

## CLINICAL STUDY

## Effect of a Traditional Chinese Medicine combined therapy on adolescent idiopathic scoliosis: a randomized controlled trial

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### Abstract

**OBJECTIVE:** To evaluate the effectiveness of a combined Traditional Chinese Medicine (TCM) therapy versus conventional treatment on adolescent idiopathic scoliosis.

**METHODS:** One hundred twenty outpatients with mild and moderate adolescent idiopathic scoliosis were randomly divided into a TCM group (TCMG) and a brace group (CG). TCMG patients underwent Daoyin, Tuina, and acupotomy therapies. CG patients were treated with a Milwaukee brace. Each patient's Cobb angle was measured after 12 and 24 months of treatment, and pulmonary function was determined after 12 months of treatment. Average electromyogram (AEMG) ratio of the surface electromyogram was measured after 6 and 12 months of treatment and followed-up after 18 and 24 months.

**RESULTS:** The Cobb angle significantly decreased in both groups after 12 months of treatment compared with before treatment ( $P < 0.05$ ). The percentages of original Cobb angle in TCMG and CG were 51.4% and 47.8% ( $P > 0.05$ ) after 12 months and 62.5% and 34.7% ( $P < 0.05$ ) after 24 months, respectively. Pulmonary function significantly improved after 12 months in TCMG ( $P < 0.05$ ) but significantly decreased in CG ( $P < 0.05$ ). The AEMG ratio was significantly lower ( $P < 0.01$ ) and tended to remain at 1 after stopping treatment in TCMG, but increased in CG ( $P < 0.05$ ).

**CONCLUSION:** TCM combined therapy can prevent the progression of scoliosis. The AEMG ratio is a promising index that could replace radiography in the evaluation of treatment effect and progression in scoliosis.

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**Key words:** Medicine, Chinese traditional; Scoliosis; Adolescent; Electromyography; Treatment outcome; Respiratory function tests; Randomized controlled trial

### INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is the fifth most common developmental disease in adolescents after myopia, mental health, obesity, and phimosis, and AIS is one of the most common spinal deformities.<sup>1</sup> Early assessment and treatment is important to avoid rapid aggravation in adolescence with resultant heart and lung dysfunction, or weakness and paralysis of the lower limbs. AIS has a serious impact on patient physiolo-

gy and psychology, and early alleviation or prevention is essential to reduce the need for orthopedic interventions.<sup>2,3</sup> At present, the use of a brace in patients with mild or moderate AIS is generally considered an acceptable and effective intervention in Europe and America.<sup>4,5</sup> However, poor compliance is a factor for its poor outcomes. Furthermore, the long-term effects and surgical rate reduction of the brace are controversial. During evaluation of the scoliosis progression with the brace, repeated radiography is required and may be harmful to the patients.<sup>6,7</sup> In addition, studies have indicated adverse effects of long-term brace use, including diminished quality of life, development problems, and physiological and pulmonary effects.<sup>8,9</sup> Based on the Traditional Chinese Medicine (TCM) theories of "association of activity and inertia" and "balance of *Yin* and *Yang*,"<sup>10</sup> and previous findings that the convex/concave average electromyogram (AEMG) ratio in AIS is positively correlated with the Cobb angle,<sup>11,12</sup> we proposed a combined therapy including Daoyin, Tuina, and acupotomology. This treatment aimed to address the muscular imbalance between scoliosis sides and spinal disorder.<sup>13-15</sup> Compared with the brace method, this therapy emphasizes patient activeness, neither affecting daily life nor having adverse effects on physical and psychological development.<sup>16</sup> Furthermore, this treatment was more available and patients were more willing to accept it.

