

Report 10

Evaluation of clinical curative effects of Traditional Chinese medicine in treatment of patients convalescing from SARS

Jiang Zaiyang³⁵, Tang Xudong³⁵, Qi Wensheng³⁵, Bian Yongjun³⁵, Song Qingqiao³⁵, Li Gongsu³⁵, Zhang Zhongzhong³⁵, Fu Yalong³⁵, Wang Yinghui³⁵, Xiang Xiaopei³⁶, Wang Rongbing³⁶, Chen Yifan³⁶, Liu Baoyan³⁷ and Xie Yanming³⁷

Abstract The objective was to evaluate the efficacy and safety of integrated treatment with Traditional Chinese medicine (TCM) and Western medicine in patients convalescing from SARS. Eighty-five SARS patients were selected for clinical research, 62 received the integrated treatment with TCM and Western medicine, and 23 were in the control group. Patients received an orally administered TCM regimen daily and were observed for 2-3 weeks. Observations recorded included clinical symptoms, serology, lung X-rays and self-rated quality-of-life scores. SPSS 10.0 software was used for the statistical analysis. The database was established and after data had been entered they were made read-only for the analysis. The total score of symptoms decreased more obviously in patients in the integrated treatment group than that in those in the control group ($p = 0.04$). There was a significant difference in both treatment groups before and after treatment, but compared with the control group, the number of patients with hepatic dysfunction in the integrated treatment group decreased more after treatment ($p = 0.002$). There were significant differences between the two groups in the level of improvement seen on the lung X-rays after treatment ($p = 0.04$); in the total score on the quality-of-life questionnaire ($p = 0.04$) and in the score of mental sentiment factors ($p = 0.02$). The results of integrated treatment were superior to those obtained in the control group. TCM was superior to treatment with Western medicine alone in improving the total score of symptoms, lung X-rays, hepatic function, total score for the quality of life and mental sentiment factors in SARS patients at the convalescent stage.

Introduction

SARS is a new and serious infectious disease. It was observed that the absorption of lung inflammation in some patients was rather slow and there were signs of pulmonary interstitial fibrosis to different degrees after recovery from SARS. Most of the patients suffered from various types of discomfort, yet modern medicine offers no effective treatment for SARS at this stage. The study reported here focused on evaluating the clinical curative effects of therapy with integrated

³⁵ Guang'Anmen Hospital Affiliated to China Academy of traditional Chinese medicine

³⁶ Beijing Ditan Hospital

³⁷ China Academy of traditional Chinese medicine

TCM and Western medicine in treating SARS patients at the convalescent stage. The research method adopted was that of differentiating diseases in combination with differentiating symptoms and signs, so as to evaluate the efficacy and safety of TCM in treating patients convalescing from SARS.

Design of Study

A prospective, concurrent control, study design was adopted.

Subjects

Source of cases

All the cases were from Beijing Ditan Hospital, and 85 patients hospitalized during the period from 22 May to early June 2003 were selected; 62 cases were included in the integrated treatment group and the remaining 23 in the control group.

General information

Seven male and 16 female patients were included in the control group and 19 male and 43 female patients were included in the integrated treatment group. The average age of the patients in the control group was 39.43 ± 15.32 years old and that of the patients in the integrated treatment group was 36.26 ± 11.40 ($p = 0.30$). The average duration of disease of the patients in the control group was 33.00 ± 8.93 days whereas that of the patients in the integrated treatment group was 34.02 ± 8.23 days ($p = 0.62$). Sixteen of the patients in the control group were treated with glucocorticoid as were 49 patients in the integrated treatment group. There was no significant difference between the two groups ($p = 0.40$).

Symptoms

No statistically significant difference was apparent between the integrated treatment group and the control group in the distribution of any of the symptoms before treatment. These findings showed that the two groups were comparable with regard to sex, age, course of illness and distribution of symptoms.

Case selection criteria

Inclusion criteria

Patients who met the following requirements simultaneously were eligible for inclusion in the study.

