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COMPARATIVE EVALUATION OF SOFT TISSUE LASER THERAPY AT 660NM AND 810NM FOR REDUCING LOCAL ANAESTHESIA REVERSAL TIME IN CHILDREN AGED 6-10 YEARS: A RANDOMIZED CONTROLLED TRIAL

Dentistry

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ABSTRACT

Introduction: Local anaesthesia (LA) plays a crucial role in pain management during dental procedures, especially in children. However, its prolonged effects can lead to complications such as speech impairment, cheek biting, and difficulty in eating, causing discomfort. To address this, researchers have explored photobiomodulation therapy to expedite anaesthesia reversal. **Aim:** To compare and evaluate the reduction in local anaesthesia reversal time using soft tissue LASER at 660nm and 810nm respectively. Material & Method: This randomised controlled trial allocated children into two groups: Group A1 received LASER (Light Amplification by Stimulated Emission of Radiation) irradiation at 810nm, and Group B1 at 660nm. Both groups were further divided into subgroups—A2 and B2, which received sham LASER as controls. Reversal of the soft tissue anaesthetic effect was assessed using palpation and pinprick tests every 15 minutes. The LASER irradiation cycle continued until complete anaesthesia reversal. The outcome was measured by the time anaesthesia took to wear off. **Result:** The reduction in soft tissue anaesthesia reversal time was 157 minutes for 810nm LASER and 156 minutes for 660nm LASER, compared to 195 minutes in the sham LASER groups. **Conclusion:** Photobiomodulation therapy at 660nm and 810nm diode LASER has been proven to significantly reduce the duration of anaesthesia in children, aged 6 to 10 years. However, there is no significant difference between reversal time required by photobiomodulation at 660nm & 810nm.

KEYWORDS

pain modulation, local anaesthesia reversal, photobiomodulation, lip and cheek biting, phentolamine mesylate

INTRODUCTION

Local anaesthetics (LA) are frequently used in dentistry before starting many dental procedures. However, the prolonged effects of LA, post-treatment may lead to additional problems such as speech impairment, cheek biting, problems with swallowing, eating and drinking.[1] The prolonged effect of local anaesthesia on soft tissues, even after completion of the dental treatment, has been observed as an issue in 15% of children. [2] The numbness in the soft tissue has been observed to last for approximately 3 to 5 hours, which is much more than required. [3] To overcome this, researchers have proposed a soft tissue LASER therapy, using the property of photobiomodulation to reduce the time for reversal of the anaesthesia. This treatment modality is a safe, non-invasive and painless technique, especially in children and omits the second step of injection compared with Phentolamine mesylate, a known local anaesthetic reversal agent. [4]

Photobiomodulation therapy uses visible and near-infrared light sources using LASER, which increases the microcirculation and promotes vasodilation, encouraging the reversal of local anaesthesia from the injection site. [5,6] This study aims to compare and evaluate the reduction in the reversal of local anaesthesia time using soft tissue LASER at 660nm and 810nm respectively.

SUBJECTS AND METHODS

The present randomized controlled double-blinded clinical study was conducted in the Department of Paediatric & Preventive Dentistry, Government Dental College & Hospital, Mumbai. The study was conducted abiding by all human ethical principles as per the Declaration of Helsinki and guidelines of the Occupational Safety and Health Administration [OSHA].

A sample size of 50 was established by G*Power version 3.0.1(Franz Faul universitat, Kiel, Germany) using t test where the effect size was 0.7, power 0.80 and significance level was 0.05.

Sample Allocation & Randomisation

In this split-mouth study, a total of 50 children meeting the inclusion criteria were divided into 2 groups at random using the lottery method. Written informed consent in a language best understood by the parent was obtained before starting the procedure

Blinding

The current research was double blinded using the blinding of co-investigators who performed test for evaluating the reversal time and statisticians.

The Selection Criteria are as follows:

Inclusion Criteria

a) Children in the age group of 6-10 years.
b) Children undergoing treatment which requires local anaesthesia using maxillary buccal infiltration for extraction of primary molars, bilaterally.
c) Children in category 3 or 4 according to Frankl's behaviour rating scale.
d) Children aged 6 to 10 years old with the ability to understand and respond to the sensation of soft tissue.

