

ORIGINAL ARTICLE

ANALGESIC EFFECT OF DIRECT BREASTFEEDING DURING BCG VACCINATION IN HEALTHY NEONATES

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Background: Pain during painful procedures in neonates has far reaching consequences. In developed countries many non-pharmacological interventions are used for neonatal pain reduction. Breast feeding has been proved to be an effective analgesic during mild to moderate painful procedures in neonates. **Methods:** The study, randomized controlled trial was conducted in CMH, Quetta. The study period extended from June to November 2015. Neonates included in the experimental group were breastfed during BCG vaccination and neonates in the control group were provided with routine care. Duration of cry with needle insertion was recorded with a digital stopwatch till the baby is silent for more than 5 seconds. **Results:** The mean crying duration in experimental group was significantly less than control group. In experimental group mean crying duration was 16.48s (12.76) whereas in control group mean crying duration was 34.93 s(45.26). Statistically significant difference was observed between the mean crying times of the two groups ($p<0.05$). **Conclusion:** Mean duration of crying with breastfeeding is shorter than without breast feeding during BCG immunization. Breast feeding reduces pain during minor painful procedures in neonates.

Keywords: Breast feeding; Neonatal pain; BCG; Immunization

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INTRODUCTION

A few decades back, it was thought that neonates could not experience pain and analgesia was considered unnecessary. There was paucity of appropriate tools for pain assessment in neonates and risk of adverse effects of analgesics also augmented this practice. In 1987 Anand and Hickey showed that neonates have the neurophysiological ability to perceive pain resulting in today's routine analgesic administration for minor painful procedures.¹ Neonates undergo many painful procedures like intramuscular and intradermal injection for immunization, heel pricks and venepuncture. All these interventions cause significant suffering depending on the kind of pain stimulus.² These painful events during the early years of life have far reaching consequences and leads to increased behavioural and endocrinological response to subsequent events in adult life. Clinical studies have shown significant post analgesic pain reduction in neonates and infants. There are two types of analgesic interventions, non-pharmacological e.g. holding, pacifier, breastfeeding; and pharmacological e.g. acetaminophen, sucrose and opioids.³ Sweet-tasting solutions have been proved very effective for pain relief in infants. Glucose and sucrose are extensively investigated for their analgesic effects in infants. Another effective non-pharmacologic intervention is breastfeeding or expressed breast milk.⁴ Studies showed that breastfeeding causes cortical activation by multisensory stimulation and reduces pain perception whereas glucose and sucrose have no

significant effect at cortical level.⁵ Many pain scoring tools are devised to precisely estimate pain in neonates. Research proved that first cry after pain is very sensitive to painful stimuli. The severity of pain has been assessed by the duration of first cry in many studies.⁶ Pakistan is a developing country with a very high birth rate. Gradual increase in literacy rate and awareness regarding preventable diseases paved the pathway for increased immunization. Unfortunately, unlike many developed and developing countries no routine analgesia is given to neonates and infants during these procedures resulting in unnecessary pain and discomfort.⁷ The rationale of my study is to test the hypothesis that breast feeding is a good analgesia in neonates for BCG vaccination.

Breast feeding is safe, cost effective and natural remedy to reduce pain in neonates and infants. Breastfeeding for minor procedural pain reduction can be implemented in rural and urban health centres without any cost. No such study is previously conducted in Pakistan. If breastfeeding is found to be a good analgesia in neonates in this study then it will be adopted as a routine practice during BCG immunization in our hospital.

MATERIAL AND METHODS

This randomised controlled trial was conducted in the Department of Paediatrics, Combined Military Hospital Quetta. The study period extended from 1st Jun to 30th Nov 2015. Sample size had been calculated by using

WHO calculator. Sampling technique used was non-probability consecutive sampling. Healthy full-term neonates of both genders who came for BCG vaccination and neonates who were partially or exclusively breast fed, determined on history, were included in the study. Sick neonates admitted in hospital, neonates with 5 min Apgar score <7 were excluded from study.

