The effect of auricular acupuncture (AT4) when combined with electro-acupuncture in recovery cerebral infarction: A randomized trial

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Abstract

Background and Objectives: Cerebral infarction can lead to severe consequences. According to traditional medicine theory, electro-acupuncture and ear acupuncture are some of the successful treatments for rehabilitating the motor functions of paralyzed limbs. The goal of this study is to evaluate the efficacy of combining ear acupuncture (AT4) with traditional electro-acupuncture to aid in the recovery of individuals experiencing limb paralysis due to a brain infarction. **Methods:** Patients at the Traditional Medicine Hospital in Ho Chi Minh City provided 108 samples for a clinical experiment. The research follows a randomized, unblinded, and controlled design. The evaluation criteria include the number of rounds the patient puts into the hole in 1 and 3 minutes, the time to walk 10 meters with support equipment, and the Barthel index (BI) score in 4 weeks. **Results:** The number of rounds the patient puts into the hole in 1 minute and 3 minutes increased, while the time to walk 10 meters with support equipment decreased. The difference from the baseline demonstrated the effectiveness of acupuncture in general and presented the results of combining acupuncture and ear acupuncture in particular. Compared to the two Groups, BI scores in the Treatment Group improved more than in the Control Group with a statistically significant difference. No patient had any adverse events during the study. **Conclusion:** Combining auricular acupuncture and electro-acupuncture can improve motor rehabilitation in patients with cerebral infarction.

Keywords: *Stroke recovery, AT4, auricular acupuncture, electro-acupuncture, Barthel index.*

1. INTRODUCTION

Stroke is the second-leading cause of death and the third-leading cause of death and disability combined in the world [1]. Stroke includes cerebral infarction, cerebral hemorrhage, and subarachnoid hemorrhage. Post-stroke patients experience a range of health issues including substantial motor and sensory impairment, cognitive deficits, difficulty swallowing (dysphagia), communication troubles, pain in the shoulder on the affected side (hemiplegic shoulder pain), and problems with bowel and urine control (incontinence). Motor impairments in stroke patients lead to deconditioning and decreased degrees of independence [2].

Nowadays, a large number of people prefer acupuncture therapy, a procedure that involves minimal invasion, as a means of physical rehabilitation. Multiple papers have evaluated the efficacy of acupuncture in improving motor function [3].

To begin with, acupuncture and electro-acupuncture can bring remarkable benefits to stroke patients during their rehabilitation through five primary processes. These actions encompass stimulating new neurons and cell growth in the central nervous system. In addition, control of blood flows in the areas that are affected by blood supply reduction, preventing cell death in influenced brain fields, regulating neurochemicals, and enhancing poor long-term synaptic strength and memory after a stroke [4].

Auricular acupuncture is a form of acupuncture that stimulates specific acupoints on ear parts according to the Chinese Ear Chart recognized by the World Health Organization. It has been described to support stroke survivors with dyskinesia, and many scientists believe that stimulating the M1 area of the brain can be a key part of using auricular acupuncture to help stroke patients with upper limb dysfunction [5].

However, the mechanism of acupuncture and ear acupuncture, with their effectiveness in improving activity abilities after a cerebral infarction, have not been addressed in depth. This study will investigate whether combining auricular acupuncture (AA) and electroacupuncture (EA) could enhance motor

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recovery and reduce dependency on others in the daily activities of patients suffering from cerebral infarction.

2. METHODS

2.1. Study design

This research was a randomized clinical study with no blind participants. A study was undertaken at the Traditional Medicine Hospital in Ho Chi Minh City, Vietnam, involving 108 patients from September 2020 to March 2022.

The study included patients in the early recovery period of cerebral infarction, which was the period from day 8 to the end of 3 months after cerebral infarction. The participants must have agreed to participate in the analysis and met the following criteria: They must have been alert, cooperative with the doctor, have a good awareness of space and time, be paralyzed, have a Barthel Index (BI) less than 60, and have a Body Mass Index (BMI) less than 30 [6].

The exclusion criteria included patients with inflammation and sores in the ear skin and acupuncture points area. Patients with serious systemic disease were also removed from the chosen list.

