Original Article

Comparison between Transcranial Direct Current Stimulation and Acupuncture on Upper Extremity Rehabilitation in Stroke: A Single-Blind Randomized Controlled Trial

Hathaiareerug C, MD[1], Vearasilp A, MD[2]

[1] Department of Physical Medicine and Rehabilitation, Phramongkutklao Hospital, Bangkok, Thailand

[2] Department of Physical Medicine and Rehabilitation, Panyananthaphikkhu Chonprathan Medical Center Srinakharinwirot University, Nonthaburi, Thailand

Objective: To compare the effects of transcranial direct current stimulation (TDCS) with traditional Chinese acupuncture on upper-extremity (UE) function among patients with stroke.

Materials and Methods: Participants with subacute to chronic stroke who had moderate to severe UE functional impairment were randomly allocated to the TDCS or electro-acupuncture group, then underwent three weeks of physical therapy and occupational therapy, with 20 minutes of a-TDCS (2 mA) or electro-acupuncture applied during training once weekly. Primary outcome was determined using the Fugl-Meyer Assessment of motor recovery at 1-month follow-up.

Results: The 18 participants were allocated into two groups. Fugl-Meyer Assessment increased in both the TDCS and electro-acupuncture groups (5.00±3.08, p=0.001 and 7.4±4.9, p=0.002, respectively). However, no difference was found between groups, and no significant difference was observed in grip strength and task specific performance in both groups.

Conclusion: The application of TDCS might provide benefits in recovering hand motor function among patients with subacute to chronic stroke but does not go beyond those of electro-acupuncture.

Keywords: Stroke, TDCS, Acupuncture

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According to the World Stroke Organization, one of the leading causes of long-term disability is stroke. However, only 12% of stroke survivors may achieve complete motor recovery after six months[1]. Around 50% to 60% of stroke survivors experience some degree of motor impairment and require partial assistance in activities of daily living (ADLs). After a stroke, interhemispheric excitability is relatively imbalanced resulting in poor upper extremity (UE) motor recovery outcomes[1]. These pose significant disability in functional performance and affect the quality of life, especially when the disability involves hand functions[2].

Without treatment, functional limitations may persist or worsen over time and lead to increasing dependency[2]. Because of the severe impact on the quality of life following a stroke, many studies have been conducted to minimize disability and improve performance in ADLs. Among these studies, transcranial direct current stimulation (TDCS) and acupuncture are outstanding newcomer interventions and appealing therapeutic options against stroke. These are given in addition to conventional therapy.

TDCS has shown the ability to rebalance interhemispheric excitability, gain motor recovery, and improve motor function in stroke[1]. Application of TDCS is particularly attractive due to its simplicity, safety, painless, minimal adverse effects, and is usually imperceptible during application[3].

Correspondence to:

Hathaiareerug C.

Department of Physical Medicine and Rehabilitation, Phramongkutklao Hospital, Bangkok 10400, Thailand.

Phone: +66-81-9165287

Email: chanasak.h@pcm.ac.th

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On the other hand, acupuncture has been increasingly practiced as adjunctive therapy for stroke and is widely accepted. Recently, more clinical trials have revealed positive effects in rehabilitation after acupuncture as complementary therapy. The positive effects include improved motor function and ADLs, decreased spasticity, and increased quality of life when administered during the subacute and chronic stages of stroke recovery[2,4,5].

The purpose of the present study was to compare the effects of TDCS and acupuncture on improving UE motor function. The authors hypothesis was that TDCS combined with conventional therapy improves functional outcome in upper extremities equivalent to conventional therapy with acupuncture among patients during subacute to chronic stroke stage of recovery.

Materials and Methods

Participants

Thirty patients with subacute to chronic stroke of more than one month were evaluated between May 1, 2015 and April 1, 2016 in the authors' rehabilitation department. Inclusion criteria for the study comprised of age between 20 to 80 years, presence of moderate to severe UE functional impairment (Fugl-Meyer Assessment [FMA] score 0 to 47), able to speak Thai, and demonstrated hemorrhagic or ischemic stroke by cerebral imaging. Exclusion criteria included unstable medical condition, upper limb contracture more than functional range of motion (ROM), presence of contraindication for TDCS such as metal in the head, implanted brain medical devices, presence of contraindication for electro-acupuncture (EA) such as wearing a pacemaker or embedded neural stimulator, epilepsy, malignant cardiac arrhythmia, pregnancy, traumatic conditions of the affected hand or peripheral nerve injury, presence of cognitive impairment as evaluated with the Thai Mental Status Examination with a score of less than 24, or psychiatric disorder and being unable to perform the given task or understand the instructions. According to these criteria, 18 patients were eligible for the study. All participants submitted informed consent and the study protocol was approved by the local ethics committee. The study protocol was registered in the Thai Clinical Trial Registry (registration number: TCTR20150629002).

