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Treatment of mild to moderate carpal tunnel syndrome in patients with diabetic neuropathy using low level laser therapy versus ultrasound controlled comparative study

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ABSTRACT

Aim: The aim of the present study was to investigate and compare between Low Level Laser Therapy (LLLT) and Ultrasound (US) in treatment of Carpal Tunnel Syndrome (CTS) using the advantage of application of treatment directly over the transverse carpal ligament, as well as over the course of the median nerve in the forearm simultaneously.

Design: Fifty patients (25–55 years) with diabetic neuropathy, diagnosed as unilateral carpal tunnel syndrome participated in the study. They were equally divided and randomly assigned into two groups; each group consisted of 25 patients.

Materials and methods: Patients in group (A) received a program of IR Gallium Arsenide LLLT (wavelength 904 nm, average power 20 mW, laser probe 7 mm diameter), with a total application of 4.8 J, while patients in group (B) received a program of US (frequency 1 MHz, power 1.0 W/cm^2, pulsed mode 1:5).

Results & discussion: The results of our study showed that there were no statistical significance differences ($P > 0.05$) were observed between the two groups. It was concluded that both low level laser (20 mW power, 904 nm Wavelength) and ultrasound (1.0 w/cm^2 power, 1 MHz frequency) are effective in the treatment of mild and moderate CTS patients.

1. Introduction

Carpal tunnel syndrome is the most common of all entrapment syndromes [1]. It affects the performance of daily living activities. Long-standing disease can produce irreversible damage, in the form of scarring or fibrosis, and loss of motor endplates, causing muscle atrophy [2]. Several standard treatments such as splints, local injection of corticosteroids, and surgical decompression are in use. Patients respond and benefits of either surgery or non-surgical treatment seem to be limited and there is no consensus about the best way to manage CTS [3]. Conservative management for CTS patients is frequently offered to those with mild to moderate symptoms [4,5,1] and may reduce the number of patients undergoing surgical intervention [4–6]. Surgical intervention is indicated in refractory cases or those do not respond to conservative treatment [7], or for advanced and chronic cases [1].

Among the different options for conservative treatment, low level laser therapy and ultrasound therapy have been used. Some studies found that low-level laser [8–10,3] and ultrasound therapy [6,11,12,3] may have the potential to induce biophysical effects in CTS patients. LLLT accelerates inflammation, promotes fibroblast proliferation in experimental and clinical models [13]. Experimentally, the histological and morphometric studies showed increasing nerve fiber density and increasing number of blood vessels on irradiated nerves [14].

The most common uses for US were to decrease soft tissue inflammation, increase tissue extensibility, enhance scar tissue remodeling, increase soft tissue healing, decrease pain, and decrease soft tissue swelling [15]. The present study was conducted to investigate and compare the efficacy of low level laser therapy versus ultrasound treatment on the pain, pinch grip, hand grip and electrophysiological measures of median nerve including DML, DSL, MCV, and motor amplitude of action potentials (AMP) of the median nerve in carpal tunnel syndrome patients.

Carpal tunnel syndrome (CTS) associated with diabetic neuropathy (DN) are common among diabetic patients [16].

Abbreviations: $\bar{x}$, mean; SD, standard deviation; MD, mean difference; t value, unpaired t value; *p* value, probability value; †, non-significant $P > 0.05$; VAS, Visual Analogue Scale; DML, Distal Motor Latency; DSL, Distal Sensory Latency; MCV, Motor Nerve Conduction Velocity; AMP, Amplitude

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2. Materials and methods

This was open label comparative prospective study was conducted using the facilities of the National Institute of Laser Enhanced Science, Cairo University, Egypt for two months.

2.1. Inclusion criteria

Patients diagnosed as Diabetic peripheral neuropathy (DPN) T2DM.

2.2. Exclusion criteria

- Patients with type 1 diabetes mellitus
- Patients with fractures and joint injuries
- Patients with other vascular abnormalities rather than diabetes mellitus.

2.3. Randomization method

Randomization has been done using simple randomization method by generating a random digit table as per *Pocock and Simon* method [17]. Based on generated numbers all even numbers enrolled in low level laser therapy group and odd numbers for ultrasound group.

2.4. Assessment tools

- Nerve conduction instrumentation (Neuropack, Jaban)
- Hand dynamometer (Hydraulic, Saehan, SH5001, Korea)
- Pinch dynamometer (Hydraulic Pinch gauge, Saehan, SH5005, Korea)
- Infrared laser:(Gymna, I.R, LASER 904 nm, Belgium)
- Ultrasound (Sonosan 100, Germany).

