Original Article

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Photobiomodulation by soft laser irradiation with and without ibuprofen improves success rate of inferior alveolar nerve block using 2% lignocaine with adrenaline in symptomatic irreversible pulpitis of mandibular molar teeth: a double-blind, randomized placebo-controlled trial

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Background: Achieving successful pain control and adequate anesthesia through an inferior alveolar nerve block for endodontic treatment in cases with symptomatic irreversible pulpitis (SIP) is difficult, especially in mandibular molars. This study was designed to compare the effect of oral medication with ibuprofen and soft laser therapy on inferior alveolar nerve block during endodontic treatment.

Methods: The trial comprised 180 patients (45 each group) with SIP. Four groups of patients were created: group 1 received 400 mg of ibuprofen; group 2 received soft laser irradiation; group 3 received a combination of soft laser and ibuprofen 400 mg; and group 4 received a placebo 1 h prior to local anesthesia. Patients recorded their pain scores on the Heft–Parker visual analog scale (VAS) before the start of intervention, 15 min after anesthesia, during access cavity preparation, and ultimately during root canal instrumentation. Each patient also rated their level of discomfort on a VAS. Every stage with no or minimal discomfort was deemed successful. The chi-square, Kruskal–Wallis, and one-way analysis of variance tests were used to evaluate the data.

Results: The best success rate was achieved for soft laser ibuprofen combination, ibuprofen and soft laser groups reported similar success results, and control group recorded the least pain scores. The mean pain scores were lowest for group 3 and highest for group 4 ($P < 0.001$). Ibuprofen and soft laser combination was significantly better than control group ($P < 0.001$). There was no significant difference between ibuprofen and laser groups ($P = 0.24$).

Conclusions: For teeth with irreversible pulpitis, preoperative ibuprofen treatment combined with soft laser irradiation greatly improved the success rates of inferior alveolar nerve block anesthesia.

Keywords: Inferior Alveolar Nerve; Low Level Light Therapy; Nerve Block; Symptomatic Irreversible Pulpitis.

INTRODUCTION

Dental pain is one of the common causes of pain in the orofacial region. A common reason for the occurrence of dental pain is irreversible pulpitis, for which root canal treatment is necessary. Complete pain relief is an important requirement for achieving successful endodontic

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treatment. However, achieving complete pain control is a challenge in cases of symptomatic irreversible pulpitis (SIP). One of the major techniques used to achieve pain control is local anesthesia. The standard technique to anesthetic mandibular molar teeth is the inferior alveolar nerve block (IANB) [1,2]. However, this approach has a significant failure rate. Research has indicated that it is far more difficult to provide adequate anesthesia in mandibular molars with SIP than in teeth with asymptomatic pulpitis. Numerous studies have documented a 75–90% success rate with IANB. Many factors, including the existence of supplementary innervations, anatomical variances (mandibular architecture, retro molar foramen, and skeletal placement of the jaw), operator technique, the presence of inflammation, and psychological factors, might be responsible for the failure of IANB [3-12].

When pulp becomes inflamed, the success rate drops even lower [13-18]. The tissue pH in the afflicted area may be decreased by pulpal and periapical inflammation and infection. This lessens the amount of anesthetic solution that penetrates the nerve membrane, delaying the onset of anesthesia [16-18]. Other factors that contribute to insufficient anesthesia in cases of irreversible pulpitis include tachyphylaxis of the anesthetic solution, the activation of nociceptors like capsaicin-sensitive transient receptor potential vanilloid type 1 and tetradoxin, higher amounts of substance P in pulpitis-affected teeth, and increased expression of sodium channels [19]. Several different procedures have been carried out in an attempt to increase the IANB success rate for mandibular molars. These treatments include the use of additional anesthetic methods and medications [16-18,20-22].

