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Clinical study on the treatment of ankylosing spondylitis with warming Yang and strengthening the muscle formula combined with acupoint sticking

Zhijie Liu[1#*] and Qiang Wang[2#]

[1]Department of Nephrology, Dongyang Traditional Chinese Medicine Hospital, 322100, Dongyang, Jinhua, Zhejiang Province, China

[2]Department of Emergency Medicine, Ninety-sixth Hospital of the Chinese People's Liberation Army (PLA) Joint Logistics and Security Forces, 315040, Ningbo, Zhejiang Province, China

Keywords

Warming Yang and strengthening the muscle formula, Acupoint sticking, Ankylosing spondylitis, Inflammatory factors

Correspondence

Zhijie Liu, Department of Nephrology, Dongyang Traditional Chinese Medicine Hospital, No.14, Wuning East Road, Wuning Street, 322100, Dongyang City, Jinhua, Zhejiang Province, China

Email: zyxzliu80336699@163.com

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Abstract

Background This study explored the clinical efficacy of warming Yang and strengthening the muscle formula combined with acupoint sticking in the treatment of ankylosing spondylitis (AS). **Methods** A total of 90 patients with AS were divided into the control group and observation group according to the random number table method, with 45 cases in each group. On the basis of conventional treatment, the control group was treated with acupoint sticking, and the observation group was treated with warming Yang and strengthening the muscle formula combined with acupoint sticking. **Results** After treatment, the total effective rate in the observation group was obviously higher than that in the control group. In addition, the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Bath Ankylosing Spondylitis Functional Index (BASFI) and visual analogue scale (VAS) scores in the observation group were obviously lower than those in the control group. After treatment, patients in the observation group showed better spinal mobility and less spine pain than the patients in the control group. Besides, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and tumor necrosis factor-α (TNF-α) levels in the observation group were obviously lower than those in the control group. Moreover, the incidence of adverse effects was compared and there was no significant difference between the two groups. **Conclusion** The combination of warming Yang and strengthening the muscle formula and acupoint sticking can effectively improve spinal mobility and reduce body inflammation responses in patients with AS.

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1. Introduction

Ankylosing spondylitis (AS) is a chronic autoimmune inflammatory disease that often occurs in young males (1). AS patients are mainly clinically characterized by symptoms such as joint pain, lumbar pain and morning stiffness, which can trigger spinal deformity and ankylosis in severe cases, and AS has a high disability rate, causing serious harm to the physical and mental health and quality of life of patients (2). At present, non-steroidal anti-inflammatory drugs and hormone drugs are often used in the clinical practice to treat AS (2). Although they are able to alleviate the inflammatory reaction in AS patients, the long-term use of the above drugs can produce some toxic side effects and affect the prognosis of patients (3).

In recent years, traditional Chinese medicine (TCM) has made important progress in the clinical research of AS (4). In TCM, AS belongs to the categories of "Guibeifeng", "arthralgia syndrome", and "dyphosis", and it is said in *Plain Questions*: "Yang Qi in the accumulated state can nourish the spirit, and the invasion of cold leads to ankylosing spondylitis", "Therefore, the bone arthralgia occurs unceasingly, and the body repeatedly feels wind-pathogens, and patients with spinal back pain often present with abdominal distension, caudal sacral pain implicating the heel, spinal back pain implicating the head", which pointed out that the pathogenesis of AS is congenital deficiency, the deficiency of kidney-Yang, the invasion of external pathogens and the obstruction of meridians (4). TCM scientists believe that the lesion site of AS lies in the kidney and liver, and deficiency of kidney-Yang is the root of the pathogenesis of AS (5). Deficiency of kidney and emptiness of Du meridian, obstruction of meridians and collaterals lead to the deficiency of Qi and blood, and internal accumulation of cold-pathogens, which can not nourish liver and tendons, and induce the weakness of Qi, phlegm obstruction and blood stasis, stiffness of muscle and joint, causing the state of bending of body and rigidity of limbs (4, 5). Therefore, the treatment should be based on the principles of warming the kidney to help Yang, dispersing blood stasis and removing pathogenic factors, expelling cold and strengthening Du meridian.

