Postprint: Current Status of Research on Patient-Reported Outcome Measures for Acute Exacerbations of Chronic Obstructive Pulmonary Disease

Authors: Li Chunyang, Wang Jiajia, Wei Mengyu, Li Jiansheng, Wang Jiajia

Date: 2024-07-02T00:00:00+00:00

Abstract

Chronic obstructive pulmonary disease (COPD) is one of the common respiratory diseases, and its acute exacerbation, as an acute event, seriously affects the quality of life of COPD patients. This study searched PubMed, CNKI, Wanfang Data Knowledge Service Platform, VIP, and Chinese Biomedical Literature Database, and screened out 69 representative documents according to inclusion and exclusion criteria, finding that there are currently 23 assessment tools for patient-reported outcomes applied to COPD patients during acute exacerbation domestically and internationally, and except for EXACT-PRO, all directly adopt assessment tools for patient-reported outcomes in stable phase, which can be divided into generic, disease-specific, and symptom-specific assessment tools, mainly involving domains such as symptoms, physiological domain, social domain, psychological and emotional aspects, and daily activities. It is recommended that future research on quality of life in COPD patients during acute exacerbation focus on the following aspects: (1) strengthen research on specific assessment tools; (2) emphasize the combined application of classical test theory, item response theory, and generalizability theory; (3) emphasize research on the minimal clinically important difference of assessment tools; (4) rationally select assessment tools.

Full Text

Research Status of Patient-Reported Outcome Measurements for Acute Exacerbation of Chronic Obstructive Pulmonary Disease

LI Chunyang[12], WANG Jiajia[12]*, WEI Mengyu[12], LI Jiansheng[12]

[1]Collaborative Innovation Center for Chinese Medicine and Respiratory Diseases Co-constructed by Henan Province & Ministry of Education of P.R. China/Henan University of Chinese Medicine, Zhengzhou 450046, China
[2]Department of Respiratory Diseases, the First Affiliated Hospital of Henan University of Chinese Medicine, Zhengzhou 450000, China

Corresponding author: WANG Jiajia, Lecturer/Master supervisor; E-mail: wangiahn@163.com

Abstract

Chronic obstructive pulmonary disease (COPD) is a common respiratory disease, and acute exacerbation of COPD is an acute event that severely impairs patients' quality of life. This study searched PubMed, CNKI, Wanfang Data Knowledge Service Platform, VIP, and the Chinese Biomedical Literature Database. Based on inclusion and exclusion criteria, 69 representative articles were selected, revealing that 23 patient-reported outcome (PRO) assessment tools are currently used for COPD acute exacerbation. Except for EXACT-PRO, all tools were originally developed for stable COPD patients. These assessment instruments can be categorized as generic, disease-specific, or symptom-specific tools, primarily covering domains including symptoms, physiological function, social function, psychological/emotional status, and daily activities. Future research on quality of life in COPD acute exacerbation should focus on: (1) strengthening the development of specific assessment tools; (2) emphasizing the combined application of classical test theory, item response theory, and generalizability theory; (3) prioritizing research on minimal clinically important difference (MCID) values; and (4) selecting assessment tools appropriately.

Keywords: Pulmonary disease, chronic obstructive; Scale; Patient-reported outcome; Respiratory tract diseases; Assessment tools; Review

---

Chronic obstructive pulmonary disease (COPD) is a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production) and persistent (often progressive) airflow limitation due to airway and/or alveolar abnormalities [1]. Acute exacerbation of COPD is an acute event characterized by worsening of respiratory symptoms (dyspnea and/or cough, sputum) within 14 days, often accompanied by tachypnea and/or tachycardia [2]. Studies show that COPD has high prevalence, with a protracted and recurrent course; patients experience 0.5–3.5 acute exacerbations annually, which severely affect their quality of life [2-4]. Identifying appropriate assessment tools can provide a basis for evaluating disease status, quality of life, and clinical efficacy in COPD acute exacerbation. With the development of personalized medicine and evolving healthcare service concepts, patients' role in healthcare decision-making has become increasingly prominent. Patient-reported outcomes (PROs), which emphasize patients' subjective experiences and feedback, are be-

coming important guides for clinical decision-making. PRO assessment tools help comprehensively evaluate disease status, quality of life, and clinical efficacy [5-6]. Our research team previously reviewed COPD-stable-phase-specific assessment tools, including the Clinical COPD Questionnaire (CCQ), Chronic Respiratory Disease Questionnaire (CRQ), St. George's Respiratory Questionnaire (SGRQ), COPD Patient-Reported Outcome Scale (COPD-PRO), and COPD Self-Efficacy Scale, finding that these tools effectively assess quality of life in COPD patients and can inform the improvement of clinical efficacy evaluation systems [7]. This article systematically analyzes the current status of PRO assessment tools for COPD acute exacerbation to provide references for clinical outcome measurement and efficacy evaluation.

Literature search strategy: In October 2022, we searched PubMed, CNKI, Wanfang Data Knowledge Service Platform, VIP, and the Chinese Biomedical Literature Database using Chinese search terms including "慢性阻塞性肺疾病急性加重" (COPD acute exacerbation), "生存质量" (quality of life), "患者报告结局" (patient-reported outcome), and English search terms including "pulmonary disease, chronic obstructive," "COPD," "AECOPD," "quality of life," "patient reported outcome measures," and "patient reported outcome*." Inclusion criteria: studies involving development and/or application of PRO assessment tools for COPD acute exacerbation. Exclusion criteria: duplicate publications, low-quality studies, and unavailable full texts. Finally, 69 representative articles were included.

