

Effect of using Skin-Cooling Technique on Pain Relief during and after Immunization among Infants

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ABSTRACT

Background: Immunization is often a stressful medical procedure for healthy infants and is a common cause of childhood iatrogenic pain, there is an increasing interest to recommend the use of non-pharmacological interventions in the management of pain due to their effectiveness during painful procedures. **Aim:** To evaluate the effect of using skin-cooling technique on pain relief during and after immunization among infants. **Methods:** A two group pre-post quasi-experiment was performed in EL-Sheikh Zaid's medical center affiliated to Ministry of Health, Ismailia City, Egypt, on a purposeful sample of 180 infants had two, four and six months of age who administer routine immunization. Structured interview questionnaire was used to collect the personal data, crying duration and characteristics, and vital signs. Pain assessed through using face pain scale and neonatal infant pain scale. All research ethics were applied. **Results:** Less than one quarter of infants had no pain and more than two thirds of infants had a mild pain in experimental group while more than three quarters of infants had severe pain and less than one quarter of infants had moderate pain in control group during and after immunization. After immunization, vast majority of infants had normal respiratory and heart rates in the experimental group compared with the vast majority of infants had tachycardia and tachypnea in the control group. Less mean duration of crying was detected in the experimental group than the control group during and after routine injectable immunization **Conclusion:** Immunized infants who received skin-cooling technique had no pain and reduced pain severity, less mean score of crying duration and more stable vital signs than infants in control group. **Recommendations:** Application of ice pack has to be a part of the routine care of all infants before immunization in medical health centers. Further studies on various age groups of the pediatric population and in all types of vaccines must be done.

Key words: Immunization, Infants, Nursing, Pain assessment scales, Skin-cooling technique.



INTRODUCTION

The infant nervous system is fully developed and able to respond to nociceptive stimuli even in preterm neonates, so the sense of pain and reaction to painful stimuli is observed at this stage (**Bhatt et al., 2016**). Immunization is often a stressful medical procedure for healthy infants and is a common cause of childhood iatrogenic pain. Concern about the adverse effects of immunization (including pain) may negatively influence immunization uptake (**Schuchat, 2018**).

Pain can have a direct impact on health outcomes and, if uncontrolled, may have a diverse effect on all areas of life. This is because pain is not only a sensory perception, but has emotional, cognitive and behavioral components, which also need to be recognized. The impact and perception of pain are also influenced by an infants' individual developmental, environmental, and socio-cultural background. If pain is not adequately managed acutely there is good evidence suggesting that untreated pain may have long-term negative effects on pain sensitivity, immune functioning, neurophysiology, attitudes and health care behavior (**Eerdekens et al., 2019**).

Skin cooling technique (cryotherapy) is a relatively new form of treatment in which the body is briefly exposed to very cold temperatures in order to promote healing and other therapeutic results. It can also help improve the body's circulation and healing. Also can help to reduce pain and muscle spasms in the body as well as reduce the swelling of injuries. The most common effective type of skin cooling technique is an ice pack; it is crushed ice because it conforms comfortably to the contours of the injured area (**Nogueria et al., 2019**). **Attia and Hassan (2017)** approved that cryotherapy can reduce crying, grimacing, heart rate, oxygen saturation change and other physiologic pain indexes in infants.

Minimizing pain in childhood has the potential to prevent the development of needle fears, promote consumer satisfaction and trust in health care providers because of the more positive experiences for infants and their families (**Young, 2017**). Also, the distress of infant during a procedure may have a negative impact on the memory of pain (**Noel et al., 2012**). Despite the magnitude of the effect of pain in immunization on an infant, it often inadequately assessed and treated (**Taddio et al., 2017**).

Nurses' role is crucial for recognizing and treating pain. However, knowledge of nurses' current perceptions and pain management practices in the care of an infant is required to ensure high-quality evidence-based nursing practices are available and being provided for infant with pain (**Taddio et al., 2015**). The nurse may make a



significant contribution to pain control by being able to offer a variety of non-pharmacological methods of pain relief that the patient may use as cutaneous stimulation, especially use of cold (Mawhinney et al., 2017).

Aim of the study:

Evaluate of using skin-cooling technique on pain relief during and after immunization among infants.

