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Clinical Study of Qingguo Zhike Granules Combined with Conventional Western Medical Therapy for Wind-Warm Lung-Heat Disease (Community-Acquired Pneumonia)

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Abstract: ***Objective:*** ***To evaluate the effects and safety of Qingguo Zhike Granules, when added to conventional Western medical therapy, on symptoms, signs, inflammatory markers, and clinical outcomes in patients with community-acquired pneumonia (CAP) presenting with a wind-warm lung-heat pattern.*** ***Methods:*** ***Sixty patients with CAP admitted to the emergency ward, emergency observation unit, or Department of Respiratory Medicine of Neijiang Hospital of Traditional Chinese Medicine, Sichuan Province, from February 2023 to February 2024 were enrolled. Eligible patients met both the Western diagnostic criteria for CAP and the traditional Chinese medicine diagnostic criteria for the wind-warm lung-heat pattern. Patients were assigned by a random-number table in a 1:1 ratio to a treatment group or a control group, with 30 patients in each group. Both groups received standard Western medical therapy for CAP. The treatment group additionally received Qingguo Zhike Granules (12 g per sachet, one sachet each time, three times daily) for 7 consecutive days. The two groups were compared for time to disappearance of core symptoms (length of hospital stay and time to resolution of cough, expectoration, and throat itching), cough and expectoration scores, lung rale score, body temperature, and TCM syndrome score. White blood cell count (WBC), neutrophil percentage (NEUT%), C-reactive protein (CRP), and procalcitonin (PCT) were measured, and adverse reactions were recorded.*** ***Results:*** ***Baseline characteristics were comparable between the two groups ($P > 0.05$). After treatment, cough score, expectoration score, lung rale score, and TCM syndrome score decreased significantly in both groups (all $P < 0.05$). Compared with the control group, the treatment group had a shorter hospital stay and shorter times to resolution of cough, expectoration, and throat itching (all $P < 0.05$). After treatment, cough, expectoration, and lung rale scores were lower in the treatment group (all $P < 0.05$), and the TCM syndrome score was also lower ($P < 0.001$). When improvement was assessed by the change from baseline (Δ), the reductions in cough score, expectoration score, lung rale score, and TCM syndrome score were greater in the treatment group than in the control group (all $P < 0.05$). WBC, NEUT%, CRP, and PCT decreased significantly after treatment in both groups (all $P < 0.05$), but neither post-treatment levels nor Δ values differed significantly between groups ($P > 0.05$). The total effective rates were 96% and 93% in the treatment and control groups, respectively, with no significant between-group difference ($P > 0.05$). No obvious adverse reactions were observed during the study.*** ***Conclusion:*** ***The addition of Qingguo Zhike Granules to conventional Western medical therapy may further accelerate and deepen the relief of cough, expectoration, throat itching, and lung rales in patients with CAP of the wind-warm lung-heat pattern. The combined regimen increased the magnitude of symptom and sign improvement and shortened the time to disappearance of core symptoms, although it did not provide a significant additional reduction in routine inflammatory markers. The regimen showed good safety and may serve as a useful adjunct to integrated traditional Chinese and Western treatment for CAP.***

Keywords: Community-acquired pneumonia, Wind-warm lung-heat pattern, Qingguo Zhike Granules, Randomized controlled study, Time to symptom disappearance, Integrated traditional Chinese and Western medicine.

1. Introduction

Community-acquired pneumonia (CAP) is a common acute infectious disease in clinical practice. Although standardized antimicrobial therapy can effectively control the pathogen, patients in the acute and recovery phases often continue to experience airway mucosal inflammation, thickened and increased secretions, and impaired ventilation and drainage. These changes may lead to persistent cough, expectoration, throat itching, chest tightness or pain, prolong the length of hospital stay, and compromise the quality of recovery. Therefore, beyond pathogen control, further intervention targeting airway inflammation and secretion clearance represents an important approach to optimizing CAP outcomes [1].

