

# Clinical study on Jin's three-needle plus *Xiang Ju* Capsules for allergic rhinitis

## “靳三针”结合香菊胶囊治疗过敏性鼻炎临床研究

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### Abstract

**Objective:** To observe the clinical effects of Jin's three-needle plus *Xiang Ju* Capsules for allergic rhinitis (AR).

**Methods:** Fifty patients with AR were randomly divided into an acupuncture-medication group and a medication group by the random digital table, 25 cases in each group. The acupuncture-medication group was treated with dorsal three-needle and nasal three-needle in Jin's three-needle therapy, once every day, plus oral administration of *Xiang Ju* Capsules, 4 pills each time, and three times per day. The medication group was only treated with oral administration of *Xiang Ju* Capsules, 4 pills each time, and three times per day. For both groups, 10-day treatment constituted a course. The therapeutic effects were observed after continuous 2 courses. The symptoms and signs are scored before and after treatment, and the therapeutic effects were assessed based upon the changes of the patient's symptoms and signs.

**Results:** After treatment, the total effective rate was 96.0% in the acupuncture-medication group and 72.0% in the medication group. The difference in the total effective rate between the two groups was statistically significant ( $P < 0.05$ ).

**Conclusion:** The therapeutic effect was remarkable in treating AR of Jin's three-needle plus *Xiang Ju* Capsules, better than oral administration of *Xiang Ju* Capsules alone.

**Keywords:** Acupuncture Therapy; Acupuncture Medication Combined; Rhinitis, Allergic; Jin's Three-needle

**【摘要】目的：**观察“靳三针”结合香菊胶囊治疗过敏性鼻炎(allergic rhinitis, AR)的临床疗效。**方法：**将 50 例 AR 患者根据随机数字表随机分为针药组和药物组，每组 25 例。针药组针刺“靳三针”中的背三针和鼻三针，每日治疗 1 次；同时口服香菊胶囊，一次 4 粒，一日 3 次。药物组仅口服香菊胶囊，一次 4 粒，一日 3 次。两组均治疗 10 d 为 1 个疗程，连续治疗 2 个疗程后观察疗效。于治疗前后进行症状和体征评分，根据患者症状、体征评分变化情况进行疗效评价。**结果：**治疗后，针药组总有效率为 96.0%，药物组总有效率为 72.0%。两组总有效率差异具有统计学意义( $P < 0.05$ )。**结论：**“靳三针”结合香菊胶囊治疗 AR 效果显著，疗效优于单纯口服香菊胶囊。

**【关键词】**针刺疗法；针药并用；鼻炎，变应性；靳三针

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Allergic rhinitis (AR) refers to an allergic disease occurring in the mucous membrane of the nasal cavity, characterized by itchy nose, sneezing, secretion in the nasal cavity, and tumefaction of the nasal membrane. Its incidence rate is 10%-40% in the general population<sup>[1]</sup>. AR seriously influences the daily life, study and work of the patients, and also brings heavy economic burden. It may induce bronchial asthma, otitis media, sinusitis and nasal polyp or co-occurrence with allergic conjunctivitis. Currently, AR is mostly treated with antihistamines, steroids and surgery<sup>[2]</sup>, which may cause adverse reactions and drug resistance. Acupuncture combined with medication in traditional Chinese medicine (TCM) is characterized with treating

the symptoms and root causes reason and fewer side effects. Recently, we treated AR patients with acupuncture plus medication, in comparison with the therapeutic effect of administration of medication alone. Now, the report is given as the follows.

## 1 Clinical Materials

### 1.1 Diagnostic criteria

#### 1.1.1 Diagnostic criteria in Western medicine

The diagnostic criteria in Western medicine were stipulated based upon Diagnostic and Therapeutic Principle and Suggested Draft for AR (2004, Lanzhou, by Otorhinolaryngology Committee of Chinese Medical Association<sup>[1]</sup>: at least 2 items of nasal itching, sneezing, clear nasal discharge and nasal obstruction; for continuously or cumulatively over 1 h; with congestion

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and tumefaction of nasal membrane; and watery discharge from the nasal cavity in the inspection of the nasal cavity; and at least 1 item graded (++) or above (++) in positive reaction of allergic skin test.

