Original Article

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Effect of audio distraction with thermomechanical stimulation on pain perception for inferior alveolar nerve block in children: a randomized clinical trial

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Background: Pain control is a crucial aspect of pediatric dentistry for patient management. Thermo-mechanical devices (Buzzy™ Pain Care Labs, USA) work on the concept of vibration and cooling and have shown promising results in pain control during local anesthesia in pediatric dentistry. On the other hand, audio distraction has also been used for pain management. The amount of pain endured is determined by the patient's perception and attentiveness. Thus, if audio function is added to the thermomechanical device it might increase its efficiency. Hence, the present study aimed to compare pain on injection using a thermo-mechanical device with and without audio during inferior alveolar nerve block (IANB) injection in children aged 5-10 years old.

Methods: Twenty-eight children aged between 5 and 10 indicated for IANB were included in this randomized study. Children who were undergoing the dental procedure were divided into 2 groups, with 14 children in each group. The study group was the thermo-mechanical device with audio distraction; the control group was the thermo-mechanical device without audio distraction. IANB was administered. Subjective pain evaluation was performed using the Wong–Baker Faces Pain Rating Scale (WBFPR) and objective pain evaluation was done using the Faces, Leg, Activity, Consolability, Cry (FLACC) scale.

Results: The outcome depicted a significant reduction in pain on injection for both objective and subjective evaluations in the thermo-mechanical device with an audio distraction group.

Conclusions: Less pain on injection was observed, when a thermo-mechanical device was used with audio distraction for IANB procedures.

Keywords: Audio Distraction; External Cooling; Inferior Alveolar Nerve; Nerve Block; Primary Molars; Vibration.

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INTRODUCTION

For a dental visit to be successful, efficient pain control is considered the most important aspect of behavior management. Local anesthetic administration is necessary for proper pain management in dentistry [1]. However, fear of the pain of injection in children makes it difficult to administer, and the child's negative reaction to local anesthesia at previous visits leads to avoidance of future dental appointments [2].

Thus, innumerable techniques have been enforced for pain reduction from local anesthesia. Advanced methods are recommended to achieve a pain-free environment in the dental office to uncover the best method [3].

The vibrating devices for pain reduction of local injections have received great attention in anesthetic literature. Vibrating devices are postulated to work on the gate-control theory [4].

Additionally, cooling also has a profound effect on pain

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reduction. Cooling elicits the C-fibers and intercepts the A-delta pain signal, if used prior to the pain stimulus. Cooling also aids in pain management through a mechanism of activating the descending noxious inhibitory controls [5].

The thermomechanical device is a novel and user-friendly device created to shield children from the pain associated with needle-related procedures. It works on the principle of vibration, cooling, and even distraction. It has a main vibrating body and two detachable ice wings and is designed like a bee. [6] It has been applied in children for pain management during venipuncture [7], immunization [8], and pediatric dentistry for local anesthesia [9]. However, the vibration sound of this thermo-mechanical device might be troublesome and discomforting to some children.

Audio distraction is another simple effective technique implemented for diverting a child's attention from potentially noxious stimuli [10]. Audio function if added to the thermo-mechanical device might increase the effectiveness of the device as pain endured is dependent on the patient's attentiveness and would also help mask the vibration sound, giving a soothing effect.

A thorough literature search revealed no existing evidence to advocate the efficacy of the thermo-mechanical device with an audio distraction method during the administration of local anesthesia in children. Therefore, the purpose of the present study was to determine the effectiveness of the thermomechanical device with an audio distraction method in reducing pain on IANB injection in children aged 5-10 years.

METHODS

The Department of Pediatric and Preventive Dentistry carried out this parallel-arm, experimental, randomized trial. Children's assent and Informed consent from parents was obtained, along with the institution's ethics committee's approval (IEC/VSPMDCRC/10/2022), for the dental treatment. The study was conducted from February 2023 to April 2023. The sample size was determined based on the following presumptions: alpha error = 5% and study power = 80%. One of the major outcomes for calculating the effect size was the difference in pain on injection. Based on the study results of the investigation done by Bilsin E. et al., the estimated sample size was 14 children per group.

