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Effect of vibratory stimulation on pain during local anesthesia injections: a clinical trial

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No potential conflict of interest relevant to this article was reported

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ABSTRACT

Objectives: This study aimed to assess the effect of DentalVibe on the level of pain experienced during anesthetic injections using 2 different techniques.
Materials and Methods: This randomized crossover clinical trial evaluated 60 patients who required 2-session endodontic treatment. Labial infiltration (LI) anesthesia was administered in the anterior maxilla of 30 patients, while inferior alveolar nerve block (IANB) was performed in the remaining 30 patients. 1.8 mL of 2% lidocaine was injected at a rate of 1 mL/min using a 27-gauge needle. DentalVibe was randomly assigned to either the first or second injection session. A visual analog scale was used to determine participants' pain level during needle insertion and the anesthetic injection. The paired *t*-test was applied to assess the efficacy of DentalVibe for pain reduction.
Results: In LI anesthesia, the pain level was 12.0 ± 15.5 and 38.1 ± 21.0 during needle insertion and 19.1 ± 16.1 and 48.9 ± 24.6 during the anesthetic injection using DentalVibe and the conventional method, respectively. In IANB, the pain level was 14.1 ± 15.9 and 35.1 ± 20.8 during needle insertion and 17.3 ± 14.2 and 39.5 ± 20.8 during the anesthetic injection using DentalVibe and the conventional method, respectively. DentalVibe significantly decreased the level of pain experienced during needle insertion and the anesthetic injection in anterior LI and mandibular IANB anesthesia.
Conclusions: The results suggest that DentalVibe can be used to reduce the level of pain experienced by adult patients during needle insertion and anesthetic injection.

Keywords: Local anesthesia; Pain; Vibratory stimulation

INTRODUCTION

Pain is an unpleasant sensation that is often associated with actual or potential trauma or tissue injury [1]. It is the consequence of neurophysiological processes that can be affected by a number of cultural, financial, social, and psychological factors [2].

Local anesthetics are chemical agents used to temporarily interrupt the path of signal transmission by the nerves and to eliminate pain during dental procedures. Local anesthesia is a prerequisite for the majority of dental procedures. According to Malamed [3], 55% of medical emergencies in the dental office setting occur during anesthetic injections, which

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highlights the significance of pain control and anxiety management when anesthetic injections are performed. Successful local anesthesia requires adequate knowledge of the ingredients of the anesthetic agents and the neuroanatomy of the region, as well as selection of an appropriate injection technique. Several methods have been suggested to decrease the level of pain experienced during needle insertion, such as applying topical anesthetic agents, ensuring the correct direction of the needle bevel, using a small-gauge needle, and administering low-level laser treatment [4-7]. Furthermore, some strategies have been proposed to decrease the level of pain experienced during the injection of an anesthetic agent, such as injecting the anesthetic agent slowly and warming or buffering the anesthetic agent. However, the results of studies regarding the efficacy of these strategies have been controversial [8-10].

Application of a topical anesthetic agent is the most commonly practiced method to control the pain of needle insertion. However, this technique may have complications or side effects, depending on the volume of anesthetic agent absorbed by the mucosa and the relative toxicity of its ingredients. Moreover, topical anesthetic gels and sprays often have a bad taste, which is unpleasant for many patients [11]. There is no evidence supporting any value of topical anesthetics for reducing the discomfort of deep regional block administration, such as inferior alveolar nerve block (IANB) injections [12].

Several theories have sought to explain the pain control mechanism, the most important of which is the gate control theory proposed by Melzack and Wall [13]. According to this theory, pain control occurs in the substantia gelatinosa and nucleus proprius of the spinal cord, and the cells in the nucleus proprius play a fundamental role in this respect. Upon stimulation of thick A fibers, the impulses are transferred to the posterior spinal horn. They first enter lamina I, and then laminae II and III. A series of connecting neurons are present in laminae II and III (*i.e.*, the substantia gelatinosa) that inhibit nucleus proprius cells (lamina VII), which are known as T cells. Upon stimulation of thick fibers, the activity of the connecting neurons increases, while the activity of T cells decreases, leading to a reduction in the release of substance P, followed by subsequent channel blockage and pain relief [13].

