CLINICAL RESEAPCH

Clinical Observation of Tongluo Sanyu Decoction Combined with Acupoint Massage in Treating Patients with Cerebral Infarction in Qi Deficiency and Blood Stasis Syndrome

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Keywords

Tongluo Sanyu decoction, Qi deficiency and blood stasis, Cerebral infarction, Acupoint Massage, Nerve function

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Abstract

Objective To explore the clinical efficacy of Tongluo Sanyu Decoction combined with acupoint massage in treating patients with cerebral infarction in Qi deficiency and blood stasis syndrome, in order to provide a reference for clinical treatment of cerebral infarction. Methods A total of 130 cases of patients with cerebral infarction in the syndrome of Qi deficiency and blood stasis treated in our hospital from March 2018 to March 2020 were selected for research. All participants were averagely divided into the control group (received conventional treatment and then acupoint massage) and the observation group (received all control group treatment together with Tongluo Sanyu decoction) according to the random number table method. The course of treatment was 3 weeks. TCM symptom score, levels of homocysteine (Hcy), endothelin-1 (ET-1), nitric oxide (NO), neurological deficit score (NIHSS), Barthel index (BI) and adverse reactions were compared between the two groups before and after treatment. Results After treatment, the TCM symptom scores in the two groups were significantly lower than those before treatment, with a lower trend in the observation group than that of the control group. After treatment, the Hcy, ET-1 levels and NIHSS scores of the two groups were significantly lower than those before treatment, and the observation group was significantly lower than that of the control group, and the dopamine (DA), levels of norepinephrine (NE), 5-hydroxytryptamine (5-HT), NO and BI score were significantly higher than those before treatment, and the observation group was significantly higher than that of the control group. There was no significant difference in the incidence of adverse reactions between the two groups. Conclusion Tongluo Sanyu decoction combined with acupoint massage could effectively improve the clinical symptoms of patients with cerebral infarction in Qi deficiency and blood stasis syndrome, contributing to regulation of brain neurotransmitters, improve cerebral circulation, and good prognosis of patients.

Introduction

Cerebral infarction, also known as ischemic stroke, is an ischemic necrosis of brain tissue caused by occlusion of cerebral blood vessels due to cerebral arteriosclerosis or other factors, resulting in inadequate perfusion of the blood supply area, and as a highly prevalent cerebrovascular disease, it is characterized by high mortality, high disability and low cure rate [1,2]. Patients with cerebral infarction have an acute onset and often suffer from sequelae such as hemiplegia, facial paralysis and language disorder after treatment, with poor recovery outcomes. At present, there is no standard clinical method for the treatment of this disease yet, and Western conventional symptomatic treatments such as thrombolysis and anticoagulation are mostly used to aid rehabilitation training [3]. However, with the rapid development of traditional Chinese medicine (TCM) in China in recent years, TCM therapy has been widely recognized by a growing number of patients for its unique advantages in disease prevention, treatment and rehabilitation [4]. In TCM, cerebral infarction is believed to be rooted in Qi deficiency and blood stasis, with wind, fire, phlegm and stasis being the main pathological factors, therefore, the main treatment principle needs to focus on promoting blood circulation for removing blood stasis and activating collaterals for resuscitation [5]. TCM treatment of cerebral infarction is mainly based on Chinese herbal decoctions, Chinese patent medicines, acupuncture therapy and massage, of which Chinese herbal decoctions possess the strengths of being highly targeted, flexible in prescription, and rapid in effect, while massage has a significant effect on improving the body's motor function [6]. Based on current background, this study applied Tongluo Sanyu decoction combined with acupoint massage to treat patients with Qi deficiency and blood stasis in the stable stage of cerebral infarction, and probed into the effect of this therapeutic method on their neurological function and limb function recovery, hoping to provide new ideas for the clinical treatment of cerebral infarction by combining TCM and Western medicine.

