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# The Study on the Effect of Huoxue Tongmai Capsules Combined with Edaravone Right Camphor on Serum Inflammatory Factors and Its Clinical Efficacy in Patients with Acute Cerebral Infarction

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## Abstract

**Objective:** To explore the therapeutic effect of Huoxue Tongmai capsule combined with edaravone right camphor on patients with acute cerebral infarction (Acute Cerebral Infarction) and the effect of combination therapy on serum inflammatory factors. **Methods:** In this study, 90 patients with acute cerebral infarction hospitalized in Zhuji People's Hospital from December 2023 to December 2024 were selected and divided into two groups of 45 patients in each group. The control group used standard medical treatment, and the treatment group compared the changes of serum inflammatory factors IL-CRP, TNF-$\alpha$, and Hcy with Huoxue Tongmai capsule for 7 days, 14 days and 30 days, and discussed the changes of the modified Rankin scale score (mRS) and National Institutes of Health Stroke Scale (NIHSS) score. **Results:** At 7 days, 14 days, and 30 days of treatment, the NIHSS score, mRS score, hs-CRP, IL-6, TNF-$\alpha$, and Hcy levels were statistically significant ($P < 0.05$), and the NIHSS score, mRS score, hs-CRP, IL-6, TNF-$\alpha$, and Hcy levels in the treatment group were significantly lower than those in the control group ($P < 0.05$). **Conclusion:** Patients with acute cerebral infarction received Huoxue Tongmai capsule combined with edaravone right camphor, which can reduce the inflammatory reaction, improve the nerve function and improve the prognosis.

## Keywords

Acute Cerebral Infarction, Huoxue Tongmai Capsule, Edaravone Right Camphor, Inflammatory Factors, Nerve Function

## 1. Introduction

Acute cerebral infarction (Acute Cerebral Infarction, ACI) refers to a kind of disease [1] [2] with local arterial blood perfusion reduced or completely interrupted, stop blood supply and oxygen supply, causing necrosis and softening of brain tissue. Acute cerebral infarction has been the first incidence of the neurological diseases, and the early mortality rate in the acute phase is about 7% - 10% [3]. In recent years, integrated Chinese and Western medicine treatment has made significant progress in the treatment of acute cerebral infarction. According to the theory of traditional Chinese medicine, ACI belongs to the category of "stroke-arthralgia", which is usually caused by blood stasis and depression, and clinical manifestations such as hemiplegia and crooked mouth and eye deviation. The treatment principle is "blood circulation and collateral circulation" [4] [5]. Huoxue Tongmai capsule is a kind of Chinese medicine preparation that mainly contains Leech raw powder. Its main component, leech, plays its role in the treatment of cerebrovascular diseases by various mechanisms, such as scavenging free radicals, inhibiting vascular endothelial damage, reducing platelet activation, anti-apoptosis and anti-inflammatory [6] [7]. Edaravone right camphor concentrated solution for injection is a class I new drug approved by the State Food and Drug Administration in July 2020, and it is currently widely used in the treatment of ACI [8]-[10]. The purpose of this study is to combine Huoxue Tongmai capsule and Edaravone right camphor to treat acute cerebral infarction, investigate its effect on neurological function improvement and its effect on serum inflammatory factors, and provide evidence-based basis for improving clinical prognosis of acute cerebral infarction by establishing a database.

## 2. Methodology

### 2.1. Research Objects

In this study, 90 patients with acute ischemic stroke (Acute ischemic stroke) admitted to Zhuji Municipal People's Hospital from December 2023 and December 2024 were randomly divided into two groups with 45 patients in each group. In the control group, 26 were male and 19 were female, aged 69.16 ± 11.58 years, 40 were hypertension and 16 were diabetes; in the treatment group, 27 men and 18 were aged 68.60 ± 10.40 years, including 38 had hypertension and 18 diabetes. Comparing the general data between the two groups, the difference was not statistically significant ($P > 0.05$), which was comparable (see **Table 1**). This study was approved by the hospital ethics committee.

### 2.2. Inclusion and Exclusion Standards

Inclusion standards: AIS patients with typical symptoms and signs within 48 hours of onset (including those who had been treated 24 hours after intravenous thrombolysis) met the requirements of China Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke 2018, and excluded bleeding conversion by head CT review after cerebral infarction progression; the patient had signed an

informed consent.

