



## Original Article

## Assessment of the Portable COPD-6 Device for Detecting Obstructive Airway Diseases

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## ABSTRACT

**Objectives:** To evaluate the agreement and the association with FEV<sub>1</sub>, FEV<sub>6</sub> and FEV<sub>1</sub>/FEV<sub>6</sub> measured with the Vitalograph-COPD-6 portable device and the FEV<sub>1</sub>, FVC and FEV<sub>1</sub>/FVC by conventional spirometry, and to analyse the validity of this device to detect obstruction.

**Methodology:** A cross-sectional, descriptive, prospective study, that included 180 subjects. A conventional spirometry and a spirometry with the Vitalograph-COPD-6 were sequentially performed on them. The agreement was analysed [kappa index and interclass correlation coefficient (ICC)], as well as the association [Pearson correlation coefficient (r)], area under the ROC curve (AUC) of the FEV<sub>1</sub>/FEV<sub>6</sub> in detecting obstruction, and the sensitivity, specificity, predictive values (PPV and NPV), and probability ratios (PR+ and PR-) of the different FEV<sub>1</sub>/FEV<sub>6</sub> cut-off points in the detection of obstruction.

**Results:** The prevalence of obstruction was 47%. The kappa index was 0.59 when an FEV<sub>1</sub>/FEV<sub>6</sub> < cut-off point of < 0.7 was used. The ICC and the r between the FEV<sub>1</sub> measured by the two instruments, FEV<sub>6</sub> and FEV<sub>1</sub>/FEV<sub>6</sub> measured by the Vitalograph-COPD-6 and the FVC and FEV<sub>1</sub>/FVC determined by the spirometer were all greater than 0.92. The ROC AUC was 0.97. To detect obstruction, if the cut-off point of FEV<sub>1</sub>/FEV<sub>6</sub> (for COPD-6) was < 0.70, the sensitivity, specificity, PPV, NPV, CR+ and CR- were, 58%, 100%, 100%, 73%, ∞ and 0.42, respectively. For a cut-off point of < 0.8, they were 96%, 76%, 78%, 96%, 3.8 and 0.05, respectively.

**Conclusions:** The portable Vitalograph-COPD-6 device is precise for the detection of airway obstruction. The best sensitivity/specificity of FEV<sub>1</sub>/FEV<sub>6</sub> was obtained with cut-off points greater than 0.7.

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## Validación del dispositivo portátil COPD-6 para la detección de patologías obstructivas de la vía aérea

## RESUMEN

## Palabras clave:

FEV<sub>6</sub>

Espirometría

Cribado

Enfermedad pulmonar obstructiva crónica

**Objetivos:** Evaluar la concordancia y la relación del FEV<sub>1</sub>, FEV<sub>6</sub> y FEV<sub>1</sub>/FEV<sub>6</sub> medidos con el dispositivo portátil Vitalograph-COPD-6 y del FEV<sub>1</sub>, FVC y FEV<sub>1</sub>/FVC mediante espirometría convencional y analizar la validez de este dispositivo para detectar obstrucción.

**Metodología:** Estudio prospectivo, descriptivo, transversal. Se incluyeron 180 sujetos a los que se les realizó secuencialmente una espirometría convencional y una con el Vitalograph-COPD-6. Se analizó la concordancia (índice kappa y coeficiente de correlación intraclass [CCI]), relación (coeficiente de correlación de Pear-

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son [r]), área bajo la curva (ABC) ROC del  $FEV_1/FEV_6$  en la detección de obstrucción y se calcularon la sensibilidad, especificidad, valores predictivos (VPP y VPN) y cocientes de probabilidad ( $CP+$  y  $CP-$ ) de distintos puntos de corte del  $FEV_1/FEV_6$  en la detección de obstrucción.

**Resultados:** La prevalencia de obstrucción fue del 47%. Utilizando un punto de corte del  $FEV_1/FEV_6 < 0,7$  el índice kappa fue de 0,59. El CCI y el r entre el  $FEV_1$  medido por los 2 aparatos,  $FEV_6$  y  $FEV_1/FEV_6$  medido por el Vitalograph-COPD-6 y la FVC y  $FEV_1/FVC$  determinados por el espirómetro fueron todos superiores a 0,92. El ABC ROC fue de 0,97. Para detectar obstrucción, si el punto de corte de  $FEV_1/FEV_6$  (por COPD-6) es  $< 0,70$ , la sensibilidad, especificidad, VPP, VPN,  $CP+$  y  $CP-$  fueron 58%, 100%, 100%, 73%,  $\infty$  y 0,42, respectivamente. Para un punto de corte  $< 0,80$  fueron 96%, 76%, 78%, 96%, 3,8 y 0,05, respectivamente.

