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Clinical Observation on Bu Yang Tong Luo Tang in Treating Acute Ischemic Stroke with Qi Deficiency, Blood Deficiency and Wind Syndrome

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Abstract: ***Objective:*** ***Clinical observation of Bu Yang Tong Lue Decoction in treating acute ischemic stroke with qi deficiency, blood stasis, and wind syndrome.*** ***Methods:*** ***From January to December 2024, 60 hospitalized patients diagnosed with acute ischemic stroke with qi deficiency, blood stasis, and wind syndrome were enrolled in the Neurology Department of Xi'an Traditional Chinese Medicine Hospital. The study included 30 control group patients and 30 treatment group patients. The control group received conventional Western medical treatment, while the treatment group received Bu Yang Tong Lue Decoction with modifications. Treatment duration was 2 weeks. During this period, we observed and recorded TCM syndrome scores, neurological deficits severity scores, daily living activity ability, and modified Rankin scores before and after treatment, along with safety indicators and adverse reactions.*** ***Results:*** ***Through rank sum test, significant differences (P<0.05) were observed in NIHSS scores, BI scale scores, mRs scores, and TCM syndrome scores between the treatment group and control group before and after treatment, with post-treatment improvement compared to pre-treatment. In overall efficacy observation, the treatment group demonstrated better Western medical outcomes and TCM efficacy compared to the control group.*** ***Conclusion:*** ***Bu Yang Tong Lue Decoction is an effective medication for treating acute ischemic stroke with qi deficiency, blood stasis, and wind syndrome. It can effectively improve clinical symptoms in patients during the acute phase of ischemic stroke, enhance quality of life, and does not increase the risk of adverse reactions, making it worthy of promotion and application.***

Keywords: Bu Yang Tong Luo Tang, Acute ischemic stroke, Qi deficiency and blood stasis combined with wind syndrome, Clinical observation.

1. Introduction

Acute ischemic stroke (AIS), the most prevalent type of stroke with high morbidity and mortality rates, is the leading cause of disability among residents [1]. Current treatments including thrombolysis, anticoagulation, antiplatelet therapy, nutritional support, and neuroprotective agents have shown some therapeutic efficacy [2]. Traditional Chinese Medicine (TCM) boasts a long history in stroke treatment, accumulating rich theoretical knowledge and pharmacological experience. Notably, wind-dispelling formulas like Buxiang Huanwu Decoction (created by Wang Qingren), Xunming Decoction from Gujin Luyan, and similar prescriptions have become primary therapeutic options for stroke [3]. While historical physicians offered diverse interpretations of stroke, most emphasized treating internal wind, phlegm-dampness, and blood stasis during acute phases [4], often overlooking the critical role of external wind throughout the disease process, particularly during acute episodes. Through extensive study of classical texts and clinical practice, our research team identifies wind pathogen as the key pathogenic factor in acute stroke. Adhering to the fundamental TCM pathogenesis of qi deficiency with blood stasis and wind pathogen agitation, we propose Bu Yang Tongluo Decoction for treating ischemic stroke patients presenting with qi-deficiency, blood stasis, and wind syndrome during acute phases. This study employs a randomized controlled trial design to evaluate the clinical efficacy and safety of the traditional Chinese herbal formula "Bu Yang Tong Luo Tang" in patients with acute ischemic stroke presenting with wind deficiency, blood stasis, and concurrent wind syndrome. The assessment incorporates multiple indicators including TCM syndrome scale scores, NIH Stroke Scale (NIHSS), Activities of Daily Living (BI) index, and Modified Rankin Scale (mRS). The findings aim to provide evidence-based clinical guidance for developing targeted therapies and optimizing treatment plans, thereby informing clinical medication decisions.

2. Data and Methods

2.1 General Information

This study involved 60 hospitalized patients diagnosed with acute ischemic stroke complicated by qi deficiency-blood stasis and wind syndrome at the Neurology Department of Xi 'an Traditional Chinese Medicine Hospital from January to December 2024. The patients were randomly divided into a control group (30 cases) and a treatment group (30 cases). Control group: 19 males and 11 females; average age (64.77±8.57) years. Treatment group: 16 males and 14 females; average age (67.67±8.56) years. General data comparison between the two groups showed no statistically significant differences (P>0.05), indicating comparable groups. The study was approved by the hospital's ethics committee.

2.2 Diagnostic Criteria

(I) Western medical diagnosis criteria: refer to the "Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke (2018 edition)" [5].

(1) Acute onset; (2) Focal neurological deficits (such as facial or limb weakness/numbness, speech disorders, etc.), with a minority presenting with generalized neurological deficits; (3) Imaging demonstrating a responsible lesion or

symptoms/signs persisting for over 24 hours; (4) Exclusion of non-vascular etiology; (5) Cerebral CT/MRI excluding cerebral hemorrhage.

