



GUIDELINE OPEN ACCESS

Clinical Application Guideline of Combination With Traditional Chinese Medicine and Western Medicine in the Prevention and Treatment of Chronic Obstructive Pulmonary Disease (2024)

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ABSTRACT

Aim: Chronic Obstructive Pulmonary Disease (COPD) is a common chronic airway disease that can lead to decreased lung function in patients. It places a heavy economic burden on patients and society. Traditional Chinese medicine (TCM) and Western medicine have played important roles in managing COPD. We aimed to develop an evidence-based guideline for treating COPD with Chinese and Western Medicine.

Methods: We formed a guideline panel of multidisciplinary experts. The clinical questions were identified based on two rounds of issue solicitation and expert demonstration. We searched the literature for direct evidence on the management of COPD

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and assessed its certainty-generated evidence using the grading of recommendations, assessment, development, and evaluation (GRADE) approach. The recommendations and their strengths were formulated using the Delphi method. **Results:** Our guideline covers aspects of the diagnosis and treatment of COPD such as principles and commonly used medications for both traditional Chinese medicine and Western medicine, complications, and the high-risk populations. 9 clinical questions and 35 recommendations were identified, which covered the combinations of YuPingFeng granule, Buzhong Yiqi decoction, Gushen Dingchuan Pill, Bufei Huoxue Capsules, Runfei cream, Bailing Capsule, Tanyin Pills, etc., and nonpharmacological therapy of TCM such as combined acupoint application, electroacupuncture, and Chinese exercise techniques (Tai Chi, Baduanjin), etc. Recommendations were either high or low or in the form of ungraded consensus-based statements.

Conclusions: This is a comprehensive and systematic evidence-based guideline and we hope it can systematically and effectively guide clinicians in managing COPD and improve overall medical care.

1 | Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a heterogeneous lung disease characterized by chronic respiratory symptoms (dyspnea, cough, sputum, acute exacerbations) due to airway abnormalities (bronchitis, bronchiectasis) and/or alveolar abnormalities (emphysema) that lead to persistent and progressive airflow obstruction [1]. It has high prevalence, disability and mortality rates, low public awareness rate, and early diagnosis for treatment rate [2, 3]. It also places a heavy social economic burden on patients [4, 5]. Domestic and international studies have made advancements in the diagnosis and management of COPD. However, the resolution of clinical symptoms and control of acute exacerbation risk in some patients are still individualized due to the high heterogeneity of the disease. Accumulating research evidence confirms the effectiveness and safety of combined Chinese and Western medical treatments in the prevention and treatment of COPD. Western medicine emphasizes precision diagnosis and treatment, while Chinese medicine follows a holistic concept and applies evidence-based therapy. In combination, Traditional Chinese Medicine (TCM) and conventional Western medicine complement their strengths and weaknesses to further improve the quality of life of patients, alleviate respiratory distress, reduce acute exacerbations, and has a better safety profile.

To further promote the standardized diagnosis and treatment of COPD by combining Chinese and Western medicine approaches to maximize their complementary advantages. The “Clinical Guidelines for the Prevention and Treatment of COPD by Combining Chinese and Western Medicines” has been developed. This project was set up by the State Administration of Traditional Chinese Medicine, organized by the Chinese Association of Traditional Chinese Medicine, and led by the West China Hospital of Sichuan University and the First Affiliated Hospital of Anhui University of Traditional Chinese Medicine. The guidelines adhere to evidence-, consensus-, and experience-based principles and are based on existing guidelines or consensus of Chinese medicine and Western medicine. They are oriented by clinical problems and combine evidence from Chinese and Western medicine for the treatment of COPD. Drawing on the experience of experts, a multidisciplinary team was formed to develop these guidelines. Through extensive research on clinical issues, evidence search and literature analysis, and repeated discussions at expert group meetings, the guideline project team

aims to enlighten clinicians about clinically feasible combined Chinese and Western medicine protocols to improve the overall prevention and treatment of COPD. The guideline has an English-Chinese comparison table for abbreviations of proper nouns for reader convenience (Table 1).

2 | Scope

This guideline is intended to improve the treatment and outcomes of patients who have received a confirmed diagnosis of COPD. It is targeted at medical practitioners at all levels of health-care institutions, including clinical practitioners of Respiratory and Critical Care Medicine/Pulmonary Diseases and related disciplines (including integrative medicine practitioners, TCM practitioners, and Western medicine practitioners) for reference for the diagnosis and treatment of COPD. It can also be used as a reference by relevant nursing staff and pharmacists.

This guideline has been bilingually registered on the Practice guideline REgistration for transPAREncy (PREPARE) (<http://guidelines-registry.org/>) with number PREPARE-2023CN387 on March 6, 2024.

3 | Guideline Development Process

3.1 | Construction of Clinical Problems and Identification of Outcome Indicators

Under the guidance of methodological experts, the first batch of questions was solicited using an open-ended questionnaire research method. The opinions on and suggestions of clinical questions and outcome indicators of 19 clinical experts with senior titles in Chinese and Western medicine from 18 provinces, municipalities, and autonomous regions were collected. The listed clinical problems were supplemented by the discussion opinions of the expert group. The clinical problems were deconstructed according to the PICO principles, and 20 of them were selected. Through the second round of questionnaire research, 43 Chinese and Western medicine experts from 15 provinces, municipalities, and autonomous regions voted for the initially formulated clinical problems according to the importance of the recommendation after they had summarized, categorized, standardized, and analyzed. This ensured that the key clinical

TABLE 1 | English-Chinese comparison of abbreviations for proper nouns.

Abbreviations	Full name
ABG	Arterial blood gas
AECOPD	Acute Exacerbation of Chronic Obstructive Pulmonary Disease
BORG	Borg scale
CAT	COPD Assessment Test
CASA-Q	Cough And Sputum Assessment Questionnaire
CCQ	COPD clinical questionnaire
COPD	Chronic Obstructive Pulmonary Disease
CI	Confidence interval
CRP	C-reactive protein
DPI	Dry Powder Inhale
EOS	Eosinophil
GSRS	Gastrointestinal Symptom Rating Scale
HR	Heart rate
ICS	Inhaled corticosteroids
LABA	Long acting β 2-agonists
LAMA	Long -acting muscarinic antagonist
MDI	MDI quantitative inhaler
mMRC	Modified British Medical Research Council
6MWT	6-min walking distance
MD	Mean difference
PaO ₂	Partial pressure of oxygen
PaCO ₂	Partial pressure of carbon dioxide
PCT	Procalcitonin
RR	Relative risk
RR	Respiratory rate
SABA	Short-acting β 2-agonists
SABD	Short-acting bronchodilators
SAMA	Short-acting muscarinic antagonist
SaO ₂	Oxygen saturation
SE	Standard error
SGRQ	St. George's Respiratory Questionnaire
SMD	Standard mean difference
SMI	Soft mist inhalation device
VAS	Visual Analogue Scale

problems had been optimally captured. Based on this, nine clinical problems were identified for inclusion in the study. At the same time, a pre-search of the literature was conducted, and the outcome indicators for each clinical question (St. George's Respiratory Questionnaire (SGRQ), dyspnea questionnaire (Modified British Medical Research Council, mMRC), 6-min walking distance (6MWT), COPD Assessment Test [6], and acute exac-

erbations/exacerbations and cough and sputum remission time, among others) and adverse reaction reports were summarized. The list of feasible endpoints was identified through a combination of online and offline expert meetings. The group evaluated and graded the importance of the outcome indicators and scored them on a scale of 1–9. Scores of 7–9 indicated that the outcome indicator plays a vital role in clinical decision-making, scores of 4–6 indicated that the outcome indicator was important, and scores of 1–3 indicated that the outcome indicator was unimportant. Finally, the guideline expert group evaluated and revised the clinical questions and outcome indicators and determined those to be included in the guideline systematic evaluation (Table 2).

3.2 | Evidence Retrieval, Assessment, and Synthesis

3.2.1 | Literature Search

A comprehensive search strategy and inclusion and exclusion criteria were established based on the clinical questions. Databases such as CNKI, VIP, Wanfang Data, SinoMed, PubMed, Embase, and the Cochrane Library and relevant guidelines, textbooks, and monographs were searched.

3.2.1.1 | Search Strategy and Period. A combination of subject terms and free-text keywords was used, with adjustments for each specific database. The final search strategies were determined after several preliminary searches. All references were imported into NoteExpress software for management.

The search period spanned from the inception of each database until February 2024.

3.2.1.2 | Search Terms. The disease-related search terms included standardized Western medical terms from the International Classification of Diseases Code-11 (ICD-11) and their clinical synonyms (such as COPD, AECOPD, COAD, Chronic Obstructive Pulmonary Disease, Acute Exacerbation of Chronic Obstructive Pulmonary Disease, Airflow Obstructions, Chronic, Chronic Obstructive Airway Disease, Chronic Obstructive Lung Disease, and Chronic Airflow Obstructions, among others) and corresponding TCM terms and clinical names (such as “chuan zheng” (dyspnea syndrome), “fei zhang” (lung distension/lung bloating), “ke sou” (cough), and “chuan bing” (dyspnea disease), among others).

The intervention-related search terms included, but were not limited to, Traditional Chinese Medicine, integrated Chinese and Western medicine, traditional medicine, Chinese herbal, Chinese patent medicine, integrative medicine, alternative therapies, complementary and alternative medicine, external therapies, auricular points, applications, “Dong Bing Xia Zhi” (treating winter diseases in summer), acupuncture, moxibustion, tuina (Chinese therapeutic massage), “Liu Zi Jue” (Six Healing Sounds), “Ba Duan Jin” (Eight Brocades), Tai Chi, pulmonary rehabilitation, Medicine Chinese Traditional, Traditional Chinese Medicine, Chinese Medicine, Chinese Herbal Medicine, and Chinese Patent Medicine.

TABLE 2 | Summary of Clinical Problems in the Combination Prevention and Treatment of COPD with TCM and Western Medicine.

Clinical questions	Outcome indicators		
	Critical 7–9	Important 4–6	Not important 1–3
Stable phase			
1. Can the integration of TCM therapies further enhance the quality of life of patients with COPD who are stable and are receiving conventional Western medical treatment?	SGRQ score	CAT score	
2. Can the integration of TCM therapies effectively address persistent dyspnea or exercise intolerance in patients with stable COPD who have not responded adequately to conventional Western medical treatment?	mMRC; 6MWT	BORG score	TCM syndrome score
3. Can the integration of TCM treatment reduce the frequency of acute exacerbations among patients with COPD who still experience them after conventional Western medical treatment?	Number of acute exacerbations within 1 year; acute exacerbation rate within 1 year	Risk of acute exacerbation in 1 year; duration of acute exacerbation within 1 year; interval between acute exacerbations; interval between first acute exacerbation	
4. Can patients with stable COPD benefit from the use of TCM external therapies and nonpharmacological interventions?	SGRQ score; mMRC; 6MWT; number of acute exacerbations within 1 year; acute exacerbation rate within 1 year	CAT; BORG; risk of acute exacerbation in 1 year; duration of acute exacerbation within 1 year; interval between acute exacerbations; interval between first acute exacerbation	TCM syndrome score
Acute exacerbation period			
5. Can integrating TCM treatment effectively improve the clinical symptoms of patients with acute exacerbation of COPD receiving conventional Western medical treatment?	Cough and sputum relief time	Breathing relief time; CAT score; mMRC score	Fever; CASA-Q cough symptom difference
6. Is it possible to reduce the duration of antibiotic use in patients with AECOPD who are receiving conventional Western medical treatment combined with Chinese medicine?	Duration of use of antibiotics		TCM syndrome score
7. For patients with AECOPD receiving conventional Western medical treatment, can integrating Chinese medical treatment shorten the duration of hospitalization?	Average hospitalization days		
8. For patients with COPD combined with respiratory failure, is there a benefit of integrating TCM therapy?	PaO ₂ ; PaCO ₂	Invasive ventilation time; total mechanical ventilation time	Duration of ICU stay; total length of hospital stay
9. For patients with AECOPD combined with gastrointestinal dysfunction, can combined Chinese medicine improve gastrointestinal dysfunction?	GSRS score	Abdominal distension score; constipation score	

SGRQ, St. George's Respiratory Questionnaire; CAT, COPD Assessment Test; mMRC, Improved British Medical Research Council Dyspnea Questionnaire; 6MWT, 6-min walking test; BORG, Borg rating; CASA-Q, Cough and Phlegm Assessment Questionnaire; PaO₂, arterial oxygen partial pressure; PaCO₂, arterial partial pressure of carbon dioxide; GSRS, Gastrointestinal Symptom Rating Scale.

The study type-related search terms included, but were not limited to, Randomized Controlled Trial, Meta-Analysis, and Systematic Reviews.

3.2.1.3 | Inclusion Criteria. The criteria for inclusion were based on the PICOS framework: P (Patients): We focused on individuals diagnosed with COPD, encompassing both acute exacerbation and stabilization phases. The study was inclusive and did not discriminate based on gender, geographical location, ethnicity, origin, or the duration of the disease. I (Interventions): The interventions under consideration ranged from single-use TCM to combinations of TCM and standard Western treatments, as well as specialized TCM therapies such as acupuncture, moxibustion, and acupoint applications. C (Comparisons): The items compared included single Western medicine or standard Western treatment and placebo or blank control. O (Outcomes): Study outcomes included at least one of the key outcome indicators: number of acute exacerbations, SGRQ score, mMRC dyspnea score, 6MWT, TCM syndrome score (e.g., cough, sputum, dyspnea, etc.), TCM single syndrome score, duration of antibiotic use, average hospitalization, or Gastrointestinal Symptom Rating Scale (GSRS), among others. S (Study Design): We included randomized controlled trials, systematic reviews, and meta-analyses in our study. The language of the studies was limited to Chinese and English.

3.2.1.4 | Exclusion criteria. The exclusion criteria were as follows: studies based on identical clinical data; studies with a treatment duration of less than 8 weeks for the stabilization phase of COPD; studies with changes to classical Chinese formula; nonrandomized studies or those employing incorrect statistical methods; studies for which full texts were not accessible or relevant data could not be extracted; and studies published by hospitals below the county level.

3.2.2 | Literature Screening and Data Extraction

Literature management was conducted using NoteExpress software. After removing duplicates, preliminary screening and full-text review were performed, focusing on guidelines, consensus statements, systematic reviews, and original research. Two researchers independently screened the titles, abstracts, and full texts in stages according to the inclusion and exclusion criteria. The final selection of studies was confirmed after cross-checking. An Excel-based data extraction form was designed to capture key information from the included studies: study authors, publication year, journal, study design, study population, sample size, randomization methods, blinding methods, treatment interventions, control interventions, outcome measures, and safety evaluation indicators.

3.2.3 | Literature Quality Assessment and Evidence Analysis

The methodological quality of randomized controlled trials was assessed using the RoB (Risk of Bias) tool from the Cochrane Handbook for Systematic Reviews. The risk of bias in included systematic reviews was evaluated using the AMSTAR 2 tool. If the AMSTAR 2 assessment indicated that the existing systematic

review was of high methodological quality but newer high-quality studies had been published, the systematic review was updated accordingly. If the AMSTAR 2 assessment showed low methodological quality in existing systematic reviews or no systematic review was found for a specific PICO question, original research evidence was retrieved for evaluation and synthesis.

The Review Manager 5.3 software was used to perform a meta-analysis of data from similar types of original studies. Count data were expressed as Relative Risk (RR), measurement data with consistent units were expressed as Mean Difference (MD), and measurement data with inconsistent units were expressed as Standardized Mean Difference (SMD). All results were reported with 95% Confidence Intervals (CI). For continuous variables, the analysis was based on the change values before and after treatment. If the original studies only provided mean values and standard deviations before and after treatment or Standard Errors (SE) or CIs instead of change values, the required values were calculated using formulas provided in the Cochrane Handbook for Systematic Reviews of Interventions.

Heterogeneity testing was conducted before pooling the data from the included studies for meta-analysis. If the statistical heterogeneity among the studies was acceptable ($p \geq 0.1$, $I^2 \leq 50\%$), a fixed-effect model was used. If significant heterogeneity was detected ($p < 0.1$, $I^2 > 50\%$), the sources of heterogeneity, such as differences in study design, study populations, or interventions, were analyzed. Subgroup analyses were conducted based on the potential sources of heterogeneity. If substantial heterogeneity persisted, a random-effects model was applied to combine the outcome measures, but the results were interpreted with caution. Sensitivity analyses and publication bias assessments were also conducted, and funnel plots were used to display the results.

3.2.4 | Assessment of Evidence Quality and Recommendation Criteria

The GRADE system was used to summarize and evaluate the quality of evidence from studies on both TCM and Western medicine interventions, where sufficient evidence was available. The evaluation considered five downgrading (risk of bias, inconsistency, indirectness, imprecision (random error), and publication bias) and three upgrading factors: large effect size, dose-response relationship, and the potential influence of confounding factors. Evidence quality was graded as high, moderate, low, or very low. Finally, the evidence was presented in a summary table (Table 3).

3.3 | Formulation of Recommendations

The guideline development team formulated recommendations on clinical issues based on prior evidence retrieval, systematic review results, and evidence grading. These recommendations were made after comprehensive consideration of the balance of benefits and harms, patient preferences and values, resource allocation, and other relevant factors. Preliminary recommendations were formed by 65 Chinese and Western medicine experts from 24 provinces across China. The Delphi method was employed to create expert questionnaires, and the GRADE grid counting

TABLE 3 | Evidence quality and recommendation criteria.

