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Original Article

Public Health Section

Low-cost Distraction Technique to Reduce Pain Perception among Infants and Improve Parents' Satisfaction during the Immunisation Procedure: An Interventional Study from Assam, India

DEEPANSHU SHARMA[1], RAHUL SHARMA[2], JYOTI SHARMA[3]

ABSTRACT

Introduction: Immunisation serves as a critical key indicator of community child health and plays a crucial role in reducing infant mortality. The Sample Registration System (SRS) 2021, Assam continues to report a higher Infant Mortality Rate (IMR-30) compared with the national average (IMR: 25). The aspirational district Programme emphasises strengthening maternal and child health outcomes through evidence-based interventions and local innovations.

Aim: To explore the effect of oral sucrose and the 4S technique on infant pain perception and parent satisfaction during immunisation.

Materials and Methods: The present facility-based experimental comparative study was conducted at the Immunisation Clinic of the Civil Hospital, Mangaldoi, Darrang (aspirational district), and Civil Hospital Karimganj (non-aspirational district) of Assam, India, The study is affiliated with Poornima University, Jaipur, and the University provided ethical approval through the JSPH Institutional Review Board (IRB) in Jodhpur and Ethics Committee No. JSPH/23/08/0, dated 29/08/2023. The duration of the study was from October 2023 to April 2024. The total sample size was 400, equally distributed between two study sites (200 each site), with participants at each site further divided into four groups of 50 participants each (Group A,B,C and the Control group). The 4S technique and oral sucrose were also used. The modified Riley pain scale was utilised to measure pain, and a 5-point Likert scale was used to measure parent satisfaction. Statistical analysis was performed using t-test, chi-square value and p-value <0.05 was considered statistically significant.

Results: The study found that mothers in non-aspirational districts were more aware of Universal Immunisation Programme (UIP) Programmes compared to aspirational districts since infant immunisation begins at 1.5 months of age. Intervention Group C, which combined the 4S technique with oral sucrose, had the highest proportion of infants reported no pain in both aspirational 39 (78%) and non-aspirational 33 (66%) districts. Lower pain scores were positively associated with parental satisfaction, with Group C showing the highest level of satisfaction {32 (64%) in AD and 30 (60%) in non AD}. All intervention groups showed statistically significant improvement compared to the control group (p=0.001).

Conclusion: Improving immunisation is crucial for reducing vaccine hesitancy and needle fear in aspirational and non-aspirational districts. Improving vaccination awareness can improve neonatal health and reduce the infant mortality rate. The results suggest the use of pharmaceutical and non pharmacological therapies, such as sucrose administration, to lessen vaccination-related pain, especially in children's populations.

Keywords: Aspirational district programme, Child health, Infant mortality, Needle fear, Pain management, Vaccination hesitation

INTRODUCTION

The aspirational districts Programme (ADP), which focuses on education, nutrition, health, and other development indicators, has designated several districts in Assam [1].

Vaccine hesitancy in child immunisation is exacerbated by parental fears of infant pain during injections (prevalence 8-28%), but non pharmacological interventions like the 4S technique significantly mitigate these concerns and enhance acceptance. Addressing pain associated with the vaccine through appropriate pain management techniques may reduce anxiety and improve outcomes among beneficiaries [2].

Neonatal pain is often under-recognised despite its significant short- and long-term consequences. While non pharmacological interventions such as oral sucrose and soothing techniques are effective, evidence on their combined use is limited. Additionally, parental satisfaction remains underexplored. In resource-limited settings, there is a need for low-cost and feasible strategies. Therefore, the present study aimed to evaluate the effectiveness of individual and combined interventions on neonatal pain perception and parental satisfaction [3].

In the World Health Organisation (WHO) 2022 report the 25-vaccine introduction, excluding COVID-19 Vaccination. The Global status fell to 81% in 2021 from 86% in 2019. As the estimated 25 million children reported to have not gotten the necessary childhood vaccines, the highest number since 2009. In comparison to 2019, five million more children were totally immunised in 2021 (WHO 2022) [4].

