Effect of electro-scalp acupuncture on acute ischemic stroke: a randomized, single blind, trial

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Abstract

OBJECTIVE: To determine the clinical efficacy and safety of electro-scalp acupuncture in the treatment of patients with acute ischemic stroke.

METHODS: Totally 74 patients with acute ischemic stroke were enrolled and divided into either body acupuncture (Control) or electro-scalp acupuncture (ESA) groups according to randomized controlled principle. The patients in the control group were given body acupuncture treatment once daily for 28 d, whereas except for the body acupuncture, electro-scalp acupuncture was additional treatment given to the ESA group. Neurological deficits, everyday motor function and muscle strength were evaluated at baseline and the 28th d by NIH Stroke Scale (NIHSS), Fugl-Meyer Assessment (FMA) and Modified Barthel Index Score (MBI), respectively.

RESULTS: There were not obvious between-group differences in the baseline efficacy parameters (NIHSS, FMA and MBI) (all \( P > 0.05 \)), whereas significant between-group differences were found in post-treatment NIHSS, FMA-UE and MBI scores (all \( P < 0.05 \)). After acupuncture treatment, systematic within-group improvements were found in the two groups for any of the efficacy parameters assessed (all \( P < 0.01 \)), and the ESA group showed higher significant improvements in NIHSS, FMA-UE and MBI scores (all \( P < 0.05 \)).

CONCLUSION: Electro-scalp acupuncture was efficacious in the treatment of acute ischemic stroke, which resulted in meaningful improvements in neurologic function, motor function and activities of daily living of patients.

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Keywords: Stroke; Scalp acupuncture; Neurologic manifestations; Motor disorders; Activities of daily living

INTRODUCTION

Stroke is the second commonest cause of death and leading cause of adult disability in China, which has
imposed a heavy burden on families and societies. After ischemia onset, most of the neurons in the ischemic core undergo necrosis and apoptosis, whereas in the border zone of the ischemic area, many neurons are lethargic and non-functional due to low oxygen level, which can restore their normal function if collateral vessels were formed as early as possible. Therefore, the central goal of therapy in acute ischemic stroke is to provide protection to the neurons in the ischemic penumbra, and early effective treatment after ischemia is very important to promote restoration of blood flow and neuronal function.

Scalp acupuncture is one of several specialized acupuncture techniques with a specific body location, which has been proven as an effective method for the treatment of stroke. Because the treatment zones located on the scalp usually target the corresponding areas of the brain; therefore scalp acupuncture could directly excite the cerebral cortex and produce beneficial effects on diseases. Some studies have confirmed that scalp acupuncture could improve neurological deficits and promote recovery of limb motor function in stroke patients by increasing blood flow and oxygen delivery to the brain and decreasing excitotoxic injury.

During our clinical practice, we found that the efficacy of scalp acupuncture administered twice per day was much better than once per day, suggesting the efficacy is closely associated with the quantity of stimulation. In the acute phase of stroke, it is difficult to achieve enough quantity of stimulation if the patients were given acupuncture treatment just once daily. We can increase twisting frequency and amplitude and prolong the period of time to achieve effective stimulation, but which can lead to localized pain around acupuncture points, and some elderly patients do not tolerate it. Electrical stimulation can enhance the efficacy of scalp acupuncture treatment. The stimulation intensity and frequency can be controlled through current regulation according to the reactions of patients. Although some literatures have proven that electro-scalp acupuncture was an effective method in the treatment of early ischemic stroke, clinical studies with restrictive design and conduct were still less, resulting in the evidence on the effectiveness of electro-scalp acupuncture in treating the acute stroke patients was not powerful enough. So, in this study, we designed the randomized, controlled clinical trial to determine the effectiveness and safety of electro-scalp acupuncture among patients with acute stroke.

**MATERIALS AND METHODS**

**Design**

The study was a randomized, single blind, controlled, parallel-group trial to determine the efficacy and safety of electro-scalp acupuncture (ESA) compared with body acupuncture (Control) in the treatment of patients with acute ischemic stroke (Figure 1). All 74 participants were recruited from inpatients in the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine from June 2014 to March 2015. The patients were randomly allocated into either control or ESA groups in a ratio of 1:1 under the help of a computer-generated, random allocation sequence and the random list was generated with SPSS 13.0 (SPSS Inc., Chicago, IL, USA). All patients in the two groups were given body acupuncture treatment once daily for 28 d. Except for the body acupuncture, electro-scalp acupuncture was additional treatment given to the ESA group. Neurological deficits, daily motor function and activities of daily living of patients were evaluated at 0 and the 28th d using corresponding scales.