We randomly assigned 108 patients in a 1:1 ratio to receive either electroacupuncture (EA) or a combination of auricular acupuncture (AA) and EA over four weeks. The EA Group was the Control Group, and the combination of the AA and EA Groups was the Treatment Group. They would randomly draw a sealed-numbered envelope. If the number was odd, they would go to the Treatment Group; if it was even, they will go to the Control Group.

We treated both groups and administered acupuncture at nine points in the paralyzed limb. We administered 10 points to Jianyu (LI15), Binao (LI14), Quchi (LI11), Yangxi (LI5), Shousanli (LI10), Hegu (LI4), Liangqiu (ST34), Zusanli (ST36), Fenglong (ST40), and Jiexi (ST41). We use the Korean electromagnet machine CWM-202-SENSEPLUS, intensity 02–05 mA, frequency 01 - 20 Hz, or automatic pulse Auto 2, 15 - 20 minutes each time, once a day for a total of four weeks (except Sunday). Electroacupuncture was administered in conjunction with auricular acupuncture. In addition, the patients received physical therapy once a day for a total of four weeks (except Sunday).

Participants in the Treatment Group will receive auricular acupuncture treatments once a day for a total of four weeks (except Sunday). They will have needles inserted into the Pizhixia point (AT4) on the pinna, the same side of the brain that is damaged.

Outcome Measures:

- Evaluate the level of hand recovery: The number of rounds the patient puts into the hole in 1 minute and 3 minutes.

- Evaluate the level of foot recovery: Time to walk 10 meters with support equipment

- The Barthel Index (BI): The outcome of the assessment is the degree of independence, consisting of a table of 10 questions about 10 activities: feeding, bathing, grooming, dressing, bowel control, bladder control, toilet use, transfers (bed to chair and back), mobility on level surfaces, and stairs. Each question's total score contributes to the BI score, which ranges from a maximum of 100 to a minimum of 0. The higher the score, the higher the level of independence. A total BI score of 0 - 39 suggests total dependence, 40 - 60 severe dependence, 61 - 85 assisted independence, 86 - 99 minor assisted independence, and 100 independence [6-8].

- The classification of treatment response: Good (after 4 weeks of treatment, increase in the recovery classification according to BI and BI > 60), not good (remaining).

We performed assessments 1 week, 2 weeks, 3 weeks, and 4 weeks after patients started participating in the study.

2.2. Statistical analysis

You can collect data using tracking sheets. Process and analyze data using SPSS 20.0 software. Report the mean (standard deviation) for the quantitative variable and the ratio for the categorical variable. To compare quantitative variables, use the chi-square test, and for qualitative variables, use the T-student test. Use the Fisher or Wilcoxon test when the conditions of the chi-square and T-student tests do not meet.

2.3. Ethical considerations

This study was approved by the Board of Ethics in Biomedical Research at the University of Medicine and Pharmacy in Ho Chi Minh City on September 9, 2020, No. 539/HĐĐĐ-ĐHYD. All participants signed an informed consent form that did not disclose the personal identification of the research object (name, address).

3. RESULTS

Table 1. Characteristics at baseline of subjects among Control and Treatment Group

		Control Group (n=54)		Treatment Group (n=54)		p-value
		Frequency	Ratio (%)	Frequency	Ratio (%)	
Gender	Male	30	55.6	33	61.1	**0.847**[a]
	Female	24	44.4	21	38.9	
Age	< 60	25	46.3	24	44.4	**0.558**[a]
	≥ 60	29	53.7	30	55.6	
Time since cerebral infarction	From 01 week to 01 month	28	51.9	36	66.7	**0.117**[a]
	over 1 month	26	48.1	18	33.3	
Number of cerebral infarctions	1 time	51	94.4	49	90.7	0.716[a]
	≥ 2 times	3	5.6	5	9.3	
Coma during cerebral infarction		0	0	1	1.9	1 **b**
Including diseases	Hypertension	49	90.7	51	94.4	0.716 **a**
	Diabetes	16	29.6	13	24.1	0.34 **a**
	Hyperlipidemia	52	98.1	52	98.1	1 **b**
	Fat	11	20.4	10	17	0.653 **a**
	Heart disease	11	20.4	10	17	0.62 **a**

[a] *Chi-square test;* [b] *Fisher test*

The majority of patients participating in the study were between 40 and 60 years old, with the youngest being 24 years old and the oldest being 80 years old. The distribution ratio of male and female patients in the study sample is approximately equal. Most disease onset times are less than one month. Of the accompanying diseases, the two most common chronic diseases are dyslipidemia (98.1%) and hypertension (94.4%).

