



Effectiveness of an extraoral cold and vibrating device in reducing pain perception during deposition of local anesthesia in pediatric patients aged 3-12 years: a split-mouth crossover study

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Background: Local anesthetic injections may induce pain in children, leading to fear and anxiety during subsequent visits. Among the various approaches recommended to reduce pain, one is the use of a Buzzy Bee™ device that operates on the concept of gate control theory and distraction. The literature regarding its effectiveness during the deposition of local anesthesia remains limited; hence, the aim of the present study was to determine the efficacy of extraoral cold and vibrating devices in reducing pain perception during the deposition of local anesthesia.

Methods: A split-mouth crossover study in which 40 children aged 3-12 years requiring maxillary infiltration or inferior alveolar nerve block for extractions or pulp therapy in the maxillary or mandibular posterior teeth were included. The control intervention involved the application of topical anesthetic gel for one minute (5% lignocaine gel), followed by the administration of local anesthetic (2% lignocaine with 1:80,000 adrenaline) at a rate of 1 ml/ minute. Along with the control protocol, the test intervention involved using the Buzzy Bee™ device for 2 minutes before and during the deposition of the local anesthetic injection. The heart rate and face, legs, arms, cry, and consolability revised (FLACC-R) scale scores were recorded by the dentist to assess the child's pain perception.

Results: The mean age of the participants in Group A and Group B was 7.050 ± 3.12 years and 7.9 ± 2.65 years respectively. A reduction in the mean heart rate and FLACC-R score was observed during the deposition of local anesthetic solution in the tissues when the Buzzy Bee™ was used in both groups at different visits in the same subjects ($P < 0.05$). The Buzzy Bee™ device was effective in reducing the heart rate and FLACC-R scores when used during maxillary infiltration and inferior alveolar nerve block local anesthesia techniques ($P < 0.05$).

Conclusion: The use of extraoral cold and vibrating devices significantly reduces pain perception during local anesthetic deposition in pediatric patients. Considering the results of this study, the device may be incorporated as an adjunct in routine dental practice while administering local anesthesia in children.

Keywords: Buzzy; FLACC-R Scale; Local Anesthesia; Pain; Pediatric Dentistry; Vibration.

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INTRODUCTION

The administration of local anesthesia during dental

procedures may induce pain in some children, leading to a detrimental effect on their behavior and cooperation during the present and subsequent visits [1]. Pain may be due to needle prick and/or deposition of the local

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anesthetic solution into the tissues [2]. Various pharmacological, physical, and psychological interventions have been advocated to curtail this pain namely distraction, use of topical anesthetic gel, modifying rate of infiltration, use of intra-oral vibrating devices, use of computerized delivery systems, and pre-cooling of the injection site [3]. One such method is the use of an extraoral cold and a vibrating device named Buzzy Bee™ (Pain Care Labs, USA). The device consists of a vibrating motor encompassing a bee-shaped body and a wing-shaped detachable ice pack [4]. The effectiveness of Buzzy Bee™ is based on the distraction principle and the gate-control theory given by Melzack and Wall in 1965 and is effective in children during procedures like immunization and venipuncture [5]. This device has been shown to reduce pain perception during dental injections [1,2,3,6-12]. However, the type of anesthesia administered in most studies is infiltration [2,5-10], and very few studies have used the device while treating teeth requiring inferior alveolar nerve block anesthesia [1,12]. Pain perception can be assessed at the time of needle prick, during deposition, and after deposition of the local anesthetic solution in the tissues. Only a few studies have assessed pain perception during the deposition of local anesthetic solutions in tissues [7,9,11]. Hence, considering the lacunae in the available literature, the present study aimed to evaluate the efficacy of the device in reducing pain perception during the deposition of local anesthetic solution into tissues and compare its effectiveness in reducing pain between the maxillary infiltration technique and the inferior alveolar nerve block technique in children.

