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Original Article

Comparative study of analgesic effect of breastfeeding and oral sucrose in full-term newborns

Saurabh Kumar Patel, Milnd Gajbhiye, Jyoti Singh, H P Singh

From Department of Pediatrics, Gandhi Memorial Hospital, Shyam Shah Medical College, APS University, Rewa, Madhya Pradesh, India

Correspondence to: Dr. Saurabh Kumar Patel, Department of Pediatrics, 6/450 Shivnath Bhawan, Bansghat, Near Old Bus-stand, Rewa - 486 001, Madhya Pradesh, India. E-mail: dr.patelsaurabh@gmail.com

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ABSTRACT

Objective: To study the effects of breastfeeding (BF) and oral sucrose solution on pain due to intramuscular injection in newborns. **Design:** A prospective, interventional, randomized control study. **Setting:** Tertiary care hospital. **Participants:** Randomly selected 150 full-term vaginally delivered healthy newborns. **Intervention:** A total of 150 newborn infants were randomly divided into three groups. Out of 150 neonates, 50 were included in Group I as control group; 50 were included in Group II as intervention, in which 1 ml of 25% oral sucrose solution was given 2 min before the vaccination; 50 neonates were included in Group III as intervention group, in which BF started 2 min before vaccination and continued until the end of injection. **Outcome Measure:** The primary outcome of the study was to assess pain by premature infant pain profile (PIPP) score. Secondary outcome measured was changed in heart rate (HR), oxygen saturation (SpO_2), and crying time. **Results:** Mean PIPP scores were lower in the BF group (8.36) than in the sucrose solution group (11.06), and difference was significant ($p<0.0001$). The mean difference in the increase in HR, decrease in SpO_2, and total duration of cry for the breastfeeding group were 13.47, 2.33, and 23.8, respectively, and for sucrose group, they were 16.58, 2.07, and 26.36, respectively ($p>0.05$). **Conclusion:** BF and oral sucrose both are equally efficacious in reducing crying time and physiological parameters (HR, SpO_2) after intramuscular injection in neonatal period but desaturation was more observed in oral sucrose solution. Further, PIPP score is less in BF group. Thus, BF provides superior analgesia to oral sucrose in term newborns.

Key words: *Breast feeding, Intramuscular injection, Newborn, Oral sucrose, Pain*

Anatomical, physiological, and neurochemical structures that convey pain are well-developed weeks before birth [1], so newborn experiences pain worse than children and adolescents. It is found that early painful experience in the neonatal period can alter pain response in later infancy [2]. Introduction of Hepatitis B vaccine at birth in universal immunization program, predispose to early experience of pain during the neonatal period.

Previous studies with different methodology found that breastfeeding [BF] [3-8], expressed breast milk [9,10], oral sucrose [10,11], and glucose [12-14] had an analgesic effect on procedural pain. We did a review of the literature and found that 3 randomized controlled trial (RCTs) [14-16] and 3 studies with quasi-experimental design [17-19] reported less pain for breastfed infants. However, when we reviewed the methodology, age of subject and tool for assessing pain, it is found that age group of subject was up to 12 months and pain assessment scale used were fascial pain rating scale (FPRS), neonatal infant pain scale (NIPS), DAN scale, and modified behavioral pain scale (MBPS) and duration of cry. Pain assessment tools used in previous studies were unidimensional scale except NIPS. Pain assessment tools must be reliable and valid, have clinical utility and be feasible to use [20]. In the present study, premature infant pain profile (PIPP) scale was used to assess pain over NIPS because PIPP has established adequate psychometric properties (validity and reliability) and clinical utility for use in the infants [21]. NIPS has high degree of psychometric properties but has limited reported clinical utility [22]. The present study has been carried out to know the effect of BF and oral sucrose on first exposure of pain in healthy term neonates caused by intramuscular injection using PIPP.

MATERIALS AND METHODS

This prospective, interventional, case-control study was conducted in normal healthy, full-term newborn infants who received the first dose of immunization after birth, over a period of July 2010-June 2011. The inclusion criteria were vaginally delivered, breastfeed, full-term healthy newborns. Sick newborn, formula-fed babies, those newborn whose mother received general anesthesia, opioids or other analgesics during delivery were excluded from the study. Written informed consent from parent/guardian and the local Ethical Committee Approval were obtained before starting the study.

Intervention

Randomly selected newborns were divided into 3 groups, two intervention groups - BF group, 25% sucrose group (25S), and one control group (C). Each group includes 50 newborns. Group I was designated as control group, in which newborns vaccinated on mother lap without any intervention as in routine immunization. Group II was designated as sucrose group, in which 1 ml of 25% oral sucrose (made by adding 25 g of sucrose in water to make total volume of 100 ml) was given 2 min before vaccination. Group III was designated as breastfeeding group, in which newborns were breastfed, starting 2 min before vaccination and continued throughout during the vaccination.

