

The Effects of a Comprehensive Rehabilitation Program Involving Traditional Chinese Medicine in Severe and Critical COVID-19 Patients: a Clinical Study

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Abstract

Background: A year ago, a new type of coronavirus emerged. Once treated for severe and critical COVID-19 infections, patients are discharged from the hospital for further treatment and rehabilitation. The aim of this study was to evaluate the efficacy and safety of a newly developed comprehensive rehabilitation program based on traditional Chinese medicine (TCM) in the rehabilitation of patients with severe and critical COVID-19.

Methods: We recruited a total of 72 patients who had suffered from severe and critical COVID-19 infections and were undergoing rehabilitation in Chongqing, China. A comprehensive rehabilitation program was formulated according to the TCM syndromes of these patients. Specific treatments included oral TCM, Baduanjin, Moxibustion, Acupoint application, and foot baths. Prior to the initiation of treatment, and four weeks after the initiation of treatment, we carried out a range of assessments, including the TCM Syndrome curative effect score, the modified Medical Research Council (mMRC) dyspnea score, the St. George's Respiratory Questionnaire, the Short Form (SF)-36 Quality of Life Scale, and the 6-minute walking test. We also carried out CT scans, serology tests. Statistical analysis was also conducted to evaluate the efficacy and safety of TCM on severe and critical COVID-19 patients.

Results: Analysis showed that there were significant differences ($P < 0.05$) when compared before and after four weeks of TCM treatment, in terms of the TCM syndrome curative effect score, mMRC dyspnea score, St. George's Respiratory Questionnaire score, SF-36 Quality of Life Scale score, and the 6-minute walking test. We also identified significant differences ($P < 0.05$) between these two timepoints, with regards to the neutrophil ratio, lymphoid cell ratio, lymphocytes, platelets, red blood cells, and hemoglobin. There were no significant differences when compared between the two timepoints with regards to white blood cells and neutrophils ($P > 0.05$). The efficacy of chest CT scans was 83.9%. Logistic regression showed that the CT scans of patients who did not take the TCM decoction did not improve significantly. The higher a patient's score on the 6-minute walking test, the higher the probability of no significant improvement on the CT scan.

Conclusions: A comprehensive rehabilitation program based on TCM improved a number of clinical parameters in patients suffering from severe and critical COVID-19 infections, including quality of life, clinical symptoms, exercise endurance, and respiratory function. TCM also enhanced lymphocytes, lymphocyte ratio, platelet, red blood cell (RBC) count, and hemoglobin content. TCM also appeared to contribute to the absorption of lung lesions.

Introduction

A year ago, a new type of viral infection emerged. Initial genomic sequencing data of this virus do not match with previously sequenced CoVs, thus indicating a novel CoV strain (2019-nCoV). Although COVID-19 is suspected to have originated from an animal host (zoonotic origin) followed by human-to-human transmission, the possibility of other routes should not be ruled out. There are no anti-viral drugs at

present that can be used to treat or prevent COVID-19. In severe cases, blood oxygen saturation will decrease and hypoxia will occur; critical cases require mechanical ventilation, and can suffer from shock or multiple organ dysfunction syndrome. Once treated for severe and critical COVID-19 infections, patients are discharged from the hospital for further treatment and monitoring. During this critical period, it is vital to provide patients with rehabilitation treatment and evaluate the efficacy of such treatment. Consequently, research focused on the development and application of and rehabilitation programs has become a critical factor in our efforts to reduce the impact of the current pandemic. Most patients diagnosed with severe or critical COVID-19 infection tend to be older and have existing earlier primary diseases and other characteristics. Typically, the lungs of patients show faded and patchy fibrosis on computed tomography (CT) scans ^[1]. A previous study acquired lung biopsies from four patients who died of COVID-19 and showed that hours after their deaths, there was evidence of extracellular matrix and fibrin formation and hyperplasia of the fiber cells ^[2]. Prior to death, these fibrotic changes in pulmonary function led to a significant reduction in lung function and a consequential reduction in the patient's ability to breathe and tolerate exercise; collectively, these factors lead to a severe reduction in the quality of life. The key aspect underlying the use of traditional TCM for severe and critical COVID-19 patients during their rehabilitation period is to improve lung function and their quality of life.

