Efficacy and safety of *Sanfeng Tongqiao Diwan* in patients with allergic rhinitis: a single-arm clinical trial in China

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Background: Traditional Chinese medicine (TCM) has a long history and its own characteristics in the treatment of allergic rhinitis. In this study, the efficacy and safety of patients with allergic rhinitis treated with *Sanfeng Tongqiao Diwan* were observed to support the clinical medication of patients with allergic rhinitis.

Methods: A total of 61 patients with allergic rhinitis aged 12–70 years from the First Affiliated Hospital of Guangzhou Medical University were included in this study. All the patients were treated with *Sanfeng Tongqiao Diwan* for a period of 7 days. Return visits were carried out 24 hours after the first medication, the 4th day of medication, and the 7th day of medication, during which the efficacy and safety were assessed.

Results: The effective rates of *Sanfeng Tongqiao Diwan* at 24 hours, 4 days, and 7 days were 49.2%, 60.7%, and 65.6%, respectively. Comparing the severity of various symptoms after treatment to baseline, significant differences were found in nasal secretion (2.95±0.67 *vs.* 2.26±1.30, P<0.001), stuffy nose (5.66±2.95 *vs.* 3.34±2.57, P<0.001), mucosa congestion (7.08±1.82 *vs.* 4.23±2.28, P<0.001), running nose (5.21±1.81 *vs.* 2.90±1.89, P<0.001), and sneezing (3.00±0 *vs.* 1.92±1.45, P<0.001). The full symptom scores showed progressive decline during treatment, measuring 20.21±5.13 at baseline and 12.02±6.47 at 7 days (P<0.001). Compared to the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) score of 64.61±30.27 at baseline, statistical significance (P<0.001) was found at 24 hours, 4 days, and 7 days, measuring 43.11±28.01, 40.74±28.6, and 39.97±40.48, respectively. The incidence rate of adverse events (AEs) was 3.3% (2/61), with no serious AEs.

Conclusions: In this study, the use of *Sanfeng Tongqiao Diwan* is effective in the treatment of allergic rhinitis patients, especially in patients with severe symptoms. Although the treatment system of TCM is different from that of Western medicine, the application of TCM will provide a new direction for the treatment of chronic diseases. Follow-up studies with an increased sample size are required for verification.

Keywords: *Sanfeng Tongqiao Diwan*; allergic rhinitis; traditional Chinese medicine (TCM)

Submitted May 05, 2022. Accepted for publication Jun 20, 2022.

doi: 10.21037/atm-22-2768

View this article at: https://dx.doi.org/10.21037/atm-22-2768

Introduction

Allergic rhinitis manifests as seasonal or perennial nasal itching, sneezing, runny nose, nasal mucosal congestion, or conjunctivitis caused by allergens such as pollen and dust mites, which causes inconvenience to patients' life and work (1). With the development of social industrialization and changes in lifestyles, air pollution is becoming more and more serious, and the number of patients with allergic rhinitis is growing worldwide. An epidemiological study in China has shown that the prevalence of allergic rhinitis is gradually increasing (2).

At present, the main methods for the treatment of allergic rhinitis include nasal hormones (INS), oral antihistamines, nasal antihistamines, and leukotriene receptor antagonists. Among them, there is no clinical data showing that INS has adverse reactions, while H1-antihistamines may have adverse effects on the growth of children, and the cumulative use of strong anticholinergic drugs is directly related to the prevalence of dementia (3,4). In China, traditional Chinese medicine (TCM) has also been used in the treatment of allergic rhinitis. Many Chinese herbal medicines and their compounds can relieve or treat allergic rhinitis through different mechanisms of action (5). A previous study shows that the combined treatment of TCM and moxibustion is effective in treating allergic rhinitis, and this method is better than loratadine in improving the quality of life of patients (6). Another study used Bimin Decoction in the treatment of perennial allergic rhinitis and the results showed that Bimin Decoction is not inferior to the combined treatment of fluticasone nasal spray and loratadine in relieving rhinitis symptoms. There are usually side effects when patients use Western medicine for treatment. In contrast, TCM treatment not only controls clinical symptoms, but also regulates the allergic constitution of patients (7). In addition, a meta-analysis pointed out that *Yupingfeng* granules (a TCM) combined with Western medicines (nasal corticosteroids, oral antihistamines, or other allergic reaction antagonist) can significantly improve the nasal symptoms of allergic rhinitis patients, reduce recurrence, and are safe, and these reports provide medical evidence for the treatment of AR with integrated TCM and Western medicine (8).

