

## **Detection of Airflow Limitation Using the 11-Q and Pulmonary Function Tests**

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## **ABSTRACT**

**Objective** To investigate whether chronic obstructive pulmonary disease (COPD) screening that combines screening with questionnaires and pulmonary function testing is a useful method for the early detection of COPD.

**Methods** A total of 3,367 subjects over 50 years of age underwent COPD screening. Two thousand five hundred and seventy-two of these subjects underwent “Ningen Dock” (a Japanese-English term for annual health checkup) examinations, regularly-scheduled check-ups or screenings in outpatient clinics. Of these subjects, 795 lived in one city and one town in Nagasaki Prefecture and exhibited a score of at least 5 points on the Eleven-item pre-interview questionnaire (11-Q). The prevalence of airflow limitation in each type of examination was calculated for each gender, and the odds ratios of airflow limitation with each type of examination were obtained using the subjects who underwent “Ningen Dock” examinations as the reference group.

**Results** The COPD prevalence was 6.5% in the “Ningen Dock” group (7.9% men, 1.8% women), 5.8% in the regularly-scheduled checkup group (7.4% men, 4.1% women), 9.8% in the screening in outpatient clinics group (12.1% men, 7.2% women) and 22.3% in the COPD screening group (31.1% men, 8.1% women), with the COPD screening group showing the highest prevalence. The odds ratios of the COPD prevalence confirmed that COPD screening is more effective for identifying airflow limitation than other types of examinations.

**Conclusions** Conducting COPD screening with questionnaires and pulmonary function testing among the general population is a useful examination method for the early detection and treatment of COPD.

**Key words**

COPD, prevalence, eleven-item pre-interview questionnaire (11-Q), screening

## **Introduction**

The incidence of chronic obstructive pulmonary disease (COPD) is increasing worldwide. COPD is estimated to become the 3rd leading global cause of death by 2020 (1) and is of major economic concern. However, COPD is preventable and treatable; therefore, the importance of early detection and treatment has been emphasized (2). Many epidemiological studies have been conducted to determine the prevalence of COPD (3-5). In Japan, a large-scale epidemiological study that utilized a questionnaire (the Nippon COPD Epidemiology [NICE] study) (6) reported that 10.6% of the subjects exhibited airflow limitation and at least 8.6% were thought to have COPD, thus suggesting that the prevalence of COPD in Japan is similar to that observed in other foreign countries.

COPD epidemiology research has been conducted in various populations such as outpatients, the general public and people who undergo health examinations. In a British health survey of the general public, the prevalence of COPD was 13.3% (7). The prevalence of COPD in workers commuting to a health prevention center was 7.5% in a study by Roche et al. (8). In a study by Yawn et al. (9) of an outpatient population, the prevalence of COPD was 26%. In Japan, the prevalence of COPD among outpatients was 10.3% in a study by Minakata et al. (10), while the prevalence of COPD at regularly-scheduled check-ups was 7.0% in a study by Omori et al. (11).

Because the implementation rate of pulmonary function testing, which is essential for the diagnosis of COPD, is low, questionnaires based on symptoms have been developed to screen outpatients for the early detection of COPD. Sichletidis et al. (12) proposed that the combined use of pulmonary function testing and an International Primary Care Airways Guidelines (IPAG) questionnaire is useful for the early diagnosis of COPD.

Kida et al. (13) also reported that the Eleven-item pre-interview questionnaire (11-Q) is useful for predicting COPD.

Various types of examinations have been used for the early detection of COPD, resulting in different prevalence rates. It is unknown which type of examination is most effective for the early detection of COPD.

The purpose of this study was to identify which type of examination among “Ningen Dock” examinations, regularly-scheduled check-ups, screening in outpatient clinics and COPD screening is the most useful screening method for the early detection of COPD.

