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The Effect of Shock Wave and Phonophoresis in the Improvement of the Clinical Symptoms and Function of Patients with Mild to Moderate Carpal Tunnel Syndrome: A Clinical Trial

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Abstract

Background: Carpal tunnel syndrome is a common condition that causes pain, sensory and motor symptoms in the hands, especially in the thumb, index, and middle fingers due to the compression of the median nerve in the carpal tunnel. The purpose of this research was to investigate the effect of the shock wave and phonophoresis in the improvement of clinical symptoms and function of patients with mild to moderate carpal tunnel syndrome.

Methods: The present research has employed a double-blind randomized clinical trial on 60 patients in Isfahan, Iran. Patients were randomly divided into 3 treatment groups of shock, phonophoresis, and control, and all patients received conservative treatments. Wrist thermoplastic splint, vitamin B1, and celecoxib were prescribed for all patients. The shock group received their intervention in four sessions of shock once a week for 4 weeks. Patients in the phonophoresis group received phonophoresis (pulse 1:4) 15 minutes every other day for 2 weeks. Pain scores were assessed based on the visual analog pain scale, and the Boston questionnaire severity scale was completed for each patient before, 1 and 2 months after the intervention. The used analytic tests included Fisher's exact tests, 1-way analysis of variance, and repeated measures analysis.

Results: Shock wave and phonophoresis showed a significant decrease in pain, symptom severity index ($p<0.001$), and functional status ($p<0.001$). This reduction was more persistent in the phonophoresis group.

Conclusion: The use of noninvasive shock wave and phonophoresis methods were good alternatives in the treatment of carpal tunnel syndrome.

Keywords: Shock Wave, Phonophoresis, Carpal Tunnel Syndrome

Conflicts of Interest: *None declared*
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Introduction

Carpal tunnel syndrome (CTS) is the most frequent focal mononeuropathy due to pressure on the nerve. This syndrome is a set of symptoms of pressure on the median nerve when passing through the carpal tunnel. About 10% of adult females and 1% of adult males suffer from carpal tunnel syndrome (1, 2), and more than 87% of them expe-

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↑What is "already known" in this topic:
For patients with mild to moderate carpal tunnel syndrome, available treatments include patient training, wrist splint, group B vitamins, nonsteroidal anti-inflammatory drugs, intra-articular steroid injections, and occupational adjustments.

→What this article adds:
Shock wave and phonophoresis are good alternatives in the treatment of carpal tunnel syndrome as noninvasive methods with respect to improvement of hand function and decrease in patients' symptoms. These physical modalities may be considered for the treatment of patients with mild to moderate carpal tunnel syndrome, either as single or adjunct therapy.

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rience it bil aterally (3). The prevalence of this syndrome in Iran was reported as much as 25% among 1000 people with upper limb pain (4).

Obesity, pregnancy, diabetes, amyloidosis, hypothyroidism, and rheumatoid arthritis make a person susceptible to this syndrome (5, 6). Tinel's and Phalen's diagnostic tests are positive in up to 80% of patients with classical CTS (7). Electrodiagnostic study is a gold standard means for the evaluation of suspected cases of carpal tunnel syndrome. Neuronal conduction and electromyography studies also help determine the presence and severity of median nerve neuropathy in the wrist (8). The severity of carpal tunnel syndrome is expressed as mild, moderate, and severe based on electrodiagnostic patterns (9), which requires different therapeutic approaches.

Conservative treatments, include patient training, wrist splint, group B vitamins, nonsteroidal anti-inflammatory drugs, intra-articular steroid injections, occupational adjustments, carpal tunnel pressure resection, open surgery, exercise endoscopy, yoga, laser, and magnet (6, 9, 10).

The shock wave is also an effective and noninvasive method of reducing pain in soft tissue diseases, such as Achilles tendinopathy and plantar fasciitis (11-13). This method is an appropriate therapeutic method because of negligible adverse effects and potentials of being used instead of invasive surgery, convenience, safety, and effectiveness (14).

Phonophoresis is another effective method that intensifies the absorption of a topical medicine to the underlying tissues by ultrasound; and, recently, there has been a great deal of interest in using this method (15). The mechanism of phonophoresis involves cavitation, thermal effects, and mechanical stress (16).

Since there has been no study comparing shock wave and the phonophoresis method to reduce pain and symptoms of carpal tunnel syndrome, the present clinical trial was designed to compare the pain and functional status of the upper limb in patients with CTS.

Methods

Study Population

The present research is a single-blind controlled clinical trial with registration no. IRCT20171230038142N10 in Iranian Registry of Clinical Trials (IRCT), conducted on 60 patients with CTS referred to physical medicine clinics of Isfahan University of Medical Sciences in 2017 and 2018.

