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Original Article / Оригинални рад

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

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

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

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

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 median nerve in carpal tunnel syndrome patients.

Methods: Thirty-five patients (50 hands) were randomly divided into two groups: experimental group (EG) (20 patients (29 hands)) and control group (CG) (15 patients (21 hands)). Twenty sessions of ultrasound treatment were performed over 7 weeks period and control was done during eight 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 (T1-10.3/58.6/31; 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 EG after the treatment. In 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) significant 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

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 пацијената са синдромом карпалног тунела.

Методе: Тридесетипет пацијената (50 руку) је методом случајног узорковања подељено у две групе: експериментална група (ЕГ) (20 пацијената (29 руку)) и контролна група (КГ) (15 пацијената (21 рука)). Двадесет сесија ултразвучне терапије је примењено током седам недеља и контрола је спроведена током осме недеље од почетка терапије. Праћени су следећи клинички параметри: интензитет бола, површински сензибилитет и Тинелов знак, и електродијагностички параметри (дистална моторна 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 (Т1-10.3/58.6/31; 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 уочено је 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) сигнификантно већи.

Закључак: Ултразвучна терапија са кинезитерапијом има позитивне краткорочне ефекте и бенефит 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

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 decrease in working productivity, and is a 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 [1], pointing to the need for further evaluation of prevention methods and treatment modalities.

Numerous non-surgical options for the treatment of CTS were studied, among them: ultrasound, splinting, exercises or mobilization, laser treatment, non-steroidal antiinflammatory drugs, corticosteroids, vitamins and complementary therapies [3,4]. So far there are conflicting data with regards of ultrasound (US) treatment efficacy on improvement for patients with CTS. Previous systematic reviews stated that so far there is limited data of poor quality evidence suggesting therapeutic effectiveness of ultrasound 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 (themolecular vibrations that are 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 out that US treatment might have an 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 in CTS condition 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 increase 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 NCVs are possibly due to the fact that they are intensity-dependent and might be to the certain degree the result of thermal and non-thermal effects relationship [10]. Thus, further methodologically rigorous studies are needed in order to obtain more conclusive evidence on the optimal treatment for patients with CTS including the role of US therapy in this group of patients.

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 meeting 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 Institutional Review Board (number 02/2-29/2012), and was conducted according to the declaration of Helsinki.

Patients were randomly divided into two groups: experimental group (EG) and 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 on 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 drop off of 4 patients at random during the treatment. Both patients groups followed the same rehabilitation protocol.

Our calculations of study power revealed that the study has sufficient number of patients to detect significant difference between groups regarding 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 median nerve.

Electrophysiologic analyses

Median and ulnar sensory and motor nerve conduction velocities (NCS) were performed for all patients with Medelec Synergy, Oxford instruments, UK. Motor studies were recorded with supramaximal stimulation at the wrist and registration from thenar (*abductor pollicis brevis* muscle) for median nerve and hypothenar (*abductor digiti V* muscle) for ulnar nerve, with 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 between 32-34°C. EMG testing was performed using a concentric needle electrode on *abductor pollicis brevis* and *abductor digiti V* muscles [12]. Patients were assessed electrophysiologically with NCSs at baseline, and at 8 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 have categorized pain as none - NRS 0, mild - NRS between 1-3, moderate - NRS between 4-6, or severe- NRS between 7-10 [16], and the presence of Tinel's sign.

The same board-certified physician evaluated the clinical assessment parameters both at baseline (T1) and 8 weeks after (T2) 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 for less than 1 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 7cm, and/or median nerve sensory distal latency above 3.5 ms with distal distance of 13cm, and/or median to ulnar sensory distal latency difference from 0.5 ms and above measured on digit 4, with or without pathological electromyography (EMG) findings in *abductor pollicis brevis* muscle [12,13].

Exclusion criteria

Patients with severe CTS and with axonal loss of median nerve confirmed by electrodiagnostic studies (absent or low amplitude of sensory nerve action potential (SNAP) and/or absent or low amplitude of compound muscle action potential (CMAP), 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 trauma), hypothyroidism, B12 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 as a risk factor for CTS, and previous carpal tunnel release were excluded.

Treatment protocol

Therapeutic US was administered in EG (In CG Sham US). The therapeutic dosage of US was frequency of 1MHz probe, and intensity of 1.0 W/cm^2, pulsed mode 1:4, with transducer of 5cm^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 twas 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, 5 days a week (working days only) for 2 weeks, followed by 4 treatments every other day for 2 weeks, and 6 treatments every two times pro weekly (3 weeks). Control of eligible study participants was done eight weeks after initial assessment. No side effects of the treatment were reported.

