Rehabilitation of Stroke Patients Using Yamamoto New Scalp Acupuncture: A Pilot Study

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Abstract

Objectives: The aim of this study was to investigate whether acupuncture, especially Yamamoto’s New Scalp Acupuncture (YNSA), is of value in addition to standard poststroke motor rehabilitation.

Design: A prospective, assessor-blinded randomized control trial was carried out in an inpatient stroke rehabilitation unit with day hospital service. After inclusion, patients were stratified into control group and acupuncture group, randomly.

Outcome measures: The Barthel Index, the Rivermead Scale Index, and the Visual Analogue Scale were used to follow the efficacy of treatment.

Results: In the acupuncture group, all the sensory, motor, and functional scores improved significantly during the examination period until 2 years after injury. The Barthel Index is increased from 4–2 to 95–4 in the acupuncture group. This index also increased in the control group (from 4–2 to 75–4), but the changes were significantly less than in the acupuncture group. A significant spontaneous recovery during the 2-year follow-up was found, but the YNSA treatment facilitated the functional recovery. Improved moving function and more flexible joints and ligaments were observed in comparison to the patients’ condition prior to treatment.

Conclusions: The data suggest that the YNSA is a useful method to treat stroke patients and enhance their quality of life.

Introduction

Standard treatments in stroke rehabilitation are physiotherapy, occupational therapy, and speech therapy in addition to skilled medical and nursing care. Despite intensive inpatient rehabilitation in the stroke unit, more than 30% of acute stroke patients remain moderately to severely disabled at discharge. This reality drives people to search for other modalities of treatment (e.g., complementary and alternative therapies) in an attempt to further improve the outcome of stroke rehabilitation.

Acupuncture has been used in Traditional Chinese Medicine to relieve pain and cure a variety of diseases for more than 2500 years. Acupuncture has been used for stroke in China and Korea for centuries, but scientific studies on this topic have only recently started to emerge. Some but not all of these trials have suggested a positive effect on recovery. There are numerous reports in the Chinese literature about the efficacy of acupuncture in stroke rehabilitation. However, the result was rarely quantitatively expressed by properly validated measures, and intention-to-treat analysis was never mentioned.1–3

Two (2) important reviews of acupuncture in stroke rehabilitation have been published in 1996.1,2 These reviews are open to criticism because the literature was not searched systematically2 or inappropriate studies were not excluded.1 Moreover, new data have been published since that time. In 2001 Park and colleagues published a systematic review of the previous publications.3 They focused only on the sham-controlled randomized clinical trials. They searched 25 databases and 12 major Korean traditional medicine journals. Based on the evidence of rigorous randomized controlled trials, they found there is no compelling evidence to show that acupuncture is effective in stroke rehabilitation. They suggested better-designed studies need to be done. Since that time, a few randomized controlled trials, reviews, and meta-analyses were performed, but the picture still is not clear.4–8

In the previously cited studies, the traditional form of acupuncture was used to treat the patients, but in the last few decades some new forms of acupuncture were developed. One of these is Yamamoto’s New Scalp Acupuncture (YNSA).9,10 After an intensive study of Chinese acupuncture, Dr. Yamamoto began to anesthetize patients when applying needles. He presented the YNSA points and the new scalp

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The size and anatomical location of stroke lesions is evaluated by magnetic resonance imaging using subtraction lesion analysis. Exclusion criteria were the following: (1) no motor deficit, (2) hemodynamic instability, (3) history of dementia, and (4) inability to give consent because of impaired cognition or receptive aphasia. The authors treated 25 patients with YNSA and the other 25 subjects were the nontreated control group (Fig. 1). All patients gave informed consent to participate in the study, which was performed according to the guidelines of the local ethics committee. The participants were not informed of the possibility of being assigned to either acupuncture or no acupuncture group. Ethics Committee approval was granted and the trial was performed in accordance with the Declaration of Helsinki.

All the recruited patients went under rehabilitation program using the Hungarian standard rehabilitation protocol. Twenty-five (25) of the patients received additional acupuncture therapy using the dry needling method, and these patients were regarded as the acupuncture group. The other 25 patients without acupuncture therapy were regarded as the control group, and they only received necessary rehabilitation therapies. The average age was 58.6 ± 10.4 and 59.8 ± 9.6 years (in the acupuncture and control group, respectively). In both groups, 18 patients had ischemic and 7 had hemorrhagic stroke (Table 1).

