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Comparison of Diode Laser Photobiomodulation and Ibuprofen for Postoperative Pain after Endodontic Treatment: A Randomized Controlled Trial

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ABSTRACT

Background: Postoperative pain is a common complication following endodontic treatment, particularly in teeth diagnosed with symptomatic irreversible pulpitis. While ibuprofen is routinely prescribed for pain control, Photobiomodulation (PBM) therapy has emerged as a potential non-pharmacological alternative with analgesic and anti-inflammatory effects. **Methods:** This randomized controlled clinical trial was carried out at Fatima Jinnah Dental College and Hospital, from January 2024 till June 2024. Sixty patients aged 18–65 years diagnosed with symptomatic irreversible pulpitis in mandibular molars were randomly allocated into two groups (n=30 each). Group A received ibuprofen 600 mg postoperatively, while Group B received Photobiomodulation therapy using a 635-nm diode laser (LASOTRONIX). Postoperative pain was assessed at 24 and 72 hours using the Numerical Rating Scale (NRS) and Verbal Rating Scale (VRS). Rescue analgesic (paracetamol 500 mg) consumption was documented as a secondary outcome. Data were analyzed using non-parametric statistical tests, with significance set at $p < 0.05$. **Results:** Baseline demographic and Preoperative Pain characteristics were comparable between the groups (median baseline NRS: 6 [IQR 5–7]; $p > 0.05$). The PBM group reported significantly lower pain scores than the ibuprofen group at both 24 and 72 hours postoperatively on both NRS and VRS scales ($p < 0.001$). At 24 hours, the median NRS score was 1.0 in the PBM group compared to 2.0 in the ibuprofen group. At 72 hours, the median NRS score was 0.0 for the PBM group and 1.0 for the ibuprofen group. Similar trends were observed for VRS scores. **Conclusion:** Photobiomodulation therapy demonstrated significant reduction in postoperative pain as compared to ibuprofen, suggesting its potential as an effective non-pharmacological alternative.

INTRODUCTION

Pain following dental procedures is a common clinical concern that can significantly affect patient comfort and recovery. Similarly, individuals receiving endodontic treatment may encounter significant pain or flare-up during or after the procedure which can greatly affect their comfort [1]. Several factors that can increase the intensity of pain such as over instrumentation, inadequate obturation, extrusion of filling material, extrusion of irrigating solution into periapical tissue, inadequate coronal seal and missed canals [1-3].

The development of postoperative pain is largely driven by inflammatory responses, where mediators such as prostaglandins play a key role in sensitizing nociceptors and amplifying pain signals [1]. Hence eliciting sensitivity in certain pain receptors and promoting the manifestation of signs and symptoms associated with inflammation [4]. According to a few studies, degree and duration of pain after the procedure can be affected by various endodontic techniques for the preparation of root canal such as occlusion reduction, methods for determining working length, cold lateral compaction irrigation systems, and closing procedure [1, 5].

Non-steroidal anti-inflammatory analgesics are one approach of managing postoperative pain, although they come with their own drawbacks [6, 7]. Other studies indicate that ibuprofen used before procedure for its effectiveness in treating pain associated with symptomatic irreversible pulpitis [8, 9]. Although these pharmacological strategies provide advantages, oral health practitioners must carefully evaluate the most appropriate method for each patient while minimizing related medication risks [10]. As a result, the need for non-pharmacological adjunct treatments, including anxiety reduction procedures, cryotherapy, and intracanal laser therapy, has grown [2, 11].

Photobiomodulation (PBM) treatment has shown great promise in various therapeutic applications, including analgesia, wound healing, and nerve repair [12]. PBM was used in endodontic therapy because of its capacity to promote wound healing, aid in root canal cleaning, relieve pain, and have no negative side effects [3]. Theories propose that PBM might decrease oxidative stress and increase adenosine triphosphates (ATPs), two biological processes that lessen pain [13]. This process occurs within the mitochondria, where red light in the 630–660 nm range is absorbed and converted into biochemical energy that supports cellular activity. [14].

