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Comparability of portable and desktop spirometry: a randomized, parallel assignment, open-label clinical trial

Abstract

Introduction: Portable spirometers are often perceived as inaccurate. We aimed to evaluate the performance of AioCare®, a new portable spirometer, by comparing it with a reference desktop spirometer.

Materials and methods: Sixty-two patients diagnosed with asthma or chronic obstructive pulmonary disease performed spirometry examinations on a portable and the reference spirometer. The patients were randomized to two groups with different order, in which the spirometers were used. Forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), peak expiratory flow (PEF) and FEV_1/FVC rate were compared.

Results: The study revealed a high correlation in FEV_1, FVC, FEV_1/FVC and PEF between portable and reference spirometers. The mean differences between measurements obtained from the AioCare® and reference spirometer were: 0.0079 liter for FEV_1 ($p = 0.61$), 0.05 liter for FVC ($p = 0.14$), 5.1 liter/min for PEF ($p = 0.28$) and –0.0034 for FEV_1/FVC rate ($p = 0.54$). Pearson correlation coefficient analysis showed high association of FEV_1 ($R = 0.994$; 95% CI: 0.990–0.997; $p < 0.001$), FVC ($R = 0.984$; 95% CI: 0.974–0.990; $p < 0.001$), PEF ($R = 0.965$; 95% CI: 0.942–0.979; $p < 0.001$), and FEV_1/FVC ($R = 0.954$; 95% CI: 0.924–0.972; $p < 0.001$) readings from both spirometers.

Conclusions: Our results indicate that the portable spirometer produces largely similar readings to those obtained by a stationary spirometer in patients with chronic lung diseases, and therefore it may serve as a complementary tool in daily, remote management of patients with lung diseases.

Key words: spirometry, asthma, chronic obstructive pulmonary disease

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Introduction

Spirometry is the most common test of pulmonary function and is used as a gold standard in diagnosis and management of respiratory diseases such as chronic obstructive pulmonary disease (COPD) and asthma [1, 2]. Regular assessment of spirometry parameters allows for improved monitoring of disease progression, exacerbations, patient adherence, and response to treatment [3–6]. Therefore, restricted access to spirometry hinders not only prompt diagnosis but also efficient management of numerous respiratory diseases.

Although the need for widespread access to spirometry is evident, the costs and size of spirometers play a limiting role in its implementation [7]. Portable, handheld spirometers might therefore offer an attractive alternative to costly, desktop devices, that additionally often require handling and interpretation of the results by expert personnel [8]. The broader access to and use of handheld spirometers, characterized by simplicity, utility outside the hospital, lower costs, and lower risk of cross-contamination, could significantly expand the diagnosis of respiratory diseases during routine screening, improve monitoring of patients at the bedside or disease management by patients' self-monitoring [8]. As such, portable spirometers may also reduce the economic burden of direct costs associated with

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late-onset diagnosis and exacerbations of both asthma and COPD [8].

Finally, portable spirometers being part of wider patient monitoring plan that allow for direct communication between patients and their physicians play a critical role in telemedicine. The need for telemedicine has grown dramatically during the coronavirus disease 2019 (COVID-19) pandemic and is unlikely to diminish after the pandemic [9].

Several portable devices, including AioCare®, have been recently designed and commercialized [10–14]. Yet, the use of mobile spirometers remains limited, with concerns about their accuracy being one of the biggest barriers [7].

Tests of the spirometers on adult patients with respiratory diseases such as asthma and COPD resemble real-world settings and thus are much more reliable than the measurements using simulators. Therefore, the present study aimed to determine whether there is a difference among the obtained readings from portable (AioCare) and desktop (CPFS/D) spirometry by comparing the main ventilation parameters in patients with a diagnosis of asthma or COPD, and thus to indirectly assess the utility of portable spirometry in telemedicine.