**Conclusiones:** El medidor portátil Vitalograph-COPD-6 es preciso para la detección de obstrucción de la vía aérea. La mejor relación sensibilidad/especificidad del cociente  $FEV_1/FEV_6$  se obtuvo con puntos de corte superiores a 0,7.

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## Introduction

Obstructive pathologies of the airway, especially COPD and asthma, are highly prevalent, affecting 5-10% of the population.<sup>1,2</sup> Despite their potential morbidity and mortality and the significant consumption of resources they entail, both diseases are under-diagnosed, with COPD rates reaching over 80%.<sup>1,2</sup> COPD diagnosis is based on the detection of an airway obstruction that is largely irreversible in an adequate clinical/epidemiological context, making a forced spirometry procedure indispensable in this case.<sup>1,3</sup> To fight this under-diagnosis, it is essential to carry out a screening of patients at risk of COPD in non-specialised settings such as Primary Care Centers.<sup>1,4</sup> In order to do this, it is essential that spirometry is performed routinely and with appropriate quality at that care level.<sup>5-8</sup> However, current evidence shows that this is far from reality.<sup>6-8</sup> One of the most common and significant problems when non-expert staff perform spirometric manoeuvres is the difficulty in obtaining a proper determination of the forced vital capacity (FVC), an essential parameter, along with the forced expiratory volume in one second ( $FEV_1$ ), in order to define the obstructive disorder.<sup>7,8</sup> Hence, we have proposed and demonstrated that the forced expiratory volume in six seconds ( $FEV_6$ ), a more easily determined parameter, may be an acceptable substitute for FVC in the diagnosis of obstruction in adults.<sup>9</sup>

Besides simplifying the spirometry procedure,  $FEV_6$  has the practical advantage of reducing variability, which helps improve its diagnostic capacity.<sup>9</sup> On the other hand, however, conventional spirometers would be required for determining  $FEV_6$ , which are not always available at all care-giving settings and would require a certain amount of maintenance and financial investment.<sup>6-8</sup> This has led to the recent design and commercialisation of various portable electronic devices that allow for a quick reading of  $FEV_1$ ,  $FEV_6$  and the  $FEV_1/FEV_6$  ratio, which makes them especially useful in COPD screening in non-specialised care centres.<sup>10-13</sup> However, their diagnostic accuracy compared with conventional spirometers has scarcely been studied.<sup>9,10</sup> One of the latest devices sold in Spain is the Vitalograph COPD-6 (model number 4000, Vitalograph Ltd., Ireland) (fig. 1), which according to its manufacturers is very easy to use and accurate enough to reliably determine  $FEV_1$ ,  $FEV_6$  and the  $FEV_1/FEV_6$  ratio.<sup>10</sup> To date there have been no published articles analysing its validity and safety in clinical practice as a screening tool for obstructive diseases.

The aims of this study were: firstly, to evaluate the agreement and relationship between the parameters obtained by the Vitalograph COPD-6 and those measured by a conventional spirometer; and secondly, to determine the sensitivity, specificity, predictive values and probability ratios for this device in detecting obstructions, using a conventional spirometer as a gold standard.

## Material and Methods

This was a prospective, descriptive transversal study. The included patients were recruited from those who attended our pulmonary function laboratory for functional respiratory tests over two consecutive months. Each of them was asked for their consent to participate in our study, which was approved by the ethics committee of our centre. For the final analysis, we excluded those subjects who, after a brief explanation, did not understand the technique or were unable to perform proper and reproducible spirometric manoeuvres.

The following was performed on all patients: a) a conventional spirometry measuring  $FEV_1$ , FVC and the  $FEV_1/FVC$  ratio; b) a measurement of  $FEV_1$ ,  $FEV_6$  and  $FEV_1/FEV_6$  ratio using the portable Vitalograph COPD-6 meter.