The objective of this study was to compare two approaches for managing post-operative pain in teeth that have undergone endodontic treatment in patients with Symptomatic Irreversible Pulpitis: one using PBM and the other using Ibuprofen.

This study's null hypothesis was that there wouldn't be any statistically significant difference in postoperative pain reduction between photobiomodulation therapy and ibuprofen.

MATERIAL AND METHODS

Trial Design

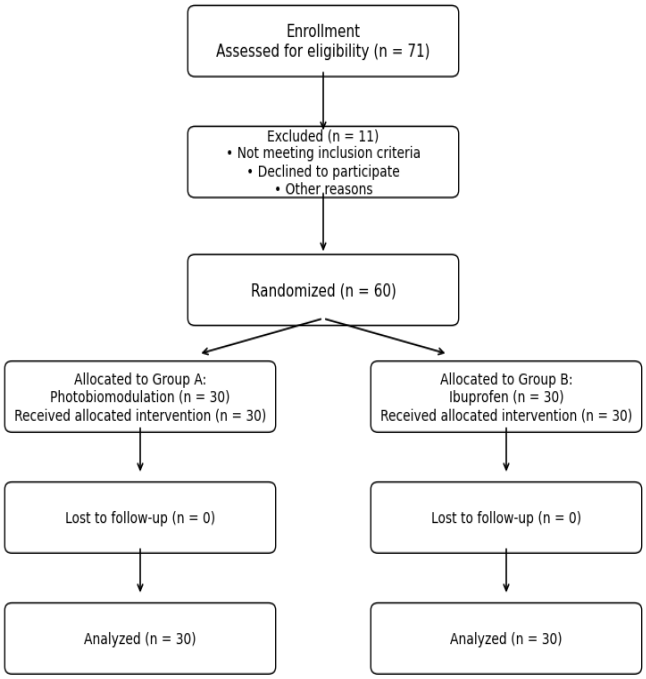
The research was carried out as a randomized controlled clinical trial following the 2010 Consolidated Standards of Reporting Trials (CONSORT) declaration [15]. Due to the nature of the interventions, participant and operator blinding was not feasible. The CONSORT flowchart (Fig 1.) shows the workflow of the study, which assessed the eligibility of 60 participants. A single operator administered PBM and Ibuprofen to separate group of patients after the surgery. This is a randomized clinical trial. No patients were lost to follow-up during the study period. The primary outcome was postoperative pain intensity measured using NRS and VRS at 24 hours with NRS serving as the principal quantitative measure. Secondary outcomes included pain intensity at 72 hours and rescue analgesic consumption within 72 hours.

Participants

This clinical study was carried out at the Fatima Jinnah Dental College and Hospital. Data was collected within a period of 6 months from 1st Jan 2024 till 30th June 2024. Ethical approval was obtained from FJDC Institutional Review Scientific Board and written informed consent was acquired from each individual. Participants were randomly allocated into two groups: Group A **(**Control group) received oral ibuprofen (600 mg) and Group B (Intervention group) received photobiomodulation therapy (PBM). Participants were divided into two parallel groups at random in a 1:1 ratio using a computer-generated random number table made with Microsoft Excel's RAND function. To ensure allocation concealment, a third-party, independent dental assistant who was not involved in clinical procedures or data processing conducted the randomization for Group A. After discussing all risks and benefits with each patient and explaining the study's objectives, each patient provided full written consent.

Figure 1

Consort Flow Chart



Inclusion criteria

1. Patient aged between 18-65 years.
2. Mandibular molars with symptomatic irreversible pulpitis
3. No systemic diseases affecting pain perception.
4. Healthy Volunteers.

Exclusion criteria

1. Pregnant women.
2. Patients under 18 years.
3. Immunocompromised patients.
4. Use of analgesics or anti-inflammatory drugs prior to treatment.
5. Periodontal or endodontic complication.

