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ORIGINAL RESEARCH

Case Identification of Subjects with Airflow Limitations Using the Handheld Spirometer "Hi-Checker^{TM}": Comparison Against an Electronic Desktop Spirometer

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Background: **Systematic case identification has been proposed as a strategy to improve diagnosis rates and to enable the early detection of subjects with COPD. We hypothesized that case identification could be possible using the handheld spirometer Hi-Checker™.** ***Aim:*** **To determine how to modify the FEV_1/FEV_6 values obtained using the Hi-Checker™ to screen for cases with airflow limitation.** ***Methods:*** **Spirometry was performed with both an electronic desktop spirometer and with the Hi-Checker™ in 312 male subjects.** ***Results:*** **The average FEV_1 (mean ± SD) measured using a conventional spirometer and the Hi-Checker™ was 2.99 ± 0.56L and 3.07 ± 0.57L, respectively. These results were significantly different ($P<0.001$, paired t-test for both). This difference of −0.08 ± 0.13L (95% confidence interval: −0.094–0.066L) was normally distributed, and thought to be random. Statistically significant correlations were found for all measurements between the spirometer and the Hi-Checker™; the Pearson's correlation coefficient (R) between the FEV_1/FVC and FEV_1/FEV_6 values was 0.881. If one defines a FEV_1/FVC smaller than 0.7 measured by the spirometer as airflow limitation, then a FEV_1/FEV_6 smaller than 0.746 measured by the Hi-Checker™ best matches this definition, and Cohen's kappa coefficient was 0.672.** ***Conclusion:*** **Although the Hi-Checker ™ estimates resembled those from conventional spirometry, it should be emphasized that the two methods did not produce identical results due to random measurement error. Although one must be careful about overinterpreting these results, since the Hi-Checker ™ is small and inexpensive, it could make a significant contribution in facilitating the case selection of patients with airflow limitation.**

Keywords: chronic obstructive pulmonary disease, spirometry, handheld spirometers, Hi-Checker™, forced expiratory volume in 6 seconds

BACKGROUND

COPD (chronic obstructive pulmonary disease) is defined by airflow limitation (also known as airway obstruction) measured using spirometry. Therefore, spirometry is essential to making a diagnosis of COPD (1). In meta-analyses regarding the prevalence of COPD, a forced expiratory volume in 1 second (FEV_1) / forced vital capacity (FVC) <0.7, as proposed by the GOLD (Global Initiative for Chronic Obstructive Lung Disease) as the criteria for airflow limitation, is most often used. Using this standard, an incidence of approximately 9–10% for COPD in adults 40 years or older has been reported (2). In Japan, the Nippon COPD Epidemiology (NICE) Study was performed in 2000, and the incidence of COPD using a similar definition was 8.5% (3). In the NICE study, 57% of asymptomatic subjects had a diagnosis of COPD, and COPD was not correctly diagnosed in 90% of these cases. COPD remains significantly under-diagnosed, with the diagnosis commonly missed or delayed until the disease is advanced.

Screening is essential if we are to identify the millions of undiagnosed COPD cases and begin treating them effectively. Targeted, systematic case-identification has been proposed as a strategy to improve the diagnosis rates and to enable early detection and management, including aggressive smoking cessation efforts. Two methods have been reported for targeted case identification screening to reduce the burden of COPD. One is screening with specific questionnaires (4, 5), and the other is using a portable device called a handheld spirometer instead of standard spirometers (6). Soriano et al. (7) and Price et al. (8) advocated the concept of case-identification spirometry to exclude those subjects with symptoms but normal lung function, and identify those who require a more complete

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Abbreviations: COPD: chronic obstructive pulmonary disease; FEV_1: forced expiratory volume in 1 second; FVC: forced vital capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; NICE: Nippon COPD Epidemiology; FEV_6: forced expiratory volume in 6 seconds; LLN: lower limit of normal; ROC: receiver operating characteristic.

