

CLINICAL STUDY

Traditional Chinese Medicine comprehensive therapy for the improvement of motor function in spinal cord injury patients

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Abstract

OBJECTIVE: To study the effect of early comprehensive therapy of Traditional Chinese Medicine (TCM) on motor function of in patients with spinal cord injury.

METHODS: Fifty-one standard spinal cord injury patients with paraplegia were randomly assigned to an experimental or control group. The experimental group received TCM comprehensive therapy, and the control group received modern Western Medicine (WM) treatment for 4 weeks. The motor score (MS), Barthel Index (BI) and American Spinal Injury Association (ASIA) grading were measured in both groups before and after treatment.

RESULTS: After treatment, the MS and BI scores of the TCM comprehensive therapy group improved significantly ($P < 0.01$), and there was no significant difference in ASIA grading ($P > 0.05$). The differences between the experimental and control groups after treatment were not significant ($P > 0.05$).

CONCLUSION: Early TCM comprehensive therapy is an effective method for improving motor function in patients with spinal cord injury.

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Key words: Spinal cord injuries; Medicine, Chinese traditional; Treatment outcome

INTRODUCTION

Spinal cord injury (SCI) has a low cure rate, a high disability rate and its incidence is on the rise¹. Such injuries can lead to severe impairments of motor, sensory, and autonomic function. Motor disorder is particularly difficult for individuals as well as their families and can result in a heavy social burden. Consequently, new therapies are needed to maximize the recovery from impaired motor function to improve the patients' quality of life and restore their ability to work.

Modern Western Medicine (WM) occupies the dominant position in prevention and treatment of SCI, and much progress has been made recently in this field². However, in China, many patients with SCI are treated with one or more types of Traditional Chinese Medicine (TCM) in addition to WM an attempt to enhance the therapeutic effects of SCI treatment. Presently, more evidence is needed to show the effects of TCM on SCI recovery and assess its degree of effectiveness. In this study, we aimed to establish the clinical efficacy of comprehensive TCM on motor function in patients with early phase SCI.

MATERIALS AND METHODS

Patients

Fifty-four patients with early stage SCI were selected at the Department of Rehabilitation at the Affiliated Hospital of Jining Medical University, from December 2011 to April 2014. Patients were randomly divided into a TCM treatment group ($n = 27$; given TCM treatment) and a WM treatment group ($n = 27$; given WM treatment). Computer-generated randomized numbers were used to divide subjects, and the allocation codes were kept in opaque envelopes.

Diagnostic criteria

International standards for neurological classification of spinal cord injury (revised 2011), published by the American Spinal Injury Association (ASIA), were referenced in diagnosing paraplegia. Paraplegia refers to impairment or loss of motor and/or sensory function in the thoracic, lumbar or sacral (but not cervical) segments of the spinal cord, secondary to damage of neural elements within the spinal canal. With paraplegia, arm functioning is spared, but, depending on the level of injury, the trunk, legs and pelvic organs may be involved.³

Inclusion criteria

To be eligible, participants were required to meet the following conditions: diagnosis in line with TCM theory for flaccidity, convulsion, paralysis syndrome; past medical history, imaging or surgical exploration confirming thoracic, lumbar or sacral spinal cord injury; stage of SCI was within 1 month of onset, and vital signs were stable; age of 18-60 years; and conscious and active cooperation with treatment. The patient or legal guardian voluntarily signed the informed consent to participate in the study. The degree of impairment was determined according to the ASIA impairment scale and ranged from A to D. On this scale, A = complete, meaning no sensory or motor function is preserved in the sacral segments S4-S5; B = sensory incomplete, indicating that sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5, and no motor function is preserved more than three levels below the motor level on either side of the body; C = motor incomplete, wherein motor function is preserved below the neurological level, and more than half of key muscle functions below the single neurological level of injury have a muscle grade less than 3 (Grades 0-2); D = motor incomplete, indicating that motor function is preserved below the neurological level, and at least half (half or more) of key muscle functions below the neurological level of injury have a muscle grade > 3 ; and E = Normal.