Evidence quality	Clarification
High quality (A)	It is very confident that the true effect values are close to the effect estimates
Moderate quality(B)	Moderate confidence in the effect estimates: It is possible that the true value is close to the estimate, but there is still a possibility that they are very different.
Low quality (C)	There is limited confidence in estimates of effects, and the true values may be very different from estimates.
Very low quality (D)	There is little confidence in effect estimates, and the true values are likely to be very different from estimates.

TABLE 4 | Grade evidence for strength of recommendations.

Strength of recommendations	Clarification
High priority (2)	The benefits of the intervention clearly outweigh the disadvantages, and it is strongly recommended and “definitely done.”
Low priority (1)	The benefits of the intervention may do more good than disadvantages, and it is weak recommended and “may do.”
Not sure ()	Interventions with comparable or uncertain advantages and disadvantages, and there is no clear recommendation.
High objection (-1)	Interventions may do more harm than good, and it is weakly not recommended and “may not be done.”
High objection (-2)	Interventions that clearly do more harm than good, and it is strongly discouraged and “must not be done.”

method was used to determine the strength of recommendations [7] (Table 4). A consensus was reached on an issue if any of the five recommendations accounted for over 50% support, allowing for direct determination of the direction and strength of the recommendation [8]. If none exceeded 50%, the proportion of “strong recommendation + weak recommendation” or “weak opposition + strong opposition” was calculated. If the sum of these two exceeded 70%, the direction of the recommendation was determined, and the strength was classified as weak [9].

The rest of the cases for which a consensus was not reached were combined with the written opinions of experts and entered into the next round of voting. The final recommendations were established after two or three consensus rounds. The strength of the recommendations was classified as high or low.

3.4 | Formation of the Guideline Draft

The research team convened a consensus meeting with both TCM and Western medicine experts. The attending experts engaged in extensive discussions and repeated deliberations, drawing on their clinical experience to finalize the recommendations in the guidelines. They enriched the details of these recommendations. The initial draft of the guideline was completed after revising the descriptions of specific recommendations based on the feedback from the TCM and Western medicine experts. The flowchart of the guideline development process is shown in Figure 1.

4 | Diagnosis and Treatment

4.1 | Diagnosis

The 2024 edition of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) [1] and other related content were used as references for the Western medicine diagnostic criteria and staging standards.

The Guidelines for the Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease with Integrated Traditional Chinese and Western Medicine (2022 edition) [10], International Clinical Practice Guideline of Chinese Medicine Chronic Obstructive Pulmonary Disease (2020 edition) [11], Diagnosis and Treatment Guideline for Chinese Medicine on Chronic Obstructive Pulmonary Disease (2019 edition) [12], and other related content were used as references for TCM diagnostic criteria and syndrome differentiation types.

4.2 | Treatment

The treatment of COPD is divided into two stages: the stable phase and the acute exacerbation phase. The treatments combine disease identification with syndrome differentiation and integrate Western medicine, TCM syndrome differentiation, and nonpharmacological approaches. The 2024 edition of the GOLD [1], Guidelines for the Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease with Integrated Traditional Chinese and Western Medicine (2022 edition) [10], International Clinical Practice Guideline of Chinese Medicine Chronic Obstructive Pulmonary Disease (2020 edition) [11], and Diagnosis and Treatment Guideline for Chinese Medicine on Chronic Obstructive Pulmonary Disease (2019 edition) were used as treatment references [12].

4.2.1 | Treatment Strategy for the Stable Phase

The main objectives of the stable phase are to alleviate current symptoms and reduce the risk of future adverse events. The management process is shown in Figure 2. The initial assessment

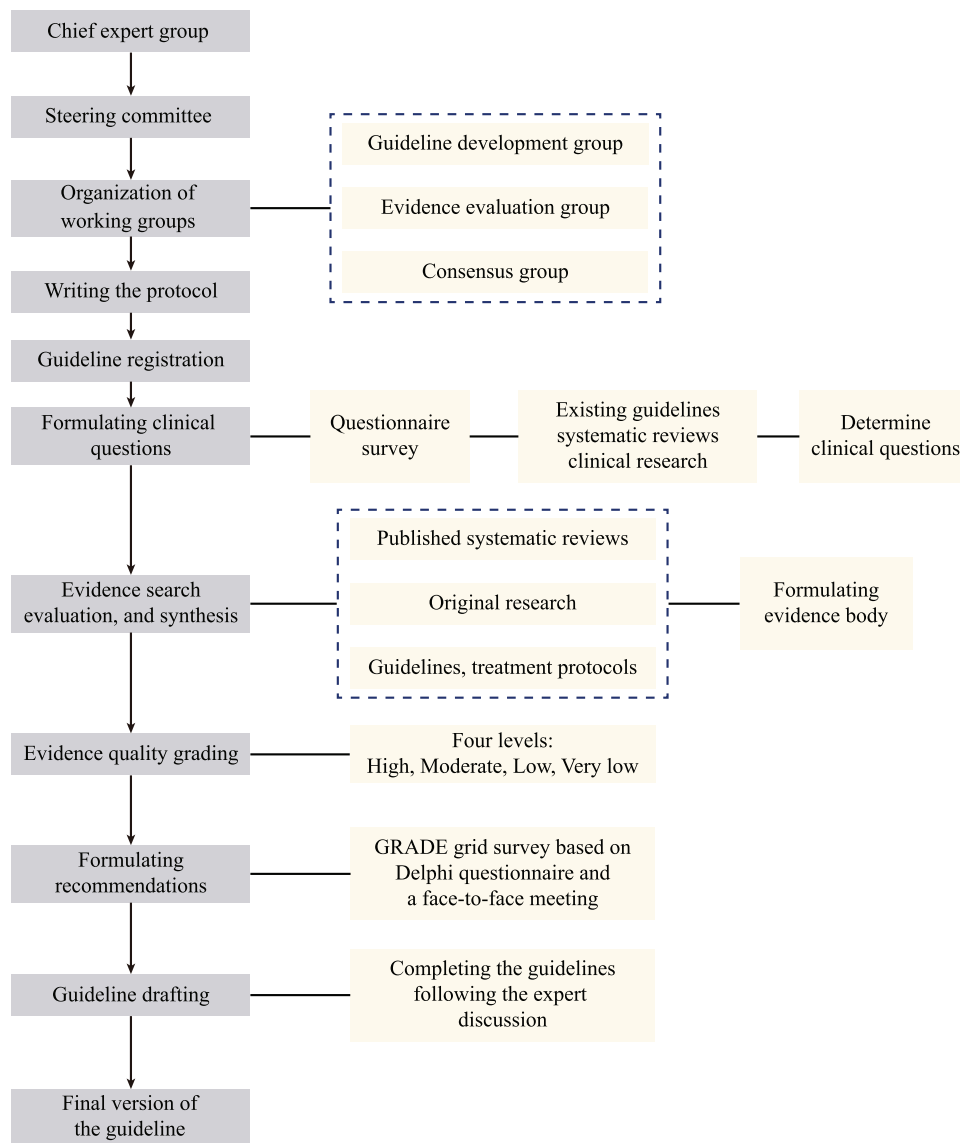


FIGURE 1 | Guideline development process.

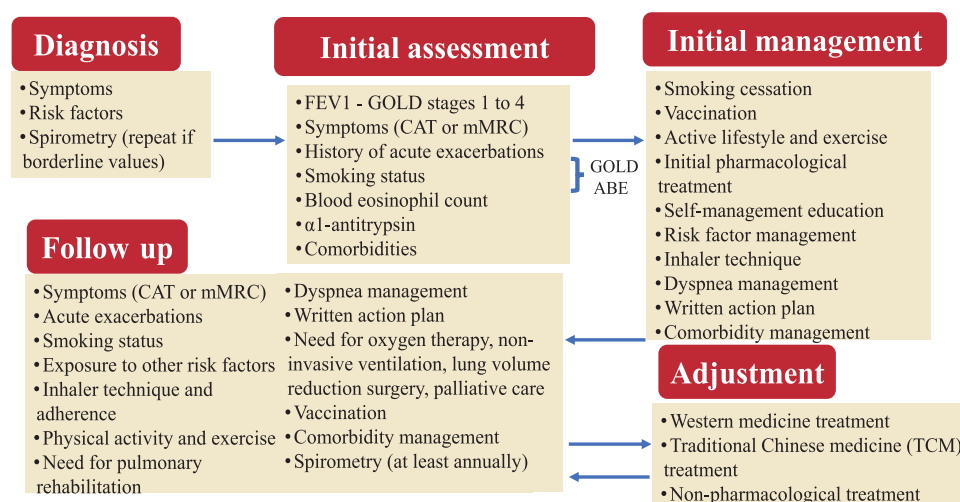


FIGURE 2 | Management process of COPD.

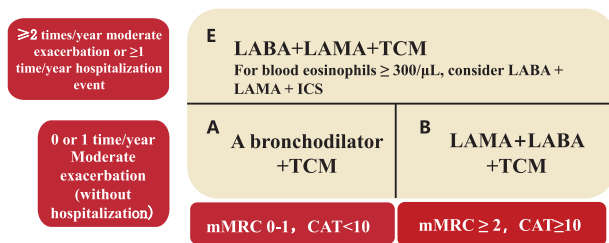


FIGURE 3 | Recommendation for initial drug treatment in stable COPD.

is based on the GOLD 2024 grouping to guide individualized initial management planning. Following the principles of review, assessment, and adjustment as needed, follow-ups are conducted at reasonable intervals to adjust the treatment plans for both Western and Chinese medicine drugs and nonpharmacological treatments. The combined therapy of Western and Chinese medicine brings more benefits to patients with COPD.

4.2.1.1 | Western Medicine Treatment. The initial management includes reducing exposure to risk factors (such as smoking cessation and limiting occupational exposure), providing comprehensive advice on vaccination, active lifestyle and exercise, offering initial drug therapy, and self-management education. The initial inhaled drug treatment strategy is shown in Figure 3. The commonly used inhaled medications are listed in Table 5.

The follow-up medication adjustment strategies are shown in Figure 4. Symptoms, risk of acute exacerbations, and achievement of treatment goals are assessed.

4.2.1.2 | Traditional Chinese Medicine Treatment. In TCM, COPD is categorized under conditions such as “lung expansion,” “asthma,” and “cough.” The underlying pathogenesis is characterized by a deficiency of vital energy and the internal obstruction of phlegm and blood stasis, with deficiency, phlegm, and stasis being omnipresent. Adhering to the principle of “treating the root in chronic conditions,” TCM treatment primarily aims to bolster the vital energy of the body while addressing pathogenic factors. Depending on the nuances of qi (yang) deficiency, yin-yang deficiency, and the varying degrees of deficiency in organs like the lungs, spleen, and kidneys, treatments may include strategies such as invigorating the spleen and boosting qi, regulating and supplementing the lungs and kidneys, balancing qi and yin, or addressing yin and yang.

4.2.1.3 | Nonpharmacological Treatment. Nonpharmacological treatment plans prioritize smoking cessation, physical activity, vaccination, and pulmonary rehabilitation training management. Interventions include patient education, encouragement for smoking cessation, pulmonary rehabilitation therapy, long-term oxygen therapy, home noninvasive ventilation, vaccination, and the application of traditional Chinese exercises such as Tai Chi and Baduanjin or external TCM treatments such as acupoint plastering, acupuncture, and lung-benefiting moxibustion. Adjustment strategies for nonpharmacological treatments during follow-up are illustrated in Figure 5.

4.2.2 | Treatment Strategies for Acute Exacerbation

During an acute exacerbation of COPD, the primary goals of treatment are to mitigate the negative effects of the current flare-up, alleviate symptoms, enhance respiratory function, prevent complications, and reduce the likelihood of future exacerbations. Integrating standardized Western medical approaches with TCM and tailoring them to specific syndromes offers significant advantages in improving clinical symptoms and decreasing the frequency of acute exacerbations while also ensuring a high level of safety.

4.2.2.1 | Western Medicine Treatment. The treatment for COPD exacerbations should be determined by the severity of the condition and presence of any complications. Patients with mild to moderate exacerbations can be managed with bronchodilators, corticosteroids, and/or appropriate antimicrobial agents on an outpatient basis. In contrast, those with severe exacerbations require hospitalization, and immediate admission to an Intensive Care Unit (ICU) is warranted if the condition is critical. Treatment strategies for the acute exacerbation phase are shown in Table 6, and commonly used treatment drugs are shown in Table 7.

4.2.2.2 | Traditional Chinese Medicine Treatment. TCM follows the principle of “treating the symptoms in acute conditions,” focusing on alleviating symptoms such as promoting lung qi circulation, reducing rebellious qi, clearing heat, transforming phlegm, activating blood circulation, promoting fluid metabolism, and opening orifices while also maintaining the balance of yin, yang, qi, and blood.

4.3 | Comorbidities

COPD frequently coexists with other diseases, which can significantly impact prognosis regardless of the severity of airflow limitation. Common comorbidities of COPD include cardiovascular diseases (such as ischemic heart disease, heart failure, atrial fibrillation, hypertension, and peripheral vascular disease), lung cancer, bronchiectasis, osteoporosis, anxiety and depression, gastrointestinal dysfunction, obstructive sleep apnea, oral infections, anemia, polycythemia, metabolic syndrome, diabetes, cognitive impairment, and frailty. Treatment plans for comorbidities are not within the scope of this guideline. Their presence should not alter the treatment plan for COPD; the guidelines for the specific disease should be followed, and consultation with relevant specialists is advised to formulate a treatment plan and assess the disease, severity, treatment, and effectiveness. Referral to a higher-level hospital is recommended if primary healthcare facilities lack the conditions for assessment. Therefore, all patients with COPD should actively seek comorbidities and receive appropriate treatment.

4.4 | High-Risk Groups for COPD

High-risk groups for COPD are defined as individuals aged 40 years or older who have a history of recurrent lower respiratory tract infections during childhood, moderate to heavy smoking, long-term exposure to dust, and clinical symptoms such as

TABLE 5 | Commonly used inhaled drugs during COPD stabilization.

Medicine	Inhalation device	Nebulization	Oral	Injection	Dosing interval
β2 adrenergic agonists					
SABA					
Fenoterol	MDI	✓	Tablets, Syrup		4–6 h
Levosalbutamol	MDI	✓			6–8 h
Salbutamol	MDI&DPI	✓	Tablets, SyrupSustained- Release Tablets	✓	4–6 h 12 h (sustained-release)
Terbutaline	DPI		Tablets	✓	4–6 h
LABA					
Arformoterol		✓			12 h
Formoterol	DPI	✓			12 h
Indacaterol	DPI				24 h
Olodaterol	SMI				24 h
Salmeterol	MDI&DPI				12 h
Anticholinergic drugs					
SAMA					
Ipratropium bromide	MDI	✓			6–8 h
Oxitropium bromide	MDI				7–9 h
LAMA					
Aclidinium bromide	DPI, MDI				MDI 12 h
Glycopyrronium bromide	DPI		Solution	✓	12–24 h
Tiotropium bromide	DPI, SMI, MDI				24 h
Umeclidinium bromide	DPI				24 h
Glycopyrronium bromide		✓			12 h
Revefenacin		✓			24 h
SABA+SAMA					
Fenoterol/ipratropium	SMI	✓			6–8 h
Salbutamol/ipratropium	SMI, DPI	✓			6–8 h
LABA+LAMA					
Formoterol/aclidinium	DPI				12 h
Formoterol fumarate/glycopyrronium bromide	MDI				12 h
Indacaterol maleate and glycopyrronium bromide	DPI				12–24 h
Indacaterol maleate and glycopyrronium bromide	DPI				24 h
Olodaterol/tiotropium	SMI				24 h
Methylxanthines					
Aminophylline			Solvent	✓	variable, ≤24 h
Theophylline sustained-release			Tablets	✓	variable, ≤24 h

(Continues)

TABLE 5 | (Continued)

Medicine	Inhalation device	Nebulization	Oral	Injection	Dosing interval
LABA+ICS					
Formoterol/Budesonide	MDI, DPI				12 h
Formoterol/Budesonide	MDI, DPI				12 h
Formoterol/Mometasone	MDI				12 h
Salmeterol/fluticasone propionate	MDI, DPI				12 h
Vilanterol/fluticasone furoate	DPI				24 h
LABA+LAMA+ICS					
Fluticasone/umeclidinium/vilanterol	DPI				24 h
Budesonide/formoterol/glycopyrronium	MDI, DPI				12 h
Budesonide/formoterol/glycopyrronium	MDI				12 h
Phosphodiesterase-4 inhibitors, PDE4 inhibitors					
Roflumilast			Tablets		24 h
Mucolytics					
Erdosteine			Tablets		12 h
Carbocisteine			Tablets		
N-Acetylcysteine			Tablets		

Abbreviations: SABA, short-acting β_2 receptor agonist; LABA, long-acting β_2 receptor agonist; SAMA, short-acting anticholinergic; LAMA, long-acting anticholinergic; ICS, inhaled corticosteroids; MDI, quantitative inhaler; DPI, dry powder inhalant; SMI, soft fog inhalation device.

