Original Article

Efficacy of High-intensity Laser Therapy in Patellofemoral Pain Syndrome: A Double-blinded Randomized Controlled Trial

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ABSTRACT

Objectives: To conduct a double-blinded randomized controlled trial study of the efficacy of high-intensity laser in patellofemoral pain syndrome patients in Ramathibodi Hospital, Thailand.

Study design: A double-blinded randomized controlled trial.

Setting: Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

Subjects: A total of 18 patients with patellofemoral pain syndrome for at least three months were studied.

Methods: Subjects were randomly allocated into two groups. The treatment group received high-intensity laser therapy (frequency 20 Hz, energy 1,530 mJ/cm^2, total energy 3,000 joules per session (6 sessions, 2-3 sessions per week) at an average power of 10.5 W). The control group received sham laser therapy (6 sessions, 2-3 sessions per week). In both groups, the patients were advised to exercise and to make lifestyle modifications. Pain (assessed by the VAS pain scale), functional ability of the lower extremity (assessed by the Thai version of the Kujala scoring questionnaire), and quality of life (assessed by Short Form-36 health survey version 2.0, SF-36V2) were collected before and at 3, 6, and 12 weeks after treatment.

Results: At baseline, demographic data as well as pain, function, and quality of life were similar between the groups. The differences in VAS decrement from baseline in the treatment and control groups after 3 weeks were 44.0 (28.0) and 34.0 (24.8), after 6 weeks were 44.0 (28.0) and 38.0 (37.3), and after 12 weeks were 47.0 (35.0) and 35.0 (41.3), respectively. There was statistically significant improvement in pain (VAS score), functional ability (Kujala score), and quality of life (SF-36V2) within both groups compared to before treatment ($p < 0.05$), but there was no statistically significant difference in those values between the treatment and control groups at 3, 6, and 12 weeks.

Conclusions: The efficacy of high-intensity laser therapy (HILT) combined with effective exercise was not significantly different from exercise alone in improving pain, function, or QOL.

Keywords: high-intensity laser therapy, patellofemoral pain syndrome, anterior knee pain, RCT

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Introduction

Patellofemoral pain syndrome is one of the most common types of knee pain. The primary symptom is usually anterior knee pain, which will increase while ascending or descending the stairs, bending the knee, jumping, or sitting in a knee-bending position for an extended time.[1] Many factors can contribute to lower extremity abnormalities, including increased Q-angle, patellar malposition, muscle imbalance, thigh muscle tension, and overactivity. These factors cause increasing forces under the patellofemoral joint.[2] Patellofemoral pain syndrome is common in teenagers and early young adults and is more common in women. The prevalence of patellofemoral pain syndrome in normal general populations is 22.7 percent and 28.9 percent in teenagers.[3] The pain is worse with knee joint movement, and hence it causes limitations in activities of daily living.[4]

The treatment goals of patellofemoral pain syndrome are to reduce pain, increase muscle strength, increase flexibility, and correct the patellar movement tract.[5] Muscle strengthening is one of the conventional physical therapies, especially for the quadriceps. Many studies have shown that strengthening the hip abductor and quadriceps muscles decreases pain and can increase knee function better than training only the quadriceps muscles, which would has the effect of decreasing force mainly in the patellofemoral joint.[6-8] Other physical modalities include Kinesio-tape around the patella area, electrical stimulation, and orthosis.[9] At this time, there are no significant differences in pain improvement between each treatment. No significant differences in pain improvement between the different treatments have been reported.[5,9]

The effectiveness of pain relief has been tested by reducing or inhibiting inflammatory mediators as well as by increasing neuroenzyme inhibition and inducing or increasing production of endorphins, opioids, and blood supplies.[10-12] Laser therapy has become popular in treating musculoskeletal problems because it is non-painful and requires less time.[10,13] A review of the literature found that many studies using lasers for

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treating chronic lower back pain, frozen shoulder, osteoarthritis, and rheumatoid arthritis have reported significant pain decreases. Additional studies are presently being conducted with high-intensity lasers, which have a higher intensity but a shorter duration than lower-intensity lasers.[13] Results of studies using high-intensity lasers with osteoarthritis patients have shown that the high-intensity laser is more efficient in decreasing pain than a lower intensity laser. Photothermal and photochemical effects of lasers include increased blood supply and cell metabolism in deep tissue.[14,15]

