Original Article Moxibustion with Chinese herbal has good effect on allergic rhinitis

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Abstract: Allergic rhinitis (AR) is a chronic inflammatory disease of rhino-ocular mucosa, affecting up to 40% of population worldwide. Chinese herbal medicines and Acupuncture, adopted thousands of years in China, has good effect on allergic rhinitis. This study evaluates the effects of Moxibustion with Chinese herbal in treating patients with allergic rhinitis over a 1-year follow-up. A randomized controlled trial was conducted in a sample of 355 participants recruited from Guangdong general hospital of China. After baseline measurements, participants were randomly assigned to treatment-group or control group. Treatment group received Moxibustion with Chinese herbal. Control group received Loratadine. The main outcomes, including symptom severity and quality of life were measured using the Allergic Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ). Both moxibustion with Chinese herbal and Loratadine improve nose symptoms such as stuffy/blocked, sneezing, runny nose, itchy nose, sore nose and postnasal drip in patients with AR. Symptoms fatigue, loss of taste, afraid of cold/wind and cold limb were improved significantly in moxibustion with Chinese herbal group. The mean quality of life scores decreased in both groups after treatment. Compare to control group, moxibustion with Chinese herbal is more effective than Loratadine in improving the quality of life in patients with AR. The results show moxibustion with Chinese herbal was effective to reduce symptoms and enhance quality of life in patients with allergic rhinitis. It is a simple, convenient and economic therapy for patients with AR. Further controlled trials of its effects in patients with allergic rhinitis are recommended.

Keywords: Allergic rhinitis, moxibustion, Chinese herbal medicine, quality of life

Introduction

Allergic rhinitis (AR, also nasal allergies or "hay fever") is a disorder of the nose induced after exposure to allergens via IgE-mediated hypersensitivity reactions [1]. The prevalence of AR is increasing worldwide, a trend that has been attributed to a variety of factors such as changing global climate conditions, improvements in hygiene, changes in diet, and increased obesity. It causes major illness and disability worldwide. Patients from all countries, all ethnic groups, and all ages suffer from AR. In the United States, AR is estimated to affect approximately 60 million peoples, and the prevalence is about 10-30% in adults and nearly 40% in children, with an annual economic burden estimated at \$11.58 billion, of which \$4.28 billion stems from indirect costs related to lost work productivity and school absence [2-5]. It can be triggered by an allergy to a particular food (peanuts or shellfish, for example), biting or stinging insects (like bees), medication (penicillin), latex (the type of rubber many balloons are made from) or a variety of other allergic triggers. Allergic rhinitis can also be triggered by the pollens of specific seasonal plants. The most widespread form of infectious rhinitis is the common cold [6, 7]. The mucous membranes become infected or irritated, producing a discharge, congestion, and swelling of the tissues. The signs and symptoms of AR includ:sneezing,itchi ng:nose,eyes,ears,palate,rhinorrhea,postnasal drip, congestion, anosmia, headache, earache, tearing, red eyes, eye swelling, fatigue, drowsiness, malaise. Complications of allergic rhinitis include: acute or chronic sinusitis, otitis media, sleep disturbance or apnea, dental problems, which is caused by excessive breathing through the mouth, palatal abnormalities, eustachian tube dysfunction [8].

Rhinitis is a risk factor for the development of asthma [9]. The more persistent and severe the rhinitis, the more likely one may develop asthma, and if poorly controlled, it may exacerbate asthma. Most patients with asthma also have rhinitis, while 10-40% of patients with rhinitis have comorbid asthma. Its relationship is supported by epidemiological, anatomical and physiological, immunopathological, clinical and therapeutic studies, mostly related to allergic rhinitis. Rhinitis and asthma occur together at rates that greatly exceed what would be expected from the baseline prevalence of each disorder alone. Many researchers have considered rhinitis as a risk factor for developing asthma. Also, the severity of rhinitis has been directly correlated with the severity of asthma. Evidence suggests that rhinitis and asthma are different facets of a broader systemic inflammatory process involving upper and lower airways. Treatment of rhinitis simultaneously produces a favorable effect on symptoms of asthma and concurrent improvement in lung function and bronchial hyperresponsiveness [10].