Initially, 63 patients with CTS were selected from patients referred to physical medicine clinics of Al-Zahra, Kashani, Isabn-e-Maryam, and Khorshid hospitals in Isfahan. Then, they were assigned to 3 treatment groups with 20 patients (shock view, phonophoresis, and control) using the triple block method. These patients were unaware of the research objectives and the comparison of treatments, but they were well aware of being in one of the groups with different treatments and receiving treatment for their disease. They were included in the study with consent (Fig. 1).

Inclusion criteria were as follows: mild to moderate

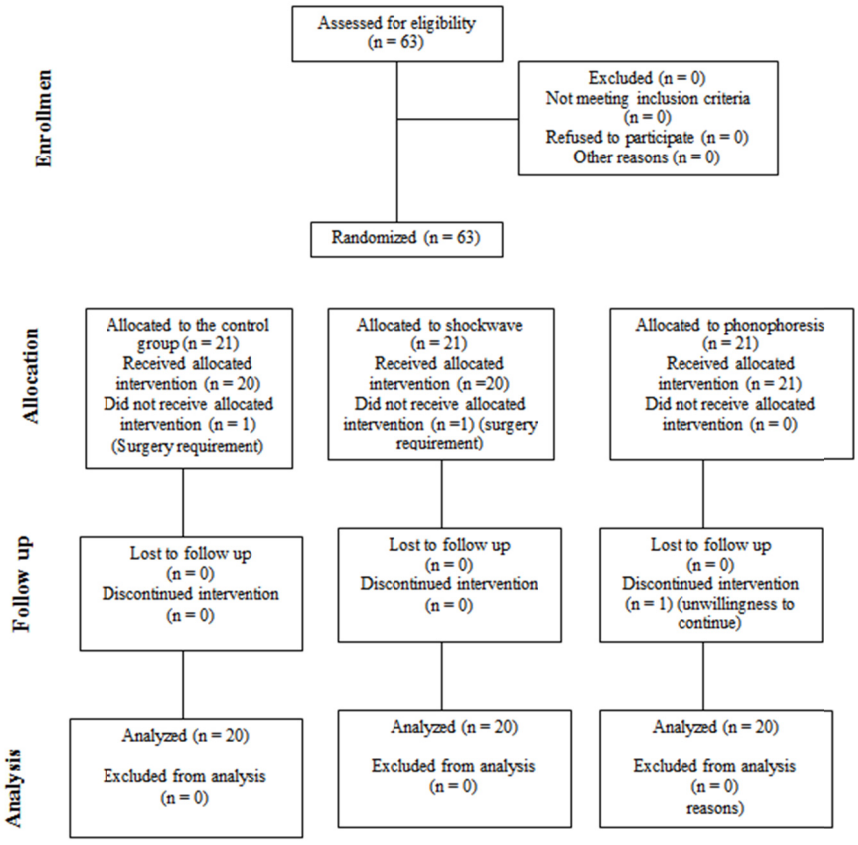

Fig. 1. Patient consort chart

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CTS according to the CTS sensory and motor examinations, Tinel's and Phalen's diagnostic tests, and electrodiagnostic findings according to the American Association of Electrodiagnostic Medicine guidelines (17); more than a month had passed from the symptoms; and willingness to participate in the study.

The unmet criteria were defined as corticosteroid injections, physical, or medicinal therapies in the past 3 months (physiotherapy), thenar atrophy, CTS underlying disease, or conditions such as hypothyroidism, diabetes, rheumatic diseases, wrist arthritis, acute trauma or pregnancy, conditions for which ultrasound treatment is prohibited, clinical or electrophysiological evidence that may interfere with CTS symptoms or imitate the symptoms, such as polyneuropathy or cervical radiculopathy, history of surgery or wrist fractures. The exclusion criteria were as follows: patients' failure to refer for follow-up, incidence of severe adverse effects leading to dismiss the therapeutic approach, intensifying the symptoms, patients' unwillingness to continue the study, patients' awareness of statistical and research objective of each of the 2 treatment groups.

The patients were randomly allocated to each of the intervention groups using the Random Allocation software. In this term, each patient was randomly provided with a particular number using this software and assigned to each of the intervention groups.

The person who performed the interventions was different from the person responsible for assessing the outcomes. Therefore, the responsible physical medicine and rehabilitation resident who interviewed and examined the patient was unaware of the procedure performed for each of the patients. In addition, the patients were encoded as 1-to-3 according to the type of the intervention, but the codes were blinded to the person who evaluated the outcomes.

