Validation study of the portable Air Next spirometer: preliminary results

K. Exarchos, A. Sioutkou, C. Chronis, S. Peristeri, A. Gogali, A. Konstantinidis, K. Kostikas

Respiratory Medicine Department, School of Medicine, University of Ioannina, Ioannina, Greece

Introduction

Chronic respiratory diseases constitute a considerable part in the practice of pulmonologists and primary care physicians as well; spirometry is integral for the diagnosis and monitoring of these diseases, yet remains underutilized. The Air Next spirometer (Nuvoair, Sweden) is a novel ultra-portable device that performs spirometric measurements connected to a smartphone or tablet via Bluetooth.
The objective of this study was to assess the accuracy and validity of these measurements by comparing them with the ones obtained with a conventional desktop spirometer.

Air Next is a certified CE Class IIa Medical Device according to ISO 27782 and 23747. Through the accompanying application the following indices are stored after spirometry: forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC), FEV_1/FVC ratio, peak expiratory flow (PEF), duration of spirometry, forced expiratory volume in 6 seconds (FEV_6), mean expiratory flow at 75% (MEF_{75}), 50% (MEF_{50}) and 25% (MEF_{25}) of the vital capacity and forced expiratory flow at 25-75% of the pulmonary volume ($FEF_{25-75\%}$). Moreover, the flow-volume loop is also presented which is valuable for diagnostic purposes.

Methods

We conducted a descriptive, cross-sectional prospective study at the outpatient clinic of the Respiratory Medicine Department of the University Hospital of Ioannina. We enrolled 200 consecutive patients and healthy volunteers, with the following stratification: 50 patients with COPD, 50 patients with asthma, 50 patients with interstitial lung disease and restrictive spirometric pattern and 50 healthy controls. All patients performed spirometry both with a conventional desktop spirometer and with the study spirometer (Air Next).
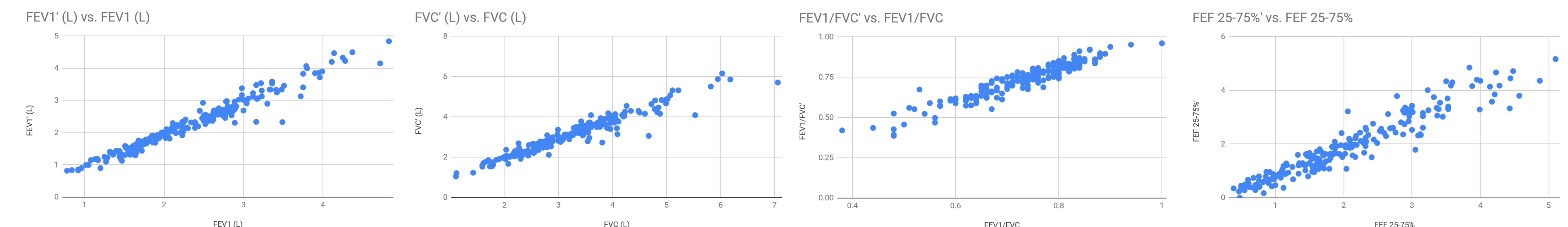From each spirometry the following metrics were recorded: FEV_1 (absolute value in L), FEV_1% predicted, FVC (absolute value in L), FVC% predicted, FEV_1/FVC ratio, PEF, $MEF_{25\%}$, $MEF_{50\%}$, $MEF_{75\%}$, $FEF_{25-75\%}$.
The agreement and relation between the aforementioned spirometric parameters for both devices were assessed by calculating the Pearson correlation coefficient and the Interclass Correlation Coefficient (ICC), using IBM SPSS statistics, version 24.
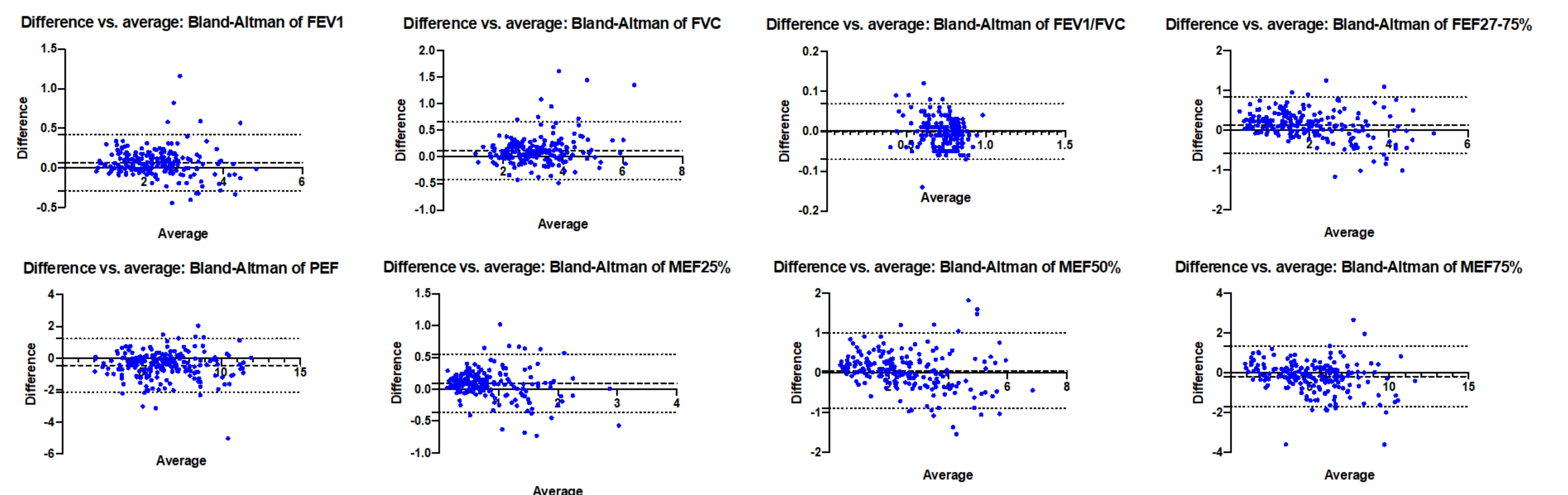
Results

