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Is Low-Level Laser Therapy Effective for Pain Reduction in Patients with Chronic Low Back Pain?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences –Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not low-level laser therapy is effective for pain reduction in patients with chronic low back pain.

STUDY DESIGN: Two randomized controlled trials published in 2010 and 2017 and one non-randomized placebo-controlled clinical trial published in 2018.

DATA SOURCES: Sources were written in English and published in peer-reviewed journal articles comparing low-level laser therapy (LLLT) to groups consisting of a combined laser therapy regimen or placebo in patients with chronic low back pain, found using PubMed.

OUTCOMES MEASURED: Low back pain was assessed using the visual analog scale (VAS). The statistics used to assess significance of the outcome measured were P-values, change in mean from baseline, and SD.

RESULTS: The first study (Ay S, Doğan Ş, Evcik D. *J Back Musculoskelet Rehabil.* 2017;30(2):235-240. doi: 10.3233/BMR-160739) compared two treatment groups who received LLLT for the treatment of chronic low back pain (CLBP). Improvements in pain were statistically significant in both groups (p-value <0.01), but no difference was found between the two LLLT regimens. Another study (Ay S, Doğan Ş, Evcik D. *Clin Rheumatol*. 2010;29(8):905-910. doi: 10.1007/s10067-010-1460-0) compared LLLT vs placebo in patients with CLBP, in addition to analyzing LLLT vs placebo in acute pain management. A statistically significant improvement in pain severity (p-value <0.001) was observed in LLLT and placebo groups for CLBP. A third study (Taradaj J, Rajfur K, Shay B, et al. *Clin Interv Aging*. 2018;13:1445-1455. doi: 10.2147/CIA.S168094) again compared LLLT to placebo for CLBP, in addition to analyzing high-intensity laser therapy (HILT) to placebo. In the LLLT and LLLT sham groups, a statistically significant (p<0.01) decrease in pain was noted.

CONCLUSION: These results superficially indicate that LLLT is an effective means of reducing pain associated with CLBP. However, comparison between sham groups and actual treatment groups seem to suggest a significant influence of placebo in the efficacy of LLLT. This evidence suggests that the general experience of undergoing laser therapy is what causes a reduction of pain, rather than science behind the laser therapy itself. The evidence provided is therefore not sufficient enough to support the claim that LLLT is an effective, appropriate or advisable treatment of CLBP. Future studies should directly compare the statistical difference in decreased pain scores between LLLT and placebo alone.

KEY WORDS: “low-level light therapy,” “low back pain”

INTRODUCTION

Low back pain (LBP) is one of the most predominant health complaints and is the second most common cause of disability among US adults.[1] During their lifetime, approximately 85-90% of American adults will experience an episode of LBP.[2] While most individuals experience full recovery within a few months of onset, some individuals will not recover and will ultimately develop chronic LBP.[1] Chronic low back pain (CLBP) is characterized by back pain that persists for greater than 3 months and is multifaceted in nature, encompassing a variety of etiologies. Some of the common causes of CLBP include lumbar sprain and strain, disc herniation, fractures, spinal stenosis, spondylosis, or degenerative processes like osteoarthritis. Although less common than some of the mechanical causes previously mentioned, CLBP may also be due to referred pain from underlying conditions such as an aortic aneurysm, prostatitis, endometriosis, pancreatitis, cholecystitis, pyelonephritis, osteomyelitis, or tumors.[3] Individuals with CLBP may experience a negative impact on their psychological and physical functioning, ultimately leading to a diminished quality of life.[4]

The impact of CLBP is extensive as it has been reported to have a lifetime prevalence of up to 85%.[4] It is a leading cause of increased healthcare costs and job-related disability, ultimately affecting 1 in 4 adults.[5] Approximately, 149 million workdays are lost annually as a result of LBP.[1] According to Freburger et al., lost wages and reduced productivity account for two-thirds of the total costs in the US, which are estimated between $100-200 billion annually.[1] While there is no exact estimate of the number of healthcare visits due to CLBP specifically, in 2010, an estimated 52 million healthcare visits were associated to LBP.[5] Additionally, in 2013 it was estimated that back pain was the most common reason for medical care among musculoskeletal disorders, accounting for more than 57 million healthcare visits.[6]

The symptoms an individual experiences from LBP may differ depending on the cause and severity. Generally, the symptoms of CLBP include a dull or sharp aching pain in the lumbosacral region, paresthesias or burning sensations, numbness, limited range of motion, and weakness in the lower extremities. Additionally, LBP may be exacerbated or triggered by certain body mechanics such as excessive flexion or extension of the lumbar spine.