Research Hypotheses:

- 1- Infants who will receive skin-cooling technique will have reduced pain severity or pain scores during and after immunization than infants who will not receive.
- 2- Infants who will receive skin-cooling technique will have less mean score of crying duration during and after immunization than infants who will not receive.
- 3- Infants who will receive skin-cooling technique will have more stable vital signs after immunization than infants who will not receive.

Subjects and Methods**Study design:**

Pre/post-test quasi experimental design was utilized to conduct the study.

Setting:

The study was conducted in EL-Sheikh Zaied's medical center affiliated with Ministry of Health, Ismailia governorate.

Sample:

A purposeful sample of 180 infants who fulfills the criteria of recruitment. This sample was recruited all over 6 months. The sample size was divided into two equal groups (90) for experimental and (90) for control group.

Inclusion criteria:

The sample includes the infants who administer their routine immunization for 2, 4, and 6 months of their age.

Exclusion criteria:

- 1- Infants with chronic health problem to respond or to feel cold (vascular diseases as Raynaud's syndrome).
- 2- Infants who have an allergic reaction to cold applications (developing a rash and blisters).

Tools of data collection:

Data were collected through the use of the following tool:

Structured Interview Questionnaire:

The questionnaire consists of three parts, part one and two was adapted from Lovepreet et al., (2009), the first two parts translated by the researcher into simple



Arabic language to suit the understanding of the infants' mothers and gather the study data. Part three including pain assessment scales (Face pain scale (Young, 2017) and Neonatal infant pain scale (Kochman et al., 2017)).

The questionnaire parts:

Part 1: It included

-Personal data and anthropometric measurements of infants: name, age, ranking, gender, weight, length, head and chest circumferences.

- The health status and temperament of infants.

- Immunization received.

Part 2: It included

- Characteristics crying, first crying and total crying time was calculated for all infants by stopwatch from the insertion of the injection up to the cessation of crying. Then, it was calculated and analyzed into groaning, crying and whining.

- Vital signs (heart and respiratory rates and temperature that were measured on two occasions before and after injection.

- Physiological indications of pain.

Part 3: It included

Face pain scale and neonatal infant pain scale were adopted to assess pain of infants during and after receiving the immunization.

Face pain scale: developed by Wong and Baker, 1983 that is the easiest scale used universally and combines pictures and numbers to allow pain to be rated by the user. There is a universal facial expression of pain in infants. The forehead becomes wrinkled with furrow; the eyes are kept tightly closed; the nose bulges; the nasal labial fold becomes deeper; the mouth is open and squares; and when the baby cries the tongue quivers. Each face was rated by number to determine the intensity of pain which (0-10) coding as the following: (Face 0 =No hurt, Face 2 = Hurts a little bit, Face 4= Hurts a little more, Face 6 = Hurts even more, Face 8 = Hurt whole lot and Face 10 = Hurts worst (Young, 2017)).

The second scale: Neonatal infant pain scale (NIPS): is a measurement used to assess pain for children between the ages of 2 months and 7 years that are unable to communicate their pain. It is composed of six indicators: facial expression, cry, breathing pattern, arm and legs movement and state of arousal. Each behavioral



indicator is scored with 0 or 1 except for cry which is scored with 0, 1 or 2. The scale is scored in a range of 0–10 with 0 representing no pain (Kochman et al., 2017).

Tool validity:

The content validity of structured interview questionnaire (part one and two) was revised by three experts in pediatric nursing and community health nursing for clarity, applicability, comprehensiveness and ease of implementation, and according to experts' opinion minor modifications were done. Face pain scale and neonatal infant pain scale are standardized tools.

Tool reliability:

Face pain scale has high test–retest reliability and convergent validity. The scale has a high reliability with a Cronbach's alpha coefficient of 0.70. The neonatal infant pain scale had adequate internal consistency, as evidenced by a Cronbach's alpha of 0.762.

Pilot study:

A pilot study was performed on 10% of the total sample (18 infants) to pre-test the data collection tools in terms of their clarity, applicability, and time of completion. Minor modifications were applied before finalizing the tools. All infants who participated in the pilot study were excluded from the sample.