Conventional spirometries were performed using two different spirometers, both Masterlab model pneumotachographs that incorporate reference values recommended by the Spanish Society of Pneumology and Thoracic Surgery (Spanish acronym SEPAR).<sup>14</sup>

COPD-6 (fig. 1) is a small portable electronic device measuring 11.3 cm high, 6.3 cm wide and 4.5 cm thick and weighs 55 g. It is powered by two disposable batteries, is easy to use and can measure  $FEV_1$ ,  $FEV_6$  and the  $FEV_1/FEV_6$  ratio. It also includes the reference values of the ECCS (European Community for Coal and Steel),<sup>15</sup> by



Figure 1. Portable COPD-6 device (Vitalograph). CI indicates confidence interval.

which it also shows for each parameter the percentage of the value obtained versus its theoretical value. It has a large easy-to-read display and a comfortable design that allows it to be easily held by the patient.<sup>13</sup> The requirement for calibration is not included in the instructions for this portable COPD-6 device.<sup>13</sup> Before taking any readings with this device, the user must enter some patient data including age, size and sex. The manoeuvre that must be performed is similar to that of a spirometry; the patient must take a deep breath, then insert the mouthpiece into their mouth and then exhale vigorously and continuously for six seconds. When that time is reached, the device emits a beep to indicate that the patient can stop the manoeuvre. COPD-6 also incorporates a flowmeter that detects errors such as the premature ending of the manoeuvre or coughing, by displaying an exclamation mark on-screen and emitting a longer beep. Another feature of this device is that it indicates with an arrow whether there is an obstruction or not (indicating yes if the FEV<sub>1</sub>/FEV<sub>6</sub> ratio is < 0.7),<sup>13</sup> and displaying on a color scale the degree of the obstruction according to the classification recommended in the GOLD guidelines.<sup>3</sup>

Measurements with both devices were performed by trained staff and were carried out in a standardised manner. Spirometer measurements were performed according to the SEPAR guidelines with previous calibration daily using the three-litre syringe and adjusted for temperature, humidity and atmospheric pressure.<sup>16</sup> With the COPD-6 portable meter, three manoeuvres were performed for each patient (as described above), which had to meet criteria for acceptability and reproducibility, selecting the best values in each case for each parameter. To further simplify the procedure, no nose clips were used in the expiratory manoeuvres performed with the COPD-6.

Upon random selection, one group was measured with COPD-6 prior to conventional spirometry and other groups were measured using COPD-6 after conventional spirometry.

#### Statistical Analysis

The qualitative variables were expressed by absolute values and percentages, and the quantitative variables by mean and standard deviation (shown as mean [standard deviation]). To express the differences between the different parameters studied the average of the difference and its 95% CI were used. The comparison of quantitative variables was performed by applying the Student's t-test for paired samples. A value of p less than or equal to 0.05 was considered statistically significant. To evaluate the agreement between both devices for detecting obstructions (FEV<sub>1</sub>/FVC and FEV<sub>1</sub>/FEV<sub>6</sub> < 0.7, the value recommended by the current guidelines for spirometry<sup>13</sup> and from the manufactures of the COPD-6),<sup>13</sup> the kappa index was used as the qualitative variable. The agreement and relationship between the values of FEV measured by both devices, the FEV<sub>1</sub>/FVC quotient and the FVC (measured using conventional spirometry) and FEV<sub>1</sub>/FEV<sub>6</sub> and FEV<sub>6</sub> (measured using the COPD-6)

were analysed by calculating the intraclass correlation coefficient (ICC) and the Pearson correlation coefficient (r) respectively, and were represented graphically using Bland and Altman graphs and correlation graphs.

The validity and specificity of the COPD-6 in detecting obstructions was determined using standard formulas, and the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive probability quotient (+PQ) and negative probability quotient (-PQ) were calculated. We also estimated the area under the ROC (Receiver-Operating Characteristic) curve of the FEV<sub>1</sub>/FEV<sub>6</sub> ratio (measured with the COPD-6) in the discrimination of the obstruction, using the FEV<sub>1</sub>/FVC < 0.7 quotient obtained with conventional spirometry as the gold standard.

The sample size calculation was performed after an interim analysis of the first 40 cases included, estimating that the COPD-6 could provide a 90% sensitivity and a 80% specificity in detecting obstructions, a 40% prevalence, and an alpha error of 5%. To achieve an estimated accuracy of 8%, the necessary sample size needed to be 162 subjects.

#### Results

Of a total 180 subjects, 162 were included in the study and 18 were excluded (four for not understanding the technique and 14 because of unacceptable or non-reproducible spirometric manoeuvres). Of these, 95 (59%) were men. The mean age was 56 (16) years. Thirty (18%) patients were diagnosed with COPD, 32 (20%) with asthma, 40 (25%) with other pathologies (bronchiectasis, tuberculosis sequelae, mixed pathologies, miscellaneous) and 60 (37%) had no specific diagnosis. Seventy-six (47%) of the cases showed an obstructive pattern in spirometry, with a mean FEV<sub>1</sub> of 66.2% (22.2). In 57 cases (75%), FEV<sub>1</sub> measured by spirometry was > 50% (compared to the baseline value) and 19 (25%) had an FEV<sub>1</sub> < 50%.

