Pulmonary Function Electronic Monitoring Devices*

A Randomized Agreement Study

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Study objectives: To compare in a clinical setting the within-session reproducibility of two pulmonary function electronic monitoring devices (PiKo-1; Ferraris Respiratory Europe; Hereford, UK; and Spirotel; MIR; Rome, Italy) with one mechanical device (Mini-Wright Peak-Flow Meter; Clement-Clarke International; Harlow, Essex, UK), and to evaluate the accuracy of these devices using as reference an office pneumotachograph.

Design, setting, and participants: After detailed instructions, adults without airways diseases and patients with stable asthma attending an outpatient clinic performed four sets of expiratory maneuvers, one set for each device, in a strictly random order. Each set comprised three maneuvers with 2 to 3 min of rest between them.

Measurements: Reproducibility of FEV_1 and peak expiratory flow (PEF) was assessed by a coefficient of variation (CV) and intraclass correlation coefficient (ICC), and accuracy was assessed by ICC and limits of agreement.

Results: Of the 38 participants evaluated, 71% were women and 61% had asthma. Ages ranged from 18 to 58 years, and FEV_1 ranged from 1.2 to 4.8 L. In all monitoring devices, CV was < 6% and ICC was > 0.94 for the reproducibility of both FEV_1 and PEF measurements. The accuracy of the PiKo-1 device was better for FEV_1 (ICC = 0.98) than for PEF (ICC = 0.90). The Spirotel device had similar results for FEV_1 and PEF (ICC = 0.95). The Mini-Wright device had the lowest accuracy (ICC = 0.87), particularly for PEF values < 500 L/min.

Conclusions: These low-cost and easy-to-use electronic monitoring devices showed a very good reproducibility and were in agreement with the pneumotachograph. Therefore, the PiKo-1 and Spirotel devices seem adequate for both screening and monitoring. However, prospective studies are still needed to assess their long-term reproducibility and usability and, particularly, the effects on the improvement of respiratory care.   *(CHEST 2005; 128:1258–1265)*

Key words: accuracy; agreement; asthma; electronic; health technology assessment; peak flowmeter; pulmonary function; reproducibility

Abbreviations: ATS = American Thoracic Society; CI = confidence interval; CV = coefficient of variation; ICC = intraclass correlation coefficient; PEF = peak expiratory flow; PFM = peak-flow meter

A sthma is global health problem that interferes with quality of life and has a high impact on health-care costs. Pulmonary function parameters are not only important diagnostic tools but are useful for monitoring interventions in asthma both in the medical office and during the patient's daily life. Nevertheless, objective monitoring of lung function parameters is underused and misused.[1]

Peak expiratory flow (PEF) monitoring has been strongly recommended by asthma guidelines,[2] and clinical studies[3,4] have shown that the routine use of peak flow meters (PFMs), along with a self-management plan and education program, can lead to better control of asthma. In the last decades, mechanical PFMs have been the most used method of lung function monitoring. They provide a simple, quantitative, and reproducible measurement of large air-

ways function. Nevertheless, several difficulties have impaired their wide use, and some authors[5–7] have questioned the need for home monitoring of PEF. The reasons put forward were the low compliance by the patients and the limitations of traditional PFM that have both low accuracy and insensitivity to changes.[8,9] These devices have other limitations, including errors in data produced by the patient, related with exclusive use of PEF, which is highly dependent on the patient effort and errors in data recording, mostly transcription errors but also forged registries.[10,11]

These limitations may be overcome with electronic monitoring devices if they prove to be reproducible and accurate, as they are already capable of recording and transmitting data for clinical analysis. It would also be beneficial to monitor additional parameters along with PEF.[12,13]

A growing number of low-cost devices have been recently developed. This has special importance to developing countries, where respiratory disease is a major public health problem and pulmonary function measurements are largely unavailable.

Most of the pulmonary function monitoring devices comply with American Thoracic Society (ATS) recommendations when tested using simulated standard waveforms by a computer-driven mechanical syringe. The performance of these devices in humans and in clinical settings is largely unknown. It is not known how they compare to the current methods used in the clinic.[14]

Agreement studies[15,16] compare the performance of an instrument throughout repeated measurements (reproducibility) and also with a reference (accuracy or validity). Reproducibility assessment is the first step in agreement studies; if acceptable, the accuracy should be checked before use in clinical trials or other clinical settings.