In traditional Chinese medicine (TCM), CAP is commonly classified under “wind-warm disease” or “lung-heat disease”. Its core pathogenesis is characterized by warm-heat invading the lung, phlegm-heat obstructing the lung, and failure of the lung to diffuse and descend [2]. Qingguo Zhike Granules, an in-hospital preparation of Neijiang Hospital of Traditional Chinese Medicine, consists of Chinese olive (Qingguo), Scrophulariae Radix (Xuanshen), Ophiopogonis Radix (Maidong), Linderae Radix (Wuyao), Belamcandae Rhizoma (Shegan), Stemonae Radix (Baibu), Lycii Cortex (Digupi), Poria (Fuling), Mori Cortex (Sangbaipi), Trichosanthis Pericarpium (Gualoupi), and Trichosanthis Semen (Gualouzi). The formula is designed to disperse wind, diffuse the lung, clear heat, resolve phlegm, nourish yin, and strengthen the spleen. These actions align with the pathogenesis of wind-warm lung-heat disease, namely heat constrained in the lung, phlegm-heat obstruction, and impaired diffusion and descent of lung qi. Modern studies have suggested that Chinese olive contains active constituents such as polyphenols and may have antibacterial and anti-inflammatory potential [3,4]. Phlegm-resolving and dampness-resolving Chinese medicines may also influence the expression of inflammatory factors, improve sputum properties, promote expectoration, and alleviate respiratory

symptoms [5,6]. These findings suggest that, when combined with antimicrobial therapy, Qingguo Zhike Granules may exert a complementary effect on local airway reactions and the impaired clearance of thick secretions.

Previous studies of integrated traditional Chinese and Western medicine have often used total effective rate or routine inflammatory markers as primary outcomes. However, when both groups receive standardized antimicrobial therapy, between-group differences in systemic inflammatory markers may be difficult to detect. In contrast, process-oriented endpoints, such as the magnitude of symptom and sign improvement (change values, Δ) and the time to disappearance of core symptoms, may more directly capture patient-perceived clinical benefit. On this basis, the present prospective randomized controlled study evaluated the added value of Qingguo Zhike Granules on top of conventional Western medical therapy for CAP, with particular attention to changes in symptoms and signs, time to symptom disappearance, changes in routine inflammatory markers, and safety. The findings may provide evidence for selecting appropriate endpoints and assessing efficacy in integrated treatment for CAP [7,8].

2. Materials and Methods

2.1 General Information

This study was conducted from February 2023 to February 2024 in the emergency ward, emergency observation unit, and respiratory ward of Neijiang Hospital of Traditional Chinese Medicine, Sichuan Province. During the study period, 120 patients with CAP were screened. After applying the Western diagnostic criteria for CAP and the TCM pattern diagnostic criteria, 60 eligible patients were ultimately enrolled, giving an inclusion rate of 50%. Patients were randomized by a random-number table in a 1:1 ratio to the treatment group or the control group, with 30 patients in each group. Baseline characteristics among patients who completed the study, including age, sex, smoking history, disease course, and disease severity scores, were comparable between groups ($P > 0.05$). The two groups were balanced in general and key baseline characteristics, supporting subsequent statistical comparison of efficacy. All participants provided written informed consent.

2.2 Sample Size and Grouping

This was a randomized controlled clinical study. The sample size was determined according to patient availability and feasibility within the study period. A total of 60 patients were planned for enrollment, with 30 patients in the treatment group and 30 in the control group. A random allocation sequence was generated using a random-number table, and patients were assigned in a 1:1 ratio. Random numbers were extracted according to a prespecified rule: numbers with a remainder of 1 were assigned to the treatment group, and those with a remainder of 2 were assigned to the control group.

2.3 Case Selection

2.3.1 Diagnostic criteria

(1) Western diagnostic criteria. The Western diagnosis of CAP was based on the Guidelines for the Diagnosis and Treatment of Community-Acquired Pneumonia issued by the Respiratory Branch of the Chinese Medical Association [9]. The criteria included: 1) clinical manifestations, such as newly developed cough or expectoration, or worsening of pre-existing respiratory symptoms, with or without purulent sputum, chest pain, dyspnea, and hemoptysis; 2) fever; 3) pulmonary signs, including signs of lung consolidation and/or moist rales; 4) laboratory findings, including an abnormal peripheral white blood cell count (WBC $> 10 \times 10^9$/L or $< 4 \times 10^9$/L), with or without a left shift of neutrophils; and 5) imaging findings, including newly developed patchy infiltrates, lobar or segmental consolidation, ground-glass opacity, or interstitial changes on chest imaging, with or without pleural effusion. A clinical diagnosis of CAP was established when any one of items 1 to 4 was present together with item 5, after excluding noninfectious pulmonary diseases such as pulmonary tuberculosis, lung tumors, noninfectious interstitial lung disease, pulmonary edema, atelectasis, pulmonary embolism, pulmonary eosinophilic infiltration, and pulmonary vasculitis.

