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EFFICIENCY OF A VIBRATING AND COLD APPLICATING DEVICE IN REDUCING PAIN OF LOCAL ANESTHESIA IN CHILDREN

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Anxiety, Buzzy bee, Children, FLACC Scale, Pain, VCARS.

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ABSTRACT

Introduction: Children often develop phobia toward needle pricks and invasive procedures. Unmanaged pain could result in short and long-term physiological, psychological, and emotional consequences. **Aim:** The aim of this study was to compare the effectiveness of (Buzzy Bee device) versus traditional topical anesthesia 20% benzocaine gel in management of pain and anxiety during nerve block and infiltration for maxillary and mandibular primary molars in children. **Materials and methods:** A randomized, split-mouth study was conducted on 60 children aged 4-6 years, with no previous dental experience, who required maxillary infiltration or inferior alveolar nerve block for pulpotomy in the maxillary or mandibular primary molars. The children were divided equally into two main groups, nerve block (n=30) and infiltration groups (n=30). Then each group was subdivided into Buzzy Bee device subgroup (examined side) and topical anesthesia 20% benzocaine gel subgroup (control side), followed by pulpotomy or extractions. An assessment of the children's pain perceptions was conducted by the dentist, using The Face Legs Activity Cry Consolability (FLACC) Scale, while anxiety levels of children were assessed by Venham's anxiety and behavioral rating scale (VCARS), recorded during and after administration of local anesthesia. Data were analyzed for statistical significance ($p<0.05$). **Results:** There was a very highly significant reduction in anxiety assessment by (VCARS), during and after injection of LA using Buzzy Bee device ($P<0.001$***). According to pain assessment by (FLACC) Scale, effective reduction during and after injection of local anesthesia observed when using Buzzy Bee device ($P<0.001$***) in both groups. **Conclusion**: In pediatric patients, the Buzzy Bee device dramatically lessens the impression of pain during local anesthetic deposition. The device could be used as a supplement to standard dental procedures when giving children local anesthetic.

INTRODUCTION

The use of local anesthetic is one of the most effective ways to manage pain and discomfort during invasive dental procedures. However, it is the most painful phase of dental treatment and often results in the treatment being stopped prematurely. Which notably affects the patient's apprehension toward dental care. The idea of receiving an injection is fear-inducing for many individuals, especially young patients. Although dentists have little influence over such fears, several complementary methods can be used to make patients feel more comfortable. [1,2]

High dental anxiety is common among children, particularly during their first dental visit and in younger age groups. [3,4] Painful local anesthetic injections often trigger needle-related fear, leading to treatment avoidance and increased caries risk. [5-6] The traditional syringe-based method of administering anesthesia frequently causes pain. from needle penetration, tissue distension, and inflammation due to percolation of the injected fluid and mucosa irritation in response to the anesthetic solution[6]. Minimizing injection pain fosters trust and positive dental attitudes.[8]

Non-pharmacological behavior guidance techniques (BGTs) have proven to be the gold standard interventions for managing children experiencing needle-related pain, such as Tell-Show-Do (TSD), modeling, voice control, hypnosis, acupuncture, biofeedback, guided imagery, and distraction using storytelling, audio, or audiovisual aids, which target the psychological facet of the child; these are highly acceptable, as they do not result in repercussions[9,10]. Pre-visit exposure through books or videos also helps familiarize children.[11]

These complementary methods include applying topical anesthetics before injection, using distraction techniques, employing counter-irritation, adjusting infiltration rates, buffering and warming the local anesthetic, reducing injection speed, utilizing fine needles with advanced syringes, applying pressure at the injection site, and adopting computer-controlled anesthesia delivery systems[12]. However, no technique ensures a completely painless experience.[12,15].

There are non-pharmacological pain-reduction techniques based on the gate control principle. For example, prior research has demonstrated that when skin temperature is lowered to 4°C, pain thresholds rise.[16,17] Furthermore, In addition to the gate control theory, which claims that non-painful stimuli lessen the transmission of pain signals, this phenomena may be explained by decreased terminal neuron sensitivity, decreased edema, and slowing of signal transmission through nerves, due to vasoconstriction.[18] Similar results are seen with vibration; the gate control theory states that when mechanoreceptors are activated by external vibration, pain impulses in the spinal cord are blocked or diverted to the spinothalamic fibers.[19]

VibraJect (VJ), DentalVibe (DV), and BUZZY are a few examples of currently available devices that use "cold and vibration" to reduce injection-associated pain and anxiety in pediatrics. [20,21]. Among all, BUZZY (Pain Care Labs, USA) concurrently provides cold and external vibration to the injection site. The gadget uses a plastic body that resembles a bee to impart vibration, and it features a "wing" section that can hold 18 grams of ice to deliver cold. Furthermore, BUZZY has an attractive appearance to distract the child's attention during injection, and only a handful of contraindications exist regarding its use.[22] Pre-working modulating video for buzzy bee device can enhance patient comfort by reducing fear of unfamiliar devices and alleviating pain and anxiety during the injection of anesthetics, which is often the most painful step in dental treatment.

