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The Efficacy of Adding Electromagnetic Therapy or Laser Therapy to Medications in Patients With Diabetic Peripheral Neuropathy

Alsayed A. Shanb[1*], Enas F. Youssef[1], Waleed I. Al Baker[2], Fahd A. Al-Khamis[3], Ali Hassan[3], Noor-Ahmad Jatoi[4]

[1]Department of Physical Therapy, College of Applied Medical Sciences, Imam Abdulrahman Bin Faisal University, Dammam, KSA
[2]Department of Internal Medicine, College of Medicine, Imam Abdulrahman Bin Faisal University, Dammam, KSA
[3]Department of Neurology, College of Medicine, Imam Abdulrahman Bin Faisal University, Dammam, KSA
[4]Department of Internal Medicine, King Fahd University Hospital and College of Medicine, Imam Abdulrahman Bin Faisal University, Dammam, KSA

***Correspondence to**
Alsayed A. Shanb,
Fax: +9663330343;
Tel: +966555786349;
Email: aashanb@iau.edu.sa

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Abstract

Introduction: Diabetes mellitus (DM) is a common disease with a highly significant burden among the Saudi population. This study aimed to investigate the effects of adding either magnetic or laser therapy to medications in patients with diabetic peripheral neuropathy (DPN).

Methods: Seventy-one medically controlled diabetic patients were randomly assigned to *1) Magnetic group:* 26 patients were exposed to magnetic therapy for 20 minutes/session, 2 sessions/week, for 3 months *2) Laser group:* 25 patients were exposed to laser therapy with intensity 5.7 J/cm^2 for 30 minutes/session, 2 times/week, for 3 months. *3) Drug group:* 20 patients received only the regular medications for diabetic control and pain analgesia. Pain and neuropathy were assessed by the visual analog scale (VAS) and the Toronto Clinical Neuropath Scoring System (TRCNSS). Conduction velocities and amplitudes of peroneal and sural nerves were measured by electromyography.

Results: The results showed significant increases in conduction velocities and amplitudes in both magnetic and laser groups in parallel with significant reductions in TRCNSS. Non-significant changes were obtained only after using only medications *($P>0.05$)*. The mean values of VAS reduced significantly in the three groups. The least significant differences showed significant changes among the three groups, whereas non-significant differences were obtained between both magnetic and laser groups.

Conclusion: There were non-significant differences between both magnetic and laser therapy groups. Addition of either magnetic or laser therapy to medications could bring extra positive benefits to patients with DPN. Both magnetic and laser therapy can be applied with medications for the treatment of patients with DPN.

Keywords: Neuropathic pain; Laser therapy; Conduction velocity.

Introduction

Diabetes mellitus (DM) is a common disease which is accompanied by a highly significant social and economic burden.[1] Diabetes has high prevalence and progressive rates among the Saudi population. It is strongly associated with both microvascular and macrovascular complications such as retinopathy, neuropathy, and cardiovascular diseases.[2] Peripheral neuropathy is the most common complication of diabetic patients.[3] Diabetic peripheral neuropathy (DPN) is commonly associated with a high rate of patients' mortality and morbidity.[4] The prevalence and progression of DPN increase in parallel with the chronicity of diabetes, poor glycemic control and pre-existing cardiovascular risk factors.[3] DPN is usually characterized by increases in pain severity, impairments in tactile and proprioceptive sensation, vibration sense, and improper postural control.[5] Distal symmetric polyneuropathy is the commonest form of diabetic neuropathy.[6]

Nevertheless, diagnostic methods of neuropathy are diverse. The highest sensitive and objective method is the conduction velocity test (CVT).[6] Diagnosis of DPN is confirmed when the symptoms and signs of peripheral nerve dysfunctions are present after the exclusion of all other causes.[3] Comprehensive evaluation of DPN also requires careful examination of the lower extremity with validated clinical tests such as light touch, vibration, and the Toronto Clinical Neuropathy Scoring System (TRCNSS) which is one of the most sensitive clinical scales to detect early neuropathies.[7]