Interventions

All patients underwent conservative treatment; thermoplastic splint at 0 to 5 degrees was prescribed for all of them for 4 weeks, and they were noticed to use the splint at night while sleeping and during daily activity. Vitamin B1 300 mg and celecoxib 200 mg tablets were prescribed daily for 30 days and daily for 2 weeks, respectively.

- ***Shockwave Therapy***

Four sessions of shock wave were performed for the shock-receiving group weekly in proximal part of carpal tunnel (with focus head, starting with 0.05 mm^2/mj energy, and increasing based on patient tolerance and protocol to 0.07, 0.1, and 0.15 mm^2/mj as well as starting with shock number 800, and increasing based on patient tolerance and protocol to 900, 1000, and 1100, with a frequency of 3Hz per session using SOLEO Sono/Zimmer device made in Germany) (18).

- ***Phonophoresis***

Following the use of gel, the probe was perpendicularly put in the hand. Patients in the phonophoresis group received phonophoresis (pulse 1:4) 15 minutes every other day for 2 weeks with 1MHz frequency and intensity of 1w.cm^2 along with 1% hydrocortisone ointment (using STORS MEDICAL AG-Type:AT made in Switzerland) (15).

- ***Control***

The control group received no other intervention in addition to wrist thermoplastic splint, vitamin medicine.

Primary Outcomes

The pain status and function of the affected hand was assessed using a visual analogue scale (VAS) rating scale, and the Boston severity scale, and Functional Status Questionnaire, respectively, were completed for all patients before, within 1, and 2 months after treatment.

- ***Boston Symptom Severity and Functional Status Questionnaire***

This questionnaire consists of 2 parts of severity of the symptoms and assessment of the patients' functional status**.** The Boston questionnaire severity scale (BQ-SS) section contains 11 questions about the severity and frequency of symptoms, including numbness at night and burning, pain, and muscle weakness during the day. The Boston questionnaire of functional status (BQ-FS) contains 8 questions about patient problems in performing specific activities, such as writing, holding a book, closing a clothing button, holding a phone, opening a glass jar, doing hard works at home, taking a shower, carrying the shopping bag, and getting dressed. The 5-point Likert scale, scoring from 1 to 5, indicating the lack of symptom, and the most severe symptoms was administered to score the questions. The Persian version of this questionnaire has been validated by Rezazadeh et al (19, 20).

- ***VAS***

This scale is a 10 cm gradient line, with numbers ranging from 0 (no pain) to 10 (severe pain). This scale has been widely used in pain-related types of research whose validity and reliability have been confirmed (18, 21).

Statistical Analysis

Eventually, the obtained data were entered into the Statistical Package for Social Sciences (SPSS Inc) Version 23. Descriptive data were presented in mean, SD, absolute numbers, and percentages. The used analytic tests included Fisher's exact tests, 1-way analysis of variance (ANOVA), and repeated measures analysis. $P < .05$ was considered significant.

Results

The results showed that the patients in the 3 groups did not differ significantly in terms of demographic variables in terms of age ($p=0.113$) and gender distribution ($p=0.781$) (Table 1).

The Boston questionnaire severity scale (BQ-SS) showed a significant decrease in the assessments of both left and right sides in the 3 groups over time ($p<0.001$) so that the interaction of time and intervention also showed a significant decrease in the left ($p=0.035$) and right side ($p=0.006$). The Boston questionnaire of functional status (BQ-FS) also showed a significant decrease on the left ($p=0.003$) and right ($p<0.001$) side.

Although the interaction between time and intervention was not significant on the left side ($p=0.06$), it was statis-

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Table 1. Summary of sample demographic information

Investigated Parameter		Shock wave	Phonophoresis	Control	P value
Gender	Female	18 (30%)	17 (27.5%)	14 (25%)	0.781*
Number(Percentage)	Male	2(2.5%)	3 (5%)	6 (10%)	
Age (year)	M±SD	50.10±8.14	50.05±5.99	51.13±9.06	0.113**

*At the 5% level of Fisher's exact test
** At the 5% level of ANOVA test

Table 2. Comparison of the mean of severity of symptoms and functional status of patients based on Boston scale by time, group therapy and side of patient body

