Original Article

Effectiveness of splinting and splinting plus local steroid injection in severe carpal tunnel syndrome: A Randomized control clinical trial

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Abstract

Background: The Study aimed to compare the effectiveness of two commonly used conservative treatments, splinting and local steroid injection in improving clinical and nerve conduction findings of the patients with severe carpal tunnel syndrome (CTS).

Materials and Methods: In this randomized control clinical trial, the patients with severe CTS selected and randomized in two interventional groups. Group A was prescribed to use full time neutral wrist splint and group B was injected with 40 mg Depo-Medrol and prescribed to use the full time neutral wrist splint for 12 weeks. Clinical and nerve conduction findings of the patients was evaluated at baseline, 4 and 12 weeks after interventions.

Results: Twenty-two and 21 patients were allocated in group A and B, respectively. Mean of clinical symptoms and functional status scores, nerve conduction variables and patients' satisfaction score were not significant between group at baseline and 4 and 12 weeks after intervention. Within the group comparison, there was significant improvement in the patients' satisfaction, clinical and nerve conduction items between the baseline level and 4 weeks after intervention and between the baseline and 12 weeks after intervention ($P < 0.01$). The difference was significant for functional status score between 4 and 12 weeks after intervention in group B ($P = 0.02$).

Conclusion: considering some findings regarding the superior effect of splinting plus local steroid injection on functional status scale and median nerve distal motor latency, it seems that using combination therapy could be more effective for long-term period specially in the field of functional improvement of CTS.

Key Words: Carpal tunnel syndrome, splint, steroid

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INTRODUCTION

Carpal tunnel syndrome (CTS) which is defined as "a symptomatic compression neuropathy of the median nerve at the level of the wrist" is considered as the most common disabling neuromascular condition of the upper extremities.[1,2] With an incidence rate of 276:100000 per year, it is known as the most prevalent

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entrapment neuropathy, accounting for 90% of all neuropathies.[3,4]

The overall prevalence rate of CTS has been reported to be 3.8% in general population and 1% for its moderate and severe forms.[5,6]

The pathophysiology of the syndrome and the mechanisms involved in the median nerve traction and compression has been investigated in several studies, but it has not clearly understood yet. It is suggested that both medical and nonmedical factors could have a role in this regard.[7]

Different treatment approaches including both surgical and various nonsurgical methods have been introduced for the patients with CTS. Though carpal tunnel release using surgical method have shown to provide an appropriate outcome for the disease specially regarding the relief of CTS related symptoms, but there are some concerns regarding the complications of surgery and direct and indirect costs of it both for the patients and the society, which limits the acceptance and implication of surgical method. Therefore, the use of nonsurgical methods has been highly regarded by patients.[8-10]

Several nonsurgical treatment methods have been introduced and their utility and effectiveness have been evaluated. Nonsurgical or conservative treatments include a wide range of options such as exercise, activity modification, splinting, oral medications (nonsteroidal anti-inflammatory drugs and corticosteroids), locally injected steroids, diuretics, lidocaine patches, ultrasound therapy, and acupuncture.[11-13] Evidences from different review studies in this field indicated that splinting and steroids (oral or locally injected) are most commonly used treatments that could have a more appropriate impact on the symptoms of CTS, although their effectiveness are not for long-term periods.[10]

However, there is not a definite conclusion for using one of the introduced nonsurgical options for better management of CTS mainly due to the heterogenicity of dosing regimens and lack of interventional trials with sufficient long-term follow-up.[12] Thus, we aimed to compare the effectiveness of two commonly used conservative treatments, splinting, and local steroid injection in improving the clinical and nerve conduction findings of the patients with severe CTS in Isfahan, Iran.

MATERIALS AND METHODS

In this randomized control clinical trial, the patients with severe CTS aged ≥18 years, referred to the outpatient clinics affiliated to Isfahan University of Medical Sciences were enrolled from September 2013 to March 2015.

The protocol of the study was approved by the regional ethics committee of Isfahan University of Medical Sciences (research project number: 392162). The IRCT number of the trial is IRCT2015050622130N1.