Pain relief upon stimulation of higher centers in the brain stem has been suggested as another mechanism. According to this proposal, electrical stimulation of the periaqueductal gray or raphe nucleus can attenuate many of the strong pain signals received from the posterior spinal roots. These nuclei are part of a descending pain suppression system that leads to the release of endogenous opiate substances (such as b-endorphin and enkephalin) in the substantia gelatinosa of the spine, thereby causing subsequent pain relief [14].

Several studies have evaluated the efficacy of various injection techniques for controlling pain during needle insertion and injection of an anesthetic agent. The DentalVibe Injection System operates according to the gate control mechanism. It creates vibrations to decrease the level of pain experienced by patients during needle insertion and anesthetic injection [13]. Shilpapriya *et al.* [15] and Tung *et al.* [16] evaluated DentalVibe in children (both males and females) and showed that children in the DentalVibe group experienced significantly lower levels of pain than those in the conventional group. Furthermore, Shaefer *et al.* [17] investigated this device in 60 volunteer dental or medical student patients aged 21 to 32 years. The results showed that the subjects who received DentalVibe reported significantly less pain, discomfort, unpleasantness, and difficulty in enduring long buccal and IANB injections. However, they recommended more studies among layperson populations [17]. Meanwhile, a

few researchers such as Raslan and Masri [18] and Elbay *et al.* [19] compared the level of pain experienced by children during buccal and palatal infiltration anesthesia of the maxilla or IANB according to whether DentalVibe was used, and found no significant difference in the level of pain experienced during injections.

In light of the above considerations, the efficacy of DentalVibe for pain reduction, especially in the adult population, has not been well investigated and evidence regarding its optimal efficacy is inconclusive. Thus, further clinical studies on patients are required to reach a final judgment regarding the efficacy of DentalVibe. This study aimed to assess the efficacy of DentalVibe for reduction of the pain experienced during needle insertion and anesthetic injection in infiltration anesthesia of the anterior maxilla and mandibular IANB.

MATERIALS AND METHODS

This clinical trial evaluated 60 patients between 18 to 60 years who were referred to the Endodontic Department, School of Dentistry, Shahid Beheshti University of Medical Sciences and required 2-session endodontic treatment of either a maxillary anterior tooth or a mandibular posterior tooth. Thirty of these patients received labial infiltration (LI) anesthesia in the anterior maxilla, while the remaining 30 received IANB. The sample size calculation, which was based on a type I error of 0.05 and a power of 0.8, indicated that ideally a sample size of 28 in each group would be required to detect a 20% difference in the pain level of 2 groups. This study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, with the registry ID of IR.SBMU.RIDS.REC.1394.110.

The inclusion criteria were systemically healthy individuals with asymptomatic, irreversible pulpitis of a maxillary anterior or a posterior mandibular tooth who required 2-session endodontic treatment. The exclusion criteria were the presence of any underlying systemic condition, allergy to the anesthetic agent, symptomatic teeth (symptomatic irreversible pulpitis, symptomatic apical periodontitis, or acute apical abscess) and consumption of medications or substances that affect the pain response (alcoholism, substance abuse, intake of analgesics, or tranquilizers). The injection technique in the first session was selected randomly using a table of random numbers in Excel; 50% of patients received anesthetic injections using DentalVibe (third generation, BING Innovations, Boca Raton, FL, USA) in their first treatment session, while the remaining 50% received anesthetic injections via the conventional technique in their first treatment session. In all injections, 1.8 mL of 2% lidocaine with 1:100,000 epinephrine (Xylocaine, Dentsply, Germany) was administered within 60 seconds using a 27-gauge needle (Septoject, Septodont, Saint-Maur-des-Fossés, France). All injections were performed by a postgraduate student of endodontics, and an equal amount of anesthetic agent was administered in all injections.

This study had a crossover design and all patients received anesthetic injection with DentalVibe in one session and the conventional method in the other treatment session, in a random fashion. All procedures in the control group (conventional method) were the same as those in the test group (DentalVibe) except for the fact that DentalVibe was used in off mode in the control group. In order to control for the confounding effect of subject-expectancy and the pressure applied to tissue due to the placement of DentalVibe, the device was placed over the injection site in both sessions. However, the patients could not be blinded to the use of DentalVibe since it creates tangible vibrations.

