

# Assessment of accuracy and applicability of a portable electronic diary card spirometer for asthma treatment

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A pocket-sized turbine flowmeter and spirometer device, integrated with an electronic diary card (EDC-spirometer, Micro Medical, U.K.), was tested with a mechanical calibrator, in an outpatient clinic and in the home situation. A screen pneumotachometer was used as flow and volume reference.

Ten devices were tested; interdevice variability was small with a mean variation coefficient of 1.1% for both forced expiratory volume in 1 s (FEV<sub>1</sub>) and peak expiratory flow (PEF) (SD 0.5 and 0.4, respectively) for eight settings of the calibrator. Mean difference from reference was  $-0.13$  l (SD 0.04) for FEV<sub>1</sub> (range 0.38–3.16) and  $0.09$  l s<sup>-1</sup> (SD 0.09) for PEF (range 4.2–11.7). No significant deviation from linearity was present.

Results obtained in the outpatient clinic confirmed the accuracy of FEV<sub>1</sub> and PEF data obtained with the calibrator. However, linear regression analysis showed a mean underestimation of 0.45 l (SD of estimate 0.29) for forced vital capacity over the whole measurement range, probably due to a restricted integration time.

In 10 optimally-treated chronic obstructive pulmonary disease patients in a family practice, PEF measurements were done in the home situation, both with the EDC spirometer and a mini-Wright peak flow meter. No significant differences in the diurnal variation of PEF were found. The PEF data from the mini-Wright meter were corrected for earlier reported flow-dependent systematic deviations. In the home situation, patients preferred the EDC spirometer. It is concluded that this device is applicable in the follow-up and treatment of asthma at home.

## Introduction

In the management of patients with asthma, the diurnal variation of peak expiratory flow (PEF) is an important variable which can be measured at home with comparatively cheap hand-held peak flow meters (1, 2). Symptoms may also be noted by the patients on diary cards. It is known, however, that compliance with asthma therapy may be poor, and completion of diary cards may be inaccurate (3–6). Moreover, systematic deviations with the use of most types of mini PEF meters have been reported recently (5).

Therefore, a pocket-sized system has been developed (electronic diary card spirometer, EDC, Micro Medical, U.K.) which uses a turbine flowmeter for the measurement of forced vital capacity (FVC), forced expiratory volume in 1 s (FEV<sub>1</sub>) and PEF.

Additionally, coded input of symptoms can be stored in a memory.

The present study aimed to test the accuracy of, and variability between, the devices (inter-system variability) with flows imposed by a mechanical calibration system. Flow and volume data from a pneumotachometer system were considered as reference. In patients from an outpatient clinic, the lung function variables, obtained with the electronic diary card (EDC) spirometer, were also compared with those from a pneumotachometer system. Diurnal variation of PEF and patient compliance were compared with a mini-Wright PEF meter in obstructive patients in the home situation.

## Patients and Methods

### DESCRIPTION OF THE APPARATUS

The flow transducer unit consists of a fixed turbine which generates a rotational flow that drives a low inertia vane. Rotational flow is converted into PEF, FEV<sub>1</sub> and FVC, displayed digitally and stored in the memory. Symptoms such as coughing and nocturnal

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dispnoea can be scored and fed into the system, which keeps track of times and dates. An alarm reminds the patients to perform a test and enter symptoms. Coupling with a PC then enables the generation of a weekly report. A detailed description has been reported previously (7).

