

Evaluation of the effect of the photobiomodulation therapy on the pain related to dental injections: A preliminary clinical trial

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Dental and Medical Problems, ISSN 1644-387X (print), ISSN 2300-9020 (online)

Dent Med Probl. 2022;59(3):421–425

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Funding sources

None declared

Conflict of interest

None declared

Acknowledgements

None declared

Received on November 17, 2020

Reviewed February 9, 2021

Accepted on February 23, 2021

Published online on September 30, 2022

Abstract

Background. Pain from dental injections is a common reason why people fear dentistry and avoid dental treatment. Thus, researchers have attempted to find methods to decrease dental injection pain.

Objectives. Considering the analgesic effect of the photobiomodulation therapy (PBMT), the aim of this study was to evaluate the effects of PBMT on the pain caused by dental anesthetic injections.

Material and methods. This randomized, split-mouth, triple-blind clinical trial evaluated 60 bilateral canine teeth in 30 dental students. After the random selection of the test (laser) quadrant, the injection site was irradiated with a 940 nm diode laser. Buccal infiltration anesthesia was then administered by injecting lidocaine plus epinephrine with a short needle. The level of pain experienced during the injection was determined using a 100-millimeter visual analog scale (VAS). The same procedure was performed for the control (no laser) quadrant, with the difference being that the laser handpiece was turned on, but no radiation was administered. The 2 groups were compared using the non-parametric Wilcoxon signed-rank test.

Results. The mean VAS pain scores were 21.2 ± 15.7 for the laser quadrant and 27.9 ± 18.9 for the control quadrant; this difference was statistically significant ($p = 0.030$), but did not seem to be clinically relevant.

Conclusions. The photobiomodulation therapy prior to dental anesthetic injections has no clinical advantage for reducing injection pain.

Keywords: pain, local anesthesia, laser, injection, low-level laser therapy

Cite as

Afkhami F, Ebrahimi H, Aghazadeh A, Sooratgar A, Chiniforush N. Evaluation of the effect of the photobiomodulation therapy on the pain related to dental injections: A preliminary clinical trial. *Dent Med Probl.* 2022;59(3):421–425. doi:10.17219/dmp/133645

DOI

10.17219/dmp/133645

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Introduction

Pain is defined as an unpleasant feeling that is experienced when actual tissue damage or trauma with the potential to cause tissue damage occur.¹ Pain from dental anesthetic injections has always been a challenge during dental treatment. Evidence has shown that the fear of dental injections is a major reason why people avoid dental visits and dental care services, which can adversely affect a person's oral health status.² Dental injection pain can be due to the mechanical trauma caused by the insertion of the needle into the tissue, the release of the anesthetic agent into the tissue or the removal of the needle. Several factors can affect the level of anesthetic injection pain, such as the type of anesthetic agent injected, the gauge of the needle, and the temperature and pH of the injected agent.³ Topical anesthetic agents in the form of anesthetic gels and sprays have been proposed to reduce injection pain. Some simple techniques, such as the compression and precooling of the injection site, have also been suggested for this purpose.^{4,5} Moreover, some fundamental advances have been made in anesthetic injection techniques in recent years, such as the use of computerized injection systems, which aim to reduce anesthetic injection pain and improve the patient's comfort. However, further studies are required to develop painless anesthetic injection techniques that can be applied for widespread use in dental offices.⁶

In recent years, the photobiomodulation therapy (PBMT) and the application of biostimulative lasers have gained prominence in this field. In this treatment modality, the laser beam is able to penetrate deeply into the tissue due to its low output power, which is usually <500 mW, and the selected laser wavelengths, which are usually between 630 nm and 1,300 nm. In PBMT, the absorbed energy does not heat or damage the living tissue; instead, the energy of the laser photons is absorbed by the cells and stimulates them, which is referred to as photostimulation.⁷ The photobiomodulation therapy has several advantages at the cellular level, including the metabolic activation of the cells and the improvement of their function, the stimulation of the repair process, anti-inflammatory effects, analgesic effects due to the release of endorphins, the stimulation of the immune system, and an increased anti-oxidative capacity of the blood.⁸

Over the years, since its approval by the U.S. Food and Drug Administration (FDA) as a pain reduction modality, PBMT has become increasingly popular.^{9,10} Although the exact mechanism of action of PBMT for pain reduction is not completely understood, evidence supports the idea that PBMT activates certain peripheral analgesic mechanisms that can affect pain perception. Thus, the PBMT protocols for pain control have been studied under different conditions.¹¹ The analgesic effects of PBMT in the management of pain following endodontic surgery, temporomandibular joint pain, trigeminal neuralgia, myalgia,

aphthous ulcers, and tooth hypersensitivity have previously been confirmed.¹² However, the effect of PBMT on pain from anesthetic injections in the oral cavity has not been thoroughly examined. Thus, the aim of this study was to evaluate the effect of PBMT on pain from dental anesthetic injections.

Material and methods

This randomized, split-mouth, triple-blind clinical trial included 30 candidates who were selected from dental students at Tehran University of Medical Sciences, Iran. The study was conducted in the Laser Department of the university.

