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A Double-blind Study with a New Monodrug Kan Jang: Decrease of Symptoms and Improvement in the Recovery from Common Colds

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In a placebo-controlled double-blind study, the therapeutic effect of Kan Jang tablets made from *Andrographis paniculata* (Barm. F.) (Ness) dried extract was tested in patients with common colds. The patients were divided in two groups, in which group 1 ($n=33$) received 1200 mg of *Andrographis paniculata* and group 2 ($n=28$) a placebo (P).

On day 3–4 after treatment the possible effect of Kan Jang tablets on selected symptoms and clinical signs of common cold was evaluated. A significant reduction in clinical symptoms at day 4 of administration of the Kan Jang tablets was observed. A better efficacy against the placebo is discussed.

The differences in the total 'sumscores' of clinical and symptomatic findings indicate that the Kan Jang treated group did far better than the placebo group. We conclude that Kan Jang in a dose of 1200 mg daily has the capacity to significantly shorten the course/duration of the disease and therefore is indicated for an enhanced resistance to common colds.

Keywords: Andrographis paniculata; common cold; efficacy; double blind.

INTRODUCTION

Virostatic and antimicrobial products derived from medicinal plants are in prospect of becoming important therapeutic tools in the treatment of uncomplicated infections, such as upper respiratory tract infections, e.g. common colds.

Kan Jang, is a natural product manufactured by the Swedish Herbal Institute (SHI) with more than 10 years use in Scandinavia. Its indications are upper respiratory tract infections and common colds (Chang and But, 1987; Thamlikitkul *et al.*, 1991).

The ingredient of Kan Jang is a standardized dried extract of *Andrographis paniculata* (Barm.f.) (Nees.), (AP) a shrub vastly distributed in India and other Asiatic countries (Pharmacopoeia of India, 1955). The active ingredients are believed to be lactones especially andrographolide, dehydroandrographolide, neoandrographolide and deoxyandrographolide (Thamlikitkul *et al.*, 1991). Pharmacological and clinical studies conducted elsewhere (Chang and But, 1987) indicate that AP is of help in epidemics. Indeed, during the influenza epidemic of 1919 in India, a tincture of AP was effective in arresting the epidemic's spread. Further studies indicate that a decoction of AP was able to inhibit the growth of *S. aurea*, *Pseudomonas aeroginosa*, *Proteus vulgaris*, *Shigella dysenteriae* and *Escherichia coli*. Therefore AP is indicated for different diseases ranging from bacterial dysentery, stomach and intestine disorders, tonsilitis, pneumonia, pyelonephritis to abscesses (Chang and But, 1987). The AP extract used in Kan Jang was tested in acute, subacute, reproductive, toxicological studies without encountering toxic effects (Sittisomwong, 1989; Burgos and Hancke, unpublished data).

The rationale to undertake this study was to test whether Kan-Jang was able to reduce or eliminate the symptoms of common colds and the duration of the disease that supports its long empirical use in Scandinavia.

MATERIALS AND METHODS

The study was conducted in a General Medicine practice. The purpose was to increase the resistance to upper respiratory tract infection, e.g. common colds.

Patients. The study involved a total of 59 persons (female and male patients) aged between 18–60 years. Demographic data are shown in Table 1. The age and sex distribution in both groups was similar.

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Table 1. Patient data, diagnoses and results in the two groups of patients, on Kang Jang treated and one placebo treated

	Kan-Jang	Placebo
Number of patients	33	28
Men	17	15
Women	16	13
Age		
mean ± SEM	32.4 ± 1.020	31,9 ± 0.770 n.s.
(*t*-test)	(*n* = 29)	(*n* = 33)
Weight		
mean ± SEM	68.7 ± 1.242	70.7 ± 1.184 n.s.
(*t*-test)	(*n* = 33)	(*n* = 33)

Design. The study was conducted as a double-blind study, placebo-controlled. Group 1 received placebo tablets 1200 mg/day. Group 2 received Kan Jang (*Andrographis paniculata* extract) tablets, 1200 mg/day.

Patient inclusion criteria. Common colds: clinical observations included evaluations of the following signs: rhinitis, phrayngitis, fever, abnormal pulmonary findings and cervical lymphadenopathy. The symptoms evaluated included nasal discharge, nasal stuffiness, sore throat, earache, cough, feverishness, headache, malaise.

