

Original Research Article

STUDY TO COMPARE THE EFFICACY OF BREASTFEEDING AND ORAL SUCROSE ON THE PAIN EXPERIENCE OF NEONATES AND INFANTS DURING VENIPUNCTURE USING NEONATAL INFANT PAIN SCALE

Sandupatla Kiran¹, M. Suma Priya², Tumukunta Vaishnavi³

¹Assistant Professor, Department of Paediatrics, Mallareddy Medical College for women, Hyderabad, Telangana, India.

²Associate Professor, Department of Paediatrics, Mallareddy Medical College for women, Hyderabad, Telangana, India.

³Senior Resident, Department of Paediatrics, Mallareddy Medical College for women, Hyderabad, Telangana, India.

Received : 20/12/2025
Received in revised form : 04/02/2026
Accepted : 22/02/2026

Corresponding Author:

Dr. Tumukunta Vaishnavi,
Senior Resident, Department of Paediatrics, Mallareddy Medical College for women, Hyderabad, Telangana, India.
Email: drvaishnavirao2019@gmail.com

DOI: 10.70034/ijmedph.2026.2.125

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (2); 727-733

ABSTRACT

Background: Aim of the Study: To compare the efficacy of breast feeding and oral sucrose on pain experience of neonates and infants during venipuncture using neonatal infant pain scale. **Objectives:** 1. To determine and compare the degree of pain in subjects receiving breastfeed and the subjects receiving oral sucrose using neonatal infant pain scale. 2. To determine the association between demographic variables and pain perception.

Materials and Methods: It was a Randomized interventional stud carried out at Department of PAEDIATRICS, Malla Reddy Narayana Multi-Specialty Hospital, Suraram, Telangana. During the period 18 months (September 2022 to February 2024).

Results: This randomized interventional study was done to compare the efficacy of breastfeeding and oral sucrose on the pain experience of neonates and infants during venipuncture using neonatal infant pain scale. 85 subjects each were allocated to two groups randomly. Group 1 received breastfeeding 10 minutes prior to the procedure and group 2 received 2ml of 24% oral sucrose two minutes prior to the procedure. Comparison of the two groups was based on the efficacy of breastfeeding and oral sucrose for pain experience during venipuncture using neonatal infant pain scale. According age of gestation, in the BF group 35 were pre- terms and 50 were term and in the sucrose group 42 were pre- term and 43 were term babies. The birth weight among the groups were in the breast-feeding group 33 were LBW and 52 had normal birth weight with the mean being 2.79 ± 0.6 . In the sucrose group 31 were LBW and 54 were normal with the mean being 2.74 ± 0.6 kgs. Mean NIPS in breastfeeding subjects was 1.12 ± 0.8 . In the sucrose group mean NIPS being 1.12 ± 0.8 . The overall mean NIPS was 1.33 ± 0.6 . A significant association was seen between the groups suggesting sucrose fed babies had higher pain. In the breast- fed group it is observed the males had a mean NIPS score of 1 ± 0.8 and in females the mean was 1.1 ± 0.8 which on comparison was statistically insignificant ($p > 0.05$). Similarly, sucrose fed group males had a mean NIPS score of 1.5 ± 0.9 and females the mean was 1.5 ± 0.8 which on comparison was statistically insignificant. When both the groups were compared a statistically significant ($p < 0.05$) difference noted between suggesting sucrose- fed group had higher NIPS with respect to gestation. When both the groups were compared a statistically significant ($p = 0.04$) difference noted between suggesting sucrose-fed group had higher NIPS with respect to normal and low birth weight.

Conclusion: According to the findings of the present study, the lowest pain score and crying time was in breastfed neonates. Considering the fact that breast

feeding is a natural, useful and free intervention and does not need any special facility, this method is suggested in pain management and control during painful procedures for infants.

Keywords: Pain score, NIPS, Oral sucrose, Breast feeding, Venipuncture.

INTRODUCTION

The neonates and the infant's body are the most supersensitive, delicate and susceptible form which can be easily harmed if not taken care of and comprises of physical, mental and social wellbeing. Pain is one of the most common adverse stimuli experienced by any neonate or infant occurring because of injury, illness and necessary medical procedures. It is associated with increased parental distress. Despite the magnitude of effects that acute pain can have on, it is often inadequately assessed and treated. Numerous myths, insufficient knowledge among care givers as well as inadequate application of knowledge contribute to the lack of effective management for taking care of neonates and infants with pain.^[1]

Since pain is an inherently subjective multi-factorial experience and should be assessed and treated as such, health workers need to expand their knowledge, use appropriate assessment tools and techniques, anticipate painful experiences and intervene accordingly, use a multimodal approach to pain management, use a multidisciplinary approach, when possible, involve families and advocate for the use of effective pain management.