Herein, 28 healthy children aged 5-10 years old with no prior experience of anesthesia who exhibited Frankl's behavior rating grade three or four, i.e. positive and definitely positive with an indication of at least one dental procedure of IANB, were included in the study [11]. Children who had a prior medical history of hospitalization or surgery, chronic illnesses, neuro-behavioral disorders, local anesthetic allergies, or infection at the site of injection were excluded.

Random allocation computer software (GraphPad Software by Dotmatics Version 7.05) was used for randomization, as per the intervention to be used. The software generated a distinctive identification code for each child, which was given to them in sealed, numbered, and opaque envelopes. Children were divided into the study (using the thermo-mechanical device with audio distraction) and control groups (using the thermo-mechanical device) in a 1:1 ratio. Enrollment, randomization, and envelope sealing for the intervention were carried out by Investigator 1. All local anesthetic administration and the necessary procedure were carried out by a single trained operator (2nd-year Postgraduate resident of Pediatric Dentistry). The allocated intervention was concealed from the operator and the investigator. All of the registered children received treatment in accordance with group allocation before the trial was called to an end (Fig. 1).

1. Clinical procedure

In the initial visit, non-invasive procedures such as fluoride application or oral prophylaxis were performed to introduce the child to the dental setting and assess the behavior. Additionally, the Wong-baker scale [12] was introduced to the child in this visit.

