

A comparison of a new transtelephonic portable spirometer with a laboratory spirometer

G. Izbic[#], S. Abboud*, P. Jordan[#], A.P. Perruchoud[#], C.T. Bolliger[#]

A comparison of a new transtelephonic portable spirometer with a laboratory spirometer. G. Izbic, S. Abboud, P. Jordan, A.P. Perruchoud, C.T. Bolliger. ©ERS Journals Ltd 1999.

ABSTRACT: The Spirophone is a new, portable transtelephonic spirometer which records the slow and the forced expiratory vital capacity tests. Data can be transmitted *via* the telephone to a remote receiving centre, where a volume-time curve and the flow-volume curve are displayed on screen in real time. The aim of this study was to compare the newly developed transtelephonic spirometer, with a laboratory spirometer according to the American Thoracic Society (ATS) testing guidelines.

Spirometry indices (slow vital capacity (SVC), forced vital capacity (FVC), forced expiratory volume in one second (FEV₁), peak expiratory flow (PEF), forced expiratory flow at 25, 50 and 75% of FVC (FEF₂₅, FEF₅₀, and FEF₇₅, respectively)) were measured from the SVC and the FVC tests in 45 subjects (30 patients, 15 healthy volunteers) according to the ATS standards. The data obtained with the laboratory system were compared to those from the Spirophone.

The Spirophone measurements of SVC, FVC, FEV₁, PEF, FEF₂₅, FEF₅₀ and FEF₇₅ correlated closely ($r=0.91-0.98$) to those from the laboratory system, whereas FEF₂₅, FEF₅₀, and FEF₇₅ were significantly higher with the Spirophone.

It is concluded that the Spirophone is comparable to the standard spirometry for home monitoring of slow vital capacity, forced vital capacity, forced expiratory volume in one second and peak expiratory flow. The validity of the manoeuvre can be assessed on screen in real time.

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[#]Pulmonary Division, Dept of Internal Medicine, University Hospital, Basel, Switzerland. *Dept of Biomedical Engineering, Tel Aviv University, Tel Aviv, Israel.

Correspondence: C.T. Bolliger
Dept of Internal Medicine
Faculty of Medicine
University of Stellenbosch
19063 Tygerberg
7505
Republic of South Africa
Fax: 27 219323105

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Patient home monitoring of peak expiratory flow (PEF) with a peak flow meter (PFM) is increasingly advocated as an aid to the better management of asthma, chronic obstructive pulmonary disease, and after lung transplantation [1, 2, 3]. However, the main limitations of the PFM are the wide individual variations and the inability to validate a correct patient performance of the forced expiratory manoeuvre (FEM) [2]. The introduction of a new portable spirometer (fig. 1) (SPIROPHONE AG-SP; Card Guard,

Rishon Le Zion, Israel) with which a slow vital capacity (SVC) as well as a forced expiratory vital capacity can be recorded and telephonically transmitted to a remote receiving centre could help to resolve this problem. The aim of the present study was to compare the Spirophone to a standard laboratory spirometer (Masterlab 4.0; Jaeger AG, Würzburg, Germany) according to the American Thoracic Society (ATS) guidelines [4, 5]. Previous studies have been able to show the reliability of the spirometry by preliminary testing [6–8].



Fig. 1. – The Spirophone portable spirometer.

Materials and methods

Test device

The Spirophone system records the SVC and forced vital capacity (FVC) tests. It operates with one 9 V battery and the data are digitized with a 12 bit analogue to digital converter with a sampling rate of 400 Hz. The Spirophone measures flow rates using a Fleisch-type pneumotachometer, and the flow-time curve is entered into the memory. The Spirophone can then perform an integration procedure, from which the volume-time curve is obtained. It allows the transmission of data, one test at a time, through a telephone using acoustic coupling to a receiving centre. The spirometric data, transmitted to the receiving centre are displayed on a computer screen as the volume-time and the flow-volume curves from the forced expiratory manoeuvre. The following parameters are calculated from the

