Acupuncture versus Rehabilitation in the Treatment of Ischemic Stroke Recovery: A Randomized Controlled Trial

Lixia Li

Guangzhou Hospital of Chinese Medicine

Weifeng Zhu

Guangzhou Hospital of Chinese Medicine

Guohua Lin

The First Affiliated Hospital of Guangzhou University of Chinese Medicine

Chuyun Chen

Guangzhou Hospital of Chinese Medicine

Donghui Tang

Liwan District Hospital of Chinese Medicine

Shiyu Lin

The First Affiliated Hospital of Guangzhou University of Chinese Medicine

Xiaorong Weng

Liwan District Hospital of Chinese Medicine

Liqin Xie

Guangzhou Hospital of Chinese Medicine

Lihong LU (✉ 915675759@qq.com)

Guangzhou Hospital of Chinese Medicine

Weilin Li

Xin Hua College of Sun Yat-sen University

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Abstract

Background: Acupuncture is a treatment for ischemic stroke recovery, but evidence of its effectiveness remains limited.

Methods: A total of 497 patients with ischemic stroke were randomized into Arm 1 (159 cases), Arm 2 (173 cases) and a control group (165 cases). In the control group, rehabilitation training was provided. In Arm 1 and Arm 2, acupoint schemes were determined by the consensus of acupuncture experts and previous clinical research. Arm 1 was based on an acupoint summary of ancient literature, and Arm 2 was based on the summary of effective acupuncture points in modern RCT literature. The treatment was given with conventional acupuncture at the appropriate position. After acupuncture, the needles were left in for 30 minutes, and checked every 10 minutes. The three groups received treatment once a day, 5 times a week, for 2 weeks. The primary outcome were the National Institute of Health stroke scale (NIHSS), and the secondary outcomes were the Barthel index (BI) and modified Ashworth scale (MAS). Outcomes were observed in patients both before and after treatment.

Results: After 2 weeks of treatment, there was no significant difference between Arm 1 and the control group for either the BI scores or the modified Ashworth scale scores ($P>0.05$). However, the NIHSS scores of Arm 1 were lower than those of the control group ($P=0.017$); the BI scores were higher in Arm 2 than they were in the control group ($P=0.020$).

Conclusion: The clinical efficacy of Arm 1 and Arm 2 (acupuncture groups) was superior to that of the control group.

Trial Registration: Chinese Clinical Trial Registry: ChiCTR-IOR-16008627, Registered 11 June 2016, <http://www.chictr.org.cn/index.aspx>.

Keywords: Acupuncture; ischemic stroke; randomized controlled trial (RCT)

Background

Incidence of stroke is widespread around the world. According to recent reports^[1-3], the incidence of stroke in China is 274-379/100,000, of which ischemic stroke accounted for 60-70%. The prevalence for individuals over 70 is 6.6 times that of those aged 40-49. Three-fourths of stroke survivors are left with varying degrees of disability, with about 40% severely disabled. In China, the annual cost of stroke treatment imposes heavy burdens on both the state and many families.

Ischemic stroke is the common term for cerebral infarction in modern medicine. It disrupts cerebral artery blood flow through several pathways, causing hypoxia and ischemic necrosis in local brain tissue. This results in a corresponding neurologic deficit^[4]. The clinical manifestations of ischemic stroke are focal neurological deficits such as hemiplegia, aphasia, dysphagia, visual impairment, and mental disturbance. Ultra-early thrombolysis has been used widely in the acute phase of stroke. However, due to its time-

restricted application, the probability of thrombolysis is only 2.4%^[5]. This leaves intravenous or oral medications, rehabilitation training, and prevention of complications as the primary treatment measures for most stroke patients.

There is a long history of acupuncture treatments for stroke. The earliest stroke symptoms and acupoints were recorded in the *Huang Di Nei Jing*, and staged syndrome differentiation and stroke treatment is recorded in *Acupuncture Dacheng*. At present, new acupuncture theories and techniques are still being developed.

