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Screening of COPD patients using the COPD diagnostic questionnaire and a portable spirometer in primary healthcare institutions: a cross-sectional, diagnostic study

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Abstract

Background Portable spirometers and chronic obstructive pulmonary disease (COPD) diagnostic questionnaires are commonly used for screening patients with COPD in primary healthcare institutions, but their accuracy is often inadequate. This study aimed to explore the accuracy of combining these two tools in screening for COPD.

Methods Participants aged ≥ 40 years were recruited from primary healthcare institutions between July 2022 and July 2023. All participants completed COPD diagnostic questionnaires (CDQs) and pulmonary function tests including pre and post bronchodilator maneuvers using a portable spirometer at primary healthcare institutions and a conventional spirometer at a tertiary hospital. COPD was diagnosed based on the forced expiratory volume/forced vital capacity (FEV_1/FVC) ratio measured by the conventional spirometer after administration of 400 μg of salbutamol sulfate. An FEV_1/FVC ratio of < 70% indicated COPD, while an FEV1/FVC ratio of ≥ 70% was classified as non-COPD. The sensitivity and specificity of combining the portable spirometer and CDQ for COPD screening were statistically analyzed. Receiver operating characteristic (ROC) curves were employed to compare the efficacy of the portable spirometer, CDQ, and their combination in diagnosing COPD.

Results Of the 2,120 participants, 264 were newly diagnosed with COPD. Among the non-COPD population, 264 participants were matched by age, sex, and BMI to form the non-COPD group. The sensitivity and specificity of the combination of the portable spirometer and CDQ in diagnosing COPD were 96.6% (95% confidence interval [CI]: 0.934–0.983) and 79.9% (95% CI: 0.745–0.845), respectively, significantly higher than those with the use of either method alone ($p < 0.05$). The area under the ROC curve for the combined diagnosis of COPD was 0.994 (95% CI: 0.983–0.999), with a Jordan index of 0.765.

Conclusions Our findings suggest that combining the portable spirometer with the CDQ enhances COPD detection and is a valuable approach for implementation in primary healthcare institutions.

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Trial Registration This study has been registered in national medical research registration and filing information system of China, www.medicalresearch.org.cn, Trail registration number: MR-11-23-020214.

Keywords Portable spirometer, Chronic obstructive pulmonary disease, Diagnostic questionnaire, Primary healthcare institutions

Background

Chronic obstructive pulmonary disease (COPD) is a prevalent condition characterized by high incidence, disability, and mortality, imposing a significant economic burden on the global economy [1]. Between 2009 and 2019, the mortality rate of COPD increased by 11.4% due to intensified urbanization, air pollution, and smoking [2]. A health-augmented macroeconomic modeling study projected that between 2020 and 2050, the global economic burden caused by COPD would reach $4.326 trillion, equivalent to 0.111% of the global economy [3]. Additionally, COPD has a long disease cycle with recurrent acute exacerbation and multiple comorbidities, severely affecting the prognosis and quality of life of middle-aged and elderly patients. A recent national survey conducted in China revealed that the incidence of COPD was 13.7% among individuals over 40 years old and 2.1% among those aged 20–39 years, with only 12% of patients having undergone pulmonary function tests (PFTs) [4]. The late diagnosis of COPD is partly due to the lack of COPD awareness among residents and general practitioners, along with the shortage of spirometers in primary care settings.

Conventional spirometry is the gold standard for diagnosing COPD, providing information on disease severity, progression, and prognosis. However, conducting conventional spirometry in primary healthcare settings is challenging due to the prohibitive costs of instruments and the lack of professional technicians. Therefore, finding suitable tools for screening COPD patients in primary healthcare institutions is urgent.

In recent years, portable spirometers have rapidly emerged, demonstrating good performance compared to conventional spirometers. They are attractive for use in primary settings due to their ease of operation, affordability, utility outside the hospital, and ability to monitor the progression of chronic airway diseases [5]. The accuracy of portable spirometers has garnered widespread attention. A meta-analysis indicated that both the sensitivity and specificity of portable spirometers in screening for COPD are 85% [6]. Another review [7] conducted in 2015 revealed that portable spirometers had a sensitivity of 79.9% (74.2–84.7%) and a specificity of 84.4% (68.9–93.0%). However, nearly 20% of COPD patients still cannot be accurately detected by portable spirometers.