Patient exclusion criteria. Patients were excluded as follows.
(a) Patients who were ill more than 3 days with a common cold.
(b) Patients not showing a good compliance.
(c) Suffering from other infections, for example urogenital.
(d) Treated with antihistamine, antibiotic drugs.
(e) Suffering from immunologically relevant diseases such as multiple sclerosis, polyarthritis or rheumatism, or other autoimmune diseases.
(f) Accompanying diseases such as bronchiolitis, pneumonia, pleuritis, septic infections, special bacterial infections as pneumoconiosis, angina tonsilaris, sublingual fever higher than 40.5 °C, sinusitis or other serious diseases.
(g) Smokers.

Test medication. The tablets were manufactured according to Good Laboratory Practices. The Kan Jang tablets (100 mg/each) were standardized to a minimum of 4 mg of andrographolides, the active principle of the plant. The placebo tablets contained glucose. All tablets were covered so that the placebo and Kan Jang could not be distinguished from each other. Neither the patients nor the evaluators were informed about the treatments.

Assessment. Two control measurements were taken: at the beginning of the treatment (C0) and 3–4 days after treatment (C4). The following parameters were monitored and recorded: Symptoms evaluated by Visual Analog Scale (VAS) (total sum score). Clinical objective findings: rhinitis, sinus pains and headaches, inflammation of lymph nodes. Symptoms evaluated and recorded by the patient (patient records): tiredness; strength of disease; sweating/shivering; sore throat; muscular pains; headaches.

Evaluation of results. The regression and disappearance of the symptoms and signs at day 5 of the treatment and the recovery or improvement of the patient's condition, were considered as a positive effect of the drug. These symptoms and signs were individually scored on a scale (0 = not present; 1 = mild; 2 = moderate; 3 = severe) and were applied by Dr Mario Ibarra who evaluated

Table 2. Clinical symptoms and signs of patients treated with tablets of Kan-Jang and placebo

Parameter	Group	Day 0	Day 4	(*p* value)
Strength of disease	Placebo	1.96 ± 0.13	1.71 ± 0.10	0.14
	Kan Jang	1.91 ± 0.11	0.94 ± 0.12	0.0001
(*p*-value)		0.60	0.001	
Tiredness	Placebo	2.17 ± 0.10	1.67 ± 0.11	0.15
	Kan Jang	2.15 ± 0.11	1.15 ± 0.11	0.0001
P*p*-value)		0.73	0.001	
Shivering	Placebo	2.14 ± 0.11	1.46 ± 0.11	0.001
	Kang Jang	2.06 ± 0.11	0.73 ± 0.11	0.001
(*p*-value)		0.78	0.010	
Sore throat	Placebo	1.70 ± 0.15	1.25 ± 0.12	0.005
	Kan Jang	1.72 ± 0.12	0.76 ± 0.13	0.0001
(*p*-value)		0.83	0.025	
Muscular ache	Placebo	2.04 ± 0.12	1.60 ± 0.13	0.001
	Kan Jang	2.06 ± 0.10	0.82 ± 0.13	0.0001
(*p*-value)		0.70	0.001	
Rhinitis	Placebo	1.76 ± 0.13	1.60 ± 0.18	0.57
	Kan Jang	1.78 ± 0.12	1.32 ± 0.15	0.03
		0.96	0.21	
Sinus pains and headaches	Placebo	1.86 ± 0.13	1.57 ± 0.14	0.21
	Kan Jang	1.78 ± 0.12	1.33 ± 0.12	0.014
(*p*-value)		0.86	0.22	
Lymphatic swellings	Placebo	1.03 ± 0.11	1.21 ± 0.14	0.54
	Kan Jang	1.09 ± 0.11	0.88 ± 0.13	0.22
(*p*-value)		0.72	0.12	