The above-mentioned exclusions could act as confounders, if included would have introduced bias in study results. Ethical review committee approval was taken before start of study. Neonates who came for BCG vaccination to outpatient department of our hospital were enrolled. Parents were briefed regarding the study and procedure was explained. Consent form were signed by parents. All neonates meeting the inclusion criteria were included in the study. Lottery method was used to randomly divide neonates into control and experimental groups. Name, age, gender, weight and height of each neonate were recorded. Breastfeeding was continued during vaccination in the experimental Neonates, whereas the other group was provided only with routine care and not breastfed. BCG was administered intradermal 0.05 ml over right deltoid with syringe provided in EPI program, in mother's lap. Duration of cry with needle insertion was noted with a digital stopwatch till the baby was silent for more than 5 seconds. **Error! Bookmark not defined.** It was recorded for each neonate in both groups on a separate proforma. The whole procedure was carried out in a separate room in presence of a female nursing assistant. Data was analysed in SPSS version 16. Duration of cry was the quantitative variable. Mean of crying durations and standard deviation for both groups, experimental and control group, were calculated. Mean duration of cry in the two groups were compared by applying *t* test. *p*-value<0.05 was taken as significant. Frequency and percentages were calculated for gender. Stratification with respect to gender, partially/exclusively breastfed was done. Post stratification chi-square test applied.

RESULTS

Out of sixty new-borns included in this study, thirty infants were in each group i.e. control and experimental. 29 were male and 31 were female. The male and female percentages were 48.3 and 51.7 respectively as given in figure-1. Thirty-four neonates were on exclusively breastfeeding and 26 on partial breastfeeding representing percentages of 56.7 and 43.3 respectively. In control group there was equal number of male and female, i.e., 15 whereas in experimental group male and female neonates were 14 and 16, respectively. In control group 19 neonates were on exclusive breastfeed and 11 were on partial breastfeed whereas in experimental group 16 neonates were on exclusive breastfeed and 14 were on partial breastfeed. The mean crying duration in experimental group was significantly less than control group as given in table-1.

In experimental group mean crying duration was 16.48 (12.76) whereas in control group mean crying duration was 34.93 (45.26). T test was applied and significance was 0.036 (equal variance assumed) and 0.039 (equal variance not assumed). Both values were less than 0.05 showing a statically significant difference between the two groups. (Table 2)

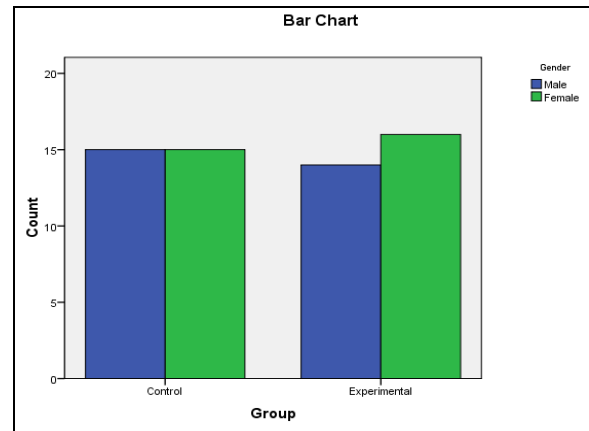


Figure-1: Sex ratio in both groups

Table-1: Group statistics of both groups

	Group	Number	Mean	Std. Deviation	Std. Error Mean	<i>p</i> -value
Crying Time (Seconds)	Control	30	34.9263	45.26152	8.26358	<0.05
	Experimental	30	16.4790	12.75966	2.32958	

Table-2: Applying independent sample t test to both groups

		Levene's Test for Equality of Variances		Means Equality (t-test)						
		F	Sig.	t	df	<i>p</i> -value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Crying Time (Seconds)	Equal variances assumed	6.461	.014	2.149	58	.036	18.44733	8.58567	1.26124	35.63343
	Equal variances not assumed			2.149	33.581	.039	18.44733	8.58567	.99111	35.90355

