

## Comparative study of analgesic effect of breast feeding versus dextrose during heel lance in neonates

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### Abstract

**Aim:** Firstly, to assess the level of pain in new-borns enrolled in the study, after heel lance. Secondly, to determine the effect of oral dextrose solution and breast feeding on procedural pain in new-borns in the experimental group.

**Materials and Methods:** The index study was conducted in neonatal nursery of tertiary care teaching hospital (MMIMSR, Mullana). The participant cases were neonates with gestational age 34 weeks to 42 weeks who were on partial or complete breast-feeding scheduled for routine new-born screening blood test via heel lance (n 106). Neonates were randomized into 2 groups for analgesia, i.e. breast-feeding and 25% oral dextrose solution. The research variables include independent variables (oral 25% dextrose solution and breast feeding). The dependant variable was procedural pain (heel lance) in neonates. PIPP (Premature Infant Pain Profile) score was the primary outcome variable. PIPP score includes two physiologic indicators of pain (i.e. heart rate and oxygen saturation), three behavioural indicators (i.e. brow bulge, eye squeeze, and nasolabial furrow); and two contextual factors (i.e. corrected gestational age and behavioural state). Higher the score greater the pain. PIPP score was assessed before giving the stimulus and again at 30 sec after the stimulus.

**Results:** In breast feeding group 89.8% children had no or minimal pain. In dextrose group maximum children 73.7% had experienced mild to moderate pain. In dextrose group 94.8% children had minimal to moderate pain, with 3(5.3%) having severe pain. But 44(89.8%) children are having no or minimal pain in breast feeding group, 10.2% suffered from mild to moderate pain. None of the children in breast feeding group showed features of severe pain. The mean pain score of 9.7 and 4.7 in dextrose and breast feeding groups respectively proves significant difference (p-value 0.000) was found in them. Lesser mean score in breast feeding group signifies the importance of breast feeding during painful procedures as compared to dextrose.

**Conclusion:** Both breast feeding and 25% oral dextrose solution have analgesic effect during heel lance but breast feeding proved to have significantly superior analgesic effect during heel lance among neonates in comparison to dextrose. 25% oral dextrose solution or preferably breast feeding should be considered as pain-control measures for the neonate during heel-stick procedures.

**Keywords:** Analgesia; Breast-Feeding; Maternal Holding; New-born; Pacifier; Pain; PIPP.

### Introduction

ISAP<sup>(1)</sup> (International Association of the Study of Pain) defines pain as “an noxious emotional & sensory experience due to actual or potential tissue damage”.

It is now a well-known fact that pain in neonates have detrimental effect but despite of being aware of this fact, neonates are still being subjected to repeated painful stimuli as a routine practice in neonatal intensive care units without proper analgesia.

Preterm babies have extended activation of hypothalamic-pituitary axis which leads to prolonged alteration in behavioural, hormonal, and physiological mechanisms.<sup>(2)</sup> Extended pain procedures stimulate oxidative stress & inflammatory reactions and halts development of premyelinating cells.<sup>(3)</sup>

Amongst the routinely performed procedures in NICU, heel prick is commonly being practiced for capillary sampling.<sup>(4)</sup>

Ranger, et al<sup>(5)</sup> suggested that repetitive skin prick procedures in neonates is associated with thinner cortical gray matter during their childhood period. Further research in this matter lead to conclusion that repetitive painful procedures in neonates results in poor cognitive and motor function during their forthcoming

development & also sub-optimal behaviors during their later life.<sup>(6)</sup>

During short term painful procedures in neonates (heel lancing), non-pharmacological pain relieving interventions are effective, economical and safe as compared to pharmacological pain relieving interventions. Non- pharmacological procedures such as oral dextrose solution, nonnutritive sucking (NNS), swaddling, breast feeding, facilitated tucking and skin-to-skin contact had been effectively used for amelioration of minor painful procedures in neonates.<sup>(7)</sup>

Pain perception in neonates during routine painful procedures in neonates can be effectively demonstrated by pain assessment tools such as PIPP scale (Premature Infant Pain Profile) devised by Stevens and colleagues<sup>(8)</sup> in 1996.

