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Clinical and electrophysiological efficacy of extracorporeal shock-wave therapy in carpal tunnel syndrome: a placebo-controlled, double-blind clinical trial

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SUMMARY

OBJECTIVE: The aim of this study was to evaluate the efficacy of radial extracorporeal shock wave therapy on pain, functionality, and electrophysiological measurements in carpal tunnel syndrome.

METHODS: Between June 2021 and January 2022, a total of 66 wrists in 45 participants with mild-to-moderate carpal tunnel syndrome were included in this double-blind, prospective, randomized, placebo-controlled study. Patients were randomized into two groups, namely, the radial extracorporeal shock wave therapy (group 1, n=33) and the sham radial extracorporeal shock wave therapy (group 2, n=33). Night splints and tendon nerve gliding exercises were given to all participants. The participants were evaluated at baseline and the first month after treatment. Participants were evaluated using a visual analog scale, the Boston Carpal Tunnel Questionnaire, Leeds Neuropathic Symptom and Symptom Assessment, and electrophysiological examinations.

RESULTS: A total of 37 participants (a total of 55 wrists, radial extracorporeal shock wave therapy n=27, and sham radial extracorporeal shock wave therapy n=28) completed the study. After the intervention, there was a significant decrease in visual analog scale values ($p<0.001$) and a significant increase in Boston Carpal Tunnel Questionnaire scores ($p<0.001$) and Leeds Neuropathic Symptom and Symptom Assessment scores ($p<0.001$). In electrophysiological measurements, there was a significant decrease in median nerve sensory ($p=0.002$) and motor ($p=0.003$) distal latency, and a significant increase in median nerve sensory conduction velocity ($p=0.026$) was found in the radial extracorporeal shock wave therapy group.

CONCLUSION: This study shows that radial extracorporeal shock wave therapy has positive effects on pain, functionality, and electrophysiological measurements for mild-to-moderate carpal tunnel syndrome 1 month after application.

KEYWORDS: Carpal tunnel syndrome. Extracorporeal shockwave therapy. Median neuropathy.

INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy resulting from compression of the median nerve at the wrist level[1]. Diabetes, rheumatoid arthritis, amyloidosis, hypothyroidism, obesity, acromegaly, previous wrist fracture, menopause, and pregnancy are known risk factors for CTS[2]. Studies have shown that the use of vibrating tools, compelling movements of the wrist, and computer use affect the development of CTS[3]. Clinical features of CTS include night pain, numbness, and tingling sensation in the median nerve dermatome[4]. It has been reported that carpal tunnel pressure increases 8–10 times compared with normal during wrist flexion and extension and causes ischemic compression in the median nerve[1], and nighttime symptoms are also explained by the increase in pressure in the canal with the wrist flexed at night[5].

Extracorporeal shock wave therapy (ESWT) can be classified as focused (fESWT) and radial (rESWT) according to the targeted area, as well as low, medium, and high energy according to the energy level[6]. ESWT, which has become widespread in the treatment of different musculoskeletal diseases, has increasing evidence in the treatment of CTS[7]. The mechanism of action of ESWT in the treatment of neuropathy is generally explained by the stimulation of neurogenesis and angiogenesis through different molecules and by the anti-inflammatory effect[8]. Although positive effects were found on functional measurements, pain, and electrophysiological parameters in the meta-analysis examining the results of ESWT application in the treatment of CTS, there are uncertainties about the optimal treatment protocol[7].

In this study, we aimed to investigate the effect of rESWT treatment on symptom severity, functional outcomes, and

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electrophysiological parameters in patients diagnosed with mild-to-moderate CTS.

METHODS

The study protocol was approved by Istanbul Kanuni Sultan Suleyman Training and Research Hospital Training and Research Hospital Ethics Committee in accordance with the Declaration of Helsinki (Date: May 27, 2021, Number: 2021.05.162). All participants were informed about the study before inclusion in the study, and their written consent was obtained.

This single-center, prospective, double-blind, randomized, placebo-controlled study was conducted at Istanbul Kanuni Sultan Suleyman Training and Research Hospital Training and Research Hospital, Physical Medicine and Rehabilitation outpatient clinic, between June 2021 and January 2022. Standard electrophysiological tests were performed on 65 participants with a preliminary diagnosis of CTS. A total of 66 wrists from 45 participants with mild-to-moderate CTS who met the inclusion criteria were included in the study. The inclusion criteria were as follows:

1. diagnosis of mild-to-moderate CTS,
2. age 40–60 years,
3. no treatment for CTS in the last 6 months,
4. positive Phalen and Tinel tests, and
5. agreement to withhold other therapeutic interventions for CTS during the study and follow-up period.