(II) TCM diagnostic criteria:

(1) Disease diagnosis: refer to the diagnostic criteria [6] of the Guidelines for Clinical Research of New Traditional Chinese Medicine Drugs.

a) Main symptoms: hemiplegia, mental confusion, speech impairment or mutism, abnormal sensation on one side of the body, facial deviation; b) Secondary symptoms: headache, vertigo, altered pupil response, choking while drinking water, uncontrolled eye movement, ataxia; c) Acute onset with preceding symptoms (numbness and weakness in one side of the body, dizziness, headache); d) Most patients are over 40 years old.

There are more than two main symptoms or one main symptom and two secondary symptoms, combined with onset, precursor and age diagnosis.

(2) TCM syndrome differentiation criteria: refer to the "Clinical Terminology of Traditional Chinese Medicine Part 2: Syndrome" [7] and "Development and Methodological Discussion of ischemic stroke Syndrome Elements Diagnostic Scale" [8] revised by the National Administration of Traditional Chinese Medicine.

2.3 Inclusion and Exclusion Criteria

Inclusion criteria: (1) Meet the diagnostic criteria for acute ischemic stroke; (2) Onset time exceeding 6 hours but within 2 weeks; (3) TCM diagnosis of qi deficiency with blood stasis combined with wind syndrome; (4) Neurological deficits with NIHSS score ≤4 and ≥20; (5) Good treatment compliance with informed consent. Exclusion criteria: (1) Secondary cerebral hemorrhage or other vascular lesions induced by ischemic stroke leading to new infarction or severe infections; (2) Concurrent conditions such as severe digestive or hematological disorders with significant liver/kidney impairment; (3) Cerebral embolism caused by rheumatic heart disease or atrial fibrillation due to cardiac etiology; (4) Pregnant or breastfeeding women; (5) Allergy to the study medication.

2.4 Treatment Methods

The control group received conventional Western medical treatment, including Aspirin Enteric-Coated Tablets (100mg/ tablet, National Medical Products Administration Approval No. HJ20160685), Clopidogrel Sulfate Tablets (75mg/ tablet, National Medical Products Administration Approval No. H20171238), and Atorvastatin Calcium Tablets (20mg/ tablet, National Medical Products Administration Approval No. H20051407), administered once daily orally. The treatment group received additional administration of Bu Yang Tong Luo Decoction with modifications (self-designed formula: 60g Astragalus, 12g Paeonia, 10g Peach Kernel, 10g Safflower, 10g Chuanxiong Rhizome, 12g Angelica, 10g Earthworm, 10g Saposhnikovia Root, 10g Ephedra, 10g Cinnamon Twig, 15g Kudzu Root, 10g Notopterygium, 15g Codonopsis). The treatment group received Bu Yang Tong Luo Decoction twice daily, taken warm one hour after breakfast and dinner. Both groups underwent continuous treatment for two weeks.

2.5 Observation Indicators

(1) Collect the scores of NIHSS scale, BI finger scale, mRs scale and TCM syndrome evaluation scale before and after treatment. (2) Observe and record the adverse reactions of the two groups of patients after taking the drug, and objectively evaluate the safety of the drugs used.

2.6 Criteria for Evaluation of Efficacy

(1) Clinical Comprehensive Efficacy Evaluation: Using the NIH Stroke Coma Scale (NIHSS), calculate the percentage improvement of scores before and after treatment based on the following formula: (Pre-treatment Score-Post-treatment Score) ÷ Pre-treatment Score × 100%. (a) Partial Recovery: Decrease in NIHSS score by 91-100%; (b) Marked Improvement: Decrease in NIHSS score by 46-90%; (c) Effective Treatment: Decrease in NIHSS score by 18-45%; (d) Ineffective Treatment: Decrease in NIHSS score below 17%. (2) Traditional Chinese Medicine Syndrome Efficacy Assessment: Following the "Guidelines for Clinical Research on New Traditional Chinese Medicine Drugs for Stroke Treatment" [6], monitor the reduction in syndrome scores before and after treatment

Degree. Efficacy index n= [(pre-treatment score-post-treatment score)/pre-treatment score] × 100% (a) Basically cured: n≥90%; (b) Markedly effective: n≥70%; (c) Effective: n≥30%; (d) Ineffective: n<30%.

2.7 Statistical Methods

The statistical software (SPSS 26.0) was used to process the data of this study. (%) = count data, () = measurement data. The t and x2 tests were performed, and P <0.05 was statistically significant.

3. Bear Fruit

A total of 60 patients were enrolled in this study, 3 were dropped due to personal reasons, 30 were in the control group and 27 were in the treatment group, including 32 males and 25 females.

