

Oral 25 Dextrose Versus Expressed Breast Milk for Pain Relief During Venipuncture in Neonates: A Comparative Study

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Abstract: ***Objective:** To compare the efficacy of oral 25% dextrose and expressed breast milk on pain score among neonates undergoing venipuncture. **Methods:** A total of 40 neonates who were advised venipuncture for blood sampling were taken as subjects using consecutive sampling technique. They were randomized into expressed breast milk group and 25% dextrose group (20 in each group) using research randomizer software. The neonate was administered 2 ml of test solution after allocation using a needleless syringe. The venipuncture was performed 2 min after the administration of test solution. During the venipuncture the child was videographed and pain scores assessed by a coder who was blinded to the intervention. The tool used to assess pain score was Neonatal Infant Pain Scale (NIPS) which was the primary outcome and the secondary outcomes were crying time and heart rate. The pre and post procedural heart rate and crying time was observed and recorded. The analysis was based on objectives of the study. **Results:** The mean Pain Score in 25% dextrose group was 2.10 ± 2.22 and mean pain score in EBM group was 5.10 ± 1.8 . The statistical analysis was done using descriptive and inferential statistics. There was statistically significant reduction in pain score in 25% dextrose group as compared to the EBM group with a p value <0.0001 . The pre procedural heart rate was similar in 25% dextrose group and EBM group with a p value >0.05 where as the post procedural heart rate in both the group had statistically significant difference with a p value <0.0001 . There was no statistically significant difference in crying time in both the groups (p value >0.05). **Conclusion:** The present study concludes that Oral 25% dextrose was more effective and efficacious as an analgesic than expressed breast milk as it reduces the pain perception of neonates.*

Keywords: 25% dextrose, Expressed breast milk, Venipuncture, Neonatal Infant Pain Scale

1. Introduction

It was once thought that neonates do not feel pain or remember pain. Recent researchers found that their underdeveloped nervous system leads to increased perception of pain. A neonate during the first 14 days of neonatal life is subjected to an average of 7.5 – 17.3 invasive procedures per day¹. The most common procedures being heel lance, suctioning, venipuncture and insertion of peripheral venous catheter.

Neonates do not have the ability to verbalize their pain and hence others must recognize it. Pain management in young children has been largely neglected in most clinical settings. Advances in neonatal analgesic pharmacology, neurobiology and stress response studies have enhanced the use of various non pharmacological methods for relieving pain. A judicious application of these interventions, backed by awareness and sensitivity to pain perception, on the part of the health care provider is likely to yield the best results.

Neonatal nurses are the best person to assess and manage pain. As professional health care provider it is our moral obligation to reduce the pain response during invasive procedures. Sucrose has been examined for its calming effects in crying newborns and its pain-relieving effects for invasive procedures in neonates. The present study assesses the efficacy of 25% dextrose and Expressed Breast Milk on neonatal pain score during venipuncture.

2. Material and Methods

A Randomised Control Trial was conducted in the Blood Collection Centre, Paed OPD and Paed ward of a Tertiary Care Hospital in Pune. Sample size was calculated based on

data from a previous trial by Malngiang B et al (2012)⁵ with $\alpha = 5\%$ and $\beta = 90\%$. Sample size was calculated to be 32 using sample size calculator software. The sample size was increased by 20% to account for the possible loss of data due to attrition. Hence the sample size was calculated to 40 neonates (20 in each experimental group). Term Neonates (>37 weeks gestation) who required venipuncture for blood sampling and who were on oral feeds were enrolled in the study. Neonates who had perinatal asphyxia (Apgar score <7 at 5 minutes), congenital malformations, metabolic disorders and those on analgesics or sedatives were excluded.

Ethical committee clearance and permission to conduct research was obtained from institutional and administrative authorities. The trial was registered in Clinical Trial Registry of India (CTRI). A written informed consent was obtained from parents before enrolling the neonates.

