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国际中医临床实践指南

慢性阻塞性肺疾病

International Clinical Practice Guideline of Chinese Medicine

Chronic Obstructive Pulmonary Disease

世界中联国际组织标准
International Standard

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前　　言

《国际中医临床实践指南 慢性阻塞性肺疾病》是在中华中医药学会2019年发布的《慢性阻塞性肺疾病中医诊疗指南》（标准号：T/CACM1319-2019 ）基础上，结合近年来的海内外临床研究证据，进行证据分级和意见推荐，经过专家讨论，而形成的国际中医临床实践指南。

本指南主要起草单位：河南中医药大学、河南中医药大学第一附属医院。

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Review Article

International Clinical Practice Guideline of Chinese Medicine: Chronic Obstructive Pulmonary Disease

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Abstract

Chronic obstructive pulmonary disease (COPD) is a major chronic disease that seriously endangers public health. Some remarkable results have shown that Chinese medicine has an obvious clinical effect in preventing and treating COPD. To further promote the normative use of Chinese medicine to better guide the clinical diagnosis and treatment of COPD, the World Federation of Chinese Medicine Societies developed a panel to establish the guidelines by systematically evaluating, based on the revision and transformation of *Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease* released by the China Association of Chinese Medicine in 2019 (Standard No: T/CACM 1319-2019), the latest clinical research evidence at home and abroad, formatting the *International Clinical Practice Guideline of Chinese Medicine—Chronic Obstructive Pulmonary Disease*, and publishing in both Chinese and English. The guidelines consist of 12 parts: preface, introduction, scope, normative references, terms and definitions, disease diagnosis and staging, severity assessment, etiology and pathogenesis, syndrome differentiation and treatment, other treatment, prevention and care, and appendix. They also standardize the contents of traditional Chinese medicine (TCM) etiology and pathogenesis, syndrome differentiation and treatment, and prevention and care of COPD. These guidelines are applicable to clinical respiratory physicians of TCM and integrated traditional Chinese and western medicine. The release of these guidelines will help improve the effect and level of Chinese medicine for COPD.

Keywords: Chinese medicine, chronic obstructive pulmonary disease, clinical practice guidelines

Introduction

Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable condition characterized by progressive airflow limitation. Cough, expectoration, dyspnea, and frequent acute exacerbations are the common symptoms of COPD. Due to high prevalence, high mortality, high disability rate, and heavy disease burden, COPD has become a major chronic disease that seriously endangers public health.[1] The global prevalence of COPD is about 11.7%,[2] with about 3.5 million deaths a year. The WHO estimates that more than 4.5 million people worldwide will die each year from COPD and related diseases by 2030. In China, the prevalence of COPD in people aged over 40 years is 13.7%, with nearly 100 million COPD patients.[3] COPD is the third leading cause of death[4] and ranks second in disease burden in terms of disability-adjusted life years[5] in China. Its prevention and treatment conditions are increasingly grim. In recent years, some remarkable results have shown that traditional Chinese medicine (TCM) has an obvious clinical effect in preventing and treating COPD.

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To further promote the normative use of Chinese medicine in guiding clinical diagnosis and treatment of COPD in China, The China Association of Chinese Medicine, Henan University of Chinese Medicine, and Lung Disease Branch of China Medical Association of Minorities jointly organized a working group of *Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease*, consisting of multidisciplinary researchers in respiratory diseases (Chinese medicine, western medicine, and integrative Chinese and western medicine), clinical epidemiology, evidence-based medicine, health economics,

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and Chinese Materia Medica. Literature document retrieval, Delphi questionnaire surveys, and conference discussions were used to develop the guidelines. First, a search strategy was developed based on the collected clinical problems and outcomes. Then, systematic research and quality evaluation were performed in Chinese literature (including modern literature and ancient books), English literature, and existing relevant international guidelines. Meanwhile, the evidence quality and evidence grading were performed based on the Grading of Recommendations Assessment Development and Evaluation (GRADE) system. The improved Delphi method was also used to conduct questionnaire surveys. After further improving the recommendations, a face-to-face expert consensus meeting was held to develop the guideline recommendations. Finally, the *Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease* was evaluated and released by The China Association of Chinese Medicine (Standard No: T/CACM 1319-2019).

In August 2019, the World Federation of Chinese Medicine Societies, to better apply the *Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease*, developed a panel to systematically evaluate the latest clinical research evidence at home and abroad and revise, transform, and format the *International Clinical Practice Guideline of Chinese Medicine—Chronic Obstructive Pulmonary Disease*.

Scope

This guideline specifies the contents of TCM etiology and pathogenesis, syndrome differentiation, and the prevention and treatment of COPD. This guideline is applicable to clinical respiratory doctors of TCM and integrated traditional Chinese and western medicine, as well as practitioners of TCM.

Normative References

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

- *Global Initiative for Chronic Obstructive Lung Disease (GOLD)*
- *China's Expert Consensus on the Diagnosis and Treatment of Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD) (Updated 2017)*
- *National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug List (2017 Edition)*
- *Chinese Medicines Clinical Application Guideline Respiratory Diseases Volume (2016 Edition)*
- *Pharmacopoeia of the People's Republic of China (2015 Edition)*
- *Diagnostic Criteria for Chinese Medicine Syndrome of Chronic Obstructive Pulmonary Disease (2011 Edition)*
- *Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease (2011 Edition)*
- *International Classification of Diseases Code (ICD-11)*.

Terms and Definitions

Chronic obstructive pulmonary disease (ICD-11: CA22)

A common disease that can be prevented and treated, characterized by persistent airflow limitation, is referred to as COPD.

Note 1: Airflow limitation is mostly progressive, associated with increased chronic inflammatory response to toxic particles or gases in the airways and lungs.

Disease Diagnosis and Staging

Acute exacerbation stage

AECOPD is an acute exacerbation of respiratory symptoms in patients, leading to additional treatment. Usually, in course of the disease, the patient has an exacerbation in cough, expectoration, and shortness of breath and/or wheezing, has an increased amount of sputum, purulent, or mucopurulent in the short term, and may be associated with fever and other manifestations of inflammation. Different treatment sites and treatment options are selected according to mild, moderate, and severe conditions. COPD is often associated with comorbid conditions; thus, AECOPD needs to be differentiated from acute coronary syndrome, acute congestive heart failure, pulmonary embolism, and pneumonia[1,6].

Acute exacerbation of the dangerous window stage

The acute exacerbation of the dangerous window period means that between the period of AECOPD and the stable period, it is highly likely that an acute exacerbation will occur again, resulting in an increase in hospitalization rate and mortality, mostly within 8 weeks after an acute exacerbation.[7]

Stable stage

This stage refers to patients with cough, expectoration, shortness of breath, and other symptoms that are stable or mild and without acute exacerbation within 6 weeks.[1,8]

Severity Assessment

The assessment of the severity of COPD should be reviewed in the GOLD.[1,9]

Etiology and Pathogenesis

COPD belongs to the category of "dyspnea" and "lung bloating" in Chinese medicine.[8] Root cause deficiency and manifestation excess are the main pathological changes of COPD. Accumulation and damage of healthy qi deficiency are the main pathogeneses of COPD.[10,11] Healthy qi deficiency means the deficiency and damage of the lung, spleen, and kidney, starting with the lung and involving the kidney long term. Healthy qi deficiency is the root cause of COPD, and accumulative damage cannot be recovered. Healthy qi deficiency does not transport generating phlegm and stasis

which often congeal into accumulation and thus damage the healthy qi. Healthy qi deficiency and accumulation damage are the cause and effect, eventually leading to damage in the shape and qi of the lung. This period is progressive, and recovery is difficult. The acute exacerbation stage is mainly excess syndromes of phlegm (phlegm heat, phlegm turbid) and stasis, combined with healthy qi deficiency. The stable stage is mainly deficiency syndromes of lung qi deficiency, lung spleen qi deficiency, lung kidney qi deficiency, and qi and yin deficiency of the lung and kidney and is commonly combined with blood stasis and phlegm turbidity. In the dangerous window stage, the pathogen excess is gradually removed and the root deficiency shows. Syndromes of phlegm turbidity, phlegm stasis and qi deficiency, and qi and yin deficiency occur. The pathological nature is intermingled deficiency and excess.[12]

Syndrome Differentiation and Treatment

In the AECOPD, syndromes of wind cold invading the lung, external cold and internal drink, phlegm turbid obstructing the lung, and phlegm-blinding spiritual orifices are commonly seen.[12-16] In the stable stage, syndromes of lung qi deficiency, lung spleen qi deficiency, lung kidney qi deficiency, and qi and yin deficiency of the lung kidney are commonly seen.[13-16] In acute exacerbation of the dangerous window stage, syndromes of lung kidney qi deficiency combined with phlegm turbid obstructing the lung, lung kidney qi deficiency combined with phlegm turbid obstructing the lung, qi and yin deficiency of lung kidney combined with phlegm turbid obstructing the lung, lung kidney qi deficiency combined with phlegm stasis obstructing the lung, and qi and yin deficiency of lung kidney combined with phlegm stasis obstructing the lung are commonly seen.[17] Blood stasis is not only the main path of COPD but also a common combining syndrome. For example, blood stasis that combined with phlegm turbid obstructing the lung is the syndrome of phlegm turbid and stasis in the lung, that combined with phlegm heat accumulating the lung is the syndrome of phlegm heat and stasis in the lung, and that combined with lung kidney qi deficiency is the syndrome of lung kidney qi deficiency and blood stasis.[15]

Treatment should be based on the principles of "treating manifestations for acute onset" and "treating the root causes in the stable stage." In the acute exacerbation stage, the principles are to clear the heat, purify the phlegm, activate the blood, ventilate the lung to descend qi, open the orifice, and consider qi yin. During the stable stage, the treatment is mainly to benefit qi (yang) and nourish yin, combined with expelling phlegm and activating blood circulation.[8,11,16] In the acute exacerbation of dangerous window stage, the syndromes of intermingled deficiency and excess are commonly seen. Treatment involves supplementing the deficiency and strengthening vital qi, resolving the phlegm, and promoting blood circulation.[7,18]

Acute exacerbation stage

Research evidence[19,20] shows that Chinese medicine syndrome differentiation and Chinese medicine combined with western medicine for the treatment of AECOPD can significantly improve clinical symptoms, improve lung function, reduce inflammation, etc.

