JTCM 中医杂志

Online Submissions: http://www.journaltcm.com
info@journaltcm.com

J Tradit Chin Med 2012 September 15; 32(3): 1-2
ISSN 0255-2922

CLINICAL OBERVATION

Influencing factors on efficacy of summer acupoint application treatment for allergic rhinitis: a retrospective study

Jin Peng, Xiaqiu Wu, Jingqing Hu, Yigong Fang, Mingjie Zi, Baoyan Liu

Jin Peng, Xiaqiu Wu, Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing 100700, China
Jingqing Hu, Baoyan Liu, China Academy of Chinese Medical Sciences, Beijing 100700, China
Yigong Fang, Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing 100700, China
Mingjie Zi, Xiyuan Hospital, China Academy of Chinese Medical Sciences, Beijing 100700, China
Suppotred by the funds of Key Projects in the National S&T Pillar Program (No. 2008BAI53B061) and Major National S&T Program (No. 2008ZX10005-013)
Correspondence to: Prof. Baoyan Liu, China Academy of Chinese Medical Sciences, Beijing 100700, China. cectcm@gmail.com
Telephone: 86-10-64014411-3310
Accepted: March 23, 2012

Abstract

OBJECTIVE: Allergic rhinitis (AR) is a common health problem. Summer acupoint application treatment (SAAT) is reported to effectively treat and prevent AR from seasonal onset. In the present study, we aimed to evaluate its effects, especially on the course of AR, through a retrospective study.

METHOD: A cross-sectional multicenter study was performed based on patients treated between 2008 and 2009 in 13 clinical centers in China. A total of 1058 outpatients aged ≥2 years with documented AR and ≥1 year SAAT were eligible for enrollment. A case report form (CRF) was completed by both patient and doctor. The CRF was designed to collect data on the patient's history of SAAT, AR condition, and self-reported health condition. The outcomes (dependent variables) were incidence and intensity of AR and concomitant medications used. Data were analyzed with ordinal logistic regression (OLR).

RESULTS: Treatment course and seasonal pattern of AR were related to all dependent variables positively. After controlling for sample bias and confounding factors, the findings suggested that a 3-year treatment course had better efficacy (*OR*/ incidence of AR: 2.57, 95% *CI*: 1.76-3.76; *OR*/intensity of AR: 2.17, 95%*CI*: 1.50-3.17; OR/ concomitant medications: 2.20, 95% *CI*: 1.50-3.23) compared with a 2-year or less treatment course.

CONCLUSION: The results showed that: 1)the length of treatment course was positively associated with the efficacy of SAAT (the longer the treatment course, the better the efficacy); and 2)SAAT was more efficacious in treating seasonal AR than non-seasonal AR.

Key words: Acupoint sticking therapy; Allergic rhinitis; Cross-sectional studies; Traditional Chinese Medicine

INTRODUCTION

Allergic rhinitis (AR) is a global health problem, with a prevalence between 10% and 20%.[1] To avoid this disease, patients usually have to stay away from their allergens, causing disruption to normal living. Under the guidance of the theory of Chinese Medicine (CM), Summer acupoint application treatment (SAAT), a treatment administered in the summer time with a

type of herbal moxibustion, has been reported to effectively prevent AR from onset.[2-4]

According to CM theory, AR, a consequence of disorders in the respiratory system, is related to lung deficiencies. Patients with AR are often sensitive to cold and have a lack of *yang Qi* inside their body. With herbal moxibustion, SAAT can improve the *yang Qi* of AR patients. Technically, one feature of SAAT is that the treatment must be administered during the three hottest days in the summer.[2] Due to the non-invasive and low-cost nature of SAAT, this method has been increasingly used in CM clinics in China. However, there still exists some debate about key factors of this method, such as the optimal treatment course, the timing of administering it, and the proper herbal composition. Most conclusions made before were based on clinical studies conducted in a short period (less than 1 year)[2,5-8] and/or with small sample size.[9,10] Therefore, the efficacy of a full treatment course of SAAT has not yet been clearly addressed.

Motivated by this aim, a retrospective study was performed to investigate the efficacy in relation to treatment course. In addition, the features (duration, onset season, onset incidence) of AR were researched as well. The results were expected to optimize the use of SAAT for AR.

