

Clinical Parameters Response to Low-Level Laser versus Monochromatic Near-Infrared Photo Energy in Diabetic Patients with Peripheral Neuropathy

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Abstract—Background: Diabetic sensorimotor polyneuropathy (DSP) is one of the most common microvascular complications of type 2 diabetes. Loss of sensation is thought to contribute to a lack of static and dynamic stability and increased risk of falling. Purpose: The purpose of this study was to compare the effects of low-level laser (LLL) and monochromatic near-infrared photo energy (MIRE) on pain, cutaneous sensation, static stability, and index of lower limb blood flow in diabetic patients with peripheral neuropathy. Methods: Forty diabetic patients with peripheral neuropathy were recruited for participation in this study. They were divided into two groups: The MIRE group, which contained 20 patients, and the LLL group, which contained 20 patients. All patients who participated in the study had been subjected to various physical assessment procedures, including pain, cutaneous sensation, Doppler flow meter, and static stability assessments. The baseline measurements were followed by treatment sessions that were conducted twice a week for six successive weeks. Results: The statistical analysis of the data revealed significant improvement of pain in both groups, with significant improvement in cutaneous sensation and static balance in the MIRE group compared to the LLL group; on the other hand, the results showed no significant differences in lower limb blood flow between the groups. Conclusion: LLL and MIRE can improve painful symptoms in patients with diabetic neuropathy. On the other hand, MIRE is also useful in improving cutaneous sensation and static stability in patients with diabetic neuropathy.

Keywords—Diabetic neuropathy, Doppler flow meter, -Low-level laser, Monochromatic near-infrared photo energy.

I. INTRODUCTION

PAINFUL Diabetic Peripheral Neuropathy (DPN) is a common complication of diabetes. It is estimated that in patients with a 25-year history of diabetes, approximately 50% will develop neuropathic pain, which is defined by the International Association for the Study of Pain as pain initiated or caused by a primary lesion or dysfunction in the nervous system. In patients with diabetes, these lesions arise from several pathophysiological mechanisms, including a persistent hyperglycemic state [1], [2]. The overall duration and degree of hyperglycemia correlates with the extent of nerve damage [3]. The neuropathic foot has pathological changes in sensory fibers [4]. Due to sensory neuropathy, patients are unable to sense pressure, pain, or microtrauma on the foot. An injury or infection in the neuropathic foot results

in a serious medical condition often leading to amputation [5].

The loss of sensation associated with DPN is thought to contribute to impaired balance, altered gait patterns, and increased risk of falling. People with DPN exhibit greater postural sway when standing and numerous gait studies have revealed characteristic changes in walking patterns associated with DPN, including decreased power generation at the ankle, decreased knee joint flexion, decreased ground reaction forces, and, ultimately, loss of balance [6], [7].

II. OBJECTIVE

The purpose of this study was to compare the effects of low-level laser (LLL) and monochromatic near-infrared photo energy (MIRE) on pain, cutaneous sensation, static stability, and index of lower limb blood flow in diabetic patients with peripheral neuropathy.

III. MATERIAL AND METHODS

A. Participants

A total of 40 male patients with painful DPN were recruited from out-patient clinics in Emirate of Sharjah, with a diagnosis of peripheral neuropathy and confirmed by an abnormal nerve conduction study. Eligible patients ranged in age from 55 to 65 years (mean = 58.36, standard deviation [SD] = 9.042). The patients had longstanding type 2 diabetes associated with painful peripheral neuropathic symptoms for ≥ 6 months duration involving both lower extremities and complained of burning pain with paresthesia in both legs [8]. Neurological examination of the patients revealed sensory abnormalities in both lower extremities [8]. Patients were excluded from the study if they had uncontrolled type 2 diabetes mellitus (fasting blood glucose greater than 300 mg/dl), Semmes-Weinstein monofilament values not more than 5.07, foot ulcer, open wounds, major or minor amputation, and/or nerve damage as a result of prior reconstructive or replacement knee surgery, back surgery, spinal stenosis, spinal compression, or radiculopathy. Participants were randomly divided into two study groups: the LLL group (n=20) and the MIRE group (n=20).

B. Measurement

All study participants underwent a baseline evaluation at the beginning of the six-week treatment followed by reevaluation across the following measures:

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1. Pain Assessment

A Visual Analogue Scale (VAS) of pain was used to record patients' subjective reports of pain. The VAS consisted of a 10 cm horizontal line, anchored with (no pain) at the left end.

2. Cutaneous Sensation Assessment

The 5.07 Semmes-Weinstein monofilaments (SWM) were applied to 10 selected areas with eyes closed: at the first, third, and fifth toes, first, third, and fifth metatarsal head, two points at mid foot, one point at the heel, and the 10th point was located at the dorsum of the foot opposite to the base of the big toe. The sites were tested in a random order with a 2- to 3-s pause between test sites. The 5.07 monofilament was held perpendicular to the skin and applied for 1–2 s. The total number of sites felt by the patients was recorded before and after the six weeks of treatment [9].

