

Clinical study of optimizing acupoint combining in treatment of bronchial asthma with acupoint application

穴位敷贴治疗支气管哮喘优化穴位组合的临床研究

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Abstract

Objective: To observe the therapeutic efficacy of acupoint application at different groups of acupoints in treating bronchial asthma in remission stage.

Methods: A total of 120 patients with bronchial asthma in remission stage were recruited and divided by the random number table method into acupoint application group 1, acupoint application group 2 and acupoint application group 3, with 40 cases in each group. In all the three groups, Tiantu (CV 22), Dazhui (GV 14) and Feishu (BL 13) were selected, with Dingchuan (EX-B 1) added in acupoint application group 1, Shenshu (BL 23) added in acupoint application group 2, and Gaohuang (BL 43) added in acupoint application group 3. Before intervention, one month and 3 months after intervention, clinical symptoms, peak expiratory flow (PEF) and forced expiratory volume in 1 second percentage of predicted value (FEV1%) of the three groups were observed, and their clinical efficacies were evaluated.

Results: Comparing the therapeutic efficacy regarding traditional Chinese medicine symptoms and signs, after 1-month treatment, the total effective rate was 87.5% in acupoint application group 1, versus 62.5% in acupoint application group 2 and 55.0% in acupoint application group 3, and the between-group differences were statistically significant. After 3-month treatment, the total effective rate was 95.0% in acupoint application group 1, versus 70.0% in acupoint application group 2 and 65.0% in acupoint application group 3, and the between-group differences were statistically significant. After intervention, the three groups all showed significant improvements in pulmonary function with statistical significance; among the three groups, the improvement in acupoint application group 1 was more significant than that in the other two groups.

Conclusion: Tiantu (CV 22), Dazhui (GV 14) and Feishu (BL 13) as basic prescription plus Dingchuan (EX-B 1) can improve symptoms of bronchial asthma in remission stage, and it works better in improving pulmonary function than the basic prescription plus Shenshu (BL 23) or Gaohuang (BL 43).

Keywords: Acupoint Sticking Therapy; Application Therapy; Asthma; Respiratory Function Tests; Forced Expiratory Volume; Peak Expiratory Flow Rate; Point Selection

【摘要】目的: 观察敷贴不同穴位组合治疗缓解期支气管哮喘的疗效。**方法:** 共纳入 120 例缓解期支气管哮喘患者, 按随机数字表法分为穴位敷贴 1 组、穴位敷贴 2 组和穴位敷贴 3 组, 每组 40 例。三组均选用天突、大椎和肺俞, 穴位敷贴 1 组加定喘, 穴位敷贴 2 组加肾俞, 穴位敷贴 3 组加膏肓。观察三组治疗前和治疗 1 个月、3 个月后的临床症状, 测定呼气流量峰值(PEF)和第一秒用力呼气容积占预计值比值(FEV1%), 并评价三组临床疗效。**结果:** 三组病例中医证候疗效标准比较, 治疗 1 个月后, 穴位敷贴 1 组总有效率为 87.5%, 穴位敷贴 2 组总有效率为 62.5%, 穴位敷贴 3 组总有效率为 55.0%, 三组间有效率有显著性差异。治疗 3 个月后, 穴位敷贴 1 组总有效率为 95.0%, 穴位敷贴 2 组总有效率为 70.0%, 穴位敷贴 3 组总有效率为 65.0%, 三组间有效率有显著性差异。治疗后, 三组肺功能均较治疗前有明显改善, 组内治疗前后差异均有统计学意义; 三组组间比较, 穴位敷贴 1 组改善明显优于其它两组。**结论:** 天突、大椎、肺俞基本穴位加定喘在改善支气管哮喘缓解期症状, 提高肺功能方面优于基本穴位加肾俞或膏肓。

【关键词】 穴位贴敷法; 敷贴疗法; 哮喘; 呼吸功能试验; 用力呼气量; 呼气峰流速; 取穴

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Bronchial asthma, or asthma for short, is a commonly encountered respiratory disease featured by chronic airway inflammation^[1-2]. According to incomplete statistics, about 180 000 people died from asthma each year on a global scale and the number of new cases is increasing year after year^[3]. Currently, there are approximately 0.3 billion asthma patients worldwide. The burden of disease caused by asthma accounts for 1% regarding the global disability adjusted of life years (DALYs) for the whole disease list, which is equivalent to that of diabetes^[4]. In China, around 30 million people are now suffering with asthma. Therefore, it is urgent to conduct studies about the prevalence rate and risk factors of asthma in China, for developing ideal health policy to tackle the increasing burden brought by this disease.

