Effect of Breast Feeding on Immunization Pain Intensity level among Infants

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Abstract

Pain can be managed by using both pharmacological and non-pharmacological methods. The non-pharmacological method used is breastfeeding for managing pain and it is the preferred method during infancy**. The aim was to** identify the effect of breastfeeding on immunization pain intensity level among infants. **Subjects and method: Design:** A quasi-experimental research design was used to fulfill the aim of the current study. **Setting:** the research was conducted in the Maternal and Child Health Center (Dar El-salaam Abdallah)**. Subjects**: A purposive sample of 200 mothers and their infants was included and assigned into control and study group, 100 infants in each group (100 breastfed before, during, and after immunization and 100 not breastfed). **Two tools were used:** Tool (I) A structured interview questionnaire and Tool (II) Neonatal Infant Pain Scale. **Results**: The results revealed that majority of the infants in the study group their facial expressions were relaxed, half of them did not cry at all, and the breathing pattern was relaxed among 66% of them. Highly statistical significance differences between infants six behavioral pain indicators including facial expression, crying, breathing pattern, arms, legs, and state of arousal in the study group and control groups. There were significant differences between pain scores of the infants after immunization in the study and control groups (at $P<0.0001$). In study group, more than half of infants had no pain compared to all infants in the control group who felt pain. **Conclusion:** It was concluded that breastfeeding was had highly statistically significant positive effect non-pharmacological method for reducing immunization pain intensity level among the studied infants in the study group versus control group. Pain intensity was significantly less among the infants administered immunization during breastfeeding. **Recommendations:** It is recommended to use breastfeeding during immunization as an intervention to reduce pain among infants. It needs less time, minimum effort, and is cost-effective without side effects which can be used easily in clinical settings. Replication of the current study with a larger sample of infants in different settings is required for generalizing the results.

Keywords: Breastfeeding, Infant, Immunization, Pain intensity.

Introduction:

Immunization, venipuncture, intramuscular injections, heel lancing, and other painful treatments are common among newborns and babies. Vaccination throughout the first year of life is now one of the most common procedures in babies. In childhood, routine vaccine injections are a common uncomfortable practice. When regular treatments like intramuscular injections and immunizations are performed on infants, it is believed that they may cause some discomfort **(Kaur et al., 2019).**

Pain is an unpleasant sensory and emotional experience that is linked to or defined in terms of actual or potential damage. Routine vaccination is an essential component of the healthcare delivery system because it is an effective health intervention for lowering newborn morbidity and mortality. Immunization shots are the most common cause of iatrogenic discomfort in children **(Schechter et al., 2017)**.

Throughout infancy, childhood, and adolescence, intramuscular immunization is given several times. Vaccine injection pain

causes anxiety and anguish in vaccine recipients, children, and their parents, and if not treated, it can lead to pre-procedural worry, future medical anxieties, and health-care avoidance behaviors, such as non-adherence to immunization regimens. It is claimed that up to 25% of children are afraid of needles. The majority of people develop needle phobias as children. Because of more positive experiences for children and their families, efforts to decrease pain in childhood have the potential to prevent the development of needle fears and enhance customer satisfaction and trust in the health care delivery system **(Efe, & Ozer, 2017).**

Injection-related discomfort in infants is still mainly ignored. Pain that is not addressed has immediate and significant negative consequences, the most obvious of which are child and parent discomfort. Untreated pain in childhood may have negative impacts on the developing central nervous system, according to preliminary research. Several basic strategies have been proven to lessen the pain response of newborns undergoing routine procedures. Given the short- and long-term consequences of uncontrolled pain, as well as the clear necessity of vaccination, an effective and secure pain control strategy, appears to be required **(Esfahani et al., 2018).**

Breastfeeding sweet solutions (oral sucrose, glucose), pacifiers, and skin-to-skin contact are examples of non-pharmacological methods. Furthermore, milk protein and fat can reduce crying; grimacing, heart rate, and another physiologic pain index in premature and full-term infants, as well as produce analgesic effects. Certain tastes and flavors have been shown to relieve neonatal pain in recent research. Infants' pain is reduced and spontaneous weeping is eliminated with as little as 2 mL of milk, which contains fat, protein, and pleasant compounds **(Abdel Razek & Az El-Dein, 2019).**

Although the infliction of pain during vaccination is unavoidable, nurses should strive to give the best possible comfort and security for patients throughout these procedures, using approaches that cause the least amount of discomfort. In any immunization center, pain during vaccination is a typical occurrence. There had never been researching like this done before in West Bengal's rural society. Breastfeeding is an effective analgesic, simple to implement, and safe remedy for newborn infants experiencing discomfort **(Efe & Ozer, 2017)**.