3. Balance and Gait

The Tinetti Scale for balance and gait was used according to the following instructions: (a) Balance: Balance at sitting, standing up, attempts to stand up, immediate standing (the first 5 seconds), standing and pushing, standing with eyes closed, turning 360 degrees, and sitting down' (b) Gait: starting to walk, length, height, symmetry and succession of steps, route, oscillation of the trunk, and width of gait. The score was 16 for static balance section and 12 for gait section, the overall score, was recorded, for a total of 28 [10].

4. Ankle-Brachial Pressure Index Doppler for Assessment of Peripheral Circulation

Systolic pressure was first recorded for the posterior dorsal artery from a semi-recumbent position, and second from brachial artery the electronic equipment was recording the index of systolic pressure at the ankle divided by the same measurement at the brachial artery.

C. Intervention

1. The MIRE therapy System (Anodyne Therapy LLC, Tampa) was used for patients in the MIRE group. The system was delivering 1-3 joules of photo energy twice a week for six weeks, twice a week. Electrodes were placed over the anterior and posterior aspects of participants' leg and sole of feet.
2. The Low-level laser (LLL) group, Terra Quant TQ Solo Portable Cold Laser System, Super-pulsed 15,000 mW (15 watt Peak @ 905 nm) laser, 60 mW (875 nm) infrared light, 7.5 mW (660 nm) red light was used for patients in the LLL group: Twenty patients received LLL twice weekly, applied to an area of pain along the sole or dorsum of the foot. The instrument covered a 6-cm-diameter area of skin. The laser was applied to two painful sites on each foot for a period of 5 min. for both feet.

All participants were informed about the nature and effect of the trial. They were given an informed written consent form to sign and return to the study researcher(s).

D. Statistical Analyses

All data were expressed as mean \pm SD. Statistical significance was evaluated via a two-tailed Student's t test (for paired and unpaired values). Analyses were performed using SPSS underpin, statistical package, version 20 a personal computer. A $p \leq 0.05$ was considered statistically significant.

IV. RESULTS

TABLE I
PRE AND POST VALUES FOR BOTH GROUPS

| Variables | Group | Pre | Post | P-Value |
|---------------|-------|------------------|------------------|---------|
| | | X \pm SD | X \pm SD | |
| VAS | LLL | 6.15 \pm .28 | 4.3 \pm 0.24 | 0.001* |
| | MIRE | 6.6 \pm .06 | 5.1 \pm 0.24 | 0.005* |
| SWM | LLL | 5.28 \pm 0.5 | 5.12 \pm .654 | .432 |
| | MIRE | 5.63 \pm 0.60 | 7.15 \pm 0.83 | 0.005* |
| Tinetti score | LLL | 18.8 \pm 0.78 | 19.22 \pm 0.84 | 0.12 |
| | MIRE | 17.95 \pm 0.83 | 24.65 \pm 0.39 | 0.005* |
| ABI | LLL | 1.25 \pm 0.4 | 1.24 \pm 0.4 | 0.909 |
| | MIRE | 1.26 \pm 0.03 | 1.25 \pm 0.3 | 0.621 |

X = Mean, SD=Standard deviation, VAS= Visual Analogue Scale, SWM=Semmes-Weinstein monofilament, ABI= Ankle brachial pressure index. and a P-value= level of significance (level of significance = $P \leq 0.05$ was considered statistically significant*).

TABLE II
COMPARISON OF THE POT TREATMENT VALUES IN BOTH GROUPS

| Variables | | LLL | MIRE | P-Value |
|---------------|------|------------------|------------------|---------|
| | | X \pm SD | X \pm SD | |
| VAS | Pre | 6.15 \pm .28 | 6.6 \pm .06 | 0.780 |
| | Post | 4.3 \pm .240 | 5.1 \pm .240 | |
| SWM | Pre | 5.28 \pm 0.5 | 5.63 \pm 0.60 | 0.001* |
| | Post | 5.12 \pm 0.65 | 4.156 \pm 0.83 | |
| Tinetti score | Pre | 18.8 \pm 0.78 | 17.95 \pm 0.83 | 0.001* |
| | Post | 19.22 \pm 0.48 | 24.65 \pm 0.34 | |
| ABI | Pre | 1.25 \pm 0.4 | 1.26 \pm 0.03 | 0.771 |
| | Post | 1.24 \pm 0.4 | 1.25 \pm 0.3 | |

X = Mean, SD=Standard deviation, VAS= Visual Analogue Scale, SWM= Semmes-Weinstein monofilament, ABI= Ankle brachial pressure index, P-value= level of significance ($P \leq 0.05$), $P \leq (0.01)$ =*highly significant