At present, there is very little information relating to the use of TCM in patients with severe and critical COVID-19 during their rehabilitation period. In the present study, we investigated the clinical efficacy of a comprehensive rehabilitation program, based on TCM, in patients with severe and critical COVID-19 infection during their rehabilitation period in Chongqing.

Methods

Diagnostic criteria

The diagnostic criteria used in this study were based on the diagnosis and treatment protocol for COVID-19 (Trial version 7) that was issued by the National Health Commission and the State Administration of Traditional Chinese Medicine ^[3]. Adult patients were classified as having a 'severe' infection if they experienced any of the following criteria: (1) onset of shortness of breath, respiratory rates (RR) ≥ 30 times/min; (2) an oxygen saturation $\leq 93\%$ at rest; (3) a partial pressure of blood oxygen (PaO₂)/oxygen absorption concentration (FiO₂) ≤ 300 mmHg; or (4) pulmonary imaging showing significant progression of lesions within 24 to 48 hours. In total, 50% of the patients recruited into this study were treated as severe. Adult patients were classified as having a 'critical' infection if they experienced any of the following criteria: (1) respiratory failure and the need for mechanical ventilation; (2) shock; or (3) the patient experienced other organ failure and needed to be monitored in the intensive care unit (ICU).

Inclusion criteria

In order to be included in this study, patients needed to (1) meet all of the COVID-19 diagnostic criteria; (2) be clinically classified as severe or critical, based on clinical symptoms and laboratory test indicators; (3)

show improvement following treatment involving a combination of TCM and western medicine treatment, and who had attained the indications for discharge indications; and (4) provide their signatures on informed consent forms and were able to cooperate with rehabilitation treatment in an active and diligent manner.

Exclusion criteria

Patients were excluded from the present study for the following reasons: (1) severe liver and kidney function impairment (serum alanine aminotransferase was 3-fold higher than the normal upper limit and/or a serum creatinine level $\geq 265 \mu\text{mol/L}$); (2) severe cerebrovascular diseases, disorders of the blood system, nervous system diseases, and malignant tumors; (3) combined acute myocardial infarction and cardiogenic shock; (4) pregnant or lactating women; (5) mental disorders or unwillingness to cooperate; and (6) patients involved in other research studies.

Demographic information

Patients were recruited after discharge from the hospital. All 72 patients (41 males and 31 females) who suffered from severe or critical COVID-19 during the experimental period were treated in four centralized centers in Chongqing, China, including 28 patients from the municipal public health center, 10 patients from the Yongchuan district treatment center, 32 patients from the Wanzhou District treatment center, and 2 patients from the Qianjiang District treatment center. Patient age ranged from 25 to 89 years, with a mean of 56 years, and a median age of 69 (56–79).

Treatment protocol

All of the patients included in this study were given comprehensive rehabilitation treatment based on TCM for four weeks after discharge from hospital care. TCM was taken orally once in the morning and evening and Baduanjin (a type exercise of traditional Chinese medicine) was applied once a day for 15 minutes each time. The points of application included the bilateral Dingchuan, bilateral Shenshu, Shenque, and Danzhong; these were treated once a week for four to six hours. Moxibustion was selected for Qi Hai, Guan Yuan, bilateral Zusanli, and bilateral yuji, each for 10-15 minutes once every week. A Chinese herbal medicine foot bath was used once a day for approximately 20-30 minutes but not less than 5 times a week. We considered the clinical manifestations of patients with severe and critical COVID-19 following discharge into Yin and Yang syndrome types (Qi and Yin deficiency: phlegm and blood stasis syndrome; Yang Qi deficiency: phlegm and blood stasis syndrome). Patients experiencing the Yin syndrome type were administered with the following decoction: Radix Astragali 15g, Codonopsis pilosula 15 g, Lily 15 g, Ophiopogon japonicas 15 g, Pinellia ternata 10 g, thunberg fritillary bulb 10 g, Angelica 10 g, red peony root 10 g, Ligusticum wallichii 10 g, Alisma 10 g, Zedoary turmeric 6 g, and licorice root 6 g. Patients experiencing the Yang syndrome were administered with the following decoction: Codonopsis pilosula 15 g, Epimedium 15 g, Fructus psoraleae 15 g, cuscuta 15 g, cinnamon 10 g, baked ginger 10 g, Pinellia ternata 10 g, Thunberg fritillary bulb 10 g, Angelica 10 g, red peony root 10 g, Zedoary turmeric 6 g, and licorice root 6 g.