Nouri et al., 2019 investigated the efficacy of high-intensity lasers (300 J/session for five consecutive sessions) with exercise versus sham laser treatment plus exercise. Pain reduction was measured by VAS, WOMAC, and Kujala scores in 44 patients. The patients in the high-intensity laser group experienced a significantly greater decrease in pain than the sham group at the third week.[16] The 2019 Nouri study is a single-blind randomized control trial that advised patients to train only the quadriceps muscles. In contrast, another study showed that training the abductor as well as the and quadriceps muscles was more effective in decreasing pain.[6-8] There have been few studies of using high-intensity lasers for patello-femoral pain syndrome. Additional research is needed to evaluate the efficacy of high-intensity lasers combined with muscle training in patients suffering from patellofemoral pain syndrome.

Method

Study Design

This double-blinded, randomized controlled trial was approved by the Office of the Committee for Research of the Faculty of Medicine Ramathibodi Hospital Mahidol University (approval number: 2019/903). The Thai Clinical Trials Registry number is TCTR20220418007.

Participants

Study participants were adults aged 20-50 years with anterior knee pain for at least three months and who engaged in two or more physical activities that induced knee pain: standing with the knee bent, ascending or descending the stairs, kneeling, jumping, or sitting in a knee-bending position for an extended time, or contracting the quadriceps muscle. Additionally, anterior knee pain was discovered using the patellar grind test[17] as well as by a pain score of 3 or higher on the VAS scale. Exclusion criteria were a history of knee surgery, recent knee trauma or infection, any signs of knee osteoarthritis (OA), use of corticosteroids or anti-inflammatory drugs in the past 6 months, severe neurological or cardiovascular disorders, and contraindications for laser therapy and a desire not to participate in the study. All participants provided written informed consent.

Sample size

The sample size was determined based on our pilot study of 8 participants, which had a mean difference and standard deviation of VAS of 1.0 and 0.46, respectively. For an alpha level of 0.05, a power of 80% and an estimated dropout rate of 20%, the sample size of this study was calculated to be 18 participants (9 participants per group).

Randomization

The researcher performed block randomization using computer-generated randomization for a block of four. A letter in a concealed envelope indicated to which group the patient belonged; the letter was delivered to the physiotherapist who provided the treatment to the patient. The patients and the assessor were blinded to the treatment allocation.

Intervention

The treatment group was treated with high-intensity laser therapy using a Hilterapia®, HIRO TT® (pulsed, high-power Nd: YAG laser, λ 1064 nm, peak power (max): 3 kW, average power (max): 10.5 W) (ASA S.r.l., Vicenza, Italy). We applied the laser using a global approach method and 5 points surrounding the anterior knee in 30-degree of flexion.[18] The control group received a sham laser treatment using the same technique but with the laser cable switched so the laser energy did not go into the joint (Figure 1). All patients received six treatments (2-3 sessions per week). In addition to the laser treatment, both groups participated the same muscle-strengthening program.

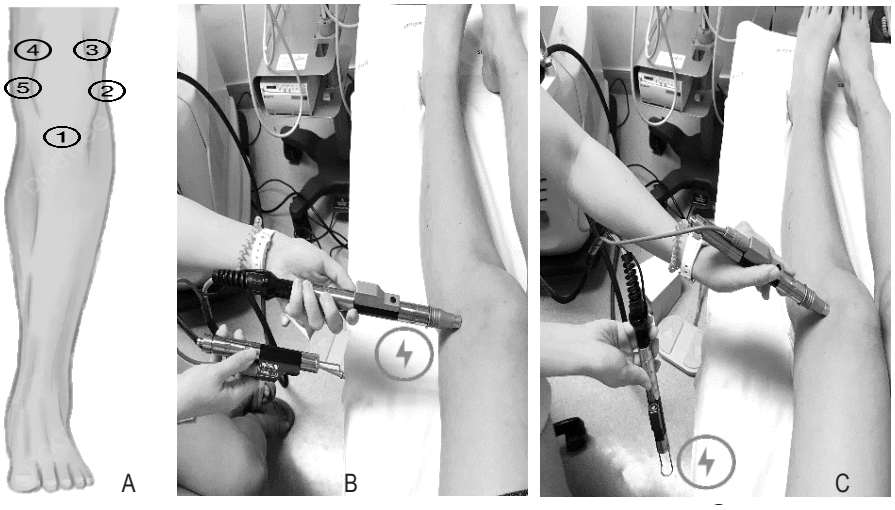

Figure 1. Treatment area around the anterior knee (A), methods of laser application in the treatment group (B) and in the control group (C).