METHODS

Study population

This was a cross-sectional multicenter study based on patients from 13 clinical centers in China. Outpatients aged ≥2 years with documented AR and treatment with SAAT for 1 year or more, were eligible for enrolment. The diagnostic standard for AR that we used was the Principles of Diagnosis and Recommended Treatment of Allergic Rhinitis.[11]

All patients recruited were treated in the summers of 2008 and 2009. Those who were excluded: 1) were pregnant or lactating; 2) were allergic to the herb or excipient; 3) had a body temperature of 37.5°C or above; 4) produced yellow and thick sputum; 5) presented with uncontrolled diabetes; and 6) were previously diagnosed with bronchiectasis, endobronchial tuberculosis, pulmonary fibrosis, severe heart, liver or kidney disease, mental disease or cancer. Written informed consent was signed by each patient or his guardian.

The protocol was approved by the Ethics Committees of the Institution of Basic Research in Clinical Medicine, CACMS (China Academy of Chinese Medicine).[12] This study was also registered in the Chinese Clinical Trial Registry with the registration No. of ChiCTR-TNRC-10001292.

Data collection

Patients were interviewed at the screening center by doctors trained for the purpose using a questionnaire divided into 2 parts. In the first part, patients reported: age, sex, main symptoms to be treated (cough, sputum, wheezing, shortness of breath, asthma, nasal congestion, sneezing), duration of AR (years), seasonal pattern of AR (seasonal, non-seasonal), incidence of AR before SAAT treatment("1"=less than once per month, "2"=2-3 times per month, "3" = 1-2 times per week, "4"=more than 3 times per week), intensity of AR (from "0" = least severe level to "10" = most severe level), and duration of treatment course (years). For patients under 12 years' old, the questions were answered by their guardians. In the second part, doctors reported the information of diagnosis and intensity of AR (3 levels, "1"=l ight, "2"=moderate, "3"=heavy), according to the Principles of Diagnosis and Recommended Treatment of Allergic Rhinitis.[11]

Outcomes measured

Outcomes (dependent variables) included incidence and intensity of AR, and concomitant medications. Incidence and intensity of AR were defined as the number of times and the level of severity of AR occurring in the previous year for each patient, respectively. Concomitant medication included the types of medications and their course of administration during AR episodes and/or remission.

These outcomes were evaluated by the patients themselves or their guardians, with the level of symptoms being compared to the baseline before SAAT treatment. The efficacy (outcomes) was rated in five categories: " 1"=much worse than before, "2"=mildly worse, "3"=no change, neither better nor worse, "4" =mildly effective and "5"=very effective.

Data analysis

The original data were double-entry, inspected and stored as e-documents in the "Clinical Data Collection & Management Database", which was developed by CACMS.

The association between eight individual factors and three outcomes was evaluated with ordinal logistic regression (OLR).[13] The statistical software R Version 2.12.1 and package "epicalc" were used.

Eight factors were: age (groups of >65 years old and ≤ 65 year old), sex, duration of AR (groups of >10 years and ≤10 years), seasonal pattern of AR (non-seasonal, seasonal), treatment course (groups of 1, 2, and ≥3 years duration), incidence of AR before SAAT treatment, intensity of AR reported by patients, and intensity of AR reported by doctors. Three outcomes are: incidence of AR, intensity of AR, concomitant medications.

RESULTS

A total of 1058 patients (41.63% male and 58.37% female) were enrolled in this research. The mean age was 34.97 (SD=20.45) years, the mean duration of AR was

8.75 (SD=8.45) years, the mean treatment course of SAAT was 1.82 (SD=1.71) years. The most prevalent allergic symptoms were sneezing (81.10%) and nasal congestion (79.10%). Of all the cases, seasonal onset accounted for 62.9%, of which 68.54% occurred in winter.