1. Disease-Specific Assessment Tools

Disease-specific assessment tools demonstrate high sensitivity to disease changes and can accurately reflect subtle variations in patients' quality of life. Currently, nine disease-specific PRO assessment tools are used for COPD acute exacerbation, six developed abroad and three in China, covering 2–8 domains with 8–76 items, mostly using Likert-type response scales. The three most frequently used tools are CAT, SGRQ, and CCQ. Basic information on these disease-specific assessment tools for COPD acute exacerbation is summarized in .

1.1 Chronic Respiratory Disease Questionnaire (CRQ)

Developed by GUYATT et al. [8] in 1987, CRQ was the earliest assessment tool for COPD, comprising four domains and 20 items in an interview format to evaluate quality of life. While simple to use, CRQ is time-consuming and heavily researcher-dependent. Therefore, WILLIAMS et al. [9] developed and validated the self-administered standardized version (CRQ-SAS), which is simple, time-efficient, and effective for assessing quality of life in chronic respiratory disease patients [10]. WU Shangjie et al. [11] translated CRQ and evaluated its reliability and validity, demonstrating statistically significant psychometric properties in Chinese COPD patients. HE Mei et al. [12] used CRQ-SAS to evaluate the impact of respiratory rehabilitation on quality of life in COPD acute exacerbation patients, showing significantly improved domain scores in the rehabilitation

group, providing preliminary evidence that respiratory rehabilitation training can effectively improve health status during hospitalization for COPD acute exacerbation.

1.2 St. George's Respiratory Questionnaire (SGRQ)

SGRQ is a self-administered questionnaire developed by JONES et al. [13-14] in 1991 to assess the impact of chronic lung disease on quality of life. It includes three domains and 76 items (50 items in the US version), with scores ranging from 0–100; higher scores indicate worse quality of life. SGRQ has been translated into multiple languages and is widely used to assess quality of life in respiratory disease patients worldwide. ZHANG Xisheng et al. [15] used SGRQ to evaluate symptoms and quality of life in 60 COPD acute exacerbation patients with phlegm-heat obstructing the lung pattern before and after traditional Chinese medicine iontophoresis treatment, reporting significantly reduced domain scores post-treatment and demonstrating SGRQ's sensitivity to clinical changes. MEGURO et al. [16] modified SGRQ for COPD patients, developing the St. George's Respiratory Questionnaire-COPD version (SGRQ-C). SGRQ-C includes three dimensions with 40 items; each item has specific scoring, with domain scores calculated as the sum of positive item scores divided by the total possible score multiplied by 100. The total score is calculated similarly across all items, ranging from 0–100, where lower scores indicate better quality of life. TAO Xuexia et al. [17] used SGRQ-C to evaluate the impact of anxiety and depression on quality of life in COPD acute exacerbation patients, finding that patients with anxiety or depression had higher SGRQ-C domain scores and total scores than those without.

1.3 Seattle Obstructive Lung Disease Questionnaire (SOLQ)

SOLQ is a COPD-specific quality of life self-assessment scale developed by TU et al. [18] in 1997, comprising four domains and 29 items using Likert 5-point or 7-point scoring, with total scores ranging from 0–400; higher scores indicate better quality of life. SOLQ has relatively few items and is suitable for community, inpatient, and outpatient settings, though some items (e.g., bowling, golf) are not culturally appropriate for China and require adaptation during translation. LI Yuelian [19] used SOLQ to evaluate quality of life in COPD acute exacerbation patients with type II respiratory failure receiving home non-invasive ventilation, showing significantly higher quality of life scores in the treatment group after one year, demonstrating that long-term home non-invasive ventilation can significantly improve quality of life.

1.4 Adult COPD Quality of Life Scale (COPD-QOL)

COPD-QOL was developed by CAI Yingyun et al. [20-21] in 2001, adapted from SGRQ for Chinese cultural contexts. It includes four domains and 35 items using a 4-point Likert scale, where higher scores indicate worse quality of life. Compared with SGRQ, COPD-QOL has fewer items and adds a mental status

domain. HUANG Yingfeng et al. [22] used COPD-QOL to evaluate the impact of Suhuang Zhike capsules on quality of life in 90 COPD acute exacerbation patients, reporting significantly reduced quality of life scores in the study group, indicating that Suhuang Zhike capsules can improve patients' quality of life.

1.5 Clinical COPD Questionnaire (CCQ)

CCQ is a self-administered questionnaire developed by MOLEN et al. [23] in 2003, comprising three domains and 10 items using a 7-point Likert scale, where higher scores indicate worse quality of life. CCQ is simple to implement with good reliability and validity, though its application in Chinese COPD acute exacerbation patients requires further research and promotion compared to CAT and SGRQ [24]. LIN Jingming et al. [25] used CCQ, SGRQ, CAT, and modified Medical Research Council (mMRC) dyspnea scale to compare the effects of different immunotherapy regimens on disease changes in 100 elderly COPD acute exacerbation patients before and after treatment, showing significant reductions in all scores post-treatment, with the study group scoring significantly lower than the control group, demonstrating the efficacy of thymopentin in treating elderly COPD acute exacerbation patients.

1.6 Quality of Life Instrument for Chronic Diseases-COPD (QLICD-COPD)

QLICD-COPD was developed by YANG Zheng et al. [26] in 2007 as a quality of life scale for chronic disease patients, consisting of a generic module for chronic diseases and a COPD-specific module. The generic module includes three domains (physical function, psychological function, social function) with 10 facets and 30 items, while the specific module includes four facets (cough, sputum, oxygen therapy, psychosocial impact) with 15 items. ZHOU Jiadong [27] applied QLICD-COPD to evaluate quality of life and its relationship with objective indicators in 124 COPD acute exacerbation patients, demonstrating good clinical feasibility and showing that QLICD-COPD can more comprehensively and sensitively reflect treatment effects than traditional clinical objective indicators.