On the second visit, the child then underwent the

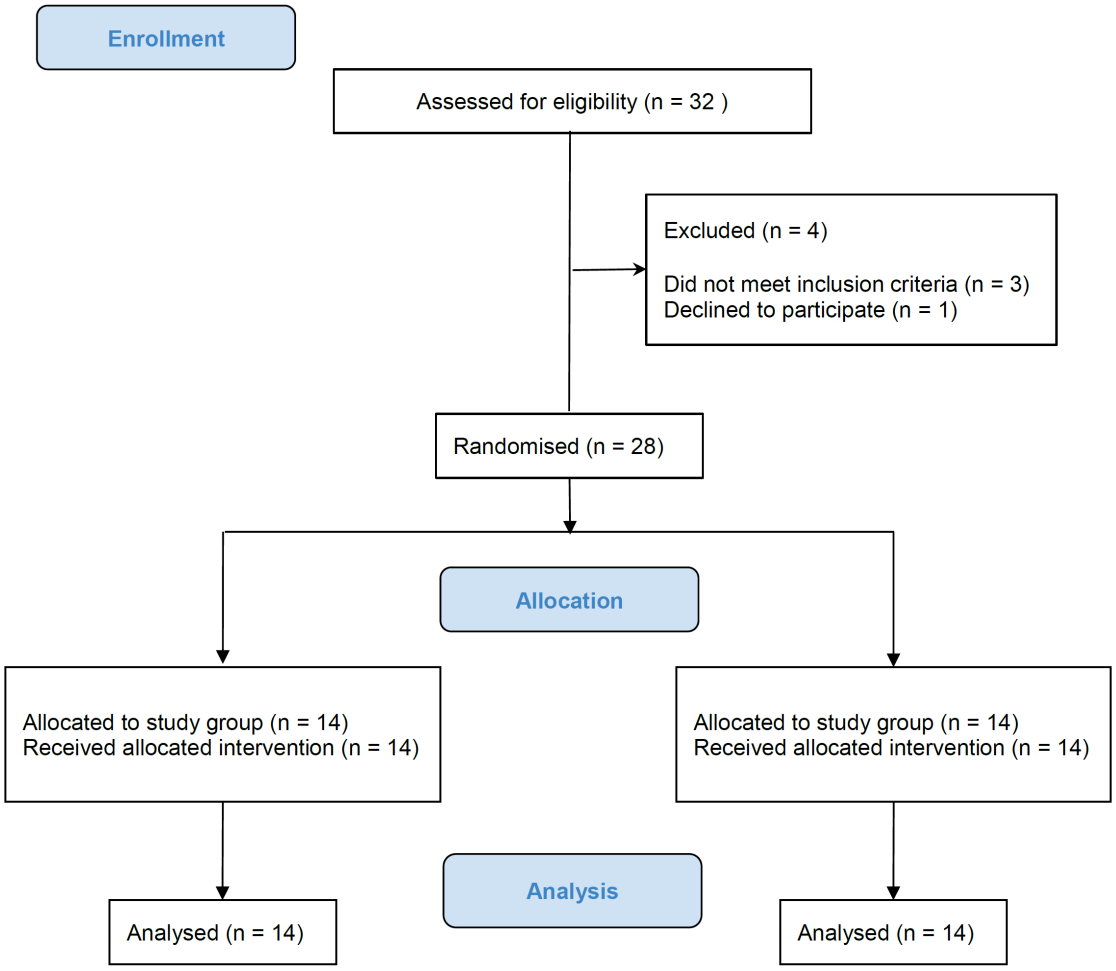

Fig. 1. CONSORT flowchart. CONSORT, consolidated standards of reporting trials; n, sample size.

needed dental treatment as per standard protocol under IANB with the allocated group either with a thermo-mechanical device along with audio distraction or with only a thermo-mechanical device. Behavior was assessed before commencing the procedure.

Thermomechanical device group (group 1): The child was first made familiar by allowing them to play with the thermo-mechanical device (Buzzy™ Pain Care Labs, USA, Fig. 2). along with frozen wings and explaining how it worked. The entire thermo-mechanical device with wings attached was placed extra orally nearby the site of injection (on the ramus of the mandible almost covering the coronoid notch till the posterior border) (Fig. 3) [13]. Mobile headphones connected to the phone were placed in the child's ear; however, no audio was played. With the thermo-mechanical device in place and after drying the mucosa with sterile gauze, topical anesthesia (Lignospan-O 5% Lidocaine Septodont Healthcare India Pvt. Ltd.) on a cotton-tip applicator was applied at the site of injection for 1-2 minutes. IANB was then administered using 2% lidocaine with 1:2,00,000 adrenaline (Cignoken™ ADR 2%) multi-draw vial using the conventional technique described in the Handbook of Local Anaesthesia. The injection rate was approximately 1.5 mL/minute3 with an average duration of nearly 2 minutes [14]. The IANB injection was administered by the same operator for all children.

2. Thermomechanical device with audio distraction group (group 2)

In group 2, the clinical procedure stayed the same as that for group 1, except that the Bluetooth wireless

Fig. 2. Thermomechanical device (Buzzy™)

Fig. 3. Placement of the thermomechanical device

earphones played a preselected audio [15]. The task of putting the headphones and playing the selected audio was done by an assistant who was not involved in the clinical procedure and outcome assessment. The video was recorded from the time the child sat on the dental chair till the completion of local anesthesia injection for objective assessment of pain on injection for both groups using FLACC. A mobile video recorder was used to record the video from a specific distance away from the dental chair, ensuring that the child was completely visible.

Pain on injection was assessed subjectively soon after injection using WBFPR and objectively using FLACC scales from the video recordings. The WBFPR scale comprises six faces that range in severity from left to right. Each face is associated with a numerical rating on a scale of 0 to 10, providing a clear representation of pain severity. The FLACC pain assessment tool incorporates five classes of pain behaviors: (1) facial expression; (2) leg movement; (3) activity; (4) crying; and (5) consolability. Every category is scored from zero to 2, leading to a complete score between 0 to 10.

Data entries were done in Microsoft Office Excel 2010, and results were analyzed using Statistical Product and service solution (SPSS) version 27.0 version and Fig.Pad Prism 7.0 version. The level of significance was considered to be $P < 0.05$. Descriptive statistics such as mean and standard deviation were calculated for quantitative variables. Data normality was checked using the Shapiro-Wilk test. In relation to quantitative parametric data, an unpaired t-test was used to compare both groups. To compare both groups in relation to qualitative non-parametric scale-based parameters Mann Whitney U test was utilized. The chi-square test was used to compare percentage-based parameters between the groups.

RESULTS

All 28 children underwent required dental procedures with no refusal of treatment in between or dropouts; hence data from 14 children within each group were analyzed (Fig. 1).

There was no statistically significant difference in the age (χ^2-value = 0.40, P = 0.81) or gender (χ^2-value = 0.14, P = 0.70) of the children in groups 1 and 2 (Table 1).