Asthma can cause airway hyperresponsiveness, and recurrent wheezing, shortness of breath, chest tightness or coughing. It is more likely to attack or aggravate at night and/or in the early morning hours. Most people can get better on their own or after treatment^[5]. Since the pathogenesis of bronchial asthma has not been fully unveiled, modern medicine usually treats it by focusing on anti-inflammation and immunotherapy. So far, glucocorticoid has been considered the most effective anti-inflammatory drug. However, it is unable to correct the immune defect, not to mention the adverse reactions after long-term use. Hence, it is indeed necessary to find an effective treatment that is economic and has no toxic or side effects.

In recent years, acupoint application has gained certain progress in the treatment of asthma, receiving better acceptance and more attention. To further optimize the acupoint combining in acupoint application treatment of asthma, we conducted a study of 120 participants. The details are as below.

1 Clinical Materials

1.1 Criteria for recruiting participants

1.1.1 Diagnostic criteria

① Recurrent wheezing, shortness of breath, chest tightness or coughing, usually triggered by allergens, cold air, physical or chemical stimulation, viral upper respiratory infection, and sports, etc.; ② during an attack, scattered or diffuse wheezing rales can be detected mostly at expiration, with prolonged expiration; ③ the above symptoms and signs can be relieved after treatment or on their own; ④ panting, shortness of breath and coughing caused by other diseases should be excluded; ⑤ the atypical cases (e.g., no obvious wheezing or signs) should be diagnosed with the presence of at least one of the following features: a. bronchial provocation test or

exercise provocation test showed positive; b. bronchial dilation test showed positive, forced expiratory volume in 1 second percentage of predicted value (FEV1%) increased by $\geq 12\%$, and FEV1 increased to >200 mL; c. the diurnal (or 2-week) variation of peak expiratory flow (PEF) $\geq 20\%$.

Asthma was diagnosed when ①-④ or ④ and ⑤ were met.

Stage criteria: Bronchial asthma can be divided into acute attack stage, chronic persistent stage, and clinical remission stage based on the manifestations. This study only recruited patients in clinical remission stage, in which the relevant symptoms and signs are gone with or without treatment, and the pulmonary function is back to the level before the acute attack and manages to maintain for over 3 months.

1.1.2 Inclusion criteria

Conformed to the diagnostic criteria of bronchial asthma in remission stage; 10-60 years old, gender unlimited; agreed to terminate other treatments during the period of study; willing to participate in this clinical trial and signed the informed consent form.

1.1.3 Exclusion criteria

Bronchial asthma in acute attack or persistent stage; presented wheezing or shortness of breath but had other diseases (such as tuberculosis, bronchial dilation, and tumor); chronic pulmonary heart disease; pregnant or breast-feeding women; those who quit midway or lost to visit; aggravation or severe complications occurred during the study.

1.2 Statistical analysis

The SPSS version 21.0 was used for statistical analysis of the data. Measurement data were presented as mean \pm standard deviation ($\bar{x} \pm s$); intra-group comparisons were analyzed by paired sample *t*-test, multi-group comparisons were analyzed by Chi-square test for completely randomized design and least significant difference (LSD) *t*-test for between-group comparisons. Enumeration data were expressed as rate or percentage and processed using Chi-square for multi-sample rate comparisons, while partitions of Chi-square method was used for pairwise comparisons. $P < 0.05$ was indicative of statistical significance.

1.3 Clinical data and grouping method

A total of 120 patients were recruited from the outpatients between December 2014 and December 2016. The participants were divided into three groups using the random number table method, i.e., acupoint application group 1, acupoint application group 2 and acupoint application group 3, with 40 cases in each group. There were no statistical significance comparing the age, gender and disease duration among the three groups (all $P > 0.05$), indicating the groups were comparable (Table 1).