In India, UIP aims to immunise 2.7 crore children and approximately 2.9 crore Pregnant women per year (United Nations International Children Emergency Fund (UNICEF)-2022) [5].

As per the National Family Health Survey (NFHS)-5 data, the percentage of children aged 12-23 months in India FIC coverage increased from 62 to 76%. Immunisation and Low Birth Weight

(LBW) are both key indicators of public health challenges that significantly affect child health. Immunisation risk indicates from a zero-doser child, and left-out and a dropout child. In both districts, 57.1% children were vaccinated age group 12-23 months in the aspirational district Darrang, and 75.1% in the non-aspirational district Karimganj. The Infant mortality rate of Assam is 30, and India is 25 (SRS-2021). Immunisation is a proven public health intervention for reducing childhood morbidity and mortality due to Vaccine-Preventable Diseases (VPDs). However, a substantial gap persists, particularly in disadvantaged and aspirational districts. According to NFHS-5, 3.8% of children remain unvaccinated, 19.8% are partially vaccinated, and 6.4% are zero-dose children, placing them at increased risk of VPDs [6-9].

According to the National Institution for Transforming India (NITI) Aayog Champions of Champions, in 2023, Darrang had the lowest full immunisation coverage among all aspirational districts of Assam. As per the intensified Mission Indra Dhanush 5.0 (IMI) 2023, Darrang (AD) and Karimganj (non AD) districts have been classified as high-risk districts for immunisation coverage [10].

Comparing an aspirational district with a non-aspirational one offers critical insights into how targeted policy interventions influence development outcomes. Darrang, with its historical challenges in literacy, healthcare delivery, and economic diversification, has experienced increased policy focus and systematic monitoring under the ADP. Karimganj, while demonstrating relatively stronger literacy performance and demographic indicators, continues to grapple with structural issues such as limited electrification, inadequate irrigation infrastructure, and slow-paced industrial growth [11].

A 25% of individuals claim to have had a needle phobia since childhood, which causes 10% of people to avoid needle-related procedures like vaccinations, as per the Taddio A et al., study (2010) [12].

Parents have admitted that vaccination hesitation stems from pain during immunisation (Chattopadhyay D et al., 2011). There was no other option but immunisation; thus, research into pain management methods was required. Numerous pharmaceutical and non pharmacological treatments have been shown to reduce vaccination-related pain. However, the literature of these professions frequently reflected experience rather than scholarship [13].

In 210 infants (split into 3 groups) at Sri Amritsar, Kumar A et al., (2019) reported that infants receiving oral sucrose during immunisation experienced significantly less pain compared to those receiving topical anaesthetics. In the oral sucrose group, the modified behaviour pain score was 1.34, 5.09, and 6.43 at 15 seconds and one minute after vaccination; in the topical anaesthetics group, it was 1.37, 5.74, and 7.17; and in the control group, it was 1.39, 6.70, and 8.33. These findings showed that the oral sucrose group experienced the lowest pain scores, followed by the topical anesthetics group, while the control group had the highest pain scores during immunization [14]. Adedemy JD et al., descriptive, cross-sectional, and analytical study on vaccination pain and its management in Parakou City hospitals was completed in 2020. A total of 375 mothers of children between the ages of 0 and 11 months were identified using a non-random sampling technique. Mothers said that 64.8% of them thought their child were experiencing moderate post-vaccination pain, and 54.2% reported using drugs such as paracetamol and ibuprofen rather than a diversion, breastfeeding, sugared solution, cream application, syrups, and honey [15].

The present study intended to assess and compare infants' perceptions of pain during immunisation and parental satisfaction. Additionally, it aims to ascertain whether parental pleasure and the perceived pain experienced by the infants during the treatment are related. The study also looks into how certain demographic factors affect newborns' pain reactions and parental satisfaction.

Alternative hypothesis (H1): The use of a low-cost distraction technique during immunisation significantly reduces pain perception among infants and improves parental satisfaction compared to routine immunisation procedures.

Null hypothesis (H0): There is no significant difference in pain perception among infants or parental satisfaction between immunisation procedures performed with or without the low-cost distraction technique.

