Concerns with the Health Check-up System for Chronic Obstructive Pulmonary Disease on two Japanese Islands

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Abstract

Objective Early diagnosis is a key factor in the management of chronic obstructive pulmonary disease (COPD). Although mass screening is widely used, little is known about its accuracy and efficacy. This study investigated whether using spirometry during mass screening to detect COPD among community residents might be ineffective because of variability in the training and experience of examiners.

Participants and Methods Both spirometry and a self-written questionnaire-based survey, including questions designed to detect respiratory symptoms, were conducted on community residents. Two separate studies were conducted on islanders living in similar environments. Study I was performed from 2004 to 2007 on Hachijyo Island residents, while study II, with a similar study design, was performed in 2003 on Inno Island residents.

Results In study I, 3,592 subjects underwent examination over the 4-year study period; of these, 378 subjects underwent repeated examinations. Approximately 25% of the subjects had respiratory symptoms. Acceptable spirometry recordings were obtained for 62.0% (2004) to 84.1% (2006) of the subjects. In study II, 167 of the 254 subjects (65.7%) had respiratory symptoms. Acceptable assessment recordings were achieved in 254 subjects (95.5%). The suitability of the recordings was influenced by the extent/level of training of the examiners and the accompanying thoracic specialists.

Conclusion We concluded that the effectiveness of health check-ups for COPD evaluation using spirometry was greatly influenced by the quality of the examiners, even when the subjects had respiratory symptoms. Thus, we recommend caution when screening for early signs of COPD during health check-ups.

Key words: COPD screening, respiratory symptoms, health check-up, islanders, efficacy of diagnosis

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Introduction

Chronic obstructive pulmonary disease (COPD) is a slowly progressive lung disease characterized by chronic cough, sputum production, and exertional dyspnea (1, 2). The patients may have no symptoms or may accommodate to the loss of respiratory capacity, and thus, fail to report early symptoms. Underdiagnosis, which is more often an issue in primary practice, results from the long silent phase of the disease (3, 4). Clinicians are culpable because they underuse spirometry for assessing at-risk patients (3). The failure to employ routine spirometry in the evaluation of smokers and ex-smokers not only leads to the under-diagnosis of early COPD but also to misdiagnosis. Screening systems for various chronic diseases have widely been applied (Japan Society of Ningen Dock; http://www.ningen-dock.jp/); however, little is known about the efficacy of mass screening for COPD. We investigated whether mass screening for detecting COPD among community residents was effective. The study design was used to help detect the minor discrepancies and related problems in COPD detection caused by mass screening.

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Participants and Methods

The study was performed on the residents of 2 isolated islands with similar environments. Study I was conducted with financial support from the local government of Hachijyo Island in Tokyo, Japan, and was supervised by a local community health center. Study II was performed in Inno Island, Hiroshima, Japan; this was a 1-day screening funded by Japan Broadcasting Company. In both the studies, subjects were recruited from the general population, and were provided with information on COPD in advance during recruitment (see below). Subjects who had already experienced respiratory symptoms and/or those receiving therapy for chronic respiratory diseases such as bronchial asthma or interstitial lung disease might be more interested in participating in the study; therefore, such added effects on patient recruitment were unavoidable.

Study I was an annual mass-screening service conducted between 2004 and 2007 by the community government to detect COPD in all adult inhabitants. All subjects were invited to the screening by a personalized letter from the local government, explaining the nature and aim of the study. The causes, symptoms, signs, and natural history of COPD were described in a newsletter, and a lecture was delivered before the study by one of the authors. The importance of early diagnosis for prevention of severe life-threatening disease was emphasized. Subject examination commenced with weight and height measurements, followed by spirometry after completion of the previously described questionnaire (5). Each subject chose 1 of the 6 possible testing days according to their schedule, and waited for his or her turn in a waiting room.

Study II was performed on randomly selected volunteers. The examination included spirometry and the same questionnaire as in Study I, and the same information on COPD was provided in advance to all enrolled subjects.

Questionnaire

The COPD questionnaire (5) was completed by all subjects, and those needing assistance were assisted by staff members. Illiteracy was a criterion for exclusion.