Procedure of study:

Before conduction of the study, an official letter was obtained from the dean of the Faculty of Nursing- Suez Canal University to the directors of EL-Sheikh Zaied's medical centers to carry out the study after explaining the aim of the study. Infants were divided into two groups experimental and control (90 infants in each group). The infants in the control group was administered the routine care of immunization. The experimental group received skin-cooling technique (ice pack) before routine immunization. The control group infants were taken first.

The researchers interviewed each mother accompany her infant attending EL-Sheikh Zaied's medical center for injectable immunization individually, the researchers introduce herself to infants' mothers and explained the purpose of the study after that oral affirmative consent was obtained from the mothers. Structured interview questionnaire was filled by the researchers from mothers in a special room at the center and then the researchers assess vital signs before immunization for every infant in experimental and control groups. The researchers assessed pain immediate after immunization; also the vital signs were assessed when the infants stop crying by



two minutes. The duration was spent with every infant individually in the control group about 20-30 minutes.

Regarding infants of experimental group before immunization the researchers carry-out the ice pack sensitivity test on the thigh opposite to injection site for 5 minutes and observe the results of test (only three infants had skin sensitivity and excluded from the study). Then skin cooling technique were applied at puncture site before needle puncture for 15 minutes after application of olive oil and putting a towel between the infant thigh and ice pack to protect infants' skin, the infant was administered injections of vaccine by assigned nurse and the researchers assessed pain immediate after injections while vital signs was monitored after immunization when infants stop crying by two minutes. The duration was spent with every infant individually about 35-45 minutes. The actual field work was carried out over a period of 6 months, which started from 30/1/2017 to 30/7/2017. The researchers were available 2 days per week (Sunday and Tuesday) from 9.00 am.-1.00 pm.

Ice pack used for skin cooling: was an economical product that can be used over and over again on any part of the body or a portable plastic filled with water with an internal water seal to prevent leakage. It was frozen for 24 hours in the freezer at 8°C. Its size was modified by the researcher to be the 15 cm. length×9 widths, 4 cm. thickness and capacity was 161g.

Ethical Considerations:

Approval was obtained from the research ethical committee in the Faculty of Nursing, Suez Canal University which approved the oral consent which obtained from the infants' mothers after complete description of the purpose and nature of the study in order to obtain their acceptance as well as to gain their cooperation. Mothers were informed about their voluntary participation and their right to withdraw from the study at any time. Mothers were also assured that all gathered information were confidential and will be used only for the purpose of the study.

Statistical Design:

The collected data were organized, tabulated and summarized using statistical package for social sciences (SPSS) program version 21. According to the type of data, the following tests were used to test differences for significance; Chi square and t-test. Univariate analysis, including: t-test was used to test the significance of results of quantitative variables and Chi square was used to test the significance of results of qualitative variables. Level of significance was set at $p < 0.05$.



Results:**Table (1): Differences in personal data of infants who administered routine injectable immunization among the experimental and control groups (n= 180)**

Variables	Experimental group (No=90)		Control group (No=90)		X ²	P
	No	%	No	%		
Age in months:						
2 months	30	33.3	30	33.3	0.00	1.00
4 months	30	33.3	30	33.3		
6 months	30	33.3	30	33.3		
Gender						
Male	36	40	29	32.2	1.1	0.28
Female	54	60	61	67.8		
Infant's ranking:						
First	15	16.7	17	18.9	1.2	0.77
Second	39	43.3	41	45.5		
Third	27	30	21	23.3		
More than third	9	10	11	12.2		
Residence:						
Rural	3	3.3	0	0	3.1	0.08
Urban	87	96.7	90	100%		

X²: Chi-Square test ^{MCP}P: Monte Carlo corrected P-value *significant at P≤0.05

Table (1) shows that the age of infants is equal 33.3% for 2, 4 and 6 months of age for both groups, regarding gender 67.8% versus 60% were females, Concerning infant's ranking, 45.5% versus 43.3 % of infants were ranked as the second child, all infants (100%) and vast majority (96.7%) were came from urban area, among the control and experimental groups respectively. There were no statistically significant differences between infants in experimental and control groups in relation to their age, gender, ranking and residence.



