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Chinese Medicine Acupoint Herbal Patching for Allergic Rhinitis: A Randomized Controlled Clinical Trial

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Abstract: The aim of this study is pursue the effect of herbal point-patch treatment on allergic rhinitis patients by investigation of the changes of serum total IgE (T-IgE) and eosinophile cationic protein (ECP) levels and through assessment of the results of SF-36 and rhinitis severity questionnaires. A prospective, randomized, single-blind, parallel, controlled study was used. Forty- three eligible participants were selected from outpatients of the Dept. of Ear, Nose, and Throat and Chinese medicine clinic, and 33 eligible participants completed the treatment satisfactorily. Participants used a Chinese herbal point-patch or a placebo patch once a week, for three hours at a time, after being randomly assigned to a control or an experimental group. Each treatment course was three weeks in duration, and each participant underwent two courses of treatment. Before and after each

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course, participants evaluated the effectiveness of the treatment by completing a questionnaire, and blood samples were collected for T-IgE and ECP analysis. The data revealed that the acupoint herbal patch is a valuable treatment for allergic rhinitis, especially in the symptoms of sneezing, running and itchy nose. The results of the SF-36 indicate a distinct improvement in GH (general health) and VT (vitality) in patients treated with acupoint herbal patches. This study supports the belief that the acupoint herbal patch is an effective treatment for allergic rhinitis and can significantly improve general health, social life and vitality in quality of life.

Keywords: Herbal Point-Patch; Allergic Rhinitis; ECP; SF-36; RS.

Introduction

As there have been great changes in our living environments and lifestyles in recent decades, the global population of asthma sufferers has increased by 45% each year since 1970s. It is now estimated that there are at least 300 million people worldwide who suffer from asthma (Masoli *et al.*, 2003). Incidence of allergic rhinitis in both adults and children also shows an increasing trend. Using the capital city of Taiwan as an example, Taipei City shows a prevalence of allergic rhinitis in as high as 53% of the population and approximately one fourth of these sufferers also suffer from associated asthma, atopic dermatitis or urticaria (Huang, 2003). Symptoms of allergic rhinitis include sneezing; nasal congestion; itching of the nose, eyes and throat; and rhinorrhea (Horak, 2000).

In addition to allergen avoidance and dietary control, current treatments for allergic rhinitis in conventional Western medicine include antihistamine treatment, nasal cromones, topical steroids, immunotherapy and surgical turbinate reduction (Van Cauwenberge *et al.*, 2000).

On the other hand, practitioners of Chinese medicine usually use herbal medication or acupuncture (Bydzovsky, 1987; Drasnar and Palecek, 1981; Gerardi *et al.*, 1983; He *et al.*, 1990; Langevin *et al.*, 2001; Lin and Chen, 2009; Wolkenstein and Horak, 1998; Xue *et al.*, 2002) and in recent years acupoint herbal patches have been widely used to treat allergic diseases such as asthma and allergic rhinitis. One of the most commonly used acupoint herbal patches is the Sanfu herbal patch. Although this has shown good clinical effectiveness, there has been only a few objective "randomized controlled trial (RCT)" to establish its efficacy (Tai and Chien, 2004; Tai *et al.*, 2007).

Despite thousands of years of history to support its effectiveness, Chinese medicine, due to a differing theory to that of Western medicine and the lack of scientific evidence and records to verify its efficacy, is facing difficulties for further development (Cabioglu and Cetin, 2008; Lin and Chen, 2008). The purpose of this study was to adopt the RCT model for testing the effects of acupoint herbal patches on serum total immunoglobulin E (T-IgE), eosinophil cationic protein (ECP), and quality of life and rhinitis severity in patients with allergic rhinitis.

Material and Methods

Study Design and Data Collection

The subjects enrolled in this study were patients from a specialized clinic for allergic rhinitis set up by the Department of ENT with the Department of Chinese Medicine at Dalin Tzuchi General Hospital, with the approval of the hospital's IRB. The study design and trail procedures are shown in Fig. 1. It includes two times treatment courses and these treatment courses are compared to see the difference between before and after treatment. Subjects that fit the inclusion criteria were assigned randomly into an experimental or a control group. The criteria were listed as follows: aged between 8 and 45; history of allergic rhinitis; perennially, seasonally or habitually recurrent sneezing; allergic rhinitis symptoms (rhinorrhea, sneezing, stuffiness, itching) for over 2 years; specific allergen identified with elevated T-IgE ($8 \sim 10$ years old $> 88\,\mathrm{IU/ml}$; adult $> 165.3\,\mathrm{IU/ml}$; Elevated ECP.