Regarding the real-world effectiveness of BUZZY in reducing injection-associated pain/ anxiety of children, results of previous studies have been contrary; the effectiveness seems to vary based on site of injection, and its type [23, 24]. In pediatric dentistry a systematic review and meta-analysis study concluded that inadequate data is available on the effectiveness of BUZZY in controlling injection pain [25]. Therefore, this clinical trial aimed to evaluate the efficiency of the buzzy bee device and traditional topical anesthetic gel and to compare their effectiveness in management of pain and anxiety between the maxillary infiltration technique and the inferior alveolar nerve block

technique during the deposition of local anesthetic solution into tissues and during dental treatment of primary molars in children. This study tested a null hypothesis which stated that, there is no difference in management of pain and anxiety of the compared behavioral techniques.

MATERIALS AND METHODS

The study was a split-mouth randomized-controlled clinical study conducted on sixty patients from the Outpatient Clinic at the Department of Pediatric Dentistry, Faculty of Dentistry, Suez Canal University, from December 2021 to May 2022. Complying with the World Medical Association Declaration of Helsinki (version 2008), The Research Ethical Committee of faculty of Dentistry, Suez Canal University accepted the study proposal (448/2022), and all clinical procedures were performed in accordance to its guidelines and regulations. The current proposal was recorded at www.ClinicalTrials.gov ((26/08/2021), study identifier: (NCT05021809). Data reporting was in line with the Consolidated Standards of Reporting Trials Statement (CONSORT) checklist (Fig.1). The randomization sequence was created using computer-generated random numbers (CGRNs).

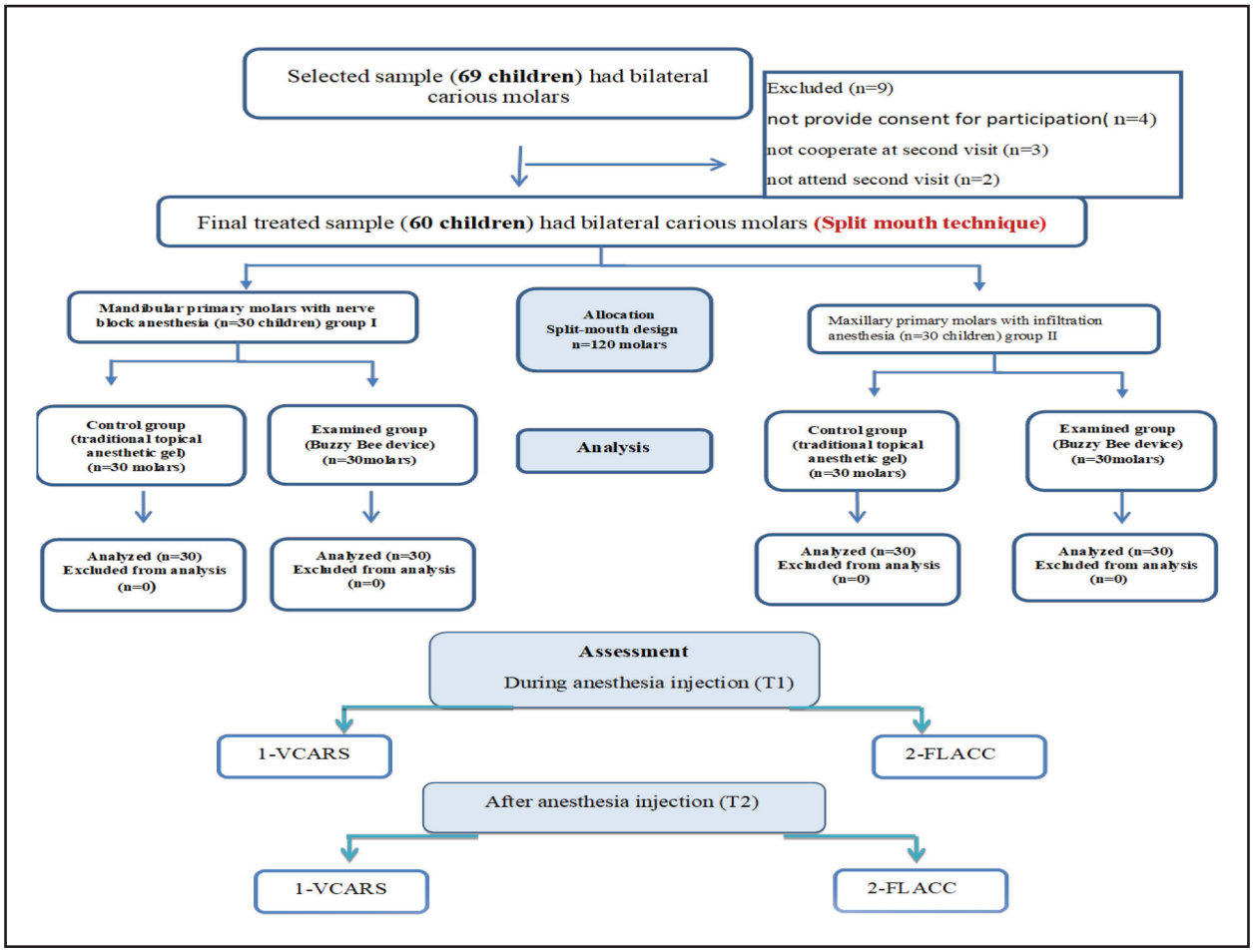

Fig. (1) CONSORI flow diagram of the study

Prior to the study, written informed consent was obtained from the parents or guardians of the participating children explaining the study procedures and the related possible complications and indicating their agreement to the treatment.