## **Materials and Methods**

### **Subjects**

For the “Ningen Dock” examinations, regularly-scheduled check-ups and screening in outpatient clinics, a retrospective epidemiological survey was performed in 4,135 subjects who attended one of 17 hospitals in Saitama, Ibaraki, Shiga, Kyoto, Osaka, Kagoshima or Okinawa between February and March of 2008.

For COPD screening, 795 subjects (488 men, 307 women) among the residents of one city and one town in Nagasaki Prefecture who were 50 years of age or older with a score of at least 5 points on the 11-Q, were enrolled during 2006 and 2007.

A diagnosis of airflow limitation was made when the forced expiratory volume in one second (FEV<sub>1</sub>)/forced vital capacity (FVC) ratio was 70% or less. The staging of the disease was divided into stages I to IV based on the GOLD criteria (2).

### **Definitions of the examinations**

“Ningen Dock”: This is a voluntary health examination in which many tests are

conducted with the aim of achieving early detection and early treatment of disease in addition to disease prevention.

Regularly-scheduled checkup: This is a compulsory health examination for all employees and is required by the Industrial Safety and Health Law. An annual examination is obligatory.

Screening in outpatient clinics: This screening method utilizes pulmonary function testing in patients who have not been diagnosed with respiratory disease and who are attending hospital outpatient clinics for the management of other chronic conditions.

COPD screening: This is a test protocol that determines those at risk for COPD by conducting pulmonary function testing in individuals who score 5 points or more on the 11-Q completed by all residents 50 years of age or older in a specified region.

## **Measurements**

The 11-Q was used for COPD screening. It consists of 11 items, including smoking status, age, cough, phlegm and shortness of breath. A score of 5 points was used as the cutoff value, and people scoring 5 points or more were identified as subjects for COPD screening (13).

Age and smoking status were ascertained by questioning. Smoking status was defined according to the Brinkman Index (BI) divided into seven classes (BI less than 200 (score 0), BI 200–400 (score 1), BI 401–600 (score 2), BI 601–800 (score 3), BI 801–1,000 (score 4), BI 1,001–1,200 (score 5), BI 1,201–1,600 (score 6), BI over 1,601 (score 7)) and smoking history (lifetime nonsmoker, current smoker, ex-smoker). The FEV<sub>1</sub> and FVC were measured and used to calculate the FEV<sub>1</sub>/FVC ratio. Spirometry was conducted by clinical technologists and physiotherapists in the screening facilities

using equipment that satisfied the medical equipment standard of the Japanese Respiratory Society. The best of three technically correct maneuvers was taken as the measured value. Reversibility testing with inhaled bronchodilators was not performed due to the screening.

### **Statistics**

Comparisons of age, FVC, FEV<sub>1</sub> and the FEV<sub>1</sub>/FVC ratio in each type of examination were made using one-way analyses of variance followed by Scheffe's post-hoc tests. The Kruskal-Wallis test was performed to investigate differences in smoking status. The chi-square test was performed to investigate differences in GOLD stage with respect to the four types of examinations.

The ratio of subjects with airflow limitation determined according to age and all medical examinations was used to calculate the prevalence of airflow limitation. A multivariate logistic regression analysis was conducted with the presence of airflow limitation as the dependent variable and the type of screening ("Ningen Dock", regularly-scheduled check-up, screening in outpatient clinics, COPD screening) as well as age as the explanatory variables. The odds ratio of airflow limitation for each type of examination was obtained with "Ningen Dock" as the reference, when corrected by sex, age and smoking status.

The analyses were performed separately for men and women. A probability (p) value of < 0.05 was considered to be significant.

### **Results**

A flow-chart of the study subjects who underwent "Ningen Dock" examinations,

regularly-scheduled checkups and screening in outpatient clinics is shown in Figure 1. Ultimately, 2,572 subjects (1,581 men, 991 women) were deemed eligible for this study. The gender distribution was as follows: 941 subjects (721 men, 220 women) in the “Ningen Dock” group, 1,457 subjects (769 men, 688 women) in the regularly-scheduled checkup group and 174 subjects (91 men, 83 women) in the screening in outpatient clinics group.