1.7 COPD Assessment Test (CAT)

CAT was developed by JONES et al. [28] in 2009 to assess the impact of COPD on quality of life, providing a simple and rapid evaluation of health status. The scale includes eight items using a 5-point Likert scale, with total scores ranging from 0–100; higher scores indicate worse quality of life. CAT has been translated into multiple languages, and studies show that the Chinese version can reliably and validly assess quality of life in Chinese COPD patients [29]. SU Rina et al. [30] used CAT to evaluate quality of life and clinical efficacy in 120 COPD acute exacerbation patients, reporting significantly reduced CAT scores post-treatment, demonstrating CAT's effectiveness in assessing quality of life in COPD acute exacerbation.

1.8 COPD Exacerbations Patient-Reported Outcome (EXACT-PRO)

EXACT-PRO is a disease-specific assessment tool developed by LEIDY et al. [31] in 2010, comprising eight domains and 23 items that collect patient-reported data to document exacerbation frequency and assess severity and duration. It has been translated into multiple languages and serves as an effective tool for evaluating AECOPD severity. JONES et al. [32] condensed EXACT-PRO to 14 items through clinical investigation, and LEIDY et al. [33] further refined it to create the 11-item EXACT-PRO Respiratory Symptoms (E-RS) to evaluate the impact of interventions on respiratory symptom severity in COPD patients. CHOI et al. [34] evaluated the reliability, validity, and responsiveness of EXACT-PRO in COPD acute exacerbation patients, demonstrating that it can comprehensively and sensitively assess symptom relief during treatment.

1.9 COPD "Patient-Reported Outcome" Scale

The COPD "Patient-Reported Outcome" scale was developed by GUAN Pin et al. [35] in 2015 as a disease-specific assessment tool comprising five domains and 35 items. This scale integrates Chinese cultural characteristics with Traditional Chinese Medicine (TCM) syndrome elements, evaluating quality of life across TCM syndromes, physical health, psychological and mental status, personal living conditions, and satisfaction with disease treatment and medical care. HU Xuejun et al. [36] used this scale in a clinical survey of 60 COPD acute exacerbation patients to evaluate its reliability, validity, responsiveness, and clinical feasibility, demonstrating that the scale meets standards for content and construct validity and can serve as a tool for clinical efficacy evaluation in COPD acute exacerbation.

2. Symptom-Specific Assessment Tools

COPD acute exacerbation patients primarily present with symptoms such as cough, sputum production, and dyspnea. Symptom-specific assessment tools can evaluate COPD severity and patient quality of life from a single-symptom perspective. Currently, six symptom-specific PRO assessment tools are used for COPD acute exacerbation, all developed abroad, covering 1–6 domains with 1–40 items, mostly using Likert-type response scales. Basic information on these symptom-specific assessment tools for COPD acute exacerbation is summarized in .

2.1 Modified Medical Research Council Dyspnea Scale (mMRC)

The mMRC is a unidimensional self-assessment scale modified from the Medical Research Council (MRC) scale [37], classifying dyspnea severity into grades 0–4, with higher grades indicating more severe dyspnea. Compared with CAT, mMRC is simpler and more convenient, better reflecting the correlation between disease severity and quality of life in COPD patients, and is commonly

used as an evaluation index for interventions [38], with widespread application in epidemiological surveys and clinical studies of chronic respiratory diseases worldwide. LI Ningning et al. [39] used mMRC and CAT to evaluate the effects of Yifei Huatan Dingchuan Decoction on respiratory improvement and quality of life in COPD acute exacerbation patients, showing reduced mMRC and CAT scores post-treatment, indicating that the decoction can effectively control clinical symptoms and improve quality of life.

2.2 Borg Dyspnea Scale (Borg)

The Borg scale, developed by BORG [40] in 1970, is a self-assessment tool primarily measuring patients' perceived symptoms, such as dyspnea intensity or severity during exercise, with scores ranging from 0–10; higher scores indicate more severe dyspnea [41-42]. LIANG Huifang et al. [43] used the Borg scale to assess dyspnea and fatigue levels during 6-minute walk tests in 60 COPD acute exacerbation patients, showing reduced Borg scores post-treatment, with the treatment group scoring lower than the control group.

2.3 Modified Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ-M)

PFSDQ-M was revised by LAREAU et al. [44] in 1998 from the Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ) to evaluate quality of life in COPD patients. It includes three domains with 40 items, with five questions each for dyspnea and fatigue. HUANG et al. [45] translated PFSDQ-M into Chinese and validated its psychometric properties, demonstrating good reliability and content validity for stable COPD patients in China, and showing it can effectively assess treatment effects, making it one of the commonly used self-assessment questionnaires for COPD by the American Thoracic Society [46]. LI Jiansheng et al. [47] used PFSDQ-M, WHOQOL-BREF, and COPD-QOL to evaluate quality of life changes in blood stasis syndrome COPD acute exacerbation patients treated with blood-activating and stasis-resolving herbal medicine, demonstrating significant quality of life improvements.

2.4 Cough Quality of Life Questionnaire (CQLQ)

CQLQ is a symptom-specific questionnaire proposed by FRENCH et al. [48] in 2002, comprising six domains and 28 items using a 4-point Likert scale, with total scores ranging from 28–112; higher scores indicate worse subjective symptoms. MA Hongming et al. [49] translated CQLQ and evaluated its reliability and validity, reporting a Cronbach's α coefficient of 0.935 and 24-hour test-retest reliability of 0.931, demonstrating good psychometric properties for the Chinese version. SHI Ming et al. [50] used CQLQ to evaluate clinical efficacy in COPD acute exacerbation patients, showing it is simple, economical, and can effectively reflect patient responses to treatment from both symptomatic and psychological perspectives, making it a suitable simple indicator for efficacy observation in COPD acute exacerbation.

