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Is Laser Therapy an Effective Alternative Treatment for Women With Fibromyalgia?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not, "Is the use of laser therapy an effective alternative treatment for women with fibromyalgia?"

STUDY DESIGN: Review of three English language primary studies, published between 2002 and 2013.

DATA SOURCES: Three randomized controlled trials (RCTs) were found using Cochrane Systematic Reviews. These studies analyzed the effectiveness of laser therapy in women with fibromyalgia.

OUTCOMES MEASURED: Main outcomes measured were improvement in pain, number of tender points, muscular spasm, skinfold tenderness, sleep disturbance, fatigue and morning stiffness measured by an ordinal likert scale, Pain and FM impact measured by the FM Impact Questionnaire (FIQ), Body flexibility measured by the continuous scale physical functional performance test (CS-PFP), number of tender points measured by distal palpation, and well being measured by the verbal scale of global evaluation by the patient concerning her well-being (VSGI). P-values were used to assess the significance of the outcomes.

RESULTS: All three studies showed significant improvement in the functioning of women with fibromyalgia. In the Panton et all study, it was shown that there were improvements in pain, upper body flexibility, and FM impact. The Gur et all study showed improvements in pain, muscle spasm, morning stiffness, and total tender point number, and the Armagan et al study showed improvements in the FIQ, VSGI, and total myalgia after laser therapy.

CONCLUSION: The results of three RCTs which compared before and after laser treatment groups to before and after placebo laser therapy groups showed laser therapy to be an effective treatment for women with fibromyalgia.

KEY WORDS: Fibromyalgia, Laser therapy.

INTRODUCTION

Fibromyalgia is a rheumatologic disorder characterized mainly by widespread chronic body pain.[5] The American College of Rheumatology goes on to define the diagnosis as pain in three out of four of the body quadrants for at least a duration of three consecutive months as well as tenderness with palpation at eleven or more out of eighteen of specific tender points.[5] Although pain is the most common complaint, fibromyalgia patients commonly report insomnia, fatigue, headaches, irritable bowel syndrome, morning stiffness, parenthesias, anxiety, and depression.[1]

Fibromyalgia is considered the second most common rheumatologic disorder in the United States in that it is found in approximately four to six million people.[5] In total, it is said to affect about 3% of the female population but it has also been found to occur in both men and children.[1] Additionally, women tend to be diagnosed with the disorder between the ages of 20 and 50 but the prevalence does increase with age.[5] By the age of 80, 8% of women are diagnosed with fibromyalgia.[5]

Due to the commonality of the disorder, there is a definite economic burden in the United States due to heath care costs pertaining to fibromyalgia patients. The total annual cost to the United States economy is twelve to fourteen billion dollars.[7] In addition, 34% of all fibromyalgia patients tend to spend between $100 and $1,000 per month above what their insurance will cover in order to be seen and treated by a healthcare professional in their times of need.[5] The average fibromyalgia patient a goes to see a healthcare professional thirteen times per year.[6]

Although fibromyalgia is a rather common disorder, research has yet to discover the exact cause leading to its development. It is, however, thought that central sensitization is the

main mechanism involved, as well as many other components such as genetic predisposition, environmental stressor exposure, alterations in sleep architecture, hypothalamic-pituitary adrenal axis alterations, and autonomic nervous systems alterations. Genetics are thought to be involved in the disorder because there is a strong familial link. Patients with the diagnosis had an eight times greater chance of a first-degree relative having the diagnosis as well. The environmental triggers that are thought to be involved are a prior history of trauma or abuse, as well as infection and psychological stress. In terms of alteration of the sleep cycle, it is thought that patients with fibromyalgia are experiencing intermittent arousal from the brain, leading to constant interruption of their deepest and most refreshing sleep. Lastly, the hypothalamic-pituitary-adrenal axis and autonomic nervous systems alterations seem to play a role in the development of the disorder because studies have shown that patients have a higher heart rate at rest as well as less variability in their heart rate throughout the day.[7]

In addition to the multiple contributing factors to the development of fibromyalgia, there are also multiple modalities used for treatment and comfort in patients with fibromyalgia. Firstly, the typical pharmacologic interventions utilized are tricyclic antidepressants, serotonin antagonists, nonsteroidal anti-inflammatory drugs, anti-epileptic drugs, sedatives, muscle relaxants, and opiates.[5] Secondly, alternative interventional techniques such as trigger point injections, massage therapy, exercise, physical therapy, electrotherapy, and biofeedback training have also been used in treatment.[1] Typically, patients will use multiple management techniques in order to control their pain level as much as possible.[1]