![Flowchart for this clinical research study](image)

**Inclusion criteria**

The acute ischemic stroke patients were diagnosed in accordance with the standards for diagnosis of cerebral
infection developed by the Fourth National Academic Meeting of Cerebrovascular Disease in 1995. Inclusion criteria for subjects were: (a) meeting the diagnostic criteria and the types of cerebral infarction of these patients were atherosclerotic infarcts or lacunar infarcts confirmed by head CT or MRI scanning; (b) physical signs of brain function damage persisted for 2 to 15 d; (c) at Brunnstrom stages 1 to 2.

Exclusion criteria
Individuals should be excluded: (a) patients with intracerebral hemorrhage or subarachnoid hemorrhage; (b) patients with transient ischemia attack, and patients with cerebral infarction caused by brain tumor, traumatic brain injury, metabolic disorders, rheumatic heart disease, coronary heart disease or other heart diseases combined with atrial fibrillation; (c) patients with severe diseases of liver, kidney, hematopoietic system or endocrine system; patients with acute and chronic infections; patients with bone and joint disease; (d) patients with secondary epilepsy, mental disorder, Parkinson’s disease or severe sensory deficits; patients in an unstable condition; patients with needle phobia; (e) pregnancy or breastfeeding women; (f) patients not in the acute phase; (g) patients at Brunnstrom stages ≥ 3.

Termination criteria
Termination Criteria were (a) patients occurred serious adverse events or complications which resulted in discontinued treatment; (b) patients themselves decided to withdraw the treatment; (c) patients could not complete the treatment.

Treatments
All patients were given basic medical care, including control of infection, maintenance of appropriate electrolytes balance, oxygenation and blood pressure, as well as other symptomatic treatment. The treatment strategies for acupuncture were developed in a consensus process with experienced acupuncture experts. The acupuncture therapy was performed by six acupuncturists who qualified Chinese medicine practitioner license from the Ministry of Health of the People’s Republic of China and had more than 7 years of clinical experience. The sterile, disposable needles with a diameter of 0.25 mm and a length of 40 mm (Huatuo, Suzhou Medical Instruments Factory, China) were used in this study. The prescription for body acupuncture treatment consisted of Neiguan (PC 6), Renzhong (GV 26), Sanyinjiao (SP 6), Jiujian (HT 1), Weizhong (BL 40) and Chize (LU 5), which were usually applied in clinical practice for patients with acute cerebral infarctions. The needles were manipulated until “De Qi” arrived (in which patients experience an acid expansion or numbness feeling considered to be indicative of effective needling). To evoke needle sensation, the needles were inserted perpendicularly 10-20 mm into Neiguan (PC 6), then were twirled for 1 min and were lifted and thrust 2-3 times. The needles were inserted obliquely 6-10 mm into Renzhong (GV 26), then were vigorously stimulated with bird pecking technique until tears came to the eyes. The needles were inserted perpendicularly 20-30 mm into Jiujian (HT 1) and Chize (LU 5), then were stimulated with lifting and thrusting technique until movement of the upper limbs was elicited. The needles were inserted obliquely 20-30 mm into Sanyinjiao (SP 6) and perpendicularly 10-20 mm into Weizhong (BL 40), then were stimulated with lifting and thrusting technique until movement of the lower limbs was elicited.

Except for the body acupuncture, electro-scalp acupuncture was additional treatment given to the ESA group. The MS6 line (anterior oblique parietal-temporal line) corresponds to the primary motor area. The MS6 line is divided into three segments: the superior 1/5 which corresponds to the motor segment of the inferior limb and the trunk; the middle 2/5 which correspond to the motor segment of the superior limb; the inferior 2/5 which correspond to the motor segment of the face and language. So, the upper 3/5 of MS6 line was selected as the region using electro-scalp acupuncture stimulation. The upper 3/5 of MS6 line was divided into three equal parts and each part was inserted equidistantly with an acupuncture needle from top to bottom. The needles were obliquely inserted into the scalp’s subaponeurotic layer at 30-degree angle, then paralleled to the scalp and pierced 25 to 35 mm deep along the MS6 line. The needles were connected with an electro-stimulator, stimulated with electrical pulse (200 Hz) for 10 min and retained at the position for another 20 min. All the patients were given respective treatment once daily for 28 d and had a rest every 7 d.

