

The Long-Term Stability of Portable Spirometers Used in a Multinational Study of the Prevalence of Chronic Obstructive Pulmonary Disease

Rogelio Pérez-Padilla MD, Juan Carlos Vázquez-García MD, María Nelly Márquez MD, José Roberto B Jardim MD, Julio Pertuzé MD, Carmen Lisboa MD, Adriana Muiño MD, María Victorina López MD, Carlos Tálamo MD, María Montes de Oca MD, Gonzalo Valdivia MD, Ana Maria B Menezes MD, and the Latin American COPD Prevalence Study (PLATINO) Team

BACKGROUND: We report the performance of an ultrasound-based portable spirometer (EasyOne) used in a population-based survey of the prevalence of chronic obstructive pulmonary disease, conducted in 5 Latin American cities: São Paulo, Brazil; México City, México; Montevideo, Uruguay; Santiago, Chile; and Caracas, Venezuela (the Latin American COPD Prevalence Study [PLATINO]). **METHODS:** During the survey period (which ranged from 3 months to 6 months in the various locations) we collected daily calibration data from the 70 EasyOne spirometers used in the 5 survey cities. The calibrations were conducted with a 3-L syringe, and the calibration data were stored in the spirometer's database. **RESULTS:** Ninety-seven percent of the calibration volumes were within ± 64 mL (2.1%) of the 3-L calibration signal. Excluding data from the first city studied (São Paulo), where one calibration syringe had to be replaced, 98% of the calibration checks were within ± 50 mL (1.7%). The measured volume was affected only minimally by the syringe's peak flow or emptying time. **CONCLUSION:** In these 70 EasyOne spirometers neither calibration nor linearity changed during the study. Such calibration stability is a valuable feature in spirometry surveys and in the clinical setting. *Key words:* spirometry, quality control, calibration, pulmonary function tests, reliability. [Respir Care 2006;51(10):1167-1171. © 2006 Daedalus Enterprises]

Introduction

The American Thoracic Society (ATS) has issued recommendations regarding spirometers and spirometry, to assure quality-testing of the equipment and test-performance,^{1,2} for standardized interpretation,^{3,4} and for quality-control strategies.⁵ The quality of spirometers has im-

proved, as can be seen by comparing the results of an independent evaluation of available spirometers in 1980 with those available in 1990.^{6,7}

The accepted standard for spirometer evaluation is a sophisticated, computer-controlled air pump that introduces 24 standard waveforms into the spirometer, as

Rogelio Pérez-Padilla MD and Juan Carlos Vázquez-García MD are affiliated with the Instituto Nacional de Enfermedades Respiratorias, México City, México. María Nelly Márquez MD, Adriana Muiño MD, and María Victorina López MD are affiliated with the Universidad de la República, Montevideo, Uruguay. José Roberto B Jardim MD is affiliated with the Universidade Federal de São Paulo, São Paulo, Brazil. Julio Pertuzé MD, Carmen Lisboa MD, and Gonzalo Valdivia MD are affiliated with Pontificia Universidad Católica de Chile, Santiago, Chile. Carlos Tálamo MD and María Montes de Oca MD are affiliated with the Universidad Central de Venezuela, Caracas, Venezuela. Ana Maria B Menezes MD is affiliated with the Universidade Federal de Pelotas, Pelotas, Brazil.

The Latin American Chronic Obstructive Pulmonary Disease (COPD) Prevalence Study (PLATINO) was organized by Cesar Gomes Victora MD and Pedro Curi Hallal MD, Universidade Federal de Pelotas, Pelotas, Brazil.

This study was supported by a grant from Boehringer-Ingelheim that was also used to purchase the spirometers. The study did not receive any support from nnd Medical Technologies, the maker of the EasyOne spirometer.

Correspondence: Rogelio Pérez-Padilla MD, Instituto Nacional de Enfermedades Respiratorias, Tlalpan 4502, Distrito Federal, Ciudad de México, México 14080. E-mail perezpad@servidor.unam.mx.

proposed by the American Thoracic Society.¹ However, this evaluation method has several limitations. First, the equipment required is expensive and is not widely available. Second, only one new spirometer of each type is usually tested, and only on one occasion. Thus, a device might pass the standard test but then deteriorate quickly with time, or there might be unacceptably high interdevice variability. Therefore, additional strategies to assure short-term and long-term equipment reliability are required, but they must also be easily obtainable. A spirometer that maintains its calibration is especially important to promote office spirometry.⁸ We report the performance of 70 portable spirometers used during an international study designed to measure the prevalence of chronic obstructive pulmonary disease in 5 Latin American cities, in which spirometry was the primary diagnostic method.