MATERIALS AND METHODS

The present facility-based experimental study was conducted at the Immunisation Clinic of the Civil Hospital, Mangaldoi, Darrang (aspirational district), and Civil Hospital Karimganj (non-aspirational district) of Assam, India, from October 2023 to April 2024. The study is affiliated with Poornima University, Jaipur, and the University provided ethical approval through the JSPH Institutional Review Board (IRB) in Jodhpur and Ethics Committee No. JSPH/23/08/0, dated 29/08/2023.

Sample size calculation: The sample was calculated through the G-power 3.1.9.7 analysis tool. A total sample size was 400, equally distributed between two study sites (200 each site), with participants at each site further divided into four groups of 50 participants each. Eligible infants were divided into four groups: three intervention groups and one control group. In the intervention group, a low-cost distraction technique such as visual or auditory stimulation was used during the immunisation procedure. The control group received routine immunisation without distraction. Pain perception was assessed using a standardised pain assessment scale immediately after vaccination. Parental satisfaction was also recorded using a structured questionnaire.

The participants in the present study differed from those in the previously published pilot study. To minimise bias in the study, a pilot study was conducted before the main survey to refine procedures [16].

Inclusion criteria:

- Infants age between 6 and 16 weeks;
- Infants accompanied by mother and father;
- Infants are immunised with the Pentavac vaccine;
- Infants whose parents are willing to take part in the study;
- Infants whose mothers can speak Assamese or English.

Exclusion criteria:

- Infants with fever, sickness, neurological conditions, gastrointestinal issues, and congenital defects.

Study Procedure

Allocation of participants into three experimental groups receiving oral sucrose, 4S technique, and their combination, along with a control group, with all groups assessed for pain perception and parental satisfaction is depicted in [Table/Fig-1].

Group	Interventions	Pain perception	Parental satisfaction
Group A (Experimental)	*1	**1	**2
Group B (Experimental)	*2	**1	**2
Group C (Experimental)	*3	**1	**2
Control group		**1	**2

[Table/Fig-1]: Study group wise interventions and outcome measures. *1-Oral sucrose, *2- 4 S technique, *3 Oral sucrose with 4 S technique; **1-Assessment of Pain, **2- Assessment of Parental Satisfaction

To ensure intervention fidelity, all healthcare workers involved in the study were trained in the standardised procedure for administering the distraction technique and oral sucrose. The intervention was delivered according to a predefined protocol for all participants to maintain consistency across the study groups.

The present study used the 02 Scale to assess infants' pain and parent satisfaction, and pain scoring was conducted by trained observers to ensure consistency and reliability of the measurements. The infant's pain assessment and parental satisfaction were performed immediately after the immunisation procedure.

1. **The modified riley pain scale:** Modified Riley Pain Scale (MRPS) is an observational tool used to assess pain in neonates and infants, especially in situations where they cannot verbally express pain, which evaluates behavioural indicators such as facial expression, crying, body movement, and consolability. The total score ranges from 0 to 8, with higher scores indicating greater pain intensity [Table/Fig-2] [17].

Indicators	Score 0	Score 1	Score 2
Facial expression	Relaxed/no grimace	Mild grimace	Full grimace/crying face
Cry	No cry	Whimpering/Mild cry	Loud/vigorous cry
Body movement	Relaxed/normal	Restless/slight movement	Agitated/thrashing
Posture / Muscle tone	Normal/relaxed	Slight tension	Right/stiff

[Table/Fig-2]: Modified Riley Pain Scale (MRPS).
Total score: 0: No pain, 1-3: Mild pain, 4-6: Moderate pain, 7-8: Severe pain.

Clinical significance:

- Helps in the objective comparison of pain levels across intervention groups.
- Widely used in studies evaluating non pharmacological interventions like Oral sucrose and the 4S technique.

2. **5-point Likert scale:** Parental satisfaction was assessed using a 5-point Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). The 5-point Likert scale is a widely used method for measuring attitudes, perceptions, and satisfaction levels in research studies. It allows respondents to express how strongly they agree, feel, or perceive something [Table/Fig-3].