Outcome measures
Neurological deficits, daily motor function and activities of daily living of all the patients were evaluated before and after treatment.
Neurological deficits were evaluated by NIH Stroke Scale (NIHSS), which is a 15-item impairment scale, intended to evaluate neurologic outcome and degree of recovery for patients with stroke. The total scores for NIHSS range from 0 to 42, and higher scores indicate more severe stroke.

Motor function of upper and lower extremities were determined by Fugl-Meyer Assessment (FMA), which is a scale to assess motor functioning, balance, sensation and joint functioning in patients with post-stroke hemiplegia. The FMA scores range from 0 to 66 for upper extremity (FMA-UE) and from 0 to 34 for lower extremity (FMA-LE); and lower scores suggest poorer motor function.

Activities of daily living of patients were measured by Modified Barthel Index Score (MBI), which shows the degree of independence of a patient from any assistance. The MBI includes 10 domains of functioning...
(activities) and its total scores range from 0 to 100 with higher scores indicating greater independence.

Statistical methods
The results were presented as mean ± standard deviation (x ± s) or frequencies according to the type of variables. For the results of NIHSS, FMA and MBI scales, paired sample t test and independent sample t test were used for intergroup and intragroup comparisons, respectively. The baseline characteristics of patients in the two groups were compared using the Pearson’s χ² test. The significance level for all statistical analyses was set at P < 0.05. All statistical analyses were performed using SPSS 13.0 (SPSS Inc., Chicago, IL, USA).

RESULTS
Participants
The demographic characteristics (age and sex) and the baseline efficacy parameters (NIHSS, FMA and MBI) of the patients in the two groups were shown in Table 1. There were no significant differences in any of the demographic or baseline characteristics between the two groups. All the patients completed their treatments according to the present time schedule.

<table>
<thead>
<tr>
<th>Item</th>
<th>Control</th>
<th>ESA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>65.5±19.2</td>
<td>66.8±16.1</td>
<td>0.282</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>26/11</td>
<td>30/7</td>
<td>0.306</td>
</tr>
<tr>
<td>NIHSS</td>
<td>10.9±2.6</td>
<td>11.3±3.1</td>
<td>0.084</td>
</tr>
<tr>
<td>FMA-UE</td>
<td>3.2±1.3</td>
<td>3.1±0.8</td>
<td>0.206</td>
</tr>
<tr>
<td>FMA-LE</td>
<td>3.4±1.4</td>
<td>3.6±1.7</td>
<td>0.183</td>
</tr>
<tr>
<td>MBI</td>
<td>18.8±5.1</td>
<td>18.5±4.9</td>
<td>0.176</td>
</tr>
</tbody>
</table>

Notes: both the control and ESA groups were given body acupuncture treatment, and the prescription included Neiguan (PC 6), Renzhong (DU 26), Sanyinjiao (SP 6), Jiquan (HT 1), Weizhong (BL 40) and Chize (LU 5). Electro-scalp acupuncture was additional treatment given to the ESA group, and the upper 3/5 of MS6 line was stimulated with electrical pulse. All the patients were given respective treatment once daily for 28 d and had a rest every 7 d. NIHSS: NIH stroke scale; FMA-UE: Fugl-Meyer assessment of upper extremity; FMA-LE: Fugl-meyer assessment of lower extremity; MBI: modified barthel index score; ESA: electro-scalp acupuncture; P value: between-group differences.

Outcome measures
There were not obvious between-group differences in pre-treatment NIHSS scores (P > 0.05), but significant differences were found in post-treatment NIHSS scores between the two groups (P < 0.05). After acupuncture treatment, significant within-group improvements were detected in the two groups (all P < 0.01), and the ESA group showed higher significant improvements (Table 2). There were not significant between-group differences in pre-treatment FMA-UE scores (P > 0.05), but obvious differences were found in post-treatment FMA-UE scores between the two groups (P < 0.05). After acupuncture treatment, systematic within-group improvements were found in the two groups (all P < 0.01), and the ESA group showed higher significant improvements (P < 0.05, Table 2).