Patients needed to be differentiated into one of the two syndromes before they were discharged from their hospital. This differentiation was carried out by two attending doctors. The patients were then given the decoction that corresponded to their respective syndrome type.

We acquired instructional videos relating to Baduanjin, Acupoint sticking therapy, Moxibustion therapy, and application of the Chinese herbal medicine foot bath. At the time of their discharge, our researchers gave each patient a "rehabilitation bag" that included including the relevant TCM decoction and videos on a USB flash drive.

Since COVID-19 is a highly infectious disease, the researchers conducted rehabilitation guidance with social distancing and via remote digital methods. We recorded the WeChat numbers and telephone numbers of all convalescent patients were prior to their discharge from hospital. The researchers conducted regular follow-ups regularly (once a week) using WeChat or mobile phones and provided instruction with regards to rehabilitation exercise.

Efficacy and safety evaluation

Efficacy evaluation

Efficacy was evaluated by administering a range of questionnaires. Patients were asked to complete the Traditional Chinese Medicine Syndrome curative effect score scale, the mMRC dyspnea scale, the St. George's respiratory questionnaire, the SF - 36 quality of life scale, and the 6-minute walking test a specific website (<https://www.wjx.cn/jq/62881624.aspx>.) We also carried out a chest CT scan, and laboratory tests for routine blood routine parameters, C-reactive protein, and erythrocyte sedimentation rate. These tests and the questionnaires were carried out two months after discharge.

Safety evaluation

With regards to patient safety, we acquired the following information: general condition, liver function, renal function, adverse reactions, and adverse events (two months after discharge).

Statistical methods

Data were analyzed by IBM SPSS Statistical Software version 22.0 was used in this research. If measurement data were normally distributed with the K-S test, we carried out statistical comparisons using the student's t-test and analysis of variance (ANOVA). However, if data was not normally distributed, we used non-parametric analyses (the rank sum test) for comparisons. The Chi-squared test was used to compare counting data while logistic regression analysis was conducted to compare indicators, mean scale values, and the chest CT-scans.

Results

After four weeks, 62 patients had completed the TCM syndrome curative effect score scale, the mMRC dyspnea scale, the St. George's respiratory questionnaire scale, the SF-36 quality of life scale, the 6-minute walking test, and had undergone a chest CT scan. Of these 62 patients, there were 43 cases with deficiency of Qi and Yin-Phlegm and blood stasis, and 19 cases with deficiency of Yang Qi-Phlegm and blood stasis. In total, 56 patients completed serological examinations, including routine blood examinations, liver function tests, and kidney function tests. Fifty-seven of the included patients took the TCM decoction; five patients did not take the decoction due to their own personal reasons.

Changes on chest CT scans

Chest CT scans were performed before the rehabilitation program and for weeks after the program had commenced. We considered the pre- and post-rehabilitation CT scans with regards to the patient's lesions and graded these changes as follows: (1) obvious absorption: disappearance of the lesion by $\geq 70\%$; (2) improvement: a reduction in the area of the lesion by $\geq 30\%$; (3) no change; and (4) aggravation: the lesion area was increased by $\geq 30\%$. We then calculated the efficacy rate (%) using Eq. (1), Cases of obvious absorption are eight, proportion is 12.9%; Cases of improvement are forty-three, proportion is 69.35%; Cases of no change are eight, proportion is 12.9%; Cases of aggravation are three, proportion is 4.84%; Efficacy rate of CT scans is 82.26%. as shown in Table 1.