COPD screening questionnaires are also commonly used in primary healthcare institutions to screen for COPD patients. Commonly used Questionnaires for COPD include the COPD Diagnostic Questionnaire (CDQ), the Revised COPD Diagnostic Questionnaire (Revised-CDQ), the COPD Population Screener (COPD-PS), and the COPD Screening Questionnaire (COPD-SQ). The CDQ is recognized globally as an effective tool for screening COPD patients [8, 9]. Previous studies have identified a cut-off score of 16.5 for the CDQ, with an area under the receiver operating characteristic (ROC) curve (AUC) of 0.731 (0.695–0.762) [10, 11]. Zhou and his colleagues compared the accuracy of six different COPD screening questionnaires, demonstrating that all possess good screening efficacy [12]. This study aimed to screen COPD patients using the combination of the CDQ and portable spirometers, thereby improving the ability to screen for COPD in primary settings.

Methods

Design

This was a cross-sectional, diagnostic study evaluating the combined use of the CDQ and a portable spirometer for screening COPD among patients in primary healthcare institutions. COPD was diagnosed in patients with a forced expiratory volume/forced vital capacity (FEV1/FVC) ratio of < 70% after bronchodilator use or a CDQ score of 16.5 or higher. The gold standard for COPD diagnosis was an FEV1/FVC ratio of < 70%, measured using a conventional spirometer after bronchodilator administration, in accordance with GOLD diagnostic criteria for COPD [13].

Participants

We recruited 2,120 participants aged > 40 years from July 2022 to October 2023 using the CDQ and a portable spirometer (Spirolab III, MIR, Italy) for COPD screening in five community healthcare institutions in Fangshan District, Beijing. All participants underwent PFTs at a tertiary hospital using a conventional spirometer (MasterScreen PFT, Jaeger, Germany). The PFTs were conducted with participants seated and wearing a nose clip. All operators were trained and adhered to the pulmonary function test protocol established by American Thoracic Society/European Respiratory Society (ATS/ERS) standards to ensure result reliability and repeatability [14]. Key points of the PFT protocol included: (1) initiating without hesitation or ensuring the volume of the back-extrapolated FVC was < 5% or 0.150 L, (2) no coughing in the first second, (3) no early termination of expiration, (4) the curve showing no change in volume within one

second or an expiration time > 6 s. FEV1, FEV1%, FVC, FVC%, and FEV1/FVC% measured by both spirometers were recorded during the tests.

Participants were excluded if they had any of the following: previously diagnosed obstructive airway diseases, such as asthma and bronchiectasis; other concurrent pulmonary diseases, such as pulmonary interstitial fibrosis, untreated pulmonary tuberculosis, advanced lung cancer, or severe bullous lung disease; thoracic surgery within the past six months; serious cardiac diseases, such as unstable angina, acute myocardial infarction, heart failure, or severe arrhythmias; severe liver or kidney dysfunction; or an inability to cooperate with pulmonary function tests.

This study was approved by the Ethics Committee of Liangxiang Teaching Hospital Affiliated with Capital Medical University, Beijing (ethical approval number: 2016164). All participants signed an informed consent form. The sex, age, respiratory symptoms, smoking history, and comorbidities of participants were recorded.

Methods

We defined suspected COPD patients as those with a CDQ score ≥ 16.5 points or FEV1/FVC ratio of < 70% measured using a portable spirometer after inhaling a bronchodilator. The diagnostic criterion for COPD was an FEV1/FVC ratio of < 70% measured using a conventional spirometer after bronchodilator administration. According to the results from the conventional spirometer, participants were divided into the COPD group ($n = 264$) and non-COPD group ($n = 264$). Sex, age, BMI, smoking history, symptoms, FEV_1, and FVC were compared between the two groups. The sensitivity and specificity of combining the CDQ and portable spirometer in screening patients with COPD were statistically analyzed. The effectiveness of the CDQ, portable spirometer, and their combination in diagnosing COPD was also compared.