TCM has a long history and its own characteristics in the treatment of allergic rhinitis. As a therapeutic drug, *Sanfeng Tongqiao Diwan* is mainly composed of 4 TCMs, namely Huangqin (skullcap), Jingjie, Xi xin, and Qianghuo. It has anti-inflammatory and anti-allergic effects, and is widely used in the treatment of allergic rhinitis in China. Internationally, however, there is a lack of research on monitoring the efficacy of *Sanfeng Tongqiao Diwan* for allergic rhinitis. Therefore, in this study, we observed the changes in the efficacy and immunological indicators of allergic rhinitis patients treated with *Sanfeng Tongqiao Diwan* at 24 hours after the first administration and at 4 and 7 days after administration, and analyzed the curative effect of *Sanfeng Tongqiao Diwan*. The differences in the efficacy of *Sanfeng Tongqiao Diwan* among patients provide support for the clinical medication of patients with allergic rhinitis. We present the following article in accordance with the STROBE reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-2768/rc).

Methods

Design

This is a single-arm clinical trial in China. A total of 61 patients with allergic rhinitis aged 12–70 years were enrolled from the First Affiliated Hospital of Guangzhou Medical University, including 32 male patients and 29 female patients, with an average age of 30.0±9.9 years. In addition to the guidelines for the diagnosis and treatment of rhinitis, all patients were treated with *Sanfeng Tongqiao Diwan* according to the instructions of the drug. The treatment cycle was 7 days, and a return visit was conducted 24 hours after the first administration and at 4 and 7 days after administration. Clinicians recorded information, among which, routine urine, routine blood, liver and kidney function tests, and biochemical analysis were performed before and after treatment.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the First Affiliated Hospital of Guangzhou Medical University (No. GYFYY-2020-100). Informed consent was taken from all the patients or patients' legal guardians.

Inclusion criteria

According to the guidelines for the diagnosis and treatment of allergic rhinitis (9), the following criteria were used for diagnosis: (I) clinical symptoms: more than 2 (including 2) symptoms such as watery rhinitis, nasal itching, nasal congestion, and sneezing, and the symptoms persisted or accumulated for more than 1 hour. They may

be accompanied by eye symptoms such as eye itching and conjunctival congestion; (II) signs: pale nasal mucosa, edema, and watery nasal discharge; (III) the patient had a history of allergic diseases or family history; (IV) skin prick test positive (wheal >3 mm, 2+ or more). The following patients were excluded: (I) pregnant and lactating women; (II) serious infection occurred in the medical records and the infection was not controlled; (III) patients who had taken H1-antihistamines or corticosteroids within 7 days; (IV) those who were participating in other clinical trials; (V) no behavioral and cognitive ability, unable to understand the content of informed consent; (VI) in addition to the above, the investigator judged that the patient was not suitable to participate in this clinical study.

Efficacy indicators

All patients underwent the same assessments throughout the study period and completed patient diaries regularly under the guidance of hospital professionals. Assessments included the Visual Analogue Scale (VAS), Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), and the Epworth Sleepiness Scale (ESS) score and symptom score.

VAS was used to assess the degree of pain and the range was 0 to 10. RQLQ was used to assess activity, sleep quality, nasal symptoms, eye symptoms, and non-nasal eye symptoms, the range was 0 to 6. ESS was used to assess the degree of drowsiness. The higher the score, the more serious the symptom.