METHODS

1. Study design and ethical approval

The present study is a split-mouth crossover study conducted in the Department of Pediatric and Preventive Dentistry. Ethical approval was obtained from our Institutional Review Board [IREB/2023/PEDO/03]. This

study was registered under the Clinical Trial Registry, India [REF/2023/07/070727].

2. Sample size

The sample size was calculated using G*Power (Universitat Kiel, Kiel, Germany) sample size calculation software version 3.1.9.7. Twelve patients per group met the minimum requirement for an alpha of 0.05 and a power of 0.95.

3. Sample selection

1) Inclusion criteria

- (1) 3-12-year-old children requiring local anesthesia administration for bilateral extractions or pulp therapy in maxillary or mandibular posterior teeth.
- (2) Children with no previous experience of intraoral local anesthesia.

2) Exclusion criteria

- (1) Children with systemic illness or known allergy to local anesthesia or any of its components.
- (2) Children belonging to Frankl's definitely negative category (I).
- (3) Children whose parents did not give consent for participation in the study.

4. Intervention description

Children were recruited from the outpatient department of the Department of Pediatric and Preventive Dentistry, requiring local anesthesia administration for dental treatment. They were divided into Group A and Group B using a lottery-randomization technique. At the first visit, the children in Group A received the test intervention and those in Group B received the control intervention. A washout period of 7 days was observed, after which the second visit was scheduled. At the second visit, the children in Group A received the control intervention and those in Group B received the test intervention. Demographic details, informed consent from the parents, and assent from the children were obtained



Fig. 1. Placement of Buzzy Bee™ device for maxillary infiltration technique of anaesthesia

before the commencement of the study.

5. Control intervention

The control intervention comprised of application of 5% lignocaine topical anesthetic gel (Lignospan-O, Septodont Healthcare, India) for 1 min, followed by the administration of 2% lignocaine 1:80,000 adrenaline solution in a cartridge (Lignospan Special, Septodont Healthcare, India). For the maxillary infiltration technique, a 30 gauge, 0.30 × 26-inch short disposable needle (Septoject, Septodont Healthcare, India), and for inferior alveolar nerve block a 27 gauge, 0.40 × 35-inch-long disposable needle (Septoject, Septodont Healthcare, India) along with a self-aspirating metal syringe (Septodont Healthcare, India) were used.

6. Test intervention

The test intervention included the application of the Buzzy Bee™ (Pain Care Labs, USA) device along with the control intervention procedure mentioned above. The vibrating Buzzy Bee™ device was attached to the gel ice pack comprising of water, sodium polyacrylate, and mixed isothiazolinones that had been precooled to 50°C. The children were introduced to this device using the 'Tell-show-do' technique. They were allowed to play with



Fig. 2. Placement of Buzzy Bee™ device for inferior alveolar nerve block technique of anaesthesia

the device before the extraoral application. The Buzzy Bee™ was placed vibrating throughout the procedure of the deposition of local anesthesia. The Buzzy Bee™ was positioned at the ramus of the mandible for the inferior alveolar nerve block (Fig. 1) and at the zygomatic arch for the maxillary infiltration method (Fig. 2) [1]. All procedures were performed by a single examiner.

7. Outcome measures

a. Heart rate: A fingertip pulse oximeter (Mievida, MedMongers Inc., India) with a digital display of the pulse rate and oxygen saturation values was used in the present study. An independent examiner recorded the heart rate values. The index finger was used as the attachment point for the pulse oximeter, and heart rate values were taken at baseline, during, and after deposition of the local anesthetic solution in the tissue.

b. Pain: The face, legs, arms, cry, and consolability revised (FLACC-R) scale was used to assess the objective signs of pain behavior in children [13]. This tool provides an overall pain score ranging from 0 (relaxed and comfortable) to 10 (severe discomfort or pain) by rating five behavioral parameters on a scale of 0–2. Scoring was performed by an independent examiner during the deposition of the local anesthetic solution.

