

Agreement Between Pneumotachograph and PiKo-1 Measurements of PEF and FEV₁

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OBJECTIVE: To assess how well values for peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV₁) agree when measured with the PiKo-1 device and with a conventional pneumotachograph.

PATIENTS AND METHODS: This randomized, single-blind study included 40 patients who attended the clinic for lung function testing. The 2 measurement devices were the Masterlab pneumotachograph and the PiKo-1. A correction factor estimated by the manufacturer was applied to the measurements taken with the PiKo-1.

RESULTS: The values obtained with the 2 devices differed by a mean of 5.8218 L/min for PEF (95% confidence interval [CI], -9.4809 to 21.1387) and 0.001 L for FEV₁ (95% CI, -0.0616 to 0.0636). The intraclass correlation coefficient was 0.9652 (95% CI, 0.9336-0.9819) for PEF and 0.9876 (95% CI, 0.9761-0.9936) for FEV₁.

CONCLUSIONS: The PiKo-1 is a simple and easy-to-use device that can be very useful for monitoring and assessing the severity of obstructive pulmonary diseases. The results must be corrected for altitude and the estimated correction factor should be applied.

Key words: Peak expiratory flow rate. Lung function. Pulmonology.

Estudio de la concordancia de 2 aparatos para la medida del PEF y FEV₁: neumotacógrafo y PiKo-1

OBJETIVO: Evaluar la concordancia de las mediciones del flujo espiratorio máximo (PEF) y del volumen espiratorio forzado en el primer segundo (FEV₁) entre el medidor PiKo-1 y un neumotacógrafo de uso habitual.

PACIENTES Y MÉTODOS: Se incluyó a 40 pacientes que acudieron al laboratorio de pruebas funcionales respiratorias para el estudio de su función pulmonar. El estudio se realizó de forma aleatorizada y ciega con los 2 sistemas de medida (neumotacógrafo Masterlab y PiKo-1). En las mediciones del PiKo-1 se introdujo el factor de corrección estimado por el fabricante.

RESULTADOS: Las diferencias medias obtenidas fueron para el PEF de 5,8218 (intervalo de confianza [IC] del 95%, -9,4809 a 21,1387) y para el FEV₁ de 0,001 (IC del 95%, -0,0616 a 0,0636). El coeficiente de correlación intraclass fue de 0,9652 (IC del 95%, 0,9336-0,9819) para el PEF y de 0,9876 (IC del 95%, 0,9761-0,9936) para el FEV₁.

CONCLUSIONES: El PiKo-1 es un aparato de medida sencillo y de fácil manejo que puede ser de gran utilidad para el seguimiento y la valoración de la gravedad en las enfermedades obstructivas pulmonares. Los resultados deben corregirse en función de la altitud y el factor de corrección estimado.

Palabras clave: Flujo espiratorio máximo. Función pulmonar. Neumología.

Introduction

Chronic obstructive pulmonary disease (COPD) and asthma cause extensive morbidity and mortality and are very costly for national health systems.¹ Study of lung function, and spirometry in particular, forms a fundamental part of the procedures to diagnose, assess, and monitor these respiratory diseases.²⁻⁴ Everyone

agrees that lung function testing should be done in primary health care and specialist care⁵ but, according to a study carried out in a health district of Barcelona, only 36% of family physicians performed or requested such testing for diagnosis of COPD.⁶ The technique is underused mainly because of the limited availability of spirometers and the lack of appropriate training and motivation. Devices that are easier to use could be very useful for diagnosing and monitoring respiratory diseases.⁷

The aim of this study was to assess how well values for peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV₁) agree when measured with the PiKo-1 electronic device and with a conventional pneumotachograph.

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Patients and Methods

The PiKo-1 (Ferraris Cardiorespiratory, Louisville, CO, USA) is a lightweight, small, inexpensive electronic sensing device that can measure PEF and FEV₁. The device can store 96 readings and report errors in the procedure. The reading itself is displayed along with a corresponding color zone, which can be adjusted according to the reference values. Data stored in the device can also be transferred to a computer or transmitted to other units¹ (Figure 1).