The following are some of the methods employed for pain management in neonates and infants:

- Facilitated tucking-positioning and restraining the infant in a relatively flexed posture.^[2]
- Stroking involves stimulation of nerve fibers transmitting tactile and thermal sensations.
- Combining the above methods with soothing and vocal stimulation.^[3]
- Breast feeding.^[4,5]
- Instillation of compounds like sucrose,^[6,7] glucose,^[8] and saccharine.^[9]
- Use of paracetamol/opioids.^[10]

Components of breast feeding that may be analgesic include presence of a comforting person (mother),^[11] physical sensation (skin to skin contact with comforting person),^[11] diversion of attention and sweetness of breast milk (preference of lactose or other ingredients present in the breast milk) and hind milk with increase fat content and high concentration of tryptophan produces sedative effect.

Oral sucrose administration has been associated with calming effects and reductions by increasing the concentration of endogenous opioids in observed pain behaviors and hence can be used a safe, convenient, and immediate-acting analgesic.

Rationale of the Study: Though ample number of studies were done related to non-pharmacological methods of pain relief, only meager studies are available in the country, especially in the southern

part. Only few studies used behavioral scales to assess pain, especially the NEONATAL INFANT PAIN SCALE-which is a well-known and accepted pain scale.

Evaluation of pain in neonates and infants is difficult due to the subjective nature of pain and the inability of neonates, infants to verbally express pain. Finding of this study will determine that the breastfeeding and oral sucrose will reduce the pain experienced by neonates/ infants during venipuncture.

Aim of the Study:

To compare the efficacy of breast feeding and oral sucrose on pain experience of neonates and infants during venipuncture using neonatal infant pain scale.

Objectives

1. To determine and compare the degree of pain in subjects receiving breastfeed and the subjects receiving oral sucrose using neonatal infant pain scale.
2. To determine the association between demographic variables and pain perception.

MATERIALS AND METHODS

Study design: Randomized interventional study.

Study place: Department of PAEDIATRICS, Malla Reddy Narayana Multi-Specialty Hospital, Suraram, Telangana.

Study period: 18 months (September 2022 to February 2024).

Study population: Neonates and infants.

Sample size: 170

Sample size was calculated using G* Power software with an alpha- error of 0.05 and power of 80% for equivalence of groups, by substituting the mean difference and standard deviation of the pain score (0.83 + 1.64 and 0.63 + 1.09) based on the findings of Rioualen et al.⁴⁸ The estimated sample size after the substitution of the above findings with adjusted effect size to 0.45 was 79 samples in each group. Considering the dropouts in the study, a sample size of 85 samples was taken in each.

Eligibility Criteria

Inclusion Criteria

1. Infants and neonates undergoing venipuncture.
2. Neonates and infants who are receiving intravenous therapy (intravenous line insertion, intravenous medication, intravenous fluids).
3. Neonates and infants who are breastfeeding.

Exclusion Criteria

1. Infants/neonates receiving analgesics, sedative medication.
2. Neonates/infants on ventilation.

Methods

1. Institutional research and ethical committee clearance was obtained, following informed consent was obtained from the parent.
2. On inclusion, the neonates/infants were randomly assigned to two groups by simple randomization techniques.
3. Subjects in the 24% sucrose group were given 2ml of 24% sucrose solution 2 minutes before the venipuncture.
4. Subjects of the breastfeeding group were given direct breastfeeding 10 minutes prior to the procedure.
5. The baby was placed in a cot in a quiet, diffusely lighted room.
6. The dorsum of the hand was held between the thumb and index finger just tight enough to make the vein prominent, and venipuncture was done with a needle with instructions to avoid squeezing, manipulation of the needle tip or removal/reintroduction of the needle.
7. Facial expression, cry, breathing pattern, arms [relaxed or restrained], legs [relaxed or restrained], state of arousal were noted.

