

A quasiexperimental study to assess the perception of pain in infants after intramuscular vaccination

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ABSTRACT

Background: Intramuscular (IM) vaccination injections are an important cause of iatrogenic pain. Nonpharmacological intervention helps to reduce pain perception during immunization. **Purpose:** To compare the pain perception during IM injection, among infants who were breastfed versus local cold application in the vaccination clinic of a tertiary referral center. **Materials and Methods:** This study was conducted in the immunization clinic of a tertiary center. 60 infants (30 each in the intervention and control group) were selected for the study using simple random sampling method. Demographic proforma, Face, Legs, Activity, Cry, and Consolability (FLACC) pain scale was used to collect data of infants aged of 0–6 months. One group was breastfed and the other group local cold application was applied before the IM vaccine. Infant pain was assessed using the Modified FLACC Pain Scale. **Results:** Majority of the infants (36.6%) perceived moderate pain when the injection was given after local cold application, whereas least (23.3%) demonstrated moderate pain when the injection was administered after breastfeeding. The median score of infants in the local cold application group (5.5) was greater than that of the breastfeeding group (4.0). **Conclusion:** The study concluded that the application of cold can be used to reduce pain during IM vaccination in children <6 months of age where breastfeeding is not possible.

Key Words: Breast feeding, intramuscular injection, local cold application, pain

Introduction

International Association for the Study of Pain defines pain as an “uncomfortable sensory and emotional experience secondary to tissue damage.”^[1] Acute pain can occur following an injury, illness, or medical procedures. It accounts for one of the most common negative stimuli experienced by children. This unpleasant experience in a child should be addressed quickly and effectively. Pain can have Long-term physical and psychological sequelae if not tackled early. Long-term effects include anxiety prior or during procedures, decreased pain threshold, reduced efficacy of analgesics, and increased analgesic requirements.^[2]

There is no doubt about immunization having a positive influence on a child's health. However, vaccination injections are also one of the important causes of iatrogenic pain.^[3] Providing pain relief is therefore considered the most basic human right, as well as a responsibility of all health care providers. According

to studies, 85% of parents feel that it is the primary responsibility of the health care providers to make the immunization procedure less painful. Not addressing pain mitigation during immunization may be one of the several factors having a negative impact on health attitude and behavior. One of the negative impacts is delay or avoidance of future vaccinations. This ambivalent behavior toward vaccination can result in reduced vaccine coverage and thus expose the child to increased risk of acquiring vaccine-preventable disease.^[4]

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How to cite this article: Mathew M, Mathew S, Krishna S. A quasiexperimental study to assess the perception of pain in infants after intramuscular vaccination. Muller J Med Sci Res 2022;13:44-7.

Submitted: 10-Jan-2022

Accepted: 02-Feb-2022

Published: 02-Sep-2022

Access this article online

Quick Response Code



Website:

www.mjmsr.net

DOI:

10.4103/mjmsr.mjmsr_3_22

A number of nonpharmacological techniques are known to help pain perception. These techniques include distraction, relaxation, guided imagery, and cutaneous stimulation. The underlying mechanism involved with these methods for reducing pain perception is increasing pain threshold, reducing anxiety, and increasing the efficacy of analgesics.^[5] Several methods are used for cutaneous stimulation. These include simple techniques of application of pressure or massaging the area. Application of heat or cold at the site of injection or use of electric vibrator could also be used to reduce pain. Application of heat or cold is a relatively simple method. Impulses transmitted through the pain fibers is slowed with the application of cold.

Breastfeeding effectively reduces pain due to vaccination injections. There are several studies which conclude the same including the Cochrane study.^[6] Breast milk is natural, readily available with no adverse effects. This intervention is well accepted by both the health-care providers and by the parents. This cost-effective intervention would easily adopt for pain mitigation in infants receiving immunizations.

Materials and Methods

Study design

Quasi-experimental study with posttest design was used.

Population, sample size, sampling

This quasi-experimental study was conducted in the immunization clinic of a tertiary referral hospital between January and July 2018.

To find a mean difference of 8.36 units with standard deviation of 0.77 and 3.83 with 95% level of significance, the number required was 30 in interventional and 30 in the local cold application group, respectively.^[7] The subjects were allocated to breastfeeding and local cold application groups using the lottery method.

Instrument

All the required demographic details were collected. Modified Face, Legs, Activity, Cry and Consolability (FLACC) Pain Scale was used to assess the pain level among infants. Modified FLACC Pain Scale scores five aspects which include Facial expression, Legs, Activity, Cry, and Consolability. Each of the five categories was scored from 0 to 10, with a maximum score of 10. Inter-rater reliability was established using the Modified FLACC Pain Scale among 6 children. The coefficient of correlation was 0.91. Hence, the tool was found to be reliable.

