

The efficacy of high-intensity laser therapy in low back pain: A critical appraisal

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Abstract

The current narrative review was planned to identify the most likely factors that influence the diversity of the findings among clinical studies that investigate the use of high-intensity laser therapy in treating low-back pain. It also planned to provide recommendations with respect to the methodological drawbacks identified in literature. An extensive literature search of clinical and randomised, controlled trials was conducted using Embase, MEDLINE, Cinahl databases and the Cochrane Controlled Trial Register as well as a search by hand. The search yielded only six studies that could be critically reviewed. This limited number of studies exhibited different treatment approaches, parameters, blinding procedures, symptom durations, irradiated areas and testing occasions. The studies assessing the efficacy of high-intensity laser therapy in treating low-back pain showed controversial findings, which may be due to diversity in treatment parameters, approaches, symptom duration, blinding and / or randomisation procedures and testing occasions.

Keywords: Back pain, High-intensity laser therapy, Laser therapy, Low-intensity laser therapy, Photobiomodulation, Phototherapy.

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Introduction

Low-back pain (LBP) is a highly prevalent condition related to disability and work-absence and represents high costs.¹ LBP represents high costs in Western countries.¹ There are different approaches that have been indicated to be beneficial in treating LBP. These included physical therapy (interferential therapy, shortwave diathermy, transcutaneous electrical stimulation, therapeutic ultrasound,²⁻⁶ medications (non-steroidal anti-inflammatory drugs [NSAIDs], muscle relaxants^{7,8} and injections (botulinum toxin and epidural steroid injection).^{9,10} However, the rates of success are inconsistent, and many of these approaches are only marginally beneficial, ineffective or even harmful.^{11,12}

Low-intensity laser therapy (LILT) is a painless, non-invasive

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treatment modality used to reduce pain and inflammation and improve functioning for various conditions, such as osteoarthritis, musculoskeletal pain and postoperative pain.¹³⁻¹⁶ LILT has the potential to raise microcirculation, stimulate immunological processes and nerve regeneration and activate angiogenesis. It also has an analgesic effect through the influence of endorphin production mechanisms without undesired effects.^{15,17,18}

More recently, a painless and non-invasive modality called high-intensity laser therapy (HILT) was presented as a solution for medical rehabilitation.^{19,20} This type of laser operates with high peak power up to 3 Kilowatt and a wavelength of 1.064nm. Researchers report that it has the capability to treat parts that are hard to reach with LILT through its anti-inflammatory, anti-oedematous and analgesic effects.¹⁹⁻²² The current narrative review was planned to identify the possible factors influencing the controversial findings between clinical trials that have assessed the use of HILT in treating LBP, and to provide recommendations regarding the methodological shortcomings identified.

Methods

An extensive literature search was conducted using the terms 'high-intensity laser therapy', 'laser therapy' and 'back pain' was done on Embase, MEDLINE, Cinahl databases and the Cochrane Controlled Trial Register as well as a search by hand with no constraint on dates up to December 2018. One reviewer defined whether the studies were eligible and assessed the methodological quality. Therefore, the Cochrane guidelines for a systematic review were not utilised.

The inclusion criteria limited the review to clinical and randomised, controlled trials published in English language that investigated the usage of HILT in LBP treatment.

Trials with no details of HILT irradiation treatment parameters and studies that had no comparative group or groups and only having HILT groups were excluded.

Results

Of the 51 studies identified initially, 9(17.6%) were shortlisted. Of them, 1(11.1%)trial had no details at all of HILT treatment parameters, and 2(22.2%)did not have a

Table 1: Clinical studies that used high-intensity laser therapy (HILT) for low-back pain (LBP): an overview of the treatment parameters of the included studies.