- ◆ Patients who met the *Clinical diagnosis criteria for infectious SARS* (proposed) issued by the Ministry of Health of the People's Republic of China on 3 May 2003 (1).
- ◆ Patients who met the diagnostic criteria of the SARS convalescent stage:
The following three conditions had to be met at the same time:
 - ◆ obvious improvement shown on chest radiograph;
 - ◆ obvious improvement in symptoms in the respiratory system; and
 - ◆ body temperature had returned to normal for at least 7 days, or there had been low fever (temperature ≤ 37.5 °C) for more than 2 weeks.

- ◆ Patients who were allowed to leave hospital after 1 week.
- ◆ Patients aged between 18 and 70 years old.

Exclusion criteria

Patients with any one of the following were not eligible for inclusion in the study:

- ◆ those patients who, before being infected by SARS, had underlying severe cardiovascular diseases, liver and kidney diseases, blood diseases, internal secretion diseases, lung diseases, neuropsychosis or other severe diseases such as tumours or acquired immunodeficiency syndrome;
- ◆ women who were gestating or lactating; and
- ◆ patients with a history of allergies.

Criteria for terminating the treatment

The criteria for terminating the treatment were as follows:

- ◆ Disappearance of symptoms;
- ◆ No obvious damage to lung or other viscera; the immunological functions had returned to normal; and
- ◆ SARS antibodies had been produced.

Criteria for the termination of treatment had to include at least the first two items.

Case distribution

Twenty-three patients formed the control group and 62 patients formed the integrated treatment group.

Treatment Method

Therapeutic regimen

Standard treatment

The principles of the standard treatment were as follows.

- ◆ The patients were advised to restrict their movement and to avoid fatigue or physical exertion.
- ◆ Mental irritation was avoided and patients who had cough with phlegm were given antitussives and apophlegmatics.
- ◆ Appropriate treatment was given to patients with functional damage to organs including the heart, liver and kidneys.
- ◆ Nutritional support was given.

Therapeutic regimen for traditional Chinese medicine

The TCM therapeutic regimen was developed by referring to the *TCM prevention and treatment regimen of SARS in Beijing Area* developed and recommended by specialists and organized by the Beijing Municipal Administration of Traditional Chinese Medicine (2); the *Routine therapeutics of integrated traditional and Western medicine for treatment of SARS* developed by the Guang'anmen Hospital which is affiliated to the China Academy of TCM; and by drawing on recent practical experience in the prevention and treatment of SARS as well as using the recent experience of fever experts together with information dating back to the Qing

Dynasty regarding recuperation from febrile diseases. The therapeutic regimens are specific to three types of illness:

- ◆ deficiency of both *qi* and *yin*;
- ◆ deficiency of *qi* in the lung and spleen; and
- ◆ lingering of pathogenic factor leading to deficiency of *yin*.

Based on this classification, three agreed prescriptions, adjusted to individual needs, were developed. The herbal decoction was taken orally, one dose per day. Details of the regimens are provided below.

Prescriptions

Prescription 1 for supplementing *qi* and nourishing *yin*, used against the deficiency of both *qi* and *yin*:

Radix Panacis Quinquefolii (6 g), Radix Ophiopogonis (12 g), Fructus Shisandrae (6 g), Radix Astragali (18 g), Rhizoma Polygonati Officinalis (12 g), pollen (12 g), Atractylodes macrocephala (15 g), Poria cocos (12 g), mulberry leaf (12 g), Radix Angelica Sinensis (9 g), Radix Paeoniae Lactiflorae (12 g), Rhizoma Ligustici Wallichii (12 g), lotus leaf (10 g) and *liu yi san* (10 g).

Prescription 2 for tonifying the lung and strengthening the spleen, used against the deficiency of *qi* in the lung and spleen:

Radix Astragali seu Hedysari (raw, 30 g), Radix Codonopsis Pilosula (15 g), Rhizoma Atractylodes Macrocephala (15 g), Yunnan tuckahoe (15 g), Radix Bupleuri (9 g), Radix Paeoniae Alba (12 g), Radix Angelicae Sinensis (9 g), Rhizoma Agustici Chuanxiong (12 g), Radix Aucklandiae (12 g), Fructus Amomi (add later when preparing the decoction, 6 g), tangerine peel (12 g), Rhizoma Pinelliae (9 g), Herb Agastachis (10 g) and charred triplet (10 g each).

