TITLE OF MANUSCRIPT EFFECT OF LASER NEEDLE-KNIFE COMPOUND THERAPY ON VERTEBRAL ARTERY BLOOD FLOW IN C5-6 SEGMENT OF VERTEBRAL ARTERY TYPE CERVICAL SPONDYLOSIS

Fang Liu, Caifen Wang*, Xin Yang, Yang Ye, Chenghao Liu, Jin Yabei, Fangjun Wang, Wei Wei, Cunxin Wang

Hangzhou Redcross Hospital, No.208 East Huancheng Road, Hangzhou, China.

*Corresponding Author: wcf0342030@aliyun.com

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ABSTRACT

According to CSA diagnostic criteria, inclusion criteria and exclusion criteria, the qualified CSA subjects are determined as research objects, which were randomly divided into treatment group and control group; treatment group adopts the laser needle-knife combined with supine restoration massotherapy method, while the control group only adopts supine restoration therapy. In the treatment group, He-Ne laser radiation was performed for 30 minutes after the needle was released, 1 times every 10 days, 3 times for a course, 2 courses of treatment in total, which is combined with supine restoration massotherapy for 20 minutes, 3 times a week, 10 times for 1 course, 2 courses of treatment in total. In control group, supine restoration massotherapy was only adopted for 20 minutes of treatment, 3 times a week, 10 times for 1 course of treatment and 2 courses of treatment in total. Color Doppler ultrasound was used to respectively observe the patients from two groups before treatment and on the sixtieth day after treatment for the changes in vertebral artery diameter (D) of C5-6 segment of bilateral vertebral artery, systolic peak velocity (PSV), end diastolic velocity (EDV), resistance index (RI) and pulsatility index (PI), so as to analyze the effects of laser needle-knife combined with supine recumbent massage on vertebral artery morphology and hemodynamics in patients. Results: There was significant difference between the improvement of PSV before and after treatment in the vertebral artery C5-6 segment and the control group ($P < 0.05$), compared with the control group, the EDV improvement was statistically significant, PI was significantly improved before and after treatment, compared with the control group, it was statistically significant ($P < 0.05$). Conclusions: The vertebral artery diameter (D) hemodynamics index (PSV, EDV, RI, PI) in vertebral artery C5-6 segment of patients with CSA can be improved by laser needle-knife compound therapy to varying degrees. The clinical study registration number is No.2013临审第 (03) 号.

INTRODUCTION

Cervical spondylotic vertebral arteriopathy (CSA) refers to the vertebral artery blood flow disorders caused by cervical vertebral lesions, resulting in cerebral insufficiency, the clinical symptoms take vertigo as the main symptoms. The author in this paper used laser needle-knife compound therapy to treat vertebral artery cervical spondylosis, and adopted vertigo symptom and function evaluation scale to evaluate the patients' disease. Before and after treatment, the color Doppler ultrasonography was used to detect the change of cervical vertebral artery blood flow imaging so as to explore the effect and mechanism of the disease, and the report is as follows.

2. CLINICAL INFORMATION

2.1 Inclusion criteria

① Which is in line with the diagnostic basis of modern medical vertebral artery cervical spondylosis and vertebral artery mixed

cervical spondylosis. And it is revised based on the diagnostic criteria of TCM syndrome in TCM issued by State Administration of traditional Chinese Medicine: patients who have cataplexy history, and associated with cervical vertigo, neck rotation test is positive, and the top test is positive, too; X showed segmental instability or uncovertebral joint hyperplasia; ②Aged at 26-68 years; ③Clinical observation showed the patients did not accepted similar drugs or techniques and any physical therapist within 4 weeks before treatment; ④Clinical observation showed the patients who didn't have trauma to fracture within 4 weeks before the treatment.

