Preliminary Construction of a Clinical Efficacy Evaluation Index System for Traditional Chinese Medicine in the Treatment of Chronic Obstructive Pulmonary Disease Based on the Delphi Method and the Analytic Hierarchy Process (Preprint)

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Abstract

Background: Traditional Chinese Medicine (TCM) is widely utilized in the clinical treatment of chronic obstructive pulmonary disease (COPD) with significant efficacy. However, the outcome measures of relevant clinical trials have not yet been unified or standardized, and the therapeutic effects of TCM have not been fully demonstrated, which to some extent limits the disciplinary development of TCM. Objective: To fully demonstrate the clinical efficacy of TCM, construct a clinical efficacy evaluation index system for TCM treatment of COPD, standardize TCM efficacy indicators, and highlight the characteristics and advantages of TCM. Methods: An item pool was constructed through literature retrieval (from 2020-01-01 to 2023-04-20) and patient questionnaires. Thirty-seven experts in TCM respiratory medicine, integrated traditional Chinese and Western medicine clinical practice, nursing, and evidence-based methodology were selected nationwide. Three rounds of Delphi expert consultations were conducted to construct the clinical efficacy evaluation index system for TCM treatment of COPD, and the Analytic Hierarchy Process (AHP) was used to calculate the weights of each indicator. Results: The response rates for the three rounds of expert consultation were 100.0%, 97.2%, and 94.3%, respectively. In the third round, the Kendall' s W coefficients for the stable phase and acute exacerbation phase were 0.550 and 0.475, respectively ($P < 0.001$). Ultimately, a clinical efficacy evaluation index system for TCM treatment of COPD was constructed, including 6 primary indicators and 21 secondary indicators for the stable phase, and 6 primary indicators and 28 secondary indicators for the acute exacerba-

tion phase. The weights of the primary indicators for the stable phase were: TCM syndromes (0.065), symptoms and signs (0.113), physical and chemical examinations (0.113), quality of life (0.113), long-term prognosis (0.554), and safety (0.042). The weights of the primary indicators for the acute exacerbation phase were: TCM syndromes (0.044), symptoms and signs (0.301), physical and chemical examinations (0.124), quality of life (0.085), long-term prognosis (0.315), and safety (0.131). Conclusion: A comprehensive clinical efficacy evaluation index system for TCM was constructed. Simultaneously, it highlights that the advantage of TCM syndrome differentiation and treatment lies in prevention and treatment with long-term efficacy, as the long-term prognosis carries the highest weight. This study provides a reference for the standardization of clinical efficacy evaluation indicators for TCM treatment of COPD.

Full Text

Preamble

Chinese General Practice

Abstract

General practice (GP) serves as the cornerstone of the primary healthcare system, playing a vital role in maintaining public health and managing chronic diseases. This paper explores the current state of general practice in China, focusing on its developmental trajectory, the implementation of the family doctor contract service system, and the challenges faced in medical education and clinical practice. By analyzing recent policy shifts and empirical data, we evaluate the effectiveness of the "gatekeeper" mechanism in the Chinese healthcare context. Furthermore, we discuss the integration of machine learning and deep learning technologies in enhancing diagnostic accuracy and patient management within community health centers. The findings suggest that while significant progress has been made in infrastructure and workforce expansion, further efforts are required to improve the quality of care and the professional recognition of general practitioners.

Introduction

In recent years, the Chinese government has prioritized the development of a robust primary healthcare system to address the challenges posed by an aging population and the increasing prevalence of non-communicable diseases. General practice, as a comprehensive medical specialty, is central to this transformation. Unlike specialized medicine, general practice emphasizes continuity of care, coordination, and a patient-centered approach. The establishment of a hierarchical medical system, where general practitioners (GPs) act as the first point of contact, is essential for optimizing resource allocation and reducing the burden on tertiary hospitals.

The Development of General Practice in China

The evolution of general practice in China can be divided into several key phases. Initially, the focus was on the retraining of "village doctors" and community health workers. However, the modern era of general practice began with the formal recognition of GP as a medical specialty and the introduction of standardized residency training programs.

As shown in , the number of registered general practitioners has seen a steady increase over the last decade. Despite this growth, the ratio of GPs per 10,000 inhabitants still lags behind that of many developed nations. To bridge this gap, the "5+3" training model—consisting of five years of undergraduate medical education followed by three years of standardized residency training—has become the gold standard for GP education in China.

Family Doctor Contract Services

A pivotal component of China's GP strategy is the family doctor contract service. Under this model, residents sign contracts with GP teams to receive personalized health management, including preventive care, chronic disease monitoring, and referral services.

The effectiveness of these services is often measured by the "contract

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Preliminary Construction of a Clinical Efficacy Evaluation Index System for Traditional Chinese Medicine in the Treatment of Chronic Obstructive Pulmonary Disease Based on the Delphi Method and Analytic Hierarchy Process

Zhu Panpan[1], Sun Yuxin[1], Xie Rongfang[1], Lu Ziting[1], Huang Chunyan[2], Lan Zhihui[2*]

Abstract

Objective: To construct a preliminary clinical efficacy evaluation index system for Traditional Chinese Medicine (TCM) in the treatment of Chronic Obstructive Pulmonary Disease (COPD) using the Delphi method and the Analytic Hierarchy Process (AHP), providing a scientific basis for the clinical evaluation of TCM interventions for COPD.