(Charred triplet is a mixture of equal parts of the following: charred medicated leaven, charred hawthorn fruit and charred germinated barley for improving digestion.)

Prescription 3 For replenishing the vital essence and removing heat, used against deficiency of *yin* caused by the lingering of pathogenic factor:

American ginseng (3 g), Radix Adenophorae Strictae (15 g), Radix Ophiopognis (12 g), Radix Bupleuri (9 g), Radix Scutellariae (12 g), mulberry leaf (15 g), Cortex Lycii Radicis (12 g), Herba Artemisiae (15 g), Rhizoma Phragmitis (15 g), Radix Angelicae Sinensis (9 g), Radix Paeoniae Alba (12 g), Rhizoma Pinelliae (9 g), roasted malt (15 g) and *liu yi san* (10 g).

Adjustment to individual symptoms

The following adjustments were made in response to specific symptoms.

- ◆ Plus Herba Artemisiae and chicken-bone herb for those with damaged liver functions or accompanied with increased level of cholerythrin;
- ◆ Plus tendrill-leaved fritillary bulb and steamed stenona root for those who had cough without phlegm;
- ◆ Plus fritillaria bulb and perilla fruit for those who had cough with profuse sputum;

- ◆ Plus Rhizoma Anemorrhhenae and yellow corktree bark for those who had dysphoria with feverish sensation in chest, palms and soles as well as those with yellow urine;
- ◆ Plus jade-screen powder and calcined dragon's bone and oyster shell for those who were prone to sweating;
- ◆ Plus pulp of dogwood fruit and prepared rehmannia root for those who suffered from deficiency of *yin*, which in turn affected the kidney, and those with reddened tongue and little fur, hot palms and soles, deficiency of *qi* and feebleness of the knees.
- ◆ Plus scutellaria root, Fructus Gardeniae and Herba Pogostemi for those who had damp-heat pathogen and greasy fur on tongue;
- ◆ Plus *Trichosanthes kirilowii* maxim and Semen Cannabis for those who suffered from constipation;
- ◆ Plus baked ginger and parched Semen Dolichoris for those who had loose stools;
- ◆ Plus mother-of-pearl and jujube kernel for those who suffered from insomnia.

Course of treatment

The course of treatment, which began at the time the patient had reached the convalescent stage, had the following three components:

- ◆ administration of herbal decoction and hospitalization for observation for 1 week;
- ◆ administration of herbal decoction for 2 weeks after leaving hospital; and
- ◆ follow-up visits which were continued until the termination of at least the first two indicators listed above under "Criteria for terminating the treatment".

Observations

General information

The general information collected included: name, sex, age, profession, home addresses, postcode, contact phone number, date of disease onset, dates of hospitalization and discharge, main symptoms at time of inclusion in the treatment groups, past medical history, diagnosis by Western medicine and differentiation of TCM. These details were entered after the patients had been included in one of the treatment groups.

Symptoms and signs

Observations recorded included hypodynamia, shortness of breath, sweating, palpitations, poor appetite, insomnia, characteristics of urine and stools, appearance of tongue, and characteristics of pulse. A quantitative method was adopted for recording the severity of the symptoms: none, light, moderate and severe were scored as 0, 1, 2 and 3, respectively. This information was collected once every three days for hospitalized patients, once a week during follow-up and at the last return visit by patients who had left hospital.

Laboratory examinations

The results of routine blood tests, myocardial enzymograms, tests of liver and kidney function, chest radiography and antibody detection were first recorded at the time the patients were included in one of the treatment groups and again at the time the course of treatment ended.

Rating of the quality of life

Quality of life was assessed by means of a self-rating scale questionnaire. The scale was prepared by referring to the contents and formats of the St. George's questionnaire on respiratory diseases, a questionnaire on the quality of life for adult asthma patients (1) and the health investigation questionnaire, and by noting the comments of specialists in pneumology, experts on clinical epidemic diseases and statisticians, as well as the physical symptoms of the patients. The scale consists of 16 questions on three aspects of life: restriction of day-to-day activities (1-5), symptoms of dyspnoea (6-10) and mental health (11-16). There were five options ranging from poor to very good, which were scored on a scale of 1 to 5; the option representing the best quality of life was scored as 5, and that representing the worst was scored as 1. The rating was ascertained first when the patients were included in one of the treatment groups and again when the course of treatment ended.

