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Comparative study of high-intensity laser therapy versus low-intensity laser therapy as an add-on therapy in chronic myofascial pain syndrome at upper trapezius; randomized controlled trial

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Abstract

The study compared the effects of high-intensity laser therapy (HILT) and low-intensity laser therapy (LILT) for treating patients with chronic myofascial pain syndrome in the upper trapezius muscle through a randomized controlled trial. Eligible participants were randomly assigned to either the HILT (n=30) or LILT (n=30) groups. Both groups were instructed to perform daily home-based muscle stretching exercises. HILT or LILT was administered twice a week for four weeks based on the assigned group. The study assessed pain score, cervical range of motion, and pressure pain threshold of the upper trapezius muscle at baseline, after the first session, after treatment, and four weeks after treatment. Results showed all outcomes significantly improved in both groups over the measured period. However, no significant differences were found between groups. The study concluded that HILT combined with home-based stretching exercises did not yield superior clinical outcomes compared to LILT combined with home-based stretching exercises.

Keywords: Laser therapy, Neck pain, Pain treatment, Physical therapy

1. Introduction

Myofascial pain syndrome (MPS) is characterized by a localized pain condition distinguished by the existence of myofascial trigger points (MTrPs), which are sensitive nodules within the muscle fibers of the skeletal system. It is a common condition which the incidence up to 85% of people presenting to pain clinic [1] and can affect every age-group. MTrPs more commonly affect postural muscles including the trapezius [2].

People with MPS can develop both local and referred pain which is often associated with a decreased of quality of life [3]. The stiffness of MTrPs can cause the restriction of the range of motion of joint that located muscle involve as well as increase pain pressure threshold [4].

The treatment of MPS are stretching exercise, patient education on proper ergonomics, MTrP injections, medications, physical modalities and other alternative therapies [1, 5]. To the best of our knowledge, stretching exercises are the mainstream approach to managing this group of patients. When combined with other physical modalities, they yield better results [6]. There is ongoing effort to find effective physical modalities that can be used as add-on therapies to help treat MPS. Laser therapy is one such modality, used to treat MPS conditions because it increases the pain threshold and stimulates the healing process. Additionally, laser therapy is noninvasive, painless, and easy to administer. Three potential mechanisms of action were suggested, including: modulation of neurotransmitter; stimulation of the local metabolism; laser-induced neuronal suppression and anti-inflammatory effect [7]. The low-intensity laser therapy (LILT) therapy has been confirmed the efficacy to treat MPS and chronic neck pain conditions [7-9].

Laser therapy is widely used as an add-on physical therapy for pain management and tissue healing. Recently, high-intensity laser therapy (HILT) has emerged as a novel treatment alternative. HILT, by theory, has been claimed that it has the capability to access and activate larger and/or deeper joints and regions as well as a shorter therapy time compared to LILT [10]. Both HILT and LILT have been utilized, but their comparative effectiveness remains unclear. Understanding which modality offers superior pain relief can significantly enhance treatment outcomes.

The primary research question is whether HILT is more effective than LILT as an add-on therapy in providing pain relief. Objectives include evaluating pain relief, functional improvement, and side effects of each therapy.

2. Materials and methods

2.1 Study design

This controlled trial, randomized and double-blinded for both patients and assessors, took place in an outpatient rehabilitation setting at Srinagarind Hospital, Khon Kaen University.

2.2 Participants

Patients who met the following criteria were recruited: diagnosis of MPS as determined by a physiatrist according to Simon and Travel's criterion [4], age of 18 years or older, reported pain with a numeric rating scale score of at least 5 (out of 10), and the onset of pain more than 3 months. Patients were excluded if they had undergone any previous treatment for this condition within the past 4 weeks, had contraindications for laser therapy (e.g., cancer, tattoo, history of irradiation, infection at the treatment area, pregnancy), had a history of other potential precipitating conditions such as cervical spondylosis, cervical herniated disc pulposus, or fibromyalgia, or had a history of head and neck surgery.

The sample size was calculated based on pre- and post-treatment assessments using the visual analog scale from Kannan P [11], With a dropout rate of 20%, a statistical significance level of 5% ($\alpha = 0.05$), and assuming a study power of 80% ($\beta = 0.20$), the required sample size calculated was 30 patients per group.

