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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Effectiveness of combined ultrasound and exercise therapy in the treatment of carpal tunnel syndrome – randomized, placebo-controlled investigation

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SUMMARY

Introduction/Objective The aim of the paper was to evaluate the short-term effectiveness of ultrasound treatment procedure on defined clinical parameters and changes of electrodiagnostic parameters at the median nerve in carpal tunnel syndrome patients.

Methods Thirty-five patients (50 hands) were randomly divided into two groups: the experimental group (EG) (20 patients (29 hands)) and the control group (CG) (15 patients (21 hands)). Twenty sessions of ultrasound treatment were performed over a period of seven weeks and control examination was performed during the eighth week from the initial session. Clinical assessment parameters (pain intensity, superficial sensibility, and Tinel sign), and electrodiagnostic parameters (motor distal latency – mDL), median sensory nerve conduction velocity (SNCV), and median sensory nerve action potential (SNAP) were assessed both at baseline (T1) and at control (T2).

Results There is significant improvement of pain intensity (T1 – 10.4/58.6/31; T2 – 65.5/27.6/6.9; $p < 0.001$) and superficial sensibility (T1 – 3.4/69/27.6; T2 – 44.8/34.5/20.7; $p < 0.001$) in the EG after the treatment. In the EG, there is significant reduction in frequency of positive Tinel's sign (T1 – 100/0; T2 – 62.1/37.9; $p < 0.001$), and mDL significantly decreased after the treatment (T1 – 4.7 ± 1.3; T2 – 4.5 ± 1.2; $p = 0.007$), while SNAP (T1 – 20.2 ± 15.4; T2 – 24.4 ± 16.5; $p < 0.001$) and SNCV (T1 – 36.5 ± 9.8; T2 – 42.6 ± 9.7; $p < 0.001$) significantly increased.

Conclusion Ultrasound treatment along with exercises have positive short-term effects and benefits on improvement of clinical and electrodiagnostic findings in individuals with carpal tunnel syndrome.

Keywords: carpal tunnel syndrome; ultrasound treatment; clinical findings; electrodiagnostic parameters; short-term outcome

INTRODUCTION

Carpal tunnel syndrome (CTS) represents the most frequent compressive neuropathy of the median nerve at the wrist level, with the prevalence of around 0.7/10,000 of working population [1]. Such state might be associated with a decrease in productivity, and is the second most common cause of absence from work between 1997 and 2010 [1, 2]. It should be underlined that the frequency of CTS has temporal increase, pointing to the need for further evaluation of prevention methods and treatment modalities [1].

Numerous non-surgical options for the treatment of CTS were studied, among them ultrasound (US), splinting, exercises or mobilization, laser treatment, non-steroidal antiinflammatory drugs, corticosteroids, vitamins, and complementary therapies [3, 4]. So far, there are conflicting data with regard to US treatment efficacy on improvement in patients with CTS. Previous systematic reviews stated that so far there is limited data, of poor quality evidence, suggesting therapeutic effectiveness of US in patients with CTS [5, 6]. As a therapeutic modality, US can be administered with various biological effects as an adjunct modality in treatment of various musculoskeletal pathology. US therapeutic effects can be obtained via thermal (the molecular vibrations generated by acoustic waves while penetrating the tissue) and/or non-thermal (cavitation, standing waves, and media motion) mechanisms [7, 8]. Previous experimental studies stressed that US treatment might have anti-inflammatory and tissue-stimulating effects via numerous mechanisms, including modification of membrane permeability, blood flow, tissue metabolism, connective tissue extensibility, and nerve function [9, 10]. Yildiz et al. [11] suggested that US treatment effects on CTS are more likely due to the process of pressure formation and resolution in carpal tunnel canal, and opposing anti-inflammatory effects. It is also stated that US treatment can influence the ability of nerve fibers to propagate an action potential; however, the potential physiologic mechanisms of such function are not well understood [10]. Positive effects of US therapy on the increase

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of sensory nerve conduction velocity were reported, while there are conflicting effects on motor nerve conductions in terms of increase and decrease of the velocities. These effects on motor nerve conduction velocities are possibly due to the fact that they are intensity-dependent and might be to a certain degree the result of the relationship between thermal and non-thermal effects [10]. Thus, further methodologically rigorous studies are needed in order to obtain more conclusive evidence on the optimal treatment of patients with CTS, including the role of US therapy.

The aim of our study was to evaluate in a placebo-controlled study the short-term effectiveness of US on defined clinical parameters and changes of electrodiagnostic parameters in CTS patients.