Any pain relieving measure in neonates which is cost effective, natural, & safe can be ideal for use in NICU receiving heel lance. Ongoing research has proved that both breast feeding & 25% oral dextrose solution are effective measures to ameliorate pain in neonates during painful procedures such as heel lancing.

### Aim and Objective

- To assess effect of oral dextrose solution or breast feeding on procedural pain in neonates of experimental group.
- To determine the association of level of pain with sample characteristics of the neonates enrolled in the study.

### Materials and Methods

This index study was conducted in NICU of Maharishi Markandeshwar Institute of Medical Sciences and Research, Department of Pediatrics, Mullana.

The study includes 106 neonates. Sample size is estimated based on previous studies<sup>6</sup>. Our sample size came out to be 47 cases per group, out of total 106 cases, with power = 80%, confidence interval = 95 % and error = 0.5. For possible dropouts, it was decided to include 10% extra subjects so finally it was decided to include 106 cases in total for both the groups.

The criteria met during the study were as follows:

**Inclusion criteria:** Neonates 0 to 28 days of age (with gestational age 34 weeks to 42 weeks) who are undergoing heel lance procedure for blood sugar estimation and those babies on exclusive or partial breast feed. Gestational age was estimated by New Ballard's Score.

**Exclusion criteria:** Those excluded were:

- Sick neonates who are hemodynamically or on oxygen,
- With neurological abnormalities, or facial palsy,
- Babies at high risk for necrotizing enterocolitis
- Babies with severe birth asphyxia (i.e. Apgar score of 3 or less than 3 at 1 minute)
- Babies who are nil per oral
- Babies with congenital heart disease
- Babies with intestinal obstruction or, feed intolerance
- Babies with major congenital defects such as cleft lip, tracheal oesophageal fistula cleft palate or oesophageal atresia
- Babies on pharmacological sedated or on other pain medications

Research variables used includes independent variables such as oral 25% dextrose solution and breast feeding and dependent variable such as procedural pain (heel lance) in neonates.

The babies enrolled in the study were randomly assigned into 2 groups via computer generated random no's. Even no's; were assigned to breast feeding group while odd numbers were assigned to dextrose group; and these numbers were kept in serially arranged sealed envelopes. The individual assigned to produce random no's & issuing them was not the part of study.

The individual particulars such as name, age, sex & anthropometric parameters such as weight, length, and head circumference were recorded in Performa which

was pre structured. Neonates selected for study were then subjected to purposeful heel lancing. The intervention (breast feeding or 25% oral dextrose) to be given to baby was finalized in accordance to the assigned random no.

**Breast feeding group:** In this group cases were breast fed, starting 2 minutes before, during and 2 minutes after the heel lance procedure. During breast feeding, lateral one side of face was visible to the examiner thus; all facial particulars were in accordance to the visible side of face side which examiner can observe. However, nil score was assigned for cases in which facial parameters could not be recorded.

**25% dextrose group:** In this group, babies were fed with 2 ml of 25% dextrose, 2 minutes prior to heel lance procedure by a sterile syringe. Only one individual was assigned the task of giving intervention to the baby. A 23 gauge needle (used as lancet) was pricked on lateral aspect of babies' heel after sterilizing the skin with sanitizer. Heel lancing was subjected to the baby in mother was holding the baby in her lap. The procedure was recorded by female invigilator on a video camera, to ensure mother's compliance. The outcome variables were recorded and analyzed by principal investigator recorded the vital parameters, 2 minutes before, during and after the heel lance cases. Confounding during the procedure was scrutinized by ensuring that the subjects were randomly assigned the pain relieving intervention. All enrolled cases were breast fed before procedure. Time of last feed was not more than 2 hours. In all the cases heel lancing was subjected to the baby while he/ she was lying in mother lap and during the pain relieving intervention. In all the cases, during procedure mothers were allowed to cuddle the baby. The observer assessed the arousal state by visualizing the following parameters: eyes closed/open, regular/irregular respiration, body movements, crying. Baby was soothed to awake full state if they were found sleeping before procedure. So as to bias the diurnal variation, the procure was carried out between 8 a.m. to 2 p.m. Similar role was performed by the investigator in all the cases. Prior to the procedure a written informed consent was duly signed by the mother. The Ethical Committee of M.M.I.M.S.R, Mullana had issued ethical clearance for our study.