All the measurements were performed pre (at base line) and post treatment (at 6 weeks).

- Pain level was assessed using Visual analogue scale was, on which the patients could indicate their assessment along a 10 cm line ranging from 0 ('no pain at all') to 10 ('the most severe pain').
- Sensory and motor distal latency, median nerve motor amplitude and Conduction Velocity of median nerve were recorded using the nerve conduction studies (NCS) of the median nerves according to the recommendations of American Association of Electrodiagnostic Medicine, (2002).

The room temperature was maintained around 31 °C. For the motor nerve conduction studies, compound muscle action potentials amplitude were recorded with a pair of surface recording electrodes placed on the abductor pollicis brevis muscle. The stimulating electrodes were placed at the wrist proximal to carpal tunnel for the distal segment stimulation with a distance of 7 cm from the recording electrode, and at the elbow for the proximal segment stimulation. The distal motor latency was measured from the onset of the stimulating artifact to the onset of the compound muscle action potential. The nerve conduction velocity was also calculated to rule out any median nerve lesions such as polyneuropathy. In the study of sensory nerve conduction, a pair of ring electrodes was placed on the index finger for recording, and the sensory nerve was stimulated antidromically at the same site used for distal motor stimulation with a distance of 14 cm from the recording electrode. Sensory peak latency was measured from the stimulating artifact to the onset of the sensory nerve action potential.

According to the recommendations' of American Association of Electrodiagnostic Medicine [18], and based on the nerve conduction data, normal sensory distal latency of the median nerve was < 3.6 msec. The patients with mild CTS, only sensory NCS abnormalities (increased distal latency) were detected. In these patients, their sensory peak latency of the median nerve was > 3.6 msec, but the motor latency was < 4.5 msec [19], as it is the closest measurement obtained [20]. The patients with moderate CTS had both sensory and motor NCS abnormalities. Sensory peak latency of the median nerve was > 3.6 msec, and motor latency > 4.5 msec and < 7 msec [8]. The same physician conducted the NCS testing.

- Maximum grip strength was measured using a hand held dynamometer according to the American Society of Hand Therapist recommended position for grip strength measurement [21]. Grip strength was obtained by taking the average of 3 measurements of maximal contraction [22].
- Pinch strength was obtained using pinch gauge. The same steps were done as in the assessment of grip strength to assess pinch strength.

The two groups were treated 3 sessions weekly for 6 weeks with total of (18) sessions. All the patients were treated at the palmar area directly over the carpal tunnel as well as over the course of median nerve.

- Patients in group (A) received a program of IR Gallium Arsenide LLLT (904 nm wavelength, 20 mW average power, laser probe 7 mm diameter), an energy of 1.2 J per point at four points was applied, a tape measurement was used to locate each point, the first point applied over the carpal tunnel at midpoint at the level of the wrist 1 cm distal to the distal wrist crease, the second point was 0.5 cm medial to the first point, the third point was 0.5 cm lateral to the first point and the fourth one was 5 cm proximal to the distal wrist crease at the same line of the first point over the course of median nerve where the median nerve becomes superficial to the flexor digitorum superficialis muscle bellies [23]. Each point was treated for 60 s with a total application of 4.8 J and 360 s total time application. It was applied perpendicularly while the hand supinated, relaxed and supported well, and the wrist at the neutral position.
- While patients in group (B) received a program of US (1 MHz, 1.0 W/cm^2, pulsed mode 1:5, 15 min/session) with aquasonic gel as a couplant. It was transcutaneously applied on the same area as in group (A). It was applied perpendicularly with slow movement of the head of US while the hand supinated, relaxed and supported well, and the wrist at the neutral position.

2.5. Outcome

The main outcome of the present study was to investigate and compare between Low Level Laser Therapy (LLLT) and Ultrasound (US) efficacy in treatment of Carpal Tunnel Syndrome.

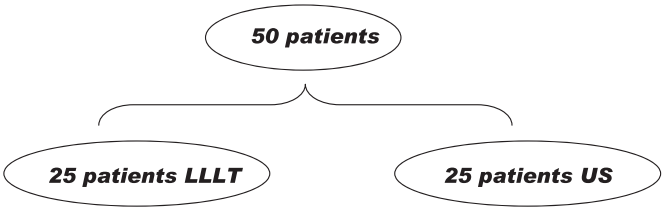
2.6. Statistical analysis

Data were collected, tabulated and statistically analyzed using Statistical Package for the Social Sciences (SPSS) v. 23. Descriptive analysis was done to show the mean of the assessed parameters, which expressed as mean ± SD. Data obtained from both groups pre and post treatment program (at 6 weeks) regarding, pain level, hand grip, pinch grip, DML, DSL, MCV, and motor amplitude of action potentials (AMP) of the median nerve were statistically analyzed and compared using independent sample *t*-test and paired sample *t*-test. Data was considered significant at $\alpha \leq 0.05$.