Study design

The authors used a randomized controlled trial, single-blind design. All participants were allocated to the TDCS or EA groups using computer-generated blocks of four randomizations. The assessments were achieved by a physician who was blinded to group allocation.

Intervention

The study protocol including risks and benefits were explained to all participants and after obtaining informed consents, all participants were questioned regarding sex, age, dominant hand, paretic hand, onset of stroke, and characteristic of stroke. Participants were allocated to either TDCS or EA groups by sealed envelope with computer-generated blocks of four randomizations. The authors' blind-assessors recorded baseline participant characteristics including ROM, Brunnstrom stage, FMA, grip strength, and Purdue pegboard task score.

Both TDCS and EA groups received a 3-week intensive physical therapy and occupational therapy according to the patient-specific conventional stroke rehabilitation program, performed hour sessions three times weekly.

Dual-TDCS was performed with a DC-stimulator (NeuroConn, Germany). TDCS session was provided for 20 minutes once weekly for three weeks. TDCS delivered stimulation with electrical current intensity 2 mA (fade-in/-out 8s) through saline-soaked (0.9% NaCl) electrodes (35 cm^2) (anode placed over ipsilesional primary motor cortex (M1) region and cathode positioned over contralesional M1 region). The electrodes were secured above the area of M1 by experienced technicians. Current intensity gradually increased and decreased at the beginning and the end of sessions to diminish participants' perceptions.

In the EA group, an experienced acupuncturist performed individualized treatment based on traditional Chinese medicine (TCM) protocol, which was acupuncture at the acupoints prescribed base on Chinese medicine diagnosis, individually for each patient, for three sessions, with one session weekly. Acupuncture points were selected from the following, LI15 (Jian Yu), LI11 (Qu Chi), LI10 (Shou San Li), SJ5 (Wai Guan), LI4 (He Gu), DU20 (Bai Hui), DU24 (Shen Ting), GB13 (Ben Shen), and EX-HN1 (Si Shen Cong). The authors used sterilized disposable stainless-steel needles (diameter 0.25 to 0.32 mm, length 25 to 40 mm) for all treatments.

All patients received a TCM evaluation at each visit determining the specific acupuncture points and stimulation strategies. After routine disinfection, participants were punctured at acupoints with specific body acupuncture points used as an appendix.

Needles were inserted to acupoints until participants obtained Deqi response[6]. Then electrical

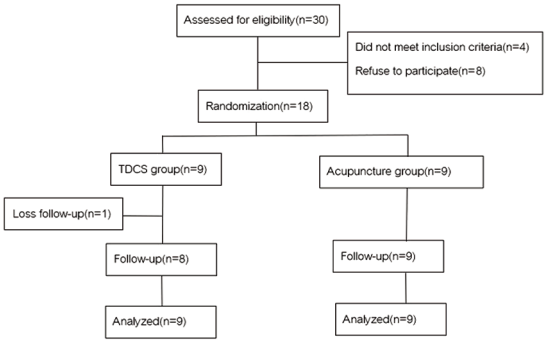

Figure 1. Consort diagram.

stimulator (SDZ-II nerve and muscle stimulator, Hwato) was connected using discontinuous wave, a frequency of 2 Hz and at an intensity within the patient's tolerance for 20 minutes[5,7].

After completing three sessions of TDCS or EA and at 1-month follow-up, all participants were assessed for FMA, grip strength, and Purdue pegboard task by blind assessor (Figure 1).

Outcome measurement

Fugl-Meyer assessment: Motor function was assessed using FMA with a sub-section of the upper extremities (scale range 0 to 66). During the test, the authors used a tennis ball, a small spherical shaped container, a reflex hammer, and a pen as the equipment to perform FMA. The test was conducted in a quiet space to allow patients to move around freely. FMA were scored on a 3-point ordinal scale, 0=cannot perform, 1=performs partially, and 2=performs fully. Severe and moderate UE functional impairment were defined as FMA score 0 to 19 point and 20 to 47 points, respectively[8].

The blind-assessor assessed participants three times for each item, and the highest scores was used. Except for the coordination task, only scores of the first performance were recorded[4,7].

Grip strength: A dynamometer was used to evaluate grip strength while participants were seated with their hand resting on a desk. Participants were asked to grasp against the dynamometer as hard as possible for three seconds (thumbs in the beneath position) with the other hand resting on the thigh.