Information

Basic information

A total of 130 cases of patients with cerebral infarction in the syndrome of Qi deficiency and blood stasis treated in our hospital from March 2018 to March 2020 were selected for research. All participants were divided into the observation group (n=65) and the control group (n=65) according to the random number table method. In the control group, there were 36 males and 29 females, aged 40-82 years, with a mean age of (58.63±9.34) years, duration of illness 12-72 h, with a mean duration of (35.43±8.60) h. There were 28 infarcts in the basal nucleus, 22 in the thalamus and 15 in the lateral ventricles. In the observation group, there were 38 males and 27 females, aged 42-80 years, with a mean age of (57.48±8.86) years, duration of illness 10-72 h, with a mean duration of (34.90±9.23) h. There were 29 infarcts in the basal nucleus, 25 in the thalamus and 11 in the lateral ventricles. There was no statistically significant difference between the two groups in terms of gender, age, duration and the area of infarction (P>0.05), and the data were clinically comparable. The study was approved by the Ethics Committee of our hospital, and all patients volunteered to participate and signed an informed consent form.

Diagnosis criteria

Western diagnostic criteria

The diagnostic criteria related to cerebral infarction were referred to the *Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke 2018* [7]. The patient was diagnosed with cerebral infarction by CT and MRI, with symptoms such as dysphagia, dyskinesia, sensory aphasia, incontinence and focal neurological deficits.

Diagnostic criteria for TCM syndromes

Patients suffering from cerebral infarction were diagnosed with the syndrome of Qi deficiency and blood stasis according to the *Standards for the Diagnosis and Evaluation of the Efficacy of TCM in Stroke Diseases* [8]. Primary symptoms: hemiplegia, slaver cheek, motor dysfunction, hypophrasia and aphasia. Minor symptoms: pale complexion, short breath and weak, spontaneous sweating, palpitation and loose stool, dark tongue and white moss, tooth margin and deep and thread pulse.

Inclusion criteria

Patients who met the diagnostic criteria for cerebral infarction and who had been identified having syndrome of Qi deficiency and blood stasis; patients who received treatment within 72h of onset and whose vital signs tended to be good; patients with no abnormalities in coagulation function.

Exclusion criteria

Patients with combined malignancy; patients with severe combined heart, liver and kidney organ dysfunction; patients who were allergic to the medication used in this study; patients with a history of craniotomy, interventional or thrombolytic treatment; patients accompanied with severe hematological, immunological and neurological disorders.

Methods

Treatment methods

After patients in both groups were admitted to hospital and underwent relevant investigations, they were given regular symptomatic treatments such as aspirin against platelet aggregation, water-electrolyte balance, improvement of cerebral circulation, nerve nutrition, reduction of intracranial pressure (ICP) and anti-inflammation. On the basis of conventional therapies, the control group were not given acupoint massage until the patients' condition were stabilized. The massage was as follows: (i) With the patient in a seated position, the technician kneaded points of Baihui and Fengchi on the head and massaged Yintang, Taiyang, Xiaguan, Jiache, Yingxiang points on the face in turn, with about 15 times on each point; (ii) With the patient in a seated position, the technician used palm to massage points of Jianjing, Jianyu, Jugu and Jianliao on the affected side of the patient from the shoulder to the forearm, followed by pressing Quchi, Shousanli, Waiguan and Hegu points with the

thumb, from top to bottom for about 10 minutes (min); (iii) With the patient in a prone position, the technician performed massage on his or her back at the Tianzong, Danshu and Ganshu points, 3 times from the bottom up; (iv) With the patients in a lateral position, the technician performed a rolling massage on his or her lower limbs from top to bottom, followed by massaging Zusanli, Taichong, Yangling, Weizhong, Liangqiu and Chengshan points for 20 min each time. Acupiont massage was performed once a day, with a break of 2 days after 5 consecutive days of massage, for a total of 3 weeks of treatment.