#### 1.1.2 Diagnostic criteria in Chinese medicine

The diagnostic criteria of Chinese medicine in this study were stipulated based upon the *Otorhinolaryngology of Chinese Medicine*<sup>[3]</sup> and *Guiding Principles for Clinical Study of New Chinese Medicines*<sup>[4]</sup>: susceptible to cold, nasal itching, sneezing and clear nasal discharge aggravated by exposure to cold or heat, fever with restlessness, red or dark red color in the nasal membrane, tumefaction in the turbinalia, a red tongue, and rapid pulse.

#### 1.2 Inclusion criteria

In conformity with the above diagnostic criteria for AR, with the duration over 1 year, and no treatment for AR within the recent half a month.

#### 1.3 Exclusion criteria

Those not in conformity with the above inclusion criteria and diagnostic criteria; those complicated with deviation of the nasal septum, nasal polyps and sinusitis; those treated by other therapeutic methods for AR within the recent half a month.

#### 1.4 Drop-out criteria

The subjects were unable to go on with the treatment, and failed to complete this study because of certain reasons during the observation; the subjects quitted voluntarily halfway for other therapies.

#### 1.5 Removal criteria

Those who were not in conformity with the inclusion criteria after being recruited; and those who did not receive any treatments after recruitment.

#### 1.6 Statistical methods

The SPSS 19.0 version statistical software was used for statistical analysis and management. The measurement data were expressed by mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ). One-way ANOVA was used for comparison between the groups. The paired *t*-test was used for comparison before and after treatment within the groups. The Chi-square test was used for the enumeration data.  $P < 0.05$  was used to express a statistical significance.

#### 1.7 General data

The subjects in this study were out-patients and in-patients from the Acupuncture Department in our hospital between September 2013 and May 2015, totally 50 cases, including 28 males and 22 females, with the age ranged from 14 to 63 years old and the duration ranged from half a year to 15 years. All the patients were numbered based upon their visit order and were divided into an acupuncture-medication group and a medication group by the random digital table, 25 cases in each group. There were no statistically

significant differences in gender, age and duration between the two groups (all  $P > 0.05$ ), indicating the two groups were comparable (Table 1).

**Table 1. Comparison of general data between the two groups**

Group	n	Gender (case)		Average age ( $\bar{x} \pm s$ , year)	Average duration ( $\bar{x} \pm s$ , month)
		Male	Female		
AM	25	13	12	32.7 $\pm$ 5.1	5.6 $\pm$ 3.3
Medication	25	15	10	33.2 $\pm$ 4.3	6.4 $\pm$ 2.7

Note: AM=Acupuncture-medication group

## 2 Therapeutic Methods

### 2.1 Acupuncture-medication group

#### 2.1.1 Jin's three-needle

The dorsal three-needle and the nasal three-needle of Jin's three-needle therapy were selected.

Acupoints: Bilateral three acupoints of the back [Dazhu (BL 11), Fengmen (BL 12) and Feishu (BL 13)] and three acupoints around the nose [Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and Yintang (GV 29)].

Method: After the patient took a prone position, the bilateral three acupoints on the back were punctured first with the filiform needles of 0.30 mm in diameter and 30 mm in length, obliquely toward the spine for 0.8-1.0 cun, with lifting, thrusting, twisting and whirling manipulations for reinforce. After the patient had the local sore and distending sensation, the needles were retained for 30 min. The needles were manipulated for three times during the retaining, 5 min each time. After withdrawal of the needles, the patient took a supine position for the three acupoints around the nose [Yintang (GV 29), bilateral Yingxiang (LI 20) and Shangyingxiang (EX-HN 8)] to be punctured with the filiform needles of 0.30 mm in diameter and 30 mm in length. Yintang (GV 29) was punctured with the needle tip downward subcutaneously to the root of the nose for 0.8-1.0 cun. Yingxiang (LI 20) and Shangyingxiang (EX-HN 8) were punctured obliquely toward the ethmoidal sinus. After the arrival of the needling sensation, the needles were manipulated with the moderate needling technique, till the patient had local sore and distending sensation. The needles were retained for 30 min, during which the needles were manipulated for 3 times, 5 min each time. The treatment was given once every day and ten sessions constituted a course. After continuous two courses, the therapeutic effects were observed.

