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Diagnostic and Therapeutic Methods

Relevance of a Portable Spirometer for Detection of Small Airways Obstruction

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Summary. While portable spirometers are increasingly used, little attention has been paid to test their validity for measurement of flows in small airways. The aim of this study was to compare the Spirotel portable spirometer to a laboratory spirometer (Jeager PFT), with regard to accuracy in measuring forced expiratory flows, and more specifically those influenced by small airways (FEF_{25-75}). Fifty-nine children (mean age, 12 years; range, 7–17), were studied at baseline and after a bronchodilator inhalation. Spirometers were tested separately in a randomly designed order. A total of 117 sessions of flow-volume curves was performed with each spirometer. We obtained at least two acceptable and reproducible curves in 88% and 76% of the sessions, with the laboratory and the portable spirometers, respectively. Unacceptable curves were easily detected by visual inspection of flow-time and flow-volume waveforms. Agreement was excellent between spirometers for the measurement of all expiratory flows, both at baseline and postbronchodilator. More specifically, agreement between spirometers was as high for measurements of FEF_{25-75} (intraclass correlation coefficients 0.97) as for proximal flows. High correlations were found between baseline expiratory flows measured by each spirometer (and expressed as percent of predicted values), both in large and small airways ($P < 0.001$). The portable spirometer was highly sensitive for detecting small airways obstruction, as compared to the laboratory spirometer. Finally, the magnitudes of bronchodilator-related flow changes were also highly correlated, both in large and small airways ($P < 0.001$ and $P = 0.004$, respectively). We conclude that the Spirotel portable spirometer is reliable for measurement of forced expiratory flows, in large and small airways, provided that all curve waveforms can be stored and available for visual inspection. **Pediatr Pulmonol. 2005; 39:178–184.**

Key words: portable spirometry; small airways; child.

INTRODUCTION

Small airways injuries leading to airway obstruction are thought to be early lesions during the course of many lung diseases.[1] Thus, detecting small airways obstruction may allow earlier recognition of lung function alteration. Consequently, treatments may be provided earlier, and/or preventive treatments may be used, so that severe airflow obstruction may be prevented. This issue is of interest in many lung diseases such as asthma.[1] More interestingly, it is of critical importance for those very severe lung diseases with low-effective curative treatments, such as post-lung or bone marrow transplantation bronchiolitis obliterans syndrome.[2–4] Early identification of these cases relies on early detection of small airways obstruction.[3] For this purpose, the use of spirometry, and furthermore of portable spirometry, is a real challenge.

In the last few years, home monitoring using portable spirometers has gained increasing interest in children for various reasons.[5–9] Portable spirometry recently became available for measuring forced expiratory flow in 1 sec (FEV_1) and instantaneous flows during the entire forced expiration.[9] Moreover, young children were shown to be able to provide reproducible measurements over a prolonged period of time.[7,9]

However, little attention has been paid to testing the validity of portable spirometers for measuring flows in small airways. In fact, even during lung function tests attended in the laboratory by experienced technicians, not

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all children older than 6–7 years can sustain an adequate forced expiration down to residual volume. Thus, determination of flows which are influenced by the end of expiration may be altered, i.e., the forced expiratory flow between 25–75% of forced vital capacity (FEF_{25-75}), which characterizes the flows in both large and small airways, and the forced expiratory flow at 75% of forced vital capacity (FEF_{75}), which explores small airways.

The aim of this study was to assess the validity of a portable spirometer (Spirotel, MIR, Rome, Italy) in comparison to a reference laboratory spirometer (Jeager PFT, Jeager, Germany). More specifically, we aimed to assess the accuracy of the portable for measuring flows in small airways. Children with various lung diseases were studied, and the effects of an acute bronchodilator inhalation were measured.

PATIENTS AND METHODS

Patients

Fifty-nine children (38 male, 21 female) agreed to participate to the study during their routine lung function tests in the Department of Physiology of the Robert Debré Hospital (Paris, France). The median age was 12 years (range, 7–17), median heigth was 151 cm (122–181), and median weight was 43 kg (25–92). Underlying diseases were stable asthma (n = 39), chronic cough (n = 10), or sickle-cell disease (n = 10). All children had previously performed spirometric testing at least once, and many had used the Jeager laboratory spirometer, whereas none had experienced the Spirotel portable spirometer. The study was approved by the appropriate ethics committee, and informed consent was obtained from the child and accompanying parent.