Table (2): Differences in categories of pain among infants during and after routine injectable immunization by NIPS in the experimental and control groups (n= 180)

Variables	Experimental group (No=90)				Control group (No=90)				X ² (1)	P1	X ² (2)	p2
	During immunization (1)		After immunization (2)		During immunization (1)		After immunization (2)					
	No	%	No	%	No	%	No	%				
Categories of pain:												
No pain	20	22.2	20	22.2	0	0	0	0	154.5	001	154.5<	.<001
Mild pain	63	70	63	70	0	0	0	0				
Moderate pain	0	0	0	0	21	23.3	21	23.3				
Severe pain	7	7.8	7	7.8	69	76.7	69	76.7				

X²: Chi-Square test ^{MC}P: Monte Carlo corrected P-value *Significance level at P≤0.05

P1 (during immunization among experimental and control).

P2 (after immunization among experimental and control).

Table (2) Shows that 22.2% and 70% of infants who underwent ice pack application technique had no pain and a mild pain during and after routine injectable immunization in the experimental group respectively, while 23.3% and 76.7% had moderate pain and severe pain in the control group respectively, these differences were statistically significant.



Table (3): Differences in categories of pain among infants during and after routine injectable immunization by using faces pain scale in the experimental and control (n= 180)

Variables	Experimental group (No=90)				Control group (No=90)				X ² (1)	P1	X ² (2)	P2
	During immunization		After immunization		During immunization		After immunization					
	n (1)		(2)		(1)		(2)					
	No	%	No	%	No	%	No	%				
Categories of pain:												
No pain	20	22.2	20	22.2	0	0	0	0	154.6	<.001	154.6	<.001
Less than mild	16	17.8	16	17.8	0	0	0	0				
Mild pain	47	52.2	47	52.2	0	0	0	0				
Moderate pain	0	0	0	0	21	23.3	21	23.3				
Severe pain	7	7.8	7	7.8	69	76.7	69	76.7				

X²: Chi-Square test

* Significance level at P≤0.05

P1 (during immunization among experimental and control).

P2 (after immunization among experimental and control).

Table (3) reveals that 22.2% of infants had no pain, 17.8% and 52.2% respectively had less than mild and mild pain during and after routine injectable immunization in the experimental group, while in the control group less than one quarter (23.3%) had a moderate pain and most (79.7%) of infants had severe pain, these differences were statistically significant.



Table (4): Differences between vital signs of infants before and after routine injectable immunization in the experimental and control groups (n= 180)

Variables	Experimental group (No=90)				Control group (No=90)				X ² (1)	P1	X ² (2)	P2
	During immunization (1)		After immunization (2)		During immunization (1)		After immunization (2)					
	No	%	No	%	No	%	No	%				
Heart rate:												
Normal (80- 150 b/m)	87	96.7	83	92.2	88	97.8	0	0	1.006	1.00	142.5	<.001
Bradycardia (< 80 b/m)	2	2.2	0	0	2	2.2	0	0				
Tachycardia (> 150 b/m)	1	1.1	7	7.8	0	0	90	100				
Respiratory rate:												
Normal (30 b/m)	87	96.7	83	92.2	88	97.8	2	2.2	00 ^a	146.2	1.0	<.001
Bradypnea (< 30 b/m)	2	2.2	0	0	2	2.2	0	0				
Tachypnea (> 30 b/m)	1	1.1%	7	7.8	0	0	88	97.8				
Temperature:												
37°- 37.5°	90	100	90	100	90	100	13	14.4	Equal	134.56	Equal	<.001
37.6°- 37.9°	0	0	0	0	0	0	77	85.6				

* Vital signs were measured by two minutes after immunization.

P1 (during immunization among experimental and control).

P2 (after immunization among experimental and control).

Table (4) Proves that after immunization 92.2%, 92.2% and 100% versus 0%, 2.2% and 14.4% of infants have a normal heart, respiratory rate and temperature among experimental and control group respectively. These differences were statistically significant except for temperature.



