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Original Article

Efficacy of External Vibration versus Music Distraction on Dental Anxiety and Pain Perception during Local Anaesthetic Administration in Children: A Randomized Clinical Study

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Abstract

Introduction: Local anaesthetic (LA) injections in pediatric patients remain one of the most stress-inducing procedures. This study aimed to compare the efficacy of the Buzzy device and upbeat music on dental anxiety and pain perception during LA administration in children.

Subjects and Methods: This split-mouth randomized controlled study involved 90 children, comparing an external vibrating device (Buzzy) with upbeat music during local anaesthesia administration. Pain, anxiety, pulse rate, and oxygen saturation were measured using standardized scales and a pulse oximeter**.**

Results: showed that music significantly reduced pain and anxiety before, during, and after anaesthesia, while the Buzzy device had a more pronounced effect during the procedure. Both interventions led to significant changes in pulse rate, but oxygen saturation remained unaffected. The study demonstrates that both methods effectively alleviate pain and anxiety associated with dental anaesthesia in pediatric patients, providing dental professionals with non-pharmacological options to enhance patient comfort and cooperation during procedures.

Conclusion: Both interventions proved to have positive effects in decreasing both pain and dental anxiety in children during the LA administration.

Keyword: Local anesthesia. Child Anxiety. Behavior management

I. INTRODUCTION

Early affection by oral diseases in pediatric patients often leads to emergency dental procedures, causing stress and anxiety with long-term effects on pain perception and related behaviours. Usually, infants and children require special consideration of their age, developmental stage, cognitive and communication skills, previous pain

experiences, and beliefs. ***(McGrath, and Frager, G., 1996)*** Local anaesthesia is important for pain management in dentistry, but injection-related discomfort often causes patient anxiety. Various techniques can minimize injection pain, including topical anaesthetics, slow injection speeds, fine needles, improved syringes, buffered or warmed anaesthetics, and distraction methods. Additional strategies like intranasal sprays, jet injectors, vibration, and acupressure have been proposed to reduce injection pain and associated dental anxiety further. By employing these complementary approaches, dental professionals can enhance patient comfort and potentially alleviate fears surrounding dental procedures, ultimately improving overall treatment experiences and outcomes. ***(Avisaet al., 2018 and Remi et al., 2023).***

The Buzzy device (BD) offers an innovative, cost-effective, and reusable solution for managing injection-related pain, particularly in acute situations with limited preparation time ***(Kearl et al., 2015).*** Developed by healthcare professionals, this bee or ladybug-shaped apparatus combines vibration and cold therapy. Its design is based on the gate control theory of pain, which suggests that non-painful stimuli can interfere with pain signal transmission. The device's vibration component activates non-noxious nerve fibres (A-beta), which in turn stimulate inhibitory interneurons. This process reduces the pain information transmitted to the spinal cord by blocking the pain-responsible A-delta and C-fibers. Additionally, the vibration creates a distracting sensory environment, occupying the brain's attention and potentially diminishing pain perception during anaesthetic injection. By incorporating both mechanical and neurological approaches to pain management, the Buzzy device presents a promising alternative for enhancing patient comfort during dental procedures, especially for children or anxious individuals. ***(Shilpapriya et al., 2015 and Faghihian et al.,2022).***

Behaviour guidance techniques (BGTs) are effective in managing needle-related pain in pediatric dentistry. These include Tell-Show-Do, modelling, voice control, hypnosis, acupuncture, biofeedback, guided imagery, and distraction. Distraction stands out as a particularly successful method, diverting children's attention from painful stimuli during invasive procedures. This technique not only reduces pain and improves behaviour management but also shortens treatment time and enhances the overall dental experience. Additionally, distraction can decrease the number of staff needed for procedures, making it an efficient and child-friendly approach to dental care. ***(Dharet al., 2023)***

Audio distraction, where patients listen to music or stories during stressful procedures, is a non-invasive technique. Studies have shown reduced pain and anxiety in adult patients using video distraction and audiotaped relaxation alongside local anaesthesia, though music alone was less effective. However, pediatric patients who received music intervention before or during needle insertions or immunizations exhibited less pain and anxiety-related behaviours compared to those in a no-music control group. ***(Caprilli et al., 2007 and Bekhuis, et al., 2009)***