2.7. Power of the study and sample size

Sample size was calculated assuming 80% power to detect a 20% improvement in pain (VAS), with a standard deviation of 2 points and a significance level of 5%. The required sample would be 25 patients per group. Fifty patients diagnosed as unilateral carpal tunnel syndrome participated in the study. Their ages ranged from 25 to 55 years.

Patients subdivided randomly into two groups, each group consisted of 25 patients. Patients in group (A) received a program of IR Gallium Arsenide LLLT (wavelength 904 nm, average power 20 mW), while patients in group (B) received a program of US (frequency 1 MHz, power 1.0 W/cm^2, pulsed mode 1:5). They were referred from the hand surgery unit. Elsahel Teatching Hospital. The study was approved by the General Organization of the Teaching Hospitals committee and all the patients signed an informed consent. Patients with diabetes mellitus, rheumatoid arthritis, carpal bone fractures and wrist joint injuries or those who were treated with anti-inflammatory drugs or other treatments were excluded from the study.



3. Results

Regarding the age in both groups, the results of the present study showed that the age is ranging between 25 and 55 years, with a mean value of 38.08 ± 1.11 years and 39.56 ± 1.49 years for group A and group B respectively. Regarding the gender the results of our study showed that there were 40 female patients and 10 male among the fifty patients participated in the study, where there were 21 (84%) females and 4 (16%) males, were included in group A and 19 (76%) females and 6 (24%) males, were included in group B. Among the fifty patients; the affected hand was the right one in 22 (88%) of the patients and the left one in 3 (12%) of the patients for group A, The affected hand was the right one in 21 (84%) of the patients and the left one in 4 (16%) of the patients for group B. Comparing the general characteristics of the patients of both groups revealed that there was no significance difference between both groups in the mean age, sex distribution, or side of affection ($p > 0.05$). The results showed that there were no statistical significance differences ($P > 0.05$) were observed pre-treatment (at baseline) between the two groups for any of the measured parameters. The results showed that there were no statistical significance differences ($P > 0.05$) were observed post treatment (at 6 weeks) between the two groups for any of the measured parameters (Table 1) (Figs. 1–6).

Table 1
Comparison between assessment parameters at pre and post-treatment among group (A) and group (B).

	Group A		Group B	
	Mean ± SD	*P* value	Mean ± SD	*P* value
VAS pre	6.36 ± 1.6	0.0001	6.12 ± 1.6	0.0001
VAS post	1.76 ± 1.7		1.6 ± 1.7	
Hand grip (kg) pre	23.74 ± 5.65	0.0001	25.96 ± 5.7	0.0001
Hand grip (kg) post	26.76 ± 5.8		30.04 ± 6.8	
Pinch grip (pound) pre	6.41 ± 2	0.0001	7.1 ± 2.23	0.0001
Pinch grip (pound) post	7.7 ± 2.1		8.5 ± 2.3	
DML pre	5.48 ± 1	0.0001	5.45 ± 0.9	0.0001
DML post	5.07 ± 0.93		5.04 ± 0.8	
DSL pre	4.05 ± 0.4	0.05	3.97 ± 0.34	0.0001
DSL post	3.96 ± 0.4		3.83 ± 0.35	
MCV pre	54.76 ± 6.5	0.026	54.75 ± 6.1	0.283
MCV post	56.92 ± 5.4		55.89 ± 5.12	
AMP pre	7.91 ± 3.24	0.0001	9.52 ± 2.7	0.0001
AMP post	8.70 ± 3.2		10.21 ± 2.9	

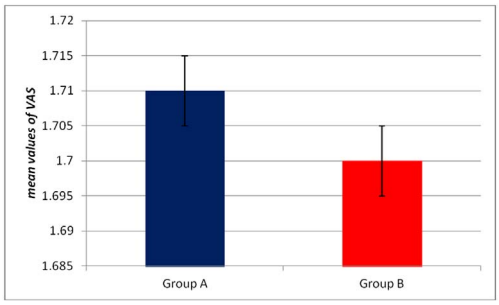


Fig. 1. Comparison between post treatments means values of VAS of group A and group B.