Interventions

Medications

The subjects in the experimental group were treated with herbal patches on acupoints on the back and lasted 3 hours/1 time, while the subjects in the control group were given placebo patches (ingredients: flour, water and edible pigments) on the same sites. The herbal regimen employed in the experimental group was according to *Zhang Shi Yi Tong* (Zhang Lu from the Chin Dynasty), and includes five herbs. The four herbs (*Sinapis Semen*, *Corydalis Rhizoma*, *Euphorbiae Kansui Radix, Asari Herba Cum Radice*) were ground into powder (mesh aperture number 80, Japanese standard 0.175 mm aperture

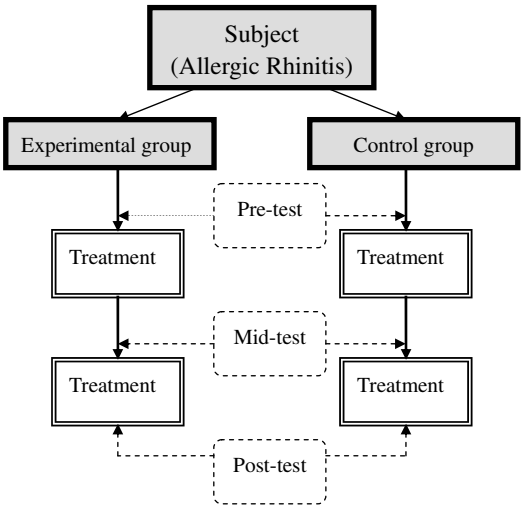

Figure 1. Study design flowchart. A prospective, randomized, single-blind, parallel, controlled study was used.

sieve), mixed thoroughly at the ratio of 7:7:4:4, and the mixed powder was later mixed with fresh ginger juice in the ratio of 22 g to 30 ml before use (Tian, 2000).

Acupoints

The herbal paste was smeared across pieces of nonwoven fabric of 8×6 cm, each weighing 5 g. The patch was applied just below the seventh cervical vertebra, covering a rectangular area including acupoints such as Dazhui (Pm 14), Dashu (BL 11), Fengmen (BL 12), Feishu (BL 13) and Dingchuan (NX 04).

Courses of treatment

As listed in Table 1.

Experiments

The four assessment tools used in this study were serum T-IgE and ECP concentrations, rhinitis severity (RS) assessment, and the health-related quality of life SF-36 questionnaire (SF-36).

Serum T-IgE and ECP

Serum T-IgE and ECP concentrations were measured using a fluorescence enzyme-linked immunosorbent assay with the UniCAP 100 System (Pharmacia, Sweden) according to manufacturer's suggestion.

RS assessment

The allergic rhinitis symptom rating scale (RS) was based on Majani *et al.* (2001) which evaluates eight typical major symptoms of allergic rhinitis, including five nasal symptoms (rhinorrhea, congestion, sneezing, itching and hyposmia) and three ocular symptoms (itching, watering and redness). Scores were assigned to each of the items, ranging from

Table 1. Courses of Treatment

Week	Treatment
1st	Preliminarily diagnosed by ENT doctors; blood sample taken.
2nd	*Pre-Test* Complete consent form*, case report form*, SF-36* and rhinitis severity assessment*; grouping; applied herbal patches or placebo patches.
3rd–5th (in the end of 5th Week)	Patch applied once weekly; 3 hours each time; 3 times comprising one course. *Mid-Test* Fill in the SF-36 questionnaire and rhinitis symptom scale for the 2nd time one week after the end of the 1st course.
6th–8th (in the end of 8th Week)	Continue on the 2nd course. *Post-Test* Fill in the SF-36 questionnaire and rhinitis severity assessment form for the 3rd time.

no symptoms (score 0) to severe symptoms (score 3), the total score therefore ranging from 0 to 24.

Quality of life scale

Short Form-36 (SF-36) Taiwan version (Lu *et al.*, 2002). The SF-36 is a general psychological instrument, not specifically designed for certain diseases, ages or treatments. With a total of 36 items, it consists of eight scales mainly adapted from the health-related quality of life survey used in the Medical Outcomes Study.