**Design and acupuncture protocol**

A prospective, assessor-blinded randomized controlled trial was carried out in an inpatient stroke rehabilitation unit with day hospital service in Yamamoto Centre, Budapest, Hungary. After inclusion, patients were stratified into a control group and an acupuncture group. A simple randomization method was performed to create an acupuncture group and a control group.

YNSA is a special form of traditional acupuncture. The method is based on a somatotopic of the scalp. In the same way as for ear or mouth acupuncture, the total organism is projected onto a defined area on the scalp. The locomotor system is situated on either side of the boundary between forehead and hair; the internal organs are represented by Y points on both sides of the temple region. According to the currently applicable official rules of YNSA, before treatment can begin an examination must be made of the lateral neck triangle by YNSA neck diagnostics. In the case of disorders affecting regions below the diaphragm, an inspection of the palms of both hands and palpation according to Hegu (Di 4) can be dispensed with. Neck diagnostics always start with palpation of the two kidney points. The diagnostics provide basic information about the side on which treatment should begin and, depending on the subjective perception of the person being treated, about whether needles should be applied to the frontal yin or dorsal yang treatment area. If the person being treated experiences sensitivity to pressure during palpation of the Kidney point, then treatment will be applied in the front yin area. Either the partially located Y points can be used or exclusively the Cranial Nerve points located in the yin area. At the moment, there are no hard and fast rules concerning when Cranial Nerve points or Y points are to be used. The choice is up to the therapist. Cranial Nerve points and Y points can also be combined. If, for example, a treatment area has been destroyed by trauma or an

**Materials and Methods**

**Patients**

Recruitment commenced between 2006 and 2009, after 50 patients had been enrolled (25 to receive acupuncture treatment and 25 for control). Fifty (50) consecutive patients admitted to the stroke rehabilitation unit were included in the study after informed consent. Inclusion criteria were the following: (1) patients with hemorrhagic or ischemic stroke, (2) admission within 6 weeks of stroke, (3) patients should have movement coordination problems including muscular atrophy, central paralysis, and also myasthenic symptoms, and (4) the degree of brain damage of stroke patients did not exceed 30% of damaged brain tissue. The last statement is important, because when the brain damage exceeds 30%, usually the dry needling treatment would not be successful.
operation, especially in treatment for apoplectic insult due to cerebral hemorrhage, or if the treatment is made more difficult due to the lack of a cranial vault or restricted by extensive scarring, then, depending on anatomical conditions, the points may be freely selected from both somatotopes. YNSA is not “ready-made” acupuncture but rather a treatment tailored to the individual patient. 16,17

The patients in the acupuncture group had been treated once in each month during the whole period of the clinical trial using the dry needling method with removable dry needles according to YNSA (Fig. 2). The “time release” dry needling system with the inserted and permanently entered insertion with the help of a special needle was applied. 18 The length of the special stainless-steel needle is 10.8 cm, and the diameter of the lumen is 0.7 mm. The threads (MAXOL-M Monofilamentum) were cut into 0.7–1-cm pieces and then applied with the needle. The threads were placed into this needle and the material was applied to the “acupoints.” Twelve (12) needles were inserted into every subject per session. The depth of thread insertion is 0.7–0.9 mm. There was no other needle manipulation performed. The insertions are applied once a month, based on the total absorption time of the previous threads being 4 weeks. The YNSA points (Cerebrum, Cerebellum, Basal Ganglia, Liver on the skull)

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### Table 1. Demographic and Clinical Characteristics of Treated Patients, by Group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control group (standard rehabilitation therapy) (n=25)</th>
<th>Acupuncture group (standard rehabilitation therapy with YNSA) (n=25)</th>
<th>p (Fisher’s exact test for categorical variables, t-test for continuous variables [age])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender, %</td>
<td>40</td>
<td>32</td>
<td>0.5</td>
</tr>
<tr>
<td>Mean age in years (SD)</td>
<td>59.8 (9.6)</td>
<td>58.6 (10.4)</td>
<td>0.8</td>
</tr>
<tr>
<td>Current smoking, %</td>
<td>36</td>
<td>40</td>
<td>0.7</td>
</tr>
<tr>
<td>High school or higher educational level, %</td>
<td>40</td>
<td>36</td>
<td>0.6</td>
</tr>
<tr>
<td>Depression (clinical diagnosis), %</td>
<td>0</td>
<td>4</td>
<td>0.2</td>
</tr>
<tr>
<td>Very intense pain at presentation, %</td>
<td>30</td>
<td>30</td>
<td>1</td>
</tr>
<tr>
<td>Lesion of brain tissue, %</td>
<td>15.8</td>
<td>17.1</td>
<td>0.7</td>
</tr>
<tr>
<td>Ischemic stroke vs all, %</td>
<td>72</td>
<td>72</td>
<td>1</td>
</tr>
</tbody>
</table>

YNSA, Yamamoto’s New Scalp Acupuncture; SD, standard deviation.
and additionally Kidney Shu back point bilaterally were stimulated by embedded filaments. The patients in the control group had not been treated by any form of acupuncture.

