Detection of airflow limitation using a handheld spirometer in a primary care setting

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ABSTRACT

Background and objective: Early diagnosis of chronic obstructive pulmonary disease (COPD) in primary care settings is difficult to achieve chiefly due to lack of availability of spirometry. This study estimated the prevalence of airflow limitation among chronic smokers using a handheld spirometer in this setting.

Methods: This is a cross-sectional study performed on consecutive patients who were ≥40 years old with ≥10 pack-years smoking history. Face-to-face interviews were carried out to obtain demographic data and relevant information. Handheld spirometry was performed according to a standard protocol using the COPd-6 device (Model 4000, Vitalograph, Ennis, Ireland) in addition to standard spirometry. Airflow limitation was defined as ratio of forced expiratory volume in 1 s (FEV1)/forced expiratory volume in 6 s <0.75 (COPd-6) or FEV1/forced vital capacity <0.7. Multiple logistic regression analyses were used to determine predictors of airflow limitation.

Results: A total of 416 patients were recruited with mean age of 53 years old. The prevalence of airflow limitation was 10.6% (n = 44) with COPd-6 versus 6% as gauged using standard spirometry. Risk factors for airflow limitation were age >65 years (odds ratio (OR) 3.732, 95% confidence interval (CI): 1.100–1.280), a history of ‘bad health’ (OR 2.524, 95% CI: 1.037–6.142) and low to normal body mass index (OR 2.914, 95% CI: 1.191–7.190).

Conclusions: In a primary care setting, handheld spirometry (COPd-6) found a prevalence of airflow limitation of ~10% in smokers. Patients were older, not overweight and had an ill-defined history of health problems.

KEY WORDS: chronic obstructive pulmonary disease, Malaysia, prevalence, primary care, smoke.

ABBREVIATIONS: BMI, body mass index; CI, confidence interval; COPD, chronic obstructive pulmonary disease; FEV1, forced expiratory volume in first seconds; FEV6, forced expiratory volume in first six seconds; FVC, forced vital capacity; IQR, interquartile range; OR, odds ratio.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD), a progressive partially reversible airflow obstructive condition, is a growing public health problem globally. In its advanced stage, the disease causes severe disabilities and poor quality of life.1-3 By 2030, it is projected to be the third leading cause of death worldwide with Asia, having three times the number of patients than the rest of the world.4-6 Systematic reviews have reported the prevalence of at least moderately severe COPD among adult smokers, aged 40 years and above is in the range of 9.9–15.4%.7 Thus, early detection of COPD is important to prevent the continuous deterioration of lung function through pharmacological intervention and more targeted measures of smoking cessation.8-10

SUMMARY AT A GLANCE

Prevalence of COPD is unknown in Malaysia. The prevalence of COPD using a handheld spirometer (COPd-6TM) was 10.6% versus 6% as gauged using standard spirometry. Predictors of COPD were older age, lower BMI and a history of ‘bad health’. Case-finding for COPD should be targeted in this special population.

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Received 28 June 2013; invited to revise 18 August, 29 October 2013 and 1 January 2014; revised 29 September, 18 December 2013 and 23 January 2014; accepted 23 January 2014 (Associate Editor: Graham Hall).

Article first published online: 7 April 2014

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In primary care settings, early diagnosis of COPD is a daunting task. Patients in the early stage of COPD are relatively less symptomatic, thus tend not to highlight their symptoms to health-care providers. By the time the disease is brought to clinical attention, it is usually in a more advanced stage, where the forced expiratory volume in 1 s (FEV₁) is typically below 50% of predicted. Nevertheless, even if they do complain, measurements of airflow limitation that are crucial for the diagnosis are often not performed. Many of the patients are misdiagnosed as having bronchial asthma. General lack of availability and experience in using spirometry among primary care physicians contribute to this unfortunate circumstance.

In recent years, handheld spirometers have been made available by various manufacturers. These are inexpensive, ultra-portable and easy to use. Thus, these devices could be used as a case-finding tool for COPD, particularly in primary care settings. Handheld spirometer has good sensitivity and specificity to identify airflow limitation compared with standard laboratory-based spirometry.