This study aims to compare in stable asthma patients and individuals with normal airways the following: (1) the within-session reproducibility of two pulmonary function electronic monitoring devices (PiKo-1; Ferraris Respiratory Europe; Hereford, UK; and Spirotel; MIR; Rome, Italy) with the widely used Mini-Wright Peak-Flow Meter (Clement-Clarke International; Harlow, Essex, UK) during the same set of maneuvers; and (2) to evaluate their accuracy comparing with an office pneumotachograph as reference. Our hypothesis is that the measurements of PEF and FEV_1 of the two electronic monitoring devices are in close agreement with those of a pneumotachograph. We also hypothesized that those measurements have better discriminative properties than the measurements of one of the most used PFMs in Europe: the Mini-Wright PFM.

Materials and Methods

Instruments

The PiKo-1 is a monitoring device that uses a patented pressure/flow sensor technology for PEF and FEV_1 measurement. Is a low-cost, pocket-size, easy-to-use device that can storage 96 measurements with date and time stamp, plus test-quality alerts indicating an abnormal blow or cough. It can measure PEF in the range of 15 to 999 L/min with a 1 L/min resolution and an accuracy of 6.5% or 15 L/min, whichever is greater. The measurement of FEV_1 has a range of 0.15 to 9.99 L (0.01-L resolution) and an accuracy 4% or 0.1 L, whichever is greater. The cost of the device is approximately €25. The PiKo device has an optional, serial interface cradle to allow downloading PiKo-1 data to a computer and companion software, allowing communication of results using the Internet to track and trend patient data. This optional cradle and personal software costs €25 more.

The Spirotel device is a turbine with an infrared interruption spirometer and has a built-in modem and an optional oximeter. It was developed both for screening in the doctor's office and for home-care monitoring. The Spirotel device records spirometry parameters including FVC; FEV_1; percentage of predicted FEV_1; PEF; forced expiratory flow, midexpiratory phase; forced expiratory time; flow/volume curve; and date and time of the test. It can also record symptoms and the responses to programmable questions. Its has a flow range of ± 16 L/s and a maximal volume of 10 L, a flow accuracy of 5% or 200 mL/s, and a volume accuracy of 3% or 50 mL, whichever is greater. Each unit costs approximately €400. Both PiKo-1 and Spirotel devices have been laboratory tested (data on file), and both met or exceeded the latest ATS accuracy standards.

The standard range version of the Mini-Wright PFM was used. It has 10-L increments from 60 to 800 L/min, and its performance has been studied.[17–23] Each unit costs approximately €20. The monitoring devices used in the study were new and were acquired directly from the manufacturers without their knowledge of our purpose.

A widely available, well-known technology was used as reference: a Fleisch-type pneumotachograph (model 2120; Vitalograph; Maids Moreton, Buckingham, UK).[24] Each day, the pneumotachograph was calibrated using a 3-L syringe. All other devices were calibrated before the study and, in accordance to the manufacturers, did not required calibration during the time period of the study.

Population

Patients attending an asthma and allergy outpatient clinic of a teaching hospital between 10 AM and 12 noon of 20 alternate days during a period of 12 weeks were invited to participate in the study. Patients were considered eligible for participation if they were > 17 years old, had a documented medical diagnosis of asthma, were currently receiving prescribed medication for asthma, and were clinically stable. Stability was defined as no asthma exacerbation or acute illness in the last 4 weeks, and no clinical indication of deterioration of asthma control in the last week. No pulmonary function exclusion criteria were established. The diagnoses of airways diseases other than asthma or neuromuscular or psychiatric diseases were exclusion criteria. Two groups of participants were defined: asthma patients (asthmatics) and patients without any airways disease (normal subjects). Asthmatics had a previous medical diagnosis of asthma, were currently receiving asthma medications, and were attending the clinic for asthma follow-up. Normal subjects were defined as

patients followed up at the clinic for allergic diseases without airways involvement and with no history of pulmonary disease.