The Masterlab pneumotachograph (Jaeger AG, Würzburg, Germany) is a device that is widely used in clinical practice for measuring spirometric variables. However, the size of the device is a hindrance, and personnel with specific training are required. For these reasons, other devices, such as the PiKo-1 are under development. The aim is to make these devices easier to operate so that, once their readings have been shown to agree with those of the pneumotachograph, physicians can use them in the clinical practice.

In clinical research, the reliability of a device is usually assessed by comparing the results with those of another one widely used in clinical practice for agreement or discrepancies. If a more practical alternative to the reference device becomes available, the agreement between systems should be determined.

When a variable in a comparative analysis is continuous and quantitative, the intraclass correlation coefficient (ICC) is more appropriate than the Pearson correlation coefficient (r), as it can indicate general agreement between 2 or more methods of measurement or different observations.⁸ Another simple and visual method is the so-called Bland-Altman analysis to assess agreement between 2 systems of measurement.⁹

We have undertaken a randomized, single-blind, cross-sectional study of agreement between 2 measurement devices in a specialist care setting—the lung function testing laboratory of the Hospital General Yagüe in Burgos, Spain, at 867 m above sea level.

Population

Patients were recruited from those attending our specialist laboratory between March 15 and April 24, 2004 for lung function testing. Patients aged between 20 years and 80 years were included, and those who did not understand the technique after a brief explanation were excluded in order to avoid procedural errors.

Sample Size and Selection

A table of random numbers was used to select patients from among those who attended the lung function testing laboratory and who met the inclusion criteria. A sample size of 40 patients was calculated to be sufficient to detect mean differences between the 2 measurement devices.

Procedures

All measurements were taken according to standardized procedures by trained personnel who were blinded to which device was used. Pneumotachograph readings were taken according to the guidelines of the Spanish Society for Pulmonology and Thoracic Surgery (SEPAR)¹⁰ in order to obtain the flow-volume curve after daily calibration with a 3 L syringe and adjustment for atmospheric pressure, temperature, and humidity. For measurements with the PiKo-1 device, the best of 3 tests was selected. The time between readings for the 2



Figure 1. PiKo-1 device.

measurement systems was 15 minutes. The readings were expressed in L/min for PEF and L for FEV₁.

The values for PEF and FEV₁ obtained with the PiKo-1 were corrected for altitude according to the manufacturer's recommendations. (For every 300 m above sea level, 1.5% should be added; that is, the reading should be multiplied by 1.015.) The percentage difference between the mean pneumotachograph readings and the mean PiKo-1 readings (mean pneumotachograph reading – mean PiKo-1 reading/mean pneumotachograph reading) was also added.

Statistical Analysis

The results were analyzed with the SPSS statistical program version 10. ICC were calculated and the Bland-Altman graphs were plotted.

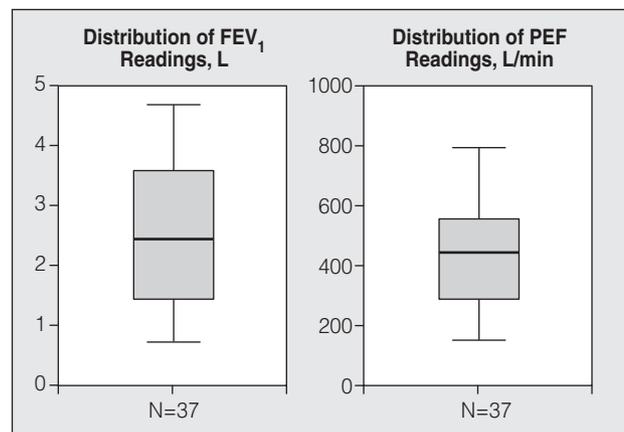


Figure 2. Mean peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV₁) measured with the pneumotachograph.

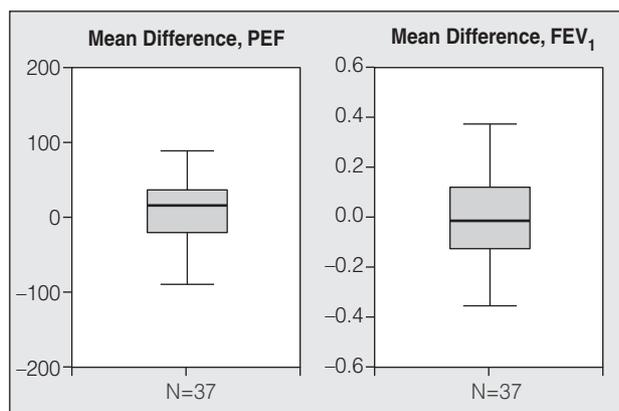


Figure 3. Mean differences in peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV₁) measurements for the pneumotachograph and the PiKo-1.

