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A Report on a Panel Study of the Therapeutic Effects of a Chinese Herbal Spray, "Allergic Rhinitis Nose Drops / 鼻敏皇", on Patients with Allergic Rhinitis

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Introduction

A randomized, double-blinded and placebo-controlled study to investigate the therapeutic effects of a Chinese herbal formula, "Allergic Rhinitis Nose Drops / 鼻敏皇" (AND), on 35 subjects with perennial allergic rhinitis (PAR) over a period of seven weeks was conducted. The subjects were monitored by a registered Chinese medicine practitioner (CMP) and a specialist in internal medicine (SIM) at 2-3 weeks intervals, and were given AND or placebo at the dosage recommended by the manufacturer according to a cross-over arrangement.

During the trial period, the changes in clinical symptoms of patients and quality of life (QOL) were observed. Laboratory investigations with respect to general testing of liver function, kidney function, hematological status and specific markers of allergic rhinitis (AR) were performed. Ethical approval was obtained from the Committee on the Use & Animal Subjects in Teaching and Research, Hong Kong Baptist University.

Materials and Methods

Patients

For this study, we recruited 40 volunteered patients with clinically confirmed PAR. The patients were not receiving specific immunotherapy or topical corticosteroids and were not using any traditional Chinese medicine therapy for AR one month prior to entering the study. Of the 40 patients, 21 with a mean age of 35 ± 15.0 years (range 14-71 years) were women, and 19 with a mean age of 41 ± 15.8 years (range 8-76 years) were men.

Allergic Rhinitis Nose Drops / 鼻敏皇

The Allergic Rhinitis Nose Drops / 鼻敏皇 (AND) manufactured by Lai Sing Medicine Factory Limited (Lai's Medicine) is a formula of 100% Chinese herbs and is claimed to be effective in relieving symptoms in patients with AR. The composition of AND was as follows[1]:

Herba Centipedae (鵝不食草)	23%
Rhizoma Coptidis (黃連)	4%
Floz Lonicerae (金銀花)	5%
Radix Platcodi (桔梗)	6%

Radix Ledebouriellas (防風)	5%
Pericarpium Citri Reticuulatae (陳皮)	4%
Herba Menthae (薄荷)	16%
Radix Scutellariae (黃芩)	10%
Radix Glycyrrhizae (甘草)	6%
Radix Paeoniae Alba (白芍)	16%
Fructus Zizyphi Jujubae (大棗)	5%

Methods

The study was a randomized, double-blinded and placebo-controlled model, with a cross-over arrangement for the administration of AND or placebo. Forty patients with PAR were recruited. All patients were assessed by the SIM for their clinical condition prior to the entry of the study. The patients were divided into 2 groups: Group A (n = 20) administered AND (2 sprays per nostril, 5 times a day) first followed by a washout period and then placebo while Group B (n = 20) started with placebo first along the schedule shown below (Table1). Five patients who were uncomfortable with the smell of Chinese medicines dropped out during the course of study, ending up with 20 patients in Group A and 15 patients in Group B.

Table 1 Arrangement of patient groups and schedule of treatment

Group	No. of patients	Treatment		
		0 – 2 weeks	3 – 5 weeks	6 - 7 weeks
A	20	AND	Washout	Placebo
B	15	Placebo	Washout	AND

Clinical assessment and relevant investigations including laboratory analyses and assessment of QOL were conducted at baseline, end of 2nd, 5th and 7th weeks.

Clinical Symptoms Score

Before and after administration of AND or placebo, the patients, under the guidance of the SIM, scored their rhinitis symptoms, based on the Clinical Symptoms Score (CSS), i.e. nasal obstruction, sneezing, nasal itching, and running nose, on a scale of four : 0 :

no symptoms; 1 : slight symptoms; 2 : moderate symptoms; 3 : severe symptoms. The total score ranging from 0 to 12 for the four symptom types was recorded.

Laboratory Analysis

Laboratory tests for fasting glucose, renal function (creatinine), liver function (ALT), haematological status (complete blood picture), C-reactive protein (CRP), total IgE, absolute eosinophil count and eosinophil cationic protein (ECP) were performed at baseline, end of 2nd, 5th, and 7th weeks with 10 ml of blood each time. Specific IgE antibodies against common inhalant allergens (house dust, house dust mite, cat, dog, cockroach and mixed mould) and food allergens (milk, egg white, fish, peanut, wheat and soya) were performed at baseline and end of 7th week. All the above tests were performed by Diagnostix Medical Centre (DMC), a NATA (National Accreditation Testing Authority of Australia) – accredited medical laboratory.

Quality of Life

The change in QOL of the patients was measured using an instrument, ChQol (Quality of Life questionnaire in Chinese version), designed by the research team at the Research and Development Division, School of Chinese Medicine, Hong Kong Baptist University to assess whether there was any improvement in the QOL of the subjects after treatment [2].

Statistics

Paired t-test was used to compare data before and after treatment with AND as well as administration of placebo.

Results

Clinical Symptoms Score

Fig 1 shows the results of the CSS of Group A patients before and after administration of AND or placebo. Disappearance of symptoms as reflected by the decrease in the total values of CSS was observed in nearly all patients after treatment with AND at the end of 2nd week. The decreases in CSS results narrowed at end of 5th and 7th weeks only and did not return to or beyond its baseline level. No change or less obvious

improvement was observed in the same group of patients after administration of placebo at the end of 7th week. Fig 2 shows the CSS results of Group B patients. Similarly, patients showed no change or less obvious improvement after administration of placebo at the end of 2nd week, but disappearance of symptoms occurred after treatment with AND at the end of 7th week.