Exclusion criteria

Participants with the following conditions were excluded: serious heart, liver, kidney, hematopoietic system, or endocrine system-related diseases, or blood coagula-

tion dysfunction, severe mental disorders or dementia; pregnant or breast-feeding; general allergies, or allergies to Chinese herbal medicine ingredients; and/or participation in other clinical trials within the past 3 months.

Criteria for withdrawal from the study

Withdrawal from the study occurred when participants: requested to withdraw; suffered serious adverse events or deterioration, or needed to take emergency, compensatory medical measures during the trial; failed to comply with treatment programs; or had incomplete assessment data or records. The ethics committees of the Affiliated Hospital of Jining Medical University approved the study. The purpose, nature and potential risks of the experiments were explained to the patients and their families and all participants gave written, informed consent before participating in the study.

Interventions

Patients in both the TCM treatment group (experimental) and the WM treatment group (control) received all necessary Western medical treatment, including: life support, surgery, medication, standard care and health education. Two interventions were conducted for 4 weeks of treatment using the following methods. The WM intervention group received modern Western rehabilitation care, including physiotherapy and occupational therapy to conduct functional training involving standing bed training, muscle strength training, range of motion training, stretching, balance exercises for sitting and standing, ambulation training for those who had potential for walking, walking tools training and activity of daily living skills training. The modes, intensities, durations, and frequencies of the training program were tailored to the individual based on the degree of dysfunction. The TCM group received several types of TCM treatment methods including acupuncture, moxibustion, massage, Chinese herbs and TCM health education in addition to the necessary Western medicines. All TCM methods were used unless individual contraindications or lack of need was evident. The specific methods are detailed below.

Body acupuncture (the affected side): Acupuncture points were at the neurological level of injury and upper and lower two vertebral spaces on the governing vessel or Huatuo Jiaji points (EX-B 2) which are located 0.5 cun lateral of the paravertebral space on the back. In the lower limb we selected acupuncture points on the muscles antagonistic to muscles of spasm to avoid acupuncture aggravated spasms. To treat extensor spasms in the lower limb we selected Yinmen (BL 37), Weiyang (BL 39), Weizhong (BL 40), Heyang (BL 55), Chengjin (BL 56). Flexor spasms in the lower limb were treated with Futu (ST 32), Yinshi (ST 33), Liangqiu (ST 34), Zusanli (ST 36), Fenglong (ST 40). Foot drop was treated with Jiexi (ST 41), Chongyang (ST 42), Xianggu (ST 43), Qiuxu (GB 40). If muscle spasms were not present we selected acupoints on the

paralyzed muscles. The above acupoints are referred to in the People's Republic of China, State Standard Name and Location of Acupoints (GB12346-2006).⁴ The acupuncture needles were purchased from Huanqiu (Suzhou Acupuncture Goods Co., Ltd., Suzhou, China). After the needle penetrated into the points and the arrival of *Qi* was achieved (patients have the sensation of soreness, numbness of a distending feeling around the point), we twirled the needle. Afterward, electroacupuncture was used for 20 min, once a day, 10 times as a course of treatment, with 5 days rest between treatments. If patients had lower limb spasticity, moxibustion treatment was conducted. In this treatment we selected two to three points on the muscle spasm and placed a seed-sized moxa-cone on the selected acupoints and ignited it. When the patient felt a burning sensation, the moxa-cone was removed and replaced with another using tweezers. Typically, each acupoint can receive three cones of moxibustion.