2.2 Exclusion criteria

Where any of the following circumstances are not selected: ①Patients with severe primary diseases such as cardiovascular disease, cerebrovascular disease, liver, kidney, hematopoietic system and endocrine system and psychotic patients; ② Patients who are confirmed by examination to have the cervical vertebra joint tuberculosis, the brain inflammatory tumor, the spinal canal occupying lesion; ③Patients who

have trauma, inner ear diseases and eye diseases, etc.; ④ Patients who have history of drug allergy; ⑤ Pregnant or lactating women; ⑥ Patients who failed to complete the procedure according to the test plan.

2.3 General information

According to the diagnostic criteria, inclusion criteria and exclusion criteria, the qualified CSA patients are determined as research object, according to the randomized double-blind principles, patients are divided into the treatment group (laser needle-knife combined with supine massage therapy) and control group (supine massage monotherapy). The treatment group: 45 cases, 21 males and 24 females, with a maximum age of 68 years, a minimum of 23 years, with an average age of 40.8 years, with a maximum course disease up to 6 years and a minimum course disease of 10 days, with an average of 8.6 months. The control group: 45 cases, 21 males and 24 females, the oldest patients is 69 years old, the youngest one is 26 years old, with an average age of 41.1 years; and the maximum disease duration is up to 8 years, the minimum one is 12 days, with an average of 8.8 months. There was no statistically significant difference in sex, age, disease duration and severity between the two groups.

3. TREATMENT METHODS

The laser needle-knife combined with supine recitation method was adopted. Laser needle knife operation is as follows: (1) Posture: in the special cervical vertebra treatment table, the prone position is taken, the cervical vertebra to bend forward, and the treatment point is selected along the spinous process and the vertebra side, the following three principles should be followed: 1. The lesion site is shown according to imaging; 2. Spasm, the starting and ending of muscle strain; 3. Tenderness point (2) Skin disinfection: conventional iodophor is used for skin disinfection with sterile-hole towel. (3) Local anesthesia with 1% lidocaine. (4) Laser needle-knife was used for fixed point cutting, stripping, release, no nodules or block is felt, and needle He-Ne laser radiation is used (Shanghai Jiading Photoelectric Instrument Co., Ltd., JH30C). The laser output power is 200 mW, with the beam mode, and it is output through on-off mode, the total time is 30 minutes. After the needle therapy, the band aid is applied externally and keeps the wound dry for 24 hours. Every 10 days is 1 course, 3 times as a course of treatment with 2 courses in total.

The supine recumbent massage was adopted on the next day after treatment. The specific operation is as follows: (1) to gently release neck, shoulder and back soft tissue with touch or pressing or one-finger massage. (2) The patient takes supine position, the surgeon holds tightly the patient's occipitalia and chin with the right hand so that the patient's neck is 45° horizontal to the plane; the traction lasts 1 to 2 minutes, and then gently turn and swing the head around to hear the reset sound. (3) To gently touch or press the both sides of the cervical spine up and down with one-finger massage, a straight brush on both sides of the cervical spine with moderate heating. Touch the Fengchi acupoint, Shuaigu acupoint, Head-Linqi acupoint and other acupoints with a straight brush on both sides of the cervical spine. The duration is 20 minutes, 3 times every week, 10 times for a course of treatment, with 2 treatment courses in total.

4. OBSERVATION OF EFFICACY

4.1 Observation index

The observation index adopts the contrast research based on the patient's own data, that is, based on "Cervical Vertigo Symptoms and Functional Assessment Scale" developed by Wang Chuhuai before treatment and the 60th day after treatment to assess the disease; the doctor who is charge in color Doppler Ultrasound synchronously conducted vertebral artery color Doppler ultrasound examination on the patients, dynamically observed the changes of carotid artery blood flow parameters in patients on the first time and the 60th day after treatment.

