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Low-level Laser Therapy in the Management of Diabetic Sensorimotor Polyneuropathy

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Abstract

Background & Objective:Diabetes Mellitus is one of the most common progressive and disabling diseases. Population affected with Diabetes may experience numbness or insensitivity to pain and temperature, a tingling, burning or prickling sensation, sharp pains or cramps, extreme sensitivity to even a light touch, loss of balance and coordination. Low-Level laser therapy (LLLT) has been advocated for the treatment of chronic pain disorders. This therapy has been suggested for relief of symptoms of pain, inflammation and utilized in wound healing & nerve regeneration. With this evidence Laser has been advocated in this study. The aim of this study is to evaluate the effectiveness of Low-Level Laser Therapy for relieving the symptoms of Diabetic Sensorimotor Polyneuropathy. Methodology: This randomized controlled trial was conducted in a private Medical College Hospital, Chennai. The materials required for conducting the study includes Tuning Fork, Reflex Hammer, 10gm Semmes Weinstein monofilaments, Goggles and a Ga As LASER unit. The study was conducted among 40 subjects satisfying selection criteria in the age group of 40-60 years and was randomly assigned in to control(Group-A) or experimental group(Group-B) and was assessed for degree of neuropathy and pain using Toronto clinical neuropathy score and Numerical Pain Rating Scale (NPRS) respectively. Participants in the respective groups are treated for five weeks with 4 joules for 4 days in a week. Results: Within-group analyses showed a significant difference in both outcome measures with $p < 0.05$. The pre-test mean in Group-A was 9.80 and post-test mean value of Toronto Clinical Neuropathy Score is 8.25 and in the Group-B the pretest mean was 10.10 and post-test mean was 6.30 this shows that Toronto Clinical Neuropathy Score in group B were comparatively significantly less than group A, $P<0.05$. The Post Test mean value of Numerical Pain Rating Scale in group A is 5.15 and in the group, B is 3.90 compared to their pre-test values of 6.25(Group-A) and 6.30(Group-B) respectively. The Numerical Pain Rating Scale analysis in Group B were comparatively significant than Group A, which indicates a significant difference between groups with $p < 0.05$. Conclusion: This study concludes that Low-Level Laser Therapy is more effective in patients with Diabetic sensorimotor Polyneuropathy in reducing Pain and relieving symptoms.

Keywords: *Diabetic Sensorimotor Polyneuropathy, Low-Level Laser Therapy*

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INTRODUCTION

Diabetes is one among the most progressive and disabling disease. Recently 150 million people were with diabetes all over the world and in the year 2025, their number is expected to increase to 300 million (WHO)

[1]. Diabetic sensorimotor polyneuropathy is 27.6% prevalent among those with diabetes [2]. It was also noted that 13% of persons with glucose tolerance impairment had polyneuropathy, which suggests that neuropathy can also be developed due to the pre-diabetic state caused by impaired glucose tolerance [3]. In another population-based study conducted among diabetic cohorts, it was recorded that 25-30% had peripheral neuropathy graded to be either moderate or severe. [4]

Distal symmetrical neuropathy is also termed as sensorimotor neuropathy and is one of the most common types of diabetic neuropathy. The affected individual develops pain which may be worst at night, impaired or loss of sensation, disturbance in balance and coordination. The symptoms may be predominant in the distal part of the leg and hands which may progress later proximally. The Lower limb is likely to be affected first than the upper limb. Diabetic Peripheral neuropathy can also produce hyperalgesia. Chronic painful neuropathy symptoms may affect the individual's quality of life and can be a factor to induce stress, anxiety, depression and reduced mobility. [5] Sensorimotor neuropathy or distal symmetrical neuropathy is often termed based on their clinical appearance as a stocking-glove neuropathy and in this case, distal long nerves are affected first and later progress proximally [6].

Painful symptoms of Diabetic neuropathy is often resilient to medications. Analgesics and various other drugs are recommended to manage symptoms of pain, such as phenothiazine's, anticonvulsants, and tricyclic antidepressants, which might induce numerous adverse effects. Low-level laser therapy (LLLT), is a form of physiotherapy practice which is widely used for tissue healing, pain, and inflammation, and this therapy is classified in the group of "Other physical therapies in the management of diabetic peripheral neuropathy" [7].

Symptoms associated with early pathophysiological stages of Diabetic Sensorimotor Polyneuropathy can be measured using the Toronto Clinical Neuropathy Score because of its content validity and of construct validity towards nerve conduction velocity measures [8, 9]. The Toronto Clinical Neuropathy Score has been used widely in clinical trials because of its reliability, user-friendliness, and acceptability by patients and also essential for its ability to identify the intensity of clinical stages associated with Diabetic Sensorimotor Polyneuropathy and its progression [10].

