CLINICAL SCIENCE

The effectiveness of low laser therapy in subacromial impingement syndrome: a randomized placebo controlled double-blind prospective study

Sebnem Koldas Dogan, Saime AY, Deniz Evcik

Ufuk University, Department of Physical Rehabilitation and Medicine, Ankara, Turkey.

OBJECTIVES: Conflicting results were reported about the effectiveness of Low level laser therapy on musculoskeletal disorders. The aim of this study was to investigate the effectiveness of 850-nm gallium arsenide aluminum (Ga-As-Al) laser therapy on pain, range of motion and disability in subacromial impingement syndrome.

METHODS: A total of 52 patients (33 females and 19 males with a mean age of 53.59 $\pm$ 11.34 years) with subacromial impingement syndrome were included. The patients were randomly assigned into two groups. Group I (n = 30, laser group) received laser therapy (5 joule/cm^2 at each point over maximum 5-6 painful points for 1 minute). Group II (n = 22, placebo laser group) received placebo laser therapy. Initially cold pack (10 minutes) was applied to all of the patients. Also patients were given an exercise program including range of motion, stretching and progressive resistive exercises. The therapy program was applied 5 times a week for 14 sessions. Pain severity was assessed by using visual analogue scale. Range of motion was measured by goniometer. Disability was evaluated by using Shoulder Pain and Disability Index.

RESULTS: In group I, statistically significant improvements in pain severity, range of motion except internal and external rotation and SPADI scores were observed compared to baseline scores after the therapy ($p<0.05$). In Group II, all parameters except range of motion of external rotation were improved ($p<0.05$). However, no significant differences were recorded between the groups ($p>0.05$).

CONCLUSIONS: The Low level laser therapy seems to have no superiority over placebo laser therapy in reducing pain severity, range of motion and functional disability.

KEYWORDS: Shoulder; Pain; Disability; Range of motion; Placebo.

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E-mail: sebnemkoldas@yahoo.com

Tel.: +905323935662

INTRODUCTION

Shoulder pain is one of the major symptoms of upper extremity.[1] The most frequent cause of shoulder pain is subacromial impingement syndrome (SAIS).[2] It is associated with repetitive overuse and caused by compression of supraspinatus tendon between humerus and coracoacromial arc during elevation of arm or overhead activities. This painful condition leads decreases in muscle strength and range of motion (ROM) of the shoulder which adversely affect the patients' quality of life.[3]

The SAIS causes edema, inflammation and can become chronic if adequate treatment isn't applied. Conservative and surgical treatment approaches can be used to reduce pain, improve joint stiffness, impaired muscle strength and quality of life in patients with SAIS. The conservative treatment methods include analgesic and nonsteroidal antiinflammatory drugs, resting, modification of daily activities, physical therapy approaches, range of motion and strengthening exercises, subacromial local anesthetic or corticosteroid injections.[4-6]

Laser is a noninvasive, nonionising, monochromatic electromagnetic high concentrated light beam. Recently, low level laser therapy (LLLT) is widely used in various rheumatologic and musculoskeletal disorders which have analgesic, anti-inflammatory and biostimulating effects. The LLLT induces cell proliferation, collagen synthesis, protein synthesis, tissue reparation, wound healing and pain relief through direct irradiation without thermal response.[7-12] However, conflicting results were reported about its effectiveness on musculoskeletal disorders. Some of the randomized controlled studies suggest that LLLT may be effective in pain relief in different musculoskeletal disorders.[13,14] On the other hand some of them have failed to show any superiority over placebo.[9,15-17]

Limited number of studies were investigated the effectiveness of LLLT in shoulder disorders.[13,17-20] One of them was reported no beneficial effect when combined with exercise.[20] When compared to placebo, no differences were detected in two studies.[17,18] The aim of this study was to investigate the effectiveness of 850-nm gallium arsenide aluminum (Ga-As-Al) laser therapy on pain, range of motion (ROM) of shoulder joint and disability in subacromial impingement syndrome (SAIS).

MATERIALS AND METHODS

Patients

A total of 52 patients (33 females, 19 males) with a mean age of 53.59 ± 11.34 years with SAIS were included in the study. The diagnoses of SAIS were made according to detailed physical and neurologic examination. After physical examination magnetic resonance imaging (MRI) were done to exclude rotator cuff tears. Complete blood count, biochemical markers, erythrocyte sedimentation rate and C-reactive protein were also evaluated. The exclusion criterias were; presence of acute trauma, acromioclavicular arthritis, glenohumeral arthritis, tears of rotator cuff, neurologic or inflammatory diseases, referring pain due to neck pathologies and history of physical therapy, surgery, subacromial or intraarticular injection within 6 months.

Treatment groups

The patients were randomly assigned into two groups. Randomization was allocated by numbered envelopes method. Treatment program either LLLT or placebo was written in these closed envelopes and patients selected one of them and randomly assigned into two groups.

Group I (n = 30, laser group) received cold pack therapy, LLL therapy (3 joule/cm^2 at each point over maximum 5-6 painful points for 1 minute) and exercise program.