Results

Forty patients were studied, although 3 were excluded because of defective technique. Of those included, 62.2% were male, with a mean (SD) age of 49.65 (17.25) years, and 40.5% had obstructive disease. The mean values of the pneumotachograph readings were 425.4 L/min (95% confidence interval [CI], 368.16-482.65) for PEF and 2.6989 L (95% CI, 2.3051-3.0927) for FEV₁ (Figure 2).

With the pneumotachograph, mean values of both PEF (425.4 [28.224] L/min) and FEV₁ (2.6989 [0.19418] L) were greater than those obtained with the PiKo-1 (419.5765 [29.0206] L/min and 2.6979 [0.1978] L, respectively).

The mean differences were 5.8218 L/min (95% CI, -9.4809 to 21.1387) for PEF and 0.001 L (95% CI, -0.0616 to 0.0636) for FEV₁ (Figure 3).

The mean ICC was 0.9652 (95% CI, 0.9336-0.9819) for PEF and 0.9876 (95% CI, 0.9761-0.9936) for FEV₁.

As can be observed in the Bland-Altman plots for PEF and FEV₁ (Figure 4), pneumotachograph readings were consistently higher than PiKo-1 readings. In the case of PEF, differences tended to be larger at higher values.

Discussion

Study of respiratory function is essential for diagnosis, monitoring, and assessment of exacerbations in obstructive pulmonary diseases. Spirometry is the cornerstone of these studies,^{2-4,10} but only 20% to 30% of health professionals have spirometers at their disposal.¹¹ Moreover, in a study in a health district of Barcelona, only 36% of the physicians performed or requested lung function tests.^{6,7} Another study of lung function testing by family physicians, allergists, and pulmonologists found that only 43% of physicians in primary health care had spirometers and that only 34% of these physicians measured lung function in 75% of patients with asthma.¹²

This technique is becoming more widespread thanks to simpler, easier-to-use spirometers, and discrepancies between studies done in lung function laboratories and those done in primary health care have become smaller.¹³ The PiKo-1 is an easy-to-use device that measures PEF and FEV₁, provides a report of the procedure, selects the best of 3 readings, stores the

