

CLINICAL STUDY

Efficacy evaluation of summer acupoint application treatment on asthma patients: a two-year follow-up clinical study

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fill out a questionnaire evaluating asthma degree, exacerbation frequency, concomitant medications and self-satisfaction. The self-rate and doctor-report outcomes obtained in parallel were evaluated to assess the efficacy of SAAT.

RESULTS: A total of 527 asthma patients were initially enrolled in this study, of which 97 elderly patients and those with more severe cases of asthma were lost to follow-up. Thus, a total of 430 patients were valid for analysis using self-rate data. Nevertheless, occasional negative returns were obtained; almost all of the outcomes were rated as "No change", "Moderate effective", or "Very effective". In addition, 80% of the patients were satisfied with this treatment. Moreover, 391 (91.4%) patients were somewhat improved after SAAT in 2009, and further improvement was observed in 2010. After SAAT, the average asthma-degree score decreased from 5.3 in 2008 to 4 in 2009 and, subsequently to 3.5 in 2010.**CONCLUSION:** With pronounced patient satisfaction, SAAT can reduce the exacerbation severity and frequency, concomitant medications and asthma degree. Prolonging the treatment course might enhance the efficacy of SAAT.

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Key words: Acupoint sticking therapy; Quality of Life; Self efficacy; Asthma; Chinese medicine, traditional**INTRODUCTION**

Asthma is one of the most prevalent diseases, affecting

as many as 300 million people and accounting for approximately 250 000 annual deaths worldwide.¹ Despite improvements in the quality of care, there is no overall global downward trend in the prevalence of asthma.² The number of asthmatic patients was estimated to increase by 100 million individuals by 2025.¹ In the United States, the prevalence of asthma was 8.5% of the population in 2012,³ and both the period prevalence and the current prevalence of asthma have consistently increased during the last decade.⁴ The prevalence of asthma in China is much lower than that in Western countries and varies between different regions in the country.⁵ In large cities, the asthma prevalence is 11 percent and rising.⁶ A literature survey indicated that the current average prevalence of asthma for children in China had increased from 0.9% in 1990 to 1.5% in 2000.⁷ It was also estimated that the rates of asthma prevalence have increased as much as 40 percent over the last five years in China.⁶

Asthma affects the lives of patients and their families, including their quality of life, productivity at work and school, and health care use, and this disease can even result in death. An estimated 15 million disability-adjusted life years have been lost per year worldwide due to asthma.¹ Treating patients with severe asthma would be a heavy burden on healthcare resources and economics. For instance, the financial burden on patients with asthma in different Western countries ranges from \$300 to \$1300 per patient per year.⁸ In 2007, in the United States, the total incremental cost of asthma to society was \$56 billion, where the productivity losses due to morbidity and mortality accounted for \$3.8 and \$2.1 billion, respectively.⁹ Prescription drugs have typically been used to treat chronic pulmonary disease, potentially creating heavy economic burden for asthmatic patients. This burden is particularly heavy in developing countries due to limited health care. Complementary treatment methods have emerged due to their lower cost and lighter side effects. Several complementary treatment methods have been developed, such as acupuncture, moxibustion (direct and indirect), herbal remedies, inspiratory muscle training, and massage and chiropractic therapy. In China, acupuncture and moxibustion are the common treatment methods. Summer acupoint application treatment (SAAT), also known as Sanfujiu¹⁰ is one type of direct moxibustion administered in the summer through the direct application of an irritating herbal paste to acupuncture points.¹¹ Unlike normal direct moxibustion, SAAT substitutes the use of moxa with herbal paste during disease treatment. Several clinical studies have shown a favorable effect of SAAT for asthma.¹² Due to the cheap price and fast and convenient application, SAAT has been extensively used in Chinese hospitals and clinics. More importantly, there is almost no risk of burns for patients with SAAT compared with other moxibustion treatments.

Despite the extensive use of SAAT on asthmatic patients in China, the therapeutic effects of SAAT remains insufficiently understood. Thus, we conducted a clinical observation study with a two-year follow-up.