A prospective randomized-controlled trial was conducted to explore an optimal plan for acupuncture treatment of ischemic stroke, and to provide scientific evidence for the effectiveness of acupuncture as a stroke treatment.

Methods

Settings and subjects

The present study is a randomized controlled trial, conducted at the Guangzhou Hospital of Chinese Medicine, the First Affiliated Hospital of Guangzhou University of Chinese Medicine, and the Liwan District Hospital of Chinese Medicine. The study program was authorized by the Ethics Committee of the Guangzhou Chinese Medicine Hospital (Reference no. 2016NK001) before the implementation of the trial. The reporting of the study complied with the requirements of the CONSORT 2010 statement^[10].

Patients were randomly divided into either Arm 1, Arm 2 or the control group. The grouping was performed by personnel from the Key Research Laboratory of Clinical Research Methodology at the Guangdong Provincial Hospital of Chinese Medicine. SAS 9.2 was used to complete the procedure and for randomization. The trials were single-blind so that the data analyst and evaluator were unaware of the groupings. Neither patients nor the clinical doctors performing the interventions were blinded. In order to avoid bias, the individual responsible for the evaluation of the efficacy was hired separately, and was unaware of patient groupings. Analysts were also chosen separately and did not participate in the clinical implementation or design of the project.

The trial was conducted between July 2016 and July 2017, and patients who met the following criteria were included in the study:

- (1) diagnosed with ischemic cerebrovascular disease by either CT or MRI^[11]
- (2) recovery period (2 weeks to 6 months after acute stroke), sequelae period (June to December)
- (3) number of strokes ≤ 3
- (4) aged between 40 and 75, male or female

(5) clear cognitive faculties, stable vital signs, no obvious mental retardation, no obvious hearing impairment, and ability to cooperate with rehabilitation training

Exclusion criteria were as follows:

(1) had already received other treatments that were not part of this research plan

(2) suffered from transient ischemic attack, or reversible neurological deficit (RIND)

(3) neurological deficit was not related to ischemic stroke

(4) suffering from mental disorders or other severe diseases

(5) patients with severe aphasia, sleep apnea, deafness, severe cognitive impairment, or communication barriers

Treatment process

The criteria to participate in this study were to meet the requirements of the list for items in the *Standards for Reporting Interventions in Clinical Trials of Acupuncture* (STRICTA) 2010^[12]. Before the trial began, the research team was authorized by the Ethics Committee of the Guangzhou Chinese Medicine Hospital, the First Affiliated Hospital of Guangzhou University of Chinese Medicine, and the Liwan District Chinese Medicine Hospital (Reference no. 2016NK001) to conduct this study. All included cases were treated with basic drugs, such as those to improve circulation, nourish nerves, prevent platelet aggregation, and condition blood pressure, blood sugar, and blood lipids. Patients also received rehabilitation training^[11]^[13]. Rehabilitation training followed the guidelines from the *Rehabilitation Treatment Guide 2011 of Stroke in China*^[14] and *Practical Rehabilitation*^[15].

Acupoints

The optimal acupoint scheme for this test was determined by the consensus of acupuncture experts and previous clinical research^[16]. One group's treatment was based on the acupoint summary of ancient literature^[17-18], and the other's was based on a summary of effective acupuncture points in modern RCT literature by the consensus of acupuncture experts (Follow 1). The most frequently used twelve acupoints in the ancient books and the modern RCT literature were determined by the consensus of acupuncture experts and previous clinical research. In treatment Arm 1, these included DU20 (baihui), DU26 (shuigou), PC9 (zhongchong), ST6 (jiache), ST4 (dicang), LI15 (jianyu), LI11 (quchi), LI4 (hegu), GB30 (huantiao), GB31 (fengshi), GB34 (yanglingquan) and GB39 (xuanzhong). In treatment Arm 2, they were DU20 (baihui), PC6 (neiguan), LI11 (quchi), LI10 (shousanli), SJ5 (waiguan), LI4 (hegu), GB30 (huantiao), ST36 (zusanli), GB34 (yanglingquan), SP6 (sanyinjiao), ST41 (jiexi) and LR3 (taichong). Other than PC9 and PC6, all acupoints were selected on the affected side.