In addition, using Student's unpaired t-test, no significant difference was found in weight among children of the two groups (Table 1).

Mann Whitney U test was performed for intergroup and subgroup analysis of pain on injection. Intergroup analysis of pain on injection, assessed using the WBFPR and FLACC scales, showed significantly less pain in

Table 1. Distribution of patients according to their age, sex, weight

	Group 1	Group 2	χ^2-value t-value	P value
Gender				
Male	8 (57.14%)	7 (50%)	0.14	0.70
Female	6 (42.86%)	7 (50%)		
Age in years				
5-7 years	8	7	0.14	0.70
8-10 years	6	7		
Weight (kg)	22.10 ± 1.88	21.25 ± 2.02	1.15**	0.25

*Not significant, Chi-square test **Not significant, Student's Unpaired t-test

Table 2. Intergroup analysis of WBFPR and FLACC scores for pain on injection

WBFPR score					
Group	Mean ± SD	Median (Q1-Q3)	Min	Max	P value
Group 1	4.42 ± 1.78	4 (4-6)	2	8	0.002*
Group 2	2.35 ± 1.54	2 (2-2.75)	0	6	
FLACC score					
Group 1	4.35 ± 1.49	4 (4-5)	1	7	< 0.001*
Group 2	2.21 ± 1.12	2 (2-3)	0	4	

*significant (Mann Whitney U test); FLACC, Faces, Leg, Activity, Cry, Consolability; N, sample size; SD, standard deviation; SEM, Standard error of the mean; WBFPR, Wong–Baker Faces Pain Rating.

Table 3. Subgroup analysis of WBFPR and FLACC scores for pain on injection

Age group	WBFPR score					
	Groups	Median (Q1-Q3)	Min	Max	Mann Whitney U test	P value
5-7 years	Group A	4 (3.5-4.5)	2	6	9	0.017*
	Group B	2 (2-2)	0	4		
8-10 years	Group A	5 (4-6)	2	8	8.5	0.021*
	Group B	2.5 (1.5-3.75)	0	6		
Age group	**FLACC score**					
5-7 years	Group A	4.5 (3.75-5.25)	1	6	7	0.018*
	Group B	2 (2-2.75)	0	4		
8-10 years	Group A	4 (4-4.75)	3	7	5.5	0.013*
	Group B	2.5 (1.75-3.25)	1	4		

FLACC, Faces, Leg, Activity, Cry, Consolability; WBFPR, Wong–Baker Faces Pain Rating.

group 2 (Table 2).

For the age subgroups of 5-7 and 8-10 years, subgroup analysis for subjective and objective pain on injection using the WBFPR and FLACC scales was done. Age-wise subgroup analysis was done as the older children are more likely to use externalizing and problem-solving coping mechanisms as compared to the younger children. [16] The mean WBFPR and FLACC scores in Group 1 were significantly higher than those in Group 2 for the age ranges of 5-7 years and 8-10 years (Table 3).

DISCUSSION

Vibrating devices alleviate pain and work on gate control theory. It articulates that pain transmission is from the peripheral nervous system to the central nervous system and there is modulation by a gating system that happens in the dorsal horn of the spinal cord. More specifically, A-delta fibers (the afferent pain receptors) conveying acute pain signals are activated by injection, and C fibers (unmyelinated slower) conveying chronic

pain signals, are intercepted by A-beta (fast non-noxious motion nerves) caused by vibrations [17].

Another technique to alleviate the pain on injection is pre-cooling the injection site. It functions by lowering tissue metabolic rate and causing vasoconstriction, which reduces the flow of inflammatory mediators and reduces edema. Additionally, it is thought that local cooling will reduce or completely stop the transmission of pain signals and neuromuscular signals. It also works by stimulating medullated A fibers and activating inhibitory pain pathways, that successively raise the absolute threshold [18].

The thermomechanical device (Buzzy™ Pain Care Labs, USA) works on the principle of vibration and cooling for pain management. It has shown promising results in the field of medicine as well as pediatric dentistry for pain management. However, the vibration sound might be troublesome to some children.