2.5 Breathlessness, Cough, and Sputum Scale (BCSS)

BCSS was developed by LEIDY et al. [51] in 2003 to evaluate COPD symptom severity and treatment effectiveness, comprising three domains using a 5-point Likert scale with scores ranging from 0–12; higher scores indicate more severe symptoms. BCSS research in Chinese populations remains rare. DEVRIES et al. [52] used BCSS to survey 168 COPD patients during stable phase and acute exacerbation, showing strong correlation between BCSS and acute exacerbation with certain sensitivity and specificity, suggesting BCSS may help predict COPD acute exacerbation.

2.6 Cough and Sputum Assessment Questionnaire (CASA-Q)

CASA-Q was developed by CRAWFORD et al. [53] in 2008, comprising four domains and 20 items using a 5-point Likert scale with scores ranging from 0–100; higher scores indicate milder airway mucus hypersecretion symptoms. Its validity has been verified in COPD patients from multiple countries. CHEN Xin et al. [54] used CASA-Q and CAT to evaluate quality of life in 106 COPD acute exacerbation patients treated with acetylcysteine solution combined with terbutaline, showing significantly increased CASA-Q total scores and reduced CAT scores post-treatment, with greater improvements in the treatment group than the control group, demonstrating that this combination can effectively relieve respiratory symptoms and improve quality of life.

3. Recommendations

Currently, 23 PRO assessment tools are used for COPD acute exacerbation, mostly developed abroad and categorized as generic (8 tools), disease-specific (9 tools), or symptom-specific (6 tools). These tools primarily cover symptoms, physiological function, social function, psychological/emotional status, and daily activities, with development and evaluation based on classical test theory. While these tools provide some basis for quality of life assessment in COPD acute exacerbation, certain limitations exist. Future research should focus on the following aspects:

3.1 Strengthen Development of Specific Assessment Tools

Except for EXACT-PRO, all current PRO assessment tools for COPD acute exacerbation were developed for stable-phase COPD and cannot reflect the characteristics of acute exacerbation. Their reliability, validity, and responsiveness for COPD acute exacerbation patients require further evaluation. COPD acute exacerbation severely affects quality of life, yet clinical practice tends to focus on objective indicators such as lung function, laboratory tests, and mortality, with insufficient attention to subjective indicators like clinical symptoms and quality of life. Since COPD acute exacerbation diagnosis relies primarily on clinical symptoms, and symptom improvement is valuable for evaluating quality of life and intervention efficacy [7,38], PROs represent important clinical

outcome measures for assessing symptoms and quality of life. Development of specific assessment tools for COPD acute exacerbation should be strengthened to provide effective instruments for scientifically evaluating quality of life and intervention efficacy.

3.2 Emphasize Combined Application of Classical Test Theory, Item Response Theory, and Generalizability Theory

Current development and evaluation of PRO assessment tools for COPD acute exacerbation primarily employ classical test theory, the most widely used measurement theory with simple mathematical models and strong practicality for item selection and scale evaluation. However, classical test theory has limitations including imprecise reliability estimation, generalized and singular error metrics, and limited generalizability of test results. Item response theory addresses these limitations through modern measurement approaches that enable more detailed and in-depth analysis of scale items, improving item quality. Generalizability theory analyzes sources and structures of measurement error in detail using analysis of variance to assist test development, providing more precise reliability estimates [62-65]. Future research on quality of life in COPD acute exacerbation should emphasize the combined application of classical test theory, item response theory, and generalizability theory to better guide item selection and scale evaluation.

3.3 Prioritize Research on Minimal Clinically Important Difference

As PRO assessment tools are increasingly used for clinical efficacy evaluation, interpretation of scale scores becomes increasingly important. Minimal clinically important difference (MCID), defined as the smallest threshold indicating clinically meaningful change in scale scores, bridges the gap between scale scores and clinical interpretation, providing clinical meaning for quality of life assessment tools [66-67]. Among existing COPD quality of life assessment tools, MCID values have been established for CAT, CRQ, SGRQ, and CCQ [67-68], providing some basis for COPD quality of life research. However, MCID stability and variability are influenced by population characteristics, language environment, study duration, and disease characteristics [67,69]. Therefore, research on MCID values for COPD acute exacerbation assessment tools should be prioritized to provide quantitative benchmarks for clinical efficacy evaluation.

3.4 Select Assessment Tools Appropriately

Numerous assessment tools are available for COPD acute exacerbation, with varying domains and items, creating challenges for researchers in selecting appropriate instruments. Existing foreign-developed tools are relatively mature and widely used; for example, CAT is brief and clear with good reliability and validity, making it one of the most effective tools for assessing quality of life in COPD acute exacerbation. SGRQ, though time-consuming and requiring

certain education levels, is classical and accurate [13-14,29]. Due to cultural differences between East and West, some scale items are not suitable for Chinese contexts. Domestically developed tools such as QLICD-COPD and COPD-QOL are more culturally appropriate for China but were developed for stable-phase COPD and require large-sample psychometric testing for acute exacerbation. Traditional Chinese Medicine emphasizes "patient-centered" and "holistic" concepts, focusing on diet, sleep, bowel movements, etc., which correlates strongly with PROs that reflect patients' direct reports of health status [70-71]. Most assessment tools cannot fully capture TCM clinical efficacy characteristics or comprehensively evaluate quality of life in COPD acute exacerbation, highlighting the need for strengthened related research. We recommend that in COPD acute exacerbation clinical trials, researchers should select appropriate assessment tools based on study needs, considering specific tool characteristics and patients' education levels and cooperation.