Chinese herbal medicine: there are three periods of syndrome differentiation for SCI, and the prescription of Chinese herbs is based on syndrome differentiation at different times after injury. We formulated the treatment protocol using ancient literature as well as expert experience. At the early stage, within 10 days after injury, the treatment was focused on the syndrome of stagnation of *Qi* and blood stasis and clinical manifestations of meridians barrier and localized swelling. The prescription promoted blood circulation to remove blood stasis and induce diuresis for removing edema. The basic ingredients of the formulas were Danshen (*Radix Salviae Miltiorrhizae*) 10 g, Taoren (*Semen Persicae*) 15 g, Danggui (*Radix Angelicae Sinensis*) 15 g, Honghua (*Flos Carthami*) 5 g, Mutong (*Caulis Akebiae*) 10 g, at one dose per day. In the developing stage, occurring 10-20 days after injury, the treatment focused on the syndrome of stasis and deficiency, clinical manifestations of swelling and pain relief, defecation difficulty and urine retention. The prescription was warming and activating meridian, invigorating spleen, warming kidney, and the reunion of fractured tendons and bones. The basic ingredients of the formulas were Gouqizi (*Fructus Lycii*) 30 g, Gusuibu (*Rhizoma Drynariae*) 15 g, Niuxi (*Radix Achyranthis Bidentatae*) 15 g, Tusizi (*Semen Cuscutae*) 15 g, Danggui (*Radix Angelicae Sinensis*) 15 g, Fuling (*Poria*) 15 g, at one dose per day. In the late stage, occurring 20 days to 2 months after injury, the treatment focused on the syndrome of deficiency, clinical manifestations of *Yang* deficiency of spleen and kidney and low back and limbs weakness. The prescription was warming meridians, dredging collaterals and invigorating the liver and kidneys. The basic ingredients of the formulas were Baijiezi (*Semen Sinapis*) 10 g, prepared Dihuang (*Radix Rehmanniae*) 30 g, Duzhong (*Cortex Eucommiae*) 15 g, Niuxi (*Radix Achyranthis Bidentatae*) 10 g, Dangshen (*Radix Codonopsis*) 15 g, Shenjincao (*Herba Lycopodium Japonici*) 15 g, at one dose per day.

Massage: during the early rehabilitation, the limbs were massaged then paraspinal massage was increased after the spine fracture healing was stable, 30 min each time, once a day, for a 10-day treatment period. The acupoints along the meridians and collaterals distribution area were point pressured, kneaded, pressed, poked and rubbed as appropriate. The manipulation stimulated the circulation of blood and caused the muscles and joints to relax. Palm-taping and flapping were the main manipulation methods used during the flaccid paralysis period. During the spastic paralysis period, pressing and pointing were the main methods, supplemented with active and passive movement of the limb joint and, stretching.

Measurement

The assessment data was collected at baseline and 4 weeks after completing the treatment. The following information was recorded in a case report form: (a) the neurological function impairment degree according to the ASIA Impairment Scale (AIS) (modified from Frankel); (b) the numerical summary scores of motor function (MS) according to ASIA' international standards;^{3,5} (c) the Barthel Index (BI) to assess activities of daily living (ADL).

Statistical analysis

All analyses were performed using SPSS Version 17.0 (SPSS Inc., Chicago, IL, USA). Data were reported as mean \pm standard deviation ($\bar{x} \pm s$). All tests were two-sided, and $P < 0.05$ was considered statistically significant. Student's *t*-test and the *Chi*-square (χ^2) test were conducted to test the difference between groups.

RESULTS

Participants clinical data

From December 2011 to April 2014, there were 54 eligible SCI patients who underwent the trial. A total of 27 patients were assigned to the experimental group. Two cases were dropped from the study and 25 patients remained for per-protocol analyses. A total of 27 patients were allocated to control group. One case was dropped from the study and 26 patients remained for the per-protocol analyses. The study flow chart is shown in Figure 1. There were no significant differences in the dropout rate between the two groups, and the χ^2 and *t* tests showed no significant differences in age, gender, spinal injury level, injury degree at baseline between the two groups (Table 1).

Comparison of the score of MS before and after treatment (Table 2)

As shown in Table 2, before treatment, there was no difference in MS scores between the two groups, indicating their comparability ($P > 0.05$). Analysis of variance for repeated measurements showed significant differences in MS scores before and after 4 weeks of treat-

