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Effect of Acupuncture in the Treatment of Seasonal Allergic Rhinitis: A Randomized Controlled Clinical Trial

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Abstract: The clinical efficacy and safety of acupuncture in the treatment of Seasonal Allergic Rhinitis (SAR) was evaluated by employing a two-phase crossover single-blind clinical trial. Thirty subjects were randomly assigned to two groups with 17 and 13 subjects respectively and treated with real or sham acupuncture (three times per week) for four consecutive weeks and then a crossover for treatments for a further four weeks without a washout period. The administration of real acupuncture treatment was guided by a syndrome differentiation according to Chinese Medicine Theory. Subjects were assessed by various criteria before, during and after the treatments. Outcome measures included subjective symptom scores using a five-point scale (FPS), relief medication scores (RMS) and adverse effect records. Twenty-six (26) subjects completed the study. There was a significant improvement in FPS (nasal and non-nasal symptoms) between the two types of acupuncture treatments. No significant differences were shown in RMS between the real acupuncture treatment group and the sham acupuncture treatment group. No side effects were observed for both groups. The results indicate that acupuncture is an effective and safe alternative treatment for the management of SAR.

Keywords: Seasonal Allergic Rhinitis (SAR); Acupuncture; Efficacy; Safety; Differentiation; Randomized Controlled Trial.

Introduction

Seasonal Allergic Rhinitis (SAR), also known as hay fever or pollinosis, is a common condition among the general population in Western countries. For example, the reported

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prevalence of SAR in Australia varies from 10.3% in the Australian population (ABS, 1989–1990) to 40% in young Victorian adults (Woods *et al.*, 1999) and in the Tasmanian population (Hopper *et al.*, 1995). Similar figures have been reported in the United Kingdom (10–15%) (Varney, 1991) and the United States (20%) (Bernstein, 1993). SAR has been reported to affect quality of life (The European Academy of Allergology and Clinical Immunology (EAACI), 1998) and results in significant direct and indirect healthcare cost (van Cauwenberge *et al.*, 2000).

Current Western medical treatments for SAR include symptomatic management, using drugs such as antihistamines, decongestants, mast cell stabilizers and topical corticosteroids (van Cauwenberge *et al.*, 2000), as well as immunotherapy (EAACI, 1998; van Cauwenberge *et al.*, 2000). The effects of these treatments for SAR are well documented, although some are also associated with certain side effects such as sedation, rebound nasal congestion and septal perforation or the risk of anaphylaxis (British Society For Allergy and Clinical Immunology (BSACI), 1993; International Rhinitis Management Working Group (IRMWG), 1994; EAACI, 1998; van Cauwenberge *et al.*, 2000). In addition, not all SAR patients can be successfully treated by these methods. Therefore, other alternative therapies, including acupuncture and Chinese herbal medicine (CHM), have been used in the management of SAR. According to a report by the World Health Organization (WHO), acupuncture is regarded as effective for allergic rhinitis (WHO, 1995). It has also been reported to be useful in the management of other Type I allergic diseases (Lau *et al.*, 1975; Christensen *et al.*, 1984; Chari *et al.*, 1988; Jin and Wang, 1989; Huang, 1990; Lai, 1993; Liu, 1995). Furthermore, acupuncture can reduce hypersensitivity to non-specific stimuli and may thus help in treating allergic diseases such as rhinitis and asthma (Mann, 1971; Guan and Zhang, 1995). However, the clinical evidence for the effect of acupuncture in the treatment of SAR is still controversial and there is lack of adequate designed randomized controlled trials, especially on incorporating both Western and Chinese medicine diagnosis and treatments within the context of Chinese medicine.

The aim of this study was to evaluate the efficacy and safety of acupuncture in the treatment of SAR, guided by syndrome differentiation in Chinese medicine, through a randomized crossover single-blind sham controlled trail.

Methods

The study was conducted at the University Clinic, Bundoora West Campus, RMIT University and the research protocol was approved by the RMIT Human Research Ethics Committee.

Subjects

Convenience sampling methodology was employed in this study through the public media (newspapers) to recruit SAR adult subjects residing in the Northern Suburbs of Melbourne. A screening questionnaire was sent to all potential subjects who responded to the advertisement. When the questionnaire was returned, preliminary selection processes were conducted based on the information provided. Those who met the basic criteria were then invited for an interview.

