

## Original Research Article

# Comparison of the effectiveness of oral sucrose solution and topical anaesthetics during immunization in infants between age 6 weeks-6 months

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### ABSTRACT

**Background:** Routine childhood immunization is a proven tool for eradicating and controlling infectious diseases. Despite its key role in maintaining global public health, many individuals either refuse or delay immunization because of pain from the needle puncture. Several methods have been employed to reduce injection pain during immunization in children.

**Methods:** Study comprised of 210 healthy infants coming for immunizations. They were divided into three groups A, B and C having equal number of infants. Group A was given oral sucrose solution, group B was given topical anaesthetic prior to immunization; whereas group C acted as controls. Response to pain was recorded among the three groups and findings were analyzed.

**Results:** Infants enrolled in group A, i.e. those who were given 24% oral sucrose solution before immunization showed significant reduction in pain (measured by modified behaviour pain scale) as compared to control group at 15 seconds and 60 seconds of injection administration. Infants enrolled in group B, i.e. those who were sprayed topical local anaesthetics (10% lignocaine spray) before immunization showed significant reduction in pain as compared to control group at 15 seconds and 60 seconds of injection administration.

**Conclusions:** Administration of oral sucrose solution and application of topical local anaesthetics are effective measures to reduce injection pain during immunization. Administration of oral sucrose solution before immunization showed greater reduction in pain as compared to application of topical local anaesthetics in present study.

**Keywords:** Immunization, Oral sucrose solution, Topical local anaesthetics

### INTRODUCTION

Immunization is a necessary aspect of health care of children. It is the safest and most effective way to prevent serious illness and death. In fact, vaccinations prevent approximately 2.5 million deaths every year. The Centers for Disease Control and Prevention recommends vaccinations to prevent 17 life threatening diseases; consequently adherence to recommended vaccination

schedule means children will receive an average of 18-24 injections by the time they are 2 years old.<sup>1</sup> The pain associated with such injections is a source of distress for children, their parents and those administering the injections. If not addressed, this pain can lead to pre-procedural anxiety in future, needle fears and healthcare avoidance behaviour, including non-adherence to vaccine schedules.<sup>2</sup> It is estimated that 25% of adults have fear of needles with most fears developing in childhood.<sup>3</sup> About

10% of population avoids vaccination and other needle procedures because of needle fears.<sup>3</sup> During injection, parental behaviour, securing the child, distraction, use of sucrose, topical anaesthetics, injection techniques, site, pressure and sequence of injections are the factors which determine pain experienced by child.<sup>4</sup>

It is believed that learning about pain starts with first painful experience and it may have effects on subsequent pain perception and response. There is also some evidence that neonatal pain experience may have far reaching effects even upto the preschool age and beyond.<sup>5,6</sup> Multiple influences, including infant factors as well as characteristics of caregivers, together contribute to such events in development.

Omer SB studied the vaccine refusal and the risks of vaccine preventable diseases in children.<sup>7</sup> Authors reported that there is an association between an increase in vaccine refusal and geographical clustering of cases of vaccine preventable diseases. Children with exemption from school immunization requirements are at increased risk of measles and pertussis and can infect others who are too young to be vaccinated, cannot be vaccinated for medical reasons, or were vaccinated but did not have a sufficient immunologic response. One of the well documented barriers to immunization is pain from the requisite needle puncture or shot. Taddio A, et al studied the inadequate pain management during routine childhood immunizations.<sup>3</sup>

Studies have addressed the use of various pharmacological and non-pharmacological methods as measure of pain prevention in infants. Oral sucrose has been the most extensively studied procedure-related pain reduction strategy in neonatal care. The calming and pain relieving effects of sucrose are thought to be mediated by endogenous opioid pathways activated by sweet taste. The orogustatory effects of sucrose have been demonstrated in animals, preterm and fullterm human infants during painful procedures.<sup>8</sup> The most commonly used dosage of oral sucrose solution is 2ml of 25% strength (weight/volume) with analgesic effect lasting for up to 10 minutes.