(2) TCM diagnostic criteria. The TCM disease name and pattern diagnosis were based on the Guiding Principles for Clinical Research of New Chinese Medicines [10] and the TCM Syndrome Diagnostic Criteria for Community-Acquired Pneumonia (2018 edition) [2]. CAP falls within the category of “lung-heat disease” in TCM. The present study focused on the wind-warm lung-heat pattern in CAP. The diagnostic features were as follows: 1) main symptoms: fever, cough, expectoration of yellow or white sticky sputum, and chest tightness or chest pain; 2) accompanying symptoms: thirst, irritability, shortness of breath, yellow urine, constipation, and abdominal distension; and 3) tongue and pulse: red tongue with yellow or yellow-greasy coating, and a rapid or slippery-rapid pulse. The pattern was diagnosed when the main symptoms were present and supported by accompanying symptoms and tongue-pulse findings.

2.3.2 Inclusion criteria

Patients were included if they met all of the following criteria: 1) fulfilled both the Western diagnostic criteria for CAP and the TCM pattern diagnostic criteria for wind-warm lung-heat disease; 2) were of either sex and aged 18 to 60 years; 3) developed pulmonary infection outside the hospital; 4) volunteered to participate in the study, had no obvious mental or intellectual impairment, were conscious, and were able to understand the study procedures and complete relevant questionnaires and follow-up; 5) had complete clinical data, including clinical manifestations, laboratory results, and outcome-related information, available through medical records or telephone follow-up; and 6) had good compliance, were willing to complete the trial procedures, and signed written informed consent.

2.3.3 Exclusion criteria

Patients were excluded if they met any of the following criteria: 1) severe CAP, defined according to IDSA/ATS criteria as respiratory failure requiring mechanical ventilation or septic shock requiring vasopressor therapy; 2) severe

cardiovascular or cerebrovascular disease, severe hepatic or renal dysfunction, hematological disease, malignant tumor, or other conditions that could interfere with efficacy assessment; 3) immune system disease or long-term use of immunosuppressive agents; 4) other concomitant infections that could affect clinical observation despite meeting the inclusion criteria; 5) diabetes-related infection that could affect observation despite meeting the inclusion criteria; or 6) other circumstances that did not meet the inclusion criteria or could affect efficacy and safety evaluation.

2.3.4 Withdrawal and dropout criteria

Patients were withdrawn or considered dropouts under the following circumstances: 1) poor compliance affecting efficacy or safety evaluation; 2) death or discharge within 72 hours of treatment; 3) missing key data affecting efficacy assessment; 4) pregnancy during the trial with a request to discontinue participation; 5) voluntary withdrawal because of perceived poor efficacy or failure to complete the prescribed procedures; 6) loss to follow-up after enrollment; or 7) unwillingness to continue participation at any time and for any reason.

2.4 Treatment Methods

Both groups received conventional Western medical therapy for CAP. The control group received only this basic treatment, whereas the treatment group additionally received Qingguo Zhike Granules. The details are described below.

2.4.1 Conventional Western medical therapy

1) Anti-infective therapy: Empirical antimicrobial therapy was formulated according to the Guidelines for the Diagnosis and Treatment of Community-Acquired Pneumonia [9], local pathogen epidemiology and resistance patterns, and the patient's individual condition.

2) Supportive care: Bed rest, oxygen therapy, adequate caloric intake and nutritional support, and maintenance of water-electrolyte and acid-base balance were provided.

3) Symptomatic treatment: Physical cooling was used for high fever, and nebulization or sputum suction was provided when sputum volume was excessive.

2.4.2 Control group

The control group received the conventional Western medical therapy described above for 7 days.

