ORIGINAL RESEARCH

Low-level Laser Therapy to Alleviate Pain of Local Anesthesia Injection in Children: A Randomized Control Trial

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Abstract

Aim: The aim of our study was to evaluate and compare pain perception following photobiomodulation (PBM), topical anesthesia, precooling of the injection site, and vibration during administration of local anesthesia injection in pediatric patients aged 6–13 years.

Materials and methods: In this split-mouth study, a total of 120 patients between the age group of 6 and 13 years were selected and randomly divided into three equal groups with 40 subjects in each. Pain was assessed using visual analog scale (VAS) and the Wong–Baker Faces Pain Rating Scale after the administration of local anesthesia. Behavior during the procedure was assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) scale filled by the operator. Pulse rate was recorded before and during the administration of local anesthesia using pulse oximeter. After the procedure, patient compliance was also recorded using validated questionnaire. The level of significance was set at $p < 0.05$.

Results: The study showed PBM exhibited the lowest mean scores of anxiety/pain using VAS, Wong–Baker Faces Pain Rating Scale, FLACC scale and pulse rate as compared to precooling, vibration, and topical anesthesia. The differences in pain scores recorded were found to be statistically significant. Children were not anxious about the PBM method and exhibited good compliance ($p < 0.001$).

Conclusion: Photobiomodulation (PBM) was found to be effective means of reducing injection pain, demonstrating much better efficacy than other tested methods.

Clinical significance: Photobiomodulation (PBM) can be used effectively to better manage procedures that patients frequently find painful without the need for prescription drugs, which frequently have several side effects.

Keywords: Injection, Local anesthesia, Low-level laser therapy, Pain, Photobiomodulation.

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Introduction

Pain control is a challenging task in pediatric dentistry. Effective local anesthesia is the single most significant pillar on which modern dentistry stands.[1,2] Researchers have revealed that the main reasons why pediatric patients put off their dental appointments are needle anxiety, discomfort, and injection-related biting injuries. Pedodontists who do not hurt and painless injections were identified by parents as important factors to consider when selecting an exodontist.[3,4] Every year, new ways to improve anesthetic agents, delivery systems, and techniques are sought and developed in order to provide patients with better pain control and relief while also ensuring their comfort.[5] One such technique that makes analgesic claims is photobiomodulation (PBM). Due to its analgesic, regenerative, and anti-inflammatory qualities, it has been employed in dentistry. The effectiveness of using low-level laser therapy (LLLT) to reduce injection pain in oral cavity is still being studied. Thus, the purpose of this study was to assess and compare the effectiveness of LLLT with alternative techniques prior to needle insertion in pediatric patients.

Materials and Methods

The study was done over the course of 18 months. Based on inclusion and exclusion criteria, samples were drawn from outpatients visiting the Pediatric Dentistry department. In this split-mouth and parallel design study, G*Power software version 3.1.9.2 was used to estimate the sample size. Considering the margin of error at 5%, the study's power at 80%, and the effect size to be measured (f) at 29%, sample of 120 was randomly allocated by a computerized allocation system into three groups of 40 each, which were—group I: PBM and topical anesthesia; group II: PBM and precooling of injection site; and group III: PBM and vibration. Institutional Ethics Committee and Review Board approval was secured for the study (EC No: EC650).

Patients indicated for bilateral extraction and requiring inferior alveolar nerve block (IANB), aged 6–13 years, classified as positive on Frankl's behavior rating scale, and parents and patients who willingly gave informed consent and assent, respectively, were included in the study. The study excluded individuals with specific needs, those allergic to local anesthetic, those experiencing local inflammation or tenderness at the injection site, those exhibiting acute symptoms necessitating immediate medical attention, and those who had previously experienced painful dental procedures.

A diode laser of 980 nm with a single dosage wavelength of 15 J/cm^2 was used to irradiate with a low-level laser tip for 20 seconds before anesthesia was administered to accomplish PBM. Lidocaine

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hydrochloride gel 2% was applied to the dry mucosa for 1 minute before administering local anesthetic injection. For precooling of the injection site, an ice tube was applied for 60 seconds before local anesthesia administration. The vibration method entailed positioning the device about 2 cm away from the injection site (near the angle of the mandible) during local anesthesia administration.

Pain was assessed using visual analog scale (VAS) and the Wong–Baker Faces Pain Rating Scale after the administration of local anesthesia. Behavior during the procedure was assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) scale filled by the operator. Prior to and throughout the administration of local anesthetic, the pulse rate was monitored. After the procedure, patient compliance was also evaluated using validated questionnaire. The CONSORT flowchart has been depicted in Figure 1.

