Lasers Med Sci
DOI 10.1007/s10103-013-1472-5

ORIGINAL ARTICLE

Long-term effect of high-intensity laser therapy in the treatment of patients with chronic low back pain: a randomized blinded placebo-controlled trial

Mohamed Salaheldien Mohamed Alayat · Azza Mohamed Atya · Mohamed Mohamed Ebrahim Ali · Tamer Mohamed Shosha

Received: 18 February 2013 / Accepted: 16 October 2013

Abstract The aim of this study was to compare the effect of high-intensity laser therapy (HILT), alone or combined with exercise, in the treatment of chronic low back pain (CLBP). A total of 72 male patients participated in this study, with a mean (SD) age of 32.81 (4.48) years. Patients were randomly assigned into three groups and treated with HILT plus exercise (HILT + EX), placebo laser plus exercise (PL + EX), and HILT alone in groups 1, 2, and 3, respectively. The outcomes measured were lumbar range of motion (ROM), pain level by visual analog scale (VAS), and functional disability by both the Roland Disability Questionnaire (RDQ) and the Modified Oswestry Disability Questionnaire (MODQ). Statistical analyses were performed to compare the differences between baseline and post-treatment measurements. The level of statistical significance was set as $P<0.05$. ROM significantly increased after 4 weeks of treatment in all groups, then significantly decreased after 12 weeks of follow-up, but was still significantly more than the baseline value in groups 1 and 2. VAS, RDQ, and MODQ results showed significant decrease post-treatment in all groups, although the RDQ and MODQ results were not significantly different between groups 2 and 3. HILT combined with exercise appears to be more effective in patients with CLBP than either HLLT alone or placebo laser with exercise.

M. S. M. Alayat (✉) · A. M. Atya
Basic Science Department, Faculty of Physical Therapy, Cairo University, 7 Ahmed Elziat Street from Eltahrir Street, Cairo, Egypt
e-mail: mohsalahpt@hotmail.com

M. M. E. Ali
Department of Physical Therapy for Musculoskeletal Disorders, Faculty of Physical Therapy, Cairo University, Cairo, Egypt

M. M. E. Ali · T. M. Shosha
Department of Physical Therapy, Faculty of Applied Medical Sciences, Umm Al-Qura University, Mecca, Saudi Arabia

Published online: 02 November 2013

Keywords CLBP · HILT · Exercise · Pain · Functional disability

Introduction

Low back pain is a common problem and is related to disability and work absence, accounting for high economic costs in Western societies [1]. In the United States, it is estimated that 70–85 % of the population is affected by back pain at some point in their lifetime, with an annual prevalence of 15–45 % [1]. In Britain, the prevalence of low back pain has reportedly rising from 36.5 % in 1987 to 49.1 % in 1997 [2].

Although most studies on low back pain come from industrialized nations, the condition is also considered to be a major problem in Arab countries. In the United Arab Emirates, the prevalence of low back pain and its associated risk factors is 64.6 % [3], and in Kuwaiti schoolchildren in the Hawalli Governorate, a cross-sectional study of 400 schoolchildren aged 10 to 18 years showed that low back pain has a lifetime prevalence of 57.8 % (50.8 % in males and 64.7 % in females) while the point prevalence was 35 % (20.6 % in male and 39.3 % in females) [4]. Low back pain is a similar health problem in Saudi Arabia, with Al-Arfaj et al. (2003) reporting a prevalence in the adult population of 18.8 %. The prevalence increases with age over 30 years, and low back pain is more common in married than in unmarried individuals (23.3 % vs. 6.4 %) [5]. Approximately 26.2 % of school workers in the city of Jeddah have low back pain [6].

Chronic low back pain (CLBP) is defined as pain in the lumbosacral area of the spine, of more than 12 weeks' duration. The pain may or may not be referred to other locations, and it usually causes limitations in range of motion (ROM) [7]. CLBP is generally considered a result of mechanical causes and not related to an underlying condition

such as infection, neoplasm, or fracture. The causes may stem from nociceptive, neuropathic, or psychological processes, or a combination of these [8]. The management includes different approaches including patient education; behavioral treatment; lumbar support; traction; or the use of physical therapy modalities such as massage, superficial heat or cold, exercise, transcutaneous electrical nerve stimulation, and laser therapy [9].

Laser treatment is noninvasive, painless, and can be easily administered in primary care settings for a wide range of conditions [10]. It has been reported that the use of laser therapy significantly reduces pain levels in both acute and chronic conditions such as rheumatoid arthritis, chronic osteoarthritis, carpal tunnel syndrome, fibromyalgia, knee injury, shoulder pain, and postoperative pain [11–13]. Although low level laser therapy does not elevate tissue temperatures more than a few degrees [11], studies have found that the treatment has the potential to reduce inflammation, pain and improve function [10, 14]. Low level laser therapy significantly increases microcirculation, activates angiogenesis, and stimulates immunological processes and nerve regeneration. Moreover, it has an analgesic effect through stimulating an increased production of endorphins [13].