According to the sum of symptom relief scores, the total curative effect of TCM syndromes was determined based on the nimodipine method. Efficacy index = (symptom score before treatment – symptom score after treatment)/ symptom score before treatment × 100%. The patients were divided into the following 4 categories: Cure: complete clinical symptoms, disappearance of signs or almost disappearance, curative effect index ≥95%; Markedly effective: clinical symptoms and signs significantly improved, and the curative effect index was greater than or equal to 70%; Effective: the clinical symptoms and signs improved, and the curative effect index was ≥30%; Invalid: no significant improvement in clinical symptoms and signs, curative effect index <30%.

Blood collection

Venous blood was drawn from all subjects in a sitting position, collected in a vacuum blood collection tube (Becton Dickinson and Company, New Jersey, USA) containing anticoagulant, and thoroughly mixed before sending for inspection.

Allergen skin pricks

Allergens in 61 patients with allergic rhinitis were detected using the stinging liquid (ALK, Denmark) of house dust mites, dust mites, cat hair, dog hair, fungus, and cockroach.

Routine urine test

A volume of 5 mL of fresh and clean mid-section urine was collected, and the urine biochemical test was carried out within 1 hour using the Sysmex UF-1000i (TOA Medical Electronics, Kobe, Japan) system using a dry chemical strip method and an automatic urine analyzer.

Routine blood test

After mixing 1 mL of whole blood with a K2 EDTA vacuum tube (Becton Dickinson and Company, New Jersey, USA), Beckman Coulter LH750 (Beckman Coulter, Miami, FL, USA) was used to detect white blood cells, red blood cells, eosinophils, and other cells within 1 hour.

Biochemical analysis

A volume of 5 mL of blood was collected into blood collection tubes containing heparin anticoagulant, stood still for 30 minutes, and centrifuged at 1,200 g for 10 minutes at 20 ℃. After taking the supernatant, the kidney function and liver function indexes were detected on the AU5800 analyzer (Beckman Coulter Inc., Brea, CA, USA) using Beckman Coulter reagent.

Statistical analysis

Statistical analyses were conducted with SPSS 22.0 (SPSS, Chicago, IL, USA). Parametric quantitative data such as nasal symptoms scores, RQLQ scores was presented as the mean ± standard deviation. Categorical data was reported as a percentage showing the proportion of positive results. Proportions were compared between groups with chi-square tests (χ^2) or F-tests. The one-way repeated measures ANOVA method was used before and after comparisons of the continuous variables. A P value less than 0.05 (two-sided) was considered to be statistically significant.

Table 1 Baseline characteristics of the subjects

Characteristics	Statistics
Demographic	
Education level, n (%)	
Primary school	1 (1.6)
Secondary school	5 (8.2)
High school	9 (14.8)
College/university	37 (60.7)
Postgraduate	9 (14.8)
Ethnic group, n (%)	
Han	61 (100.0)
Other minority ethnic groups	0
Age	
Median [range]	30 [14, 52]
Qrange [quartile]	14 [22, 36]
Gender, n (%)	
Male	32 (52.5)
Female	29 (47.5)
Medical history, n (%)	
Medical history	
None	42 (68.9)
With previous comorbidities	19 (31.1)
Medication	
None	39 (65.0)
With combination therapy for chronic diseases	21 (35.0)
Smoking	
Never	56 (91.8)
Used to	2 (3.3)
Occasionally	2 (3.3)
Frequently	1 (1.6)
Alcohol intake	
Never	53 (86.9)
Used to	3 (4.9)
Present	5 (8.2)
Scale score	
Nasal secretion	2.95±0.67
Stuffy nose	5.66±2.95
Mucosa congestion	7.08±1.82
Chills	0.05±0.38
Fever	0±0
Running nose	5.21±1.81
Sneezing	1±0
Limb pain	0.02±0.13
Headache	0.08±0.28
Full symptom	20.21±5.13
Epworth Sleepiness Scale	6.57±3.8
RQLQ Scale	64.61±30.27

Data are presented as n (percentage) for categorized variables and mean ± standard deviation for continuous variables. RQLQ, Rhinoconjunctivitis Quality of Life Questionnaire.