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Figure 1. Photograph of the Hi-Checker™. The unit is 113 mm × 63 mm × 48 mm. It weighs 55 g and uses 2 AAA batteries as its power source.

investigation for COPD, including standard diagnostic spirometry. Previously, there were two kinds of spirometers: rolling seal and electronic desktop spirometers, and these are referred to as "conventional spirometers" hereafter. Recently, handheld spirometers which are small, inexpensive and portable but do not have the capability to print have become available (9, 10). The objectives of handheld spirometry performed for case identification are to exclude those with normal lung function, and to identify those who require a more complete investigation for COPD. These devices do not replace conventional spirometry performed for the purpose of achieving a definitive diagnosis. Standard diagnostic spirometry must still be performed according to internationally accepted standards set by the European Respiratory Society (ERS) and the American Thoracic Society (ATS) (10, 11).

One handheld device is manufactured by Vitalograph, and is sold as the Hi-Checker™ by Takara Tsusho Co. Ltd. in Japan (Figure 1). It is a simple handheld spirometer, and is quick and easy to use as a motivational tool for smoking intervention by healthcare professionals. The Hi-Checker™ measures the FEV_1, forced expiratory volume in 6 seconds (FEV_6) and the ratio of the FEV_1 to the FEV_6 (FEV_1/FEV_6). It also compares a subject's FEV_1 with the predicted normal values to calculate the subject's 'lung age'. Because the FVC cannot be measured with this device, we measured the FEV_6 instead as a substitute, and used it as an index of airflow limitation.

We hypothesized that the case identification of subjects with airflow limitation may be possible using the Hi-Checker™. The purpose of the present study was to investigate whether the levels measured by the Hi-Checker™ were accurate, and to determine how to modify the FEV_1/FEV_6 values obtained using the Hi-Checker™ to screen for patients with airflow limitation. There are two definitions of airflow limitation using the FEV_1/FVC measured using conventional spirometers: a fixed ratio of the $FEV_1/FVC < 70\%$, and the lower limit of normal (LLN) definition. Because there has been some debate as to the better definition of airflow limitation (12, 13), we evaluated both definitions in this study.

MATERIALS AND METHODS

Subjects

A total of 312 male subjects were included in the present study. All underwent a comprehensive health screening between May and July 2010 at the Niigata Association of Occupational Health Incorporated, Niigata, Japan. They were healthy industrial workers who underwent annual health checks at this Association. We divided the subjects into subgroups with an average of ten in each (minimum of 3, maximum of 15) for 31 days and performed the experiments. In this study, the patients' history of smoking, illness, and other clinical information was not recorded, and there were no specific inclusion criteria. Written informed consent was obtained from all participants.

Methods

Initially, spirometry was performed with a Spiro Sift sp-470TM Spirometer (Fukuda Denshi Co., Ltd., Tokyo, Japan) until three acceptable forced expiratory curves were obtained in the standing position. Thereafter, each subject blew into a handheld spirometer (Hi-Checker™) 3 times while in the standing position. All measurements were performed by a laboratory technician (A.K.) in accordance with guidelines published by the Japanese Respiratory Society. The spirometric FVC and FEV_1 values were obtained from a single curve that yielded the largest sum of the FVC plus FEV_1. The patients pinched their nostrils without the use of nose clips. The predicted values for pulmonary function and the lung age were calculated based on the proposal from the Japanese Respiratory Society (14).

Statistics

The degree of difference in the FEV_1 values obtained using the conventional spirometer and the Hi-Checker™, as well as the difference between the FVC values obtained from the conventional spirometer and the FEV_6 obtained from the Hi-Checker™, were evaluated by histograms and the Shapiro-Wilk test. The differences between the FEV_1 values as well as between the FVC and FEV_6 were assessed with a paired t-test. The correlation between the two sets of data obtained from conventional spirometry and the Hi-Checker™ was determined by their Pearson's correlation coefficients. When we examined the degree to which the diagnoses were in agreement using the two different sets of criteria, we calculated and compared Cohen's kappa coefficient (15). The significance level of all analyses was set at $p < 0.05$.

