

Clinical Effect of the Modified Huatan Tongluo Formula on Acute Cerebral Infarction Patients with Wind-Phlegm Obstruction Syndrome

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Abstract: *Objective:* To analyze the clinical effect of the modified Huatan Tongluo formula on acute cerebral infarction patients with wind-phlegm obstruction syndrome. *Methods:* 70 cases of acute cerebral infarction with wind-phlegm blocking syndrome admitted from May 2022 to May 2023 were selected as the study subjects. The subjects were divided into a control group and an observation group by randomized numerical table method, each with 35 cases; the control group was treated with conventional Western medicine, and the observation group was treated with the modified Huatan Tongluo Formula in addition to conventional treatment. The two groups were compared in terms of traditional Chinese medicine (TCM) evidence points, quality of life, clinical efficacy, and adverse reactions. *Results:* Before treatment, there were no significant differences in each index between the two groups of patients ($P > 0.05$); after treatment, the observation group scored better in terms of TCM evidence and quality of life compared to the control group. Besides the total clinical efficacy of the treatment received in the observation group was also higher than that of the control group ($P < 0.05$). However, there was no significant difference in terms of incidence of adverse reactions between the two groups ($P > 0.05$). *Conclusion:* The modified Huatan Tongluo formula can improve the clinical symptoms and the quality of life of acute cerebral infarction patients with wind-phlegm obstruction syndrome.

Keywords: Acute cerebral infarction; Wind-phlegm obstruction syndrome; Modified Huatan Tongluo formula

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1. Introduction

Cerebral infarction is a cerebrovascular condition characterized by ischemic necrosis of brain tissue due to a sudden interruption in blood supply. This disease is prevalent among middle-aged and elderly individuals. Its onset is abrupt, with symptoms including dizziness, headache, unilateral limb dysfunction, speech disorders, or impaired consciousness^[1]. The time window for thrombolysis and endovascular treatment is limited, making drug treatment, such as anticoagulation and antiplatelet therapy, the primary approach. Western medicine alone comes with certain limitations when it comes to the rehabilitation of cerebral infarction. In recent years, Chinese medicine has been developing rapidly, and it has also been widely popularized and clinically applied.

According to Chinese medicine, cerebral infarction belongs to the category of stroke^[2], and it often comes with wind-phlegm obstruction syndrome, so it is necessary to extinguish the wind, resolve the phlegm, and clear the collaterals. Therefore, the effect of the modified Huatan Tongluo formula in treating acute cerebral infarction patients with wind-phlegm obstruction was observed in this study.

2. Information and methods

2.1. Data

70 cases of acute cerebral infarction patients admitted to our hospital were selected as the study subjects (admission time: May 2022 to May 2023). They were divided into a control group and an observation group by the random number table method, with 35 cases in each group.

The control group consisted of 20 males and 15 females aged 52–78 years (average: 65.26 ± 5.13 years). The observation group consisted of 21 males and 14 females, aged 51–79 years (average: 65.38 ± 5.20 years). There were no significant differences in the baseline data of both groups ($P > 0.05$).

Inclusion criteria: (1) Patients who meet both Chinese and Western medical diagnostic criteria and fall under the wind-phlegm obstruction syndrome in Chinese medicine. Primary symptoms encompass crooked mouth, tongue, hemiplegia, speech and sensory loss, while secondary symptoms include phlegm and mucus, dizziness, and vertigo. Additional diagnostic indicators involve a thin and white tongue coating, pale tongue, and a slippery pulse. (2) NIHSS scores between 5 and 15 before the treatment. (3) The patients and their family members were informed of and agreed to the treatment plan. (4) Patients with complete clinical data.

Exclusion criteria: (1) The existence of thrombolysis or vascular intervention thrombolysis indication; (2) The combination of other serious diseases; (3) The existence of mental disorders can not be normal communication; (4) At the same time participate in other medical research projects.

2.2. Methods

Control group: Conventional Western medical treatment. Aspirin enteric-coated tablets (oral, once a day, 100 mg each time), Rosuvastatin calcium tablets (oral, once a day, 10 mg each time), etc. for two weeks. Other glycemic control, blood pressure, and other symptomatic treatment were also given if needed. Patients who experienced difficulty swallowing, were given nasal feeds, and guidance for rehabilitation exercises was provided.

Observation group: Modified Tongluo Huatan formula for resolving phlegm and clearing collaterals combined with Western medicine. The basic formula included: 3 g scorpions, 6 g gall bladder, 9 g Angelica, 9 g Atractylodes, 9 g *Atractylodes macrocephala*, 9 g *Pinellia ternata*, 10g *Paeonia lactiflora*, 10g Poria mushroom, 12 g tall Gastrodia, and 15 g *Salvia miltiorrhiza*. Dialectical additions and subtractions: (1) If the patient had slurred speech 6 g *Polygala tenuifolia* 10 g calamus, and 12 g *Radix curcumae* were added; (2) if the patient had severe headache, 0.3 g antelope horn powder, 3 g Asarum, 6 g Radix Saposhnikoviae, 6 g *Angelica dahurica*, 9g cranberries; (3) if the patient had heavy leg and foot stagnation, 15 g mistletoe and 15 g *Eucommia ulmoides* were added; if the patient experienced sweating, 6 g Radix Saposhnikoviae, 15 g Fructus Triticis Levis, and 15 g Radix Oryzae Glutinosae were added. The patients were given 300 mL of the decoction once a day.