The inclusion criteria were as follows: age between 18 and 70 (inclusive); a history of typical symptoms of SAR including watery rhinorrhoea, sneezing, nasal obstruction, nose and eyes itch for at least the last two to three years; providing a written informed consent for their participation. Participants with one or more of the following conditions were excluded from the study: history of HIV; current pregnancy; previous history of specific immunotherapy; systemic corticosteroids therapy within the last three years; other active respiratory diseases such as asthma; nasal polyposis; hepatitis B and C; and previous acupuncture experience.

During the interview, baseline data was collected including the severity of symptoms by using the five-point scale (FPS, see below). Subjects were then randomly allocated into two groups by employing a randomization procedure. Thirty subjects were included with 17 for group A and 13 for group B. During the Phase I study, subjects in both group A (real treatment) and group B (sham treatment) were treated three times per week for a four-week period. During each visit, subjects were asked to assess the severity of symptoms by using the FPS. At the end of Phase I, a general assessment was conducted for all subjects. Subjects then entered into the second phase of treatment in which group A received sham treatment and group B real treatment for a further four weeks. The same procedure was followed and another overall assessment was carried out for all subjects at the end of Phase II.

Symptom data were also collected on the day of the first treatment to determine whether baseline data were still representative of SAR symptoms. As the data from the initial interview were found to be not different from the pre-treatment assessment, pre-treatment data are also referred to as baseline data.

Syndrome Differentiation and Acupoint Selection

Differentiation of syndromes was carried out for all subjects according to published criteria of syndrome differentiation in Chinese medicine (The state administration of traditional Chinese medicine (SATCM), 1994). This was classified into syndromes of Lung Qi Deficiency, Spleen Qi Deficiency and Kidney Qi Deficiency. The outcome of syndrome differentiation was used to guide the selection of supplementary acupoints. The key points selected for all subjects were Yingxiang (LI 20), Yintang (Extra point) and Fengchi (GB 20). Added supplementary points for different syndromes were: Feishu (BL 13), Taiyuan (LU 9) for Lung Qi Deficiency Syndrome; Pishu (BL 20), Zusanli (ST 36) for Spleen Qi Deficiency Syndrome; and Shenshu (BL 23), Qihai (CV 6) for Kidney Qi Deficiency Syndrome (Qiu, 1993).

Needling Procedures

"Hwato" disposable pre-sterilized needles were used in the trial. For the real acupuncture treatment, the needle selected was 0.30 mm in diameter. The length of the needle selected varied according to the point location. For the sham treatment, needles used for all points were 0.26 mm in diameter and 15 mm in length. Subjects were advised to lie in a supine position for needling of the main points and in a prone position for needling of the Back-Shu points. In both treatments, pre-injection swabs with 70% v/v isopropyl alcohol and dry

sterile cotton wool were used when withdrawing the needles. The administration of real (Qiu, 1993) or sham acupuncture (Vincent, 1989) was performed according to the standard techniques as described in the literature. In brief, for real acupuncture, the needle was inserted transversely, obliquely or perpendicularly depending on the acupoints selected with 10–40 mm in depth. The needle was retained for 25 minutes with applying one of the needle techniques (even movement, reducing or tonification) and scraping every 10 minutes before the needle was withdrawn (Table 1). For sham acupuncture, the needle was inserted gently 1.5 cm lateral to the related points. Neither tonification, sedation nor even movement method was conducted. All real and sham acupuncture treatments were performed by the same acupuncturist consistently throughout the study.

Table 1. Needling Procedure for Real Treatment

Point	Direction	Depth (mm)	Needle Technique
Yingxiang (LI 20)	Transversely, upward and medially to the bridge of the nose	20	Even movement
Yintang (EX 1)	Transversely, downward towards the root of the nose	15	Even movement
Fengchi (GB 20)	Obliquely, downward and centrally to the tip of the nose	15	Reducing
Feishu (BL 13)	Obliquely to the spine	20	Tonifying
Taiyuan (LU 9)	Obliquely, upward to the radius	10	Tonifying
Pishu (BL 20)	Obliquely to the spine	20	Tonifying
Zusanli (ST 36)	Obliquely between the tibia and the fibula	40	Tonifying
Shenshu (BL 23)	Obliquely to the spine	20	Tonifying
Qihai (CV 6)	Perpendicularly at the anterior midline below the umbilicus	20	Tonifying

Timing of the Study

This randomized, single-blind, sham-controlled, parallel trial was conducted between October and December 1995, a period that has been reported to be with the highest pollen count in Melbourne (Ong *et al.*, 1995).