curve: SVC, FVC, forced expiratory volume in one second (FEV₁), FEV₁/vital capacity (VC), FEV₁/FVC, forced expiratory volume in three seconds (FEV₃), FEV₃/VC, FEV₃/FVC, PEF and the maximal expiratory flow when 75, 50 and 25% of the FVC remain to be expired (FEF₇₅, FEF₅₀, and FEF₂₅, respectively). FEV₁ and FEV₃ are obtained by back extrapolation as recommended by the ATS [5]. All parameters are displayed in absolute values and in per cent of predicted normal values. The results from each patient are stored in a database program with software for data management (Card Guard Scientific Survival Ltd., Rishon Le Zion, Israel). The receiving centre requires a 486 personal computer with four megabytes of random access memory, a receiving demodulator unit, and a printer. On receiving a call from a patient, an operator at the receiving centre instructs the patient to transmit the data by placing the phone handset on to the Spirophone's speaker. The receiving unit demodulates the data, performs a body temperature and pressure saturated condition (BTPS) correction [9], and displays it on screen with the spirogram and flow-volume curve. If the exhalation is deemed acceptable according to the ATS recommendations [4, 5] it is stored in the database and the patient can then be instructed with respect to further exhalations or the clinical management. The program recalls previous respiratory curves from a memory and displays windows with the patient's personal data and clinical history. Comparison of pre- and postmedication spirometric data can be displayed.

Patients

Patients eligible for this study were routine patients from the authors' Division intended for the measurement of a full pulmonary function (comprising the SVC and the forced flow-volume curve with FVC, FEV₁ and PEF). The device was tested on 30 patients and 15 healthy human subjects (21 females and 24 males, age range 24–73 yrs; mean 48.8±13.3 yrs) according to the ATS standards [4, 5].

Trial Design

The Spirophone was compared with a commercial standard spirometer (Masterlab 4.0). Three out of 10 available Spirophones had been selected at random. The Spirophones selected for testing were production models. The testing procedures were performed according to the ATS testing guidelines [4, 5]. In order to achieve a balanced design, each subject performed alternating man-

oeuvres between the standard spirometer and the Spirophone, performing three manoeuvres on each device, for a total of six manoeuvres. Each subject was randomly assigned to perform the first manoeuvre either on the standard spirometer or on the device being tested, allowing the learning effect to be equally distributed across both instruments. The recordings of the Spirophone were transmitted telephonically to the remote receiving centre which was in the same institution but in a different section. A trained technologist received the data, which were redisplayed instantly on a computer screen, and decided if the curves were acceptable.

Statistical analysis

All curves from both devices were assessed as to their acceptability and reproducibility according to the ATS criteria. The best value from all acceptable curves of each device was compared for SVC, FVC, FEV₁ and PEF. The FEF₇₅, FEF₅₀, and FEF₂₅ were compared from the best test (test with the highest sum of FVC + FEV₁) of each device.

In order to test whether the measurements of the Spirophone correlated with those from the Jaeger device, the correlation coefficient (*r*) between the data obtained from both devices was calculated. To further elucidate whether the measurements of both spirometers can be used interchangeably, the mean of the differences between the indices measured by both devices (\pm limit of agreements), was calculated as described by BLAND and ALTMAN [10].