The absolute and percentage values of the different parameters measured with the spirometer and with the COPD-6 are shown in

**Table 2**

Contingency table of the number of subjects diagnosed with obstruction determined by conventional spirometry and by the COPD-6 meter following the manufacturer's recommendations

	Obstruction by COPD-6 <sup>a</sup>		Total
	No	Yes	
Obstruction by spirometry <sup>b</sup>			
No	86	0	86
Yes	32	44	76
Total	118	44	162

<sup>a</sup>Defined as FEV<sub>1</sub>/FEV<sub>6</sub> < 0.7.

<sup>b</sup>Defined as FEV<sub>1</sub>/FVC < 0.7.

<sup>c</sup>Median of the difference and 95% confidence interval of the median.

**Table 1**

Average values and differences in the various parameters determined using spirometry and COPD-6

	Spirometer <sup>a,b</sup>	COPD-6 <sup>a,c</sup>	p	Spirometer-COPD-6 Differences <sup>d</sup>
FEV <sub>1</sub>	2,460 (996) ml	2,292 (957) ml	< 0.001	167 ml (CI95%: 144 to 190)
FVC vs. FEV <sub>6</sub>	3,516 (1,150) ml	3,031 (1,062) ml	< 0.001	485 ml (CI95%: 442 to 528)
FEV <sub>1</sub> /FVC vs. FEV <sub>1</sub> /FEV <sub>6</sub>	0.69 (0.13)	0.74 (0.12)	< 0.001	-0.05 (CI95%: -0.04 to -0.06)
% FEV <sub>1</sub>	81.3 (25)	80.5 (25)	0.11	0.7% (CI95%: -0.8 to +2)
% FVC vs. % FEV <sub>6</sub>	87.4 (10)	88.4 (21)	0.36	-0.9% (CI95%: -2.2 to +0.2)

CI indicates confidence interval.

<sup>a</sup>Median (standard deviation).

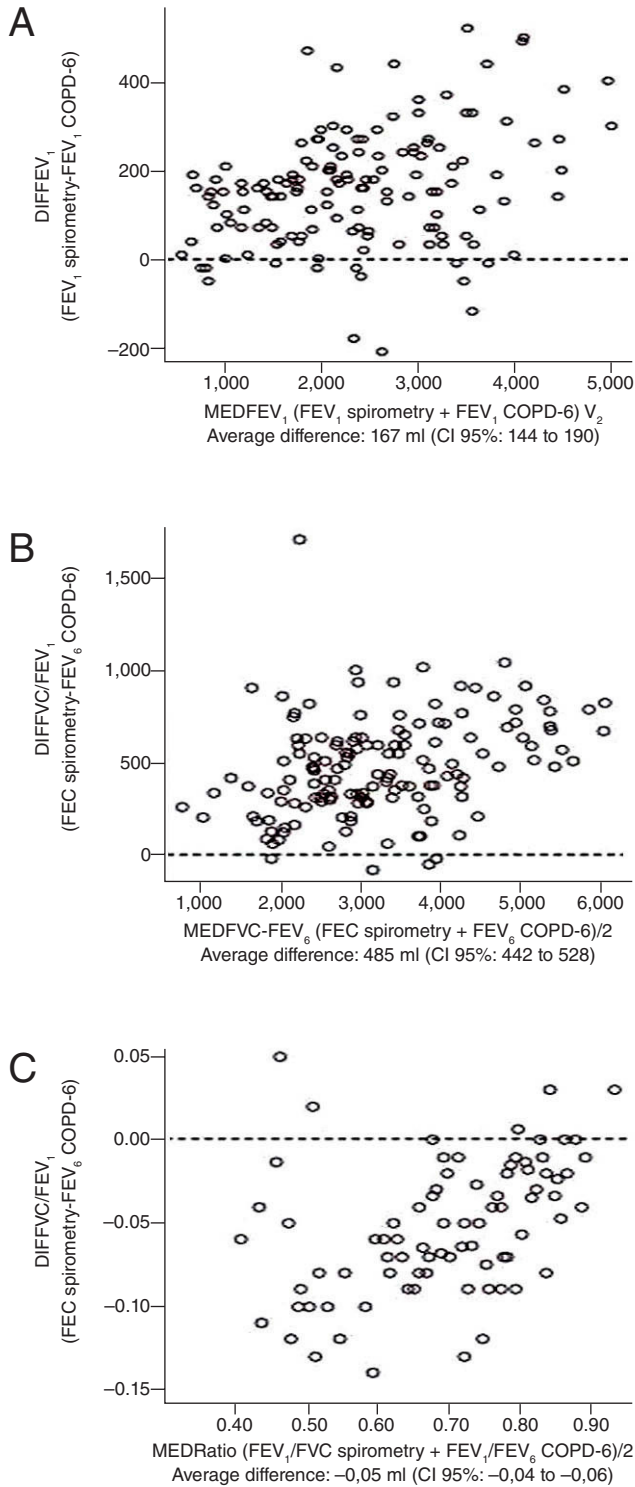
<sup>b</sup>SEPAR-recommended reference values.<sup>14</sup>