Spirometers

The laboratory spirometer is the Jeager PFT, provided with a heatable pneumotachograph which is connected to a computer. It meets American Thoracic Society (ATS) standards for laboratory spirometers. Calibration is performed on site twice a day, according to the manufacturer's recommendations. A real-time display of flow-volume waveform is available on screen.

ABBREVIATIONS

ATS	American Thoracic Society
CoV	Coefficient of variation
FEF_{75}	Forced expiratory flow at 75% of forced vital capacity
FEF_{25-75}	Forced expiratory flow between 25–75% of forced vital capacity
FEV_1	Forced expiratory volume in 1 sec
FVC	Forced vital capacity
ICC	Intraclass correlation coefficient
PEF	Peak expiratory flow

The Spirotel portable spirometer is an integrated handheld and battery-powered device (dimensions, 70 × 80 × 30 mm; weight, 100 g). Its digital turbine flow sensor with infrared interruption is not sensitive to humidity (thus no heating is required), and is easily extracted from the unit to be cleaned. Each spirometer is factory-calibrated. During testing, coaching messages are displayed by the quality-control software, based on ATS criteria. Memory storage is available for several hundred spirometric data, including parameters as well as curve waveforms, symptom scores, and date. Volume-time and flow-volume waveforms are available after data transfer, using Winspiro software. Data may be transferred, either using a cable during a medical visit, or by internet using normal home telephone and the internal modem inserted into the portable.

Forced Maneuvers

Children were asked to perform one session of flow-volume curves using each spirometer, at baseline and after a bronchodilator inhalation (Ventolin, 200 μg). The two spirometers were tested separately, in a randomly determined order at baseline, and in reverse order post-bronchodilator. ATS guidelines allow up to 8 forced expirations per session.[10,11] In order to assess the feasibility of testing children who might be fatigued by their underlying disease, we decided to limit testing to a maximum of 3 forced expirations per session. An interval of 10 min was allowed between sessions.

To use the laboratory spirometer, the children, with noseclips in place, were asked to seal their lips around the mouthpiece connected to an air filter (PAL, Saint Germain en Laye, France; volume, 40 ml; resistance, <0.008 cm/l/sec). Children were instructed to breathe normally for 3 or 4 cycles, and after a given visual and audible beep, to take maximal inspiration, and then to perform a maximal expiration for as long as possible, followed by a further deep inspiration. Volume-time and flow-volume waveforms were displayed on-screen during maneuvers.

To use the portable spirometer, the children, with noseclips in place, were instructed to take a maximal inspiration, then place their mouth directly around the mouthpiece (no air filter), and perform a maximal expiration for as long as possible. Two beeps were audible 6 sec after onset of expiration. As all children were naive to the use of the Spirotel, a 5-min period was allowed for instructions given by an experienced technician.

Analysis

We analyzed the following lung function parameters: forced vital capacity (FVC), forced expiratory volume in 1 sec (FEV_1), peak expiratory flow (PEF), forced expiratory flow between 25–75% of FVC (FEF_{25-75}), and forced expiratory flow at 75% of FVC (FEF_{75}).

To evaluate the acceptability and reproducibility of the curves, ATS criteria were used,[10,11] except for forced expiratory time. Indeed, based on previous findings in a large pediatric population, a forced expiratory time of 2 sec or greater was accepted.[12]

Acceptable curves were those with: 1) a good start of expiration (backward extrapolated volume must be <5% of FVC or 0.15 l, or time to PEF <100 msec); 2) no hesitation, no coughing, no glottis closure, no air leak, and no obstruction of the mouthpiece during maneuvers; 3) and no early ending of expiration (final flow must be <0.2 l/sec, or the patient must be exhausted; forced expiratory time must be ≥2 sec). Also, volume-time and flow-volume waveforms were visually inspected to eliminate unacceptable curves.[11] Attention was paid to determine those which missed end-expiration criteria.

Reproducibility of measurements was evaluated for sessions with at least two acceptable curves. Sessions with reproducible curves were those with a difference ≤5% between the two highest values of FVC and FEV_1 within the session.[10,11] The number of sessions with at least two acceptable and reproducible curves was determined for each spirometer.