Investigated Parameter		Before	Within one month after the interventions	Within two months after the interventions	P2 Time	P3 Time*intervention	P4 Intervention
Left	Shock wave	2.99±1.06	1.90±0.90	1.63±0.56	0.002	0.035	<0.001
BQ-	Phonophoresis	3.37±0.59	2.29±0.93	1.78±0.83	<0.001		
SS*	Control	1.97±0.48	1.32±0.23	1.37±0.31	0.001		
	P1	<0.001	0.008	0.243			
Right	Shock wave	3.71±0.66	1.99±0.58	1.97±0.55	0.001	0.006	<0.001
BQ-	Phonophoresis	3.18±0.63	2.23±0.67	1.83±0.68	0.001		
SS*	Control	1.91±0.71	1.07±0.13	1.37±0.63	0.013		
	P1	<0.001	<0.001	0.146			
Left	Shock wave	3.04±1.33	2.25±1.24	1.63±0.68	<0.001	0.063	0.003
BQ-	Phonophoresis	3.25±0.82	2.16±1.06	1.75±0.75	0.004		
FS**	Control	1.99±0.69	1.32±0.31	1.43±0.36	0.01		
	P1	0.004	0.003	0.418			
Right	Shock wave	3.62±1.07	2.57±0.55	2.36±0.68	0.034	<0.001	<0.001
BQ-	Phonophoresis	3.13±0.82	2.38±0.84	1.90±0.73	0.010		
FS**	Control	1.99±0.56	1.18±0.36	1.43±0.56	0.021		
	P1	0.001	<0.001	0.033			

P1 at 5% level of Anova test
P2, p3, p4 at 5% level of Repeated Measures test
* Boston questionnaire severity status
** Boston questionnaire of functional status

tically remarkable on the right side (p<0.001). On the other hand, the in-group comparisons (p1) showed a decrease in the shock wave and phonophoresis and relative stability in the control group at each time period for each of the indicators (Table 2).

Figure 2 shows the trends of changes in the severity of symptoms and functional status of patients based on the Boston scale.

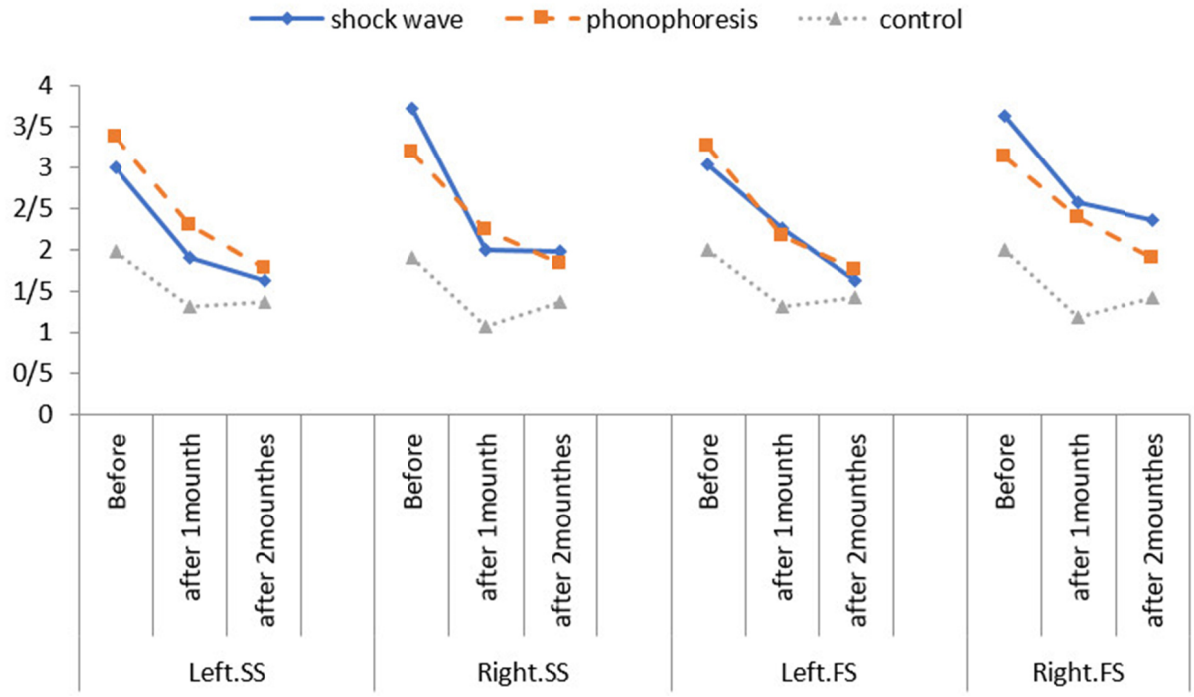

Fig. 2. Trends of changes in the severity of symptoms and functional status of patients based on the Boston scale

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Table 3. Comparison of VAS score based on time, treatment group, and side of patient body