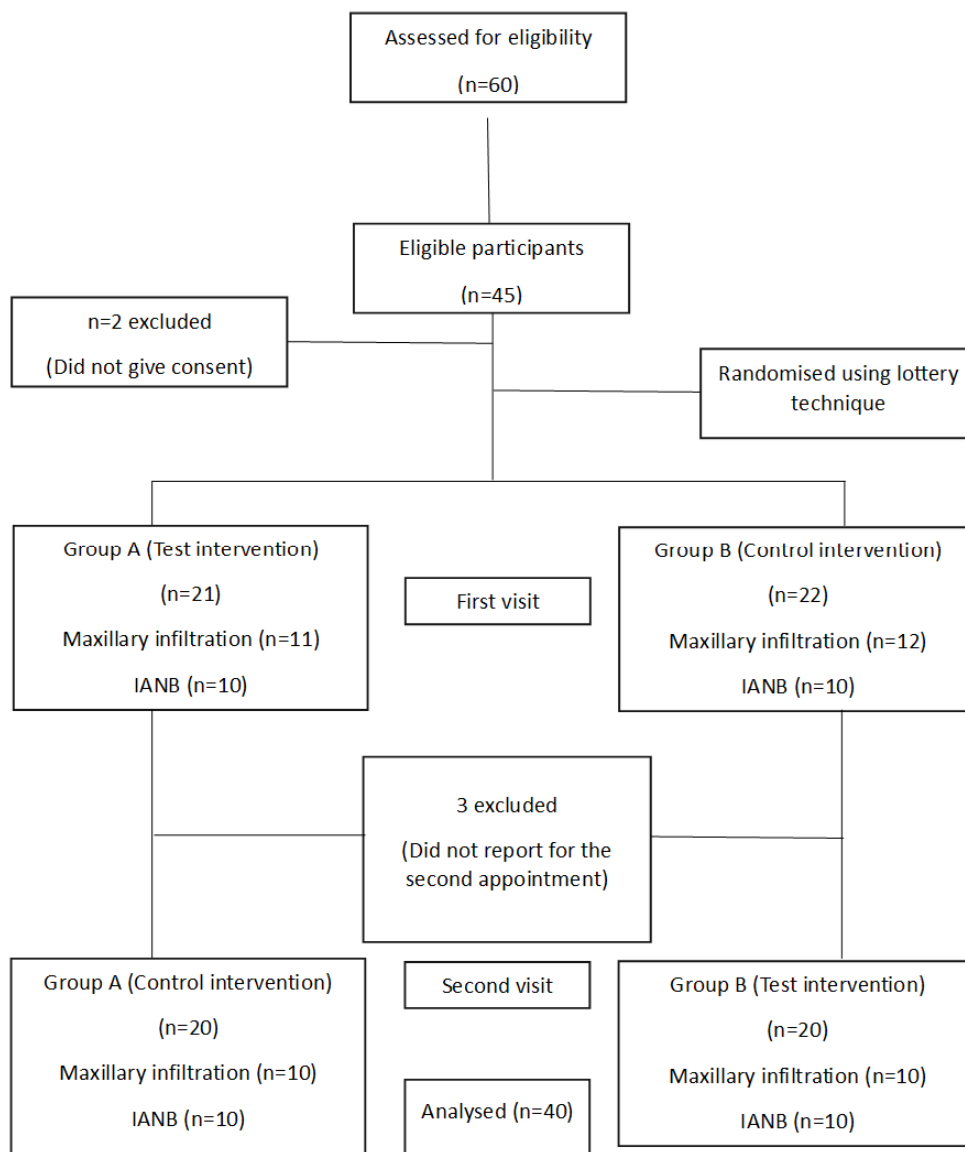


Fig. 3. Schematic representation of study design from assessment of eligibility of the participants to analysis. IANB, inferior alveolar nerve block.

