

CLINICAL RESEARCH

Clinical Efficacy of Modified Erchen Decoction on Cervical Spondylotic Vertebral Arteriopathy with Stagnation and Blockade of Phlegm-dampness Syndrome and Effects on Cerebral Blood Flow Parameters

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ABSTRACT

OBJECTIVE: To observe the effect of Modified Erchen Decoction on cervical spondylotic vertebral arteriopathy with stagnation and blockade of phlegm-dampness syndrome and effects on cerebral blood flow parameters. **METHODS:** A total of 80 cervical spondylotic vertebral arteriopathy (CSA) patients with stagnation and blockade of phlegm-dampness syndrome admitted to our hospital from October 2016 to April 2017 were selected and randomly divided into observation group and control group, with 40 cases in each group. The observation group was treated with Modified Erchen Decoction and the control group was given conventional treatment with Western medicine. After 4 weeks of treatment, the main clinical symptoms and signs (vertigo, neck and shoulder pain, headache, psychological and social adjustment, daily life and work) and cerebral blood flow parameters [the peak values of intracranial vertebral-basal artery diastolic blood flow velocity (Vd) and systolic blood flow velocity (Vp)] were compared between the 2 groups. The total clinical effective rate and adverse reactions during treatment were also compared. **RESULTS:** After treatment, the total effective rate of the observation group was 90.0%, which was significantly higher than that of the control group (77.5%). The difference between the two groups was statistically significant ($P < 0.05$). After treatment, The scores of vertigo, neck and shoulder pain, headache, psychology and society adaptation, daily life and work were significantly increased ($P < 0.05$), and the above scores of the observation group were increased more obviously. The difference between the groups was statistically significant ($P < 0.05$). After treatment, the levels of Vd and Vp were significantly increased ($P < 0.05$), and the increase of the above indexes was more obvious in the observation group. The difference between the 2 groups was statistically significant ($P < 0.05$). There were no significant abnormalities in blood routine, urine routine, liver function and renal function. There was no significant difference in the incidence of adverse reactions between the 2 groups. ($P > 0.05$). **CONCLUSION:** The treatment of vertebral artery type cervical spondylopathy with stagnation and blockade of phlegm-dampness syndrome by Modified Erchen Decoction can effectively relieve the main clinical symptoms and signs, improve cerebral blood flow parameters, and improve the peak values of vertebral-basal artery diastolic blood flow velocity (Vd) and systolic blood flow velocity (Vp), which is safe and effective, and helps to promote the recovery of cervical function.

KEYWORDS: Vertebral artery type cervical spondylopathy; Stagnation and blockade of phlegm-dampness; Modified Erchen Decoction; Cerebral blood flow parameters

Cervical spondylotic vertebral arteriopathy (CSA) refers to insufficient blood supply of the vertebral artery, which is caused by a variety of factors such as degenerative changes of the cervical spine or imbalance of the internal and external vertebral column etc., resulting in insufficient blood supply to the vertebral-basal artery, and a series of clinical symptoms and signs^[1]. The disease is a common type of cervical spondylosis, and

the incidence rate accounts for 15% to 20% of cervical spondylosis. In recent years, people's work styles and lifestyles have changed a lot, and they have been sitting and working at desks for a longer period of time. The incidence rate of CSA is increasing year by year, and the age of onset is becoming younger^[2]. Vertigo is the main clinical manifestation of CSA during the attack period. The symptoms of vertigo are exacerbated in the lateral

flexion and extension of the neck. Some patients are also accompanied by other symptoms such as different degrees of headache, unclear vision, neck and shoulder pain, shoulder numbness, tinnitus. Symptoms such as nausea, tripping will happen in severe cases, which have serious adverse effects on the normal work and life of patients^[3].