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To date, although one-third of diabetic patients are affected with neuropathic pain, its treatment is still very complex.[6] The focus of management is usually on disease modifications and the relief of symptomatic pain. Up till now, no specific treatment has been able to completely prevent or reverse the progression of DPN.[6] As hyperglycemia is the essential contributing factor in DPN, proper glycemic control is the main therapeutic target for its treatment.[8] Neuropathy happened because of reductions in the nerve blood flow and increases in nerve hypoxia, thus vasodilating drugs as prostaglandin analogues are usually beneficial in the treatment of neuropathic pain.[4,9] Although many drugs have been used for the treatment of DPN, their roles are still unconfirmed.[10] The administration of analgesics as tricyclic anti-depressants and topical agents may be effective but with limited success and unsatisfactory results.[11] However, around half of the patients with DPN have shown adequate symptomatic pain relief in association with frequent side effects such as drowsiness, lethargy and unsteadiness.[11] In addition, these analgesics do not stop or delay the progression of the underlying pathological neuropathic changes.[12]

Physical therapy can actively relieve the signs and symptoms of DPN. Active exercises have had many benefits for diabetic patients.[1,3,5,8] At the same time, there are limitations for many diabetic patients to practice physical exercise, which enforce us to seek other alternative therapeutic modalities for diabetic neuropathic pain.[1] Magnetic and laser therapy are recent interventions that may enhance the treatment of DPN.[13,14]

Pulsed electro-magnetic therapy (PEMT) was applied mostly to animals in experimental studies.[15] The application of PEMT for 12 consecutive days for 30 minutes relieved neuropathic pain and increased nerve conduction velocity.[16] In general, PEMT is considered safe and supplemental therapy for DPN.[17] Unfortunately, there are still contradictions about the benefits of magnetic therapy despite its wide uses on diabetic patients.[15,16,18] The application of PEMT for 20 minutes/session for 3 weeks resulted in a non-significant improvement in pain intensity and sleep conditions of patients with DPN.[18] The properly used parameters for the clinical application of PEMT are also still controversial.[14] Its limited uses on human beings aroused our enthusiasm for increasing applied studies into the effects of magnetic therapy on human beings.[15]

Low-level laser therapy (LLLT) is generally and safely applied to many patients with co-morbid diseases.[19,20] There is an unambiguous piece of evidence that LLLT with different wavelengths has different effects on the cellular level.[21] It was previously applied for 1 minute/site on 4 para-vertebral points in the lumbosacral spine, 3 points on the ischial region, and 2 points on the dorsum of the foot.[21] Also, LLLT has been applied on 6 para-spinal points (L4-S1) to irradiate along the output of the right and left sciatic nerve.[22] Despite a wide range of LLLT uses in a clinical setting, there is non-sufficient evidence to confirm its effects on neuropathic pain in humans.[23] Some authors suggested its usage as a new therapeutic modality for patients with DPN.[24] and others proved that LLLT has been effective in the repair of nerve damage.[25] However, objective clinical studies have failed to detect the exact benefits of laser therapy on DPN.[26] Furthermore, up till now, there have been controversies over the effects and proper parameters of laser application techniques that can be used for the treatment of DPN to prevent unnecessary sufferings and to reduce direct and indirect costs to those patients and their families.[20] There is still a need for more randomized controlled trials on physical therapy advanced modalities for the treatment of patients with DPN.[23] Therefore, the objective of the current study was to investigate the effects of adding either magnetic or laser therapy to drug therapy in patients with DPN and to compare them.

Materials and Methods

Subjects

Nineteen type-II diabetic patients with peripheral neuropathy were enrolled in this study after screening by specialized physician (Figure 1). The patients' demographic data, including age, sex, the duration of diabetic history and beginning of neuropathy, the body mass index, fasting blood glucose (FBG), and the used medications are shown in Table 1.

Inclusion criteria: Patients (male and female) with painful DPN lasted > 6 months. Their age ranged from 35 to 70 years. Patients have sensory abnormalities, burning pain with paresthesia in both lower extremities,[4,27] impaired sensory and/or motor conduction velocity (MCV) in a minimum one nerve of the lower limbs.[13] All patients were medically controlled. The usage of analgesic medications such as anti-depressants and anticonvulsants could be received without any change for at least 4 weeks prior to recruitment and during the study.[4,6] A consent form was signed by all the patients prior to their participation. They were informed that the collected data would be published.

