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Original Article

Efficacy of Sanfujiu to Treat Allergies: Patient Outcomes at 1 Year after Treatment

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Sanfujiu is a treatment method of applying herbal paste onto the acupoints Fengmen and Feishu during the three hottest days of summer to treat patients with allergies. The objectives of this study were to determine the treatment efficacy at 1 year after the Sanfujiu treatment, and examine variations in the perceived efficacy of Sanfujiu among different subgroups, based on the patients' ages, diagnoses and number of reactive symptoms immediately after the treatment. We enrolled 105 patients who completed Sanfujiu treatment at a medical university hospital in Taipei as the subjects. One year after treatment, trained interviewers conducted telephone interviews with the patients. Approximately 60% of them perceived the treatment as being effective at 1 year later, which was higher than that at 1 week after treatment (45.7%). Younger subjects (<19 years of age) and patients with asthma were more likely to report the treatment as being effective. Patients who had more reactive symptoms after the third Sanfujiu treatment were more likely to report the treatment as being effective. The results demonstrated that Sanfujiu was moderately effective, as perceived by patients in Taiwan, in treating their allergic symptoms.

Keywords: allergy – Sanfujiu – therapeutic effect – traditional Chinese medicine

Introduction

Symptoms associated with allergies are very common in developing and developed countries alike. The most common types of allergic symptoms include eczema, rhinitis and asthma. Allergies have increased substantially during the past two or three decades in many countries around the world (1). A study comprised mostly of the Chinese children aged 6–7 years in Hong Kong showed that lifetime prevalence of asthma, rhinitis and eczema were 7.9, 33.9 and 30.7% (2). In Taiwan, the prevalence of physician-diagnosed asthma among elementary and middle school students was 8.1% for boys and 5.6% for girls (3). In a survey of middle-school students in Taiwan, Lee *et al*. (4) reported the prevalence was 25.0–30.1% for physician-diagnosed allergic rhinitis, and 40.2–43.0% for questionnaire-determined allergic rhinitis.

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According to traditional Chinese medicine (TCM) theory, qi is part of everything that exists (5). Qi has been described as a type of metaphysical energy that sustains living beings. Proponents of TCM assert that natural patterns of qi are associated with the body that circulates in channels (or meridians). The environment also has natural patterns of qi that circulate in natural order, such as sunrise and sunset, and changes of the four seasons. By adjusting the circulation of qi inside the body, health of individuals can be improved. There are two main kinds of qi, yang qi and yin qi. Yang qi moves like sun with a nature of hotness, whereas yin qi moves like moon with a nature of coldness. According to TCM theory, allergies are related to deficiencies in the lungs, which indicates disorders in the respiratory system. In TCM, patients with allergies are viewed as being cold and lacking yang qi inside the body. Traditionally, Sanfujiu is a treatment method of applying Chinese herbal medicine paste onto the acupoints Fengmen and Feishu during the three hottest days (or dog days) of the summer (6). The rationale is that the dog days are those days with the highest amount of yang qi according to the

lunar calendar. Treatment during the peak summer days allows the patient to gather qi from the environment, which enhances the herb's effect as it penetrates the acupoints, and strengthens lung qi. This type of treatment is believed to help prevent allergic attacks during the winter and early spring months.

Because of the non-invasive and easy-to-administer nature of the Sanfujiu treatment, Sanfujiu has been increasingly used in TCM clinics in Taiwan. We previously reported the immediate reactions (adverse effects and perceived efficacy) to Sanfujiu treatment at 1 week after treatment (7). In that study, we reported that reactive symptoms to treatment were common, but were usually mild. About 45% of patients perceived treatment as being effective at 1 week later. However, the actual treatment efficacy of Sanfujiu should be determined at the end of winter and spring, when allergic symptoms are the most evident. This study followed the same group of patients for 1 year after completion of the Sanfujiu treatment. The objectives were to describe treatment efficacy at 1 year after Sanfujiu and examine variations in the perceived efficacy of Sanfujiu among different subgroups based on the patients' ages, diagnoses and number of reactive symptoms immediately after treatment.