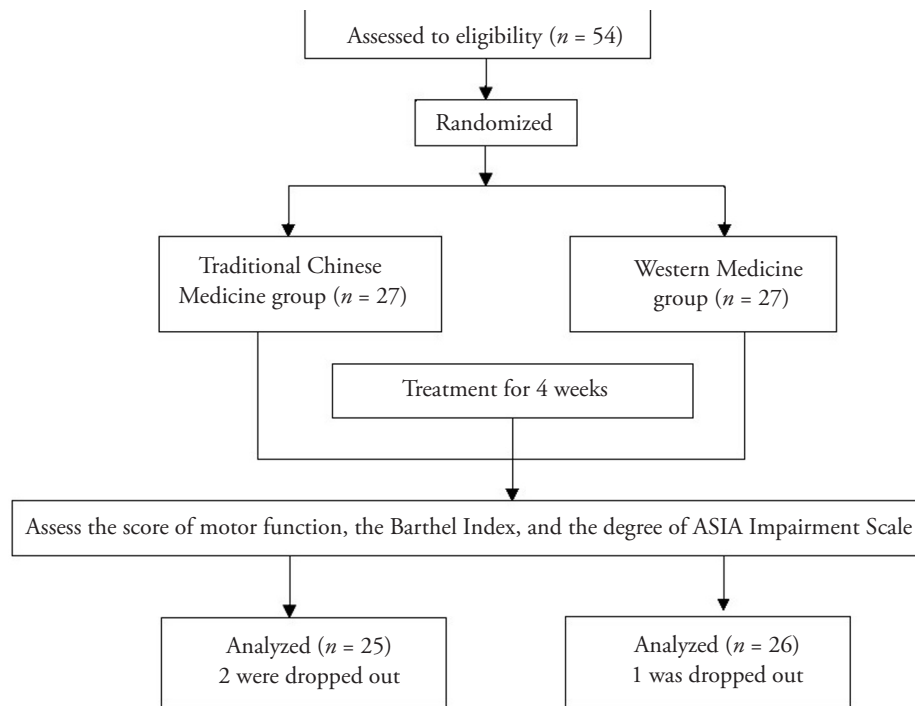


Figure 1 Study flow chart

ASIA: American Spinal Injury Association.

Table 1 Participants clinical data ($\bar{x} \pm s$)

Group	n	Age (years)	Gender (n)		Injury level (n)		Injury degree (n)	
			Male	Female	Thoracic	Lumbosacral	Complete injury	Incomplete injury
TCM	25	47±12	15	10	15	10	6	19
WM	26	43±12	21	5	16	10	8	18

Notes: TCM group: Traditional Chinese Medicine group, treated with acupuncture, moxibustion, Chinese herbs, massage of TCM treatment methods in addition to the necessary western medical treatment; WM group: Western Medicine group, treated with modern western rehabilitation training including physiotherapy and occupational therapy in addition to the necessary western medical treatment.

ment in the TCM group ($P < 0.01$). The MS scores were not significantly different after treatments between the two groups ($P > 0.05$).

Comparison of the score of BI before and after treatment (Table 3)

As shown in Table 3, before treatment, there was no difference in BI scores between the two groups ($P > 0.05$) indicating their comparability. Analysis of vari-

ance for repeated measurements showed significant differences in BI scores before and after 4 weeks treatment in TCM group ($P < 0.01$). The BI score difference was not statistically significant after treatment between the two groups ($P > 0.05$).

Comparison of the degree of AIS before and after treatment

As shown in Table 1, before treatment, there was no

Table 2 Comparison of the score of motor function (MS) before and after treatment ($\bar{x} \pm s$)

Group	n	Before	After	P value
TCM	25	56±9 ^a	58±10 ^{ab}	0.000
WM	26	59±13	61±14 ^b	0.001

Notes: TCM group: Traditional Chinese Medicine group, treated with acupuncture, moxibustion, Chinese herbs, massage of TCM treatment methods in addition to the necessary western medical treatment; WM group: Western Medicine group, treated with modern western rehabilitation training including physiotherapy and occupational therapy in addition to the necessary western medical treatment. ^a $P > 0.05$, as compared with the data in the WM group; ^b $P < 0.01$, as compared with the data before treatment in the same group.