A flow-chart of the study subjects who underwent COPD screening using the 11-Q is shown in Figure 2. Regarding COPD screening, the total number of subjects over 50 years of age was 12,013. Of the 6,136 subjects who responded to the 11-Q, the numbers of subjects who scored less than 5 points on the 11-Q or had missing data were 3,830 and 12, respectively. Of the 2,294 subjects with an 11-Q score of 5 points or more, 804 underwent COPD screening. Ultimately, 795 subjects (488 men, 307 women) were deemed eligible, excluding one person of age unknown and eight people who did not perform spirometry (Figure 2).

Table 1 shows the characteristics of the subjects. The percentages of men and women over 60 years of age for the four types of examinations were 35.8% and 21.8% in the “Ningen Dock” group, 55% and 49.7% in the regularly-scheduled checkup group, 67.1% and 68.6% in the screening in outpatient clinics group and 72.6% and 76.9% in the COPD screening group, respectively.

Table 2 shows the smoking status and smoking history according to the type of examination. The COPD screening group exhibited the highest smoking status among men. The “Ningen Dock” group contained the highest number of current smokers (men: 83.4%, women: 43.2%). Among men, the “Ningen Dock” group had the highest ratio of people with a smoking history, including smokers and former smokers at 90.8%,

followed by the COPD screening group at 82.3%, the screening in outpatient clinics group at 81.3% and the regularly-scheduled checkup group at 69.1%. The proportion of men smokers (current or former) was significantly higher than that of women smokers in all types of examinations (the gender ratios of the subjects were as follows: “Ningen Dock”: 90.8%/46.4%, regularly-scheduled checkup: 69.1%/19.2%, screening in outpatient clinics: 81.3%/21.7%, COPD screening: 82.3%/15.0%,  $p < 0.0001$ ).

Table 3 shows the prevalence of airflow limitation and the odds ratios for airflow limitation according to the type of examination. The COPD screening group had the highest prevalence of airflow limitation among men at 31.1%. Furthermore, the prevalence of airflow limitation increased in association with age in men. The COPD screening group had the highest odds ratio for airflow limitation in men (OR: 2.469; 95% CI: 1.714 – 3.555). The odds ratios for the ages of the men and women were 1.090 (CI: 1.072 – 1.108) and 1.057 (CI: 1.028 -1.088), respectively, and the odds ratio for the smoking status of men was 1.163 (CI: 1.091 – 1.240). Among women, no statistical significance regarding the odds ratios for COPD was observed in items other than age.

According to the COPD severity determined based on the GOLD stage, the percentage of stage I-II subjects tended to be higher than the percentage of stage III-IV subjects in the COPD screening group for men (Table 4).

## **Discussion**

The present study showed that detection of any airflow limitations using both the 11-Q and pulmonary function tests is the most useful type of COPD screening in patients 50 years of age or older. Even after the detection rate was corrected for sex, age and smoking habits, the method using both the 11-Q and pulmonary function testing had

a higher probability of successfully screening for airflow limitations compared with the other types of examinations. COPD screening was especially useful in elderly people and people with a high smoking status. Indeed, the number of people 60 years or older accounted for over 70% of all subjects in the COPD screening group (men: 72.6%, women: 76.9%). This study indicated that the prevalence of COPD is highest among people in their sixties, seventies and eighties, consistent with the fact that the prevalence of COPD increases with age (6, 14, 15).

The men in the COPD screening group exhibited the highest prevalence of COPD among the four groups. These subjects also had a high risk for COPD caused by smoking. Miravittles et al. and Zhone et al. (14, 15) reported that the prevalence of COPD is high among people with a high smoking index. In the present study, the smoking status was associated with detection of airflow limitation. Although the smoking history in the Ningen Dock group was the highest among the four groups, the prevalence of airflow limitation was low in both men and women. It may be that the subjects in this group were younger than those in the other groups. Conversely, many elderly subjects with a smoking history were included in the COPD screening group, thus resulting in a higher rate of detection of airflow limitation. Therefore, the rate of detection of airflow limitation may be associated with age and smoking status rather than smoking history.