Listening to music has both biological and psychological effects on emotions, making it a useful tool for reducing anxiety in clinical settings. Some studies have shown decreased anxiety levels in pediatric dental patients when exposed to short periods of music, demonstrating its potential as an effective intervention. ***(Aravena, et al., 2020 and Hao, et al., 2023)***

Research suggests that both the Buzzy device (BD) and music may help improve pain and anxiety responses, but no studies have compared these techniques. Additionally, it is essential to explore how modern children respond to audio distractions during medical procedures. This study was designed to assess the effectiveness of the Buzzy device (BD) and music in reducing dental anxiety and pain perception during local anaesthesia infiltration in children. The null hypothesis proposes that there is no significant difference between BD and music in alleviating dental anxiety and pain in pediatric patients.

II. SUBJECTS AND METHODS:

Study design and study Settings:

The study followed a randomized clinical, split-mouth design with a 1:1 sample allocation ratio. Conducted between August

and November 2023, the research involved children attending the Department of Pediatric Dentistry at New Giza University, Egypt.

Sample size calculation:

The sample size was determined based on a previous study by ***Sahithi et al. (2021)*** as a reference. This study indicated a minimum required sample of 76 patients (split-mouth design) when the mean ± standard deviation of pulse rate in the Buzzy device group was 90.11 ± 12.28, with an estimated mean pulse rate difference of 4. The calculation assumed 80% power and a type I error probability of 0.05, using a t-test through P.S. Power 3.1.6 software. To account for potential losses and enhance the study's power, the total sample size was increased to 90 patients.

Study Participants

Ninety healthy children, aged 5 to 11 years, with normal body mass index percentiles for their age, who required bilateral infiltration anaesthesia for simple extractions in the maxillary arches, were included in the study. None had received analgesics or sedatives within two days before the dental visit. Children with a history of painful medical or dental injections or those with mental or physical disabilities requiring pharmacological behaviour management were excluded. Treatments were conducted over two visits, spaced one week apart. To minimize variations in injection technique, the same pediatric dentist and dental assistant treated all patients throughout the study.

Study procedures

Randomization was conducted using sealed opaque envelopes to determine the intervention for the first visit. Each child selected one of two envelopes, with the intervention written inside. The chosen intervention was applied to the right side of the arch during the first visit, while the other intervention was applied to the left side in the second visit, one week later.

The needle prick site was dried with sterile gauze, and 20% benzocaine topical anaesthetic gel (I-Gel, USA) was applied for 30 seconds using a cotton applicator. Local anaesthesia was then administered with 1.8 ml Mepivacaine HCl 2% - Levonordefrin 1:20000 (Carpule Mepecaine-L, Alexandria Pharmaceuticals, Egypt, #1423) using a 30-gauge needle (C-K DENTAL IND.CO., LTD, Korea). Standard dental treatment, involving simple extraction, was performed after five minutes to ensure profound anaesthesia.

BD intervention: Children were assigned to use the Buzzy® device before and during local anesthesia administration, without the external cooling component. Each child was given 5 minutes to familiarize themselves with the device before the injection procedure.

MU intervention: Children were assigned to listen to upbeat, age-appropriate music through headphones during local anaesthesia administration. They did not choose the music, which was played via a portable disc player throughout the procedure.

At baseline and during local anaesthesia administration, physiological parameters such as pulse rate and oxygen saturation were measured using a pulse oximeter to assess anxiety levels. Venham's Clinical Anxiety Rating Scale (VCARS) was recorded for both groups. After anaesthesia, these measures were repeated, and self-reported pain perception was evaluated using the Wong-Baker Faces Pain Rating Scale (WBFPS).

The child's behaviour before, during, and after the LA injection was videotaped with an iPhone X. An external evaluator reviewed all videos to verify the recorded Venham's Clinical Anxiety Rating Scale.

Outcome measuring methods:

1. Physiological parameters (pulse rate and oxygen saturation) were recorded using a pulse oximeter at baseline, during, and after local anaesthesia administration.

