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Breaking Barriers in Paediatric Pain Management: Combined Cryotherapy and Vibration Therapy vs. Audio-Visual Aids for Alleviating Discomfort During Inferior Alveolar Nerve Block Administration in Children: A Randomized Controlled Study

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Abstract

Background: Behavioural and pain management in paediatric dental procedures, especially during the administration of an inferior alveolar nerve block, can be challenging due to the common occurrence of fear and anxiety in these scenarios. Diverse distraction techniques are deployed to alleviate the discomfort stemming from needle insertion, including the utilization of audiovisual aids, cold temperature and vibrations. Recently, there has been growing interest in the synergistic application of cryotherapy and vibration therapy, offering a promising alternative approach in this domain.

Aim: The primary objective of this study was to investigate the effectiveness of combined cryotherapy and vibration therapy in alleviating pain during inferior alveolar nerve block (IANB) administration in children, with a comparison to the use of audiovisual aids.

Methods: A randomized controlled trial was conducted on children aged five to twelve years requiring inferior alveolar nerve block (IANB) administration. 60 Children meeting the inclusion criteria were randomly divided into three groups: control, audio-visual aid group, and combined therapy group. Each group received either no intervention audio-visual aid or combined cryotherapy and vibration therapy respectively. Throughout the administration of the IANB, the behavioural response was evaluated using the Faces Legs Activity Cry Consolability Scale (FLACC), while the severity of pain was assessed using the Wong-Baker FACES Pain Rating Scale (WBFS).

Results: The mean WBFS score of control group, combined cryotherapy and vibration therapy group and audiovisual intervention group were 4.70 ± 2.8, 2 ±1.9, 4.20 ±2.8 respectively. The combined use of ice pack and vibrating device had statistically significant impact on pain intensity reduction. The comparison was found to be statistically significant with P value <0.05.

Conclusion: The study revealed that the combination of cryotherapy and vibration therapy yielded superior results compared to the use of audiovisual aids, demonstrating statistically significant outcomes.

Keywords: Audio-visual aid, pain Management, Cryotherapy, Inferior Alveolar Nerve Block, Vibration Therapy, Distraction, Paediatric dentistry.

Introduction

Administering local anesthesia (LA) is a routine practice in paediatric dentistry, frequently utilized to alleviate dental pain, effective dental treatment and behaviour management.[1,2] Paradoxically, the discomfort stemming from the injection of local anesthetic is a primary source of dental apprehension and distress, particularly among children.[3]The fear of pain from injections commonly leads to behavioural issues, resistance to treatment and avoidance of dental care in the future.[4] Managing pain during dental procedures, particularly for children, is crucial for maintaining effective behavior management principles. [5] Effective pain management during LA administration not only fosters a trusting rapport between the dentist child but also alleviates fear and anxiety, cultivating a positive attitude towards dental care.[6]

Multiple approaches have been proposed to alleviate pain during local anesthetic injections, including the application of topical anesthetics, buffering local anesthetics, warming the anesthetic agents, employing distraction techniques, utilizing computer-assisted injection systems, and adjusting the infiltration rate.[7]

Distraction is the technique of diverting the patient's attention from what may be perceived as an unpleasant procedure. Audiovisual distraction is a method of passively distracting two types of sensations—hearing and seeing.[8] It has proven to be an effective strategy in diverting attention of child and reducing the needle associated pain perception. Vibrating devices have proven to be a useful aid in last few years for both diverting young patients and numbing the pain associated with injections. However, the data regarding distraction techniques is quite lacking and preliminary findings does not seem much encouraging.[9]

Another efficient and recommended method for lowering perceptions of pain is the use of cryotherapy. Temperature, particularly cold, has emerged as a potent factor in pain-relieving treatments, suggesting its potential application in the management of dental pain.[10] Cryotherapy provides patients with both psychological and physiological benefits by potentially diverting their attention from discomfort. [11] Lately, there has been growing interest among dental professionals in the innovative concept of incorporating cold temperatures alongside vibrating devices as a supplementary approach.[10] Although this approach has demonstrated effectiveness in contexts such as immunizations [12] and venipuncture [13] its efficacy in dental settings has been somewhat limited and warrants further exploration. Hence, primary aim present study was to evaluate the efficacy of combined cryotherapy and vibration therapy on pain and behaviour of children following inferior alveolar nerve block (IANB) administration and its comparison with the audiovisual distraction technique. Additionally, the study aimed to assess the disparity in pain perception between children who had previous experience with local anesthetic administration and those receiving it for the first time.