In this context, researchers have also sought to determine whether analgesics and non-steroidal anti-inflammatory medicines (NSAIDS) should be used prior to surgery. These drugs block the cyclo oxygenase enzyme pathway, thereby reducing prostaglandins, which in turn decrease inflammation and pain. Recently, another method for alleviating pain in endodontics has been the use of laser therapy. Modern dentistry has made great use of lasers in clinical settings, thanks to advancements in laser technology and a growing comprehension of the bio interactions between various laser systems. A low-level laser, also called a soft or a cold laser, has no thermal effect on tissues. These lasers have an average output power range between 5 and 100 mW. Soft lasers do not cause heat damage to tissues; instead, they use light to trigger a process in cells known as photobiositimulation or photochemical reaction. Photobiomodulation (PBM) is a technique by which light is used to stimulate living things into healing themselves. The American Society for Laser Medicine and Surgery uses the term PBM to describe the mechanistic/scientific basis for photonic specialty and photobiomodulation therapy (PBMT) as the term for its therapeutic application. PBMT was first developed in the 1960s. A number of terms were introduced during this time, such as biostimulation, cold/cool laser, low level laser therapy, soft laser, and low power laser therapy. Based on a recently achieved consensus in the field, PBM and PBMT are now considered the terms of choice [10-12]. Because cold laser treatment has anti-inflammatory, analgesic, and regenerative properties, it is well-established in clinical medicine and dentistry [21,22]. Cold laser therapy has been shown to have analgesic and anti-inflammatory properties in recent studies. PBM has many uses in dentistry, including: to minimize postoperative pain, edema, and inflammation in order to lessen the need for medication [23]; to decrease discomfort during dentin cutting or dental fillings by inhibiting the pulp nervous system [24]; therapeutic use in physiotherapy, thanks to its anti-inflammatory action [25]; to hasten the development of bones and lessen discomfort and edema following implantation [26]; to decrease discomfort during orthodontic therapy, hasten tooth movement, and hasten the concurrent production and destruction of bone [27]; and to minimize dentinal hypersensitivity discomfort by preventing the nerve flow that causes it [28].

To date, research on how laser PBM affects the effectiveness of IANB in generating anesthesia in patients

with symptomatic irreversible molar pulpitis is scarce. To address this, this study sought to evaluate the impact of soft laser treatment and ibuprofen premedication with a placebo on the success rates of IANB during endodontic therapy for mandibular molar teeth with SIP.

METHODS

The study was designed as a prospective, randomized double-blind clinical trial. Patients for the study were recruited from the routine patients reporting to the Department of Conservative Dentistry and Endodontics Faculty of Dentistry, Jamia Millia Islamia New Delhi. Ethical clearance was obtained from internal research review committee (approval no. FOD/IRRC/131/13122023C/F) and the trial was registered in the clinical trial registry of India (trial no. CTRI/2023/12/060840). The PICOT for the study were as follows: (i) population: patients with irreversible pulpitis in mandibular molars; (ii) intervention: soft laser therapy, ibuprofen; (iii) comparison: placebo; (iv) outcome: success of IANB; (v) time: during access cavity preparation and instrumentation of root canal. The inclusion and exclusion criteria used for patient selection in this study are detailed in the following sections.

1. Exclusion criteria

The presence of any systemic disorders, including cardiovascular disease, diabetes, or renal diseases, a sensitivity to lidocaine or to NSAIDs, a history of peptic ulcers, the presence of a periapical lesions, the use of antibiotics or analgesics in previous 24 h, and having a full crown.

2. Inclusion criteria

Patients with SIP in their first or second mandibular molar teeth who also have a history of spontaneous pain were identified using heat and electric pulp sensitivity tests. Only patients with moderate to severe pain, as determined by the VAS, were included prior to the patients being divided into the experimental groups. The Heft–Parker visual analog pain scale (VAS) was used by patients to report their level of pain. The cold test was performed using Green Endo-Ice (1, 1, 1, 2 tetrafluoroethane; Hygenic Corp.) and a digital electrical pulp tester (Parkell Inc.) was used to diagnose IP in the teeth of the study cohort. A favorable reaction to electric pulp testing and a prolonged response to cold testing verified pulp sensitivity. Radiographic assessment was performed and only those cases that showed no appearance lamina dura widening or periapical radiolucency were included.