2. Self-reported pain was assessed using the Wong-Baker Faces Pain Rating Scale (WBFPS), which features six faces ranging from a smiling face to a very sad face. The child selects the face that best represents their feelings.

3. Anxiety levels were assessed using Venham's Clinical Anxiety Rating Scale (VCARS), which includes six defined behavioural levels ranging from 0 to 5, with the highest score indicating

the highest anxiety level or least cooperation. ***(Narayan and Samuel 2019)***

Ethical considerations

The study commenced after receiving ethical approval from the Research Ethics Committee, Faculty of Dentistry, Cairo University, Egypt (Ref. No. 76723). Parents or guardians were informed about the treatment, the study's purpose, and the use of videotaping to assess the child's anxiety. They were asked to sign an informed consent form to enroll their child in the study. Additionally, verbal assent was obtained from the participating children.

Statistical analysis:

Statistical analysis was conducted using SPSS 16® (Statistical Package for the Social Sciences), GraphPad Prism, and Microsoft Excel, with results presented in four tables and four graphs. Data normality was assessed using the Shapiro-Wilk and Kolmogorov-Smirnov tests, which indicated that the data were non-parametric. Therefore, comparisons of VCARS scores at baseline, during, and after the procedure were made using the Wilcoxon matched-pairs signed-rank test. For comparisons of oxygen saturation and pulse rate levels across these time points, Friedman's test followed by Dunn's multiple comparisons test was used. Additionally, Wilcoxon Signed-Rank tests were employed to compare the effects of the Buzzy device (BD) and upbeat music (MU) interventions on VCARS, WBFPS, oxygen saturation, and pulse rate levels.

III. RESULTS

Recruitment, randomization, allocation to the buzzy device or music and analysis of the study sample are represented in the CONSORT flow diagram (Fig 1)

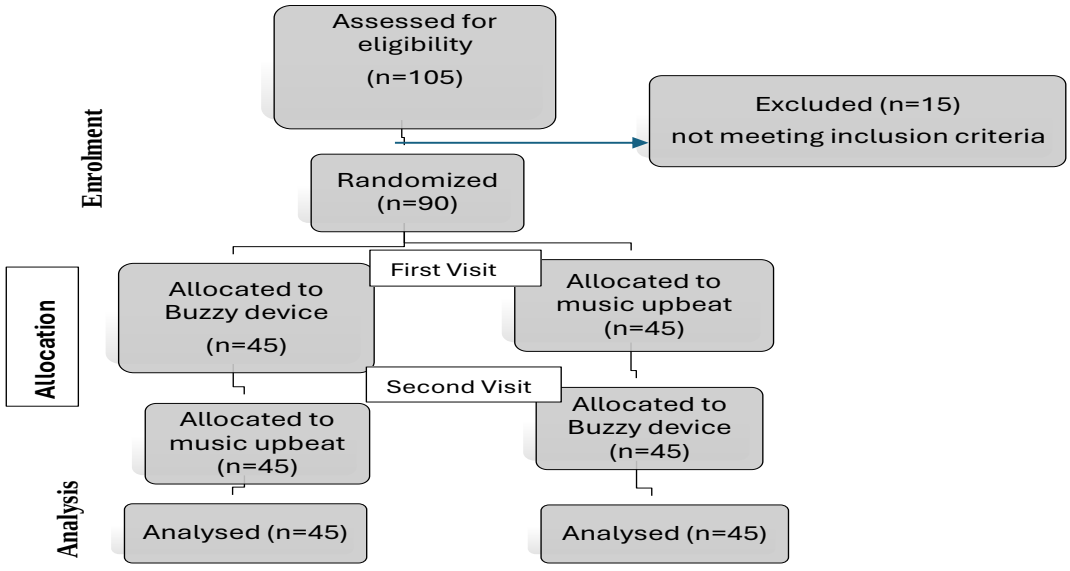

Figure 1: CONSORT flow diagram of enrolment, randomization, allocation and analysis of the study sample

A total of 90 children were included in the current study after they met the inclusion criteria with the mean age of the patients being 8.12±1.69. There was no statistical significance regarding gender distribution among children as males constitute 48% of the total patients with a mean age (7.19 ±1.4), while females represent 52 % of total patients, with a mean age (8.48 ± 1.67).

