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Research Article

Meta-Analysis of Integrative Chinese and Western Medicine for Severe Pneumonia of Phlegm-Heat Obstructive Lung Pattern

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Abstract

Background and Objective: Severe pneumonia involves significant lung inflammation from pathogens, causing dyspnea, cough, fever and organ damage. The research integrates Chinese-Western medicine, focusing on "phlegm-heat obstructing the lung" to enhance efficacy. The purpose of this meta-analysis is to rigorously assess the clinical efficacy and safety of the integrated approach of traditional Chinese medicine (TCM) and Western medicine in treating severe pneumonia of phlegm-heat obstructive lung pattern (SPPHOLP). **Materials and Methods:** Comprehensive literature retrieval of clinical Randomized Controlled Trials (RCTs) on integrated TCM and Western Medicine for SPPHOLP patients was conducted on China Knowledge Network (CNKI), Chongqing VIP Chinese Science and Technology Journal Database (VIP), Wanfang database, PubMed and Web of Science database up to June, 25, 2023. A meta-analysis was conducted employing RevMan 5.4 and Stata18. **Results:** Twenty-five studies involving 2116 patients (1046 cases in the experimental group and 1070 cases in the control group) were included. The adjunctive TCM regimen significantly improved outcomes in SPPHOLP compared to standard Western medicine treatment. It reduced clinical fever, relieved cough and phlegm congestion, mitigated dyspnea, increased oxygen partial pressure, decreased inflammatory markers (TNF-α, IL-6 and IL-10), improved immune response (CD4+ activity) and enhanced lung function (FVC, FEV), with statistically significant differences. **Conclusion:** The fusion of TCM and Western medicine in the treatment of SPPHOLP substantially improves treatment efficacy, alleviates clinical symptoms, reduces carbon dioxide partial pressure, increases oxygen partial pressure, attenuates various inflammatory reactions and boosts immune function.

Key words: Severe pneumonia, phlegm-heat obstruction of the lung, integrated Chinese and Western medicine, meta-analysis

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

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INTRODUCTION

Severe pneumonia represents a distinct class of pneumonia, typically characterized by profound lung inflammation instigated by bacterial, viral or other pathogens. Predominant clinical manifestations encompass dyspnea, cough, fever, altered consciousness, tachycardia and concomitant systemic tissue and organ damage^{1,2}. Pathologically, the ailment primarily denotes an inflammatory disease of the pulmonary tissues with extensive lesion coverage, which escalates the risk of severe complications such as cardiovascular complications, sepsis, septic shock, organ failure and subsequently, high mortality rates³. The etiology of this disease remains nebulous; however, it is conjectured to be intimately associated with immunological imbalance, genetic predisposition and inflammatory response. Western medical therapies primarily hinge on anti-inflammatory and anti-infection treatments, aspiration nebulization, nutritional support and correction of electrolyte imbalances². Nevertheless, issues of multi-drug resistance and frequent relapses often thwart effective treatment, leading to uncontrolled complications such as airway secretion aggregation, bacterial discharge difficulty in airway secretions and blood and suboptimal ventilation⁴. Hence, the optimization of treatment protocols for severe pneumonia is under the intense scrutiny of the medical community.

In tandem with anti-infective therapy, proactive adjuvant treatments are sought to enhance clinical effectiveness. Many researchers often amalgamate traditional Chinese medicine (TCM) into the treatment regimen, yielding notable improvements in dyspnea, fever, cough, phlegm congestion, chest tightness and chest pain, alongside bolstering the body's immunity⁵. The TCM postulates this disease under the rubrics of "lung carbuncle," "pneumonia, wheezing and coughing", "wind temperature and lung fever," among others. Clinically, this condition is commonly categorized into eight types of syndromes, with "phlegm-heat obstructing the lung" being the most prevalent. Numerous scholars have delved into the treatment of severe pneumonia of phlegm-heat obstructing lung pattern (SPPHOLP) in clinical practice⁶. This study, therefore, aimed to conduct a comprehensive search for Randomized Controlled Trials (RCTs) about the integration of Chinese and Western medicine in treating SPPHOLP and perform a meta-analysis of the included literature, thereby providing evidence for the safety and efficacy of this combined treatment approach for SPPHOLP.

MATERIALS AND METHODS

Literature search: The literature search utilized the databases of China Knowledge Network (CNKI), Chongqing Vip Chinese Science and Technology Journal database (VIP), Wanfang, PubMed and Web of Science. The search period extended from the inception of each database up to June, 25, 2023. Literature related to Randomized Controlled Trials (RCTs) assessing the efficacy of integrative Chinese and Western medicine in treating patients with severe pneumonia of phlegm-heat obstructing lung pattern (SPPHOLP) was systematically collected. The Chinese search terminologies encompassed terms such as "Chinese medicine", "Chinese medicine compound", "Phlegm-heat obstructing the lung", "Integrative Chinese and Western medical therapies", "Severe pneumonia" and "Severe lung inflammation". In English, the search terms included "Traditional Chinese Medicine", "Traditional Chinese Medicine compound", "Phlegm-heat obstructing lung", "Chinese and Western medicine therapy", "TCM", "Severe pneumonia" and "Severe pulmonary inflammation", among others. A hybrid application of subject terms and free words was used to search. Illustrative examples of search strategies are as follows:

- Taking the China Biological Medicine database (CBM) as an example:
 - #1 "Chinese medicine" or "Chinese medicine compound" or "Phlegm-heat obstructing lung" or "Integrative Chinese and Western medical therapy"
 - #2 "Integrative Chinese and Western medical therapies" or "Severe pneumonia" or "Severe lung inflammation"
 - #3 #1 and #2
- Using PubMed search strategy as an example:
 - #1 "TCM" or "Chinese medicine" or "Chinese medicine compound" or "Phlegm-heat obstructing lung" or "Chinese and Western medicine therapy"
 - #2 "Chinese and Western medicine therapy" or "Severe pneumonia" or "Severe lung inflammation"

Selection criteria

Inclusion criteria: The PICOS strategy (Table 1) was employed to determine the inclusion of literature.