More recently, the pulsed neodymium-doped yttrium aluminum garnet (Nd:YAG) laser, a form of high-intensity laser therapy (HILT), was introduced to the field of physical therapy. This laser works with high peak power (3 kW), and a wavelength of 1,064 nm, and is considered to be a nonpainful and noninvasive therapeutic modality. It is able to stimulate areas that are difficult to reach with the low-power laser, such as the large and/or deep joints [15]. The use of the pulsed Nd:YAG laser has been increasing, with patients reporting significant pain reduction [16]. Studies have documented the anti-inflammatory, anti-oedematous, and analgesic effects of the Nd:YAG laser, justifying its use in patients with pain issues [17, 18].

This randomized, blinded study was designed to compare the effect of HILT, both alone and combined with exercise, in the treatment of CLBP patients.

Methods

A randomized, single-blinded, placebo-controlled design was employed. Patients diagnosed with CLBP were referred to the study from the orthopedic department and recruited from the rehabilitation department of Al-Noor Hospital, Makkah, Saudi Arabia. Patient selection was based on history and physical examination. The inclusion criteria were male patients with a history of CLBP for at least 1 year, and age between 20 and 50 years [14]. Patients with a history of spinal surgery [14], degenerative disc disease, disc herniation, spine fracture, spondylosis, spinal stenosis, neurological deficits, abnormal laboratory findings, and systemic and psychiatric illnesses were excluded [19]. Patients with a previous history of low back pain episodes and radiographic findings positive for mild pathology were allowed to participate [14].

After baseline examination, all patients were given a full explanation of the treatment protocol and asked to sign written informed consent for study participation and for publication of the results. The study was approved by the departmental council of the Faculty of Applied Medical Science, Umm Al-Qura University, Makkah, Saudi Arabia.

Power analysis

A total sample size of 69 patients was calculated by preliminary power analysis, using a power of 90 % and $\alpha = 0.05$ to detect a difference of 10° with a standard deviation (SD) of 3.5 in lumbar ROM. Repeated-measures analysis of variance (ANOVA) was used in three study groups to produce an effect size of 0.48 with a correlation of 0.5 between measurements. The effect size chosen was based on a pilot study and on the results of previous studies on low level laser therapy [14, 19]. The high effect size was recommended in order to observe only major differences between groups; this yielded a realistic sample size that allowed for the observation of major differences in the variables measured [20].

Participants

This study included 72 male patients recruited from the male section of the rehabilitation department with CLBP who were assigned specific identification numbers and randomized into three groups using a GraphPad program (GraphPad Software, Inc., San Diego, CA, USA). Patients did not know to which group they were assigned or which treatment they would be offered. Group 1 was treated with HILT and exercise (HILT + EX group), group 2 received placebo laser and exercise (PL + EX group), and group 3 was treated by HILT alone (HILT group).

Pain assessment

For the assessment of pain intensity, a visual analog scale (VAS) was used both pre- and post-treatment. The VAS has been shown to be a reliable and valid measure of pain. Pain was measured as the average level of low back pain over the past few days, using a 10-cm VAS. Patients were asked to estimate the severity of pain by placing a mark on a line, with 0 (no pain) and 10 (the worst imaginable pain) marking the ends of the VAS line [21].

Functional activity assessment

The Roland Disability Questionnaire (RDQ), a reliable, valid, and sensitive questionnaire, was used to measure patients' level of functioning in performing daily tasks. Scores range from 0 to 24, with patients instructed to place a mark next to each appropriate statement in a list of 24 statements [22].

The Modified Oswestry Disability Questionnaire (MODQ) consisted of 10 items addressing different aspects of functioning. Each item was scored from 0 to 5, with higher values representing greater disability [23]. The total score was multiplied by 2 and expressed as a percentage [24].

Back range of motion assessment

A back range of motion (BROM) device was used to measure spinal ROM. This device was a modified protractor goniometer designed to measure trunk motion and not based on a gravity inclinometer, thus eliminating the frequent sources of measurement error encountered with traditional inclinometers [25]. For measurement of flexion/extension, a combination inclinometer and goniometer was used. This device consisted of a modified protractor fixed on a base unit, placed on the sacrum with an arm extended to T_{12}. The protractor pivoted on the base and the pointer indicated flexion and extension angles on the protractor degree scale. The upper contact point of the fixed unit was secured to the sacrum over $S_{1,}$ using a strap placed around the patient's pelvis just below the anterior superior iliac spines. The strap was fastened as tightly as possible without causing discomfort and as the patient moved forward and backward, the flexion and extension ROM were recorded. For rotation and lateral flexion, an inclinometer in a positioning frame and a compass on a magnetic booster were used. The inclinometer was mounted on the vertical plane for measuring lateral flexion and the compass was mounted on the horizontal plane for measuring rotation. The magnetic booster included a belt and a magnet that was encased in vinyl in a Velcro strap. The booster provided a stable magnetic field for the compass, which in turn provided a quick response and accurate rotation readings [25, 26]. Each patient was given three warm-up repetitions for each movement to provide a pre-test stretch to the soft tissue of the lumber spine in each plane of motion.

Pulsed Nd:YAG laser therapy

Patients received pulsed Nd:YAG laser treatment, produced by a HIRO 3 device (ASA Laser, Arcugnano, Italy). The apparatus provided pulsed emission (1,064 nm), very high peak power (3 kW), a high level of fluency/energy density (510–1,780 mJ/cm), a brief duration (120–150 μs), a low frequency (10–40 Hz), a duty cycle of about 0.1 %, a probe diameter of 0.5 cm, and a spot size of 0.2 cm^2 [15].