The number of samples required per group was decided *a priori* by keeping the power of study at 80%, the α error at 0.05, and effect size at 0.780 by using G-power computer software (Germany). A total of 40 samples were taken from each group. A dropout rate of approximately 10% to 12% was assumed and an enrollment of 45 subjects in each group was conducted. One hundred eighty patients eligible to participate in the study were included. All patients were adults over 18 years of age. Before the start of treatment, the procedure was explained to the patients and a written informed consent was obtained. All patients were made aware of the possible discomfort and risks associated with participation. The concept of pain and the measurement by VAS was also explained. Randomization was achieved by using a computer software generated random sequence (Microsoft Excel), for which each patient was provided with a computer-generated code number for identification. One hundred eighty patients were randomly divided into four groups using a computer random table generator (www.random.org) with a 1:1:1:1 allocation ratio by one dental assistant. A flow chart describing the flow of patients through the trial is provided in Figure 1. All patients who consented to participate in the trial were randomly assigned to one of four groups consisting of 45 patients each. Patients recorded the preoperative pain score (denoted as VAS0) on the pain rating scale before the start of the procedure. In group 1 (n = 45), patients took 400 mg ibuprofen 1

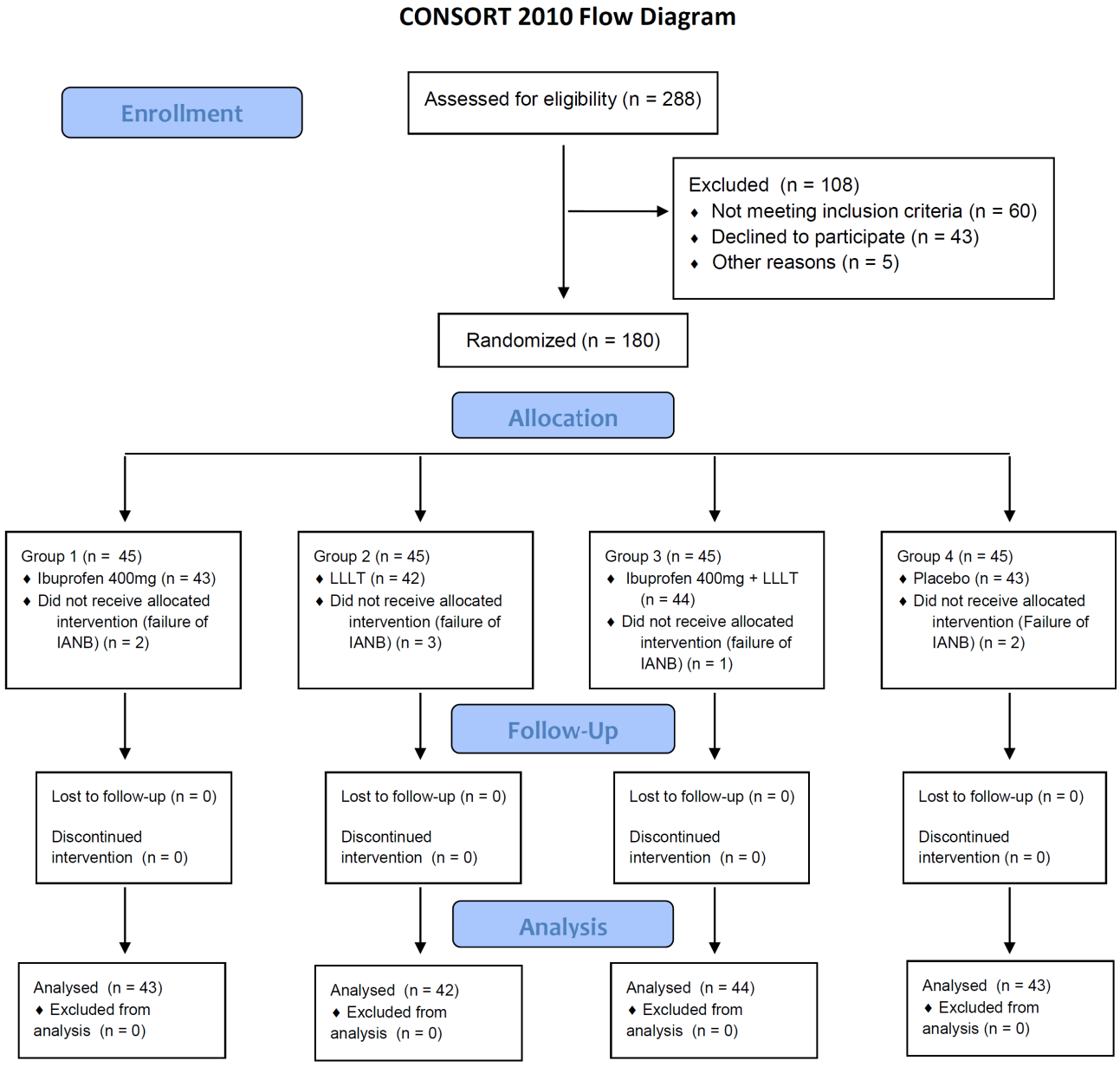

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) 2010 Flow diagram. IANB, inferior alveolar nerve block; LLLT, low level light therapy.

h before IANB; in group 2 (n = 45), patients received soft laser therapy at the periapical area of the involved tooth for 10 min and 1 h before IANB; in group 3 (n = 45), patients received ibuprofen 400 mg and 10 min laser therapy 1 h before IANB; and in group 4 (n = 45), no ibuprofen or soft laser was administered 1 h preoperatively, but rather a placebo laser irradiation was provided by applying the laser tip to the periapical area without activating the laser. Laser irradiation in groups 2 and 3 was conducted by applying the tip to the periapical area of the