Subjects' baseline characteristics (age, sex, time of disease onset, number of cerebral infarctions, coma at disease onset, and accompanying disease) were not significantly different between the Control Group and the Treatment Group.

Table 2. The number of rounds the patient puts into the hole in 1 minute and 3 minutes

The number of rounds the patient puts into the hole	Control Group (n=54)			Treatment Group (n=54)			p3
	Medium	Standard deviation	p1	Medium	Standard deviation	p2	
1 minute							
Baseline	1.19	2.66		0.85	1.82		0.734[a]
After 1 week	1.20	2.66	0.871[a]	0.94	2.067	0.846[a]	0.753[a]
After 2 weeks	1.94	3.51	0.067[a]	2.06	3.22	0.001[a]	0.266[a]
After 3 weeks	2.61	4.81	0.008[a]	3.02	3.91	<0.001[a]	0.209[a]
After 4 weeks	3.3	5.94	0.002[a]	3.85	4.03	<0.001[a]	0.107[a]
3 minutes							
Baseline	2.96	7.08		2.24	4.8		0.756[a]
After 1 week	3.15	7.32	0.729[a]	2.74	6.13	1[a]	0.694[a]
After 2 weeks	5.11	8.89	0.035[a]	5.59	9.7	0.001[a]	0.383[a]
After 3 weeks	6.54	10.76	0.004[a]	7.59	11.08	<0.001[a]	0.292[a]
After 4 weeks	7.96	11.91	<0.001[a]	9.51	11.37	<0.001[a]	0.158[a]

p1: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and baseline in the Control Group.

p2: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and Baseline in the Treatment Group.

p3: p-value in comparison between the Control Group and the Treatment Group after each week of treatment.

[a] *Wilcoxon signed rank-sum test*

During this study, table 2 shows a declining trend in the number of rounds the patient puts into the hole in 1 minute and 3 minutes in both groups. Between the control and treatment groups, the number of rounds the patient puts into the hole in 1 minute and 3 minutes was not significantly different.

Table 3. Comparison of time to walk 10 meters with support equipment

Time	Control Group (n=54)			Treatment Group (n=54)			p3
	Medium	Standard deviation	p1	Medium	Standard deviation	p2	
Baseline	169.33	20.78		168.13	16.45		0.284 [a]
After 1 week	163.03	21.49	0.023 [a]	159.06	21.49	0.041 [a]	0.389 [a]
After 2 weeks	151.43	23.05	<0.001 [a]	147.37	21.12	<0.001 [a]	0.152 [a]
After 3 weeks	139.13	20.36	<0.001 [a]	131.96	23.06	<0.001 [a]	<0.05 [a]
After 4 weeks	127.81	19.6	<0.001 [a]	116.94	23.88	<0.001 [a]	<0.05 [a]

p1: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and baseline in the Control Group.

p2: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and Baseline in the Treatment Group.

p3: p-value in comparison between the Control Group and the Treatment Group after each week of treatment.

[a] *Wilcoxon signed rank-sum test*

The 10-meter walking time with support equipment in each Group at T1, T2, T3, and T4 differed statistically significantly. In T3 and T4, the Treatment Group recovered better than the Control Group; the difference was statistically significant.