Diagnosis of severe CTS was based on the clinical signs and symptoms of CTS including pain, paresthesia, hypoesthesia, numbness, tingling, positive Tinel test (at least 2 symptoms or 1 sign plus 1 symptom) and electrodiagnostic evidence of severe CTS (severe: Median nerve distal sensory latency [MNDSL] >3.6 ms and median nerve distal motor latency [MNDML] >4.2 ms with an absent sensory nerve action potential amplitude [SNAP], or absent thenar compound muscle action potential [CMAP] or decreased thenar CMAP height).[14]

Patients with severe CTS who have thenar muscle atrophy and patients with a history of inflammatory arthritis, hypothyroidism, diabetes, coexisting serious illness, malignancy, distal radius fracture, fibromyalgia, CTS related to systemic diseases and pregnancy, cervical disc herniation, previous wrist trauma, and history of steroid injection, splint or operation of the carpal tunnel were excluded.

The patients were selected by the simple random sampling method.

Written informed consent was obtained from each selected participant.

Selected patients with CTS were randomly allocated in two intervention groups using random allocation software. One group of patients (group A) was prescribed to use full time (24 h) neutral wrist splint for a 12 weeks period. Group B was injected with 40 mg Depo-Medrol (Pefizer-Belgium) (1 cc) and prescribed to use the full time neutral wrist splint during the study period for 12 weeks.

Baseline characteristics of the studying population were recorded using a standard questionnaire. Clinical condition of each patient was evaluated at baseline, after 4 weeks intervention and after 12 weeks intervention. In addition, the patients' satisfaction was evaluated at baseline and 4 and 12 weeks after interventions in participants of each group.

For the clinical evaluation, Persian version of the Boston Carpal Tunnel Questionnaire (BCTQ),

was used for assessment of symptom severity and functional disability. The validity and reliability and internal consistency of the questionnaire have been evaluated previously.[15] BCTQ symptom severity scale (SSS) and functional status scale (FSS) has 11 and 8 questions respectively. Each of the questions uses a 5 point scale. Higher scores represented more severe symptoms and functional impairment. The BCTQ SSS and FSS calculated as a mean of the scores for each participant. The clinical evaluation was done by a physical medicine and rehabilitation specialist (Amir Ebrahim Mahmoodian).

The patients satisfaction was evaluated using the Likert scale with five options of 1–5 (completely satisfied, almost satisfied, moderately satisfied, somewhat satisfied, and dissatisfied). Lower scores represented more satisfaction.

The questionnaire was completed by the patients. Trained personnel of the clinic explained about the questionnaire.

A nerve conduction study was done for each patient at baseline and 12 weeks after intervention. Nerve conduction study was performed using Medelec Synergy (UK) electromyograph by an expert electro-myographer who was blinded to random assignment (Masoud Emadi). All the reports were checked by two physical medicine and rehabilitation specialists (Masoud Emadi and Saeid Khosrawi). Studied electrophysiological parameters were as follows; MNDML, MNDSL, median nerve, sensory and motor nerve conduction velocity (MSNV and MMNV), CMAP and SNAP. The details of the method has been described previously.[13]

Interventions

Steroid injection

For steroid injection a 25G needle was inserted to the wrist-flexion crease, just ulnar to the palmaris longus tendon. The needle was introduced slowly with a 30° angle. If the patients complain of pain, sensation of pins and needle in the median nerve distribution, the injection was stopped. The injection was performed by a physical medicine and rehabilitation specialist (Amir Ebrahim Mahmoodian).

Splinting

A wrist splint (cock-up) immobilized the wrist by neutralize flexion and extension of the wrist to decrease the carpal tunnel pressure. The splint was prescribed for full time (24 h) use. The splint was performed by a physical medicine and rehabilitation specialist (Amir Ebrahim Mahmoodian).

Statistical analysis

Data were processed by SPSS statistical software program version 20 (SPSS Inc., Chicago, IL, USA). Continuous variables were presented as mean ± standard deviation (SD). Characteristics of studied groups were compared using *t*-test. Studied variables at baseline and 4 and 12 weeks after interventions in the studied groups were compared using the Wilcoxon signed rank test. Differences between the groups were investigated using the Mann–Whitney U-test. P value < 0.05 was considered statistically significant.

RESULTS

During this trial, 56 patients fulfilled the inclusion criteria and were enrolled in the study. Thirteen patients were excluded and 22 and 21 patients were allocated in group A and B, respectively [Figure 1].

Characteristics of studied population in group A and B are presented in Table 1. Two studied groups were age and sex matched ($P > 0.05$).