A handpiece was positioned in contact with and perpendicular to the treated area, with the patient in the prone position. Scanning was performed transversely and longitudinally in the lower-back area of L_1–L_5 and $S_{1,}$ to cover the fasciae, sacral ligaments, ileum, latissimus dorsi, obliquus externus abdominis, and the upper part of the gluteus maximus [27].

A total energy dose of 3,000 J was administered through three phases of treatment. The initial phase was performed with fast manual scanning for a total of 1,400 J. In the initial phase, the laser fluency was set to three successive subphases of 610, 710, and 810 mJ/cm^2, for a total of 1,400 J. An intermediate phase applied the handpiece to the eight paravertebral points from L1 to S3 [14], with 25 J, a fluency of 610 mJ/cm^2, and a time of 14 s at each point, for a total of 200 J. The final phase was the same as the initial phase, except that slow manual scanning was used. The application time for all three phases was approximately 15 min. The HILT device calculated the energy received during each phase and the total energy delivered to the patient during the treatment session. HILT was applied for a total of 12 treatment sessions over 4 consecutive weeks (three sessions per week). Patients in group 1 received HILT, and then the exercises were performed thereafter. For placebo laser treatment, the patient attended the physical therapy clinic three times weekly for 4 weeks and received sham laser before applying exercises.

Exercises

The exercise program was designed to be easily carried out at home. There was no need for special equipment or access to a gym or fitness facility. The exercises included strengthening, stretching, mobilizing, coordinating, and stabilizing the abdominal, back, and pelvic muscles, and were personalized for each patient's clinical findings [19]. Participants were taught by a physiotherapist to perform the exercises correctly, with the physiotherapist conducting the first session before patients continued exercising at home. A family member confirmed that the participant carried out the exercises at home. All treatment groups were given instructions to perform the exercises two times daily for 4 weeks.

Outcome measures

Baseline evaluation of the measured outcomes was performed at the beginning of the study, and evaluation was repeated after 4 weeks of treatment and again after 12 weeks of further follow-up. The measured outcomes were lumbar ROM, pain levels, and disability scores. Lumbar ROM was measured using the BROM device described above and expressed in degrees. Pain was measured using the VAS, and functional assessments were measured using the RDQ and MODQ.

Statistical analysis

All analyses were performed using Statistical Package for the Social Sciences (SPSS) for Windows, version 16 (SPSS Inc., Chicago, IL, USA) except for the sample size and power calculations, performed by GPower 3.1 for Windows, and the repeated measures one-way ANOVA, analyzed by GraphPad InStat (GraphPad Software, Inc., San Diego, CA, USA). The ROM comparison between groups was carried out by ANOVA with post-hoc least significance difference testing. The difference between the baseline and post-treatment measurements for each group was computed by repeated measures ANOVA with post-hoc Bonferroni testing.

For nonparametric measures (VAS, RDQ, and MODQ), the difference between the baseline and post-treatment scores for each group was computed using the Friedman test. The Wilcoxon signed ranks test was performed to compare each group's results, between baseline, 4 weeks, and 12 weeks. The differences between treatment groups were calculated by Kruskal–Wallis testing. The Mann–Whitney *U*-test was used to compare the same measurement intervals (4 weeks, 12 weeks) between groups to determine significance. The level of statistical significance was set at $P<0.05$.

Results

A total of 72 male patients participated in this study, with a mean (SD) age of 32.81 (4.48) years, a mean weight of 84.02 (10.90) kg, and mean duration of illness of 13.88 (1.80) months. Group 1 (HILT + EX) consisted of 28 patients, group 2 (PL + EX) consisted of 24 patients, and group 3 (HILT alone) consisted of 20 patients. Testing for homogeneity of variance revealed a non-significant difference in the subjects' age ($P=0.943$), weight ($P=0.535$), and duration of illness between the groups ($P=0.450$) (Table 1).There were no significant differences between the three treatment groups in baseline lumbar ROM (Table 2; Fig. 1) or the baseline VAS, (Table 3; Fig. 2) RDQ, and MODQ scores (Table 3; Figs. 3 and 4).

The HILT + EX group showed a significant difference in post-treatment ROM results compared with baseline. ROM significantly increased after 4 weeks and then significantly decreased after an additional 12 weeks of follow up, although the value was still significantly higher than at baseline (Table 2). There were significant changes in post-treatment VAS, RDQ, and MODQ scores compared with baseline. These scores decreased after 4 weeks and then significantly increased after 12 weeks, although they were still significantly lower than at baseline (Table 3).

The effect seen in the PL + EX group was similar to that seen in the HILT + EX group, in that ROM increased and VAS, RDQ, and MODQ scores decreased after 4 weeks, with these changes reversed at 12 weeks (Tables 2 and 3).

In the HILT group, ROM significantly increased after 4 weeks of treatment and then decreased significantly after 12 weeks compared with the 4-week values, with a non-significant difference ($P>0.05$) between the baseline values and the 12-week values for all ROM measurements (Table 2). There were significant decreases in the VAS, RDQ, and MODQ scores after 4 weeks, compared with baseline, with subsequent significant increases after 12 weeks, although these values remained significantly lower than at baseline (Table 3).