Study	Wavelength	Power output	Time / point and the total time of irradiation	Energy/point and total energy	Spot size or diameter/total irradiated area	Power density	Radiant exposure	Frequency of irradiation and length of irradiation course
Alayat et al (2013)²⁵	1,064 nm (Nd: YAG)	Peak power: 3 KW Avg power: N/S	-14 s/point -15 min (total time of irradiation)	.25 J/point (intermediate phase) .3000 J (total energy)	-0.2 cm ² (spot size) -0.5 cm (spot dia) -Total irradiated area (N/S)	N/S	-610 mJ/cm ² (Intermediate phase) -610-810 mJ/cm ² (Initial and final phase)	3 sessions/week for 4 weeks
Fiore et al (2011)²⁴	1064 nm (Nd: YAG)	-Peak power: 1 KW -Avg power: 6 W	. Time/point (N/S) . 10 min (total time)	- Energy/point (N/S) . 2600 J (total energy)	- 0.2 cm ² (Spot size) - Total irradiated area (N/S)	-5000 W/cm ²	-710 mJ/cm ²	5 sessions/week for 3 weeks
Boyras et al (2015)²⁶	1,064 nm (Ga Al As)	-Avg power: 3.4 W -Peak power: low	-14 min (total time of irradiation)	-1800 J (total energy)	-Spot size: N/S -Spot dia: N/S -120cm ² (total irradiated area)	N/S	N/S	5 sessions/week for 2 weeks
Choi et al (2017)²⁷	N/S	N/S	-10 min (total time of irradiation)	-Energy/Point: N/S -Total energy: N/S	N/S	N/S	1,378 mJ/cm ²	3 sessions/week for 4 weeks
Tradaj et al (2018)²⁸	1,064 nm (Ga Al As)	10 w	-10 min (total time of irradiation)	1,200 J (total energy)	6×5 cm (total irradiated area)	N/S	60 J/cm ²	3 sessions/week for 3 weeks
Kolu et al (2018)²⁹	N/S	-10 w Followed by 7 W	-4 min followed by 6 min (total time of irradiation)	-12 J/cm ² -120 J/cm ²	-25 cm ² (total irradiated area)	N/S	12 J/cm ²	5 sessions/week for 2 weeks

J: Joule; μ s: Micro-second; ms: Milli-second; mJ: Milli-Joule; cm²: Square centimeter; s: Second; min: Minutes; NS: Not specified; Dia: Diameter; cm: Centimetre; Aver: Average; W: Watt; KW: Kilowatt; nm: Nanometre; Nd-YAG: Neodymium-doped yttrium aluminium garnet; GaAlAs: Gallium aluminium arsenide..

comparative group. The rest of the 6(66.6%) studies were analysed in detail (Figure). The studies exhibited different treatment parameters, technique approaches and courses of irradiation (Table-1). The methodologies the studies used, including the variable intervention groups, testing occasions, symptom durations and blinding procedures were noted and analysed (Table-2).

Discussion

Power density is used to represent the intensity of radiation. A number of researchers have stressed the potential importance of power density as one of the most vital treatment parameters.²³ Disappointingly, only one study revealed this crucial parameter. The study was a randomised clinical trial²⁴ using 1,064-nm irradiation at a 5,000-W/cm² power density. The study group comprised 30 male and female patients allocated randomly to two HILT and ultrasound therapy groups. This study showed that HILT was more beneficial with regard to pain, functional activities and quality of life (QOL) than ultrasound therapy. However, no control group or objective assessments were used.

Objective outcome assessments, like range of motion (ROM) were taken into account in a clinical study²⁵ to assess the effect of HILT alone or coupled with exercise in chronic LBP patients. It had 72 male

Table2: Clinical studies that used high-intensity laser therapy (HILT) for low-back pain (LBP): General overview of the methodology of the included studies.

