



DentalVibe reduces pain during the administration of local anesthetic injection in comparison to 2% lignocaine gel: results from a clinical study

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Background: This study was designed to compare the efficacy of DentalVibe against 2% lidocaine gel in reducing pain during the administration of local anesthetic injection in the adult population.

Methods: This was a split-mouth open-label, randomized, controlled clinical study conducted in the Department of Oral and Maxillofacial Surgery of a dental institute. Fifty patients who were scheduled for bilateral dental extractions requiring an inferior alveolar nerve block were enrolled in the study. Site A (n = 50) was coated with 2% lidocaine gel followed by a local anesthetic injection, and DentalVibe with local anesthetic injection was used for Site B (n = 50). The primary outcome was pain, which was recorded immediately after the administration of anesthetic injection using the Visual Analogue Scale [VAS 0 - 10].

Results: The VAS pain scores ranged from 4 to 10 for site A and 0 to 6 for site B. Comparison between the two sites showed a statistically significant difference [Mann-Whitney U test value = 51.50, P < 0.001] favoring site B.

Conclusion: This study showed that DentalVibe reduces pain during injection of local anesthesia compared to topical anesthetic gel.

Keywords: Anesthesia; DentalVibe; Local; Pain; Topical Anesthetics.



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INTRODUCTION

Although administration of local anesthesia achieves a painless field, the administration of the injection itself is painful. Clinicians usually try to minimize the pain of needle prick by reassurance, correct technique, and local medications. Dental treatment might cause anxiety due to various reasons, such as negative or traumatic past experiences, experiences of family members, individual personality traits, and visualizing fear-provoking posters

or videos of dental surgeons. Anxiety can also be triggered by the sight of needles or the sound of rotary instruments in the dental office [1].

Several methods such as psychosomatic techniques, low-level laser therapy, cold application to the soft tissues, therapeutic music, counter distraction, and topical anesthesia are used to overcome the anxiety and discomfort caused by the pain [1-7]. Other alternative techniques include the use of thinner gauge needles, use of Computer-Controlled Local Anesthetic Delivery (CCLAD) system, and Jet injections [8-11]. However,

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each method has limitations, and there is a need for a better alternative to minimize or avoid pain of the injection.

In 2014, Ching et al. [12] used vibration before injecting local anesthesia to reduce the pain of the needle prick in a pediatric population aged between 10-17 years. They studied the effect of vibration on pain while administering local anesthesia injections, compared to the use of lignocaine gel using a split-mouth design. The results were very promising. They found that the vibrating device was effective at a physiological [justified by the gate control theory of pain] and psychological [caused by the audible distraction of the device] level. The gate control theory states that the brain can distinguish only one instance of stimulation at a time; thus, the vibration technique can mask the pain during the injection [13].

Considering the beneficial effect of DentalVibe and the lack of literature about its efficacy among the adult population, this study was designed to compare the use of DentalVibe against 2% lignocaine gel in reducing pain during the administration of local anesthetic injection during dental procedures.

METHODS

This was a split-mouth, open-label, randomized, controlled clinical study conducted in the Department of Oral and Maxillofacial Surgery. The research protocol was approved by the Scientific Committee and the Institutional Ethics Committee (DYPDCH/696/2016/45).

1. Calculation of sample size

The sample size was calculated using the online OpenEpi sample size calculator. A pilot study was conducted among 10 patients and the results of this study were used for sample size calculation [mean \pm SD = 8.36 \pm 2.76 (group 1), mean \pm SD = 6.4 \pm 4.1 (group 2), power = 80%, confidence interval = 95%]. The calculated total sample size was 100, and it was equally distributed between the two sites.

2. Inclusion and exclusion criteria

Inclusion criteria were patients aged between 18 and 50 years, scheduled for bilateral tooth extractions requiring inferior alveolar nerve block, and willing to participate in the study. The exclusion criteria were allergy to local anesthesia, regular consumption of antidepressant or anti-psychotic drugs, patients with a high level of anxiety, and unwillingness to participate in the study.