Outcome Measures

Subjects' Symptom Scores

Severity of symptom scores has been widely employed in clinical research including studies on SAR (Prenner *et al.*, 1996). Subjects were asked to record their severity of symptoms, including nasal symptoms (sneezing, watery rhinorrhoea, nasal congestion and itching nose) and non-nasal symptoms (itching eyes and eye watering). All subjects independently completed this record each time they attended the clinic throughout the treatment period. At the end of Phase I and II, subjects were also asked to assess the overall severity of

symptoms over the four-week period. The details of the five-point scale (FPS) used are as follows: 0 = no symptoms; 1 = very slight symptoms but noticeable; 2 = moderate severity of symptoms; 3 = severe symptoms; 4 = very severe symptoms.

Relief Medication Scores (RMS)

All subjects were required to keep a record of the usage of Western medications during the trial. The RMS were calculated by using a scoring system as follows: (1) nasal spray/eye drop (over-the-counter, OTC) — each daily dose was equivalent to 1 point; (2) OTC antihistamines — each daily dose was equivalent to two points — multiple use of different types of antihistamines were added to the total scores; and (3) prescription only medications such as steroid nasal sprays — each daily dose was equivalent to three points.

Adverse Effects Record

Participants were required to record any unexpected signs, symptoms and feelings during the treatment period, such as headache, nausea and dizziness. They were asked to report potential side effects such as headache, nausea and dizziness to the authors and to record them in the severity of symptoms record form.

Chinese Medicine Syndrome Differentiation

All subjects were categorized into either Lung Qi Deficiency, Spleen Qi Deficiency or Kidney Qi Deficiency according to published criteria of syndrome differentiation in Chinese medicine (SATCM, 1994) to guide the selection of supplementary acupoints.

Statistics

There is no reliable data available for sample size calculation. It is estimated that the real treatment provides 70% of effect and the sham treatment 30%, for power of 80% and a significance level of 5%, a sample size of 28 subjects in each treatment group was needed. With the crossover design, 28 subjects were required in total for this study to determine the clinical efficacy of acupuncture treatment.

Data were collected on three variables (general assessment of severity, nasal and non-nasal symptoms) and were expressed as mean and standard deviation. The data were analyzed using statistical software for Windows (Statistical Package for the Social Sciences, Version 8). The repeated measure analysis of variance was conducted utilizing the General Linear Model (GLM), with focus on tests of between-subjects effects. The data from non-repeated measures were analyzed using t-test. In all cases, $p < 0.05$ was considered as statistically significant.

Results

Demographic Data

Four subjects withdrew from the trial during Phase I. Of these, three were from Group A and one from Group B (equivalent to 17.6% and 7.7% of total subjects, respectively). No post-treatment measurement was conducted for these four subjects and no efficacy data was collected. Therefore, they were not included in the data analysis. The homogeneity test between the two groups after exclusion of these subjects indicated that the two groups were comparable on all aspects ($p>0.05$) (Table 2).

Table 2. Summary of Demographic Data

		Group A	Group B	X^2 (p value)	t-Test (p value)
Number of Subjects		17	13		
Mean Age (± SD)		44.24 (±15.69)	44.54 (±10.88)		−0.059 (0.953)
Gender	**Male (%)**	6 (35.3%)	8 (61.5%)	2.039 (0.269)	
	Female (%)	11 (64.7%)	5 (38.5%)		
Duration of Disease Mean (± SD)		20.47 (±16.04)	20.62 (±9.46)		0.051(0.977)
Mean Total Score (MTS)		12.00 (±5.07)	11.08 (±6.06)		0.454 (0.653)
Family History of SAR	**Yes**	12	11	0.810 (0.427)	
	No	5	2		

FPS Symptom Assessment: Real Acupuncture Treatment versus Sham Acupuncture Treatment

When data in both Phases I and II were combined, there was no significant difference in both nasal ($t = 0.970$, $p = 0.337$) and non-nasal ($t = 0.782$, $p = 0.438$) pre-treatment symptom scores between the acupuncture and sham control groups. In contrast, there was a significant difference in both nasal ($t = -3.078$, $p = 0.003$) and non-nasal ($t = -2.206$, $p = 0.032$) after-treatment symptom scores between these groups (Table 3). The overall assessment of severity of SAR symptoms indicated a significant difference between the real and sham acupuncture treatments ($t = -2.593$, $p = 0.012$) (Table 3).

