



# Comparison of the Efficacy of Carpal Tunnel Release vs. Local Steroid Injection in the Management of Mild to Moderate Carpal Tunnel Syndrome: A Clinical Trial

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## Abstract

**Background:** Although carpal tunnel release (CTR) is accepted in severe cases of carpal tunnel syndrome (CTS), it is not clear if CTR overweighs the local steroid injection (LSI) in the treatment of patients with mild symptoms.

**Objectives:** Here, we compared the efficacy of LSI with CTR on improving signs and symptoms of mild to moderate CTS.

**Methods:** In a randomized clinical trial, we used the Boston carpal tunnel questionnaire (BCTQ) to evaluate the change of functional status scale (FSS) and symptom severity scale (SSS), in addition to the patients' satisfaction, over a follow - up period of 6 months.

**Results:** In total, 68 patients (33 in the LSI and 35 in the CTR group), with the mean age of  $45.8 \pm 8.1$  years and mean BMI of  $30.5 \pm 6.1$  kg/m<sup>2</sup> were included. The baseline clinic - demographic characteristics of the patients were not significantly different between the 2 study groups. Both treatments significantly improved the FSS ( $p = 0.002$  for LSI and  $p = 0.001$  for CTR) and SSS ( $p = 0.001$  for both groups). However, no significant difference was observed between FSS ( $p = 0.36$ ) and SSS ( $p = 0.29$ ) of the 2 groups. Although the patients' satisfaction was also not significantly different between the 2 groups, the number of completely satisfied patients was more in the LSI group.

**Conclusions:** Considering no significant difference between the outcome and satisfaction rate of patients treated with LSI or CTR, it can be concluded that both treatments are efficacious in the treatment of mild to moderate CTS, at least for a period of 6 months. However, the durability of treatments needs further evaluation.

**Keywords:** Carpal Tunnel Syndrome, Carpal Tunnel Release, Local Steroid Injection

## 1. Background

Carpal tunnel syndrome (CTS) is the most common compressive neuropathy of upper extremity. Symptoms include paresthesia, numbness (hypoesthesia), tingling of thumb, index, middle and radial half of ring fingers, and deep pain at the thenar region. In severe cases weakness and atrophy of abductor pollicis muscle and opponens pollicis muscle are evident (1). Several risk factors such as female gender, age of 30 - 60 years, obesity, and others have been reported for CTS (2-5). Although underlying medical condition is not detectable in many patients, conditions such as tumor, infection, and distal radius fracture can cause CTS through putting an excess pressure on the wrist and on the median nerve (6). Sleep disturbance due to paresthesia is the main diagnostic clue for CTS (7).

Both conservative and surgical treatments are currently used for the management of CTS. Conservative op-

tions for CTS treatment include splinting, nonsteroidal anti-inflammatory drugs (NSAIDs), local steroid injection (LSI), and systemic steroids. Surgical treatment of CTS includes surgical decompression through carpal tunnel release (CTR), which is usually applied for patients with progressive and persistent signs and symptoms, especially the thenar atrophy (8).

Although CTR and LSI have been widely used in the treatment for CTS, there is no clear consensus regarding their effectiveness in the treatment of mild to moderate CTS as well as if one of these methods overweighs the other one in terms of patients' outcome and satisfaction.

## 2. Objectives

Here, we designed a randomized clinical trial (RCT) to compare the clinical effects of LSI with CTR surgery on im-

proving signs and symptoms of CTS, beside patients' satisfaction, over a follow - up period of 6 months.

