Original articles

Long term performance of a hand held spirometer

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Abstract

***Background* – A study was undertaken to test the long term performance of a small hand held spirometer for self-administered serial spirometric testing.**

***Methods* – Thirty turbine pocket spirometers (MicroMedical DiaryCard) were used in a clinical trial on 22 emphysematous patients with severe α_1-antitrypsin deficiency. The spirometers were able to store the date, time, forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), peak expiratory flow (PEF), and flow-volume loop for each blow. Every four weeks when the patients came for α_1-antitrypsin infusions the performance of their spirometer was checked before and after retrieval of the data from the spirometer. Calibration checks were threefold and included volume calibration with a 1.0 litre and 3.0 litre syringe, and flow calibration with a decompression calibrator.**

***Results* – After two years of study the mean number of spirometric recordings performed per spirometer was 693 (range 237–1178), and the mean number of calibration checks was 33 (range 2–57). The coefficient of variation of the calibration signal was 1–2% for syringes and 0.5–1% for the decompression calibrator. The bearings of one turbine exhibited excessive friction after 17 months. None of the other 29 instruments showed drift, and a general drift of all spirometers towards larger or smaller readings could not be shown. However, unforeseen problems in the stability of the calibrating devices were observed.**

***Conclusions* – The small hand held turbine spirometers are suitable for long term patient-administered serial spirometric testing. The two year durability is acceptable and the long term reproducibility excellent.**

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Keywords: patient-administered serial spirometry (PASS), hand held turbine spirometer, long term reproducibility, volume and flow calibration.

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Spirometric testing is usually performed in a hospital or a clinic under supervision of specially trained personnel, whereas peak expiratory flow (PEF), which is a simpler measurement, is used for monitoring subjects in their home surroundings. In many conditions, such as emphysema, peak flow is an insensitive measurement of changes in lung function and spirometric measurements of forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC) are required. The introduction of small hand held spirometers with a timer and data storage capability has made it possible to monitor patients by daily self-administered spirometric tests.[1] By increasing the number of measurements, serial spirometric testing may improve the statistical power of clinical trials, provided the variability of patient-administered tests is no greater than when tested in the laboratory.[2]

Based on these considerations, we decided in 1990 to apply daily patient-administered spirometric testing in a long term randomised placebo controlled trial of α_1-antitrypsin augmentation therapy in patients with α_1-antitrypsin deficiency and moderate emphysema. Provided augmentation therapy is effective, only small differences in the decline in lung function such as FEV_1 between active treatment and placebo can be expected, even after several years of treatment,[3] and in this situation reproducibility of spirometric measurements becomes critical.

The accuracy of spirometers has received much attention, but little is known about their long term performance and reproducibility. This is the first study to examine the stability of calibration of a spirometer suitable for home use within the context of a long term clinical trial.

Methods

Since 1991, 22 patients with α_1-antitrypsin deficiency (phenotype PiZ) have been included in a clinical trial of augmentation therapy with α_1-antitrypsin. The patients were instructed to perform self-administered spirometric tests (three maximal forced expirations) every morning and evening throughout the whole study. Furthermore, three of the authors (AD, FM and AK) performed daily home spirometric testing for six months to two years.

Thirty pocket sized turbine spirometers were used for the study (MicroMedical DiaryCard, MicroMedical Ltd, Rochester, UK) because, in a previous short term pilot study,[4] they were

found to be highly accurate and easy to use. In this spirometer a fixed turbine generates rotational flow that drives a low-inertia vane.[5] Rotations of the vane are detected by an infrared light emitting diode and photo diode sensor enclosed in the turbine housing. This turbine volume transducer is attached by a cable to a small control unit with keypad, graphical/alphanumeric display, microprocessor, and clock/calendar. The control unit has memory for several hundred spirometric recordings including graphical storage of flow-volume curves, and also acts as an electronic diary which allows the patients to enter responses (usually symptom scores) to questions appearing on the display.