Materials and Methods

Study design A randomized controlled trial was conducted with children undergoing treatment at the

Department of Paediatric & Preventive Dentistry, Govt. Dental College, Shimla, India over a period of 3 months. Prior to their participation, both the children and their parents or guardians provided written informed consent. Detailed explanations regarding the study's objectives, benefits, and potential risks were provided to the parents.

Sample size: The sample size was calculated using G*Power (Universitat Kiel, Kiel, Germany) sample size calculation software version 3.1.9.7. 18 patients per group met the minimum requirement for an alpha of 0.05 and a power of 0.95. Given the anticipated reluctance of patients to fully participate during injection administration and the possibility of discontinuing treatment prematurely, a sample size of 20 patients per group was selected.

Eligibility standards: The study included children aged 5 to 12 years who met specific inclusion criteria. These criteria comprised children requiring dental procedures on any mandibular tooth that necessitated the use of an Inferior Alveolar Nerve Block (IANB), those classified as ASA I according to the American Society of Anesthesiologists Physical Status Classification System (ASA-PS), and those who provided consent for participation. Children who were excluded from the study met certain criteria. These criteria included children with cognitive or developmental delays, those with any medical condition or allergy deemed to affect child safety, and those presenting with an existing orofacial edema, infection, abscess, or the presence of systemic comorbidities requiring special dental treatment considerations.

Randomisation and Data collection Children in the study were recruited from the outpatient department of the Department of Pediatric and Preventive Dentistry, requiring Inferior alveolar nerve block administration for dental treatment. They were divided into Group A, Group B and Group C using a lottery-randomization technique. Participants were randomly divided into one of the three groups: Group A (Control group), Group B (Combined cryotherapy and vibration therapy group) and Group C (Audio-visual aid group). During the administration of inferior alveolar nerve block (IANB), participants in Group A received no intervention, while those in Group B underwent a combined intervention involving ice pack cryotherapy and vibration therapy. Participants in Group C were provided with audio-visual aids during the procedure. The research data were gathered longitudinally, with data from all the groups collected at three distinct time points: before, during, and after injection administration, recorded on a demographic information sheet(Figure 3). Prior to injection, a questionnaire and interview were utilized to ascertain the participants' previous injection experiences, if any. Following this, the Wong-Baker FACES Pain Rating Scale (WBFS) was utilized before the injection to gauge the pain experienced in previous injection encounters among experienced children. Subsequently, the Face, Legs, Activity, Cry, Consolability (FLACC) scale was employed to evaluate the behavioural response of the children to pain during the IANB injection. Finally, after the injection procedure, the WBFS was once again employed to measure the actual pain experienced by all included children during the present injection procedure.The Face, Legs, Activity, Cry, and Consolability (FLACC) scale serves as an observational pain assessment tool commonly employed in the infants and children who cannot articulate their discomfort verbally.[14] Instead, the FLACC scale facilitates the understanding of their pain experience through observation of facial expressions and behavioural cues, enabling healthcare providers to administer appropriate pain interventions.[15] The Wong–Baker FACES Pain Rating Scale, developed by Wong and Baker in 1988, comprises a series of six graphically or cartoon-depicted faces displaying expressions of increasing distress. Unlike numeric scales, face scales obviate the need for understanding magnitude or sequencing, making them accessible to preschool-aged children. Extensively researched,

the Wong-Baker Faces Pain Scale has demonstrated reliability and validity, particularly in children aged 3 to 18 years.[16]