Table 4. Comparison of BI in 2 Groups

	Control Group (n=54)			Treatment Group (n=54)			p3
	Medium	Standard deviation	p1	Medium	Standard deviation	p2	
Baseline	38.61	12.3		36.57	9.5		0.197 [a]
After 1 week	41.11	13.76	0.428 [a]	39.26	9.29	0.125 [a]	0.267 [a]
After 2 weeks	47.31	14.23	0.002 [a]	48.33	11.9	<0.001 [a]	0.664 [a]
After 3 weeks	52.31	13.9	<0.001 [a]	56.3	9.72	<0.001 [a]	0.064 [a]
After 4 weeks	56.39	13.26	<0.001 [a]	61.13	10.08	<0.001 [a]	<0.05 [a]

p1: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and baseline in the Control Group.

p2: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and Baseline in the Treatment Group.

p3: p-value in comparison between the Control Group and the Treatment Group after each week of treatment.

[a] *Wilcoxon signed rank-sum test*

When comparing before and after treatment in each Group from the second week, the BI increased. After was a statistically significant difference in BI between the two Groups after four weeks of study.

Table 5. Comparison of the dependency classification according to BI in 2 Groups

	Control Group (n=54)		Treatment Group (n=54)		p3
	Frequency	p1	Frequency	p2	
Baseline					
total dependence	21		29		0.123[b]
severe dependence	33		25		
After 1 week					
total dependence	18	0.149[a]	22	0.247 [a]	0.368[a]
severe dependence	32		31		
assisted independence	4		1		
After 2 weeks					
total dependence	10	0.001[a]	7	<0.001[a]	0.431 [b]
severe dependence	36		42		
assisted independence	8		5		
After 3 weeks					
total dependence	5	<0.001[a]	0	<0.001[a]	<0.05 [a]
severe dependence	37		47		
assisted independence	12		7		
After 4 weeks					
total dependence	3		0		
severe dependence	36	<0.001[a]	28	<0.001[a]	<0.05 [a]
assisted independence	15		23		
minor assisted independence	0		3		

p1: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and baseline in the Control Group.

p2: p-value in comparison between after 1 week, 2 weeks, 3 weeks, and 4 weeks of treatment and Baseline in the Treatment Group.

p3: p-value in comparison between the Control Group and the Treatment Group after each week of treatment.

[a] Fisher's exact test, [b] Chi-square test

At baseline and after 1 week, the dependency classification according to BI in the 2 Groups did not differ. After 2 weeks, the dependence level in the two Groups changed in an improving direction, gradually decreasing the number of total dependences and progressively increasing the number of severe dependences and assisted independence. When compared between the two Groups, the Treatment Group improved dependency more than the Control Group after 3 and 4 weeks, differing statistically significantly.

Table 6. The classification of treatment response after 4 weeks of treatment

	Control Group (n=54)		Treatment Group (n=54)		p-value
	Frequency	Ratio (%)	Frequency	Ratio (%)	
Good	39	72.2	28	51.9	<0.05 [a]
Not good	15	27.8	26	48.1	

[a] Chi-square test

The Treatment Group had a higher rate of good treatment response compared to the Control Group. The Treatment Group has a lower rate of poor response to treatment than the Control Group; the difference is statistically significant.

4. DISCUSSION

Traditional medicine theory links the ear to the meridian system and the viscera in the body. As a result, we use the ear to diagnose and treat diseases. When choosing acupoints for treatment, we can either combine or select them individually. The Technical Procedures of the Ministry of Health state that the following ear acupuncture points are frequently used to treat stroke sequelae: subcortical, heart cell, autonomic nerve, shoulder arm, spine, spleen, liver, and kidney. This shows that ear acupuncture is effective in recovering paralyzed limbs [9].

Modern medicine asserts that the central nervous system also controls the ear. Specifically, the X nerve, which connects during treatment, plays a crucial role in regulating corresponding dysfunctions, including those in the brain. Studies demonstrate that the X nerve has a regulatory effect on muscle strength and dystonia in hemiplegic patients[10, 11]. On the other hand, according to the anatomical structure and physiological function, the subcortical area is responsible for transmitting sensations to the cerebral cortex (somatic sensations, vision, hearing, and other types of stimuli), which is the link that guides the brain. The center of the subcortical system carries out complex automatic reflexes and regulates processes inside the body as well as the activity of internal organs, thanks to its relationship with the hypothalamus and cerebral cortex. When this part is disturbed, we acupuncture the subcortical acupoint to stimulate the X nerve to adjust the function of the subcortical area to return to normal. There are two methods available for selecting acupoints: applying traditional medicine theory or selecting acupoints based on meridian lines. In the Treatment Group, not only did we select acupuncture points based on traditional medicine theory, but we also applied modern medicine theory: stimulating nerve X enhanced the strength of the flexor muscles in the upper and lower limbs, as well as the extensors in the lower limbs [10, 12].