Exclusion criteria: The patients were excluded if they had DPN from other causes than diabetes, lack of blood sugar control, vascular insufficiency, other neurological impairments, uncontrolled medical conditions (e.g. tumors and thyroid dysfunctions), pregnancy, metallic implantation, drug abuse, and a TRNCSS total score <5.[4,7,8,27,28]

Treatment Equipment

1- BEMER mattress: BEMER International AG (Liechtenstein) mattress product was used for producing magnetic therapy. The maximum average flux density (intensity) of BEMER on its highest output level is 150 microtesla (μT). The B. BOX Professional control units

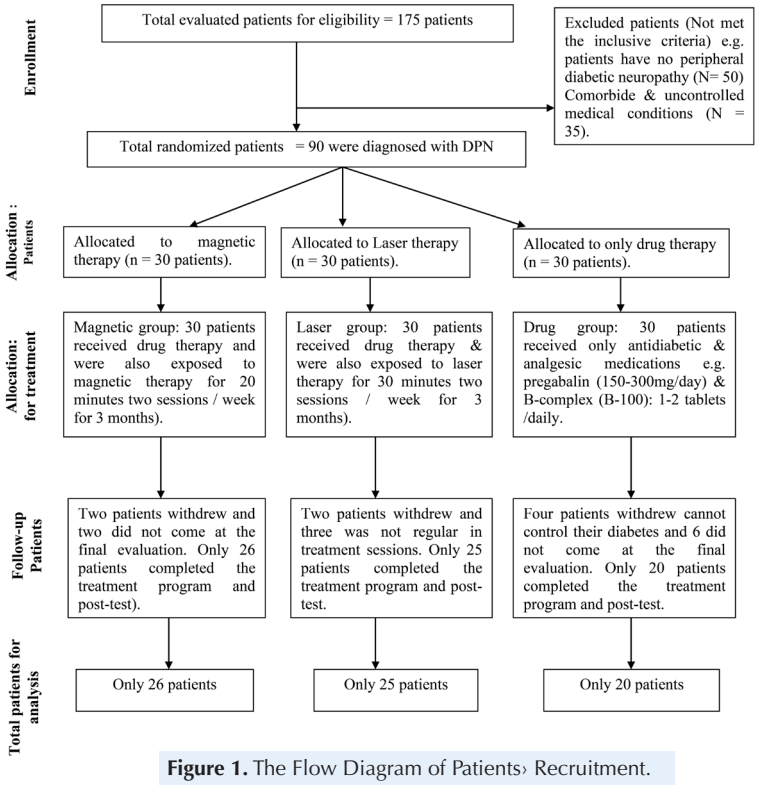

Figure 1. The Flow Diagram of Patients› Recruitment.

had 3 pre-stored programs with different intensity and treatment times. [29]

2- The Laser Scanner device (ASA Com. srl, Arcugnano, Italy): It emits a mixed light of both the He-Ne continuous wavelength of 850 nanometers (nm) and the pulsed infrared laser with the wavelength 905 nm. The device had maximum power of 10 watt (W). The output density of the device is calibrated at each applied program and selected frequency.[4]

Procedures

Assessment Procedure

The following measures were employed for all recruited patients by a blinded investigator.

a. Fasting Blood Glucose

A venous fasting blood sample was drawn from the anti-cubital vein to detect the blood glucose level (pre-intervention, after 6 weeks and at the end of treatment) for all patients.[28]

b. Electrophysiological Test

MCV of the peroneal nerve and sensory conduction velocity (SCV) of the sural nerve in addition its amplitudes were measured by a neuro-consultant.[22,28] The patients with conduction velocity from 33-48 meter/second were