Exclusion criteria: Studies were excluded if they met any of the following conditions: (1) Subjects were animals, (2) Experiment lacked a control group, (3) Study was not a

Table 1: Inclusion criteria of literature according to PICOS strategy

PICOS	Inclusion criteria
Study subjects (P)	(i) Literature publicly accessible, encompassing randomized controlled clinical trials investigating the efficacy of integrative Chinese
	and Western medicine for the treatment of patients diagnosed with SPPHOLP, regardless of the blinding status
	(ii) Original studies adopting a prospective clinical trial design
	(iii) Participants possessing a pathologically confirmed diagnosis of severe pneumonia
Interventions (I)	For the combined Chinese and Western medical treatment
Control measure (C)	General standard of care should be applied, entailing conventional Western medical treatment, encompassing patient-specific
	anti-infection therapy, respiratory support, sputum aspiration and nebulization, nutritional supplementation and correction of
	electrolyte imbalances. Further interventions should be adjusted according to the patient's condition and pathogenetic results, with
	the potential implementation of mechanical ventilation if necessary. Rigorous daily monitoring of the patient's vital signs is crucial
Outcome factors (O)	Outcome measures should include both efficacy and traditional Chinese medicine (TCM) symptom scores. Secondary outcome
	measures should encompass arterial blood gas analysis, immune functional indicators such as T-cell subsets CD4+, CD8+, CD4+/CD8+, CD4+/CD8+/CD8+, CD4+/CD8+, CD4+/CD8+/CD8+, CD4+/CD8+/CD8+/CD8+/CD8+/CD8+/CD8+/CD8+/CD8
	ratio, pulmonary function markers (FVC: Forced vital capacity, FEV1: Forced expiratory volume in one second, MVV: Maximum voluntary and capacity
	ventilation) and inflammatory markers including Interleukin-6 (IL-6), Interleukin-8 (IL-8), Interleukin-10 (IL-10), Procalcitonin (PCT),
	C-Reactive Protein (CRP), White Blood Cell count (WBC), Clinical Pulmonary Infection Score (CPIS) and the Pneumonia Severity Index
Type of study design (S)	Randomized Controlled Trials (RCTs)

randomized controlled trial, (4) Study failed to provide outcome indicators and measures, (5) Type of study was a review, commentary, case report or meta-analysis and (6) Study's content did not align with the present research topic.

Information and data extraction: A data extraction form was devised and two researchers independently carried out the literature screening and data extraction in a parallel manner, based on the inclusion and exclusion criteria. Any discrepancies or uncertainties were resolved through discussion or consultation with a third party. Data extraction encompassed the following: Title, first author, year of publication, sample size, interventions, treatment duration and primary and secondary outcome measures. The primary outcome measures included therapeutic efficacy and traditional Chinese medicine symptom scores. The secondary outcome measures comprised arterial blood gas analysis, functional T-cell subpopulation (CD4+, CD8+ and CD4+/CD8+ ratio) immune indicators, pulmonary function parameters (FVC, FEV1 and MVV) and inflammatory markers (IL-6, IL-8, IL-10, PCT, CPR, WBC, CPIS and Pneumonia Severity Index), among others.

Quality assessment: The quality of the included studies was evaluated using the Cochrane Handbook for Systematic Reviewers' recommended risk of bias assessment tool. The evaluation considered factors such as randomization method, allocation concealment, blinding status, completeness of outcome data, selective reporting of results and other potential sources of bias. Each factor was categorized as either 'high risk,' 'low risk' or 'unclear.' Risk propensity charts were created using RevMan 5.4 software.

Statistical analysis: Data were consolidated and heterogeneity was assessed using RevMan 5.4 software, followed by a meta-analysis. If the I² test for statistical heterogeneity among studies resulted in p<0.05 and I²>50%, it indicated significant heterogeneity, in which case a randomeffects model was used for meta-analysis. Conversely, if p>0.05 or l²<50%, indicating no significant heterogeneity, a fixed-effects model was applied. Categorical variables were expressed as risk ratio (RR) with a 95% confidence interval (CI), while continuous variables were represented as standardized mean difference (SMD) with a 95% Cl. A p-value less than 0.05 was deemed statistically significant. In cases where I² was ≥50%, sources of heterogeneity were explored through subgroup and sensitivity analyses. Funnel plots were generated to assess potential publication bias among the included studies, with Egger's test employed to examine the symmetry of these plots. A p-value less than 0.05 was indicative of a significant difference.

RESULTS

Search process and results: The comprehensive search across various databases yielded 1303 articles. Following layered screening, 25 studies were ultimately included. The literature screening process and bias were depicted in Fig. 1 and 2.

Characteristics of included studies: In total, 25 studies were incorporated into this review, representing 2116 patients, of which 1046 were in the experimental group and 1070 were in the control group. The number of patients included in each study ranged from a minimum of 20 to a maximum of 60. The duration of treatment for the included patients varied between 1 to 2 weeks. Specific attributes and quality assessments of the included literature were presented in Table 2.