Notably, 20 of the initially evaluated participants with mild-to-moderate CTS were excluded from the study according to the exclusion criteria. The exclusion criteria were as follows: brachial plexopathy, polyneuropathy, other upper extremity entrapment neuropathies and cervical radiculopathy, history of wrist fracture, history of cervical spinal and wrist surgery, steroid injection for CTS in the last 6 months, bleeding disorder, and pregnancy.

All participants were evaluated before treatment and 1 month after treatment. Participants were randomized into two groups (rESWT and sham rESWT groups) using a computer program. If a participant had bilateral CTS, both wrists were assigned to the same treatment group (i.e., rESWT or sham rESWT). The study flowchart is shown in Figure 1. The ESWT intervention was performed by an investigator blinded to outcome measures and randomization.

Treatment methods

Shock wave therapy

While the participant was in the sitting position, the forearm was placed on the table with the finger and palm facing up. The median nerve was found using musculoskeletal ultrasonography Digital Sonoace 5500 machine (Medison America Inc., Cypress, CA, USA), and the ESWT probe was placed perpendicular to the median nerve. rESWT was performed using a Vibrolith ESWT device (Elmed Medical Systems, Orlando, FL, USA). The proximal carpal tunnel located at the level of the pisiform bone in the transverse ultrasonography (USG) image was also included in the treatment area. rESWT was performed on the participants once per week for three consecutive weeks, for a total of three sessions (2,000 shots, with 1.6 bar and frequency of 6 Hz rESWT). ESWT was performed similarly to the participants in the sham rESWT group (group 2) but without skin contact. The participants were evaluated in terms of adverse effects and safety after treatment. In three participants in the rESWT group, no additional complications were observed except for paresthesia symptoms in the median nerve trace, which regressed in a short time without the need for additional intervention after the treatment session.

Wrist splint

All the participants included in the study were advised to use a wrist splint of the appropriate size as much as possible, every night and day during the study period. Splint use of the participants was monitored through weekly phone calls.

Exercise

An exercise program based on nerve and tendon gliding exercises developed by Totten and Hunter[9] was taught and given in written format to all participants in the study. To monitor exercise compliance, weekly phone calls were made to the participants, and they were asked to maintain a diary with the exercise details. Participants were asked to repeat each exercise 10 times with three times per day.

Outcome measures

The participants were evaluated two times, at the beginning and the first month after the treatment. Participants were evaluated using a visual analog scale (VAS), the Boston Carpal Tunnel Questionnaire (BCTQ), Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), and nerve conduction studies.

The VAS was used to measure the hand pain experienced by the participants, with a scale ranging from 0 (no pain) to 10 (extremely severe pain)[10].

The BCTQ is the most commonly used questionnaire in clinical trials to assess the symptom severity and functional status of patients with CTS. There are 11 questions in the symptom severity subscale and eight questions in the functional status subscale[11].

The LANSS pain scale is used to evaluate neuropathic pain. In the first part of the test, there are five descriptive questions about neuropathic pain. In the second part of the test, the painful and painless area is compared in a physical examination[12].

Nerve conduction study (NCS) was performed using a Neuropack S1 MEB-9400© (Nihon Kohden, Japan) device by a neurologist. The compound muscle action potential (CMAP) and sensory nerve action potential (SNAP) of

