

## Original Research Article

# 25% oral dextrose as analgesia during neonatal immunisation with BCG

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## ABSTRACT

**Background:** Various animal studies have shown that repeated painful exposures can have deleterious long-term effects on neonates. Sick newborns are exposed to multiple painful procedures such as venipunctures, suctioning even removal of plasters. There are various physiologic and behavioral indicators of pain used in various standardized pain scales such as NIPS, NFCS, FLACC scale and Wong-Baker Faces pain scale. Sucrose, as an analgesic, has been used and recommended for minor painful procedures in neonates. The optimal dose of oral sucrose has not been established. The objective of this study was to study the analgesic effect of oral administration of 2 ml of 25% oral dextrose during neonatal immunization with BCG vaccine using NIPS (Neonatal/Infant Pain Scale).

**Methods:** 40 consecutively selected newborns were given 2 ml of 25% oral dextrose solution 2 minutes prior to receiving the routine intradermal BCG vaccination. 40 consecutively selected newborns served as controls. The pain response in both groups was assessed using the standardized Neonatal Infant Pain Scale (NIPS).

**Results:** Of the total 80 neonates included in the study, 40 were included in the dextrose group and 40 served as controls. 77.5% of the dextrose group were term babies compared to 72.5% in the control group. 20% of the dextrose group showed a NIPS score  $\geq 6$  while 40% in the control group had a similar NIPS score.

**Conclusions:** A total of 80 newborns were included in this study, of which 40 (22 males, 18 females) received 25% oral dextrose solution prior to the BCG vaccine. The group which received dextrose was found to have less indicators of pain such as change in breathing pattern, cry and facial expression.

**Keywords:** Analgesia, BCG, Dextrose, NIPS, Routine immunisation

## INTRODUCTION

Pain management in the neonate is a much-neglected aspect of newborn care. It is considered to be of prime importance since various animal studies have shown that repeated painful exposures can have deleterious long-term effects such as altered pain perception and permanent neuroanatomic and behavioral abnormalities. However, there is no definitive conclusive data in humans. Sick newborns are exposed to multiple painful procedures such as blood sampling, heel pricks, suctioning, gavage tube placement and even tape

removal. However, pain reducing therapies are often underused and overlooked in neonates. Adequate pain management requires competent pain assessment, which is difficult to perform in neonates.

Physiologic indicators of pain include changes in heart rate, respiratory rate, blood pressure, oxygen saturation and plasma cortisol or catecholamine concentrations. Behavioral indicators include changes in facial expressions, body movements, and crying. Various tools for assessment of pain are available such as NIPS (Neonatal Infant Pain scale), NFCS (Neonatal Facial

Coding System), FLACC (Face, Legs, Activity, Cry, Consolability) scale and Wong-Baker Faces pain scale.

Sucrose is a disaccharide consisting of fructose and glucose. Dextrose is another name for glucose, a monosaccharide. These substances have been shown to produce calming behaviors and to reduce procedural pain in neonates. The mechanism of action of sweet taste in producing analgesia appears to be opioid-mediated and it has been shown that repeated doses may result in tolerance. This has been studied in rat models.<sup>1</sup>

As an analgesic, oral sucrose has been used and recommended by the American Pain Society for minor painful procedures in neonates. Various amounts and concentrations of sucrose have been tested but the optimal dose of oral sucrose has not been established.

In a Cochrane review of various randomized controlled trials on the subject, it has been found that a single dose of 0.05 to 2 ml of 12% to 50% sucrose delivered by non-nutritive sucking (NNS) using a pacifier for approximately 2 minutes prior to a painful event is considered safe and effective in decreasing the pain experienced by the infant.<sup>2</sup>

Expressed breast milk, oral sucrose and oral dextrose have been accepted methods for non-pharmacological analgesia in neonates in addition to NNS and swaddling.

Various pain assessment scales exist for newborns, but none have demonstrated their superiority. These scales may be one-dimensional, measuring only the pain intensity or multi-dimensional, measuring the multiple dimensions of pain. Among the several multi-dimensional pain scales for children and infants, commonly used are the Neonatal Facial Coding System (NFCs), the Neonatal Infant Pain Scale (NIPS) and the Premature Infant Pain Profile (PIPP).