MATERIALS AND METHODS

Study population

We conducted a two-year follow-up study based on patients from 3 clinical centers in China. They were Guang'anmen Hospital, China Academy of Chinese Medical Science (Beijing), The First Hospital of Hunan University of Chinese Medicine (Changsha, Hunan), The Second Hospital of Anhui University of Chinese Medicine (Hefei, Anhui). Patients diagnosed with asthma according to previously established guidelines¹³ were consecutively recruited during July 19th to August 18th in 2008. We excluded patients (a) aged < 2 years; (b) during pregnancy or lactation; (c) with allergies to the herb or accessories; (d) temperature ≥ 37.5 Celsius degree; (e) producing yellow and thick sputum; (f) exhibiting bronchiectasis, endobronchial tuberculosis, lung cancer, pulmonary fibrosis, and uncontrolled diabetes; or (g) previously diagnosed with severe heart, liver or kidney disease, mental disease, or cancer. A complete description of the patient selection criteria has been reported elsewhere.¹⁴ This study protocol (Registration No. ChiCTR-OCH-10001292), for all clinical centers, was approved through the Ethics Committees of the Institution of Basic Research in Clinical Medicine, China Academy of Chinese Medicine. Written informed consent was provided by each study participants or his/her guardian.

Treatment method

The patients were treated with SAAT at each clinic. The herbal pastes comprised approximately 35% Semen Baijizezi (*Semen Sinapis*), 10% Gansui (*Radix Kansui*), 25% Xixin (*Herba Asari Mandshurici*), and 30% Yanhusuo (*Rhizoma Corydalis Yanhusuo*). These herbs were ground into a powder, mixed and made into paste using old ginger juice. The resulting paste was cut into small cubes of 1 cm \times 1 cm in size and glued onto a medical tap for SAAT. For clinical treatment, the medical taps with herbal pastes were placed onto the selected acupuncture points, remaining at least 2 h. The standard acupoints included Feishu (BL 13) and Fengmen (BL 12), — the meridians named Taiyang Bladder Meridian of Foot.

Both Feishu (BL 13) and Fengmen (BL 12) are important acupoints in the pathway of the lung meridian. The appealing associations between Feishu (BL 13) and/or Fengmen (BL 12) with asthma have been previously reported.^{15,16} The treatments were conducted from July 19th to August 18th (3 times, 10 days per time), the hottest days in summer, according to the lunar calendar, in 2008, 2009 and 2010.

Data collection

The patients were enrolled and initially treated at the screening centers by well-trained doctors during the July 19th to August 18th in 2008. The information collected before treatment included age, gender, disease and treatment (SAAT) history. In subsequent (2009 and 2010), all patients were invited for return visits to receive continued treatment. An assessment of the efficacy of the last period treatment was obtained using synthetic indicators. Because neither active nor sham acupuncture treatments significantly affected pulmonary function, according to Choi *et al*¹⁷ using pulmonary function as a primary outcome would be inappropriate in clinical investigation. Instead, doctor-report outcomes were used in this study. At the return visits, the patients completed a questionnaire, assessing exacerbation severity and frequency, concomitant medications and self-satisfaction. After each treatment period, the outcomes were rated in five categories: "much worse", "worse", "no change", "moderate effective", and "very effective". The asthma degree was assessed using a visual analog scale, from 0 (mildest) to 10 (severest).¹⁸ The treatment procedure, follow-up and data collection are schematically illustrated in Figure 1.

Data analysis

Descriptive statistics were generated to examine the demographic and disease characteristics of the patients. Figures showing the changes in the severity, exacerbation frequency, concomitant medications and self-satisfaction were constructed. Differences between groups were tested using the *t* test or *Chi*-squared test, depend-

ing on the nature of the variables. $P < 0.05$ was considered statistically significant. The data were analyzed using the "epicalc" package of software R, version 2.12.1 (R Core Team, Vienna, Austria).