Mean of studied clinical variables at baseline and 4 and 12 weeks after interventions in studied groups are presented in Figure 2. Mean ± SD of studied nerve conduction studies at baseline and 12 weeks after the interventions in group A and group B are

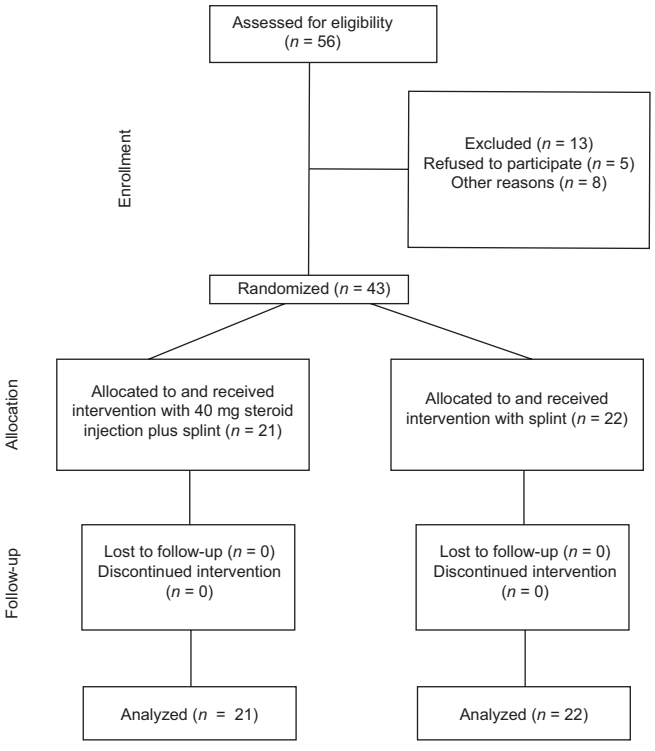

Figure 1: Consort diagram of the study

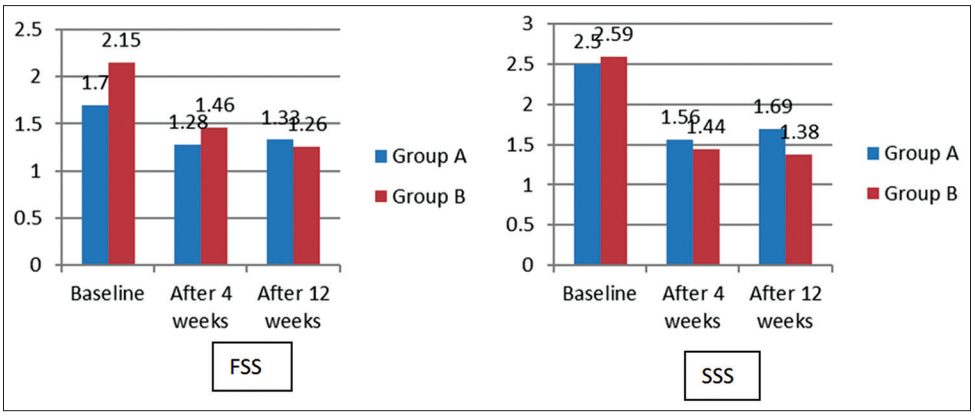

Figure 2: Mean of studied clinical variables, symptom severity scale and functional status scale, at baseline and 4 and 12 weeks after interventions in group A (splint) and group B (splint + steroid) ($P < 0.001$ due to the significant differences between baseline and 4 weeks after intervention and baseline and 12 weeks after intervention) (not significant between 4 and 12 weeks after intervention). FSS: Functional status scale, SSS: Symptom severity scale

presented in Table 2. Mean of studied variables were not significantly different between group A and B at baseline and 4 and 12 weeks after intervention. Within the group comparison, there was a significant improvement in both clinical and nerve conduction items between baseline level and 4 weeks after intervention and between baseline and 12 weeks after intervention ($P < 0.01$) for group A and B. There was not the significant difference between studied variables at 4 weeks after intervention and at 12 weeks after intervention ($P > 0.05$). The difference was significant for FSS between 4 weeks after intervention and last follow-up in group B ($P = 0.02$).

Mean differences (after 12 weeks – baseline) of studied variables was significantly different for FSS and MNDML between groups A and B ($P < 0.01$).

Mean difference of FSS at baseline and 12 weeks after study was significantly higher in group B than group A (−0.88 in group B vs. −0.36 in group A, $P = 0.005$).

Mean difference of MNDML at baseline and 12 weeks after study was significantly higher in group B than group A (−1.67 in group B vs. −0.72 in group A, $P = 0.002$).

