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Clinical Observation of Xiaochaihu Decoction Combined with Xiaoxianxiong Decoction in the Treatment of Post-stroke Pneumonia

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Abstract: *Objective*: To investigate the clinical efficacy of Xiaochaihu Decoction combined with Xiaoxianxiong Decoction in the treatment of post-stroke pneumonia. *Methods*: To complete the sample grouping comparison, all patients with post-stroke pneumonia were investigated, and the number of cases was 60. These patients' diseases were consistent with the dialectical standards of traditional Chinese medicine (phlegm-heat obstructing lungs). The patients were randomly divided into a control group (30 cases, treated with antibiotics and symptomatic methods) and a treatment group (30 cases, treated with Xiaochaihu Decoction and Xiaoxianxiong Decoction on the basis of the control group). Various indicators were compared. *Results*: The total clinical effective rates were 93% and 80% in the treatment group and the control group, respectively, with statistical significance ($P < 0.05$). The improvement of various clinical symptoms was compared, and the values in the treatment group were reduced, showing significance ($P < 0.05$). Analysis of serum factor indicators showed that the overall trend of the treatment group was reduced, and the comparison between groups was below 0.05. *Conclusion*: Xiaochaihu Decoction combined with Xiaoxianxiong Decoction has a significant clinical effect in the treatment of post-stroke pneumonia (phlegm-heat obstructing lungs syndrome), which can reduce inflammatory reactions and has few adverse reactions, worthy of clinical application.

Keywords: Post-stroke pneumonia; Xiaochaihu Decoction combined with Xiaoxianxiong Decoction; Traditional Chinese medicine therapy; Cough

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1. Introduction

Stroke disease poses significant risks to the body, characterized by high probabilities of disability, morbidity, and mortality [1]. For example, lung inflammation, fully known as stroke-associated pneumonia (SAP for short), can lead to death if not treated promptly [2]. Relevant studies suggest that SAP patients are in critical condition, which can significantly increase the short-term and long-term mortality rates of stroke patients, with the

mortality rate increasing threefold within one month [3]. Domestic research indicates a 35.97% incidence of SAP. This disease can prolong hospital stays and require higher treatment costs. Therefore, while ensuring the control of the patient's condition, intervention measures need to be optimized and adjusted according to the specific situation of the patient. Most Western medicine treatments involve the use of anti-inflammatory and anti-infective drugs to target the patient's condition specifically. However, the long-term effects are not satisfactory, and they can lead to drug resistance in pathogenic bacteria and various complications.

Traditional Chinese medicine has conducted in-depth and meticulous research and analysis on SAP, and relatively satisfactory results can be achieved through integrated traditional Chinese and Western medicine treatment [4, 5]. The combination of Xiaochaihu Decoction and Xiaoxianxiong Decoction can achieve the effects of controlling inflammation, suppressing viruses, and adjusting the body's immune function. To demonstrate the effectiveness of the combined treatment with Xiaochaihu Decoction and Xiaoxianxiong Decoction, the following content investigates stroke-associated pneumonia patients and conducts a deep exploration.

2. Basic information and methodology

2.1. Basic information

From January 2023 to May 2024, Si Yang Kangda Hospital conducted a study on patients visiting different departments. A total of 60 patients were selected for the study, coming from the departments of neurology, intensive care unit (ICU), and respiratory medicine. These patients were diagnosed with post-stroke pneumonia according to Western medicine standards, and their TCM syndrome differentiation was phlegm-heat obstructing the lungs. A randomized controlled study was conducted using a random number table based on patient medical record numbers. The patients were divided into a treatment group and a control group, with 30 patients in each group. In the treatment group, the male-to-female ratio was 17:13. The age range was 40-84 years, with a mean age of (68.68 ± 8.35) years. The types of underlying diseases included 23 cases of ischemic stroke and 7 cases of hemorrhagic stroke. In the control group, the male-to-female ratio was 16:14. The age range was 39–86 years, with a mean age of (69.11 ± 8.97) years. The types of underlying diseases included 22 cases of ischemic stroke and 8 cases of hemorrhagic stroke. All patients in both groups voluntarily participated in the study, and there were no significant differences in their basic characteristics ($P > 0.05$). This study has been ethically reviewed and approved by the hospital's medical ethics committee (Ethics Approval Number: 20221202). Both patients and their families signed informed consent forms for this study.

