

EFFECT OF EXTERNAL COLD AND VIBRATION (BUZZY DEVICE) VERSUS THE CONVENTIONAL INJECTION TECHNIQUE ON PAIN PERCEPTION DURING LOCAL ANESTHESIA ADMINISTRATION IN CHILDREN: A SPLIT-MOUTH RANDOMIZED CLINICAL TRIAL STUDY

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ABSTRACT

Aim: This study aims to assess the influence of external cold and vibration (Buzzy device) compared to the conventional injection technique on the perception of pain during local anesthesia administration in children.

Materials and Methods: Twenty-one children aged 6-11 years with bilateral decay in primary or permanent teeth needing restoration, extraction, or pulp therapy were randomly split into two groups. Group (A) received local anesthesia with the buzzy device on the first visit and conventional injection technique on the next visit, and group (B) received conventional injection technique on the first visit and local anesthesia with the buzzy device on the next visit. The face leg activity crying consolability (FLACC) scale and pulse oximeter were utilized for the objective evaluation, while the Wong-Baker faces pain scale (WBFPS) was used for the subjective assessment. The results were statistically analyzed.

Results: There was no statistically significant difference in pain score between the buzzy device and conventional methods using the WBFPS. After applying the two methods, there was no statistically significant difference observed between heart rates. Using the FLACC scale, there was no statistically significant difference concerning the two methods for the child's behavior during the injection of local anesthesia.

Conclusion: Buzzy devices can effectively control pain during nerve block injection technique. There is no difference in the buzzy device's effectiveness compared to the conventional injection technique in reducing children's pain during a nerve block injection.

KEYWORDS: Child behavior, dental anxiety, buzzy device, anesthesia.

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INTRODUCTION

The most common dental operation that induces anxiety and pain is the local anesthetic injection, which also causes pain and discomfort, especially for young patients. Extreme fear and worry may also intensify the experience of pain (Cantile et al., 2017).

A child's cooperation and attitude toward dental care are typically impacted by their fear of pain. The psychological effects of pain have a negative effect on children's attitudes toward dental care (Armfield et al., 2013).

Ineffective pain management can cause increased pain sensitivity, postponing or avoiding medical or dental care, and painful memories that might persist into adulthood (Gagliani & Gross, 2018).

Pain management may be pharmacological or non-pharmacological. The term "non-pharmacological pain therapy" describes methods of managing pain that do not use medication. The goal of non-pharmacological treatments is to reduce pain, fear, anger, and anxiety while giving patients a sense of control (Geziery et al., 2018).

Local anesthesia is considered a key to maintaining a dental treatment without pain. Another challenge during therapy is children's fear of local anesthetic. Although local anesthetic was created to manage discomfort during dental procedures, it is thought to be the source of pain and the reason people avoid dental treatment (Zurfluh et al., 2015).

Though aspirating syringes are still the most widely used tool for administering local anesthetics, newer technology has made it possible for dentists to treat patients more effectively with fewer unpleasant injections and adverse effects. Examples of modern methods of local anesthetic delivery include vibrotactile devices, buzzy devices, safety dental syringes, jet injectors, computer-controlled

local anesthetic delivery (CCLAD) systems, and procedures for intraosseous anesthesia (Saxena et al., 2013).

One of the newest tools for administering local anesthesia that can reduce injection anxiety and manage discomfort is the buzzy device. As far as we are aware, the buzzy device's combination of cold and vibration with the child's distraction has, thus far, shown promise in reducing injection discomfort. More research is required to provide more light on how this vibrating device affects children's experience of pain (Faghihian et al., 2020). Therefore, this study aimed to assess the effect of the Buzzy device against the conventional injection method on the perception of pain during local anesthesia administration in children aged 6-11 years.

MATERIALS & METHODS

This research is a split-mouth randomized clinical trial study with a 1:1 allocation ratio. The trial is registered on www.clinicaltrials.gov with protocol ID: NCT05067218.

Eligibility criteria:

Inclusion criteria:

- Children categorized as cooperative or potentially cooperative based on Wright's behavior classification system for children.
- Children who appear to be in good health (ASA I, II) and mental capable to communicate.
- Children in the 6–11 years age range.
- Patient with bilateral decay in primary or permanent molars and in need of nerve block injection in two visits.

Exclusion criteria:

- Children with behavioral management problems.
- Parental refusal of participation.

Sample Size:

A power analysis was considered to have acceptable power to consider a two-sided statistical test of the null hypothesis that no variation would be revealed in pain perception throughout local anesthesia injection using the buzzy device compared to the conventional technique. The expected sample size (n) was a total of (19) cases by using an alpha level of (0.05), a beta of (0.2), or power=80%, and an effect size (d) of (1.11) (Hegde et al., 2019). To account for the possibility of dropouts, the sample size was expanded by 25% to include (24) cases. To calculate the sample size, G*Power 3.1.9.7 was used.