2.3 Randomization and blinding

Patients underwent random assignment to receive either HILT (experimental group) or LILT (control group) in a 1:1 ratio using a block randomization method. Treatment allocations were concealed within sequentially numbered, opaque sealed envelopes. Throughout the study, patients were blinded to their assigned treatments.

2.4 Interventions

The high intensity laser device (BTL-6000, 12 W, 1,064 nm wavelength, BTL Medical Technologies Ltd.) was used by a well-trained medical doctor for both HILT and LILT groups. Patients received treatment while seated, with the affected side of their MPS left uncovered. In case of both trapezius muscles are affected by MPS, then the higher numeric rating scale of pain were selected to have intervention and analysis. Automatic laser source calibration was conducted prior to each treatment session to ensure optimal performance and accuracy. The laser probe was placed and scanned perpendicular to the entire muscle treated with 0.5 cm away from skin.

Patients in HILT group received a 12 W of laser in a biostimulation mode over entire affected trapezius muscle with a dosage of 50 J/cm^2 for 50 cm^2 and total energy 2,500 J per session. This treatment regimen was received by patients twice a week for a total of four weeks, resulting in a total of eight sessions.

The treatment regimen in the LILT group consisted of delivering a 500 mW laser in a biostimulation mode over the entire affected trapezius muscle, with a dosage of 3 J/cm^2 for 50 cm^2 and a total energy of 150 J per session, which was administered twice a week for four consecutive weeks, totaling eight sessions. All other procedures in LILT group were the same as in HILT group.

Patients from both groups were given instructions for a home-based exercise program that aims to stretch upper trapezius muscle in lateral cervical bending position. Static stretching exercise was prescribed by hold a stretching position for 10 seconds for 5 times per sets and 3 sets per day. The patients were advised individually and demonstrated the exercises step-by-step. The compliance of daily stretching exercises was recorded and reminded during each laser visit.

Patients were permitted to take 500 mg of acetaminophen every 4-6 hours as needed for pain relief and they have to record the time and amount of medication they have taken. They were asked neither take other pain-killer medicine nor physical therapy.

2.5 Outcome measurements

A well-trained research assistant assessed patients, blinded to their treatment groups, at four intervals. These intervals included baseline, after the first session, after the eighth session, and four weeks following the eighth session.

2.5.1 The numerical pain rating scale (NPRS)

NPRS *is* a subjective pain assessment tool where individuals rate their pain on a numerical scale. This scale ranges from 0, indicating no pain at all, to 10, representing the worst imaginable pain.

2.5.2 Cervical range of motion (CROM)

Lateral flexion range of motion of cervical spine was measured at the contralateral side of MTrPs using a combined inclinometer and magnets cervical range of motion instrument.

2.5.3 Pressure pain threshold (PPT)

PPT is a minimum force determined by applying increasing nonpainful pressure perpendicular to MTrPs until the sensation transformed from nonpainful to painful, utilizing a digital pressure algometer.

2.6 Statistical methods

The data were analyzed using STATA version 13 (StataCorp LLC, Texas, USA). Demographic data were presented as mean and standard deviation (SD) for continuous variables or as percentages for categorical variables. To compare within each group across different time points (baseline, after the first session, after the eighth session, and four weeks post-eighth session), repeated measures ANOVA was conducted. Inter-group comparisons were analyzed using two-way ANOVA. Analyses adhered to the intention-to-treat principle, with statistical significance set at $p<0.05$.

3. Results

Out of 72 patients assessed for eligibility, 60 were enrolled in the study, with 30 patients allocated randomly to each group, either HILT or LILT (Figure 1). Each group perfectly adhered to the stretching program.