At present, Western medicine treatment of CSA is mainly based on conservative treatment. The commonly methods mainly include drug treatment, physical therapy and manipulation therapy. Although it can temporarily relieve the clinical symptoms of patients, the long-term clinical efficacy is not effective, and the drug treatment has certain toxicity and side effects on the human body. CSA belongs to the category of "dizziness" in Traditional Chinese Medicine (TCM). The disease location is in the head and neck, and the pathological organs are closely related to the liver, spleen and kidney. TCM research believes that this disease belongs to the syndrome of deficiency in nature and excess in superficiality. Deficiency manifested in liver and kidney deficiency, qi and blood deficiency, leading to dizziness, and excess manifested in wind, fire, phlegm, obstruction in the meridians^[4]. In terms of treatment, TCM treatment of CSA is extremely varied, mainly including TCM decoction, massage, acupuncture, acupoint injection, catgut embedment in acupoint, manipulation, etc., and TCM treatment strictly follows the overall concept and the treatment concept of syndrome differentiation. The curative effect is exact, which is widely welcomed by the majority of patients.

In this study, the author selected 80 CSA patients with stagnation and blockade of phlegm-dampness syndrome as the study subjects, and 40 patients were treated with Modified Erchen Decoction to observe the clinical efficacy. The influence on main clinical symptoms and signs and the cerebral blood flow parameters were observed to provide a theoretical basis for TCM treatment of CSA. The report is as follows:

MATERIAL AND METHODS

General information

A total of 80 patients with CSA admitted to our hospital from October 2016 to April 2017 were selected as subjects. The diagnostic criteria for western medicine refers to the CSA regulation of the *Summary of 3rd National Symposium on Cervical Spondylosis*^[5]: cervical vertigo is the main manifestation of the patients,

and sometimes tripping occurs. Some patients may be accompanied by symptoms such as hearing impairment and blurred vision. The cervical spine test shows positive and vertebral artery color Doppler ultrasonography showed distortion of the second vertebral artery. X-ray examination showed segmental instability of the hook joint. According to the *Diagnostic and Efficacy Standards for TCM Syndrome*^[6], the prescription for vertigo is based on the clinical manifestations of patients with stagnation and blockade of phlegm-dampness syndrome: dizziness, head weight, numbness of the limbs, and anorexia; dark tongue, thick and greasy tongue coating, wiry and slippery pulse. The age ranged from 20 to 70 years old. No treatment for CSA patients was used for the last 2 weeks before they were adopted in the groups. The study was approved by the hospital ethics committee and the patient signed the informed consent. The study excluded patients with vertigo caused by traumatic brain injury, cerebral hemorrhage, brain tumor, inner ear disease, etc., and patients with primary diseases such as insufficient basilar artery caused by compression of the vertebral artery 1 segment and vertebral artery 3 segments, combined with severe cardiovascular and cerebrovascular, hepatorenal system, hematopoiesis, or patients with cervical tuberculosis, cervical spine fracture, cervical dislocation, mental diseases, or pregnant and lactating women.

According to the random number table method, patients were divided into observation group and control group, with 40 cases in each group. There were 26 males and 14 females in the observation group; the age ranged from 20 to 65 years old, with an average age of (43.8 ± 4.1) years old; the course of disease was 6 months to 9 years, and the average duration of disease was (4.1 ± 0.8) years. The control group consisted of 25 males and 15 females; the age ranged from 22 to 68 years old, with an average age of (44.1 ± 4.3) years old; the course of disease ranged from 7 months to 8 years, with an average duration of disease (4.2 ± 0.7) years. There was no significant difference in the general material between the two groups ($P > 0.05$).

