

# Effect of combining acupuncture and auricular point sticking on heart rate variability in patients with post-stroke depression

## 针刺加耳穴贴压对脑卒中后抑郁患者心率变异性的影响

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### Abstract

**Objective:** To investigate the effect of combining acupuncture and auricular point sticking on heart rate variability (HRV) in patients with post-stroke depression (PSD).

**Methods:** A total of 80 cases with PSD were randomized into a treatment group and a control group. The control group was intervened by oral administration of paroxetine hydrochloride, whereas the treatment group received acupuncture plus auricular point sticking base on the same oral administration. The Hamilton depression rating scale (HAMD) and HRV were measured before and after treatment in both groups.

**Results:** The individual and global scores of HAMD significantly dropped after 8 weeks of treatment in both groups (all  $P < 0.05$ ). In the treatment group, anxiety/somatization factor, sleep disturbance, hopelessness factor, cognition factor and global score were significantly different from those in the control group (all  $P < 0.05$ ). The 24 h standard deviation of all normal-to-normal R-R interval (SDNN), standard deviation of 5-minute average of normal R-R intervals (SDANN), root mean square of successive differences (RMSSD), percent of differences between adjacent normal R-R intervals  $> 50$  ms (PNN50) and high frequency (HF) were increased while low frequency (LF) and LF/HF decreased significantly after 8 weeks of treatment in both groups ( $P < 0.05$ ). All items in the treatment group were significantly different from those in the control group (all  $P < 0.05$ ).

**Conclusion:** Combining acupuncture and auricular point sticking can enhance the conventional medical treatment for HRV in patients with PSD.

**Keywords:** Acupuncture Therapy; Auricular Point Sticking; Stroke; Complications; Heart Rate; Depression

**【摘要】目的:** 观察针刺加耳穴贴压治疗对脑卒中后抑郁患者心率变异性(HRV)的影响。**方法:** 将80名脑卒中后抑郁患者随机分为治疗组和对照组, 每组40例。对照组口服盐酸帕罗西汀片, 治疗组在口服相同药物基础上加用针刺和耳穴贴压治疗。比较治疗前后两组患者汉密尔顿抑郁量表(HAMD)评分及HRV变化。**结果:** 治疗8星期后, 两组HAMD各因子评分及总分均较本组治疗前下降(均 $P < 0.05$ ); 治疗组焦虑/躯体化因子、睡眠障碍因子、绝望感因子、认知因子及总分分值均低于对照组(均 $P < 0.05$ )。治疗8星期后, 两组24 h内窦性心律R-R间期标准差(SDNN)、每5 min窦性心率的R-R间期平均值标准差(SDANN)、24 h内窦性心律相邻R-R间期差值的均方根(RMSSD)、24 h内相邻窦性心律R-R间期差大于50 ms的个数占百分比(PNN50)及高频成分(HF)均较治疗前增加, 低频成分(LF)及低频高频比(LF/HF)均较治疗前降低, 组内差异均有统计学意义(均 $P < 0.05$ ); 治疗组各项指标与对照组均有统计学差异(均 $P < 0.05$ )。**结论:** 在常规药物治疗基础上加用针刺和耳穴贴压可增强常规药物治疗对脑卒中后抑郁患者HRV的改善作用。

**【关键词】** 针刺疗法; 耳穴贴压; 中风; 并发症; 心率; 抑郁

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Post-stroke depression (PSD) is a mood disorder (MD) occurring after stroke, characterized by persistent low mood, loss of interest and so on<sup>[1]</sup>. Its overall prevalence

is as high as 33%<sup>[2]</sup> and it affects patients' functional rehabilitation and mental health. Heart rate variability (HRV) is an indicator used to evaluate sympathetic and parasympathetic function, vagal tone and sympathetic-vagal balance. Post-stroke patients with major or minor depression would demonstrate different degrees of

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decreased HRV<sup>[3]</sup>, which means increased mortality. It has been reported that acupuncture can regulate HRV in recent years, but there are few clinical reports followed. This study focused on the effects of acupuncture and auricular point sticking on HRV in patients with PSD on the basis of conventional drug therapy. The report is given as follows.

## 1 Clinical Materials

### 1.1 Diagnostic criteria

The diagnosis of stroke met the diagnostic criteria in the *China Guideline for Cerebrovascular Disease Prevention and Treatment*<sup>[4]</sup>. The diagnosis of depression met the diagnostic criteria in the fourth edition of *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)*<sup>[5]</sup> and the 3rd edition of *Chinese Classification and Diagnostic Criteria of Mental Disorders (CCMD-3)*<sup>[6]</sup>.