Statistical Methods

Data were collected and analyzed using SAS v8 or SPSS 10.0. The following statistical methods were employed based on the research objectives: differences in effectiveness and quality of life between the experimental and control groups were analyzed using the Wilcoxon signed-rank test; within-group differences between different points in time were assessed using the Mann- Whitney U test; internal consistency of the scales was evaluated using Cronbach's α; and validity was tested using correlation coefficients to examine the degrees of convergence and divergence.

Results

Seventy-five patients were enrolled, 42 were selected based on the inclusion criteria, and final results were obtained from 33 valid subjects at the end of study. A computer randomly assigned the subjects into a control group of 15 and an experimental group of 18.

The subjects' mean age was 22.4 ± 6.3 years, the youngest and oldest being 8 and 38. Of the subjects, 48.5% were male and 51.5% were female; all 33 patients (100%) were allergic to mites and 7 patients were allergic to household dust. The Wilcoxon signed-rank test comparing the basic data (T-IgE, ECP, RS and SF-36) from the two groups before treatment showed significant difference ($p < 0.01$) only in the symptom of nasal congestion; none of the other variables revealed a statistically significant difference (Table 2).

T-IgE and ECP

The levels of T-IgE and ECP in both the experimental and control groups showed no significant difference between pre-test and post-test results (Table 3).

RS

Compared to the pre-test results, the scores of RS showed no significant difference either during or after treatment for the control group. For the experimental group, on the other hand, scores of RS showed a significant difference ($p < 0.01$) both during and after treatment (Table 2).

Further analysis of each separate item for the eight major symptoms on the RS found that no symptoms showed significant improvement within the control group after the 1st

Table 2. Between-Groups Comparison Before Treatment

	Control Group n = 15		Experimental Group n = 18		
Variables	**Mean**	**SD**	**Mean**	**SD**	**p Value**
Age	21.4	1.5	23.2	8.4	0.229
T_IGE	402.87	273.75	505.28	371.80	0.486
ECP	18.64	14.17	23.14	16.47	0.573
RS	12.067	3.173	11.389	3.274	0.656
Sneezing	2.000	1.000	2.000	0.840	0.929
Rhinorrhea	2.067	0.884	2.389	0.778	0.325
Hyposmia	1.000	0.845	0.944	0.725	0.901
Stuffiness	2.133	0.640	1.389	0.698	0.005**
Itchy Nose	1.467	0.834	1.500	0.786	0.929
Itchy Eyes	1.400	0.632	1.444	0.856	0.789
Epiphora	0.867	0.640	1.000	0.970	0.817
Red Eyes	1.200	0.676	0.722	0.669	0.079
SF-36					
PF	98.000	4.140	93.056	17.668	0.486
RP	93.333	17.593	83.796	24.666	0.244
BP	85.467	17.460	75.944	17.665	0.135
GH	64.267	17.495	55.111	17.977	0.202
VT	65.333	15.407	60.833	17.678	0.361
SF	80.000	20.485	78.472	14.731	0.656
RE	75.556	40.760	77.778	34.300	0.929
MH	69.067	14.380	66.889	15.327	0.873

Note: *$p < 0.05$, **$p < 0.01$ (Mann-Whitney test).

course of treatment; within the experimental group, however, there was significant improvement in symptoms such as sneezing ($p < 0.05$), rhinorrhea ($p < 0.01$), itchy nose ($p < 0.05$) and itchy eyes ($p < 0.05$). After the treatment program, only the stuffiness symptom ($p < 0.05$) showed significant improvement within the control group, while in the experimental group, improvement in symptoms such as sneezing ($p < 0.01$) and rhinorrhea ($p < 0.01$) was statistically significant (Tables 3 and 4).

SF-36

One of the purposes of this study was to evaluate the improvement in the subjects' quality of life. The SF-36 health survey was taken three times by each subject — pre-test, mid-test and post-test. Analysis of the degree of improvement on patients' quality of life was processed after a reliability and validity test on the survey results of the pre-test.

