Original Article

A Study Comparing the Efficacy of Different Non-pharmacological Methods to Reduce Pain in Neonates Admitted in A Tertiary Care Hospital

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Aim : To compare the efficacy of different non-pharmacological methods for reducing pain in Neonates.

Methodology : During the study period of one year from July, 2019 to July, 2020, a total of 70 infants were consecutively recruited and divided into two groups. One group received 2ml of EBM and other group 2ml of 25% D is administered which was given 1 minute before Venepuncture. The outcome variables are the duration of cry after Venepuncture & NIPS score for both group.

Result : The duration of cry was found to be higher in the group receiving EBM. The neonates in 25%D groups had lower Neonatal Infant Pain Scale (NIPS) score than EBM group (chi-sqr-10.34 & p-0.0057).

Conclusion : In our study we found 25% Dextrose to be a better non-pharmacological Analgesic as compared to EBM during painful procedure in newborn.

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Key words **: Expressed Breast Milk (EBM), 25%D- 25% Dextrose, Neonatal Infant Pain Score (NIPS).**

Neonates receiving medical care are subjected to multiple painful procedures as a part of their medical management. Neuroendocrine Systems and neuroanatomic components of the neonate are sufficiently developed to permit transmission of painful stimuli[1]. As premature and full-term infants experience pain there is growing awareness to the fact that stress and discomfort in hospitalised infants is largely undertreated. As pre-natal pain and stress may alter neurodevelopment and later perceptions of painful stimuli and behavioural responses, prevention and control of pain likely to benefit infant.

As part of their intensive care, infants frequently require investigations and procedures,painful situation are quite common. Heel lance and Venepuncture are examples of several such painful procedures.There are pharmacological therapies available. Pharmacological treatments are often not used during these procedures due to apprehension of side effects and attending physician's ignorance. Non-pharmacological interventions are valuable alternatives. These include use of non-nutritive sucking[2], oral sucrose or Glucose solution[2,3], Kangaroo Mother Care[4,5] and breastfeeding[6,7]. Measurement of pain can be tricky in neonates, however, several tools or pain scales are there to assessment of pain in infants. The Neonatal Infant Pain Scale (NIPS), for example, has been validated as a reliable tool for measuring pain during various procedure in newborns[8,9]. Our objective is to compare the efficacy of non-pharmacological method in reducing pain during painful procedure.

Editor's Comment :

- Procedural Analgesia in newborn is often an ignored and underutilized area.
- 25% Dextrose is a readily available effective Analgesic and should be used before any painful procedure in newborn.
- Proper analgesia and prevention of pain in neonatal period has better neurodevelopmental outcome in future.

Materials and Methods

We undertook a prospective observational study between June 2019 to June 2020 at NICU of Silchar Medical College and Hospital.Written consent was taken from the parents of the participating Neonates. Institutional Ethical Clearance was also taken. Neonates were included within the study were term, weight more than 2 kgs, not receiving any pharmacological drug for pain relief. All sick babies including neurologically unstable and on Ventilator support were excluded.

For each Neonate, a pre-structured proforma was filled out, including the outcome variables used in our study as well as other pertinent information such as the mother's name, birth weight, sex, gender and the

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gestational age. Total 70 eligible babies were randomly assigned to either the EBM or the 25D groups at delivery. 2 ml of Expressed Breast Milk was drawn up in a sterile dropper by a Nurse before the procedure (for the EBM group)and for Infants in the 25D group, 2 ml of commercially available 25D was used.

Before the study one volunteer was trained in the assessment of NIPS score. We assessed pain by using NIPS during Venepuncture .The NIPS is a scale for assessment of pain during procedures in Neonates and was developed in 1993 by Lawrence, *et al*[10]. NIPS includes some behavioural parameters such as (facial expression, crying and movement of arms/legs) and two clinical indicators (state of arousal and breathing pattern). The maximum possible score is 7 and minimum score is 2. The NIPS is usually divided into mild pain (1-2/7), moderate (3-4/7) and severe pain (5-7/7). The duration of the cry was timed from the instant of Venepuncture till cessation of the cry. If the crying persisted for >180 sec, it had been simply recorded as duration >180 sec. The data was analysed using SPSS. The Fisher's Exact Test and Chi-square tests were done as test of significance between two groups.

Result

The study population consist of 70 babies who were equally divided in two groups ie, 35 in each. In the EBM group 20(57.14%) were male and 15(42.8%) babies were female. Term babies were 24(68.3%) and preterm babies were 11(31.3%). In the 25% Dextrose group 18(51.4%) babies are male and 17(48.5%) babies are female, 27(77.1%) term and 8(22.9%) are preterm. The distribution of the data on the sex, gestation week, postnatal age and type of delivery of the newborns in the study and a comparison of these characteristics has been provided in Table 1. Both groups were similar and there was no statistical difference (p>0.05).