Materials and methods

Study design and endpoints

This randomized, parallel assignment, open label, non-inferiority clinical trial compared the following ventilation parameters: forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), peak expiratory flow (PEF) and FEV_1/FVC rate obtained from portable (AioCare) and desktop (CPFS/D) spirometry in patients with a diagnosis of asthma or COPD. The trial was registered in clinicaltrials.gov; NCT03894475.

Selection of participants

Participants were recruited during routine check-up visits in 2018. The following inclusion criteria were applied: age of 18 years and more, diagnosed and treated asthma or COPD, and ability to comply with the spirometry protocol. Patients were diagnosed with asthma or COPD according to the standard clinical practice by a treating physician, and the diagnosis was reported based on the medical documentation. Exclusion criteria were: self-reported pregnancy, recent myocardial infarction (< 30 days), known thoracic, aortic, or cerebral aneurysm, recent stroke, eye surgery, thoracic or abdominal surgery, hemoptysis, recent pneumothorax, uncontrolled hypertension, pulmonary embolism, angina, chest or abdominal pain of any etiology, oral or facial pain exacerbated by a mouthpiece, stress incontinence, dementia or state of confusion, and acute diarrhea. All the patients were in stable condition at the time of the study.

Compliance with ethical standards

The clinical trial protocol for this study was approved by the Ethics Committee of the National Institute of Tuberculosis and Lung Diseases in Warsaw, Poland. Informed consent was obtained from all the patients recruited in the study.

Methodology

Patients were randomly assigned into two groups subjected to different examination sequences: sequence A — the patient first performed an examination with portable spirometer (AioCare), followed by measurements with the reference spirometer (CPFS/D); sequence B — the patient first performed an examination with the reference spirometer (CPFS/D), followed by measurements with portable spirometer (AioCare). Randomization was carried out using a mobile application (Randomizer for Clinical Trial — version 2.3; Medsharing).

The participants were asked to perform correct spirometry examinations (at least three technically acceptable maneuvers and meeting repeatability criteria for FEV_1 and FVC) on both measuring devices with a 5-minute break between devices to prevent respiratory muscle fatigue. Spirometry in arm A and B was supervised by two independent investigators. The result of each measurement was a set of spirometry parameters: FEV_1, FVC, PEF, and FEV_1/FVC. The highest value from all acceptable spirometry results was then used for analyses. All spirometry examinations followed American Thoracic Society/European Respiratory Society (ATS/ERS) 2005 standards [15].

Description of tested device

AioCare (Healthup, Poland) (Figure 1) was used as the tested device. AioCare is comprised of a portable, handheld hardware module that contains the micro-electro-mechanical system (MEMS)-based flow sensor and electronics. The unit must be used with a disposable mouthpiece fitted to the tip of the flow tube, and a nose clip. The device is connected to its dedicated mobile application, which works on iOS and Android operating systems and contains software

Figure 1. AioCare® spirometer

that shows flow-volume graphs and results in real time. It encompasses all of the widely used spirometry parameters, including PEF, FEV_1, FVC, and FEV_1/FVC ratio. The device does not require recalibration.

The manufacturer declares meeting all performance criteria for spirometers according to both Standards of Spirometry ATS/ERS 2005 [15] and the current ATS/ERS 2019 Standards (maximum permissible error of ± 2.5% for accuracy, based on validation study report provided to the authors) [16].

Spirometer USB CPFS/D (MGC Diagnostics Corporation, 350 Oak Grove Pkwy, Saint Paul, MN USA) served as the reference device. Prior to each session, a calibration of CPFS/D was performed according to the manufacturer's protocol.

Statistical analysis

To detect a 0.15 l difference in the FEV_1 and FVC values between the two groups (standard deviation: 0.4 l, significance level: 5%, power: 80%) a sample size of at least 58 patients was estimated.

