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A clinical trial comparing vibrotactile device with topical anesthetic gel in reducing injection pain during dental anesthesia in children

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Abstract
Background: Effective pain control during treatment helps in ensuring a positive relationship between doctor and patient. Vibradent® is a vibrotactile hand held device which delivers vibration in a sustained frequency as a counter-stimulation to the site of injection, thereby alleviating pain.
Aim: To assess the efficacy of vibratory device (Vibradent®) in reducing the pain perception of injections required for dental treatment in children.
Design- Split-mouth Randomized Controlled Clinical Trial.
Method- Ten children requiring bilateral inferior nerve block injection for the dental extraction were divided in two groups. The children in the experimental group received vibration device for 2 minutes before and during the needle insertion of anaesthesia, whereas the control group included the application of topical anaesthetic gel before the administration of local anaesthesia. For assessment of the pain perception, Wong Baker Faces Pain Scale (WBFPS) and Faces, Legs, Activity, Cry, Consolability (FLACC) Scales were used.
Results: Greater pain minimization was observed with use of vibration device at the injection site as compared with topical anaesthetic gel.
Conclusion: Vibrotactile device (Vibradent) can be used in reducing the pain of dental injections/anaesthesia.

Keywords: Topical anaesthesia, pain control, vibration device

Introduction

Pain caused due to administration of local anaesthesia which itself, is a stressful event rather than the disease, so management of *"injection/needle insertion pain"* in children is a major concern.[1] Needle phobia is one of the major reasons for avoiding dental treatment. Fear and anxiety are known to have negative impact on children's willingness to undergo treatment.[1, 2] Different methods by which pain can be reduced during administration of local anaesthesia includes warming/buffering of local anaesthesia, adjusting the rate of infiltration, precooling the injection site, use of topical anaesthetic gel, icing sprays, small diameter needles etc.[2] There are some newer techniques which includes vibration devices like Dental Vibe, Vibraject, acupuncture, computer controlled delivery system (e.g. WAND® system) and distraction techniques that helps in effective control of pain during treatment.[3]

Dr. Steven Goldberg introduced DentalVibe ®, which is a vibration device and one of the non-pharmacological methods for pain control. [4] This intra-oral system is a hand-held device which helps in delivering pulsed, percussive and soothing oscillations at the area of injection site. [4] It is a rechargeable, cordless device that causes activation of large diameter nerve fibre to carry non-painful stimuli (touch and vibration) to the brain by sending signals and thus reducing the perception of pain, as brain can receive only one sensation at a time. [5] Therefore, it stimulates the A-beta fibres which are large in diameter and can interrupt nociceptive signals to the brain. (According to Gate control theory of Ronald Melzack and Patrick Wall, 1965). [6] In addition to this, there is a smooth tip which provides comfort by gently massaging the area of administration of injection, thus helping in dissipation of the anaesthetic solution and also prevents the appearance of bolus when the anaesthetic solution is being injected. [5, 6]

According to American Academy of Paediatric Dentistry, non-pharmacological behaviour management techniques such as positive reinforcement, use of audio-visual distraction aids, tell-show-do method, protective stabilization, parental presence are preferred over pharmacological methods like sedation, using benzodiazepines, etc. [7] With this background, the present split-mouth randomized controlled clinical trial was done to evaluate and compare the efficacy of Vibradent® (Technomax Corporation) and topical anaesthetic gel in reducing needle insertion pain in children.

Materials and Methods

This study involved a total number of ten children aged 9-11 years old of both the genders with Frankel's Behaviour rating scale as positive and definitely positive, requiring bilateral inferior alveolar nerve block (IANB) injections for extraction of teeth. This split-mouth randomized controlled clinical trial study was conducted in the department of Pediatric and Preventive Dentistry after approval by the Institutional Ethics Committee (IEC/OUT/2021/31), and registered in the Clinical Trials Registry of India (CTRI/2021/10/037385).

Medically and mentally healthy children aged 9-11 years were included and those who had active sites of pathosis in the area of injection site or children with special health care needs were excluded. Children who were allergic to local anaesthesia were also excluded. All participants needed bilateral mandibular nerve block for extraction treatment.

Withdrawal criteria: The use of vibration device was stopped if the sound and vibration of the device lead to increase in the anxiety levels of patients.
Subjects complying with the inclusion criteria were randomly assigned, using a computer-generated list, to one of the two groups *viz* injections with the aid of the vibration device tool or topical anaesthesia.