The program included isometric quadriceps strengthening, quadriceps straight leg raise, semi-squat exercise, and hip abductor muscle strengthening for ten repetitions with 10-second holds three times a day and hamstring muscle stretching also with 10-second holds twice daily. In addition, the therapist advised on lifestyle modifications as a form of conservative treatment.[19] Followed-up assessments of patients were conducted at 3, 6, and 12 weeks following treatment after which the physiatrist and the physiotherapist contacted the patients regularly throughout the study to ensure they were continuing to follow the exercise routine and were receiving the prescribed laser therapy.

Outcome measurements

Primary outcome measurement

Pain

A visual analog scale (VAS) was used for pain assessment. The VAS is a 100-mm line on which where 0 indicates "no pain," and 100 indicates "worst pain." Patients were asked to indicate their current pain level by placing a mark at the appropriate spot on the line.

Secondary Outcome Measurement

Functional ability of the lower extremity and quality of life

The Thai version of the Kujala scoring questionnaire, a 13-item questionnaire for assessing patient-reported anterior knee pain, was used to assess lower extremity functional ability,[20] as well as symptom severities and physical limitations. This questionnaire is commonly used for measuring patello-femoral pain. Scoring ranges from 0-100, where 100 indicates no symptoms or disability and 0 indicates severe symptoms and/or disability. The Short Form-36 Health Assessment version 2.0 (Thai version), a 36-item patient-reported survey measuring physical and mental health, was used to evaluate quality of life,[21] with higher values indicating a higher quality of life. The Thai versions of both instruments have been validated and have shown excellent test-retest reliability.

Statistical analysis

All statistical tests were performed using SPSS Version 18.0 (IBM Corp, Armonk, NY, USA). Because the data was non-normally distributed, it was evaluated using the non-parametric Shapiro-Wilk W-Test. The Mann-Whitney U test was used to compare differences between groups, and the Wilcoxon matched-pair signed ranks test was used to compare differences within groups. An intention-to-treat analysis was also carried out. The results are expressed as mean (SD) for parametric data and median ± interquartile range (IQR) for non-parametric data. P values < 0.05 were considered statistically significant.

Results

In this study, 18 patients were recruited and divided into two groups of nine patients each. There were no dropouts during the study (Figure 2). At baseline, demographic data showed no statistically significant differences ($p > 0.05$).