RESULTS

General description

A total of 527 asthma patients were initially enrolled in this study, of which 97 patients were lost to follow up. Thus, the 430 remaining patients were valid for analysis. Table 1 shows the demographic and clinical characteristics of the patients who completed the study and those patients who were lost to follow up. No significant differences were observed between sex, and disease and SAAT history in these two groups. In addition, the patients lost to follow up were older, with a lesser degree, severity and frequency of exacerbations than patients included in this study. A total of 245 (57.0%) study participants were female, with a mean [standard deviation (SD)] age of 43 (23) years. The participants exhibited a moderate disease condition at baseline, with a mean (SD) degree score of 5 (2). 246 (57.6%) patients were diagnosed with moderate severity of asthma, and 283 (66.9%) individuals reported less than one exacerbation per month, with a mean (SD) disease history of 11 (11) years. A total of 174 (48.2%) patients had received SAAT before this study.

Efficacy evaluation

Except for some individual negative returns, almost all

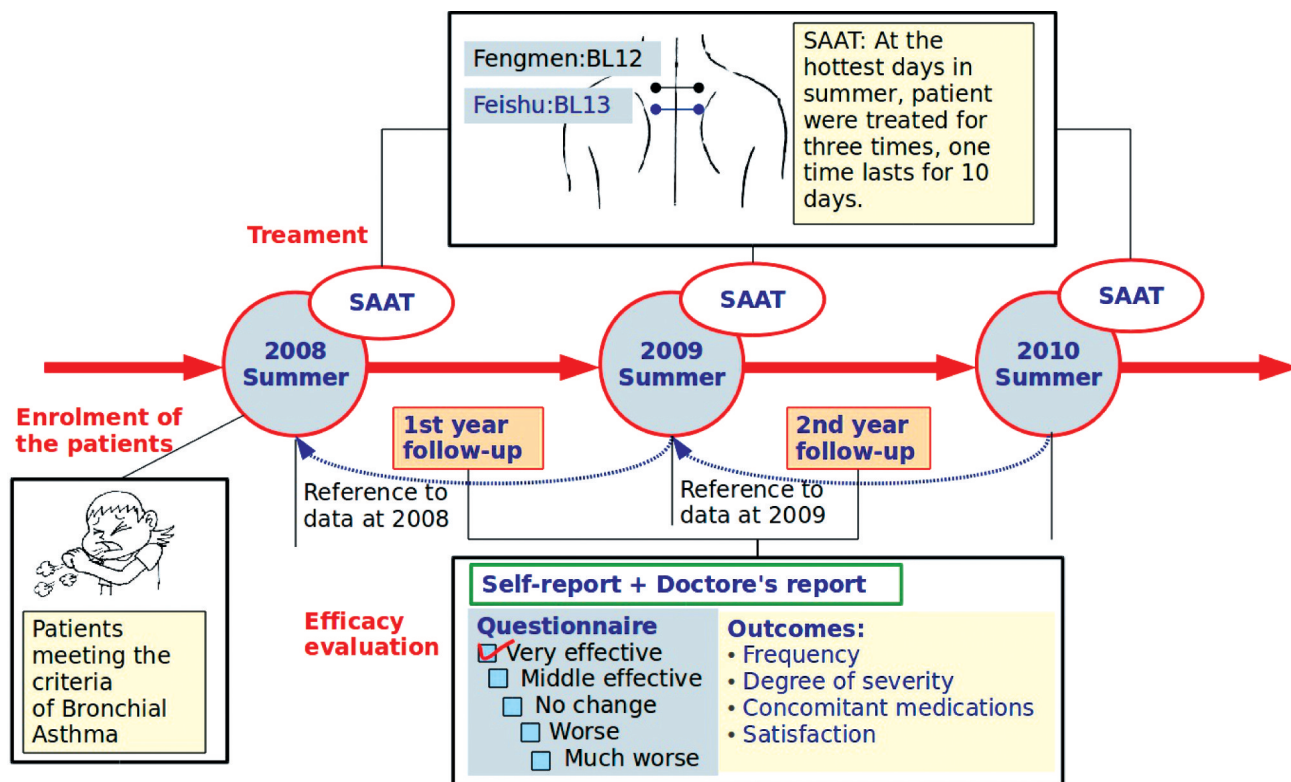


Figure 1 Procedure diagram of this study
SAAT: summer acupoint application treatment.