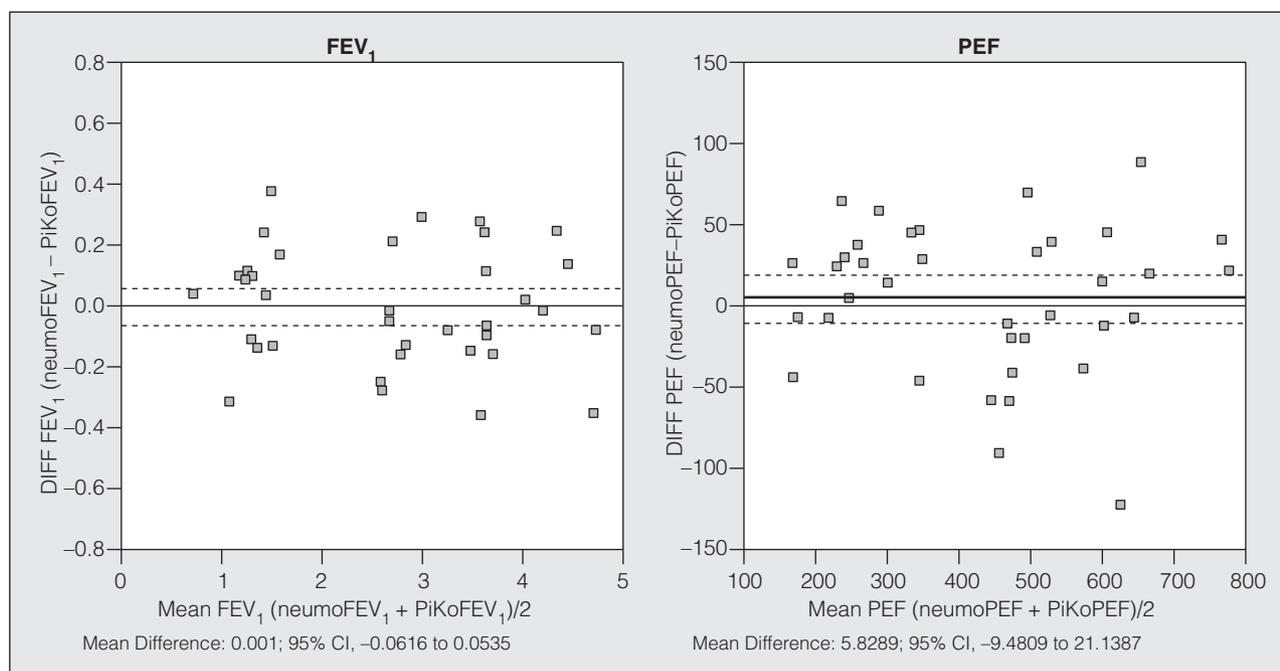


Figure 4. Bland-Altman plot for forced expiratory flow in 1 second (FEV₁) and peak expiratory flow (PEF) measured with the pneumotachograph and the PiKo-1. CI indicates confidence interval.

results of the test, and compares these results with reference values. However, the device cannot be used to measure forced vital capacity and so it is not useful for diagnosis of obstructive diseases, only for their assessment and monitoring.

Measurement of PEF is useful in outpatient monitoring of asthma, in emergency situations, and in the diagnosis of occupational asthma.¹⁴ Many studies use PEF for monitoring asthma, given the variable nature of the disease. In the case of occupational asthma, PEF is even used for diagnosis because it is easy to measure. However, a number of studies have shown that PEF is less responsive to bronchodilators and bronchoconstrictors than FEV₁ measured by spirometry, and so PEF should only be used for monitoring of asthma and not for diagnosis.¹⁵

PEF is seldom used in COPD because it is unreliable, reproducibility is poor, and reference values are not available.^{2,16,17} PEF and FEV₁ differ basically in that PEF reflects flows in the large airways because it depends on effort, whereas FEV₁ reflects obstruction in different parts of the airway.¹⁸

In COPD, FEV₁ can be used to assess the extent of obstruction. Prognosis is worse when FEV₁ is less than 50% of the theoretical value,^{2,15,16} and so a simple validated system for measuring this variable could be of great use for monitoring patients with COPD.

A certain degree of variability has been found among the different devices that measure PEF; therefore not all studies can be readily compared. Nevertheless, correlation with spirometric values estimated by pneumotachography is good. Devices such as the Mini Wright, one of the most widely used, overestimate low flows and underestimate high flows, probably because of the measurement scale, although flows between 200 L/min and 600 L/min are reliably determined.^{1,19} PiKo-1 readings after correction correlate well with those of the pneumotachograph at all flows.

The present study is the first to assess the PiKo-1, although this device could be useful in obstructive diseases.¹ The reliability and precision of a similar device, the AirWatch, have been determined using a Jones syringe and pneumotachograph, and a good correlation was found.²⁰

The ICC is defined as the proportion of overall variability that can be accounted for by differences among patients. Values below 0.4 indicate low reliability, those between 0.4 and 0.75 acceptable to good reliability, and those above 0.75 reflect excellent reliability.⁸

The agreement observed in our study after correcting only for altitude, as indicated by the manufacturer, was good, although pneumotachograph readings were consistently greater than those of the PiKo-1. A correction factor should therefore be applied. After introducing this new calculated correction factor (10.58% for PEF and 4.15% for FEV₁), excellent agreement between the 2 devices was found, both for PEF (ICC=0.9652; 95% CI, 0.9336-0.9819) and for FEV₁ (ICC=0.9876; 95% CI, 0.9761-0.9936). According to the

Bland-Altman plots, differences between corrected pneumotachograph and PiKo-1 readings were distributed about the line of 0 difference for both PEF and for FEV₁.

In conclusion, the PiKo-1 is a simple and easy-to-use measurement device that can be of great use for monitoring and assessing the severity of obstructive pulmonary diseases such as asthma and COPD though not for their diagnosis, which is based on spirometry with a bronchodilator test. Two corrections should be applied, one for altitude and the other to account for underestimation of the values with respect to the pneumotachograph.

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