## MATERIALS AND METHODS

### *Setting and design*

Patients were diagnosed with AIS at the Tuina Department of Zhejiang provincial hospital of TCM from January 2008 through May 2011. One hundred twenty outpatients were recruited in this 24-month study. Patients were randomly divided into the TCM combined therapy group (Daoyin, Tuina, and acupotomology) (TCMG;  $n = 60$ ) or into the brace group (CG;  $n = 60$ ) using the SAS 6.0 program (SAS, Inc., Cary, NC, USA). The study was approved by the Ethics Committee of the First Clinical Medicine College of Zhejiang University of TCM. Each patient and guardian signed an informed consent form. The general characteristics of the two groups are shown in Table 1.

### *Inclusion criteria*

Patients were included according to the following Scoliosis Research Society (SRS) criteria:<sup>17</sup> (a) age,  $\geq 10$  years; (b) Risser sign, 0-2; (c) Cobb angle, 20-40°; (d) initial diagnosis with no previous treatment; and (e) premenarche or within 1 year of menarche onset in female patients selected for treatment with a brace.

### *Exclusion criteria*

Patients were excluded according to the following criteria: (a) scoliosis with a definite pathology; (b) concu-

rent serious diseases such as: cardiovascular disease, liver, or kidney diseases; hematopoietic disorders; and mental illness; (c) thrombocytopenia, coagulopathy, or bleeding tendency; or (d) concern or doubt about treatment.

### *Interventions*

The TCMG received Daoyin, Tuina, and acupotomology. Daoyin spinal balance exercises are selected from ancient Chinese traditional health preserving methods, the purpose is to make soft tissue (*jin*) stronger and retain body's balance, moves include Anmoyaoyan, Fengbaiheye, Zhuanshentuibe, Zhangchahuashan, Zaixinghuandou, Baimafengzong, and Fenghuangshunci from "YiJin Jing."<sup>18</sup> Doctors taught the patients the exercises, which were carried out for 40 min twice a day by each patient until skeletal maturity. Tuina spinal balance was completed by a specialist. First, rolling, kneading, and digital-pressing manipulations were carried out on the Du channel (GV) and both sides of the Bladder channels (BL). Second, pushing and pulling of successive muscle and spinous processes were applied from the convex side toward the concave side for 5 min. Third, with the patient in the prone position, pressure was applied with one palm on Mingmen (GV 4) while the other hand pulled the patient's shoulder to bring the hands together for about 1 min, thereby extending the spine as far as possible. This was repeated 3-5 times. The whole procedure took 20-25 min and was repeated twice a week for 12 months. For acupotomology, Zhu Hanzhang's type II knife was used to release and dredge the soft tissues of the concave side and the convex side and cross the contracture band in compensatory scoliosis to remove the scoliosis pathological structures. Successive sites included the lumbodorsal fascia ligament, thoracolumbar junction ligament, and soft tissue around the neck, thoracic facet, and adhesions due to scarring. This was performed once a week, with release at 5 to 7 points, for ten treatments. Daoyin and Tuina were suspended for 3 days after each acupotomology treatment.

Patients in CG wore a Milwaukee brace for at least 22 h every day, allowing for 2 h for skin care and breathing exercises to maintain the body's flexibility. A course of treatment was 12 months. Spine radiographs were taken with and without the brace in the standing position every 3 months, and the Cobb angle was recorded. According to the progression of scoliosis, the ring and cushion positions of the brace were adjusted at the appropriate time. Furthermore, the doctor counseled patients to give confidence to overcome the disease and stress the importance of standard wear to help ensure completion of the entire treatment course.

### *Main outcome measurements*

A Nicolet evoked-potential instrument (produced by Nicolet Corporation, 525 West Monroe Street, Suite 1900, Chicago in USA) was used to detect changes in

surface electromyogram (sEMG) on each side of the convex/concave muscle before treatment and after 6, 12, 18, and 24 months of treatment. Readings were collected at room temperature, without strenuous physical activity for 24 h before the experiment. Patients were positioned in the prone position with arms relaxed on either side of the trunk. Electrodes labeled as 1 and 3, and 2 and 4, were attached 2 cm from the midline of the top of the lateral bending arc and the bottom of the lateral bending arc, respectively, for "C" shape scoliosis. For "S" shape scoliosis the electrodes were attached 2 cm from the midline of the top of the maximum lateral bending arc and the top of the minimum lateral bending arc, respectively. Four leads of sEMG signals were recorded in each patient. Then, the Biering-Sorensen test (BST) was performed. In this test, the lower part of the body is fixed with 3 straps to the examination bed, and the upper body is forced back to the maximum and held for as long as tolerated by the patient. sEMG signals were recorded throughout the test. Signals were transferred into MegaWin2.3 signal processing software, processed, and the average electromyogram (AEMG) was extracted to obtain the convex/concave AEMG ratio.

