Scalp-cluster acupuncture with electrical stimulation can improve motor and living ability in convalescent patients with post-stroke hemiplegia

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RESULTS: Following 4 weeks treatment, all the patients exhibited significant improvements in aspects of motor ability, living ability, and the severity of neurological deficits. The experimental group (SC + ES) scored higher on the Fugl-Meyer assessment scale (68 ± 12) and the modified Barthel Index (49 ± 9) than the control (SC) group (50 ± 13, 36 ± 13, respectively).

CONCLUSION: When patients with post-stroke hemiplegia are treated using SC acupuncture with ES, motor and living ability can improve more than if they were treated with SC acupuncture alone.

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Keywords: Stroke; Rehabilitation; Hemiplegia; Electrical stimulation; Scalp cluster acupuncture

INTRODUCTION

Cerebral stroke is common across the globe and leads to a wide range of disabilities. Hemiplegia is one of the most common complications following stroke. It often causes motor impairment, which is a major reason for reduced activities of daily life and socialization. Various physical therapies have been used in patients with post-stroke hemiplegia to improve their motor ability and daily living. However, the outcomes for some patients with hemiplegia are not satisfactory. Acupuncture has been used to treat several chronic diseases, including chronic pain, weight management, functional dyspepsia, and especially hemiplegia. Reports show that acupuncture can improve post-stroke depression, and that scalp-cluster (SC) acupuncture is more effective than traditional scalp acupuncture in...
treating patients with post-stroke hemiplegia. However, this method requires keeping needles in patients' scalp acupoints repeatedly over several months. Additionally, it can result in complications such as skin edema and pain, which might force some patients to discontinue treatment.

Electrical acupuncture is an improved method that stimulates acupoints by passing a certain frequency electrical current through needles. Compared with the traditional needle-twirling method, stimulation frequency in electrical acupuncture is higher, which results in stronger stimulation of the acupoints. In theory, electrical acupuncture might be more effective than traditional acupuncture, which would shorten the duration of treatment and decrease complications that result from long-term acupuncture. To our knowledge, there have not been any similar studies that examined the effect of SC acupuncture combined electrical stimulation in treatment of convalescent patients with post-stroke hemiplegia.

Here, the aim of this study was to determine whether SC acupuncture combined with ES is more effective than SC acupuncture alone in the treatment of patients with post-stroke hemiplegia.

METHODS

Participants

This was a blinded randomized controlled trial (RCT) that aimed to determine whether SC acupuncture combined with electrical stimulation (ES) was more effective than SC acupuncture alone in treating post-stroke hemiplegia. All patients were diagnosed with cerebral stroke according with the diagnostic criteria for hemorrhagic stroke in “Diagnostic Essentials of Cerebrovascular Diseases” revised by the Chinese Fourth Conference on Cerebrovascular Disease of the Chinese Medical Association in 1995. Patients with post-stroke hemiplegia, hospitalized in the department of rehabilitation at the Second Hospital of Shandong University from January 2013 to December 2015, were enrolled with the following inclusion criteria: (a) the diagnosis of stroke was confirmed by CT or MRI of the head; (b) the diagnosis met the criteria outlined in “stroke syndrome diagnostic criteria (Trial)”, established in 1994 by the acute encephalopathy research group of the State Administration of Traditional Chinese Medicine of the P. R. C.; (c) timing was ≥2 weeks and ≤3 months after stroke, and hemiplegia presented on their affected sides; (d) they were at the stable stage of the disease and with clear consciousness; (e) the severity of neurological deficits was at least 10. These scores were determined according to “The scoring criteria of degree of clinical neurological deficits for patients with cerebral stroke (1995)” established in 1995 by the Chinese Fourth Conference on Cerebrovascular Disease of the Chinese Medical Association. Exclusion criteria were: (a) unconsciousness; (b) medically unstable; (c) uncontrolled seizures (>1 per week for the last 2 months); (d) severely impaired communication or cognition; (e) other confounding neurological conditions affecting the rehabilitation training; (f) other medical issues affecting the rehabilitation training or acupuncture therapy.