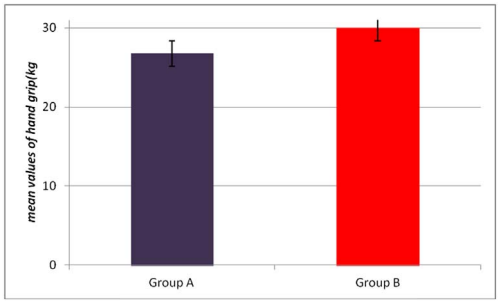


Fig. 2. Comparison between post treatment mean values of hand grip (kg) of group A and group B.

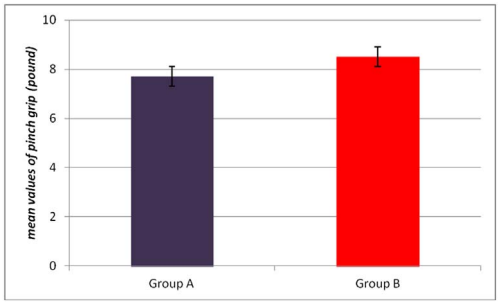


Fig. 3. Comparison between post treatment mean values of pinch grip (pound) of group A and group B.

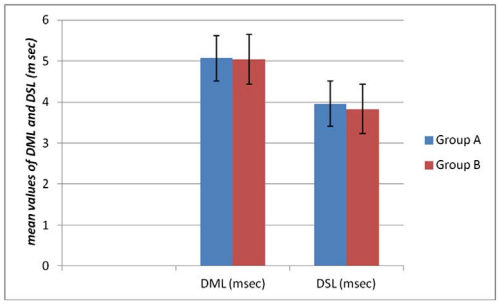


Fig. 4. Comparison between post treatment mean values of DML and DSL (msec) of group A and group B.

4. Discussion

It was the first study comparing the efficacy of low level laser (904 nm wavelength) and ultrasound (1.0 W/cm^2) using the advantage of application of treatment directly over the transverse carpal ligament, as well as over the course of the median nerve in the forearm simultaneously in carpal tunnel syndrome patients.

All the previous studies used low level laser or ultrasound either

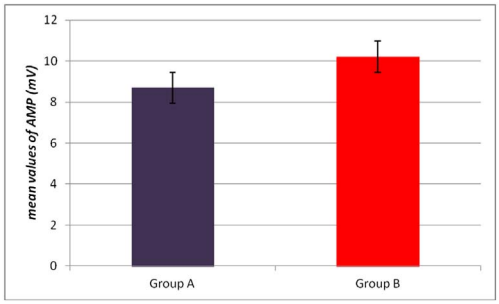


Fig. 5. Comparison between post treatment mean values of AMP (mV) of group A and group B.

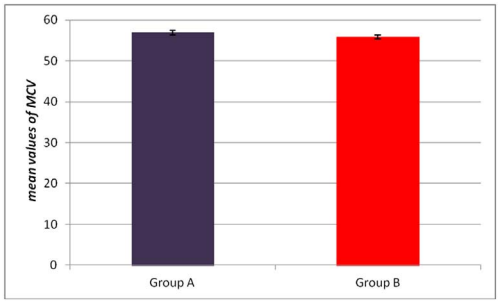


Fig. 6. Comparison between post treatment mean values of MCV of group A and group B.

directly over the transverse carpal ligament or over the course of the median nerve, either in the neck or in the forearm. Regarding the results of clinical measures including pain, pinch grip and hand grip, the results of the present study were in accordance with the results obtained by Elwakil et al. [1], regarding pain measure, they found that LLLT by Helium Neon laser (632.8 nm), 20 J/cm^2 showed significant results in in patients with CTS.

The results of the present study supported by the results obtained by Chang et al. [9] regarding hand grip measure, they used diode 830 nm, 60 mW, 9.7 J/cm^2 over the transverse carpal ligament. Also, Evcik et al. [24], investigated the effectiveness of the LLLT using diode 830 nm, 7 J per point for 2 min, statistically significant improvements were found regarding hand grip strength and pinch strength. On the other hand, Ilker et al. [25] compared the short term efficacy of splinting and splinting plus LLLT, diode 830 nm, 30 mW in mild and moderate idiopathic CTS patients. The dose over the median nerve at the level of the wrist area was 8.1 J/cm^2.

There were no improvements in clinical parameters including pain and tingling sensation using Boston Questionnaire. The conflicts of the results may be due to the ignorance of application of the treatment over the TCL. Also, a study conducted by Chang et al. [9] used 830 nm diode laser, 9.7 J/cm^2 found no improvement regarding grip and pinch strength in CTS patients. The contradictory results of this study with the results of the present study may be due to the limited time of follow up at 2 weeks of treatment. However, the results of the present study obtained after 6 weeks of treatment. Oztas et al. [26] compared the short term effects of continuous ultrasound treatment of different intensities (1.5 W/cm^2 or 0.8 W/cm^2).