However, few studies have used handheld devices to detect the prevalence of airflow limitation in the at-risk population in primary care, especially in a developing country like Malaysia. Therefore, this study aimed to determine prevalence and predictors of airflow limitation in chronic smokers in a primary care clinic.

METHODS

Study population
This cross-sectional study enrolled patients registered with the public primary health-care clinic at the Sepang District in the state of Selangor in Malaysia from January to June 2012. The clinic is located in a suburban area serving a predominantly Malay population. All consecutive patients aged 40 years and above who had smoking history of more than 10 pack-years, irrespective of whether a diagnosis of COPD has been made previously, were recruited into the study. Patients with recent active tuberculosis, haemoptysis, pneumothorax and human immunodeficiency virus were excluded from the study. Approvals for this study were obtained from the Medical Research Ethics Committee of the Ministry of Health Malaysia (NMRR11-456-9126) and Institutional Review Board.

Data collection
Patient demographics were captured using a standard questionnaire form. A face-to-face interview was carried out to obtain demographic data, detailed smoking history and health status. The Canadian case-finding questionnaire was used to ascertain the likelihood of airflow limitation in all subjects. It contains five questions to capture information such as presence of dyspnoea on exertion, chronic cough, sputum production, wheeze and recurrent respiratory infections. A score of one was awarded for every ‘yes’ response and a zero score for every ‘no’ response. Hence, a total score could range between 0 and 5. If the score is ≥3, it is defined as ‘at risk’ and if it is <3, it is considered as ‘not at risk’.

In addition, we also assessed the subjects’ perceived health status as a potential predictor for airflow limitation by asking ‘How do you rate your current health status?’; a five-point Likert scale (1 = very bad, 2 = bad, 3 = neutral, 4 = good, 5 = very good) was used to rate the subjects’ perception of their health status. Those who rated their health status as 4 or 5 were defined as having ‘good health’, whereas those who rated theirs 1 or 2 were considered to have ‘bad health’.

Once these questionnaires were completed, all patients were instructed to perform the forced expiratory manoeuvre (for at least 6 s) using the COPd-6 device (Model 4000, Vitalograph, Ennis, Ireland).

Although the handheld spirometry measures FEV₁ and forced expiratory volume in 6 s (FEV₆), it was unable to measure forced vital capacity (FVC); nevertheless, FEV₆ was taken as surrogate for FVC as studies have shown that FEV₆ in this handheld spirometry is able to reflect quite accurately the actual value of measured FVC. Handheld spirometry test was conducted by two trained nurses. A measurement was deemed to be satisfactory when a beep sound was heard, indicating that expiration of at least 6 s had been achieved. Any attempt that did not produce a beep sound was rejected as unacceptable. At least three acceptable measurements were recorded for each patient. Any patient with ratio of FEV₁/FVC <0.75 was considered to have possible airflow limitation.

These patients were asked to return for formal spirometry testing, which included a postbronchodilator test in accordance to the standardized procedure. The highest values of the FEV₁ and FVC were used in the analysis. Diagnosis of COPD was made when the postbronchodilator FEV₁/FVC is <0.70.

Height and weight were measured, and body mass index (BMI) was calculated. Obesity was defined using the Asian cut-off of ≥27.5 kg/m².

Statistical analysis
SPSS statistical software version 21 (SPSS IBM, Armonk, New York, USA) was used for analysis. Continuous data were described as mean and standard deviation if the distribution is normal, and when it is not, median and interquartile range (IQR; 25–75th percentiles) were also used. Categorical data were reported as proportions (percentage). Chi-square test or Fisher’s exact tests were used for the categories or dichotomous predictors while multivariate logistic regression analysis was used to search for predictors of patient with airflow limitation. All variables with a P-value of less than 0.25 in the univariate analyses and clinical significant variables were entered into the multiple logistic regression analysis. All analyses were performed with 95% confidence intervals (CI), and the level of significance was set at P < 0.05.
RESULTS

A total of 437 subjects were enrolled in the study, and all underwent COPD-6 measurement. Twenty-one patients had self-reported asthma and were excluded from our analysis. This gave a total of 416 patients qualified for final analysis. Of this number, 99.8% of the respondents were male, and their median age was 53 years (IQR = 15). The majority (78.8%) were of Malay extraction. Demographic and clinical characteristics of all patients are presented in Table 1. There were seven patients with a past history of tuberculosis, but none with lung cancer, occupational lung disease or bronchiectasis.