In summary, this article systematically reviews the psychometric characteristics and application of existing PRO assessment tools for COPD acute exacerbation. Current tools, mostly developed abroad and based on stable-phase COPD (except EXACT-PRO), cover symptoms, physiological function, social function, psychological/emotional status, and daily activities, with development based on classical test theory. Research on MCID values for acute exacerbation is lacking. Future efforts should strengthen development of COPD acute exacerbation-specific assessment tools, emphasize combined application of multiple measurement theories, prioritize MCID research, and select appropriate tools based on study requirements.

Author Contributions: WANG Jiajia conceived and designed the study, oversaw the entire manuscript, and supervised the project. LI Chunyang conducted literature searches and drafted the manuscript. LI Chunyang and WEI Mengyu performed literature screening and data extraction. WANG Jiajia and LI Jiansheng were responsible for quality control and manuscript review.

Conflict of Interest: The authors declare no conflict of interest.

ORCID:
WANG Jiajia: https://orcid.org/0000-0001-5882-8175
LI Jiansheng: https://orcid.org/0000-0002-6485-2371

References

[1] LENFANT C, KHALTAEV N. Global Initiative for chronic obstructive lung disease. Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease (2023 Report) [EB/OL]. (2022-11-15) [2022-11-20]. https://goldcopd.org/2023-gold-report-2/.

[2] Expert Group on Diagnosis and Treatment of Acute Exacerbation of Chronic Obstructive Pulmonary Disease. Chinese expert consensus on diagnosis and treatment of acute exacerbation of chronic obstructive pulmonary disease (2023

revision) [J]. International Journal of Respiration, 2023, 43(2): 132-149. DOI: 10.3760/cma.j.cn131368-20221214-01156.

[3] ZHAO Chuangyi, YUAN Kongjun, YANG Yuan, et al. Prediction of disease burden of chronic obstructive pulmonary disease in China based on ARIMA and NNAR models [J]. Chinese General Practice, 2022, 25(16): 1942-1949. DOI: 10.12114/j.issn.1007-9572.2022.0045.

[4] Chinese Thoracic Society COPD Group, Chinese Medical Association; COPD Working Committee, Chinese Association of Chest Physicians. Chinese expert consensus on identification and management of high-risk patients with acute exacerbation of chronic obstructive pulmonary disease [J]. International Journal of Respiration, 2022, 42(24): 1845-1863. DOI: 10.3760/cma.j.cn131368-20221030-00961.

[5] SHI Zhao, DOU Lei, LI Shunping. Current status and research progress of patient-reported outcomes at home and abroad [J]. Chinese General Practice, 2023, 26(4): 401-408. DOI: 10.12114/j.issn.1007-9572.2022.0805.

[6] CAO Yang, YU Xiaoping. Recent research on PRO scales at home and abroad [J]. Journal of Traditional Chinese Medicine, 2014, 55(8): 710-714. DOI: 10.13288/j.11-2166/r.2014.08.023.

[7] ZHANG Xiaoli, XIE Yang, LI Jiansheng. Current status and considerations of assessment tools for chronic obstructive pulmonary disease [J]. World Science and Technology-Modernization of Traditional Chinese Medicine, 2014, 16(7): 1664-1667. DOI: 10.11842/wst.2014.07.038.

[8] GUYATT G H, BERMAN L B, TOWNSEND M, et al. A measure of quality of life for clinical trials in chronic lung disease [J]. Thorax, 1987, 42(10): 773-778. DOI: 10.1136/thx.42.10.773.

[9] WILLIAMS J E, SINGH S J, SEWELL L, et al. Development of a self-reported Chronic Respiratory Questionnaire (CRQ-SR) [J]. Thorax, 2001, 56(12): 954-959. DOI: 10.1136/thorax.56.12.954.

[10] VALERO-MORENO S, CASTILLO-CORULLÓN S, PRADO-GASCÓN V J, et al. Chronic Respiratory Disease Questionnaire (CRQ-SAS): analysis of psychometric properties [J]. Arch Argent Pediatr, 2019, 117(3): 149-156. DOI: 10.5546/aap.2019.eng.149.

[11] WU Shangjie, ZHU Lanyan, CHEN Ping. Clinical application evaluation of the Chronic Respiratory Disease Questionnaire [J]. Journal of Hunan Medical University, 2001, 26(2): 141-142. DOI: 10.3321/j.issn:1672-7347.2001.02.016.

[12] HE Mei, YU Su'e, HONG Guangchao, et al. Impact of respiratory rehabilitation during acute exacerbation of chronic obstructive pulmonary disease on health-related quality of life changes [J]. Chinese Journal of Rehabilitation Medicine, 2018, 33(6): 636-641. DOI: 10.3969/j.issn.1001-1242.2018.06.004.

[13] JONES P W, QUIRK F H, BAVEYSTOCK C M. The St George's respiratory questionnaire [J]. Respir Med, 1991, 85(Suppl B): 25-31; discussion 33-37. DOI: 10.1016/s0954-6111(06)80105-9.

[14] JONES P W, QUIRK F H, BAVEYSTOCK C M, et al. A self-complete measure of health status for chronic airflow limitation. The St. George's Respiratory Questionnaire [J]. Am Rev Respir Dis, 1992, 145(6): 1321-1327. DOI: 10.1164/ajrccm/145.6.1321.

[15] ZHANG Xisheng, WANG Sheng. Clinical observation of traditional Chinese medicine iontophoresis in treating acute exacerbation of chronic obstructive pulmonary disease with phlegm-heat obstructing lung pattern [J]. Journal of Anhui University of Chinese Medicine, 2022, 41(2): 12-16. DOI: 10.3969/j.issn.2095-7246.2022.02.004.