Treatment methods

The Observation group

The Observation group was treated with Modified Erchen Decoction: *Rhizoma Alismatis* 30 g, *Radix Puerariae Lobatae* 15 g, *Fructus Mume* 15 g, *Poria* 15 g, *Rhizoma Atractylodis Macrocephalae* 15 g, *Rhizoma*

Atractylodis 15 g, *Rhizoma Pinelliae Concisum* 6 g, *Rhizoma Chuanxiong* 6 g, *Radix et Rhizoma Glycyrrhizae* 6 g, *Radix Angelicae Dahuricae* 6 g, *Radix et Rhizoma Glycyrrhizae* 6 g, *Rhizoma Zingiberis* 3 g. These TCM medicinal materials were boiled with water. Patients were required to take one dose respectively in the morning and evening for 4 weeks as a course of treatment, and for a total of 1 course.

The Control group

The control group was treated with oral betahistine mesylate tablets (Guangdong Shixin Pharmaceutical Co., Ltd., national medicine quasi-word H20100025, specification: 6 mg), 6 mg each time, 3 times a day; and with oral eperisone hydrochloride tablets (Hunan Yada Pharmaceutical Co., Ltd., national medicine quasi-word H20020170, specifications: 50 mg), 50 mg each time, 3 times a day. The above medication was continuously given for 4 weeks. The clinical efficacy of both groups were evaluated after 4 weeks of treatment.

Observation index

Main clinical symptoms and signs

We referred to the *Preliminary Study on the Evaluation of Symptoms and Function of Patients with Cervical Vertigo*^[7] to evaluate 5 main clinical symptoms and sign changes of vertigo, neck and shoulder pain, headache, psychological and social adjustment, daily life and work before and after treatment. Total vertigo score is 16 points. Total neck and shoulder pain score was 4 points. Total headache score was 2 points. Total psychological and social adjustment score was 4 points. Total daily life and work score was 4 points. The higher the score was, the lighter the symptom was. The lower the score was, the more severe the symptom was.

Cerebral blood parameters

Vertebral artery and basilar artery were detected and analyzed by transcranial Doppler (TCD) blood flow analyzer to check the changes of intracranial vertebral-basal artery diastolic blood flow velocity (Vd) and systolic blood flow velocity (Vp).

Adverse reactions

The occurrence of adverse reactions between the two groups of treatment was compared.

Curative effect evaluation

According to the curative standard formulated by the *Guidelines for Clinical Research of New Drugs in Traditional Chinese Medicine*^[8], the clinical efficacy can be categorized as (1) clinical cured: after treatment, the clinical symptoms and signs such as vertigo disappeared, the function of the neck returned to normal, and the improvement rate exceeded 90%; (2) improved: after treatment, the clinical symptoms and signs such as vertigo were significantly relieved, and the neck function was basically normal. The improvement rate was 70%-90%. (3) effective: After treatment, the clinical symptoms and signs such as vertigo were alleviated, and the improvement rate was 30%-70%; (4) invalid: After treatment, the patient's clinical symptoms and signs such as dizziness did not improve or even worsened, and the improvement rate was less than 30%. Improvement rate = [(pre-treatment score - post-treatment score) / pre-treatment score] × 100%. Clinical cured + improved + effective = total effective.

Statistical methods

Statistical analysis was performed using SPSS 22.0 statistical software. The measurement data was expressed by ($\bar{x} \pm S$), *t* test; the comparison of counting data was represented by *n* (%), χ^2 test; the rank data was analyzed by rank sum test. The difference was statistically significant ($P < 0.05$).

RESULTS

Comparison of clinical efficacy after treatment between the two groups

After treatment, the total effective rate of the observation group was 90.0%, which was significantly higher than that of the control group, and the difference was statistically significant ($P < 0.05$). See Table 1.

Comparison of main clinical symptoms and physical signs before and after treatment

The differences between the two groups before

Table 1. Comparison of clinical efficacy between the two groups after treatment cases (%)

Group categories	Number of cases	Cure	Improvement	Effective	Invalid	Total Effective rate
Observation group	40	18 (45.0)	12 (30.0)	6 (15.0)	4 (10.0)	36 (90.0) ^①
Control group	40	11 (27.5)	11 (27.5)	9 (22.5)	9 (22.5)	31 (77.5)

Note: ① Compared with the control group, $P < 0.05$.