Sample size calculations

Sample size calculation was carried out to compare between different treatments using G*power version 3.1.9.5.[26] The study determined that 60 patients is adequate to identify an effect size of 0.39 using alpha (α) level of 0.05 and Beta (β) level of 0.05, i.e. power = 95%; the estimated sample size (n) should be **120 samples** for this study, from both the right and left sides of these 60 patients, will be included, with random allocation to either the control or test groups.

Sample selection

The research encompassed 60 children attending the outpatient clinic of pediatric and preventive dentistry department, Suez Canal University. Their ages between 4 and 6 years old, of both genders, who needed pulpotomy of their right and left mandibular or maxillary primary molars. The need for treatment was established both clinically and radiographically. They were physically and mentally healthy, did not take any analgesics. Only children who had never received previous dental treatment and demonstrated cooperative behavior, specifically those rated as "positive (+2)" or "negative (–3)" according to the Frankl Behavior Scale (FBS).[27]

Children with developmental or systemic conditions, allergies to materials (topical or local anesthetic) or equipment (cold sensitivity –Raynaud's disease or sickle disease) used in the study. Uncooperative children or those with no need for local anesthesia (very simple restorations) were excluded from the study.

Additionally, the child was not allowed to participate in the trial if the proposed location for the device was inflamed or had pathology at the injection site. Absence of parental consent also resulted in exclusion.

Sample grouping and Study design

The study was conducted as a randomized clinical trial using split-mouth technique with 60 children, who were assigned into two main groups based on the type of local anesthesia: the mandibular nerve block anesthesia group (n=30 patients), and the maxillary infiltration group (n=30 patients). Then, each main group was subdivided according to the method of pain control during the injection into the Buzzy bee (BB) subgroup (experimental side) and topical gel (TG) subgroup (control side). Randomization was in a split-mouth fashion using a simple randomization with a 1:1 allocation ratio, each side of each participant's mouth allocated on one of the study arms based on computergenerated random sequence was obtained using the True Random Number Service, which may be accessed online at www.random.org. Sequentially numbered opaque sealed envelopes held the allocation sequence, numbered from 1 to 30, each envelope was taken by a patient in ascending sequence. Participants received local anesthesia using Buzzy Bee device in first visit for better assessment of the device efficiency. Participants underwent their dental procedures in two sessions separated by a washout period of 7 days, after which the second visit was scheduled, each session on one of the mouth sides.

Initially, a pilot study was conducted on 20 children, 17 of whom exhibited a completely negative response and refused treatment. The children attributed their refusal to fear caused by the crowded and noisy environment of the faculty clinic, as well as apprehension about the vibration action of the device. To address these concerns, a controlled

clinical trial was conducted involving 60 children presenting with bilateral deeply carious maxillary or mandibular primary molars. The trial was held in the VIP room of the Pedodontic Department at the Faculty of Dentistry, Suez Canal University, in an effort to reduce anxiety associated with the clinical environment. As part of the intervention, each child was shown a specially designed animated video introducing the Buzzy Bee device and explaining its mechanism of action. This video, produced specifically for the present study by Dar Maymon Advertising Company, aimed to alleviate apprehension related to the device's vibratory and cold application.

Clinical procedures

To ensure that all children fulfill the eligibility criteria, each child participant was subjected to a thorough examination. Medical history was taken from the patients or caregiver to ensure good health status. Moreover, extra-oral and intra-oral examinations and radiographic examination were performed under dental and all data collected. According to the Frankl Behavior Scale (FBS), the children were classified as displaying "negative" or "positive" dental behavior based on their capacity to comply with the dentist's instructions during the clinical examination and to finish the radiographic examination using periapical films without sobbing. Both children and their parents or caregiver were provided with a concise, age appropriate explanation of the procedures.

All dental instruments and procedures, including the Buzzy Bee device (Fig. 2), were introduced to the participants using the "tell-show-do" technique. Additionally, the local anesthesia procedure was explained in an age-appropriate, child-friendly manner. For instance, the explanation included phrases such as "two different methods were used to put your tooth to sleep" to describe the anesthetic process without causing anxiety. The Buzzy Bee device was employed during the child's first dental visit to enable an accurate assessment of its effectiveness. However, participants were not informed that one method might be less painful than the other in order to prevent anticipatory anxiety or bias. Prior its application and while the child was seated comfortably in the dental chair, they were shown an engaging animated video designed to introduce the Buzzy Bee device and explain its mechanism of action. They were also given the opportunity to handle and interact with the device, allowing for familiarization and further reduction of procedural fear.

Fig. (2) Buzzy Bee Device

The anesthesia protocol in this study adhered to the 2023 AAPD guidelines.[28] For both nerve block and infiltration techniques, 2% lidocaine with 1:100,000 epinephrine (Novocol, Canada) was administered.

During the first visit, patients in GI (nerve block) and Group II (infiltration) received local anesthesia with the aid of the Buzzy® device (subgroups A), which combines external cold and vibration. The device was connected to the frozen wing; then Buzzy Bee™ was positioned extra-orally at the ramus of the mandible for the inferior alveolar nerve block technique (Figure 3a), and at the zygomatic arch for the maxillary infiltration technique where

the LA was to be administered (Figure 4a). It was positioned in place for 2 minutes before local anesthesia injection and maintained throughout the injection. To avoid ice burn a piece of cloths placed under the iced wings of the buzzy bee to prevent direct contact with skin further more prevent ice burn. In this step the Buzzy bee device was held by an assistant (parents or nurse) in some cases, during injection of local anesthesia to provide appropriate adaptation of device during injection. Meanwhile, during LA injection (T1); the Face, Legs, Activity, Cry, and Consolability (FLACC) scale and Venham's Clinical Anxiety and Behavioral Rating Scale (VCARS) were recorded.