Group II (n = 22, placebo laser group) received cold pack therapy, placebo laser therapy and exercise program.

The placebo laser group consisted in patients who were sex- and age-matched to the patients in laser group.

The Gallium-Aluminum-Arsenide (GaAlAs, infrared laser) diode laser device (Chattanooga group, USA) with a wavelength of 850nm, power output of 100mV, continuous wave and 0.07cm^2 spot area laser were used for the laser therapy. The laser was applied with a dosage of 5 joule/cm^2 (totally 15-20 joule) at maximum 5-6 painful points for 1 minute at each point over subacromial region of the shoulder.

Placebo laser was applied in the same way but the device was turned off during treatment sessions. Patients and physiotherapist were asked to use protective eyeglasses during therapy for safety.

Cold pack therapy during 10 minutes was applied to all patients in both groups.

Also patients were given an exercise program which included range of motion, stretching and progressive resistive exercises. Each exercise was performed once a day with 10-15 repetitions. The therapy program was applied 5 times a week, once a day for 14 sessions.

Outcome measures

At the beginning, sociodemographic (age, sex) and clinic (disease duration, localization of shoulder pain) characteristics of the patients were recorded. Pain severity, range of motion and functional status of all patients were evaluated before and after the treatment by different physicians. Both of the physicians and patients were blinded. Only the physiotherapist was aware of the procedure.

Pain severity was assessed by visual analogue scale (VAS, 0-10cm; 0 means no pain, 10 means severe pain).

Range of motion including flexion, abduction, adduction, internal and external rotation was measured by using goniometer in supin position. Extension was measured in prone position.

Functional status was evaluated by using Shoulder Pain and Disability Index (SPADI). This is a self-administered shoulder specific questionnaire including two subscales; pain and disability. Pain subscale consists of 5 items and disability subscale consists of 8 items. Patients were asked to answer each items using 0-100 mm VAS. The possible score of SPADI was ranged from 0 to 100. Higher scores indicate high level of disability.[21] The Turkish version of SPADI was found to be reliable and valid by Bumin et al.[22]

Signed written informed consent was obtained from all patients. The Human Research Ethics Committee at School of Medicine of Ufuk University approved the study.

Statistical analysis

All the data were analyzed using SPSS-16.0 statistical package for Windows. The mean values and frequencies of the parameters were assessed by descriptive statistics. Mann-Whitney U test was used for comparing groups. The differences before and after treatment for each group were assessed by Wilcoxon test. And $p<0.05$ was accepted to be statistically significance level.

RESULTS

Fifty two patients (33 females, 19 males) with a mean age of 53.59 ± 11.34 years with SAIS were included in the study. All patients were able to complete the therapy program without any adverse effects. The results of complete blood count, biochemical markers, erythrocyte sedimentation rate and C-reactive protein of the patients were found to be normal.

The sociodemographic and clinic characteristics of the patients were given in Table 1. No statistically significant differences were detected between the groups in initial values ($p>0.05$).

In group I, after the therapy statistically significant improvements in pain severity, ROM except internal and external rotation and SPADI scores were observed compared to baseline scores ($p<0.05$).

In Group II, all parameters except ROM of external rotation were improved ($p<0.05$). However, no significant differences were recorded between the groups ($p>0.05$) (Table 2).

DISCUSSION

The results of this study indicated that both LLLT and placebo LLLT combined with cold pack and exercise program showed significant improvements in pain severity, ROM measurements and functional status.

The LLLT has become popular in the treatment of musculoskeletal disorders in recent years. The mechanism of analgesic effect of LLLT is not well known. The increased peripheral β-endorphin precursor mRNA expression in

Table 1 - The sociodemographic and clinic characteristic of the patients.

	Group I (n, %)	Group II (n, %)	p
Age , year (mean±SD)	53.7±12.6	53.45±9.64	0.933
Gender			
Female	20 (%66.7)	13(%59.1)	
Male	10 (%33.3)	9(%40.9)	0.579
Disease duration, month (mean±SD)	11.66±18.04	15.27±25.13	0.237
Localization			
Right	17 (%56.7)	12(%54.5)	
Left	13 (%43.3)	10(%45.5)	0.880
VAS	7.16±1.64	7.59±1.76	0.343

VAS: Visual analog scale; SD: Standard deviation.
**p<0.01
*p<0.05

Table 2 - Comparison of mean values of pain severity, ROM and SPADI scores before and after the treatment between the groups.