Acupoint sticking, a TCM therapy combining TCM science and meridian science, has achieved relatively good results in the treatment of osteoporosis, bronchitis and other diseases (6). During the care of AS, it was found that the TCM drugs used for acupoint sticking alleviates the symptoms of patients through penetration, with direct and long-lasting effects and quick onset, which can effectively improve the patient's quality of life (7). In addition, it has been shown that TCM decoction plays an important role in the treatment of patients with AS (8). For example, Duhuo Jisheng decoction decoction combined with Western medicine has been found to improve the effective rate, functional scores, and symptoms of AS patients, with a reduced rate of adverse reactions (9). Currently, there are few clinical studies on TCM decoction combined with acupoint sticking in the treatment of AS, and in view of this, this study employed warming Yang and strengthening the muscle formula combined with acupoint sticking in the treatment of AS, in order to provide reference for the clinical treatment of AS, the result of which is reported below.

2. Materials and methods

2.1 General data

The sample size calculation was performed with the formula: $N = Z^2 \times P \times (1\text{-}P) / E^2$. A total of 90 AS patients treated in our hospital from February 2019 to February 2020 were selected and divided into the control and observation groups according to the random number table method, with 45 patients in each group. The general data of the two groups were not significantly different (P>0.05) and comparable, see Table 1. This study was reviewed by the ethics committee of our hospital, and all patients gave written informed consent. Inclusion criteria: the diagnosis of Western medicine was in accordance with the standard of *Ankylosing spondylitis: diagnosis and management* (10); the diagnosis of TCM was in accordance with the standard of *Guiding principles for clinical research of new Chinese medicine* (11). Exclusion criteria: pregnant or lactating women;

patients with severe joint deformities or those with advanced AS; patients with severe heart, liver and kidney dysfunction; patients allergic to drugs in this study; patients with no cooperation.

2.2 Methods

After admission, patients in both groups were given loxoprofen sodium tablets (specification: 60 mg, Tianjin Xinfeng Pharmaceutical Co., Ltd, H20030617), 60 mg/time, 3 times/day; in the first week, patients orally administrated sulfasalazine enteric-coated tablets (specification: 0.25 g, Huarun Shuanghe Pharmaceutical Co., Ltd, H11020818), 0.25 g/time, 3 times/day, and the dose was increased by 0.25 g/time every week until 1 g/time. At this time, the frequency of administration was adjusted to 2 times/day, and the treatment cycle was 3 months.

2.3 Control group

On the basis of the routine treatment, the control group was given self-made removing phlegm and promoting blood circulation acupoint sticking prescription, which consisted of: *Radix Paeoniae lactiflora* 300 mg, peach kernel 200 mg, *bile arisaema* 200 mg, *Bombyx batryticatus* 200 mg and *semen brassicae* 200 mg. After being ground into powder, the drugs above were reconstituted to the cream using ginger juice and applied to the Pishu acupoint, Geshu acupoint, Shenshu acupoint and Yanglingquan acupoint for 4 h with 1 application per week, and the treatment cycle was 3 months.

2.4 Observation group

On the basis of the control group, the observation group was given warming Yang and strengthening the muscle formula, the formula composition: *paeony* 30 g, fried *dipsacus asper* 15 g, *Ramulus Cinnamomi* 15 g, *Semen Cuscutae* 15 g, *Radix Cyathulae* 15 g, *Rhizoma cibotii* 15 g, peach kernel 15 g, prepared *rehmannia glutinosa* 10 g, *Psoralea corylifolia* 10 g, *Chinses angelica* 15 g, *Cornus officinalis* 10 g, fried *Cortex eucommia* 10 g, Herba eclipta 8 g, and Ligustrum lucidum 8 g. The drug decoction of 200 ml/dose was prepared 1 dose per day, which was divided into portions and taken in the morning and evening. The treatment cycle lasted for 3 months.