Descriptive statistics included means, standard deviations (SD), direct differences of each pair of parameters, and percentage differences. The differences were calculated as the value obtained from the reference device minus the value from tested device. The parametric paired t-Student test was used to verify the hypothesis about the agreement of obtained results (statistical significance was set to 0.05) or Wilcoxon rank sum test if the assumption of normal distribution was not met (The Kolmogorov-Smirnov test was used to evaluate normality, $p < 0.05$). Additionally, Pearson correlation coefficients between reference and tested device results were calculated for each spirometry parameter.

A Bland-Altman plot was used as a graphical representation of results to further evaluate the agreement between lung function parameters measured with AioCare and the desktop spirometer, comparing FEV_1, FVC, PEF, and FEV_1/FVC from all patients enrolled in the study. One assumption of the Bland-Altman plot is normal distribution of the input data. The Kolmogorov-Smirnov test was used to evaluate this criterion. In case of rejecting the zero hypothesis, adequate transformation of data was performed using the Box-Cox method or logarithmic transformation.

Results

Patients' demographics

Among 87 patients assessed for eligibility, 67 were randomized, and spirometry measurements were performed on 62 patients: 44 females, mean age: 58 (SD 17) years, and 18 males, mean age: 52 (SD 19) years at the Institute of Tuberculosis & Lung Diseases in Warsaw, Poland. Five participants who were unable to perform technically acceptable measurements were excluded from the study. There were 30 patients analyzed in examination sequence A group and 32 patients in examination sequence B group. The flow of the study participants is depicted in Figure 2.

Clinical testing results

Mean differences between measurements obtained by AioCare, the handheld device and desktop spirometer (reference values) calculated for all patients in the study (n = 62) are presented in Table 1. The mean differences between devices were 0.0079 l for FEV_1 ($p = 0.61$) and 0.053 l for FVC ($p = 0.14$). The mean difference of 5.1 l/min was recorded for PEF ($p = 0.28$) and –0.0034 for FEV_1/FVC ($p = 0.54$).

Next, we plotted the reference FEV_1, FVC, PEF values and FEV_1/FVC rate against these obtained with the AioCare spirometer. Pearson correlation coefficient analysis showed very high association of FEV_1 ($R = 0.994$; 95% confidence interval [CI]: 0.990–0.997; $p < 0.001$), FVC ($R = 0.984$; 95% CI: 0.974–0.990; $p < 0.001$), PEF ($R = 0.965$; 95% CI: 0.942–0.979; $p < 0.001$), and FEV_1/FVC ($R = 0.954$; 95% CI: 0.924–0.972; $p < 0.001$) readings from both analyzed spirometers (Figure 3).

The Bland-Altman plots showed homogenous distribution of the sample values (Figure 4). Moreover, the lines of equality (H_0: Mean difference = 0) are within the confidence inter-