Post-hoc testing revealed a significant ROM improvement in the HILT + EX group, greater than that seen in the PL + EX group; the least effect was seen in the HILT group, at both 4 and 12 weeks (Table 2). There was a non-significant difference between the PL + EX and the HILT groups in RDQ and MODQ scores (Figs. 3 and 4). The HILT + EX group had a larger significant decrease in the VAS score than the PL + EX group, with the least effect experienced by the HILT group, at both 4 and 12 weeks (Table 3; Fig. 2).

Table 1 Patients demographic data

	HILT + EX (mean ± SD)	PL + EX (mean ± SD)	HILT (mean ± SD)	*P*
Age	33.4286 ± 4.40	31.54±4.47	33.50±4.51	0.234[a]
Weight	84.53±13.67	83.29±9.41	84.20±8.38	0.918 [a]
Duration of illness	13.92±1.88	13.33±1.49	14.50±1.90	0.100 [a]

HILT high-intensity laser therapy, *PL* placebo laser, *EX* exercises, *SD* standard deviation, *P* probability value

[a] Non-significant difference

Discussion

This study was conducted to compare the efficacy of HILT, either alone or combined with exercise, in the treatment of patients with CLBP. The main findings were (1) that HILT combined with exercise is effective in increasing lumbar ROM and in decreasing the VAS, RDQ, and MODQ pain and disability scores after 4 weeks of treatment and 12 additional weeks of follow-up; (2) HILT alone is effective in increasing ROM and decreasing VAS, RDQ, and MODQ scores after 4 weeks of treatment, but with a non-significant difference in ROM after 12 weeks of follow up compared with baseline; (3) there is no significant difference between HILT alone and placebo laser with exercise in RDQ and MODQ scores at either follow-up point; and (4) HILT combined with exercise is the most effective treatment for patients with CLBP.

Low-intensity laser therapy is currently used in the treatment of patients with CLBP. It is considered an effective physical therapy modality for increasing ROM [14, 18] and

Table 2 Changes in ROM among treatment groups

		HILT + EX (mean ± SD)	PL + EX (mean ± SD)	HILT (mean ± SD)	*P* value
Flexion	Pre	20.54±4.97	21.25±4.95	20.50±4.56	0.835[c]
	4 weeks	33.75±3.99	30.08±3.32	26.65±5.824	>0.0001[a]
	12 weeks	29.46±3.69	25.54±3.43	23.00±2.99	>0.0001[a]
	P value	<0.0001[a]	<0.0001[a]	0.0005[a]	
Extension	Pre	3.96±1.90	3.50±1.93	3.20±1.79	0.369[c]
	4 weeks	8.79±1.91	6.88±2.47	5.20±2.31	>0.0001[a]
	12 weeks	7.04±2.24	5.62±1.91	3.5±2.351	>0.0001[a]
	P value	<0.0001[b]	<0.0001[b]	0.0022[b]	
Rt rotation	Pre	10.46±2.89	9.875±3.38	9.15±2.46	0.322[c]
	4 weeks	18.93±1.93	15.63±3.06	12.45±2.45	>0.0001[a]
	12 weeks	16.14±2.33	13.54±2.75	10.25±3.01	>0.0001[a]
	P value	<0.0001[b]	<0.0001[b]	<0.0001[b]	
Lt rotation	Pre	10.42±2.69	9.70±2.9	9.90±2.34	0.603[c]
	4 weeks	15.25±2.49	15.58±3.11	12.70±2.56	>0.0001[a]
	12 weeks	15.5±3.16	13.25±3.90	10.25±2.55	>0.0001[a]
	P value	<0.0001[b]	<0.0001[b]	0.0007[b]	
Rt bending	Pre	18.71±4.34	19.29±4.70	19.60±5.13	0.800[c]
	4 weeks	33.36±3.60	28.96±4.16	24.60±4.16	>0.0001[a]
	12 weeks	29.46±4.16	24.16±3.81	20.50±3.94	>0.0001[a]
	P value	<0.0001[b]	<0.0001[b]	0.0036[b]	
Lt bending	Pre	17.82±4.39	19.17±4.82	18.65±3.25	0.520[c]
	4 weeks	32.17±3.62	29.21±3.764	24.05±4.77	>0.0001[a]
	12 weeks	28.39±3.61	24.79±3.12	20.75±3.35	>0.0001[a]
	P value	<0.0001[b]	< 0.0001[b]	0.0003[b]	

HILT high-intensity laser therapy, *PL* placebo laser, *EX* exercises, *SD* standard deviation, *Rt* right, *Lt* left, *P* probability value

[a] Significant difference in the same measurement interval among treatment groups (one-way ANOVA; $P<0.05$)

[b] Significant difference among the repeated measurement intervals in each treatment group (repeated-measures ANOVA; $P<0.05$)

[c] Non-significant difference

for decreasing pain levels [28], functional disability [14, 18], and the radiculopathy associated with CLBP [29]. Recently, pulsed Nd:YAG laser therapy, a form of HILT, has been used for a wide range of conditions. HILT applications include wound repair (as in diabetic foot ulcers) [30] and pain relief. It has been used to provide relief from the symptoms of

