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Effects of High - Intensity Laser in Treatment of Patients with Chronic Low Back Pain

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Abstract

BACKGROUND: Chronic low back pain lasts longer than 12 weeks and is characterised by pain, muscle weakness, reduced functional ability and psychosocial burden.

AIM: To compare the effects of two physical modalities, high-intensity laser against ultrasound therapy in the treatment of patients with chronic low back pain.

MATERIAL AND METHODS: This was a prospective, monocentric, controlled clinical study comprising a group of 54 patients at the age between 25 and 65 years. Patients were divided into two groups: an examined group of 27 patients (high-intensity laser and exercises) and a control group of 27 patients (ultrasound therapy and exercises). The results were evaluated by the Numeric Pain Rating Scale, Oswestry Disability Index and Schober's test. Clinical findings were evaluated at the same time points for all patients, before treatment, at two weeks and three months following treatment. Statistical analyses were made to compare the differences between the results obtained on admission and the two consecutive control check-ups. Statistical significance was defined as a P value < 0.05.

RESULTS: The examined group showed statistically significantly better results than the control group after completion of the treatment (at two weeks) and at follow up after three months.

CONCLUSION: This study has shown that patient with chronic low back pain treated with a high-intensity laser has significantly reduced low back pain, reduced disability and improved range of motion. Its positive effect maintained for three months. It seems to be an effective, safe and useful physical modality in the treatment of a patient with chronic low back pain.

Introduction

Pain is an unpleasant sensory and emotional experience associated with actual or potential injury of some part of the body [1]. Pain intensity is not always associated with the degree of tissue damage since pain is not only a physical but also a mental process with a wide range of repercussions and consequences.

Low back pain is a sum of symptoms from different aetiology that are manifested with a pain in the lumbar or lumbosacral spine, with or without pain radiation in the legs [2]. Low back pain is a common musculoskeletal disorder with high prevalence in the general population [3].

Chronic low back pain lasts longer than 12 weeks, and it can persist even after discontinuation of the action of nociceptive stimuli [4]. Characteristics of chronic low back pain include long-term pain, muscle weakness, reduced functional ability and psychosocial burden, which make the treatment of chronic low back pain a complex process. Therapeutic procedures for treatment of chronic low back pain comprise multidisciplinary approach, education of patients, therapeutic exercises, application of physical agents and psychological counselling [5].

Over the last years, aggressive conservative treatment has been recommended by increasing the number of therapeutic programs that include a multidisciplinary team and numerous treatment modalities [6]. Therapeutic program is individually designed for each patient depending on the local and general clinical findings in the patient.

Exercise therapy has become a standard procedure for the management of spinal pain. Combined exercises for gluteal muscles strengthening and exercises for lumbar segmental stabilisation have shown improvement in balance, larger muscle endurance and a decrease in disability pain index in patients [7].

Ultrasound therapy as a physical modality is very often practised in the treatment of chronic low back pain. Its mechanical action is considered to be predominant, and it consists of alternating ultrasound pressure that is manifested as molecular vibration in the tissue. Analgesic effect of ultrasound therapy has also been confirmed, resulting in improvement of functional disability in patients with chronic low back pain [8].

Laser therapy is a painless and non-invasive treatment that can be used in the treatment of different clinical conditions. It has been confirmed that laser therapy significantly reduces acute and chronic pain as well as rheumatoid arthritis, chronic osteoarthritis, carpal tunnel syndrome, fibromyalgia, knee injuries, pain in the shoulders and postoperative pains [9], [10]. A reduction of pain after laser treatment is a result of its anti-inflammatory effects, increase in microcirculation, and stimulation of immunological processes, nerve regeneration and increased secretion of β-endorphins [11]. Recently a high-intensity laser therapy (HILT) has been introduced in the field of physical medicine. HILT is considered to be a non-invasive and painless modality because of its high intensity and specific wavelength. By application of this type of laser larger regions and deeper tissue structures can be more effectively treated than with the other types of lasers [12]. Clinical studies have documented the anti-inflammatory, anti-edematous and analgesic effect of the high-intensity laser, thus justifying its use in patients with pain problems [12].