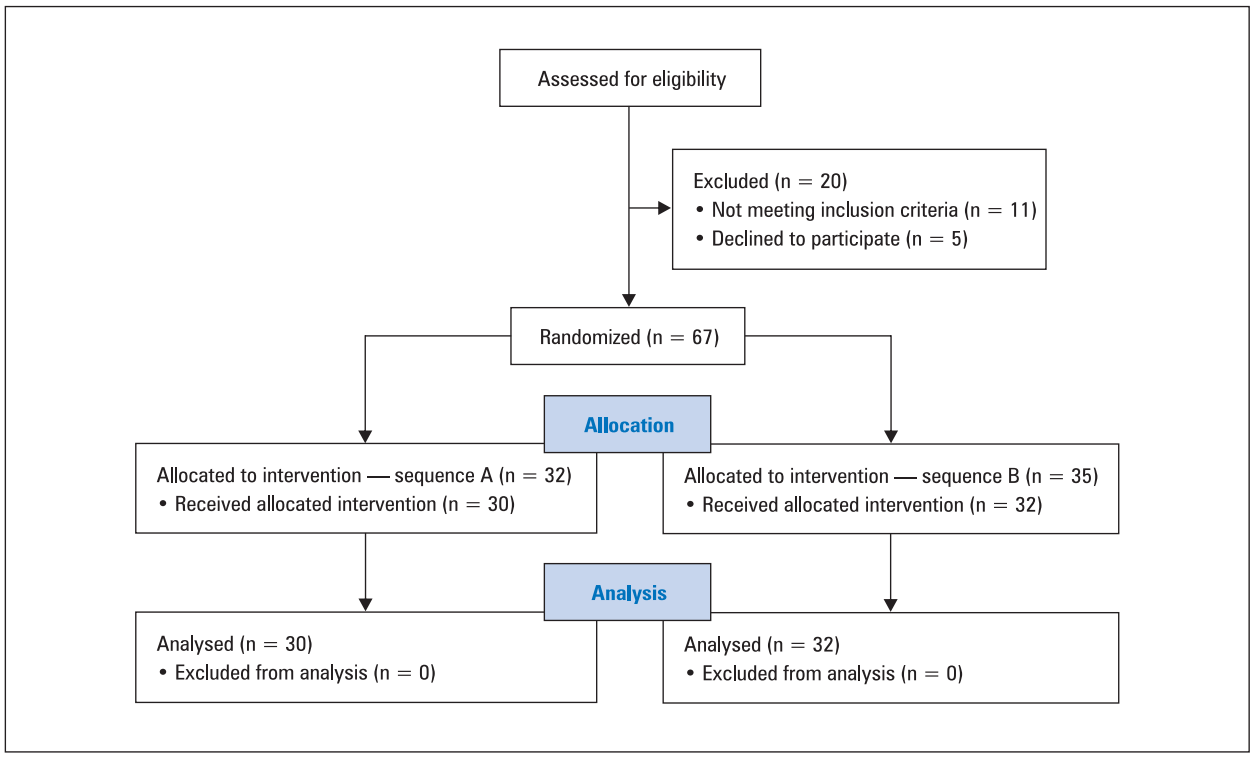

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) participant flow diagram

Table 1. Mean values and differences of FEV_1, FVC, PEF, and FEV1/FVC readings obtained with reference and AioCare spirometers

Parameter	Mean reference (SD)	Mean AioCare (SD)	Mean difference (SD)	P-value
FEV_1 [L]	2.56 (1.09)	2.55 (1.12)	0.0079 (0.1221)	0.61
FVC [L]	3.72 (1.21)	3.66 (1.20)	0.053 (0.214)	0.14
PEF [L/min]	372 (142)	367 (152)	5.1 (40.0)	0.28
FEV_1/FVC	0.680 (0.145)	0.684 (0.145)	–0.0034 (0.0442)	0.543

Statistical significance was established at $p < 0.05$; FEV_1 — forced expiratory volume in one second; FVC — forced vital capacity; PEF — peak expiratory flow; SD — standard deviation

vals of calculated biases for FEV_1 (0.0079; 95% CI: –0.0231–0.0389; p = 0.612), FVC (0.05403; 95% CI: –0.00060–0.10866; p = 0.052), PEF (5.05; 95% CI: –5.17–15.28; p = 0.327), and FEV_1/FVC (–0.00343; 95% CI: –0.09001–0.08315; p = 0.543). The bias did not change with the mean value (x axis), although PEF parameter differences for higher values of the mean were relatively under the equality line. There were also a few outliers outside the ± 1.96 × standard deviation borders. We found no common characteristics in patients with the outlying values. Nevertheless, cumulatively the results indicate no difference between measurements obtained with the handheld and the reference spirometer.

Lastly, the differences in FEV_1, FVC, PEF values and FEV_1/FVC rate for scenarios when the handheld spirometer was used prior to reference spirometer (sequence A) and when the reference spirometer was used prior to handheld spirometer (sequence B), were compared (Table 2). The hypothesis regarding equal distribution of the differences between sequence A and sequence B cannot be rejected for outcomes of FEV_1 measurement (p = 0.25). However, the significant differences between values obtained in sequence A and sequence B were observed for FVC (p = 0.0036), PEF (p = 0.0031), and FEV_1/FVC (p = 0.0046). Overall, the differences were greater if the reference spirometer was used first (sequence B).