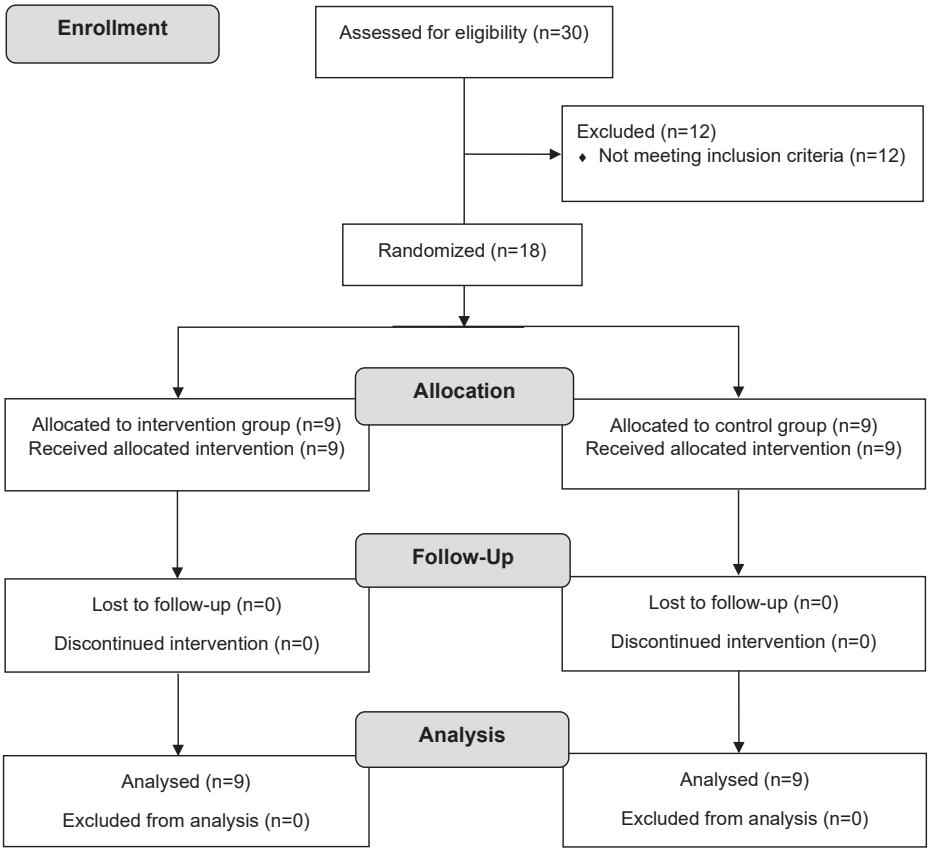

Figure 2. Flowchart of the trial

In the treatment group and control group, the mean ages (SD) were 36.4 (7.5) and 34.3 (8.84) years, the mean BMIs (SD) were 22.2 (3.4) and 25.8 (6.2) kg/m^2, and the mean length of duration of pain were 26.4 (23.8) and 10.7 (10.1) months, respectively. Additional demographic data is provided in Table 1.

Before treatment, the median VAS (IQR) was 60.0 (21.0) and 58.0 (27.5), the median Kujala scores (IQR) were 73.0 (15.5) and 75.0 (16.0), and the median SF-36V2 scores (IQR) were 599.6 (121.0) and 578.8 (151.9) in the treatment and control groups, respectively (Table 2).

At three weeks after treatment, the median VAS (IQR) scores were 16.0 (17.5) and 24.0 (36.5); at six weeks, the scores were 16.0 (18.0) and 17.0 (41.5), and at 12 weeks they were 6.00 (16.0) and 23.0 (32.0) for the treatment and control groups, respectively.

At 3, 6, and 12 weeks there was a statistically significant decrease in VAS compared to before treatment in both groups (Table 2). The differences in VAS decrement between the treatment and control groups at baseline and at three weeks were 44.0 (28.0) and 34.0 (24.8), respectively. At six weeks the differences were 44.0 (28.0), 38.0 (37.3), and at 12 weeks they were 47.0 (35.0) and 35.0 (41.3), respectively. The differences in VAS between the treatment and control groups after 3, 6, and 12 weeks of treatment were not statistically significant, just as with the Kujala scores and the SF-36V2 (Table 3). Similarly, there were no statistically significant differences in VAS scores, Kujala scores, or SF-36V2 within groups or between groups at three weeks after treatment compared to 6 and 12 weeks.

Discussion

In this study, the pretreatment situation of the group that received the high-intensity laser and the group that received the sham laser, both of which included muscle training exercises to decrease pain, improve functional ability, and improve quality of life, were compared following both long-term and short-term treatment. It is noteworthy that the improvement in both groups was much greater in the first three weeks and slightly better, but then improved only slightly between three weeks and six weeks and between six weeks and twelve weeks, similar to a study by Nouri et al.[15] Comparison of the treatment results between the two groups in this study, however, showed no significant difference, unlike a study by Nouri et al.[15] which found statistically significant VAS improvement in

Table 1. Baseline demographic data

	Treatment group (N=9)	Control group (N=9)	*p*-value
Gender, female,1 male[1]	7; 2	6; 3	0.599
Age (year)[2]	36.4 (7.5)	34.3 (8.8)	0.624
Body mass index (kg/m^2)[2]	22.2 (3.4)	25.8 (6.2)	0.200
Duration of pain (month)[2]	26.4 (23.8)	10.7 (10.1)	0.161
Q-angle (degree)[2]	13.6 (3.4)	13.8 (2.4)	0.653
Ober's angle (degree)[2]	4.2 (1.8)	6.6 (3.8)	0.127
Arch of foot, low, normal, high[1]	0, 7, 2	2, 6, 1	0.300
Patellar tilt angle (degrees)[2]	8.8 (7.6)	10.6 (6.3)	0.345
VAS pretreatment[2]	60.0 (21.0)	58.0 (27.5)	0.930
Kujala score pretreatment[2]	73.0 (15.5)	75.0 (16.0)	0.479
SF-36V2 pretreatment[2]	599.6 (121.0)	578.8 (151.9)	0.536

[1]Number, [2]mean (SD)

Q-angle, Quadriceps angle; VAS, visual analog scale; SF-36V2, short-form survey version 2.0