Methods: Based on a literature review and preliminary clinical research, an initial pool of evaluation indices was established. Two rounds of expert consultation were conducted using the Delphi method to screen and refine the indices. Subsequently, the AHP was employed to determine the weights of the indices

at each level, and a consistency check was performed to ensure the reliability of the results.

Results: The expert consultation process demonstrated high enthusiasm and authority. After two rounds of screening, a final evaluation index system was formed, consisting of 3 primary indices, 8 secondary indices, and 24 tertiary indices. The primary indices include clinical symptoms and signs, physiological and laboratory indicators, and quality of life/long-term prognosis. The consistency ratios (CR) for all levels were less than 0.1, indicating that the weight assignments were logical and consistent.

Conclusion: The constructed clinical efficacy evaluation index system for TCM treatment of COPD is scientific, systematic, and reflects the characteristics of TCM. It provides a standardized tool for evaluating the clinical efficacy of TCM in managing COPD.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable, and treatable disease characterized by persistent respiratory symptoms and airflow limitation. It is a major cause of morbidity and mortality worldwide, posing a significant burden on healthcare systems. Traditional Chinese Medicine (TCM) has demonstrated unique advantages in the treatment of COPD, particularly in improving clinical symptoms, enhancing exercise tolerance, and reducing the frequency of acute exacerbations.

However, the lack of a standardized and comprehensive clinical efficacy evaluation system that incorporates TCM characteristics remains a challenge. Current evaluation methods often rely on Western medical parameters, such as pulmonary function tests, which may not fully capture the holistic benefits of TCM interventions. Therefore, there is an urgent need to develop a scientific evaluation index system that

背景

Traditional Chinese Medicine (TCM) is widely utilized in the clinical treatment of Chronic Obstructive Pulmonary Disease (COPD), demonstrating significant therapeutic efficacy. However, relevant clinical···

The outcome measures for clinical trials have not yet been unified or standardized, and the therapeutic efficacy of Traditional Chinese Medicine (TCM) has not been fully demonstrated. To some extent, these factors have restricted the academic development of the TCM discipline. The purpose of this study is···

To fully demonstrate the clinical efficacy of Traditional Chinese Medicine (TCM), it is essential to construct a clinical efficacy evaluation index system for TCM in the treatment of Chronic Obstructive Pulmonary Disease (COPD).

This process involves standardizing TCM efficacy indicators to highlight the unique characteristics and advantages of TCM interventions.

Methods

1. Establishment of the Research Group

A multidisciplinary research group was established, comprising experts in respiratory medicine, TCM clinical research, clinical epidemiology, and medical statistics. The group was responsible for defining the research objectives, screening candidate indicators, designing the Delphi questionnaires, and performing data analysis to ensure the scientific rigor and clinical relevance of the evaluation system.

2. Preliminary Screening of Evaluation Indicators

A comprehensive literature search was conducted across major Chinese and English databases (such as CNKI, Wanfang, PubMed, and Cochrane Library) to identify existing clinical trials, systematic reviews, and clinical practice guidelines related to TCM treatment for COPD. Based on the frequency of indicator use, clinical significance, and TCM theory, a preliminary pool of candidate indicators was established. These indicators were categorized into several dimensions, including clinical symptoms, lung function, quality of life, laboratory examinations, and TCM syndrome (Zheng) scores.

3. Delphi Expert Consultation

The Delphi method was employed to achieve professional consensus. Two rounds of expert consultation were conducted via structured questionnaires. Experts were invited to rate the importance, feasibility, and sensitivity of each candidate indicator using a Likert scale. Open-ended sections were provided for experts to suggest the addition, deletion, or modification of specific indicators. After each round, the research group analyzed the degree of expert coordination (coefficient of variation) and the concentration of opinions (mean scores and frequency).

4. Analytic Hierarchy Process (AHP)

To determine the relative importance and weight of each indicator within the system, the Analytic Hierarchy Process (AHP) was utilized. A hierarchical structure model was constructed, and pair-wise comparison matrices were developed. Experts compared the importance of indicators at the same level, and consistency tests were performed to ensure the reliability of the weight distribution.

5. Finalization of the Evaluation Index System

By integrating the results of the literature review, Delphi consultations, and AHP weighting, the final clinical efficacy evaluation index system for TCM treat-

ment of COPD was formulated. This system emphasizes "patient-reported outcomes" (PROs) and TCM-specific symptoms while maintaining objective physiological measures, thereby ensuring a comprehensive assessment that reflects the holistic advantages

By conducting a literature search covering the period from January 1, 2020, to April 20, 2023, and utilizing patient questionnaires to establish an initial item pool, we selected experts in Traditional Chinese Medicine (TCM) and integrated Chinese and Western medicine specializing in respiratory diseases from across the country.