Topical anaesthetics reduce the pain associated with needle procedures, including venepuncture and intravenous cannulation. The most commonly used forms are local anaesthetics sprays with or without vapocoolants, gel or cream preparations with a patch. This is achieved by reversible binding of anaesthetics with sodium channels and inactivating them. Sodium influx through these channels is necessary for the depolarization of nerve cell membranes and subsequent propagation of impulses along the course of the nerve. This change in permeability result in decreased depolarization and an increased excitability threshold that ultimately prevents nerve action potential from forming.<sup>9</sup> At present, the optimal pain relieving measures for nullifying pain, rather than simply diminishing pain is

unknown. Additional research is required to determine which pain relieving regimens reliably prevent pain in children of different age groups. Currently, no such study has been conducted comparing the use of oral sucrose solution and topical anaesthetics as pain relieving measures during immunization in infants.

## METHODS

It was a case control study comprising of all healthy infants coming for immunizations in the Immunization Clinic of Sri Guru Ram Das Institute of Medical Sciences and Research from 1<sup>st</sup> January 2017 to 30<sup>th</sup> June 2018. After approval from Institutional Thesis and Ethical committee and taking informed consent from parents such infants were assessed. Pain scores were measured by modified behaviour pain scale (MBPS).<sup>6</sup> MBPS was recorded during the injection, at 15 seconds and 60 seconds after injection. The infants were randomly and equally divided into 3 groups in a chronological order:

- Group A (n=70)-Infants were given 24% oral sucrose solution (algopedol). Each infant was given 1ml of the solution 10 seconds before injection.
- Group B (n=70)-Infants were given topical local anaesthetic (10% lignocaine spray). It was sprayed 10 seconds before injection over injection site.
- Group C (n=70)-Control group including infants who were not given anything before injection.

**Table 1: Modified behaviour pain scale in infants (MBPS).**

Behaviour observed	Score
<b>Facial expression</b>	
Definite positive expression i.e. (smiling)	0
Neutral expression	1
Slightly negative expression (i.e. grimace)	2
Definite negative expressions (i.e. furrowed brows, eyes tightly closed)	3
<b>Cry</b>	
Laughing or giggling	0
Not crying	1
Moaning, quiet vocalizing, gentle or whimpering cry	2
Full lunged cry or sobbing	3
Full lunged cry more than baseline cry	4
<b>Movements</b>	0
Usual movements/activity, or resting/relaxed	0
Partial movement or attempt to avoid pain by withdrawing the limb where the puncture is done	2
Agitation with complex movements involving the head, torso or other limbs or rigidity	3

Where: a) Slightly negative expressions include brow bulging and naso-labial furrow. b) Definitely negative expressions include brow bulging, naso labial furrow, eyes closed and tight open lips with or without a reddened face.

In modified behaviour pain scale, sum of points for all the 3 parameters were interpreted as: (a) Minimum score: 0, (b) Maximum score:10.

**Inclusion criteria**

- All healthy, active and fully awake infants from 6 weeks to 6 months of age and weight more than 2.5kg brought for immunization in Immunization Clinic of Sri Guru Ram Das Institute of Medical Sciences and Research, Amritsar.
- The infant should be carried by mother/ any other family member during the immunization.
- All the vaccinations should be carried out by a single vaccinator.
- All pain relieving measures i.e. oral sucrose solution and lignocaine spray should be given by a single investigator.

**Exclusion criteria**

- Crying infant
- Any coexisting acute or chronic painful condition.
- Infant on medication (analgesics, sedatives, antiepileptic drugs).
- CNS disorders, birth asphyxia, HIE.
- Breastfeeding and/or other distraction strategies during the procedure.
- Any known sensitivity to topical anaesthetic.

**RESULTS**

This case control hospital based study was conducted in the Immunization clinic of the Department of Paediatrics of Sri Guru Ram Das Institute of Medical Sciences and Research, Vallah, Sri Amritsar. Total of 210 healthy infants (between 6 weeks to 6 months of age) coming for immunization in the Immunization clinic were enrolled to

study and compare the effectiveness of oral sucrose solution and topical local anaesthetics during immunization after satisfying inclusion and exclusion criteria and getting a written informed consent from their parents. The results were statistically analysed using chi square test and student's t test.

**Table 2: Distribution of patients according to age group (in months).**

Age ( in months)	Frequency	Percent
<2 months	85	40.4
2-4	121	57.6
>4	4	1.9

Out of 210 subjects, maximum number of cases 121(57.6%) were in the age group of 2-4 months followed by 85 (40.4%) in <2 months age group and only 4 cases (1.9%) were observed in >4 months age group (Table 2).