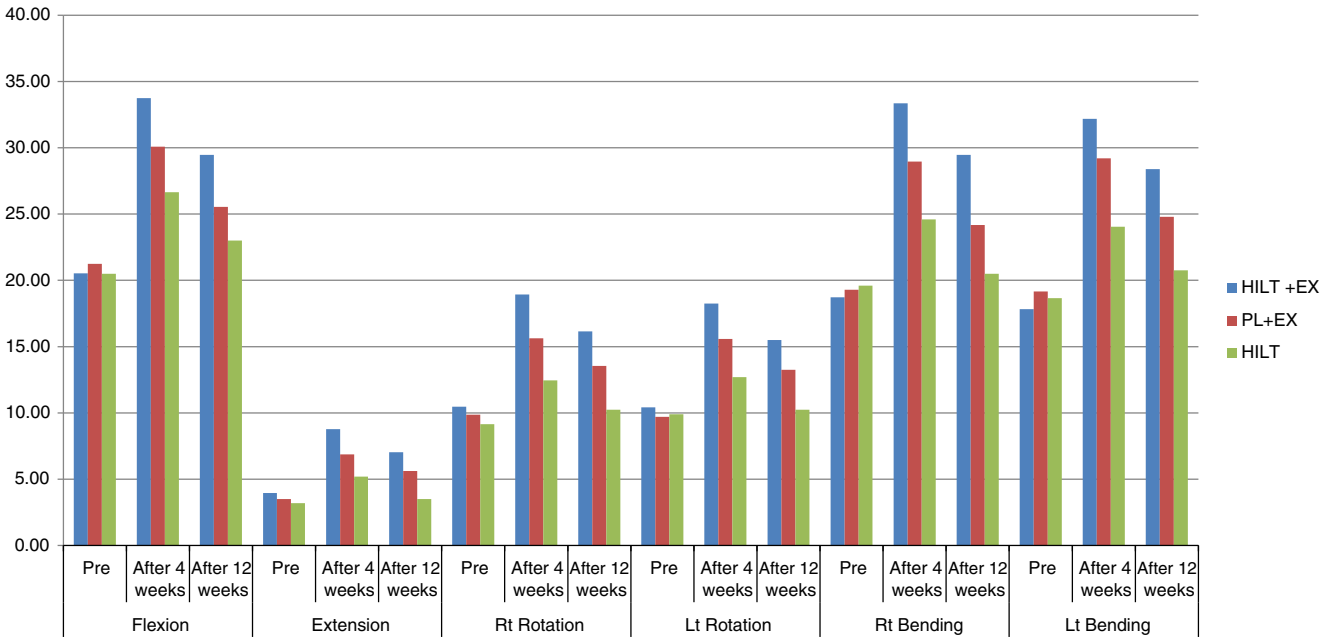

Fig. 1 ROM changes among treatment groups

Table 3 Changes in the VAS, RDQ and MODQ among treatment groups

	VAS				RDQ				MODQ			
	Pre	4 weeks	12 weeks	P value	Pre	4 weeks	12 weeks	Value	Pre	4 weeks	12 weeks	P value
HILT + EX	8.36±0.95	2.04±0.83	2.64±1.25	<0.0001[b]	15.46±1.17	4.43±1.28	5.5±1.17	<0.0001[b]	34.11±3.14	13.9±3.83	15.14±4.3	<0.0001[b]
PL + EX	8.21±1.1	3.21±0.83	3.71±1.30	<0.0001[b]	15.63±1.56	5.75±0.99	6.92±0.78	<0.0001[b]	34.5±2.93	16.41±3.01	18.75±3.07	<0.0001[b]
HILT	8.35±0.88	4.15±2.03	5.65±1.04	<0.0001[b]	15.4±1.19	6.35±1.6	7.35±1.5	<0.0001[b]	35.55±3.62	17.25±3.14	19.05±2.96	<0.0001[b]
P value	0.873[c]	0.0001[a]	0.0001[a]		0.917[c]	0.0001[a]	0.0001[a]		0.287[c]	0.002[a]	0.0001[a]	

VAS visual analogue scale (score: 0–10) measures the intensity of pain (a higher were indicated higher pain intensity); *RDQ* Roland Disability Questionnaire (score: 0–24) measures function (a lower score indicates less dysfunction), *MODQ* Modified Oswestry Disability Questionnaire (score: 0–50) measures function (a lower score indicates less dysfunction)

[a] Significant difference in the same measurement interval between treatment groups (Kruskal–Wallis test; $P<0.05$)

[b] Significant difference between the measurement intervals (Pre, 4 weeks and 12 weeks) in each treatment group (Friedman test; $P<0.05$)

[c] Non-significant difference in Pre-treatment mean values

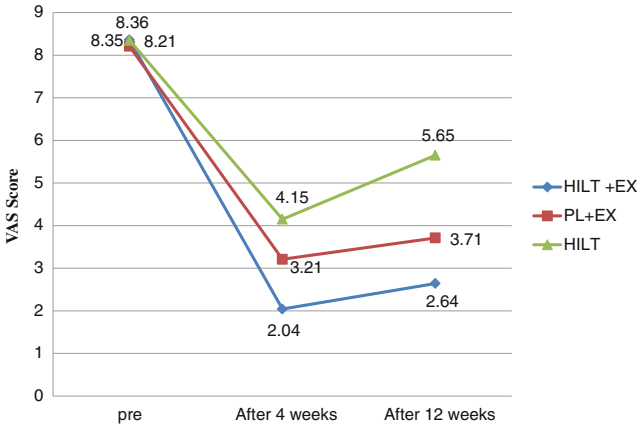

Fig. 2 VAS changes among treatment groups

shoulder pain [16], knee arthritis [17, 31, 32], and chronic ankle pain [18]. Fiore et al. [27] compared the short-term effectiveness of HILT with ultrasound therapy in the treatment of low back pain. Study participants received HILT over a period of 3 consecutive weeks and showed a significant decrease in pain levels, greater than with ultrasound treatment [27].