Implication of Study

The simple and commonly used invasive procedure like venipuncture produces severe pain in a significant number of neonates/infants with considerable physiological and behavioral changes and hence non pharmacological interventions can be used to reduce pain during venipuncture.

Statistical Analysis

The data was compiled and analyzed using the following statistical analysis. Data was analyzed using SPSS version 20.

Normally distributed continuous variables were compared using the t test and qualitative data using chi square test.

Mann Whitney U Test/Wilcoxon test was used to compare ordinal data and numerical data if not normally distributed.

For all statistical data, p-value less than 0.05 is considered as a significant difference.

RESULTS

This randomized interventional study was undertaken with the purpose of comparing the efficacy of breast feeding and oral sucrose with regard to pain experienced during venipuncture which was assessed using neonatal infant pain scale.

A total of 170 neonates/infants were included and divided equally into two groups i.e. breast-feeding group (BF) and sucrose group (S). The subjects in the BF group were fed 10 min prior and the sucrose group 2 minutes prior venipuncture.

BF: Breast- fed group

S: Sucrose fed group

Table 1: Distribution according to age

Age	BF	S	Total
<1 month	57	54	111 (65.3%)
1-6 months	19	25	44 (25.8%)
6- 12 months	9	6	15 (8.9%)
Total	85	85	170 (100%)
Mean age	55.1± 80.3 days	54.3± 74.3 days	54.7± 77.3 days

Table 2: Gender distribution

Gender	BF	S	Total
Male	42	43	85 (50%)
Female	43	42	85 (50%)
Total	85	85	170 (100%)
Sex ratio [M: F]	0.9: 1	1: 0.9	1: 1

Table 3: Distribution according to gestation

Gestation	BF	S	Total
Preterm	35	42	77 (45.3%)
Term	50	43	93 (54.7%)
Total	85	85	170 (100%)

Table 4: Gestation BF S Total

Birth weight	BF	S	Total
Low birth weight (<2.5kgs)	33	31	64 (37.6%)
Normal (≥2.5kgs)	52	54	106 (62.4%)
Total	85	85	170 (100%)
Mean weight (kgs)	2.79± 0.6	2.74± 0.6	2.76± 0.6

Table 5: Neonatal infant pain scale (NIPS) findings

NIPS	BF	S	Total	p- value
No pain (0- 2)	80	73	153 (90%)	>0.05
Moderate pain (3-4)	5	11	16 (9.4%)	0.04
Severe pain (>4)	-	1	0.5	>0.05
Total	85	85	170 (100%)	-
Mean NIPS	1.12± 0.8	1.54± 0.5	1.33± 0.6	-

Table 6: Comparison of birth weight and NIPS in both groups

Birth weight	Bf	NIPS	
		S	p- value
Normal birth weight	1.7± 0.8	2.2± 0.8	0.04*
Low birth weight	0.73± 0.5	1.1± 0.5	0.04*
p- value	0.02*	0.01*	

Table 6 shows the NIPS score among normal birthweight and low birthweight between both the groups. In the breast- fed group it is observed the normal birth weight had a mean NIPS score of 1.7± 0.8 and LBW mean was 0.73± 0.5 which on comparison was statistically significant (p= 0.02). Similarly, the sucrose fed group the normal birth

weight had a mean NIPS score of 2.2± 0.8 and LBW mean was 1.1± 0.5 which on comparison was statistically significant (p= 0.03).

When both the groups were compared a statistically significant (p= 0.04) difference noted between suggesting sucrose- fed group had higher NIPS with respect to normal and low birth weight.

Table 7: Comparison of gestation and NIPS in both groups

Gestation	Bf	NIPS	
		S	p- value
Preterm	1.6± 0.9	2.1± 0.8	0.03*
Term	0.7± 0.5	0.9± 0.4	0.01*
p- value	0.01*	0.01*	

Table 7 shows the NIPS score among preterm and term gestation between both the groups. In the breast- fed group it is observed the preterm babies had a mean NIPS score of 1.6± 0.9 and term gestation mean was 0.7± 0.5 which on comparison was statistically significant (p= 0.01). Similarly, sucrose fed group pre- terms had a mean NIPS score of 2.1± 0.8 and

term gestation mean was 0.9± 0.4 which on comparison was statistically significant (p= 0.01).

When both the groups were compared a statistically significant (p< 0.05) difference noted between suggesting sucrose- fed group had higher NIPS with respect to gestation.