Equation (1): Efficacy rate = (basic absorption + improvement) / total number of patients \times 100%.

Table 1
Changes on chest computed tomography (CT) scans

Chest CT finding	Number of cases	Proportion (%)
Obvious absorption	8	12.9
Improvement	43	69.35
No change	8	12.9
Aggravation	3	4.84
Efficacy rate		82.26

Changes in clinical symptoms and quality of life

Data relating to the TCM syndrome curative effect score, the mMRC dyspnea scale score, the St. George's respiratory questionnaire score, and the SF - 36 quality of life scale score, were not normally distributed. Consequently, non-parametric tests were used for data analysis and quartiles were used to reflect the distribution of each characteristic between the two groups of data, and before and after four weeks of the rehabilitation program. Two groups of data were then analyzed before and 4 weeks after their inclusion. The TCM Syndrome Curative effect score of prior to the treatment is 6 (2.5–10) and 4 weeks after is 2 (1–6.5); mMRC Dyspnea Score of prior to the treatment is 2 (1–2) and 4 weeks after is 21 (1–2); St

George's Respiratory Questionnaire Score of prior to the treatment is 23 (12–32) and 4 weeks after is 11 (5–8); SF-36 Quality of Life Scale Score of prior to the treatment is 100 (87–110) and 4 weeks after is 114 (98–122.5). Difference was statistically significant ($P < 0.05$), as shown in Table 2.

Table 2
Changes in clinical symptoms and quality of life

Time	The TCM Syndrome Curative effect score	mMRC Dyspnea Score	St George's Respiratory Questionnaire Score	SF-36 Quality of Life Scale Score
Prior to the treatment	6 (2.5–10)	2 (1–2)	23 (12–32)	100 (87–110)
4 weeks after	2 (1–6.5)	1 (1–2)	11 (5–8)	114 (98–122.5)
Z	- 4.173	- 3.579	- 4.414	- 3.906
P	< 0.05	< 0.05	< 0.05	< 0.05

Changes in the 6-minute walking test

Chi-square analysis showed that there were significant differences ($P < 0.05$) between the two timepoints (before and four weeks after the commencement of the rehabilitation program), There are 21 normal, 19 mild, 9 moderate, 9 severe, 5 extremely severe at prior to treatment, and there are 33 normal, 21 mild, 3 moderate, 5 severe, 1 extremely severe at prior to treatment. Difference was statistically significant ($P < 0.05$), as shown in Table 3.

Table 3
Changes in the outcome of the 6-minute walk test

	Normal	Mild	Moderate	Severe	Extremely severe	P
Prior to treatment	21(33.9%)	19(30.6%)	9(14.5%)	9(14.5%)	5 (7.2%)	< 0.05
4 weeks after treatment	33(53.2%)	21(33.9%)	3 (4.8%)	5 (8.1%)	1 (1.4%)	

Changes in serological parameters

Several blood parameters (before and four weeks after commencement of the rehabilitation program) were not normally distributed, including leukocytes, neutrophils, neutrophil ratio, lymphocytes, lymphocyte ratio, and platelets. Consequently, we used non-parametric tests to compare this data before and after the rehabilitation program. Quartiles were used to reflect the distribution characteristics of the two groups of data. There were no significant differences between the two timepoints with regards to white blood cell

and neutrophil ($P > 0.05$). However, there were significant differences between the two timepoints with regards to neutrophil ratio, lymphocyte, lymphocyte ratio, and platelet ($P < 0.05$), as shown in Table 4. Data relating to red blood cells and hemoglobin were normally distributed; the Student's t-test identified significant differences when these data were compared between the two timepoints ($P < 0.05$), as shown in Table 5.