Allergic rhinitis is a very common disorder that affects quality of life and generates important health care and social costs. It has been well known that pediatric allergic rhinitis was associated with poor performance at school due to attention deficit. The attention scores of omission and commission errors on divided attention task were significantly lower in children with allergic rhinitis than in children with nonallergic rhinitis. Management of allergic rhinitis is associated with improvement of attention [11]. Compared to healthy controls, seasonal allergic rhinitis (SAR) patients had a slow development speed during both symptomatic and non-symptomatic allergy periods. Additionally, they showed a more flexible adjustment in attention control, which may serve as a compensatory strategy. Reduction in processing speed was positively associated with total IgE levels, whereas flexible adjustment of attention was linked with anxious mood. SAR represents a state that is crucially linked to impairments in information processing and changes in attention control adjustments. These cognitive alterations are more likely to be influenced by mood and basal inflammatory processes than sleep impairments or subjective symptom severity [12, 13].

The management of AR includes allergen avoidance, pharmacotherapy, immunotherapy, and surgery. Allergen avoidance and pharmacother-

apy are first-line treatments for AR, but recurrence of the disorder makes medication less effective over time. Although a new generation of medications with decreased side effects has been developed, side effects have not been completely eliminated. We need to look for another more effective and less side effect management for AR.

Materials and methods

Patients

This trial is a prospective trial, which was performed at the Integrated Division of Chinese and Western Medicine of Guangdong General Hospital, China. We enrolled 355 patients. The treatment group is consisted of 182 patients (93 males, 89 females; age, 12-45 years; mean age, 18.81 ± 5.37 years). The duration of disease in the treatment group ranged from 3 to 5 years (mean, 4.15 ± 1.32 years). The control group is consisted of 173 patients (88 males, 85 females; age, 12-44 years; mean age, 17.12 ± 5.01 years). The duration of disease in the control group ranged from 3 to 5 years (mean, 4.41 ± 1.53 years). The two groups were similar in terms of patient gender, duration of disease, and patient conditions (P > 0.05).

Inclusion criteria

Each participant must have a diagnosis of AR according to the criteria listed in 'Allergic Rhinitis and its Impact on Asthma' [14]. Patients who will be recruited in this study should meet the following inclusion criteria: (1) Male or female aged between 7 and 45 years. (2) Presenting with typical symptoms of AR, such as rhinorrhea, sneezing, nasal obstruction, and pruritus. These symptoms should last for more than one hour on most days. Some patients may have ocular symptoms due to outdoor allergens. (3) Having at least one positive result among the following laboratory findings: elevated total blood IgE level or positive skin prick test reaction. (4) Providing an informed written approval. (5) No current participation in any other clinical trials.

Exclusion criteria

Individuals will be excluded from the study if any of the following are applicable. (a) Patients have suffered from diseases related to the nose, paranasal sinus, or upper respiratory tract such as acute paranasal sinusitis or an

Table 1. Mean Rhinoconjunctivitis Quality of Life Questionnaire scores in patients treated for 8 weeks with moxibustion (n = 182)

| | Before | After | |
|--|---------------|---------------|--|
| | treatment | treatment | |
| Nose symptoms | | | |
| Stuffy/blocked | 3.8 ± 0.7 | 1.9 ± 0.6 | |
| Sneezing | 3.6 ± 1.1 | 2.2 ± 0.9 | |
| Runny nose | 4.9 ± 1.2 | 2.7 ± 0.8 | |
| Itchy nose | 2.8 ± 0.6 | 1.3 ± 0.4 | |
| Sore nose | 2.6 ± 0.7 | 1.1 ± 0.5 | |
| Post-nasal drip | 3.1 ± 1.1 | 2.0 ± 0.8 | |
| Eye symptoms | | | |
| Itchy eyes | 3.4 ± 1.2 | 2.2 ± 0.8 | |
| Watery eyes | 3.5 ± 0.8 | 2.0 ± 0.4 | |
| Sore eyes | 2.2 ± 0.8 | 1.1 ± 0.6 | |
| Swollen eyes | 1.8 ± 0.5 | 1.2 ± 0.6 | |
| Red eyes | 1.8 ± 0.4 | 1.1 ± 0.5 | |
| Sleep symptoms | | | |
| Difficulty getting to sleep | 3.6 ± 0.9 | 2.4 ± 0.7 | |
| Wake up during the night | 2.8 ± 0.7 | 1.8 ± 0.4 | |
| Lack of a good night's sleep | 3.8 ± 0.6 | 2.2 ± 0.3 | |
| Non eye/nose symptoms | | | |
| Fatigue | 3.3 ± 1.1 | 1.3 ± 0.4 | |
| Thirst | 2.5 ± 0.8 | 1.4 ± 0.2 | |
| Reduced productivity | 3.1 ± 0.7 | 1.6 ± 0.6 | |
| Tiredness | 3.2 ± 0.8 | 1.4 ± 0.6 | |
| Poor concentration | 2.8 ± 0.8 | 1.3 ± 0.3 | |
| Headache | 3.4 ± 1.2 | 1.7 ± 0.6 | |
| Worn out | 3.7 ± 1.3 | 1.6 ± 0.4 | |
| Itchy throat | 3.6 ± 0.9 | 1.3 ± 0.4 | |
| Loss of taste | 2.7 ± 0.6 | 1.1 ± 0.3 | |
| Afraid of cold/wind | 3.9 ± 0.8 | 1.2 ± 0.2 | |
| Cold limb | 3.7 ± 1.0 | 1.8 ± 0.6 | |
| Practical problems | | | |
| Inconvenience of having to carry tissues or handkerchief | 4.1 ± 0.9 | 2.3 ± 0.8 | |
| Need to rub nose/eyes | 3.6 ± 0.5 | 2.1 ± 0.5 | |
| Need to blow nose repeatly | 3.7 ± 0.8 | 2.4 ± 0.5 | |
| Emotional function | | | |
| Frustrated | 1.7 ± 0.4 | 1.2 ± 0.5 | |
| Impatient or restless | 2.1 ± 0.8 | 1.4 ± 0.7 | |
| Irritable | 3.4 ± 0.8 | 2.1 ± 0.9 | |
| Embarrassed by your symptoms | 4.2 ± 1.2 | 2.3 ± 1.1 | |
| Note: At 9 weeks after treatment, Mean Phinoconjunctivitis Quality of Life Questionnaire | | | |