The study was approved by the institutional Ethics Committee at Tehran University of Medical Sciences (IR.TUMS.DENTISTRY.REC. 1397.067) and registered in the Iranian Registry of Clinical Trials (IRCT2019042904418N1). All patients signed informed consent forms prior to their participation in the study, and they were free to withdraw at any point during the study.

A total of 60 sound maxillary canine teeth were selected bilaterally. The teeth had no carious lesions, periapical lesions, extensive restorations, or anatomical anomalies or cracks; teeth with any of these problems were excluded from the study. The participants were healthy and had no cardiovascular diseases, thyroid disorders, or any other systemic conditions. There could be no history of taking antibiotics or nonsteroidal anti-inflammatory drugs (NSAIDs) in the past 2 months, which would contraindicate lidocaine plus epinephrine injections.

Considering the results of a pilot study on 3 samples and using the feature for comparing two means with the Minitab® Sample Size Calculation software (Minitab, State College, USA), the minimum sample size was calculated to be 22. The following were assumed: $\alpha = 0.05$; $\beta = 0.2$, standard deviation of the mean of 5, and a minimum difference between the 2 mean values of 4.4. Thirty patients were recruited to ensure accuracy and an adequate sample size. Since the study had a split-mouth design, the statistician randomly selected the test (laser) quadrant by flipping a coin and reported the result to the laser specialist.

In the test (laser) quadrant, the handpiece of a semiconductor diode laser (Epic 10; BIOLASE Inc., Foothill Ranch, USA) was positioned at the buccal vestibule of the maxillary canine and the injection site, with a cross-sectional area of 0.785 cm². It was irradiated with 15.28 J/cm² energy density, 200 mW power, and 940 nm wavelength for 60 s, using the continuous-wave mode. The anesthetic was injected immediately after the removal of the laser tip by means of the buccal infiltration anesthesia technique with a short 27-gauge needle (Soha, Tehran, Iran). Half of the anesthetic cartridge containing 2% lidocaine plus epinephrine 1:100,000 (Persocaine-E; Darou Pakhsh, Teh-

ran, Iran) was injected. The bevel of the needle faced the bone at the site of the apex of the canine tooth at an angle of 45° and the anesthetic agent was injected at a speed of 1 mL/min. All injections were performed by the same operator to ensure optimal quality and consistency, and to eliminate the confounding effect of interindividual differences in experience and expertise.

Immediately after the completion of the injection in the test quadrant, the level of pain experienced by the participant during the injection was quantified using a 100-millimeter visual analog scale (VAS). The participants had been instructed on how to use the scale earlier.

The same procedure was performed for the control quadrant, with the difference being that the laser hand-piece was turned on, but no radiation was administered.

The participants, the operator who performed the injections and the examiner who recorded the VAS pain scores were all blinded to the laser and control quadrants (triple-blind design).

Statistical analysis

For statistical analysis, the IBM SPSS Statistics for Windows software, v. 21.0 (IBM Corp., Armonk, USA), was used.

The measures of central dispersion, such as mean (*M*), standard deviation (*SD*), and minimum and maximum levels of pain according to VAS, were calculated for the laser and control groups. Since the pain score was an ordinal variable and the pain score data was not normally distributed, the 2 groups were compared using the non-parametric Wilcoxon signed-rank test. A *p*-value <0.05 was considered statistically significant.

Results

A total of 30 patients between 22 and 30 years of age (with a mean age of 26.5 years) were evaluated in this study. Twenty (66.7%) were males, and 10 (33.3%) were females. The level of pain was measured using VAS. A VAS score of 0 indicated no pain at all, while a score of 100 indicated the most excruciating pain imaginable. Table 1 presents the measures of central dispersion of the pain scores.

The distribution was assessed using the Shapiro–Wilk normality test, and it was determined to be not normal. According to the Wilcoxon signed-rank test, the mean VAS pain score in the laser group was significantly lower than in the control group (*p* = 0.030).

Table 1. Measures of central dispersion of the dental injection pain score determined with a 100-millimeter visual analog scale (VAS)

Variable	Group	<i>M</i> ± <i>SD</i>	Minimum	Maximum
Pain	laser	21.1 ± 15.7	0.0	60.0
	control	27.9 ± 18.9	0.0	70.0

M – mean; *SD* – standard deviation.

Discussion

Anesthesia through injection is an essential aspect of most kinds of dental treatment. Patients seeking dental treatment are often concerned about anesthetic injections and the pain they cause. Painless anesthetic injections can increase the patient's comfort and cooperation, positively affect the quality of treatment, and build the patient's trust. Thus, several methods have been suggested to reduce dental anesthetic injection pain.^{13,14} Considering the favorable biological effects of PBMT, including its analgesic action,⁸ this study evaluated the influence of PBMT on the pain caused by dental anesthetic injections.