Although it is currently unknown why some progress to develop CLBP while others with acute LBP recover completely,[7] research has proposed various risk factors that can precipitate an individual's risk. Some risk factors include increasing age, low fitness level or sedentary lifestyle, obesity, pregnancy, mental health factors such as depression, smoking, or occupational factors requiring heavy lifting, pushing, pulling, or bending.

Due to the multifaceted nature of CLBP, there are many different treatment modalities designed to combat and improve the functional disability associated with this condition. Nonpharmacologic methods include patient education centered around proper lifting mechanics, heat and ice therapy, weight loss counseling, lumber strengthening exercises, transcutaneous electrical nerve stimulation (TENS), acupuncture, spinal manipulation, and lumbar support.[7,8] In addition, pharmacologic therapies may be utilized if minimal relief is achieved non-pharmacologically. These include NSAIDs, analgesics such as acetaminophen and prescription opioids, anticonvulsants, antidepressants, epidural steroid injections, and nerve block therapies.[7] Surgical treatments may include discectomy, laminectomy, vertebroplasty, kyphoplasty, and spinal fusion.[7] Although the treatment options mentioned above play an effective role and are widely used to improve symptoms in patients with CLBP, there is currently no accepted gold standard or treatment of choice, promoting the need for research to continue.

Due to the extensive effects of CLBP, an effective and innocuous alternative to the current standard treatments for CLBP is desired. Low-level laser therapy (LLLT) is a non-invasive treatment modality that utilizes non-ionizing, monochromatic, highly concentrated electromagnetic light beams to provide analgesic, anti-inflammatory, and biostimulating effects.[4,8] Although the analgesic effect of LLLT remains unclear and is still controversial, it is hypothesized that this therapy alters peripheral nociceptive afferent fibers' input to the central nervous system, ultimately decreasing localized pain perception and offering a valuable role in the treatment of musculoskeletal disorders.[8,9] Increased anti-inflammatory cytokines, ATP production, deposition of collagen fibers, cell metabolism, and chondrocyte and fibroblast proliferation appear to be associated with the biostimulating effects of LLLT, which may be responsible for the analgesic, anti-inflammatory and anti-edematous properties of this therapy.[4,8] This selective EBM review will evaluate three studies comparing the efficacy of LLLT for the treatment of CLBP.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not low-level laser therapy is effective for pain reduction in patients with chronic low back pain.

METHODS

The data sources used for this EBM review were identified by searching PubMed using the keywords "low-level light therapy" and "low back pain." All articles included in this review were written in English and published in peer-reviewed journal articles. The articles were selected based on their relevance to the clinical question and because the outcomes of the studies mattered to patients, otherwise known as Patient Oriented Evidence that Matters (POEMs). Identifying data sources with outcomes that were POEMs was one of the main objectives while

performing research, and thus, each article included in this review was carefully selected to satisfy this requirement. The inclusion criteria included randomized controlled or clinical trials involving humans, POEMs, and studies published after 2008. The exclusion criteria included animals trials and studies published in 2008 or earlier. The summary of statistics reported or used in all three data sources included P-values, change in mean from baseline, and standard deviation (SD).[4,8,9] Table 1 on page 5 includes the demographics and characteristics of the included studies.

All three studies in this selective EBM review were selected based on a population of patients with CLBP. This systematic review compares LLLT as an intervention to comparison groups consisting of either a combined LLLT regimen or a placebo LLLT in patients with CLBP. The types of studies included in this review are two double-blinded RCTs and one non-randomized placebo-controlled clinical trial. [4,8,9]

OUTCOMES MEASURED

Although multiple outcomes were assessed in all three studies, the primary outcome analyzed for the purpose of this review was the change in participants' severity of LBP from pre-treatment to post-treatment. Change in pain was evaluated by using a subjective pain assessment tool, otherwise known as the visual analog scale (VAS), which scores participants' pain on a scale from 0 to 10. A score of 0 indicates no pain while a score of 10 signifies severe pain. In the first two studies performed by Ay et al., participants' degree of pain was assessed before and after three weeks of treatment.[4,8] In the third study performed by Taradaj et al., severity of pain was measured at baseline, post-treatment, and during a follow up period of one and three months.[9]

