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Research Article

Effect of electro-scalp acupuncture on acute ischemic stroke: A randomized, single blind, trial[☆]Liu Xiaoxi^a, Zhang Xuezhong^{a,*}, Nie Kun^a, Jia Yujie^a, Li Jing^a, Ling Zhenzhen^b, Wang Yao^b, Chang Shichen^b^a Department of Acupuncture and Moxibustion, First Teaching Hospital of Tianjin University of Traditional Chinese Medicine, Tianjin 300193, China^b Graduate School, Tianjin University of Traditional Chinese Medicine, Tianjin 300193, China

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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 $P < 0.05$).**Conclusions:** 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.© 2018 Traditional Chinese Medicine Periodical Press. Published by Elsevier B.V.
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1. 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 [1]. 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 [2]. 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 effect 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 [3–5].

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

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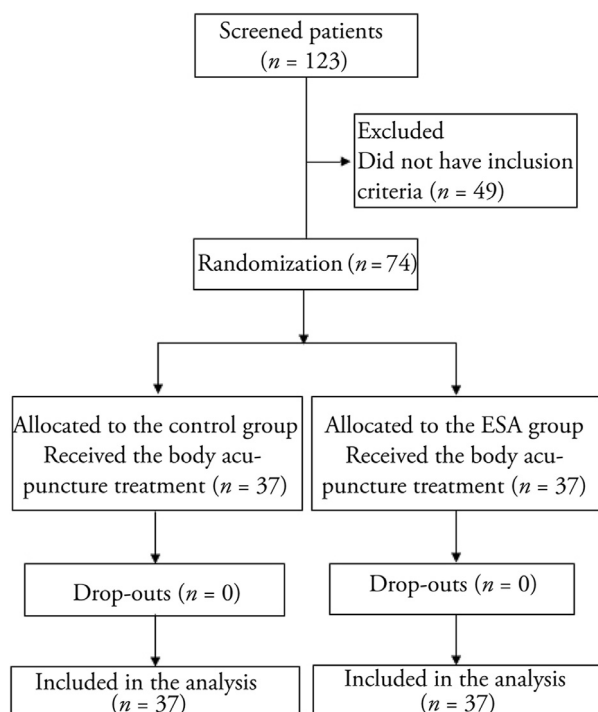


Fig. 1. Flow chart for this clinical research study.

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 [6], 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.

2. Material and method

2.1. 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 (Fig. 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.

In this study, the physicians and acupuncturists could not be blinded due to the nature of the intervention. Blinding was maintained for data collection and analysis, which were performed by two blinded evaluators respectively. Apart from the differences in treatment methods used between the two groups, all subjects were treated as equally as possible. During the intervention, acupuncturists and data collection staff would visit patients at different time so they could not exchange information with each other.

All participants were provided written informed consent. The study was performed according to common guidelines for clinical trials [Declaration of Helsinki, International Conference on Harmonization (ICH)/WHO Good Clinical Practice standards (GCP) including certification by an external audit].

2.2. Inclusion criteria

The acute ischemic stroke patients were diagnosed in accordance with the standards for diagnosis of cerebral infarction 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.

2.3. 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 .

2.4. 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.

2.5. 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 6 years (median 7.2 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), Jiquan (HT 1), Weizhong (BL 40) and Chize (LU 5), which were usually applied

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