Based on the treatment of the control group, the observation group was additionally given Tongluo Sanyu decoction. The formula consisted of sargentgloryvine stem 30g, Chinese starjasmine stem 15g, spinyleaf pricklyash root 15g, cibot rhizome 15g, aleppo dock rhizome 15g, leech 10g and Chinese clematis root 10g. The above herbals were decocted with water to obtain 200ml of decoction as 1 dose. The decoction was divided into two portions warmly taken by the patient every morning and evening for a total of 3 weeks.

Observed indicators

(i) Patients were observed and asked about their TCM symptoms before and after treatment to assess the TCM symptom score, which included five aspects: hemiplegia, distortion of the mouth and tongue, hypologia, speech disorder and obnubilation, using a 5-point scale from 1 to 5, with 1 point: no symptoms, 2 points: mild symptoms, 3 points: moderate symptoms, 4 points: severe symptoms, and 5 points: serious symptoms. The higher the score the more severe the patient's symptoms. (ii) Before and after treatment, 3 ml of venous blood were drawn from each fasting patient and performed centrifugation (3000r/min) for 15 min to obtain the supernatant. The enzyme-linked immunosorbent assay (ELISA) kit (Shanghai Ruifan Biotechnology Co., Ltd.) was used to measure the levels of homocysteine (Hcy), endothelin-1 (ET-1) and nitric oxide (NO) strictly according to the protocols. (iii) Before and after treatment, ET analyzer (ML-2001, Beijing Tongren

Optoelectronic Technology Co., Ltd, China) was used to detect the levels of dopamine (DA), norepinephrine (NE), 5-hydroxytryptamine (5-HT). (iv) National Institute of Health stroke scale (NIHSS) and Barthel index (BI) were applied to assess the degree of neurological deficits and the self-care ability of the patients before and after treatment [9]. The NIHSS evaluation includes 11 indicators such as consciousness, visual field, limb movement, speech and sensation, with a total score of 42 points. A higher score indicated a more severe neurological deficit. The BI evaluation includes 10 indicators such as eating, bathing, dressing and toileting, with a total score of 100. A higher score indicated that the patient was more capable of taking care of himself or herself. (v) We observed and recorded adverse reactions during treatment in both groups, including dizziness, gastrointestinal disturbances and diarrhea.

Statistical analysis

SPSS software (version 20.0) was used for statistical analysis. Count data were compared using χ^2 test. Quantitative data was expressed as the mean \pm standard ($\bar{x}\pm s$), with comparison using the *t*-test. Differences were considered statistically significant at P<0.05.

Results

Comparison of TCM syndrome scores between the two groups

Before treatment, there was no statistically significant difference in TCM symptom scores between the two groups in terms of hemiplegia, distortion of the mouth and tongue, hypologia, speech disorder and obnubilation (P>0.05). After treatment, the TCM symptom scores in both groups were significantly lower than those before treatment, and the TCM symptom score in the observation group was significantly lower than that in the control group (P<0.05), as shown in Table 1.

		hemiplegia		distortion of the	he mouth and	hypologia	
	e cas			tongue		nypologia	
group		pre-treatme	post-treatme	pre-treatme	post-treatme	pre-treatme	post-treatme
		nt	nt	nt	nt	nt	nt
observatio n group	65	4.20±0.45	3.25±0.53*	4.02±0.55	3.22±0.35*	3.74±0.48	2.83±0.52*
control group	65	4.25±0.50	3.56±0.62*	4.08±0.60	3.50±0.45*	3.70±0.45	3.06±0.46*
t		-0.599	-3.064	-0.594	-3.960	0.490	-2.671
Р		0.550	0.003	0.553	0.000	0.625	0.009
group			speech disorder		obnubilation		
		case —	pre-treatment	post-treatment	pre-treatment p		ost-treatment
observation group		65	3.68±0.45	2.84±0.47*	3.46±0.58		2.47±0.38*
control group		65	3.62±0.50	3.12±0.52*	3.50±0	.62	2.88±0.45*
t			0.719	-3.221	-0.38	30	-5.612

