

The effect of gallium arsenide aluminum laser therapy in the management of cervical myofascial pain syndrome: a double blind, placebo-controlled study

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Abstract The efficacy of low-level laser therapy (LLLT) in myofascial pain syndrome (MPS) seems controversial. A prospective, double-blind, randomized controlled trial was conducted in patients with chronic MPS in the neck to evaluate the effects of low-level 830-nm gallium arsenide aluminum (Ga–As–Al) laser therapy. The study group consisted of 64 MPS patients. The patients were randomly assigned into two groups. In group 1 ($n=32$), Ga–As–Al laser treatment was applied over three trigger points bilaterally for 2 min over each point once a day for 15 days during a period of 3 weeks. In group 2 ($n=32$), the same treatment protocol was given, but the laser instrument was switched off during applications. All patients in both groups performed daily isometric exercise and stretching exercises for cervical region. Parameters were measured at baseline and after 4 weeks. All patients were evaluated with respect to pain (at rest, movement, and night) and assessed by visual analog scale, measurement of active range of motion using an inclinometer and a goniometer, and the neck disability index. In both groups, statistically significant improvements were detected in all outcome measures compared with baseline ($p<0.05$). However, no significant differences were obtained between the two groups ($p>0.05$). In conclusion, although the laser therapy has no superiority over placebo groups in this study, we cannot exclude the possibility of effectivity with another treatment regimen including different laser wavelengths and dosages (different intensity and density and/or treatment interval).

Keywords Cervical myofascial pain syndrome · Low-level laser therapy

Introduction

Myofascial pain syndrome (MPS) is one of the most frequent causes of chronic musculoskeletal pain. It is characterized by an intense and deep pain originating from one or more skeletal muscles and their fasciae. It is characterized by the presence of one or more hypersensitive sites in the involved muscles referred to as myofascial trigger points [1, 2]. The pressure stimulation of this point causes intense pain in terms of both local pain and referred pain. The trigger point is the most sensitive spot in a taut band where the muscle appears as a tight and rigid structure upon manual palpation. Also, limited mobility, weakness, and referred pain are associated with MPS [3].

Neck and upper back pain is the most common complaint in MPS because of the involvement of trapezius muscle in most cases [4]. The prevalence of this syndrome has shown a dramatic increase in recent years, and it is known to rank high among the other causes of musculoskeletal pain [5].

The pathophysiology of MPS is largely unknown. Thus, numerous therapeutic approaches have been used with varying success rates (maybe some of them have no efficacy) and can be categorized into pharmacologic and nonpharmacologic treatments [2]. Pharmacologic therapies include injection of local anesthetic or saline [6], botulinum toxin [7–9], nonsteroidal antiinflammatory drugs (NSAIDs) [10, 11], antidepressants, benzodiazepine, tramadol, anticonvulsives, and α_2 -adrenergic agonists [12]. Nonpharmacologic group comprises dry needling [13], physiotherapy and rehabilitation [14], ultrasound therapy, transcutaneous electrical nerve stimulation [15], relaxation techniques, acupunc-

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ture [16], stretching exercise [17], mesotherapy, massage therapy [18], and low-level laser therapy (LLLT) [19].

In physical therapy modalities, LLLT is one of the most recently employed treatments. LLLT has been applied in several rheumatoid and soft-tissue disorders with varying rates of success [20–22]. However, the efficacy of LLLT in MPS seems controversial [23, 24]. In this study, we planned to evaluate the effects of low-level 830-nm gallium arsenide aluminum (Ga–As–Al) laser therapy in patients with chronic MPS in the neck region.

Materials and methods

The study group consisted of 64 cervical MPS patients with an age range of 20–60 years. Patients with pathological finding in blood count, urinalysis, sedimentation, or cervical X-ray were excluded from the study. Also, patients who had physical therapy program and who were injected into the trigger points with or without local anesthetics within 6 months were excluded. Diagnosis of cervical MPS was based on the following criteria (to make the clinical diagnosis of MPS, five major criteria and at least one of three minor criteria is needed), as suggested by Simons [25]:

Major criteria:

1. Regional pain complaint in the neck
2. Pain complaint or altered sensation in the expected distribution of referred pain from a myofascial trigger point
3. Taut band palpable in an accessible muscle
4. Exquisite spot tenderness at one point along the length of the taut band
5. Some degree of restricted range of motion (ROM) when measurable

Minor criteria:

1. Reproduction of clinical pain complaint, or altered sensation, by pressure on the tender spot
2. Elicitation of a local twitch response by transverse snapping palpation at the tender spot or by needle insertion into the tender spot in the taut band
3. Pain alleviated by elongating (stretching) the muscle or by injecting the tender spot (trigger point)

All patients were instructed not to take NSAIDs or any other analgesic during the treatment and control periods.

