beta endorphins increase the pain threshold and lessen or completely abolish pain perception. **(Güngör & Öztürk Şahin, 2021**).

Heat application is the process of applying a heated substance that is warmer than skin to the surface of the body in either a moist or dry form in order to increase body temperature, encourage suppuration, speed up healing, reduce muscle tone, and relieve pain and congestion. Additionally, applying a warm compress before an injection may boost local blood flow and speed up systemic absorption. (**Sapçi et al., 2021).**

Numerous earlier studies showed that one of the techniques most frequently employed by pediatric nurses as a pain treatment strategy for newborns was a heat compress. Another studies found that applying a cold compress helped to lessen pain. Although there are researches stating that both cold and hot compresses can alleviate pain, there aren't enough studies examining how well these two treatments work together **(Karaman et al., 2019).** The current study was conducted to determine the effectiveness of local heat and cold applications for newborns experiencing pain after receiving the Pentavalent vaccine injection. Pediatric nurses have a significant role in managing vaccination-related discomfort in children.

Significance of the study:

One in ten children worldwide did not receive vaccines in 2016, according to the **World Health Organization (WHO, 2022)**, placing them at great risk of contracting these potentially lethal diseases. According to UNICEF data on Egypt, 91% of children between the ages of 18 and 29 months were fully immunized in 2014, with 91.4% of those children living in urban areas and 90.9% in rural areas **(Al-Wahaidy, 2017).**

Egypt's main programme is the extended programme of immunization (EPI), which can save lives at a low cost. Through an increase in vaccination coverage and ongoing surveillance, EPI has successfully managed several vaccine-preventable diseases in Egypt, including a strong national vaccination coverage of over 90%, which has decreased illness, disability, and death from illnesses like diphtheria, tetanus, whooping cough, measles, and polio. The Ministry of Population and Health in Egypt reported that the coverage rates for mandatory vaccinations varied from 96–98% in 2010 but decreased to 94–96% in 2018. Additionally, in the same report, the coverage rate for the birth dose of the newly added hepatitis B vaccine was just 89% **(El-Hawy & Said, 2018).**

Since ancient times, cold therapy has been used to lessen pain. As skin temperature approaches 0 °C, pain relief starts to become more pronounced at the threshold temperature of 10 °C. Vanpooling sprays and ice packs' capacity to decrease autonomic reactions by lowering blood flow and skin conduction levels further enhances their analgesic effects. In addition to these outcomes, cooling procedures, when used properly, are inexpensive and cause few, if any, negative effects (**Hall et al., 2020).** Therefor; the present study aimed to investigate the effect of local heat and cold application for Pentavalent vaccine injection pain in infants.

Aim of the study:

This study aimed to investigate the effect of local heat and cold application for Pentavalent vaccine injection pain in infants at El-Salam district family health center in Ismailia city.

Research hypotheses:

- Appling local cold to the injection site prior to receiving the Pentavalent vaccine reduces vaccine-associated pain.
- Appling local heat to the injection site prior to receiving the Pentavalent vaccine reduces vaccine-associated pain.
- Applying local cold is more beneficial than applying heat for treating vaccine-associated pain.
- The infant's gender affects vaccine-associated pain.
- The infants' age affect vaccine-associated pain.
- The infants' weight affects vaccine-associated pain.

Subjects and Methods

Research Design:

Quasi experimental study design was used in the present study.

Setting: This study was conduct at El-Salam family health center in Ismailia City.

Sample size equation: The number of subjects enrolled in this study was estimated according to the following equation:

n= t2 x p (1- p)/m2

Where: n = is the sample size

t = confidence level at 95% (standard value 1.96)

P = is estimated prevalence in the study area = .085

m= margin of error at 5% (standard value of 0.05)

* By applying the previous figures to the equation the sample size is:

$$N = \frac{(1.96)^2 X 0.085(1 - 0.085)}{(0.05)^2} = 119.512 \sim 120$$

Sample type: A convenience sampling of 120 infants who were brought to the previously mentioned setting throughout the period of data collection to have diphtheria, pertussis tetanus, Haemophilus Influenza type B and Hepatitis B (Pentavalent vaccine). Based on the observations of the nurses working in family health centers, infants have the heights response to this vaccine; so that Pentavalent was the selected vaccine in the current study. According to childhood mandatory obligatory vaccination schedule in Egypt, Pentavalent vaccine is applied as a total three doses including the end of second, fourth and sixth months. A booster dose of vaccine is given at the end of eighteenth month. Infants aged between 2-6 months of age from both sexes were divided randomly into 40 infants for first intervention group (Local heat application), 40 infants for second intervention group (local cold application) and 40 infants for control group (no intervention).