Indices and criteria for evaluation of curative effects

The curative effects were evaluated on the basis of the criteria described below.

Change of symptoms: the change in the total score was noted.

Quality of life: this was assessed by evaluation of the self-rated quality-of-life scale completed for the SARS patients.

Chest radiograph: absorption of inflammation as seen on the chest radiograph was evaluated using a scoring system.

This scoring system was based on *Clinical studies on the treatment of SARS cases with therapeutics integrating traditional and Western medicine*, one of the key national projects – an 863 key project – developed under the tenth Five-Year Plan developed by the State Ministry of Science and Technology. The scoring principles are based on the density and size of the shadow on the chest radiograph. There are 12 evaluation spots distributed in the upper, middle and lower parts as well as the inner and outer zones of the left and right lungs, and three levels (high, low and cord strip) for the density of the pathological changes; attention is also paid to heart size and complications in the pleura and other factors. The scores were assigned by designated radiologists blinded as to the identity of the patients; the standard normal chest radiograph was scored as 0, and the score for the greatest possible lung damage was 38.

Damage to liver functions

Improvement of liver function was assessed in patients who had abnormal alanine aminotransferase (ALT) levels before treatment.

Quality control

Management and coordination

A task group leader responsibility system was established, head specialists were appointed and personnel for quality supervision, logistic support and follow-up visits were suitably equipped.

Training

Centralized and rapid training was provided for the research team following its formation, so that the researchers would fully understand the clinical research plan and its indicators and implications.

Key points for quality control

The personnel involved in this research were required to:

- ◆ strictly observe the criteria for the inclusion and exclusion of cases;
- ◆ truthfully and carefully record all items in the case report form according to the standard requirements so as to ensure an accurate and reliable record;
- ◆ check all observation results and findings to ensure that data were reliable and that all conclusions from the research came from original data;
- ◆ record all symptoms as per the quantitative standard with no omission of any important examination indicators with clinical significance, such as hepatic function and chest radiograph;
- ◆ try to adopt the TCM prescription designed for this study with appropriate adjustments to meet special situations; and
- ◆ record the correct contact information and address, conduct regular follow-up visits, ensure that patients made return visits to a fixed location and communicate and coordinate with patients early on to improve the adherence of patients and avoid any negligence or omission.

The quality of all the decoction pieces used complied with the standards in the *Chinese Pharmacopoeia*, (2000 Edition, Volume I), and all the Chinese patent drugs used had been approved by the State Drug Administration of China and were commercially available.

Ethics and informed consent

This research was conducted with the approval of the Ethics Commission of Guang'anmen Hospital, and the proposed treatment was discussed with the patients and their consent obtained.

Statistical analysis

Data were analysed by use of SPSS 10.0 software. After the database was set up, the data were entered and verified and then made read-only for analysis. All the quantitative indicators were expressed as mean \pm standard deviation, and tested using a *t*-test and a chi-squared test. A *p*-value <0.05 indicated that the results were statistically significant (two-tailed test).

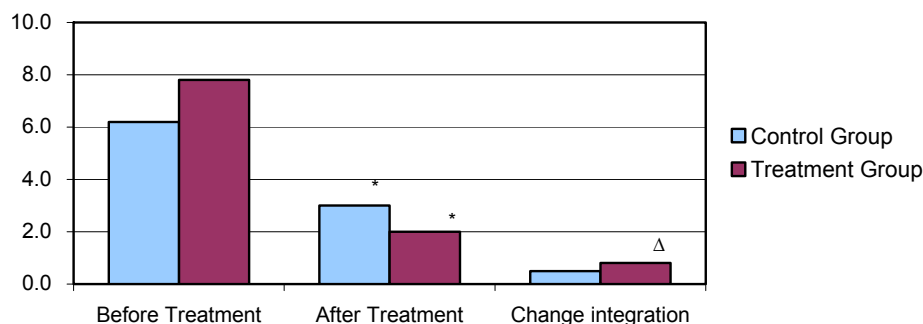
Results

Comparison of symptom scores before and after treatment

The total symptom scores in the two treatment groups before and after treatment were not significantly different, but the scores for each of the symptoms after treatment were significantly different ($p < 0.01$) from those before the treatment in both groups. In terms of improvement in symptom scores, the integrated

treatment group was superior to the control group, and the difference was significant ($p < 0.05$) (Fig. 1).

