Scalp-acupuncture for patients with hemiplegic paralysis of acute ischaemic stroke: a randomized controlled clinical trial

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Abstract

OBJECTIVE: To evaluate the efficacy of scalp-acupuncture on subjects with hemiplegic paralysis of acute ischaemic stroke (AIS).

METHODS: One hundred and twenty patients with hemiplegic paralysis of 1 to 7 d post stroke, aged 40 to 75 years, were randomly allocated to receive either standard care (control group) or standard care plus 30 min of scalp-acupuncture applied to the bilateral anterior oblique line of the vertex-temporal (MS6) for 14 d (6 d/week) (trial group). The outcome measures included the National Institutes of Health Stroke scale (NIHSS) for neurological deficits, the Fugl-Meyer assessment (FMA) for limb impairment, and Barthel index (BI) for activities of daily living before and after intervention. The manual muscle test (MMT) was assessed at pre-intervention, at the first post-intervention immediately, and at the 14th day after intervention commencement. Measurements were recorded by a blinded investigator at different time points after initiating the intervention.

RESULTS: The trial group had a greater increase in MMT (P < 0.05), FMA, and BI scores (P < 0.01), and a greater decrease in NIHSS scores (P < 0.01) from pre-intervention to post-intervention, and the control group had a greater increase in MMT scores (P < 0.05), and a greater decrease in NIHSS scores (P < 0.01) from pre-intervention to post-intervention. The improvement in MMT (P < 0.01), FMA, BI (P < 0.05), and NIHSS (P < 0.01) scores in the trial group was superior to that of the control group. Meanwhile, scalp-acupuncture intervention had an immediate effect on myodynamia of patients with hemiplegic paralysis after acute ischaemic stroke in this randomized controlled trial.

CONCLUSION: The early scalp-acupuncture intervention after stroke effectively increased myodynamia of the affected limbs, improved neurological deficit degrees, and daily living ability.

Keywords: Stroke; Paralysis; Scalp-acupuncture; Randomized controlled trial
INTRODUCTION

Ischaemic stroke, which accounts for approximately 60% to 80% of strokes, is one of the most common types of stroke and is an important cause of limb hemiplegic paralysis, causing severe disability.1 Ischaemic stroke morbidity in China is 8.6-314 out of every 100 000 males and 76.7-212.2 out of every 100 000 females, and this percentage increases by 8.7% annually.2 The mortality of ischaemic stroke decreased significantly in the past, but its disability has been stably high.3 Limb hemiplegic paralysis is a common clinical symptom of ischaemic stroke, and its characteristic manifests as a loss or reduction of the autonomous activity of motor units.4 A study showed that patients’ satisfaction with life was related to the intensity of activity at one year after a stroke.5 Hence, it is particularly important to promote the recovery of motor function of hemiplegic limbs in ischaemic stroke patients, especially in the acute phase, to improve the patient’s activity ability and to assist with patients return to society. Acupuncture, as a complementary and alternative medicine, has been the focus of some public attention because the evidence has shown that acupuncture can improve the motor function of the limbs and the quality of life in ischaemic stroke patients.6 Scalp-acupuncture, which is based on the theory of traditional acupuncture, modern anatomy, neurophysiology, and biological holography, is a minor acupuncture therapeutic method that stimulates subcutaneous tissue of the scalp projection region of the cortical functional region by acupuncture needles. Several studies have shown that scalp-acupuncture could improve the myodynamia,7 limb motor function,8-11 and haemorheology index,8,12 and reduce the level of nitric oxide and nitric oxide synthase in blood plasma in patients with hemiplegic paralysis.13-15 But another randomized controlled trial (RCT) showed that single scalp-acupuncture did not improve limb motor function in patients with hemiplegic paralysis [Barthel index (BI) and Rankin scores], but only improved the National Institutes of Health Stroke scale (NIHSS) scores.13 These studies drew a controversial conclusion. Hence, there is a question about scalp-acupuncture being beneficial for ischaemic stroke.