Table 1. Comparison of the general data of the three groups

Group	n	Gender (case)		Average age ($\bar{X} \pm s$, year)	Average duration ($\bar{X} \pm s$, year)
		Male	Female		
Acupoint application group 1	40	8	32	48.3±9.1	15.1±8.9
Acupoint application group 2	40	7	33	49.1±7.6	14.6±9.6
Acupoint application group 3	40	10	30	49.8±8.1	16.1±7.9
Statistic value		0.707 ¹⁾		0.326 ²⁾	0.299 ²⁾
P-value		0.702		0.723	0.742

Note: 1) χ^2 value; 2) F-value

2 Treatment Methods

The three groups of patients all received acupoint application treatment, with same medication and application method.

2.1 Medicinal cake

The medicinal cakes were self-made by Shanghai First People's Hospital, Shanghai Jiao Tong University School of Medicine.

Medicines: *Yan Hu Suo* (*Rhizoma Corydalis*), *Bai Jie Zi* (*Semen Brassicae*), *Ma Huang* (*Fructus Aristolochiae*), *Rou Gui* (*Cortex Cinnamomi*), *Gan Sui* (*Radix Kansui*), *Ding Xiang* (*Flos Caryophylli*) and *Xi Xin* (*Herba Asari*) were mixed at 2:2:1:1:1:1:1 and ground into powder. After filtered by a 200-mesh sieve, the powder was sealed in plastic bags. At the time to use, the powder would be mixed with fresh ginger juice and made into medicinal cakes of 1 cm in diameter and 2 mm thick.

2.2 Basic acupoints

In the three groups, Tiantu (CV 22), Dazhui (GV 14) and Feishu (BL 13) were selected as the basic acupoints.

2.3 Application method

Operation: The medicinal cakes were applied to each acupoint and fixed by specific paper tape.

Duration: The application lasted for 4 h in adults and 2 h in children each time, and the treatment was conducted once every week, for 6 consecutive weeks. Patient's tolerance should be taken into consideration, and they could tear the plasters off when they felt significantly uncomfortable.

2.4 Adjunct acupoints

2.4.1 Acupoint application group 1

Bilateral Dingchuan (EX-B 1) were added.

2.4.2 Acupoint application group 2

Bilateral Shenshu (BL 23) were added.

2.4.3 Acupoint application group 3

Bilateral Gaohuang (BL 43) were added.

3 Observation of Treatment Results

3.1 Observation items and methods

3.1.1 Pulmonary function indexes

PEF and the FEV1% were measured.

3.1.2 Asthma symptom score

According to the *Guideline for the Prevention and Treatment of Bronchial Asthma* (2016)^[6], the *Guiding Principles for Clinical Study of New Chinese Medicines*^[7] and the *Criteria of Therapeutic Effects of Syndromes in Traditional Chinese Medicine*^[8], the asthma symptom scoring criteria were made to comprehensively evaluate the major symptoms, including wheezing, coughing, expectoration and chest tightness. The disease condition was scored 0, 2, 4 and 6 from mild to severe. The sum of the four component scores made the total symptom score.

Therapeutic efficacy index = (Pre-treatment total symptom score – Post-treatment total symptom score) ÷ Pre-treatment total symptom score × 100%.

3.2 Criteria of therapeutic efficacy

Cured: The clinical symptoms and signs were gone or basically gone, and the therapeutic efficacy index ≥90%.

Markedly effective: The clinical symptoms and signs showed significant improvement and the therapeutic efficacy index ≥70% but <90%.

Effective: The clinical symptoms and signs showed certain improvement, and the therapeutic efficacy index ≥30% but <70%.

Invalid: The clinical symptoms and signs were not improved or even went worse, and the therapeutic efficacy index <30%.

3.3 Results

3.3.1 Comparison of the clinical efficacy

After 1-month treatment, the total effective rate was 87.5% in acupoint application group 1, versus 62.5% in acupoint application group 2 and 55.0% in acupoint application group 3. Chi-square test of the R×C contingency table with Pearson Chi-square formula showed that the difference was statistical significant comparing the effective rate among the three groups ($P=0.030$). The pairwise comparison using partitions of Chi-square method showed that the effective rate of acupoint application group 1 was significantly different from that of acupoint application group 2 and acupoint application group 3 ($P=0.010$, $P=0.001$), while the difference between acupoint application groups 2 and 3 was statistically insignificant ($P=0.496$).