While these treatments have been shown to somewhat alleviate the pain, their use for treatment has been limited and there is currently no complete cure for the condition.[1] It has been shown that pharmacologic therapy has achieved successful improvement in only 50% of patients, as well as leading to many side-effects such as weight gain, morning drowsiness, abdominal pain, and

increased tolerance to the treatment overtime.[5] It is also shown that 47% of the women with fibromyalgia are nonadherent with their medications.[5] For these reasons, alternative interventions such as laser therapy have shown an increase in popularity among patients and may be used to help relieve the symptoms of fibromyalgia.[5]

OBJECTIVE

The objective of this selective EBM review is to determine whether or not, "Is the use of laser therapy an effective alternative treatment for women with fibromyalgia?"

METHODS

The population of the studies used for this review includes women with fibromyalgia. Their ages ranged from 33 to 64. One of the studies involved in the review used class IV laser therapy, one used class III b laser therapy, and the other one used low-level energy laser therapy. The comparison groups were given sham laser therapy that was a visually matched placebo. The different outcomes measured in the studies included improvement in pain, number of tender points, muscular spasm, skinfold tenderness, sleep disturbance, fatigue, morning stiffness, FM impact, body flexibility, and well-being. All three studies were randomized controlled trials that compared laser therapy to placebo laser therapy.

The author, using the key words "fibromyalgia" and "laser therapy, carried out a detailed search using the Cochrane Systematic Review and PubMed. Each of the articles was published in English and in peer-reviewed journals. Each of the articles was selected based on their relevance to the clinical question as well as their evidence falling in the category of a POEM. Inclusion criteria consisted of articles that involved randomly controlled trials published after 2000. Studies excluded were those that involved male participants. The statistic that was reported in the three studies was a p-value with a $p \leq .05$ deemed statistically significant. Table 1 displays the demographics and characteristics of these three articles.

Table 1: Demographics & Characteristics of included studies

Study	Type	#pts	Age (yrs)	Inclusion criteria	Exclusion criteria	W/D	Interventions
(Panton)[5] 2013	Double blind RCT	38	52 ±11 yrs	Female At least 11 out of 18 tender points.	Uncontrolled hypertension/ DM, Active heart disease, history of cancer, Long term steroid use, Pregnant, Endocrine disease, anticoagulation, bleeding disorders, stroke, chronic infection, malignancy, taking medication that causes photosensitivity, contraindication to light or thermal therapy, under the care of a chiropractic physician, acupuncture physician, massage therapist, or other forms of manual therapy.	3	Class IV laser therapy
(Gur)[2] 2002	Single blind RCT	40	40 ±15 yrs	Female At least 11 out of 18 tender points Widespread pain for 3 months	A recent or past history of psychiatric disorders, Immunocompromised subjects, Subjects with neurological, inflammatory, endocrine or clinically, significant chronic disease, Abnormal liver function tests, Pregnancy	0	Low power laser therapy
(Armagen) [1] 2006	Single blind RCT	32	38.94 ± 4.85	Female Widespread pain for at least 3 months on both sides of body, above and below the waist. At least 11 tender points	Inflammatory cause of pain; Inability to interrupt therapy with analgesic, anti-inflammatory medications, antidepressants, sleeping/ central nervous system-active drugs;neurological, inflammatory, endocrine, or chronic disease, such as IBD, rheumatoid arthritis, lupus, or DM; Severe disease such as a tumor, liver, renal disease; Pregnancy; major psychiatric disorders.	0	Low level laser therapy

OUTCOMES MEASURED

Each outcome measured was a POEM and was measured in a variety of ways. Firstly, Gur et al measured the outcomes of improvement in pain, number of tender points, skinfold tenderness, morning stiffness, sleep disturbance, muscular spasm, and fatigue using an ordinal likert scale. The categories on the scale were, No (0), moderate (1), severe (3), and extreme (4).