The median smoking history was 20.4 (IQR = 18) pack-years with 63.7% of them still actively smoking. Average BMI was 27.2 (IQR = 5.8) kg/m².

Comorbidities were present in 236 (56.7%) individuals. Hypertension (46.2%) and dyslipidaemia (42.8%) were the two most common comorbidities. Other comorbidities and general health status were shown in Table 2.

Prevalence of airflow limitation was 10.6% (n = 44/416) and 6% (n = 15/251) based on the COPD-6 and spirometry test, respectively. Of the 44 patients who had abnormal COPD-6 reading, only 27 came back for a confirmatory test, with 29.6% (8/27) having spirometry confirmed COPD. On the other hand, among the 224 patients who were screened negative for COPD with COPD-6, only 3.1% (7/224) emerged with a diagnosis of COPD after spirometry.

More than half (53.4%) of the 416 chronic smokers in this study were symptomatic. The common complaints were chronic cough particularly in the morning (32.0%), productive cough (25.5%), dyspnoea on exertion (20.2%), wheezing (13.5%) and recurrent respiratory infections (7.5%). Using the Canadian case-finding questionnaire scoring system, 11.8% were at risk of having airflow limitation.

Over half of the chronic smokers (54.6%) perceived their health status as ‘good’, 33.6% as ‘neutral’ and 10.8% as ‘bad’. And among the 44 subjects with airflow limitation, 38.6% subjects reported good health and 18.2% subjects reported bad health.

Table 3 shows the result of multiple logistic regression. After adjusting for all the variables in the model, older patients were 3.7 odds more likely to have airflow limitation (odds ratio (OR) 3.732, 95% CI: 1.100–1.280). Patients with ‘bad health’ were 2.5 odds more likely to have airflow limitation than those with ‘good health’ (OR = 2.524 95% CI: 1.037–6.142). Patient who were under or normal weights were 2.9 odds (OR = 2.914 95% CI: 1.191–7.130) more likely to have airflow limitation compared to the obese patients.

DISCUSSION

In our study, the prevalence of airflow limitation based on the handheld COPD-6 spirometer was 10.6%. This is the first study that used a handheld device in Malaysia. However, when airflow limitation was confirmed with spirometry, the prevalence of

| Variables | No airflow limitation (n = 372) | Have airflow limitation (n = 44) | P-value |
|-----------|-------------------------------|-------------------------------|---------|
| Age, years (median, IQR) | 53 (13) | 60 (20) | <0.001 |
| BMI, kg/m² (n, %) | | | |
| Underweight ≤ 18.5 and normal weight (BMI of 18.5–22.9) | 60 (84.5) | 11 (15.5) | 0.043 |
| Overweight BMI of 23.0–27.4 | 129 (86.6) | 20 (13.4) | |
| Obese BMI ≥27.5 | 183 (93.4) | 13 (6.6) | |
| Male gender, n (%) | 371 (99.7) | 44 (100.0) | 0.731 |
| Ethnicity, n (%) | | | |
| Malays | 297 (90.5) | 31 (9.5) | 0.287 |
| Chinese | 29 (80.6) | 7 (19.4) | |
| Indians | 44 (88.0) | 6 (120) | |
| Education level, n (%) | | | |
| Primary | 81 (21.8) | 16 (36.4) | 0.080 |
| Secondary | 223 (59.9) | 23 (52.3) | |
| Tertiary | 68 (18.3) | 5 (11.4) | |
| Smoking history, pack-years, n (%) | | | |
| <20 | 171 (46.0) | 13 (29.5) | 0.038 |
| ≥20 | 201 (54.0) | 31 (70.5) | |
| Salary, RM (median, IQR) | 1500 (2200) | 1500 (1773) | 0.213 |
| Approximate USD (median, IQR) | 450 (660) | 450 (530) | - |