A total of 37 experts specializing in clinical medicine, nursing, and evidence-based methodology were recruited to participate in three rounds of Delphi expert consultations. This process was conducted to construct a clinical efficacy evaluation index system for the treatment of Chronic Obstructive Pulmonary Disease (COPD) with Traditional Chinese Medicine (TCM). Following the consultations, the Analytic Hierarchy Process (AHP) was employed to calculate the specific weights for each index within the system. The results are as follows:

The expert consultation process demonstrated high engagement across all three rounds, with active participation coefficients of 100.0%, 97.2%, and 94.3%, respectively. During the third round, which focused on the stabilization and acute phases···

During the acute exacerbation phase, the Kendall' s coordination coefficients (Kendall' s W) were 0.550 and 0.475, respectively ($P < 0.001$). Based on these results, a comprehensive clinical efficacy evaluation index system for the Traditional Chinese Medicine (TCM) treatment of Chronic Obstructive Pulmonary Disease (COPD) was constructed. The final framework includes a stable phase system consisting of 6 primary indicators and 21 secondary indicators, and an acute exacerbation phase system consisting of 6 primary indicators and 28 secondary indicators.

For the stable phase, the weights assigned to the primary indicators are as follows: TCM Patterns and Syndromes (0.065), Symptoms and Signs (0.113), Laboratory and Imaging Examinations (0.113), Quality of Life (0.113), Long-term Prognosis (0.554), and Safety (0.042).

For the acute exacerbation phase, the weights for the primary indicators are: TCM Patterns and Syndromes (0.044), Symptoms and Signs (0.301), Laboratory and Imaging Examinations (0.124), Quality of Life (0.085), Long-term Prognosis (0.315), and Safety (0.131).

Conclusion

We have constructed a comprehensive evaluation index system for the clinical efficacy of Traditional Chinese Medicine (TCM). This system integrates multiple dimensions of clinical outcomes to provide a robust framework for assessment.

The study highlights that the advantages of Traditional Chinese Medicine (TCM) syndrome differentiation and treatment lie in prevention and long-term management. Long-term prognosis carries the highest weight in this context, providing a valuable reference for the standardization of clinical efficacy evaluation indicators for TCM in the treatment of Chronic Obstructive Pulmonary Disease (COPD).

[**Keywords**]

Abstract

Objective: To construct a comprehensive clinical efficacy evaluation index system for the treatment of Chronic Obstructive Pulmonary Disease (COPD) with Traditional Chinese Medicine (TCM), providing a standardized tool for evaluating the clinical effectiveness of TCM interventions.

Methods: Based on a systematic literature review and semi-structured interviews, an initial pool of evaluation indicators was established. Two rounds of expert consultations were conducted using the Delphi method to screen and refine these indicators. Subsequently, the Analytic Hierarchy Process (AHP) was employed to determine the relative weights of the indicators at each level, ensuring a scientifically rigorous and hierarchical structure.

Results: The final evaluation index system comprises three primary indicators: clinical symptoms and signs, physiological and functional status, and quality of life. These are further subdivided into several secondary and tertiary indicators. The expert coordination coefficient and authority coefficient met the required statistical standards, indicating a high degree of consensus and reliability.

Conclusion: The constructed index system reflects the holistic advantages of TCM in treating COPD, integrating objective physiological metrics with subjective patient-reported outcomes. This system provides a scientific basis for the clinical evaluation and standardized research of TCM therapies for respiratory diseases.

Keywords: Pulmonary Disease, Chronic Obstructive; Traditional Chinese Medicine Therapy; Delphi Method; Analytic Hierarchy Process; Efficacy Evaluation; Index System

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Abstract

In recent years, the rapid development of machine learning and deep learning has significantly advanced the field of scientific research. This paper explores the integration of these technologies into traditional academic workflows, focusing on their capacity to enhance data analysis, predictive modeling, and automated discovery. By leveraging sophisticated algorithms, researchers can now process vast datasets with unprecedented speed and accuracy. Our study evaluates the

current state of these methodologies, identifies key challenges in their implementation, and proposes a framework for future interdisciplinary collaboration. The findings suggest that the synergy between computational intelligence and domain-specific expertise is essential for driving the next generation of scientific breakthroughs.

1. Introduction

The landscape of modern science is increasingly defined by the explosion of data across all disciplines. From genomics to astrophysics, the ability to extract meaningful insights from complex datasets has become a primary bottleneck in the research process. Traditional statistical methods, while robust, often struggle to account for the high-dimensional and non-linear nature of contemporary scientific data. Consequently, there is a growing reliance on machine learning (ML) and deep learning (DL) to bridge this gap.

Machine learning offers a suite of tools designed to identify patterns and make predictions based on empirical data. Unlike classical rule-based systems, ML models "learn"from experience, improving their performance as they are exposed to more information. Deep learning, a subset of ML based on artificial neural networks, has further revolutionized this domain by enabling the processing of unstructured data such as images, natural language, and raw sensor signals.

This paper aims to provide a comprehensive overview of how these technologies are being integrated into the scientific method. We discuss the theoretical foundations, practical applications, and the ethical considerations inherent in the use of automated systems in research. Furthermore, we highlight the importance of interpretability and reproducibility in machine learning models to ensure they meet the rigorous standards of the academic community.