Wind cold invading lung syndrome[15]

Symptoms

Primary symptoms are cough, wheezing, aversion to cold, white and clear expectoration, thin and white tongue fur, and tight pulse. Secondary symptoms are fever, anhidrosis, nasal obstruction, clear nasal discharge, soreness pain in the body, and floating pulse.

Diagnosis

(1) Cough or wheezing, white and clear expectoration; (2) fever, aversion to cold, anhidrosis, or soreness and pain in the body; (3) nasal obstruction, clear nasal discharge; (4) white tongue fur, floating pulse, or floating and tight pulse. Diagnose with 1 and 2 plus one of 3 and 4.

Therapeutic methods

Ventilating the lung to dispel cold, relieve cough, and relieve antiasthmatics.

Formula and herbs

Modified Sanao decoction (*Prescriptions of the Bureau of Taiping People's Welfare Pharmacy*) and Zhisou powder (*Medical Revelations*) (D, high priority):[8] 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.

Addition and subtraction

For patients with white and greasy phlegm or white and greasy tongue fur, add Fabanxia (*Rhizoma Pinelliae Preparatum*) 9 g, Houpo (*Cortex Magnoliae Officinalis*) 9 g, and Fuling (*Poria*) 12 g. For patients with soreness and pain in the body, add Qianghuo (*Rhizoma et Radix Notopterygii*) 9 g and Duhuo (*Radix Angelicae Pubescentis*) 9 g. For patients with headache, add Baizhi (*Radix Angelicae Dahuricae*) 9 g and Gaoben (*Rhizoma Ligustici*) 6 g. For patients with obvious wheezing, change Zisu (*Folium Perillae*) into Zisuzi (*Fructus Perillae*) 9 g and add Houpo (*Cortex Magnoliae Officinalis*) 9 g.

Chinese patent medicines

(1) Tongxuan Lifei pills (D, high priority): Oral administration, 7 g/time (water-honeyed pills) or 2 pills/time (large honey bolus), 2–3 times/day. (2) Xingsu Zhike granules (D, low priority): Administration after dissolving, 12 g/time, 3 times/day.

External cold and internal drink syndrome[15]

Symptoms

Primary symptoms were cough, wheezing, shortness of breath, profuse white and thin foam phlegm, chest tightness, inability to lie down, aversion to cold, white and slippery tongue fur,

stringy, and tight pulse. Secondary symptoms were ease in coughing up, snoring in the throat, anhidrosis, sore limbs, stuffy nose, clear nasal discharge, and floating pulse.

Diagnosis

(1) Cough or wheezing; (2) aversion to cold, anhidrosis, or stuffy nose, clear nasal discharge, or sore limbs; (3) white and thin foam phlegm, ease in coughing up; (4) snoring in the throat; (5) chest tightness or even reversed flow of qi leading to an inability to lie down; (6) white and slippery tongue fur, stringy and tight pulse, or floating, stringy, and tight pulse. Diagnose with 1 and 2 and two items of 3, 4, 5, and 6.

Therapeutic methods

Expelling wind and cold pathogens and warming the lung to dissolve fluid retention.

Formula and herbs

Modified Xiaoqinglong decoction (*Treatise on Cold Pathogenic Diseases*)[21-23] (D, high priority): 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 Chinensis*) 6 g, Xingren (*Semen Armeniacae Amarum*) 9 g, Zisuzi (*Fructus Perillae*) 9 g, Houpo (*Cortex Magnoliae Officinalis*) 9 g, and Zhigancao (*Radix Glycyrrhizae*) 6 g.

Addition and subtraction

For patients with qi ascending while coughing and snoring in the throat, add Shegan (*Rhizoma Belamcandae*) 9 g and Kuandonghua (*Flos Farfarae*) 9 g. For patients with water retention depression transforming into heat, irritation and thirst, and bitter mouth, subtract Guizhi (*Ramulus Cinnamomi*) and add Shengshigao (*Gypsum Fibrosum*) 30 g (decocting first), Huangqin (*Radix Scutellariae*) 9 g, and Sangbaipi (*Cortex Mori*) 12 g. For patients with sore limbs, add Qianghuo (*Rhizoma et Radix Notopterygii*) 9 g and Duhuo (*Radix Angelicae Pubescentis*) 9 g. For patients with headache, add Baizhi (*Radix Angelicae Dahuricae*) 9 g.

Chinese patent medicines

Xiaoqinglong Granules (D, high priority): Administration after dissolving, 13 g/time, 3 times/day.

Phlegm heat accumulating the lung syndrome[15]

Symptoms

Primary symptoms were cough, wheezing, chest tightness, profuse yellowish greasy phlegm, difficult expectoration, red tongue, yellowish and greasy tongue fur, slippery, and rapid pulse. Secondary symptoms were chest pain, fever, thirst, preference for cold drinks, dry and hard stool, and thick tongue fur.

Diagnosis

(1) Cough or wheezing; (2) profuse yellowish or white greasy phlegm; (3) fever or thirst, preference for cold drinks; (4) constipation; (5) red tongue, yellowish and greasy tongue fur, or rapid or slippery and rapid pulse. Diagnose with 1 and 2 and two items of 3, 4, and 5.

Therapeutic methods

Clearing the lung to dissolve the phlegm and descending adverse qi for antiasthmatic.

Formula and herbs

Modified Qingqi Huatan Pills (*Investigations of Medical Formulas*) and Beimu Gualou Powder (*Medical Revelations*)[8,24,25] (D, low priority): Gualou (*Fructus Trichosanthis*) 15 g, Qingbanxia (*Rhizoma Pinelliae Preparata*) 9 g, Zhebeimu (*Bulbus Fritillariae Thunbergii*) 9 g, Zhizi (*Fructus Gardeniae*) 9 g, Sangbaipi (*Cortex Mori*) 12 g, Huangqin (*Radix Scutellariae*) 9 g, Xingren (*Semen Armeniacae Amarum*) 9 g, Baitouweng (*Radix Pulsatillae*) 12 g, Yuxingcao (*Herba Houttuyniae*) 15 g, Maidong (*Radix Ophiopogonis*) 12 g, and Chenpi (*Pericarpium Citri Reticulatae*) 9 g.

Addition and subtraction

For patients with high fever and irritation and constipation, combine with Modified Xuanbai Chengqi decoction (*Detailed Analysis of Epidemic Warm Diseases*)[26] (B, high priority). For patients with profuse greasy phlegm and difficult expectoration, combine with Sangbaipi decoction (*Medical Complete Book; Ancient and Modern*)[27-31] (C, high priority). For patients with gurgling with sputum, wheezing, and inability to lie down, add Tinglizi (*Semen Descurainiae*) 9 g (wrap decoction), Shegan (*Rhizoma Belamcandae*) 9 g, and Jiegeng (*Radix Platycodonis*) 9 g. For patients with fishy phlegm, add Jinqiaomai (*Rhizoma Fagopyri Dibotryis*) 20 g, Yiyiren (*Semen Coicis*) 12 g, Taoren (*Semen Persicae*) 9 g, and Dongguaren (*Semen Benincasae*) 12 g. For patients with obvious chest tightness and pain, add Yanhusuo (*Rhizoma Corydalis*) 9 g, Chishao (*Radix Paeoniae Rubra*) 12 g, and Zhiqiao (*Fructus Aurantii*) 12 g. For patients with little but greasy phlegm, thirst, red tongue, eroded tongue fur, and a fine and rapid pulse, subtract Qingbanxia (*Rhizoma Pinelliae Preparata*) and add Taizishen (*Radix Pseudostellariae*) 12 g and Shashen (*Radix Glehniae*) 12 g. Patients with combined blood stasis syndrome of dark complexion and lips, dark purple or blush tongue, and ecchymosis can be treated with Tongsai granules formula[32] (D, low priority): Tinglizi (*Semen Descurainiae*), Dilong (*Lumbricus*), Zhimahuang (*Herba Ephedrae*), Zhebeimu (*Bulbus Fritillariae Thunbergii*), Zhidahuang (*Radix et Rhizoma Rhei*), Chishao (*Radix Paeoniae Rubra*), Renshen (*Radix Ginseng*), Maidong (*Radix Ophiopogonis*), Shichangpu (*Rhizoma Acori Tatarinowii*), and Aidicha (*Japanese Ardisia Herb*).

Chinese patent medicines

(1) Tanreqing injection[33-39] (C, high priority): 20–40 mL, add 5% glucose injection or normal saline 250–500 mL, intravenous drip, once a day. (2) Tingbei capsules (D, high priority): Oral administration, four capsules each time, 3 times a day. (3) For patients with intermingled phlegm heat and blood stasis, choose Xuebijing injection[40] (C, high priority): 50 mL, intravenous drip of normal saline 100 mL, 2 times a day.

Phlegm turbid obstructing the lung syndrome[15]

Symptoms

Primary symptoms were cough, wheezing, excessive phlegm, white and greasy phlegm, sticky and greasy mouth, white and greasy tongue fur, and slippery pulse. Secondary symptoms were shortness of breath, foam phlegm, ease in coughing up, chest tightness, fullness in the stomach, indigestion and loss of appetite, less food intake, thin tongue, and taut pulse.

Diagnosis

(1) Cough or wheezing, shortness of breath; (2) excessive phlegm, white greasy or in foam shape; (3) fullness in the stomach; (4) sticky and greasy mouth, indigestion and loss of appetite, less food intake; (5) white greasy tongue fur, or slippery pulse or slippery taut pulse. Diagnose with 1 and 2 and two of 3, 4, and 5.

Therapeutic methods

Drying dampness to resolve phlegm and ventilating lung to descend qi.

Formula and herbs

Banxia Houpo decoction (*Synopsis of Golden Chamber*) and Sanzi Yangqin decoction (*Wide Collection of Miscellaneous Diseases*)[8,41] (D, high priority): Fabanxia (*Rhizoma Pinelliae Preparatum*) 12 g, Houpo (*Cortex Magnoliae Officinalis*) 9 g, Chenpi (*Pericarpium Citri Reticulatae*) 9 g, Xiebai (*Bulbus Allii Macrostemonis*) 12 g, Fuling (*Poria*) 15 g, Zhiqiao (*Fructus Aurantii*) 9 g, Zisuzi (*Fructus Perillae*) 9 g, Laifuzi (*Semen Raphani*) 9 g, Doukou (*Fructus Amomi Rotundus*) 6 g, and Shengjiang (*Rhizoma Zingiberis Recens*) 6 g.