Table 1. Demographic Data of Recruited Patients

Variables	Magnetic Group	Laser Group	Drug Group	F Value	*P* Value
	Mean ± SD	Mean ± SD	Mean ± SD		
Age (y)	60.31 ± 9.82	58.88 ± 12.15	54.05 ±10.69	1.971	0.147
BMI, kg/ m²	27.32 ± 1.75	28.17 ± 1.97	27.79 ± 1.46	1.493	0.232
Sex, No. (%)				0.209	0.812
Males	18 (69.3)	16 (64)	12 -- (60)		
Females	8 (30.7)	9 (36)	8 -- (40)		
Duration of incidence of diabetes (y)	16.31 ±7.61	18.8 ±7.58	13.65 ± 6.71	2.726	0.073
Duration of beginning of diabetic neuropathy (y)	4.11 ±2.55	5.0 ±2.71	3.25 ± 2.07	2.767	0.070
Pre-FBG, mg/dL	142.38 ±6.8	140.68 ±6.77	141.5 ± 7.01	0.395	0.675
in-FBG, mg/dL	136.38 ±5.32	136.08 ±4.99	135.85 ±5.16	0.044	0.957
Post-FBG, mg/dL	136.5 ±5.46	136.2 ±5.17	136.6 ±5.19	0.062	0.940
Oral drugs, No. (%)	21 (80.8)	21 (84)	16 (80)	0.142	0.931
Insulin, No. (%)	5 (19.2)	4 (16)	4 (20)		

BMI: body mass index; FBG, fasting blood glucose; in-FBG mg/dL: fasting blood glucose after 6 weeks.

recruited as confirmed DPN. [16,21] All measures were performed by using (Nicolet™ EDX- Viking version 20 software Germany) at a controlled temperature of 25°C.[27,28]

1. Peroneal nerve conduction velocity: It was investigated by putting standard surface electrodes. The distal stimulation was applied at 8 cm near to the active pickup electrode, just lateral to the Tibialis Anterior Tendon. The ground electrode was put at mid-calf. The proximal stimulation was applied just below the head of the fibula while the recording electrode was applied over the Extensor Digitorum Brevis to get a supra-maximal stimulus. [4,22,27]

2. Sural nerve conduction velocity: It was investigated by putting an active pick-up electrode posterior and below the lateral malleolus. The reference electrode was put at 3 cm distal to the active electrode and the ground electrode was put between the cathode of the stimulator and the active pickup electrode. Stimulation was applied slightly lateral to the midline in the lower third of the posterior aspects of the leg with the cathode distally about 17 cm from the active electrode (10-14 cm). [4,8,22,27]

c. Neuropathy Severity

It was also evaluated by the TRCNSS which is an objective method to detect the presence and intensity of DPN. Total scores ranged from 0 (normal) to 19 points (maximum).[7]

d. Pain

It was measured by VAS which is a valid instrument for the determination of perceived pain. Every patient was asked to point to his or her pain level ranged from 0 (no pain) to 10 (maximal pain). [4,27]

e. Vibration Sense

It was evaluated by using a 128-Hz tuning fork from the bony prominence of the big toe. [5]

f. Deep Tendon Reflexes

The ankle and knee reflexes were evaluated from relaxed sitting position. [22]

Treatment Procedure

Only 90 patients were randomly and equally assigned to 3 treatment groups by an independent blinded research assistant who opened sealed envelopes that contained a computer-generated randomization card (Figure 1).

1. Magnetic group: Twenty-six patients received drug therapy and they were exposed to magnetic therapy by a BEMER mattress (the density of the magnetic field was between 35 and 50 μT for 20 minutes/session, 2 sessions/week, for 3 months. The BEMER mattress was applied from a relaxed supine lying position. After connecting the appliance to the electrical supply, the action of PEMT was adjusted below the affected parts from the lower back to the feet. The program 3 was applied to achieve the proper treatment for 20 minutes.[29]