The objective of the study is to find out the effectiveness of low-level laser therapy in the management of distal symmetrical diabetic neuropathy.

METHOD

The study was conducted in the Physiotherapy Out Patient Department of a private medical college teaching Hospital at Chennai. The study was approved by the Institutional Human Ethical Committee of the University. The participants were selected randomly and assigned to the groups based on a block randomization procedure. The materials required for conducting the study includes Tuning Fork, Reflex Hammer, 10gm Semmes Weinstein monofilaments, Goggles, and a LASER therapy unit. The Population who satisfy the selection criteria attending the outpatient department of the study centre were included in the study. They were grouped into two, one as control N=20 (Group-A) and the other as intervention group N=20 (Group-B). The selection criteria include Participants with known type2 diabetes mellitus with more than 10 years duration aged between 40-60 years, presenting with diabetic neuropathy symptoms based on the Toronto Clinical Neuropathy Score [11]. Population presenting with gangrene, unstable medical conditions (e.g., malignancy, active/untreated thyroid disease), and other neurologic problems that might interfere with the assessment of neuropathy, Metallic implants, Chronic Alcohol or illicit drug abuse were excluded from the study [12].

All participants were explained about the procedure and informed consent was obtained. The outcome measures used were Toronto clinical neuropathy score to measure the degree of neuropathy [6, 7] and Numerical Pain Rating Scale (NPRS) to measure pain [13]. Both outcome measures were tested by a clinical physiotherapist blinded to group allotment before and after an intervention.

Intervention:

The control group-A did not receive any Physiotherapy intervention, they received only standard drug routine as prescribed by the physician to alleviate the symptoms associated with Diabetic neuropathy. The interventional group-B received LLLT along with the standardized medications to alleviate the symptoms associated with Diabetic neuropathy. All the participants of the group-B were explained about the nature of the

treatment and need to wear goggles throughout the treatment to obviate any risk of accidental application of laser beam into the eye was informed. Laser apparatus is positioned and goggles were given to the patient. The patient is made to lie down in a comfortable position. Treatment area was cleaned with alcohol to remove any material that might absorb or reflect the radiation. The following parameters were used with laser source by a Gallium Arsenide: wavelength of 904 nm, the maximum power of 25 W, a pulse duration of 100 ns and frequency of 1,000 Hz. The treatment was for 4days/week for 5 weeks with an energy dose of 4 joules [14] for 60 sec. at each point. The therapy was applied by positioning the diode applicator with 1 cm^2 diameter and at four located points along the sciatic nerve in each lower extremity. The Laser was kept in contact with the tissues and the beam was applied at right angles on treatment areas. Single point or spotting method of application was applied. Laser was spotted around the neck of the fibula just below the head of the fibula for common peroneal nerve, for deep peroneal nerve Laser was spotted between extensor hallucis longus and extensor digitorum longus, for posterior tibial nerve Laser was spotted just behind and distal to the medial malleolus, for superficial peroneal and Laser was spotted over lateral aspect of the Achilles tendon across the lateral malleolus and medial malleolus to the medial aspect of the Achilles tendon. The device is switched off before removing the applicator from the skin [12], [15].

Clinical findings and Results:

Table -1:Pre-test & Post-test values comparison between Groups –A (Control group)

Group A		Mean	Standard deviation	t value	Significance
Toronto Clinical Neuropathy Scores	Pre-test	9.80	1.54	7.33	<0.05
	Post-test	8.25	1.21		
Numerical Pain Rating Scale	Pre-test	6.25	1.01	5.39	<0.05
	Post-test	5.15	0.81		

Table- 2: Pre-test & Post-test values comparison between Groups –B (Interventional group)

Group B		Mean	Standard deviation	t value	Significance
Toronto Clinical Neuropathy Scores	Pre test	10.10	1.51	15.67	<0.05
	Post test	6.30	1.59		
Numerical Pain Rating Scale	Pre test	6.30	0.86	7.05	<0.05
	Post test	3.90	1.25		

The student t-test is used for statistical analysis. From statistical analysis, the quantitative data revealed a statistically significant difference between the Group A & Group B, and also within the group. The post-test mean value of Toronto Clinical Neuropathy Score in Group A is 8.25 and in the Group, B is 6.30 this shows that Toronto Clinical Neuropathy Score in Group B was comparatively significant than group A, $P<0.05$. The Post Test mean value of Numerical Pain Rating Scale in Group, A is 5.15 and in the Group, B is 3.90. This pain outcome results also proves that the mean score of Numerical Pain Rating Scale in Group B was comparatively significant than Group A, $P<0.05$.