Addition and subtraction

For patients with excessive phlegm and wheezing, chest tightness, and inability to lie down, add Mahuang (*Herba Ephedrae*) 6 g and Tinglizi (*Semen Descurainiae*) 9 g (wrap decoction). For patients with epigastric distension and depression, add Muxiang (*Radix Aucklandiae*) 9 g and Jiaobinglang (*Semen Arecae*) 9 g. For patients with diarrhea, subtract Zisuzi (*Fructus Perillae*) and Laifuzi (*Semen Raphani*) and add Baizhu (*Rhizoma Atractylodis Macrocephalae*) 12 g, Zexie (*Rhizoma Alismatis*) 9 g, and Gegen (*Radix Puerariae*) 9 g. For patients with constipation, add Jiao binglang (*Semen Arecae*) 9 g and Zhishi (*Fructus Aurantii Immaturus*) 9 g.

Chinese patent medicines

(1) Suzi Jiangqi pills (D, low priority): Oral administration, 6 g/time, 1–2 times/day; (2) Linggui Kechuanning capsules[42] (D, low priority): Oral administration, five capsules per time, 3 times/day.

Phlegm-blinding spiritual orifices syndrome[15]

Symptoms

Primary symptoms were wheezing, shortness of breath, absent-mindedness, lethargy, coma, delirium, white, greasy, and yellowish tongue fur. Secondary symptoms were snoring in the throat, convulsions in the limbs, dark red, purple tongue, slippery, and rapid pulse.

Diagnosis

(1) Abnormality of mentality (irritation, absent-mindedness, lethargy, delirium, coma); (2) convulsions in the limbs; (3) wheezing, short breath; (4) snoring in the throat; (5) pale or red tongue, white greasy or yellow greasy tongue fur, or slippery or rapid pulse. Diagnose with one of 1 and 2 plus two of 3, 4, and 5.

Therapeutic methods

Dissipating phlegm for resuscitation.

Formula and herbs

Modified Ditan decoction[8] (*Fine Prescriptions of Wonderful Efficacy*) (D, high priority): 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.

Addition and subtraction

For patients with cold syndromes of white greasy tongue fur, add Suhexiang pills (D, high priority), taken with ginger decoction or warm water, 1 pill/time, 1–2 times/day. For patients with body heat, delirium, red tongue, and yellowish tongue fur, subtract Xixin (*Herba Asari*) and Tiannanxing (*Rhizoma Arisaematis*) and add Shuiniujiao (*Cornu Bubali*) 30 g (decocting first), Dannanxing (*Rhizoma Arisaematis Cum Bile*) 6 g, Xuanshen (*Radix Scrophulariae*) 12 g, Lianqiao (*Fructus Forsythiae*) 12 g, Huanglian (*Rhizoma Coptidis*) 6 g, Chao Zhizi (*Fructus Gardeniae*) 9 g, or Angong Niuhuang pills or Zhibao pills (D, low priority). For patients with constipation and obstruction of Fu-qi, add Shengdahuang (*Radix et Rhizoma Rhei*) 6 g (decocting later) and Mangxiao (*Natrii Sulfas*) 9 g (administration after dissolving). For patients with obvious convulsion, add Gouteng (*Ramulus Uncariae Cum Uncis*) 9 g (decocting later), Quanxie (*Scorpio*) 6 g, Dilong (*Lumbricus*) 12 g, and Lingyangjiaofen (*Cornu Saigae Tataricae* powder) 0.6 g (administration after dissolving).

Chinese patent medicines

(1) Xingnaojing injection (D, high priority): 10–20 mL/time, add 5%–10% glucose injection or 250–500 mL normal saline, intravenous drip, 1–2 time/day. (2) Qingkailing injection[43] (D, low priority): 20–40 mL, add 10% glucose injection 200 mL or normal saline 100 mL, intravenous drip, 2 times a day.

Acute exacerbation of the dangerous window stage

The acute exacerbation of the dangerous window stage is a period between the end of the acute exacerbation stage and the stable stage. The pathogenesis is both with deficiency and excess, mainly with qi (yang) deficiency and qi yin deficiency, and commonly combined with phlegm and stasis. Therefore, the treatment should eliminate pathogens (resolve phlegm, activate blood) and reinforce healthy qi (tonify and benefit

lung qi, tonify the lung and invigorate the spleen, and tonify and benefit the lung kidney).[7,17] A multicenter trial study[18] showed that the sequential treatment of combined Chinese medicine and western medicine in the acute exacerbation of the dangerous window stage has significant improvements on the curative effect when compared to the western medicine standard alone, by reducing the number of acute exacerbations, improving the clinical symptoms such as dyspnea, and improving the quality of life.

Stable stage

Research evidence[44-49] shows that the efficacy of Chinese medicine syndrome differentiation treatment and Chinese medicine combined with western medicine in the treatment of COPD is more effective than placebo or western medicine alone, mainly in improving symptoms, reducing the number of acute exacerbations, improving exercise capacity, and improving the quality of life. For early COPD patients with pulmonary function Grades 1 and 2 in a stable stage, Chinese medicine syndrome differentiation treatment program (lung qi deficiency syndrome uses Bufei recipe, lung spleen qi deficiency syndrome uses Bufei Jianpi recipe, and lung and kidney qi deficiency syndrome uses Bufei Yishen recipe) can reduce the number of acute exacerbations, improve lung function and dyspnea, improve clinical symptoms, improve exercise endurance and quality of life, and have better long-term effects.[50] For COPD patients with pulmonary function grades 3 and 4, based on the conventional treatment of western medicine, Chinese medicine syndrome differentiation treatment program (lung spleen qi deficiency syndrome uses Bufei Jianpi recipe, lung and kidney qi deficiency syndrome uses Bufei Yishen recipe, and lung and kidney qi yin deficiency syndrome uses Yiqi Zishen recipe) can reduce the number and extent of acute exacerbations, improve the quality of life and exercise endurance, and improve clinical symptoms and dyspnea.[51]

Lung qi deficiency syndrome[15]

Symptoms

Primary symptoms were cough, fatigue, ease in catching a cold. Secondary symptoms were wheezing, shortness of breath, aggravation of movement, spiritual tiredness, spontaneous sweating, aversion to wind, pale tongue, white tongue fur, fine, deep, weak pulse.

Diagnosis

(1) Cough or wheezing, shortness of breath, aggravation of movement; (2) spiritual tiredness, fatigue, or spontaneous sweating; (3) aversion to wind, ease in catching a cold; (4) pale tongue, white tongue fur, or fine, deep pulse or weak, and fine pulse. Diagnose with three items from 1, 2, 3, and 4.

Therapeutic methods

Tonifying lung, benefiting qi, and consolidating defensive qi.

Formula and herbs

Modified Renshen Hutao decoction (*Jisheng Formula*) and Renshen Yangfei pills (*Prescriptions of the Bureau of Taiping People's Welfare Pharmacy*)[8] (D, low priority): Dangshen (*Radix Codonopsis*) 15 g, Huangqi (*Radix Astragali seu Hedysari*) 15 g, Baizhu (*Rhizoma Atractylodis Macrocephalae*) 12 g, Hutaorou (*Semen Juglandis*) 15 g, Baibu (*Radix Stemonae*) 9 g, Chuanbeimu (*Bulbus Fritillariae Cirrhosae*) 6 g, Xingren (*Semen Armeniacae Amarum*) 9 g, Houpo (*Cortex Magnoliae Officinalis*) 9 g, Zisuzi (*Fructus Perillae*) 9 g, Dilong (*Lumbricus*) 12 g, Chenpi (*Pericarpium Citri Reticulatae*) 9 g, Jiegeng (*Radix Platycodonis*) 9 g, and Zhigancao (*Radix Glycyrrhizae*) 6 g.

Addition and subtraction

For patients with excessive spontaneous sweating, add Fuxiaomai (*Fructus Tritici Levis*) 15 g and Duanmuli (*Concha Ostreae*) 15 g (decocting first). For patients with alternative chills and fever and disharmony between nutrient qi and defensive qi, add Guizhi (*Ramulus Cinnamomi*) 6 g and Baishao (*Radix Paeoniae Alba*) 9 g. This syndrome could also use Yiqi Gubiao formula[52] (B, low priority) (Dangshen [*Radix Codonopsis*], Fuxiaomai [*Fructus Tritici Levis*], Baizhu [*Rhizoma Atractylodis Macrocephalae*], Banxia [*Rhizoma Pinelliae*], Chenpi [*Pericarpium Citri Reticulatae*], Zisu [*Folium Perillae*], Fuling [*Poria*], Fangfeng [*Radix Saposhnikoviae*], Yiyiren [*Semen Coicis*], Kuandonghua [*Flos Farfarae*], Huangqin [*Radix Scutellariae*], Chuanbeimu [*Bulbus Fritillariae Cirrhosae*], and Pipaye [*Folium Eriobotryae*]).

Chinese patent medicines

Yupingfeng granules (Electuary)[53,54] (B, high priority): Administration after dissolving, 5 g/time, 3 times/day.

Lung spleen qi deficiency syndrome[15]

Symptoms

Primary symptoms were cough, wheezing, shortness of breath, aggravation of movement, poor appetite, fatigue, ease in catching a cold, enlarged tongue, tooth marks, pale tongue, and white tongue fur. Secondary symptoms were spiritual tiredness, less food intake, abdominal fullness, loose stools, spontaneous sweating, aversion to wind, deep, fine, slow, and weak pulse.

Diagnosis

(1) Cough or wheezing, shortness of breath, aggravation of movement; (2) spiritual tiredness, fatigue or spontaneous sweating, aggravation of movement; (3) an aversion to wind, ease in catching a cold; (4) poor appetite or less food intake; (5) abdominal fullness or loose stools; (6) enlarged tongue or with tooth marks, thin white or white greasy tongue fur, or deep fine pulse or deep slow or fine weak pulse. Diagnose with two items from 1, 2, and 3 and two items from 4, 5, and 6.

Therapeutic methods

Tonifying the lung, invigorating the spleen, descending qi, and resolving phlegm.

Formula and herbs

Modified Liujunzi decoction (*Orthodox Lineage of Medicine*) referred to *Prescriptions of the Bureau of Taiping People's*

Welfare Pharmacy[8] and Huangqi Buzhong decoction (*Medical Creation*) (D, high priority): 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, Houpo (*Cortex Magnoliae Officinalis*) 9 g, Ziwan (*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.