Individuals from 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 ultrasound (0.0 W/cm2 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 8 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 90 degrees of flexion. Each position was maintained for 5 sec. 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 1 month before or during the investigation period. For occasional pain relief, analgesic (Paracetamol) were allowed, but not non-steroidal antiinflammatory drugs (NSAID) drugs. None of the patients reported using Paracetamol during treatment period.

Clinical assessment and NCSs were evaluated at baseline and at 8 weeks after the initial assessment.

Statistical analysis

Data are presented as counts (percents) or means ± standard deviations (SD) depending on data type. Group comparisons were performed using Pearson chi square test, Cochrane-Armitage test (chi square test for trend) and Mann-Whitney U test. Within group testing was performed using Wilcoxon Signed Ranks test. Data analysis was performed in SPSS 20 (IBM corporation) 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, 2 (10%) males and 18 (90%) females, of whom 11 (55%) patients had unilateral and 9 (45%) bilateral CTS. EG Patient's age ranged between 34-69 years (mean 53.5±8.3 years). The CG was composed of 19 patients (26 hands) at baseline with drop off of 4 patients at random during the treatment. Therefore, we included only those (15 patients (21 hands) who finished the study. In CG there were 2 (13.3%) males and 13 (86.7%) females, of whom 9 (60%) with unilateral and 6 (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 treatment period.

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

There was significant improvement in EG group regarding pain intensity after the treatment (T2), while such difference was not observed in CG group (Table 2). The same improvement was noticed regarding superficial sensibility, where in the EG group, where a significant improvement of superficial sensibility was noticed after 8 weeks (T2) (Table 2).

In EG, there was significant reduction in frequency of positive Tinel's sign between baseline period (T1) and 8 weeks from the baseline assessment (T2) (Table 2).

In table 3 electrodiagnostic findings at baseline (T1) and after 8 weeks (T2) were presented. There was significant reduction in mDL values in individuals of EG, while significant increase in SNAP and SNCV were noticed in individuals of EG. Significant increase in SNCV was noticed for individuals of EG when compared with individuals of CG, 8 weeks after initial assessment (T2). For all evaluated electrodiagnostic parameters (distal latency, SNAP and SNCV) there was significant differences in delta values between EG and CG.

DISCUSSION

In our study, we aimed 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. We demonstrated after the treatment (T2), significant improvement in pain intensity and superficial sensibility in EG group versus CG group. Further, in EG, we noticed significant reduction in frequency of positive Tinel's sign between baseline period (T1) and 8 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 ultrasound may be offered. However, the effectiveness and duration of benefit of such 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 such treatment was shown to be beneficial in symptoms improvement after seven weeks period in another studies [4,11]. Ebenbichler et al. [17] also stressed out 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 8 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 positive sign was found in the EG group.

We 50%, while the percentage of patients with moderate pain intensity was reduced almost 3fold. 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 effects on pain symptom rather than on superficial sensibility.

Because on possible positive effects on US on nerve function and regeneration, as previously mentioned, significant changes in electrodiagnostic evaluation might be absent despite the significantly positive effects on symptoms improvement. In the study of 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 that are responsible for somatic pain are more sensitive to US treatment. It should be stressed as well that prolonged compression in carpal tunnel canal might lead to the loss of axons along with demyelination, thus disabling significant

improvement particularly in amplitude increasement, and in cases with severe axonal losses disabling improvement in conduction velocities as well. Thus, early and adequate diagnosis with an on-time proper treatment modality for patients with CTS is needed for optimal outcome.

Our results regarding electrodiagnostic evaluations in CTS patients that were treated with US therapy, are consistent with previous reports. We have obtained significant reduction in distal latency values in EG along with significant increase in SNAP and SNCV parameters in 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 sample are advised.

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

CONCLUSION

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

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

Characteristic	Treatment group (EG)	Control group (CG)	p value
Personal characteristics	**n=20 patients (29 hands)**	**n=15 patients (21 hands)**	
Age (years)	53.5±8.3	52.6±8.7	0.758[a]
Gender			
Female	18 (90%)	13 (86.7%)	1.000[b]
Male	2 (10%)	2 (13.3%)	
Job type			
Physical job	9 (45%)	6 (40%)	0.913[b]
Administrative work	6 (30%)	4 (26.7%)	
Housewife or other	5 (25%)	5 (33.3%)	

[a]t test;

[b]chi-square test

Table 2. Obtained results in patients with carpal tunnel syndrome (CTS) at baseline (T1) and after 8 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**	-

[a]between groups;

[b]within groups

Table 3. Electrodiagnostic findings at baseline (T1) and after 8 weeks (T2) (results are presented as means ± standard deviations)

Subjective symptoms	**T1**	**T2**	**p-value[b]**	**Delta**
mDL (II 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 (II 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 (II 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**

[a]Between groups;

[b]within groups

