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CLINICAL STUDY

The comparison of ultrasound treatment and local steroid injection plus splinting in the carpal tunnel syndrome: a randomized controlled trial

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Abstract: *Objectives:* This study aimed to compare the efficacy of ultrasound treatment to local corticosteroid injection plus splinting in carpal tunnel syndrome (CTS). There is still limited knowledge on the efficacy of conservative treatment options for CTS.
Methods: Fourty-nine hands of 34 patients with CTS were enrolled in this study. Patients were randomly assigned to the ultrasound treatment (group A) or local corticosteroid injection plus splinting (group B). The primary outcome measures included clinical parameters such as symptoms severity score, visual analogue scale (VAS) pain, functional status score, grip strength and two-point discrimination. The secondary outcome measures were the electrophysiological tests. The examinations were performed at baseline, and then at 4th and 8th weeks.
Results: At the end of the study, a statistically significant improvement was obtained in all clinical parameters in the group B: VAS pain, severity of symptoms, functional status, grip strength ($p<0.001$ for each) and two-point discrimination ($p<0.016$). Also the group A showed significant improvements in all clinical parameters ($p<0.001$ for each), except for the grip strength. Additionally, significant improvements in the median nerve sensory conduction velocity and distal motor latency were also found in both groups at the end of the 8 week follow-up period. There was no significant difference between the groups in the primary and secondary outcome measures, except for the grip strength.
Conclusions: Both ultrasound treatment and corticosteroid injection plus splinting were effective on the clinical symptoms and the electrophysiological findings of CTS. Thus, the ultrasound therapy may be an alternative treatment for CTS, particularly in patient who do not accept injection or splinting *(Tab. 3, Fig. 2, Ref. 36).* Full Text in free PDF *www.bmj.sk.*
Key words: carpal tunnel syndrome, splinting, corticosteroid injection, ultrasound treatment.

The carpal tunnel syndrome (CTS) is the most common compressive neuropathy of the upper extremity. Any condition that reduces the size of the carpal tunnel or increases the volume of its content will cause a compression of the median nerve (1–3). The estimated prevalence of clinically and electrophysiologically confirmed CTS in the general population is 2.7 % (4–6). The symptoms of CTS are paresthesia or pain in the wrist, hand and fingers, often occurring during sleep (2, 7–9).

Although clinical guidelines have been suggested, there is no universally accepted therapy for CTS (7). A non-surgical treatment of CTS is frequently offered to those with mild to moderate symptoms. Conservative treatment options include splinting the wrist in a neutral position, local injection of corticosteroids, and ultrasound therapy (4, 8, 10–13). Injection of local steroid into the carpal tunnel, either alone or perhaps in combination with splinting, may be a helpful conservative treatment option for a rapid symptomatic improvement. If symptoms are refractory to conservative treatment or nerve conduction studies show a severe entrapment, open or endoscopic carpal tunnel release may be necessary (4, 7).

Several studies have demonstrated that splinting and local injection of corticosteroids are effective on the clinical symptoms and the electrophysiological findings of CTS (4, 7, 10–13). But, there is still limited knowledge on the efficacy of the most conservative treatment options for CTS. The ultrasound therapy may have the potential to induce biophysical effects within the nerve tissue. Ultrasound is assumed to have thermal effects on the target tissue resulting in an increase in blood flow, local metabolism and tissue regeneration, and also reducing inflammation, edema and pain (8, 14, 15). But there is limited evidence in literature on the effectiveness of ultrasound treatment for CTS (4). It is necessary to compare ultrasound treatment with the standard conservative treatment options.

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The aim of this study was to compare the efficacy of the ultrasound treatment to the local corticosteroid injection plus splinting on symptoms and electrophysiological findings in the carpal tunnel syndrome.

Methods

Patients enrolled in this study had clinical symptoms and signs of CTS confirmed by standard electrodiagnosis, with no abnormalities in the radial and ulnar nerve. Patients with either thenar atrophy or spontaneous activity (fibrillation potentials and positive sharp waves) on electromyographic examination of the abductor pollicis brevis muscle were excluded from the study. Pregnant female patients, and those with previous wrist trauma and a history of steroid injection into the carpal tunnel, rheumatic diseases, cervical radiculopathy, diabetes or other pathologic conditions predisposing to peripheral neuropathies were also excluded.