Procedure

Written consent was obtained from parents of infants who were recruited for the study. Infants whose age was below 6 months were selected according to inclusion criteria through a simple random sampling technique. Infants who had developmental delay or neurological impairment, infants in the postoperative period, or infants receiving analgesics were excluded from the study. Subjects who received more than one intramuscular (IM) injection on the same day, only the first IM injection were considered. The subjects were then allocated to breastfeeding and local cold application groups using the lottery method.

Breastfeeding group

The mothers of babies allocated to this group were advised to breastfeed the infant 2 min before the injection. IM injection was then given by placing the infant on the table with thigh exposed, by the staff nurse who was posted in immunization clinic of Outpatient Department (OPD). The timing of the breastfeed was supervised by the researcher.

Local cold application group

Ice cube of size 2 cm × 3 cm covered in a plastic case was used for the local cold application group. The cold application was applied by the researcher for 30s before IM immunization after disinfection with spirit before application. After 30s of application of ice cube, IM injection was given by placing baby on the examination table. The staff nurse who is posted in the immunization clinic of OPD gave the injection.

A video of 1 min duration of the child's reaction toward the pain was then taken by the researcher for both the interventions. The video was later used to score the pain using the Modified FLACC Pain Scale by a third person who was not part of the study for both the interventional groups. Thus, making it a single-blinded study.

Data analysis

Descriptive statistics were used. The median, inter quartile range, and Mann–Whitney *U*-test value of pain scores of breastfeeding and local cold application groups were determined and compared for the effectiveness of the intervention. The Mann–Whitney *U*-test value calculated was used to find the association between pain score and the selected baseline variable in both breastfeeding and local cold application groups.

Results

Out of 60 children, 53.3% of them were <2 and a half

months of age. There was the equal number of male and female infants in the breastfeeding group, whereas most of the infants were male (53.3%) in the other group. Infants in both the groups (68.3%) had received IM injection \leq two times [Table 1].

Pain scores for comfort, mild pain, i.e., lower scores were seen in the breastfeeding group. Whereas moderate pain score was more in the cold application group. Severe pain was experienced similarly in both groups. Although the median score for pain in the local cold application group (5.5) was greater than that of the breastfeeding group (4.0) and the P value was (0.346) not statistically significant at 0.05 level [Table 2 and Figure 1].

The median pain score was higher in males when compared to females in both groups. In the breastfeeding group babies older than 2.5 months had greater pain scores when compared to babies younger than 2.5 months [Table 3]. However, in the cold application group [Table 4] the younger babies perceived more pain than the older. Similarly, the median pain score was higher in babies who received more than 2 IM injections in the breastfed group, whereas in the cold application group the lesser pain score was observed in infants with more than 2 IM injections. However, none of the above were statistically significant.

Discussion

Immunization plays a major role on children health. On the other side, it is also well known that injections during immunization are also an important cause for acute pain in children. Evidence-based efficacious and safe methods to decrease pain during immunization exists but these are underutilized.^[8]

Breastfeeding is a simple and inexpensive intervention to reduce pain during vaccination injections. Breastfeeding reduces the duration of crying and pain due to vaccine injections.^[6] Multiple mechanisms are hypothesized

through which breastfeeding reduces distress during vaccination. The mechanisms proposed include reduced anxiety due to physical comfort, sucking at the breast along intake of sweet-tasting milk. These individually or altogether have an effect on pain relief.^[9] WHO recommends to breastfeed the infants during or shortly before immunization to reduce pain if culturally acceptable. Prerequisites for breastfeeding for reducing pain related to injections are good latching by the infant at the breast, time by the clinical staff to help the mother achieve the good latch. Hindrance to breastfeeding, before vaccination, could be discomfort and shyness of mothers to breastfeed in a place which is visually accessible to others such as the vaccination room.^[10] Hence this study was done to compare breastfeeding with other nonpharmacological methods, i.e., cold application.

This study involved comparison of two noninvasive methods of pain reduction, i.e., cold application versus breastfeeding in children with age <6 months was done. In this study pain scores of both the intervention groups were the same. It can be concluded that ice pack the application can be used to reduce pain during immunization when breastfeeding is not possible.

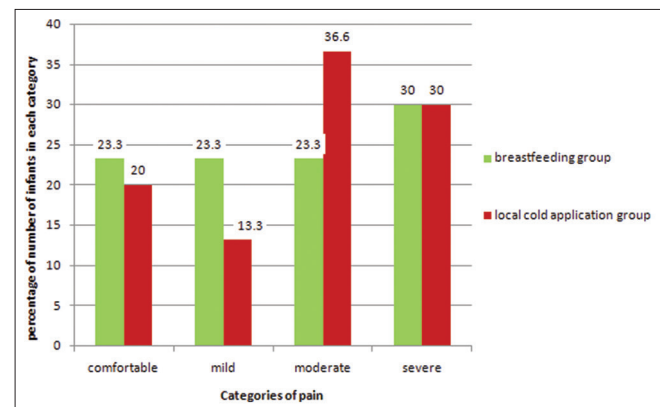


Figure 1: Percentage distribution of the subjects according to the severity of pain

Table 1: Assessment of pain score among children receiving intramuscular injection in both the groups

