Effect of Diode Laser in the Treatment of Patients with Nonspecific Chronic Low Back Pain: A Randomized Controlled Trial

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Abstract

Background data: Low back pain is a common, highly debilitating condition, whose severity is variable. This study evaluated the efficacy of treatment with Ga-Al-As diode laser (980 nm) with a large diameter spot (32 cm²), in association with exercise therapy, in reducing pain. Objective: The present study aimed to evaluate the pain reduction efficacy of treatment with the Ga-Al-As diode laser (980 nm) in combination with exercise therapy, in patients with chronic low back pain (CLBP). Methods: This study evaluated 100 patients with CLBP (mean age 60 years) who were randomly assigned to two groups. The laser plus exercises group (Laser + EX: 50 patients) received low-level laser therapy (LLLT) with a diode laser, 980 nm, with a specific handpiece [32 cm² irradiation spot size, power 20 W in continuous wave (CW), fluence 37.5J/cm², total energy per point 1200 J] thrice weekly, and followed a daily exercise schedule for 3 weeks (5 days/week). The exercises group (EX: 50 patients) received placebo laser therapy plus daily exercises. The outcome was evaluated on the visual analogue pain scale (VAS), before and after treatment. Results: At the end of the 3 week period, the Laser + EX group showed a significantly greater decrease in pain than did the EX group. There was a significant difference between the two groups, with average Δ VAS scores of 3.96 (Laser + EX group) and 2.23 (EX group). The Student’s t test demonstrated a statistically significant difference between the two groups, at p < 0.001. Conclusions: This study demonstrated that the use of diode laser (980 nm) with large diameter spot size, in association with exercise therapy, appears to be effective. Such treatment might be considered a valid therapeutic option within rehabilitation programs for nonspecific CLBP.

Introduction

Chronic low back pain (CLBP) was defined by van Tulder in 1998 as pain in the lumbosacral area of the spine of >12 weeks’ duration, which may or not have the characteristics of limiting the patient’s range of movements.1 The etiopathology of this form of pain is not specific; however, it is often related to disc degeneration or other spinal disorders. It is a major cause of morbidity and affects 80–85% of people at some time during their lifetime.2 The severity of symptoms is variable; some are self-limiting, others require therapy, and others again require emergency room treatment.

The main goal of CLBP therapy is rarely the complete eradication of pain. Because of the etiopathology of this disorder, there may be many underlying causes, and often no specific cause can be found. Management of CLBP can choose from a range of different strategies, including surgery and drug therapy, together with nonmedical interventions including exercise therapy, manipulation, acupuncture, electrical treatments, and cognitive-behavioral interventions. During recent years, a large number of randomized controlled trials have been published. It currently appears that the ideal treatment for CLBP is a multidisciplinary intervention with a stepwise approach; studies examining the effectiveness of this approach are now numerous.3–5

In a systematic review, Marienke et al.3 analyzed 83 clinical trials on physical therapy and rehabilitation for CLBP; they suggest that the only treatments that are effective in reducing CLBP are multidisciplinary treatment and behavioral therapy. Treatment with low-laser level therapy (LLLT) has given contrasting results; Jang et al. conducted a meta-analysis on the pain relief effects of laser irradiation, and

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concluded that LLLT is efficacious for pain reduction.6 Bjordal et al. reviewed 22 clinical trials1 with high scores on the PEDro scale, a measure of the methodological quality of clinical trials.5 They examined laser therapy in pain disorders, including temporomandibular joint disorders, CLBP, neck pain, and rheumatoid arthritis. The review concluded that laser therapy has no reported side effects, and that laser irradiation on joint areas, in association with exercises, can be an effective pain relief treatment. A recent study reported a reduction in both CLBP and the underlying condition,9–11 although other studies have found no significant results for CLBP.[12,13]

Pain reduction is among the claimed effects of irradiation with diode laser14; the effect has variously been posited to be caused by changes in peripheral nerve conduction,15 an increase in peripheral blood flow, or inhibition of the release of pain-related substances at the nerve terminals.16 It appears probable that the inhibitory effect of laser irradiation on nerve fibers, in particular the effect on Aδ and C fibers, may be caused by inhibition of the axonal volley, either in both Aδ and C fibers, or in C fibers alone.17,18 Aδ and C fibers are fibers of the somatic system that conduct nociceptive stimuli (pain, heat, cold, and chemical stimuli) from the peripheral terminals to the spinal cord, with slow conduction velocities.