The study was conducted at the rehabilitation department of an urban general hospital in China and approved by the ethics committee of the Second Hospital of Shandong University. The research was conducted in accordance with the Declaration of the World Medical Association. All participants were informed about the study and signed the informed consent to agree that their data could be used for research purposes. All participants were numbered sequentially according to the order of enrollment and then divided into the control (SC) and experimental (SC + ES) groups using a randomized digital table.

Interventions

All participants received rehabilitation training. Those randomized to the control group received SC acupuncture and those entering the experimental group received SC acupuncture combined with ES.

Selection of the therapeutic acupoints followed the following principles. According to the method developed by Yu Zhishun, the surface of the scalp was divided into seven sections: (a) parietal area: the line from Baihui (GV 20) to Qiandong (GV 21) and the bilateral parallel lines 1 and 2 inches to either side; (b) anterior parietal area: the line from Qiandong (GV 21) to Xinhui (GV 22) and the bilateral parallel lines 1 and 2 inches to either side; (c) frontal area: the line from Xinhui (GV 22) to Shenting (GV 24) and the bilateral parallel lines 1 and 2 inches to either side; (d) occipital area: the line from Qiangian (GV 18) to Naohu (GV 17) and the bilateral parallel lines 1 inch to either side; (e) suboccipital area: the lines from Naohu (GV 17) to Fengfu (GV 16) and from Yuzhen (BL 9) to Tianzhu (BL 10); (f) nuchal area: the line from Fengfu (GV 16) to Fengchi (GB 20), including five acupoints; (g) temporal area: one point 0.5 inches inferior to Touwei (ST 8), the point 0.5 inches anterior and inferior to the parietal nodule, and the line between these two points. Major acupoints, including the parietal area and the anterior parietal area were used in all patients. Additionally, adjacent acupoints were selected as follows: (a) for patients with language disorders, we selected the temporal or nuchal area; (b) for patients with visual impairment, we selected the occipital area; (c) for patients with mental impairments, we selected the frontal area; (d) for patients with dysphagia, we selected the nuchal area. Two traditional Chinese medical practitioners were asked to verify the choice and location of the selected acupoints at the beginning of each treatment.

Acupuncture therapy was given 5 times a week for 4 weeks using sterilized needles (0.40 mm × 50 mm). Three to five needles were used in each area.
were angled 15 degrees to the skin and inserted 40 mm into the acupoint, reaching below the galea aponeurotica. Needles remained this way for 6 h per day. In the control group, the needles were twirled every 2 h. In experimental group, the needles in the parietal and anterior parietal areas were connected to the electric acupuncture apparatus (Huatuoo® SDZ-II, Suzhou medical supplies factory Co., LTD, Suzhou, China), which stayed energized during the whole treatment. The stimulation parameters were: dilatational waves at a frequency of (10 ± 3)-(50 ± 10) times/min and a current intensity of 0.6-1.0 mA.

**Rehabilitation training**

Patients with post-stroke hemiplegia generally require additional rehabilitation therapy to during their recovery. Due to ethical considerations, rehabilitation therapy following the Bobath concept was administered to all patients throughout the entire study, including correction of poor posture, active and passive movement of joints in the extremities while lying down, training of hand function, turning and movement on the bed, training of sitting balance, and others. Rehabilitation therapy lasted 30-45 min, once per day, 5 d per week.

**Outcomes**

All participants underwent 3 blinded assessments: The Fugl-Meyer assessment scale for motor ability, the modified Barthel Index for living ability, and a scale that quantified the degree of neurological deficit. Outcome assessment was completed before randomization, at the beginning of treatment, and after the 4-week treatment period.