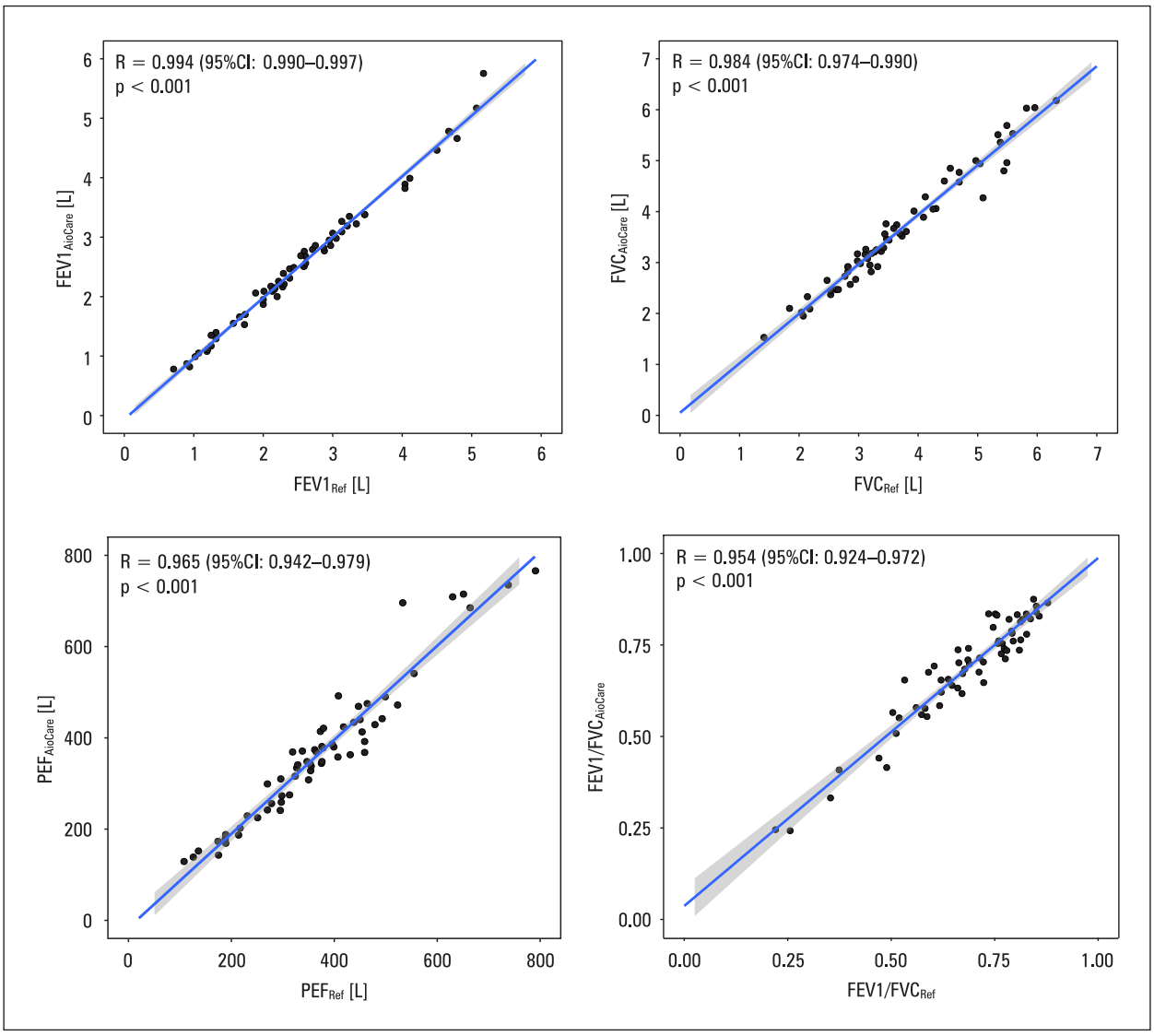

Figure 3. Correlation plot of forced expiratory volume in first second (FEV_1), forced vital capacity (FVC), peak expiratory flow (PEF) values and FEV_1/FVC rate obtained with reference and AioCare spirometers with a line fitted to the data (blue line) with 95% confidence intervals (grey bands)

Discussion

Cumulatively, our study showed that the values of the main spirometry parameters, FEV_1, FVC, PEF, and FEV_1/FVC obtained from a portable spirometer do not significantly differ from the values obtained from the reference spirometer which confirms usability of portable spirometer in daily, remote monitoring of patients with chronic lung diseases.

An accurate and high-quality spirometry measurement is critical in monitoring and managing patients with respiratory diseases [17]. Ambulatory and mobile spirometry is increasingly being used for early detection of chronic obstructive lung diseases, improving medication adherence, monitoring of acute exacerbations and, most recently, to prevent asthma exacerbations [3–6]. The possibility to complete conventional spirometry with a portable device may have a beneficial impact on pulmonary disease management and the direct and indirect costs associated with setting up a spirometry lab versus having a pocket-sized portable spirometer. Yet, concerns about the accuracy of portable spirometers significantly limit their use, highlighting the need for their validation and information about the results of such tests [7]. Therefore, in our study, we compared the main ventilation parameters obtained from portable (AioCare) and desktop (CPFS/D) spirometers in patients with asthma or COPD.

Assessment of the portable spirometer against the reference spirometry in a clinical setting showed high correlation of values of the