Statistical analysis

Quantitative variables are presented as mean and standard deviation for normal distributions or median and quartiles [M(P25, P75)] for non-normal distributions. Qualitative variables are expressed as absolute values and percentages. The independent sample t-test and Mann–Whitney U test were used to compare differences between the two groups. Sensitivity, specificity, positive, and negative predictive values were calculated using a 2 × 2 table. ROC curves for diagnosing COPD using the portable spirometer, CDQ, and their combination were plotted, comparing their accuracy through the AUC.

Results

A total of 264 COPD patients were diagnosed using the conventional spirometer and 264 age, sex, and BMI-matched non-COPD participants were enrolled in this study. The baseline demographic characteristics are presented in Table 1. No significant differences in age and sex were observed between the two groups. Compared to the non-COPD group, the COPD group had a lower BMI ($p < 0.05$), a higher proportion of smokers ($p < 0.05$), and more frequent symptoms such as dyspnea and coughing ($p < 0.05$). PFTs revealed lower FEV_1 and FVC values in the COPD group ($p < 0.05$), as well as higher CDQ scores.

Table 1 Demographic characteristics of the subjects

	COPD Group ($n_1 = 264$)	**Non-COPD Group ($n_2 = 264$)**	***P* value**
Age (year)	66.0 (59.0, 71.8)	67.0 (61.0, 73.0)	0.167
Sex (% female)	196 (74.2)	183 (69.3)	0.209
BMI (kg/m^2)	24.6±3.6	25.5±3.1	0.003
Smoking status			
Current (*n*, %)	98 (37.1)	48 (18.2)	0.000
Ex-smokers (*n*, %)	74 (28.0)	40 (15.2)	0.000
Never (*n*, %)	92 (34.8)	176 (66.7)	0.000
Symptoms			
Dyspnea (*n*, %)	142 (53.8)	98 (37.1)	0.000
Cough	202 (76.5)	187 (70.8)	0.005
Fatigue (*n*, %)	31 (11.7)	25 (9.5)	0.396
Post-bronchodilator FEV1(ml)	1.65 (1.29, 2.13)	2.51 (2.08, 2.77)	0.000
Post-bronchodilator FVC (ml)	2.38 (2.00, 2.68)	3.33 (2.96, 3.82)	0.000
Post-bronchodilator FEV1/FVC (%)	67.90 (58.80, 79.40)	77.75 (66.30, 86.65)	0.000
CDQ	22.00 (18.00, 26.00)	17.00 (15.00, 21.00)	0.000

Notes: Abbreviations: COPD, chronic obstructive pulmonary disease; BMI, body mass index; FEV1, forced expiratory volume; FVC, forced vital capacity; CDQ, COPD diagnostic questionnaire.

Table 2 Sensitivity and specificity analysis for CDQ in diagnosing COPD

		Conventional Spirometer		
		True	**False**	**Total**
CDQ ≥ 16.5 points	True	215 (40.7%)	53 (10.0%)	268 (50.8%)
	False	49 (9.3%)	211 (40.0%)	260 (49.2%)
	Total	264 (50.0%)	264 (50.0%)	528 (100.0%)

Notes: Abbreviations: COPD, chronic obstructive pulmonary disease; CDQ, COPD diagnostic questionnaire

Table 3 Sensitivity and specificity analysis for portable spirometer in diagnosing COPD

		Conventional Spirometer		
		True	**False**	**Total**
Portable Spirometer	True	221 (41.9%)	0 (0.0%)	221 (41.9%)
	False	43 (8.1%)	264 (50.0%)	307 (58.1%)
	Total	264 (50.0%)	264 (50.0%)	528 (100.0%)

Notes: Abbreviations: COPD, chronic obstructive pulmonary disease

Table 4 Sensitivity and specificity analysis for combination of CDQ and portable spirometer in diagnosing COPD

		Conventional Spirometer		
		True	**False**	**Total**
Combination	True	255 (48.3%)	53 (10.0%)	308 (58.3%)
	False	9 (0.2%)	211 (40.0%)	220 (41.7%)
	Total	264 (50.0%)	264 (50.0%)	528 (100.0%)

Notes: Abbreviations: CDQ, COPD diagnostic questionnaire; COPD, chronic obstructive pulmonary disease