### 1.2 Inclusion criteria

Patients who met the diagnostic criteria of stroke and depression at the same time, brain CT or MRI showing clear disease location; score of Hamilton depression rating scale (HAMD)  $\geq 20$  points; aged between 18 and 75 years; no history or family history of depression or other mental illnesses before stroke; patients and their families agreed and signed the informed consent.

### 1.3 Exclusion criteria

Those with cancer, severe heart, liver, kidney or other severe organic diseases, primary hematopoietic, or endocrine system diseases; those with organic brain disease, tumor or parasitic disease; those with severe intelligence disturbance, logopathy, or mental disorder; those not suitable for acupuncture; those had long-term use of various types of sedatives and psychotropic drugs or had a history of alcohol dependence; those using other types of antidepressant drug or still in the washout period.

### 1.4 Research design

The study protocol was approved by the Second Affiliated Hospital of Hunan University of Chinese Medicine. This study designed 2 groups with same

sample size. According to clinical experiment and literature, bilateral  $\alpha=0.05$ ,  $1-\beta=0.8$ . PASS 2011 was used for calculating and the minimum sample size was 38 cases in each group. This is a prospective study and the designed sample was 40 in each group.

#### 1.4.1 Randomization

The visiting order number was regarded as the random number, and the patients were divided into two groups according to the number. The random grouping scheme was predetermined by SPSS 21.0 version software.

#### 1.4.2 Blind method

Researchers, therapists and evaluators were separated. Researchers and therapists knew the grouping situation while evaluators not.

### 1.5 Statistical method

The data were processed using the SPSS 21.0 version software. The mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ) was used to describe the measurement data in normal distribution and variance homogeneity. Paired-sample *t*-test was used for intra-group comparison. Rank-sum test was used for non-normal distribution data and non-homogeneity variance. Chi-square test was used for comparison of enumeration data. Rank-sum test was carried out for ranked data. A *P* value of less than 0.05 indicated a statistical significance.

### 1.6 General data

Cases were enrolled from the Stroke Clinic or Inpatient Department of the Second Affiliated Hospital of Hunan University of Chinese Medicine between October 2014 and June 2016. A total of 151 subjects were preliminarily screened, 84 cases met the inclusion criteria, but 3 patients in the treatment group quit because of time management issues, 1 patient in the control group quit because of digestive side effect. Thus, a total of 80 patients were enrolled in the study, 40 cases in each group. The age was 45-72 years old and duration was 2-18 months. There were no significant differences in comparing the gender, age, disease duration, and HAMD score between the two groups (all  $P>0.05$ ), indicating the comparability (Table 1).

**Table1. Comparison of the baseline between the two groups**

Group	<i>n</i>	Gender (case)		Mean age ( $\bar{x} \pm s$ , year)	Mean duration ( $\bar{x} \pm s$ , month)	Type of stroke (case)	
		Male	Female			Cerebral infarction	Cerebral hemorrhage
Treatment	40	19	21	58.8 $\pm$ 6.3	8.1 $\pm$ 3.4	25	15
Control	40	18	22	57.6 $\pm$ 5.7	7.8 $\pm$ 3.2	27	13
Statistical value		0.00 <sup>1)</sup>		0.71 <sup>2)</sup>	0.99 <sup>2)</sup>	0.00 <sup>1)</sup>	
<i>P</i> -value		1.00		0.42	0.68	1.00	

Note: 1)  $\chi^2$  value; 2) *t*-value

## 2 Treatment Methods

Both groups were given conventional treatments based on their conditions, such as improving cerebral circulation, nourishing nerve cells, control complications, and other basic treatments (e.g. control of blood pressure, blood glucose, blood fats and anticoagulant therapy).

### 2.1 Control group

On the base of conventional treatment, patients in the control group were given oral paroxetine hydrochloride tablets (produced by Zhejiang Huahai Pharmaceutical Co., Ltd., China, lot number: H20031106, specifications: 20 mg/tablet). Initial dosage was 10 mg per day, and 10 mg increment would be added at 1 week interval if needed. The maximum dosage was 50 mg per day. No other psychotropic medications were allowed. The total course was 8 weeks.

### 2.2 Treatment group

Acupuncture and auricular point sticking were given to patients in the treatment group based on the same treatment in the control group.

#### 2.2.1 Acupuncture therapy

Scalp acupoints: Baihui (GV 20), Sishencong (EX-HN 1), Shenting (GV 24) and Yintang (GV 29).

Body acupoints: Bilateral Shenmen (HT 7), Neiguan (PC 6), Taichong (LR 3), Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6) and Fenglong (ST 40).