Thirty-four patients (49 hands) were enrolled in this study. Written informed consent was obtained from each patient before enrollment into study. The randomization was performed by using sequentially numbered and sealed opaque envelopes. Following the baseline assessment, patients were randomized to either ultrasound treatment (group A) or local corticosteroid injection plus splinting (group B). For occasional pain relief, paracetamol was allowed (1500 mg/day), but no non-steroidal anti-inflammatory drugs (NSAIDS).

Physical examination included phalen's sign, tinnel's sign, two-point discrimination, and grip strength measurement. Measurement of static two-point discrimination was performed on the pulp of the three radial digits, and the mean was recorded. Grip strength was tested with a hand-held dynamometer. The patient's positioning was standardized and the average force of three consecutive trials was calculated.

The pain was also assessed by the visual analog scale (VAS). A self administered Boston Questionnaire which has been validated in the Turkish population was used for the assessment of the severity of symptoms and functional status (16, 17). The symptom severity scale (SSS) assesses the symptoms with respect to severity, frequency, time and type. The scale consists of eleven questions with multiple-choice responses, scored from 1 point (mildest) to 5 points (most severe). The overall symptom severity score was calculated as the mean of the scores for the eleven individual items. The functional status scale consists of eight activities (difficulty in writing, buttoning clothes, opening jars, holding a book, gripping a telephone handle, household chores, carrying grocery bags, bathing and dressing). The answers were rated from 1 point (no difficulty in the activity) to 5 points (cannot perform the activity at all). The overall score for functional status was calculated as the mean of the eight items. All patients were examined by the same physician (AB).

Electrophysiological studies

Electrophysiological studies were performed according to the American Association of of Electrodiagnostic Medicine criteria by the same physician (AB) with a Nihon Kohden-Neuropack MEB 7102 K (Japan) at a room temperature of 25 – 27 °C (18). The skin temperatures of the forearm and wrist were kept at 32–33 during all measurements.

Median sensory and motor nerve conduction studies were performed on both hands of all the patients. Electrodiagnostic criteria for the diagnosis of CTS are as follows: median sensory velocity (SNCV) should be less than 40 m/sec, or median distal motor latency (MDL) schould be higher than 4.0 m/sec. The normal limits routinely used in our laboratory were as follows: DML from the wrist to abductor pollicis brevis < 3.5 m/sec, or median SNCV >45 m/sec. Stainless steel surface disk electrodes were used for motor nerve conduction studies while ring electrodes were used for the antidromic sensory nerve conduction studies.

The median motor conduction studies were performed by recording the compound muscle action potential (CMAP) from the abductor pollicis brevis, with the active recording electrode (G1) placed over the muscle belly and the reference recording electrode (G2) placed over the distal tendinous insertion. A ground electrode was placed on the dorsum of the hand. The median nerve was stimulated at the wrist 7 cm proximal to the G1 and at or below the elbow as a second stimulation point. All the stimulations were supramaximal. The distal motor latencies were measured from the onset of the CMAP.

The median sensory nerve conduction velocity was determined by antidromic stimulation at the wrist 14 cm proximal to the recording electrodes placed over the proximal phalanx of the third finger (G1), with the reference electrode placed 4 cm distally (G2). The placement of the ground electrode was the same as in the motor studies. The conduction velocities were calculated by dividing the distances by the onset latencies.

The local steroid injection was given using a 22-gauge needle at the proximal part of the carpal tunnel to the wrist crease just medial to the tendons of the flexor radial muscle involving a single 4 mg dexamethasone injection without lidocaine (19). The patients were instructed to wear light weight, neutral-positioned wrist splints at night and day as much as possible.

Ultrasound treatment was administered as the monotherapy for the Group A. Ultrasound treatment was given under water, five times per week, for 4 weeks, with an intensity of 1.5 watt/cm^2 for 5 minutes, with a 2.5 cm^2 soundhead. The frequency of ultrasound was 3 MHz.

The clinical evaluation and electrophysiological examinations were performed in each patient at baseline, at the 4th week and finally at the 8th week.

Statistical analysis

We analyzed the data according to the number of wrists that completed the study. The Student t-test was used to determine the difference between two groups in all clinical parameters both before and after the treatment. $p < 0.05$ was considered statistically significant. To determine the difference between the baseline and the 4th week and the 8th week, in each group, ANOVA was

used in repeated measures. When there was a statistically significant difference in the group, Bonferroni corrected paired-t test was applied. As we had three repeated measurements, at baseline, the 4th and 8th weeks, we calculated the p value as 0.05/3 = 0.016, and those under this level were accepted to be statistically important (20). The groups were compared by using the chi square test according to the handedness. $p < 0.05$ was considered statistically significant.