Laser therapy is generally believed to alter cellular and tissue function, depending on the characteristics of the laser itself (e.g., wavelength, coherence) [33]. The pulsed Nd:YAG laser has a wavelength of 1,064 nm and works in a therapeutic window that allows it to penetrate and spread more easily through tissue, as human skin does not have an adequate concentration of endogenous chromophores to efficiently absorb this wavelength [15]. Absorption at the tissue level is characterized by light diffusion in all directions (the scattering phenomenon), which increases the mitochondrial oxidative reaction and subsequently increases adenosine triphosphate (ATP), RNA, and DNA production. These so-called photochemistry effects result in the phenomenon of tissue stimulation, also known as the photobiology effect [15]. When the Nd:YAG laser is used in a continuous fashion,

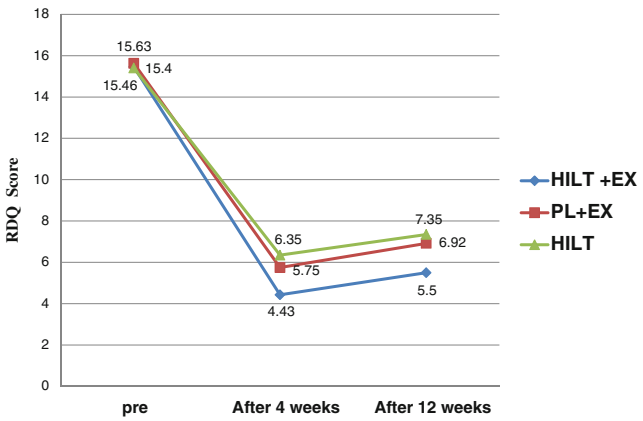

Fig. 3 RDQ changes among treatment groups

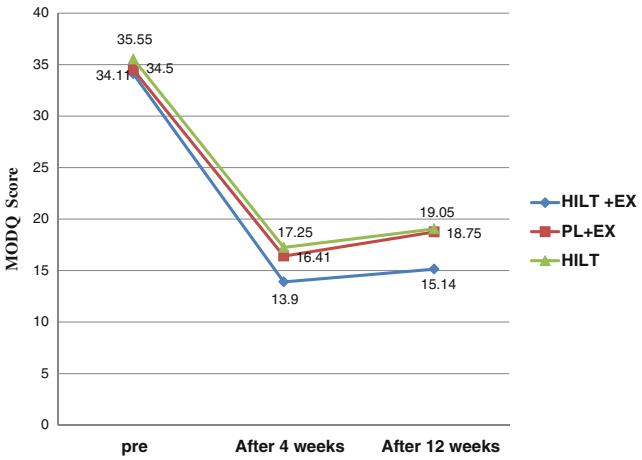

Fig. 4 MODQ changes among treatment groups

thermal accumulation occurs. For HILT, the laser is used with a particular waveform, a peak power of up to 3 kW, regular peaks of elevated amplitude for a very brief duration and a very short duty cycle to decrease thermal accumulation in tissues, and to rapidly induce the deep-tissue photochemical and photothermal effects [15]. These features result in greater radiation propagation in the target tissues with a very low histological risk, leading to the possibility of treating deep tissues and structures. The photothermal effect can be controlled for patient safety and comfort by modulating the pulse intensity and frequency [34, 35].

The efficacy of the pulsed Nd:YAG laser has been proven in the treatment of many musculoskeletal diseases and it is believed to have anti-inflammatory, anti-edema, analgesic, and reparative effects [35]. The analgesic effect of HILT is based on different mechanisms of action, including its ability to slow the transmission of the pain stimulus and to increase the production of morphine-mimetic substances in the body [15]. In addition, it may have a direct effect on nerve structures, which could increase the speed of recovery from conduction block or inhibit Aδ- and C-fiber transmission [36]. The treatment also increases blood flow, vascular permeability, and cell metabolism [37].

In the present study, the effect of combined laser therapy with exercise was greater than that of placebo laser with exercise. It has been suggested that placebo treatments are important tools that can be used by the medical community to complement regular therapies; most physicians reportedly believe their use to be ethically permissible [38]. However, the use of placebo treatments in clinical medicine remains controversial [39]. The results of this study agree with the findings of many studies, that laser therapy has a greater effect than sham laser in treating pain and disability, as measured by VAS and MODQ results [14, 19, 33]. A systemic review examined the placebo effect associated with the treatment of CLBP and showed that none of the included studies could demonstrate a clinically meaningful improvement in pain and disability scores after the use of sham laser [40].

CLBP is considered to compromise patients' physical activity. The reason for the persistence of functional disability in CLBP sufferers may be the patients' own fear of physical activity: many patients with CLBP believe that engaging in job-related and indoor physical activity might worsen their pain [41].