The primary outcome of our study was to find the most effective method of minimizing discomfort during local anesthesia administration, and the secondary outcome was to find the preferred technique by children which can be used in day-to-day clinical practice.

The data for all variables obtained in the study was tabulated and statistically analyzed using descriptive analysis. Frequency and proportions for categorical variables and mean and standard deviation (SD) for continuous variables were used to compute all the explanatory and outcome parameters. To perform statistical analysis, Windows Version 22.0 with Statistical Package for the Social Sciences (SPSS) software was utilized, and a value of $p < 0.05$ was regarded statistically significant.

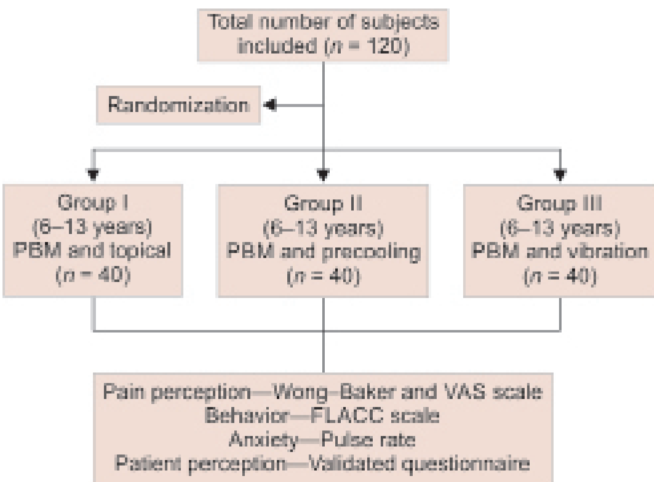

Fig. 1: The CONSORT flowchart

Results

Age of the study participants varied between 6 and 13 years. The total sample was divided into three groups.

Intragroup comparisons of FLACC scores in split-mouth design, as shown in Table 1, revealed that in group I, 12.5% of the study participants were relaxed during PBM method and 72.5% had mild discomfort, whereas 27.5% had mild discomfort and 57.5% had moderate discomfort in topical anesthesia method. Severe pain was experienced by 15% of the participants in topical anesthesia method ($p < 0.01$). In group II, 30% of the participants were relaxed in PBM method, whereas only 10% were relaxed in precooling method ($p < 0.006$). In group III, 17.5% of the participants were relaxed in PBM method, whereas only 5% were relaxed in vibration method. Severe pain was experienced by 2.5% of the participants in vibration method. The differences were statistically significant at $p < 0.001$.

Intragroup comparisons of Wong–Baker Faces Pain Rating Scale scores in split-mouth design, as shown in Table 2, revealed that in group I, PBM had the least mean score in comparison to topical anesthesia, indicating children were more anxious while topical anesthesia method ($p < 0.001$). In comparison to the precooling procedure, PBM had the lowest mean score in group II ($p < 0.005$). In comparison to the vibration method, PBM had the lowest mean score in group III ($p < 0.001$).

Intragroup comparisons of VAS scores in split-mouth design, as shown in Table 3, revealed that PBM showed significantly lower mean score values in all the groups in comparison to other tested methods. Comparison of mean pulse rate between groups with PBM before and during procedure time using Kruskal–Wallis test was not statistically significant. Comparison of mean pulse rate between groups with different interventions during procedure time using Kruskal–Wallis test followed by Mann–Whitney's *post hoc* test showed statistically significant results between the groups as shown in Table 4.

Table 1: Comparison of FLACC scores between PBM and different interventions using Chi-squared test

		PBM		*Different interventions*		
Groups	*FLACC*	*n*	*%*	*n*	*%*	*p-value*
Group I (PBM and topical)	Relaxed	5	12.5%	0	0.0%	<0.001*
	Mild discomfort	29	72.5%	11	27.5%	
	Moderate pain	6	15.0%	23	57.5%	
	Severe pain	0	0.0%	6	15.0%	
Group II (PBM and precooling)	Relaxed	12	30.0%	4	10.0%	0.006*
	Mild discomfort	25	62.5%	27	67.5%	
	Moderate pain	2	5.0%	8	20.0%	
	Severe pain	1	2.5%	1	2.5%	
Group III (PBM and vibration)	Relaxed	7	17.5%	2	5.0%	<0.001*
	Mild discomfort	32	80.0%	20	50.0%	
	Moderate pain	1	2.5%	17	42.5%	
	Severe pain	0	0.0%	1	2.5%	

*statistically significant; FLACC, Face, Legs, Activity, Cry, Consolability scale; *n*, total number of participants in each group; PBM, photobiomodulation

Comparison of patient compliance questionnaire between three study groups for question 1—"Did you experience pain/discomfort during administration of local anesthesia (for PBM)?"—showed that 72.5% of the study subjects answered they did not have pain/discomfort during treatment. In group I, 92.5% of the study subjects preferred PBM method; only 7.5% of them preferred topical anesthesia. In group II, 92.1% of the study subjects preferred PBM method, whereas 7.9% preferred precooling of injection site. In group III, 89.2% of the study subjects preferred PBM method, whereas 10.8% preferred vibration method. Almost 75% of the participants preferred to have future treatments, if any have to be done with PBM method. Overall, it can be seen that not many children were anxious to PBM method. The findings were found to be statistically significant at $p < 0.001$ as shown in Table 5.