0.002

Table 1. Comparison of TCM syndrome scores between the two groups (point)

Note: compared to the pre-treatment, *P<0.05

Р

Comparison of Hcy, ET-1 and NO levels between the two groups

0.473

Before treatment, no statistical significance was found in the comparison of Hcy, ET-1 and NO levels between the two groups (P>0.05). After treatment, Hey and ET-1 levels were significantly lower than before treatment in both groups, and significantly lower in the observation group than in the control group (P<0.05), and NO levels were significantly higher in both groups than before treatment, and

0.000

0.705

significantly higher in the observation group than in

the control group (P < 0.05), as shown in Table 2.

	000	Hcy (µmol/L)		ET-1 (ng/L)		NO (µmol/L)	
group	cas	pre-treatme	post-treatme	pre-treatme	post-treatme	pre-treatme	post-treatme
	e	nt	nt	nt	nt	nt	nt
observatio n group	65	25.34±4.38	16.24±3.58*	78.56±8.23	52.34±6.25*	48.34±6.10	67.34±6.72*
control group	65	25.80±4.76	19.34±4.02*	77.82±7.65	58.30±5.70*	47.86±6.54	62.58±7.14*
t		-0.573	-4.643	0.531	-5.681	0.433	3.914
Р		0.567	0.000	0.596	0.000	0.666	0.001

Table 2. Comparison of Hcy, ET-1 and NO levels between the two groups

Note: compared to the pre-treatment, *P < 0.05

Comparison of neurotransmitter levels between the two groups before and after treatment

Before treatment, there was no statistically significant difference in the levels of DA, NE and 5-HT between the two groups (P>0.05). After treatment, the levels of

DA, NE and 5-HT in both groups were significantly higher than before treatment, and the levels of DA, NE and 5-HT in the observation group was significantly higher than those in the control group (P<0.05), as shown in Table 3.

Table 3. Comparison of neurotransmitter levels between the two groups before and after treatment

aroun		DA (µg/L)		NE (pg/mL)		5-HT (ng/mL)	
group	case	pre-treatment	post-treatment	pre-treatment	post-treatment	pre-treatment	post-treatment
observation group	65	118.34±20.54	195.72±22.38*	82.36±12.54	142.38±16.74*	65.46±8.40	125.62±18.34*
control group	65	116.40±18.62	176.50±23.57*	83.30±10.58	125.26±18.55*	66.13±7.20	108.26±15.67*
t		0.564	4.768	-0.462	5.524	-0.488	5.802
Р		0.574	0.000	0.645	0.000	0.626	0.000

Note: compared to the pre-treatment, *P<0.05

Comparison of NIHSS and BI scores between the two groups before and after treatment

Before treatment, NIHSS and BI scores of patients in both groups showed no statistically significant difference (P>0.05). After treatment, NIHSS scores of patients in both groups were significantly lower than before treatment, and the NIHSS score in the observation group was significantly lower than that in the control group (P<0.05), and BI scores of patients in both groups were significantly higher than before treatment, and the BI score in the observation group was significantly higher than that in the control group (P<0.05), as shown in Table 4.

	case -	NIF	ISS	BI		
group		pre-treatment	post-treatment	pre-treatment	post-treatment	
observation group	65	22.45±3.56	13.72±3.15*	48.34±7.24	68.26±6.33*	
control group	65	21.92±4.16	16.34±3.72*	49.23±6.85	$62.47 \pm 5.80^*$	
t		0.780	-4.333	-0.720	5.437	

Р	0.437	0.000	0.473	0.000
	 *			

Note: compared to the pre-treatment, $^*P < 0.05$

Comparison of adverse reactions between the two groups

The incidence of adverse reactions in the observation group was 9.23% (6/65), including 3 cases of dizziness, 2 cases of gastrointestinal disturbances and 1 case of diarrhea. The incidence of adverse reactions in the control group was 6.15% (4/65), including 2 cases of dizziness and 2 cases of gastrointestinal disturbances. There was no statistically significant difference in the incidence of adverse reactions between the two groups (χ^2 =0.433, *P*=0.510).