The Cobb angle was measured before treatment and after 12 months of treatment.

Lung function parameters including vital capacity (VC), forced expiratory volume in the first second percentage of forced vital capacity (FEV<sub>1</sub>/FVC), and maximal ventilation volume per minute (MVV) were measured before treatment and after 12 months of treatment.

Blood pressure, heart rate, and respiratory rate were monitored during treatment, and any adverse reactions such as fracture, dislocation, syncope, and hemorrhage were recorded.

### Statistical analyses

Data and changes in the disease were recorded in Excel (Microsoft, Redmond, WA, USA) and observation data were expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ). Statistical analysis was performed with SPSS 13.0 version (SPSS Inc., Chicago, IL, USA). Comparisons before and after treatment within each group were carried out with a paired *t*-test. Differences between groups were tested by *t*-test. A *P*-value of less than 0.05 was considered significant.

## RESULTS

In TCMG, 58 patients (96.7%) completed the treatment and follow-up, and two were lost to follow-up. In CG, 49 patients (81.7%) completed the treatment, and 11 were lost to follow-up. There was a significant difference between the groups ( $P < 0.05$ ), which suggested that TCMG had better compliance than that of CG (Figure 1).

There were significant improvements in the correction percentage of the Cobb angle after 12 months in both groups ( $P < 0.05$ , Table 2). No significant difference was observed between the two groups at 12 months ( $P > 0.05$ ). After 24 months, the angle was 62.5% in TCMG and 34.7% in CG that of the original angle ( $P < 0.05$ , Table 2).

There was a significant reduction in AEMG ratio, which tended to remain at 1 in TCMG after 6, 12, 18, and 24 months of treatment ( $P < 0.05$ , Figure 2). In contrast, the AEMG ratio significantly increased in CG ( $P < 0.05$ ). These results suggest that the imbalances in muscle tension from scoliosis improved with the combined therapy and tended to remain balanced even if treatment was stopped. The muscle imbalance in CG was aggravated, which could result in further development of scoliosis.

Pulmonary function improved significantly in TCMG ( $P < 0.05$ , Table 3) after 12 months of treatment, while pulmonary function diminished in CG ( $P < 0.05$ ) because of limitations caused by the brace to lung development. No adverse reactions were found in either group.

## DISCUSSION

TCM combined therapy can significantly decrease the Cobb angle, partially correct scoliosis, and can improve the muscle imbalances on either side of scoliosis. This therapy also showed good compliance and safety.

Clinical studies have found that use of a brace can effectively prevent scoliosis progression.<sup>19</sup> However, a brace requires timely adjustment according to improvement or aggravation and spinal radiography every 3 months until skeletal maturity.<sup>20</sup> Radiation exposure several times a year at long exposure times poses inevitable health risks, particularly in growing children. It was previously found that the convex/concave AEMG ratio was positively correlated with the Cobb angle.<sup>21-22</sup> The "bowstring effect" caused by asymmetrical muscle strength on either side of scoliosis is the leading factor in scoliosis progression. We observed a correlation between the AEMG ratio and Cobb angle, indicating a new evaluation strategy for the progression and curative effect of scoliosis.