To compare measurements between spirometers, only data from children with at least two acceptable and reproducible curves by both spirometers were analyzed. The coefficient of variation (CoV) of measurement for a given lung function parameter was calculated as the standard deviation of the two highest values of each individual subject divided by their mean.

For each child, FVC and FEV_1 were determined as the largest values obtained, even they did not come from the same curve. The other expiratory flows were derived from the single curve with the largest sum of FVC plus FEV_1.[11] All parameters were expressed as a percentage of predicted values (previously established from healthy children as a function of height in our department; unpublished data). The ability of each of the two spirometers to detect airway obstruction was assessed. For this purpose, small airways obstruction was defined as FEF_{25-75} ≤75% of predicted values.[3,11] In addition, we also evaluated the criterion of FEV_1 ≤90% of predicted values, as recently suggested for diagnosis of potential bronchiolitis obliterans syndrome.[3] Finally, the magnitudes of bronchodilator-related flow changes were compared between spirometers.

Statistical Analysis

Data are given as median (and range), unless otherwise specified. Differences between spirometers were compared using Wilcoxon signed-rank tests. Correlation between measurements was assessed using Spearman's test. Agreement of measurements between spirometers was assessed using Bland-Altman plots[13] and by calculating intraclass correlation coefficients (ICC) in a two-way mixed model. The sensitivity of the portable for detecting airway obstruction was calculated, with the laboratory spirometer as reference. $P < 0.05$ was used as the threshold of statistical significance. All analyses were performed with SPSS software (SPSS, Chicago, IL).

RESULTS

A total of 117 sessions was completed using each spirometer. One child did not perform flow-volume curves postbronchodilator.

Acceptability

When the laboratory spirometer was used, 98% of the sessions had at least two curves that met end-expiration criteria, compared to 95% when using the portable (Table 1). Two children were unable to maintain expiration longer than 2 sec. In the remainder, early ending of expiration produced a high final flow which abruptly dropped to the zero line, easily seen on the flow-volume waveform. A high percentage of sessions had at least two curves that met all acceptability criteria (98% and 92% with the laboratory and the portable spirometers, respectively).

Reproducibility

Among the accepted sessions, 96% (110/115) and 86% (93/108) showed a difference ≤5% between the two highest FVC using the laboratory spirometer and the portable, respectively. Similarly, 88% (101/115) and 82% (89/108) of accepted sessions had a difference ≤5% between the two highest FEV_1. Thus, among all sessions performed, 88% (103/117) and 76% (89/117) had at least two acceptable and reproducible curves with the laboratory spirometer and the portable, respectively (Table 1).

Comparisons between lung function values measured by the spirometers were limited to sessions with at least

TABLE 1—Number (and Proportion) of Sessions That Met Acceptability and Reproducibility Criteria With Each Spirometer

	Laboratory spirometer	*Portable*
Sessions completed	117	117
Sessions with at least 2 curves that met end-expiration criteria[1]	115 (98%)	111 (95%)
Sessions with at least 2 curves that met all acceptability criteria	115 (98%)	108 (92%)
Sessions with at least 2 acceptable and reproducible curves	103 (88%)	89 (76%)

[1]Final flow <0.2 L/sec and forced expiratory time ≥2 sec.

TABLE 2—Comparison of Measurements and CoVs for Different Lung Function Parameters at Baseline and After Bronchodilator for Each of the Two Spirometers ($N = 51$ Patients)

	Baseline values[1]		Baseline CoV[2]		After bronchodilator CoV[2]	
	Laboratory spirometer	*Portable*	*Laboratory spirometer*	*Portable*	*Laboratory spirometer*	*Portable*
FVC (l)	2.84 ± 0.78	2.94 ± 0.79	1.1	2.2	1.0	3.0
FEV_1 (l)	2.41 ± 0.66	2.42 ± 0.64	1.4	2.0	1.1	2.7
FEF_{25-75} (l/sec)	2.48 ± 0.95	2.51 ± 0.82	4.4	3.7	3.8	4.5
FEF_{75} (l/sec)	1.19 ± 0.56	1.25 ± 0.43	6.7	6.5	6.2	7.7

[1]Mean $\pm$ SD.
[2]Median.

two acceptable and reproducible measurements by both methods, and included 51 children.

Variability of Measurements

Table 2 compares measurements from both spirometers. CoVs for flows which depended on small airways (FEF_{25-75} and FEF_{75}) were slightly higher than those of FEV_1 when using the same spirometer. However, CoVs for each lung function parameter were comparable between spirometers. More specifically, the CoVs for FEF_{25-75} and FEF_{75} were similar between spirometers, both at baseline and postbronchodilator (Table 2).

