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Special Topic Study

Clinical observation on acupoint injection of Chuankezhi injection plus acupoint sticking in treating bronchial asthma

穴位注射喘可治加贴敷治疗支气管哮喘的临床观察

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Abstract
Objective: To observe the clinical efficacy of acupoint injection of Chuankezhi plus acupoint sticking treatment for bronchial asthma, and provide clinical evidence for the synergy of the two therapies, and explore their synergistic mechanism.
Methods: A total of 70 patients were randomized into an acupoint injection plus sticking group and an acupiont sticking group by the random number table, with 35 cases in each group. The treatment took place in July and August. The acupoint injection plus sticking group was treated with acupoint injection and acupiont sticking, while the acupiont sticking group was treated only with acupiont sticking therapy. The treatment course was 4 weeks. After the treatment, the scores of symptom scale in the two groups before treatment, 3 months and 6 months after the treatment were observed.
Results: During the treatment, there were 5 dropouts in the acupoint injection plus sticking group with 30 cases remained, and 4 dropouts in the acupiont sticking group with 31 cases remained. Before the treatment, there was no significant difference in the total scores of symptom scale between the two groups. Three months after the treatment, the total scores of symptom scale of both groups were lower than those before treatment, and the intra-group differences were statistically significant (both $P<0.05$). In the inter-group comparison, there was no significant difference in the difference values of the scores before treatment and 3 months after treatment ($P>0.05$). Six months after the treatment, the total scores of symptom scale in both groups were lower than those before treatment, and the intra-group differences were statistically significant (both $P<0.05$), so were the differences in the difference values of the scores before treatment and 6 months after treatment (both $P<0.05$).
Conclusion: Acupoint injection of Chuankezhi plus acupoint sticking or acupoint sticking alone both can improve the symptoms of patients with bronchial asthma. Acupoint injection of Chuankezhi plus acupoint sticking has a higher total effective rate than single acupoint sticking therapy.
Keywords: Acupoint Therapy; Hydro-acupuncture; Acupoint Sticking Therapy; Point, Feishu (BL 13); Point, Dingchuan (EX-B 1); Point, Gaohuang (BL 43); Asthma

【摘要】目的：观察穴位注射喘可治加穴位贴敷治疗支气管哮喘的临床疗效，为两种疗法的协同作用提供临床依据，并探讨二者的协同作用机制。**方法：**将70例符合纳入标准的患者根据随机数字表法分为穴位注射加贴敷组和贴敷组，每组35例。治疗时间选在7月和8月。穴位注射加贴敷组患者接受穴位注射和穴位贴敷两种疗法；贴敷组患者仅接受穴位贴敷治疗。治疗时间为4周。治疗结束后，观察两组患者治疗前及治疗后3个月、6个月的症状量表评分。**结果：**治疗过程中，穴位注射加贴敷组脱落5例，剩余30例；贴敷组脱落4例，剩余31例。治疗前，两组症状量表总分无统计学差异。治疗后3个月两组患者的症状量表总分低于治疗前，组内均有统计学差异(均$P<0.05$)，但治疗前与治疗后3个月的症状量表总分差值组间无统计学差异($P>0.05$)。治疗后6个月，两组症状量表总分均低于治疗前，组内均有统计学差异(均$P<0.05$)，治疗前与治疗后6个月的症状量表总分差值组间有统计学差异($P<0.05$)。**结论：**穴位注射喘可治加穴位贴敷或单独穴位贴敷均能有效改善支气管哮喘患者的症状。穴位注射喘可治加穴位贴敷的总有效率高于单独穴位贴敷。

【关键词】穴位疗法；水针；穴位贴敷法；穴，肺俞；穴，定喘；穴，膏肓；哮喘
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Asthma, also known as bronchial asthma, has a continual increase of prevalence and mortality due to changes in environment, living habits and dietary structure in recent years. The current global asthma incidence rate is 5% to 6%. The total prevalence of asthma in developed countries is 7% to 8% with an upward trend year by year[1]. The incidence of asthma in China is about 1% to 4%. Investigation of the prevalence of asthma in children under 14 years old in cities of China found that the prevalence rate was 1.54% in 2000[2], and 3.02% in 2010[3], which had nearly doubled in 10 years.