Relief Medication Score (RMS)

Only one subject in Group B used an antihistamine (Demazin) six times during Phase I, adding up to a total of 12 points. Likewise, only one subject in Group A took an antihistamine (Teldane) seven times during Phase II, adding up to a total of 14 points. Both subjects had taken relief medication during the phases when sham acupuncture was applied. No subject recorded using any relief medication during the real acupuncture treatment phase. As the number of subjects who took relief medication is small, no statistical analysis was performed.

Table 3. Real Acupuncture Treatment versus Sham Acupuncture Treatment

	Group	N	Mean	Std. Deviation	p Value
Pre-Severity of Symptom: Overall	Real	26	2.5577	0.7788	0.236
	Sham	26	2.2885	0.8387	
Post-Severity of Symptom	Real	26	1.0385	0.7736	0.012*
	Sham	26	1.6731	0.9792	
Pre-Nasal Symptom	Real	26	1.9423	0.7923	0.337
	Sham	26	1.7260	0.8155	
Post-Nasal Symptom	Real	26	0.6538	0.5961	0.003*
	Sham	26	1.2788	0.8465	
Pre-Non-Nasal Symptom	Real	26	1.6058	1.1139	0.438
	Sham	26	1.3846	0.9171	
Post-Non-Nasal Symptom	Real	26	0.3942	0.6677	0.032*
	Sham	26	0.9135	0.9974	

Data were presented as means and standard deviations.
*indicates a significant difference ($p < 0.05$) ($n = 26$ in both acupuncture and sham treatment groups).

Table 4. Differentiation in CM

Syndrome	Group A	Group B	Total
Lung Qi Deficiency	3	4	7
Spleen Qi Deficiency	4	5	9
Kidney Qi Deficiency	10	4	14
Total	17	13	30

Side Effects Record

No side effects such as headache, nausea or dizziness were reported by any subject throughout the trial.

Chinese Medicine Syndrome Differentiation

The Chinese medicine syndrome differentiation revealed that in Group A, 14 out of 17 subjects had Spleen or Kidney syndromes compared with Group B, who had nine out of 13 subjects with Spleen or Kidney syndromes. About 58.82% (ten subjects) were differentiated into syndrome involving Kidney Qi deficiency for Group A compared to 30.77% (four subjects) for Group B (Table 4). Due to the small number of subjects in individual subgroups, no statistical test was performed.

Discussion

Previous studies (Chari *et al.*, 1988; Jin and Kang, 1989; Huang, 1990; Liu, 1995) on the acupuncture treatment for allergic rhinitis have been associated with a number of weaknesses

in experimental designs, such as lack of sham/placebo controls, lack of clear selection criteria or including a mixture of SAR and perennial allergic rhinitis subjects, thus weakening the validity of their conclusions (Ernst, 1994) even though similar findings have been reported. In addition, some studies failed to provide sufficient details of the acupuncture treatment procedure, particularly those related to the rationale of acupoint selection and needling techniques (Chari *et al.*, 1988; Huang, 1990; Liu, 1995) or have used more than one therapy, i.e. acupuncture, electro-acupuncture and moxibustion concurrently (Jin and Kang, 1989; Huang, 1990). As far as we are aware, the present study is the first randomized controlled trial that fully adheres to the traditional CM diagnosis and at the same time employs a strict methodological protocol to study the efficacy of acupuncture in the treatment of SAR. In addition, the study was timed to coincide with a period with the highest levels grass pollen in Melbourne (Ong *et al.*, 1995), thus the effectiveness of acupuncture treatment for allergic rhinitis is demonstrable in a high pollen season, a condition previously associated with SAR (Ong *et al.*, 1995).