RESULTS

A total of 312 male subjects participated in the present study. The distribution of the lung function indices measured by conventional spirometry is shown in Table 1. The average age of the subjects was 55.0 years. The FEV_1/FVC ratio used as an index of airflow limitation ranged from 55.6% to 89.2% with a mean of 75.9%. In 48 out of 312 patients (15.4%), the

Table 1. Distribution of ages and results of pulmonary function testing measured by conventional spirometry and by the Hi-Checker™ in 312 male subjects

		Mean	SD	Median	Minimum	Maximum	LLN
Age (years)		55.0	9.4	55.0	33.0	82.0	39.0
FVC (L)	Conventional spirometry	3.94	0.63	3.96	2.03	5.53	2.98
FEV_6 (L)	Hi-Checker™	3.87	0.64	3.91	1.76	5.56	2.84
FEV_1 (L)	Conventional spirometry	2.99	0.56	2.99	1.18	4.51	2.12
FEV_1 (L)	Hi-Checker™	3.07	0.57	3.07	1.17	4.57	2.17
FEV_1 (%pred)	Conventional spirometry	89.3	11.0	89.3	63.2	124.4	71.4
FEV_1 (%pred)	Hi-Checker™	91.7	11.5	91.8	62.4	132.7	72.3
FEV_1/FVC (%)	Conventional spirometry	75.9	6.0	76.3	55.6	89.2	65.0
FEV_1/FEV_6 (%)	Hi-Checker™	79.5	6.4	79.3	60.5	93.5	68.9

FEV_1/FVC was lower than 70%. The LLN of the FEV_1/FVC in all participating patients (5th percentile) was 65.0%.

Because the differences between the FEV_1 values measured by conventional spirometry and the Hi-Checker™, as well as the differences between the FVC and FEV_6 values were normally distributed (using the Shapiro-Wilk tests, $P = 0.200$ and $P = 0.534$, respectively), these differences must have been generated at random. The mean ± SD values for the FEV_1 and FVC measured by conventional spirometry were 2.99 L ± 0.56 L and 3.94 L ± 0.63 L, respectively. The mean ± SD values for the FEV_1 and FEV_6 measured by the Hi-Checker™ were 3.07 L ± 0.57 L and 3.87 L ± 0.64 L, respectively. The difference in the measurements was −0.08 L ± 0.13 L (95% confidence interval [CI] : −0.094 L – −0.066L) for the FEV_1 and 0.07 L ± 0.14 L (95% CI: 0.051 –0.090 L) for the FEV_6 and FVC, respectively. The values measured by conventional spirometry and the Hi-Checker™ were significantly different (paired *t*-test, both $P<0.001$).

Statistically significant correlations were found between all measurements made by conventional spirometry and those made by the Hi-Checker™; Pearson's correlation coefficient (r) was 0.975 for FEV_1(L), 0.963 for FVC(L) and FEV_6(L), 0.958 for lung age (years), 0.944 for FEV_1(%pred), 0.881 for FEV_1/FVC(%) and FEV_1/FEV_6(%) (all P values < 0.001). The correlation between the FEV_1/FVC values measured by conventional spirometry and the FEV_1/FEV_6 values measured by the Hi-Checker™ was not as high as the correlations between other indices. This was probably because the values were quotients of the FEV_1 and FEV_6, and were affected by the combined differences between conventional spirometry and the Hi-Checker™ in FEV_1 and FEV_6.

