

# Application and Safety Evaluation of Integrated TCM-WM in the Treatment of COVID-19

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**Running Title: The Intergrated TCM-WM treatment for COVID-19**

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**Abstract:** Introduction: With the emergence of more infectious mutant strains and the appearance of new crown sequelae, early precise treatment is particularly important. The traditional Chinese medicine and Western medicine (TCM-WM) treatment plan exhibits unique superiority in the COVID-19 treatment, but the efficacy and safety have not been fully elucidated. Methods: A analysis of the clinical characteristics of 7 COVID-19 patients diagnosed in our hospital, as well as the results of precise individual intervention treatment with TCM-WM, including laboratory examination, and CT changes of imaging. Results: On admission, laboratory results showed that 7 patients' overall Lymphocyte count (LYM#), Percent Lymphocytes (LYM %), and Alanine aminotransferase (ALT) were reduced, but Neutrophil percentage (NEU%) were increased. CT imaging showed that most patients had multiple patchy shadows and ground-glass shadows in both lungs. After TCM-WM treatment, the above pathological states were significantly improved. All patients were followed up and had a good prognosis. Conclusions: Accurate therapy with TCM-WM can quickly and effectively alleviate and treat patients with COVID-19, without severe Long Covid.

**Keywords:** COVID-19; TCM-WM; CT; Long Covid; Omicron

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## Introduction

COVID-19 is a respiratory system disease and followed by a series of sequelae. Therefore, early and precise intervention treatment is particularly important.<sup>[1]</sup> Through continuous improvement of TCM-WM treatment plans and a series of medical measures, more patients have benefited.<sup>[2]</sup>

The main Clinical manifestations of the COVID-19 infection are fever and dry cough, along with pneumonia.<sup>[3]</sup> Based on the basic treatment plan combined with the clinical efficacy of Lianhua Qingwen Granules, Qingfei Paidu Decoction and other TCM prescriptions, the observation shows that TCM can significantly improve the clinical symptoms and laboratory indicators of patients, which establishes the value of TCM treatment in this field.<sup>[4]</sup>

In this article, we retrospectively analyzed the clinical characteristics and outcomes of 7 cases of COVID-19 patients who passed the integrated TCM-WM precision diagnosis and treatment plan. The purpose is to help clinical teams to clarify the individualized TCM-WM precision diagnosis and treatment plan. Early development of individualized treatment regimens can speed up treatment and reduce disease progression and aftereffects.

## 1. Materials and Methods

### 1.1 Ethics

Our institutional review committee waived written informed consent for this retrospective case series, which evaluated unidentified data and presented no potential risk to patients. There was no link between the patient and the researcher.

## 1.2 Inclusion and Exclusion Criteria

We reviewed the laboratory data and CT images of the 7 patients with COVID-19, from January 20, 2020, to May 27, 2020. Other pneumonias caused by common bacterial and viral pathogens were excluded.

## 1.3 Study Design

Individualized precision treatment plans are formulated according to the patient's admission diagnosis and treatment progress. Followed the Mild and Common prescription (Qingfei Paidu Decoction). On the basis of this general prescription, the patient was given antiviral treatment with drugs (Abidor hydrochloride, Ribavirin granules, Lianhua Qingwen capsule).

## 1.4 Data Collection

2mL of cubital venous blood from COVID-19 patients was collected. Routine blood test and liver and kidney function test were performed by sysmexXN-9000 automatic blood cell analyzer and KHB ZY-1280 automatic biochemical analyzer within 4h at room temperature.

All patients underwent thin-section CT scans. CT imaging examination recorded the changes of CT imaging during the whole process from early onset to TCM-WM treatment, and prognosis tracking. Three fellowship-trained cardiothoracic radiologists used a viewing console to independently review all CT images and finally reached a consensus.

## 1.5 Statistical Analysis

Statistical data comparisons were performed using GraphPad Prism 5 software. Data are expressed as mean  $\pm$  standard deviation (SD). Paired t-test was used for the changes of a single indicator before and after treatment. One-way analysis of variance and analysis of variance of repeated measurement data (One-way ANOVA) was used for comparison between groups and then Tukey test.  $P < 0.05$  indicates a statistically significant difference.

## 2. Results

### 2.1 Clinical Features

The subjects included 3 men and 4 women, aged between 25 and 55. The most common symptoms were fever and cough, mostly low-grade fever. No other symptoms included fatigue, abdominal pain, chest tightness, et al, as detailed in Table 1.