Score	Response option
1	Very dissatisfied
2	dissatisfied
3	Neutral
4	Satisfied
5	Very Satisfied

[Table/Fig-3]: 5-point Likert Scale.

Operational definitions: The low-cost distraction technique reduces pain perception by diverting the infant's attention from the injection stimulus through sensory and cognitive engagement. This mechanism is explained by the gate control theory of pain, where competing sensory inputs reduce the transmission of pain signals, thereby decreasing perceived pain and distress during immunisation.

The quantifiable effects of the chosen interventions on infants' perceptions of pain during vaccination and parental satisfaction are referred to as efficacy in the present study. The measure of parental satisfaction used a 5-point Likert scale, and infant pain perception used the Modified Riley Pain Scale, facilitating objective comparisons across study groups [17].

Oral sucrose, the 4S technique, and a combination of oral sucrose and the 4S technique are the chosen therapies; all are administered in accordance with established protocols. A commercially available 25% sucrose solution is administered orally, and opened (unsealed) bottles are kept in the refrigerator for up to a week to preserve stability. The four non pharmacological soothing techniques swaddling, side-lying, swinging, and shushing that make up the 4S technique are used in tandem to give the baby multimodal comfort. In evaluating intervention outcomes, the use of these operational definitions ensures methodological precision, consistency, and repeatability.

STATISTICAL ANALYSIS

Data were entered and analysed using SPSS version 16. Descriptive statistics were presented as frequency and percentage for categorical variables and mean±standard deviation for continuous variables. The comparison between the intervention and control groups was performed using appropriate statistical tests such as the chi-square test and independent t-test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

During a period of 1.5 months, Group A and the control group had the highest proportions (36% each), followed by Group C (26%), and Group B (14%). The distribution of participants changed at 2.5 months, with the bulk of participants falling into Group C (42%) and B (40%). Group A (42%) and B (46%) had the highest representation by 3.5 months [Table/Fig-4].

After 1.5 months, Group A had the highest proportions (54%), while the Control group had the lowest (34%). Group C had the greatest percentage (32%) while Group A had the lowest (10%) for 2.5 months. 3.5 months, Group A had the lowest percentage at 26% and the control group at 36% [Table/Fig-5].

The gender distribution was uniform in both studies locations, 50% male children and 50% female children.

Demographic Variables of Mangaldoi Civil Hospital					
Age group of infants					
Variables	Group A n (%)	Group B n (%)	Group C n (%)	Control group n (%)	chi-square value
Age					
1.5 Month	18 (36%)	7 (14%)	13 (26%)	18 (36%)	χ^2 : 1.6 p: 0.26
2.5 Month	11 (22%)	20 (40%)	21 (42%)	14 (28%)	
3.5 Month	21 (42%)	23 (46%)	16 (32%)	18 (36%)	
Gender of the infants					
Gender					
Male	25 (50%	25 (50%)	25 (50%)	25 (50%)	χ^2 : 0.00 p: 1.0
Female	25 (50%	25 (50%)	25 (50%)	25 (50%)	
Birth weight of the infants					
Birth weight					
<2.5 Kg	10 (20%)	7 (14%)	5 (10%)	8 (16%)	χ^2 : 0.06 p: 0.74
>2.5 Kg	40 (80%)	43 (86%)	45 (90%)	42 (84%)	

[Table/Fig-4]: Demographic variables and percentage of infants at Mangaldoi Civil Hospital (AD).

Demographic variables of Karimganj Civil Hospital					
Age group of Infant					
Variables	Group A n (%)	Group B n (%)	Group C n (%)	Control group n (%)	chi-square value
Age					
1.5 Month	27 (54%)	20 (40%)	18 (36%)	17 (34%)	χ2 : 1.8 p: 0.32
2.5 Month	10 (20%)	13 (26%)	16 (32%)	15 (30%)	
3.5 Month	13 (26%)	17 (34%)	16 (32%)	18 (36%)	
Gender of the infants					
Gender					
Male	25 (50%)	25 (50%)	25 (50%)	25 (50%)	χ2 : 0.00 p: 1.0
Female	25 (50%)	25 (50%)	25 (50%)	25 (50%)	
Birth weight of the infants					
Birth weight					
<2.5 KG	1 (2%)	3 (6%)	4 (8%)	5 (10%)	χ2 : 0.04 p: 0.88
>2.5 KG	49 (98%)	47 (94%)	46 (92%)	45 (90%)	

[Table/Fig-5]: Demographic variables and percentage of infants at Karimganj Civil Hospital (Non AD).