**Table 3: Distribution of patients according to gender.**

Gender	Frequency	Percent
Male	127	60.4
Female	83	39.5
Total	210	100

In this study, out of 210 children, 127 (60.4%) were males and 83 (39.5%) were females (Table 3). The infants were randomly and equally divided into 3 groups in a chronological order having 70 infants in each group.

Group A- Infants were given 24% oral sucrose solution (Algopedol). Group B- Infants were given topical local anaesthetic (10% lignocainespray). Group C- Control Group including infants who were not given anything before injection.

**Table 4: Mean MBPS before 15 seconds and 60 seconds after injection.**

Group	MBPS before injection		MBPS 15 sec injection		MBPS 60 sec injection	
	Mean	SD	Mean	SD	Mean	SD
A	1.34	0.90	5.09	0.91	6.43	0.88
B	1.37	0.92	5.74	0.58	7.17	0.51
C	1.39	0.92	6.70	0.77	8.33	0.61

The mean values of MBPS (modified behaviour pain scale) observed during administration of injection were 1.34, 1.37 and 1.39 in groups A, B and C respectively. There was an increase in mean values of MBPS at 15 seconds.

The mean values at 15 seconds were 5.09, 5.74 and 6.70 in groups A, B and C respectively. The mean values of

MBPS observed at 60 seconds were 6.43 in group A, 7.17 in group B and 8.33 in group C respectively (Table 4).

The mean values of Modified Behavior Pain Scale before injection administration were 1.34, 1.37 and 1.39 in groups A, B and C respectively. There was no statistically significant difference when mean values of MBPS were compared between the groups A, B and C (p>0.05) (Table 5).

**Table 5: Comparison of MBPS before injection.**

Group	Mean	SD	p-value		
			A/B	B/C	A/C
A	1.34	0.90	0.43	0.46	0.39
B	1.37	0.92			
C	1.39	0.92			

At 15 seconds of injection administration, the mean values of MBPS were 5.09, 5.74 and 6.70 in groups A, B and C respectively. When compared, the mean value of MBPS was lesser in group A and B as compared with group C (p value 0.0 in both). The mean MBPS in group A (5.09) was observed to be significantly lesser than mean MBPS (5.74) in group B (Table 6).

**Table 6: Comparison of MBPS at 15 seconds of injection.**

Group	Mean	SD	p-value		
			A/B	B/C	A/C
A	5.09	0.91	0.00	0.00	0.00
B	5.74	0.58			
C	6.70	0.77			

Furthermore, the mean values of MBPS at 60 seconds of injection administration were 6.43, 7.17 and 8.33 in groups A, B and C respectively. The mean MBPS was observed to be significantly lesser in groups A and B as compared to the group C (p value 0.0 in both groups). The mean MBPS in group A was significantly lesser than mean MBPS in group B at 60 seconds of injection administration (p value 0.0) (Table 7).

**Table 7: Comparison of MBPS at 60 seconds of injection.**

Group	Mean	SD	p-value		
			A/B	B/C	A/C
A	6.43	0.88	0.00	0.00	0.00
B	7.17	0.51			
C	8.33	0.61			

## DISCUSSION

Routine childhood immunization is a proven tool for eradicating and controlling infectious diseases and vaccines are considered as the most powerful, safe and cost effective measures for prevention and control of number of diseases. Despite its key role in maintaining global public health, many individuals either refuse or delay immunization. One of the well documented barriers to immunization is pain from the needle puncture. Needle fear among children and their parents is the primary reason non-compliance of immunization. Several methods have been employed to reduce injection pain during immunization in children. Among these, administration of oral sucrose solution before immunization and application of topical local anaesthetics are the two most effective measures which

reduce pain during immunization. In this study, authors have used 24% oral sucrose solution and 10% lignocaine spray before immunization in infants to see their efficacy against injection pain and also compared their effects.