Addition and subtraction

For patients with cough, excessive phlegm, and white greasy tongue fur, subtract Huangqi (*Radix Astragali seu Hedysari*) and add Fabanxia (*Rhizoma Pinelliae Preparatum*) 12 g and Doukou (*Fructus Amomi Rotundus*) 9 g. For patients with thin phlegm and an aversion to cold, add Ganjiang (*Rhizoma Zingiberis*) 9 g and Xixin (*Herba Asari*) 2 g. For patients with a poor appetite and obvious decreased food intake, add Shenqu (*Massa Medicata Fermentata*) 12 g, Doukou (*Fructus Amomi Rotundus*) 12 g, and Chaomaiya (*Fructus Hordei Germinatus*) 12 g. For patients with abdominal fullness, subtract Huangqi (*Radix Astragali seu Hedysari*) and add Muxiang (*Radix Aucklandiae*) 9 g, Laifuzi (*Semen Raphani*) 9 g, and Doukou (*Fructus Amomi Rotundus*) 9 g. For patients with loose stools, subtract Ziwan (*Radix Asteris*) and Xingren (*Semen Armeniacae Amarum*) and add Gegen (*Radix Puerariae*) 9 g, Zexie (*Rhizoma Alismatis*) 12 g, and Qianshi (*Semen Euryales*) 15 g. For patients with spontaneous sweating, add Fuxiaomai (*Fructus Tritici Levis*) 15 g and Duanmuli (*Concha Ostreae*) 20 g (decocting first). This syndrome could also use the modified Buzhong Yiqi decoction (*Clarifying Doubts about Damage from Internal and External Causes*)[55] (B, high priority) or Bufei Jianpi formula[56,57] (B, low priority): Huangqi (*Radix Astragali seu Hedysari*), Huangjing (*Rhizoma Polygonati*), Dangshen (*Radix Codonopsis*), Baizhu (*Rhizoma Atractylodis Macrocephalae*), Fuling (*Poria*), Zhebeimu (*Bulbus Fritillariae Thunbergii*), Dilong (*Lumbricus*), Houpo (*Cortex Magnoliae Officinalis*), Chenpi (*Pericarpium Citri Reticulatae*), Ziwan (*Radix Asteris*), Aidicha (*Japanese Ardisia Herb*), and Yinyanghuo (*Herba Epimedii*).

Chinese patent medicines

(1) Yupingfeng granules (Electuary)[53,54] (B, low priority): Administration after dissolving, 5 g/time, 3 times/day; (2) Liujunzi pills (D, low priority): Oral administration, 9 g/time, 2 times/day.

Lung kidney qi deficiency syndrome[15]

Symptoms

Primary symptoms were wheezing, shortness of breath, aggravation of movement, spiritual tiredness, fatigue, soreness and weakness of the waist and knees, ease in catching a cold, pale tongue, white tongue fur, fine pulse. Secondary symptoms were aversion to cold, spontaneous sweating, edema of the face, chest tightness, tinnitus, frequent urination at night, cough while enuresis, enlarged tongue, tooth marks, deep and weak pulse.

Diagnosis

(1) Wheezing, shortness of breath, aggravation of movement; (2) fatigue, spontaneous sweating, aggravation of movement; (3) easy to catch cold, aversion to cold; (4) soreness and weakness of the waist and knees; (5) tinnitus, dizziness, or edema of the face; (6) frequent urination and that at night; (7) pale tongue, white tongue fur, or deep fine pulse or fine weak pulse. Diagnose with two items from 1, 2, and 3 plus two items from 4, 5, 6, and 7.

Therapeutic methods

Tonifying the kidney, benefiting the lung, inspiration, and relieving asthma.

Formula and herbs

Bufei Yishen formula[56,57] (B, high priority): Renshen (*Radix Ginseng*) 6 g, Huangqi (*Radix Astragali seu Hedysari*) 15 g, Shanzhuyu (*Fructus Corni*) 9 g, Gouqizi (*Fructus Lycii*) 12 g, Wuweizi (*Fructus Schisandrae Chinensis*) 9 g, Yinyanghuo (*Herba Epimedii*) 9 g, Zhebeimu (*Bulbus Fritillariae Thunbergii*) 9 g, Chishao (*Radix Paeoniae Rubra*) 12 g, Dilong (*Lumbricus*) 12 g, Zisuzi (*Fructus Perillae*) 9 g, Aidicha (*Japanese Ardisia Herb*) 9 g, and Chenpi (*Pericarpium Citri Reticulatae*) 9 g.

Addition and subtraction

For patients with an obvious cough, add Zhiziyuan (*Aster tataricus*) 12 g and Xingren (*Semen Armeniacae Amarum*) 12 g. For patients with cough, excessive phlegm, and white greasy tongue fur, add Fabanxia (*Rhizoma Pinelliae Preparatum*) 9 g and Fuling (*Poria*) 15 g. For patients with wheezing after movement, add Gejiefen (*Gecko*) 2 g (administration after dissolving). For patients with edema of the face and aversion to wind, add Rougui (*Cortex Cinnamomi*) 5 g (decocting later), Zexie (*Rhizoma Alismatis*) 9 g, and Fuling (*Poria*) 12 g. For patients with soreness and weakness of the waist and knees, add Tusizi (*Semen Cuscutae*) 12 g and Duzhong (*Cortex Eucommiae*) 12 g. For patients with obviously frequent urination, add Yizhiren (*Fructus Alpiniae Oxyphyllae*) 9 g and Jinyingzi (*Fructus Rosae Laevigatae*) 12 g. For patients with an aversion to cold and insufficient body warmth, add Zhifuzi (*Radix Aconiti Lateralis Preparata*) 9 g (decocting first) and Ganjiang (*Rhizoma Zingiberis*) 6 g. This syndrome could also use the modified Renshen Bufei decoction (*Symptoms, Causes, Pulse and Treatment*)[8] (D, low priority) or modified Renshen Gejie powder[58-60] (C, low priority).

Chinese patent medicines

For patients with lung kidney qi deficiency and blood stasis, choose Bufei Huoxue capsules[61-66] (C, low priority): Oral administration, 4 capsules per time, 3 times/day.

Lung kidney qi yin deficiency syndrome[15]

Symptoms

Primary symptoms were cough, wheezing, shortness of breath, aggravation of movement, fatigue, spontaneous

sweating, night sweating, soreness and weakness of the waist and knees, ease in catching a cold, red tongue, and rapid pulse. Secondary symptoms were dry mouth and throat, dry cough with less phlegm, unwillingness to cough up, feverishness in the palms and soles, tinnitus, dizziness, pale tongue, less and eroded tongue fur, weak, deep, slow and stringy pulse.

Diagnosis

(1) Wheezing, shortness of breath, aggravation of movement; (2) spontaneous sweating or fatigue, aggravation of movement; (3) easy to catch cold; (4) soreness and weakness of the waist and knees; (5) tinnitus, dizziness; (6) dry cough with less phlegm, unwillingness to cough up; (7) night sweating; (8) feverishness in the palms and soles; (9) pale or red tongue, thin, less, or eroded tongue fur, or deep fine pulse, fine weak pulse, or fine rapid pulse. Diagnose with two items from 1, 2, and 3 plus one item from 4 and 5 and two items from 6, 7, 8, and 9.

Therapeutic methods

Tonifying the lung, nourishing the kidney, inspiration, and relieving asthma.

Formula and herbs

Modified Baoyuan decoction (*Bo Ai Xin Jian*) and Renshen Bufei decoction[8] (D, high priority): 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.

Addition and subtraction

For patients with severe cough, add Zhipipaye (*Folium Eriobotryae*) 12 g and Xingren (*Semen Armeniacae Amarum*) 9 g. For patients with greasy phlegm that is difficult to expectorate, add Baihe (*Bulbus Lilii*) 15 g, Yuzhu (*Rhizoma Polygonati Odorati*) 12 g, and Shashen (*Radix Glehniae*) 12 g. For patients with feverishness in the palms and soles, add Zhimu (*Rhizoma Anemarrhenae*) 9 g, Huangbai (*Cortex Phellodendri*) 9 g, Digupi (*Cortex Lycii*) 12 g, and Biejia (*Carapax Trionycis*) 15 g. For patients with night sweating, add Duanmuli (*Concha Ostreae*) 20 g (decocting first) and Nuodaogen (*Oryza sativa*) 15 g. This syndrome could also use Yiqi Zishen Formula (B, low priority) (Renshen [*Radix Ginseng*], Huangjing [*Rhizoma Polygonati*], Maidong [*Radix Ophiopogonis*], Wuweizi [*Fructus Schisandrae Chinensis*], Gouqizi [*Fructus Lycii*], Shudihuang [*Radix Rehmanniae Preparata*], Rougui [*Cortex Cinnamomi*], Zhebeimu [*Bulbus Fritillariae Thunbergii*], Dilong [*Lumbricus*], Danpi [*Cortex Moutan Radicis*], Zisuzi [*Fructus Perillae*], Baibu [*Radix Stemonae*], Chenpi [*Pericarpium Citri Reticulatae*]); Bufei Granules[67-69] (B, low priority) (Dangshen [*Radix Codonopsis*], Shudihuang [*Radix Rehmanniae Preparata*], Shanyurou [*Fructus Corni*], Mimahuang [*Herba Ephedrae*], Danggui [*Radix Angelicae Sinensis*], Chishao [*Radix Paeoniae Rubra*], Huangqin [*Radix Scutellariae*], Chenpi [*Pericarpium Citri Reticulatae*], Miziwan [*Radix Asteris*], Gancao [*Radix Glycyrrhizae*]).

Chinese patent medicines

(1) Shengmaiyin oral liquid (D, low priority): Oral administration, 10 mL/time, 3 times/day. (2) Yangyin Qingfei pills (for patients with lung yin deficiency and dryness heat) (D, low priority): Oral administration, 6–9 g/time, 2 times/day. (3) Baihe Gujin pills (for patients with lung kidney yin deficiency) (D, low priority): Oral administration, 9 g/time, 2 times/day. (4) Gejie Dingchuan pills (for patients with lung kidney yin deficiency and internal heat cough and wheezing) (D, low priority): Oral administration, 6 g/time (water-honeyed pills), 2 times/day.

