Background and Objectives: The aim of this study was to determine whether low power laser therapy (Gallium–Arsenide) is useful or not for the therapy of chronic low back pain (LBP).

Study Design/Materials and Methods: This study included 75 patients (laser + exercise—25, laser alone—25, and exercise alone—25) with LBP. Visual analogue scale (VAS), Schober test, flexion and lateral flexion measures, Roland Disability Questionnaire (RDQ) and Modified Oswestry Disability Questionnaire (MODQ) were used in the clinical and functional evaluations pre and post therapeutically. A physician, who was not aware of the therapy undertaken, evaluated the patients.

Results: Significant improvements were noted in all groups with respect to all outcome parameters, except lateral flexion ($P < 0.05$).


Key words: low back pain; exercise; low power laser; therapy

INTRODUCTION

Low back pain (LBP) affects a considerable proportion of the population [1,2]. In a methodological review of prevalence studies of LBP [3] a mean point prevalence of 19.2% and a mean 1-year prevalence of 32.7% were estimated. Research on the effectiveness of therapy of LBP has yielded inconsistent results [4–6], and studies often contained methodological flaws [6–9] such as inadequate randomization procedures and lack of a placebo control.

Since the middle of the 20th century, laser therapy has become popular and was approved for usage in surgery, but not for the therapy of musculoskeletal pains [10]. Medium and low energy lasers, such as Helium–Neon or Gallium–Arsenide, whose wavelengths are between 600–984 nm, are used for a variety of purposes in physical therapy [11].

Low power lasers (LPL) have been shown to affect many sub-cellular and cellular processes, although the mechanisms have not been well defined [12]. However, it is important to note that LPL does not produce significant tissue temperature changes, so any potential physiological effect appears to be non-thermal [13]. Even though therapies do not elevate tissue temperatures more than a few degrees, laboratory studies find that 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.

LPL therapy has been used experimentally to treat a wide variety of clinical conditions, but no consensus regarding indication or effectiveness has been established [14–16]. The equipment, experimental designs, and techniques used in the low-energy laser literature are highly variable, and close attention should be paid to therapy parameters when reviewing and comparing these studies. Although this laser therapy is available in many parts of the world, it has yet to receive FDA approval for any indication [17,18]. Still, the efficacy of this therapy method is controversial.

Uncontrolled studies have shown that low energy bio-stimulation can be used for the therapy of neck pain and LBP, and there is a symptomatic recovery with an estimate of 70–80% in the treated patients [19,20].

Many authors have reported significant pain reduction with LPL in acute and chronic painful conditions such as rheumatoid arthritis, osteoarthritis, fibromyalgia and post-operative pain [20–23]. However, some have failed to show such an effect in painful musculoskeletal pathologies [24,25].

This single blind and randomized study was designed to compare LPL therapy, exercise and laser combined with exercise, and to determine whether laser therapy is useful or not for the therapy of chronic LBP.

MATERIALS AND METHODS

This study included 75 patients (laser + exercise—25 patients, laser alone—25 patients, and exercise alone—25 patients) suffering from LBP diagnosed clinically and radiologically as chronic LBP, and admitted to Dicle
University, Faculty of Medicine, Physical Medicine and Rehabilitation Department between May 1999 and March 2000.

The criteria for inclusion of the patients to the study were chronic LBP for at least a year, age between 20–50 years, not being pregnant, and having no previous spinal surgery. In addition, patients with neurological deficits, abnormal laboratory findings and systemic and psychiatric illnesses were not included in the study. The screening process relied on self-reported criteria plus information concerning the existence of medical conditions, medication use and the possibility of serious injuries. Patients with a history of previous episodes of LBP and a positive radiography finding of mild pathology were not excluded from the study. At initial examination, patient characteristics and health information, informed consents and baseline measures (demographic characteristics, functioning, pain, and lumbar range of motion) were recorded. Post-therapy measures were obtained after one month of therapy.

In this study, visual analogue scale (VAS) was used in the evaluation of pain. Roland Disability Questionnaire (RDQ) and Modified Oswestry Disability Questionnaire (MODQ) were used in the functional evaluation. Schober test, flexion and lateral flexion measures were used in the evaluation of lumbar range of motion in the pre and post-therapy period. A physician who didn’t know which therapy was taken evaluated the patients.