In local infiltration anesthesia, the 2 U-shaped heads of DentalVibe were placed on the oral mucosa with light pressure at the respective site. The device was turned on, and after 5 seconds the needle was inserted into the tissue. To assess the level of pain during needle insertion, the needle was maintained in this position for 10 seconds. Then, the anesthetic agent was injected within 60 seconds. DentalVibe was removed 5 seconds after completion of injection and needle extraction.

For IANB, the anterior border of the ramus was first touched conventionally by a finger to locate the pterygomandibular depression. Finger pressure was then removed and the retracting part of the DentalVibe device was placed over the injection site to create vibrations. The pressure applied by DentalVibe for lip and cheek retraction was the same as the pressure applied by a dental mirror. The needle was placed as close to one tip of the device as possible without touching it, according to the manufacturer's instructions. The vibrations continued for 5 seconds prior to needle insertion, and then a 27-gauge needle was inserted into the tissue between the internal oblique ridge and pterygomandibular raphe until it reached the bone. Aspiration was performed and the needle was kept in this position for 10 seconds to assess the level of pain experienced by patients during needle insertion. The anesthetic agent was then injected for 60 seconds. DentalVibe was removed 5 seconds after removing the needle. Finally, the patients were requested to express the level of pain experienced during needle insertion and injection of the anesthetic agent using a 100-mm visual analog scale (VAS).

Data were analyzed using SPSS version 22 (IBM Corp., Armonk, NY, USA). The mean and standard deviation of pain scores during needle insertion and the anesthetic injection were calculated for both groups after maxillary LI and mandibular IANB. The paired *t*-test was used to assess the efficacy of DentalVibe for pain reduction compared to the conventional injection method. The generalized estimating equation method was used to assess the effect of DentalVibe on the level of pain after controlling for confounding factors. The effects of order of treatment with DentalVibe, sex, and site of injection on pain severity in the DentalVibe and conventional groups were analyzed using the independent *t*-test. The correlation between age and pain reduction for the 2 methods was analyzed using the Pearson correlation test, with p values < 0.05 considered to indicate statistical significance.

RESULTS

In total, 60 patients (28 men and 32 women) between 18 to 60 years were evaluated (**Table 1**). The mean and standard deviations of the pain scores upon needle insertion and anesthesia injection in maxillary infiltration and mandibular IANB are summarized in **Tables 2** and **3**, respectively.

Table 1. Frequency distribution of patients in terms of age and sex in the infiltration anesthesia and IANB groups

Variable	Infiltration anesthesia (n = 30)	IANB (n = 30)	Total (n = 60)
Sex			
Male	13 (43.33)	15 (50.00)	28 (46.66)
Female	17 (56.66)	15 (50.00)	32 (53.33)
Age (yr)	36 (18–52)	31.9 (18–60)	33.6 (18–60)

Values are presented as number (%) or mean (minimum–maximum).
IANB, inferior alveolar nerve block.

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Table 2. Pain score using a visual analog scale for maxillary infiltration anesthesia according to the use of DentalVibe or the conventional method (n = 30)

Pain	Method	Pain score
Needle insertion	DentalVibe	12.0 ± 15.5
	Control	38.1 ± 21.0
Anesthetic injection	DentalVibe	19.1 ± 16.1
	Control	48.9 ± 24.6

Scores are presented as mean ± standard deviation.

Table 3. Pain score using a visual analog scale for mandibular inferior alveolar nerve block according to the use of DentalVibe or the conventional method (n = 30)

Pain	Method	Pain score
Needle insertion	DentalVibe	14.1 ± 15.9
	Control	35.1 ± 20.8
Anesthetic injection	DentalVibe	17.3 ± 14.2
	Control	39.5 ± 20.8

Scores are presented as mean ± standard deviation.