2. Laser group: Twenty-five patients received drug therapy and they were exposed to the infrared laser (850 nm) in the continuous wave mode with the total power of 5.7 J/cm^2 for 30 minutes /session, 2 times per week, for 3 months. [4,22,27] Both the plantar surface of the feet and the lumbosacral area were treated by laser therapy from a comfortable prone lying position . The distance between the laser head and the treated area of every patient was adjusted at 30 cm. The X-Y dimensions of the lumbo-sacral area were marked by 4 points, one on the lumbar 2, one on the sacral 1, and 2 points laterally to the spine by about 2 cm. The plantar surface and the lumbosacral areas were cleaned with alcohol (95%). Both areas were exposed to laser therapy through a sweeping computerized scan at an angle of 30° ± 15°. The power density was 6.3 mW/cm^2 and irradiation time was set to 90 sec/cm^2 to achieve the total dose of 5.7 J/cm^2 through 15 min/site/session. Every patient and the physical therapist wore protective glasses for protection from the laser beam.[4,22,27]

3. Drug group: Twenty patients received only their regular drug therapy in the form of anti-diabetic drugs (either oral or insulin) and analgesic medications for peripheral neuropathic pain, including pregabalin (150 mg/d-300 mg/d) and B-complex multivitamin (B-100), one tablet once or twice daily. [9,14,22]

Statistical Analysis

All measured variables with their output data were analyzed by using SPSS software (version 23.0) in the form of descriptive and inferential analysis. A repeated measures ANOVA was used to evaluate the therapeutic effects within each group and among 3 groups. ANOVA and Pearson's chi-square were used to compare demographic data of all groups. Statistical significance was measured at a P value <0.05 with a confidence interval of 95%.

Results

Statistical analysis was applied to seventy-one patients who completed this study (Figure 1) as nineteen patients dropped out.

Demographic Characteristics of Recruited Patients

The data were reported by using the percent. The Pearson chi-square showed non-significant differences in gender and used drugs among the 3 groups. The results of ANOVA proved non-significant differences in the mean values of age, body mass index (BMI), FBG, the duration of diabetes, and the beginning of neuropathy among 3 groups prior to the interventions. The baseline demographic data were similar among the 3 groups except for increases number of participated men than women (Table 1).

Rate of Adherence

The mean values of patients' adherence of both magnetic

and laser groups were 20.85 ± 1.78 and 21.32 ± 1.49, *P* value = 0.309, with the percent of 86.87% and 88.83% respectively.

Electro Diagnosis Parameters in the 3 Treatment Groups

The results of the repeated measures ANOVA showed measured conduction velocities of the peroneal and sural nerves and its amplitudes increased significantly after adding either magnetic or laser therapy to drug therapy *(P* < 0.05*)*, whereas non-significant changes were obtained only after usage of drug therapy *(P* > 0.05*)* (Table 2; Figures 2 & 3).

Toronto Clinical Neuropath Scoring System and VAS in Treatment Groups

The TRCNSS reduced significantly after adding either magnetic or laser therapy to drug therapy *(P* < 0.05*)*, whereas non-significant changes were obtained only after usage of drug therapy *P* > 0.05*)* (Figure 4). The VAS reduced significantly after interventions in the 3 treatment groups *(P* < 0.05*)* (Figure 5).

Comparison Among the 3 Treatment Groups

The repeated measures ANOVA showed significant differences in the mean values of MCV, SCV, amplitudes and TRCNSS among the 3 groups (*P* < 0.05). The comparison of the least significant difference (LSD) by the post hoc test proved that there were significant differences in the mean values of measured conduction velocities, amplitudes, and TRCNSS between the magnetic and drug groups. Also, there were significant differences between the laser and drug groups (*P* < 0.05), whereas non-significant differences were obtained between the magnetic and laser groups (*P* > 0.05) (Table 3). In addition, the post hoc test proved that there were non-significant differences in the mean values of VAS among the 3 groups after the interventions *(P* > 0.05*)* (Table 3).