With a variety of non-pharmacological approaches during infancy, breastfeeding is the recommended way of pain management. A study on breastfeeding in which 478 infants (aged 12 months) were compared to either no intervention or breastfeeding before, during, and after vaccination injections. [i.e. mother seated with an infant in her arms **(Dilli et al., 2018)** or routine care (**Moddares et al., 2016**) or restraint of infants by mothers and reported that interventions help in reducing pain during vaccination among infants.

Significance of the study:

The majority of injectable immunizations are given to infants during their first year of life, and it is causing pain for them. Infants can't communicate vocally, and it's a problem that's often overlooked. So, it is very necessary to reduce pain intensity for them through non-pharmacological methods as breast-feeding. So, this study aimed to identify the effect of breastfeeding on pain intensity among infants receiving immunization.

Aim of the study:

To identify the effect of breastfeeding on pain intensity among infants receiving immunization through:

- Assessing mothers' knowledge regarding breastfeeding.
- Assessing mothers' practice regarding breastfeeding.
- Assessing pain intensity level among infants receiving immunization on breast feeding study group versus other group (control group).

Research hypothesis:

Infants in study group who received immunization after providing breastfeeding would have pain intensity levels less than in the control group.

Subjects and Method:

Research design:

A quasi-experimental research design was used to fulfill the aim of the current study. Quasi-experimental research is a prospective or retrospective study in which patients self-select or are selected into one of some different treatment groups to compare the real effectiveness and safety of non-randomized treatments **(Maciejewski, 2020).**

Setting:

The research was conducted in Maternal and Child Health Center (Dar El-salaam Abdallah), Sohag City, Egypt, this setting was selected due to the high prevalence of infants in the selected setting, and also it serves the biggest region of the population.

Subjects:

Sample size calculation:

The sample size was calculated based on considering the level of significance of power analysis of 0.95(β=1-0.95=0.5) at alpha .05 (one-sided) (90% test power) with a large effect size (0.5) was used as the significance, 0.001 was used as the high significance.

A purposive sample of 200 infants with their mothers assigned into study group and control group, 100 infants in each group (100 were breastfed during immunization and 100 were not breastfed) who met the inclusion criteria within six months and received care from the previously mentioned setting. Inclusion criteria included infants who were within 1 year of age and visited the previously mentioned setting for their routine immunization. Exclusion criteria included: infants with congenital conditions and ulcers present in their mouth

Data collection tools:

Two tools were used to collect the data of the study as the following:

Tool (I): A structured interview questionnaire: It was developed by the researchers and consisted of two parts:

Part (1): It included information related to demographic data of mothers such as age, residence, level of education, phone number, and occupation.

Part (2): It included information related to demographic data of infants such as age, gender, and birth weight.

Tool (II): Neonatal Infant Pain Scale:

Neonatal Infant Pain Scale (NIPS) Ages Birth - One Year **(Lawrence et al., 1993):** A behavioral scale and can be utilized with both full-term and pre-term infants. The tool was adapted from the CHEOPS scale and uses the behaviors that nurses described as being indicative of infant pain or distress, composed of six (6) indicators. *f* facial expression *f* cry *f* breathing patterns *f* arms *f* legs *f* state of arousal. Each behavioral indicator scored with 0 or 1 except "crying", which had three possible descriptors, therefore, being scored with a 0, 1 or 2. Infants should be observed for one minute to fully assess each indicator. Total pain scores ranged from 0-7. The suggested interventions based upon the infant's level of pain are listed below. The difficulty with any tool that is not self-report is the ability to differentiate between pain and agitation; however, the nonpharmacological intervention may help differentiate between these two (i.e. changing the wet diaper, feeding the infant, repositioning, etc.). Pain Level Intervention 0-2 = mild to no pain 3-4 = mild to moderate pain. Non-pharmacological intervention with a reassessment in 30 minutes >4 = severe pain. Non-pharmacological intervention and possibly a pharmacological intervention with a reassessment in 30 minutes.