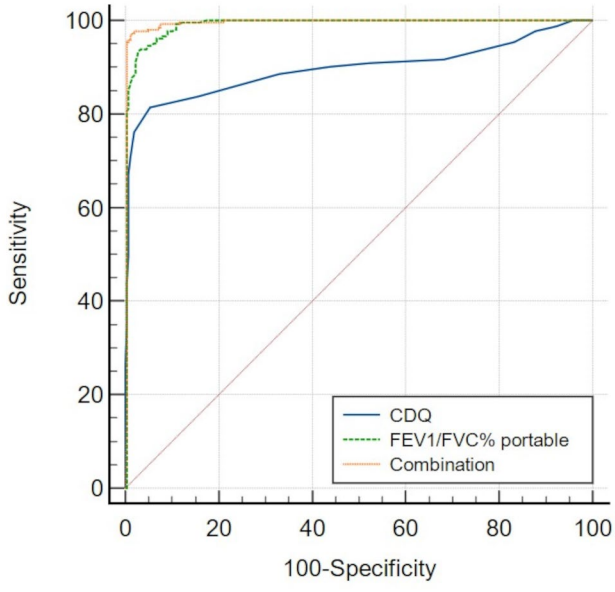

Fig. 1 ROC curves for the CDQ, portable spirometer, and their combination in diagnosing COPD. Abbreviations: CDQ, COPD diagnostic questionnaire; COPD, chronic obstructive pulmonary disease; ROC, receiver operating characteristic curve; FEV1, forced expiratory volume; FVC, forced vital capacity

Using a CDQ score of ≥ 16.5 points as the diagnostic criterion for COPD, 215 cases were detected, with 49 false negatives and 53 false positives, yielding a sensitivity of 81.4% (95% CI: 0.761–0.858) and a specificity of 79.9% (95% CI: 0.745–0.845) (Table 2). Using a post-bronchodilator FEV1/FVC ratio of < 70% measured by the portable spirometer as the diagnostic criterion for COPD, 221 COPD patients were identified, with 43 false negatives and 0 false positives, achieving a sensitivity of 83.7% (95% CI: 0.786–0.878) and a specificity of 100% (95% CI: 0.982-1.000) (Table 3). When combining the two screening tools, 255 COPD patients were identified, with 9 false negatives and 53 false positives, achieving a sensitivity of 96.5% (95% CI: 0.934–0.983) and a specificity of 79.9% (95% CI: 0.745–0.845) (Table 4).

The ROC curves for the CDQ, portable spirometer, and their combination in diagnosing COPD showed areas under the curve (AUC) of 0.989 (95% CI: 0.977–0.996), 0.897 (95% CI: 0.868–0.922), and 0.994 (95% CI: 0.983–0.999), respectively, with p-values < 0.05 between each other (Fig. 1).

Discussion

Primary healthcare institutions are the frontline of screening COPD patients. The mortality and disability rates of COPD could potentially decline if general practitioners raised awareness of COPD screening and provided early-stage treatment. Despite the high prevalence, over half of the patients are classified as GOLD I, exhibiting either no obvious symptoms or only mild respiratory symptoms [15], which often leads to neglect of COPD by both patients and general practitioners. A previous study [16] revealed that the misdiagnosis and missed diagnosis rates for COPD reached 22.92% and 22.09% in primary healthcare institutions due to the lack of spirometry equipment, professional technicians, and inadequate awareness of COPD screening among general practitioners.

In recent years, the development of portable spirometers has facilitated PFTs to be conducted in community settings, enabling general practitioners to screen, diagnose, and monitor pulmonary function changes in COPD patients. However, the accuracy of portable spirometers has been a concern. Zhou reviewed 31 studies on COPD screening and found the sensitivity and specificity of portable spirometers in screening COPD were both as high as 85% [6]. In the present study, the MIR spirometer, which is a commonly used portable spirometer, demonstrated a sensitivity of 83.7% and a specificity of 100% in screening COPD patients. Despite this, about 15% of COPD patients remained undiagnosed and thus did not receive early intervention at the first opportunity. Previous studies have shown that lung function decline in COPD patients can be rapid, even at the GOLD I level

[13], and that pathological changes in the lungs, primarily damage to and reduction in the number of small airways, are already present in the early stages of COPD [17, 18]. Therefore, early identification and intervention are crucial. This study aimed to improve the screening capabilities for COPD in primary healthcare institutions through the combination of portable spirometers and the CDQ.