involved tooth for 5 min buccally and 5 min lingually for a total time of 10 min. The laser was used in contact continuous mode at 905 nm wavelength, with a total dose of 15 J/tooth (Quanta Pulse Pro Jsc, Milta, Moscow, Russia). A senior oral surgeon blinded to the treatment protocol administered the block. The injection was of comprised of 1.8 ml 2% lidocaine with 1/80000 epinephrine (Lignox Warren, India). Each

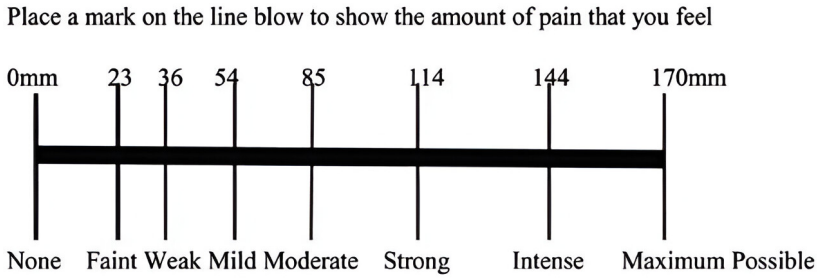

Fig. 2. Heft Parker Visual Analog Scale

Table 1. Demographics

Group	Number of patients	Gender distribution			Age distribution			
					Mean age	SD	Range	
Group 1	43	males	18	P-value = 0.856* non statistically significant difference)	32.3	11.5	18-60	P-value = 0.956* non statistically significant difference)
		females	25					
Group 2	42	males	21		34.2	13.4	21-59	
		females	21					
Group 3	44	males	19		36.3	9.8	22-60	
		females	25					
Group 4	43	males	20		35.5	12.5	19-59	
		females	23					

Group 1, ibuprofen 400 mg; Group 2, LLLT; Group 2, ibuprofen 400 mg + LLLT; Group 4, placebo; LLLT, low level light therapy; SD, standard deviation.

patient had their subjective and objective symptoms assessed 15 min after administering the anesthetic. The block was considered a success if the patient reported with lip numbness and two consecutive electric pulp tests failed to illicit any response from the patient. By contrast, IANB was deemed unsuccessful and the patient was removed from the research if they did not report significant lip numbness. After securing a rubber dam around the teeth, endodontic access cavity preparation was initiated. A skilled endodontist who was blinded to the treatment groups conducted the cold test to assess the patients for discomfort. A second endodontist, who was likewise blinded to the treatment group, prepared the access cavities. Patients that participated in the study marked the pain scores on the description lines according to their perceived intensity. The first pain score (denoted as VAS1) was recorded after 15 min of IANB following a cold test, the second pain score (denoted as VAS2) was recorded during access cavity preparation, and the third pain score (denoted as VAS3) was recorded during instrumentation. All patients were observed for 48 h for any adverse signs and symptoms.