The results of the paired t-test regarding the efficacy of DentalVibe for pain reduction during needle insertion and anesthetic injection showed that DentalVibe led to a significant reduction in the pain scores for both needle insertion and the anesthetic injection in the maxillary infiltration and mandibular IANB groups ($p < 0.0001$). According to the independent t-test, no significant relationship was observed between the order of use of DentalVibe (first or second session) and differences in the pain score between the test and control groups ($p > 0.05$). No significant correlation was noted for sex or the pain score between the 2 methods ($p > 0.05$). The independent t-test found no significant relationship between the site of injection (maxilla/mandible) and the pain score in either the test or control group ($p > 0.05$). No significant differences were found in the pain levels experienced between needle insertion and the anesthetic injection ($p > 0.05$). In other words, the efficacy of DentalVibe for pain reduction during needle insertion was the same as its efficacy during the anesthetic injection. In both the test and control groups, the Pearson correlation coefficient showed no significant correlation between age and pain reduction.

DISCUSSION

According to the results of this study, DentalVibe creates vibrations that significantly decrease pain during needle insertion and the anesthetic injection in infiltration anesthesia of the maxilla and IANB of the mandible. The current findings may have several applications in dental treatments, and are in line with the results of some previous studies that confirmed the efficacy of vibration tools for pain control during local anesthetic injections [15,17,19,20].

Similar to our study, Shilpapriya *et al.* [15] and Tung *et al.* [16] reported that the mean pain score during infiltration anesthesia of the maxilla and IANB of the mandible in children who received injections using DentalVibe was significantly lower than that in the control group.

In agreement with our findings, Ungor *et al.* [20] concluded that the vibration technique is an efficient tool for reducing patients' pain and anxiety during anesthetic injections. The same results were reported by Nanitsos *et al.* [21]. In their study, adult patients in the vibration group experienced lower levels of pain during anesthetic injections than those in the control group. They assessed pain levels using a VAS and the McGill pain questionnaire. They additionally performed extra-oral vibrations, which could have decreased the effects of

vibration exerted through the gate control mechanism of pain control due to the presence of a distance between the injection site and the device [21]. In addition, Shaefer *et al.* [17] showed a significant reduction in injection pain and discomfort levels following the use of the DentalVibe Injection System in adult volunteers.

In contrast to the findings of the abovementioned studies, Roeber *et al.* [22] evaluated the efficacy of another vibration tool known as VibraJect (VibraJect, LLC, Anaheim, CA, USA). The manufacturer proposed that causing a needle to vibrate with VibraJect could result in a reduction in injection pain on the basis of the gate control theory, but in a different way compared to DentalVibe, as it causes the syringe to vibrate, rather than causing vibrations at the site of injection. However, they found no significant difference with regard to the pain score during anesthetic injections in children [22]. This finding may have been because their study did not have a crossover design, the absence of which can cause bias and lead to non-significant differences between 2 groups. Saijo *et al.* [23] and Yoshikawa *et al.* [24] found no significant difference in pain scores following the use of VibraJect. One possible reason may be that the vibrations created by the device were not strong or effective enough to trigger the nerve ends at the injection site in most patients [21]. The sample size of the study by Saijo *et al.* [23] was too small, and the penetration depth and the amount of anesthetic agent injected in their study were also lower than the standard level [22]. All these factors could have contributed to their findings.

In most previous studies, topical anesthetic agents were applied on the surface before the anesthetic injection in order to minimize the level of pain and discomfort experienced during needle insertion; this can also affect the severity of pain experienced during the injection [25]. However, topical anesthetic was not used in the current study, since it could function as a confounder and thereby affect the results. Instead, DentalVibe was placed over the mucosa without application of a topical anesthetic agent.

Although vibration decreased the pain score during needle insertion and anesthetic injection in the current study, several factors can affect the severity of pain during anesthetic injection, including the type, amount, and speed of the anesthetic injection and the dental clinician's experience and expertise [4-10]. In addition to treatment-related factors, psychological variables such as fear and anxiety also affect pain severity. Evidence shows that patient anxiety increases the duration and severity of pain [26]. This anxiety, which can be due to preoperative pain, may increase during the procedure [27]. Since the patients in our study were asymptomatic, the possibility of stress and anxiety caused by preoperative pain, and their subsequent effect on pain sensation, was minimal.

The participants in our study had no prior experience with DentalVibe, which might have raised their expectations, resulting in an overestimation of the efficacy of this device.