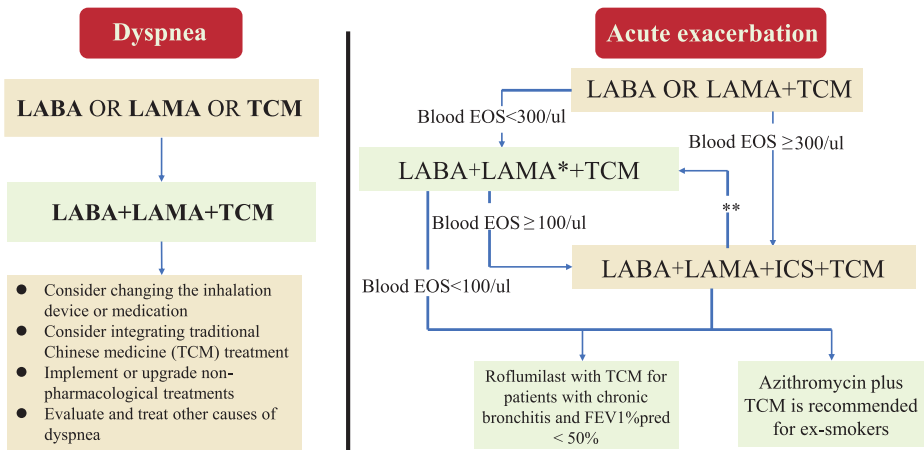


FIGURE 4 | Treatment Strategies during the follow-up phase of COPD. *It is recommended that a single unit inhalation is more convenient and effective than multiple device inhalation. **In the event of pneumonia or other adverse reactions, but with EOS 300 / μ L. TCM: Traditional Chinese Medicine.

chronic cough, sputum production, and dyspnea [13]. The first global RCT study using dual bronchodilators to intervene for early-stage COPD populations did not achieve the goals of improving quality of life or significantly improving lung function [14]. On the other hand, clinical studies using combined

treatment with TCM, such as the Gubenkechuan granules, to treat patients with chronic bronchitis have reported improved symptoms such as cough and sputum production and shortened durations of acute exacerbations with the use of these granules. For high-risk groups of COPD, comprehensive management

Non pharmacological treatment during the follow

If the initial treatment response is favorable, maintain the treatment and provide:

Annual influenza vaccination and other guideline-recommended vaccinations

Self-management education

Behavioral risk factor assessment, such as smoking cessation (if applicable) and environmental exposure

Ensure:

Maintenance of exercise programs and physical activity

Adequate sleep and a healthy diet

Otherwise, consider targeting the primary treatable traits.

Dyspnea Management

Comprehensive self-management education (including a written action plan) that incorporates the following aspects: Dyspnea management, energy conservation techniques, and stress management strategies

- Pulmonary rehabilitation (PR) programs and/or post-PR maintenance exercise programs
- **Traditional Chinese medicine (TCM) practices/TCM external therapies**

Acute Exacerbation Management

Personalized self-management education (including a written action plan) focusing on the following aspects:

Avoidance of exacerbating factors

How to monitor/manage worsening symptoms

Contact information in case of an acute exacerbation

Pulmonary rehabilitation (PR) programs and/or post-PR maintenance exercise programs

Traditional Chinese medicine (TCM) practices/TCM external therapies

All patients with advanced COPD should be considered for end-of-life care and palliative support to optimize symptom management and enable informed decision-making for future disease management by the patient and their family.

FIGURE 5 | Nondrug treatment during the follow-up period of COPD.

measures should be taken to reduce exposure to risk factors, strengthen health education, conduct pulmonary function tests, identify patients with COPD early, and provide early diagnosis and standardized treatment. According to the TCM theory of “preventive treatment,” early preventive strategies should be implemented, focusing on health preservation, adjusting to cold and warm temperatures, preventing colds, eating scientifically, ensuring adequate nutrition, strengthening physical exercise, maintaining an optimistic mood, and enhancing resistance to diseases.

Currently, evidence from both Western and Chinese medicine research on high-risk groups for COPD is lacking, and this guideline does not provide recommendations. Further in-depth research is anticipated.

5 | Clinical Questions and Recommendations

5.1 | Clinical Question 1: Can the Integration of TCM Therapies Further Enhance the Quality of Life of Patients With COPD Who Are Stable and Are Receiving Conventional Western Medical Treatment?

The commonly used medications for patients with stable COPD include bronchodilators, ICS combined with bronchodilators, and expectorants. These medications can alleviate clinical symptoms, prevent acute exacerbations, and improve the quality of life of patients. However, there are still issues such as incomplete symptom control, limited preventive effects against acute exacerbations, and tolerability issues. Consequently, these treatments do not fully meet the multifaceted needs of patients and improve their quality of life. Integrating TCM therapy and conventional Western medical treatment is recommended

to further enhance the quality of life of patients with stable COPD.

Recommendation 1: For patients with COPD who are stable and susceptible to colds and recurrent acute exacerbations, adding Yupingfeng granules to conventional Western medical treatment is recommended. This approach has been shown to significantly reduce the CAT score and enhance the quality of life of patients. (High priority; C)

(Summary of the evidence)

Three RCTs [15–17] have demonstrated that the addition of Yupingfeng granules to conventional Western medical treatment for patients with stable COPD significantly reduced their CAT score relative to that of the control group ($n = 344$, $MD = -2.85$, 95% $CI [-4.01, -1.69]$, $p < 0.00001$).

(Safety)

Of these three studies, two [15, 17] reported no adverse reactions. The remaining study [16] reported adverse events such as gingivitis, toothache, dizziness, and acute exacerbations during the 52-week treatment with Yupingfeng granules. However, there was no statistically significant difference in the incidence of adverse events between the treatment and control groups ($n = 240$, $RR = 0.46$, 95% $CI [0.18, 1.17]$, $p = 0.1$). The drug insert indicates that the adverse reactions are not yet clear.

(Recommendation basis)

Yupingfeng granules, derived from the classical TCM formula Yupingfeng San, are known for their benefits in invigorating Qi, consolidating the exterior, and strengthening the resistance of the body to pathogens. They can improve symptoms such as

TABLE 6 | Treatment strategies for the acute exacerbation phase of COPD.

		Order of severity	Variable thresholds for severity	Treat	
Suspected acute exacerbation of COPD patient	Diagnosed with acute exacerbation of COPD	Mild (default)	Mild (default) dyspnea with VAS score <5; RR <24 times/min; HR <95 times/min; oxygen saturation (SaO ₂) >92% on room air (or the patient's usual oxygen prescription) with a change ≤3% (if data is available from before exacerbation); C-reactive protein (CRP) <10 mg/L (if obtained)	Treated with short-acting bronchodilators only, SABDS (outpatient setting)	Identifying the etiology: Viral testing, sputum culture, others
		Moderate (meeting at least three of the five criteria*)	Dyspnea with VAS score ≥5; RR ≥24 breaths per minute; HR ≥95 beats per minute; oxygen saturation (SaO ₂) <92% on room air (or the patient's usual oxygen prescription) with a change >3% (if data is available from before exacerbation); CRP ≥10mg/L *If arterial blood gas (ABG) analysis was performed, it might show hypoxemia (PaO ₂ ≤60 mmHg) and/or hypercapnia (PaCO ₂ >45 mmHg), but without acidosis.	Treated with SABDS and oral corticosteroids plus antibiotics (outpatient)	
		Severe	Dyspnea, RR, HR, SaO ₂ , and CRP are consistent with moderate severity. ABG reveals new-onset/exacerbated hypercapnia and acidosis (PaCO ₂ >45 mmHg and pH <7.35).	Hospitalization or emergency visit needed. Severe exacerbations may lead to acute respiratory failure; life-threatening cases require urgent ICU admission.	
	Consider differential diagnosis	Heart failure, pneumonia, pulmonary embolism		Appropriate examinations and treatment	

Abbreviations: SABD, short-acting bronchodilator; VAS score, visual scale of dyspnea; RR, respiratory rate; HR, heart rate; SaO₂, oxygen saturation; CRP, C-reactive protein; ABG, arterial blood gas; PaO₂, arterial oxygen partial pressure; PaCO₂, arterial carbon dioxide partial pressure.

recurrent acute exacerbations, susceptibility to colds, exertional dyspnea, and fatigue in patients with stable COPD and enhance their quality of life. The drug is included in the 2023 edition of the National Health Insurance Catalog (NHIC) as a Category A drug. It is recommended for the treatment of stable COPD in the “Guideline of integrated Chinese and Western Medicine for diagnosis and treatment of chronic obstructive pulmonary disease (2022 edition)” [10], “Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease (2021)” [6], “International Clinical Practice Guideline of Chinese Medicine Chronic Obstructive Pulmonary Disease” [11], and “Diagnosis and treatment guideline for Chinese medicine on chronic obstructive pulmonary disease (2019 edition)” [12].

(Dosage and administration)

Yupingfeng granules should be taken orally at a dosage of 5 g per intake for three times daily. The medication was administered in the included study for 6–12 months.

Recommendation 2: For patients with stable COPD experiencing post-exertional dyspnea and fatigue accompanied

by anorexia, adding Buzhong Yiqi decoction to conventional Western medical treatment is recommended. This can significantly reduce the SGRQ score and improve the quality of life of patients. (Low priority; D)

(Summary of the evidence)

One RCT [18] reported that the combination of Buzhong Yiqi decoction and Budesonide Formoterol + Tiotropium Bromide for 12 weeks in patients with stable COPD significantly reduced the SGRQ score ($n = 116$, $MD = -5.62$, 95% $CI [-7.35, -3.89]$, $p < 0.00001$). Another RCT [19] reported that the combination of Buzhong Yiqi decoction and Tiotropium Bromide for the treatment of patients with severe but stable COPD for 12 weeks significantly reduced the SGRQ score ($n = 98$, $MD = -10.88$, 95% $CI [-12.52, -9.24]$, $p < 0.00001$).

(Safety)

One of the two included studies [18] reported adverse events related to the 12-week concurrent use of Buzhong Yiqi decoction and conventional Western medical treatment, including

TABLE 7 | Commonly used drugs during the acute exacerbation period of COPD.

Medicine	Inhalation device			Atomization	Taken orally	injection	Drug interval
SABA	Fenoterol	MDI	✓		Tablets, syrup		
	Levosalbutamol	MDI	✓				
	Salbutamol	MDI&DPI	✓		Tablets, sustained-release syrup	✓	4-6 h/12 h (delayed release)
SAMA	Terbutaline	DPI			Tablets	✓	4-6 h 6-8 h
	Ipratropium Bromide	MDI	✓				
	Oxitropium Bromide	MDI					7-9 h 6-24 h
Glucocorticoids	Budesonide		✓				
	Cortisone				Tablets		
	Hydrocortisone				Tablets	✓	12 h
	Prednisone		✓		Tablets		12-24 h
	prednisolone		✓		Tablets		12-24 h
	Methylprednisolone				Tablets	✓	12-24 h
Mucohydrotics	Dexamethasone				Tablets	✓	
	Betamethasone				Tablets	✓	
	Erdosteine				Tablets		12 h
	Carbocysteine				Tablets		
	N-Acetylcysteine		✓		Tablets		

Abbreviations: SABA, short-acting β_2 receptor agonist; SAMA, short-acting anticholinergic drug; MDI, quantitative inhaler; DPI, dry powder inhaler.

dry mouth, diarrhea, nausea, and palpitations. However, the incidence of these adverse effects did not differ significantly for the treatment and control groups ($n = 116$, $RR = 0.83$, 95% $CI [0.27, 2.58]$, $p = 0.75$). The study did not elaborate on the associations between these events and the decoction.

(Recommendation basis)

Buzhong Yiqi Decoction, originating from the “Differentiation of Internal and External Injuries,” is known for its effects in replenishing the middle qi and lifting yang to rectify prolapse. It can nourish the Qi of the lungs and spleen and alleviate symptoms such as cough, wheezing, and anorexia. This improves the quality of life of patients with stable COPD. It is recommended for the treatment of stable COPD (with Qi deficiency of the lung and spleen syndrome) in the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease (2023 Edition)” [13], “International Clinical Practice Guideline of Chinese Medicine Chronic Obstructive Pulmonary Disease” [11], and “Diagnosis and treatment guideline for Chinese medicine on chronic obstructive pulmonary disease (2019 edition)” [12].

(Dosage and administration)

Buzhong Yiqi decoction should be prepared with the following ingredients: Huangqi (Radix Astragaliseu Hedysari) 18 g, Zhigancao (Radix Glycyrrhizae) 9 g, Renshen (Radix Ginseng) 6 g, Danggui (Radix Angelicae Sinensis) 3 g, Chenpi (Pericarpium Citri Reticulatae) 6 g, Sheng Ma (Rhizoma Cimicifugae) 6 g, Chaihu (Radix Bupleuri) 6 g, Baizhu (Rhizoma Atractylodis Macrocephalae) 9 g. One dose is taken per day; it is decocted in water and taken in two parts. The drug was used for 12 weeks in the included studies.

Recommendation 3: For patients with stable COPD who experience coughing with white, sparse sputum; dyspnea that worsens after physical activity; and soreness in the waist and knees, the use of Gushen Dingchuan pill in addition to conventional Western medical treatment is recommended. This treatment approach can help reduce the SGRQ score, and improve the quality of life of patients. (Low priority; D)

(Summary of the evidence)

An RCT [20] reported a significant reduction in SGRQ scores after 12 weeks of treatment with Gushen Dingchuan pill combined with salmeterol xinafoate and fluticasone propionate powder for inhalation and pulmonary rehabilitation training for patients with stable COPD who had lung and kidney qi deficiency syndrome at GOLD stages 2–3 relative to the control group ($n = 103$, $MD = -7.52$, 95% $CI [-9.21, -5.83]$, $p < 0.00001$). Two other RCTs [21, 22] reported significant reductions in the SGRQ scores after 12 weeks of treatment with Gushen Dingchuan pill combined with conventional Western medicine for patients with stable COPD ($n = 184$, $MD = -7.51$, 95% $CI [-10.31, -4.71]$, $p < 0.00001$).

(Safety)

None of the three studies [20–22] included in this review reported safety outcomes. A systematic review [23] indicated that one of

two studies that reported on the safety of Gushen Dingchuan pill treatment over 14 days observed no adverse reactions; the other study observed adverse reactions such as chest pain, fatigue, wheezing, and rash, but their prevalence did not differ significantly in the two groups ($p > 0.05$). The studies did not elaborate on the association between these events and the medication. The instructions for the drug indicate that adverse reactions are not yet clear.

(Recommendation basis)

Gushen Dingchuan pill has warming and tonifying effects on the kidneys and lungs, and it can strengthen the spleen and resolve phlegm. It can alleviate symptoms such as dyspnea, shortness of breath, cough, sputum production, and soreness in the waist and knees of patients with stable COPD. It is included in the 2023 edition of the “National Medical Insurance Directory” and is recommended for the treatment of stable COPD (with deficiency of both lung and kidney) in the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease (2023 Edition)” [13].

(Dosage and administration)

Gushen Dingchuan pill should be taken orally at a dose of 1.5–2.0 g for two to three times daily. In this study, the drug was administered for 12 weeks.

Recommendation 4: For patients with stable COPD who experience symptoms such as shortness of breath, dry cough with less phlegm, frequent colds, soreness and weakness of the waist and knees, and spontaneous sweating and night sweats, the use of Baoyuan decoction and Renshen Bufei decoction in addition to conventional Western medical treatment is recommended. This treatment can help improve the quality of life of patients. (Low priority; expert consensus)

(Recommendation basis)

Baoyuan and Renshen Bufei decoctions originated from “Bo ai Xinjian” and “Waike Shuyao,” respectively. They can tonify the lung, nourish the kidney, improve inspiration, and relieve asthma and are expected to improve the quality of life of patients with COPD. They are recommended for the treatment of stable COPD (lung and kidney Qi Yin deficiency syndrome) in the “Guideline of Integrated Chinese and Western Medicine for Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease (2022 Edition)” [10], “International Clinical Practice Guideline of Chinese Medicine Chronic Obstructive Pulmonary Disease” [11] and “Diagnosis and Treatment Guideline for Chinese Medicine on Chronic Obstructive Pulmonary Disease (2019 edition)” [12].

(Dosage and administration)

Modified Baoyuan and Renshen Bufei decoctions: Renshen (Radix Ginseng) 6 g, Huangqi (Radix Astragali seu Hedysari) 15 g, Huangjing (Rhizoma Polygonati) 15 g, Shudihuang (Radix Rehmanniae Preparata) 15 g, Gouqizi (Fructus Lycii) 12 g, Maidong (Radix Ophiopogonis) 15 g, Wuweizi (Fructus Schisandrae

Chinensis) 9 g, Rougui (Cortex Cinnamomi) 3 g (decocting later), Zisuzi (Fructus Perillae) 9 g, Zhebeimu (Bulbus Fritillariae Thunbergii) 12 g, Mudanpi (Cortex Moutan Radicis) 9 g, Dilong (Lumbricus) 12 g, Baibu (Radix Stemonae) 9 g, Chenpi (Pericarpium Citri Reticulatae) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g. One dose is taken a day. They are decocted in water, divided into 2 servings for a day, and taken for 1–3 months.

Recommendation 5: For patients with stable COPD who have symptoms of coughing and wheezing accompanied by cyanosis of lips and a pale or dark purple tongue, Bufe Huoxue capsules are recommended in addition to conventional Western medical treatment to improve the quality of life of patients. (Low priority; D)

(Summary of the evidence)

An RCT [24] reported that the use of Bufe Huoxue capsules in combination with conventional Western medical treatment for 60 days significantly reduced the SGRQ score of patients with stable COPD relative to the control group ($n = 120$, $MD = -13.47$, 95% CI [-16.55, -10.39], $p < 0.00001$).