Agreement of Measurements

Figure 1 displays the Bland-Altman plots for FVC, FEV_1, FEF_{25-75}, and FEF_{75} at baseline. High values of ICC were found for all lung function parameters. Most interestingly, ICC values were as high for FEF_{25-75} and for FEF_{75} as for FEV_1, both at baseline and postbronchodilator (Table 3). This indicates that the portable provides reliable measurements of expiratory flows, including those exploring small airways.

Detection of Airway Obstruction

High correlations were found between FVC and all expiratory flows, including FEF_{25-75} and FEF_{75} measured by the two spirometers ($P < 0.001$, Fig. 2). The sensitivity of the portable spirometer for detecting small airways obstruction, or an $FEV_1 \leq 90\%$ of predicted values, was as high as 92% when compared to the laboratory spirometer.

Effects of Bronchodilator

Significant correlations were found between the magnitudes of bronchodilator-related changes in both FEV_1 and FEF_{25-75} (expressed as percent difference of predicted values) by the two spirometers ($P < 0.001$ and $P = 0.004$, respectively; Fig. 3). One patient provided outliers for changes in both FEV_1 and FEF_{25-75}. Two other outliers were identified for changes in FEF_{25-75}. Thus, for those 3 patients, the bronchodilator response showed an 8–20% increase in FEF_{25-75} as measured by the laboratory spirometer, but a 25–39% decrease as measured by the portable.

DISCUSSION

This study shows that the Spirotel portable is reliable for measuring forced expiratory flows, both in large and small airways. The sensitivity of the portable for detection of airway obstruction is as high as that of the laboratory spirometer, both in large and small airways.

The ideal home spirometer should be small and light, easy to use, and easy to clean, and should provide accurate data with curve waveforms which are stored and transferrable using the internet. In this study, all children were able to use the Spirotel rapidly after initial instructions. Moreover, we limited ourselves to a maximum of 3 forced expirations per session, although ATS guidelines allow up to 8.[11] Despite this limitation, a substantial number of sessions showed at least two acceptable and reproducible curves. This suggests that even children who may be fatigued are able to produce valid data using the portable spirometer.

Nevertheless, failure in the expiration technique is likely to occur in many young children. In this study, nearly 10% of the sessions performed with the portable spirometer had unacceptable curves. The latter were easily identified by visual inspection of both volume-time and flow-volume waveforms.[10,11] Thus, in order to ensure the quality of data, it is of importance that all waveforms be saved in the portable spirometer and are available for further visual inspection. We suggest that spirometers which do not store curve waveforms or only provide curves rebuilt from a few flow points[14] should be considered with caution.

There is no consensus on the reproducibility level of forced expiratory flows measured in children. Many pediatric studies used a reproducibility level lower than 10%,[6,8,9] a less stringent criterion than that proposed by the ATS.[11] Some authors argued that higher variability of