Table 2. Comparison of main clinical symptoms and physical signs before and after treatment ($\bar{x} \pm S$, min)

Group categories	Treatment period	Dizziness	Neck and shoulder pain	Headache	Psychological and social adjustment	Daily life and work
Observation group (n=40)	Before treatment	7.22 \pm 0.62	1.75 \pm 0.22	0.57 \pm 0.09	1.95 \pm 0.54	1.82 \pm 0.31
	After treatment	14.02 \pm 0.98 ^{①②}	3.41 \pm 0.33 ^{①②}	1.65 \pm 0.22 ^{①②}	3.66 \pm 0.64 ^{①②}	3.41 \pm 0.27 ^{①②}
Control group (n=40)	Before treatment	7.25 \pm 0.65	1.74 \pm 0.25	0.56 \pm 0.11	1.92 \pm 0.53	1.80 \pm 0.32
	After treatment	11.05 \pm 0.83 ^①	2.28 \pm 0.32 ^①	1.35 \pm 0.20 ^①	2.65 \pm 0.58 ^①	2.59 \pm 0.25 ^①

Note: ① Compared with the same group before treatment, $P < 0.05$; ② compared with the control group, $P < 0.05$.

treatment including dizziness, neck and shoulder pain, headache, psychological and social adjustment, daily life and work scores, and the differences were not statistically significant ($P > 0.05$). After treatment, scores of vertigo, neck and shoulder pain, headache, psychological and social adjustment, daily life and work scores of the two groups were significantly increased ($P < 0.05$), and the above scores of the observation group were more obvious. The differences between the groups were statistically significant ($P < 0.05$). See Table 2.

Comparison of cerebral blood flow parameters before and after treatment

There was no significant difference in the levels of Vd and Vp between the two groups before treatment ($P > 0.05$). After treatment, the levels of Vd and Vp in the two groups were significantly increased ($P < 0.05$), and the above indexes were more obviously increased in the observation group. The difference between the groups was statistically significant ($P < 0.05$). See Table 3.

Table 3. Comparison of cerebral blood flow parameters before and after treatment ($\bar{x} \pm S$, min)

Group categories	Treatment time	Vd	Vp
Observation group (n=40)	Before treatment	15.55 \pm 2.23	43.49 \pm 5.19
	After treatment	26.41 \pm 2.80 ^{①②}	53.68 \pm 4.59 ^{①②}
Control group (n=40)	Before treatment	15.61 \pm 2.25	43.55 \pm 5.28
	After treatment	21.08 \pm 2.78 ^①	49.11 \pm 4.52 ^①

Note: ① Compared with the same group before treatment, $P < 0.05$; ② compared with the control group, $P < 0.05$.

Adverse Reaction

There were no significant abnormalities in blood routine, urine routine, liver function and renal function during the treatment of the two groups. There was no significant difference in the incidence of adverse reactions between the two groups ($P > 0.05$).

DISCUSSION

CSA, also known as "dizzy cervical spondylosis",

refers to the compression of the vertebral artery caused by a variety of factors, resulting in stenosis or distortion of the blood vessels, and further leading to insufficient blood supply to the vertebral artery, which in turn triggers ischemic syndrome with vertigo as the main clinical manifestation. The basic research of modern anatomy confirmed that the vertebral artery begins from the 1st segment of the subclavian artery, moves forward along the anterior scalene muscle to the anterior pleural ventricle, through the 6th to the 1st cervical vertebrae, and then enters the cranial cavity through the occipital foramen and finally distributes in the inner ear and cerebellum. The main cause of CSA occurrence is vertebral artery compression. The compression site is located in the C1-C2 segment of the vertebral artery. The transverse process of this region is distributed with transverse protrusion and uncinat bone, which directly compresses the vertebral artery. A wide range of sympathetic nerves are distributed on and around the vertebral arteries, causing the transverse process and the humeral epiphysis to compress the vertebral artery, which is easy to stimulate the sympathetic nerves, causing paralysis of the vertebral artery, which in turn causes a series of vertebral artery ischemia symptoms^[9,10].

