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Special Topic Study

Therapeutic observation on acupuncture-moxibustion at different intervals for persistent allergic rhinitis

不同频次针灸治疗持续性变应性鼻炎的疗效观察

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Abstract

Objective: To observe the therapeutic effect of acupuncture-moxibustion at different intervals on persistent allergic rhinitis.

Methods: A total of 90 patients conforming to the inclusion criteria were randomized into three groups named A, B and C by randomized block method. Patients in all three groups received the same treatment of acupuncture and herbal cake-partitioned moxibustion at the same acupoints, while the treatment frequency was different. Patients in group A received the treatment once a week, group B twice a week and group C three times a week, and all the treatment lasted for 4 weeks. The total nasal symptom score (TNSS), total ocular symptom score (TOSS) and Sino-nasal outcome test-20 (SNOT-20) were evaluated before and after treatment. The self-rating score of symptoms was evaluated during treatment and 2 weeks after treatment.

Results: The total effective rate was 80.0% in group A, 93.3% in group B, and 100.0% in group C. The total effective rate in group A was statistically different from that in group B and group C (both $P<0.05$), but there was no significant inter-group difference in total effective rate between group B and group C ($P>0.05$). After treatment, scores of TNSS, TOSS and SNOT-20 in all three groups dropped significantly, and statistically different from those before treatment (all $P<0.05$); between-group comparison showed group B and group C decreased more obvious than group A (all $P<0.05$). In self-rating score of symptoms, there were no inter-group statistically significant differences in the first 3-week treatment (all $P>0.05$); after 4-week treatment, the score in group A was higher than that in group B and group C, and showed statistical significant (both $P<0.05$); at 2 weeks after treatment, the score in group A was higher than that in group B and group C based on an everyday record, showing statistical significance (both $P<0.05$). At the 11th day after treatment, the score in group B was higher than that in group C ($P<0.05$). There were no significant differences between group B and group C at other time points (all $P>0.05$).

Conclusion: All three protocols are effective for allergic rhinitis. With the increase of treatment frequency, the therapeutic efficacy with a treatment frequency of twice a week and three times a week is superior to that of once a week. Frequency of three times a week has a better long-term effect than once and twice a week, together with the least fluctuation of symptoms.

Keywords: Acupuncture Therapy; Acupuncture-moxibustion Therapy; Moxibustion Therapy; Herbal Cake Separated Moxibustion; Rhinitis, Allergic; Frequency

【摘要】目的：观察不同频次针灸治疗持续性变应性鼻炎的临床疗效。**方法：**将符合纳入标准的90例患者，采用随机区组法分为A组、B组和C组。三组治疗方法相同，均采用相同穴位进行针刺和隔药饼灸，但三组治疗频次不同，A组每周治疗1次，B组每周治疗2次，C组每周治疗3次。三组均治疗4周。观察三组治疗后鼻部症状总评分(TNSS)、眼部症状总评分(TOSS)和鼻腔鼻窦结局评分(SNOT-20)的变化。观察治疗期间及治疗结束后2周患者症状自主评分变化。**结果：**A组总有效率80.0%，B组总有效率93.3%，C组总有效率100.0%；A组总有效率与B、C组的差异均有统计学意义(均$P<0.05$)，B组和C组总有效率无统计学差异($P>0.05$)。TNSS，TOSS和SNOT-20评分方面，治疗后，三组评分均较同组治疗前降低，组内差异有统计学意义(均$P<0.05$)；组间比较，B、C两组评分较A组降低更明显(均$P<0.05$)。症状自主评分方面，治疗前3周三组评分无统计学差异(均$P>0.05$)；第4周时A组评分高于B组和C组，组间差异有