<sup>c</sup>ECCS reference values.<sup>15</sup>

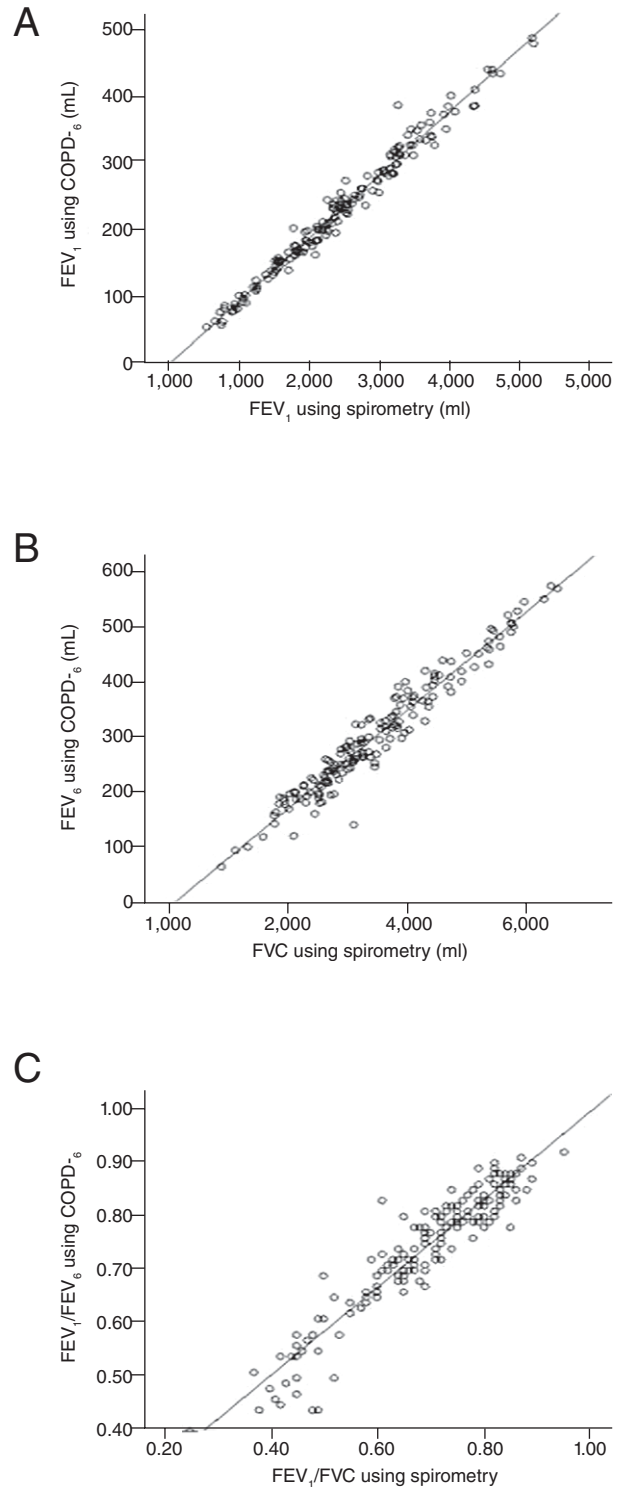
<sup>d</sup>Median of the difference and 95% confidence interval of the median.

table 1. The table also lists the average of the differences and their 95% CI. As can be seen, the absolute values of FEV<sub>1</sub> measured by conventional spirometers were significantly higher than the measurements by the COPD-6, with a 95% CI between 144-190 mL. The FVC value was also significantly higher than the FEV<sub>6</sub>, with a 95% CI between 442-528 mL. However, the FEV<sub>1</sub>/FVC value (measured

with spirometry) was significantly lower than the FEV<sub>1</sub>/FEV<sub>6</sub> (measured with the COPD-6) and its 95% CI between 0.04-0.08. The baseline values used in the two devices were different (SEPAR for the spirometers and ECCS for the COPD-6) and the theoretical values of ECCS were significantly lower than those of SEPAR.<sup>17,18</sup> For this reason, in the analysis of the percentage differences as a function of their



**Figure 2.** Bland and Altman graphs for a) the FEV<sub>1</sub> measured with the spirometer versus the COPD-6, b) the FVC measured with the spirometer versus the FEV<sub>6</sub> measured with the COPD-6, and c) the FEV<sub>1</sub>/FVC ratio measured with the spirometer versus the FEV<sub>1</sub>/FEV<sub>6</sub> measured with the COPD-6.