PIPP<sup>(10)</sup> score was used for assessment of neonatal pain during the procedure. In the PIPP scoring system the min. score that could be assigned 0 and max. score was 21. PIPP score includes 3 behavioral indicators such as eye squeeze, brow bulge & nasolabial furrow; 2 physiologic parameters such as heart rate & oxygen saturation; 2 contextual parameters such as behavioral state & corrected gestational age. In PIPP scoring system a 4-point scale was used ranging from 0-3. These scores on the seven indicators were summated to calculate a total pain score. For all the neonates, interpretation of gross pain score was interpreted as:

- <6 = no pain

- 6-10 = moderate pain
- >10 = severe pain.

Higher the score greater the pain. PIPP score was calculated at 30 sec after the painful stimulus.

Results were analyzed by using appropriate statistical tests. PIPP score was the primary outcome variable and the sample size was calculated for this variable. Results were analyzed using SPSS version 20 software. Analysis of descriptive data was done by using percentage calculation. Inferential data was interpreted by independent t- sample test for mean comparison & chi-square test for proportion comparison.

## Results

Dextrose was used for neonates of one group (n-57), simultaneously breast feeding was used for another group (n-49) during heel lance and the comparison was done on the basis of various parameters according to PIPP criteria.

The table-1 shows that neonates aged 1 to 10 days were included in the study with mean age 1.2 days. The male (65) and females (41) were in the gestation age of 32 to 41.1 weeks with men gestation age of 37.7 weeks. The average birth weight was  $2648.1 \pm 412.2$  with

range 1563-3632. The overall pain score among 106 neonates ranged from 3 to 13 with  $7.4 \pm 3.3$  mean score.

**Table 1: Profile of the infants included in the study**

S. No	Profile	Descriptive statistics
1.	<b>Age(days)</b>	
	Range	1 – 10
	Mean $\pm$ SD	$1.2 \pm 1.6$
2.	<b>Gender</b>	
	Male : Female	65 : 41
3.	<b>Gestational age(weeks)</b>	
	Range	32.0 – 41.1
	Mean $\pm$ SD	$37.7 \pm 1.8$
4.	<b>Birth Weight (gms.)</b>	
	Range	1563 – 3632
	Mean $\pm$ SD	$2648.1 \pm 412.2$
5.	<b>Analgesic group</b>	
	Dextrose : Breast feeding	57 : 49
6.	<b>PIPP score</b>	
	Range	3 – 13
	Mean $\pm$ SD	$7.4 \pm 3.3$

In table-2, frequency distribution and average score among neonates related to various parameters of PIPP criteria are shown. Out of 106, 89(84.0%) neonates