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统计学意义(均P＜0.05)；治疗结束后2周A组每天的评分均高于B组和C组，组间差异有统计学意义(均P＜0.05)；治疗结束后第11天B组高于C组(P＜0.05)，其余时间B组和C组差异无统计学意义(均P＞0.05)。**结论：**三种治疗频次对于持续性变应性鼻炎患者均有效，且随着治疗时间的累计，每周2次及每周3次治疗的疗效优于每周1次。每周3次较每周1次及每周2次更能维持疗效，且治疗结束后患者症状波动最小。

【关键词】针法；针灸疗法；灸法；药饼灸疗法；鼻炎，变应性；频率

【中图分类号】R246.8　　**【文献标志码】**A

Allergic rhinitis (AR) is a common disease with a high incidence in the ear, nose and throat (ENT) department[1]. According to the eEpidemiological data,survey shows that 10%-20% of the world population suffer from AR, and the incidence of AR was around 11.1% in China[2]. The major clinical symptoms of AR include nasal obstruction, runny nose, itching and sneezing, which may be accompanied by e. Eye or throat symptoms may also be present. AR can be subdivided into intermittent AR (symptoms <4 d/week, or < 4 consecutive weeks) and persistent AR (symptoms ≥4 d/week, and ≥4 consecutive weeks)). The severity of AR can be classified into mild AR [without obvious influence on patients' quality of life (QOL) including sleeping, daily activities and work or study performance] and moderate-severe AR (with obvious influence on patients' QOL)[3]. Current researches have proved the therapeutic effect and advantages of acupuncture-moxibustion for the treatment of AR from the perspective of clinical, laboratory and literature studies. We used randomized block design and set disease severity as the blocking factor to observe the clinical effect of acupuncture-moxibustion at different intervals in treating AR, and to discuss its mechanism focusing on the immune system. The report is now given as follows.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria in Western medicine

This was based on *Guidelines for the Diagnosis and Treatment of Allergic Rhinitis* (Tianjin, 2015)[3].

Clinical symptoms: At least 2 symptoms among coughing, runny nose, itching and nasal obstruction; daily attack time accumulating to at least 1 h; may be accompanied with itching, tears or red eyes.

Signs: The nasal mucosa usually appears pale, and swelling or watery secretion in nasal canal.

Allergen test: With at least 1 positive skin prick test (SPT) result or the positive result of serum specific immunoglobulin E (SIgE).

1.1.2 Diagnostic criteria in traditional Chinese medicine (TCM)

This was based on the diagnostic criteria in *Otolaryngology of Traditional Chinese Medicine*[4].

Main symptoms: Nasal obstruction, runny nose, sneezing and itching.

Main signs: Swelling and pale nasal mucosa, clear secretion in nasal cavity.

Course: With repeated attack for more than 1 year.

With at least 2 main symptoms in combination with relevant signs.

1.2 Inclusion criteria

Met the above diagnostic criteria; no fear of acupuncture treatment; good compliance and easy to follow up, together with the following characteristics.

With a duration above 4 weeks; symptoms lasted ≥4 d in a week; sensitive to specific allergen with a clear medical history; aged between 18 and 70 years; with normal consciousness, communication capability and good cooperation; signed informed consent.

1.3 Exclusion criteria

Acute nasosinusitis or active asthma; structural abnormality of nasal cavity or with nasal polyp; was using anti-histamine, anticholinergic agent, glucocorticoid, decongestant or antibiotics; received systematic administration of glucocorticoid within recent 1 year or specific immuno-therapy; received acupuncture or herbal medical treatment for AR within recent 1 month; with serious cardiovascular, liver, kidney or hematologic diseases; with mental disorder; with serious disease affecting QOL; women during pregnancy or lactation.

1.4 Statistical methods

All data were processed using SPSS statistics 21.0. Comparisons of gender, total effective rate were done using non-parameter test. Between-group comparisons of age, course and different scales used variance analysis in random block design, least significant difference (LSD) Duncan or multi-sample Friedman M-test. Two-sample pairwise comparison Q-test with randomized block design was used for multiple comparisons. Intra-group comparison was processed using paired sample t-test or Wilcoxon signed-rank test. Repeated variance or multivariate analysis was used for repeated measurement data. P<0.05 indicated statistical significance.