Allocation concealment: Each child included in the study was given a serial number that was used in allocation. These numbers were written on identical sheets of paper with the group to which each child was allocated and placed inside opaque envelopes carrying the respective names of the children. A trial-independent person was assigned to the role of keeping the envelopes and unfold them only at the time of the local anaesthesia injection session, so that the group to which the child was allocated, was concealed from the outcome evaluator.

Grouping: The participants (injection sites) were randomly divided into two groups.
Group 1: (experimental sites, n=10) assigned to injection with the aid of Vibradent* (vibration) tool (Figure 1).

Fig 1: Vibradent device

Group 2*:* (control sites, n=10) assigned to injection with the aid of LOX* 2% (Lignocaine hydrochloride gel) (Figure 2).
Simple Random Sampling was done using Lottery Method and 20 injection sites are divided into 10 each per group. Gender matching was done, with 5 boys and 5 girls included in the study to avoid confounding factor.

Fig 2: Topical Anesthetic Gel

Procedure: A consent form was provided before the procedure to the guardians/parents of the children in the local language to ensure that they understand the procedure. The children were examined using basic diagnostic instruments and preoperative radiographs to determine the need for local anaesthesia for extraction purpose. The children were informed of the procedure and the site of the injection of IANB was determined and isolated. Before the IANB procedure, Vibradent and Lox 2% gel was used on either side randomly at two different appointments specifically with a gap of one week. Two investigators were trained to assess pain using the Faces, Legs, Activity, Cry, Consolability (FLACC) scale to develop an acceptable degree of inter-examiner reliability to ensure standardization.

1. **Vibradent Procedure:** Using basic behaviour management techniques such as communication and tell-show-do technique, Vibradent was introduced at the injection site with a light touch pressure when contacting the tissue and applied for a minute before and during IANB procedure and continued for few seconds after injecting the local anaesthesia solution i.e. 2.0 mL of 2% lignocaine hydrochloride with 1:2,00,000 adrenaline (XICAINE*) at a rate of 1 mL/ min to help spread the solution (Figure 3).

Fig 3: Application of Vibration device during dental injection

2. **Lox* 2% Gel Procedure:** Using the same basic behaviour management technique as mentioned in the VIBRADENT procedure, Lox* 2% gel was applied to the opposite side of same arch. The site of injection was cleaned and dried with a gauze piece before the application of topical Lox 2% gel for 2 min, followed by this IANB was administered, 2 mL of 2% lignocaine hydrochloride with 1:2,00,000 adrenaline (XICAINE*) at a rate of 1mL/min, using a 2 mL syringe of a 26-gauge needle (UNOLOK*) (Figure 4).

Fig 4: Clinical application of Topical Anaesthetic Gel

Assessment of Pain reaction

- **Subjective Evaluation:** Universal pain assessment scale i.e. Wong-Baker Face's Pain Rating Scale (WBFPRS) was used. The WBFPRS measures the unpleasantness of a child's experience using a set of cartoon faces with varying facial expressions, ranging from smile/laughter to tears, and each child will be asked to select the facial expression that will best represent his/her experience or discomfort, each face has a numerical value (Figure 5).

Fig 5: Wong-Baker Face's Pain Rating Scale

- **Objective Evaluation:** Pain reaction was evaluated using the Faces, Legs, Activity, Cry, Consolability (FLACC) scale. Each of the 5 categories is scored from 0 to 2, and final score from 0-10, in which zero is the minimum and 10 is maximum (Figure 6).

Fig 6: Faces, Legs, Activity, Cry, Consolability Scale

According to this scale

0 = relaxed and comfortable (no pain)
1 to 3 = mild discomfort
4 to 6 = moderate pain
7 to 10 = severe discomfort or pain.

Statistical Analysis & Results

Data was analysed using SPSS Statistical Software. Level of significance was set at P≤ 0.05. Mann Whitney U test was used for intergroup comparison & Mean and Standard deviation was calculated. The mean age of the children was 9.7 ± 0.82 years.

According to the WBFPRS, results showed significance difference in the Group-I Vibradent and Group-II topical anaesthetic gel (P ≤ .001), the mean pain score in the Vibradent group was 1.5± 0.70, the topical gel group scored 3.5± 0.84 with a significant difference P≤.000 (Table 1). Mean pain score in the FLACC scale rating showed 4.0± 1.24 for Vibradent device and 7.1± 1.19 for topical anaesthetic gel group with a significant difference P≤.000 (Table 2). The mean rank in the FLACC scale category for Vibradent group was 6.40 and for topical gel group was 14.60 (Table 3). A positive correlation in between the two groups stated that Vibradent device performed relatively better in reducing the pain as compared to topical anesthetic gel in pediatric patients.