That the percentage of people with GOLD stage I-II disease tended to be higher than the percentage of people with stage III-IV disease in the COPD screening of men indicates that COPD screening may contribute to the early detection of COPD.

We identified the advantages and disadvantages of each of the four types of examinations. The “Ningen Dock” examination is a common type of examination for

people in their fifties in Japan, although it is optional. However, because the rate of smoking was high among subjects completing the regularly-scheduled checkups, this examination may be effective in detecting people at risk for COPD. Annual screening is obligatory during regularly-scheduled checkups; therefore, continuous screening of individuals is possible. Screening in outpatient clinics is limited to people with symptoms and/or underlying diseases. However, since COPD is a major comorbidity in subjects with underlying diseases, screening in outpatient clinics may be effective for identifying COPD. It is important to realize that COPD can be detected with any screening method when clinicians are aware of the high prevalence of the disease. We considered that COPD screening involving a questionnaire that includes the two items of smoking and respiratory distress as risk factors for COPD may effectively detect latent COPD. Reversibility tests with bronchodilators were not performed in this study. Therefore, subjects with an FEV<sub>1</sub>/FVC ratio < 70% in the screening may have included those with diseases other than COPD that are characterized by airflow limitation.

COPD screening does not lead to a definitive diagnosis of COPD; however, it is important to identify people at risk for COPD among a wide range of community residents and to encourage such persons to consult specialists in pulmonary medicine. Although COPD screening requires time and expense, it can detect people at risk for COPD and lead to early diagnoses. Early diagnosis promotes early intervention before the burden of COPD on society becomes significant. Therefore, COPD screening may ultimately help to reduce the burden of COPD on society.

We conclude that the COPD screening examination is an effective method leading to the early diagnosis of COPD. Furthermore, the 11-Q can serve as a first screening to identify people at risk for COPD among a wide range of community residents.

A limitation associated with the present study is the presence of some selection bias because the subjects were not randomly selected. Additionally, reversibility testing was not conducted, which may have led to an overestimation of the prevalence of airflow limitation due to COPD. With respect to women, the number of subjects receiving any form of examination was small. Therefore, no statistical significance was observed in the odds ratios for airflow limitation for variables other than age.

### **Conclusion**

When comparing the prevalence of airflow limitation in subjects undergoing various types of examinations in this study, we found that the prevalence of COPD was highest in the COPD screening examinations. COPD screening, which incorporates the use of the 11-Q questionnaire, may selectively identify people at risk for COPD by providing questionnaires to a wide range of community residents and recruiting them as subjects for additional screening with pulmonary function testing. Accordingly, COPD screening is a type of examination that may be effectively used for the early detection of COPD.