Grouping of the participants:

The whole sample was split into the following two groups:

Group A (intervention group): On the first visit, children in this group received anesthesia from an inferior alveolar nerve block using a buzzy device, and on the second visit, they received a conventional injection.

Group B (Control group): On the first visit, children received an inferior alveolar nerve block injection using the conventional injection technique, and on the second visit, they received a nerve block injection using the buzzy device.

Informed Consent:

An explanation of the goals, procedures, and potential drawbacks of the study was given to the parent or legal guardian. Every child participating in the study provided verbal assent, and the parent or legal guardian signed an informed consent form.

Randomization and allocation concealment:

Using simple randomization with a 1:1 allocation ratio, children were randomized at random to intervention and control groups. A computer-generated 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, which the assistant supervisor kept hidden from the principal investigator. Numbered from 1 to 24, each envelope was taken by a patient in ascending sequence. The assistant supervisor put the participants in the intervention or control group based on the information in the randomization table. The individuals were enrolled by the principal investigator.

Blinding:

Because of the differences in the approaches used, blinding of the patient and the operator was not applicable. The statistician only was blinded.

Intra-operative procedures:

First, preparation of all the needed equipments and materials and place them out of the patient's vision to avoid provoking anxiety in the patient (Vallakatla et al., 2020) and psychological preparation was performed. The patients were split into two groups: Group (A): who received local anesthesia with the buzzy device at the first visit and conventional local anesthesia at the second visit, and Group (B), who received conventional local anesthesia at the first visit and local anesthesia with the buzzy device at second visit. Then, readings of the pulse oximeter, FLACC scale scores, and Wong-Baker Faces Pain scale score were recorded for the patient (Suoho, 2020). Then, the principal investigator dried the tissues at the site of injection and held the topical analgesic gel against the tissue for 1 minute and the child was told that we would make the tooth go to sleep using the gel (Wright, 2014), (Nair & Gurunathan, 2019). Then cotton swab was removed and received the syringe in principle's right hand from an assistant (Aravena et al., 2018) and start nerve block injection. Explanation to the children how the buzzy device works was done in the intervention visit, so they became acquainted with

it. When the children were ready, the frozen wing was linked to the buzzy device and positioned extra orally above the area where the local anesthesia was delivered (Suoho et al., 2020). During the injection, the pulse oximeter and FLACC scale measurement were recorded again, and the child was requested to select a face from the WBFPS scale again (Suoho, 2020). Then the needle was then withdrawn, handed to the assistant below the child's field of vision, and safely recapped. The child was told that the tooth now "went to sleep" and "it felt funny" (Wright & Kupietzky, 2014).

Assessment of the outcomes:

Pain perception during local anesthesia injection was assessed by WBFPS (subjective scale). Heart rate during injection by a pulse oximeter and the child's behavior during local anesthesia injection were assessed using the FLACC Scale as the objective method.

Statistical analysis:

Exploration of the given data was performed using the Shapiro-Wilk and Kolmogorov-Smirnov test for normality. Pain and FLACC scores showed a non-normal distribution, while heart rate showed a normal distribution. A significant value of $P \leq 0.05$ was used. Statistical analysis was done using IBM SPSS. Statistics for Windows, Version 0.23. Armonk, NY-based IBM Corp.

RESULTS

Demographic characteristics

A total of 24 children participated in the present study with 3 patients losing the second visit to be of a total of 21 children participated in both visits. Regarding the age distribution of the participating children, 11 (52.4%) were aged 6 – 8 years old, and 10 children were 9 – 11 years old. Concerning the gender distribution, 11 children (57.1%) were boys, while 10 children (42.9%) were girls.

1. Pain perception during local anesthesia injection using the WBFPS Scale

Pre- and post-operative pain levels for the two groups did not show statistically significant difference at the first visit (P-value = 0.414, Effect size = 0.362 and P-value = 0.177, Effect size = 0.617, respectively). The pain scores of the two groups at the second visit, whether pre- or post-operatively (P-value = 0.317, Effect size = 0.447) and (P-value = 1, Effect size = 0), respectively, did not show statistically significant difference as shown in table (1).

2. Heart rate during injection of local anesthesia:

The heart rates of the two groups did not show statistically significant difference at the first visit, either before or after anesthesia (P-value = 0.370, Effect size = 0.101 for the pre-operative group and P-value = 0.610, Effect size = 0.034 for the post-operative group). The heart rates of the two groups did not show statistically significant difference at the second visit, either before or after anesthesia (P-value = 0.813, Effect size = 0.007) and after surgery (P-value = 0.390, Effect size = 0.094), respectively, as shown in table (2).