3.1 Comparison of Efficacy between Western Medicine and Chinese Medicine

As shown in the table below, the intergroup comparison of the two groups after treatment showed statistically significant differences (P<0.05), indicating that the clinical efficacy of the treatment group was significantly better than that of the control group. (Table 1)

Table 1: Comparison of efficacy between western medicine and Chinese medicine

Group	Recure	Excellence	Valid	Of no avail	Effective percentage
Control group	2[a]	16	9	3[a]	90%
Treatment group	5	19	1[a]	2[a]	92.6%

Note: A represents the theoretical frequency less than 5, and Fisher test is adopted. After chi-square-Fisher test, the comparison between the two groups P =0.04 <0.05.

3.2 Comparison of NIHSS, BI and mRS Scores

As shown in the table below, there was a significant improvement in NIHSS, BI and mRS scores of both groups before and after treatment (P<0.05), and the treatment group was significantly better than the control group in terms of NIHSS, BI and mRS scores. (Table 2)

Table 2: Comparison of NIHSS, BI and mRS scores

Group	NIHSS grade		BI grade		mRS grade	
	pretherapy	post-treatment	pretherapy	post-treatment	pretherapy	post-treatment
Control group	7.63±2.16	3.83±3.05	67.17±11.94	83.83±15.85	3.03±0.25	1.83±0.83
Treatment group	8.15±1.96	2.70±3.15	56.48±9.98	86.11±16.08	3.11±0.32	1.44±0.75

Note: According to the rank test, the comparison of NIHSS scores between the two groups showed Z=-3.973, P=0.000<0.05; BI scores showed Z =-2.897, P =0.004<0.05; mRS scores showed Z =-2.318, P =0.02<0.05.

3.3 Comparison of Efficacy of TCM

As shown in the table below, the total effective rate of the treatment group was better than that of the control group, and the comparison of the efficacy of TCM syndrome between the two groups was statistically significant (P <0.05). (Table 3)

Table 3: Comparison of efficacy of TCM

Group	Recure	Excellence	Valid	Of no avail	Effective percentage
Control group	0	8	20	2[a]	93.3%
Treatment group	0	17	9	1[a]	96.3%

Note: A represents the theoretical frequency less than 5, and Fisher test is adopted. After chi-square-Fisher test, P=0.033<0.05 for the comparison between the two groups.

3.4 Comparison of TCM Syndrome Points

After treatment, there was a significant difference in TCM syndrome scores between the two groups (P<0.05), indicating that both drugs were effecQtive in improving TCM syndrome in patients; there was a significant difference in TCM syndrome scores between the two groups (P<0.05), indicating that the treatment group was significantly better than the control group in improving TCM syndrome. (Table 4)

Table 4: Comparison of TCM syndrome points

Group	Pretherapy	Post-treatment
Control group	30.60±4.04	16.87±7.25
Treatment group	30.81±3.15	14.30±6.70

Note: After rank test, the comparison between the two groups showed that Z = -3.310 and P =0.01 <0.05.

3.5 Adverse Reactions

During the treatment and within 2 weeks after the treatment, no significant abnormalities and no significant adverse events were observed in either group.

4. Discussion

The theory of stroke originated in the Huangdi Neijing. Before the Tang and Song dynasties, Zhang Zhongjing established his theory based on the Neijing concept of "external wind affecting the middle, " which was later developed by Liu Wansu during the Jin and Yuan dynasties with his "internal wind" doctrine emphasizing fire-related pathogenesis. Li Dongyuan proposed a new theory focusing on qi deficiency and external wind invasion, while Zhu Danxi further categorized it into phlegm-dampness theories. Yu Tianmin followed Jingyue's theory of "non-wind (internal injury and accumulated damage)" treatment, advocating both tonification and depletion [9]. Wang Qingren innovatively distinguished previous diagnostic methods, proposing the theory of "Yuanqi convergence" based on non-wind principles, treating stroke through qi deficiency and blood stasis, and creating his own formula Buxiang Huanwu Decoction [10]. Overall, while the external wind theory declined from the Tang-Song period to modern times, some physicians recognized that internal and external winds mutually influence each other during disease progression, with internal wind often triggered by external wind [11], making them inseparable. Li Ke further proposed that internal and external winds should not be strictly divided [12]. Master Zhou Zhongying argued that external wind as a stroke trigger could induce internal wind through exterior-to-interior transmission, thus the external wind theory and its triggering mechanism should not be neglected [13]. A survey [14] showed that in stroke patients, wind syndrome constituted the most prominent symptom during acute phases. Research by Xin Xiyang [15] et al. demonstrated strong correlations between traditional Chinese medicine formulas used in acute cerebral infarction and wind syndrome elements. The *Emergency Cases of Internal Medicine* [16] notes that although internal wind theory holds significant clinical value, many practitioners still frequently use Xuling Decoction throughout history, suggesting the external wind theory remains valid. In general, the above all reflect the importance of external wind in the acute phase of stroke differentiation. The theory of external wind still has certain clinical guiding significance, and individual etiology and pathogenesis should still be paid attention to in clinical practice, so as not to lose the opportunity of treatment.