A total of 20% low birth weight infants during the birth time (<2.5 kg) in Group A, as compared to other groups, while Group B had more high birth weight babies (>2.5 Kg) [Table/Fig-4].

The proportion of low-birth-weight infants (<2.5 kg) was highest (10%) in the control group, in contrast to other groups. The higher proportion of infants (98%) was in Group A. The analysis showed a higher proportion of low-birth-weight children in the aspirational district Darrang compared to the non-aspirational district Karimganj [Table/Fig-5].

The duration of infants' last feeding among the study groups in aspirational district. The proportion of babies with a last feeding time of <30 minutes was highest in Group C (58%), while the 31-60 minute duration was most common in Group A (42%). Group B had the largest frequency of the 60-90 minute duration (22%), whereas Group A (18%) had the highest proportion of the 90-120 minute duration. The statistically significant p-value was 0.004 and the chi-square was 3.07 [Table/Fig-6].

In a similar vein [Table/Fig-6] demonstrates the last nap that among the comparison groups, Group A had the largest last feeding duration of less than 30 minutes (30%), and the Group A, Group C also had the maximum duration of 31 to 60 minutes (38%). Group B had the largest frequency of the 60-90-minute duration (44%), whereas the control group had the highest frequency of the 90-120-minute duration (38%). The statistically significant p-value was 0.003, and the chi-square was 4.26.

The last feeding of the infants, where the control group (66%) had the highest percentage of infants in the non-aspirational district whose most recent nap was less than 30 minutes. The control group had the highest prevalence of 31-60-minute naps (30%), while Group A had the highest prevalence of 60-90-minute Last feeding (40%), and the control group had the highest prevalence of 90-120-minute feeding (28%). The statistically significant p-value was 0.002 and the chi-square was 4.30 [Table/Fig-7].

According to [Table/Fig-7], Group A had the largest percentage of newborns in the non-aspirational district (36%), with a last nap lasting less than 30 minutes. Group B had the highest frequency of 31-60-minute naps (34%), followed by Group C (44%) in 60-90 minute, and the control group (26%) highest frequency of 90-120-minute naps. The statistically significant p-value was 0.004 and the chi-square was 4.14.

According to [Table/Fig-8] of aspirational district, pain perception among infants was assessed using the Modified Riley Pain Scale, and Intervention included as per [Table/Fig-1]. Group C had the largest percentage of newborns reporting no pain (78%), whereas the control group had the highest percentage of infants experiencing mild pain (48%) and moderate pain (34%) in control group. There were no reports of severe pain in either group, and the control group also had the greatest level of moderate pain. The statistically significant p-value was 0.004 and the chi-square was 6.07.

According to [Table/Fig-8] the parental satisfaction was assessed using a 5-point Likert scale, and Intervention included as per [Table/Fig-1]. Group C had the largest percentage of "satisfied" parents in the aspirational district (64%), while Group A had the highest percentage of "extremely satisfied" parents (66%). The statistically significant p-value was 0.005 and the chi-square was 7.26.

According to [Table/Fig-9] of non-aspirational district, pain perception among infants was assessed using the Modified Riley

Last feeding of the infants					
Variables	Group A n (%)	Group B n (%)	Group C n (%)	Control group n (%)	chi-square value
Last feeding					
<30 min	13 (26%)	15 (30%)	29 (58%)	9 (18%)	χ2 : 3.07 p: 0.004
31-60 Min	21 (42%)	12 (24%)	13 (26%)	11 (22%)	
60-90 Min	7 (14%)	11 (22%)	8 (16%)	9 (18%)	
90-120 Min	9 (18%)	4 (8%)	2 (4%)	4 (8%)	
Last nap of the infants					
Last nap					
<30 min	15 (30%)	11 (22%)	13 (26%)	9 (18%)	χ2 : 4.26 p: 0.003
31-60 Min	19 (38%)	5 (10%)	19 (38%)	13 (26%)	
60-90 Min	9 (18%)	22 (44%)	7 (14%)	13 (26%)	
90-120 Min	6 (12%)	14 (28%)	14 (28%)	19 (38%)	

[Table/Fig-6]: Frequency and percentage of infants feeding and last nap at Mangaldoi Civil Hospital (AD).