### 3. Methods

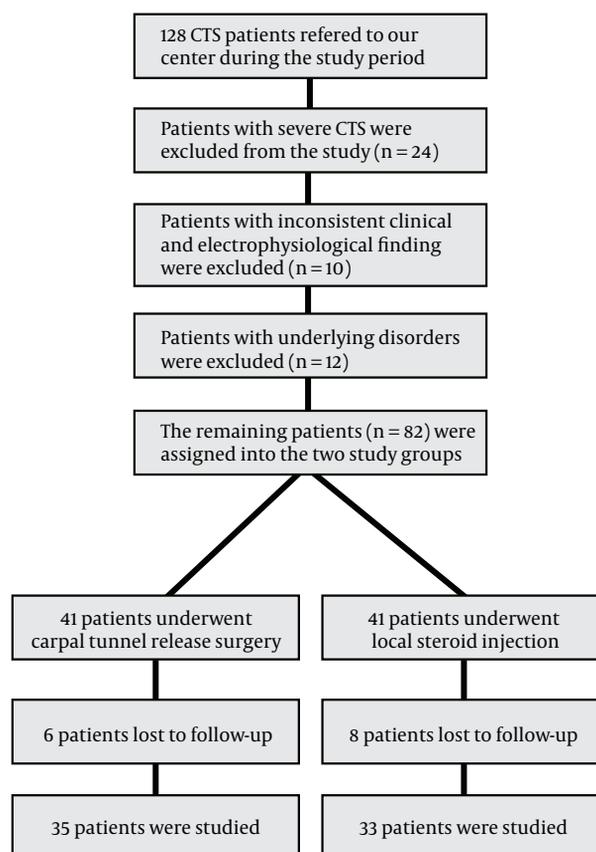
All patients with the diagnosis of mild to moderate CTS, admitted at the Shafa orthopedic hospital (Tehran, Iran), from February 2005 to April 2008, were randomly assigned into the study groups. A CTS diagnosis was made through the evaluation of patients' history of the symptoms, confirmed by its signs such as Tinel, Phalen, and Durkan compression (9). CTS severity was determined by the electrophysiological study all performed at 1 center (Shafa hospital electrophysiological study center). In this respect, nerve conduction velocity (NCV) were graded according to the previously introduced neurophysiological grading with a spectrum of grades from 0 to 6, showing normal, very mild, mild, moderate, severe, very severe, and extremely severe, respectively (10).

Those patients in whom electrophysiological findings were not in accordance with clinical findings were excluded from our study. All patients with severe CTS were excluded from the study as well. Moreover, patients with underlying diseases such as double crush syndrome, rheumatoid arthritis, diabetes mellitus, and thyroid disorders were excluded from the study.

At admission and 6 months after the treatment, the outcome was assessed by the Boston Carpal Tunnel Questionnaire (BCTQ), which consisted of the symptoms severity scale (SSS) with 11 questions and functional status scale (FSS) with 8 questions. Each question contained a scale of 1 - 5 points, in which 1 indicates no symptoms and 5 indicates severe symptoms (11). Patients' satisfaction was evaluated with a five - point scale (from 0 to 5) indicating completely satisfied, almost satisfied, moderately satisfied, somewhat satisfied, and dissatisfied, respectively.

In total, 128 CTS patients were referred to our center during the study period. In 24 patients, severe CTS was noticed. These patients were excluded from the study. In 10 patients electrophysiological findings were not in accordance with the clinical findings. These patients were removed from the study as well. Underlying disorders led to the exclusion of 12 patients. The remaining 82 patients were randomly assigned into 2 study groups, 41 patients each (Figure 1). Predesigned blocks were used for randomization purposes. A computer-generated random number list was used for random allocation of the patients. Group assignment remained concealed from investigators during the course of data gathering. In total, 14 patients missed the final evaluation session (8 in steroid injection and 6 in CTR group). The final evaluation was performed

for the remaining 68 patients (33 in steroid injection and 35 in CTR group).



**Figure 1.** The flow diagram of the inclusion and exclusion of carpal tunnel syndrome (CTS) patients.

This RCT has been recorded in the Iranian clinical registry center under the code number of IRCT 20170.183246 N1. Moreover, it was approved by the ethical committee of Iran University of Medical Sciences, and written consent was obtained from each patient before inclusion in the study.