Table 8: Comparison of gender and NIPS in both groups

Gender	Bf	NIPS	
		S	p- value
Male	1± 0.8	1.5± 0.9	0.02*
Female	1.1± 0.8	1.5± 0.8	0.03*
p- value	>0.05	>0.05	

Table 8 shows that breast- fed group it is observed the males had a mean NIPS score of 1± 0.8 and in females the mean was 1.1± 0.8 which on comparison was statistically insignificant (p> 0.05). Similarly, sucrose fed group males had a mean NIPS score of 1.5± 0.9 and females the mean was 1.5± 0.8 which on comparison was statistically insignificant (p>0.05). When both the groups were compared a statistically significant (p< 0.05) difference noted between suggesting sucrose- fed group had higher NIPS with respect to gender.

Mean total NIPS pain score was low in the subjects on breastfeeding as compared to the subjects on sucrose.

- The oral sucrose- fed group had higher NIPS with respect to normal and low birth weight.
- Preterm neonates and infants had higher NIPS score when compared to term neonates and infants in both subjects on breastfeeding and subjects on oral sucrose.
- Subjects on oral sucrose had higher NIPS with respect to gestational age and gender.

R Ors et al,^[11] in 1999 Jan. Compared sucrose and breast milk on pain response in newborns and concluded that the antinociceptive effect of breast milk is not as effective as an analgesic as a sucrose solution.

The above study findings are contradictory to the findings of the present study.

Carbajal et al,^[12] conducted a study to investigate whether breast feeding is effective for pain relief during venipuncture in term neonates and compare any effect with that of oral glucose combined with a pacifier and concluded that breastfeeding and oral glucose significantly reduced the pain intensity of the neonates during heel lance in comparison with the control group, but no significant difference was

DISCUSSION

The present study is a randomized, interventional study **“TO COMPARE THE EFFICACY OF BREASTFEEDING AND ORAL SUCROSE ON THE PAIN EXPERIENCE OF NEONATES AND INFANTS DURING VENIPUNCTURE USING NEONATAL INFANT PAIN SCALE.”**

NIPS was selected as the scoring tool of pain analysis mainly because of fact, that it investigates the baseline behavioral status of the neonates, which would influence the pain response of the neonates.

observed between the pain intensity of breastfeeding and oral glucose groups. The findings are similar to the above study that breastfeeding can be used as an effective analgesic.

However, in the above study, there was no comparison between demographic parameters.

The study findings of Malekan Rad et al,^[42] showed that crying time during vein puncture was significantly shorter in the group in which 33% oral glucose solution was administered, in comparison with the control group. But breastfeeding did not bring about a significant decrease in crying time and pain score. In contrary to the above study, the present study concluded that breastfeeding is a effective analgesic] in reducing pain scores.

Dilli D et al,^[13] investigated in 2009 interventions that affect pain reduction during vaccination in infants and children attending a well-child unit demonstrating that breast-feeding may have an analgesic effect up to age 6 months and is statistically significant which is similar to our study and that in older children up to 48 months, both sucrose and lidocaine-prilocaine reduce vaccination pain. In the present study it was founded that breastfeeding was more too significant in reducing pain in both neonates and infants.

Sahebiagh et al,^[14] in 2011 conducted a quasi-experimental study on “The effect of breastfeeding, oral sucrose and combination of oral sucrose and breastfeeding in infant’s pain relief during vaccination.” Neonatal Infant Pain Scale (NIPS) was used to determine the pain after the vaccination and found that no significant difference was observed between the studied groups in terms of demographic data. The mean nips score immediately after the injection was 5.73,5.16, and 5.70 and was statistically significant in all the 3 groups. Breastfeeding significantly reduces vaccination pain comparing with the control group. However, oral sucrose and combination of sucrose and breastfeeding did not have any significant pain reduction intensity in comparison with the control group. Also, breastfeeding significantly reduced crying time in comparison with the control group but had no effect on preventing the following tachycardia after the procedure. The duration of the infants’ crying, and pulse rate was also measured and found that the lowest pain score and crying time was in breastfed neonates. The findings in the present study are similar to the above study that breastfeeding was more efficacious than oral sucrose. In contrary, the mean nips score was lower in the present study (1.12 ± 0.8 for breastfed subjects, 1.54 ± 0.5 for subjects on oral sucrose) and there was significant difference in terms of demographic data.