	Pearson correlation	ICC
FEV_1	0.976	0.976
FVC	0.963	0.962
FEV_1/FVC	0.947	0.945
$FEF_{25-75\%}$	0.953	0.948

As we can see both metrics (Pearson correlation and ICC), and for all spirometric parameters considered is quite high, i.e. greater than 0.94. Next, we present correlation plots for FEV_1, FVC, FEV_1/FVC and $FEF_{25-75\%}$ between the two spirometers.

In order to further evaluate the reproducibility of the measurements with the Air Next vs. the conventional spirometer, we have developed Bland-Altman plots. In these plots, we provide a visualization of the difference vs. the average (mean), for the evaluated spirometric parameters. In all cases we observed a small mean difference between the two devices, with the majority of measurements being well within the limits of agreement. These plots support a good agreement between the two devices.

Conclusions

Portable spirometers feature a multitude of characteristics that makes them an ideal solution for extensive adoption in several medical and non-medical settings. Specifically, the Air Next spirometer is an ultra-portable, low cost spirometric device that does not need calibration and can be operated via a user-friendly smartphone application. Besides these practical characteristics, the most important feature of Air Next spirometer is the quality of reported results. After the careful and extensive validation performed in the current work, the results yielded by the Air Next and a conventional spirometer, exhibit very good agreement and reproducibility. Our results support the use of Air Next as a reliable spirometer for the screening and diagnosis of various spirometric patterns in clinical practice.

Bibliography

1. Wheatley JR. Spirometry: key to the diagnosis of respiratory disorders [Internet]. Medical Journal of Australia. 2017. pp. 422–423. doi:10.5694/mja17.00684
2. Celli BR. The importance of spirometry in COPD and asthma: effect on approach to management. Chest. 2000;117: 15S–9S.
3. Ramos Hernández C, Núñez Fernández M, Pallares Sanmartín A, Mouronte Roibas C, Cerdeira Domínguez L, Botana Rial MI, et al. Validation of the portable Air-Smart Spirometer. PLoS One. 2018;13: e0192789.
4. Du Plessis E, Swart F, Maree D, Heydenreich J, Van Heerden J, Esterhuizen TM, et al. The utility of hand-held mobile spirometer technology in a resource-constrained setting. S Afr Med J. 2019;109: 219–222.