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Respiratory Investigation

journal homepage: www.elsevier.com/locate/resinv

Original article

The efficacy of mass screening for chronic obstructive pulmonary disease using screening questionnaires in a medical health check-up population

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ARTICLE INFO

Article history:
Received 27 June 2022
Received in revised form
25 July 2022
Accepted 30 July 2022
Available online 31 August 2022

Keywords:
Chronic obstructive pulmonary disease
Mass screening
Screening questionnaire
Medical health check-up population

ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease, highlighting the need for efficient screening strategies to identify patients with COPD. However, there is little evidence regarding the efficacy of mass screening for COPD, and no epidemiological studies on COPD have been conducted in the Shikoku region of Japan.

Methods: In this cross-sectional study, we originally investigated the efficacy of mass screening for COPD among community residents in the aforementioned region using two COPD screening questionnaires.

Results: From July 2018 through January 2019, 688 participants were enrolled. COPD was diagnosed using the Global Initiative for the Chronic Obstructive Lung Disease criteria. Twenty-one patients were newly diagnosed with COPD and 19 (90.5%) had early stages COPD. The prevalence of COPD in this study was 3.1%. The COPD Population Screener (COPD-PS) questionnaire and the International Primary Care Airways Guidelines (IPAG) questionnaire had extremely high negative predictive values in discriminating participants with COPD from those without. The scores of both questionnaires were correlated with spirometric tests and with each other. The COPD-PS questionnaire had significantly better

Abbreviations: COPD, chronic obstructive pulmonary disease; FVC, forced vital capacity; FEV_1, forced expiratory volume in 1 s; GOLD, Global Initiative for the Chronic Obstructive Lung Disease; COPD-PS, COPD Population Screener; IPAG, International Primary Care Airways Guidelines; PPV, positive predictive value; NPV, negative predictive value; SD, standard deviation; ROC, receiver operating characteristic; AUC, area under the ROC curve; BMI, mean body mass index; $\%FEV_1$, FEV_1 %predicted.

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https://doi.org/10.1016/j.resinv.2022.07.005

specificity and area under the receiver operating characteristic curve value than the IPAG questionnaire. Moreover, only the COPD-PS questionnaire was identified as an independent factor for predicting COPD diagnosis in the multivariate analysis.

Conclusions: : Mass screening for COPD using screening questionnaires, particularly the COPD-PS questionnaire, might be useful to identify the early stages of COPD in a medical health check-up population.

1. Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive disease characterized by chronic inflammation of the airways and persistent airflow limitation [1], and it is anticipated to be the third largest global cause of mortality by the year 2030 [2]. COPD is highly prevalent worldwide [3] and therefore also in Japan [4], and it is becoming a major health challenge. Ordinary people are becoming more conscious of the significance of COPD; however, most still lack sufficient knowledge of the disease [5]. Moreover, while it is indispensable to have precise knowledge of the disease prevalence to design a public health strategy, no epidemiological studies on COPD have been conducted in the Shikoku region of Japan.

Since COPD is a "preventable and treatable disease," the early detection of COPD patients is critical before the disease becomes clinically apparent and leads to disability. However, patients with early-stage COPD are inclined to be either unaware of their condition or reluctant to consult their physician for respiratory symptoms [6]. One of the best ways to detect early-stage COPD is to screen airflow limitations either at the primary care level or during medical health check-ups. However, spirometry is not suitable for primary screening owing to the high cost of equipment and requirement of well-trained laboratory technicians. Thus, it is not yet sufficiently widespread within primary care or medical health check-up [7,8]. In Japan, screening systems for various chronic diseases have widely been applied, and many Japanese individuals undergo routine medical health check-up even if they are healthy [9]. However, there is little evidence that mass screening for COPD in asymptomatic individuals improves their quality of life, morbidity, and mortality [10]; thus, screening of the general population is not recommended in Western populations [11].

Self-administered questionnaires may identify individuals with a high probability of showing airflow limitation and enhance the detection of COPD. Some questionnaires have been validated and proved to be effective in detecting COPD in the primary care setting [12–14]. However, few studies have addressed the validation of COPD screening questionnaires in Asian populations, particularly in the Shikoku region of Japan. Given considerable heterogeneity in genetic background and lifestyle between Asian and Western populations [15], it is meaningful to determine the validity of COPD screening questionnaires in the aforementioned region.