Results

A total 49 hands of 34 patients (24 women and 10 men) were enrolled in this study. 16 patients were randomly assigned to the group A, and 18 patients were randomly assigned to the group B. Three patients did not complete the 8 week follow-up. One patient in group B did not allow to be injected into her hand after randomization. Two patients (one in each group) could not be reached and were lost to follow-up. They were excluded from this study and data analysis. Thus, 15 patients (23 hands) in the Group A and 16 patients (22 hands) in the Group B completed

Tab. 1. Baseline characeristics of the patients.

	Group A n=15 patients/ 23 hands	Group B n=16 patients/ 22 hands	p
Age (years) mean±SD	47.33±7.44	44.15±9.30	>0.05
Sex, male/female	5/10	4/12	>0.05
Duration of symptoms (month) mean±SD	46.33±34.04	46.29±61.36	>0.05
Phalen's sign positive (n, %) negative (n, %)	16 (69.6%) 7 (30.4%)	16 (72.7%) 6(27.3%)	>0.05
Tinel's sign positive (n, %) negative (n, %)	18(78.3%) 5(21.7%)	17(77.3%) 5(22.7%)	>0.05

SD = standard deviation

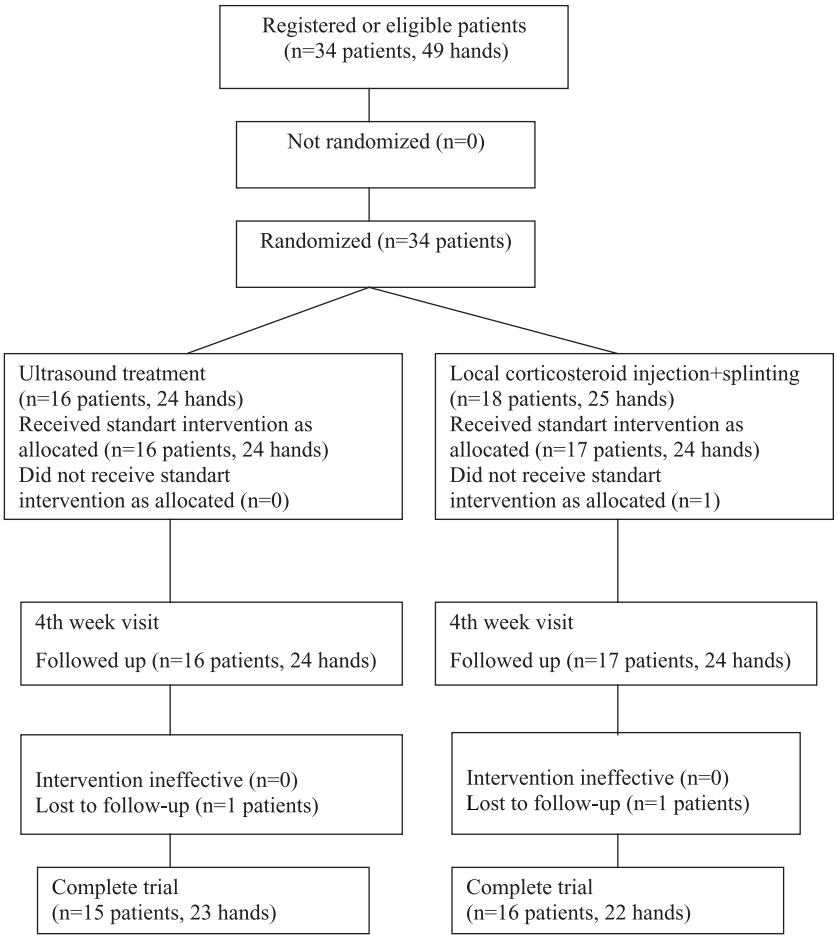

Fig. 1. The flow chart of the randomized controlled trial.

Tab. 2. The comparison of clinical variables before and after treatment.