Laboratory Analysis

No abnormal results were documented for renal function, liver function and haematological tests during the entire course of study.

Quality of Life

Significant changes in the scores of different facets and domains of patients of Group A, Group B and the combined cohort were documented. For Group A (n = 20), significant improvements in complexion and sleep ($P < 0.05$ for both) were observed after treatment with AND, but no such changes were observed after placebo when the scores were compared with those after the washout period. Furthermore, significant deteriorations of consciousness and spirit of the eye ($P < 0.05$ for both) leading to a significant decrease in the score of the domain of spirit ($P < 0.05$) were observed for Group A patients after administering placebo, but no such changes were observed after AND.

For Group B (n = 15), no significant change in any facet or domain was observed when the patients administered placebo for the first two weeks. However, significant improvements in appetite and digestion ($P = 0.01$) as well as joy ($P < 0.05$) were observed at the end of treatment with AND after the washout period. Table 2 shows the above-mentioned changes of Group A and Table 3 of Group B.

Table 2 Changes in the scores (mean ± SD) of ChQoL of patients in Group A (n = 20) after administration of AND or placebo. Only those scores with significant changes are listed. Weeks administration of 3rd, 4th and 5th were the washout period. NS stands for non-significant.

ChQoL Facets (F) & Domains (D)	On AND		On Placebo		P-value
	Baseline	End of 2nd Week	End of 5th Week	End of 7th Week	
Complexion (F1)	35.6 ±19.6	45.6 ± 16.6	NS	NS	< 0.05
Sleep (F2)	47.5 ± 16.7	58.3 ± 19.9	NS	NS	< 0.05
Consciousness (F6)	NS	NS	62.9 ± 14.9	55.8 ± 17.3	< 0.05
Spirit of Eye (F8)	NS	NS	55.6 ± 20.5	47.5 ± 19.3	< 0.05
Spirit (D2)	NS	NS	58.6 ± 15.8	53.7 ± 14.7	< 0.05

Table 3 Changes in the scores (mean ± SD) of ChQoL of patients in Group B (n = 15) after administration of AND or placebo. Only those scores with significant changes are listed. Weeks 3rd, 4th and 5th were the washout period. NS stands for non-significant.

ChQoL Facets (F) & Domains (D)	On Placebo		On AND		P-value
	Baseline	End of 2nd Week	End of 5th Week	End of 7th Week	
Appetite & Digestion (F4)	NS	NS	60.4 ± 12.0	67.1 ± 16.1	0.01
Joy (F10)	NS	NS	51.7 ± 20.8	57.1 ± 23.4	< 0.05

When the two groups were combined to form a whole cohort of 35 patients, significant improvements in complexion ($P < 0.05$) and sleep ($P < 0.01$) were observed at the end of the AND treatment period (Group A from 0 to 2nd week and Group B from 6th to 7th week). No such changes were observed for the whole cohort after the placebo period (Group A from 6th to 7th week and Group B from 0 to 2nd week). Table 4 shows the results.

Table 4 Changes in the scores (mean ± SD) of ChQoL of 35 patients in both Group A and Group B as a whole cohort after treatment with AND. Only these scores with significant changes are listed. Weeks 3rd, 4th and 5th were the washout period.

ChQoL Facets (F) and Domains (D)	Pre-treatment with AND	Post-treatment with AND	P-value
Complexion (F1)	42.1 ± 19.2	47.9 ± 17.4	< 0.05
Sleep (F2)	49.5 ± 15.3	56.9 ± 17.3	< 0.01
Physical Form (D1)	52.3 ± 10.5	56.6 ± 13.2	< 0.05

Discussion

As indicated by both Fig 1 and Fig 2, the patients' clinical condition improved after treatment with AND for two weeks. The relief of symptoms was less obvious after placebo for patients in both groups. On the other hand, no adverse effect was observed clinically as well as indicated by renal function, liver function and haematological tests.

It has been recognized that AR symptoms can have detrimental effects on the physical, psychological, and social aspects of patients' lives, and that a variety of pharmacological therapies with western medicine can significantly improve the health-related quality of life (HRQOL) of patients with AR[4,5]. In the present study, a Chinese herbal formula was used for treatment of AR and the ChQoL instrument (modification of the HRQOL for use with the practice of Chinese medicine) was employed to assess the integrity of health well being in terms of the patients' physical form, emotion, and interaction with nature and the society. As indicated in Tables 1 and 2, several facets in the domains of physical form and spirit in both Group A and Group B patients showed significant improvements after treatment with AND. However, no such changes were observed when the patients administered placebo. In fact, consciousness and spirit of eye in Group A patients deteriorated significantly after placebo (Table 2), giving rise to a significant decrease in the spirit domain. Furthermore, when the QOL of patients in both groups were viewed as a whole, significant improvements in complexion and sleep were observed after treatment with AND, leading to a significant increase in the physical form domain (Table 4). The diversity of different facets and domains showing improvements in patients of different groups may be associated with the difference in severity of symptoms in different patients.

Conclusion

It is believed that AND has therapeutic effect on PAR based on this study. It can relieve clinical symptoms in patients with PAR and improve their QOL.

Acknowledge

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Reference

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