Results

Baseline characteristics

Overall, all 61 patients completed the 7-day study. *Table 1* shows the baseline characteristics of the subjects. The medium age and interquartile range of participants were 30 and 14–52, and 32 (52.5%) participants were male. The mean full symptom score was 20.21±5.13, the mean ESS score was 6.57±3.8, and the mean RQLQ score was 64.61±30.27.

Effectiveness for nasal symptom relief

Table 2 shows the effectiveness for nasal symptom relief 24 hours, 4 days, and 7 days after initiating treatment. The effective rate (effective, markedly effective, cured) of *Sanfeng Tongqiao Diwan* at 24 hours was 49.2%. At 4 and 7 days, the effective rates were 60.7% and 65.6%, respectively.

Nasal symptoms during treatment with Sanfeng Tongqiao Diwan

The nasal secretion scores at baseline and 24 hours, 4 days,

Table 2 Effectiveness for nasal symptom relief 24 hours, 4 days, and 7 days after initiating treatment

Effectiveness	24 hours, n (%)	4 days, n (%)	7 days, n (%)
Ineffective	31 (50.8)	24 (39.3)	21 (34.4)
Effective	8 (13.1)	10 (16.4)	8 (13.1)
Markedly effective	20 (32.8)	25 (41.0)	30 (49.2)
Cured	2 (3.3)	2 (3.3)	2 (3.3)

Effectiveness was categorized into 4 levels by the symptom remission rate, calculated by the formula: (symptom score during the treatment – symptom score at baseline)/symptom score at baseline × 100%, where cured was defined as symptom remission rate ≥95%, and markedly effective, effective, and ineffective were defined as ≥70%, ≥30%, and <30%, respectively. Data are presented as n (percentage).

and 7 days after initiating treatment with *Sanfeng Tongqiao Diwan* and the P values compared with baseline were 2.95±0.67, 2.66±1.46 (P=0.155), 2.56±1.53 (P=0.07), and 2.26±1.3 (P≤0.001), respectively. The stuffy nose scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 5.66±2.95, 4.08±2.95 (P=0.004), 3.3±2.75 (P≤0.001), and 3.34±2.57 (P≤0.001), respectively. The mucosa congestion scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 7.08±1.82, 4.03±2.32 (P≤0.001), 3.59±2.44 (P≤0.001), and 4.23±2.28 (P≤0.001), respectively. The chills scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 0.05±0.38, 0.05±0.38 (P=1), 0.3±0.9 (P=0.053), and 0±0 (P=0.321), respectively. The fever scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 0±0, 0±0 (P=1), 0.2±0.75 (P=0.045), and 0±0, respectively. The running nose scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 5.21±1.81, 3.44±2.11 (P≤0.001), 3±1.73 (P≤0.001), and 2.9±1.89 (P≤0.001), respectively. The sneezing scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 3±0, 2.46±1.16 (P=0.001), 2.07±1.4 (P≤0.001), and 1.92±1.45 (P≤0.001), respectively. The limb pain scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 0.05±0.38, 0.2±0.75 (P=0.174), 0.2±0.75 (P=0.174), and 0.05±0.39 (P=0.991), respectively. The headache scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 0.25±0.83, 0.34±0.96 (P=0.547), 0.45±1.08 (P=0.247), and 0.15±0.65 (P=0.469), respectively. The full symptom scores at baseline and 24 hours, 4 days, and 7 days after initiating treatment were 20.21±5.13, 13.48±6.27 (P≤0.001), 11.8±6.1 (P≤0.001), and 12.02±6.47 (P≤0.001), respectively. Significant differences are shown in *Figure 1*.

Full symptom scores at baseline and effectiveness at 24 hours, 4 days, and 7 days after treatment

Patients were stratified into 4 groups based on full symptom scores at baseline according to quartile. Frequencies of effectiveness was visualized in *Figure 2*. Comparing to baseline, the result of 4 and 7 d after treatment initiation showed that the higher the baseline score, the higher the effective rate at 4 and 7 days.