During the second visit, patients in GI (nerve block) and Group II (infiltration) received local anesthesia with the aid of traditional topical gel (subgroups B). Following the drying of the injection area, a small quantity of topical anesthetic gel (20% benzocaine) was applied to the injection site with cotton pellet and kept in place for 1-2 min, then followed by administering local anesthesia. (Figure 3b & 4b). After injection (T2), the Face, Legs, Activity, Cry, and Consolability (FLACC) scale and Venham's Clinical Anxiety and Behavioral Rating Scale (VCARS) were recorded.

Fig. (3) The child receiving nerve block local anesthesia using (a) Buzzy Bee device and (b) topical gel anesthesia

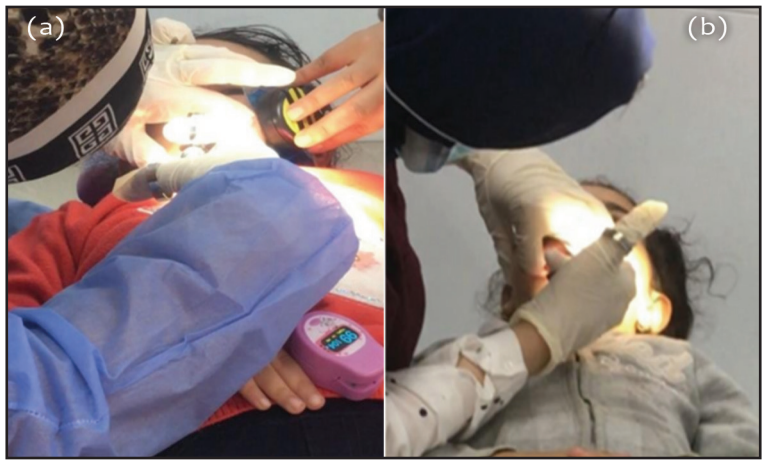

Fig. (4) The child receiving infiltration local anesthesia using (a) Buzzy Bee device and (b) topical gel anesthesia

Assessment methods

Two validated tools were used for assessment: the Face, Legs, Activity, Cry, and Consolability (FLACC) scale and Venham's Clinical Anxiety and Behavioral Rating Scale (VCARS).

The FLACC scale is an internationally acclaimed tool for assessing pain in children who are unable to self-report. It assesses pain by scoring five behavioral categories which provide an overall pain score ranging from 0 (relaxed and comfortable) to 10 (severe discomfort or pain). (Table4).Scores were recorded at two time points: during injection (T1) and after injection (T2). Scoring was performed by an independent examiner during the deposition of the local anesthetic solution.

VCARS objectively measures situational anxiety in children using a six-point scale (0–5) across five behavioral levels (Table 3). It was similarly recorded at T1 and T2. To ensure intra-examiner reliability, all procedures were video-recorded and later re-evaluated by the supervisor, providing two independent scores per child for each visit.

Table 1. *The Face Legs Activity Cry Consolability Pain Scale FLACC*

Category	Score 0	Score 1	Score 2
Face	No expression orsmile.	Occasional grimace or frown, withdrawn, disinterested.	Frequent to constant quivering chin, clenched jaw.
Legs	Normal position orrelaxed.	Uneasy, restless,tense.	Kicking or legsdrawn up.
Activity	Lying quietly, normal position, moves easily.	Squirming, shifting back andforth, tense.	Arched, rigid orjerking.
Cry	No cry (awake or sleep)	Moans orwhimper occasional compliant	Crying steadily,screams or sobs, frequent complaints.
Consolability	Content andrelaxed.	Reassured by occasional touching, huggingor being talked to,distrsctible.	Difficult toconsole or comfort.

Table 2. *Venham's Anxiety and Behavioral Rating Scale VCARS*

Rating	Anxiety rating scale
0.	Relaxed, smiling, willing, and able to converse
1.	Uneasy, concerned. During stressful procedure may protest brieflyand quietly to indicate discomfort. Hands remain down or partiallyraised to signal discomfort. Child willing and able to interpret experience as requested. Tense facial expression, may have tears ineyes.
2.	Child appears scared. Tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, (quiet) crying, hands tense and raised, (not interfering much may touch dentists hand or instrument, but not pull at it). Child interprets situation withreasonable accuracy and continues to work to cope with his/her anxiety.
3.	Shows reluctance to enter situation, difficulty in correctly assessingsituational threat. Pronounced verbal protest, crying. Using hands totry to stop procedure. Protest out of proportion to threat. Copes with situation with great reluctance.
4.	Anxiety interferes with ability to assess situation. General crying notrelated to treatment. More prominent body movement. Child can be reached through verbal communication, and eventually with reluctance and great effort he or she begins the work of coping withthe threat.
5.	Child out of contact with the reality of the threat. Genera1 loud crying, unable to listen to verbal communication, makes no effort tocope with threat.