It is well known that acupuncture efficacy is closely related to starting time, frequency of acupuncture sessions, and course of the treatment, but especially to starting time. Hsing et al’s15 RCT had methodological deficits, including inclusion criteria [recovery time patients, 1.5-6 years of duration, (7.9 ± 4.3) years], indeterminate randomizing scheme, lack of sample size estimation, and no use of the intention-to-treat (ITT) analysis. These design deficits may make their findings far from conclusive. More high-quality clinical RCTs are required to investigate the effectiveness of scalp-acupuncture treatment for hemiplegic paralysis following ischaemic stroke. In this study, we investigated the effectiveness of scalp-acupuncture for hemiplegic paralysis in the acute phase of ischaemic stroke.

MATERIALS AND METHODS

Participants

Inpatients with hemiplegic paralysis of post ischaemic stroke were recruited at the second hospital of the University of Lanzhou from October 1st 2015 to September 30th 2016. The researcher in charge of recruitment explained the study in detail and summarized the potential benefits of this RCT to patients with hemiplegic paralysis following ischaemic stroke. Patients who showed interest in participating were assessed according to the inclusion and exclusion criteria on their first visit.

Inclusion criteria included: (a) participants will be male or female, 40-75 years of age; (b) meeting the criteria of diagnosis of cerebral infarction,12 and classification criteria of ischaemic stroke;13 (c) cerebral infarction will be in unilateral intracereval artery system, and verified by magnetic resonance imaging (MRI) and diffusion-weighted imaging (DWI); (d) first onset, course of 1 to 7 d; (e) total Fugl-Meyer assessment scores will be less than 85, and various degree of hemiplegic paralysis will be at upper or lower limbs; (f) the grade of yodynamia of the affected side at the upper limb will be between 0 and 2 and that of affected side at the lower limb will be between 0 and 3; (g) patients will be conscious, and their vital signs (VS) will be stable.

Exclusion criteria included: (a) transient ischaemic attack (TIA); (b) reversible ischaemic neurological deficit (RIND); (c) complete stroke (CS); (d) pregnancy; (e) other diseases that seriously affect limb motor function; (f) past medical history of craniocerebral trauma, encephalitis, tubercular meningitis; (g) other complication (cognitive disorder, alollalia, swallowing disorder, pneumonia, urination disorder, deep venous thrombosis); (h) severe primary diseases of other systems that are a threat to life; (i) severe mental illness (depression, chronic dementia, epilepsy).

Prior to enrolling in the study, all participants signed a statement of informed consent, and volunteered for this RCT. The research protocol has been reviewed and approved by the Ethics Committee of the second hospital of the University of Lanzhou (2016A-003). All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5).18

Study design

This was a single-centre, assessor-blinded, parallel group RCT that conformed with the Consolidated Standards of Reporting Trials19 and the Standards for Reporting Interventions in Clinical Trials of Acupuncture Guidelines for acupuncture studies.20
Sample size estimation

The sample size estimation for this RCT was based on the change in the FMA scores according to our previous study. The calculative parameters were set as follows: polled standard deviation \( \sigma = 18 \), difference (d) = 10, size of test \( \alpha = 0.05 \), power of test \( \beta = 0.20 \), \( Z_{\alpha/2} = 1.96 \), \( Z_{\beta} = 1.28 \), and 0.842. According to formula\(^{27} \) of a sample size of 50 participants would be recruited in each group. With an attrition rate of 20%, we would estimate 120 participants to complete this RCT, with 60 individuals in each group.

Randomization

After baseline assessment, participants were allocated randomly to two groups: (a) the trial group (scalp-acupuncture group plus standard care) and (b) the control group (standard care). Computer-generated randomization (random permuted blocks of varying sizes: block 1: BI ≤ 40, block 2: 40 < BI ≤ 60, block 3: 61 ≤ BI ≤ 99, block 4: BI = 100) using SPSS version 13.0 software (SPSS Inc., Chicago, IL, USA) and stratification by the grade of total FMA (grade 1: FMA ≤ 50, grade 2: 51 ≤ FMA ≤ 84) were prepared by an independent biostatistician to ensure balanced assignment of participants to the two groups. Eligible participants were randomly divided into the trial group and the control group in a 1:1 allocation ratio.