(Safety)

This study [24] reported no adverse reactions. However, another RCT study [25] involving patients with COPD complicated by pulmonary hypertension who received additional treatment with Bufe Huoxue capsules for 12 weeks reported adverse reactions such as decreased blood oxygen saturation and gastrointestinal symptoms. However, the prevalence of these adverse reactions did not differ significantly from that of the control group ($p > 0.05$). The study did not elaborate on the associations between these events and the use of Bufe Huoxue capsules.

Bufe Huoxue capsules contain Fructus Psoraleae (Bu Gu Zhi), and liver injury is a notable clinical hepatotoxic adverse effect associated with Fructus Psoraleae. Clinical manifestations of liver injury include yellowing of the skin and sclera, dark urine, generalized fatigue, and anorexia. These are accompanied by abnormal blood biochemical indicators such as elevated alanine aminotransferase, total bilirubin, and direct bilirubin concentrations. Therefore, close monitoring of liver function is necessary during the clinical use of this product. Patients with liver function impairment should avoid using it.

(Recommendation basis)

Bufe Huoxue capsules have the effects of nourishing the lungs and kidneys, promoting blood circulation, and removing blood stasis. They can alleviate symptoms such as cough, chest fullness, shortness of breath, dull complexion, and cyanosis of the lips of patients with stable COPD. This medication is included in the 2023 edition of the “National Medical Insurance Catalog” and is recommended for the treatment of stable COPD with deficiency of both lung and kidney, as well as blood stasis, in the “Guideline of Integrated Chinese and Western Medicine

for Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease” [10], “Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease (2021)” [6], “International Clinical Practice Guideline of Chinese Medicine Chronic Obstructive Pulmonary Disease” [11], and “Diagnosis and Treatment Guideline for Chinese Medicine on Chronic Obstructive Pulmonary Disease (2019 edition)” [12].

(Dosage and administration)

Bufe Huoxue capsules should be taken orally at a dose of 1.4 g per intake for three times daily. In this study, the drug was administered for 60 days.

Recommendation 6: For patients with stable COPD who have symptoms such as chest tightness, asthma, cough, expectoration, sweating, pale tongue, and slippery pulse, Runfei cream is recommended in addition to conventional Western medical treatment to improve the quality of life of patients. (High priority; C)

(Summary of the evidence)

An unpublished gray literature (a prospective, multi-center cohort study) shows that the use of Runfei cream in the treatment of patients with COPD with symptoms of both qi and yin deficiency and residual heat can significantly improve the CAT score after 24 weeks of observation ($n = 2423$, $MD = -1.18$, 95% CI [-1.86, -0.5], $p = 0.0006$).

(Safety)

During the treatment period of this study, the two groups showed no statistically significant differences in the incidence of adverse events, severe adverse events, and adverse events leading to withdrawal. No adverse reactions occurred during the study period. The drug insert indicates that the adverse reactions are not fully known.

(Recommendation basis)

Runfei cream has the effects of nourishing the lungs, invigorating qi, relieving cough, and eliminating phlegm, which can alleviate the symptoms of chest tightness, cough, expectoration, asthma, and sweating in patients with stable COPD. This medicine is included in the 2023 edition of the “National Medical Insurance Catalog” and is recommended for the treatment of stable COPD (Qi deficiency of the lung and spleen syndrome) in the “Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease (2021)” [6].

(Dosage and administration)

Runfei cream: Oral administration or dissolved in boiling water: dose is 15 g twice a day. In the above study, the medication was administered for 36.97 ± 45.85 days. The actual daily dosage was 35.70 ± 10.89 g, and the actual total dosage was 1228.44 ± 1412.29 g.

5.2 | Clinical Question 2: Can the Integration of TCM Therapies Effectively Address Persistent Dyspnea or Exercise Intolerance in Patients With Stable COPD Who Have Not Responded Adequately to Conventional Western Medical Treatment?

For patients with stable COPD who continue to experience dyspnea or exercise intolerance despite Western medical treatment, a retrospective evaluation may suggest the need to replace the inhalation device or medication, upgrade the pharmacotherapy to include LAMA + LABA, enhance nonpharmacological treatment strategies, or investigate other potential causes of dyspnea. For cases of refractory dyspnea, a multidisciplinary, integrated palliative approach and respiratory care services can facilitate more effective management. Additionally, for patients with malnutrition, nutritional supplements can enhance respiratory muscle strength and exercise tolerance.

The combination of TCM with Western medical treatments can significantly reduce the mMRC score and Borg rating (BORG) of perceived exertion and increase the 6MWT distance. It improves the symptom scores for wheezing and shortness of breath. Therefore, TCM therapies should be combined with standard Western medical treatments on an as-needed basis for patients who continue to experience persistent dyspnea or exercise intolerance after conventional Western medical treatments to improve patient outcomes.

Recommendation 1: For patients with stable COPD who still experience exercise intolerance, frequent colds, and recurrent acute exacerbations while on treatment with LAMA+LABA and other Western medications, adding Yupingfeng granules is recommended, as it can improve 6MWT and increase exercise tolerance. (Low priority; C)

(Summary of the evidence)

Two RCTs [17, 26] have reported that the Yupingfeng granules in combination with conventional Western medical treatment significantly improved the 6MWT of patients with stable COPD relative to the control group ($n = 163$, $MD = 27.93$, 95% CI [9.23, 46.63], $p = 0.003$).

(Safety)

The two studies [17, 26] included in this analysis reported no severe adverse events. The drug insert indicates that the adverse reactions are not yet clear.

(Recommendation basis)

Yupingfeng granules are known for their effects in replenishing qi and strengthening the resistance of the body. They can improve the exercise tolerance, and they are endorsed in multiple guidelines for the treatment of stable COPD [6, 10–12].

(Dosage and administration)

Yupingfeng granules should be taken orally, at a dosage of 5 g per intake for three times daily. They were used for 6 to 12 months in the included studies.

Recommendation 2: For patients who still experience exercise intolerance, fatigue, and loss of appetite despite treatment with LAMA+LABA and other Western medications, combination treatment with Buzhong Yiqi decoction is recommended, which can improve the 6MWT and increase exercise tolerance. (Low priority; D)

(Summary of the evidence)

An RCT [18] reported that Buzhong Yiqi decoction combined with budesonide/formoterol and tiotropium bromide significantly increased the 6MWT in patients with stable COPD, relative to a control group, after 12 weeks ($n = 116$, $MD = 33.57$, 95% CI [22.76, 44.38], $p < 0.00001$).

Another RCT [19] reported that Buzhong Yiqi decoction combined with tiotropium bromide significantly increased the 6MWT in patients with severe but stable COPD after 12 weeks of treatment relative to tiotropium bromide alone ($n = 98$, $MD = 43.74$, 95% CI [35.65, 51.83], $p < 0.00001$). However, the difference between the BORG scores of the combination therapy and control groups ($MD = -0.52$, 95% CI [-1.28, 0.24], $p < 0.18$) was not statistically significant.

(Safety)

In one of the two included studies [18], adverse reactions associated with the use of Buzhong Yiqi decoction for 12 weeks were reported. They included dry mouth, diarrhea, nausea, and palpitations. However, there was no statistically significant difference in the incidence of these adverse reactions in the treatment and control groups ($n = 116$, $RR = 0.83$ 95% CI [0.27, 2.58], $p = 0.75$). The study did not analyze the correlation between these events and the medication.

(Recommendation basis)

Buzhong Yiqi decoction, known for its effects in replenishing middle qi and lifting yang, can improve the exercise intolerance of patients with COPD by nourishing the spleen and stomach and enhancing qi and blood. This medicine has been recommended in several guidelines (consensus) [11–13] for the treatment of stable COPD (lung and spleen qi deficiency).

(Dosage and administration)

Buzhong Yiqi decoction contains the following: Dangshen (Radix Codonopsis) 15 g, Huangqi (Radix Astragali seu Hedysari) 15 g, Baizhu (Rhizoma Atractylodis Macrocephalae) 12 g, Fuling (Poria) 12 g, Xingren (Semen Armeniacae Amarum) 9 g, Chuanbeimu (Bulbus Fritillariae Cirrhosae) 6 g, Dilong (Lumbricus) 12 g, Houpu (Cortex Magnoliae Officinalis) 9 g, Ziwang (Radix Asteris) 9 g, Zisuzi (Fructus Perillae) 9 g, Yinyanghuo (Herba Epimedii) 6 g, Chenpi (Pericarpium Citri Reticulatae) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g. The duration of drug administration in this study was 12 weeks.

Recommendation 3: For patients with persistent dyspnea, cough, white and thin sputum, and soreness and weakness of the waist and knees after receiving Western medical treatment such as LAMA+LABA, combination treatment with the Gushen

Dingchuan pill is recommended; it can reduce the syndrome scores of wheezing and shortness of breath, lower the mMRC score, and improve dyspnea symptoms. (Low priority; D)

(Summary of the evidence)

One RCT [20] reported that 12 weeks of treatment with Gushen Dingchuan pill combined with salmeterol xinafoate and fluticasone propionate and pulmonary rehabilitation training led to improved wheezing ($n = 103$, $MD = -0.95$, 95% $CI [-1.04, -0.86]$, $p < 0.00001$) and shortness of breath scores ($MD = -0.72$, 95% $CI [-0.80, -0.64]$, $p < 0.00001$) of patients with stable COPD with lung and kidney qi deficiency syndrome at GOLD stages 2–3 relative to the control group.

Another RCT [21] reported that 12 weeks of treatment with Gushen Dingchuan pill combined with conventional Western medicine resulted in significant reductions in the mMRC scores ($n = 94$, $MD = -0.24$, 95% $CI [-0.44, -0.04]$, $p = 0.02$) and improved wheezing ($n = 90$, $MD = -0.26$, 95% $CI [-0.40, -0.12]$, $p = 0.0002$) and shortness of breath ($MD = -0.19$, 95% $CI [-0.27, -0.11]$, $p < 0.00001$) syndrome scores of patients with stable COPD relative to the control group [22].

(Safety)

None of the three studies included in this review [20–22] reported on safety. A systematic review [23] indicated that two of the studies reported on the safety of Gushen Dingchuan pill for 14 days of treatment. One study reported no adverse reactions, while the other study reported adverse reactions including chest pain, fatigue, wheezing, and rash, but the prevalence was not different from that of the control group ($p > 0.05$). The study did not elaborate on the correlation between these events and the drug. The drug insert states that the adverse reactions are not yet clear.

(Recommendation basis)

Gushen Dingchuan pill is efficacious for warming the kidney and regulating qi, which can alleviate symptoms such as dyspnea and soreness and weakness of the waist and knees of patients with stable COPD.

(Dosage and administration)

Gushen Dingchuan pill: oral administration, 1.5–2.0 g/dose, 2–3 times/day. In the studies included, the duration of drug administration was 12 weeks.

Recommendation 4: For patients with exercise intolerance, cough, asthma, and soreness and weakness of the waist and knees after receiving Western medical treatment such as LAMA+LABA, combination treatment with Bailing capsule is recommended, which can improve 6MWT and increase exercise tolerance. (Low priority; D)

(Summary of the evidence)

An RCT [27] reported that 6 months of treatment with Bailing capsule combined with ipratropium bromide aerosol led to a

significant increase in the 6MWT of patients with stable COPD at GOLD stage 2 with lung and kidney qi deficiency syndrome relative to the control group ($n = 120$, $MD = 35.00$, 95% $CI [7.43, 62.57]$, $p = 0.01$).

(Safety)

The studies included in this review [27, 28] did not report on safety. The drug insert indicates that adverse reactions may include throat discomfort in some patients.

(Recommendation basis)

Bailing capsule is efficacious for nourishing the lungs and kidneys and supplementing vital energy and essence and can improve symptoms such as exercise intolerance, fatigue, and soreness and weakness of the waist and knees caused by deficiency of the lungs and kidneys. This medication is included in the 2023 edition of the “National Medical Insurance Directory” and is recommended for the treatment of stable COPD (lung and kidney qi deficiency) in the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease(2023 Edition)” [13], “Guideline of Integrated Chinese and Western Medicine for Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease” [10] and “Guidelines for Clinical Application of Traditional Chinese Medicine in the Treatment of Chronic Obstructive Pulmonary Disease (2021)” [6].

(Dosage and administration)

Bailing capsule: oral administration, 1–3 g/dose, 3 times/day. The duration of drug administration in this study was 6 months. The indications for Bailing capsule under medical insurance is limited to organ transplantation anti-rejection, renal failure, and pulmonary fibrosis. Clinicians may select to use Bailing capsule based on the condition of the patient, treatment needs, and subjective preferences.

Recommendation 5: For patients who still experience persistent dyspnea or exercise intolerance despite treatment with western medicines such as LAMA+LABA and also have symptoms of soreness and weakness in the waist and knees and a thin yellow tongue coating, combination treatment with Huanglong Kechuan capsules is recommended. This treatment can improve 6MWT and reduce the symptom score for wheezing and shortness of breath. (Low priority; B)

(Summary of the evidence)

A randomized, placebo-controlled, multicenter, double-blind trial reported [29] that Huanglong Kechuan capsules administered for 3 months, relative to placebo, significantly improved the 6MWT scores of patients with stable COPD who have lung and kidney qi deficiency and phlegm heat obstructing the lungs ($n = 240$, $MD = 35.65$, 95% $CI [13.85, 57.45]$, $p = 0.001$). It also reduced the symptom scores for wheezing and shortness of breath ($MD = -2.49$, 95% $CI [-2.86, -2.12]$, $p < 0.00001$).

(Safety)

A study [29] reported no adverse reactions after 3 months of combined treatment with Huanglong Kechuan capsules. Another RCT [30] reported adverse reactions such as rash, abdominal pain, diarrhea, headache, nausea, and vomiting in 53 older patients with chronic bronchitis treated with Huanglong Kechuan capsule for 30 days. However, their prevalence of these adverse effects did not significantly differ from that of the control group ($p > 0.05$). The study did not elaborate on the correlation between these events and the drug. The drug insert indicates that the adverse reactions are not yet clear.

(Recommendation basis)

Huanglong Kechuan capsule is proficient in nourishing the lungs and kidneys, clearing heat, and resolving phlegm. It can alleviate dyspnea in patients with stable COPD, improve exercise tolerance, and alleviate symptoms such as thick, sticky, and yellow sputum.

(Dosage and administration)

Huanglong Kechuan Capsule: oral administration, 1.2 g/dose, 3 times/day. In this study, the duration of drug administration was 3 months.

Recommendation 6: For patients who still experience persistent dyspnea or exercise intolerance despite treatment with Western medicines such as LAMA+LABA and also have symptoms of cyanosis of the lips and a pale or dark purple tongue, combination treatment with Bufei Huoxue capsules is recommended. This combined treatment can improve 6MWT and reduce the symptom score for shortness of breath. (Low priority; C)

(Summary of the evidence)

An RCT [31] reported that the combination of Bufei Huoxue capsules, tiotropium bromide powder inhaler, and azithromycin tablets for the treatment of patients with stable COPD over 180 days resulted in a significant improvement in 6MWT ($n = 128$, $MD = 17.71$, 95% $CI [14.57, 20.85]$, $p < 0.00001$).

Another RCT [24] showed that the combination of Bufei Huoxue capsule with conventional Western medical treatment for 60 days significantly increased 6MWT ($n = 120$, $MD = 73.05$, 95% $CI [67.06, 79.04]$, $p < 0.00001$) and reduced the symptom score for shortness of breath ($MD = -1.07$, 95% $CI [-1.60, -0.54]$, $p < 0.0001$).

(Safety)

One of the included studies [24] reported no adverse reactions. The other study [31] reported two cases of mild nausea after 180 days of combined Western medical treatment with Bufei Huoxue capsule, but the difference in the adverse effect incidence between the two groups was not statistically significant ($n = 128$, $RR = 1.82$, 95% $CI [0.17, 19.58]$, $p = 0.52$). Another RCT study [25] reported on the treatment of 39 patients with COPD complicated by pulmonary hypertension for 12 weeks with Bufei Huoxue capsule. The adverse reactions recorded included decreased blood oxygen saturation and gastrointestinal symptoms, but the prevalence was not significantly different from that of the

control group ($p > 0.05$). The study did not elaborate on the association between these events and the drug. This product contains Fructus Psoraleae, which has hepatotoxicity. Therefore, close monitoring of liver function is required during clinical use, and it is contraindicated for patients with liver function impairment.

(Recommendation basis)

Bufei Huoxue capsule is effective for nourishing the lungs and kidneys, promoting blood circulation, and removing blood stasis. It can alleviate symptoms of shortness of breath in patients with stable COPD, improve exercise tolerance, and improve symptoms such as dull complexion and cyanosis of the lips. This medication is recommended in multiple guidelines [6, 10–12] for the treatment of stable COPD (with lung and kidney deficiency and blood stasis).

(Dosage and administration)

Bufei Huoxue Capsule: oral administration, 1.4 g/dose, 3 times/day. In the included studies, the duration of drug administration ranged from 60 to 180 days.

5.3 | Clinical Question 3: Can the Integration of TCM Treatment Reduce the Frequency of Acute Exacerbations Among Patients With COPD Who Still Experience Them After Conventional Western Medical Treatment?

For patients with COPD who experience repeated acute exacerbations, it is necessary to examine their medication adherence, inhalation technique, comorbidities, vaccination status, and smoking habits. Based on the treatable characteristics of patients with acute exacerbation, the treatment plan should be upgraded to LAMA+LABA or LAMA+LABA+ICS, and the combination of roflumilast, macrolides, mucolytics or antioxidants, and vitamin D or pulmonary rehabilitation therapy should be considered.