Statistical analysis

Data were collected using Microsoft Excel 2016, checked, Data were analyzed for descriptive statistically both graphical and numerical description, parametric data were presented and described in terms of mean and standard deviation. While nonparametric data was represented in terms of frequency (n, %). For evaluating and comparing between two different groups (nerve block, infiltration) and two pain control methods (Buzzy bee device vs. topical anesthesia) at different time of observations; a two-way repeated measure analysis of variance is proposed (2-way ANOVA) were applied or corresponding nonparametric analyses at significance levels of 0.05.One-way repeated measure ANOVA was applied for intra group difference, and one way ANOVA for inter group different at each time points. ANOVA were followed by Tukey's HSD post hoc tests (HSD) to compare between treatment groups. Difference between two subgroups (B1, B2) would be carried out by independent sample t test or corresponding statistical analysis. Data analyses were carried out using computer software Statistical Package for Social Science SPSS (IBM-SPSS ver. 23.0 for Mac OS).

RESULTS

A total of 69 children were screened, 60 children met the inclusion criteria. However, four children were excluded because their parents did not provide consent for participation in the study, three children who did not report for the second visit were excluded and two of them not cooperate at the second visit. Hence, a total of 60 children (28 boys and 32 girls) were analyzed at the end of the study.

1. Demographic parameters (age and gender):

In this study, 60 children completed both visits, including boys (46.7%) and girls (53.3%) with a mean age of 5.0±0.66 years. While the males (4.95±0.61 years) were slightly younger than the females (5.1±0.69 years), the difference was not statistically significant as revealed by chi-square test, (p=0.443 ns). **Table (3).**

Table 3. *Demographic data for age distribution among genders in the study*

Age Gender	N	%	Mean ±SD	p-value
Boys	28	46.7	5.0±0.61	**0.443 ns**
Girls	32	53.3	5.1±0.69	
Total	**60**	**100**	5.0±0.66	

The patients were divided in to two main groups; Nerve block anesthesia group (GI) and infiltration anesthesia group (GII) (n=30 in each group). GI included 13 boys (21.7%) and 17 girls (28.3%), with mean age of 5.2±0.54 years, and GII included 15 boys (25%) and 15 girls (25%) with mean age of 4.8±0.71 years. **Table (4&5).** There was no statistically significant difference between the groups in terms of gender and age.

Table 4. *Demographic data for gender distribution in groups and subgroups.*

Gender	Nerve block anesthesia (GI)				Infiltration anesthesia (GII)				Chi-square
	GIA (Buzzy Bee)		GIB (Topical get)		GIIA (Buzzy Bee)		GIIB (Topical gel)		
	N	%	N	%	N	%	N	%	
Boys	**13**	21.7	13	21.7	15	25.0	15	25.0	**0.911 ns**
Girls	**17**	28.3	17	28.3	15	25.0	15	25.0	
Total	**30**	**50.0**	**30**	**50.0**	**30**	**50.0**	**30**	**50.0**	

Table 5. *Demographic data for age distribution among studied groups.*

Age distribution among groups					
Age	**N**	**Min**	**Max**	**Mean ±SD**	**p-value**
GI (NB)	30	4.5	6	5.2±0.54	0.009**
GII (Inf.)	30	4	6	4.8±0.71	
Total	**60**	4	6	5.0±0.66	

2. VCARS

Table 6 and 7 illustrate a statistically significant difference observed in the objective parameter, VCARS, recorded before and after LA administration in both groups. In **GI and GII,** VCARS scores revealed a reduction in the Buzzy bee subgroup at time of injection (T1) and after injection (T2), where most patients recorded a score (0). While in Topical gel subgroup, most of the patients recorded a score (2).

Table 8 showed that a very highly significant difference was detected between the mean values of VCARS in Buzzy Bee and Topical gel subgroups, during and after injection of LA (T1 and T2), where children received Buzzy Bee (subgroup IB and IIB) showed higher records in VCARS as they experienced less anxiety level than those received topical gel (subgroups IA and IIA), (p**<0.001*****) in both groups. However, within-group comparisons using the Wilcoxon signed-rank test indicated no statistically significant change in VCARS scores from T1 to T2 in any group ($p > 0.05$). These findings suggest that the Buzzy Bee device effectively reduces procedural anxiety in children receiving local anesthesia, with sustained effects observed immediately after the procedure.

Table 6. *Comparison of VCARS in nerve block group:*

Group I	**VCARS**	**T1 (at time of injection)**		**T2 (after injection)**		Wilcoxon's signed rank
		GIA Buzzy Bee	GIB Topical gel	GIA Buzzy Bee	GIB Topical gel	
		N (%)	N (%)	N (%)	N (%)	
Nerve Block group	**0**	15(12.5%)	3(2.5%)	15(12.5%)	5(4.2%)	**<0.001*****
	1	9(7.5%)	10(8.3%)	9(7.5%)	8(6.7%)	
	2	5(4.2%)	12(10%)	5(4.2%)	11(9.2%)	
	3	1(0.8%)	2(1.7%)	1(0.8%)	3(2.5%)	
	4	0(0.0%)	3(2.5%)	0(0.0%)	3(2.5%)	
	5	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	
	Mean ±SD	**0.7** ±0.9 b	1.7±1.1 a	**0.8** ±0.9 b	1.7±1.2 a	