The aim was to compare the effects of both physical modalities, therapy with high-intensity laser versus ultrasound therapy, and to point out the differences in the analgesic effect, reducing disability and the range of motion in the lumbar spine.

Material and Methods

This prospective, monocentric, controlled clinical investigation was conducted in the Institute of physical medicine and rehabilitation. The diagnoses of the patients were established by medical history, physical examination, and x-ray findings of the lumbosacral spine. In total, 54 male and female patients between the ages of 24 and 65 were enrolled in the study. The patients were divided into two groups: Group 1 included 27 patients treated with high-intensity laser and exercises, and Group 2 (control group) included 27 patients treated with ultrasound therapy (US) and exercises. Each patient received 10 sessions in total, continuously each day in two weeks, with breaks during weekends. The research was approved by the Ethics committee of the Medical Faculty in Skopje (03-6283/1).

Patients who were not working on occupations requiring intensive effort and who had sufficient mental capacity to understand and answer the questions asked in the assessment scales were included in the study. Inclusion criteria for the study were patients with chronic low back pain that persisted for more than three months and pathological findings on lumbar X-rays. Patients agreed not to take any medication (anti-inflammatories, analgesics, or muscle relaxants) throughout the study or receive any treatment for back pain. Patients were excluded if they had a positive neurological examination (presence of positive motor or sensory abnormalities indicating spinal root compression), lumbar spine surgery, congenital malformation, trauma, metabolic disorders or cancer, inflammation, infection or known photosensitivity or other illnesses unrelated to back pain which precluded involvement for practical reasons.

Patients who met the inclusion criteria participated in the study. Taking part in the study was voluntarily, and all participants were informed in details about the purpose of this study. All subjects read and signed consent forms, by the ethical standards of the Declaration of Helsinki.

Application of the high-intensity laser therapy (HILT) was performed with the apparatus PRESTIGE LINE VIKARE 4WHL1361 (Medical Italia), the power of 4W, the intensity of 1.50 J/cm², scanning regime. Scanning was performed longitudinally in the lower-back area of L1-L5 and S1, on dry skin previously cleaned with alcohol. Laser probe was in contact with the skin. The procedure lasted for 15 minutes and the total dose of absorbed energy in the tissue was 2400 J. HILT was calibrated for constant output throughout the experiment. All protection measures for applying laser therapy were respected. The therapy is painless and with no risk for patient's health.

Control group of patients received ultrasound therapy (continuous waveform) with an intensity of 0.5 W/cm² due to the chronicity of the condition and deep position of lower back musculature. The therapy was applied for 5 minutes to the lumbar paravertebral area. The treating physical therapist, with the technique of using slow circular movements, applied the transducer head over the lumbar and dorsal muscles.

All patients in both groups performed isometric and static exercises for strengthening back, abdominal, lumbar and gluteal muscles under the supervision of a physiotherapist for 15 min once a day. The standardised program included posterior

pelvic tilts, quadriceps exercises, and posterior hip and knee muscles stretching. Core stability training for the lumbar area was applied in supine and prone positions. Participants were taught by a physiotherapist to perform the exercises correctly, and all treatment groups were given instructions to perform the exercises at home. The exercise program was designed to be easily carried out at home. Patients were asked to maintain the daily home exercises for three further months. There was no need for special equipment or access to a gym or fitness facility. The patients were informed that the key to prevent recurrences and provide functional recovery was making the exercises part of their lives.

The patients were assessed for pain, lumbar range of motion and disability. Evaluation of the measured outcomes was performed at the beginning of the study, and evaluation was repeated after 2 weeks of treatment and again after 3 months of further follow-up.

Numeric Rating Pain Scale (0-no pain and 10-worst possible pain) have been validated in the assessment of pain and were used to quantify subjective assessments [13]. In the three time points of examination, the doctor filled in the Numeric Rating Pain Scale. Schober's test for assessment of the range of motion, i.e. lumbar spine flexion was made by the researcher [14]. Schober's test was measured before, after the two-week treatment and after 3 months follow-up. Oswestry Disability Index (ODI) was used to evaluate the function of a patient with chronic back pain [15]. Subjects were evaluated before the first treatment, at the end of treatment (after 2 weeks) and 3 months follow-up after the treatment.