Panton et al used multiple methods to measure the chosen outcomes of tender-point sensitivity, the Fibromyalgia Impact Questionnaire (FIQ), and functionality. Firstly, at the participants initial visit as well as after their four week long treatment, they had a tender points assessment performed by a rheumatologist who then decided on their number of tender points, as well as rating those points on a sensitivity scale from 0, meaning no pain, to 3, meaning withdrawal of patient from examiner. The FM Impact Questionnaire (FIQ) was also used as an outcome to measure the impact that the disorder had on their quality of life. The FIQ is able to measure physical functioning in activities of daily living, general-well being of the patient, as well as fibromyalgia related-symptoms like pain and body flexibility. Lastly, the Continuous Scale Physical Functional Performance (CS-PFP) test was used revealing the participant's level of physical functioning. This test simulates different tasks of common daily activities. At the completion of the four-week intervention, participants repeated the testing that was completed in the initial visit again. The investigators who measured tender-point sensitivity, FIQ, and functionality were blinded to the group assignment of the participants.[5]

Lastly, Armagen et al used multiple methods to study their outcomes as well. Number of tender points was measured using digital palpation. The point was recorded as tender if the patient reported it upon palpation. Morning stiffness was measured using an ordinal Likert scale defined as no (0), mild (1), moderate (2), severe (3), and extreme (4). This study also used the

Fibromyalgia Impact Questionnaire (FIQ) and the Verbal scale of global evaluation by the patient concerning her well-being (VSGI). The VSGI created a score from 1 to 5 in which 1 means great improvement, 2 means moderate improvement, 3 means slight improvement, 4 means no improvement, and 5 means worsening. A Total myalgia score was then created through response to a digital force of 4 kg after which the participants said whether they felt no discomfort (0 points), tenderness (1 point), pain without grimace, flinching, or withdrawal (2 points), or pain with grimace, flinching, or withdrawal (3 points).[1]

RESULTS

Armagon et al included 32 female patients ages 26 to 47 in the trial. All 32 of them carried out the entirety of the study. All patients received treatments once a day, five days a week, for a total duration of ten days. The laser beam was applied to each tender point for one minute and the same physician treated all of the patients. All of the patients in the study, whether in the laser treatment or placebo group, had similar conditions prior to treatment. In the laser treatment group, participants showed significant improvements in all categories measured after laser therapy. Tender point number decreased by an average of 1.87, morning stiffness decreased by an average of .62, VSIQ score decreased by an average of .88, FIQ scores decreased by an average of 7, and total myalgia scores decreased by an average of 5.5. For these scores, $P < 0.05$. On the contrary, the only categories in which significant improvement could be seen in those treated with placebo laser therapy were number of tender points and morning stiffness. Tender point number decreased by an average of 1.06 and morning stiffness decreased by an average of .56. In these two categories, $P < 0.05$. These results can be seen in table 2. There were no systemic or local side effects that were reported during or after the treatment period in either group of participants.[1]

Table 2: Mean change from baseline, Armagon et al [1]

	Tender points	Morning stiffness	VSIQ score	FIQ score	Total Myalgia
Laser therapy	-1.87*	-.62*	-.88*	-7*	-5.5*
Sham laser therapy	-1.06*	-.56*	-.19	-1.75	-1.56

* $p < .05$

Gur et all included 40 females with fibromyalgia. All patients carried out the entirety of the study. Each patient experienced a two-week treatment period of five days per week for a total of ten treatments. The laser therapy included three minutes of treatment on each tender point. Prior to the treatment, the two groups showed no significant difference in any of the categories studied when compared to each other. However, significant changes in all categories were seen in those participating in the actual laser therapy group. Pain improved by an average of 1.82, skinfold tenderness improved by an average of 1.28, muscle spasm improved by an average of 1.46, morning stiffness improved by an average of 1.45, tender point number improved by an average of 6.55, sleep disturbance improved by an average of 1.09, and fatigue improved by an average of 1.73. For these values $p<0.05$. On the contrary, the placebo group only showed significant improvement in pain, muscle spasm, morning stiffness, and tender point number. Pain improved by an average of 1.0, muscle spasm improved by an average of .9, morning stiffness improved by an average of .69, tender point number improved by an average of 4.15. For these values $p<0.05$. These results are shown in table 3. None of the participants in the study reported increased discomfort as a result of their treatment or an increase in any of the measured outcomes, whether they received the laser or the placebo therapy.[2]

Table 4. Mean change from baseline, Gur et al[2]

	Pain	Skinfold tenderness	Muscle spasm	Morning stiffness	Tender points	Sleep disturbance	Fatigue
Laser therapy	-1.82*	-1.28*	-1.46*	-1.45*	-6.55*	-1.09*	-1.73*
Sham laser therapy	-1.0*	-.77	-.9*	-.69*	-4.15*	-.04	-.06