Intervention Before injection, the site of needle penetration was numbed using topical anesthetic gel containing 15% w/w Lidocaine U.S.P (Lidayn, Khanna Enterprises, India) in both groups. Children in the control group received the IANB using a conventional technique, with the entire cartridge, containing 1.8 mL of 2% lignocaine with 1:80,000 adrenaline (Septodont Healthcare India Pvt. Ltd, Maharashtra, India), being injected. In test group 1, the audiovisual group, children underwent IANB administration while enjoying cartoons displayed on a television screen affixed to the dental chair. Conversely, children in test group 2 received the injection in conjunction with combined cold and vibration therapy. Cold therapy involved the application of a frozen ice pack, while vibration therapy utilized a commercially available vibrating massager. Both the ice pack and vibrating massager were placed simultaneously on the cheek area, corresponding to the ramus of the mandible, for 30 seconds prior to injection delivery. (Figure 1) They remained in position throughout the administration of the IANB. Once the anaesthetic solution was fully administered, the massager was turned off, and both the massager and ice pack assembly were removed.

Statistical Analysis Data regarding demographic characteristics, previous and present injection experience, WBFS Score and FLACC Score in control group, audiovisual group and combined cryotherapy and vibration therapy group were entered into Microsoft Excel and analysed using IBM SPSS Statistics for Windows, Version 20 (IBM Corp., Armonk, N.Y., USA). Data was investigated for normality using the Kolmogorov-Smirnov test and it showed that the data deviated from the normal distribution. Descriptive statistics were derived as mean, standard deviation, frequencies and percentages. The Chi-square test was utilized to analyze the distribution of WBFS and FLACC scores among the three groups during the present injection experience. Furthermore, the comparison of mean WBFS scores between the experienced and non-experienced populations was also conducted using the Chi-square test. One-way ANOVA test was used to analyse WBFS and FLACC Scores between 3 groups, followed by multiple pairwise comparisons using post hoc Tukey's Honest Significant difference test. WBFS and FLACC Scores based on present injection compared to previous injection experience was analysed using independent t-test. The level of statistical significance was determined at $p \leq 0.05$.

Results

Participants' demographic characteristics. Figure 2 shows the flow chart of this trial. Out of the initial 100 children assessed for eligibility, 40 did not meet the inclusion criteria. Among the 60 patients who did meet the criteria, 37 (61.7%) were males and 23 (38.3%) were females. The mean age of the study population was 9.37 years (standard deviation +/- 1.75 years). Of these, 22 (36.7%) children had prior experience with injections, while 38 (63.3%) were receiving injections for the first time.

Primary outcome: Pain intensity outcomes and intergroup comparision: The primary outcome i.e. the pain intensity outcomes were assessed using the WBFS and FLACC scores. The mean WBFS scores obtained among the study population were 4.70 ± 2.8 for the control group, 2 ± 1.9 for the combined cryotherapy and vibration therapy group, and 4.20 ± 2.8 for the audiovisual intervention group. This comparison yielded a statistically significant result with a P-value of <0.05.(Table 2) which showed that the combined use of Ice pack and vibrating device had statistically significant impact on pain intensity reduction Similarly, the FLACC scores among the study population were 3.95 ± 2.2 for the control

group, 1.05 ± 1.4 for the combined cryotherapy and vibration therapy group, and 4.25 ± 2.3 for the audiovisual intervention group. Again, a statistically significant difference was found with a P-value of <0.05.(Table 3) Post hoc Tukey's Honest Significant Difference test for both WBFS and FLACC scores revealed a significant difference between audiovisual aids group and combined cryotherapy and vibration therapy group, as well as between the control group and both test groups. However, no significant difference was found between the no intervention group and the audiovisual aids group.

Secondary outcomes: Upon comparison, it was observed that the mean WBFS scores in non-experienced children (3.95 + 2.80) were higher than those in the experienced population (3.09 + 2.74). However, this difference was not statistically significant (P= 0.256).