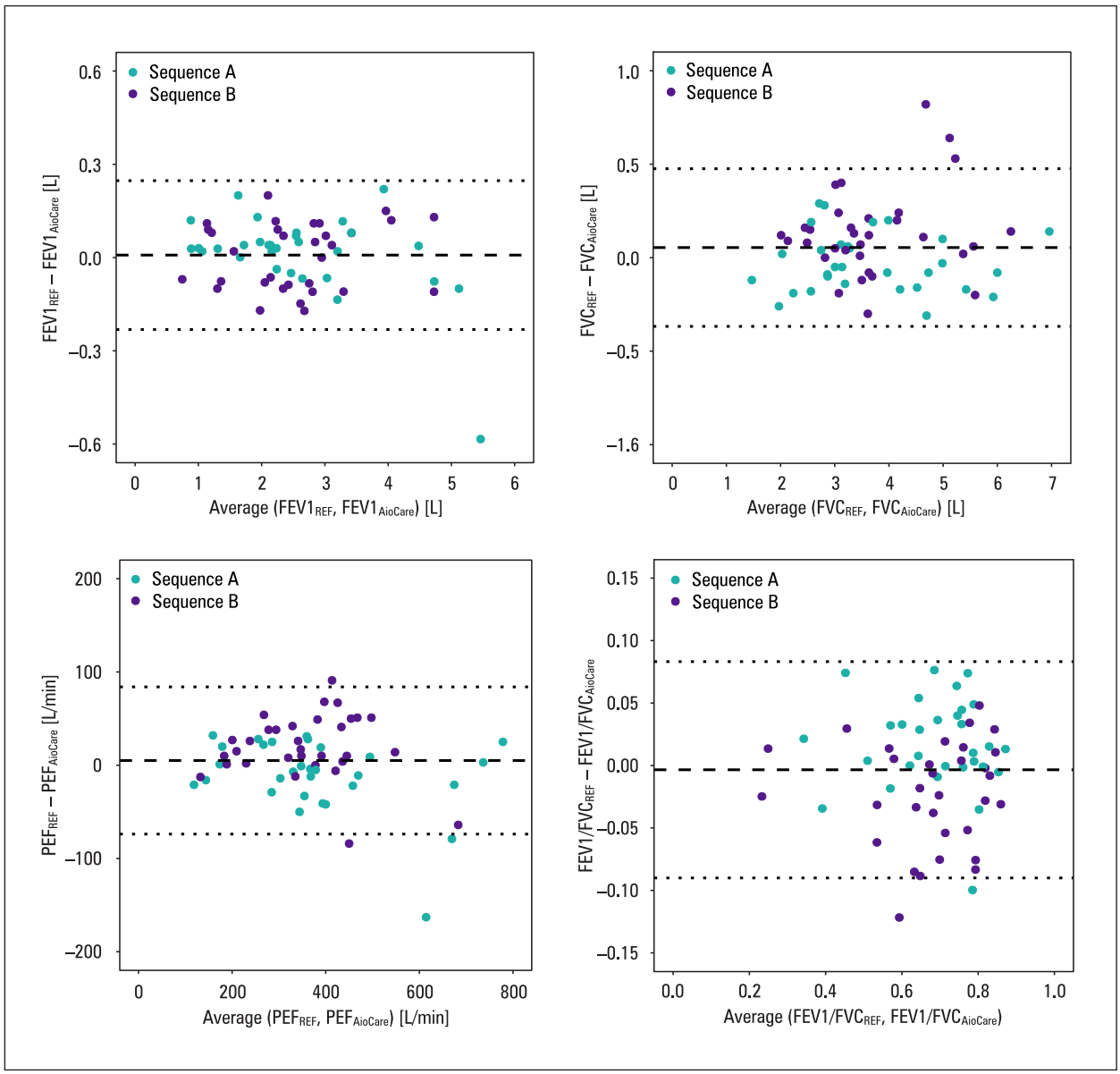

Figure 4. Bland-Altman plots calculated for forced expiratory volume in first second (FEV_1), forced vital capacity (FVC), peak expiratory flow (PEF), and FEV_1/FVC. The dashed lines show the mean value of the difference of spirometry parameters between the devices and the dotted ones indicate ± 95% limits of agreement values. Results of the group following examination sequence A are shown in turquoise and the group following examination sequence B in purple

pulmonary function parameters and no statistical significance between the mean differences in FEV_1, FVC, PEF and FEV_1/FVC readings obtained from both devices.

Our results are consistent with multiple previous reports, confirming non-inferiority of portable versus laboratory spirometers [10–14]. However, the precision of mobile devices varies significantly, even if the obtained results are comparable to those from laboratory spirometers. AirSmart spirometer (Pond Healthcare Innovation, Sweden), the first portable device accepted by the European Commission, delivered significantly lower absolute values of FEV_1 and FVC compared to a conventional spirometer [13]. The next generation of this device, Air Next spirometer (NuvoAir, Sweden) was tested on a large population of healthy subjects, as well