Treatment recommendations for clinical combined syndromes and complex syndromes

Combined syndrome – Blood stasis syndrome[15]

Blood stasis often appears in both excess and deficiency syndromes as a combined syndrome. In the treatment, it often uses herbs promoting blood circulation and removing blood stasis based on strengthening healthy qi or replenishing deficiency and removing pathogens. Primary symptoms include cyanosis of the lips, dark redness of the tongue, ecchymoses, and a hesitant and deep pulse. Secondary symptoms include chest tightness and pain and a dark complexion. Diagnosis requires (1) a purple and dark face; (2) blue and purple lips and nails; (3) dark purple tongue or ecchymosis or sputum; and (4) distorted and rough sublingual veins. It can be diagnosed with one of 1, 2, 3, and 4. Therapeutic methods include promoting blood circulation and removing blood stasis. According to the different combined syndromes, clinicians can add or subtract herbs that promote blood circulation and resolve blood stasis[8,70] (such as Chuanxiong [*Rhizoma Ligustici Chuanxiong*] 9 g, Chishao [*Radix Paeoniae Rubra*] 12 g, Taoren [*Semen Persicae*] 9 g, Honghua [*Flos Carthami*] 9 g, and Ezhu [*Rhizoma Curcumae*] 9 g).

Complex syndromes

Root excess, manifestation deficiency, and both excess and deficiency are the characteristics of the pathogenesis of COPD. In clinical practice, syndromes often appear with complex syndromes. Even complex syndromes have primary and secondary pathogenesis, such as acute exacerbation stage and stable stage. In the acute exacerbation stage, it is common to see phlegm-heating accumulating the lung or phlegm turbid blocking lung syndrome, among others. This is often combined with spleen qi deficiency or lung and kidney qi deficiency syndrome, etc., or with blood stasis, mainly with excess syndromes of phlegm heat, phlegm dampness, or blood stasis, and followed by lung spleen qi deficiency, lung

and kidney qi deficiency, and other deficiency syndromes. The treatment is to clear the lungs and dissolve phlegm, dry dampness, and dissolve phlegm; promote blood circulation and resolve phlegm; etc., supplemented by tonifying the lung and invigorating the spleen or tonifying the lung and kidney. In the stable stage, it is common to see lung qi deficiency, lung spleen qi deficiency, lung and kidney qi deficiency, and other deficiency syndromes, often combined with phlegm turbid, blood stasis or phlegm stasis mutual resistance, and other excess syndromes, mainly with deficiency syndromes, followed by excess syndromes. The treatment is mainly to tonify and benefit, including tonifying lung qi, tonifying the lung and invigorating the spleen, and tonifying the lung and benefiting the kidney, accompanied by eliminating pathogens, such as resolving phlegm and promoting blood circulation. Due to the complex and variable clinical syndromes of COPD, it is difficult to list all of the complex syndromes in this guideline. It is recommended that in clinical practice, when syndrome differentiation is a complex syndrome, the prescriptions of the syndromes listed in the guideline be used for treatment, considering the primary and secondary and excess and deficiency.[10,11,14-16]

Other Treatment Methods

Studies have shown that Taijiquan,[71] acupuncture,[72] respiratory guidance,[73] acupoint application (such as Shufei paste[74] and Xiaochuan cream[75]), Yifei moxibustion,[76] and other techniques relieve the clinical symptoms of patients with COPD by improving exercise endurance, delaying lung function decline, and improving the quality of life.

Prevention and Regulation

Prevention of exogenous pathogens

Keeping the air moist is conducive to the discharge of respiratory secretions. Encourage patients to cough for sputum excretion, quit smoking, and prevent colds and respiratory infections. Carry out appropriate rehabilitation exercises under strict care to improve the body's resistance.[10]

Improve nutrition

Malnutrition can make diaphragm fatigue worse. Patients should have more meals a day, but less food at each, with a light, digestible, and nutritious diet that avoids spicy foods to keep the stool smooth.[10]

Mental nursing

Patients with COPD suffer from a long-term disease. The mental burden is very heavy. It is easy to coexist with anxiety and depression. Patients should be helped to establish confidence in fighting the disease.[10]

Appendix: Description

The leading drafting organizations of the guideline: Henan University of Chinese Medicine and the First Affiliated Hospital of Henan University of Chinese Medicine.

The participating drafting organizations of the guideline: Evidence-based Medicine Center of Beijing University of Chinese Medicine, China-Japan Friendship Hospital, the Second Affiliated Hospital of Liaoning University of Chinese Medicine, Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, Jiangsu Province Hospital of Chinese Medicine, the First Affiliated Hospital of Anhui University of Chinese Medicine, Affiliated Hospital of Jiangxi University of Chinese Medicine, Shanxi Province Hospital of Chinese Medicine, Xiyuan Hospital of Chinese Academy of Chinese Medicine Sciences, and Peking University People's Hospital.

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The doses of Chinese Materia Medica listed in this guideline are reference doses for clinical use.

The Chinese patent medicines listed in this guideline are derived from the Pharmacopoeia of the People's Republic of China (2015 Edition), the National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug List (2017 Edition), and the Chinese Medicines Clinical Application Guideline • Respiratory Diseases Volume (2016 Edition) and other documents.

This guideline is not a standard or norm for medical conduct, but a declarative document based on the existing research evidence and specific methods. In clinical practice, physicians can refer to this guideline and conduct individualized treatment combining for specific conditions.

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Conflicts of interest

There are no conflicts of interest.

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规范与标准

国际中医临床实践指南 慢性阻塞性肺疾病

世界中医药学会联合会

摘要 慢性阻塞性肺疾病(COPD)是严重危害公众健康的重大慢性疾病。中医药防治COPD具有较好的临床疗效,并获得了一些显著成果。为进一步完善诊疗规范,促进中医诊治水平的提高,更好地指导慢阻肺中医临床诊疗工作,世界中医药学会联合会组织专家小组,在中华中医药学会2019年发布的《慢性阻塞性肺疾病中医诊疗指南》(标准号:T/CACM 1319-2019)基础上,评估最新海内外临床研究证据,修订转化形成《国际中医临床实践指南 慢性阻塞性肺疾病》并进行双语发布。指南内容主要包括前言、引言、范围、规范性引用文件、术语和定义、疾病诊断分期、严重程度评估、病因病机、辨证论治、其他治法、预防调护、附录12个部分,规范了慢阻肺的中医病因病机、辨证论治、预防调护的内容。该指南适用于于中医、中西医结合临床呼吸内科医师。该指南发布将有助于提升中医药防治慢阻肺水平。

关键词 慢性阻塞性肺疾病;中医;临床实践指南

International Clinical Practice Guideline of Chinese Medicine Chronic Obstructive Pulmonary Disease

World Federation of Chinese Medicine Societies

Abstract Chronic Obstructive Pulmonary Disease (COPD) is a major chronic disease that seriously endangered public health. Traditonal Chinese medicine has an obvious clinical effects on the prevention and treatment of COPD, and some remarkable results have been obtained. In order to further promote the norms and the level of diagnosis and treatment, and to better guide the clinical diagnosis and treatment of COPD, World Federation of Chinese Medicine Societies (WFCMS) established the expert panel for Guidelines, systematically evaluated the latest clinical research evidence at home and abroad, based on the revision and transformation of Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease released by China Association of Chinese Medicine in 2019 (Standard number: T/CACM 1319-2019), and then formulated the International Clinical Practice Guideline of Chinese Medicine—Chronic Obstructive Pulmonary Disease and publishing in both Chinese and English. The Guidelines has 12 parts, which are the Preface, Introduction, Scope, Normative References, Terms and Definitions, Disease Diagnosis and Staging, Severity Assessment, Etiology and Pathogenesis, Syndrome Differentiation and other Treatment, Prevention and Care, and Annex. It also standardizes the contents of TCM etiology and pathogenesis, syndrome differentiation and treatment, prevention and care of COPD. This guide is applicable to clinical respiratory physicians of TCM and integrated traditional Chinese and Western medicine. The release of the guideline is helpful to improve the effects and levels of TCM for COPD.

Keywords Chronic obstructive pulmonary disease; Traditional Chinese Medicine; Clinical practice guidelines

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慢性阻塞性肺疾病(Chronic Obstructive Pulmonary Disease, COPD)是一种常见的、可以预防和治疗的疾病,以进行性的气流受限为特征,患病率高、死亡率高、致残率高、疾病负担重,已成为严重危害公众健康的重大慢性疾病[1]。全球COPD患病率约为11.7%[2],每年死亡约350万人,世界卫生组织预计到2030年全球每年约有超过450万人死于COPD及其相关疾病。我国40岁以上人群患病率为13.7%,有近1亿COPD患者[3],居我国疾病死亡原因的第3位[4]。以伤残调整生命年衡量,其疾病负担已居我国疾病的第2位[5],防治形势日益严峻。COPD常见的症状为咳嗽、咳痰、呼吸困难,常出现急性加重。急性加重是COPD临床过程中重要事件,是患者健康状况及预后的重要影响因素[1]。近年来,中医药防治COPD具有较好的临床疗效,并获得了一些显著成果。

为进一步完善诊疗规范,促进中医诊治水平的提高,更好地指导COPD中医临床诊疗工作,由中

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华中医药学会、河南中医药大学及中国民族医药学会肺病分会组织成立了由呼吸病学（中医、西医、中西医结合）、临床流行病学、循证医学、卫生经济学、中药学等多学科人员组成的《慢性阻塞性肺疾病中医诊疗指南》工作小组，采用了文献检索、Delphi 法问卷调查、会议讨论的方法制订指南。依据收集的临床问题和结局指标，制定检索策略，对中文文献（含现代文献和古籍）、英文文献和现存相关国际指南进行系统检索并进行质量评价；参照推荐分级的评估、制定和评价（The Grading of Recommendations Assessment Development and Evaluation，GRADE）系统进行证据体质量和证据分级；采用改良德尔菲法进行问卷调研，进一步完善推荐意见后，召开面对面专家共识会议，形成指南推荐意见，经中华中医药学会评审论证形成并发布《慢性阻塞性肺疾病中医诊疗指南》（标准号：T/CACM 1319-2019）。

2019 年 8 月，为更好应用《慢性阻塞性肺疾病中医诊疗指南》，世界中医药学会联合会组织专家小组，评估最新海内外临床研究证据，修订转化形成《国际中医临床实践指南　慢性阻塞性肺疾病》。