Newborns were attached with Multipara monitor (BPL ACCURA MPM5553) using a neonatal probe. One lady attendant/staff nurse along with mother was present when breastfed newborns were vaccinated. With all aseptic precaution, 0.5 ml hepatitis B vaccine was administered intramuscular on anterolateral aspect of mid thigh to all neonates by auto disposable syringe. Position of baby (mother lap), the vaccinator, brand of vaccine, and syringe used were same throughout the study.

The two observers were present during vaccination. One observer was recording the facial expression of the baby, for later analysis and second observer analyzed the heart rate (HR) and oxygen saturation (SpO_2). The intervention was blinded for an observer in control and sucrose groups, while it was not possible in breastfeeding group. The gestational age was calculated by new Ballard score, and behavioral state was assessed 15 s before vaccination, along with baseline recording of HR and SpO_2. The maximum HR and minimum SpO_2 were noted between 0 and 30 s; cry time was defined as the total duration of audible cry and calculated from the recording using the video time bar at 30, 60, 90, and 120 s after vaccinations. The facial expression component of PIPP score was analyzed by the single observer by watching the video for the 30 s immediately following the vaccination.

The primary outcome of the study was the PIPP score. It is the validated pain measure that includes contextual (behavioral state and gestational age), behavioral (brow bulging, eye squeezing, and nasobasal furrowing), and physiological (HR and SpO_2) indicators of pain. Each indicator is scored in a 4 point scale (0-3), and score ranges from 0 to 21. However, in the present study, eligibility criteria included only term neonates, so the maximum score was 18. The secondary outcomes were changes in HR and SpO_2 and crying time.

Statistical analysis was done with SPSS statistical software package 18. Appropriate univariate and bivariate analysis were carried out using the Student t-test for the continuous variable and two-tailed fisher exact test or Chi-square test for categorical variables. The comparisons between three groups were done using ANOVA followed by Bonferroni post-test for multiple comparisons. The PIPP score was compared using ANOVA test. The critical levels of significance were considered at 0.05 levels, i.e., $p<0.05$ was considered significant.

RESULTS

Around 150 newborns were randomly selected. 74 were males and 76 were females. The neonatal characteristics such as, mean birth weight, length, head circumference, mean age of vaccination and baseline HR and SpO_2 (Table 1) were comparable between the groups. The primary outcome, mean PIPP score was 8.36, 11.06, and 14.26 for breastfeeding, sucrose, and control groups, respectively, and the difference between groups was statistically significant (Table 2).

Among secondary outcomes, mean of total duration of cry was lower in breastfeeding (23.8 s) and sucrose (26.36 s) than control group (61.38 s). The duration of cry was significantly reduced when comparing between the groups, but reduced duration of cry was not significant between breastfeeding and sucrose group ($p>0.05$) (Table 2).

The mean increase in HR was 13.47, 16.58, and 27.35, respectively, in breastfeeding, sucrose, and control groups (Table 2). The mean difference in increase in HR between control and sucrose groups was 10.76, the mean difference in increase in HR between control and breastfeeding groups was 13.88,

Table 1: Neonatal infant baseline characteristics

Baseline characteristics	Control (C)	Sucrose (25S) solution	BF
Males	22 (44.0%)	29 (58.0%)	23 (46.0%)
Females	28 (56.0%)	21 (42.0%)	27 (54.0%)
Birth weight, mean (g)	2597	2732	2641
Length, mean (cm)	47.74	48.73	48.4
Head circumference, mean (cm)	33	33.94	34.06
Mean age of vaccination (h)	46	42	44
HR, mean	126.88	128.76	136.76
SpO_2, mean (%)	96.30	96.86	95.66

HR: Heart rate, SpO_2: Oxygen saturation

Table 2: Measures of primary and secondary outcome variables

Variable	Control	Sucrose solution	BF	p value
PIPP scale, mean (range)	14.26 (9 to 18)	11.06 (5 to 17)	8.36 (1 to 12)	PIPP score $t^{1/2}$ (0.0001) $t^{1/3}$ (0.0001) $t^{2/3}$ (0.0001)
Total duration of cry, mean (s)	61.38 (15-135)	26.36 (7-76)	23.8 (0-90)	Total duration of cry $t^{1/2}$ (0.001) $t^{1/3}$ (0.0001) $t^{2/3}$ (>0.05)
Increase in HR from baseline to 30 s after vaccination, mean	27.35	16.58	13.47	
Decrease in SpO_2 from baseline to 30 s after vaccination, mean	4.19	2.07	2.33	