	Baseline-1	Fourth week-2	Eighth week-3	p^{1-2}	p^{1-3}
Two-point discrimination					
Group A (n=23 hands)	4.94±2.59	3.87±1.90	3.34±1.38	>0.016	**<0.001**
Group B (n=22 hands)	4.04±0.32	3.57±0.39	3.02±0.22	>0.016	**<0.016**
$p^{Group\ A-B}$	>0.05	>0.05	>0.05		
Grip strength (mmHg)					
Group A	37.16±3.06	40.22±3.71	41.28±3.41	>0.016	>0.016
Group B	33.65±2.15	37.42±2.28	37.85±2.43	>0.016	**<0.001**
$p^{Group\ A-B}$	>0.05	>0.05	**<0.05**		
VAS pain (cm)					
Group A	4.02±2.44	2.33±3.11	1.53±2.03	**<0.016**	**<0.016**
Group B	4.88±2.21	2.88±2.39	1.65±2.29	**<0.001**	**<0.001**
$p^{Group\ A-B}$	>0.05	>0.05	>0.05		
Symptom severity score					
Group A	3.61±2.41	2.23±1.92	1.52±1.21	**<0.001**	**<0.001**
Group B	4.00±2.31	2.89±2.26	1.34±0.94	**<0.001**	**<0.001**
$P^{Group\ A-B}$	>0.05	>0.05	>0.05		
Functional status score					
Group A	3.72±1.74	2.39±1.13	2.06±0.90	<0.001	<0.001
Group B	3.93±1.39	3.20±1.83	2.30±1.62	<0.001	<0.001
$p^{Group\ A-B}$	>0.05	>0.05	>0.05		

p^{1-2}; comparison of baseline values with the values at 4th week, p<0.016 was accepted as statistically significant (Bonferroni correction).
p^{1-3}; comparison of baseline values with the values at 8th week, p<0.016 was accepted as statistically significant (Bonferroni correction).
$P^{Group\ A-B}$; Comparison of values between the group A and group B, p<0.05 was accepted as statistically significant.
Data are expressed as mean ± standard deviation.

Tab. 3. The comparison of electrophysiologic parameters before and after treatment.

	Baseline-1	Fourth week-2	Eighth week-3	p^{1-2}	p^{1-3}
Motor distal latency (m/sec)					
Group A(n=23hands)	5.36±0.55	5.10±0.58	5.12±1.54	<0.016	<0.016
Group B(n=22hands)	5.62±1.24	5.15±1.05	5.01±1.05	<0.001	<0.001
$p^{GroupA-B}$	>0.05	>0.05	>0.05		
Sensory nerve conduction velocity (m/sec)					
Group A	33.27±6.64	35.86±6.85	34.98±6.94	<0.016	<0.016
Group B	29.96±7.67	32.15±7.36	32.66±7.44	<0.001	<0.001
$p^{GroupA-B}$	>0.05	>0.05	>0.05		

p^{1-2}; comparison of baseline values with the values at 4th week, p<0.016 was accepted as statistically significant (Bonferroni correction).
p^{1-3}; comparison of baseline values with the values at 8th week, p<0.016 was accepted as statistically significant (Bonferroni correction).
$p^{Group\ A-B}$; Comparison of the values between the group A and group B, p<0.05 was accepted as statistically significant.
Data are expressed as mean ± standard deviation.

the follow-up at 8 weeks. Figure 1 presents a flow chart of the randomization.

The per-protocol analyses included 45 hands. The mean age was 47.33 ± 7.44 years (ranging from 37 to 59) in Group A and 44.15 ± 9.30 years (ranging from 31 to 63) in Group B (p > 0.05). Eight patients in the Group A and 6 patients in the Group B had bilateral CTS. Baseline characteristics such as the mean age and duration of symptoms for the groups were similar. Demographic data and baseline characteristics of the patients in the two groups are shown in Table 1. The numbers of dominant hands were similar in both groups (15 dominant hands in group A and 13 dominant hands in group B). There was no difference between two groups in numbers of dominant hands ($\div^2 = 0.2$, df = 1, p > 0.05).