Patients were randomly assigned to two treatment groups (randomization was allocated by using numbered envelopes method). An infrared (the low-level laser) Ga–As–Al diode laser device (Maestro CCM, Medicom, Czeck) with a wavelength of 830 nm and a maximum power output of 450 mW was used for the treatment. In group 1 ($n=32$), Ga–

As–Al laser was applied over three trigger points bilaterally with a frequency of 1,000 Hz for 2 min over each point once a day for 15 days during a period of 3 weeks. Laser device was used with a power output of 58 mW/cm² by a pulse frequency of 1,000 Hz. A 2-min irradiation at each point was considered as one irradiation dose. The dose per point was 7 J. The total dose per treatment was 42 J, and the accumulated dose for 15 treatments was 630 J. We estimated the depth of myofascial trigger points, which was approximately on 1 cm. The laser probe (1 cm diameter) was applied directly and perpendicularly to and in slight contact with the skin. In group 2 ($n=32$), the same treatment protocol was given, but the laser instrument was switched off during applications. All patients in both groups performed daily isometric exercise and stretching exercises for cervical region under the supervision of a physiotherapist. LLLT continued daily for 3 weeks (15 sessions). All laser applications were performed by the same physiotherapist.

Before the treatment, one of the physicians evaluated the clinical assessment parameters. Posttreatment outcome measures were assessed by another physician, and both of them were blinded to the treatments. Only the physiotherapist who did not join the study was aware of the therapy and applied it to the patients. So both the patient and the evaluator were blinded, while the therapist was not blinded. Parameters were measured at baseline and after 4 weeks. All patients were evaluated with respect to pain, cervical active ROM, and functional disability.

Pain was assessed at rest, at movement, and at night by using a 10-cm-long visual analog scale (VAS) (0 means no pain while 10 means worst pain). Active ROM (cervical flexion extension, lateral flexion and rotation) was measured by using an inclinometer and a goniometer. Smallest detectable difference of measurements on the inclinometer and the goniometer was 1°.

The neck disability index (NDI) was used to measure the changes in functional disability. The NDI has become a standard instrument for measuring self-rated disability due to neck pain and is used by clinicians and researchers alike. Each of the 10 items is scored from 0 to 5. The maximum score is therefore 50. The obtained score can be multiplied by 2 to produce a percentage score. Also, in this study, the obtained score was multiplied by 2 [26].

Informed consent was obtained before the examination, and approval for the study was granted by the local ethical committee of the university.

Statistical analysis

All parametric results were expressed as mean±SD for each group. The baseline and the mean values of the percentage

changes calculated for both groups were compared by using the independent sample *t* test. To determine the differences before and after the treatment for all groups, paired *t* test was used.

The chi-square test was used for comparison of categoric variables. Local statistical significance was assumed as $p < 0.05$ for all parameters.

Results

All patients completed the study, and no side effect was observed. Demographic features and pretreatment values of the groups were detailed in Table 1. There were no statistically significant differences in pretreatment parameters between the groups ($p > 0.05$).

At the end of the therapy (week 4), both groups showed significant improvement for all parameters. The results and statistical comparisons of the pretreatment (week 0) and posttreatment (week 4) evaluation of laser group and placebo laser group are summarized in Tables 2 and 3.

Comparison of the percentage changes 4 weeks after the treatment relative to pretreatment values did not show a significant difference between the two groups (Table 4) ($p > 0.05$).