2.4.3 Treatment group

On the basis of conventional therapy, the treatment group received Qingguo Zhike Granules, an in-hospital preparation of Neijiang Hospital of Traditional Chinese Medicine. Each sachet contained 12 g of granules. The formula consisted of Qingguo, Xuanshen, Maidong, Wuyao, Shegan, Baibu, Digupi, Fuling, Sangbaipi, Gualoupi, and Gualouzi. The medication was taken orally after dissolving in hot water, one sachet each time, three times daily, for 7 consecutive days.

2.4.4 Treatment course and criteria for early completion

The prescribed treatment course was 7 days. If clinical cure was achieved within 7 days, defined as normal body temperature for at least 72 hours, a cough symptom score of no more than 3 points, and normalization of inflammatory markers, the treatment course could be completed early.

3. Observation Indicators

3.1 Diagnostic Indicators

The diagnostic indicators included: 1) clinical symptoms, signs, and TCM pattern manifestations; 2) routine blood tests; 3) chest imaging; and 4) sputum smear and culture or serological tests.

3.2 Efficacy Indicators

Clinical symptoms and signs were recorded in detail before and after treatment on day 1 and day 7 of hospitalization. Symptom grading and scoring criteria were developed with reference to the grading and scoring principles in the Guiding Principles for Clinical Research of New Chinese Medicines [10] and the Terminology of Traditional Chinese Medicine Clinical Diagnosis and Treatment: Syndromes [11]. Main symptoms included fever, cough, expectoration, and chest tightness or pain. Secondary symptoms included shortness of breath, fatigue, excessive sweating, dry mouth and thirst, poor appetite, and abnormal bowel movements. TCM syndrome scores were evaluated at the start and end of treatment. Time-related indicators included the time to relief of cough, expectoration, and throat itching, as well as treatment duration. Laboratory indicators were assessed using venous blood collected on day 1 and day 7 of hospitalization, including WBC, NEUT%, CRP, and PCT.

3.3 Safety Indicators

Adverse reactions were closely monitored and recorded during the study, including type, time of onset, duration, management, and outcome. Safety was evaluated in relation to severity and causal association.

3.4 Efficacy Assessment

Efficacy was assessed according to the Guiding Principles for Clinical Research of New Chinese Medicines (trial version) [10]. Based on changes in clinical symptoms, signs, and TCM syndrome scores before and after treatment, efficacy was categorized as cured, markedly effective, effective, or ineffective.

Cured: Clinical symptoms and signs had basically or completely disappeared after treatment, the syndrome score improvement rate was at least 95%, and relevant objective indicators had basically returned to normal.

Markedly effective: Clinical symptoms and signs improved substantially after treatment, the syndrome score improvement rate was at least 70% but less than 95%, and relevant objective indicators improved.

Effective: Clinical symptoms and signs improved after treatment, the syndrome score improvement rate was at least 30% but less than 70%, and relevant objective indicators improved.

Ineffective: Clinical symptoms and signs showed no improvement or worsened after treatment, the syndrome score improvement rate was less than 30%, and relevant objective indicators failed to improve or worsened.

The syndrome score improvement rate was calculated using the nimodipine method: syndrome score improvement rate (%) = (total score before treatment – total score after treatment) / total score before treatment × 100%.

The total effective rate was calculated as: total effective rate (%) = (number of cured cases + number of markedly effective cases + number of effective cases) / total number of cases × 100%.

3.5 Observation Procedures

On the day of admission, eligible patients completed a face-to-face questionnaire to collect TCM four-diagnostic information, underlying diseases, and physical signs. After admission, relevant examinations were performed, including routine blood tests, comprehensive biochemical tests, procalcitonin (PCT), C-reactive protein (CRP), D-dimer, and chest X-ray or computed tomography (CT). Arterial blood gas analysis was performed in patients with peripheral oxygen saturation (SpO_2) below 95%. Reference ranges were as follows: WBC, 4–10 × 10^9/L; granulocyte percentage, 50%–70%; K^+, 3.5–5.5 mmol/L; Na^+, 135–148 mmol/L; Cl^-, 96–112 mmol/L; and D-dimer, <0.5 mg/L. For arterial blood gas analysis, a PaO_2 value 10 mmHg below the predicted value was considered hypoxemia. At sea level and standard atmospheric pressure while breathing room air, PaO_2 < 60 mmHg with normal or low $PaCO_2$ was defined as type I respiratory failure, whereas PaO_2 < 60 mmHg with $PaCO_2$ > 50 mmHg was defined as type II respiratory failure.