3. Patient selection, randomization, and allocation

Two hundred and thirty-nine patients were screened from December 1, 2016, to March 31, 2017. The details of the selection and allocation are explained in Fig. 1. Fifty patients requiring bilateral dental extraction were selected. Hence, the total number of extraction sites was 100. The investigator [KB] randomized the extraction sites into sites A and B using a computer-generated random number table. The sequence of allocation, i.e., which site was to be treated first, was generated using Sequentially Numbered, Opaque, Sealed Envelope (SNOSE) technique. Site A was written on 25 pieces of paper, and site B was on another 25 pieces of paper. These papers were placed in opaque, sealed envelopes. Each participant was allowed to pick an envelope. The investigator then opened the sealed envelope, and the participant was treated accordingly. Site A received topical 2% lidocaine gel (Lox-2% Jelly, Neon Laboratories Ltd, India) application followed by local anesthetic injection (Lox 2% adrenaline 1: 200000, Neon Laboratories Ltd, India), while site B received vibration with DentalVibe followed by local anesthetic injection. The time interval between the two procedures was seven days. This was to prevent the crossover effects of the drug. This was an open-label study because the patient [outcomes assessor] could not be blinded due to the nature of the investigated device. A single clinician [SJ] performed the procedure to prevent bias. SJ used the classical inferior alveolar block technique, depositing the local anesthetic solution at a rate of 1 ml/minute.