Spirometry examinations and diagnostic criteria

In study I, spirometry was performed by 2-4 examination specialists, employed by commercial companies. Chest specialist physicians did not participate in any of the examinations in study I. According to government policy, each company was chosen by a bid system with a government budget, providing fair dealings and quality control. However, all examiners were qualified, had passed national examinations in study I. We refer to the data classified into the top 3 grades of forced expiratory volume in 1 s (FEV1) and FVC. In this study, we adopted the data classified into the top 3 grades (A, B, or C) (at least 2 acceptable maneuvers with FEV1 matching within 0.2 L), and considered these acceptable for analysis in studies I and II.

Portable spirometers (Chestgraph Jr. H1-101; Chest Co., Japan) were used in both the studies. Spirometry was conducted for all eligible subjects by the procedure recommended by the American Thoracic Society (8). Subjects with an FEV1/FVC ratio of <0.70 were diagnosed with COPD, according to the guidelines of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) (9); however, post-bronchodilator measurements were not performed in either of the studies. The “at risk” group was defined according to the previous GOLD severity classification (10), and the COPD stages I-IV were determined according to the severity of the GOLD score (9). The normative FEV1 values in the Japanese population were predicted based on a previous report by the Japan Respiratory Society (11).

Studies I and II were approved by the local government committee. All of the participating subjects gave written informed consent.

Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) Version 11.1 for Windows (SPSS Inc., Chicago, IL.). Results were considered significant when p<0.05. Quantitative data were described using the mean.

One-way analysis of variance (ANOVA) and χ2 test were used to compare the continuous and categorical variables, respectively, among the 4-year groups. Post-ANOVA comparisons between the groups were conducted using the Tukey test. Paired Student’s t-tests were employed to test...
Table 1. Comparison of Findings of Study I

<table>
<thead>
<tr>
<th>Year</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>838</td>
<td>911</td>
<td>839</td>
<td>1004</td>
</tr>
<tr>
<td>Number of subjects receiving spirometry and questionnaire (M/F)</td>
<td>816 (257/559)</td>
<td>895 (288/607)</td>
<td>814 (274/540)</td>
<td>970 (330/640)</td>
</tr>
<tr>
<td>Mean age (y)</td>
<td>60.6</td>
<td>62.3</td>
<td>63.3*</td>
<td>62.9†</td>
</tr>
<tr>
<td>Number of acceptable spiromgrams§</td>
<td>506 (62.0%)</td>
<td>568 (63.5%)</td>
<td>685 (84.1%)</td>
<td>689 (71.0%)</td>
</tr>
<tr>
<td>Number and rate of acceptable spiromgrams for 4 years§</td>
<td>238 (63.0%)</td>
<td>256 (67.8%)</td>
<td>327 (86.5%)</td>
<td>283 (74.9%)</td>
</tr>
<tr>
<td>Mean FEV1 (%) of subjects who received spirometry over 4 years</td>
<td>83.9</td>
<td>81.9</td>
<td>78.4‡</td>
<td>80.3‡</td>
</tr>
<tr>
<td>Number of examiners</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Mean years of experience as examiners</td>
<td>14/2/5</td>
<td>15/6</td>
<td>15/20/25/2</td>
<td>10/25</td>
</tr>
<tr>
<td>Mean time per person</td>
<td>5 min 20 s</td>
<td>5 min 13 s</td>
<td>6 min 13 s</td>
<td>3 min 53 s</td>
</tr>
<tr>
<td>Number of subjects with respiratory symptoms</td>
<td>410 (50.2%)</td>
<td>571 (63.8%)</td>
<td>500 (61.4%)</td>
<td>619 (63.8%)</td>
</tr>
</tbody>
</table>

* p < 0.001 vs. 2004; † p < 0.005 vs. 2004; § p < 0.0001 vs. 2004; ‡ p < 0.0001 (χ² test)
Characteristics of Subjects from 2004 to 2007

Results

Study I

During the 4-year study period, 3,592 eligible subjects joined the study. The mean duration of spirometry per person was 5 min 20 s, 5 min 13 s, 6 min 13 s, and 3 min 53 s, for the years 2004-2007, respectively (Table 1). Women were predominant among the cohort, but no gender differences were observed with respect to age, lung function tests, or completed questionnaires of those who underwent the examination (data not shown). Approximately 50-60% of all subjects complained of respiratory symptoms every year. During the 4-year study, the acceptable rate of spirometry was the highest (n=685; 84.1%) in 2006 compared to the other years. The maximum number of subjects underwent the examination (n=327; 86.5%) in 2006; therefore, the data from that year are depicted in a flow chart as the best example of the testing process (Fig. 1). Four examiners participated in the study in 2006, and tests for each subject were performed on 1 of the 6 consecutive days. In that year, each subject was tested for a mean of 6 min 13 s, which was the longest testing time among all the 4 years (Table 1). Of the 630 subjects, 59 (9.4%) had airflow obstruction (FEV1/FVC <0.7).