Table 2. Mean Values of Motor Conduction Velocities and Amplitudes of the Peroneal Nerve in the Treatment Groups

Treatment Groups		Mean	SD	Mean Square	*F* Value	*P* Value
Magnetic group						
MCV m/s	Pre	43.02	3.37	15.84	13.354	0.001*
	Post	44.13	2.94			
M-ampl mv	Pre	1.28	0.55	2.862	31.008	<0.001*
	Post	1.75	0.2			
Laser group						
MCV m/s	Pre	42.51	3.15	161.31	13.453	0.001*
	Post	43.64	2.79			
M-ampl mv	Pre	1.21	0.68	3.645	17.963	<0.001*
	Post	1.75	0.29			
Drug group						
MCV m/s	Pre	40.28	4.3	0.342	0.356	0.558
	Post	40.47	3.74			
M-ampl mv	Pre	1.24	0.56	0.025	0.175	0.68
	Post	1.09	0.28			

MCV m/s: Motor condition velocity in meter per second.
M -ampl mv: Motor amplitude in millivolt.
* Significance *P* value < 0.05.

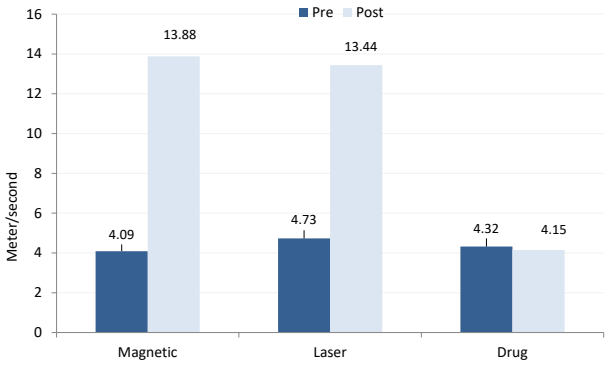

Figure 2. Mean Values of Sensory Conduction Velocity of the 3 Groups.

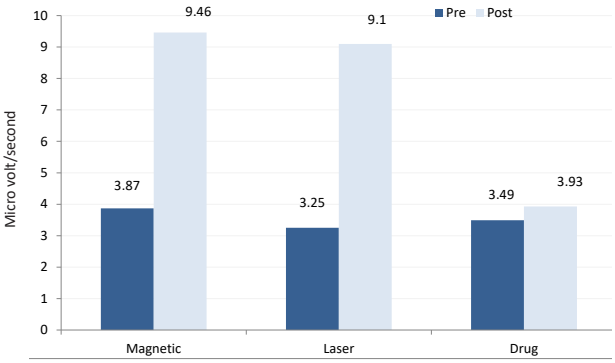

Figure 3. Mean Values of Sensory Amplitudes of the 3 Groups.

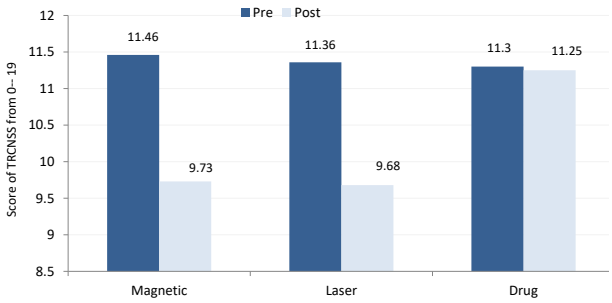

Figure 4. Mean Values of the Toronto Clinical Neuropath Scoring System of the 3 Groups.

Discussion

DPN is a common significant source of diabetic patients' distress.[6] Although one-third of diabetic patients are affected with neuropathic pain, its treatment is still very complex.[3] The drugs of diabetic control and neuropathic pain remain the standard line of treatment because the

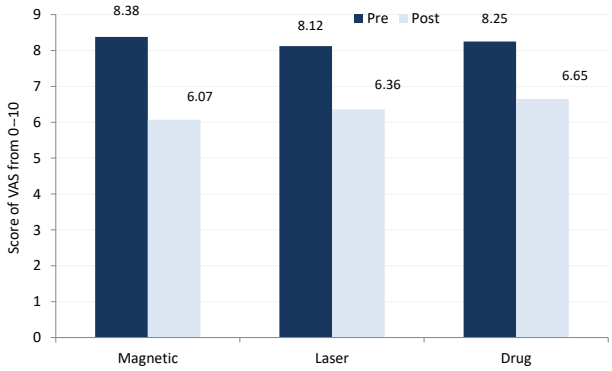

Figure 5. Mean Values of the Visual Analog Scale of the 3 Groups.