Exclusion Criteria

a) Children with any underlying systemic disease.
b) Lack of proper understanding of the patient during the training to evaluate the response to soft tissue anaesthesia.
c) History of allergy to materials used for anaesthesia.
d) Children who had received analgesic drugs within 24 hours before treatment.
e) Children whose parents are not willing to give consent.

The study population was divided into two main groups, Group A and Group B, based on the wavelength of LASER therapy applied. Each group was further subdivided as follows:

- Group A1: LASER irradiation at 810nm wavelength- 25 children
- Group A2: Sham LASER therapy, where the LASER module was placed intraorally without actual irradiation- 25 children
- Group B1: LASER irradiation at 660nm wavelength- 25 children
- Group B2: Sham LASER therapy, similar to Group A2- 25 children

This subdivision allowed for both active and placebo-controlled comparisons in the same patient in this split-mouth design at the same time.

Method of Application: After the administration of LA, the timer was started. Extraction was done and hemostasis was achieved. Photobiomodulation therapy was then performed mesial & distal to the site of injection, at the commissure of the lip & on the skin overlying the site of injection. The reversal of the soft tissue local anaesthetic effect was evaluated using palpation and pinprick tests every 15 minutes and the LASER irradiation cycle was continued until reversal of the soft tissue local anaesthesia was achieved. The outcome was assessed based on the time taken for the anaesthesia to wear off completely.

Figure 1: Indilase Unit For Photobiomodulation Using Soft Tissue Diode LASER

Figure 2: LASER therapy Directed On The Commissure Of The Lip

Figure 3: LASER Therapy Directed On The Skin Over Site Of LA Administration

Figure 4: LASER Therapy Directed Mesial And Distal To The Site Of LA Administration

Statistical Analysis

Statistical analysis was performed using Statistical Package for Social science (SPSS) version 21 for Windows (SPSSInc Chicago, IL). Data normality was checked by using Shapiro – Wilk test. Confidence interval was set at 95% and probability of alpha error (level of significance) set at 5%. Power of the study was set at 80%.

Intergroup comparison between both groups in respect to qualitative study parameters was done using Chi square test. Intergroup comparison between both groups in respect to quantitative study parameters was done using unpaired t test.

RESULTS

There was highly significant statistical difference between the results obtained through the photobiomodulation vs the SHAM LASER (p<0.001). However, there is no significant difference between the two groups when comparing the results of the 810 and 660nm wavelengths (p>0.05). [Table1- 2]

Table 1: Comparison Of Duration Of Anaesthesia Between LASER Irradiation & Sham Groups Expressed In Minutes

	Mean	SD	Mean Difference (SE)	Unpaired t-test	P value, Significance
Group A (810 nm)	157.8	16.83	36.0 (4.86)	t = -7.518	P< 0.001**
SHAM	194.4	17.57			
Group A (660 nm)	156.6	17.89	38.4 (5.05)	t = -7.595	P<0.001**
SHAM	195.0	17.85			

**p<0.001 – highly statistically significant difference

Table 2: Comparison Of Duration Of Anaesthesia Between Both Types Of Diode LASER Expressed In Minutes

	Mean (min)	SD (min)	Mean Difference (SE)	Unpaired t-test	P value, Significance
Group A (810 nm)	157.8	16.83	1.2 (4.91)	t = 0.244	P=0.808
Group B (660nm)	156.6	17.89			

p>0.05 – no statistically significant difference

DISCUSSION

Most of the patients report fear of pain and unpleasant experiences as the main reason for not following and receiving care and dental treatments. [7,8]. To minimize this discomfort, local anaesthetic solutions have been routinely used in dental practice to relieve pain lined with various dental procedures since the 19th century[9]. Patients often feel unwell during long periods of anaesthesia and mention it as an experience associated with functional impairments such as problems with ingestion, drinking, talking and smiling [5,10]. In addition, longer periods of anaesthesia usually involve a greater risk of accidental lip and cheek biting, especially in children. The administration of LA could result in self inflicted injuries to surrounding tissues in 13% of subjects according to studies[11].