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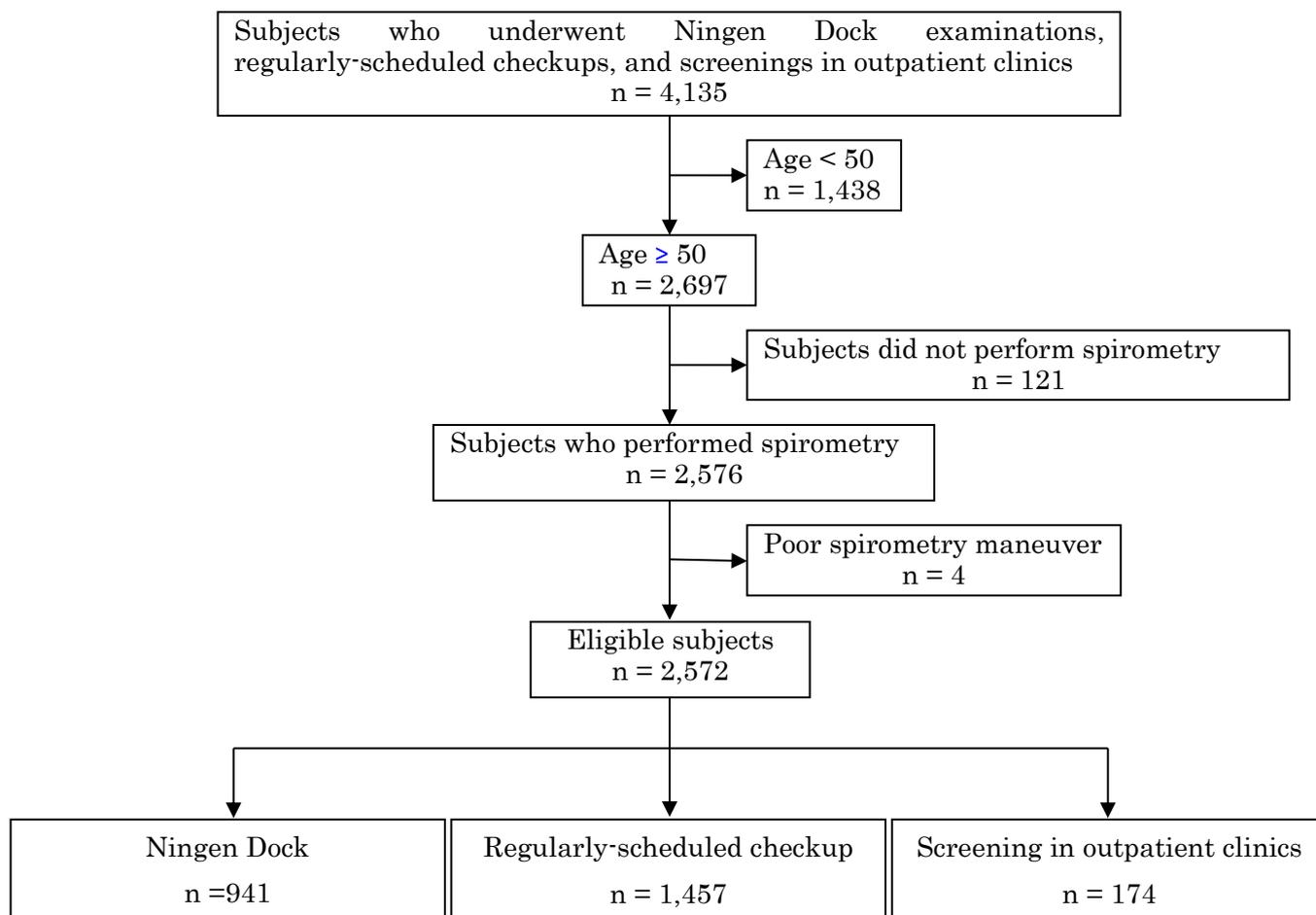


Figure 1. Flow-chart of the study subjects who underwent Ningen Dock examinations, regularly-scheduled checkups, and screenings in outpatient clinics.