### ***Need for the Study***

Optimal pain management in newborns is an integral yet much neglected aspect of routine newborn care. Most of the studies done previously were conducted on 6, 10 and 14 weeks old infants receiving the intramuscular DPT vaccine. This study aims to assess the efficacy of oral dextrose as analgesia during the newborn intradermal BCG vaccination.

## **METHODS**

This prospective, hospital based study was carried out in the Department of Pediatrics of Yenepoya Medical College Hospital; a tertiary health care referral centre in Mangalore, Karnataka over a 3-month period from August 2017 to October 2014.

All stable consecutively selected inborn neonates were included in the study after obtaining informed consent

from the parents. The study has been cleared by the Institution's Ethics Committee.

### ***Inclusion criteria***

All hemodynamically stable newborns receiving their BCG vaccination irrespective of their gestational age or birth weight

### ***Exclusion criteria***

- Sick babies who were admitted in NICU at the time of this study
- Febrile babies
- Babies who were hemodynamically unstable.

40 stable consecutive newborns admitted in our postnatal ward during the study period included in the dextrose group were administered 2 ml of 25% dextrose solution orally using a dropper 2 minutes prior to immunization by a trained volunteer.

All babies received the standard dose of intradermal BCG vaccine on their left upper arm, administered by a pediatrician. The baby was observed for 1 minute before the pain response was recorded on the NIPS by the trained volunteer. Similarly, 40 stable consecutively selected newborns were included in the control group and were not given anything orally. Their pain response was again recorded using NIPS by the same volunteer. Each baby was allotted a serial number and the details of each baby in both groups were recorded including the age (calculated from date and time of delivery), gender, birth weight and mode of delivery. These details were recorded in a preformed study proforma.

The data thus collected was analysed using the Chi-square test on SPSS version 21. No blood tests were done for the purpose of this study.

## **RESULTS**

This study was conducted on a total of 80 newborns, 40 in the dextrose group with 18 females and 22 males and 40 in the control group of which 22 were females and 18 males. 31 (77.5%) babies in the dextrose group and 29 (72.5%) in the control group were term babies while 9 (22.5%) in the dextrose group and 11 (27.5%) in the control group were preterm babies. The average birth weight of the dextrose group was 2.91 kg and that of the control group was 2.74 kg. The minimum age of the babies was <24 hours while the maximum was 20 days with an average age of 4.35 days in both groups. 8 babies (20%) in the dextrose group had a NIPS score >4 indicative of severe pain as compared to 16 babies (40%) in the control group. 42.5% of the babies in the dextrose group experienced mild to moderate pain.

The most common manifestation of pain in both the groups was found to be grimace, i.e., 72.5% in the

dextrose group and 70% in the control group. The most significant differences were found in the parameters 'arms' and 'legs'. 87.5% of babies in the dextrose group had arms relaxed/restrained as opposed to 55% in the control group ( $p$  value = 0.001).

Similarly, 85% babies had relaxed/restrained legs in the dextrose group while only 57.5% in the control group had the same ( $p$  value = 0.0006).

**Table 1: Demographic and clinical data of the two study groups.**

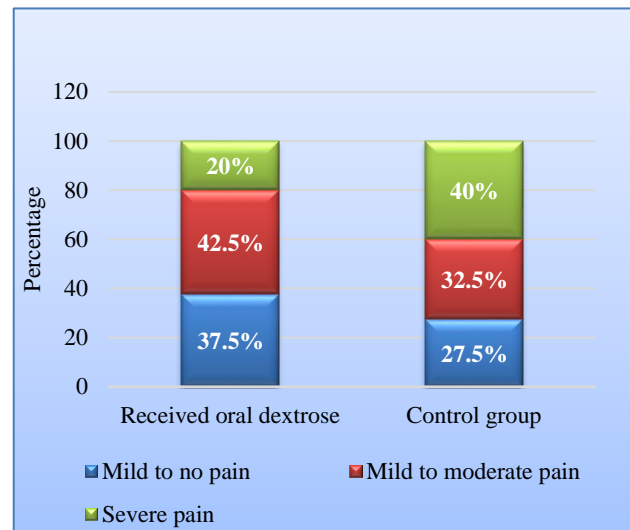
	Received dextrose	Control group
<b>Gestation</b>		
Term	31 (77.5%)	29 (72.5%)
Preterm	9 (22.5%)	11 (27.5%)
<b>Gender</b>		
Male	22 (55%)	18 (45%)
Female	18 (45%)	22 (55%)
<b>Postnatal age</b>		
>5 day	11 (27.5%)	14 (35%)
<5 days	29 (72.5%)	26 (65%)
<b>NIPS score (p-value 0.15)</b>		
Mild to no pain	15 (37.5%)	11 (27.5%)
Mild to moderate pain	17 (42.5%)	13 (32.5%)
Severe pain	8 (20%)	16 (40%)
Total	40	40