Combining conventional Western medicine treatment with TCM syndrome differentiation intervention can significantly reduce the number and rate of acute exacerbations and extend their intervals. For patients with COPD who still experience acute exacerbations after routine Western medicine treatment, combined oral administration of traditional Chinese medicines and/or external treatment and nonpharmacological interventions of TCM is recommended to mitigate the risk of acute exacerbations.

Recommendation 1: For patients who still experience acute exacerbations despite receiving Western medical treatments such as LAMA+LABA+ICS and are prone to catching colds, it is combination therapy with Yupingfeng granules is recommended to reduce the frequency and number of acute exacerbations within a year and increase the interval between episodes. (Low priority; C)

(Summary of evidence)

An RCT [26] reported that Yupingfeng granules combined with conventional Western medical treatment for 6 months

can significantly reduce the number of acute exacerbations of patients with stable COPD within 1 year ($n = 80$, $MD = -1.70$, 95% $CI [-2.49, -0.91]$, $p < 0.0001$). Another RCT [15] reported that Yupingfeng granules combined with conventional Western medicine treatment for 1 year can significantly reduce the rate of acute exacerbations within 1 year (the proportion of patients with COPD who have acute exacerbations) ($n = 80$, $RR = 0.72$, 95% $CI [0.53, 0.98]$, $p = 0.04$).

A randomized, double-blind, parallel, placebo-controlled RCT [16] reported that 52 weeks of treatment with Yupingfeng granules for stable COPD significantly reduced the risk of acute exacerbation in patients at 1 year (survival curve analysis based on acute exacerbation events at multiple time points) ($n = 181$, $RR = 0.68$, 95% $CI [0.53, 0.86]$, $p < 0.05$). It also extended the interval between acute exacerbations ($MD = 21.6$, 95% $CI [2.5, 40.7]$, $p = 0.027$).

(Safety)

Of the three included studies, one [15] did not report on safety, another [26] reported no adverse reactions, and the remaining study [16] reported adverse events included gingivitis, toothache, dizziness, and acute exacerbation during the 52-week observation period for reactions in the Yupingfeng granule group. However, the prevalence of the adverse events did not differ significantly in the Yupingfeng granule and control groups ($n = 240$, $RR = 0.46$, 95% $CI [0.18, 1.17]$, $p = 0.1$). The drug instructions indicate that the safety profile is still unclear.

(Recommendation basis)

Yupingfeng granules can help prevent acute exacerbations by invigorating Qi, consolidating the exterior and preventing wind, regulating lung function and strengthening health, and helping prevent external pathogens. Yupingfeng granules are recommended in the “Guideline of Integrated Chinese and Western Medicine for the Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease (2022)” [10] and “Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease (2021)” [6] to reduce the annual number of and prolong the interval between acute exacerbations.

(Dosage and administration)

Yupingfeng granules: oral administration, 5 g/time, 3 times/day. In the three included studies, the drug was used for 6 months to 1 year.

Recommendation 2: For patients who still experience acute exacerbation after receiving Western medicine treatment such as LAMA+LABA+ICS accompanied by symptoms of cough, asthma, and soreness and weakness in the waist and knees, combination treatment with Bailing capsules is recommended to reduce the number of acute exacerbations within 1 year. (Low priority; D)

(Summary of evidence)

An RCT [27] reported that the combination of Bailing capsules and basic Western medical treatment significantly reduced the number of acute exacerbations within 1 year in patients with GOLD grade 2 lung and kidney qi deficiency syndrome and stable

COPD after 6 months of treatment ($n = 120$, $MD = -1.80$, 95% $CI [-2.48, -1.12]$, $p < 0.00001$).

Another RCT [28] reported that the combination of Bailing capsules and tiotropium bromide powder mist for the treatment of patients with stable COPD (GOLD 2–3) for 12 months significantly reduced the number of acute exacerbations within 1 year relative to the control group treated with Western medicine alone ($n = 100$, $MD = -0.56$, 95% $CI [-0.75, -0.37]$, $p < 0.00001$).

(Safety)

There are no safety reports for the included studies [27, 28]. The drug instructions indicate that some patients may experience throat discomfort.

(Recommendation basis)

The efficacy of Bailing capsules is to nourish the lungs and kidneys, benefit essence and qi, and reduce the risk of acute exacerbation in patients with COPD. This drug is recommended for the treatment of stable COPD in multiple guidelines (consensus) [6, 10, 13].

(Dosage and administration)

Bailing capsules: oral administration, 1–3 g/time, 3 times/day. The medication was used for 6 months in the study.

Recommendation 3: For patients who still experience acute exacerbation, cough and wheezing, phlegm with multiple colors and white, chills and cold limbs, and back pain after receiving Western medicine treatments such as LAMA+LABA+ICS, combination treatment with Tanyin pills is recommended to delay the first acute exacerbation within 52 weeks. (High priority; B)

(Summary of evidence)

An unpublished gray literature (a randomized, double-blind, placebo-controlled, parallel, multicenter RCT study) shows that combination treatment with Tanyin pills for spleen-kidney yang deficiency and phlegm drink obstruction syndrome significantly delayed the first acute exacerbations within 52 weeks in patients with stable COPD (GOLD stages 2–3) ($n = 308$, $MD = 40.06$, 95% $CI [23.85, 56.27]$, $p < 0.00011$).

(Safety)

The incidence of adverse reactions in 168 patients who received the combination treatment with Tanyin pills for 8–52 weeks in the study was 3.57%, including three cases of dry mouth, one case of cough, one case of abdominal discomfort, and one case of oral ulceration. The difference was not statistically significant ($n = 339$, $RR = 0.87$, 95% $CI [0.30, 2.54]$, $p = 0.8$). No severe adverse reactions were observed during the trial.

(Recommendation basis)

Tanyin pills are known for warming and tonifying the spleen and kidneys and promoting yang transformation. When used in

combination with conventional Western medical treatment, it can improve cough and asthma symptoms in patients with COPD and delay the first acute exacerbation. This medicine has been included in the 2020 edition of the Chinese Pharmacopoeia and is recommended for stable COPD (syndrome of spleen-kidney yang deficiency and fluid retention in the lungs) in the “Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease (2021)” [6].

(Dosage and administration)

Tanyin pills: oral administration, 14 pills/time, 2 times/day. The duration of use of the medication in this study was 8–52 weeks.

5.4 | Clinical Question 4: Can Patients With Stable COPD Benefit From the Use of TCM External Therapies and Nonpharmacological Interventions?

External therapies and nonpharmacological interventions are crucial components of TCM lung rehabilitation, and they work synergistically with pharmacological treatments. TCM external therapies, which encompass methods such as acupoint application, lung-nourishing moxibustion, and warm needling, are widely applied in lung rehabilitation. Traditional Chinese exercises, including Tai Chi and Ba Duan Jin, share similar mechanisms with modern medical approaches to physical training, respiratory training, and emotional regulation. In the comprehensive management of stable COPD, combining TCM external therapies with nonpharmacological interventions is recommended to improve the quality of life of patients, alleviate symptoms of dyspnea, and reduce the risk of acute exacerbations.

Recommendation 1: For patients with stable COPD, combining TCM external treatment and nonpharmacological interventions based on the condition of the patient is recommended to improve their quality of life. (Tai Chi, high priority, C; Baduanjin, low priority, D; Acupoint application, low priority, C; Yifei moxibustion, low priority, D)

(Summary of evidence)

Two RCTs [32, 33] reported that the combination treatment with Tai Chi rehabilitation exercise treatment significantly reduced the SGRQ ($n = 276$, $MD = -3.93$, 95% $CI [-5.29, -2.57]$, $p < 0.0001$) and CAT [32] ($n = 60$, $MD = -745$, 95% $CI [-8.32, -6.58]$, $p < 0.0001$) scores relative to conventional Western medical treatment as a control.

An RCT [34] reported that combination treatment with fitness qigong Baduanjin training can significantly reduce CAT scores relative to conventional Western medical treatment ($n = 180$, $MD = -2.92$, 95% $CI [-3.72, -2.12]$, $p < 0.0001$). Another RCT [35] reported an increase in the difference between the CAT scores before and after the intervention ($n = 59$, $MD = 7.60$, 95% $CI [4.94, 10.27]$, $p < 0.0001$).

Several RCT studies [36–38] have reported that combination treatment with acupoint application can significantly reduce SGRQ ($n = 297$, $MD = -6.63$, 95% $CI [-9.32, -3.93]$, $p < 0.00001$)

and CAT scores [39] ($n = 72$, $MD = -2.77$, 95% $CI [-4.43, -1.11]$, $p = 0.001$).

A multicenter, randomized, controlled RCT study [40] reported that Yifei moxibustion therapy significantly reduces CAT scores in combination with, but relative to, conventional Western medicine alone ($n = 155$, $MD = -2.03$, 95% $CI [-3.95, -0.11]$, $p = 0.04$).

(Safety)

Tai Chi: the two included studies [32, 33] reported that no adverse reactions were found during the 1 year of combination treatment with Tai Chi training.

Ba Duan Jin: No safety reports were available in the two studies [34, 35].

Yifei moxibustion: The included study [40] did not provide safety reports. A meta-analysis [41] showed that the main adverse reactions reported among 320 patients with COPD treated with Yifei moxibustion were redness, heat, itching, or a few blisters at the treatment site, which are normal reactions and generally do not require treatment. Large blisters have to be punctured to release their fluid content. The area should be disinfected and kept clean and dry to prevent infection. In the presence of excessive foaming, medical attention should be sought at a hospital.

Acupoint application: Among four studies [36–39], two [38, 39] reported two cases of itching at the application site and one case of skin blistering in the acupoint application group. There was no statistically significant difference between the incidence of these adverse effects in the two groups ($n = 164$, $RR = 3.91$, 95% $CI [0.44, 34.32]$, $p = 0.22$, $I^2 = 0\%$).

(Recommendation basis)

RCT studies have shown that the combination of Tai Chi, Ba Duan Jin, acupoint application, and Yifei moxibustion can significantly improve the quality of life of patients. In the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease (2023 Edition)” [13], the “Guideline of integrated Chinese and Western medicine for the Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease (2022)” [10], and the “Diagnosis and Treatment Guideline for Chinese Medicine on Chronic Obstructive Pulmonary Disease (2019)” [12], Tai Chi, acupoint application, and Yifei moxibustion are all recommended for the treatment of stable COPD. The 2023 edition of the expert consensus has added Ba Duan Jin as one of the recommended therapies.

(Instructions for use)

Please refer to Table 8 for instructions on how to use it.

Recommendation 2: For patients with persistent dyspnea or exercise intolerance, a comprehensive treatment approach combining external therapies of TCM and nonpharmacological interventions is recommended to improve dyspnea symptoms and increase exercise tolerance. (Tai Chi, high priority, C; Baduanjin, low

TABLE 8 | Dosage and course of treatment with external Chinese medicine and nonpharmacological interventions for stable COPD.

Tai Chi	Each training session should last for 30 min, 1–2 times/day. Persistence in long-term training is recommended. It is advisable to increase the respiratory rate to < 5 times/min and the heart rate to < 20 times/min during the training. Pay attention to avoiding forced exercise.
Ba Duan Jin	Each training session should last for 30 min, once daily. Persistence in long-term training is recommended. During the training, it is advisable to increase the respiratory rate to < 5 times/min and the heart rate to < 20 times/min when compared to a resting state. It is important to avoid forced exercise.
Acupoint application	Each application lasts for 4–6 h, and the Dog Days of summer or in combination with the Cold Spells of winter is recommended. Guided by syndrome differentiation for acupoint selection, the patches are mostly made with drugs such as white mustard seed and asarum or products like Shufei Tie (lung soothing patch) and Xiaochuan Gao (asthma-relieving plaster). They are applied to acupoints such as Feishu (BL13), Geshu (BL17), Tiantu (RN22), and Dazhui (GV14).
Yifei moxibustion	Each session lasts for approximately 2 h for 1–2 times/month, with a total treatment course of 3 months. The area from Dazhui (GV14) to Yaoshu (GV2) along the Governor Vessel is the acupuncture point for moxibustion.
Warm acupuncture and moxibustion	Each session lasts for approximately 20–30 min, once every other day, with a total treatment course of 8 weeks. During the acupuncture session, moxa wool or a moxa stick of approximately 2 cm in diameter is wrapped around or placed on the handle of the needles and ignited from the lower end to perform moxibustion. Acupoints are selected based on syndrome differentiation, and they commonly include Feishu (BL13), Zusanli (ST36), Danzhong (CV17), and Shenshu (BL23).

priority, D; Acupoint application, low priority, D; Warm acupuncture and moxibustion, low priority, C)

(Summary of evidence)

A single-blind, randomized, controlled RCT [32] reported Tai Chi training combined with whole-body recumbent stepper exercise significantly reduced the mMRC scores of in patients with COPD after 12 months relative to the whole-body recumbent stepper exercise alone ($n = 60$, $MD = -0.57$, 95% $CI [-0.67, -0.47]$, $p < 0.00001$), reduced the BORG score ($MD = -1.15$, 95% $CI [-1.51, -0.79]$, $p < 0.00001$), and increased the 6MWT distance ($MD = 35.64$, 95% $CI [27.32, 42.68]$, $p < 0.00001$).

An RCT [34] reported that a 6-month combination of Baduanjin Qigong, cycling exercise training, and conventional Western medical treatment for patients with COPD significantly increased the 6MWT distance ($n = 180$, $MD = 86.50$, 95% $CI [78.24, 94.76]$, $p < 0.00001$) and reduced the BORG score ($MD = -0.60$, 95% $CI [-0.68, -0.52]$, $p < 0.00001$).

An RCT [42] reported that acupoint application combined with budesonide formoterol inhalation for the treatment of patients with stable COPD and pulmonary and kidney deficiency for 1 year significantly reduced asthma and shortness of breath symptom scores ($n = 130$, $MD = -1.08$, 95% $CI [-1.22, -0.94]$, $p < 0.0001$). Another RCT [37, 39] reported that the combination of acupoint application therapy significantly increased the 6MWT distance relative to conventional Western medical treatment ($n = 152$, $MD = 13.3$, 95% $CI [5.90, 20.7]$, $p = 0.0004$). A study reported that the combination of acupoint application therapy also reduced the mMRC dyspnea score ($n = 80$, $MD = -0.68$, 95% $CI [-1.06, -0.3]$, $p = 0.0004$) [37].

An RCT [43] demonstrated that warm acupuncture and moxibustion combined with salmeterol and fluticasone powder inhalation can significantly improve the syndrome scores of 6MWT ($n =$

97, $MD = 25.98$, 95% $CI [3.91, 48.05]$, $p = 0.02$), dyspnea ($MD = -0.5$, 95% $CI [-0.83, -0.17]$, $p = 0.003$), and shortness of breath ($MD = -0.52$, 95% $CI [-0.85, -0.19]$, $p = 0.002$) in patients with stable COPD relative to salmeterol and fluticasone powder inhalation treatment.

(Safety)

Warm acupuncture and moxibustion: One study [43] reported no obvious adverse events.

Tai Chi [32] and Ba Duan Jin [34]: There are no safety reports for them.

Acupoint application: Of the three studies included [37, 39, 42], one [39] reported one case of skin blistering in the acupoint application group, with no statistically significant difference between the prevalence in the two groups ($n = 72$, $RR = 3$, 95% $CI [0.13, 71.28]$, $p = 0.5$).

(Recommendation basis)

RCTs have shown that combined treatment with Tai Chi, Baduanjin Qigong, acupoint application, and warm acupuncture significantly improves dyspnea symptoms and/or exercise tolerance. Tai Chi, Baduanjin Qigong, acupoint application, and warm acupuncture are recommended for the treatment of stable COPD in multiple guidelines (consensus) [10, 12, 13]. The GOLD 2024 guidelines [1] recommend Tai Chi training for patients with stable COPD to improve their exercise capacity.

(Instructions for use)

Please refer to Table 8 for instructions on how to use it.

Recommendation 3: For patients at high risk of acute exacerbations, the use of Tai Chi therapy in

addition to conventional Western medical treatment is recommended to reduce the risk of acute exacerbations. (low priority, D)

(Summary of evidence)

One RCT [33] reported that the use of Tai Chi as adjunctive therapy with conventional Western medical treatment for 52 weeks significantly reduced the risk ratio of acute exacerbations within 1 year for patients with stable COPD (GOLD stages 2–3) relative to conventional Western medical treatment ($n = 216$, $RR = 0.59$, 95% CI [0.40, 0.74], $p < 0.05$).

(Safety)

No adverse reactions were reported by the study [33].

(Recommendation basis)

Tai chi is recommended in several guidelines (consensus) [1, 10, 12, 13] for the treatment of stable stages of COPD.

(Instructions for use)

Please refer to Table 8 for instructions on how to use it.

5.5 | Clinical Question 5: Can Integrating TCM Treatment Effectively Improve the Clinical Symptoms of Patients With Acute Exacerbation of COPD Receiving Conventional Western Medical Treatment?

Acute exacerbation of COPD (AECOPD) refers to an event characterized by increased difficulty breathing and/or coughing and expectoration within 14 days, which may be accompanied by shortness of breath and/or tachycardia. It is usually associated with worsening local or systemic inflammatory reactions caused by respiratory infections, air pollution, or other reasons [1]. The routine Western medical treatment for acute exacerbation includes: (a) drug therapy: includes bronchodilators (such as β_2 receptor agonists, anticholinergic drugs), corticosteroids, antibiotics (for patients with concurrent infections), and mucus diluents; (b) respiratory support: includes controlled oxygen therapy, nasal high flow humidification therapy, noninvasive mechanical ventilation, and invasive ventilation.