Results

Forty-three out of 45 curves were acceptable (two patients were not able to perform a third manoeuvre with the Spirophone because of fatigue) and the analysis was therefore performed with 43 patients. The ATS-reproducibility criteria (FEV₁ and FVC of the best and second best curve of each device differing <5% or <200mL) were not met by four out of 28 (14%) patients with the Jaeger (this criteria was met by all 15 healthy subjects) and by five out of 28 (18%) patients as well as by five out of 15 (33%) healthy subjects, with the Spirophone. As defined by the ATS, the reproducibility criteria were not used for excluding results from reports or for excluding subjects from this study [4]. The measurements of SVC, FVC, FEV₁, PEF, FEF₇₅, FEF₅₀, and FEF₂₅ performed with the Spirophone correlated closely with the results of the Jaeger system (all *r*-values >0.9) (table 1). Figure 2 shows the correlations of

Table 1. — Correlation and limits of agreement analysis

Spirometric index	Spirophone	Jaeger	Correlation coefficient	Differences*	Limits of agreement	p-value
SVC L	3.82 (1.20)	3.88 (1.19)	0.98	0.07 (0.26)	-0.44–0.59	NS
FVC L	4.10 (1.32)	3.77 (1.15)	0.96	-0.30 (0.40)	-1.10–0.50	NS
FEV ₁ L	3.03 (1.19)	2.82 (1.01)	0.98	-0.22 (0.27)	-0.76–0.32	NS
PEF L·s ⁻¹	8.74 (2.94)	8.07 (2.37)	0.92	-0.66 (1.18)	-3.01–1.71	NS
FEF ₂₅ L·s ⁻¹	6.80 (3.16)	5.19 (2.33)	0.91	-1.61 (1.44)	-4.45–1.23	<0.01
FEF ₅₀ L·s ⁻¹	3.86 (2.36)	2.77 (1.65)	0.95	-1.09 (0.96)	-3.01–0.83	<0.05
FEF ₇₅ L·s ⁻¹	1.48 (1.19)	0.96 (0.76)	0.95	-0.52 (0.52)	-1.56–0.52	<0.05

Data are presented as mean (SD). *: mean Jaeger reading - mean Spirophone reading. SVC: slow vital capacity; FVC: forced vital capacity; FEV₁: forced expiratory volume in one second; PEF: peak expiratory flow; FEF₂₅, FEF₅₀ and FEF₇₅: forced expiratory flow at 25, 50 and 75%, respectively, of FVC.