Acupuncture intervention

The acupuncture treatment was performed by 16 different acupuncturists (with between 2 and 7 year's experience) at 3 different hospitals. 7 of the acupuncturists had bachelor's level educations, 6 had master's degrees, and 3 had doctorates and were registered practitioners of Chinese medicine. All researchers and acupuncturists were required to undergo a four-day training session prior to the start of the trial.

Appropriate positioning of the needles is the key to good acupuncture results. The patients in the study lay in a lateral position with the affected side facing up, the hemiparalysis shoulder stretched forward, the shoulder joint flexed 90 degrees, and the paraplegic upper limb placed on the pillow at a 100° angle to the trunk. The elbow was straightened, with arm, wrist and fingers extended, and palm facing up. Next, the paraplegic side of the lower extremity was placed on the pillow, revealing a step-like shape (with hips and knees flexed). The disposable sterile acupuncture needles used had varying specifications (0.30 x 25 mm, 0.30 x 40 mm, 0.30 x 50 mm, or 0.30 x 75 mm). Conventional disinfection with 75% alcohol was employed after acupuncture point positioning, in accordance with *Standard Acupuncture and Moxibustion Positioning by WHO*^[9]. During the acupuncture session, patients would feel numbness, tingling, or pressure, demonstrating that needling had been effective. In order to stimulate needle sensation, the needles were inserted flat and backwards, 25 mm into DU20, and 8-15 mm obliquely and upward into DU26. Then, a reducing method was used for 30s, rotating at small-amplitude and high-frequency. The other acupoints utilized the reinforcing-reducing method 2.5 mm deep into PC9; 15-20 mm vertically into ST6, ST4, GB39, ST41 and LR3; 15-25 mm perpendicularly into LI4, PC6, and SJ5; 25-40 mm obliquely and downward into LI15; 25-40 mm perpendicularly into LI11, GB34, GB31, LI10, ST36, and SP6; and 50-70 mm perpendicularly into GB30. After insertion, the needles were left in situ for 30 minutes. The course of treatment was 5 times a week for 2 weeks. All necessary precautions were taken to prevent, record and treat any adverse events that occurred during treatment (e.g. fainting, broken needles).

Outcomes

The treatment effect of this trial was evaluated through three scales, at different time points (Baseline=T0, Week 1 = T1, Week 2 = T2 and Follow up). The primary outcome was expressed using the National Institute of Health Stroke Scale (NIHSS). It ranged from 0 to 40, and included 11 items: consciousness, limb movement, freemasons, eye movement, vision, facial paralysis, feeling, language, dysarthria and neglect. It also determined the improvement of neurological function in the three groups (i.e. the lower the score, the lesser the patient's neurological deficit). The secondary outcomes were Barthel Index Table (BI) and Modified Ashworth Scale (MAS). The BI scale is typically used to assess patient self-care ability, and if the score was below 20, this meant that the patient's self-care ability was seriously impaired. A score over 60 indicated patients were able to care for themselves. The improvement and difference in muscle tension within the three groups was determined by the changes in the modified Ashworth scale, both before and after treatment—the higher the score, the higher the patient's muscle tone.

Sample size

According to Yang^[20], the NIHSS score for simple stroke rehabilitation was (12.78±2.99), and the NIHSS score for acupuncture combined with stroke rehabilitation was (16.06±4.57). Setting α to 0.05, β to 0.1, and substituting the sample size formula of the two groups of means, the results showed that 30 patients were necessary for each group to complete the trial. Considering that the two treatment groups were compared with the control group, in order to control for type 1 error, the number of patients in each group was increased to 30*3=90. Assuming a 10% drop-out rate per group, each group was adjusted to 100, with a total of about 300 patients.