Table- 3: Post-test values comparison between Groups A & B

The post-test measure of mean and standard deviation for Toronto Clinical Neuropathy Score, Numerical Pain Rating Scale in Group A and Group B in respect with 't' value (student 't' test)

Parameter	Post Test Values				't' test	Significance
	Group A		Group B			
	Mean	Standard deviation	Mean	Standard deviation		
Toronto Clinical Neuropathy Score	8.25	1.21	6.30	1.59	5.86	<0.05
Numerical Pain Rating Scale	5.15	0.81	3.90	1.25	3.74	<0.05

Statistical Analysis of Toronto Clinical Neuropathy Score and Numerical Pain Rating Scale post-test scores analyzed with unpaired t-test showed significant difference between Group A and Group B. The analyzed data reveals that the interventional group(A) had better recovery in pain and symptoms compared to control group(B).

DISCUSSION

The study results showed significant improvement with LLLT with 4 joules of irradiation, no significant adverse effects were reported in any of the groups. Therefore, LLLT could be offered safely to patients with diabetic neuropathy.

The Toronto clinical neuropathy scale and numerical rating scale was followed as outcome measures to analyze the alleviation of symptoms associated with distal symmetrical sensorimotor neuropathy. The outcome of the study proved a significant decline in symptoms and pain associated with diabetic neuropathy in all the participants.

Despite various pharmacological treatment approaches to manage the symptoms associated with diabetic neuropathy is available, the safety of long-term advocacy of drugs without side effects is arguable. Moreover, physical measures of treatment for this condition has a dearth in literature support and there is a lacuna in physiotherapy intervention for managing diabetic neuropathy. In this study, LLLT with a dosage of 4j/cm^2 was taken and studied for its significance in the selected population based on its proven neuro-regenerative effects.

Further multidimensional studies would be very beneficial since diabetes induced peripheral neuropathy is a condition involving multiple symptom which may affect autonomic function, sensation and motor function and future studies may direct towards functional outcome through this modality.

Anders et al. underwent study on Neuro regenerative and Neuroprotective effects of low-level laser and concluded that there is massive axonal sprouting and increase in various molecules such as growth associated protein – 43 (GAP- 43), calcitonin gene-related (CGRP) and transforming growth factors betal. They concluded that laser irradiation activates the proliferation of the Schwann cells which will help in process of nerve regeneration. [16]

Various other studies have also reported the effect of Laser irradiation in diabetic neuropathy and the physiological association related to its pathological changes provides evidence of laser irradiation facilitating collagen synthesis, altering DNA synthesis, and improving the function of degenerated neuron and also by facilitating ATP synthesis, improving serotonin and endorphins, promotion of anti-inflammatory mechanisms by reducing prostaglandin synthesis. This process of cellular alterations may also help tissue in improving local circulation, by reducing inflammation which in turn reduces pain [17], [18],[19

Peric et al[11], and Zinman et al [12] from their study results concluded that LLLT does not produce significant improvement in symptoms and pain associated with Diabetic polyneuropathy. In contrary this study

established a significant effect of LLLT on relieving symptoms and decreasing pain on distal symmetric polyneuropathy. In a study done by Enwemeka et al. reported that laser therapy was highly effective for tissue repair and pain relief [20].

Morshedi et al. demonstrated that the low-level laser therapy is an effective mean of treatment for pain and inflammation to a target tissue without any adverse effects if the criteria of therapeutic parameters are followed appropriately [21]. Similarly our study also did not show any adverse reactions to laser therapy. Considering the absence of any significant adverse event with LLLT, Further studies are needed to investigate the effect of LLLT on Distal Symmetric Polyneuropathy of varied sternness. One of the significant limitation of our study was small sample size and follow up. Upon further follow-up studies, LLLT can be a recommendable choice of modality in treating Distal Symmetric Polyneuropathy of diverse severity. Although this study demonstrated a significant improvement in pain and symptoms associated with diabetic neuropathy with low-level laser therapy, the observed trend warrants further investigation. The exact mechanism related to the progression of the condition is still debatable.

CONCLUSION

Results of the present study recommend Low-Level Laser Therapy as an effective treatment procedure for Diabetic sensorimotor Polyneuropathy in reducing Pain and relieving symptoms.

Conflict of Interest: None

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Ethical Clearance: Obtained

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