Method: The acupoints were located according to *Nomenclature and Location of Acupuncture Points* (GB/T12345-2006). Patients took a supine position. Upon routine sterilization, disposable filiform needles of 0.35 mm in diameter and 25-40 mm in length were used. Scalp acupoints were transversely penetrated for 5-15 mm, while body acupoints were perpendicularly penetrated 10-15 mm. Puncture depth was adjusted by local muscular condition. After qi arrival, even reinforcing-reducing manipulation was used, twirling manipulation for scalp acupoints, and lifting-thrusting for body acupoints. The needles were retained for 30 min and manipulated 1-3 min. The treatment method was done every other day, 3 times a week, total course was 8 weeks.

#### 2.2.2 Auricular point sticking

Ear points: Shenmen (TF<sub>4</sub>), Subcortex (AH<sub>4</sub>), Endocrine (CO<sub>18</sub>), Heart (CO<sub>15</sub>) and Liver (CO<sub>12</sub>).

Method: Upon routine sterilization, *Wang Bu Liu Xing* (*Semen Vaccariae*) seeds were pressed to the selected acupoints with tweezers. The seeds were pressed on both ears alternatively and changed every 3-5 d. 3-minute kneading was required in the morning, at noon and before bedtime respectively. It was better to feel distending pain, sour or numb. The total course was 8 weeks.

## 3 Treatment Results

### 3.1 Observation items

#### 3.1.1 HAMD score

HAMD 17 includes depressed mood, difficulty falling asleep, agitation, psychic anxiety and other items for evaluating the severity of depression. These items can be classified into 7 types of factors: anxiety/somatization symptoms, diurnal variation, retardation, sleep disturbance, hopelessness, weight, and cognitive disturbance, and they are different characteristics of depression.

#### 3.1.2 HRV analysis

Method: All patients were detected before and after treatment by Medsun electrocardiogram system for HRV. Collecting time was 9:00-11:00 a.m after a 15-minute rest to make patients completely relaxed. And then 24 h Holter was recorded. Smoking, drinking and coffee were prohibited since 12 h before collection to the end of collection to ensure adequate sleep and avoid strenuous exercise. Acquisition results were analyzed by a professional electrocardiograph (ECG) physician independently.

Detection items: Time domain item including 24 h standard deviation of all normal-to-normal R-R interval (SDNN), which reflects the general functional status of autonomic nerve; standard deviation of 5-minute average of normal R-R intervals (SDANN), which reflects the sympathetic tone size; root mean square of successive differences (RMSSD), and percent of differences between adjacent normal R-R intervals > 50 ms (PNN50) which reflect vagal tone size. Frequency domain item including low frequency (LF, 0.04-0.15 Hz), which reflects sympathetic nerve function level; high frequency (HF, 0.15-0.40 Hz), which reflects vagus nerve function level; and LF/HF, which reflects the balance between sympathetic and vagal function.

### 3.2 Results

#### 3.2.1 HAMD score

There were no significant differences in comparing HAMD global score and every single factor between the two groups before the treatment (all  $P > 0.05$ ). After 8 weeks of treatment, global HAMD score and every component scores were decreased significantly in both groups (all  $P < 0.05$ ). In the treatment group, global HAMD score, scores of anxiety/somatization, sleep disturbance, hopelessness and cognitive disturbance factors were lower than those in the control group (all  $P < 0.05$ ), (Table2).

#### 3.2.2 HRV time domain indicator

There was no significant difference between the two groups in pre-treatment time-domain ( $P > 0.05$ ). After treatment, SDNN, SDANN, RMSSD and PNN50 in both groups were increased, with statistically significant

intra-group differences (all  $P < 0.05$ ). Except SDANN, the other three items in the treatment group were higher than those in the control group, the differences between the two groups were statistically significant (all  $P < 0.05$ ), (Table 3 and Table 4).

### 3.2.3 HRV frequency domain

There was no significant difference in pre-treatment HRV frequency domain between the two groups (all

$P > 0.05$ ). After treatment, LF and LF/HF in both groups were lower, while HF increased compared with pre-treatment in both groups, and the differences were statistically significant (both  $P < 0.05$ ). In the treatment group, LF and LF/HF were lower than those in the control group while HF was higher, the between-group differences were statistically significant ( $P < 0.05$ ), (Table 5 and Table 6).