good control of FBG can postpone or delay the onset of neuropathy and its associated symptoms.[9,10,12] Thus all participated patients primarily and regularly received the needed drugs.[6,9,12,22]

The current results revealed that adding magnetic therapy to drug therapy significantly increased the mean values of measured conduction velocities and amplitudes in parallel with a significant reduction in the mean values of TRCNSS. These benefits of PEMT are supported by a study by Lei et al.[15] They found that PEMT restores nerve abnormalities in treated rats with induced DPN. Also, some authors reported that PEMT has direct therapeutic effects on injured nerves and it has a hypoglycemic effect which may explain the relief of DPN.[15,30] The underlying mechanisms for these positive effects of PEMT may be due to the fact that it modifies peripheral nerve functions, increases microvascular blood flow,[13,30] accelerates nerve conduction velocity,[17] and increases the compound action potential of peripheral nerves.[31] Moreover, PEMT has an anti-inflammatory effect accompanied by pain relief. It reverses the damage of the peripheral neuropathy and finally restores normal conduction velocity.[16] In contrast to the current results,[14,18] they did not recommend the usage of PEMT for the treatment of DPN because they failed to demonstrate any significant positive effects on those patients with DPN. Also, other authors found that PEMF did not induce any significant reduction in neuropathic pain.[32,33] These contradictions between the previous studies and the current results may be due to the differences in applied parameters, the qualifications of magnetic equipment, and the used techniques of PEMF.

The results of the current study also revealed significant improvements in conduction velocities, amplitudes and TRCNSS in patients with DPN after treating with LLLT in combination with drug therapy. These results were supported by some recent studies.[4,22,24,25,27] They have reported that LLLT is a clinically safe therapy for DPN.[24,25] Some authors stated that LLLT was effective in nerve protection and repair with different damage degrees.[4,22,24,27] Other authors have postulated that LLLT can effectively reduce DPN, increase MCV, SCV, neural amplitudes, and increase microcirculation in patients with DPN.[3,22,27] The underlying mechanisms of these induced improvements by LLLT may be due to the fact that it improves tissue perfusion and microcirculation of the ischemic area, has an anti-inflammatory effect on the site of injury through the reduction of prostaglandin synthesis, increases lymphatic flow, decreases local edema, and improves neurological functions.[19,34] Laser therapy can also allow higher neural metabolism and increase myelination and

Table 3. Post Hoc Test Comparison Among the 3 Treatment Groups

Variables	Groups	Mean Differences	Standard Error	95% CI		*P* Value
				Upper	Lower	
MCV m/s	Magnetic & drug	3.2	0.97	5.15	1.25	0.002*
	Laser & drug	2.69	0.98	4.66	0.73	0.008*
	Magnetic & laser	0.59	0.92	2.34	-1.33	0.586
M-ampl mv	Magnetic & drug	0.25	0.12	0.48	0.01	0.030*
	Laser & drug	0.27	0.11	0.51	0.04	0.023*
	Magnetic & laser	-0.01	0.11	0.27	0.26	0.892
SCV m/s	Magnetic & drug	4.58	2.06	8.71	0.46	0.030*
	Laser & drug	4.68	2.08	8.84	0.51	0.028*
	Magnetic & laser	-0.09	1.95	3.79	-3.98	0.961
S-ampl µv	Magnetic & drug	2.45	1.15	4.65	0.26	0.029*
	Laser & drug	2.46	1.11	4.68	0.24	0.030*
	Magnetic & laser	-0.01	1.04	2.06	-2.07	0.993
TRCNSS	Magnetic & drug	-0.68	0.14	-0.39	-0.96	0.000*
	Laser & drug	- 0.75	0.14	-0. 47	- 1.04	0.000*
	Magnetic & laser	0.07	0.13	0.34	- 0.19	0.571
VAS	Magnetic & drug	-0.22	0.16	0.09	-0.53	0.169
	Laser & drug	-0.21	0.16	0.11	-0.53	0.191
	Magnetic & laser	-0.01	0.15	0.29	-0.31	0.951

