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Original Article

Assessment of Efficacy of Sucrose Analgesia in Newborns Undergoing Painful Medical Procedures

Prashant Choudhary[1], Saurabh Piparsania[2], Randheer Khurana[3]

[1,2]Assistant professor, [3]Senior resident, Department of Pediatrics; Index Medical College Hospital and Research Centre, Indore. (M.P.)-452016, India.

***ABSTRACT*:**

Background: Newborn babies experience pain similarly and probably more intensely than older children and adults.From the neonatal literature, which most frequently examined pain responses to heel lance, it seems that sucrose is a safe, easy-to-administer, inexpensive and effective analgesic for short painful procedures. Hence; we planned the present study to assess the efficacy of sucrose analgesia in newborns undergoing painful medical procedures. **Materials & methods:** The present study included evaluation of efficacy of sucrose analgesia in newborns undergoing painful medical procedures. 24 percent of sucrose solution was given to newborns under going painful medical procedures .We measured the primary outcome in terms of pain. A validated pain measure was used for assessing the pain. This was followed by calculation of NFCS for each procedure. All the results were analyzed by SPSS software. **Results:** In the present study, we analyzed a total of 100 newborns. All these subjects were broadly divided into two study groups; the sucrose group and the placebo group. Both the groups were further divided into two subgroups each; non-diabetic mother's subgroup and diabetic mother's subgroup. We observed statistically significant results while comparing the NFCS during venepuncture in between the sucrose group and placebo group among all the subgroups. **Conclusion:** By the use of sucrose statistically significant pain reduction occurs among newborns for painful medical procedures conducted during the first two days of birth.

Key words: Analgesia, Sucrose, Newborn

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Corresponding Author: Dr. Saurabh Piparsania, Assistant professor, Department of Pediatrics; Index Medical College Hospital and Research Centre, Indore. (M.P.)-452016, India.

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INTRODUCTION

Infants, including newborn babies, experience pain similarly and probably more intensely than older children and adults.[1] They are also at risk of adverse long term effects on behaviour and development, through inadequate attention towards pain relief in early life. However, the issue of analgesia in young babies has been largely neglected in most clinical settings, despite subjecting them to painful diagnostic and therapeutic procedures.[2, 3] Several therapeutic and preventive strategies, including systemic and local pharmacological and non-pharamacological interventions, are reported to be effective in relieving pain in infants.4

From the neonatal literature, which most frequently examined pain responses to heel lance, it seems that sucrose is a safe, easy-to-administer, inexpensive and effective analgesic for short painful procedures. A growing number of studies, looking at infants undergoing immunizations, suggest that this analgesic effect may indeed extend past the neonatal period into infancy. Nevertheless, the upper limit of this effect is unknown in terms of age and appropriate sucrose strength.[5- 7]Hence; we planned the present study to assess the efficacy of sucrose analgesia in newborns undergoing painful medical procedures.

MATERIALS & METHODS

The present study was planned in the department of Paediatrics of the Index medical college and research centre and it included evaluation of efficacy of sucrose analgesia in newborns undergoing painful medical procedures. Inclusion criteria for the present study included:

- Healthy newborns more than 36 weeks of gestation were included in the present study,
- Mothers with negative history of any other systemic illness

- Newborns with absence of neurologic or congenital anomalies

24 percent of sucrose solution or placebo was given to all the newborns orally within 48 hours of birth based on the criteria described previously in the literature.[8]
A syringe was used by the nurse, assigned to each and every newborn, to deliver sucrose or placebo to the anterior portion of the tongue. We measured the primary outcome in terms of pain.During intramuscular injection of vitamin K within first hour after birth, all recording of the procedure was done. A validated pain measure was used for assessing the pain. This was followed by calculation of new born facial coding system for each procedure.[9] Monitoring of all the adverse events was done. All the results were analyzed by SPSS software. Student t test and chi- square test was used for assessment of level of significance. P- value of less than 0.05 was taken as significant.

RESULTS

In the present study, we analyzed a total of 100 newborns. All these subjects were broadly divided into two study groups; the sucrose group and the placebo group. Both the groups were further divided into two subgroups each; non-diabetic mother's subgroup and diabetic mother's subgroup. All the subgroup consisted of 25 newborns in each group. While assessing the NFCS during intramuscular injection, we observed that NFCS during intramuscular injection in the sucrose group and placebo groups of non-diabetic mothers was found to be 6.5 and 7.6 . We observed statistically significance results while comparing the NFCS during heel lance and venepuncture in between the sucrose group and placebo group among all the subgroups.