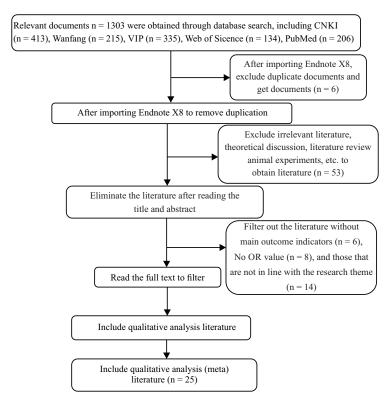


Fig. 1: Process and results of study inclusion and exclusion

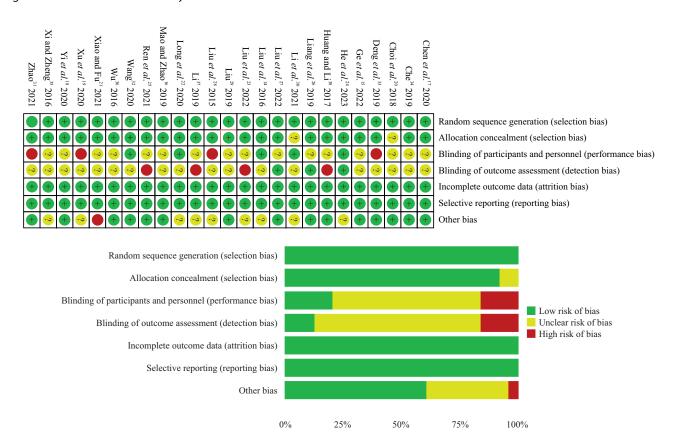


Fig. 2: Quality evaluation of included studies

Table 2: Basic characteristics of the included studies

		Number of people	Intervention	Duration of treatment	
No.	Author/year	(control group/trial group)	(control group/trial group)	(test group/control group)	Outcome indicators
1	Liu <i>et al</i> . ¹⁴ 2016	48/48	Linezolid injection/control group+QFCQD	2 weeks/2 weeks	1-7
2	Ge <i>et al.</i> ¹⁵ 2022	40/40	Conventional treatment+Broad-Spectrum	2 weeks/2 weeks	2, 3, 6-10
			antimicrobials/control group+QFHTD		
3	Mao and Zhao16 2019	9 40/40	Conventional treatment/control group+QFTFD	2 weeks/2 weeks	2, 7, 11-13
4	Chen <i>et al</i> . ¹⁷ 2020	52/52	Conventional treatment/control group+QFXYD	2 weeks/2 weeks	1-4, 12-16, 23
5	Yi <i>et al.</i> ¹⁸ 2020	37/37	Conventional treatment/control group+	10 days/10 days	1, 2, 4, 12, 14, 15, 17
			Clearing formula		
6	Xu <i>et al</i> . ¹⁹ 2020	46/46	Conventional treatment/control group+QHD	1 week/1 week	1, 3, 6, 7, 8, 10
7	Cui <i>et al.</i> ²⁰ 2018	38/37	Conventional treatment/control group+QHD	10 days/10 days	2, 9-11, 18
8	Xiao and Fu ²¹ 2021	30/30	Conventional treatment/control group+QHD	2 weeks/2 weeks	2, 6-8, 19, 20
9	Long <i>et al.</i> ²² 2020	55/55	Conventional treatment+IV piperacillin	2 weeks/2 weeks	1-3, 11
			sulbactam+Ambroxol treatment/QHJP		
10	Liu <i>et al.</i> ²³ 2022	42/42	Conventional treatment/control group+QTD	2 weeks/2 weeks	2, 3, 6, 7, 10
11	He <i>et al.</i> ²⁴ 2023	53/52	Conventional treatment/control group+SJS	2 weeks/2 weeks	1, 2, 12, 13, 15, 21
12	Ren <i>et al.</i> ²⁵ 2021	34/40	Conventional treatment/control group+SJS	1 week/1 week	1,2,6,7,9,10,13,15,19,2
13	Liang <i>et al.</i> ²⁶ 2019	36/36	Conventional treatment/control group+XBSXXD	2 weeks/2 weeks	1, 2, 4, 16, 23, 24
14	Liu <i>et al</i> . ²⁷ 2022	30/30	Conventional treatment+Piperacillin	10 days/10 days	1, 2, 6, 7, 8, 13, 25, 26
			tazobactam sodium/control group+XFTFD		
15	Liu <i>et al</i> . ²⁸ 2015	60/60	Conventional treatment/control group+	10 days/10 days	1
			XRJDTFD		
17	Liu ²⁹ 2019	48/48	Conventional treatment/control group+XBCQD	10 days/10 days	1, 6, 12, 13
18	Li <i>et al</i> . ³⁰ 2021	30/30	Conventional treatment/control group+XBCQD	7 days/7 days	2, 4, 15, 27, 28
19	Zhao ³¹ 2021	50/50	Conventional treatment/control group+XBCQD	7 days/7 days	1, 11
20	Wang and Zha ³² 2020) 44/44	Conventional treatment/control group+QFTFD	2 weeks/2 weeks	2, 7, 12, 13
21	Deng <i>et al</i> . ³³ 2019	41/41	Conventional treatment/control group+XBCQD	1 week/1 week	1, 2, 6, 7, 13
22	Che ³⁴ 2019	47/47	Conventional treatment/control group+	2 weeks/2 weeks	1, 4, 28, 29, 30
			ZNXYQFD		
23	Xi and Zheng35 2016	20/40	Conventional treatment/control group+	2 weeks/2 weeks	1, 2, 4, 12, 13, 31, 32
			SSYHQJWJD		
24	Wu ³⁶ 2016	32/32	Conventional treatment/control group+	2 weeks/2 weeks	2, 32, 34
			Reed stem soup		
25	Li ³⁷ 2019	38/38	Conventional treatment/control group+BNTFYF	D 1 week/1 week	1, 6, 7, 11, 15
26	Huang and Li ³⁸ 2017	55/55	Conventional treatment/control group+ZNXYQF		1, 2, 8, 32, 33, 34

1: Therapeutic Efficacy, 2: Traditional Chinese Medicine Symptom Scores, 3: Arterial, 4: Blood Gas Analysis, 5: APACHE II Score, 6: Receptor for Advanced Glycation End-products (RAGE), 7: Tumor Necrosis Factor-Alpha (TNF-α), 8: Interleukin-6 (IL-6), 9: Functional T-cell Subpopulations (Immune Indicators), 10: Interleukin-8 (IL-8), 11: Interleukin-10 (IL-10), 12: Pulmonary Function Indices (FVC, FEV1), 13: White Blood Cell Count (WBC), 14: C-Reactive Protein (CRP), 15: Clinical Pulmonary Infection Score (CPIS), 16: Procalcitonin (PCT), 17: Soluble Triggering Receptor Expressed on Myeloid Cells-1 (sTREM-1), 18: Sequential Organ Failure Assessment (SOFA) Score, 19: Neutrophil Elastase (NE), 20: Interleukin-1 (IL-1), 21: Natural Killer Cells (NK), 22: Time to Primary Symptom Resolution, 23: Interleukin-2 (IL-2), 24: Soluble Intercellular Adhesion Molecule-1 (sICAM-1), 25: Soluble Urokinase Plasminogen Activator Receptor (suPAR), 26: Duration of Mechanical Ventilation, 27: Length of ICU Stay, 28: Interleukin-13 (IL-13), 29: Systemic Inflammatory Response Syndrome (SIRS), 30: Multiple Organ Dysfunction Score (MODS), 31: Acute Lung Injury Score (ARDS), 32: Oxygenation Index, 33: Pneumonia Severity Index (PSI), 34: Follow-up Mortality Rate, XBCQD: Xuanbai Chengqi decoction, QHD: Qingjin Huatan decoction, QHJP: Qingre Huatan Jiedu prescription, QTD: Qingre Tongfei decoction, XBSXXD: Xie Bai San and Xie Xin decoction, QFCQD: Qing Fei Cheng Qi decoction, QFHTD: Qing Fei Hua Tan decoction, QFTD: Qing Fei Tong Fu decoction, QFXYD: Qing Fei Xiao Yong decoction, SJS: Sheng Jiang San, XFTFD: Xie Fei Tong Fu decoction, XRJDTFD: Xie Re Jie Du Tong Fu decoction, ZNXYQFD: Zi Ni Xuan Yong Qing Fei decoction, SSYHQJWJD: Shen Su Yin He Qian Jin Wei Jing decoction and BNTFYFD: Bai Ni Tong Fu Yi Fei decoction

Meta-analysis outcomes

Recent efficacy: Seventeen out of the twenty-five included studies presented data on the recent efficacy of the combined approach of traditional Chinese medicine and Western medicine in the treatment of SPPHOLP. The cohort involved 768 patients in the experimental group and 742 in the control group. The absence of heterogeneity (p = 0.98, $I^2 = 0\%$) warranted the execution of a meta-analysis using a fixed-effect model. The findings demonstrated a significant

improvement in patient efficacy with the combined treatment when compared to the control group [RR = 1.22,95% CI (1.16,1.27), p<0.00001] (Fig. 3).