Braces have been used in mild to moderate AIS treatment for nearly half a century. However, there is increasing concern about adverse consequences from the long-term fixed position, including muscle stiffness that can aggravate symptoms, problems with thoracic development, declines in pulmonary function, and loss of bone mass.<sup>23,24</sup> The majority of patients experience self-consciousness, physical discomfort, and other social pressures.<sup>25</sup> The treatment principles of TCM in orthopedics and trauma emphasizes the "association of activity and inertia" and "laying equal stress on Jin and bones."<sup>11,26,27</sup> In this study, the TCM treatment encour-

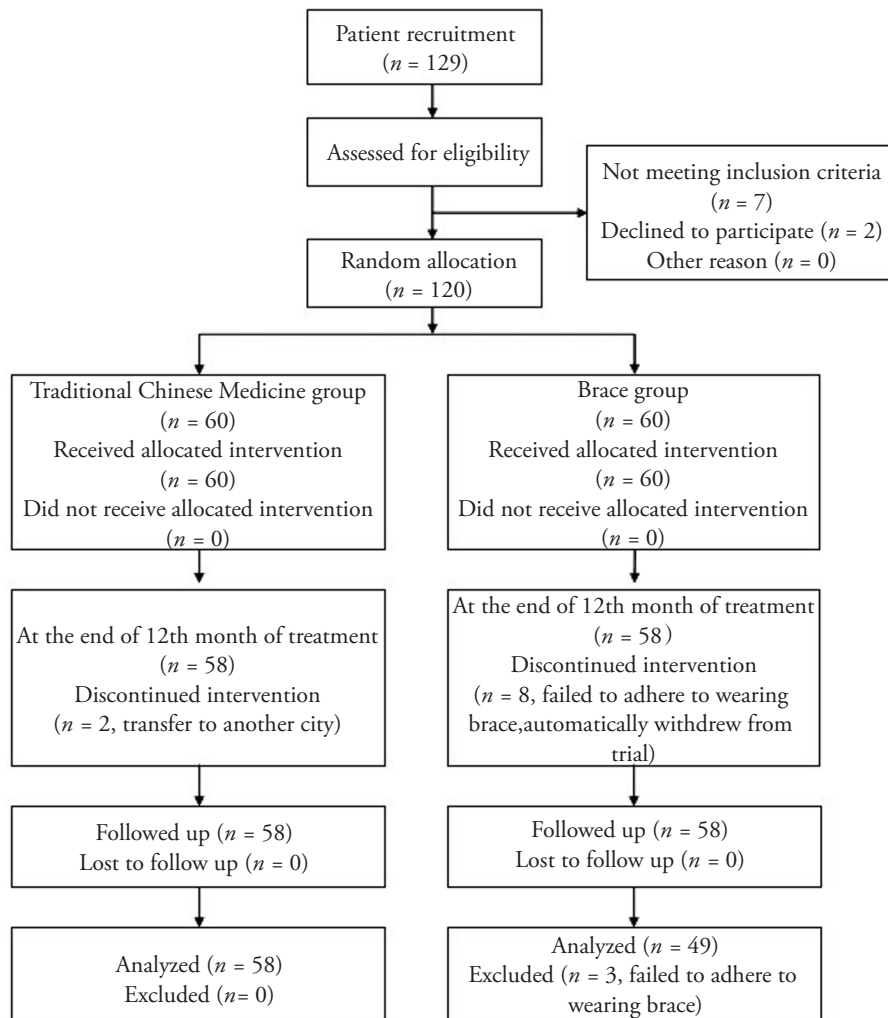


Figure 1 Flow chart of study

Table 1 General data of both groups ( $\bar{x} \pm s$ )

Group	n	Male (n)	Female (n)	Age (years)	Cobb angle (°)
TCMG	58	18	40	9.1±0.4	30.4±3.7
CG	49	10	39	8.9±0.6	31.5±3.2

Notes: TCMG: Traditional Chinese Medicine group, treated with Daoyin, Tuina, and acupotomy for 12 months; CG: control group, treated with brace for 12 months. There were no significant differences in sex, age, or Cobb angle between TCMG and CG ( $P > 0.05$ ).