Participants performed one practice trial before two measurements, with a 60-second rest between each trial. The authors averaged and recorded the results[4,9].

Task specific test: The Purdue pegboard test was used to determine dexterity. Patients had to pick up pegs one by one and inserted as many as possible in the holes of the board in 30 seconds. The score comprised the number of pegs placed in holes. Patients had three trials and mean scores for each hand were recorded[1].

Statistical analysis

The authors calculate sample size using Shoulder FMA score from prior study[10] with 80% power and alpha error at 0.05, our sample size for each group of intervention is 15.

Data were analyzed by intention to treat analysis protocol. Demographic data and baseline variables were expressed as mean ± standard deviation (SD) and median (interquartile range). The Shapiro-Wilk test was used to identify whether the data were normally distributed. Paired t-test and repeated measure ANOVA were used to analyze primary outcomes for pre- and post-treatment and between group comparison respectively. Mann-Whitney U and Wilcoxon sign rank tests were used to analyze secondary outcomes. The data were analyzed with SPSS 18.0 (SPSS Inc.) for Windows, the results with a p-value of less than 0.05 were considered statistically significant.

Results

In all, 18 participants underwent the TDCS or EA program between May 1, 2015 and April 1, 2016. Only one of the participants missed the follow-up evaluation at one month, so single imputation with mean was used for the missing data. The baseline demographic of TDCS and control group are shown in Table 1.

Table 2 summarizes the present study outcomes at immediately after completing the 3-week rehabilitation program with TDCS or EA, and at 1-month follow-up. The study revealed FMA score significantly improved in both TDCS and EA groups one month after finishing intervention (mean±SD: 5.0±3.1; p=0.001, and 7.4±4.9; p=0.002, respectively). The EA group showed significant increase in grip strength (p=0.049), but not in pegboard score (p>0.05). Moreover, both pegboard score and grip strength significantly improved in the TDCS group (p=0.027 and 0.028, respectively). However, neither the TDCS nor the EA groups showed significant different benefits over the other group regarding FMA, pegboard score, and grip strength (p=0.420, 0.425, and 0.193, respectively).

Discussion

The addition of TDCS or EA to conventional therapy did not provide significant difference in hand motor function improvement among patients

Table 1. Baseline demographic data

Variables	TDCS group (n=9) n (%)	Electro-acupuncture group (n=9) n (%)
Age (years), Mean±SD	56.4±7.7	58.8±9.7
Sex: female	1 (11.1)	2 (22.2)
Dominant hand: right	9 (100)	8 (88.9)
Paretic hand: right	4 (44.4)	2 (22.2)
Onset of stroke		
Subacute (1 to 3 months)	7 (77.7)	7 (77.7)
Chronic (more than 3 months)	2 (22.2)	2 (22.2)
Average time from onset to randomization, Mean±SD	6.4±4.4	5.4±2.7
Characteristic		
Ischemic	6 (66.6)	7 (77.7)
Hemorrhagic	3 (33.3)	2 (22.2)
Area		
Cortical	1 (11.1)	1 (11.1)
Corticosubcortical	4 (44.4)	5 (55.5)
Subcortical	4 (44.4)	3 (33.3)
Upper extremity dysfunction status		
Moderate	4 (44.4)	3 (33.3)
Severe	5 (55.5)	6 (66.6)
Fugl meyer assessment, Mean±SD	38.2±17.1	31.6±13.6
Brunnstrom stage, Median (IQR)	5 (2, 5)	3 (2.5, 5)
Pegboard score, Median (IQR)	0 (0, 1.5)	0 (0, 2)
Grip strength (kg), Median (IQR)	7.1 (2.5, 13.5)	5.1 (0, 6.5)

SD=standard deviation; IQR=interquartile range

with subacute to chronic stroke. The present randomized control trial was the first trial to answer this research question. However, both TDCS and EA groups improved hand function compared with pre-intervention. Obvious enhancement was seen in FMA and hand dexterity, yet little improvement was observed in grip strength. These adjunctive therapies were proven to benefit stroke treatment although the present study did not compare the results with conventional therapy alone. The additional effects of TDCS have been reported in several articles[1,11-14]. A meta-analysis of eight high quality RCT focusing on hand function recovery in chronic stroke provided evidence that TDCS may benefit motor function of the paretic upper limb[2]. Traditional Chinese acupuncture also proved to benefit patients with stroke[5,15,16]. Some studies reported additional effects of acupuncture on UE recovery[4,17].

