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Special Topic Study

Therapeutic effect observation on acupuncture plus medication for post-stroke depression

针刺配合药物治疗卒中后抑郁的疗效观察

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Abstract
Objective: To observe the clinical efficacy of acupuncture with medication for post-stroke depression.
Methods: A total of 96 patients with post-stroke depression were randomized into an observation group and a control group, with 48 cases in each group. The control group was treated with oral fluoxetine hydrochloride capsules, and the observation group was treated with acupuncture on the basis of the treatment of the control group. After 6 months of treatment, the traditional Chinese medicine (TCM) symptom scores, and Hamilton depression scale (HAMD) component scores and total scores of the two groups before and after treatment were observed, and the clinical efficacy and adverse reaction rate were compared between the two groups.
Results: The total effective rate was 95.8% in the observation group and 83.3% in the control group, and the difference between the two groups was statistically significant (P<0.05). After treatment, the intra-group differences in TCM symptom scores and HAMD score of both groups were statistically significant (all P<0.01). In the observation group, the scores of indifferent expression, emotional restlessness, and sentimentality in the TCM symptoms were statistically different from those in the control group (all P<0.01). The scores of desperate factor and sleep disorder factor and total score in HAMD in the observation group were significantly different from those in the control group (all P<0.01). The incidence of adverse reactions was 6.3% in the observation group and 4.2% in the control group, and the difference was not significant between the two groups (P>0.05).
Conclusion: Acupuncture plus medication is an effective method for post-stroke depression, and it can further improve the patient's bad mood.
Keywords: Acupuncture Therapy; Stroke; Complications; Depression; Emotions; Acupuncture Medication Combined; Points, Head & Neck

【摘要】目的：观察针刺配合药物治疗卒中后抑郁的临床疗效。**方法：**将96例卒中后抑郁患者随机分为观察组和对照组，每组48例。对照组采用口服盐酸氟西汀胶囊治疗，观察组在对照组基础上采用针刺治疗。治疗6个月后，观察两组治疗前后各项中医证候评分、汉密尔顿抑郁量表(HAMD)各因子评分及总分的变化情况，并比较两组临床疗效及不良反应发生率。**结果：**观察组总有效率为95.8%，对照组为83.3%，两组比较差异具有统计学意义(P＜0.05)。两组治疗后各项中医证候评分、HAMD各因子评分及总分与同组治疗前比较，差异均具有统计学意义(均P＜0.01)。观察组治疗后中医证候中表情冷漠、情绪不宁、多愁善感评分与对照组差异具有统计学意义(均P＜0.01)。观察组治疗后HAMD中绝望因子、睡眠障碍因子评分及总分与对照组差异具有统计学意义(均P＜0.01)。观察组不良反应发生率为6.3%，对照组为4.2%，两组比较差异无统计学意义(P＞0.05)。**结论：**针刺配合药物是一种治疗卒中后抑郁的有效方法，能进一步改善患者不良情绪。

【关键词】针刺疗法；中风；并发症；抑郁；情绪；针药并用；穴位，头颈部
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Post-stroke depression (PSD) is an affective disorder characterized by decreased interest, low mood, and slow thinking after stroke[1]. Studies have shown that the incidence of PSD in foreign countries is 25% to 79%, and the incidence in China is 23% to 76%[2]. Emotion has a great impact on the recovery of limbs and speech in stroke patients. The occurrence of PSD goes against the improvement of stroke. At present, there are various drugs for depression in clinic. Although those drugs have certain effects, they have shortcomings such as slow effect and drug dependence.

Traditional Chinese medicine (TCM) believes that acupuncture can regulate the meridian qi, refresh the

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mind and open the orifices, and thus is suitable for the treatment of depression.