We conducted a cross-sectional study to evaluate the prevalence and characteristics of COPD in a medical health check-up population for the early prevention and treatment of COPD. We also investigated the efficacy of mass screening for detecting COPD among community residents in the Shikoku region of Japan using two COPD screening questionnaires.

2. Patients and methods

2.1. Participants

The participants were 709 Japanese people who underwent a medical health check-up at the Department of Health Care, Shikoku Central Hospital of the Mutual aid Association of Public School teachers from July 2018 through January 2019. The current addresses of participants in this study were within a radius of approximately 100 km around the city of Shikoku-Chuo, Japan. Eligible participants were those aged ≥30 years with informed consent irrespective of smoking history and respiratory symptoms. The exclusion criterion was a previous medical diagnosis of bronchial asthma or chronic pulmonary diseases (bronchiectasis, lung cancer, tuberculosis, and interstitial lung disease) including COPD. After exclusion, 688 participants were enrolled in this study (Fig. 1).

The study was conducted in accordance with the principles of the Declaration of Helsinki and the study protocol was approved by the Institutional Review Board of Shikoku Central Hospital of the Mutual aid Association of Public School teachers (approval number: 2017-03, approval date: 2017/8/11). Informed consent for medical research was obtained from all study participants. This study was not registered in a publicly accessible database as it was an observational study without any interventions.

2.2. Study design

Questionnaires concerning occupation, respiratory symptoms, and current smoking status including the number of cigarettes smoked per day and smoking duration were assessed. The smoking index was calculated by multiplying the number of cigarette packs smoked per day by smoking years (pack-years) to estimate how participants were exposed to smoking. A chest radiograph was also evaluated to exclude other undiagnosed diseases. All participants underwent spirometry (Autospiro system-7®; Minato Medical Science, Osaka, Japan) after inhalation of 30 μg procaterol through an ultrasonic nebulizer. All measurements were performed

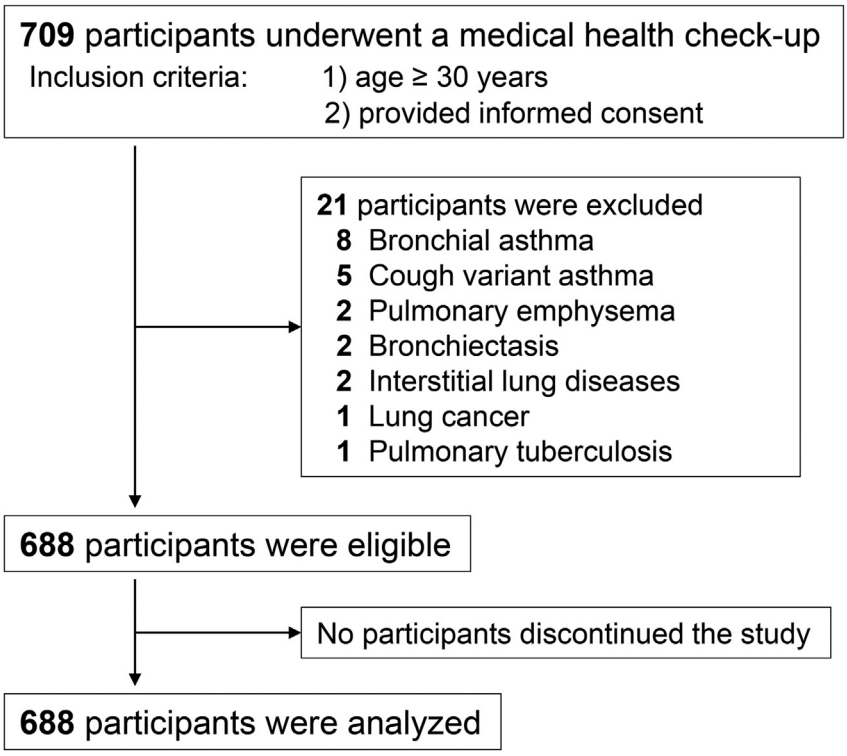

Fig. 1 – Study flowchart demonstrating participant enrollment.

according to the criteria of the American Thoracic Society/European Respiratory Society task force [16]. We used the values for forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV_1) according to the Global Lung Function 2012 equations [17]. All spirometric tests were interpreted by an experienced pulmonologist (criteria for acceptability and reproducibility as well as final diagnostic evaluation of the spirometry). Participants with an FEV_1/FVC <0.7 following bronchodilation were defined as having COPD according to Global Initiative for the Chronic Obstructive Lung Disease (GOLD) guideline [1]. The final medical diagnosis of COPD was based on a spirometric criterion, clinical status (medical history, symptoms, and physical examination), and exclusion of other diseases [1].