Table 7. *Comparison of VCARS in Infiltration group:*

Group II	VCARS	T1 (at time of injection)		T2 (After injection)		Wilcoxon's signed rank
		GIIA Buzzy Bee	GIIB Topical gel	GIIA Buzzy Bee	GIIB Topical gel	
		N (%)	N (%)	N (%)	N (%)	
Infiltration	**0**	10(8.2%)	0(0.0%)	10(8.2%)	0(0.0%)	**<0.001*** **
	1	15(12.5%)	11(9.2%)	15(12.5%)	11(9.2%)	
	2	5(4.2%)	18(15%)	5(4.2%)	18(15%)	
	3	0(0.0%)	1(0.8%)	0(0.0%)	1(0.8%)	
	4	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	
	5	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	
	Mean ±SD	**0.8** ±0.7 b	1.7±0.5 a	**0.8** ±0.7 b	1.7±0.5 a	

*S.D = Standard Deviation; ns = non-significant p>0.05; * = significant difference p<0.05; ** = highly significant p<0.01; *** = very highly significant p<0.001;N: number; HSD = Honest Significant Difference, [a,b] means followed by different letters vertically or horizontally are significantly different according to Tukey's HSD post hoc test*

Table 8. *Comparison of VCARS in nerve block and Infiltration groups:*

Groups	Assessment duringanesthesia(T1)			Assessment afteranesthesia(T2)			Wilcoxon's signed rank
	Mean	SD	HSD	Mean	SD	HSD	
Group(IA) Nerve block(BB)	**0.7**	0.9	B	**0.8**	0.9	B	**0.655 ns**
Group(IB) Nerve block(TG)	**1.7**	1.1	A	**1.7**	1.2	A	**0.564 ns**
Group(IIA) Infiltration(BB)	**0.8**	0.7	B	**0.8**	0.7	B	**>0.999 ns**
Group(IIB) Infiltration(TG)	**1.7**	0.5	A	**1.7**	0.5	A	**>0.999 ns**
ANOVA		**<0.001*** **			**<0.001*** **		

*S.D = Standard Deviation; ns = non-significant p>0.05; * = significant difference p<0.05; ** = highly significant p<0.01; *** = very highly significant p<0.001;N: number; HSD = Honest Significant Difference, [a,b] means followed by different letters vertically or horizontally are significantly different according to Tukey's HSD post hoc test*

3. FLACC:

Regarding the assessment of the amount of change in FLACC score, In group I results showed that during and after anesthesia the most prevalent score was (0) 13.3% at for GIA (BB) and score (5) 6.7% for GIB (TG). While in group II the most prevalent score during anesthesia was (0), (3) 8.3% for the subgroup GIIA (BB) and score (5) 10.0% for subgroup GIIB (TG). While after anesthesia the most prevalent score was (0), (3) 9.2% and 8.3% for the Buzzy Bee subgroup (GIIA) and score (5) 9.2% for the Topical gel subgroup (GIIB).

In GI, the mean score of the FLACC behavioral pain assessment scale measured during (T1) and after LA injection (T2), was slightly higher among the control groups TG (3.8±2.5 and 3.6±2.7) compared with the test group (BB) (1.7±2.1 and 1.4±1.5), with statistically significant difference between them (p<0.001), as children in the test subgroup expressed a significantly lesser pain than those in the control subgroup. **Table (9).**

In GII, children in the test groups (BB) exhibited lower pain scores on the FLACC scale at T1 and T2 compared to those in the control groups (TG). **Table (10).** However the difference among subgroups was not statistically significant (p= 0.317).

Table 11 showed that there were no significant difference between GI and GII in both subgroups during and after anesthesia injection. Results showed that all subgroups induced a very highly significant change in FLACC scale (p<0.001***). Also, there was a high significant change in FLACC scale among time overall groups (p=0.025*). Furthermore, the interaction between treatment groups and time points were found to be non-significant (p=686ns), as revealed by two way ANOVA, and Post. Hoc statistical analysis performed using Tukey's test for multiple range comparison, where means with different letters were statistically significant.

Table 9. *FLACC in GI (Nerve Block):*

GI Nerve Block			FLACC											Mean±SD
			0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	
T1	**(GIA) BB**	**N%**	16 (13.3%)	0 (0%)	5 (4.2%)	3 (2.5%)	2 (1.7%)	2 (1.7%)	1 (.8%)	1 (.8%)	0 (0%)	0 (0%)	0 (0%)	1.7± 2.1b
	(GIB) TG	**N%**	3 (2.5%)	4 (3.3%)	1 (.8%)	4 (3.3)%	6 (8%)	8 (6.7%)	1 (.8%)	0 (0%)	1 (.8%)	1 (.8%)	1 (.8%)	3.8± 2.5a
T2	**(GIA) BB**	**N%**	16 (13.3%)	1 (.8%)	5 (4.2%)	3 (2.5%)	3 (2.5%)	1 (.8%)	1 (.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1.4± 1.5b
	(GIB) TG	**N%**	6 (5%)	2 (1.7%)	1 (.8%)	4 (3.3%)	5 (4.2%)	8 (6.7%)	1 (.8%)	1 (.8%)	1 (.8%)	1 (.8%)	1 (.8%)	3.6± 2.7a
Wilcoxon's			**<0.001*** **											

*S.D = Standard Deviation; ns = non-significant p>0.05; * = significant difference p<0.05; ** = highly significant p<0.01; *** = very highly significant p<0.001;N: number; HSD = Honest Significant Difference, [a,b] means followed by different letters vertically or horizontally are significantly different according to Tukey's HSD post hoc test*