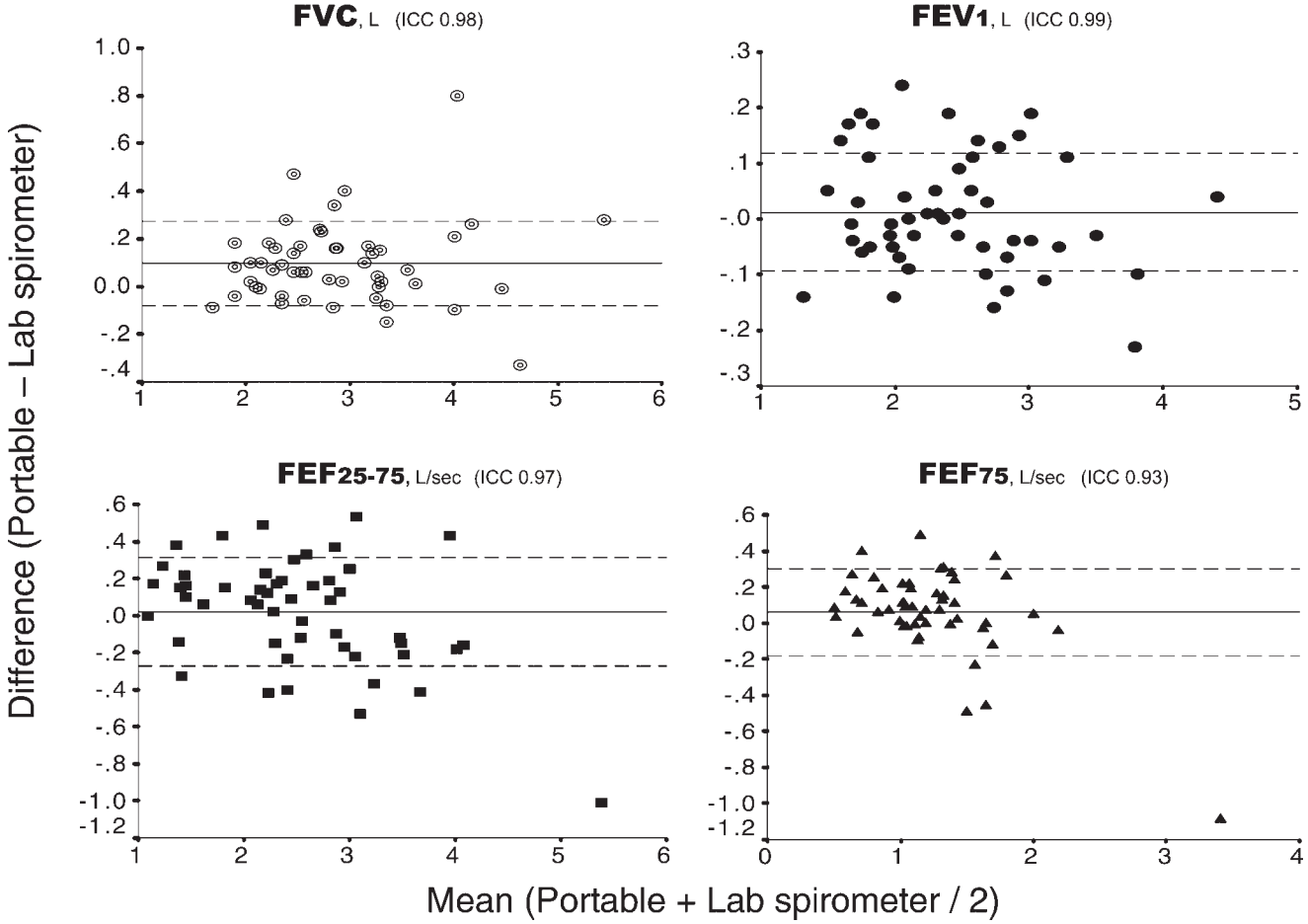

Fig. 1. Bland-Altman plots for FVC, FEV_1, FEF_{25-75}, and FEF_{75} at baseline. Mean of individual values for each parameter measured by both spirometers (X axis) is plotted against their difference (Y axis). Solid horizontal line represents mean of all differences, whereas broken horizontal lines represent mean ± 1 SD. ICC, intraclass correlation coefficient. Units are indicated for each parameter.

measurements may occur in children with asthma, due to maneuver-induced bronchospasm.[6] Even when using the ATS criteria, we found a substantial number of sessions with acceptable and reproducible curves by both spirometers. Many of our children were familiar with spirometric testing, confirming the positive effects of training on reproducibility of measurements.[15]

We found excellent agreement for the measurements of FVC as well as of all expiratory flows between the two spirometers tested. Most interestingly, agreements for flows which are influenced by end-expiration were as high as those for proximal flows. The Spirotel portable was as sensitive as the laboratory spirometer for detecting airway obstruction, both in large and small airways. Moreover, the magnitudes of bronchodilator-related changes in flows were comparable between spirometers. We found only 3 outliers for changes in FEF_{25-75} in the 50 patients tested. This may be due to a high intrasubject variability of measurements. Indeed, high coefficients of variation were found for postbronchodilator parameters, either using the

TABLE 3— Agreement Between Spirometers for Different Lung Function Parameters at Baseline and After Bronchodilator[1]

	Baseline		After bronchodilator	
	ICC	Difference (portable − Laboratory)	ICC	Difference (portable − Laboratory)
FVC (l)	0.98 (0.97–0.99)	0.09 (0.04–0.14)	0.98 (0.98–0.99)	0.08 (−0.02 to 0.13)
FEV_1 (l)	0.99 (0.99–0.99)	0.01 (−0.02 to 0.04)	0.98 (0.98–0.99)	0.01 (−0.03 to 0.04)
FEF_{25-75} (l/sec)	0.97 (0.95–0.98)	0.02 (0–0.10)	0.93 (0.87–0.92)	−0.07 (−0.19 to 0.06)
FEF_{75} (l/sec)	0.93 (0.89–0.96)	0.06 (0–0.13)	0.87 (0.77–0.92)	−0.01 (−0.10 to 0.07)

[1]ICC, intraclass correlation coefficient. Mean (and 95% confidence interval).