**Fugl-Meyer assessment scale**

This scale comprises four interdependent parts: motor function in the extremities, range of motion in the joint (including pain score), balance, and sensation. The maximum score is 226. In this study, we used the scale for motor function in the extremities (max 100 points) to evaluate motor ability. Motor ability was divided into the following five levels: 100 was normal, 96-99 was mild motor disorder, 85-95 was moderate disorder, 50-84 was apparent disorder, and ≤ 50 was a severe disorder.

**Modified barthel index**

This scale comprises 10 topics, with each topic ranging from 0 to 15 points. The maximum score is 100 points and higher scores indicate better living ability. Living ability was divided into four levels: > 60, 60-40, 40-20, and ≤ 20.

**Neurological deficit scale**

A neurological deficit scale that included unconsciousness, staring, facial paralysis, myodynamia of extremities and hands, and poor walking ability, was generally used to quantitatively evaluate the severity of neurological deficits. According to the diagnostic criteria of the Chinese Fourth Conference on Cerebrovascular Disease in 1995, the degree of neurological deficits were divided into three levels as follows: mild (0-15 points), moderate (16-30 points) and severe (31-45 points).

**Adverse events**

All patients were required to report any adverse events during acupuncture treatment. If any were reported, the doctor interviewed the patient and evaluated the validity of the adverse event. If necessary, the doctor stopped the procedure and treated the adverse event immediately. The evaluator recorded the date and seriousness of the event and analyzed the relationship between the event and the treatment. The ethics committee was then tasked with deciding whether or not to remove this patient from the study.

**Statistical analysis**

The results are presented as mean ± standard deviation (\( \bar{x} \pm s \)). The \( \chi^2 \) test and Student-t test were used to determine whether differences were statistically significant. A \( P \)-value less than 0.05 was considered significant. All statistical tests are two tailed. Statistical analysis was performed using SPSS 19.0 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY, USA).

**RESULTS**

**Patient characteristics (Trial profile)**

Twenty patients enrolled in this study (\( n = 10 \) per group). Twenty patients were enrolled. Five patients were excluded due to serious complications before the experiment. Clinical characteristics did not differ between the two groups (Table 1). There were no reported adverse events in the study.

**Changes in motor ability**

The Fugl-Meyer assessment scale showed no difference between groups at the beginning of treatment. Following 4 weeks of treatment, scores increased significantly in both groups. Further, the SC + ES group scored even higher than the SC group, indicating that motor ability of experimental group improved more than that of the control group (Table 2).

**Changes in living ability**

The modified Barthel Index indicated that living ability clearly improved in both groups following 4 weeks of treatment. As with motor ability, living ability improved more in the experimental group than in the control group (Table 3).
Changes of the severity of neurological deficits

After 4 weeks of treatment, neurological deficits became less severe in both groups. However, the amount of improvement did not significantly differ between the experimental group and the control group (Table 4).

Adverse events

No adverse events were observed in any patient during the experiments.

DISCUSSION

Here, we aimed to determine whether SC acupuncture plus ES could improve the condition of people with hemiplegic syndrome. Our findings show that the treatment improved daily living and motor abilities significantly more than traditional scalp acupuncture. Following 4 weeks of treatment, the severity of motor disorder was lessened from severe to moderate in both groups, which indicates that scalp acupuncture can improve motor ability in patients with hemiplegic. Furthermore, mean Fugl-Meyer scores in the experimental group averaged 18 points higher than those in the control group. This means that the ES can increase the efficacy of SC acupuncture. In terms of daily living ability, the average modified Barthel Index revealed that the experimental group (49.00) had a greater living ability than the control group (36.00). Importantly, SC + ES can be considered a safe procedure because no adverse events were reported by the patients of this clinical investigation, and none withdrew from this study. However, this trial provides no evidence that SC acupuncture combined ES results in a greater decrease in severity of neurological deficits than single SC acupuncture. One reason might be that neurological deficits require a relative long time to improve, and our observation period of only 4 weeks might not have been adequate for detecting a difference between the treatments. Another possible reason is that the sample size was too small to confirm whether differences between the two groups were significant. In future studies, we will enroll more patients and design a longer observation period of only 4 weeks might not have been adequate for detecting a difference between the treatments. Another possible reason is that the sample size was too small to confirm whether differences between the two groups were significant. In future studies, we will enroll more patients and design a longer observation time to more conclusively determine any differences in the efficacies of the two treatment methods in terms of improvement in neurological deficits of hemiplegic patients.