Frequency of patients satisfaction scores at baseline, 4 and 12 weeks after interventions are presented in Table 3. Comparison of patients satisfaction between group A and B was not significant at baseline, 4 weeks after intervention and 12 weeks after intervention. Within group comparison (at baseline, 4 weeks after intervention and 12 weeks after intervention) in each group indicated that the level of satisfaction improved significantly in two studied groups. The within group

Table 1: Baseline characteristics of studied population in group A (splint) and group B (splint + steroid)

Baseline characteristics	Group A (*n*=22)	Group B (*n*=21)	*P*
Age (years)	50.91±10.41	51.86±11.86	0.78
Sex (female/male)	18/4	19/2	0.35
Duration of CTS (months)	25.41±19.52	18.29±18.43	0.22
Height (cm)	160.0±7.94	160.29±6.50	0.89
Weight (kg)	70.41±7.63	69.81±8.08	0.80
BMI (kg/m^2)	27.54±2.72	27.17±2.86	0.66

BMI: Body mass index, CTS: Carpal tunnel syndrome

Table 2: Mean±SD of nerve conduction studies at baseline and 12 weeks after interventions and mean differences (after - before intervention) in group A (splint) and group B (splint + steroid)

Variables	Baseline	After 12 weeks	*P*	Mean differences	*P*
MNDML					
Group A (*n*=22)	5.76±0.69	5.04±0.49	<0.001	−0.72±0.14	0.002
Group B (*n*=21)	6.55±1.80	4.88±1.11	<0.001	−1.67±0.26	
CMAP					
Group A (*n*=22)	4.58±1.93	6.63±1.64	<0.001	2.05±0.48	0.42
Group B (*n*=21)	5.10±2.49	6.58±1.77	0.01	1.48±0.52	
MMNV					
Group A (*n*=22)	56.21±6.87	56.25±6.98	0.78	0.04±0.15	0.92
Group B (*n*=21)	54.33±4.59	54.39±4.46	0.57	0.05±0.1	
MNDSL					
Group A (*n*=22)	6.86±1.65	5.14±1.28	<0.001	−1.72±0.43	0.39
Group B (*n*=21)	7.19±1.97	4.95±1.47	<0.001	−2.24±0.41	
SNAP					
Group A (*n*=22)	7.30±6.97	12.67±7.62	0.01	5.37±1.96	0.1
Group B (*n*=21)	4.58±6.20	14.70±8.83	<0.001	10.12±2.08	
MSNV					
Group A (*n*=22)	17.26±7.19	26.30±7.11	<0.001	9.04±1.92	0.47
Group B (*n*=21)	15.38±7.10	26.36±8.10	<0.001	10.98±1.84	

MNDML: Median nerve distal motor latency, CMAP: Compound muscle action potential, MMNV: Median motor nerve velocity, MNDSL: Median nerve distal sensory latency, SNAP: Sensory nerve action potential amplitude, MSNV: Median sensory nerve velocity, SD: Standard deviation

Table 3: Frequency (*n* (%)) of patients satisfaction scores at baseline, 4 and 12 weeks after interventions

Patients satisfaction scores	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)	*P**
At baseline						
Group A	0 (0)	2 (9.1)	7 (31.8)	4 (18.2)	9 (40.9)	0.34
Group B	0 (0)	0 (0)	4 (19.0)	8 (38.1)	9 (42.9)	
After 4 weeks						
Group A	3 (13.6)	6 (27.3)	12 (54.5)	0 (0)	1 (4.5)	0.44
Group B	4 (19.0)	8 (38.1)	7 (33.3)	1 (4.8)	1 (4.8)	
After 12 weeks						
Group A	6 (27.3)	8 (36.4)	2 (9.1)	3 (13.6)	3 (13.6)	0.38
Group B	7 (33.3)	8 (38.1)	5 (23.8)	0 (0)	1 (4.8)	

**P* value between group A and B

significance was due to its significant difference between baseline and 4 weeks after intervention ($P < 0.001$ for both groups) and baseline and 12 weeks after intervention ($P < 0.001$ for both groups). The Patients satisfaction was not significantly different between 4 weeks and 12 weeks after intervention periods (0.86 for group A and 0.07 for group B).

During the study, we did not find any complication related to the procedures.

DISCUSSION

In this intervention study the effectiveness of splinting versus splinting plus local steroid injection on clinical symptoms and functional status of patients with severe CTS as well as the electromyographic characteristics of the patients was investigated. The results indicated that both methods have significant effects on clinical symptoms, functional status, and nerve conduction status of the studying patients. It seems that combination therapy has more significant impact on FSS and MNDML specially during the follow-up periods.