In this study, we used acupuncture plus medication to treat 48 patients with PSD, and compared with 48 patients treated only by medication.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria for stroke

This study referred to the diagnostic criteria of stroke for Western medicine proposed by the Neurology Branch of Chinese Medical Association[3], and confirmed the diagnosis by clinical manifestations, MRI or CT examination. The diagnostic criteria for Chinese medicine referred to the diagnostic criteria of stroke in the *Diagnostic Standards or Syndrome Differentiation on Apoplexia*[4].

1.1.2 Diagnostic criteria for depression

The diagnostic criteria for Western medicine referred to the diagnostic criteria of depression proposed by the Chinese Medical Association[5]. The diagnostic criteria for Chinese medicine referred to the relevant standards in the *Traditional Chinese Medicine Treatment for Emotional Diseases*[6].

1.2 Inclusion criteria

Those who met the above diagnostic criteria of stroke and depression; duration of depression ≥7 d; stable condition, clear consciousness, no history of psychological disorders such as anxiety and depression; Hamilton depression scale (HAMD) score ≥20 points at admission; without organic lesions; patients and their families agreed to participate in this clinical trial and signed informed consent.

1.3 Exclusion criteria

Those with severe language barriers and unable to communicate properly; women during pregnancy or lactation; those with depressive symptoms before stroke; had long-term use of psychotropic drugs or sedatives; unstable condition or in a coma; intolerant of acupuncture or unwilling to be included in the study; combined with severe organ dysfunction such as hematopoietic system, liver or kidney damage; patients with malignant tumors.

1.4 Statistical methods

All data were statistically analyzed by the SPSS version 20.0 statistical software. Measurement data in normal distribution were expressed as mean ± standard deviation ($\bar{x} \pm s$), and analyzed by *t*-test. Counting data was expressed as rate, and processed by Chi-square test. $P<0.05$ was considered to indicate a statistically significant difference.

1.5 General data

A total of 96 patients with PSD were enrolled from the Clinic of Urumqi Chinese Medicine Hospital between January 2014 and January 2017. All patients were randomly divided into two groups by the random number table according to the visiting sequence, with 48 cases in each group. There were no statistically significant differences in gender, age, duration of disease and the type of stroke between the two groups (all $P>0.05$), indicating that the two groups were comparable (Table 1).

Table 1. Comparison of the general data between the two groups

Group	*n*	Gender (case)		Average age ($\bar{x} \pm s$, year)	Average duration ($\bar{x} \pm s$, month)	Type of stroke (case)	
		Male	Female			Hemorrhagic	Ischemic
Observation	48	26	22	57.2±8.5	16.7±6.0	8	40
Control	48	28	20	58.5±7.8	15.7±6.3	9	39
Statistics value		0.169[1)]		0.767[2)]	0.829[2)]	0.072[1)]	
P-value		0.681		0.445	0.409	0.789	

Note: 1) x^2 value; 2) *t*-value

2 Treatment Methods

Both groups were given symptomatic treatments such as routine control of blood pressure and blood sugar. No other medication treatment except for the treatment plan developed in this study. Patients were told to keep good living habits.

2.1 Control group

Oral fluoxetine hydrochloride capsules, starting at 20 mg, once per day, orally taken after waking up in the morning. After 2 weeks of treatment, the dosage was adjusted to 20 mg if the symptoms did not change significantly, twice a day, orally taken in the morning and evening. The treatment lasted 6 months in total.

2.2 Observation group

Acupuncture treatment was added to the intervention in the control group.

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

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

Method: The patient took a supine position. After routine disinfection, the physician punctured the acupoints with acupuncture needles of 0.30 mm in diameter and 40 mm in length. Needles were punctured into scalp points by 5-10 mm in depth, with twirling manipulation of even reinforcing-reducing. According to the local muscle thickness of the acupuncture point, the needle was inserted by 10-15 mm in depth, with even reinforcing-reducing manipulation by lifting-thrusting. After arrival of qi, the needles were retained for 30 min. The treatment was performed once every other day, for 6 months in total.