Distraction with audio is a simple and effective technique that directs children's attention away from noxious stimuli [19]. Actively listening to music in a structured fashion yields a cognitive strategy that alters the perception of pain by involving attention, distraction, emotion, imagery, catharsis, and relaxation [20]. The combination of audio distraction and the thermo-mechanical device might further decrease pain on injection and also mask the vibration sound which might be troublesome to some children.

All the children included in the present study according to Frankl's behavior rating scale were cooperative (positive or definitely positive), as uncooperative children can give inaccurate pain assessments. The age range of 5 to 10 years old was chosen for this study because it has been suggested that at this age, cognitive development starts to manifest itself. Young children below this age group may have inadequate cognitive development and their feedback depends on their parents' perception; hence, they were not included in the study [21].

The IANB was chosen for this study to compare the pain of injection, as it has been considered the most painful injection and results in more discomfort than infiltration, intra-ligamentary injection, and mental nerve block [22]. In the current study, all local anesthesia administrations in children were carried out by the same operator to eliminate inter-examiner variability, while objective pain assessment was done by investigator 2.

Since, pain is enormously challenging to quantify in children, in the current study pain on injection was assessed during the administration of IANB by both subjective and objective methods. The Wong-Baker Faces Scale (WBFPR) was chosen because it has good construct validity and adequate psychometric properties, is easy and quick to use, and is inexpensive to reproduce [23]. A systematic review by Tomlinson D et al [24] identified (WBFPR) as one of the scales that have undergone extensive psychometric testing and have been used to assess acute and disease-related pain in children.

The FLACC scale was used as an objective pain measuring tool because it has enhanced interrater responsibility and provides an easy framework for quantifying pain behaviors in children who might not be ready to verbalize the presence or severity of pain [25].

Intergroup comparison of the WBFPR and FLACC scores for pain on injection in both groups revealed that the mean WBFPR and FLACC scores were significantly higher in group 1.

Audio distraction and thermo-mechanical devices have not been used together earlier. However, the use of audio distraction and the thermomechanical device have been evaluated individually in studies.

In a study conducted by Suohu et al. [21], the Wong-Baker Faces Scale did not reveal a significant difference between the thermomechanical group and the conventional anesthesia group. In addition, in the study conducted by Faghihen et al. [26] the Wong-Baker Faces Scale did not reveal a significant difference between the thermomechanical group and the conventional anesthesia with cold application group. However, Alanazi KJ et al. [9] and Bilsin E et al. [27] compared thermomechanical device to conventional anesthesia and concluded that the application of a combination of external cold with vibration at the anesthesia site resulted in a significantly lower injection pain during dental procedures in children.

Aitken et al. [28] and Harihar VP et al. [10] concluded that audio analgesia decreases pain perception. However, the results obtained by Neha Gupta [29] concluded that music didn't have any effect on pain perception. The variation in the results of these studies could be due to the age group and type of audio used.

In the current study, the choice of music was according to the child's preference for nursery rhymes or Hindi movie songs. The selection of music was left to the child so that they enjoyed and easily felt comfort toward familiar music, thereby gaining control over the unpleasant stimuli. It also provides them with a sense of being in familiar surroundings thereby contributing to audio distraction. Marwah N [30] and Kaur R [31] in their study, also gave children the choice to play music of their interest and found that playing music of their interest gave better results in anxiety management.

Navit et al. in their study, compared various types of audios and concluded that stories, movie songs, and nursery rhymes led to better anxiety alleviation [20]. The probable reason for these results might be that the children are familiar with the nursery rhymes and songs, thus listening to them was not a new experience.

The limitations of the current study are as follows: the results of the study were obtained from cooperative children and could not be generalized to noncooperative children. The utilization of a topical anaesthetic introduces a potential confounding factor in the current study and could be addressed as a limitation in the current study. However, this was offset to some extent as topical anaesthesia was used in both the groups.

In conclusion, thermomechanical stimulation with audio distraction resulted in less pain on injection during IANB than the thermomechanical device alone as inferred from the results of the study. There is scarcity of evidence regarding audio distraction with the thermo-mechanical device, more studies are needed to substantiate the effectiveness of combined use of audio and thermomechanical stimulation in pain control during IANB.

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