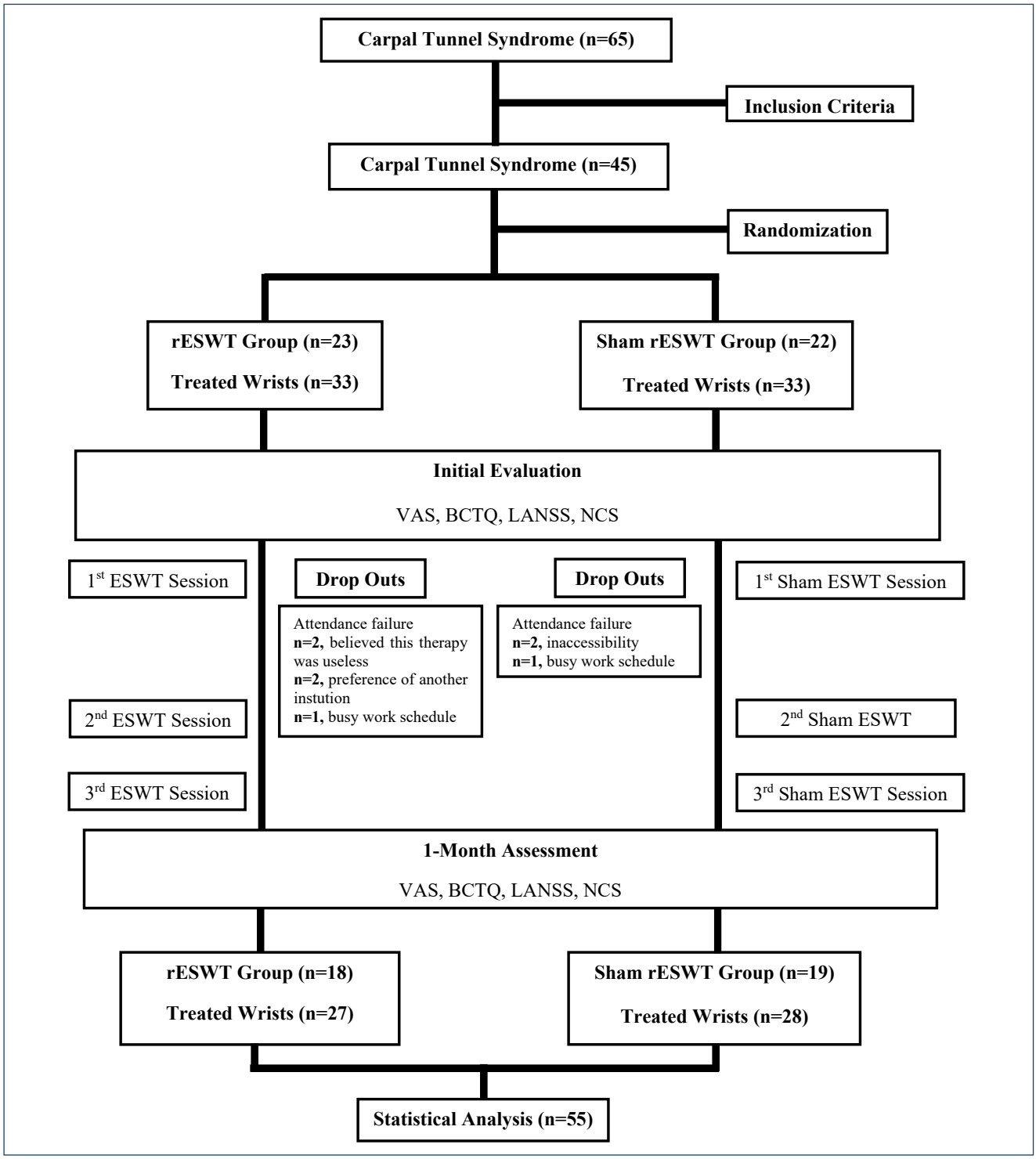

Figure 1. Patient flow and study profile. rESWT: radial extracorporeal shock wave therapy group; sham rESWT: sham radial extracorporeal shock wave therapy group; VAS: visual analog scale; BCTQ: Boston Carpal Tunnel Questionnaire; LANSS: Leeds Assessment of Neuropathic Symptoms and Signs; NCS: nerve conduction study.

the median and ulnar nerves were measured in the upper extremities. The onset latency and the baseline-to-peak amplitude of the CMAPs were measured. Onset latency, peak-to-peak amplitude, and conduction velocity were recorded for each measurement. The results were processed according to published reference values accepted by our EMG laboratory[13].

Data analysis

The sample size of the study was calculated using the G*Power version 3.1.9 program (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) based on the change in pain intensity. According to the sample size calculation, to achieve $\alpha<0.05$ and $\beta=95\%$ according to the VAS scores with an effect size of 0.98, it was calculated that a minimum of 24 participants would be required for each group as described by Xu et al.[14].

The IBM SPSS for Windows version 21.0 software (IBM Corp., Armonk, NY, USA) was used for statistical analysis. For intra-group analysis, the paired-sample t-test or Wilcoxon signed-ranks test was used, and for inter-group analysis, the independent samples t-test or Mann-Whitney U test was used according to the distribution of the variables.

RESULTS

Of 45 participants, 37 completed the study, and a total of 55 wrist results were analyzed (n=27 in the rESWT group and n=28 in the sham-rESWT group). The participants' reasons for leaving the study are given in Figure 1.

The demographic and clinical characteristics of the participants are shown in Table 1.