Self-reported measurements of disability have been used as an outcome measure for people with LBP. Several disability scales have been developed for people with LBP, and their importance as measures for therapy outcome in clinical trials has been emphasized [26]. Two of the most commonly used disability scales for people with LBP are the RDQ and the MODQ [27]. The measurement properties of both of these scales have been studied extensively, and a recent report of the International Forum for Primary Care Research in LBP contended that both scales are acceptable for measuring disability related to LBP [26]. The RDQ [28], an adaptation of the Sickness Impact Profile, was used to measure subjects’ level of functioning when performing daily tasks. Scores can range from 0 to 24 based on responses to 24 questions to which subjects answer yes or no. A score of 14 or more is considered a poor outcome [27]. This questionnaire has shown reliability, validity and sensitivity [28,29] and has been used in trials of LBP therapy [30,31]. The MODQ consists of 10 items addressing different aspects of functioning. Each item is scored from 0 to 5, with higher values representing greater disability [32]. The total score is multiplied by 2 and expressed as a percentage [33]. To detect limitation of forward flexion of the lumbar spine, the Schober test is quite useful [34]. It has been used in studies regarding the effectiveness of subacute LBP therapy [35,36].

The gallium–arsenide laser is known to penetrate to depths of 1–5 cm in soft tissue. This depth of penetration should be adequate to treat the major posterior ligaments, fascia, and apophyseal capsules of the lower back in the patients of normal body weight recruited for our study. Laser therapy was applied to the patients over a period of 4 weeks, five times a week. Application of the laser was external over a series of standardized fields designed to include the L4 to L5 and L5 to S1 apophyseal capsules, dorsiolumbar fascia, and interspinous ligaments, as well as the gluteal fascia, posterior sacroiliac ligaments, hamstring, and gastrosoleus muscles of which pain points were palpated from the low back to the foot. Stimulation time of four minutes was used for each point, producing energy of approximately 1 J/cm² (10.1 cm² energy density, 2.1 kHz pulse frequency, 10 W diode power, 4.2 mW average power, 1 cm² surface) at each point. Approximately 30 min of total stimulation time was needed to cover the entire area of therapy for each patient. Two physical therapist investigators used a standard technique, with a gallium–arsenide laser (class IIIb Laser Product, Frank Line IR 30, Fysiomed, Belgium). The Human Studies Research Committee of the University of Dicle, Diyarbakir, approved all procedures and informed written consent was obtained from each subject prior to inclusion in the study.

In two groups, lumbar flexion and extension, knee flexion, hip adduction exercises, and strength exercises of extremity muscle groups, were given two sessions a day, making a total of 40 sessions for 4 weeks. The first session of the exercises was conducted with a physiotherapist and continued at home by the patients themselves.

STATISTICAL ANALYSES

Statistical analyses were done by SPSS 8.0 PC programme. The results were expressed as, means ± standard deviations. Statistical significance was tested using the paired t test for paired observations and was tested by multivariate analysis of variance (MANOVA) for different groups of comparisons. In addition, when the cell number was small, Chi-square test or Fisher’s exact test were used for categorical variables. The level of statistical significance was set at a two-tailed P-value of 0.05.

RESULTS

The characteristics of the patients who entered the study are shown in Table 1. The exercise ± laser and laser alone groups consisted of 18 females and 7 males and there were 17 females and 8 males in the exercise group. The mean age, BMI and duration of LBP of all patients were 35.6 ± 10.3, 14.6 ± 10.3, and 24.8 ± 4.3, respectively. The randomization resulted in three comparable groups and there was not any statistically significant difference between the three treatment groups with respect to demographic data such as age, BMI, duration of LBP, gender, educational level, and occupational activity (Table 1).

Baseline and post-therapy values of pain, Roland disability Questionnaire, Modified Oswestry Disability Questionnaire, Schober test, and flexion were compared in all therapy groups, but no significant differences were observed between any of the therapy groups (P > 0.05).

Pain levels in the all groups decreased significantly after therapy (P < 0.05). Although there was no significant difference between any therapy groups, pain levels in the laser plus exercise and laser alone groups decreased more than...
the exercise alone group. Although there was a significant improvement in antero-posterior flexion after therapy in all therapy groups ($P < 0.05$), there was no significant improvement in lateral flexion ($P > 0.05$). Additionally, measures of Schober test were significantly improved in all groups after therapy ($P < 0.05$).

**DISCUSSION**

LBP appears as a general health problem in industrialized societies. The 80% of the people contract LBP in some part of their life; about 1% of those face physical, social, psychological and economic problems led by LBP [37]. The therapy of such a serious health problem is rather difficult and needs a multidisciplinary approach.

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 therapy modality, principally in the Soviet Union and the Far East, where it has found a range of applications. Consequently, acceptance of this new modality is limited. 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 availability [19].

Literature searches failed to provide a coherent picture of current clinical practice upon which to base future research. One of the chief problems was the wide variation in therapy regimes employed, principally in terms of such parameters as wavelength, power output and pulsing frequency. Additionally, the majority of the published papers were in Russian, often with no English language abstracts. It is important to remember that the literature on LPL studies is uneven and disorganized. 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, therapy techniques (for example, irradiating a single point or sweeping), and therapy schedules may be important enough to complicate the evaluations [38,39].

