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Effect of Breastfeeding on Pain Relief among Infants during Intramuscular Vaccination

Ashwini A. Shinde[1], Prakash Naregal[2]

[1]Student, Department of Child Health Nursing, Krishna Institute of Nursing Sciences, "Deemed to be University", Karad, Maharashtra, India

[2]Assistant Professor, Department of Child Health Nursing, Krishna Institute of Nursing Sciences, "Deemed to be University", Karad, Maharashtra, India

Abstract: ***Background: Intramuscular administration of vaccines in infants is common to induce immunity against preventive diseases. Nevertheless, it increases anxiety and pain distress in infants, which has to be minimised. Not many studies have implicated the role of breast feeding on pain distress. Objective: Study was designed to observe the pain related behavioural changes associated with breast feeding in infants post vaccination. Methodology: This quasi-experimental study involved 60 infants (1-12 months) attending outpatient department in a tertiary care hospital for vaccination. Infants were administered for Diphtheria-Tetanus-Pertussis (DTP) vaccine, experimental group (n=3) could breast feed for 3 mins post vaccination whereas the control group (n=30) was observed without any breast feeding post vaccination. Socio-demographic data was noted, and behavioural change pattern was scored as per Neonatal Infant Pain Scale (NIPS) for infants. Significance of behaviour change and association of changes with socio-demographic variables were assessed by Chi-square test with Monte-Carlo simulation. Results: Infants with age group of <6 months were majorly present in both the groups with <5 kg weight. Significant difference in crying, facial patterns, arm, and leg movements (P<0.001), and state of arousal (P=0.004) was observed between the experimental and the control group. Breathing patterns had no significant variation in both groups (P=1). Experimental group infants showed mild to no pain (n=24) after vaccination, while control group showed severe pain (n=30). Conclusion: Thus, breast feeding has induced behavioural change pattern in infants after vaccination which minimally reduces the anxiety and non-adherence to future medical fears.***

Keywords: Breast feeding, crying, ertussis vaccine, pain measurement, vaccination

1. Introduction

Infants are repeatedly administered with vaccines for prevention of possible diseases. The intramuscular vaccination procedure is painful though essential in child wellbeing.[1] On an average, the child receives 13-15 needle-based vaccines before their 5th birthday, which creates pain and distress in both infants and parents, which may result in development of anxiety and fear with needles in early age.[1,2,3] Also, it is known to alter thermal pain sensitivity for prolonged painful stimulation, hypoalgesia, thereby varying the activity induced changes in pathways involved in pain behavioural pattern which can persist even after adolescence.[4,5] This also can impact children in receiving assistance and pre-procedural care for any medical reason in future.[6,7] This distress with needle assisted pain has to be prevented from infancy, which otherwise may have a grave psychological effect on the child in the later stages of life.[8] Reports suggesting the documentation of pain during vaccination for 2-3-day old neonate can enable the child to experience and react for the same for consecutive terms.[3,9,10] Also, infants are unable to express their distress, which can be observed only through their behaviour. Therefore, every effort towards reducing painful stimuli in rendering better child-care is required.

Characteristic way of massaging, swaddling, smile is known to relieve the infants of the distress but is nevertheless not instant. There are reports on administration of oral solutions like glucose, sucrose, non-nutritive suckling (honey) and breast feeding.[1,7,8] However, breast feeding is known to have added benefits over other oral solutions. Breast feeding reduces pain by combined effect of presence of comforting person, diversion of attention (sucking and distraction), physical sensation of skin to skin contact, sweet taste and analgesic and relaxation effect by tryptophan and B-endorphins present in the breast milk.[7,8]

Therefore, in the light of the above information an interventional study assessing the efficacy of breast feeding for reducing pain stress was required, as there are very less reports on the effect of breast feeding in association with demographics data. Thus, the study was designed to observe the intramuscular vaccination assisted pain distress in infants and their behavioural changes after breast feeding.

2. Material and Method

Study design

This quasi-experimental post-test control research design was performed for a period of one month at a tertiary care hospital, Maharashtra, India. Before commencement of the study the Institutional Ethics Committee clearance was obtained along with a prior written consent from the mothers of the infants participating in the study. The study subjects included 60 infants with the following inclusion criteria: infants aged between 1 - 12 months, attending outpatient department (OPD) clinic for Diphtheria-Tetanus-Pertussis (DTP) vaccination. Infants with concurrent illness, having congenital anomalies were excluded from the study. A simple random sampling technique was done for both the experimental and control group with 30 infants in each group. In the experimental group (n=30) breastfeeding was allowed for the infants as an intervention after intramuscular vaccination for 3 min, while the control group (n=30) did not receive breast feeding post vaccination.