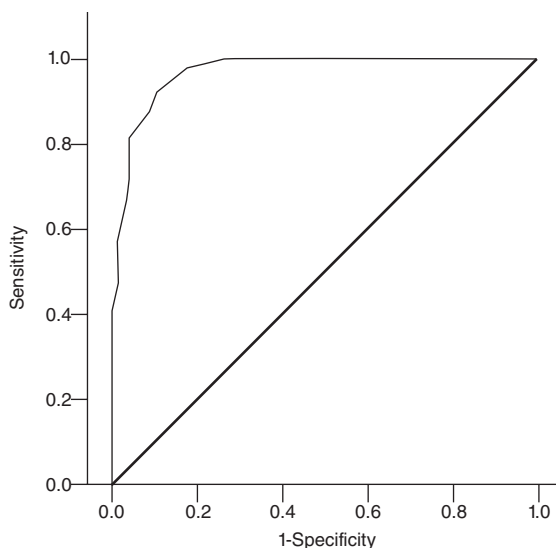


**Figure 3.** Correlation graphs for a) FEV<sub>1</sub> correlation with both devices, b) correlation between FVC by spirometry and FEV<sub>6</sub> by COPD-6, and c) correlation between FEV<sub>1</sub>/FVC ratio by spirometry and FEV<sub>1</sub>/FEV<sub>6</sub> ratio by COPD-6.

reference value, no significant differences were determined between the FEV<sub>1</sub> percentage determined by both devices and the FVC percentage (by spirometry) and the FEV<sub>6</sub> percentage (by COPD-6) compared to the theoretical values. The average differences were even lower than the unit.

A contingency table (table 2) was created for patients diagnosed with obstruction using spirometry and COPD-6, using a quotient <0.7 in both cases (recommended by the manufacturers of the COPD-6).<sup>3</sup> Of the 76 patients with FEV<sub>1</sub>/FVC < 0.7 measured by spirometry, 32 (42.1%) would not have been detected using this cutoff point for FEV<sub>1</sub>/FEV<sub>6</sub>. In this sense, the kappa index value was 0.59 (moderate).

The agreement and relationship between the various parameters analysed was: FEV<sub>1</sub> (spirometry) vs. FEV<sub>1</sub> (COPD-6): CCI = 0.98 (p < 0.001), r = 0.99 (p < 0.001); FVC (spirometry) vs. FEV<sub>6</sub> (COPD-6): CCI = 0.96 (p < 0.001), r = 0.97 (p < 0.001); FEV<sub>1</sub>/FVC (spirometry) vs. FEV<sub>1</sub>/FEV<sub>6</sub> (COPD-6): CCI = 0.93 (p < 0.001), r = 0.94 (p < 0.001); The Bland and Altman graphs are shown in figure 2 showing a tendency towards non-homogeneity in the differences in the three graphs. Instead, the difference is larger as the values of FEV<sub>1</sub> and FVC increase and larger when the FEV<sub>1</sub>/FVC quotient is lower. However, the ICC values were excellent, which made the difference between the measurements of little importance in terms of the variation of the subjects.



**Figure 4.** ROC curve of the FEV<sub>1</sub>/FEV<sub>6</sub> ratio measured with the COPD-6 for detecting obstructions.

**Table 3**

Values for sensitivity, specificity, predictive values and probability quotients for detecting obstructions (FEV<sub>1</sub>/FVC < 0.7 by spirometry) for different cutoff points for the FEV<sub>1</sub>/FEV<sub>6</sub> ratio measured with the Vitalograph COPD-6

FEV <sub>1</sub> /FEV <sub>6</sub> (Vitalograph COPD-6)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+PQ	-PQ
< 0.70	58	100	100	73	∞	0.42
< 0.71	66	100	100	77	∞	0.34
< 0.72	74	100	100	81	∞	0.26
< 0.73	83	98	97	87	35.6	0.18
< 0.74	85	97	97	88	36.7	0.15
< 0.75	87	96	97	88	36.0	0.14
< 0.76	89	94	96	91	25.6	0.11
< 0.77	90	92	92	91	12.7	0.12
< 0.78	92	88	87	93	8.0	0.09
< 0.79	96	83	84	95	5.7	0.06
< 0.80	96	76	78	96	3.8	0.05

-PQ indicates negative probability quotient; +PQ, positive probability quotient; ∞, infinite; NPV, negative predictive value; PPV, positive predictive value.