Discussion

Clinical studies have shown that after the acute phase of cerebral infarction, patients will enter a long recovery period, during which a timely and effective rehabilitation treatment is an important measure to reduce the degree of disability caused by cerebral infarction and influence their quality of life in the future [10]. TCM classifies cerebral infarction into the category of "stroke", which results from insufficiency of natural endowment and deficiency of vital Qi, leading to hyperactivity of yang causing wind and blood stasis blocking brain collaterals, and resulting in numbness of the limbs, distortion of the mouth and tongue as well as a series of illnesses eventually triggering stroke [11]. As old saying in Jingyue's Complete Works goes that "Patients with symptomatic stroke disease are nothing more than a depletion of vital Qi", suggesting that Qi deficiency is an important factor leading to this disease, and therefore, cerebral infarction is rooted in the deficiency of vital Qi, and is caused the insufficiency Qi and blood, wind-fire invasion and blood stasis. The main treatment should be to focus on dispelling wind, activating blood, regulating collaterals and removing stasis. Acupoint massage is a common external therapy in TCM that is guided by the theory of acupoint and meridian and focuses on the connection between the body surface and the internal organs. By stimulating the meridians and acupoints on the surface

of the body, the massage can exert functions in expelling wind and cold pathogens, promoting blood circulation for removing blood stasis, regulating qi-flowing for relieving pain and relieving rigidity of muscle and activating collaterals in order to regulate the joints, release spasm, improve blood circulation, prevent muscle atrophy, and improve the mobility of the limbs [13]. Besides, a growing number of publications have reported in recent years that the TCM treatment based on syndrome differentiation has outstanding advantages and characteristics in the management of patients with stroke [14, 15]. According to the pathogenesis of stroke, patients with cerebral infarction in Qi deficiency and blood stasis type mainly have clinical manifestations of wind, fire, phlegm, heat, stasis, meridian blockage and paralysis, while most of herbals in TCM decoctions have the effect of activating blood circulation for clearing stasis, removing obstruction in collaterals, regulating the bodily meridian-qi, improving the blood circulation system, activating blood and relaxing tendons. Based on the above treatment methods, this study applied Tongluo Sanyu decoction combined with acupoint massage to treat patients with cerebral infarction in Qi deficiency and blood stasis type. As a result, the clinical symptoms of patients in the observation group improved significantly after treatment compared with those in the control group, suggesting that the combination of Tongluo Sanyu decoction and acupoint massage had a positive effect on relieving the clinical symptoms of cerebral infarction.