In this study, intergroup comparisons between the mean values of VCARS, and BD showed high statistically significant differences than MU during L A administration P=0.003. (Table 1) Regarding, the intragroup comparison the BD showed an insignificant difference in the mean value VCARS recorded at baseline, during and after L.A(P=0.08).On the other hand, music intervention showed a significant difference recorded at baseline, during, and after the L.An administration (P=0.004*). (Table 1)

Table (1): Venham's Clinical Anxiety Rating Scale (VCARS) scores at baseline, during and after local anaesthesia administration in both interventions

VCARS	Buzzy device (BD)					Music upbeat (MU)							P value
	Range	Median	95%CI	Mean	SD	Range	Median	95%CI	Mean	SD	Median difference	95%CI	
At baseline	0 to 0	0	0 to 0	.00(a)	0	0 to 1	0	0 to 0	.03(a)	0.18	0	0 to 0	0.25
During	0 to 1	0	0 to 0	0.03(a)	0.18	0 to 2	0	0 to 0	0.17(b)	0.46	0	0 to 0	0.003*
After	0 to 0	0	0 to 0	.00(a)	0	0 to 1	0	0 to 0	.03(a)	0.18	0	0 to 0	0.25
P value			0.08					0.004*					

**Significant difference as P<0.05.*

Means with the same superscript letters were insignificantly different as P>0.05.
Means with different superscript letters were significantly different as P<0.05.

On the other hand, in intergroup comparisons between the mean value of self-reported pain, the (MU) group had a significantly lesser pain response during LA than the (BD) group as P=0.019. (Table 2)

Table (2): WBFPS scores in Buzzy device (BD) and music upbeat (MU) interventions after local anaesthesia administration:

WBFPS	Range	Median	95%CI	Mean	SD	P value
Buzzy device (BD)	0-10	2	2 to 4	3.07	2.39	0.019*
Music upbeat (MU)	0-10	2	0.45 to 2	2.2	2.59	
Median difference	-1					
95%CI	-2 to 0					

**Significant difference as P<0.05.*
Means with the same superscript letters were insignificantly different as P>0.05.
Means with different superscript letters were significantly different as P<0.05.

Analysis of physiological measurements revealed notable intragroup variations. Both BD and MU interventions exhibited a significant rise in pulse rate from baseline to during the procedure, followed by a marked decrease post-L.A. (P=0.0001 and P=0.02 , respectively). However, when comparing pulse rates between the two interventions, no significant differences were found throughout the process (as illustrated in Figure 2).