Development of a tool

The study tool involved socio-demographic profile (age, gender, weight, birth order, route, and type of vaccination), and neonatal infant pain scale (NIPS) data. Pain scale data was based on NIPS for infants (1-12 months) which is an adaptation of Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) for 1-4 years.[11] These are based on the behaviours posed by infants described by nurses for pain or distress, constitutive of six variables (facial expression, cry, breathing patterns, state of arousal, and arms and leg movements). The behaviour pattern was observed for a minute and scored based as 0 or 1 for all five except for cry, which has 0, 1, and 2 scoring patterns. Behavioural scores were interpreted as mild/ no pain (0-2), mild to moderate (3-4), and severe pain (>4).[11] Further, the tool was validated by experts (2 paediatricians, 3 nurses, and 1 statistician), with 100% agreement for their suggestions regarding relevance, adequacy and appropriateness were provided. Reliability of the study tool was examined, and a pilot study was performed with 6 infants in each group prior to the main study. The infants considered for pilot study were not included in the main study.

Procedure

During administration of DTP, an intramuscular vaccine, pain related behaviour for all infants in the control and experimental groups were assessed using NIPS. After vaccination, the experimental group was allowed for breastfeeding (3 min), post-test measurements were noted, however none of the groups could breast feed prior to immunization.

Statistical analyses

Data was analyzed using statistical software R (Version 3.6.3). Categorical variables were represented in frequency and percentage. Mann Whitney test was applied to evaluate the comparison in behavioural changes between the control and experimental groups. Chi-square test was performed to observe the association between socio-demographic variables amongst the control and experimental groups. Statistical significance was defined at $P \leq 0.05$.

3. Results

The quasi-experimental study was carried out on 60 infants (1-12 months) for behavioural changes after intramuscular vaccination. The reliability of the study tool was r=0.8132 using Karl Pearson's correlation and Spearman's Brown Prophecy formula. Table 1 indicates the distribution of socio-demographic variables within the control and experimental groups.

Majority of the infants were below 6 months in both control (93.3%) and experimental (96.7%) groups. Control group had equal number of female and male infants, whereas the gender ratio in the experimental group was 3:2 (male: female). Many of the infants, 20 from control and 17 from experimental group were having weight of $\leq$ 5 kg. The experimental group had only children born in 1st and 2nd order. All infants irrespective of groups, received intramuscular DTP vaccination (Table 1).

Post-test measures of both control and experimental group were measured with NIPS scale. Facial expression was found to be significantly higher in control group (0.97±0.18) than in the experimental group (0.17±0.38) at P<0.001 (Table 2). Crying was observed only in the control group (1.50±0.51) with a median value of 1.5, which was highly significant (P<0.001). Arms and leg movement was also significant between the two groups (P<0.001). Though the median values for state of arousal was similar in both the groups, it was significantly different (P=0.004) as the experimental group received breast milk soon after vaccination which subsided the crying and state of arousal unlike that observed in the control group. However, there was no significant difference observed with the breathing pattern in infants of both the group. The total NIPS score was observed to be more in the control group than the experimental group which was noted to be statistically significant (P<0.001) (Table 2).

Number of infants with NIPS score was significantly higher in the mild to no pain category (n=24), followed by mild to moderate (n=5) and only one showed severe pain for experimental group. However, severe pain was observed in all the infants (n=30) of the control group. Since all infants of control group demonstrated severe pain after vaccination, no association was observed between total scores of behavioral patterns with their selected demographic variables. The pain severity for experimental group and its association with demographic variables were noted in Table 3. With respect to all the variables, the severity of pain noted was mild to no pain with score ranging from 3-4 on NIPS scale. Though there was scattered pattern of pain severity, there was no significant association with demographic variables (age, gender, weight, and birth order) (P>0.05) (Table 3).

4. Discussion

Imparting immunity through vaccination is important in infancy, for the prevention of diseases. However, the consequences of pain and distress induced through injectable vaccines to the infants and children may have a long-lasting impact on the psychological development of the child in future. The study highlighted the importance of breast feeding in infants to alleviate pain induced during vaccination.