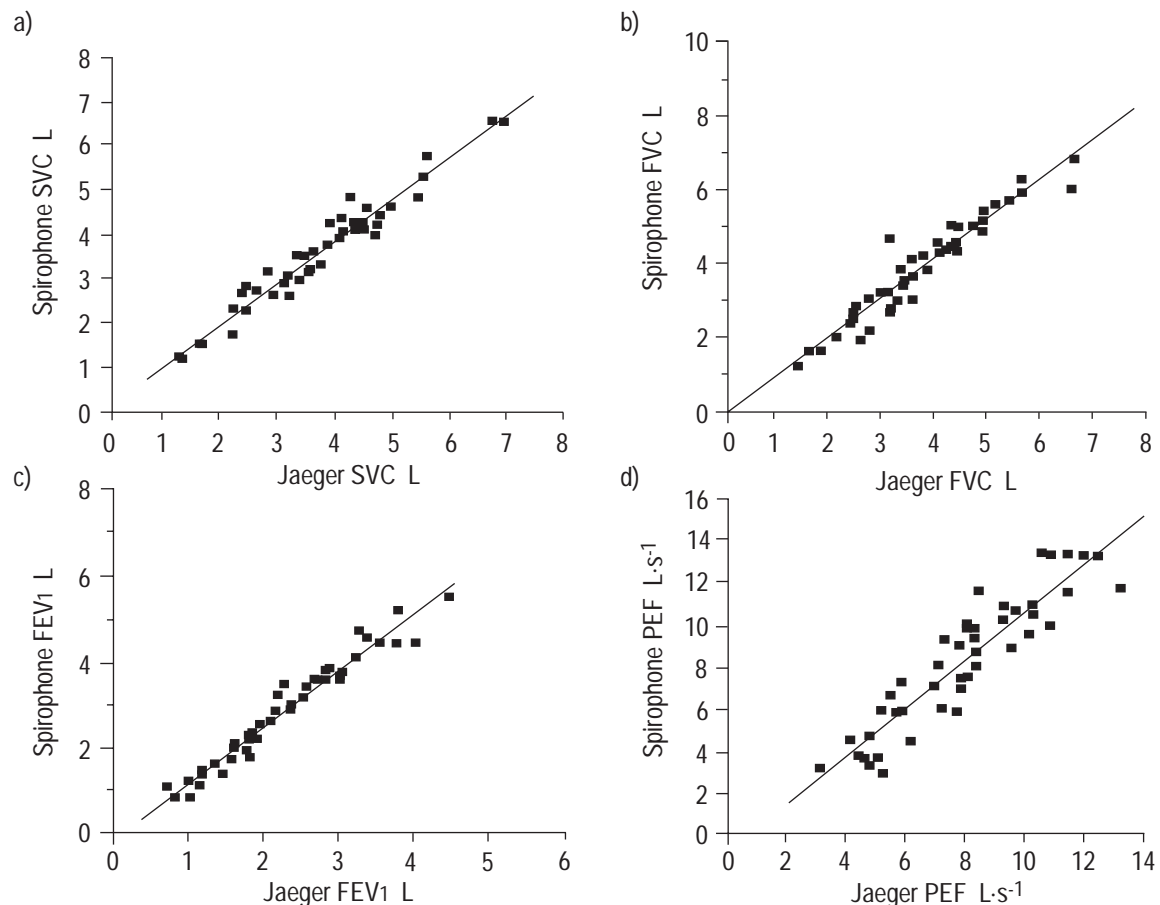


Fig. 2. – Correlation of the: a) slow vital capacity (SVC, $r=0.98$), b) forced vital capacity (FVC, $r=0.96$), c) forced expiratory volume in one second (FEV₁, $r=0.98$), and d) peak expiratory flow (PEF, $r=0.92$) measurements of the 43 patients using the Spirophone *versus* the Jaeger. Regression lines are shown.

SVC, FVC, FEV₁, and PEF measured with the Spirophone *versus* the Jaeger for the 43 subjects who met the acceptability criteria. Figure 3 shows the plots of the differences between the readings of two spirometers against their mean for SVC, FVC, FEV₁, and PEF. For SVC, FVC, FEV₁, and PEF, the differences were not significant, whereas for FEF₇₅, FEF₅₀, and FEF₂₅ the values obtained with the Spirophone were significantly higher than the ones from the Jaeger (table 1).

Discussion

The results show that all Spirophone measurements of FVC, SVC, FEV₁, PEF, FEF₇₅, FEF₅₀, and FEF₂₅ correlate closely with the results of the Jaeger system. However, FEF₂₅, FEF₅₀ and FEF₇₅ were significantly higher with the Spirophone. These differences between the spirometers in flow rates and the fact that the Spirophone showed nonsignificant lower readings for SVC but higher readings for FVC are probably due to nonlinearity of the pneumotachometer. Usually the calibration procedure is performed at low flow and as a result the parameter calculated during the SVC test (low flow) is accurate. When the pneumotachometer is nonlinear it is not calibrated for high flows and the parameters calculated during the FVC test are less accurate. In order to use the Jaeger system as a

standard spirometer it is necessary to eliminate any systematic bias in its calibration. This was not performed in this study. In a study by JOHNS *et al.* [11], it was found that the Jaeger system showed a nonlinear relationship between both FEV₁ and peak expiratory flow rate (PEFR) and their respective pulmonary waveform generator reference values. It was concluded that the reading on subjects must be adjusted to account for the systematic bias in their respective calibrations. This information was not available for the present study, and it was assumed that no systematic errors are present in the Jaeger system.

Because humans have their own inherent variability with repeated exhalations [12], and since the results of the FVC test show a significant reliance on patient's effort, the wider level of agreement observed with certain indices may be expected. In the limits of agreement analysis, the difference against the mean is plotted since the true value of the mean is not known. The mean of the two measurements is the best estimate available [10], and the consistent observation that the Spirophone shows higher readings for all the FVC spirometric indices may be a result of a calibration problem.