Inclusion criteria:

Infants who were considered to be pain-free and received a "0" on the FLACC Pain Scale. Infants with a gestational age of 37 to 42 weeks, birth weights of 2500 grams and higher, and Pentavalent vaccinations were also required for enrollment.

Exclusion criteria:

Infants with any physical, emotional, or mental health issue (such as a congenital abnormality) were excluded, as were infants who had taken antipyretic or analgesic-like medications within the previous two weeks prior to vaccination, had a chronic pain-causing illness, had a body temperature greater than 38.0°C, or had a skin condition that would preclude local application of heat or cold.

Tools of data collection:

Two tools were used to collect the required data:

Tool 1: Infant Information Form: It was a form that was developed by the researchers to obtain information about the infants. There were 8 questions in the form collecting information such as gestational age, age, sex, weight, length, head circumference, chest circumference and nutrition type of the infants.

Tool 2: FLACC Pain Scale, it was adopted from **Merkel et al (1997) & Malviya et al (2006)** in order to be used in evaluation of pain among infants who were aged 2-6 months and had limited verbal communication. The evaluation of the scale's five behavioral categories served as the measurement. Infants' facial expression, leg posture, activity, cries, and concealability were assessed on a scale of 0 to 2. The scale had a possible total score that varied from 0 to 10. An increase in the scale's score indicated greater pain, and a reduction in the score indicated lessening pain.

Operational design:

Preparatory phase:

An official permission to conduct the study was obtained from the director of El-Salam district family health center after explaining the aim of the study and method of data collection by the researchers.

Validity and reliability of the study tools:

The study tools were subjected to jury of 5 nursing experts' consultant in pediatric and community nursing, at Suez Canal University in the field of the study to check its validity, all modifications and recommendations were done.

Pilot study:

A pilot study was carried out on 12 infants who represented 10% of the studied participants at the previously mentioned settings in order to test the feasibility, applicability and clarity of the study tools and time needed to complete it as well. The pilot's findings indicated that no adjustments were necessary. The study's overall sample includes the pilot study's participants.

Ethical consideration was followed through:

Ethical approval was obtained by the Ethical Committee of Faculty of Nursing Suez Canal University (approval number: 172/9-2022). Informed

written consent was obtained from each infant's caregivers before the beginning of the study, after explanation of the purpose of the study to gain their approval about their infants' participation. The researchers assured maintaining anonymity and confidentiality of the collected data throughout the study phases. The infant's caregivers were informed that they have the right to withdraw from the study at any time without any effect on the care provided by the outpatient pediatric clinic. A written permission to conduct the study was obtained from the target primary care center.

Fieldwork

The period of data collection was extended over a period of 6 months, started from beginning of October 2022 to the end of March 2023. The researchers were available in the study setting during working hours two days/week. Studied infants were assessed through the following phases:

Pre intervention phase: It was started by meeting the infant's caregivers. At the beginning of the interview, the researchers introduced themselves to participants and presented a brief explanation about the aim and nature of the study. Each participant was interviewed individually and Infant Information Form (Tool 1) was filled from the caregivers; also, FLACC Pain Scale (Tool 2) was applied to all infants (2-6 months). Infants who fulfilled inclusion criteria were submitted randomly into three equal groups: first intervention group (local heat application), second intervention group (local cold application) and control group (no intervention).

Intervention phase: The first intervention group received localized heat treatment at this stage, the second intervention group received localized cold application, and the third group received no intervention. One of the researchers conducted heat and cold treatments just prior to the vaccination. The refrigerator at the family health center was used to store the cold applications that were employed in the study. Prior to the operation, heat applications were kept in the boiling water for 15 minutes. Before the process, a sheath was placed over the heat and cold treatments to prevent skin contact. One of the researchers applied it locally for a continuous 2 minutes to the infant's injection site.

Post intervention phase:

Pentavalent vaccine was administered immediately to the infants following the heat and cold applications without waiting. The vaccine was applied by the same nurse to ensure consistency of vaccine injection skill performance for all infants in the three study groups. FLACC Pain Scale was applied to all infants in the three study groups by one of the researchers during vaccination.