The correlation graphs are shown in figure 3. Notice that the correlation is excellent for all parameters studied.

Figure 4 shows the ROC curve obtained from the FEV<sub>1</sub>/FEV<sub>6</sub> ratio measured with COPD-6 for the detection of obstructions (considering FEV<sub>1</sub>/FVC quotient < 0.7 as the reference pattern), with the ABC equal to 0.97 (95% CI 0.95-0.99).

Table 3 shows the values for sensitivity, specificity, PPV, NPV, +PQ and -PQ for determining obstructions (using the value FEV<sub>1</sub>/FVC < 0.7 obtained by spirometry as the gold standard) for the different cutoff points of the FEV<sub>1</sub>/FEV<sub>6</sub> quotient measured by COPD-6.

## Discussion

In order to carry out a proper screening of COPD and thereby face the problem of under-diagnosis, it is essential that spirometries are performed in primary care settings. This fact has been accepted and recommended by all scientific societies<sup>3,4</sup> and is reflected in the National Health System's recently published COPD National Strategy, which secondary goal is improving early diagnosis. However, we know that due to the lack of time, availability of spirometers, limited space, lack of education and training and poor motivation of many health professionals, this technique is little used at this level of care.<sup>5-11</sup> Furthermore, in many centres that do perform spirometries, the quality of the studies are very much in doubt, mostly due to the difficulty in obtaining a proper FVC in spirometry manoeuvres. This parameter tends to have the most disagreement when comparing studies performed by personnel specialised in the technique with those performed by other practitioners.<sup>6-8</sup> Furthermore, the manoeuvre that should be performed to achieve a proper reading of FVC is responsible for rare cases of dyspnea, dizziness and syncope reported with spirometry.<sup>7,8,19</sup>

The substitution of this parameter with one that is easier to obtain, such as FEV<sub>6</sub>, could improve implementation of spirometry. A recent meta-analysis that included 11 studies showed that the FEV<sub>1</sub>/FEV<sub>6</sub> quotient reported an average sensitivity of 89% and a specificity of 98% when compared to the classic definition of obstruction based on the FEV<sub>1</sub>/FVC value.<sup>9</sup> This meta-analysis obtained an area under the ROC curve of FEV<sub>1</sub>/FEV<sub>6</sub> for detecting obstructions of 0.97. However, the sensitivity of the reported FEV<sub>1</sub>/FEV<sub>6</sub> quotient varied according to the various definitions for obstruction and the different cutoff points considered, without any agreement as to which should be considered.<sup>9</sup>

Another key element for enhancing COPD screening in non-specialised care settings may be the substitution of spirometry with easier-to-use portable devices. Three published studies in 2009 that combined these two aspects have demonstrated that the use of a small and simple electronic device such as the Piko-6

(Ferraris Co., London, United Kingdom) could be useful in detecting obstructive pathologies.<sup>10-12</sup> In Japan, Toda et al (in a population with a obstruction prevalence of 35.4%) observed that the area under the ROC curve for detection of obstructions for this device was 0.86 and that with the cutoff point for FEV<sub>1</sub>/FEV<sub>6</sub> of 0.75 they obtained better validity and precision (79% sensitivity, 86% specificity, 75.8% PPV and 88.4% NPV).<sup>10</sup> In Vietnam, Duong-Quy et al studied a cohort in which 13.5% of the subjects had obstruction by spirometry. Using a cutoff point of FEV<sub>1</sub>/FEV<sub>6</sub> < 0.70, they obtained a sensitivity of 97.8%, a specificity of 93.8%, a PPV of 71% and a NPV of 99.6%.<sup>11</sup> The differences between both studies may be due to methodological reasons and also to the differences in the prevalence of obstruction and the cutoff points used to define obstruction. Lastly, an Austrian group performed spirometries on 74 patients through a primary care screening program. The patients had an FEV<sub>1</sub>/FEV<sub>6</sub> < 80% as measured by the Piko-6, finding only that 32 (43%) were diagnosed with COPD or asthma. Despite this, the authors concluded that this device was effective in detecting previously undiagnosed obstructive pathologies.<sup>12</sup>

Our study is the first to analyse the diagnostic validity and precision of the new Vitalograph COPD-6 device. From this study we can make the following conclusions and reflections.