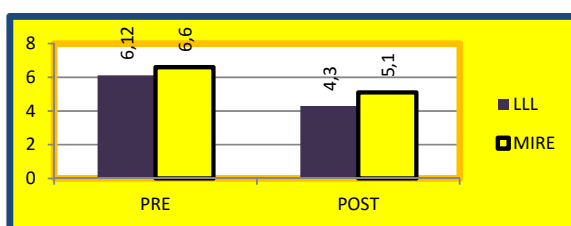


Fig. 1 The mean values of VAS Pre and Post 6 Weeks in Both Groups

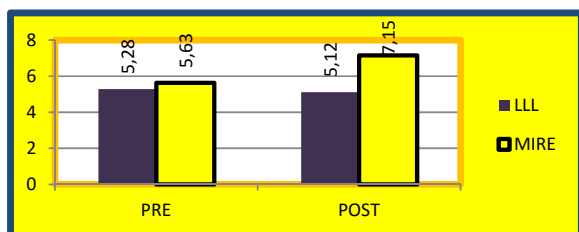


Fig. 2 The mean values of SWM Pre and Post 6 Weeks in Both Groups

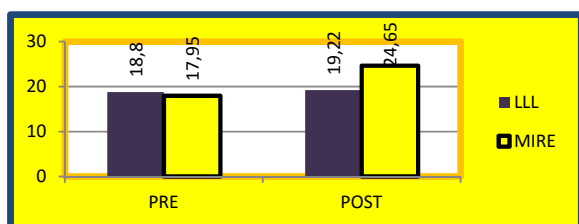


Fig. 3 The mean values of Tinetti score Pre and Post 6 Weeks in Both Groups

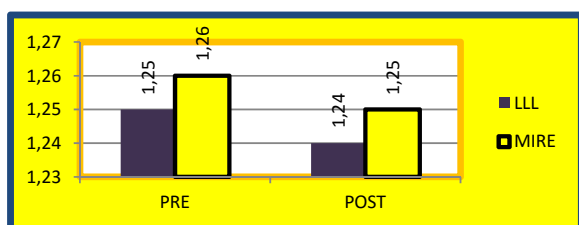


Fig. 4 The mean values of ABI Pre and Post 6 Weeks in Both Groups

V. DISCUSSION

The significant improvements in pain and cutaneous sensation after six weeks of treatment in both groups could be attributed to the analgesic effects related to the local release of neurotransmitters such as serotonin, increased mitochondrial ATP production, increased release of endorphins, or anti-inflammatory effects, as well as the possibility of increasing the skin microcirculation [11].

It is obvious that changes in pain are difficult to objectively measure. A 10-point VAS has been widely validated and is not subject to evaluator bias because it is reported by the patient. The extent of the reduction in reported pain by the patients in this study were 42% for patients in the LLL group and 29% in the MIRE group, and can be considered clinically relevant [11]. This analgesic effect could also be attributed to the activation of neuron metabolism [12], increased endorphin release, and increase in pain threshold [13]. This result was in accordance with a previous study that stated that the reduction in pain and the improvement of foot sensation would be associated with significant improvement in balance and gait, and with a significant reduction of the objective measures of fall risk [14]-[16].

The improvement in neural function may be due to improved circulation related to the localized release of nitric oxide. It has been discovered that 890 nm near-infrared photo

energy can be very effective in improving circulation and, subsequently, muscle performance [17]. In their study, effect was mediated by endothelial nitric oxide synthases or nitric oxide; the vasodilatation was sustained for several hours, even after the photo energy was removed; however, in the current study, improvement of neural function indicated by sensation was not significant for patients in the LLL group. This result was not in agreement with Perić [18] who concluded that 12 weeks treatment with Low- Intensity Laser Therapy (LILT) can significantly reduce spatial perception threshold (SPT) (scored as number from 1 to 8) determined with Tactile Circumferential Discriminator on dorsal part of foot's big toe skin; however, this result can be argued with the extended duration of intervention and according to this recommendation further investigation is needed to confirm the same result [18].

The results of this study included significant improvement of overall stability as an index of balance in diabetic patients with peripheral neuropathy after six weeks of MIRE that could be attributed to the reduction of pain and improvement of foot sensation, produced by the use of MIRE. This result was in accordance with a previous study that stated that the reduction in pain and the improvement of foot sensation would be associated with significant improvement in balance and gait, with significant reduction in the objective measures of fall risks [20], [21].

In the current study, the significant improvement in the neural function for patients in the MIRE group compared to those in the LLL group may be attributed to the sensory perception reported by patients in the MIRE group during application; however, further investigation is needed to confirm similar results with an adequate follow-up period and may include a third group, a placebo group.

VI. CONCLUSION

It was concluded from this study that LLL and MIRE therapy can improve painful symptoms in patients with diabetic neuropathy. On the other hand, MIRE is useful in improving cutaneous sensation and static stability in patients with diabetic neuropathy.

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