Statistical design:

Data from the study were examined using SPSS version 21. For the analysis of nominal data as demographic information about the children who were the subject of the study; descriptive statistics, including the frequency distribution and percentages, were utilized. The T-test was used to analyze differences across variables over time. The arithmetic means, standard deviation (SD), chi square test, Pearson's, and Spearman's tests used to explore correlation between the variables were utilized to evaluate the statistical significance and relationships. A p 0.05 significant level was determined.

Results:

Table (1): Percentage distribution of descriptive characteristics of the studied groups regarding demographic data (n=120):

Items	Heat Application group (n= 40)		Cold Application group (n= 40)		Control group (n= 40)		Test	P value
	N	%	N	%	N	%		
Age (months)								
a) 2	14	35.0	12	30.0	11	27.5	X^2 7.06	.133
b) 4	14	35.0	10	25.0	20	50.0		
c) 6	12	30.0	18	45.0	9	22.5		
Sex								
a) Male	22	55.0	18	45.0	25	62.5	X^2 2.48	.289
b) Female	18	45.0	22	55.0	15	37.5		
Weight								
a) 4:<6	27	67.5	24	60.0	17	42.5	X^2 5.36	.068
b) ≥6	13	32.5	16	40.0	23	57.5		
Nutrition type								
a) Breast feeding	12	30.0	8	20.0	7	17.5	X^2 2.81	.591
b) Bottle feeding	13	32.5	16	40.0	13	32.5		
c) Breast +Bottle feeding	15	37.5	16	40.0	20	50.0		

X^2 is Pearson chi-square test, *P value is significant <. 05*

Table (2): Mean descriptive characteristics of studied groups regarding demographic data (n=120):

Items	Heat Application group (n= 40)		Cold Application group (n= 40)		Control group (n= 40)		Test	P value
	N	%	N	%	N	%		
Gestational age (week)								
Mean ±SD	38.55 ± 1.04		39.10 ± 1.10		38.95 ± 1.15		**F**	.073
Weight/kg								
Mean ±SD	5.74±1.06		5.83±1.08		6.16±1.03		**F** 1.79	.171
Length/cm								
Mean ±SD	59.68±4.68		59.68±4.53		60.68±4.02		**F** .684	.507
Head circumference/cm								
Mean ±SD	39.93±2.62		39.15±2.40		40.23±2.45		**F** 1.98	.142
Chest circumference/cm								
Mean ±SD	37.68±2.35		38.13±2.50		37.55±2.25		**F** .651	.523

X^2 is Pearson chi-square test& F= One-way Anova test, P value is significant <. 05

Table (3): Comparison of mean total FLACC Pain Scale scores post intervention (n=120):

Items	Heat Application group (n= 40)	Cold Application group (n= 40)	Control group (n= 40)	F test (P value), (η2)
	Mean ± SD	Mean ± SD	Mean ± SD	
FLACC Pain score				
Post- intervention	7.97±.76	5.73±.78	8.45±.67	121.78 (<.000*) (.68)
(P 1), (delta)	.014 (.72)			
(P 2), (delta)	<.001(3.66)			
(P 3), (delta)	<.001(2.53)			

F test is one-way ANOVA, P value is significant <.05, → significant in comparison with Control group (Tukey HSD post hoc test was used); η2 is Partial Eta Squared, and delta is Glass's delta effect size.

Table (4): Correlation between demographic characteristics and total FLACC Pain score in three groups (n=120):

Items		Heat Application group (n= 40)	Cold Application group (n= 40)	Control group (n= 40)
		FLACC Pain score		
Gestational age	r	.147	-.059	.062
	P value	.367	.717	.702
Weight	r	-.543	-.870	-.531
	P value	**<.001***	**<.001***	**<.001***
Length	r	-.331	-.072	-.671
	P value	**.037***	.658	**<.001***
Head circumference	r	-.601	-.082	-.664
	P value	**<.001***	.617	**<.001***
Chest circumference	R	-.517	-.731	-.704
	P value	**<.001***	**<.001***	**<.001***

r is Pearson correlation and P value is significant <.05

Table (5): Relation between demographic characteristics and total FLACC Pain score in three groups (n=120):