Changing the calibration set by the manufacturer could be a source of error and we therefore decided to check, but not change, the calibration of the spirometers during the study. Furthermore, because long term performance of calibration methods for spirometers was virtually unknown, we had to apply independent calibration methods to assure quality. Volume calibration was effected with a 1.0 litre syringe with internal valves (Vitalograph, Buckingham, UK) and a 3.0 litre syringe without valves (MicroMedical, Rochester, UK). A modification of a previously described decompression calibrator,[6] as recommended by the European Respiratory Society,[7] was used for flow and volume calibration. The calibrator consists of an eight litre pressure chamber which empties through a valve. The valve is opened by a falling weight that pushes a cone through an internal orifice with an opening time of about 40 ms. The falling weight outside the pressure chamber is connected to the outlet valve by a plunger that was sealed airtight by a rubber O-ring. A stenosis with 4 mm internal diameter inserted in the outlet ensured flows in an adequate (physiological) range. The precision manometer (Nuova Fima, Italy; accuracy ± 0.25%, 0.01 bar intervals) of the calibrator was checked quarterly with a J-type mercury manometer (Struers, Rødovre, Denmark), and annual service of the calibrator was undertaken at the Department of Environmental and Occupational Medicine at the University in Århus.

Every four weeks when the patients came for α_1-antitrypsin infusions the spirometers were checked as follows. The atmospheric pressure from a mercury barometer was recorded and then the spirometer recorded three blows with the 1.0 litre syringe, three blows with the calibrator at each of three fixed inflation pressures (0.200, 0.300, and 0.400 bar above atmospheric pressure), and finally three blows with the 3.0 litre syringe. Free rotation of the vane of the turbine was checked visually by looking at the vane while gently moving the turbine through the air. A full calibration check procedure was performed before and after the retrieval of the patient's data from the spirometer.

Because the output of the calibrator was influenced by the ambient pressure, calibrator data were corrected for atmospheric pressure by an equation derived from Boyle's and Bernoulli's laws. The correction was tested in a hyperbaric chamber and found to be adequate.

The syringe measurements were standardised by dividing by the known "true" values for the syringes (1.0 and 3.0 litres). For the calibrator the "true" values for FEV_1, FVC, and PEF at each inflation pressure were not known from the outset. They were estimated as the grand means of the readings from all spirometers over the whole duration of the study, and the calibrator measurements were retrospectively standardised by dividing by these grand means.

The calibration level of each spirometer was then defined as the mean of all the standardised measurements. Provided accurate calibration from the manufacturer and no change with time and use, the calibration levels of the spirometers should centre around 1.0. The calibrator measurements were further standardised by dividing by the calibration level of the spirometer, in order to eliminate the influence of differences in calibration levels between instruments. The mean and standard error of the mean were calculated for both syringes, and also for the calibrator readings of FEV_1, FVC, and PEF at each inflation pressure. The long term stability of the spirometers was demonstrated by plotting the means of the standardised measurements over two month periods starting with November and December 1992.

Results

At the start of 1994 the mean number of self-administered spirometric recordings per spirometer was 693 (range 237–1178), and the mean number of calibrations was 33 (range 2–57). For one spirometer the calibration level was found to be low (93%), and for the other 29 instruments the calibration levels ranged from 98.4% to 101.5% (mean (SD)100.0 (0.8)%). The vane of one turbine did not rotate freely after working perfectly for 17

Table 1 Variation within calibrations

	FEV_1			FVC			PEF		
Instrument	*df* ($\Sigma(n-1)$)	*SD (ml)*	*CV (%)*	*df* ($\Sigma(n-1)$)	*SD (ml)*	*CV (%)*	*df* ($\Sigma(n-1)$)	*SD (ml)*	*CV (%)*
Syringe									
1 litre	—	—	—	2583	17	1.72	—	—	—
3 litres	—	—	—	2577	41	1.36	—	—	—
Calibrator									
0.2 bar	2572	12	0.93	2575	12	0.79	2575	19	1.02
0.3 bar	2587	14	0.80	2587	15	0.66	2587	20	0.84
0.4 bar	2573	16	0.73	2583	17	0.56	2583	21	0.74

FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity; PEF = peak expiratory flow; df = degrees of freedom; SD = standard deviation; CV=coefficient of variation.