Ear acupuncture is a simple and cheap technique that helps patients save a lot of money on treatment, especially for chronic diseases. After two weeks with the combination of subcortical ear acupuncture and body acupuncture, we found that the improvement in paralyzed limbs was faster than the simple body acupuncture method, but this is just a general feeling. This opinion lacks a scientific foundation and fails to garner consensus from both experts and acupuncture researchers. The research team decided to select only subcortical acupoints from the Ministry of Health protocol, targeting the subcortical area of the brain to stimulate muscle movement and restore stronger limb movement [9].

The study results demonstrate the effectiveness of upper limb motor rehabilitation, specifically in the dexterity test. Over time, the Treatment Group and control Group both increased the number of rounds for 1 minute and 3 minutes, a statistically significant difference from baseline. When compared between the two Groups, the effect on upper limb motor rehabilitation differed without statistical significance. Our research shows the role that ear acupuncture plays in the central nervous system, especially the X nerve, to improve muscle movement, helping to restore upper and lower extremity motor function. However, when one hand performs a movement that requires many small muscle Groups and many joints to work together in the process of rehabilitating sequelae in patients with cerebral infarction, it takes time to recover. The problem of restoring movement in the hand needs more time, and research needs to apply more local acupuncture points or atrial acupuncture points in the hand and brain points through nerve X stimulation for more optimal efficiency. This is an issue that helps us expand our research [10].

Both Groups improve lower extremity motor recovery compared to baseline. In comparison, the Treatment Group had time to walk 10 meters with support equipment, which improved more than the Control Group in weeks 3 and 4. The movement of the lower limbs requires performing simpler, non-sophisticated movements, balancing only when moving. Therefore, we see a clearer improvement in the lower limb motor skills than in the upper extremities.

The Barthel Index is an ordinal scale that assesses performance in daily living activities. This is a popular method in the field of rehabilitation. Motor rehabilitation scores, according to the BI, changed statistically significantly when comparing before and after treatment in two Groups. The results showed that there was a statistically significant difference between the two Groups after 4 weeks [8].

Many research authors have applied the BI to evaluate the recovery of functions in stroke patients, including head and face hygiene, eating, urination, and limb movement. Based on the Barthel index, we can assess how independent or dependent a patient is on self-care. The two Groups helped improve patient dependency over time. The Treatment Group

improved dependency better than the Control Group; the difference was statistically significant after three and four weeks. The Treatment Group had a higher rate of a good treatment response compared to the Control Group. The Treatment Group has a lower rate of poor response to treatment than the Control Group; the difference is statistically significant. This result demonstrates that auricular acupuncture when combined with electroacupuncture, plays a different role in restoring motor function compared with electroacupuncture alone. The treatment effect is also higher than with simple electroacupuncture [8].

In contrast to previous studies on electroacupuncture, author Doan TN's study utilized acupuncture to enhance exercise coordination. The study included all patients with cerebral stroke, cerebral infarction, and cerebral hemorrhage, with disease onset times of less than one month and more than one month. Implementation method: acupuncture points on both ends of paralyzed muscle bundles combined with 5Hz (low frequency) and 50Hz (high frequency) electromagnetic currents treated every 10 days. This method results in a rate of 68.25% [13]. In addition, the topic has some limitations: the person performing the procedure must be uniform in the way they choose acupuncture points, and the improvement in foot movement is not clear. Strokes: During the course of the project, we did not record needle screwing, bleeding, pricks, or infections due to atrial screwing.

5. CONCLUSION

In patients with cerebral infarction, combining auricular acupuncture and electro-acupuncture can improve motor rehabilitation.

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