According to the intra-group analysis results, there were statistically significant changes in terms of VAS (p<0.001), BCTQ (p<0.001), LANSS (p<0.001), median nerve sensory distal latency (p=0.002), median nerve sensory conduction velocity (p=0.007), and median nerve motor distal latency (p=0.004) in the rESWT group. No statistically significant changes were found in any parameters in the sham-rESWT group.

A statistically significant decrease was found in the VAS (p<0.001), BCTQ (p<0.001), and LANSS scores (p<0.001) in the rESWT group in the inter-group analysis. In addition, in the rESWT group, there was a significant increase in median nerve sensory conduction velocity (p=0.026), and a significant decrease in the electrophysiological values of median nerve motor (p=0.003) and sensory distal latency (p=0.002). Detailed information is shown in Table 2.

DISCUSSION

This study aimed to investigate the effect of rESWT performed in addition to splint and exercise in the treatment of CTS. In this prospective, randomized, placebo-controlled, and double-blind study, the results showed that rESWT reduced pain and improved functional and electrophysiological findings in mild-to-moderate CTS.

In the literature, low-energy ESWT applied to nervous tissue is stated to be a safe and effective treatment[15], and high-energy ESWT has no negative effect on peripheral nerves. ESWT is used for peripheral neuropathies such as interdigital neuroma and distal symmetric polyneuropathy, as well as CTS[16,17].

Table 1. Demographic and clinical characteristics of the participants.

Variables	ESWT (n=27)	Sham ESWT (n=28)	p
Age (year)	43.8 (8.3)	46.9 (9.3)	0.415
BMI (kg/m^2)	29.8 (5.1)	30.9 (4.9)	0.715
Laterality			
Right wrist	17 (63)	13 (46.4)	0.221
Left wrist	10 (37)	15 (53.6)	
Duration of symptoms, month	16.5 (16.6)	17.3 (20.0)	0.376
Duration of symptoms, range			
3–6 months	11 (40.7)	12 (42.9)	0.529
6–12 months	4 (14.8)	7 (25.0)	
>12 months	12 (44.5)	9 (32.1)	
VAS	6.4 (2.1)	6.9 (1.6)	0.207
Boston SSS	2.7 (0.5)	2.8 (0.4)	0.979
Boston FCS	3.0 (0.8)	2.7 (0.7)	0.431
Boston-total score	5.7 (1.2)	5.5 (1.0)	0.744
LANSS	12.1 (4.7)	9.8 (5.0)	0.745
mSNDL (ms)	3.3 (0.8)	3.3 (0.7)	0.645
mSNA (mV)	12.6 (6.9)	11.3 (6.8)	0.852
mSNCV (m/s)	35.8 (6.9)	36.3 (6.5)	0.518
mMNDL (ms)	4.2 (0.8)	3.9 (0.6)	0.080
mMNA (mV)	7.8 (1.9)	8.5 (2.3)	0.512
mMNCV (m/s)	58.7 (4.7)	54.9 (5.4)	0.901

ESWT: extracorporeal shock wave therapy group; sham ESWT: sham extracorporeal shock wave therapy group; BMI: body mass index; VAS: visual analog scale; SSS: Symptom Severity Scale; FCS: Function Severity Scale; LANSS: Leeds Assessment of Neuropathic Symptoms and Signs; mSNDL: median sensory nerve (2. Finger-wrist) distal latency; mSNA: median sensory nerve (2. Finger-wrist) amplitude; mSNCV: median sensory nerve (2. Finger-wrist) conduction velocity; mMNDL: median verve motor distal latency; mMNA: median motor nerve amplitude; mMNCV: median motor nerve conduction velocity. p<0.05 is considered significant for the homogeneity of variables.

Table 2. Intra- and inter-group analysis of the outcome measures.