**Table 2: Comparison of scores in the various parameters of NIPS.**

	Received dextrose	Control group	
<b>Facial Expression</b>			
Relaxed muscles	11 (27.5%)	12 (30%)	p-value 0.8
Grimace	29 (72.5%)	28 (70%)	
<b>Cry</b>			
No cry	9 (22.5%)	6 (15%)	p-value 0.69
Whimper	16 (40%)	17 (42.5%)	
Vigorous cry	15 (37.5%)	17 (42.5%)	
<b>Breathing pattern</b>			
Relaxed	24 (60%)	18 (45%)	p-value 0.18
Change in breathing	16 (42.5%)	22 (55%)	
<b>Arms</b>			
Relaxed/restrained	35 (87.5%)	22 (55%)	p-value 0.001
Flexed/extended	5 (12.5%)	18 (45%)	
<b>Legs</b>			
Relaxed/Restrained	34 (85%)	23 (57.5%)	p-value 0.0006
Flexed/Extended	6 (15%)	17 (42.5%)	
<b>State of Arousal</b>			
Sleeping/Awake	19 (47.5%)	17 (42.5%)	p-value 0.58
Fussy	20 (50%)	23 (57.5%)	

Vigorous cry was seen in 37.5% of babies in the dextrose group while it was seen in 42.5% of babies in the control group ( $p$  value = 0.69). 40% of babies in the control group experienced severe pain when compared to 20% in the dextrose group. The difference in the NIPS scores

between the two groups were not however found to be statistically significant ( $p$  value 0.15).



**Figure 1: Comparison of the NIPS score of the two groups.**

## DISCUSSION

A study was done by Gibbins et al, among term and preterm babies to compare between 3 different interventions as analgesics namely, sucrose and NNS, only oral sucrose and sterile water with NNS serving as controls.<sup>3</sup> There were significant differences in the pain responses among the three groups. It was concluded that a combination of sucrose and nonnutritive sucking was the most efficacious intervention for procedural pain relief.

Various clinical trials including the one done by Gradin M et al found that oral glucose was effective in reducing pain response and it was also found to be better than local anesthetic creams.<sup>4</sup> Both the pain scale scores and the duration of crying were less in the group which received oral 30% glucose prior to the procedure.

In another study by Gradin M et al comparing the analgesic effect of oral sucrose versus breast feeding shortly before the painful procedure, a solution of 30% sucrose was used.<sup>5</sup> Results showed that a combination of oral glucose and breast-feeding showed the lowest pain score and significantly shorter duration of crying. Similar results have been published by Hatfield LA et al where babies receiving oral sucrose 2 minutes before the painful procedure showed lower pain scores.<sup>6</sup>

A randomized, controlled trial was conducted by Gray L et al on full term newborns who were given 1 ml of 25% sucrose solution 2 minutes before the vaccination (D.P.T), and an additional group was given radiant warmth from an infant warmer prior to the vaccination. Their results showed that the sucrose plus warmer group cried and grimaced for 50% less time after the

vaccination than the sucrose alone group and they also showed less physiological response to pain.<sup>7</sup> Many such studies have proved that oral dextrose (different concentrations have been used in different studies) reduced the crying time of infants experiencing procedural pain.<sup>8-11</sup>

The other methods commonly used for management of pain include expressed breast milk, non-nutritive sucking or oral sucrose.

This study sought to determine if 25% oral dextrose solution had a significant analgesic effect in the neonates during immunisation procedure. The advantages of this study were the easy availability of the 25% oral dextrose and the use of the standardised pain scale, NIPS. The drawbacks of this study include the relatively small sample size and the fact that the dextrose and control groups were not exactly. It was not determined if the babies were fed prior to the procedure. All the babies did not receive the vaccination on a fixed postnatal day which might have some influence on their experience of pain.

## CONCLUSION

Based on the results of the study, oral dextrose solution given orally has not been found to have a statistically significant analgesic effect but can be considered as an adjunct to other proven analgesic means.

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*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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