Validity of the tools:

The content validity of the tools, their clarity, comprehensiveness, appropriateness, and relevance was reviewed by five experts' professors; two professors from them were in pediatric nursing and three professors in the community health nursing field. Content validity index (CVI) was 0.95. Modifications were made according to the panel judgment to ensure sentence clarity and content appropriateness.

Reliability of the tools:

The Cronbach's α test was used to assess the reliability of the questions relating to

knowledge was 0. 89, the practice was 0. 88, and the Neonatal Infant Pain Scale was 0. 84.

Pilot study:

A pilot study was done by 10 % of the study subjects (20 mothers and their infants) before starting the actual data collection; to evaluate the effectiveness of the study tools, clarity, techniques, and the availability of the study sample; and infants who participated in the pilot study were excluded.

Ethical considerations:

Official permission for conducting the study was obtained from the Faculty of Nursing after a complete explanation of the study purpose and data collection procedure. The researchers obtained official permission from the manager of the previously selected setting and the head nurse of the Maternal and Child Health Center (Dar El-salaam Abdallah), Sohag City, Egypt).

The procedure and purpose of data collection were explained in detail to the parents of the infants. Oral consent was obtained from the patients to participate in the study; the researchers informed mothers that participation in this study was voluntary and they could withdraw at any time without giving reasons. The purpose of the study was explained to them and they were reassured that any information obtained would be confidential and would be used only for the study purpose.

Fieldwork:

- Data Collection was within six months from the beginning of March 2021 till to the end of August 2021. They were randomly assigned into two equal groups (study and control group) 100 infants in each group (100 were breastfed during immunization and 100 were not breastfed).
- Researches were attended the previously mentioned setting for data collection two days per week, from 9 am to 1 Pm.
- The researchers introduced themselves to the mothers. The researchers asked the mother to breastfeed her infant and observe the breastfeeding process. It was composed of four steps like the position of the mother, technique of holding the infant, way of sucking of the breast by the infant, and duration of breastfeeding. All these steps were constructed to provide a comfortable position for breastfeeding. The steps were
- Mother was seated on a comfortable chair with their infants in one side of the clinic
- Mother's breast was open, baby's chin touched the breast, cheek touched the nipple and baby opened mouth so that nipple & most of the areola went into the mouth. Breastfeeding was started two minutes before the administration of the vaccine and it was continued during and after the procedure.
- After the mothers had breastfed their infants for two minutes before, during, and after the procedure, the vaccinations began. During and after the vaccine, as well as during and after the immunization, the infant was guaranteed to be breastfed from the same breast and in the same position without interruption.
- Breastfeeding was started two minute before, during, and after administration of the vaccine in the study group.
- The control group was administered the vaccine without breastfeeding before, during, and after immunization.
- The immunization was given by a nurse. During immunization, the nurse held both legs of the baby without applying pressure to administer the vaccine to the correct area. After the last immunization.
- Soon after the administration of the intramuscular injection, the intensity of pain was assessed by observing the parameters such as facial expression, cry, breathing patterns, arms, legs, and state of arousal up to a maximum of 3 minutes was recorded with a stopwatch by the researcher and average score was taken.
- During the vaccination phase, it included injecting the vaccine by the staff and observation of the infant's behavior by the researcher in the post-vaccination phase included the recording of the infant's behaviors on NIPS. Then the intensity of pain for both the groups was assessed by the

behavioral assessment for measurement of pain through the Neonatal Infant Pain Scale.