Reviewing currently available studies in the field of CTS management indicated that splinting and corticosteroids are the most commonly utilized conservative treatment options with appropriate outcome.[16,17] Moreover, the results of the European HANDGUIDE Study showed that multidisciplinary treatment considered as the most effective and efficient treatment option for CTS. According to their recommendation, corticosteroid injections plus splinting is one of the suitable treatments for CTS.[18]

In this study, we evaluated the effectiveness of splinting and corticosteroid injections plus splinting on different aspects of the CTS management procedure.

In this study, we used the neutral splint which is considered as the commonly splinting method.[19] There are different splinting methods such as volar wrist cock-up, soft hand splints, and modified ulnar gutter splints, but evidences demonstrated that they could not have the efficacy of neutral splint specially for long-term treatment.[20] However soft hand splinting recommended as an alternative to neutral splinting.[20]

A Cochrane review study have reviewed studies which evaluated the effectiveness of splinting for CTS treatment by comparing it with no treatment, placebo and other conservative treatment options. They concluded that splinting could not be effective enough for short-term treatment, but it has a superior effect than other nonsurgical interventions.[21]

In another Cochrane study the effectiveness of local corticosteroid injection for CTS versus placebo or other nonsurgical interventions have been reviewed.[22] Local corticosteroid injection is another nonsurgical treatment option which is commonly used for this group of patients.

Reviewing literature indicated that though there were studies which compared splinting versus local steroid injection for treatment of CTS, but there were a few studies which comparing their combination use. In addition, there were few studies of patients with severe form of the disease.

Graham *et al*., in a prospective study have compared the outcome of steroid injections with splinting for the treatment of CTS. They reported similar effects for both methods and they showed that the combination of the two methods have not more significant effect.[23]

Sevim *et al*. have evaluated the long-term efficacy of local corticosteroid injection and splint wearing in 60 patients. They indicated that the long-term effectiveness of splint is more significant than corticosteroid. But, both methods have improving effect on symptom relief and electrophysiologic findings.[24]

The current study was similar to the study of Ucan *et al*. in Turkey.[25] They compared the outcomes of splinting versus splinting plus local steroid injection in the patients with CTS. Our findings were similar to their results. In our study, both methods have improving effect on clinical and electrophysiological characteristics of the patients with CTS.

In our study, SSS and FSS improved in both interventional groups during follow-up, but the scores were not significantly different in the two groups at baseline and after 12 weeks. Our results were similar to the reported results of Ucan *et al*.[25] Mean

differences of FSS was significantly higher in group B than group A.

In this study, nerve conduction variables including, MNDML, CMAP, MNDSL, SNAP, and MSNV had significant improvement after interventions in two studied groups. The differences were not significant between groups at baseline and after 12 weeks. Our findings were similar to the results of Ucan *et al*.[25] Mean differnces of MNDML was significantly higher in group B than group A.

Considering some of our findings regarding FSS, MNDML and patients satisfaction, it is suggested that the combination therapy would have more proper results. However for obtaining more conclusive results, studies with larger sample size is recommended. In addition, evaluation of different doses of injected corticosteroids or longer duration of using splint would be more helpful in this regard.

There were reports regarding the better improvement for longer use of splint (6 weeks or more).[26]

In our study, we did not find any significant difference for MMNV in two studied groups. Our results were similar to the results of Ucan *et al*.[25]

Some studies indicated that corticosteroids use could have significant improvement in the clinical symptoms of CTS.[27,28] Lee and colleagues have demonstrated that different doses of local steroid injection are effective for improving the clinical scales of CTS but they have limited effect on nerve conduction status of the patients with moderate to severe CTS.[27]

The strength of current study was that there was not any similar study, which compares the effectiveness of two conservative treatment methods in severe CTS. The limitation of our study was the small sample size of the participants, shorter duration of intervention as well as follow-up period.

In sum, the findings of this interventional trial indicated that though splinting versus splinting plus local steroid injection have similar effect on the clinical improvement of CTS symptoms and function and nerve conduction activity in accordance with proper patients satisfaction, but considering some findings regarding superior effect of splinting plus local steroid injection on FSS and MNDML, it seems that using combination therapy could be more effective for long-term period specially in the field of functional improvement of CTS. However further studies with larger sample size and longer duration of follow-up is recommended.

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Conflicts of interest
There are no conflicts of interest.

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