In recent years, with the increase of people's work pressure, the popularity of mobile phones, computers and other electronic products, people work and bow their heads for a longer period of time, resulting in a gradual weakening of the neck muscles. And the cervical spine biomechanics is gradually unbalanced and the clinical incidence of CSA increases. At present, conservative treatment is the basic treatment of CSA in Western medicine. Most patients can be relieved clinically after vasodilator drugs combined with cervical traction. However, conservative treatment takes a long time, and some were invalid for patients with severe disease after long-term conservative treatment. After invalidation, they had to choose surgery, which seriously affected his normal work and life.

Although there is no CSA in Chinese medicine,

it is classified as "dizziness" according to the clinical manifestation of the patient. The term "dizziness" first appeared in Yan's *Jishengfang Dizziness Gate*. Chinese medicine research believes that the pathological changes of this disease are nothing more than deficiency and excess. The deficiency syndrome is mainly related to liver, kidney and blood deficiency. Excess is related to the internal obstruction of blood, wind, coldness, dampness and other external contraction. The disease is basically the relationship between head and neck, and liver, spleen and kidney. The specific manifestations are as follows. If it is in the liver, it is attributed to suffering from excessive internal heat and the unbalance between yin and yang. If it is in the spleen, it is attributed to qi and blood deficiency. If it is in the kidney, it is attributed to kidney and qi deficiency. The phlegm-dampness type is a common type of TCM syndrome. This type of patients are usually glutton and alcoholism, leading to spleen and stomach damage, the failure of the spleen to transport, foods and drinks indigestion, thus transforming dampness to phlegm, and lucid yang qi being interfered. Clinical treatment should be based on the principle of benefiting spleen and moving qi, expelling phlegm and dampness.

Erchen Decoction is from Tai Ping Hui Min and Agent Bureau Formulas. The whole formula is composed of *Rhizoma Pinelliae*, *Poria*, *Exocarpium Citri Rubrum*, *Radix Rhizoma Glycyrrhizae*, etc, which has the function of resolving phlegm and drying dampness, regulating the flow of qi and harmonizing the middle-energizer. The formula is used for coughing with profuse sputum, heavy body, dizziness, chest burping and a stuffy lump in the abdomen, nausea and vomiting etc. In this study, Modified Erchen Decoction is based on the original prescription and has some changes. In the formula, *Rhizoma Alismatis* is for urine excretion to remove edema, and straining off dampness and purging heat. *Radix Puerariae Lobatae* is for tonifying kidney and benefiting spleen, ascending yang to stop diarrhea. *Fructus Mume* is for astringing the intestines and arresting diarrhea and producing body fluids. *Poria* is for urine excretion to strain off dampness, benefiting spleen and harmonizing stomach. *Rhizoma Atractylodis Macrocephalae* is for urine excretion to resolve dampness, and fortifying spleen and boosting qi. *Rhizoma Atractylodis* is for fortifying spleen, resolving dampness, expelling wind and overcoming dampness. *Rhizoma Pinelliae* is for harmonizing stomach, stopping vomiting, resolving dampness and dissolving phlegm. *Rhizoma Ligustici Chuanxiong* is for expelling

wind to relieve pain, moving qi to remove qi stagnation. *Pericarpium Citri Reticulatae* is for removing dampness and phlegm with herbs dry in property, and regulating the flow of qi and harmonizing the middle-energizer. *Radix Angelicae Dahuricae* is for promoting tissue regeneration, stopping pain, expelling wind and overcoming dampness. *Rhizoma Zingiberis* is for restoring yang, dredging channels, warming the middle-energizer and dissipating coldness. *Radix et Rhizoma Glycyrrhizae* is for supplementing the middle-energizer, boosting qi, expelling phlegm and stopping cough.