HR: Heart rate, SpO_2: Oxygen saturation

Table 3: Comparative analysis of mean difference of HR and SpO_2

Physiological parameters	Group	Group	Mean difference	Standard error	p value
HR_DIFF	Control (n=50)	Sucrose	10.77*	2.28791	0.000
		Breast fed	13.89*	2.28791	0.000
	Sucrose (n=50)	Breast fed	3.12	2.28791	0.526
SpO_2_DIFF	Control (n=50)	Sucrose	2.12*	0.70678	0.010
		Breast fed	1.86*	0.70678	0.028
	Sucrose (n=50)	Breast fed	−0.26	0.70678	1.000

*The mean difference is significant at the 0.05 level. HR: Heart rate, SpO_2: Oxygen saturation

and the mean difference in increase in HR between sucrose and breastfeeding groups was 3.11. The difference was significant when compared with control ($p<0.05$) and not significant between breastfeeding and sucrose ($p>0.05$) (Table 3).

The mean of decrease in SpO_2 was 2.33, 2.07, and 4.19, respectively, in breastfeeding, sucrose, and control groups (Table 2). The mean difference in decrease in SpO_2 between control and sucrose groups was 2.11, the mean difference in decrease in SpO_2 between control and breastfeeding groups was 1.86, and the mean difference in decrease in SpO_2 between sucrose and breastfeeding groups was −0.25. The difference was significant when compared with control ($p<0.05$) and not significant between breastfeeding and sucrose ($p>0.05$) (Table 3). Minimum level of desaturation was observed in sucrose group.

DISCUSSION

We observed that both BF and 25% sucrose reduced pain response, i.e., behavioral and physiologic parameter in full-term neonates after intramuscular injection when compared with control group. The mean PIPP score were 8.36, 11.06, and 14.26, respectively, in breastfeeding, sucrose, and control groups. The mean of total duration of cry was breastfeeding (23.8 s), sucrose (26.36 s), and control (61.38 s). The mean increase in HR and SpO_2 was breastfeeding (13.47, 2.33%), sucrose (16.58, 2.07%), and control (27.35, 4.19%), respectively.

In the present study, we used reliable and validated pain assessment tool PIPP score and first exposure of intramuscular injection in full-term vaginally delivered newborns. BF is considered as combined analgesic intervention because several aspects of BF (holding the child, skin to skin contact, the sweet tasting milk, and act of sucking) may individually attenuate pain responses. However, this study was to not evaluate the effect of individual component of BF.

Analgesic effect of BF was analyzed by different investigators, and we reviewed the available literature and found 3 RCT and, 3 quasi-experimental studies with different methodological quality and similar nature. Out of three RCT, only one study had a similar methodology with the present study. Moddares et al. [16] reported that mean of DAN scale score was 3.5 and 6.7 for case and control, respectively, and the difference was significant ($p<0.0001$). In our study, results are comparable and pain assessment tool used was PIPP, cry behavior, and physiological parameter (HR, SPO_2). Rest two RCT was done during DPT vaccination. Efe and Ozer [15] found a significant decrease in cry duration in BF (35.85 s) than in control group (76.24 s), but increase in HR and desaturation was equal in both the groups. These results were comparable in cry behavior, but physiological parameters were significantly changed in the present study except between breastfeeding and sucrose groups. Dilli et al. [14] demonstrated that crying time and median NIPS scores were significantly lower in breastfed than in control group, and these results were similar to that of our study.

All three quasi-experimental studies were done during DPT vaccination. Sahebihag et al. [19] compared the effect of BF, oral sucrose, and combination of both and found that cry time was significantly reduced in BF (32.26 s) than in control group (46.16 s, $p=0.007$), and mean of NIPS score was significantly less in BF (5.16) than in control group (6.53 s, $p<0.05$). The difference in mean of NIPS score between sucrose (5.73), combination of sucrose and BF (5.7) and control (6.53) was not significant ($p>0.05$). The increase in HR was seen in all groups, but the difference was not significant. In the present study, PIPP score was significantly reduced between breastfeeding and control, sucrose and control, and breastfeeding and sucrose group. A significant difference was observed when cry behavior and physiological parameters were compared between breastfeeding and sucrose and control group, but no difference was observed when compared between breastfeeding and sucrose groups. Abdel-Razek and Az El-Dein [17] found that NIPS and FPRS scores were significantly reduced in BF group, and results were comparable with the present study. The study by Kaur et al. [18] observed that duration of cry was reduced in BF (49.4 s) than in control group (87.4 s), and MBPS score was significantly reduced in BF than in control group. These results were comparable with the present study.

The limitation of the present study was a lack of blinding. It was not possible to blind in BF group, and we could not study the role of the different components of BF or the mechanism behind the analgesic effect of sucrose. To avoid any potential bias in the pain score evaluation, objective outcomes assessed were increase in HR, decrease in SpO_2 and duration of cry. PIPP scale, which validated and proven to discriminate painful from non-painful stimuli, was used for the assessment of pain in newborn.