TCM symptom score

Fever symptoms: Eleven studies contributed to the fever symptom score, including 450 patients in the experimental group and 452 in the control group. Significant heterogeneity amongst the studies (p<0.00001, $I^2 = 95\%$) necessitated the

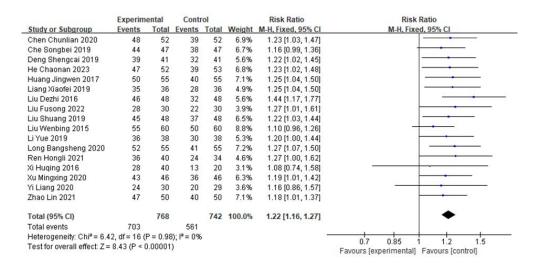


Fig. 3: Meta-analysis of the efficacy of the combination of Chinese and Western medicine in the treatment of SPPHOLP

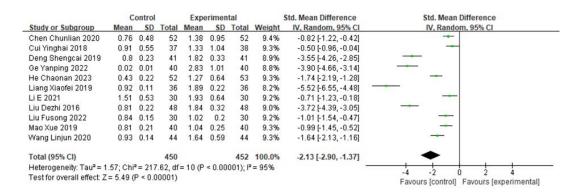


Fig. 4: Meta-analysis of the combined treatment of Chinese and Western medicine in the management of fever symptoms in SPPHOLP

use of a random-effects model. The analysis revealed that the combined treatment of SPPHOLP with Chinese and Western medicines resulted in a significant improvement in fever symptoms and a reduction in fever symptom score [SMD = -2.13, 95% CI (-2.9, -1.37), p<0.00001] (Fig. 4).

Cough symptoms: Twelve studies were considered for the cough symptom scores, encompassing 524 patients in both the experimental and control groups. The large heterogeneity between the studies (p<0.00001, $I^2 = 95\%$) called for the use of a random-effects model. The combined treatment of SPPHOLP with Chinese and Western medicine significantly improved cough symptoms and reduced cough symptom scores [SMD = -2.14, 95% CI (-2.82, -1.46), p<0.00001] (Fig. 5).

Phlegm congestion symptoms: Eleven studies addressed the sputum congestion symptom score. The sample included

471 patients in the experimental group and 473 in the control group. High heterogeneity between studies (p<0.00001, $I^2=97\%$) justified the use of a random-effects model. Compared to the control group, the combination of Chinese and Western medicine significantly improved phlegm congestion symptoms and decreased the phlegm congestion symptom score [SMD=-2.75, 95% CI (-3.71, -1.79), p<0.00001] (Fig. 6).

Shortness of breath symptoms: Ten studies were analyzed for shortness of breath symptom scores, with 413 patients in the experimental group and 414 in the control group. High heterogeneity between studies (p<0.00001, $I^2 = 96\%$) required the use of a random-effects model. The combined treatment of SPPHOLP with Chinese and Western medicine significantly improved shortness of breath symptoms and reduced shortness of breath symptom scores [SMD = -2.78, 95% CI (-3.77, -1.79), p<0.00001] (Fig. 7).

	Expe	Experimental Control						Std. Mean Difference	Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
Chen Chunlian 2020	0.89	0.62	52	1.64	1.27	52	8.6%	-0.74 [-1.14, -0.35]	-		
Cui Yinghai 2018	1.23	1.07	37	2.05	1.62	38	8.5%	-0.59 [-1.05, -0.13]	-		
Deng Shengcai 2019	0.76	0.13	44	1.8	0.24	41	7.6%	-5.39 [-6.33, -4.46]			
Ge Yanping 2022	0.93	0.16	40	3.12	1.13	40	8.3%	-2.69 [-3.30, -2.08]			
He Chaonan 2023	0.79	0.34	52	1.94	0.64	53	8.5%	-2.22 [-2.71, -1.73]	-		
Liang Xiaofei 2019	0.79	0.34	52	1.94	0.64	53	8.5%	-2.22 [-2.71, -1.73]			
Li E 2021	1.47	0.47	30	2.08	0.51	30	8.4%	-1.23 [-1.78, -0.67]			
Liu Dezhi 2016	0.77	0.18	48	1.79	0.25	48	7.9%	-4.65 [-5.43, -3.86]			
Liu Fusong 2022	0.81	0.13	30	0.98	0.17	30	8.4%	-1.11 [-1.65, -0.56]	-		
Long Bangsheng 2020	1.62	0.39	55	2.89	0.43	55	8.4%	-3.07 [-3.63, -2.52]			
Mao Xue 2019	0.85	0.23	40	1.1	0.26	40	8.5%	-1.01 [-1.48, -0.54]	-		
Wang Linjun 2020	1.01	0.32	44	1.62	0.58	44	8.5%	-1.29 [-1.75, -0.83]			
Total (95% CI)			524			524	100.0%	-2.14 [-2.82, -1.46]	•		
Heterogeneity: Tau ² = 1.37; Chi ² = 219.74, df = 11 (P < 0.00001); I ² = 95%											
Fest for overall effect: Z = 6.15 (P < 0.00001)									-4 -2 U 2 4 Favours [control] Favours [experimental]		

Fig. 5: Meta-analysis of the combined treatment of Chinese and Western medicine in the management of cough symptoms in SPPHOLP

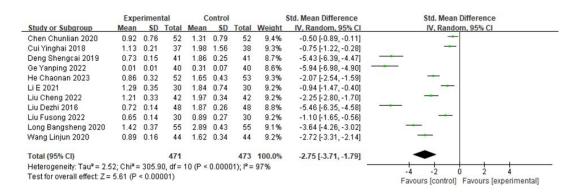


Fig. 6: Meta-analysis of the combined treatment of Chinese and Western medicine in the management of phlegm congestion symptoms in SPPHOLP

Alterations in arterial blood gas

Partial Pressure of Carbon Dioxide (PaCO₂): This analysis incorporates five studies on PaCO₂. Both the experimental and control groups encompassed 243 patients. The studies demonstrated significant heterogeneity (p<0.00001, I^2 = 85%), necessitating the application of a random-effects model. Findings suggested that the amalgamation of Chinese and Western medicinal treatment for SPPHOLP notably lowered the partial pressure of carbon dioxide relative to the control group [SMD = -8.86, 95% CI (-11.50, -6.23), p<0.00001] (Fig. 8).

PaO₂: The analysis incorporated six studies on PaO₂. A total of 283 patients were included in both the experimental and control groups. The heterogeneity amongst studies was high (p<0.00001, $I^2 = 89\%$), thereby, a random-effects model was utilized. Data analysis revealed that the combined therapeutic approach significantly enhanced the partial pressure of blood oxygen in SPPHOLP patients relative to the control group [SMD = 10.90, 95% CI (7.08, 14.71), p<0.00001] (Fig. 9).

APACHE II: A total of seven studies on APACHE II were incorporated, involving 283 patients in the experimental group and 262 in the control group. The studies displayed considerable heterogeneity (p<0.00001, $I^2 = 94\%$), thereby mandating a random-effects model. Results indicated a significant reduction in APACHE II scores following the integrated treatment approach in comparison to the control group [SMD = -3.89, 95% CI (-5.87, -1.92), p = 0.0001] (Fig. 10).