Study Protocol

In Figure 1, a schematic representation of the study is presented. After providing written informed consent, patient demographics, height, weight, smoking status, previous medical diagnosis, current medical status (including acute illnesses in previous 4 weeks), and inhaled medication in previous 12 h were assessed. To ensure clinical stability, patients completed the Asthma Control Questionnaire[25] and a modified Borg dyspnea scale that was repeated at the end of the expiratory maneuvers.[26] The self-administered version of Asthma Control Questionnaire has six questions regarding asthma control in the previous week; scores range from 0 to 6 (no control). The modified Borg dyspnea scale has a range from 0 (no dyspnea) to 10 (maximal dyspnea).

One trained medical technician used a step-by-step protocol for the instruction of maneuvers and demonstrated the techniques to all subjects. Instructions were provided in simple terms to the participants in their native language. Patients were asked to perform four sets of expiratory maneuvers, one set for each device. The order of the sets was previous randomized using software (SPSS version 11; SPSS; Chicago, IL). Each set comprised three adequate maneuvers according to the instructions of the manufacturer and ATS recommendations.[27] A maximum of eight trials was set, but no more than six trials were necessary throughout the study. Maneuvers were performed in standing position; a nose clip was used only with the pneumotachograph. The FVC maneuvers used the open-circuit technique. In brief, after a complete inhalation, the mouthpiece was inserted in the mouth, passing the teeth, and the lips were completely sealed around the mouthpiece. With minimal delay, the subjected started exhalation with maximal effort and continued until end-of-test criteria were met. Forced expiratory maneuvers that met all acceptability criteria were performed until the two best efforts were reproducible (minimum of three). The test curve with the highest sum of the FVC and FEV_1 was considered the best curve, and the largest FVC and FEV_1 measurements were stored. Between each set of maneuvers, the patients rested 2 to 3 min. FEV_1 and PEF values for the best three acceptable maneuvers were recorded for analysis.

Statistical Analysis

Within-session reproducibility was defined as the agreement of the measurements performed with the same device and individual during one set of maneuvers. Within-session reproducibility was assessed between the two best maneuvers by the coefficient of variation (CV) and the intraclass correlation coefficient (ICC). The association between the PEF and FEV_1 measurements by the pneumotachograph and the different monitoring devices were plotted with the respective regression lines. Accuracy was defined as the agreement of measurements performed with measurements performed with a reference device in the same individual.

Considering the pneumotachograph as the reference instrument, the accuracy for PEF and FEV_1 measurements was assessed by the determination of the ICC with the monitoring devices measurements as dependent variables and by the limits of agreement according to Bland and Altman.[28] The mean differences between each electronic monitoring device and the pneumotachograph data were plotted against the mean values of FEV_1 and PEF from each device and the pneumotachograph, and limits of agreement were estimated at ± 2 SD of the differences. The random error, computed as $1\text{-}r^2$, was defined as the deviation of the tested device values from the regression line. This random error, sometimes named precision, was considered another proxy for accuracy.

Statistical analysis was carried out using statistical software (SPSS version 11.5; SPSS). A probability of $< 5\%$ was considered to be significant. For ICC and CV, 95% confidence intervals (CIs) were calculated.