Bronchial asthma belongs to dyspnea syndrome and wheezing disease in Chinese medicine. Main clinical manifestations are cough, dyspnea and phlegm, with obvious characteristics of seasonal attacks. Acupuncture, acupoint injection and acupoint sticking are common methods to treat bronchial asthma[4-6]. Acupoint sticking therapy is an ingenious combination of Chinese herbal medicine and acupuncture points that leads the medicine to the affected area through meridian and collateral system, amplifying the effect of medicine. It has the characteristics of less toxic and side effects, easy operation, economic and easy to popularize. Acupoint sticking therapy is often combined with acupoint injection in the application of treatment for bronchial asthma[7]. Acupoint injection therapy is based on meridians and collaterals, and acupoints. It is a combination of meridian and collateral system in Chinese medicine and injection technique in Western medicine that can develop the specificities of drugs and acupoints thoroughly[8-9].

In order to observe the efficacy of acupoint injection plus acupoint sticking in treating bronchial asthma, we conducted this study.

1 Clinical Materials

1.1 Diagnostic criteria

Referring to the *Guidelines for the Prevention and Treatment of Bronchial Asthma* (2016)[10], the diagnostic criteria of this study were established.

1.2 Inclusion criteria

Those who met the diagnostic criteria of bronchial asthma: In mild or moderate persistence or clinical remission; aged 18-65 years old; who had no other treatment of Chinese medicine within 6 months before this trial (if with other diseases at the same time, it had to be ensured that no special processing was required during the treatment, and no influence on this trial); during this trial, discontinued other therapies that might affect the assessment of this therapy, using only the necessary regular drugs; agreed to participate in this trial after understanding the whole implementation process and signed informed consent.

1.3 Exclusion criteria

Chronic cough and dyspnea caused by tuberculosis, fungi, tumor, silicosis, irritating gases, or allergies confirmed by examination; with severe complications and cardiopulmonary dysfunction; coupled with severe primary diseases such as cardiovascular and cerebrovascular, nervous or hematopoietic system disease, and psychiatric patients; women during pregnancy or lactation; with other major diseases or severe allergic constitution, or those who were unsuitable for acupuncture treatment.

1.4 Elimination criteria

Those turned out to unmeet the inclusion criteria during the trial; those had to discontinue treatment for irresistible reasons; those presenting with severe adverse reaction; unable to adhere to the required treatment plan; dropped out during the trail; failed to return to the hospital on time.

1.5 Statistical methods

All data were statistically analyzed by the SPSS version 18.0 statistical software. Measurement data in normal distribution were expressed as mean ± standard deviation ($\bar{x} \pm s$). Independent sample *t*-test was applied for data that met the normal distribution and had homogeneous variance. If data did not meet the normal distribution, non-parametric test was applied. Counting data were expressed as rate, and processed by Chi-square test. Repeated measurement data were analyzed by repetitive measurement and analysis of variance, and trend analysis. Statistically significant level was considered as α=0.05.

1.6 General data

All cases in this study were patients with bronchial asthma enrolled from Dong Bing Xia Zhi (Treating Winter Disease in Summer) Clinic of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine and Wujing Hospital, Minhang District, Shanghai, between July and August 2015. A total of 70 cases who met the inclusion criteria were randomly divided into an acupoint injection plus sticking group and an acupiont sticking group according to a random number table generated by the SPSS version 18.0, with 35 cases in each group. There were no statistically significant differences in age, duration of disease, total scores of symptom scale and gender before treatment (all P>0.05), indicating that the two groups were comparable (Table 1).

Table 1. Comparison of baseline data between the two groups

Group	*n*	Gender (case)		Average age ($\bar{x}$ ±*s*, year)	Average duration ($\bar{x}$ ±*s*, year)	Total score of symptom scale before treatment ($\bar{x}$ ±*s*, point)
		Male	Female			
Acupoint injection plus sticking	35	7	28	50.5±12.0	7.2±3.1	17.2±2.9
Acupiont sticking	35	8	27	51.0±11.7	7.1±3.3	16.8±2.6

2 Treatment Methods

2.1 Basic treatment

Patients in both groups received the same basic treatment. During the treatment, the basic treatment was performed according to the disease condition: if the patients were in chronic persistence stage and at level 1-3 of disease grading, the salbutamol aerosols was given. During the observation after treatment, the routine treatment like anti-inflammation, antiasthmatic, and oxygen inhalation, or salbutamol aerosols was allowed for the emergency symptomatic treatment for all patients with acute attack.