Table 1: Clinical Characteristics of COVID-19 patients (n=7)

Characteristic		Number of patients (%)
sex	Men	3 (43%)
	Women	4 (57%)
Age(years)	Mean	40.14
	Standard Deviation	11.23
	Rang	25-55
Symptoms	Fever	4 (57%)
	Cough	3 (43%)
	Expectoration	1 (14%)
	Fatigue	0
	Chest distress	0

### 2.2 Laboratory test results before and after the intervention

The 7 COVID-19 patients were all positive for nucleic acid tests. Laboratory examination results at admission showed

that 7 patients had overall declines in LYM#, LYM% and ALT, and increased NEU%. Among them, hs-CRP was significantly increased in 4 patients; Cr was significantly increased in 1 case (case 8, previous gout 6 years); Some patients had elevated UA, LDH and AST (Table 2).

Combined with the actual situation of the patients, and carry out precision individualized intervention treatment for 7 COVID-19 patients. Results indicated that LYM# and LYM% are increased, while NEU% and ALT are decreased. Follow-up results indicated a good overall prognosis (Table 3).

Table 2: Comparison of blood routine, liver and kidney function test results between early COVID-19 patients and healthy subjects

Index	COVID-19 patients (n=7, ≥15 years)							Healthy subjects (n=7, ≥15 years)
	1	2	3	4	5	6	7	Median (reference range)
WBC (10 <sup>9</sup> /L)	6.30	4.62	4.89	4.18	7.10	4.70	7.65	6.50 (3.5-9.5)
LYM (%)	14.0	32.9	31.1	21.8	30.4	31.4	27.5	35.91 (20-40)
NEU (%)	84.6	58.6	63.2	73.7	63.5	65.8	61	56.25 (50-75)
LYM# (10 <sup>9</sup> /L)	0.88	1.52	1.52	0.91	1.9	1.76	2.1	2.06 (0.8-4)
NEU# (10 <sup>9</sup> /L)	5.34	2.71	3.09	3.08	4.50	3.15	4.67	3.28 (2-7.7)
hs-CRP (mg/L)	0.48	2.12	0.36	29.36	0.46	6.53	2.57	1.02 (0-2.1)
ALT (U/L)	23.4	50.8	12.5	21.5	20.5	25.4	56.5	24.5 (7-40)
Cr (umol/L)	66.6	66.5	47.7	45.2	73.7	86.4	83.4	62.3 (41-73)
UA (umol/L)	285.4	335.6	300.5	85.8	358.3	385.1	514.8	305.1 (90-357)
LDH (U/L)	213.7	158.7	125.9	285	165	135.7	135.4	152.4 (120-250)
AST (U/L)	26.1	28.9	15.1	27.8	18.5	16	21.9	19.4 (13-35)

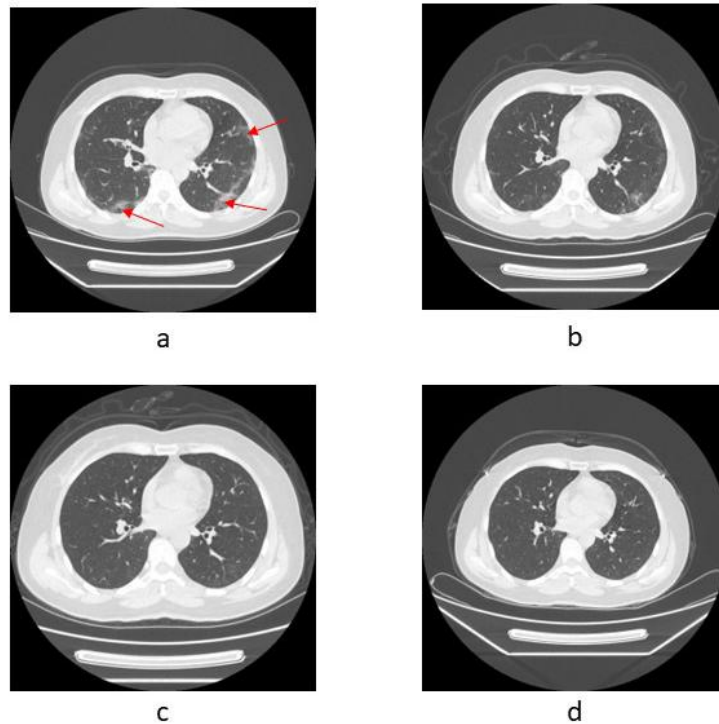
Table 3: Changes in blood routine, liver and kidney function related indicators of COVID-19 patients before and after treatment