Although controversial, it has been suggested that exercise therapy should be combined with laser therapy in the treatment of patients with CLBP [14]. Several researchers have shown that there is no advantage of using laser alone or combined with exercise over exercise alone, but it should be noted that these studies only analyzed effects of laser in the short term [19].

The present study indicates that exercise therapy is clinically able to decrease pain, increase ROM, and improve function. It is proving to be economical, practical, and safe to emphasize the importance of an active exercise program in rehabilitation aimed at functional recovery. The combined use of exercise and HILT has shown to be of clinical significance, improving CLBP and having this positive effect last for a period of up to 3 months.

The clinical improvement in the present study was evaluated by lumbar ROM measurements and by VAS, RDQ and MODQ pain and disability scores. Future research with measurements of back-muscle activity (by electromyography) and back-muscle power (by isokinetic dynamometer) may be needed to correlate these findings.

Conclusion

Pulsed Nd:YAG laser treatment (HILT) is an effective physical therapy modality for patients with CLBP. In fact, HILT combined with exercise is more effective and has a more prolonged effect than sham laser with exercise or laser alone in increasing lumbar ROM and in decreasing pain and functional disability, with effects lasting up to 3 months.

Recommendation

Pulsed Nd:YAG is an adjuvant physical therapy modality that may provide better outcomes for patients with CLBP when used in combination with exercise.

Limitations

The patients were recruited from the male section of the rehabilitation department in the hospital, and therefore all patients were male. All patients were instructed to perform exercises at home, and a report of exercise compliance was obtained from family members. Despite the fact that 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.

Acknowledgements The authors express their appreciation to all subjects who participated in this study with all content and cooperation, and give special thanks to their colleagues at the Department of Physical Therapy, Faculty of Applied Medical Science, Umm AL-Qura University, Saudi Arabia. They also thank Dr. Hesham Gad Alrab, assistant professor, Faculty of Education, Mansura University, Egypt, for technical support and statistical analysis.

Conflict of interest There is no financial and personal relationship with other people or organizations that could inappropriately influence this work.