To overcome these problems and reverse soft tissue anaesthesia, some medications such as Phentolamine mesylate have been introduced in past. It acts as a competitive inhibitor against epinephrine owing to its similar chemical structure [12]. Injection of this substance with the same volume and at the same area targeted for anaesthetic injection can help to return the normal sense to the soft tissue quickly. But it also leads to more trauma to the child due to repeated injections. This led to a search for new modalities which were less invasive. Photobiomodulation also known as Low Level LASER therapy is a recent development which has come into light for the reversal of anaesthesia.[13]

In the last decade, several studies have been done focusing on the application of LASER in dental practice[14]. In summary, the results of these investigations claimed that LASER can facilitate innovative and minimally invasive therapies in different treatment modalities including preventive and restorative dentistry and surgical procedures in high-power mode as well as biostimulative, anti-inflammatory and analgesic effects in low-power mode named as photobiomodulation. In Pediatric dentistry, LASER also offers more acceptance and tolerance of treatment for children due to its non-invasive form[15].

LASER therapy has shown encouraging results in previous studies like enhancement of microcirculation, stimulation of release of an endothelium-dependent vasodilator and rescuing vascular dysfunction, and acceleration of collateral circulation in the vascular bed of deprived tissue after an injury. [16,17] So, we decided to utilize this benefit of LASER in pediatric dentistry to accelerate the elimination of soft tissue anaesthesia.

Photobiomodulation targets the Cytochrome C complex. It is found in the inner membrane of the mitochondria and is a vital component of the electron transport chain that regulates cellular metabolism including elimination of drugs & their metabolites.[18]

Photobiomodulation also enhances the production of nitrous oxide in the vasculature which is responsible for vasodilation and thus, the elimination of local anaesthetic from the target site. [19]

Additionally, LASER irradiation can induce cellular alkalinisation, induce TRPV (Transient Receptor Potential Vanilloid) gate opening and a consequent Ca^{2+} influx. This Ca^{2+} influx can mediate histamine release in mast cells, which ultimately results in vasodilatation and contributes to elimination of LA.[20]

Podogrodzki et al. concluded the positive effect of low-power 680-nm

LASER irradiation on the amount of blood flow in the skin of children between the ages of 3 and 15 years and stated that LASER application significantly increased the blood flow in the skin and none of the patients reported the warming sign of the irradiated area [21]. Also, Seraj et al. (2020) conducted a study including 34 children aged 4–8 years to reverse soft-tissue local anaesthesia using 810nm LASER and found a reduction of 43 min in the reversal duration of soft-tissue local anaesthesia in comparison to those without photobiomodulation. [5]

According to the results of the present study, photobiomodulation therapy by 810-nm and 660nm diode LASER with an energy density of 6.3 J/cm2, reduced the time of soft tissue anaesthesia significantly by about 40 min in comparison with the Sham LASER group. The reduction in the reversal time of soft tissue local anaesthesia at 810 nm was 36.6 minutes and for 660nm was 38.4 minutes respectively.

This clinical trial is a preliminary one that evaluated the effect of photobiomodulation therapy as a non-invasive treatment modality for the reversal of soft tissue local anaesthesia instead of the invasive method of Phentolamine Mesylate injection which makes it novel and different in comparison with previous studies. Further research, encompassing a broader array of analytical methods and more sample size is warranted to reveal more in-depth evidence of the effect of photobiomodulation on the reversal of local anaesthesia.

CONCLUSION

According to the encouraging results of this study, photobiomodulation therapy both at 660 nm and 810 nm diode LASER has been proven to significantly reduce the duration of anaesthesia in children aged 6 to 10 years with negligible difference using either wavelength .

This treatment modality is a safe, non-invasive and painless technique beneficial especially in children and omits the second injection step compared with Phentolamine mesylate.

Further studies with different wavelengths, a combination of two wavelengths, and different energy densities in different age groups with larger populations under study are necessary to substantiate the results and probably find exact parameters for more reduction in anaesthetic reversal time.

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