Items		Heat Application group (n= 40)	Cold Application group (n= 40)	Control group (n= 40)
		Total FLACC Pain score		
		Mean ± SD	Mean ± SD	Mean ± SD
Age (months)	2	8.83±.51	6.83±.71	8.81±.40
	4	8.21±.42	5.64±.00	8.60±.50
	6	7.17±.72	5.44±.51	7.67±.71
	t test (P value)	**18.61 (<.001*)**	**25.41(<.001*)**	**13.23(<.001*)**
Weight	4:<6	8.38±.50	6.63±.72	8.82±40
	≥6	7.7±.181	5.58±.50	8.31±.71
	t test (P value)	**2.94(.006*)**	**5.398 (<.001*)**	**2.22(.032*)**
Sex	Male	7.82±.59	5.34±.97	8.12±.67
	Female	8.17±.92	5.56±.61	9.00±.0
	t test (P value)	**3.42(.043*)**	**7.62(.002*)**	**5.09(<.001*)**
Feeding	Breast feeding	8.00±1.00	5.25±.86	8.23±.44
	Bottle feeding	8.33±.49	5.59±.53	9.00±.0
	Breast +Bottle feeding	7.67±.62	5.50±.52	8.40±.82
	F test (P value)	2.75(.077)	1.53(1.000)	1.44(.156)

P value is significant <.05

Table (1): Illustrates that more than one third (35%) of infants in heat application group, one quarter (25%) in cold application group and half (50%) in control group have 4 months of age. It was also found that more than half (55%) of heat application group, less than half (45%) of cold application group and less than two thirds (62.5%) in control group were males. The table shows that more than two thirds (67.5%) of heat application group, more than half (60%) of cold application group and less than half (42.5%) of control group their weight were between 4 to less than 6 kilograms.Regarding nutrition type this table revealed that, more than one third (37.5%) of heat application group, two fifths (40%) of cold application group and half (50%) of control group were feeding with breast and bottle feeding. There were no statistically significant differences between three groups regarding age, sex, weight and nutrition type.

Table (2): Reveals that there were no statistically significant differences were found between three groups in terms of gestational age (week), weight, length, head circumference and chest circumference

Table (3): Clarifies that mean FLACC Pain Scale score of infants was (5.73±.78) in cold application group, (7.97±.76) in heat application group and (8.45±.67) in control group. There was statistically significant difference between the mean pain scores of the three groups. This table shows that there was statistically significant reduction in total scores of associated vaccine pain in cold application group.

Table (4): Shows that there was no statistically significant correlation between gestational age (week) and total FLACC Pain score in all groups. While, there were statistically significant correlation between weight and chest circumference of infants in the three groups and their total FLACC Pain scores. Also; it was found that there was statistically significant correlation between length and head circumference of infants in heat application group and control group and their total FLACC Pain scores. While, there was no significant correlation between length and head circumference of infants in cold application group and their total FLACC Pain scores.

Table (5): Illustrates that mean FLACC Pain scores were higher among infants who have 2 months of age and infants whose weight between 4 to less than 6 kilograms in all groups. The current finding shows that mean FLACC Pain scores were higher among female infants compared to male infants in all groups. There were statistically significant differences between age, weight and sex of the infants in the three groups and their mean FLACC Pain scores. Regarding feeding type it was found that mean FLACC Pain scores were higher among infants who depend on bottle feeding, but there was no statistically significant difference was found between feeding type of the infants in the three groups and their mean FLACC Pain scores.

Discussion

The most frequent cause of iatrogenic pain in children is vaccinations, which also cause significant anguish for the newborns who must undergo the treatment as well as for their parents and the nurses who carry it

out. (**Fontes et al., 2018)**. The pain results throughout the research were largely consistent, mainly comprising a range of physiological measures such as heart rates, blood oxygen saturation, and blood pressure, as well as pain scales, weeping time, and behavioral abnormalities. **(Karaman et al., 2019).**

It is well recognized that non-pharmacological therapies are secure and reliable ways to reduce and manage pain. Infants with vaccine-related discomfort can be managed using a variety of techniques, including taste, touch, odor, vision, exercise, postural adjustments, injection technique, and finally, the use of heat and cold. **(Wu et al., 2022).** This implies that in their clinical work, health providers must use pain management techniques. **(McMurtry et al, 2015)**. Accordingly, the present study was conducted to investigate the effect of local heat and cold application for Pentavalent vaccine injection pain in infants.