We used two different COPD screening questionnaires: the COPD Population Screener (COPD-PS) [12] and International Primary Care Airways Guidelines (IPAG) [13]. Both questionnaires were translated and culturally adapted from the original English version using an internationally recognized forward-backward methodology. Cut-off points for a positive response were ≥4 for the COPD-PS questionnaire and ≥17 for the IPAG questionnaire based on a previous Japanese study [18]. The sensitivities, specificities, positive predictive values (PPVs), and negative predictive values (NPVs) were calculated for the two questionnaires.

2.3. *Statistical analysis*

Significant differences between populations were evaluated using Fisher's exact and Student's t-tests in categorized and continuous variables, respectively. Results are reported as the means ± standard deviations (SDs). Correlations between the scores of COPD screening questionnaires and results of pulmonary function tests were analyzed using Spearman's rank correlation test. Univariate analyses were performed to evaluate patient characteristics that were significantly associated with the diagnosis of COPD, and variables that had *P*-values <0.15 in the univariate analyses were included in the multivariate logistic regression analysis. Receiver operating characteristic (ROC) curves and areas under the ROC curves (AUCs) were generated to reflect quantitatively the ability of the COPD-PS and IPAG questionnaires to discriminate between participants with and without COPD using the DeLong method. Two-tailed *P*-values <0.05 were considered significant. All analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria) [19].

3. Results

This study enrolled 688 Japanese participants (445 men and 243 women) who underwent a medical check-up in Shikoku Central Hospital of the Mutual aid Association of Public School teachers from July 2018 through January 2019. Clinical characteristics of the participants are listed in Table 1. The mean ± SD age, smoking index, and body mass index (BMI) of the study population was 54.8 ± 5.8 years, 8.6 ± 12.9 pack-year, and 24.3 ± 3.8 kg/m^2, respectively. Three hundred and eight (44.8%) participants had a history of smoking (current or former smokers).

Among 688 study participants, we newly discovered 21 patients with COPD without prior medical diagnosis and all

Table 1 – Patient characteristics.

Variables	
Participants, n	688
Age, years	54.8 ± 5.8[a]
Sex, n (%)	
Male	445 (64.7%)
Female	243 (35.3%)
Smoking status, n (%)	
Current or former	308 (44.8%)
Never	380 (55.2%)
Smoking index[b], pack-years	8.6 ± 12.9[a]
BMI, kg/m^2	24.3 ± 3.8[a]

BMI, body mass index; SD, standard deviation
[a] Data are presented as means ± SDs.
[b] Smoking index is defined as multiplying the number of cigarette packs smoked per day by smoking years (pack-years).

of them had a history of smoking. The prevalence of COPD was 3.1% (21/688) in all study participants and 6.8% (21/308) in participants with a history of smoking. Nineteen of 21 (90.5%) participants had early stage disease defined by the GOLD guidelines (Table 2), indicating that mass screening for COPD in a medical health check-up might be effective for the early detection of undiagnosed disease. The age distribution of the prevalence of newly diagnosed COPD participants was as follows: 30–39 years, 0.0% (0/11); 40–49 years, 1.1% (1/93); 50–59 years, 3.4% (15/440); and ≥60 years, 3.5% (5/144) (Table 3).

We next investigated the discriminative ability of the COPD-PS and IPAG questionnaires in diagnosing COPD (Table 4). There were no significant differences in sensitivities, PPVs, and NPVs between the two questionnaires. The diagnostic accuracy of the COPD-PS questionnaire was more likely to be better than that of the IPAG questionnaire ($P = 0.062$). The COPD-PS questionnaire had significantly better specificity and AUC than the IPAG questionnaire (80.1% vs. 67.8% and 0.79 vs. 0.67, respectively). It is noteworthy that both questionnaires had extremely high NPVs (≥98.0%), indicating that the diagnosis of COPD could be quite safely excluded in individuals with negative results for both questionnaires. Moreover, the scores of the COPD-PS and IPAG questionnaires were correlated with FEV_1/FVC ($r = -0.196$ and $r = -0.202$, respectively, $P < 0.001$), and they were also correlated with each other ($r = 0.527$, $P < 0.001$; Table 5), suggesting that both questionnaires are useful screening tools for detecting COPD.