"Cervical Vertigo Symptoms and Functional Assessment Scale": the questionnaires are filled out by the patients under the guidance of the doctor. The scale includes 5 items: 16 points in total for

vertigo (8 points for vertigo degree, 4 points for frequency, and 4 points for duration); 4 points for shoulder pain, 4 points for daily life and work, 4 points for psychological and social adaptation, 8 points for physical examination (2 points for neck test, 2 points for vertebral artery twist test, 2 points for neck flexion and extension test, 2 points for vertebral artery point tenderness test), the full score of the scale is 36 points. Each item is divided into 5 levels (excluding physical examination item, which has only 2 grades). When it is used, the scores of the evaluation scale were added up, and the scores were counted by doctor before treatment and on the sixtieth day after treatment. The higher the score is, the lighter the symptoms are.

4.2 Color Doppler ultrasound examination

The color Doppler technology reflecting the hemodynamic changes of extracranial vertebral artery is used (carotid, vertebral artery Doppler color Doppler ultrasound) to observe the two-dimensional structure of bilateral cervical artery C5-6 segment and hemodynamic index and measure the neck diameter; C5-6 segment diameter, EDV (end diastolic velocity) PSV, (peak systolic velocity) PI, (pulsatility index), RI (resistance index); and the trend etc., the spectrum analysis system is used to calculate all kinds of data.

Inspection methods: the Philips IE33 color Doppler ultrasound diagnostic instrument is used with the frequency of 5.5 MHz, high frequency linear array probe L11-3, and condition Carotid. The subjects were taken supine position and the head was tilted to the right side about 15 degrees. The probe was placed in the posterior part of the common carotid artery, and the vertebral artery was displayed above the clavicle, and then the lumbar vertebra was displayed upward along the line, until the second cervical vertebra. Two-dimensional images were used to observe the vertebral artery, the wall condition and the external pressure of the lumen, and the diameter of the vertebral artery (D) and pulse Doppler were measured with the 4 to 5 intervertebral segments as the measuring point, pulse Doppler is used to sample and measure the blood and to obtain more than 4 satisfactory spectrum, so as to measure the peak systolic velocity (PSV), end diastolic velocity (EDV) and resistance index (RI) and pulsatility index (PI), then they were registered and statistically analyzed.

4.3 Efficacy evaluation criteria

Efficacy evaluation criteria base on the "Guidelines for Clinical Research on New Drugs of Traditional Chinese Medicine", and then regulate the efficacy evaluation criteria on one's own [1]. Cured: the total score of cervical spondylosis symptoms and functional decreased by $\geq 95\%$; Excellently: the total score of cervical spondylosis symptoms and functional reduced by $\geq 70\%$, $<95\%$; Effectively: the total score of symptoms and function of cervical spondylosis reduced by $> 30\%$, $< 70\%$; invalidly: The total score of symptoms and function of cervical spondylosis reduced by 30% . Formula: (the score before treatment plus the score after treatment, then is divided by the score before treatment) * 100%.

4.4 Statistical processing

SPSS 17.0 statistical software was used for data analysis. The measurement data were expressed as mean $\pm$ standard deviation ($\pm s$), the paired design data with normal distribution were tested by t test; The rank sum test was used to measure the measurement data that do not conform to the normal distribution; the comparison of enumeration data were used for chi-square test, and grade data were analyzed by Ridit. When ($P < 0.05$), the difference was statistically significant.

5. RESULTS

5.1 Comparison of the changes in carotid and vertebral artery diameter in each group before and after treatment

It can be seen from Table 1 and Figure 1 (see below) that there was no significant difference in the diameter of the left cervical segment of the treatment group on the 60th day before treatment and

after treatment ($P > 0.05$), there was a significant difference in the diameter of the right cervical segment of the treatment group compared with that before the treatment ($P < 0.05$). There was no significant difference between the left and right cervical segments in the control group before and after treatment ($P > 0.05$). There was a significant difference in the diameter of the right cervical segment of the treatment group when compared with the control group ($P < 0.05$). There was no significant difference between the left and right cervical segments in the control group before and after treatment ($P > 0.05$). There was no significant difference in the diameter of the left C5-6 segment vertebral artery of the treatment group when compared with the control group ($P > 0.05$), there was a significant difference in the right vertebral artery diameter of C5-6 segment of the treatment group compared before the treatment group ($P < 0.05$). There was no significant difference between the left and right vertebral artery of C5-6 segment in the control group before and after treatment ($P > 0.05$). Comparison between groups, there was significant difference in the right C5-6 segment vertebral artery diameter of the treatment group when compared with the control group ($P < 0.05$) on the sixtieth day after treatment. The results showed that the treatment group was better than the control group in the improvement of the internal diameter of the right C5-6 segment vertebral artery.

