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# Effect of Integrated Traditional Chinese and Western Medicine Based on Syndrome Differentiation on Neurological Outcome and Safety in Patients with Acute Ischemic Stroke Due to Large Vessel Occlusion after Endovascular Treatment: A Prospective Randomized Controlled Trial

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## Abstract

**Background and Purpose:** Despite successful endovascular treatment (EVT) in acute ischemic stroke due to large vessel occlusion (AIS-LVO), the rate of futile recanalization remains high. This study aimed to evaluate the effect of integrated traditional Chinese and Western medicine (ITCWM) based on syndrome differentiation on neurological recovery and safety in AIS-LVO patients after EVT. **Methods:** This was a prospective, single-center, randomized controlled trial. A total of 200 AIS-LVO patients with successful recanalization (modified Thrombolysis in Cerebral Infarction [mTICI] ≥ 2b) were enrolled and randomly assigned 1:1 to either the treatment group or the control group (n = 100 per group). Both groups received standard post-EVT management, including antiplatelet therapy, statins, blood pressure and glucose control, and early rehabilitation. The treatment group additionally received individualized Chinese herbal decoctions or proprietary Chinese medicines according to seven TCM syndrome differentiations starting 24 - 72 h post-EVT. The primary outcomes were the National Institutes of Health Stroke Scale (NIHSS) score at 14 days post-treatment and the shift in NIHSS score (ΔNIHSS = baseline - 14-day score). The secondary outcome was good functional outcome (modified Rankin Scale [mRS] ≤ 2) at 90 days. Safety outcomes included symptomatic intracranial hemorrhage (sICH), mortality, and adverse drug reactions. **Re-**

**sults:** Baseline characteristics, including age, sex, baseline NIHSS, and ASPECTS, were comparable between groups (all $P > 0.05$). At 14 days, both groups showed significant reductions in NIHSS scores compared with baseline (both $P < 0.001$). The mean 14-day NIHSS score was 8.95 ± 5.72 in the treatment group versus 9.19 ± 6.54 in the control group ($P = 0.780$). The ΔNIHSS was 10.49 ± 6.39 in the treatment group and 9.33 ± 6.87 in the control group ($P = 0.218$). At 90 days, the proportion of patients achieving mRS ≤ 2 was 47.0% in the treatment group and 43.0% in the control group ($P > 0.05$). No significant differences were observed in the incidence of sICH (4.0% vs. 10.0%, $P > 0.05$), mortality (5.0% vs. 6.0%, $P > 0.05$), or hepatic/renal dysfunction (6.0% vs. 3.0%, $P > 0.05$). **Conclusions:** Adjunctive TCM treatment based on syndrome differentiation did not increase safety risks but failed to demonstrate statistically significant superiority over standard Western medicine alone in improving NIHSS scores or 90-day functional outcomes. A trend toward greater neurological improvement was observed in the ITCWM group, warranting further investigation in larger, multicenter trials.

## Keywords

Acute Ischemic Stroke, Large Vessel Occlusion, Endovascular Treatment, Integrative Medicine, Syndrome Differentiation, Randomized Controlled Trial

## 1. Introduction

Acute ischemic stroke (AIS) accounts for 60% - 80% of all stroke cases and is characterized by high morbidity and mortality [1]. Among these, AIS due to large vessel occlusion (AIS-LVO) is particularly devastating, posing a direct threat to life and long-term quality of life. Since 2015, multiple landmark randomized controlled trials have established mechanical thrombectomy as the first-line therapy for AIS-LVO [2] [3]. However, despite successful reperfusion (mTICI 2b/3), a substantial proportion of patients experience poor functional outcomes. Real-world data from the RESCUE-RE registry indicate that the rate of futile recanalization after EVT in AIS-LVO patients reaches up to 49% [4], with studies suggesting this rate may be higher in Asian populations compared with Western cohorts [5]. Advanced age, high baseline NIHSS scores, hypertension, diabetes mellitus, and poor collateral circulation are well-established predictors of unfavorable prognosis [6]-[8].

In Traditional Chinese Medicine (TCM), AIS-LVO corresponds to "Zhongfeng" (apoplectic stroke). The core pathogenesis involves derangement of Qi and blood, with intermingled phlegm, fire (heat), and stasis obstructing the cerebral collaterals. These pathological products not only result from Qi dysfunction but also exacerbate cerebral ischemia-reperfusion injury and microcirculatory disturbance [9]. Therefore, early intervention with therapies that clear heat, resolve stasis, eliminate phlegm, and detoxify following arterial recanalization may interrupt the cascade of "ischemia-inflammation-neuronal damage", thereby exerting dual effects

of promoting reflow and neuroprotection [10].