Comparison of the levels of various inflammatory factors

TNF-\alpha: Ten studies on TNF- α , involving 403 experimental group patients and 397 control group patients, were included. High heterogeneity was detected amongst the studies (p<0.00001, $I^2=93\%$), hence a random-effects model was utilized. The analysis revealed a significant reduction in the level of TNF- α in SPPHOLP patients following the combined Chinese and Western medicinal treatment relative to the control group [SMD=-2.53, 95% CI (-3.22, -1.84), p<0.00001] (Fig. 11).

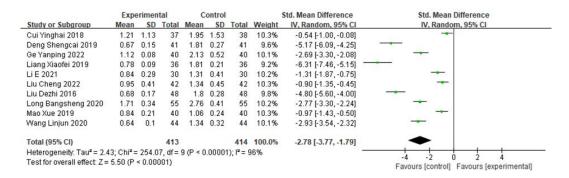


Fig. 7: Meta-analysis of the symptoms of shortness of breath in SPPHOLP treated with combination of Chinese and Western medicine

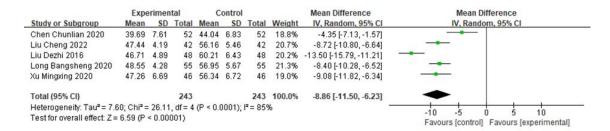


Fig. 8: Meta-analysis of PaCO₂ reduction in SPPHOLP patients via combined Chinese and Western medicinal therapies

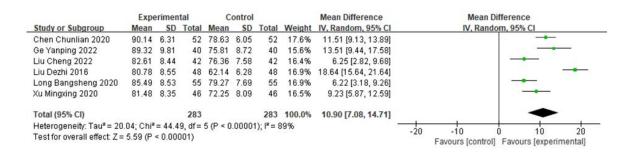


Fig. 9: Meta-analysis of combined Chinese and Western medicinal therapies in enhancing PaO₂ in SPPHOLP patients

IL-6: This analysis includes 11 studies on IL-6, involving 439 patients in the experimental group and 433 in the control group. The high heterogeneity amongst studies (p<0.00001, $I^2 = 95\%$) led to the application of a random-effects model. The combined therapeutic approach significantly reduced IL-6 levels in SPPHOLP patients compared to the control group [SMD = -4.30, 95% CI (-5.34, -3.27), p<0.00001] (Fig. 12).

IL-10: Four studies on IL-10, involving 165 patients in the experimental group and 166 in the control group, were included. High heterogeneity was detected between studies (p = 0.03, $I^2 = 66\%$), thereby necessitating the use of a

random-effects model. The combined Chinese and Western medicinal treatment significantly reduced IL-10 levels in SPPHOLP patients relative to the control group [SMD = -1.71, 95% CI (-2.15, -1.27), p<0.00001] (Fig. 13).

WBC: Six studies on WBC were included, encompassing 254 patients in the experimental group and 235 in the control group. High heterogeneity was detected (p<0.00001, $I^2 = 93\%$), hence a random-effects model was employed. The combined therapeutic approach significantly reduced WBC levels in SPPHOLP patients compared to the control group [SMD = -1.37, 95% CI (-2.13, -0.60), p = 0.0004] (Fig. 14).

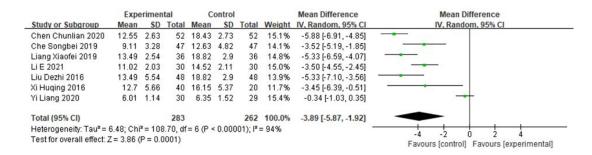


Fig. 10: Meta-analysis of APACHE II score reduction in SPPHOLP patients via combined Chinese and Western medicinal therapies

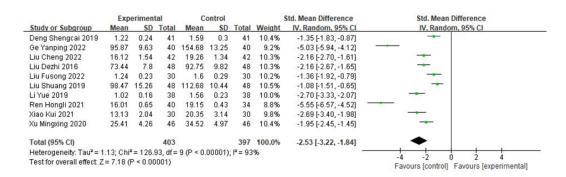


Fig. 11: Meta-analysis of combined Chinese and Western medicine therapies to reduce TNF- α levels in patients with SPPHOLP

	Expe	eriment	al	C	ontrol			Std. Mean Difference	Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
Deng Shengcai 2019	51.47	5.33	41	67.9	6.44	41	9.5%	-2.75 [-3.36, -2.14]	-		
Ge Yanping 2022	125.46	21.35	40	212.53	13.48	40	9.2%	-4.83 [-5.71, -3.95]	-		
Liu Cheng 2022	25.75	1.31	42	29.72	1.59	42	9.5%	-2.70 [-3.30, -2.10]	*		
Liu Dezhi 2016	5.73	0.63	48	12.61	1.94	48	9.3%	-4.73 [-5.52, -3.94]	-		
Liu Fusong 2022	14.52	5.29	30	27.85	6.34	30	9.4%	-2.25 [-2.91, -1.60]	+		
Li Yue 2019	10.32	0.68	38	18.48	1.56	38	8.7%	-6.71 [-7.90, -5.53]	-		
Mao Xue 2019	23.05	5.28	40	51.3	6.79	40	9.2%	-4.60 [-5.45, -3.75]			
Ren Hongli 2021	14.86	0.32	40	20.8	0.6	34	6.9%	-12.52 [-14.64, -10.40]			
Nang Linjun 2020	23.01	6.14	44	50.73	8.75	44	9.4%	-3.64 [-4.33, -2.94]	+		
Kiao Kui 2021	78.97	6.23	30	107.17	9.12	30	9.2%	-3.56 [-4.40, -2.73]	-		
Xu Mingxing 2020	76.13	8.26	46	89.37	9.28	46	9.6%	-1.49 [-1.96, -1.03]	*		
Total (95% CI)			439			433	100.0%	-4.30 [-5.34, -3.27]	•		
Heterogeneity: Tau ² = 2	2.84; Chi2:	= 212.3	9, df = 1	0 (P < 0.	00001);	$1^2 = 95$	%		-10 -5 0 5 10		
est for overall effect: Z = 8.15 (P < 0.00001)									-10 -5 0 5 10 Favours [control] Favours [experimental		

Fig. 12: Meta-analysis of combined Chinese and Western medicine therapies to reduce IL-6 levels in SPPHOLP patients

CPR: This analysis incorporated nine studies on CPR, involving 387 experimental group patients and 362 control group patients. Owing to high heterogeneity (p<0.00001, $I^2 = 95\%$), a random-effects model was applied. The combined treatment approach notably reduced the level of CPR in SPPHOLP patients relative to the control group [SMD = -1.93, 95% CI (-2.70, -1.15), p<0.00001] (Fig. 15).