2.2. Inclusion criteria

2.2.1. Reference standards for Western medicine diagnosis of SAP

The diagnosis of Western medicine refers to the "Chinese Expert Consensus on the Diagnosis and Treatment of Stroke-Associated Pneumonia (2019 Updated Edition)" [1]:

(1) Combined with fever symptoms, with a body temperature not lower than 38℃.

(2) Imaging examination reveals the presence of lesions in the lungs, which show infiltrative growth.

(3) Investigation of patient symptoms reveals frequent coughing, expectoration, chest pain, and severe respiratory conditions.

(4) Diagnostic examination reveals substantial lesions in the lungs, and auscultation reveals wet rales.

(5) White blood cell count level in routine blood tests is below 4×10^9/L or above 10×10^9/L.

Criteria (1) is a necessary condition for the diagnosis of SAP, and meeting any two of the remaining criteria is sufficient for a diagnosis of SAP. However, in the diagnostic process, it is necessary to differentiate it from other types of lung diseases, such as pulmonary edema, tuberculosis, and non-infectious interstitial lung diseases.

2.2.2. Reference standard for syndrome differentiation of traditional Chinese medicine

The diagnosis of traditional Chinese medicine refers to the "Guiding Principles for Clinical Research of New Chinese Medicines" [6]. The patient's TCM symptoms include "sticky phlegm, excessive phlegm, fever, chest tightness and chest pain", constipation, abdominal discomfort.

2.3. Exclusion criteria

(1) Patient has lung infection.
(2) Patient's disease diagnosis does not match the "Chinese Expert Consensus on the Diagnosis and Treatment of Stroke-Associated Pneumonia (2019 Updated Edition)".
(3) Allergic symptoms appear during treatment.
(4) Abnormal cognitive understanding ability, unable to communicate normally.
(5) Abnormal function of major organs in the body.
(6) Accompanied by comprehensive diseases of the blood and endocrine systems.
(7) Gastrointestinal bleeding.

2.4. Therapeutic methods

All patients completed baseline treatment with antibiotics and symptomatic medications, with specific antibiotics selected according to drug susceptibility tests (sputum culture and blood culture) [7]. In addition to the control group's regimen, the treatment group received modified Xiaochaihu Decoction (Minor Bupleurum Decoction) combined with Xiaoxianxiong Decoction (using Tianjiang Pharmaceutical's standardized granules): *Bupleurum* root (Chaihu) 18g; *Scutellaria* root (Huangqin), *Pinellia* rhizome (Banxia), Ginseng (Renshen), prepared licorice root (Zhigancao), fresh ginger (Shengjiang), and jujube (Dazao) 6g each; *Coptis* root (Huanglian) 3g, and *Trichosanthes* seed (Gualouzi) 10g [8].

Modifications included: for high fever, gypsum (Shigao) granules 30–90g; for constipation, rhubarb (Dahuang) granules 9g; for cerebral infarction, earthworm (Dilong) granules 10g and angelica root (Danggui) granules 6g; for cerebral hemorrhage, leech (Shuizhi) granules (processed by scalding) 3g. The decoction was administered orally or via nasogastric tube twice daily for 1–2 weeks.

2.5. Observation indicators

(1) Record the time of fever resolution, disappearance of lung rales on auscultation, and length of hospital stay.
(2) Observe traditional Chinese medicine symptoms such as cough, expectoration, sputum volume, and wheezing.
(3) Monitor changes in blood routine (white blood cells, neutrophils), hypersensitive C-reactive protein, and procalcitonin levels.

2.6. Evaluation criteria for therapeutic effect

The evaluation criteria are based on whether the patient's symptoms have improved and whether laboratory test results are within the normal range. The evaluation is divided into three categories: cured, improved, and ineffective. Finally, investigate the total effective rate, calculated based on both cured and improved cases.