3. Child's behavior during local anesthesia injection using the FLACC scale:

The FLACC scores of the two groups did not show statistically significant difference at the first visit, either before or after anesthesia (P-value = 0.180, Effect size = 0.885) and (P-value = 0.571, Effect size = 0.347), respectively. The FLACC scores of the two groups, pre- and post-operatively (P-value = 0.180, Effect size = 0.885 and P-value = 0.090, Effect size = 1.187), did not show statistically significant difference at the second visit, as shown in table (3).

TABLE (1) Descriptive statistics and results of Wilcoxon signed-rank test for comparison between pain (Wong-Baker Faces Pain Scale) for the two groups.

| Visit | Time | Group (A) | | Group (B) | | P-value | Effect size (d) |
|--------------|----------------|----------------|-------------|----------------|------------|---------|-----------------|
| | | Median (Range) | Mean (SD) | Median (Range) | Mean (SD) | | |
| First visit | Pre-operative | 0 (0-6) | 0.73 (1.85) | 0 (0-10) | 2.2 (4.16) | 0.414 | 0.362 |
| | Post-operative | 2 (0-6) | 2.55 (2.21) | 6 (0-10) | 6 (4) | 0.177 | 0.617 |
| Second visit | Pre-operative | 0 (0-10) | 2.22 (4.41) | 0 (0-2) | 0.18 (0.6) | 0.317 | 0.447 |
| | Post-operative | 6 (0-10) | 6 (4.24) | 4 (0-10) | 3.64 (2.8) | 1 | 0 |

*: Significant at $P \leq 0.05$

TABLE (2) Descriptive statistics and results of repeated measures ANOVA test for comparison between heart rate (Beat/minute) for both groups.

| Visit | Time | Group (A) | | Group (B) | | P-value | Effect size (Partial Eta squared) |
|--------------|----------------|-----------|------|-----------|------|---------|-----------------------------------|
| | | Mean | SD | Mean | SD | | |
| First visit | Pre-operative | 100.9 | 12.8 | 107.9 | 21.9 | 0.370 | 0.101 |
| | Post-operative | 119.3 | 21.7 | 123.6 | 22.9 | 0.610 | 0.034 |
| Second visit | Pre-operative | 100.6 | 26.3 | 98.4 | 24.8 | 0.813 | 0.007 |
| | Post-operative | 123.7 | 24.2 | 117.3 | 21.4 | 0.390 | 0.094 |

*: Significant at $P \leq 0.05$

TABLE (3) Descriptive statistics and results of Wilcoxon signed-rank test for comparison between FLACC scores for the two groups.

| Visit | Time | Group (A) | | Group (B) | | P-value | Effect size (d) |
|--------------|----------------|----------------|-------------|----------------|-------------|---------|-----------------|
| | | Median (Range) | Mean (SD) | Median (Range) | Mean (SD) | | |
| First visit | Pre-operative | 0 (0-1) | 0.09 (0.3) | 0 (0-3) | 0.4 (0.97) | 0.180 | 0.885 |
| | Post-operative | 1 (0-4) | 1.82 (1.66) | 2 (0-8) | 2.7 (2.45) | 0.571 | 0.347 |
| Second visit | Pre-operative | 0 (0-4) | 0.56 (1.33) | 0 (0-2) | 0.18 (0.6) | 0.180 | 0.885 |
| | Post-operative | 2 (0-6) | 3 (2.29) | 1 (0-4) | 1.36 (1.43) | 0.090 | 1.187 |

*: Significant at $P \leq 0.05$

DISCUSSION

The application of local anesthetic is a common way to relieve dental pain. Nonetheless, children's fear and anxiety are primarily caused by needle-related procedures. Ignoring the need to prevent needle pain can have numerous psychological effects, such as phobias and anxiety as well as a rise in pain perception in the future (**Susam et al., 2018; Sahithi et al., 2021**).

Buzzy is a new medical device that blends vibration and external skin cooling. It is a removable, refrigerable bee-shaped box with wings. The Buzzy device's effectiveness can be elucidated by the gate control hypothesis (**Suoho et al., 2020**).

The study population involved children aged 6-11 years. Children younger than 6 years were excluded as most children at this age do not receive nerve block injections to anesthetize mandibular molars. Also, most children develop the ability to cooperate and self-report pain around the age of 5 years (**Pourkazem et al., 2017**). Children older than 11 years were not included because they always display positive behavior and willingness to cooperate and undertake needed treatment (**Sharma et al., 2011**).

The participants with both right and left mandibular decay in their mandibular molars indicated for extraction, restoration, or pulp therapy were selected (**Hedge et al., 2019**).

