

Research Article

Sucrose and Facilitated Tucking for Pain Among Neonates Receiving Vaccination, in Puducherry

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ABSTRACT

Neglected pain in neonates leads to various ill effects and it can be prevented by using simple and safe non-pharmacological pain relieving measures. Pharmacologic agents are not recommended in neonates for acute pain due to invasive procedures however, administration of 24% oral sucrose solution is found to be effective. The objective of this study was to assess the efficacy of 24% oral sucrose in combination with Facilitated tucking during BCG Vaccination through intradermal route in term neonates which is not done elsewhere. Fifty five healthy term neonates who fulfilled the inclusion criteria such as gestational age above 37 weeks, within 24 hours of birth age, and neonates delivered only through spontaneous vaginal delivery were included in the study. The study intervention consists of administration of 2 ml of oral 24% sucrose 2 minutes before BCG Vaccination through intradermal route and Facilitated tucking at the time of vaccination. The primary outcome measure of cumulative NIPS score at 0, 3, 5 minutes was not significant in both the study groups. Whereas there was significant reduction in the level of pain and mean cry time in the neonates of sucrose group. Heart rate and oxygen saturation after intradermal injection also showed significant ($p < 0.001$) difference among the neonates, who received 24% of oral sucrose & Facilitated tucking than for neonates of control group. Thus oral (24%) sucrose solution given 2 minutes before injection was effective in reducing level of neonatal pain following Intradermal Vaccination. It is a simple, safe and fast acting analgesic and should be considered for minor invasive procedures in term neonates which last for 5-7 minutes.

Keywords: BCG Vaccine, sucrose, facilitated tucking, Neonates, Procedural pain, NIPS score.

INTRODUCTION

Vaccination is a routine as well as important procedure in the pediatric health care system which brings down the mortality as well as morbidity rate. Even though the vaccine has its own advantages it also has its adverse effects as well as complications such as swelling, pain, redness. Pain produced by this intentional vaccination procedure varies based on various factors such as the medications used, quantity of the medications used, size of the gauge of the needle used, position of the neonate and the muscles used/handled by the health care providers during vaccination procedure. Vaccination does not produce pain alone but also causes anxiety and stress in neonates and among their parents. Neonates respond to painful stimuli in a different way and it is difficult to identify and treat. Generally there is a myth among people that a neonate does not feel pain as it has immature neural development, it is dangerous to give the neonates powerful analgesia because of the risk of addiction. In 2014 a review of neonatal pain management practice in intensive care highlighted that the neonates experience an average of 11 painful procedures per day out of which 60% of neonates do not receive any kind of pain reducing or management medication. There is a need for evidences that are safe and

effective in relieving the pain among neonates during intradermal vaccination. The pain management intervention used should be simple, practicable, cost effective and safe. There are various individual non-pharmacological interventions which were proved effective in alleviation of pain in newborns in various situations¹.

Various researchers recommend for clubbing of two non-pharmacological interventions which can be more effective than the application of individual interventions². The American academy of pediatrics, along with the Canadian Pediatric Society, and the American Pain Society developed policy to address the need to minimize painful or stressful procedures and eliminate pain-associated suffering^{3,4}.

Sucrose has been widely recommended for routine use during painful procedures in newborn and young infants. Research demonstrates that sucrose can safely and effectively provide analgesia for neonates' undergoing painful procedures. The analgesic effect of sucrose is mediated via opioid receptors in the tongue and it was also proved that it is not effective if the sucrose given via Ryle's tube and it was also proved that the sucrose concentration less than 24% was found to be not so effective⁵⁻¹¹.

The administration of sucrose or the combination of sucrose with non-nutritive sucking is one of the most frequently studied interventions for the relief of procedural pain in neonates¹². But none of the researchers clubbed the 24% oral sucrose solution with the facilitated tucking procedure which is also one method of non-pharmacological intervention used for acute pain in neonates and also addresses the psychological need like warmth of the neonate.

MATERIALS AND METHODS

After formal approval from the Ethical Committee of Pondicherry Institute of Medical sciences and individual informed consent from mothers of the neonates, data were collected from 55 healthy newborn delivered at Pondicherry Institute of Medical sciences, Puducherry. In addition the mothers of the neonates were informed of their right to withdraw any time during the course of the study. Neonates of gestational age above 37 weeks, age within 24 hours, and neonates delivered only through spontaneous vaginal delivery were included in the study. Neonates receiving any other vaccination apart from BCG like Hepatitis B Vaccine or any other injection and birth trauma, Mothers/Neonates with known HIV or other immunosuppressive disorders were excluded from the study. All neonates who cried before BCG vaccination or passed stool/urine during sampling were excluded from analysis. Neonates were randomly assigned in to the study and control group. The number of samples in each group was 55 and 100 respectively.