In the EBM group 18 babies cried until 1 min,10 babies ceased to cry within 1-2minutes, 3 babies cried within 2-3 minutes and 4 babies cried after 3 minutes. Mean±SD of cry in EBM group is 1.65±0.92. Likewise in the 25% Dextrose group 22 babies didn't cry at all or cease to cry within 1 minute, 9 babies ceased cry within 1-2 minutes, 2 babies in 2-3minutes and 2 babies in more than 3 minutes mean±SD of cry in 25 dextrose group is 1.31±0.79. The Mann-whitney U test doesn't reveal any statistically significant difference between EBM and 25% Dextrose group (p= 0.138) (Table 2).

The mean NIPS score in EBM group (3.86±1.7) and in 25% Dextrose group (3.05±1.50). A total of 6 babies in EBM group experienced mild pain, 16 babies had NIPS score of moderate pain and 13 babies had severe NIPS score. 8 babies in 25 Dextrose group NIPS score of mild pain, 25 babies of moderate NIPS score and 2 babies of severe NIPS score. When the NIPS score was compared between two group a highly statistically significant result was found in favour of 25% Dextrose group (Chi sq=10.32, p=0.0057).

Discussion

Procedural pain has been reduced using a variety of non-pharmacological approaches. Our study result suggests that 25% Dextrose is more Analgesic than EBM.This result is evident from lower pain score obtained in Neonates receiving 25% Dextrose during Venepuncture. A study conducted by Stevene B, *et al*[11] showed that Sucrose is effective for reducing procedural pain from single events like heel lance, venepuncture and intramuscular injection in both preterm and term Neonates. Another study by R Carbajal, *et al*[12] have shown that infant with oral Glucose or Sucrose of around 20% concentration feels less pain during heel puncture indicated by less cry and these effects will be blocked by naltrexone, an opioid antagonist, suggesting a link between the orogustatory effects of a sweet solution orally and endogenous opioid pathways.

Table 1 — *Distribution of Descriptive Characteristics of Neonates*

	EBM	25% Dextrose	Chi-sqr	p-value
SEX :				
Male	20(57%)	18(51%)	0.05	P=0.810
Female	15(42%)	17(48%)		
Gestational Age :				
<36 Weeks	24(68%)	27(77%)	0.28	P= 0.591
36-38 Weeks	11(31%)	8(22%)		
Delivery Mode :				
Caesareans	18(51.4%)	17(48.6%)	0.00	P=0.99
Normal	17(48.6%)	18(51.4%)		
Postnatal age	1.29±1.322	1.09±1,12	Z=0.57	P=0.569

Table 2 — *Duration of Cry in Two Study Group*

Duration	EBM	25 Dextrose	Test Value	P Value
0-1 minute	18	22		
1-2 minutes	10	9		
2-3 minutes	3	2		
>3 minutes	4	2		
Mean±SD	1.65±0.92	1.31±0.79	Z= 1.48	P=0.138

Table 3 — *NIPS Score of Two Subgroup*

NIPS	EBM	25% Dextrose	Test Value	P Value
Mild	6	8	Chi-sq=10.32	P=0.0057
Moderate	16	25		
Severe	13	2		

A study by Osinaike *et al*[13] showed that breastfeeding during Venepuncture reduces pain in infants. Another study done by Upadhyaya, *et al*[14] observed similar analgesic effects of EBM during painful procedure.

A review by Harrison, *et al*[15] showed sufficient evidence of the effectiveness of sweet-tasting solutions. In another study by Gradin, *et al*[16], comparing the Analgesic effect of oral Sucrose (30%) with breastfeeding, shortly before the invasive procedure, showed that a combination of oral Glucose and breastfeeding have lowest pain score and significantly shorter duration of crying, however in our study duration of cry was not statistically significant. Shann reported that combination of breastfeeding and Sucrose acts better than breastfeeding or Sucrose alone for procedural pain in infants[17]. However, Brovedani, *et al*[18], using the Premature Infant Pain Profile (PIPP), found no difference in groups where infants were given 20% Glucose along with breastfeeding during Venepuncture and those who were only breastfed. Their inference was that using Glucose on a regular basis would add to the nursing burden. In another study done by Harrison *et al*[18] to compare pain responses in late preterm during heel lances demonstrated that as compared to breast milk, 25% Glucose reduces both pain scores and duration of cry more effectively.

Our study was comparing the efficacy of non-pharmacological methods like EBM and 25% Dextrose to reduce procedure pain like Venepuncture in neonates. We found that 25% Dextrose is better in reducing pain perception during Venepuncture. Vigorous cry was seen in more Neonates of the EBM group when compared to that of the 25D group.

Limitations of this study are : Consecutively admitted newborns were included in the study rather than randomised Neonates. Preterm babies are not included as appreciation of sweetness would possibly be different in them. The precise time till the cry ended was not clearly defined. Both the outcome variables in our study were subjective.

Conclusion

For procedural Analgesia in Neonate, the first-choice should be 25% Dextrose as we have demonstrated significant reduction of pain score during Venepuncture.

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