Table 2: Comparison of mean Wong–Baker Faces Pain Rating Scale scores between PBM and different interventions using Mann–Whitney *U* test

Groups	*Category*	*n*	*Mean*	*SD*	*Mean difference*	*p-value*
Group I	PBM	40	3.50	1.41	–3.25	<0.001*
	Topical	40	6.75	1.96		
Group II	PBM	40	2.70	2.42	–0.90	0.005*
	Precooling	40	3.60	2.13		
Group III	PBM	40	2.85	1.49	–2.20	<0.001*
	Vibration	40	5.05	2.08		

*statistically significant; *n*, total number of participants in each group; PBM, photobiomodulation; SD, standard deviation

Table 3: Comparison of mean VAS scores for pain between PBM and different interventions using Mann–Whitney *U* test

Groups	*Category*	*n*	*Mean*	*SD*	*Mean difference*	*p-value*
Group I	PBM	40	2.85	1.90	–3.43	<0.001*
	Topical	40	6.28	1.94		
Group II	PBM	40	2.63	2.70	–1.57	<0.001*
	Precooling	40	4.20	2.52		
Group III	PBM	40	2.40	1.41	–2.80	<0.001*
	Vibration	40	5.20	1.74		

*statistically significant; *n*, total number of participants in each group; PBM, photobiomodulation; SD, standard deviation; VAS, visual analog scale

Table 4: Comparison of mean pulse rate between groups with different interventions before and during procedure time using Kruskal–Wallis test followed by Mann–Whitney's *post hoc* test

Intervention	*Groups*	*n*	*Mean*	*SD*	*p-value[a]*	*Significant difference*	*p-value[b]*
Pre-procedure	Group I	40	94.43	7.18	0.34	1 vs 2	0.08
	Group II	40	91.88	6.53		1 vs 3	0.46
	Group III	40	92.60	9.77		2 vs 3	0.51
During procedure	Group I	40	107.35	5.62	<0.001*	1 vs 2	<0.001*
	Group II	40	95.75	5.27		1 vs 3	0.001*
	Group III	40	101.98	8.21		2 vs 3	<0.001*

*statistically significant; *n*, total number of participants in each group; PBM, photobiomodulation; *p*-value[a], derived by Kruskal–Wallis test; *p*-value[b], derived by Mann–Whitney *post hoc* test; SD, standard deviation

Table 5: Comparison of distribution of responses for patient feedback questions using Chi-square goodness of fit test

Questions	*Responses*	*n*	*%*	*χ^2 value*	*p-value*
Did you experience pain/discomfort during administration of local anesthesia? (Light method)	Yes	33	27.5%	24.300	<0.001*
	No	87	72.5%		
Which method did you like?	PBM	89	73.8%	155.067	<0.001*
	Topical	9	7.5%		
	Precooling	9	7.9%		
	Vibration	13	10.8%		
Would you prefer the same light method in future prior to administration of local anesthesia?	Yes	90	75.0%	30.000	<0.001*
	No	30	25.0%		

*statistically significant; light method signifies PBM; *n*: total number of participants in each group; PBM: photobiomodulation

Discussion

The foundation of pain management strategies is local anesthetic, which is necessary for a painless dental procedure. However, one of the most frightening procedures for children is the administration of local anesthetic injections. The basis of successful behavior guidance is effective pain management during dental treatment of pediatric patients, and one of the elements influencing the amount of dental anxiety in them is age. As children in this age range have good cognitive abilities, patients aged between 6 and 13 years were considered for the study. Gender distribution among each group was almost the same. However, studies done by Aminabadi and Farahani,[6] Wright,[7] and Versloot et al.[8] proved that there was no significant difference in the perception of pain in children between boys and girls. We selected a VAS and the Wong–Baker Faces Pain Rating Scale for subjective evaluation since these tools are simple to use, reliable, and applicable across all age groups. Subjective measurement is typically regarded the gold standard for measuring pain. The FLACC scale was used for objective measurement of pain as it considers facial features, legs, activity, crying, consolability, and movements of the body. The FLACC scores recorded gave a clear idea of the degree of discomfort in children while administering local anesthesia injection. The values show that the majority of the participants in the PBM method had mild discomfort, whereas the topical anesthesia method showed the most discomfort, with 57.5% of children responding towards moderate discomfort (group I). Precooling (group II) and vibration method (group III) showed higher discomfort in comparison to the PBM but not more than the topical method.