Methods

A detailed description of the Sanfujiu treatment can be found in our previous publication (7). Briefly, Sanfujiu is the application of an herbal paste onto the acupoints Fengmen (BL12) and Feishu (BL13) during the three dog days of summer. Fengmen is located at the level of the lower border of the spinous process of the second thoracic vertebra. Feishu locates at the level of the lower border of the spinous process of the third thoracic vertebra. Using TCM theory, these two acupoints regulate lung qi, open the lungs and benefit all aspects of lung function (8). According to the lunar calendar, the three dog days (peak summer days) are the third and fourth Geng days after the summer solstice, and the first Geng day after the beginning of autumn, respectively (6). In the year 2003, these days corresponded to July 16, July 26 and August 15. The herbal paste was composed of equal amounts of dried Bai Jie Zi (*Semen Sinapis Albae*), dried Xi Xin (*Herba Asari*), dried Gan Sui (*Radix Kansui*), dried Yan Hu Suo (*Rhizoma Cordalis*) and fresh ginger (*Zingiber officinale*). Except for the ginger, the four dried herbs were ground into a powder. The ginger was blended into a juice. Then the powder and juice were mixed and made into a paste. All of the five herbs except for the ginger were imported from Mainland China. The ginger was obtained locally in Taipei, Taiwan. One licensed pharmacologist and one doctor in Chinese Medicine checked the crude herbs. Unlike concentrated extracted medicine, the crude herbs are not seen or labeled as products of a company and there is no quality control policy toward the crude herbs. The herbal paste was divided into small cubes of 3 g each and placed on the Fengmen (BL12) and Feishu (BL13), bilaterally (a total of four acupoints). Medical tape was used to keep the medicinal paste in place on the acupoints for 2 h (see Fig. 1).

Subjects

In 2003, 119 patients completed the Sanfujiu treatment at a medical university hospital in Taipei. The inclusion criteria were patients who had undergone this treatment and had been diagnosed with allergies by a medical doctor based on the patients' reports. Of the 119 patients, 105 (88.2%) patients were successfully followed up in June 2004. Reasons for loss to follow-up included an incorrect phone number, nobody answered the phone and refusal. There were no significant differences between the patients that were followed up and those who were not followed up in sex, diagnoses and presence of reactive symptoms. However, patients who were not followed up appeared to be older than the patients who were followed up.

Measurements

Structured questionnaires were designed to determine the patients' reactions to the treatment and it's perceived efficacy. Subjects gave their consent to participate in the study during their first visit for Sanfujiu at the hospital. One week after each of the three treatments and 1 year after completion, a telephone interview was conducted with the patients by trained interviewers. For patients under 12 years of age, questions were answered by their primary caregivers. At 1 week after treatment, the variables included patient background information (age, sex, history of allergic diseases and medicine used before treatment), reactive symptoms to treatment (blisters, itching, pain, local heat, local redness, headache, insomnia, runny nose, nasal congestion, sore throat, aches all over the body, itching all over the body, constipation and diarrhea) and perceived efficacy of treatment. At 1 year after treatment, the variables included the number of allergic attacks, changes in the use of medicine for allergic symptoms and perceived efficacy. Perceived treatment efficacy was obtained by asking the patient to rate the efficacy as very effective, somewhat effective, no change (neither good nor bad) or worse than before the treatment.

Data Analysis

Statistical analyses were carried out using the Statistical Package for the Social Sciences, SPSS for Windows, Version 12.0 (SPSS Inc., Chicago, IL). Individual variables were examined using the percentage, median, mean and standard deviation. Chi-squared statistics were performed to examine variations in the perceived treatment efficacy among different subsets of patients. Student's *t*-test was used to determine mean differences in the number of reactive symptoms by perceived treatment efficacy.