**Physiotherapy**

In our department, Institute of Complementary and Alternative Medicine, University of Pecs, as in many rehabilitation centers in Hungary, stroke rehabilitation was mainly based on the Dévényi-Pető method in an attempt to restore normal movement and improve strength. Each patient received certain modalities of treatment (3 times a week) as decided by the supervising senior physiotherapist according to the patient’s need at different stages of recovery.

**Measurements**

*Barthel Index (BI)* is a validated and widely used instrument to measure disability in ADL. The original BI a disability profile scale developed by Barthel in 1965 to evaluate a patient’s self-care abilities in 10 areas, including bowel and bladder control. The patient is scored from 0 to 15 points in various categories, depending on his or her need for help, such as in feeding, bathing, dressing, and walking. In the present study, the version used was the one described by Wade and Collin in 1988, which has a total BI score of 20.

*Rivermead Mobility Index (RMI)* is a measurement of mobility disability which concentrates on body mobility. The RMI comprises a series of 14 questions and one direct observation, and covers a range of activities from turning over in bed to running. Its validity as a measure of mobility after head injury and stroke was tested by concurrent measurement using gait speed and endurance, and by standing balance. It is short, simple, and clinically relevant, and can be used in the hospital or at home.

*Visual-Analogue Scale (VAS)* is a subjective factor that describes the patient’s general and physical status.

**Data analysis**

The sensory and motor assessment data were gathered during initial admission to the rehabilitation ward and 2 years after stroke. Statistical comparisons were performed based on these two time points. Categorical variables were analyzed using the \( \chi^2 \) test or Fisher’s exact test for small samples. Measurement data were analyzed using two-tailed t-tests. All recorded data were input using Epi Info software (CDC, Atlanta, GA) and statistically analyzed using SPSS 11.5 statistical software (SPSS, Chicago, IL). For all analyses, \( p < 0.05 \) was considered to be statistically significant. Chi-square analysis of the acupuncture group and control group was also performed to determine homogeneity between both groups in terms of age, gender, and pretreatment measurement outcomes.

The calculation of the sample size is based on the primary outcome measure. It was estimated that 23 patients were required in each group to detect a clinically relevant 2-point difference in Barthel, Rivermead, and Ritchie-Hegyi scores with a power of 80% and an \( \alpha \) value of 0.05. Assuming a 20% dropout rate, it was planned to randomize 28 patients to each group. Unfortunately, 3 patients in both groups needed to be excluded for different reasons.

**Results**

During initial admission to the hospital, all of the 50 stroke patients were randomly distributed to the acupuncture and
The acupuncture group with 25 patients in each group as described in the Materials and Methods section. The neurologic and functional status of members of each group at the time of admission to the rehabilitation ward, discharge from the hospital, and 2-year postinjury follow-up examination are summarized in Figure 3. In the acupuncture group, all the sensory, motor, and functional scores improved significantly during the examination period until 2 years after injury.

The BI is increased from 4 ± 2 to 95 ± 4 in the acupuncture group. This index also increased in the control group (from 4 ± 2 to 75 ± 4), but the changes were significantly less than those of the acupuncture group (acupuncture versus control p < 0.01 at 24 months). The continuously increasing BI during the examination period showed an improvement of self-support ability in both groups, but the acupuncture treatment helped accomplish a faster and better recovery. The change of the other parameters under the examination period shows at least two important results. There was a significant spontaneous recovery during the 2-year follow-up; however, the YNSA treatment facilitated the recovery. The improved moving function (Rivermead scale, from 3 ± 2 to 29 ± 2; from 2 ± 1 to 20 ± 2; treated and control group, respectively, p < 0.01 at 24 months) and the more flexible joints and ligaments as compared to their condition before treatment were observed.

A subjective index (VAS from 27 ± 13 to 71 ± 12; from 20 ± 10 to 53 ± 7; treated and control group, respectively, p < 0.05 at 24 months) was also determined during the follow-up period. The VAS scale was also enhanced in all cases, but the members of the acupuncture group had more efficient function than the control group. In summary, according to the abovementioned results, changes of the indexes are better in the acupuncture group than in the control group.