#### 3.1. Technique

Steroid injection and CTR were done by a fellowship trained hand surgeon. For LSI group, a dose of 40 mg/mL of Triamcinolone Acetonide was injected into the carpal tunnel at the volar aspect of the wrist, just ulnar to the palmaris longus tendon, with a syringe making an angle of 60° to the horizon, and entering 10 mm into the transverse carpal ligament depth. If the patient felt paresthesia in the hand during the procedure, the process was halted and repeated again from the first step.

Carpal tunnel releases were done according to Green's classic approach (1). Accordingly, a curvilinear incision of about 3 cm was made 6 mm ulnar to thenar crease in line with 4<sup>th</sup> finger longitudinal axis. Then, 2 cm of antebrachial fascia, transverse carpal ligament, and palmar fascia between the thenar and hypothenar muscles were incised. Carpal tunnel was examined for possible abnormalities like ganglion cyst. Median nerve external neurolysis only performed when median nerve was adherent to radial leaf of the transverse carpal ligament. Short arm splints were applied for 2 weeks after the operation.

### 3.2. Statistical Analysis

Data were analyzed using IBM SPSS for Windows version 16. Descriptive statistics were presented as frequencies (%), means  $\pm$  standard deviation (SD), or medians with ranges as appropriate. Comparison of pre - and post - operative scores within each group were performed using paired t - test for parametric variables or Wilcoxon signed ranks test for nonparametric variables. Change of the scores across the 2 treatment groups were investigated with independent samples t - test for parametric variables or Mann - Whitney U test for nonparametric variables. Chi - square test was used for the comparison of categorical variables. A P-value of less than 0.05 was considered significant.

## 4. Results

The outcome of 68 patients with mild to moderate CTS, from those, 33 underwent steroid injection and 35 were treated surgically, were evaluated in this study. The study population consisted of 12 males and 56 females with the mean age of  $45.8 \pm 8.1$  years. The mean body mass index (BMI) of the patients was  $30.5 \pm 6.1$  kg/m<sup>2</sup>. The clinical and demographic characteristics of the 2 study groups have been demonstrated and compared in [Table 1](#).

In the LSI group, mean SSS changed from  $2.27 \pm 0.6$  at baseline to  $1.58 \pm 0.4$  at final evaluation (6 weeks after the treatment) ( $p = 0.001$ ). Mean FSS changed from  $1.5 \pm 0.47$  at baseline to  $1.29 \pm 0.31$  at final evaluation ( $p = 0.002$ ). Median patient satisfaction score was 5 (ranged 2 - 5).

In the CTR group, mean SSS changed from  $2.32 \pm 0.8$  at baseline to  $1.6 \pm 0.5$  at final evaluation (6 weeks after the treatment) ( $p = 0.001$ ). Mean FSS changed from  $1.62 \pm 0.55$  at baseline to  $1.39 \pm 0.48$  at final evaluation ( $p = 0.001$ ). Median patient satisfaction score was 5 (ranged 2 - 5).

SSS and FSS change was not significantly different between the 2 study groups ( $p = 0.29$  and  $p = 0.36$ , respectively). A number of 24 patients in the LSI group and 21 patients in the CTS group were completely satisfied with the

results of therapy. However, this difference of patient satisfaction between the 2 study groups was not statistically significant ( $p = 0.3$ ).

## 5. Discussion

In spite of the high incidence of CTS, there is no universally accepted procedure for its treatment. Although surgical treatment is generally accepted in severe cases, it is not clear if surgical treatment outweighs the non - surgical approaches such as steroid injection in the treatment of CTS patients with mild to moderate symptoms (12).

Here we designed an RCT to compare the outcome of CTR vs. LSI in CTS patients with mild to moderate symptoms. According to our results, both treatments significantly improved the symptoms at a follow-up period of 6 months. No significant difference was observed between the 2 groups in terms of functional status, symptom severity, and the patients' satisfaction. Even so, the number of patients with complete satisfaction was more in the LSI group.