It was found A significant difference regarding pain. Piravej and Boonhong [27] investigated and compared the efficacy of low intensity ultrasound 0.5 W/cm^2 in CTS patients, and those took Diclofenac 75 mg/day in divided doses. The ultrasound was applied 5 days a week for 4 weeks. There were statistically significant improvements ($p < 0.05$) regarding pain for both groups after treatment. This study supports the results of the present study, confirming the advantage of application of ultrasound over Diclofenac 75 mg without its adverse effects. Also, Bakhtiary and Rashidy [11] compared the efficacy of ultrasound 1 MHz, 1.0 W/cm^2 and LLLT 830 nm applied at five different points, at a dose of 1.8 J for each point, to the area innervated by the median nerve at the level of the wrist.

It was applied on the carpal tunnel for 15 daily treatment sessions (5 sessions/week). They found improvement regarding pain, pinch grip and hand grip. Regarding the results of electrophysiological measures of median nerve, the results of the present study were in accordance with the results obtained by Shooshtari et al. [10] they evaluated the effects of laser therapy using diode 830 nm (9–11 J/cm^2). They found significant improvements ($p < 0.001$) in NCS findings. DSL and DML were significantly decreased ($p < 0.001$), and sensory conduction velocity.

The results of the present study were in agreement with the results obtained by lker et al. [24] used diode 830 nm, 30 mW. It was concluded that laser therapy provided better outcomes regarding sensory nerve velocity, sensory and motor distal latencies and compound muscle action potentials amplitude. On the other hand, Ayse et al. [28] evaluated the effect of (LLLT) diode, power of 50 mW, 780 nm wavelengths. No significant difference was detected for electrophysiological parameters. The results were not in accordance with the results of the present study because all the patients included in this study were rheumatoid arthritis patients with CTS who are excluded in the present study.

A study conducted by Chang et al. [9] used 830 nm diode lasers, 9.7 J/cm2 and found no improvement regarding median NCS. The contradictory results of this study with the results of the present study may be due to the ignorance of application of the treatment over the course of the median nerve. Koyuncu et al. [29] compared the short term effects of ultrasound with different frequencies (1 MHz or 3 MHz) on pain, paresthesia, sensation, grasping ability, provocative tests (Phalen, Tinel) and peripheral nerve conduction in CTS patients. No significant effect of varying frequency of ultrasound delivery was demonstrated for any of the measured parameters.

The present study had the advantage of selection of 1 MHz frequency, as it consider more deep than 3 MHz frequency [30] so, it may reach deep to the site of the median nerve. The results of the present study was supported by a study done by Bakhtiary and Rashidy [11] they compared the efficacy of ultrasound 1 MHz, 1.0 W/cm^2 and LLLT 830 nm applied at five different points, at a dose of 1.8 J for each point, to the area innervated by the median nerve at the level of the wrist. It was applied on the carpal tunnel for 15 daily treatment sessions (5 sessions/week). There was a significant difference in both groups for DML, motor action potential amplitude, but improvement was significantly more pronounced in the ultrasound group than in low level laser therapy group.

The results of the present study was supported by Dincer et al. [3] compared splinting, splinting plus ultrasound, and splinting plus low level laser therapy found that the combinations of the ultrasound, and low level laser therapy with splinting seems more effective than only splinting in the CTS treatment. On the other hand, Oztas et al. [26] did not find any significant difference from using ultrasound treatment of different intensities (1.5 W/cm^2 or 0.8 W/cm^2) on median nerve conduction study. The conflicts of the results of this study with the results of the present study may be due to selection of continuous wave with its pro inflammatory response [31]. However, the present study had the advantage of selection of pulsed mode with its positive effects on tissue regeneration [32].

5. Conclusion

It was concluded that both low level laser (904 nm Wavelength) and ultrasound (1.0 w/cm^2) are effective in the treatment of mild and moderate CTS patients.

Ethical consideration

The study was approved by the appropriate regulatory authorities

and institutional review board/ethics committees for each center and was performed in accordance with the ethical standards contained in the 1964 Declaration of Helsinki. Signed, informed consent was obtained from all patients before study enrollment.

Transparency document

The http://dx.doi.org/10.1016/j.bbacli.2017.07.001 associated with this article can be found in the online version.

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