#### FLOW AND VOLUME CALIBRATION

Flow and volume calibration was done with a mechanical calibrator, based on explosive decompression of a known amount of air over a resistor (8). Peak expiratory flow was varied by changing the pressure of the system in case of a fixed resistor and, because decompression was complete within 1 s, the volume obtained was denoted as FEV<sub>1</sub>. Flow and volume values, at eight calibrator settings, were obtained with both the EDC spirometer and with a heated screen pneumotachometer (Jaeger, Germany); the latter data were considered as reference. The pneumotachometer has proven to give a negligible phase and amplitude distortion between 0.5 and 70 Hz (9), and a deviation in flow measurement of less than 3% up to 15 l s<sup>-1</sup> (10), thus fulfilling the ERS requirements (11). Volume calibration of the screen pneumotachometer was performed with a 1-l syringe with room air before each series of measurements. The temperature of the pneumotachometer head was such that the volume deflection at this calibration also represented 1 l under BTPS conditions because, in cases of measurement of expired air, the effects of humidity and temperature on viscosity are counteractive (11). This was verified by comparison of FEV<sub>1</sub> measurements in patients with both a water-sealed spirometer and the pneumotachometer system (unpubl. data). Ten EDC spirometers were tested and compared with the pneumotachometer reference. The EDC data were also considered to represent BTPS conditions. For the EDC signals, no external adjustment is possible.

#### MEASUREMENTS IN AN OUTPATIENT DEPARTMENT

In 20 patients (six female) selected at random from those attending the outpatient clinic, PEF, FVC and FEV<sub>1</sub> were measured both with the EDC spirometer and with a Jaeger screen pneumotachometer system. Mean age of the patients was 50.8 years (SD 18.4, range 11–78).

#### MEASUREMENTS IN PATIENTS IN THE HOME SITUATION

In 10 patients with chronic obstructive disease, diurnal variations of PEF were measured in a family practice (Zevenbergen, NI), both with a mini-Wright PEF meter and the EDC spirometer. Medication ( $\beta_2$ -sympathomimetics) was continued during the

study which lasted 4 weeks; the first 2 weeks using a mini-Wright PEF meter, then using an EDC spirometer, or vice versa. Diurnal variation was obtained from the ratio between the difference between PEF, measured at 0700–0800 h and 1800–1900 h, and mean PEF of the two measurements. Mini-Wright readings were corrected according to the relation between measured and true PEF as found by Miller *et al.* (5). Each day, symptom scores were noted, such as nocturnal dyspnoea and coughing. After the study period, the patients completed a questionnaire concerning user-friendliness and preference for either of the measurement systems.

#### DATA ANALYSIS

According to Bland and Altman (12), mean differences between the EDC and pneumotachometer data were plotted against the mean values of the FEV<sub>1</sub> and PEF from the two devices, and limits of agreement were estimated as  $\pm 2$  SD of the differences. Diurnal variations in PEF, measured in the home situation with the EDC spirometer and the mini-Wright meter, were compared using the Wilcoxon sign test.

## Results

#### MECHANICAL CALIBRATOR

For ten devices, PEF and FEV<sub>1</sub> were compared with the pneumotachometer values in the eight calibration settings, with PEF ranging from 4.2 to 11.7 l s<sup>-1</sup> and FEV<sub>1</sub> from 0.38 to 3.16 l. The inter-system variation coefficient (SD/mean in %) for PEF was 1.1 (SD 0.4) and for FEV<sub>1</sub> was 1.1 (SD 0.5). Mean deviations from reference were  $-0.13$  l (SD 0.04) for FEV<sub>1</sub> and  $-0.091$  s<sup>-1</sup> (SD 0.09) for PEF. No systematic deviations from linearity were present.

#### TESTING IN THE OUTPATIENT DEPARTMENT

In the patients, the FEV<sub>1</sub> range was 0.99–5.41 l and the PEF range was 2.8–11.3 l s<sup>-1</sup>. Mean differences from the pneumotachometer values were  $-0.10$  (SD 0.11) for FEV<sub>1</sub> and  $0.091$  s<sup>-1</sup> (SD 0.68) for PEF. Figure 1 shows the differences between the EDC measurements of FEV<sub>1</sub> from the mechanical calibrator and the patients vs. the pneumotachometer estimates, plotted against mean FEV<sub>1</sub>. Mean difference and limits of agreement ( $\pm 2$  SD levels) are indicated. As with the PEF data, no significant deviation from linearity was found. The regression equation for FVC was FVC (EDC) =  $[-0.45 + 1.00 \text{ FVC (Pt)}]1$  with a standard error of estimate of 0.29 l, indicating, on average, equal underestimation of 0.45 l for the whole measurement range.