Study II

A total of 363 subjects, consisting of 171 men and 192 women, were randomized and selected from 1,300 participants. A total of 266 subjects were over 40 years of age, and spirometry data were acceptable for 254 of these subjects (95.5%). A study flow diagram and data are shown in Fig. 2. The study II participants underwent the same examination as the participants of study I, but this study was performed in 1 day and required 7 qualified examiners from a different company compared to study I. The mean duration of spirometry measurement was 6 min 45 s. A total of 167 subjects (167/266=62.8%) had respiratory symptoms (Table 2). Sixty-three subjects were considered to be in the “at risk” for COPD group. Among the 254 subjects over 40 years old, 22 showed airflow obstruction, with an FEV1/FVC value of <0.7 (8.7%).

Discussion

We performed 2 studies, each involving 2 interior Japanese islands with no significant sources of air pollution. We investigated the efficacy of mass screening for COPD in different communities. Study II involved 1-day screening, and validated the data from study I, which was performed over 4 consecutive years. COPD prevalence on the 2 islands was similar (study I vs. II: 9.4 vs. 8.7%) and the findings were in line with that found in a previous study performed on the Japanese mainland (12). Mass screening would encourage the awareness or prevention of COPD, for example, by promoting cessation of smoking; however, the present study found that such screening does not efficiently identify true COPD patients in situations in which the quality and training of examiners is not guaranteed.

The 2 studies illustrated that the efficiency of COPD...
screening is hampered by the time and effort required by both the patients and healthcare system, as elucidated in the current recommendations of the new United States Preventive Service Task Force (USPSTF) (13). There is a continuing debate about the usefulness of spirometry in the primary care setting (14, 15), and further research is necessary before a positive recommendation can be made (16). However, the present study revealed that completely different problems, which differed from those in the previous reports (14, 15), arise during mass screening for COPD compared to screening in primary care settings. Similar mass screening has been performed in other countries, as part of a campaign to shorten the detection period for COPD (17). The usefulness of such data obtained during mass screening has not been conclusively proven. In this study, 84.1% of the spirometry data obtained during 2006 was deemed acceptable for assessment in study I; the data from the other 3 testing years were poor in study I, and were not cost-effective in terms of disease assessment. In study II, 95.5% of the data was acceptable. Mass screening in study I was markedly disadvantaged by the fact that many examinees underwent spirometry within a limited period, because of the large number of subjects waiting for tests and shortage of examiners. In addition, we found that the quality of examiners influenced the results of studies I and II. If the examinees did not fully understand the maneuver, better-qualified examiners could explain the process properly even in a limited time. The age and gender of the examinees did not significantly differ among the 4 groups (2004-2007) in study I or between studies I and II. This suggests that the differences between studies I and II could be mainly attributed to at least 2 examiner-related factors: training and duration of spirometry measurements. The present results suggest that spending a longer time with each subject (more than 6 min) would improve the spirometry data. Further mass screening tests in different settings will validate this hypothesis. It should be noted that 378 subjects repeatedly underwent spirometry in study I, but the effects of training were not observed among the subjects. This is consistent with Moore’s recommendation (18) for better use of support staff and improved scheduling for spirometry. Further study is required to assess examiner-related problems in mass screening using spirometry.