Study	Number of subjects/groups	Intervention (group)	Standardized testing position	Irradiated area	Symptoms duration	Testing occasions	Blinding procedures	Outcome assessments/Results
Alayat et al (2013)²⁵	72 (male) subjects randomly allocated into 3 groups	.G1 (HILT + EX) .G2 (PL + EX) .G3 (HILT)	Prone position	N/S	13.9-14.5 months	At the start of the study After 4 weeks of treatment After 12 weeks as a follow-up	Patient (blinded) .Treating person (unblinded) .Assessing person (N/S)	- VAS, RDQ, MODQ / G1 had > decrease than G2 and G3 (after 4weeks and after 12 weeks)a - ROM/ G1 had > improvement than G2 and G3 (after 4 weeks and after 12 weeks)a. - VAS, ROM, RDQ and MODQ/ G1 (HILT+EX) showed a significant difference post treatment (after 4 weeks and after 12 weeks) ^b
Fiore et al (2011)²⁴	30 male & female subjects randomly allocated to 2 groups	.G1 (HILT) .G2 (US)	Prone position	N/S	N/S	.At the start of the study .After 3 weeks of treatment	.Patient (unblinded) .Treating person (unblinded) .Assessing person (blinded)	- VAS and OLBDQ / G1 (HILT) had a greater decrease than G2 (US) (after 3weeks)a - VAS and OLBDQ / Both groups showed a significant difference post treatment (after 3 weeks) ^b
Boyraz et al (2015)²⁶	65 patients male and female randomly allocated to 3 groups	-G1 (HILT) -G2 (U.S) -G3 (Medical therapy +Isometric exercises)	N/S	-Large areas up to 120 cm ²	N/S	-Before treatment -After 10 sessions -After 3 months from the end of the treatment	N/S	_ VAS, OS and SF-36 /VAS score is statistically significant between groups (in the 3rd month after treatment) ^a
Choi et al (2017)²⁷	20 patients randomly allocated to 2 groups -Gender (N/S)	-G1 (Hot pack+ Interference wave+ deep heat injection -G2 (HILT+ hot packs+ interference wave+ heat injection)	N/S	L1-L5 And S1 regions	>3 months	-Before the treatment -After 4 weeks of treatment	N/S	- VAS and ODI/ G2 (HILG) had a greater decrease than G1 (PTG) after 4 weeks (p value: N/S)a -VAS and ODI/ Both groups showed a significant difference post treatment after 3 weeks (p value: N/S) ^b
Taradaj et al (2018)²⁸	68 patients male and female allocated to 4 groups	-G1 (HILT) -G2 (HILT Placebo) -G3 (LLIT Placebo)	N/S	-An area of 3 cm lateral to L5-S1 on the lower back	Median (56-58 months)	-Before treatment -after 3 weeks of treatment -after 1 and 3 months from the end of the treatment	-Assessing person (blinded)	differences among comparative groups in all testing occasions

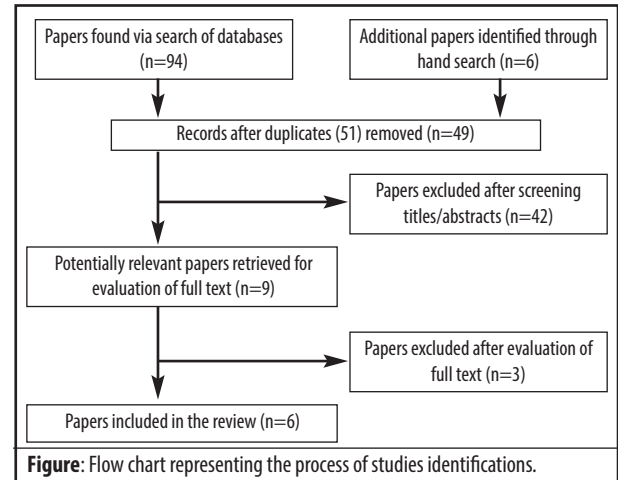
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Table2: Continued from previous page.

Study	Number of subjects/groups	Intervention (group)	Standardized testing position	Irradiated area	Symptoms duration	Testing occasions	Blinding procedures	Outcome assessments/Results
Kolu et al (2018)²⁹	54 patients male and female randomly allocated to 2 groups	- G1 (hot pack+ TENS+US+EX) -G2 (Hot pack +HILT+EX)	N/S	-Lumbar Region, Over 25cm ² area	-Group 1 (mean= 3.66 years) -Group 2 (mean=5.18 years)	-Before the treatment -After 2 weeks of treatment -After 4 weeks of a follow-up	-Patient (unblinded) -Treating person (unblinded) -Assessing person (blinded)	-VAS and ODI/ G1 had > decrease than G2 (after 2 weeks of treatment and 4 weeks later) ^a

a: Significant difference between treatment groups; b: Significant difference within each treatment group. VAS: Visual analogue scale; OLBPDQ: Oswestry low-back pain disability questionnaire; OS: Oswestry scale; ODI: Oswestry disability index; LQIP: Laitinen questionnaire indicators of pain; RMDQ: Roland-Morris disability questionnaire; ST: Schober's test; LT: Laseque test; >: greater than; G: Group; RDQ: Roland disability questionnaire; MODQ: Modified Oswestry disability questionnaire; ROM: Range of motion; US: Ultrasound.

patients who were randomised into three unequal groups: HILT plus exercise, sham HILT plus exercise, and HILT only groups. The trial reported favourable results for the HILT (1,064nm irradiation) plus exercise group. The majority of the HILT treatment parameters were specified. However, the average output power and the power density were not specified.