2.7. Statistical methods

Statistical software used was SPSS version 23.0. Data were counted using two modes: mean and percentage. The corresponding test methods used were *t*-test and chi-square test to verify whether the *p*-value was below 0.05.

3. Results

3.1. Evaluation of therapeutic effectiveness between groups

The total clinical effective rates were compared between the treatment group and the control group. The survey values were 93% and 80%, respectively, which was statistically significant ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of clinical therapeutic effectiveness between two groups of SAP patients (%)

Group	Cases (n)	Recovered n(%)	Effective n(%)	Ineffective n(%)	Total efficacy (%)
Treatment	30	28	28	2	93*
Control	30	24	24	6	80

Note: *$P < 0.05$ compared with the control group

3.2. Disappearance time of various symptoms

The improvement of various clinical symptoms was compared, and the numerical values were reduced in the treatment group, which was statistically significant ($P < 0.05$), as shown in **Table 2**.

Table 2. Comparison of disappearance time of main symptoms and signs between two groups of SAP patients ($\bar{x} \pm s$, n=30)

Group	Cough duration (days)	Sputum duration (days)	Fever resolution (days)	Rales resolution (days)
Treatment	2.12 ± 0.55*	2.23 ± 0.63*	3.75 ± 1.12*	3.37 ± 0.89*
Control	4.81 ± 0.77	4.18 ± 0.82	4.33 ± 1.78	5.16 ± 1.18

Note: *$P < 0.05$ compared with the control group

3.3. Comparative analysis of inflammatory markers (WBC, N%, CRP, PCT) before and after treatment

The comparison between the two groups before and after treatment regarding White Blood Cells (WBC), Neutrophil Percentage (N%), C-Reactive Protein (CRP), and Procalcitonin (PCT) in serum showed no significant difference before treatment, but significant differences were observed after treatment, with a P-value within 0.05. Specifically, all indicators in the treatment group decreased, and the comparison between groups yielded a *P*-value below 0.05, as shown in **Table 3**.

Table 3. WBC, N%, CRP, PCT (before and after treatment) ($\bar{x} \pm s$, n=30)

Group	Time Point	WBC (×10⁹/L)	Neutrophils (%)	CRP (mg/L)	PCT (ng/mL)
Treatment	Pre-Tx	14.66 ± 2.77	84.38 ± 4.37	68.22 ± 10.06	0.21 ± 0.59
	Post-Tx	5.92 ± 3.12*#	62.87 ± 4.22*#	7.18 ± 2.49*#	0.06 ± 0.02*#
Control	Pre-Tx	14.43 ± 2.58	85.67 ± 4.29	67.18 ± 9.78	0.22 ± 0.62
	Post-Tx	7.78 ± 4.22#	71.19 ± 4.56#	16.61 ± 3.53#	0.10 ± 0.03#

Note: *$P < 0.05$ compared with before treatment, #$P < 0.05$ compared with the control group after treatment

4. Discussion

SAP is a common complication after stroke, influenced by factors such as infection, malnutrition, multiple organ dysfunction, multidrug resistance, sepsis, gastrointestinal bleeding, and other complications. SAP increases economic burden and mortality rate, especially for patients with large-area cerebral infarction or cerebral hemorrhage who have undergone tracheotomy, where the incidence of multidrug-resistant bacteria is increased. Western medicine often uses antibiotics and other comprehensive interventions to treat this disease, along with symptomatic treatment, but the treatment effect is poor. Currently, there is no direct description of SAP in ancient Chinese medical books, but it can be diagnosed and treated as diseases such as fever, cough, and asthmatic syndrome. In the pathogenesis of SAP, phlegm, deficiency, heat, and blood stasis are the main influencing factors [9]. In SPA patients with internal deficiency and evil invasion, phlegm and heat evil invade the lungs, leading to typical symptoms such as cough and fever. As the disease progresses, clinical symptoms such as hematemesis and constipation may appear, significantly increasing the difficulty of treatment. In the treatment of SAP with Chinese medicine, based on the patient's pathogenesis, comprehensive use of heat-clearing, blood stasis-removing, meridian-dredging, and strengthening the body and eliminating evil intervention programs can achieve relatively good treatment results [9].