Exclusion standards: Patients diagnosed with cardiogenic cerebral embolism; patients with large cerebral infarction in anterior circulation, patients with lesions greater than 2/3 of the cerebral hemisphere; patients with NIHSS score 21; patients with intracranial hemorrhage; patients with iatrogenic stroke; patients with 180/110 mmHg after treatment; patients with allergy to Huoxue Tongmai capsule or edaravone right camphor; patients not considered suitable by the investigator to participate in this clinical study (e.g., mental or conscious abnormalities).

### 2.3. Treatment Methods

The control group received standard medical treatment, including routine antiplatelet, blood pressure control, blood glucose control, statin stabilization and plaque stabilization, and the treatment group received standard medical therapy + Huoxue Tongmai capsule + edaravone right camphor. Edaravone right alcohol followed the treatment instructions of Edaravone alcohol, with the recommended dose: 15 mL (including 30 mg of edaravone, 7.5 mg of right alcohol), intravenous infusion, twice daily; oral use: Huoxue Tongmai capsule 0.25 g (hirudin), oral, 3 tablets at a time, three times a day, treatment in all three groups for 7 - 14 days, and standard medical treatment for secondary prevention on day 8 - 30. We asked patients to record the time, doses and times of their medication daily. The investigators regularly check these records for patient medication adherence.

### 2.4. Index Observation Test

The levels of hypersensitive C-reactive protein (hs-CRP), interleukin 6 (IL-6), tumor necrosis factor-$\alpha$ (TNF-$\alpha$) and homocysteine (Hcy) were determined by enzyme-linked immunosorbent assay before 7, 14, and 30 days after treatment. Using the National Institutes of Health Stroke Scale (NIHSS), a higher NIHSS score indicates a more severe neurological deficit. The modified Rankin scale score (mRS) was used to evaluate the prognosis of patients. The mRS score was between 0 and 5. The higher the score, the worse the disability and the worse the prognosis.

### 2.5. Statistical Process

The software was performed using version SPSS 26.0. All measurement data were tested for normality, normal data are expressed by (± s), analyzed by independent t-test and paired t-test within groups; non-normal data are represented by M (IQR), Mann-Whitney test and Wilcoxon test between groups; counting data are compared by chi-square test. Differences were considered statistically significant when $P < 0.05$.

## 3. Results

### 3.1. Basic Information of Patients between the Two Groups

The age of both groups met the normal distribution (Shapiro-Wilk treatment = 0.970, P treatment = 0.291 > 0.05, Shapiro-Wilk control = 0.983, P control =

0.747 > 0.05), thus independent t-test, t = 0.239, P = 0.811 > 0.05; P > 0.05 in the two groups.

**Table 1.** Basic information of patients between the two groups.

| Group | n | Age (Mean ± SD) | Sex | | Hypertension | | Diabetes | |
|---|---|---|---|---|---|---|---|---|
| | | | Male | Female | No | Yes | No | Yes |
| Treatment Group | 45 | 68.60 ± 10.40 | 27 | 18 | 7 | 38 | 27 | 18 |
| Control Group | 45 | 69.16 ± 11.58 | 26 | 19 | 5 | 40 | 29 | 16 |
| t/2 | | 0.239 | 0.046 | | 0.385 | | 0.189 | |
| P | | 0.811 | 0.830 | | 0.535 | | 0.664 | |

### 3.2. Comparison of the NIHSS Scores between the Two Patient Groups

The Shapiro-Wilk statistics before treatment, 7 days, 14 days, and 30 days were 0.935, 0.871, 0.893, 0.813, respectively, all the Shapiro-Wilk P values were less than 0.05; The Shapiro-Wilk statistics of the control patients with NIHSS score before treatment, 7, 14, and 30 days were 0.975, 0.958, 0.960, 0.937, respectively, The Shapiro-Wilk P values were 0.441, 0.104, 0.128, and 0.016, respectively; Therefore, the comparison of NIHSS scores between the two groups was performed by Mann-Whiteny test, Z = −0.146, −2.292, −2.386, −2.568, respectively, P = 0.884, 0.022, 0.017, 0.010, suggested that there was no significant difference in NIHSS scores between the two groups (P > 0.05), The NIHSS scores for 7, 14, and 30 days of treatment were significantly lower than those in the control group (P < 0.05).

NIHSS scores at 7, 14 and 30 days and the Wilcoxon test before treatment (P < 0.05).