1　适用范围

本指南规范了 COPD 的中医病因病机、辨证论治、预防调护的内容。

本指南适用于中医、中西医结合临床呼吸内科医师。

2　规范性引用文件

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

《慢性阻塞性肺疾病诊断、治疗及预防全球策略（GOLD）》

《慢性阻塞性肺疾病急性加重（AECOPD）诊治中国专家共识（2017 年更新版）》

《国家基本医疗保险、工伤保险和生育保险药品目录（2017 版）》

《中成药临床应用指南·呼吸系统疾病分册（2016 版）》

《中华人民共和国药典（2015 年版）》

《慢性阻塞性肺疾病中医证候诊断标准（2011 版）》

《慢性阻塞性肺疾病中医诊疗指南（2011 版）》

国际疾病分类标准编码［ICD-11］

3　术语和定义

下列术语和定义适用于本《指南》。

慢性阻塞性肺疾病（ICD-11：CA22）

一种以持续气流受限为特征的可以预防和治疗的常见疾病，简称 COPD。

气流受限多呈进行性发展，与气道和肺对有毒颗粒或气体的慢性炎性反应增强有关。

4　病因病机

COPD 多属于中医学的“喘病”“肺胀”等范畴[8]。本虚标实为 COPD 的主要病理变化，正虚积损为 COPD 的主要病机[10-11]。正虚是指肺脾肾虚损而以肺虚为始、久必及肾，以气虚为本，积损难复；正虚不运，酿生痰瘀，痰瘀常互结成积，复愈损伤正气。正虚积损互为因果，终致肺之形气俱损，呈持续进展而恢复困难。急性加重期以痰（痰热、痰浊）、瘀及其互阻的实证为主并兼有正虚；稳定期以肺气虚、肺脾气虚、肺肾气虚、肺肾气阴两虚的虚证为主，常兼见血瘀、痰浊。危险窗期则邪实渐去，本虚显露，出现以痰浊、痰瘀与气虚、气阴两虚相互兼夹的证候，病理性质为虚实夹杂并重[12]。

5　疾病诊断分期

5.1　急性加重期　急性加重是指 COPD 患者呼吸症状急性恶化，导致需要额外的治疗。通常在疾病过程中，短期内患者咳嗽、咳痰、气短和/或喘息加重，痰量增多，呈脓性或黏液脓性，可伴发热等炎性反应明显加重的表现，需根据病情的轻、中、重度选择不同的治疗场所及治疗方案。COPD 患者常伴有共患疾病，临床上急性加重需与急性冠脉综合征、急性充血性心力衰竭、肺栓塞和肺炎等疾病鉴别[1,6]。

5.2　急性加重危险窗期　急性加重危险窗期是指在一次 COPD 急性加重后至稳定期之前的时期内，极有可能再次出现急性加重，导致住院率和病死率增高，大多集中在一次急性加重后的 8 周内[7]。

5.3　稳定期　指患者咳嗽、咳痰、气短等症状稳定或症状轻微，6 周内没有出现急性加重[1,8]。

参照《慢性阻塞性肺疾病诊断、治疗及预防全球策略（GOLD）》进行 COPD 疾病严重程度评估[1,9]。

6　辨证论治

COPD 急性加重期常见风寒袭肺、外寒内饮、痰热壅肺、痰浊阻肺、痰蒙神窍等证[12-16]，稳定期常见肺气虚、肺脾气虚、肺肾气虚、肺肾气阴两虚等证[13-16]，急性加重危险窗期常见肺肾气虚兼痰浊阻肺、肺脾气虚兼痰浊阻肺、肺肾气阴两虚兼痰浊阻肺、肺肾气虚兼痰瘀阻肺和肺肾气阴两虚兼痰瘀阻

肺等证[17]。血瘀既是 COPD 的主要病机环节，也是常见兼证，常兼于其他证候中，如兼于痰浊阻肺证则为痰浊瘀肺证，兼于痰热壅肺证则为痰热瘀肺证，兼于肺肾气虚证则为肺肾气虚血瘀证[15]。

治疗应遵“急则治其标”“缓则治其本”原则。急性加重期以清热、涤痰、活血、宣肺降气、开窍而立法，兼顾气阴。稳定期以益气（阳）、养阴为主，兼祛痰、活血[8,11,16]。急性加重危险窗期多虚实夹杂并重，治当以补虚扶正、化痰活血[7,18]。

6.1 急性加重期

研究证据[19-20]表明，采用中医辨证治疗、中药联合西医常规治疗 COPD 急性加重，可以显著改善临床症状、改善肺功能、降低炎性反应等。

6.1.1 风寒袭肺证 症状：主症：咳嗽，喘息，恶寒，痰白、清稀，舌苔薄、白，脉紧。次症：发热，无汗，鼻塞、流清涕，肢体酸痛，脉浮[15]。

诊断：1）咳嗽或喘息，咳痰白、清稀；2）发热、恶寒、无汗，或肢体酸痛；3）鼻塞、流清涕；4）舌苔白，脉浮或浮紧。具备 1）、2）2 项，加 3）、4）中的 1 项。

治法：宣肺散寒，止咳平喘。

方药：三拗汤（《太平惠民和剂局方》）合止嗽散（《医学心悟》）加减[8]（证据级别：D；推荐强度：强推荐使用）：炙麻黄 9 g、杏仁 9 g、荆芥 9 g、紫苏 9 g、白前 9 g、百部 12 g、桔梗 9 g、枳壳 9 g、陈皮 9 g、炙甘草 6 g。

加减：痰多白黏、舌苔白腻者，加法半夏 9 g、厚朴 9 g、茯苓 12 g；肢体酸痛甚者，加羌活 9 g、独活 9 g；头痛者，加白芷 9 g、藁本 6 g；喘息明显者，紫苏改为紫苏子 9 g，加厚朴 9 g。

中成药：1）通宣理肺丸（证据级别：D；推荐强度：强推荐使用）：口服，7 g/次（水蜜丸）或 2 丸（大蜜丸），2 ~ 3 次/d。2）杏苏止咳颗粒（证据级别：D；推荐强度：弱推荐使用）：冲服，12 g/次，3 次/d。

6.1.2 外寒内饮证 症状：主症：咳嗽，喘息气急，痰多，痰白稀薄、泡沫，胸闷，不能平卧，恶寒，舌苔白、滑，脉弦、紧。次症：痰易咯出，喉中痰鸣，无汗，肢体酸痛，鼻塞、流清涕，脉浮[15]。

诊断：1）咳嗽或喘息；2）恶寒、无汗，或鼻塞、流清涕，或肢体酸痛；3）痰白稀薄或兼泡沫、痰易咯出；4）喉中痰鸣；5）胸闷甚至气逆不能平卧；6）舌苔白滑，或脉弦紧或浮弦紧。具备 1）、2）2 项，加 3）、4）、5）、6）中的 2 项。

治法：疏风散寒，温肺化饮。

方药：小青龙汤（《伤寒论》）加味[21-23]（证据级别：D；推荐强度：强推荐使用）：炙麻黄 9 g、桂枝 9 g、干姜 6 g、白芍 9 g、细辛 3 g、法半夏 9 g、五味子 6 g、杏仁 9 g、紫苏子 9 g、厚朴 9 g、炙甘草 6 g。

加减：咳而上气，喉中如有水鸡声，加射干 9 g、款冬花 9 g；饮郁化热，烦躁口渴、口苦者，减桂枝，加生石膏 30 g（先煎）、黄芩 9 g、桑白皮 12 g；肢体酸痛者，加羌活 9 g、独活 9 g；头痛者，加白芷 9 g。

中成药：小青龙颗粒（证据级别：D；推荐强度：强推荐使用）：冲服，13 g/次，3 次/d。

6.1.3 痰热壅肺证 症状：主症：咳嗽，喘息，胸闷，痰多，痰黄、白黏干，咯痰不爽，舌质红，舌苔黄、腻，脉滑、数。次症：胸痛，发热，口渴喜冷饮，大便干结，舌苔厚[15]。

诊断：1）咳嗽或喘息气急；2）痰多色黄或白黏，咯痰不爽；3）发热或口渴喜冷饮；4）大便干结；5）舌质红、舌苔黄或黄腻，或脉数或滑数。具备 1）、2）2 项，加 3）、4）、5）中的 2 项。

治法：清肺化痰，降逆平喘。

方药：清气化痰丸（《医方考》）合贝母瓜蒌散（《医学心悟》）加减[8,24-25]（证据级别：D；推荐强度：弱推荐使用）：瓜蒌 15 g、清半夏 9 g、浙贝母 9 g、栀子 9 g、桑白皮 12 g、黄芩 9 g、杏仁 9 g、白头翁 12 g、鱼腥草 15 g、麦冬 12 g、陈皮 9 g。

加减：热甚烦躁、大便秘结者，可联合宣白承气汤（《温病条辨》）加减[26]（证据级别：B；推荐强度：强推荐使用）；痰多质黏稠、咯痰不爽者，可联合桑白皮汤（《古今医统》）加减[27-31]（证据级别：C；推荐强度：强推荐使用）；痰鸣喘息而不得平卧者，加葶苈子 9 g（包煎）、射干 9 g、桔梗 9 g；咳痰腥味者，加金荞麦 20 g、薏苡仁 12 g、桃仁 9 g、冬瓜仁 12 g；胸闷痛明显者，加延胡索 9 g、赤芍 12 g、枳壳 12 g；痰少质黏，口渴，舌红苔剥，脉细数者，减清半夏，加太子参 12 g、沙参 12 g。兼有面色紫暗，口唇发绀，舌质紫暗或黯红，舌有瘀斑等血瘀证的患者，可采用通塞颗粒方[32]（证据级别：D；推荐强度：弱推荐使用）（葶苈子、地龙、炙麻黄、浙贝母、制大黄、赤芍、人参、麦冬、石菖蒲、矮地茶）。

中成药：1）痰热清注射液[33-39]（证据级别：C；推荐强度：强推荐使用）：20 ~ 40 mL，加入 5% 葡萄糖注射液或生理盐水 250 ~ 500 mL，静脉滴注，1 次/d。2）葶贝胶囊（证据级别：D；推荐强度：强推荐使用）：口服，4 粒/次，3 次/d。3）痰热与血瘀互结者，可选血必净注射液[40]（证据级别：C；推荐强度：强推荐使用）：50 mL，加入生理盐水 100 mL 静脉滴注，