[16] MEGURO M, BARLEY E A, SPENCER S, et al. Development and validation of an improved, COPD-specific version of the St. George respiratory questionnaire [J]. Chest, 2007, 132(2): 456-463. DOI: 10.1378/chest.06-0702.

[17] TAO Xuexia, SHAO Yinyan. Impact of anxiety and depression on quality of life in hospitalized patients with acute exacerbation of chronic obstructive pulmonary disease [J]. Zhejiang Journal of Preventive Medicine, 2016, 28(6): 613-615. DOI: 10.19485/j.cnki.issn1007-0931.2016.06.020.

[18] TU S P, MCDONELL M B, SPERTUS J A, et al. A new self-administered questionnaire to monitor health-related quality of life in patients with COPD. Ambulatory Care Quality Improvement Project (ACQUIP) Investigators [J]. Chest, 1997, 112(3): 614-622. DOI: 10.1378/chest.112.3.614.

[19] LI Yuelian. Clinical study of home non-invasive ventilation in treating acute exacerbation of chronic obstructive pulmonary disease with type II respiratory failure [J]. Guangxi Medical Journal, 2016, 38(2): 282-284. DOI: 10.11675/j.issn.0253-4304.2016.02.44.

[20] CAI Yingyun, LI Zhuozhe, FANG Zongjun. Quality of life assessment in chronic obstructive pulmonary disease patients [J]. Chinese Journal of General Practitioners, 2004, 3(4): 225-227. DOI: 10.3760/cma.j.issn.1671-7368.2004.04.005.

[21] WANG Minghang, LI Jiansheng, YU Xueqing, et al. Reliability and validity evaluation of the Adult COPD-QOL scale in stable chronic obstructive pulmonary disease [J]. Liaoning Journal of Traditional Chinese Medicine, 2010, 37(12): 2320-2323. DOI: 10.13192/j.ljtcm.2010.12.53.wangmh.079.

[22] HUANG Yingfeng, SUN Guangxin, ZHOU Lijuan, et al. Clinical efficacy of Suhuang Zhike capsules in patients with acute exacerbation of chronic obstructive pulmonary disease [J]. World Chinese Medicine, 2017, 12(9): 2023-2027. DOI: 10.3969/j.issn.1673-7202.2017.09.009.

[23] VAN DER MOLEN T, WILLEMSE B W, SCHOKKER S, et al. Development, validity and responsiveness of the Clinical COPD Questionnaire [J].

Health Qual Life Outcomes, 2003, 1: 13. DOI: 10.1186/1477-7525-1-13.

[24] ZHOU Zijing, ZHOU Aiyuan, ZHAO Yiyang, et al. Application of the Clinical COPD Questionnaire (CCQ) in COPD patients [J]. Chinese Journal of Physicians, 2017, 19(11): 1623-1626. DOI: 10.3760/cma.j.issn.1008-1372.2017.11.006.

[25] LIN Jingming, ZHOU Xiangqun, WANG Biyu, et al. Effects of different immunotherapy regimens on clinical efficacy and cellular immune function in elderly patients with acute exacerbation of COPD [J]. Chinese Journal of Gerontology, 2020, 40(17): 3668-3671. DOI: 10.3969/j.issn.1005-9202.2020.17.026.

[26] YANG Zheng, LI Xiaomei, WAN Chonghua, et al. Development and evaluation of a quality of life scale for chronic obstructive pulmonary disease patients [J]. Chinese General Practice, 2007, 10(13): 1080-1083. DOI: 10.3969/j.issn.1007-9572.2007.13.015.

[27] ZHOU Jiadong. Application study of the Quality of Life Instrument for Chronic Diseases-COPD (QLICD-COPD) in chronic obstructive pulmonary disease patients [D]. Kunming: Kunming Medical University, 2013.

[28] JONES P W, HARDING G, BERRY P, et al. Development and first validation of the COPD Assessment Test [J]. Eur Respir J, 2009, 34(3): 648-654. DOI: 10.1183/09031936.00102509.

[29] CHAI Jingjing, LIU Tao, CAI Baiqiang. Evaluation of clinical application significance of the Chinese version of the COPD Assessment Test [J]. Chinese Journal of Tuberculosis and Respiratory Diseases, 2011, 34(4): 256-258. DOI: 10.3760/cma.j.issn.1001-0939.2011.04.009.

[30] SU Rina, LI Shuixia, MA Xianjun, et al. Application of CAT in evaluating efficacy of acute exacerbation of COPD [J]. Journal of Baotou Medical College, 2015, 31(8): 28-29. DOI: 10.16833/j.cnki.jbmc.2015.08.016.

[31] LEIDY N K, WILCOX T K, JONES P W, et al. Development of the EXAcerbations of Chronic Obstructive Pulmonary Disease Tool (EXACT): a patient-reported outcome (PRO) measure [J]. Value Health, 2010, 13(8): 965-975. DOI: 10.1111/j.1524-4733.2010.00772.x.

[32] JONES P W, CHEN W H, WILCOX T K, et al. Characterizing and quantifying the symptomatic features of COPD exacerbations [J]. Chest, 2011, 139(6): 1388-1394. DOI: 10.1378/chest.10-1240.

[33] LEIDY N K, MURRAY L T, MONZ B U, et al. Measuring respiratory symptoms of COPD: performance of the EXACT-Respiratory Symptoms Tool (E-RS) in three clinical trials [J]. Respir Res, 2014, 15(1): 124. DOI: 10.1186/s12931-014-0124-z.