Methods

We obtained approval from each of the ethics committees of the institutions involved in the study. The sampling and testing methods⁹ and main results¹⁰ of the Latin American Project for the Investigation of Obstructive Lung Diseases (PLATINO) have been described previously. Briefly, the study involved multi-stage cluster sampling, with a similar study design in São Paulo, Brazil (mean altitude 800 m above sea level); México City, México (2,240 m); Montevideo, Uruguay (35 m); Santiago, Chile (543 m); and Caracas, Venezuela (950 m). Sixty-eight census tracts were selected from each city, representative of their metropolitan areas, including suburbs, and the aim was to obtain a minimum sample of 800 subjects per city. For the house-by-house survey we selected a portable, battery-operated, ultrasound-transit-time based spirometer (EasyOne, ndd Medical Technologies, Zürich, Switzerland), which can store up to 400 spirometry tests in memory, including the 3 best maneuvers and graphs.

The survey used a total of 70 EasyOne spirometers: 16 in São Paulo, 15 each in Montevideo and Caracas, 7 in México City, and 17 in Santiago. All 70 spirometers used in the field were set to the same options, except for mean altitude, which was set in each city. The EasyOne lacks a calibration routine, implying modifications in gains or linearity, and includes only a calibration verification routine. Before each day's field use, the calibration was checked by the spirometry supervisor in that city, who used a 3-L syringe (Hans-Rudolph, Kansas City, Missouri) and an adaptor specifically for the spirometer. Five calibration syringes (one per city) were used, although in São Paulo the survey began with a different type of syringe, which was later replaced. The initial calibration goal was a maximum error of ± 90 mL ($\pm 3\%$) and, for the last 4 cities the calibration goal was a maximum error of ± 50 mL. Tests and calibration data were downloaded daily from the spirom-

eters to a computer. The spirometry database included the calibration verification data, including the measured volume, the syringe-emptying time, and the peak flow. We report routine calibration results throughout the study and in different cities and spirometers, as well as the impact of the syringe's emptying time and peak flow on measured volume. The calibration protocol was in accordance with the 1994 ATS standards,¹ which included only one syringe-emptying speed, instead of three, as currently recommended by the ATS.²

The spirometric measurements in our study are not independent: they are clustered or grouped according to device and city (or calibration syringe). That is, measurements from one device tend to be more similar than measurements from different devices, and this must be acknowledged during statistical analysis. Data analysis was done with statistics software (STATA 9.0, StataCorp, College Station, Texas) and took into account grouping by city and device in all statistical models, by using the "survey" commands in STATA. We also used multi-level models (mixed models)¹¹ that separate the measurement variance due to city (syringe) and device (spirometer) and also deal effectively with clustered measurements.

Results

The field work lasted between 3 months and 6 months in the various survey cities. Only 35 (1%) of the 3,486 calibration checks done at all sites and with all devices fell outside the ± 90 mL ($\pm 3.0\%$) of the 3-L signal recommended by the ATS standards, and 92.9% of all calibration checks were within ± 50 mL of the standard. Thirty-two of the 35 out-of-range calibration values occurred at the beginning and at the first site studied, and such out-of-range values disappeared once that site's spirometry supervisor had obtained a new syringe that had a more reliable connection to the spirometer (see Fig. 1). Calibration verifications remained in memory, even if a technical limitation was identified. Excluding the first study site, 98.1% of the calibration checks fell within 50 mL of the 3-L standard. Figure 1 shows Levey-Jennings charts of the measured calibration volumes over the course of the study. The mean calibration bias for all 70 devices (and calibration checks) was -0.8 mL, which does not differ statistically from zero (95.0% confidence interval [CI] -2.97 to 1.34), and the standard deviation was 31.2 mL. The range of calibration error (mean ± 1.96 SD) was from -64 mL to $+63$ mL, whereas 90% of the observations were from -42 mL to $+52$ mL (5th and 95th percentiles, respectively). Excluding the data from São Paulo reduces the error to 3.4 ± 23.6 mL: 90% of those measurements were within ± 38 mL, and 95% were within ± 44 mL.