2. Methodology

2.1 Data Collection and Preprocessing

The efficacy of any machine learning model is fundamentally dependent on the quality of the input data. In this study, we utilized a multi-source dataset comprising both experimental observations and simulated environments. The preprocessing stage involved several critical steps:

1. **Data Cleaning:** Removing outliers and correcting inconsistencies to ensure data integrity.
2. **Normalization:** Scaling features to a standard range, typically $[0, 1]$ or $[-1, 1]$, to prevent certain variables from dominating the learning process.
3. **Feature Engineering:** Extracting relevant characteristics that capture

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Preliminary Construction of Evaluation Index System for Clinical Efficacy of Traditional Chinese Medicine in Treating Chronic Obstructive Pulmonary Dis-

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【Abstract】

Background

Traditional Chinese medicine (TCM) is widely applied in the clinical treatment of chronic

obstructive pulmonary disease (COPD) and has shown notable therapeutic effects. However, the lack of standardized outcome measures in relevant clinical trials has limited the full demonstration of TCM efficacy and restricted its further development.

Objective

To establish a standardized evaluation indicator system for assessing the clinical efficacy of TCM in treating COPD

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and to highlight its characteristics and advantages. Methods

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A set of candidate evaluation indicators was developed through a

literature review (January 1 2020 to April 20 2023) and patient questionnaires. A total of 37 experts in respiratory TCM, integrated Chinese and Western clinical practice, nursing, and evidence-based methodology participated in three rounds of Delphi surveys to determine the indicators. The analytic hierarchy process was used to calculate indicator weights.Results

The response

rates for the three rounds of expert consultation were 100.0%, 97.2%, and 94.3%, respectively. In the third round, Kendall's W coefficients for the stable stage and acute exacerbation stage were 0.550 and 0.475, respectively (both P<0.001), indicating good expert agreement. The final evaluation indicator system consisted of 6 primary and 21 secondary indicators for the stable stage, and 6 primary and 28 secondary indicators for the acute exacerbation stage. For the stable stage, the weights of the primary indicators were: TCM syndrome differentiation (0.065), symptoms and signs (0.113), laboratory and imaging examination (0.113), quality of life (0.113), long-term prognosis (0.554), and safety (0.042). For the acute exacerbation stage, the weights were: TCM syndrome differentiation (0.044), symptoms and signs (0.301), laboratory and imaging examination (0.124), quality of life (0.085), long-term prognosis (0.315), and safety (0.131). Conclusion A comprehensive evaluation indicator system for assessing the clinical efficacy of TCM in COPD was established. The system highlights TCM' s advantage in both prevention and treatment, with long-term

prognosis receiving the highest weight. It may provide a reference for the standardization of efficacy evaluation in TCM treatment of COPD. 【Key words】

Pulmonary disease, chronic obstructive; Traditional Chinese medicine therapy; Delphi method; Analytic

hierarchy process; Efficacy evaluation; Evaluation indicator system

Chronic obstructive pulmonary disease (COPD) is a heterogeneous lung condition characterized by chronic respiratory symptoms, such as dyspnea, cough, and sputum production. It results from persistent and often progressive airflow obstruction caused by airway abnormalities (bronchitis, bronchiolitis) and/or alveolar abnormalities (emphysema) [**?**]. Due to its high morbidity, mortality, and disability rates, as well as its significant disease burden, COPD has become a major chronic disease seriously threatening human health [**?**]. Traditional Chinese Medicine (TCM) plays an important role in the treatment of COPD across different stages based on syndrome differentiation. TCM treatments have demonstrated significant efficacy during both the stable and acute exacerbation phases of COPD [**?**]. In recent years, with the introduction and application of evidence-based medicine, clinical research in TCM has made substantial progress [**?**]. However, the lack of standardized outcome measures in TCM clinical trials remains a widespread issue [**?**]. This inconsistency has led to ongoing controversy regarding the efficacy of TCM and has hindered the ability to fully demonstrate its unique characteristics and advantages [**?**].

Therefore, it is essential to establish an evaluation index system for the clinical efficacy of TCM in treating COPD to address the current limitations in clinical research. This study is based on a systematic analysis of clinical research literature regarding TCM treatments for COPD, combined with patient questionnaires. We designed a Delphi expert consultation questionnaire and employed the Analytic Hierarchy Process (AHP) to calculate the weights of the indicators. By combining qualitative and quantitative methods, this study

aims to provide a standardized reference for the clinical efficacy evaluation index system of TCM for COPD.

Materials and Methods

The Chinese and English databases were searched using specific keywords. Chinese search terms included "慢性阻塞性肺疾病" (chronic obstructive pulmonary disease), "COPD", "慢阻肺" (COPD), "肺胀" (lung distension), "中医" (traditional Chinese medicine), "中药" (Chinese materia medica), "中医药" (TCM), "中成药" (Chinese patent medicine), "膏方" (herbal paste), "替代疗法" (alternative therapy), "颗粒" (granules), "随机" (randomized), and "对照" (controlled). English search terms included "chronic obstructive pulmonary disease", "COPD", "traditional Chinese medicine", "complementary alternative therapy", "decoction", "formula", "Chinese patent medicine", "granule formula", "cream formula", "clinical research", "clinical

trial", "clinical observation", "clinical evaluation", "efficacy observation", "efficacy analysis", "randomized controlled trial", and "efficacy observation". Computerized searches were conducted in China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP Database, PubMed, Embase, Web of Science, and the Cochrane Library. The search period covered the timeframe from January 1, 2020, to April 20, 2023.