RESULTS

Thirty-eight patients were included. Their demographic characteristics, height, weight, smoking status, FEV_1, and PEF descriptive data are presented in Table 1. All individuals were white; 23 patients (61%) had asthma. Twenty-five patients (66%) had
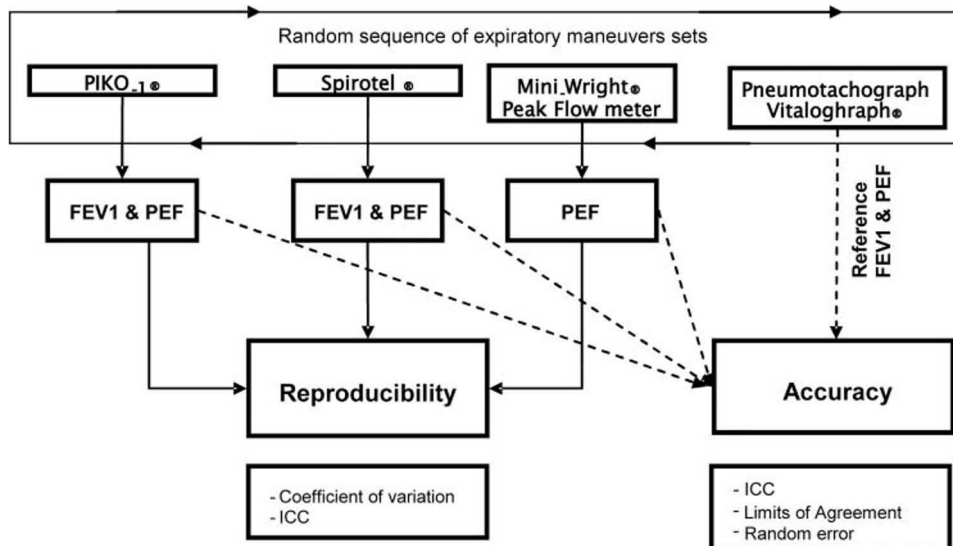

FIGURE 1. Schematic presentation of study methods.

Variables	Total (n = 38)	Asthmatics (n = 23)	Normal Subjects* (n = 15)	p Value
Sex, No. (%)				0.232†
Male	11 (29)	6 (26)	5 (33)	
Female	27 (71)	17 (74)	10 (67)	
Age				0.172‡
Mean (SD)	33 (14)	28 (11)	40 (14)	
Minimum/maximum	18/58	18/54	21/58	
Height, cm				0.997‡
Mean (SD)	164 (9)	163 (9)	165 (9)	
Minimum/maximum	150/185	151/185	150/179	
Smoking status, No. (%)				0.529†
Nonsmoker	30 (79)	19 (83)	11 (73)	
Previous smoker	6 (16)	3 (13)	3 (20)	
Current smoker	2 (5)	1 (4)	1 (6)	
FEV_1, L				0.409‡
Mean (SD)	2.98 (0.72)	2.90 (0.76)	3.11 (0.66)	
Minimum/maximum	1.25/4.82	1.25/4.37	2.09/4.82	
FEV_1, % predicted				0.012‡
Mean (SD)	104 (0.19)	98 (0.21)	113 (0.11)	
Minimum/maximum	34/162	34/162	97/139	
PEF, L/min				0.450‡
Mean (SD)	444 (118.8)	425 (113)	474 (126)	
Minimum/maximum	290/698	290/669	329/698	

*Without airways disease.
†Pearson χ^2 test.
‡t test.

previous experience of using PEF meters, and 16 patients (42%) remembered performing spirometry previously.

Mean Asthma Control Questionnaire scores were 0.58 (SD, 0.51; minimum, 0; maximum, 1.83) for asthmatics and 0 (SD, 0; minimum and maximum, 0) for normal subjects. The dyspnea scale at the beginning of tests ranged from 0 to 2, with a mean of 0 (SD, 0) for both groups. At the end of the four sets of maneuvers, the dyspnea scale was similar and no more than a 1-U increase was observed. The within-session reproducibility had similar ICCs for all devices, and when assessed by CV was ≤ 5% for both PEF and FEV_1 (Table 2).

In Figure 2 the scatter plot between the pneumo-

Table 2—Within-Session Reproducibility Assessed by CV and ICC

Variables	CV, % (95% CI)	ICC (95% CI)
FEV_1, L		
PiKo-1	4.2 (3.5–5.6)	0.97 (0.95–0.99)
Spirotel*	4.2 (3.3–6.4)	0.98 (0.94–0.99)
PEF, L/min		
PiKo-1	5.0 (4.1–6.7)	0.96 (0.92–0.98)
Spirotel*	4.0 (3.2–5.9)	0.97 (0.93–0.99)
Mini-Wright	3.8 (3.1–5.0)	0.95 (0.90–0.97)

*Spirotel firmware does not allow the visualization of more than two values per session.

tachograph and Mini-Wright PEF is the most distant to the identity line. The plots for FEV_1 were closer to the identity line, particularly for the PiKo-1 device.