The intervention was well tolerated by patients. Any "throw-out reaction" of monofilament and side-effect was not observed under the treatment. According to the results in this study, dry-needling elevated the microcirculation of the brain, which was verified by brain-scan investigation. Cerebral blood flow detected by single-photon emission computed tomography was increased by 15% ± 5% after YNSA treatments.

Discussion

Stroke is the third major cause of death worldwide, and it is the most frequent cause of invalidity in old age. Apart from in-patient lysis treatment for a minority of those affected, no efficient methods of treatment addressing the cause of the insult are available for stroke patients. There is an 8.8% risk of cerebral hemorrhage after lysis therapy. As a valuable complement to this type of therapy, YNSA can be offered to all stroke patients who do not fulfill the criteria for lyses treatment.24

The aim of this study was to examine the long-term effects of repeated embedded YNSA treatment on balance and activities of daily living in postacute stroke patients compared with the no-acupuncture group. "So, what is the truth about acupuncture in stroke rehabilitation?" was asked at the end of the Introduction section. In the authors' opinion at least two things are important to determine the efficacy of the acupuncture treatment in stroke rehabilitation. The most important is to enhance the life quality of the stroke patients.
during and after the acupuncture treatment. The second thing is to find the possible link between the acupuncture treatment and the cellular mechanisms that activated in the recovery period of stroke.

Previous studies have reported the ineffectiveness of sensory stimulation by acupuncture or transcutaneous electrical nerve stimulation, functional electrical stimulation, electromyographic feedback, force feedback or body weight supported treadmill training on balance in patients with stroke. Recent evidences have shown that impairment-focused programs (biofeedback, electric stimulation, muscle strengthening) failed to generate functional improvements whereas therapies that administered functional training improved activity levels. Unfortunately, there are no previous data published about the YNSA treatment in stroke survivors. However, in the current study, the generally used BI, the RMI, and theVAS were applied to determine the changes of life qualities of participants. The patients were followed in a 2-year period after the stroke. All of the four parameters were increased in the 24-month follow-up period in the acupuncture and control group; however, the changes were significantly greater in the acupuncture group than in the control group. The data suggest that the YNSA is a useful method to treat the stroke patients and enhance the quality of life.

Using BI, RMI, and VAS for the motor-status evaluation, the results showed that YNSA is effective in patients with stroke (ischemic and hemorrhagic) for motor recovery. To the authors’ knowledge, this is the first study to demonstrate that YNSA has beneficial effects on body motor performance in patients with stroke. In terms of functional improvement, both the study group and the control group showed improvement in functional performance at follow-up assessments. However, there was a tendency for the study group to be superior to the control group in the total scores at follow-up stages, and at the end of the follow-up period it did reach statistical significance.

However, the link still must be found between the acupuncture and the cellular changes after stroke. Some evidence suggests that the acupuncture stimulation with needle has some cellular and tissue effects and that the acupuncture can enhance the release of transmitters that can facilitate angio- and neurogenesis in the central neural system. In 2006, Li and in 2009 Ding and colleagues reported that electroacupuncture therapy could cause depolarization and enhance Ca$^{2+}$ influx of neurons. Moreover, intracellular Ca$^{2+}$ elevation may stimulate an autocrine neurotrophic mechanism, leading to the synthesis and release of neurotrophic factors. Recently, in 2009 Longhurst described that electroacupuncture modulates the sympathoexcitatory reflex responses by decreasing the release of γ-aminobutyric acid. Carmichael reported that axonal sprouting and neurogenesis are induced in stroke rehabilitation. On a cellular level, the phenomenology of neural repair after stroke has been defined and unique regenerative environments in the poststroke brain identified. These data suggest that acupuncture facilitates some molecular and cellular mechanisms that have an important role in the angiogenesis, neurogenesis, and tonic neuronal inhibition in brain tissue. This it can be concluded that acupuncture, especially the YNSA, is a useful complementary tool to facilitate stroke rehabilitation.

Conclusions

These data suggest that the use of YNSA therapy with embedded threads after stroke can contribute to significant neurologic and functional recoveries. There are several limitations of this study. Because there was no sham control, it is not known how much the YNSA intervention contributed to the improvement of subjects in the acupuncture group because it is not known how much of the improvement was due to placebo effect. Further data exploration suggested that these complete case analyses are likely to provide valid statistical interferences.

Disclosure Statement

All authors and contributors declare that no conflict of interest exists.

References


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