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Clinical Study on Acupuncture Treatment of Perennial Allergic Rhinitis (PAR) Based on Zelen's Design

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Abstract

Objective: Perennial allergic rhinitis (PAR) is clinically defined as an inflammatory condition of the nose characterised by nasal obstruction, sneezing, itching, or rhinorrhea, occurring for an hour or more on most days throughout the year. The study aimed to evaluate the effectiveness of acupuncture treatment for PAR. **Methods**: 76 subjects were enrolled with inclusion criteria and randomly divided into the acupuncture group (AG) and drug group (DG) based on Zelen's design. In AG, Yintang (EX-HN3), LI20 (bilateral), LI11 (left), LI4 (left), ST36 (bilateral) were selected as primary acupoints, and adjunct acupoints were added based on syndrome differentiation. Acupuncture treatment for four weeks was performed once every two days. In DG, *Desloratadine Citrate Disodium* tablet was administrated orally once every day for four weeks. The variations of total nasal symptom score (TNSS) and overall non-nasal symptom score (TNNSS) were tested

within three days before, at Week-4 during, and at Week-4 (follow-up) after the treatment. **Results**: Thirty-two subjects in the AG and 38 subjects in the DG completed the trial. The differences between TNSS and TNNSS scales in the same groups showed a statistical difference ($P<0.05$) before, during, and after the treatment. The statistic differences between TNSS and TNNSS in those two groups were not obtained ($P>0.05$) before and after the treatment. The differences in those two groups during the follow-up visit were statistically different ($P<0.05$). **Conclusion**: Acupuncture could effectively control the nasal and systemic symptoms of PAR, and its effect was more persistent than the administration of *Desloratadine Citrate Disodium*.

Key Words: Zelen's design; Allergic rhinitis (AR); Acupuncture; Traditional Chinese Medicine

Allergic Rhinitis (AR) refers to IgE-mediated chronic immune disease of the nasal mucosa, also referred to as "anaphylactic rhinitis". Allergic inflammation of the nasal mucosa with paroxysmal sneezing, runny nose, and nasal obstruction as the main symptoms after stimulated. It can also be accompanied by conjunctivitis, secretory otitis media, sinusitis, and nasal polyps, which affect the quality of life of patients and even threaten life in severe cases. Recently, AR's incidence rate across the world varies from 10% to 40%, and this figure has been on the increase [1]. In China, its incidence has also increased significantly in recent years ranging from 8.7% to 24.1% [2].

Additionally, AR patients often suffer respiratory diseases, e.g. asthma, cough[3], which leads to massive economic, society, and health burdens. However, the pathogenesis of AR remains unclear. Clinically, AR consists of two types: perennial (PAR) and seasonal. Chen et al. [4] strictly followed Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines in selecting drugs, however, the uncontrolled patients accounted for 26.1% after 15 days of treatment. Studies abroad have shown that AR, which cannot be controlled by immunisation and drug therapy is 18.9% [5]. AR is featured with high incidence and challenging to cure. Usually, patients are not satisfied with the control of symptoms after the routine treatment with western medicine. They seek Traditional Chinese Medicine (TCM) treatment. AR is called "Biqiu" in TCM, which refers to clear nasal discharge, nasal congestion, and itching. TCM has certain advantages in the treatment of Biqiu. Acupuncture is one of the essential treatment methods. The common acupuncture points for the treatment of AR are the local and related meridian points of hand Taiyin, hand and foot Yangming meridians, bladder meridian, and Du meridian. The common acupuncture points are LI20, BL13, Yintang (EX-HN3), DU14, ST36, BL23, and LI4 [6]. Previous studies have shown that acupuncture is better than *Loratadine* or *Cetirizine* in treating AR in terms of symptom improvement and laboratory tests [7-13]. This study intended to investigate the efficacy of acupuncture treatment for PAR.

1. Clinical Data

1.1 Patients

In this study, we selected patients with perennial allergic rhinitis (PAR) as the research object. The PAR patients who sought medical advice were screened at the outpatient clinic, Affiliated Hospital of Chengdu University of TCM, from January 2017 to June 2018 with the inclusion criteria.

1.2 Diagnostic criteria

The diagnostic criteria for AR were designed based on the diagnostic standard and therapy guidelines for AR (2015, Tianjin) [14].

1.3 Inclusion and exclusion criteria

The inclusion criteria were consistent with the

diagnostic criteria mentioned above. The subjects who were previously in heath condition; received no other therapy scheme or stopped theory for two weeks or more; aged in 18-65; could correctly describe the personal intention; consented to participate in clinical trials, signed informed consent. Drop-out was not supplemented.