Reliability analysis

For reliability analysis, all data of the 33 patients from the pre-test were analyzed with Cronbach's α to determine the internal consistency among the eight dimensions of the SF-36. With the exception of the dimension on role limitation due to physical problems (RP),

Table 3. Within-Group Comparison Before and After Treatment (Post-Test)

	Control Group (n = 15)					Experimental Group (n = 18)				
	Pre-Test		Post-Test			Pre-Test		Post-Test		
Variables	**Mean**	**SD**	**Mean**	**SD**	**p Value**	**Mean**	**SD**	**Mean**	**SD**	**p Value**
T_IGE	402.867	273.745	402.600	265.418	0.865	505.278	371.792	538.833	423.793	0.485
ECP	18.643	14.168	20.134	24.238	0.308	23.137	16.473	17.949	19.431	0.112
RS	12.067	3.173	10.533	4.454	0.092	**11.389**	**3.274**	**8.222**	**4.166**	**0.002****
Sneezing	2.000	1.000	1.667	0.976	0.059	**2.000**	**0.840**	**1.278**	**0.895**	**0.003****
Rhinorrhea	2.067	0.884	1.800	1.014	0.248	**2.389**	**0.778**	**1.500**	**0.985**	**0.005****
Hyposmia	1.000	0.845	1.067	0.799	0.792	0.944	0.725	0.833	0.707	0.527
Stuffiness	**2.133**	**0.640**	**1.667**	**0.900**	**0.035***	1.389	0.698	1.111	0.676	0.129
Itchy Nose	1.467	0.834	1.267	0.704	0.317	1.500	0.786	1.111	0.832	0.117
Itchy Eyes	1.400	0.632	1.067	0.799	0.190	1.444	0.856	1.056	0.998	0.083
Epiphora	0.867	0.640	0.867	0.834	1.000	1.000	0.970	0.833	0.924	0.366
Red Eyes	1.200	0.676	0.933	0.961	0.102	0.722	0.669	0.500	0.618	0.248
SF-36										
PF	98.000	4.140	96.000	8.062	0.161	93.056	17.668	96.667	4.851	0.317
RP	**93.333**	**17.593**	**75.000**	**37.796**	**0.038***	83.796	24.666	76.852	29.505	0.403
BP	85.467	17.460	85.067	18.140	0.888	75.944	17.665	79.722	14.191	0.451
GH	64.267	17.495	67.533	10.986	0.375	**55.111**	**17.977**	**68.778**	**19.019**	**0.010***
VT	65.333	15.407	69.000	16.058	0.208	**60.833**	**17.678**	**68.333**	**17.489**	**0.013***
SF	80.000	20.485	80.000	14.790	0.903	78.472	14.731	83.333	11.344	0.134
RE	75.556	40.760	80.000	37.374	0.577	77.778	34.300	87.037	32.618	0.281
MH	69.067	14.380	68.800	13.624	0.929	66.889	15.327	64.667	18.623	0.855

Note: *$p < 0.05$, **$p < 0.01$ (Wilcoxon signed-rank test).

Table 4. Within-Group Comparison Before and After Treatment (Mid-Test)

	Control Group (n = 15)					Experimental Group (n = 18)				
	Pre-Test		Mid-Test			Pre-Test		Mid-Test		
Variables	**Mean**	**SD**	**Mean**	**SD**	**p Value**	**Mean**	**SD**	**Mean**	**SD**	**p Value**
RS	12.067	3.173	11.933	4.383	1.000	**11.389**	**3.274**	**8.833**	**3.294**	**0.010***
Sneezing	2.000	1.000	1.667	0.976	0.059	**2.000**	**0.840**	**1.389**	**0.698**	**0.013***
Rhinorrhea	2.067	0.884	2.000	0.845	0.705	**2.389**	**0.778**	**1.667**	**0.840**	**0.005****
Hyposmia	1.000	0.845	1.200	0.862	0.366	0.944	0.725	0.778	0.647	0.455
Stuffiness	**2.133**	**0.640**	**1.867**	**0.640**	**0.046***	1.389	0.698	1.167	0.514	0.102
Itchy Nose	1.467	0.834	1.600	0.828	0.480	**1.500**	**0.786**	**0.833**	**0.707**	**0.015***
Itchy Eyes	1.400	0.632	1.467	0.915	0.763	**1.444**	**0.856**	**0.944**	**0.725**	**0.030***
Epiphora	0.867	0.640	1.067	0.884	0.317	1.000	0.970	1.056	0.725	0.792
Red Eyes	1.200	0.676	0.933	0.799	0.102	0.722	0.669	0.833	0.618	0.480
SF-36										
PF	98.000	4.140	95.333	6.935	0.054	93.056	17.668	93.056	10.865	0.439
RP	93.333	17.593	85.000	29.580	0.357	83.796	24.666	82.407	29.826	0.852
BP	85.467	17.460	84.400	16.128	1.000	75.944	17.665	82.722	18.667	0.141
GH	64.267	17.495	65.067	11.010	0.659	**55.111**	**17.977**	**61.889**	**17.993**	**0.040***
VT	65.333	15.407	66.333	15.864	0.750	60.833	17.678	65.278	16.581	0.093
SF	80.000	20.485	80.000	19.933	0.963	**78.472**	**14.731**	**88.194**	**10.908**	**0.008****
RE	75.556	40.760	80.000	41.404	0.577	77.778	34.300	79.630	30.548	0.739
MH	69.067	14.380	68.000	14.182	0.572	66.889	15.327	68.000	16.234	0.624