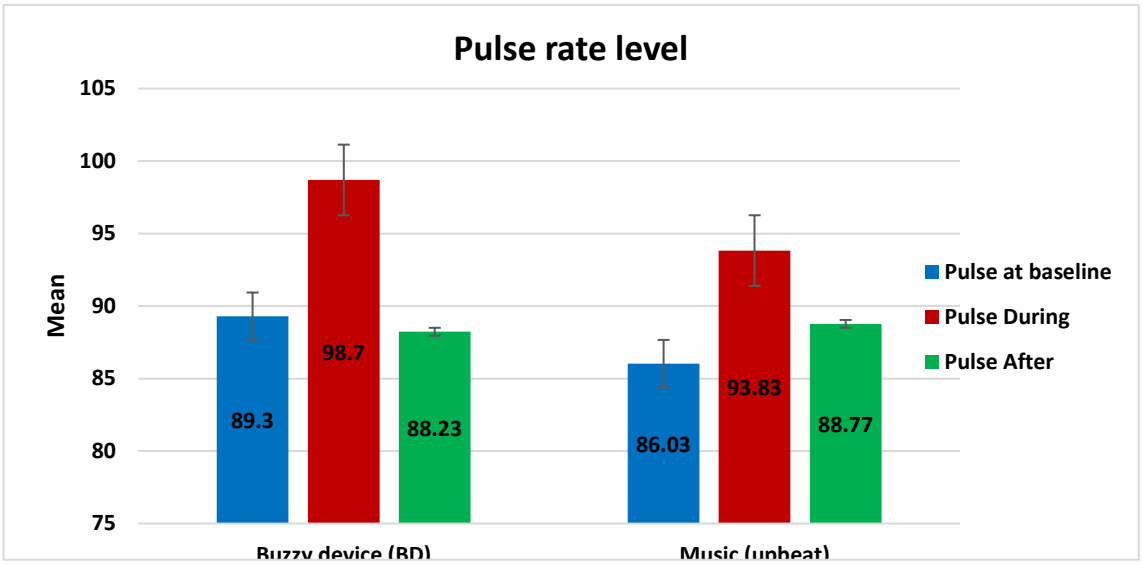

Figure (2): Bar chart showing Pulse rate level at Baseline, during, and after local anaesthesia administration in both interventions.

Additionally, oxygen saturation levels showed no significant changes in either inter- or intragroup comparisons across all stages of the procedure (refer to Table 3).

Table (3): Oxygen level at baseline, during, and after local anaesthesia administration in both interventions:

	Buzzy device (BD)					Music upbeat (MU)							P value
	Range	Median	95%CI	Mean	SD	Range	Median	95%CI	Mean	SD	Median difference	95%CI	
O2 at Baseline	96-99	99	99 to 99	98.4	1.06	93 to 99	99	99 to 99	98.4	1.36	0	0 to 0.5	0.55
O2 During	94-99	99	99 to 99	98.13	1.57	92 to 99	99	99 to 99	98.5	1.46	0	0 to 0	0.09
O2 After	90 to 113	99	99 to 99	98.7	3.45	92 to 99	99	99 to 99	98.27	1.49	0	-0.5 to 0	0.23
P value			0.19					0.32					

IV. DISCUSSION:

Administering local anaesthetic injections, particularly in pediatric patients, is highly stressful. Effective pain management and pain-free dentistry rely crucially on the use of local anaesthesia***.(Sanosane et al., 2023)*** This study was designed as a randomized clinical trial adhering to CONSORT guidelines to compare the effectiveness of two approaches—Buzzy device (BD) versus upbeat music (MU)—in reducing pain and anxiety during local anaesthesia administration. Given that pain reporting is subjective and varies widely among children, comparing interventions across different individuals can be challenging. The split-mouth design was used to address these variations by applying both interventions within the same child, allowing for a more accurate comparison of their effectiveness. ***(Hegde et al., 2019 and Ananthu, et al., 2023)***.

In this study, the Buzzy® device (excluding its cooling component) and upbeat music interventions were employed to reduce

pain and anxiety during injection procedures. Vibrating or buzzing devices are thought to create a distracting environment, which may help in pain relief by diverting the brain's focus. Additionally, music therapy is effective in managing pain and anxiety in pediatric patients, providing beneficial therapeutic outcomes ***(Stouffer, et al., 2007).***

Children aged 5-11 years were chosen for this study, aligning with other research. This age range corresponds to Piaget's late pre-operational and operational stages, during which significant cognitive development occurs ***(Sanghvi, P., 2020).***

Pain and discomfort are subjective and can be influenced by social, cognitive, and physiological factors, affecting children's dental fear and anxiety. Thus, relying on a single parameter to measure anxiety may not provide reliable results **(Narayan and Samuel 2019)** Behavioural and physiologic signs should be observed in conjunction with self-reported pain to determine the level of pain ***(Sansone et al.,2023).*** To measure pain and anxiety levels in children, this study used a combination of a self-reported pain scale (WBFPS), an objective anxiety scale (VCARS), and physiological parameters (pulse rate and oxygen saturation).

In this study, Venham's Clinical Anxiety Rating Scale (VCARS) was employed to evaluate situational anxiety in children using a six-point scale. Comparisons revealed that the Buzzy device (BD) showed significantly lower VCARS mean values than music (MU) both at baseline and after local anaesthesia (LA) administration, with a notable statistical significance during LA administration (P=0.003). Consistent with these findings, another study found that extra-oral vibration effectively reduced injection pain ***(Suohu, et al., 2020).***

Additionally, our findings are comparable to previous findings of ***(Sahiti et al.,2021).*** The BD group showed a significant decrease in anxiety before and after LA administration. This can be attributed to the children's consistent engagement with the BD device during treatment, which distracted them from the dental instruments and the pain of the injection.