In present study, modified behaviour pain scale was used to assess the pain in infants, which showed mean score of 1.34, 5.09 and 6.43 in oral sucrose group at the baseline, 15seconds and 1 minute of injection administration. The mean pain score observed in the control group was 1.39, 6.70 and 8.33 at the baseline, 15 seconds and 1 minute respectively, after injection administration. On comparing, there was no statistical difference between pain scores at the baseline (p value 0.39). However, there was a statistical difference between pain scores of two groups at 15 seconds and 60 seconds of injection administration (p value 0.0). Furthermore, in present study, the highest mean pain scores were observed at 1 minute of injection administration, i.e. 6.43 in oral sucrose group and 8.33 in control group. Several studies have shown similar results. Firstly, placebo controlled study was conducted by Hatfield in the year 2008.<sup>10</sup> In this study, 110 healthy term infants were randomly stratified into 2 or 4 month study groups, and further randomly assigned to receive 24% oral sucrose and pacifier or the sterile water control solution. The Children's Hospital Pain Scale measured serial acute pain responses for the treatment and control groups at baseline and 2, 5, 7 and 9 minutes after solution administration. Two and 4 months old infants receiving oral sucrose (n=38) displayed reductions in pain scores 2 minutes after solution administration compared with 2 and 4 months old infants in the placebo group (n=45). The oral sucrose and placebo groups demonstrated highest mean pain score at 7 minutes, with a mean pain score of 3.8 and 4.8 respectively. At 9 minutes, the placebo group had a mean pain score of 2.91 whereas the mean pain score for the oral sucrose group returned to near baseline, reflecting a 78.5% difference in mean pain score relative to the placebo mean. Another study was done by Hatfield LA to evaluate the effectiveness of oral sucrose as a pre procedural intervention during immunization in infants at 2 and 4 months of age using CHEOPS scale.<sup>11</sup> Infants receiving oral sucrose (n=20) showed a significant reduction in behavioural pain response 5 minutes after administration compared to those in placebo group. A randomized controlled trial was conducted by Yilmaz G, et al, in 2014 to determine the effect of oral sucrose solution on infant crying times in 16-19 months age group.<sup>12</sup> Infants receiving a 75% sucrose solution had significantly reduced total crying times and Children's Hospital Eastern Ontario Pain Scale score compared with infants in the control group and 25% sucrose solution groups (p<0.001). Lewindon P conducted a double blinded placebo controlled trial to see the effectiveness of 75% sucrose solution.<sup>13</sup> A total of 107 healthy infants attending 2, 4 and 6 month immunizations were randomized to receive 2ml of 75% sucrose solution or sterile water by mouth before the intramuscular injections. Infants receiving 75% sucrose solution had a

significant reduction in all measures of crying. Allen KD et al conducted a similar double-blind, randomized control trial in infants in the age group of 2 weeks to 18 months.<sup>14</sup> The children who received either the sterile water or sucrose solution cried significantly less than the infants who received no intervention ( $F=5.92$ ,  $P<0.005$ ).

However, there were few trials which showed neutral outcome. Firstly, a blinded randomized controlled trial was conducted by Wilson S et al, in 2013, to evaluate the effectiveness of oral sucrose in decreasing pain during minor procedures in infants of 1-6 months of corrected age.<sup>15</sup> In this study, no statistical differences were found in pain scores between treatment and control groups at any data collection points in any age group. Similarly, a case control study was conducted by Curry DM in 2012, to examine the effects of oral sucrose as an analgesic agent during routine immunizations in infants at 2, 4 and 6 months of age.<sup>16</sup> It showed no significant difference. Consolability factors might be responsible for such results in these studies.

Our study showed mean modified behaviour pain score of 1.37, 5.74 and 7.17 in the local anaesthetic group at the baseline, 15 seconds and 60 seconds of injection administration respectively whereas mean pain score in the control group was 1.39, 6.70 and 8.33 respectively. There was significant reduction in pain score in local anaesthetic group as compared to control group at 15 seconds and 60 seconds of injection administration ( $p$  value of 0.0 at 15 seconds and 60 seconds respectively).

Similar to present findings, few other studies also recorded the positive effect of using local anaesthetics at the time of immunization. Taddio A et al studied the use of lidocaine-prilocaine cream for vaccination pain in infants.<sup>17</sup> Authors evaluated a total of 49 evaluable infants who received lidocaine-prilocaine 5% eutectic mixture of local anaesthetics (EMLA) and 47 infants who received placebo. The median difference in pre-vaccination and post-vaccination MBPS scores was lower for lidocaine-prilocaine 5% cream (EMLA) than for placebo ( $p=0.001$ ).