Table 1: Details of the subjects included in the present study

Parameter		Value	Value
Sucrose group	Newborns of non-diabetic mothers	25	50
	Newborns of diabetic mothers	25	
Placebo group	Newborns of non-diabetic mothers	25	50
	Newborns of diabetic mothers	25	
Total subjects		100	100

Graph 1: Distribution of subjects included in the present study

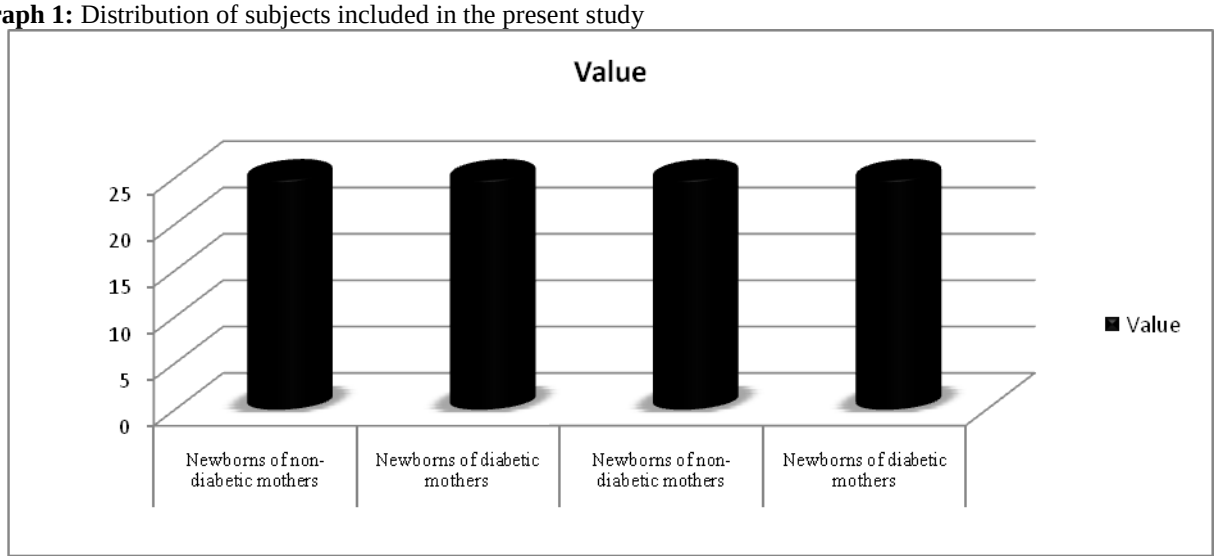
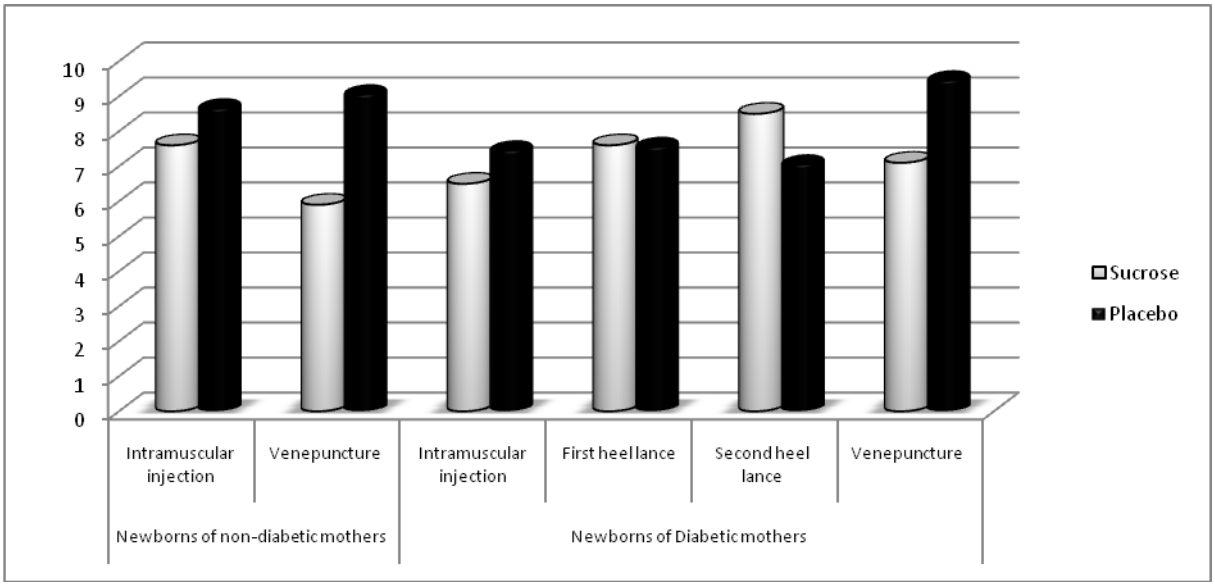


Table 2: NFCS during intramuscular injection

Group		Sucrose	Placebo	P- value
Newborns of non-diabetic mothers	Intramuscular injection	6.5	7.6	0.52
	Venepuncture	4.3	7.7	0.01*
Newborns of Diabetic mothers	Intramuscular injection	6.0	6.9	0.81
	First heel lance	6.3	6.4	0.27**
	Second heel lance	5.5	7.1	0.02*
	Venepuncture	4.6	7.7	0.03*