Figure 2 shows the calibration volumes as a function of the peak flow from the syringe. The peak flow from the

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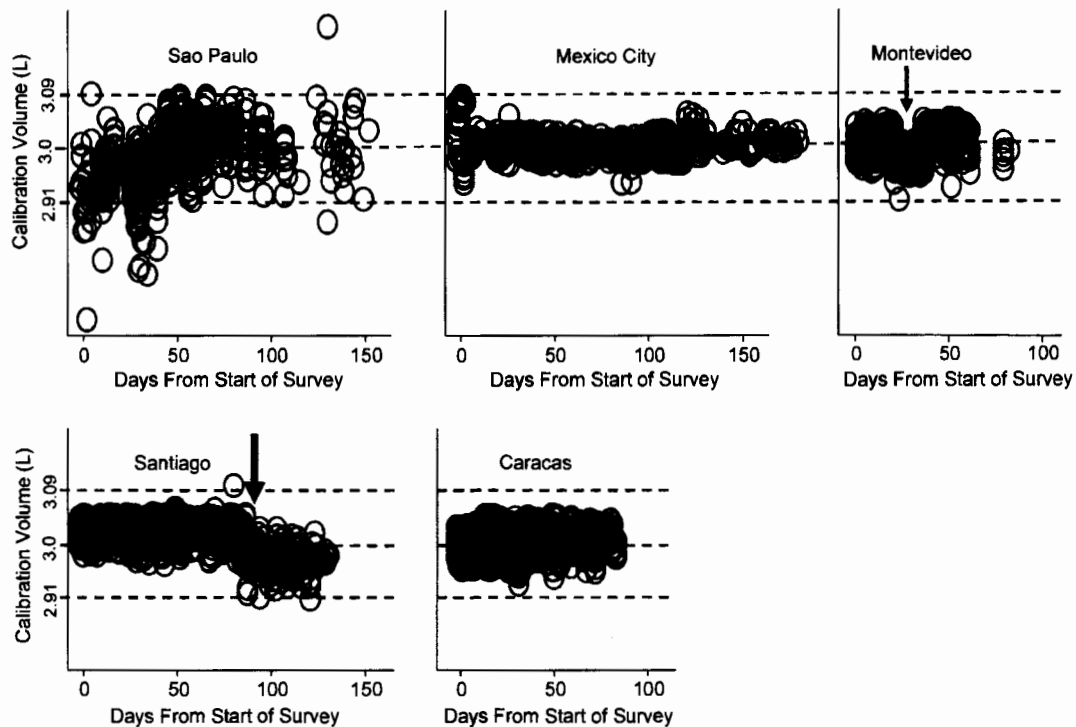


Fig. 1. Calibration volumes of the 70 EasyOne spirometers used in the 5 surveyed cities. Almost all the calibration checks fell within the ± 90 mL (3.0%) suggested by the American Thoracic Society (dashed lines), and most were within ± 50 mL throughout the study. In the first city studied (São Paulo) the calibrations improved after the spirometry supervisor began using a different calibration syringe and syringe-spirometer connector. In Montevideo there was a brief period (arrow) during which the calibration volumes were lower. A similar phenomenon occurred in Santiago (thick arrow), but there the calibration volume remained lower for the rest of the survey. Although the calibrations remained within the suggested range, we suspect there was a small change in the calibration syringe's volume, especially in Santiago, because the change affected all the spirometers used there, and there was no change in equipment, personnel, or syringe-emptying time.

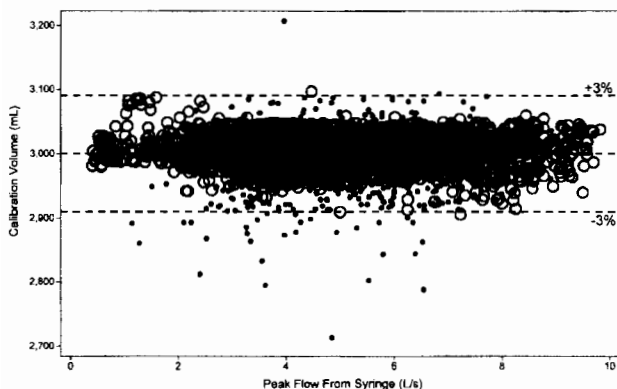


Fig. 2. Calibration volume versus peak flow from the 3-L calibration syringe. The 70 EasyOne spirometers used in the survey responded properly to different flows, suggesting a linear response. The dots correspond to the calibration checks from the first city (São Paulo), where most of the outlier data points came from, due to a defective connection between the syringe and the spirometers. A similar graph is obtained by plotting mean flow or 1/emptying time instead of peak flow.

syringe had a high correlation with its mean flow ($r = 0.98$) and with the inverse of its emptying time ($r = 0.86$). The mean \pm SD syringe-emptying time was 2.9 ± 1.4 s; 5.0%

of the syringe-emptying time values were shorter than 1.8 s, and 5.0% were longer than 4.8 s.

We used a mixed model (multi-level model)¹¹ to estimate the calibration error, adjusting by device and syringe, and using the calibration peak flow as the independent variable. The calibration volume was:

$$3,006 \text{ mL} - (1.45 \times \text{peak flow})$$

and $r^2 = 0.0006$. That is, variation in the syringe's peak flow explained less than 0.1% of the variation in the volume measured by the spirometer. In the same model, the variability of the calibration error (standard deviation) was 8 mL (0.3%, 95% CI 4 to 18 mL) between syringes (ie, between cities), 28 mL (0.9%, 95% CI 21 to 38 mL) between spirometers, and 28 mL (0.9%, 95% CI 27 to 28.5 mL) within spirometers.