Statistical analysis was made with the statistical package Statistic for Windows 7.0 and SPSS 17.0. Numerical (quantitative) series were analysed by using the measures of central tendency (mean and median) and measures of dispersion (standard deviation). Chi-square test for two parameters was used for comparison of certain features between the two groups of participants as well as for determination of the association between certain features in the group of participants. Non-parametric Mann Whitney U test was used for testing the significance in the difference between the mean values in both independent groups. Statistical significance was defined as a P value < 0.05.

Results

A total of 54 patients with chronic low back pain participated, and both groups completed the study. No side effects were observed during HILT, US therapy and exercise therapy throughout the study. No subject report taking the analgesic/anti-inflammatory drug during the period of their participation in the study. There was no statistically significant difference in terms of gender distribution between the two groups (Table 1). The mean age was 55.4 ± 6.7 years in HILT group and 55.3 ± 7.2 years in US therapy group. There was no significant difference between the groups in terms of age (Mann-Whitney U Test Z = -0.5103; p = 0.6087).

Table 1. Patients demographic data

Category		HILT No (%)	Ultrasound No (%)
Gender	Men	15 (55.6%)	14 (51.8%)
	Women	12 (44.4%)	13 (52%)

Pearson Chi-square test: 0.0745; df = 1; p = 0.7849; *significant for p < 0.05.

An analysis was made of the average score on standardised Numeric Rating Pain Scale applied in both groups of patients at three-time points, on admission, at two weeks and after three months. On admission, there was no significant difference (p > 0.05) between the two groups. The analysis of pain score after two weeks and after three months showed a significant difference (p < 0.05) between the two groups. The HILT group shows greater improvement in pain score (Table 2).

Table 2. Changes in Numeric Rating Pain Scale among treatment groups

Pain Scale	Mean	Number	Standard Deviation	Median (IQR)	p
On admission					
HILT	7.22	27	0.85	7 (7-8)	Mann-Whitney U Test: Z = 0.874, p = 0.382
Ultrasound therapy	6.96	27	0.94	7 (6-8)	
2 weeks					
HILT	2.11	27	0.80	2 (2-3)	Mann-Whitney U Test: Z = -5.519, p = 0.0001*
Ultrasound therapy	4.26	27	1.06	4 (3-5)	
3 months					
HILT	1.89	27	0.64	2 (1-2)	Mann-Whitney U Test: Z = -6.271, p = 0.0001*
Ultrasound therapy	4.89	27	0.85	5 (4-5)	

* significant for p < 0.05.

The analysis by using the Oswestry Disability Index (ODI) in both groups of patients showed a significant change (p < 0.05) between the groups after two weeks and after three months (Table 3). There was a statistically significant improvement in the ODI in the group treated with HILT.

Table 3. ODI changes among treatment groups

ODI	Means	Number	Standard Deviation	Median (IQR)	P
On admission					
HILT	44.33	27	3.92	44 (41 – 46)	Mann-Whitney U Test: Z=-1.021, p=0.307
Ultrasound	45.22	27	3.91	44 (43 – 47)	
2 weeks					
HILT	16.29	27	4.83	14 (12 – 20)	Mann-Whitney U Test: Z=-5.588, p=0.0001*
Ultrasound	26.74	27	4.51	26 (22 – 30)	
3 months					
HILT	15.89	27	4.58	14 (12 – 19)	Mann-Whitney U Test: Z=-5.891, p=0.0001*
Ultrasound	26.63	27	3.73	28 (25 – 29)	

* significant for p < 0.05.

In both groups, the analysis showed no significant difference (p > 0.05) in the Schober's test on admission and after two weeks. There was a significant difference (p < 0.05) in the range of motion by Schober's test after three months, that means better lumbar flexion in the group treated with HILT

(Table 4).