Table 6 shows a comparison of the characteristics of participants with or without COPD. The proportions of male sex and smokers, smoking index, and FVC were significantly higher in patients with COPD than in those without. The mean total scores of the COPD-PS and IPAG questionnaires were significantly worse in participants with COPD than in those without (3.8 vs. 2.3 and 17.0 vs. 14.4, respectively). In contrast, FEV_1 %predicted (%FEV_1) was significantly lower in patients with COPD. Age, BMI, and FEV_1 did not differ between the two groups. Variables that had *P*-values <0.15 in the univariate analyses were included in the following multivariate logistic regression analysis to evaluate the one that could predict COPD diagnosis. Smoking status and pulmonary function test results were excluded from further analyses owing to

Table 2 – Distribution of stages of COPD defined by the GOLD guideline in 21 newly diagnosed cases.

Stage	N	(%)
I	10	(47.6)
II	9	(42.9)
III	1	(4.8)
IV	1	(4.8)

COPD, chronic obstructive pulmonary disease; GOLD, Global Initiative for Chronic Obstructive Lung Disease

Table 3 – Age distribution of the prevalence of newly diagnosed patients with COPD.

Age (years)	COPD (N)	Non-COPD (N)	Prevalence (%)
30–39	0	11	(0.0)
40–49	1	92	(1.1)
50–59	15	425	(3.4)
≥60	5	139	(3.5)

COPD, chronic obstructive pulmonary disease

Table 4 – Discriminative ability of two case-finding questionnaires for COPD diagnosis.

Variables	COPD-PS		IPAG		*P* value
Sensitivity, %	47.6	(25.7–70.2)	61.9	(38.4–81.9)	0.796[a]
Specificity, %	80.1	(76.8–83.0)	67.8	(64.1–71.3)	0.048[a]
PPV, %	7.0	(3.4–12.5)	5.7	(3.1–9.6)	0.663[a]
NPV, %	98.0	(96.4–99.0)	98.3	(96.6–99.2)	1.000[a]
Diagnostic accuracy, %	79.1	(75.8–82.1)	67.6	(63.9–71.1)	0.062[a]
AUC	0.79	(0.74–0.85)	0.67	(0.56–0.79)	0.031[b]

Numbers in parentheses indicate a 95% confidence interval.
COPD, chronic obstructive pulmonary disease; PPV, positive predictive value; NPV, negative predictive value; AUC, area under the receiver operating characteristic curve; COPD-PS, COPD Population Screener; IPAG, International Primary Care Airways Guidelines
[a] Fisher's exact test.
[b] Delong test.

Table 5 – Correlation between COPD screening questionnaire scores and pulmonary function tests.

Variables	COPD-PS		IPAG	
	Correlation coefficient	*P* value	Correlation coefficient	*P* value
IPAG questionnaire	0.527	<0.001	-	-
FEV_1/FVC	−0.196	<0.001	−0.202	<0.001
FEV_1	0.12	<0.01	−0.0381	0.318
FVC	0.187	<0.001	0.0455	0.237
%FEV_1	−0.237	<0.001	−0.0759	<0.05

Correlation coefficients and *P* values were analyzed using Spearman's rank correlation test.
COPD, chronic obstructive pulmonary disease; COPD-PS, COPD Population Screener; IPAG, International Primary Care Airways Guidelines; FEV_1, forced expiratory volume in 1 s; FVC, forced vital capacity

Table 6 – Comparison of individual variables between participants with and without COPD.

Variable	COPD	Non-COPD	P value
Participants, n (%)	21 (3.1%)	667 (96.9%)	
Age, years	56.5 ± 3.4	54.6 ± 6.1	0.14[c]
Sex (male/female)	20/1	425/242	<0.01[d]
Smoking status (current or former/never)	21/0	287/380	<0.01[d]
Smoking index[b], pack-year	20.0 ± 10.6[a]	8.2 ± 12.8[a]	<0.01[c]
BMI, kg/m^2	25.3 ± 4.4[a]	24.2 ± 3.8[a]	0.19[c]
FVC, L	4.01 ± 0.88[a]	3.59 ± 0.78[a]	0.02[c]
FEV_1, L	2.65 ± 0.70[a]	2.91 ± 0.64[a]	0.07[c]
FEV_1/FVC, %	65.4 ± 6.7[a]	81.0 ± 5.4[a]	<0.01[c]
%FEV_1, %	79.3 ± 19.4[a]	97.5 ± 12.5[a]	<0.01[c]
COPD-PS	3.8 ± 1.0[a]	2.3 ± 1.4[a]	<0.01[c]
IPAG	17.0 ± 4.0[a]	14.4 ± 4.1[a]	<0.01[c]

COPD, chronic obstructive pulmonary disease; BMI, body mass index; FVC, forced vital capacity; FEV_1, forced expiratory volume in 1 s; COPD-PS, COPD Population Screener; IPAG, International Primary Care Airways Guidelines; SD, standard deviation

[a] Data are presented as means ± SDs'

[b] Smoking index is defined as multiplying the number of cigarette packs smoked per day by smoking years (pack-years).