| Variables | No airflow limitation (n = 372) | Have airflow limitation (n = 44) | P-value |
|-----------|-------------------------------|-------------------------------|---------|
| Canadian case-finding scoring | | | |
| Not at risk with the score <3, n (%) | 328 (88.2) | 39 (88.6) | 0.928 |
| At risk with score ≥3, n (%) | 44 (11.8) | 5 (11.4) | |
| Patients’ perception on their general well-being | | | |
| Bad, n (%) | 37 (9.9) | 8 (18.2) | 0.096 |
| Not in bad condition, n (%) | 335 (90.1) | 36 (81.8) | |
| Comorbidities | | | |
| Hypertension, n (%) | 168 (45.2) | 24 (54.5) | 0.238 |
| Dyslipidaemia, n (%) | 159 (42.7) | 19 (43.2) | 0.956 |
| Cardiovascular heart disease, n (%) | 12 (3.2) | 1 (2.3) | 0.731 |
| Heart failure, n (%) | 22 (5.9) | 3 (6.8) | 0.811 |

Data are presented as n and %. n, number.
COPD was 6.0%. This suggests that handheld spirometry tends to overestimate the prevalence of COPD. On the other hand, overestimation could be due to the higher cut-off point for FEV1/FVC (less than 0.75) based on handheld spirometry compared with FEV1/FVC (less than 0.70) using spirometry, the gold standard test to determine airflow limitation. Among those screened positive with COPD-6, about one third were confirmed to have COPD. One possible reason could be due to the failure of almost 40% of those screened as having COPD by COPD-6 to have a confirmatory test.

The prevalence of airflow limitation in our study is higher compared with the reported estimated prevalence of COPD of 4.7% in Malaysia. However, the reported prevalence is not based on direct spirometry measurements, but on theoretical modelling of smoking rates and levels of air pollution in Malaysia 10 years ago. In addition, the estimation was calculated for patients with at least moderately severe COPD. When compared with other studies performed in Asia, this prevalence of COPD (6%) is lower compared with the spirometry-based prevalence reported by other countries, which varied from 6.5% in India, 7.50% in Korea and 8.55% in Japan. Extensive use of biomass fuel relating to indoor cooking, which is uncommon in Malaysia, particularly in this non-remote area of this population, may contribute to these differences.

This study demonstrated that poorer health status is a predictor for the presence of airflow limitation (OR = 2.524 95% CI: 1.037–6.142). Self-reported health status outcomes are often relevant in patients with COPD as they reflect the well-being of patients with COPD attributed to the relatively asymptomatic early stage of this disease. The Canadian case-finding questionnaire scoring system was not helpful to identify patients at risk of airflow limitation. There could be a possible cultural influence to this finding. Studies have reported that the majority of patients in Asia who had COPD did not report symptoms of cough, sputum production and breathlessness—three symptoms that were included in the Canadian case-finding questionnaires. Further research is needed to validate the usefulness of these questionnaires in Asian.

In this study, almost all the respondents were males. Tobacco smoking among women is regarded as a socially unaccepted behaviour in Malaysia. Therefore, fewer females in the country smoke, thus contributing to the low prevalence of airflow limitation compared with Nepal and other western countries. The chief limitation of this study is that more than 60% of the patients with a positive diagnosis of COPD with the handheld device did not come back for the confirmatory standard spirometry testing. However, under the circumstances of a limited budget and resources in the primary care setting, together with the previous report of good sensitivity and specificity of the handheld spirometer, we consider that using the handheld device would be appropriate in these settings. The diagnosis of asthma and bronchiectasis were based on self-report; thus, this could have caused over or under estimation of COPD prevalence.

In conclusion, this study found that using the handheld spirometer (COPD-6), the prevalence of airflow limitation was estimated as ~10%. Risk factors for airflow limitation were identified.

Acknowledgements

The authors would like to acknowledge the Director of Health for their support in the study and clinical staffs for providing support during the data collection. We also extend our thanks to Universiti of Putra Malaysia, which funded the study with grant number RUG (9199775) UPM 2011. Special thanks are herein attached to Chang Wing Lioung, Teoh Yan Jun, Tey Yin Yee, Chua Yan Ping, Haw Chui San and late Dr Zaiton Ahmad for her contribution to the early stages of this study.

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