Blinding method

The scalp-acupuncture manipulator was not blinded to the treatment, as he or she administered the scalp-acupuncture session and was responsible for discussion with the participants between visits and with those in the control group. All assessments were done by a separate person (outcome assessor) from the person allocating and applying the scalp-acupuncture (scalp-acupuncture allocator) to further control as blinding.

Outcome measures

As this was a pilot study surveying the clinical effect of scalp-acupuncture on acute ischaemic stroke, assessments were made by a trained physical therapist, blind to group assignment, at 3 dissimilarly spaced time intervals over 2 weeks, \( T_0 \), \( T_1 \), and \( T_2 \). The measurement protocol was administered at baseline (\( T_0 \)), at the first post-intervention immediately (\( T_1 \)) and at the 14th day (\( T_2 \)) after intervention commencement. We did not include a follow-up test.

Primary outcomes

The primary outcomes of this RCT included the manual muscle test (MMT) and Fugl-Meyer assessment (FMA) scores. The scores in MMT were assessed at baseline (\( T_0 \)), at the first post-intervention immediately (\( T_1 \)), and at the 14th day (\( T_2 \)) after intervention commencement, while FMA scores were assessed at baseline (\( T_0 \)) and at the 14th day (\( T_2 \)) after intervention commencement. All questionnaires were in Chinese. Manual muscle test (MMT): representative scores of MMT from six muscle groups in the affected limb, shoulder flexor, elbow flexor, 3rd finger proximal interphalangeal flexor, hip flexor, knee extensor, and ankle dorsiflexor of the affected extremities were selected for summated scores in five grades (Zero = 0, Trace = 1, Poor = 2, Fair = 3, Good = 4, Normal = 5), which made the total score of 30.\(^{21} \)

Fugl-Meyer assessment (FMA): FMA assesses sensorimotor recovery of the upper and lower limb in post-stroke hemiplegic paralysis. The maximum score for the motor section of FMA is 100. The subtest scores comprise upper extremity (FMA-UE), 66 [upper arm (FMA-UA) = 36 and hand (FMA-WH) = 30]; lower extremity (FMA-LE), 34; and balance, 14.\(^{29,30} \) FMA-UE and FMA-LE were used in this RCT.

Secondary outcomes

Secondary outcomes of this RCT included the NIHSS scores, BI scores, and safety assessment. The NIHSS scores and BI scores were assessed during the 2-week trial at baseline (\( T_0 \)) and at the 14th day (\( T_2 \)) after treatment commencement. All questionnaires were presented in Chinese.

National Institutes of Health Stroke Scale (NIHSS): the NIHSS is a stroke-specific quantitative scale used to assess neurological deficits in terms of consciousness, eye movements, visual fields, facial palsy, motor and sensory impairments, ataxia, language function, and neglect. It contains 30 questions, and participants will obtain 1 point if the answer is correct but 0 points if the answer is wrong.\(^{27} \) A total score less than 27 indicates cognitive dysfunction.\(^{15} \) A higher score indicates a more severe neurological deficit.\(^{27} \) Each participant was assessed by a trained, certified investigator at baseline, 2 weeks after treatment commencement.

BI: BI is the most commonly used functional measure in stroke-rehabilitation settings and the second most commonly used functional outcome measure across stroke trials.\(^{30-34} \) The BI assesses ten functional tasks of daily living (activities of daily living, ADL), scoring the individual depending on independence in each task. Scores ranged from 0 and 100, with a higher score indicating greater independence.\(^{27} \)

Safety assessment: during the whole period of the study, all the participants in the trial group were guided to report any adverse events. They included fainting, a stuck needle, bent needle, broken needle, and haematoma during scalp-acupuncture treatment. CBCs with differential cell count, serum glucose, BUN, creatinine, electrolyte (Na, K, Cl) levels, and ECG were checked weekly in the trial group. Vital signs, including blood pressure and heart rate, were assessed daily during the whole period of the study.