Last feeding of the infants					
Last feeding	**Group A n (%)**	**Group B n (%)**	**Group C n (%)**	**Control group n (%)**	**chi-square value**
<30 min	20 (40%)	29 (58%)	31 (62%)	33 (66%)	χ2: 4.30 p: 0.002
31-60 Min	6 (12%)	7 (14%)	6 (12%)	15 (30%)	
60-90 Min	20 (40%)	8 (16%)	5 (10%)	11 (22%)	
90-120 Min	4 (8%)	14 (28%)	6 (12%)	8 (16%)	
Last nap of the infants					
Last nap					
<30 min	18 (36%)	14 (28%)	10 (20%)	11 (22%)	χ2: 4.14 p: 0.004
31-60 Min	9 (18%)	17 (34%)	7 (14%)	10 (20%)	
60-90 Min	15 (30%)	8 (16%)	22 (44%)	12 (24%)	
90-120 Min	9 (18%)	9 (18%)	8 (16%)	13 (26%)	

[Table/Fig-7]: Frequency and percentage of infants feeding and last nap at Karimganj Civil Hospital (Non AD).

Pain perception of the infants					
Pain perception	**Group A n (%)**	**Group B n (%)**	**Group C n (%)**	**Control group n (%)**	**chi-square value**
No pain	26 (52%)	29 (58%)	39 (78%)	9 (18%)	χ2: 6.07 p: 0.004
Mild pain	13 (26%)	8 (16%)	6 (12%)	24 (48%)	
Moderate pain	11 (22%)	13 (26%)	5 (10%)	17 (34%)	
Severe pain	0	0	0	0	
Parental satisfaction					
Parental satisfaction					
Very dissatisfied	0	0	0	0	χ2: 7.26 p: 0.005
Dissatisfied	0	0	0	4 (8%)	
Neutral	0	0	0	0	
Satisfied	17 (34%)	18 (36%)	32 (64%)	28 (56%)	
Very satisfied	33 (66%)	32 (64%)	18 (36%)	18 (36%)	

[Table/Fig-8]: Pain of infants and parental satisfaction at Mangaldoi Civil Hospital (AD).

Pain Scale, and Intervention included as per [Table/Fig-1]. Group C had the largest percentage of newborns reporting no pain (66%), whereas the control group had the highest percentage of infants experiencing mild pain (32%) and moderate pain (46%). There were no reports of severe pain in either group, and the control group also had the greatest level of moderate pain. The statistically significant p-value was 0.002, and the chi-square was 5.10.

According to [Table/Fig-9] the parental satisfaction was assessed using a 5-point Likert scale, and Intervention included as per [Table/Fig-1]. Group A had the largest percentage of "satisfied" parents in the non-aspirational district (62%), while Group C had the highest percentage of "very satisfied" parents (60%). The statistically significant p-value was 0.003 and the chi-square was 4.10.

Pairwise comparison using independent t-test revealed no statistically significant difference between Group A and Group B (p=0.383). However, both groups showed significantly lower pain perception compared to the control group (p=0.001). Group C demonstrated a statistically significant reduction in pain perception when compared with Groups A, B, and control (p<0.05), indicating that the combined intervention was the most effective [Table/Fig-10].

Group C showed the greatest reduction in pain perception, while Group A and B had similar effects, and the control group had the highest pain scores.

Pairwise comparison using independent t-test revealed no statistically significant difference in parental satisfaction between Groups A and B (p=0.26) and between Groups A and C (p=0.58). However, a significant difference was observed between Groups B and C (p=0.03). All experimental groups demonstrated significantly higher parental satisfaction compared to the control group (p=0.001).