The Wong–Baker Faces Pain Rating Scale, and VAS scores showed that patients had less pain with PBM method. This was in accordance with the study done by Sattayut.[9] The results were also in agreement with the studies of Jagtap et al.[10] and Ezzat et al.[11]

The results of our study were consistent with the studies done by Aras and Gungormus,[12] Gray et al.,[13] Bertolucci and Grey,[14] Fikácková et al.,[15] Mazzetto et al.,[16] Lassemi et al.,[17] Çetiner et al.,[18] Venezian et al.,[19] Pawar et al.,[20] and Arslan et al.[21] where pain reduction was associated with LLLT application. Research has demonstrated the effectiveness of LLLT in reducing pain during surgical endodontic therapy as well as in individuals with temporomandibular joint pain, hypersensitivity, myalgia, aphthae, and trigeminal neuralgia.[22,23]

There are a limited number of studies comparing PBM and other techniques. In our study, we found that PBM was better than topical anesthesia, precooling, and vibration method. In a similar study done by Sattayut,[9] no discernible variations in pain ratings were seen across the various strategies employed while evaluating the efficacy of low-intensity laser therapy (LILT), topical anesthetic, pressure, and gentle touch for pain reduction during palatal injection. Our study was not consistent with the study done by AmruthaVarshini et al.[24] and Ghaderi et al.[25] These discrepancies are most likely due to variances in the selection of laser parameters, including wavelength, power supplied, application method (contact or noncontact), period of exposure, type and physiological state of the exposed tissue, all of which might influence the result.

There was a decrease in mean pulse rate during the administration of local anesthetic using the PBM approach in the current study, showing that the degree of anxiety in children is lowered when this method is used for a dental injection. However, in the other tested techniques, pulse rate was variable, and the difference was not statistically significant.

Patient compliance was evaluated through a questionnaire given to the child in the present study. The results showed that PBM did not provoke much anxiety in children and that they were compliant with the procedure. The majority of the participants preferred to have future treatments done with the PBM method.

In our study, the pain experience of the children during the administration of local anesthesia for different interventions other than PBM showed that precooling of the injection site was better than vibration, and vibration was better than topical anesthesia. Similar results were seen in study done by Aminah et al.[26] where precooling group showed the most reduction in pain, with a Wong–Baker Faces mean pain score of 2.4. This was followed by the vibration group, which had a mean pain score of 2.6; buffered local anesthesia had a mean score of 5.6; and topical anesthesia had a mean score of 6.2. Precooling the injection site is a useful approach for reducing pain and facilitating clinical treatment. This was supported by Harbert,[27] Mohiuddin et al.,[28] Aminabadi and Farahani,[6] and Kosaraju and Vandewalle,[29] who also found similar results from their studies. The results were also in agreement with the studies done by Bilsin et al.,[30] who found that the mean pain score was lower in the ice group in comparison to vibration group ($p < 0.05$) and Kosaraju and Vandewalle,[29] found that the group applying cold had lower pain levels than the gel group and that applying refrigerant greatly decreased the agony of receiving anesthetic injections.

The findings of our study align with the studies done by Joshi et al.[31] where DentalVibe site had a lower pain score than the topical anesthetic gel. The results were also in agreement with studies done by Dak-Albab et al.,[32] where a significant difference was noted ($p = 0.002$) in the pain score, supporting the use of DentalVibe. Research, however, indicates that DentalVibe did not decrease pain. In well-behaved children, Brignardello-Petersen[33] found that the use of a vibrating device did not lower pain levels and that the device was not well accepted in comparison to conventional local anesthetic injections.

Conclusion

Based on the findings of our study, we can infer that among the methods tested, PBM was more effective in reducing injection pain than topical anesthesia, precooling, and the vibration method. Further research with a larger sample size and a comparison of different methodologies is possible.

Clinical Significance

Low-level laser therapy (LLLT) is a rapidly developing technology. More information about laser therapy mechanisms, dosages, treatment sites, and diseases that can benefit from laser therapy is being found on a daily basis. We have a tool at our disposal that can control the inflammatory response, promote wound healing, and lessen pain. In dental specialties, LLLT can be used effectively to better manage procedures that patients frequently find painful without the need for prescription drugs, which frequently have several side effects.

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