The present study showed improvement of grip strength in both groups (TDCS p=0.028, EA p=0.049). However, when compared between the two groups, no significant difference was observed. Related studies have suggested that EA improved hand function especially grip strength and dexterity both in patients with acute and chronic stroke and the effects persisted for more than six months[2,4]. In addition, several studies have revealed TDCS produced benefits in grip strength and dexterity as well. On the other hand, pegboard score significantly improved only in the TDCS group (p=0.027). The present study showed improvement in the EA group too, but without significance. This may have been due to the small sample size.

Related studies have proposed that inter-hemispheric interaction changes after stroke. Downregulation of excitability was found in

Table 2. Outcomes at baseline and end-of-study by group

Outcome	TDCS (n=9)	Electro-acupuncture (n=9)	Between group		
			Different	p-value	95% CI
FMA, Mean±SD					
Baseline	38.2±17.1	31.6±13.6			
After treatment	40.4±16.7	33.4±12.7	7.0±6.9	0.296[d]	–7.8 to 21.8
1 month post treatment	43.2±16.0	38.6±13.9	5.9±7.1	0.420[d]	–9.2 to 20.9
Baseline to 1 month diff	5.0±3.1	7.4±4.9			
p-value (95% CI)	0.001 (2.6 to 7.3)[f]	0.002 (3.6 to 11.2)[f]			
PEG, Median (IQR)					
1 month post treatment	3 (0, 3.5)	0 (0, 4.5)		0.425[e]	
Baseline to 1 month, p-value	0.027[a]	0.065[a]			
GRIP, Median (IQR)					
1 month post treatment	8.4 (2.7, 16.2)	8.0 (2.5, 12.0)		0.193[e]	
Baseline to 1 month, p-value	0.028[a]	0.049[a]			

TDCS=transcranial direct current stimulation; FMA=Fugl-Meyer Assessment score; PEG=pegboard score; GRIP=grip strength; SD=standard deviation; IQR=interquartile range; CI=confidence interval

[f] Paired t-test, [d] Repeated measure ANOVA, [e] Mann-Whitney U, [a] Wilcoxon sign rank

ipsilesional M1, while upregulation of excitability was found in contralesional M1. TDCS rebalances cortical excitability through the cathode (inhibited unaffected motor cortex) and anode (increased excitability in affected cortex)[1-3,11,14,18]. Thus, motor function recovery was enhanced. Acupuncture was proven to improve functional recovery in stroke as well[2,4,5] by increasing activity in the ipsilesional motor cortex.

Minor side effects were reported in related studies of TDCS, such as tingling sensation, dizziness, nausea, and anxiety[11,12,18]. The present study also documented that few of our participants reported a similar effect. In contrast to former studies, one of our participants reported a brief aggressive mood after second TDCS stimulation. However, his basic personality was previously described as aggressive, but this did not interfere with the training. Most patients with stroke were prescribed antiplatelet or anticoagulant therapy, which may cause bleeding tendency. Applying TDCS could be a good option for patients with bleeding tendency or needle-phobia instead of EA.

Limitation

The present research was limited in the numbers of cases eligible to study. Most patients with stroke would like to obtain the authority to choose the modality of treatment themselves or to achieve both of our interventions. The number of participants, which was less than expected, might have affected to the result. The authors suggest recruiting more participants to increase the accuracy of the study. As a result of unstratified randomization, baseline FMA between the two groups were numerical different; however, the authors found no statistical difference. These potential biases were managed by using mean difference between baseline and post-intervention. Another limitation was that there was no comparison among TDCS, EA, and conventional therapy groups. In addition, most of the participants were patients of subacute stroke. Thus, the effects of spontaneous recovery or placebo effects could not be excluded. Furthermore, the authors did not follow the effect of the modality over a long period. A long-term study is needed to know whether the improvements persisted or not.

Conclusion

The present study could not conclude that TDCS contributed UE advantages beyond EA among stroke patients. However, adding TDCS and EA provided benefits in hand motor function recovery among patients with subacute to chronic stroke. Using TDCS as an adjunctive therapy should be considered, and further studies using a larger scale are recommended.

What is already known on this topic?

Acupuncture is widely used as an adjunct treatment in term of acceptable alternative for stroke,

however, many patients had problems with needle phobia and bleeding risks owing to antiplatelet taken.

What this study adds?

To enhance upper extremities recovery in stroke patients, it is suggested that transcranial direct current stimulation might be used in place of acupuncture. TDCS also is a good option for patients with bleeding tendency.

Conflicts of interest

The authors declare no conflict of interest.

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