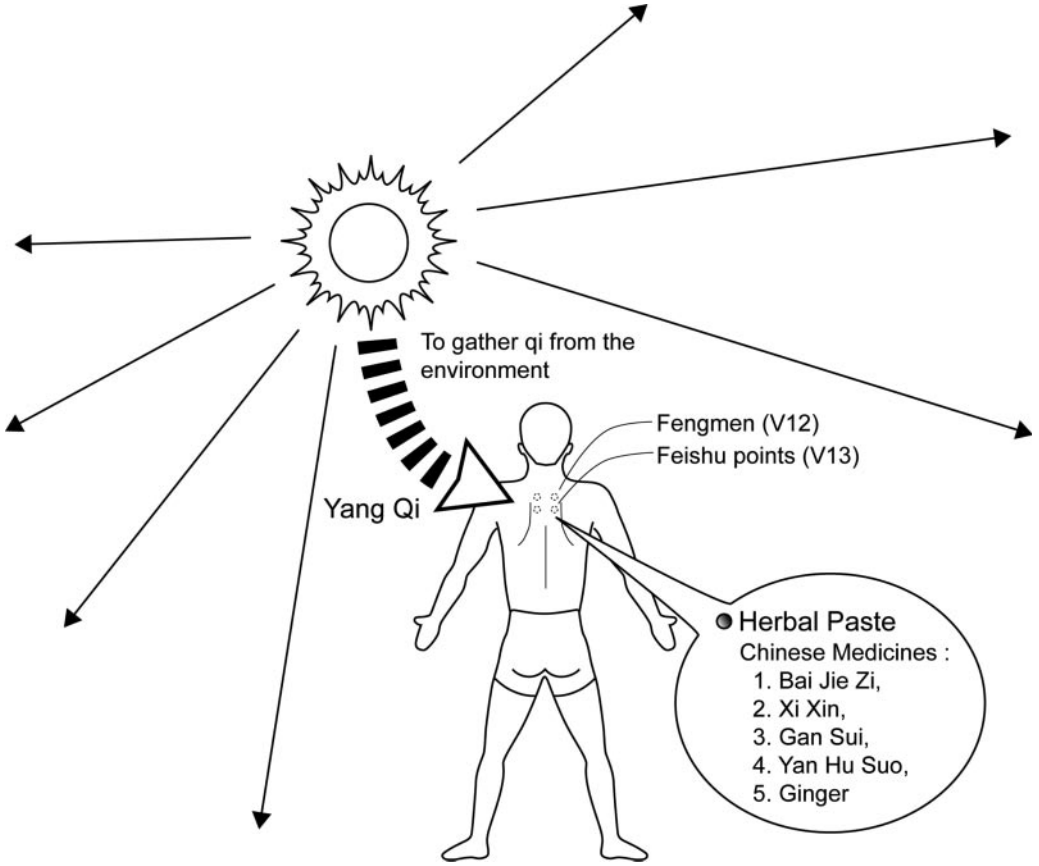

Figure 1. Descriptive figure of the Sanfujiu treatment.

Results

Characteristics of the Subjects

The median age of the study subjects was 15 years (range, 1–78 years). About 57% of the study subjects were males. The most-prevalent allergic diagnoses were allergic rhinitis (61.0%), asthma (37.1%) and allergic eczema (24.8%). As for the allergic symptoms before the treatment, more than 75% had nasal congestion and runny noses. More than 50% reported coughing, itchy nose and eyes, and dark circles around the eyes. A high proportion of patients reported having had reactive symptoms 1 week after the Sanfujiu treatment. Overall, ~80% of patients reported having local redness or local heat after removal of the drug paste at one or more of the three treatment times. Local itching, runny nose, nasal congestion or local pain occurred in more than 50% of the study subjects (Table 1).

Perceived Severity of Allergic Symptoms after Treatment

The perceived severity of allergic symptoms during the follow-up period is presented in the Table 2. The most-prevalent symptoms were nasal congestion, runny nose, itchy nose and itchy eyes, with more than 60% of patients reporting such symptoms. More than 20% of patients reported that their symptoms of runny nose, nasal congestion, itchy nose, itchy eyes, itchy skin and dark circles around eyes were 'severe'. When the severity of the allergic symptoms was compared with that before the treatment, 23.6–52.1% of patients reported that their symptoms had lessened. Except for the dark circles around the eyes, all other symptoms had a rate of improvement of greater than 40% (Table 2).

Treatment Efficacy

At 1 week after treatment, six patients (5.7%) perceived treatment as being 'very effective', and 42 (40.0%) reported it as 'somewhat effective'. At 1 year after the treatment, 24 patients (22.9%) perceived the treatment as being 'very effective', and 38 (36.2%) reported it as 'somewhat effective'. In terms of the number of allergic attacks during the period, 46 (43.8%) subjects reported that the number of attacks had decreased, while another 52 (49.5%) and 7 (6.7%) patients reported no changes and increases in the number of attacks. Aside from the 14 patients who did not use any drugs to treat their allergies, 21 (23.1%) patients reported decreases in their drug use for allergies, while 3 (3.3%) patients reported increases in drug use (Table 1).

Factors Associated with Perceived Treatment Efficacy

To examine factors associated with perceived efficacy of treatment, we divided the variable of perceived efficacy into