RESULTS

The first study conducted by Ay et al. was a double-blinded RCT that randomly allocated

Table 1. Demographics and Characteristics of Included Studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Ay, Doğan, Evcik[4] (2017)	RCT	49	Group 1: 25-69 Group 2: 27-70	Age 25 or older, history of low back pain exceeding 3 months, and willingness to comply with randomly chosen treatment plans	Neurological deficits, abnormal labs, fractures, spondylosis, spinal stenosis, spondylolisthesis, inflammatory, infectious, or malignant disease of vertebrae, psychiatric illnesses, hx of previous spinal surgery, pregnancy, tx for pain ≤6 mo	0	Hot pack + laser therapy 1 (Ga-Al-As laser) VS. Hot pack + laser therapy 2 (He-Ne and Ga-Al-As combined plaque laser)
Ay, Doğan, Evcik[8] (2010)	RCT	40	Group 3: 52.25± 10.77 Group 4: 54.75 ±15.02	Author did not report any	Neurological deficits, spondylosis, spinal stenosis, spondylolisthesis, inflammatory infectious, or malignant disease of the vertebra, previous spinal surgery, pregnancy	0	Hot pack + laser therapy VS. Hot-pack + placebo laser therapy
Rajfur, Shay, Taradaj[9] (2018)	Placebo-controlled clinical trial	33	LLLT group: 45.19 LLLT (p): 45.76	Lumbar degenerative dysfunction, chronic pain deficits, pseudoradicular pain syndrome, no surgical hx, MRI confirmation, x-ray changes at L5-S1 level, hx of ca ≥ 1 yr after end of tx	Acute pain syndrome, radicular syndrome, pathology in another part of the spine, fractures, tumors, spondylolisthesis, rheumatic diseases, cauda equina syndrome, pregnancy, cardiovascular dysfunction, pacemaker, metal implants, skin lesions, sensory problems, psychosomatic disorders, hx of cancer < 1 yr after end of tx, psoriasis, scleroderma, viral, fungal, bacterial infections, use of NSAIDs	Author did not report	LLLT VS. Sham LLLT

participants with CLBP into two different LLLT treatment groups. Physicians and participants were blinded to the treatments and only the physiotherapist who applied the therapy was aware of the procedure. The diagnosis of CLBP was determined based on a thorough physical and neurological exam, encompassing laboratory and radiological studies. Participants in each treatment group underwent a series of 15 exposures performed once a day, five days a week, for

three weeks. Group 1 (n=20) received a hot pack and laser therapy 1 (Gallium-Aluminum-Arsenide [Ga-Al-As] laser with a wavelength of 850nm). Utilizing a dosage of approximately 10J/cm^2, the laser was applied in 2 separate areas over the L4-L5 and L5-S1 paravertebral tissues for a duration of four minutes at each site. Group 2 (n=29) received a hot pack and laser therapy 2 (Helyum-Neon [He-Ne] with a wavelength of 650nm, 785nm and 980 nm Gal-Al-As combined plaque laser). With a dosage of 3J/cm^2, this laser was applied for a duration of 20 minutes over the low back at levels L4-L5 and L5-S1. Participants included men and women with CLBP between 25-70 years of age. All participants were able to complete the treatment program without any adverse effects. The mean change in pain severity from baseline to post-treatment for group 1 and group 2 was 3.35 and 3.69 respectively. Based on the author's definition of statistical significance ($p < 0.01$), both of these reductions in pain were statistically significant (Group 1 – $p < 0.01$; Group 2 – $p < 0.01$). The evaluation between the two groups, however, showed a difference that was not statistically significant at baseline or post-treatment, demonstrated by p-values of 0.551 and 0.901 respectively.[4] Table 2 displays the outcome of pain severity recorded at baseline and after 3 weeks of therapy.

