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Research Article

Effect of Photobiomodulation Therapy with 915 nm Diode Laser on Pain Perception during Local Anesthesia of Maxillary Incisors: A Randomized Controlled Trial

Hamid Kermanshah[1], Nasim Chiniforush[2]*, Mahsa Kolahdouz Mohammadi[3] and Fariba Motevasselian[1]*

[1]Department of Restorative Dentistry, School of Dentistry, Tehran University of Medical Sciences, Tehran, Iran
[2]Laser Research Center of Dentistry, Dentistry Research Institute, Tehran University of Medical Sciences, Tehran, Iran
[3]School of Dentistry, Tehran University of Medical Sciences, Tehran, Iran

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ABSTRACT

This study aimed to evaluate the effect of photobiomodulation therapy (PBMT) with 915 nm wavelength on pain reduction during *maxillary incisors' local infiltration* in a randomized clinical trial study. A prospective triple-blinded split-mouth clinical trial was designed to assess pain perception during needle insertion and local anesthetic injection in 32 healthy patients required operative caries management on contralateral maxillary incisors. After laser treatment (915 nm, power of 1.5 W, duty cycle of 60% and energy density of 72 J cm^{-2}) in active group and no irradiation in sham group, the injection was performed. Patients' perception of pain was immediately assessed using numerical rating scale (NRS) for pain. Washout period between two appointments was one week. Wilcoxon signed-rank and Pearson correlation statistical analyses were used to assess the comparison of pain score between two appointments and the effect of anxiety level of previous dental injections. The mean scores of pain for the active laser and sham laser groups were 2.5 ± 2.19 and 4.34 ± 2.52, respectively, with a statistically significant higher NRS in the sham laser group ($P < 0.05$). In this study's condition, diode PBMT reduced pain during infiltration on maxillary incisors. Anxiety experience of dental injection had no significant effect on pain perception scale ($P > 0.05$).

INTRODUCTION

The primary cause of fear and anxiety toward dental treatments is pain. It is an unpleasant subjective feeling. Several factors may influence pain perception, and it is a complex process with multidimensional nature. There are some patient-related factors such as anxiety and previous experience of dental treatment which may influence pain perception (1,2).

Invasive dental treatments such as restorations and crowns/bridges are associated with pain. Many patients avoid getting dental treatment that leads to progression of dental disease (2).

Injection of local anesthesia (LA) forms the major part of pain control to minimize or prevent pain during dental procedure. However, needle insertion and local anesthetic agent injection produces trauma to the tissue and result in pain. Local anesthesia is often perceived by some patients as the most painful part of the dental treatment (2,3).

A variety of techniques have been attempted to improve patient comfort during dental anesthetic administration, including smaller gauge needle sizes, slow computer-regulated administration, vibrating devices, topical agents, distraction technique and photobiomodulation therapy (PBMT) on the soft tissue (4–9).

Low-level laser therapy (LLLT) sometimes known photobiomodulation (PBM) use low-power intensity lasers from 5 to 500 mW with a wavelength between 600 and 1000 nm. These wavelengths have the ability to penetrate soft and hard tissue and are proven in clinical trials to have a good effect on pain relief, inflammation and tissue repair (10).

The pain perceived by the patient depends on the anatomical location, and it is one of the most important determinants of the resulting pain perception of intraoral injection due to the anatomy of nervous system (11,12). Several studies demonstrated that maxillary incisors are the most painful locations on injection (11,13).

The innervation of the canine and incisor teeth is normally due to anterior superior alveolar nerve (14,15); nevertheless, there is a wide variation to the branching pattern of the anterior superior alveolar nerve and the middle superior alveolar nerve within the anterior face of the maxilla. There are no anatomical predictors of the innervation pattern (15).

There is a controversy for optimal laser irradiation for pain reduction on local anesthesia, and literature data are not enough to exactly establish which laser characteristics are most effective in pain relief during needle injection in anterior maxilla (5,16,17).