[c] Student's t-test.

[d] Fisher's exact test.

ineligibility for multivariate logistic regression analysis and inclusion in the diagnostic criteria of COPD, respectively. As shown in Table 7, only the COPD-PS questionnaire was identified as an independent factor for predicting COPD diagnosis in the multivariate analysis.

4. Discussion

In this cross-sectional study, we evaluated the prevalence and characteristics of COPD among community residents in an attempt to inform the early prevention and treatment of COPD. To the best of our knowledge, this is the first and largest population-based study on case findings of patients with COPD in the Shikoku region of Japan. The prevalence of COPD was 3.1% in all study participants, and all patients were newly diagnosed with COPD. Nineteen of 21 (90.5%) patients had early stage disease, indicating that mass screening for COPD in a medical health check-up population might be effective for the early detection of undiagnosed disease.

Table 7 – Multivariate logistic regression analysis for prediction of COPD diagnosis in screening participants.

Variables	Odds ratio	(95% CI)	P value
Age	1.010	(0.923–1.110)	0.771
Sex	5.120	(0.621–42.20)	0.129
Smoking index[a]	2.600	(0.747–9.050)	0.133
COPD-PS	0.626	(0.416–0.941)	0.024
IPAG	0.956	(0.832–1.100)	0.528

CI, confidence interval; COPD, chronic obstructive pulmonary disease; COPD-PS, COPD Population Screener; IPAG, International Primary Care Airways Guidelines.

[a] Smoking index is defined as multiplying the numbers of cigarette pack smoked per day by smoking years (pack-years).

In the present study, there were no patients with COPD below 40 years of age and most of them were aged ≥50 years (20/21:95.2%). In accordance with our findings, previous studies showed that the diagnosis of COPD in participants aged <40 years was rare and that the proportion of COPD increased with age [20]. For instance, Kojima et al. demonstrated that there were no patients with COPD aged 25–35 years and that the increase per 10 years of age in the estimated proportion was 1.79-fold in men and 1.55-fold in women. Çolak et al. also reported that only 20% of early COPD were aged 20–39 years and that the remaining 80% were aged 40–49 years [21]. The prevalence of COPD in this study (3.1%) was lower than that in the NICE (8.6%) [4] and Hisayama studies (9.3%) [22]. A possible explanation for these discrepancies might be the age distribution. The mean age in our study population was 54.8 years, whereas that in the NICE and Hisayama studies was 59.2 and 68.8 years, respectively. Additionally, we excluded participants with previously diagnosed COPD, which might have affected the lower prevalence in this study compared with previous reports. Sufficient attention should be paid to the interpretation of these epidemiological reports.

In this study, we investigated the efficacy of the COPD-PS and IPAG questionnaires for detecting patients with COPD in a medical health check-up population. The mean score of the two questionnaires was significantly higher in patients with COPD than in those without. The scores of the COPD-PS and IPAG questionnaires were correlated with FEV_1/FVC and with each other. Additionally, both questionnaires had extremely high NPVs (≥98.0%) for the diagnosis of COPD. These findings indicate that the COPD-PS and IPAG questionnaires are useful screening tools for detecting COPD and that the diagnosis of COPD could be quite safely excluded in individuals with negative results for both questionnaires. Although cut-off points of 4 and 17 on the COPD-PS and IPAG questionnaire are commonly used in general practices and health checkup settings in Japan [18], discrepancies in the best cut-off point of COPD screening questionnaires were reported [18, 23]. The reasons for these discrepancies are unknown; however, it might be partly because of the characteristics of the study participants. We determined the best cut-off point on an exploratory basis for the diagnosis of COPD in two screening questionnaires and revealed that the best cut-off point with AUC value was 3 with 0.81 on the COPD-PS questionnaire and 16 with 0.70 on the IPAG questionnaire, respectively (data not shown). Therefore, a cut-off point of 3 on the COPD-PS questionnaire and 16 on the IPAG questionnaire would be better for COPD screening in our study population. Under such conditions, it is convincing that the mean COPD-PS questionnaire scores were 3.8 and 2.3 points in COPD and non-COPD participants, respectively. Similarly, it is also plausible that the mean IPAG questionnaire scores were 17.0 and 14.4 points in COPD and non-COPD participants, respectively.