COPD screening questionnaires, based on factors such as smoking history and symptoms commonly associated with COPD, are simple yet practical screening tools in primary healthcare institutions. These tools can help general practitioners identify high-risk COPD populations and provide early intervention. Commonly used questionnaires include the Lung Function Questionnaire (LFQ), COPD Population Screener (COPD-PS), COPD Screening Questionnaire (COPD-SQ), COPD Diagnostic Questionnaire (CDQ), revised CDQ, and CAPTURE, each with recommended cut-off values. An Italian study validated the accuracy of five common COPD questionnaires and suggested higher screening efficiencies for CDQ and CAPTURE, with revised cut-off values of 22 and 10 points, respectively [19, 20]. Another study in Japan also showed high sensitivity and specificity for both COPD-PS and CDQ, with the CDQ cut-off value of 16.5 points, yielding a sensitivity of 86.0% and an AUC of 0.66 [20]. Our study adopted a CDQ cut-off of 16.5 points, achieving a sensitivity of 81.4% and an AUC of 0.89, indicating high screening effectiveness.

Although both portable spirometers and COPD screening questionnaires demonstrate high screening effectiveness in primary care settings, some COPD patients remain undiagnosed promptly. Consequently, researchers have begun to compare various screening tools, and some have combined different tools to improve COPD screening abilities. Yang and colleagues used COPD-SQ, CAPTURE, and peak expiratory flow (PEF) to screen COPD patients in the community, finding that CAPTURE combined with PEF achieved the highest sensitivity of 62.2% [21]. Studies have also shown that the combination of the Chinese symptom-based questionnaire (C-SBQ) and COPD-6 in primary healthcare institutions had sensitivities and specificities of 81.4% and 68.0%, respectively [22]. Our study showed that combining the MIR portable spirometer with CDQ achieved better screening results, with a sensitivity of 96.6%, a specificity of 79.9%, and an AUC of 0.994, significantly improving screening ability and provide us a new way to screen COPD patients in primary care settings. Using two or more screening tools has enhanced the ability to screen for COPD patients in primary healthcare institutions, aiding general practitioners in the early detection and treatment of COPD patients.

This study had some limitations, including the homogeneous patient group from a single region, which does not reflect variations across different regions or ethnicities. Furthermore, the study only investigated one type of portable spirometer and one COPD questionnaire. It is well known that different screening tools vary in accuracy; therefore, future research should compare different types of screening tools. Additionally, during the COVID-19 pandemic, many participants experienced varying degrees of respiratory symptoms, with a smaller proportion of asymptomatic participants, possibly introducing selection bias into the cohort. Considering these limitations, future studies will include more diverse populations from different regions and ethnicities, compare multiple screening tools, and incorporate more asymptomatic participants to identify the most suitable COPD screening tools for primary healthcare settings in China.

Conclusion

In primary healthcare institutions, both portable spirometers and CDQs can serve as effective tools for the early screening of COPD populations. Combining these two tools may enhance the detection rate of COPD patients, facilitating early treatment and slowing the decline in lung function among COPD patients.

Abbreviations

COPD	Chronic Obstructive Pulmonary Disease
CDQs	COPD Diagnostic Questionnaires
FEV1/FVC	Forced Expiratory Volume/Forced Vital Capacity
PFTs	Pulmonary Function Tests
Revised-CDQ	the Revised COPD Diagnostic Questionnaire
COPD-PS	the COPD Population Screener
COPD-SQ	the COPD Screening Questionnaire
ROC	Receiver Operating Characteristic
AUC	Area Under the Curve
ATS/ERS	American Thoracic Society/European Respiratory Society
LFQ	Lung Function Questionnaire
PEF	Peak Expiratory Flow
C-SBQ	Chinese Symptom-Based Questionnaire

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Author contributions

FC and QN designed the study. QL, FX, XH, and CL participated in data organization. FC and QL participated in the data analysis. FC and QL drafted the manuscript. All authors have contributed to the last version of the manuscript. All authors read and approved the final manuscript.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study adhered to the Declaration of Helsinki, and was approved by the Ethics Commission of Liangxiang Teaching Hospital, Affiliated with Capital Medical University, Beijing, No. 2016164. Participants were fully informed about the purpose of study, and all provided written informed consent before the examination. All methods were conducted in accordance with relevant guidelines and regulations.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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