**Table 2. Comparison of HAMD score ( $\bar{x} \pm s$ , point)**

Factor	Treatment group (n=40)		Control group (n=40)	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Anxiety/somatization	6.53±1.13	3.13±1.07 <sup>1)2)</sup>	6.21±1.08	4.46±1.36 <sup>1)</sup>
Diurnal variation	0.69±0.25	0.64±0.12 <sup>1)</sup>	0.71±0.33	0.61±0.19 <sup>1)</sup>
Retardation	5.35±1.43	3.59±1.67 <sup>1)</sup>	5.81±1.62	3.82±1.94 <sup>1)</sup>
Sleep disturbance	4.73±1.08	2.65±0.87 <sup>1)2)</sup>	4.59±1.38	3.26±1.44 <sup>1)</sup>
Hopelessness	4.47±1.84	1.88±0.69 <sup>1)2)</sup>	4.21±1.08	2.79±1.06 <sup>1)</sup>
Weight	0.76±0.43	0.64±0.11 <sup>1)</sup>	0.71±0.56	0.59±0.28 <sup>1)</sup>
Cognitive disturbance	1.44±1.02	1.33±1.26 <sup>1)2)</sup>	3.81±1.21	2.91±1.18 <sup>1)</sup>
Global score	22.72±7.63	10.56±4.91 <sup>1)2)</sup>	22.97±8.16	14.20±4.34 <sup>1)</sup>

Note: Intra-group comparison, 1)  $P < 0.05$ ; compared with the control group after treatment, 2)  $P < 0.01$

**Table 3. Comparisons of SDNN and SDANN ( $\bar{x} \pm s$ , ms)**

Group	n	SDNN				SDANN			
		Pre-treatment	Post-treatment	t-value	P-value	Pre-treatment	Post-treatment	t-value	P-value
Treatment	40	70.11±6.45	110.89±5.45	35.6548	0.000	68.69±4.36	95.06±8.71	17.1225	0.000
Control	40	68.30±5.77	80.72±5.77	10.0378	0.000	66.57±8.15	91.06±9.39	6.3564	0.000
t-value		1.323	20.031			1.451	1.975		
P-value		0.189	0.000			0.152	0.052		

**Table 4. Comparisons of RMSSD and PNN50 ( $\bar{x} \pm s$ )**

Group	n	RMSSD (ms)				PNN50 (%)			
		Pre-treatment	Post-treatment	t-value	P-value	Pre-treatment	Post-treatment	t-value	P-value
Treatment	40	19.31±8.18	33.54±11.72	3.318	0.000	7.42±1.96	12.54±3.04	8.953	0.000
Control	40	17.63±10.44	25.98±9.73	6.417	0.000	7.72±2.67	10.54±1.01	6.248	0.000
t-value		0.801	3.142			0.573	3.949		
P-value		0.426	0.002			0.569	0.000		

**Table 5. Comparison of LF and HF ( $\bar{x} \pm s$ , ms<sup>2</sup>/Hz)**

Group	n	LF				HF			
		Pre-treatment	Post-treatment	t-value	P-value	Pre-treatment	Post-treatment	t-value	P-value
Treatment	40	979.33±311.75	715.71±353.77	3.5339	0.0007	539.78±379.99	859.39±376.92	3.7767	0.0003
Control	40	934.95±288.53	887.03±389.84	0.6249	0.5340	504.32±393.41	684.11±399.31	2.0285	0.0460
t-value		0.661	2.051			0.410	2.019		
P-value		0.511	0.043			0.683	0.047		

**Table 6. Comparison of LF/HF ( $\bar{x} \pm s$ )**

Group	n	Pre-treatment	Post-treatment	t-value	P-value
Treatment	40	2.21±0.42	1.38±0.73	6.233	0.000
Control	40	2.33±0.44	1.74±0.82	4.009	0.000
t-value		1.248	2.074		
P-value		0.216	0.041		

#### 4 Discussion

PSD is a common psychiatric complication after stroke. Its pathogenesis is not completely clear, and it is generally believed to be related to cerebral low perfusion, neurotransmitter abnormality and reactivity mechanism<sup>[7]</sup>. HRV can reflect the activity of the autonomic nervous system of the heart, vagal tone and sympathetic-parasympathetic balance which includes the information of the neurohumoral regulation of the cardiovascular system<sup>[8]</sup>. Decreased HRV is associated with sudden cardiac death, heart failure and arrhythmia. There is an extensive literature on the association of decreased HRV with PSD patients<sup>[3]</sup>, and decreased HRV means increased mortality. According to the research of Burton CL, *et al*<sup>[9]</sup>, after brain injury, the nervous center is involved, which affects the release of many neurotransmitters, such as monoamines, as well as the connection and balance between the autonomic nervous system and cardiac function, affecting the biological rhythms and neurological functions such as HRV, therefore a decrease in HRV occurs. There is abundant evidence-based medical literature showing that acupuncture is effective for PSD and its mechanism may be related to the promotion of monoamine neurotransmitter release and regulation of autonomic function<sup>[10]</sup>.