3.6 Statistical Analysis

A database was established and analyzed using SPSS version 26.0. Measurement data were first tested for normality. Normally distributed data are expressed as mean ± standard deviation ($\bar{x} \pm s$); between-group comparisons were performed using the independent-samples t test, and within-group comparisons before and after treatment were performed using the paired t test. Non-normally distributed data are expressed as median (P25, P75); between-group comparisons were performed using the Mann–Whitney U test, and within-group comparisons were performed using the Wilcoxon signed-rank test. Count data are expressed as number (%), and between-group comparisons were performed using the χ^2 test. Fisher's exact test was used when the expected frequency was <5 or when a cell count was 0. Ranked data were analyzed using the rank-sum test. A two-sided P value < 0.05 was considered statistically significant.

4. Results

4.1 Comparison of General Characteristics

The general characteristics of the two groups are shown in Table 1.

Table 1: Comparison of general characteristics between the two groups

Item	Treatment group	Control group	χ^2/t/Z	P / Total
Sex, n (%)			1.153	0.422
Male	17 (56.6%)	21 (70.0%)		
Female	13 (43.3%)	9 (30.0%)		
Age, years ($\bar{x}\pm s$)	45.30 ± 12.09	48.53 ± 10.30	0.896	0.370
Smoking history, n(%)			0.711	1.000
Yes	19 (63.3%)	18 (60.0%)		
No	11 (36.6%)	12 (40.0%)		
Comorbidities				
Hypertension	8	7	-	15 (25%)
Coronary heart disease	6	5	-	11 (18%)
Cardiac insufficiency	1	1	-	2 (3%)
Diabetes mellitus	4	5	-	9 (15%)
Hyperlipidemia	4	4	-	8 (13%)
Hyperuricemia	1	1	-	2 (3%)
Fatty liver	2	2	-	4 (7%)
Bronchial asthma	2	3	-	5 (8%)
Tumor disease	2	1	-	3 (5%)
Cerebrovascular disease	0	1	-	1 (2%)
PSI grade, n (%)			0.017	0.313
Grade I	29	30		
Grade II	1	0		
Chest CT score*	3.90 ± 0.75	3.90 ± 0.71	0.164	0.869

* The chest CT score was used for baseline severity assessment.

4.2 Comparison of Time to Disappearance of Core Symptoms

Compared with the control group, the treatment group had significantly shorter length of hospital stay and shorter times to disappearance of cough, expectoration, and throat itching (all P < 0.05; Table 2).

Table 2: Comparison of time to relief of core symptoms ($\bar{x} \pm s$)

Group	n	Length of hospital stay	Time to disappearance of cough	Time to disappearance of expectoration	Time to disappearance of throat itching
Control group	30	10.70 ± 1.685	7.37 ± 1.542	6.30 ± 1.878	4.81 ± 1.981
Treatment group	30	8.07 ± 2.243	4.87 ± 1.074	5.13 ± 2.763	3.50 ± 0.860
t		5.143	5.750	2.010	2.353
P		<0.001	0.010	0.04	0.01

4.3 Comparison of Cough Symptom Scores

Before treatment, cough symptom scores did not differ significantly between the two groups (P > 0.05). After treatment, cough symptom scores decreased significantly in both groups compared with baseline (both P < 0.001; Table 3). In the between-group comparison after treatment, the treatment group had a lower cough symptom score than the control group (P < 0.001; Table 3).

Further comparison of the pre- to post-treatment change (Δ) showed that the reduction in cough symptom score was greater in the treatment group than in the control group ($P < 0.05$; Table 4).

Table 3: Comparison of cough symptom scores before and after treatment ($\bar{x} \pm s$)

Group	n	Before treatment	After treatment	t/Z	P
Control group	30	5.00 ± 1.017	1.73 ± 1.01	4.832	<0.001
Treatment group	30	5.00 ± 1.14	0.47 ± 0.86	4.867	<0.001
Z		0.127	4.402		
P		0.899	<0.001		

Table 4: Comparison of changes in cough symptom scores before and after treatment ($\bar{x} \pm s$)

Group	Δ cough symptom score
Control group	3.27 ± 1.337
Treatment group	4.53 ± 1.570
Z	3.078
P	0.02

Note: Δ indicates the difference between the pre-treatment and post-treatment values.