Exclusion criteria: Patients who suffered respiratory tract infection or acute paranasal sinusitis within 14 days; those with chronic rhinitis (or sinusitis), and asthma patients; people with a mental health condition; haemophilia and other acupuncture contraindications; patients who took antihistamines, and corticosteroids within 14 days; those who didn't cooperate with the treatment; pregnant women, those who prepared to get pregnant or travel during the procedure; and those suffered tuberculosis and hepatitis were excluded.

1.4 Grouping

PAR patients were divided into acupuncture group (AG) and drug group (DG) following the principle of randomisation and obtaining the random numbers in the order of entry based on the random number table generated from a computer. Informed consent from the subjects in the acupuncture group was obtained. If the patients agreed to join the randomised grouping of AG, they were assigned to the AG. Or they were assigned to the control group.

2. Treatment Scheme

2.1 Main materials

Filiform needle: disposable needle 0.25*25mm and 0.25*40mm (Changchun Aikang Medical Instrument Co., Ltd.).

Drug: *Desloratadine Citrate Disodium* tablet, 8.8 mg*6 tablets/box, (Guangzhou Hairui Pharmaceutical Co., Ltd., Yangzi River Pharmaceutical Group, SFDA Approval No.: H20090138).

2.2 Selection and operation of acupoints

Acupoints were localised following WHO 90/8579-Atar-8000, A proposed standard international acupuncture nomenclature.

Acupuncture treatment was performed by licensed acupuncturists with more than three years' experience. Participants in AG received 12 sessions of acupuncture treatment (3 times weekly for four weeks); each session lasted 30 minutes. The use of acupoints other than those prescribed was not allowed. Disposable stainless-steel needles were used in acupuncture treatments. Insertion was followed by stimulation performed by lifting and thrusting the needle combined with twirling and rotating the needle sheath to produce the sensation known as Deqi (feeling of soreness, numbness, distention, or radiating, which is considered to indicate effective needling) [15].

2.3 Intervention methods

AG: for the 34 subjects who were qualified for the inclusion criteria, the primary acupoints were selected including Yintang (EX-HN3), LI20 (bilateral), LI11 (left), LI4 (left), ST36 (bilateral). According to the syndrome differentiation in Chinese Medicine, BL13 (bi-lateral) was added for the pattern of cold in the lungs; DU14 was added fro the pattern of latent heat in the lungs. After the feeling of Deqi, needles retained in the body for 30 minutes. Meanwhile, the needles were manipulated once every 15 minutes. Acupuncture therapy was applied once every other day, three days a week for four weeks. In total, 12 sessions of acupuncture therapy were performed.

DG: *Desloratadine Citrate Disodium* tablets were given orally, once a day, for four weeks.

3. Efficacy evaluation

The evaluation was performed based on "Principles and Recommendations for Diagnosis of Perennial AR". The scores were assigned according to the nasal and accompanying symptoms before, Week-4 during, and Week-4 (follow-up visit) after the treatment.

3.1 Main observation index

TNSS was recorded as the main observation index from day to day during the treatment and follow-up visit. TNSS covered four symptoms: snuffling, running nose, nasal itching, and sneezing. Each symptom was divided into five levels according to the severity: asymptomatic (0 scores), mild (1 score), moderate (2 scores), rather severe (3 scores), and very severe (4 scores). The cumulative total score referred to the total score of nasal symptoms. The highest score was 16. Scores were recorded by the evaluator at the time of evaluation and patients' self-evaluation in the form of a daily diary.

3.2 Secondary observation index

TNNSS covers the existence of running nose from the pharynx, tear, the pain of the nose or eye, the pain of nasal or oral palate, headache, and other symptoms. The scores were assigned to no (0 scores) and yes (1 score). The cumulative total score referred to the total score of accompanying symptoms. The highest score was 5. The scores were recorded by the evaluator and the patients in the form of daily diary self-evaluation.

3.3 Statistical analysis

The database was established with Microsoft Excel 2015 spreadsheets. Statistical analysis was performed with the Chinese version of Statistical Product and Service Solutions (SPSS) 20.0. The Data analysis was performed according to Intention-to-Treat (ITT) and Per-protocols (PPs) analysis. The measurement data were counted in the form of mean ± standard deviation and were analysed by the adoption rate and ratio of classified variables. For the analysis of measurement data, data conformed to the normal distribution, with homogeneity of variance, the inter-group analysis was analysed using an independent sample T-test, the intra-group before and after the study was analysed using paired sample T-test. For the data that didn't conform to the normal distribution, the non-parametric test was performed. Statistical results were judged by P-value (0.05).