Table 4. Changes in Schober's test among treatment groups

Schober's test	Means	Number	Standard Deviation	Mediana (IQR)	P
On admission					
HILT	4.67	27	0.71	4.3 (4.1-5.3)	Mann-Whitney U Test:
Ultrasound Therapy	4.58	27	0.76	4.3 (4-5.4)	Z = 0.562, p = 0.574
2 weeks					
HILT	6.42	27	0.82	6 (5.8-7.2)	Mann-Whitney U Test:
Ultrasound therapy	6.13	27	0.69	6 (5.7-6.5)	Z = 1.375, p = 0.169
3 months					
HILT	6.48	27	0.88	6 (5.8-7.2)	Mann-Whitney U Test:
Ultrasound Therapy	6.08	27	0.74	5.9 (5.7-5.4)	Z = 1.859, p = 0.044*

* significant for $p < 0.05$.

Discussion

This study was conducted to compare the efficacy of two different physical modalities and to determine which of them gives better results in achieving the analgesic effect, disability of patients and flexibility of the lumbar spine. The study included 54 patients with chronic low back pain treated with high-intensity laser, ultrasound therapy and exercise therapy. The comparison of the parameters in the examined group (patients treated with high-intensity laser and exercises) at the beginning of therapy, at two weeks and three months after completion of therapy revealed significant changes in the results obtained by the Numeric Rating Pain Scale, Schober's test and Oswestry Disability Index. The group of patients who were treated with high-intensity laser and exercises showed statistically significantly better results in all three parameters when compared to the control group of patients treated with ultrasound therapy and exercises. High-intensity laser in combination with exercise therapy proved to be effective in patients with chronic low back pain. Its analgesic effects after ten days of application were maintained in the next three months. It resulted in a better functional performance in patients and improved flexibility in the lumbar spine.

Low-intensity laser therapy is still being used in the treatment of chronic low back pain and with its analgesic effects contributes to the better functional ability of patients and better range of lumbar spine motion [16]. Since recently, the new type of lasers, the high-intensity ones, has been introduced in the physical rehabilitation medicine as a non-invasive and safe physical modality. The use of high-intensity laser in physical medicine is a relatively new technology, which is continuously developing. By its high-intensity power and specific wavelength, it enables treatment of different clinical conditions. It is used in the treatment of shoulder pain [12], degenerative knee disease [17], and chronic pain in the ankle [18]. Clinical studies have confirmed the use of high-intensity laser in the treatment of acute and chronic pain associated with chronic arthritis, tendinitis, fibromyalgia as well as knee injuries [9], [10]. The analgesic effect is due to inhibition of painful sensation at different levels. Histamine and bradykinin release from inflammatory tissue [19] is reduced, and the pain threshold is increased. Also, laser light reduces the secretion of substance P from peripheral nociceptors, thus reducing the pain relay and preventing the development of hyperalgesia [20]. The laser analgesic effect is due to increased secretion of endogenous opioids such as β-endorphins, by which the pain is centrally inhibited [21]. Absorbed laser light in the tissue increases the mitochondrial oxidative process; hence the production of ATP, RNA and DNA is increased resulting in a photobiological effect [22].

This study aimed to determine the impact of the high-intensity laser on pain and functionality of patients with chronic low back pain. Alayat et al., 2014, reported that a combined treatment of exercises and high-intensity laser gave a better range of lumbar spine motion, reduced pain and better functionality in patients than that with a high-intensity laser, but without exercises and placebo laser with exercises. They found out that four weeks of treatment with laser and exercises resulted in statistically significant improvement on the VAS scale. Functional ability of these patients, which was measured by the Oswestry Disability Index, also showed a statistically significant difference compared to the other two groups of patients [23].

Angelova A and Ilieva EM, 2016, in their pilot, a randomised clinical study from 2016 investigated the analgesic effect of high-intensity laser in patients with osteoarthritis. Pain intensity was compared by VAS scale and dolorimeter, which showed a significant pain decrease in patients after seven days [24]. Efficacy of high-intensity laser in patients with knee osteoarthritis was proved by Gppl-Joo Kim et al., 2016 [25]. They showed that therapy with high-intensity laser was more effective in these patients than conventional physical therapy. Kheshie et al. demonstrated significantly better results of high-intensity laser than of low-intensity one in the treatment of chronic pain associated with knee osteoarthritis [26].