The subjective pain was measured using the WBFPS. Two recordings of the scores were made, one before and one after LA was administered. The self-assessment tool called the WBFPS scale is used by people to talk about their physical pain. It provides users with multiple ways to express their degree of pain by integrating faces, numbers, and words. (**Balasubramanian et al., 2022**).

For patients who are nonverbal or preverbal and are incapable of self-reporting their level of pain, the FLACC is a behavioral (objective) pain assessment

tool. Five categories—the face, legs, activity, cry, and consolability are used to measure pain. It is a valid, dependable, practical, and convenient method for recognizing and documenting pain (**Crellin et al., 2018; Peng et al., 2022**).

Because a pulse oximeter is beneficial in assessing the level of tension and anxiety in patients receiving dental treatment, it was utilized in this study to evaluate heart rate and oxygen saturation levels before and throughout the administration of local anesthesia (**Guinot Jimeno et al., 2011**).

The statistical analysis of this study data showed no statistically significant difference in pain perception during inferior alveolar anesthesia injection between the intervention group (buzzy device) and control group (conventional injection) using the WBFPS. This result aligns with **Suoho et al. (2020)**, who found no statistically significant difference between injection with the buzzy device and conventional injection technique using WBFPS.

In contrast to the previous finding, **Alanazi et al. (2018)**, **Hedge et al. (2019)**, **Faghihian et al. (2021)**, stated that injection with the buzzy device showed a significantly lower WBFPS score than conventional injection techniques. Moreover, **Sahithi et al. (2021)** stated that injection with the buzzy device showed delayed pain perception after LA injection, which was more prominent than conventional injection techniques. The combined action of vibration and cooling can explain this. Additionally, Buzzy's distracting function may contribute to some of its favorable effects. Attention can be diverted by distraction, particularly in children (**Faghihian et al., 2020**).

There was no statistically significant difference between the intervention and control groups when it came to the pulse oximeter's assessment of pain perception during the injection of an inferior alveolar nerve block. This is in line with the findings of **Suoho et al. (2020)**, who reported that the oxygen saturation levels and pulse rate

demonstrated statistically nonsignificant results because their values were the same both before and after the injection.

Nevertheless, it was discovered by **Alanazi et al. (2018)**, **Hedge et al. (2019)**, and **Sahithi et al. (2021)** that the operators of the buzzy device saw a significantly reduced heart rate during injection than they did during the conventional injection technique.

Between the intervention group and the control group, there was no statistically significant difference in the assessment of pain perception during inferior alveolar nerve block injection using the FLACC Scale. According to **Alanazi et al. (2018)**, **Suoho et al. (2020)**, and **Hedge et al. (2019)**, the operators noticed a substantial decrease in the FLACC score during the intervention visit (using a buzzy device) compared to the control visit (using a conventional injection). This result could be explained by the device's distracting qualities, which let children get over their uncomfortable pain perception without really changing their behavior (**Alani et al., 2016**).

The inconsistent results regarding the buzzy device's and traditional injection technique's differences in intraoperative pain perception may be explained by the fact that each has unique qualities that may make it better in certain investigations. As stated by the gate control theory, which suggests that pain is directed from the peripheral nervous system to the central nervous system by modulation by a gating system in the dorsal horn of the spinal cord, the buzzy device's improved performance in certain studies may be explained by this mechanism of action. This device's vibration component will stimulate the rapid, non-noxious motion nerves called A-beta fibers, which will gradually block the afferent pain-receptive nerves called A-delta. The A-delta pain signal will be blocked by applying the cold component before the pain stimulus, which will, on the other hand, stimulate the C fibers. According to certain research, the advantages of conventional

injection methods can be traced back to their ease of use and ability to eliminate the distracting noises produced by buzzy devices (**Bilsin et al., 2020**).

These contradicting results could be explained by the fact that pain is a complex, multidimensional phenomenon in which biological, psychological, emotional, cultural, and environmental factors can affect each individual's pain experience (**Gazernai et al., 2021**).

The literature comparing the efficacy of the buzzy device on pain perception compared to the conventional injection technique shows that there is little evidence to support the advantage of the buzzy device in the injection of nerve block local anesthesia over conventional local anesthesia injection. In several studies, the buzzy device reduced injection-related discomfort and produced encouraging results; in other studies, there was no significant difference in pain perception between the buzzy device and the conventional method (**Suoho et al., 2020**).

CONCLUSION

Buzzy devices can effectively control pain during nerve block injection techniques. There is no difference in the effectiveness of the Buzzy device compared to the conventional injection technique in controlling pain during nerve block injection in children.

Conflict of interest:

No conflicts of interest are disclosed by the authors.

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Ethics:

This study protocol was approved by the ethical committee of the Faculty of Dentistry-Cairo University with approval number 5 2 22.

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