Although the calibration values remained within the expected range, in Santiago and Montevideo there was a small decrease in the calibration volumes, which affected all the spirometers used in those cities (see the arrows in Fig. 1), though in Montevideo this volume-decrease was

transient. During those 2 periods of decreased calibration volumes there was no change in operators, syringes, or syringe-emptying time. One spirometer had a memory malfunction and had to be removed from service.

Discussion

The 70 spirometers used did not show significant calibration drift or bias, nor change in variability during the survey period (3–6 months). That is, both accuracy (how well the readings agree with the standard, or the absence of bias) and precision (how well a series of readings agree with each other, or repeatability) were maintained, which supports the manufacturer's claim that equipment calibration is not required (see Figs. 1 and 2). In fact, the device lacks a true calibration routine; instead it has only a calibration-check routine. Although we did not attempt during each calibration to test the 3 syringe injections at different speeds, as recommended by current ATS standards,² we did observe considerable differences in the syringe-emptying times and the syringe-emptying peak flows during the study, but with no inaccuracies on the various flows (see Fig. 2). We also observed a sudden small volume decrease (approximately 15 mL) in the calibration volumes in Montevideo and Santiago (see Fig. 1), but these decreases did not produce calibrations outside the 3.0% range, and this decrease was not associated with a change in the syringe emptying time. We were not able to identify the cause of the calibration-volume decrease, but we suspect it was due to a change in the syringe's ejected volume, because it affected all the spirometers similarly in the 2 cities, and in Montevideo it reverted spontaneously. Acceptable performance of another handheld spirometer was previously reported after 2 years of use,¹² in accordance with improvements in the quality of current equipment.

We were not able to trace the performance of all the spirometers back to one single syringe or calibration signal,¹³ only to one syringe (from the same manufacturer) per city. Variations in the performance of syringes are known,^{13,14} and efforts to trace all devices used in one particular study to one calibration signal would be worthwhile, although difficult if the study is carried out in multiple countries. On the other hand, the estimated inter-city and inter-device variability were 8 mL and 28 mL, respectively, which is much lower than that suggested for spirometers (3.0% of the reading or ± 50 mL, whichever is greater²) and for a computer-controlled mechanical syringe, which is the accepted standard for spirometer testing (± 50 mL).²

Demonstrating a constant calibration across high and low flows (linearity) by varying the emptying time of the 3-L syringe does not prove a successful response to the standard waveforms, but is much more rigorous than just a traditional one-speed volume calibration,¹⁵ and does not

require additional equipment. Furthermore, by demonstrating that calibration is sustained across multiple devices and over time, two of the most important limitations of the current evaluation of new spirometers are overcome: testing is done only once, and on only one device. Another relatively simple option that improves the standard volume calibration is a flow-volume syringe,^{13,16} which has a microprocessor that reads the displacement of the piston shaft and displays both inspiratory and expiratory instantaneous forced vital capacity, forced expiratory volume, forced expiratory flow, and peak flow values.

There is a consensus that in order to assure spirometry quality in a multi-center trial, feedback to each center and technician is essential, but there is no agreement on the components that should be assessed and reported. We included in our quality report a Levey-Jennings-type calibration-check chart, as in Figure 1, per center and per device, to assure that verifications were indeed carried out every day and that all equipment was in good working order.

Conclusions

Calibration was maintained in all 70 portable spirometers after the 3–6 months of use, which is a valuable feature for spirometry surveys and in-office use.⁸ Detailed exploration of spirometer performance can be accomplished using a 3-L syringe, which avoids the need for sophisticated equipment. During the survey we found one defective calibration syringe and one spirometer that had a faulty memory.

ACKNOWLEDGMENTS

Thanks to the members of the Burden of Obstructive Lung Disease (BOLD) survey group for their ongoing participation in discussions of the PLATINO study, an original project of the Latin-American Thoracic Association (ALAT). Advisory Committee: Bartolomé Celli MD, Sonia Buist MD, William Vollmer PhD, and Roberto Rodríguez-Roissin MD. Executive Committee: Juan Manuel Luna, Carmen Lisboa MD, Carlos Torres MD, and Carlos Luna.

Thanks also to the coordinators of the spirometry teams: Fernanda W Rosa, Aquiles Camelier MD, Oliver Nascimento, Elisa Sánchez-Gallén, Abigail Guzmán, Marcela Araya, and Dolores Moreno MD.

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