Table 2 shows the level of agreement between the two methods in the diagnosis of airflow limitation based on the criterion of FEV_1/FVC below 0.7 for conventional spirometry and FEV_1/FEV_6 below 0.7 for the Hi-Checker™. For the 48 subjects who were determined to have airflow limitation by conventional spirometry, 22 subjects (45.8%) were determined not to have airflow limitation according to the Hi-Checker™. In other words, if we used $FEV_1/FVC < 0.7$ for conventional spirometry as the gold standard, then there is a 45.8% chance that subjects with airflow limitation would be misdiagnosed as not having airflow limitation. Cohen's kappa coefficient was 0.644. To improve the diagnostic rate, we also investigated a way to calibrate the FEV_1/FEV_6 values obtained using the Hi-Checker™ in order to set a new cut-off point.

The regression equation for the FEV_1/FEV_6 obtained by the Hi-Checker™ to predict the FEV_1/FVC values measured by conventional spirometry was $Y = 0.836\ X + 9.477$ (Y = FEV_1/FVC% from conventional spirometry, X = FEV_1/FEV_6% from the Hi-Checker™). If $FEV_1/FVC < 0.7$ from conventional spirometry is used as the gold standard for diagnosis, then the level of agreement using the calibrated $FEV_1/FEV_6<0.7$ from the Hi-Checker™ is shown in Table 3.

Using $FEV_1/FVC < 0.7$ by conventional spirometry as the definition of airflow limitation, a receiver operating characteristic (ROC) curve was analysed to set a cut-off point for the FEV_1/FEV_6 obtained using the Hi-Checker™. The area under the ROC curve was 0.953 (95% CI: 0.927 −0.980), and the sensitivity and specificity were at their maximum when the FEV_1/FEV_6 using the Hi-Checker™ was 0.746 (Figure 2). Therefore, the level of agreement for the case definition of airflow limitation using a cut-off value of 0.746 for FEV_1/FEV_6 using the Hi-Checker™ and $FEV_1/FVC < 0.7$ for conventional spirometry is shown in Table 4.

Using $FEV_1/FVC < 0.7$ as the case definition of airflow limitation, the sensitivity, specificity, accuracy, false positive

Table 2. Agreement of airflow limitation case definitions: $FEV_1/FVC < 0.7$ using conventional spirometry versus $FEV_1/FEV_6 <0.7$ using the Hi-Checker™

		$FEV_1/FVC < 0.7$ using Conventional Spirometry		
		Positive	Negative	Total
$FEV_1/FEV_6 < 0.70$ using Hi-Checker™	Positive	26	2	28
	Negative	22	262	284
	Total	48	264	312

Table 3. Agreement of airflow limitation case definitions: $FEV_1/FVC < 0.7$ using conventional spirometry versus calibrated $FEV_1/FEV_6 <0.7$ using the Hi-Checker™ with the regression equation obtained from the linear regression analysis

		$FEV_1/FVC < 0.7$ using Conventional Spirometry		
		Positive	Negative	Total
Calibrated $FEV_1/FEV_6 <$ 0.7 using Hi-Checker™	Positive	31	8	39
	Negative	17	256	273
	Total	48	264	312

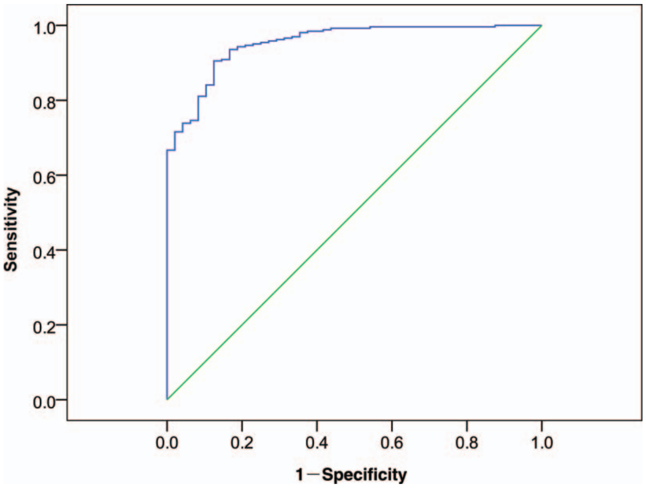

Figure 2. The receiver operating characteristic (ROC) curve that discriminates the optimal cut-off level of the FEV_1/FEV_6 measured using the Hi-Checker™.