Discussion

LLLT has been a wide spectrum of applications in medicine. During the previous decades, attention has been focused on the effects of laser photostimulation on a variety of pathological conditions including wounds, musculoskel-

Table 1 Demographic features and pretreatment values (mean±standard deviation) for evaluation parameters of both groups

	Laser group (n=32)	Placebo laser group (n=32)	<i>p</i>
Age (years)	40.8±10.4	40.0±12.2	0.719
Sex (F/M)	27/5	28/4	0.775
Pain at rest (VAS) (cm)	4.1±1.9	4.2±2.2	0.900
Pain at movement (VAS) (cm)	6.0±2.0	5.1±2.0	0.074
Pain at night (VAS) (cm)	4.9±2.5	3.9±2.8	0.147
Flexion (°)	58.2±9.8	58.9±9.9	0.788
Extension (°)	59.9±9.9	62.7±11.4	0.288
Right lateral flexion (°)	42.0±5.3	42.3±4.2	0.806
Left lateral flexion (°)	42.3±4.8	42.5±4.2	0.954
Right rotation (°)	78.9±5.0	76.7±5.5	0.571
Left rotation (°)	77.5±5.0	75.7±9.1	0.261
Neck disability index	29.4±12.1	30.8±13.4	0.430

ROM Range of motion, VAS visual analog scale, F female, M male, °degree

Table 2 The results (mean±standard deviation) and statistical comparisons of the pretreatment (week 0) and posttreatment (week 4) evaluation parameters in laser group (group 1)

Laser group	Pretreatment (n=32)	Posttreatment (n=32)	<i>p</i>
Pain at rest (VAS) (cm)	4.1±1.9	3.2±2.5	0.014*
Pain at movement (VAS) (cm)	6.0±2.0	3.9±2.5	0.000**
Pain at night (VAS) (cm)	4.9±2.5	2.6±2.4	0.000**
Flexion (°)	58.2±9.8	65.7±7.2	0.000**
Extension (°)	59.9±9.9	66.7±10.9	0.001*
Right lateral flexion (°)	42.0±5.3	43.4±3.9	0.035*
Left lateral flexion (°)	42.3±4.8	44.8±4.4	0.028*
Right rotation (°)	78.9±5.0	81.4±4.1	0.040*
Left rotation (°)	77.5±5.0	81.4±4.1	0.000**
Neck disability index	29.4±12.1	18.8±10.9	0.000**

* $p < 0.05$

** $p < 0.001$

VAS Visual analog scale, °degree

etal complications, and pain controls [27]. Clinical studies have shown LLLT to be as effective as analgesics and to accelerate the healing of injured tissue and, having recently been adopted in North America, is a noninvasive therapy that was added to medicine and physiotherapy in the treatment of rheumatoid arthritis and osteoarthritis for joint pain control and functional improvement. There has been an increasing recognition that the bioeffect of low-power laser is not thermal but related rather to photochemical cellular reactions mediated by photochemical actions at the cellular level in animal and human tissues [28, 29].

There is still a debate on the analgesic effect of laser, and its mechanism of action is not clear. One explanation has focused on the systemic effect of laser, which may alter the

Table 3 The results (mean±standard deviation) and statistical comparisons of the pretreatment (week 0), and posttreatment (week 4) evaluation parameters in placebo laser group (group 2)

Placebo laser group	Pretreatment (n=32)	Post-treatment (n=32)	<i>p</i>
Pain at rest (VAS) (cm)	4.2±2.2	3.2±2.3	0.023*
Pain at movement (VAS) (cm)	5.1±2.0	3.5±2.4	0.001*
Pain at night (VAS) (cm)	3.9±2.8	2.2±2.7	0.000**
Flexion (°)	58.9±9.9	65.2±6.3	0.001*
Extension (°)	62.7±11.4	69.7±10.5	0.000**
Right lateral flexion (°)	42.3±4.2	43.9±2.8	0.005*
Left lateral flexion (°)	42.5±4.2	44.5±3.5	0.002*
Right rotation (°)	76.7±5.5	80.3±3.8	0.000**
Left rotation (°)	75.7±9.1	79.3±4.7	0.014*
Neck disability index	30.8±13.4	23.7±12.9	0.020*

* $p < 0.05$

** $p < 0.001$

VAS Visual analog scale, °degree

Table 4 Comparison of the two groups on the basis of the posttreatment (week 4) percentage changes and difference scores relative to pretreatment (week 0) values