Discussion

Pain is defined by the International Association of the Study of Pain as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage. Effectively managing the pain associated with local anesthetic (LA) administration stands as a pivotal aspect of patient care, particularly in pediatric dentistry. A painful injection experience can be distressing, not only for the child undergoing the procedure but also for the dental provider and parents involved. This discomfort may lead to challenging behavior, heightened dental fear, and a tendency to avoid future dental visits in the child. Moreover, childhood pain experiences have the potential to shape how individuals perceive and cope with pain in adulthood. [17]

Various strategies and tools are employed to mitigate the discomfort caused by needle insertion during dental procedures. Distraction aids, including audiovisual elements such as video games, television shows, cartoons, and stories, as well as more advanced virtual reality experiences, are commonly utilized. Mechanical resources, such as vibrotactile devices that generate sensations to divert the child's attention and temporarily interrupt the transmission of pain signals, also play a crucial role in reducing pain during injections.[5]

The present study investigated the efficacy of combined vibration and cryotherapy and its comparison with audiovisual aids on the pain perception of pediatric patients during the administration of IANB. The findings of the current study revealed a statistically significant reduction in pain reactions during the administration of the inferior alveolar nerve block (IANB) when cold and vibrations were used simultaneously. These results are consistent with previous research, which has also demonstrated success in utilizing the combined application of cold and vibration to alleviate discomfort in children undergoing maxillary infiltration dental anesthesia.[18]

This combination operates based on the principles of distraction and the Gate Control Theory. According to the Gate Control Theory, pain signals travel from the peripheral nervous system to the central nervous system, where they are regulated by a gating mechanism in the dorsal horn of the spinal cord.[19] It is proposed that the transmission of pain messages through afferent pain-receptive nerves (including A-delta fibers and slower C fibers) can be inhibited by faster non-noxious motion nerves (A-beta fibers). Consequently, the perception of pain can be diminished by stimulating nerve fibers that transmit non-painful stimuli.[20] Prolonged exposure to cold stimulates the C fibers, potentially blocking the transmission of A-delta pain signals. Additionally, cold exposure may enhance the activation of supraspinal mechanisms, thereby increasing the body's overall pain threshold [12] cryotherapy directly decreases pain by slowing down or completely stopping pain transmission. This significantly alters pain thresholds and augments the pain tolerance of tissue nociceptors.[21] The gate

control mechanism can also be activated by rhythmic and repetitive vibrations. Moreover, vibration therapy has been shown to increase the levels of beta-endorphins. These elevated beta-endorphin levels are attributed to the transmission of vibration stimuli by large myelinated nerve fibers located near the peripheral neurological pain gates. As a result, both the pain threshold and pain perception are elevated by beta-endorphins. [11,22] Vibrations also activate mechanoreceptors, including Pacinian corpuscles and Meissner's corpuscles, not only in the skin and subcutaneous tissue but also in the underlying bone.[23] Therefore, when the underlying bone near the injection site is stimulated, greater pain reduction can be achieved. Consequently, during the local anesthesia deposition procedure, the device was positioned over the bone in close proximity to the injection site.

Limited studies [18,23,24] have explored the use of combined cryotherapy and vibration therapy for pain relief during intraoral local anesthesia (LA) administration, including the maxillary infiltration and inferior alveolar nerve block techniques. However, further research is warranted in this area to identify the most effective method for reducing injection pain. Although the efficacy of combined cryotherapy and vibration therapy technique has proved in previous studies, no study has previously compared this approach to other adjunctive methods for decreasing pain during LA administration. The current study addresses this gap by comparing this technique to audio-visual distraction methods. In the results, both WBFS and FLACC scores revealed a statistically significant difference in mean pain scores between audiovisual aids group and combined cryotherapy and vibration therapy group, showing lower pain perception in combined therapy group.