Note: At 8 weeks after treatment, Mean Rhinoconjunctivitis Quality of Life Questionnaire scores were calculated respectively. Data are shown as mean \pm SD (n = 182).

upper respiratory infection within the last 14 days; show signs of chest inflammation in an X-ray; have a history of chronic paranasal sinusitis as shown by accessory nasal cavity X-ray examination; or have had organic nasal cavity disease, have undergone nasal cavity surgery,

or have paroxysmal respiratory diseases such as asthma. (b) patients are receiving or have received treatment that might influence the assessment of results including H1 antihistamines, steroids, antihistamines, decongestants (nasal, oral, or ophthalmic), corticosteroids, or antibiotics within 14 days of enrollment; have had specific immunotherapy or systematic hormone therapy in the last year; have had acupuncture, moxibustion, cupping, nasal inhalation of herbal medicine, or other physical alternative medicine therapy within the last 14 days; or have taken herbal preparations for AR within the last 14 days. (c) patients that have suffered from mental disorders, tuberculosis, hepatitis, or have blood Cr or AST/ ALT values twice the normal level. (d) patients that are pregnant, lactating, or planning to become pregnant. (e) patients that have a history of smoking more than 10 cigarettes daily over 10 consecutive years. (f) patients presenting with scars at the acupoint locations or suffering from a systemic disease and are therefore considered unsuitable for acupuncture. (g) patients that

are determined to be unable to cooperate in the trial. (h) patients with asthma requiring daily treatment and patients sensitized to seasonal allergens. And any other condition that might affect nasal breathing or nocturnal sleep pattern.

Withdrawal from the study

All participation in the trial is voluntary. Participants have the right to withdraw from the study at any time for any reason without any consequences for further medical treatment. Also, investigators have the right to terminate the participation of any patients if any severe adverse events occur or any events that may hurt the participant's interest. The reasons and circumstances for study discontinuation will be documented in the case report form.

Recruitment

Patients will be recruited at the Integrated Division of Chinese and Western Medicine of Guangdong General Hospital.

Interventions

During the treatment process, all participants will be explained the effects of moxibustion with Chinese herbal by the trained doctors in the same way. Control group participants received Loratadine Tablets (Schering-plough Labo N.V), 10 mg, once per day for 8 weeks. The treatment group participants received moxibustion with Chinese herbal treatments, 2 twice a week for a total of 16 sessions over 8 weeks. The moxibustion performed for 30 minutes each time, then the herbal will be withdrawn. The acupuncture points used were: Tiantu, Dazhui, Feishu, Zusanli, Shenshu. The location of acupuncture points was performed on the basis of individual body size using measuring units equal to the transverse width of finger (TF), or 'cun', according to the People's Republic of China, State Standard Name and Location of Acupoints (GB 12346-2006) [15, 16]. The Chinese herbal used were White Mustard Seed, Euphorbia, Corydalis Tuber and Ginger juice. All participants were followed up for one year.