rates, false negative rates, positive predictive values, negative predictive values, and kappa coefficients of the different raw and calibrated cut-off points were matched between conventional spirometry and the Hi-Checker™ (Table 5). The kappa coefficient was highest at 0.672 when 0.746 was used as the cut-off point for the FEV_1/FEV_6 obtained from the ROC curve.

Many researchers have argued that the LLN should be used to define airflow limitation instead of the fixed ratio of FEV_1/FVC. Although the subjects were not randomly selected in the present study, we investigated what FEV_1/FEV_6 ratio cut-off would make the diagnosis the most accurate using the LLN of the FEV_1/FVC (65.0%) as the standard (Table 1). We compared the level of agreement of the FEV_1/FVC-based definition with three different criteria: below the LLN (68.9%) of the FEV_1/FEV_6, below the LLN (67.0%) of the calibrated FEV_1/FEV_6, and below 65.0% of the calibrated FEV_1/FEV_6 measured using the Hi-Checker™ (below the LLN of the FEV_1/FVC from conventional spirometry) (Table 6). Cohen's kappa coefficient was the highest at 0.627 when the cut-off was set at the LLN of the FEV_1/FEV_6.

DISCUSSION

To our knowledge, this is the first study which proved that a handheld spirometer, the Hi-Checker™, could be used for the case identification of subjects with airflow limitation. However, it should be emphasized that these handheld spirometric measurements were not identical to measurements made by conventional spirometry due to random measurement errors. The cut-off level for the FEV_1/FEV_6 measured by the Hi-Checker™ was 74.6% accurate in identifying those subjects with airflow limitation defined as $FEV_1/FVC < 0.7$ measured by conventional spirometry. Although one must realize that this device has important limitations and avoid over-interpreting these results, since the Hi-Checker™ is small and inexpensive, it can contribute to case selection for airflow limitation.

When one considers the possibility of screening for COPD using the Hi-Checker ™, there are two important issues. First, the FVC cannot be measured by the Hi-Checker™ and thus the FEV_6 must be used as an alternative. Therefore, we must determine whether FEV_1/FEV_6 can be used for screening instead of FEV_1/FVC. The other issue is that the American Thoracic Society and European Respiratory Society have published spirometer guidelines (9–11). Although it is written in the guidelines which spirometers are acceptable, the Hi-Checker™ is relatively new, and there are insufficient published data on its accuracy.

The debate over whether to use a fixed ratio of FEV_1/FVC or the LLN to define COPD cases has continued (12, 13). The GOLD guideline recommends the former ($FEV_1/FVC < 0.7$) from a clinical standpoint rather than an epidemiological

Table 4. Agreement of airflow limitation case definitions: FEV_1/FVC <0.7 using conventional spirometry versus FEV_1/FEV_6 <0.746 using the Hi-Checker™

		$FEV_1/FVC < 0.7$ using Conventional Spirometry		
		Positive	Negative	Total
$FEV_1/FEV_6 < 0.746$ using Hi-Checker™	Positive	42	25	67
	Negative	6	239	245
	Total	48	264	312

Table 5. Using $FEV_1/FVC < 0.7$ from conventional spirometry as the case definition to compare the level of agreement of FEV_1/FEV_6 values using the Hi-Checker™