Note: *$p < 0.05$, **$p < 0.01$ (Wilcoxon signed-rank test).

which had a reliability coefficient of less than 0.7, all other dimensions have a reliability coefficient higher than 0.7. Thus, SF-36 was shown to be a reliable test in the study of patients with allergic rhinitis.

Convergent and discriminant validity

The results showed that the whole convergent validity was 96.9%. As for discriminant validity was being 95%. Thus, SF-36 was proven to be valid for use in the study of patients with allergic rhinitis.

SF-36 result

The control group showed no significant difference in scores for all dimensions of the SF-36 questionnaire between pre-test and mid-test results, while the experimental group showed a significant increase in the scores for GH ($p < 0.05$) and SF ($p < 0.01$) between pre-test and mid-test results (Table 4).

The control group scores showed a significant decrease ($p < 0.05$) for the RP dimension when compared to all dimensions of the SF-36 between pre-test and post-test. The experimental group showed a significant improvement in the scores for GH ($p < 0.05$) and VT ($p < 0.05$) between pre-test and post-test results (Table 4).

Discussion

The acupoint herbal patches used in this study were adapted from the Bai Jie Zi plastering method for treating cold wheezing, as described in *Zhang Sshi yi Tong* (Zhang Lu from the Qing Dynasty).

Bai Jie Zi has effect of expelling phlegm, easing shortness of breath and killing microorganisms. However, Bai Jie Zi oil can be irritating to skin, causing blood congestion, scorching pain, or even blisters. Therefore the Bai Jie Zi plastering method no longer utilizes Bai Jie Zi alone, instead adding Yan Hu Suo, Gan Sui, Shi Shin and Sheng Jiang to form a fangji (formula), and patched upon acupoints after being powdered and mixed into a paste.

Of the ingredients, Yan Hu Suo is able to promote circulation of blood and movement of qi, and alleviate pain; its analgesic effect is excellent. As described in Vol. 13 of *Ben Chao Gang Mu* (*Compendium of Materia Medica*), Yan Hu Suo "specializes in treating all body pain; used appropriately, its effects are beyond words." It has no obvious toxic side effects, with no apparent irritation to skin when used externally (Yan, 1991; Song, 1999).

The study design was prospective, randomized and single-blind and used parallel group comparison. A total of 75 patients took part in the program, 43 met the inclusion criteria, 9 dropped out during the study, and 33 completed the trial. The completion rate was therefore 79%. This fitted the standard of Level II evidence (unicenter randomized controlled trial) defined in evidence-based medicine. Mainstream medicine now emphasizes evidence-based medicine. In order for traditional Chinese medicine to be performed and widely accepted, modern research is required. It was on this belief that this trial was designed to

evaluate the effectiveness of using traditional acupoint herbal patches for treating allergic rhinitis. Although according to the original method, this therapy is more suitable for treating asthma (Zhang Lu in Qing Dynasty), however there are difficulties in reality in testing on asthma patients.

In fact, from the perspective of modern pathophysiology, asthma and allergic rhinitis share the same molecular mechanism; there is the concept of "one airway, one disease," (Yan, 2003). Based on this concept, we believe that if acupoint herbal patches work to combat allergic rhinitis, they will help in the treatment of asthma.

The level of T-IgE is generally used to diagnose allergic disease and to indicate the level of allergic constitution in patients. It is not directly participating in inflammatory reactions. Although the half-life of IgE in the serum is only 2–3 days, once IgE has been bound to its receptor on mast cells and basophils, it will stable for a number of weeks (Goldsby *et al.,* 2003). Therefore our results are in agreement with their report.