as on individuals diagnosed with asthma and COPD [14]. Analysis of numerous lung function parameters led the authors to conclusion that the Air Next is non-inferior to a reference laboratory spirometer. However, the spirometry values returned by the Air Next had a large deviation and, particularly for FEV_1 and FVC, were on average 0.1–0.2 l lower than those measured with the reference device [14].

Table 2. Mean differences in FEV_1, FVC, PEF values and FEV_1/FVC rate obtained in examination sequence A and examination sequence B

Parameter	Mean difference (SD)		P-value
	Sequence A	Sequence B	
FEV_1 [L]	0.011 (0.138)	0.0049 (0.1075)	0.25
FVC [L]	–0.031 (0.153)	0.131 (0.234)*	0.0036
PEF [L/min]	–10.9 (39.6)	20.0 (35.3)*	0.0031
FEV_1/FVC	–0.023 (0.042)	0.017 (0.037)*	0.0046

The difference was calculated by subtraction of portable spirometer values from reference spirometer values. Statistical significance was established at $p < 0.05$; FEV_1 — forced expiratory volume in one second; FVC — forced vital capacity; PEF — peak expiratory flow; SD — standard deviation; *$p<0.05$

Tests of the other portable spirometer, the Spirotel (Medical International Research, Italy), showed high accuracy and reliability of measurements, both for large and small airways, compared to the reference device [11].