MCV m/s, Motor condition velocity in meter per second; M-ampl mv, Motor amplitude in millivolt; SCV m/s, Sensory conduction velocity in meter/second; S-ampl µv, Sensory amplitudes in microvolt; VAS, visual analog scale; TRCNSS, Toronto Clinical Neuropath Scoring System.
* Significance *P* value < 0.05.

axon regeneration.[35] It increases adenosine triphosphate synthesis and both serotonin and endorphins secretions.[22] The combined effects of all these various mechanisms can justify the induced positive effects of LLLT on the pathogenesis of DPN. [24]

In contrast to the current results, Bril et al[14] recommended that LLLT cannot be used as a treatment modality for DPN. Also, Zinman et al[26] did not support its usage in DPN because they did not find any sufficient evidence for the usage of LLLT in painful DPN. The different laser responses might be due to the differences in the intervention time adopted in the 2 studies.[21] They found LILT has non-significant influences on MCV and SCV values in patients with painful DPN. The LLLT parameters used in the current study are completely different from those applied in a study by Peric and Cvetkovic.[21] They applied laser therapy for one minute/site on nine points, while in the current study the target areas were the plantar surface of the feet and the lumbo-sacral area. Each one was exposed for 15 minutes 2 times per week for 3 months. In addition, the patients received laser therapy only without proper medical control in Peric and Cvetkovic,[21] whereas in the current study, the patients received laser therapy combined with proper analgesic medications. The proper parameters of laser application are still controversial in the literature, and consequently high scientific rigor is needed to define the optimum LLLT protocol which is specific in the treatment of DPN.[20] There are numerous factors can influence the effects of LLLT such as the type of laser, radiation characteristics, the type of underlying pathology, and treatment regimens such as specific type of laser radiation can have different results on different pathologies.[24] Consequently, more studies may be needed prior to generalizing these results.[36,37]

This study also revealed a significant reduction in the VAS score in the 3 treated groups with non-significant differences among them. It means that proper medical treatment alone or in addition to magnetic or laser interventions can achieve satisfactory analgesic effects for patients with DPN.[4,11,27] Thus analgesic medications are still the most commonly used option to manage DPN. These drugs can achieve the analgesic effects for neuropathic pain with wide variability depending upon the used drugs and the extent of underlying neuropathic pathology changes.[11,23] In addition, in the long run, the required analgesic doses of those patients who will be exposed to magnetic or laser therapy will be less because of extra positive changes in underlying neuropathic pathology. The TRCNSS reduced significantly after adding either magnetic or laser therapy to drug therapy, but non-significant reductions were obtained in those patients who received only drug therapy. This may be due to the fact that TRCNSS includes a pain measure in addition to other parameters such as touch sensation, tendon reflexes and vibration sense which improved significantly in those patients exposed to both magnetic and laser therapy because of the achievements of other physiological advantages in addition to the effectiveness of drug therapy.

Unfortunately, the results of the current study did not find any significant differences between the effects of adding either magnetic therapy or laser therapy to drug therapy in patients with DPN. To the best of investigators' knowledge, no previous study compared both magnetic therapy and laser therapy combined with analgesic medications.

Conclusion

It was concluded that the addition of either magnetic or laser therapy to analgesic medications could bring extra positive therapeutic benefits to patients with DPN. There were non-significant differences between the effect of both magnetic and laser therapy on DPN. Both magnetic and laser therapy can be applied in combination with analgesic medications as therapeutic modalities for the treatment of patients with DPN.

Limitations

Small sample size, evaluation with measurements taken only before and after treatment without long-term follow-up.

Recommendations

Further studies are needed to compare the effects of different intensities of laser and magnetic on DPN using a larger sample size for a longer time and with long-term follow up.

Ethical Considerations

All procedures were approved by the Ethics Research Committee of the Institutional Review Board of Imam Abdualrahman Bin Faisal University (IRB-2014-04-061.No. 2014171). Also, This study was registered in ClinicalTrials.gov (Identifier: NCT03049605).

Conflict of Interests

The authors declare no conflict of interest.

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