Given the above factors, we aimed to evaluate the effect diode PBMT on pain perception by patient during maxillary incisors LA infiltration compared with sham laser. The second objective was to assess the effect of anxiety of previous dental injections on pain intensity perception during maxillary local infiltration anesthesia. We hypothesized that patients undergoing maxillary

*Corresponding authors emails: fariba.motevaselian@yahoo.com; f-motevaselian@sina.tums.ac.ir (Fariba Motevasselian) and n-chiniforush@sina.tums.ac.ir (Nasim Chiniforush)
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incisors LA would benefit from PBMT performed prior to injection, with regard to reduced pain. To test this hypothesis, we conducted a triple-blind randomized controlled trial (RCT) in healthy patients undergoing dental restorative treatment.

MATERIALS AND METHODS

Study population and selection of subjects. The study protocol was reviewed and approved by the research ethics committee of Tehran University of medical sciences (TUMS.DENTISTRY.REC.1399) and registered in the Iran Registry of Clinical Trial (IRCT20210618051613N1).

The minimum sample size was calculated to be 29, based on a previous study (5) considering $\alpha = 0.05$ and SD = 0.2 using paired means power analysis to detect significant pain scale difference for 2 units on a numerical pain intensity scale (0–10) (PASS11, Chicago, IL).

A total of 32 patients aged 20–50 years old were included in the current clinical trial who referred to the restorative dentistry department of Tehran University of medical Sciences, school of dentistry in 2021. The selected subjects were in complete physical and mental health without any confounding medical history determined using an interviewer-administered questionnaire (see Data S1). Sociodemographic status including gender, age and educational level was determined. The effect of anxiety level from previous dental injections was also assessed. A score of 0 was considered indicative of no anxiety, 1, 2 and 3 scores indicated mild, moderate and severe anxiety, respectively.

The patients were informed of the experimental details and enrolled in the trial after receipt of a signed consent form from the patients.

The following criteria were considered for the inclusion in the study:

- Existence of two contralateral carious maxillary incisors necessitating administration of an anesthetic agent
- Physical health condition
- Mental health condition free of disorders that affect mood, thinking and behavior for examples depression, anxiety disorders

The following criteria were considered for exclusion in the study

- Allergic reaction to lidocaine
- Contraindications to vasoconstrictor administration
- Patients who take analgesia or sedative
- Patients who smoke tobacco and patients who abused drugs or alcohol (18,19)
- Patients who have severely destroyed painful teeth
- Patients who have painful soft or hard tissue lesions
- Patients with denture stomatitis
- Patients with orofacial pain

PBMT and administration of the local anesthesia. A triple-blinded split-mouth experimental design was chosen to remove all issues related to the variances between subjects. To blind the volunteers and the operators, 32 empty envelops were given to the statistician and he randomly allocated them to A and B groups based on diode laser irradiation or sham laser. There were two operators. One operator applied the laser irradiation and received the envelops. The second operator carried out the local anesthetic infiltration. The clinician applying the local anesthesia was not informed of the laser treatment decision, active *vs*. sham laser.

A pilot study was performed on six patients, not included in the study group, to determine the AlGaAs diode laser (pocket laser, 88 dent, Italy) characteristics used in the final study and avoid any soft tissue irritation. Diode laser with 915 nm wavelength, power of 1.5 W, frequency of 15 KHz, duty cycle of 60% and 0.5 cm^2 beam area for 40 s was selected. The tip diameter was 8 mm, and energy density was 72 J cm^{-2}. The average power and power density were 0.9 W and 1.8 W cm^{-2}, respectively.

The intervention of two contralateral maxillary incisors was planned in two visits with a gap of seven-day washout period. At each visit, supraperiosteal (infiltration) injection for the maxillary incisors was applied based on the randomization of sham or active laser hand piece.

The calibration of the diode laser machine was checked at the beginning of the experiment by power meter (laser point, Italy).

Safety protective goggles wore by both the patient and the operator during the treatment sessions (Fig. 1). During exposure to both types of intervention, the laser device was still switched on to produce sound.