Table 10. *FLACC in GII (infiltration group).*

GII Infiltration			FLACC											Mean±SD
			0	1	2	3	4	5	6	7	8	9	10	
T1	**(GIIA) (BB)**	**N%**	10 (8.3%)	0 (0%)	8 (6.7%)	10 (8.3%)	1 (.8%)	1 (.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1.8± 1.5b
	(GIIB) (TG)	**N%**	0 (0%)	0 (0%)	7 (5.8%)	6 (5%)	5 (4.2%)	12 (10%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1.8± 1.5b
T2	**(GIIA) (BB)**	**N%**	11 (9.2%)	0 (0%)	7 (5.8%)	10 (8.3%)	1 (.8%)	1 (.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3.7± 1.2a
	(GIIB) (TG)	**N%**	0 (0%)	0 (0%)	7 (5.8%)	7 (5.8%)	5 (4.2%)	11 (9.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3.7± 1.2a
Wilcoxon's test			0.317ns											

*S.D = Standard Deviation; ns = non-significant p>0.05; * = significant difference p<0.05; ** = highly significant p<0.01; *** = very highly significant p<0.001;N: number; HSD = Honest Significant Difference, [a,b] means followed by different letters vertically or horizontally are significantly different according to Tukey's HSD post hoc test*

Table 11. *FLACC in nerve block and Infiltration groups at T1&T2:*

	Type of treatment				
	GI		GII		Wilcoxon's signed rank
Time	**GIA**	**GIB**	**GIIA**	**GIIB**	
T 1	**1.7±2.1 b**	3.8**±2.5 a**	1.8**±1.5 b**	3.7**±**1.2 a	<0.001***
T 2	**1.4±1.8 b**	3.6**±2.7 a**	1.8**±1.5 b**	3.7**±1.2 a**	<0.001***
Wilcoxon's	**0.257 ns**	0.063 ns	0.317 ns	0.317 ns	
Two way ANOVA					
Treatment groups	<0.001***				
Time of assessment	0.025*				
Treatment group x Time	0.686 ns				

*S.D = Standard Deviation; ns = non-significant p>0.05; * = significant difference p<0.05; ** = highly significant p<0.01; *** = very highly significant p<0.001; HSD = Honest Significant Difference, [a,b] means followed by different letters vertically or horizontally are significantly different according to Tukey's HSD post hoc test*

DISCUSSION

Pain control is achieved typically by means of injection of local anesthesia for invasive procedures to carry out procedures with a little pain or discomfort as possible. Although this method is highly effective, patients frequently struggle with fear and anxiety from the sight of a needle during administration of local anesthetic than from the treatment [(1)]. So effective pain control in children during regional dental injections is important to achieve comfort, cooperation, and compliance with dental care. Various pharmacologic and non-pharmacologic behavior management techniques have been put forth to combat this issue.[(27.28)]

Children aged 4–6 years were included, as this age group demonstrates improved cognitive and emotional development, enhancing cooperation where mental understanding became more evolved as they grow older according to Veerkamp et al,. 2021. [(29)] Moreover, most of children attend their first dental visit late, at age of 4 years with 3.82% of their teeth affected with caries on accordance to Mika et al., 2018. [(30)] All children included in this study should be apparently healthy, free from any systemic diseases to avoid confounding physiological responses and potential complications. [(31)] Hospitalized children were excluded due to prior exposure to frequent injections, which may heighten needle-related fear.[(32)]

Children with no previous dental experience were selected to accurately assess the Buzzy® device's efficacy, as dental-naïve children exhibit higher anxiety levels.[(33,34)] Those with Raynaud disease were excluded due to risks associated with cold-induced vasoconstriction and ischemia.[(35)] Similarly, sickle cell patients were excluded, as cold exposure can trigger vaso-occlusive crises. It has been hypothesized that hypothermia leads to exaggerated reflex vasoconstriction, increased capillary transit time, red cell sludging, and may lead to shunting of blood from the bone marrow, so sickle cell patients not included in the present study.[(36)]

The selected children were following Frankel scale scored 2 or 3, those were expected to comply with dentist instructions cooperatively or those with some evidence of negative attitude but still can cooperate, both could provide good measures for pain and anxiety related to dental anesthesia [(37)]. Also, patients who had allergies to any material used were excluded, so no barrier in completing dental procedure.

Based on the fact that inferior alveolar nerve block injections are more painful than local infiltration due to the increased volume and duration of injection, a two main groups of infiltration and nerve block included in accordance to Shetty et al., 2023 and Aditya et al., 2023. [(38, 39).] Topical anesthetics may be associated with toxic sequel because of the amounts of drug absorbed, the taste associated with the gels and sprays can make the child uncomfortable and reduced effectiveness due to dissolution in saliva. Because of these problems, a predictable means of pain control for injections is desirable [(12)]. The Buzzy bee device has been proposed in the current study to reduce pain and anxiety during local anesthesia injection depending on distraction, the descending inhibitory controls and Gate control theory.