Table 3 Comparison of the score of the Barthel Index before and after treatment ($\bar{x} \pm s$)

Group	n	Before	After	P value
TCM	25	25±18 ^a	37±2 ^{ab}	0.000
WM	26	19±17	41±22 ^b	0.000

Notes: TCM group: Traditional Chinese Medicine group, treated with acupuncture, moxibustion, Chinese herbs, massage of TCM treatment methods in addition to the necessary Western medical treatment; WM group: Western Medicine group, treated with modern western rehabilitation training including physiotherapy and occupational therapy in addition to the necessary western medical treatment. ^a $P > 0.05$, as compared with the data in the WM group; ^b $P < 0.01$, as compared with the data before treatment in the same group.

difference in AIS grades between the two groups ($P > 0.05$) indicating their comparability. As shown in Table 4, after four weeks treatments, three patients (12.0%) in the TCM group and four patients (15.4%) in the control group showed 1 grade improvement in the AIS. The ratio of the AIS grade showed no significant difference in AIS before and after 4 weeks treatment in TCM group ($P > 0.05$). The ratio of AIS grades was not statistically significant after treatments between the two groups ($P > 0.05$).

DISCUSSION

TCM including acupuncture is used for the improvement of motor function in patients with spinal cord injury. In ancient Chinese medical literature, we found no exact records of spinal cord injury. Muscle weakness, paralysis, atrophy and other symptoms due to spinal cord injury were similar to bodily indolence, flaccidity syndrome categories in TCM.⁶ The governing vessel runs posterior along the interior of the spinal column and relates to the function of the spinal cord according to the traditional theory in TCM.⁷ TCM states that flaccidity syndrome in SCI is due to damage to the governing vessel caused by blood stasis, which blocks the channels resulting in imbalance of *Yin* and *Yang*, *Qi* and blood disharmony, and organs and meridians disorders which cause limited movement in the affected limb as well as bowel and bladder dysfunction. Treatments should regulate the governing vessel and enhance kidney-*Yang*.

In TCM theory, because of the governing vessel is damaged in SCI patients, acupuncture at these points can dredge the channels, activate the collateral circulation, regulate zang-fu viscera and balance *Qi* and blood. Acupuncture Jiaji therapy can balance *Yin* and *Yang* in limbs and promotes flow of meridian-*Qi*. Needling the points of the stomach channel of the foot-*Yangming* can harmonize the stomach, strengthen the spleen, and nourish blood, muscles and tendons.

The specific mechanisms are still being explored. Dorsher *et al*⁸ reviewed acupuncture's effect in the treatment of the sequelae of SCI, and suggested that there is evidence for the use of electroacupuncture in acute SCI to significantly improve long-term neurologic re-

covery in terms of motor, sensory and bowel/bladder function. Many experts believe that acupuncture stimulation on the governing vessel can improve the excitability of spinal neurons, reduce and delay the early pathological damage, improve the spinal cord microcirculation, promote axonal regeneration, and promote the recovery of neurological function.⁶ Jiaji acupoints were near the spinal cord, and beneath them were the posterior rami of spinal nerves and blood vessels. Acupuncture of these points could improve the nutritional status of local lesion, stimulate the spinal nerves, regulate the function, and promote regeneration in order to recover limb function. Jiang *et al*⁷ showed that electroacupuncture and manual acupuncture could improve functional recovery by reducing apoptotic cell death after SCI. The neuroprotective effects were thought to be mediated in part by antioxidative, anti-inflammatory, and antiapoptotic effects following injury. Additionally, the study indicated that stimulating the governing vessel, especially with electroacupuncture, was an effective therapeutic strategy in acute SCI. Du *et al*⁹ reported that needle therapy had an obvious effect on acute SCI in rabbits, and its mechanism was made possible by inhibiting the expression of the Fas → caspase-3 cascade, thereby inhibiting cell apoptosis.

In agreement with the *Yin* and *Yang* balance method, we chose acupoints on muscles antagonistic to existing muscle spasms to inhibit the spasms if present. In the case of muscle weakness, we selected acupoints on these muscles to maintain the muscle excitation, improve muscle tone, and prevent muscle atrophy. Our study showed that this method integrated with other TCM methods could increase patients' MS and ADL ability significantly ($P < 0.01$).