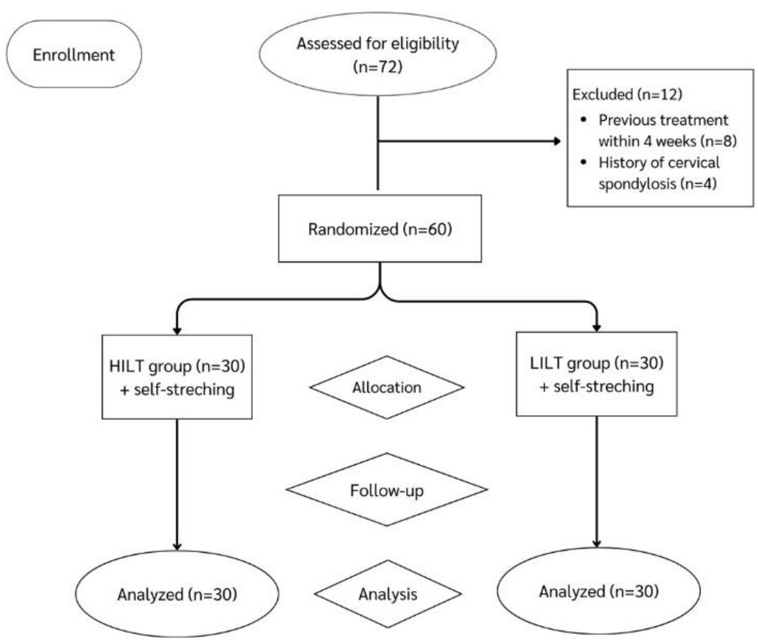

Figure 1 CONSORT diagram outlining the identification, enrollment, and allocation of participants to the two groups: HILT and LILT group.

Table 1 Baseline demographics and clinical characteristics of the patients in this study.

Characteristic	HILT (n = 30)	LILT (n = 30)	*p*-value
Age (years)[1]	45.4 (11.0)	45.0 (9.7)	0.892[a]
Female gender[2]	23 (76.7)	25 (83.3)	0.519[b]
Affected side, right[2]	15 (50.0)	20 (66.7)	0.190[b]
NPRS[1] (0-10)	6.6 (1.1)	7.4 (1.3)	0.017[a]*
Lateral flexion CROM[1] (degree)	44.4 (11.7)	39.8 (11.2)	0.125[a]
PPT[1] (kg/cm^2)	3.3 (1.2)	3.5 (1.0)	0.591[a]

[1]Mean (SD), [2]number (%), [a]Unpaired t-test, [b]Chi-square test.
NRPS, numeric pain rating scale; CROM, cervical range of motion; PPT, pressure pain threshold.

The clinical characteristics of patients in the HILT and LILT groups were compared, as depicted in table 1. In the HILT group, there were 23 females and 7 males, while in the LILT group, there were 25 females and 5 males. The mean age of the patients was 45.2 years, with 80 percent of them being women. MTrPs affected the right side in 58.3 percent of cases. The baseline NPRS was significant difference between group at 6.6 and 7.4 in HILT and LILT group respectively ($p = 0.017$). However, no significant differences of other features were observed between the two groups.

Both groups exhibited significant improvement in the NPRS and lateral flexion CROM after the first session, the eighth session, and four weeks after the eighth session ($p = 0.000$) (as demonstrated in table and Figure 2). Additionally, PPT improved over time, except after the first session compared to baseline.

No statistically significant difference was observed between the HILT and LILT groups in NPRS, lateral flexion CROM, and PPT (p = 0.21, 0.13, 0.26).

Three patients in the HILT group and five patients in the LILT group reported taking acetaminophen tablets. No complications were reported in either group.

Table 2 Changes in NPRS, CROM and PTT between treatment groups.

Outcomes	**HILT (n=30)**		**LILT (n=30)**		Mean difference between group (95% CI)
	Mean (SD)	Mean difference from baseline (95% CI)	Mean (SD)	Mean difference from baseline (95% CI)	
NPRS (score 0-10)					
Baseline	6.6 (1.1)		7.4 (1.3)		
After 1st session	5.5 (1.1)	-1.1 (-0.7, -1.56)*	5.6 (1.9)	-1.8 (-1.3, -2.4)*	0.1 (-0.7,0.9)
After 8th session	4.6 (1.3)	-2.0 (-1.6, -2.5)*	5.1 (1.4)	-2.3 (-1.7, -2.8)*	0.5 (-0.2,1.2)
4-week posttreatment	3.0 (1.1)	-3.6 (-3.2, -4)*	2.4 (1.2)	-5.0 (-4.3, -5.7)*	-0.6 (-1.2,0.1)
CROM (degree)					
Baseline	44.4 (11.7)		39.8 (11.2)		
After 1st session	49.1 (49.1)	4.8 (1.8,7.8)*	46.1 (12.1)	6.3 (2.9,9.8)*	-3.0 (-9.1,3.1)
After 8th session	52.1 (10.1)	7.7 (3.6,11.8)*	49.8 (11.8)	10.0 (5.4,14.6)*	-2.3 (-8.0,3.4)
4-week posttreatment	54.0 (8.8)	9.6 (5.7,13.5)*	51.7 (8.8)	12.0 (8.3,15.7)*	-2.2 (-6.7,2.3)
PPT (kg/cm^2)					
Baseline	3.3 (1.2)		3.5 (1.0)		
After 1st session	3.4 (1.1)	-0.1 (-0.2,0.2)	3.7 (1.1)	0.2 (0.0,0.5)	0.4 (-0.2,1.0)
After 8th session	3.9 (0.8)	0.5 (0.2,0.7)*	4.0 (0.9)	0.5 (0.3,0.8)*	0.2 (-0.2,0.7)
4-week posttreatment	4.2 (0.7)	0.9 (0.4,0.1.1)*	4.3 (0.7)	0.7 (0.5-1.1)*	0.3 (-0.1,0.6)