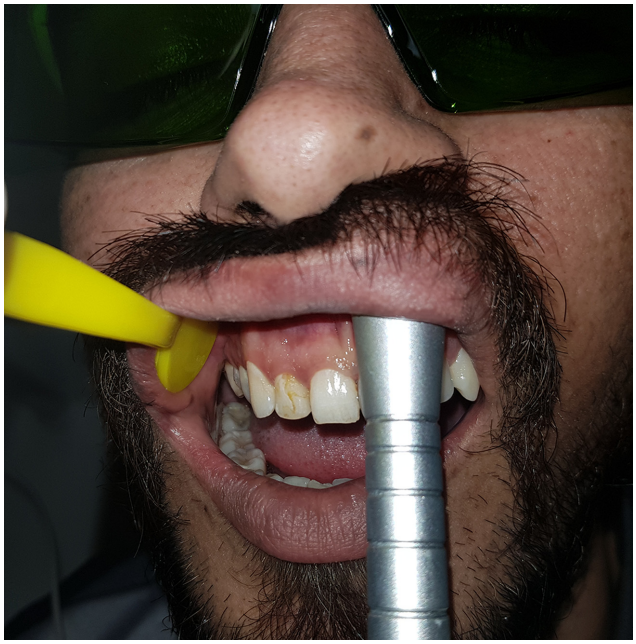

Figure 1. PBM therapy before local anesthesia.

Upper lip was lifted, and PBMT was directed to the mucosa at the site of injection (active or sham laser). Subsequently, local anesthesia was administered. Injection procedures followed the recommendations as described in The Handbook of Local Anesthesia (14). The upper lip was lifted and one-third of 1.8 mL cartridge containing 2% Lidocaine 2% plus 1:80 000 epinephrine (persocaine-E, Daru Pakhsh, Tehran, Iran) reached to room temperature was slowly injected over 20 s using a 27-gauge short needle if aspiration was negative at the approximate location of the apex of the tooth to be restored. The depth of needle penetration was only a few millimeters (14). The injections were performed in the height of mucobuccal fold above the apex of the tooth being anesthetized while the needle bevel faced the bone. Contralateral maxillary incisor was treated at the second visit using the same procedure explained above.

The patients were asked to record the intensity of pain they experienced upon insertion of the needle and local anesthetic agent injection-based numerical pain rating scale (NPRS) immediately after injection by marking a line, which 0 rating no pain and 10 being unbearable pain.

Statistical analysis. The results were averaged (mean ± standard deviation) for the outcome parameter. SPSS 25 (IBM Corp., Release 2017. IBM SPSS Statistics for Windows, Armonk, NY) was used. Wilcoxon signed rank was used for the comparison of NPRS between the intervention groups. Pearson correlation test was used to assess the effect of anxiety level from previous dental injections on NPRS.

RESULTS

Age, gender and educational levels of subjects are presented in Table 1. There were 23 (71.9%) female and 9 (28.1%) male participants, and the mean age was 36.4 ± 10.45 years. Considering the educational background, 4 (12.5%) had educational level below a high school diploma, 21 (65.6%) had a high school diploma, and 7 (21.9%) had collage/university education. Regarding anxiety level from previous dental injections, 14 (43.8%) of the participants did not have negative experience and 8 (25%) reported having felt severe pain. Anxiety from previous dental injections had no statistically significant effect on pain perception ($P > 0.05$).

The mean NPRS for the active laser (experimental) and sham laser (control) groups were 2.5 ± 2.19 and 4.34 ± 2.52,

Table 1. Demographic data and anxiety level of previous dental injection.

Variables	
Age (years)	
(Min-Max)	20–50
(Mean ± SD)	36.4 ± 10.45
Gender, *n* (%)	
Female	23 (71.9)
Male	9 (28.1)
Educational level, *n* (%)	
<Diploma	4 (12.5)
Diploma	21 (65.6)
>Diploma	7 (21.9)
Anxiety level from previous dental injections, *n* (%)	
None	14 (43.8)
Mild	3 (9.4)
Moderate	7 (21.9)
Severe	8 (25)

SD = standard deviation; *n* = number.

respectively, with a statistically significant higher NPRS score in the control group (P -value < 0.05) (Fig. 2).

DISCUSSION

The aim of this study was to compare the efficacy of PMBT with wavelength of 915 nm and power of 1.5 w in 40 s irradiation on perception on pain severity by adult patients with sham laser during local anesthesia for maxillary incisors. It was found that PBMT had a significant effect on pain reduction during either needle penetration or injection. Therefore, the null hypothesis was accepted. In addition, no correlation between anxiety level from previous dental injections and pain perception was found.