Modern pharmacological studies have shown that the ingredients such as Alisol in *Rhizoma Alismatis* can significantly improve the function of the reticuloendothelial system and have a good function of immune regulation^[11]. In addition, *Rhizoma Alismatis* has a good function of lowering blood pressure and blood lipid, anti-atherosclerosis and anti-vertigo; *Radix Puerariae Lobatae* has the function of protecting vascular endothelial cells, preventing thrombosis, dilating cerebral blood vessels, increasing cerebral blood flow, improving microcirculation, regulating bone metabolism, etc.^[12]

Ursolic acid in *Fructus Mum* has the effect of lowering the level of triacylglycerol, regulating blood lipids and improving blood rheology^[13]; *Poria* has the function of significant anti-inflammatory, hypolipidemic and enhancing immune function; *Rhizoma Atractylodes* has significant antibacterial, anti-inflammatory, anti-hypoxia effect; *Rhizoma Pinelliae* can improve blood rheology by reducing blood viscosity, inhibiting red blood cell aggregation, and improving red blood cell deformability. In addition, *Rhizoma Pinellia* has significant anti-sputum effect. The longer the storage time is, the more obvious the effect is^[14]; Ligustrazine has significant analgesic effect on rats with neuropathic pain. In addition, ligustrazine has better function of anti-thrombosis and immune enhancement^[15]; *Radix Angelicae Dahuricae* has obvious analgesic and antispasmodic effects; *Pericarpium Citri Reticulatae* can play a role in carotid atherosclerosis by inhibiting the expression of matrix metalloproteinase-9 and cell adhesion molecule-1^[16].

The vertebral-basal artery is the main artery supplying the brain stem and cerebral. If the vertebral-basal artery is insufficiently supplied, it may cause a series of ischemic symptoms such as dizziness, nausea and vomiting. TCD detection is an objective indicator of clinical diagnosis of CSA, which can effectively reflect the blood flow velocity

of vertebral-basal artery. Vd and Vp are important indicators for TCD detection. Tian Ruowen's research^[17] showed that some X-rays of the neck were not detected abnormality. After TCD detection, the Vd value was lower than that of normal people, and the Vd blood flow velocity difference was more than 20 cm/s. Therefore, TCD can effectively reflect changes in intracranial hemodynamics. Clinically, patients with no abnormalities in cervical X-rays can observe the dynamic changes of TCD to understand the cerebrovascular circulation, which provides important objective basis for acclinical diagnosis and identification of CSA.^[18] In this study, the levels of Vd and Vp in the two groups were significantly increased ($P < 0.05$), and the levels of Vd and Vp in the observation group were significantly increased. The difference between the groups was statistically significant ($P < 0.05$), indicating that both Modified Erchen Decoction and Western medicine treatment can effectively improve the peak value of vertebral-basal artery diastolic blood flow velocity (Vd) and systolic blood flow velocity (Vp). The effect of Modified Erchen Decoction is more obvious. The vertigo, neck and shoulder pain, headache, psychological and social adjustment, daily life and work scores of the observation group were significantly higher than that of the control group ($P < 0.05$), and the total effective rate of the observation group was significantly higher than that of the control group, indicating that Modified Erchen Decoction can better improve the patient's main clinical symptoms and signs and improve clinical efficacy. In addition, there were no significant abnormalities in blood routine, urine routine, liver function and renal function during the two treatment periods, indicating that the clinical medications in both groups were safe and reliable. In summary, the use of Modified Erchen Decoction for the treatment of phlegm-dampness type CSA can quickly relieve the main clinical symptoms and signs of patients, improve cerebral blood flow parameters, and improve the peak values of vertebral-basal artery diastolic blood flow velocity (Vd) and systolic blood flow velocity (Vp). It is safe and effective and helpful to promote the recovery of cervical function.

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