Stevens B et al,^[15] conducted a study in 2011 to determine the efficacy, effect of dose and safety of oral sucrose for relieving procedural pain in neonates. When Premature Infant Pain Profile (PIPP) scores were analyzed, it was found that sucrose groups had significantly lower scores at 30 seconds and 60 seconds post-heel lance. For retinopathy of

prematurity (ROP) examinations, sucrose did not significantly reduce PIPP scores There were no differences in adverse effects between sucrose and control groups. Results of the study suggests that sucrose significantly reduced duration of total crying time (but not the duration of first cry during heel lance. The Oxygen saturation (%) was also significantly lower in infants given sucrose during ROP examination compared to controls. The author concluded that sucrose is safe and effective for reducing procedural pain from single events. The findings are comparable to the present study as sucrose was used as an analgesic to reduce procedural pain and produced adequate analgesia.

Shah PS et al,^[16] conducted a study on breastfeeding or breast milk for procedural pain in neonates and concluded that breastfeeding likely reduces the Neonatal Infant Pain Scale (NIPS) score compared to no intervention, holding by mother, heel warming, music, EMLA cream, moderate glucose concentration, swaddling, swaddling and holding. Supplemental breast milk results in little or no difference in NIPS score compared to no intervention, pacifier, moderate concentration of glucose, eye drops, gentle touch and verbal comfort, and breast milk odor and verbal comfort. The study concluded that breastfeeding or supplemental breast milk may reduce pain in neonates undergoing painful procedures compared to nointervention/positioning/holding or placebo or non-pharmacological interventions. The findings are similar to the present study that breastfeeding significantly reduces the pain during venipuncture. Breast milk was found not to be effective in reducing validated and non-validated pain scores such as NIPS, neonatal facial coding system score, and DouleurAigue Nouveau (DAN) score; it was only being significantly better when compared to placebo (water) or massage. The author concluded that breastfeeding can be used to alleviate pain when undergoing intervention, but didn’t evaluate the effectiveness of breastfeeding/breastmilk as an analgesic alone without any control. In contrary to the above study, there was a significant reduction in NIPS pain score on giving breastfeeding prior to the intervention.

Kavthekar S et al,^[17] in 2016 compared the analgesic effect of 24% sucrose and breast milk in healthy infants less than 2months of age and concluded the analgesic effect was better for 24% sucrose as compared to breast milk. In contrary, breastfeeding was more efficacious in the present study.

Patel et al,^[18] evaluated “Breastfeeding (BF) and oral sucrose solution on pain due to intramuscular injection in newborns using PIPP.” and concluded that BF and oral sucrose both are equally efficacious in reducing crying time and physiological parameters (HR, SpO₂) after intramuscular injection, which is contrast with our study in which breastfeeding was more efficacious than oral sucrose.

Saumil Desai et al,^[19] 2017 conducted a study to compare then effect of expressed breast milk and

swaddling and oral sucrose administration on pain associated with suctioning in preterm neonates on assisted ventilation using Pipp and concluded that there was no difference between EBM, swaddling, and sucrose in relieving pain associated with suctioning.

On contrary to the above study conclusion, our study found that breastfeeding was more efficacious than sucrose and the pain scale used was neonatal infant pain scale as it has better utility clinic.

Tasgaonkar et al,^[20] conducted a study on the effectiveness of Oral Sucrose on Level of Pain among Infants after Pentavalent Immunization using NIPS and found that

the mean nips score in the experimental group was 2.17 and the control group was 5.17 and was statistically significant. The percentage of subjects having moderate and severe pain in experimental group was 16.67, 83.33 respectively. The author concluded that Infants receiving oral sucrose experienced lesser pain than infants who don't hence oral sucrose in reducing level of pain was seen to be effective.

In contrary to the above study, the mean nips score in subjects receiving oral sucrose was 1.54 ± 0.5 and the percentage of subjects with moderate and severe pain was 12.9, respectively.

Rioualen S et al,^[21] conducted a randomized, prospective, controlled trial assessing the cortical pain response of newborn infants to venipuncture comparing the analgesic effects of sucrose and breastfeeding and concluded that no difference in the cortical responses to pain during venipuncture was noted between both the subjects but the breastfed neonates presented more behavioral expressions that indicated more pain compared with sucrose-administered neonates. In contrast to the above study, the breastfeeding subjects of the present study had less behavioral expressions indicating lesser pain when compared to the subjects on oral sucrose.