Firstly, the device demonstrates excellent validity as a diagnostic tool for obstruction when compared to conventional spirometry. Although this device tends to determine absolute values of FEV<sub>1</sub> and especially FEV<sub>6</sub> lower than the FEV<sub>1</sub> and FVC measured by conventional spirometry, these differences have a relatively narrow margin. This allows us to estimate with a minimum possibility of error (as shown in table 1) the values that would be obtained using spirometry, knowing those determined by the COPD-6. The quantitative variables of agreement and relationship between the different parameters compared has been excellent and the area under the ROC curve obtained in this study are exactly equal to that reported in the meta-analysis by Jing et al,<sup>9</sup> which includes a large number of studies where different parameters were obtained with spirometry.

Logically, FEV<sub>6</sub> is proportionally lower than the FVC as this accounts for the whole expiratory volume, while the FEV<sub>6</sub> only accounts for six seconds and is therefore always lower. This does not depend on the equipment or on the measurement. This makes the average FEV<sub>1</sub>/FEV<sub>6</sub> quotient higher than the FEV<sub>1</sub>/FVC, by which the cutoff point that determines the obstruction cannot be 0.70 as recommended by the manufacturer. In this sense, when analysing the agreement using the same point for the two devices, only this one was moderate. If the manufacturer's recommendations are followed, more than 40% of patients with spirometric obstruction would not have been detected as having an obstruction with the COPD-6. This issue has already been observed in numerous studies that validate FEV<sub>6</sub> as a spirometric substitute for FVC. In several of these studies, the cutoff point for the FEV<sub>1</sub>/FEV<sub>6</sub> quotient for the definition of obstruction was significantly higher than that recommended for FEV<sub>1</sub>/FVC by the current guidelines.<sup>9,20-22</sup> With the Vitalograph COPD-6 device, if we set it to around 0.75-0.76, we get the best sum of sensitivity and specificity, which makes it useful in detecting obstructions. If we increase it up to 0.79-0.80, we would have a more sensitive tool although less specific, which would make it especially useful in screening obstructive airway pathologies.

Despite the fact that the device incorporates a flowmeter that warns us of errors such as a slow start or an abrupt termination, the device does not provide a graph analyses of the volume/time or flow/volume curves, which are essential (especially the latter ones) in detecting errors. For this reason, we believe that the Vitalograph COPD-6 and the Piko-6<sup>10,11</sup> may be excellent screening tools for obstructive pathologies, such that if the results are normal one can rule out the existence of pathology with acceptable confidence. If the results are altered then a conventional spirometry should be performed to confirm the findings. This makes the COPD-6 an

especially useful device for general visits and as a "pocket" instrument for rapid assessments.

As a curiosity, we note the excellent agreement and correlation shown with the reference values of FEV<sub>1</sub> and of FVC vs. FEV<sub>6</sub> obtained with spirometry and the COPD-6 (data shown only partially). This could be explained by the lowest values obtained with the COPD-6 are offset by the fact that the reference values included with this device are those of the ECCS, which are significantly lower than those of SEPAR<sup>17,18</sup> incorporated into conventional spirometers used in the current study.

The present study has several limitations. Firstly, the study was performed with trained personnel, a fact that could limit its external validity in other areas in which the practitioners have less experience. We believe it necessary to validate this device in other non-specialised care locations and have therefore begun another study on this issue. Following the current recommendations,<sup>13</sup> the gold standard used was the FEV<sub>1</sub>/FVC quotient < 0.70, an index that is not exempt from criticism due to its possible inaccuracy.<sup>23</sup> However, for the purposes of this study and in order to validate this device for use by professionals with limited experience in pulmonary function techniques, we believe it to be the most appropriate given that it simplifies diagnosis.

Finally, taking into account the limitations discussed, we can conclude that the portable Vitalograph COPD-6 meter is a simple and very accurate device, which could be of use in screening and detecting obstructive airway pathologies. This makes it a useful tool in non-specialised care centres where it could help improve early diagnosis of pathologies such as COPD. For this to be possible, however, it should be noted that the cutoff point for the FEV<sub>1</sub>/FEV<sub>6</sub> quotient for defining obstruction recommended by the manufacturer appears not to be valid. Our study indicates that it must be established between 0.75-0.80. While a result greater than these figures would rule out obstruction with acceptable confidence, a lower result would establish the indication for a conventional spirometry study to confirm the obstruction.

### Conflict of interest

The authors confirm the lack of any conflict of interest with the commercial companies mentioned in this study.

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