Laser irradiation has a demonstrable effect in vitro on both metabolism and surface charges on cells in culture, but the ultra-structure is unchanged [40]. Research studies of the effects of low power laser irradiation on biological functioning, 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

<table>
<thead>
<tr>
<th>Variables</th>
<th>Exercise + Laser (n = 25)</th>
<th>Exercise (n = 25)</th>
<th>Laser (n = 25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years</td>
<td>35.2 ± 10.51 (20–50)</td>
<td>36.4 ± 9.83 (21–50)</td>
<td>35.4 ± 11.2 (22–49)</td>
</tr>
<tr>
<td>Body mass index (kg/cm$^2$)</td>
<td>24.7 ± 4.3 (22–29)</td>
<td>25.1 ± 4.6 (23–30)</td>
<td>24.9 ± 4.1 (22–30)</td>
</tr>
<tr>
<td>Duration of LBP, months</td>
<td>15.3 ± 10.5 (8–26)</td>
<td>14.6 ± 9.6 (7–28)</td>
<td>15.1 ± 11.2 (8–31)</td>
</tr>
<tr>
<td>Female, %</td>
<td>72</td>
<td>68</td>
<td>72</td>
</tr>
<tr>
<td>Relationship status, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partnered or married</td>
<td>72</td>
<td>68</td>
<td>68</td>
</tr>
<tr>
<td>Single, divorced or widowed</td>
<td>28</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Educational level, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary</td>
<td>48</td>
<td>44</td>
<td>52</td>
</tr>
<tr>
<td>High School</td>
<td>32</td>
<td>36</td>
<td>32</td>
</tr>
<tr>
<td>University</td>
<td>20</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>Occupational activity, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housewives</td>
<td>32</td>
<td>28</td>
<td>36</td>
</tr>
<tr>
<td>Not working or retired</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Student</td>
<td>4</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>At desk mainly</td>
<td>16</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>At desk and movement</td>
<td>28</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Physical labor</td>
<td>12</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Problem, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not known</td>
<td>20</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Mild strain</td>
<td>12</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>Sports injury</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Bending or lifting injury</td>
<td>36</td>
<td>40</td>
<td>36</td>
</tr>
<tr>
<td>Fall or accident</td>
<td>12</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>Stress related</td>
<td>12</td>
<td>8</td>
<td>12</td>
</tr>
</tbody>
</table>

Figures represented mean (and standard deviations), unless stated to be a percentage of the group.

No significant difference between groups (Chi-square test or Fisher’s exact test when the cell number is small).
find “systemic” rather than simply “local” effects, many studies fail to show either local or systemic benefits. Currently, no universally accepted theory has explained the mechanism of either “laser analgesia” or “laser bio-stimulation.” Although a theoretical understanding is unnecessary to establish a benefit, the lack of knowledge complicates the evaluation of the conflicting results [19].

The analgesic effects of LPL therapy in musculoskeletal disorders are still being debated. Some authors report the efficacy of LPL therapy to be superior to placebo therapy in rheumatoid arthritis, posttraumatic joint disorders, myofascial pain syndrome, and fibromyalgia [6, 7, 21]. However, not all authors have observed beneficial effects on pain, for example Krasheninnikoff et al. [8], who reported that LPL had no superior effect over placebo in lateral epicondylitis. This controversy may be related to the various efficacies of LPL therapy in different painful musculoskeletal conditions.

The success of LPL therapy on pain and functions in LBP may be due to several mechanisms, one of which may possibly be through its positive effects on chondrocyte proliferation and matrix synthesis [5, 41, 42]. Skinner [43] reported that low power Ga–As pulse laser had significant stimulatory effects on fibroblast function and enhanced connective tissue repair. These effects seem to be related to the bio-stimulation effect of LPL at the cellular level [44]. LPL has been suggested to increase the activation of cytoplasmic enzymes, oxygen consumption, ATP production and the synthesis of nucleic acids and proteins [45, 46]. It has also been reported that LPL therapy had anti-inflammatory and anti-edematous action owing to its influence reducing prostaglandin synthesis. In particular, its inhibitive effect on prostanycin has been reported to provide pain and inflammation regression, especially in acute exacerbations of osteoarthritis and sciatica [47]. It has also been suggested that LPL has effects on peripheral nerve stimulation and microcirculation regulation, interrupting the pain mechanisms and thereby providing analgesia [5]. The normalization of the microcirculation and the speed of nerve transmission obtained have been reported to interrupt the vicious circle of the origin and development of the pain [4]. Konstantinovic et al. [47] demonstrated a spasmylocytic effect of LPL in muscles. Thus, LPL seems to break the pain-spasm-pain cycle by dual effect.