3. Statistical analysis

A total of 180 patients were recruited: 172 received interventions and 8 were excluded. Since the data was parametric for outcomes, repeated measures ANOVA with Bonferroni multiple comparison was used to compare the outcomes amongst the four groups. Data at different stages of groups was non-parametric and compared using the Kruskal–Wallis test. To assess qualitative data, the chi-square test was employed (SPSS version 22.0). Comparisons between groups were considered significant at $P < 0.001$.

RESULTS

Each of the patients was monitored for 48 h. No serious side effects or problems were observed in any of the patients. Table 1 provides a summary of the distribution of the gender and age characteristics of the participants in the current study. The mean pain scores of the four groups 1 h after taking the medication did not differ

Table 2. Intergroup comparison of mean pain scores

Time	Group 1 (mean ± SD)	Group 2 (mean ± SD)	Group 3 (mean ± SD)	Group 4 (mean ± SD)	P-value
VAS0	107.3 ± 26.0	115.2 ± 33.5	109.3 ± 28.4	113.3 ± 29.7	0.591
VAS1	11.7 ± 16.3	11.4 ± 16.5	12.4 ± 20.1	12.3 ± 18.2	0.993
VAS2	17.8 ± 22.4	14.1 ± 19.1	7.1 ± 14.2*	22.7 ± 22.6	0.003
VAS3	8.0 ± 14.2**	9.5 ± 14.1**	3.5 ± 10.1**	23.9 ± 22.5	< 0.001

Statistically significant difference (*P = 0.002, **P < 0.001) compared to Group 4 using repeated measures ANOVA with Bonferroni adjustment. Group 1, ibuprofen 400 mg; Group 2, LLLT; Group 3, ibuprofen 400 mg + LLLT; Group 4, placebo; LLLT, low level light therapy; SD, standard deviation;VAS0, before the start of intervention; VAS1, 15 min after IANB;VAS2, during access cavity preparation; VAS3, during root canal instrumentation.