PCT: The meta-analysis incorporated six studies that examined PCT levels. These studies included a total of 264 patients in the experimental group and 260 in the control group. Owing to significant heterogeneity amongst the

studies (p = 0.003, I^2 = 72%), a random-effects model was adopted. Our analysis revealed that, in comparison to the control group, the amalgamation of traditional Chinese medicine and Western medicine therapies significantly decreased PCT levels in patients with SPPHOLP [SMD = -1.95, 95% CI (-2.35, -1.54), p<0.00001] (Fig. 16).

Comparison of immune function indexes

CD4+ **and CD8**+: Five studies that examined CD4+ and CD8+ indices were considered for this meta-analysis, comprising of 201 patients in both the experimental and control groups. The analysis yielded that the combined Chinese and Western

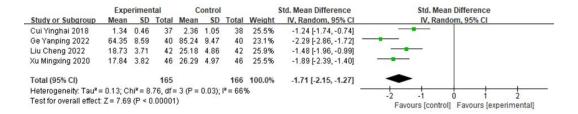


Fig. 13: Meta-analysis of combined Chinese and Western medicine therapies to reduce IL-10 levels in patients with SPPHOLP

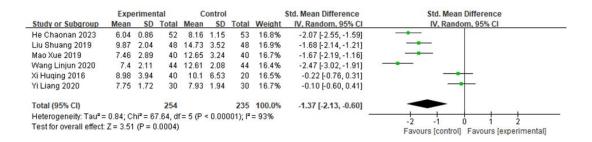


Fig. 14: Meta-analysis of the reduction of WBC levels in patients with SPPHOLP by combined Chinese and Western medicine therapies

	Exp	eriment	tal	(Control			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean SD Total		Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Chen Chunlian 2020	30.04	5.34	52	41.43	5.92	52	11.3%	-2.01 [-2.48, -1.53]	
Deng Shengcai 2019	6.08	1.23	41	8.14	1.55	41	11.3%	-1.46 [-1.95, -0.97]	
He Chaonan 2023	11.03	1.42	52	19.54	2.61	53	10.8%	-4.01 [-4.68, -3.34]	
Liu Fusong 2022	36.1	9.16	30	48.22	10.58	30	11.1%	-1.21 [-1.76, -0.66]	-
Liu Shuang 2019	8.77	2.59	48	10.14	1.43	48	11.4%	-0.65 [-1.06, -0.24]	-
Mao Xue 2019	40.37	7.08	40	70.97	9.02	40	10.7%	-3.74 [-4.48, -3.00]	
Ren Hongli 2021	18.6	7.33	40	26.1	6.4	34	11.3%	-1.07 [-1.56, -0.58]	
Wang Linjun 2020	40.21	8.56	44	72.68	12.34	44	11.0%	-3.03 [-3.65, -2.41]	-
Xi Huqing 2016	54.4	56.17	40	74.3	53.83	20	11.2%	-0.35 [-0.90, 0.19]	-
Total (95% CI)			387			362	100.0%	-1.93 [-2.70, -1.15]	•
Heterogeneity: Tau ² = 1	.34; Chi	= 152.	38, df=	8 (P < 1	0.00001); I ² = 9	5%		-
Test for overall effect: Z	= 4.85 (P < 0.00	0001)						Favours [control] Favours [experimental]

Fig. 15: Meta-analysis of combined Chinese and Western medicine therapies to reduce CPR levels in patients with SPPHOLP

medicine therapies led to a statistically significant increase in CD4⁺ activity [SMD = 1.23, 95% CI (0.71, 1.74), p<0.00001], as well as a noteworthy decrease in CD8⁺ level [SMD = -1.48, 95% CI (-1.70, -1.26), p<0.00001] (Fig. 17 and 18).

CD4+/CD8+: Three studies concerning the CD4+/CD8+ ratio were included in the meta-analysis, which covered 141 patients in both the experimental and control groups. Owing to a high degree of heterogeneity amongst the studies (p<0.0001, $I^2 = 90\%$), a random-effects model was utilized. The combined Chinese and Western medicine treatment for SPPHOLP led to a statistically significant elevation in CD4+/CD8+ ratios when compared to the control group [SMD = 1.75, 95% CI (0.85, 2.65), p = 0.0001] (Fig. 19).

Comparison of lung function indicators

FVC: Four studies scrutinizing FVC were incorporated into the meta-analysis, which encompassed 170 patients in the experimental group and 171 in the control group. Given the high heterogeneity amongst the studies (p<0.0001, $I^2 = 88\%$), a random-effects model was employed. Our analysis demonstrated that the integrated Chinese and Western medicine therapy significantly improved FVC levels in patients with SPPHOLP compared to the control group [SMD = 1.12, 95% CI (0.45, 1.79), p = 0.001] (Fig. 20).

FEV: Five studies investigating FEV were included in the meta-analysis, with a total of 220 patients in the experimental group and 221 in the control group. Given the negligible heterogeneity amongst these studies (p = 0.40, $l^2 = 2\%$), a

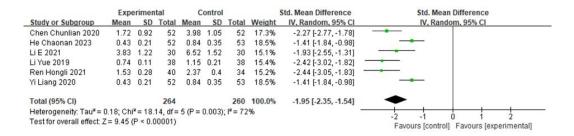


Fig. 16: Meta-analysis of the combination of Chinese and Western medicine therapy for reducing the PCT levels of patients with SPPHOLP

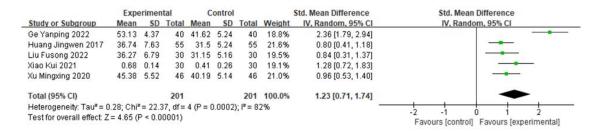


Fig. 17: Meta-analysis of CD4+ activity

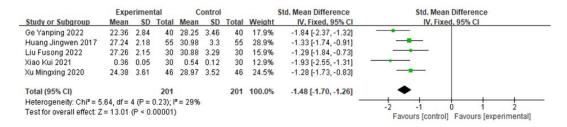


Fig. 18: Meta-analysis of CD8+ activity

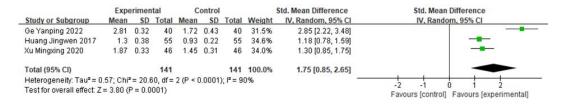


Fig. 19: Meta-analysis of CD4+/CD8+ levels

fixed-effect model was adopted. The combined Chinese and Western medicine therapy was found to significantly enhance FEV levels in SPPHOLP patients in comparison to the control group [SMD = 0.74, 95% CI (0.54, 0.93), p<0.00001] (Fig. 21).

Subgroup analysis: A subgroup analysis was conducted using the cough index from the TCM symptom score. The remedies QFCQD, QFHTD, QFTFD, QFXYD and QHD were employed in

the relevant studies for treating the disease. The therapeutic strategies of lowering qi to pass through the bowels, harmonizing the ascent and descent of body gases, clearing the lungs and resolving phlegm formed the basis for subgroup categorization.