Table 1: Cervical diameter and C5-6 segment diameter on the 60th day before and after treatment (mm)

Item		Treatment group (45 cases)		Control group (45 cases)	
		before treatment	after treatment	before treatment	after treatment
Cervical diameter	left	3.16±0.43	3.19±0.38	3.13±0.40	3.16±0.29
	right	2.76±0.21	2.92±0.46 [*]	2.79±0.33	2.89±0.31
C5-6 diameter	left	2.97±0.52	2.96±0.48	2.92±0.54	2.92±0.66
	right	2.66±0.23	2.80±0.42 ^{★△}	2.62±0.25	2.71±0.27

Notes: Comparison within the two groups before and after treatment^{*} $P < 0.05$; Comparison between the two groups before and after treatment[△] $P < 0.05$

Figure 1: Changes of diameter of carotid artery and vertebral artery before and after treatment in two groups

Notes. Comparison within the two groups before and after treatment^{*} $P < 0.05$; Comparison between the two groups before and after treatment[△] $P < 0.05$

5.2 Comparison of changes in hemodynamic parameters of vertebral artery in each group before and after treatment

It can be seen from Table 2 and Fig 2 that, there was significantly different in the bilateral V5-6 vertebral artery end-diastolic blood flow velocity (EDV) on the 60th day compared with before treatment ($P < 0.05$). In the control group, there was statistically different in the EDV of the vertebral artery in the left C5-6 segment on the 60th day after treatment when compared with before treatment ($P < 0.05$); There was no significant difference in vertebral artery EDV of the left C5-6 segment compared with before treatment ($P > 0.05$). Comparison between group, there was statistically significant difference in the right vertebral artery C5-6 segment EDV of the treatment group on the sixtieth day after treatment when compared with the control group ($P < 0.05$).

There was statistically significant difference in peak systolic blood flow velocity (PSV) of the bilateral C5-6 segment vertebral artery of the treatment group on sixtieth day after treatment when compared with that of before treatment ($P < 0.05$), there was statistically significant difference in PSV of the right C5-6 segment vertebral artery of the treatment group on sixtieth day after treatment when compared with that before treatment ($P < 0.05$), and there was no significant difference in PSV of the right C5-6 segment vertebral artery when compared with that of before treatment ($P > 0.05$). Comparison within groups: there was statistically significant difference in PSV of the bilateral C5-6 segment vertebral artery of the treatment group on sixtieth day after treatment when compared with that of the control group ($P < 0.05$).

Table 2: Comparison of changes in EDV and PSV of vertebral artery in C5-6 segment before treatment and on the sixtieth day after treatment (cm/s)

Item		Treatment group (45 cases)		Control group (45 cases)	
		before treatment	after treatment	before treatment	after treatment
EDV	LVA	18.10±5.33	25.76±5.78 [*]	17.54±5.68	19.74±6.63 [*]
	RVA	16.57±6.42	22.85±5.38 [△]	16.42±6.21	17.30±4.36
PSV	LVA	57.60±4.28	65.92±5.11 [*]	58.10±6.22	60.42±4.54
	RVA	47.14±5.47	60.22±4.59 [△]	47.24±5.36	51.47±5.88 [*]

Notes: Comparison within the two groups before and after treatment^{*} $P < 0.05$; Comparison between the two groups before and after treatment[△] $P < 0.05$

Figure 2: Changes of hemodynamic parameters of vertebral artery in each group before and after treatment