2.3. Observation indexes

- (1) Traditional Chinese medicine (TCM) evidence points: The TCM evidence points of both groups were compared before and after treatment. The points include hemiplegia, dysarthria, crooked mouth, and

numbness of limbs, according to the relevant standards of the “Guide to Diagnosis and Treatment of Common Diseases in Internal Medicine of Chinese Medicine” [3]. The scores ranged from 0 (no symptoms) to 3 (severe symptoms), with 1 and 2 indicating mild and moderate symptoms, respectively.

- (2) Quality of life: The quality of life of the patients was assessed using the World Health Organization Quality of Life Measurement Scale Brief Form (WHOQOL-BREF) [4], which includes four dimensions, i.e., physiological, psychological, environmental, and social relations, with higher scores indicating higher quality of life.
- (3) Clinical efficacy: The clinical efficacy of the treatments was assessed using the National Institutes of Health Stroke Scale (NIHSS), in which the score ranges from 0–42 points [5]. A 90–100% decrease in this score indicated “full recovery,” a 46–89% decrease indicated significant progress, a decrease of 18–45% indicated “progress,” and a decrease of less than 18% or an increase in this score was considered “ineffective.” The total efficacy was the sum of “full recovery,” “significant progress,” and “progress.”
- (4) Adverse reactions: Drowsiness, nausea and vomiting.

2.4. Statistical analysis

The patients’ data were analyzed using SPSS 25.0. The measurement data were represented as mean \pm standard deviation (conforming to normal distribution), and the count data were represented as percentages. Independent samples *t*-tests and χ^2 tests were conducted, with $P < 0.05$ indicating statistical significance.

3. Results

3.1. TCM evidence points

As shown in **Table 1**, there were no significant differences in the TCM evidence points between the groups of patients before treatment ($P > 0.05$); after treatment, all the evidence points of the observation group were lower than those of the control group ($P < 0.05$).

Table 1. TCM evidence points (mean \pm standard deviation, points)

Group	Cases (n)	Hemiplegia		Slurred speech		Slanting of the corners of the mouth		Numbness of the limbs	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	35	2.13 \pm 0.15	0.93 \pm 0.20	2.15 \pm 0.28	0.90 \pm 0.17	2.19 \pm 0.17	0.86 \pm 0.13	2.21 \pm 0.20	0.91 \pm 0.17
Observation group	35	2.17 \pm 0.14	0.41 \pm 0.15	2.17 \pm 0.20	0.40 \pm 0.13	2.22 \pm 0.16	0.43 \pm 0.10	2.25 \pm 0.17	0.45 \pm 0.15
<i>t</i>	-	1.153	12.305	0.344	13.822	0.760	15.511	0.902	12.004
<i>P</i>	-	0.253	0.000	0.732	0.000	0.450	0.000	0.370	0.000

3.2. Quality of life scores

As shown in **Table 2**, there were no significant differences in the quality-of-life scores between the two groups before treatment ($P > 0.05$). However, after treatment, the scores for all dimensions in the observation group were significantly higher than those in the control group ($P < 0.05$).

Table 2. Quality of life scores (mean \pm standard deviation, points)

Group	Cases (n)	Physiology		Psychology		Environment		Social relations	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	35	10.12 \pm 2.13	13.59 \pm 2.15	10.18 \pm 1.36	13.54 \pm 2.15	11.52 \pm 2.13	14.10 \pm 2.18	9.52 \pm 1.16	12.31 \pm 1.58
Observation group	35	10.05 \pm 2.29	16.18 \pm 2.17	10.23 \pm 1.51	17.02 \pm 2.13	11.48 \pm 2.10	17.21 \pm 2.34	9.50 \pm 1.12	13.91 \pm 1.15
<i>t</i>	-	0.132	5.016	0.146	6.803	0.079	5.753	0.073	4.844
<i>P</i>	-	0.895	0.000	0.885	0.000	0.937	0.000	0.942	0.000

3.3. Clinical efficacy

As indicated in **Table 3**, the total efficacy of treatment in the observation group was higher compared to the control group, with a statistically significant difference ($P < 0.05$).