**Table 2.** Comparison of the NIHSS scores between the two patient groups.

| Group | n | Pre-treatment | Day 7 Treatment | Day 14 Treatment | Day 30 Treatment |
|---|---|---|---|---|---|
| Treatment Group | 45 | 14 (10, 19) | 7 (4, 13)* | 5 (2, 10)* | 3 (0, 8)* |
| Control Group | 45 | 14 (10, 19.5) | 11 (6.5, 16.5)* | 9 (4, 14.5)* | 6 (2, 12)* |
| Z | | −0.146 | −2.292 | −2.386 | −2.568 |
| P | | 0.884 | 0.022 | 0.017 | 0.010 |

Note: *P < 0.05.

### 3.3. Comparison of the mRS Scores between the Two Patient Groups

The Shapiro-Wilk statistics before treatment, 7, 14, and 30 days of treatment were 0.747, 0.872, 0.832, 0.795, respectively, all the Shapiro-Wilk P values were less than 0.05; The Shapiro-Wilk statistics of mRS score before, 7, 14, and 30 days, were 0.706, 0.902, 0.872, 0.846, respectively, All the Shapiro-Wilk P values were less than 0.05; Therefore, the mRS scores between the two groups was compared by

the Mann-Whiteny test, Z = −0.912, −2.996, −2.173, −2.591, respectively, P = 0.362, 0.003, 0.030, 0.010, suggested that the two groups (P > 0.05), The mRS score of 7, 14, and 30 days of treatment was significantly lower than that of the control group (P < 0.05).

The 7, 14 and 30 days of treatment were compared with the previous treatment (P < 0.05).

**Table 3.** Comparison of the mRS scores between the two patient groups.

| Group | n | Pre-treatment | Day 7 Treatment | Day 14 Treatment | Day 30 Treatment |
|---|---|---|---|---|---|
| Treatment Group | 45 | 4 (4, 4) | 1 (1, 2)* | 1 (0, 2)* | 1 (0, 1.5)* |
| Control Group | 45 | 4 (4, 4.5) | 3 (1, 3.5)* | 1 (1, 3)* | 1 (1, 2)* |
| Z | | −0.912 | −2.996 | −2.173 | −2.591 |
| P | | 0.362 | 0.003 | 0.030 | 0.010 |

Note: *P < 0.05.

### 3.4. Comparison of hs-CRP, IL−6, TNF-*α*, and Hcy Levels in the Two Groups

The Shapiro-Wilk statistics of hs-CRP before, 7, 14, and 30 days were 0.712, 0.672, 0.593, 0.588, respectively, all the Shapiro-Wilk P values were less than 0.05; The Shapiro-Wilk statistic before hs-CRP before, 7, 14, and 30 days were 0.575, 0.599, 0.628, and 0.758, respectively, All the Shapiro-Wilk P values were less than 0.05; Therefore, the hs-CRP contrast between the two groups used the Mann-Whiteny test, Z = −0.706, −3.063, −2.446, −3.145, respectively, P = 0.480, 0.002, 0.014, 0.002, Show that there was no significant difference in hs-CRP contrast between the two groups (P > 0.05), The hs-CRP of treatment days was significantly lower than that in the control group (P < 0.05).

The Shapiro-Wilk statistics of IL−6 before treatment, 7 days, 14 days and 30 days were 0.919, 0.908, 0.941, 0.874, respectively, All the Shapiro-Wilk P values were less than 0.05; The Shapiro-Wilk statistics of control patients with IL−6 treatment before, 7, 14, and 30 days were 0.874, 0.872, 0.847, and 0.819, respectively, All the Shapiro-Wilk P values were less than 0.05; Therefore, the IL−6 contrast between the two groups was performed by the Mann-Whiteny test, Z = −0.420, −3.067, −2.191, −2.397, respectively, P = 0.675, 0.002, 0.028, 0.017, Show that there was no significant difference in IL−6 contrast between the two groups (P > 0.05), IL−6 for 7, 14, and 30 days was significantly lower than that in the control group (P < 0.05).