METHODS

Patients and study design

The prospective randomized, placebo-controlled double-blind study included 39 patients (55 hands) at baseline with diagnosed CTS. Patients who met the inclusion criteria were included in the study. Prior to inclusion in the study, participants were informed about the study protocol and consent was obtained. The study was conducted at the Institute for Rehabilitation in Belgrade, Serbia, after the study protocol had been approved by the Institutional Review Board (number 02/2-29/2012), and was conducted according to the Declaration of Helsinki.

The patients were randomly divided into two groups: the experimental group (EG) and the control group (CG). In the CG, the US probe was applied without turning the device on. Randomization was allocated by using the "numbered envelopes" method. Printed paper with allocation was put in aluminum foil to prevent possible transparency in strong light. Sealed envelopes were mixed. Every enrolled patient got to pull an envelope from a pile of envelopes. The EG was composed of 20 patients (29 hands) at baseline with no drop-off during the treatment. The CG was composed of 19 patients (26 hands) at baseline with a drop-off of four patients at random during the treatment. Both patient groups followed the same rehabilitation protocol.

Our calculations of the study power revealed that the study has sufficient number of patients to detect a significant difference between the groups regarding the difference between delta motor distal latency (mDL) (1-beta = 0.93), sensory nerve action potential (SNAP) (1-beta = 0.86) and sensory nerve conduction velocity (SNCV) (1-beta = 0.99) for the median nerve.

Electrophysiologic analyses

For all the patients, median and ulnar sensory and motor nerve conduction velocities (NCSs) were determined by Medelec Synergy, Oxford instruments, UK. Motor studies were recorded with supramaximal stimulation at the wrist and registration from the thenar (the *abductor pollicis brevis* muscle) for the median nerve and hypothenar (the *abductor digiti V* muscle) for the ulnar nerve, with a distance of 7 cm between these two sites. SNAPs of median and ulnar nerves were recorded antidromically, with stimulation at the wrist, and registration with ring-electrodes from digit 2 and digit 4 [12–15]. For the confirmation of CTS diagnosis, we followed recommendations for median-to-ulnar comparison studies measured on digit 4, by stimulating both nerves at the wrist, 13 cm proximal to the detection electrode for both sensory median evaluation and sensory ulnar evaluation [13]. In motor and sensory NCSs, the latency was measured from the onset of the stimulus to the initial negative deviation, and the amplitudes were measured from the baseline to the negative peak. All measurements were performed bilaterally, and by the same electromyographer. Hand temperature was registered and maintained at 32–34°C. Electromyography (EMG) testing was performed using a concentric needle electrode on the *abductorpollicis brevis* and the *abductor digiti V* muscles [12]. The patients were assessed electrophysiologically with NCSs at baseline, and at eight weeks after the initial assessment.

The palmar side sensitivity of the first three fingers and half of the fourth finger was determined by the palpatoric differentiation test of the two points. The main outcome measures were pain intensity assessed by numeric rating scale (NRS) (for statistical analyses, we categorized the pain as none – NRS 0, mild – NRS 1–3, moderate – NRS 4–6, or severe – NRS 7–10) and the presence of Tinel's sign [16].

The same board-certified physician evaluated the clinical assessment parameters at both baseline (T1) and eight weeks after (T2) the initial assessment.

Inclusion criteria

The study included patients aged 18 years and above, with symptoms (pain and/or numbness) in at least two digits on one hand (digits 1–4) lasting less than one year, no thenar atrophy, and mild to moderate CTS based on NCSs. Patients were eligible for the study if NCSs demonstrated any of the following: median nerve motor terminal latency above 4.4 ms with distal distance of 7 cm, and/or median nerve sensory distal latency above 3.5 ms with distal distance of 13 cm, and/or median to ulnar sensory distal latency difference from 0.5 ms and above measured on digit 4, with or without pathological EMG findings in the *abductor pollicis brevis* muscle [12, 13].

Exclusion criteria

Patients with severe CTS and with axonal loss of the median nerve confirmed by electrodiagnostic studies (absent or low amplitude of SNAP) and/or absent or low amplitude of compound muscle action potential, and/or presence of denervation potentials and/or presence of neurogenic motor unit potentials on needle EMG examination [13], thenar atrophy, or severe pain intensity (> 7) based on the NRS [16], were excluded from the study. Other criteria

for exclusion from the study were pregnancy, presence of diabetes mellitus, connective tissue disorders or arthritis involving hand or wrist, occlusive blood vessel disease, other neurological diseases (central and peripheral nervous system diseases and traumas), hypothyroidism, B_{12} vitamin deficiency, previous chemotherapy, previous injuries and upper limb surgery, as well as alcoholism in the history. Individuals with the type of employment that could be considered a risk factor for CTS, and previous carpal tunnel release, were excluded.