The study design can affect the result of clinical trial. In this prospective study, split-mouth design was conducted for its advantages. The split-mouth design eliminates inter-individual variability to assess the effectiveness of treatments.

There are several studies which assessed the effect of PBMT on pain on injection of local anesthetic agents. A prospective, split-mouth study was conducted on patients required bilateral extraction and alveolar nerve block injection. Diode laser by wavelength 660 nm and output power 60 mW was directed to the mucosa at the site of injection for 3 min. The result demonstrated that PBMT reduced pain perception during injection of local anesthesia (6). However, in a RCT study which used 980 nm wavelength of diode laser with output power of 300 mW, total energy of 6 J and energy density of 15.62 J cm^{-2} in the anterior maxillary region, pain perception was not reduced during injection compared with placebo group (16). This might be attributed to the study design which was not a split-mouth study and patients with different personal characteristics. A split-mouth study design also failed to show aluminum gallium arsenide (GaAlAs) PBMT for 1 min with wavelength 960 nm, energy density of 4 J cm^{-2} and power 100 mW reduced pain perception on the buccal mucosa of the maxillary canine during needle insertion (5). This difference could be due to variation in sample participants, differences in the self-reported pain assessment and laser characteristics such as type of laser, output power, energy, duration, pulse rate and wavelength of laser.

Diode laser has been the most popular PBMT technique in dentistry due to its good tissue penetration, lower financial costs, small size for portable application and convenience to use (20). It has been stated that infrared spectrum lasers ranging from 800 to 950 nm demonstrate greater diffusion than red spectral range and do not have any tissue damages (6,10,21). Furthermore, 915 nm diode laser is less absorbed by pigmented tissues, so the likelihood of heat production and thermal damage is reduced (20). Therefore, in the present study, we used low-level laser or diode photobiomodulation therapy with 915 nm wavelength.

There are several factors which contribute to pain during local anesthesia. They include technique of injection, sharpness of the needle, injection speed, temperature of the solution and level of anxiety of the patient (14). Pain is sensed through free nerve endings, nociceptors, which pick up painful stimuli and transmit them to the higher order (17). There are two sequential pain perception during application of local anesthetics. The first sensation is pricking or fast pain. It is followed few seconds later with additional pain sensation (22).

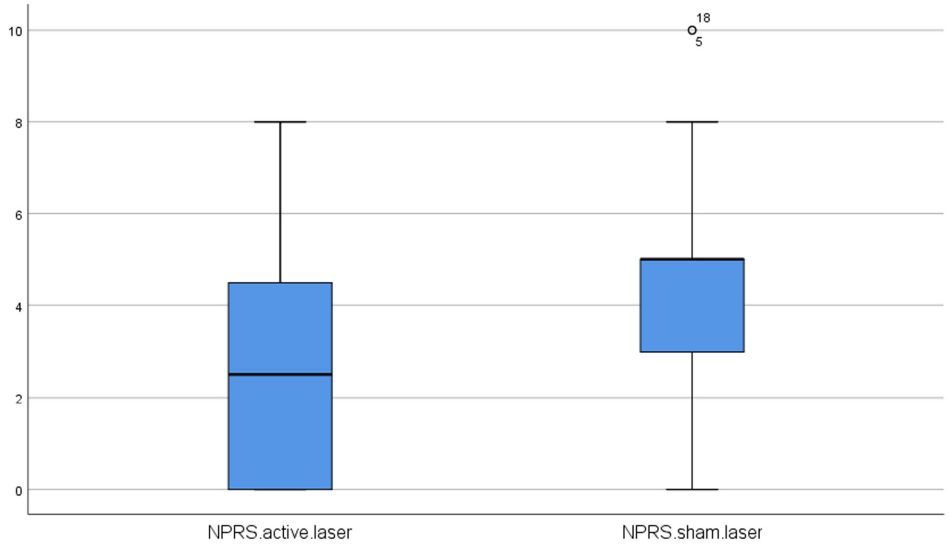

Figure 2. Numerical pain rating scale (NPRS) during needle insertion and injection during active and sham laser. [Color figure can be viewed at wileyonlinelibrary.com]

There is dense beds of C and A-delta nerve endings in gingiva (17). A-delta are thinly myelinated axons that convey sharp pain signals activated by any noxious mechanical stimulus such as that delivered by a sharp pointed instrument or needle. C fibers are slow conducting, unmyelinated axons and are characterized by dull and diffuse pain. They respond to thermal, chemical and mechanical stimulation (23). The pain felt while depositing the LA solution into the target site is caused by chemical irritation and distension of tissue space (24). A-delta and C fibers are very superficial and are within the penetration depths of the wavelengths used in PBMT. Laser diodes with infrared wavelengths spectrum can transmit light energy from 2 to 4 cm beyond the tissue surface (10).

