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Original Work

Low-level laser therapy versus local steroid injection in patients with idiopathic carpal tunnel syndrome: a single blind randomized comparative trial

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ABSTRACT: The objective of this study was to compare corticosteroid injection with low-level laser therapy for the short-term treatment of mild or moderate idiopathic carpal tunnel syndrome. Single blind randomized clinical trial was conducted from May 2010 to October 2010 in outpatient clinic and research center at a university hospital. Thirty-eight patients (female to male ratio was 5.3 to 1) with a new episode of carpal tunnel syndrome of mild or moderate severity participated in this study. Corticosteroid injection and low level laser therapy were used as the interventions. Primary outcome measure was the severity of the disease. Based on the electrophysiological findings, we proposed three grades: mild, moderate and severe. Visual analogue scores were used to measure subjective severity of pain. We measured median distal motor and sensory latencies. All participants were followed for two months. Analyses showed favorable outcomes in both groups in terms of visual analogue scores and median distal motor and sensory latencies ($p<0.001$ for all comparisons). Electrophysiologic studies did not imply any significant difference in the severity (Chi-squared test $p = 0.28$), and change in the grade of the disease between the two groups. Also there was no significant difference between the groups in mean visual analogue scores (Mann-Whitney test $p = 0.45$), median motor distal latency (Mann-Whitney test $p = 0.08$), and sensory distal latency (Mann-Whitney test $p = 0.70$), 8 weeks after the treatments. Both corticosteroid and laser are advantageous in the short-term treatment of carpal tunnel syndrome and provide satisfactory pain relief, electrophysiological improvement, and are well tolerated by patients.

KEY WORDS: ***Carpal tunnel syndrome; Low level laser; Corticosteroid; Median nerve; Electrophysiologic studies; Peripheral compression neuropathy; Randomized clinical trial; Hydrocortisone***

INTRODUCTION

Carpal tunnel syndrome (CTS) is the leading cause of peripheral compression neuropathy in the upper extremity, and its prevalence is 3.7% in the adult general population[1]. Occupational and intrinsic risk factors are related to the occurrence of the disease[2-4]. However, in the majority of patients the exact cause and pathogenesis of CTS is unclear[5]. The diagnosis of CTS is based on a suggestive history, and on physical examination. Electrodiagnosis also helps in the diagnosis of CTS, especially when the manifestations are equivocal. Besides, electrodiagnosis is used for the diagnosis of conditions with symptoms similar to those of CTS e.g., cervical radiculopathy, polyneuropathy and other median nerve entrapment syndromes.[6]

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Endoscopic or open surgery is indicated in severe cases of the disease. Mild to moderate symptoms are commonly managed with conservative measures[5]. Steroid injection into the carpal tunnel is easy to perform, and the rate of complications is low. In addition, response to the treatment may confirm the diagnosis[7]. Also, low-level laser therapy has been reported to have favorable effects for the treatment of CTS[8] and various musculoskeletal conditions[9]. Positive effects on hand and pinch grip strengths have been reported following laser therapy[8].

Local corticosteroid injection is effective in the short term for the treatment of musculoskeletal problems[10] including CTS[11,12]. However, evidence for its efficacy beyond one month has been established in few randomized controlled trials[12]. Iatrogenic injury to the median nerve is a major complication and the safest location for the injection is highly debated [7,13].

Fewer studies on comparison of laser with other conservative treatments have been performed. Lack of uniformity in clinical studies and variation in diagnostic criteria are major drawbacks in the evaluation of treatment modalities. Self-reported symptoms and physical signs may be unreliable determinants of efficacy. Moreover, physical signs have poor reproducibility and their correlation with symptoms may be hard to establish.

Laser therapy is not invasive and its side effects are not common. Local corticosteroid injection is used frequently for CTS, and is administered at single dose. The aim of conducting this study was to compare the efficacy of low-level laser with local steroid injection, for the short-term treatment of idiopathic CTS. We performed a randomized comparative trial, and tried to use objective criteria for baseline and follow-up assessments.