4. Results

Among the 76 subjects who suffered PAR, 34 subjects received acupuncture treatment, and 42 subjects received orals. With the informed consent from the acupuncture group, four subjects who were reluctant to receive acupuncture treatment were included in the drug group. During the clinical trials, one subject was unable to receive follow-up treatment at the hospital, because he went on business travel after finishing four treatments, and one subject was excluded. Therefore, a total of 32 subjects in the acupuncture group finally finished the treatment according to the defined scheme. Two subjects in the drug group were excluded as they additionally applied intranasal corticosteroids due to self-perceived reduced efficacy. Two subjects dropped out because both of them were unable to receive a follow-up visit after moving. Therefore, a total of 38 subjects in the drug group finally finished the treatment according to the defined scheme. During the clinical intervention, six samples dropped out at a rate of 7.89% (6/76) <20%, which was in line with the design requirement for clinical trials.

4.1 General data

The statistical significance of the comparison of general data between these two groups was statistically significant and comparable (Table 1).

With Intention-to-Treat (ITT) and Per-protocol set (PPs) analysis, the primary efficacy analysis was performed to analyse TNSS and TNNSS scales. Data were collected before, during (Week-4), and after the treatment (Week-4 (follow-up visit). Besides, intra-group comparison was analysed between the two groups during (Week-4) and after the treatment (Week 4, fol

Table 1. Baseline data comparison between the two gro

Group	Gender		Age	History of Disease
	Male	Female		
Acupuncture Group (n=34)	11 （32.35%）	23 （67.65%）	32.97±7.36	5.41±4.12
Drug Group (n=38)	12 （31.58%）	26 （68.42%）	31.87±8.08	5.35±3.63
Statistical Value	x^2=1.72		t=0.694	t=-0.36
P-value	P=0.168		P=0.471	P=0.790

low-up).

4.2 ITT analysis

4.2.1 Comparison of TNSS, TNNSS between the two groups at Week-4 of the treatment

After the paired T-test and Man-Whitney signed-rank test were conducted. The statistical differences (Intra-group comparison) of the TNSS and TNNSS between the acupuncture group and the drug group at Week-4 of the treatment were significant (P<0.001). On the contrast, the differences(comparison between those two groups) were not statistically significant (P＞0.05) (Table 2), suggesting that acupuncture therapy and oral administration of *Desloratadine Citrate Disodium* were not only effective in the treatment for local nasal symptoms but also complications. Acupuncture treatment showed a similar effect to the medicine.

Table 2: ITT analysis of TNSS and TNNSS between the acupuncture group and the drug group at Week-4 during the treatment (before and after treatment)

	Acupuncture Group (AG)	Drug Group (DG)	AG vs DG
TNSS	T=10.17	T=7.23	Z=-4.78
TNNSS	T=10.21	T=7.32	Z=-5.12
P	P=0.000	P=0.000	P=0.120

4.2.2 Comparison of TNSS, TNNSS between the two groups on the follow-up visit

As is shown in Table 3, the statistical differences (Intra-group comparison) in TNSS and TNNSS between the AG and DG on the follow-up visit were identified (P<0.05); the differences (comparison between those two groups) were statistically significant (P<0.05). The scores of AG (TNSS 5.93 ± 1.76, TNNSS 2.51 ± 0.82)

Table 3. ITT analysis of TNSS and TNNSS between the acupuncture group and the drug group on the follow-up visit

	Acupuncture Group (AG)	Drug Group (DG)	AG vs DG
TNSS	T=5.31	T=4.05	Z=-3.98
	P =0.031	P=0.039	P=0.048
TNNSS	T=5.49	T=4.90	Z=-4.01
	P=0.032	P=0.036	P=0.046

was superior to those of the DG(TNSS 6.81 ± 1.93 TNNSS, 3.03 ± 0.80)，suggesting that acupuncture therapy was more durable than the oral administration in control over local nasal symptoms and its systemic accompanying symptoms.

4.3 PPs analysis

4.3.1 PPs analysis of TNSS and TNNSS between AG and the DG at Week-4 during the treatment

As is shown in Table 4, the statistical intra-group differences (TNSS and TNNSS) between the AG and DG were significant (P<0.05) at Week 4 during the treatment. However, the differences in the comparison between AG and DG were not significant (P>0.05). The acupuncture therapy and oral administration of *Desloratadine Citrate Disodium* were effective in the control over local nasal symptoms and its systemic accompanying symptoms. Besides, they had comparable efficacy.