Laser therapy is also reported to have positive effects in treating musculoskeletal disorders, through its analgesic, myorelaxant, tissue healing, and biostimulatory effects.19 The ways in which laser light can reduce pain are: by stimulating ligament repair, the Ways in which laser light can reduce pain are: by stimulating ligament repair, through anti-inflammatory action,21 by reducing interstitial swelling, and by stimulating lymphatic motility.22,23

There is strong evidence that exercise24 is as effective as other conservative treatments for CLBP, and that pain outcomes improve more significantly in groups engaging in exercises than they do in those undergoing other treatments. Studies indicate that stretching and strengthening exercises can improve pain and function. Home exercises combined with therapist supervision have been identified as the most effective strategy for patients with CLBP.25

It is recognized that the abdominal muscles, back extensors, and gluteus muscles tend to be weak in patients with CLBP25; this can cause significant spinal loading. Patients with CLBP also exhibit tightness of the hamstrings and hip extensors, which may impair spinal mechanics. Strengthening and flexibility exercises are, therefore, important for a healthy lower back.25

The present study evaluated the pain reduction efficacy of treatment with the Ga-Al-As diode laser (980 nm) in combination with exercise therapy, in patients with CLBP.

Materials and Methods

This study reviewed all patients who had been seen from 2011 to 2013 at the University Hospital (San Martino University Medical School) in Genoa, Italy. The records of patients whose chief complaint was first time LBP were reviewed in detail, including their medical histories, examinations, imaging, and consultations with other specialists. The study protocol was approved by the Ethical Committee of the San Martino Hospital, Genoa, Italy (no. 191069). A total of 100 patients (117 patients were eligible for the study, but 17 did not consent to participate) were selected for inclusion in the study. Patients were recruited by inclusion and exclusion criteria.

Inclusion criteria were (1) nonspecific LBP of >6 months’ duration, and (2) age >18 years.

Exclusion criteria were (1) nerve root symptoms; (2) systemic diseases and specific conditions revealed by magnetic resonance imaging (MRI), including neoplasms, fracture, spondylolisthesis, spondyloysis, spinal stenosis, ankylosing spondylitis, previous low back surgery, or prolapsed disc; (3) medication for specific psychological problems; or (4) pregnancy.

Patients were evaluated by medical history and physical examination findings, in correlation with MRI, plain anteroposterior and lateral radiographs of the lumbosacral spine (two views), erythrocyte sedimentation rate (ESR), complete blood count, and C-reactive protein level. Patients were requested not to take any pain medication during the study period, and not to engage in any other exercise or treatment program.

All patients received nine treatment sessions, thrice weekly on alternate days. Patients were provided with verbal and written information about the study, and were asked to sign a consent form.

Patients were subdivided randomly into two groups: randomization was achieved via opaque sealed envelopes, prepared by a statistician using a computer-generated randomization schedule. The envelopes were in two batches of 50, so that the two groups (laser + EX group and EX group) would be of equal size. The laser + EX group received laser treatment; the EX group received identical treatment excepting that the laser light was not activated. Both groups engaged in an identical exercise program.

Pain score

A 10 cm visual analogue scale (VAS) was employed to assess levels of pain intensity before and after treatment.26 The VAS has been shown to be a reliable and valid measure of pain; it consists of a standard 10 cm line with verbal anchors indicating “no pain” at 0 cm and “severe pain” (the worst imaginable pain) at 10 cm. Participants were asked to indicate the severity of their pain by placing a mark at the appropriate place on the line.

Laser therapy

A 980 nm GaAlAs laser unit was used for this study (LEONARDO BIO, DMT dental medical technologies, Lissone, Italy) with a specific handpiece (32 cm² spot size), peak power of 20 W, and fluence 37.5 J/cm². The power output was calibrated with a power meter. Irradiation time was 1 min per spot in continuous wave (CW) mode (total irradiation energy 1200 J per spot). The handpiece was kept in skin contact over the painful paravertebral low back region. At each session, following the protocol published by Benedicenti et al.,27 a series of standardized fields including six spots in the paravertebral region (L2 to S2–S3) were irradiated by a single laser probe in stationary contact mode28 (total energy 1200 J per point). The average local exposure time was planned at 1 min per spot; the effective radiating area of the handpiece was 32 cm². For the EX group, applications were delivered by the same handpiece; the therapist moved the handpiece at the same rate and pressure as for the laser + EX group.
group. The machine and the light-emitting diode that indicated “power on” were in view of the subject, but the dials showing power settings were not. At the start of diode laser treatment, patients were generally unaware of what to expect. Because even with active laser irradiation subjects feel no sensation at most therapeutic intensities, patients in both groups were told that they might feel some heat. All were advised that, should this cause discomfort, the therapist must be notified, so as to safeguard patients against overheating.

