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Efficacy of Low Power Laser Therapy in Fibromyalgia: A Single-blind, Placebo-controlled Trial

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Abstract. Low energy lasers are widely used to treat a variety of musculoskeletal conditions including fibromyalgia, despite the lack of scientific evidence to support its efficacy. A randomised, single-blind, placebo-controlled study was conducted to evaluate the efficacy of low-energy laser therapy in 40 female patients with fibromyalgia. Patients with fibromyalgia were randomly allocated to active (Ga-As) laser or placebo laser treatment daily for two weeks except weekends. Both the laser and placebo laser groups were evaluated for the improvement in pain, number of tender points, skinfold tenderness, stiffness, sleep disturbance, fatigue, and muscular spasm. In both groups, significant improvements were achieved in all parameters ($p<0.05$) except sleep disturbance, fatigue and skinfold tenderness in the placebo laser group ($p>0.05$). It was found that there was no significant difference between the two groups with respect to all parameters before therapy whereas a significant difference was observed in parameters as pain, muscle spasm, morning stiffness and tender point numbers in favour of laser group after therapy ($p<0.05$). None of the participants reported any side effects. Our study suggests that laser therapy is effective on pain, muscle spasm, morning stiffness, and total tender point number in fibromyalgia and suggests that this therapy method is a safe and effective way of treatment in the cases with fibromyalgia.

Keywords: Fibromyalgia; Low power laser therapy

INTRODUCTION

Low power lasers have been used for 30 years to lessen pain and speed healing. Even though treatments do not elevate tissue temperatures more than a few tenths of a degree, laboratory studies find irradiation stimulates collagen production, alters DNA synthesis, and improves the function of damaged neurological tissue. Unfortunately, extension of these effects to humans is far less convincing. Although this laser therapy is available in many parts of the world, it has yet to receive Food and Drug Administration (FDA) approval for any indication [1,2].

Laser therapy has achieved popularity in the media in recent years. Laser surgical devices have been approved by the FDA and are heavily promoted, but laser devices have not been approved for the treatment of musculoskeletal pain syndromes [3].

Laser treatment is widely used in clinical medicine as a therapeutic tool. Earlier, it was used in surgery and ophthalmology, but recently, a growing interest has focused on its possible influence in relieving pain [4,5]. However, the mechanism for this action remains obscure [6,7]. It is suggested that prolonged laser exposure may produce photochemical reactions which alter neuronal activity, since low-power laser causes no thermal changes [8,9]. Still, the efficacy of this treatment method is controversial. Airaksinen et al. [10] have published preliminary results of the laser irradiation effects at trigger points.

Low energy lasers are now used to treat a variety of musculoskeletal conditions including fibromyalgia, despite the lack of scientific evidence to support its efficacy. A randomised, single-blind, placebo-controlled study was conducted to evaluate the efficacy of low-energy laser therapy in patients with fibromyalgia. The purpose of this study was to examine the

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effectiveness of laser therapy in patients with fibromyalgia. The low-power gallium-arsenide (Ga-As) infrared laser is ideally suited for a single-blind study since the laser light is invisible and emits no heat or other physically detectable indication when it is activated.

PATIENTS AND METHODS

Forty female patients with fibromyalgia, recruited from the Department of Physical Therapy and Rehabilitation, University Hospital of Dicle, Diyarbakir, Turkey, were randomly allocated to active (Ga-As) laser or placebo laser treatment. All procedures were approve by the Human Studies Research Committee of the University of Dicle, Diyarbakir, and written informed consent was obtained from each subject prior to inclusion in the study.

They were randomly assigned to either an Actual Laser Group ($n=20$) or a Placebo Laser Group ($n=20$) by drawing 1 of 40 envelopes labelled 'A' (treatment), or 'B' (placebo). Fibromyalgia patients fulfilled the American College of Rheumatology (ACR) criteria for fibromyalgia [11]. These criteria include: (a) a history of widespread pain for at least 3 months, i.e. pain in the left side of the body, pain in the right side of the body, pain above and below the waist, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back pain); and (b) the presence of at least 11 tender point sites (measurements performed using a digital pressure device a force of 4 kg): occiput L or R, low cervical L or R, trapezius L or R, supraspinatus L or R, second rib L or R, lateral epicondyle L or R, gluteal L or R, greater trochanter L or R and knee L or R.

Major clinical conditions other than fibromyalgia were excluded by physical examinations and routine blood cells and differentials, red blood cells, haematocrit and haemoglobulin, baseline thyroid-stimulating hormone and antinuclear autoantibodies.

Furthermore, exclusion criteria for fibromyalgia patients and normal controls were: (a) a recent or past history of psychiatric disorders, e.g. major depressive disorder, alcohol dependence, substance abuse, schizophrenic or paranoid disorder, personality disorders, and somatoform disorders; (b) immunocompromised subjects; (c) subjects with neurological, inflammatory, endocrine or clinically significant chronic disease, such as diabetes mellitus, rheumatoid arthritis, inflammatory bowel disease, and organic brain disorders; (d) abnormal liver function tests, such as serum aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and γ-glutamyl transpeptidase; and (e) pregnancy.