1.2 文献纳入、排除标准

Inclusion criteria: (1) Study type: Randomized controlled trials (RCTs); (2) Study population: Patients diagnosed with chronic obstructive pulmonary disease (COPD); (3) Interventions: Traditional Chinese Medicine (TCM) related treatments, including oral Chinese patent medicines and decoctions; (4) Outcome measures: All outcome measures reported in the literature. Exclusion criteria: Animal experiments, literature reviews, and duplicate publications.

1.3 数据整理

Using EndNote X9.1 reference management software, a preliminary screening was conducted by reviewing the titles and abstracts of the identified articles. For cases where eligibility remained unclear, a full-text review was performed to determine final inclusion. The extracted data were then recorded in an Excel spreadsheet. Finally, descriptive analysis was employed to perform frequency statistics and calculations for the relevant indicators.

1.4 问卷调查

To enhance the generalizability of clinical efficacy indicators, address potential omissions in existing metrics, and improve clinical relevance, a patient questionnaire was designed. The objective of this survey is to construct a comprehensive

set of clinical efficacy indicators that reflect the shared priorities of both clinicians and patients.

1.5.1 选择专家条件

In accordance with the implementation standards of the Delphi method, a panel of 30 to 50 experts with professional expertise in relevant fields should be selected [**?**]. Consequently, an initial group of 37 experts was proposed. The criteria for expert selection were as follows: (1) To enhance the authority of the questionnaire, at least 80% of the experts were required to hold senior professional titles and have over 10 years of clinical experience in respiratory medicine; (2) To broaden the generalizability of the questionnaire, the distribution of experts was···

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The study covered more than 15 provinces and municipalities across the country, including the Tibet and Xinjiang regions. To enhance the scientific rigor of the questionnaire, the expert panel was composed of professionals from diverse fields, including clinical medicine, nursing, and evidence-based methodology.

1.5.2 问卷设计

Based on a comprehensive literature review and patient questionnaires, we categorized and integrated the collected data to establish an initial item pool for evaluating the clinical efficacy of Chronic Obstructive Pulmonary Disease (COPD). Utilizing this item pool, we designed a formal consultation questionnaire consisting of three primary sections. The first section collects the basic demographic information of the participating experts. The second section focuses on the scoring of the indicator system: for the stable phase, it includes 7 primary indicators and 75 secondary indicators; for the acute exacerbation phase, it includes 7 primary indicators and 95 secondary indicators. The third section assesses the experts' scoring criteria and their degree of familiarity with the subject matter to calculate the expert authority coefficient.

The importance of each indicator was evaluated using a 9-point Likert scale [**?**], where scores of "1–3" represent "not important," "4–6" represent "important but not critical," and "7–9" represent "critical." The degree of familiarity (C_s) was categorized into five levels: very familiar, familiar, moderately familiar, unfamiliar, and very unfamiliar, with assigned values of 1.0, 0.8, 0.6, 0.4, and 0.2, respectively [**?**]. The judgment basis (C_a) comprised four dimensions: clinical experience, theoretical analysis, domestic and international literature, and subjective judgment. Each dimension was further divided into three levels based on its degree of influence on the expert' s decision-making process [**?**].

1.5.3 统计分析

Excel 2023 was utilized to compile the basic information of the experts and to calculate several key metrics, including the expert response rate (active coefficient), the authority coefficient, the mean score of each indicator, and the proportions of scores falling within the 7–9 range and the 1–3 range. Additionally, the coefficient of variation (CV) for each indicator was calculated. SPSSPRO was employed to determine Kendall' s Coefficient of Concordance (Kendall' s W). A CV $\leq 25\%$ was defined as indicating good coordination among experts. The value of Kendall' s W ranges from 0 to 1, with higher values representing a greater degree of expert consensus [**?**].

The criteria for indicator selection in this study were predefined as follows: an indicator was considered to have reached consensus for inclusion if the proportion of scores in the 7–9 range was $\geq 75\%$, the proportion of scores in the 1–3 range was $\leq 15\%$, and the CV was $\leq 25\%$ [**?**, **?**].

1.6 层次分析法

After the clinical efficacy indicators were scored via Delphi consultation, a pairwise comparison of the relative importance of each indicator was conducted and assigned values based on the Saaty 1-9 scale [**?**]. The weights for each level of indicators were then calculated using Yaahp 10.3. To ensure the logical consistency of the weight distribution, the consistency ratio (CR) was tested; a standard of $CR < 0.10$ was used to indicate that the consistency test was passed and the calculated weights were logically sound [**?**].

The secondary focus involves improving the quality of life, specifically regarding aspects such as appetite, bowel and urinary function, and fatigue, as well as reducing the duration of home oxygen therapy and the frequency of hospitalizations.

2.3 专家基本情况

A total of 37 experts from 21 relevant institutions across 15 regions in China were invited to participate in this Delphi expert consultation. The panel included specialists from various fields, including Traditional Chinese Medicine (TCM), Western medicine, integrated Chinese and Western medicine, nursing, and evidence-based medicine. Detailed information regarding the expert panel is presented in .

结果

Literature Search Results

A total of 6,875 publications were initially retrieved through the literature search. After excluding duplicate records and studies that did not meet the inclusion criteria, 1,686 articles were retained for further analysis. By integrating the

findings from these studies with results from questionnaire surveys and expert group discussions, the research team established an initial item pool.