We also noted a similar prevalence of airflow obstruction compatible with COPD between the 2006 data obtained in studies I and II. The prevalence of COPD was similar to that stated in a previous report from the Nippon COPD Epidemiology study (12). However, the number of subjects with COPD identified in studies I and II was small compared to the large number of initial participants, indicating that the method was not cost-effective for accurate identification. A previous report (14) suggested that screening using spirome-

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Figure 1. Study flow diagram and summary of the data obtained in 2006 from study I conducted on Hachijo Island. In 2006, 839 subjects were registered, and 630 subjects showed acceptable spiromgrams. COPD was suspected in 59 subjects based on pre-bronchodilator spiromgrams during mass screening. Subsequently, only 9 subjects had a confirmed diagnosis of COPD after spirometry at a local hospital (see text for details). Abbreviations: FEV1: forced expiratory volume in 1 s, FVC: forced vital capacity.
try influences the physicians’ diagnosis of airflow obstruction in patients with moderate-to-severe obstruction; the majority of patients in the present study who had abnormal spirometry data were classified as at-risk patients or showed mildly severe obstruction.

Our results suggest that it may be efficient to employ...
both spirometry and a questionnaire-based survey at the same time, consistent with the findings of our previous study (5) and another study (19). However, the rate of cough and sputum production, wheezing, or dyspnea on exertion varied greatly between studies I and II. This observation differed from that of a previous study involving general subjects in Japan who showed a similarly high prevalence of COPD (20). However, it could not be concluded from the present data whether spirometry should be performed to diagnose airflow obstruction in patients with exertional dyspnea (21), because the prevalence of subjects who complained of dyspnea was high throughout the 4 years of study I as well as in the 1-day screening used in study II. The present study suggests that advanced screening using a questionnaire system could be more effective than spirometry for COPD screening.

One notable characteristic of this study was that the number of female participants was higher in study I in all 4 years, whereas in study II, the number of female participants was only slightly greater than that of male participants. Although the precise reasons for this are unknown, the discrepancies between the 2 studies suggests that women might be more interested checking for COPD, or in other words, they might take a more active interest in their health than men. Moreover, recent data from a population-based study from 14 countries (BOLD study) indicate that non-smokers comprise a substantial proportion of individuals with COPD. Increased age, prior diagnosis of asthma, and among women, lower education levels are associated with an increased risk for COPD among the non-smokers (22). Clearly, this subject requires further study in the Japanese population.

Our study has some limitations. First, we did not perform post-bronchodilator examination because of shortage of time for mass screening. Similar problems may have arisen in a previous study (12). Post-bronchodilator prediction equations can facilitate better management of COPD patients by avoiding false high FEV₁ values (23). Moreover, post-bronchodilator examination is necessary to rule out the possibility of bronchial asthma, since COPD has historically been associated with asthma (24), and sometimes it might be difficult to distinguish asthma from exacerbations of COPD, which occasionally involve wheezing episodes. Similarly, other chronic respiratory diseases such as interstitial lung diseases, bronchiectasis, panbronchiolitis, or pulmonary tuberculosis might be included among the cases with chronic airflow obstruction that mimic COPD (2, 25). All these factors might be shortcomings of the present study. Second, mass screening for COPD is becoming common in Japan, but it is usually performed by examiners from commercial companies, and according to Japanese government rules, these companies are selected by a bidding process. Therefore, thoracic specialists should be involved in spirometry during mass screening, and/or commercial examiners should regularly receive training to ensure a high quality of the test.

Despite all these limitations, the utility of mass screening for COPD cannot be denied based on the present data. Simple COPD screening questions should be answered by maximum number of smokers (19, 26, 27), and spirometry data should be collected to provide a better understanding of COPD. The implementation of studies I and II might have helped promote the prevention or awareness of COPD and may have a more pronounced effect than the use of newspapers, magazines, and the internet; this should be assessed in a future study. In a recent commentary, Grumbach (28) suggested a Bauhaus Delivery Systems Principles approach for re-designing the health-care delivery system: all health-care workers should function at their maximum level of training and skill with genuine teamwork. In this regard, the guidelines for the certification of ERS Spirometry training programs should be noted by internationally recognized educational documents and activities, and we consider that similar guidelines are urgently needed in Japan (29). This is also true of the management of COPD in terms of prevention, early diagnosis, or treatment, and suggests the usefulness of a strategy that increases the skill level of all health workers associated with COPD management.

In conclusion, in this study, mass screening for COPD was highly influenced by the quality of examiners even when the subjects had respiratory symptoms. Thus, we recommend caution when screening for the early signs of COPD during health check-ups.

Human Investigations were performed after approval by the Institutional Human Investigations Committee, and in Accordance with the declaration of Helsinki.

Author’s disclosure of potential Conflicts of Interest (COI).
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