[34] CHOI H S, PARK Y B, SHIN K C, et al. Exacerbations of Chronic Obstructive Pulmonary Disease Tool to assess the efficacy of acute treatment [J]. Int J Chron Obstruct Pulmon Dis, 2019, 14: 471-478. DOI: 10.2147/COPD.S189300.

[35] GUAN Pin. Development of a Traditional Chinese Medicine evaluation scale for "patient-reported outcomes" in chronic obstructive pulmonary disease [D]. Changsha: Hunan University of Chinese Medicine, 2015.

[36] HU Xuejun, YANG Chuan, BAI Zhengping, et al. Efficacy evaluation of the "patient-reported outcome" Traditional Chinese Medicine evaluation system for AECOPD patients [J]. World Clinical Medicine, 2016, 10(1): 107-108.

[37] FLETCHER C M, ELMES P C, FAIRBAIRN A S, et al. The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population [J]. Br Med J, 1959, 2(5147): 257-266. DOI: 10.1136/bmj.2.5147.257.

[38] YUAN Qian. Application progress of assessment tools for stable chronic obstructive pulmonary disease [J]. Heilongjiang Medicine, 2022, 46(9): 1144-1146. DOI: 10.3969/j.issn.1004-5775.2022.09.040.

[39] LI Ningning, NIAN Liquan, SUN Yafei, et al. Effects of Yifei Huatan Dingchuan Decoction on blood gas indices, pulmonary function, and coagulation function in acute exacerbation of chronic obstructive pulmonary disease [J]. World Journal of Integrated Traditional and Western Medicine, 2021, 16(9): 1737-1741, 1745. DOI: 10.13935/j.cnki.sjzx.210937.

[40] BORG G. Perceived exertion as an indicator of somatic stress [J]. Scand J Rehabil Med, 1970, 2(2): 92-98.

[41] BORG G A. Psychophysical bases of perceived exertion [J]. Med Sci Sports Exerc, 1982, 14(5): 377-381.

[42] WANG Ruiying, XU Jianying, LIU Xiansheng. Clinical application of self-management assessment tools in chronic obstructive pulmonary disease patients [J]. Journal of Clinical Pulmonary Medicine, 2023, 28(3): 407-411. DOI: 10.3969/j.issn.1009-6663.2023.03.017.

[43] LIANG Huifang, LI Ming, HU Wenlong, et al. Effects of Xiaoqinglong Decoction combined with aerobic exercise on pulmonary function and arterial blood gas indices in acute exacerbation of chronic obstructive pulmonary disease [J]. Hebei Journal of Traditional Chinese Medicine, 2020, 42(3): 355-359. DOI: 10.3969/j.issn.1002-2619.2020.03.008.

[44] LAREAU S C, MEEK P M, ROOS P J. Development and testing of the modified version of the pulmonary functional status and dyspnea questionnaire (PFSDQ-M) [J]. Heart Lung, 1998, 27(3): 159-168. DOI: 10.1016/s0147-9563(98)90003-6.

[45] HUANG T Y, Moser D K, Hsieh Y S, et al. Validation of Chinese version of the Modified Pulmonary Functional Status and Dyspnea Questionnaire with heart failure patients in Taiwan [J]. Am J Crit Care, 2008, 17(5): 436-442.

[46] WANG Minghang, LI Jiansheng, YU Xueqing, et al. Reliability, validity, and responsiveness evaluation of the Pulmonary Functional Status and Dyspnea Questionnaire in stable chronic obstructive pulmonary disease [J]. Chinese

Journal of Traditional Chinese Medicine, 2011, 26(10): 2384-2387.

[47] LI Jiansheng, LI Bin, YU Xueqing, et al. Clinical efficacy evaluation of blood-activating and stasis-resolving herbal medicine in treating blood stasis syndrome of acute exacerbation of chronic obstructive pulmonary disease [J]. Chinese Journal of Integrated Traditional and Western Medicine in Intensive and Critical Care, 2011, 18(1): 9-13. DOI: 10.3969/j.issn.1008-9691.2011.01.003.

[48] FRENCH C T, IRWIN R S, FLETCHER K E, et al. Evaluation of a cough-specific quality-of-life questionnaire [J]. Chest, 2002, 121(4): 1123-1131. DOI: 10.1378/chest.121.4.1123.

[49] MA Hongming, CHEN Qiudong, LIU Xiaoyan, et al. Reliability, validity, and responsiveness evaluation of the Chinese version of the Cough Quality of Life Questionnaire [J]. Chinese Journal of Practical Internal Medicine, 2013, 33(6): 473-475.

[50] SHI Ming, LI Wei, CHENG Li, et al. Study on using Cough Quality of Life Questionnaire to evaluate efficacy in patients with acute exacerbation of chronic obstructive pulmonary disease [J]. Journal of Clinical Internal Medicine, 2012, 29(5): 344-345. DOI: 10.3969/j.issn.1001-9057.2012.05.019.

[51] LEIDY N K, RENNARD S I, SCHMIER J, et al. The breathlessness, cough, and sputum scale: the development of empirically based guidelines for interpretation [J]. Chest, 2003, 124(6): 2182-2191. DOI: 10.1378/chest.124.6.2182.

[52] DEVRIES R, KRIEBEL D, SAMA. Validation of the breathlessness, cough and sputum scale to predict COPD exacerbation [J]. NPJ Prim Care Respir Med, 2016, 26: 16083. DOI: 10.1038/npjpcrm.2016.83.

[53] CRAWFORD B, MONZ B, HOHLFELD J, et al. Development and validation of a cough and sputum assessment questionnaire [J]. Respir Med, 2008, 102(11): 1545-1555. DOI: 10.1016/j.rmed.2008.06.009.