Laser therapy has rarely been presented in the management of patients who have fibromyalgia in spite of the benefits described in two controlled studies conducted by Gür et al., [27], [10]. These researchers have demonstrated that low-intensity laser alone and in combination with amitriptyline was safe and effective in the treatment of fibromyalgia if administered every day in 2 weeks.

A large number of studies have examined the treatment options of osteoporosis, such as exercise therapy, vibration therapy, pulsed electromagnetic field therapy and low-level laser therapy [28]. Laser beams can stimulate the proliferation by increasing the synthesis of DNA and RNA of osteoblasts in vitro

[29]. High-intensity laser combined with exercises is more effective in decreasing pain and in improving quality of life in male patients with osteopenia or osteoporosis [30].

Fiore et al., 2011, in their randomised trial have also proved the analgesic effect of high-intensity laser in patients with low back pain. Patients in their study received 15 treatment sessions of the high-intensity laser during three consecutive weeks against a control group of participants who received ultrasound therapy. The results obtained in both groups of patients were analysed by the VAS scale and Oswestry Disability Index immediately after the completed therapy and showed a significantly greater pain decrease in patients treated with a high-intensity laser [31].

It is assumed that exercises for the strengthening of spinal, abdominal and gluteal muscles, which are applied in patients with chronic low back pain, should be combined with laser therapy for achieving better results [16]. Several researchers have shown no advantages of using laser therapy alone or conducting exercises alone in the treatment of chronic pain, but these studies have analysed only the short-term effects of laser therapy [16].

It should be emphasised that ultrasound therapy as a physical agent is important in the treatment of musculoskeletal disorders [32]. Until nowadays ultrasound therapy has proved to be a good choice of physical agent in the treatment of chronic pain. The application of ultrasound energy in the treatment of low back pain was presented in the study of Safoora Ebadi et al. The results they obtained in their randomised controlled study showed the analgesic effect of ultrasound therapy, which resulted in improvement in functional disability in patients with chronic low back pain [33]. Durmus et al., 2010, also evaluated three groups of patients with low back pain that were given ultrasound therapy and exercised therapy, electric stimulation and exercise therapy and only exercise therapy. They observed that exercises combined with ultrasound therapy reduced pain when compared to patients treated with the other two physical modalities [34].

The present study indicates that exercise therapy is clinically able to decrease pain, increase ROM, and improve function. It is providing to be economical, practical, and safe to emphasise the importance of an exercise program in rehabilitation aimed at functional recovery. The combined significance, improving chronic low back pain and having this positive effect last for a period of up to 3 months.

Moreover, HILT can be useful to reduce pain and disability related, but this is important to add rehabilitation programs with the exercise of leg and spine and stretching to reduce the frequency of low back pain.

The study has several limitations. The main limitation of our study is the low number of patients included in the study. Second, we could not perfectly control the daily routine of the subjects. All patients were instructed to perform exercises at home, and report of exercise compliance was obtained from family members. Even though neither the family members nor the participants themselves reported any deficiency in the exercise prescription at home, we considered this to be a limiting factor in the present study. Also, the limitation of the study is that the occupation of patients and the body mass index have not been considered. Further studies with a larger number of patients, more demographic features and controls are required to evaluate the long-term effects of the therapies. We believe that many new studies on the effects of HILT will be required to complement the limitations of this study.

In conclusion, this study has shown that patients with chronic low back pain treated with a high-intensity laser have significantly reduced low back pain, reduced disability and improved range of motion. Its positive effect maintained for three months. It seems to be an effective, safe and useful physical modality in the treatment of a patient with chronic low back pain. Exercise therapy should never be ignored to treat and prevent lumbar back pain.

HILT is an adjuvant physical therapy modality that may provide better outcomes for a patient with chronic back pain when used in combination with exercise.

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