In present study, it was found that non-experienced children had slightly higher mean WBFS scores compared to experienced children. This suggests that children without prior injection experience may perceive more pain during dental procedures. However, the difference in mean scores between the two groups was not statistically significant. This finding suggests that while there may be a trend towards higher pain perception in non-experienced children, it is not substantial enough to be considered statistically significant. Other factors such as individual pain thresholds, anxiety levels, and coping mechanisms may also play a significant role in influencing pain perception during dental procedures.

A commercially available device called Buzzy Bee TM (Pain Care Labs, USA) is accessible in the USA. This device incorporates a vibrating motor housed within a bee-shaped body and a detachable wing-shaped ice pack, offering simultaneous cold and vibrations. It has demonstrated effectiveness in reducing pain perception during dental injections.[17,28,29] However, it is expensive and not readily accessible in developing countries like India. The simultaneous use of an ice pack and a vibrating massager, both of which are readily available and inexpensive, can serve as an acceptable alternative, as demonstrated in the present study.

The present study had some limitations such as cold and vibrations may be less tolerable for certain children, and discomfort from ice contact is influenced by subjective thresholds and time dependency. Additionally, the size of the device may have been cumbersome for children with smaller faces, although all participants accepted its application. Some children exhibited discomfort with the cold wings. Furthermore, subjective pain scales were employed, and objective measures such as heart rate were not utilized to assess pain perception. Despite these limitations, the combined therapy demonstrated several merits, including its non-invasiveness, ease of use, effective pain relief, and cost-effectiveness.

Conclusion

The intervention of using combined cryotherapy and vibration therapy was effective in reducing pain levels of IANB injection among children. Combined cryotherapy and vibration therapy was found to be better when compared to audiovisual aids and showed statistically significant results.

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Table 1: Demographic characteristics of the study population

Demographic characteristics	Groups			Total (n = 60)	Chi-square value (p-value)
	No intervention group (n = 20)	Audiovisual intervention group (n = 20)	Cryotherapy + Vibration therapy intervention group (n = 20)		
Age (years)	9.70 + 1.52	8.95 + 2.01	9.45 + 1.76	9.37 +	-

Mean + SD [Min. – Max.]		[7 - 13]	[6 - 13]	[6 - 12]	1.75 [6 - 13]	
Gender n (%)	**Male**	10 (50)	16 (80)	11 (55)	37 (61.7)	4.371 (0.112)
	Female	10 (50)	4 (20)	9 (45)	23 (38.3)	

Table 2: Intergroup comparison of WBFS Score among the study population

WBFS Score based on Present injection experience (n = 60)	**Mean + SD**	**95% Confidence Interval for Mean**		**F value**	**p-value**
		Lower Bound	**Upper Bound**		
No intervention group	4.70 + 2.84	3.37	6.03	6.223	0.004*
Audiovisual intervention group	4.20 + 2.82	2.88	5.52		
Cryotherapy + Vibration therapy intervention group	2.00 + 1.94	1.09	2.91		
Total	3.63 + 2.79	2.91	4.35		

***Statistically Significant (p<0.05); F value – One way ANOVA test value**

Table 3: Intergroup comparison of FLACC Score among the study population

FLACC Score based on Present injection experience (n = 60)	**Mean + SD**	**95% Confidence Interval for Mean**		**F value**	**p-value**
		Lower Bound	**Upper Bound**		
No intervention group	3.95 + 2.21	2.91	4.99	15.239	0.000*
Audiovisual intervention group	4.25 + 2.31	3.17	5.33		
Cryotherapy + Vibration therapy intervention group	1.05 + 1.43	.38	1.72		
Total	3.08 + 2.46	2.45	3.72		

***Statistically Significant (p<0.05); F value – One way ANOVA test value**

Table 4: Comparison of Mean WBFS Score during Present injection to previous injection experience

	Previous Injection experience	Mean + SD	Mean difference	95% Confidence Interval of the Difference		Independent t-test value (p-value)
				Lower	Upper	
WBFS Score based on Present injection experience	**No (n = 38)**	3.95 + 2.80	0.856	-.637	2.350	1.148 (0.256)
	Yes (n = 22)	3.09 + 2.74				