The Spirophone has previously been shown [6, 7] to be reliable and accurate in both the recording and transmission of forced expiratory manoeuvres from a patient's home to a remote centre for analysis and comment. Such a system being free of problems in day-to-day use under

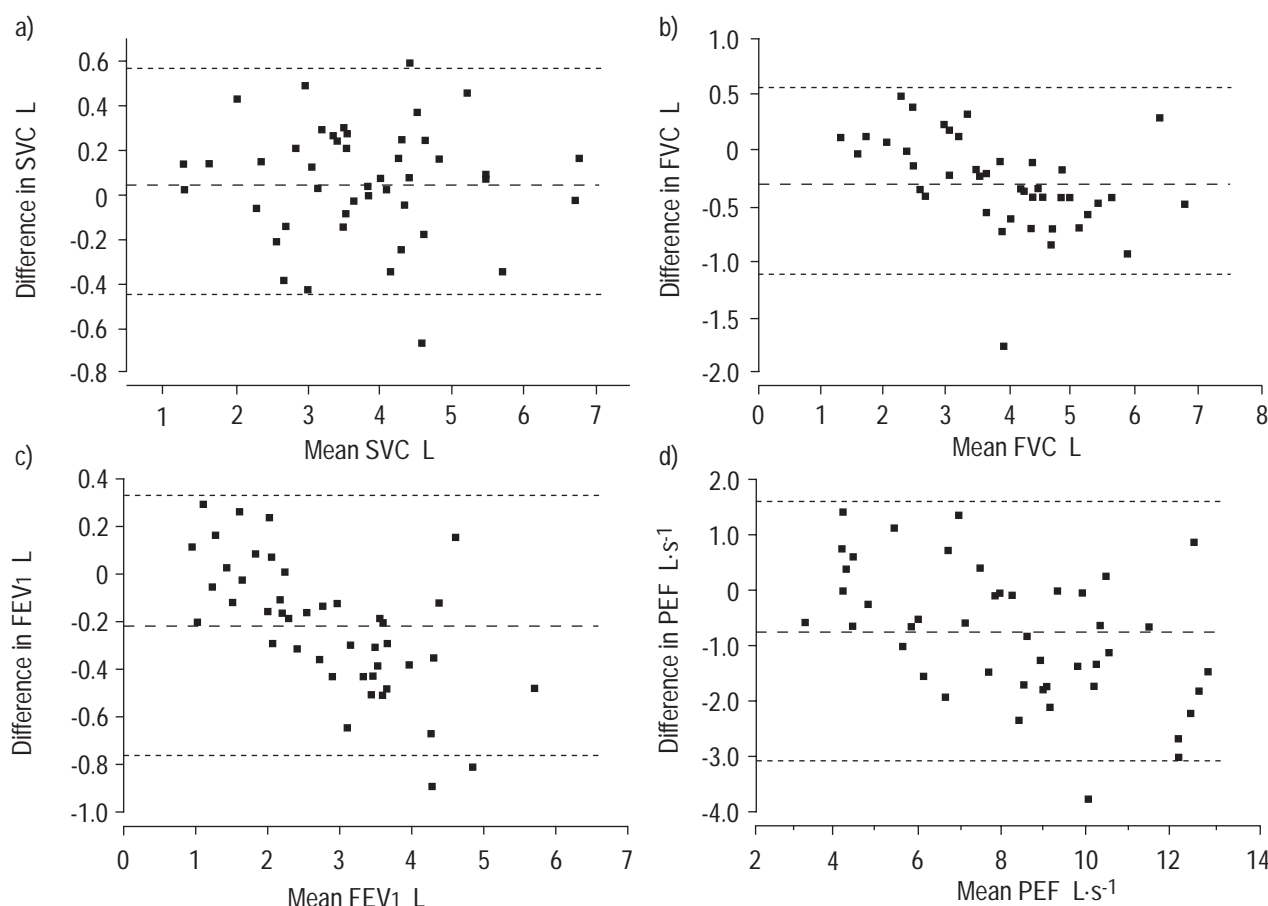


Fig. 3. — Plots of the difference between the readings of the two spirometers against their mean for: a) slow vital capacity (SVC), b) forced vital capacity (FVC), c) forced expiratory volume in one second (FEV₁), and d) peak expiratory flow (PEF). The mean (—) and upper and lower control limits (± 2 SD; ---) are shown.

circumstances where it cannot be specially protected and serviced by trained personnel, and including the possibility of instant expert advice, should be able to improve the current inherent problems of asthma therapy and other respiratory diseases such as cystic fibrosis, follow-up after lung transplantation and therapeutic bronchoscopy. Understanding of asthma self-management has developed greatly during the past 15 yrs, and there is a worldwide consensus that more effective methods of patient self-education and an objective measure of lung function at home are needed to reduce both morbidity and mortality from the disease [13–16]. Many trials have confirmed the utility of peak flow monitoring associated with an educational programme in reducing morbidity, improving lung function, and optimizing the use of medication in adult asthma patients [12, 17–22].

However, these devices are inadequate because they measure only one parameter, the PEF, which indicates air-flow changes in large airways only, and they have no visual display of the spirographic curves and thus lack the ability to evaluate the patient's cooperation. The main problem stems from the fact that PEF measurements can be very unreliable [12, 23, 24]. The Spirophone monitors function of both the large and small airways. Moreover, on the basis of the shape of the transmitted flow-volume curve, the operator at the receiving centre can assess whether the

forced expiratory manoeuvre was correctly performed and therefore the Spirophone, combining the advantage of home monitoring with remote quality control, can be a big help.