8. Statistical analysis

The mean and standard deviation of heart rate and FLACC-R scores were calculated for both groups at both visits. The comparative statistics for the demographic characteristics like the age and sex of the children were performed using the chi-square test. Intra-group comparisons of heart rate and FLACC-R score for both visits were performed using the Mann-Whitney U test. Intergroup comparison of heart rate and FLACC-R score for both visits was performed using the Friedman test. The comparative statistics for heart rate and FLACC-R

score depending on the type of anesthesia used were obtained using the Wilcoxon signed-rank test. IBM SPSS version 21(IBM Corp., Armonk, NY, USA) was used for statistical analysis.

RESULTS

A total of 60 children were screened, 45 of whom met the inclusion criteria. However, two children were excluded because their parents did not provide consent for participation in the study, and three children who did

Table 1. Age and sex-wise distribution of the study population

		Group A	Group B	Chi square test		Significance
Age (in yrs) (Mean \pm SD)		7.050 \pm 3.12	7.9 \pm 2.65	0.12		P = 0.73
Gender	Males	13 (65)	8 (40)	1.8	0.8	P = 0.75
	Female	7 (35)	12 (60)	0.18	0.37	

*statistically significant difference as assessed using Chi square test if P < 0.05

Table 2. Mean and standard deviation of heart rate and FLACC-R for Group A and Group B at first and second visit

		Heart rates	Groups	N	Minimum	Maximum	Mean	Std. deviation
First visit	At baseline		A	20	80.0	122.0	96.40	12.52
			B	20	73.0	114.0	96.40	12.14
	During deposition		A	20	72.0	139.0	100.25	15.47
			B	20	76.0	141.0	112.40	16.86
	After deposition		A	20	72.0	139.0	100.25	15.47
			B	20	84.0	136.0	116.55	17.04
	FLACC-R		A	20	0.0	6.0	1.85	1.56
			B	20	1.0	6.0	3.75	1.25
Second visit	At baseline		A	20	86.0	126.0	99.70	12.26
			B	20	78.0	118.0	94.30	8.65
	During deposition		A	20	92.0	130.0	112.10	13.40
			B	20	86.0	126.0	108.45	13.04
	After deposition		A	20	88.0	132.0	113.70	13.87
			B	20	88.0	122.0	105.95	10.70
	FLACC-R		A	20	0.0	8.0	3.80	1.70
			B	20	0.0	6.0	2.30	1.38

FLACC-R, face, legs, arms, cry, and consolability revised; N, number.

Table 3. Inter-group comparison of heart rate and FLACC-R score at first and second visit between Group A and Group B

		Heart rates	Groups	N	Mean rank	Sum of ranks	Mann-Whitney U test	Significance
First visit	At baseline		A	20	19.50	390.0	180.00	0.587
			B	20	21.50	430.0		
	During deposition		A	20	16.18	323.50	113.50	0.019*
			B	20	24.83	496.50		
	After deposition		A	20	14.53	290.50	80.50	0.001*
			B	20	26.48	529.50		
	FLACC-R		A	20	13.80	276.00	66.00	0.00*
			B	20	27.20	544.00		
Second visit	At baseline		A	20	22.70	454.00	156.00	0.229
			B	20	18.30	366.00		
	During deposition		A	20	22.20	444.00	166.00	0.357
			B	20	18.80	376.00		
	After deposition		A	20	24.18	483.50	126.5	0.04*
			B	20	16.83	336.50		
	FLACC-R		A	20	13.80	276.00	66.00	0.00*
			B	20	27.20	544.00		

*statistically significant difference as assessed using Mann-Whitney U test if P < 0.05

FLACC-R, face, legs, arms, cry, and consolability revised; N, number.

not report for the second visit were excluded. Hence, a total of 40 children (21 males and 19 females) were analyzed at the end of the study (Fig. 3). The mean age of the participants in Group A and Group B was 7.05

\pm 3.12 years and 7.9 \pm 2.65 years, respectively, with no statistically significant difference (P = 0.73) (Table 1). In both groups, 10 children received maxillary infiltration anesthesia, and 10 children received inferior alveolar