Table 2 Changes in correction angle and percentage of Cobb angle before and after 12 and 24 months of treatment ( $^{\circ}, \bar{x} \pm s$ )

Group	n	Before treatment	After 12 months' treatment		After 24 months' treatment	
			Angle	Percentage	Angle	Percentage
TCMG	58	30.4±3.8	10.2±2.2	51.4 <sup>a</sup>	12.0±2.5	62.5 <sup>b</sup>
CG	49	31.6±3.1	9.0±2.0	47.8	7.9±0.8	34.7 <sup>c</sup>

Notes: TCMG: Traditional Chinese Medicine group, treated with Daoyin, Tuina, and acupotomy for 12 months; CG: control group, treated with brace for 12 months. <sup>a</sup> $P > 0.05$ , compared with CG; <sup>b</sup> $P < 0.05$ , <sup>c</sup> $P < 0.05$ , compared with 12 months' treatment.

aged spinal movement and exercise. We found improved pulmonary function and AEMG ratios, which suggested that TCM combined therapy can not only avoid adverse consequences of treatment with a brace, but also yield superior results.

It is difficult to provide effective braces for parents and children with scoliosis, and many patients delay brace treatment or do not maintain the correction.<sup>28</sup> Therefore, children who have clinical scoliosis may still re-

quire surgery despite effective control with a brace. According to our results in clinical follow-up, steady improvements in the Cobb angle and improved balance reflected by the AEMG ratio indicated that management of reversible scoliosis with a conservative approach using TCM therapies is promising. Moreover, the therapy is simple and more cost effective than the conventional brace treatment.

The present study demonstrated that TCM combined

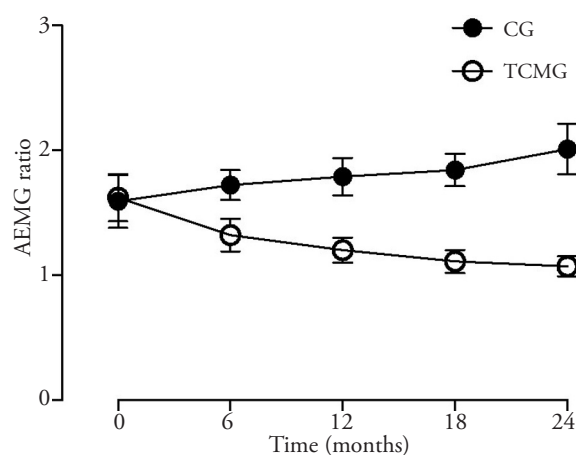


Figure 2 Changes in AEMG ratio before and after 6 and 12 months' treatment and at follow-up after 18 and 24 months CMG: Traditional Chinese Medicine group, treated with Daoyin, Tuina, and acupotomology for 12 months; CG: control group, treated with brace for 12 months. AEMG: average electromyogram.

therapy is effective and safe for AIS treatment. The therapy can continuously ameliorate muscle imbalances in scoliosis, maintain steady improvements in Cobb angle, and improve pulmonary function.

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Table 3 Changes in pulmonary function before and after 12 months' treatment ( $\bar{x} \pm s$ )

Item	TCMG (n = 58)		CG (n = 49)	
	Before treatment	After treatment	Before treatment	After treatment
VC (mL)	90±9	93±10 <sup>a</sup>	90±9	87±8 <sup>a</sup>
FEV <sub>1</sub> /FVC	89±7	93±7 <sup>a</sup>	90±7	88±6 <sup>a</sup>
MVV (mL)	73±10	76±11 <sup>a</sup>	72±10	69±8 <sup>a</sup>

Notes: TCMG: Traditional Chinese Medicine group, treated with Daoyin, Tuina, and acupotomology for 12 months; CG: control group, treated with brace for 12 months. VC: vital capacity; FEV<sub>1</sub>/FVC: forced expiratory volume in the first second percentage of forced vital capacity; MVV: maximal ventilation volume per minute. <sup>a</sup>P < 0.05, compared with before treatment.

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