#### 2.1.2 Oral administration of *Xiang Ju* Capsules

*Xiang Ju* Capsules (China Food and Drug Administration approval number: Z19991040, manufactured by Shandong Buchang Pharmaceuticals, Co. Ltd.), oral administration, 4 pills each time, 3 times

per day. Ten days constituted a course and the therapeutic effects were observed after the continuous two courses.

## 2.2 Medication group

The patients in the medication group were treated with the oral administration of *Xiang Ju* Capsules, with same usage and dose and same therapeutic effects as that in the acupuncture-medication group.

## 3 Observation of Therapeutic Effects

### 3.1 Observed items

#### 3.1.1 Scores of signs

3 points: The inferior turbinate, nasal bottom and

nasal septum were close to each other, and the middle turbinate was seen, or polypoid change took place in the mucosa of the middle turbinate with formation of the polyps.

2 points: The inferior turbinate and the nasal septum (or nasal bottom) were close to each other, and there was small cleft between the interior turbinate and nasal bottom (or nasal bottom).

1 point: Slight tumefaction appeared in the inferior turbinate, and the nasal septum and middle turbinate were visible.

#### 3.1.2 Sores of symptoms

The scores were assessed in accordance with the four major symptoms of AR patients (Table 2).

**Table 2. Sores of symptoms**

Score	Sneezing <sup>1)</sup>	Nasal discharge <sup>2)</sup>	Nasal obstruction	Nasal itching
1 point	3-9	≤4	Occasional	Intermittent
2 points	10-14	5-9	Intermittent or alternative	Ant crawling, tolerable
3 points	≥15	≥10	Mouth breathing all day	Ant crawling, intolerable

Note: 1) Number of a continuous sneezing, 2) number of daily nose blowing

### 3.2 Criteria of the therapeutic effects

The therapeutic effects were assessed in accordance with the Criteria for Evaluation of Therapeutic Effects of AR revised in Haikou conference of 1997<sup>[5]</sup>. The symptoms and signs were scored before and after the treatment in the two groups. In accordance with the total sum of the scores in the symptoms and signs before and after the treatment, the improving rate was calculated by the following formula:

Improving rate = (Total score before treatment — Total score after treatment) ÷ Total score before treatment × 100%.

The therapeutic effects were evaluated in accordance with the improving rate.

Remarkable effect: The improving rate ≥51%.

Effect: The improving rate ≥21%, ≤50%.

Failure: The improving rate <21%.

### 3.3 Therapeutic results

During the study, there were no dropped-off and removed cases in the two groups. After the treatment for two courses, the total effective rates were 96.0% in the acupuncture-medication group and 72.0% in the medication group. The difference in the total effective rate between the two groups was statistically significant by Chi-square test ( $P<0.05$ ), indicating that the total effective rate was higher in the acupuncture-medication group than that in the medication group (Table 3).

**Table 3. Comparison of therapeutic effect between the two groups (case)**

Group	<i>n</i>	Remarkable effect	Effect	Failure	Total effective rate (%)
Acupuncture-medication	25	14	10	1	96.0 <sup>1)</sup>
Medication	25	9	9	7	72.0

Note: Compared with the medication group, 1)  $P<0.05$

## 4 Discussion

In Chinese medicine, AR falls under the category of 'Bi Qiu'<sup>[6]</sup>. Like many TCM physicians, we believe that deficiency is the root cause of AR; however, AR patients may present with excess symptoms. Generally, AR patients are susceptible to common cold and their AR can be triggered by exposure to both cold and heat. This indicates that the lung-(Wei) defense in AR patients is too weak to defend against external pathogenic factors

(deficiency in root cause). On the other hand, AR patients often present with itchy nose, stuffy nose, sneezing, and profuse clear nasal discharge (excess in symptoms)<sup>[7]</sup>.