Endodontic Treatment

Following the initial clinical evaluation to confirm the diagnosis of Symptomatic Irreversible Pulpitis, patients were to voluntarily sign the Informed Consent Letter to participate in the study. Treatment was performed by a single operator. After a successful Inferior Alveolar Nerve Block (IANB) using 1.8ml cartridge of 2% lidocaine with 1:100,000 epinephrine (Medicaine), the tooth was isolated with a rubber dam to ensure an aseptic environment. Following the application of the rubber dam, the clinical procedure began with caries removal and straight line access opening using a sterile high-speed diamond bur under water cooling. After negotiating all canals, the working length (WL) was established using an electronic apex locator and confirmed radiographically, set at 0.5 mm to 1mm short of the radiographic apex to prevent periapical extrusion. Canals instrumentation was done using a standardized rotary file system (ProTaper Gold). Copious irrigation with 2.5% sodium hypochlorite was carried out throughout instrumentation using a side-vented 30-gauge needle to minimize the risk of apical extrusion, followed by a final rinse with 17% EDTA and sterile saline to eliminate the smear layer. Canals were

dried with sterile paper points and obturated during the same visit using gutta-percha and a resin-based sealer via the cold lateral compaction. The access cavity was temporarily restored using a resin-based restorative material. After treatment participants were allocated to their respective intervention groups (ibuprofen or photobiomodulation therapy) according to the randomization protocol. In the active control group, two Ibuprofen 600 mg tablets will be administered within a 12-h interval.

Intervention

In the PBM therapy group, the device that was used for the irradiation on the patients was DiodeLX diode Laser SMART™ PRO (LASOTRONIX, Zytnia 1 str., 05-500 Piaseczno, Poland) using 635nm wavelength. The irradiation was performed using 635nm wavelength, 400 mW power with an optical cylindrical fiber delivery system attached to a therapy handpiece providing a spot size of 0.52cm^2 immediately after the endodontic treatment, in contact with the mucosa at 4 points, buccal and lingual, respectively; two points on each side corresponded to the apex of each root of mandibular molar. Each mucosal site received 30 seconds of radiation exposure. All patients received information about the process to assess postoperative development following the treatment. The evaluation of postoperative pain was carried out by the same operator. Pain intensity was assessed using the Numerical Rating Scale (NRS) and Verbal Rating Scale (VRS), both of which are validated and widely used instruments for pain assessment in clinical research [16-17]. The researcher initially requested the patient to assess pain utilizing the VRS, followed by ranking the pain on the NRS ranging from 0 to 10 Patients were instructed to contact the researcher if they suffered from severe breakthrough pain.

A standardized rescue analgesic (Paracetamol 500mg) was permitted if necessary. The use of rescue analgesic was recorded as a secondary outcome variable and included in the statistical analysis.

VRS

After 24 hours

0	1	2	3
No pain	mild	moderate	Severe

After 72 hours

0	1	2	3
No pain	mild	moderate	Severe

NRS

After 24 Hours

0 ——————————— 10

After 72 hours

0 ——————————— 10

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY, USA). The sample size was calculated based on the primary outcome of postoperative pain intensity measured using the Numerical Rating Scale (NRS). The effect size (Cohen's d = 0.8) was derived from previously reported differences in postoperative pain scores between PBM and NSAID groups in a comparable RCT [1]. With a significance level (α) of 0.05 and a power of 80%, a minimum of 27 participants per group was required. To account for potential dropouts, 30 participants were recruited in each group, resulting in a total sample size of 60 participants. Data were analyzed using non-parametric statistical tests. Between-group comparisons were performed using Mann–Whitney U test for continuous variables and Chi-square test for categorical variables.

RESULTS

A total of 71 patients were assessed for eligibility, of whom 11 were excluded due to not meeting inclusion criteria or declining participation. Sixty patients were randomized equally into two groups (n = 30 each), and all participants completed the study with no loss to follow-up.