Table 1 Baseline characteristics of the patients

Characteristic	Completed flow up (<i>n</i> = 430)	Lost to follow up (<i>n</i> = 97)	<i>P</i> value ^a	
Sex (female) [<i>n</i> (%)]	245 (57.0)	59 (61.5)	0.579	
Mean (<i>SD</i>) age (years)	43 (23)	48 (19)	0.019	
Mean (<i>SD</i>) degree (scores)	5 (2)	4 (2)	< 0.001	
Severity of asthma [<i>n</i> (%)]	Mild	141 (33.0)	54 (55.7)	< 0.001
	Moderate	246 (57.6)	40 (41.2)	-
	Heavy	40 (9.4)	3 (3.1)	-
Mean (<i>SD</i>) disease history (years)	11 (11.1)	12 (11.6)	0.281	
Frequency of exacerbations [<i>n</i> (%)]	≤ 1 time/m	283 (66.9)	76 (80.0)	0.006
	2-3 times/m	75 (17.7)	16 (16.8)	-
	1-2 times/w	37 (8.7)	1 (1.1)	-
	≥ 3 times/w	28 (6.6)	2 (2.1)	-
SAAT history [<i>n</i> (%)]	174 (48.2)	39 (47.6)	1.000	

Notes: *SD*: standard deviation; m: month; w: week; SAAT: summer acupoint application treatment. ^aDifferences between two groups were tested using the χ^2 or *t* tests according to the nature of the variables.

of the outcomes were rated as "No change", "Moderate effective", "Very effective". These results suggest that the symptoms of asthma relief after SAAT, i.e., the severity and frequency of exacerbations, were reduced, and the concomitant medications were substantially reduced (Figure 2A-2C). In addition, 80% of the patients were more or less satisfied with this treatment (Figure 2D).

Moreover, 391 (91.4%) patients were somehow improved after SAAT in 2009, and further improvement (93%) was observed in 2010 according to the doctor-report outcome (Table 2). This result suggests that the efficacy of this treatment is enhanced with prolonged treatment time.

After SAAT, the average value for the asthma degree scores was substantially reduced from 5.2 ± 2.0 in 2008 to 4.0 ± 1.6 in 2009, and subsequently to 3.5 ± 1.3 in 2010. This result confirms the therapeutic efficacy of SAAT on asthma and the benefit of enduring treatment.

DISCUSSION

Asthma is a chronic respiratory disease characterized by episodes or attacks of impaired breathing. The inflammation and narrowing of small airways can cause shortness of breath, coughing, wheezing, chest pain, etc. Large efforts have been made to control and prevent the development of asthma. The well-established treatment of asthma includes the use of medication for short-term relief to decrease inflammation and avert attack and the daily use of preventive medication to control inflammation and airway hyperreactivity. In addition, doctors typically recommend the establishment of sufficient health care measures, such as monitoring early symptoms, avoiding factors that trigger attacks, and re-

moving risks. However, concomitant medications for morbidity and direct/indirect health care costs due to asthma continue to pose a high burden for patients and their families. The use of complementary and alternative treatment could provide an option to control the symptoms of asthma and lower the economic burden of health care and therapy. As a typical and conventional treatment method for pulmonary disease, SAAT has demonstrated promising effects.¹⁷⁻²⁶ Most clinical reports have suggested that SAAT substantially improves the life quality of patients. Yet the mechanisms of SAAT for the treatment of asthma remain elusive.