Table (5): Differences between total crying time of infants who administered routine immunization in the experimental and control groups (n= 160)

Variables	Experimental group (No=90)				Control group (No=90)				X ² (1)	P1	X2 (2)	P2
	During immunization		After immunization		During immunization		After immunization					
	No	%	No	%	No	%	No	%				
Crying:												
Yes	70	77.8	70	77.8	90	100	90	100	16	0.0001	16	0.0001
No	20	22.2	20	22.2	0	0	0	0				
First crying time:												
1 second	6	8.6	0	0	10	11.1	0	0	11.5	0.0001	.40	0.0001
2 seconds	40	57.1	0	0	50	55.6	0	0				
3 seconds	24	34.3	0	0	20	22.2	0	0				
4 seconds	0	0	0	0	0	0	10	11.1				
Crying intensity:												
Groaning	63	90	63	90	0	0	0	0	13.8	0.0001	11	0.0001
Crying	7	10	7	10	21	23.3	21	23.3				
Whining	0	0	0	0	69	76.7	69	76.7				

X²: Chi-Square test
P≤0.05

^{MC}P: Monte Carlo corrected P-value * Significance level at

P1 (during immunization among experimental and control).

P2 (after immunization among experimental and control).

Table (5) indicates that the total crying time, vast majority (90%) of infants who underwent ice pack application technique were crying for 10-15 seconds in the experimental group while the majority (85.6%) of infants was crying for 45-60 seconds in control groups. Mean crying time of experimental group was $\bar{X} \pm SD = 13.5 \pm 1.6$ seconds while the mean of control group was $\bar{X} \pm SD = 47.1 \pm 6.3$, this difference was a highly statistically significant at $p < 0.0001$.



Discussion

The current study results regarding categories of pain by using a neonatal infant pain scale, it was found that less than one quarter of infants had no pain and more than two thirds of infants had a mild pain in experimental group while more than three quarters of infants had severe pain and less than one quarter of infants had moderate pain in control group during and after routine injectable immunization. These findings were supported by **Geen, (2015)** in a study entitled "The effectiveness of cold application on a level of pain associated with intramuscular immunization among infants in selected hospital at Ernakulam" who concluded that cold application is effective on reducing the pain associated with intramuscular immunization among infants. Also, the current study findings were in agreement with **Presila et al., (2017)** in a study entitled "The effectiveness of ice cube application on a specific acupoint to reduce pain before intramuscular injection among the children in selected hospital at Kanyakumari district" who found that children received ice cube application had less level of pain than children not received.

Additionally, **Ponzone et al., (2011)** in study entitled "Effect of cold application on pain relief during immunizations among infants in Jordan by using Facial Pain Rating Scale and Neonatal/Infant Pain Scale (NIPS)" who reported that ice reduce pain occurred during immunization compared to the control group. Also, **Hassett et al., (2011)** found that using a cold application reduced pain during pediatric immunization over a wide range of ages compared to control group, in study entitled "Compare the acute pain response of infant during immunization using a cold application among infants aged 4-6 months". In the same line the current study findings were in accordance with **Binu, (2014)** in a study entitled "Effectiveness of ice application on pain perception among children receiving immunization in selected hospital, kanyakumari distric" who concluded that providing ice application was very effective in reducing pain perception.

Regarding categories of pain by using FLACC pain scale, the findings of the current study found that the same results of the previous scale of pain, but differed in the presentation of mild pain among the experimental group, where less than one quarter of infants had less than mild pain and more than half of infants had mild pain. While in the control group less than one quarter had a moderate pain and most of infants had severe pain, these differences were statistically significant. These findings were in accordance with **Alalo et al., (2016)** in a study entitled "Pain intensity after an ice pack application prior to venipuncture among school-age children: an experimental study" who reported that children in the study group who had an ice pack application experienced no pain, less than mild and mild pain, while children in the control group have moderate and severe pain intensity.



Also, **Annabel et al., (2017)** in a study entitled "Effectiveness of ice cube application upon pain perception of children during intramuscular injection" who reported that the effectiveness of skin cooling technique in relieving pain among children and most children in the intervention group were mild pain while in the control group were severe pain. **Pravin et al., (2019)** in a study entitled "Effect of ice pack application on pain during venipuncture among the children admitted in selected pediatric units of Sangli, Miraj, Kupwad Corporation Area" reported that the pain during venipuncture was assessed using FLACC pain scale; the severe pain found to be less in experimental group compared to control group. The results of the current study prove the first study hypothesis said "Infants who will receive skin-cooling technique will have reduced pain severity or pain scores during and after immunization than infants who will not receive".