CI, confident interval; NPRS, numeric pain rating scale; CROM, lateral cervical flexion range of motion; PPT, pressure pain threshold; HILT, high-intensity laser therapy; LILT, low-intensity laser therapy
**p*<0.05 in two-way repeated ANOVA.

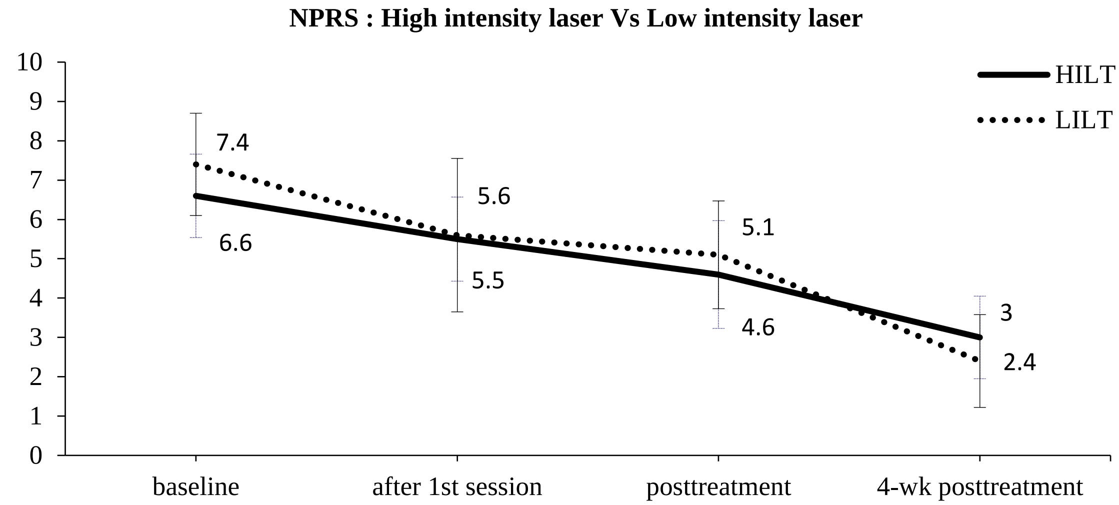

Figure 2 Mean NPRS score changes among treatment groups over time; HILT, high-intensity laser therapy; LILT, low-intensity laser therapy.

4. Discussion

This randomized controlled trial examined the effectiveness of HILT for treatment of chronic upper trapezius MPS compared to LILT. It was found that patients in both groups showed improvement of pain, cervical range of motion, and pressure pain threshold after treatment both immediate and prolong effects (4 weeks after treatment). Despite the higher baseline NPRS in the LILT group, there was no discrepancy between the groups regarding pain scores and lateral flexion cervical range of motion. Consequently, there was no indication that HILT combined with home-based stretching exercises yielded a more advantageous outcome than LILT combined with home-based stretching exercises in patients with chronic myofascial pain syndrome affecting the upper trapezius muscle. Patients could well tolerate with no adverse effects found in both groups.

The prolonged effects of pain reduction observed at four weeks post-treatment cannot be solely attributed to either the laser therapy or the stretching exercises alone, as no previous study included a comparison with a solely laser treatment group [10, 11], given that stretching exercise is the standard treatment for MPS. However, the continued pain reduction may be due to the combined effect of the laser therapy and the stretching exercises.