Table 4. Intragroup comparison of heart rate and FLACC-R score within the first and the second visit of Group A and Group B

Heart rate	Groups	Mean rank	Friedman test	Significance
At baseline	First visit- A	2.03	8.2	0.04*
	Second visit- A	2.75		
	First visit- B	3.03		
	Second- B	2.20		
During injection	First visit- A	1.80	9.984	0.01*
	Second visit- A	2.93		
	First visit- B	2.85		
	Second- B	2.43		
After injection	First visit- A	1.60	16.72	0.00*
	Second visit- A	3.03		
	First visit- B	3.00		
	Second- B	2.38		
FLACC-R score	First visit- A	1.65	31.69	0.00*
	Second visit- A	3.23		
	First visit- B	3.35		
	Second- B	1.78		

*statistically significant difference as assessed using Friedman’s test if $P < 0.05$
 FLACC-R, face, legs, arms, cry, and consolability revised.

Table 5. Comparison of heart rate and FLACC-R score between the group with test intervention and with control intervention based on the type of anesthesia administered

Type of anesthesia	Heart rate	Groups	N	Mean rank	Sum of rank	Mann- Whitney U test	Significance
Maxillary infiltration	At baseline	Buzzy	20	16.58	331.50	121.5	0.032*
		Control	20	24.43	488.50		
	During deposition	Buzzy	20	15.45	309.00	99.0	0.006*
		Control	20	25.55	511.00		
	After deposition	Buzzy	20	14.28	285.50	75.5	0.00*
		Control	20	26.73	534.50		
	FLACC-R	Buzzy	20	12.55	251.00	41.0	0.00*
		Control	20	28.45	569.00		
Inferior alveolar nerve block	At baseline	Buzzy	20	20.15	403.00	193.0	0.849
		Control	20	20.85	417.00		
	During deposition	Buzzy	20	19.30	386.00	176.0	0.516
		Control	20	21.70	434.00		
	After deposition	Buzzy	20	16.78	335.50	105.5	0.044*
		Control	20	24.23	484.50		
	FLACC-R	Buzzy	20	15.78	315.50	105.5	0.009*
		Control	20	25.53	504.50		

*statistically significant difference as assessed using Mann-Whitney U test if $P < 0.05$
 FLACC-R, face, legs, arms, cry, and consolability revised; N, number.

nerve block. The minimum and maximum heart rates and FLACC-R scores, along with the mean and standard deviation for Group A and Group B at the first and second visits, are shown in the (Table 2).

1. Test intervention (Buzzy Bee™) vs control intervention

A reduction in the mean heart rate was observed when the test intervention was used at the first visit in Group

A and the second visit in Group B, as assessed using the Mann-Whitney U test (Table 3). On the first visit, in Group A where test intervention was performed, the heart rate was significantly lower during the deposition of the solution in the tissues and after the deposition of the solution ($P < 0.05$). At the second visit, in group B, where the test intervention was performed, the heart rate was significantly lower after the deposition of the solution ($P < 0.05$). Similarly, the FLACC-R score was signifi-

cantly lower at both visits when the test intervention was performed ($P < 0.05$).

A comparison of the heart rate between the first and second visits in Groups A and B showed a statistically significant reduction prior to, during, and after the deposition of the local anesthetic solution into the tissue ($P < 0.05$). The FLACC-R score was significantly lower at the visit where the test intervention was performed ($P < 0.05$) (Table 4).

2. Maxillary infiltration vs inferior alveolar nerve block

The Buzzy Bee™ device was effective in both maxillary infiltration and inferior alveolar nerve block type of local anesthesia techniques (Table 5). The heart rate was significantly lower when the test intervention was performed during maxillary infiltration at baseline, during deposition of the solution, and after deposition of the solution ($P < 0.05$). The heart rate was significantly lower after the deposition of the solution when the test intervention was performed during inferior nerve block anesthesia ($P < 0.05$). Similarly, the FLACC-R score was significantly lower when the test intervention was performed during the maxillary infiltration and inferior nerve block technique of anesthesia ($P < 0.05$).