Despite the significant efficacy of vibration for pain reduction during anesthetic injections, many factors are involved in this process and need to be investigated. Since these devices are battery-operated, the frequency and intensity of vibrations may change over time and may also be variable for different patients. Furthermore, different operators may perform injections differently, and the level of pressure applied by operators to the vibration device may vary as well. In the present study, a postgraduate student of endodontics carried out all the injections. For maxillary injections, only a light touch or slight pressure is needed when using DentalVibe on soft tissue. However, for IANB, the vibrating prongs should be pushed

deeper into the buccal mucosa to make the mandible vibrate during the injection. The device has a pressure-sensing feature, causing the unit to temporarily shut off if excessive force is applied during use. In the current study, using the vibration tool decreased the level of pain experienced during needle insertion and anesthetic injection irrespective of the type of anesthesia (infiltration or IANB).

The pain experienced during a local anesthetic injection can be divided into 2 components: pain experienced upon needle insertion, which lasts for a short time, and pain following the activation of pain receptors by chemical agents present in the anesthetic agent and tissue injury caused by needle insertion. The secondary pain is more severe and lasts longer than the initial pain [28].

According to the current findings, the site of injection and order of using DentalVibe (first or second session) had no significant effect on the pain score experienced during needle insertion and anesthetic injection. Sex also had no significant effect on the level of pain. Age had no significant correlation with the level of pain experienced in either group.

Moreover, attempts should be made to minimize the differences between the 2 injection methods (with and without DentalVibe) with regard to the speed of injection, placement of DentalVibe close to the injection site, experience of the operator, and not using a topical anesthetic agent before injection. The anatomical location of the injection site also affects the pain score, which may explain the discrepancies in the results of previous studies.

Infiltration anesthesia in the anterior maxilla and IANB of the mandible are among the most painful, yet most common intraoral injections; therefore, only these 2 types of injections were evaluated in the present study to minimize bias.

Careful needle insertion and gentle release of the anesthetic agent into the tissue can decrease the pain experienced by the patient during this process [28]. Primosch and Brooks [29] demonstrated that slowly injecting the anesthetic agent significantly decreased pain compared to fast injections. Nonetheless, pain experience during an anesthetic injection is influenced by a number of factors such as fear, anxiety, and previous experiences of anesthetic injections [30]. Previous painful experiences increase patients' level of anxiety, and measuring pain in such patients can be very difficult. Clinically, enrolling patients with a low level of anxiety with asymptomatic pulpitis would be beneficial for improving the reliability of pain measurements in studies of this issue [31].

In the present study, all patients received injections both with DentalVibe and using the conventional method. In other words, each patient served as his or her own control group, which minimized the risk of errors. Furthermore, the method of injection in the first session was selected randomly. Due to the crossover design of the study, the pain threshold of patients was standardized. The main limitation of this study was the fact that neither the dental clinicians nor the patients could be blinded to the group allocation due to the tangible vibrations induced by DentalVibe.

Several indices can be used to measure the level of pain experienced during anesthetic injections. Pain is a subjective phenomenon, and several physical and psychological factors play a role in its severity. Thus, patients' level of anxiety should be determined before any intervention. Furthermore, many variables are involved in pain expression, and errors can

occur in pain measurements. However, a VAS is a reliable tool for estimating levels of pain, assuming that it is correctly designed and the patients are thoroughly briefed about it [32].

Further studies are required on the efficacy of vibrations for pain control. For example, certain frequencies of the device may have a particularly high efficacy for pain control, a possibility that should be investigated in future studies. Furthermore, future studies should also investigate the role of related factors such as dental fear and anxiety, previous painful experiences, and the presence of dental pathologies.

CONCLUSIONS

The current results revealed significantly lower pain scores during needle insertion and anesthesia injection in the vibration group than in the control group. The effects of site of injection, order of using DentalVibe, sex, and age on the level of pain experienced during needle insertion and the anesthetic injection were not significant. Thus, DentalVibe seems to be an effective tool in adult patients for pain control during needle insertion and anesthetic injections in infiltration anesthesia of the maxilla and IANB of the mandible in clinical settings.

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