All interventions improved parental satisfaction compared to control, with minimal differences among experimental groups.

Pain perception of the Infants					
Pain perception	**Group A n (%)**	**Group B n (%)**	**Group C n (%)**	**Control group n (%)**	**chi-square value**
No pain	26 (52%)	28 (56%)	33 (66%)	11 (22%)	χ2 : 5.10 p: 0.002
Mild pain	9 (18%)	14 (28%)	10 (20%)	16 (32%)	
Moderate pain	15 (30%)	8 (16%)	7 (14%)	23 (46%)	
Severe pain	0	0	0	0	
Parental satisfaction					
Parental satisfaction					
Very dissatisfied	0	0	0	0	χ2 : 4.10 p: 0.003
Dissatisfied	0	0	0	10 (20%)	
Satisfied	31 (62%)	22 (44%)	20 (40%)	20 (40%)	
Very satisfied	19 (38%)	28 (56%)	30 (60%)	20 (40%)	

[Table/Fig-9]: Pain of infants and parental satisfaction at Karimganj Civil Hospital (Non AD).

Group (pain perception)	Comparison group	t-Test	p-value	Group (parental satisfaction)	Comparison group	t-Test	p-value
A	B	0.87	0.383	A	B	1.1	0.26
	C	3.1	0.002		C	0.54	0.58
	Control group	3.09	0.001		Control group	3.4	0.001
B	A	0.87	0.383	B	A	1.13	0.26
	C	2.1	0.03		C	1.7	0.03
	Control group	5.2	0.001		Control group	4.1	0.001
C	A	3.1	0.002	C	A	0.54	0.58
	B	2.1	0.03		B	1.7	0.03
	Control group	7.7	0.001		Control group	2.6	0.001
Control group	A	3.9	0.001	Control group	A	3.4	0.001
	B	5.2	0.001		B	4.1	0.001
	C	7.7	0.001		C	2.6	0.001

[Table/Fig-10]: Comparison of pain perception and parental satisfaction between groups (A, B, C), and control group.

DISCUSSION

The present study showed the effectiveness of sucrose (Group A), the 4S technique (Group B), and their combination (Group C) in reducing pain perception among infants across aspirational and non-aspirational districts of Assam. The findings clearly indicated that the combined intervention (Group C) was the most effective in reducing pain perception, followed by individual interventions. At the same time, the control group consistently showed higher pain scores.

A key strength of the present study is the comparative evaluation of both pharmacological and non pharmacological interventions. The most effective aspect of Group C can be explained by a synergistic interaction between sucrose and the 4S technique. Sucrose is known to exert analgesic effects through activation of endogenous opioid pathways, whereas the 4S technique (swaddling, side positioning, shushing, and sucking) provides behavioural comfort and sensory modulation. The simultaneous targeting of both physiological and behavioural components of pain likely resulted in enhanced analgesic efficacy in the combination group. Similar findings have been reported in recent studies, where multimodal pain management strategies were found to be significantly more effective than single interventions alone [18-20].

In the present study, Group A (sucrose) and Group B (4S technique) showed comparable effects, with no statistically significant difference between them. However, in certain parameters, sucrose alone appeared to be more effective than the 4S technique. This may be attributed to the direct biochemical mechanism of sucrose-induced analgesia, which provides a more consistent reduction in pain compared to non pharmacological techniques that rely on environmental and caregiver-dependent factors. Previous studies have also reported that while non pharmacological interventions are beneficial, their effectiveness may vary depending on implementation and infant responsiveness [20,21].

The findings related to feeding and nap duration suggest that preprocedural physiological states significantly influence pain perception. Infants with shorter durations since last feeding or nap demonstrated variations across groups, which may have contributed to differences in pain response. These findings are consistent with earlier research indicating that hunger, fatigue, and sleep states can modulate neonatal pain perception and behavioural responses [22]. Therefore, controlling such variables is important in clinical settings to ensure optimal pain management.