	Laser group (n=32)	Placebo laser group (n=32)	<i>p</i>
Pain at rest (VAS) (cm)	-0.24±0.20	-0.16±0.18	0.388
Pain at movement (VAS) (cm)	-0.34±0.14	-0.29±0.19	0.671
Pain at night (VAS) (cm)	-0.42±0.21	-0.42±0.15	0.974
Flexion (°)	0.14±0.07	0.14±0.06	0.883
Extension (°)	0.13±0.08	0.11±0.05	0.707
Right lateral flexion (°)	0.04±0.09	0.04±0.08	0.872
Left lateral flexion (°)	0.03±0.09	0.05±0.08	0.463
Right rotation (°)	0.06±0.07	0.04±0.06	0.686
Left rotation (°)	0.04±0.06	0.05±0.03	0.689
Neck disability index	-0.26±0.18	-0.18±0.21	0.177

VAS Visual analog scale, ROM range of motion, °degree

sensorial input to the central nervous system and decrease the perception of localized pain in the treated area [29]. Other researchers have suggested a mechanism which includes the secretion of endogenous opioids, like as in acupuncture and transcutaneous electrical nerve stimulation, leading to clearance of the algescic substances via stimulation of the microcirculatory system [30, 31].

LLLT has been used to control pain in different musculoskeletal conditions. Despite its widespread use, the results of the experimental and clinical studies are conflicting. The results of some placebo-controlled studies suggest that low-power laser treatment may be useful for reducing the pain in cervical osteoarthritis [32], medial and lateral epicondylitis [33], and MPS [19, 34]. On the other hand, a number of placebo-controlled, randomized double-blind studies have not been able to demonstrate any significant or convincing, clinically relevant effects over placebo in the treatment of cervical MAS [24, 35], lateral epicondylitis [36], rotator cuff tendinitis [37], and rheumatoid arthritis [38]. The results of our study showed no superiority of Ga–As–Al laser plus exercises over placebo laser plus exercise in the treatment of MPS, though improvement was observed in both groups.

Similarly, at the end of the treatment, both groups showed significant improvement for NDI. However, the differences between groups were not statistically significant. Significant improvement in these parameters may seem to be attributable to exercise more than the laser therapy. Treatment of myofascial pain requires the inactivation of trigger points, the restoration of normal muscle length, and the elimination or correction of the factors that created or perpetuated the trigger points. Stretching exercises comprise a basic treatment approach in myofascial pain and are known to allow restoration of normal activity by gradually decreasing the

muscle tightness and shortening, thereby eliminating pain [4, 39, 40].

Myofascial trigger points can be inactivated by inserting a needle into the trigger point. Properly, a local twitch response occurs, and then the taut band relaxes, and tenderness diminishes or sometimes disappears [41]. Also, the effects of laser therapy on trigger points may resemble this inactivation process. It may be postulated that laser may activate somatosensory receptors and decrease the perception of localized pain, which cause the relaxation of taut band. However, this hypothesis may not work if there is deeper lying trigger points. One of the reasons of our negative results may be due to the presence of deeper lying trigger points.

In this study, we found no statistical difference between the laser and placebo groups in all outcome measures after 15 treatments or follow-up. This may be related to various factors. Different lasers may have different effectiveness in different diagnoses and parameters such as wavelength, duration of treatment, energy density, and number of treatments, and mode of delivery may be important [42]. In the evaluation of a therapy, it is often difficult to determine the optimal dosage and treatment schedule. For laser therapy, the minimal effective dosage is in most cases unknown. An additional problem is which wavelength will be optimal [43]. There is little evidence in the literature giving clues to the optimal dosage of laser energy with regard to intensity, frequency, wavelength, and peak pulse on the one hand and to the various pathological conditions on the other hand [21].

In conclusion, no statistical difference between the treatment and the placebo groups could be determined. Although no statistically significant differences were obtained between the laser and placebo groups, it is difficult to exclude the possibility of efficacy with another treatment regimen. Further studies employing different laser wavelengths and dosages (different intensity and density and/or treatment interval) are necessary to investigate the effect of laser therapy in MPS.

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