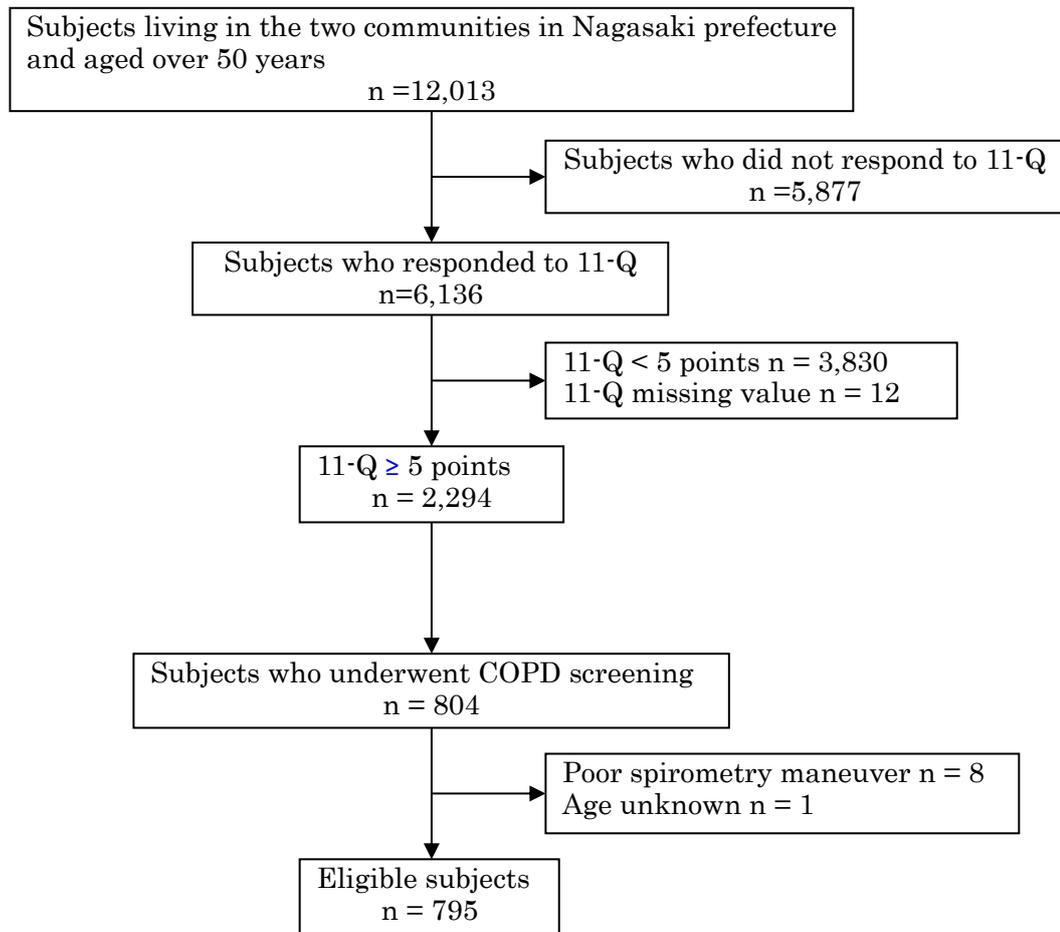


Figure 2. Flow-chart of the study subjects in the COPD screening using the 11-Q.