Treatment protocol

Therapeutic US was administered in EG (In CG Sham US). Probe frequency of the therapeutic dosage of US was 1 MHz, and the intensity was 1.0 W/cm^2, pulsed mode 1:4, with transducer of 5 cm^2 (Eko Medico-Sono Din, Electronic Design Medical, Belgrade, Serbia), and with aquasonic gel as the couplant [17]. The US was applied in contact over the carpal tunnel area of the skin on the volar side of the wrist for 15 minutes. The 1 MHz frequency US mode was used in our study due to the fact that deeper penetration has the potential to reach the median nerve [18]. Before study inclusion of eligible participants, the US devise was calibrated. A total of 20 treatments were administered in each case, with the following schedule: 10 treatments were administered once a day, five days a week (working days only) for two weeks, followed by four treatments every other day for two weeks, and six treatments twice a week for three weeks. Control of eligible study participants was done eight weeks after the initial assessment. No side effects of the treatment were reported.

Individuals from the CG were not given therapeutic US treatment, but placebo (sham) treatment without affecting the normal ultrasonic output when the key was turned to the "on" position (placebo US (0.0 W/cm^2 intensity)).

Patients in both groups were instructed to perform nerve and tendon gliding exercises developed by Totten and Hunter [19], which they continued to perform at home during the investigation period of eight weeks. During tendon gliding exercises, the fingers were placed in five positions. During the median nerve gliding exercise, the median nerve was mobilized by putting the hand and wrist in six different positions. During these exercises, the neck and the shoulder were in a neutral position, and the elbow was in supination and in 90° of flexion. Each position was maintained for 5 seconds. These exercises were applied as five sessions daily. Each exercise was repeated 10 times at each session.

Other treatments, such as acupuncture, physical therapy, and wearing splints, were forbidden. The patients included in the study had neither local, nor oral administration of glucocorticoids for at least one month before or during the investigation period. Paracetamol was allowed for occasional pain relief, but non-steroidal antiinflammatory drugs were not allowed. None of the patients reported using paracetamol during the treatment period.

Clinical assessment and NCSs were evaluated at baseline and at eight weeks after the initial assessment.

Statistical analysis

Data are presented as counts (percentage) or means ± standard deviations (SD) depending on the data type. Group comparisons were performed using Pearson χ^2 test, Cochran–Armitage test (χ^2 test for trend) and Mann–Whitney U-test. Within the group, testing was performed using Wilcoxon signed-rank test. Data analysis was performed in IBM SPSS Statistics, Version 20.0 (IBM Corp., Armonk, NY, USA) statistical software. All p-values less than 0.05 were considered significant.

RESULTS

The EG was composed of 20 patients (29 hands) at baseline, with no drop-off during the treatment, two (10%) males and 18 (90%) females, of whom 11 (55%) patients had unilateral and nine (45%) bilateral CTS. The EG patients' age ranged 34–69 years (mean 53.5 ± 8.3 years). The CG was composed of 19 patients (26 hands) at baseline, with drop-off of four patients at random during the treatment. Therefore, we included only those (15 patients, 21 hands) who finished the study. In the CG, there were two (13.3%) males and 13 (86.7%) females, of whom nine (60%) with unilateral and six (40%) with bilateral CTS. The mean age of the CG patients was 52.6 ± 8.7 years (range 35–64 years). None of the patients reported using paracetamol during the treatment period.

In Table 1, personal characteristics and job type of the studied individuals are presented. There were no significant differences between the EG and the CG regarding observed baseline parameters (Table 1).

Table 1. Frequency distributions of demographic characteristics in patients with carpal tunnel syndrome in the ultrasound group (EG) and the control group (CG) (the results are presented as count (%) or mean ± standard deviation)

Personal characteristics	EG n = 20 (29 hands)	CG n = 15 (21 hands)	p-value
Age (years)	53.5 ± 8.3	52.6 ± 8.7	0.758a
Sex			
Female	18 (90%)	13 (86.7%)	1.000b
Male	2 (10%)	2 (13.3%)	
Job type			
Manual labor	9 (45%)	6 (40%)	0.913b
Administrative work	6 (30%)	4 (26.7%)	
Housewife or other	5 (25%)	5 (33.3%)	

[a]t-test;
[b]χ^2 test

There was a significant improvement in the EG regarding pain intensity after the treatment (T2), while such difference was not observed in the CG (Table 2). Significant improvement for superficial sensibility was noticed in the EG as well, after eight weeks (T2) (Table 2).