1.5 General data

A total of 90 cases with persistent AR included in this study were all from the Acupuncture Department of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine between March 2017 and March 2018. All patients finished the whole treatment without drop-out cases. The patients were subdivided into mild AR and moderate-severe AR. According to their visiting sequence, patients of different severities were blocked

in the sequence of 3, and then were randomly allocated to three treatment groups by the random number table method. Between-group comparison showed no statistical significance in age, gender, duration and severity among the three groups (all $P>0.05$), indicating that the three groups were comparable (Table 1).

Table 1. Comparison of general data

Group	*n*	Gender (case)		Average age ($\bar{x}\pm s$, year)	Average duration ($\bar{x}\pm s$, year)	Severity (case)	
		Male	Female			Mild	Moderate-severe
A	30	17	13	33.6±1.7	5.7±0.7	14	16
B	30	14	16	31.1±1.7	5.3±0.7	14	16
C	30	13	17	34.4±1.7	5.8±0.7	14	16

2 Treatment Methods

Patients in three groups all received acupuncture plus herbal cake-partitioned moxibustion treatment.

2.1 Acupuncture

Acupoint: Bilateral Yingxiang (LI 20), Hegu (LI 4), Xiaguan (ST 7), Zusanli (ST 36), Sanyinjiao (SP 6); Yintang (GV 29) and Shangxing (GV 23).

Methods: Patients took a supine position. Yintang (GV 29) was punctured with a filiform needle of 0.25 mm in diameter and 25 mm in length, with lifting-thrusting manipulation. Other acupoints were punctured with filiform needles of 0.25 mm in diameter and 40 mm in length. After routine sterilization, needles were punctured at each acupoint with even reinforcing-reducing manipulation, the depth of insertion was dependent on when the patient felt soreness, distending and numbness. The needles were retained for 30 min after qi arrival.

2.2 Herbal cake-partitioned moxibustion

Acupoint: Yintang (GV 29).

Method: Herbs including *Fu Zi* (*Radix Aconiti Lateralis Preparata*), *Rou Gui* (*Cortex Cinnamomi*), *Dan Shen* (*Radix Salviae Miltiorrhizae*) and *Gan Jiang* (*Rhizoma Zingiberis*) were ground into powder at 2:2:1:1:0.5. Mixed 2.5 g herbal powder with rice wine to make a cake of 2.3 cm in diameter and 0.5 cm in height with a mould. Placed a herbal cake on Yintang (GV 29) firstly, and then placed a piece of moxa stick (class A moxibustion stick of Han Medical Brand, Nanyang Han Medical Moxibustion Company Ltd., Series: 18 mm× 200 mm) on the herbal cake and lighted. If the patient felt burning pain, a piece of medical gauze could be put under the herbal cake to avoid scald. The combustion of the moxa stick lasted for 30 min when the treatment was finished.

2.3 Treatment frequency and course

Patients in group A received treatment once a week on any day between Monday and Saturday; patients in group B received treatment twice a week either on Monday and Friday or Tuesday and Saturday; patients in group C received treatment three times a week either on Monday, Thursday and Friday or Tuesday, Thursday and Saturday. Four weeks of treatment constituted one course of treatment, and the therapeutic efficacy evaluation was done after one course of treatment.

3 Therapeutic Efficacy Evaluation

3.1 Evaluation items

3.1.1 Total nasal symptom score (TNSS), total ocular symptom score (TOSS) and Sino-nasal outcome test-20 (SNOT-20)

TNSS, TOSS and SNOT-20 were evaluated both before and after treatment. The evaluation was based on the quartering method of quartering, in which symptom severity was scored 0 to 3 points. 0 point indicated no symptom at all; 1 point indicated mild symptoms (light and bearable symptomsawareness but not troubled); 2 points indicated moderate symptoms (obvious and annoying symptoms, while bearabletroublesome but not interfering with normal daily activities or sleep); 3 points indicated severe symptoms (unbearable symptoms interfering with normal daily activities or sleep). TNSS and TOSS both included 7 questions with a maximum score of 21 points. Before treatment, patients were subdivided into a mild group (scored 1-7) and a moderate-severe group (scored 8-21). SNOT-20 included 20 questions with a maximum score of 60 points; a lower score indicated mild symptoms; whereas a higher score indicated worse symptoms.