The study²⁵ described the treatment technique using a hand piece perpendicular to the treated area to perform scanning irradiation on the low-back region and a static approach on eight vertebral points. However, the treatment area was not specified.

The blinding procedures of this randomised, single-blinded study²⁵ were not clearly stated. It was also revealed that the irradiation type was unknown to the patients in contrast to the treating person. However, the results of this study may highly negatively influence and potentially be biased if the irradiation type was not specified and if it was known to the assessing person.

A more recent randomised clinical study²⁶ used 1,064nm irradiation. The study group comprised 65 patients with LBP (53 had disc protrusion, 12 had disc extrusion and 32 had compression of the nerve roots) assigned to three groups; 20 HILT patients, 25 ultrasound patients, and 20 NSAID plus exercise patients. The researchers concluded that HILT, ultrasound therapy and exercise were beneficial treatments for lumbar discopathy. However, there was notable variability in the patient selection criteria in the study, the randomisation procedure was not reported and the conclusions of the investigators did not accurately reflected the actual significance reported in the results section.²⁶

Another positive finding in favour of the effectiveness of HILT was found in a study²⁷ which equally divided 20 patients with chronic LBP into conservative physical therapy group and a HILT group. It utilised a treatment regimen carried out for three sessions a week over four weeks. Post-treatment findings reported significant improvements for all outcomes in the HILT group compared to the conservative physical therapy group. However, the number of participating patients in this trial was quite small, rendering it hard to make inferences about the generalisability of the findings. It is also impossible to replicate the findings because a number of crucial treatment parameters were not reported, like wavelength, power output, mode of emission, energy/point, total energy and energy density.²⁷

Conversely, a negative result was reported in a more rigorous prospective and placebo-controlled trial²⁸ using 1,064nm irradiation at an energy density of 60J/cm². The study group comprised 68 male and female patients assigned to four groups: HILT, sham HILT, LILT at 785nm and sham LILT. The study revealed that neither HILT nor LILT were effective in short- and long-term assessments. However, testing and

/ or treating positions were not specified, and the number of participating subjects in each group was small, ranging 16-18 patients.²⁸

Another finding not in favour of HILT was shown in a less rigorous study,²⁹ though the study had a greater number of participating subjects (n=54). The patients in the study were randomly allocated into Group 1 (n=27) receiving a combination of transcutaneous nerve stimulation (TENS), ultrasound, hot pack and exercise, and Group 2 (n=27) receiving HILT, hot pack and exercise. The measurements were carried out before and at the end of the two-week course of treatment and four weeks later. The researchers concluded that Group 1 showed more improvement than Group 2. However, the findings of this study may be adversely influenced by the design, which included no control group, and the absence of the irradiation wavelength and the technique utilised.

The study²⁹ also utilised variable treatment regimes in each group. Thus, a great possibility of multiple treatment interference may have already occurred. Therefore, it would be hard to single out the efficacy of HILT and exercise, as both groups were asked to carry out exercises.

Clinical implications: Current treatment approaches are only marginally beneficial, ineffective or even harmful. Failure to respond to treatment can lead to considerable disability and work-absence. Thus, it is imperative to find a treatment approach that can be administered effectively and safely.

The current findings of HILT in treating LBP may have important implications for future research and clinical practice. Healthcare providers can contribute greatly to the further determination of optimal treatment regimes.

A study supporting this relatively new modality has yet to advocate its use in treating LBP which is due to inadequate evidence with respect to the most effective treatment parameters. Future clinical studies should emphasise improving the methods that result in evidence of treating patients more effectively. This might be achieved by avoiding the main method of research design drawbacks in prior studies of HILT: lack of control groups, lack of objective outcome assessments, poor treatment parameters, considerable diversity in patient selection criteria, inaccurate conclusions, and poor descriptions for treatment approaches and blinding and / or randomising procedures.

Conclusion

The literature search revealed an insufficient number of studies investigating the efficacy of HILT in treating LBP. It also yielded studies with variable treatment approaches, blinding and / or randomisation procedures and testing occasions.

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Conflict of Interest: None.

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