2.2 Acupoint injection plus sticking group

2.2.1 Acupoint sticking

Medicine preparation: *Yan Hu Suo* (*Rhizoma Corydalis*) 1 portion, *Gan Sui* (*Radix Kansui*) 2 portions, *Bai Jie Zi* (*Semen Sinapis Albae*) 1 portion, *Shu Fu Zi (Radix Aconiti Lateralis Preparata*) 2 portions, *Rou Gui* (*Cortex Cinnamomi*) 0.6 portion, *Bu Gu Zhi* (*Fructus Psoraleae*) 2 portions, *Xi Xin* (*Herba Asari*) 1 portion, and *Ding Xiang* (*Flos Syzygii Aromatici*) 0.6 portion, altogether mashed and ground into powder, mixed and reserved. Mixed the powder with fresh ginger juice and water (ginger juice and water at proportion of 2:3) before use, and made into a medicinal cake of about 2 cm in diameter.

Acupoints: Bilateral Dingchuan (EX-B 1), Feishu (BL 13) and Gaohuang (BL 43).

Methods: Pressed the medicinal cake into a cone to stick onto the acupoints, fixed by a disposable infusion paste of 3 cm×5 cm, and tore off 2 h later.

2.2.2 Acupoint injection

Acupoint: Zusanli (ST 36) on one side.

Medicine: Chuankezhi injection, 2 mL each, produced by Guangzhou Jianxin Pharmaceutical Co., Ltd.

Method: After sticking, the patient took a sitting position. The physician used a 2 mL disposable syringe to extract 1.5 mL of Chuankezhi injection after disinfection with 75% alcohol cotton balls, rapidly perpendicularly punctured the point by about 3.0 cm in depth. Then the physician slowly injected the drug solution if no blood was drawn, and the injection was no more than 1 mL (the patient was told to keep still during the process of acupoint injection). Bilateral Zusanli (ST 36) were alternately selected and injected.

2.3 Acupiont sticking group

Patients in the acupiont sticking group only received acupiont sticking therapy alone. The herbs, acupoints and methods were all the same as those in the acupoint injection plus sticking group.

2.4 Course of treatment

Both groups were treated in July and August, 2015. The treatment was performed 3 times a week, for 4 weeks in total.

2.5 Cautions

The patients were informed that the skin would have different degrees of burning sensation after acupoint sticking, and the degree varied. Long-term application was not required. The sticking lasted for 2 h or shorter depending on whether patient felt uncomfortable.

It was normal if there were blisters on the skin after application. The patient should avoid scratching and smashing. Normally, it would not affect the follow-up treatment. If the blisters were large, it was necessary to give feedback to the physician to deal with the blisters. The physician would decide whether to continue the treatment according to the situation.

Needle manipulations such as lifting-thrusting or twirling was forbidden due to the thickness of the syringe needle.

The acupoint injection must be stopped with needle withdrawal if there were any faint symptoms such as dizziness, nausea, or chest tightness during the injection. The patient would be told to stay in a comfortable position, relax and drink warm water to divert attention. If severe allergic or shock symptoms occurred, the patient should be sent to the emergency department immediately.

The patient was told to take less spicy and greasy food during the treatment, so as to avoid affecting the therapeutic effect.

3 Observation of Curative Efficacy

3.1 Observation item

According to the *Guiding Principles for Clinical Study of New Chinese Medicines*[11], the asthma symptoms classification scale was established to quantitatively score the major symptoms of bronchial asthma according to mild, moderate and severe levels (Table 2). Recorded the symptoms scores of the latest onset at the time of enrollment, and then at the follow-up 3 and 6 months after the treatment, in order to compare the total scores before treatment and 3 months and 6 months after treatment.

3.2 Criteria of curative efficacy

The curative effect index was calculated by nimodipine method.