2.5 Outcome measures

2.5.1 Efficacy of TCM syndromes

After treatment, the efficacy of TCM syndromes in the two groups was evaluated according to the *Clinical effect analysis of ankylosing spondylitis treated by Chinese medical syndrome differentiation* (12), the evaluation criteria were listed as follows: clinical remission: symptoms and physical signs such as restricted spinal mobility and lumbar pain basically disappeared; markedly effective: the symptoms and physical signs significantly improved; effective: the symptoms and physical signs improved; ineffective: the symptoms and physical signs were unchanged or even aggravated. Total effective rate = cases of (clinical remission + markedly effective + effective)/total cases × 100%.

2.5.2 Lumbar function and joint pain

Before and after treatment, the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Bath Ankylosing Spondylitis Functional Index (BASFI) were used to assess lumbar function in both groups (13), in which the BASDAI mainly included items scores such as spinal pain, localized tenderness, and peripheral joint pain, and the total score is 10 points. The higher the score, the worse the lumbar function of the patients; BASFI mainly included 10 activities such as climbing stairs and taking clothes from high places with a total score of 10 points. The higher the score, the worse the lumbar function. Visual analogue scale (VAS) was used to evaluate the joint pain degree of the patients in the two groups (14). The total score was 10 points, with higher scores indicating more intense joint pain in patients.

2.6 Serum indicators

Before and after treatment, 3 ml of fasting inferior venous blood was collected from the two groups. Erythrocyte sedimentation rate (ESR) was detected by HT-100 automatic hemorheology analyzer (Zibo hengtuo Analytical Instrument Co., Ltd.), and the

levels of C-reactive protein (CRP) (Prospect tany, pro-557) and tumor necrosis factor-α (TNF-α) (Elabscience, E-EL-R0019c) were detected by enzyme-linked immunosorbent assay (ELISA).

2.7 Physical signs

Before and after treatment, the finger to ground distance, thoracic mobility and Schober test of the patients in the two groups were evaluated respectively. ① Finger to ground distance: the shortest distance between the fingers and the ground was measured when the patient's knees were upright and the upper body was bent downward as far as possible. ② Thoracic mobility: the patient was upright and his hands were naturally drooping, and the soft ruler was placed at the fourth intercostal space to measure the chest circumference difference of deep exhalation and inhalation, and repeated the measurement twice, and the average of the two results was taken as the thoracic mobility; ③ Schober test (15): the patient was upright, marked as 0 at the posterior iliac crest of the midline of the back, and marked at 5 cm below and 10 cm above. When the patient's knees were upright and the upper body was bent downward as far as possible, the separation between the two markers was measured, and smaller separation indicated the lower the activity of the patient's lumbar spine.

2.8 Adverse reactions

During the treatment, the occurrence of adverse reactions was recorded for both groups.

2.9 Statistical analysis

SPSS 20.0 was used for statistical analysis. The count data were compared by χ^2 test, the rank sum test was used for grade data, the mean ± standard deviation ($\bar{x}\pm s$) was used for measurement data, and the comparison was performed using t test, $P<0.05$ was considered as the difference with statistical significance.

3. Results

3.1 Warming Yang and strengthening the muscle formula increased the total effective rate of AS patients treated with acupoint sticking

After treatment, the total effective rate was 86.67% in the observation group and 66.67% in the control group. Compared with the control group, the total effective rate in the observation group was significantly higher ($P<0.05$), as shown in Table 2.