Intervention methods

Participants in both groups received standard care...
(Western Medicine therapy) for ischaemic stroke according to the Guidelines for the Diagnosis and Treatment of Acute Ischaemic Stroke in China in 2014, and clinical nursing at the second hospital of the University of Lanzhou. According to individualized treatment principle, the specific treatment methods were as follows: (a) oxygen inhalation and respiratory support, electrocardiogram monitoring, body temperature control; (b) monitoring of blood pressure: individualized treatment used to stabilize blood pressure lower than 140/90 mm Hg; (c) blood glucose control: use of proper blood glucose-lowering drugs to keep blood glucose level within the normal range; (d) blood lipid regulation: oral use of atorvastatin 10 mg per day according to serum levels of triglycerides and cholesterol; (e) antiplatelet aggregation: oral use of aspirin 0.1 g, once per day; (f) neurotroph: intravenous administration of ganglioside 40 mg, once per day; (g) free radical scavenger: intravenous administration of edaravone 30 mg, once per day; (h) microcirculation improvement: intravenous administration of Shuxuetong 6 mL, once per day; (i) symptomatic treatment, prevention against complications, and providing nutritional support. To ensure adherence to intervention protocols, all participants received intervention and assessments by a separate person.

In addition to standard care, participants in the trial group, lying in the supine position, were treated with amicrobic stainless steel needles (0.30 × 40 mm; Beijing Keyuan Da Medical Products Factory, Beijing, China) at the bilateral anterior oblique line of the vertex-temporal (MS 6) [from Qianding (GV 21) to Xuanli (GB 6)] for 14 d (6 d/week). After routine skin sterilizing, the bilateral MS6 were punctured respectively with three needles into the substratum of the galea aponeurotica by horizontal insertion of a needle (approximately 15° between skin and needle body) at 1/5 of its upside, 2/5 of its midpoint, and 2/5 of its underpart by the relay mode.

Licensed and experienced acupuncturists conducted needle manipulation by 100 r/min of twirling frequency and 180° of angle to obtain the proper needling sensation (De-Qi sensation). The manipulation lasted 1 min, and repeated one time at intervals of 9 min. After a 30-min retention period, the needles were removed. The interventions in the two groups are detailed in Table 1, Figure 1 for details on location of needles.

### Adverse reaction treatment

If adverse reaction incidences occurred during manipulation of scalp-acupuncture in the trial group, treatment of scalp-acupuncture was stopped at once, and the therapeutic methods were applied to handle adverse reactions according to the Operation Standard of Acupuncture and Moxibustion Technology, Part 2: Scalp Acupuncture.

### Monitoring

To guarantee the quality of this RCT, it was carried out at the second Hospital of Lanzhou University. Because of the Data Monitoring Team to identify problems in the RCT, examine collected data, and control bias, the Clinical Research Centre of the second Hospital of Lanzhou University had access to these interim results and made the final decision to terminate the trial. A qualified clinical trial expert was invited to monitor this RCT.

### Statistical analysis

We used intention-to-treat (ITT) analysis to reduce deviation. All data were analysed by SPSS (version 13.0 for Windows, SPSS Inc, Chicago, IL, USA). The data of normal distribution were reported as the mean ± standard deviation, whereas the non-normal distribution data were reported as the median (50th percentile) to describe the central tendency and the 1st quartile (25th percentile) and 3rd quartile (75th percentile) to describe the variability of the distribution. For the normal distribution data, we used 2-sample t tests for between-group differences, whereas not equidistant analysis of variance of repeated measurements was used to evaluate within-group differences at different time points. For the data of nonnormal distribution, we

### Table 1 Details of intervention methods in the two groups

<table>
<thead>
<tr>
<th>Item</th>
<th>Trial group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupoints</td>
<td>Bilateral anterior oblique line of vertex-temporal (MS6)</td>
<td>No acupoints</td>
</tr>
<tr>
<td>Depth of needle insertion</td>
<td>30 mm</td>
<td>No scalp acupuncture intervention</td>
</tr>
<tr>
<td>Needle retention time</td>
<td>30 min</td>
<td>No scalp acupuncture intervention</td>
</tr>
<tr>
<td>Needle type</td>
<td>Stainless steel needles (Beijing Keyuan Da Medical Products Factory, Beijing, China)</td>
<td>No needles</td>
</tr>
<tr>
<td>Frequency and duration of treatment sessions</td>
<td>Six times a week for the total of 14 d,</td>
<td>No scalp acupuncture intervention</td>
</tr>
<tr>
<td>Needle stimulation</td>
<td>De-Qi sensation</td>
<td>No scalp acupuncture intervention</td>
</tr>
<tr>
<td>Medication</td>
<td>Standard care (Western Medicine therapy)</td>
<td>Standard care (Western Medicine therapy)</td>
</tr>
</tbody>
</table>