3.1.2 Self-rating score of symptoms

The self-rating score of symptoms was made by our research group to record patients' nasal and ocular symptoms. Such item was recorded at a fixed time each day during the treatment period and 2 weeks after treatment. During the treatment period, a clinical observer evaluated patients' nasal and ocular symptoms each week at a fixed time. At 2 weeks after treatment, the self-rating score of symptoms was collected at follow-up visits.

3.2 Therapeutic evaluation criteria

This was based on the *Diagnostic and Treatment Principle for Allergic Rhinitis and A Recommended Scheme*[5]. The score was calculated according to the

following formula. Reduction rate of symptoms score = (Score before treatment – Score after treatment) ÷ Score before treatment × 100%.

Marked effect: Reduction rate of symptoms score ≥66%.

Effective: Reduction rate of symptoms score ≥26%, but <66%.

Invalid: Reduction rate of symptoms score <26%.

3.3 Results

3.3.1 Comparison of clinical efficacy

After 4 weeks of treatment, the total effective rate was 80.0% in group A, 93.3% in group B and 100.0% in group C. The total effective rate in group A was lower than that in group B and group C, and the between-group comparisons showed statistical significance (both $P<0.05$); the between-group comparison of group B and group C showed no statistical significance ($P>0.05$), (Table 2).

Such results showed that the treatment efficacy of once a week was inferior to those of twice a week and three times a week, while twice a week and three times a week showed no significant difference in comparison of clinical efficacy.

Table 2. Comparison of clinical efficacy among the three groups (case)

Group	*n*	Marked effect	Effective	Invalid	Total effective rate (%)
A	30	16	8	6	80.0
B	30	20	8	2	93.3[1)]
C	30	22	8	0	100.0[1)]

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

3.3.2 Comparison of scores of TNSS, TOSS and SNOT-20

Before treatment, comparisons of the three scores among the three groups showed no statistical significance (all $P>0.05$), indicating the comparability. After treatment, the scores dropped significantly, and the intra-group comparisons showed statistical significance (all $P<0.05$). After treatment, the three scores in group A were higher than those in group B and group C, and the between-group comparisons showed statistical significance (all $P<0.05$); the between-group comparison showed no statistical significance between group B and group C ($P>0.05$), (Table 3).

Such results showed that the improvements of symptoms and QOL of once a week was inferior to those of twice a week and three times a week, while treatment of twice a week and three times a week showed no statistical difference.

3.3.3 Comparison of self-rating score of symptoms during treatment

During treatment, between-group comparisons showed no statistical significance (all $P>0.05$) among the three groups in the 1st, 2nd and 3rd week; in the 4th week, the score in group A was higher than that in group B and group C, and the between-group comparison showed statistical significance (all $P<0.05$); while the comparison between group B and C showed no statistical significance ($P>0.05$), (Table 4).

Such results showed that symptom alleviation was similar among the three groups before the 3rd week of treatment. With the increase of treatment time and from the 4th week, the treatment efficacies of twice a week and three times a week were better than that of once a week, while the efficacy of twice a week and three times a week showed no obvious difference ($P>0.05$).