There were not significant between-group differences in either pre- or post-treatment FMA-LE scores (all P > 0.05). After acupuncture treatment, obvious within-group improvements were found in the two groups (all P < 0.01, Table 2).

No significant between-group differences were found in pre-treatment MBI scores (P > 0.05), but obvious differences were found in post-treatment MBI scores between the two groups (P < 0.05). After acupuncture treatment, obvious within-group improvements were found in the two groups (all P < 0.01), and the ESA group showed higher significant improvements (P < 0.05, Table 2).

Safety and tolerability outcomes
During the treatment of acute ischemic stroke, 8 patients (5 in the control group and 3 in the ESA group) experienced punctate hemorrhage after withdrawing the needles (we can stop the bleeding when pressing for 5-10 s with the help of sterile dry cotton), and 5 patients (2 in the control group and 3 in the ESA group) had small bruises located around acupuncture points on the limbs, but the bruises would fade in several d without any treatment. No serious adverse events were reported by the patients in the two groups.

Unexpected finding
Interestingly, some patients in the ESA group (9/37, 24.32%) were able to complete complex fine motor tasks of the hands, such as the ability to hold and move pencils with control and to use a toothbrush and hairbrush. However, only 2 patients (5.41%) in the control group could perform these fine motor skills.

DISCUSSION
Scalp acupuncture is an acupuncture technique that targets brain functional zones, such as sensory, memory and motor. It is effective in treating disorders of the central nervous system, such as stroke, cerebral injury, hemiplegia, aphasia, senile dementia, Parkinson’s disease and other brain disorders. Studies have shown that scalp acupuncture could significantly improve muscle strength and muscle tension of the upper and lower limbs of acute ischemic stroke patients, and facilitate the sensory and motor functional recovery at the end of treatment and 2-year follow-up. The MS6 line extends from Sishengcong oblique to Xuanli (GB 6) and traverses the Gall Bladder and Bladder Meridians diagonally. The MS6 line corresponds to the primary motor area, therefore it is usually chosen as stimulation area.
of acupuncture for the treatment of stroke patients. The MS6 line is divided into three segments: the superior 1/5 which corresponds to the motor segment of the inferior limb and the trunk; the middle 2/5 which correspond to the motor segment of the superior limb; the inferior 2/5 which correspond to the motor segment of the face and language. So, in this study, the upper 3/5 of MS6 line was stimulated to treat paralysis of the upper and lower extremity. We found significant positive changes in NIHSS, FMA-UE, FMA-LE and MBI scores for acute stroke patients after scalp acupuncture treatment, indicating meaningful improvements in their neurological function, motor function and activities of daily living. Moreover, we also found selective influence on fine motor tasks of hands in patients of the ESA group.

Acupuncture had revealed the ability to exert a continuing influence on the different areas of the brain, even after the needles were removed from the body, suggesting that acupuncture stimulation have a time-variant feature, and may be acupoint-specific. As a result, the neurological function, motor function and the motor function activities of daily living of stroke patients could be improved significantly after acupuncture treatment.

Scalp acupuncture has advantages over traditional body acupuncture. It is much more effective in treating neurological conditions. Furthermore, scalp needles do not interfere with bodily movements, whereas body needles must be withdrawn to avoid bending or breaking. Because a pulsating electrical current was applied to acupuncture needles to stimulate the acupuncture points, electro-scalp acupuncture could provide stronger and longer stimulus, and reduce total treatment time of patients. Therefore, electro-scalp acupuncture combined with body acupuncture could achieve better efficacy in acute ischemic stroke patients than traditional body acupuncture.

In conclusion, electro-scalp acupuncture treatment was efficacious and well tolerated in treating acute phase of stroke, resulting in meaningful improvements in neurological function, motor function and activities of daily living of patients. Electro-scalp acupuncture gives physicians a promising and effective treatment option for stroke, with few adverse effects or contraindications.

**REFERENCES**