DISCUSSION

Pediatric dental patients frequently struggle with fear and anxiety regarding dental procedures. Children requiring local anesthesia for dental treatment in the age group of 3-12 years were included in our study as it helped in assessing the efficacy of the Buzzy Bee™ device in both pre-cooperative and cooperative stages of development. A split-mouth crossover design was adopted to minimize possible bias in the assignment of treatments and therapeutic responses [14].

Pain during local anesthesia deposition can be attributed to needle prick during deposition of the solution into the tissue and after removal of the needle [15]. In the present study, we considered the pain perception of

the patient during the deposition of the local anesthetic solution into the tissue, which could be due to the expansion of the tissues, activation of both A-delta and C fibers, and the pH of the solution [16]. Buzzy Bee™ device functions on the principle of distraction and Gate control theory. According to gate control theory, a modulating center in the dorsal horn of the spinal cord serves as a pathway for pain signals that are transmitted from the peripheral nervous system to the central nervous system. Pain perception can be reduced by activating nerve fibers that transmit nonnoxious stimuli [17]. Unmyelinated A-delta and C-type nerve fibers transmit pain at a speed of 6-30 m/s and 0.5-2 m/s, respectively, whereas myelinated A-beta type fibers transmit vibration stimulus at a speed of 30-70 m/s [18,19]. The vibration component of the Buzzy Bee™ device blocks the A-delta fibers and stimulates the A-beta fibers whereas, the cold component stimulates the C fibers and further blocks the A-delta fibers when used before the pain stimulus [10]. Vibrations also stimulate mechanoreceptors, such as Pacinian corpuscles and Meissner's corpuscles, not just in the skin and subcutaneous tissue, but also in the underlying bone [18]. Hence, greater pain reduction can be achieved when the underlying bone is stimulated near the injection site [17]. Therefore, the device was placed over the bone close to the injection site during the local anesthesia deposition procedure. The present study included treatment procedures performed under maxillary infiltration and inferior alveolar nerve block technique. Inferior alveolar nerve block injections are more painful than local infiltration [20]. Based on this fact, we compared the pain perception between both these techniques of anesthesia under the use of a Buzzy Bee™ device. The device was equally effective in reducing the pain perception for both maxillary infiltration and inferior alveolar nerve block technique of anesthesia.

The heart rate is a definite indicator of the amount of stress experienced by individuals undergoing dental treatment [21]. A pulse oximeter was used in the present study as it helps accurately gauge the heart rate. The observations in the present study were that, the heart rate

was found significantly lower when the Buzzy Bee™ device was used similar to the study done by Hegde et al. [12], Alanazi et al. [9], and contrary to the studies done by Jain et al. [3] and Suohu et al. [10] where no statistically significant reduction in the heart rate was observed.

The study included the use of a revised version of the FLACC scale with the addition of precise descriptors and children's distinctive behaviors, as reported by their parents. [13]. The FLACC-R scores were significantly lower when the Buzzy Bee device was used, similar to the results of the study by Jain et al., in which the FLACC-R score was significantly lower in the Buzzy Bee group ($P = 0.001$) [3].

The limitations of the device observed were that the size of the device (7.2 cm × 4.8 cm × 2.2 cm) was large for children with smaller facial morphology and although most of the children accepted the application of the device, two children aged 4 and 6 years, showed discomfort with the application of the cold wings.

The use of extraoral cold and vibrating devices significantly reduces pain perception during local anesthetic deposition among pediatric patients. Considering the results of this study, the device may be incorporated as an adjunct in routine dental practice while administering local anesthesia in children.

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Rucha Bhise Patil: Supervision, Validation, Visualization

Parnaja Sanjay Valke: Conceptualization, Methodology, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing

Sonal Mali: Investigation, Methodology

Diksha Patil: Investigation, Methodology

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