	Group I	Group II	p
VAS			
Baseline (mean±SD)	7.16±1.64	7.59±1.76	0.343
Posttreatment (mean±SD)	3.76±1.45	4.63±2.10	0.216
p	0.000**	0.000**	
Shoulder flexion			
Baseline (mean±SD)	156±30.77	167.50±21.14	0.284
Posttreatment (mean±SD)	168±22.65	174.31±14.98	0.313
p	0.001**	0.011*	
Shoulder extension			
Baseline (mean±SD)	38.16±13.42	39.31±8.20	0.372
Posttreatment (mean±SD)	42.66±3.40	42.95±3.98	0.457
p	0.007**	0.006**	
Shoulder abduction			
Baseline (mean±SD)	147.16±33.52	160.68±30.71	0.145
Posttreatment (mean±SD)	166.66±21.38	172.72±16.67	0.140
p	0.001*	0.007**	
Shoulder adduction			
Baseline (mean±SD)	38.50±15.98	38.40±7.92	0.438
Posttreatment (mean±SD)	42.00±4.27	42.04±5.26	0.556
p	0.003**	0.008**	
Shoulder internal rotation			
Baseline (mean±SD)	47.50±9.89	47.95±5.26	0.718
Posttreatment (mean±SD)	49.33±9.62	49.77±4.49	0.344
p	0.439	0.039*	
Shoulder external rotation			
Baseline (mean±SD)	44.16±10.09	44.77±8.23	0.752
Posttreatment (mean±SD)	44.83±5.64	44.09±1.97	0.517
p	0.205	0.480	
$SPADI_{pain}$			
Baseline (mean±SD)	70.66±24.37	70.09±16.76	0.330
Posttreatment (mean±SD)	48.13±22.10	40.99±20.98	0.211
p	0.000**	0.000**	
$SPADI_{disability}$			
Baseline (mean±SD)	58.12±24.36	55.17±19.02	0.282
Posttreatment (mean±SD)	40.54±21.40	31.87±21.08	0.115
p	0.000**	0.000**	
$SPADI_{total}$			
Baseline (mean±SD)	64.39±23.65	62.63±16.58	0.236
Posttreatment (mean±SD)	44.33±2.80	36.39±20.53	0.201
p	0.000**	0.000**	

VAS: Visual analog scale; SPADI: Shoulder pain and disability index; SD: Standard deviation.
**p<0.01
*p<0.05

blood cells of the rats by 830 nm Ga-Al-Ar Laser irradiation was demonstrated.[23] The analgesic mechanisms of LLLT in rheumatoid arthritis were associated with reduced proinflammatory cytokines such as TNF-alpha, IL-1 beta, IL-8.[24] Decreased mitochondrial membrane potential, blockage of axonal flow in dorsal root ganglion neurons of rats were emphasized.[25] Some authors explained the analgesic effect of laser therapy by altering sensorial input to the central nervous system leading the decrease of pain perception.[16,26] Moreover, reduced prostaglandin concentrations with LLLT were reported.[27,28] The stimulation of deposition of collagen fibers can be related to the biostimulating effect of LLLT.[29]

Since the anti-inflammatory, biostimulating, anti-edematous and analgesic effects of laser therapy were demonstrated.[23-25,27-29] It is thought to be beneficial in the treatment of SAIS. England et al. compared the effectiveness of laser, placebo laser therapy and naproxen sodium in patients with supraspinatus or bicipital tendonitis. After 2 weeks of treatment, they found improvement in laser therapy group compared to placebo laser or naproxen sodium treatment groups.[13] Bingol et al. investigated the efficacy of LLLT in shoulder pain. Patients received laser and placebo laser therapy combined with exercise protocol of 10 sessions for 2 weeks. Laser therapy was found to be superior over placebo in palpation sensitivity and passive extension but no significant differences were shown in pain severity, active ROM and algometric sensitivity between the groups.[18] Stergioulas applied LLLT and placebo laser for 12 sessions during 8 week in patients with frozen shoulder and concluded that LLLT was more effective in pain relief, disability than placebo.[19]

Our results failed to demonstrate the superiority of LLLT over placebo. Both groups showed improvements in pain severity, ROM measurements and functional status. Improvements in both groups may be due to additional coldpack application and exercise program. It is known that superficial cold induces vasoconstriction and reduces local blood flow leading to decrease tissue swelling, inflammation and pain severity.[30] Nevertheless, the efficacy of therapeutic exercise programs on pain reduction and functional improvement in the treatment of SAIS was well defined.[31,32] Similar to our findings, Yeldan et al., also found improvements with both LLLT and placebo LLLT combined with superficial cold and exercise program in pain severity, functional status and muscle strength in patients with SAIS.[17] In another study, the authors compared the effectiveness of laser therapy combined with home exercise program and home exercise program alone. They indicated no additional effect of laser therapy over exercise alone.[20]

There are several limitations of this study. First of all was the small sample size. Another limitation was not to have an only placebo LLLT group because of ethical reasons and therefore coldpack and exercise program were associated to LLLT. Finally, the assessment parameters were measured after the therapy and long term results of the therapy were not evaluated.

CONCLUSIONS

Finally there are controversial results about the efficacy of laser therapy on shoulder pain. Our results showed improvements on pain severity, ROM and functional status of the patients with SAIS with the therapy program of laser therapy, coldpack and exercise. However no superiority over placebo laser therapy was observed. Further studies

with large samples, longer follow up durations were required to demonstrate its efficacy, optimum dosage, type, frequency and duration.

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