2 次/d。

6.1.4　痰浊阻肺证　症状：主症：咳嗽，喘息，痰多，痰白黏，口黏腻，舌苔白、腻，脉滑。次症：气短，痰多泡沫，痰易咳出，胸闷，胃脘痞满，纳呆，食少，舌质淡，脉弦[15]。

诊断：1）咳嗽或喘息、气短；2）痰多、白黏或呈泡沫状；3）胃脘痞满；4）口黏腻，纳呆或食少；5）舌苔白腻，或脉滑或弦滑。具备 1）、2）2 项，加 3）、4）、5）中的 2 项。

治法：燥湿化痰，宣降肺气。

方药：半夏厚朴汤（《金匮要略》）合三子养亲汤（《杂病广要》引《皆效方》加减[8,41]（证据级别：D；推荐强度：强推荐使用）：法半夏 12 g、厚朴 9 g、陈皮 9 g、薤白 12 g、茯苓 15 g、枳壳 9 g、炒白芥子 9 g、紫苏子 9 g、莱菔子 9 g、豆蔻 6 g、生姜 6 g。

加减：痰多咳喘，胸闷不得卧者，加麻黄 6 g、葶苈子 9 g（包煎）；脘腹胀闷，加木香 9 g、焦槟榔 9 g；便溏者，减紫苏子、莱菔子，加白术 12 g、泽泻 9 g、葛根 9 g；大便秘结，加焦槟榔 12 g、枳实 9 g。

中成药：1）苏子降气丸（证据级别：D；推荐强度：弱推荐使用）：口服，6 g/次，1～2 次/d。2）苓桂咳喘宁胶囊[42]（证据级别：D；推荐强度：弱推荐使用）：口服，5 粒/次，3 次/d。

6.1.5　痰蒙神窍证　症状：主症：喘息气促，神志恍惚、嗜睡、昏迷、谵妄，舌苔白、腻、黄。次症：喉中痰鸣，肢体瘛疭甚则抽搐，舌质暗红、绛、紫，脉滑、数[15]。

诊断：1）神志异常（烦躁、恍惚、嗜睡、谵妄、昏迷）；2）肢体瘛疭甚则抽搐；3）喘息气促；4）喉中痰鸣；5）舌质淡或红、舌苔白腻或黄腻，或脉滑或数。具备 1）、2）中 1 项，加 3）、4）、5）中的 2 项。

治法：豁痰开窍。

方药：涤痰汤（《奇效良方》）加减[8]（证据级别：D；推荐强度：强推荐使用）：清半夏 9 g、天南星 6 g、天竺黄 6 g、茯苓 15 g、陈皮 9 g、枳实 9 g、丹参 15 g、人参 9 g、石菖蒲 6 g、细辛 3 g、生姜 6 g。

加减：舌苔白腻有寒象者，加用苏合香丸（证据级别：D；推荐强度：强推荐使用），姜汤或温开水送服，1 丸/次，1～2 次/d。身热，谵语，舌红绛、苔黄者，减细辛、天南星，加水牛角 30 g（先煎）、胆南星 6 g、玄参 12 g、连翘 12 g、黄连 6 g、炒栀子 9 g，或加用安宫牛黄丸或至宝丹（证据级别：D；推荐强度：弱推荐使用）；大便秘结，腑气不通者，加生大黄 6 g（后下）、芒硝 9 g（冲服）；抽搐明显者，加钩藤 9 g（后下）、全蝎 6 g、地龙 12 g、羚羊角粉 0.6 g（冲服）。

中成药：1）醒脑静注射液（证据级别：D；推荐强度：强推荐使用）：一次 10～20 mL，加入 5%～10% 葡萄糖注射液或生理盐水 250～500 mL，静脉滴注，1～2 次/的。2）清开灵注射液[43]（证据级别：D；推荐强度：弱推荐使用）：20～40 mL，加入 10% 葡萄糖注射液 200 mL 或生理盐水 100 mL，静脉滴注，2 次/d。

6.2　急性加重危险窗期　急性加重危险窗期是介于急性加重期结束至稳定期的一段时期，其病机常以虚实并重，以气（阳）虚、气阴两虚为主，常兼痰瘀，故治疗当祛邪（化痰、活血）扶正（补益肺气、补肺健脾、补益肺肾等）并重[7,17]。一项多中心试验研究表明[18]：急性加重—危险窗期采用中西医结合序贯治疗方案较单纯西医规范方案的疗效提高显著，减少了急性加重次数，改善了呼吸困难等临床症状，提高了生命质量。

6.3　稳定期

研究证据表明[44-49]，中医辨证治疗、中西医结合治疗 COPD 稳定期的疗效较安慰剂或单用西医治疗显著，主要表现在改善症状、减少急性加重次数、提高运动耐力、改善生命质量等。对于早期肺功能 1、2 级的 COPD 稳定期患者，中医辨证治疗方案（肺气虚证用补肺方，肺脾气虚证用补肺健脾方，肺肾气虚证用补肺益肾方）能够减少患者急性加重次数，改善肺功能和呼吸困难程度，改善临床症状，提高运动耐力和生命质量等，并具有较好的远后效应[50]。肺功能 3、4 级的 COPD 患者，在西医常规治疗基础上，中医辨证治疗方案（肺脾气虚证用补肺健脾方，肺肾气虚证用补肺益肾方，肺肾气阴两虚证用益气滋肾方）治疗能够减少患者急性加重次数和程度，提高生命质量和运动耐力，改善患者临床症状和呼吸困难等[51]。

6.3.1　肺气虚证　症状：主症：咳嗽，乏力，易感冒。次症：喘息，气短，动则加重，神疲，自汗，恶风，舌质淡，舌苔白，脉细、沉、弱[15]。

诊断：1）咳嗽或喘息、气短，动则加重；2）神疲、乏力，或自汗；3）恶风，易感冒；4）舌质淡、苔白，或脉沉细或细弱。具备 1）、2）、3）、4）中的 3 项。

治法：补肺益气固卫。

方药：人参胡桃汤（《济生方》）合人参养肺丸（《太平惠民和剂局方》）加减[8]（证据级别：D；推荐强度：弱推荐使用）：党参 15 g、黄芪 15 g、白术 12 g、胡桃肉 15 g、百部 9 g、川贝母 6 g、杏仁 9 g、厚朴 9 g、

紫苏子 9 g、地龙 12 g、陈皮 9 g、桔梗 9 g、炙甘草 6 g。

加减：自汗甚者，加浮小麦 15 g、煅牡蛎 15 g（先煎）；寒热起伏，营卫不和者，加桂枝 6 g、白芍 9 g。此证亦可选用益气固表方[52]（证据级别：B；推荐强度：弱推荐使用）（党参、浮小麦、白术、半夏、陈皮、紫苏、茯苓、防风、薏苡仁、款冬花、黄芩、川贝母、枇杷叶）。

中成药：玉屏风颗粒[53-54]（冲剂）（证据级别 B；推荐强度：强推荐使用）：冲服，5 g/次，3 次/d。

6.3.2 肺脾气虚证 症状：主症：咳嗽，喘息，气短，动则加重，纳呆，乏力，易感冒，舌体胖大、齿痕，舌质淡，舌苔白。次症：神疲，食少，脘腹胀满，便溏，自汗，恶风，脉沉、细、缓、弱[15]。

诊断：1）咳嗽或喘息、气短，动则加重；2）神疲、乏力或自汗，动则加重；3）恶风，易感冒；4）纳呆或食少；5）胃脘胀满或腹胀或便溏；6）舌体胖大或有齿痕，或舌苔薄白或白腻，或脉沉细或沉缓或细弱。具备 1）、2）、3）中的 2 项，加 4）、5）、6）中的 2 项。

治法：补肺健脾，降气化痰。

方药：六君子汤（《医学正传》引《太平惠民和剂局方》）合黄芪补中汤（《医学发明》）加减[Ⅳ]（证据级别：D；推荐强度：强推荐使用）：党参 15 g、黄芪 15 g、白术 12 g、茯苓 12 g、杏仁 9 g、川贝母 6 g、地龙 12 g、厚朴 9 g、紫菀 9 g、紫苏子 9 g、淫羊藿 6 g、陈皮 9 g、炙甘草 6 g。

加减：咳嗽痰多、舌苔白腻者，减黄芪，加法半夏 12 g、豆蔻 9 g；咳痰稀薄，畏风寒者，加干姜 9 g、细辛 2 g；纳差食少明显者，加神曲 12 g、豆蔻 12 g、炒麦芽 12 g；脘腹胀闷，减黄芪，加木香 9 g、莱菔子 9 g、豆蔻 9 g；大便溏者，减紫菀、杏仁，加葛根 9 g、泽泻 12 g、芡实 15 g；自汗甚者，加浮小麦 15 g、煅牡蛎 20 g（先煎）。此证亦可选用补肺健脾方[55-56]（证据级别 B；推荐强度：弱推荐使用）：黄芪、黄精、党参、白术、茯苓、浙贝母、地龙、厚朴、陈皮、紫菀、矮地茶、淫羊藿；或补中益气汤（《内外伤辨惑论》）加减[57]（证据级别 B；推荐强度：强推荐使用）。

中成药：1）玉屏风颗粒[53-54]（冲剂）（证据级别 B；推荐强度：弱推荐使用）：冲服，5 g/次，3 次/d。2）六君子丸（证据级别：D；推荐强度：弱推荐使用）：口服，9 g/次，2 次/d。

6.3.3 肺肾气虚证 症状：主症：喘息，气短，动则加重，神疲，乏力，腰膝酸软，易感冒，舌质淡，舌苔白，脉细。次症：恶风，自汗，面目水肿，胸闷，耳鸣，夜尿多，咳而遗溺，舌体胖大、有齿痕，脉沉、弱[15]。

诊断：1）喘息，气短，动则加重；2）乏力，或自汗，动则加重；3）易感冒，恶风；4）腰膝酸软；5）耳鸣，头昏或面目虚浮；6）小便频数、夜尿多，或咳而遗溺；7）舌质淡、舌苔白，或脉沉细或细弱。具备 1）、2）、3）中的 2 项，加 4）、5）、6）、7）中的 2 项。

治法：补肾益肺，纳气定喘。

方药：补肺益肾方[55-56]（证据级别 B；推荐强度：强推荐使用）：人参 6 g、黄芪 15 g、山茱萸 9 g、枸杞子 12 g、五味子 9 g、淫羊藿 9 g、浙贝母 9 g、赤芍 12 g、地龙 12 g、紫苏子 9 g、矮地茶 9 g、陈皮 9 g。