Investigated Parameter		Before	1 Month After	2 Months after	P2 (Time)	P3 (Time*intervention)	P4 (Intervention)
Left. VAS	Shock wave	4.28±3.35	4.42±2.5	1.14±0.69	0.021	0.231	<0.001
	Phonophoresis	6.50±2.41	3.10±2.51	2.50±3.27	0.056		
	Control	2.10±1.59	0.80±0.78	1.10±1.28	0.103		
	P1	0.001	0.091	0.504			
Right. VAS	Shock wave	5.25±1.70	2.50±1.73	1.73±1.50	0.091	0.005	<0.001
	Phonophoresis	6.30±1.41	2.90±2.23	1.50±1.58	0.000		
	Control	2.09±1.97	0.81±1.07	0.63±0.92	0.057		
	P1	<0.001	0.027	0.138			

P1 at 5% level of Anova test
P2, p3, p4 at 5% level of Repeated Measures test

The pain assessment based on the VAS rating scale also showed a significant decrease in the 3 studied groups on the left ($p<0.001$) and right side ($p<0.001$). Although the interaction between time and intervention was significant on the right side ($p=0.005$), it was not significant on the left side ($p<0.001$). In-group comparisons (P1) also confirmed a decrease in the 2 intervention groups, but not for the control group (Table 3).

Discussion

Shock wave therapy and phonophoresis are among the modern and noninvasive treatments, which have been well reflected in recent decades in patients with CTS (22, 23). The present research showed that the mentioned treatments caused a significant reduction in the parameters of severity scale and functional status based on the Boston scale as well as pain based on the VAS index. There was a continuous and almost nonrecurrent decrease in the phonophoresis group. There was a slight increase in symptoms of the control and shock wave groups during the 2-month study, but, generally, both intervention methods, phonophoresis and shockwave therapy, have had approximately the same effect on pain reduction and symptoms. Both shock wave and phonophoresis have had relatively similar contributions in reducing pain and functional indicators, and this study showed that noninvasive treatments are effective in addition to medication and splint. Of strength of our study was to assess both hands because the dominant hand may be more involved with more severe courses of CTS; therefore, the probable bias due to dominance of daily chores performance by a hand has been controlled.

Soek and Kim represented that the noninvasive method of shock wave could be as effective as corticosteroid in improving patients' symptoms and reducing pain (22). Raeisi et al also observed a significant improvement in the distal sensory latency of the median nerve in the shockwave-treated group compared with the controls, which is in line with the present results (23). In 2019, a systematic review by Kim et al reported that shockwave therapy led to improved symptoms, functional outcomes, and electrophysiological parameters in CTS patients. However, there was no obvious significant differences between shockwave and local corticosteroid injection efficacies (24). The potential mechanisms of shockwave therapy are anti-inflammatory (reduce the perineural pressure) and neuronal regeneration pathways of this modality (25). Neuronal regeneration may be induced by increasing Schwann cell proliferation, accelerating the elimination of the injured axon and increasing axonal regeneration in animal experiments (26). However, studies on the therapeutic effect of the shockwave in CTS captured neuropathies are very limited (27-29).

Yildiz et al showed that adding phonophoresis with ketoprofen to splint was effective in the treatment of CTS, but adding the ultrasound to splint was not superior to using splint alone (15). Bakhtiari et al showed that the effect of phonophoresis with dexamethasone sodium phosphate has a better effect on CTS treatment than with iontophoresis with dexamethasone sodium phosphate (30). Soyupek et al evaluated the effect of phonophoresis with corticosteroids, phonophoresis with NSAIDs, topical injections of corticosteroids, and splint. They showed that only the pain score decreased after the follow-up period in the splint group, while the 2 methods of phonophoresis have significant effects on patients' pain, function, and electrodiagnostic findings (31), which is consistent with the present research.

Generally, shock wave and phonophoresis are appropriate noninvasive methods for reducing pain and measuring the severity of symptoms and functional status of patients. The results obtained limitations in a 2-month follow-up because of impossibility of initiating concurrent treatment for all patients to have a longer follow-up as a longitudinal study. The strength of the study was the lower cost of phonophoresis compared with shock wave, which is significant based on the results. Since a 2-month follow-up of the electromyography was not possible, it is suggested to assess the function of organs in future studies.

Conclusion

Carpal tunnel syndrome is the most common focal mononeuropathy due to nerve pressure. Given the importance of treatment for this disorder and the lower risk of noninvasive therapies compared with medicine and surgical injections and citing the efficacy of shockwave therapy and phonophoresis in the treatment of musculoskeletal disorders in similar therapies, using shock wave and phonophoresis methods are a good alternative in the treatment of carpal tunnel syndrome.

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IRCT Registration Number: IRCT20171230038142N10.

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Conflict of Interests

The authors declare that they have no competing interests.

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