Statistical analysis:

Data were coded and transformed into a specially designed format suitable for computer feeding. All entered data were verified for any errors. Data were analyzed using statistical package for social sciences (SPSS) version 20 windows and were presented in tables and graphs. Chi-square analysis was performed independent sample t-test, repeated measures ANOVA, and mean and standard deviations were computed. P-value at 0.05 was used to determine significance regarding:

• P-value > 0.05 to be statistically insignificant.

• P-value ≤ 0.05 to be statistically significant.

• P-value ≤ 0.001 to be highly statistically significant.

Results

Table 1: Shows that (57% and 52%) of mothers in the study group and control group respectively were between 20-< 30 years of age. Regarding residence, (52% and 59%) of mothers in the study group and control group respectively were living in urban areas. As much as 47% of mothers in the study group were had secondary education compared to (55%) in the control group. Meanwhile, 65% of the mothers were housewives in the study group and (83%) in the control group, with no statistically significant differences between both groups regarding demographic characteristics p>0.05.

Table 2: Illustrates that the age of the studied infants ranged from 6 weeks to 9 weeks in (55% and 54%) in study and control groups respectively. Half of the studied infants (50%) were girls in the study group compared to 51% in the control group. More than half of the infants (58% and 55%) their weight was 2.5-5KG in the study group and control group respectively, with no statistically significant differences between both groups regarding demographic characteristics p>0.05.

Table 3: Demonstrates that in 73% of infants in the study group their facial expressions was relaxed and in 27% of them were grimace. 47% of infants did not cry at all, 46% of infants whimpered and 7% of infants had vigorous crying. Among 77% of infants, the breathing pattern was relaxed. And 23% of them had change in breathing. The arms of 46% of infants were restrained or relaxed manner and 54% of infants had their arms in a flexed or extended manner. 59% of them had their legs in a restrained or relaxed manner and 41% of them had their legs in a flexed or extended manner. 80% of them were sleeping and 20% of them were awake.

The data presented in **Table 4** revealed the comparison of six behavioral pain indicators between the infants after vaccination in study and control groups, with statistically significant differences (at P<0.0001).

Figure 1: Highlights distribution of the infants after vaccination among the study group and control group. In the study group, 57% of infants had no pain whereas in control group every infant felt pain. Also, (37%) and (12%) had moderate pain in the study group and control group respectively. Only (6 %) had severe pain in the study group but (88%) had severe pain in control group.

Table (5): Revealed that there was a statistically significant correlation between total six behavioral pain indicators and pain intensity level, six behavioral pain indicators, and demographic data of children, pain intensity level, and demographic data of children at p<0.001**.**

Table 1: Frequency and percentage distribution of the studied mothers according to their demographic characteristics (n =200)

Variables	Study Group(n=100)		Control Group (n=100)		X^2(P)
	No.	%	No.	%	
Age					
20-< 30	57	57	52	52	0.714
30- ≤ 35	43	43	48	48	(0.933)
Residence					
Urban	52	52	59	59	0.742
Rural	48	48	41	41	(0.843)
Educational level					
Illiterate	8	8	15	15	0.612
Primary school	45	45	30	30	(0.745)
Secondary school	47	47	55	55	
Occupation					
Working	35	35	17	17	0.512
Housewife	65	65	83	83	(0.642)

Table 2: Frequency and percentage distribution of the studied infants according to their demographic characteristics (n =200)

Variables	Study Group (n=100)		Control Group (n=100)		X^2(P)
	No	%	No	%	
Age (WKS)					
6-9 Weeks	55	55	54	54	0.63
9>12 Weeks	45	45	46	46	0.862
Gender					
Boys	50	50	49	49	1.66
Girls	50	50	51	51	0.197
Infant weight					
2.5-5KG	58	58	55	55	3.94
5.1-7.5 KG	35	35	40	40	0.139
7.6-10 KG	7	7	5	5	

Table 3: Frequency and percentage distribution of the studied infants according to six behavioral pain indicators (facial expression, crying, breathing patterns, arms, legs, and state of arousal) (n =200)