References

1. Andersson GB (1999) Epidemiological features of chronic low back pain. Lancet 354:581–585
2. Palmer KT, Walsh K, Bendall H, Cooper C, Coggan D (2000) Back pain in Britain: comparison of two prevalence surveys at an interval of 10 years. BMJ 320:1577–1578
3. Abdulbari B, Omer F, Abdulrahim S, Mohammed S, Ferenc T, Gyorgy L (2004) Epidemiology of low back pain in the United Arab Emirates. J APLAR Rheumatol 7:189–195
4. Shehab D, Al-Jarallah K, Al-Ghareeb F, Sanaseeri S, Al-Fadhli M, Habeeb S (2004) Is low-back pain prevalent among Kuwaiti children and adolescents? J Med Princ Pract 13:142–6
5. Al-Arfaj AS, Al-Saleh SS, Alballa SR, Al-Dalaan AN, Bahabri SA, Al-Sekeit MA, Mousa MA (2003) How common is back pain in Al-Qaseem region. Saudi Med J 24(2):170–173
6. Abalkhail BA, Bahnassy AA, Ghabrah TM (1998) Low back pain among Saudi school workers in Jeddah 19(4):491–495
7. Manchikanti L (2000) Epidemiology of low back pain. Pain Physician 3:167–192
8. Grabois M (2005) Management of chronic low back pain. Am J Phys Med Rehabil 84(3):S29–41
9. Van Middelkoop M, Rubinstein SM, Kuijpers T, Verhagen AP, Ostelo R, Koes BW, van Tulder MW (2011) A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. Eur Spine J 20(1):19–39
10. Brown AW, Weber DC (2000) Physical agent modalities. In: Braddom RL (ed) Physical medicine and rehabilitation. WB Saunders, Harcourt Health Sciences Company, London, pp 440–458
11. Ozdemir F, Birtane M, Kokino S (2001) The clinical efficacy of low power laser therapy on pain and function in cervical osteoarthritis. Clin Rheumatol 20:181–184
12. Gur A, Karakoc M, Nas K (2002) Efficacy of low power laser therapy in fibromyalgia: a single-blind, placebo-controlled trial. Lasers Med Sci 17:57–61
13. Peplow PV, Chung T, Baxter GD (2010) Application of low level laser technologies for pain relief and wound healing overview of scientific bases. Physical Therapy Reviews 15(4):253–285
14. Gur A, Karakoc M, Cevik R, Nas K, Sarac AJ, Karakoc M (2003) Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain. Lasers Surg Med 32(3):233–8
15. Zati A, Valent A (2006) Physical therapy: new technologies in rehabilitation medicine (translated to English). Edizioni Minerva Medica 2006:162–185
16. Santamato A, Solfrizzi V, Panza F, Tondi G, Frisardi V, Leggin BG, Ranieri M, Fiore P (2009) Short-term effects of high-intensity laser therapy versus ultrasound therapy in the treatment of people with subacromial impingement syndrome: a randomized clinical trial. Phys Ther 89(7):643–52
17. Viliani T, Ricci E, Mangone G, Graziani C, Pasquetti P (2009) Effects of Hilterapia vs. Viscosupplementation in knee osteoarthritis patients: a randomized controlled clinical trial. Energy for Health; International journal of information and scientific culture (3): 14–17.
18. Saggini R, Bellomo RG, Cancelli F (2009) Hilterapia and chronic ankle pain syndromes. Abstract from Energy for Health; International journal of information and scientific culture. 3 (3):22–25: 38.
19. Djavid GE, Mehrdad R, Ghasemi M, Hasan-Zadeh H, Sotoodeh-Manesh A, Pouryaghoub G (2007) In chronic low back pain, low level laser therapy combined with exercise is more beneficial than exercise alone in the long term: a randomized trial. Aust J Physiother 53(3):155–60
20. Welkowitz J, Ewen RB, Cohen J (1982) Introductory statistics for the behavioral sciences, 3rd edn. Harcourt Brace Jovanovich, San Diego, CA
21. Wewers ME, Lowe NK (1990) A critical review of visual analogue scales in the measurement of clinical phenomena. Res Nurs Health 13(4):227–36
22. Roland AI, Morris R (1983) A study of the natural history of back pain: Part I. Development of a reliable and sensitive measure of disability in low-back pain. Spine 8:141–144
23. Fairbank JC, Couper J, Davies JB, O'Brien JP (1980) The Oswestry low back pain disability questionnaire. Physiotherapy 66:271–273
24. Firtz JM, Irrgang JJ (2001) A comparison of a modified Oswestry low back pain disability questionnaire and the Quebec back pain disability scale. Phys Ther 81:776–778
25. Kachingwe AF, Phillips BJ (2005) Inter- and intrarater reliability of a back range of motion instrument. Arch Phys Med Rehabil 86(12): 2347–53
26. Tousignanta M, Morissetteb J, Murphy M (2002) Criterion validity study of lumbar goniometers BROM II and EDI-320 for range of motion of lumbar flexion of low back pain patients. J Back Musculoskelet Rehabil 1 16(4):159–67
27. Fiore P, Panza F, Cassatella G, Russo A, Frisardi V, Solfrizzi V, Ranieri M, Di Teo L, Santamato A (2011) Short-term effects of high-intensity laser therapy versus ultrasound therapy in the treatment of low back pain: a randomized controlled trial. Eur J Phys Rehabil Med 47(3):367–73
28. Hadi M, Ali SV, Isa MZ, Zeidi BM (2009) Low level laser therapy (LLLT) for chronic low back pain (LBP). European Journal of Scientific Research 29(1):76–81
29. Jovicić M, Konstantinović L, Lazović M, Jovicić V (2012) Clinical and functional evaluation of patients with acute low back pain and radiculopathy treated with different energy doses of low level laser therapy. Vojnosanit Pregl 69(8):656–62
30. Ebid AA, Thabet AA, Helal OF (2011) Effect of pulsed high intensity Nd:YAG laser in treatment of chronic diabetic foot ulcer. Energy for Health; International journal of information and scientific culture 7: 25–30
31. Zati A, Fortuna D, Benedetti E, Zaghini I, Bigotta TW (2006) HILT Therapy in the treatment of knee osteoarthritis: the first clinical cases and protocol for a multicenter double-blind randomized trial. Proceedings of 1st National conference dominate energy, scientific report HILT therapy.
32. Stiglić-Rogoznica N, Stamenković D, Frlan-Vrgoc L, Avancini-Dobrović V, Vrbanić TS (2011) Analgesic effect of high intensity laser therapy in knee osteoarthritis. Coll Antropol 35(2):183–5
33. Basford JR (1995) Low intensity laser therapy: still not an established clinical tool. Lasers Surg Med 16(4):331–42
34. Stadler I, Lanzafame R, Oskoui P, Zhang R, Coleman J, Whittaker M (2004) Alteration of skin temperature during low level laser irradiation at 830nm in a mouse model. Photomedicine and Laser Surgery 22(3):227–231

35. Monici M, Cialdai F, Fusi F, Romano G, Pratesi R (2009) Effects of pulsed Nd:YAG laser at molecular and cellular level. A study on the basis of Hilterapia. Energy for Health; International journal of information and scientific culture 3:(3).
36. Chow R, Armati P, Laakso EL, Bjordal JM, Baxter GD (2011) Inhibitory effects of laser irradiation on peripheral mammalian nerves and relevance to analgesic effects: a systematic review. Photomed Laser Surg 29(6):365–81
37. Kujawa J, Zavodnik L, Zavodnik I, Buko V, Lapshyna A, Bryszewska M (2004) Effect of low-intensity (3.75–25 J/cm^2) near-infrared (810 nm) laser radiation on red blood cell ATPase activities and membrane structure. J Clin Laser Med Surg 22(2):111–7
38. Tilburt JC, Emanuel EJ, Kaptchuk TJ, Curlin FA, Miller FG (2008) Prescribing "placebo treatments": results of national survey of US internists and rheumatologists. BMJ 337:a1938
39. Miller FG, Colloca L (2009) The legitimacy of placebo treatments in clinical practice: evidence and ethics. Am J Bioethics 9:39–47
40. Puhl AA, Reinhart CJ, Rok ER, Injeyan HS (2011) An examination of the observed placebo effect associated with the treatment of low back pain — a systematic review. Pain Res Manag 16(1):45–52
41. Akindele MO (2007) Comparison of functional disability with physical activity in patients with low back pain. Nigerian Medical Practitioner 52(4):97–99