Curative effect index = (Total score of symptom scale before treatment – Total score of symptom scale after treatment) ÷ Total score of symptom scale before treatment × 100%.

Clinical controlled: The clinical symptoms and physical signs disappeared or basically disappeared, and curative effect index ≥95%.

Improved: The clinical symptoms and physical signs were improved obviously, and curative effect index ≥70%, but <95%.

Effective: The clinical symptoms and physical signs were improved, and curative effect index ≥30%, but <70%.

Invalid: No obvious improvements in clinical symptoms or physical signs, or even worse, and curative effect index <30%.

3.3 Results analysis

3.3.1 Dropout cases

A total of 70 cases were enrolled in the beginning. There were 9 dropouts during the treatment in total. There were 5 dropouts in the acupoint injection plus sticking group (2 cases of interruption, and 3 cases lost contact) with 30 cases remained, and 4 dropouts in the acupiont sticking group (1 case of interruption, and 3 cases lost contact) with 31 cases remained.

3.3.2 Baseline test

Statistical analysis was performed on the general data of the remaining 61 cases. There were no statistically differences in age, duration of disease, total scores of symptom scale and gender before treatment in the inter-group comparison (all P>0.05), indicating that the two groups were comparable (Table 3).

Table 2. Asthma symptoms classification scale

Symptom	Mild (1 point)	Moderate (3 points)	Severe (5 points)
Asthmatic	Occasional, low level, no influence on rest or activity	More frequent, but not affect sleep, panting with movement	Obvious when sitting still, unable to lie down, sleep or activity affected
Cough	Discontinuous cough during the day, mild degree	More frequent, but not affect sleep	Frequent cough or paroxysmal cough during day and night, sleep or activity affected
Expectoration	Small volume, 10-15 mL in day and night, or 5-25 mL from night to morning	51-100 mL in day and night, or 26-50 mL from night to morning	Large volume, over 100 mL in day and night, or over 50 mL from night to morning
Fullness and oppression in the chest	Occasional, low level, no influence on rest or activity	More frequent, but not affect sleep, with obvious feeling, has to lie flat	Sleep or activity affected
Wheezing rale	Occasionally after coughing or deep and fast breathing	Dispersion	Suffusion

Note: Tongue manifestation and pulse condition were only described but not scored

Table 3. Baseline test of the two groups excluding the dropout cases

Group	n	Gender (case)		Average age ($\bar{x}$ ±s, year)	Average duration ($\bar{x}$ ±s, year)	Total score of symptom scale before treatment ($\bar{x}$ ±s, point)
		Male	Female			
Acupoint injection plus sticking	30	5	25	53.0±10.4	7.5±3.4	17.0±2.6
Acupiont sticking	31	6	25	52.6±11.0	7.1±3.2	17.4±2.9

3.3.3 Comparison of clinical efficacy

Six months after the treatment, the total effective rate was 90.0% in the acupoint injection plus sticking group according to the scores of symptom scale, and 71.0% in the acupoint sticking group. The comparison result of the curative effect between the two groups was presented as χ^2=3.495, P>0.05, indicating that there was no statistical difference in the total effective rate between the two groups as α=0.05 (Table 4).

3.3.4 Changes in total score of symptom scale

Six months after the treatment, the normality test and homogeneity of variance test were applied for the difference value of total scores of symptom scale before and after treatment in both groups. The result was presented as P<0.05, suggesting a non-normal distribution. The independent-sample nonparametric test was performed, and the result was presented as P<0.05, suggesting that the difference value of total scores of symptom scale before and after treatment in the two groups was statistically significant, indicating a better improvement of symptoms in the acupoint injection plus sticking group than that in the acupoint sticking group (Table 5).

According to the requirement of variance analysis of repeated data, the normality test and homogeneity of variance test were applied for the total scores of symptom scale before treatment, and 3 months and 6 months after treatment. The results of Shapiro-Wilk were both presented as $P>0.05$, suggesting a normal distribution and homogeneous variance. Then the sphericity test was performed, and the result was presented as $P=0.387$, suggesting that the spherical property of covariance matrix was proved. The total scores of symptom scale in the two groups were significantly correlated with time factors ($F=265.94$, $P=0.0001$). There was no statistical difference in the difference value of the total score of symptom scale before treatment and 3 months after treatment between the two groups, but the difference of the difference value of the total score of symptom scale before treatment and 6 months after treatment between the two groups was statistically significant (Table 5).