Table 1: Subjective assessment of pain with WBFPRS

	Groups	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	t	P value
Wong-Baker's	Gp - I VIBRADENT	10	1.5000	.70711	.22361	-2.00000	-5.721	.000

Face's Pain Rating Scale	Gp - II Topical Anesthesia	10	3.5000	.84984	.26874			

Table 2: Objective assessment of pain with FLACC scale

	Groups	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	t	P value
FLACC SCALE	Gp - I VIBRADENT	10	4.0000	1.24722	.39441	-3.10000	-5.670	.000
	Gp - II Topical Anesthesia	10	7.1000	1.19722	.37859			

Table 3: Comparison of FLACC Scale in group I & II

			Groups		Total
			Gp - I VIBRADENT	Gp - II Topical Anesthesia	
FLACC SCALE (Category)	1.00	n	4	0	4
		%	100.0%	0.0%	100.0%
	2.00	n	6	3	9
		%	66.6%	33.4%	100.0%
	3.00	n	0	7	7
		%	0.0%	100.0%	100.0%
		Mean Rank	6.40	14.60	
		Mann-Whitney U	9.000		
		P value	.001		

Discussion

The present study was conducted to evaluate and compare the efficacy of Vibradent with that of topical anesthetic gel in minimizing of pain perception during the local anesthesia administration (pain of needle insertion). Frankel's Behaviour rating scale as positive and definitely positive were included to rule out different factors such as anxiety, tension, depression and few other emotional factors which might have affected the study outcome.[5] Various methods and devices have been developed to minimize pain during injection.[6] There are various vibrotactile device available in market which differs in design, including DentalVibe (DV), Accupal, Buzzy, Vibraject ad Syringe Micro Vibrator.[7] This Vibradent device helps the dentist to hide the syringe from paediatric patients during injection and thus safely manipulating the needle. [7, 8]

According to Ronald Melzack and Patric Wall's Gate Control theory (1965), pain can be minimized by activating large-diameter nerve fibers to carry non-painful stimuli (touch and vibration), as brain can receive only one sensation at a time and thus application of vibration acts as a counter-stimulation during injection. [8] Part of the device includes 2 prongs that touches the mucosa of the injection site and one of the prongs is kept close to the needle. Comfort tips helps in rapid dissipation of the solution and producing a profound anesthetic effect. The handle of the device delivers unique soothing pulsed vibration to block pain and discomfort.

Subjective Evaluation was done using universal pain assessment scale i.e. WBFPRS which measures the unpleasantness of a child's experience using a set of cartoon faces with varying facial expressions, ranging from smile/laughter to tears. Each child was asked to select the facial expression that will best represent his/her experience or discomfort. Objective Evaluation is done by evaluation of pain reaction using FLACC scale. Each of the 5 categories is scored from 0 to 2, where zero is the minimum and 10 is maximum. Some recent studies have included the Sound-Eye-Motor (SEM) scale which observes the patient's voice, eyes and movement caused due to discomfort during injection. [8] Pain measurement does not completely rely on verbal and behavioural rating scales and psychological indicators are also considered for the same. [9]

The bone of the mandible in a child is usually less dense which makes the anaesthetic solution diffuse rapidly and thus mandibular buccal infiltration is also effective as IANB injection.[10] The other techniques such as computer controlled local anaesthetic delivery, needless system, intraseptal or intrapulpal injections improve comfort in patients by better control in the rate and pressure of administration. [10, 11]

Few Studies conducted by Amin Nasehi ***et al,*** stated that mean visual analogue scale (VAS) score was lower with vibration device than without vibration device. [12] Whereas, a study conducted by Ozgur Erdogan, concluded that there was a discomfort due to vibratory device itself and was not effective in pain reduction during maxillary anterior infiltration local anesthetic administration. [13] For better results, independent measure, pain behaviour reliability, dentist perception, child pain behaviour and child pain ratings parameters were included by Brandi Roeber *et al*. [14]

Various advances in armamentarium and local anesthesia agents are available to the dentist and therefore right choice of drug and dosage adjustment should be considered, as well as with thorough knowledge of toxicity due to anaesthetic agents can be avoided. [15] Since children have varying capacities to deal with different situations, it is always helpful if we know how children perceive different stressful stimuli in different situations. [16] In current study, Vibradent is been found to be quite effective in reducing pain as compared to topical anaesthetic gel in pediatric patients. But, further studies on pediatric patients with various levels of cooperation with different age group and inclusion of other nerve block injection techniques are recommended.

Conclusion

With the limitations of the current study, and based on the results, it can be concluded that using Vibradent during intra oral dental injections can help in minimizing the pain. Therefore, this tool can be used as easy and convenient alternative technique.

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