Baseline Characteristics

The two groups were comparable at baseline with no statistically significant differences in demographic or preoperative pain characteristics. The median age was 29.5 years (IQR: 26.0–33.0) in the ibuprofen group and 29.0 years (IQR: 25.25–34.0) in the PBM group (p = 0.899). Gender distribution was also similar between the groups (p = 0.439).

Baseline pain intensity, measured using the Numerical Rating Scale (NRS), showed a median score of 6 (IQR: 5–7) in both groups (p = 0.84). On the Verbal Rating Scale (VRS), moderate pain was reported by 18 patients (60%) in the ibuprofen group and 17 patients (56.7%) in the PBM group, while severe pain was reported by 12 patients (40%) and 13 patients (43.3%), respectively, with no statistically significant difference (p = 0.79) (Table 1).

Table 1

Baseline Demographic and Preoperative Pain Characteristics (Between Group Comparison)

Characteristic	Group A (Ibuprofen) (n=30)	Group B (PBM) (n=30)	p-value
Age (years), Median [IQR]	29.5 [26.0–33.0]	29.0 [25.25–34.0]	0.899
Gender, n (%)			
Female	16 (53.3%)	13 (43.3%)	0.439
Male	14 (46.7%)	17 (56.7%)	
Baseline NRS, median (IQR)	6 (5-7)	6(5-7)	0.84
Moderate Pain n (%)	18 (60%)	17 (56.7%)	0.79
Severe Pain n (%)	12 (40%)	13 (43.3%)	

Postoperative Pain Assessment (Primary Outcome)

Postoperative pain was evaluated at 24 hours and 72 hours using the Numerical Rating Scale (NRS) and the Verbal Rating Scale (VRS). The analysis revealed that the Photobiomodulation group (Group B) experienced statistically significant lower pain scores than the Ibuprofen group (Group A) at both time points. A graphical comparison of these outcomes is presented in Figure 2 (NRS) and Figure 3 (VRS).

Figure 2 further demonstrates that at both 24 hours (Figure 2a) and 72 hours (Figure 2b), the PBM group showed lower median NRS scores with a narrower distribution compared to the ibuprofen group, which exhibited greater variability and higher residual pain. Outliers (o) represent individual variations in pain scores.

Similarly, Figure 3 shows that on the VRS scale, the PBM group had a greater proportion of patients reporting mild or no pain at both 24 hours (Figure 3a) and 72 hours (Figure 3b), whereas the ibuprofen group continued to show moderate pain in some patients. Outliers (o) indicate deviations from the overall trend.

At 24 hours, the median NRS score in the ibuprofen group was 2.0 (IQR: 2.0–3.0), whereas the PBM group reported a significantly lower median score of 1.0 (IQR: 1.0–1.75) ($p < 0.001$). Similar findings were observed with VRS scores, where the median score was 2.0 (IQR: 2.0–3.0) in the ibuprofen group and 1.0 (IQR: 1.0–1.75) in the PBM group ($p < 0.001$).

At 72 hours, pain levels decreased in both groups; however, the PBM group continued to demonstrate significantly lower pain scores. The median NRS score was 1.0 (IQR: 1.0–2.0) in the ibuprofen group and 0.0 (IQR: 0.0–1.0) in the PBM group ($p < 0.001$). Corresponding VRS scores were also significantly lower in the PBM group ($p<0.001$) (Table 2).

Figure 2

Comparison of Postoperative Pain Scores between Groups Using NRS at 24 and 72 Hours.