Table 4
Changes in white blood cell, neutrophil, neutrophil ratio, lymphocyte, lymphocyte ratio and platelet

Time	WBC ($10^9/L$)	Neutrophil ($10^9/L$)	neutrophil ratio (%)	Lymphocyte ($10^9/L$)	lymphocyte ratio (%)	Platelet ($10^9/L$)
Prior to treatment	5.45 (4.43–6.76)	3.39 (2.62–4.43)	64.45 (57.7–69.88)	1.24 (0.95–1.65)	23.2 (18.08–28.25)	220 (178.25–292.25)
Four weeks after treatment	5.46 (4.5–6.85)	3.36 (2.66–4.14)	59 (53.33–63.9)	1.7 (1.5–1.19)	31.55 (25.23–35.05)	201 (167.25–249.75)
Z	-3.352	-0.958	-3.385	-5.794	-4.989	-2.2
P	0.725	0.338	< 0.05	< 0.05	< 0.05	< 0.05

Table 5
Changes in red blood cell and hemoglobin

Time	RBC ($10^{12}/L$)	Hemoglobin (g/L)
Prior to treatment	3.8 ± 0.58	115.13 ± 18.16
Four weeks after treatment	4.6 ± 0.58	139.52 ± 18
P	< 0.05	< 0.05

Logistic regression analysis

Next, we carried out logistic regression analysis, using a range of independent variables: age, gender, TCM syndrome curative effect score, whether the patient took the TCM decoction, 6 minute-walk test, mMRC dyspnea score, St. George's respiratory questionnaire score, SF-36 quality of life scale score, white blood cells, neutrophils, neutrophil ratio, ratio of lymphoid cells, lymphocytes, red blood cells, hemoglobin, and platelets. Chest CT scan acted as the dependent variable in this analysis. The analysis aimed to identify factors that might be associated with an improvement in chest CT scan, "Whether taking TCM decoction" and "6-minute walk test" were statistically significant ($P < 0.05$), as shown in Table 6.

Table 6
Logistic regression analysis

variable	B	Standard Deviation	P	OR	95% confidence interval	
					Lower limit	Upper limit
Age	-0.051	0.041	0.212	0.950	0.877	1.030
Whether taking TCM decoction	-2.527	1.219	0.038	0.080	0.007	0.871
Gender	0.981	1.173	0.403	2.667	0.268	26.556
The TCM Syndrome curative effect score	0.144	0.147	0.327	1.154	0.866	1.539
6-minute walk test	1.314	0.611	0.032	3.721	1.124	12.325
MMRC dyspnea score	-1.084	0.813	0.182	0.338	0.069	1.665
St. George respiratory questionnaire score	0.029	0.077	0.708	1.029	0.886	1.196
SF-36 Quality of Life Scale score	0.013	0.045	0.776	1.013	0.927	1.107
White blood cells	-0.650	1.928	0.736	0.522	0.012	22.855
Neutrophils	-0.233	1.727	0.893	0.792	0.027	23.384
Neutrophils ratio	0.380	0.193	0.050	1.462	1.001	2.137
Lymphocytes	3.711	4.473	0.407	40.887	0.006	262268.239
Ratio of lymphoid cells	0.133	0.264	0.615	1.142	0.681	1.914
Red blood cells	1.131	1.906	0.553	3.099	0.074	130.001
Hemoglobin	-0.052	0.059	0.381	0.949	0.845	1.066
Platelet	-0.002	0.007	0.784	0.998	0.985	1.011
Note: OR, odds ratio						

Adverse reactions

None of the included patients with severe and critical COVID-19 infection who were treated by TCM-based rehabilitation intervention experienced any significant adverse reactions or damage to liver and/or kidney function during the four weeks of analysis.

Discussion

Pulmonary rehabilitation is a comprehensive form of intervention that is based on the comprehensive assessment of a patient followed by treatments that are in accordance with the individual patient's specific condition. The aim of these interventions is to improve the physical and psychological status of patients with respiratory diseases while promoting long-term adherence to health-promoting behavior^[4]. In combination with the modern concept of pulmonary rehabilitation, this strategy can help patients with severe and critical COVID-19 infection to return to their normal life from numerous aspects, such as exercise tolerance, appetite, sleep quality, etc.