Notes: Western Medicine therapy included oxygen inhalation and respiratory support, electrocardiogram monitoring, body temperature control, monitoring of blood pressure, blood glucose control, and blood lipid regulation (atorvastatin, 10 mg, p.o., q.n., 14 d), and antiplatelet aggregation (aspirin, 0.1 g, p.o., q.n., 14 d), neurotroph (ganglioside, 40 mg, ivgtt, q.d., 14 d), and free radical scavenger (edaravone, 30 mg, ivgtt, q.d., 14 d), and microcirculation improvement (Shuxuetong, 6 mL, ivgtt, q.d., 14 d).

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used Wilcoxon signed rank tests to evaluate within-group differences and Wilcoxon rank sum tests for between-group differences. The χ² test was used to analyse categorical data. Two-tailed probability values of $P < 0.05$ were considered as statistically significant.

**Clinical trial registration**
We applied for registration of this RCT in the Chinese Clinical Trial Registry (ChiCTR-IOR-16008083). This would reduce the bias in clinical research, increase the openness of trials, and ensure the high quality of clinical trials and test processes, and the credibility of results.

**RESULTS**

**Baseline data**

One hundred and twenty participants were included in this RCT. Sixty participants (21 female, 39 male) were randomly allocated to the trial group, and sixty participants (19 female, 41 male) were randomly allocated to the control group. The characteristics of both groups are summarized in Table 2. The 2 groups did not differ significantly at baseline regarding demographic characteristics and disease-related parameters. A total of 115 participants fulfilled the protocol. In the trial group, 57 of the 60 participants (95.0%) fulfilled the protocol. One dropout in this group was due to family-related factors, and two dropouts were due to the pain from scalp-acupuncture. In the control group, 58 of the 60 participants (96.7%) fulfilled the study, with 2 dropouts. One participant discontinued the protocol in the 1st week because he did not like being randomly allocated to the control group and accepted transcutaneous electrical stimulation (TES); another participant also dropped out in the 1st week because he abandoned treatment and left the hospital. Data for all 120 participants were included in the analysis (intention-to-treat) by carrying the last available score forward (Figure 2).

**Scores of MMT, FMA, BI, and NIHSS**

The data for measures below (except MMT) were not normally distributed. Thus, we used the median (50th percentile) to describe the central tendency and the 1st quartile (25th percentile) and 3rd quartile (75th percentile) to describe the variability of the distribution. The primary outcome measure (i.e., MMT and FMA) showed a significant within-group increase in the MMT from T₀ at 10.1 ± 5.5 degrees to T₁ at 15.8 ± 5.4 degrees ($P = 0.000$) and to T₂ at 18.2 ± 6.3 degrees ($P = 0.015$) for the trial group and an increase from T₀ at 9.4 ± 5.0 degrees to T₁ at 10.4 ± 5.4 degrees ($P = 0.042$) for the control group. Furthermore, whereas the between-group difference in MMT at T₀ was non-significant, the between-group difference in change in MMT from T₀ to T₁ and T₀ to T₂ was significant ($P = 0.000$), favouring the trial group (Figure 3A). Median FMA showed a significant increase from T₀ at 35 (31, 45) degrees to T₁ at 41 (32, 50) degrees ($P = 0.000$) for blandness.
Table 2 baseline characteristics of the trial groups and control groups