The Buzzy® device combines cold and vibration to reduce pain perception. Vibration stimulates fast-conducting myelinated A-beta fibers (30–70 m/s), which inhibit the slower unmyelinated A-delta (6–30 m/s) and C fibers (0.5–2 m/s) responsible for pain transmission. According to the gate control theory, activation of A-beta fibers by vibration and cold blocks pain signals in the spinal cord, preventing transmission via A-delta and C fibers to the brain. [(40,41,42)]

Furthermore, persistent application of cold (30–60 seconds), exerts its effect by slowing down the signal conduction speed and stopped it completely in the range of 0– 10°C, as it reduces the activity and tone of the muscle spindles by cooling. Moreover, it stimulates A-myelinated fibers and C fibers further blocks the A-delta fibers and activates pain control pathways, which in turn increases the pain threshold.[43,44] Suohu et al. suggested that the Buzzy bee device was placed extraorally over the bone, close to the injection site, during the local anesthesia deposition procedure in maxillary and mandibular teeth. [45]

The current study incorporating animated motion graphics video in the smartphones in conjunction with the conventional Tell-Show-Do technique to generate a positive synergic effect. This digital approach aids in familiarizing children with dental instruments and procedures, thereby reducing anxiety. Notably, children aged 4–6 years have shown discomfort with traditional methods, such as the application of cold wings. Utilizing smartphones—a ubiquitous tool in the era of E-learning—offers a convenient, cost-effective, and engaging means of behavior modification. These findings align with previous studies by Sahebalam et al. and Reddy et al. [46, 47]

In this study, objective behavioral scales—VCARS and FLACC—were utilized to evaluate anxiety and pain levels in children. The Venham's Anxiety and Behavioral Rating Scale was employed to assess dental anxiety; it demonstrated high reliability, even when used by untrained observers. [46,48] The FLACC scale, a validated behavioral assessment tool, was applied to measure pain perception, particularly effective in children and individuals with cognitive impairments. Its reliability and validity for assessing procedural pain in young, cognitively intact children are supported by Narayan and Samuel[49], and it is commonly used in studies focused on pain and its management during medical procedures[50]. To minimize observer bias, both scales were independently assessed by the operator and verified by a supervisor through video recordings at two time points: during injection (T1) and post-injection (T2).

With respect to results of demographic data in the current study, age distribution recorded a non-significant difference between both groups. Additionally, gender distribution recorded a non-significant difference denoting proper sample selection. In this study, there was no distinction between boys and girls because it was hypothesized that gender was less important for behavioral changes in this younger age group, this is in agreement with Rajwar et al. and Vasakova et al. [51, 52] However, this result was in contrary to Chaudhry et al., 2015 , they examined 20 children aged 8–14 years. In the first visit, conventional anesthesia was performed, and in the second visit, anesthesia was performed along with VibraJect. They found that, stress measurement criteria, including heart rate, blood pressure, and temperature were not significant unlike pain measurement criteria [53].

Regarding VCARS results here was no significant difference between (T1) and (T2) in all subgroups. However, the mean of VCARS score at different time points was significantly lower in the Buzzy bee subgroups (examined group) than in the topical gel subgroups (control group). This objective assessment using the VCARS scores revealed that anxiety level decreased in children receiving local anesthesia with Buzzy bee device than those who received local anesthesia with topical gel and this in accordance to Sahithi et al. [48]

According to the FLACC scale results, no significant differences were observed between time points T1 (during injection) and T2 (post-injection) across all subgroups. However, the mean FLACC scores were significantly lower in the intervention subgroup (BB) compared to the control subgroup (TG), consistent with previous studies. [54,19,43,55]

Suohu et al.[43] conducted a study involving 50 children aged 5–10 years, where the intervention group received external cold and vibration, and the control group underwent conventional anesthesia. The FLACC scores showed significantly reduced pain in the intervention group, suggesting that external vibration is more effective in alleviating procedural pain. In contrast, Elbay et al. reported no significant difference in pain perception between traditional syringe administration and the DentalVibe injection comfort system during inferior alveolar nerve blocks.[56]

In the current study, the Buzzy Bee device demonstrated greater effectiveness in reducing pain during nerve block compared to infiltration in children aged 4–6 years. The findings indicate that external cold and vibration via the Buzzy Bee device were superior to 20% benzocaine topical gel in managing both pain and anxiety during local anesthesia for various pediatric dental procedures. These results are consistent with Ballard et al. who reported that the Buzzy Bee device is a promising tool for managing procedural pain in children. [57] Also recent evidence by Shetty et al. (2023) supports the efficacy of external cold and vibration in significantly reducing pain perception during anesthetic administration in pediatric patients. [37] Mittal et al. (2023) further demonstrated that both ice application and electric toothbrush-induced vibration effectively reduce injection-related pain and can serve as adjuncts in pediatric anesthesia, although they were found to be equally effective as topical anesthetics. [58]

While the Buzzy Bee device showed comparable effectiveness in reducing pain during both maxillary infiltration and inferior alveolar nerve block techniques, Faghihian et al.[55] found it particularly beneficial for reducing pain from maxillary infiltration. However, they noted it was less effective in alleviating anxiety and stress.

The study has limitations, is that buzzy bee device needed an assistant to be kept on child's cheek during anesthetic injection. The study conducted on more than one visit. Some children didn't come to clinic for second visit so we had excluded 9 patients. Further research is needed to use Buzzy Bee device in anterior mandibular teeth and to Combine of both objective and subjective assessments. Thus the null hypothesis was rejected, supporting the use of BB as an effective behavioral management tool in pediatric dentistry.

CONCLUSION

Based on our findings the Buzzy Bee device proved to be a valuable behavior guidance tool in reducing both pain and anxiety during infiltration and nerve block local anesthesia in children, compared to topical anesthetics. Buzzy bee is cost effective, easy to use and provide accessibility that supporting its role in pediatric dental practices as a beneficial tool to improve patient comfort.

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