Fig. 1. Comparison of symptom scores before and after treatment

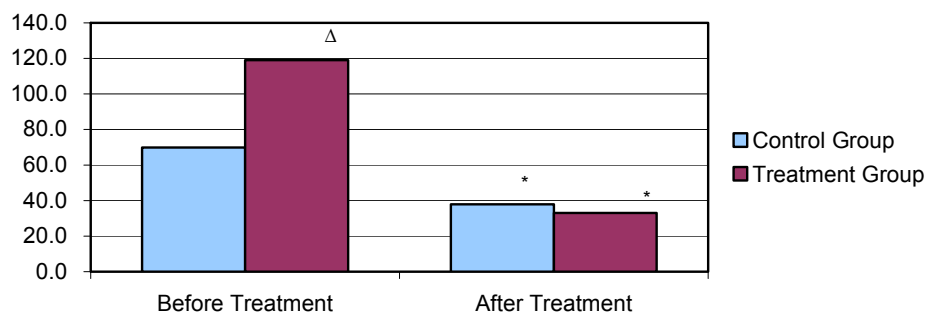


* $p < 0.01$, compared with score before treatment; $\Delta p < 0.05$, compared with score in control group.

Comparison of alanine aminotransferase before and after treatment

For patients who had abnormal levels of ALT at the time they were assigned to a treatment group, the mean ALT of the patients in the integrated treatment group before treatment was higher than that of patients in the control group ($p < 0.01$). After treatment the ALT levels of both groups had returned to normal, and the difference was not significant ($p > 0.05$). The ALT level of patients in both groups was significantly different before and after the treatment ($p < 0.01$) (Fig. 2).

Fig. 2. Comparison of levels of alanine aminotransferase before and after treatment

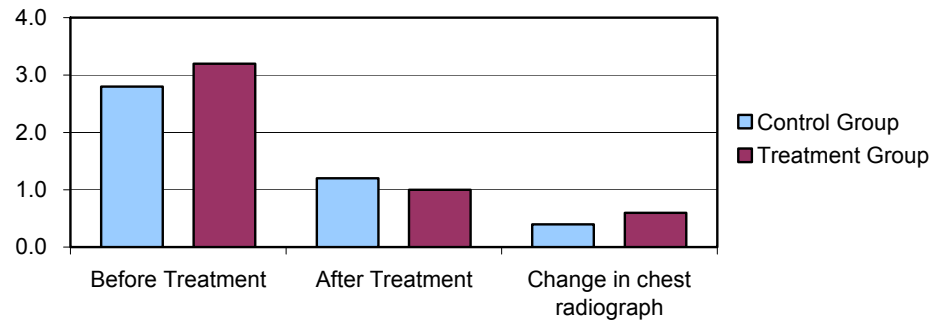


* $p < 0.01$, compared with levels before treatment; $\Delta p < 0.01$, compared with levels in control group

Comparison of chest radiographs before and after treatment

The scores for the chest radiographs before and after treatment were not significantly different between the two groups, but the scores after treatment were significantly different ($p < 0.01$) from those before treatment. In terms of improvement after treatment, the scores of the treatment group were better than those in the control group and the difference was statistically significant ($p < 0.05$) (Fig. 3).

Figure 3. Comparison of change in chest radiograph before and after treatment



Assessment of the quality of life before and after treatment

Altogether 85 self-rated quality-of-life questionnaires were distributed before the treatment and 81 usable questionnaires were returned. Six out of the 85 questionnaires were excluded after treatment, therefore the number of usable questionnaires finally analysed was 79. The total scores and scores in the three aspects (restricted day-to-day activities, symptoms of dyspnoea and mental health) of the two groups before treatment were not significantly different ($p > 0.05$). The differences in total scores and the scores for mental health of both groups before and after treatment were significantly different ($p < 0.05$). The differences in total scores, and those for mental health and dyspnoea in the integrated treatment group before and after treatment were highly significant ($p < 0.01$), and the score for restricted activities in the integrated treatment group before and after treatment was also significantly different ($p < 0.05$). The total scores and the scores for each individual factor before and after treatment in the control group were significantly different ($p < 0.05$) (Table 1).