Jin's three-needle therapy is advantageous in the selection of acupoints and remarkable in the therapeutic effects. The three acupoints on the back and three acupoints around the nose in Jin's three-needle therapy are selected based upon the thoughts to treat both the causative factors and symptoms in

Chinese medicine, and Prof. Wang Hua's theory of combining the major acupoints and adjunct acupoints. Three acupoints on the back [Dazhu (BL 11), Fengmen (BL 12) and Feishu (BL 13)], belonging to the Bladder Meridian of Foot Taiyang, have the effects to dissipate wind, disperse cold, tonify qi and strengthen the exterior. Three acupoints around the nose [Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and Yintang (GV 23)] are situated in the cheek and around the nose and have the effects to expel wind, disperse the pathogens, and dredge the nose. The combination of the two groups of the acupoints can correct deficiency of the lung qi and also expel excess of the nose for dealing with both the causative factors and external symptoms<sup>[8-12]</sup>. Lin HX treated guinea pig with AR with the three acupoints of the nose and observed the change of its symptoms and change in the contents of interleukin-4 (IL-4) of peripheral blood. It has been proven by the experiments that the therapeutic effects are satisfactory in the treatment of AR guinea pig with the three acupoints of the nose, with the remarkable effective rate of 33.3% and the effective rate of 66.7%. It has also been observed that the number of treatments, the number of needle manipulation and the intensity of needle stimulation showed positive correlation in the acupuncture effect<sup>[13]</sup>.

*Xiang Ju* Capsules, composed of *Hua Xiang Shu Guo Xu* (*Platycarya strobilacea* Sieb. et Zucc. seedless), *Huang Qi* (*Radix Astragali*), *Xia Ku Cao* (*Spica Prunellae*), *Ye Ju Hua* (*Flos Chrysanthemi Indici*), *Fang Feng* (*Radix Saposhnikovia*), *Xin Yi* (*Flos Magnoliae*), *Bai Zhi* (*Radix Angelicae Dahuricae*), *Gan Cao* (*Radix Glycyrrhizae*), and *Chuan Xiong* (*Rhizoma Chuanxiong*), have the effects to disperse and expel wind by spicy herb, benefit qi, strengthen the constitution, open the orifice, stop pain and itching, regulate the immune functions, resist inflammation and resist allergic action<sup>[14]</sup>. It has been proven by Chinese pharmacological study that *Xiang Ju* Capsules can produce stronger and extensive anti-inflammatory, anti-allergic and anti-viral effect, and also can induce white cells to produce interferon, so as to inhibit the proliferation of virus<sup>[15]</sup>. Therefore, *Xiang Ju* Capsules have been extensively used in the treatment of acute and chronic rhinitis and sinusitis. In the recent years, there are many reports about the treatment of AR by *Xiang Ju* Capsules.

Shi QY treated 120 patients with perennial AR by *Xiang Ju* Capsules, with a remarkable effective rate of 85.8% and total effective rate at 95.0%<sup>[14]</sup>. Du FL treated 35 cases of the patients with rhino-sinusitis and 74 cases of non-surgical patients by *Xiang Ju* Capsules and *Huo Xue Hua Yu* (Blood-activating and Stasis-dispersing) Capsules. After a course of treatment, VAS scores were obviously improved in the ventilation of the nose in the surgical and non-surgical patients<sup>[16]</sup>. Shi ZF, *et al*, treated 110 cases of AR patients with antihistamines

plus *Xiang Ju* Capsules, with a total effective rate of 92.7%, and the therapeutic effects were obviously higher than that of administration of anti-histamines alone<sup>[17]</sup>. Li X, *et al*, treated 50 cases of AR patients by *Xiang Ju* Capsules plus ear point seed-embedding method. After a course of treatment (4 weeks), the remarkable effective rate was 50.0% and the total effective rate was 76.0%, all better than that of application of Loratadine tablets alone<sup>[18]</sup>.

It has been proven in the clinical study that Jin's three-needle plus *Xiang Ju* Capsules, remarkable in the therapeutic effects in treatment of AR and better than application of *Xiang Ju* Capsules alone, can be used as a common method for AR and needs clinically popularizing.

#### Conflict of Interest

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

#### Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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