The results of this study indicate that applying PBMT prior to an anesthetic injection significantly decreased the level of pain experienced during the injection. In vivo studies on the effects of PBMT on oral mucosal innervation have shown that PBMT decreases the frequency of pain signals transferred by the nerve fibers and increases the stimulation threshold of the nerve fibers.⁷ Laser has an inhibitory effect on A-delta and C fibers, and consequently decreases the speed of transfer of pain signals, lowers the action potential and inhibits neurogenic inflammation.¹⁵ In this study, the pain reduction experienced on the laser side can be attributed to changes in the synthesis, release and metabolism of the chemical mediators of pain in the peripheral nervous system.¹⁶

Evidence indicates that PBMT can be used as an effective non-pharmaceutical modality for pain relief following nonsurgical endodontic treatment.^{17,18} In their study on 10 children between 6 and 9 years of age, Tanboga et al. evaluated the effect of a low-level erbium-doped yttrium aluminum garnet (Er:YAG) laser on the pain caused by cavity preparation.¹⁹ They concluded that patients who underwent PBMT prior to cavity preparation experienced a lower level of pain during this process.¹⁹ Shapiro et al. reported that the application of a low-level Er:YAG laser in a laser anesthesia device along with lidocaine caused a significant reduction in needle insertion pain in intramuscular injections.²⁰ This finding was attributed to the destruction of the stratum corneum layer through PBMT, which consequently enhanced the penetration and faster action of lidocaine.²⁰ In addition, it has been demonstrated that the use of aluminum gallium arsenide (AlGaAs) PBMT along with regional intravenous anesthesia can decrease the level of pain experienced during and after treatment.¹¹ Jagtap et al. determined that PBMT prior to anesthetic injections for tooth extraction caused a significant reduction in the level of pain experienced during the injection.³

On the contrary, some studies have reported that PBMT did not have any clinical advantage with regard to pain reduction in dental procedures.^{21,22} Payer et al. evaluated the effects of PBMT on inflammation, the course of healing and pain following endodontic surgical procedures, and concluded that there were no significant differences

between the laser and placebo groups in any of the assessed parameters.²³ There are a number of factors, such as radiation dosage, wavelength, exposure time, the type of tissue, and the optical properties of the laser, that can affect the efficacy of PBMT in pain control.^{3,8} In addition, variability in the results of studies can be due to different treatment protocols.

In 2016, Ghaderi et al. evaluated the effect of PBMT on the pain caused by dental anesthetic injections and demonstrated that patients who received topical anesthetic gel along with PBMT prior to anesthetic injections reported significantly lower VAS pain scores as compared to those who received topical anesthetic gel alone; however, this difference was not clinically significant.¹⁴ Similar results were obtained in the present study. Although the mean pain score was significantly lower in the laser group, this difference may not have been clinically relevant, as several studies have determined that a minimum change of 13–30 mm in the VAS score is needed in order to achieve clinical significance.²⁴ In this study, the difference in the mean pain scores between the 2 groups was below this range.

This prospective clinical trial had a split-mouth design, which eliminated the confounding effects of interindividual differences. Moreover, considering the blinding of the participants to the laser side and the random allocation of the laser and control sides, the carry-over effect, which is an inherent drawback of split-mouth studies,²⁵ was eliminated in this design.

This study used a triple-blind design. The dental clinician who performed the anesthetic injections and the examiner who recorded the pain scores were not aware of which side underwent irradiation. In addition, the laser handpiece light was turned on for both the laser and control sides. Furthermore, laser irradiation did not cause any visual or auditory stimulation, did not create heat, and had no vibration.²⁶ Thus, the patients were not aware of which side received PBMT.

To quantify the level of pain experienced, VAS was employed in the present study. This scale was used due to its simplicity and compatibility with different populations and study designs. Its application does not require a training course and it can be easily completed in less than 1 min. Moreover, evidence has demonstrated that VAS is sensitive to changes in pain perception.²⁷

Accelerated collateral circulation as well as an increased blood vessel diameter can be observed with PBMT. Therefore, when PBMT is applied prior to injection, the risk of hematoma formation should be considered.

Laser therapy is a novel field of science, and its application methods and treatment protocols are under constant development. Considering the inconsistency and controversy in the results of other PBMT studies, and the fact that this study had a small sample size and was performed on dental students, further investigations with larger sample sizes from the general public are imperative. Furthermore, due to the small sample size, it was impossible to make

a comparison between men and women concerning the VAS scores, or a comparison between the 1st and 2nd injection. Future studies should evaluate the efficacy of PBMT for other dental conditions that cause pain, such as the root canal treatment of inflamed teeth, as well as its potential for use as an alternative to supplement anesthetic injections. It should be noted that the risks and possible complications of laser therapy should be carefully investigated.

Conclusions

The results of the current study indicate that although PBMT with the set parameters had a statistically significant impact on the pain caused by injections with the buccal infiltration anesthesia technique, there was not a considerable clinical effect.

Ethics approval and consent to participate

The study was approved by the institutional Ethics Committee at Tehran University of Medical Sciences, Iran (IR.TUMS.DENTISTRY. REC. 1397.067), and registered in the Iranian Registry of Clinical Trials (IRCT2019042904418N1) Written informed consent was obtained from all participants.

Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

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