METHODOLOGY

Design and setting

We performed a prospective single blind randomized clinical trial. The study was conducted from May 2010 to October 2010 in an outpatient clinic at the university hospital, Imam Reza, a physical medicine and rehabilitation practice and research center in Tehran. Two groups of participants, steroid injection and laser therapy, were compared before assignment and at four weeks after treatment. Before recruitment, research physicians and nurses had to pass written and practical examinations for certification in their clinical knowledge and skills.

Recruitment

All potential participants were referred by physical medicine and rehabilitation specialists to the research center. A general practitioner obtained demographic data and medical history at the first visit. Patients filled in a standardized questionnaire on possible causes of CTS. The recruitment questionnaire asked about various lifestyle and personal characteristics. Two residents, and then, two board-certified physical medicine and rehabilitation specialists visited the participants and completed a detailed medical history and performed physical examinations and conducted further investigations. Information was entered into a computer database.

Inclusion Criteria

Potential eligible patients with idiopathic carpal tunnel syndrome (ICTS) identified were invited to participate. Briefly, patients aged more than or equal to 18 years were enrolled for the study if they had an episode of ICTS within the last month of visit and if the manifestations were present at the time of enrolment. The inclusion criteria were the clinical diagnosis of ICTS and electrophysiological evidence of median nerve entrapment at the wrist.

Exclusion Criteria

All participants were screened to exclude secondary CTS. We excluded patients with diabetes mellitus, history of trauma or surgery for CTS in the affected hand, joint disorders and connective tissue diseases, kidney or thyroid abnormalities, polyneuropathy, cervical radiculopathy, double crush syndrome, thoracic outlet syndrome, vibration-induced neuropathy or occupational CTS, previous steroid injection for CTS in the same wrist, pregnancy, and presence of CTS therapy in the last 6 months with local injection of steroid or low potent laser. Participants with severe symptoms, two-point discrimination exceeding 8 mm, thenar atrophy or any indication for surgery were referred to a surgeon and excluded from the study. Patients were also excluded if they were willing to undergo surgery, were unable to provide informed consent, or if they could not complete all phases of the study. We did not include patients with involvement of the little finger or with manifestations of possible ulnar neuropathy in the same hand. None of our patients were drug-abusers or alcoholics. Alcoholic or diabetic patients were excluded due to the possibility of neuropathy.

Ethical Considerations

This trial has been registered in Iranian Registry of Clinical Trials (IRCT) web-site http://www.irct.ir/, a WHO Primary Register set up, with registration code: Irct ID: ACTRN12609000701224. The study was conducted in accordance with the Declaration

of Helsinki, and the research protocol was approved by the institutional review board. The trial investigators explained the aims and rationale of the trial to eligible patients at the physical medicine and rehabilitation research center. A study nurse provided patients with information leaflets and verbal information if needed. All participants gave signed written consent at the beginning of the study, and did not pay for the treatment. Patients were informed that they were free to withdraw from the study at any time.

Randomization and Blinding

We considered two treatment groups; steroid injection, and low-level laser. Eligible patients were randomly assigned to the groups at the coordination room of the research center according to a computer-generated randomization list. We performed blocked randomization with different size blocks. The sizes of blocks were unknown to the research staff involved in recruiting patients. The assessors were unaware of the treatment assignments. Different operators checked the accuracy of data entry with double entry. Immediately after the allocation, patients received the assigned treatments.

Interventions

In the steroid group, patients were given a single local corticosteroid injection of hydrocortisone 50 mg (2 ml) into the carpal tunnel via a 25- gauge needle. The wrist was positioned on a firm surface in slight dorsiflexion and the needle was introduced at 30-degree angle to the skin, medial to the palmaris longus. The medication was injected subfascially in the soft tissue of the carpal tunnel. The physician who performed the injections was a resident of physical medicine and rehabilitation. She had received extensive training and passed a practical examination administered by an expert to demonstrate her competence in the procedure.

In the laser group, laser therapy was administered at physiotherapy ward by applying a low potent laser characterized by the amplitude of 775 nm, frequency of 6500 Hz and an intensity of 20 j/cm2, at five points over 11 seconds along the median nerve passage, above the carpal tunnel. Usual safety protocols were followed strictly. A total of 10 laser therapy sessions were performed every other day for 3 week. An attending physical medicine and rehabilitation specialist who was experienced in laser therapy performed the procedure for all participants. Considering that the studies showing non-significant clinical benefits, we used more power for our laser therapy regime.