The results showed that the incidence and the intensity of AR and the concomitant medications decreased with the duration of the treatment course. Taking the incidence of AR as an example, the percentages of "effective" ("very effective" plus "mildly effective") for 1-year, 2-year, and ≥3-year durations of treatment were 69.5%, 75.4% and 79 %, respectively, compared with those of "no change" (30%, 24.8% and 21%) and those of "worse" (0.5%, 0% and 0%). This suggested that SAAT was a potential method to prevent AR from onset. Interestingly, the percentages of "very effective" with ≥3-year duration of treatment were all significantly higher than those with 1-year or 2-year durations of treatment (P<0.001) for all the three outcomes. This indicated the importance of treatment course for the efficacy of SAAT on AR, which was also observed by Wu et al.[14]

OLR analysis showed that duration of treatment course had a positive association with incidence (*OR*: 1.21; 95%*CI*: 1.12-1.33), intensity (*OR*: 1.19; 95%*CI*: 1.10-1.30), and concomitant medication (*OR*: 1.18; 95%*CI*: 1.09-1.29), as depicted in Table 2. The same trend could be found for the seasonal pattern of AR (incidence *OR*: 1.66; 95%*CI*: 1.29-2.14; intensity *OR*: 1.75; 95% *CI*: 1.36-2.26; concomitant medication *OR*: 1.59; 95%*CI*: 1.23-2.05). On the other hand, the incidence of AR before SAAT treatment showed a negative association with incidence (*OR*: 0.82; 95% *CI*: 0.73-0.92), intensity (*OR*: 0.81; 95% *CI*: 0.73-0.91), and concomitant medication (*OR*: 0.82; 95% *CI*: 0.73-0.92) in the present year. The other five factors (gender, duration of disease, intensity of AR-Doctors, and intensity of AR-Patients) showed no significant effect on the outcomes (Table 2).

Table 1 Distribution of the outcomes in three levels of treatment course

Treatment course	Very effective (%)	Mildly effective (%)	No change (%)	Worse[a](%)	Total (%)	*P* value
Incidence of AR (missing=9)						
1 y	122(20.8)	286(48.7)	176(30)	3(0.5)	587(100)	
2 y	67(23.4)	148(51.7)	71(24.8)	0(0)	286(100)	0.24
≥3 y	72(40.9)	67(38.1)	37(21)	0(0)	176(100)	<0.001[a]
Intensity of AR onset (missing=11)						
1 y	134(22.9)	264(45.1)	183(31.2)	5(0.9)	586(100)	
2 y	64(22.5)	150(52.6)	70(24.6)	1(0.4)	285(100)	0.07
≥3 y	64(36.4)	77(43.8)	35(19.9)	0(0)	176(100)	<0.001[a]
Concomitant medications (missing=41)						
1 y	88(15.4)	232(40.7)	249(43.7)	1(0.2)	570(100)	
2 y	48(17.3)	114(41)	116(41.7)	0(0)	278(100)	0.76
≥3 y	55(32.5)	60(35.5)	52(30.8)	2(1.2)	169(100)	<0.001[a]

Notes: [a]Since no case fell in the category of "much worse than before", it was combined with the category of "mildly worse" to form a new category named "worse".

Table 2 The association between all factors and outcomes by OLR analysis, adjusted *OR* (95%*CI*)

	Incidence of AR	Intensity of AR	Concomitant medications
Treatment course[a]	1.21(1.12,1.33)	1.19(1.10,1.30)	1.18(1.09,1.29)
Gender(female vs male)	1.11(0.87,1.42)	1.03(0.80,1.31)	0.90(0.70,1.15)
Age (>65 vs ≤65)	1.00(1.00,1.01)	1.01(1.00,1.01)	1.00(1.00,1.01)
Duration of disease (>10 vs ≤10)	0.99(0.97,1.01)	0.99(0.98,1.01)	1.00(0.99,1.02)
Intensity of AR-D (reported by doctor)	0.97(0.75,1.26)	1.02(0.78,1.32)	1.28(0.99,1.68)
Intensity of AR-P (reported by patient)	0.93(0.85,1.01)	0.90(0.82,0.98)	0.91(0.83,1.00)
Incidence of AR before SAAT[a]	0.82(0.73,0.92)	0.81(0.73,0.91)	0.82(0.73,0.92)
Seasonal pattern of AR[a]	1.66(1.29,2.14)	1.75(1.36,2.26)	1.59(1.23,2.05)

To avoid the bias of sample selection, the adult sample aged 18-83 were retained to mine the effect of treatment course. In addition, we put "age" and "duration" in the OLR model along with our key factor – duration of treatment course - to eliminate the potential confounding effects. The result again suggested that the longer treatment course, the better the efficacy. As shown in Table 3, the odds ratios of incidence, intensity, and concomitant medications for patients with ≥ 3-year treatment durations vs. patients with 1-year treatment durations were 2.75, 2.17 and 2.20, respectively. However, the odds ratios for patients with 2-year treatment durations vs. patients with 1-year treatment durations were around 1, which meant no significant difference between the efficacy of 1-year treatment durations and that of 2-year treatment durations (Table 3).