CONCLUSION

The present study suggests that BF provided superior analgesia than oral sucrose for intramuscular injection when the pain was

assessed by PIPP. No significant difference was noted between two groups when physiological parameters such as increase in HR, decrease in SpO_2, and total duration of cry were compared. Oral sucrose and BF both were equally efficacious in reducing crying time and a physiological parameter of pain.

REFERENCES

1. Fitzgerald M, McIntosh N. Pain and analgesia in the newborn. Arch Dis Child. 1989;64(4):441-3.
2. Taddio A, Katz J, Ilersich AL, Koren G. Effect of neonatal circumcision on pain response during subsequent routine vaccination. Lancet. 1997;349(9052):599-603.
3. Shah PS, Herbozo C, Aliwalas LL, Shah VS. Breastfeeding or breast milk for procedural pain in neonates. Cochrane Database Syst Rev. 2012;12:CD004950.
4. Carbajal R, Veerapen S, Couderc S, Jugie M, Ville Y. Analgesic effect of breast feeding in term neonates: Randomised controlled trial. BMJ. 2003;326(7379):13.
5. Gray L, Watt L, Blass EM. Skin-to-skin contact is analgesic in healthy newborns. Pediatrics. 2000;105(1):e14.
6. Phillips RM, Chantry CJ, Gallagher MP. Analgesic effects of breast-feeding or pacifier use with maternal holding in term infants. Ambul Pediatr. 2005;5(6):359-64.
7. Gray L, Miller LW, Philipp BL, Blass EM. Breastfeeding is analgesic in healthy newborns. Pediatrics. 2002;109(4):590-3.
8. Upadhyay A, Aggarwal R, Narayan S, Joshi M, Paul VK, Deorari AK. Analgesic effect of expressed breast milk in procedural pain in term neonates: A randomized, placebo-controlled, double-blind trial. Acta Paediatr. 2004;93(4):518-22.
9. Ors R, Ozek E, Baysoy G, Cebeci D, Bilgen H, Türküner M, et al. Comparison of sucrose and human milk on pain response in newborns. Eur J Pediatr. 1999;158(1):63-6.
10. Stevens B, Yamada J, Lee GY, Ohlsson A. Sucrose for analgesia in newborn infants undergoing painful procedures. Cochrane Database Syst Rev. 2013;1:CD001069.
11. Skogsdal Y, Eriksson M, Schollin J. Analgesia in newborns given oral glucose. Acta Paediatr. 1997;86(2):217-20.
12. Deshmukh LS, Udani RH. Analgesic effect of oral glucose in preterm infants during venipuncture – A double-blind, randomized, controlled trial. J Trop Pediatr. 2002;48(3):138-41.
13. Sahoo JP, Rao S, Nesargi S, Ranjit T, Ashok C, Bhat S. Expressed breast milk vs 25% dextrose in procedural pain in neonates, a double blind randomized controlled trial. Indian Pediatr. 2013;50(2):203-7.
14. Dilli D, Küçük IG, Dallar Y. Interventions to reduce pain during vaccination in infancy. J Pediatr. 2009;154(3):385-90.
15. Efe E, Ozer ZC. The use of breast-feeding for pain relief during neonatal immunization injections. Appl Nurs Res. 2007;20(1):10-6.
16. Moddares M, Rahimparvar VF, Mehran A, Jazayeri AS. Effect of breast feeding on pain of injection in newborns. Hayat. 2006;12(4):32-8.
17. Abdel-Razek A, Az El-Dein N. Effect of breast-feeding on pain relief during infant immunization injections. Int J Nurs Pract. 2009;15(2):99-104.
18. Kaur L, Kaur S, Kalia R, Bharti B. Analgesic effect of breast feeding in infants during immunization injections: Randomized control trial. Nurs Midwifery Res J. 2009;5(4):142-54.
19. Sahebihag MH, Hossinzadeh M, Pourasl AM, Kosha A. The effect of breast feeding, oral sucrose and combination of oral sucrose and breast feeding in infants pain relief during the vaccination. Iran J Nurs Midwifery Res. 2011;16(1):9-15.
20. Duhn LJ, Medves JM. A systematic integrative review of infant pain assessment tools. Adv Neonatal Care. 2004;4(3):126-40.
21. Waldem M. Pain Assessment and Management - Guideline for Practice. Glenview, IL: National Association of Neonatal Nurses; 2001.
22. Lawrence J, Alcock D, McGrath P, Kay J, MacMurray SB, Dulberg C. The development of a tool to assess neonatal pain. Neonatal Netw. 1993;12(6):59-66.

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