Several studies have shown that combining conventional Western medical treatment with TCM dialectical intervention can effectively alleviate symptoms such as cough, expectoration, chest tightness, wheezing, and difficulty breathing in patients with acute exacerbation of COPD and improve their quality of life.

Recommendation 1: For patients with cough, wheezing, chills, fever, white phlegm, runny nose, limb soreness, and thin white tongue coating during acute exacerbation of COPD, the combination of Sanao decoction and Zhisou powder is recommended to improve symptoms such as chills, fever, nasal congestion, and runny nose. (Low priority; expert consensus)

(Recommendation basis)

Sanao decoction and Zhisou powder are respectively derived from “Prescriptions of the Bureau of Taiping People’s Welfare Pharmacy” and “Medical Revelations.” Their combination has the effects of dispelling wind and cold, promoting lung function, and stopping cough. The combined use can improve symptoms such as cough, wheezing, chills, and fever in patients with COPD who have wind cold attacking the lungs. This medicine is recommended for the treatment of acute exacerbation of COPD (Wind cold invading lung syndrome) in the “Guideline of Integrated Chinese and western medicine for Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease (2022 Edition)” [10], “Diagnosis and Treatment guideline for Chinese Medicine on Chronic Obstructive Pulmonary Disease (2019 Edition)” [12], and “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease (2023 Edition)” [13].

(Usage and dosage)

Sanao decoction and Zhisou powder: Zhimahuang (Herba Ephedrae) 9 g, Xingren (Semen Armeniacae Amarum) 9 g, Jingjie (Herba Schizonepetae) 9 g, Zisu (Folium Perillae) 9 g, Baiqian (Rhizoma Cynanchi Stauntonii) 9 g, Baibu (Radix Stemonae) 12 g, Jiegeng (Radix Platycodonis) 9 g, Zhiqiao (Fructus Aurantii) 9 g, Chenpi (Pericarpium Citri Reticulatae) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g. One dose is taken a day in two servings for 7–14 days. Decoction in water is required.

Recommendation 2: For patients with fever, cough, headache, and sore throat during the acute exacerbation of COPD, Shufeng Jiedu capsules are recommended in combination with oxygen therapy, rest, anti-infection, antispasmodic, and anti-asthmatic treatments to reduce phlegm and relieve cough and improve symptoms such as fever and excess sputum. (Low priority; D)

(Summary of evidence)

One RCT [44] reported that Shufeng Jiedu capsules can significantly improve expectoration ($n = 100$, $MD = -1.15$, 95% CI [-1.47, -0.83], $p < 0.0001$), body heat ($MD = -0.53$, 95% CI [-0.62, -0.44], $p < 0.0001$), dry and bitter mouth ($MD = -0.04$, 95% CI [-0.07, -0.01], $p = 0.02$), and constipation ($MD = -0.07$, 95% CI [-0.11, -0.03], $p = 0.0003$) syndrome scores.

(Safety)

The study [44] reported no adverse reactions. A meta-analysis [45] revealed five cases of adverse reactions, including nausea, upper abdominal discomfort, and phlebitis, in 521 adult patients with community-acquired pneumonia treated with Shufeng Jiedu capsules for 7 days. There was no statistically significant difference compared with the control group ($RR = 0.84$, 95% CI [0.26, 2.67], $p = 0.76$). The study did not elaborate on the association between the above events and the medication. The drug instructions indicate that nausea may occur occasionally.

(Recommendation basis)

Shufeng Jiedu capsules are good at dispelling wind and clearing heat, detoxifying and benefiting the throat. When used in combination with conventional Western medical treatment, it can

effectively alleviate symptoms such as fever, cough, headache, and sore throat in patients with COPD. This drug is included in Class A of the catalog of medicines covered by medical insurance across the country (2023 Edition), the National Directory of Essential Medicines (2018 Edition), and the list of over-the-counter drugs.

(Dosage and administration)

Shufeng Jiedu capsules: Oral administration, 4 capsules/time, 3 times/day. The medication was used for 7 days.

Recommendation 3: For patients with cough, wheezing, chest tightness, thin phlegm, easy expectoration, chills, and white tongue coating in the acute exacerbation stage of COPD, Xiaoqinglong decoction in combination with conventional Western medical treatment is recommended to improve symptoms such as expectoration and chest tightness. (Low priority; expert consensus)

(Recommendation basis)

Xiaoqinglong decoction originates from the “Treatise on Cold Pathogenic Diseases.” Its effects include warming the lungs, dispelling cold, transforming fluids, and reducing reflux. It can improve symptoms such as coughing phlegm, wheezing, and chest tightness in patients with COPD. It is recommended for the treatment of AECOPD (External cold and internal drink syndrome) in the “Guideline of integrated Chinese and western medicine for diagnosis and treatment of chronic obstructive pulmonary disease(2022 Edition)” [10], “Diagnosis and treatment guideline for Chinese medicine on chronic obstructive pulmonary disease (2019 Edition)” [12], “National Health and Family Planning Commission ‘13th Five-Year Plan’ planned parenthood,” and “Internal Medicine of Chinese Medicine (Third Edition) published by People’s Health Publishing House” [46].

(Dosage and administration)

Xiaoqinglong decoction: Zhimahuang (Herba Ephedrae) 9 g, Guizhi (Ramulus Cinnamomi) 9 g, Ganjiang (Rhizoma Zingiberis) 6 g, Baishao (Radix Paeoniae Alba) 9 g, Xixin(Herba Asari) 3 g, Fabanxia(Rhizoma Pinelliae Preparatum) 9 g, Wuweizi (Fructus Schisandrae) 6 g, and Zhigancao(Radix Glycyrrhizae) 6 g. One dose per day; decoct in water; take two servings daily for 7–14 days.

Recommendation 4: For patients with cough, excessive phlegm, white and sticky or foam, and white and greasy tongue coating in the acute exacerbation stage of COPD, combination therapy of Erchen decoction with Sanzi Yangqin decoction or of Suzi Jiangqi decoction with Sanzi Yangqin decoction is recommended to improve the symptoms of cough and excessive phlegm. (Low priority; expert consensus)

(Recommendation basis)

Erchen decoction and Suzi Jiangqi decoction are both derived from the “Prescriptions of the Bureau of Taiping People’s Welfare Pharmacy,” while Sanzi Yangqin Decoction is derived from the “Wide Collection of Miscellaneous Diseases.” They have the

effects of resolving phlegm, reducing qi, strengthening the spleen, and nourishing qi. They can improve symptoms such as cough, excessive phlegm, white, and sticky sputum color in patients with COPD. This medicine is recommended for the treatment of AECOPD (Phlegm turbid obstructing the lung syndrome) in the “Guideline of integrated Chinese and western medicine for diagnosis and treatment of chronic obstructive pulmonary disease(2022 Edition)” [10], “National Health and Family Planning Commission ‘13th Five-Year Plan’ planned parenthood,” and “Internal Medicine of Chinese Medicine (Third Edition) publish by People’s Health Publishing House” [46].

(Dosage and administration)

Erchen decoction: Banxia (Pinellia ternata) 6 g, Juhong (Citrus reticulata Blanco) 6 g, Fuling (Poria) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g

Suzi Jiangqi decoction: Zisuzi (Fructus Perillae) 9 g, Fabanxia (Rhizoma Pinelliae Preparatum) 6 g, Danggui (Angelica sinensis) 6 g, Zhigancao (Radix Glycyrrhizae) 6 g, Qianhu (peucedanum root) 6 g, Houpo (Cortex Magnoliae Officinalis) 6 g, Rougui (Cinnamomum cassia) 3 g, Shengjiang (Rhizoma Zingiberis Recens) 6 g

Sanzi Yangqin decoction: Baijiezi (Semen sinapis) 9 g, Zisuzi (Fructus Perillae) 9 g, Laifuzi (Semen Raphani) 9 g

Comprehensive Erchen decoction and Suzi Jiangqi decoction: Banxia (Pinellia ternata) 6 g, Juhong (Citrus reticulata Blanco) 6 g, Fuling (Poria) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g, Baijiezi (Semen sinapis) 9 g, Zisuzi (Fructus Perillae) 9 g, Laifuzi (Semen Raphani) 9 g, 1 dose/day, decoct in water, take twice, take 7–14 days.

Comprehensive Suzi Jiangqi decoction and Suzi Jiangqi decoction: Zisuzi (Fructus Perillae) 9 g, Fabanxia (Rhizoma Pinelliae Preparatum) 6 g, Danggui (Radix Angelicae Sinensis) 6 g, Zhigancao (Radix Glycyrrhizae) 6 g, Qianhu(peucedanum root) 6 g, Houpo (Cortex Magnoliae Officinalis) 6 g, Rougui (Cinnamomum cassia) 3 g, Shengjiang (Rhizoma Zingiberis Recens) 6 g, Baijiezi (Semen sinapis) 9 g, Laifuzi (Semen Raphani) 9 g. One dose per day; decoct in water; take two servings daily for 7–14 days.

Recommendation 5: For patients with fever, cough, sticky yellow phlegm, and red tongue with yellow coating in the acute exacerbation stage of COPD, it is recommended to use Tanreqing injection in combination with reducing phlegm and relieving cough, relieve wheezing, provide continuous low flow oxygen therapy, and anti-infection to shorten the disappearance time of cough and sputum symptoms. (Low priority; D)

(Summary of evidence)

One RCT [47] reported that combination treatment with Tanreqing injection can shorten the durations of cough and excess sputum ($n = 74$, $MD = -2.6$, 95% $CI [-3.24, -1.96]$, $p < 0.0001$) and fever ($MD = -2.6$, 95% $CI [-3.24, -1.96]$, $p < 0.0001$).

(Safety)

This study [47] did not report any adverse reactions. A meta-analysis [48] on the treatment of severe pneumonia in older adults with Tanreqing injection for 7–15 days revealed 10 cases of adverse reactions among 216 patients, including nausea, rash, vomiting, dizziness, local pain, and others. The drug instructions indicate occasional allergic reactions, including dizziness, nausea, vomiting, redness, itching, or rash.

(Recommendation basis)

Tanreqing injection has the effects of clearing heat, resolving phlegm, and detoxifying and can improve symptoms such as fever, cough, and yellow phlegm in patients with acute exacerbation of COPD. This medicine was included in the catalog of medicines covered by medical insurance across the country (2023 Edition) and is recommended for the treatment of AECOPD (Heat phlegm accumulating the lung syndrome) in the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease (2023 Edition)” [13] and “Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease (2021)” [6].

(Dosage and administration)

Tanreqing injection: Intravenous injection; usually 20 mL/time for adults; 40 mL can be used once for critically ill patients; 1 dose/day. The dosage for the study was 20 mL/shot for 12 days.

Recommendation 6: For patients with cough, wheezing, sputum, white or yellow sputum, and red tongue and yellow moss in the acute exacerbation stage of COPD, combination treatment with Danlong oral liquid is recommended. It can effectively alleviate the symptoms of cough, sputum, and difficulty expelling phlegm through coughing and improve the quality of life. (Low priority; C)

(Summary of evidence)

A multicenter, prospective randomized controlled trial [49] reported that the combination of ICS/LABA/LAMA and Danlong oral liquid can improve the CAT scores ($n = 395$, $MD = 0.77$, 95% $CI [0.16, 1.38]$, $p = 0.01$) and TCM syndrome score ($MD = 1$, 95% $CI [0.23, 1.77]$, $p = 0.01$) in patients with moderate exacerbation of COPD.

(Safety)

The study [49] reported three cases of allergic reactions during combination therapy, two cases of palpitations in the observation group, and positive urine white blood cell counts in both groups (four cases in the observation group and two cases in the control group). There was no statistically significant difference between the two groups ($p > 0.05$). Other adverse events included arrhythmia, abdominal distension, and biochemical changes, and no severe adverse events were observed. The drug instructions indicate that nausea, rash, diarrhea, dizziness, and headache may occur in a few cases.

(Recommendation basis)

Danlong oral liquid has the effects of clearing heat, relieving gasp, expelling phlegm, and dispersing blood stasis. It can alleviate clinical symptoms such as cough, wheezing, and sticky phlegm in patients with COPD and improve their quality of life. This medicine was included in the catalog of medicines covered by medical insurance across the country (2023 Edition) and was recommended for the treatment of AECOPD (Heat phlegm accumulating the lung syndrome) in the “Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease(2021)” [6].

(Dosage and administration)

Danlong oral liquid: oral administration; 10 mL/time, 3 times/day; literature review period of 7 days.

Recommendation 7: For patients with cough, wheezing, excessive phlegm, and a red tongue with yellow fur in the acute exacerbation stage of COPD, it is recommended to use Guilong Kechuanning capsules in combination with oxygen therapy, bronchodilators, anti-infections, nutritional support, and expectorant therapy. This can reduce the relief time of cough, sputum, and wheezing in patients and improve their quality of life. (Low priority; C)

(Summary of evidence)

One RCT [50] showed that the combination of Guilong Kechuanning capsules can speed up relief from the main symptoms and signs: cough, ($n = 114$, $MD = -2.19$, 95% $CI [-2.92, -1.46]$, $p < 0.0001$); sputum ($MD = -1.62$, 95% $CI [-2.27, -0.97]$, $p < 0.0001$); wheezing ($MD = -1.08$, 95% $CI [-1.64, -0.52]$, $p = 0.0002$); pulmonary wheezing sound ($MD = -1.79$, 95% $CI [-2.63, -0.95]$, $p < 0.0001$). It can also improve the CAT score ($MD = -3.55$, 95% $CI [-4.58, -2.52]$, $p < 0.0001$).

(Safety)

This study [50] reported the treatment of 57 patients with acute exacerbation of COPD using Guilong Kechuanning capsules for 14 days. The treatment group experienced one case of gastrointestinal discomfort and two cases of nausea, while the control group experienced one case of loss of appetite and one case of nausea. There was no statistically significant difference between the two groups ($n = 114$, $RR = 1.5$, 95% $CI [0.26, 8.64]$, $p = 0.65$). The study did not explain the correlation between the above events and the medication. The adverse reactions indicated in the drug instructions are not yet clear.

(Recommendation basis)

Guilong Kechuanning capsules are good at relieving cough and phlegm, lowering qi, and relieving gasp. They can speed up relief from cough, sputum, and wheezing in patients with COPD and improve their quality of life. This drug is included in Class A of the catalog of medicines covered by medical insurance across the country (2023 Edition), the Pharmacopoeia of the People's Republic of China (2020 Edition), the National Directory of Essential Medicines (2018 Edition), and list of over-the-counter drugs.

(Dosage and administration)

Guilong Kechuangning capsules: oral administration, 3 capsules/time, 3 times/day, with a literature review period of 14 days.

Recommendation 8: For patients with cough, wheezing, purulent sputum with yellow color, and red tongue with yellow coating in the acute exacerbation stage of COPD, Qingfei Xiaoyan pills in combination with oxygen therapy, anti-infection, expectoration, and maintenance of fluid and electrolyte balance is recommended to speed up relief from cough, excess sputum, and wheezing; alleviate respiratory difficulties; and improve quality of life. (Low priority; C)

(Summary of evidence)

One RCT study [51] reported that the combination of Qingfei Xiaoyan pills can speed up relief from major symptoms and signs (cough ($n = 106$, $MD = -1.65$, 95% $CI (-2.36, -0.94)$, $p < 0.0001$), sputum ($MD = -1.37$, 95% $CI (-2.02, -0.72)$, $p < 0.0001$), wheezing ($MD = -1.19$, 95% $CI (-1.79, -0.59)$, $p = 0.0001$), lung wheezing ($MD = -1.47$, 95% $CI (-2.29, -0.65)$, $p = 0.0005$)) and improve the mMRC score ($MD = -0.36$, 95% $CI [-0.48, -0.24]$, $p < 0.0001$) and CAT score ($MD = -3.89$, 95% $CI [-5.06, -2.72]$, $p < 0.0001$).

(Safety)

This study [51] reported the use of Qingfei Xiaoyan pills in the treatment of 53 patients with COPD for 14 days, resulting in one case each of headache, nausea, and tachycardia. In the control group comprising 53 patients, one case of headache and another case of tachycardia were reported. There was no statistically significant difference between the two groups ($n = 106$, $RR = 1.5$, 95% $CI [0.26, 8.62]$, $p = 0.65$). The study did not explain the correlation between the above events and the drug, and the drug instructions indicated that adverse reactions were not yet clear.

(Recommendation basis)

Qingfei Xiaoyan pills have the effects of clearing the lungs and resolving phlegm, relieving cough and gasp. They can effectively shorten the duration of coughing, expectoration, and wheezing in patients with COPD, alleviate breathing difficulties, and improve their quality of life. The drug was included in the catalog of medicines covered by medical insurance across the country (2023 Edition), the Class A of list of over-the-counter drugs, and the Pharmacopoeia of the People's Republic of China (2020 Edition). It and was recommended for the treatment of AECOPD in the "Clinical Application Guidelines of Chinese Patent Medicine for Chronic Obstructive Pulmonary Disease (2021)" [6].

(Dosage and administration)

Qingfei Xiaoyan pills: oral administration, 60 pills/time for adults, 3 times/day. The medication was for 14 days in this study.