4.4 Comparison of Expectoration Symptom Scores

Before treatment, expectoration symptom scores did not differ significantly between the two groups ($P > 0.05$). After treatment, expectoration symptom scores decreased significantly in both groups compared with baseline (both $P < 0.001$; Table 5). In the between-group comparison after treatment, the treatment group had a lower expectoration symptom score than the control group ($P < 0.05$; Table 5).

Further comparison of the pre- to post-treatment change (Δ) showed that the reduction in expectoration symptom score was greater in the treatment group than in the control group ($P < 0.05$; Table 6).

Table 5: Comparison of expectoration symptom scores before and after treatment ($\bar{x} \pm s$)

Group	n	Before treatment	After treatment	t/Z	P
Control group	30	2.67 ± 1.60	1.20 ± 0.99	3.345	<0.001
Treatment group	30	2.93 ± 2.00	0.60 ± 0.93	4.417	<0.001
t/Z		0.952	2.316		
P		0.341	0.021		

Table 6: Comparison of changes in expectoration symptom scores before and after treatment ($\bar{x} \pm s$)

Group	Δ expectoration symptom score
Control group	1.46 ± 1.88
Treatment group	2.33 ± 1.58
Z	1.989
P	0.047

Note: Δ indicates the difference between the pre-treatment and post-treatment values.

4.5 Comparison of Physical Signs: Lung Rales and Body Temperature

After treatment, lung rale score and body temperature decreased significantly in both groups compared with baseline (both $P < 0.001$; Table 7). In the between-group comparison after treatment, the treatment group had a lower lung rale score than the control group ($P < 0.05$; Table 7).

Further comparison of pre- to post-treatment changes (Δ) showed that the reduction in lung rale score was greater in the treatment group than in the control group ($P < 0.05$), whereas the change in body temperature did not differ significantly between groups ($P > 0.05$; Table 8).

Table 7: Comparison of physical signs before and after treatment

Group	n	Time point	Lung rale score	Body temperature
Control group	30	Before treatment	2.43 ± 0.49	38.85 ± 1.72
		After treatment	1.47 ± 0.62[1]	36.95 ± 0.84[1]
Treatment group	30	Before treatment	2.47 ± 0.50	38.21 ± 3.19
		After treatment	1.00 ± 0.52[12]	36.71 ± 0.51[12]

Note: [1]$P < 0.001$ compared with before treatment within the same group; [2]$P < 0.05$ compared with the control group after treatment.

Table 8: Comparison of changes in physical signs before and after treatment

Group	Δ lung rale score	Δ body temperature	Group
Control group	1.00 ± 0.74	1.89 ± 2.05	Control group
Treatment group	1.46 ± 0.57	1.49 ± 3.22	Treatment group
Z	2.486	0.573	Z
P	0.013	0.569	P

Note: Δ indicates the difference between the pre-treatment and post-treatment values.

4.6 Comparison of Inflammatory Markers

After treatment, WBC, NEUT%, CRP, and PCT decreased significantly in both groups compared with baseline (all $P < 0.05$; Table 9). In the between-group comparison after treatment, there were no significant differences in WBC, NEUT%, CRP, or PCT between the treatment and control groups (all $P > 0.05$; Table 9).

Further comparison of the changes from baseline (ΔWBC, ΔNEUT%, ΔCRP, and ΔPCT) also showed no significant between-group differences (all $P > 0.05$; Table 10).

Table 9: Comparison of inflammatory markers before and after treatment

Group	n	Time point	WBC ($\times 10^9$/L)	NEUT (%)	CRP (mg/L)	PCT (ng/mL)
Control group	30	Before treatment	11.18 ± 4.13	82.51 ± 10.17	71.67 ± 20.99	0.40 ± 0.24
		After treatment	7.85 ± 2.04[1]	64.83 ± 8.81[1]	19.67 ± 8.55[1]	0.14 ± 0.08[1]
Treatment group	30	Before treatment	10.2 ± 4.67	85.42 ± 7.41	75.10 ± 28.04	0.52 ± 0.23
		After treatment	6.61 ± 2.49[1]	66.08 ± 5.67[1]	24.07 ± 12.33[1]	0.15 ± 0.06[1]

Note: [1]$P < 0.05$ compared with before treatment within the same group.