	FEV_1/FEV_6 <0.70 using Hi-Checker™	Calibrated FEV_1/FEV_6 <0.70 using Hi-Checker™	FEV_1/FEV_6 <0.746 using Hi-Checker™
Sensitivity	54.2%	64.6%	87.5%
Specificity	99.2%	97.0%	90.5%
Accuracy	92.3%	92.0%	90.1%
False Positive Rate	0.8%	3.0%	9.5%
False Negative Rate	45.8%	35.4%	12.5%
Positive Predictive Value	92.9%	79.5%	62.7%
Negative Predictive Value	92.3%	93.8%	97.6%
Kappa Coefficient	0.644	0.667	0.672

Table 6. Using below the LLN of FEV_1/FVC from conventional spirometry as the case definition to compare the level of agreement of FEV_1/FEV_6 values using the Hi-Checker™ and different criteria

FEV_1/FEV_6	< 68.9%[1]	< 67.0%[2]	< 65.0%[3]
Sensitivity	66.7%	60.0%	33.3%
Specificity	98.0%	98.0%	100.0%
Accuracy	96.5%	96.2%	96.8%
False Positive Rate	2.0%	2.0%	0.0%
False Negative Rate	33.3%	40.0%	66.7%
Kappa Coefficient	0.627	0.580	0.488

1Below the LLN of FEV_1/FEV_6 measured using the Hi-Checker™
2Below the LLN of FEV_1/FEV_6 measured using the Hi-Checker™ calibrated with the regression equation obtained from the linear regression analysis.
3Below 65.0% of the calibrated FEV_1/FEV_6 measured using the Hi-Checker™ (below the LLN of FEV_1/FVC from conventional spirometry).

one (1). Historically, it has been the index most often used. However, airflow limitation in the elderly has been reported to be over-diagnosed when the fixed ratio of FEV_1/FVC was used. Further discussion on which definition should be used depending on the background and environment is necessary.

Swanney et al. first reported in 2000 that the FEV_6 is an accurate and reliable alternative to the FVC for diagnosing airway obstruction measured by dry rolling seal spirometers (16). A meta-analysis conducted by Jing et al. concluded that the FEV_6 obtained by conventional spirometry can be used as an alternative airflow limitation index (17). Vandevoorde et al. demonstrated that FEV_1/ FEV_6 <73% can be used as a valid alternative to FEV_1/FVC < 70% for the detection of obstruction (18). Melbye et al. also reported that the value for the FEV_1/FEV_6 ratio which best predicted a FEV_1/FVC ratio of 70% was 73%, and that very good agreement was found between these two cut-off values (19).

On the other hand, Rosa et al. reported that when using FEV_1/FVC <0.70, the cut-off point for the FEV_1/FEV_6 ratio with the highest sum for sensitivity and specificity was 0.75 (20). However, these studies were performed with conventional spirometers. Since we used the Hi-Checker ™, a handheld spirometer, in the current study, we cannot blindly extrapolate these values from the literature to our study. The best cut-off point for FEV_1/ FEV_6 determined in the present study was 74.6%, which is almost identical to the cut-off point found in the study by Rosa et al. that used a conventional spirometer. Although there is a study that reported reasonable diagnostic accuracy using the same 0.7 cut-off point for both FEV_1/ FEV_6 and FEV_1/FVC (16), a more accurate diagnosis may be possible if a cut-off point higher than 0.7 is used for FEV_1/FEV_6, as was also shown in the present study.

In 2011, there were two studies on the validity of the PiKo-6™, a handheld expiratory flow meter (21, 22). Frith et al. reported that a FEV_1/FEV_6 cut-off < 0.75 provided optimal sensitivity (81%) and specificity (71%) for COPD screening (21). Sichletidis et al. reported that the International Primary Care Airways Guidelines questionnaire and the PiKo-6™ spirometer can be used in combination to increase the possibility of an early and accurate diagnosis of COPD (22). However, unfortunately, the measurement properties of the PiKo-6™ flow meter have not been fully examined.