Index	COVID-19 patients (n=7, ≥15 years)			Reference range
	Pro treatment	Post treatment	Prognosis review	
WBC (10 <sup>9</sup> /L)	5.42±1.21	5.18±1.17	5.50±1.44	3.5-9.5
LYM (%)	27.88±7.19	33.94±6.35	37.62±6.19#	20-40
NEU (%)	66.51±8.66	59.56±6.02	55.51±7.33#	50-75
LYM# (10 <sup>9</sup> /L)	1.48±0.41	1.8±0.30	2.13±0.36##	0.8-4
NEU# (10 <sup>9</sup> /L)	3.42±1.0	3.10±0.94	3.16±1.07	2-7.7
ALT (U/L)	38.99±14.66	28.81±11.41	26.18±9.35#	7-40
AST (U/L)	22.06±1.73	19.52±3.66	21.03±2.60	13-35
Cr (umol/L)	64.32±15.13	64.34±10.91	65.96±9.19	41-73
UA (umol/L)	337.6±87.71	326.00±58.77	335.1±113.20	90-357
LDH (U/L)	170.1±50.39	158.4±18.47	186.2±15.30	120-250

Mean±SD. #P < 0.05; ##P < 0.01 vs. Pro treatment.

## 2.3 CT test results before and after treatment

Six patients were diagnosed as ordinary types and presented early imaging manifestations. All patients with COVID-19 were given individualized treatment with TCM-WM in accordance. The results showed that the pulmonary lesions were obviously absorbed, and after 2-3 courses of treatment, the pulmonary lesions disappeared. CT Follow-up showed good prognosis (Figure 1).



**Figure 1** Imaging CT of Mild COVID-19 patients. a. Strip and ground glass shadows in both lungs, with unclear boundaries. b. Some lesions were resolved. c. The lesions had subsided significantly. d. Reexamination results showed that the lesions are fully absorbed in both lungs.

## 3. Discussion

COVID-19 is a new and highly contagious disease that spreads mainly through the respiratory tract and contact.<sup>[5]</sup> At present, omicron has become a major circulating variant in the world, with faster transmission, and atypical symptoms.<sup>[6]</sup> Early isolation and treatment is important to prevent the spread of the virus in the population.<sup>[7]</sup>

The rapid guidelines for the diagnosis and treatment of COVID-19 recommend that its CT findings be divided into early-stage, progressive stage, and severe stage.<sup>[8]</sup> The combined treatment of TCM-WM can reduce the chance of mild COVID-19 patients developing into severe.<sup>[9]</sup> Based on the retrospective analysis of 7 confirmed COVID-19 patients admitted to our hospital, To evaluate the role of TCM-WM precision therapy in the treatment of patients, to provide reference for the early diagnosis and treatment of diseases.

Related reports pointed out that COVID-19 patients had mild symptoms in the early stage, but suddenly worsened in the later stage. The analysis of clinical experts in the first-line treatment is related to the “inflammatory storm”.<sup>10</sup> TCM advocates strengthening immunity, reducing pulmonary inflammation, and protecting vital organs.<sup>11</sup> Our study showed that the curative effect of integrated TCM-WM is clear.

To sum up, with the evolution of virus mutations, the virus is relatively mild, coupled with the vaccination and rapid screening, the cases are mainly mild.<sup>12</sup> With the introduction of the COVID-19 Diagnosis and Treatment Program (Trial Ninth Edition), the integration of TCM-WM is closer, and personalized precision medicine is developing rapidly.<sup>13</sup> At present, these strategies and measures are very effective.

Of course, our study had several limitations. Due to the small sample size and single-center clinical research, the results may not fully reflect the efficacy of integrated TCM-WM. At present, a more thorough and comprehensive research on the precise and individualized treatment plan of integrated TCM-WM is being carried out in local cases.

## 4. Conclusion

This work affirmed the role of integrated TCM-WM precision therapy in the treatment of patients, providing a reference for the early prevention and treatment. Future research will be helpful to formulate more precise integrated TCM-WM diagnosis and treatment plans based on patients, and reduce the occurrence of sequelae of Long Covid.

### Author Contributions

Designed and wrote the manuscript: Dr. Qu, Mr. Wang. Performed the experiments: Mr. Wang, Mr. Ma, Ms. Wang, Dr. Yue, Mr. Chen, Dr. Dong. All co-authors have reviewed the manuscript and agreed with the manuscript results and conclusions.

### Author Disclosure Statement

The authors declare no conflict of interest.

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