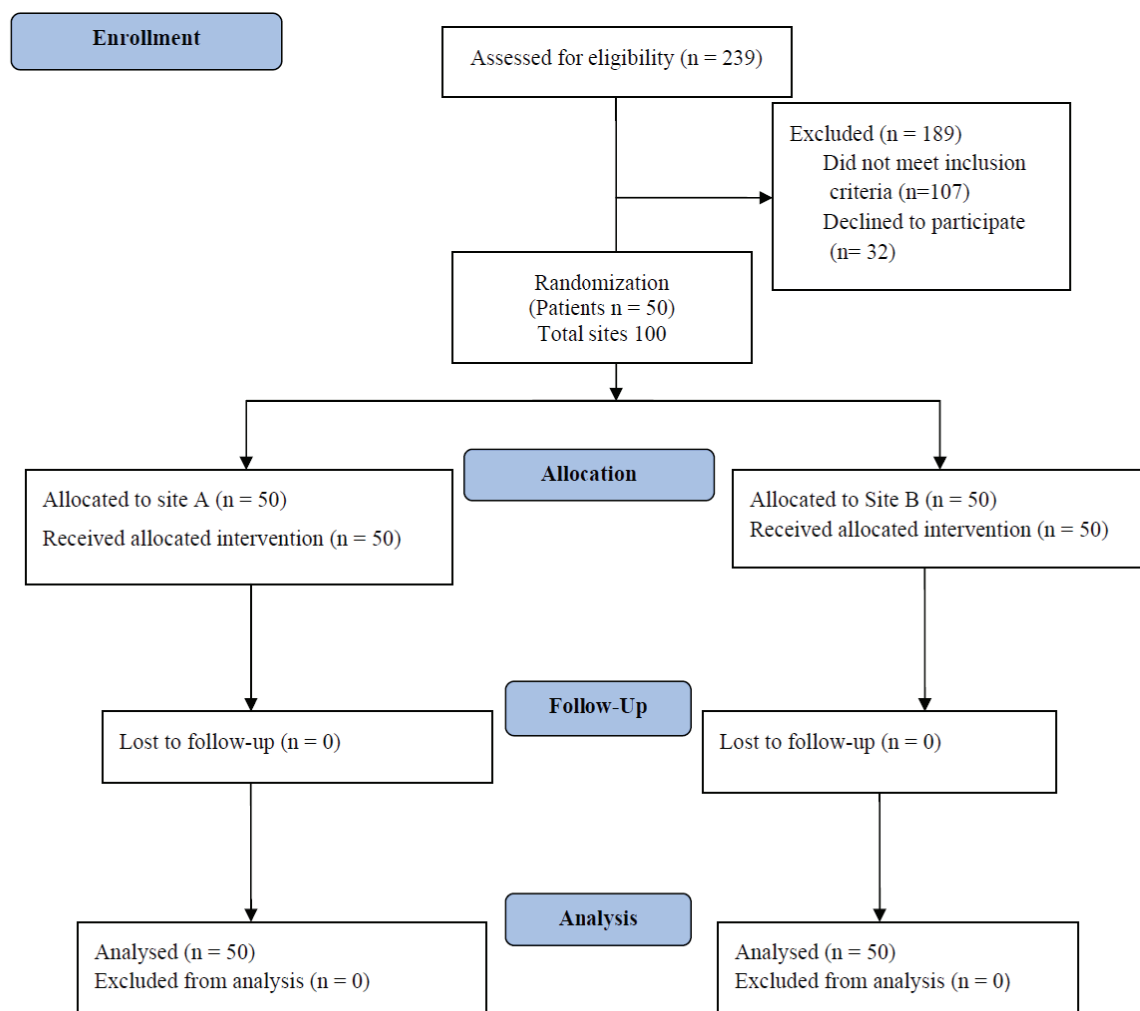


Fig. 1. Patient selection and allocation

4. Procedure

A detailed case history and written informed consent were obtained from each patient. Before initiating the procedure, the use of the Visual Analog Scale (VAS) was explained to the patients. Thirty-gauge and 1.5-inch-long needles were used for the injection. For site A, topical 2% Lignocaine gel was applied using a cotton applicator tip. The amount of gel that coated the applicator tip was used. The gel was gently rubbed on the dried soft tissue in the area of the injection using a cotton applicator tip, and the patient's mouth was kept open using a mouth prop. Intermittent suctioning was performed to prevent pooling of the saliva. After five min, a standard local anesthetic injection was administered. For site B,

DentalVibe (BING Innovations, Boca Raton, Fla., USA], comfort tip prongs were positioned in the area of the injection, and the mucosa was retracted using the same. DentalVibe was turned on to stimulate the area of needle penetration. After one min of vibration, the local anesthetic injection was administered. It continued vibrating during the needle insertion and delivery of the anesthetic. After the anesthesia was delivered, the needle was withdrawn, and DentalVibe was removed after 10 seconds.

The primary outcome measure was the pain felt during the administration of the local anesthesia injection, which was self-reported by the patient immediately after the injection, using a VAS of 0 – 10, where 0 implied no pain and 10 implied worst possible pain [14].

5. Statistical analysis

The data were analyzed using SPSS for Windows version 16.0. (IBM Corp., Armonk, NY, USA). The median VAS score was calculated. The Mann-Whitney U test was used to compare the data (i.e., VAS score) between the groups. The level of significance was set at 5%.

RESULTS

Fifty patients aged 18 to 50 years (mean age, 25.06 \pm 7.32) participated in the study. The sex distribution was 26 [52%] females and 24 [48%] males.

The VAS score for pain ranged from 4 to 10 for site A and from 0 to 6 for site B. The Mann-Whitney U test showed a statistically significant difference (Mann-Whitney U test value = 51.50, $P < 0.001$) between the two sites. The median pain scores for sites A and B were 7 and 3, respectively.

DISCUSSION

Pain control during local anesthesia injection remains an important step in reducing pain and anxiety during dental procedures. Dentists should try to minimize or eliminate this pain to the maximal extent possible [13].

Local anesthetic gels are routinely used for pain reduction. They numb the surface area where the needle is to be inserted, which reduces the pain on insertion of the needle. However, a higher concentration of topical anesthesia is required for absolute painlessness. Thus, the depth of anesthesia remains limited, and the patient might feel the pressure of the injection into the deeper tissues [6].

DentalVibe is a cordless, rechargeable, handheld device (Fig. 2) that delivers pulsed micro-oscillations to the injection site. It requires no modification to be made to the traditional anesthetic technique [12]. DentalVibe is designed such that it retracts the buccal or labial mucosa. It can be held easily and operated with the non-working



Fig. 2. DentalVibe

hand, leaving the operating hand free for administering the injection. Massaging with the VibraPulse technology at the injection site prevents the swelling caused by the bolus of the anesthetic solution and assists in its dissipation, resulting in faster and more profound anesthesia [15]. It has an embedded light source, which helps in better visualization of the injection site [12].

The present study indicates that the pain score at the site with DentalVibe was lower than that at the site with topical anesthetic gel during the local anesthetic injection.