In the EG, there was a significant reduction in frequency of positive Tinel's sign between the baseline period (T1) and eight weeks from the baseline assessment (T2) (Table 2).

Table 2. Obtained results in patients with carpal tunnel syndrome at baseline (T1) and after eight weeks (T2)

Subjective symptoms	T1 (n) (%)	T2 (n) (%)	p-value[b]
Pain intensity	No pain/Mild/ Moderate	No pain/Mild/ Moderate	
EG	3/17/9 10.4/58.6/31	19/8/2 65.5/27.6/6.9	< 0.001*
CG	1/14/6 4.7/66.7/28.6	2/15/4 9.5/71.4/19	0.083
p-value[a]	1.000	< 0.001*	-
Superficial sensibility	normal/weakened/ extinguished	normal/weakened/ extinguished	p-value[b]
EG	1/20/8 3.4/69/27.6	13/10/6 44.8/34.5/20.7	< 0.001*
CG	1/14/6 4.8/66.7/28.6	1/14/6 4.8/66.7/28.6	1.000
p-value[a]	1.000	0.021*	-
Tinel sign	positive/negative	positive/negative	p-value[b]
EG	29/0 100/0	18/11 62.1/37.9	< 0.001*
CG	0/21 0/100	0/21 0/100	1.000
p-value[a]	< 0.001*	< 0.001	-

CG – control group; EG – experimental group
*statistically significant;
[a]between groups;
[b]within groups

Table 3. Electrodiagnostic findings at baseline (T1) and after eight weeks (T2) (means ± standard deviations)

Subjective symptoms	T1	T2	p-value[b]	Delta
mDL (2nd finger)				
EG (ms)	4.7 ± 1.3	4.5 ± 1.2	0.007*	0.2 ± 0.3
CG (ms)	5.0 ± 2.0	5.0 ± 2.0	1.000	0
p-value[a]	0.794	0.536	-	0.009*
SNAP (2nd finger)				
EG (μV)	20.2 ± 15.4	24.4 ± 16.5	< 0.001*	5.0 ± 3.7
CG (μV)	17.4 ± 12.4	17.9 ± 14.1	0.151	0.6 ± 5.6
p-value[a]	0.758	0.164	-	0.002*
SNCV (2nd finger)				
EG (m/s)	36.5 ± 9.8	42.6 ± 9.7	< 0.001*	6.9 ± 3.2
CG (m/s)	35.3 ± 9.4	36.6 ± 9.8	0.086	1.3 ± 2.9
p-value[a]	0.690	0.047*	-	< 0.001*

CG – control group; EG – experimental group; mDL – motor distal latency; SNAP – sensory nerve action potential; SNCV – sensory nerve conduction velocity;
*statistically significant;
[a]between groups;
[b]within groups

In Table 3, electrodiagnostic findings at baseline (T1) and after eight weeks (T2) are presented. There was a significant reduction in mDL values in individuals of the EG, while a significant increase in SNAP and SNCV were noticed in individuals of the EG. A significant increase in SNCV was noticed in individuals of the EG when compared with CG individuals, eight weeks after initial assessment (T2). For all evaluated electrodiagnostic parameters (distal latency, SNAP, and SNCV) there were significant differences in delta values between the EG and the CG.

DISCUSSION

In our placebo-controlled study, we aimed to evaluate the short-term effectiveness of US on defined clinical parameters and changes of electrodiagnostic parameters in CTS patients. We demonstrated after the treatment (T2) significant improvement in pain intensity and superficial sensibility in the EG group versus the CG group. Furthermore, in the EG, we noticed significant reduction in frequency of positive Tinel's sign between baseline period (T1) and eight weeks from the baseline assessment (T2).

In a recent Cochrane Systematic Review, it was suggested that for those individuals who are experiencing mild to moderate symptoms of CTS, therapeutic US may be offered. However, the effectiveness and duration of the benefit of such an intervention remain unclear [5].

In a systematic review of O'Connor et al. [20], it was pointed out that US treatment in patients with CTS over the course of two weeks is not considered to be beneficial, while in other studies such treatment was shown to be beneficial in improving symptoms after seven weeks [4, 11]. Ebenbichler et al. [17] also stressed positive short-term effects and even suggested satisfying medium term effects for patients with mild to moderate idiopathic CTS.