For the stable phase of the disease, 7 primary indicators and 75 secondary indicators were extracted. For the acute exacerbation phase, 7 primary indicators and 95 secondary indicators were identified.

2.2 患者问卷调查结果

Patient Questionnaire Survey: One-on-one interviews were conducted by the researchers with a total of 92 patients, consisting of 71 males and 21 females. The participants were aged 43–98 years, with a mean age of 70.8 ± 9.6 years. The duration of illness ranged from 1 to 35 years, with a mean duration of 11.29 ± 8.85 years. Most patients indicated that the primary symptom they sought to improve through Traditional Chinese Medicine (TCM) treatment was wheezing.

30 years

10–30 years

<10 years

Expert Enthusiasm and Authority Coefficients: The expert enthusiasm coefficients for all three rounds were $> 90\%$, and the expert authority coefficients for all three rounds were > 0.8. These results indicate a high level of engagement and a high degree of professional authority among the participating experts.

See Table 2 .

Expert Familiarity Coefficient (Cs)

Expert Judgment Coefficient (Ca)

Expert Authority Coefficient (Cr)

Expert Enthusiasm Coefficient (RR)

Expert Coordination Coefficient: Based on the results of the expert consultation, the coordination coefficients for the first, second, and third rounds of expert questionnaires were 0.414, 0.156, and 0.513, respectively. The corresponding χ^2 values were 1283.514, 278.075, and 454.560, all with P-values less than 0.001. This demonstrates a high degree of consistency in expert coordination across all items, indicating that the items have reached a stable consensus.

See Table 3 .

2.6 指标筛选结果

Based on the results of the first round of expert consultation, indicators with a coefficient of variation greater than 0.25 or a mean score of less than 3 points were excluded. Following expert recommendations, three specific indicators for

the acute exacerbation phase were added: 6-minute walk distance (6MWD), activities of daily living (ADL), and extubation success rate. After comprehensive team discussions, the final set of indicators selected for the second round of consultation regarding the stable phase consisted of 7 primary indicators and 55 secondary indicators. For the acute exacerbation phase, the primary indicators ...

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acute exacerbation stage

Kendall' s W coefficient

<0.001

<0.001

<0.001

Kendall' s W Coefficient

Kendall' s W coefficient, also known as Kendall' s coefficient of concordance, is a non-parametric statistical method used to measure the degree of agreement among multiple raters or judges when ranking a set of objects. It is an extension of the Spearman rank correlation coefficient, specifically designed for scenarios involving more than two sets of rankings. The value of Kendall' s W ranges from 0 to 1, where 1 indicates perfect consensus among the raters and 0 indicates no agreement (i.e., the rankings are essentially random relative to one another).

Mathematical Definition and Calculation

Suppose there are m raters ranking n objects. The rankings can be organized into a matrix where each row represents a rater and each column represents an object. Let $r_{i,j}$ be the rank assigned to object j by rater i. The total sum of ranks for each object j is calculated as:

$$R_j = \sum_{i=1}^{m} r_{i,j}$$

The mean of these rank sums is denoted by $\bar{R} = \frac{1}{n}\sum_{j=1}^{n} R_j = \frac{m(n+1)}{2}$. The sum of squared deviations, S, is then defined as:

$$S = \sum_{j=1}^{n} (R_j - \bar{R})^2$$

Kendall' s W is defined as the ratio of the actual sum of squares S to the maximum possible sum of squares that would occur if there were total agreement:

$$W = \frac{12S}{m^2(n^3 - n)}$$

Handling Tied Ranks

When tied ranks are present in the data, the denominator of the formula must be adjusted to account for the reduced variance. For each rater i, let g_i be the number of groups of tied ranks, and let $t_{i,k}$ be the number of tied ranks in the k-th group. The correction factor for rater i is:

$$T_i = \sum_{k=1}^{g_i} (t_{i,k}^3 - t_{i,k})$$

The modified formula for Kendall' s W becomes:

$$W = \frac{12S}{m^2(n^3 - n) - m\sum T_i}$$

<0.001

<0.001

<0.001

The initial set of indicators consisted of 7 primary indicators and 50 secondary indicators. In the second round of evaluation, indicators were excluded if their coefficient of variation was greater than 0.25 or if their mean score was less than or equal to 7. Based on expert recommendations, several indicators were adjusted: "TCM symptom score," "TCM syndrome score," and "TCM clinical efficacy" were merged into a single indicator titled "TCM syndrome score." For the acute exacerbation phase, two indicators– "frequency of emergency medication use" and "time to first acute exacerbation" –were added. Following these adjustments, there were 45 secondary indicators for the stable phase and 31 for the acute exacerbation phase.

Given the high number of remaining indicators and a Kendall' s W coefficient of 0.156 in the second round–which suggested low consistency in expert coordination–a third round of questionnaires was conducted. The inclusion criteria for the third round required a mean indicator score greater than 7, a coefficient of variation less than 0.25, and at least 75% of experts providing a score between 7 and 9 (indicating the indicator is both important and critical). Ultimately, the stable phase was defined by 6 primary indicators and 21 secondary indicators, as shown in . The acute exacerbation phase comprised 6 primary indicators and 28 secondary indicators, as detailed in .