The current study findings revealed that less than one quarter of infants who received ice pack application (experimental group) were not crying while all infants of control group were crying during and after routine injectable immunization. Also the crying time among the experimental group was less than the control group. These findings were in agreement with **Ponzone et al., (2011)** found that infant's crying was increased in the control group than in the intervention (cold application) group. Also, **Geen, (2015)** support the current study findings who reported that infants in control group were more crying than infants in study group.

Additionally, the study findings were in agreement with **Zillingim et al., (2012)** in a study entitled "The effect of local refrigeration prior to intramuscular injection on pain related response among infants" who found that infants who were provided ice application had less crying than infants who were not provided with this intervention. Recently, **Khan et al., (2018)** accept the current study findings in study entitled "Assessment of pain: tools, challenges and special populations" who explain the cause of crying among the control group who stated that majority of infants are exploring the pain by crying and body movements.

The findings of the present study clarified that the vast majority of infants had groaning crying in the experimental group while more than three quarters of infants had whined crying during and after routine injectable immunization in the control group. These findings were in agreement with **Mehmet et al., (2019)** in a study entitled "Application of ice and vapocoolant spray to reduce tetanus vaccine pain" who reported that the intensity of crying were less in the infants who received ice application than infants not received.

Also, these findings were in agreement with **Jose, (2013)** in a study entitled "The effectiveness of cold application on pain reduction prior to intramuscular



injection among infants" who indicated that the intensity of crying in the control group were more than study group. Additionally, **Ponzzone et al., (2011)** stated that pain during immunization sequences different crying sounds expressing different levels of pain intensity.

The current study results illustrate that the experimental group had less mean duration of crying than control group, this finding was in agreement with **Binu, (2014)** who reported that the durations of crying were less in the infants who received ice application than infants not received. From the researchers' point of view, during pain assessment, the different features of crying discriminated between different categories of pain. Also, groaning crying associated with mild pain in the experimental group while whining crying associated with moderate and severe pain in the control group, this could be attributed to the application of ice pack technique which decreased pain in the experimental group more than the control group. This study finding prove second stated research hypothesis stated "Infants who will receive skin-cooling technique will have less mean score of crying duration during and after immunization than infants who will not receive".

The current study results revealed that, regarding temperature, the majority of infants in the control group had a low grade fever after immunization compared with normal temperature in the experimental group. These findings were in agreement with **Leifer, (2018)** who reported that the factors that raise the temperature are muscle activity, excessive crying, physical, emotional stress such as anxiety. From the researcher point of view, a low grade fever may result from excessive movements and crying as a reaction to pain in control group.

The findings of the study illustrated that, respiratory and heart rates among vast majority of infants in the experimental group were normal compared with the vast majority of infants had tachycardia and tachypnea in the control group after routine injectable immunization and these differences were statistically significant. These findings were in agreement with **Zillingim et al., (2012)** who found that infants who were provided with ice application had normal physiological responses as pulse and respiration than infants who were not provided with this intervention. Also, **Jose, (2013)** reported that there were significant relationship between levels of pain and physiologic indicators as heart and breathing rates.

Additionally, these findings were in agreement with **Attia and Hassan, (2017)** who reported that all physiological parameters showed improvements after cryotherapy either before or after the needle puncture, in a study entitled "Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis". Also **Alalo et al., (2016)** who indicated that children in the study group had a lower mean pulse rate than those in the control group. These findings related to vital signs accept the third research hypothesis which



stated that "Infants who will receive skin-cooling technique will have more stable vital signs after immunization than infants who will not receive".

On the other hand, the current study findings were in disagreement with **Malakian et al., (2017)** in a study entitled "Assessment of cooling effect on neonatal pain during heel prick blood sampling: A randomized clinical trial" who claimed that the changes in physiological parameters were not strongly correlated to pain sensation, but could be highly responsive to other factors, including increased body temperature or physical activity. From the researcher point of view instability of heart and respiratory rates in control group could be attributed to more crying duration and reactions during painful procedure.

Conclusion

Immunized infants who received skin-cooling technique had no pain and reduced pain severity, less mean score of crying duration and more stable vital signs than infants in control group.

Recommendations

1. Application of an ice pack has to be a part of the routine care of infants before immunization procedure.
2. Further studies about application of ice pack before immunization injection must be done in various age groups of the pediatric population and in all types of vaccines.

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