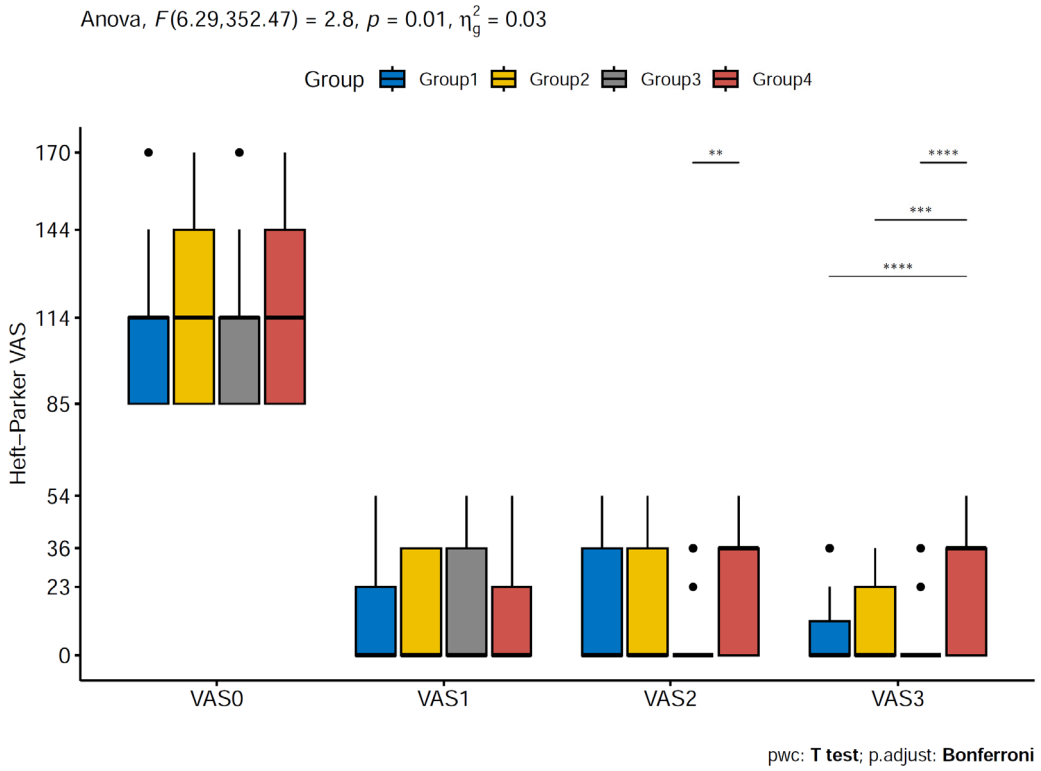

Fig. 3. Depicting boxblot at four different intervals in all groups. **(P = 0.002), ***(P < 0.001), ****(P < 0.0001). Group1, ibuprofen 400 mg; Group2, LLLT; Group3, ibuprofen 400 mg + LLLT; Group4, placebo; LLLT, low level light therapy; VAS0, before the start of intervention; VAS1, 15 min after IANB;VAS2, during access cavity preparation; VAS3, during root canal instrumentation.

significantly (P = 0.591) based on the Heft–Parker VAS. However, after adjusting for baseline VAS values, a statistically significant difference (P < 0.001) was observed in the level of pain relief between individuals who received a placebo and those who received either PBM or both soft laser and ibuprofen. The overall success rates (P ≤ 0.001) for the ibuprofen, soft laser group, soft laser ibuprofen group, and placebo group are shown in Table 2 and Figure 3. The ibuprofen and soft laser groups showed significantly better success rates in comparison to the placebo group. No statistically significant difference was observed between ibuprofen and soft laser treatment (P = 0.20). That being said, treatment with ibuprofen achieved a higher efficacy rate than the soft laser intervention.

DISCUSSION

Comparison to the placebo, premedication with ibuprofen or PBM was found to greatly improve the success rate of IANB anesthesia for mandibular molar

teeth with SIP. The patient demographics did not substantially differ across the three groups, which had no bearing on the study's findings. Since pain is a very personal experience, a wide range of variables, including behavioral, psychological, physiological, and cultural, can affect it. Anesthesia that works well is crucial for endodontic therapy. One of the most difficult parts of root canal therapy is providing anesthesia for mandibular molar teeth with irreversible pulpitis [29,30]. PBM treatment is one alternative technique available to address to the negative effects of intraosseous and intraligamentary injections [31]. It can also be used instead of traditional analgesics, which can themselves cause serious adverse effects. The objective of this research was to assess how soft laser affects the level of anesthesia.

Before the anesthetic was administered, there was no discernible difference in the pain scores of the four groups. Prior research evaluating the efficacy of anesthesia following premedication has employed a VAS or the electric pulp test to measure pain [32]. The Heft–Parker VAS was utilized in this study to determine patient pain both before and after the injection of a local anesthetic. In dental pain research, the Heft–Parker VAS is very helpful since it allows for an accurate assessment of pain intensity, which is essential for determining how well anesthetics and analgesics work. With its descriptive anchoring, it provides increased sensitivity and greater communication, making it an invaluable tool for determining the level of discomfort (Fig. 2). The majority of earlier studies on anesthetic methods and the effectiveness of solutions have employed the same assessment methodology. In the present study, 2% lidocaine combined with 1:80000 epinephrine was used [29-31], since the majority of previous studies employed this same anesthetic solution and it is a standard procedure in dentistry [18]. Semiconductor diode lasers are widely used in commercial PBM systems. Typically, they emit in the 700–940 nm near infrared range [25] for 20 s at a wavelength of 905 nm and 15 J/cm2. In this study, a diode laser was employed.