Adverse events

Any unexpected events will be recorded on an adverse event report form during the trial. Blood, liver function, and kidney function will be tested by a routine blood test, Cr, BUN, ALT, and AST during preparatory screening and after treatment.

Ethics

The study protocol was approved by the institutional review board at Guangdong General

Hospital and conducted in accordance with the Declaration of Helsinki and its amendments. After a full explanation of the study, all patients were given written informed consent.

Outcome measurements

Data about the participations was collected using the Allergic Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) [17-19]. Healthrelated quality of life was assessed using the RQLQ adapted for the Chinese population and filled by researchers during patient interview. This questionnaire contains 32 items in six domains (nose symptoms, sleep problems, eye symptoms, non-nose noneye symptoms, practical problems and emotional function). Each item was scored from 0 (no troubling) to 6 (extremely troubling). Before and after the 8 week treatment the RQLQ was filled by researchers by interviewing patients.

Statistical analysis

Statistical analysis was conducted using Statistical Package for Social Sciences software version 19.0. The data are presented as the mean \pm S.E. Student's t-test was performed for comparisons between groups, and the χ^2 test was used for numerical data. For all statistical analysis, P < 0.05 was considered statistical significant.

Results

The effect of moxibustion with Chinese herbal

Nose symptoms: stuffy/blocked, sneezing, runny nose, itchy nose, sore nose and post-nasal drip in patients of treatment group were improved. Symptoms fatigue, loss of taste, afraid of cold/wind and cold limb were improved obviously. Compare to control group, moxibustion with Chinese herbal is more effective than Loratadine on the quality of life in patients with AR (**Table 1**).

The effect of loratadine

Loratadine can improve nose symptoms: stuffy/blocked, sneezing, runny nose, itchy nose, sore nose and post-nasal drip in patients with AR in a shorter time than moxibustion with Chinese herbal does. But symptoms fatigue, loss of taste, afraid of cold/wind and cold limb were not improved obviously. Comparing to moxibustion with Chinese herbal Loratadine is less effective on the quality of life in patients with AR (Table 2).

Table 2. Mean Rhinoconjunctivitis Quality of Life Questionnaire scores in patients treated for 8 weeks with Loratadine (n = 173)

| | Before | After treat- |
|--|----------------|-----------------|
| | treatment | ment |
| Nose symptoms | | |
| Stuffy/blocked | 3.85 ± 1.0 | $1.8 \pm 0.7*$ |
| Sneezing | 3.7 ± 1.2 | $2.1 \pm 0.8*$ |
| Runny nose | 4.7 ± 1.2 | $2.5 \pm 0.9*$ |
| Itchy nose | 2.9 ± 0.7 | 1.2 ± 0.6* |
| Sore nose | 2.5 ± 0.8 | 1.3 ± 0.5* |
| Post-nasal drip | 3.3 ± 1.0 | $2.4 \pm 0.9*$ |
| Eye symptoms | | |
| Itchy eyes | 3.3 ± 1.1 | $2.3 \pm 0.9*$ |
| Watery eyes | 3.4 ± 0.9 | $2.3 \pm 0.8*$ |
| Sore eyes | 2.1 ± 0.8 | 1.3 ± 0.7* |
| Swollen eyes | 1.8 ± 0.6 | 1.5 ± 0.4* |
| Red eyes | 1.7 ± 0.5 | 1.3 ± 0.3* |
| Sleep symptoms | | |
| Difficulty getting to sleep | 3.5 ± 0.8 | 2.2 ± 0.9* |
| Wake up during the night | 2.8 ± 0.8 | 1.6 ± 0.4* |
| Lack of a good night's sleep | 3.5 ± 0.7 | $2.1 \pm 0.3*$ |
| Non eye/nose symptoms | | |
| Fatigue | 3.4 ± 0.6 | 2.3 ± 0.7** |
| Thirst | 2.5 ± 1.0 | 1.8 ± 0.6* |
| Reduced productivity | 3.1 ± 0.9 | 2.6 ± 0.3** |
| Tiredness | 3.2 ± 0.8 | 2.4 ± 0.9** |
| Poor concentration | 2.8 ± 0.7 | 1.9 ± 0.8** |
| Headache | 3.4 ± 0.9 | 2.7 ± 0.5** |
| Worn out | 3.7 ± 1.2 | 2.6 ± 1.0** |
| Itchy throat | 3.6 ± 1.0 | 2.3 ± 0.9** |
| Loss of taste | 2.7 ± 0.9 | 2.1 ± 0.8** |
| Afraid of cold/wind | 3.8 ± 1.0 | 3.2 ± 0.9** |
| Cold limb | 3.9 ± 1.0 | 3.8 ± 0.8** |
| Practical problems | | |
| Inconvenience of having to carry tissues or handkerchief | 4.1 ± 1.1 | 2.2 ± 1.0* |
| Need to rub nose/eyes | 3.7 ± 0.9 | 2.4 ± 0.6* |
| Need to blow nose repeatly | 3.8 ± 0.7 | 2.8 ± 0.8 * |
| Emotional function | | |
| Frustrated | 1.6 ± 0.7 | 1.3 ± 0.6* |
| Impatient or restless | 2.2 ± 0.8 | $1.4 \pm 0.7*$ |
| Irritable | 3.2 ± 1.0 | $2.2 \pm 0.9*$ |
| Embarrassed by your symptoms | 4.3 ± 1.3 | 2.4 ± 1.1* |