The study comprised of infants below 6 months of age, who were on a breast-feeding diet and received DTP intramuscular vaccination. Breast feeding immediately after vaccination for 3 min as an intervention observed a difference in the behaviour pattern among the experimental group in consideration with the control group as per the NIPS protocol.[11] Crying was observed to be less in the experimental group. Also, the other changes observed were reduction in movement of arms and legs, state of arousal in the experimental group, whereas breathing patterns were similar in both the groups. Facial changes with crying pattern were observed to be higher in the control group indicative of pain and distress after intramuscular vaccination. This was in harmony with the findings of the study done by Erkul et al. who reported that breast feeding

along with swaddling and skin-skin contact is known to act as an analgesic for pain distress.[12]

Majority of the infants in experimental group scored mild to no pain, whereas the control group experienced severe pain on receiving intramuscular DTP vaccination. Kaur et al. in their study, evidenced the reduced pain distress measured by audible crying, through breast feeding before and during DTP vaccination.[13] Esfahani et al. conducted a comparative study to relate the massage therapy and breast feeding in pain distress. The study indicated reduced pain scores when breast feeding (3.4) was used as an intervention in contrast to the control group (4.8), suggesting the efficient use of breast feeding as a non-invasive, safe and accessible method for pain relief in infants.[14] Similar results were also obtained in studies by Patel et al, depicting that pain distress was not observed through massaging or by swaddling alone but when used along with breast feeding.[15] Studies have reported the enhancement of oxytocin in both mother and infants by an act of breast feeding. It has been stated that in infants, oxytocin can reduce the stress through skin-skin contact, breast feeding, by counteracting the activity of non-adrenergic pathways.[16] Breast feeding is also known to stimulate opioids which activates the pathway and reduce pain distress and offsets the other hormones in regulating the stress.[8] However, there was no association observed between the behavioural changes and socio-demographic variables documented. This suggests that there is no key relationship between the age, gender, weight, and birth order of the infant on pain distress after breast feeding.

Infant management is a skill necessary for any healthcare provider as they need to manage both infants and parents at the same point of time. The study portrayed the effectiveness of breast feeding as an intervention in reducing pain during vaccination. This is a promising, cost effective, safe, simple, and convenient technique. The present evidence based study thus establishes the efficacy of breast feeding in alleviating pain distress in infants over other substitutes such as bottle feeding of breast milk or formula.

The study however has few potential limitations. Firstly, the sample size of the study was 1-12 months. Secondly, the study was conducted for a short span of time. Lastly, the patterns of pain relief with other vaccines and also breast feeding before, after and during vaccination was not evaluated neither was any follow up considered to evaluate the child's wellbeing post vaccination. Therefore, a multicentric study of longer time duration with a larger sample size needs to be extensively researched upon to arrive at more conclusive results.

5. Conclusions

Breast feeding after intramuscular vaccination (DTP) is intended to reduce pain distress in infants through behavioural changes. Also, it is the best-known practice which is not only less time consuming but is also cost-effective in reducing pain in infants after intramuscular vaccination.

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Tables

Table 1: Distribution of subjects based on demographic variables

Variables	Control Group n (%) [a]	Study Group n (%)
Age (months)		
< 6	28 (93.3)	29 (96.7)
≥ 6	2 (6.7)	1 (3.3)
Gender		
Male	15 (50)	18 (60)
Female	15 (50)	12 (40)
Weight		
≤ 5 kg	20 (66.7)	17 (56.7)
> 5 kg	10 (33.3)	13 (43.3)
Birth order		
1	18 (60)	22 (73.3)
2	11 (36.7)	8 (26.7)
4	1 (3.3)	0 (0)
Route of Vaccination		
Intramuscular	30 (100)	30 (100)
Type of Vaccine		
DPT [b]	30 (100)	30 (100)

[a] number (percentage); [b] DPT, Diphtheria-Tetanus-Pertussis vaccine

Tables 2: Comparison of pain related behaviors among infants in control and study group for essential parameters

Group	Median	*P* value [a]
Facial expression		
Control	1	< 0.001*
Study	0	
Cry		
Control	1.5	< 0.001*
Study	0	
Breathing		
Control	1	1
Study	1	
Arms		
Control	1	< 0.001*
Study	1	
Legs		
Control	1	< 0.001*
Study	0	
State of arousal		
Control	0	0.004*
Study	0	
Total		
Control	6	< 0.001*
Study	2	

[a] Mann Whitney U test, * significant at $P<0.05$

Table 3: Association of severity of pain among infants in experimental group with demographic variables

Demographic variable	Mild to moderate pain	Mild to no pain	Severe pain	*P* value [a]
Age				1
< 6 months	5	23	1	
≥ 6 months	0	1	0	
Gender				
Male	3	15	0	0.779
Female	2	9	1	
Weight				
≤ 5 Kgs	2	14	1	0.789
> 5 Kgs	3	10	0	
Birth order				
1	3	18	1	0.714
2	2	6	0	

[a] Chi square test with Monte-Carlo Simulation