In Table 3, the accuracy of the monitoring devices is summarized. The FEV_1 ICC was > 0.95 for both the PiKo-1 and Spirotel devices. For PEF, the ICC was lower but still > 0.90 for both electronic instruments. For the Mini-Wright device, the ICC was lowest (0.87). Also, in the limits of agreement analysis, the Mini-Wright device had a mean difference more than three times greater than the Spirotel device and six times greater than the PiKo-1 device. The Mini-Wright PFM was the only device with a nonlinear distribution of the differences (Fig 3). In higher PEF values, the differences to the pneumotachograph are small, but in lower values the differences are bigger, with the Mini-Wright device overestimating PEF. The only measurements with random error > 5% was FEV_1 assessed with the PiKo-1 device (3.5%) [Table 3]; however, the PiKo-1 device had the worst random error (18.4%) when measuring PEF.

DISCUSSION

Main Findings

We have shown a very good reproducibility and an excellent agreement with an office pneumotacho-
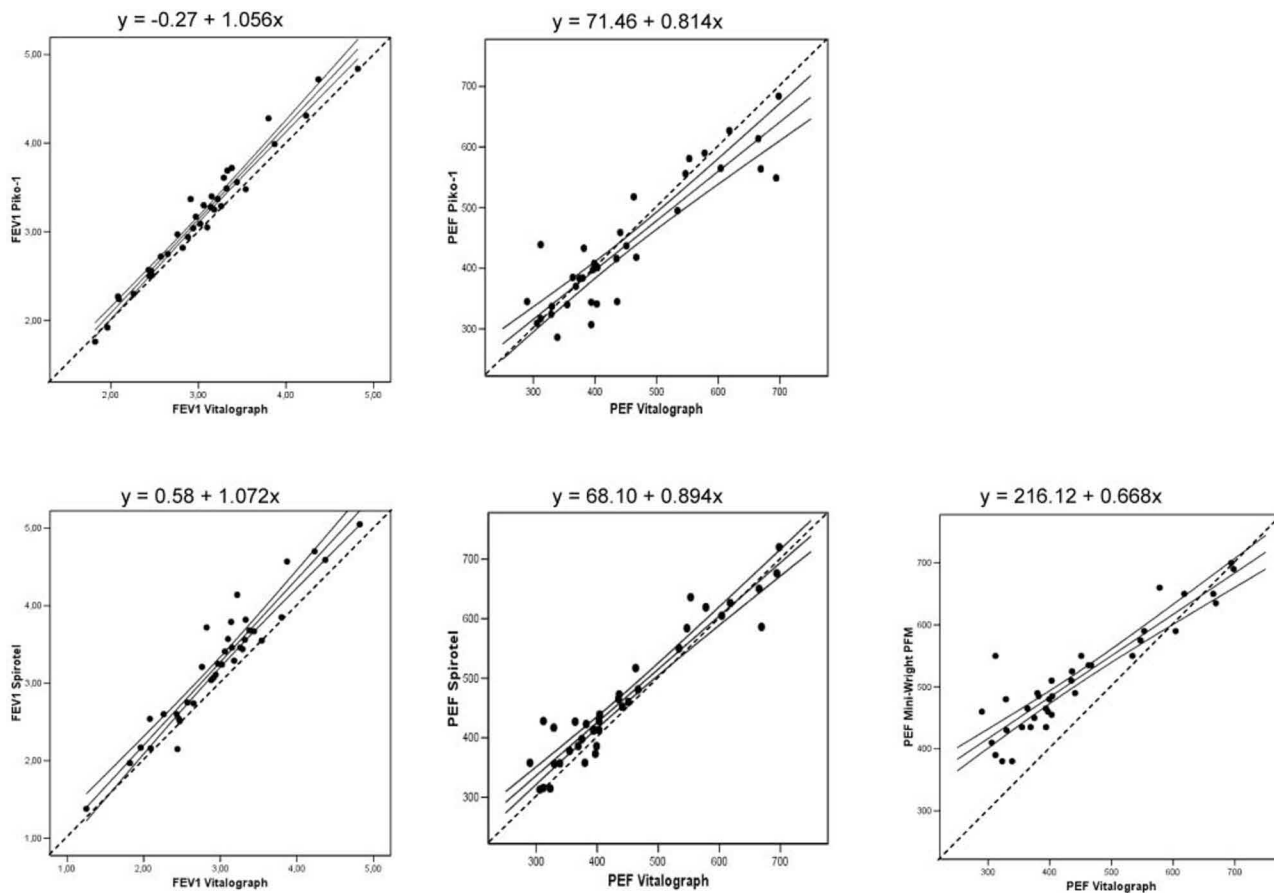
FIGURE 2. Scatter plots of Vitalograph pneumotachograph measurements against PiKo-1, Spirotel, and Mini-Wright PFM measurements. FEV_1 units are expressed in liters, and PEF values are expressed in liters per minute. Dotted lines represent the lines of identity; full lines represent regression and 95% CIs for mean lines. Regression equations are shown at the top of the plots.