In this study, acupuncture and auricular point sticking were added to the PSD treatment on the basis of conventional treatment under the guidance of the traditional Chinese medicine theory. The primary pathogenesis of PSD is phlegm and stasis obstructing meridians and disharmony of yin, yang, qi and blood. Then that will lead to liver qi stagnation. Therefore, methods of regulating qi, activating blood, dredging meridians, soothing the liver, tranquilizing the mind should be used in treating PSD. Baihui (GV 20) can open the orifices, modulate the Governor Vessel. Sishencong (EX-HN 1), Shenting (GV 24) and Yintang (GV 29) are local selections. Neiguan (PC 6) is the Luo-Connecting point of the Pericardium Meridian, Shenmen (HT 7) is the Yuan-Primary point of the Heart Meridian, and both acupoints can nourish the heart to calm mind. Zusanli (ST 36) and Sanyinjiao (SP 6) can harmonize qi and blood in three jiao. Taichong (LR 3) and Hegu (LI 4) can disperse stagnated liver qi to relieve depression. Fenglong (ST 40) can eliminate phlegm and dredge the

collaterals.

Besides, meridians and collaterals are gathered in the ear area, and the ear is closely connected with internal organs. In 1975, some scholars drew the earliest ear acupoints map revealing the relationship between neurological, muscular, visceral, endocrine systems and ear ministries<sup>[11]</sup>. Studies have shown that stimulation to auricular points can regulate the activation of the brain reticular system orderly, so that the excitability and inhibition of cerebral cortex tend to balance, thereby reducing the patient's depression<sup>[10]</sup>. Auricular plaster method can generate small but long-time stimulation. Acupuncture plus ear plaster means to combine both the effect of acupuncture on the regulation of meridians and the effect of auricular points on the ear-neuro-visceral reflex to enhance the acupuncture-meridian cumulative stimulus effect<sup>[12]</sup>. In this study, we selected Shenmen (TF<sub>4</sub>), Heart (CO<sub>15</sub>) and Liver (CO<sub>12</sub>) according to the basic theory of traditional Chinese medicine (TCM), and selected the Subcortex (AH<sub>4</sub>) and Endocrine (CO<sub>18</sub>) based on modern medical research. Those acupoints can not only nourish the heart to tranquilize, disperse stagnated liver qi to relieve depression, but also regulate the function of the endocrine system, thus regulating autonomic function.

After treatment, global score and every component score of HAMD were decreased in the both groups. In the treatment group, HAMD global score, the scores of anxiety/somatization, sleep disturbance, hopelessness and cognitive disturbance were lower than those in the control group.

HRV analysis can make quantitative assessment of cardiac autonomic nervous tension, and is of great value in evaluating malignant arrhythmias and sudden cardiac death. SDNN mainly reflects the total sympathetic and parasympathetic tone size, used to measure the overall status of HRV. RMSSD and PNN50 mainly reflect vagal tone situation. LF is co-modulated by the vagus nerve and the sympathetic nerve, but it mainly reflects sympathetic nerve activity. HF is regulated by the vagus nerve, and LF/HF is a sensitive indicator reflecting the balance of sympathetic and vagal tone<sup>[13]</sup>. Depression patients have autonomic dysfunction, mainly appearing as reduced vagal function. The results of this study showed that RMSSD, PNN50 and HF in the treatment group were higher after the treatment, suggesting that acupuncture plus

auricular plaster therapy can enhance vagal nerve modulation. What's more, SDANN increased while LF, LF/HF decreased, suggesting the improvement of sympathetic tone, indicating that acupuncture plus auricular point sticking can enhance the sympathetic/vagal function coordination. These results are consistent with previous studies<sup>[14-15]</sup>.

Above results show that combing acupuncture and auricular point sticking with conventional treatment can improve HRV in PSD patients, and can regulate autonomic nerve function. However, there are some problems in this study: the sample size is small; no placebo control group; not double-blinded. The other problem is that this study failed to explain the synergistic mechanism of meridian and ear-neuro-visceral regulation. And neurotransmitter and regeneration after brain injury or other aspects of the mechanism of efficacy were missed in this study. These limitations need to be addressed in future studies.

#### Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

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#### Statement of Informed Consent

Informed consent was obtained from all individual participants or their relatives included in this study.

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