Walker had some successful results in the therapy of chronic pain with laser. He stated that laser decreased pain by increasing serotonin and endogen opioid oscillation in this recovery and therefore laser therapy can be effective on serotonin metabolism [48]. Synder-Mackler and Bork [49] 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 hypothesized that this increase in sensory latency could be a mechanism for pain relief, and thus the He–Ne laser may be a beneficial analgesic modality.

Klein et al. contrasted 10 patients who had LPL stimulation and exercise therapy to 10, who had only exercise therapy. They indicated significant improvements in pain in both groups, but no difference between the two groups. They found significant improvements in the post-therapy period in the evaluation of the low-back joint movements in both groups but no additional use of laser. Researchers concluded that LPL therapy does not have any advantage over exercise therapy alone in the frame of short-term situations [50]. Additionally, Basford et al. indicated that LPL therapy causes an improvement in function and a decrease of pain in patients with LBP. Besides, they stated that those uses do not have a long-term effect [51].

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### TABLE 2. Comparisons of Outcome Measures Pre- and Post-Treatment in All Therapy Groups

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Laser + Exercise (n = 25)</th>
<th>Exercise (n = 25)</th>
<th>Laser (n = 25)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-therapy</td>
<td>Post-therapy</td>
<td>Pre-therapy</td>
</tr>
<tr>
<td>Pain (visual analogue scale)</td>
<td>6.2 ± 2.1</td>
<td>1.8 ± 1.2</td>
<td>6.5 ± 1.6</td>
</tr>
<tr>
<td>Roland disability questionnaire</td>
<td>17.8 ± 4.6</td>
<td>6.3 ± 3.5</td>
<td>15.1 ± 4.2</td>
</tr>
<tr>
<td>Modified Oswestry disability questionnaire</td>
<td>32.4 ± 10.6</td>
<td>14.8 ± 8.6</td>
<td>30.5 ± 12.3</td>
</tr>
<tr>
<td>Schober test, cm</td>
<td>14.6 ± 1.8</td>
<td>18.3 ± 3.6</td>
<td>15.3 ± 2.1</td>
</tr>
<tr>
<td>Antero-posterior flexion, cm</td>
<td>30.5 ± 15.3</td>
<td>10.6 ± 4.9</td>
<td>32.3 ± 14.4</td>
</tr>
<tr>
<td>Lateral flexion (right), cm</td>
<td>27.6 ± 14.8</td>
<td>30.8 ± 16.3</td>
<td>28.3 ± 15.3</td>
</tr>
<tr>
<td>Lateral flexion (left), cm</td>
<td>26.5 ± 13.7</td>
<td>32.7 ± 15.5</td>
<td>27.3 ± 14.1</td>
</tr>
</tbody>
</table>

Visual analogue scale (score: 0–10) measures intensity of pain (a higher score indicates higher pain intensity); Roland disability questionnaire (score: 0–24) measures function (a lower score indicates less dysfunction); Modified Oswestry disability questionnaire (score: 0–50) measures function (a lower score indicates less dysfunction); Schober test, flexion and lateral flexion measure lumbar range of motion in centimeters.

No significant difference between all groups in pre- and post-treatment (Multivariate analysis of variance, MANOVA).

| bSignificant different from pre-treatment in exercise plus laser group.  
| cIn alone exercise group.  
| dIn alone laser group (P < 0.05) (two tailed paired t test).  

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Our study approves that exercise programme, which is cheap, safe, practical and economic, is an effective and a sufficient therapy. In fact, recent studies emphasize the importance of active exercise programs in the rehabilitation operations towards the functional recovery of the patients with chronic LBP [52].

In the planning stage of this study, we had difficulty in finding the literature related to the use of laser therapy in chronic LBP. We saw that there was no standard therapy programme concerning the dosage and the duration of laser therapy and there were various results in the current publications. These variations in the literature may have come from the selection of the patients, application of the therapy, and the dosage, duration and type of the laser. Because of these reasons, in this study, we had trouble in the use of laser and the evaluation of the results. In order to cope with these problems, we need controlled studies that involve increased patient populations and different therapy alternatives.

There are many open questions. What is the real mechanism of the therapy? What is the correct dosage per point? We know that the penetration of the skin differs between Ga-As and He-Ne lasers. Most of the energy is absorbed in the first 2 ml. 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 therapies, further clinical evaluation of laser therapy is warranted.

In conclusion, LPL therapy seemed to be an effective method in reducing pain and functional disability in the therapy of chronic LBP. LPL therapy does not bring any additional benefits to exercise therapy and exercise therapy is of primary importance in the therapy of the patients with chronic LBP. Further investigations on the exact beneficial mechanisms of LPL should be performed in the future.

REFERENCES