Table 1. Comparison of quality-of-life rating of patients in the two treatment groups before and after treatment

Sub-scale	Treatment group	Time of rating (n)	Score after treatment (mean \pm standard deviation)
Restricted activities	Treatment group	Before treatment (61)	7.54 \pm 0.34
		After treatment (59)	5.54 \pm 0.16*
	Control group	Before treatment (20)	8.00 \pm 0.70
		After treatment (20)	5.95 \pm 0.34*
Dyspnoea	Treatment group	Before treatment (61)	9.57 \pm 0.57
		After treatment (59)	6.44 \pm 0.23**
	Control group	Before treatment (20)	9.20 \pm 0.92
		After treatment (20)	6.80 \pm 0.57*
Mental affection	Treatment group	Before treatment (61)	12.43 \pm 0.61
		After treatment (59)	7.95 \pm 0.27** Δ
	Control group	Before treatment (20)	12.70 \pm 0.97
		After treatment (20)	9.35 \pm 0.56*
Total scores	Treatment group	Before treatment (61)	29.54 \pm 1.29
		After treatment (59)	19.93 \pm 0.48** Δ
	Control group	Before treatment (20)	29.90 \pm 2.25
		After treatment (20)	22.10 \pm 1.10*

* $p < 0.05$, ** $p < 0.01$, compared with score before treatment; $\Delta p < 0.05$, compared with score of control group.

Discussion and conclusions

Effects of Traditional Chinese medicine prescription series in improving the symptoms of patients at the convalescent stage

The symptoms of the 85 SARS patients at the convalescent stage could be ranked from most severe to least severe as follows: hypodynamia; palpitations; shortness of breath; sweating; low fever; yellowish urine; dysphoria with feverish sensation in chest, palms and soles; insomnia; anorexia; cough; dry mouth; constipation; diarrhoea; and bitter taste in mouth. In terms of symptom improvement, the scores before and after treatment were significantly different, and the TCM prescriptions were especially effective in improving the main symptoms, such as hypodynamia and palpitations, and other symptoms were also improved to a certain extent.

SARS is a disease caused by strong pathogens that have a severe impact on the body's resistance and patients have been treated with various medicines at different doses. In view of the fact that any drug may be toxic to certain extent,

continued use and high doses will result in impairment to the vital functions of the human body. In addition, although at the later stage of the disease the high fever has been allayed, the residual heat still remains and the body has not yet returned to normal; the pathogens may therefore continue to impair the vital-*qi* of the body, which results in deficiency of *qi*, deficiency of *yin* or deficiency of both *qi* and *yin*. The TCM prescriptions used to treat patients in this study were mainly aimed at supplementing *qi* and nourishing the *yin*, and are based on *shengmai yin* (ginseng + lilyturf root) and *sijunzitan* decoctions, which can be added to other drugs that can be used to reduce fever, remove dampness, promote blood circulation, remove toxic substances, improve appetite and digestion, and discharge mucus through the urethra. Such decoctions have certain effects in restoring the immunological functions of the patients, balancing *yin* and *yang*, enhancing the healthy-*qi* and coordinating the functions of the visceral organs.

In terms of the evolution of the symptoms in the course of treatment, based on Traditional Chinese knowledge, only two patients experienced conversion from weakened health *qi* and body resistance, to domination of the pathogen (damp-heat and stagnated blood). These two patients were treated with *ganluxiaodudan* and *shengjiangsan* mixed with *ganluxiaodudan*, and *xuefuzhuyutang* and *shengmai yin* mixed with *xuefuzhuyutang*, respectively, for 2 weeks, after which the domination of pathogen gradually receded. It is not yet known whether the symptoms of weakened body resistance that lead to dominance of the pathogen are due to increased viral load, and this needs to be studied further. Also, the conversion law between the deficiency of *qi*, the deficiency of *yin* and the deficiency of both *qi* and *yin* needs to be established by means of further statistical analysis.