This research project is based on the philosophy of Professor Lin Hai, focusing on clinical observation of patients with qi deficiency and blood stasis syndrome combined with wind syndrome during the acute phase of ischemic stroke. Modern medical research reveals that qi deficiency and blood stasis syndrome is one of the most important early symptoms in ischemic stroke [17]. The mentor's years of clinical experience indicate that internal deficiency is a consensus in stroke patients, with seasonal wind-induced conditions being particularly common during winter and spring. Qi serves as the commander of blood circulation; when qi is deficient, blood flow weakens. Over time, accumulated stasis hinders new blood production. As blood is the mother of qi, dual deficiency of qi and blood leads to insufficient nourishment of meridians. This type of patient experiences prolonged internal deficiency and external pathogenic factors triggering sudden stroke. From an integrated Chinese-Western medical

perspective, constitutional differences, chronic conditions like hypertension and hyperlipidemia, and unhealthy lifestyle habits contribute to internal deficiency formation. Combined with cerebral infarction mechanisms, multiple causes of blood flow obstruction lead to stagnant circulation. Prolonged local blood stasis gradually forms plaques, further narrowing vascular lumens and impairing blood flow. These two adverse effects mutually reinforce each other, accumulating into gradual deterioration. External pathogens easily exploit this weakened state to directly invade meridians and organs. Therefore, in clinical treatment, breaking through internal-external wind barriers is crucial. For acute ischemic stroke patients with qi deficiency and blood stasis syndrome exhibiting limb paralysis, facial paralysis, or wind-related symptoms like chills, fever, or floating pulse, Bu Yang Tong Luo Tang (Yang-Nourishing Collateral-Opening Decoction) is prescribed. The formula emphasizes expelling pathogens without harming the body, resolving stasis without injuring vital energy, and achieving mutual support between blood stasis removal and pathogen elimination. This approach has proven highly effective in clinical practice. This study employs Bu Yang Tong Luo Decoction, which builds upon the classic formulas Bu Yang Huan Wu Tang and Xu Ming Tang by modifying wind-dispelling herbs like Ephedra. The formula demonstrates qi-tonifying, blood-activating, and meridian-connecting properties. With Astragalus as the principal herb, it emphasizes warming and potent qi-tonifying effects to enhance blood circulation. Angelica is used as a secondary agent to unblock meridians without harming blood flow, achieving synergistic effects to resolve stasis and restore circulation. Supporting herbs include red peony root, peach kernel, safflower, and Chuanxiong (Sichuan Lovage) to enhance blood-activating and stasis-resolving functions. Wind-dispelling herbs like Saposhnikovia, Ephedra, and Cinnamon Twig regulate defensive and nutritive qi. Qianghuo (Chinese Angelica) and Kudzu root eliminate wind and unblock meridians through their warming-cooling properties. Earthworm, with its penetrating action, guides all herbs to the meridians as a supportive agent. Combined, these herbs eliminate wind, strengthen qi, resolve stasis, and restore meridian connectivity. Modern pharmacological studies [18] demonstrate that the combined use of wind-dispelling herbs and blood-activating/stasis-resolving herbs synergistically enhances stroke treatment. Their combined effects reduce blood-brain barrier permeability, effectively alleviate cerebral edema, prevent brain tissue damage, and achieve superior neuroprotective outcomes.

5. Summary

With the continuous development of integrated Chinese-Western medicine therapies, their advantages over traditional Chinese or Western treatments have become increasingly evident. The study results indicate that the treatment group achieved higher overall efficacy rates than the control group, suggesting that Bu Yang Tong Luo Decoction combined with conventional Western medical treatments can enhance clinical outcomes for ischemic stroke cases presenting qi deficiency, blood stasis, and wind syndrome. Both groups showed improved TCM syndrome scores post-treatment compared to pre-treatment levels, with the treatment group demonstrating more significant improvements. Post-treatment NIHSS and mRS scores decreased while BI scores increased in both groups, with the treatment group outperforming the control group across all metrics. This demonstrates that Bu Yang Tong Luo Decoction effectively alleviates symptoms, promotes self-care ability and neurological recovery, improves quality of life, and avoids adverse reactions, making it a clinically valuable approach worthy of widespread adoption.

Fund Project

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