Table 3 The association between treatment course and outcomes in adult group (aged 18-83), adjusted *OR* (95%*CI*)

	Incidence of AR	Intensity of AR	Concomitant medications
Treatment course ref.=1 y			
=2 y	1.20(0.88,1.64)	1.13(0.83,1.55)	0.99(0.72,1.34)
≥3 y	2.57(1.76,3.76)[a]	2.17(1.50,3.17)[a]	2.20(1.50,3.23)[a]

Notes: [a]adjusted *OR*: adjusted by age and duration.

DISCUSSION

The efficacy of SAAT on AR has been confirmed extensively,[10,15,16] but the effect of treatment course duration is still under debate. Xia[8] recommended that the proper treatment course be one year, whereas Xu[10] and Chen[15] suggested a 3-year course. Clinical reports have shown that 1-year and 3-year treatment durations had no significant difference on AR, i.e., the effectiveness rate with a 1-year course was 69%-96.9% ,[8,15,17] while that of a 3-year course was 71.4%-96.7% .[10,16] Meanwhile, a few studies have indicated the tendency to increased effectiveness with longer treatment course.[16,18] We obtained a similar conclusion as well. Nevertheless, we found that the efficacy of a 3-year treatment duration was better than that of either a 1-year or 2-year treatment duration.

A seasonal pattern of SAAT had been clearly depicted in previous analyses, which is a result of the principle of SAAT. According to CM, insufficient Lung-*Qi* in the human body facilitates AR seasonal onset.[19] Herbal moxibustion, especially SAAT, can warm and strengthen the Lung-*Qi*. First, the basic herbal composition can expel cold and promote circulation of *Qi*. Second, with the help of this herbal composition, this treatment can stimulate the special acupuncture points belonging to Back-shu, e.g., Fengmen (UB 12) and Feishu (BL 13), and motivate dorsal root ganglia and spinal nerves. This may help to regulate the synthesis and release of neurotransmitters.[20] Third, this treatment is performed during the three hottest days in summer, when *yang qi* is believed to be at the highest level. This can enhance the herbal effect as it penetrates the acupoints.

This study attempted to assess the efficacy of SAAT in regard to AR incidence, intensity and concomitant medications used. The results of OLR analysis showed that the treatment course duration was positively associated with the efficacy of SAAT: the longer the treatment course, the better the efficacy. In addition, it was found that SAAT was more efficacious for treating seasonal AR compared with non-seasonal AR.

The measurement of disease symptoms and the outcomes in this study deserve attention. All measured variables in this study were self-rated. Even the intensity of AR reported by the doctor was based on subjective judgment rather than objective measures. Therefore, future studies on the optimal treatment course conducted with high quality design are needed.

ACKNOWLEDGMENTS

The authors are grateful to 13 clinical centers for recruiting patients for this study. They are Guanganmen Hospital, Xiyuan Hospital, Dongzhimen Hospital, Dongfang Hospital, Guangdong Hospital of TCM, The First Affiliated Hospital of Hunan University of Traditional Chinese Medicine, Affiliated Hospital of Liaoning University of Traditional Chinese Medicine, Affiliated Hospital of Shandong University of Traditional Chinese Medicine, Hubei Hospital of TCM, Jiangsu Hospital of TCM, Affiliated Hospital of Chengdu University of Traditional Chinese Medicine, The Second Affiliated Hospital of Hunan University of Traditional Chinese Medicine, and The First Affiliated Hospital of Guiyang University of Traditional Chinese Medicine.

REFERENCES

1 **Brożek JL**, Bousquet J, Baena-Cagnani CE, et al. Allergic rhinitis and its impact on asthma (ARIA) guidelines: 2010 Revision. J Allergy and Clin Immunol. 2010; 126(9): 466-476.