Although the Chinese Expert Consensus on Emergency Diagnosis and Treatment of Acute Ischemic Stroke with Integrated Traditional Chinese and Western Medicine incorporates TCM syndrome differentiation, high-quality evidence regarding TCM interventions after EVT for AIS-LVO remains scarce. This prospective randomized controlled trial was designed to evaluate the impact of ITCWM based on syndrome differentiation on neurological prognosis and safety, aiming to provide an evidence base for integrative stroke management.

## 2. Materials and Methods

### 2.1. Study Design

This was a prospective, single-center, randomized controlled trial conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all patients or their legal surrogates. The trial was designed in reference to the Chinese Expert Consensus on Emergency Diagnosis and Treatment of Acute Ischemic Stroke [11].

### 2.2. Participants

We enrolled consecutive patients admitted to our center between January 2024 and December 2025 who underwent successful EVT for AIS-LVO.

Inclusion criteria: 1) Age 40 - 94 years; 2) DSA-confirmed large vessel occlusion with successful recanalization (mTICI ≥ 2b) by mechanical thrombectomy; 3) Pre-treatment NIHSS score ≥ 4; 4) Pre-stroke mRS score ≤ 2.

Exclusion criteria: 1) Non-vascular causes of symptoms (e.g., brain tumor, subdural hematoma); 2) Pregnancy or lactation; 3) Severe congenital disability; 4) Multiple drug allergies or contraindications to TCM herbs.

Discontinuation criteria: 1) Withdrawal of consent or loss to follow-up; 2) Duration of TCM intervention < 2 weeks.

### 2.3. Randomization and Intervention

Eligible patients were randomly allocated 1:1 to the treatment group or control group using a computer-generated random number table. All patients received standardized post-EVT care, including antiplatelet agents, statin therapy for lipid modulation, strict control of blood pressure and glucose, and early rehabilitation.

In the treatment group, individualized TCM therapy was initiated 24 - 72 hours post-EVT based on syndrome differentiation according to the Chinese Expert Consensus [11], categorized into seven syndromes:

1) Phlegm-Misting the Orifices: Treated with Ditan Decoction to dry dampness, resolve phlegm, and resuscitate the spirit; 2) Phlegm-Heat Obstructing the Orifices: Treated with Lingjiao Gouteng Decoction combined with Wendan Decoction to clear heat, resolve phlegm, and open the orifices; 3) Yuan-Qi Collapse with Cold Extremities: Treated with Shenfu Decoction to supplement Qi, restore Yang,

and stabilize collapse; 4) Wind-Fire Harassing Upward: Treated with Tianma Gouteng Decoction to pacify the liver, suppress Yang, clear heat, and extinguish wind; 5) Wind-Phlegm Obstructing the Collaterals: Treated with Huatan Tongluo Formula to extinguish wind, resolve phlegm, and unblock collaterals; 6) Phlegm-Heat with Fu-Organ Excess: Treated with Xinglou Chengqi Decoction to resolve phlegm and unblock the bowels; 7) Yin Deficiency with Wind Stirring: Treated with Zhengan Xifeng Decoction to nourish Yin and extinguish wind.

Decoctions were administered orally or via nasogastric tube, supplemented with appropriate proprietary Chinese medicines according to syndrome type.

### 2.4. Outcome Measures

1) Baseline data: Age, sex, comorbidities (hypertension, diabetes, cardiac disease), pre-treatment ASPECTS, and site of arterial occlusion. 2) Efficacy outcomes: NIHSS score before treatment and at 14 days post-treatment; ΔNIHSS (baseline minus 14-day score); mRS score at 90 days; good functional outcome defined as mRS ≤ 2. 3) Safety outcomes: Symptomatic intracranial hemorrhage (sICH), all-cause mortality, and drug-related adverse events (hepatic/renal dysfunction, gastrointestinal reactions).

### 2.5. Statistical Analysis

Statistical analyses were performed using SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were tested for normality using the Shapiro-Wilk test. Normally distributed data were expressed as mean ± standard deviation (SD) and compared using independent samples t-test; paired t-tests were used for within-group comparisons. Non-normally distributed continuous data were presented as median (interquartile range) and compared using the Mann-Whitney U test. Categorical variables were expressed as frequencies (percentages) and compared using the chi-square test or Fisher's exact test where appropriate. Ordinal data (e.g., mRS scores) were analyzed using the Mann-Whitney U test. Binary logistic regression was applied to calculate adjusted odds ratios (ORs) with 95% confidence intervals (CIs) for subgroup analyses. A two-tailed $P < 0.05$ was considered statistically significant.