Table 3. Comparison of TNSS, TOSS and SNOT-20 before and after treatment ($\bar{x}\pm s$, point)

Group	*n*	Time	TNSS+TOSS	SNOT-20
A	30	Before treatment	9.90±0.46	15.27±1.07
		After treatment	3.85±0.42[1)]	8.46±0.95[1)]
B	30	Before treatment	10.00±0.46	13.91±1.07
		After treatment	1.92±0.42[1)2)]	4.84±0.95[1)2)]
C	30	Before treatment	10.13±0.46	15.29±1.07
		After treatment	1.77±0.42[1)2)]	4.93±0.95[1)2)]

Note: Intra-group comparison, 1) $P<0.05$; compared with group A, 2) $P<0.05$

Table 4. Comparison of the self-rating score of symptoms during treatment ($\bar{x}\pm s$, point)

Group	*n*	First week	Second week	Third week	Fourth week
A	30	7.60±3.20	4.53±2.53	2.80±2.43	2.40±2.35
B	30	7.85±2.27	3.69±1.65	1.69±1.18	1.00±1.00[1)]
C	30	9.33±3.38	4.50±2.36	2.33±2.45	1.28±1.18[1)]

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

3.3.4 Comparison of self-rating score of symptoms 2 weeks after treatment

Two weeks after treatment, the self-rating score of symptoms in group A was higher than that in group B and group C, and the differences showed statistical significance (both $P<0.05$). On the 11th day after treatment, the score in group B was higher than that in group C, and the difference showed statistical significance ($P<0.05$), while the difference between group B and group C showed no statistical significance at other time points (all $P>0.05$). The score varied most significantly in group A, followed by group B and group C (Table 5).

Such results showed that the treatment frequency of three times a week had a better and more stable treatment effect than once a week and twice a week, and treatment frequency of once a week performed the worst regarding the stability of treatment effect.

Table 5. Comparison of self-rating score of symptoms 2 weeks after treatment ($\bar{x}\pm s$, point)

Time	*n*	Group A	Group B	Group C
Day 1	30	2.40±2.35	1.00±1.00[1)]	1.29±1.21[1)]
Day 2	30	2.47±2.42	1.00±1.00[1)]	1.29±1.21[1)]
Day 3	30	2.53±2.36	1.08±1.04[1)]	1.29±1.21[1)]
Day 4	30	2.60±2.26	1.00±1.00[1)]	1.29±1.21[1)]
Day 5	30	3.13±2.33	1.15±1.14[1)]	1.29±1.21[1)]
Day 6	30	3.27±2.25	1.23±1.09[1)]	1.29±1.21[1)]
Day 7	30	3.00±2.83	1.07±0.95[1)]	1.35±1.22[1)]
Day 8	30	3.67±2.71	1.07±0.95[1)]	1.47±1.50[1)]
Day 9	30	3.87±2.90	1.54±1.27[1)]	1.52±1.28[1)]
Day 10	30	3.27±3.10	1.38±1.32[1)]	1.59±1.37[1)]
Day 11	30	3.27±2.63	2.23±2.00[1)]	1.35±1.27[1)2)]
Day 12	30	3.27±2.63	1.38±1.26[1)]	1.35±1.27[1)]
Day 13	30	3.40±2.50	1.69±1.65[1)]	1.35±1.22[1)]
Day 14	30	3.53±2.55	1.77±1.42[1)]	1.35±1.41[1)]

Note: Compared with group A at the same time point, 1) $P<0.05$; compared with group B at the same time point, 2) $P<0.05$