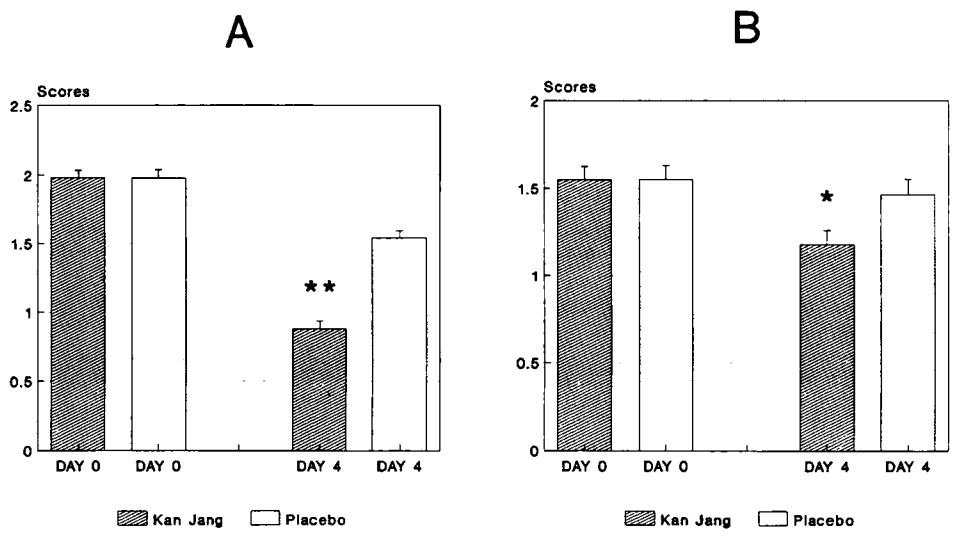

Figure 1. Sum scores of clinical symptoms (A) and signs (B) of patients treated for 4 days with 1200 mg of Kan Jang ($n=33$) and placebo ($n=28$). Mean ± SEM, * $p<0.05$, ** $p<0.01$.

patients at the same time daily. All patients were informed before the beginning of the study about the code of ethics (see Helsinki declaration). The test plan and test sheets were analysed by an ethical commission and approved.

Statistics. All data were evaluated by Wilcoxon and Mann-Whitney tests. A level of significance of 0.05 was utilized and the mean, SEM and p value obtained were recorded in tables. A total sum of scores for signs and symptoms was done (Steele and Torrie, 1985).

RESULTS AND DISCUSSION

All persons completed the study. No adverse effects were reported and laboratory tests (full blood count, SGOT, SGPT, sodium, potassium, calcium, creatinine, alkaline phosphatase, urinalysis) were within the normal limits for all persons at the end of the study (data not shown).

In Table 1 the demographic parameters of the patients participating in this study are shown. The age and sex distribution in both groups is similar.

The clinical symptoms at the beginning of the study in both groups of patients were not different at time 0 between placebo and Kan Jang (Table 2) making the two groups comparable. The symptoms such as the strength of the disease, tiredness, shivering, sore throat, muscular ache were reduced highly significantly at day 4 of treatment in the Kang Jang treated group as compared with the control group (Table 2). Also, there was a significant diminution between day 0 and day 4 of treatment in both groups. In this sense, the group treated with Kan Jang showed a lowering in the intensity of the symptoms compared with the placebo.

The clinical signs shown in Table 2 (rhinitis, sinus pains and headaches, lymphatic swellings) in both groups of patients were not different at time 0 between placebo and and Kan Jang making the two groups comparable. At day 4 after treatment no significant difference between the two groups was observed. However, if the groups are compared throughout time (time 0 vs. time 4), it becomes evident that the Kan Jang treated group showed a diminution of the intensity of the signs of rhinitis and sinus pains and headache ($p<0.05$).

The clinical signs and symptoms recorded individually were accumulated (Fig. 1a and 1b). The objective was to observe the overall effect of the treatments (placebo and Kan Jang) on the total sum of the symptoms or signs, as there is a close correlation between the latter and the disease (Hoeprich, 1982). As seen in Fig. 1a, in both groups there is a diminution of the intensity of the symptoms, which is more intense in the Kan Jang group. In Fig. 1b, at day 4 there is a significant decrease in the intensity of the clinical signs of the disease ($p<0.05$). In the placebo group there was no evident temporal recuperation of the clinical signs.

As cited in the literature, the active ingredient of Kan Jang, *Andrographis paniculata* possesses a variety of antibacterial and antiviral effects *in vitro* and *in vivo* (Chang and But, 1987) making the extract of AP of therapeutic value in different degrees of respiratory tract infections, such as upper repiratory tract infections, acute tonsilitis, influenza, bronchitis and pneumonia (Chang and But, 1987).

In a study of 152 patients with pharyngotonsillitis *Andrographis paniculata* was compared with paracetamol in improving symptomatology. The baseline evaluation showed no significant difference between the two groups. Evaluation of the results between the two groups showed that the treatment with 6 g *Andrographis paniculata* at day 3 were equally effective to treatment with paracetamol in all symptoms. For both groups the difference between base line symptoms and final evaluation were highly significant (Thamlikitkul *et al.*, 1991).

Most of the preclinical and clinical studies have been done using different galenic preparations in the far east. Kan Jang is a product containing AP standardized to a content of 4% andrographolides, the active principle that exhibit an effect on the upper respiratory tract infections (Chang and But, 1987). In this study it was demonstrated that a statistical association between the administration of Kan Jang and the recuperation of the common cold existed. It is concluded that the treatment

with Kan Jang accelerates the recuperation of the symptoms of the patients affected with common colds favouring the spontaneous recovery of the disease. As to the signs, Kan Jang attenuates the signs of common cold at day 4 after treatment which is not observed with the placebo.

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