Patients were asked not to make any lifestyle modifications, for example intense repetitive wrist motions, during the trial and not to use other therapeutic measures.

Outcome Measures

Primary outcome measure was the severity of the disease. Based on the electrophysiological findings, we propose three grades: mild (prolonged sensory distal latency more than 3.6 ms ± sensory nerve action potential [SNAP] amplitude below the lower limit of the normal range), moderate (abnormal median sensory distal latency more than or equal to 3.6 ms, and motor distal latency more than 4.1 ms), and severe (prolonged median motor and sensory distal latencies with either an absent SNAP or low-amplitude, or absent thenar compound muscle action potential [CMAP])[14].

Visual analogue scores (VAS) were used to measure subjective severity of pain. Participants recorded their resting pain perception within last 24 hours by corresponding it to a 100-mm line ranging from 0 (no pain at all) to 10 (the most severe pain that I can imagine).

For nerve conduction studies median sensory nerve action potential was evaluated antidromically by a surface electrode. The electrode was placed on the digit 3, and the distance between the active and reference electrodes were set to 4 cm. The wrist area was stimulated 14 cm from the active electrode. Motor conduction for median nerve was performed using the surface electrodes over the abductor pollicis brevis. The stimulation was done at 8 cm proximal to the active electrode. We used a bandwidth of 20 Hz to 3 KHz (3 to 20 KHz), a sweep speed of 1 millisecond/division, the gain of 10 to 20 μv/cm for sensory conduction study and the gain of 1μv/cm for motor conduction study. The skin temperature of the forearm and wrist were kept between 32-33˚C during all the measurements. All nerve conduction velocities were recorded and analyzed by one physiatrist, who was blinded to the treatment of the participants.

Outcome assessments were performed by blinded study physicians before the randomization code of the trial was broken, and at eight weeks. A study nurse phoned participants every week throughout the first month of the study for checking any possible side effect or providing additional advice. At follow-up visit, we asked the patients whether they had noted an increase in severity or frequency of the symptoms and whether they had had any new symptom.

Burning pain with tingling and numbness in the distribution of median nerve distal to wrist and nocturnal awakening owing to the symptoms were questioned. Also, all patients were assessed for positive physical signs and tests such as Phalen's, Tinel's, and closed fist signs, flexion and extension of wrist, and pressure provocation tests. Katz hand diagram was used to characterize symptoms.

Pinprick sensation in the distribution of median nerve was compared to the ipsilateral little finger.

Statistical Analysis

Data is presented as mean and standard deviation, for continuous variables, and as numbers and proportions for categorical variables. Chi-squared and Fisher's exact tests were used to assess differences in demographic characteristics, and in clinical and electrophysiological findings between the two groups. Within-group analyses were carried out by the use of Wilcoxon test, and between-group comparisons were performed by using Mann–Whitney U test. A p value of less than 0.05 was considered significant. Data were analyzed using a commercially available statistical soft ware package (SPSS for Windows, version 9.0, SPSS, Inc., Chicago, IL, USA).

RESULT

We identified 38 patients (50 CTS-affected hands) who met the eligibility criteria. In our sample, mean age (SD) was 47.4(10) and female to male ration was 5.3. We had 33% participants with bilateral CTS, and right to left involvement was 1.4 to 1. There was no reported or recognizable side effect during the course of the study. Loss to follow-up was not seen among the patients.
Of these patients, 16 (21 hands) were randomized to laser, and 17 (23 hands) to corticosteroid group. All participants were followed for two months (**Figure 1**). Baseline demographic and clinical characteristics of the two groups were similar (**Table 1**). There was no statistically difference between the two groups, except for the median sensory amplitude (p=0.04).