The action of hydrogel herbal paste used in SAAT on acupoint meridian can be triggered through the permeation of active medicines through the skin.²⁷ According to the Traditional Chinese Medicine theory, people with an imbalanced flow of energy (so called "Qi") along the meridians will suffer chronic pulmonary diseases, and the herbal paste in SAAT could regulate the flow of "Qi".^{28,29} The stimulation of a function-specific point [Fengmen (BL 12) and Feishu (BL 13)] for an organ might affect the meridian (lung meridian) associated with that organ through an enhancement of the flow of Qi. With functions to dredge and activate the lung meridian, the stimulation of Fengmen (BL 12) could regulate the flow of the meridian "Qi".¹⁶ The theory of energy flow within the meridian system has been explained in Western Medicine by the semiconducting properties of the skeletal and connective tissue systems.³⁰ Carneiro *et al*³¹ demonstrated the effect of asthma therapy on asthmatic rats through the stimulation of the acupoint Feishu (BL 13), showing that both lung inflammation and cellular inflammatory in the bronchoalveolar lavage was significantly reduced through acupoint stimulation. Ngai *et al*³² applied transcutaneous electrical nervous stimulation over Fei-

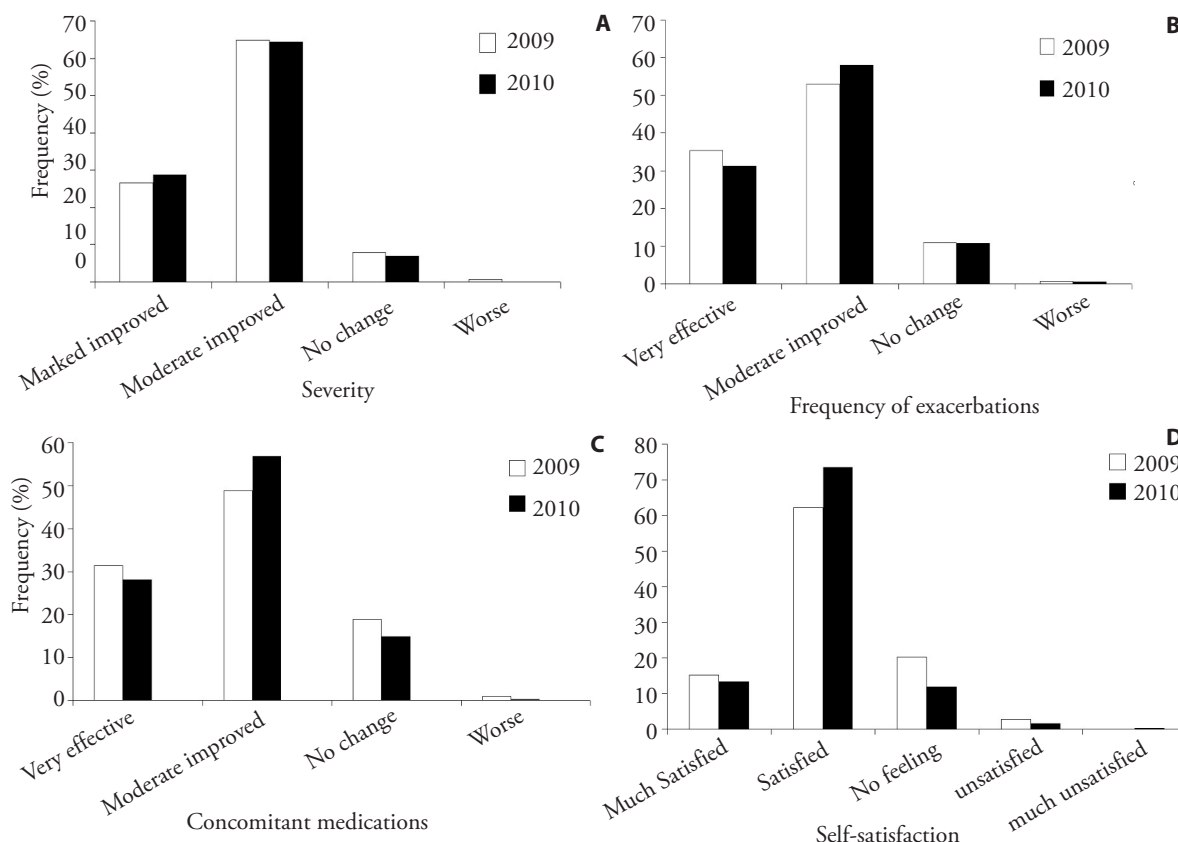


Figure 2 Changes in asthma conditions of the patients
 A: severity; B: frequency of exacerbations; C: concomitant medications; D: self-satisfaction.