Data were collected in a quiet room in the postnatal ward. Neonates were brought to a quiet alert state for data collection. The sequence of phases were

Primary Phase

During this phase placement of pulse oximeter (MASIMO) electrodes on left hand to assess Respiratory rate (RR), Heart rate (HR) and blood O₂ saturation (O₂) before intervention by the blinded principal Investigator.

Interventional Phase

2 ml of 24% oral sucrose was given to all the neonates of experimental groups 2 minutes before BCG Vaccination by a pediatric nurse and also kept neonates in facilitated tucking position during vaccination procedure. Another pediatric nurse administered BCG Vaccine. To minimize variability of the stimulus, the same Pediatric nurse performed the injection procedure throughout the study. Neonates of control group received only the facilitated tucking which was the routine care of the institution. The 0.5 ml of BCG Vaccine injected into the right deltoid region through intra dermal route with a 24G syringe and pressure held with gauze.

Post interventional phase

the blinded researcher observed the parameters: like cry, breathing pattern, face expression, arms and legs movements and state of arousal of NIPS scale, to assess the level of pain immediately (i.e) at 0, 3 & 5 minutes. The Physiological parameter like respiratory rate, heart rate and blood O₂ saturation were also measured. The Neonatal Infant Pain Scale is a behavioral scale and can be utilized in both full term and preterm infants⁽¹³⁾. The secondary

outcomes of the study "cry" which is measured from the time of onset to till 5 minutes. Neonates were observed for five minutes in order to fully assess each indicator. Total pain score ranges from 0-7. The pain levels are: 0-2, No pain to mild pain; 3-4, mild to moderate pain; > 4 - severe pain¹³.

Totally 10 neonates were excluded from the study. The details are that from study group 2 neonates were cried at the time of data collection due to wet diaper, 3 mothers of neonates declined to participate in the study and 5 neonates were not included in the study as they became sick and shifted to NICU from the postnatal ward.

The data collected was scored and tabulated. The data was entered in master coding sheet and saved in EXCEL. Analysis was done with SPSS 21.00 version. Statistical analysis was done with ANOVA (analysis of variance) to assess the effect within the groups. Post-hoc analysis was done using inferential statistical method. Crying time was analyzed by Independence sample test. Repeated measures ANOVA were used to compare the Respiratory rate, heart rate and SpO₂ over time and its interaction with the intervention group. A p value of <0.05 was considered a statistically significant level of difference.

RESULTS

Average gestational age of the neonatal participants was 36.5% in the study group. In the study group the female neonates were found to be more 32 (58%) than male neonates 22 (42%). Most of the neonates were delivered through spontaneous vaginal delivery 22 (42%) and remaining 32 (58%) born through assisted type of delivery like forceps and vacuum delivery and none born through caesarian session. The mean APGAR score of the neonates at 0 min was 7.7 and at 5 min was 8.7.

When both the study groups were compared using the group averages for the physiological parameters (RR, HR, SPo₂) the RR and SPo₂ was statistically significant in the sucrose group than control group at all the three observations (Table 1&2).

The Neonatal and Infant Pain Score was used to score level of pain in newborn and it was found that in sucrose group 25.3% neonates had moderate pain 29.2% had mild pain. In control group more than half of the neonates 58.6% had moderate pain and 43.4% neonates had mild level of pain, which shows that more number of neonates had reduction in the degree of pain from moderate to mild level of pain in the sucrose group thus the effectiveness of sucrose and facilitated tucking for pain management was more (Table 3).

There was no significant difference in the total NIPS score, both in sucrose and control group. There was highly significant difference in the mean cry time among the sucrose and control group neonates. There were no adverse events observed in neonates of any groups.

DISCUSSION

The quantification of neonatal pain still remains a challenge among the health care personnel. There is raise in need on concentration about neonatal pain, its

Table 1: Comparison of Respiratory rate between Control group and Sucrose group.

RR at different time	Control Group [n = 100] Mean±SD	Sucrose Group [n = 55] Mean±SD	t-Value	p Value	95% CI	
					Lower	Upper
Before Painful Procedure	60.72 ±2.503	59.31±3.13	3.066	0.003**	0.501	2.320
0 Min	58.64±3.423	70.327±3.328	20.543	0.000***	-12.811	-10.563
3 Min	70.95±3.398	68.945±2.460	3.853	0.000***	0.977	3.032
5 Min	69.88±5.968	57.018±3.525	14.627	0.000***	11.1247	14.599

**Highly Statistical Significant at (p < 0.01)

***Very Highly Statistical Significant at (p < 0.001)

Table 2: Comparison of Oxygen saturation between Control group and Sucrose group

SPo2 at different time	Control Group [n = 100] Mean±SD	Sucrose Group [n = 55] Mean±SD	P Value	95% CI	
				Lower	Upper
Before Painful Procedure	97.06±1.377	96.982±1.421	0.738	-0.384	0.540
0 Min	97.41±1.239	96.525±1.321	0.000***	0.464	1.305
3 Min	97.57±1.103	97.025±1.357	0.008**	0.147	0.942
5 Min	97.77±0.7895	96.084±1.091	0.000***	1.385	1.987

**Highly Statistical Significant at (p < 0.01)

***Very Highly Statistical Significant at (p < 0.001)

Table 3 Comparison of level of pain between groups.