## 3. Results

### 3.1. Baseline Characteristics

A total of 200 eligible patients were randomized equally to the treatment (n = 100) and control (n = 100) groups. Baseline demographics, vascular risk factors, occlusion sites, pre-treatment ASPECTS, and NIHSS scores were well balanced between groups (all $P > 0.05$), indicating good comparability (Table 1).

### 3.2. Neurological Outcomes

At baseline, no significant difference in NIHSS scores was observed between groups ($t = 0.685$, $P = 0.494$). At 14 days post-treatment, both groups demon-

strated significant improvements in NIHSS scores compared with baseline (treatment group: t = 16.187, P < 0.001; control group: t = 13.437, P < 0.001). The mean 14-day NIHSS score was 8.95 ± 5.72 in the treatment group and 9.19 ± 6.54 in the control group, with no statistically significant difference (t = −0.279, P = 0.780). The ΔNIHSS was 10.49 ± 6.39 in the treatment group versus 9.33 ± 6.87 in the control group (t = 1.237, P = 0.218) (Table 2).

Table 1. Baseline characteristics of the study population.

| Variable | Treatment (n = 100) | Control (n = 100) | Statistic | P value |
|---|---|---|---|---|
| Sex (M/F) | 60/40 | 54/46 | $\chi^2 = 0.510$ | 0.475 |
| Age (years, mean ± SD) | 70 ± 15 | 68 ± 14 | t = 0.998 | 0.320 |
| Hypertension, n (%) | 51 (51%) | 50 (50%) | $\chi^2 < 0.001$ | 1.000 |
| Diabetes mellitus, n (%) | 48 (48%) | 58 (57%) | $\chi^2 = 1.626$ | 0.202 |
| Cardiac disease, n (%) | 49 (49%) | 57 (56%) | $\chi^2 = 0.984$ | 0.321 |
| Occlusion site, n (%) | | | | |
| ICA | 22 (22%) | 22 (22%) | — | — |
| MCA-M1 | 42 (42%) | 54 (54%) | — | — |
| MCA-M2 | 19 (19%) | 12 (12%) | — | — |
| ACA | 7 (7%) | 5 (5%) | — | — |
| Basilar artery | 10 (10%) | 7 (7%) | — | — |
| Pre-treatment ASPECTS (mean ± SD) | 6.2 ± 2.2 | 6.4 ± 2.1 | t = −0.658 | 0.511 |
| Pre-treatment NIHSS (mean ± SD) | 19.55 ± 8.19 | 18.73 ± 8.73 | t = 0.685 | 0.494 |
| Pre-stroke mRS = 0, n (%) | 94 (94%) | 93 (93%) | $\chi^2 < 0.001$ | 1.000 |

Table 2. Comparison of NIHSS scores before and after treatment (mean ± SD).

| Group | n | Baseline NIHSS | 14-day NIHSS | ΔNIHSS | Within-group (t/P) |
|---|---|---|---|---|---|
| Treatment | 100 | 19.55 ± 8.19 | 8.95 ± 5.72 | 10.49 ± 6.39 | t = 16.187/P < 0.001 |
| Control | 100 | 18.73 ± 8.73 | 9.19 ± 6.54 | 9.33 ± 6.87 | t = 13.437/P < 0.001 |
| **Between-group (t/P)** | — | t = 0.685/P = 0.494 | t = −0.279/P = 0.780 | t = 1.237/P = 0.218 | |

### 3.3. Functional Outcome at 90 Days

At the 90-day follow-up, 47.0% (47/100) of patients in the treatment group achieved a good outcome (mRS ≤ 2), compared with 43.0% (43/100) in the control group (P > 0.05). Mortality rates were 5.0% (5/100) in the treatment group and 6.0% (6/100) in the control group (Table 3).

### 3.4. TCM Syndrome Distribution and Prognosis

The most prevalent syndromes were Wind-Phlegm Obstructing Collaterals (treatment: 35%; control: 38%) and Phlegm-Heat with Fu-Organ Excess (treatment:

19%; control: 23%). No significant differences in 90-day good outcome rates were detected across any syndrome subtypes between groups (all P > 0.05). Adjusted ORs with 95% CIs all crossed 1.0, indicating no independent association between specific TCM syndromes and functional prognosis in this cohort (Table 4).