The results show that the experimental group has lower ECP level than the control group, but not up to a statistically significant level. A possible reason is that the properties of ECP were not fully understood, and there are many factors that may influence ECP level. Although the level of ECP directly reflects the degree of activation in eosinophils, some studies have shown that ECP levels remain high even after the disappearance or obvious improvement of some symptoms or restoration of pulmonary functions, and in some severe cases of asthma, ECP can be normal or near normal (Zhu *et al.*, 1997). Some researchers even believe that serum ECP level in patients with allergic rhinitis has no correlation with the severity of the disease, that the inflammatory reactions in patients with allergic rhinitis tend to be of a more localized condition (Rasp *et al.*, 1994). Some, using the perspective of traditional Chinese medicine diagnostics, argue that patients with a hot pattern of asthma have significantly higher ECP levels than those with a cold pattern of asthma (Hsu *et al.*, 2003). For all these reasons, the ECP level is usually regarded as a mere reference in clinical practice. The effect of sample size on the study results also needs to be considered.

Further analysis of each separate item within the 8 major symptoms on the RS found that no symptoms showed any significant improvement within the control group after the 1st course of treatment. Within the experimental group, however, there was significant improvement in symptoms of sneezing, rhinorrhea, itchy nose and itchy eyes, but the efficacy on nasal stuffiness was poor, a similar situation occurred for antihistamine treatment (Eriksson, 1990). Whether a similar mechanism shared between the therapeutic effects of acupoint herbal patches and antihistamine treatment is worth of further exploration. On the other hand, the significant improvement in nasal stuffiness shown by both mid-test and post-test results in the control group was probably a placebo effect triggered by using patches that affected the regulation of the autonomous nervous system. However, since some errors existed when collecting data on this separate item for nasal stuffiness, this part should wait for further clarification.

SF-36 is a general health survey, not employed in any specific disease but used extensively in evaluating many diseases. For example, SF-36 is commonly chosen as a measuring instrument in efficacy evaluation of allergic rhinitis treatments. Schapowal (2002), Ciprandi *et al.* (2002) and Majani *et al.* (2001) all used SF-36 in their

clinical researches regarding allergic rhinitis. Schapowal's study adopted the RCT model to compare effects on seasonal allergic rhinitis of petasites herbal formula and the 2nd-generation antihistamine cetirizine, concluding that petasites herbal formula and the antihistamine cetirizine have a similar efficacy, and the choice between the two of the petasites herbal formula is more appropriate when the subject is doing a job that requires a high level of alertness.

This study also used SF-36 to evaluate the efficacy of acupoint herbal patches in the treatment allergic rhinitis. The whole program involved the SF-36 health survey taken three times by each subject; pre-test (before treatment), mid-test (following the 1st course of treatment) and post-test (following the 2nd course of treatment). In the pre-test, the two groups showed no significant difference in their SF-36 scores for quality of life, indicating that the two groups, randomly assigned, were similar to each other at baseline, while also fitting the analysis on reliability and validity.

For the control group, the mid-test scores of all dimensions of the SF-36 did not show any significant difference compared to pre-test scores. The experimental group, when comparing scores for all dimensions of the SF-36 mid-test and pre-test, demonstrated a significant increase in GH ($p < 0.05$) and SF ($p < 0.01$). This indicates that patients showed a significant improvement in self-reported health and social functioning after completing one course of treatment.

RP scores of the SF-36 dimensions were found to have significantly decreased in the post-test of the control group as compared to the pre-test. This seems to correspond with the improvement in nasal stuffiness revealed on the rhinitis symptom rating scale of the control group, which could be attributed to experiment errors or psychogenic effects on the regulation of the autonomous nervous system. In the experimental group, the scores for GH ($p < 0.05$) and VT ($p < 0.05$) of the SF-36 dimensions showed a significant improvement between pre-test and post-test, indicating patients' improvement in self-reported health and an increase in vitality.

In conclusion, this study, along with previous research, (Tai and Chien, 2004; Tai *et al.*, 2007) proved that acupoint herbal patches were effective in treating allergic rhinitis — and was especially effective in treating common symptoms such as sneezing, rhinorrhea and an itchy nose. As shown by the results of the quality of life survey, the treatment caused a significant improvement in patients' general health, social life and vitality.

We therefore suggest that treatment of allergic diseases with acupoint herbal patches should work best if applied three times during one course of treatment. Further study is needed to determine how long each course of treatment can maintain its efficacy, and what length of time between two courses produce the best results.

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