DISCUSSION

Neonates undergo many painful procedures.⁸ Some are routine procedures like heel prick for Guthrie test, BCG and hepatitis vaccination whereas many painful procedures are performed in neonatal nursery and intensive care settings.^{9,10} The pain intensity of these procedures vary from mild to severe. For severely painful procedures anaesthesia is preferred but mild to moderate pain is usually ignored in third world countries. There are many non-pharmacological interventions which are used for mild to moderate pain in the developed world like oral sucrose, oral dextrose, non-nutritive sucking, skin to skin contact with mother, facilitated tucking and breastfeeding.¹¹ Breastfeeding reduces the pain in different ways; infant's distraction by sucking, skin touch of mother and due to milk contents such as fat, protein, sugar, tryptophan, and precursors of melatonin and by blocking neuron pathways in the spinal cord. It is safe, cost effective and can be implemented in any setting.¹²

In our study neonates who were breastfed before, during and after the BCG vaccination cried less than neonates who were not breastfed and provided with just routine care. The mean crying duration in the breastfed group was 16.48 (12.76) whereas in the control group the mean crying duration was 34.93 (45.26). There was no significant difference between the two groups with respect to gender and feeding. T test showed that significance was 0.036 (equal variance assumed) and 0.039 (equal variance not assumed) depicting a significant difference between the two groups.

Results of our study are similar to many other studies conducted on analgesic effects of breastfeeding. Sahebihag *et al* showed that mean crying duration in infants who were breastfed before DPT vaccination was 66.6 (32.62) seconds versus 126.26 (46.15) seconds in infants who were not breastfed.¹³ Efe *et al*. studied the analgesic effect of breast-feeding in healthy neonates during immunization. They randomised 66 infants who came for DPT vaccination into control and experimental groups. Breast feeding was offered to experimental group during DPT vaccination whereas the control group was provided with routine care during vaccination (no breast-feeding). The outcome variables were cry duration, oxygen saturation and heart rates. The study revealed that the duration of cry in breastfeeding group was shorter than the non-breastfeeding group (Mean±SD, 36±40sec and 75±50 sec, respectively; $p=.001$). The oxygen saturation levels and heart rate did not differ significantly between the two groups.¹⁴

Weissman *et al*. conducted a study including 180 term neonates who were assigned to six groups; first group received no intervention, second group received non-nutritive sucking, third group was held by mother, fourth group received oral glucose solution, fifth group received formula feed and sixth group received breastfeeding. The duration of cry was the lowest in breastfed group infants and in those who were given oral solutions (5 and 13 seconds, respectively, vs 49; $p<.001$), compared with the other groups.¹⁵

Codipietro *et al*. carried out a randomised controlled trial to compare the analgesic effect of sucrose oral solution and breastfeeding during heel prick procedures at a neonatal unit. One hundred and one term neonates were randomised into two groups, one group was breastfed during blood sampling and the other group of neonates were administered 1 mL of 25% sucrose solution. The results showed that the median of duration of first cry for the breastfeeding group was 3.0 seconds (range 0.0–120.0) and for sucrose group was 21.0 seconds (0.0–120.0) with p value 0.004. This study revealed that in healthy neonates, for heel prick procedures, breastfeeding is a better analgesic than the oral sucrose solution.¹⁶

It is further recommended to carry out large trial to establish the beneficial analgesic effects of breastfeeding in neonates. Also, there is need for neonatal pain protocols in developing countries like Pakistan.

CONCLUSION

It was concluded that breastfeeding during BCG vaccination in healthy term neonates has analgesic effects compared to no intervention and it can be used in minor painful procedures in neonates to prevent the short-term effects of such painful events, i.e., physiological and behavioural as well as long-term consequences in form of exaggerated or decreased response to pain.

AUTHORS' CONTRIBUTION

JYD: Data collection, interpretation and drafting. LG: critical review of the final article. SAS: statistical analysis and drafting of article

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