**Table 2: Distribution of Premature Infant Pain Profile among patients**

S. No.	Parameter	0	1	2	3	Mean $\pm$ SD
1.	What is gestation of infant?	89(84.0)	17(16.0)	0(0.0)	0(0.0)	$0.2 \pm 0.3$
2.	Behavioral state before the procedure (15 sec.).	42(39.6)	38(35.8)	13(12.3)	13(12.3)	$1.0 \pm 1.0$
3.	Difference between baseline HR & max. HR during procedure.	26(24.5)	37(34.9)	43(40.6)	0(0.0)	$1.2 \pm 0.8$
4.	Difference between baseline SO <sub>2</sub> % & min. SO <sub>2</sub> % during the procedure.	64(60.4)	22(20.8)	20(18.9)	0(0.0)	$0.6 \pm 0.8$
5.	Observe baby for 30 sec after procedure for brow bulge.	27(25.5)	36(34.0)	23(21.7)	20(18.9)	$1.3 \pm 1.0$
6.	Observe baby for 30 sec after procedure for eye squeeze.	14(13.2)	13(12.3)	57(53.8)	22(20.8)	$1.8 \pm 0.9$
7.	Observe baby for 30 sec after procedure for nasolabial furrow.	26(24.5)	38(35.8)	22(20.8)	20(18.9)	$1.3 \pm 1.0$
	Total PIPP score					$7.4 \pm 3.3$

gestational age was at least 36 weeks at birth and rest 17(16.0%) were 32 to less than 36 weeks old. Average score for gestation age was 0.2 as all babies scored 0 or 1 for age.

Behavioral state of neonates before procedure was noticed to be awakened before procedure with 42(39.6%) active awake and 38(24.9%) quite awake. Only 26(24.6%) in sleeping state results in lower mean value i.e. 1.0. The increase in heart rate was recorded among 80(75.5%) with 37(34.9%) 5-14/min. and 43(40.6) showing 15-24/min. increase over baseline. The SPO<sub>2</sub> fall was recorded in <2.5 in most of the cases 64(60.4%). The brow bulge was noticed among 43(40.6%) with moderate to maximum time.

Eye squeeze was the most common sign for showing pain by the infants. A large number 79(74.6%) babies practiced it for moderate to maximum time.

When observed nasolabial furrow among neonates the response was not one sided but varied from 0-3 scores.

The overall pain score among 106 neonates ranged from 3 to 13 with overall average PIPP score was  $7.4 \pm 3.3$  out of the range 0-21. Overall pain level of neonates in both groups has been depicted in Fig. 1. In breast feeding group 89.8% children had no or minimal pain. In dextrose group maximum children 73.7% had reported mild to moderate pain.



**Fig. 1: Pain level among neonates of both groups**

The overall pain scores of neonates according to PIPP criteria was calculated and distributed in three categories from minimal to severe pain. Maximum babies 56(52.8%) had no or minimal pain. Out of 106, 47(44.3%) had mild to moderate pain. Only 3(2.8%) babies had moderate to severe pain.

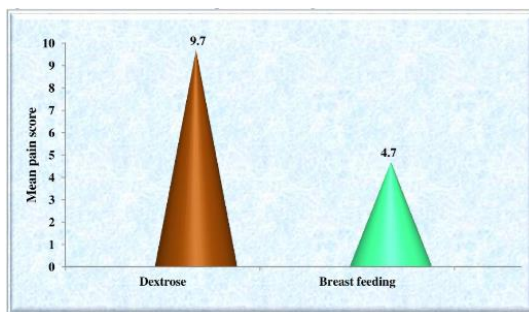
The table-3 shows the distribution of pain level among neonates of both groups. In dextrose group

94.8% babies had minimal to moderate pain, with 3(5.3%) having severe pain. But 44(89.8%) babies having no or minimal pain were spotted in breast feeding group, 10.2% suffered from mild to moderate pain. None of the babies in breast feeding group showed symptoms of severe pain.

**Table 3: Distribution of pain level among neonates of both groups**

Pain Level	N	Dextrose (n-57)		Breast feeding (n-49)		X <sup>2</sup>	df	p-value
		F	%	F	%			
Minimal or no pain	56	12	21.1	44	89.8	53.443 <sup>#</sup>	2	0.000*
Mild to moderate pain	47	42	73.7	5	10.2			
Moderate to severe pain	3	3	5.3	0	0.0			

The mean pain scores of both groups showed in Fig. 2 justifies that pain was more prevalent in dextrose group than breast feeding group. Hence it is clear that the effect of breast feeding reduced the pain among neonates in comparison to dextrose.