The exact mechanism for pain relief during injection is unknown. However, the effect of PBMT is photochemical not thermal (17,25). A number of mechanisms may contribute to pain relief during needle insertion and local anesthesia following PBMT (17). It has been shown that that PBMT may provide an immediate pain relief effect and act by rapid modulation of neurophysiological processes in peripheral nerves (17,25).

PBMT can act by altering nerve excitation and directly affects nerve conduction in peripheral nerves. It has been shown that the generation of an action potential is inhibited. Nerve conduction velocity is reduced (17,25). PBMT modifies a neuronal cell membrane's behavior and cause a temporary disruption in the Na-K pump and depolarization and repolarization process. It results in loss of impulse transmission and in achieving pain relief (26). It has been shown that blockade is more selective for A delta fibers which evoke rapid sharp pain than slowly conducting C-fibers (27).

PBMT can also modulate inflammatory process which is associated with the blockade of late phase of neurogenic inflammation. PBMT decreases the release of substances that stimulate pain receptors such as histamine, acetyl choline and prostaglandin E2 and significantly increases the pain threshold by stimulating the synthesis of endorphins. Therefore, the modulation of neurotransmitters prevents synaptic transmission from the soft tissue to the brain (17). PBM changes and the conduction block are reversible with no side effects or nerve damage (17).

Pain is affected by physiological, psychological and emotional components and research has demonstrated that anxiety and previous experience can influence pain perception (28). In the current study, there was no significant positive association between severity of pain perception during administration of local anesthesia and previous experience of dental injection. In contrast, other studies found positive association between anxiety from previous experience with receiving injections and amount of pain felt during local anesthesia (29,30).

In the dental context, anxiety is classified to dental anxiety (DA) which predicts the patient's pain through the entire period (*i.e.* before, during and after) of treatment. State anxiety (SA) is a response to a specific stage of the dental treatment. Previous dental experiences are among the factors which affect DA and SA (31,32).

Some studies showed that SA shows a stronger association with pain perception. Considering that the association between SA and pain perception is stage sensitive, a patient may perceive a decrease in pain due to the therapeutic effect or local anesthesia (31,32).

These explanations may serve as a justification for rejection of a relationship between anxiety of previous dental injection and the perceived pain by the patient in the current study.

In this study, the efficacy of PBMT of diode laser with 915 nm wavelength was evaluated on the severity of pain perception marked by patient on a NPRS during injection of local anesthetic for maxillary incisors. The result was conclusive of PBMT being beneficial in reducing pain. Therefore, this study justifies that PBMT can be a helpful aid in reducing pain during local anesthesia. However, the literature often provides conflicting results and treatment protocols are not always comparable since there are a large number of parameters in the application of PBMT.

CONCLUSION

The current study showed that the diode PBMT with 915 nm wavelength and 1.5 W power and energy density of 72 J cm^{-2} applied for 40 s on mucobuccal fold before local infiltration anesthesia for maxillary incisors when compared to sham laser was effective in decreasing pain perception due to needle insertion and LA injection. There was no significant effect of the anxiety of previous experience regarding local anesthetic administration on pain perception during local anesthetic injection in the present study.

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CONFLICT OF INTEREST

The authors have no relevant financial or non-financial interests to disclose.

FUNDING

It is declared that it was a self-funded research study.

ETHICAL APPROVAL

The study protocol was reviewed and approved by the research ethics committee of Tehran University of medical sciences (TUMS.DENTISTRY.REC.1399), and it is certified that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. This research study was registered in the Iran Registry of Clinical Trial (IRCT20210618051613N1).

INFORMED CONSENT

Informed consent was obtained from all individual participants included in the study.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Data S1. Questionnaire.

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