In young asthmatics, home monitoring of PEF twice daily correlates well with clinical indices of asthma and rescue bronchodilator consumption in those with more severe disease, but poorly in those with mild asthma [25]. UWYED *et al.* [25] concluded that better methods of obtaining objective information on the status of ambulatory patients are required, especially for the less severe asthmatics, possibly by real time monitoring of the forced expiratory flow-volume curve, symptoms and drug consumption. It has also been shown that the use of daily home spirometry when monitoring single lung recipients with emphysema as well as in patients following heart-lung transplantation offered early detection of complications such as acute lung rejection and opportunistic infections, allowing early transbronchial lung biopsy as well as assessment of their therapy [26–28]. Thus, a small portable spirometer that is easy to use such as the Spirophone, and capable of monitoring patient compliance, symptoms and both large and small airway function, may offer clear advantages. This would be especially true for patients living in remote areas or for those who have difficulty in reaching medical help due to disability or

other reasons. The fact that the Spirophone can store and transmit only one test at a time makes it more suitable for monitoring patients with severe respiratory problems. This device would also be very useful for clinical trials and other research studies.

Although frequent use of the Spirophone is associated with higher costs (device cost and need for more personnel at the receiving centre) the authors believe that its use could save money in general patient management. In the authors' experience, the use of the Spirophone, especially in severe asthmatics, cystic fibrotics, occupational diseases and in patients after interventional bronchoscopy [29], was associated with a decrease in consultations (urgent, night, weekend and emergency-room consultations) and in laboratory pulmonary function measurements. It is still not clear if this decrease counterbalances the supplementary costs associated with a widespread use of the Spirophone.

In conclusion, these results demonstrate that the Spirophone is comparable to standard laboratory spirometry for home monitoring of forced vital capacity, slow vital capacity, forced expiratory volume in one second, and peak expiratory flow. The validity of the manoeuvre can be assessed on screen in the centre in real time and when necessary, expert advice can be transmitted.

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