Detailed demographic data was recorded. Demographic questionnaire consisted of age, sex, birth weight, mode of delivery, last feed, whether cried immediately after birth, indication of venipuncture and previous experience of venipuncture. The pre and post procedural heart rate, respiratory rate and crying time was recorded in the observation record. Pain during venipuncture was assessed using Neonatal Infant Pain Scale (NIPS). NIPS is a standardised behavioural assessment tool for measurement of pain in preterm and full-term neonates. It was developed at the Children's Hospital of Eastern Ontario by Lawrence J, Alcock D, McGrath P Kay J, McMurray SB and Dulberg C in 1992. It is composed of six indicators. Each behavioral indicator is scored with 0 or 1 except "cry", which has three possible descriptors therefore, being scored with a 0, 1 or 2. Infants should be observed for one minute in order to fully assess each indicator. Total pain scores range from 0-7⁶. A

score of 0-2 indicates no pain, 3-4 - mild to moderate pain and >4 indicates severe pain.

A total of 40 neonates who were advised venipuncture for blood sampling were taken as subjects using consecutive sampling technique. The neonates was randomized using randomizer software, into two interventional groups-25% dextrose group and Expressed Breast milk group with 20 neonates in each group. Allocation concealment was done using numbered, opaque sealed envelopes containing intervention codes. It was ensured that the time interval between the procedure and the previous breast feed was at least one hour. The neonates were not swaddled during the procedure for pain assessment.

The basal heart rate and respiratory rate was checked and recorded. Neonates were given the test solution as per allocation 2 min prior to the procedure. All venipunctures were done using 23-gauge needle 2 minutes after the test solution was administered. All venipunctures was be done by same individual who has adequate experience in neonatal care to minimize variation in pain during venipuncture. The neonate was videographed in real time by a videographer using Casio Exilim digital camera EX-Z223 for later analysis. The response to pain during this period was recorded and scored from the video by a single observer who was blinded to the intervention. The primary outcome of the study was the NIPS score and secondary outcomes were heart rate and crying time.

Statistical analysis was performed using SPSS version 29.0. The two groups were compared in terms of demographic data, pre and post procedural heart rate, crying time and NIPS score. Group differences in categorical data were analysed using the Chi-square test. In cases of not normally distributed data, Mann-Whitney Z test was used to determine whether the difference between the two groups were statistically significant. A value of $p < 0.05$ was considered statistically significant.

3. Results

A total of 40 neonates who underwent venipuncture were enrolled in the study, 20 in each group. The mean age of

samples in the 25% dextrose group were 6.30 ± 3.526 and EBM group were 5.55 ± 2.724 ($p > 0.05$). The 25% dextrose group had 8 males and 12 females and the EBM group had 11 males and 9 females ($p > 0.05$). The mean weight of neonates in 25% dextrose group was 2.83 ± 0.368 and in EBM group was 2.78 ± 0.402 ($p > 0.05$). Mode of delivery was FTND in 14(70%) in 25% dextrose and 16(80%) in EBM group ($p > 0.05$). The mean time of last feed in 25% dextrose is 71 ± 13.630 min and in EBM group is 76 ± 17.538 min ($p > 0.05$). The indications for blood sampling were Neonatal Jaundice (72.5%), Poor feeding (15%) and G6PD(5%). There was previous history of venipuncture in 14(70%) of 25% dextrose group and 12(60%) of EBM group. The mean pre procedural heart rate was similar in 25% dextrose group and EBM group 130 ± 6.77 and 136 ± 7.26 respectively ($p > 0.05$). This shows that both the groups were homogeneous in nature.

Table 1: Crying time wise distribution of cases in 25% dextrose group and EBM group, n=40

Crying time (Sec)	25% Dextrose	EBM	Total
<10	15(75)	9 (45)	24
10 & above	5(25)	11 (55)	16
Total	20	20	100

Chi-square = 3.75, P=0.051 (df=1, 3.84)

*Figure in parenthesis shows percentages

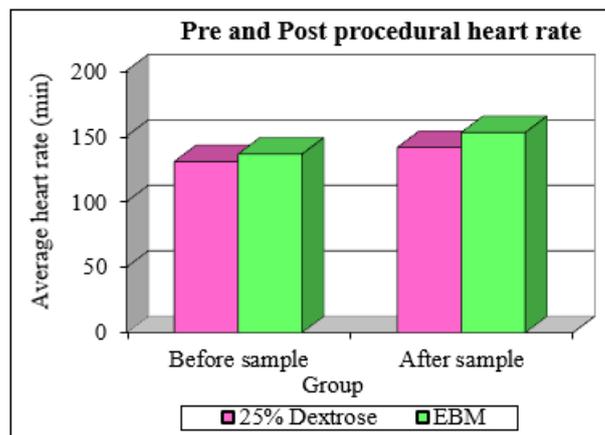


Figure 1: Comparison of heart rate before and after blood sample in 25% dextrose group and EBM group, n=40