Table 1. Patient characteristics and treatment efficacy ($N = 105$)

	n	Percent
Age (years)		
<19	59	56.2
19–40	27	25.7
>40	19	18.1
Sex		
Male	60	57.1
Female	45	42.9
History of allergies		
Allergic rhinitis	64	61
Asthma	39	37.1
Allergic eczema	26	24.8
Others	18	17.1
Presence of reactive symptoms immediately after the treatment		
Local redness	85	81
Local heat	83	79
Local itching	65	61.9
Runny nose	61	58.1
Nasal congestion	58	55.2
Local pain	53	50.5
Dry mouth or thirst	29	27.6
Insomnia	23	21.9
Sore throat	18	17.1
Headache	18	17.1
Itching all over the body	18	17.1
Constipation	13	12.4
Diarrhea	13	12.4
Aches all over the body	12	11.4
Local blisters	12	11.4
Others	8	7.6
Perceived efficacy immediately after the treatment		
Very effective	6	5.7
Somewhat effective	42	40
Neither good nor bad	53	50.5
Allergic symptoms worsened	4	3.8
Perceived efficacy 1 year after the treatment		
Very effective	24	22.9
Somewhat effective	38	36.2
Neither good nor bad	41	39
Allergic symptoms worsened	2	1.9
Number of allergic attacks during the past year		
Decrease	46	43.8
No changes	52	49.5
Increase	7	6.7
Use of medicine to treat allergies during the past year*		
Decrease	21	23.1
No changes	67	73.6
Increase	3	3.3

*Fourteen patients who did not use any drugs to treat their allergies were excluded.

two categories: effective and ineffective. A younger age was associated with perceived efficacy of treatment: 69.5% of patients with an age of <19 years perceived the treatment as being effective, while the corresponding figures were 48.1 and 42.1% for patients aged 19–40 and >40, respectively ($P = 0.04$). The cut-off point of 19 years of age was selected because it is the usual age to determine whether the patient is a pediatric patient. The cut-off point of 40 years was selected to preserve enough sample size for the older age group (>40 years, $n = 19$). Patients with a diagnosis of asthma were more likely to report the treatment as being effective (71.4 versus 50.8%, $P = 0.035$). The perceived efficacy of the Sanfujiu treatment was not related to the patient's sex or diagnosis of allergic rhinitis or allergic eczema (Table 3). The mean numbers of reactive symptoms immediately after each of the three Sanfujiu treatment were 3.06 (SD = 2.10), 3.21 (SD = 2.28) and 3.12 (SD = 1.84), respectively. There were no significant differences in the mean number of reactive symptoms for the first two treatments between patients who perceived the treatment as effective and those who perceived the treatment as ineffective. At the third treatment, patients who perceived the treatment as effective had a higher number of reactive symptoms than patients who perceived the treatment as ineffective (with a mean number of reactive symptoms of 3.45 versus 2.65, $P = 0.03$; Table 4).

Discussion

The results of this study demonstrated that 45.7 and 59.1% of patients perceived the Sanfujiu treatment as being effective at 1 week and 1 year after the treatment. The figure at 1 year was higher than that at 1 week after treatment. Previously, researchers in China showed that Sanfujiu had effectiveness rates of greater than 80% in treating rhinitis, chronic bronchitis and asthma (9–14). However, those studies generally lacked common criteria for determining treatment efficacy. Thus, a comparison of effectiveness rates cannot be made. In our study, we found that over 40% of patients reported a decrease in the severity of each of the included allergic symptoms, except for dark circles around the eyes. In addition, 43.8 and 23.1% of patients reported decreases in the number of allergic attacks and decreases in the amount of medicine used for their allergic symptoms. Altogether, these results demonstrated that Sanfujiu treatment was moderately effective in treating patients with allergies.

Here, we found that patients who were younger (<19 years) were more likely to report the treatment as being effective. This finding is consistent with the results of previous studies in that the treatment effects were better for children than adults (12). Further, we found that patients with the diagnosis of asthma were more likely to report an effective outcome. Studies in China have shown the effects of Sanfujiu in treating rhinitis, chronic bronchitis and asthma (9–14). However, they did not compare the perceived efficacy across diagnoses. In our study, we found effectiveness rates of 71.4% for asthma, 61.3% for rhinitis and 54.8% for eczema. Since these allergic

Table 2. Perceived severity of allergic symptoms after completion of Sanfujiu treatment ($N = 105$)

Symptoms	*n* (%) with each symptom	Severity of symptoms		Symptom severity compared with before the treatment		
		Mild %	Severe %	Improved %	No different %	Worsened %
Wheezing	39 (37.1)	22.9	14.3	48.7	41.0	10.3
Runny nose	82 (78.1)	51.4	26.7	47.6	48.8	3.7
Nasal congestion	83 (79.0)	54.3	24.7	47.0	49.4	3.6
Cough	48 (45.7)	31.4	14.3	52.1	41.7	6.3
Nose itching	76 (72.4)	47.6	24.8	42.1	53.9	3.9
Eye itching	66 (62.9)	40.0	22.8	40.9	53.0	6.1
Dark circles around eyes	55 (52.4)	32.4	20.0	23.6	74.5	1.8
Skin itching	55 (52.4)	30.5	21.9	40.0	52.7	7.3
Others	11 (10.5)	5.7	4.8	45.5	45.5	9.1