4 Discussion

We chose bilateral Yingxiang (LI 20), Hegu (LI 4), Xiaguan (ST 7), Zusanli (ST 36) and Sanyinjiao (SP 6), plus Yintang (GV 29) and Shangxing (GV 23) in acupuncture treatment, while applied herbal cake-partitioned moxibustion to Yintang (GV 29). Yingxiang (LI 20) is the crossing point of the Hand and Foot Yangming Meridians, and is close to nasal cavity. It can improve symptoms of nasal obstruction and dysosmia[6-8], decrease serum immunoglobulin E (IgE) and nasal eosinophils levels[9]. Yintang (GV 29) connects to the lung, and its skin texture can reflect the pathological status of the lung[10]. This acupoint can dredge meridian and promote yang. Meanwhile, with the warm effect of *Ai Ye* (*Folium Artemisiae Argyi*) and other herbs, herbal cake-partitioned moxibustion has the functions of dispersing wind-cold, opening nasal orifice, exciting yang and nourishing lung qi. The supratrochlear nerve passes through Yintang (GV 29)[11], stimulating Yintang (GV 29) can regulate nerve conduction from the trigeminal nerve to the central nerve system, and thus intervene the secretion of histamine in the nasal mucosa to alleviate symptoms in AR. Researches of acupuncture for AR in the recent decade showed that Yintang (GV 29) was the basic acupoint for AR[12]. Xiaguan (ST 7) belongs to the Stomach Meridian, which starts from the nose. Moreover, Xiaguan (ST 7) is located nearby the nose, and needling Xiaguan (ST 7) can alleviate nasal symptoms. Clinical and experimental researches showed that needling Xiaguan (ST 7) had the function of reducing the release of mastocyte[13] and regulating the secretion function of nasal mucosa and gland, and changing the diameter of nasal capillaries, thus to alleviate symptoms[14]. As recorded in *Zhen Jiu Jia Yi Jing Jing Xue Chong Ji* (*Recompile of Acupoints in A-B Classic of Acupuncture and Moxibustion*), Shangxing (GV 23) can treat runny nose and nosebleed. Needling Shangxing (GV 23) can regulate meridian qi of the Governor Vessel, and disperse wind from the superficies, remove wind evil to stop itching and alleviate symptoms[15]. Hegu (LI 4) is the Yuan-Primary point of the Large Intestine Meridian, and the lung and large intestine are in an exterior-interior relationship. Therefore, Hegu (LI 4) can be selected to treat pulmonary diseases[16]. According to the theory that an acupoint can treat the disorders where its meridian distributes, needling Hegu (LI 4) can alleviate AR symptoms. Based on the documents in history and recent studies, Hegu (LI 4) is the most frequently used acupoint for AR[11,17-18]. The combination of Sanyinjiao (SP 6) and Zusanli (ST 36) can regulate the spleen and stomach functions, strengthen the middle Jiao to reinforce healthy qi, and eliminate the pathological factors[19]. At the same time, according to the rules of generation-inhibition among the five elements, the combination of the two points has the function of reinforcing the earth to generate the metal[20].

After the first acupuncture treatment, acupuncture efficacy decreased after the periods of latency and peak[21]. Such phenomenon showed that acupuncture efficacy had a certain time limit. The efficacy of acupuncture dropped until disappeared beyond the time limit[22]. The stimulation of acupuncture rises with the accumulation of the treatment frequency, together with the treatment efficacy. Whereas such efficacy accumulation has a certain limit, and overabundant

treatment frequency may turn effective stimulation into ineffective one, or even adverse one[23]. Acupuncture frequency can influence treatment effect through stimulation intensity[24-27]. Former acupuncture frequency study of AR normally lacked description of the treatment interval. Therefore, our study focused on the correlation between the treatment frequency and effect and set the specific treatment interval, in which treatment frequencies of once a week, twice a week and three times a week were observed respectively, for analyzing and evaluating the clinical effects of acupuncture with different treatment frequencies for AR.

The results of this study showed that acupuncture treatment can alleviate symptoms, and promote QOL in AR patients with a sustained treatment effect. For alleviating symptoms and promoting QOL, treatment frequencies of twice a week and three times a week were better than once a week; for sustaining treatment effect, treatment frequency of three times a week was better than once a week and twice a week. While due to the limitation of the small sample size, comparison of the effect of different treatment frequencies on different symptom severities cannot be done. In our further research, symptoms severity will be classified and observed, in combination with the study on acupuncture frequency, and acupuncture treatment scheme for AR can be optimized.

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 all individual participants.

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