Table 2. Parameters before treatment and at 3, 6, and 12 weeks after treatment: median (interquartile range)

		Treatment group	Control group	*p*-value
VAS	Pretreatment	60.0 (21.0)	58.0 (27.5)	0.930
	3 Weeks	16.0 (17.5)	24.0 (36.5)	0.508
	6 Weeks	16.0 (18.0)	17.0 (41.5)	0.724
	12 Weeks	6.00 (16.0)	23.0 (32.0)	0.351
Kujala score	Pretreatment	73.0 (15.5)	75.0 (16.0)	0.479
	3 Weeks	93.0 (6.0)	89.0 (15.5)	0.132
	6 Weeks	95.0 (11.5)	90.0 (13.0)	0.307
	12 Weeks	94.0 (16.5)	91.0 (14.5)	0.424
SF-36V2	Pretreatment	599.6 (121.0)	578.8 (151.9)	0.536
	3 Weeks	682.5 (76.9)	676.7 (116.8)	0.354
	6 Weeks	697.92 (71.9)	732.9 (109.9)	0.691
	12 Weeks	706.3 (115.4)	707.50 (96.3)	0.596

VAS, visual analog scale; SF-36V2, short-form survey version 2.0

Table 3. Changes in VAS and Kujala score and SF-36V2 among groups: median (interquartile range)

	Weeks	Treatment group	Control group	*p*-value
Δ VAS	3	44.0 (28.0)	34.0 (25.8)	0.627
	6	43.0 (42.0)	38.0 (37.3)	0.596
	12	47.0 (35.0)	35.0 (41.3)	0.791
Δ Kujala score	3	19.0 (11.5)	10.9 (20.5)	0.122
	6	21.0 (16.0)	12.0 (17.5)	0.111
	12	44.0 (28.0)	34.0 (25.8)	0.233
Δ SF-36V2	3	104.1 (55.4)	91.65 (163.3)	1.00
	6	116.3 (113.3)	130.4 (170.5)	0.627
	12	100.0 (71.3)	95.0 (173.1)	0.627

VAS, visual analog scale; SF-36V2, short-form survey version 2.0

the active laser group over the sham laser group. Training of hip abductor and quadriceps muscles in our study was more effective than quadriceps muscle training alone in reducing pain in patellofemoral pain syndrome [6,7] as it decreased force in the patellofemoral joint, as well as improving functional ability because of increased coordination of lower extremity muscles, results in concordance with studies by Sharif et al.,[6] Alammari et al.[7] and Ferber et al.[8] The reduction of pain and other symptoms additionally combined to result in a better quality of life.[22] In the control group in the present study that had only been advised to exercise but received no laser therapy, the average VAS score decreased by 34.0, a clinically significant reduction. This could be one reason why the results in both level of improvement in the two groups showed no statistically significant difference.

High-intensity lasers have photothermal, photochemical, and photomechanical effects that help reduce inflammation and pain while promoting tissue repair.[23] They are typically used with patients who have inflammation and arthritis of joints, tendons, ligaments, and muscles. In patellofemoral joint pain, there are many potential causative factors. The most common factor is a muscle imbalance in the knee joint area. That imbalance affects patellar movement and results in more force around the patellofemoral joint during flexion and extension of the knee.[24] That is why high-intensity laser treatment of patellofemoral pain syndrome may not be effective in patients with muscle imbalance. Between groups comparisons in the present study showed no significant difference in pain relief between the sham group and the laser treatment group. Researchers found which suggests that higher laser energy may not help reduce pain in patients with patellofemoral pain syndrome.

This study's population consisted of more women than men, similar to the Smith et al. study.[3] However, in the present study there were few patients with anatomical abnormalities: only two patients had flat feet, and no patients had iliotibial band syndrome or an unusual Q-angle making it more likely that strengthening exercises alone may be sufficient to relieve pain. However, this study did not was not able to answer the question of the efficacy of high-intensity lasers in patellofemoral pain syndrome treatment.

Limitations

One limitation is that this study did not collect data on patient activity level, which could be one of the factors influencing treatment outcomes. Moreover, the sample size, calculated based on a small pilot study, might have been insufficient to accurately estimate the outcome's standard deviation.

Conclusions

This study found that the efficacy of high-intensity laser treatment combined with effective exercise is not significantly different from exercise alone in terms of pain reduction, function improvement, and increase in QOL.

Conflict of interests

The authors declare no conflict of interest.

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