Table 2. VAS measured at baseline and post-treatment: mean (SD), change from baseline and p-values[4]

	Group 1	Group 2	*P*
Baseline	6.00 (SD = 2.29)	6.44 (SD = 2.74)	0.551
Post-treatment	2.65 (SD = 1.42)	2.75 (SD = 2.13)	0.901
Mean change from baseline	3.35	3.69	
p	<0.01*	<0.01*	

**Statistically significant, P-value < 0.01*

The second study also conducted by Ay et al. involved a randomized, double-blinded, placebo-controlled study that allocated a total of 80 patients with acute (n=40) and chronic (n=40) LBP caused by lumbar disc herniation (LDH). Groups 1 and 2 were excluded by this analysis due to their acute type pain—only the participants with CLBP were analyzed for the

purpose of this selective review. Physicians and participants were blinded to the treatments and only the physiotherapist who applied the therapy was aware of the procedure. Participants included men and women with an average age of 41-66 years old, who were placed into two treatment groups over a period of three weeks at five days a week and once a day for a duration of 15 sessions. Group 3 (n=20) received a hot pack and laser therapy (wavelength of 850nm Ga-Al-As laser). With a dosage of approximately 40J/cm^2, the laser was applied over two to four areas of paraspinal tissues bilaterally for four minutes at each site. Group 4 (n=20) received a hot pack and placebo laser therapy. Without turning the device on, the placebo laser was applied in the same area and for the same duration as the first group. All participants were able to complete the study without any adverse effects. The authors utilized a p-value of < 0.001 to determine a statistically significant pain reduction from pre-treatment to post-treatment for each group alone. The mean change in pain severity from pre-treatment to post-treatment for group 3 and group 4 was 3.35 and 3.95 respectively, indicating that the treatment used in each of the two groups was statistically significant (group 3 – $p = 0.000$; group 4 – $p = 0.000$). No statistically significant difference was detected between all four groups at baseline or post-treatment, demonstrated by a post-treatment p-value of 0.405.[8] Unfortunately, this statistical test compared all four groups, rather than only the CLBP group who received LLLT or placebo alone, and therefore could not be used for this analysis of LLLT versus placebo. See Table 3 for the results.

Table 3. VAS measured from pre-treatment to post-treatment: mean (SD), change from baseline and p-values[8]

	Group 3	Group 4
Pre-treatment	6.00 (SD = 2.29)	6.60 (SD = 2.25)
Post-treatment	2.65 (SD = 1.42)	2.65 (SD = 1.46)
Mean change from baseline	3.35	3.95
p	0.000*	0.000*

**Statistically significant, P-value < 0.001*

The third study conducted by Taradaj et al. involved a non-randomized placebo-controlled clinical trial that included 68 qualified participants with chronic discogenic LBP. Participants included men and women with an average age of 45 years old, who were placed into four comparative groups in the order in which they volunteered. For the purpose of this selective review, only the participants who received LLLT (n=16) and LLLT placebo (n=17) were analyzed—the patients who underwent HILT and HILT placebo therapy were excluded. The LLLT group received He-Ne laser therapy at a wavelength of 785nm, with an energy density of $8J/cm^2$ for 8 minutes over the L5-S1 region. The LLLT placebo group received treatments for an identical period of time although the device not generating laser beams. Similarly, participants underwent a series of 15 exposures performed once a day, five days a week, for three weeks. Although the physiotherapist performing the therapy was not blinded, each participant was blinded and the technician measuring the outcome was unaware of each participants group. The participants had current results of a MRI examination, confirming the diagnosis of the disease with notable radiological changes in the intervertebral discs at the L5-S1 level. The authors of the study did not mention whether or not all participants were able to complete the study without any adverse effects. The authors utilized a p-value of <0.01 to determine a statistically significant pain reduction from pre-treatment to post-treatment for each group alone. The mean change in pain severity from pre-treatment to post-treatment for LLLT and LLLT sham was 4.87 and 4.42 respectively, indicating that the treatment used in each of the two groups was statistically significant (LLLT –$p = 0.0000$; LLLT (sham) –$p = 0.0000$).[9] Analyzing intergroup comparison, improvement in pain severity was observed between all four groups. Two of these groups were intentionally excluded for this analysis and are irrelevant to the focus of this review. Thus, the statistical difference between LLLT and LLLT sham was not determined.

At 1 and 3 month follow-ups, the repeated measurements indicated a gradual relapse of symptoms in both LLLT and LLLT placebo groups. The change scores for the LLLT group were 3.75± 1.57 and 4.31 ± 1.25, measured at 1 and 3 month follow-ups respectively. Regarding the LLLT placebo group, the 1 and 3 month follow-up change scores were 2.82 ± 1.63 and 2.88 ± 1.69 respectively.[9] Table 4 summarizes the results of the study.