Additional factors that may contribute to insufficient anesthesia in cases of irreversible pulpitis include the anesthetic solution's tachyphylaxis, the production of more sodium channels, elevated quantities of substance P in teeth with irreversible pulpitis, and the activation of nociceptors, such as tetradotoxin and capsaicin-sensitive transient receptor potential vanilloid type 1 [19]. Research indicates that the difficulty in inducing total pulpal anesthesia can exacerbate anxiety and panic in patients, worsen underlying medical issues, prolong the duration of the session, and cast doubt on the dentist. Each of these results may potentially lead to the idea that receiving root canal treatment is an uncomfortable procedure [33]. Ibuprofen's anti-inflammatory properties have been documented in earlier studies. According to Gould et al.'s animal study prostaglandins are crucial for the augmentation of sodium channels when there is inflammation [31]. Furthermore, ibuprofen pretreatment prevented the upregulation of the sodium channels Nan 1.7 and Nan 1.8. Specifically, Nan 1.7 had more of an impact. When ibuprofen dosages of 200, 400, and 600 mg were assessed by Seymour and Ward for the treatment of post-surgery dental pain, they found a better degree of pain alleviation in individuals administered the 600 mg dose [19]. The preoperative administration of 400 mg of ibuprofen had comparable outcomes in the current investigation as well.

However, we still do not completely understand how soft laser reduces pain. Soft lasers have the ability to regulate inflammatory processes, according to Bjordal et al. [34]. Based on their findings, PGE2 can decrease inflammatory pain by lowering levels of edema, oxidative stress, interleukin 1 beta, and TNFa. Moreover, PBM can lessen nociceptors' frequency of release [35]. Furthermore, it has been shown that PBM can specifically block nociceptive impulses in peripheral nerves [36]. In previous study, Yang et al. [37] found that histamine release and the intracellular calcium levels rose after PBM. The impact of PBM on post-endodontic pain has only been examined in a small portion of the literature. After gentle laser pre- and post-implant procedures, Lizarelli saw a marked decrease in discomfort [38]. The

laser group showed greater pain relief in the first day following endodontic surgery than the placebo group, according to Kreisler et al. [39]. In addition, treatment with a soft laser was shown by Nabi et al. to significantly lessen post-endodontic discomfort for up to 48 h [40]. The success of IANB was also markedly enhanced in the current investigation by PBM. In the current study, the ibuprofen and PBM group achieved the highest pain reduction, while the placebo group achieved the lowest pain reduction. According to these results, the use of analgesics or PBM may significantly raise the success rate of IANB in comparison to the placebo. If NSAIDS are not appropriate for a patient, PBM is another noninvasive option to increase IANB success.

The quantity of radiation that actually reaches the target region is a significant drawback when using PBM, and could be a serious limitation of this study. In a previous study, a 100 mw 850 nm laser lost 66% of its power after penetrating 1 mm into human skin, according to research by Esnouf et al. [41]. While there is no single wavelength acceptable by everyone, PBM is primarily utilized in dentistry in the 600–1000 nm region [42]. Further studies are required to further evaluate the different wavelengths and energy outputs to enhance the PBM effect.

In conclusion, this study concluded that the combination of ibuprofen and laser PBM enhances the efficacy of local anesthetic in patients with irreversible pulpitis. PBM can act as a successful alternative to the use of adjunct techniques of intraligamentary and intraosseous anesthesia. Furthermore, this technique can also be used as an alternative to NSAIDS, thereby avoiding its adverse effects. However, further research on the use of PBM in this clinical context will be needed in the future.

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Sweta Rastogi: Conceptualization, Data curation, Methodology, Writing – original draft, Writing – review & editing
Vivek Aggarwal: Data curation, Methodology, Software, Validation
Sanjay Miglani: Conceptualization, Project administration, Supervision, Validation, Writing – review & editing

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