Table 3. Distribution of 90-day mRS scores.

| mRS Score | Treatment (n = 100)/Control (n = 100) |
|---|---|
| 0 (No symptoms) | 19 (19%)/9 (9%) |
| 1 (No significant disability) | 15 (15%)/14 (14%) |
| 2 (Slight disability) | 13 (13%)/20 (20%) |
| 3 (Moderate disability) | 8 (8%)/25 (25%) |
| 4 (Moderately severe disability) | 23 (23%)/13 (13%) |
| 5 (Severe disability) | 17 (17%)/13 (13%) |
| 6 (Death) | 5 (5%)/6 (6%) |
| mRS ≤ 2 (total) | 47 (47%)/43 (43%) |

Table 4. TCM syndrome distribution and 90-day good outcome (mRS ≤ 2).

| TCM Syndrome | Tx (n/%) | Tx Good (n/%) | Ctrl (n/%) | Ctrl Good (n/%) | P value | Adjusted OR (95% CI) |
|---|---|---|---|---|---|---|
| Yuan-Qi Collapse | 8 (8%) | 4 (50.0%) | 7 (7%) | 2 (28.6%) | 0.608 | 2.500 (0.292 - 21.399) |
| Phlegm-Heat Obstructing Orifices | 7 (7%) | 2 (28.6%) | 9 (9%) | 2 (22.2%) | 1.000 | 1.400 (0.144 - 13.569) |
| Phlegm-Heat with Fu-Organ Excess | 19 (19%) | 13 (68.4%) | 23 (23%) | 10 (43.5%) | 0.130 | 2.817 (0.790 - 10.040) |
| Phlegm-Misting Orifices | 3 (3%) | 2 (66.7%) | 0 (0%) | 0 (0%) | 1.000 | — |
| Yin Deficiency with Wind Stirring | 13 (13%) | 5 (38.5%) | 8 (8%) | 2 (25.0%) | 0.656 | 1.875 (0.266 - 13.203) |
| Wind-Fire Harassing Upward | 15 (15%) | 7 (46.7%) | 15 (15%) | 9 (60.0%) | 0.715 | 0.583 (0.137 - 2.481) |
| Wind-Phlegm Obstructing Collaterals | 35 (35%) | 14 (40.0%) | 38 (38%) | 18 (47.4%) | 0.638 | 0.741 (0.293 - 1.875) |

### 3.5. Safety Evaluation

Safety profiles were comparable between groups. The incidence of sICH was 4.0% in the treatment group versus 10.0% in the control group (P > 0.05). Drug-related mild diarrhea occurred in 4.0% of the treatment group and resolved spontaneously without treatment discontinuation. Hepatic or renal dysfunction was observed in 6.0% of the treatment group and 3.0% of the control group (P > 0.05). No cases of anaphylactic shock were reported (Table 5).

## 4. Discussion

This prospective RCT evaluated the efficacy and safety of ITCWM based on syndrome differentiation in AIS-LVO patients after successful EVT. Our findings indicate that adjunctive TCM therapy did not yield statistically significant improvements in 14-day NIHSS scores or 90-day functional independence compared with standard Western medical care alone. However, the treatment group

**Table 5.** Safety outcomes.

| Adverse Event | Treatment (n = 100) | Control (n = 100) |
|---|---|---|
| Symptomatic intracranial hemorrhage (sICH) | 4 (4%) | 10 (10%) |
| Death (90 days) | 5 (5%) | 6 (6%) |
| Mild diarrhea (drug-related) | 4 (4%) | 0 (0%) |
| Hepatic/renal dysfunction | 6 (6%) | 3 (3%) |
| Anaphylactic shock | 0 (0%) | 0 (0%) |

exhibited a numerical trend toward greater neurological improvement (ΔNIHSS 10.49 vs. 9.33), and no increase in adverse events was observed.