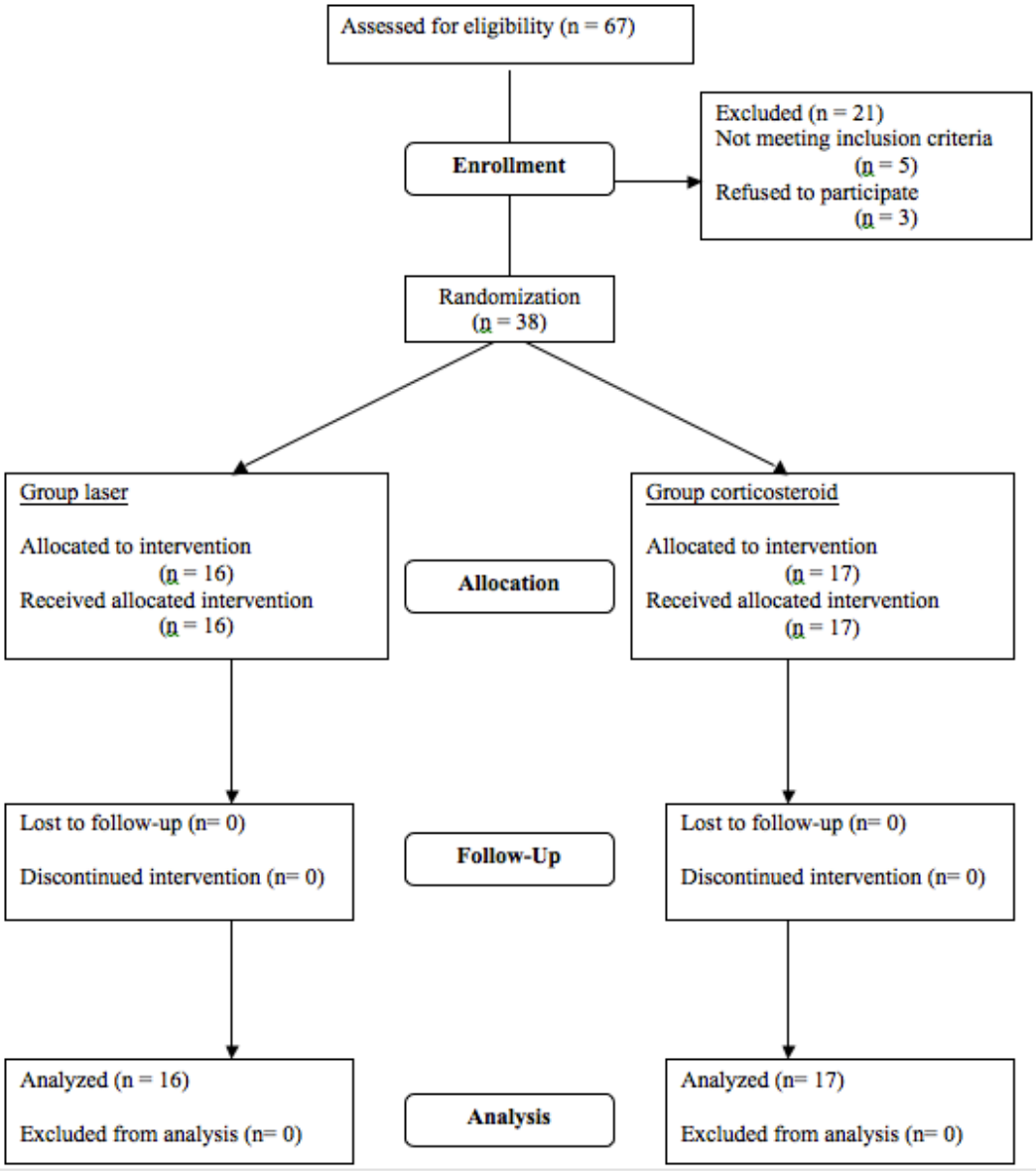

Figure 1 Flow of participants through each stage of the randomized trial

Table 1: Baseline characteristics of laser and corticosteroid groups

	Study Groups		
Characteristics	**Laser**	**Corticosteroid**	**p**
Female to male ratio	6	4.8	p>0.05*
Mean age (SD), (years)	48.2 (10.4)	46.7 (9.8)	p>0.05**
Severity of the symptoms (mild/total) (%)	33.3	26.1	p>0.05*
Mean VAS for the pain	5.8(1.0)	6.0(1.0)	p>0.05**
Mean duration of the pain (months)	8.1(5.5)	8.7(5.4)	p>0.05**
Distal Sensory Latency (millisecond)	4.2(0.4)	4.3(0.3)	p>0.05**
Sensory Amplitude (μv)	17.3(6.4)	20.9(4.3)	0.04**
Distal Motor Latency (millisecond)	4.5(0.7)	4.5(0.7)	p>0.05**
Motor Amplitude (mv)	3.9(0.6)	4.1(0.6)	p>0.05**