**Exercise protocol**

A semi-supervised exercise program was developed, including posterior pelvic tilts, situps, bridging, quadruped exercises, and posterior hip and knee muscle stretching. Patients were instructed to perform two to three stretches (of all muscles) per day, and to hold the stretch for 20 sec unless it hurt. Strengthening exercises began with 5 repetitions and progressed according to each patient’s improvement, to three sets of 10 repetitions. Patients received an illustrated pamphlet describing the exercises.

The exercise program comprised the following five exercises, whose goal is to enhance postural control and achieve active stabilization of the lower spine.

- Pelvic tilt in a horizontal position; the patient was supine with hands behind head, knees bent, and feet on the ground, to facilitate muscle release. The patient was instructed to contract both the abdominal and the gluteus muscles, and then to exhale. This creates a posterior pelvic tilt: the pubis rises and the lumbar region is flattened into close contact with the floor.
- Exercise to relax hip flexor muscles, particularly the psoas muscles. The patient was supine, with knees and hips bent, to relax both ileopsoas muscles. In this position, the patient was instructed to bring one knee to the chest while extending the other leg; the exercise was repeated on the other side. If the ileopsoas muscle, a flexor muscle of the hip, is excessively contracted, a posture of hyperlordosis may result, because of the forward position taken on by the lower spine.
- Exercise for the abdominal muscles (abdominal rectus, external oblique, internal oblique, abdominal transversus). The patient was supine, with hands behind the head, knees bent, feet on the floor. From this position the upper part of the torso was bent forward, maintaining the lower spine in contact with the floor. This produces a contraction of the abdominal rectus muscle that induces posterior rotation of the pelvis (retroversión), decreasing lumbar lordosis.
- Exercise to control lumbar lordosis, on hands and knees. Starting from a position on hands and knees with the back parallel to the floor, lower spine relaxed, the patient modified the posture from lordosis or hyperlordosis to kyphosis, by briefly contracting the gluteus and abdominal muscles.
- Exercise to distend the hip in a prone position with support of trunk and lower limbs. The muscles involved in leg distention are: gluteus maximus, semitendinosus, semimembranosus, and the long head of the biceps femoris. The patient was prone with a pillow under the abdomen to reduce lordosis of the lower spine. The patient bent one knee to a 90 degree angle, without raising the other leg. The position was held for a few seconds.

To ensure that the program was followed correctly at home, each exercise was observed by the therapist at each treatment session, to check that it was being performed correctly at home.

Patients were instructed to perform the exercises daily, the stretching exercises before the strengthening exercises. They were advised to be active throughout the day, and to walk for at least 15 min before exercising, which could act as a warmup. After completion of all treatment sessions, patients were asked to continue exercising daily at home for a further 3 weeks.

**Statistical method and data analysis**

The Statistical Package for Social Sciences (SPSS) software (Windows version 18.0) was used to analyze the data, through the independent t test (provided data were normally distributed). The normality of the variables was checked by mean of histograms, and confirmed by the Shapiro–Wilk normality test: all variables were found to have normal distribution.

Count and percentage for categorical factors, and mean with standard deviation (SD), or median with interquartile range (IQR), were shown for each clinical characteristic, both at baseline (t0) and after completion of treatment (t1). A paired sample t test was used to detect any statistically significant differences between the pre- and post-treatment for both groups.

Differences in the VAS scores between the Laser+EX group and the EX group were analyzed by means of the Student’s t test for independent samples; p < 0.05 was considered statistically significant, with a statistical power of 90%.