Table 1 Comparison of general data between the two groups

Group	Cases	Age (years)	Gender (cases)		Course of disease (years)	Pathological staging (cases)		
			Male	Female		Ⅱ	Ⅲ	Ⅳ
Control group	45	36.33±6.23	28	17	6.88±1.85	15	20	10
Observation group	45	35.71±5.89	25	20	6.72±1.79	13	23	9
$\chi^2/t/Z$		0.485	0.135		0.417	-0.175		
P		0.629	0.713		0.678	0.861		

Table 2 Comparison of the efficacy of TCM syndromes between the two groups [Cases (%)]

Group	Cases	Clinical remission	Markedly effective	Effective	Ineffective	Total effective rate
Control group	45	7（15.56）	10（22.22）	13（28.89）	15（33.33）	30（66.67）
Observation group	45	10（22.22）	17（37.78）	12（26.67）	6（13.33）	39（86.67）
χ^2						5.031
P						0.025

3.2 Warming Yang and strengthening the muscle formula decreased the BASDAI, BASFI and VAS scores of AS patients treated with acupoint sticking

Before treatment, there was no significant difference in BASDAI, BASFI and VAS scores between the two groups (P>0.05). After treatment, BASDAI, BASFI and VAS scores in the two groups were significantly lower than those before treatment (P<0.05), and the scores in the observation group were significantly lower than those in the control group (P<0.05), as shown in Table 3.

3.3 Warming Yang and strengthening the muscle formula combined with acupoint sticking improved the spinal mobility and reduced the spine pain of AS patients

Before treatment, there was no significant difference in finger to ground distance, thoracic mobility and Schober test between the two groups (P>0.05). After treatment, the finger to ground distances in the two groups was significantly lower than those before treatment (P<0.05), and the finger to ground distance in the observation group was significantly lower than that in the control group (P<0.05). After treatment, thoracic mobility and Schober test in the two groups were significantly higher than those before treatment (P<0.05), and thoracic mobility and Schober test in the observation group were significantly higher than those in the control group (P<0.05), see Table 4.

3.4 Warming Yang and strengthening the muscle formula combined with acupoint sticking alleviated the inflammatory reaction in AS patients

Before treatment, there was no significant difference in ESR, CRP and TNF-α levels between the two groups (P>0.05). After treatment, ESR, CRP and TNF-α levels in the two groups were significantly lower than those before treatment (P<0.05), and the levels in the observation group were significantly lower than those in the control group (P<0.05), as shown in Table 5.

3.5 Combined treatment of warming Yang and strengthening the muscle formula with acupoint sticking showed certain safety in the treatment of AS patients

After treatment, the incidence of adverse reactions in the observation group was 8.89%, and that in the control group was 11.11%. There was no significant difference in the incidence of adverse reactions between the two groups (P>0.05), as shown in Table 6.

Table 3 Comparison of BASDAI, BASFI and VAS scores between the two groups before and after treatment [$\bar{x}$±s, points]

Group	Cases	BASDAI		BASFI		VAS	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	45	5.83±1.23	3.42±0.93*	5.75±1.31	3.21±1.01*	6.25±1.39	3.31±1.21*
Observation group	45	5.97±1.51	2.78±0.88*	5.61±1.13	2.47±0.78*	5.99±1.26	2.75±0.94*
t		-0.482	3.353	0.543	3.890	0.930	2.452
P		0.631	0.001	0.589	<0.001	0.355	0.016

Note: compared with before treatment: *P<0.05.

Table 4 Comparison of physical signs between the two groups before and after treatment [$\bar{x}$±s, cm]

Group	Cases	Finger to ground distance		Thoracic mobility		Schober test	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control	45	23.83±5.23	18.42±3.93*	3.25±1.11	4.31±1.01*	3.25±1.39	4.31±1.21*

group							
Observation group	45	22.97±5.51	10.78±2.88*	3.11±0.93	4.97±1.08*	3.15±1.26	5.05±1.24*
t		0.759	10.519	0.649	-2.994	0.358	3.966
P		0.450	<0.001	0.518	0.004	0.722	<0.001

Note: compared with before treatment: $^{*}P<0.05$.