**Fishers Exact test; ** Mann-Whitney test; NS: Non-significant*

Within group analyses showed that the outcomes were obviously desirable in both groups (**Table 2**). However, there was no statistically significant difference between the groups in mean VAS for the severity of pain 8 weeks after the treatments (Mann-Whitney test p = 0.45). Also, we did not find statistically significant difference between the groups - corticosteroid injection and laser, regarding median motor distal latency (Mann-Whitney test p = 0.08). In addition, we were unable to find a significant difference between the two groups in term of median sensory distal latency (Mann-Whitney test p = 0.70).

Eight weeks after the treatments, mean (SD) amplitude of median motor action potential was 4.3 (0.7) mv in the corticosteroid group and 4.1(0.7) mv in the laser group. Moreover, mean (SD) amplitude of median sensory nerve action potential was 22.7(4.4) μv for the corticosteroid, and 18.9(6.5) μv for the laser group. Compared to the initial point, motor and sensory amplitudes had not been changed significantly for both groups. Electrophysiologic studies did not imply any significant difference in the severity (Chi-squared test P = 0.28), and change in the grade of the disease between the two groups (**Table 3**).

Table 2: Within group comparisons

Group	**Outcome**	**Result (eight weeks) Mean(SD)**	**Mean difference (baseline vs. eight weeks)**	**P***
Corticosteroid	Severity of the pain (VAS)	2.5(2.0)	-3.5	<0.001
	Median distal motor latency (millisecond)	4.0(0.7)	0.5	<0.001
	Median sensory distal latency (millisecond)	3.8(0.4)	-0.5	<0.001
Laser	Severity of the pain (VAS)	2.0(1.8)	-3.8	<0.001
	Median distal motor latency (millisecond)	4.0(0.7)	0.5	<0.001
	Median sensory distal latency (millisecond)	3.6(0.5)	-0.6	<0.001

**Wilcoxon Rank test*

Table 3: Severity of the disease and grade improvement, 8 weeks after the treatments, based on electrophysiological findings

	Study Groups	
outcome	**Laser**	**Corticosteroid**
Severity of the disease at 8 weeks (%)		
Symptom free	66.7	43.5
Mild	14.3	30.4
Moderate	19.0	26.1
Grade improvement (%)		
No improvement	19.0	37.5
One grade improvement	47.6	33.3
Two grades improvement	33.3	29.2

DISCUSSION

We compared low potent laser with corticosteroid injection for the short-term treatment of CTS. Addressing our research questions, specifically, we tried to use an objective means to evaluate the severity and improvement of the disease. The results showed that by eight weeks, both steroid injection and laser made significant improvement as assessed by median nerve motor and sensory distal latencies, VAS for the severity of pain, and disease severity. However, sensory and motor amplitudes did not show any significant change, irrespective of the initial treatment. Our results are consistent with some previous studies regarding the short-term effects of corticosteroid and laser in the treatment of CTS.

The clinical symptoms of the syndrome depend upon the severity of the disease. In early stages, symptoms are mainly because of involvement of the sensory component of the nerve. Later in the natural history, motor fibers are involved. Burning pain is a common complaint, and usually accompanied with tingling and numbness in the distribution of median nerve distal to wrist. Typically the thumb, index and middle finger, and radial half of the ring finger are involved but the little finger is spared. Patients may experience awakening pain, nocturnal paraesthesia or weakness in the affected hand that is aggravated by activity. Pain radiating to the forearm, elbow or even the shoulder may be seen in some patients[5].

Previous studies have highlighted the potential of corticosteroids to improve the outcome of CTS, at least, in the short-term[15]. In a recent study on the options for nonsurgical management of carpal tunnel syndrome, researchers reported that bracing and corticosteroid injections may be useful in the short term nonsurgical treatment of CTS. They suggested that further studies are needed to evaluate the clinical usefulness of other proposed therapeutic modalities[16].