To our knowledge, little research has been conducted in the field of SCI early rehabilitation and Chinese herbal medicine efficacy, especially in the mechanism area. Jia *et al*¹⁰ study demonstrated that Shu-Xue-Tong can significantly promote SCI healing by improving spinal cord blood flow, minimizing secondary injury, protecting neurons in the ischemic area, and facilitating motor recovery. Research by Long¹¹ has shown that early and late stage SCI patients who took oral Chinese decoctions intended to promote blood circulation to

Table 4 Comparison of the degree of ASIA Impairment Scale before and after treatment [n (%)]

Group		n	A	B	C	D	E	P value
TCM	Before treatment	25	6 (24.0)	6 (24.0)	9 (36.0)	4 (16.0)	0 (0.0)	0.540
	After treatment		6 (24.0)	4 (16.0)	11 (44.0)	3 (12.0)	1 (4.0)	
WM	Before treatment	26	8 (30.8)	5 (19.2)	8 (30.8)	5 (19.2)	0 (0.0)	0.199
	After treatment		8 (30.8)	3 (11.5)	10 (38.5)	3 (11.5)	2 (7.7)	

Notes: TCM group: Traditional Chinese Medicine group, treated with acupuncture, moxibustion, Chinese herbs, massage of TCM treatment methods in addition to the necessary Western medical treatment; WM group: Western Medicine group, treated with modern Western rehabilitation training including physiotherapy and occupational therapy in addition to the necessary Western medical treatment. ASIA: American Spinal Injury Association

dissipate blood stasis, clear and active the channels and collaterals experienced a clear curative effect.

In Western cultures, massage is used for the reduction of functional limitations resulting from musculoskeletal impairments, and for muscle recovery from fatigue in specific muscle groups.¹² Although the specific mechanisms of massage therapy remain unknown for both non-disabled and disabled populations, massage is thought to reduce lactic acid levels in the muscles, stimulate healing of the connective tissues and increase lymphatic and venous circulation.¹³ However, there is little evidence to support this approach in people with SCI, aside from the recommendation that that people with SCI seek massage for the management of pain.^{14,15} Diego *et al*¹⁶ demonstrated improvements in range of motion (ROM) and strength of the upper limbs after the application of a set routine of massage and stretching in people with chronic cervical SCI. Chase *et al*¹³ found that broad compression massage was safe and well tolerated in patients with SCI. The mechanism behind these improvements maybe due to the neural influence on muscles, such as reductions in H-reflex amplitudes which occur during a period of 3 min of petrissage, reflecting a statistically significant reduction in motor neuron excitability.^{17,18} Through massage, promotion of proper length-tension relationships in spastic muscles may encourage proper firing patterns and decrease motor-neuron excitability.¹² In recent years, clinical studies of nerve injury disease were generally performed with both acupuncture and massage therapy, and showed a beneficial effect.¹⁹

In TCM theory, point-pressing, kneading, pressing and poking channels and manipulations along the meridians were performed on paralyzed limbs to stimulate the circulation of blood and cause the muscles and joints to relax. In our study, palm-taping, nipping, flapping were used on regions of flaccid paralysis of the limbs, because these methods could excite muscles and promote muscle contraction. Rolling, pressing, and finger pointing type moderate manipulations were used on regions of spastic paralysis of the limbs to decrease muscle tone, improve tendon relaxation, activate blood circulation, smooth the arthrosis and eliminate muscle fatigue. Additionally, rotating and shaking manipulations were beneficial to maintain the range of joint motion and increase the stimulation of joint position sense. When the spinal fractures were stabilized, para-spinal massage could be performed to promote spinal nerve functional recovery.

The present study used the international standards for neurological classification of SCI to assess the efficacy of comprehensive TCM for promoting motor function in early stage SCI patients with paraplegia. This is an objective and quantitative evaluation method which is a widely used standard for judging efficacy of treatment strategies for SCI studies in WM. At present, there are no TCM standards for judging efficacy of treatment strategies for SCI and this study presented

methods to measure improvement while in the clinical phase without addressing the mechanism of action. However, this study is limited by a small sample size with short-term efficacy evaluation and the results need to be confirmed with larger trials of longer duration in the future. Our findings demonstrate that TCM comprehensive therapy used in the early phase the condition, and can improve motor function in SCI patients and deserves further exploration.

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