Table 3. Perceived efficacy of Sanfujiu in alleviating allergic symptoms 1 year after treatment based on patient characteristics

	Percent improved	*P*
Age (years)		
<19	69.5	0.04
19–40	48.1	
>40	42.1	
Sex		
Male	64.4	0.18
Female	51.2	
Allergic rhinitis		
Yes	61.3	0.45
No	53.3	
Asthma		
Yes	71.4	0.035
No	50.8	
Allergic eczema		
Yes	54.8	0.57
No	60.8	
Other allergies		
Yes	61.1	0.85
No	58.6	

P-value from χ^2 statistics.

Table 4. Mean number of reactive symptoms (SD) after each of the three treatments by perceived efficacy of Sanfujiu in alleviating allergic symptoms 1 year after treatment

	Effective	Ineffective	*P*
Mean number of reactive symptoms after the first treatment	3.16 (2.19)	2.91 (1.99)	0.55
Mean number of reactive symptoms after the second treatment	3.50 (2.38)	2.79 (2.09)	0.12
Mean number of reactive symptoms after the third treatment	3.45 (1.75)	2.65 (1.89)	0.03

P-value from the Student's *t*-test.

symptoms may be comorbid, further studies are needed to compare the relative efficacies of the Sanfujiu treatment for different combinations of symptoms and diagnoses. We acknowledge that our study and previous studies relied on patients' reports of having been diagnosed with an allergic disease. Future studies should use standardized diagnostic procedures in order to address this problem.

We previously documented the reactive symptoms to Sanfujiu treatment (7). Although a wide range of reactive symptoms was noted, the reactive symptoms were usually mild and were relieved by removing the herbal paste. In this study, patients who perceived the treatment as being effective had higher numbers of reactive symptoms after the third Sanfujiu treatment. In a previous study, researchers reported that among patients with asthma, patients with topical reactions immediately after the treatment exhibited higher effectiveness rates (15). Since according to TCM theory the Sanfujiu treatment strengthens the qi by means of the herbal paste, the acupoints and the seasonal qi in the environment, it may be that these reactions are evidence of expelling the illness via the acupoints. Further study is needed to validate this speculation.

The application of Chinese herbal medicine on acupoints for treating allergic diseases is an area that has not been studied much. According to the theory of Chinese medicine, allergic diseases are classified as 'winter diseases' since allergic symptoms usually become worse during the winter. The winter diseases are best treated in the summer according to the theory (16). The Sanfujiu treatment applies the principles of the 'winter disease being treated in the summer'. The elements involved in the Sanfujiu treatment include yang qi associated with the peak summer days, qi inside the body and medicinal effects through the acupoints. In TCM, humans and their environment are seen as one. According to the lunar calendar, the dog days are the days with the highest temperatures and highest amount of yang qi. During these days, the surface and blood vessels of the human body are ecstatic; therefore, it is easier for the herbs to penetrate the acupoints and enhance the lung qi through the environmental yang qi. We speculate that Sanfujiu may strengthen qi and the immune system of the body, and increase the threshold to induce an allergic attack. However, the proposed mechanisms are based on theories rather than empirical studies. In addition, five herbs were used

to make the herbal paste. These herbs induce sweating, expel cold, relieve pain, and promote circulation of blood and qi in TCM. However, the active constituents of these herbs and their effects are not clear. Another problem is whether the Sanfujiu treatment could be given on days besides the dog days. A study showed that treating patients with asthma during the three dog days had similar effects to treating patients a few days apart from the dog days. However, the effects disappeared when the patients were treated in the autumn (17). More rigorous studies are needed to examine the mechanisms of this treatment.

Conclusions

The results demonstrated that the Sanfujiu treatment was moderately effective, as perceived by patients, in treating their allergic symptoms. The presence of reactive symptoms immediately after treatment was associated with a perceived efficacy. Sanfujiu is appealing since it is non-invasive, reactive symptoms are minor, and the course is relatively short and easy. This study was limited by the lack of a control group, thus the possibility of placebo-like effectiveness cannot be ruled out. Also the subjects had some knowledge about Sanfujiu prior to receiving treatment, which may influence their perceived effectiveness. In order to address this concern, we added information on the use of medicine and the number of allergic attacks in addition to perceived efficacy. Our results appeared to be consistent in supporting the efficacy of the Sanfujiu. Randomized controlled trails are still needed to determine the actual efficacy.

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