Both group A and group B showed statistically significant improvements in pain, symptoms' severity and functional scores as compared to the baseline values at the 4th week and this improvements remained until the end of the study. Also a statistically significant improvement for the two-point discrimination test was obtained in both groups at the 8th week. No significant change was observed for grip strength in the group A during the study, whereas the group B showed a statistically significant improvement at the 8th week. At the end of the study, no significant difference was observed between the treatment groups in all

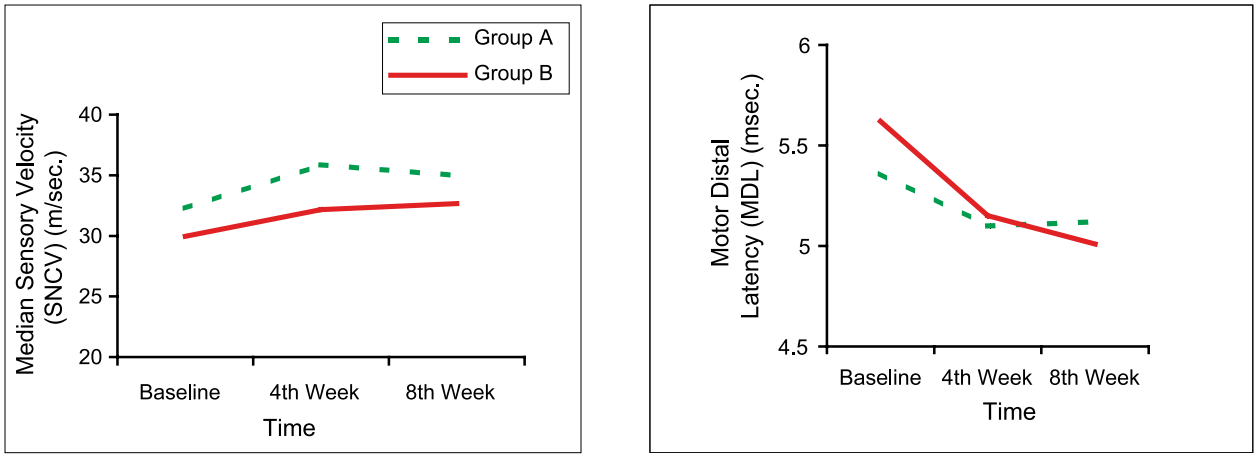

Fig. 2. Changes in SNCV and MDL of the median nerve after the treatment. Group A: ultrasound treatment, Group B: local corticosteroid injection plus splinting.

clinical variables, except for the grip strength. The data obtained in both groups before and after treatment are listed in Table 2.

Table 3 shows the conduction values in both groups before and after treatment. The SNCV of the median nerve showed a significant increase at 4th and 8th weeks when compared to the baseline values in both groups. Furthermore, MDL was decreased at 4th week as compared to the baseline values in both groups and these improvements remained until the end of the study. The comparison of the electrophysiological parameters between the two groups did not reveal any statistically significant differences before and after treatment ($p > 0.05$). Figure 2 shows the change of electrophysiological parameters in both groups during the study.

Adverse side effects were not recorded in both groups, except for transient local injection pain in the group B.

Discussion

To our knowledge, this is the first randomized controlled study comparing the efficacy of ultrasound treatment and splinting combined with local steroid injection for CTS. The results of this study suggested that there was a marked improvement for all clinical parameters in both treatment groups, except for the grip strength in the group A. The same significant improvement was found in the electrophysiological parameters. The electrophysiological and clinical improvements were maintained at the follow-up in both groups.

Among the conservative treatments of CTS, splinting is the most popular method. There are many studies stressing the effectiveness of neutral-angle wrist splinting in CTS (4, 10, 11, 21, 22). Immobilization of the wrist in a neutral position with a splint maximizes carpal tunnel volume and minimizes pressure on the median nerve. The therapeutic effect of splinting is related to wrist position itself (direct splint effects) or to the reductions in the use of upper extremity (indirect splint effects) (6, 23). CTS splints may not be compatible with certain jobs. Many CTS patients complain that splinting will hinder their work or daily activities (9). Walker et al (23) found that subjects receiving full-time wear instructions showed a superior distal latency improvement, both motor and sensory when compared to the subjects receiving only night wear instructions. A randomized controlled study showed that a 6-week trial of wrist splinting reduced discomfort scores, that there was a trend toward improvement in the Levine symptom severity scores, and that the improvements persisted for a year (11).