Influence of Traditional Chinese medicine prescriptions on the liver functions of patients convalescing from SARS

The liver impairment in SARS patients at the convalescent stage may be related to the direct action of the SARS virus and endotoxaemia as well as the release and attack of inflammatory factors, and the administration of antiviral drugs, antibiotics and hormones may also damage liver cells.

The number of patients with abnormal liver functions (reflected in levels of ALT) in the integrated treatment group before treatment was greater than that in the control group before treatment. No obvious differences between the treatment group and the control group were seen after treatment but, in terms of the degree to which ALT was lowered, the integrated treatment was better than the treatment received by the control group. This indicates that the TCM prescriptions have superior effects in eliminating the negative impact on the liver of drugs such as cortical hormone, and restoring liver cell function following damage by the SARS virus.

The liver has powerful storing and compensating functions. It is not known whether the abnormal liver functions found in SARS patients resulted from the toxicity and side-effects of drugs used to treat the disease, or from transient damage to the liver caused by the virus. Alternatively, there may have been hidden chronic liver impairment factors which, in combination with some stress

factors, caused a “cell hormone storm”. Long-term clinical observations are required to answer this question.

Effects of Traditional Chinese medicine prescriptions in promoting the absorption of inflammation in the lungs of patients convalescing from SARS

SARS may produce violent cellular immunoreactions in the lungs of patients, resulting in immunological injury to target organs (mainly lung tissues) and may cause violent and severe injuries to the lung tissues. The major sequelae in SARS patients are pulmonary interstitial fibrosis and pulmonary hypofunction. Pulmonary interstitial fibrosis is obvious in SARS patients who have previously had lung diseases. In spite of the normal chest radiographs obtained from some SARS patients 1 month after the onset of the disease when their clinical symptoms had completely abated, patches and bar shadows could still be detected using CT examinations. These patients showed slow absorption of pulmonary inflammation or signs of pulmonary fibrosis, which lowered the lung compliance and reduced the lung volume, manifesting as restrictive and diffuse ventilating functional disorders and progressive dyspnoea, leading to a reduced quality of life (3, 4).

Most patients in the integrated treatment group had abnormal pulmonary changes and two patients were particularly seriously affected. After being treated with TCM prescriptions for 3 weeks, the abnormalities in the lungs of these two patients had completely disappeared. The results of the statistical analysis also indicate that the improvement shown on the chest radiographs of the patients in the integrated treatment group was significantly better than that of the patients in the control group. This finding provided evidence that TCM, through integral regulation and treatment based on the overall analysis of symptoms and signs, has definite effects in promoting the absorption of inflammation in the lungs of the patients.

It is not known whether the abnormal changes in the lungs of SARS patients at the convalescent stage indicate that the absorption of pulmonary inflammation is not complete or that pulmonary interstitial fibrosis has occurred. Further research is needed to answer this question. Further studies are also required to determine whether pulmonary interstitial fibrosis is pathologically different from acute pulmonary diseases such as idiopathic pulmonary interstitial fibrosis.

Effects of Traditional Chinese medicine prescription series in improving the quality of life of the patients (5)

During 3–4 weeks of treatment in an isolation ward, the SARS patients were in a mental state of melancholia due to isolation. In a context in which more and more attention is paid to the overall health of patients, we recognized that the aim of clinical medicine is not only to cure “the diseases suffered by patients”, but to place more emphasis on “the people suffering the diseases”, so as to help patients to achieve a state of overall health from the social, physiological and psychological points of view and enable them to return successfully to life in their societies (6). The present study shows that the improvement in quality of life of the integrated treatment group was better than that of the control group, as

reflected in the total quality-of-life scores and the scores of mental health factors. Although the difference in the scores of restricted activities and dyspnoea was not statistically significant, the patients in the integrated treatment group showed a greater tendency towards further improvement than those in the control group. The reason that there is no statistically significant difference may be the small size of the control group; to answer this question would require further studies.

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