The results of this study demonstrated that comprehensive TCM-based rehabilitation programs can improve the quality of life of patients suffering from severe or critical COVID-19 infection and improve their clinical symptoms, exercise endurance, and respiratory function. This strategy also helps to increase the total count of red blood cells, hemoglobin, lymphocytes, and lymphocytes, and can also reduce the total count of platelets and neutrophils. Research has shown that most COVID-19 patients exhibit reduced lymphocyte counts, hemoglobin counts, as well as thrombocytopenia^[5]. Lymphocyte and platelet counts have also been shown to reduce gradually in patients with mild, severe, and critical COVID-19 infection^[6]. After four weeks of comprehensive TCM-based rehabilitation, we found that our patients had significantly higher lymphocytes, lymphocyte ratio, and hemoglobin; although there was a significant reduction in platelet count. The factors and mechanisms underlying these observations need to be investigated in future research.

Logistic regression showed that patients who did not take the TCM decoction did not show a significant improvement in their CT scans. This indicates that the administration of TCM decoctions can significantly improve the efficacy rate of chest CT scans. The higher a patient's score on the 6-minute walking test, the higher the probability of them not showing an improvement on CT scans. According to the clinical data, the higher a patient scored on the 6-minute walking test, and the shorter the distance walked, the larger the lesions would be on chest CT scans, thus implying poor levels of absorption. Therefore, the 6-minute walking test could be used to predict chest CT scan results in this patient population. The worse the exercise endurance is, the more severe the lesions might appear on chest CT scans. Conversely, the better the exercise endurance is, the milder the lesions might be on chest CT scans. Therefore, it is evident that the improvement of clinical symptoms and serological parameters may differ from the improvements shown on CT scans of the chest.

The clinical manifestations of severe and critical COVID-19 patients are Qi deficiency of the lungs and spleen, deficiency of Yin and body fluid, and deficiency of Yang. During the course of clinical treatment, and due to the serious condition and long disease duration, some patients developed pathological products, such as phlegm turbidity and blood stasis; this creates accumulation in the lungs and can block the lungs and bronchi. We divided patients with severe and critical COVID-19 upon discharge from hospital into Yin and Yang syndromes. We then administered a comprehensive TCM-based rehabilitation program. Via body movement, the administration of Baduanjin can lead to improvements in breathing

and mental status, can alleviate symptoms, increase exercise endurance, and improve the quality of life [7]. Therefore, a comprehensive TCM-based rehabilitation program can alleviate the symptoms of fatigue, shortness of breath, poor appetite, and insomnia.

The study still has some limitations that need to be considered, including a small sample size and a short follow-up time. Because this disease is contagious, the rehabilitation program could not be strictly monitored by the researchers. Future studies should involve an appropriate control group. However, our current results do show that those who followed the comprehensive rehabilitation program of TCM did receive benefit. Thus, a comprehensive rehabilitation program involving TCM might be a useful way to help severe and critical patients with COVID-19.

Conclusion

Based on the results of this study, we were able to demonstrate that the modern concept of pulmonary rehabilitation and a comprehensive TCM-based rehabilitation program can improve the quality of life for patients with severe and critical COVID-19 infection. This program also helped to improve clinical symptoms, exercise endurance, respiratory function, while also helping to facilitate the absorption of lung lesions.

Abbreviations

TCM: traditional Chinese medicine; mMRC: modified Medical Research Council; SF: Short Form; RBC: red blood cell; CT: computed tomography; RR: respiratory rates; ICU: intensive care unit; ANOVA: analysis of variance.

Declarations

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

All participants gave signed informed consent to participate in the study, which was approved by the local Ethics Committees(No.2020-ky-ks-ZDP).

Authors' contributions

Guo-Qing Zuo designed the research, Yi Ren performed the research and wrote the manuscript; Yu-Jin Wang evaluated the endpoints and performed statistical analysis; Hua-Bao LIU, Fang-Zheng Mou, Xiao-Feng Yan and Li-Lin Tang collected the clinical data. All the authors read and approved the final manuscript.

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Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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