Before, 7, 14, and 30 days of TNF-*α* (Shapiro-Wilk treatment = 0.970, 0.970, 0.980, 0.981, P treatment = 0.287, 0.284, 0.616, and 0.663; Shapiro-Wilk control = 0.972, 0.965, 0.963, 0.986, P control = 0.332, 0.185, 0.164, 0.867), Therefore, the TNF-*α* contrast between the two groups was performed by an independent t-test, And t = −0.578, 2.303, 3.256, and 2.419, respectively, P = 0.565, 0.024, 0.002, 0.018,

TNF-$\alpha$ difference between the two groups (P > 0.05), TNF-$\alpha$ for 7, 14, and 30 days of treatment was significantly lower than that in the control group (P < 0.05).

Before, 7, 14, and 30 days of Hcy treatment (Shapiro-Wilk treatment = 0.986, 0.979, 0.982, 0.979, P treatment = 0.846, 0.599, 0.709, and 0.566; Shapiro-Wilk control = 0.974, 0.971, 0.975, 0.967, P control = 0.401, 0.325, 0.440, 0.229), Therefore, the two groups were tested by independent t-test, And t = −0.353, 2.557, 2.951, and 3.265, respectively, P = 0.725, 0.012, 0.004, 0.002, Show that there was no significant difference in Hcy contrast between the two groups (P > 0.05), Hcy for 7, 14, and 30 days of treatment was significantly lower than that in the control group (P < 0.05).

CRP, IL−6 at 7, 14, and 30 days with pre-treatment (P <0.05), TNF-$\alpha$, Hcy with paired t-test (P < 0.05).

**Table 4.** Comparison of the ADL scores between the two patient groups.

| Inflammatory Factor | Group | N | Pre-treatment | Day 7 Treatment | Day 14 Treatment |
|---|---|---|---|---|---|
| hs-CRP | Treatment Group | 45 | 9.3 (7.75, 12.31) | 2.3 (1.40, 5.45)* | 1.8 (0.8, 3.2)* |
| | Control Group | 45 | 9.3 (7.05, 11.91) | 5.5 (3.2, 8.54)* | 2.82 (1.35, 6.64)* |
| Z | | | −0.706 | −3.063 | −2.446 |
| P | | | 0.480 | 0.002 | 0.014 |
| IL−6 | Treatment Group | 45 | 15.85 (13.85, 17.35) | 8.51 (6.53, 9.75)* | 4.21 (2.26, 5.89)* |
| | Control Group | 45 | 15.3 (12.65, 19.16) | 10 (7.75, 14.16)* | 5.6 (3.3, 8.56)* |
| Z | | | −0.420 | −3.067 | −2.191 |
| P | | | 0.675 | 0.002 | 0.028 |
| TNF-$\alpha$ | Treatment Group | 45 | 26.45 ± 5.21 | 18.31 ± 4.8* | 13.7 ± 3.92* |
| | Control Group | 45 | 25.69 ± 7.08 | 21.18 ± 6.84* | 17.33 ± 6.37* |
| t | | | −0.578 | 2.303 | 3.256 |
| P | | | 0.565 | 0.024 | 0.002 |
| Hcy | Treatment Group | 45 | 24.56 ± 3.8 | 17.39 ± 2.73* | 13.23 ± 2.72* |
| | Control Group | 45 | 24.32 ± 2.45 | 19.13 ± 3.64* | 15.07 ± 3.18* |
| t | | | −0.353 | 2.557 | 2.951 |
| P | | | 0.725 | 0.012 | 0.004 |

Note: Compared to before treatment, *P < 0.05.

## 4. Discussions

According to traditional Chinese medicine, the occurrence of acute cerebral infarction is often closely related to factors such as insufficient vital qi, irritability, phlegm and turbidity [11]. Huoxue Tongmai capsule has the dual effects of clearing heat and benefiting dampness, promoting blood circulation and dredging collaterals. The treatment of thrombo-occlusive vascular disease combined with western medicine alprostadil can significantly improve the clinical symptoms

[12]. As a novel drug, edaravone right camphor, the main component of edaravone, can effectively scavenge free radicals and thus reduce the damage of brain tissue [13]. At the same time, right alcohol components further improve the efficacy by regulating the excessive secretion of inflammatory mediators and reducing cell apoptosis, but the effect of their separate application is relatively limited [14] [15]. This study aims to investigate the clinical efficacy of Huoxue Tongmai capsule and edaravone right camphor.

