

## Clinical observation on therapeutic effect of traditional Chinese medicine granules made by formula of Shegan Mahuang decoction for patients with asthma

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**Abstract: Objective:** To observe the therapeutic effect of traditional Chinese medicine (TCM) granules made by formula of Shegan Mahuang decoction for patients with asthma. **Method:** 70 patients with mild asthma who were in Taizhou Hospital of Traditional Chinese Medicine and Western Medicine from December, 2013 to December, 2014 were selected. They were randomly divided into control group and observation group with 35 patients in each group. All the patients were given salbutamol aerosol inhalation, patients in observation group were additionally given the above mentioned TCM granules. After 12 weeks, the therapeutic effects of the two groups were evaluated. **Results:** Control rate of the observation group is 97.14% while that of the control group is 74.29%, and there was significantly statistical difference ( $P < 0.01$ ). Before treatment, there was no statistical difference between the two groups in asthma control test (ACT) score, peak expiratory flow (PEF), forced expiratory volume in 1 second (FEV1) and FEV1% predicted value ( $P > 0.05$ ). After treatment, the ACT score, PEF, FEV1 and FEV1% predicted value of the patients in observation group were obviously higher than that in control group, and the differences were statistically significant ( $P < 0.05$ ). **Conclusion:** TCM granules made by formula of Shegan Mahuang decoction combined with salbutamol aerosol can obviously improve the pulmonary function of patients with mild asthma, so it is worthy of being generalized.

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**Keywords:** Shegan Mahuang decoction; combination of traditional Chinese and western medicine; bronchial asthma

### Introduction

Bronchial asthma is a common disease of respiratory system, the morbidity of which gradually increases. So far the main treatment method for bronchial asthma depends on inhalation of glucocorticoid for a long time<sup>[3-4]</sup>. TCM holds that the pathogenesis of bronchial asthma is cold-phlegm in the lung, the main treatment method is to relieve spasm, eliminate phlegm and dispel wind<sup>[5-6]</sup>. 70 patients with mild asthma who were in Taizhou Hospital of Traditional Chinese Medicine and Western Medicine from December, 2013 to December, 2014 were selected to observe the therapeutic effect of traditional Chinese medicine granules made by formula of Shegan Mahuang decoction, and now it was reported as follows.

### 1. Materials and methods

#### 1.1 Materials

70 patients with mild asthma who were in hospital from December, 2013 to December, 2014 were selected. They were randomly divided into control group and observation group with 35 patients in each group. There were 18 males and 17 females in observation group aged from 19 years old to 57 years old (average  $43.29 \pm 11.9$  years old). While there were 17 males and 18 females in control group aged from 22 years old to 61 years old (average  $44.21 \pm 10.23$

years old). There were no significantly statistical differences between the two groups in age, gender and other general information ( $P > 0.05$ ). In addition, this experiment had been approved by medical ethics committee of Taizhou Hospital of Traditional Chinese Medicine and Western Medicine, all patients and their relatives signed the informed consent before experiment.

#### 1.2 The inclusion and exclusion criteria

The inclusion criteria are: ① aged more than 18 year-old; ② patients who can cooperate to complete the curative observation and related inspection; ③ patients with mild asthma diagnosed by TCM doctor; ④ patients who signed the informed consent.

The exclusion criteria are: ① exclude patients with tuberculosis, bronchiectasia or other basic respiratory diseases; ② exclude patients with heart, liver, brain, kidney or other organic diseases; ③ exclude patients with a worsening of their asthma control; ④ exclude patients who did not cooperate on treatment and observation; ⑤ exclude patients who were in pregnancy and lactation period.

#### 1.3 Methods

Patients in these two groups were given salbutamol aerosol inhalation (Shanghai Sine Pharma

co., LTD., approved by H21020560), 100 $\mu$ g each time, four times per day. Patients in observation group were additionally given TCM granules made by formula of Shengan Mahuang decoction (Hubei Tian Ji Chinese Herbal Sliced Medicine co., LTD.), which is comprised of 12g Mahuang, 12g Shengan, 9g fresh ginger, 3g asarum, 12g aster, 10g dates, 6g schisandra chinensis, 10g flos farfarae and 12g rhizoma pinellinae praeparata, 1 dose/day dissolved in water and taken twice, once in morning and another once in the evening. The therapeutic effect was evaluated after 3 months.

#### 1.4 Judgment standards of the therapeutic effect

Complete control: symptoms and signs of patients disappear; Partial control: symptoms and signs of patients obviously improve, syndrome integral reduces more than 30%; Out of control:

symptoms and signs of patients don't obviously improve, syndrome integral reduces less than 30%, control rate is the sum of complete control rate and partial control rate.

#### 1.5 Statistical methods

The clinical trial data were recorded in Excel 2013 database, SPSS19.0 statistical analysis software was adopted for data processing,  $\chi^2$  test was taken in comparison between the counting data, t test was taken in comparison between the measurement data, if  $P < 0.05$ , there were significant differences.