Considerations of dosimetric parameters involve several factors. In the treatment of MPS, LILT typically utilizes an effective dosage ranging from 2.4 to 3.5 J/cm² [12, 13], with each session lasting a minimum of 5 minutes [14]. Conversely, HILT administers dosages per session ranging from 1,060 to 3,000 J [10, 11, 15]. Treatment patterns varied from a single session to a course of 15 treatments, administered daily to twice a week. The LILT and HILT parameters used in our study is in between the previous study [8], [10-11], [15-16].

Our study findings aligned with prior research on LILT for MPS [17-20], indicating its efficacy in alleviating MPS symptoms. LILT, also referred to as "low-energy" or "low-power" laser therapy, was a noninvasive treatment option for individuals with acute or chronic neck pain, administered at low radiation intensities. The biological effects stemmed from the direct impacts of photonic radiation [21]. A meta-analysis even suggested that LILT could provide pain relief for up to 22 weeks in patients suffering from chronic neck pain [8]. HILT has been introduced to treat low back pain [15, 22], knee osteoarthritis [23-25], subacromial impingement syndrome [26], and chronic diabetic foot ulcers [27]. Compared to LILT, HILT used a particular waveform with regular peaks of elevated amplitudes and durations of time which more rapidly induced photochemical and photothermic effects in deep tissue, increasing blood flow, vascular permeability, cell metabolism, and an analgesic effect on nerve endings [28, 29]. Our study was the first to compare HILT and LILT. However, more evidence was needed to draw conclusions regarding the effectiveness of HILT in treating MPS.

Only two studies had investigated the efficacy of HILT in the treatment of MPS in the neck and shoulder area. In 2015, Dundar et al [10], demonstrated effect of HILT accompanied with exercise compared to sham laser with exercise in female patients with MPS of the trapezius muscle. The results of their study are concordant with ours that HILT can improve pain and cervical range of motion. Another study of Hatem M. Ahmed et al [11], also showed the benefit of HILT on acute MPS of upper trapezius muscle but they compared HILT plus traditional treatment, which included transcutaneous electrical nerve stimulation, ultrasound, passive stretch, and isometric exercise, with traditional treatment alone.

This study addresses the existing knowledge gap regarding the comparative effectiveness of HILT and LILT. Our findings indicate that HILT is not superior to LILT, suggesting that the acquisition of new HILT devices may not be necessary, thereby promoting cost-effectiveness. These results have significant implications for clinical practice, potentially guiding more efficient resource allocation and treatment decisions. Additionally, this study provides a foundation for future research, with the potential to enhance patient outcomes in physical therapy.

The main limitations of our study are as follows. First, a head-to-head comparison with stretching exercises alone is lacking because previous studies have demonstrated that laser therapy provides additional benefits as an add-on therapy for MPS [6-10]. Given the need to compare HILT and LILT, this study aims to extend existing knowledge by focusing on this comparison. Therefore, an exercise-only group is not included in this study. Second, we treated and analyzed only the upper trapezius MTrPs on the more painful side. Consequently, if patients had adjacent untreated MTrPs, it might interfere with the results. Lastly, a standard treatment protocol for laser therapy in MPS has yet to be determined. Our study introduces a new laser protocol, so the results cannot be directly compared with previous studies.

Further studies are necessary to assess various parameters and frequencies of laser therapy application to attain optimal energy levels within the patient's tolerance limits. Additionally, laser treatment for MPS in other muscles of the neck and shoulder region, as well as any potential adverse effects across different stages of MPS, should be investigated to establish a standardized treatment protocol.

5. Conclusion

Based on the findings of our study, administering HILT twice a week for four weeks, in addition to a home-based exercise regimen, offers no additional advantage over LILT plus home-based exercise in reducing pain, improving lateral cervical flexion range of motion, and increasing pain pressure threshold in patients with chronic MPS. Importantly, no side effects were reported. However, both treatment groups demonstrated significant improvements in all measured outcomes over the study period.

6. Ethical approval

Ethics approval for this study was obtained from the Human Research Ethics Committee at Khon Kaen University (Approval No: HE601421). Prior to enrollment, all participants provided written informed consent.

7. Acknowledgement

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8. Conflicts of interest

I declare no conflicts of interest related to this study or its findings.

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