3 Efficacy Observation

3.1 Observation items

3.1.1 TCM symptom scores[7]

The TCM symptoms were scored before and after treatment in the two groups. The main manifestations were indifferent expression, decreased interest, sentimentality and emotional restlessness. The minor manifestations were early awakening, dizziness and tinnitus. Each item was scored 1 to 3 points. The higher the score, the more severe the symptoms.

3.1.2 HAMD[8]

Effects of the two groups were evaluated by HAMD before and after treatment. HAMD is scored 8 points as the threshold, and is divided into 4 levels according to the mental state: normal (<8 points), possible depression (8 to 20 points), positive depression (21 to 35 points), and severe depression (>35 points).

3.1.3 Adverse reactions

The adverse reactions during the treatment in both groups were observed and recorded.

3.2 Criteria of curative efficacy

According to the *Criteria of Diagnosis and Therapeutic Effect of Disease and Syndromes in Traditional Chinese Medicine*[9], and the reduction rate of TCM symptom scores, the curative efficacy was assessed. TCM symptom score reduction rate = (Total score before treatment − Total score after treatment) ÷ Total score before treatment × 100%.

Cured: Depressive symptoms completely disappeared.

Marked effect: TCM symptom score reduction rate ≥75%.

Effective: TCM symptom score reduction rate >50%, but <75%.

Invalid: TCM symptom score reduction rate ≤50%.

3.3 Results

No dropout cases occurred during the treatment in the two groups.

3.3.1 Comparison of clinical efficacy

The total effective rate was 95.8% in the observation group and 83.3% in the control group. The difference between the two groups was statistically significant (P<0.05), (Table 2).

Table 2. Comparison of clinical efficacy between the two groups (case)

Group	n	Cured	Marked effect	Effective	Invalid	Total effective rate (%)
Observation	48	10	17	19	2	95.8
Control	48	8	11	21	8	83.3
x^2 value						4.019
P-value						0.045

3.3.2 Comparison of various TCM symptom scores

The comparisons of TCM symptom scores between the two groups before and after treatment are shown in Table 3-Table 5. There were no significant differences between the two groups in the scores of TCM symptoms (indifferent expression, emotional restlessness, sentimentality, decreased interest, dizziness, early awakening, and tinnitus) before treatment (P>0.05). After treatment, the intra-group differences in the scores of TCM symptoms were statistically significant (both P<0.01). In the observation group, the scores of indifferent expression, emotional restlessness, and sentimentality were significantly different from those in the control group (P<0.01). The differences in the other TCM symptom scores were not statistically significant between the two groups (P>0.05).

3.3.3 Comparisons of every factor score and total score of HAMD

There were no significant differences in the factor scores and total score of HAMD between the two groups before treatment (all P>0.05). After treatment, the intra-group differences in the factor scores of HAMD were statistically significant in both groups (all P<0.01). In the observation group, the scores of despair factor, sleep disturbance factor and HAMD total score were significantly different from those in the control group (all P<0.01). There were no significant differences in the other HAMD factor scores between the two groups (all P>0.05). The details are shown in Table 6-Table 8.

Table 3. Comparisons of indifferent expression score and emotional restlessness score between the two groups ($\bar{x}$ ±*s*, point)

Group	*n*	Indifferent expression		*t*-value	*P*-value	Emotional restlessness		*t*-value	*P*-value
		Before treatment	After treatment			Before treatment	After treatment		
Observation	48	2.02±0.18	0.84±0.11	38.755	0.000	2.74±0.06	0.87±0.12	96.566	0.000
Control	48	2.03±0.15	1.15±0.24	21.542	0.000	2.71±0.09	1.23±0.18	50.951	0.000
t-value		0.296	8.135			1.922	11.529		
P-value		0.768	0.000			0.058	0.000		

Table 4. Comparisons of sentimentality score and decreased interest score between the two groups ($\bar{x}$ ±*s*, point)