Table 5 Comparison of serum indicators between the two groups before and after treatment [$\bar{x}\pm s$]

Group	Cases	ESR (mm/h)		CRP (mg/L)		TNF-α (ng/L)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	45	47.83±9.23	31.42±6.93*	24.75±10.11	17.31±8.01*	153.25±17.39	124.31±13.21*
Observation group	45	46.97±9.51	22.78±4.88*	22.61±9.93	12.97±7.08*	152.15±16.26	95.05±11.24*
t		0.435	6.838	-1.013	2.723	0.310	11.316
P		0.664	<0.001	0.314	0.008	0.757	<0.001

Note: compared with before treatment: $^{*}P<0.05$.

Table 6 Comparison of adverse reactions between the two groups [cases (%)]

Group	Cases	Nausea and vomiting	Diarrhea	Indigestion	Abnormal liver function	Total incidence
Control group	45	2 (4.44)	1 (2.22)	1 (2.22)	1 (2.22)	5 (11.11)
Observation group	45	2 (4.44)	1 (2.22)	1 (2.22)	0 (0.00)	4 (8.89)
χ^2						0.123
P						0.725

4. Discussion

In this study, the self-made resolving phlegm and promoting blood circulation acupoint sticking prescription was composed of *Radix Paeoniae lactiflora,* peach kernel, *bile arisaema*, *Bombyx batryticatus* and *semen brassicae*, in which *Radix Paeoniae lactiflora* and peach kernel have the efficacy of activating blood circulation and eliminating stasis (16). *Bile arisaema* have the efficacy of clearing heat and resolving phlegm (17). *Bombyx batryticatus* could resolve phlegm and disperse stasis, dispel wind and relieve spasm (18). *Semen brassicae* could eliminate stagnation to activate meridians (19). The application of all kinds of drugs to Pishu, Geshu and Shenshu acupoints could strengthen the spleen and stomach, promote blood circulation and clear blood stasis, remove phlegm and disperse stagnation; the application of all kinds of drugs to Yanglingquan acupoint has the effect of relaxing muscles and activating collaterals, relieving spasm and tonifying Yang. In addition, warming Yang and strengthening the muscle formula is composed of paeony, fried *dipsacus asper*, *Ramulus Cinnamomi*, *Semen Cuscutae*, *Radix Cyathulae*, *Rhizoma cibotii*, peach kernel, prepared *rehmannia glutinosa*, *Psoralea corylifolia*, *Chinses angelica*, *Cornus officinalis*, and fried *Cortex eucommia*. Among them, paeony has the effects of softening liver and relieving pain, calming liver-Yang, nourishing blood and regulating menstruation (20). Fried *dipsacus asper* has the

effects of tonifying the liver and kidney, strengthening the muscle and bones, promoting the concrescence of fracture and regulating the blood vessels (21). *Ramulus Cinnamomi* has the effect of dispersing cold and relieving pain, activating Yang and promoting the activity of Qi (22). *Semen Cuscutae* has the effect of tonifying liver and kidney (23). *Radix Cyathulae* has the effect of promoting blood circulation and removing blood stasis, dispelling wind and removing dampness (24). *Rhizoma cibotii* has the effect of strengthening waist and knee, expelling wind and dampness, tonifying liver and kidney (25). Prepared *rehmannia glutinosa* has the effect of tonifying essence and filling marrow, nourishing blood and moistening (26). All kinds of herbs are used together here, which can disperse blood stasis and remove pathogenic factors, activate blood circulation and relieve pain, expel cold and warm kidney. In this study, after treatment, BASDAI, BASFI, VAS scores, finger to ground distance in the two groups were significantly lower than those before treatment, while thoracic mobility, Schober test were significantly higher than those before treatment, and the above indicators in the observation group were better than those in the control group. Meanwhile, the total effective rate in the observation group was significantly higher than that in the control group, which indicated that warming Yang and strengthening the muscle formula combined with acupoint sticking had significant effect on patients with AS, could effectively improve the spinal mobility of the patients and reduce the pain of the spine.