Recommendation 9: For patients with cough, wheezing, yellow and sticky sputum, red tongue and yellow fur in the acute exacerbation stage of COPD, Qingke Pingchuan granules in

combination with oxygen therapy, cough and phlegm reduction, spasmolysis and gasp relief, and antibacterial therapy is recommended to improve cough scores and respiratory distress symptoms. (Low priority; B)

(Summary of evidence)

A randomized, double-blind, placebo-controlled trial [52] demonstrated that oral administration of Qingke Pingchuan granules reduced the cough symptom score in the Cough And Sputum Assessment Questionnaire (CASA-Q) of patients with AECOPD ($n = 56$, $MD = 12.50$, 95% $CI [0.84, 24.16]$, $p = 0.04$) and the mMRC score ($MD = -1$, 95% $CI [-1.65, -0.35]$, $p = 0.003$). However, there were no statistically significant differences observed between the treatment and control groups in terms of cough impact ($MD = 3.69$, 95% $CI [-3.65, 11.03]$, $p = 0.32$), expectoration symptoms ($MD = -2.38$, 95% $CI [-11.55, 6.79]$, $p = 0.61$), expectoration impact ($MD = -0.6$, 95% $CI [-7.25, 6.05]$, $p = 0.86$) scores, CAT score ($MD = -1.52$, 95% $CI [-4.26, 1.22]$, $p = 0.28$), and quality of life (COPD clinical questionnaire, CCQ) score, ($MD = -0.29$, 95% $CI [-0.77, 0.19]$, $p = 0.24$) CASA-Q scores.

(Safety)

The study [52] reported on the treatment of 60 cases of AECOPD with Qingke Pingchuan granules. Over 14 days, the experimental group had one case of paroxysmal atrial fibrillation, while the control group had three cases of abdominal pain and diarrhea, one case of nausea and vomiting, and one case of rash. Neither group experienced any severe adverse events. The adverse events and the drug were deemed possibly unrelated, and there was no statistically significant difference between the experimental and control groups ($n = 59$, $RR = 0.21$, 95% $CI [0.03, 1.67]$, $p = 0.14$). The drug instructions indicated that the adverse reactions were not yet clear.

(Recommendation basis)

Qingke Pingchuan granules have the effects of clearing heat and promoting lung circulation and relieving cough and asthma and can alleviate cough scores and improve respiratory distress symptoms in patients with COPD. This drug is included in the catalog of medicines covered by medical insurance across the country (2023 Edition) and is recommended for the treatment of acute exacerbation of COPD (Phlegm heat accumulating the lung syndrome) in the "Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease (2023 Edition)" [13].

(Dosage and administration)

Qingke Pingchuan granules: Take with boiling water at 10 g/time, 3 times/day. The used it for 14 days.

Recommendation 10: For patients with wheezing, shortness of breath, confusion, limb restlessness or even convulsions, drowsiness, coma, delirium, greasy or yellowish fur in the AECOPD, combination treatment with Ditan decoction is recommended. For those with fever, delirium, red tongue, and yellowish fur, Angong Niu Huang pills should be added. (Low priority; expert consensus)

(Recommendation basis)

Ditan decoction and Angong Niu Huang pills are respectively derived from the “Fine Prescriptions of Wonderful Efficacy” and “Wen Bing Tiao Bian.” They are effective in clearing phlegm and opening orifices and can effectively alleviate symptoms such as confusion in patients with acute exacerbation of COPD. This medicine is included in the “Guideline of integrated Chinese and western medicine for diagnosis and treatment of chronic obstructive pulmonary disease” [10], “Diagnosis and treatment guideline for Chinese medicine on chronic obstructive pulmonary disease (2019 edition)” [12], the “National Health and Family Planning Commission ‘13th Five-Year Plan’ planned parenthood,” and the “Internal Medicine of Chinese Medicine (Third Edition) published by People’s Health Publishing House” [46]. It is recommended for the treatment of AECOPD (Phlegm-blinding spiritual orifices syndrome).

(Dosage and administration)

Ditan decoction: Qingbanxia (Rhizoma Pinelliae Preparata) 9 g, Tiannanxing (Rhizoma Arisaematis) 6 g, Tianzhuhuang (Concretio Silicea Bambusae) 6 g, Fuling (Poria) 15 g, Chenpi (Pericarpium Citri Reticulatae) 9 g, Zhishi (Fructus Aurantii Immaturus) 9 g, Danshen (Radix Salviae Miltiorrhizae) 15 g, Renshen (Radix Ginseng) 9 g, Shichangpu (Rhizoma Acori Tatarinowii) 6 g, Xixin (Herba Asari) 3 g, and Shengjiang (Rhizoma Zingiberis Recens) 6 g, 1 dose/day, decoct in water, take twice, for 7–14 days.

Angong Niu Huang pills: Niu Huang (Calculus Bovis), Yujin (Rhizoma Curcumae), Xijiao (Cornu Rhinocerotis) concentrated powder of buffalo horn, Huanglian (Rhizoma Coptidis), Huangqin (Radix Scutellariae), Zhizi (Fructus Gardeniae), Zhusha (cinnabar), Xionghuang (realgar), Meipian (borneol), Shexiang ([Moschus] or artificial musk), Zhenzhu (pearl), Jinboyi (gold leaf garment). The medication instructions are as follows: oral administration. 2 pills/time (1.5 g per pill) or 1 pill (3 g per pill), once a day for 7–14 days. Please follow the doctor’s advice for details. For patients with high fever and coma due to stroke who find it difficult to take this product orally, nasal feeding is recommended.

5.6 | Clinical Question 6: Is It Possible to Reduce the Duration of Antibiotic Use in Patients With AECOPD Who Are Receiving Conventional Western Medical Treatment Combined With Chinese Medicine?

According to GOLD 2024 [1], a viral or bacterial infection may serve as the catalyst for an acute exacerbation of COPD. Antimicrobials are necessary when patients exhibit at least two of the three symptoms of increased dyspnea, increased sputum volume, and purulent sputum or when mechanical ventilation (either noninvasive or invasive) is required. The recommended course of antibiotic therapy is five to seven days. The decision to use antibiotics should be based on the specific circumstances of the patient, including the severity of the infection, strain of bacteria, and general condition of the patient. At the same time,

the choice of antibiotics should be based on the local bacterial resistance situation. Improvement in dyspnea and reduction in purulent sputum suggest that treatment is effective.

Combined Chinese and Western medicine is an effective treatment strategy to improve the symptoms and quality of life in patients with AECOPD. Studies have shown that it is possible to reduce the duration of antibiotic use with interventions based on syndrome differentiation combined with TCM.

Recommendation: For patients with cough, sputum with yellow color, sore throat and yellowish tongue in acute exacerbation of COPD, based on oxygen therapy, anti-infection, expectorant and asthma treatment, Qingjin phlegm soup is recommended. It can reduce the time of antimicrobial drug use. (Low priority; D)

(Summary of evidence)

Two RCTs [53, 54] reported that combination treatment with Qingjin phlegm soup decreased the length of antimicrobial use by 2.25 days ($n = 144$, $MD = -2.25$, 95% $CI [-2.47, -2.03]$, $p < 0.00001$, $I^2 = 0\%$) and improved the TCM symptom score ($n = 144$, $MD = -3.4$, 95% $CI [-6.12, -0.69]$, $p = 0.01$).

(Safety)

Adverse responses were not reported by the two studies [53, 54]. A Meta-analysis [55] revealed 24 cases of gastrointestinal symptoms, such as nausea, vomiting, and diarrhea, among 536 older adults with community-acquired pneumonia treated with combined Qingjin phlegm soup for 7 to 14 days. These cases were reported by two studies (160 cases), and none of the differences between the groups were statistically significant. One study mentioned abnormalities in liver and kidney function in the test and control groups, with no statistically significant differences. These returned to normal on review after treatment. The study did not elaborate on the relevance of the above events to the drug.

(Recommendation basis)

Qingjin phlegm soup originates from “Miscellaneous Diseases” quoted in “General Principles of Medicine.” It is effective in clearing the lungs and dissolving phlegm. Combined treatment with Qingjin phlegm soup can significantly alleviate the symptoms of cough, yellow-colored sputum, and sore throat in patients with COPD and shorten the duration of antimicrobial medication usage. It is recommended for the treatment of AECOPD (phlegm-heat congestion of the lungs syndrome) in the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease (2023 Edition)” [13].

(Dosage and administration)

Qingjin phlegm soup: Huangqin (Radix Scutellariae) 15 g, Zhizi (Fructus Gardeniae) 10 g, Zhimu (Rhizoma Anemarrhenae) 12 g, Sangbaipi (Cortex Mori) 12 g, Gualouren (Fructus Trichosanthis) 15 g, Zhebeimu (Bulbus Fritillariae Thunbergii) 15 g, Chenpi

(Pericarpium Citri Reticulatae) 15 g, Fuling (Poria) 10 g, Maidong (Radix Ophiopogonis) 15 g, Jiegeng (Radix Platycodonis) 15 g, Zhigancao (Radix Glycyrrhizae) 6 g. One dose is required per day in two servings for 14 days. It should be decocted in water.

5.7 | Clinical Question 7: For Patients With AECOPD Receiving Conventional Western Medical Treatment, Can Integrating Chinese Medical Treatment Shorten the Duration of Hospitalization?

GOLD 2024⁽¹⁾ states that Western medical treatments for AECOPD include medications (bronchodilators, corticosteroids, antibiotics, etc.), oxygen therapy, noninvasive or invasive mechanical ventilation, and rehabilitation training, which can effectively improve the clinical symptoms, rapidly control the condition, decrease the frequency of acute exacerbations, and the length of hospitalization. By regulating qi and blood, yin and yang, internal organs and others, Chinese medicine enhances physical fitness, improves resistance, and prevents further deterioration and relapse of the condition. In addition, Chinese medicines contain components with anti-inflammatory, antioxidant, and immunomodulatory effects, which can complement the effects of Western medical treatment, improve therapeutic efficacy, and shorten the duration of hospitalization.

Recommendation: For patients with fever, cough, adverse sputum production, and red tongue with yellow fur in the AECOPD, Tanreqing injection in addition to conventional Western medical treatment is recommended based on oxygen, anti-infection, and phlegm-reducing and asthma-alleviating treatments, which can shorten the average length of hospitalization. (Low priority; C)

(Summary of evidence)

Two RCTs [56, 57] reported that combination treatment with Tanreqing injection can shorten the mean duration of hospitalization by 3.75 days relative to the control ($n = 248$, $MD = -3.75$, 95% $CI [-4.20, -3.31]$, $p < 0.00001$, $I^2 = 34\%$).

(Safety)

Adverse events were not reported in the two studies included [56, 57]. A meta-analysis of [48] Tanreqing injection for severe pneumonia in older adults revealed that 216 patients treated with combined Tanreqing injection for 7–15 days experienced 10 cases of adverse interactions. These reactions included nausea, rash, vomiting, dizziness, localized pain, and other symptoms. The study did not explain the association between the events described and the drug. The drug insert suggests occasional allergic reactions, such as dizziness, nausea, vomiting, generalized redness, itching, or rash.

(Recommendation basis)

Tanreqing injection focuses on clearing the heat, purifying the phlegm, and detoxification. Combination treatment with Tanreqing injection can improve the symptoms of fever and yellow sputum in patients with AECOPD and shorten the length of hospitalization. It is recommended by several expert con-

sensus/guidelines for the treatment of AECOPD (phlegm-heat congestion syndrome).

(Dosage and administration)

Tanreqing injection: The dosage of 20 mL/time, once a day for 7–10 days was recorded in the two included studies [56, 57].

5.8 | Clinical Question 8: For Patients With COPD Combined With Respiratory Failure, Is There a Benefit of Integrating TCM Therapy?

GOLD 2024⁽¹⁾ recommends that noninvasive mechanical ventilation should be the first mode of ventilation for patients with COPD with acute respiratory failure who have no absolute contraindication. This can improve oxygenation and acute respiratory acidosis and shorten the length of hospital stay. If noninvasive mechanical ventilation proves ineffective initially, we recommend invasive mechanical ventilation. These patients have more complications, longer hospital stays, and higher mortality rates. The indications for the application of mechanical ventilation are shown in Figure 6.

Several studies have indicated that the combination of Chinese and Western medicine in treating patients with acute exacerbation of respiratory failure in COPD is more efficacious than the use of either Chinese or Western medicines alone and is more likely to benefit the patients.

Recommendation 1: For patients with AECOPD and respiratory failure accompanied by fever, cough, unfavorable sputum output, red tongue, and yellow moss, combined treatment with Tanreqing injection is recommended based on intermittent noninvasive positive-pressure ventilation, oxygen, asthma-relieving, and anti-infective treatments, which can improve the ventilatory dysfunction. (Low priority; C)

(Summary of evidence)

Two RCTs [58, 59] reported that combination therapy with Tanreqing injection for 14 days for patients with AECOPD and respiratory failure improves the PCO_2 index ($n = 314$, $MD = -5.67$, 95% $CI [-8.21, -3.13]$, $p < 0.0001$, $I^2 = 72\%$).

Another RCT [60] reported that adding phlegm-heat-clearing injection can effectively improve the PCO_2 index ($n = 97$, $MD = -1.73$, 95% $CI [-2.87, -0.59]$, $p = 0.003$), inflammatory index (Procalcitonin, PCT) ($MD = -0.20$, 95% $CI [-0.30, -0.10]$, $p < 0.0001$), CRP ($MD = -6.89$, 95% $CI [-10.05, -3.73]$, $p < 0.0001$), and the quality of life CCQ scores of patients with AECOPD and respiratory failure ($MD = -0.09$, 95% $CI [-0.17, -0.01]$, $p = 0.04$). It can also shorten the length of hospitalization of the patients ($MD = -1.79$, 95% $CI [-2.89, -0.69]$, $p = 0.001$). However, there were no differences in the rate of tracheal intubation ($RR = 0.41$, 95% $CI [0.08, 2.00]$, $p = 0.27$) and morbidity and mortality rates during hospitalization between the groups ($RR = 0.51$, 95% $CI [0.05, 5.45]$, $p = 0.58$).

(Safety)

Indications for the application of mechanical ventilation in COPD combined with respiratory failure	
Indications for Noninvasive Mechanical Ventilation (NIV)	Indications for Invasive Mechanical Ventilation
<p>At least one of the following:</p> <ol style="list-style-type: none"> 1. Respiratory acidosis ($\text{PaCO}_2 \geq 6.0 \text{ kPa}$ or 45 mmHg and arterial $\text{pH} \leq 7.35$) 2. Severe dyspnea with clinical signs suggestive of respiratory muscle fatigue, increased work of breathing, or both, such as use of respiratory accessory muscles, paradoxical motion of the abdomen, or retraction of the intercostal spaces 3. Persistent hypoxemia despite supplemental oxygen therapy 	<ol style="list-style-type: none"> 1. Unable to tolerate NIV or NIV failure 2. Status post-respiratory or cardiac arrest 3. Diminished consciousness, psychomotor agitation inadequately controlled by sedation 4. Massive aspiration or persistent vomiting 5. Persistent inability to remove respiratory secretions 6. Severe hemodynamic instability without response to fluids and vasoactive drugs 7. Severe ventricular or supraventricular arrhythmias 8. Life-threatening hypoxemia in patients unable to tolerate NIV

FIGURE 6 | Indications for the application of mechanical ventilation in acute exacerbations of COPD.

Adverse responses were not reported in the two studies included [58, 59]. One study evaluated for safety, and no adverse effects were observed. A meta-analysis [48] of Tanreqing injection for severe pneumonia in older adults revealed that 216 patients treated with combined Tanreqing injection for 7–15 days experienced 10 cases of adverse interactions. These reactions included nausea, rash, vomiting, dizziness, localized pain, and other symptoms. The study did not explain the correlation between the events described and the drug. The drug insert suggests occasional allergic reactions, such as dizziness, nausea, vomiting, generalized redness, itching, or rash.

(Recommendation basis)

Tanreqing injection focuses on clearing the heat, purifying the phlegm, and detoxifying toxins. Combination treatment with Tanreqing injection can improve the symptoms of fever and yellow sputum in patients with AECOPD and shorten the length of hospitalization. It is recommended by several expert consensus/guidelines [6, 13] for the treatment of AECOPD (phlegm-heat congestion syndrome).

(Dosage and administration)

Tanreqing injection: 20 mL/time, once a day for 14 days was recorded in the three included studies [58, 59].

Recommendation 2: For patients with AECOPD; respiratory failure; and invasive mechanical ventilation indications, combined with cough, breathlessness, panic, pallor, cold limbs, cold sweat, mental depression, the combination of Shenfu injection is recommended based on invasive-noninvasive sequential mechanical ventilation and basic treatment (antispasmodic and asthma medications, glucocorticosteroids, antibiotics, phlegm medications, nutritional supportive therapy, and physiotherapy). This may improve ventilatory dysfunction. (Low priority; C)

(Summary of evidence)

One RCT study [61] found that the combination of adjuvant therapy with Shenfu injection reduced the invasive ventilation time ($n = 60$, $MD = -1.33$, 95% $CI [-1.65, -1.01]$, $p < 0.00001$), total mechanical ventilation time ($MD = -2.64$, 95% $CI [-3.33, -1.95]$, $p < 0.00001$), ICU length of stay ($MD = -3.70$, 95% $CI [-4.98, -2.42]$, $p < 0.00001$), and total length of stay ($MD = -3.00$, 95% $CI [-4.66, -1.34]$, $p = 0.0004$) of patients with AECOPD, respiratory failure, and invasive mechanical ventilation.