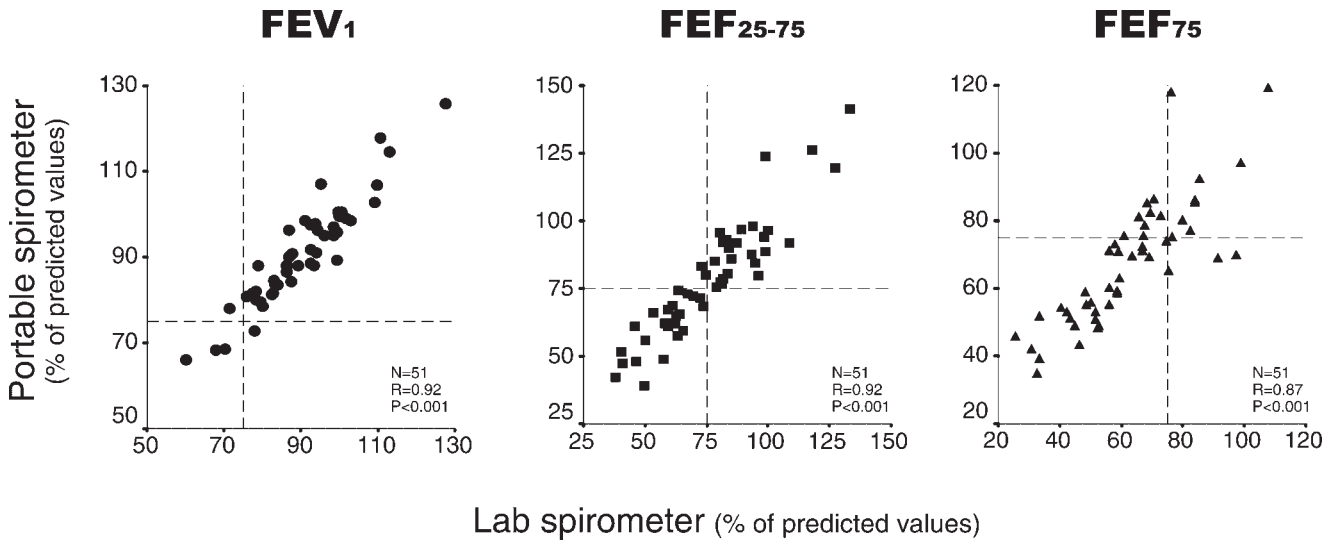

Fig. 2. Correlation between baseline FEV_1 values measured by two spirometers (left), FEF_{25-75} (middle), and FEF_{75} (right). Broken lines indicate 75% of predicted values cutoff.

laboratory spirometer in one patient (CoV, 19), or using the portable in the remainder (CoVs, 9.3 and 26). These 3 patients were asthmatic children.

In a previous study, Mortimer et al. compared laboratory and portable spirometers by connecting them in series.[9] In contrast, in this study, we decided to assess spirometers separately. First, we wanted to evaluate the portable spirometer in the context of a clinical study. Second, it is likely that connecting two spirometers in series may introduce some biases. Indeed, expiratory flows are likely to decline between the first spirometer and the second which is connected. Although ther effect on proximal flows may be negligible, flows which depend on end-expiration may be affected in a more significant