*: Significant
**: Assessment of results of heel lances was done using multivariate analysis

Graph 2: Comparison of NFCS during intramuscular injection



DISCUSSION

In the present study we observed that while assessing the NFCS during intramuscular injection in the sucrose group and placebo groups of non-diabetic mothers was found to be 7.6 and 8.7. We observed statistically significant results while comparing the NFCS during venepuncture in between the sucrose group and placebo group among all the subgroups. Stevens B et al determined the efficacy, effect of dose and safety of oral sucrose for relieving procedural pain in neonates. They used the standard methods of the Cochrane Neonatal Review Group. Electronic and manual searches were performed in November 2011 for published randomised controlled trials (RCTs) in MEDLINE (1950 to November 2011), EMBASE (1980 to 2011), CINAHL (1982 to November 2011) and the Cochrane Central Register of Controlled Trials (The Cochrane Library). RCTs in which term, preterm, or both term and preterm neonates (postnatal age maximum of 28 days after reaching 40 weeks' postmenstrual age) received sucrose for procedural pain. Control conditions included no treatment, water, pacifier, positioning/containing or breastfeeding. Main outcome measures were physiological, behavioural, or both pain indicators with or without composite pain scores. A mean difference (MD) with 95% confidence intervals (CI) using the fixed-effect model was reported for continuous outcome measures. Trial quality was assessed as per The Cochrane Collaboration Fifty-seven studies enrolling 4730 infants were included. Results from only a few studies could be combined in meta-analyses. When Premature Infant Pain Profile (PIPP) scores were pooled, 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. Sucrose significantly reduced duration of total crying time, but did not reduce duration of first cry during heel lance. Oxygen saturation (%) was significantly lower in infants given sucrose during ROP examination compared to controls. Results of individual trials that could not be incorporated in meta-analyses supported these findings. The effects of sucrose on long-term neurodevelopmental outcomes are unknown. Sucrose is safe and effective for reducing procedural pain from single events. An optimal dose could not be identified due to inconsistency in effective sucrose dosage among studies.[10]

Taddio A et al evaluated the effectiveness and safety of sucrose in newborns undergoing various medical procedures within 2 days of birth. They performed a double-blind, randomized controlled trial. They included newborns (≥ 36 weeks gestation) of diabetic mothers and nondiabetic mothers. Each newborn received 2 mL of a 24%-sucrose or placebo solution before all procedures. They used the Premature Infant Pain Profile to assess pain during intramuscular injection of vitamin K, venipuncture for the newborn screening test and the first 3 heel lances for glucose monitoring (newborns of diabetic mothers only). Scores ranged from 0 (no pain) to 18 (maximum pain). They included 240 newborns (120 from diabetic mothers, 120 from nondiabetic mothers). The overall mean pain score was lower among newborns who received sucrose than among those who received a placebo. They found that pain scores during intramuscular injection did not differ significantly between the sucrose and placebo groups for newborns of diabetic or nondiabetic mothers. During venipuncture, newborns who received sucrose had lower pain scores compared with those who received a placebo. Among newborns of diabetic mothers, there was no difference in pain during the first 3 heel lances or mean glucose levels between the sucrose and placebo groups. They found a modest reduction of pain in newborns of both diabetic and nondiabetic mothers when sucrose was used for all medical procedures performed in the first 2 days after birth.[11]Curtis SJ et al reported of the effect of sucrose, pacifier or the combination thereof for the procedural pain of venipuncture in infants in the pediatric emergency department population. The study design was a double

(sucrose) and single blind (pacifier), placebo-controlled randomized trial--factorial design carried out in a pediatric emergency department. The study population was infants, aged 0-6 months. Eighty-four patients were randomly assigned to one of four groups: a) sucrose b) sucrose & pacifier c) control d) control & pacifier. Each child received 2 ml of either 44% sucrose or sterile water, by mouth. The primary outcome measure: FLACC pain scale score change from baseline. Sucrose did not significantly reduce the FLACC score, crying time or heart rate. However sub-group analysis revealed that sucrose had a much greater effect in the younger groups. Pacifier use reduced FLACC score (not statistically significant), crying times (statistically significant) but not heart rate. Subgroup analysis revealed a mean crying time difference of 76.52 seconds ($p < 0.0171$) (0-1 month) and 123.9 seconds ($p < 0.0029$) (1-3 month). For subgroup age > 3 months pacifier did not have any significant effect on crying time. Age adjusted regression analysis revealed that both sucrose and pacifier had significant effects on crying time. Crying time increased with both increasing age and increasing gestational age. Pacifiers are inexpensive, effective analgesics and are easy to use in the PED for venipuncture in infants aged 0-3 months.[12]

CONCLUSION

Under the light of above results, the authors concluded that by repeated use of sucrose, statisticaly significant pain reduction occure among new born for heel lance and venepunture during the first 2 days of birth. However; future studies are recommended.

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