graph and both pulmonary function electronic monitoring devices. Additionally, we confirmed the low accuracy and the nonlinear response of the Mini-Wright PFM. The best agreement with the pneumotachograph was observed for PiKo-1 FEV_1, and the worst was observed for Mini-Wright PEF.

The inadequate performance of the Mini-Wright PFM is consistent with the observations of other

studies.[17–19, 22] In fact, a model with a different scale has been introduced in the market to reduce errors.[29] The lack of linear response is not necessarily characteristic mechanical PFMs.[30]

To our best knowledge, no studies have been published regarding the clinical performance of the PiKo-1 or Spirotel devices. Other home spirometers and electronic monitoring devices have been stud-

Table 3—*The Accuracy of PiKo-1, Spirotel, and Mini-Wright Monitoring Devices Assessed by the Agreement With an Office Pneumotachograph*

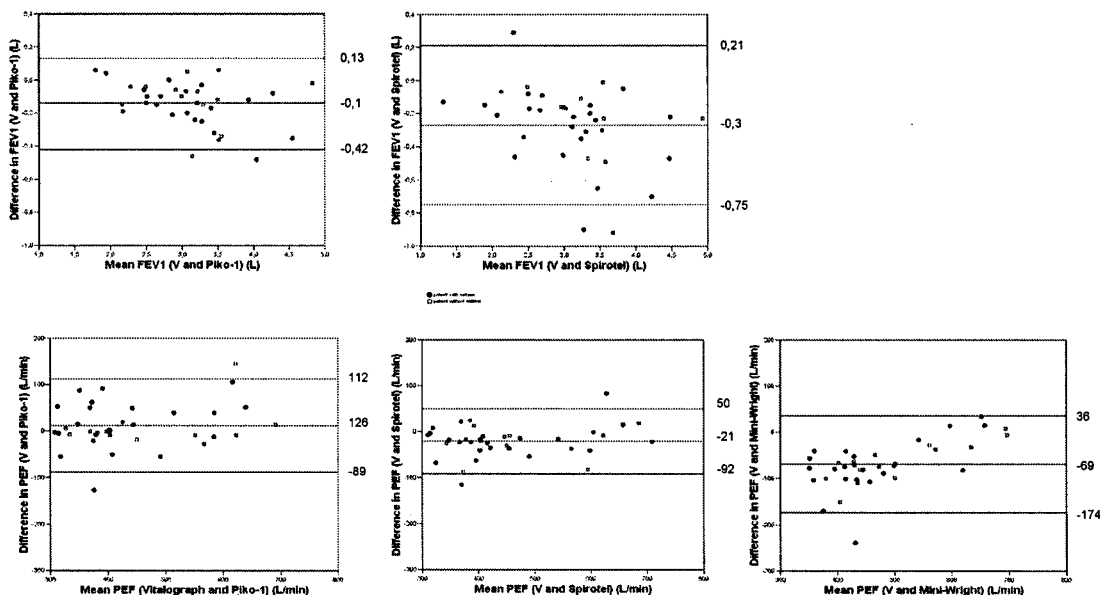| Monitoring Devices | ICC (95% CI) | Limits of Agreement | | | Random Error, $(1 - r^2) \times 100$ |
		Mean Difference	− 2 SD	+ 2 SD	
FEV_1, L					
PiKo-1	0.98 (0.96–0.99)	− 0.1	− 0.42	0.13	4
Spirotel	0.95 (0.91–0.97)	− 0.3	− 0.75	0.21	9
PEF, L/min					
PiKo-1	0.90 (0.82–0.95)	13	− 89	112	18
Spirotel	0.95 (0.91–0.98)	− 21	− 92	50	9
Mini-Wright	0.87 (0.77–0.93)	− 69	− 174	36	16