Due to the long-term effect of Dong Bing Xia Zhi (Treating Winter Disease in Summer), the efficacy could not be fully reflected in 6 months after treatment. Therefore, the overall difference between the groups was not obvious ($F=0.900$, $P=0.400$), (Table 6).

Table 4. Comparison of total effective rate between the two groups

Group	*n*	Clinical controlled	Improved	Effective	Invalid	Total effective rate (%)
Acupoint injection plus sticking	30	0	0	27	3	90.0
Acupiont sticking	31	0	0	22	9	71.0

Table 5. Comparison of total score of symptom scale between the two groups ($\bar{x}$ ±*s*, point)

Group	*n*	Before treatment	3 months after treatment	6 months after treatment	Difference value before and 3 months after treatment	Difference value before and 6 months after treatment
Acupoint injection plus sticking	30	17.4±2.9	10.1±2.8	13.4±2.9	7.3±2.2	4.0±2.5
Acupiont sticking	31	17.0±2.6	10.6±2.7	15.0±2.2	6.4±2.5	2.0±2.5
t-value		–0.560	–22.408	–8.797	–1.458	–3.161
P-value		0.578	0.000	0.000	0.150	0.003

Table 6. Variance analysis for the total scores of symptom scale of three times

Source of variation	Sum of square of mean deviation (SS)	Degree of freedom (v)	Mean square between groups (MS)	*F*-value	*P*-value
Time	1 428.1	2	714.0	265.9	0.00001
Intervention * time	30.6	2	15.3	5.7	0.0
Intra-individual error	316.8	118	2.7	--	--
Intervention	14.3	1	14.3	0.900	0.400
Inter-individual error	970.4	59	16.4	--	--

4 Discussion

Bronchial asthma is similar to cough, dyspnea syndrome or wheezing in traditional Chinese medicine in both clinical manifestations and etiology and pathogenesis. The pathogenesis of bronchial asthma has not yet been determined by Western medicine. So far, two confirmed important aspects of bronchial asthma are environmental factor and genetic susceptible individual. Various factors cause the disorder of T-cell immune mediator release mechanism, which results in inflammation and airway hyperreactivity by inflammatory factors acting on the respiratory tract. In the pathogenesis of bronchial asthma, the decrease of interferon-γ (IFN-γ) released from T-helper 1 cells (Th1) is closely related to the increase of interleukin (IL)-4, IL-5 released from T-helper 2 cells (Th2). And the interaction and influence of IFN-γ and IL-4 are key factors in the whole pathological process[10]. Current studies indicate that the imbalance of Th1 and Th2 cells is the main theory of the pathogenesis of asthma and other allergic diseases, and it is also an important aspect of current study of asthma mechanism[11]. Related studies have shown that IFN-γ and transforming growth factor-β (TGF-β) released from Th1 decrease in acute attack of bronchial asthma, while IL-4, IL-5 released from Th2 increase, and the ratio of Th1 cells to Th2 cells in peripheral blood decreases[12].

A large number of clinical and experimental studies have shown that there are three main mechanisms of acupoint application in the treatment of bronchial asthma. One is to relax airway smooth muscle, to

alleviate emphysema and atelectasis caused by long-term airway obstruction to varying degrees. The second is anti-allergic effect. Chinese medicine has a special effect in stabilizing the mast cell membranes, thus inhibiting the release of allergic mediators, thereby improving various symptoms. The third is the effect of regulating immunity. In the pathogenesis of bronchial asthma, the balance of death and activation of lymphatic T cells is in disharmony, mainly manifested by the increased value and enhanced function of $CD4^+$ cells, and corresponding reduction of the number and function of $CD8^+$ cells. With the treatment of acupoint sticking, the expression of immunoglobulin E (IgE) in body fluid decreases obviously, $CD4^+$ and $CD4^+/CD8^+$ decrease significantly, and function of $CD8^+$ cell increases, indicating that this therapy has a regulatory effect on cellular immunity[13].