Quality of life and sleepiness

Table 3 shows the RQLQ scores and the incidence of sleepiness during treatment. RQLQ scores progressively declined, and measured 43.11±28.01 at 24 hours, 40.74±28.6 at 4 days, and 39.97±40.48 at 7 days. Compared to the RQLQ score of 64.61±30.27 measured at baseline, statistical significance was found at 24 hours, 4 days, and 7 days (P<0.001). Sleepiness was evaluated by the ESS, which did not show significant differences during treatment.

Safety assessment

Two adverse events (AEs) occurred during treatment with *Sanfeng Tongqiao Diwan*. The incidence rate was 3.3%. The 2 AEs were both mild rash, which resolved without any intervention.

Discussion

The treatment system of TCM is different from that of Western medicine. Exploring the treatment mode of the combination of TCM and Western medicine can provide new ideas for the prevention and treatment of allergic diseases. Our study showed that the allergic rhinitis

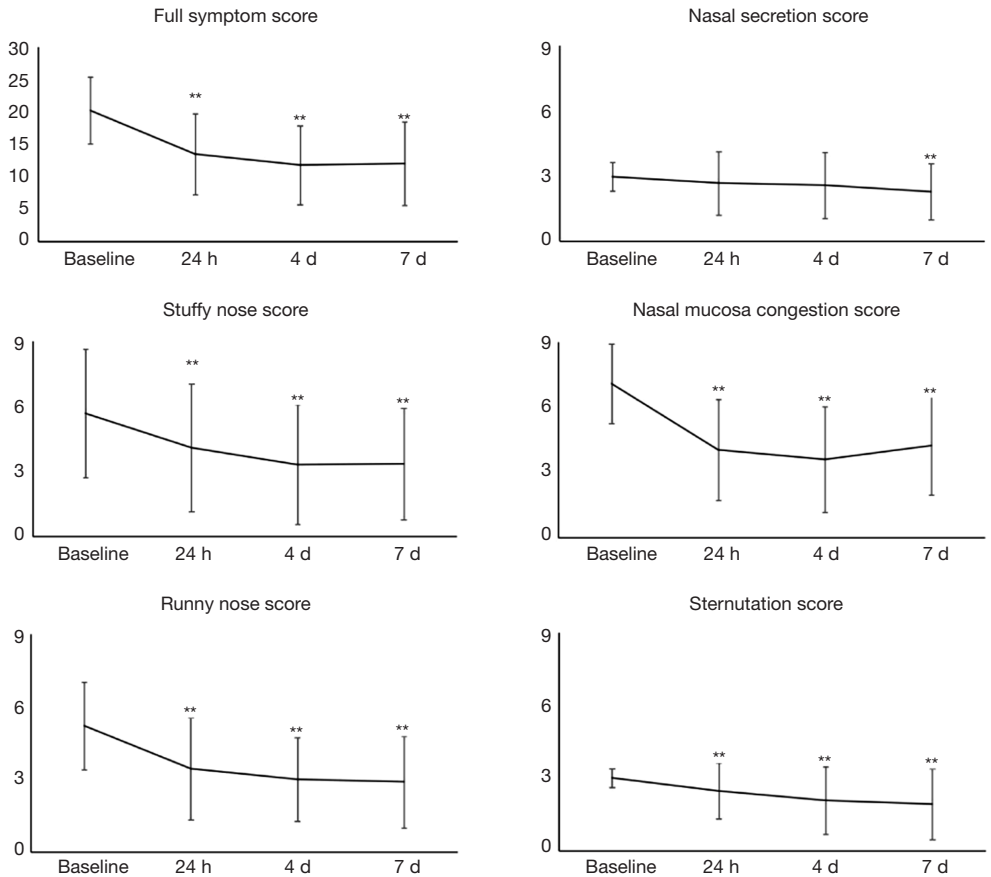

Figure 1 Nasal symptoms during treatment with *Sanfeng Tongqiao Diwan*. At 24 hours after the first treatment with *Sanfeng Tongqiao Diwan*, the full symptom score decreased significantly, and the effectiveness could be maintained to 4 and 7 days. Compared to baseline, scores of stuffy nose, mucosa congestion, runny nose, and sternutation showed statistical significance 24 hours after treatment initiation and the difference was maintained until 4 and 7 days, while scores of nasal secretion showed statistical significance 7 days after treatment initiation. **, compared to baseline, statistical significance ($P<0.01$) was found.