Intragroup comparisons revealed no significant difference in anxiety levels with BD throughout the procedure. However, the MU group showed a statistically significant increase in mean anxiety during LA administration compared to baseline and after the procedure. These findings are partly consistent with previous studies that reported significant anxiety reduction with audio distraction ***(Lahmann, et al., 2008 and Sandeep, et al., 2010).***

Immediate emotional reactions to dental injections were assessed using the Wong-Baker Faces Pain Rating Scale (WBFPS) through verbal communication with children **(Srouji, et al., 2010)** . The current study found that the MU intervention significantly reduced self-reported pain during the injection procedure compared to BD, as measured by the WBFPS. This result aligns with findings from ***(Packyanathan et al., 2019)*** who found music therapy to be effective as an anxiolytic agent for stressful dental procedures. However, our results disagreed with a systemic review by ***(Ainscough et al.,2018)*** who found that the effectiveness of using music to alleviate dental anxiety in children was indecisive and of limited effect.

The mean total WBFPS for BD intervention in the present study was 3.07+2.39, which is slightly higher than the values reported by ***(Faghihian et al., 2022)*** .In their study, the mean total Wong-Baker score was 2.53±2.72, showing no statistically significant difference from the control group, leading to the conclusion that BD was ineffective in reducing anxiety and stress. This result may be due to the scale's tendency to exaggerate pain levels. Similar findings were reported in a clinical trial by ***(Suohu et al., 2020)*** revealed that the Wong-Baker scale showed no significant difference between control and intervention groups, likely due to children selecting higher-scale faces when experiencing discomfort during dental procedures.

The result of our study showed that BD reduced pain and anxiety during and after LA administration as denoted by both used scales. Similar results were obtained by ***(Anantho et al.,2023)*** they found that the Buzzy device significantly reduced both self-reported and observer-reported pain reactions during the

administration of the inferior alveolar nerve block.

Stressful situations during dental procedures often lead to increased oxygen saturation and pulse rate. Measuring these parameters with a pulse oximeter is useful for directly assessing physiological arousal. An elevated pulse rate is commonly associated with heightened pain perception in patients ***(Fakhruddin, et al., 2016. and Alanazi, et al., 2019).*** Moreover, the literature has shown a direct correlation between a patient's pulse rate and level of fear ***(Raghav et al., 2016).*** In this study, patients in both groups experienced a significant pulse rate increase during the injection, followed by a notable decrease after local anaesthesia administration. There was no significant difference between the groups. These findings are consistent with previous research, which also showed that audio distraction effectively reduced anxiety levels ***(Greeshma et al., 2021 and Janthasila, and Keeratisiroj 2023)*** Likewise, ***(Buhsari et al.,2023 and Gurav et al.,2022)*** found that auditory beats showed a statistically significant reduction in anxiety levels as per pulse rate scores as compared to conventional treatment techniques. On the contrary, ***(Faghihian et al 2022)*** found that the mean heart rate difference before and during injection was not significantly reduced in the BD group in their study.

Stress and anxiety can affect and change the oxygen saturation and/or carbon dioxide levels in the blood ***(Padma et al., 2012)*** and hence, Oxygen saturation levels were used to assess anxiety in this study. However, the measurements were not significantly different in either group throughout the procedure, contrasting with previous findings that reported variations in oxygen saturation levels ***(Raghav et al., 2016).***

V. CONCLUSIONS:

- BD and MU interventions were beneficial in reducing both pain and dental anxiety in children.

- BD demonstrated statistically significant differences compared to MU in mean VCARS scores during local anaesthesia administration.

- MU resulted in lower self-reported mean pain scores.

VI. LIMITATIONS OF THE STUDY

Children needing pharmacological management were excluded, so results may not apply to all children. Additionally, the study only tested maxillary buccal infiltration, limiting the generalizability to other types of local anaesthesia injections.

Conflict of interest: No conflict of interest.

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Ethics: This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 31/7/2023, approval number: Egypt (Ref. No. 76723).

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