Figure 1: Intervention with Combined cryotherapy and vibration therapy during IANB administration

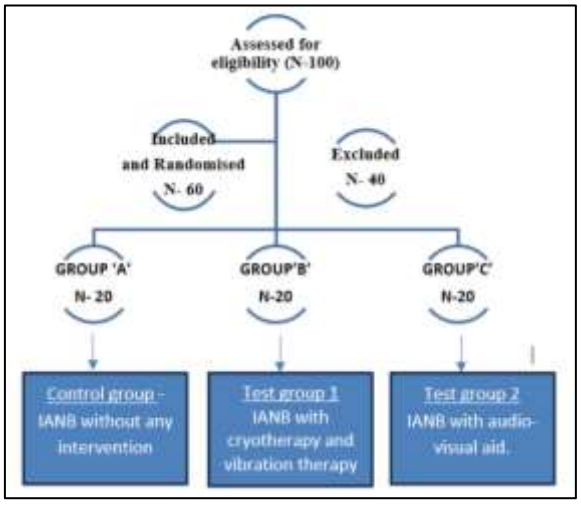
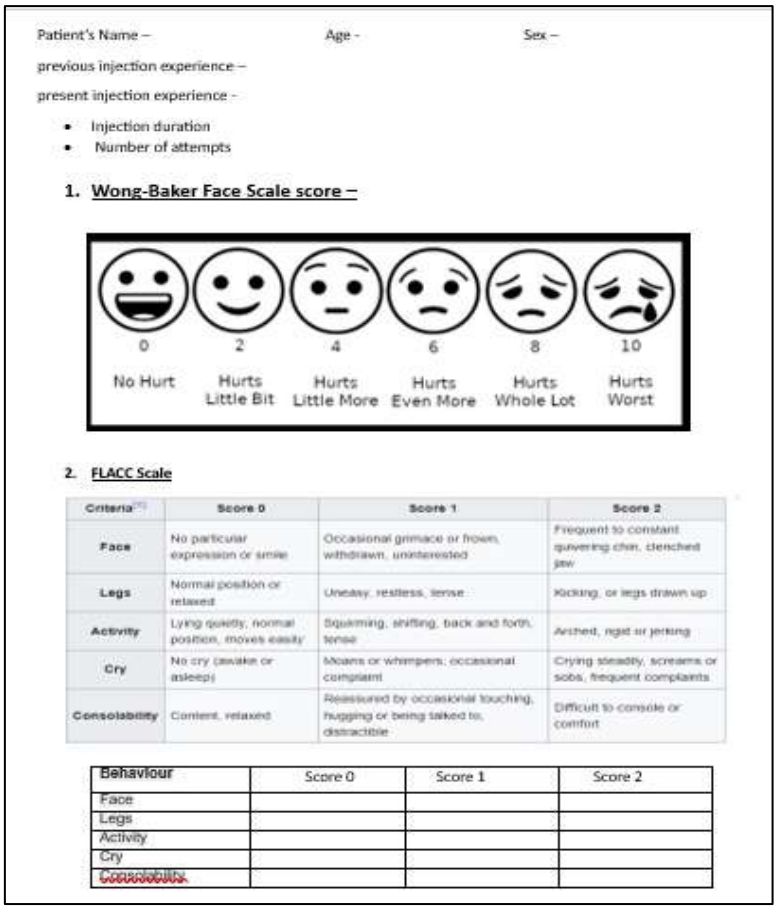


Figure 2: Flow chart of methodology



Patient's Name – Age - Sex –

previous injection experience –

present injection experience -

- Injection duration
- Number of attempts

1. **Wong-Baker Face Scale score –**

2. **FLACC Scale**

Criteria	Score 0	Score 1	Score 2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting, back and forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

Behaviour	Score 0	Score 1	Score 2
Face			
Legs			
Activity			
Cry			
Consolability			

Figure 3: Demographic sheet used in the study