The action of DentalVibe is explained by the gate control theory of pain [13]. It was first proposed by Ronald Melzack and Patrick Wall in 1965. This suggests the presence of a neurological "gate" located within the substantia gelatinosa of the dorsal horn of the spinal cord - in this case, within the trigeminal ganglion. It states that this "gate" can either block pain signals or allow them to proceed to the brain. The theory states that there are various types of nerve fibers based on their size and speed of conducting the impulse. The A [δ] delta fibers are relatively large, myelinated fibers approximately 1 – 22 μm in diameter [13]. They stimulate pain receptors, which rapidly communicate the initial information about pain to the body. These signals are sent to the brain and spinal cord, where they are usually interpreted as acute, sharp pain [14]. The second type of fibers, i.e. the B fibers, are not found in the dorsal root. The third type of fibers, i.e. the C fibers, are small, unmyelinated nerve fibers, about 0.05 to 1 micron in diameter. These transmit slow or second pain at a rate of 0.5 to 2 meters per second. The Gate Control Theory hypothesizes an action system for the nervous system. It states that when counter stimulation, i.e. vibration technique [in the context of this study] is applied during a painful incident [i.e., dental injection], the sensation of vibration reaches the brain

first, and this results in closure of the pain gate to the sensation of the pain of injection [16].

Our results agree with the results reported in previous studies. DiFelice et al. conducted a randomized, block, split-mouth design study to assess the use of a vibratory device with topical anesthetic against topical anesthetic only for pain experienced during an inferior alveolar nerve block [17]. The group that received the vibratory device with topical anesthetic had a mean VAS score of 21.2 ± 18.6 mm, while the group receiving only the topical anesthetic had a VAS score of 38.7 ± 23.3 mm. This showed that the vibratory device, along with topical anesthetic, significantly reduced the pain experienced during the administration of a local anesthetic injection compared to the use of topical anesthetic alone [$P = 0.006$].

Mangalampally et al. conducted a split-mouth study among 30 patients aged 6 to 12 years, requiring bilateral anesthesia [15]. Local anesthetic administration with vibration resulted in significantly less pain ($P = 0.001$) compared to injections without the use of vibration.

Dak Albab et al. conducted a crossover, double-blind, randomized clinical trial among 30 children aged 8 to 12 years [18]. All patients received mandibular nerve block with benzocaine 20% gel on one side and DentalVibe on the other at the injection site. A significant difference was observed ($P = 0.002$) in the pain score, favoring the use of DentalVibe.

However, three studies have suggested that DentalVibe did not reduce pain [19-21]. Brignardello-Petersen revealed that the use of a vibrating device did not reduce the pain levels, and the device was not well accepted compared to traditional local anesthetic injections in well-behaved children [19].

Erdogan et al. conducted a study among 32 children requiring maxillary local anesthesia injections [one with conventional technique and the other with DentalVibe [20]. DentalVibe used in this study did not minimize pain levels associated with maxillary infiltration of the local anesthesia.

Raslan and Masri compared pain levels during three types of anesthesia injections and the effect of DentalVibe

on pain reduction in children [21]. No statistically significant difference in pain scores was noted compared to the traditional injection technique.

The literature reveals mixed results regarding the use of DentalVibe. Heterogeneity in the study design, type of injection, location of the injection, and the pain threshold of the patients influenced the outcome. However, all the studies that were compared were conducted among young children.

This is a unique study in that it has been conducted among adults, and the split-mouth study design was used, wherein the patient was his own control. This is advantageous in reducing outcome variability [22].

However, there are two limitations to this study. First, the baseline anxiety score of each patient was not recorded. There is a high possibility that patients with high anxiety levels can bias the outcome measure.

Second, the measurement of pain as an outcome assessor was subjective and patient dependent. Since every patient has a different pain threshold, this might have had an effect on the final outcome.

In conclusion, compared to topical anesthetic gel, DentalVibe showed lower pain scores during the administration of the local anesthetic injection. Further studies among the adult population are needed to corroborate this finding.

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Kapil Kshirsagar: Conceptualization, Methodology, Writing - original draft, Writing - review & editing

Vivek Pawar: Project administration, Resources, Supervision, Visualization

Pradnya Kakodkar: Formal analysis, Methodology, Software, Validation, Writing - original draft, Writing - review & editing

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