### 4.1. Theoretical Basis of ITCWM in Stroke Reperfusion

The pathophysiology of AIS-LVO extends beyond arterial occlusion to include complex ischemia-reperfusion injury cascades. While EVT restores macrovascular flow, microcirculatory disturbances, oxidative stress, and neuroinflammation often persist. In TCM theory, post-stroke pathology centers on the interplay of phlegm, stasis, wind, and fire, which obstruct the meridians and exacerbate cerebral damage. As stated in the Huangdi Neijing (Plain Questions), "Blood and Qi prefer warmth and dislike cold," supporting therapeutic strategies such as warming Yang, resolving phlegm, and unblocking the bowels. The predominance of Wind-Phlegm and Phlegm-Heat syndromes in our cohort aligns with the classical understanding of phlegm-stasis intermingling as the core mechanism of AIS-LVO. Syndrome-specific interventions—targeting phlegm resolution, bowel unblocking, and wind extinction—reflect the principle of "treating the branch in acute stages, treating the root in convalescence."

### 4.2. Interpretation of Neutral Efficacy Findings

The lack of statistically significant benefit in our primary endpoints is consistent with several prior integrative stroke trials [12] [13]. Several factors may explain these findings. First, the sample size (n = 100 per arm) may have been underpowered to detect modest but clinically meaningful differences. Second, the NIHSS primarily captures motor deficits and may inadequately reflect TCM's holistic effects on cognition, dysphagia, urinary function, and overall quality of life [14]. Third, TCM pharmacodynamics are often cumulative; a 14-day window may be insufficient to capture full therapeutic effects. Although the 90-day mRS is a robust endpoint, it is susceptible to confounding by rehabilitation intensity, caregiver support, and post-discharge complications. Notably, the numerical superiority in ΔNIHSS in the treatment group echoes trends reported in previous studies [15], suggesting that larger trials may yet confirm a true clinical benefit.

### 4.3. TCM Syndromes and Prognostic Implications

Exploratory analyses revealed no significant association between specific TCM

syndromes and 90-day outcomes. This null finding likely reflects limited statistical power, particularly for rare syndromes such as Phlegm-Misting Orifices (only 3 cases). Future studies with larger samples should employ multivariate logistic regression to adjust for confounders and explore syndrome subtypes as potential prognostic biomarkers. Standardized, objective scales or artificial intelligence-assisted diagnostic tools may further reduce inter-rater variability in TCM pattern differentiation.

### 4.4. Safety Profile

The comparable safety profile between groups reinforces the clinical feasibility of integrating TCM into post-EVT care. Of note, the lower-than-expected sICH rate in the treatment group (4.0% vs. 10.0% in controls), while not statistically significant, warrants attention in future meta-analyses. Mild diarrhea in the treatment group was self-limiting, and no severe organ toxicity or anaphylaxis was observed, corroborating previous systematic reviews demonstrating the favorable safety of TCM in acute stroke [16].

### 4.5. Limitations

Several limitations must be acknowledged. First, the sample size limits statistical power. Second, as a single-center study, selection bias and center-specific practice patterns may affect generalizability; multicenter validation is required. Third, the 90-day follow-up period may miss longer-term benefits; extended follow-up (e.g., 180 days, 1 year) is recommended. Fourth, TCM syndrome differentiation inherently carries subjectivity; future protocols should incorporate standardized assessment tools and assess inter-rater reliability. Finally, we did not collect data on inflammatory biomarkers or imaging markers of reperfusion injury, which could elucidate potential mechanisms of TCM action.

## 5. Conclusions

In patients with AIS-LVO undergoing successful EVT, adjunctive TCM therapy based on syndrome differentiation appears safe but did not significantly improve 14-day NIHSS scores or 90-day functional outcomes compared with standard care alone. A trend toward greater neurological improvement in the integrative treatment group suggests that larger, multicenter RCTs with longer follow-up are warranted to definitively assess the clinical value of ITCWM in this high-risk population.

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## Author Contributions

Conceptualization, Gang Yang; methodology, Gang Yang; software, Xiangrui Gong; validation, Gang Yang, Tianya Wu, and Long Ai; formal analysis, Xiangrui Gong and Tianya Wu; investigation, Tianya Wu and Xiangrui Gong; resources,

Feng Ding; data curation, Xiangrui Gong; writing—original draft preparation, Xiangrui Gong and Feng Ding; writing—review and editing, Xiangrui Gong and Feng Ding; visualization, Feng Ding; supervision, Gang Yang; project administration Gang Yang; funding acquisition, Gang Yang. All authors have read and agreed to the published version of the manuscript.

## Declaration of AI Assistance

AI tools (ChatGPT, Yuanbao AI) were used for language editing, translation, and literature organization during manuscript preparation. AI was not involved in research design, data analysis, or conclusion drawing. Authors reviewed all content and accept full responsibility.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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