Unexpectedly, we found that the COPD-PS questionnaire had a significantly better specificity and AUC value than the

IPAG questionnaire and that only the COPD-PS questionnaire, but not the IPAG questionnaire, was identified as an independent factor for predicting COPD diagnosis in the multivariate analysis. The reason for these differences is not clear; however, some previous studies indicated that the screening questionnaires for COPD had different diagnostic characteristics. For example, Spyratos et al. investigated the profiles of three screening questionnaires for COPD in the primary care setting. They demonstrated that the COPD-PS questionnaire had the highest PPV; however, the IPAG questionnaire and Lung Function Questionnaire showed higher sensitivities than the COPD-PS questionnaire [24]. Tsukuya et al. reported that the COPD-PS and IPAG questionnaires had only a marginal difference in their abilities to detect COPD. However, they recommended the COPD-PS questionnaire as an adequate measure for large-scale screening tools owing to its simplicity [18]. The IPAG questionnaire contains symptom-related items, such as morning sputum, wheezing, and allergies, to exclude asthma. While the significance of these items for COPD screening had been well validated in smokers [13], their utility in never-smokers was had not been fully elucidated. Moreover, the diagnostic accuracy of the IPAG questionnaire is considered to be insufficient owing to low discrimination ability [25], relatively low specificity [25,26], and low positive predictive values [18,26]. Additionally, owing to some challenges, such as misunderstanding of the questionnaire and failure to accurately recall smoking histories and missing data, we may not always obtain precise data from self-reported questionnaires [27], which leads to insufficient power to detect significant differences among questionnaires. The COPD-PS questionnaire comprises five items, which is fewer than the IPAG questionnaire (eight items), and it requires less time to fill out. As the COPD-PS questionnaire is easier and simpler to complete, it might have a lower risk of misunderstanding and missing data. Further studies are required to draw a definite conclusion regarding the profiles of screening questionnaires for COPD in the future.

The prevalence of COPD was shown to be overestimated when participants underwent spirometry without a bronchodilator [4]. However, in almost all previous studies on screening for early-stage COPD either in general practice or at medical health check-ups, a bronchodilator was not administered before spirometry owing to various restrictions. In the present study, all participants were evaluated using post-bronchodilator spirometry, which might be a strong point of this trial. In contrast, several major limitations should be considered in interpreting our findings. First, the number of participants was somewhat small; thus, definite determination of the efficacy of mass screening for COPD in a medical health check-up population is challenging. Second, as this study was performed at a single institution, the results should not be generalized to the general population. Third, we were unable to completely exclude the possibility of other diseases mimicking COPD, such as bronchial asthma and other chronic pulmonary diseases (bronchiectasis, lung cancer, tuberculosis, and interstitial lung disease).

5. Conclusions

We conducted a cross-sectional study to investigate the efficacy of mass screening for COPD using two screening questionnaires during a medical health check-up. To the best of our knowledge, this is the first and largest population-based study on case findings of patients with COPD in the Shikoku region of Japan. Twenty-one patients were newly diagnosed with COPD, and the prevalence of COPD was 3.1%. The COPD-PS and IPAG questionnaires had extremely high NPVs in discriminating participants with COPD from those without. The scores of the COPD-PS and IPAG questionnaires were correlated with FEV_1/FVC and with each other. The COPD-PS questionnaire had significantly better specificity and AUC value than the IPAG questionnaire. Additionally, only the COPD-PS questionnaire was identified as an independent factor for predicting COPD diagnosis in the multivariate analysis. Collectively, mass screening for COPD using screening questionnaires, particularly the COPD-PS questionnaire, might be useful to identify patients with early stage COPD in a medical health check-up population.

Conflict of Interest

The authors have no conflicts of interest.

Acknowledgments

We thank our colleagues at Shikoku Central Hospital of the Mutual aid Association of Public School teachers, particularly Yukari Ishimura for technical assistance to conduct this study. This study was supported by the grants-in-aid for occupational area research of the Mutual aid Association of Public School teachers.

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