Hui et al. assessed the efficacy of surgery vs. steroid injection in relieving CTS symptoms in a clinical trial study composed of 50 patients, 25 patients for each group. Over a follow - up period of 20 weeks, their results showed a better symptomatic and neurophysiologic outcome in patients of the CTR group (13).

Ly - Pen et al., in a randomized clinical trial, compared the efficacy of surgical decompression vs. LSI in 163 patients with clinical diagnosis and neurophysiological confirmation of CTS, over a follow - up period of 2 years. Based on their results, both LSI and CTR were effective in alleviating symptoms of CTS. However, surgery had an additional benefit (14).

While we observed no significant difference between the outcome of LSI and CTR in the management of CTS, other investigations showed the priority of surgical decompression. The present inconsistency could be associated with the difference in the follow - up period of the studies, which has also been pointed out in earlier investigations.

Demirci et al. compared the efficacy of LSI and open CTR in 90 CTS patients. Although both groups showed significant improvement at 3 and 6 months follow - ups, by the end of follow - up, 5% of the hands in CTR group and 13% of the hands in the LSI group showed electrophysiological worsening. Moreover, 5% of the hands in the CTR group and 22% of the hands in the LSI group showed symptomatic worsening. They concluded that although steroid injection provides an improvement comparable with surgical decompression, this improvement is not long-lasting (15).

**Table 1.** Comparison of Clinical and Demographic Characteristics of the Patients<sup>a,b</sup>

Variable	Steroid Injection Group (N = 33)	CTR Surgery Group (N = 35)	P Value
Age (years)	45.4 ± 8.4	46.2 ± 7.8	0.63
<b>Gender</b>			
Male	6 (18)	6 (17)	0.51
Female	27 (82)	29 (83)	
BMI (kg/m <sup>2</sup> )	30.2 ± 6.2	30.7 ± 5.8	0.47
<b>Preoperative Signs</b>			
Tingling	33 (100%)	33 (94%)	0.11
Finger numbness	31 (94%)	32 (91%)	
Tinnel	23 (70%)	25 (71%)	
Phallen	28 (85%)	32 (91%)	
Compression Test	33 (100%)	32 (91%)	
Pain	18 (55%)	25 (71%)	
Weakness	9 (27%)	21 (60%)	
Mean SSS change	0.69	0.72	0.29
Mean FSS change	0.21	0.23	0.36
Median patient satisfaction score	5	5	0.3

Abbreviations: CTR, Carpal Tunnel Release; FSS: Functional Status Scale; SSS, Symptom Severity Scale.

<sup>a</sup>Data are shown as mean ± SD or number (%).

<sup>b</sup>A P - value of < 0.05 is considered significant.

The study of Ismatullah, in a short series of 40 patients, also showed that steroid injection only provides transient relief in CTS, whereas CTR operation results in long-lasting alleviation (16).

Shi et al., compared the efficacy of surgical treatment of CTS with conservative treatment in a systematic review. They found that while the positive impact of conservative management plateaus within 3 months, surgical intervention has a superior benefit in both symptoms and function at 6 and 12 months after the treatment. They also found that the patients who underwent CTR surgery were 2 times more likely to have normal nerve conduction studies. Even so, the complication and side effects of CTR were more considerable as well. Altogether, they concluded that since conservative management is effective in relieving symptoms in a certain proportion of cases and can avoid the complications of the surgery, it remains a justified first line treatment (8).

Based on the results of earlier investigations, it seems that longer follow-up of the patients or multi - steps evaluation of outcome would further clarify the potential of each treatment in the management of CTS. Consequently, short - term and single - step follow-up of the patients could be considered as the biggest limitations of our study.

Our study showed no significant difference was observed between the outcome of CTS patients following the LSI or CTR. However, at a mean follow - up period of 6 months, the number of patients with complete satisfaction was more in the LSI group. Despite this privilege, longer follow - up period of patients is needed to determine the durability of each treatment.

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