This study shows that the total clinical effective rate, comparing between the treatment group and the control group, was 93% and 80% respectively, with statistical significance ($P < 0.05$). Comparing the improvement of various clinical symptoms, the values decreased in the treatment group, showing significance ($P < 0.05$). Analysis of serum factor indicators revealed that the overall trend in the treatment group decreased, and the comparison between groups was below 0.05. Xiao Chai Hu Tang has a significant effect in eliminating inflammation and resisting viruses, effectively regulating immune function in the body. After treatment intervention, it can control patients' body temperature in a short time and stabilize their condition [10]. Chai Hu is a Chinese herbal medicine with anti-inflammatory effects. After administration, it can improve the permeability of capillaries, effectively reduce local inflammatory reactions, regulate the comprehensive permeability of capillaries, and strengthen the interference effect on inflammatory reaction mechanisms. The anti-inflammatory components of Huang Qin are baicalin and its experience in treating acute and critical illnesses such as lung infection and acute exacerbation of chronic obstructive pulmonary disease, as well as baicalein. These components significantly control the release of proinflammatory cells. As the level of anti-inflammatory cytokines increases, various adverse inflammatory reactions in patients improve. Ginseng enhances nonspecific immunity, while licorice root has a significant anti-inflammatory effect. Ginger, like licorice root, can exert an anti-inflammatory effect and promote gradual fever reduction in the body, effectively relieving fever symptoms [11].

Xiaoxianxiong Tang is a classic formula derived from the "Treatise on Febrile Diseases". It consists of

three herbs: Gualou, Banxia, and Huanglian. It is suitable for the treatment of typhoid and diseases related to external evil heat invasion. It can alleviate the treatment of diseases related to phlegm-heat stagnation in the heart, and its efficacy is stable and lasting, with high treatment safety [12, 13]. Through pharmacological analysis, it can be found that the main function of Xiaoxianxiong Tang is antibacterial and anti-inflammatory. It can kill pathogenic bacteria infected in patients, reduce local inflammatory reactions, and thereby alleviate the clinical symptoms of respiratory diseases. Clinically, it is often used in the comprehensive treatment of pleurisy, acute bronchitis, and other diseases.

Leech is specifically used to treat blood stagnation, dispel blood stasis, dissipate masses, and unblock meridians. Its nature tends to penetrate deeply, effectively reducing masses and dispelling blood stasis, easily breaking blood without damaging new blood, and attacking phlegm, blood stasis, turbidity, and toxin in the brain. Modern pharmacological studies have shown that this product has anticoagulation, antithrombotic, thrombosis prevention, thrombus dissolution, promotion of cerebral edema absorption, improvement of microcirculation, and protection of brain tissue. Earthworm has the functions of clearing heat, calming wind, and promoting meridian activity. The medicinal properties are wandering, and it is good at activating meridians. Earthworm can activate meridians and collaterals, and also has the effect of dispelling phlegm, treating both phlegm and blood stasis [14].

5. Conclusion

In summary, the clinical efficacy of Xiaochaihu Tang combined with modified Xiaoxianxiong Tang in the treatment of SAP (syndrome of phlegm and heat obstructing the lungs) is significant, which can reduce inflammatory reactions with few adverse reactions. Its application value is suitable for further clinical research in the future. For drug treatment methods, doctors need to actively investigate various situations of patients, complete comprehensive management based on the comprehensive condition, inform patients of issues that need attention during treatment, including diet, exercise, and other content, and guide patients to self-monitor their condition and conduct regular check-ups. However, the sample size of this study is small, especially for stroke-associated pneumonia patients with syndrome of phlegm and heat obstructing the lungs. In the future, it is necessary to further optimize and adjust various experimental procedures, increase research time, and add medical records from multiple centers for comprehensive comparative analysis and research. The specific mechanism of Xiaochaihu Tang combined with modified Xiaoxianxiong Tang in the treatment of SAP (syndrome of phlegm and heat obstructing the lungs) still requires further analysis and research.

Disclosure statement

The authors declare no conflict of interest.

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