| Parameter                        | Trial group (n = 60) | Control group (n = 60) | P value
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Sex [n (%)]</td>
<td>Male</td>
<td>39 (65.0)</td>
<td>41 (68.3)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>21 (35.0)</td>
<td>19 (31.7)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.4±9.0</td>
<td>59.5±8.9</td>
<td>0.829</td>
</tr>
<tr>
<td>CD (days)</td>
<td>3.3±1.6</td>
<td>3.0±1.6</td>
<td>0.122</td>
</tr>
<tr>
<td>Frontal lobe</td>
<td>L 12 (20.0)</td>
<td>L 15 (25.0)</td>
<td>0.078</td>
</tr>
<tr>
<td></td>
<td>R 5 (8.3)</td>
<td>R 8 (13.3)</td>
<td>0.926</td>
</tr>
<tr>
<td>BGR</td>
<td>L 9 (15.0)</td>
<td>L 5 (8.3)</td>
<td>0.078</td>
</tr>
<tr>
<td>D reg. [n (%)]</td>
<td>R 14 (23.3)</td>
<td>R 10 (16.7)</td>
<td>0.078</td>
</tr>
<tr>
<td>Lateral ventricle</td>
<td>F 10 (16.7)</td>
<td>F 9 (15.0)</td>
<td>0.078</td>
</tr>
<tr>
<td>Centrum ovale</td>
<td>B 3 (5.0)</td>
<td>B 6 (10.0)</td>
<td>0.078</td>
</tr>
<tr>
<td>Type 2 diabetes [n (%)]</td>
<td>42 (70.0)</td>
<td>38 (63.3)</td>
<td>0.439</td>
</tr>
<tr>
<td>Hypertension [n (%)]</td>
<td>38 (63.3)</td>
<td>40 (66.7)</td>
<td>0.702</td>
</tr>
<tr>
<td>Hypercholesterolemia [n (%)]</td>
<td>49 (81.7)</td>
<td>51 (85.0)</td>
<td>0.624</td>
</tr>
<tr>
<td>NIHSS</td>
<td>6 (5.6)</td>
<td>6 (5.6)</td>
<td>0.621</td>
</tr>
<tr>
<td>Upper limb</td>
<td>15 (10.5, 20)</td>
<td>17.5 (13, 18.5)</td>
<td>0.095</td>
</tr>
<tr>
<td>Lower limb</td>
<td>20 (14, 22.5)</td>
<td>20 (15, 21.5)</td>
<td>0.968</td>
</tr>
<tr>
<td>Total score</td>
<td>35 (31, 45)</td>
<td>34 (32, 37)</td>
<td>0.570</td>
</tr>
<tr>
<td>BI</td>
<td>40 (35, 55)</td>
<td>40 (35, 45)</td>
<td>0.687</td>
</tr>
<tr>
<td>MMT</td>
<td>10.1±5.5</td>
<td>9.4±5.0</td>
<td>0.535</td>
</tr>
</tbody>
</table>

Notes: ‘CD: course of disease; D reg: diseased region; BGR: basal ganglia region; L: left; R: right; F: forehead; B: back foot; NIHSS: National Institutes of Health Stroke Scale; FMA: Fugl-Meyer assessment; BI: Barthel index; MMT: manual muscle test. ‘P values are based on χ² test for independent proportions or a 2-sided, 2-group t test for difference in group MMT means, and 2-group Mann-Whitney U test for difference in group NIHSS, FMA, and BI median. Baseline data include all patients who were randomized before intervention.

Figure 2 Consolidated Standards of Reporting Trials (CONSORT) flow chart of participant recruitment and enrollment.

The number of participants evaluated at each stage of the study. ITT: intention-to-treat.

the trial group, while in control group, a trend towards an increase from T₀ at 34 (32, 37) degrees to T₁ at 34.5 (32, 38) degrees (P = 0.078). The between-group difference in FMA change was significant (P =0.041) (Fig-
ure 3B). BI exhibited a median increase from T1 at 40 (35, 55) degrees to T2 at 47 (40, 60) degrees (P = 0.000) for the trial group, whereas in the control group, a trend towards an increase from T1 at 40 (35, 45) degrees to T2 at 41.5 (35, 49.5) degrees (P = 0.064). The between-group difference in BI change was significant (P = 0.028), also favouring the trial group (Figure 3C). Median NIHSS showed a significant decrease from T1 to T2 at 6 (5, 6) degrees to T1 at 1 (1, 2) degrees (P = 0.000) for the trial group, and in the control group, there was a median decrease from T1 at 6 (5, 6) degrees to T2 at 3 (3, 4) degrees (P = 0.000). The between-group difference in NIHSS was significant (P = 0.000) (Figure 3D).