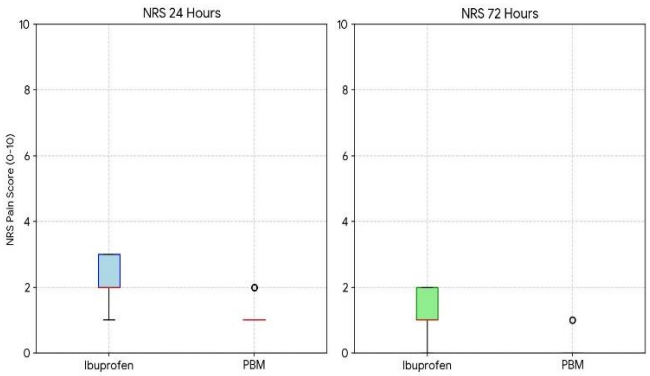
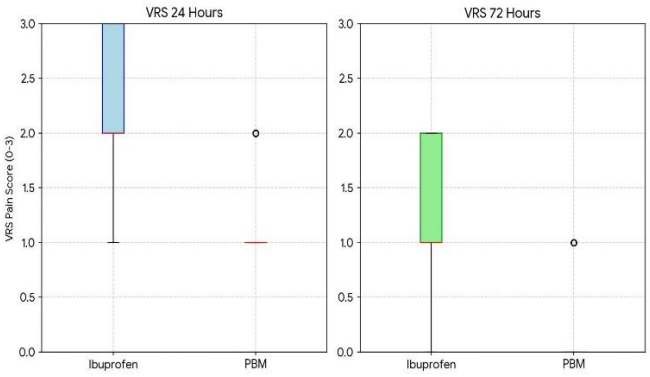


Figure 3

Comparison of Postoperative Pain Scores between Groups Using VRS at 24 and 72 Hours.



Rescue Analgesic Consumption (Secondary Outcome): Within the 72-hour postoperative period, 5 participants (16.7%) in the Photobiomodulation (PBM) group and 8 participants (26.7%) in the Ibuprofen group needed a rescue analgesic. The difference between the groups was not statistically significant (Chi-square test, $p = 0.34$), despite the fact that fewer patients in the PBM group needed supplemental analgesic medicine.

The median number of rescue tablets consumed was 1.0 (IQR: 1–2) in the PBM group and 2.0 (IQR: 1–3) in the Ibuprofen group, with no statistically significant difference observed (Mann–Whitney U test, $p = 0.28$) (Table 3).

Table 2

Comparison of Rescue Analgesic Consumption

Variable	Ibuprofen (n=30)	PBM (n=30)	p-value
Patients requiring rescue n (%)	8 (26.7%)	5 (16.7%)	0.34
Median tablets consumed [IQR]	2.0 [1–3]	1.0 [1–2]	0.28

Table 3

Comparison of Postoperative Pain Scores

Outcome Measure	Group A (Ibuprofen) (n=30) Median [IQR]	Group B (PBM) (n=30) Median [IQR]	Mann-Whitney U	p-value
VRS - 24 Hours	2.0 [2.0–3.0]	1.0 [1.0–1.75]	127.5	< 0.001
NRS - 24 Hours	2.0 [2.0–3.0]	1.0 [1.0–1.75]	127.5	< 0.001
VRS - 72 Hours	1.0 [1.0–2.0]	0.0 [0.0–1.0]	184.5	< 0.001
NRS - 72 Hours	1.0 [1.0–2.0]	0.0 [0.0–1.0]	184.5	< 0.001

DISCUSSION

This study at Fatima Jinnah Dental College & Hospital compared postoperative pain in patients receiving diode-laser Photobiomodulation therapy versus standard systemic analgesia with 600 mg ibuprofen, after single-visit endodontic treatment for symptomatic irreversible pulpitis in mandibular molars. The findings of this study led to the rejection of the null hypothesis, as Photobiomodulation therapy demonstrated significantly greater reduction in postoperative pain compared to ibuprofen. Photobiomodulation therapy (PBM) is receiving significant interest as a non-pharmacological approach for the early management of postoperative pain following endodontic treatments.