Note: At 8 weeks after treatment, Mean Rhinoconjunctivitis Quality of Life Questionnaire scores were calculated respectively. Data are shown as mean \pm SD (n = 173). *P > 0.05; **P < 0.01 vs moxibustion.

Discussion

Allergic rhinitis is a chronic inflammatory disease of rhino-ocular mucosa mediated by

immunoglobulin E (Ig-E). Apart from classical known symptoms such as runny nose, post nasal drip, sneezing and nasal congestion, patients may also suffer from daytime fatigue, poor concentration, cognitive impairment, daytime sleepiness and sleep disturbance. Currently, treatment includes pharmacotherapy, allergen avoidance and immunotherapy [20].

Allergen avoidance and pharmacotherapy are the cornerstones of AR management. Pharmacotherapy is individualized to the patient based on type of symptoms, duration and severity, comorbidities, response to prior treatment, and patient preference. Classes of drugs used to treat AR include antihistamines, corticosteroids, mast cell stabilizers, decongestants, nasal anticholinergics, and leukotriene-receptor antagonists. The most effective medication in persistent rhinitis used singly is tropical corticosteroid, which decreases all symptoms, including ocular ones. Antihistamines reduce nasal itch, sneeze and rhinorrhea and can be used orally or

topically. When intranasal antihistamine is used along with topical corticosteroid, the combination is more effective and acts more rapidly than either drug used alone [21-23].

As to immunotherapy, subcutaneous and sublingual routes are currently used, the former being perhaps more efficient and the latter safer [24]. Sublingual tablets are now available. Efforts have been made to develop more effective and simple immunotherapy by modifying allergens and developing alternative routes. Standard allergen avoidance procedures used alone do not provide positive results. A comprehensive, multi-trigger, multi-component approach is needed, including avoidance of pollutants such as cigarette smoke.

Pharmacotherapy and immunotherapy cannot cure AR completely. Although a new generation of medications with decreased side effects has been developed, side effects have not been completely eliminated. We need to look for another more effective and less side-effect management for AR.

Alternative therapies, such as homeopathy, intranasal carbon dioxide, or devices such as nasal air filters or intranasal cellulose, have produced some positive results in small trials but are not recommended by Allergic Rhinitis and its Impact on Asthma [25, 26].

Available data indicate that acupuncture and Chinese herbal can improve nasal symptoms in patients with allergic rhinitis [27-29]. They are safe and valuable therapeutic support, and can reduce the use of medications (antihistamines, decongestant, antibiotics, corticosteroids). Acupuncture and Chinese herbal have function on the immune system of patients with allergic rhinitis. The treatment of allergic rhinitis with moxibustion with Chinese herbal, adopted thousands of years in ancient China, has recently raised much attention among researchers. It has both the function of acupuncture and Chinese herbal. The results of this study show that Moxibustion with Chinese herbal has good effect on nasal symptoms in patients with allergic rhinitis. It can reduce the frequency of common cold, the most important cause of AR. It can eliminate the symptoms of afraid of cold/ wind, cold limb, fatigue/tiredness, and headache, and improve the concentration of patients with AR. In addition, AR is popular in children and adults under 50 years. Moxibustion with Chinese herbal is simple, convenient and economical. The patients can have the treatment at home. It will not affect their work and study, which is a good choice for patients with AR.

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Disclosure of conflict of interest

None.

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