Statistical analysis

An intention-to-treat population was surveyed before analyses, which included the patients carrying out baseline assessment and at least one evaluation after treatment. The NIHSS, BI and MAS scores, along with changes over time, were compared by using repeated measures design between the three groups. We also employed Analysis of Variance (ANOVA) to define the among-group differences at each measure time point. A Chi-square or Fisher Exact test was used to analyze categorical variables, including categorical baseline variables and incidence of adverse events. Last observation carried forward (LOCF) was used in the ITT analysis to address missing data due to attrition and shedding. Statistical significance was defined as a two-tailed $P < 0.05$. Statistical analysis was performed with PASW 20.0 (IBM SPSS Inc., Armonk, New York, USA).

Results

Baseline data

Between July 2016 and July 2017, a total of 2,369 patients were assessed for eligibility. 497 of them participated in the trial (Guangzhou Hospital of Chinese Medicine = 200, First Affiliated Hospital of Guangzhou University of Chinese Medicine = 247, Liwan District Hospital of Chinese Medicine = 50). They were randomly divided into 3 groups (Arm 1 = 159, Arm 2 = 173, control group = 165). Ten patients dropped out before the trial ended, six stopped because of sudden serious diseases such as heart failure or lung infection, and three could not cooperate with the researcher. One patient was lost due to a change in contact phone number (Fig. 1).

Table 1 lists the basic information for the patients involved in the study, totaling 311 males and 186 females, all aged around 65. Most of the patients were not college educated, and most lived in urban areas. 74.2% of the patients had a history of smoking and 84.5% had a history of alcohol. There were no statistically significant relationships between the general variables (e.g. gender, age, education, career). There were also no statistically significant differences in ischemic stroke characteristics (disease course, number of strokes, infarct size and family history, see Table 2)

Mean scores and changes in NIHSS, BI and MAS at different time points in the three study arms are shown in Table 3. In the statistical analysis of the above three items, no difference was found between the three groups in the repeat measurement design.

The NIHSS scores of the three groups at each time point were analyzed and the results showed no significant difference in NIHSS scores at T0 and T1 ($P>0.05$). However, the difference between the NIHSS scores at T2 was statistically significant ($P = 0.014$). Further between-group comparisons found that there was a statistically significant difference between Arm 1 and the control group. As shown by Fig. 2 (A), the NIHSS score in Arm 1 had the largest decrease.

During the treatment and follow-up period, BI scores of the three groups trended upwards, and between-group comparisons showed a statistically significant difference in the Arm 2 BI scores at T2 and follow-up (see Fig. 2B). However, we found no other apparent differences at other time points.

Although there was an obvious decrease in MAS scores during the treatment period, no statistically significant difference across the three groups was found at any time point (see Fig. 2C).

Safety assessment

Over the course of treatment for the three groups, there were no obvious changes in blood routine, urine routine, liver function, renal function, or heart enzymes. There were 5 adverse events in Arm 1, 7 adverse events in Arm 2, and no adverse events in the control group. Of these adverse events, 9 were cases of bleeding and 3 were cases of delayed needles. We stopped the bleeding by pressing for 10 seconds with a sterile swab, and gently poking the needle handle, thus facilitating needle removal. No patients withdrew from the trial due to adverse events.

Discussion

Based on the above results, the following conclusions can be drawn: After comparison with the control group, Arm 1 and Arm 2 were determined to be clinically effective and safe. At present, ischemic stroke treatment is mostly performed in the stroke unit, which is considered to be the most effective way to deal with the disease^[21-23]. In the stroke unit, various therapies and specialties are combined to provide patients with drugs, physical, language, and psychological rehabilitation, as well as health education^[24]. In the near future, acupuncture may also play an indispensable role in clinical rehabilitation^[25-26].