Table 1. Characteristics of the subjects

		Ningen Dock	Regularly-scheduled checkup	Screening in outpatient clinics	COPD screening	Total	
Men	n	721	769	91	488	2,069	
	Age	Mean(SD)	58.7±7.0 <sup>***</sup>	60.9±8.9 <sup>***,†</sup>	60.7±9.0 <sup>***</sup>	66.1±8.5	61.3±8.6
	50-59	n(%)	463(64.2)	346(45.0)	30(33.0)	134(27.5)	973(46.0)
	60-69	n(%)	181(25.1)	270(35.1)	27(29.7)	156(32.0)	634(30.6)
	70-79	n(%)	72(10.0)	125(16.3)	33(36.3)	177(36.3)	407(19.7)
	≥80	n(%)	5(0.7)	28(3.6)	1(1.1)	21(4.3)	55(2.7)
	≥60	n(%)	258(35.8)	423(55.0)	61(67.1)	354(72.6)	1096(53.0)
	FVC	(l)	3.51±0.65 <sup>***</sup>	3.24±0.7 <sup>*,†</sup>	3.17±0.78 <sup>†</sup>	3.13±0.73	3.30±0.71
	FEV <sub>1</sub>	(l)	2.80±0.59 <sup>***</sup>	2.65±0.6 <sup>***,†</sup>	2.55±0.75 <sup>***,‡</sup>	2.30±0.68	2.61±0.65
	FEV <sub>1</sub> /FVC	(%)	79.7±7.5 <sup>***</sup>	81.9±8.8 <sup>***,†</sup>	80.1±12.4 <sup>***</sup>	72.7±11.6	78.9±10.0
Women	n	220	688	83	307	1,298	
	Age	Mean(SD)	56.3±5.3 <sup>***</sup>	60.3±9.5 <sup>***,†</sup>	60.2±8.4 <sup>***,‡</sup>	66.5±8.0	61.1±9.2
	50-59	n(%)	172(78.2)	346(50.3)	26(31.3)	71(23.1)	615(47.4)
	60-69	n(%)	42(19.1)	203(29.5)	31(37.3)	108(35.2)	384(29.6)
	70-79	n(%)	6(2.7)	109(15.8)	24(28.9)	121(39.4)	260(20.0)
	≥80	n(%)	0(0.0)	30(4.4)	2(2.4)	7(2.3)	39(3.0)
	≥60	n(%)	48(21.8)	342(49.7)	57(68.6)	236(76.9)	683(52.6)
	FVC	(l)	2.64±0.48 <sup>***</sup>	2.30±0.52 <sup>***,†</sup>	2.41±0.59 <sup>***,‡</sup>	2.13±0.53	2.32±0.55
	FEV <sub>1</sub>	(l)	2.19±0.41 <sup>***</sup>	1.91±0.45 <sup>***,†</sup>	1.93±0.47 <sup>***,‡</sup>	1.70±0.44	1.91±0.47
	FEV <sub>1</sub> /FVC	(%)	83.0±5.5 <sup>***</sup>	83.6±7.8 <sup>***</sup>	80.1±7.7 <sup>§,¶</sup>	80.0±7.5	82.4±7.5

Data are mean (SD) or number (%) of subjects.

FEV<sub>1</sub>: forced expiratory volume in one second

FVC: forced vital capacity

\*\*\* p<0.0001, \*\* p<0.01, \* p<0.05 in comparisons versus COPD screening

†p<0.0001, ‡ p<0.01, §p<0.05 in comparisons versus Ningen Dock

¶ p<0.01 in comparisons versus regularly-scheduled checkup

Table 2. Smoking status and smoking history of the subjects

		Ningen Dock	Regularly-scheduled checkup	Screening in outpatient clinics	COPD screening	Total	
Men	Smoking status	2.04±1.81 <sup>***</sup>	1.97±2.15 <sup>***</sup>	2.66±0.91 <sup>**¶</sup>	3.48±2.13	2.38±2.13	
	Smoking history	Never smoker	67(9.3)	238(30.9)	17(18.7)	36(7.4)	358(17.3)
		Current smoker	601(83.4)	516(67.1)	67(73.6)	252(51.6)	1,436(69.4)
		Former smoker	53(7.4)	15(2.0)	7(7.7)	150(30.7)	225(10.9)
		Unknown	0(0)	0(0)	0(0)	50(10.2)	50(2.4)
Women	Smoking status	0.38±0.86 <sup>†</sup>	0.24±0.82	0.31±0.91	0.39±1.13	0.31±0.92	
	Smoking history	Never smoker	118(53.6)	556(80.8)	65(78.3)	231(75.2)	970(74.7)
		Current smoker	95(43.2)	130(18.9)	17(20.5)	34(11.1)	276(21.3)
		Former smoker	7(3.2)	2(0.3)	1(1.2)	12(3.9)	22(1.7)
		Unknown	0(0)	0(0)	0(0)	30(9.8)	30(2.3)

Data of smoking status are mean ± SD and data of smoking history are numbers (%) of subjects grouped according to smoking status for the four types of examination (Ningen Dock, regularly-scheduled checkup, Screening in outpatient clinics, and COPD screening).