Study Group	NIPS Score			
	Mild		Moderate	
	Frequen cy	Percenta ge	Frequen cy	Percenta ge
Contr ol	49	43.4	51	58.6
Sucros e	33	29.2	22	25.3

assessment and management of acute pain produced due to painful procedures in clinical settings. A variety of pain assessment approaches namely behavior observation; physiological technique have been used to accurately quantify neonates pain perception¹⁴.

The use of oral sucrose has been the most extensively studied pain intervention in newborn care today. More than 150 published studies relating to sucrose effect in newborn have been identified¹⁵. None of the study addressed the level of pain produced due to intra dermal injection/Vaccination. But there are number of studies reveals about the pain produced by IM injection, IV injection, Heels tick, removal of adhesive tapes etc.,

The present study findings revealed that oral administration of 24% of sucrose and facilitated tucking during BCG vaccination (intra dermal injection) results in decreased level of pain by the neonates as compared to intra dermal injection administration with routine interventions. A reduction in response to pain was observed among neonates who received 24% oral sucrose solution and facilitated tucking during Intra dermal injection administration (BCG Vaccination).

The present study used crying as an indicator of pain. Cry time was markedly suppressed in the sucrose group. The study intervention was associated with the total cry time

and there was significantly reduced total mean cry time in neonates receiving sucrose and facilitated tucking during an intra dermal injection administration than the control group neonates.

Other studies have reported similar results for example; skin to skin contact was shown to be effective in reducing the pain experienced during a heel lance¹⁶. Bilgen et al (2001) compared the analgesic effects of sucrose, expressed breast milk and breast feeding during heel pricks¹⁷. Gray et al (2002) reported that breast feeding before, during and after heel prick markedly reduced crying as well as grimacing and prevented an increase in heart rate in term neonates as compared with swaddled infants in their cots¹⁸. Giving infants a few drops of 24% sucrose solution and exposing them briefly to radiant warmth, which mimics some elements of breast-feeding, before vaccination led to a 50% reduction in time the newborns cry and grimacing after the vaccination¹⁹.

Horwitz (2002) found that following the administration of the Sucrose, either with a syringe, dropper or a pacifier, transient desaturation and choking were noted in some neonates. And concluded that the volume as well as the administration techniques will influence the degree of these adverse effects²⁰. Thus, in the present study it was made sure that the 1ml of sucrose is given from the corner of the mouth through a new disposable syringe which ensure the slow and aseptic administration of the sucrose solution.

Management requires accurate pain assessment and its treatment by pharmacological and non pharmacological interventions²¹. Although, the use of sucrose and recognizing its advantage in minimizing procedure related pain in the neonates, the advantage is valid only when discussing sucrose analgesic effect during a single painful event (heel lancing or venipuncture). Thus, the researcher

Table 4: Comparison of Total NIPS score and Cry time.

Outcome	Control Group		Sucrose Group		p Value	95% CI	
	[n = 100]	Mean ± SD	[n = 55]	Mean ± SD		Lower	Upper
Cry time (Seconds)		60.940±3.434		44.273± 2.004	0.000**	15.669	17.664
NIPS Score		3.600±0.4924		3.873±4.933	0.589	-1.253	0.708

** Highly Statistical Significant at [p < 0.01]

wants to club two interventions like sucrose and facilitated tucking where the analgesic effect provided by these two interventions which may last longer than the single individual intervention. Therefore, implementing interventions to reduce the level of pain in neonates is essential. However, there has been very little research to determine a natural, cost-effective intervention to pain perception in the neonates²². Since the two interventions of oral sucrose solution and Facilitated tucking are safe, cost effective, and easy to use and also no study has been conducted on the effectiveness of the two interventions on the pain induced by BCG vaccination in neonates, the researchers have conducted this trial.

CONFLICT OF INTERESTS

The authors declare that they have no competing interests. In addition, this study was not funded.

STATEMENT OF HUMAN AND ANIMAL RIGHTS

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (Institutional and National) and with the Helsinki Declaration of 1975, as revised in 2008(5).

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