**Adverse reaction and safety analysis**

The adverse events were observed at comparable frequencies in each group. No serious adverse events related to the intervention were observed in the control group, while 3 (5%) participants had mild fainting, which disappeared after being given warm boiled water and a few moments of rest, and 15 (25%) participants had scalp hematomata, which improved via an ice compress on the locality in the trial group. We checked CBCs with differential cell counts and serum glucose, BUN, creatinine, and electrolyte (Na, K, Cl) levels in each group. The values of CBC with differential cell counts and serum glucose, BUN, creatinine, and electrolyte (Na, K, Cl) levels in each group were all within the normal range. Vital signs, including blood pressure and heart rate, were not significantly changed by scalp-acupuncture administration.

**DISCUSSION**

This single-blind, randomized, blank-controlled study evaluated the effects of scalp-acupuncture on hemiplegic paralysis after acute ischaemic stroke. To our knowledge, this was the first study to evaluate the effect of scalp-acupuncture intervention on participants with hemiplegic paralysis after acute ischaemic stroke. In this RCT, the differential effect of scalp-acupuncture intervention was found for MMT, BI, FMA and NIHSS, whereas the differential effect was found for MMT and NIHSS in the control group. Participants with the acute ischaemic post-stroke hemiplegic paralysis, who received scalp-acupuncture intervention, experienced more improvement in MMT (P = 0.000), BI (P = 0.028), FMA (P = 0.041), and NIHSS (P = 0.000) than the control group. In addition, there were no serious adverse events with scalp-acupuncture intervention during the whole study period. This RCT suggested that scalp-acupuncture intervention is generally a safe and effective therapy for patients with hemiplegic paralysis after acute ischaemic stroke.

Numerous studies have focused on scalp-acupuncture therapy for ischaemic post-stroke hemiplegic paralysis. However, findings regarding the effects of scalp-acupuncture on post-stroke hemiplegic paralysis remain controversial. Several studies have suggested positive effects of scalp-acupuncture on post-stroke hemiplegic paralysis. One study reported that scalp-acupuncture intervention could not improve the Barthel index and Rankin scores in patients with post-stroke...
hemiplegic paralysis, but only decreased the NIHSS scores. Our study found that not only NIHSS scores but also MMT, FMA and BI scores of acute ischemic stroke participants with hemiplegic paralysis could be improved after 2 weeks of scalp-acupuncture intervention.

Hemiplegic paralysis is the inability or decreased ability to volitionally activate motor units and is one of the most common manifestations of stroke. Clinically, hemiplegic paralysis presents as muscle weakness and reduced speed of activation, and the inability to generate functionally useful movement of the affected limb. Lang et al studied the relative strengths of the associations between specific upper limb impairments and function and concluded that hemiplegic paralysis was the strongest contributor to the loss of function. In the lower limb, hemiplegic paralysis, along with the inability to grade muscle contractions, poor motor coordination, poor endurance, spasticity, and impaired balance, have significant consequences on ambulation. Thus, it is most important for patients with hemiplegic paralysis after acute ischemic stroke to recover the muscle force of affected limbs. In this RCT, we set MMT and FMA scores as primary outcomes and reported the total scores of affected limbs by Fugl-Meyer assessment (FMA) and Manual muscle test (MMT). Our results indicated that FMA and MMT scores improved in both the trial group and control group after 2 weeks of intervention, but the trial group was superior to the control group. What was more interesting was that scalp-acupuncture intervention had an immediate effect on myodynamia of participants with hemiplegic paralysis after acute ischemic stroke in this study. Meanwhile, the improvement of BI and NIHSS scores in the trial group was more remarkable than that of control group in our study. These results indicated that scalp-acupuncture improved the ability of daily living activities by improving muscle strength.