The literature revealed 6 articles, 4 articles and 2 articles focusing on the strategy of lowering qi and promoting the internal organs and 2 articles on harmonizing the ascent and descent of body gases. This indicates a statistically

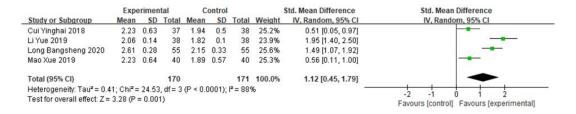


Fig. 20: Meta-analysis of the combination of Chinese and Western medicine therapies to reduce the level of FVC in patients with SPPHOLP

	Exp	eriment	tal	(Control			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Cui Yinghai 2018	82.84	9.67	37	78.12	9.23	38	17.7%	0.49 [0.03, 0.95]	-
i Yue 2019	2.43	0.35	38	2.04	0.36	38	16.0%	1.09 [0.60, 1.57]	2
ong Bangsheng 2020	85.79	10.39	55	79.11	10.32	55	25.5%	0.64 [0.26, 1.02]	-
Mao Xue 2019	64.25	9.56	40	56.03	8.19	40	17.6%	0.91 [0.45, 1.38]	-
Zhao Lin 2021	66.63	14.02	50	58.01	12.23	50	23.1%	0.65 [0.25, 1.05]	- • -
Total (95% CI)			220			221	100.0%	0.74 [0.54, 0.93]	•
Heterogeneity: Chi ² = 4.0	8, df = 4	(P = 0.4)	$0); I^2 =$	2%				-	1 05 1 05 1
Test for overall effect: Z = 7.46 (P < 0.00001)									-1 -0.5 0 0.5 1 Favours [control] Favours [experimental]

Fig. 21: Meta-analysis of the reduction of FEV levels in patients with SPPHOLP by combined Chinese and Western medicine therapies

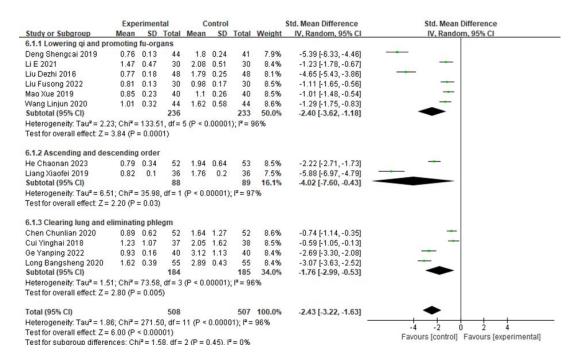


Fig. 22: Subgroup analysis: Therapeutic efficacy among the three subgroups between the control and experimental groups

significant disparity in therapeutic efficacy among the three subgroups between the control and experimental groups (Fig. 22).

Publication bias analysis: A funnel plot was created to assess the potential publication bias of the included studies, using

the standard error of RR and logRR as variables. The results, displayed in Fig. 23, revealed symmetry in the funnel plot, indicating minimal publication bias. This was further confirmed by Egger's test, which yielded p=0.326>0.05, suggesting no significant publication bias (Table 3 and Fig. 24).

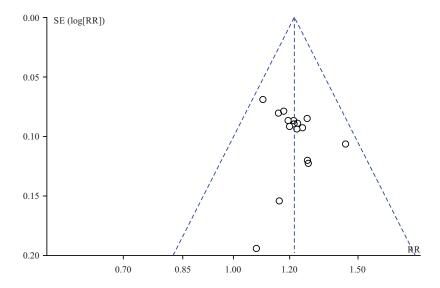


Fig. 23: Treatment efficacy funnel plot

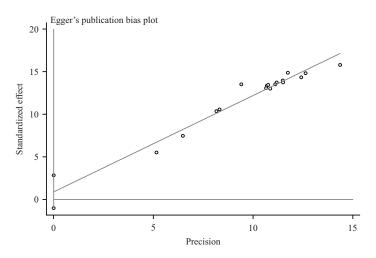


Fig. 24: Treatment efficacy Eggers' bias plot

Table 3: Egger's test plot for publication bias analysis

					95% Conf	f. Interval
Std_Eff	Coefficient	Standard error	t	P> t		
Slope	1.129154	0.0852588	13.24	0.000	0.947429	1.310879
Bias	0.9211777	0.9069587	1.02	0.326	-1.011959	2.854314

DISCUSSION

The current study revealed that the adjunctive TCM regimen significantly improved outcomes in SPPHOLP compared to standard Western Medicine treatment. Severe pneumonia, a prevalent infectious disease with a poor prognosis, poses a significant public health threat due to its rapid progression and high mortality rates⁷. Over the past decade, the primary treatment for severe pneumonia has

involved anti-infection measures and supportive therapies, which have generally yielded good results. However, the emergence of multidrug-resistant bacteria has negatively impacted the effectiveness of these treatments. Consequently, the search for alternative therapeutic options has become a focal point of recent clinical research. Current findings suggested that, while traditional treatment methods remain in use, emerging therapies may offer greater potential in improving outcomes, contrasting with the alternative

treatment strategies proposed in existing literature. This highlights the necessity for further exploration and validation of new treatment approaches.

Although there are no explicit references to severe pneumonia in ancient texts, the symptoms of this illness are described in the "Huangdi Neijing" (Yellow Emperor's Classic of Internal Medicine). Phrases such as "patients with lung disease wheeze, cough and suffer from shoulder and back pain, sweating the deficient are short of breath" and "those with lung fever loathe wind and cold, have a yellow tongue and body heat; when the heat is intense, they wheeze and experience pain in the chest and back" represent these references⁸. The disease mechanism, identified through the analysis of a multitude of literature, primarily involves deficiency and excess: Deficiency refers to depleted vital energy (Qi), while excess denotes the accumulation of phlegm, heat, toxins and blood stasis.

Therefore, in traditional Chinese medicine, the treatment of severe pneumonia often involves clearing heat, dissolving phlegm and promoting lung and bowel function. These methods aim to control the inflammatory response, alleviate symptoms such as coughing, breathlessness and fever, thereby improving the treatment's effectiveness. Commonly used medicines include *Pinellia ternata* (Ban Xia), *Scutellaria baicalensis* (Huang Qin), almonds, *Citrus reticulata* (Chen Pi), *Magnolia officinalis* (Hou Po), *Rheum palmatum* (Da Huang), *Trichosanthes kirilowii* (Gua Lou), *Citrus aurantium* (Zhi Shi), *Rheum palmatum* (Da Huang) and *Verbena officinalis* (Ma Bian Cao)⁹⁻¹³.