Inflammatory response is closely related to the occurrence and development of acute ischemic stroke (AIS). As an important inflammatory factor, the level of IL-6 significantly increased after stroke, thus exacerbating the progression of the inflammatory response [16]. Hyperhomocysteine (Hcy) can induce the production of a large number of oxygen free radicals, triggering an inflammatory response, leading to the damage and apoptosis of vascular endothelial cells. Elevated Hcy levels have been demonstrated as an independent risk factor for stroke [17]. Modern pharmacological studies show that the leech components in Huoxue Tongmai capsule have strong movement force, which can promote blood circulation, anti-inflammatory, anti-liver fibrosis, anti-apoptosis, lipid reduction and other multiple effects [18]. As early as recorded in Shennong Medica Classic, leeches said that "the Lord went for the evil blood, the blood stasis, the closed, the broken blood accumulation, no children, benefit the waterway" [19]. Clinical studies have found that leech preparations can not only reduce the level of inflammatory factors, but also improve neurological function. The combination of leeches with *Gastrodia elata* drink can significantly reduce the NIHSS score in stroke patients and effectively improve the prognosis [20]. In addition, C-reactive protein (CRP) As a common inflammatory factor, C-reactive protein (CRP) can exacerbate the damage of brain cells. Studies have shown that leech capsules combined with benphthalein solution can significantly reduce CRP levels in stroke patients [21]. Edaravone right camphor consists of two components, edaravone and dexol, which is effective in preventing the release of secondary inflammatory factors after stroke [22]. In a model of photochemically induced cerebral ischemia, right alcohol inhibited inducible nitric oxide synthase (iNOS) and tumor necrosis factor- $\alpha$ (TNF-$\alpha$) production in a dose-dependent manner. The results of this study showed that the treatment and control groups showed significant differences at 7, 140 and 30 days ($P < 0.05$), and the levels of inflammatory factors gradually decreased after treatment. This result is consistent with the conclusion of previous studies, which further validates the effective reduction of the level of inflammatory factors in patients with acute cerebral infarction. Specifically, the combination of edaravone right camphor and Huoxue Tongmai capsule can exert a synergistic effect, significantly improve the treatment effect and improve the prognosis of patients.

This study showed that the NIHSS score and mRS score were significantly lower in the treatment group than those in the control group (see **Table 2** & **Table 3**), and the level of inflammatory factors decreased significantly after the combined intervention (see **Table 4**). These results indicate that the combination therapy

can not only significantly improve the neurological function and improve the quality of prognosis, but also effectively inhibit the release of inflammatory factors. Since its launch in 2020, edaravone right camphor has become the preferred brain protective drug for clinical treatment of AIS. As a hydroxyl free radical scavenger, its mechanism of action mainly includes: 1) Promoting the synthesis of prostacyclin by reducing xanthine oxidase and the activity of hypoxanthine oxidase, and then reducing the level of inflammatory factors; 2) Removing toxic free radicals and reducing the oxidation of fat, so as to reduce the damage to nerve cells and blood vessels [23] [24]. Right alcohol can effectively inhibit the release of inflammatory factors and prevent the response between oxygen free radicals and inflammatory cytokines, thus providing better protection for brain cells in [25] [26]. In addition, the leech component in the vein capsule contains heparin, peptide, antithromboxane, amino acid, analgesic enzymes, anti-inflammatory enzymes and effective ingredients, can by removing free radicals, reduce platelet activation, inhibit vascular endothelial injury, anti-inflammatory, anti-apoptosis multiple mechanism, synergistic promote nerve function recovery, reduce the level of inflammatory factors [27] [28]. The combination of edaravone right camphor and Huoxue Tongmai capsule can exert a neuroprotective effect through a dual mechanism. On the one hand, edaravone right camphor reduces brain damage by removing free radicals and inhibiting oxidative stress and inflammation; on the other hand, leeches and *Gastrodia elata* improve cerebral blood circulation, blood circulation and nutrition supply, thus promoting the recovery of nerve function. The study of Li Ming *et al*. showed that combination therapy can significantly improve the clinical efficacy of patients with acute ischemic stroke [29].

In conclusion, the combination of traditional Chinese medicine Huoxue Tongmai capsule and edaravone right camphor to treat patients with acute ischemic stroke (AIS) can significantly improve the clinical efficacy. This combined treatment regimen can not only effectively reduce the level of inflammatory cytokines and improve the neurological function in patients with AIS, but also significantly improve the prognosis quality of patients.

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## Conflicts of Interest

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

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