Table 10: Comparison of changes in inflammatory markers before and after treatment

Group	n	ΔWBC ($\times 10^9$/L)	ΔNEUT (%)	ΔCRP (mg/L)	ΔPCT (ng/mL)
Control group	30	3.32 ± 4.24	17.68 ± 12.08	51.94 ± 21.66	0.28 ± 0.25
Treatment group	30	3.65 ± 5.53	19.34 ± 9.44	51.02 ± 27.38	0.36 ± 0.22
t/Z		0.251	0.595	0.958	1.363
P		0.802	0.555	0.885	0.178

Note: Δ indicates the difference between the pre-treatment and post-treatment values.

4.7 Comparison of TCM Symptom Scores

After treatment, TCM symptom scores decreased

significantly in both groups compared with baseline (both $P < 0.001$; Table 11). In the between-group comparison after treatment, the treatment group had a lower TCM symptom score than the control group ($P < 0.001$; Table 11).

Further comparison of the pre- to post-treatment change (Δ TCM symptom score) showed that the reduction was greater in the treatment group than in the control group ($P < 0.001$; Table 12).

Table 11: Comparison of TCM symptom scores before and after treatment

Group	n	Before treatment	After treatment	t/Z	P
Treatment group	30	13.56 ± 1.88	3.63 ± 2.20	17.969	<0.001
Control group	30	12.86 ± 3.27	8.23 ± 2.56	13.468	<0.001
t		1.215	5.489		
P		0.225	<0.001		

Table 12: Comparison of changes in TCM symptom scores before and after treatment

Group	Δ TCM symptom score
Treatment group	9.90 ± 3.11
Control group	5.23 ± 2.60
Z	4.954
P	<0.001

Note: Δ indicates the difference between the pre-treatment and post-treatment values.

4.8 Comparison of Efficacy Between the Two Groups

The total effective rate was 96% (29/30) in the treatment group and 93% (28/30) in the control group, with no statistically significant between-group difference ($P > 0.05$; Table 13). The difference in the markedly effective rate between groups was also not statistically significant ($P > 0.05$; Table 13), although the number of markedly effective cases was slightly higher in the treatment group.

Table 13: Comparison of clinical efficacy between the two groups

Group	n	Cured	Markedly effective	Effective	Ineffective	Total effective rate
Treatment group	30	1	14	14	1	96%
Control group	30	0	8	20	2	93%

5. Discussion

Community-acquired pneumonia is a common acute infectious disease. Although standardized antimicrobial therapy can effectively control the pathogen, the acute phase is often accompanied by airway mucosal inflammation, increased and thickened secretions, and impaired ventilation and drainage. These changes contribute to persistent cough, expectoration, throat itching, and chest tightness, thereby affecting the length of hospital stay and the recovery process [12,13]. In TCM, CAP is usually categorized as “wind-warm disease” or “lung-heat disease”, with a core pathogenesis of warm-heat invading the lung, heat constrained in the lung collaterals, phlegm-heat obstructing the lung, and failure of the lung to diffuse and descend. In this study, both groups received conventional Western medical therapy, and the treatment group additionally received Qingguo Zhike Granules. The aim was to evaluate the incremental effect of the combined regimen on clinical outcomes, symptoms and signs, and inflammatory markers.

The results showed that cough, expectoration, throat itching, lung rales, and TCM syndrome scores improved after treatment in both groups (all $P < 0.05$). When the magnitude of improvement was assessed using change values (Δ), the treatment group showed greater reductions in cough score, expectoration score, and lung rale score than the control group (all $P < 0.05$), and the reduction in TCM syndrome score was also more pronounced ($P < 0.001$). In addition, the time to disappearance of core symptoms, including cough, expectoration, and throat itching, was shorter in the treatment group ($P < 0.05$). These findings suggest that the combined treatment may offer advantages in both the speed and the magnitude of symptom relief. Previous studies have shown that symptom recovery in CAP follows different time courses, and process-oriented endpoints may be more sensitive in capturing benefits that are meaningful to patients [14]. By contrast, routine inflammatory markers, including WBC, NEUT%, CRP, and PCT, decreased significantly from baseline in both groups ($P < 0.05$), but neither post-treatment levels nor Δ values differed significantly between groups ($P > 0.05$). Because both groups received standardized antimicrobial therapy and inflammatory markers declined substantially overall, the ability to detect an additional between-group difference may have been limited. Recent guideline updates also emphasize that, under standardized antimicrobial treatment, outcomes directly related to clinical recovery and disease course should receive greater attention [15].