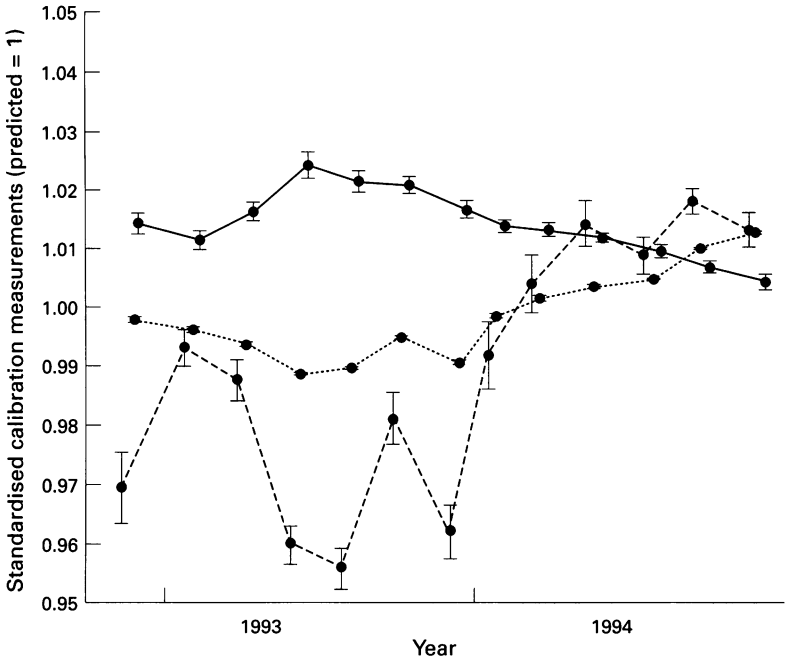

Figure 1 Volume measurements obtained by calibrating 30 small turbine spirometers with 1.0 litre (———) and 3.0 litre (– – – –) syringes. Each point represents the mean of a two month period, and results obtained with the 3.0 litre syringe were scaled by dividing by three. Error bars indicate the standard error of mean. The dotted line is the mean flow recorded by the spirometers that, for graphical reasons, was scaled to a mean of 1.0 and a standard deviation of 0.01.

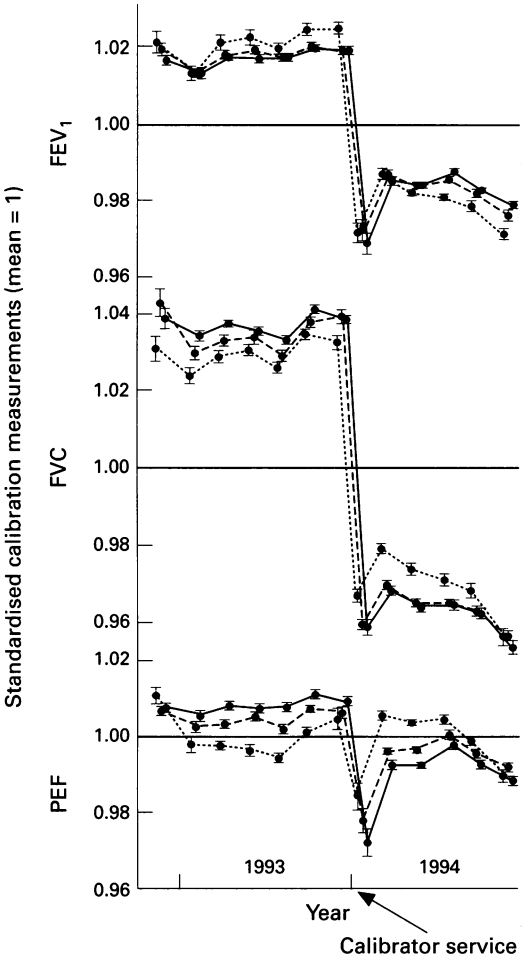

Figure 2 FEV_1, FVC and PEF measurements obtained by calibrating 30 small turbine spirometers with a calibrator at three fixed inflation pressures: 0.2 bar (.....), 0.3 bar (– – – –), and 0.4 bar(———). All measurements were divided by the overall mean of measurements at that particular inflation pressure, and each point represents the mean of a two month period. Bars indicate the standard error of the mean.

months. Subsequent data from this instrument have been omitted from further analysis.

Table 1 shows the variation within the threefold measurements for all of the calibration checks. The coefficient of variation of the syringe volumes was approximately twice that of the calibrator volumes, and for the calibrator the coefficient of variation was largest for PEF and least for FVC.

Changes over time in the mean measurements for all instruments are shown in figs 1 and 2. Figure 1 shows that the measurements of the 3.0 litre syringe were more accurate than those of the 1.0 litre syringe. The measurements with the 3.0 litre syringe increased by 1.3% during the first half of 1993 and then gradually decreased by 2.0% during the next 18 months. The measurements with the 1.0 litre syringe showed inverse fluctuations – that is, they decreased by 3.7% during the first half of 1993 and then increased by 6.3% towards the end of 1994.