Our findings are consistent with the studies reporting positive effects of US therapy in CTS patients regarding symptoms' improvement over the period of eight weeks [4, 11]. Our study showed that the proportion of those individuals with CTS with mild to moderate degrees of pain intensity significantly decreased, while those with no pain symptoms increased. This is also true for those with impaired superficial sensibility. Regarding the presence of Tinel's sign, a significant reduction in frequency of those individuals with the positive sign was found in the EG group.

We noticed a reduction in frequency of mild pain intensity symptom by almost one half**,** while the percentage of patients with moderate pain intensity was reduced almost three-fold. However, greater decrease in the frequency of superficial sensibility was noticed for those with a weakened degree (50%) than for those with extinguished degree (around 25%). These trends imply that in severe cases, US treatment might have more effect on the pain symptom rather than on superficial sensibility.

Because of possible positive effects of US on nerve function and regeneration, as previously mentioned, significant changes in electrodiagnostic evaluation might be absent despite the significantly positive effects on symptom improvements. In the study by Yildiz et al. [11], it was explained that such effects might be due to the fact that electrodiagnostic studies predominantly measure conduction of A fibers, while C fibers, which are responsible for somatic pain, are more sensitive to US treatment. It should also be stressed that prolonged compression in the carpal tunnel canal might lead to the loss of axons along with demyelination, thus disabling significant improvement particularly in the amplitude increase, and in cases with severe axonal losses disabling improvement in conduction velocities as well. Thus, for patients with CTS, early and

adequate diagnosis with a timely and adequate treatment modality is needed for optimal outcome.

Our results regarding electrodiagnostic evaluations in CTS patients treated with US therapy are consistent with previous reports. We obtained a significant reduction in distal latency values in the EG, along with a significant increase in SNAP and SNCV parameters in the EG, thus suggesting positive effects of US treatment on electrodiagnostic findings.

The limitation of the study refers to the number of participants – thus, further studies on larger samples are advised.

The necessity for further research of potential benefits of non-surgical treatment options for individuals with diagnosed CTS is advised due to the fact that despite numerous systematic reviews that have been published, evidence for many treatment modalities, among them US, is inconclusive [6, 7, 21].

CONCLUSION

Our results suggest that US treatment along with exercises has positive short-term effects and benefits on improvement of clinical and electrodiagnostic findings in individuals with CTS.

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Ефекти комбинованог ултразвука и кинезитерапије у терапији синдрома карпалног тунела – рандомизовано, плацебо-контролисано испитивање

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САЖЕТАК

Увод/Циљ Циљ рада је био да се испитају краткорочни ефекти ултразвучне терапије на одређене клиничке параметре и промене електродијагностичких параметара средишњег живца руке (*n. medianus*) код болесника са синдромом карпалног тунела.

Методе Тридесет пет болесника (50 руку) методом случајног узорковања је подељено у две групе: експериментална група (ЕГ) (20 болесника – 29 руку) и контролна група (КГ) (15 болесника – 21 рука). Примењено је 20 сесија ултразвучне терапије током седам недеља и спроведена је контрола током осме недеље од почетка терапије. Праћени су клинички параметри (интензитет бола, површински сензибилитет и Тинелов знак), електродијагностички параметри (моторна дистална латенца – мДЛ), сензорна брзина провођења *n. medianusa* (СБП) и сензорни акциони нервни потенцијал *n. medianusa* (САНП) на почетку третмана (Т1) и на контроли (Т2).

Резултати Дошло је до значајног побољшања у интензитету бола (Т1 – 10,4/58,6/31; Т2 – 65,5/27,6/6,9; $p < 0,001$) и суперфицијалног сензибилитета (Т1 – 3,4/69/27,6; Т2 – 44,8/34,5/20,7; $p < 0,001$) у ЕГ после терапије. У ЕГ је уочено значајно смањење у учесталости позитивног Тинеловог знака (Т1 – 100/0; Т2 – 62,1/37,9; $p < 0,001$), и мДЛ је значајно снижена после терапије (Т1 – 4,7 ± 1,3; Т2 – 4,5 ± 1,2; $p = 0,007$), док су САНП (Т1 – 20,2 ± 15,4; Т2 – 24,4 ± 16,5; $p < 0,001$) и СБП (Т1 – 36,5 ± 9,8; Т2 – 42,6 ± 9,7; $p < 0,001$) значајно већи.

Закључак Ултразвучна терапија са кинезитерапијом има корист и позитивне краткорочне ефекте на побољшање клиничких и електродијагностичких параметара код особа са синдромом карпалног тунела.

Кључне речи: синдром карпалног тунела; ултразвучна терапија; клинички параметри; електродијагностички параметри; краткорочни исход