Table 3. Clinical efficacy (n [%])

Group	Cases (n)	Full recovery	Significant progress	Progress	Ineffective	Total efficacy
Control group	35	3 (8.57)	10 (28.57)	12 (34.29)	10 (28.57)	25 (71.43)
Observation group	35	9 (25.71)	18 (51.43)	5 (14.29)	3 (8.57)	32 (91.43)
χ^2	-	-	-	-	-	4.629
<i>P</i>	-	-	-	-	-	0.031

3.4. Adverse reactions

As shown in **Table 4**, there was no significant difference in the incidence of adverse reactions between the two groups ($P > 0.05$).

Table 4. Adverse reactions (n [%])

Group	Cases (n)	Drowsiness	Nausea and vomiting	Dizziness	Total
Control group	35	2 (5.71)	1 (2.86)	1 (2.86)	4 (11.73)
Observation Group	35	1 (2.86)	1 (2.86)	1 (2.86)	3 (8.57)
χ^2	-	-	-	-	0.159
<i>P</i>	-	-	-	-	0.690

4. Discussion

Cerebral infarction is a complex condition involving mechanisms such as the formation of carotid atherosclerosis plaques, intracerebral thromboembolism, and the development of intracerebral arterial stenosis or occlusion. This leads to the necrosis of cerebral tissue due to hypoxia and ischemia, resulting in clinical symptoms such as dizziness, headache, and numbness of the limbs. It is a type of cerebrovascular disease associated with a high rate of disability and mortality. Cerebral infarction damages the brain nerve tissue, which then leads to neurological dysfunction, manifested as speech disorder, cognitive abnormality, limb disorder, etc. Conventional Western medicine treatment advocates symptomatic treatment, which does not cure the disease fundamentally, resulting in slow recovery or recurrence.

Chinese medicine categorizes cerebral infarction as “stroke,” which is caused by a deficiency of the liver and kidney, deficiency of qi and blood, etc, which can be stimulated by factors such as weather, diet, emotions,

etc., leading to qi and blood disorder and dysfunction of internal organs, manifested as wind and phlegm blocking the collaterals. The basic ingredients of the Huatan Tongluo formula include scorpions, gall bladder, Angelica, *Atractylodes*, *Atractylodes macrocephala*, *Pinellia ternata*, *Paeonia lactiflora*, Poria, tall Gastrodiae, *Salvia miltiorrhiza*. Scorpions are effective in alleviating wind and clearing channels for pain relief, while gall bladder dispels wind, stops spasms, and clears away heat and phlegm. Angelica invigorates blood and opens channels for pain relief. *Atractylodes macrocephala* and poria strengthen the spleen and eliminate dampness. *Pinellia ternata* dries dampness and resolves phlegm, and *Paeonia lactiflora* nourishes and activates blood. Poria calms the liver and quenches wind, while *Salvia miltiorrhiza* activates and cools the blood. This formula exhibits effects such as meridian dredging, wind dispelling, and phlegm resolution. Modern pharmacological analysis suggests that scorpions have satisfactory antihypertensive, sedative, and anticoagulant properties. Gall bladder improves the hypoxia and ischemia state of cerebral tissues and regulates lipids. *Salvia miltiorrhiza* enhances microcirculation, lowers blood pressure, and expands blood vessels. Poria demonstrates antioxidant effects, tall Gastrodia lowers blood pressure and lipids while protecting cerebral nerves, and *Pinellia ternata* contributes to blood pressure reduction and resistance to atherosclerosis^[7,8]. In this study, 35 patients in the observation group received treatment with the modified Huatan Tongluo formula. The results indicated that the patients in the observation group had a lower TCM symptom score and a higher overall treatment efficacy, suggesting that the therapy in the observation group was more satisfactory. Patients with cerebral infarction experience significant physiological, psychological, and functional impairments, leading to a decline in their ability to live. Their quality of life is substantially worse than before, and enhancing the quality of life for these patients is a key objective of clinical treatment^[9-11]. Furthermore, cerebral infarction often results in numerous sequelae, accompanied by substantial mood changes, leading to a significant decline in the quality of life. The outcomes reveal that patients in the observation group exhibited lower scores and higher overall treatment efficacy, signifying that the therapy applied in the observation group yielded more satisfactory results. Across all dimensions of quality of life, the scores for patients in the observation group were higher than those in the control group, indicating an enhanced quality of life following treatment. This suggests that the treatment regimen employed in the observation group had a more favorable impact on improving both the condition and quality of life. Addressing adverse drug reactions remains a major concern for most patients^[12]. Based on the results of this study, there were no differences in the adverse reactions between patients who received TCM treatment and those who did not. Therefore, it is evident that the addition of Chinese medicine prescription will not increase the adverse reactions.

5. Conclusion

In short, the Huatan Tongluo formula increased the efficacy of the treatment for cerebral infarction patients suffering from wind-phlegm obstruction syndrome. Besides, the addition of this TCM regimen does not result in a higher incidence of adverse reactions. Therefore, this treatment regimen should be popularized in clinical practice.

Disclosure statement

The author declares no conflict of interest.

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