Two single-blind acupuncture trials have been previously reported, although both reported clinical significance but no statistical significance between treatment groups (Williamson *et al.*, 1996; Wolkenstein and Horak, 1998). However, their conclusions should be judged on the ground of lack of details in the description of acupoints selection or no CM theory being applied in the selection of acupoints; either inadequate treatment dose (e.g. once a week treatment for 5 minutes) (Williamson *et al.*, 1996) or adoption of relatively strong sham treatments (Wolkenstein and Horak, 1998). In contrast, the present study adopted a longer (four weeks) treatment period with the frequency of treatment being three times per week and each treatment lasted for 25 minutes. In addition, all acupoints selected in the present study were based on the traditional CM diagnosis, which also guided the needling procedures. It has been reported that patients diagnosed with Kidney Qi Deficiency syndrome would be less responsive to the acupuncture treatment (Jin and Kang, 1989). Although Group A had a higher percentage of subjects with Kidney Qi Deficiency syndrome (10/17, 58.82%) in comparison to Group B (4/13, 30.77%), the major finding is that the real acupuncture, guided by the traditional CM theory, is effective in the relief of both nasal and non-nasal symptoms in SAR. It thus rejects the hypothesis that real acupuncture treatment for SAR based on traditional CM diagnosis and treatment procedures is of no value. However, the findings of this study need to be interpreted with certain caution due to a relatively small sample size used and the generally recognized difficulty in sham treatment control in acupuncture trials.

Regarding the usage of Relief Medication, only one subject from each group recorded taking some relief medications (antihistamines). This established a total medication score of 26. The use of relief medication by both subjects coincided with the sham acupuncture treatment phase. Hence, this is consistent with a real treatment effect from acupuncture, although definitive conclusions cannot be drawn from such a small number. On the other hand, no side effects were reported from any of the participants throughout the trial. This suggests that acupuncture adopted in the present study is a safe therapeutic option for the clinical management of SAR.

The views for mechanisms underlying the effect of acupuncture in the treatment of SAR are quite different in CM compared with conventional Western medicine. From a CM viewpoint, all diseases are due to a loss of balance between Yin and Yang (Qiu, 1993). For SAR, the key pathogenesis is the deficiencies of Lung and/or Spleen and/or Kidney functions with an invasion of pathogenic wind and cold. Combining these two factors, Lung fails to disperse Qi and descend water, which results in the key signs and symptoms of SAR (SATCM, 1994). Therefore, CM treatment focuses on the restoration of the deficiencies while simultaneously expelling the pathogenic wind and cold. Key acupoints were selected for the purpose of eliminating wind and cold pathogens and to consolidate body surface resistance (Qiu, 1993). Yingxiang (LI 20), Yintang (Ex) and Fengchi (GB 20) are all local and adjacent acupoints which have the effect to disperse the Qi, expel the wind and cold pathogens and unblock the nose. For individual syndromes, additional acupoints were added to correct the deficiency of the relevant organs. In theory, these outcomes would be achieved when proper needling techniques, as specified in the "Methods" section.

On the other hand, there was limited evidence in Western scientific literature to elucidate the mechanism of acupuncture for SAR. In clinical studies, acupuncture reduced Total IgE (Chari *et al.*, 1988; Lai *et al.*, 1991) and specific IgE (Lai *et al.*, 1991). The results for changes of IgA and IgG levels, however, have been inconsistent (Chari *et al.*, 1988; Zhou and Zhang, 1999). Acupuncture has also been reported to reduce nasal and blood eosinophil counts (Lau *et al.*, 1975; Zhou and Zhang, 1999). Other effects of acupuncture reported include regulating cyclic neucleotide levels. Cyclic AMP has been found to inhibit the release of histamine and other mediators. Acupuncture has been shown to statistically increase cAMP and therefore, increase the value of cAMP/cGMP because of the unchanged level of cGMP (Feng and Chen, 1986). A study by Lai and Jia (1992), however, showed that acupuncture increased cAMP and reduced cGMP levels for asthma subjects. Lai *et al.* (1992) also reported that acupuncture markedly reduced human basophilic degranulation level in subjects with Type I allergies. These regulatory effects might stabilize mast cells and basophils to reduce or inhibit the release of the mediators (Lai *et al.*, 1992).

Conclusions

In this randomized crossover single-blind sham-controlled trial, subjects receiving the real acupuncture treatment had a significant improvement in both nasal symptoms (sneezing, watery rhinorrhoea, nasal congestion and itching nose) and non-nasal symptoms (itching eyes and eye watering) compared to the sham treatment group. The effect is not associated with any side effects and usage of relief medications other than acupuncture given. The findings supported the clinical use of traditional Chinese acupuncture as an option for symptomatic management of SAR. Further study with a larger sample size as well as more objective outcome measures is required.

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