2 **Tai CJ**, Chang CP, Huang CY, Chien LY. Efficacy of Sanfujiu to Treat Allergies: Patient Outcomes at 1 Year after Treatment. eCAM 2006; 4(2): 241-246.

3 **Chen WH**, Xin K, Cai CA, Hao F, Cao Y. Observation on therapeutic effect of acupoint application of Chinese medicine on bronchial asthma. Zhongguo Zhen Jiu 2009; 29(4): 272-274.

4 **Xia CX**. Analysis of effectiveness of Sanfu moxibustion based on 360 cases of allergic rhinitis . Liaoning Zhong Yi Yao Za Zhi 1996; 23(4): 184.

5 **Lu YK**. Analysis of effectiveness of Sanfu moxibustion based on 327 cases of chronic bronchitis. Zhongguo Zhen Jiu 1994; 14(S1): 31-32.

6 **Liu LL**, Zhu XH, Liu YS, Wu Y. Therapeutic effect of methods of treating winter-season diseases in summer on chronic obstructive pulmonary disease: a report of 300 cas-

es. Xin Zhong Yi 2011; 43(2): 116-118.

7 **Chen K**, Li S, Shi Z, Liu S, Zhao L. Two hundred and seventeen cases of winter diseases treated with acupoint stimulation in the summer. J Tradit Chin Med 2000; 20(3): 198-201.

8 **Xia CX**. Analysis of effectiveness of Sanfu moxibustion based on 360 cases of allergic rhinitis, Liaoning Zhong Yi Za Zhi 1996; 23(4): 184.

9 **Lang XM**. The effect of acupoint application treatment on allergic rhinitis in summer: a report of 30 cases. Zhong Yi Yao Lin Chuang Za Zhi 2007; 19(1): 31-32.

10 **Xu SN**, Chen S, Xu Y. The effect of acupoint application treatment on allergic rhinitis: a report of 30 cases. Fujian Zhong Yi Yao Za Zhi 2005; 36(3): 47-47.

11 Editor Committee of Otolaryngology Head and Neck Surgery Magazine, Chinese society of Otolaryngology Branch. Principle of Diagnosis and Recommended Treatment on Allergic Rhinitis. Zhonghua Er Bi Yan Hou Toujing Wai Ke Za Zhi 2005; 40(3): 166-167.

12 **Peng J**, Wu XQ, He LY, et al. Effects of summer-acupoint-application-therapy on reducing exacerbation frequency of chronic lung diseases in winter: protocol of a retrospective & prospective study. Zhong Xi Yi Jie He Xue Bao 2012; 10(1): 39-47.

13 **Bender R**, Ulrich G. Ordinal logistic regression in medical research. J Roy Coll Phys Lond 1997; 31(5): 546-551.

14 **Wu XQ**, Peng J, Liu BY. Efficacy of Sanfujiu treatment on acute exacerbations of chronic bronchitis: a retrospective study. The 2012 International Symposium on Public Health and Environmental Protection (PHEP2012). 2012; In press.

15 **Chen Q**, Chen XY. The research progress of acupoint application method in treating allergic rhinitis. Hunan Zhong Yi Yao Da Xue Xue Bao 2007; 27(1): 75-79.

16 **Chen LY**. 3-year clinical observation on Sanfujiu treatment for allergic rhinitis. Zhen Jiu Lin Chuang Za Zhi 1999; 15(8): 7-8.

17 **Lu ZN**, Bi GW, Liu QC, Shen ZM. Clinical observation on Sanfujiu treatment for allergic rhinitis: a report of 55 cases. Chengdu Zhong Yi Yao Da Xue Xue Bao 2007; 30 (3): 22-24.

18 **Shi TS**, Liu XJ, Zhu ZH. Clinical Observation on point injection combined with acupoint application for allergic rhinitis. Huanan Mei Tan Yi Xue Yuan Xue Bao 2011; 13 (2): 231-232.

19 **Qiu BS**, Wang SZ, Zhong YP, Mu RY. Study on correlativity of syndrome types of allergic rhinitis with their clinical characteristics. Zhong Yi Za Zhi 2004; 45(5): 373-376.

20 **Cui CB**, Wang JJ, Wu ZC. On functional area of Back-shu based on relationship between Back-shu points and Jiaji points. Zhongguo Zhen Jiu 2005; 25(7): 483-486.