*$p < .05$

The Panton et al study included 42 women with fibromyalgia, 38 of whom completed the entirety of the study. One woman did not follow up after the initial assessments, two women did not return due to scheduling conflict, and a final woman could not complete the study due to major depressive disorder. In order for this study to make the two groups appear to have the same treatment, the treatment group was given laser and heat therapy, while the placebo group was given sham and heat therapy. Both groups had treatment twice each week for four weeks, totaling in eight treatments. When looking at the baseline statistics alone, the treatment and control groups did not significantly differ. Of the different outcomes measured in the laser and heat therapy group, significant improvement resulted in total tender points, myalgic score, pain, upper body flexibility, and the CS-PFP score. Total tender points decreased by an average of 3, myalgic score decreased by an average of 3, pain decreased by an average of .9, upper body flexibility increased by an average of 7, and CS-PFP score increased by an average of 7. In order to show significance in these numbers, $p<0.05$. On the other hand, the group that received sham and heat treatment showed significant changes in only the number of tender points, myalgic score, and CS-PFP score. Number of tender points decreased by an average of 3, myalgic score decreased by an average of 3, and CS-PFP scores increased by an average of 4. These results can be seen in table 5.[5]

Table 5. Mean change from baseline, Panton et al[5]

	Tender points	Myalgic score	Pain	Upper body flexibility	CS-PFP
Laser therapy	-3*	-3*	-.9*	7*	7*
Sham laser therapy	-3*	-3*	.3	0	-4*

* $p < .05$

DISCUSSION

The three randomized controlled trials discussed in this review suggest that laser therapy is an effective alternative treatment for fibromyalgia. All three studies demonstrated a statistically significant reduction in at least two of the outcomes measured with a statistical significance threshold set at $p \leq .05$. One other study conducted by Gur et al compared laser therapy to sham laser therapy as well as the traditionally used Amytriptyline. This study showed that the laser therapy was above all else in terms of decreasing pain intensity, fatigue, morning stiffness, FIQ score, and depression score, which shows great promise for the use of laser therapy in fibromyalgia treatment.[1]

The Panton et al study showed the least positive difference when comparing the experimental and control groups, but there are a few possible explanations for this contradiction to the other two studies. This study decided that in order to make the control and experimental groups similar enough, both groups would require heat application to the treated area. Since heat has been shown to have some therapeutic properties in the treatment of fibromyalgia, this would explain the improvement in the outcomes of the control group. However, since the women that received the laser as well as heat therapy showed additional positive outcomes as well as a

greater difference in the outcomes when compared to the control group, this study still suggests that laser therapy is an effective alternate treatment for fibromyalgia.[5]

On the other hand, it is important to note that there are still many limitations regarding laser therapy as a treatment mechanism in that literature laser treatment has been inconsistent and disorganized.[2] Information surrounding the specificities of the laser treatment parameters such as the optimal dose, intensity, frequency, wavelength, and peak that should be used, as well as the best mode of delivery, is still unknown.[1] There are also different treatment techniques such as irradiating one single point or sweeping across it. One technique has not yet been shown to be more effective than the others.[2] Additionally, it is unknown if certain parameters must be altered based on the specific areas to be irradiated and diagnosis of the person being treated. These parameters could include the minimally effective dose, duration, number, and schedule of the treatment.[1] The different bodily tissues on the body may have different absorption spectra and could respond in a different manner to the laser.[2] As a result of these various unknowns about the use of laser therapy as a treatment method, further clinical evaluation and research is needed. Research is also needed to provide information on when the treatment should be terminated and how long the benefits will last.

Laser therapy continues to be used for treatment in many disciplines. The FDA has approved the usage of low-level laser therapy, however, there are some contraindications to its usage.[3] Currently, known contraindications include a history of malignant carcinoma, radiation in the thyroid region, epilepsy, exposure of the retina during treatment, and pregnancy.[4] Additionally, most insurance companies do not typically cover laser therapy, but as research on its treatment for fibromyalgia continues, there is hope of future coverage for patients.[3]

CONCLUSION

Laser therapy is an effective treatment alternative for women with fibromyalgia. The three randomized controlled trials discussed in this review showed improvement in outcomes measured after the application of laser therapy. Based on these results, low-level laser therapy should be considered as monotherapy or as an additional supplement to other treatment modalities in women with fibromyalgia.

Despite this convincing evidence, additional research needs to be done in order to answer questions about the best treatment protocol in terms of scheduling, wavelength, frequency, and intensity, as well as deducing whether different areas of a patient's body will require different protocols. Additional research should also be completed to compare currently used therapeutic treatment regimens to the laser therapy, as well as comparing whether monotherapy or polytherapy would be most cost effective. Lastly, additional research is needed to decide if there are long-term benefits to each laser therapy treatment or if the laser treatments will have to be continued on a life-long basis.

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