The local steroid injection is one of the most common and effective non-surgical method for the treatment of CTS. Inflammation of the flexor tenosynovium causes thickening of the synovium, which in time may result in median nerve compression. Treatment with injections of corticosteroids into the carpal tunnel reduces this tenosynovitis (4, 10, 11). Recent studies have shown short term effects of steroid injections into the carpal tunnel, with modest or complete pain relief in up to 92% of the patients, although long term recurrence rates seem variable (6, 10, 15, 24–26). Gelberman et al (27) reported a recurrence of symptoms in most patients by 9-15 months after steroid injection for CTS. Girlanda et al (24) also demonstrated significant clinical improvement at one and two months after local steroid injection compared to controls. They noted that 50 per cent of hands showed symptomatic worsening within 6 months. The recently published Cochrane review on the effectiveness of local corticosteroid injections concluded that injections result in better clinical improvement in symptoms after one month, compared to placebo (4). Our study suggests that local steroid injection along with splinting improves the clinical and electrophysiological findings of CTS.

The most common neurophysiologic abnormality found in CTS is the increase in the DML and sensory median nerve latencies (SDL) or decrease in the SNCV. Steroid injection and splinting for CTS resulted in a significant decrease of sensory and motor distal latencies in a study by Celiker et al (28). In that study, the follow-up was limited to eight weeks. The duration of

our study was also the same. Giannini et al (15) also found that median nerve sensory and motor distal latencies improved after local steroid injection. These findings are highly consistent with our results.

In general, the local steroid injection is more successful in patients with mild CTS. However, potential adverse effects to nerves and tendons with repeated injections (such as rupture of tendons and irritation of the nerves) and the possibility of systemic toxic effects (such as hyperglycemia and hypertension) as well as high recurrence rates have limited the value of this treatment (4, 6, 10, 26, 28, 30).

Several studies have reported some beneficial effects of other conservative treatments such as ultrasound therapy (4, 6,1 3). It is known that ultrasound is used to treat a variety of inflammatory and traumatic conditions. Ultrasound treatment within an intensity range of 0.5–2.0 w/cm^2 may have the potential to induce various biophysical effects within tissue. Ultrasound therapy may accelerate the healing process in damaged tissues; in the early stages of healing, Ultrasound may decrease edema and increase blood flow and delivery of oxygen. Further it may increase collagen deposition and remodeling (8, 14, 31, 32). The experiments on the stimulation of nerve regeneration and on nerve conduction by ultrasound treatment along with the findings of anti-inflammatory effect of ultrasound support the concept that ultrasound treatment might facilitate recovery from nerve compression (8, 14).

The effect of US therapy on electrophysiological values is not clear. There is a general agreement that ultrasound produces its greatest heating effect in deeper tissues and that nerve is selectively heated (31). Increased local blood flow induced by ultrasound treatment may contribute to nerve regeneration or recovery nerve conduction in compression neuropathy (14, 31, 32). However, higher doses of ultrasound may cause a decrease of conduction velocity or even a conduction block. A decrease in conduction velocity may be attributed to the mechanical effect of ultrasound rather than to a thermal effect (14, 33). There was an evidence of reversible conduction block with increased temperature in demyelinated fibers in experimental and human multiple sclerosis (34). This effect should be considered during the treatment.

There are few reports in the literature evaluating the effect of ultrasound therapy on entrapment neuropathy in human beings. Oztas et al (35) investigated the overall therapeutic effect of different intensities of repeated ultrasound application compared to placebo ultrasound on CTS. They found a slight increase in MDL and motor NCV at both intensities 1.5 w/cm^2 and 0.8 w/cm^2. But this difference was not more statistically significant than placebo ultrasound. In contrast, Ebenbichler et al (13) recently demonstrated that improvement was significantly more pronounced in actively treated than in sham treated wrists for both subjective symptoms and electroneurographical variables (MDL and SNCV). The effects sustained at 6 months' follow-up. Their results were similar to ours. A recent study reported that splinting, exercise and ultrasound therapy combination was more favorable compared to the other combinations (36). In their study, no significant improvement was recorded in MDL and SDL in the splinting and ultrasound group at the end of the study. This discrepancy may be explained by the different method, period, and intensity of ultrasound application than our study.

Finally, this study showed that ultrasound treatment provided an improvement comparable to the local corticosteroid injection plus splinting on clinical and electrophysiological findings in patients with CTS. Some patients may not accept injection treatment. According to the results obtained from this study, we think that ultrasound can be comfortably used in the management of CTS with minimal side effect risk. But this study had some limitations. First, all patients had mild to moderate CTS, so results cannot be generalized to those with more severe CTS. Second, the sample size was small and the follow-up period was limited to 8 weeks. Therefore, we cannot comment on long-term results. Further research including long term follow-up evaluations is required to confirm these findings.

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