FIGURE 3. Agreement of PiKo-1, Spirotel, and Mini-Wright PFM measurements with an office pneumotachograph (Vitalograph). Lines represent mean differences and upper and lower agreement limits (± SD).

ied, indicating their performance is fairly adequate for different clinical situations.[31–38]

Limitations and Strengths

Our participants had a relatively high pulmonary function, which is probably related to the clinical stability inclusion criterion. This criterion was set in order to ensure the security of the protocol and to avoid maneuver-induced bronchospasm.[39] These objectives have been achieved as indicated by the observation of measurement values (data not shown) and the minimal change in the dyspnea scale after the maneuvers. Nevertheless, the population studied is quite typical of the asthma patients seen in most medical settings, as the majority of asthma severity is mild, and also patients with more severe asthma have normal or near-normal pulmonary function after adequate treatment. In fact, clinical evaluation of medical devices and diagnostic tests should be performed with subjects with similar characteristics to those who are expected to benefit from their use.[40] Some authors[32,39] also recommend that the assessment include a second group of subjects without the disease under study; we did this by including 15 subjects with no respiratory disease.

In our study, only 42% of subjects had previously performed spirometry; this can be regarded as strength of this study because if we had used experienced, too-well-trained subjects, this would have biased positively the results. We chose to use a pneumotachograph as reference. This is an accepted way of testing PFMs.[20] In fact, in clinical settings the use of monitoring devices along with office spirometers is much more frequent than with sophisticated laboratory equipment.

We have not fully evaluated the measurement capabilities of the Spirotel device; parameters such as FVC or forced expiratory flow, midexpiratory phase were not focused on in this study. Also, we did not intend to study the recording and transmitting functions of the devices. Finally, this study did not assess the reproducibility over a period of time. Long-term reproducibility may be more important in monitoring than accuracy if the devices are to be used to assess variations of the disease over time.

Implications for Clinical Practice

The availability of a simple, low-cost device with a very good agreement with a pneumotachograph may have a profound impact in low-income countries where pulmonary function laboratories cannot be easily implemented. In spite of the good agreement between monitoring devices and the pneumotachograph, the devices are not interchangeable as can be inferred by the outliers, albeit in small number, observed in Figure 3. When treating a patient, a measurement with one device should not be compared directly with a measurement done with another device, a well-known warning for other pulmonary function devices.

It is expected that the storage of data by electronic monitoring devices diminishes transcription errors

and allows a better assessment of compliance. Also, the possibility of measuring other parameters such as FEV_1 along with PEF may be advantageous in long-term management of respiratory disease. Of the monitoring devices tested, only the Spirotel device can measure FVC and FEV_1/FVC, which are also relevant in many clinical situations. Other particular features of Spirotel device, such as the built-in modem and optional oximeter, can also prove interesting for specific settings.

The cost of the PiKo-1 device is much less than most other pulmonary function electronic monitoring devices and is similar to a mechanical PFM. In light of the results of this and other studies,[11,23] the acquisition of mechanical PFM may not be the best option.

Future Research

Future work is needed in order to determine the clinical performance of the PiKo-1 and Spirotel devices in children, in COPD patients, and in unstable asthma patients with lower pulmonary function. Furthermore, it is necessary to study their long-term reproducibility, assess practical utilization issues (such as battery life and download of data), other parameters measured (in the case of the Spirotel device), and the acceptability by the patients of electronic monitoring. Finally, the impact of electronic monitoring devices in improvement of asthma and COPD clinical and economic outcomes also needs to be established.

Conclusion

The low-cost and easy-to-use electronic monitoring devices tested showed a very good reproducibility and were in agreement with the pneumotachograph. Therefore, they seem adequate both for screening and monitoring. However, prospective studies are needed to assess long-term reproducibility, usability, and especially the effects on the improvement of respiratory care.

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