Effective treatment is dependent on proper choice of acupuncture points. The acupoints in this study were selected based on both ancient literature and modern RCT literature. They were chosen because of their wide application, frequent usage and exact curative effect. These acupoints each possess the following characteristics: The first is that they connect to the *yangjing*. In Chinese medicine, *yin* and *yang* are balanced. The acupoints on the *yangjing* have the effect of replenishing *yangqi*. This is in line with the *yin* symptoms for hemiplegia. The other feature of the acupoints in this study is that they each have a unique therapeutic effect a specific name. This provides a sound theoretical basis for effective stroke treatment.

Arm 1 was superior to the control group in treating neurological deficits, however there was no difference between Arm 2 and the control group. Previous studies have shown that GV20-based acupoint

combination combined with rehabilitation is more effective than simple rehabilitation in reducing NHSS scores after 8 courses of treatment. This is because these acupoints can balance the body's *yin* and *yang*, and dredge the *qi* and blood of the meridians^[20]. In terms of improving patient self-care ability, the effect of Arm 2 was better than the control group, but there was no difference between Arm 1 and the control group. A multi-center RCT revealed that the BI scores of patients with subacute stroke were significantly higher after 6 months of body and scalp acupuncture treatment, but no obvious improvements were found when compared with the rehabilitation group^[27]. In the authors' opinion, this negative result was due to the acupoints in the program deviating from the viewpoint of TCM syndrome differentiation. Thus, we should not only focus on the proximity to afferent nerve fibers, but also select points according to the specific conditions of the patients. The acupoints in this study were derived from a combination of multiple clinical trials and the experience of several trained acupuncturists. The two treatment groups tested comparably to the control group in improving muscle tension. However, many experiments have shown that acupuncture or electroacupuncture combined with rehabilitation can improve muscle tone and release spastic limbs^[28-31]. In our opinion, this is likely related to insufficient treatment time or observation time. Confirming this would require further research.

Limitations of this study

Although this trial was one of the few random, multi-center, and large-sample trials of acupuncture treatment for stroke^[32], there are some limitations that require attention. First, the course of treatment was short. However, the results reveal that with the passage of treatment time, positive effects did emerge in the treatment group. Secondly, our study was not double-blinded. This may have led to treatment outcome bias.

Conclusions

The interventions with acupuncture showed better results than did the simple rehabilitation group, but there was no difference between the effects of the two acupuncture groups.

Abbreviations

NIHSS: National institutes of Health Stroke Scale; BI: Barthel index; MAS: Modified Ashworth Scale; STRICTA: Reporting Interventions in Clinical Trials of Acupuncture; WHO: World Health Organization.

Declarations

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions

L.X., C.Y. and L.H. designed and led the study. Z.F., T.H., W.R., L.L. and L.Y. analyzed and interpreted the patient data for generating the study results. L.L.H and X.Q. drafted the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

The consent form for the study participants was incorporated into the study protocol, and was approved by the Ethics Committee of the Guangzhou Hospital of Chinese Medicine. Study consent, including that for data publication, was obtained from each participant prior to joining the study.

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee at the Guangzhou Hospital of Chinese Medicine in writing (Reference no. 2016NK001) before the study commenced. Informed consent to participate was obtained from all participants prior to their involvement.

Author details

Department of Acupuncture and Moxibustion, Guangzhou Hospital of Chinese Medicine, Guangzhou 510130, China; Department of Acupuncture and Moxibustion, The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou 510405, China; Department of Physiatry, Liwan District Hospital of Chinese Medicine, Guangzhou 510145, China; Xin Hua College of Sun Yat-Sen University, Guangzhou 510000, China.