**Results**

A total of 100 patients (43.0% male; 57.0% female; median age 68 years, range 24–89) were enrolled for the

<table>
<thead>
<tr>
<th>Patients (n=100)</th>
<th>Mean (±SD)</th>
<th>p Value</th>
<th>Mean (±SD)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX group</td>
<td>VAS (t0)</td>
<td>VAS (t1)</td>
<td></td>
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<tr>
<td>6.36 (±1.52)</td>
<td>4.08 (±1.40)</td>
<td>&lt;0.001a</td>
<td>2.32 (±1.78)</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>Laser+EX group</td>
<td>VAS (t0)</td>
<td>VAS (t1)</td>
<td></td>
<td></td>
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<tr>
<td>6.64 (±1.77)</td>
<td>2.68 (±1.92)</td>
<td>&lt;0.001a</td>
<td>3.96 (±2.20)</td>
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Student’s t test; (t0) baseline; (t1) after treatment.

aThe different in ΔVAS was statistically significant in both groups.

EX, exercise; VAS, visual analogue scale.
study. A statistically significant decrease in VAS score between \( t_0 \) and \( t_1 \) was observed for both Laser + EX group \((p<0.001)\) and EX group patients \((p<0.001)\). Differences pre–post treatment \((t_0–t_1)\) between the two groups were significantly different \((p<0.001)\), with a bigger decrease in VAS score in the Laser + EX group than in the EX group.

A \( T \) test analysis of the two groups (Laser + EX and EX) showed that the average difference among VAS scores before and after treatment was significant \((p<0.001)\) in both groups; intergroup comparison showed there to be a significant difference between the two groups.

\[ \Delta \text{VAS} = \text{final VAS score at } t_1 - \text{initial VAS score at } t_0 \]

\( \Delta \text{VAS} \) was calculated by subtracting the final VAS score \((t_1)\) from the initial VAS score \((t_0)\). In the Laser + EX group (laser therapy plus exercise) there was an average reduction in VAS score of 3.96, compared with 2.32 for the EX group (exercises alone). The difference between the average value of \( \Delta \text{VAS} \) in the two groups was 1.64. In the Laser + EX group, five patients \((10\%)\) reported complete eradication of pain, whereas six patients \((12\%)\) reported no positive effects; in the EX group, only one patient \((2\%)\) reported complete eradication of pain, whereas nine patients \((18\%)\) reported no improvement in pain symptoms. The results are summarized in Table 1.

### Discussion

CLBP is defined as pain in the lumbosacral area of the spine of \( >12 \) weeks’ duration, which may or not have the characteristic of limiting the patient’s range of movements, and is a complex and multifactorial condition; numerous treatments have been proposed, and management is still controversial. Despite the frequency of CLBP, in many cases it is difficult to achieve a definite diagnosis of the origin of the pain. Drug therapy and surgery should if possible be avoided, because of the risk of negative side effects. Many studies have demonstrated that drug therapy for pain disorders can create problems; the same may be said of surgery.30

The rationale for the use of laser therapy as an adjunct to treatment for CLBP is that it has shown beneficial effect in reducing pain and inflammation, and lacks significant complications.3 The possible mechanisms underlying the reduction of pain by light therapy include: (1) increased endogenous opioid neurotransmitter production; (2) enhanced thermal pain threshold and local blood circulation; (3) increased oxygen consumption and adenosine triphosphate (ATP) production at the cellular level; and (4) anti-inflammatory effects.

The benefits offered by LLLT are still debatable, and there is as yet no consensus about the ideal laser parameters for CLBP treatment. Two studies, Klein et al.12 and Ay et al.13 report randomized double-blind trials to test the efficacy of low-energy laser gallium-arsenide laser treatment. Neither study found any significant difference between the laser-treated and the placebo groups; further, no relative advantage accrued to either group. In both cases, it was concluded that low-energy laser stimulation plus exercise fails to provide a significant advantage over exercise alone.

It would appear from existing reports that laser therapy can only be effective if the laser beam area is between 0.22 and 4.9 cm².3 It appears probable that the recommended doses for LLLT suggested by the World Association of Laser Therapy (WALT) were not applied in the clinical protocols used in some studies, which could be a cause of their lower treatment efficacy.38 In the present study, the beam area was 32 cm², to simplify irradiation of the selected points.

Our data indicate that both treatments provided pain reduction, but that the improvement was more significant in the Laser + EX group. Patients in neither group reported any collateral or other undesired effects.

LLLT with 980 nm diode laser and large diameter spot size combined with an exercise program appears to be effective in reducing pain, and may be promising as a new therapeutic option in the rehabilitation of CLBP. However, large randomized control trials demonstrating clear clinical benefit are needed to gain evidence-based support for their use.

### Author Disclosure Statement

No competing financial interests exist.

### References

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