patients in the *Sanfeng Tongqiao Diwan* treatment group had significantly improved clinical symptoms such as nasal itching, nasal congestion, improved quality of life, and lower levels of inflammation. Among the 4 TCM ingredients contained in *Sanfeng Tongqiao Diwan*, Huangqin is rich in baicalin and baicalin aglycones. A review from China has shown that baicalin and baicalin aglycones can interfere with the enzyme activation system (SH-enzyme) of mast cells, thereby inhibiting the release of allergic mediators, and has a relieving effect on allergic airway contraction and overall allergic asthma in guinea pigs (10). Jingjie contains 1-pulegone, benzofurans, 3-octanol, and B-pinene. In addition, Xixin contains methyl eugenol and N-isobutyl dodecatetraenamide, among others, and its water or alcohol extract can reduce the release of total allergic mediators in immediate allergic reactions by more than 40% (11). Qianghuo contains substances such as purpurin, among others, which have anti-inflammatory and analgesic effects (12).

At present, the international treatment methods for allergic rhinitis are environmental control, drug therapy, and allergen immunotherapy. Drug therapy includes intranasal and oral antihistamines, intranasal and oral decongestants, intranasal and oral corticosteroids, intranasal cromolyn, intranasal anticholinergics, and oral leukotriene receptor antagonists. Immunotherapy includes subcutaneous immunization therapy, sublingual immunotherapy, and nasal light therapy. Western medicine mainly targets a certain symptom of a disease, and uses ingredients that can target the symptom or the pathogen that causes the

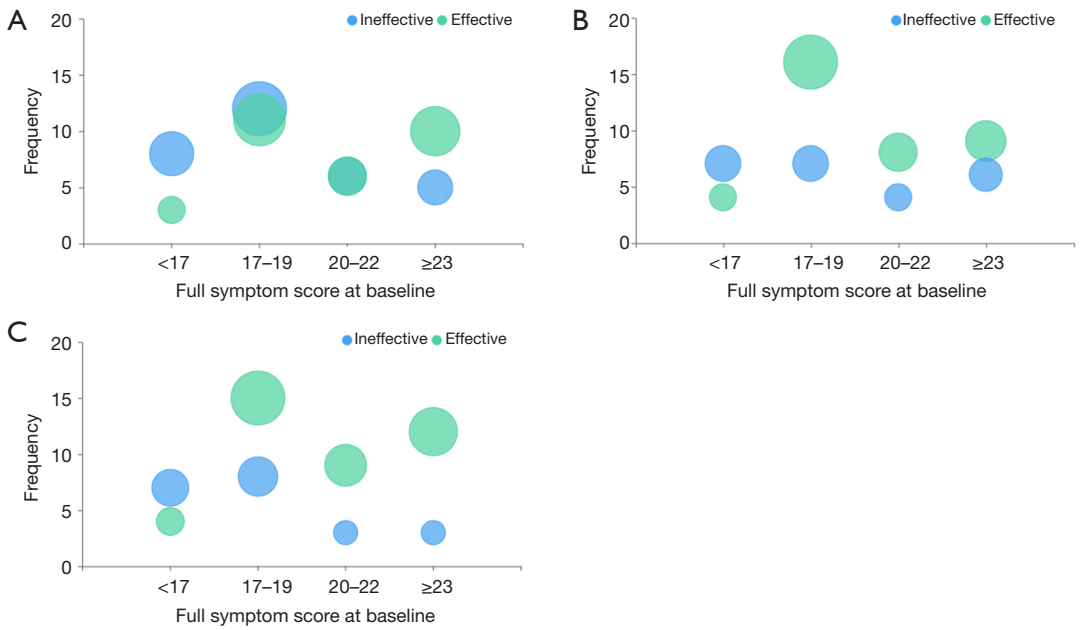

Figure 2 Full symptom scores at baseline and effectiveness at 24 hours, 4 days, and 7 days after treatment. Based on full symptom scores at baseline, patients were stratified into 4 groups according to quartile. The X-axis shows the groups of baseline full symptom scores, while the Y-axis and the area of the bubbles show the frequencies of patients in which treatment with *Sanfeng Tongqiao Diwan* was effective or ineffective (A) 24 hours after initiation, (B) 4 days after initiation, and (C) 7 days after initiation. The higher the baseline score, the higher the effective rate at 4 and 7 days.