The FEV_1 measured by the Hi-Checker™ was, on average, 0.08 L higher than the FEV_1 measured by conventional spirometry. The FEV_1 measured by the Hi-Checker ™ was statistically significantly greater than the FEV_1 measured by conventional spirometry, and the differences were normally distributed. Although it is thought that these differences are simply random based on the normal distribution of the differences, they may in fact represent a consistent error in measurement due to the mechanical properties of the Hi-Checker ™.

In this study, the order in which the Hi-Checker™ and conventional spirometry were used was not randomly assigned. The Hi-Checker™ was always used after conventional spirometry, and hence some of these errors may be due to the order of examination (a so-called learning effect) (23). However, the FVC measured by conventional spirometry was consistently and statistically larger than the FEV_6 measured by the Hi-Checker ™. Therefore, the difference between these two sets of measurements did not indicate the presence of a learning effect, and we considered that the difference was unique to the FVC and FEV_6 values themselves.

We investigated the accuracy of diagnoses made by the Hi-Checker™ assuming the diagnosis made by conventional spirometry was the gold standard. Using FEV_1/FVC < 0.7 as the case definition for airflow limitation, Cohen's kappa coefficient was 0.672 when FEV_1/FEV_6 <0.746 was used to match the cases. Using below the LLN of FEV_1/FVC as the airflow limitation case definition, the kappa coefficient was 0.627 when below the LLN of FEV_1/FEV_6 was used to match the cases. A match is generally considered good to fair when Cohen's kappa coefficient is 0.61 –0.80, and excellent when the coefficient is above 0.80 (24). Therefore, the diagnosis of airflow limitation using the Hi-Checker™ can be considered to be "good to fair" relative to the diagnosis by conventional spirometry.

A study by Melbye et al. reported that the kappa coefficient was 0.86 when the airflow limitation diagnosis made by FEV_1/ FEV_6 was compared to the diagnosis made by FEV_1/FVC using conventional spirometry (19). Cohen's kappa coefficient was 0.909 in Swanney et al.'s study (16), 0.875 in Vandevoorde et al's study (18), and 0.845 in Rosa et al.'s study (20). In other words, FEV_1/ FEV_6 and FEV_1/FVC match very well (kappa coefficient of around 0.9) when both were measured by conventional spirometry, but the kappa coefficient was not that high when FEV_1/FEV_6 was obtained using the Hi-Checker™. Measurement differences attributed to the Hi-Checker™ may occur randomly, thus preventing a better level of agreement in diagnosis.

Some limitations of the present study should be mentioned. Most of these issues are related to the study design. Since the study subjects were not randomly sampled and we did not have any clinical information, the prevalence of airflow limitation was unknown and could not be compared with previous investigations. The present study was also limited by the small number of participants, and only male subjects were included in this study. To improve our comparison of conventional spirometry and the Hi-Checker™, we should have determined the FEV_6 using conventional spirometry and then compared this value with the FEV_6 using the Hi-Checker™. In addition, the GOLD defines airflow limitation as a post-bronchodilator FEV_1/FVC < 0.70. However, this study did not evaluate post-bronchodilator values.

In conclusion, the handheld spirometer Hi-Checker™ can be used for the purpose of the case identification of subjects with airflow limitation. To identify those subjects with airflow limitation as defined by FEV1/FVC < 0.7 measured by conventional spirometry, the cut-off level for FEV_1/FEV_6 measured using the Hi-Checker ™ should be 74.6%. When we used below the LLN of the FEV_1/FVC from conventional spirometry as the definition of airflow limitation, the best match was below the LLN of the raw FEV_1/FEV_6 values from the Hi-Checker™.

However, it should be emphasized that the Hi-Checker ™ measurements were not identical to those from conventional spirometry due to random measurement errors. Although one must be careful about over-interpreting these results, since the Hi-Checker ™ is small and inexpensive, it can make a great contribution to identifying cases with airflow limitation. The Hi-Checker™ should not be used for a final diagnosis of airflow limitation in clinical practice.

DECLARATION OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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