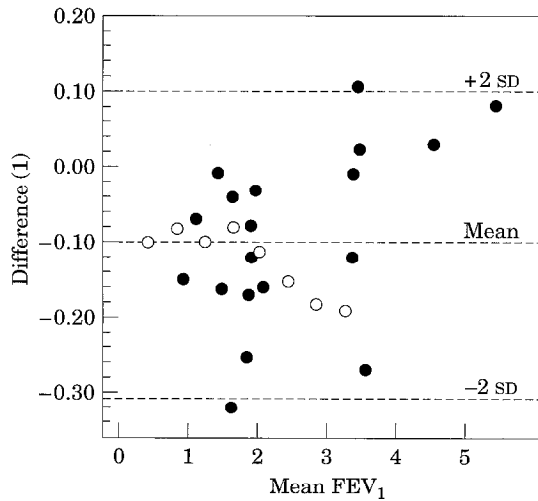


Fig. 1 Comparison of FEV<sub>1</sub> measured with the EDC and with a pneumotachometer system (Jaeger, Germany). ○, mean of 10 EDC systems by mechanical calibrator; ●, patients from outpatient clinic.

Table 1 Preference for various aspects of user-friendliness of the mini-Wright PEF meter and manual diary card [PEF(DC)] and the electronic diary card spirometer (EDC), respectively. Numbers indicate number of patients expressing preference

	EDC	PEF(DC)	No pref.
Recording symptoms	9	0	1
Alarm option	6	1	3
Readability	5	0	5
Portability	0	3	7
Maintenance	3	2	5
Overall preference	6	3	1

#### TESTING IN THE HOME SITUATION

Mean diurnal variation, as defined in the Methods section, was 11.3% (range 2.8–17.8%) for the EDC spirometer and 8.8% (range 3.7–14.3%) for the mini-Wright PEF meter. The mean difference between the EDC spirometer and mini-Wright was 2.4% (SD 2.4), which was not significant (Wilcoxon sign test). In three of the patients, diurnal variation measured with the mini-Wright meter was higher than measured with the EDC spirometer. Table 1 gives the results of the questionnaire, and values indicate the number of patients concerning use of the instruments.

#### Discussion

Comparisons of different types of portable PEF meters have been reported (13,14). In a recent

detailed study, eight commercially available devices were tested with a computer-served controlled pump, designed for flow calibrations (5). In that study, as in the present study, all tested devices gave remarkably reproducible results, but only the turbine device (as used in the present study) showed an absolute error within the ATS specification (15), up to about  $91 \text{ s}^{-1}$ , and an increasing but slight underestimation at higher flows (5, 16).

In the present case, the results from the mechanical calibration device indicate that the turbine flow meter met the ATS requirements from 4 to  $141 \text{ s}^{-1}$ . The present reference system, the pneumotachometer device, was tested in earlier studies (9, 10) and can be considered to be sufficiently linear up to  $141 \text{ s}^{-1}$ .

The FEV<sub>1</sub> also proved to be a reliable variable, both in the tests with the calibration device and in the patient comparisons, showing only a slight underestimation. This may give a definite advantage over the portable PEF devices because FEV<sub>1</sub> is a better indicator of lung and airway mechanics than PEF alone; this needs further investigation in the home situation.

Over the whole FVC range, a mean underestimation of about 0.45 l was found, probably due to a premature re-set of flow integration. Although, for asthma treatment and follow-up, PEF and FEV<sub>1</sub> are the variables of choice, a fixed correction may give a reasonably accurate FVC value.

The patient group in the home situation continued regular medication and had no exacerbations during the study, which may explain the low diurnal variation. Although the EDC spirometer showed a higher mean diurnal variation than the mini-Wright, this difference was not significant due to the large spread in values from the individual patients. On average, there was a marked preference for the EDC spirometer (Table 1). Important aspects were the alarm option, prompting regular measurements and entry of symptom recordings which was preferred to a conventional diary card. It is concluded that the EDC system may be a valuable tool in the follow-up and treatment of asthma, especially in the home situation.

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