All subjects were free from any infections, inflammatory or allergic reactions for at least 2 weeks prior to the blood sampling and free of drugs known to affect immune or endocrine functions and of hormonal preparations. All patients were free of any medications for at least one month.

The patients were treated for 3 min at each tender point daily for two weeks, except weekends, at the same time in the afternoon in a sitting position, and at a temperature of 20°C. A stimulation time of 3 min was used at each tender point, producing an energy density (radiant exposure) at each point of approximately 2 J/cm^2. Two physical therapy investigators used a standard technique, with a Ga-As laser (20 W maximum output per pulse, 904 nm, 200 ns maximum pulse duration, 2.8 kHz pulse frequency, so 11.2 mW average power, and 1 cm^2 surface, class III b Laser Product, Frank Line IR 30, Fysiomed, Belgium). The same unit was used for the placebo treatment, for which no laser beam was emitted.

Both the laser and placebo laser groups were evaluated for the improvement in pain, number of tender points, skinfold tenderness, morning stiffness, sleep disturbance, muscular spasm and fatigue. An ordinal Likert scale scoring system for grading the severity of all outcome parameters as pain intensity, skinfold tenderness, morning stiffness, sleep disturbance, muscle spasm and fatigue was used: no (0), mild (1), moderate (2), severe (3), extreme (4) [12].

Statistical Analysis

Statistical analysis were done by SPSS 8.0 PC program. The results are expressed as means ± standard deviation. Statistical significance was tested using the Wilcoxon test for paired observations and Mann–Whitney U test for two different group comparisons. The level of statistical significance was set at a two-tailed α-value of 0.05.

Table 1. Comparisons of clinical outcomes before and after therapy in laser and placebo laser therapy groups

	Actual laser ($n=20$)		Placebo laser ($n=20$)	
	Before therapy	After therapy	Before therapy	After therapy
Pain	3.09 ± 0.52^a	1.27 ± 0.76^c	3.48 ± 0.8^b	2.44 ± 0.98
Skinfold tenderness	2.18 ± 0.95^a	0.90 ± 0.5	2.10 ± 0.71	1.33 ± 1.37
Muscle spasm	2.27 ± 0.45^a	0.81 ± 0.73^c	2.3 ± 0.47^b	1.33 ± 0.68
Morning stiffness	2.54 ± 0.8^a	1.09 ± 0.92^c	2.7 ± 0.86^b	2.01 ± 0.8
Tender point number	13.18 ± 2.3^a	6.63 ± 3.86^c	12.7 ± 0.71^b	8.55 ± 4.11
Sleep disturbance	2.36 ± 1.25^a	1.27 ± 1.07	1.7 ± 1.12	1.66 ± 1.60
Fatigue	3.09 ± 0.81^a	1.36 ± 1.17	2.10 ± 0.71	2.04 ± 1.09

Values are mean ± standard deviation for all variables; where no superscript appears, there is no significant difference.
[a]Significantly different from clinical outcome after actual therapy (Wilcoxon paired sample test; $p<0.05$).
[b]Significantly different from clinical outcome after placebo laser therapy (Wilcoxon paired sample test; $p<0.05$).
[c]Significantly different from clinical outcome after placebo laser therapy (Mann–Whitney U test; $p<0.05$).

RESULTS

In both groups, significant improvements were achieved in all outcome parameters ($p<0.05$) except sleep disturbance, fatigue and skinfold tenderness in the placebo laser group ($p>0.05$).

It was found that there was no significant difference between the two groups with respect to all parameters before therapy whereas a significant difference was observed in parameters as pain, muscle spasm, morning stiffness and tender point numbers in favour of laser group after therapy ($p<0.05$) (Table 1).

No patient in either group reported discomfort related to the laser or placebo therapy, and no patient complained of an increase in outcome parameters at the conclusion of the study.

DISCUSSION AND CONCLUSION

One of the most fascinating developments within the field of electrotherapy in recent years has been the introduction of low-power lasers. Since then, laser has become a popular treatment modality, principally in the Soviet Union and the Far East, where it has found a rang of applications. Consequently, acceptance of this new modality is currently limited.

Literature searches failed to provide a coherent picture of current clinical practice on which to base future research. One of the main problems was the wide variation in treatment regimes employed, principally in terms of such parameters as wavelength, power output and pulse frequency. Additionally, the majority of published papers were in Russian, often with no English abstract.