Table 4. VAS measured from pre-treatment to post-treatment and at 1 and 3 month follow-up: mean (SD), change from baseline and p-values[9]

	LLLT	LLLT (Sham)
Before	8.50 (SD = 1.55)	7.18 (SD = 1.67)
After	3.63 (SD = 1.45)	2.76 (SD = 1.25)
Mean change from baseline	4.87	4.42
1-month follow-up	3.75 (SD = 1.57)	2.82 (SD = 1.63)
3-month follow-up	4.31 (SD = 1.25)	2.88 (SD = 1.69)
p	0.0000*	0.0000*

**Statistically significant, P-value = <0.01*

DISCUSSION

While the results of these studies appear to indicate LLLT as an effective means to decrease pain severity due to CLBP, the comparison between treatment and placebo groups seem to suggest a significant influence of placebo in the efficacy of LLLT. In all cases, LLLT resulted in reduced subjective pain scores.[4,8,9] However, post-treatment pain scores were found to be lower in those who also received the placebo LLLT treatment. Therefore, the general experience of undergoing laser therapy treatment could be the underlying cause of pain reduction, rather than the science and analgesic effects behind the laser therapy itself. This is further supported by the lack of statistically significant difference between HILT versus LLLT with placebo,[9] LLLT for acute versus chronic LBP with placebo,[8] and differing LLLT treatment types[4] explored in greater detail in these cited references, though the focus of these in-depth comparisons is beyond

the scope of this analysis. Thus, the data provided is not sufficient enough to support LLLT as an effective, appropriate or advisable treatment of CLBP.

While no FDA warnings against the use of LLLT for the relief of musculoskeletal pain exist,[10] there are some contraindications for use of this therapy including individuals with pacemakers, pregnancy, epileptic seizures, cancer, and exposure over thyroid gland or eyes.[10,11] In addition to the contraindications, there may also be some inadequacies in insurance coverage for this treatment modality, as LLLT is classified as experimental by insurance companies and is considered not medically necessary due to insufficient evidence supporting the effectiveness.[10,12]

Discussing limitations of the selected studies, the first study lacked a placebo group, which therefore limited the ability to determine the treatment effect of the laser therapy overall. Furthermore, the He-Ne laser therapy group by itself was not included in the first study.[4] In the first and second studies, the application of a hot-pack due to ethical reasons may have influenced the improvements in pain severity, which increases local blood stream and tissue metabolism, flexibility of fibrous tissues, and relaxation of muscles.[4,8] Additionally, all three studies had follow-up times inconsistent with the chronicity of their condition – patients with CLBP symptoms often have pain for multiple years, yet none of the studies followed-up for longer than 3 months after treatment. Patients may have pain return or potentially worsen beyond this time frame, but these sources failed to study this data.[4,8,9] The second and third studies collectively failed to demonstrate the potential effectiveness of LLLT over the placebo group in CLBP by calculating the statistical significance of all four groups together, therefore decreasing the ability to detect differences between groups. Additionally, all studies had a small sample size, ranging from 33 to 49,[4,8,9] further limiting the ability to detect differences. The third study alone was not a randomized double-blinded study, which may have impacted the validity of the data.[9] Further

studies with longer follow-up times and larger patient populations need to be performed to determine the efficacy of LLLT.

CONCLUSION

Although the results of some clinical studies suggest that LLLT may be successful for the treatment of reducing pain in musculoskeletal conditions, some investigators have described no superiority of laser therapy over placebo in the treatment of musculoskeletal conditions.[8] Therefore, we cannot tell if LLLT is an effective, appropriate, or advisable treatment modality for pain reduction in all patients with CLBP. While these studies are promising for the future of LLLT, more research is warranted to determine the statistical significance of LLLT for pain reduction in patients with CLBP.

Future studies should directly compare the statistical difference in decreased pain scores between LLLT and placebo alone. Studies should also attempt to compare LLLT treatment groups with placebo without the use of hot-packs as these studies have done. Lastly, additional research should explore cost-benefit analysis to evaluate the utility of LLLT for the management of CLBP. Research into LLLT should continue as this treatment modality has the potential to offer significant relief in patients with one of the most common musculoskeletal complaints.

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