After 1-month treatment, the total effective rate was

95.0% in acupoint application group 1, versus 70.0% in acupoint application group 2 and 65.0% in acupoint application group 3. Chi-square test of the R×C table with continuity correction Chi-square equation showed that the difference was statistical significant comparing the effective rate among the three groups ($P=0.003$). The pairwise comparison using partitions of Chi-square method showed that the effective rate of acupoint application group 1 was significantly different from that of acupoint application group 2 and acupoint application group 3 ($P=0.008$, $P=0.002$), while the difference between acupoint application groups 2 and 3 was statistically insignificant ($P=0.811$). The details are shown in Table 2 and Table 3.

3.3.2 Comparison of pulmonary function

There were no significant differences in pulmonary function among the three groups before treatment

(FEV1: $P=0.877$; PEF: $P=0.895$). After treatment, the three groups all showed obvious improvements in pulmonary function, all with statistical significance (all $P=0.000$); the improvements in acupoint application group 1 were more significant than those in the other two groups. After treatment, FEV1% in acupoint application group 1 was significantly different from that in acupoint application groups 2 and 3 (both $P=0.000$), while the difference between acupoint application groups 2 and 3 was statistically insignificant ($P=0.558$); PEF in acupoint application group 1 was significantly different from that in acupoint application groups 2 and 3 (both $P=0.000$), and the difference between acupoint application groups 2 and 3 also showed statistical significance ($P=0.030$). The details are shown in Table 4 and Table 5.

Table 2. Comparison of the clinical efficacy after 1-month treatment (case)

Group	n	Cured	Markedly effective	Effective	Invalid	Total effective rate (%)
Acupoint application group 1	40	7	17	11	5	87.5 ¹⁾²⁾
Acupoint application group 2	40	4	12	9	15	62.5
Acupoint application group 3	40	2	10	10	18	55.0

Note: Compared with acupoint application group 2, 1) $P<0.05$; compared with acupoint application group 3, 2) $P<0.05$

Table 3. Comparison of the clinical efficacy after 3-month treatment (case)

Group	n	Cured	Markedly effective	Effective	Invalid	Total effective rate (%)
Acupoint application group 1	40	8	18	12	2	95.0 ¹⁾²⁾
Acupoint application group 2	40	5	12	11	12	70.0
Acupoint application group 3	40	4	12	10	14	65.0

Note: Compared with acupoint application group 2, 1) $P<0.05$; compared with acupoint application group 3, 2) $P<0.05$

Table 4. Comparison of FEV1% ($\bar{x} \pm s$, %)

Group	n	Pre-treatment	Post-treatment
Acupoint application group 1	40	60.55±6.21	82.36±3.13 ¹⁾²⁾³⁾
Acupoint application group 2	40	60.17±5.95	70.23±4.25 ¹⁾
Acupoint application group 3	40	60.87±6.16	69.73±3.93 ¹⁾

Note: Intra-group comparison, 1) $P<0.01$; compared with acupoint application group 2 after treatment, 2) $P<0.05$; compared with acupoint application group 3 after treatment, 3) $P<0.05$

Table 5. Comparison of PEF ($\bar{x} \pm s$, L/min)

Group	n	Pre-treatment	Post-treatment
Acupoint application group 1	40	53.22±5.35	63.12±6.63 ¹⁾²⁾³⁾
Acupoint application group 2	40	53.57±4.23	55.82±4.99 ¹⁾
Acupoint application group 3	40	52.98±4.45	53.76±4.13 ¹⁾

Note: Intra-group comparison, 1) $P<0.01$; compared with acupoint application group 2 after treatment, 2) $P<0.05$; compared with acupoint application group 3 after treatment, 3) $P<0.05$

4 Discussion

Bronchial asthma can be classified under Xiao Bing (disease of wheezing) in traditional Chinese medicine (TCM). In TCM, the causes and pathogenesis of Xiao Bing mainly include the theory of perennial root (dormant pathogenic factors including cold and phlegm, and stagnated qi and phlegm, abnormal innate endowment, incomplete recovery from previous asthma and development of perennial root), theory of external pathogens, theory of emotional and exertion factors, and theory of deficient healthy qi^[9], etc., which can never avoid the factors of wind, fire, cold, phlegm, stasis and deficiency^[10].