Table 2 Crosstab of doctor report outcome in 2009 (Horizontal) and 2010 (Vertical) [n (%)]

Parameter	Very effective	Moderate effective	No change	Worse	Total
Very effective	91 (21.2)	29 (6.7)	3 (0.7)	0 (0.0)	123 (28.6)
Moderate effective	22 (5.1)	235 (54.7)	16 (3.7)	3 (0.7)	276 (64.2)
No change	2 (0.5)	14 (3.3)	15 (3.5)	0 (0.0)	31 (7.2)
Worse	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	115 (26.8)	278 (64.8)	34 (7.9)	3 (0.7)	430 (100.0)

shu (BL 13) and showed that this stimulation modifies the skin impedance of acupoints along a related meridian and likely modulates sympathovagal balance, as the stimulation of these points might impact nerve endings *via* ionic or electrical changes. In addition, stimulating meridian acupoints indicating nerve responses have also been directly evidenced through functional magnetic resonance imaging.³³ Ultrasonic imaging supports an association between acupoints, muscular connective tissue,³⁴ collagenous bands³⁵ and blood flow.³⁶ A study using laser Doppler flowmetry also demonstrated the strengthening of blood flow after acupoint stimulation, likely reflecting the activated circulation of tissue fluid inside the meridian.³⁷ In the neural hypothesis, the clinical influence of acupoint stimulation provides signals to the brain through sensory nerves, causing clinical changes associated with treatment.³⁸

From the point view of immunomodulation, acupoint stimulation might improve immunity. Numerous studies of general immune parameters (IgA, IgM, IgG and IgE, etc.) have shown a statistically significant enhance-

ment of immunity through SAAT.²¹ Significant changes in cytokine concentrations (e.g., IL-6 and IL-10, IL-8) under acupoint stimulation were also observed.³⁹ Drugs used for asthma treatment, such as steroids and b2-agonists, shift the balance of Th1/Th2 towards Th1.⁴⁰ The effect of restoring balance to the Th1/Th2 responses through acupoint stimulation has also been extensively reported.^{41,42}

However, numerous have suggested that the effects of real and/or sham acupoint treatment on pulmonary function in asthmatic patients remain insignificant.^{17,23,24} Randomized controlled trials (RCTs) on asthmatic patients using acu-TENS have also confirmed that there are no obvious effects on the improvement of pulmonary function,²⁵ while some clinical studies have reported the positive effect of acupoint treatment on pulmonary function in asthmatic patients.^{22,43} Literature surveying suggests that the treatment of stimulating acupoints, using needles, paste or acu-Tens, is a placebo. However, clinical observations from a large amount of patients in different hospitals in China have shown

that SAAT can certainly and remarkably improve the quality of life of patients.^{18,19,21} Moreover, the apparent efficacy of SAAT on patients with asthma is substantially high (> 80%, Table 3). Moreover, Chen *et al*⁴⁴ conducted a comparative study, showing that therapeutic effect of SAAT is superior to that of routine needle acupuncture (SAAT vs needle acupuncture: 94% vs 76%). More rigorous studies (i.e., RCTs, long time follow-up, pulmonary function tests) are needed to further understand the mechanisms and the factors that influence the therapeutic efficacy of SAAT.

Herein, we presented a two-year follow-up study to investigate the therapeutic effects of SAAT in 430 valid patients in China. Younger patients and those with more severe symptoms are more likely to complete a two-year or more treatment course. Based on self-rate and doctor-report outcomes, SAAT can reduce the severity and frequency of asthma exacerbations and concomitant medications with plausible satisfaction. The efficacy of this treatment is enhanced with a prolonged treatment course.

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