It is evident from fig 2 that a change in the output of the decompression calibrator occurred in January 1994 following the annual service when the O-ring of the plunger was changed because of wear. The new O-ring proved to be too small, slowing the free movement of the plunger, so it was changed again in February 1994. The quarterly checks of the manometer of the calibrator did not show any drift during the study.

Discussion

Patient-administered serial spirometric testing is a new concept with considerable potential due to the combination of close monitoring and high quality measurements. The statistical power of clinical trials of new drugs may be improved by serial measurements, which may provide significant results with fewer patients and within a shorter time.[2] Such an approach requires meticulous control of the spirometers.

For the first two years we used well tried equipment in a rather laborious setup.[8] In 1992 we compared the bellows spirometer with two hand held flow based (Fleisch type pneumotach or turbine) spirometers attached to small computers with the capacity to store the date, hour, FEV_1, FVC, and PEF of several hundred tests.[9] Both types of small spirometer had problems during the initial phase which resulted in a considerable loss of data. For one type the problems were related to software, and for the other type the transducer cable had to be replaced on several occasions because of internal breaks. The problems were corrected by the manufacturer and, at the end of 1992, we decided to change from the bellows spirometers to the small turbine spirometers.

These hand held spirometers have been used successfully in the monitoring of lung transplants[10 11] but, apart from that, little is known about their long term durability and reproducibility. Hence, we considered it very important to monitor the long term performance of these new instruments by calibration checks at four week intervals. Initially we found

that the coefficient of variation within a calibration procedure was smaller with the decompression calibrator than with the 1.0 and 3.0 litre syringes,[4] which suggested that the calibrator could be a more sensitive indicator of drift of the spirometers.

The present study revealed calibration problems that could not be anticipated. We found fluctuations in the mean measurements of the calibrator output of the order of 5% (fig 2) which is not acceptable when trying to detect an annual difference in decline in lung function between treatment groups of only 1–2%. However, the pattern of fluctuations (identical for all meters) suggested that the problem was the calibration procedure and not the spirometers. A sudden change in the mean level occurred in January 1994 and could be ascribed to the change of an O-ring of the calibrator. The fact that the change in measurements was largest for FVC, which spans up to 10 seconds, and least for PEF (fig 2) suggested a leak in the calibrator. This suspicion was confirmed and localised to the O-ring.

The sudden fall in reading after the service in January was compatible with there being a leak and another O-ring was fitted with some improvement, but there was a further slight fall in the reading at the end of 1994 which suggested an increase in leak during this time. Our results suggest that, despite the problems with this calibrator, the spirometer readings themselves were stable because the standard error of the mean did not vary with time. If some of the spirometers had changed their reading over time the standard error would have altered and there would have been evidence of a drift in the syringe readings.

It is a prerequisite for the detection of drift of an instrument that the observation procedure is more stable than the instrument under observation. In the present study the calibrator did not live up to this ideal. Standardisation of calibration equipment and procedures are well described,[12] although there is no information on the long term stability of syringes and more complex calibrators. The ATS recommends that volumetric spirometer systems must be evaluated for leaks on a daily basis.[12] This should apply to calibration devices as well. The results also underline the importance of applying several independent methods of calibration checks, especially in long term studies.

The fluctuations of the syringe calibrations were smaller and in the opposite direction for the 1.0 and 3.0 litre syringes (fig 1). Further analysis showed that the variation was related to a gradual change in our handling of the syringes. Initially we emptied the syringes gingerly and slowly but, as our routine improved, we gradually put more pressure on the piston and, as shown in fig 1, an increase in flow could be documented by the flow-volume data of the spirometers. The fact that the volumes obtained with the 1.0 litre syringe decreased with increasing flows, whereas the opposite applied to the 3.0 litre syringe, was explained by a small deviation from linearity that has previously been shown for the turbine flow measurements.[5] Thus, the fluctuations in the syringe calibrations mainly reflected variations in flow. Again we were reassured by the fact that the standard error of the mean kept stable throughout the whole study period.

This is the first study to examine, in detail, the performance of turbine spirometers suitable for home monitoring. Durability was acceptable over a two year period with only one spirometer failing out of 30. Reproducibility was excellent, exceeding that of the calibration equipment. The use of such spirometers may increase the power of clinical investigations designed to detect changes in lung function.

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