Qingguo Zhike Granules is an in-hospital preparation of Neijiang Hospital of Traditional Chinese Medicine. The formula contains Qingguo, Xuanshen, Maidong, Wuyao, Shegan, Baibu, Digupi, Fuling, Sangbaipi, Gualoupi, and Gualouzi. Its therapeutic actions include dispersing wind, diffusing the lung, clearing heat, resolving phlegm, nourishing yin, and strengthening the spleen. In the formula, Qingguo plays a central role in clearing heat, soothing the throat, resolving phlegm, and relieving cough. Sangbaipi, Gualoupi, Shegan, and Baibu help clear heat, transform phlegm, diffuse the lung, and benefit the throat. Xuanshen and Maidong nourish yin and moisten the lung, thereby protecting the lung collaterals. Fuling strengthens the spleen and supports transformation and transportation, while Wuyao regulates qi to support the diffusion and descent of lung qi and the transformation of phlegm with the movement of qi. Overall, the compatibility of the formula matches the pathogenesis of wind-warm lung-heat disease, namely phlegm-heat obstruction and impaired lung diffusion and descent.

Modern research has summarized the nutritional, chemical, and pharmacological basis of Chinese olive and suggested potential anti-inflammatory, antibacterial, and multi-pathway effects [16]. Chinese olive contains active constituents such as polyphenols [17] and may have antibacterial and anti-inflammatory potential [3,4,18]. In vitro studies also suggest possible inhibitory effects against Streptococcus pneumoniae, group B Streptococcus, and Klebsiella

pneumoniae, potentially through regulation of inflammation-related pathways. In addition, studies of phlegm-resolving and dampness-resolving Chinese medicines indicate that they may modulate pro- and anti-inflammatory factors and improve sputum properties, thereby promoting expectoration and relieving respiratory symptoms [5,6]. Taken together, traditional theory and existing evidence suggest that, in addition to pathogen control achieved by antimicrobial therapy, Qingguo Zhike Granules may mainly act by improving local airway reactions and the viscosity and clearance of secretions. This interpretation is consistent with the greater improvement in symptoms and signs and the shorter time to symptom disappearance observed in this study.

This study has several limitations. First, it was a single-center study with a limited sample size and mainly included patients with non-severe CAP. The generalizability of the findings should be confirmed in multicenter studies with larger samples and patients of different severity levels. Second, the study did not include key indicators of local airway inflammation and mucus hypersecretion, such as IL-6, TNF-α, broader inflammatory factor profiles, sputum mucins, or sputum viscosity. As a result, the mechanistic interpretation of potential anti-inflammatory, antibacterial, phlegm-resolving, and cough-relieving synergy remains mainly based on clinical inference. Third, although symptom and syndrome scores were quantified, they remain partly subjective. Future studies should more closely follow reporting and protocol standards for randomized controlled trials, such as CONSORT and SPIRIT, strengthen blinding and assessor training, and improve the completeness and comparability of adverse event reporting [19–21].

Future research may proceed in two directions. First, multicenter, large-sample, stratified randomized controlled trials should be conducted, with subgroup analyses to identify populations most likely to benefit and to clarify the applicable boundaries of treatment. Second, dynamic monitoring should be performed around key links including local airway inflammation, mucus hypersecretion and impaired clearance, and cough reflex sensitization. This could integrate inflammatory factor profiling, quantitative imaging, and sputum or mucin indicators. When necessary, pharmacokinetic-pharmacodynamic exploration may help clarify the relationships among active components, target pathways, and clinical benefits, thereby providing higher-quality evidence for precision use and clinical translation of integrated traditional Chinese and Western treatment for CAP.

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