The fact that laser therapy is effective in the treatment of CTS has been reflected in previous studies, too[17]. Laser has also been used in combination therapy with other treatment modalities[18]. In a recent prospective study, investigators compared splinting with splinting plus low-level laser therapy in the short-term treatment of mild or moderate idiopathic CTS. Forty-five patients who had symptoms over 3 months completed the study. In the group splinting plus laser, 21 participants underwent ten sessions of laser therapy. Both groups were evaluated at the baseline and after 3 months of the treatment. The investigators reported that the patients who had received laser therapy yielded more desirable results on electrophysiological parameters while the other group had only experienced symptomatic relief[19]. Low-level laser therapy has been effectively used for the patients with concomitant CTS and rheumatoid arthritis, too[20]. In a prospective randomized placebo-controlled trial, the efficacy of laser therapy was investigated for the treatment of CTS. A total of 81 patients were randomly assigned into two groups. The laser group (n = 41) received laser therapy (7 joules/2 min) and for the other group (n = 40) placebo laser therapy was performed. All patients had five episodes of therapy per week, for a total of 10 sessions. Statistically significant improvements in VAS, pinch grip, and functional capacity measurement were observed in both groups ($p < 0.001$). Handgrip was reported to have improved in the group laser therapy. Also, statistically significant improvements were seen in sensory nerve velocity, and sensory and motor distal latencies in the laser group ($p < 0.001$). In the placebo group, sensory nerve velocity was the only meaningful outcome measure[21].

Different types of lasers have been successfully used in the treatment of CTS. In a placebo-controlled trial, therapeutic effects of the 830-nm diode laser on CTS were investigated in the short-term. Thirty-six individuals with mild to moderate degree of CTS were randomly assigned into two groups. For one group laser treatment (10 Hz, 50% duty cycle, 60 mW, 9.7 J/cm^2, at 830 nm) was applied, while the placebo group received sham laser therapy. The treatments continued for two weeks consisting of a ten-minute laser therapy session each day; five days a week. The therapeutic effects were evaluated for symptomatic and functional changes immediately after treatment and at two-week follow-ups. The study showed favorable results for low-level laser therapy in decreasing pain and relieving symptoms, and in improving functional ability and finger and hand strength for mild and moderate CTS. In addition, no side effects were reported[22]. In another trial, a total of 80 participants with CTS were randomly assigned into laser (9-11 joules/cm2), and control (sham laser therapy) groups. Following fifteen sessions of therapy (five times per week), the laser group has significantly experienced desirable clinical and electrophysiologic outcomes, while the control group only experienced symptomatic improvement[23]. In a controlled trial of low-level laser therapy, 15 patients with CTS were randomly assigned into control (n = 8) and treatment (n =7) groups. All participants were irradiated three times per week for 5 weeks. The treatment group received 860 nm gallium/aluminum/arsenide laser of 6 J/cm^2, while patients in the control group received sham laser. Within-group analyses showed a significant symptomatic alleviation in both groups. But, the study failed to show any statistical significant difference between the groups. Of course, the small sample size seems to be a limitation of the study[24].

To date, there has been no randomized clinical trial comparing the effectiveness of low-potent laser and corticosteroid injections for the treatment of CTS. Our patients were of various socioeconomic classes with high compliance. We did not have any loss to follow-up or missing data. Our physicians were expert in the related procedures for the diagnosis and treatment of CTS. Owing to the lack of side effects we were not able to compare the two groups with respect to complications of the treatments. We did not have a control group and it was not possible to determine the effects over placebo. In addition, short follow-up period was another limitation of our study, and we could not comment on recurrence rates or long-term results. Further research is needed with larger samples and longer follow-up.

CONCLUSION

Overall, we have good evidence that both corticosteroid and laser are advantageous in the short-term treatment of CTS. Both treatments provide satisfactory pain relief, restoring function, electrophysiological improvement, and are also well tolerated by patients. Steroid injection is partially invasive and painful and should be performed by an expert. However, with laser, frequent treatment sessions are not desirable.

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