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Tables

Table 1 Baseline characteristics of patients (n = 497)

General information	Arm 1 (n=159)	Arm 2 (n=173)	Control group (n=165)	Total
Gender				
Male	107(67.3)	107(61.8)	97(58.8)	311
	52 (32.7)	66(38.2)	68(41.2)	186
Female				
Age	64.3±8.3	65.2±8.5	65.4±6.9	64.9±8.3
Education				
Primary school or illiterate	31(19.5)	31(18.0)	36(22.0)	98(19.8)
Secondary school	53(33.3)	68(39.5)	62(37.8)	183(37.0)
High school	61(38.4)	61(35.5)	61(35.5)	176(35.6)
University	14(8.8)	12(7.0)	54(32.9)	38(7.7)
Master's or above	0(0)	0(0)	0(0)	0(0)
Career				
Mental worker	23(14.5)	23(13.3)	18(10.9)	64(12.9)
Manual worker	22(13.8)	27(15.6)	31(18.8)	80(16.1)
Student	0(0)	0(0)	0(0)	0(0)
Retired	84(52.8)	99(57.2)	87(52.7)	270(54.3)
Unemployed	11(6.9)	13(7.5)	12(7.3)	36(7.2)
Other	19(11.9)	11(6.4)	17(10.3)	47(9.5)
Residence				
Town	132(83.0)	150(86.7)	137(83.0)	419(84.3)
Village	27(17.0)	23(13.3)	28(17.0)	78(15.7)
Smoking				
None	114(71.7)	123(71.1)	132(80.0)	369(74.2)
Former smoker	31(19.5)	27(15.6)	20(12.1)	78(15.7)
Current smoker	14(8.8)	23(13.3)	13(7.9)	50(10.1)
Alcohol				
None	130(81.8)	151(87.3)	139(84.2)	420(84.5)
Former user	19(11.9)	13(7.5)	17(10.3)	49(9.9)
Current user	10(6.3)	9(5.2)	9(5.5)	28(5.6)

Table 2 Ischemic stroke characteristics

General information	Arm 1 (n=159)	Arm 2 (n=173)	Control group (n=165)	F/	P
Disease course					
Month	4.69±8.39	8.52±26.55	6.19±13.74	1.858	0.157
Number of strokes	1.26±0.53	1.25±0.44	1.28±0.50	0.134	0.857
Infarct size					
Lacunar	28(17.7)	29(17.8)	45(27.4)	6.467	0.373
Multiple	81(51.3)	87(53.4)	78(47.6)		
Large area	16(10.1)	15(9.2)	13(7.9)		
Other	33(20.9)	32(19.6)	28(17.1)		
Family history of stroke					
No	129(81.1)	134(77.9)	123(74.5)	4.635	0.324
Unknown	26(16.4)	36(20.9)	35(21.2)		
Yes	4(2.5)	2(1.2)	7(4.2)		

Table 3 Scores and changes for NIHSS, BI and MAS in the three study arms (x±SD)

	Group	T0=baseline	T1=1 week	T2=2 weeks	Follow up
NIHSS	Arm 1	7.13±4.91	5.98±3.72	4.59±3.47 ^{ab}	
	Arm 2	6.88±4.08	6.11±4.01	4.88±4.11	
	Control group	6.98±3.93	6.62±4.03	5.81±4.11	
BI	Arm 1	54.94±27.01	60.00±27.92	67.50±28.22 ^a	69.54±27.69 ^a
	Arm 2	57.82±27.40	61.84±27.58	69.26±28.64 ^c	71.15±28.73 ^c
	Control group	54.34±27.52	56.62±28.31	60.52±28.69	62.68±28.69
MAS	Arm 1	2.17±1.32	2.03±1.18	1.78±0.99	
	Arm 2	2.34±1.38	2.06±1.24	1.80±1.06	
	Control group	2.18±1.37	2.09±1.24	1.96±1.17	

^aThere were significant differences between the three groups. ^b A comparison between Arm 1 and the control group was statistically significant. ^cA comparison between Arm 2 and the control group was statistically significant.

Figures

CONSORT 2010 Flow Diagram

Figure 1

Flow diagram.

Figure 2

Scores of NIHSS, BI and MAS in three groups.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [supplement1.doc](#)
- [supplement2.doc](#)