Regarding percentage distribution of descriptive characteristics of the studied infants (table 1), the present study revealed that there were no statistically significant differences between three groups regarding age, sex, weight and nutrition type. From the researcher point of view many factors can affect infants' response to pain infants' age, sex, weight & nutritional type are among these factors so that; the researchers focused on the homogenous distribution of these characteristics which thought to affect vaccine associated pain in the three groups and the possible confusing factors were eliminated. These findings are goes in line with a study conducted by **Güngör & Öztürk Şahin (2021**) who conducted a study about analysis of two non-pharmacological pain management methods for vaccine injection pain in infants and reported that there were no statistically significant differences were found between three groups in terms of gender and nutrition type.

Furthermore, these results were supported by **Karimi et al., (2022)** who conducted a study about the effect of breastfeeding versus sensorial saturation on infants' behavioral responses of pain following vaccination and reported that there were no statistically significant differences regarding sex and weight of the study groups. These results contradict with **Das et al., (2020)** who reported in their study about the effectiveness of local cold application on pain among infants receiving immunization in a selected immunization center that there was statistically significant difference regarding age of the studied infants in the study and control groups.

Concerning mean of descriptive characteristics of the present studied infants (table 2), the current study revealed that there were no statistically significant differences between three groups in terms of gestational age (week), weight, length, head circumference and chest circumference. From the researchers point of view these current finding confirms the homogeneity of the three study groups. These results were similar to **Güngör & Öztürk Şahin (2021**) who revealed that there were no statistically significant differences between the mean scores of the three groups. In contrast to current finding **Gol & Ozsoy (2017)**, who reported in their study about effects of rapid vaccine injection without aspiration and applying manual pressure before vaccination on pain and crying time in infants that there was a statistically significant difference regarding weight of the study groups.

On assessing the mean total pain scores post intervention for the cold application group (table 3), the current study clarified that mean pain scores of infants in cold application group were found to be significantly lower than mean score in control group which confirm the research hypothesis "Appling local cold to the injection site prior to receiving the Pentavalent vaccine reduces vaccine-associated pain". From the researchers point of view these finding might be related to that the cold application act as a substitute for anesthesia, the interval between the cold application and the injection shouldn't be more than one minute, so that the cold application works optimally. In agreement with this finding, a study conducted by **Hall, et al., (2020)** about cooling to reduce the pain associated with vaccination and found that Children in the experimental group who were given cold compresses and vibration during immunization reported less pain and anxiety, and nurses likewise reported less pain and fear in the experimental group than in the control group.

Moreover **Gaikwad et al., (2017)** reported in their study which was conducted to assess the effectiveness of ice application on pain response prior to intravenous procedures among children at tertiary care hospital, that the mean pain score of experimental groups was 0.66 after local cold application and control group was 8.93, which showing significant difference between mean pain score level among children in control and experimental groups. Also, the study of (**Binay et al., 2019)** about a comparison of the effectiveness of two different methods of decreasing pain during phlebotomy in children and revealed that pain score were lower in the groups of external cold and vibration and blowing soap bubbles than pain scores in the control group. In contrast a study conducted by **Choirunissa et al., (2021)** about effectiveness of warm compress and cold compress for pain management in DPT-HB-Hib immunization and illustrated that the FLACC scale's overall score rose from the previous one based on observations in

newborns following a cold compress and DPT-HB-Hib vaccination.

Regarding the mean total pain scores after intervention for the heat application group (table 3), the current study clarified that mean pain score of infants in heat application group was found to be significantly lower than mean score in control group which confirm the research hypothesis "Appling local heat to the injection site prior to receiving the Pentavalent vaccine reduces vaccine-associated pain". From the researchers point of view heat application creates a calming psychological impact and can ease muscular tension, it can lessen the intensity of injection discomfort. Similar to the current finding **Güngör & Öztürk Şahin (2021**) who reported that pain scores in warm compress group was lower than control group. Contradicted to the current finding **Choirunissa et al., (2021)** who found that before the warm compress was applied, the FLACC scale's overall score was 1.53, but after the warm compress and vaccination, the average FLACC scale overall score rose to 8.