Group	*n*	Sentimentality		*t*-value	*P*-value	Decreased interest		*t*-value	*P*-value
		Before treatment	After treatment			Before treatment	After treatment		
Observation	48	2.41±0.20	0.75±0.14	47.109	0.000	1.85±0.32	0.48±0.07	28.976	0.000
Control	48	2.39±0.19	0.96±0.08	48.058	0.000	1.86±0.36	0.51±0.09	25.205	0.000
t-value		0.502	9.023			0.144	1.823		
P-value		0.617	0.000			0.886	0.072		

Table 5. Comparisons of dizziness score, early awakening score and tinnitus score between the two groups ($\bar{x}$ ±*s*, point)

Group	*n*	Dizziness		*t*-value	*P*-value	Early awakening		*t*-value	*P*-value	Tinnitus		*t*-value	*P*-value
		Before treatment	After treatment			Before treatment	After treatment			Before treatment	After treatment		
Observation	48	1.52±0.10	0.31±0.02	82.203	0.000	1.98±0.03	0.56±0.05	168.721	0.000	1.71±0.02	0.36±0.06	147.885	0.000
Control	48	1.53±0.12	0.32±0.04	66.274	0.000	1.99±0.06	0.54±0.08	100.459	0.000	1.70±0.04	0.38±0.06	126.821	0.000
t-value		0.444	1.549			1.033	1.469			1.549	1.633		
P-value		0.658	0.125			0.304	0.145			0.125	0.106		

Table 6. Comparisons of somatization factor and cognitive factor between the two groups ($\bar{x}$ ±*s*, point)

Group	*n*	Somatization factor		*t*-value	*P*-value	Cognitive factor		*t*-value	*P*-value
		Before treatment	After treatment			Before treatment	After treatment		
Observation	48	6.21±1.04	3.09±1.42	12.281	0.000	4.69±1.27	2.41±1.56	7.852	0.000
Control	48	6.20±1.06	3.12±1.79	10.258	0.000	4.67±1.23	2.43±1.52	7.937	0.000
t-value		0.047	0.091			0.078	0.064		
P-value		0.963	0.928			0.938	0.949		

Table 7. Comparisons of despair factor and sleep disturbance factor between the two groups ($\bar{x}$ ±*s*, point)

Group	*n*	Despair factor		*t*-value	*P*-value	Sleep disturbance factor		*t*-value	*P*-value
		Before treatment	After treatment			Before treatment	After treatment		
Observation	48	5.32±1.76	1.07±0.23	16.589	0.000	5.35±1.24	2.83±0.56	12.832	0.000
Control	48	5.35±1.78	2.24±0.26	10.258	0.000	5.34±1.19	3.12±0.32	12.481	0.000
t-value		0.083	23.351			0.040	3.115		
P-value		0.934	0.000			0.968	0.002		

Table 8. Comparisons of retardation factor and HAMD total score between the two groups ($\bar{x}$ ±*s*, point)

Group	*n*	Retardation factor		*t*-value	*P*-value	HAMD total score		*t*-value	*P*-value
		Before treatment	After treatment			Before treatment	After treatment		
Observation	48	6.21±1.72	3.42±1.12	9.418	0.000	28.72±4.11	12.82±3.41	20.627	0.000
Control	48	6.19±1.74	3.45±1.16	9.078	0.000	27.73±3.95	15.36±3.27	16.713	0.000
t-value		0.057	0.129			1.203	3.710		
P-value		0.955	0.898			0.232	0.000		

3.3.4 Comparison of the incidence of adverse reactions during treatment

In the observation group, there were 2 cases of skin redness and swelling on the next day after acupuncture treatment, and 1 case of constipation occurred on the 6th day of treatment. The incidence of adverse reactions was 6.3%. In the control group, there was 1 case of constipation occurred on the 3rd day of treatment, and 1 case of abdominal distension occurred on the 3rd day of treatment. The incidence of adverse reactions was 4.2%. There was no significant difference in the incidence of adverse reactions between the two groups (P>0.05). The adverse reactions were all mild and relieved 1 to 2 d after the treatment was stopped, which did not affect the course of treatment.