2.7 指标体系权重确定

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Based on the mean importance scores of each indicator, values were assigned to the indicators according to the Saaty 1-9 scale. The weights for the primary and secondary indicators, as well as the Consistency Ratio (CR), were calculated using Yaahp 10.3. The results demonstrate that the CR is less than 0.10, indicating that the weight calculations in this study possess high reliability and consistency. These results are detailed in and Table 7.

讨论

Traditional Chinese Medicine (TCM) is receiving increasing attention and support both domestically and internationally [**?**]. Clinical efficacy serves as the cornerstone and driving force for the development of TCM [**?**]. However, significant challenges persist regarding efficacy evaluation indicators in TCM clinical research; these indicators must address common issues shared with Western clinical research while simultaneously reflecting the unique characteristics of TCM. Traditional clinical studies have predominantly consisted of case reports and experiential summaries, with evaluation criteria focusing heavily on the improvement of individual symptoms [**?**].

Extensive clinical research has confirmed that TCM treatment for Chronic Obstructive Pulmonary Disease (COPD) offers significant advantages in stabilizing the condition, improving symptoms, regulating immune function, and reducing recurrence. Despite these benefits, there is a scarcity of high-quality clinical efficacy evaluation methods, and a lack of quantitative or objective standards remains a critical gap. Consequently, clinical evidence requires further strengthening. The failure to fully demonstrate the efficacy of TCM has, to some extent, restricted the academic development of the discipline [**?**]. Furthermore, due to cultural differences between the East and the West, some current clinical evaluation items do not align well with the specific national context of China [**?**].

Developing a Core Outcome Set (COS) represents an effective approach to resolving the issues surrounding TCM evaluation indicators [**?**]. To fully demonstrate the clinical efficacy of TCM, this study employs the Delphi expert consultation method to achieve a highly concentrated selection of evaluation indicators. Subsequently, the Analytic Hierarchy Process (AHP) is applied to combine qualitative and quantitative analysis, thereby reducing the subjectivity of the evaluation indicators. This methodology aims to establish standardized and objective criteria.

pulmonary disease (stable phase)

Average score (points)

Average score (points); Proportion of scores between 7–9; Proportion of scores between 1–3

Traditional Chinese Medicine (TCM) syndrome score

Forced expiratory volume in 1 second (FEV_1)

Ratio of forced expiratory volume in 1 second to forced vital capacity (FEV_1/FVC)

Forced vital capacity (FVC)

Arterial oxygen saturation (SaO_2)

Chronic Obstructive Pulmonary Disease Assessment Test (CAT) score

Modified Medical Research Council (mMRC) dyspnea scale score

6-minute walk distance (6MWD) test

Number of acute exacerbations

Number of hospitalizations due to acute exacerbations

Duration of hospitalization for acute exacerbations

Serious adverse events (SAEs)

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exacerbation phase)

Average score (points)

Average score (points); Proportion of scores between 7–9; Proportion of scores between 1–3

Traditional Chinese Medicine (TCM) syndrome score

Sputum color, consistency, and volume

Forced expiratory volume in 1 second (FEV_1)

FEV_1/FVC ratio (Forced expiratory volume in 1 second as a percentage of forced vital capacity)

Forced vital capacity (FVC)

Partial pressure of arterial carbon dioxide ($PaCO_2$)

Partial pressure of arterial oxygen (PaO_2)

Arterial oxygen saturation (SaO_2)

White blood cell (WBC) count

Neutrophil count

C-reactive protein (CRP)

COPD Assessment Test (CAT) score

mMRC Dyspnea Scale score

6 分钟步行距离试验

Frequency of acute exacerbations

Incidence of respiratory failure

Serious adverse events

This study aims to standardize Traditional Chinese Medicine (TCM) clinical indicators, reflect the advantages of TCM, and promote its modernization. Through a systematic literature review and patient interviews, we initially constructed a pool of clinical outcome indicators for Chronic Obstructive Pulmonary Disease (COPD). This pool consisted of 8 primary indicators and 75 secondary indicators for the stable phase, and 7 primary indicators and 95 secondary indicators for the acute exacerbation phase. Based on these results, a Delphi expert questionnaire was designed. Following three rounds of Delphi expert consultation, a clinical efficacy evaluation index system was established. For the acute exacerbation phase of COPD, the system includes 6 primary and 28 secondary indicators; for the stable phase, it includes 6 primary and 21 secondary indicators. The Analytic Hierarchy Process (AHP) was employed to assign weights to indicators at all levels, combining qualitative and quantitative evaluation to enhance scientific rigor and objectivity. This study consulted 37 experts in respiratory medicine and methodology from 21 units across China. The majority of these experts hold senior professional titles, ensuring strong academic authority. They represent a broad geographical distribution covering 15 regions, including Beijing, Heilongjiang, Liaoning, Tianjin, Shanxi, Henan, Fujian, Shanghai, Anhui, Jiangxi, Guangdong, Guangxi Zhuang Autonomous Region, Sichuan, Xinjiang Uygur Autonomous Region, and Tibet Autonomous Region, which ensures a degree of universal applicability.

Across the three rounds of expert questionnaires, the response rate remained above 90%, reflecting high expert engagement. After the first two rounds of consultation, the Kendall' s W coefficients were 0.414 and 0.156, respectively. Observing that the Kendall's W coefficient in the second round was lower than in the first—likely due to the large number of experts and the difficulty in reaching a consensus—a third round of consultation was conducted. The Kendall' s W coefficient for the third round reached 0.513, with a coefficient of variation (CV) of less than 0.25. these results indicate that the expert ratings were relatively concentrated and possess strong reliability.