Parameters		Study Group (n=100)		Control Group(n=100)		X^2	P-value
		No	%	No	%		
Facial Expression	Relaxed	73	73	6	6	36.78	<0.001
	Grimace	27	27	94	94		
Crying	No cry	47	47	0	0	38.56	<0.001
	Whimper	46	46	63	63		
	Vigorous crying	7	7	37	37		
B pattern	Relaxed	77	77	15	15	28.84	<0.001
	Change in breathing	23	23	85	85		
Arms	Restrained or Relaxed	46	46	7	7	40.33	<0.001
	Flexed or Extended	54	54	93	93		
Legs	Restrained or Relaxed	59	59	5	5	33.24	<0.001
	Flexed or Extended	41	41	95	95		
State of arousal	Sleeping	80	80	12	12	30.94	<0.001
	Awake	20	20	54	54		
	Fussy	0	0	34	34		

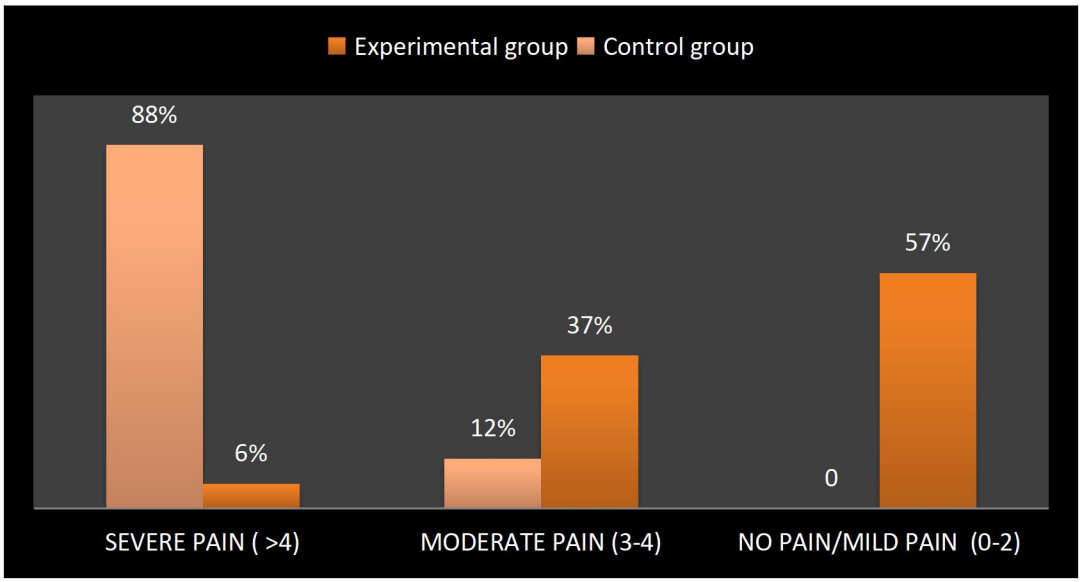
*highly significance at 0.001 levels

Table (4): Comparison of six behavioral pain indicators between the infants in both groups

Items	Study group		Control group		Unpaired T -test	P-value
	MEAN	SD	MEAN	SD		
Facial Expression	0.27	0.46	0.97	0.19	10.94	<0.001
Crying	0.57	0.58	1.79	0.43	12.79	<0.001
B pattern	0.24	0.47	0.89	0.33	0	1
Arms	0.52	0.58	0.97	0.23	6.13	<0.001
Legs	0.42	0.494	0.97	0.19	8.06	<0.001
State of arousal	0.19	0.38	0.83	0.38	8.98	<0.001

*highly significance at 0.001 levels

Figure (1): Percentage distribution regarding infants' pain level after receiving immunization in both groups (n=200)



X2=34.8 - **P-value**<0.001*

*highly significance at 0.001 levels

Table (5): Correlation matrix between six behavioral pain indicators, pain intensity level, and demographic data of children

Items	Pre-test		Post-test	
	r	P	r	p
behavioral pain indicators VS pain intensity level	0.384**	<0.001*	0.306 **	<0.001*
behavioral pain indicators VS demographic data	0.354*	0.005*	0.704**	<0.001*
pain intensity level VS demographic data	0.462**	<0.001*	0.603**	<0.001*

(*) Statistically significant at p<0.05
(**) statistically significant at p<0.00

Discussion:

Vaccinations are given periodically during childhood to limit the number of vaccine-preventable infections. However, it causes discomfort and pain in newborns, which can contribute to pre-procedural anxiety as well as future medical anxieties and avoidance behaviors. Thus the present study was undertaken to assess the effect of breastfeeding on immunization pain level among infants.