Baseline data	Frequency (%)			χ^2	P
	Breastfeeding group (n=30)	Local cold application group (n=30)	Total		
Age (months)					
<2.5	16 (53.3)	16 (53.3)	32 (53)	0	1
>2.5	14 (46.7)	14 (53.3)	28 (46.7)		
Gender					
Male	15 (50)	16 (53.3)	31 (51.6)	0	1
Female	15 (50)	14 (46.7)	29 (48.3)		
Number of previous IM injection exposure					
<2	20 (66.7)	21 (70)	41 (68.3)	0	1
>2	10 (33.3)	9 (30)	19 (31.7)		

IM=Intramuscular

Table 2: Range, median, and interquartile range of pain score with local cold application and breastfeeding

Groups	Maximum score	Median	IQR	Mann-Whitney U-test	P
Breastfeeding group	10	4.00	2-7	386.5	0.346
Local cold application group	10	5.5	1.5-7		(NS)

IQR=Interquartile range; NS=Not significant

Table 3: Association of pain with selected baseline variables in breastfeeding group (n=30)

Baseline data	Median	IQR	Mann-Whitney U-test	P
Age (months)				
<2.5	3.0	0-4.75	68	0.066
>2.5	5.071	3.25-7		(NS)
Gender				
Male	4.0	1-7	126	0.584
Female	3.0	2.5-6		(NS)
Number of previous IM injection exposure				
≤2	3.5	0-6.2	79.5	0.372
>2	4.00	3-7		(NS)

IQR=Interquartile range; NS=Not significant; IM=Intramuscular

Table 4: Association of pain with selected baseline variables in the local cold application group

Baseline data	Median	IQR	Mann-Whitney U-test	P
Age (months)				
<2.5	6.0	2.5-7.5	132.5	0.399
>2.5	4.5	3-6.25		(NS)
Gender				
Male	6.0	3-6.25	114	0.949
Female	4.5	1.5-7.75		(NS)
Number of previous IM injection exposure				
≤2	6	3-7	120	0.251
>2	4.00	0-6		(NS)

IQR=Interquartile range; NS=Not significant; IM=Intramuscular

The limitation of the study was not having a control group. From this study, it could not be concluded that which among breastfeeding and cold application were better in reducing pain. Although the study showed that both the interventions reduce pain, having a control group could have helped to decide the best intervention to reduce pain among both the groups (i.e. breastfeeding or cold application).

The second limitation was that infants were breastfed only before the IM injection. Mothers refused to breastfeed during vaccination in the initial conducted pilot study, hence, it was not done in this study. The

WHO recommends to breastfeed prior, during, and after the vaccination. In a systematic review, it was suggested that breastfeeding before vaccination injections also offers advantage in reducing distress by satisfying the infant.^[9] There are no studies to compare pain reduction with the timing of breastfeeding (i.e., before, during, and after the procedure). The possibility of alteration in pain score if the infants were breastfed before, during, and after the vaccination cannot be ruled out.

Conclusion

It can be concluded that the application of cold can be used to reduce pain during IM vaccination in children <6 months of age where breastfeeding is not possible.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

- Kumar K, Elavarasi P. Definition of pain and classification of pain disorders. *J Adv Clin Res Insights* 2016;3:87-90.
- Shave K, Ali S, Scott SD, Hartling L. Procedural pain in children: A qualitative study of caregiver experiences and information needs. *BMC Pediatr* 2018;18:324.
- Halpert C, Meier S, Naus M. Reducing immunization injection pain in infants. *BC Med J* 2015;57:189.
- Reducing pain at the time of vaccination: WHO position paper – September 2015. *Wkly Epidemiol Rec* 2015;90:505-10.
- Pak SC, Micalos PS, Maria SJ, Lord B. Nonpharmacological interventions for pain management in paramedicine and the emergency setting: A review of the literature. *Evid Based Complement Alternat Med* 2015;2015:873039.
- Harrison D, Reszel J, Bueno M, Sampson M, Shah VS, Taddio A, *et al.* Breastfeeding for procedural pain in infants beyond the neonatal period. *Cochrane Database Syst Rev* 2016;10:CD011248.
- Erkul M, Efe E. Efficacy of breastfeeding on babies' pain during vaccinations. *Breastfeed Med* 2017;12:110-5.
- Taddio A, McMurtry CM, Shah V, Riddell RP, Chambers CT, Noel M, *et al.* Reducing pain during vaccine injections: Clinical practice guideline. *CMAJ* 2015;187:975-82.
- Shah V, Taddio A, McMurtry CM, Halperin SA, Noel M, Pillai Riddell R, *et al.* Pharmacological and combined interventions to reduce vaccine injection pain in children and adults: Systematic review and meta-analysis. *Clin J Pain* 2015;31:S38-63.
- Coomson JB, Aryeetey R. Perception and practice of breastfeeding in public in an urban community in Accra, Ghana. *Int Breastfeed J* 2018;13:18.