Our study suggests that the AioCare is characterized by high sensitivity and accuracy. High Pearson correlation co-efficient between a portable and desktop spirometer indicates that much of the spirometry in the outpatient and in-patient setting might be performed with portable spirometer by medical personnel or even by the patients themselves, at home.

Indeed, during large, multicenter, cross-sectional study, 9855 patients performed spirometry examinations with AioCare at routine visits, under supervision of their primary care practitioners. Forty-nine percent of measurements met ERS/ATS criteria of both acceptability and repeatability [18]. Also, the device proved to be useful in active screening for COPD performed by medical students among hospitalized smoking patients [19]. In another study, patients with asthma used AioCare for home self-monitoring, with good technical and patient satisfaction outcomes [20]. Finally, AioCare was used during large environmental study investigating the impact of air pollution on lung function among 770 children [21], proving that the mobile spirometry gains acceptance in clinical and non-clinical setting.

The comparability of portable spirometers and laboratory devices seems to be especially relevant taking into consideration an increasing need for remote patient management and efficient communication between physicians and patients; solutions for which offers telemedicine. Telemedicine supports patients with asthma and COPD with distant medical consultations, easy-to-access monitoring, and remote rehabilitation [22, 23]. Teleconsultations have been used successfully, saving time and travel costs. The use of portable spirometers might additionally provide the possibility for in-home patient monitoring, improving disease management and thus quality of life [22, 23]. A large population-based cohort study of an impact of telemonitoring for COPD conducted in Germany revealed that patient self-care program, including home spirometry, significantly reduced mortality, hospitalization rates, and general costs of disease management [24]. However, it is noteworthy that the current ATS/ERS guidelines still lack the clear standards for unattended home monitoring spirometry [16].

Our study had several limitations. Firstly, this randomized controlled trial had an explorative character, and thus formal calculation of the minimal required number of participants was not conducted *a priori*. However, the *post-hoc* analysis confirmed that the number of analyzed participants met the required criteria. Secondly, despite no differences between cumulative measurements generated by both spirometers, we observed an impact of the sequence of device used. We speculate that it could be caused by patients' fatigue and lack of focus when a portable spirometer was used as a second test. Finally, the observed outliers suggest a need for further studies to dispute whether these were incidental findings or an indicator of unrevealed tendency.

Additionally, these future studies, spanning more centers and larger populations, including measurements performed at the patient's bedside or by patients themselves, could provide valuable information about AioCare accuracy and ease of use. Overall, a broader research on mobile spirometry in patients with chronic pulmonary diseases is required before it can gain widespread acceptance.

Conclusions

With a high Pearson correlation co-efficiency and mean differences in FEV_1, FVC, PEF values and FEV_1/FVC showing no differences between the compared devices, we conclude that AioCare might be a beneficial option offered to respiratory health care. Its use may improve outcomes by allowing or facilitating screening, monitoring, and daily management of pulmonary diseases. Additionally, it may reduce the economic burden incurred by pulmonary diseases and their complications. In general, our study supports the use of a portable spirometer as a complementary option in remote management of patients with lung diseases, i.e. telemedical care. Nevertheless, further studies across different clinical scenarios are required before mobile spirometry can gain widespread acceptance.

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Conflict of interest

Piotr W. Boros, Stefan Wesołowski: clinical trial contracts; serving on an advisory board to HealthUp; Adrian Maciejewski: previous employee of Healthup (circa 2018); Michał Maciej Nowicki: no conflict of interest.

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