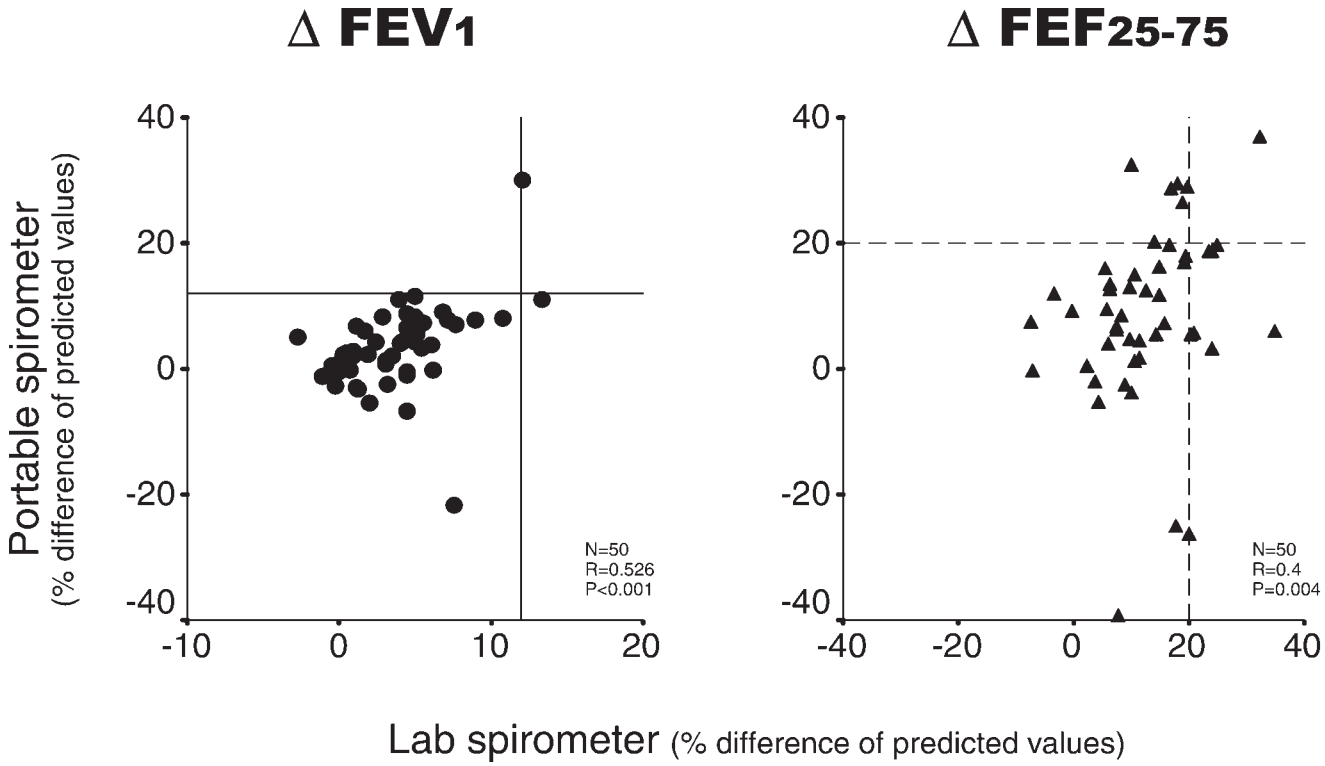

Fig. 3. Correlation between bronchodilator-related changes in FEV_1 (ΔFEV_1) measured by two spirometers, and in FEF_{25-75} (ΔFEF_{25-75}). Solid lines indicate ΔFEV_1 of 12% of difference of predicted values, whereas broken lines indicate ΔFEF_{25-75} of 20%.

manner. Therefore, this may have contributed to the low agreement found for FEF_{25-75} between in-series spirometers by Mortimer et al.[9] Indeed, in the same study, they found that agreement of measurements improved when spirometers were tested separately.

Another essential advantage of some portable spirometers, such as the one used here, is that data can be stored and transferred by internet. This should help the patient avoid frequent visits to the physician and lung function tests in the hospital. This is of particular importance for patients who may be fatigued and/or immunodepressed by their underlying disease. The International Society for Heart and Lung Transplantation considers spirometry a major tool for early diagnosis of bronchiolitis obliterans syndrome.[2] One may hope that home spirometry using portable devices during the posttransplant period may allow earlier detection of small airways obstruction, which in turn should prompt complete lung function testing in the laboratory and examination of the patient by a physician.[2,14]

In conclusion, this study shows that the Spirotel portable spirometer is well-accepted by children and is reliable for measuring forced expiratory flows, including those exploring the small airways. Large-scale multicenter studies are needed to investigate the feasibility and clinical benefits of internet-based home spirometry in early detection of airway obstruction and assessment of responses to treatments in many lung diseases.

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