	ESWT (n=27)	p[a]	Sham ESWT (n=28)	p[b]	p[b]
VAS					
PreT	6.4±2.1	<0.001	6.9±1.6	0.05	<0.001
1st month	3.5±2.1		6.6±1.8		
Boston SSS					
PreT	2.77±0.50	<0.001	2.85±0.45	0.058	<0.001
1st month	1.89±0.61		2.68±0.59		
Boston FCS					
PreT	3.00±0.84	<0.001	2.70±0.71	0.155	<0.001
1st month	1.98±0.61		2.57±0.61		
Boston-total score					
PreT	5.77±1.20	<0.001	5.42±0.97	0.076	<0.001
1st month	3.87±1.16		5.24±1.03		
LANSS					
PreT	5.39±1.85	<0.001	5.33±1.54	0.302	<0.001
1st month	3.62±1.44		4.76±1.65		
mSNDL (ms)					
PreT	3.3±0.8	0.002	3.3±0.7	0.245	0.002
1st month	3.0±0.7		3.4±0.8		
mSNA (mV)					
PreT	12.6 ±6.9	0.641	11.3 ±6.8	0.061	0.189
1st month	13.4±8.9		9.6±5.6		
mSNCV (m/s)					
PreT	35.8±6.9	0.007	36.3±6.5	0.961	0.026
1st month	39.7±9.4		36.4±5.9		
mMNDL (ms)					
PreT	4.2±0.8	0.004	3.9 ±0.6	0.308	0.003
1st month	3.9±0.7		3.9±0.7		
mMNA (mV)					
PreT	7.8±1.9	0.332	8.5±2.3	0.553	0.251
1st month	7.4±1.3		8.7±2.1		
mMNCV (m/s)					
PreT	58.7±4.7	0.400	54.9±5.4	0.516	0.873
1st month	58.4±5.3		54.6±5.9		

ESWT: extracorporeal shock wave therapy group; sham ESWT: sham extracorporeal shock wave therapy group; VAS: visual analog scale; SSS: Symptom Severity Scale; FCS: Function Severity Scale; LANSS: Leeds Assessment of Neuropathic Symptoms and Signs; mSNDL: median sensory nerve (2. Finger-wrist) distal latency; mSNA: median sensory nerve (2. Finger-wrist) amplitude; mSNCV: median sensory nerve (2. Finger-wrist) conduction velocity; mMNDL: median verve motor distal latency; mMNA: median motor nerve amplitude; mMNCV: median motor nerve conduction velocity; PreT: pre-treatment; [a]p: p-value for intra-group analysis; [b]p: p-value for inter-group analysis; p<0.05 is considered significant.

Studies on the effectiveness of ESWT in the treatment of CTS were conducted in the following years, compared with oral nutraceutical capsule treatments[18], USG intervention[19], and sham rESWT[8], and it has been seen that ESWT is an effective and safe treatment method in the treatment of CTS. In a study investigating the optimal number of ESWT sessions to be performed in the treatment of CTS, better functional results were observed in three sessions of ESWT compared with one

session and a placebo group[20]. Similar to these results, in the present study, three sessions of ESWT were found to be effective on clinical and electrophysiological results compared with sham applications.

The mechanism of action of ESWT in an entrapment neuropathy such as CTS is not fully understood. Studies have reported that the biological effects of ESWT include tissue regeneration, wound healing, angiogenesis, bone remodeling, and anti-inflammation[21]. The anti-inflammatory effect of ESWT is generally like the mechanism of action indicated in other musculoskeletal diseases where ESWT is widely used[22]. Different studies have shown that ESWT provides anti-inflammatory effects by increasing nitric oxide (NO) levels through enzymatic and non-enzymatic NO production[23]. Reduction of inflammation in the carpal tunnel as a result of its anti-inflammatory effect can reduce perineural pressure and improve symptoms[7].

There are also studies on the effect of ESWT on peripheral nerve regeneration. Studies have shown increased Schwann cell proliferation and axonal regeneration in nerve tissue after treatment with ESWT[24]. The improvement in electrophysiological parameters detected in the present study can be explained by this mechanism.

In the evaluations made in terms of ESWT safety, no serious adverse effects of the treatment were reported. In general, mild complications such as pain and redness that resolve spontaneously have been reported[7]. In our study, ESWT treatment was found to be safe and well-tolerated, except for mild symptoms that resolved without the need for local and additional intervention.

The strengths of this study are as follows. This is a double-blind, randomized, sham-controlled, and prospective study. In addition, determining the treatment area with USG and using rESWT before ESWT is performed on patients are also strong points. The main limitation of this study is the short follow-up period after treatment. Studies investigating the long-term effectiveness of rESWT are needed.

CONCLUSION

This study shows that the rESWT application has positive effects on pain, functionality, and electrophysiological measurements in patients with mild-to-moderate CTS.

ETHICAL STATUS

The study protocol was approved by the Clinical Research Ethical Board of Kanuni Sultan Suleyman Training and Research Hospital (Approval no: KAEK/2021.05.162) in conformity with the Declaration of Helsinki. The study was registered at https://clinicaltrials.gov (ID number: NCT04896398).

AUTHORS' CONTRIBUTIONS

AKM: Conceptualization, Data curation, Formal Analysis, Writing – original draft. **MDK**: Data curation, Formal Analysis, Writing – review & editing. **HS**: Data curation, Writing – review & editing.

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