Pinellia ternata, with its warm, pungent and dry properties, has a notable effect on transforming phlegm, making it a crucial medication for treating phlegm-related conditions. It is often paired with Scutellaria baicalensis, the bitterness of which dries up the phlegm in the lungs and the coldness of which clears heat from the lungs. Together, they treat both the spleen and the lungs, thereby preventing the creation of phlegm while clearing the organ that stores it. Modern pharmacology shows that Pinellia ternata contains alkaloids, organic acids and amino acids. Among them, alkaloids notably suppress coughs and demonstrate antitumor and antiemetic effects⁹. Baicalein found in Scutellaria baicalensis can down-regulate inflammatory indicators, leading to an anti-inflammatory effect. It also regulates immunity and shows antibacterial and antiviral properties¹⁰.

To treat phlegm, it is necessary to first reduce its heat and for treating heat, it's essential to ensure smooth Qi flow. Thus, *Citrus reticulata* is often used to regulate Qi, strengthen the spleen and dry dampness to alleviate the condition. The compound 'hesperidin' found in *Citrus reticulata* can inhibit

lipopolysaccharide-induced inflammatory responses by suppressing NF- κ B activation, thereby protecting against acute lung injury¹¹.

Furthermore, due to the interconnectedness of the lung and the large intestine in traditional Chinese medicine, maintaining normal bowel function relates to the proper downward flow of lung Qi. If the lung Qi is properly directed downwards, then bowel movements are regular. However, if phlegm and heat obstruct the lungs, symptoms such as constipation and abdominal distension can occur. Therefore, when treating severe pneumonia, in addition to clearing the lungs and resolving phlegm, it is also necessary to ensure the smooth flow of Qi in the organs.

Medicines such as Magnolia officinalis are used to dry dampness, resolve phlegm and relieve fullness. Citrus aurantium is used to break up Qi, dissolve phlegm and open up the chest, while the bitter and cold properties of Rheum palmatum help purge, remove heat and detoxify the blood. When used together, they form the traditional medicine "Xiao Cheng Qi Tang", helping regulate Qi flow in the body, adjust water pathways, disperse pathogens and remove accumulation. This combination of medicines achieves a balance between clearing heat, resolving phlegm, reducing heat and regulating bowel movements¹². Verbena officinalis is used to clear heat and detoxify, resolve abscesses and drain pus, dispel blood stasis and relieve pain, in a similar way to how a lung infection would be treated. This helps renew the system by removing the old and bringing in the new¹³.

This study performed a meta-analysis on 25 published clinical trials investigating the integrated treatment of traditional Chinese and Western medicine in severe pneumonia cases characterized by phlegm-heat obstructing the lung, with 1046 trial subjects and 1070 control subjects 14-38. The included studies used various traditional Chinese medicine (TCM) formulas like Qingfei Chengqi Decoction, Qingfei Hua Tan Decoction, Qingfei Tongfu Decoction, Qingfei Xiao Ying Decoction, Shengjiang San and Xuanbai Chengqi Decoction, demonstrating promising clinical effects.

The meta-analysis results revealed that, compared to the use of Western medicine alone, the integrated approach significantly enhanced therapeutic outcomes [RR = 1.22 (1.16, 1.27)], alleviated fever [SMD = -2.13 (-2.9, -1.37)], reduced coughing [SMD = -2.14 (-2.82, -1.46)], improved phlegm blockage symptoms [SMD = -2.75 (-3.71, -1.79)] and eased shortness of breath [SMD = -2.78 (-3.77, -1.79)]. It also statistically significantly reduced the partial pressure of carbon dioxide [SMD = -8.86 (-11.50, -6.23)], while increasing the

partial pressure of oxygen [SMD = 10.90 (7.08, 14.71)], drastically lowering the APACHE II score [SMD = -3.89 (-5.87, -1.92)] and significantly reducing the levels of TNF- α [SMD = -2.53 (-3.22, -1.84)], IL-6 [SMD = -4.30, (-5.34, -3.27)], IL-10 [SMD = -1.71 (-2.15, -1.27)], WBC [SMD = -1.37 (-2.13, -0.60)], CPR [SMD = -1.93 (-2.70, -1.15)] and PCT [SMD = -1.95 (-2.35, -1.54)]. Furthermore, the combined therapy enhanced CD4+ activity [SMD = 1.23 (0.71, 1.74)], decreased CD8+ activity [SMD = -1.48 (-1.70, -1.26)], elevated the CD4+/CD8+ ratio [SMD = 1.75 (0.85, 2.65)] and improved lung function FVC [SMD = 1.12 (0.45, 1.79)] and FEV levels [SMD = 0.74 (0.54, 0.93)].

This meta-analysis mostly showed high heterogeneity, possibly due to the use of various scales, different TCM compounds and divergent conventional Western treatments.

There are certain limitations in this study: (1) Each study used the integrated TCM and Western medicine approach, but biases could arise due to variations in chosen antibiotics, daily care approaches, treatment duration and prescriptions; (2) Regarding the methodological quality of the studies, the largest study had a sample size of 60 and the smallest one, 20. These were all single-center, small-scale studies, with limited reporting of mortality rates, follow-up rates and drug side effects; (3) None of the studies mentioned blinding, potentially causing bias in implementation and outcome evaluation; (4) Many studies only mentioned "random grouping" without specifying the randomization method, introducing a risk of selection bias; (5) While subgroup analysis was used to reduce heterogeneity, significant heterogeneity was still found in aspects like TCM symptom scores, arterial blood gas analyses and APACHEII scores, potentially related to the use of different TCM formulas, patient age, disease duration and variations in scales and (6) Number of studies and patient cases included was relatively small and all originated from China, limiting the global representativeness.

CONCLUSION

This meta-analysis on the combined treatment of severe pneumonia cases characterized by phlegm-heat obstructing the lung with TCM and Western medicine revealed that this integrative approach can effectively improve therapeutic outcomes, alleviate clinical symptoms, decrease the partial pressure of carbon dioxide, enhance the partial pressure of oxygen, reduce inflammatory reactions and augment immune function levels. However, due to the low quality of the included studies, there's a need for more high-quality,

multi-center, large-scale studies to provide more robust evidence-based medical data for clinical practice, increasing the argument's credibility and providing a theoretical basis for promoting TCM therapies.

SIGNIFICANCE STATEMENT

This meta-analysis evaluates the combined use of traditional Chinese medicine (TCM) and Western medicine for treating severe pneumonia of phlegm-heat obstructing lung pattern (SPPHOLP). The findings revealed that integrating TCM with standard Western treatments significantly enhances overall efficacy, alleviates symptoms such as fever, cough and dyspnea and improves key physiological and biochemical markers, including reduced carbon dioxide partial pressure and increased oxygen levels. Additionally, this combined approach reduces inflammatory markers and enhances immune function, suggesting a comprehensive benefit beyond conventional methods alone. However, the variability in study quality underscores the need for further rigorous research to substantiate these promising results and refine clinical practice guidelines.

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