The present study findings indicated that age of the half of the studied infants ranged

from 6 weeks to 9 weeks in both groups. The result of the present study is in the same line with the findings of **Rashmimala et al., (2016)** who studied "Breastfeeding's Effect on Pain Intensity before Immunization Intramuscular Injection in Infants" and reported the same results.

The present study findings revealed that majority of infants in the study group their facial expressions were relaxed, nearly half of them did not cry at all, and majority of them, their breathing pattern was relaxed. This is reflected in the positive effect of breastfeeding on reducing pain among infants during vaccination.

The finding of the present study is in the same line with the findings of **Efe and Ozer, (2017)** who conducted a study about "The use of breast-feeding for pain relief during neonatal immunization injections which found crying time was shorter in the breastfeeding group in comparison with the control group.

The present study findings indicated that a highly statistically significant difference was found between the pain scores of the infants after vaccination in study and control groups. These findings are supported by **Shah et al., (2017)** who studied "Breastfeeding or breast milk to alleviate procedural pain in neonates" and reported that there was a significant difference between the intensity of immunization pain of experimental and control groups.

Also, **Tisvy et al., (2018**) carried a similar study about" Role of breastfeeding in pain response during injectable immunization among infants" and reported that a significant difference was found between the pain score of the experimental group and control group immediately after administration of the vaccine.

Similary, **Sangita**, **et al., (2020**) conducted a study in West Bengal about "Effect of Breastfeeding on Immunization pain among infants in a selected immunization clinic" It was concluded that the perception of pain intensity was less among the infants when vaccine injection was administered during breastfeeding.

Another study conducted by **Boroumandfar et al., (2018)** for 310 infants about "Comparison of vaccination-related pain in infants who receive vapor coolant spray and breastfeeding during injection" in Iran and showed that reported NIPS scores during immunization.

Also, a study conducted by **Bueno**, **et al., (2019)** entitled "A systematic review and meta-analyses of non-sucrose sweet solutions for pain relief in neonates" and found that breastfeeding behavioral responses and composite pain scores reduced during painful procedures.

The present study findings revealed that more than half of the infants in the study group had no pain whereas in the control group every infant felt pain. From the researchers' point of view, this confirms that providing breastfeeding during vaccination can reduce pain among infants.

This result is supported by **Esfahani et al., (2018)** who studied "Referring to the Navabsafavi Health Care Centre in Isfahan, a comparison study on vaccination discomfort in the methods of massage therapy and mothers' breastfeeding during injection of newborns was conducted" and reported that breastfeeding during injecting vaccine reduced pain more than message therapy.

Similary, **Kaur et. al. (2019)** conducted a study about "Analgesic effect of breastfeeding in infants during immunization injection" and found that breastfeeding during vaccine as an intervention could minimize vaccine-related pain.

Findings of the current study revealed that there was a statistically significant correlation between total six behavioral pain indicators and pain intensity level, six behavioral pain indicators, and demographic data of children, pain intensity level, and demographic data of children at $p<0.001$**.**

From the researchers' point of view, it reflected the success of the study aim and that providing breastfeeding had a positive effect on reducing immunization pain intensity among infants.

Conclusion:

Based on the results and hypotheses of the present study, it was concluded that breastfeeding was had highly statistically significant positive effect non-pharmacological method for reducing immunization pain intensity level among the studied infants in the study group versus control group. Pain intensity was significantly less among the infants administered immunization during breastfeeding.

Recommendations:

Based on the current study results, the following recommendations are proposed:

- It is recommended to use breastfeeding before, during, and after receiving immunization as an intervention to reduce its associated pain among infants. It needs less time, minimum effort, and is cost-effective without side effects which can be used easily in clinical settings.
- Replication of the current study with a larger sample of infants in different settings is required for generalizing the results.

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