Studies have shown that inflammatory factors are closely related to the occurrence and development of AS (27). ESR is a common indicator that can reflect the degree of erythrocyte aggregation in the body, and its level rises when there is an inflammatory reaction inside the body (28). CRP is an acute phase response protein, and its level rises as the body tissue damage and inflammatory reaction exacerbates (29). TNF-α is secreted by macrophages and T lymphocytes and can act on osteocytes and fibrocytes and participate in the process of joint stiffness (30). After treatment, the levels of ESR, CRP, TNF-α in the two groups were significantly lower than those before treatment, and the levels in the observation group was significantly lower than those in the control group, indicating that warming Yang and strengthening the muscle formula combined with acupoint sticking can effectively reduce the inflammatory reaction in patients with AS with good efficacy. Modern pharmacology has found that medicines such as *Radix Paeoniae lactiflora*, peach kernel, *bile arisaema*, and *semen brassicae* from the self-made resolving phlegm and promoting blood circulation acupoint sticking prescription have an anti-inflammatory utility, and the application of these medicines to Yanglingquan acupoint can inhibit inflammatory factor expression and attenuate the body's inflammatory response. According to a study by Wei Fan et al. (31), the acupuncture at Yanglingquan acupoint could significantly reduce the expression of serum TNF-α, interleukin-6 (IL-6) and other inflammatory factors in rats, regulate the body's immune function, and promote cartilage repair, which in turn achieves a better efficacy. Meanwhile, according to modern pharmacology, total glucosides of paeony has been shown to down-regulate κ-light chain enhancing protein expression of nuclear factor κB (NF-κB) cells, which in turn can inhibit the expressions of inflammatory factors such as TNF-α and CRP in chondrocytes and alleviate inflammation in the body (32). The volatile oil of *Ramulus Cinnamomi* and cinnamaldehyde can inhibit the expression of toll like receptor (TLR) and intervene in the NF-κB signaling pathway, exerting a strong anti-inflammatory utility (33). The water decoction with peach kernel can reduce the levels of inflammatory factors such as TNF-α and enhance immune function of the body. Flavonoids in *Semen Cuscutae* have pharmacological effects such as free radical scavenging, antioxidant, and anti-inflammatory (34). *Radix Cyathulae* can participate in the generation and regulation of immune active cells and alleviate the local infiltration of inflammatory cells in the body, and then exert immune enhancing effects (24). Compared with these previous studies, the novelty of this study lies in that we discovered the combined treatment of warming

Yang and strengthening the muscle formula with acupoint sticking inhibiting the inflammation in AS patients through lowering the levels of inflammatory factors (ESR, CRP and TNF-α). In addition, the results of this study showed that there was no significant difference in the incidence of adverse effects between the two groups, suggesting that warming Yang and strengthening the muscle formula combined with acupoint sticking has a certain safety and feasibility for the treatment of patients with AS.

5. Conclusion

The combination of warming Yang and strengthening the muscle formula and acupoint sticking has a significant effect in the treatment of AS patients, which can effectively improve spinal mobility, alleviate spinal pain in patients, and reduce the levels of body inflammatory factors.

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Conflict of interest

The authors declare no conflict of interest.

Author contributions

Conceptualization, Z. J. L.; Data curation, Q. W.; Formal analysis, Z. J. L. and Q. W.; Methodology, Q. W.; Writing-original draft, Z. J. L.; Writing-review and editing, Z. J. L. and Q. W.; All authors have read and agreed to the published version of the manuscript.

Ethical Approval and Consent to Participate

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Availability of Data and Materials

The data presented in this study are availability on request from the corresponding author.

Supplementary material

Not applicable.

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