Most of the composing prescriptions for the sticking referred to Zhang's cold wheezing prescription. In this study, the prescription consisted of Chinese herbs such as *Bai Jie Zi* (*Semen Sinapis Albae*), *Xi Xin* (*Herba Asari*), *Yan Hu Suo* (*Rhizoma Corydalis*), *Gan Sui* (*Radix Kansui*), *Ding Xiang* (*Flos Syzygii Aromatici*), *Rou Gui* (*Cortex Cinnamomi*), etc. *Bai Jie Zi* (*Semen Sinapis Albae*) is pungent in property, and good at clearing internal and external phlegm, with the effect of warming the lung and assisting yang, and benefiting qi and suppressing cough. Modern pharmacological studies have found that the water-soluble components of *Bai Jie Zi* (*Semen Sinapis Albae*) are good at dispelling phlegm, and the fat-soluble components are good at suppressing cough. But clinical use should be cautious because it contains allyl thiocyanate that will cause skin blistering, so it should be used according to clinical practice[14]. *Xi Xin* (*Herba Asari*) enters both the Lung and Kidney Meridians, which exactly meets the disease location of asthma, not only dissipating exterior cold, but also the interior cold. Pharmacological studies have shown that *Xi Xin* (*Herba Asari*) has effect of anti-allergy and can relieve bronchospasm[15-16]. *Yan Hu Suo* (*Rhizoma Corydalis*) can move qi and activate blood, and regulate qi movement, together with producing the effect of inhibiting the phosphorylation of P38 mitogen-activated protein kinase (P38 MAPK)[17-18]. Therefore, it can regulate immunity, and relieve asthma. *Gan Sui* (*Radix Kansui*) can expel retained fluid in the chest by purgation, and regulate immunity[19]. *Shu Fu Zi (Radix Aconiti Lateralis Preparata*) can restore yang, dissipate cold, and expel cold-phlegm, which exactly meets the etiology and pathogenesis of bronchial asthma in Chinese medicine. *Bu Gu Zhi* (*Fructus Psoraleae*), *Ding Xiang* (*Flos Syzygii Aromatici*) and *Rou Gui* (*Cortex Cinnamomi*) are warm in property and can enter into kidney. They have the effect of tonifying kidney and assisting yang, warming and unblocking the meridians.

The efficacy of acupoint injection is achieved by two main aspects[20]. One is the local stimulating effect of acupoints, that is, the mechanical stimulation on acupoint tissue by needles and injection of the drug solution that causes local sensation of sour and heaviness, and transmission of sensation along meridian. The other is the biological effect of the drug itself, that is, the specific therapeutic effect of the drug. Lin XM, *et al*[21] found out that the amplification effect showed after the drugs passed through acupoint was nonlinear, but geometrically multiplied. The effect of sequential meridians can be generated after the drugs enter the body through acupoints, and the drugs can be led directly to the disease location through meridian and collateral system[22]. Compared with the traditional intravenous infusion, the required dose of the drug for acupoint injection is smaller, but still has a strong effect and can prolong the effective time[23].

The results showed that the difference in the total score of symptom scale between the two groups was statistically significant 6 months after treatment (P<0.05), indicating that there was a statistical difference in the improvement of symptoms between the two groups, and the efficacy of acupoint injection plus sticking group was better than that of the acupiont sticking group. There was synergy in treating asthma by combining acupoint injection and acupiont sticking. To analyze the reason: compared with the acupiont sticking group, the acupoint injection plus sticking group applied Chuankezhi injection at Zusanli (ST 36) in addition. Zusanli (ST 36) has the effect of fortifying the spleen to assist transportation and transformation. Chuankezhi injection contains *Ba Ji Tian* (*Radix Morindae Officinalis*) and *Yin Yang Huo* (*Herba Epimedii*), which have the effect of dispelling wind and eliminating dampness, invigorating yang and tonifying essence[24]. Moreover, the efficacy could be amplified when medicines passed through the acupoints by acupoint injection. Therefore, the acupoint injection plus sticking group had a better therapeutic effect than acupiont sticking group.

Conflict of Interest

There was no potential conflict of interest in this article.

Acknowledgments

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Statement of Informed Consent

Informed consent was obtained from the patients in this study.

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