4 Discussion

Stroke commonly affects the middle-aged and elderly patients. Stroke can cause language and physical dysfunction. It has a long course, and is difficult to treat. Studies have shown that PSD is a common psychological disorder in stroke patients. The main cause is that multiple dysfunctions after stroke lead to decreased self-care ability, which might cause pessimism, depression, and even suicidal tendency[10-11]. PSD is a secondary depression manifested with irritability, fatigue, low mood, and depression. At present, the clinical treatment is still based on Western medicine. Fluoxetine hydrochloride capsule is a commonly used antidepressant, and can correct the depression and improve the condition to some extent. However, studies have confirmed that the treatment of PSD with antidepressant alone affects slowly. Moreover, patients are highly prone to drug dependence[12]. Therefore, a better treatment plan is still in need at clinic.

PSD belongs to depression syndrome in TCM. In addition to symptoms such as hemiplegia caused by stroke, there are also a series of psychological obstacles, such as emotional restlessness, fatigue, rib pain, and depression[13]. Studies have shown that the occurrence of PSD is associated with dysfunction of qi, blood, and Zang-fu organs. Stroke can cause phlegm stasis and qi depression, leading to blocked meridians and collaterals, and moodiness with internal damage[14]. When stroke attacks, the disorder of qi and blood and abnormal movement of internal wind may cause the mental disorder. The main pathological changes of PSD are congealing phlegm and blood stasis. Therefore, the main treatment is to move qi and activate blood circulation, unblock the meridians and activate collaterals.

Acupuncture therapy is a common method for unblocking the meridians and activating collaterals in TCM. It has the effect of regulating qi and blood. Nie RR, *et al*[15] applied acupuncture to treat PSD, and the results showed that acupuncture had a regulating effect on norepinephrine, which had a great impact on emotional mechanisms. Related studies had shown that when emotion was stress, norepinephrine levels increased, and acupuncture could improve the emotional stress response by down-regulating this indicator level[16]. Huang WX, *et al*[17] performed the study that showed the effect of acupuncture in benefiting neurological function and improving depression in patients with PSD. Related studies had confirmed that acupuncture therapy was suitable for the treatment of PSD[18-19].

In this study, the total effective rate of the observation group was 95.8%, which was significantly higher than that of the control group (83.3%). Moreover, the scores of indifferent expression, emotional restlessness and sentimentality in the TCM symptom scores of the observation group were significantly lower than those of the control group (P<0.01). The results suggested that acupuncture plus drugs was more effective than conventional medication alone. The reason may be that acupuncture has a regulating effect on qi-blood and stagnant qi, and it can not only dredge sinews and bones, relax sinews and activate collaterals, but also relieve emotion disorders. In this study, the vascular nerves around Shenting (GV 24), Sishencong (EX-HN 1) and Baihui (GV 20) are rich, which can cause a strong needle sensation. And, they can produce good excitatory effects with high sensory conduction sensitivity. Therefore, it has a better therapeutic effect for emotional disorders such as restlessness and indifferent expression.

Feng W, *et al*[20] held that acupuncture can induce the release of nerve impulses and transmit the signal to the central nervous system, thereby regulating the activity of the corresponding nerve cells and correcting the depression condition. In this study, the results showed that the scores of despair factor and sleep disturbance factor, and the HAMD total score in the observation group after treatment were significantly lower than those inthe control group (both P<0.01), which was consistent with the conclusions of the above studies. There were no significant differences in the scores of somatization factor, cognitive factor and retardation factor between the two groups after treatment (P>0.05), which may be caused by the short observation time in this study and the slow improvement of the above factors.

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 in this study.

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