## 2. Results

### 2.1 Clinical therapeutic effect

The control rate of observation group was 97.14% while that of control group was 74.29%, and the difference was statistically significant ( $P < 0.01$ ) (See Table 1).

Table 1. Clinical effect Comparison of the patients in two groups [ n(%) ]

Group	Case	Complete control	Partial control	Out of control	In control
Observation group	35	18 (51.43)	16 (45.71)	1 (2.86)	34 (97.14)
Control group	35	10 (28.57)	16 (45.71)	9 (25.71)	26 (74.29)
$\chi^2$		3.81	0.00	7.47	7.47
P		>0.05	>0.05	<0.01	<0.01

### 2.2 Pulmonary function comparison of patients before and after treatment

There was no statically significant difference between two groups in the ACT score, PEF, FEV1 and FEV1% predicted value before treatment ( $P > 0.05$ ). After treatment, these indicators in observation group were obviously higher than that in control group, and the differences were statistically significant ( $P < 0.05$ ) (See Table 2).

Table 2. Pulmonary function comparison of patients before and after treatment (X $\pm$ SD)

Group	Case	ACT score		PEF (L/min)		FEV1% predicted value		FEV1(L)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	35	18.91 $\pm$ 2.03	23.04 $\pm$ 1.89	243.31 $\pm$ 43.13	325.45 $\pm$ 43.21	0.93 $\pm$ 0.12	0.65 $\pm$ 0.11	1.94 $\pm$ 0.41	2.87 $\pm$ 0.52
Control group	35	18.42 $\pm$ 2.14	20.42 $\pm$ 1.32	242.41 $\pm$ 41.89	276.53 $\pm$ 32.29	0.92 $\pm$ 0.13	0.85 $\pm$ 0.07	1.95 $\pm$ 0.20	2.14 $\pm$ 0.43
T		0.68	4.68	0.06	3.74	0.23	6.32	0.09	4.46
P		>0.05	<0.05	>0.05	<0.05	>0.05	<0.05	>0.05	<0.05

## 3. Discussion

The main clinical manifestations of asthma are cough, chest tightness, shortness of breath, wheezing and so on. It will threaten life if it wouldn't be controlled well. Patients usually have a asthma attack in the morning or at night mainly because of airway hyperresponsiveness induced by chronic airway inflammation<sup>[7-9]</sup>. To reduce the seizure of asthma, currently glucocorticoid inhalation and regular medication are taken which can obviously control and prevent the asthma<sup>[10-11]</sup>. However regular glucocorticoid inhalation may increase the burden on patients. TCM treatment for patients with mild asthma is effective and relatively inexpensive, but the patients' medication compliance is low<sup>[12]</sup>.

TCM holds that patients are usually attacked by asthma when it is cold. The Symptoms includes chest congestion, less sputum, white foam, spit hardly and be afraid of cold etc. Shengan Mahuang decoction is a classical prescription for the treatment of asthma. Shengan is bitter and cold reaching pulmonary channel, it is antiviral and anti-inflammatory, it can resist allergy and remove free radicals, etc<sup>[13]</sup>. Mahuang is good for lung, can relieve asthma, leads sweat and resist cold, so Shengan and Mahuang are main drugs<sup>[14]</sup>. Asarum can resolve phlegm, stop cough, relieve asthma and diminish inflammation. Asarum is also good for rise and fall of pulmonary pneuma when mixed with schisandra chinensis, raw ginger can resist cold<sup>[15-16]</sup>. There are terpenes,

flavonoids and alkaloid in flos farfarae which can diminish inflammation, relieve asthma and stop cough. Flos farfarae can inhibit capillary permeability and also resolve airway inflammation deformity caused by ammonia sensitization<sup>[17]</sup>. Rhizoma pinellinae praeparata can resolve phlegm and date can recuperate body<sup>[18]</sup>. All parts used to stop cough and resist cold can significantly improve the lung of patients.

According to the clinical data collected in this experiment, the control rate of observation group is obviously higher than that of control group. At the same time, according to pulmonary function of the two groups before and after treatment, there was no significantly statistical difference in indicators of pulmonary function between the two groups before treatment ( $P > 0.05$ ), but after treatment the pulmonary function of the two groups improved obviously ( $P < 0.05$ ), and the indicators of pulmonary function in observation group are obviously better than control group ( $P < 0.05$ ), which indicates that the therapeutic effect of traditional Chinese medicine granules made by formula of Shegan Mahuang decoction for patients with asthma is well. Simultaneously making Mahuang and Shegan decoction into granules can avoid the trouble of decocting, which obviously improves the medication compliance.

In summary, the therapeutic effect of TCM granules made by formula of Shegan Mahuang decoction combined with salbutamol aerosol is well and it can obviously improve pulmonary function of patients with mild asthma, so it is worthy of being generalized.

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