Notes. Comparison within the two groups before and after treatment^{*} $P < 0.05$; Comparison between the two groups before and after treatment[△] $P < 0.05$

Table 3: Comparison of PI and RI changes of vertebral artery in C5-6 segment before treatment and on the sixtieth day after treatment

Item		Treatment group (45 cases)		Control group (45 cases)	
		before treatment	after treatment	before treatment	after treatment
PI	LVA	1.36±0.43	1.14±0.20*	1.23±0.38	1.22±0.14
	RVA	1.72±0.26	1.21±0.17* △	1.69±0.27	1.50±0.13*
RI	LVA	0.75±0.20	0.71±0.45	0.73±0.33	0.71±0.61
	RVA	0.83±0.13	0.55±0.15* △	0.81±0.26	0.79±0.33

Notes: Comparison within the two groups before and after treatment*P<0.05 ; Comparison between the two groups before and after treatment △P<0.05

Figure 3: Changes in PI and RI of vertebral artery in C5-6 segment on the sixtieth day in each group before and after treatment

Notes. Comparison within the two groups before and after treatment*P<0.05 ; Comparison between the two groups before and after treatment △P<0.05

It can be seen from Table 3 and Fig 3 that there was significantly difference in PI and RI of vertebral artery in the right C5-6 segment of the treatment group after treatment when compared with before treatment (P<0.05); when compared with before treatment, there was a significant difference in PI of the left C5-6 vertebral artery (P<0.05). There was not significantly different in the RI of vertebral artery in bilateral C5-6 segment on the 60th day before treatment of the control group (P> 0.05), there was statistically significant difference in the PI value of vertebral artery in the right C5-6 segment compared with that before treatment (P<0.05). Comparison within groups: there was statistically significant difference in the PI, RI of the right C5-6 segment vertebral artery of the treatment group on sixtieth day after treatment when compared with the control group (P<0.05), indicating that the changes in PI, RI of the right C5-6 vertebral artery of the treatment group were better than those of the control group.

6. DISCUSSIONS

In recent years, with the rise of e-commerce, mobile phones and iPad and other electronic products and the increasing pressure on people increase the incidence of cervical disease. Cervical spondylotic vertebral arteriopathy (CSA) refers to the vertebral artery blood flow disorders caused by cervical vertebral lesions, thereby causing cerebral insufficiency, it is embodied as a series of symptoms of the clinical vertigo, accounting for about 40% of cervical spondylosis [1-5]. It is predicted that in the next 50 years, CSA will become an important

clinical disease source for acupuncture, orthopedics, neurology, and rehabilitation [6].

Vertebral artery cervical spondylosis (CSA) is a common type of cervical spondylosis, yet the Chinese medicine has no name of CSA disease. According to its symptoms, it should belong to the scope of traditional Chinese medicine "vertigo". Vertigo is a syndrome of deficiency in origin and excess in superficiality. It is said in The Yellow Emperor's Internal and Ancient Theory that "after forty-eight years old men's kidney became weak, hair was less, the teeth were slowly broken, too; when the men reach the age of 56, the liver began to decline, and the limbs became awkward." Deficiency in origin mainly attributes to liver spleen and kidney, liver governs tendon and blood, and deficiency of liver causes deficiency of blood; Deficiency of Qi and blood cannot be filled in the brain, that is "Deficiency of blood leads to vertigo." It was said in The Yellow Emperor's Inquiry to Qi Bo Leisurely that "Deficiency of Qi leads to non-filling of the brain and vertigo". "Convulsions and vertigo mostly are caused by liver lesions", which reveals a close relationship between vertigo and the liver. The spleen is the basis, is the source of Qi and blood. The sufficiency of Qi causes blood in the brain to nourish and moisten the body, the deficiency of spleen cannot generate Qi and blood, semen, and the deficiency of brain can't be nourished, resulting to vertigo. Spleen is the source of phlegm, that is the so-called "no sputum no vertigo," deficiency in spleen cannot transport water, too much water results in the disease of internal water staying in body, too much sputum leads to vertigo. Kidney is in charge of bone marrow, the deficiency in kidney results in loss in bone marrow, the loss in bone marrow leads to vertigo. It is said in "Pivot, Helen": "deficiency in bone marrow leads to vertigo, tinnitus and soft and weak leg." kidney regulates the internal water balance, deficiency in kidney results in deficiency in water; therefore, it cannot nourish the liver, if the liver yang cannot be restricted, and Yang is over, resulting in blind mind and vertigo. Liver and kidney are homologous, spleen and kidney and the foundation, the three organs affect each other, and are closely related.