(Safety)

Security was not reported in this study [61]. The drug insert suggests occasional clinical tachycardia, allergic reactions, rash, dizziness and headache, eructation, tremor, dyspnea, nausea, visual abnormalities, abnormalities of hepatic function, and urinary retention.

(Recommendation basis)

Given its efficacy in restoring yang and rescuing patients from collapse and invigorating qi for relieving desertion, Shenfu injection can improve the symptoms of coughing and suffocating, wheezing, cold limbs, and mental depression in patients with AECOPD and respiratory failure. It can also alleviate ventilatory dysfunction. This drug is included in Class A of the catalog of medicines covered by medical insurance across the country (2023 Edition). It is also recommended in the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease(2023 Edition)” [13] for critical care resuscitation of COPD.

(Dosage and administration)

The dosage is 60 mL at a time, once a day. It was administered via intravenous drip in the included studies.

Recommendation 3: For patients with AECOPD, type II respiratory failure, tracheal intubation indications, and fatigue,

palpitation, shortness of breath, spontaneous sweating and night sweating, dyspnea and cyanosis, based on the application of invasive-noninvasive sequential mechanical ventilation; anti-infective, expectorant, and antispasmodic effects; correction of electrolyte disorders; regulation of acid-base imbalance; and nutritional support therapy, shenmai injection is recommended to improve ventilation dysfunction. (Low priority; D)

(Summary of evidence)

One RCT [62] reported that adjuvant treatment with Shenmai injection was effective in reducing the duration of invasive mechanical ventilation ($n = 58$, $MD = -70.80$, 95% $CI [-75.28, -66.32]$, $p < 0.00001$) and ICU length of stay ($MD = -3.80$, 95% $CI [-5.06, -2.54]$, $p < 0.00001$) for patients with AECOPD and type II respiratory failure, ineffective treatment with noninvasive ventilator ventilation and respiratory stimulant therapy, and an indication for endotracheal intubation.

Another RCT [63] showed that adjuvant treatment with Shenmai injection reduced the duration of invasive mechanical ventilation ($n = 56$, $MD = (-39.80$, 95% $CI (-54.02, -25.58]$, $p < 0.00001$)) and ICU length of stay ($MD = -2.80$, 95% $CI [-4.17, -1.43]$, $p < 0.0001$) for patients with AECOPD and type II respiratory failure who required invasive mechanical ventilation therapy.

(Safety)

Safety was not reported in the two included studies [62, 63]. A meta-analysis [64] showed that during the 14-day treatment of 1469 patients with pulmonary heart disease with Shenmai injection in combination with western medicines, nine cases of adverse reactions occurred in the treatment group (including headache, dizziness, thirst, loss of appetite, and panic) and three cases occurred in the control group (including headache, dizziness, and panic) There was no significant difference between the two groups ($RR = 2.93$, 95% $CI [0.80, 10.78]$, $p = 0.11$). The study did not explain the association between the events described and the drug. The drug specification suggests that allergic reactions such as skin rash, flushing, palpitations, chest tightness, cyanosis of lips and mouth, and infusion reactions such as fever and chills may occur, and severe anaphylactic shock is possible.

(Recommendation basis)

Shenmai injection focuses on replenishing qi and consolidating the exterior, nourishing yin and promoting the production of body fluid, and promoting the production of pulse. It can improve the symptoms of fatigue, palpitation, shortness of breath, spontaneous sweating and night sweating in patients with AECOPD complicated with respiratory failure, and relieve dyspnea. This drug is included in Class A of the catalog of medicines covered by medical insurance across the country (2023 Edition) and National Directory of Essential Medicines (2018 Edition). It is also recommended in the “Expert Consensus on Integrated Traditional Chinese and Western Medicine Management for Chronic Obstructive Pulmonary Disease(2023 Edition)” [13] for critical care resuscitation of COPD.

(Dosage and administration)

The dose was 40 mL/time, once a day for 14 days in the two included studies.

5.9 | Clinical Question 9: For Patients With AECOPD Combined With Gastrointestinal Dysfunction, Can Combined Chinese Medicine Improve Gastrointestinal Dysfunction?

Gastrointestinal dysfunction is a common comorbidity of COPD, and patients may exhibit gastrointestinal symptoms such as nausea, vomiting, abdominal distension, and abdominal pain. It often interacts with the existing respiratory symptoms, may aggravate dyspnea, and can affect the nutritional status and quality of life of patients. Current studies have found that gastrointestinal dysfunction in patients with COPD is related to abnormal gastrointestinal dynamics, impaired intestinal barrier, imbalance of gastrointestinal flora, imbalance of gastrointestinal hormone secretion, and abnormal psychological state. Therefore, targeted dietary adjustment, improvement of nutritional status, and treatment of gastrointestinal dysfunction are also needed for these patients.

TCM can significantly improve respiratory and gastrointestinal symptoms, regulate nutritional status, and improve exercise capacity in patients with AECOPD combined with gastrointestinal dysfunction. The use of Chinese medical treatments such as Jiawei Liangge powder and electroacupuncture is recommended.

Recommendation 1: For patients with AECOPD combined with gastrointestinal dysfunction, abdominal distension, and constipation, Jiawei Liangge powder is recommended based on the use of oxygen therapy and anti-infectives, asthma, and cough and phlegm treatment. (Low priority; D)

(Summary of evidence)

An RCT [65] reported that combination treatment with Jiawei Liangge powder had a protective effect on the abdominal distension syndrome score ($n = 120$, $MD = -1.12$, 95% $CI [-1.25, -0.99]$, $p < 0.00001$), constipation syndrome score ($MD = -1.69$, 95% $CI [-1.90, -1.48]$, $p < 0.00001$), and intra-abdominal pressure ($MD = -7.27$, 95% $CI [-8.80, -5.74]$, $p < 0.00001$) compared with the control group.

(Safety)

This study [65] reported no adverse effects.

(Recommendation basis)

Liangge powder is from Prescriptions of the Bureau of Taiping People's Welfare Pharmacy. It is beneficial for diarrhea and detoxification and clearing the upper and draining the lower part of the body. It can relieve symptoms of bloating and constipation in patients with COPD.

(Dosage and administration)

Liangge powder contains Chuandahuang (*Radix et Rhizoma Rhei*) 10 g, Gancao (*Radix Glycyrrhizae*) 6 g, Shanzhizi (*Fructus Gardeniae*) 10 g, Boheye (*Herba Menthae*) 6 g (decocting later), Huangqin (*Radix Scutellariae*) 10 g, Lianqiao (*Fructus Forsythiae*) 15 g, Zhuye (*Folium Phyllostachys*) 10 g, Zhebeimu (*Bulbus Fritillariae Thunbergii*) 10 g, Kuxingren (*Semen Armeniacae Amarum*) 10 g, Gualouren (*Fructus Trichosanthis*) 15 g, Qianhu (*Radix Peucedani*) 10 g, and Xuanmingfen (*Natrii Sulfas Exsiccatus*) 10 g, (*Semen Descurainiae*, administration after dissolving). One dose is required each day. It is taken warm in the morning and evening after meals. It was used for 7 days in the study.

Recommendation 2: For patients with gastrointestinal dysfunction dyspepsia and constipation combined with AECOPD based on the application of low-flow oxygen, anti-infection, anti-inflammation and asthma and supportive therapy, the use of electroacupuncture in combination therapy is recommended. This can improve the symptoms of dyspepsia and constipation in patients. (Low priority; C)

(Summary of evidence)

An RCT [66] reported that the combination of electroacupuncture (electroacupuncture therapeutic device, taking acupoints such as foot-sanli, yinlingquan and zhongwan) had a protective effect on gastrointestinal function in patients with COPD, and it reduced the GRSR scores ($n = 97$, $MD = -3$, 95% $CI [-3.92, -2.08]$, $p < 0.00001$), and improve dyspepsia ($MD = -1.75$, 95% $CI (-2.04, -1.46)$, $p < 0.00001$) and constipation scores ($MD = -1$, 95% $CI [-1.59, -0.41]$, $p = 0.0009$).

(Safety)

This study [66] reported no adverse effects.

(Recommendation basis)

Derived from traditional acupuncture, electroacupuncture treats diseases by applying electric current at specific frequencies to acupuncture points through electrodes attached to needles. This method provides two-way regulation of gastrointestinal peristalsis through multiple pathways and dimensions. Combined electroacupuncture can effectively alleviate the symptoms of indigestion and constipation in patients with COPD.

(Dosage and administration)

The acupoints for this study: foot-sanli, yinlingquan, zhongkou, shui, tianshu, shakuzawa, and leiqui. It should be administered for 30 min per session, once a day, for a total of five sessions. The study administered it for 5 days.

6 | Limitations and Shortcomings of the Guidelines

These guidelines were formulated based on an extensive collection of clinical questions, comprehensive evidence retrieval, literature analysis, and expert discussions. However, there are still certain limitations. First, the current literature evidence on integrated traditional Chinese and Western medicine treatment for COPD is limited and of low quality, resulting in limited recommended treatment options. Second, As COPD is a chronic airway disease with a long treatment cycle, the long-term efficacy of integrated traditional Chinese and Western medicine treatment requires further research. Third, the duration and safety evaluation of the recommended treatments need continuous observation during future clinical applications. Fourth, the formulations and Chinese medicines recommended in these guidelines are based solely on existing research evidence and practical experience. Clinicians should make appropriate adjustments based on actual conditions during application. Fifth, Certain clinical questions lack evidence and consensus; thus, no recommendations were made in this edition. For example, can early intervention with integrated traditional Chinese and Western medicine benefit the early stages or high-risk groups of COPD? Can integrated treatment reduce the use of ICS? Is there a benefit in using TCM alone for patients with mild COPD? Further exploration and practice are required to provide more high-level evidence-based support.

7 | Guideline Update Plan

According to relevant management regulations, these guidelines are intended to be updated or further developed every 3 to 5 years. The content of the updates will depend on whether new relevant evidence emerges after the publication of the guidelines, and whether changes in the evidence affect the recommendations and their strength. The update standards will follow the “Check Up” norms for international guideline update reports. The entire process will be achieved through a combination of literature research, questionnaire surveys, and expert discussion meetings.

Summary Table of Opinions on the Clinical Application Guideline for the Integration of Traditional Chinese Medicine and Western Medicine in the Prevention and Treatment of COPD

Staging/ comorbidities	Purpose	Applicable people	Syndrome differentiation in		Basic Western medicine treatment	Recommendations	Recommendation level	Evidence level
			TCM					
Stable phase	Improve quality of life	Patients with stable COPD	Qi deficiency of the lung syndrome:		Reference to the GOLD 2024 Treatment Strategy:	Combined with YuPingFeng granule	High priority	C
			Qi deficiency of the lung and spleen syndrome		Initial inhaled medication therapy.	Combined with Buzhong Yiqi decoction	Low priority	D
			Qi deficiency of the lung and kidney syndrome		Group A patients chose a bronchodilator. Groups B and E chose	Combined with Gushen Dingchuan pill	Low priority	D
			Qi and yin deficiency of the lung and kidney syndrome		LABA+LAMA as the initial treatment option, while the combination	Combined with Baoyuan decoction and Renshen Buwei decoction	Low priority	Expert consensus
			Deficiency of both lung and kidney complicated with blood stasis syndrome		therapy of ICS was guided based on EOS levels. Follow-up medication adjustment strategy: If the	Combined with Buwei Huoxue capsules	Low priority	D
			Qi and yin deficiency		initial treatment is effective, maintain it; If the effect is unsatisfactory,	Combined with Runfei cream	High priority	C
			Qi deficiency of the lung syndrome, Qi deficiency of the lung and spleen syndrome, or Qi deficiency of the lung and kidney syndrome		adjust the treatment strategy based on the treatable characteristics of the patients (dyspnea or acute exacerbation), and replace the inhalation device or medication type.	Combined with Tai Chi Combined with Baduanjin Combined with acupoint application	High priority Low priority Low priority	C D C
						Combined with Yifei moxibustion	Low priority	D

(Continues)

Staging/ comorbidities	Purpose	Applicable people	Syndrome differentiation in TCM	Basic Western medicine treatment	Recommendations	Recommendation level	Evidence level
	Alleviate dyspnea or exercise intolerance	Patients with persistent dyspnea or exercise intolerance after standardized Western medicine treatment during the stable stage of COPD	Qi deficiency of the lung syndrome		Combined with Yupingfeng granules	Low priority	C
			Qi deficiency of the lung and spleen syndrome		Combined with Buzhong Yiqi decoction	Low priority	D
			Qi deficiency of the lung and kidney syndrome		Combined with Gushen Dingchuan pill	Low priority	D
			Qi deficiency of the lung and kidney syndrome		Combined with Bailing capsule	Low priority	D
			Deficiency of lung and kidney with heat phlegm syndrome		Combined with Huanglong Kechuan capsule	Low priority	B
			Deficiency of lung and kidney with blood stasis syndrome		Combined with Bufei Huoxue capsules	Low priority	C
			Qi deficiency of the lung syndrome Qi deficiency of the lung and spleen syndrome or Qi deficiency of the lung and kidney syndrome		Combined with Tai Chi	High priority	C
					Combined with Baduanjin	Low priority	D
					Combined with acupoint application	Low priority	D
					Combined with Warm acupuncture and moxibustion	Low priority	C
Reduce the frequency of acute exacerbations		After standardized Western medicine treatment, there are still patients with stable COPD with frequent acute exacerbations	Qi deficiency of the lung syndrome		Combined with Yupingfeng granules	Low priority	C
			Qi deficiency of the lung and kidney		Combined with Bailing capsule	Low priority	D
			Yang deficiency of spleen and kidney, phlegm retention obstructing lung syndrome		Combined with Tanyin pills	High priority	B
			Qi deficiency of the lung syndrome, Qi deficiency of the lung and spleen syndrome		Combined with Tai Chi	Low priority	D

(Continues)

Staging/ comorbidities	Purpose	Applicable people	Syndrome differentiation in TCM	Basic Western medicine treatment	Recommendations	Recommendation level	Evidence level
Acute Exacerbation of Chronic Obstructive Pulmonary Disease	Improve clinical symptoms	Mild, moderate, and severe patients with acute exacerbation	Wind cold invading lung syndrome	(1) GOLD 2024 recommends that patients with mild-to-moderate symptoms receive treatment such as bronchodilators, glucocorticoids, and/or antibiotics in outpatient settings. Patients with severe disease should be hospitalized for treatment.If the condition is life-threatening, admit to the ICU as soon as possible. (2) Treat acute exacerbations with short-acting inhaled β_2 receptor agonists (with or without short-acting anticholinergic drugs) as initial bronchodilators.(3) The recommended duration of antimicrobial therapy is 5–7 days.(4) The use of systemic glucocorticoids is limited to no more than 5 days, with a recommended dose of prednisone 40 mg per day.(5) Provide respiratory support such as oxygen therapy, noninvasive mechanical ventilation, and invasive mechanical ventilation according to the condition, and pay attention to monitoring fluid balance and nutrition.	Combination with Sanao decoction and Zhisou powder	Low priority	Expert consensus
			Wind and heat invading lung syndrome		Combination with Shufeng Jiedu capsules	Low priority	D
			External cold and internal water syndrome		Combination with Xiaoqinglong decoction	Low priority	Expert consensus
			Phlegm turbid obstructing the lung syndrome		Combine Erchen decoction with Sanzi Yangqin decoction or Suzi Jiangqi decoction with Sanzi Yangqin decoction	Low priority	Expert consensus
	Reduce the duration of antibiotic use Reduce length of stay		Heat phlegm accumulating in the lung syndrome		Combination with Tanreqing injection	Low priority	D
			Heat phlegm accumulating in the lung syndrome		Combination with Danlong oral liquid	Low priority	C
			Heat phlegm accumulating in the lung syndrome		Combination with Guilong Kechuanning capsules	Low priority	C
			Heat phlegm accumulating in the lung syndrome		Combination with Qingfei Xiaoyan pills	Low priority	C
			Heat phlegm accumulating in the lung syndrome		Combination with Qingke Pingchuan granules	Low priority	B
			Heat phlegm accumulating in the lung syndrome		Combination with Qingjin phlegm decoction	Low priority	D
			Heat phlegm accumulating in the lung syndrome		Combination with Tanreqing injection	Low priority	C

(Continues)

Staging/ comorbidities	Purpose	Applicable people	Syndrome differentiation in TCM	Basic Western medicine treatment	Recommendations	Recommendation level	Evidence level
Comorbidities	Improve ventilation dysfunction	Patients with combined respiratory failure receiving intermittent noninvasive positive pressure ventilation	Fever, cough, unfavorable sputum, red tongue, yellow coating		Combination with Tanreqing injection	Low priority	C
	Improve gastrointestinal dysfunction	Patients with combined respiratory failure receiving invasive mechanical ventilation who are hemodynamically unstable	Coughing, breathlessness, panic, pallor, cold limbs, cold sweat, mental depression		Combination with Shenfu injection	Low priority	C
	Improve gastrointestinal dysfunction	Combined gastrointestinal disorders	Bloating and constipation		Combination with Jiawei Liangge powder	Low priority	D
	Improve respiratory symptoms and consciousness disorders	Combined pulmonary encephalopathy	Phlegm-blinding spiritual orifices syndrome		Combination with Ditan decoction or (and) Angong Niu Huang pills	Low priority	Expert consensus

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Conflicts of Interest

The authors declare no conflicts of interest.

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