Similarly, O'Brien L et al studied the role of topical 4% amethocaine gel in reducing the pain of subcutaneous Measles-Mumps Rubella vaccination.<sup>18</sup> Authors reported that Amethocaine significantly reduces pain of Measles-Mumps-Rubella vaccination in infants when compared with placebo. Lastly, a randomized, double-blind, controlled trial conducted by Halperin SA, et al to see the effectiveness of EMLA patch (5%-1g) or placebo before MMR immunization in infants up to 12 months of age revealed similar results.<sup>19</sup>

## CONCLUSION

To conclude, administration of oral sucrose solution and application of topical local anaesthetics are effective

measures to reduce injection pain during immunization. Administration of oral sucrose solution before immunization showed greater reduction in pain as compared to application of topical local anaesthetics in present study.

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## REFERENCES

- Centers for Disease Control and Prevention. Recommended immunization schedule for persons 0 through 18 years. Atlanta, GA: Centers for Disease Control and Prevention; Available at: <http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.
- Shah V, Taddio A, McMurtry CM. Pharmacological and combined interventions to reduce vaccine injection pain: systematic review of randomized controlled trials and quasi-randomized controlled trials. *Clin J Pain.* 2015;31(10).
- Taddio A, Chambers C, Halperin S, Ipp M, Lockett D, Rieder MJ, et al. Inadequate pain management during childhood immunization: the nerve of it. *Clin Ther.* 2009;31:S152-67.
- Schechter NL, Zempsky WT, Cohen LL, Patrick J. Pain reduction during pediatric immunizations: Evidence based review and recommendations. *Pediatr.* 2007;119(5):25-32.
- Jain A, Rutter N. Local anesthetic effect of topical amethocaine gel in neonates: randomized controlled trial. *Arch Dis Child Fetal Neonatal.* 2000;82:42-5.
- Houck CS. Anesthetic agents- actions and toxicity. In: Holbrook PR, ed. *Textbook of pediatric critical care.* Philadelphia: WB Saunders; 1993:967-970.
- Omer SB, Salmon DA, Orenstein WA, DeHart P, Halsey N. Vaccine refusal, mandatory immunization, and the risks of vaccine preventable diseases. *New Engl J Med.* 2009;360:1981-8.
- Gibbins S, Stevens B. Mechanisms of sucrose and non-nutritive sucking in procedural pain management in infants. *Pain Res Manag.* 2001;6(1):21-8.
- Kundu S, Achar S. Principles of office anesthesia: part II. Topical anesthesia. *Am Fam Physician.* 2002;66(1):99-102.
- Hatfield LA, Gusic ME, Dyer AM. Analgesic properties of oral sucrose during routine immunizations at 2 and 4 months of age. *Pediatr.* 2008;121:327-34.
- Hatfield LA. Sucrose decreases infant biobehavioral pain response to immunizations: a randomized controlled trial. *J Nurs Scholarsh.* 2008;40:219-25.
- Yilmaz G, Caylan N, Oguz M. Oral sucrose administration to reduce pain response during immunization in 16-19-month infants: a

- randomized, placebo-controlled trial. *Eur J Pediatr*. 2014;173(11):1527-32.
13. Lewindon PJ, Harkness L, Lewindon N. Randomised controlled trial of sucrose by mouth for the relief of infant crying after immunisation. *Arch Dis Childhood*. 1998;78(5):453-6.
  14. Allen KD. Sucrose as an analgesic agent for infants during immunization injections. *Arch Pediatr Adolesc Med*. 1996;150(3):270-4.
  15. Wilson S, Bremner AP, Mathews J, Pearson D. The use of oral sucrose for procedural pain relief in infants up to six months of age: a randomized controlled trial. *Pain Management Nursing*. 2013;14(4):e95-105.
  16. Curry DM. Effectiveness of oral sucrose for pain management in infants during immunizations. *Pain Manag Nurs*. 2012;13(3):139-49.
  17. Taddio A, Nulman I, Goldbach M. Use of lidocaine-prilocaine cream for vaccination pain in infants. *J Pediatr*. 1994;124:643-8.
  18. O'Brien L, Taddio A, Ipp M, Goldbach M, Koren G. Topical 4% amethocaine gel reduces the pain of subcutaneous measles-mumps-rubella vaccination. *Pediatrics*. 2004;114(6):e720-4.
  19. Halperin SA, McGrath P, Smith B, Houston T. Lidocaine-prilocaine patch decreases the pain associated with the subcutaneous administration of measles-mumps-rubella vaccine but does not adversely affect the antibody response. *J Pediatr*. 2000;136:789-94.

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