加减：咳嗽明显者，加炙紫菀 12 g、杏仁 12 g；咳嗽痰多、舌苔白腻者，加法半夏 9 g、茯苓 15 g；动则喘甚者，加蛤蚧粉 2 g（冲服）；面目虚浮、畏风寒者，加肉桂 5 g（后下）、泽泻 9 g、茯苓 12 g；腰膝酸软者，加菟丝子 12 g、杜仲 12 g；小便频数明显者，加益智仁 9 g、金樱子 12 g；畏寒，肢体欠温者，加制附子 9 g（先煎）、干姜 6 g。此证也可采用人参补肺饮（《症因脉治》）合大补元煎（《景岳全书》）加减[Ⅳ]（证据级别：D；推荐强度：弱推荐使用）或采用人参蛤蚧散（《博济方》）加味[58-60]（证据级别 C；推荐强度：弱推荐使用）。

中成药：肺肾气虚兼血瘀者，可选补肺活血胶囊[61-62]（证据级别：C；推荐强度：弱推荐使用）：口服，4 粒/次，3 次/d。

6.3.4 肺肾气阴两虚证 症状：主症：咳嗽，喘息，气短，动则加重，乏力，自汗，盗汗，腰膝酸软，易感冒，舌质红，脉细、数。次症：口干，咽干，干咳，痰少，咯痰不爽，手足心热，耳鸣，头昏，头晕，舌质淡，舌苔少、花剥，脉弱、沉、缓、弦[15]。

诊断：1）喘息、气短，动则加重，2）自汗或乏力，动则加重；3）易感冒；4）腰膝酸软；5）耳鸣，头昏或头晕；6）干咳或少痰、咯痰不爽；7）盗汗；8）手足心热；9）舌质淡或红、舌苔薄少或花剥，或脉沉细或细弱或细数。具备 1）、2）、3）中 2 项加 4）、5）中的1 项加 6）、7）、8）、9）中的 2 项。

治法：补肺滋肾，纳气定喘。

方药：保元汤（《博爱心鉴》）合人参补肺汤（《外科枢要》）加减[Ⅳ]（证据级别：D；推荐强度：强推荐使用）：人参 6 g、黄芪 15 g、黄精 15 g、熟地黄 15 g、枸杞子 12 g、麦冬 15 g、五味子 9 g、肉桂 3 g（后下）、紫苏子 9 g、浙贝母 12 g、牡丹皮 9 g、地龙 12 g、百部 9 g、陈皮 9 g、炙甘草 6 g。

加减：咳甚者，加炙枇杷叶 12 g、杏仁 9 g；痰黏难咯者，加百合 15 g、玉竹 12 g、沙参 12 g；手足心热

甚者，加知母 9 g、黄柏 9 g、地骨皮 12 g、鳖甲 15 g；盗汗者，加煅牡蛎 20 g（先煎）、糯稻根 15 g。此证亦可选用益气滋肾方[55-56]（证据级别：B；推荐强度：弱推荐使用）（人参、黄精、麦冬、五味子、枸杞子、熟地黄、肉桂、浙贝母、地龙、牡丹皮、紫苏子、百部、陈皮）；补肺颗粒[67-69]（证据级别 B；推荐强度：弱推荐使用）（党参、熟地黄、山萸肉、蜜麻黄、当归、赤芍、黄芩、陈皮、蜜紫菀、甘草）。

中成药：1）生脉饮口服液（证据级别：D；推荐强度：弱推荐使用）：口服，10 mL/次，3 次/d。2）养阴清肺丸（偏肺阴虚而有燥热者）（证据级别：D；推荐强度：弱推荐使用）：口服，6～9 g/次，2 次/d。3）百合固金丸（偏肺肾阴虚者）（证据级别：D；推荐强度：弱推荐使用）：口服，9 g/次，2 次/d。4）蛤蚧定喘丸（偏肺肾阴虚而内热咳喘者）（证据级别：D；推荐强度：弱推荐使用）：口服，6 g/次（水蜜丸），2 次/d。

6.4　临床兼证及复杂证候的治疗建议

6.4.1　兼证-血瘀证　血瘀常以兼证出现于实证、虚证之中，治疗时可在扶正或补虚祛邪基础上，佐以活血化瘀方药。主症：口唇发绀，舌质黯红、紫黯、瘀斑，脉涩、沉。次症：胸闷痛，面色紫暗[15]。

诊断：1）面色紫暗；2）唇甲发绀；3）舌质紫暗或有瘀斑或瘀点；4）舌下静脉迂曲、粗乱。具备 1）、2）、3）、4）中的 1 项即可诊断。治法：活血化瘀。方药：根据所兼证候的不同，临床上可增减活血化瘀方药[8,70]（如川芎 9 g、赤芍 12 g、桃仁 9 g、红花 9 g、莪术 9 g）。

6.4.2　复杂证候　本虚标实而虚实兼见是 COPD 的病机特点。临床实际中，证候多以复杂证候出现，即使是复杂证候，病机也有主次之分，如 1）急性加重期：多见痰热壅肺或痰浊阻肺证等，常兼肺脾气虚或肺肾气虚证等，时或兼瘀，以痰热、痰湿或血瘀等实证为主，肺脾气虚、肺肾气虚等虚证为次，故治疗当以清肺化痰、燥湿化痰、活血化瘀等为主，辅以补肺健脾或补益肺肾等。2）稳定期：多见肺气虚、肺脾气虚、肺肾气虚等虚证，常兼痰浊、血瘀或痰瘀互阻等实证，以虚证为主，以实证为次，故治疗以补益为主如补益肺气、补肺健脾、补肺益肾等，佐以祛邪如化痰、活血等。由于 COPD 临床证候复杂多变，本指南难以将所有复杂证候全部列出，建议临床实践中，辨证为复杂证候时可参考指南所列证候的治法方药进行治疗，根据虚实主次而谴方用药[10-11,14-16]。

7　其他治法

研究表明，太极拳[71]、针刺[72]、呼吸导引[73]、穴位贴敷（如舒肺贴[74]、消喘膏[75]等）、益肺灸[76]等技术在缓解 COPD 患者临床症状、提高运动耐力、延缓肺功能下降、提高生命质量等方面具有较好疗效。可参考相关指南对 COPD 患者进行中医肺康复的临床实践。

8　预防调护

8.1　预防外感　保持空气湿润，有利于呼吸道分泌物的排出；鼓励患者咳嗽、排痰、戒烟、预防感冒及呼吸道感染；在严格的看护下进行适当的康复锻炼，提高机体抵抗力[10]。

8.2　改善营养状况　营养不良可使膈肌疲劳加重，应少食多餐，给以清淡、易消化、营养丰富的饮食，避免辛辣刺激性食物，保持大便通畅[10]。

8.3　心理护理　COPD 患者长期受疾病折磨，精神负担十分沉重，易合并焦虑抑郁，应帮助患者树立战胜疾病的信心[10]。

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说明

与中华中医药学会版指南相比，本指南主要技术变化如下：

——删除了指南研制方法；

——增加了附录《慢性阻塞性肺疾病中医证候诊断标准》；

——增加了部分方剂、中成药参考文献。

本指南所列的中药剂量为参考剂量，供临床应用时参考。

本指南所列的中成药来源于《中华人民共和国药典(2015 年版)》《国家基本医疗保险、工伤保险和生育保险药品目录(2017 版)》《中成药临床应用指南·呼吸系统疾病分册(2016 版)》等文件。

本指南不是医疗行为的标准或者规范，而是依据现有的研究证据、特定的方法制定出的声明性文件。在临床实践中，医师可参考本指南并结合患者具体情况进行个体化诊疗。

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刘清泉院长解读第七版诊疗方案 持续改进,发挥中医药优势

3 月 3 日,国家卫健委、国家中医药管理局印发《新型冠状病毒肺炎诊疗方案(试行第七版)》(以下简称"第七版诊疗方案")。通知要求,有关医疗机构要在医疗救治工作中积极发挥中医药作用,加强中西医结合,完善中西医联合会诊制度,促进医疗救治取得良好效果。第七版诊疗方案的中医药疗法有哪些改进,对于救治患者有哪些效果?国家中医医疗救治专家组副组长、北京中医医院院长刘清泉给您带来权威解读。

"相对于第六版诊疗方案,第七版的中医药疗法整体上改变不大,主要在危重症患者救治方面进行了修订和改善"。刘清泉院长介绍,这段时间以来,专家组经过研究,将救治方法和药物更加细化,把重点放在如何降低危重症患者的病亡率上。

"我们提出了更多的药物治疗方法,希望医生在查房救治的过程中,针对患者进行更加个性化的治疗"。刘清泉院长说,中医讲究辨证施治,不同的患者之间病情不一样。第七版诊疗方案的中医药治疗部分只是给医护人员提供了一个可供更多选择的原则性的方案,保障他们在具体诊治患者的过程中有更多的选择空间。

武汉的危重症患者很多都使用了呼吸机,如何发挥中医药的优势,减少使用呼吸机对人体产生的不良反应,让呼吸功能达到最好的状态,这是刘清泉院长和其他专家组成员一直在研究解决的问题。"第七版诊疗方案,也增加了中医药支持呼吸机治疗的方案"。刘清泉说。

"新冠肺炎对于我们来说还是一个新发病。第七版诊疗方案对于中成药和中药注射剂的使用做出了更科学的规定"。刘清泉院长表示,中成药临床使用说明书中的规定使用剂量在实际救治的过程中可能不一定适用所有的患者,需要医生根据患者身体情况和病情进行判断。第七版诊疗方案更加注重中药注射剂在危重症患者救治过程中的使用。

"第七版诊疗方案中针对危重症患者中医药治疗方案是专家组成员经过长时间跟踪危重症患者的救治形成的经验"。刘清泉院长介绍,特别是近 20 天以来,国家卫健委和国家中医药管理局联合成立了中西医协同救助专家组,对武汉市各个定点医院的重症病房、ICU 进行了巡诊、会诊、查房等。"在这个过程中,我们对危重症患者病情和治疗的认识更加深刻"。

刘清泉院长表示,第七版诊疗方案整体上是对第六版的改进,对于广大医护人员救治新冠肺炎患者具有很好的指导作用。接下来,专家组会不断总结在救治患者过程中的有益经验,持续改进诊疗方案。"是否会推出新的诊疗方案要根据疫情的形势来确定"。

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