Clinically, it has been shown that vascular injury or dysfunction is a key factor triggering cerebral infarction. Vascular intimal damage can narrow the lumen of the cerebral arteries, leading to local thrombosis as well as causing ischemia, hypoxia and necrosis in the brain tissue, which severely threatens the life of the patient. ET-1 is a vasoactive substance that plays an important role in maintaining vasoconstriction and elasticity, and when vascular endothelial damage occurs, ET-1 is released into the blood, leading to a series of inflammatory reactions and the production of a large number of free radicals, thus aggravating neurological damage in the brain [16]. NO is a vessel-dilating substance that would be generated in large quantities to improve cerebral perfusion after cerebral vascular injury [17]. Hcy, as a sulphur-containing amino acid, has been clinically shown to be an independent risk factor for the development of atherosclerosis, disrupting the normal function of blood coagulation and increasing the risk of thrombosis and stroke [18]. From this, it can be seen that stabilization of Hcy, ET-1 and NO levels in the serum is important in the treatment of cerebrovascular disease. The results of this study showed that the levels of Hcy and ET-1 in the observation group were significantly lower than those in the control group after treatment, while the levels of NO were significantly higher than those in the control group, suggesting that Tongluo Sanyu decoction combined with acupoint massage could contribute to reducing the damage of cerebrovascular endothelial function. The formula of Tongluo Sanyu decoction consists of sargentgloryvine stem, Chinese starjasmine stem, spinyleaf pricklyash root, cibot rhizome, aleppo dock rhizome, leech and Chinese clematis root. Among them, sargentgloryvine stem is effective in clearing heat and removing toxicity as well as promoting blood circulation for dispelling pathogenic wind, and Chinese starjasmine stem, spinyleaf pricklyash root and cibot rhizome are effective in activating blood circulation and relieving rigidity of muscles as well as removing obstruction in collaterals and detumescence. Therefore, the combination of all these herbs works together to eliminate blood stasis, invigorate pulse, promote blood circulation and remove obstruction in collaterals. In addition, Modern pharmacological studies have shown that the phenols, organic acids, flavonoids and other active ingredients contained in sargentgloryvine stem and Chinese starjasmine stem possess antibacterial, anti-inflammatory and repairing effects on blood vessel damage [19]. Hence, it has a certain value that applying Tongluo Sanyu decoction in the treatment of reducing inflammatory response and protecting vascular function in patients with cerebral infarction. The sequelae such as aphasia and hemiparesis in patients with acute cerebral infarction after treatment can be classified as neurological deficits, and improving the neurological impairment of patients is of great importance to their prognosis. DA, NE and 5-HT are all critical neurotransmitters that govern neuronal excitation exerting neuroprotective effects, and changes in their levels are closely related to neurological recovery after treatment of cerebrovascular disease. Our study found that the DA, NE, 5-HT levels and BI score in the observation group were significantly higher than those in the control group after treatment, while the NIHSS score were significantly lower than that in the control group, indicating that Tongluo Sanyu decoction combined with acupoint massage facilitate the improvement of neurological function and capacity for daily living in patients with cerebral infarction. According to the theory of TCM, the mechanism of neurological impairment in cerebral infarction lies in the blockage of blood stasis and occlusion of collaterals in the brain, and the loss of nourishment for the meridians over time. In this study, the decoction we used is based on the fundamental principle of removing obstruction in collaterals for dissipating blood stasis. By cooperating with Chinese herbals and following the principles of treatment based on syndrome differentiation, the decoction could give fully play to effect of invigorating blood circulation for removing blood stasis, dispelling wind and regulating the meridians. Moreover, modern pharmacological studies have shown that arctiin contained in Chinese starjasmine stem plays a stimulating role in the central nervous system to promote the release of neurotransmitters, and butylphthalide in aleppo dock rhizome can prevent or attenuate neuronal apoptosis, which has a protective function on neuronal cells as well as could inhibit the further expansion of cerebral infarction. Additionally, the massage treatment in this study is carried out at important points on the head and face, upper and lower limbs and back. Through the stimulating effects of pushing, pinching, pressing,

rubbing and kneading and other techniques, it can improve the local blood circulation, prevent the loss of function of activities, and by massaging from one point to the whole area, the joints and muscles of the body can be stimulated to receive comprehensive rehabilitation exercises. Also, it has been found that the functions of various parts of the body are regulated by the nervous system. The combination treatment in this study could play a synergistic role in relieving spasm and removing nerve blockage, which is consistent with the findings of Man Bin et al [20]. Furthermore, there was no significant difference in the incidence rate of adverse reactions between the two groups, indicating that the treatment method we devised in this study showed no significant side effects with safe and reliable results.

In conclusion, Tongluo Sanyu decoction combined with acupoint massage could effectively improve the clinical symptoms of patients with cerebral infarction in Qi deficiency and blood stasis type, relieve cerebrovascular endothelial damage and protect neurological function, showing a high safety profile.

Declaration of conflict-of-interest

The authors declare no conflict-of -interest.

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