[54] CHEN Xin, SUN Rongyuan, ZHANG Bowei, et al. Clinical study of acetylcysteine solution combined with terbutaline in treating acute exacerbation of chronic obstructive pulmonary disease [J]. Modern Medicine & Clinical, 2021, 36(12): 2611-2616. DOI: 10.7501/j.issn.1674-5515.2021.12.029.

[55] LUO Jian, SUN Yan. Revision of the Quality of Life Index for cancer patients [J]. Chinese Mental Health Journal, 1999, (1): 5-8.

[56] GAO F, NG G Y, CHEUNG Y B, et al. The Singaporean English and Chinese versions of the EQ-5D achieved measurement equivalence in cancer patients [J]. J Clin Epidemiol, 2009, 62(2): 206-213. DOI: 10.1016/j.jclinepi.2008.03.007.

[57] LI Lu, WANG Hongmei, SHEN Yi. Development and performance testing of the Chinese version of the SF-36 Health Survey [J]. Chinese Journal of Preventive Medicine, 2002, (2): 38-42. DOI: 10.3760/j:issn:0253-9624.2002.02.011.

[58] FANG Jiqian, HAO Yuantao, LI Caixia. Reliability and validity of the Chinese version of the WHO Quality of Life Scale [J]. Chinese Mental Health Journal, 1999, (4): 203-205.

[59] WU Sheng, RAO Ping, WU Qingsong. Clinical observation of two glucocorticoid regimens in treating elderly AECOPD patients [J]. China Pharmacy, 2017, 28(14): 1972-1975. DOI: 10.6039/j.issn.1001-0408.2017.14.28.

[60] GAO Qinghuan, YI Xiubiao, ZHANG Na. Efficacy observation of Compound Danshen Dripping Pills combined with doxofylline in treating acute exacerbation of chronic obstructive pulmonary disease [J]. Chinese Journal of Hospital Pharmacy Evaluation and Analysis, 2019, 19(6): 713-716, 720. DOI: 10.14009/j.issn.1672-2124.2019.06.023.

[61] HOU Shuo. Study on the effect of non-invasive ventilation on treatment compliance and quality of life in patients with acute exacerbation of chronic obstructive pulmonary disease [J]. China Practical Medicine, 2022, 17(7): 38-40. DOI: 10.14163/j.cnki.11-5547/r.2022.07.012.

[62] FANG Jiqian, LU Ying. Modern Medical Statistics [M]. 2nd ed. Beijing: People's Medical Publishing House, 2015: 144-174.

[63] XIE Yang, WANG Jiajia. Application of item response theory in quality of life research for respiratory diseases [J]. Chinese Journal of Gerontology, 2017, 37(4): 1038-1039. DOI: 10.3969/j.issn.1005-9202.2017.04.113.

[64] DAI Haiqi, ZHANG Feng. Psychological and Educational Measurement [M]. 4th ed. Guangzhou: Jinan University Press, 2018: 307-332.

[65] VISPOEL W P, MORRIS C A, KILINC M. Applications of generalizability theory and their relations to classical test theory and structural equation modeling [J]. Psychol Methods, 2018, 23(1): 1-26. DOI: 10.1037/met0000107.

[66] XUE Honghong, YANG Zheng, WAN Chonghua, et al. Methods for establishing minimal clinically important difference (MCID) based on scale scores [J]. Chinese Journal of Health Statistics, 2019, 36(3): 508-512.

[67] SUN Hui, XIE Yang, LI Jiansheng. Application of minimal clinically important difference in COPD quality of life assessment tools [J]. Chinese General Practice, 2015, 18(23): 2826-2829. DOI: 10.3969/j.issn.1007-9572.2015.23.019.

[68] CAZZOLA M, HANANIA N A, MACNEE W, et al. A review of the most common patient-reported outcomes in COPD—revisiting current knowledge and estimating future challenges [J]. Int J Chron Obstruct Pulmon Dis, 2015, 10: 725-738. DOI: 10.2147/COPD.S77368.

[69] YAO Simeng, HU Qiyan, LIU Fengbin, et al. Analysis and considerations on minimal clinically important difference in medical scales [J]. China Journal of Traditional Chinese Medicine and Pharmacy, 2022, 37(10): 5939-5943.

[70] ZHANG Jun, SHEN Yi, PAN Liqun. Philosophical considerations on applying PRO to clinical efficacy evaluation of Traditional Chinese Medicine [J].

Chinese Archives of Traditional Chinese Medicine, 2010, 28(8): 1736-1737. DOI: 10.13193/j.archtcm.2010.08.170.zhangj.009.

[71] ZENG Lingfeng, YANG Weiyi, LIANG Guihong, et al. Discussion on translation, construction, and optimization model of patient-reported outcome scales in TCM clinical practice [J]. World Science and Technology-Modernization of Traditional Chinese Medicine, 2021, 23(6): 2092-2099. DOI: 10.11842/wst.20200623002.

Funding: National Natural Science Foundation of China (81830116, 82004500); "Hundred, Thousand, and Ten Thousand" Talent Project for Inheritance and Innovation of Traditional Chinese Medicine—Chief Scientist of Qihuang Project (National TCM Education Letter [2020] No. 219); Henan Provincial Traditional Chinese Medicine Science Research Special Project (2023ZY2039); Henan Provincial Characteristic Backbone Discipline Construction Project for Traditional Chinese Medicine (STG-ZYXKY-2020006).

Citation: LI C Y, WANG J J, WEI M Y, et al. Research status of patient-reported outcome measurements for acute exacerbation of chronic obstructive pulmonary disease [J]. Chinese General Practice, 2024. [Epub ahead of print]. DOI: 10.12114/j.issn.1007-9572.2023.0617.

(Received: June 7, 2023; Revised: June 12, 2024)

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