Table 4. PPs analysis of TNSS and TNNSS between the acupuncture group and the drug group at Week 4 during the treatment (before and after treatment)

	Acupuncture Group (AG)	Drug Group (DG)	AG vs DG
TNSS	T=9.78 P =0.025	T=8.75 P=0.024	Z=-5.48 P=0.070
TNNSS	T=8.86 P=0.028	T=8.60 P=0.026	Z=-6.12 P=0.069

4.3.2 Comparison of TNSS and TNNSS between the acupuncture group and the drug group on the follow-up visit

As is shown in Table 5, the statistical differences (Intra-group comparison) in TNSS, TNNSS of both AG and the DG on the follow-up visit were significant (P<0.05); such differences(comparison between AG and DG) were statistically significant (P<0.05). The scores of the acupuncture group (TNSS 4.85 ± 1.59 TNNSS 2.03 ± 0.81) were superior to the drug group (TNSS 6.03 ± 2.01 TNNSS 2.85 ± 0.83), suggesting that acupuncture therapy was more durable than oral administration in control over local nasal symptoms and its systemic accompanying symptoms.

Table 5. PPs analysis of TNSS and TNNSS between the acupuncture group and the drug group during the follow-up visit

	Acupuncture Group (AG)	Drug Group (DG)	AG vs DG
TNSS	T=3.47 P=0.039	T=3.41 P=0.042	Z=-4.68 P=0.049
TNNSS	T=3.52 P=0.040	T=2.91 P=0.047	Z=-4.72 P=0.048

5. Discussion

The Zelen's design [16] was firstly proposed by Professor Marvin Zelen from Harvard University. Even though it differs from Randomized Controlled Trial (RCT), it is considered as a reference to RCT designs. Both methods can be combined in clinical studies. After randomisation, the patients in the observation group (acupuncture group) will sign the informed consent. In contrast, the patients in the control group can be assigned to the group without informed consent. The specific steps of Zelen's design: 1) divide subjects into two groups, among which one group is intervened by the same method as the control group while another group enters the informed consent process; 2) ask if the subjects are willing to accept the new intervention method; 3) the subjects who refuse will be assigned to the control group, while those who consent to do so will be assigned to a new group, namely the treatment group; and 4) compare the efficacy between the new intervention method and traditional treatment method [17-19].

The advantage of this design is that the wills of the subjects are fully respected in practice. During the clinical trial, the subjects showed good compliance, which in turn contributed to the progressing of the trial.

There are two statistical methods in the design, i.e. ITT and PP. ITT often underestimates the efficacy of the observation group, and on the contrary, PP often overestimates the efficacy of the observation group. In clinical trials, both methods are usually combined. If both showed the same result, the reliability is much higher. The results of this study were consistent, and the results were highly reliable.

In addition to Chinese herbal medicine treatment, acupuncture has been frequently used and showed a favourable effect. In acupuncture treatment, local and distal acupoints are combined. Liu et al. [20] reported that the "Three Nasal Needles," i.e. LI20 (bilateral) and EX-HN3 could significantly improve the symptoms and quality of life of the patients and the long-term efficacy was better than that of the *Loratadine* group. Sheng et al [21] reported that acupuncture treatment for 34 cases of moderate-to-severe PAR with acupuncture achieved a total effective rate of 91.2%.

The hand Yangming large intestine meridian and hand Taiyin lung meridian hold an exterior-interior relationship. Therefore, the puncturing on LI20 dispels wind and pathogenic factors, dredges nasal orifices, and regulates the lung meridian Qi. According to modern research, acupuncture treatment on LI20 (bilateral) could effectively improve the local symptoms, e.g. nasal obstruction, runny nose, sneezing, and nasal itching, and also reduce the number of eosinophils in nasal secretions [22-24]. EX-HN3 (Yintang) could dredge local meridional blockage, relieve nasal congestion, stop headache, ease dizziness, invigorate Yang Qi, dispel cold, and unblock collaterals [25-26]. LI4 and LI11 are commonly selected to treat diseases on the head and face [27-29]. ST36 can activate the neuro-endocrine-immune network through blood or lymph to regulate the cellular and humoral immunity of the human body. Zheng et al [30] reported that acupuncture treatment on EX-HN3, LI4 and ST36 quickly relieved various symptoms of AR.

Limitation

The difference in short-term control of nasal symptoms was not obtained. The reason could be attributed to the short treatment period and small sample size. Therefore, the study could not reveal the possible difference. In this study, the mechanism of the acupuncture treatment was not involved. Undoubtedly, the above limitations will be considered in our next project.

Conclusion

The findings showed that acupuncture was effective to control the symptoms of PAR and presented with better long-term efficacy (follow-up four weeks after the treatment) than the oral administration of *Desloratadine Citrate Disodium*.

Conflicts of Interest

The authors declare that they have no completing interest.

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