Superficial laser therapy was described by Kleinkort and Foley [13] as potentially useful in managing chronic pain syndromes, including chronic myofascial pain. They recommended that laser radiation be applied to acupuncture points and suggested that laser therapy was actually a form of needleless acupuncture. Seitz and Kleinkort [14] devoted an entire chapter in a physical therapy text to laser therapy and advocated its use for wound healing and pain management. Bischko [15] described early work with laser acupuncture in 1979 and concluded that the effect of the laser beam was similar to needle acupuncture, was painless and safe, and had the advantage of sterility. Kleinkort and Foley [13] indicated, after three years experience using laser therapy, that 'laser stimulation is markedly more effective in acute and chronic pain than electrical acupuncture point stimulation in the great majority of cases'. Basford [16] pointed out that although a 'wide variety of painful syndromes have been treated with low-energy laser (usually He-Ne or Ga-As as the laser source) with claims of success, the written reports are inadequate to establish, with any certainty, the effectiveness of the treatments'. Basford [16] also noted that most of the reports are simply 'case reports of individuals with

chronic refractory pain, who with laser treatment, were rapidly relieved of pain and restored to an active useful life'.

The infrared gallium–aluminium–arsenide and the visible helium–neon lasers are the most frequently used low-power lasers in the United States. The reason for this preference seems to be a combination of ease of use, broader experimental background, low cost and wide availability [17].

Although the substantiation of results has varied greatly in detail and quality, many investigators have described successful treatment of a wide variety of painful musculoskeletal, rheumatological and neurological conditions with low-energy lasers. For example, Walker [8], Krotlinger [18], and Calderhead et al. [19] reported dramatic effects from laser treatment of osteoarthritis. Despite the differences in techniques and number of patients, all three investigations revealed that 70–80% of the treated patients reported substantial benefits. Walker [8] reported success with laser irradiation in relief of chronic pain. The pain reduction was accompanied by an increase in the urinary excretion of 5-hydroxyindolacetic acid, or by-product of serotonin. Subsequently, she concluded that laser irradiation may have an effect on serotonin metabolism, thereby serving as a mechanism of pain suppression. A double-blind study by Snyder-Mackler and Bork [20] determined that He-Ne laser treatment increased the distal sensory latency (corresponding to a decrease in the sensory nerve conduction velocity) of the superficial radial nerve in humans. They hypothesised that this increase in sensory latency could be a mechanism for pain reduction, and therefore He-Ne laser may be a beneficial analgesic modality.

Walker also described the benefits of laser therapy in 19 of 26 chronic pain patients (multiple diagnoses), with no response in ten control patients with similar diagnoses who received only placebo therapy. McAuley and Ysla [21,22], in a pair of double-blind studies on laser therapy, failed to show any benefit in treating carpal tunnel syndrome pain or osteoarthritic pain by using low-power laser stimulation. Goldman et al. [23] reported that 20 of 21 rheumatoid arthritis patients noted improvement of proximal interphalangial (PIP) joints, and 26 of 30 noted improvement of metacarpophalangial (MCP) joints as the result of laser therapy in a study that also used sham laser therapy.

It is important to remember that the literature on low-energy laser studies is uneven and disorganised. Future work may show that results now in apparent conflict are actually different aspects of the same problem. For example, it seems reasonable that various tissues with dissimilar absorption spectra could respond differently to diverse stimulating frequencies. In addition, discrepancies in energy dosages, treatment techniques (for example, irradiating a single point or sweeping), and treatment schedules may be important enough to complicate evaluation [24,25].

In a study by Longo et al. [26], diodes and CO_2 lasers are used in fibromyalgia patients and indicate that there are greater advantages in the use of laser over other presently available methods.

Laser irradiation has a demonstrable effect in vitro on both metabolism and surface charges on cells in culture, but the ultrastructure is unchanged [27]. Research studies of the effects of low-power laser irradiation on biological function are growing in number and scope. Although many experiments show alleviation of pain, the quality of the investigations, the number of subjects, and the varied techniques frequently preclude statistical verification. Although some investigators have claimed to find 'systemic' rather than simply 'local' effects, many studies fail to show either local or systemic benefit. Currently, no universally accepted theory has explained the mechanism of either 'laser analgesia' or laser 'biostimulation'. Although a theoretical understanding is unnecessary to establish benefit, the lack of knowledge complicates the evaluation of conflicting results [17].

There are many open questions. What is the real mechanism of the treatment? What is the correct dosage per point? We know that the penetration of the skin differed between Ga-As and He-Ne lasers. Most of the energy is absorbed in the first 2 mm. Also there are differences in the technology and in the devices, and differences between the geometry of the laser beam, the divergence of the beam and the system of collimation of the diode laser equipment. Because of the large number of positive reports and the innocuous nature of the treatments, further clinical evaluation of laser therapy is warranted.

In conclusion, our study suggests that laser therapy is effective on pain, muscle spasm, morning stiffness, and total tender point number in fibromyalgia and suggests that this

therapy method is a safe and effective way of treatment in the cases with fibromyalgia. The present study suggests that the low power laser therapy (Ga-As) can be used as monotherapy or as a supplementary treatment to other therapeutic procedures for pain treatment in fibromyalgia.

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