**Fig. 2: Mean difference in overall pain score among neonates**

The mean pain score of 9.7 and 4.7 in dextrose and breast feeding groups respectively proves significant difference (p-value 0.000) was found in them. Lesser mean score in breast feeding group signifies the importance of breast feeding during painful procedures as compared to dextrose.

## Discussion

In this study overall average PIPP score was  $7.4 \pm 3.3$  ranging from 0-21. The mean PIPP score of 9.7 and 4.7 in dextrose and breast feeding groups respectively. Similarly, Stevens et al,<sup>(11)</sup> in their study on initial development and validation of PIPP scale during heel lance found mean PIPP score to be  $8.8 \pm 2.4$ . Heish et al,<sup>(12)</sup> found in their study, PIPP score to be 8.6 (mean= 7-12) among breast feeding group and 9.5 (6.75-11.25) among oral dextrose group. Codi Pietro et al,<sup>(13)</sup> in their

study of breastfeeding or oral sucrose solution in term neonates receiving heel lance reported that the median difference of PIPP score was 5.0 among the two groups. But Gradin et al,<sup>(14)</sup> during their comparison of analgesic effect of breastfeeding versus glucose alone,

and in combination, with controls receiving no interventions, on full term infant's pain response during heel lance, found that although breastfeeding alone decreased duration of crying time compared to control,

PIPP scores and crying duration were lowest in the group receiving both interventions.

In this index study, in dextrose group 94.8% babies had minimal to moderate pain, with 3(5.3%) having severe pain. But 44(89.8%) babies having no or minimal pain were spotted in breast feeding group, 10.2% suffered from mild to moderate pain. None of the babies in breast feeding group showed symptoms of severe pain. The mean pain score of 9.7 and 4.7 in dextrose and breast feeding groups respectively proves significant difference (p-value 0.000) was found in them. Gradin et al<sup>14</sup>, in their study found that the PIPP score (median) was 7, which is lower in breastfed/glucose group than during breastfeeding alone with mean PIPP score of 10. There was a similar difference between the PIPP scores in the glucose fed group was 9 in comparison to the control groups where PIPP score was 11.

Similarly, Codipietro et al,<sup>(13)</sup> studied that median PIPP scores was 3.0, in the breastfeeding group which was lesser than those babies receiving 1 ml sucrose solution, with PIPP score of 8.5. The median group difference was 5.0. Heish et al,<sup>(12)</sup> found in their study, PIPP score to be 8.5 (mean= 6-11) among breast feeding group and 9.5 (mean= 6.75-11.25) among oral dextrose group. Their study showed significant statistical difference (p<0.05) among breast feeding and oral dextrose groups.

From the current discussion, inference can be drawn that lesser mean score (PIPP score) in breast feeding group signifies the importance of breast feeding during painful procedures as compared to dextrose. Hence it is clear in our study that the effect of breast feeding reduced the pain among neonates in comparison to dextrose during heel lance.

## Conclusion

In this study, 106 neonates aged 1 to 10 days were included with mean age 1.2 days. The overall pain score among 106 neonates ranged from 3 to 13 with  $7.4 \pm 3.3$  mean score. In breast feeding group 89.8% children had no or minimal pain. In dextrose group maximum children 73.7% had mild to moderate pain. In dextrose group 94.8% children had minimal to moderate pain, with 3(5.3%) having severe pain. None of the children in breast feeding group showed features of severe pain. Lesser mean score in breast feeding group signifies the importance of breast feeding during painful procedures as compared to dextrose. It is clear in our study that breast feeding more effectively reduces the pain among neonates in comparison to dextrose during heel lance.

### What is already known?

Breastfeeding and sweet solutions have pain relieving effects in minor out-patient procedures (heel lance).

### What this study adds?

Breast feeding during and before heel lance is superior to 25% dextrose as an analgesic in neonates.

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