The current finding (table 3), illustrated that the cold application group had the lower pain score than the heat application and control group which confirms the research hypotheses "Applying local cold is more beneficial than applying heat for treating vaccine-associated pain". From the researcher point of view these finding might be related to the fact that cold application can reduce pain induced by vaccine injection by releasing endorphins that block the transmission of larger, faster A-beta sensory nerve fibers and also reduce pain transmission in C and delta A fibers, cold application can lessen the pain caused by vaccine injection by closing the synaptic gate and blocking the transmission of pain implants. Additionally, applying cold helps to constrict the blood flow around the injection site and lower prostaglandin synthesis. These finding goes on line with **Choirunissa et al., (2021)** who reported in their study that cold compress group had the lower mean pain score than warm compress and control group.

The current study results found a highly statistical significant correlation between the studied infants' weight and their total pain scores in the three groups (table 4) and confirm the research hypothesis "The infants' weight of the infant affects vaccine-associated pain". From the researchers point of view this finding might be related to presence of a relationship between the size of the muscle that was injected which is largely associated with the infant's weight and the degree of pain which felt during vaccine injection. In agreement with this finding **Gol & Ozsoy (2017)** who found that pain score of the studied infants decreased as their weight increased and concluded that weight of the infant affected vaccine-associated pain. In contrast, **Das et al., (2020)** reported that there was no statistically significant association between weight of child and pain level.

The present study illustrated that mean FLACC Pain score was higher among infants who have 2 months of age and there were a statistically significant differences between age of the studied infants in the three groups and their total pain scores (table 5), and confirm the research hypothesis "The infants' age affect vaccine-associated pain". From the researchers' point of view these finding emphasizes on the fact that, the results are consonant with a Piagetian developmental model, suggesting the possibility of delineating typical concepts of pain which correspond to successive stages of cognitive development. The current finding was supported by **Güngör & Öztürk Şahin (2021**) who revealed that there were statistically significant differences between age of the three groups and their mean pain score. In contradicted with the current study, the study of **Das et al., (2020)** who revealed that there was no statistically significant association between age of the studied infants and their level of pain during immunization.

Concerning sex of the studied infants, the current study revealed that mean pain score was higher among female infants compared to male infants in all groups and there were statistically significant differences between sex of the studied three groups and their total pain scores (table 5), and confirm the research hypothesis "The infant's gender affects vaccine-associated pain". From the researchers' point of view, these findings can be attributed to the fact that recent studies show that females show greater sensitivity to pain, and reduced pain inhibition compared to males, although the magnitude of these gender differences varies across the results of the studies, but biological factors seem to contribute significantly. In these facts, emerging evidence suggests that genotype and endogenous opioid action play a strong role in these gender disparities. In contrast of these finding **Sapçi et al., (2021)** who conducted a study about effects of applying external cold and vibration to children during vaccination on pain, fear and anxiety and revealed that there was no statistically significant difference between the gender and the pain rating scores of the children in the experimental and control groups.

Conclusion:

Based on the current study finding, there was statistically significant difference between the mean pain scores of the three studies' groups and there was statistically significant reduction in total score of associated vaccine pain in cold application group. There were statistically significant differences

between age, weight and sex of the infants in the three groups and their mean FLACC Pain scores. Also; there was statistically significant correlation between weight of infants in the three groups and their total FLACC Pain scores.

Recommendations:

In the light of study results, the present study recommended that:

- Implementation of ongoing training programs for pediatric, community nurses, and parents on the use of heat and cold as non-pharmacological pain management techniques.
- Additional research should be done to enhance pediatric nurses' expertise and methods for using cold therapy in various contexts and with large samples.
- To ascertain the efficacy and usability of skin heating and cooling treatments for minimizing immunization pain in primary healthcare settings, more study designs are required.
- For older children, a multi-center, large-sample, randomized controlled trial ought to be conducted to improve the cold application's focus on non-pharmacological therapies.
- To determine the optimum treatment strategies for each age group, future research will divide children into age groups and compare the analgesic effects of various non-pharmacological approaches.

Strength of study

This study emphasizes the value of non-pharmacologic pain management techniques for infants getting vaccinations, such as topical cold applications. Cold application is a simple, safe, straightforward, effective, and affordable independent nursing intervention that can be used to reduce discomfort in infants who have had vaccinations with little to no risk to children's safety and comfort. The nurse or parents might use ice bags in the immunization center to decrease pain before injections.

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