Smoking status: BI less than 200 (score 0), BI 200–400 (score 1), BI 401–600 (score 2), BI 601–800 (score 3), BI 801–1000 (score 4), BI 1001–1200 (score 5), BI 1201–1600 (score 6), BI over 1601 (score 7)

“Unknown” indicates number of the subjects who did not provide data on smoking status.

\*\*\* p<0.0001, \*\* p<0.01 in comparisons versus COPD screening

†p<0.0001, ¶ p<0.01 in comparisons versus regularly-scheduled checkup

Table 3. COPD prevalence and odds ratio of four screening types

Type of screening		No airflow limitation (n)	Airflow limitation (n)	Prevalence of airflow limitation (%)	Odds ratio	95% confidence interval	p value
Men	Ningen Dock	664	57	7.9	1.000	reference	—
	Regularly-scheduled checkup	712	57	7.4	0.701	0.470 - 1.046	0.082
	Screening in outpatient clinics	80	11	12.1	1.132	0.552 - 2.324	0.735
	COPD screening	336	152	31.1	2.469	1.714 - 3.555	< 0.0001
	Smoking Status	—	—	—	1.163	1.091 - 1.240	< 0.0001
	Age	—	—	—	1.090	1.072 - 1.108	< 0.0001
	50-59	921	52	5.3	—	—	—
	60-69	549	85	13.4	—	—	—
	70-79	286	121	29.7	—	—	—
	≥80	36	19	34.5	—	—	—
Women	Ningen Dock	216	4	1.8	1.000	reference	—
	Regularly-scheduled checkup	660	28	4.1	1.673	0.567 - 4.940	0.351
	Screening in outpatient clinics	77	6	7.2	3.233	0.876 - 11.933	0.078
	COPD screening	282	25	8.1	2.611	0.853 - 7.995	0.093
	Smoking Status	—	—	—	1.055	0.821 - 1.356	0.674
	Age	—	—	—	1.057	1.028 - 1.088	< 0.0001
	50-59	599	16	2.6	—	—	—
	60-69	369	15	3.9	—	—	—
	70-79	231	29	11.2	—	—	—
	≥80	36	3	7.7	—	—	—

Men ( $\chi^2=175.238$ ,  $df=3$ ,  $p<0.0001$ ), Women ( $\chi^2=13.513$ ,  $df=3$ ,  $p=0.004$ ) in four types of examination

Men ( $\chi^2=169.257$ ,  $df=3$ ,  $p<0.0001$ ), Women ( $\chi^2=30.528$ ,  $df=3$ ,  $p<0.0001$ ) by age

Table 4. Spirometric classification of COPD severity

		Ningen Dock	Regularly-scheduled checkup	Screening in outpatient clinics	COPD screening	Total
Men	n	721	769	91	488	2,069
	Stage I-II	47(6.5)	49(6.4)	6(6.6)	113(23.2)	215(10.4)
	Stage III-IV	10(1.4)	8(1.0)	5(5.5)	39(8.0)	62(3.0)
Women	n	220	688	83	307	1,298
	Stage I-II	2(0.9)	5(0.7)	3(3.6)	8(2.6)	18(1.4)
	Stage III-IV	2(0.9)	23(3.3)	3(3.6)	17(5.5)	45(3.5)

Data are number (%) of Spirometric Classification of COPD Severity for the four types of examination (Ningen Dock, Regularly-scheduled checkup, screening in outpatient clinics, and COPD screening)

Stage I:  $FEV_1 \geq 80\%$  predicted

Stage II:  $50\% \leq FEV_1 < 80\%$  predicted

Stage III:  $30\% \leq FEV_1 < 50\%$  predicted

Stage IV:  $FEV_1 < 30\%$  predicted

Men ( $\chi^2=7.363$ ,  $df=3$ ,  $p=0.061$ ), Women ( $\chi^2=3.969$ ,  $df=3$ ,  $p=0.265$ )