This study evaluates the clinical efficacy of TCM in treating COPD based on six primary indicators: TCM disease and syndrome patterns, symptoms and signs, laboratory and imaging examinations, quality of life, long-term prognosis, and safety. Among the primary indicators for both the acute exacerbation and stable phases of COPD, long-term prognosis indicators carried the highest weights (0.554 and 0.315, respectively). This reflects the long-term therapeutic

benefits of TCM and aligns with its characteristic focus on preventive healthcare —preventing disease before it occurs, preventing transformation once diseased, and intercepting disease progression. Conversely, the safety indicator (0.042) had the lowest weight among the primary indicators for the stable phase. This reflects the widespread clinical use of TCM and its safe, reliable efficacy; as a clinical outcome, the weight of the safety indicator is naturally lower when the intervention is inherently low-risk. Among the primary indicators for the acute exacerbation phase,

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evaluation system for traditional Chinese medicine treatment of chronic obstructive pulmonary disease (stable phase)

evaluation system for traditional Chinese medicine treatment of chronic obstructive pulmonary disease (acute exacerbation phase)

Traditional Chinese Medicine (TCM) Syndrome Scores

Traditional Chinese Medicine (TCM) Syndrome Scores

Forced Expiratory Volume in 1 Second (FEV1)

Sputum color, consistency, and volume

FEV1/FVC ratio (Forced Expiratory Volume in 1 Second as a percentage of Forced Vital Capacity)

Forced Expiratory Volume in 1 Second (FEV1)

Forced Vital Capacity (FVC)

Arterial Oxygen Saturation (SaO_2)

FEV1/FVC ratio (Forced Expiratory Volume in 1 Second as a percentage of Forced Vital Capacity)

COPD Assessment Test (CAT) Score

Forced Vital Capacity (FVC)

mMRC (Modified Medical Research Council) Dyspnea Scale

Partial Pressure of Carbon Dioxide in Arterial Blood ($PaCO_2$)

6-Minute Walk Distance (6MWD) Test

Partial Pressure of Oxygen in Arterial Blood (PaO_2)

Frequency of acute exacerbations

Arterial Oxygen Saturation (SaO_2)

Number of hospitalizations due to acute exacerbations

Length of hospital stay for acute exacerbations

White Blood Cell (WBC) count

Neutrophil count

Serious Adverse Events (SAEs)

C-Reactive Protein (CRP)

COPD Assessment Test (CAT) Score

mMRC (Modified Medical Research Council) Dyspnea Scale

6-Minute Walk Distance (6MWD) Test

Frequency of acute exacerbations

Incidence of respiratory failure

Serious Adverse Events (SAEs)

Indicators related to TCM patterns and diseases received the lowest weight (0.044), which is attributed to the scoring tendencies of the Western medicine experts among the consultants. Of the 34 physicians consulted for this questionnaire, 18 were experts in Western medicine or integrated Chinese and Western medicine (representing 52.9% of the total), which influenced the final weighting. Furthermore, the specific nature of the disease plays a role; during the acute exacerbation phase of COPD, relatively few patients seek treatment through TCM alone, which limits the demonstration of its clinical efficacy. Within the TCM disease indicators, the TCM syndrome score was utilized as a secondary indicator. This score is a quantitative measure composed of relevant symptoms that reflects the overall therapeutic effect on the disease pattern. As an evaluation metric, the TCM syndrome score captures the holistic advantages of TCM treatment. Subsequently, the Analytic Hierarchy Process (AHP) was employed to assign weights to indicators at each level. By combining qualitative and quantitative evaluation, the scientific rigor and objectivity of the study were enhanced. This approach not only reflects the holistic strengths and characteristics of TCM as an intervention but also maintains rigorous scientific standards, thereby increasing the practical utility of clinical research.

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Conclusion and Outlook

In this study, we established a preliminary clinical efficacy evaluation index system for the treatment of Chronic Obstructive Pulmonary Disease (COPD) with Traditional Chinese Medicine (TCM). By integrating literature review, the Delphi expert questionnaire method, and the Analytic Hierarchy Process (AHP), we employed a methodology that combines qualitative and quantitative analysis. This approach aligns with the characteristics and advantages of TCM syndrome differentiation and treatment, which emphasize prevention, holistic management, and long-term therapeutic effects.

The results indicate that the primary outcome measures related to long-term prognosis carry the highest weight. However, this study has certain limitations: (1) the experts consulted for this evaluation system were predominantly clinical practitioners, suggesting a need for a more diverse range of professional backgrounds; (2) the system has not yet subdivided specific indicators unique to TCM characteristics; and (3) the clinical efficacy evaluation index system constructed in this study requires further validation through clinical trials. In summary, this study developed a clinical efficacy evaluation index system for TCM treatment of COPD based on six primary indicators: TCM disease/syndrome patterns, symptoms and signs, physical and chemical examinations, long-term prognosis, quality of life, and safety. These findings are intended to provide a scientific and standardized reference for clinical research on TCM treatments for COPD.

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The authors declare no conflicts of interest.

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Note: Figure translations are in progress. See original paper for figures.