Table 1 Group characteristics (x ± s)

<table>
<thead>
<tr>
<th>Item</th>
<th>Experimental group (n = 10)</th>
<th>Control group (n = 10)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (n)</td>
<td>7</td>
<td>6</td>
<td>0.639</td>
</tr>
<tr>
<td>Age (years)</td>
<td>63.5 ± 6.4</td>
<td>66.3 ± 7.9</td>
<td>0.393</td>
</tr>
<tr>
<td>Time since Stroke (weeks)</td>
<td>6.9 ± 2.6</td>
<td>7.5 ± 2.6</td>
<td>0.609</td>
</tr>
<tr>
<td>Left/Right hemiplegia (n)</td>
<td>6/4</td>
<td>4/6</td>
<td>0.371</td>
</tr>
</tbody>
</table>

Notes: control group received scalp-cluster acupuncture. Experimental group received scalp-cluster acupuncture combined with electrical stimulation. Categorical variables: χ² test. Continuous variables: Student-t test.

Table 2 Changes in motor ability for each group and between groups (x ± s)

<table>
<thead>
<tr>
<th>Item</th>
<th>Experimental group (n = 10)</th>
<th>Control group (n = 10)</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>32 ± 10</td>
<td>30 ± 12</td>
<td>0.265</td>
<td>0.794</td>
</tr>
<tr>
<td>Week 4</td>
<td>68 ± 12</td>
<td>50 ± 13</td>
<td>3.171</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Note: control group received scalp-cluster acupuncture. Experimental group received scalp-cluster acupuncture combined with electrical stimulation.

Table 3 Changes in living ability for each group and between groups (x ± s)

<table>
<thead>
<tr>
<th>Item</th>
<th>Experimental group (n = 10)</th>
<th>Control group (n = 10)</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>21 ± 8</td>
<td>21 ± 10</td>
<td>0.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Week 4</td>
<td>49 ± 9</td>
<td>36 ± 13</td>
<td>2.528</td>
<td>0.021</td>
</tr>
</tbody>
</table>

Notes: control group received scalp-cluster acupuncture. Experimental group received scalp-cluster acupuncture combined with electrical stimulation.

Table 4 Changes in the degree of neurological deficit for each group and between groups (x ± s)

<table>
<thead>
<tr>
<th>Item</th>
<th>Experimental group (n = 10)</th>
<th>Control group (n = 10)</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>25 ± 10</td>
<td>24 ± 6</td>
<td>0.302</td>
<td>0.766</td>
</tr>
<tr>
<td>Week 4</td>
<td>12 ± 10</td>
<td>14 ± 7</td>
<td>-0.628</td>
<td>0.538</td>
</tr>
</tbody>
</table>

Notes: control group received scalp-cluster acupuncture. Experimental group received scalp-cluster acupuncture combined with electrical stimulation.
Our study has some limits: (a) the sample size was too small and it only included one center of research. Thus, the results might not be applicable in all the cases of hemiplegia; (b) objective markers such as blood analysis data are missing; (c) the mechanism through which scalp acupuncture works is largely unknown. These limitations should be considered in future research.

In conclusion, our study provided evidence that SC acupuncture combined ES is an effective and safe treatment for patients with post-stroke hemiplegia, which is even more effective than traditional SC acupuncture.

REFERENCES