The needle-knife is a new appliance combined the Chinese medicine "needle" and Western medicine "knife", it can not only have the effect of acupuncture, it also can play the role of knife cutting releasing and so on. The needle-knife can conduct closed cutting, release, reduction and decompression by using its closed surgery theory, and it can completely break the four pathological states of adhesion, scar, contracture, blocking so as to cure the disease.

Treatment mechanism of the needle-knife [7]: ①Reconstruct mechanical balance, ②Restore dynamic balance, ③Dredge the meridians and improve microcirculation disorder, ④Promote energy release and energy supplement, ⑤Promote body fluid reflux and dredge body fluid retention, ⑥Stimulate the biological energy into biological current. Needle-knife Medicine thinks [8]: the four pathological factors of scar, obstruction, adhesions, and contracture constitute the body's dynamic imbalance, and cause chronic soft tissue injury. It occupies the first position in the course of the onset of cervical spondylosis. Soft tissue strain or damage of the neck causes muscle tension, edema or muscle fiber rupture, oozing, bleeding, adhesion, causing disorder of muscle balance on both sides of the spine, dislocation of intervertebral joints, stimulating the adjacent nerve or the oppression of blood vessels, thereby appearing accordingly signs and symptoms. In order to repair the damaged organism, the organism starts the nerve reflex and the body fluid regulation system, which causes the human body to recover the disturbed physiological function. Through releasing the contracture, peeling adhesions, scraping the scars, dredging, the needle-knife makes the surrounding muscles in depression, fracture and retraction, relieve muscle spasm, loosen adhesions and scar tissue, improve the blood circulation and body fluid circulation of the soft tissue around the neck, promote the transport and degradation of inflammatory substance, thereby restoring the dynamic balance of the neck, realizing the purpose of the treating disease [9-11].

In this study, it is found that, compared with the control group, the clinical comprehensive efficacy of the patients from the treatment group was significantly better on the 60th day after treatment, and the efficacy of laser needle-knife combined with supine restoration massotherapy method was significantly better than that of the supine

recumbent massage monotherapy ($P < 0.05$). In terms of ESCV score (cervical vertigo symptoms and functional assessment scale score) comparison, laser needle-knife combined with supine restoration massotherapy method can significantly improve the clinical symptoms of CSA, and the efficacy of some symptoms ("vertigo", "headache" and "psychological and social adaptation") is better than the supine recumbent massage monotherapy. The results of color Doppler ultrasound showed that in the diameter improvement of the right vertebral artery of C5-6 segment, the treatment group was better than the control group on the sixtieth day after treatment, and was better than that of the control group. The EDV of vertebral artery in the right C5-6 segment of the treatment group was significantly superior to that of the control group. On the 60th day after treatment, the PSV of the bilateral C5-6 vertebral artery in the treatment group had obvious advantages compared with the control group. In terms of the changes in PI and RI in vertebral artery C5-6 segment and the changes in PI and RI in vertebral artery of right C5-6 segment, the treatment group was higher than those in control group.

In summary, laser needle-knife compound therapy to treat CSA has a good clinical efficacy and better patient compliance and safety; laser needle-knife compound therapy can improve clinical symptoms by effectively improving vascular morphology and hemodynamics and other aspects. The efficacy of the therapy is accurate, safe and reliable, low-cost, non-toxic side effects, and is worthy of clinical promotion.

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