The findings of the present study are consistent with several randomized clinical trials that have demonstrated early analgesic advantages of PBM after root canal procedures or surgery. A randomized pediatric RCT indicated reduced pain scores in children undergoing PBM following single-visit endodontic treatment compared to placebo for up to 48 hours, indicating the impact extends beyond adults [18]. A systematic review and meta-analysis indicated a general advantage of laser modalities in alleviating postoperative pain after primary and secondary root canal treatments, while highlighting considerable variability among studies and varying evidence quality [2]. Comprehensive data analyses validate a moderate analgesic advantage of laser-based adjuncts; for example, a 2024 meta-analysis reported a standardized mean difference (SMD) of −0.86 in pain scores at 24 hours favoring laser adjuvant therapy [19]. This is in agreement with the present study, where significantly lower pain scores were observed in the PBM group at both 24 and 72 hours. A recently published review of evidence verified these findings, revealing beneficial effects of PBM on acute pain while emphasizing that variability in parameters (wavelength, power, energy density, number/position of application points) and inconsistent reporting of blinding/randomization hinder

validity [20] . These findings further support the results of the present study, which demonstrated significantly lower postoperative pain scores in the PBM group. These consistent findings across multiple studies reinforce the reliability of PBM as an effective modality for postoperative pain control in endodontic treatment.

While previous studies have established the general utility of PBM in endodontics, significant heterogeneity exists regarding optimal wavelengths, with most trials utilizing the 600–810 nm spectrum Unlike near-infrared wavelengths, which are typically associated with deeper tissue penetration, this study utilized a 635 nm red-light wavelength. This wavelength is known to interact effectively with cellular chromophores, particularly cytochrome c oxidase within mitochondria [12, 14]. This interaction enhances mitochondrial activity, resulting in increased adenosine triphosphate (ATP) production and modulation of inflammatory mediators, which collectively contribute to pain reduction [12–14].

Previous studies have demonstrated that wavelengths within the 630–660 nm range can effectively reduce postoperative pain by promoting tissue repair and limiting inflammation [2,17,19].. The results of our study align well with these reports, given that the PBM group experienced notably lower pain levels at 24 and 72 hours. This suggests that, despite having lower tissue penetration than near-infrared light, the strong photochemical effects of red light are more than enough to achieve clinically relevant analgesia in endodontics.

Compared to the Ibuprofen group, fewer patients in the PBM group needed rescue analgesia although this difference was not statistically significant. A therapeutically beneficial effect of PBM is shown by the trend toward decreased extra analgesic usage, even if this difference did not achieve statistical significance. The lack of statistical significance for this secondary outcome may be explained by the fact that the study was powered to identify variations in pain intensity rather than the use of rescue medications.

The analgesic and anti-inflammatory properties of PBM are confirmed by extensive oral surgical literature: systematic evaluation of PBM in gingival wound healing revealed improved tissue regeneration and less postoperative pain, hence supporting physiological feasibility in endodontic contexts [21].

Limitations:

Several limitations should be considered when interpreting the findings of this trial. First, because of the nature of the interventions (oral medication versus laser application), which may induce performance bias, it was not possible to completely blind the operator and participants, even though randomization has been carried out. Second, the study was powered mainly to identify variations in pain intensity rather than in rescue analgesic consumption, and it was carried out at a single facility with a somewhat small sample size. Consequently, the study may have been underpowered to detect statistically significant differences in secondary outcomes.

Third, postoperative pain was assessed at 24 and 72 hours only; earlier time points (e.g., 6–12 hours) were not evaluated, which may have limited the assessment of immediate analgesic effects.

CONCLUSION

This randomized controlled trial demonstrates that Photobiomodulation (PBM) therapy provides significantly greater reduction in postoperative pain compared to ibuprofen following endodontic treatment of mandibular molars with symptomatic irreversible pulpitis. Although rescue analgesic consumption did not differ significantly between groups, fewer patients in the PBM group required additional medication, suggesting a potential NSAID-sparing effect. Further adequately powered studies are required to confirm this finding.

Human Ethics

Ethical approval was obtained from the FJDC Institutional and Scientific Review Board (Ref: AUG-2023-OPR-01).

Consent

Written informed consent was obtained from all participants.

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