Table 2: Comparison of Pain score(NIPS) in 25% dextrose group and EBM group, n=40

Parameter	25% Dextrose (n=20)		EBM (n=20)		MW test Z Value	P Value
	Mean	SD	Mean	SD		
NIPS score	2.10	2.22	5.10	1.80	3.73	<0.0001

1.96

The mean post procedural heart rate in 25% dextrose group and EBM group was 141 ± 10.05 and 152 ± 8.52 respectively which was statistically significant ($p < 0.0001$). The crying time was <10 sec in 15(75%) samples in 25% dextrose group and in 9(45%) samples in the EBM group where as it was >10 sec in 5(25%) of samples in 25% dextrose group and 11(55%) in the EBM group ($p > 0.05$). There was no statistically significant difference in crying time in both the groups. In the 25% dextrose group 13(65%) had no pain, 2(10%) had mild to moderate pain and 5(25%) had severe pain where as in EBM group 2(10%) had no pain, 6(30%) had mild pain or moderate pain and 12(60%) had severe

pain. The mean Pain Score in 25% dextrose group was 2.10 ± 2.22 and mean pain score in EBM group was 5.10 ± 1.8 ($p < 0.0001$) which was statistically significant.

4. Discussion

The results of this study showed that oral 25% Dextrose group was more effective in relieving pain during venipuncture as compared to expressed breast milk. In a similar study conducted by Sahoo J P et al(2011) to compare the effect of expressed breast milk, 25% dextrose and sterile water on procedural pain in neonates, 25% dextrose and

expressed breast milk group had lower pain scores than sterile water but 25% dextrose group had significantly lower pain score as compared to EBM group⁷. The findings of the study was also in accordance with a comparative study conducted by Malngiang B et al (2016) on pain relief using expressed breast milk and oral glucose in newborns undergoing skin pricking procedures. NIPS scores were significantly higher in expressed breast milk group than in oral glucose group ($P < 0.001$)⁵.

The findings of the present study are supported by Bueno M et al (2012) in a study to compare the efficacy of 25% dextrose and expressed breast milk on pain response of late preterms during heel lancing. The EBM group had moderate to severe pain as compared to 25% dextrose with a p value - 0.002⁹. However, in contrast, Gomez L et al (2014) in a randomized control trial to compare the analgesic effect of breast milk and sucrose during venipuncture stated that there was no statistical significance among two groups with p value = 0.28.⁸

The post procedural heart rate in both the group had statistically significant difference with calculated t value 3.83 ($p < 0.0001$). The heart rate increased post procedure in both the groups but the more in the EBM group. The crying time was more in EBM group but not statistically significant. In a study conducted by Jacoby J M (2017) to assess and evaluate the effectiveness of oral administration of 10 % dextrose for pain relief in neonates during venipuncture, the heart rate in both control and experimental group had increased post procedure but was significantly more in control group⁴.

Deshmukh et al³ in their study to compare the effect of different concentrations of glucose and EBM on procedural pain found that there was no significant effect on heart rate, respiratory rate or oxygen saturation with different concentrations of glucose in preterm neonates and term neonates but crying time for the EBM group was significantly longer than crying time as compared to oral glucose group ($P < 0.001$).

5. Conclusion

The present study used a true experimental approach to compare the efficacy of oral 25% dextrose and expressed breast milk on pain score among neonates undergoing venipuncture. The primary outcome of the study was Neonatal Infant Pain Scale (NIPS) and the secondary outcomes were crying time and heart rate.

6. Limitation

Double blinding was not used for this study and was limited to term neonates. The pain was assessed using Neonatal Infant Pain Scale only.

Conflict of interest

There was no conflict of interest

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