Although the exact mechanisms of acupuncture for ischemic stroke are still unclear, several studies indicated that acupuncture has an effect on the nervous system and immune system, which has an analgesic effect, immune regulation, and regulation on the function of organs. Scalp-acupuncture, as a minor acupuncture therapeutic method, also has the effects of acupuncture. Chinese traditional medicine proposes that MS6 passes through several meridians on the scalp part, and closely relates to the diseased region. MS6 is considered as a scalp projection area of anterior central convolution in modern medicine and could remedy limb motor dysfunction. Therefore, we chose bilateral MS6 for a scalp-acupuncture stimulation point.

Another important issue to be discussed is intervention methods in this study. Considering electrical stimulation a factor in the course of treatment, we did not choose electrical scalp-acupuncture but adopted regular acupuncture manipulation because Schaechter and his colleagues found that electrical scalp-acupuncture for chronic stroke showed a significant positive correlation between clinical changes in the affected upper limb and cortical activity in the ipsilesional motor cortex, and they deemed that the electrical component might be critical during acupuncture treatment for chronic stroke.

MMT is a 6-point ordinal (0-5) scale and a common, universal, economical and reliable method to evaluate muscle strength. A study showed that MMT has inter-rater reliability and intra-rater reliability. Concurrent validity of MMT with handheld dynamometers ranges from 0.61 to 0.97. In this study, group muscle strength testing was done for the shoulder (flexors, extensors, abductors, adductors, and external and internal rotators), elbow (flexors and extensors), forearm (pronators and supinators), and wrist (dorsiflexors and palmarflexors). In addition, group muscle strength testing of the unilateral lower extremity was also carried out for the hip (flexors, extensors, abductors, adductors, and external and internal rotators), knee (flexors and extensors), and ankle (dorsiflexors and plantarflexors). The Fugl-Meyer assessment (FMA) scale is a well-designed, comprehensive, and efficient clinical examination method used widely by therapists to evaluate stroke-related motor impairment. The FMA was developed to measure sensorimotor stroke recovery based on Twitchell and Brunnstrom’s concept of sequential stages of motor return in patients with hemiplegic stroke. According to previous studies, FMA shows excellent intrarater and interrater reliability, as well as good construct validity. The subtest scores comprise upper extremity (FMA-UE), 66 [upper arm (FMA-UA) = 36 and hand (FMA-WH) = 30]; lower extremity (FMA-LE), 34; and balance, 14. FMA-UE and FMA-LE were used in this study. FMA-UE and FMA-LE had exhibited good sensitivity and relative minimal detectable change, respectively, in poststroke patients.

The NIHSS is an assessment of neurological function as a result of the stroke. The Barthel index scale measures functional outcomes (e.g., level of assistance in ADLs) dependent on the level of stroke. Furthermore, the NIHSS has more scale items than the Barthel scale, and may be more sensitive with respect to scoring, because measures changes can be detected acutely in the NIHSS assessment during short-term assessment, whereas the Barthel scale can detect the level of assistance needed or competence in ADLs as a result of the neurological changes in a larger time-frame. Thus, there may be fine changes detected in the NIHSS scale that might not be reflected in the Barthel scale. We chose not only the Barthel scale but also the NIHSS scale in this RCT.

We used the ITT principle to handle statistical data to reduce deviation of the RCT. There are some inevitable limitations in this RCT. First, it is hard to make the RCT double-blinded because clinical trial blinding is difficult for scalp-acupuncture and real randomized pla-
cebo-controlled trials seem impossible. Therefore, setting up a no scalp-acupuncture control is feasible. The assessor and statistical expert will be blinded to the group assignment in this RCT; however, it will be impossible to blind the acupuncturist. Second, this RCT is restricted to a single-center hospital. Third, because many stroke patients will ask for Traditional Chinese Medicine and acupuncture treatment during the recovery period, we did not set the follow-up period. The final limitation is the small number of participants, so studies with larger populations are necessary. Further studies that overcome these limitations are needed.

In conclusion, based on the results of this study, scalp-acupuncture appears to be safe and effective in patients with hemiplegic paralysis after acute ischaemic stroke. However, there are some inevitable limitations in this study. Future investigations of scalp-acupuncture for patients with hemiplegic paralysis after acute ischaemic stroke are needed.

REFERENCES


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