The assessment of pain using the Modified Riley Pain Scale revealed that a significantly higher proportion of infants in Group C experienced no pain in both aspirational and non-aspirational districts. In contrast, the control group consistently exhibited higher proportions of mild to moderate pain. These findings are in agreement with recent literature emphasising the effectiveness of combined analgesic approaches in neonatal care [23].

Importantly, no cases of severe pain were reported, which may indicate that even minimal interventions can substantially reduce extreme pain responses in routine procedures. A systematic review (2022) reported that non pharmacological interventions such as sucrose, swaddling, and positioning are effective and safe for reducing neonatal procedural pain [24].

Parental satisfaction was also significantly higher in all intervention groups compared to the control group, with Group C and Group A showing particularly favourable outcomes. This highlights the importance of not only clinical effectiveness but also caregiver perception in evaluating paediatric interventions. Studies conducted in the last five years have similarly reported that effective pain management strategies improve parental confidence and satisfaction with healthcare services [25].

Although the statistical significance of the findings is evident ($p<0.05$), their clinical significance is equally important. The reduction in pain perception observed in the intervention groups, particularly in the combination group, has meaningful implications for neonatal care and thus the results of the present study rejected the null hypothesis. Effective pain management can reduce physiological stress, improve procedural tolerance, and potentially prevent long-term neurodevelopmental consequences associated with repeated painful stimuli [26].

From a cost-effectiveness perspective, the interventions used in this study are simple, low-cost, and feasible for implementation in resource-limited settings. Oral sucrose is inexpensive and widely available, while the 4S technique requires no additional equipment or financial input. The combination approach, therefore, represents an efficient and scalable strategy for improving neonatal pain management, especially in aspirational districts where healthcare resources may be constrained.

However, certain practical challenges may affect the implementation of these interventions. These include lack of staff training, variability in technique application, time constraints in busy clinical environments, and limited awareness regarding non pharmacological pain management strategies. Addressing these barriers through structured training programmes and standardised clinical protocols is essential for successful integration into routine practice. The findings of this study support the routine use of the combined sucrose and 4S technique as an effective pain management strategy in neonates. This approach can be easily incorporated into standard clinical protocols across both high-resource and low-resource settings, improving the quality of neonatal care. Further multicentric studies with larger sample sizes are recommended to validate these findings. Additionally, future research should focus on long-term neurodevelopmental outcomes and detailed cost-effectiveness analyses to strengthen the evidence base for policy-level implementation.

Limitation(s)

The limitation of the study the experimental study design limits causal inference between distraction and pain outcome. Observer-based pain scale may introduce measurement variability. The sample size may not fully reflect social culture influence on parent satisfaction, and unmeasured factors such as provider techniques and parental behaviours may affect the infant's response. A pilot study conducted prior to facilitate data collection facilitated refreshment of study tools and procedures, enhancing consistency, reliability, and overall internal validity. Despite these measures, some bias may persist. Observer bias was minimised through the use of Validated Infant Pain Assessment Scales and the training of the observer. Selection bias was reduced by applying uniform inclusion criteria and immunisation site. Response bias was reduced by ensuring anonymity and using the Structure Questionnaire.

CONCLUSION(S)

In conclusion, the study highlights the critical role of effective pain management in reducing vaccine reluctance and improving immunisation experiences. Both pharmacological and non pharmacological interventions, particularly oral sucrose very associated with a significant reduction in vaccine-related pain and higher parental satisfaction compared to standard care, with Group C showing the greatest benefits. Emphasising pain prevention during immunisation may enhance vaccine acceptance and overall public health impact. Further research is warranted to better understand individual differences in pain perception and satisfaction to inform optimised clinical pain management strategies.

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PARTICULARS OF CONTRIBUTORS:
1. PhD Scholar, Department of Public Health, Poornima University, Jaipur, Rajasthan, India.
2. Professor, Department of Public Health, Poornima University, Jaipur, Rajasthan, India.
3. Assistant Professor, Department of Paediatric Dentistry, Rajasthan Dental College, Jaipur, Rajasthan, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Deepanshu Sharma,
201, Vinayak Residency, Jhotwara, Jaipur-302012, Rajasthan, India.
E-mail: deepanshu041194@gmail.com

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