The wheezing disease develops when the retained phlegm encounters the inducing factors (contraction of external wind and cold, improper diet, emotional disorder and fatigue, etc.) and blocks the airways, causing dysfunction of the lung in ascending and descending, reverse flow of lung qi, and beating of phlegm qi. The onset of asthma mainly manifests as the

wheezing sound from the throat, as well as difficulty breathing and lying down. The data-mining analysis of the rules in Prof. Zhou Zhong-ying's treatment of asthma in remission stage showed that the main symptoms are sneezing, itchy nose, coughing, dry mouth and chest tightness in remission-stage asthma^[11]. Zhang C, *et al*^[12] adopted structural equation model to classify the four aspects of diagnostic information of asthma, showing that the primary information includes shortness of breath, chest tightness and wheezing sound in the throat, accompanied by wheezing aggravated by moving and lassitude, etc.

The clinical study conducted by Feng JH, *et al*^[13] showed that spleen qi deficiency is predominant in remission-stage asthma, often coupled with deficiency symptoms of multiple organs. Some study results suggested that the deficiency of Zang-fu organs often involves the lung, spleen and kidney, covering lung qi-deficiency, dual qi-deficiency of lung and kidney, dual qi-deficiency of lung and spleen, qi and yin deficiency of lung and kidney, and yang deficiency of lung and kidney^[14]. Liu YP, *et al*^[15] found that external application of Chinese medication had already been used by physicians in Qing Dynasty, i.e., applying medication to acupoints during the hot dog days to enhance the immunity of asthma patients. Acupoints can produce a bi-directional regulation effect, though some acupoints tend to reinforce and some tend to reduce. Digital acupressure has been proved to improve the FEV1%^[16]. Acupoint application-induced topical skin reactions are somewhat related to the therapeutic efficacy of application and can reflect the influence of the stimulation dose on the final efficacy^[17].

This trial considered about the acupoint selection for acupoint application from multiple aspects. Regarding the differentiation of Zang-fu organs, asthma majorly affects the lung and is closely associated with spleen and kidney. From the perspective of meridians, asthma is a disease of the lung, while the Governor Vessel controls yang qi of the whole body, and the Bladder Meridian governs the external and guides yang qi to the surface to protect against the external pathogenic factors. Therefore, Feishu (BL 13) was selected to supplement lung qi and Dazhui (GV 14) was selected to activate yang qi. Wen BL, *et al*^[18] statistically analyzed the acupoints used for acupoint application during recent years and found that most of the commonly used acupoints are from the Conception Vessel, Governor Vessel and Bladder Meridian, such as Feishu (BL 13), Xinshu (BL 15), Shenshu (BL 23), Dingchuan (EX-B 1), Gaohuang (BL 43), Dazhui (GV 14), Pishu (BL 20), Tiantu (CV 22), Geshu (BL 17) and Danzhong (CV 17). Given that, this research selected Tiantu (CV 22), Dazhui (GV 14) and bilateral Feishu (BL 13) as

the basic points, with Dingchuan (EX-B 1) added for acupoint application group 1, Shenshu (BL 23) added for acupoint application group 2, and Gaohuang (BL 43) added for acupoint application group 3. Dingchuan (EX-B 1) is an extra point, is located beneath the seventh cervical spinous process, 0.5 cun away. It works for ceasing coughing and wheezing. Shenshu (BL 23) is located beneath the second lumbar spinous process, 1.5 cun away. This acupoint is mainly used to treat diseases due to kidney deficiency. Gaohuang (BL 43) mainly treats respiratory diseases. The relevant studies all suggest that using medications of warm-hot nature in acupoint application treatment of bronchial asthma can relieve the symptoms, control the attack of asthma and enhance the patient's quality of life^[19].

Acupoint application can produce valid efficacy in treating respiratory diseases. One study discovered that application during the hot dog days produced more significant efficacy than the coldest days, and the increase in treatment frequency could obviously affect the efficacy^[20]. The current trial showed that using Tiantu (CV 22), Dazhui (GV 14), Feishu (BL 13) and Dingchuan (EX-B 1) together can produce satisfactory efficacy in treatment of bronchial asthma in remission stage. This study is limited by short follow-up term, which will be improved in the future studies, thus to make the results more convincing.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from the patients in this study.

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