Table 3 RQLQ scores and the incidence of sleepiness during treatment

Characteristic	Baseline	24 hours	P value	4 days	P value	7 days	P value
RQLQ score	64.61±30.27	43.11±28.01	<0.001	40.74±28.6	<0.001	39.97±40.48	<0.001
Sleepiness, n (%)			>0.999		>0.999		>0.999
No	38 (62.3)	38 (62.3)		38 (62.3)		38 (62.3)	
Yes	23 (37.7)	23 (37.7)		23 (37.7)		23 (37.7)	

The RQLQ measured the QOL of the subjects during treatment. Statistical differences were compared at each time point to baseline. Data are presented as mean ± standard deviation. Also, sleepiness was evaluated by the Epworth Sleepiness Scale and patients were categorized into 2 groups. Data are presented as n (percentage). RQLQ, Rhinoconjunctivitis Quality of Life Questionnaire; QOL, quality of life.

symptom. Different from the treatment ideas of Western medicine, TCM regulates the body's homeostasis by combining a variety of medicinal materials and formulating prescriptions according to the unique theoretical system of TCM. It is difficult to describe the TCM system in the language of natural science, but we can analyze the efficacy of TCM through evidence-based medicine and classify the applicable population. By analyzing the baseline data, we found that the more severe the symptoms, the more effective the use of *Sanfeng Tongqiao Diwan*. A study has shown that Jingjie and other medicinal materials can effectively relieve the symptoms of allergic rhinitis, mainly by regulating the immune capacity of the patient's body and reducing the release of inflammatory active mediators such as histamine, which makes *Sanfeng Tongqiao Diwan* effective even in patients with severe symptoms (13). This study is the first to report the efficacy of *Sanfeng Tongqiao Diwan* in patients with allergic rhinitis. The mechanism of action of TCM formulations is complex, as these medicinal materials contain both active ingredients and

indirect effective ingredients. Just as in genomics, non-coding RNA accounts for more than 90% of total RNA. However, it plays an indispensable role in the process of protein translation as these non-coding RNAs can regulate the expression of coding RNAs (14). There is a possibility that the indirect effective ingredients in TCM function under this mechanism. They can affect the activity and enhance the function of the active ingredients. After being mixed with suitable prescriptions, they can exert different medicinal effects. An insufficient number of cases is the main limitation of this paper, and there are also limitations to the groups represented, as all the patients had mild symptoms. Follow-up studies with an increased sample size are required for verification.

Conclusions

Overall, the use of *Sanfeng Tongqiao Diwan* is effective in the treatment of allergic rhinitis patients, especially in patients with severe symptoms. Although the treatment system of TCM is different from that of Western medicine, the application of TCM will provide a new direction for the treatment of chronic diseases.

Acknowledgments

We thank everyone involved in the collection, detection, and date management of the serum samples.
Funding: This study was supported by Guangzhou Science and Technology Foundation (No. 202102010327).

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-2768/rc

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-2768/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-2768/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the First Affiliated Hospital of Guangzhou Medical University (No. GYFYY-2020-100). Informed consent was taken from all the patients or patients' legal guardians.

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(English Language Editor: C. Betlazar-Maseh)

Cite this article as: Hu H, Luo J, Ma J, Liang Z, Dai J, Wang W, Zhong J, Tian L, Sun B. Efficacy and safety of *Sanfeng Tongqiao Diwan* in patients with allergic rhinitis: a single-arm clinical trial in China. Ann Transl Med 2022;10(12):684. doi: 10.21037/atm-22-2768