In contrary to the above study, the present study revealed that breastfeeding significantly reduced pain response in neonates and the pain response was more in preterm, and females.

Velumula et al,^[22] in 2022 conducted a randomized controlled trial to compare Breast milk and 24% sucrose for procedural pain relief in preterm neonates using Pipp and concluded that the findings were statistically non-significant. The differences were noted in the baseline characteristics between the two groups using PIPP. The quantile regression estimates for PIPP scores during the procedure were statistically non-significant at all percentile levels of distribution (50%ile coefficient 0, 95% CI - 0.49 to 0.49) and concluded that breast milk is not inferior to 24% sucrose in providing analgesia during heel lance in moderate and late preterm infants.

On contrary to the above study findings, our study found that breastfeeding was more efficacious than sucrose.

Pooja Mishra et al,^[23] in 2023 conducted a study of efficacy of Breast Milk versus Oral Sucrose for Pain

Relief during Minor Procedures in Infants using NIPS and assessed parameters such as age, gender, current weight, type of procedure, duration of procedure, level of pain and found that duration of cry was more in breastfeeding group when compared to subjects on oral sucrose. Most of the infants were males. Mean weight in breastfeeding group was 8.4 ± 1.3 0.09 and the sucrose group was 8.7 ± 1.2 . The mean age of in breastfeeding group was 9.2 ± 1.2 months and the mean age of infants in the other group was 8.9 ± 2.0 months. Mean pain score was lower in sucrose fed subjects (4.1 ± 2.1) when compared to the breastfeeding group (3.3 ± 1.4). The study concluded that Oral sucrose provided effective pain relief among infants who underwent minor procedures. The study was similar to the present study in terms of the pain scale used NIPS and also the parameters compared i.e. breastfeeding and oral sucrose The above study differs from the present study in the type of procedures (venipuncture, heel lance, vaccination). In the present study only, venipuncture was taken into consideration and duration of cry wasn't measured, there was equal distribution regarding gender and the mean nips score was significantly lower in the breastfeeding group (1.12 ± 0.8) when compared to oral sucrose (1.54 ± 0.5).

Charan et al 24,2024 Compared breastfeeding, music therapy, and oral sucrose's impact on pain relief among infants using the Neonatal Infant Pain Scale (NIPS) and found that half of the infants in the breastfeeding group felt severe pain, whereas the majority of infants in the musical therapy and oral sucrose groups felt severe pain with a median pain score of 4.50, 6, and 7, in breastfeeding, musical therapy, and oral sucrose was respectively and concluded that breastfeeding is a superior analgesic when compared to other interventions which is in par with the present study. In contrary to the above results, the severity of pain was different in the breastfeeding and sucrose group with the majority of the subjects experiencing mild or no pain with a median nips score of 1.12 ± 0.8 , 1.54 ± 0.5 respectively.

Limitations

The present study had certain limitations that need to be acknowledged. Firstly, pain assessment was exclusively based on the NIPS scale. Although this tool is validated, relying solely on one assessment measure may not fully capture the multifaceted nature of pain experiences. Secondly, pain scores were measured only once, without multiple follow-up assessments over time, potentially missing important variations in pain intensity and duration. Lastly, the study focused on comparing two specific interventions, which may restrict the exploration of other potential approaches to pain relief during venipuncture. As the research was conducted in a single center, it is important to recognize that the obtained results can only be generalized to the specific sample group involved in the study. These limitations highlight the need for future research to employ a more comprehensive range of assessment

measures and consider additional interventions to gain a more comprehensive understanding of pain management in this context.

CONCLUSION

From the above study, subjects who are breast fed 10 minutes prior to venipuncture have better NIPS score than the sucrose fed babies who were given sucrose 2 minutes prior to venipuncture rendering breastfeeding has better efficacy than oral sucrose. The simple and commonly used invasive procedure like venipuncture produces severe pain in a significant number of neonates/infants with considerable physiological and behavioral changes. The oral sucrose- fed group had higher NIPS with respect to normal and low birth weight. Preterm neonates and infants had higher NIPS score when compared to term neonates and infants in both subjects on breastfeeding and subjects on oral sucrose. Subjects on oral sucrose had higher NIPS with respect to gestational age and gender. No major complications or adverse effects were noted in both the groups.

Conflict of Interest: None

Funding Support: Nil

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