学 位 論 文 の 要 旨

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学 位 論 文 名　Validation of IPAG Questionnaire for Chronic Obstructive Pulmonary Disease in Shimane Prefecture

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論 文 内 容 の 要 旨

INTRODUCTION

The diagnosis of chronic obstructive pulmonary disease (COPD) requires the presence of airflow limitation on spirometry. The Nippon Chronic Obstructive Pulmonary Disease Epidemiology (NICE) study showed that the prevalence of airflow limitation was 8.6% in Japan. Because spirometry is not commonly performed in general physicians' offices, the under-recognition of COPD among general physicians might be one of the biggest hindrances to an accurate diagnosis of COPD. This problem is similar to issues observed in European countries; therefore, a questionnaire was developed to screen for COPD.

The COPD diagnostic questionnaire (CDQ) is an 8-item tool designed by the COPD Questionnaire Study Group from a cross-sectional study of primary care patients ≥40 years old from the United Kingdom and the United States with a history of smoking but no prior respiratory diagnosis. It was developed to improve the efficiency and accuracy of the COPD diagnosis in primary care by removing the need for spirometry in low-risk patients.

The present study analyzed the usefulness of this questionnaire in screening for COPD among older Japanese patients. We carried out spirometry and interviews at general physicians' offices in Shimane Prefecture in Japan to determine the COPD prevalence and evaluated the usefulness of the CDQ. Through this study, we examined the prevalence of COPD among patients with non-respiratory diseases in primary care clinics and also evaluated the usefulness of the CDQ for screening subjects.

MATERIALS AND METHODS

Study Design and Data Collection

The study protocol was approved by the Research Ethics Committee of Shimane

University.

The study protocol was conducted in patients who visited primary care clinics from October 2007 through July 2008 in Shimane Prefecture, Japan. Primary healthcare settings were recruited from amongst medical facilities in 3 different areas of Shimane Prefecture, of which 18 agreed to participate in this study. From among the patients who visited any of the 18 clinics for daily medical care, those who satisfied the inclusion criteria (≥40 years old, with diseases other than respiratory diseases, able to undergo spirometry, and provided their written informed consent) were enrolled into the study.

Study Definition

COPD was diagnosed in cases where the ratio of forced expiratory volume in 1 second (FEV1) to the forced vital capacity (FVC) was <70%. The severity of COPD was graded based on the FEV1% predicted according to the proposed guideline: Stage I ≥80%, Stage II <80% and ≥50%, Stage III <50% and ≥30%, and Stage IV <30% of the predicted value.

The Evaluation of the Pulmonary Function

Prior to the study, general information on patients that might be associated with COPD, including their age, gender, smoking habit, hospital admission for pulmonary problems in childhood, and respiratory symptoms (such as cough, sputum production and breathlessness), were obtained by the International Primary Care Airways Group (IPAG) questionnaire. We also inquired about dyspnea on effort.

Statistical Analyses

Data are expressed as the mean ± standard deviation (SD) or numbers (%) of subjects. The demography characters were compared with the χ^2 test and McNemar's test. The area under the receiver operating characteristic curve (AUC-ROC) was used to assess the sensitivity, and specificity. A P value less than 0.05 was considered statistically significant. All statistical analyses were performed using the general-purpose statistical software program StatFlex Ver. 6.0 for Windows (Artech, Co., Osaka, Japan).

Clinical parameters associated with the airflow limitation(AL) status were evaluated using a multiple logistic regression analysis. A binary variable representing the AL status was set as the objective variable, and the following parameters adopted from the IPAG questionnaire were set as explanatory variables: age (0 point, 40-49; 4 points, 50-59; 8 points, 60-69; 10points, ≥70 years old), cigarette smoking history (0 point, 0-14; 2points, 15-24; 3 points, 25-49; 7 points, ≥50 pack-years), weather-dependent cough (0 point, no; 3 points, yes), sputum without cold (0 point, no; 3 points, yes), BMI (5 points, <25.4; 1 point, 25.4-29.7; 0 point, >29.7), morning sputum (0 point, no; 3 points, yes), dyspnea (0 point, no; 3 points, sometimes/often), and allergy (0 point, no; 3 points, yes). As an additional parameter, dyspnea on effort (0 point, no; 3 points, yes) was added to the analysis.

The selection of the explanatory parameters was performed by the backward elimination method. To evaluate the utility of the IPAG score for diagnosing the AL status, an ROC analysis was performed. The summary value representing the diagnostic accuracy was expressed as the AUC-ROC. The sensitivity and specificity of the IPAG score were evaluated by serially changing the cut-off value for the score. The goodness-of-fit of the logistic regression analyses was expressed as the AUC, which was determined by secondarily making the ROC analysis using the predicted probability of belonging to the low AL group the diagnostic parameter.

RESULTS AND DISCUSSION

Patient Background Characteristics and Findings

A total of 925 subjects were initially recruited. Of these subjects, 43 were excluded due to incomplete medical records (32 subjects) and not satisfying the inclusion criteria (11 subjects). We then excluded a further 40 subjects with a VC <60%. The remaining 842 subjects (477 men and 365 women) were analyzed in this report. Among these patients, 109 (12.9%) showed AL, defined as an FEV1/FVC <70%. Of the 842 eligible subjects, 56.7% were men, and 43.3% were women.

According to the GOLD guidelines, the numbers of patients with Stage I (FEV1 ≥80% predicted), II (50% ≤FEV1 <80% predicted), III (30 ≤FEV1 <50% predicted), and IV (FEV1 <30% predicted) were 47.4%, 44.7%, 7.9%, and 0% in men and 30.3%, 60.6%, 9.1%, and 0% in women, respectively. The rate of AL increased with age in both men and women. A total of 627 people were positive for the questionnaire with a score of ≥17 (627/842, 74.5%). The sensitivity and specificity were calculated as 94.1% and 34.1%, respectively.

Results of a Multiple Logistic Regression Analysis

The goodness-of-fit of the logistic regression analysis, expressed as the AUC, was 0.765 with the inclusion of the above-mentioned three parameters. The original AUC for the analysis including all parameters was 0.778. The reduction in the AUC after eliminating less-significant parameters was very slight. We then added the parameter of dyspnea on effort to the three chosen parameters and found that the AUC was 0.786. This modified IPAG questionnaire might be a promising screening tool for Japanese older COPD cases.

CONCULUSION

The present study showed that the specificity of the original IPAG questionnaire for the screening of COPD in older Japanese subjects was lower than expected. Our modified IPAG questionnaire might be a promising tool for screening older COPD cases.